(101)

Checklist and Guidance
on Sending "Plume" and "Non-Plume" Letters

1. ☐ Veteran's unit was on the original plume list. Veteran was previously sent a "plume letter."
   Action: Provide another copy of the "plume letter" if requested.

2. ☐ Veteran's unit was on the original plume list. Veteran wasn't sent a "plume letter" for some reason.
   Action: Provide a copy of the "plume letter" if requested.

3. ☐ Veteran documents his/her status as assigned/attached to a unit on the original plume list.
   Action: Provide a copy of the "plume letter" if requested.

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4. ☐ Veteran's unit was on the original plume list, but his unit has been identified by the S3/G3 Conferences as being outside of the plume.
   Action: This situation may arise if someone writes in requesting a copy of their plume letter – coordinate carefully with CMAT and the PM on the course of action. A possible response may be to send a copy of original plume letter, but explain that attendees at the S3/G3 Conferences are analyzing unit locations and his/her status is subject to change – findings will be released when the analysis is complete.

5. ☐ Veteran's unit wasn't on the original plume list, but his unit has been identified by the S3/G3 Conferences as being under the plume.
   Action: Explain only that attendees at the S3/G3 Conferences are analyzing unit locations. Findings will be released when the analysis is complete.

---

6. ☐ Veteran's unit wasn't on the original plume list. Veteran was previously sent the "non-plume" letter because his unit was inside the 50-kilometer radius.
   Action: Provide another copy of the "non-plume" letter if requested

7. ☐ Veteran's unit wasn't on the original plume list, the veteran wasn't ever sent a letter about the plume, the veteran was outside the 50-kilometer radius, but the veteran asks for information about the plume.
   Action: Explain that if he/she was with the unit at the time, the plume didn't affect him/her. Don't send a "non-plume" letter.

8. ☑ Veteran's unit wasn't on the original plume list, the veteran wasn't ever sent a letter about the plume, the veteran was outside the 50-kilometer radius, and the veteran hasn't asked for information about the plume.
   Action: Address the veteran's issues and concerns. Don't send a "non plume" letter.

---

9. ☐ Special circumstances explained in memorandum.

Comments:
1. Fill out this sheet and attach it to all correspondence pertaining to Gulf War veterans.
2. Unit location data (e.g., map plots) may be released upon request.

(b)(6)

102-19.6.1

Exposure Letter Worksheet
4/30/98

CONGRESSIONAL or SPECIAL CORRESPONDENCE

CMAT: 9019-012

Date: 2-22-99

Office of Special Assistant for Gulf War Illnesses
Internal Routing/Tasking Sheet

Coord/ Routing	Position/Organization		Action		Comments
	Special Assistant	(SA)			
	Deputy Special Assistant	(DSA)			
2	Executive Assistant to SA	(EA)			
	Executive Assistant to DSA	(EADSA)			
	☐ Director, Investigation & Analysis _____ (IAD) ☐ DepDir _____ ☐ MED _____ ☐ VDM _____ ☐ C/B _____ ☐ ENV _____ ☐ PAG _____				
	Dir Lessons Learned Implementation	(LLI)			
	Dir Public Affairs & Outreach	(PA)			
	Dir Legislative Outreach	(LA)			
	Dir Quick Reaction Team	(QR)			
	Dir Medical Outreach & Issues	(MOI)			
	Legal Advisor	(LGL)			
1	PM, Gulf War Illnesses Support	(PM)	w/d 22Feb		
	Editorial Review ☐ AMB _____ ☐ Editors _____	(ER)			
	CMAT	(CMAT)			
	Action Management Call 845-8369 ☐ COMEBACK COPY TO: _____ ☐ GET CMAT NUMBER WHEN SIGNED & SENT ☐ READING FILE ☐ THANK YOU FILE ☐ CHRON FILE ☐ ADD TO GulfNEWS				

Send it PM

SUSPENSE:

Prepare reply for signature of:

☒ SA/GWI ☐ SD ☐ DSD ☐ DepSA/GWI

Capt (b)(6)

-re-write per your request/comments.

☐ Congress ☐ Oversight ☐ FOIA ☐ OSD ☐ WBM ☐ VSO/MSO

☐ Ltr to SA ☐ IR ☐ E-Mail ☐ OGA ☐ Other ☐ Veteran

KEYWORDS:

02/05/99 Issuance

CONGRESSIONAL or SPECIAL CORRESPONDENCE

Reopen ~~1014-012~~
CMAT: ~~3356-010~~ 8309-073
9026-053
8303-020
Date: 08 Feb 99

Office of Special Assistant for Gulf War Illnesses
Internal Routing/Tasking Sheet

Coord/ Routing	Position/Organization		Action	Info	Comments
	Special Assistant	(SA)			
	Deputy Special Assistant	(DSA)			
6	Executive Assistant to SA	(EA)			
	Executive Assistant to DSA	(EADSA)			
	☐ Director, Investigation & Analysis _____ (IAD) ☐ DepDir _____ ☐ MED _____ ☐ VDM _____ ☐ C/B _____ ☐ ENV _____ ☐ PAG _____				
	Dir Lessons Learned Implementation	(LLI)			
2	Dir Public Affairs & Outreach	(PA)			
	Dir Legislative Outreach	(LA)			
	Dir Quick Reaction Team	(QR)			
3	Dir Medical-Health & Benefits Collab	(MHB)			B, D + L are ready to go. Let's [illegible]
	Legal Advisor	(LGL)			I'll suggest a response for PAC.
5	PM, Gulf War Illnesses Support	(PM)			PM not needed
1	Editorial Review ☒ AMB ☒ Editors	(ER)			see note
4	CMAT	(CMAT)			
7	Action Management Call 845-8369 ☐ COMEBACK COPY TO: _____ ☐ GET CMAT NUMBER WHEN SIGNED & SENT ☐ READING FILE ☐ THANK YOU FILE ☐ CHRON FILE				

SUSPENSE:

Prepare reply for signature of:

☐ SA/GWI ☐ SD ☐ DSD ☐ DepSA/GWI

☐ Congress	☐ SOB	☐ FOIA	☐ OSD	☐ WBM	☐ VSO/MSO
☐ Ltr to SA	☐ IR	☐ E-Mail	☐ OGA	☐ Other	☐ Veteran

KEYWORDS:

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
FOR
GULF WAR ILLNESSES

FEB 2 3 1999

(b)(6)

Dear (b)(6)

This letter is in response to your concern about two inoculations that you received while deployed in the Gulf. From your description, we believe those shots to which you refer may have been the anthrax vaccination. This vaccine was not "classified," however, at the time the shots were given, there was not enough for all troops so the decision was made to give them to selected units. As a matter of security, we did not want potential enemies to be able to identify the units that received these protective vaccines, so the shots were not routinely entered in the service member's medical records.

As you know, prior to deploying to the Gulf, service members were required to be up to date on the required military vaccines. Troops received specific vaccines if they were required for the deployment (meningococcal vaccine and gamma globulin), if they required a booster dose, or if they lacked a record of appropriate vaccination. In the Gulf War theater of operation, the anthrax vaccine was given to a limited number of service members for protection against biological warfare agent attack. The anthrax vaccine was a licensed, commercially available product. Approximately 150,000 Gulf War veterans received at least one dose of the vaccine.

We are concerned about the safety and the effectiveness of all the vaccines, individually and in combination that we give to our military. We, like you, are distressed when anyone experiences a reaction to a vaccine. We would also be distressed if a service member became ill or died from a vaccine-preventable disease during the course of their military service, or if a military unit was rendered ineffective by a high rate of a vaccine-preventable disease. Our vaccine programs are designed to prevent such disease and disability for the individual and the military unit, while minimizing as much as possible the adverse effects associated with vaccines. We trust that our extensive research effort will enable us to better understand the health effects of service in the Gulf War.

We have added your name to our *GulfNEWS* mailing list so that in the future you may receive copies of *GulfNEWS*, our bi-monthly newsletter. Thank you for sharing information with us. If we can be of further assistance, please contact us.

Sincerely,

Bernard Rostker

IMAGE ONLY FILE. USE/VIEW IMAGE FOR COMPLETE DOCUMENT INFORMATION.

KEYWORDS:
CMAT # 1999060-0000006
MEDICAL HISTORICAL - DEPARTMENT OF DEFENSE ANTHRAX VACCINE IMMUNIZATION PROGRAM UPDATE BRIEF

CMAT Control #
1999060-0000006

Department of Defense Anthrax Vaccine Immunization Program

UPDATE BRIEF

Deputy Secretary of Defense

9 February 1999

[redacted]

ANTHRAX VACCINE IMMUNIZATION PROGRAM

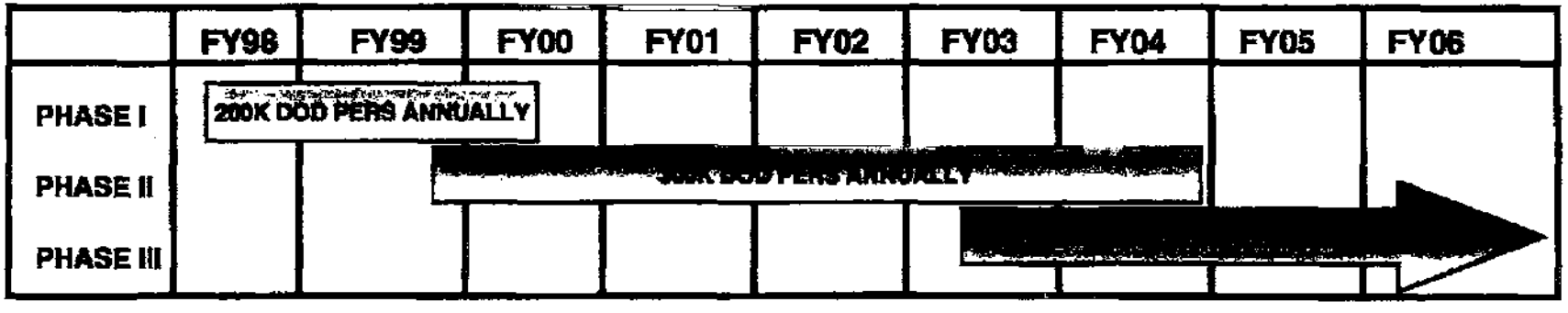
Agenda

- **AVIP Implementation Progress**
- **AVIP Policy Updates**
- **Vaccine Acquisition, Stockpiling and Distribution**
- **Adverse Reactions and Clinical Outcomes**
- **Working The Internet**
- **Resources**
- **Service Specific Discussions**

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

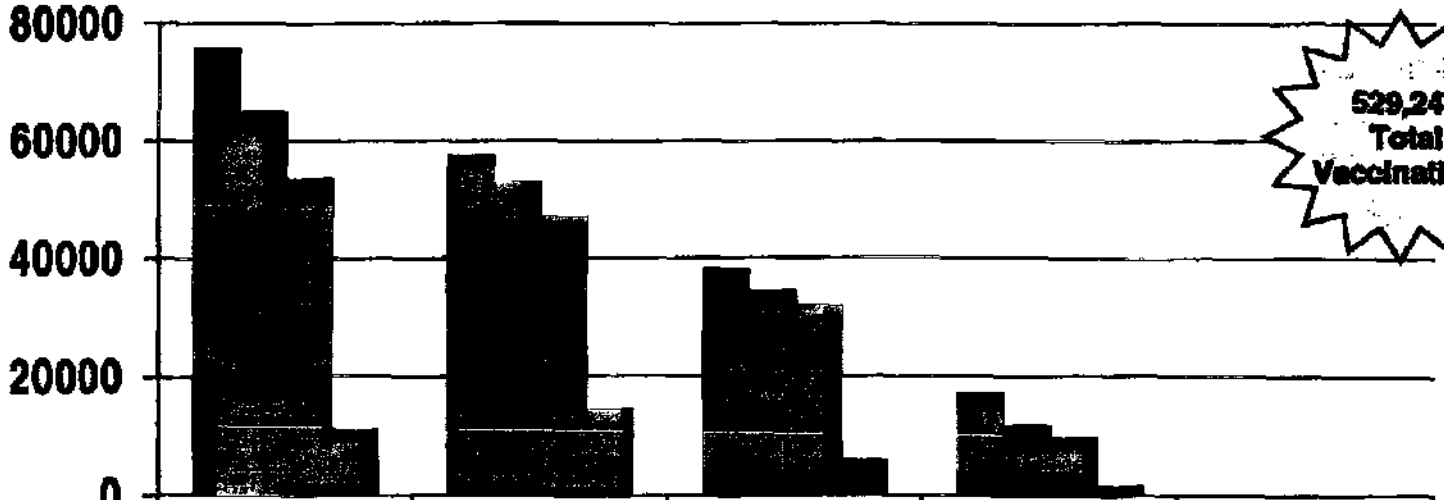
AVIP Execution Timeline

- **Phased execution across the Total Force**
  - Phase I. Forces assigned or rotating to High Threat Areas of SWA and Korea
  - Phase II. Early deploying forces (C to C+35) into High Threat Areas of SWA and Korea
  - Phase III. Remainder of total force, accessions, and program sustainment



ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Current Force Immunization Status



	Army	Air Force	Navy	Marines	Total
Shot # 1	76018	57724	38173	17304	189,219
Shot # 2	64931	52845	34686	11874	164,336
Shot # 3	53441	46983	31741	9828	141,993
Shot # 4	11247	14416	6254	1782	33,699

* All Data From DEERS 022400 Feb 99

ANTHRAX VACCINE
IMMUNIZATION PROGRAM

Compliance Rates

[redacted]

ARMY	●	76,018	90%
NAVY/MARINES	●	55,477	93%
AIR FORCE	●	57,724	92%

189,219

[redacted]

● Within DoD Standard

● Not Within DoD Standard/Minor Problem

● Not Within DoD Standard/Major Problem

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

AVIP Policy Updates

- **Zero-Day Policy (ZDP):**
  - Services and CINCs concur, staffing for USD(P&R) signature

- **Immunization Refusal Policy:** ***Consensus for NO DoD Policy***
  - Status: Each Service crafting their own policy

- **Adverse Reaction Reporting Procedures:** synchronizes guidance for reporting adverse reactions
  - Status: Staff through Service SGs, signature by ASD(HA)

[redacted]

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Vaccine Acquisition and Stockpile

Stockpile Supplemental Testing	●	**Testing Ongoing;** ➢ 6 lots/ 1.26M doses supplementally tested, packaged and labeled ➢ 2 lots, 389K recently released ➢ All lots complete supplemental testing May 99
Plant Renovation	●	**Renovation and FDA Certification** ➢ Began Mar 98; renovation completed Jan 99 ➢ New vaccine available after FDA Certification of facilities and new lots, 4QFY99

● On Track/No Impediment to Completion

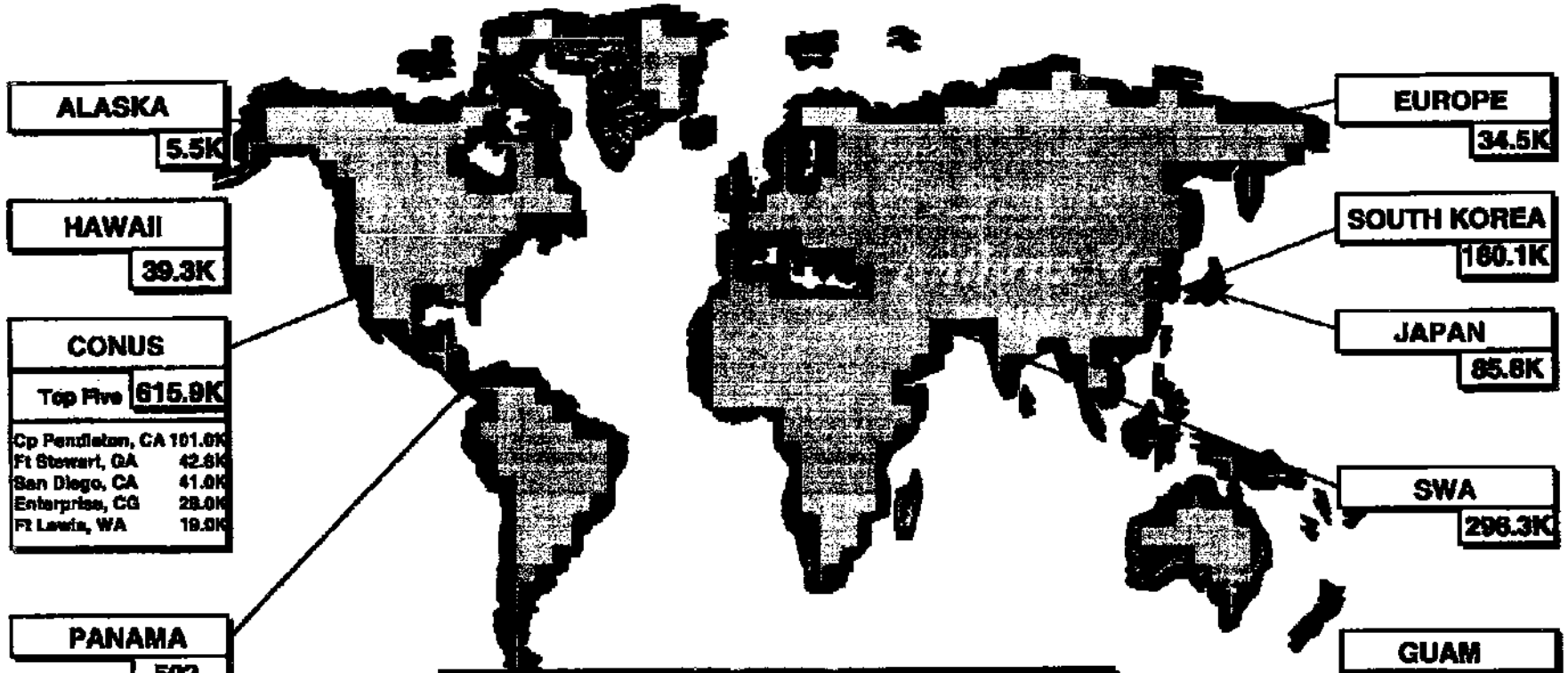
◔ Delayed/Minor Impediment

● Delayed/Major Impediment

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Anthrax Vaccine Distribution

1,270,000 Doses Shipped to 368 Locations Worldwide



USA	USAF	USN	USMC	FMS
311,360	247,610	310,640	313,660	8,209

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Anthrax Vaccine Adverse Reactions

Anthrax Vaccine Adverse Event Reporting System (VAERS)
Week Ending 1 Feb 99

Service	VAERS	Classification			
		Local Reaction			Syste Reac
		Mil	Moderate	Se	
USA		0	0		0
USN		0	0		0
USAF		0	0		0
USMC		0	0		0

Cumulative Data

Service	VAERS	Classification			
		Local Reaction			Syste Reac
		Mil	Moderate	Se	
USA		7	6		5
USN		0	0		3
USAF		2	2		6
USMC		0	0		0
		9	8	7	14

38 adverse reactions of 529,247 vaccinations given = .007%

- Duration 24 - 48 hours
- Local redness and hardness 1 to 2 centimeters

Moderate

- Local redness and hardness 5 centimeters
- Subcutaneous nodule at injection site

- Swelling at injection site and entire forearm

- Malaise
- Chills and fever
- Anaphylaxis

VAERS

- Loss of duty > 24 hours
- Hospitalization

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

Anthrax Vaccine Clinical Outcomes

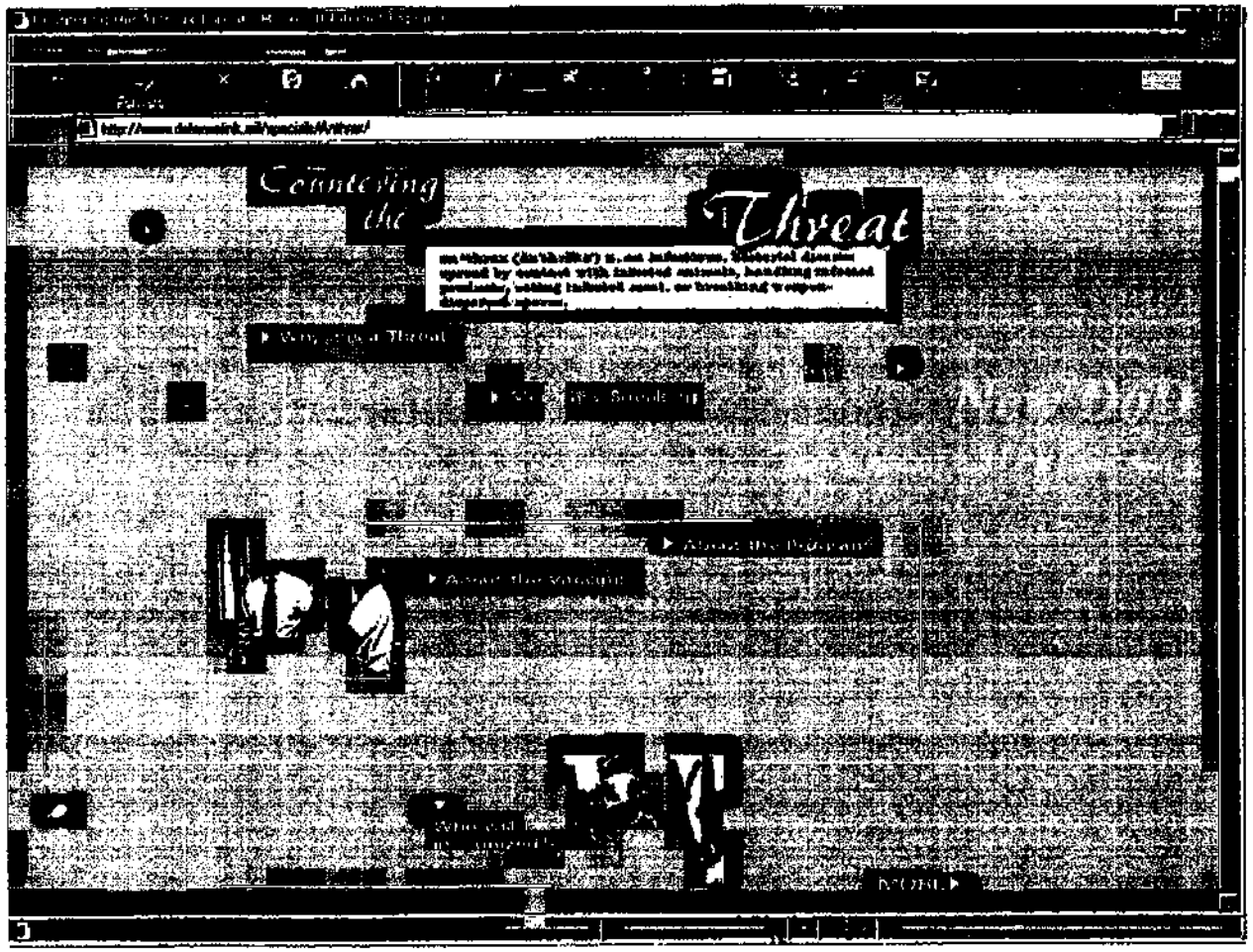
- **Armed Forces Epidemiological Board review of VAERS–3 Aug 98**
  - **Recommended no change in current DoD AVIP**
- **TAMC Survey - Korea PROFIS**
  - **Sample size–603 soldiers**
  - **3 VAERS reports–none hospitalized, 1 missed 24 hours duty**
    - **< 5% sought any medical attention for any symptom/side effects**
- **Vaccine External Review Panel of Adverse Events**
  - **Oversight--Vaccine Injury Compensation Program, Health Resource Services Administration, DHHS**
  - **Report due mid-Feb 99**

[redacted]

ANTHRAX VACCINE IMMUNIZATION PROGRAM AVIP

- **Anthrax vaccine disinformation**
  - 3 main anti-AVIP web sites; major source of disinformation
  - Television--focused on refusals
  - Press--focused on refusals
- **DoD initiatives to counter disinformation**
  - New DoD anthrax web site: www.defenselink.mil/specials/anthrax
    - Highest number of "hits" (13%) in the Defenselink "specials" category
    - Accessed 700 times/day (25-50% more than anti-AVIP sites)
  - Enhanced anthrax website (cost implications)
    - Enhanced web architecture; position within commercial search engines
    - Focused on AD, spouses, parents, scientific community, press, media
    - Feedback mechanisms
      - & Live chat rooms, bulletin boards
      - & Organized "frequently asked questions"
      - & Dedicated 1-800 number

New DoD Web Site

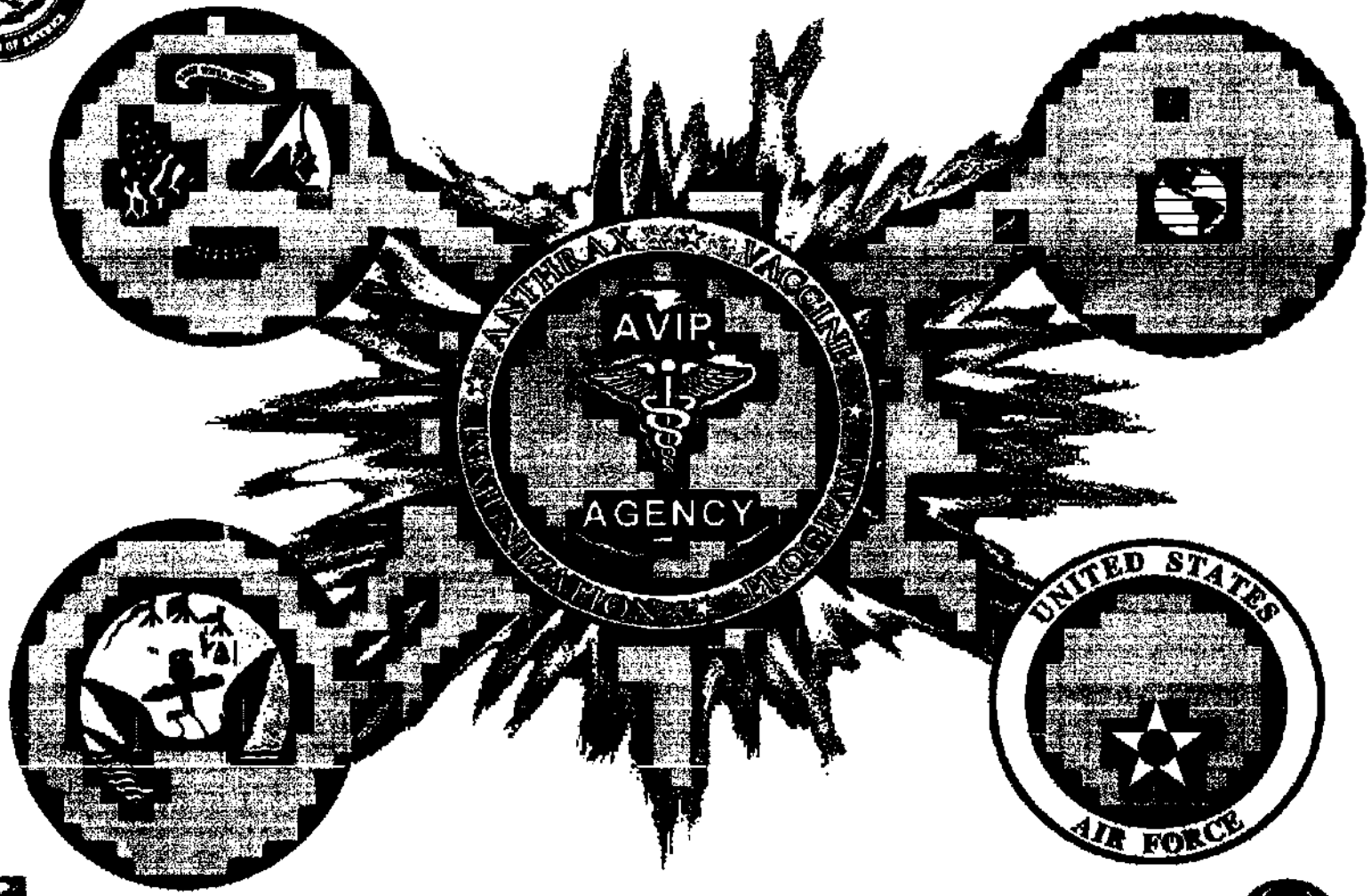


ANTHRAX VACCINE
IMMUNIZATION PROGRAM AVIP

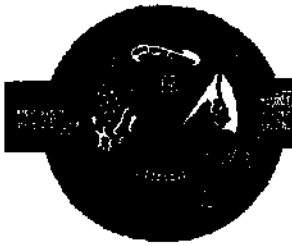
- **DoD AVIP implementation/monitoring efforts currently unfunded**

	Current	Needed
' USA	$ 2.1M DHP	$4.46M to do entire program
' USAF	(Data coming)	
' USN/USMC	(Data coming)	

- **DoD enhanced anthrax education/communications initiative**
  - ' Start and sustain FY00--$810K
- **VA/DHHS/DoD Force Health Protection Initiative**
  - ' RC access to anthrax vaccinations (FY 00 - 05)--$(Data coming)M



ANTHRAX VACCINE
IMMUNIZATION PROGRAM AVIP



Adverse Publicity/Refusals

- **9 Army refusals after extensive education/re-education/counseling**
  - **8 refusals in Korea**
  - **1 refusal at Ft Stewart, GA**

- **Revision of AR 600-20, Army Command Policy**
  - **Under normal circumstances, will not forcibly vaccinate**
  - **Clear guidance to commanders on management of soldier refusals**
  - **Use minimum force necessary to vaccinate soldiers only under conditions of imminent threat**
    - **Imminent threat determined by GCMCA**
    - **May be delegated by GCMCA to O-5 commanders and above**
  - **Status--Pending approval by CSA and SECARMY, estimate action complete and ALARACT message in Feb 99.**

CMAT Control #
1999069-0000051

(102)

OSAGWI

MAR 1 0 1999

March 5, 1999

Dr. Bernard Rostker, Undersecretary of the Army
Pentagon
Washington, D.C. 20310

Dear Undersecretary Rostker:

RE: Interview Dr. Bernard Roskter, Healthy Respect
The American Legion magazine, March 1999 issue

Your response to the statement of "Where did we fall down?" perplexes and puzzles me.

I have recently heard, seen or read about the various testing of chemical, biological, disease and radiation on the American people, including military personnel, without their knowledge or consent:

1. Long term impact of syphilis on the health and bodies of a group of black males for forty years.
2. Exposing military troops to atomic/nuclear explosions in Utah and Nevada during the late 1940's and early 1950's.
3. Releasing chemical and biological agents at eighteen different locations within the United States upon the citizens of this nation; from May 1966 thru 1986.
4. The use of Agent Orange during the Viet Nam War.?
5. The use of injectable drugs and agents in combinations that were detrimental to the health of our troops involved in the Gulf War.
6. The CIA sponsoring and paying for experimental use of LSD on mental patients in Canada. (Movie "The Sleep Room")

1. What actions have you taken to inform the American people?
2. What actions have or are you now taking to help the people that are suffering from the consequences of our government's action? Especially the Department of Defense, including Army and Navy.
3. What actions are you taking to eliminate Title 50, Chapter 32, Section 1520; which allows the testing of deadly chemical and biological agents on the American public without their consent or knowledge?

I would appreciate hearing from you and look forward to your response.

(b)(6)

[redacted]

102 12.23

CONGRESSIONAL or SPECIAL CORRESPONDENCE 9069-052

CMAT: 9069-051
9060-078
9069-024
9053-040
Date: 22-Mar-99

Office of Special Assistant for Gulf War Illnesses
Internal Routing/Tasking Sheet

Coord/ Routing	Position/Organization		Action	Info	Comments
	Special Assistant	(SA)			
	Deputy Special Assistant	(DSA)			
6	Executive Assistant to SA	(EA)	MHA 30 MAR		
	Executive Assistant to DSA	(EADSA)			
	☐ Director, Investigation & Analysis _____ (IAD) ☐ DepDir _____ ☐ MED _____ ☐ VDM _____ ☐ C/B _____ ☐ ENV _____ ☐ PAG _____				
	Dir Lessons Learned Implementation	(LLI)			
2	Dir Public Affairs & Outreach	(PA)	30 Mar		
	Dir Legislative Outreach	(LA)			
	Dir Quick Reaction Team	(QR)			
3	Dir Medical Outreach & Issues	(MOI)			DS's letter to
	Legal Advisor	(LGL)			
5	PM, Gulf War Illnesses Support	(PM)		Done	
1	Editorial Review ☐ AMB _____ ☒ Editors	(ER)			see note
4	CMAT	(CMAT)			US
7	Action Management Call 845-8369 ☐ COMEBACK COPY TO: _____ DANA ☐ GET CMAT NUMBER WHEN SIGNED & SENT ☐ READING FILE ☐ THANK YOU FILE ☐ CHRON FILE ☐ ADD TO GulfNEWS				

SUSPENSE:

Prepare reply for signature of:

☐ SA/GWI ☐ SD ☐ DSD ☐ DepSA/GWI

☐ Congress ☐ Oversight ☐ FOIA ☐ OSD ☐ WBM ☐ VSO/MSO

☐ Ltr to SA ☐ IR ☐ E-Mail ☐ OGA ☐ Other ☐ Veteran

KEYWORDS:

02/05/99 Issuance

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
FOR
GULF WAR ILLNESSES

(b)(6)

MAR 3 0 1999

Dear (b)(6)

I am writing in response to your letter regarding "Healthy Respect," an interview with me that appeared in the March 1999 issue of *The American Legion Magazine.* Thank you for reading the article and taking the time to respond.

You stated in your letter that my response to the question, "Where did we fall down?" both perplexed and puzzled you. Please allow me to take this opportunity to clear up any ambiguities in my response to the interviewer and to address the three questions you posed at the end of your letter.

In your letter, you cite six examples of acknowledged or alleged incidents of government transgressions against the health and welfare of its own citizens, particularly military members. My response to the magazine writer was specifically limited to the Department of Defense' initial failure to conduct a thorough assessment of the events in the Gulf War before attempting to address the issue of veteran health complaints resulting from this conflict. It was in no way an attempt to explain or excuse the entire historical record of possible government or DoD mistakes and misdeeds. As the Special Assistant to the Deputy Secretary of Defense appointed to oversee the Department of Defense investigation of Gulf War illnesses, my plate is more than full with tasks to ensure that Gulf War issues are completely addressed.

Among the six examples you provided, the only one I am in a position to discuss is number five, pertaining to the vaccines and other drugs prescribed for Gulf War service members. These were used to ensure their health and safety in that particular threat environment. At this point, it is premature to say that the combinations of medicines proved detrimental to the health of Gulf War troops. Investigations to date have neither proved nor disproved this point. Given other potential contributing conditions – pesticides, oil well fires, industrial chemicals, exposure to depleted uranium, desert sand, etc. – that may have induced sickness, you can see that unraveling the threads of Gulf War illnesses is no straightforward task. There are currently more than 120 studies examining all of these factors to determine the causes of the various ailments seen in our veterans.

There are some important facts about the vaccines and other medicines that are well established. As you may know, prior to deploying to the Gulf, veterans were required to have a limited number of vaccines. Most veterans were to receive a specific vaccine if it was required for the deployment, if they required a booster dose, or if they lacked a record of appropriate vaccination. In the Gulf War theater of operation, anthrax vaccine and botulinum toxoid were given to a limited number of service members for protection against biological warfare agent

attack. The anthrax vaccine was a licensed, commercially-available product. Approximately 150,000 Gulf War veterans received at least one dose of the vaccine.

The threat of Iraqi biological weapons mandated that U.S. troops in the Gulf be required to take certain drugs and vaccines as preventive or protective measures. U.S. troops were provided the investigational vaccine, botulinum toxoid. This treatment was to protect military personnel against the possible use of potentially fatal biological weapons by Iraq. The Food and Drug Administration approved the botulinum vaccine for use in an investigational new drug status though the vaccine has been used for the past 25 years in industrial and laboratory environments. It is very important to understand that investigational drugs are not administered in an experimental manner. The 8,000 available doses in theater were to be administered with informed consent, but due to the number of inoculations there is no guarantee that informed consent was obtained in all cases. To provide you with a more detailed discussion of these issues, I have enclosed sections on vaccines and prophylactic treatment from the Institute of Medicine's 1996 report *Health Consequences of Service During the Persian Gulf War: Recommendations for Research and Information Systems.*

During Operations Desert Shield and Storm, the threat of use of nerve agents by Iraq was very high. After careful deliberation by a specially constituted human-use review committee of the Food and Drug Administration, it was determined that pyridostigmine bromide could be instrumental in saving the lives of many service members. This approval was based on extensive scientific information that supported the safety and effectiveness as preventive treatment. More than 250,000 service members received the pre-treatment drug.

Pyridostigmine bromide was also administered with the approval of the Food and Drug Administration in an investigational new drug status. Drugs and vaccines may be "investigational" for several reasons, many of which are not due to any concerns about safety or effectiveness. The investigational status of pyridostigmine bromide during the Gulf War signified that it had not been formally approved for labeling, marketing, and general use as a preventive measure against nerve agent exposure. However, it has been used since 1955 as a treatment for a neuromuscular disease, myasthenia gravis.

There was no effort to withhold information from the troops or the public. In fact, pyridostigmine bromide use was widely reported by the news media at the time. The Department of Defense believes that most individuals knew they were taking an oral drug to counter the effects of a possible nerve agent attack. However, troops did not receive all intended information about the possible side effects of pyridostigmine bromide because pamphlets did not arrive before hostilities were initiated.

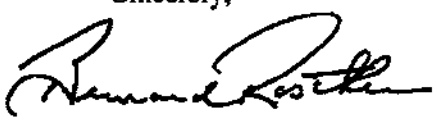
Current Department of Defense investigative activities include efforts to better understand how the drug was used by individuals during the Gulf War. The DoD is supporting research to evaluate any long-term health effects associated with combinations of pyridostigmine bromide with other exposures or risk factors experienced by troops during the war. I have enclosed a pyridostigmine bromide background paper from our Internet website and information published in the Institute of Medicine's *Health Consequences of the Persian Gulf War*. I hope this information is useful to you.

The lack of a properly coordinated and timely education process about the nature of the vaccines and drugs administered to Gulf War troops helped create a climate of uncertainty about the preventative program. In the wake of the war, when various illnesses emerged, this uncertainty mixed with the initial, inadequate DoD response to medical claims and created a belief among many veterans that the combination of medicines caused their illness. As I noted earlier, this viewpoint is being thoroughly investigated, but no conclusions have yet been drawn. Please be assured that when the investigation results are known, the information will be made available to the public.

In your letter, you also asked what actions we are taking to care for Gulf War veterans, to inform the American people of our efforts and to eliminate Title 50, Chapter 32, Section 1520. Please see the enclosure for my detailed response to these questions.

Thank you for the opportunity to respond to your concerns. You have my assurance we are doing everything possible to investigate and explain Gulf War illnesses – we owe it to the brave men and women who served our country. Unless we understand what went on in the Gulf and what may be making our veterans sick, we will never be able to make the changes necessary to ensure our forces are protected in the future. People are our first concern.

Sincerely,



Bernard Rostker

Enclosures

(103)

CONGRESSIONAL or SPECIAL CORRESPONDENCE

CMAT: 9145-E010

Date: 6-4-99

Office of Special Assistant for Gulf War Illnesses
Internal Routing/Tasking Sheet

Coord/ Routing	Position/Organization		Action	Info	Comments
	Special Assistant	(SA)			
	Deputy Special Assistant	(DSA)			
	Executive Assistant to SA	(EA)			
	Executive Assistant to DSA	(EADSA)			
	☐ Director, Investigation & Analysis _____	(IAD)			
	☐ DepDir _____ ☐ MED _____ ☐ VDM _____				
	☐ C/B _____ ☐ ENV _____ ☐ PAG _____				
	Dir Lessons Learned Implementation	(LLI)			
	Dir Public Affairs & Outreach	(PA)	X		
	Dir Legislative Outreach	(LA)			
	Dir Quick Reaction Team	(QR)			
	Dir Medical Outreach & Issues	(MOI)			
	Legal Advisor	(LGL)			
	PM, Gulf War Illnesses Support	(PM)			
	Editorial Review	(ER)			
	☐ AMB _____ ☐ Editors _____				
	CMAT	(CMAT)			
	Action Management Call 845-8369				
	☐ COMEBACK COPY TO: _____				
	☐ GET CMAT NUMBER WHEN SIGNED & SENT				
	☐ READING FILE ☐ THANK YOU FILE				
	☐ CHRON FILE ☐ ADD TO GulfNEWS				

SUSPENSE: ASAP

Prepare reply for signature of:

☐ SA/GWI ☐ SD ☐ DSD ☐ DepSA/GWI

- hard copy response

☐ Congress ☐ Oversight ☐ FOIA ☐ OSD ☐ WBM ☐ VSO/MSO

☐ Ltr to SA ☐ IR ☐ E-Mail ☐ OGA ☐ Other ☐ Veteran

KEYWORDS: 102 19.62

05/03/99 Issuance

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
FOR
GULF WAR ILLNESSES

(b)(6)

JUN 1 0 1999

Dear (b)(6)

This letter is in response to your e-mail inquiry regarding the *Vanity Fair* article. We attempted to respond to your e-mail address without success. As the Special assistant to the Deputy Secretary of Defense appointed to oversee the Department of Defense investigation of Gulf War illnesses, I assure you we are fully committed to investigating the events of the Gulf War to understand why many of our veterans are ill. Our number one priority is the health and welfare of our Gulf War veterans. We are committed to a thorough, complete and public investigation.

With regard to the article in the May issue of *Vanity Fair*, I would like to mention a few points. First, squalene is normally present in humans as part of the body's production of cholesterol. It is found in human sebum (skin oils) and plant and animal cell membranes. Second, there is no basis for believing that Gulf War-era veterans were exposed to squalene-containing vaccines.

The anthrax vaccine given to service members during the Gulf War and given to them now did not and does not contain squalene. To our knowledge, anthrax vaccine was never produced at any alternate production facilities in the United States during the Gulf War, and anthrax vaccine production at Michigan Biologic Products Institute (now BioPort) in Lansing, Michigan, never contained squalene. This fact was verified April 13, 1999, by the Army Surgeon General.

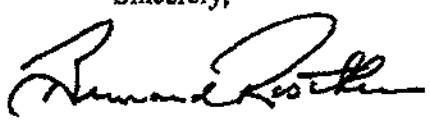
Lastly, *Vanity Fair's* recent article provides no new insight into the previous allegations regarding vaccine adjuvants and illnesses among Gulf War veterans.

While there is no clinical evidence that points to a previously unknown, unique illness or syndrome among Gulf Veterans, we know that veterans are suffering real symptoms and illnesses. Participants in the Comprehensive Clinical Evaluation Program (CCEP) have reported a wide variety of symptoms spanning multiple organ systems. Symptoms such as fatigue, joint pain, headache, or sleep disturbances are commonly reported. The most common psychological conditions found are tension headache, nonspecific, mild, or stress-related anxiety or depression; and post-traumatic stress disorder. Musculoskeletal and connective tissue disease such as osteoarthritis and backache are also common diagnoses seen in CCEP participants.

For your reference, I have enclosed information materials that explain our mission and our commitment to Gulf War veterans and their families. I hope these materials are useful to you.

Please be assured that we are doing everything possible to investigate and explain Gulf War illnesses. We owe it to the brave men and women who served our country. Unless we understand what went on in the Gulf and what may be making our veterans sick, we will never be able to make the changes necessary to ensure our forces are protected in the future. People are our first concern.

Sincerely,



Bernard Rostker

Enclosures

104

CMAT #: 1999146-0000019

LETTER FROM (b)(6) TO SECDEF COHEN REGARDING ANTHRAX/SHOT RECORDS/DOD CIVILIANS

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
FOR
GULF WAR ILLNESSES

27 JUL 1999

Senator Arlen Specter
9400 Federal Building
600 Arch Street
Philadelphia, Pennsylvania 19106

Dear Senator Specter:

This is in reply to your recent inquiry on behalf of your constituent, (b)(6) (b)(6) As (b)(6) concerns relate to his experiences during Operation Desert Shield, your correspondence, sent to the Assistant Secretary of Defense (Health Affairs), was forwarded to me for response.

(b)(6) has also written to us. We are in the process of collecting information to answer (b)(6) concerns. A letter explaining this was mailed to him June 8, 1999 and subsequently a senior member of my staff spoke with (b)(6) by phone.

(b)(6) is concerned that he and other members of his group may have been given the anthrax vaccine while serving as civilian employees of the U.S. Army deployed to Dhahran, Saudi Arabia, during Operation Desert Shield. (b)(6) letter indicates that he was in Saudi Arabia from September 13, 1990, through November 15, 1990. He is also concerned that the personnel assigned to the medical unit refused to tell them what vaccine he received, or to annotate the vaccine in his medical records. His letter indicates that he and other members of the group are sick and one member has since died.

We are currently in the process of investigating the details surrounding (b)(6) deployment to Saudi Arabia; what I can tell you at this time is that the U.S. anthrax vaccination program began in January, 1991, at least one-and-a-half months after (b)(6) duty ended. We have been able to obtain the following information from several other support team members:

- The New Cumberland Army Depot dispatched three Customer Service and Logistical Support Teams of Department of the Army civilians to Operations Desert Shield and Desert Storm between September 1990 and May 1991. These teams – designated A, B, and C – had four government civilian members assigned to each. According to (b)(6 (b)(6 Team A was in Saudi Arabia from approximately September 13, 1990, to November 15, 1990. Team B was in country from approximately mid-September 1990 through the end of December 1990 (per (b)(6), and Team C was in country from approximately late November 1990 until 02 May 1991 (pe (b)(6).

(b)(6) was the lead civilian for the group from New Cumberland Army Depot. (b)(6) were members of Team A.

- According to Department of the Army records, designated vaccination teams from Fort Detrick, Maryland accompanied all shipments of anthrax vaccine to the Persian Gulf theater. These teams arrived in the theater with the anthrax vaccine on January 2, 1991. The anthrax vaccination program was authorized by U.S. Central Command to begin January 8, 1991, and was terminated for Operation Desert Storm on February 28, 1991.

- According to signed copies of Army documents obtained from Ft. Detrick, Maryland, the 1st Air Transportable Hospital, located in Dhahran, received their first issue of anthrax vaccine January 12, 1991, with re-supply occurring on February 5 and 12, 1991. According to other Army documents, Army medical units and hospitals in the Dhahran area received their first issue of anthrax vaccine between January 10 and 12, 1991.

Based upon the "in-theater" dates provided by the members of the New Cumberland Army Depot Teams A, B, and C, and the timeframe that the anthrax vaccination program was underway, it is highly unlikely that (b)(6) received the anthrax vaccine. Only team members who would have been in Saudi Arabia between January 8, 1991 and February 28, 1991 could have received the anthrax vaccine.

We are still investigating the circumstances addressed by (b)(6). We are attempting to locate and interview other personnel involved in the immunizations administered at the time. We are attempting to determine what vaccines the personnel from New Cumberland did receive since we believe that the anthrax vaccination was not administered during the period of (b)(6) service in the Gulf. We expect to have a final response within 30 days.

Thank you for the opportunity to respond to your concern.

Sincerely,

Bernard Rostker

SECRETARY OF DEFENSE CORRESPONDENCE ACTION REPORT

This form must be completed and delivered to the Correspondence Control Division (CCD), WHS Room 3A948, not later than (YYMMDD): 990729 ('GWI')

1. DATE (YYMMDD)

2. ACTION TAKEN (X one)

- [ ] a. ACTION HAS BEEN COMPLETED (Copy attached)
- [ ] b. REQUEST CANCELLATION / EXTENSION OF SUSPENSE DATE TO _____ (Justify below)
- [x] c. INTERIM REPLY HAS BEEN SENT (Copy attached)

3. JUSTIFICATION

⇒ Initial answer provided, additional information will be sent in follow-up letter.

⇒ Question concerns specific vaccines in Gulf War

4. REPORTING AGENCY

a. ACTION AGENCY	c. TELEPHONE NO.	e. APPROVING MILITARY / EXECUTIVE ASSISTANT (Service Secretary / Under Secretary / ASD Level) Signature	
OSAGWI	(b)(6)		
b. NAME OF ACTION OFFICER	d. DATE (YYMMDD)	(b)(6)	Date Signed
Capt (b)(6)	990726		26 July 99

5. CCD CONTROL
U09268-99

6. ACTION TAKEN (For Correspondence Control Division Use Only)

a. EXTENSION / CANCELLATION		Approved		Disapproved
b. OTHER (Specify)				

SD FORM 391, AUG 87 *Previous editions are obsolete.*

ELECTRONIC FORM EXCEPTION APPROVED BY WHS/DIOR, MAR 99

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
FOR
GULF WAR ILLNESSES

JUL 21 1999

MEMORANDUM FOR SPECIAL ASSISTANT FOR GULF WAR ILLNESSES

THROUGH: Executive Assistant
Deputy Special Assistant
PM, Gulf War Illnesses Support

FROM: Director, Public Affairs (John Slepetz)

SUBJECT: Proposed interim response to Senator Arlen Specter on behalf of a constituent, (b)(6)

PURPOSE: To provide Senator Specter with an interim while the investigation is underway.

DISCUSSION: (b)(6), a DoD civilian, wrote to Senators Specter and Santorum, the Secretary of Defense, and the Secretary of the Army, seeking information about inoculations he received during Desert Shield.

(b)(6) now believes he was given the anthrax vaccine and questions why he wasn't informed at the time. He questions DoD's right to inoculate him without informed consent. He also seeks treatment and compensation.

Staff members in the Medical Outreach and Initiatives office are in the process of identifying the inoculations he received. Anthrax is unlikely due to the time frame he cites.

An inquiry sent to Health Affairs in May from (b)(6) was forwarded in May. In light of the incomplete information to date, we sent him an interim response (Tab C). In this proposed response, we inform Senator Specter of our actions to date and intent to identify the vaccine (b)(6) actually received.

RECOMMENDATION: Review and sign the proposed interim response.
OSAGWI

APPROVED: [signature] JUL 27 1999
DISAPPROVED: _____
OTHER: _____

For follow up letter
Get Info for
Civ - CCEP
- do advance
work + phone calls
To set up
physical

CONGRESSIONAL or SPECIAL CORRESPONDENCE

Office of Special Assistant for Gulf War
Internal Routing/Tasking Sheet

CMAT: 9183-037
9146-019
Date: 7-21-

Coord/ Routing	Position/Organization		Action	Info	Comments
7	Special Assistant	(SA)			
5	Deputy Special Assistant	(DSA)	7.26		
6	Executive Assistant to SA	(EA)			
	Executive Assistant to DSA	(EADSA)			
2	☐ Director, Investigation & Analysis ____ (IAD) ☐ DepDir ____ ☒ MED ____ ☐ VDM ____ ☐ C/B ____ ☐ ENV ____ ☐ PAG ____				
	Dir Lessons Learned Implementation	(LLI)			
3	Dir Public Affairs & Outreach	(PA)	26 Jul		
2A	Dir Legislative Outreach	(LA)			faxed copy 7/22
3A	Dir Medical Outreach & Issues	(MOI)	WPR - sign as such		
	Legal Advisor	(LGL)			
4	PM, Gulf War Illnesses Support	(PM)	26 Jul		
1	Editorial Review ☒ AMB ✓ ☒ Editors	(ER)			
	CMAT	(CMAT)			
8	Action Management Call 845-8369 ☒ COMEBACK COPY TO: MOI ☐ GET CMAT NUMBER WHEN SIGNED & SENT ☐ READING FILE ☐ THANK YOU FILE ☒ CHRON FILE ☐ ADD TO GulfNEWS				

SUSPENSE:

Prepare reply for signature of:
☐ SA/GWI ☐ SD ☐ DSD ☐ DepSA/GWI

- Senator Specter's interim response regarding (b)(6)

- (b)(6) interim response of Jun 8, 1999 at TAB.

☐ Congress ☐ Oversight ☐ FOIA ☐ OSD ☐ WBM ☐ VSO/MSO
☐ Ltr to SA ☐ IR ☐ E-Mail ☐ OGA ☐ Other ☐ Veteran

KEYWORDS:

06/17/99 Issuance

COPY FOR BOB

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
FOR
GULF WAR ILLNESSES

JUL 21 1999

MEMORANDUM FOR SPECIAL ASSISTANT FOR GULF WAR ILLNESSES

THROUGH: Executive Assistant
Deputy Special Assistant
PM, Gulf War Illnesses Support

FROM: Director, Public Affairs (John Slepetz)

SUBJECT: Proposed interim response to Senator Arlen Specter on behalf of a constituent, (b)(6)

PURPOSE: To provide Senator Specter with an interim while the investigation is underway.

DISCUSSION: Mr. Fink, a DoD civilian, wrote to Senators Specter and Santorum, the Secretary of Defense, and the Secretary of the Army, seeking information about inoculations he received during Desert Shield.

(b)(6) now believes he was given the anthrax vaccine and questions why he wasn't informed at the time. He questions DoD's right to inoculate him without informed consent. He also seeks treatment and compensation.

Staff members in the Medical Outreach and Initiatives office are in the process of identifying the inoculations he received. Anthrax is unlikely due to the time frame he cites.

An inquiry sent to Health Affairs in May from (b)(6) was forwarded in May. In light of the incomplete information to date, we sent him an interim response (Tab C). In this proposed response, we inform Senator Specter of our actions to date and intent to identify the vaccine (b)(6) actually received.

RECOMMENDATION: Review and sign the proposed interim response.

OSAGWI

APPROVED: [signature]
DISAPPROVED: _____
OTHER: _____

JUL 27 1999

For Follow up later
Get Info for
Civ - CCEP
do advance
work + phone calls
To set up
phone ICAL

(b)(6)

6-3. SUSPENSE DATE, INTERIM REPLIES, AND ACKNOWLEDGMENTS

a. Suspense dates are established at the time of action assignment. Suspense dates will be as outlined in Chapter 1, Paragraph 1-5d (2). Exceptions will be made in those cases in which the correspondence contains a requirement for information requiring extensive research or involvement.

b. Heads of OSD Components are responsible for preparing replies within established suspense dates. If a suspense cannot be met, the Action Agency shall forward an SD Form 391 to the CCD stating an estimated completion date and the reason for the delay. Provide information on what has been accomplished and what still needs to be done before the response is completed.

c. Action offices shall furnish interim replies when all of the information is not readily available or is of such volume or complexity as to prohibit preparation of a complete reply within the established suspense date. The interim reply shall be made promptly and shall include available information, reason for the delay, steps being taken to obtain the information requested, and the date by which a final response may be expected.

d. When initial acknowledgments are used promising substantive responses later, every effort shall be made to dispatch such follow-up letters within five working days. In those few instances when final replies cannot be made within this time limit, an interim reply shall be provided as indicated above.

e. Interim replies should be made in writing. In those exceptional cases when an interim reply is made by telephone, the Action Agency shall forward to the CCD an SD Form 391 containing the name and telephone number of the person contacted and a brief statement of the information provided.

f. Copies of all interim and final replies and acknowledgments shall be furnished to the CCD. Copies of final replies should include the original incoming correspondence. These documents then become part of the official records of the Secretary and Deputy Secretary.

g. A copy of all Reply Direct correspondence to a Member of Congress signed in the OSD shall be furnished to the Assistant Secretary of Defense (Legislative Affairs).

6-4. SUSPENSE REPORTING

a. The CCD submits weekly reports to the offices of the Secretary and Deputy Secretary of Defense, and to the Executive Secretary reflecting the status of all correspondence due or overdue. The report status must reflect accurate and current information as provided by each action office.

b. On Friday of each week (Thursday when Friday is a holiday), a machine printout of White House and Congressional suspense cases, due or to become due as the following Tuesday, is

CHAPTER 6

REPLIES TO CONGRESSIONAL, GENERAL PUBLIC, AND WHITE HOUSE CORRESPONDENCE

6-1. GENERAL. Replies to Congressional, General Public, and White House correspondence shall be prepared in accordance with the preceding chapters with more specific guidance in Chapter 2. This chapter adds instruction about the special practices that may be necessary in replying to such correspondence.

6-2. ACTION ASSIGNMENT

a. The CCD is responsible for the receipt, analysis, action assignment, and control of all Congressional and General Public correspondence addressed to the Secretary and Deputy Secretary, Congressional correspondence addressed to the Assistant Secretary of Defense (Legislative Affairs), and White House correspondence referred to the DoD for reply.

b. In the event the content of an incoming communication involves subject matter of equal responsibility to more than one OSD Component, the CCD shall assign primary responsibility to one of the offices and require appropriate coordination.

c. Designated Action Agencies may appeal the action assignment within 24 hours by contacting the appropriate CCD office (See Paragraph 1-2.b). Such appeal must be made by the Action officer, an Executive Officer, or higher level person. After the 24-hour period, action changes are the responsibility of the initial action office. Mutually agreed action transfers are made by returning the original correspondence to the CCD under cover of an SD Form 391, "Report on Secretary of Defense Correspondence," showing the name, office and telephone number of the accepting official.

d. In cases where agreement as to action responsibility cannot be reached, return the original correspondence to the CCD within 24 hours with a covering SD Form 391, signed by the action officer, an Executive Officer or higher level person, indicating agencies contacted and a brief statement of reasons for their refusing responsibility.

e. In those cases where the action assignment is for preparation of a reply for the signature of the Secretary or Deputy Secretary (PRS/PRD), and the action agency determined the correspondence does not require a reply, an SD Form 391 must be submitted to the CCD stating the reasons in full. Such statements as "overtaken by events" or "reply not necessary" are NOT acceptable unless accompanied by explicit reasons as to how the correspondence has been overtaken by events or why a reply is not necessary.

INTERIM RESPONSE LETTER 1999146-0000019

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
FOR
GULF WAR ILLNESSES

(b)(6)

JUN 0 8 1999

Dear (b)(6)

The purpose of this letter is to acknowledge that I received your letter of May 9, 1999 that you sent to the Secretary of Defense regarding the anthrax vaccination. It is my intent to be timely and responsive to letters such as yours, however, the information you requested will require my staff to do some fact-finding and coordination. I expect to provide you with a response within the next 30 days.

Thank you for contacting my office. Should you have any questions, please contact (b)(6)

Sincerely,

Bernard Rostker

CONGRESSIONAL or SPECIAL CORRESPONDENCE

Office of Special Assistant for Gulf War
Internal Routing/Tasking Sheet

CMAT: 9183-037
9146-019
Date: 7-21-99

Coord/ Routing	Position/Organization		Action	Info	Comments
7	Special Assistant	(SA)			
5	Deputy Special Assistant	(DSA)			
6	Executive Assistant to SA	(EA)			
	Executive Assistant to DSA	(EADSA)			
2	☐ Director, Investigation & Analysis ____ (IAD) ☐ DepDir ____ ☒ MED ____ ☐ VDM ____ ☐ C/B ____ ☐ ENV ____ ☐ PAG ____				
	Dir Lessons Learned Implementation	(LLI)			
3	Dir Public Affairs & Outreach	(PA)			
2A	Dir Legislative Outreach	(LA)	____	PML CINCUES 7.27.99	
3A	Dir Medical Outreach & Issues	(MOI)			
	Legal Advisor	(LGL)			
4	PM, Gulf War Illnesses Support	(PM)			
1	Editorial Review ☒ AMB ☒ Editors	(ER)			
	CMAT	(CMAT)			
8	Action Management Call 845-8369 ☒ COMEBACK COPY TO: MOI ☐ GET CMAT NUMBER WHEN SIGNED & SENT ☐ READING FILE ☐ THANK YOU FILE ☒ CHRON FILE ☐ ADD TO GulfNEWS				

SUSPENSE:

Prepare reply for signature of:
☐ SA/GWI ☐ SD ☐ DSD ☐ DepSA/GWI

-Senator Specter's interim response regarding

- (b)(6)

- (b)(6) interim response of Jun 8, 1999 at TAB C

☐ Congress ☐ Oversight ☐ FOIA ☐ OSD ☐ WBM ☐ VSO/MSO
☐ Ltr to SA ☐ IR ☐ E-Mail ☐ OGA ☐ Other ☐ Veteran

KEYWORDS:

Office of the Secretary of Defense
Legislative Affairs

Fax to: (b)(6)

Fax Number: (b)(6) (b)(6)

Location:

Pages Sent (including cover sheet): 2

From: OSD/LA

The Pentagon. Washington. D.C. 20301-1300

Telephone Number: (b)(6)

Comments:

(b)(6) @osd.pentagon.mil on 07/27/99 09:18:15 AM

To: (b)(6) /OSAGWI
cc:
Subject: RE: U09268-99 (SENATOR SPECTOR RESPONSE TO (b)(6)

I've been TDY and returned today. I just signed the coordination and my admin will fax it back to you ASAP. Thanks

> -----Original Message-----
> From: (b)(6)
> Sent: Monday, July 26, 1999 10:10 AM
> To: (b)(6) @osd.pentagon.mil
> Subject: U09268-99 (SENATOR SPECTOR RESPONSE TO (b)(6)
>
>
>
>
>
> (b)(6
>
> Did you have a chance to review the Senator Spector response?
>
(b)(6)

INTERIM RESPONSE LETTER 1999146-0000019

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
FOR
GULF WAR ILLNESSES

(b)(6)

JUN 0 8 1999

Dear (b)(6)

The purpose of this letter is to acknowledge that I received your letter of May 9, 1999 that you sent to the Secretary of Defense regarding the anthrax vaccination. It is my intent to be timely and responsive to letters such as yours, however, the information you requested will require my staff to do some fact-finding and coordination. I expect to provide you with a response within the next 30 days.

Thank you for contacting my office. Should you have any questions, please contact (b)(6)

Sincerely,

Bernard Rostker

CONGRESSIONAL or SPECIAL CORRESPONDENCE

Office of Special Assistant for Gulf War Illnesses
Internal Routing/Tasking Sheet

CMAT: 9146 - 019
Date: 5-26-99

Coord/ Routing	Position/Organization		Action	Info	Comments
	Special Assistant	(SA)			
	Deputy Special Assistant	(DSA)			
	Executive Assistant to SA	(EA)			
	Executive Assistant to DSA	(EADSA)			
	☐ Director, Investigation & Analysis _____ (IAD) ☐ DepDir _____ ☐ MED _____ ☐ VDM _____ ☐ C/B _____ ☐ ENV _____ ☐ PAG _____				
	Dir Lessons Learned Implementation	(LLI)			
	Dir Public Affairs & Outreach	(PA)	X		LEAD
	Dir Legislative Outreach	(LA)			
	Dir Quick Reaction Team	(QR)			
	Dir Medical Outreach & Issues	(MOI)	X		Assist
	Legal Advisor	(LGL)			
	PM, Gulf War Illnesses Support	(PM)			
	Editorial Review ☐ AMB _____ ☐ Editors _____	(ER)			
	CMAT	(CMAT)			
	Action Management Call 845-8369 ☐ COMEBACK COPY TO: _____ ☐ GET CMAT NUMBER WHEN SIGNED & SENT ☐ READING FILE ☐ THANK YOU FILE ☐ CHRON FILE ☐ ADD TO GulfNEWS				

SUSPENSE: 6-8-99

Prepare reply for signature of:
☒ SA/GWI ☐ SD ☐ DSD ☐ DepSA/GWI

- prepare response to (b)(6) question / coordinate through MOI

☐ Congress ☐ Oversight ☐ FOIA ☒ OSD ☐ WBM ☐ VSO/MSO
☐ Ltr to SA ☐ IR ☐ E-Mail ☐ OGA ☐ Other ☒ Veteran

KEYWORDS:
Anthrax vaccination

05/03/99 Issuance

CMAT Control #
1999146-0000019

Office of the Assistant Secretary of Defense (Health Affairs)
1200 Defense Pentagon, Room 3E346
Washington, DC 20301-1200

Assistant Secretary of Defense – Dr. Sue Bailey

FAX

Date: 25 MAY

OF PAGES: 10 (including cover sheet)

To:	From:
(b)(6)	(b)(6)
Phone	Phone:
Fax:	Fax:

REMARKS: ☐ Urgent ☐ For Your Information ☐ Reply ASAP ☐ Per Your Request
☐ Per our conversation ☐ Request Action By _____

COMMENTS:

5/20/99 **UNC - Unclassified Public Mail**

DIRECTORATE FOR CORRESPONDENCE AND DIRECTIVES
OFFICE OF THE SECRETARY OF DEFENSE

PUBLIC CORRESPONDENCE

OSD CONTROL NUMBER: **UB72592** ACTION AGENCY: **UPR** DATE ASSIGNED **5/20/99**

NAME: (b)(6) DEAN C. DOC: **5/ 9/99**

COMMENTS: ANTHRAX VACCINATION

********** PROCESSING INSTRUCTIONS **********

THIS CORRESPONDENCE IS FORWARDED FOR YOUR AGENCY'S APPROPRIATE ACTION. IF THE WRITER REQUESTS SPECIFIC INFORMATION, PLEASE RESPOND DIRECTLY TO THE WRITER. YOUR AGENCY IS THE OFFICIAL OFFICE OF RECORD FOR THIS MATTER. THE DIRECTORATE FOR CORRESPONDENCE AND DIRECTIVES DOES NOT REQUIRE A COPY OF YOUR REPLY. IF YOU HAVE ANY QUESTIONS, PLEASE CALL (b)(6)

VIR

FROM: (b)(6) **May 9,1999**

TO: Secretary of Defense
Secretary of The Army
The Honorable Senator Arlan Spector
The Honorable Senator Rick Santorum

SUBJECT: Anthrax Vaccination

Dear Sirs,

I am writing this letter in concern about the events that occurred while I voluntarily served as a civilian in Dessert Shield. I am currently employed as Deputy Chief of Special Operations Division, Defense Depot Susquehanna Pennsylvania.

During the period of September 13, 1990 through 15 November 1990, I served as part of an advance group of Army Civilian Employees in the Mideast. We were dispatch from the then New Cumberland Army Depot and temporarily home stationed in Dhahran, Saudi Arabia at ARCOM Headquarters. Our mission was to provide customer service and logistical support to Units deployed throughout the region.

In October 1991, all members of the A and B group, including myself were instructed by the Team Chief, (b)(6) **to report to the Airforce Medical Tent to receive a vaccination. We were under the assumption we were to be given a Hepatitis B Vaccination. After I received the vaccination, I asked the Nurse to annotate my Shot Record, as did others on my team. The Nurse refused. When I asked why she wouldn't annotate my shot Record, she wouldn't comment. Prior to our departure to the Gulf, the Depot Dispensary instructed us to have our Shot Records annotated if we received any vaccinations while deployed.**

Since we returned from the Persian Gulf, one of the team members had an extensive stay at Walter Reed Hospital, another died at his home at the age of (45), and most of the remaining (6) including myself have various illnesses.

On 3 May 1999, after learning of the controversy of the military receiving the Anthrax Vaccination I decided to pursue what kind of vaccination we did receive and why the Medical Nurse refused to annotate our Shot Records?

My pursuit lead to the following. I discovered we couldn't have received the Hepatitis B Vaccination. That type of vaccination requires three shots. And, there would be no reason for not recording this type of vaccination.

On 4 May 1999, while talking to our former Team Chief (b)(6), I got the rest of the story. (b)(6) told me he was informed by Col. Kuhns, our OIC at ARCOM Headquarters, approximately (6) years later in early 1997, that the vaccination given to us was the Anthrax Vaccine. Col. Kuhns also informed (b)(6) that he was forbidden to tell us what kind of shot we received at that time. (b)(6) seemed reluctant to give me this information. I can only assume he was asked to keep it confidential by Col. Kuhns.

I am very upset about this matter and do intend to pursue it to a conclusion.

1. **I want to know why the Department of Defense authorized the vaccination of Civilians with the Anthrax Vaccine through deceptive methods?**
2. **I want to know why Medical Personnel refused to annotate our Shot Records?**
3. **I want someone to explain to us why DOD violated our right to know and obtain consent.**
4. **I want to know the chemical breakdown of the Anthrax Vaccine.**

I am extremely disturbed about the fact that my country would knowingly administer this vaccine to others and myself in a covert manner and without our consent.
As an ex-Marine and combat veteran coupled with my background in supply logistics, I thought I would be an asset for helping the Troops deal with the crisis in the Persian Gulf. I think the team accomplished it's objective, although we will never know to what extent. These kinds of actions only breed mistrust and I would have to give great thought to any future adventures.

Therefore, I am requesting the following to resolve this issue.

1. **A complete medical physical and any test recommended by our Private Physician at a Medical Facility of our choosing and follow-up treatments and examinations paid in full by the Federal Government.**
2. **Reparatory compensation for any side affects/disabilities that could be associated with the administering of the Anthrax Vaccine.**
3. **Reparatory compensation for covertly administering the Anthrax Vaccine under false and deceptive methods and without consent.**

I await your response.

Please see attached enclosures.

Respectively,

(b)(6)

North Atlantic
Regional Medical Command
...doing whatever it takes!

ANNEX J (Department of the Army Civilians and DOD Contractors) to NARMC Plan 98-01 (AVIP)

1. PURPOSE. To provide the concept of operations and assign responsibilities for implementation of the Department of the Army Civilian (DAC) and DOD Contractor portion of the plan for the Anthrax Vaccination Implementation Program (AVIP).

2. APPLICABILITY. This annex applies to Department of the Army Civilians and DOD Contractors whose duties place them at risk for exposure to anthrax used as a biological weapon in a combat, or operational , setting. Ultimately the commander determines which employees are at sufficient risk to warrant anthrax immunization under the AVIP. Examples of employees who should be immunized include those who work in, or are likely to be deployed to, areas of operations identified as a high threat area. For the purpose of this plan, risk does not include the potential for anthrax used in acts of terrorism against noncombatants. In addition, the plan does not apply to employees who may be exposed to anthrax in a medical, veterinary or research occupational setting.

3. REFERENCES.

a. DODI 14.32, DOD Civilian Work Force Contingency and Emergency Planning Guidelines and Procedures, 24 Apr 95.

b. DODI 3020.37, Continuation of Essential DOD Contractor Services During Crises, 6 Nov 90.

4. GENERAL INFORMATION.

a. Vaccination of civilian employees and contractors is voluntary.

b. Command-directed anthrax immunization will be administered without charge to the employee.

c. In most instances, employee immunization is by consent, however, in certain circumstances anthrax immunization might be determined by the appropriate authority to be a condition of employment.

5. RESPONSIBILITIES.

Medical Treatment Facility (MTF) will:

a. Obtain employee consent IAW this plan and provide required immunizations.

b. Enter immunization data into automated Immunization Tracking System IAW this plan.

6. CONCEPT OF OPERATIONS.

a. Anthrax Immunization.

(1)Immunizations will be provided IAW medical guidance in Annex C.

(2) The determination of which employees are at sufficient risk to warrant anthrax immunization will be determined by the supervisor and ultimately the commander of the employee. Supervisors will work with their servicing Civilian Personnel Office (CPO) and their command to determine which employees will be included in the AVIP and will provide this information to the MTF.

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(1) In most cases, employee immunization is by consent. Normal immunization consent procedures will be followed. Employees will be encouraged to accept anthrax immunization when offered. However, in certain instances, anthrax immunization might be determined by the appropriate authority to be a condition of employment.

(2)The effect on a Department of the Army employee who refuses immunization when indicated will be determined by the supervisor and commander in conjunction with representatives of the servicing Civilian Personnel representatives.. Refusal of anthrax immunization must be documented in the employee personnel record and the occupational health record.

c. Health Education/Risk Communication. Health education on anthrax, the anthrax vaccine risks and benefits will be provided to all DACs and DOD Contractors prior to immunization IAW Annex K.

d. Documentation.

(1) Risk Communication. Supervisors will be responsible for ensuring that employees are adequately trained and aware of the health risk of anthrax as a biological weapon, and document that this training was received.

(2) Refusal of Immunization. Refusal must be documented as indicated in paragraph 6b above.

(3) Administration of Immunization. All anthrax immunizations will be recorded in the Civilian Employee Medical Record (CEMR) and on the PHS Form 731 (Yellow Shot Record) which will be provided to the employee. Written entries will contain the data elements described in Annex C.

(4) Immunization Tracking System. DAC and DOD Contractor immunizations will be entered into the automated Immunization Tracking System in the manner described in Annex K.

(5) Adverse Reactions. Serious adverse reactions to the immunization will be recorded in the CEMR and reported through the Army Medical Surveillance System IAW Annex C.

e. Tracking of Immunization. Supervisors are responsible for tracking their employees to ensure that they complete the anthrax immunization series.

[redacted] **December 1998**

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The Department of Defense's Anthrax Vaccine Experiment

by Meryl Nass, MD

What do you expect from a vaccine or other pharmaceutical? Only two things: it should be effective and safe. In reality, of course, no drug or biologic product is 100% safe; each is associated with side effects that occur in some proportion of users. The American public relies on the FDA to make careful and balanced decisions about risks and benefits when licensing products.

Recently, however, the licensing process has come under scrutiny. Five FDA-approved drugs had to be taken off the market in the past year due to unacceptable side effects. The vaccine for anthrax, developed and manufactured for the Department of Defense and never marketed commercially, could be next to be recalled.

According to the head of Bacteriology at Fort Detrick, Dr. Arthur Friedlander, no data on the effectiveness of this vaccine in humans exists. None was required by FDA until two years after the license was granted in 1970. Furthermore, the efficacy data in animals shows only moderate protection at best. According to Hambleton and Turnbull, British anthrax researchers, "Such vaccines can produce some protective activity in experimental animals and may be effective in humans."

Anthrax, used as an agent of biological warfare, is expected to be nearly 100% fatal in those who develop the disease. Therefore, a vaccine which provides only modest protection is still better than nothing, provided it is safe.

However, establishing safety for this vaccine is difficult. The vaccine never underwent the surveillance afforded to commercially produced vaccines . This should have consisted of a series of trials in humans who were carefully observed for short and longer-term side effects. But Kathryn Zoon, head of FDA's Center for Biologics Evaluation and Research, has written, "Data for clinical studies conducted on the long term effects of taking the anthrax vaccine have not been submitted to the FDA."

This would be less of a concern if the first large-scale use of the vaccine in humans had been carefully studied for adverse effects. The opposite happened. 150,000 Gulf War troops were given one or more doses of anthrax vaccine, but were told that their anthrax inoculations were secret. The immunizations were not entered into their medical records. Furthermore, according to the Defense Department, the master lists which recorded the vaccinations are all lost. Thus determining which soldiers received the vaccine and whether the vaccine contributed to subsequent illness is not possible. A 1994 report of the Senate Committee on Veterans' Affairs concluded that safety of the anthrax vaccine was in question, noting that Gulf War illness was higher in support troops, who were more likely to be vaccinated.

Despite the lack of safety data, the Department of Defense has moved forward with an even larger human experiment. A program to vaccinate all 2.4 million active duty, reserve, coast guard and national guard troops in the United States began in March 1998, and service members who have refused the inoculations have been punished severely. Many have been given general discharges from the military. With astounding indifference toward appropriate vaccine surveillance during the current round of vaccinations, the Defense Department announced that it will perform no particular follow-up of service members following anthrax vaccination, because the vaccine is not considered experimental.

As the military was readying for the anthrax vaccinations, the public learned that FDA had issued the vaccine manufacturer a warning letter in 1995, and threatened to shut the plant down in 1997. It later was learned that the Army, not the FDA, had been inspecting anthrax vaccine production since 1991 or earlier. (FDA had regularly inspected other facilities at the plant.) Finally, a month before troops began their vaccinations, FDA performed an inspection. The February 1998 FDA inspection report contains 11 pages of deviations from "good manufacturing practices" in anthrax vaccine production alone. These included re-dating of expired vaccines after retesting for potency but not degradants, and use of vaccine from lots in which many bottles were discarded for contaminants, without further testing of the remaining bottles. Vaccine production has now stopped for repairs, but the millions of doses of existing vaccine are to be used.

Immunizing US troops against anthrax may be a worthy goal. But vaccinating service members with a shoddily produced vaccine, which has a poor record of effectiveness and may be dangerous, is neither good medical practice nor sound military strategy.

***

Meryl Nass is a Brunswick, Maine internist and emergency physician with a BS from MIT and an MD from the University of Mississippi. She has done

research on chemical and biological warfare epidemics in Cuba and Zimbabwe, developed methodology for determining whether an epidemic is natural or was deliberately caused, and is a member of the Federation of American Scientists Working Group on Biological Weapons Verification. Recently, she has published widely on the military's anthrax vaccine program, and the possible contribution of the vaccine to Gulf War illness. She can be contacted at mnass@igc.apc.org.

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Maine Activists | About the Dissident

The Dissident
P.O. Box 361
Brunswick, ME 04917
dissident@dissident.org

Last updated December 15, 1998

DEPARTMENT OF DEFENSE
MEDICAL REGISTRY

P.O. BOX 130
SEASIDE, CA 93955-0130

16 January 1997

(b)(6)

The purpose of this letter is to confirm information provided to the Department of Defense Medical Registry by (b)(6) on 14-Jan-1997. As a result of this contact, we have recorded the following information in a computer database.

SPONSOR	SSN:	(b)(6)
PARTICIPANT	SSN:	
	Name:	
	Identifier:	
	Birth Date:	
	Daytime Telephone:	
	Alternate Telephone:	
	Address:	

If you have any questions or if any of the information, above, is incorrect, please let us know by calling the Medical Registry at 1-800-796-9699. For your information, a Privacy Act Notice for the DoD Medical Registry is enclosed.

Robert J Brandewie
Coordinator, DoD Medical Registry Hotline

SECRETARY OF DEFENSE CORRESPONDENCE ACTION REPORT

This form must be completed and delivered to the Correspondence Control Division (CCD), WHS Room 3A948, not later than (YYMMDD) **990729** **('GWI')**

1. DATE (YYMMDD)

2. ACTION TAKEN (X one)

- [ ] a. ACTION HAS BEEN COMPLETED (Copy attached)
- [ ] b. REQUEST CANCELLATION / EXTENSION OF SUSPENSE DATE TO _____ *(Justify below)*
- [ ] c. INTERIM REPLY HAS BEEN SENT (Copy attached)

3. JUSTIFICATION

4. REPORTING AGENCY

a. ACTION AGENCY	c. TELEPHONE NO.	e. APPROVING MILITARY / EXECUTIVE ASSISTANT *(Service Secretary / Under Secretary / ASD Level)*	
b. NAME OF ACTION OFFICER	d. DATE *(YYMMDD)*	Signature	Date Signed

5. CCD CONTROL
U09268-99

6. ACTION TAKEN *(For Correspondence Control Division Use Only)*

a. EXTENSION / CANCELLATION		Approved		Disapproved

b. OTHER (Specify)

SD FORM 391, AUG 87 ***Previous editions are obsolete.***

ELECTRONIC FORM EXCEPTION APPROVED BY WHS/DIOR, MAR 99

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Congressional

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	SECRETARY OF DEFENSE				SECRETARY OF THE ARMY		X
	DEPUTY SECRETARY OF DEFENSE				SECRETARY OF THE NAVY		
	THE SPECIAL ASSISTANT				SECRETARY OF THE AIR FORCE		
	EXECUTIVE SECRETARY						
	UNDER SEC FOR ACQUISITION & TECHNOLOGY				CHAIRMAN, JOINT CHIEFS OF STAFF		
	Director, Defense Research & Engineering				Director, Joint Staff		
	UNDER SECRETARY FOR POLICY						
	ASD (International Security Affairs)				BALLISTIC MISSILE DEFENSE ORGANIZATION		
	ASD (Special Operations/LIC)				DEFENSE ADVANCED RESEARCH PROJECTS AGENCY		
	ASD (Strategy &Threat Reduction)				DEFENSE COMMISSARY AGENCY		
	UNDER SECRETARY (COMPTROLLER)				DEFENSE CONTRACT AUDIT AGENCY		
	Director, Program Analysis and Evaluation				DEFENSE FINANCE & ACCOUNTING SERVICE		
	UNDER SEC FOR PERSONNEL & READINESS		X		DEFENSE INFORMATION SYSTEMS AGENCY		
	ASD (Force Management Policy)				DEFENSE INTELLIGENCE AGENCY		
	ASD (Health Affairs)		X		DEFENSE LEGAL SERVICES AGENCY		
	ASD (Reserve Affairs)				DEFENSE LOGISTICS AGENCY		
	ASD (C3I)				DEFENSE SECURITY COOPERATION AGENCY		
	ASD (LEGISLATIVE AFFAIRS)		X		DEFENSE SECURITY SERVICE		
	ASD (PUBLIC AFFAIRS)				DEFENSE THREAT REDUCTION AGENCY		
	GENERAL COUNSEL				NATIONAL IMAGERY AND MAPPING AGENCY		
	INSPECTOR GENERAL				NSA/CENTRAL SECURITY SERVICE		
	DIR, OPERATIONAL TEST & EVALUATION						
	DIR, ADMINISTRATION & MANAGEMENT						
				1	GWI	X	

TYPE OF ACTION REQUIRED

	PREPARE REPLY FOR SEC OF DEF SIGNATURE		COMMENTS AND/OR RECOMMENDATIONS
	PREPARE REPLY FOR DEP SEC OF DEF SIGNATURE		INFORMATION AND RETENTION
1	REPLY DIRECT *(Forward copy of reply to CCD, Room 3A948)*	X	COORDINATE REPLY WITH LA
	APPROPRIATE ACTION		

Remarks:

ACTION DUE DATE *(YYMMDD)*	ROUTING DATE *(YYMMDD)*	OSD CONTROL NUMBER	
990729	990608	U09268-99	

SECRETARY OF DEFENSE CORRESPONDENCE ACTION REPORT

This form must be completed and delivered to the Correspondence Control Division (CCD), WHS Room 3A948, not later than (YYMMDD)

1. DATE (YYMMDD) 990706

2. ACTION TAKEN (X one)

	a. ACTION HAS BEEN COMPLETED (Copy attached)
X	b. REQUEST CANCELLATION / EXTENSION OF SUSPENSE DATE TO TRANSFER (Justify below)
	c. INTERIM REPLY HAS BEEN SENT (Copy attached)

3. JUSTIFICATION

Refer to GWI for action. See attached note from (b)(6), GWI. That office is already working this letter.

OK BAH 7/8/99 GWI

90700557
USS Specter

4. REPORTING AGENCY

a. ACTION AGENCY SALL-CID	c. TELEPHONE NO. 697-4773	e. APPROVING MILITARY / EXECUTIVE ASSISTANT (Service Secretary / Under Secretary / ASD Level) Signature	Date Signed
b. NAME OF ACTION OFFICER (b)(6)	d. DATE (YYMMDD) 990706	(b)(6)	7/7/99

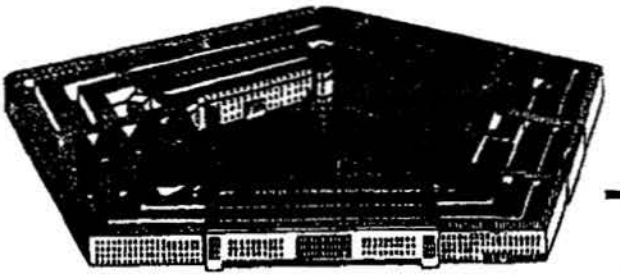
5. CCD CONTROL
U09268-99

6. ACTION TAKEN (For Correspondence Control Division Use Only)

a. EXTENSION / CANCELLATION		Approved		Disapproved
b. OTHER (Specify)				

SD FORM 391, AUG 87 *Previous editions are obsolete.*

ELECTRONIC FORM EXCEPTION APPROVED BY WHS/DIOR, MAR 90



Telefax

from

TO →

(b)(6)

Office of the Chief of Legislative Liaison
1600 Army Pentagon
Washington, D. C. 20310-1600
Telephone: (b)(6)
Fax: (b)(6)

Date: 6/30/99

Page 1 of 8

To: (b)(6)

Voice: (b)(6)

Fax: (b)(6)

Regarding response to Senator Specter on (b)(6) – we are already responding to (b)(6) on same letter and we will take action to respond to Specter.

On Hutchison, you still have it. See how we responded to Grannum – we tried to help him even though he is civilian. CCEP records show, however that he declined. The systemic problem needs to be worked by DOL Workmen's Comp folks

Subject: Gulf War Congressionals

Remarks: (b)(6) I believe the attached two inquiries might be better addressed by GWI. Please review and advise. The Hutchison inquiry has been to OSD(HA), USD(P/R). OTSG believes it should be addressed from a DoD-wide position, i.e., what are entitlements to DoD civilians for treatment/evaluation under CCEP. The Specter inquiry is about civilians unwittingly receiving the anthrax vaccine. The compensation issue can be addressed by advising on procedures to submit a claim through the Army Claims Service.

(b)(6)

THANKS (b)(6)! THESE BOTH CAME TO ARMY VIA DoD.

SECRETARY OF DEFENSE CORRESPONDENCE ACTION REPORT

This form must be completed and delivered to the Correspondence Control Division (CCD), WHS Room 3A948, not later than (YYMMDD)

1. DATE (YYMMDD) 99/06/22

2. ACTION TAKEN (X one)

	a. ACTION HAS BEEN COMPLETED (Copy attached)
X	b. REQUEST CANCELLATION / EXTENSION OF SUSPENSE DATE TO TRANSFER *(Justify below)*
	c. INTERIM REPLY HAS BEEN SENT (Copy attached)

3. JUSTIFICATION

REQUEST THE ATTACHED CASE BE TRANSFERRED TO THE ARMY, AS IT DEALS WITH AN ARMY CIVILIAN WHO APPARENTLY WAS ADMINISTERED THE ANTHRAX VACCINE DURING HIS DEPLOYMENT TO DESERT STORM AND NOW DEMANDS COMPENSATION FROM THE ARMY AS WELL AS FOLLOW-UP MEDICAL CARE FROM THE GOVERNMENT.

OK Falk 6/28/99 SA

Concur 6-24

4. REPORTING AGENCY

a. ACTION AGENCY	c. TELEPHONE NO.	e. APPROVING MILITARY / EXECUTIVE ASSISTANT (Service Secretary / Under Secretary / ASD Level)	
OASD/HA	(b)(6)	Signature (b)(6)	Date Signed 22 June 99
b. NAME OF ACTION OFFICER (b)(6)	d. DATE (YYMMDD) 99/06/22		

5. CCD CONTROL	6. ACTION TAKEN (For Correspondence Control Division Use Only)			
HA #26894 P&R 0081454	a. EXTENSION / CANCELLATION		Approved	Disapproved
OSD U 09268-99	b. OTHER (Specify)			

SD FORM 391, AUG 87 *Previous editions are obsolete.*

ELECTRONIC FORM EXCEPTION APPROVED BY WHS/DIOR, MAR 90

ARLEN SPECTER
PENNSYLVANIA

COMMITTEES:
JUDICIARY
APPROPRIATIONS
VETERANS' AFFAIRS
GOVERNMENTAL AFFAIRS

☐ 711 HART SENATE BUILDING
WASHINGTON, DC 20510-3802
202-224-4254

United States Senate

WASHINGTON, DC 20510-3802

☑ STATE OFFICES:
☐ 600 ARCH STREET, SUITE 9400
PHILADELPHIA, PA 19106
215-597-7200
☐ SUITE 2031, FEDERAL BUILDING
PITTSBURGH, PA 15222
412-644-3400
☐ ROOM 107, FEDERAL BUILDING
ERIE, PA 16501
814-453-3010
☐ ROOM 1159, FEDERAL BUILDING
HARRISBURG, PA 17101
717-782-3951
☐ ROOM 102, POST OFFICE BUILDING
ALLENTOWN, PA 18101
610-434-1444
☐ 310 SPRUCE STREET, SUITE 201
SCRANTON, PA 18503
570-348-2006
☐ ROOM 308, 116 S. MAIN STREET
WILKES-BARRE, PA 18701
717-826-6265

June 2, 1999

Department of Defense
The Pentagon
Washington, D.C. 20301

Dear Director:

My office has been contacted by (b)(6) I am forwarding to you a copy of the correspondence that I have received.

Your finding and views, in duplicate form, along with the return of the enclosure, will be greatly appreciated. Please direct your reply to my Assistant, Mary Clark, at the following address:

Senator Arlen Specter
9400 Federal Building
600 Arch Street
Philadelphia, PA 19106

Thank you for your attention to the aforementioned matter.

Sincerely,

Arlen Specter

AS/mjc

RECEIVED MAY 1 9 1999

FROM: (b)(6) [redacted]

May 9,1999

TO: Secretary of Defense
Secretary of The Army
The Honorable Senator Arlan Spector
The Honorable Senator Rick Santorum

SUBJECT: Anthrax Vaccination

Dear Sirs,

I am writing this letter in concern about the events that occurred while I voluntarily served as a civilian in Dessert Shield. I am currently employed as Deputy Chief of Special Operations Division, Defense Depot Susquehanna Pennsylvania.

During the period of September 13, 1990 through 15 November 1990, I served as part of an advance group of Army Civilian Employees in the Mideast. We were dispatch from the then New Cumberland Army Depot and temporarily home stationed in Dhahran, Saudi Arabia at ARCOM Headquarters. Our mission was to provide customer service and logistical support to Units deployed throughout the region.

In October 1991, all members of the A and B group, including myself were instructed by the Team Chief, (b)(6) [redacted] **to report to the Airforce Medical Tent to receive a vaccination. We were under the assumption we were to be given a Hepatitis B Vaccination. After I received the vaccination, I asked the Nurse to annotate my Shot Record, as did others on my team. The Nurse refused. When I asked why she wouldn't annotate my shot Record, she wouldn't comment. Prior to our departure to the Gulf, the Depot Dispensary instructed us to have our Shot Records annotated if we received any vaccinations while deployed.**

Since we returned from the Persian Gulf, one of the team members had an extensive stay at Walter Reed Hospital, another died at his home at the age of (45), and most of the remaining (6) including myself have various illnesses.

On 3 May 1999, after learning of the controversy of the military receiving the Anthrax Vaccination I decided to pursue what kind of vaccination we did receive and why the Medical Nurse refused to annotate our Shot Records?

My pursuit lead to the following. I discovered we couldn't have received the Hepatitis B Vaccination. That type of vaccination requires three shots. And, there would be no reason for not recording this type of vaccination.

On 4 May 1999, while talking to our former Team Chief (b)(6), I got the rest of the story. (b)(6) told me he was informed by Col. Kuhns, our OIC at ARCOM Headquarters, approximately (6) years later in early 1997, that the vaccination given to us was the Anthrax Vaccine. Col. Kuhns also informed (b)(6) that he was forbidden to tell us what kind of shot we received at that time. (b)(6) seemed reluctant to give me this information. I can only assume he was asked to keep it confidential by Col. Kuhns.

I am very upset about this matter and do intend to pursue it to a conclusion.

1. **I want to know why the Department of Defense authorized the vaccination of Civilians with the Anthrax Vaccine through deceptive methods?**
2. **I want to know why Medical Personnel refused to annotate our Shot Records?**
3. **I want someone to explain to us why DOD violated our right to know and obtain consent.**
4. **I want to know the chemical breakdown of the Anthrax Vaccine.**

I am extremely disturbed about the fact that my country would knowingly administer this vaccine to others and myself in a covert manner and without our consent.

As an ex-Marine and combat veteran coupled with my background in supply logistics, I thought I would be an asset for helping the Troops deal with the crisis in the Persian Gulf. I think the team accomplished it's objective, although we will never know to what extent. These kinds of actions only breed mistrust and I would have to give great thought to any future adventures.

Therefore, I am requesting the following to resolve this issue.

1. **A complete medical physical and any test recommended by our Private Physician at a Medical Facility of our choosing and follow-up treatments and examinations paid in full by the Federal Government.**
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I await your response.

Please see attached enclosures.

Respectively,

(b)(6)

DEPARTMENT OF DEFENSE
MEDICAL REGISTRY

P.O. BOX 130
SEASIDE, CA 93955-0130

16 January 1997

(b)(6)

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PARTICIPANT	SSN:	
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	Identifier:	
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	Alternate Telephone:	
	Address:	

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Robert J Brandewie
Coordinator, DoD Medical Registry Hotline

North Atlantic
Regional Medical Command
...doing whatever it takes!

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The dissident December 1998

The Department of Defense's Anthrax Vaccine Experiment

by Meryl Nass, MD

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According to the head of Bacteriology at Fort Detrick, Dr. Arthur Friedlander, no data on the effectiveness of this vaccine in humans exists. None was required by FDA until two years after the license was granted in 1970. Furthermore, the efficacy data in animals shows only moderate protection at best. According to Hambleton and Turnbull, British anthrax researchers, "Such vaccines can produce some protective activity in experimental animals and may be effective in humans."

Anthrax, used as an agent of biological warfare, is expected to be nearly 100% fatal in those who develop the disease. Therefore, a vaccine which provides only modest protection is still better than nothing, provided it is safe.

However, establishing safety for this vaccine is difficult. The vaccine never underwent the surveillance afforded to commercially produced vaccines . This should have consisted of a series of trials in humans who were carefully observed for short and longer-term side effects. But Kathryn Zoon, head of FDA's Center for Biologics Evaluation and Research, has written, "Data for clinical studies conducted on the long term effects of taking the anthrax vaccine have not been submitted to the FDA."

This would be less of a concern if the first large-scale use of the vaccine in humans had been carefully studied for adverse effects. The opposite happened. 150,000 Gulf War troops were given one or more doses of anthrax vaccine, but were told that their anthrax inoculations were secret. The immunizations were not entered into their medical records. Furthermore, according to the Defense Department, the master lists which recorded the vaccinations are all lost. Thus determining which soldiers received the vaccine and whether the vaccine contributed to subsequent illness is not possible. A 1994 report of the Senate Committee on Veterans' Affairs concluded that safety of the anthrax vaccine was in question, noting that Gulf War illness was higher in support troops, who were more likely to be vaccinated.

Despite the lack of safety data, the Department of Defense has moved forward with an even larger human experiment. A program to vaccinate all 2.4 million active duty, reserve, coast guard and national guard troops in the United States began in March 1998, and service members who have refused the inoculations have been punished severely. Many have been given general discharges from the military. With astounding indifference toward appropriate vaccine surveillance during the current round of vaccinations, the Defense Department announced that it will perform no particular follow-up of service members following anthrax vaccination, because the vaccine is not considered experimental.

As the military was readying for the anthrax vaccinations, the public learned that FDA had issued the vaccine manufacturer a warning letter in 1995, and threatened to shut the plant down in 1997. It later was learned that the Army, not the FDA, had been inspecting anthrax vaccine production since 1991 or earlier. (FDA had regularly inspected other facilities at the plant.) Finally, a month before troops began their vaccinations, FDA performed an inspection. The February 1998 FDA inspection report contains 11 pages of deviations from "good manufacturing practices" in anthrax vaccine production alone. These included re-dating of expired vaccines after retesting for potency but not degradants, and use of vaccine from lots in which many bottles were discarded for contaminants, without further testing of the remaining bottles. Vaccine production has now stopped for repairs, but the millions of doses of existing vaccine are to be used.

Immunizing US troops against anthrax may be a worthy goal. But vaccinating service members with a shoddily produced vaccine, which has a poor record of effectiveness and may be dangerous, is neither good medical practice nor sound military strategy.

* * *

Meryl Nass is a Brunswick, Maine internist and emergency physician with a BS from MIT and an MD from the University of Mississippi. She has done

research on chemical and biological warfare epidemics in Cuba and Zimbabwe, developed methodology for determining whether an epidemic is natural or was deliberately caused, and is a member of the Federation of American Scientists Working Group on Biological Weapons Verification. Recently, she has published widely on the military's anthrax vaccine program, and the possible contribution of the vaccine to Gulf War illness. She can be contacted at mnass@igc.apc.org.

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The Dissident
P.O. Box 361
Brunswick, ME 04917
dissident@dissident.org

Last updated December 15, 1998

CMAT #: 1999148-E000006

EMAIL – (b)(6)

CONGRESSIONAL or SPECIAL CORRESPONDENCE

CMAT: 9148-E006

Date: 7-21-99

Office of Special Assistant for Gulf War Illnesses
Internal Routing/Tasking Sh[redacted]

Coord/ Routing	Position/Organization		Action	Info	Comments
	Special Assistant	(SA)			
	Deputy Special Assistant	(DSA)			
	Executive Assistant to SA	(EA)			
	Executive Assistant to DSA	(EADSA)			
	☐ Director, Investigation & Analysis _____	(IAD)			
	☐ DepDir _____ ☐ MED _____ ☐ VDM _____ ☐ C/B _____ ☐ ENV _____ ☐ PAG _____				
	Dir Lessons Learned Implementation	(LLI)			
	Dir Public Affairs & Outreach	(PA)	X		
	Dir Legislative Outreach	(LA)			
	Dir Medical Outreach & Issues	(MOI)			
	Legal Advisor	(LGL)			
	PM, Gulf War Illnesses Support	(PM)			
	Editorial Review ☐ AMB _____ ☐ Editors _____	(ER)			
	CMAT	(CMAT)			
	Action Management Call 845-8369 ☐ COMEBACK COPY TO: _____ ☐ GET CMAT NUMBER WHEN SIGNED & SENT ☐ READING FILE ☐ THANK YOU FILE ☐ CHRON FILE ☐ ADD TO GulfNEWS				

SUSPENSE: ASAP

Prepare reply for signature of:

☐ SA/GWI ☐ SD ☐ DSD ☐ DepSA/GWI

- Hand copy response

☐ Congress ☐ Oversight ☐ FOIA ☐ OSD ☐ WBM ☐ VSO/MSO

☐ Ltr to SA ☐ IR ☐ E-Mail ☐ OGA ☐ Other ☐ Veteran

KEYWORDS:

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
FOR
GULF WAR ILLNESSES

(b)(6)

JUL 26 1999

Dear (b)(6)

This letter is in response to your e-mail inquiry regarding the Gulf War vaccines. We attempted to respond to your e-mail address without success. As the Special Assistant to the Deputy Secretary of Defense appointed to oversee the Department of Defense investigation of Gulf War illnesses, I assure you we are fully committed to investigating the events of the Gulf War to understand why many of our veterans are ill. Our number one priority is the health and welfare of our Gulf War veterans. We are committed to a thorough, complete and public investigation.

In your e-mail note, you asked if soldiers were told about the anthrax vaccine before going to Southwest Asia. We are unable to reconstruct the exact information provided each of the nearly 700,000 service members who deployed to the theater. Much of what we know has been through veterans' personal accounts. From their reports, we have found that some units were briefed before receiving the vaccine. Others have told us they were given the vaccine but received no information about the vaccine given. In some cases, the individual shot records were annotated with a code and in other cases, not annotated at all. This special handling was deemed an operational security issue, to prevent the Iraqis from knowing how we were protecting our troops.

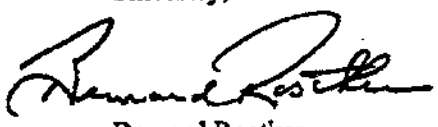
You may recall that Saddam Hussein promised the "mother of all battles." We took him at his word and prepared for the possibility that Iraq might use anthrax during the Gulf War. To protect our troops from this possible threat, an estimated 150,000 U.S. military personnel received at least one dose of the licensed, commercially-available anthrax vaccine.

Anthrax is an acute infectious disease caused by the spore-forming bacterium Bacillus anthracis. Anthrax most commonly occurs in warm-blooded animals, but can also infect people. Anthrax spores can be produced in a dry form (for biological warfare) which may be stored and ground into particles. When inhaled by people, these particles cause respiratory failure and death within a week. Anthrax in a weaponized form has the potential to cover significant areas of a battlefield. It is difficult to determine who would be at a greater risk from a biological threat. You can find out more about DoD's anthrax vaccination program, on the Internet website (*http://www.anthrax.osd.mil*). A copy of some of the informational materials are also enclosed for your reference.

We are concerned about the safety and the effectiveness of all the vaccines, individually and in combination, that we give to military personnel. We, like you, are distressed when anyone experiences a severe adverse reaction to a vaccine. We are also distressed when a service member becomes very ill or dies from a vaccine-preventable disease during the course of their military service or when a military unit's effectiveness is compromised by high rates of a vaccine-preventable disease. The vaccination programs are designed to prevent such disease and disability for the individual and the military unit, while minimizing as much as possible the adverse effects associated with vaccines. Our medical research programs, in collaboration with civilian vaccine researchers and manufacturers, seek to develop and produce more effective vaccines with minimal adverse effects.

Thank you writing. I hope this information is helpful to you.

Sincerely,



Bernard Rostker

Enclosures

(106)

CONGRESSIONAL or SPECIAL CORRESPONDENCE

CMAT: 9181-004

Date: 7-20-99

Office of Special Assistant for Gulf War Illnesses
Internal Routing/Tasking Sheet

Coord/ Routing	Position/Organization		Action	Info	Comments
7	Special Assistant	(SA)			
5	Deputy Special Assistant	(DSA)	7-27		
6	Executive Assistant to SA	(EA)			
4A	Executive Assistant to DSA	(EADSA)			
	☐ Director, Investigation & Analysis _____ (IAD) ☐ DepDir _____ ☐ MED _____ ☐ VDM _____ ☐ C/B _____ ☐ ENV _____ ☐ PAG _____				
	Dir Lessons Learned Implementation	(LLI)			
3	Dir Public Affairs & Outreach	(PA)			
	Dir Legislative Outreach	(LA)			
2	Dir Medical Outreach & Issues	(MOI)	7/21		Col Donnell
	Legal Advisor	(LGL)			
4	PM, Gulf War Illnesses Support	(PM)			
1	Editorial Review ☒ AMB ☑ ☒ Editors	(ER)			
	CMAT	(CMAT)			
8	Action Management Call 845-8369 ☒ COMEBACK COPY TO: MOI ☐ GET CMAT NUMBER WHEN SIGNED & SENT ☐ READING FILE ☐ THANK YOU FILE ☒ CHRON FILE ☐ ADD TO GulfNEWS				

SUSPENSE:

Prepare reply for signature of:

☐ SA/GWI ☐ SD ☐ DSD ☐ DepSA/GWI

☐ Congress ☐ Oversight ☐ FOIA ☐ OSD ☐ WBM ☐ VSO/MSO

☐ Ltr to SA ☐ IR ☐ E-Mail ☐ OGA ☐ Other ☐ Veteran

KEYWORDS:

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
FOR
GULF WAR ILLNESSES

(b)(6)

JUL 28 1999

Dear (b)(6)

This is in response to your questions regarding the anthrax and botulism vaccines administered to some service members during the Gulf War. As the Special Assistant to the Deputy Secretary of Defense appointed to oversee the Department of Defense (DoD) investigation of Gulf War illnesses, I assure you we are fully committed to investigating the events of the Gulf War to understand why some of our veterans are ill. We welcome information from everyone who has ideas that may contribute to our understanding and thereby help our Gulf War veterans.

As you know, prior to deploying to the Gulf, service members were required to have a limited number of vaccines. Most received one or more specific vaccines if they were required for the deployment and booster dose was due, or if they lacked a record of appropriate vaccination. In the Gulf War theater of operations, anthrax vaccine and botulinum toxoid were also given to a limited number of service members for protection against biological warfare agent attack. The anthrax vaccine was a licensed, commercial product. Approximately 150,000 Gulf War veterans received at least one dose of the vaccine.

Anthrax is deadly. The only known, practical means of protecting large numbers of people from anthrax infection is by administering the vaccine prior to potential exposures. The vaccine has been licensed and approved by the Food and Drug Administration and used safely for almost 30 years. The vaccine is safe and effective. The use of this vaccine is endorsed by the Centers for Disease Control and Prevention, the World Health Organization, the National Institutes of Health, the Institute of Medicine and virtually every public health organization in this country.

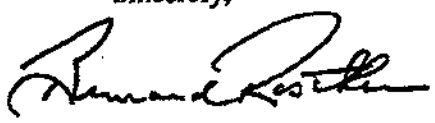
In recent months, a few researchers have postulated that squalene was used as an adjuvant (adjuvants are compounds added to enhance the immune response to a vaccine, thereby making it more effective) in the anthrax vaccine administered to Gulf War troops. Squalene was not used as a vaccine adjuvant in the vaccination of U.S. Gulf War participants. The Food and Drug Administration (FDA) has approved only one type of adjuvant for routine use in the United States. This adjuvant is alum. No vaccines given to U.S. troops during the Gulf War contained any adjuvant other than alum. There have been no reports of reactions or symptoms from alum that can be associated with symptom complexes described by Gulf War veterans.

A limited number of U.S. troops were also provided the investigational vaccine, botulinum toxoid. This vaccine was to protect military personnel against the possible use by Iraq of the potentially fatal biological weapon botulinum toxin. The Food and Drug Administration approved the botulinum vaccine for use in an investigational new drug status though the vaccine has been used for the past 25 years in industrial and laboratory environments.

It is very important to understand that this investigational drug was not administered in an experimental manner. To provide you with a more detailed discussion of these issues, I have enclosed sections on vaccines and prophylactic treatment from the Institute of Medicine's 1996 report *Health Consequences of Service During the Persian Gulf War: Recommendations for Research and Information Systems* and the *Final Report of the Presidential Advisory Committee on Gulf War Veterans' Illnesses.*

You have my assurance we are doing everything possible to investigate and explain Gulf War illnesses – we owe it to the brave men and women who served our country. Unless we understand what went on in the Gulf and what may be making our veterans sick, we will never be able to make the changes necessary to ensure our forces are protected in the future. People are our first concern.

Sincerely,



Bernard Rostker

Enclosures

CMAT #: 1999183-0000006

FT BRAGG OUTREACH (b)(6)

CMAT # 1999183-0000006

(b)(6)

Checklist and Guidance on Sending "Plume" and "Non-Plume" Letters

1 ☒ Veteran's unit was on the original plume list. Veteran was previously sent a "plume letter."
Action: Provide another copy of the "plume letter" if requested. *
Re-send Plume Letter to new address.

2. ☐ Veteran's unit was on the original plume list. Veteran wasn't sent a "plume letter" for some reason.
Action: Provide a copy of the "plume letter" if requested.

3. ☐ Veteran documents his/her status as assigned/attached to a unit on the original plume list.
Action: Provide a copy of the "plume letter" if requested.

---

4. ☐ Veteran's unit was on the original plume list, but his unit has been identified by the S3/G3 Conferences as being outside of the plume.
Action: This situation may arise if someone writes in requesting a copy of their plume letter – coordinate carefully with CMAT and the PM on the course of action. A possible response may be to send a copy of original plume letter, but explain that attendees at the S3/G3 Conferences are analyzing unit locations and his/her status is subject to change -- findings will be released when the analysis is complete.

5. ☐ Veteran's unit wasn't on the original plume list, but his unit has been identified by the S3/G3 Conferences as being under the plume.
Action: Explain only that attendees at the S3/G3 Conferences are analyzing unit locations Findings will be released when the analysis is complete.

---

6 ☐ Veteran's unit wasn't on the original plume list. Veteran was previously sent the "non-plume" letter because his unit was inside the 50-kilometer radius.
Action: Provide another copy of the "non-plume" letter if requested

7. ☐ Veteran's unit wasn't on the original plume list, the veteran wasn't ever sent a letter about the plume, the veteran was outside the 50-kilometer radius, but the veteran asks for information about the plume.
Action: Explain that if he/she was with the unit at the time, the plume didn't affect him/her. Don't send a "non-plume" letter.

8. ☐ Veteran's unit wasn't on the original plume list, the veteran wasn't ever sent a letter about the plume, the veteran was outside the 50-kilometer radius, and the veteran hasn't asked for information about the plume.
Action: Address the veteran's issues and concerns. Don't send a "non plume" letter.

---

9. ☐ Special circumstances explained in memorandum.

Comments:
1. Fill out this sheet and attach it to all correspondence pertaining to Gulf War veterans.
2. Unit location data (e.g., map plots) may be released upon request.

(b)(6)

CMAT
Exposure Letter Worksheet
4.30.98 19Jul99

CONGRESSIONAL or SPECIAL CORRESPONDENCE

CMAT: 9183-006

Date: 18-Aug-99

Office of Special Assistant for Gulf War Illnesses
Internal Routing/Tasking Sheet

Coord/ Routing	Position/Organization		Action	Info	Comments
	Special Assistant	(SA)			
	Deputy Special Assistant	(DSA)			
5	Executive Assistant to SA	(EA)			
	Executive Assistant to DSA	(EADSA)			
	☐ Director, Investigation & Analysis _____ (IAD) ☐ DepDir _____ ☑ MED 2nd ☐ VDM _____ ☐ C/B _____ ☐ ENV _____ ☐ PAG _____				OK
	Dir Lessons Learned Implementation	(LLI)			
3	Dir Public Affairs & Outreach	(PA)	E		ok
	Dir Legislative Outreach	(LA)			
2	Dir Medical Outreach & Issues	(MOI)	WJR		OK
	Legal Advisor	(LGL)			
4	PM, Gulf War Illnesses Support	(PM)	[illegible]		
1	Editorial Review ☐ AMB _____ ☒ Editors	(ER)			see edits
	CMAT	(CMAT)			
6 DAM	Action Management Call 845-8369 ☐ COMEBACK COPY TO: _____ ☐ GET CMAT NUMBER WHEN SIGNED & SENT ☐ READING FILE ☐ THANK YOU FILE ☐ CHRON FILE ☐ ADD TO GulfNEWS				

SUSPENSE:

Prepare reply for signature of:

☐ SA/GWI ☐ SD ☐ DSD ☐ DepSA/GWI

☐ Congress ☐ Oversight ☐ FOIA ☐ OSD ☐ WBM ☐ VSO/MSO

☐ Ltr to SA ☐ IR ☐ E-Mail ☐ OGA ☐ Other ☐ Veteran

KEYWORDS:

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
FOR
GULF WAR ILLNESSES

(b)(6)

SEP 02 1999

Dear (b)(6)

This letter is in reply to your request for information concerning the vaccines you received during the Gulf War. As the Special Assistant to the Deputy Secretary of Defense appointed to oversee the Department of Defense investigation of the Gulf War illnesses, I assure you we are fully committed to investigating the events of the Gulf War to understand why some of our veterans are ill. We welcome information from everyone who has ideas that may contribute to our understanding and, thereby, help our Gulf War veterans.

As you know, all troops were required to have their immunizations screened prior to their deployment into the Gulf. If an individual was missing a required vaccine or was behind on his or her booster doses, the shots were administered before deployment. These routine vaccinations should have been recorded in the individual's health records.

Prior to the start of the War, the intelligence community assessed that Iraq had anthrax and botulinum toxin biological warfare agents. Because of this assessment, two vaccines were administered to troops in the Gulf region who were considered to be at risk from these agents. The anthrax vaccine was a U.S. Food and Drug Administration (FDA) licensed vaccine, commercially available and in use since 1970. Approximately 150,000 veterans received at least one dose of the anthrax vaccine during the Gulf War. Approximately 8,000 veterans received at least one dose of the botulinum toxoid vaccine. This vaccine was (and still is) an investigational new drug registered with the FDA, to be used under certain restrictions. The FDA approved the use of the botulinum toxoid vaccine by the U.S. military during the Gulf War, to protect the troops from a potentially fatal biological warfare threat from Iraq. Although the botulinum toxoid vaccine is listed as an investigational product, it has been safely used for the past 25 years to protect industrial and laboratory workers. Please let me assure you that our troops were not test subjects for new drugs.

For operational security reasons, the fact that vaccines were being given and to whom, was to be kept secret. During the war the vaccines were typically recorded on unit rosters with code names such as Vacc-A for anthrax vaccine and Vacc-B for the botulinum toxoid vaccine. After the War these rosters were to be transcribed into the individual's health records. In many cases this did not happen. We searched all the records that we have for information about vaccinations given to your unit. We are

unable to confirm that the shots you received were either anthrax vaccine or botulinum toxoid vaccine. However, it is possible that you did receive these vaccines. Other immunizations that were given in the theater were the meningococcal vaccine, the influenza vaccine, and gamma globulin.

As you requested, I have also enclosed a copy of the plume letter we originally sent to you in 1997. Thank you for the opportunity to address your concerns. I hope this information is helpful.

Sincerely,

Bernard Rostker

Enclosure

(108)

CMAT Control #
1999127-0000011

OASD(HA)/HOP
April 7, 1999

REPORTED LABORATORY EVIDENCE OF AN EXPERIMENTAL VACCINE ADJUVANT IN THE BLOOD OF GULF WAR VETERANS

- *Vanity Fair*'s recent article provides no new insight into the previous allegations regarding vaccine adjuvants and Gulf War veterans.
- There is no basis for believing that Gulf War-era veterans were exposed to squalene-containing vaccines.
- The anthrax vaccine given to service members during the Gulf War and given to them now did not and does not contain squalene.
- We disagree with the recommendation in the General Accounting Office's March 1999 report for the reasons stated in our published formal response to their report. We will prepare our formal response to Congress over the next month.
- We already have been in contact with the researcher at Tulane University, will evaluate their work when they share a report with us, and look forward to publication of their work in the medical literature.

A recently released *Vanity Fair* article "The Pentagon's Toxic Secret" (May 1999) alleges that the Department of Defense possibly used "an illicit and secret anthrax vaccine" on its own soldiers. According to a Vanity Fair news release "the licensed formula for...anthrax vaccine may have been altered, without formal FDA approval, to contain an experimental, and potentially dangerous, additive. The additive—squalene—improves vaccine effectiveness but causes incurable diseases in lab animals and may be the cause of some cases of Gulf War syndrome." The author refers to declassified DoD documents from the Gulf War era that report on the planning to expand the availability of a variety of vaccines. The documents have been available for over two years on the Department's GulfLINK website. The article does suggest that the modified anthrax vaccine "may be part of the stockpile now being administered in the wake of the DoD's December 1997 decision to immunize 2.4 million people in the armed services against anthrax."

The allegations and the reported "clinical evidence" are not new. An *Washington Times* article "Anti-HIV mix found in Gulf veterans" (August 11, 1997) alleged that there was evidence of squalene, an experimental vaccine adjuvant, in the blood of ill Gulf War veterans. Subsequent *Insight on the News* articles included "Sickness and Secrecy" (August 25, 1997), "Gulf War Mystery and HIV" (November 3, 1997), "Breakthrough on Gulf War Illness" (April 19, 1999), and "GAO Calls for Squalene Tests" (April 26, 1999).

On Monday, March 29. 1999, Congressman Jack Metcalf (Washington) announced the release of a General Accounting Office (GAO) report, which he had requested, regarding squalene antibodies in veterans suffering from Gulf War illnesses. The GAO Report "Gulf War Illnesses: Questions about the Presence of Squalene Antibodies in Veterans Can be Resolved"

(GAO/NSIAD-99-5) recommended that the Department of Defense "conduct research designed to replicate or dispute the independent research results that revealed the presence of squalene antibodies in the blood of ill Gulf War-era veterans."

There is no basis for believing that Gulf War-era veterans were exposed to squalene-containing vaccines. Military members did not receive any vaccines containing squalene during the Gulf War. There is no evidence that Gulf War veterans or other U.S. service members received modified anthrax vaccine or "experimental" AIDS vaccines without their knowledge or informed consent. Approximately 8,000 service members deployed to the Gulf did receive botulinum toxoid vaccine as an investigational new drug. The Michigan Biologic Products Institute, producer of vaccines against the biological warfare agents, anthrax and botulinum toxoid, verified that they have never used adjuvant formulations containing squalene in their vaccines. Since the war, squalene has been a component of vaccines undergoing testing by Walter Reed Army Institute of Research. Volunteers received the vaccines in well-controlled studies that followed Food and Drug Administration (FDA) regulations.

The presence of anti-squalene antibodies in the blood of Gulf War-era veterans would not establish an association of squalene or squalene antibodies with illnesses among Gulf War veterans. The clinical significance of the information is unknown. Although squalene is normally present in humans as part of the body's production of cholesterol, little scientific work has been done on squalene's role in human health and disease. There may be alternative explanations for the reported laboratory findings including: detection of naturally occurring squalene; cross-reaction with compounds similar to squalene; elevated levels of squalene due to known or unknown disease process causing the veterans' illnesses; or laboratory error or contaminant.

The assay for anti-squalene antibodies developed by independent researchers at Tulane University has not been validated through publication in the scientific literature. The investigators have submitted a manuscript to a medical journal; after initial peer review the journal editors have requested revisions. Until their findings are published in the scientific literature and reviewed by other scientists, DoD cannot make a reasonable judgment on why antibodies to squalene are reportedly found in the blood of Gulf War veterans.

The GAO initially reported that they had found no evidence that Gulf War-era veterans were given adjuvants containing squalene. The GAO began an investigation into the allegations regarding squalene in vaccines in August 1997. The Department of Defense cooperated with the GAO investigation. In a draft report dated October 20, 1998, GAO concluded that "...we found no evidence to conclude that Gulf War-era veterans, either military or civilian personnel, were given adjuvants containing squalene." The Department of Defense provided a formal response to that report in which DoD agreed with this conclusion, but disagreed strongly with the GAO's recommendation to develop a test and evaluate Gulf War veterans for antibodies to squalene. In the released report the GAO deleted the above statement from the Results in Brief section. Instead, in a later section the GAO now states "We cannot say definitely whether or not Gulf War-era veterans were given vaccines with adjuvant formulations containing squalene for a number of reasons."

(109)

CONGRESSIONAL or SPECIAL CORRESPONDENCE

CMAT: 9239-005
Date: 8-27-99

Office of Special Assistant for Gulf War Illnesses
Internal Routing/Tasking Sheet

Coord/ Routing	Position/Organization		Action	Info	Comments
	Special Assistant	(SA)			
	Deputy Special Assistant	(DSA)			
	Executive Assistant to SA	(EA)			
	Executive Assistant to DSA	(EADSA)			
	☐ Director, Investigation & Analysis _____ (IAD) ☐ DepDir _____ ☐ MED _____ ☐ VDM _____ ☐ C/B _____ ☐ ENV _____ ☐ PAG _____		X		assist
	Dir Lessons Learned Implementation	(LLI)			
	Dir Public Affairs & Outreach	(PA)			
	Dir Legislative Outreach	(LA)			
	Dir Medical Outreach & Issues	(MOI)	X		LETTO
	Legal Advisor	(LGL)			
	PM, Gulf War Illnesses Support	(PM)			
	Editorial Review ☐ AMB _____ ☐ Editors _____	(ER)			
	CMAT	(CMAT)			
	Action Management Call 845-8369 ☐ COMEBACK COPY TO: _____ ☐ GET CMAT NUMBER WHEN SIGNED & SENT ☐ READING FILE ☐ THANK YOU FILE ☐ CHRON FILE ☐ ADD TO GulfNEWS				

SUSPENSE: 9-10-99

Prepare reply for signature of:
☐ SA/GWI ☐ SD ☐ DSD ☐ DepSA/GWI

- MOI take appropriate action with assist from LETTO

☐ Congress ☐ Oversight ☐ FOIA ☐ OSD ☐ WBM ☐ VSO/MSO
☐ Ltr to SA ☐ IR ☐ E-Mail ☐ OGA ☒ Other ☐ Veteran

KEYWORDS: Anthrax

06/17/99 Issuance

INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
400 ARMY NAVY DRIVE
ARLINGTON, VIRGINIA 22202-2884

AUG 24 1999

MEMORANDUM FOR SECRETARY OF THE ARMY

SUBJECT: General Accounting Office Letter, "DoD Efforts to Address Adverse Reactions to the Anthrax Vaccine," (GAO Code 713047): NOTIFICATION OF GAO REVIEW

On August 19, 1999, the Department of Defense (DoD) received the enclosed General Accounting Office (GAO) notification letter announcing a new review. At the request of Representative Jan Schakowsky, the GAO plans to evaluate how the DoD has addressed adverse reactions to the anthrax vaccine, with a particular emphasis on different rates of reactions between men and women.

The DoD Directive 7650.2 designates this office as the central DoD liaison for tasking, controlling, and monitoring GAO survey, review, and report activities. The enclosed Information Sheet describes the specific DoD procedures for tasking GAO surveys/reviews and the DoD Primary Action Office (PAO) responsibilities.

Your office is the PAO for the review. We have been advised that Col (b)(6), located in the Office of the Army Surgeon General, is your action officer for this case. An identification of the collateral action offices (CAOs) follows this memorandum. The CAOs are requested to provide Col (b)(6) and this office, if they have not already done so, with the name, phone number, fax number, and mailing address of their action officers as soon as possible.

This office has contacted the GAO to arrange a joint, headquarters level entrance meeting so that the GAO can identify and discuss its detailed work plans and begin work. The entrance conference is scheduled for Monday, August 30 at 10:00 in room 691, Skyline 6. Each action office should send a representative to the entrance conference, as appropriate.

Staying informed on GAO survey/review activity depends on the PAO, the other involved DoD components, and this office working closely together. Your full support is requested in these efforts to prevent surprises related to the GAO review and to ensure that the DoD obtains the maximum benefits from the GAO work.

If you have questions, please contact my action officer for this case, (b)(6) e-mail (b)(6) If he is not available, please call (b)(6) (b)(6) Our fax number is (b)(6)

Sincerely,

Arnold J. Freitag
for Carlos J. Chapa
Deputy Director for
GAO Affairs

Enclosures: GAO notification letter
Information sheet

CAO Copies: SEC NAVY
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CMDT, USMC
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ASD(RA)
DIR, JS

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DSD/SA-Gulf War Illnesses
DGC(F)

GAO

United States
General Accounting Office
Washington, D.C. 20548

National Security and
International Affairs Division

August 18, 1999

The Honorable William S. Cohen
The Secretary of Defense

Attention: DOD Office of the Inspector General
Deputy Director for GAO Affairs

Dear Mr. Secretary:

This is to advise you that the U.S. General Accounting Office is beginning a study examining how DOD has addressed adverse reactions to the anthrax vaccine, with a particular emphasis on different rates of such reactions between men and women. The assignment code is 713047. This study is in response to a request from Representative Jan Schakowsky, a member of the Government Reform Committee.

The objectives of the study include addressing the following three major issues:

1) to what extent do gender differences exist with regard to anthrax vaccine, what scientific research has been done with regard to this issue, and how have those military personnel who developed adverse reactions to anthrax vaccine been treated by DOD medical personnel;

2) To what extent does DOD incorporate women in military medical research (past and ongoing); and

3) What strategies has DOD developed for management of adverse reactions for vaccines.

If you have any questions regarding this work, please contact me at (b)(6) or (b)(6), Assistant Director, at (b)(6)

Sincerely yours,

(b)(6)

Kwai-Cheung Chan
Director, Special Studies and Evaluations

INFORMATION SHEET
(Revised 11/96)

DoD PROCEDURES FOR PROCESSING, MONITORING, AND MANAGING GENERAL ACCOUNTING OFFICE (GAO) SURVEYS AND REVIEWS
(References: DoD Directives 7650.1, 7650.2)

1. GAO Notification Letters of Surveys and Reviews

Before contacting DoD officials to initiate new survey/review work, the GAO has agreed to issue a notification letter to the Secretary of Defense, Attention: OIG, DoD, Deputy Director for GAO Affairs. The notification letter includes the objectives of the planned work and a six digit GAO assignment code. When the GAO staffs contact DoD personnel, they should be asked if they have properly announced their work with a notification letter through the OIG, DoD. The GAO staffs should be prepared to provide a copy of the notification letter on request. The DoD personnel should verify that the GAO work has been announced within the Department. They can contact the appropriate component audit liaison, collateral action office, or this office. If the GAO work has been announced, this office can telefax a copy of the GAO notification letter along with the DoD official announcement. Meetings should not be scheduled nor information released until the GAO work is properly announced. All questions or special arrangements on GAO surveys and reviews should be coordinated with GAO Affairs-- the address, phone number and telefax number is as follows:

Office of the Inspector General, DoD
Deputy Director for GAO Affairs
400 Army Navy Drive, Room 539A
Arlington, VA 22202-2884

Commercial:	(b)(6) redacted	DSN:	(b)(6) redacted
Telefax:		DSN:	
Telefax:		DSN:	

2. GAO Notices of Visit and Security Clearances

Besides the GAO notification letter, the GAO should notify appropriate agency officials about 10 days before any proposed visit using the "Notice of GAO Visit" form. The GAO should provide a copy of that form to GAO Affairs. In cases of unusual urgency, the GAO should make arrangements with the agency officials by phone. The responsibility for assuring that a GAO representative has the proper clearance to review/receive classified information rests with the DoD individual providing the information.

If a GAO representative does not provide the notice of visit or if the DoD contact needs additional information, the assigned GAO Affairs action officer should be contacted for assistance.

3. Tasking of GAO Surveys and Reviews

On receipt of a GAO notification letter, GAO Affairs identifies the primary action office (PAO) and a PAO point of contact through discussions with DoD component audit liaison offices and DoD officials. For most surveys/reviews, the PAO is at the Office of the Secretary of Defense (OSD) staff level. The OIG issues a tasking memorandum assigning responsibility for the GAO effort to the PAO with copies to identified collateral action offices (CAO).

The DoD component audit liaisons receive action or information copies of the GAO Affairs tasking memorandum for further distribution to the appropriate offices. The memorandum is given wide distribution to help identify action offices and inform them of the GAO review. This is important so that the correct DoD components attend the GAO entrance, interim status, and exit meetings.

4. GAO Entrance, Interim Status, and Exit Meetings

The GAO Affairs action officer will work with the PAO and the CAO to arrange a joint, headquarters level entrance meeting. The purpose of the entrance meeting is to provide the PAO, CAOs and other DoD components with details about the GAO review. It is an opportunity to ask questions and provide the GAO the names of DoD points of contact.

The PAO, CAO, and GAO Affairs should work together to help ensure that (1) interim status and exit meetings are held, when appropriate, (2) the PAO, CAO, and OIG action officers attend such meetings, and (3) the meetings include all key DoD officials. The PAO and CAO action officers, through their ongoing contacts with the GAO, should be alert to the need for interim status and exit meetings, and should advise GAO Affairs in advance so that appropriate actions can be taken to facilitate the meeting.

Before any interim status or exit meeting at the headquarters level, the GAO usually holds separate meetings at the field activity level. Action officers at the field level should advise the PAO of such meetings through the component CAO or the component audit liaison.

The purpose of interim status and exit meetings with the GAO is to provide the DoD an opportunity to discuss the accuracy and completeness of the GAO work results and to avoid surprises to the DoD. The GAO Affairs action officer will normally ask for an exit meeting before the GAO issues a draft or final report.

The interim status and exit meetings are particularly important because these meetings may be the only DoD opportunity to comment on GAO work that could result in budget reductions or program direction decisions by the Congress. The GAO Affairs action officer will ask the GAO to provide work products (fact sheets, draft reports, advance testimony, or other written documents not officially issued) before the meetings to better prepare DoD officials in providing accurate and complete comments.

The DoD officials' comments provided at interim status and exit meetings are unofficial. The only official DoD comments (whether oral or written) are those that are properly coordinated with all the appropriate DoD offices through the OIG, DoD.

5. Access to Records

Under 31 U.S.C. 716(a), the GAO has broad access rights. The DoD Directives 7650.1 and 7650.2 provide the DoD policy and procedures regarding GAO access to records. Both oral and written requests from GAO representatives should be handled informally. Efforts should be made to accommodate the GAO needs at the lowest organization level possible.

If it is unclear what information the GAO is requesting orally, it may be appropriate to ask the GAO to put its request in writing, listing the specific documents requested and explaining the need in connection with the survey or review. While oral requests should be acceptable, written requests can help clarify the information desired.

The DoD components and action officers should not deny the GAO access without further checking through the appropriate channels. Depending on the document(s) requested, that could include: officials in the chain of command, the component legal office, the audit liaison office, the PAO, and the appropriate OSD general counsel's office. The GAO Affairs action officer will provide assistance as necessary, working with DoD component liaison officials in processing action requests and arranging meetings between DoD and GAO representatives.

If informal attempts fail and the GAO decides to pursue its request, the Comptroller General, by law, may issue a formal demand letter to the Secretary of Defense. By law, the DoD has 20 days to respond to the GAO. If after 20 days full access has not been granted, the Comptroller General may file a written report with the President of the United States, the Director of the Office of Management and Budget, and the Attorney General. Following that, the Comptroller General may seek a court order to compel the release of Federal records or subpoena nonfederal records.

6. GAO Questionnaires and other Data Collection Instruments

All questionnaires and other data collection instruments should be coordinated with the Deputy Director for GAO Affairs before distribution within the DoD. Any DoD component or official receiving GAO questionnaires or other data collection instruments should ask the GAO staff if they have properly coordinated the instrument through the OIG. Responses should not be provided nor information released until the GAO has properly coordinated its work.

7. Termination of Surveys/Reviews

The GAO should notify the DoD through the Deputy Director for GAO Affairs when it decides to terminate a survey or review without issuing an external report. The GAO sometimes overlooks issuing a termination letter to the DoD. If the PAO or CAO action officers learn that GAO work is terminated, they should alert GAO Affairs.

CMAT Control # (110)
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OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000
UNCLASSIFIED

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

INFO MEMO

February 7, 2002, 4:00PM

FOR: ASD (HA)

THROUGH: DASD, FHP&R

FROM: Michael E. Kilpatrick, M.D., Director, Deployment Health Support Directorate

SUBJECT: UK Questions and Answers from the Shays Hearing and Biographies

- Tab A - UK Questions and Answers from the Shays Hearing
- Tab B - Biographies of Dr. Kilpatrick and Colonel Eric Daxon.

COORDINATION: None

Attachments:
As Stated

UNCLASSIFIED

Prepared By: Ed Rushin, 703-575-2672

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TAB B: Biographies

Dr. Michael Kilpatrick

COL Eric Daxon

1. Right Honorable Mr. George:

Dr. Winkenwerder, to what extent has the Department of Defense learned from the Gulf War experience in terms of how to best protect the health of military personnel for subsequent wars.

In particular, what do you think you have gained from the Gulf War and maybe other deployments in rather dangerous areas, so that your men and women are exposed to less risk?

Proposed Response:

Force health protection lessons learned from the Gulf War include:

- More comprehensive and standardized deployment health directives and policies
- Pre- and post-deployment health assessments
- Deployment medical surveillance and DNBI reporting
- Medical intelligence capability
- Automated record keeping systems such as Theater Medical Information Program (TMIP), Common Access Card (CAC), and Palm Pilot-type tools
- Immunization tracking systems
- Three Deployment Health Centers: clinical, research, and surveillance
- Post-deployment Clinical Practice Guidelines
- Robust research studies
- Coordination between DoD and VA

Response at Testimony:

Dr. Winkenwerder: Mr. George, that is an excellent question, and I think cuts to the heart of what are we doing and what have we learned, and what are we going to do going forward. I would say this is a good news and a bad news story, bad news in the sense that sometimes our best lessons are our most painful lessons, but as those lessons occur, changes can be made and I think in this case, have been made. I'll talk just about a few of them.

To try to summarize, I think in order to understand and respond to and treat people in the battlefield situation, what's very important is the collection of information so that there is a baseline of information. And that needs to occur both before people get deployed on the battlefield, even before the fight begins, if you will, and then after. With that kind of information, it's much easier to draw a picture of what might have happened to any given individual.

I think that's one of the problems we face with the Gulf War situation. The database to start with was not optimal, so we've learned a lot about that. Currently, it's just in the past two to three years we have begun doing pre and post-deployment assessments so that there is a standardized

form that the medical provider goes through a checklist of information and that is collected prior to deployment, also after deployment.

Another sort of pre-deployment activity relates to assessment of battlefield risks. The U.S. Army Center for Health Promotion and Preventive Medicine, we call it CHPPM acronym, does an industrial hazards assessment for base camps and for surrounding areas and it's sort of an on the ground sample assessment of air, water, other risks. That has been done in the current deployment in Afghanistan.

There is also the Armed Forces Medical Intelligence Center, which gathers information regarding things that might be known about various installations or plants or chemicals and that gets incorporated into the medical planning effort.

In addition to that, it's very important that information be collected during the engagement and we have a reporting system that is known as the DNBI Disease Non-battle Injury Surveillance. Weekly reports are generated from the battlefield, from the unit level and are placed into software systems for each of the services and then aggregated up to DOD-wide level, again, through this CHPPM organization.

We have future plans to have this more real time, but even now, we believe it serves as a sort of early warning system for chemical, biological or radiologic weapons.

I can tell you that this information is being collected. I was just visiting last week with our Central Command headquarters with General Franks and Deputy General DeLong and the leader of our special operations command, as so many of our forces are special operations right now. And I spoke with the medical leadership of those commands.

They are collecting that information. One of things that we're working on as just an example is Palm Pilot sorts of tools, particularly, if you can imagine for the special operations soldier, that kind of soldier could be out in the field and who knows where they are for what period of time. They're in small units, so it's difficult to collect that information, but we're funding a Palm Pilot system for that kind of collection of information.

So, the only thing that has changed since the Gulf War is immunization tracking. Again, that's all been placed under software, so that we have information about who got what vaccines at what point in time.

Then, the final stage is really the capability to do the research and analysis and we've done three things there. One is to set up a research center, the Naval Research Center in San Diego, and that was done just two years ago, and secondly, a clinical center, which is at the Walter Reed Army Hospital here locally, that looks at things like development of practice guidelines.

And then finally, the Deployment and Health Surveillance Center, which is part of the CHPPM organization that I spoke of earlier, so I think we're doing a lot more. I feel much better about what we're doing today than what we've done in the past. Time will tell how effective all these efforts are at getting to answers that have been elusive in the past.

2. Right Honorable Mr. George:

And if there is something called an Afghan War Syndrome, although the numbers perhaps involved would be rather different, are you collecting information or examining military personnel upon return to be able to get off to a swift start should there be any psychological or physical injuries, illnesses as a result of this current conflict.

Proposed Response:

Yes, the experiences of the Gulf War have taught us to better anticipate and prepare for illnesses that may follow other deployments. Accordingly, we have established policies for and set in place a number of initiatives, including:

- Enhanced environmental surveillance to have exposure data which could be evaluated if there are subsequent illnesses
- Pre- and post-deployment health assessments to gather health information that closely brackets the period of deployment
- A post-deployment health clinical practice guideline that will help health care professionals deal promptly and effectively with deployment related concerns.

Response at Testimony:

Dr. Winkenwerder: Absolutely and to that end, there is a clinical practice guideline. One of the important things is as people come back; they're not all going to come to one place. They're obviously going to be seen in multiple places. So, the question is, what sort of a standardized tool that the care providers will have across all services so that the right questions get asked and the information gets collected and that is the clinical practice guideline that is going into implementation just month.

3. Right Honorable Mr. George:

Now, as a politician, I can recall myself and my colleagues, whenever the media raised the possibility of the cause of the Gulf War Syndrome, then parliament was filled with people asking hostile question. I recall some of the causes: bacteria, sand, organic chemicals, including organic phosphates, burning oil wells, known illnesses such as post traumatic stress disorder, chronic fatigue syndrome and multiple chemical sensitivity, exposure to depleted uranium contained in shell tips and tank armor, chemical and/or biological attack from the Iraqis, medical counter biological/chemical warfare measures, et cetera, et cetera, et cetera. And all of these were seen to be causes.

What advice would you give to perhaps where the answer lies? Is it in any of these, all of these, others, combinations?

Proposed Response:

No single, unique, or previously unknown illness has been identified among those ailing Gulf War veterans. Most veterans reporting symptoms of illnesses believed to be associated with their service in the Gulf War have been clinically evaluated and found to have recognizable medical diagnoses. More than 500 known illnesses and diagnoses have been identified with sixty of these conditions accounting for approximately 75 percent of the recorded diagnoses.

There have been extensive investigations into the many theories put forth such as oil well fires, organic phosphates, depleted uranium and possible exposure to chemical weapons. To date, no causal link has been established between these exposures and veterans unexplained illnesses.

Not knowing the cause of some Gulf War veterans illnesses has not and should not interfere with our doing everything we can to provide them medical treatment to alleviate their symptoms. We believe that medical research should continue until answers are found and the Departments of Defense, Veterans Affairs and Health and Human Services are cooperating with one another to achieve this end.

4. Right Honorable Mr. George:

After 10 years of want of success [in finding the cause of Gulf War illnesses], why? Is it because the causes are too complicated? Is this too big to be solved? The researchers in my country and ours not up to the task? Should we be more patient? Have they misspent money? Is there any justification in the conspiracy theories that one hears? Can you advance to me why you think researchers in my country and yours; administrators in my country and yours, politicians in my country and yours have not yet come up with the goods? Why?

Proposed Response:

There has been more research done on the Gulf War than all other wars together. It is important to focus first on what we do know. We do know that no single, unique or previously unknown illness has been identified among ill Gulf War veterans. The rates of recognized illnesses such as diabetes, kidney disease, heart disease, cancer, etc in Gulf War veterans are comparable with the rates seen in their colleagues who did not deploy to the Gulf. There is preliminary information about an increase in the rate of ALS, but that is still under study. The mortality rates, hospitalization rates and rates of birth defects in children are also comparable for Gulf War veterans and those who didn't deploy. However, we also know that the rate of symptoms, particularly medically undiagnosed physical symptoms, are two to three times higher in Gulf War veterans. Because similar symptoms are seen, although less frequently in the non-deployed, medical science is now working to better understand why such symptoms occur and how to best provide care for individuals with these symptoms.

5. Right Honorable Mr. George:

Would French research on a more significant level give American or British researchers greater insight to the ailments among veterans?

Proposed Response:

We understand that French researchers are beginning a comprehensive epidemiological study of the illnesses in Gulf War veterans. British, Canadian, and American researchers have already collaborated successfully. Additional research in military and civilian populations with these perplexing symptoms may well provide new insights into the causes and possible treatments. Such studies are welcomed and encouraged.

6. Right Honorable Mr. George:

The GAO identified differences between the U.S. and the U.K. and France in the use of medical counter-measures. Now, in the U.K., the Ministry of Defense is conducting a vaccine interactions research program at our chemical weapons research establishment at Porton Downs to assess whether the combination of napstables (ph) and vaccines might have given rise to adverse health effects. This research is not due out until next year.

Has there been any similar research undertaken in the U.S.?

Proposed Response:

No. Currently there are no plans in the U.S. to study the interaction between Pyridostigmine Bromide (PB) and various vaccines. Further, there are no funded studies looking specifically at the issue of multiple vaccines. Several epidemiologic studies have examined the issue of vaccine receipt as one of many variables explored as possibly associated with subsequent illness. All American studies have depended upon self-report by participants as to the types of vaccines they may have received prior to or during the Gulf War.

The major UK study which implicated vaccines depended not only on self reports of vaccine receipt but also on written records of vaccination.

7. Right Honorable Mr. George:

And, lastly, [are you] evaluating care and treatment programs for Gulf veterans to assess which ones were best to alleviate the symptoms of ill health?

Proposed Response:

Yes, two large, multi-center studies have been concluded and will soon be published. One evaluated 12 months of antibiotic treatment compared to placebo and one evaluated exercise and behavior modification. The antibiotic treatment program showed no improvement in clinical symptoms compared to placebo. Exercise and exercise with behavior modification both showed an improvement in symptoms, while behavior modification alone did not. There are multiple other therapeutic intervention trials ongoing at various VA medical centers, and those results are still pending

8. Right Honorable Mr. George:

There was some research done by a team from Guy's, King's and St. Thomas' School of Medicine entitled "Ten Years On, What Do We Know About the Gulf War Syndrome?" And this was published in the Journal of the Royal College of Physicians, and it coincided with the 10th anniversary of the ending of the Gulf conflict.

It said this, quote, "The paper noted that a syndrome implies a unique constellation of signs or symptoms," and that, quote -- this is the pretentious part, quote, "The balance of evidence is against there being a distinct Gulf War syndrome." It said in its report that, quote, "No evidence has emerged to date of why the distinct biomedical abnormalities nor premature mortality," end of quote.

It goes on to say that it noted, quote, "Gulf service has affected the symptomatic health of large numbers of those who took part in the campaign. The team speculated, says our Ministry of Defense, that the most plausible causes were exposures that affected the majority of those in the theater, such as medical counter-measures or psychosocial factors."

The question I wish to ask is it that there is a dispute over the definition of what a syndrome is, or is this research an aberration? Is there such a thing as the Gulf War syndrome?

Proposed Response:

The medical definition of a "syndrome" is a similar set of signs or symptoms which progress in a similar way over time and result in a similar manner in all individuals affected. For Gulf War veterans it is important to focus first on what we do know. We do know that no single, unique or previously unknown illness has been identified among ill Gulf War veterans. The mortality rates, hospitalization rates and rates of birth defects in children are comparable for Gulf War veterans and those who didn't deploy. However, we also know that the rate of symptoms, particularly medically undiagnosed physical symptoms, is two to three times higher in Gulf War veterans. While there is no evidence for a new medical "syndrome" among Gulf War veterans, we must recognize that some people who were previously well are now experiencing various symptoms. Our focus should be first to provide care and second to continue research to be able to understand the possible etiologies. Only by doing so will we be able to provide better protection for the men and women today who deploy to protect our freedom.

9. Lord Morris:

I understand from a highly authoritative source that the clinical neurology-immunology studies in which Professor Simon Wessely is involved have basically confirmed the Rook-Zumbler (ph) hypothesis. Can [you] comment today on that? The Rook-Zumbler (ph) hypothesis is basically confirmed, which I think is a very important finding. What's the DoD's response to that?

Proposed Response:

Preliminary reports from Dr. Wessely's studies show results that are consistent with the hypothesis, but they do not provide confirmation. Other research will be needed to provide the kind of biological evidence that substantiates the hypothesis or undermines it.

It is my understanding that there have been only a few cases of motor neuron disease identified among Gulf War veterans and there has been no indication of an excess incidence. Because this condition can be quite serious, it is of concern, but so far there is no evidence that Gulf War veterans have a risk greater than other members of the general population.

10. Lord Morris:

In regard to the recent statement by the secretary for Veterans Affairs about the increasing significance of motor neuron disease among Gulf War veterans, how do [you] respond to the secretary's obvious concern about that finding?

Proposed Response:

The Secretary of the VA has made ALS a service connected disease for Gulf War veterans serving in the theater from August 2, 1990, to July 31, 1991, based on preliminary evidence from a case ascertainment study from the 700,000 Gulf War veteran population and the 1.8 million non-deployed military population. Researchers identified 40 cases of ALS in the Gulf War veterans and 69 in the non-deployed veterans. This study has not yet been peer reviewed and published. However, researchers are working to try to identify differences in environmental and other exposures experienced by these patients with ALS. Unfortunately nearly half of them have already died.

Medical science does not yet know the cause of ALS, and there is no cure for this rapidly fatal disease.

11. Lord Morris:

We heard earlier today speakers for the administration say that one lesson that had been learned from Gulf War experience was that it's dangerous to get as many as 14 inoculations all at the same time. But how does that help reservists. How does it help reservists, now being deployed and who haven't had their immunization topped up from time to time, but who come in, as in the case of reservists in the Gulf War, in need of a mass immunization program. How does it help them? How does it help the reservist?

Proposed Response:

Most immunizations for active duty and reserve troops are not given because of a specific geographic area to which they are soon deploying. Most are given to eliminate the occurrence of diseases that could occur no matter where they are stationed, either at home or overseas.

As a result, most are given either once (because their protective effect is very long lasting) or on some predictable schedule (such as tetanus booster every ten years or influenza every year).

Accordingly, troops preparing for a specific deployment need only receive those vaccines which protect against a specific kind of infection not covered by the routine immunizations described above. That is actually very few, such as yellow fever, typhoid, and Japanese encephalitis, as examples.

It is DoD policy that active duty and reserve personnel are to have their immunizations kept up to date on a routine basis. When that policy is observed, deploying troops should need very few new inoculations, if any.

The key to avoiding giving many inoculations all at the same time is to observe the routine immunization requirements.

It is hard to imagine why anyone would need 14 inoculations all at the same time if they had received their basic immunizations upon entry to the military.

The British study which suggests an association between receipt of inoculations and subsequent self-reports of ill health is not conclusive. Its findings merit further attempts to confirm or refute this reported association.

12. Lord Morris:

Can the witness say how compulsory it was for U.S. troops deployed to the Gulf to have the anthrax vaccine, and how compulsory it is for those now deployed, those U.S. troops now on active service?

Proposed Response:

Yes, during the Gulf War, the anthrax vaccination was compulsory. However, the US only had sufficient vaccine for 150,000 personnel to receive two shots. Record keeping was inconsistent.

In 1998 DoD established a compulsory anthrax vaccination program for personnel deploying to high threat areas and for those who could be rapidly deployed. That program was slowed because of vaccine supply shortages. However, the FDA has just recently approved the Bioport anthrax vaccine production facility and the DoD will soon announce its policy for resumption of the vaccination program.

13. Lord Morris:

Reverting to Khamisiyah and the destruction of Iraqi weapons there, my understanding is that the agents released were sarin and cyclosarin. Do you have any comments on the significance of that action?

Proposed Response:

Khamisiyah was a watershed event for the US. It made the Department of Defense focus on the importance of developing and implementing a Force Health Protection policy which would aggressively monitor the environment where our troops are deployed and combine this with pre and post deployment medical assessments and a robust medical monitoring program in the deployment theater. We have just added a clinical practice guideline for primary care health providers to ask people if they are concerned or believe their symptoms are related to a deployment. In this manner the military healthcare system will embrace the individual's concerns and appropriately address them at the onset.

Although nobody died and no acute symptoms were recognized as a result of the release of nerve agent at Khamisiyah, there is now a significant thrust to understand what possible medical outcomes could result from low level, asymptomatic exposures. DoD and the VA also have a prospective, longitudinal study called the Millennium Cohort Study which will evaluate 140,000 military personnel over 21 years to better determine the effects of military life and deployment on their future health.

14. Lord Morris:

But, again, another study, a British study, pointed out that amongst the Brits, the mortality levels were statistically almost identical between a group selected that didn't go and the group that did go. Now, is it because our people are pretty hearty and resilient, eating their different fatty foods? Is there any difference between the statistics in the United States?

Proposed Response:

There has been a great deal of concordance between the UK and US studies of mortality among Gulf War veterans. Both studies compared the Gulf veterans to a comparison group of contemporaries who did not go to the Gulf. Both found that the slight excess mortality rate among Gulf veterans was due to excess rates of death due to accidents, especially motor vehicle accidents. Deaths from natural causes actually occurred at a lower rate among Gulf War veterans. In the US study, mortality rates were less than half those of comparable segments of the general US population. It would be premature to use these results to conclude that Gulf War veterans have not been exposed to causes of fatal diseases. Some diseases have long latency periods (e.g., cancer), so these studies must be repeated periodically to continue to monitor the possibility of late changes in mortality risks.

15. Lord Morris:

The findings that you led at Manchester University that Gulf veterans suffer more and have more ill health than service personnel who did not go to the Gulf. What kinds of research should now focus on what subject? Given we've had 10 years experience of research, much of which was of no consequence whatsoever, what now should the ... DoD, the Veterans Administration, private benefactors, focus be? Is it better to say should the energies be put on, if not researching the causes, at least delivering better services to those who have survived, or should there be the same balance as there has been between research into causes, symptoms, and, indeed, services provided to our military personnel?

Proposed Response:

The past and current research into these illnesses has been broad-based with special focus on what appear to be plausible causes of and contributing factors to these illnesses. This broad-based research should continue to be a mix of government and privately sponsored high quality work. At the same time research has turned toward evaluating a variety of potentially therapeutic strategies to help these veterans. Developing treatments for conditions of uncertain cause is not easy research. Several clinical trials including cognitive behavioral therapy, exercise behavioral therapy, and empiric antibiotic therapy have been completed and will soon be published. Meanwhile, we are enhancing our service to these veterans by better educating our professionals about post-deployment illnesses, and sensitizing them to the special needs of these veterans.

Deployment Health Support Directorate

MICHAEL E. KILPATRICK, MD

Director, Deployment Health Support

Michael E. Kilpatrick, M.D., is the Director of Deployment Health Support in the TRICARE Management Activity and the Office of the Assistant Secretary of Defense for Health Affairs. The directorate supports the Special Assistant for Gulf War Illnesses, Medical Readiness and Military Deployments. Dr. Kilpatrick is responsible for continuing the mission of providing assistance to Gulf War veterans, facilitating Force Health Protection initiatives, and coordinating health-related deployment issues between the Office of the Assistant Secretary of Defense for Health Affairs and the Military Departments.

A San Francisco native, Dr. Kilpatrick was awarded a Bachelor of Arts degree at the Johns Hopkins University, Baltimore, Maryland, in 1965. He received his Medical Degree in 1969 from the University of New Mexico School of Medicine, Albuquerque, New Mexico, and completed his Internal Medicine residency in 1972 and Infectious Disease fellowship in 1974 at the University of California, Irvine.

Dr. Kilpatrick served in the U. S. Navy from 1974 to 1999. He was a staff physician in the Infectious Disease division at the Naval Regional Medical Center, San Diego, California, and then had five tours with the Naval Medical Research and Development Command. He was a research physician at Naval Medical Research Unit Three in Cairo, Egypt, and at the Naval Health Research Center, San Diego. Dr. Kilpatrick was the first Officer in Charge of the Navy's first medical facility in South America, Naval Medical Research Institute Detachment Lima, Peru. He then was the Research Area Manager for Infectious Disease at Naval Medical Research and Development Command, Bethesda, Maryland, and in 1998 returned to Naval Medical Research Unit Three as Commanding Officer. The Navy Forward Laboratory was deployed from Naval Medical Research Unit Three in support of Operations Desert Shield and Desert Storm. It provided high technology laboratory diagnostic capability for medical treatment facilities and for medical environmental surveillance, including monitoring for evidence of biological warfare agents. After Cairo, he served as Executive Officer at Naval Hospital, Orlando, Florida, and as Commanding Officer of the Naval Hospital Millington, Tennessee.

Dr. Kilpatrick completed his Navy career as the senior medical advisor to the Special Assistant for Gulf War Illnesses and then served as an independent consultant involved in the medical aspects of all investigations and research related to Gulf War illnesses. He was selected as a member of the Senior Executive Service in December 2000 and served as the Chief of Staff for the Office of the Special Assistant for Gulf War Illnesses, Medical Readiness and Military Deployments.

Dr. Kilpatrick is a Fellow of the American College of Physicians and the Royal Society of Tropical Medicine and Hygiene and a member of the American Society of Tropical Medicine and Hygiene, the Association of Military Surgeons in the United States and the American College of Physician Executives. His military awards include the Defense Superior Service Medal, two Legion of Merit awards, three Meritorious Service medals, the Navy Unit Commendation, the Meritorious Unit Commendation, two National Defense medals, the Southwest Asia Service medal, nine Navy and Marine Corps Overseas Service ribbons, and the Peruvian Navy Cross. He has co-authored more than 70 peer-reviewed publications on tropical medicine and infectious diseases.

COL Eric Daxon, Ph.D., CHP

COL Daxon began his service to the Army in 1974 as a Platoon Leader and Motor Officer. He has been involved in the health physics field since completing his graduate work in 1977 when he began working at the Armed Forces Radiobiology Research Institute (AFRRI) as a Radiological Physicist. Since that time he has served the Army in several Health Physics positions with much of his work focusing on depleted uranium. In October 1993, COL Daxon became the Chairman of the Radiation Biophysics Department at AFRRI where he initiated biomedical research, served as a team leader for the depleted uranium research team, and provided advice to the Army and DOD on the health effects of depleted uranium. He left AFRRI to serve as the Staff Nuclear Medical Science Officer at the US Army Medical Command (MEDCOM) from August 1995 – June 1999. He was responsible for the US Army MEDCOM Radiation Protection Program for all US Army hospitals worldwide, he developed Army and DOD policy for treating personnel wounded by depleted uranium, and revised the current Army depleted uranium training program. COL Daxon currently serves as the Director of the Proponency Office for Preventive Medicine located at Fort Sam Houston, San Antonio, TX. He took this position in June 1999. As the Director, he is responsible for Preventive Medicine policy, MEDCOM Radiation Protection Program for all US Army hospitals worldwide, and serves as the Depleted Uranium Consultant to The Surgeon General.

COL Daxon has authored and co-authored many technical articles. Among his publications are: "Operation Chernobyl Challenge The Public Health Response by US Military Forces in Europe," co-authored with Larry Luckett and John Parker, "Establishment of an Animal Model to Evaluate the Biological Effects of Intramuscularly Embedded Depleted Uranium Fragments," co-authored with C.A. Castro, K.A. Benson, and V. Bogo, "Desert Storm Casualties: Impact of Depleted Uranium."

COL Daxon graduated from the US Military Academy, West Point, NY in 1973 with a Bachelor of Science degree. He earned his M.S. degree from Massachusetts Institute of Technology, Department of Nuclear Engineering, Cambridge, MA in 1978, and completed his Ph.D. in 1992 through the University of Pittsburgh, Department of Occupational and Environmental Health. COL Daxon is a Certified Health Physicist and a member of the Health Physics Society.

CMAT Control #
2002183-0000004

111

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Mr. Tom Green
Marine Corps Reserve Officers Association
110 North Royal Street Suite 406
Alexandria, Virginia 22314

Dear Mr. Green:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the members of the Marine Corps Reserve Officers Association.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil*. The URL for the website is *http://www.anthrax.osd.mil/*.

Sincerely,

Barbara A. Goodno

Barbara A. Goodno
Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Ms. Erin M. Harting
Enlisted Association of the
National Guard of the United States
1219 Prince Street
Alexandria, Virginia 22314-2916

Dear Ms. Harting:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the members of the Enlisted Association of the National Guard of the United States.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil.* The URL for the website is *http://www.anthrax.osd.mil/.*

Sincerely,

Barbara A. Goodno
Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Ms. Tameka Rawlings
Navy League
2300 Wilson Boulevard
Arlington, Virginia 22201

Dear Ms. Rawlings:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the members of the Navy League.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil*. The URL for the website is *http://www.anthrax.osd.mil/*.

Sincerely,

Barbara A. Goodno
Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Mr. Ken Goss
Air Force Association
1501 Lee Highway
Arlington, Virginia 22209-1198

Dear Mr. Goss:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the members of the Air Force Association.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil.* The URL for the website is *http://www.anthrax.osd.mil/.*

Sincerely,

Barbara A. Goodno
Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Mr. John Grady
Association of the
United States Army
2425 Wilson Boulevard
Arlington, Virginia 22201-3326

Dear Mr. Grady:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the members of the Association of the United States Army.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil.* The URL for the website is *http://www.anthrax.osd.mil/.*

Sincerely,

Barbara A. Goodno
Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Mr. Brooks Corley
Marine Corps League
8626 Lee Highway #201
Merrifield, Virginia 22031

Dear Mr. Corley:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the members of the Marine Corps League.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil*. The URL for the website is *http://www.anthrax.osd.mil/*.

Sincerely,

Barbara A. Goodrie

Barbara A. Goodrie
Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Mr. Chuck Partridge
National Association of the Uniformed Services
5535 Hempstead Way
Springfield, Virginia 22151

Dear Mr. Partridge:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the members of the National Association of the Uniformed Services and the Society of Military Widows.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil.* The URL for the website is *http://www.anthrax.osd.mil/.*

Sincerely,

Barbara A. Goodno
Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Mr. Jim Durkin
The Military Order of the Purple Heart
5413 Backlick Road Suite B
Springfield, Virginia 22151

Dear Mr. Durkin:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the members of the Military Order of the Purple Heart.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil.* The URL for the website is *http://www.anthrax.osd.mil/.*

Sincerely,

Barbara A. Goodno
Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Mr. George Culpepper
Fleet Reserve Association
125 North West Street
Alexandria, Virginia 22314

Dear Mr. Culpepper:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the members of the Fleet Reserve Association.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil.* The URL for the website is *http://www.anthrax.osd.mil/.*

Sincerely,

Barbara A. Goodrich
Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Mr. Jim Carey
Naval Reserve Association
1619 King Street
Alexandria, Virginia 22314-2793

Dear Mr. Carey:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the members of the Naval Reserve Association.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil.* The URL for the website is *http://www.anthrax.osd.mil/.*

Sincerely,

Barbara A. Goodno

Barbara A. Goodno
Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Mr. Bob Norton
The Retired Officers Association
201 North Washington Street
Alexandria, Virginia 22314

Dear Mr. Norton:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the members of the Retired Officers Association.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil.* The URL for the website is *http://www.anthrax.osd.mil/.*

Sincerely,

Barbara A. Goodhe
Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Ms. Lilly Cannon
National Military Family Association
2500 North Van Dorn, Suite 102
Alexandria, Virginia 22302

Dear Ms. Cannon:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the members of the National Military Family Association.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil.* The URL for the website is *http://www.anthrax.osd.mil/.*

Sincerely,

Barbara A. Goodno
Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Mr. Herb Rosenbleeth
Jewish War Veterans of the U.S.A.
1811 R. Street Northwest
Washington, D.C. 20009-1659

Dear Mr. Rosenbleeth:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the Jewish War Veterans.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil.* The URL for the website is *http://www.anthrax.osd.mil/.*

Sincerely,

Barbara A. Goodnow
Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Mr. John Goheen
National Guard Association of
the United States
One Massachusetts Avenue Northwest
Washington, D.C. 20001

Dear Mr. Goheen:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the members of the National Guard Association of the United States.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil.* The URL for the website is *http://www.anthrax.osd.mil/.*

Sincerely,

Barbara A. Goodno
Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Ms. Shannon Middleton
The American Legion
1608 K Street Northwest
Washington, D.C. 20006

Dear Ms. Middleton:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the members of the American Legion.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil.* The URL for the website is *http://www.anthrax.osd.mil/.*

Sincerely,

Barbara A. Goodno
Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Mr. Blake Ortner
Paralyzed Veterans of America
801 Eighteenth Street, Northwest
Washington, D.C. 20006-3517

Dear Mr. Ortner:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the members of the Paralyzed Veterans of America.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil.* The URL for the website is *http://www.anthrax.osd.mil/.*

Sincerely,

Barbara A. Goodno
Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Mr. Steve Anderson
Reserve Officers Association
1 Constitution Avenue Northeast
Washington, D.C., 20002

Dear Mr. Anderson:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the members of the Reserve Officers Association.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil.* The URL for the website is *http://www.anthrax.osd.mil/.*

Sincerely,

Barbara A. Goodno

Barbara A. Goodno
Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Mr. Brian Lawrence
Disabled American Veterans
807 Maine Street, Southwest
Washington, D.C. 20400

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the members of the Disabled American Veterans.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil.* The URL for the website is *http://www.anthrax.osd.mil/.*

Sincerely,

Barbara A. Goodno
Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Mr. Bob Gardner
The Veterans of Foreign Wars
200 Maryland Avenue, Northeast
Washington, D.C. 20002

Dear Mr. Gardner:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the members of the Veterans of Foreign Wars.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil.* The URL for the website is *http://www.anthrax.osd.mil/.*

Sincerely,

Barbara A. Goodno
Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Mr. Howie DeWolf
AMVETS
4647 Forbes Boulevard
Lanham, Maryland 20706

Dear Mr. DeWolf:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the AMVETS membership.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil.* The URL for the website is *http://www.anthrax.osd.mil/.*

Sincerely,

Barbara A. Goodno

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Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Mr. Tom Green
Marine Corps Reserve
Officers Association
337 Potomac Avenue
Quantico, Virginia 22134-3460

Dear Mr. Green:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the members of the National Guard Association of the United States.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil.* The URL for the website is *http://www.anthrax.osd.mil/.*

Sincerely,

Barbara A. Goodno

Barbara A. Goodno
Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 2002

Mr. Walt Davis
Marine Corps Association
Box 1775
Quantico, Virginia 22134

Dear Mr. Davis:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the members of the Marine Corps Association.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil.* The URL for the website is *http://www.anthrax.osd.mil/.*

Sincerely,

Barbara A. Goodno
Deputy for Public Affairs and Outreach

Enclosures

OFFICE OF THE UNDER SECRETARY OF DEFENSE
PERSONNEL AND READINESS
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

SPECIAL ASSISTANT FOR
GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JUL 2 - 2002

Mr. Pat Eddington
Vietnam Veterans of America
8605 Cameron Street, Suite 400
Silver Spring, Maryland 20910-3710

Dear Mr. Eddington:

Enclosed are copies of the Department of Defense June 28, 2002, anthrax vaccine policy memorandum and press release, as promised last week on Friday. I've also enclosed a folder of information materials prepared by staff at the Anthrax Vaccine Immunization Program. You'll note that they've included multiple copies of the information paper and a computer disk containing all the materials in the folder. I hope you find the materials useful to you and the members of the Vietnam Veterans of America.

If you have additional questions about the vaccine or the Department of Defense policy, please contact the Anthrax Vaccine Immunization Program office toll-free at (877) 438-8222 (800-GET VACC). Staff members are available Monday through Friday, from 8 a.m. to 6 p.m. (Eastern Daylight Savings Time). For those who would like to communicate via e-mail, the Internet address is *AVIP@otsg.amedd.army.mil.* The URL for the website is *http://www.anthrax.osd.mil/.*

Sincerely,

Barbara A. Goodno
Deputy for Public Affairs and Outreach

Enclosures

(112)

MEMORANDUM

DATE: January 12, 2000

TO: (b)(6) DoD/OLA

CC: Lawrence Halloran/Subcommittee Staff Director & Counsel

FROM: Robert Newman/Subcommittee on National Security/B-372, RHOB

SUBJECT: Gulf War/Anthrax

(b)(6) It has come to our attention that Dr. Rostker's OSAGWI shop is sending replies to inquiries from Gulf veterans about use of anthrax vaccines as follows:

"In your e-mail, you wrote the vials that contained the anthrax vaccine given to our unit did not have any numbers on them. **We are aware that there were a few isolated cases where the lot numbers were removed from the vials,** however this was in no way standard practice."

Is this true? How many removed? Why? After a four-year investigation into Gulf War veterans' illnesses including 13 hearings, a major report and legislation, this is the first time we on the Subcommittee have heard of this situation from any government officials or witnesses. Also we held five hearings last year on anthrax alone and this never came up either.

Please check with OSAGWI and provide us with their written report on everything they know and have on file about "lot numbers removed [or missing] from anthrax vials" that were used on Gulf troops. We would like a written response delivered to the Subcommittee no later than **January 19** of next week.

Please verify receiving this request by calling me today on (202) 225-2548. Thanks.

Bob

a7

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
FOR
GULF WAR ILLNESSES

JAN 19 2000

Mr. Robert A. Newman
B372 Rayburn House Office Building
Washington, DC 20515

Dear Mr. Newman:

The Office of the Assistant Secretary of Defense for Legislative Affairs forwarded your January 12, 2000 memorandum regarding anthrax vaccine use in the Gulf War to me for response.

During our investigation of vaccine use, we encountered a Navy physician, CDR (b)(6), who served in the Gulf as a flight surgeon for a Marine Aviation Group. He reported that when they administered vaccines, the vaccines were kept on ice. He was given unlabelled vials and told to administer them and record the first shot as "A1" and the second shot as "A2." Since it was important to keep the vaccines cold under field conditions, vials were put on ice and it was assumed that the labels came off when they became wet. There was no intent to deceive. CDR (b)(6) also reported that he recalled some service members refused to be vaccinated from the vials without labels, however, most did not have a problem with the vaccinations after he explained the circumstances.

Other than the recent report from Mr (b)(6) who contacted your office, this is the only instance we encountered that involved lot numbered labels missing from vaccine vials. Our report on the vaccine use in the Gulf War and a report by RAND have been drafted and we expect to publish both documents in the near future.

Sincerely,

Francis L. O'Donnell
Colonel, MC, USA
Director, Medical Outreach & Issues

Enclosures
Mr. Bann's e-mails

Gulf War Illnesses

Bernard Rostker

CMAT Number: 1999337-E000016 Date Received: 12/03/99 03:24:44 PM

To: (b)(6) /O=OSAGWI

From: (b)(6)

cc:

Subject: Re: shots

I say again, the vials that contained the so called anthrax vaccine that my

unit was administered, Did not have any numbers on them.

OK, so now we know that the pills screwed us up, the so-called anthrax shot

screwed us up, the exposure to chemical warfare screwed us up, and don't tell

me there wasn't any used cause that bull crap. I guess its cheaper for you

people to do autopsies on us vets then to do the proper testing now.

(b)(6)

CMAT Controlled

Comments:

Cross with 9302-e05 (outbound) and 9337 -17

VDM Controlled

Comments:

PAO Controlled

Comments:

These issues were addressed in a previous e-mail to him 9302-05.

Response:

Dear (b)(6) :

Thank you for your recent e-mail notes regarding Gulf War illnesses. My name is (b)(6) and I am responding on behalf of Dr. Bernard Rostker, the Special Assistant for Gulf War Illnesses. Dr. Rostker was appointed by the Deputy Secretary of Defense to oversee the Department of Defense investigation of Gulf War illnesses. Our number one priority is the health and welfare of our Gulf War veterans. We are committed to a thorough, complete and public investigation.

In your e-mail, you wrote the vials that contained the anthrax vaccine given to your unit didn't have any numbers on them. We are aware that there were a few isolated cases where the lot numbers were removed from the vials, however this was in no way standard practice.

In another e-mail note, you also asked if the nerve agent antidote Mark 1 is the same antidote as atropine, 2 Pam Chloride. As you surmised, it is. The Mark 1 is the same thing as Atropine, 2 Pam Chloride.

In your e-mail you mentioned three particular topics - pyridostigmine bromide pills, anthrax vaccinations, and exposure to chemical warfare. Each topic has been the focus of substantial investigation by the Department of Defense and the Special Assistant's office. I'll briefly review some of our efforts.

In October 1999, the Department of Defense and the RAND Corporation released a report that examined the safety and effectiveness of pyridostigmine bromide used during the Gulf War as a pre-treatment to protect military personnel from the nerve agent soman. This scientific literature review was performed to identify hypotheses or theories that might link pyridostigmine bromide to illnesses in Gulf War veterans. The report concludes that while medical research has not established pyridostigmine bromide as a cause of Gulf War illnesses, it can't be ruled out as a possible contributor to the development of unexplained or undiagosed illnesses in some Gulf War veterans. Currently, pyridostigmine bromide is part of the medical protection our troops have for soman, which is extremely lethal. However, pyridostigmine bromide does have known short-term side-effects and we need to continue our efforts to protect our troops against deadly nerve agents.

As you know, anthrax is considered the number one biological threat in the world today. Currently, at least 10 nation states and two terrorist groups are known to possess, or have in development, a biological warfare capability. Anthrax is considered an effective biological weapon because it is almost always lethal if not treated immediately after contact, or pre-vaccinated. Spores can be produced in large quantities using basic knowledge of biology. Spores can be easily spread in the air by missiles, rockets, aerial bombs and sprayers. Moreover, there is no effective treatment for unvaccinated victims who inhale anthrax once symptoms are exhibited.

The Department of Defense is using a vaccine that is both proven safe and effective against all known strains of anthrax pathogen. It has been approved by the Food and Drug Administration (FDA) for nearly 30 years. The Department is committed to fully educating servicemembers and their families on the purpose and value of anthrax vaccination. We suggest you visit the DoD website at (www.defenselink.mil) for additional information on the program.

You also mentioned the effect of possible chemical exposure to troops during the

Gulf War. Our investigation found that when rockets were destroyed in the pit area at Khamisiyah on March 10, 1991, the nerve agents sarin and cyclosarin may have been released into the air. Our team performed a very extensive analysis of the incident and concluded that the exposure levels would have been too low to cause any symptoms at the time.

Although little is known about the long-term effects from a brief, low level exposure to nerve agents such as the one that occurred, the current medical evidence indicates that long-term health problems are unlikely. Because the scientific evidence is limited, the Department of Defense and the Department of Veterans Affairs are committed to gaining a better understanding of the potential health effects of brief, low level nerve agent exposures, and they have funded several projects to learn more about them.

We hope this information is helpful to you. Please do not hesitate to continue to contact us should you have any additional questions or concerns.
000110

Gulf War Illnesses

CMAT

CMAT Number: 1999337-E000017 Date Received: 12/03/99 04:00:51 PM

To: (b)(6) O=OSAGWI

From: (b)(6)

cc:

Subject: Re: shots

You also stated the PB pills were to be used in conjunction with the nerve

agent antidote Mark 1. Well, is that the same antidote as atropine, 2 Pam

Chloride? Because that's the nerve agent antidote my unit carried.

(b)(6)

CMAT Controlled

Comments:
Input in

MEDICAL PER PAO PLEASE PROVIDE INPUT

Cross with 9302-e05 (outbound) and 9337 -16

VDM Controlled

Comments:

PAO Controlled

Comments:

Response:

PAO Manager Controlled

Comments:
2000 0108 p.m. Bill – Recommend NFA. Response incorporated in previous e-mail. VR, bg

Gulf War Illnesses

Bernard Rostker

CMAT Number: 1999302-E000005 Date Received: 10/29/99 01:25:59 PM

To:
From: (b)(6)
cc:
Subject: shots

Dr. Rostker.

Could you please answer 3 questions? One, why is it, that the anthrax shot my unit was injected with didn't have and lot number on it? Two, why is it that my unit had to take PB pills every 8 hr. and other units were taking them at different time schedules? for example: 2x a day, once a day, only when there was a verified scud launch. I'm no scientist. but I do believe that someone was doing experiments here. Third and final question, why is it we only received one injection when the anthrax vaccine being administered now is a series of injections? I guess we received a "different" shot.

Regards,

(b)(6)

CMAT Controlled

Comments:
see medical

VDM Controlled

Comments:

PAO Controlled

Comments:

Response:

Dear (b)(6)

Thank you for your recent e-mail regarding Gulf War illnesses. My name is (b)(and I am responding on behalf of Dr. Bernard Rostker, the Special Assistant for Gulf War Illnesses. Dr. Rostker was appointed by the Deputy Secretary of Defense to oversee the Department of Defense investigation of Gulf War illnesses. Our number one priority is the health and welfare of our Gulf War veterans. We are committed to a thorough, complete and public investigation.

In your e-mail you asked several questions that I would like to address. First, you asked why the anthrax shot you received did not have a lot number on it. The vial containing the anthrax vaccine from which the needles were filled would have had the manufacturer's lot number on it as required by the FDA. Lot numbers would not have been recorded on either the roster that was used to record who received the anthrax vaccine or, if posted to it, your individual shot record. According to standard procedures at that time, no lot numbers were required to be recorded on Standard Forms 601, Immunization Record, except for the yellow fever vaccine.

You also asked why your unit had to take pyridostigmine bromide -- PB -- pills every eight hours when other units were taking them at different schedules. Your unit took PB pills every eight hours because your unit commander was following the guidance to protect those under his/her command. Other units who took the tablets on a different schedule were not following guidance. The prescribed dosage for pyridostigmine bromide was one 30mg tablet every eight hours, upon the direction of the unit commander based on the threat of chemical agent exposure. Pyridostigmine bromide is not an "experimental" drug. It is an effective pre-treatment medication that helps to reduce the severity of nerve agent poisoning when taken within eight hours prior to a nerve agent exposure and used in conjunction with the nerve agent antidote Mark I. It is the only known pre-treatment against the nerve agent soman.

Prior to the Gulf War, the Department of Defense had recognized pyridostigmine bromide to be an effective antidote against nerve agent exposure and had the tablets in its inventory of chemical defense items. A Tri-Service Field Manual Treatment of Chemical Agent Casualties and Conventional Military Chemical Injuries (Army FM 8-285/Navy NAVMED P-5041/Air Force AFM 160-11) explained how PB worked and its proper usage. Additionally, during the Gulf War, numerous messages were sent to commands in the theatre providing information on the proper use of PB. And finally, each PB tablet set had directions for use printed on each package sleeve and the blister pack, as well.

You also asked why you received only one anthrax injection during your time in the Gulf when the anthrax vaccine is now being administered in a series of injections. The intention was to provide the series of shots however, the war ended so quickly that the need to continue with the series was deemed to be unnecessary. The vaccine given today is the same vaccine given during the Gulf War.

Please accept our apologies for the delay in responding to your questions. Our intent is to answer inquiries as quickly as possible. As you might imagine, we received a large number of questions related to pyridostigmine bromide. And though we answered questions in the order they were

received, the process took longer than anticipated. For that we are sorry.
We know this information is important to you. If you have any further questions, please let us know.
991203

01/19/00 16:59 FAX (b)(6) SpAsst GulfWar Illnesses 001

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	4903
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	Natl. Security S
ST. TIME	01/19 16:57
USAGE T	01'56
PGS. SENT	9
RESULT	OK

Office of the Special Assistant for Gulf War Illnesses
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
(b)(6)
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET

TO: MR. ROBERT NEWMAN
FROM: COLONEL O'DONNELL MD
ORGANIZATION:
FAX NUMBER: (b)(6)
TOTAL NO. OF PAGES INCLUDING COVER: 9
PHONE NUMBER: (b)(6)
SENDER'S PHONE NUMBER: (b)(6)
SUBJECT: RESPONSE TO YOUR QUESTIONS

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

(113)

Editor GulfNews

(b)(6)

CMAT Control #
2000032-0000009

Jan. 23. 2000
FAX (b)(6)

Bernard D. Rostker
Sp. Asst.- Gulf War Illnesses, DOD

Regarding the DOD innoculation program for chem/bio -anthrax-soman - your sources and studies (RAND CO) admit there was a lack of information causing fear and confusion.

You are innoculating against Anthrax currently - I don't know if you are still operating with PB. Every day we read of servicemen being courtsmartialed for not agreeing to these innoculations.

Admiral (RADM) Michael Cowan says that DOD planners are posessed of "terror regarding the potential uses of chem/bio weapons by terrorists." (Doesn't sound like calm thinking to me).

So DOD thinks there is a possible danger not a probable danger. DOD gives vaccinations against anthrax and soman which have a probable danger to some servicemen. (Proven)

The United States has never been attacked by either agent. We are not currently at war with a nation using anthrax or soman. There is an international treaty signed by Pres.Nixon for the USA against chem/bio weapons.- The research conducted by NIH at Fort Detrick was transfered to the U.S.Army there at Fort Detrick (many of the same researchers are still involved that worked for the Cancer Institute of the NIH.).

The British conducted research with anthrax - an island off the coast of Scotland was used. This island is still off-limits to anyone.

The point is that there is a very small possibility that anyone will use these chem/bio weapons against the USA.
Yet because of the terror in the minds of DOD planners regarding these weapons we innoculate our troops(possibly even reserve personnel) with something that has a proven probability in a percentage of our people of causing terrible illnesses.

DOD says the danger is from terrorists. Yet we innoculate not our population but troops. We know the probability of terrorist activity against troops is small - larger against the civilian population where terrorist activity has been recorded.

Of course, we recognize that any innoculation against anthrax or soman using our civilian population is impossible -impossible politically, morally, and expensive beyond our means. So we use DOD personnel in an investigational way. Do they sign a consent form required in medicine for any experimental practice?

I think not. There are two other chem/bio agents DOD is studying. Are these to be investigated inthe same way?

Very truly yours,

(b)(6)

(b)(6)

CONGRESSIONAL or SPECIAL CORRESPONDENCE

CMAT: 0032-009

Date: 2/18/00

Office of Special Assistant for Gulf War Illnesses
Internal Routing/Tasking Sheet

Coord/ Routing	Position/Organization		Action	Info	Comments
5	Special Assistant	(SA)			sign letter sign memo TAB A
3	Deputy Special Assistant	(DSA)			
4	Executive Assistant to SA	(EA)			
	Executive Assistant to DSA	(EADSA)			
	☐ Director, Investigation & Analysis _____ (IAD) ☐ DepDir _____ ☐ MED _____ ☐ VDM _____ ☐ C/B _____ ☐ ENV _____ ☐ PAG _____				
	Dir Lessons Learned Implementation	(LLI)			
	Dir Public Affairs & Outreach	(PA)			
	Dir Legislative Outreach	(LA)			
	Dir Medical Outreach & Issues	(MOI)	Originator		
	Legal Advisor	(LGL)			
2	PM, Gulf War Illnesses Support	(PM)			
1	Editorial Review ☐ AMB _____ ☐ Editors _____	(ER)			
	CMAT	(CMAT)			
	Action Management Call 845-8369 ☐ COMEBACK COPY TO: _____ ☐ GET CMAT NUMBER WHEN SIGNED & SENT ☐ READING FILE ☐ THANK YOU FILE ☐ CHRON FILE ☐ ADD TO GulfNEWS				

SUSPENSE:

Prepare reply for signature of:

☐ SA/GWI ☐ SD ☐ DSD ☐ DepSA/GWI

Enclosed is a response to (b)(6) (his letter is at TAB B)

Also enclosed is a memo to Dir. AVIP which will send copy of (b)(6) letter and our response.

☐ Congress ☐ Oversight ☐ OSD ☐ WBM ☐ VSO/MSO ☐ Outgoing

☐ Ltr to SA ☐ IR ☐ E-Mail ☐ OGA ☐ Other ☐ Veteran

KEYWORDS:

12/07/99 Issuance

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
FOR
GULF WAR ILLNESSES

(b)(6)

FEB 2 3 2000

Dear (b)(6)

In regard to your recent letter about chemical and biological weapons and measures to protect our service members, as the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses I can address the use of the anthrax vaccine and pyridostigmine bromide (PB) during the Gulf War. Regarding your concerns on DoD's current anthrax vaccination program, I have forwarded your letter to the Director of the Anthrax Vaccine Immunization Program so that the program's managers are made aware of your views.

As your letter indicates, during the Gulf War many of our servicemembers were not well informed about the purposes for the use of pyridostigmine bromide (PB) tablets and the anthrax vaccine. As a result, some veterans and servicemembers are suspicious of the reasons for those protective measures and they fear that their health may have been adversely affected. However, the anthrax vaccine is FDA-approved; it was not given as part of an experiment. Anthrax vaccine was given during the Gulf War as a force protection measure based on the risks faced by our servicemembers. Service members are informed about the anthrax threat and the safety and efficacy of the vaccine through the current anthrax vaccine program. In addition, the vaccinations, and any data on side effects, are being well documented. These steps are being taken as a result of the lessons learned during the Gulf War.

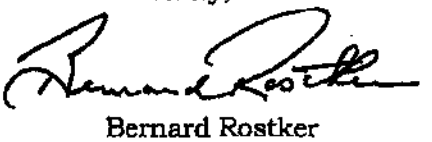
Regarding your comments about PB, it is not being used at this time. During the Gulf War, PB tablets were taken orally when the threat assessment indicated that the enemy use of nerve agent in the area of operations was possible. The frequency of use (for instance, every eight hours) indicates that the medication does not stay in the body for a long period. Fortunately, Iraq did not use chemical or biological weapons against coalition forces during the Gulf War. Inspections following the war confirmed intelligence estimates that Iraq possessed and had weaponized both biological (anthrax) and chemical agents (nerve agents and mustard).

PB is not an experimental drug. The FDA approved it in 1955 for use in treating a neuromuscular disease that causes muscle weakness and fatigue. Thousands of people with myasthenia gravis have taken high doses of PB for many years without lasting adverse effects. PB has also been approved for use in reversing the effects of general anesthesia. However, as used in the Gulf, PB was an investigational new drug. This classification means that PB had not been formally approved for general commercial marketing as a nerve gas

antidote. This was because, although the safety of the drug was not in question, there was no proof in humans that PB would work to protect against soman. That is still the situation because there is no ethical way to do an experiment to prove that humans exposed to soman will be protected by use of PB. In non-human primates, the protection provided by PB against soman is very dramatic. Because PB remains an investigational product for the pretreatment of exposure to soman, in the future only the President of the United States can authorize its use to protect personnel without their informed consent.

I understand these are important issues and that we must do our utmost to protect our military men and women on the battlefield. As the Special Assistant for Gulf War Illnesses, I want to ensure those making decisions on these subjects today have the benefit of the lessons learned from the Gulf War. Thank you for taking the time to write. As a former servicemember and an officer, I know these issues are important to you.

Sincerely,



Bernard Rostker

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
FOR
GULF WAR ILLNESSES

FEB 2 3 2000

MEMORANDUM FOR DIRECTOR, ANTHRAX VACCINE IMMUNIZATION PROGRAM

SUBJECT: Correspondence From (b)(6)

The purpose of this memorandum is to provide you a copy for appropriate action of correspondence we recently responded to regarding the anthrax vaccination.

Dale A. Vesser
Deputy Special Assistant

Enclosures
1. Letter from (b)(6)
2. OSAGWI response

(114)

2000049- 00021

(b)(6)

02/29/2000 05:58 PM

To: (b)(6)
cc:
Subject: Re: (b)(6)

CALL WAS MADE TO (b)(6) (LEAD ID: 26151). Last week, I talked to AVIP and they said they'd carry the ball from there. I talked to (b)(6) today who said AVIP is getting the information he needs together (SEE BELOW):

(b)(6) 2/29/00
(b)(6) says he's been contacted by AVIP and that they are putting together an information packet to answer his specific questions. (b)(6) was asked to notify the OFFICE when he receives the packet and inform the OFFICE as to whether all his questions have been answered and answered to his satisfaction.

Tasked to AMB,

Close.

No action needed.

0049-021

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
FOR
GULF WAR ILLNESSES

(b)(6)

MAR 0 8 2000

Dear (b)(6)

This is in response to your recent conversation with a member of my staff about the Department of Defense Anthrax Vaccine Immunization Program (AVIP). As the Special Assistant for Gulf War Illnesses, my office is not directly associated with the DoD anthrax program; however, because the first large-scale military inoculations against anthrax were carried out during the Gulf War we are familiar with the issue.

You requested an information pack about the anthrax vaccine and the AVIP. I have enclosed several informational products that cover the most frequently asked topics. All of these materials were obtained from the AVIP office and are also available on their website (*www.anthrax.osd.mil*) along with much more information. They also have a toll-free number (877) 438-8222.

Thank you for the opportunity to address your concerns. I hope this information is helpful to you.

Sincerely,

Bernard Rostker

Enclosures

(115)

CMAT Control #
2000306-0000004

10-5-00

Dear Mr Berry

I have reviewed my diary from the Gulf War. I hope that the following information will be of value.

My unit was the 13th Evac Hospital Army National Guard from Madison WI. The unit was deactivated as part of the down sizing. In Saudi Arabia our hospital was located 1.5 Km off Dodge road near Wadi Al Batin in the VII Corp Area.

Prior to the start of the War the unit was ordred to administer anthrax vaccine. Anthrax vaccine was given to approximately nine thousand troops. Only one dose of the vaccine was given. The vaccine was not recorded on on the health record of the soldier as we were told not to record the vaccine. Each day a team would go out to the various units in our area. The last group sent out to give the vaccin came under fire at that location.

The following includes dates, unit and number soldiers that recived the vaccine. At this date I'm not sure if the number are correct.

Date	Unit	Number
2-11-91	89th GS	580
2-12-91	" "	720
2-13-91	" "	360
2-14-91	" "	735
2-15-91	317 BN	160
2-15-91	Transportation 4th	320
2-16-91	" "	700
2-17-91	" "	?
2-18-91	101 St	900
2-19-91	300 S+S	?
2-21-91	34th Signal BN	600

- Units attached or Living in our camp.

289 PSC
87 Med Dental
273 Med Detachment
358 Med Detachment
148 Preventive Med
343 Amb Co
449 Med Co
122 RAC
378 Med Neuro
318 Anesth

Gamma globulin was given to fifteen members of a CID unit that was sent to KK MC and then back to Germany

Prior to going into the desert to set up the hospital, our unit lived in Khober Towers in Dhahran. There was a scud attack each night sometimes two or three times a night. We usually spent the night in mopp level 4. Debris from the scuds were in our area.

We were told to start taking the Pyridostigmine on 21 January. A day or so later were told stop taking it. 23 January told to take again. We were told there were no side effects. Many of us became ill. I could not left my head off the floor (we slept on the floor) and was nauseated. I stopped taking the pills.

In the desert the chemical alarms went off frequently. We were told they were false alarms. We were also told the Hospital tents would protect us from Chemical and bio attacks. The first sand storm proved this to be false.

On 26 March 91 I was admitted as a patient to the 312 Evac Hospital located across from our hospital in the desert. On admission I was nauseated, vomiting, diarrhea and with a blood presure over 200/100. I have a copy of those records

which are very difficult to read.

Our mobilization station before and after Desert Storm was Fort McCoy Sparta WI. Prior to departure to the Gulf I recived a series of vaccines. I do not know what they were.

In our Camps in the desert there were many diffent insects. Rats ran under the wood floor in the sleeping tents at night. There were numerous sand storms. Sometimes 2-3 a day and at night. Some sand storms were so bad you could not leave the tent or see a few inches in front of you.

I bilive the Gulf War illness is a result of many factor including but not limited to Constant temperatures over a 100° degrees, MREs very high in salt content, insects, sand storms, burning oil wells etc. Many of us were not the young eighteen and nineteen olds.

Thank you for your Concern

Sincerely

(b)(6)

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
TO THE SECRETARY OF DEFENSE
FOR GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

DEC 2 1 2000

(b)(6)

Dear (b)(6)

Thank you for taking the time to provide information from your Gulf War diary. We welcome information from everyone who has documentation that may contribute to our understanding of Gulf War events and thereby help our veterans. As the Special Assistant to the Deputy Secretary of Defense appointed to oversee the Department of Defense investigation of Gulf War illnesses, insight such as yours is very useful.

We have incorporated your comments in our database for future use. Much of what we know about the events of the Gulf War has been through eyewitness accounts such as yours. In particular, we noted your comments about the lack of medical record-keeping – some by operational direction, as in the case with the anthrax vaccine, and others for unknown reasons, such as you experienced prior to your deployment. This is one of the lessons learned from the Gulf War – we must improve medical record keeping. I have enclosed a copy of our information paper on the subject for your review. If you have any comments, please let us know.

We have just released a report on vaccine administration that you might find useful, and have enclosed a copy to you. Again, we would be interested in your comments.

It is unfortunate you were told to expect no side-effects with the use of pyridostigmine bromide tablets. Various side effects can be expected to occur in some people, based upon the drug's mechanism of action. Increases in acetylcholine activity can produce nausea, diarrhea, stomach cramps, frequent urination or headaches, dizziness, shortness of breath, worsening of peptic ulcer disease, and eye tearing. The side effects of pyridostigmine bromide taper off when individuals stop taking the drug. This is information that should have been given to you and other members of your unit.

As you may know, pyridostigmine bromide has been used for years in the treatment of myasthenia gravis. Based on approval from the FDA, it was used during the Gulf War to pre-treat troops when the threat of Iraqi use of the chemical warfare agent soman was high. Without pre-treatment, nerve agent antidotes are ineffective in treating exposure to soman. To date, there is no other treatment for this particular nerve agent.

At the time it was used in 1991, there were few health concerns about pyridostigmine bromide. As I mentioned earlier, it had been licensed and used for many years in much larger doses to treat myasthenia gravis. Its track record in such patients remains excellent. However, there is limited research on the effects when used by people who are healthy.

Last year, the RAND Corporation published a review of the scientific literature of pyridostigmine bromide. This report underscores the need for the on-going research on its possible health effects. Although it does not conclude the pre-treatment drug is a cause of illnesses among Gulf War veterans, it identifies several hypotheses that, based on current medical literature, cannot be ruled out at this time. Currently, there are 26 research projects that examine the long-term health effects of pyridostigmine bromide. I have enclosed a copy of RAND's report and the list of research projects for your reference.

I have also enclosed a folder that contains information about our office and identifies resources available to Gulf War veterans. Please feel free to share this information with other veterans. If you need additional copies, please let us know.

Again, thank you for taking the time to write to us. We appreciate your thoughtful insight.

Sincerely,

Bernard Rostker

Enclosures

Office of the Special Assistant to the Secretary of Defense for Gulf War Illnesses, Medical Readiness, and Military Deployments

CMAT #: 0340-013
0306-004
Date: DEC 12 2000

Action Tasking // Internal Routing Sheet

			Action	Info	Comments
7	Special Assistant	(SA)			signature
5	Deputy Special Assistant	(DSA)	12/12-19		
6	Executive Assistant to SA	(EA)			
	Executive Assistant to DSA	(EADSA)			
	☐ Director, Investigation & Analysis ☐ C/B ☐ ENV ☐ PAG ☐ VDM	(IAD)			
	Dir Lessons Learned Implementation	(LLI)			
2	Dir Public Affairs & Outreach	(PAO)	OK 12000	12-15-2000	
3	Dir Medical Readiness	(MR)	18 Dec 00		
	Legal Advisor	(LGL)			
	Info Technology & Security	(ITS)			
4	PM Support	(PM)	[illegible]	18 Dec	
	☐ CMAT ☐ OPNS ☐ DMT				
1	Editorial Review	(ER)			
8	AMB ☐ COMEBACK COPY TO: ☐ GET CMAT # WHEN SIGNED ☐ READING FILE ☒ CHRON FILE				

SUSPENSE:

Prepare reply for signature of:
☐ Special Assistant ☐ Deputy Special Assistant

☐ Congress	☐ Oversight	☐ FOIA	☐ OSD	☐ WBM	☐ VSO/MSO	☐ Outgoing
☐ Ltr to SA	☐ IR	☐ E-Mail	☐ OGA	☐ Other		☐ Veteran

KEYWORDS:

09/07/00 Issuance

(116)

OFFICE OF THE SECRETARY OF DEFENSE
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WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
TO THE SECRETARY OF DEFENSE
FOR GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

JAN 1 2 2001

(b)(6)

Dear (b)(6)

This letter is in response to your conversation with a representative from my office. As the Special Assistant to the Secretary of Defense appointed to oversee the Department of Defense investigation of Gulf War illnesses, I assure you we are fully committed to investigating the events of the Gulf War in order to understand why some of our veterans are ill.

During your conversation you asked questions about the inoculations which you received in the Persian Gulf. Your description of the secrecy with which the shots were given leads us to believe that the vaccine in question was the anthrax vaccine, as you have surmised yourself. To protect our forces in the Persian Gulf against the biological weapon anthrax, the anthrax vaccine was given to about 150,000 Americans beginning in January 1991. Because there was only enough vaccine to cover part of our force and there was none for our coalition allies, the leadership wanted to make sure that Iraq did not find out which of our forces were protected against anthrax and which forces were not. Accordingly, guidance was that the immunization program be carried out as quietly as possible. This guidance resulted in much of the program being regarded as a secret, and troops receiving the shots sometimes had experiences like the one you described. Shot records often were not marked; some soldiers were not told the identity of the shot; in some units, the shots were mandatory and in others, voluntary. One of the lessons learned from the Gulf War is that we should never give immunizations in that way.

The warning to female soldiers to avoid pregnancy for two to five years after receiving the shot is erroneous. Such a warning is not justified for any vaccine and it is difficult to understand why your unit was told that. Whoever said that was badly mistaken. Such a warning about pregnancy was not part of the instructions to those who were distributing the anthrax vaccine.

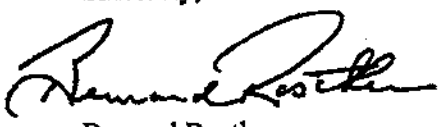
Good medical practice is to not give vaccines to any pregnant woman unless absolutely necessary. The reasons for this cautious approach are two-fold. First, the safety of vaccines during pregnancy is normally not studied when vaccines are being researched prior to licensure. Thus, there are usually no data to prove the safety of vaccines during pregnancy. Secondly, in the absence of such data, it is considered simple prudence to defer vaccines until a pregnancy is over.

Women are usually advised to avoid pregnancy after they have received a live virus vaccine such as measles, mumps, rubella, chickenpox, and yellow fever vaccines. However, the

warning is usually to avoid pregnancy for three months. The reason for that time frame is simply to allow a sufficiently long time to pass so that there is no chance that the fetus could be exposed to the live virus contained in the vaccine. With vaccines which do not contain living microorganisms, such as anthrax or influenza, there is no need to postpone pregnancy at all. In any event, avoiding pregnancy for years after any vaccine is completely unjustified.

We hope that this answers your questions. A comprehensive narrative on vaccines in the Gulf War has been published by our office and is available in its entirety on the our GulfLINK website (www.gulflink.osd.mil). If you have any further questions please do not hesitate to ask.

Sincerely,



Bernard Rostker

2001030-E000017

(117)

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SPECIAL ASSISTANT
TO THE SECRETARY OF DEFENSE
FOR GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

MAR 23 2001

(b)(6)

Dear (b)(6)

Thank you for your recent e-mail regarding Gulf War illnesses. We attempted to respond to your e-mail without success. I am the Director of Public Affairs and Outreach and I have been asked to respond to you on behalf of Dale A. Vesser, the Acting Special Assistant to the Secretary of Defense for Gulf War Illnesses, Medical Readiness, and Military Deployments.

In your e-mail you asked about statements which our chief of staff, Dr. Kilpatrick, made on a recent C-SPAN appearance regarding causes of diarrhea and whether there was a connection between anthrax vaccine and the bacteria which causes diarrhea. Dr. Kilpatrick read your e-mail and has provided the bulk of this response.

Bacteria of many types are the most common causes of diarrhea around the world. During the Gulf War, the vigorous measures of our military forces to supply wholesome food and water to our troops were very effective in minimizing the occurrence of diarrheal disease. Nevertheless, many U.S. forces in the Gulf experienced at least one episode of diarrhea.

There is no connection between diarrhea causing bacteria and the anthrax vaccine. That vaccine's active ingredient is a protein extracted from the anthrax bacterium. There are no living bacteria in the vaccine. Preservatives in the vaccine prevent the growth of any bacteria, which might later contaminate a vaccine vial. Disease caused by the anthrax bacterium can affect the skin (a slow-growing, ulcerating sore), the lungs (rapidly progressive lung and chest infection leading to death), and the throat, stomach, and intestines (vomiting, fever, pain, and diarrhea, leading to death in at least half the cases). No cases of anthrax occurred in U.S. forces in the Gulf.

With regard to your question about mycoplasm, *Mycoplasma fermentans incognitus* is not known to be a cause of diarrheal disease in humans, although that does not mean it is impossible. Mycoplasma have been theorized to be a cause of a variety of unexplained physical symptoms in both Gulf veterans and people who have never left the United States. That theory has not yet been satisfactorily verified and is the subject of continuing research. The Department of Veterans Affairs is conducting a large, multi-center study of the possibility that long-term antibiotic therapy may improve the health status of veterans with unexplained symptoms and a positive result on a research test for mycoplasma.

I hope this information clarifies Dr. Kilpatrick's reference to the causes of diarrhea. If you still would like to speak to someone about this subject, feel free to contact us at (800) 497-6261. One of our staff members will take any specific questions you have and make sure you receive a complete answer.

Thank you for the opportunity to respond to your concerns. We hope this information is helpful to you.

Sincerely,

Barbara A. Goodno
Director, Public Affairs and Outreach

2000153-0000003 (118)

RAND

May 26, 2000

LTG Dale Vesser
Office of the Special Assistant
for Gulf War Illnesses
5113 Leesburg Pike
Suite 901
Falls Church, Virginia 22041

Dear LTG Vesser:

Attached are two copies of "A Review of the Scientific Literature as It Pertains to Gulf War Illnesses, Volume 1: Infectious Disease," (MR-1018/1-OSD) by Lee Hilborne and Beatrice Golomb. This report has now been externally reviewed twice. You may recall, Mike Kilpatrick thought an earlier version should have been more expansive. We accommodated his concerns and then received a set of comments that indicated that OSAGWI and agency reviewers thought the document should focus on the infectious diseases found in the Gulf which was closer to the approach taken in the first round. We have redrafted this report and attempted to respond to reviewers' comments. We consulted with and utilized Frank O'Donnell's comments as the basis from which to respond.

We are now sending this package to RAND's publication department for editing and publication. As is our practice, I will forward a copy of the edited version to you for transmittal to DoD Public Affairs when the editing is completed. Terri Tanielian will provide you with an expected timetable for printing the document.

Sincerely yours,

Ross Anthony

C. Ross Anthony, Ph.D.

cc: Capt. Steve Wellock

1200 South Hayes Street
Arlington, VA 22202-5050

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Review #2:

OSAGWI Comments and RAND's Response

Response to reviewer comments to "A Review of the Scientific Literature as it Pertains to Gulf War Illnesses, Volume 1: Infectious Diseases.

We very much appreciate the time and effort that OSAGWI reviewers put into this document. The comments were integrated for the most part into the document and changes made accordingly. Because of the large number of comments, we will address the recommended changes in groups rather than discuss each one individually.

Spelling Corrections
The draft reviewers received had not been proofed for spelling and grammatical errors. The recommended spelling and grammar corrections, in addition to others, have been made.

Reduced Number of Diseases Discussed
We concur with the reviewer recommendations to reduce the number of specific infectious diseases discussed. The decision to add this more in depth discussion, one that can be generally found in textbooks of infectious diseases or medicine, was completed on the recommendation of a previous reviewer. We have also reduced the general discussions in the sections of infectious disease that remain in the document, per OSAGWI's suggestion. We have no objections whatsoever to these recommended simplifications.

Discussion of Botulinum Toxin
The reviewers point out that in an effort to oversimplify the discussion, statements were made that were incorrect. The discussion has been changed to reflect appropriate action of acetylcholine and the actions of the toxin.

Use of the Term "Gulf War Illnesses
In many places the term has been replaced with a more generic term, as suggested "illnesses in GW veterans". However, because the term is used in some places, there is a footnote at the beginning of the document that discusses the use of the term and the meaning it has in the present discussion.

Reactive Arthritis
Questions were raised about the association of reactive arthritis with illnesses in Gulf War veterans. Reactive arthritis is discussed in more detail now, an acknowledgement is made that in fact some veterans may actually have chronic reactive arthritis, but that because of the strong association with HLA B27 and the fact that most cases are of a limited duration, beginning weeks after infectious exposure, the likelihood of many cases of reactive arthritis is not high.

Rickettsial Disease
Although a discussion of rickettsia was in an initial draft of this manuscript, we were not asked to include it in this particular draft. We acknowledge that rickettsial infections did occur and other rickettsial infections were considered a potential source of infection. A decision was made to exclusively discuss those infectious diseases requested by OSAGWI.

Conclusions and Recommendations
The pieces of the manuscript that were either general conclusions or specific recommendations were moved to this brief concluding section.

Comments on the RAND Paper "A Review of the Scientific Literature as It Pertains to Gulf War Illnesses, Volume I: Infectious Diseases" September 17, 1999

GENERAL COMMENTS

Overall, the document is an adequate overview of infectious diseases that may have been encountered in the Persian Gulf Theater of Operations. The discussion appears complete but could also be found in infectious and tropical medicine texts, and it is felt that this paper does not add to the existing literature on infectious diseases. There are sections that described the correlations (or lack thereof) of these diseases to the Gulf War. Much of this could easily be stated in a much more concise document. (DHHS)

The reviewer limited comments on the paper to substantive and policy matters. Of particular note, the title of the paper is misleading. The author should change the title to reflect that this is not a review of "Scientific Literature," but rather a review of published and unpublished reports including anecdotal comments. Alternatively, the author could revise the paper to include only scientific literature in their review. (HA)

Basic questions remain as to the purpose, design, and readership for this paper. There is a limited amount of published literature about infectious diseases and the Gulf War, and even less about infectious diseases *as they pertain to the Gulf War illnesses*, which makes it difficult to write *a review of the scientific literature*. The authors have provided a mini-textbook of selected infectious diseases, which is irregular in coverage and depth. Even if it were more successfully done, it is not clear whom this would serve. The basic information is already available in established textbooks of medicine, tropical medicine, or infectious diseases, and in current published reviews of specific diseases. As a prelude to something more unique, basic information for each disease probably could be summarized in a paragraph or two, with references to good current reviews and texts for further reading. (OSAGWI)

What might be more interesting and unique – and that the reviewer suspects would be very useful to individuals and groups working with these issues – would be a review more narrowly focused on (a) the infectious diseases that are of concern to veterans, organizations, and researchers as explanations of the yet unexplained post-conflict illnesses,[1] (b) the infections and infectious diseases anticipated or actually experienced by service members in the Gulf *that have the potential to cause chronic conditions*,[2] and (c) the infections and infectious diseases that might mimic the unexplained illnesses reported by veterans. This would require more substantial sub-sections on the Gulf War relationships than are now in the paper,[3] and would eliminate

[1] This list might include HB Urnovitz and retrotransposons (HERVs), E Hyman and urinary bacteria, and the technologist and microsporidia-like structures, as well as G Nicolson and mycoplasma.

[2] Perhaps brucellosis, sand-fly fever, certain gastrointestinal infections, and others.

[3] For sand-fly fever, as an example, it would have been reasonable to include the Swedish military experience, which suggests a protracted illness and recovery in some individuals, and to look hard for other similar information. Also a (critical) review of the scientific literature could go into some greater detail

from discussion diseases for which there is little likelihood of connection.[4] In the current paper, they appear almost as "straw man" diseases, set up and easily dismissed from consideration. The review could provide a single source of current information as a background for further research and analysis. (OSAGWI)

Readership selection is important. Some rather simple terms are explained and other more technical jargon is left unexplained, which may require a better definition of the intended readership. The review cannot be all things to all readers, so the reviewer recommends deciding this one early. (OSAGWI)

The pagination of the draft and the table of contents show some disagreement. The table of contents provides pages that are incorrect for most of the subjects listed. The table of contents is on page iii, but it states that the preface is on page iii. Incidentally, no preface was included in the draft. (OSAGWI) Also, numbering of the tables within the text should be consistent with the numbering on graphs themselves. For example, page 9 of the text indicated "Table 4," while the table itself is listed as "Table 1.4." There are many instances in the text where this occurs. (DHHS) The page listing the Tables contains numerous asterisks and extraneous numbers of uncertain significance. (OSAGWI)

This document has been in preparation for several years and this is out of date regarding the latest literature on illness among Gulf War veterans. For example, the description of the CDC does not cite the published article and seems to be based on conversations between Dr. Reeves and Dr. Hilborne conducted prior to the study being completed. The description of the Air Force study also contains a number of factual errors. For instance, the response rate from one unit was 35%, not 30%; 4036 questionnaires were completed (of these 313 subjects were excluded due to not being members of the selected units and being younger than 17 years of age during the Gulf War, leaving 3723 subjects); 15% of non-deployed veterans were classified as a case (not 10 – 12% as reported). The description does not describe results from the clinical evaluation component of this study. The clinical evaluation component of the study found that neither mild-to-moderate nor severe cases were associated with clinically significant physical examination or routine laboratory test abnormalities. The reviewer recommends that this section be re-written based on the results presented in The Journal of the American Medical Association publication (JAMA 1998; 280: 981 – 988). Additionally, the Air Force study is incorrectly referred to as one of the first studies reporting Gulf War illnesses. The other CDC-funded study, the Iowa study, was completed and published prior to the Air Force study (JAMA, 1997; 227: 238 – 245). The results of this study should also be described as well as the findings from the various studies from the Naval Health Research Center (hospitalization and mortality studies). (DHHS)

Throughout the document the authors use both "Persian Gulf War" and "Gulf War." Currently, acceptable terminology is simply "Gulf War." (HA)

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about the testing of the 100 or so individuals for this illness, including the methods used and the adequacy of the numbers and in doing so provide some assessment of the strength of the data reported.

[4] The reviewer can, perhaps, see the inclusion of tuberculosis infection as a potential asymptomatic infection acquired in the Gulf, but not as a cause of or contribution to the unexplained illnesses. (Have any data from pre- and post-deployment testing been reported?) The reviewer has an even harder time with the inclusion of rabies, which is generally not considered a chronic infection in humans and for which even the longest recorded incubation periods have already been exceeded.

The phrase "Gulf War illnesses" is undefined. Throughout the text this term is sometimes used to refer to any and all illnesses suffered by Gulf War veterans, but there are other instances when it seems to be referring to the undiagnosed illnesses or unexplained physical symptoms afflicting some veterans. Because relatively few of the diagnosed ailments of Gulf War veterans have been clearly attributed to their service in the Gulf, and because the same situation applies for undiagnosed illnesses, the preferred way to refer to the totality of the veterans' ailments is "illnesses among Gulf War veterans." (OSAGWI)

All use of the phrase "Gulf War illnesses" should be replaced with "illnesses among Gulf War veterans." The authors themselves make note of this distinction in the summary when they cite an early study by the Centers for Disease Control and Prevention, which found that "the illnesses defined were not unique to service in the Persian Gulf War." This has been noted in previous reviews of similar RAND documents, and the distinction should be communicated to all RAND document authors. It is a subtle but very important decision. (HA)

Throughout the document, referenced literature should be cited so that accuracy and interpretation can be verified. In the summary, the authors cite an "early study by the Centers for Disease Control." Are they referencing the Iowa study or the Air Force study? In addition, these studies are certainly not the only studies to find that veterans suffer symptoms and illnesses common to both the general population and veterans of prior conflicts. A more general, more appropriate, and referenced statement for this summary conclusion would be "Veterans of previous wars reported similar physical (somatic) symptoms as are now being reported by Gulf War veterans, particularly: fatigue, headache, sleep problems, and concentration and memory difficulties. These symptoms are also reported frequently in all adult populations, especially among individuals who are under physiological stress or have undergone a traumatic experience. None of the infectious diseases that troops encountered during this wartime deployment are likely causes of chronic health problems. In health registry examinations and an epidemiological study of Gulf War veterans conducted by the U. S. Centers for Disease Control and Prevention, no indication was found of an infectious etiology for chronic somatic symptoms [1 – 4]."

1. Joseph SC, Blanck R, Gackstetter G, et. al. A Comprehensive Clinical Evaluation of 20,000 Gulf War veterans. Mil Med 1997; 162:149-155.

2. Goss Gilroy Inc. Canadian Epidemiological Study of Gulf War Veterans. June 1998.

3. Coker, WJ, Bhatt BM, Blatchley NF, Graham JH. Clinical findings from the first 1000 Gulf War veterans in the Ministry of Defence's Medical Assessment Programme. BMJ 1999; 318:290-294.

4. Fukuda K, Nisenbaum R, Stewart G, et. al. Chronic multisymptom illness affecting Air Force veterans of the Gulf War. JAMA 1998; 280:981-988.

In summary, the authors make the statement that "we cannot entirely rule out some unknown infectious disease as a possible cause of illnesses for some individuals."

While this may be true, it is reflective of our overall inability to prove the negative and is an inappropriate statement for a literature review. (HA)

Summary sections after each disease are not necessary and should be removed. Enough information is included in each section so as not to be overly burdensome that a summary is not required. (DHHS)

The statement that no direct evidence refutes the hypothesis that mycoplasma contamination of the anthrax vaccine occurred, although correct in face, should be qualified with the available data that suggest otherwise. Studies including the CDC study found no association between the chronic multisymptom illness and risk factors specific to combat in the Gulf War (month or season of deployment, duration of deployment, duties in the Gulf War, direct participation in combat, or locality of Gulf War service). Many similar findings have been published, including findings from the Canadian studies. (HA)

The discussions of non-mycoplasma infectious diseases are flawed by:

a. Excessively long dissertations on the minutiae of clinical presentations, laboratory abnormalities, pathophysiology, and therapy which are not directly germane to the questions of whether or not unexplained illnesses in Gulf War veterans could be due to chronic manifestations of the infections in question. When these aspects of the infections are relevant, they certainly could be condensed, focusing on the features that are directly applicable to the question of interest.

b. As noted in the specific comments, some of the assertions in these sections are incorrect, illogical, scientifically imprecise, or vague to the point of incomprehensibility.

c. Most of the graphs do not materially add to the discussions for they do not support either arguments or conclusions about the question at hand.

d. No mention is made of the vaccines or prophylactic drugs that were administered to personnel going to the Gulf region.

e. Reference is made to the "findings" in Gulf War veterans in a context that implies that the veterans of interest are those with unexplained physical symptoms. Such patients are presumed to be without physical findings, so perhaps "symptoms" should be used instead.

f. The promised section on rickettsial disease has not been written.

g. The risk factors for Hepatitis C have some definite differences from those for Hepatitis B.

h. The repetition of paragraphs and tables in the hepatitis section belies the assertion that this draft has been carefully reviewed prior to submission for external review.

i. The repeated assertion that the spring and summer seasons were over before U. S. troops deployed to the Gulf is simply erroneous.

j. The fundamental errors scattered throughout this section indicate that this paper has not had the benefit of a knowledgeable infectious disease physician in either its writing or in the review process, which has allegedly already taken place.

The figures and tables (most of which did not appear in the first draft) appear haphazardly chosen for inclusion (Did someone tell the author to spruce up this paper with some pictures?). Some examples:

- The two maps of the Rift Valley fever (RVF) outbreaks (pages 82 and 83) are of Africa and therefore don't include the major areas of operation in the Gulf War. Presumably the connections are proximity to the Gulf, earlier spread of RVF within Africa to Egypt, availability of appropriate vectors in Southwest Asia, and concern that the disease may be seen there, but the authors don't cite this literature or make these connections.
- There are photomicrographs of giardia and entamoeba (pages 115 and 120), but none of the many other microorganisms mentioned, and one "life cycle" diagram (page 119) (obligatory fare for most parasites in infectious disease and tropical medicine textbooks, but hardly important here)
- The maps and tables of specific diseases and vectors often cover period long before or after the Gulf War. Some provide data from the United States only (OSAGWI)

The authors fail to make note in the document of the reason for the exceptionally low morbidity and mortality from infectious diseases. The below text and references should be inserted:

"Based on very high morbidity rates in the Arabian Gulf during World War II (WWII), coalition troops were expected to be at an increased risk of sandfly fever, malaria, diarrheal disease, and cutaneous leishmaniasis [1]. To monitor these infections, the U. S. military established a diagnostic laboratory in Saudi Arabia, which collected extensive surveillance data [2]. A combination of factors was probably responsible for very low rates of serious infectious disease [3]. For one, rapid medical care was available for acute diarrheal and respiratory infections, which reduced morbidity. In addition, extensive preventive medicine efforts – vaccinations, immune serum globulin for hepatitis A prophylaxis, use of insect repellents, camp hygiene, and monitoring of food and water supplies – contributed to reduce transmission of infectious diseases.

"Two chance factors may have played an even greater role in reducing infectious disease morbidity: the time of the year when most troops were deployed (the cooler winter months) and the location of the deployment (the barren desert) [2, 3]. Cold weather reduced the risk of insect-borne diseases at the height of the buildup, as did deployment of most troops away from areas where

arthropod vectors and mammal hosts are more plentiful. In comparison, WWII troops were stationed throughout the year and were more likely to be camped in oases, riverine areas of southern Iraq, and urban locations where infectious diseases are of greater threat [1]."

1. Quin NE. The impact of diseases on military operations in the Persian Gulf. Mil Med 1982; 147:728-734.

2. GulfLINK.osd.mil Medical Surveillance during Operations Desert Shield/Desert Storm. November 6, 1997. http://www.gulflink.osd.mil/nfl.

3. Hyams KC, Hanson, K, Wignall FS, Escamilla J, Oldfield EC. The impact of infectious disease on the health of U. S. troops deployed to the Persian Gulf during Operations Desert Shield and Desert Storm. Clin Infect Dis 1995; 20:1497-1504. (HA)

The author fails to include the results of testing anthrax vaccine for the presence of mycoplasma and for the ability of anthrax vaccine to support the growth of mycoplasma introduced into vaccine vials. Because the dubious hypothesis that the vaccine might be contaminated with mycoplasma provokes much discussion in the text, it would be far more useful and informative to dismiss this hypothesis on the basis of experimental data. This testing was performed in 1999, so the authors should endeavor to obtain this late-breaking information. (OSAGWI)

The discussion about human herpesvirus 6 (HHV-6) appears to be founded solely on one reference, which happens to be a personal communication. The length of the discussion and the recommendation for testing for HHV-6 in everyone in treatment trials are not only completely unjustified by one personal communication, they fly in the face of what is known about HHV-6. Among the relevant facts that the authors neglect are the well-known documentation that antibodies to HHV-6 are present in about 80% of adults in the U. S. and that HHV-6 can often be isolated from the saliva and blood of healthy, seropositive individuals. As a herpes virus, HHV-6 can be expected to exhibit lifelong latency in healthy persons with this infection. (OSAGWI)

Several places throughout the report cite CDC as the source for determining which diseases are/were endemic in the area - for example, cholera on page 63. It may be useful if AFMIC products were used for determining disease endemicity/risk, as they are both comprehensive and current. Infectious Disease Risk Assessments are unclassified and posted on Intelink immediately after period update occurs. (AFMIC)

The report lacks conclusions and recommendations. (OSAGWI)

The report needs a "Glossary of Terms" section at the end for the "average" Internet reader or the report will lose credibility. If this report goes to the Internet, then some "big words" need to be replaced with "smaller words" throughout. The reviewer has suggested terms that need definitions and explanations. (CIA)

The paper is well written and fairly thorough. Most infectious diseases that are endemic in that area were discussed, but not all that may be applicable to the region. Q fever was not discussed in the report as a potential concern/cause of illness in Gulf War veterans – at least three military members were diagnosed with Q fever while/after

serving in the Persian Gulf area. Q fever is enzootic in the region and serological data from the late 1960s found antibodies in up to 70% of Saudis. Hepatitis E was mentioned in the report in only a couple of sentences as one of the causes of non-A/non-B hepatitis and not discussed in as much detail as hepatitis A/B/C were. Hepatitis E is endemic; seroprevalences of 8.4% to 14.9% were found in 1993. (AFMIC)

The reviewer strongly suggests that for future coordination, a more final draft that has previously received peer review by independent subject matter experts be provided, as tremendous staff time and effort is required providing multiple reviews of these draft documents in preparation of publication. (HA)

In summary, this paper appears to have been carelessly prepared and reviewed, as reflected in numerous scientific and editorial errors, omissions, and ambiguities in language. (OSAGWI)

EDITORIAL REACTION

The reviewer only read through page 62, but thinks that's more than enough. The reviewer cannot address the science of the paper, but editorially, it's a mess. There are moments of clarity – the first 15 pages are readable – but then it descends into the opacity of medical jargon and tortured, run-on prose:

- "Mycoplasma 'adhesins' have extensive sequence homology to mammalian structure proteins, and for decades it has been suggested that this mimicry may cause mycoplasma to provoke an anti-self response that triggers immune disorders. Mycoplasma adhesins exhibit sequence homologies with human CD4 and class II major histocompatibility complex lymphocyte proteins, which would generate autoreactive antibodies and trigger cell killing and immunosuppression. Mycoplasmas, through 'superantigens' for instance, may serve as B-cell and T-cell mitogens (substances that promote splitting or 'mitosis,' and cell transformation, of B- and T-type lymphocytes) and induce autoimmune disease through activation of T-cells directed against self, or polyclonal B-cells.[11, 50, 51] For instance, ***Mycoplasma arthritidis*** superantigen appears to induce a lymphkine profile that favors activation of B-cell function, which may heighten the risk of triggering autoimmune disease in rodents[52]. The multi-organ protean manifestations of mycoplasma infections in humans are considered by some to be consistent with pathogenesis of autoimmunity." (page 34 and 35)
  [Also, why the strange, non-sequential footnoting?]
- "If there is any merit to the hypothesis that cytokine shifts favoring a Th2 cytokine profile occur as a result of PGW exposures, as has been postulated, and if this results in heightened susceptibility to

intracellular infections including mycoplasma infections, then acquisition of mycoplasma infection could have occurred at a higher rate in PGW veterans than in controls long after the cytokine-shifting 'exposures' occurred in the PGW." (page 35 and 36)

Perhaps language like this makes sense to medical doctors, but the reviewer can't make anything of it, and the reviewer doesn't think the average veteran can either. The prose here is exclusionary, impenetrable, and mind numbing.

And sometimes, it's unintentionally funny:

- "Bacterial culture is the gold standard for diagnosis, although gram-negative diplococci can be seen with abundant infections on initial Gram's stain." (page 54)
- "The disease was first recognized over a decade ago during the Crimean War as causing 'Mediterranean gastric remittent fever." (page 56)

The reviewer could go on and on at the sentence and paragraph level: sentence fragments, different font types and sizes, subject-verb agreement, repetition, etc. At the macro-format level, the reviewer was bothered by the disconnect between the table of contents and the body of the paper: The page numbers listed in the table of content don't correspond with where things actually are in the body; there are many sub-sections in the body that do not appear in the table of contents, etc.

In short, this is not a readable, presentable paper. It should be returned to the author for a rigorous rewrite. (OSAGWI)

SPECIFIC COMMENTS

The reviewer didn't examine the document specifically for this purpose, so there are probably more errors like the ones mentioned below. It seems that many of these should ordinarily have been found by RAND editorial review and proofreading. The organization might have enlisted the services of a good infectious disease specialist (of which there are many near RAND's home office) to avoid some of the errors included in this paper. For example, there are mixtures of microorganism and disease names in the table of contents, section headings and tables (*Mycobacteria tuberculosis* should be *Mycobacterium tuberculosis*.). Also, the footnote numbers often do not agree with the references in the endnotes, nor the table of contents page numbers with the text, making review very difficult. (OSAGWI)

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RAND

A Review of the Scientific Literature as It Pertains to Gulf War Illnesses, Volume 1: Infectious Diseases

Lee H. Hilborne and

Beatrice Alexandra Golomb

MR-1018/1-OSD

June 2000

Prepared for the Office of the Secretary of Defense

National Defense Research Institute

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Special Briefing on the Anthrax Vaccine Program

NEWS TRANSCRIPT from the United States Department of Defense

DoD News Briefing
Dr. William Winkenwerder, Assistant Secretary of Defense for Health Affairs
Friday, June 28, 2002, 2 p.m. EDT

(Special briefing on the anthrax vaccine program. Also participating were William F. Raub, Ph.D., deputy director, Office of Public Health Preparedness, Department of Health and Human Services, and Navy Vice Adm. Gordon S. Holder, director for logistics, J-4, the Joint Staff.)

Winkenwerder: Good afternoon, ladies and gentlemen. I'm Dr. Bill Winkenwerder, assistant secretary of defense for health affairs. I'm pleased to be joined here with Adm. Gordon Holder, from the Office of the Joint Chiefs of Staff, and Dr. William Raub, Bill Raub, from the Department of Health and Human Services.

I'm here to announce the department's resumption of our anthrax vaccine program, and the coordinated efforts of the Department of Defense, the Department of Health and Human Services and other federal agencies for the stockpiling of both antibiotics and FDA-approved anthrax vaccine for civilians.

I'd like to briefly review the principal elements that informed our decision. First, the health and safety of our men and women

in uniform is our top concern. We have a responsibility for them from illness and injury.

Second, we continue to believe that the threat of anthrax being used against our armed forces is very real. Anthrax is highly lethal and it's easily stored. We know that potential adversaries do possess it.

Third, we have a vaccine that protects against anthrax exposure. The vaccine is safe and effective. The Food and Drug Administration approved the vaccine for use and the FDA certified the manufacturing facility that produces the vaccine. After a comprehensive independent study, the National Academies of Science's Institute of Medicine fully endorsed the safety and effectiveness of the vaccine just a few months ago in March.

Finally, we recognize that there is a domestic need for access to the vaccine. In collaboration with the Department of Health and Human Services and in coordination with the Office of Homeland Security, we are reserving a portion of the anthrax vaccine for stockpiling for the Department of Health and Human Services to use in the event of a domestic emergency.

In balancing the military requirements and domestic needs, our policy will be to vaccinate servicemembers, essential civilians and contractor personnel, who are assigned or deployed for more than 15 days in higher-threat areas of the world, whose performance is essential for certain mission-critical capabilities.

Again, our responsibility to our servicemembers is to do all we can to protect their health and safety. The anthrax vaccine offers an important layer of protection for them, in addition to antibiotics, and we begin -- we plan to begin our vaccination right away.

I would be happy, as well as my colleagues, to take any of your questions.

Q: How many people will be vaccinated, receive vaccinations under the program? And what are the -- what's considered a high-threat area?

Winkenwerder: With respect to the first question, we're not providing specific numbers. It will be a significant increase from the current number. As you may know, we have continued to vaccinate a relative few number of people -- special mission forces, et cetera -- and so that number will be increased. But we're not identifying just who those forces are and how many. You might surmise certain areas of the world might pose a greater threat, and it will be in those areas.

Q: You're not going to identify the areas, though?

Winkenwerder: No, we're not.

Yes?

Q: Can you say what portion of the supply will be set aside for civilian use?

Winkenwerder: Right now we anticipate roughly half. Now that

could change, depending upon changing threat conditions. But a significant portion is being reserved and set aside for stockpiling use, for the Department of Health and Human Services and for other federal departments.

Q: What sort of -- what is the rate of delivery of doses of vaccine now that the plant in Michigan has been served by -- I presume it's up and running.

Winkenwerder: That's correct.

Q: Is it operating at maximum capacity? And if so, how many doses does it give you a month or whatever --

Winkenwerder: The BioPort manufacturing facility was licensed by the FDA and received a -- I think the vernacular would be "good manufacturing approval" -- back in -- around the 1st of February. And they soon thereafter began a production cycle, and they're producing hundreds of thousands of doses on roughly a monthly basis. So it's into the millions of doses that will be produced over the coming years.

Q: Now the Pentagon's vaccination program had to be cut back because of a shortage of vaccine. Now that you have this influx of new vaccine, are you going to be able to go back to the original plans that the Pentagon had for vaccinating -- eventually vaccinating everybody in the military? Or, because some of this has to be set aside, are you going to have to cut back some of those --

Winkenwerder: Well, this is a shift from our earlier policy, which was to vaccinate everyone, a total force vaccination policy. So, this is a policy that's focused on those in higher-threat areas. It does not intend to vaccinate everybody. We're committed to the goal of protecting everybody through antibiotics, protective clothing and equipment, intelligence, detectors and other medical countermeasures. But until conditions change, we'll continue on this track of focusing the use on higher-threat areas.

Q: One more question about the new -- is the new vaccine essentially the same as the old vaccine? Or is this new and improved?

Winkenwerder: It is the same vaccine. It's under what you might call a new-and-improved manufacturing process.

Q: Do you have even more confidence in this vaccine?

Winkenwerder: Well, I think it's fair to say that the FDA has given -- along with our assistance, worked with the BioPort company, and has given a very thorough review to them, under what I understand is a new and more rigorous manufacturing review process, and so, we're very confident in the quality of the manufactured product of BioPort.

Q: (inaudible) Will the vaccine you're going to be using just be the new BioPort production, or will you have to go back to the old lots and certify them?

Winkenwerder: We'll be using just the newly produced vaccine.

Q: Back on the -- ramp down the program. There were any number of servicemembers that only took a portion of the six-shot series. Do they have to start all over from the beginning? Can they pick it up from where they ended? If they're not in this group that you're talking about, will they even have to have the shots at all?

Winkenwerder: They'll be able to pick right back up where they left off. And this is something that -- this approach is something that's been reviewed and approved by the FDA. And so, they'll start back up as supplies become available for them to resume their vaccination series.

Q: Okay. If they're not in that group that's going to these high-threat areas, are they going to continue with the shot series?

Winkenwerder: They will. There may be a matter of timing of weeks or months before they restart, but they will eventually in order to comply with the FDA requirement that the vaccine be used to give six full doses. They would be picked back up with their schedule.

Q: When you -- I'm sorry, sir, when you first started this, the idea that there was a certain amount of time between each shot seemed to be important. I take it it's not anymore, then?

Winkenwerder: There is an approved schedule, which calls -- it's a six-shot series taken at day zero, if you will, the first day, two weeks, four weeks, six months, 12 months, and 18 months. It's a rather complex series, and so it's important to stay on that schedule if one can, obviously. But if one cannot, we've been given assurance that there is a level of immunity that's there that can be picked back up with the resumption of the series.

Yes?

Q: Is it your intention that people will get the full series of shots before they go into these high-risk areas? Or would you be sending them after one, two --

Winkenwerder: We would -- we have a possible intent to begin vaccinating 45 days in advance, so that they would get at least three doses.

Q: And also, did I understand you to say that not everybody going into these high-risk areas will get the shots, only those who are judged to be in critical jobs? So, I mean, you're saying to people that we're going to send you into a high-risk area, but we don't think you're as important as your fellow servicemember, so we're not getting you --

Winkenwerder: The likelihood is that most everybody, if not everybody, in that area would be vaccinated.

Q: Why the shift from the pre-policy of total force? I'm not clear on that. And then, if you could answer, sir, who in the

civilian world should be -- would be given access to these doses if there was a --

Winkenwerder: I think the shift was driven by a couple of factors. The first is that we are dealing in a constrained supply situation, one. And two, we now have the potential need for use of a vaccine in a domestic or civilian situation. And so, our approach seeks to balance both military and civilian needs.

Raub: On the question you asked, the current policy in the civilian side is to vaccinate the workers in laboratories, research laboratories and clinical laboratories who are working with bacillus anthracis, either as private research or as part of some testing activity. And we will continue that. The purpose of having a civilian stockpile that is consistent with the DoD force protection requirements is for a post-exposure situation. But were we to have a situation of an anthrax exposure, we would offer the combination of vaccination and antibiotics.

Q: I'm not -- why not administer the vaccine as they are in the military ahead of time to people who would be at high risk in the event of an anthrax incident? There already have been some anthrax incidents in which first responders have been in a situation where they could have potentially been exposed. Why isn't that population being looked at and being inoculated prophylactically?

Raub: The immediate policy is constrained by what has been the supply limitation. As the supply improves, especially if the joint efforts of the Department of Defense and HHS to develop a new anthrax vaccine that can produce some tissue culture, and therefore potentially in indefinitely large quantities, as that prospect becomes closer to reality, I think we will be obliged to revisit the question of whether some prophylactic administration of it to identify first responders would be appropriate policy. And we would do that in conjunction probably with the public health community, with the first responder community.

Q: Let me just -- you have a newer more improved version of anthrax vaccine in the works? Or being developed?

Raub: Yes. I, I -- underway now through a joint effort of the two departments initiated by work of Fort Detrick and built upon by the work of the National Institutes of Health, is an effort to develop a cell-culture-base vaccine based on recombinant technology. That would have the virtue of being able to produce almost indefinitely large quantities of vaccine in carefully controlled production methods and a very rapid flexible production system. It's in both of our interest to have that kind of capability as soon as we can achieve it.

Q: (Off mike) with fewer shots too, right?

Raub: Potentially fewer shots. Again --

Q: How far out would that -- (inaudible) --

Raub: Right now the research and development is in the advance

stage. The funding is in the budget for this year for that advanced development. Moreover the president's budget request for next fiscal year includes $250 million for the acquisition of the first lots of such vaccine on the presumption that the R&D this year will be successful. The hope in it, as always in new vaccine development, is to have something that can achieve protection with either fewer doses or fewer quantity, that will be consistently safe, and while we're optimistic about it, no-one -- (inaudible) -- until it's finished, and so right now it's in intense research and development effort with the hope of having a safe effective vaccine in larger quantity with more ready productions.

Q: (Inaudible) -- how you come up with the 50/50 -- (inaudible) -- if you have certain numbers of -- (inaudible) -- what the needs would be or --

Winkenwerder: We have attempted to do a lot of coordination -- we did a lot of coordination and discussion and attempted to model out what we thought the production would be over the next few years, under the -- with the current manufacture, and then looked at proposed requirements or needs from other departments, and then tried to balance that against what we thought our requirements and needs were. So it really was an integrated effort, and it came out --

Q: (Off mike) -- have a number of people that they --

Winkenwerder: A number of doses

Q: What -- I mean, do we know that?

Winkenwerder: Into the millions

Q: Millions?

Winkenwerder: On the domestic side.

Q: Because, as they said, there are like two million -- estimated two million first responders. Is that --

Winkenwerder: Well, you got to remember, again, it's six doses for one person. So even two or three or four million doesn't vaccinate that many people.

Raub: Yeah. I should add that the Centers for Disease Control and Prevention, one of our agencies, has funding in its budget to conduct some clinical trials of alternative shot schedules with the current anthrax vaccine, to develop the information base that might allow for either an accelerated administration or fewer doses. Again, that's in the early clinical trial stages, and for the moment, the six-dose regimen that Dr. Winkenwerder indicated still applies.

Q: Would the new vaccine go through the same trials and take -- you know, take the same length of time as a regular drug? And also, is there -- are there any procedures being put in place to track the health of the people who, you know, were given the vaccine?

Winkenwerder: (Off mike) -- the first question. I'll take --

Raub: Yes. Mm-hmm. Okay.

On the first question, the general answer is yes, that any new vaccine must meet the basic statutory and regulatory requirements for safety and efficacy that apply to any vaccine. In this particular instance, the Food and Drug Administration is prepared to give it the highest priority, because of the important military and civilian need for it.

Also, by the nature of this disease, we cannot knowingly expose individuals to anthrax to test the vaccine. So we are heavily dependent on looking at those measures within ethical constraints that will allow us to judge the safety and the efficacy of this vaccine, compared to the current vaccine. We will rely heavily upon animal models, and we have a new regulation issued by the Food and Drug Administration that creates a better defined path for the kind of evidence a sponsor would need with animal models in those instances where it's unethical to expose humans to the actual disease. So we're doing everything we can to anticipate this need and to accelerate the development, but nevertheless the vaccine will not be approved unless it is determined by all available knowledge to be safe and efficacious.

Winkenwerder: With respect to the second part of your question, I think, in terms of how we are following people, roughly 2.2 million doses, I believe, in total, have been distributed and provided, administered to service members. I believe over 550,000 individuals or so have received the vaccine, either in full or part of the series. And so we've built a fairly significant database that tells us something about any side-effect profile and so forth.

And I think it's fair to say that we really have enhanced our systems, medical recordkeeping, et cetera, to monitor any side effects and we have an office that's dedicated to doing that for every single individual. And I think the sum of what we've learned from that is the vaccine is safe and effective. It has a not-insignificant set of local reactions associated with it, but not different from things like typhoid vaccine of influenza or hepatitis-A; it's in that same range of side effects.

Yes, sir.

Q: Last fall when there were **the anthrax exposures, obviously antibiotics were given to lots of people. And I think a vaccine was offered, I think, to people, and is there any data back from that on the post-exposure use of that vaccine and whether that was significantly better than just having the antibiotics alone?**

Raub: Analogous to what Dr. Winkenwerder was saying, those individuals are being followed, those that chose to accept the vaccine at the time. It's too early whether there are significant differences, but we have -- the early information indicates that is was efficacious in the sense of complementing the antibiotics. And as we continue to gather that information and analyze it, it will help inform the policy as to how we would use this stockpile.

Q: Can I follow on that? Before the anthrax exposure, I think you had something like 450 servicemembers decline to take the inoculations. First, do you think there's -- you're going to have a little easier sell this time?

Winkenwerder: Yes.

Q: And second, Admiral, is there any benefit to inoculating everybody? Do you think that we should go back, sometime in the future when the quantities are back up, to inoculating everybody in the armed services?

Holder: The first answer to ensure the safety and health of our people, so administering the vaccine, as Dr. Winkenwerder has said, is our first goal, and then, ultimately, protecting our people with the best techniques available. So, in the future, if that means full vaccination, it may be that, or it may be that there's a better technique through technology that -- because this is not going to happen in thirty days.

Q: Going back to the potential side effects, as we've noted, a small number of military personnel refused to take the anthrax shots. An even smaller number than that believes that they have serious health problems as a result of the vaccine. What does the science tell us about whether or not there are truly serious -- potential for serious side effects from this vaccine, and will the program in any manner be voluntary?

Winkenwerder: I'll take the first -- actually, both parts of that. The program is mandatory for those for whom the policy applies.

With respect to the side effect profile, in serious side effects, the percentage really is quite small. In following all of those vaccines that have been administered and the people, we have no documented death that has occurred as a result of vaccination. Obviously, when you have that many vaccines given to that many people, the chance that someone might die within, you know, some period of time following a vaccination is just -- by chance is going to happen. Of course, if someone is having a reaction, you know, in that window, then the question is whether there was an association or not.

I think many of those questions are well addressed in this report from the Institute of Medicine. That really goes into great detail and has looked at the data. And their conclusion was that the serious side effects were really quite small. There are probably -- as with any vaccine, there probably are a very, very small number of people who may have what, you know, one would call as a serious reaction. And -- but -- and we intend to follow those people very closely, if they come in, and they'll be evaluated medically.

Q: Do you think there's an irrational fear among some people about this vaccine?

Winkenwerder: I think that we did not do the job that we needed to to fully educate people and inform them in the way that they need to be, and I think that had to be balanced against the risk

or perceived risk at that point in time. And I think that equation has changed.

Q: Would you get the vaccine, and have you --

Winkenwerder: Absolutely. I'd have no -- I wouldn't -- I don't -- have not had it, because I'm not covered under the policy. But I'd have no hesitation about taking it.

Q: **You're not** important enough to -- (soft laughter) --

Winkenwerder: (Chuckles.) Not deployable currently.

Yes, sir?

Q: Just to clarify a couple things, Mr. **Raub,** I think you **said one of the advantages of the new vaccine is that it can be produced indefinitely. That implies that there's some limit on what you can produce of the -- what's being done at BioPort. Can you tell us, is there a capacity there, or at some point are they going to be no longer able to produce vaccine, because they don't have the raw materials or -- can you clarify that?**

Raub: No, the issue is the nature of the production methods. Cell culture systems are comparatively easy to establish. They're comparatively easier to replicate. And so it's more of an efficiency and volume of production than any inherent other limitation.

Q: But then the other thing -- I was just trying to clarify that. I think I'm right, but just to be absolutely certain. If John Q Civilian out there hears about this and the vaccine has now been approved and he or she wants to go to their doctor and say, "You know, I'd like to get this anthrax vaccine," they're not going to be able to do that, right? The doctor's not going to be able to help them. Unless they're a first responder or --

Raub: It is not still available --

Q: It's not going to be available publicly?

Raub: That's correct.

Q: What are the side effects?

Winkenwerder: I'm sorry?

Q: What are the specific side effects?

Winkenwerder: Locally, swelling, and again this is not for everybody; it's a percentage. A little bit of erythema, redness, swelling, pain at the injection site. Sometimes people feel a little bit of what we call malaise or, you know, flu-like feeling. Those are the main side effects.

Yes?

Q: You said earlier that some servicemembers would be able to be sent over to a high-risk area without finishing the cycle. At what point does the vaccine become effective if you are going to

be sending people there and they only have two or three doses?

Winkenwerder: Well, there's evidence that a fairly significant level of immunity builds even after as few as three doses. That's the purpose of this study, is to validate that with certainty. So, we believe that a significant level of protection is achieved after three doses, but obviously the current FDA-approved regimen requires the full six doses. So, we want to get those first three doses before or as they're going into an area, and then continue their series after that.

Q: After they get back? Or while they're still on deployment, can they continue to --

Winkenwerder: Both. Both.

Q: Can you tell us a little bit about how you'll define the high-risk areas? For example, would someone on a ship offshore of a combat zone or high-risk area also be considered in the high-risk area? Or a pilot flying over -- missions over an area, would he or she be considered in the high-risk area? Or would it be just people on the ground?

Winkenwerder: People on the ground and people who were deployable ashore from ships, not people in airplanes.

Yes, sir?

Q: Could you just sketch a little bit more of the debate you folks had in reaching this decision? Was the decision not to inoculate everyone in the military based solely on quantity available, or was it partly a result of concerns about opposition within the military? Or are there other factors here that I'm not aware of?

Winkenwerder: It was a very good discussion, one that was well-informed by facts, and involved the military leadership, civilian leadership, science experts, et cetera. And I don't think that there was any one predominant factor. I think it was really all those factors, when one considers the supply constraint, is the principal factor operative here, and also the fact that if we want to make certain amounts available for potential domestic use, that's another important factor, and the way it's administered -- six series, having to take it over 18 months -- it was all of those factors played into the final decision.

Q: Was there a sense of it, perhaps, as supply came up -- and this is sort of a follow-up question to one asked already -- that as the supply came up, perhaps you did want to revisit at some point the idea of inoculating everyone?

Winkenwerder: I would leave you with the impression that this is certainly open to change as the situation, the threat situation, might change.

Yes?

Q: With regard to the production issue, one of the real reasons why you're in this mess is because the Pentagon, before you

came, depended on **BioPort,** an unproven company just getting into the area. What plans have there been, or are there, to establish an alternate source of supply, either a government-operated plant or going out to Pfizer or some of the big drug companies to take this on? ***As*** I **recall, last year you** put out a bid and nobody came to the show.

Winkenwerder: I'll take part of that and then I'll let Dr. Raub take part of that. I think the evidence that he's just indicated, in terms of this next generation, you let a request out and have gotten a -- I'll let you speak to it -- significant response from the private industry.

Raub: Yes.

Winkenwerder: And so we believe, from our discussions with private manufacturing -- vaccine manufacturing concerns, who represent, really, the bulk of the worldwide vaccine market across the board, that they're quite interested, actually, in coming forward to work on these vaccines, some of which, obviously, would not have the volume associated with them that, say for example, the flu vaccine or measles vaccine or something like that. But there is a great deal of interest and I think it's incumbent upon us to work together between Department of Defense and the Department of Health and Human Services to together define our requirement or what we think we might need, and to speak in a coordinated way, and that's what we're doing here and that's what we intend to do going forward on smallpox and other issues as well.

Q: What about a go-co [government-owned, contractor-operated], though, a specialized government plant -- there was thinking about that. Where's that thinking **at today?**

Winkenwerder: We believe that the private sector companies that, again, we've talked with, and that have approached us, as well as Health and Human Services, provide a ready set of great scientific assets that are ready to respond and that they can move relatively quickly, probably more quickly than the time it would take to build a large facility and hire the people and so forth. That quickest and best response is through working with the private sector. That's what happened with the smallpox vaccine and --

Raub: Yeah. In fact, I can add to that. The representatives of the vaccine industry consistently have said to us that if the government is clear that what it wants is scientifically and technically feasible, if it's clear in its requirements with respect to the volume, and if it provides some certainty that the monies are in fact in hand for that multi-year acquisition to be achieved, for them in turn to invest in it, then the industry will respond.

We've had the occasion to test that within the last year with respect to a new smallpox vaccine. So far, so good. This -- it was an excellent response, and we're moving along.

The money's in the budget this year that I mentioned, for the advanced development, and next year for -- if the Congress agrees, for the acquisition -- will be another test of that

prospect. And again, so far, so good.

So we're optimistic that the needs with respect to new smallpox vaccine and a new anthrax vaccine can indeed be met by this approach with the private sector.

Q: For the foreseeable future, BioPort is the production facility --

Raub: For anthrax vaccine. That's correct.

Winkenwerder: Correct.

Raub: They're the only --

Winkenwerder: The only licensed.

Raub: -- the only licensed manufacturer.

Q: I guess my point -- my question is, is there progress in trying to get alternate companies to pony -- to make this stuff? And you're saying that there's some interest right now, but they need to see more by way of dollars and --

Winkenwerder: BioPort holds the only license for the Anthrax Vaccine Adsorbed, the name of vaccine that we have right now. Are there other companies that are interested? Yes, they're interested in working with Health and Human Services, who will -- is and will take the lead on this new generation vaccine.

Raub: But they're interested in a different production method, one that uses the recombinant materials, rather than the whole organism.

Q: Have you come up with any -- did you provide any estimates on how many ***members*** of the military you expect to be vaccinated?

Winkenwerder: We didn't, and we don't intend to.

Q: Have you classified that --

Winkenwerder: We're just not sharing that right now. We think it's best to leave others guessing as who and how many.

Q: You think there's some sort of deterrent value in that?

Winkenwerder: Could be.

Staff: -- two more here, right here

Winkenwerder: Yes, sir?

Q: Yeah. We've learned today about a couple of -- we've got this one vaccine program. We've got the next generation vaccine program.

You refer at one point to other layers of things that you're doing. I know that there's been work at the department on point detectors for biological agents. Are there any other things -- other things that you want to tell us about? And are there, for

example, use of -- development of point detectors to be used in the civilian world as well as the military?

Winkenwerder: We're not prepared to talk about that at this time. But I would just say that, yes, there's a lot of talk and effort to evaluate those issues. And detection, and early detection, is a key element of an overall protection scheme. And so, there are others in the department specifically in the acquisition area -- the nuclear, chemical, biological program -- who are involved in the procurement and the purchase of that kind of equipment, but we work together closely. And they're working on those issues.

Q: Will the anthrax shot be recorded in the servicemember's shot records?

Winkenwerder: Yes, I believe it --

Q: (So they'll be aware that they're getting ?) --

Winkenwerder: Oh, yes. Yes.

Q: Just to follow up on a question here a moment ago. I think there's a common perception among people working in this building that the detectors have been placed on the perimeter here since September 11th to detect anthrax. Is that not accurate?

Winkenwerder: I'm not going to comment on that.

Q: All right. Thank you very much.

Winkenwerder: Thank you.

[Web version: http://www.defenselink.mil/news/Jun2002/t06292002_t0628ww.html]

(b)(6)
Deputy for Public Affairs and Outreach
Deployment Health Support Directorate
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Chief, Case Management Assignment Team
Deployment Health Support Directorate
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(b)(6)
06/03/2002 01:42 PM

To: (b)(6) @OSAGWI
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Subject: Qs

2b attachment please
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Subject: Qs

HVAC QUESTIONSAnswers14Mar02WithoutCh

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Question 1:
I appreciate both views of DoD and VA in respect to actions now being taken to protect troop health, and to ensure transitions of records and information from DoD and VA. Can you help us by forecasting how your improved systems will deal with veterans coming home from this new war?
Answer:
Both the DoD and VA healthcare systems will respond to veterans of the new war by addressing their health concerns as individuals. The key to recognizing there may be a problem is the use of the Post Deployment Clinical Practice Guideline by all DoD and VA healthcare providers when evaluating health concerns of these veterans and their families. The DoD and VA systems will be actively monitoring both our active duty members and our veterans for health issues. We are training our health care providers to specifically ask returning troops if they believe or are concerned that a medical problem may be related to a deployment. If there appears to be an increase in various symptoms or recognized illnesses researchers will have access to baseline medical information on individuals before and after their deployments and to environmental surveillance data from the theaters.

Question 2:
Ms. Embrey, Senator Reigle asserted that thousands of chemical alarms were sounded during Desert Storm, but the Defense Department maintained that every one was a false alarm—that our troops in fact were not exposed to dangerous chemical substances in Kuwait or Iraq. Many efforts to review the Gulf War referred back to those alarms and the Department's posture that chemicals were not involved. Is that the Department's current position in light of the health status of Gulf War veterans?
Answer:
After reviewing the relevant evidence, the Department of Defense has concluded that chemical alarms that alerted during Desert Shield/Desert Storm were likely to have been false alarms. The evidence can be summarized as follows. The M8A1 chemical alarms are capable of detecting only nerve agents and not blister agents. The M8A1 alarms begin to signal a warning at a concentration of nerve agent which can cause noticeable physical effects in people exposed to that concentration. That is why such alarms are positioned upwind of troops so that troops can don protective equipment before the nerve agent vapors reach them. There were no confirmed instances of nerve agent poisoning in any troops who were in the vicinity of chemical alarms that alerted. There were no definitive reports of confirmation of chemical nerve agent presence with more sensitive equipment. M8A1 alarms will sound in the presence of other, common, non-toxic substances and when their batteries need replacement. The Central Intelligence Agency assessed that Iraq did not use its chemical warfare agents against Coalition forces. The United Nations Special Commission on Iraq testified to the Presidential Advisory Committee that they found no evidence that Iraq moved chemical warfare agent munitions or bulk agents any farther south than Khamisiyah, Iraq, and our investigations support this conclusion. The Department of Defense does recognize that small numbers of special forces operating in Iraq may have possibly been exposed to chemical nerve agents during the allied bombings of a chemical warfare storage facility at Muhammadiyat during the Air Campaign. Over 100,000 US forces were possibly exposed to low levels of chemical nerve agent when US troops unknowingly destroyed rockets filled with sarin and cyclosarin at Khamisiyah, Iraq, in March 1991. There were no confirmed instances of nerve agent poisoning in any troops who were in the vicinity of Khamisiyah. In summary, there is no evidence that M8A1 chemical alarms were exposed to chemical agents in concentrations capable of setting them off. Given that premise, the explanation for the alarms sounding is that they were false alarms.

Question 3:
What actions have you taken to upgrade chemical alarms and develop biological alarms? Do the troops in Afghanistan now have access to better chemical alarms?
Answer:
Since the Gulf War, we have developed and fielded more sensitive chemical agent detectors which detect blister agent in addition to nerve agents. The policy remains to evaluate any chemical alarm with a more sensitive chemical detector to confirm if a chemical agent caused the initial alarm. These detectors are also less prone to the false alert problems that we experienced in the Gulf. We have also developed and fielded a biological detection and identification capability. In addition, doctrine and training has addressed and is still addressing the technological advances being made in detection to ensure commanders have the tools to accruately assess their current situation. Our forces in Afghanistan have access to the best equipment we have fielded consistent with the expected threat.

Question 4:
General Blanck's written statement reviews the issue of missing or non-existent records having hindered the Army's work in trying to discover the underlying causes for problems Gulf War troops were experiencing. Give me a bit of insight into what kinds of records DoD and VA would have needed to be able to capture information sufficient to address a cause and effect. In other words, what kinds of records were missing or non-existent?
Answer:
The Institute of Medicine, in its literature review of various substances to which Gulf War veterans were exposed, has stated that to determine cause and effect or even association, it is necessary to know the concentrations of airborne substances, duration of exposure and the amount inhaled. For things like drugs taken or vaccines received, it is necessary to know who, how often, how much and for how long. Examples of Gulf War records that do not exist include those described below. There were no centralized records kept of troops vaccinated with the anthrax vaccine or the botulinum toxoid vaccine. From the amount of vaccine taken to the theater, it is estimated about 150,000 US personnel received at least one anthrax vaccination and 8,000 US troops received the botulinum toxoid vaccine. In some instances, these vaccines were recorded on the yellow World Health Organization (WHO) immunization record carried by the individual. In some cases, recipients' names were recorded in log books indicating the vaccines they received. There was no plan in place to consolidate the contents of these log books after the war. There are no records of troops who took pyridostigmine bromide tablets as a pre-treatment for exposure to the nerve agent soman, nor are there records of the duration the drug was taken. From the amount of drug taken to the theater, it is estimated about 250,000 US forces took pyridostigmine bromide. Paper health care records for individuals were kept by the medical units responsible for their care However, if treatment was received at another unit, the individual health record was not available. Standard Forms 600 (Chronological Record of Care) documenting health care were often kept in a box at treatment facilities, but there was no plan for uniting them with the individual health record. Even if paper records of medications, vaccines, and health care were complete and were all placed in individual health records, such paper records are kept in hundreds (if not thousands) of clinics, units, and archives. This distributed storage of paper health records is an insurmountable obstacle to developing a consolidated record of persons with common characteristics, such as receipt of a particular vaccine, in order to study potential health effects. Overcoming this obstacle is one of the principal benefits anticipated from the fielding of automated medical records keeping systems with a central data repository.

Question 5:
Ms. Embrey, your statement placed a separation between what DoD is attempting to do for the active duty members and your references to veterans, whom you say would be, and I quote "best served" by scientific research to address their health concerns. All of your active duty members eventually become veterans, because veterans are "made" by military service, not "born" as veterans. Does the Department intend to continue to make such a distinction with respect to the current deployment in Central Asia, or do you acknowledge some responsibility within DoD for the health status of all veterans?
Answer:
In addition to providing active duty servicemembers care for illness and injury, DoD has direct responsibility for protecting their health. That responsibility for protection underlies the Department's long-standing commitment to safety, occupational health, health promotion, preventive medicine, and what is called force health protection. Each of these is aimed at minimizing the occurrence of preventable illness and injury. Such preventive efforts are crucial for the Department's goal of fielding a fit and healthy force in support of its mission to defend the country. One result is a veteran population whose health status has been affected as little as possible by their military service. This outcome is crucial, for the extent to which DoD protects the health of the men and women who volunteer for military service can affect the confidence of the American people in its military. DoD efforts must be guided by knowledge about the impact of military service on both active duty personnel and veterans. The latter group is best assessed through coordination with the VA on questions or concerns about service-connected health problems that occur in veterans after they leave active military service. There are many examples of DoD and VA cooperating on issues that are health related for those who are currently serving and for those who have previously served. The DoD - VA Millennium Cohort study will follow 140,000 servicemembers and chronicle their health status for 21 years to determine possible effects from military service in general and from deployments in particular. The VA centers to study war related illnesses and DoD's Deployment Health Centers share a common goal of better understanding health effects from military service. The DoD -VA Post Deployment Clinical Practice Guideline, which has DoD and VA healthcare providers asking patients if health concerns are believed to be related to a deployment, is an example of a unique concern about veterans' health that DoD and VA share.

Question 6:
Ms Embrey, you indicate the Department of Defense is, and I quote, "assessing and monitoring current deployments" for health care needs. What kinds of mechanisms is the Department using to carry out such assessment and monitoring?
Answer:
The implementation of Force Health Protection policies is done at the individual Service level. In the pre-deployment process, baselines for each individual's health are established by their periodic medical examination and validated prior to deployment with the pre-deployment medical assessment. Data are also generated on reasons personnel are found not to be qualified for deployment. During deployments, data from outpatient healthcare visits and inpatient hospitalizations are monitored for the possible need for preventive measures. Post deployment medical assessments document individual's health status when they return home. After that, the Post Deployment Clinical Practice Guideline being implemented by DoD and VA healthcare providers will monitor for trends of health issues for which veterans are seeking care.

Question 7:
Ms. Embrey, you testified about the Institute of Medicine's three-year study that made a series of recommendations to the Department on protecting the health of deployed U.S. forces. Can you tell us among the recommendations made, how many have been implemented and explain those that haven't been accepted and why?
Answer:
The IOM study contained six major strategies with 32 recommendations to protect the health of deployed forces. The Department of Defense concurs with these strategies and has created the position of Deputy Assistant Secretary of Defense for Force Health Protections and Readiness in the Office of the Assistant Secretary of Defense for Health Affairs. The Department has made significant progress with 20 recommendations to date and we continue to work to implement the remaining 12 where possible. Some recommendations, such as using Global Positioning System for unit and individual locations, will require considerable deliberation and analysis before a workable solution can be achieved. Several recommendations for a closer working relationship between the military intelligence communities and the declassified medical community will also require some effort for a solution. Recommendations to integrate risk communication into the medical and operational communities will first require a recognition of risk communication in all phases of training, probably to include training prior to entry into the military. An admirable recommendation of obtaining medical information from civilian healthcare providers caring for Reserve Component personnel will require major changes in the medical ethics and privacy regulations.

Question 8:
I am especially concerned about reserves and their status. As I said in my opening statement, I recently witnessed the deployment of a reserve unit in Kansas. These are civilians who are called up, coming from all walks of life. In terms of preparation, do members of activated reserves get the full platter of preventive training, health baseline examination, equipment and other facets of DoD policies? In other words, is there one standard applied to both the "professional" soldier and the activated reserve? How do you monitor the reserves to ensure this is so?
Answer:
Across the Department of Defense, there is a single standard of medical readiness that applies to the reserve component and active component alike. Preparation for mobilization is a constant in all unit and individual training. DoD recognizes that for some units, especially in the reserves, there may not be adequate personnel or training for medical and dental assessments, or preventive medicine and environmental surveillance. The FedsHeal program was instituted by DoD to utilize VA capacities to provide the medical and dental evaluations for reserve component personnel being activated. Active component activities such as the Army's Center for Health Promotion and Preventive Medicine work to provide support and training in preventive medicine and environmental surveillance whenever necessary. For deployments, reserve units are expected to receive the same pre-deployment disease threat and prevention training as active units. Topics would include individual hygiene and sanitation, vector control, unit sanitation, and food and water sanitation. Additional material would cover unique environmental threats and hazards associated with the area of operations. Monitoring of the reserve component medical readiness is done by unit commanders, by Reserve Affairs, and by Force Health Protection and Readiness in Health Affairs.

Question 9:
Low-level environmental hazards are generally difficult to detect. Is the Department developing technologies with chemical and biological sensors capable of detecting sub-lethal doses of chemical or biological agents? What is the state of development of such devices?
Answer:
The Department has had detectors capable of detecting sub-lethal doses of chemical warfare agents for over thirty years. We are currently developing detectors with greater sensitivities in the event on-going research reveals that even lower doses have a negative long term health effect.
Unlike detecting sub-lethal levels of chemical poisons, detection of biological agents means that an exposure to a disease-causing organism has occurred. Whether that exposure actually results in disease depends on a number of factors: virulence, availability of vaccines, etc. Some are more virulent than others. We can detect and identify most of the biological agents we feel constitute the threat. We do not have preventive measures, such as vaccines, for all biological agents that could potentially be used as weapons or an unintended exposure

Question 10:
Can you confirm for the Committee that DoD has developed better operational tracking systems for personnel and units so that the costly effort of trying to learn where people were located after we discover a problem — such as an exposure to chemical weapons — can be reduced and we can better identify who may be at risk? Would you call this a lesson learned from the Gulf War?
Answer:
The need to improve tracking and archiving of individual assignment and unit location data was a key lesson of the Gulf War. To track individuals and units on the fluid battlefield remains a challengefor the Department. Generally, one must associate individuals with units (a personnel function) and units with locations (an operations function). Since the Gulf War, the Department has enhanced the ease and accuracy of both types of tracking. The Services and joint commands regularly forward individual assignment and unit location data to the Defense Manpower Data Center (DMDC) in Monterey, CA, where it is archived indefinitely. We continue to take action to insure programs like Personnel Tempo (Pers-Tempo), Joint Personnel Asset Visibility (JPAV), and Defense Integrated Military Human Resources System (DIMHRS) will further refine the space and time resolution, accuracy, and accessibility of personnel and unit tracking information. Tracking systems for personnel and units is a lesson from the Gulf War which DoD is working hard to make a "lesson learned." Unit locations are an operational database and data are maintained at the company level, a significant improvement since the Gulf War. DoD is working to integrate the operational database for unit locations with the personnel database for individual assignments and the healthcare database to create a system that can be shared with the VA for care of veterans years after their deployments.

Question 11:
What other lessons did we learn from the Gulf War that we are now putting to use in Operation Enduring Freedom? Can you give me specific examples of something identified then as an error or commission that is now implemented and is specifically addressed in the current deployment?
Answer:
A very important lesson was that we need to listen to the veterans. This has led to the cooperative DoD -VA development of the Post Deployment Clinical Practice Guideline. DoD and VA healthcare providers will be asking veterans and their families seeking care if they believe their health concerns may be related to a deployment. We also have information for veterans and their families on DoD Websites such as GulfLINK, DeploymentLINK, and the Anthrax Vaccine Immunization Program, as well as an 800 hot-line for people to call with concerns or problems. The creation of the U.S. Army Center for Health Promotion and Preventive Medicine provides environmental surveillance data to identify hazardous sites in the theater. All personnel receive awareness training on depleted uranium and training on chemical warfare agent detectors, which includes their limitations and the importance of informing troops about alarms that are not confirmed with more sensitive testing. Healthcare systems in the theater are reporting weekly on rates of diseases and injuries and the Defense Medical Surveillance System serves as the repository and does analysis for trends.

Question 12:
Will we able to know where every uniformed DOD member has served on the ground during Enduring Freedom? In other words, should we identify a disease or illness after the fact associated with particular areas, in Kandahar or Tora Bora for example, will we be able to overlay troop movements to determine the individuals who may have been exposed? What is the mechanism DoD is using to do such tracking, and will you be able to transfer this data to VA for VA's use in providing health care, conducting biomedical research and for benefits purposes?
Answer:
It is impossible to track every servicemember's exact location during a deployoment due to the nature of the operation. For example, Special Forces Units work in small, highly mobile units with classified locations. Using technologies such as Global Positioning Systems (GPS) is not an option because of the risk of mission compromise. Unit locations are an operational database and data are maintainedat the company level, a significant improvement since the Gulf War. DoD is working to integrate the operational database for unit locations with the personnel database for individual assignments and the healthcare database to create a system that can be shared with the VA for care of veterans years after their deployments.

Question 13:
The Committee understands that the Office of the Special Assistant for Gulf War Illnesses has spent in excess of $130 million over the past five years on publishing "case narratives" and "literature reviews?" Are these activities subjected to scientific peer review?
Answer:
Much of the information for The Office of the Special Assistant for Gulf War Illnesses case narratives, environmental reports and information papers came from interviews with Gulf War veterans who provided their first-hand accounts of what they encountered during the war. Through the use of an 800 hot-line call center, over 21,500 veterans have contributed their first-hand accounts of service in the Gulf. Using public forums – "town hall meetings" – outreaches were conducted in 13 major metropolitan areas so that we could obtain veteran feedback. In order to ensure that the active duty, National Guard, Reserves, military health care providers and family members received information on Gulf War issues and provided their experiences, total force outreach programs were conducted at 96 military installations and their surrounding communities, worldwide. Additionally, briefing teams provided exhibits at 81 conferences hosted by veterans, service organizations, military support offices, and health organization associations. Since outreach began in 1997, these programs provided the Office of Special Assistant for Gulf War Illnesses the opportunity to reach out to more than 70 thousand active duty military personnel, reserve component members, veterans, family members, military health care providers, and the general public. The 800 hot-line number remains available for servicemembers and their families to call and get instant feedback to their first-hand reports, questions and concerns.
From November 1996 to October 2001, DoD has obligated $148 million through the Office of the Special Assistant for Gulf War Illnesses. The purpose of that office was to listen to the concerns of Gulf War veterans about why some believed they were ill, toensure those with health problems had the access to healthcare they deserved, and to investigate what Gulf War veterans were reporting as suspected chemical or biological events during the Gulf War.
Some $35 million was spent going across the country and listening to Gulf War veterans, interviewing Gulf War veterans and telling Gulf War veterans what was being done to find answers as to why some were ill.
Some $500K was spent coordinating with coalition countries' military and civilian medical personnel to evaluate if their Gulf War veterans were experiencing health problems similar to those of our veterans.
Some $15 million was spent identifying and declassifying medically relevant documents from the Gulf War to fully explain incidents that veterans believed may have been biological or chemical exposures.
Some $64 million was spent on the investigation of these incidents and on the analysis of the data to produce the interim case narratives, environmental exposure reports and information papers. The peer review of these products was done by the Gulf War veterans, both those involved with the incidents and others who were in the theater. Their comments, questions, concerns and additional information were used to create the final reports. These interim and final reports are present on our Website GulfLINK, which continues to get over 200,000 hits per week.
Some $4 million was spent on the medical literature reviews done by the RAND Corporation. The 11 subjects that were addressed reflected the concerns of Gulf War veterans about various exposures they believed could possibly be related to subsequent symptoms. These literature

reviews are a RAND product and were peer reviewed through the usual RAND process. The Office of the Special Assistant did review these RAND products for factual accuracy of events that occurred in the Gulf War.

Some $3.5 million was spent in response to questions and concerns raised by organizations responsible for oversight of the work of the Office of the Special Assistant. These included the Presidential Advisory Committee, the Presidential Special Oversight Board, the GAO, the Senate Investigative Unit, the House Veterans Affairs Committee, and the SenateVeterans Affairs Committee.

Finally, some $26 million was spent on office space and administrative support.

Question 14:
How much funding has DoD expended for Gulf-related medical research over the past five years? Can you point to anything you learned from either the case narratives, reviews or research that has been put to use for the troops in the field today, particularly for those in Afghanistan?
Answer:
DoD has been a partner with VA and HHS on Gulf War-related medical research since The DoD commitment of over $120 million has resulted in evaluations of two major treatment programs, which have documented the increased rate of medically undiagnosed symptoms in Gulf War veterans, determined that birth defect rates are not higher in Gulf War veterans' children, and led to better health monitoring for current deployments and a Post Deployment Clinical Practice Guideline for DoD and VA healthcare providers. The DoD-VA Millennium Cohort study is evaluating 140,000 active duty personnel, some deployed today, for the next 21 years to monitor their health. The DoD Birth Defects Registry is actively monitoring all births to military personnel. Appropriate training on the health risks of depleted uranium is being given to all servicemembers, and techicians for chemical warfare agent detectors are better trained in the limitations of their equipment and the importance of notifying troops of the results of test confirmation with more sensitive equipment whenever there is an alarm.

Question 15:
The Senate Committee on Veterans' Affairs made a significant investigation in researching the possible causes of Gulf War veterans' health problems. That effort was thoroughly documented in a 1998 report. Among its finding were failures on the part of the Department of Defense to protect troops we sent to the Gulf. Specifically cited were failures in issuing proper equipment, training, vaccinations, documentation and record keeping. The report included 29 important recommendations in all, most directed at DoD and VA. How many of these recommendations have been implemented, and do you believe these recommendations helped DoD and VA learn some of the lessons of the Gulf War? How so? (Is this part of the answer?)Answer:
The Senate Committee on Veterans' Affairs report was a comprehensive review and affirmation of issues which surfaced from many sources. This helpful compendium had 29 recommendations, with 11 applying to DoD, 6 applying to DoD and VA, 11 applying to VA and 1 applying to Congress. Six of the recommendations to DoD have been implemented, two deal with the military intelligence community and there is some progress(can this be said better?), two deal with HHS developing technology or information that is not yet ready for military mission use, and one deals with a tracking system that has not been approved. All six of the DoD/VA recommendations have been implemented. The VA-managed depleted uranium medical follow-up program at the Baltimore VA has been expanded to over 60 individuals involved with friendly fire. Urine testing is available to any veteran with a concern about possible depleted uranium exposure. No adverse depleted uranium health effects have been identified in any veteran to date. In general, the recommendations helped to focus DoD efforts on what were agreed to be the more significant issues from the Gulf War.
How have these recommendation helped?

Question 16:
As you are probably aware, patient advocates are often included as voting members on peer-review panels within NIH-funded programs. Given that fact, why are veteran advocates excluded from representation on the Research Working Group, the body responsible for deciding which Gulf War illnesses studies will or will not be funded? What is your justification for excluding advocates from this body?
Answer:
The Federal Advisory Committee Act allows government departments to create civilian advisory panels to provide input from advocates on specific issues or broad topics. The secretary of Veterans Affairs has created such an advisory panel to provide input on research on medical research on the symptoms and illnesses seen in Gulf War veterans. This advisory panel under the sponsorship of the VA is charged to review and comment on the recommendations of the Research Working Group, which is staffed by members of three governmental departments; Defense, Veterans Affairs, and Health and Human Services. This oversight is similar to the review process in place at the National Institute of Health in regard to medical research. However, current Federal law reserves the authority of the Research Working Group to obligate funds for research to be solely by government representatives.

Question 17:
Recent media reports indicate that a new, as-yet unpublished study concerning the anthrax vaccine shows, for women, an association between anthrax inoculation and an increase in risk for birth defects. Are you aware of this study and what is the Department planning to do with respect to women active duty members and the anthrax vaccines? Are you coordinating your work with VA, and how so?

Answer: DoD is aware of this work, done by researchers from the Naval Health Research Center. The work is preliminary. Review of these preliminary data indicated important limitations in computerized medical records that underlay the data analyzed in this study. Investigators are conducting a systematic evaluation of original medical records, including vaccination and infant health records. This evaluation will require several months. In the interim, the DoD has reinforced its existing policy to avoid immunization of pregnant women. The VA is already aware of this information and action.

The outcome of the above review is not relevant to the process of seeking waivers from the FDA for investigational new drugs (IND). The anthrax vaccine is not an investigational product. The process by which DoD might seek waivers from the FDA for military use of IND is well spelled out in law (Section 1107 of title 10, United States Code), presidential executive order 13139, and Department of Defense Directive 6200.2. Both DoD and the FDA would consider the available evidence about safety and efficacy of any IND product for which it would consider requesting a waiver.

Question 18:
Section 765 of the 1998 National Defense Authorization Act (PL 105-85) requires the Defense Department to conduct pre-and post-deployment health examinations including mental health screenings and blood sample to record the baseline health of each active duty member before deployment and any changes in health during the course of deployment. Are they being done and can you provide the Subcommittee evidence to confirm this is the policy?

Answer: The Assistant Secretary of Defense for Health Affairs Policy of October 6, 1998, established the requirement for pre- and post-deployment health assessments and blood samples. The value of these assessments is not to record the medical condition of members but, rather, to ensure that their medical condition is checked before they deploy and as they return. If there is an indication of a medical problem, then the full and accurate documentation of that medical problem and its management employs the usual systems of inpatient and outpatient treatment records. The forms which document the performance of the pre- and post-deployment assessments are sent to the Defense Medical Surveillance System at the U.S. Army Center for Health Promotion and Preventive Medicine. These assessments complement the rigorous physical examination required for entry into the military, the periodic physical examinations, the annual dental screenings, and the annual medical record check for updating routine vaccinations for all military personnel. Coupled with the immediate access to military healthcare providers for all military personnel, these routine evaluations assure that those serving in today's military are fit and healthy. While this office believes that the percentage of servicemembers completing pre-deployment health assessments is significantly higher than for the early days of the Bosnia deployment, actual figures are not yet available for a more precise answer. The paper forms have not yet been incorporated into a computer database.

Question 19:
What role has VA played in helping DoD develop appropriate pre-and post-deployment health survey instruments and testing procedures to be used by DoD?
Answer:
The VA partnered with DoD in the development of the Post Deployment Clinical Practice Guideline for use by DoD and VA healthcare providers when evaluating health concerns of service members, veterans, and their families.
DoD formulatedthe pre- and post-deployment health assessments through several versions. These questionnaires are designed to identify outstanding health problems just before and after deployment. This type of screening is essential to ensure that troops are healthy before being sent on deployment and to identify troops who should receive health care immediately on their return.
The Clinical Practice Guidelines establish standard criteria to be used by both departments when conducting physical evaluations of veterans for illnesses and injuries attributed to active service.

Question 20:
Ms. Embrey, despite the difficulties with the vaccination program in the Persian Gulf War, the Department's vaccination protocol is of interest to the Committee. Please provide a copy of this protocol; the current official protocol for vaccinations applicable to the forces being deployed in Central Asia; and, the vaccinations protocol for troops now deployed in the Philippines operation.
Answer:
DoD's basic policy for vaccinations is in the DoDI 6205.2 - Immunizations Requirements, which was signed in 1986. Updates to this instruction have been for specific vaccines like hepatitis A and B, anthrax and influenza. A recent Chairman of the Joint Chiefs of Staff Memorandum MCM-0006-02, effective March 1, 2002, provides standardized procedures for assessing health readiness and conducting health surveillance in support of all military deployments. This instruction requires the combatant command to determine the need for deployment-specific medical countermeasures, including immunizations, chemoprophylactic medications and other individual personal protective measures. Attached are the CENTCOM and PACOM instructions for immunizations for travel to its area of operations.

Question 21:
Ms. Embrey, you stated DoD has implemented 12 policy changes, based on lessons learned following the Gulf War, to improve the delivery of health care to our active duty personnel. What are those policies and how has their implementation changed the pre and post-deployment health assessment protocol? Is DoD better informed to quickly identified health hazards and to forward that information to the Department of Veterans Affairs? Please provide the Committee each of the 12 directives or other documentation establishing these new post-Persian Gulf War force protection polices.
Answer:
A list of the twelve policies and directives is attached. Copies of the documents are also enclosed. A thirteenth, a recent update of the Joint Staff Memorandum on Deployment Health Surveillance and Readiness, is also enclosed.
DoDD 6490.2, DoDI 6490.3, the Joint Staff Memoranda on Deployment Health Surveillance and Readiness, and the ASD Health Affairs Policy for Pre- and Post-Deployment Health Assessment and Blood Samples all describe the pre- and post-deployment procedure and forms to be used. The implementation of these assessments gives all deploying servicemembers an opportunity to declare their health concerns or problems that require attention. The objectives are to verify deployability of individuals, provide prompt health interventions they may require, and track changes in their health status possibly due to exposures and experiences during deployment. DoDD 6490.2, DoDI 6490.3, and the Joint Staff Memoranda on Deployment Health Surveillance and Readiness spell out the steps (called environmental surveillance) in identifying and documenting the occurrence of possible health hazards in the environment where troops' are deployed. When significant exposures are identified and documented in troops health records, that information will be provided to the VA in the servicemembers' health records when they leave military service.

Major DoD FHP Policies

Policy Name/Number	Title	Date
DoD Directive 6490.2	Joint Medical Surveillance	30-Aug-97
DoD Instruction 6490.3	Implementation and Application of Joint Medical Surveillance for Deployments	7-Aug-97
Joint Staff Memorandum MCM-251-98	Deployment Health Surveillance and Readiness	4-Dec-98
Joint Staff Memorandum MCM-0006-02	Updated Procedures for Deployment Health Surveillance and Readiness	1-Feb-02
ASD Health Affairs Policy	Policy for Pre- and Post-Deployment Health Assessment and Blood Samples	6-Oct-98
DoD Directive 4715.1	Environmental Security	24-Feb-96
DoD Directive 6490.5	Combat Stress Control Programs	23-Feb-99
DoD Directive 6205.3	DoD Immunization Program for Biological Warfare Defense	26-Nov-93
DoD Instruction 6055.1	DoD Safety and Occupational Health Program	19-Aug-98
ASD Health Affairs Policy	Policy for National Surveillance for Birth Defects Among Department of Defense Health Care Beneficiaries	17-Nov-98
ASD Health Affairs Policy	Establishment of DoD Centers for Deployment Health	30-Sep-99
DoD Directive 6200.2	Use of Investigational New Drugs for Force Health Protection	1-Aug-00
ASD Health Affairs Policy	Implementation of Post-Deployment Health Clinical Practice Guideline [URL unavailable]	7-Dec-00

House Committee on Veterans Affairs
Health Subcommittee
Questions to the VA
(POA: Craig Hyams)

Question 1:
The Senate Committee on Veterans' Affairs made a significant investigation in researching the possible causes of Gulf War veterans' health problems. That effort was thoroughly documented in a 1998 report. Among its findings were failures on the part of the Department of Defense to protect troops we sent to the Gulf. Specifically cited were failures in issuing proper equipment, training, vaccinations, documentation and records keeping. The report included 29 important recommendations in all, most directed at DoD and Va. How many of these recommendations have been implemented, and do you believe these recommendations helped VA learn some of the lessons of the Gulf War? Please enumerate the lessons.
Answer:
The Senate Committee on Veterans' Affairs report had 29 recommendations, with 11 applying to DoD, 6 applying to DoD and VA, 11 applying to VA and 1 applying to Congress. Six of the recommendations to DoD have been implemented, two deal with the military intelligence community and there is some progress along those recommended lines, two deal with HHS developing technology or information that is not yet ready for military mission use, and one deals with a tracking system that has not been approved. All six of the DoD/VA recommendations have been implemented. The VA-managed depleted uranium medical follow-up program at the Baltimore VA has been expanded to over 60 individuals involved with friendly fire. Urine testing is available to any veteran with a concern about possible depleted uranium exposure. No adverse depleted uranium health effects have been identified in any veteran to date.

Question 2:
At this point, do you expect DoD to provide VA any health-related data concerning troops now serving in Afghanistan? What kind of data are expected, if any? Is VA aware of the mechanism(s) DoD may be using to track troop health, and will you be able to employ any such data for VA use in providing health care, conducting research or in making benefits decisions? Please expand on your answers.

Answer:
The Department routinely cooperates with the VA to provide data on servicemembers necessary to meet the VA's needs.
DoD will provide to the VA any and all relevant information from its records to aid in the VA's delivery of health care and in making benefits decisions for troops exiting the military after service in Afghanistan. Expected data include service health records. Possible data include the findings from environmental surveillance, document exposure to substances with possible health effects. Although some data might prove useful in generating research hypotheses, the purposes of collecting health data during a deployment do not include research.

Question 3:
What role has VA played in helping DoD developed appropriate pre- and post-deployment health survey instruments and testing procedures to be used by DoD? Will the results obtained through these instruments be made available to VA?

Answer:
VA has been involved in the formulation of the pre- and post-deployment health survey instruments. These questionnaires are designed to identify outstanding health problems just before and after a hazardous deployment. This type of screening is essential to ensure that troops are healthy before being sent on a dangerous deployment and to identify troops who should receive health care immediately on their return. These screening questionnaires are not designed to collect comprehensive health data. VA assumes it will have access to this data when needed for patient care and disability determination.

(121)

CMAT Control #
1999061-0000054

(b)(6)
03/02/99 12:00 PM

To: (b)(6) @OSAGWI, (b)(6) @OSAGWI
cc:
Subject: Forwarded: DefenseLINK Comment(ANTHRAX)

I received this earlier this a few minutes ago....

---------- Forwarded by (b)(6) on 03/02/99 11:58 ----------

(b)(6) @otsg.smtplink.amedd.army.mil on 03/02/99 10:24:07

To: (b)(6)
cc:
Subject: Forwarded: DefenseLINK Comment(ANTHRAX)

LCDR (b)(6)

Here is the e-mail that I referenced. Our office is responding to many of the questions, however, for purposes of continuity, could you please respond to question 2. Also if you have any thoughts on questions 6 or 7, we would like to incorporate them into our response. These questions originated from a someone who is very active in the anti-anthrax movement so it is fair to say that the responses we provide will end up on the web and be disected. Thank you for your attention to this matter and should you have any questions, please call me at (b)(6) Thank you.

(b)(6)
Anthrax Vaccine Immunization Program Agency
Office of the Surgeon General
(b)(6)

_____ Forward Header _____

Subject: Forwarded: DefenseLINK Comment(ANTHRAX)
Author: (b)(6) @osd.pentagon.mil> at
INTERNET-MAIL
Date: 2/17/99 2:08 PM

Sir:

I forwarding another e-mail dealing with the anthrax vaccination. Thank you for your assistance.

Sincerely,
(b)(6)
Directorate for Public Communication
(b)(6)

-----Original Message-----
From: (b)(6) @txdirect.net]>
(b)(6)
Sent: Wednesday, February 17, 1999 12:47 PM
To: (b)(6) @osd.pentagon.mil>
(b)(6)
Subject: DefenseLINK Comment(ANTHRAX)

Hi. I am a concerned Army Reservist who has been doing quite a bit of research on the subject of the Anthrax vaccine and as you may have guessed, have quite a few questions which I don't think the DoD's web sites properly addresses.

Here are my questions:

1. Is the vaccine being given to U.S. troops the EXACT same vaccine that was tested on the mill workers in the 70's and that was part of the basis for FDA approval?

2. Where are all the long term studies on the "thousands of people" who have taken this vaccine? Were not records made of who received those vaccines? Has anyone at the FDA or the DoD bothered to contact these people? Why were the records of the Gulf War Veterans lost? Was anyone held accountable for this monumental mistake or were the records intentionally destroyed? Is it not true that many of the panels who investigated the Gulf War Illness came to their conclusions on the Anthrax vaccine based on the fact that they didn't have ample shot records to study and thus no hard data to make links between Gulf War Syndrome and the vaccine?

3. Does a soldier receiving this vaccine have the right to know what lot# of the vaccine they are receiving? Doesn't this information have to go on their medical records (this has not been happening in some Active Duty units). If so, where can incorrect shot recording procedures be reported besides the immediate chain of command or if that chain of command fails to provide corrective action?

4. What strain of Anthrax is in the current vaccine?

5. The DoD website also states that their are "No long term side-effects".

This information is on:
<http://www.defenselink.mil/specials/Anthrax/qna.htm>
http://www.defenselink.mil/specials/Anthrax/qna.htm Queston/Answer #10
Should that not be changed to "No proven long term side-effects"? Or at least "No known long term side-effects"?

6. The DoD also sites Dr. Burrow has reviewing and putting his stamp of approval on the vaccine, when in actuallity he has been giving some strange answers or no answers at all when questioned about his involvement. One of the studies he's quoted as reviewing he says he has never seen before. Was his name incorrectly used by the DoD?

7. Where can I find the 3 year study that Mr. Cohen keeps mentioning to the media?

8. And finally, if the DoD did screw up and our military begins coming down with serious and similar illness far more then the general civillian population, that are linked by independent experts to the vaccine, will the government fess up to a mistake and take care of its troops or will deny everything and abandone us to cope as best we can? If I do get sick through the governement's/military's mistakes, it would give me and most soldiers some piece of mind knowing that the military will take care of us.

So far that seems highly unlikely as no one seems to want to take accountability for any mistakes.

I would suggest that you forward my email to someone who can answer these questions. If possible to Col. Norris (public affairs specialist on Anthrax at the DoD), Army Surgeon General Lt.. (b)(6) , or even the Secretary of Defense himself if no one else can provide solid, reliable answers to at least some of my questions.

If this email is ignored (no answer within a month) I can only assume that either:

1. No one knows whats going on, or 2. There is an intentional coverup of facts surrounding the vaccine. Hopefully someone will answer these questions and alleviate those fears, thus restoring my faith in the Department of Defense.

Thank you,

(b)(6)

 - RFC822.TXT

(b)(6)
03/02/99 03:06 PM

To: (b)(6)

cc:
Subject: Re: Forwarded: DefenseLINK Comment(ANTHRAX)

The study upon which the FDA approved the vaccine was performed, not in the 70's as the writer suggests, but in the 50's. Its results are published in the American Journal of Public Health, Vol 52, pages 633-645, 1962. I don't know what 3 year study he is referring to, but the above study actually took place between 1955 and 1959, over 4 years. Long term studies have been done on workers at USAMRIID, who received multiple vaccines over many years. The results have been published, but the participants received more than just anthrax vaccine.

FO'D

(b)(6)
03/02/99 12:10 PM

To: (b)(6) @OSAGWI
cc:
Subject: Forwarded: DefenseLINK Comment(ANTHRAX)

fyi

---------- Forwarded by (b)(6) on 03/02/99 12:09 PM ----------

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cc:
Subject: Forwarded: DefenseLINK Comment(ANTHRAX)

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---------- Forwarded by (b)(6) on 03/02/99 11:58 ----------

(b)(6) on 03/02/99 10:24:07

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cc:
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anti-anthrax movement so it is fair to say that the responses we provide will end up on the web and be disected. Thank you for your attention to this matter and should you have any questions, please call me at 681-8196. Thank you.

(b)(6)
Anthrax Vaccine Immunization Program Agency
Office of the Surgeon General
(b)(6)

Forward Header

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Author: (b)(6) @osd.pentagon.mil> at INTERNET-MAIL
Date: 2/17/99 2:08 PM

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Thank you,

(b)(6)

- RFC822.TXT

Response provided via e-mail 3/8 PM
LTC (b)(6)

Information related to question #2:

"Where are all the long term studies on the 'thousands of people' who have taken this vaccine?"

The anthrax vaccine is an FDA licensed vaccine. There is no requirement to conduct long term studies of people who have taken FDA licensed vaccines. For instance, there are no studies being conducted on people who have received the influenza vaccine, or measles vaccine (MMR), etc.

There are studies which have been conducted on personnel who have taken multiple vaccinations. Long term studies have been done on workers at USAMRIID, who received multiple vaccines over many years. The results have been published, but the participants received more than just anthrax vaccine.

NOTE to Mr (b)(6) : (b)(6) *of USAMRIID* (b)(6) *is researching the reference for the study previously published. (The person at USAMRIID who is in charge of that particular program is not at work this week.) She also indicated that there is a pending publication on a study they have recently completed. Preliminary results of this newer study may be available. It may be more expeditious for your office to get this information directly from USAMRIID, rather than through OSAGWI.*

"Were not records made of who received those vaccines?"

A record of any vaccinations received by individuals should be made in the individual's health record, both in the civilian community and in the military. However, these records are not recorded in a centrally held database that is retrievable by the medical community (civilian or military). This makes tracking of who got what vaccine and when, difficult if not impossible.

During the Gulf War, the units that gave the anthrax vaccination were to record the vaccine via unit vaccination rosters, make notations directly in personal medical records, or on the 'yellow shot record'. After the war, the units were instructed to transcribe the vaccination rosters to individual medical records. By that time, the personnel in the units had returned to their previous duty station, released from active duty, or had executed PCS orders to a new duty station, making the transcriptions of the records difficult.

"Has anyone at the FDA or the DOD bothered to contact these people?"

There is no centralized database for knowing who 'these people' are. DOD has attempted to collect the unit vaccination rosters that still exist. Many of these

rosters were presumably destroyed after the unit transcribed the information into medical records as previously instructed by DOD.

In most cases there are records maintained for persons who participate in the original research that is conducted when a new drug or vaccine is being studied for approval or licensure by the FDA. These records would be held by the agency or company that conducted the original research. However, once the product is approved or licensed, there is no longer a need to keep records on who receives the product. For instance, the manufacturers have no record of vaccines given to individuals in the U.S. population since childhood.

"Why were the records of the Gulf War Veterans lost? Was anyone held accountable for this monumental mistake or were the records intentionally destroyed?"

There is no single explanation for missing records. Medical records were not the only things that 'got lost'. Some records were shipped back to the US to the home station of the parent unit, which may have been inappropriate for attached units or organizations which were made up of composite units. We have located a few records that were inappropriately archived by units to the National Personnel Records Center, in St. Louis.

"Is it not true that many of the panels who investigated the Gulf War Illness came to their conclusions on the Anthrax vaccine based on the fact that they didn't have ample shot records to study and thus no hard data to make links between Gulf War Syndrome and the vaccine?"

The FDA encourages all US healthcare providers, including the military, to report adverse reactions to vaccines and the law requires the manufacturers to report serious adverse reactions for all licensed vaccines. The FDA has not received data that raise concerns about the safety of the Anthrax Vaccine.

The Institute of Medicine reviewed DOD's use of vaccines during the Gulf War. Their findings as reported in their report Health Consequences of Service During the Persian Gulf War: Initial Findings and Recommendations for Immediate Action (1995) 'We have no evidence that vaccines in general cause the non-specific complaints associated with service during Operation Desert Storm.'

The military medical logistical system had at the time of the Gulf War, and still maintains, a Medical Materiel Complaint System for all medical equipment, medical supplies, drugs and vaccines. This system keeps track of all complaints that are officially filed on each product, to include serious adverse reactions (resulting in hospitalization), quality issues, and logistical complaints. This system is centrally maintained by Defense Supply Center – Philadelphia, and is monitored by Joint Readiness Clinical Advisory Board, Ft. Detrick, MD. (previously known as Defense Medical Standardization Board). All complaints that result in hospitalizations or deaths of patients are immediately reported to

the FDA and an investigation into the cause is conducted by both the JRCAB and the FDA (separate investigations). There was one reported hospitalization for a vaccination site infection reported during the Gulf War (the infection was related to the technique used by the person giving the vaccine, not to the vaccine itself). There were no complaints of serious adverse reactions, and no deaths due to Anthrax Vaccine during the Gulf War.

Information related to question #6:

The letter that Gerard N. Burrows, MD wrote as a consultant to DOD on the anthrax vaccine can be read at the following address:

http://www.defenselink.mil/other_info/burrows.html

Information related to question #7:

The study upon which the FDA approved the vaccine was performed, not in the 70's as the writer suggests, but in the 50's. Its results are published in the American Journal of Public Health, Volume 52, pages 633-645, 1962. The study actually took place between 1955 and 1959, over 4 years. This might be the 3 year study to which (b)(6) is referring.

CONGRESSIONAL or SPECIAL CORRESPONDENCE

CMAT: 9061 - 054

Date: 3-2-99

Office of Special Assistant for Gulf War Illnesses
Internal Routing/Tasking Sheet

Coord/ Routing	Position/Organization		Action	Info	Comments
	Special Assistant	(SA)			
	Deputy Special Assistant	(DSA)			
	Executive Assistant to SA	(EA)			
	Executive Assistant to DSA	(EADSA)			
	☐ Director, Investigation & Analysis _____ (IAD) ☐ DepDir _____ ☐ MED _____ ☐ VDM _____ ☐ C/B _____ ☐ ENV _____ ☐ PAG _____		X		lead
	Dir Lessons Learned Implementation	(LLI)			
	Dir Public Affairs & Outreach	(PA)	X		info
	Dir Legislative Outreach	(LA)			
	Dir Quick Reaction Team	(QR)			(7)
	Dir Medical Outreach & Issues	(MOI)	X		
	Legal Advisor	(LGL)			
	PM, Gulf War Illnesses Support	(PM)			
	Editorial Review ☐ AMB _____ ☐ Editors _____	(ER)			
	CMAT	(CMAT)			E-mail
					See attachment.
	Action Management Call 845-8369 ☐ COMEBACK COPY TO: _____ ☐ GET CMAT NUMBER WHEN SIGNED & SENT ☐ READING FILE ☐ THANK YOU FILE ☐ CHRON FILE ☐ ADD TO GulfNEWS				

SUSPENSE: 3-16-99

Prepare reply for signature of:

☒ SA/GWI ☐ SD ☐ DSD ☐ DepSA/GWI

- prepare response to OTSG on Questions 2 and 7.
- Cmd w/ MOI

☐ Congress ☐ Oversight ☐ FOIA ☐ OSD ☐ WBM ☐ VSO/MSO

☐ Ltr to SA ☐ IR ☒ E-Mail ☐ OGA ☐ Other ☒ Veteran

KEYWORDS:

ANTHRAX VACCINE

02/05/99 Issuance

BACKGROUND – GULF WAR ILLNESSES

DR. DAVID CHU

19 April 2001, 0930-1045

LTG (Ret) Dale Vesser, Office of the Special Assistant to the Under Secretary of Defense (Personnel and Readiness) for Gulf War Illnesses, Medical Readiness, & Military Deployments (OSAGWI/MRMD)

The approach of this paper is to present the big picture of Gulf War illnesses as it evolved, with emphasis on emerging answers from medical science, investigations, environmental studies, and research, as well as lessons learned.

DoD's embroilment in the Gulf War Illness controversy, e.g., continuous front page news, VSOs' and veterans' hostility, and media and Congressional attacks on DoD credibility, exacerbated because:

- DoD does not handle well non-traditional threats to health (e.g., Agent Orange, and Gulf War illnesses);
- DoD did not talk to or listen to its sick veterans;
- DoD repeatedly denied the presence of chemical weapons during the conflict; it did not occur to top leadership that we might have exposed ourselves (Khamisiyah);
- DoD did not know where many of the troops were located on the battlefield, further hampering identification of exposures.
- DoD was slow to develop a big picture about illnesses, exposures, or whether medical science found any relationship between them.

Numbers:

- 697,000 served during Operations Desert Shield/Storm:
  = 535,000 in Theater during period of hostilities;
  = 136,200 still on Active Duty (September 2000);

- 122,302 evaluated / 574,698 not evaluated in special medical programs run by DoD (Comprehensive Clinical Evaluation Program) and the VA (Persian Gulf Registry)

Concern about Gulf War veterans' health mounted because:

- Common expectation that troops' good health would continue after the war;
- Blood donations by GW veterans suspended (lifted in 1993) due to concerns about leishmaniasis (a sandfly-transmitted parasite);
- Onset of health problems among those who had deployed;
- Early media reports about such problems labeled as "Gulf War Illness";
- No early government or scientific explanations of illness reports;
- Understandable questions about health effects of:

  = Oil well fires
  = Pyridostigmine bromide
  = Infections (leishmaniasis)
  = Anthrax, botulinum vaccines
  = Sarin
  = Depleted uranium

- Rapid demobilization and downsizing caused loss of health care benefits for some;
- Media speculation about a "Gulf War Syndrome."

Most prominent hypotheses for illnesses among Gulf War veterans:

- Infection (leishmaniasis, mycoplasma, BW agents, other bacterial infections)
- Neurotoxic effects of nerve agents, PB, pesticides
- Vaccines, especially anthrax vaccine
- Oil well fires
- Depleted uranium
- Chemical Agent Resistant Coating, petroleum products, BW toxins
- Multiple chemical sensitivity syndrome
- Squalene
- Stress
- Combinations of exposures, like those above

Government Response:

- At first, routine DoD and VA care;
- 1992 Army investigation of illness in 123rd ARCOM – inconclusive;
- 1992 Persian Gulf Registry (VA) – Medical evaluations (concern about oil well fires' health effects);
- 1992 Oil well fires expert panel – concluded unlikely connection to illnesses;
- 1993 DU Follow-up program (DoD asked VA) – limited to friendly fire victims;
- 1994 National Institutes of Health Consensus Panel – summary of issues;
- 1994 Comprehensive Clinical Evaluation Program (DoD) - Medical evaluations;
- 1994 Senate Banking, Housing, and Urban Affairs Committee (Reigle);
- 1994 Persian Gulf Veterans Coordinating Board (PGVCB) – DoD, VA, HHS (research emphasis);
- 1995 Persian Gulf Illness Investigative Team (PGIIT) – ASD (Health Affairs);
- 1995-8 Declassification of documents by the Services;
- 1996 (November) OSAGWI – replaces PGIIT;
- 1998 Expansion of DU medical follow-up testing;
- 2000 Military and Veterans Health Coordinating Board – DoD, VA, HHS.

Research:

Government funding allocated by PGVCB based on merit ranking of proposals by an independent peer review process (Amer. Inst. Biol. Sci.)*

Results:

- GW veterans have increased symptoms (more veterans report more symptoms);
- No syndrome identifiable – the consensus view; 3 "syndromes" – the view of one researcher;
- Unexplained physical symptoms are problematic (also true for

civilians);
- No increase in birth defects among offspring of Gulf War Veterans;
- Higher rate of deaths due to motor vehicle accidents among Gulf War veterans compared to non-deployed contemporaries; both groups had much lower death rates than civilians of comparable age, sex.
- No pattern of increased diseases causing hospitalization among Gulf War Veterans.

* Three exceptions were Drs. Haley, Nicolson, and Hyman, who were funded directly by DoD with the understanding that their work would be peer reviewed.

Reports:

Institute of Medicine of the National Academy of Sciences:

= 1995 Health Consequences of Service During the Persian Gulf War
= 1996 Health Consequences of Service During the Persian Gulf War

These two reports made broad recommendations for government response to Gulf War illnesses in research, health care, and information systems.

= 1996 Evaluation of the DoD Comprehensive Clinical Evaluation Program.
= 1997 Adequacy of the Comprehensive Clinical Evaluation Program: Nerve Agents.
= 1997 Adequacy of the CCEP: A Focused Assessment.
= 1998 Adequacy of the VA Persian Gulf Registry and Uniform Case Assessment Protocol.
= 1999 Gulf War Veterans – Measuring Health. Recommended long term follow-up studies of veterans of both GW and other deployments.
= 2000 Gulf War and Health (Vol. 1) – Depleted Uranium, Pyridostigmine Bromide, Sarin, Vaccines. Could find little or no evidence for a link between these substances and unexplained illnesses in Gulf veterans.
= 2000 Strategies to Protect the Health of Deployed U.S. Forces - "...a major reason for this lack of progress is the fact that no

single authority within DoD has been assigned responsibility for the implementation of the recommendations and plans."

1998 Special Investigation Unit of U.S. Senate Veterans Affairs Committee

GAO (21 reports)

DoD IG and Army IG (3 reports)

CIA (12 reports)

Presidential Advisory Committee on Gulf War Veterans' Illnesses:

- 1996 Interim Report
- 1996 Final Report
- 1997 Special Report

Congressional Committees:

- 1994 Senate Banking, Housing, and Urban Affairs Committee (Reigle)
- Senate Armed Services Committee
- House Armed Services Committee
- Senate Veterans Affairs Committee
- House Veterans Affairs Committee
- House Committee on Government Reform Subcommittee on National Security, Veterans Affairs, and International Relations

OSAGWI: (all reports, papers, and releases are posted on GulfLINK website)

- Khamisiyah – release of nerve agents during post-war demolition of Iraqi ordnance;
- Air Campaign – releases of chemical weapons by bombing;
- Individual reports of chemical exposures or alarms;
- Declassification of official documents (1,200,000 classified files identified and evaluated for medical relevance and possible declassification) by Services;
- 55,000 declassified files posted on GulfLINK;
- CIA and UNSCOM (separate publications);
- Commissioned RAND papers (12) on reviews of the medical/scientific literature;

- Environmental Exposure Reports (9) on exposures possibly affecting health;
- International Collaborations (UK, France, Saudi Arabia, Kuwait, Czech Republic, Canada, Israel);
- Information Papers (e.g., Vaccines, medical records) (12);
- Case Narratives (33) – reports on detailed investigations of incidents;
- Close-out Reports (6) – foreshortened investigations;
- Outreach (GulfLINK, town halls, troop and veteran briefings):

  = 13 Town Hall Meetings
  = 19 Military Base Visits (to over 78,000 active personnel)
  = 17,338 E-mails
  = 15,761 Phone Calls
  = 5,287 Correspondence

- Locating and organizing hospitalization records (over 25,000) from Gulf;
- Target notification of 300,000 veterans following investigations (Appendix A).

Presidential Special Oversight Board: (Chaired by former Senator Rudman)

- 1999 Special Report
- 1999 Interim Report
- 2000 Final Report

Results: What have we found?

- OSAGWI descriptions of hazards, environmental issues, and health risk assessments defined the identified non-traditional threats to health.
- Gulf War Veterans report increased frequency of physical symptoms.
- No new, unique syndrome has been identified.
- Research has found no novel causal relationship between exposures and subsequent illness, but research continues:

  = Cumulatively, 192 projects; $155 million;
  = Major topics include PB, DU, birth defects, hospitalizations, mycoplasma, nerve agents, pesticides, interactions of chemicals,

brain and nervous system, diagnosis, treatment.

- Institute of Medicine, responding to a Congressional Mandate (Appendix A):

  = Reviewed scientific literature about DU, sarin, PB, and vaccines; Based on his review of this report, the Secretary of Veterans Affairs determined that there was no scientific basis for a presumption of service connection between illness and exposure to these 4 items;
  = Pesticides and solvents are now being reviewed; Appendix A contains a total list of 33 specified by Congress.

- DoD and VA treatment trials for medically unexplained physical symptoms;

  = Cognitive behavioral therapy and aerobic exercise – still in progress;
  = Antibiotic treatment – still in progress.

- Disability data from VA:

  = Compensation for service-connection and disability is not limited to GW, but for any disability that is related to military service;
  = Applied for Disability Compensation 186,438 (27%)
  = Number Granted Service Connection 143,138 (21%)
  = Receiving Compensation 98,262 (14%)
  = Compensation Rates – Monthly:

	Veteran w/No Dependent)	Veteran with Spouse, 2 Children
10% Rating	$ 101	$ 101
30% Rating	$ 298	$ 378
100% Rating	$ 2107	$ 2378

- Baltimore VA follow-up of DU exposed veterans, esp. those with fragments, has so far shown no kidney abnormalities, leukemia, bone or lung cancer, or any classical uranium-related outcome; monitoring continues;
- Training on avoiding unnecessary exposures to DU on battlefield strongly supported by VSO's;

- Medically unexplained physical symptoms continue to be researched.

Lessons Learned:

- Leadership needs to be sensitive to handling of non-traditional threats to health;
- Detection of chemical warfare agents: False positives need to be explained and documented;
- Medical records were lacking for outpatient health care during Gulf War;
- Need to improve pre- and post-deployment health screening;
- Need to improve training and education of troops before and during deployments;
- Need better assessment of the operational environment for potential health risks;
- Need better risk communication to leaders, troops;
- Need to raise medical awareness about post-deployment health concerns. A Clinical Practice Guideline for post-deployment medical assessments is being fielded;
- Need to defuse misconceptions with timely feedback during operations to all exposed personnel;
- Need to provide best training possible for newly fielded equipment like Fox detection vehicle and DU ammunition.

Facts:

- Science requires measurements of environmental exposures to calculate dose (concentration over time) - dose determines health effect;
- Science and objectivity in open process are necessary for credibility;
- Science evaluates population groups and conducts statistical analyses;
- Science has not been able to document cause-and-effect relationships between hazard exposures and symptoms or illnesses in Gulf War veterans;
- Science has not been able to document an association between environmental exposures and symptoms or illnesses in Gulf War veterans;
- Corroborated eyewitness accounts were seldom available, so recognized investigative processes are essential to determine what happened on the battlefield.

Public evaluations:

- Media present individuals with medical problems who express their opinions as to why they are ill;
- Media don't provide opinions of individual's illness by the treating physician or medical experts;
- Congressional hearings provide a venue of those who are ill and/or disillusioned to express concern and frustration, but limited opportunity for DoD response;
- Media balance stories from DoD by interviews with individuals or organizations who have lost confidence in government in general and DoD in particular.

Current and future deployments: - Why we (OSA) are here:

- Respond to all those involved in deployments about non-traditional threats to health;
- Coordinate, facilitate, and assess DoD's response to IOM report "Strategies to Protect the Health of Deployed U.S Forces";
- Support CINC risk management of non-traditional threats to health during deployments;
- Management of DeploymentLINK;
- Carry the Department's message about DU to NATO and the UN;
- DoD source for DU information and advice for DU training;
- DU livefire Capstone testing;
- DU testing of projectiles from Kosovo for transuranics;
- Response to VA on veterans exposures (Project SHAD [Shipboard Hazard and Defense] and Herbicide Orange handling outside of Vietnam);
- Provide advice on and support for force health protection for military deployments (e.g., NG/USAR support in the SFOR mission);
- Expanding efforts to all deployments – Balkans are first priority for expansion.

Office of the Special Assistant to the Under Secretary of Defense (Personnel & Readiness)

for Gulf War Illnesses, Medical Readiness, and Military Deployments

DoD and the Gulf War

- Did not deal with non-traditional threats to health
- Did not talk or listen to its veterans
- Denied presence of chemical weapons
- Did not know troop locations or exposures

Who Served

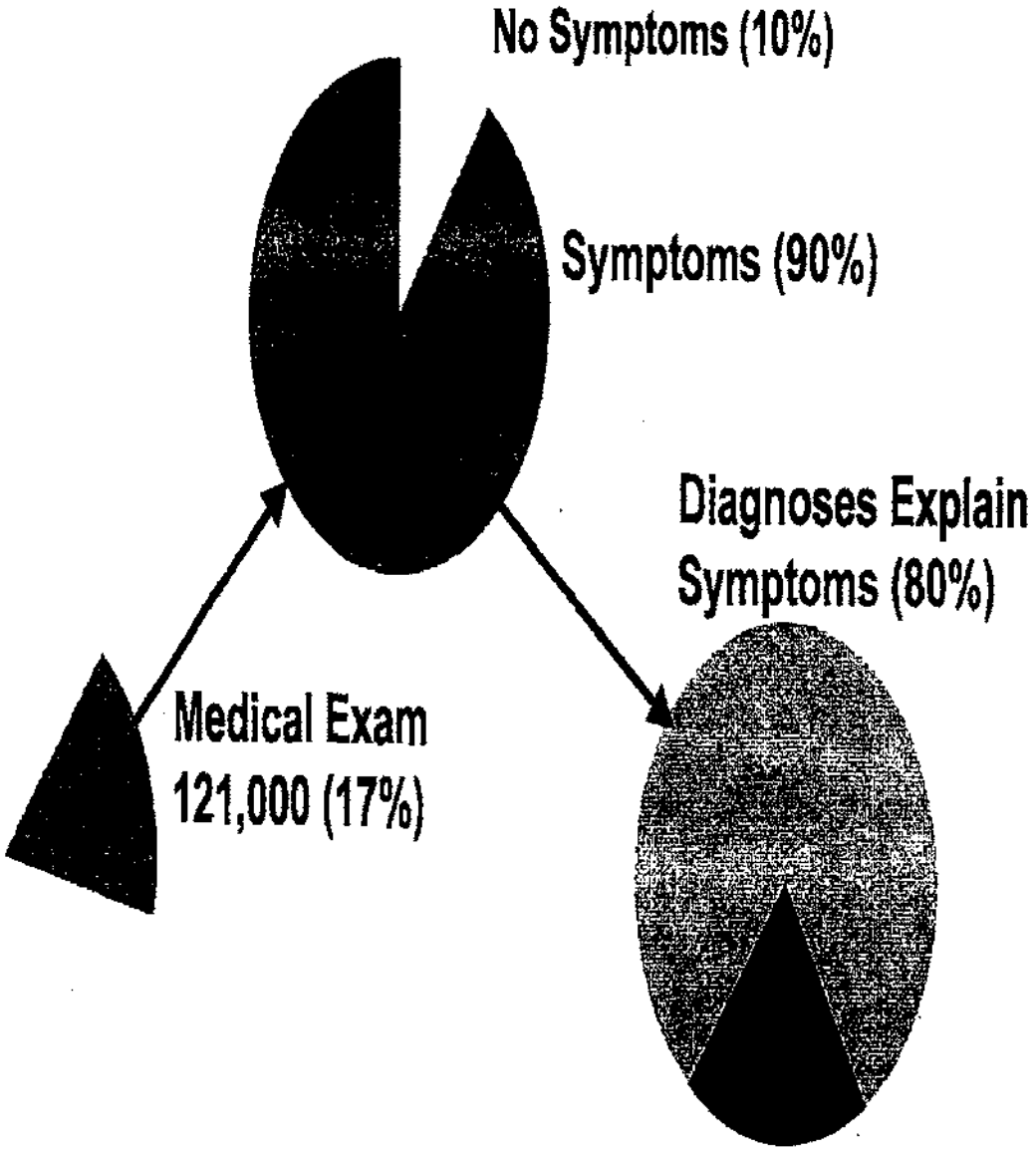
697,000 U.S. service members

ARMY	50%
NAVY	23%
MARINE	15%
AIR FORCE	12%
FEMALE	7%
RESERVE / NATIONAL GUARD	17%
ENLISTED	90%

Time Line

1991	- Gulf War
1992	- VA Persian Gulf War Registry
1994	- Comprehensive Clinical Evaluation Program - Reigle Committee - Persian Gulf Veterans Coordinating Board RWG
1995	- Presidential Advisory Committee
1996	- OSAGWI - DoD Mobilizes
1998	- Presidential Special Oversight Board
1999	- Military and Veterans Health Coordinating Board

Medical Evaluations



All GW Veterans - 697,000

Unexplained Symptoms (20%)

Veterans' Concerns About Health

- Explanation for illnesses
- Return to health
- Treatment
- Compensation

Self Diagnosed Causes

NON-TRADITIONAL THREATS

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

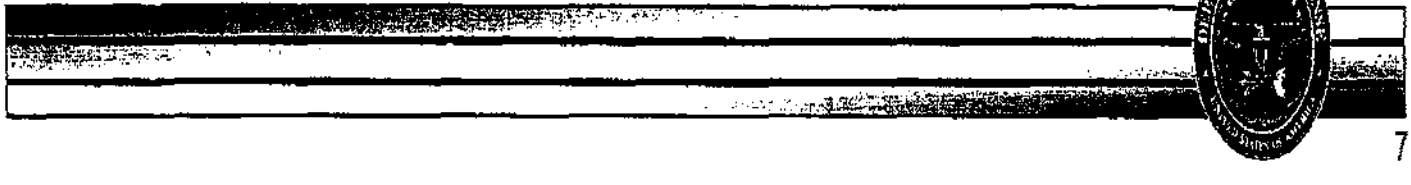
DEPLETED URANIUM

PYRIDOSTIGMINE BROMIDE

SQUALENE

STRESS

COMBINATIONS



Research Results

- No syndrome
- No increase in birth defects, hospitalizations, or deaths
- Unexplained symptoms greater (2-3 times) in Gulf War veterans

No Exposure Cause/Effect Relationship Yet

- Institute of Medicine
- Senate Special Investigation Unit
- Presidential Advisory Committee
- RAND Literature Review
- Presidential Special Oversight Board

But Research Continues

Dr. Robert Haley

- 3/97 - Original $12M research proposal::
  - Enlarging/extending case-control study (Seabees)
  - Identify 3 "Haley Syndromes" from Dallas VA
  - Exposure to low-level neurotoxins in the rat
  - PB and the blood brain barrier
  - Pharmacologic and rehabilitative treatments trials
  - Screening tests for Seabees/Dallas VA participants
- Low scientific rating by the American Institute of Biological Sciences (AIBS)
- 9/97 - DoD funded enlarging Seabee study

Cooperative Agreement
DoD - University of Texas Southwestern

- Haley proposed to "determine whether the findings of study #1 can be replicated in an independent population of Gulf War veterans."
- Haley failed to provide an "expanded set of cases and controls" by the required date (9/00)
- Submitted 2 Annual Reports
  - AIBS ruled them incomplete and noted he had not accomplished the primary task (1/99 & 4/00)

Magnetic Resonance Spectroscopy

- Haley suggests veterans with different Gulf War syndromes show evidence of neuronal damage
- Study performed on 12 Navy Seabees identified with one of Haley's syndromes and 15 control subjects (8 served in Gulf War/7 did not) from 12/97 - 6/98
- Concludes brain damage associated with low-level sarin exposure (published 9/00)
- The Seabee unit was not near any of the releases of low levels of chemical warfare agent (Khamisiyah, Muhammadiyat, Al Muthanna)

Today

- Research
  - 192 Projects
  - $155 Million
- Treatment Trials
- VA Disability
  - 27% Applied
  - 14% Compensated
- DU Medical Follow-up

Lessons Learned

- Risk communication for leaders
- Troop training and education
- Briefings on health risks
- Pre- and post-deployment screening
- Chemical/biological weapons detection
- Archive medical, CW detector and troop location records
- Timely feedback on any exposure critical
- Survey and care for troops after deployment

Mastering Future Challenges

- DoD's implementation of changes recommended by IOM "Strategies to Protect the Health of Deployed U.S. Forces"
- Informing, protecting, and caring for all those involved in deployments
- Monitoring NG/RC - unique health related issues for deployments
- DoD responsiveness to special initiatives:
  - DU information, advice, training
  - VA information requirements

Back-up Slides

Independent Assessments

- Senate Special Investigation Unit (98)
  - "nearly all of these studies were performed on "samples of convenience" and, as a result, cannot be used to draw conclusions about the larger but unstudied group of all Gulf War veterans."
- Dr. Jonathan Samet, Johns Hopkins University (6/99)
  - "needed, confirmatory work by others has not yet taken place. In spite of Dr. Haley's enthusiasm, I do have concerns about some of the findings. As I pointed out earlier this week in my remarks to the Board, Dr. Haley has been using poorly specified outcome measures, symptoms and syndromes, and exposure variables that represent surrogates for unknown agents."

Editorials on Dr. Haley's Work

- Drs. James Albers/Stanley Berent, Clinical Neurobehavioral Toxicology (8/00)

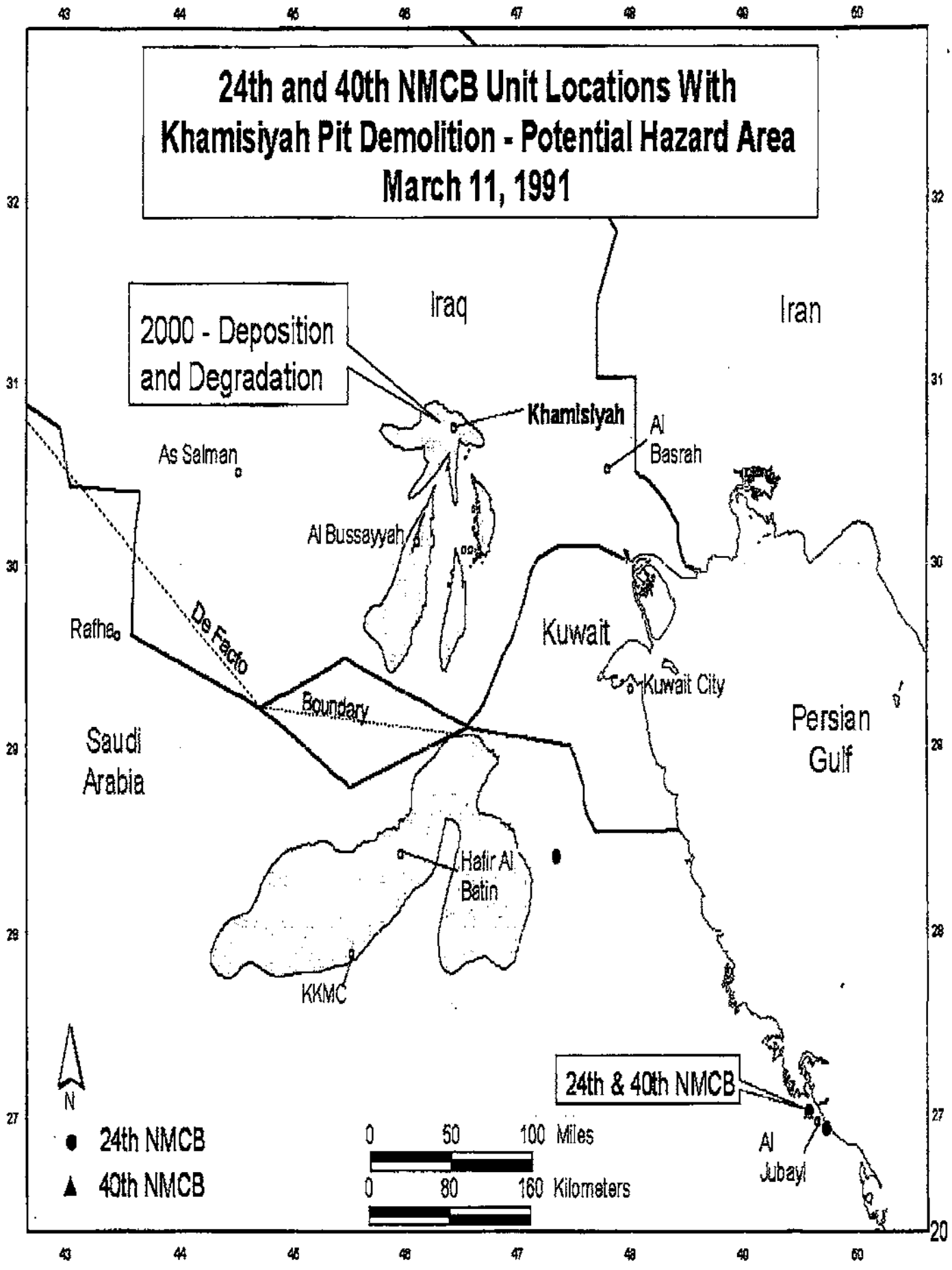
- Dr. Jeffrey Sartin, Mayo Clinic Proceedings (8/00)

- Drs. Han Kang/Tim Bullman, American Journal of Epidemiology (2/98)

- Drs. Greg Gray/David Cowan, American Journal of Epidemiology (3/98)

Researchers Verifying No Syndrome

- CAPT Greg Gray - Naval Health Research Center (9/00)
- Dr. Simon Wessely - Ministry of Defence (1/99)
- Dr. Han Kang - Department of Veterans Affairs (5/00)
- Dr. Kurt Kroenke - Indiana University (6/98)
- Iowa Persian Gulf Study Group (1/97)


24th and 40th NMCB Unit Locations With
Khamisiyah Pit Demolition - Potential Hazard Area
March 11, 1991
2000 - Deposition and Degradation
Iraq
Iran
Khamisiyah
Al Basrah
As Salman
Al Bussayyah
Rafha
De Facto
Boundary
Kuwait
Kuwait City
Persian Gulf
Saudi Arabia
Hafir Al Batin
KKMC
24th & 40th NMCB
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40th NMCB
0 50 100 Miles
0 80 160 Kilometers
43 44 45 46 47 48 49 50
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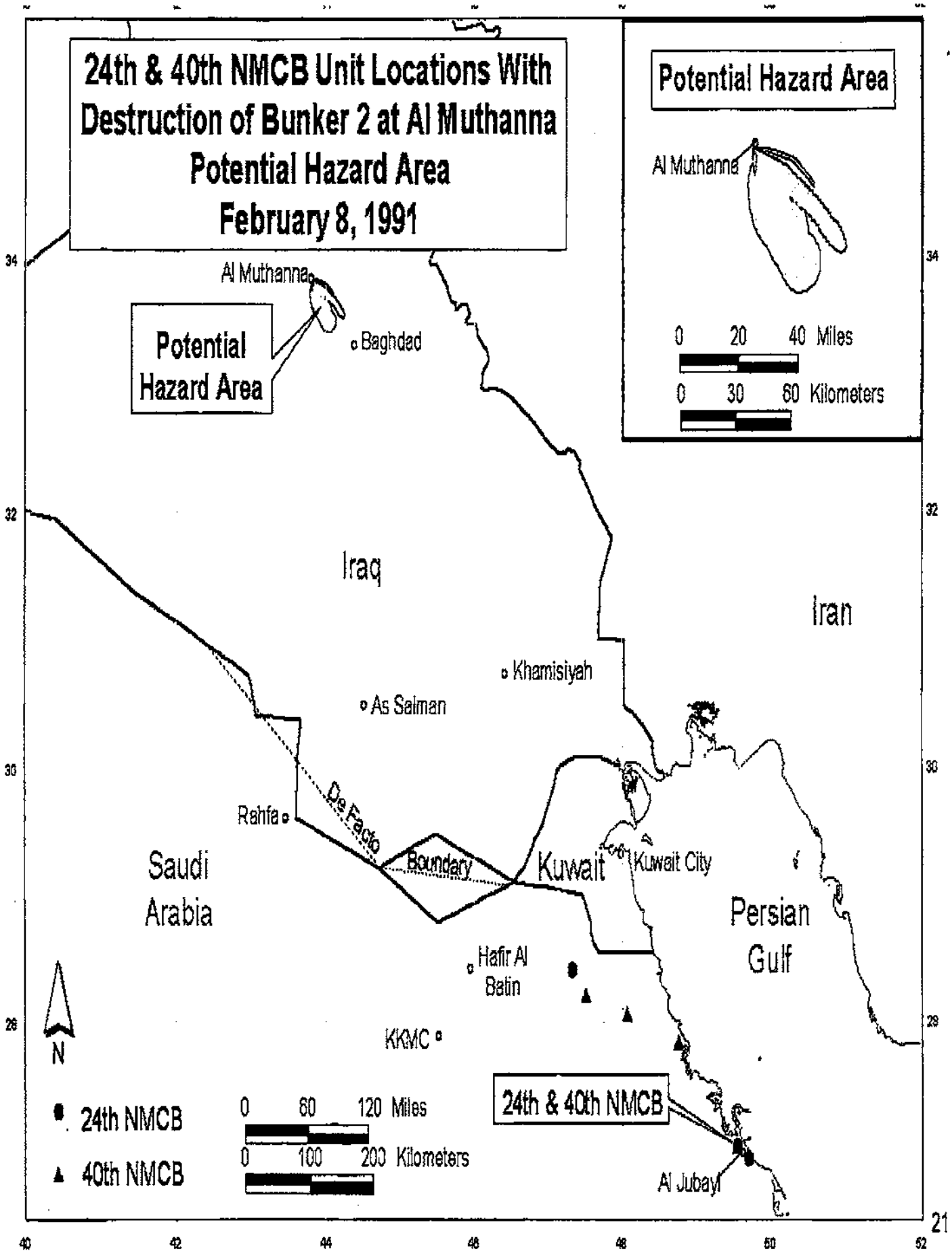
24th & 40th NMCB Unit Locations With
Destruction of Bunker 2 at Al Muthanna
Potential Hazard Area
February 8, 1991
Potential Hazard Area
Al Muthanna
0 20 40 Miles
0 30 60 Kilometers
Al Muthanna
Potential
Hazard Area
Baghdad
Iraq
Iran
Khamisiyah
As Salman
Rahfa
De Facto
Boundary
Saudi
Arabia
Kuwait
Kuwait City
Persian
Gulf
Hafir Al
Batin
KKMC
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24th NMCB
40th NMCB
0 60 120 Miles
0 100 200 Kilometers
24th & 40th NMCB
Al Jubayl
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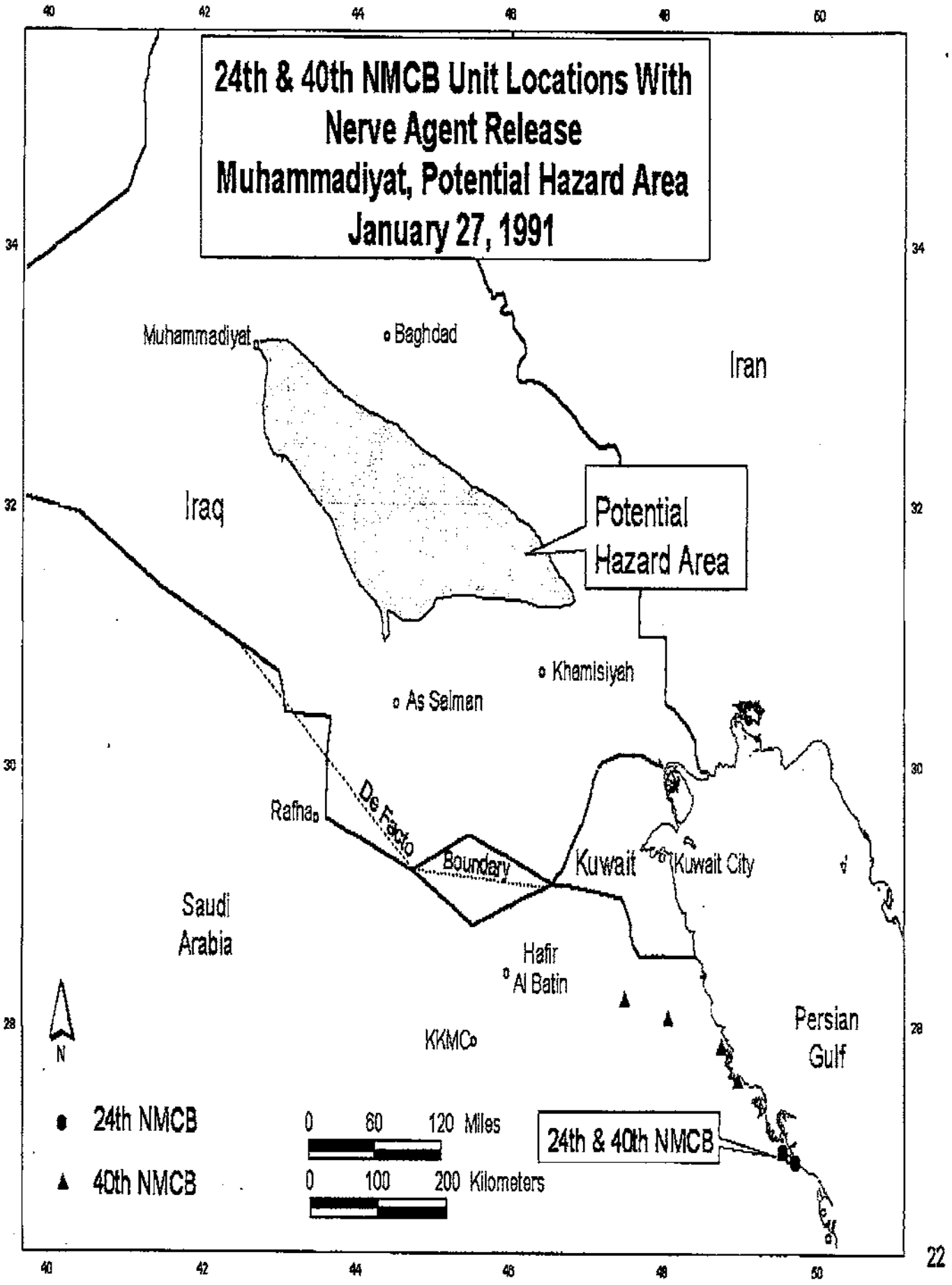
24th & 40th NMCB Unit Locations With
Nerve Agent Release
Muhammadiyat, Potential Hazard Area
January 27, 1991
Muhammadiyat
Baghdad
Iran
Iraq
Potential
Hazard Area
Khamisiyah
As Salman
Rafha
De Facto
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Kuwait
Kuwait City
Saudi
Arabia
Hafir
Al Batin
KKMC
Persian
Gulf
N
24th NMCB
40th NMCB
0 60 120 Miles
0 100 200 Kilometers
24th & 40th NMCB
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2000139-0000139

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
TO THE SECRETARY OF DEFENSE
FOR GULF WAR ILLNESSES,
MEDICAL READINESS, AND
MILITARY DEPLOYMENTS

NOV 0 8 2000

(b)(6)

Dear (b)(6)

This letter responds to several questions and concerns you raised in recent conversations with a member of our staff. If this letter misstates your questions, please contact us and we'll be happy to write back.

You first asked about the results of the study carried out by Dr. Edward Hyman. We don't know how this research turned out. To our knowledge, Dr. Hyman has not yet arranged for the publication of his results in a scientific journal. In June 2000, in response to another veteran's question about the study, we made inquiries to the Walter Reed Army Medical Center. At that time, we were told that the DoD contract attorney had requested an updated summary of the study results, but Drs. Hyman and Deming had not yet supplied such a summary. Because of your interest, we have asked for an update on the situation. We will advise you of what we find out.

With respect to the issue of squalene, a recently published article (Asa, PB, Cao, Y, and Garry, RF. Antibodies to Squalene in Gulf War Syndrome. *Experimental and Molecular Pathology* 68: 55-64, 2000) reported finding not squalene, but antibodies to squalene in the blood of the majority of ailing Gulf War veterans whose blood they tested. No other scientist had been working on a test for antibodies to squalene. Dr. Asa's reports had first appeared in non-scientific publications (for example, *Vanity Fair), so* the specifics of her data were not available to the rest of the scientific community until this year. In the testing procedure described in the medical journal article, the investigators did not use a known antibody to squalene to validate their test system.

The testing of blood for antibodies to squalene is not a standard laboratory test. The test described in the Asa report is investigational in nature and has not been validated. Department of Defense scientists have begun the process of independently researching whether or not antibodies to squalene can be provoked in animals and how to test for such antibodies. If such a test method can be developed and results reliably reproduced, then researchers can move on to the question of the possible relationship of such antibodies to human illnesses, including those of Gulf War veterans.

In response to a DoD solicitation for research on illnesses among Gulf War veterans, a DoD investigator and nationally recognized expert on antibodies to cholesterol and other lipids

In September of this year, Congressman Metcalf made public a letter that the FDA had sent to him in March, revealing the results of FDA tests for squalene about which the DoD was unaware. Using a different and more sensitive lab method, the FDA test found squalene that the independent lab (SRI) was unable to find. The FDA found squalene at 10 to 83 parts per billion in three out of three US vaccines tested: anthrax, diphtheria, and tetanus vaccines. The level of squalene identified by the FDA test is so minute that it likely represents a trace natural component of the bacteria from which the vaccines were made.

Squalene is constantly present in the human blood stream at 250 ppb (nanograms per milliliter), a concentration 25 times higher than the level detected in the FDA test. Moreover, the total amount of squalene in the human blood stream alone is approximately 1,500,000 nanograms of squalene. The amount of squalene added as an adjuvant to a European-approved influenza vaccine is 4 grams per 100 ml (4 parts per hundred), which is one million times more than the concentration of squalene detected in the FDA test.

With respect to the immune system, the expression "speeding up" the immune system is not precise medical terminology. When squalene is used as a vaccine adjuvant, such as when relatively large quantities of squalene are put into the European flu vaccine, squalene provokes a higher level of protective antibodies in response to the flu virus proteins in the vaccine. Speed is not the issue. More important is the ability of our immune system to recognize and react to the flu proteins in a stronger way. It probably doesn't act faster, just more strongly.

Might squalene be responsible for the deterioration of your immune system? There is no evidence that shows such an effect on human immune systems. Given that all of us have been exposed to squalene all of our lives, it is not possible to rule out the possibility that it might be responsible for ill health, but there is no evidence for such an effect at this time.

If we can be of further assistance, please feel free to contact us again.

Sincerely,

Francis L. O'Donnell, MD, MPH
Colonel, Medical Corps, US Army
Director, Medical Readiness

Office of *the Special Assistant to the Secretary* of Defense
for Gulf War Illnesses, Medical Readiness,
and Military Deployments

CMAT #:
Date: 0139-113
NOV 03 2000

Action Tasking // Internal Routing Sheet

		Action	Info	Comments
	Special Assistant **(SA)**			
	Deputy Special Assistant **(DSA)**			
	Executive Assistant to SA (EA)			
	Executive Assistant to DSA **(EADSA)**			
	☐ **Director, Investigation &Analysis** ___(IAD) ☐ C/B__ ☐ ENV_ ☐ PAG__ ☐ **VDM**_			
	Dir Lessons Learned Implementation (LLI)			
2	**Dir Public Affairs&Outreach** (PAO)	[illegible]		
3	**Dir Medical Readiness** **(MR)**	OSD	3 Nov 00	signature
	Legal Advisor (LGL)			
	Info Technology & Security **(ITS)**			
	PM Support **(PM)**			
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SUSPENSE:

Prepare reply for signature of:

☐ Special Assistant ☐ **Deputy Special Assistant**

☐ Congress	☐ **Oversight**	☐ FOIA	☐ **OSD**	☐ WBM	☐ VSO/MSO	☐ Outgoing
☐ Ltr to SA	☐ IR	☐ E-Mail	☐ OGA	☐ Other		☐ Veteran

KEYWORDS:

09/07/00 Issuance

CMAT Control # 2000249-0000031 (124)

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
FOR
GULF WAR ILLNESSES

AUG 17 2000

MEMORANDUM FOR DEPUTY SPECIAL ASSISTANT FOR GULF WAR ILLNESSES

THROUGH: Project Manager, Gulf War Illnesses

FROM: Director, Medical Outreach and Issues
Colonel Francis L. O'Donnell

SUBJECT: Meeting of the Institute of Medicine Committee on Identifying Effective Treatments for Gulf War Veterans' Health Problems

PURPOSE: To summarize the presentations made at the meeting and to provide copies of the written testimony

DISCUSSION: The IOM committee assembled to hear talks from government representatives, private physicians and scientists, and Gulf War veterans on effective treatment for Gulf War illnesses. The summary at Tab A outlines each talk and includes what questions the committee asked. Tabs B – J contain the written materials that the presenters submitted for the record.

Committee on Identifying Effective Treatments for Gulf War Veterans' Health Problems
August 14, 2000

Introduction

Dr. Bernard Rosof introduced himself as the committee's chair. He identified the major tasks (which also appear on the handout, "Membership Statement of Task," at Tab B). These include (1) identifying and explaining treatments for all Gulf War illnesses, including undiagnosed ones, (2) identifying the most prevalent illnesses among Gulf War veterans, and (3) identifying scientifically validated treatments. Dr. Rosof emphasized that the third task comes from a congressional mandate.

The committee has not made any conclusions (to date). The panel members can feel free to ask questions, but the direction of the questions might not reflect the final views that they express in their report. Dr. Rosof knows that they have not fully addressed all the issues yet because they are so broad.

When the committee goes to publish, a group of anonymous experts will review their draft final report. They will make suggestions but will remain anonymous. The process helps give the Institute of Medicine (IOM) its credibility.

Dr. Rosof concluded his introduction by introducing Dr. Howard Spiro. He provided some background on Dr. Spiro's qualifications. Dr. Spiro has proven himself a great teacher. He graduated from Harvard in 1947. Between 1951 and 1953 he served as the Chief of the Gastrointestinal Clinic at the Army Medical Center. In 1970, he published the first edition of a clinical gastrointestinal text that Dr. Rosof ranks as one of the most useful books of its kind. Dr. Spiro's most significant achievement was establishing the gastrointestinal center at Yale.

Dr. Spiro's Presentation

Dr. Spiro admitted straight off that he does not normally work with Gulf War issues. He learned a great deal just from talking to the other people in the room that morning. He still does not know about the veterans' most common complaints.

In describing his personality, Dr. Spiro said that he usually finds reason not to agree with the majority. For instance, he has developed his own irritable bowel definition that differs from the widely accepted description of "irritable bowel syndrome," which consensus conferences have arrived at. He used this definition as one of his main points throughout his presentation (Please refer to the slides at Tab C. The numbers beneath each slide show the order in which he displayed them.).

Dr. Spiro does not normally see patients but does act as a consultant. He believes that with true irritable bowel syndrome, the symptoms typically develop between the ages of sixteen and seventeen for men. Women have a wider range, between twelve to fourteen. When patients these ages present irritable bowel symptoms, Dr. Spiro assumes that they have irritable bowel syndrome and starts treatment right away. If a person suddenly experiences symptoms similar to "irritable bowel syndrome," Dr. Spiro does not consider them as having acquired this disease. With these sorts of patients, he starts

looking for a cause and recommends diagnostic tests to determine it. He considers the older people to have "disordered bowel function."

Dr. Spiro made a very important point about "disease" versus "illness" (slide 3). He identified the distinction between the doctor "seeing" the disease and the patient "feeling" the illness as applicable to both irritable bowel syndrome and Gulf War illnesses. The history of the conflict between disease and illness goes back to the Greeks. One set of doctors advocated certain methods to cure all patients with similar symptoms (They had to identify the disease or the cause to do so.), while another group tried to convince the patients to feel better without worrying about the disease or the cause. Their idea of telling patients, "Feel better!" has continued through history to the "alternative" medicine groups today. Alternative (or "complementary" medicine - Dr. Spiro used this word) relies on the patients stories to figure out the problem.

Doctors need to address the whole patient when trying to cure illness – the body, mind, and spirit. Major problems occur when they try to answer every question, because not all questions need an answer. When the doctor focuses too much on one issue (even in a helpful way), the patient does too. Dr. Spiro gave the example of Dr. Rosof having "no pain in his right elbow," which will make Dr. Rosof continually check on it to verify this. Medical school usually teaches this mentality by advocating the theory, "If you try hard enough, you'll find the answer." But what if the answers aren't available? Dr. Spiro takes great care to listen to a patient and address them. While it proves easier to "see" (For instance, the x-ray either reveals or doesn't reveal a problem.), the "truth" of patients' illnesses take all of their symptoms into account. At the same time, doctors need to remember to treat each patient differently and to weigh each symptom as very important.

With regards to the Gulf War, Dr. Spiro believes that veterans' irritable bowel symptoms may stem from a learned response to stress. He qualified this by mentioning that he has not extensively studied this theory, nor has he published anything on it. However, the veteran may have had an episode of diarrhea while serving in the Gulf as a result of some legitimate cause (food poisoning, infection, etc.), but subsequent episodes of stress may trigger the problem again (only this time without the original cause).

Infection can also lead to chronic diarrhea. After the original occurrence, any future episodes do not leave evidence available to pathologists. The cycle can last two to three years to forever. Dr. Spiro explained the reason for this as a difference between the body's ancient immune response, and its modern one. For the ancient immune response, cells eat foreign bacteria immediately. But evolution has also developed the body's ability to have T-cells and B-cells help out.

Dr. Spiro briefly explained the possible therapies for irritable bowel syndrome. Most of the answers will come from the neurobiology field. Anti-depressants have proven effective for people that have abdomen pain that they cannot characterize. Small doses work as pain relievers.

Dr. Spiro cited some problems with irritable bowel studies. Most people who suffer from irritable bowel symptoms never see a doctor. They assume that they have to live with their symptoms or will not admit to them. So the academic work really reflects a select population (those upset enough by their symptoms to seek professional advice).

Finally, Dr. Spiro explained the criteria for identifying irritable bowel syndrome. Again, this applies to people in their teens that have symptoms. Older ones have what he

calls "disordered bowel function." Some physicians have argued against irritable bowel syndrome as a specific disease.

In summarizing his briefing, Dr. Spiro said that doctors have overplayed making diagnoses by exclusion. They cannot rely completely on the brain because the brain leads to the mind, and perception in the mind has such an important role in the patient's health. Some people seem more aware of what happens inside them, and if they anticipate trouble, they will have it. Their mentality goes back to Dr. Rosof paying more attention to his right elbow. Doctors may even teach patients what words to use or concepts to express based on their reactions or interest in a particular aspect of the disease. Also, stress plays a part in any illness. Patients experience stress when they fear that they will not overcome their symptoms. Distress occurs from the symptoms and may even have some good qualities.

Colonel John Graham's Presentation

Colonel Graham served in the Gulf War. Since then, he has concentrated on Gulf War issues for United Kingdom veterans. He currently holds the position as the liaison between the United States and the UK for Gulf War issues.

Colonel Graham began his presentation by reviewing the UK's history during the Gulf War. Between August and November 1990, small Navy and Air Force contingents arrived in the theater. The first big hump of soldiers occurred during November. They found the environment cold and wet. After the land battle they re-deployed rapidly back to the UK. During all of this, the British thought that they had a good idea of the possible exposures. In November, the US troops experienced lots of diarrhea, and the British wanted to prevent this. However, they found the environment and their ability to respond to it slightly different from what they expected. They had organized their medical setup for a war in Europe, and it did not include recordkeeping provisions or preparation/prevention methods for disease and non-battle injuries.

Immediately, after the war, the UK veterans voiced their fears about DU, biological weapons, oil well fires, and industrial chemicals. Following, the 1993 "News Night" (a British television program) episode, the veterans' concerns coalesced, and new ones sprang up (NAPS, pesticides, and vaccines). To follow up, Colonel Graham helped establish the MAP (Medical Assessment Program), although the UK still does not have an examination program specifically for Gulf War veterans. Papers from the US (for example, on birth defects) helped put other worries into perspective.

The MAP has seen about 3,000 sick Gulf War veterans. The biggest jump in the number of people who referred themselves to this program occurred after Parliament answered some questions related to Gulf War illnesses incorrectly. The MAP published a report after seeing their first 1,000 patients. They found symptoms and diagnoses similar to what the CCEP reflects. Signs, symptoms, and ill-defined conditions proved common. The MAP also followed up psychiatric conditions diagnosed through civilian physicians, but Colonel Graham does not rely on that data because of the British care system's nature and other biases.

The British have also developed a new program, separate from the Ministry of Defence, of the highest scientific caliber. Their research program looks at the health of

the adult population and birth defects. For birth defects, they divided the subjects into three groups (two made up of Gulf War veterans and one control).

The British mortality data has appeared in the scientific literature. The researchers working on this did not find any statistically significant activity. The numbers turned out very similar to the ones from Dr. Kang's study. The British currently update their mortality data on a six-month basis.

Dr. Wessley noted that Gulf War veterans report all types of symptoms three times more frequently. While that phenomenon is quite clear, the conditions are not as clear. One argument made in connection with this study is that veterans immunized in theater had a greater chance of suffering symptoms, but Colonel Graham cited many confounders in this instance.

Colonel Graham concluded his presentation by noting that some veterans still report themselves well. The British need some handle on the natural history of Gulf War illnesses. Since he finished early, Dr. Rosof opened the floor to a question/answer session.

Questions and Answers

Dr. Rosof took the first question, asking about an excess of death due to external causes. Colonel Graham confirmed that British veterans have experienced an excess number of deaths from such causes. He defined them as "non-intentional and traumatic."

Ms. Andrea Pauly, from the audience, identified herself as coming from the NIH. She wanted the exact number of British Gulf War veterans. Colonel Graham gave this as 53,000. She then questioned him about their central registry. The British formed a central registry for their Gulf War veterans so that they could know which patients saw (or had been assigned to) which doctors. The registry has proven a valuable research tool. They can even receive copies of death certificates or cancer registrations through it. They started the registry in 1995 and will publish the findings that they gained from it after the Cherry team completes their work. They encountered some problems with soldiers who left the registry (when they moved to other countries), although they can still perform data checks on the deaths.

Dr. Dedra Buchwald wondered about an increase in deaths due to substance and alcohol abuse. The British have not done much work in this area. Lieutenant Colonel Charles Engel spoke up to emphasize the importance of that data, but no one can collect it. Simon Wessley's team acquired some, but it was not robust enough to include in their paper.

Dr. John Halperin questioned the relationship between the typical onset of a patient's symptoms and the final diagnosis. "How long have patients been suffering?" Colonel Graham guessed at "months," although he explained that they couldn't tell for sure, because in some instances symptoms began years after a veteran's Gulf War service. The veterans may not come forward right away, so the researchers have no way of knowing when the symptoms first appeared.

Ed Bryant advocated the British establishing a database of biopsies on Gulf War veterans (Some confusion occurred here due to his long speech – either he wanted one or he expected that the British already had it.). The British do have the cause of death in most cases, but they cannot obtain the biopsies or the autopsy results because of medical

confidentiality. Ed Bryant also asked a question about the British publications on pesticides, and Colonel Graham referred him to three reports on the Internet.

Colonel Engel's Presentation

Colonel Engel began his talk by showing a slide (Tab D) that included a two-paragraph quote from the Steve Straus *Lancet* editorial. Recent evidence has revealed that medically unexplained physical symptoms are an important outcome after deployments. Captain Hyams reviewed medical literature as far back as the Civil War and found similar concerns. Colonel Engel used the recent anthrax vaccine controversy to explain how scientists will not know for certain if an exposure causes illness or not until well after the event. With the symptoms that some people attribute to the anthrax vaccine, the real focus should be on doing something for them in the meantime.

In the case of Gulf War illnesses, physical symptoms have proven meaningful enough that the person experiencing them seeks help from a health care provider. The researchers have not yet come up with biological indices, but that is not because they want to deny that the symptoms exist or attribute them to psychological problems. They have simply reached the limit of their ability to explain them.

Colonel Engel advocated the need for better assessment and management within the DoD and VA health care systems. He believes that a pragmatic approach would prove the most valuable. Dr. Brown wrote an article about the CCEP, where he showed how unexplained symptoms undermine the physicians' abilities. When the physicians lose credibility over unexplained symptoms, the patients are less likely to trust them with diagnoses for other problems.

Normally, doctors want to explain the physical symptoms (going back to the disease-driven mentality that Dr. Spiro explained earlier). When they can identify some, they concentrate on these as more important than any unexplained problems. In reality, they cannot sort out the relationship between exposure and health consequences. Overly aggressive strategies, such as diagnostic tests, provide only transient reassurances.

Gulf War "heroes" have developed some of these tests and/or treatment methods. In many instances, they apply therapies with little known benefits but definite potential for harm. They have not conducted well-controlled studies. Yet the veterans flock to them because they perceive them as "doing something." Colonel Engel sees the need for research and treatments both scientifically sound and convincing to the veterans.

Colonel Engel also returned to the "distress" concept that Dr. Spiro introduced. As problems increase, psychological illnesses increase – a phenomenon that works with both explained and unexplained symptoms and serves as an important source or morbidity. Colonel Engel showed charts of how people with more symptoms missed more workdays. While this sounds elementary, Colonel Engel pointed out the importance of addressing the psychological conditions because they are so common with all illness and they lead to relatively more lost workdays.

Colonel Engel presented a slide on chronic pain (entitled "iatrogenesis"). He noted that scientists have very little information on this. Twenty-five percent of the time in the general population, the health care provider openly disputes the pain complaint. That leads to the patient's dissatisfaction with the health care system. Gulf War veterans feel the same way because the doctors cannot explain their illnesses.

For post-deployment symptoms, Colonel Engel advocated a care-based approach. In this manner, the veterans can start receiving medical assistance immediately. The researchers will not know the causes for their illnesses right away, but this should not hinder the treatment program.

Population-based care takes a structured approach. Colonel Engel thought about the need to devise tracking systems, although they can build those by using existing data. The population-based approach matches resources to needs and focuses on preventing disability/morbidity.

Veteran-centered care works around collaborative methods. The expert about medical care (the doctor) and the expert about the individual body (the patient) form a team to discover solutions for the problems. They manage the patient's care through cooperative action. The veteran takes some responsibility for feeling better by deciding on the outcome variables. Colonel Engel and Dr. Caton identified predisposing factors that might hinder this process. They came up with a range of psychosocial issues, but they believe them modifiable. As the current system stands, the veterans feel that they have to prove their illness, and most doctors identify with this.

Colonel Engel broke away from his talk to explain the term "somatization." Doctors use this (for lack of anything better) when they encounter unexplained symptoms. However, it causes problems. "If you have to prove that you are ill, you cannot get well." The veterans during the afternoon session also expressed their unhappiness with the word.

Colonel Engel summarized his presentation by returning to the veteran-centered care and the step-care approach that he and Dr. Caton developed. He outlined the multiple levels at which intervention can occur. His final quote returned to the Straus editorial. He also left time for a question/answer session.

Questions and Answers

Dr. Buchwald finds Captain Hyams' review important, pointing to how he describes ten or twelve different wars. If war syndromes happen, why doesn't the military plan for them? They can collect information before exposure. How come they do not perform prescreening? Doing so would allow them to both start thinking about prevention and have an easier time of assessing someone's disability should the need arise.

Colonel Engel knows that such programs are "in the works." The current recruit assessment program includes an SF-12 examination, which looks at physical symptoms and asks historical questions. The military can then use these surveys to identify people at risk. However, some confounding issues arise. Most deployable soldiers are in good to excellent health. Also, the doctor still needs to establish a relationship with each patient in the clinical setting.

Dr. Halperin asked for follow-up data from previous wars. Captain Hyams can probably better answer that question. Colonel Engel provided a few details. Probably no one has collected any data on veterans from earlier wars (except maybe Vietnam), and certainly no one has published any longitudinal follow-up.

Mrs. Janice Brown wondered if Colonel Engel had studied Dr. Hyman's work. She also said, "Is it possible that a bacterial strep infection could cause psychological manifestations?" Colonel Engel answered, "Definitely." All illnesses can cause this.

Ed Bryant had issues with the biomedical model. He advocates the SPECT scans. He went through the CCEP program, and it helped him, but he still needs enhancements for his diagnoses. He believes that most veterans have twenty different symptoms, although Colonel Engel replied that they experience about three per veteran, including psychological. Ed Bryant thinks that Colonel Engel just shoots for the lower numbers.

Colonel Engel explained in more detail the need to continue to research the SPECT scans. Right now, the scientists have a novel illness and a novel test, so they don't know the meaning of any association between the two. They need to determine the clinical utility of such a connection. Ed Bryant has researched the issue himself, and came across similar results for Vietnam veterans and Alzheimer's patients.

Drs. Steven Hunt and Ralph Richardson's Presentation

Both Drs. Hunt and Richardson come from the Gulf War Clinic in Seattle, Washington. Dr. Hunt is a physician, while Dr. Richardson works as a psychologist. They had a long presentation and therefore had to skip some of their slides, but all are available at Tab E.

Dr. Hunt spoke first. He reminded the audience of the reason for the meeting – Gulf War veterans had gone from feeling fine to experiencing serious health problems, and that range still applies today. The IOM wants to look for the best ways to address their concerns. The Gulf War Clinic has also done this.

In 1991, Dr. Hunt started seeing Gulf War veterans because he worked for the compensation and pension division of the VA. The hospital established the Gulf War clinic in November 1994. He outlined the setup, noting that the clinic coordinator holds a very important position, as she serves as the primary point of contact for the veterans. The early date allowed them several contributions – but most important, they started long-term follow-up right at the beginning. When they encounter healthy people, they follow them according to the schedule for their age group, but the undiagnosed illnesses have proven the most frustrating.

Dr. Hunt touched on some factors that impacted Gulf War veterans' health. He feels that anticipation of extended contact acted as the most profound stressor. The doctors can't even imagine its effects.

Dr. Richardson took over the presentation at this point. He cautioned that the clinical characteristics that they see many not represent the group of Gulf War veterans as a whole. They rely on self-reported symptoms, although these match the top three in other studies. Their veterans average five symptoms per person.

When a patient comes in for the first appointment, the clinic takes a brief symptom inventory. The doctors use that to measure psychiatric distress. The Seattle veterans have elevated scores on psychiatric sub-schedules. The diagnosis of PTSD runs at about fourteen percent in males and fifteen percent in females.

Later the same day, the veteran takes a SF-36 test, which measures how that person does on daily activities. The Seattle veterans consistently show considerable impairment. In summary, these two tests show that the veterans have problems.

Dr. Richardson feels it necessary to ask the veterans about their beliefs. "What do you need to get better?" Colonel Engel also talked about this. Dr. Richardson goes so far as to listen to anecdotal experiences.

The providers' beliefs will also impact a veteran's care. In one instance, area researchers surveyed internal medicine providers and psychological providers at three Northwest hospitals. The psychiatric doctors identified Gulf War illness as mostly a physical problem, while the physical doctors believed it more a mental problem (Incidentally, patients consistently report observing the same reactions in their health care providers). Dr. Richardson noted one caveat with the survey – the researchers also asked a question about how many people felt that the patients needed equal combinations of both physical and psychiatric treatment, and this wound up as the most prevalent response.

That led Dr. Richardson to the most impossible question, "What do we do next?" Are the symptoms physical or psychological in nature? He argued that this is the wrong question to ask.

Dr. Hunt then resumed speaking. He believes that disease overlaps illness and turned to a slide with overlaid bubbles to illustrate his point. Some diseases have no symptoms, such as diagnosing diabetes in a patient who feels fine but whose tests show elevated blood sugar levels. Other times, especially in the case of the Gulf War veterans, people experience symptoms without a disease. Gulf War veterans need "treatment that takes into account all the diseases that we can diagnose."

His theory for Gulf War illnesses is that the Gulf War disrupted the soldiers' health. Now, they have a difficult time getting it back on track. He likened it to a marathon runner approaching the twentieth mile of a race. If he stops or falters in his stride, he will have serious trouble, but if he can keep running, he will finish the race. For a Gulf War example, he found Dr. Spiro's earlier explanation about bowel disruption a good one. Fifty percent of the troops had an episode of diarrhea due to typical causes (infection, bad food, new eating routine, etc.), and that may have triggered something later.

The Gulf War Clinic developed a MUPS model (multiple unexplained physical symptoms – Colonel Engel also used this term). Doctors do not know what causes the symptoms. However, they have a few opportunities for areas of intervention: predisposing, precipitating, and perpetuating factors. The proper treatment controls the factors. The model also recommends shifting from medical management to self-management (which allows the patient and the physician to share responsibility), as well as shifting the focus from cause to effect. Oftentimes, the doctors (and their patients) keep searching for the cause, even though that is not the main issue. Dr. Hunt cited an article about cognitive behavioral therapy, which gives the case history of one of their patients. The MUPS model provides an effective approach.

Dr. Hunt touched on some other areas for treatment. Identifying the illness beliefs becomes important because if the patient finds out later that they thought wrong, that might cause harm. And the clinic counsels the veterans to avoid recurring trauma. For example, if someone considered a new career in law enforcement but showed symptoms of PTSD, the clinic would advise him against making such a move.

Dr. Hunt stated the clinic's goal, "To maximize health and overall functioning." They do not try to identify Gulf War illnesses in patients and then get rid of it. A doctor does not need to fully understand the cause in order to provide treatment.

Dr. Richardson ended the presentation by reviewing the satisfaction surveys that the veterans complete. These demonstrate that the Gulf War Clinic has done a good job. One of the biggest complaints was about a lack of parking.

Conclusion for the Morning Session

Dr. Rosof officially ended the morning presentations by noting the IOM will make their final report in January. The panel views this committee meeting as an information session. Ms. Lyla Hernandez coordinated the afternoon speakers. During that part, the panel will hear directly from the veterans about the problems they have experienced with treatment.

Mrs. Janice Brown

Mrs. Brown comes from Flint, Michigan. She lives there with her husband, a Gulf War veteran who receives 100 percent disability, although this diagnosis didn't come from a VA physician. A civilian doctor made it on October 1, 1998 after Mr. Brown tested positive two times for leishmaniasis. He currently has Medicaid services, so he cannot receive his treatments in a hospital. Mrs. Brown worries because he has them at home in front of two small children. The treatments do arrest his systemic infections, but they have not cured him.

Mrs. Brown advocated ruling out every physical illness possibility before exploring "mental causes." She did research on her husband's condition and cited some footnotes for her findings (They also appear in her written testimony at Tab F.). Viscerotropic leishmaniasis worries her the most.

Her husband has documentation for his illness from January 1991 to the present. However, this has not helped him secure treatment. The family even sought congressional aid.

Mrs. Brown concluded by listing assumptions that she feels doctors make, but that she knows are no longer valid. 1) Her husband has a genetically mutated strain of leishmaniasis that does not respond to traditional methods. 2) Leishmaniasis can lay dormant for many years (She cited a cutaneous case turning visceral after 43 years.). 3) Blood from Gulf War veterans is not safe, and the Red Cross should implement the ban on blood donations again because of this. 4) Veterans used to receive tests for leishmaniasis through biopsies and antibody methods, but she insists that doctors use PCR instead.

Dr. David Berg

Dr. David Berg runs Hemex Laboratories. He crammed a very technical discussion into ten minutes, and after awhile I did not try to take detailed notes on it because it was so far over my head. He distributed a handout, however (Tab G).

Dr. Berg uses the ISAC test, a new panel of highly sensitive markers that researchers have studied for years. In the past four years, his laboratory has put it into practice. They wanted to use it to diagnose chronic fatigue. Later they studied Gulf War veterans and autistic children. They will publish the data that they have gathered on Gulf

War veterans this October. They also have discovered similarities among the data for autistic children.

Dr. Berg suggested vaccines as a cause for Gulf War illnesses. He believes that those who fell ill had a genetic predisposition to do so. He pointed out that this is similar to now autistic children, who started out normal, received the measles vaccine, then stopped talking and developed other signs of autism.

The most frequent question that Dr. Berg receives is, "Why won't the blood clot in the patients that have demonstrated activation of the coagulation system?"

He always answers, "Because they do not have enough thrombin."

Ed Bryant

Ed Bryant stated that he works as the Health Care Liaison for Gulf War Veterans, yet in the next sentence he said that he has no job. He described his symptoms and his exposures, but he meshed them together, so I had a hard time figuring out what he considers as his health problems. Ed Bryant added that he wrote a report to Congress.

He made several recommendations. He wants the IOM to call for full medical exams for all Gulf War veterans, and these exams need to include Dr. Hyman's urine test, the SPECT scans (He acted very adamant about these throughout the whole day.), PCR, and blood tests. He believes that the doctors have used the same tests for around 100 years and figures that they should move to current (twenty-first century) tests. He also recommended "desert pack vitamins," as they rebuild the immune system. The doctors need to rule out disorders and stop using prilosec because it causes cancer. According to the veterans that he talks to, "They are all on prilosec without the proper diagnostic tests." Finally, he would find an open letter from the DoD and VA about treatments helpful.

He has researched petroleum and cited Dr. Finegold's report. He listed the possible illnesses that petroleum could cause. He views this as one of the possible culprits; food and pharmaceuticals have coal tar in them.

Ed Bryant hit on many other issues, usually with just a sentence or two, as he wanted to cover them all in his ten-minute time slot. He worries about pesticides after the GAO report on pesticides in schools. He wants to know the true measurement of the air quality and feels that he should've worn a respirator. He mentioned Alzheimer's disease and DU in Massachusetts. He explained "less stress in Maine" as the reason that people there live twenty to thirty years longer. In the rest of the US, the life expectancy hasn't changed since the 1970s. General Vesser said, "This was the most toxic battlefield since World War I." He wishes to see more databases, particularly one for biopsies and another for causes of death.

Dr. Kathleen Hannan

Dr. Hannan works with Drs. Berg and Baumzweiger. She also gave an extremely technical presentation, which proved difficult to follow in the time allowed. Unfortunately, she did not make handouts of her slides.

Dr. Hannan believes that the Gulf War infectious agent attacks neurons that have already been damaged. She uses hepron as a drug to stop coagulation, although she does

not go up to the therapeutic range that Dr. Berg prescribes. She has observed beneficial effects with small doses. She administers it through painless injections (Her reasoning for this, "The veterans already experience enough pain, and many of them don't want anything to do with needles after having taken all of those vaccines."), a technique that stretches the skin and forces the hepron in at 2,000 psi. She then uses antibiotics for mycoplasma, as this eliminates the opportunistic infections. The veterans receive anti-fungals through IVs if she finds fungi in high concentrations. A calcium channel blocker reduces exocitoxin damage. Finally, IVIG functions as an antiviral agent, and NADH destroys free radicals.

Not all of her patients have recovered completely. She has conducted a treatment trial, but she did not discuss the data because it is not yet ready for publication. When she analyzes it, she expects to see a ninety- percent improvement rate.

James Johnson

Mr. Johnson gave a short presentation, but he stayed completely on topic (effective treatments). He participated in the cognitive behavioral therapy and aerobic exercise trial. He said that it has not cured him, but has noticed the difference that it made in several areas of his life. He has especially improved personal relationships with just about everyone – his family, neighbors, and co-workers. He diligently keeps up with the limited amount of aerobic exercise that he can handle.

Ms. Venus-val Hammack

Ms. Hammack presented using slides that she did not appear familiar with, and so her talk came out very hesitantly. The delivery did not help me understand her points very well. She appeared to advocate various tests to include in the registry programs.

She started by saying that doctors needed to conduct tests for aluminum hydroxide, as this would indicate exposure to bunker demolitions. Mr. Kirt Love spoke up to correct her; apparently the test is for the anthrax vaccine. He adjusted/expanded on her testimony several more times. After running through many slides of tests for various agents (Please see Mr. Love's testimony at Tab H.), she urged the physicians to treat Gulf War veterans as if they had experienced industrial poisoning.

With regards to more logistical guidelines, she wishes to make the Phase II program mandatory. At the very least, veterans need to know about the guidelines and options for Phase II. Most health care providers request psychological tests for veterans, but she believes that they need more than this. She listed systems (bodily) and exposures to check instead.

She looked at the legal issues under Title 38 that secures treatment for veterans. She knows that additional tests will unearth more problems. She summed up her testimony with the quote, "Don't test; don't find."

Dr. Edward Hyman

At this point, Dr. Rosof telephoned Dr. Hyman so that he could participate. Dr. Hyman started by explaining his qualifications (His handouts are at Tab I.). He served in the Navy.

He does not believe that Gulf War illnesses stem from chemical injuries or germ warfare, as veterans cannot transmit these sorts of exposures to family members. Instead, the cause must come from something indigenous to the area that non-immune people in crowded conditions picked up easily. He feels that all Gulf War veterans have the same illness (He used the words, "all one illness."). All manifestations go away when the urine clears, similar to his experiences with tuberculosis and syphilis. He attributes the illnesses to streptococcus- and staphococcus-like infections. He has worked with illnesses like these for thirty-five years, and he has cured all of his cases. He presented his cured cases for the first time in June 1993, and he has continued to present them. From June 1998 to June 1999, he conducted a double-blinded study with an error level of $p = 0.001$ or $p = 0.0001$, depending on how he performed the calculations. He took his work to Dr. Engel and Dr. Feussner. He stated something about losing 245 troops to Gulf War illnesses, although I could not figure out how he obtained that number.

No one from the panel had any questions for him. Dr. Hyman acted somewhat surprised about this. The audience did not ask any questions either.

Mrs. Brown for Mark Colins Maryan

Mrs. Brown read Mr. Maryan's statement, as he could not attend due to a lack of funds, the inability to take time off of work, and health reasons. Mr. Maryan intended to advocate Dr. Hyman's treatment program. The IOM received a faxed copy of Mr. Maryan's testimony, but this was not available for the general audience.

Mr. Maryan did not receive his full treatment on schedule from Dr. Hyman, and now he does not feel so good. He detailed his participation in the double-blind treatment test. Dr. Hyman explained the procedure to him, but Mr. Maryan knew that he wound up with the placebo, since it did not improve his health at all. He later went back to undergo the proper treatment. He experienced side effects at first (rashes and painful diarrhea), but eventually he recovered.

He believes that 10,000 Gulf War veterans have died. He has a hard time keeping jobs, and now works in a salvage yard (which he does not like). He believes that Gulf War illnesses have permanently damaged his health over the last ten years and that is too long for the government to decide on treatments.

Mr. Maryan's mother faxed the testimony to the IOM for him, and she included a note of her own. She wrote, "The longer you have the bug, the harder it is to get rid of it." She pleaded for someone to help her son.

Since she still had a little extra time, Mrs. Brown added some of her own thoughts. Dr. Hyman taught his technique to Drs. Fishbeine and Walen. She also went to visit his office. Within five minutes of entering, he had cathcterized her, and he allowed her to see the bacteria in her own urine. Subsequent test revealed that her husband, their two autistic children, and her mother also have bacteria in their urine. She suggests that any money that the government gives to Dr. Hyman "will be well-spent." She asked, "Where are we on this?" She urged the IOM to answer "the people's questions."

Dr. Ruth McGill

Dr. McGill made a presentation on behalf of Dr. William Baumzweiger. She works hard to connect Gulf War veterans to physicians like Dr. Baumzweiger and Dr. Haley. She said of herself, "I'm second only to Ross Perot in philanthropy, although it's a distant second."

She has also experienced mysterious illnesses for forty years. She knows that her symptoms are real and does not like it when anyone uses the term "somatic." She said, "Death is not somatic."

Dr. McGill worried because no one has an up-to-date number on the Gulf War deaths. She showed an outline of how the number, especially the one that the VA published, has varied. The GAO decided in 1998 that they could not have an accurate count.

Dr. Baumzweiger typed her slides. He defined a clinical test that he can teach to everybody so that they can make the diagnoses in their office. He finds dysautonomia symptoms the most troubling and the most likely to wind up under a psychosomatic diagnosis. He wonders if central nervous system irritability caused her disease. Dysfunction in the brainstem killed Karl Myer. Cranial nerve dysfunction has proven important, and physicians can document it using "high-tech diagnostic methods."

Dr. McGill has paid most of the $1.2 million that her treatment cost out of her own pocket. Private insurance will not pay for it or recognize it because the government will not pay for it or recognize it. She closed with that thought.

Ms. Denise Nichols

Ms. Nichols served in Saudi Arabia during the Gulf War as a nurse with more than twenty years experience. After the war she had to step aside from nursing because of fatigue and memory loss. She did not want to have to do that and wishes that she could go back into nursing. While she talked, she had a helper flash up random pages from medical charts (never established if they were hers or someone else's) on the overhead projector.

"To treat Gulf War veterans effectively, physicians need to diagnose them correctly," she said. Right now, the VA and DoD doctors do not use SPECT scans, viral testing, specialized MRIs, etc., despite numerous presentations on these. She advocated at least a mycoplasma test for all Gulf War veterans and for those who didn't deploy but who now have the same symptoms. She feels that avoiding these tests constitutes medical malpractice.

She cannot receive diagnosis and care through the VA system. She has gone to independent labs to receive the tests that she wants. All of them showed abnormalities. Then when she took the results back to the VA, the doctors referred her to the psychiatry department. She cited that as "evidence of a non-written policy."

Ms. Nichols gave a whole list of doctors that she believes need funding. She has mentioned them during previous testimony to the PSOB and during Town Halls; Dr. Baumzweiger figured first among them. She concluded by citing 220,000 veterans as sick, and she voiced her determination to go out and conduct research on her own.

Sergeant Harold Nelson

Sergeant Nelson currently holds an active-duty position in the Army as an operations Sergeant. He participated as Dr. Hyman's double-blind study for active-duty Gulf War veterans. He referred to himself as "one of Dr. Hyman's patients."

He documented a little of his health history. In November 1990, while stationed in the Gulf, he experienced an infection that caused gross swelling in all of his lymph nodes. The swelling eventually subsided, but the lymph nodes still felt sore. In August 1991, other symptoms appeared, and his condition worsened. In 1992, his wife and son fell ill. During this time, he learned to deal with his own illnesses and requested antibiotics from the military medical system. In 1995, he rotated through a tour in Korea. While strenuous, he enjoyed the work and took pride in his accomplishments. But by September 1997, he realized that he still wasn't well. In 1998, he went through cycles of his symptoms recurring and subsiding, and at the same time he lost normal use of his right leg.

But since beginning Dr. Hyman's treatment, he has not experienced any new symptoms or flare-ups of previous problems. He leads a more active life style – jogging twelve miles a week and going on several bike rides, sometimes for as far as ten miles. He attends school, where he has earned a 4.0-grade point average.

He described a comrade with a slightly different case. That soldier experienced more symptoms, although his family members did not display any chronic illnesses. He had an extensive physical profile. He recovered more quickly than Sergeant Nelson, describing himself as "sharper" and "as well as I have ever been."

Mr. Kevin Messer

Mr. Messer started his talk by explaining that he does not have a professional degree or much experience as a public speaker. However, he gave a very forceful delivery. He thanked Drs. Hunt and Richardson for calling him a "human being" instead of a "patient."

While serving during the Gulf War, Mr. Messer didn't think that he had a choice about the PB pills or the anthrax vaccine, so he took them. Eventually, he experienced severe elbow pain, which he described as "clamps turning tighter and tighter, until you think that they can't get any tighter, and then you wake up the next day and they're even worse." He measures his endurance to this, not his pain.

He received a fibromyalgia diagnosis for this condition. At first he couldn't believe it. He wanted the VA to say that he had "Gulf War Syndrome" because he felt that the VA "owed me something." Since then, he has become his own care manager. He read the book *When the Pain Won't Go Away*, about fibromyalgia, which he recommended to the committee. He does not know if he has fibromyalgia, but he acted more accepting of the diagnosis during this part of his speech.

He and his wife also tried have more kids after the Gulf War (They had two previously.). They tried for six years before consulting a fertility doctor. The doctor said that they couldn't have children without explaining why. But shortly after starting Dr. Hyman's study, his wife told him that she was pregnant. They now have a one-year-old baby.

Mr. Messer described his cognitive deficit situation as a "fibro fog." He does not want his retirement check and disability. If someone will make him well again, he would rather return to work.

Mr. Michael Oldaker

Mr. Oldaker provided a good presentation of what specific treatments worked and didn't work for him. He started experiencing black outs immediately after receiving the anthrax vaccination. He told a story about how in 1994, while on recruiters' duty and ready for Administrator Outprocessing, he felt like he was choking to the point where his roommate called an ambulance. The emergency room doctor diagnosed this as a panic attack. At his follow-up appointment, the physician called his problem vertigo. Twenty-four hours later a psych technician made the diagnosis of stress.

In subsequent experiences, Mr. Oldaker had difficulty securing even doctor-ordered tests. While serving in Cuba, he suffered from sun poisoning/heat stroke. In 1997, he developed tremors about one year after medically retiring. Those occurred about one month after he underwent heart studies, and he still cannot control his heart's fibrillation. The VA has yet to recognize his tremors, memory loss, depressive disorder, or the joint and muscle pain in his knees that forces him to walk with a cane.

Mr. Oldaker concluded his presentation by pulling the various medications that he takes (at least ten bottles of pills) out of a grocery bag. One by one, he explained what worked, lining up each bottle on the podium in front of him. None of his cardiovascular medicines have helped. One doctor recommended that he try six ounces of whiskey for the tremors, but that still didn't control them. Antibiotics work, but the VA will not provide those. He has found non-psychological treatment the most beneficial.

Mr. Lawrence Plumlee

Mr. Plumlee represents chemically injured patients. He cited Dr. Haley's PON-1 studies as part of his testimony and believes that troops experienced exposure to low-level doses of sarin. He also conducted a very technical discussion.

He made several treatment recommendations. Nutrients will improve detoxification. He thinks that antioxidants will reduce free radicals. Veterans should lower the level of yeast in their intestinal flora. Food sensitivities may occur, and veterans need to avoid these. The problems with food sensitivity may stem from impaired metabolism. He views Gulf War illnesses as similar to pesticide poisoning.

Mr. Frank Sauer

Mr. Sauer shared his personal experiences. He is one of Dr. Hyman's patients. While serving in the Army, he saw tours in Vietnam, Australia, and the Gulf region.

He reread the committee's charge in the meeting announcement and asked, "How can they successfully identify treatments for Gulf War veterans when they only use VA and DoD data?" He traveled extensively while in the Gulf, including to countries like Syria and Jordan. He experienced symptoms as early as 1989, while stationed on the Sinai Peninsula. Since then, he has battled systemic medical problems.

He has saved his well-documented diagnoses from private physicians. Dr. Hyman told him that he had "extensive carpal tunnel syndrome" (I may have caught this wrong.). Mr. Sauer underwent Dr. Hyman's treatment and found the IV antibiotics more helpful than the oral ones. He has taken them since 1995. Between 1996 and 1998, he regressed. At the end of 1998, he resumed his treatment, and it cured his symptoms for six months. Within ten days of starting the antibiotics (while still in the hospital), he began exercising again.

He has talked to dozens of veterans (out of the thirty-six that Dr. Hyman treated), and they all tell the same story. Mr. Sauer stated, "I'm glad that I haven't succumbed to Lou Gehrig's disease." Still, the treatment has not given him 100 percent relief from his symptoms. He now manages them with the oral antibiotics that Dr. Hyman prescribes.

His wife also experiences problems. Unfortunately, she cannot receive Dr. Hyman's treatment, as she is not a veteran. Other veterans have reported similar difficulties with finding care for their family members.

Mr. Steve Smithson

Mr. Smithson represents the American Legion and holds the position of Assistant Director for Veterans' Affairs and Rehabilitation. He noted that the health care process does not take place in a vacuum. Frustration with the system aggravates the veterans' health problems. Within the VA, the compensation and treatment departments are often at odds with each other. Ill-defined conditions cause the most dispute. A diagnosis for some symptoms (leaving others as "undiagnosed") still prevents a veteran from receiving undiagnosed illnesses benefits.

Mr. Smithson focused more on the idea of, "The way that the doctor carries out the treatment affects the veteran's quality of life." He emphasized several points. Treating physicians need to receive education on Gulf War illnesses. Doctors must not make a diagnosis without first performing diagnostic tests. They should always consider their patients' quality of life. All hospitals have to implement the IOM's final recommendations consistently.

At this point it looked like the meeting might end (Ms. Hernandez had scheduled Mr. Smithson to speak last.), and Dr. Rosof rose to make his final remarks. But Ms. Nichols interrupted him to point out her dissatisfaction with the proceedings. All of the veterans traveled to testify before the committee at their own expense. Yet the committee had not asked one question during the afternoon session. "Why not?" Ms. Nichols repeated her question several times. She was angry that they finished early, as most of the veterans could've talked beyond their ten-minute time limit.

Mrs. Brown agreed with her. She wanted the veterans to speak first. Because of the extra amount of time, Dr. Rosof allowed Mr. Kirt Love to speak.

Mr. Kirt Love

Mr. Love had originally allowed Ms. Hammack to speak in his place in the interest of time, so now he wanted to give her presentation. He did not follow her written

testimony at all (Her planned comments appear at Tab J.). Instead, he talked about his concerns, with which OSAGWI is very familiar.

Mr. Love recommended putting "everything" in one location. Doing so will facilitate the agencies coordinating. The government also needs to make the information available. He recounted his difficulty in trying to secure a catalog of Gulf War samples from the AFIP. While the people that he has spoken to him assure them that such a catalog is feasible, they have not produced one and/or made it available to him. So, Mr. Love has taken to inventorying everything that the government has. He will not let Gulf War issues die in December.

He finds the various committees at which he has testified unproductive and wasteful. He alluded to their accountability, and Ms. Nichols agreed. The medical providers need to interact with each other. Many veterans will come testify if only someone will fund them. He referred to himself as a "point walker case," and he still has trouble finding enough money.

Doctors and researchers should use the registry programs for six months as a method of building a baseline. He does not agree with the somatoform and PTSD diagnoses that they make. He wants the registry programs to include other tests besides psychological ones.

The problems will not go away if the government adopts the attitude of waiting them out. The veterans need a better strategy. Mr. Love shared his plans to move to the DC area so that he can interact with all the agencies.

Questions and Answers

The question and answer session applied to all of the afternoon presentations. Dr. Isabel Hoverman began by asking for some clarifications about Dr. Hyman's treatment. Does everyone take the same amount of antibiotics? Mrs. Brown answered, "Yes." What articles has he published? Mrs. Brown could not name any articles, but she talked about his numerous presentations, including ones to government doctors (VA and DoD). He has published some abstracts. Colonel Engel "squelched" Dr. Hyman's attempts at sharing his work. Dr. Hoverman wondered, "How can Colonel Engel squelch something in the peer-reviewed, published literature?"

Another question surfaced about the Desert Storm Battle Registry. Mr. Love had stepped out of the room for a minute, so Ms. Hammack answered it for him. Mr. Love formed the registry by collecting data from other veterans. He surveyed them about the treatments that they received and took down their names and addresses. Now, he has put the registry on the Internet and included a section about exposures that veterans experienced while in the Middle East area. She had no idea how many veterans that Mr. Love has "registered."

Ms. Hernandez spoke up to say that Dr. Hyman promised to fax additional information to the IOM. Mrs. Brown has some of his abstracts and original copies of his slides; Dr. Hyman gave them to her personally. She offered to make copies for whoever wanted them and referred to others available on the Internet.

Dr. Miller believes that Dr. Hyman has jumped ahead of the other researchers because his Congressman sat on the Ways and Means Committee. She urged the IOM to expand their charge and make additional recommendations (presumably for funding Dr. Hyman, although she did not come out and say so). She argued that with the coming

election, the politicians will set the funding for the next four years, and right now the IOM can influence that.

Mrs. Brown ended the question and answer session with the quote, "Ignorance is not objectivity."

Conclusion

Dr. Rosof closed the day by telling the participants that they may submit written information to the IOM. The committee will appreciate anything that arrives in the next two months. However, they will take anything up through December, when they will submit their final report.

Committee on Identifying Effective Treatments for Gulf War Veterans Health Problems
Committee Meeting
August 14, 2000

Workshop Agenda

9:00 Welcome and Introduction
Bernard Rosof, MD, Chair

9:15 Treating U.S. Gulf War Veterans—Presentation and Discussion
Stephen Hunt, MD
Ralph Richardson, PhD

10:00 Gulf War Veterans Health in the United Kingdom—Presentation and Discussion
Col. John Graham, British Liaison Officer [Gulf Health]

10:30 BREAK

10:45 Irritable Bowel Syndrome—Presentation and Discussion
Howard Spiro, MD

11:30 Medically Unexplained Physical Symptoms
Charles Engel, MD

12:15 Concluding Discussion

12:30 LUNCH

1:30—1:40 Introduction—Bernard Rosof, MD, Chair

1:45—1:55 David Berg, MS
Director, Hemex Laboratories, Inc.

2:00—2:10 Janyce E. Brown, BFA
Editor/Publisher, The Surface Report

2:15—2:25 Edward J. Bryan, veteran
Health Care Liaison, VA-Boston University Advisory Group

2:30—2:40 Kathleen Hannan, MD, Radiologist
Osceola Regional Hospital, Orlando, Florida

2:45—2:55 Edward Hyman, MD. FACP

3:00—3:10 James Johnson, US Army (Ret.)

3:10—3:30	BREAK
3:35—3:45	Kirt Love Desert Storm Battle Registry
3:50—4:00	Mark Colins Maryan Gulf War Veteran
4:05—4:15	Ruth McGill, MD
4:20—4:30	Kevin G. Messer Staff Sergeant, USMC Ret.
4:35—4:45	Harold Nelson Staff Sergeant, US Army
4:50—5:00	Denise Nichols, Vice Chairman National Vietnam and Gulf War Veterans Coalition
5:05—5:15	Michael Oldaker USMC, Ret. Medical
5:20—5:30	Lawrence Plumlee, Co-President National Coalition for the Chemically Injured
5:35—5:45	Frank Sauer, Sergeant Major US Army Retired
5:50—6:00	Steve Smithson, Assistant Director for Veterans' Affairs and Rehabilitation, American Legion
6:00	Closing Remarks, Dr. Bernard Rosof, Chair

The National Academies
Institute of Medicine

Committee on Identifying Effective Treatments for Gulf War Veterans' Health Problems

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MembershipStatement of Task

Statement of Task

Major Unit: IOM
Division, Office or Board: Health Promotion and Disease Prevention
Sub-Unit:
Subject Committee: Identifying Effective Treatments for Gulf War Veterans' Health Problems
Staff Officer Name: Lyla Hernandez

STATEMENT OF TASK

Statement of Task: The purposes of this project are to (1) identify and describe methods for evaluating treatment effectiveness, regardless of disease or condition, (2) identify illnesses and conditions prevalent among Gulf War veterans, including medically unexplained physical symptoms, and (3) identify valid models of treatment for such illnesses (to the extent that they exist) or identify new approaches, theories, or research on management of patients with these conditions if validated treatment models are not available.

Sponsor(s): Department of Veterans' Affairs

Date of Statement: 11/04/99
Date of Previous Statement: 11/04/99

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National Research Council

Board on Health Promotion and Disease Prevention

Notice Regarding Open Sessions

This Meeting is being held to gather information to help the committee conduct its study. This committee will examine the information and material obtained during this, and other public meetings, in an effort to inform its work. Although opinions may be stated and lively discussion may ensue, no conclusions are being drawn at this time; no recommendations will be made. In fact, the committee will deliberate thoroughly before writing its draft report. Moreover, once the draft report is written, it must go through a rigorous review by experts who are anonymous to the committee; the committee then must respond to this review with appropriate revisions, and the report must adequately satisfy the Academy's Report Review committee and the chair of the NRC before it is considered an NRC report. Therefore, observers who draw conclusions about the committee's work based on today's discussions will be doing so prematurely.

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Veterans needed for medical trials across US

EXCERPTS By Diana Berardocco, Public Affairs. Edited by Wendy Wendler

The Department of Defense and the Department of Veterans Affairs will continue to recruit participants until April 2000 for two medical treatment trials which began last spring. Researchers hope the studies will advance current understanding of the illnesses affecting some veterans and explore possible treatment options.

"We have had a universally good veteran turn-out for these studies, said Army Lt. Col. Charles Engel, M.D., chief, deployment health clinical center at Walter Reed Army Medical Center in Washington, D.C. "We are on track, but we are still actively seeking Gulf War veterans who are concerned about their health."

The two treatment trials, EBT for Exercise-Behavioral Therapy and the Antibiotic Treatment Trial, are being conducted at 36 different Veterans Affairs and DoD medical facilities nationwide. The EBT study examines whether aerobic exercise and cognitive behavioral therapy will improve the life for ill Gulf War veterans. The Antibiotic Treatment Trial tests the theory that ill Gulf War veterans who test positive for an organism called Mycoplasma fermentans incognitus will feel better after receiving antibiotic treatment with doxycycline.

The response from veterans has been geographically broad-based. Engel said he is pleased that veterans are volunteering from around the country, often after receiving mailings from participating sites or attending local DoD and VA-sponsored meetings.

To be eligible for either study, veterans must have served in the Gulf War between August 1990 and August 1991 and currently have at least two of three unexplained symptoms – debilitating fatigue, joint and muscle pain, or memory and thinking problems. The symptoms must have been present for more than six months.

More than 1,300 volunteers are being recruited for the EBT study where the focus is rehabilitative rather than curative. This study will use methods proven to improve the lives of people with a variety of illnesses such as chronic fatigue syndrome, fibromyalgia and even multiple sclerosis. The study seeks to improve a person's capacity to cope with functional challenges and symptoms, Engel said. After seven months, more than 1,200 veterans have been screened, 350 people have been selected and the numbers are climbing.

Engel explained that a pattern has surfaced among potential volunteers that has made the target numbers for the exercise-behavioral therapy trial slower to achieve. Interested volunteers often prefer the option of medical treatment and choose to participate in the antibiotic study.

Engel said he is confident that both studies will achieve the needed participation even though it has been harder to enroll patients in the EBT than the antibiotic treatment trial.

"Whatever we learn from the studies, the results will significantly inform the medical community on how to help Gulf War veterans," Engel said.

Both treatment trials promise to increase the medical community's understanding of chronic multi-symptom illnesses. The void in medical knowledge for these conditions has often led veterans to become dissatisfied with medical practitioners' inability to prescribe curative treatment, Engel said.

The trials have another benefit.

"It exemplifies the spirit of veterans helping veterans," Engel said.

From the desk of Bernard D. Rostker Special Assistant for Gulf War Illnesses

In November, our team completed its 14th Total Force Outreach to Fort Benning, Ga. As we met with veterans, I was reminded of a problem that we've seen since we held the first outreach at a military installation nearly two years ago – veterans are toughing it out, rather than seeking treatment.

The Department of Defense established the Comprehensive Clinical Evaluation Program – the CCEP – to provide in-depth medical evaluations for Gulf War veterans currently serving in the active or Reserve components, or those who are retired. Personnel who have served in Southwest Asia during the war or since that time, and their eligible family members, who want medical examinations are encouraged to make an appointment.

To schedule an appointment, call toll-free at (800) 796-9699 or DSN 878-3261. For those overseas who do not have DSN access, the direct line for the CCEP is (408) 583-2500 between the hours of 6 a.m. and 4 p.m. Pacific time, Monday through Friday.

If you have health concerns, don't tough it out. We want you to receive the care you deserve. I encourage you to call either the CCEP or the VA's Persian Gulf Registry Program today.

DoD Medical Centers

Naval Health Research Center
San Diego, Calif. ..... (619) 524-0369
Walter Reed Army Medical Center
Washington, D.C. ..... (202) 782-3473

Antibiotic therapy trial

VA Medical Centers

Albany, N.Y.	(518) 462-3311 x 3080
Albuquerque, N.M.	(505) 265-1711 x 2596
Augusta Ga.	(706) 733-0188 x 2305
Birmingham, Ala.	(205) 933-8101 x 5550
Boston, Mass.	(617) 232-9500 x 4340
Bronx, N.Y.	(800) 877-6976
Brooklyn, N.Y.	(718) 630 2875
Charleston, S.C.	(843) 577-5011 x 7376
Dayton, Ohio	(937) 268-6511 x 1212
Durham, N.C.	(919) 286-6950
East Orange, N.J.	(973) 676-1000 x 2157
Fargo, N.D.	(701) 239-3700 x 3024
Hines, Ill.	(708) 202-8387 x 24509
Houston, Texas	(791) 794-766
Manchester, N.H.	(603) 624-4366 x 6898
Milwaukee, Wis.	(414) 384-2000 x 1958
Montgomery, Ala.	(334) 272-4670 x 4466
Nashville, Tenn.	(615) 327-4751 x 7925
New Orleans, La.	(504) 568-0811 x 5490
Oklahoma City, Okla.	(405) 270-0501 x 5201
Omaha, Neb.	(402) 977-5632
Providence, R.I.	(401) 457-3045 x 3460
Richmond, Va.	(804) 675-5000 x 3638
Salt Lake City, Utah	(801) 582- 1565 x 1466
San Francisco, Calif.	(415) 221-4810 x 2287
San Juan, PR	(787) 641-7582 x 13131
White River Junction, Vt.	(802) 295-9363 x 6054

Are you a Gulf War veteran (or know of one) with health concerns? Call the CCEP at: 1-800-796-9699

Your ticket to the information highway — visit our GulfLINK web site at: *http://www.gulflink.osd.mil*

Gulf War veterans seeking information on VA benefits of all types should call the Persian Gulf Helpline at: 1-800-749-8387

GulfNEWS is produced by the Office of the Special Assistant for Gulf War Illnesses, 5113 Leesburg Pike, Suite 901, Falls Church, VA 22041. Send your comments on this newsletter to Lisa Gates at the above mailing address, or by email to: *brostker@gwillness.osd.mil*

VETERAN VIEWS: *INFECTIONS PLAGUE GULF VET FAMILIES & OTHERS*

10th Anniversary

Wendy Wendler, MBA-Health Mgmt., Box 59798, Dallas,TX 75229, 888-318-9891 [With Desert Storm Justice Foundation material]

August 14, 2000

"14 Aug 90 C+7 (On Aug. 8th) the first American soldiers (arrived)...While 'Pentagon sources' (told) journalists our forces would be 'impregnable' by the first weekend, I knew the Iraqis could overrun the Saudi oil region...I'd never dealt with anything so complex, nor had to make so many key decisions so quickly, in my life...Saddam (trapped) 13,000 westerners and other foreigners...The taking of (US) hostages could be cause for war, and I felt sick to my stomach at the news." Gen. Norman Schwarzkopf, *It Doesn't Take A Hero*, 1992.

CHRONOLOGY [Life-altering and potentially lethal micro-organisms attack both allies and enemies for a decade.]

8/90-3/91 – Operations Desert Shield & Desert Storm + Provide Comfort & start of "no-fly" duty to date;

6/93 – Drs. Hyman, McGill & Rea + Hyman's Gulf-Vet patient Kimo Hollingsworth (now staffer for sick Gulf-Vet/US Rep. Steve Buyer) shed light on already known aids to House Subcommittee head, Rep. Lane Evans;

8/95 – First Lady Hillary Clinton opened 1st Presidential Advisory Committee (PAC) session, promising to "leave no stone unturned" in finding treatments for Gulf War Illnesses (GWI), as Hyman's material is submitted re ideas about communicable bacteria he'd studied (and published) since the Vietnam War era (1,000 cases);

2/96 – Dr. Hyman* (& Nicholson) gave PAC input re in-depth antibiotic therapy to remit diverse symptoms; [*forestall chronically recurrent contagious infestations of unusual "indolent" strains of familiar bacteria, readily tested by relatively simple inexpensive means & treated by cost-effective protocols with existing medications, plus nutrition and other immune boosts]; Army delayed Hyman's congressional funding;

Spring'98-Spring'99 – Louisiana Medical Foundation did $3.4 million *Army-manipulated* study of only 3 dozen Gulf Vets, tested/treated for SSB [Systemic Spherical Bacteria = Strep & Staph]; [Hyman parallel screening plan denied]

3/99 – Hyman (semi-retired, age 74) & Deming (retired, age 84) lacked funds to join CDC-GWI meeting, as key advocates pleaded for antibiotics; a Hyman/Army patient came, bemoaning dearth of long-term help;

Summer'99 – Drs. Hyman/Deming's report for Army Surgeon General (Blanck) presented only to VA/Puessner & Col. Charles Engel, head "shrink" at Walter Reed Hospital's GWI program, detailing statistically remarkable results in both blinded sets of Gulf Vets from only 3 weeks on antibiotic infusions; yet patients & loved ones were denied further testing, medicine & crucial support [while Hyman coped with Army's unpaid bills];

9/99 – Drs. Hyman/Deming, with patients better on short-term drugs in Army & '92-'93 *pro bono* studies, told IOM findings re GWI causes, touting thorough antibiotic efficacy; Army paid Hyman for secretive treatment of GI & wife, who tried to sabotage & slander him; [Hyman-tested Vet committed suicide without VA/private treatment]

Fall'99-Spring'00 – Louisiana Medical Foundation sent, revised (as suggested) and re-submitted an SSB treatise to the *Journal of Internal Medicine*, where it mysteriously remained waylaid for too many months;

3/00 – Hyman with Dr. Quentin Deming showed Drs. Fishbein & Whalen at Armed Forces Institute of Pathology how to test urine for SSB, using a "fresh" sample from Walter Reed Hospital [Whose?] and a preserved specimen from Hyman's first Gulf Vet patient's desperately sick wife [treated earlier too];

4/00 – Another ailing wife of a GWI soldier (*Viscerotropic Leishmaniasis* & SSB) filmed Hyman's test of her "sick" urine, besides positive SSB tests on her 2 birth-defective children and mother; yet her father can't be tested, as Hyman returned private funding to document infection/carrier factors among Gulf War participants' kith and kin and then suffered a stroke [likely GWI-symptomatology pattern].

POPULACE [Doesn't include other war-connected GIs + civilians: US/UN & corporate employees, alien workers, etc.]

{Note #s	US Military personnel deployed to the Gulf War area of hostilities (8-2-90 thru 7-31-91)	"696,641"
& times	US Military personnel deployed to that postwar theater of operations ('91 thru '99??)	250,000+
differ among	Current Estimation of America's Gulf War Vets	1 million
Depts.}	[Affected Relatives Hypothesis = +5] Estimated Defense/Military Family Constituents	6 million

"BUDDY COUNT" [Coordinating Board (DoD-VA-HHS) neglects consensus statistics re periodic mortality updates.]

In Their Memory

5/96 – Match deployed troop roster (8/90 thru 7/91) to recent Social Security deceased list = "4,291"

4/97 – DoD's Dr. Rostker orally reported a timely death tally at VFW, Dallas, TX = "more than 6,000"

12/97 – VA mortality study shortened period (8/90 thru 3/91) re "695,516" theater/deployed = "4,506"

1/00 – DoD/OSAGWI-Rostker re deaths (longer period, 8/90 thru 7/91 w/oilfires from VA Public Affairs) = "6,584"

[8-2-00 – BRAVO/CableTV aired Michael Moore's *The Awful Truth* re GWI losses from an unidentified source = "9,600"]

WHERE DO WE GO FROM HERE? To more meetings with Congress, the Institute of Medicine, etc...

[Ask Gulf War "heroes" Stormin' Norman, Powell, Bush & Cheney + the Clintons, VP Al Gore & Sen. Joe Lieberman.] ###

Under penalty of perjury, I swear the statements above are true & correct to the best of my knowledge, information & belief at this time. Wendy Wendler 8/12/00

Irritable Bowel

Bowel habits and character do not change throughout life, without cause

My Definition

- Abdominal pain related to (relieved,worsened) bowel movements — main point
- Present since adolescence

1

Disease and Illness

- Disease
  - What the doctor finds (sees)
  - The diagnosis
- Illness
  - What the patient feels (fears)
  - The complaint

3

The Eye and The Ear

- The eye is for Accuracy
  - Stool guaiacs
  - Lactose tolerance test
  - Colonoscopy…
- The ear is for Truth
  - Symptoms
  - Response to therapy

4

Pain

- More than the C-fibers firing
- Sometimes sorrow CS. Lewis
  anguish
  tribulation

Is IB from the colon or from the head?
Or both?

9

Psychosomatic Musing

- "The sorrow that has no vent in tears makes other organs weep" — catharsis
- Mind or Brain?
  - Perception (mind)
    - visceral hypersensitivity
    - anticipation
    - attention
  - Neurobiology (brain)
    - learned response
- Psychology and/or biology
  - Colonic pathophysiology

8

Irritable

Colon - end
Bowel - 21ft small intestine + large intestine
Gut - the whole system

2

Pelvic Pain

Irritable bowel
Endometriosis
Overactive bladder

10

Pelvic Pain

- A 35 yr old woman pediatrician with 3 kids
  Pain when lawyer/husband opens garage door at night
- Whom to see?
  - Lawyer
  - Clergy
  - Physician - usually go here
    - GI, GU, Gyn
    - (Cardiologist) deal with same pain, but focus on their system

11

Therapy for IB

- How much is placebic?

Depends on concept of cause

- Dietary
  - Fiber
  - Lactose
  - Allergy
- Pharmacology
  - Anti-muscarinics
  - Anti-depressants
  - Anti-diarrhea/constipation
  - Prokinetics
    - Alosetron
- Psychologic
  - Hypnotism
  - Psychotherapy
  - Coping mechanisms

6

Cause of IB

"The man with two brains"

- Brain/gut share hormones, mediators
- Multifactorial
  - Learned response to stress
  - sensitized colon
  - *Infection
    - Brainerd diarrhea → North Dakota
  - Toxin...
  - Deranged mediators
    - Hormones, cytokines, neurotransmitters

5

Problems In IB Studies

- Most IB "patients" never see a doctor — know what this is part of living
  - <1/3 who do get referred to GI
- Relevance of academic research
  - 2° gain → studying a select population
- Diagnosis by exclusion or by criteria
  - diagnosis as confirmation
- Symptoms come and go
  - vary
  - overlap with functional somatic syndromes
- Alarm "red flag" symptoms

7

The Manning Criteria

- Abdominal pain with 2 or more of the following:
  - relieved by defecation
  - associated with more frequent stools
  - looser stools
  - mucus
  - distension
  - feeling of incomplete evacuation

Modified from Manning, AP et al, Brit Med J 1978;2:653

12

The Rome I Criteria

At least three months continuous or recurrent symptoms of: Abdominal discomfort

- Abdominal pain or discomfort
  - relieved with defecation
  - change in frequency of stool
  - change in consistency of stool
- Two or more changes in stools, on at least 1/4 of occasions or days
  - frequency
  - form (lumpy/hard or loose/watery stool)
  - passage (straining, urgency, feeling of incomplete evacuation)
  - passage of mucus
  - bloating or abdominal distension

Modified from Thompson et al, Gastroenterology International. 1992;5:75

13

The Rome II Symptom Criteria
Irritable Bowel Syndrome

At least 12 weeks or more, which need not be consecutive, in the preceding 12 months of abdominal discomfort or pain that has two out of three features:

- Relieved with defecation; and/or
- Onset associated with a change in frequency of stool; and/or
- Onset associated with a change in consistency of stool

Symptoms that Cumulatively Support the diagnosis of Irritable Bowel Syndrome

- abnormal stool frequency (for research purposed "abnormal" may be defined as greater than 3 bowel movements per day and less than 3 bowel movements per week);
- abnormal stool form (lumpy/hard or loose/watery stool);
- abnormal stool passage (straining, urgency, or feeling of incomplete evacuation);
- passage of mucus;
- bloating or feeling of abdominal distension

In the absence of structural or metabolic abnormalities to explain the symptoms.

14

The Optimist

Irritable Bowel Alchemy

Some time back, I followed my wife into a house that was being burgled. Fortunately, she was preceded by a policeman with two pistols at the ready. While awaiting the arrival of the Black Maria, I gossiped with the officer who had apprehended the miscreant in the classic posture, gripping a pillowcase of swag.

Burglars, he assured me, often dirty their pants in the excitement of their activities, whether they are professionals skilled at their chosen line or amateurs anxious about their performance. I had always taken that phenomenon, of defecation in a living room, to be an act of contempt, but the policeman was of the opinion that was not true, because not uncommonly he had caught burglars with their trousers full of feces.

I remarked that soldiers going "over the top" in the First World War are reputed also to have had involuntary bowel movements, and we two agreed that the gastrointestinal tract remains the "sounding board" of the emotions. He seemed glad to learn about the symmetry of hormones in brain and gut. High emotions do lead to digestive troubles and have always done so.

I bring this up because some gastroenterologists now claim that irritable bowel, once known as "spastic colon" but now usually dignified as irritable bowel "syndrome" or "disease," is the most common cause of absence from work due to illness. Yet whenever I ask an audience of physicians how many of them have stayed away from work because of digestive complaints, very few if any raise a hand.

That may, of course, represent a general unwillingness to exhibit any weakness to one's peers, for industry is a trait of which physicians boast, but I take their silence to mean that because physicians enjoy their work (as I do), they certainly would not use minor discomforts to escape their duties.

If it is true that many people stay home from work because of digestive troubles, they must not be happy in their work and will take any excuse for a break. Indeed, the fixed number of "sick days" permitted by many employers must make it irresistible to enjoy the leisure of that extra-sabbatical gift.

You may object that physicians were largely self-employed in the past and that earning a living kept them working, but I suspect that even salaried physicians rarely avoid medical work. You may also object that surveys are usually carried out by specialists, because gastroenterologists see only those patients who bedevil the family doctor with complaints, and you would be right on both counts.

New agents intended to reduce the perception of abdominal sensations are about to create a need where none may have existed before.

I boast of the faithfulness of physicians not so much in acclamation as in disparagement of the reasons why others take time off. I surmise that boredom or some other graceless response makes their work less exciting and less fulfilling than ours. Tedium is the goad more than the gut.

This is important in view of a new cacophony about to assail the American public, an intent to make irritable bowel syndrome a household word, as common as the complaint itself. The new campaign comes down on us, not so much in a spirit of altruism as in a passion of venality. Several new agents intended to reduce the perception of abdominal sensations are about to create a need where none may have existed before, at least for the 60 to 70% of irritable bowel possessors (I do not like to call them patients) who keep away from doctors as much as they can.

To those who inquire whether the much-touted irritable bowel syndrome is easily recognized, several answers are not out of place. The first, a kind of logical positivism, holds that irritable bowel is a specific disorder one day to be recognized by hallmarks of motility or neuroimmunology, so that, unrolling a scroll, one will display its telltale tags.

The other, more romantic and dangerously intuitive, holds that such symptoms are an existential response to boredom, frustration, gluttony, or some other excess of human passion and that irritable bowel is a response to the troubles and temptations of living in this world. Only in paradise, we of this opinion believe, will people not suffer from digestive symptoms, unless the incessant chanting of hymns of praise brings on dyspepsia or worse.

No one has yet found the holy grail of irritable bowel, a marker like a single gene, and so consensus groups have gathered in sundry watering holes to discuss the matter, supported generously one suspects by pharmaceutical companies about to market new products. One meeting was in Rome, an apt venue given the ex cathedra pronouncements that have emanated thence, decorated appropriately with Roman numerals. The group agreed that a con-

stellation of symptoms makes the syndrome.

In this, they follow several lay proponents of chronic Lyme disease or chronic fatigue syndrome: four or five symptoms give patients the right to claim, and their doctors to assert, that they have an irritable bowel. To be sure, classical clinical judgment sees normal people on a spectrum, with frequent bowel movements at one end and constipation at the other, for which varying amounts of fiber and water are therapeutic. Abdominal pain in relation to bowel dysfunction is usually another Roman essential.

Although in other contexts physicians must be the mediators between the patient's complaints and what is found on our ubiquitous images, that is quite a different matter from lumping symptoms into a syndrome and giving patients a disease when all they have is nervous indigestion. Recognizing an irritable bowel is one thing, deeming it the equivalent of a disease is another.

For heightened perception of internal sensations, agents that reduce that perception might seem to be ideal, were it not for the advertising intended to call attention to the problem. That will also highlight the many sensations that at least half the population already and rightly ignores. Most people with irritable bowel symptoms never go to a doctor for their internal sensations because they recognize how much the quirks of daily life have to do with how they feel.

A fight with one's spouse, a colleague promoted unjustly it might be, a surfeit of food or drink, bills that cannot be paid, the slings and arrows of an errant child, all may lead to nervous indigestion that most people do not deem worth bringing to a physician. Those who do so are often described as quite a bit different from those who go about their daily work accepting what life brings.

As I understand the findings, and I emphasize that they have not been published, at least one of the new agents reduces the abdominal pain of 20% of the women who have pain and diarrhea as the main characteristic of their problem, at the price of increasing constipation, which may come as a blessing to that group. The research behind these agents is worth reviewing.

In the mid 1980's, investigators showed that odansetron, a 5-HT_3 receptor antagonist effective in the relief of nausea and vomiting, also seemed to relieve some of the sensations of irritable bowel and dyspepsia. As the intrinsic neurons containing serotonin (5-hydroxytryptamine, or 5-HT) modulate visceral sensations and also regulate gastrointestinal motility, further investigations on the irritable bowel proved irresistible, the more so as serotonin has a wide distribution in the gut and is the neurotransmitter of a subset of myenteric neurons. Most work on irritable bowel so far has focused on 5-HT_3 antagonists, which decrease colonic motility, prolong intestinal transit, and most importantly decrease sensitivity of the colon to distention.

Other agents wait in the wings, among them so-called kappa agonists, other serotonin or cholecystokinin antagonists, and newer analogs of somatostatin. Nor should the antidepressants be forgotten. Over the next few years we may expect many new agents targeted at (1) peripheral terminals of visceral afferents, (2) dorsal horn neurons in the spinal cord, and (3) the limbic system and the prefrontal cortex, which are deemed to be at least mechanistically responsible for hypervigilance and central processing of pain.

Recognizing an irritable bowel is one thing, deeming it the equivalent of a disease is another.

In the meantime, people who live with their minor digestive complaints will soon be bombarded by advertising intended to get irritable bowel patients in to see their doctors. All that may well impel people to find or seek medical help when changes in their social and emotional situation could help as well. Ivan Illich many years ago protested the "medicalization" of society, and things have gotten worse since that time. His book Medical Nemesis, recently republished as Limits to Medicine, deserves rereading.

When the new cacophony of information to enlighten, or maybe to worry, the public brings many more folk to their doctors, practicing physicians may raid the diagnostic larder for a number of endeavors, not the least of which will be a sigmoidoscopy or even, it seems likely, a colonoscopy to rule out some other cause of the problem. Having done the various tests, the doctors will then prescribe the requisite new medications, boosting the overall medical bill quite a bit.

Physicians will be happy at the increased work, instrument manufacturers will rejoice at increased use of their technology, hospitals will get their share, and pharmaceutical stocks will rise, all to prevent what many might have ignored in the first place.

If placebos relieve pain by reducing expectation or by changing perception, and if the studies so far unpublished purporting to show a 40% placebo response against a 60% drug response are correct, then it might be easier on the patients and on the general exchequer to await more studies of efficacy before spreading the nets. For many patients, taking the time to talk and listen, and a few dietary measures, might bring benefit enough. Catharsis, not cathartics.

HOWARD M. SPIRO

Program for Humanities in Medicine
Yale University School of Medicine

Stepwise Care for The Recently Deployed and Their Families

A Population-based Model of Care

Charles C. Engel, Jr., M.D., M.P.H.
Lieutenant Colonel, Medical Corps, U.S. Army
Assistant Professor of Psychiatry, Uniformed Services University
Chief, Deployment Health Clinical Center, Walter Reed Army Medical Center

"Over 50,000 British, Canadian, and American troops returned from battle as changed men. Once-vital young men who left to engage a foreign tyrant began to complain of breathlessness, grinding fatigue, irritability, headache, insomnia, and paraesthesias, rendering 70% of them unfit for further duty. 5 years later, fewer than one in six had recovered fully."

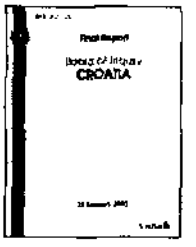
"Specialised research units were commissioned and the best medical minds were enlisted to study these men, to formulate therapeutic approaches, and to devise strategies for preventing similar outcomes in future military campaigns. Reports were published of vascular instability, hyperventilation, bacilluria, and other physiological and laboratory anomalies in the veterans. Some reports claimed that the fear of injury and exposure to poison gas had emotionally crippled these young men, especially those with inherently weak constitutions."

...."The year was 1918."

Source NR: Lancet 1999; 353:

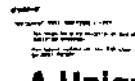
A Unique Phenomenon?

"Soldiers claim ill health after contact with contaminated soil in Croatia"
- Lancet, Aug. 1999



A Unique Phenomenon?

"Dover airmen report myriad ill effects from anthrax shots: one in four detail adverse reactions in pilot's informal survey"
- Air Force Times, April 17, 2000



A Unique Phenomenon ?

1992 El-Al Boeing crash in Amsterdam

A Unique Phenomenon?

THE SUNDAY TIMES

April 16 2000 BRITAIN

Ailing troops sue over Balkan war syndrome

SOLDIERS who served in the former Yugoslavia plan to sue the Ministry of Defence (MoD) after suffering chronic health problems they believe were caused by "Balkan war syndrome", writes *Lois Rogers*.

Doctors link their symptoms to exposure to depleted uranium in anti-tank missiles used during the Kosovo conflict. Research has shown that the heavy metal causes . . .

A Unique Phenomenon? War Syndromes and Their Evaluation

- "Poorly understood war syndromes have been associated with armed conflicts since at least the US Civil War."
- "...war syndromes have involved fundamental, unanswered questions about the importance of chronic somatic symptoms..."

Hyams et al. *Ann Intern Med* 1996;125:398

Unexplained Physical Symptoms

Physical symptoms and health care use that is inadequately explained by medical causes.

Deployment Health Cli

Assertion

Post-deployment care necessarily involves appropriate care of medically unexplained physical symptoms and management of deployment-related health concerns.

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Unexplained Physical Symptoms Medicine's "Dirty Little Secret"

Specialty	Clinical Syndrome
Orthopaedics	Low Back Pain Patellofemoral Syndrome
Gynecology	Chronic Pelvic Pain Premenstrual syndrome
ENT	Idiopathic Tinnitus
Neurology	Idiopathic Dizziness Chronic Headache
Urology	Chronic Prostatitis Interstitial Cystitis Urethral Syndrome
Anesthesiology	Chronic Pain Syndrome
Cardiology	Atypical Chest Pain Idiopathic Syncope Mitral Valve Prolapse
Pulmonary	Hyperventilation Syndrome
Endocrinology	Hypoglycemia

Specialty	Clinical Syndrome
Psychiatry	Somatoform Disorder
Rheumatology	Fibromyalgia Myofascial Syndrome Silicone Is
Internal Medicine	Chronic Fatigue Syndrome
Infectious Disease	Chronic Lyme Chronic Epstein-Barr Virus Chronic Brucellosis Chronic Candidiasis
Gastroenterology	Irritable Bowel
Psychiatry	Conversion-Hysterical Syndrome
Physical Medicine	Mild Closed Head Injury
Occ Medicine	Multiple Chemical Sensitivity
	Sick Building Syndrome

Military Medicine Gulf War Syndrome

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Sources of Morbidity

- Distress – diagnosable, treatable
- Functional impairment – real, not imagined
- Inappropriate health care use - costly
- Diminished credibility – gap is filled by "heroes"
- Iatrogenesis – conservative approach indicated

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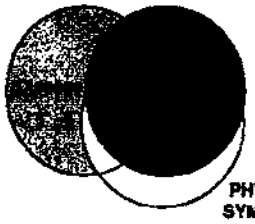
Physical Symptoms

Markers of Disease & Distress



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Distress & Physical Symptoms

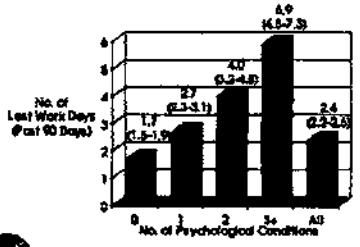
Number of Symptoms	Number of Patients	Psychiatric Disorder N (%) Anxiety	Mood	Any
Physical (N=1000)				
0-1	215	2 (1)	5 (2)	16 (7)
2-3	228	17 (7)	27 (12)	50 (22)
4-6	191	25 (13)	44 (23)	67 (35)
6-8	230	68 (30)	100 (44)	140 (61)
9+	136	58 (48)	84 (60)	113 (81)
Somatoform (N=900)				
0	654	68 (10)	107 (16)	102 (25)
1-2	143	42 (29)	60 (42)	74 (52)
3-5	87	35 (40)	40 (46)	77 (89)
6+	49	40 (82)	34 (69)	46 (94)

Kroenke et al. Arch Fam Med 19

Deployment Health Clin

Illness After The Gulf War

Mental Disorders & Morbidity



Engel, et al. J Occ Env Med. 1999; 4

Deployment Health Clin

Mental Disorders Associated With A Large Portion of Population-Based Disability

Lost	N	Days of Lost Work Total	Mean	% of All
Psychological –	2,453	8,709	3.6	28.0%
Mood:	781	3,106	4.0	10.0%
Somatoform:	608	1,764	2.9	5.7%
PTSD:	400	1,901	4.8	2.8%
Ill-Defined –	2,506	7,169	2.2	17.0%
Musculoskeletal –	2,351	6,757	2.0	15.2%
Neoplasm –	108	871	8.1	2.8%
Healthy –	1,183	866	0.7	2.8%
Total –	18,075	43,771	2.4	100.0%

Engel, et al. J Occ Env Med. 1999; 4

Deployment Health Clin

Iatrogenesis

- Adverse drug reactions alone
  - 6th leading cause of death *
  - estimated 76,000-137,000 deaths annually
- Gulf War veterans' health:
  - aggressive, unproven therapies exist
  - mortality & hospitalization studies suggest less than catastrophic illness progression
  - ∴ conservative clinical strategies indicated

Lazarou et al, JAMA 1998; 2

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Iatrogenesis: Chronic Pain

Type	% (n)
Over - investigation	27 (34)
Inappropriate MH referral	10 (12)
Over - treatment	47 (59)
Inappropriate prescribing	57 (71)
Inappropriate bed rest	50 (62)
Inadequately explained problem	45 (56)
Provider disputed pain validity	25 (31)
Total Sample	100 (125)

Kouyanou et al. Psychosomatic Medicin

Deployment Health Clin

Iatrogenesis
Chronic Fatigue Syndrome

	n=609 CFS	n=397 PriCare
Illness worsened by treatment	66%	22%
Hospitalization for med side-effects	14%	—
Dissatisfaction with healthcare	26%	8%

Twemlow et al. *Psychological Reports*

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Post-deployment Symptoms

An Insidious Public Health Problem

The Best Prevention is CARE

Deployment Health Clin

Population-Based Care of Physical Symptoms & Concerns

- Aim - to improve outcomes through structured care targeting behavior and knowledge
- Emphasis - well-defined care strategy targeting well-defined populations
- Process -
  - identify symptoms and sequelae (outcomes) of interest
  - devise tracking mechanisms for outcomes of interest
  - match resources to needs

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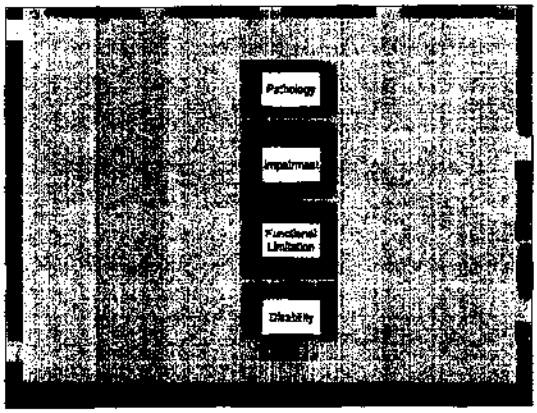
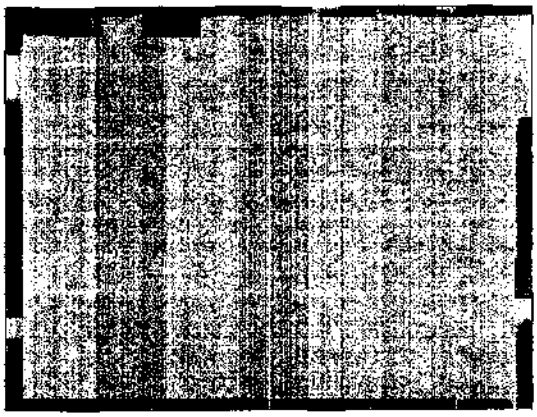


Veteran – Centered Care

The primary goal is for clinician & veteran to *collaborate* in a joint effort to *activate* positive health-related behaviors. The two parties *negotiate* exact & explicit behavioral goals. They *monitor* progress using behavioral indices (e.g., symptom reports, quality of life estimates, or capacity to function and fulfill roles).

Deployment Health Clin



Determinants of Natural History

- Predisposing Factors
  - Hereditary differences
  - Physiological differences
  - Early life adversity
  - Chronic medical illness
  - Chronic or recurrent psychiatric illness
- Precipitating Factors
  - Acute psychiatric disorder
  - Epidemic unexplained illness
- Precipitating Factors (cont'd)
  - Biological stressors
  - Psychosocial stressors
- Perpetuating Factors
  - Harmful illness beliefs
  - Labeling
  - Misinformation
  - Workplace & compensation factors
  - Social support factors

"Medicine as Usual"

History → Exam → Testing → Diagnosis → Treatment


"You're allergic to the environment. We've got to get you off the planet."

Somatization?
Issue of Medical Uncertainty

- Somatization diagnosis hinges on the absence of a medical explanation
- Logical problem: "the absence of evidence is not evidence of absence"
- Chicken – Egg problem: What is direction of causality?
- Clinical problem: what work-up is adequate?
- Research problem: reliability of determination is unknown
- Application problem: "stress" – related to physical symptoms, but for who?

"If You Have to Prove You Are Ill, You Can't Get Well."

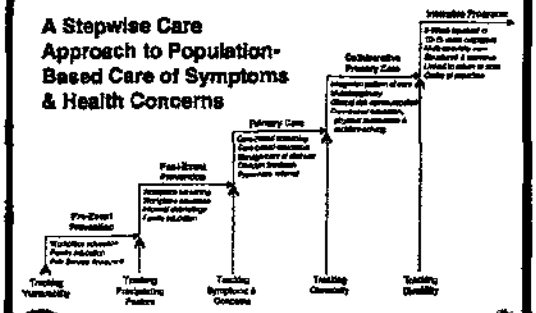
- Norlin Hadler

The Credibility Challenge

- The average American citizen has HIGH CONCERN about the potential for chemical or biological exposures from terrorism or war
- The average American citizen has LOW TRUST their government will "do the right thing" to help victims
- This *Low Trust - High Concern Atmosphere* is especially problematic for...
  - Federal, military and defense agencies
  - Federal health care providers

Deployment Health Cli

A Stepwise Care Approach to Population-Based Care of Symptoms & Health Concerns

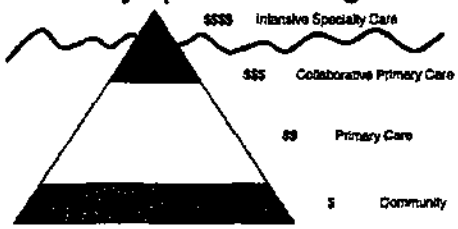


Deployment Health Cli

Why Stepped Care?

Feasible, Systematic, Practical, Efficient, & Personal

A Continuum of Care Addressing The Physical Symptom "Iceberg"



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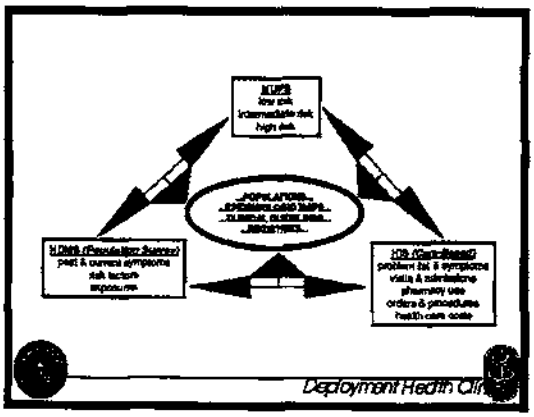

Deployment Health Cli

Summary

- Post-deployment symptoms (PDS) are something we should expect
- Lack of an appropriately caring response exacerbates PDS
- Veteran-centered care rather than disease centered care is needed
- Delivery must be coordinated, population-based and of stepped intensity

Deployment Health Cli

"Unless...wars are fought solely by machines, the human cost of warfare will remain high. The troops must...be given a commitment for all necessary care for war-related illness."

Strous RD: Lancet 1999; 35

Deployment Health Cli

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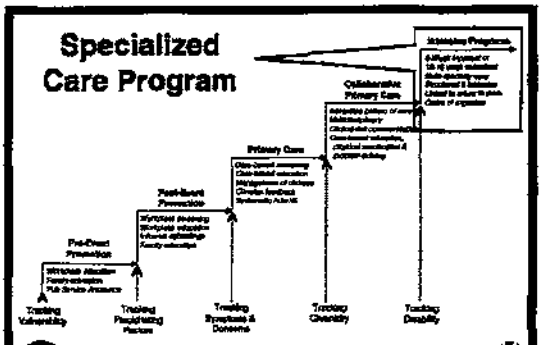
Where Are We Now?

Deployment Health Clinical Center Efforts

Deployment Health Cli

Specialized Care Program



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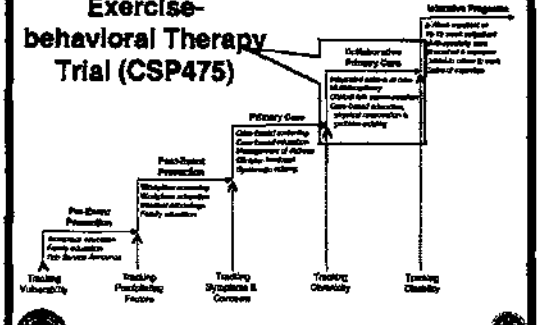
Exercise-behavioral Therapy Trial (CSP475)



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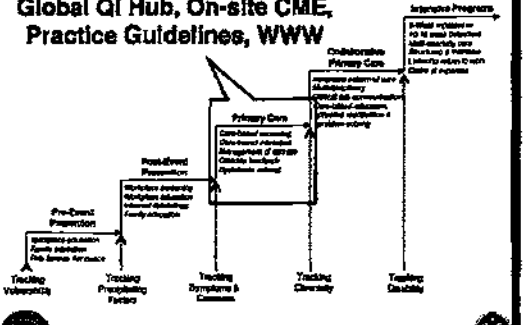
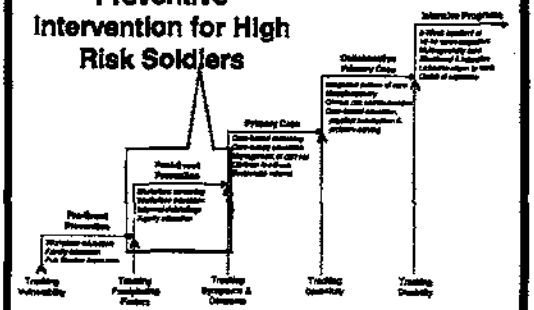
Global QI Hub, On-site CME, Practice Guidelines, WWW



Deployment Health Cli

Preventive Intervention for High Risk Soldiers



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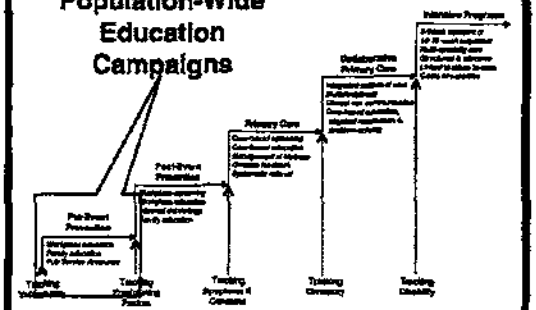
Population-Wide Education Campaigns



Deployment Health Clin

Health Services Research
VA-DoD Collaborative Clinical Trials

- Collaborating with VA Cooperative Studies Program to achieve clinical health policy research capability
- CSP 470: Exercise – Behavioral Therapy for GW vets with chronic multisymptom illness (20 sites)
- CSP 475: Antibiotic Therapy for GW vets with chronic multisymptom illness (30 sites)
- CSP 494: Psychosocial Care of Women Veterans with PTSD (10-15 sites anticipated) – submitted to DHRP
- Planning for study of early post-deployment intervention for distressed peacekeepers

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Clinical Research
Other Projects

- Cooperative agreement with Georgetown Center for Chronic Pain & Fatigue Research
- Mycoplasma portfolio
  - Reliability study of new testing procedures (done)
  - Planning case-control study to examine if organisms are associated with illness (on hold)
  - Antibiotic trial already underway
- Many other studies ongoing

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Health Services Research
Future Projects

- Clinical trials to test the utility of . . .
  - VA-DoD post-deployment clinical practice guideline
  - VA-DoD depression clinical practice guideline
  - VA-DoD CFS-FM clinical practice guideline
  - Clinical risk communication strategies
  - Illness labeling – what label improves health?
- Develop a tool for assessing post-deployment health care needs (personnel & families) during the deployment

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Efforts on the Web

- Support upcoming CPGs
- Distance CME regarding soldier-centered primary care
- DoD Evidence-Based Practice Center – collating evidence for CPGs

Deployment Health Clin

David Berg, MS, CLS(NCA), Director, HEMEX Laboratories, Inc., Phoenix, Arizona. www.hemex.com

My presentation today is based on a new laboratory diagnosis of what we call "Immune System Activation of Coagulation" or ISAC for short. ISAC is a panel of new, high sensitivity, markers of cascade and platelet activation tests. Many of these tests have been used for research for about 8 years (Dr. Ken Bauer, Dr. Ken Mann, Univ. Conn.) and have become part of the coag literature and lectures since then. We have been using part of these assays for the last 5 years, with the current ISAC Panel established just 2 years ago for the investigation of CFS/FM, fetal wastage syndrome and related disorders.

Last month on July 21, 2000, here in Wash.,DC, Dr. Arnold Peckerman, of the VA Medical Center in East Orange, NJ, stated "Our findings suggest that symptoms of illness in Gulf War veterans with chronic fatigue are linked to the circulation in a coherent and physiologically significant way. After the Persian Gulf War, many veterans reported chronic fatigue, memory, concentration and sleep difficulties, muscle and joint pain, and headaches–a pattern of symptoms resembling chronic fatigue syndrome, an illness with no known cause. The veterans with chronic fatigue appear to have a disconnect between cardiovascular stress responses (including blood pressure) and mental activities. The cause of the disconnect is not clear, but may involve injury to the brain areas involved with the regulation of cardiovascular activity." We postulate a connection between these findings and low level activation of coagulation as documented in our recent studies of CFS/FM and GWI.

The EC is a connecting point between pathogen-activated inflammation and the coagulation system and is part of the defensive host response. During inflammation, cytokines modulate the coagulation system by down regulating the expression of thrombomodulin (TM) on EC surfaces and eliminating the anticoagulant environment by blocking the activation of Protein C. At the same time, these cytokines induce expression of Tissue Factor (TF) on the EC surfaces which promotes a procoagulant environment. Immunoglobulins are formed in response to the pathogens and cross react with B2-GPI and Annexin V on EC surfaces, exposing PS. Thus, both TF and PS promote the binding of the tenase and prothrombinase complexes for the local generation of thrombin. Antithrombin should remove the unwanted thrombin. When excess thrombin is NOT controlled properly, fibrinogen is converted to SFM, which results in fibrin deposition in these ill patients. This fibrin deposition is small at first, but becomes layers upon layers over time, leading to blockage of oxygen and nutrients to the tissues around the capillaries. This is an example of SFM production on a LBA. Increased Lp(a) &/or PAI-1 can cause decreased local fibrinolysis by blocking activation of plasminogen to palsmin. This leads to fibrin buildup instead of fibrin removal. Another result of fibrin deposition is the effect of diminishing capillary size which may compromise erythrocyte integrity or impair the rate of delivery of oxygen and nutrients to the surrounding tissues.

Using the ISAC Panel to determine if Chronic Fatigue Syndrome (CFS) / Fibromyalgia (FM) could be diagnosed by such, we published these findings in Blood Coagulation & Fibrinolysis (vol 10, #3, Oct.,1999). The diagnostic criterion was 2 of the 5 tests should be positive for such a diagnosis. We presented this laboratory data of a hypercoag syndrome in CFS/FM patients at the AACFS meeting in Cambridge in Oct, 1998. In 1999, we began a study of Gulf War Illness on sick veterans (n=33) and found similar data again. This data has been accepted for publication in Blood Coagulation & Fibrinolysis (vol 11, #7, Oct.,2000). 67% of the GWI veterans demonstrated activation of the coagulation system. Only 1 out of the 33 test subjects had normal values. This soldier has been on numerous antibiotics for several years. All others were positive.

Regarding hereditary risk factors, 61% of the GWI veterans had positive risk factors noted (low AntiThrombin, low Protein C, low Protein S, APC Resistance, high Factor II, high Lp(a), high PAI-1 or high Homocysteine). 8/33 (24 %) were positive for thrombophilia risk factors and 7/33 (21%) of the patients were positive for

hypofibrinolysis. 5/33 patients (15%) had a risk factor in each group. This last combination was either increased Lp(a) &/or PAI-1 with increased Factor II levels. One patient had a homocysteine level of 20.9 (Ref Range: 0-13).

Thirteen of the veterans (27%) had normal protein levels in the hereditary risk factors screened. Nevertheless, 11 of these 13 patients (85%) had 2 or more activated coagulation markers (positive ISAC panel results). Three out of this group of 11 had increased Protein C or Protein S levels to compensate for the activated coagulation system. Two patients (6%) that had no detectable protein abnormalities, but had platelet activation. It is possible that these patients may have had other protein abnormalities, such as, heparin cofactor II, C4b binding protein, plasminogen, histadine rich Glycoprotein, factor XII, soluble thrombomodulin, dysfibrinogen, and/or tissue factor.

16/33 (48%) had evidence of activation of anticoagulation pathways as demonstrated by elevated Protein C, Protein S and/or AntiThrombin activity. This is probably a compensatory response that attempts to down regulate the hypercoagulable state which results from significantly increased fibrinolysis inhibitors or thrombophilia factors. This has also been observed in CSF/FM patients (Berg et al).

In a small subset of GWI veterans tested, those who had positive platelet activation had positive IgA B_2-GPI antibodies, indicating exposure to a pathogen through mucosal membranes, ie, the nose, mouth, lungs or the GI tract. Further studies of IgA positivity may yield better data about the concept of an air borne pathogen or mucosal membrane exposure in these veterans.

Two of the ill veterans had low fibrinogen levels and elevated SFM, which indicates developing DIC. Both of these veterans died during the study.

There is a suggestion that vaccines may be part of the cause of the hypercoagulable state in veterans. There is most likely a genetic predisposition to developing adverse reactions towards vaccinations since over 60% of the ill Gulf War veterans in our study have positive hereditary risk factors. And there may be other contributing factors to the Gulf War Illness which may have caused the illness or worsened the pre-existing disease. Activation of coagulation may be a final common endpoint for differing etiologies of GWI or CFS in patients with such predisposing genetic makeup.

Because coagulation activation is the central focus of the GWI, it can become a target for treatment. Further research into the cause of platelet activation is needed to determine if there is an infectious etiology. An in depth study of the anti-*B2*GPI-IgA antibody in the GW veterans and their families needs to be addressed.

The symptoms of CFS/FM and GWI are very similar. The positive ISAC testing of the GWI patients parallels the results seen in CFS/FM patients. The hereditary risk profile is also positive in both. The pathophysiology remains constant, cytokines activating antibodies which bind to the EC and activate platelets and the coagulation cascade.

Thanks to my colleagues who participated in this study: Dr. Hannan, Dr. Buamzweiger, Dr. Harrison, Lois Berg, MS, Rosie Rameriz, RN and Denise Nichols, RN.

Thank you for your attention to this presentation.

Coag

Capsule

IMMUNE SYSTEM ACTIVATION of COAGULATION (ISAC):[1]

Chronic Inflammatory Illnesses associated with a coagulation protein defect.

The Model - A Paradigm Shift:

The model proposes that a majority of individuals diagnosed with certain chronic inflammatory illnesses, based on clinical criteria, may be potentially defined as or involve AntiPhospholipid Antibody Syndrome (APS) with the endothelial cell (EC) as the disease target. These patients have a hypercoagulable state demonstrated by increased markers of coagulation activation and increased blood viscosity due to the generation of Soluble Fibrin Monomer (SFM). The CFS / FM process and related processes may be triggered by a variety of pathogens (CMV, HHV6, Mycoplasma, Chlamydia pneumonia, etc.), or some vaccines, resulting in pathogen-mediated immune activation that induces antibodies which cross react with EC protective proteins B_2GPI & Annexin V. These antibodies dislodge the protective proteins from EC surfaces, exposing PhosphatidylSerine (PS) on the EC surfaces in capillary beds.

Pathogens induce inflammatory responses which include cytokine modulation of EC to down regulate the antithrombotic environment (ThromboModulin, tPA) in favor of prothrombotic expression of Tissue Factor (TF). TF and PS exposure allows binding of the coagulation tenase and prothombinase complexes to EC surfaces. This results in thrombin generation leading to SFM formation. SFM dimerizes easily, increasing blood viscosity and precipitating out on EC surfaces as fibrin(oid) deposition, creating local ischemia and pathology, blocking nutrient and oxygen delivery in the microcirculation. A blood clot does not form because there is not enough of a thrombin burst to activate Factor XIII to cross link the fibrin into a clot.

A hereditary defect in a coagulation regulatory protein, such as protein C, protein S, Factor V^L, prothrombin gene mutation, Heparin Cofactor II, tPA, $PAI\text{-}_1$, Lp(a), or elevated Factor II, X, XII, or homocysteine is predispositional in greater than 75% of patients. Because this hypercoagulability does not result in an immediate thrombosis (100% occlusion), but rather in fibrin deposition (50-95%), we suggest that an appropriate name for this antiphospholipid antibody process would be Immune System Activation of Coagulation (ISAC) syndrome. This model provides an explanation for the therapeutic benefits reported with low dose anticoagulant therapy (heparin or warfarin) in some of these patients.

Diagnoses with published associations: Chronic Fatigue Syndrome/Fibromyalgia (CFS/FM), Infertility (Recurrent Fetal Loss and Fetal Wastage Syndromes), Osteonecrosis of the Jaw Multiple Sclerosis (MS) and Autism.

Diagnoses under investigation: Crohn's Disease and Inflammatory Bowel Disease (IBD), Late Lyme Disease, Sjogren's Syndrome (SS), Transient Ischemic Attack, Attention Deficit Disorder and Parkinsons Disease.

1. Berg D, Berg LH, Couvaras J, Harrison H. Chronic fatigue syndrome &/or fibromyalgia as a variation of antiphospholipid antibody syndrome (APS): An explanatory model and approach to laboratory diagnosis. Blood Coagulation and Fibrinolysis 1999: 10 435-438.

HEMEX LABORATORIES

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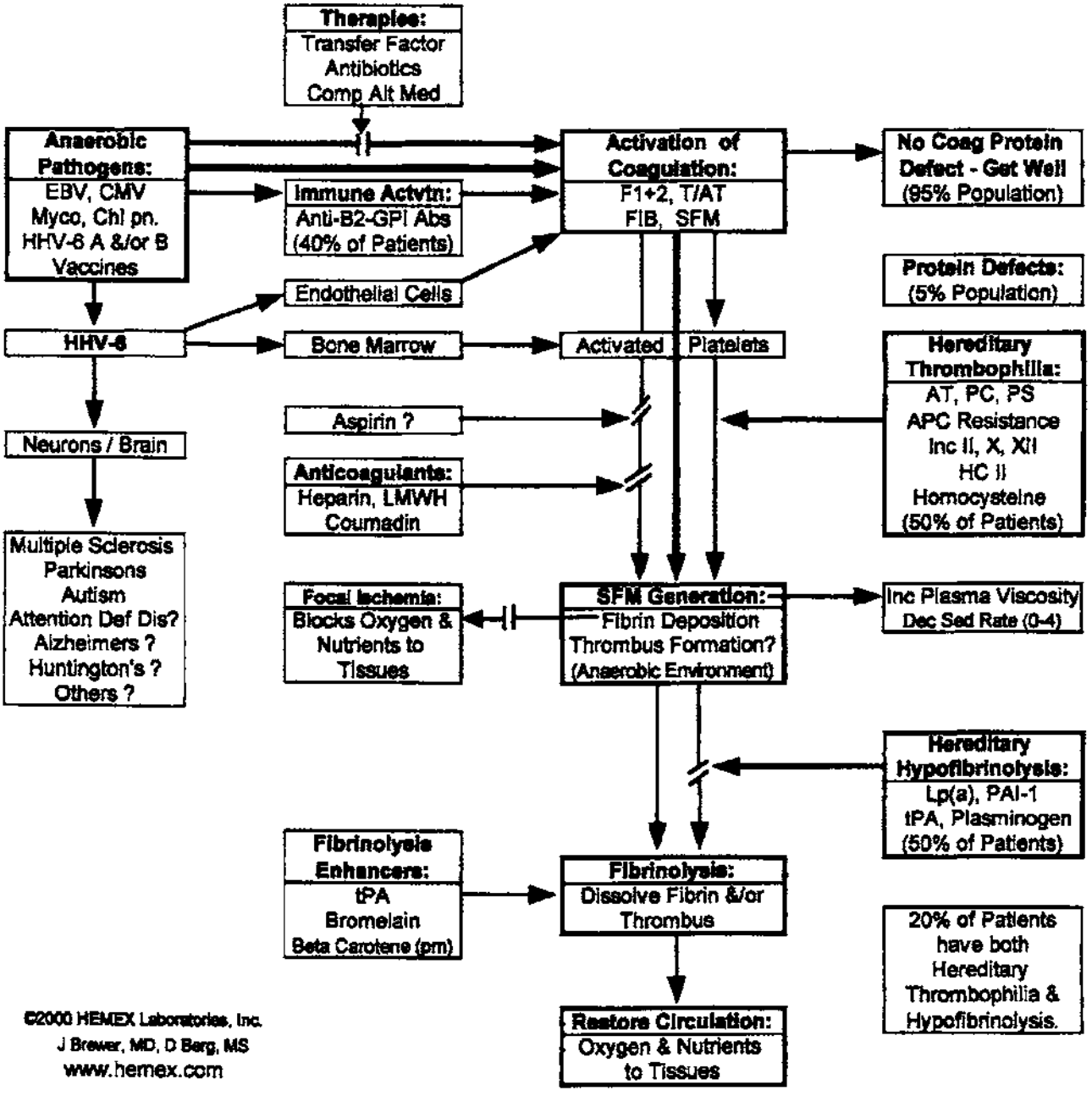
PROPOSED MODEL OF PATHOGEN INDUCED HYPERCOAGULABLE STATE and CHRONIC ILLNESSES (AntiPhospholipid Antibody Syndrome) As Seen In: Recurrent Fetal Loss (Infertility), Osteonecrosis of the Jaw, Chronic Fatigue Syndrome, Fibromyalgia, Multiple Sclerosis, Crohn's Disease, Sjogrens Syndrome, IBD, Lyme Disease, Autism, ADD and other Chronic Illnesses.©



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Blood Coagulation and Fibrinolysis 1999, 10:435–438

Chronic fatigue syndrome and/or fibromyalgia as a variation of antiphospholipid antibody syndrome: an explanatory model and approach to laboratory diagnosis

D. Berg, L. H. Berg, J. Couvaras and H. Harrison

(Received 22 June 1999; accepted 2 July 1999)

Chronic Fatigue and/or Fibromyalgia have long been diseases without definition. An explanatory model of coagulation activation has been demonstrated through use of the ISAC panel of five tests, including, Fibrinogen, Prothrombin Fragment 1+2, Thrombin/AntiThrombin Complexes, Soluble Fibrin Monomer, and Platelet Activation by flow cytometry. These tests show low level coagulation activation from immunoglobulins (Igs) as demonstrated by Anti-B_2GPI antibodies, which allows classification of these diseases as a type of antiphospholipid antibody syndrome. The ISAC panel allows testing for diagnosis as well as monitoring for anticoagulation protocols in these patients. *Blood Coag Fibrinol* 10:435–438 © 1999 Lippincott Williams & Wilkins.

Keywords: Chronic Fatigue Syndrome, Fibromyalgia, AntiPhospholipid Antibody Syndrome, Immune System Activation of Coagulation (ISAC), Anti-B_2GPI Antibodies, Fibrinogen, Prothrombin Fragment 1+2, Thrombin/AntiThrombin Complexes, Soluble Fibrin Monomer, and Platelet Activation by flow cytometry.

Introduction

Chronic fatigue syndrome (CFS) and fibromyalgia (FM) have been considered diagnoses of exclusion where no other diagnosis fits well. In 1987, the American Medical Association recognized FM as a major cause of disability [1]. In 1994, CFS was defined by specific requirements of fatigue, duration, associated symptoms, initial clinical and laboratory evaluation, and medical or psychiatric exclusions. At the most recent meeting of the American Association of Chronic Fatigue Syndrome, the prevalence, prognostic factors, pediatric and adult population studies, potential causal organisms, disruption of normal body functions, autoantibody identification and psychological implications were presented.

Antiphospholipid antibody syndrome (APS) [2] is defined by both laboratory and clinical findings. Laboratory findings include, anticardiolipin antibodies, lupus anticoagulants, anti-phosphatidylserine antibodies, anti-B2GPI antibodies, and clinical findings of thrombocytopenia, neurological complications, venous thrombosis, arterial thrombosis, and/or recurrent fetal loss. Patients with primary APS have no clinical or laboratory evidence of another definable autoimmune disease. Antiphospholipid (APL) antibodies have been long associated with a hypercoagulable state, involving both procoagulant activity as well as inhibition of anticoagulant and fibrinolytic activity [3].

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In CFS and/or FM patients, the principal antibodies found to date are the anti-B2GPI antibodies (unpublished data). This precedes the generation of a hypercoagulable state based on our proposed model. Endothelial cells are protected in the microvascular circulation by B_2GPI and Annexin V proteins. This protective layer helps endothelial cells (ECs) maintain an anticoagulant environment. Exposure to pathogens, such as herpesviruses (HV) (HHV6, EBV), cytomegalovirus (CMV), mycoplasma and chlamydia pneumonia, result in both active persistent infection [4] and latency in mononuclear and EC cells [5]. Some pathogens like CMV and HV constitutively express phosphatidylserine-like procoagulant activity, capable of binding Xa and Va to form the prothrombinase complex [6]. HHV6 is found in about 70% of all CFS patients [7]. In several studies, this same 70% infection rate is seen in Multiple Sclerosis patients with HHV6 [8]. HHV6 is also implicated in chronic myelopathy. Endothelial cells serve as a reservoir for harboring HHV6 [9]. Infected ECs lose their ability to synthesize prostacyclin with associated incapacity to deter platelet adhesion [10]. In addition, CMV and HV express tissue factor antigen on each virus surface [11]. HV can induce a prothrombotic phenotype in vascular ECs [12]. This phenotype markedly reduces heparan sulfate proteoglycan synthesis and surface expression by ECs. Thrombomodulin expression is also reduced in infected endothelium. Activation of EC is seen by surface expression of P-selectin and von Willebrand Factor (vWF). Thrombin generated after the assembly of the prothrombinase complex on the virally infected endothelium mobilizes vWF from the Weibel–Palade body to the EC surface, where it acts as a platelet receptor. Cell-independent thrombin generation may be the earliest event in vascular pathology mediated by HV [13].

Since exposure and expression of phosphatidylserine (PS) is part of the infectious process, these exposed phospholipids activate the immune system to form antiphospholipid antibodies. The primary targets of these immunoglobulin (Ig)G, IgM and IgA antibodies are the protective proteins for ECs, specifically B_2GPI and Annexin V. Both proteins bind to cells via Ca^{2+} binding [14], just as the vitamin K dependent coagulation factors. In pregnancy loss, hypercoagulability may be due to the reduction of surface bound Annexin V by APL antibodies [15]. As in other APS diseases, there is an increased incidence of thrombocytopenia in HHV6 patients. With the loss of this protective layer due to APL antibodies, coagulation proteins can bind, react and form thrombin (IIa). If this process is not properly inhibited (thrombin–anti-thrombin complexes), then excess thrombin can convert fibrinogen to soluble fibrin monomer (SFM). SFM is a sticky protein that increases blood viscosity and can coat EC surfaces as fibrin or fibrinoid material.

The explanation of why one person may become chronically ill and another patient recover when both are exposed to the same pathogen comes in part from the dental community. Glueck *et al.*, have identified that 73% of patients with neuralgia-inducing cavitational osteonecrosis have some form of genetic predisposition for thrombophilia or hypofibrinolysis [16], including: APC resistance, anticardiolipin antibodies, protein C or protein S deficiencies, increased Lp(a) or PAI-1, or decreased tPA activity. These patients responded well to oral anticoagulant therapy.

Model

Our hypothesis is that a majority of individuals diagnosed as CFS and/or FM on clinical criteria may be defined as APS with the EC as the disease target with or without platelet activation. These patients have a hypercoagulable state, demonstrated by increased markers of coagulation activation and increased blood viscosity due to the generation of SFM. Because the CFS–FM process may be triggered by a variety of pathogens, we suggest that pathogen-mediated immune activation may induce antibodies, e.g. anti-B_2GPI, anti-Annexin V antibodies, that dislodge protective proteins from EC surfaces, thereby exposing PS on the EC surfaces in capillary beds. This PS exposure would allow binding of the coagulation tenase and prothombinase complexes to EC surfaces, with subsequent thrombin generation, SFM formation and low level fibrin deposition that could create local pathology by blocking nutrients and oxygen delivery in the microcirculation. A hereditary defect in a coagulation regulatory protein, such as protein C, protein S, Factor V^L, prothrombin gene mutation, $PAI\text{-}_1$, Lp(a), or elevated homocysteine is probably predispositional. Because this hypercoagulability does not result in a thrombosis, but rather in fibrin deposition, we suggest that an appropriate name for this antiphospholipid antibody process would be immune system activation of coagulation (ISAC) syndrome. This model provides an explanation for the therapeutic benefits reported with low-dose anticoagulant therapy (heparin followed by warfarin) in the majority of CFS–FM patients.

Table 1. ISAC panel test data of controls and patients

Test	n	Fibrinogen (mg/dl)	F1+2 (nmol/l)	T–AT (μg/l)	SFM (nmol/l)	Platelet activation	CD62P (%)
Reference range		< 310	< 1.1	1.0–4.1	< 20	Normal	< 26
Controls	23	280	1.0	1.6	10	0% positive	17.5
#Abn/*n*		2/23	3/23	4/23	3/23	0/23	5/23
Patients	54	367	1.2	1.6	22	42% positive	22
#Abn/*n*		45/54	26/54	25/54	32/54	22/52	21/52
P Value		< 0.001	< 0.005	< 0.005	< 0.001	< 0.001	< 0.10

F1 + 2, prothrombin fragment 1 + 2, T–AT, thrombin–anti-thrombin complex; SFM, soluble fibrin monomer.

Results

At the American Association of Chronic Fatigue Syndrome meeting, we presented a retrospective study of 20 patients looking at a hypercoagulable state that could be reversed with anticoagulant therapies [17]. Since then, we have conducted a blinded prospective study of 54 CFS and/or FM patients and 23 controls, using a panel of five tests to determine if patients could be differentiated from controls. The tests included: fibrinogen, prothrombin fragment 1 + 2, thrombin–anti-thrombin complexes, SFM and platelet activation by flow cytometry using CD62P and ADP with mean values for each group shown in Table 1.

The criterion to separate patients from controls was positivity in two or more assays for classification as a patient. The *P* value for laboratory diagnosis based on this criterion was < 0.001. Diagnostic data were obtained after all laboratory studies were completed. Twenty-two of the 23 controls were correctly identified. One control was positive in two assays for a false positivity rate of 4%. Of the 54 patients, four had normal values, for a false negative rate of only 7.4%. This shows that greater than 92% of CFS and/or FM patients had a demonstrable hypercoagulable state. What then is the underlying disease process?

Conclusions

CFS and/or FM patients who have a hereditary deficiency for thrombophilia or hypofibrinolysis may be unable to control thrombin generation properly. We have found that three out of four CFS and/or FM patients have a genetic deficiency (unpublished data). Certain pathogens induce the immune system generation of APL antibodies and can be a triggering mechanism for APS. Once antibodies are formed, protective proteins are dislodged from endothelial cells, exposing PS. Coagulation proteins bind on exposed PS surfaces, generating thrombin on the EC surface. Excess thrombin converts fibrinogen to SFM, which may be deposited on the EC surface and/or circulate in the plasma. Fibrin deposition leads to decreased oxygen, nutrient and cellular passage to tissues around the microcirculation. This hypercoagulable state may cause localized pathology in many tissues, yielding the systemic compromises and symptoms characteristic of the CFS–FM complex.

Since this hypercoagulable state does not necessarily result in a thrombosis, but rather in fibrin deposition, we suggest that an alternative name for this antiphospholipid antibody process would be immune system activation of coagulation (ISAC) instead of antibody-mediated thrombosis [18]. Once this hypercoagulable state is detected, appropriate anticoagulant therapies may be given to relieve patient symptoms. These studies will be presented in a separate report.

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Treating Gulf War Veterans' Post-Deployment Health Problems

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Veterans Administration

Puget Sound Health Care System

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Department of Psychiatry & Behavioral Sciences

Gulf War Clinic Survey

"Most Helpful Services provided by Gulf War Clinic"

#1 Care for me as a person
#2 Complaints investigated thoroughly
#3 Deal with Gulf War issues
#4 Treat me with respect

Gulf War Clinic Survey

"Most Dissatisfying Aspects of VA Care"

#1 Unknown cause of my problems
#2 No Cure
#3 No Cause
#4 Parking

Summary

Many Gulf War veterans experience medically undiagnosed physical symptoms with associated problems in health functioning.

Medical models are often ineffective in responding to these concerns.

A multidisciplinary, biopsychosocial approach is advocated.

Gulf War Veterans' Clinic
Seattle VA

Gulf War Illness and Leishmaniasis; Identification and Effective Treatment

SSG. Arvid W. Brown,Jr. received diagnosis from civilian Infectious Disease Specialist, Gregory J. Forstall, M.D., October 1,1998. Positive IFA and Western Blot resulted in testing 2X+ for each test.

- **Admitted to local hospital and administered Amphotericin B with Lipid complex for 8 weeks intermittently, because of toxicity.**
- **It is very expensive and a difficult treatment to tolerate; we were forced to endure the treatments at home in the presense of our small children.**
- **I believe that it saved my husband's life-but, it did not cure him; it arrested the systemic infections that ravaged his body and mind.**
- **It is estimated through other studies, that visceral leishmaniasis is responsible for elements of the poorly defined illness known as Gulf War Syndrome (1)(2)(3)(4)**

1.UCAP/ IOM
2.Persian Gulf Veterans Coordinating Board Working Group/ Annual Report to Congress 1997; Appendix E: Status Report on Research on Serological Testing for the Detection of L. *Tropica* Infection
3.Health Consequences of Service During the Persian Gulf War: Recommendations for Research and Information Systems 1996/IOM
4.CCEP d.June 1994

Relevant History, Facts and Strategies

- **SSG. Brown displayed symptomology in the field and reported as such, even through his Gulf registry exams; documented from January 1991 through his C/P exams in May 1999, we were told to seek a PCR (5), because his problems were "clear and evident"**
- **Blood draw for Leish antibodies, June 19, 1998 @ VAMC- Ann Arbor, after Urgent care unit and visit to University of Michigan ER/Infectious Diseases; Dr. Engleberg(6). Not sent to CDC by FedEx. Sent REGULAR mail, unprotected and unidentified as infectious blood draw (7)(8)(9)(10).**
- **Received by the CDC , July 3, 1998.**
- **Results were negative.**
- **August 26, 1998 ; First examination by Dr. Forstall: Reviewed only VA medical records and sent for sero-testing from independent parasitology laboratory(11).**
- **Results were positive(12) (13).**
- **October 6, 1998: Amphotericin B with Lipid complex administered by IV.**

5.Hand written notes from VAMC C/P examiner; advice May 3-5, 1999
6.University of Michigan /ER discharge instructions d.6-19-98
7-10. E-mail from Capt. Michael E. Kilpatrick/ OSAGWI
11. Rx for sero-testing d. 8-26-98
12. Test results.
13. Statement of Diagnosis, From Gregory J. Forstall, M.D., d.9-8-99

Assumptions that are no longer valid

- **This is a genetically mutated strain that does not respond to the traditonally known treatments for visceral leishmaniasis.**
- **By its nature, it can lay in dormancy for many years,as in a recent case treated at Walter Reed, where it was documented that a cutaneous case turned visceral after 43 years. It could not be resolved with traditional treatments(14).**
- **The Ban on Blood donations, because of the fear of transmission of Leishmaniasis, from Gulf War Veterans by the American Red Cross and the Armed Services Blood Bank were lifted too soon, January 1, 1993(15).**
- **Biopsies and antibody testing can now be replaced by PCR(16)(17)(18)(19).**

14.Infectious Disease News: page 38,Feb. 2000,
15.Status of Temporary Donor Deferral Related to Leishmaniasis
16. - 19 PCR related abstracts

Addressing the problems and hardships

- **The World Health Organization states that Leishmaniasis has co-infected with HIV around the globe(20) and there are several outbreaks currently in Africa and India.**
- **The battle continues(21) to search out a sero-, species specific test for those deployed to endemic areas, a skin prick test for those displaying symptomology in the field and last, but not least another vaccine.There are vaccines in use(22), but not legal in the US.**
- **The effect on deployment and readiness is great; in one case of deployment the infection rate was 63% within 6 hours of paratroopers hitting the ground(23).**
- **The detection of *viscerotropic Leishmaniasis* is difficult, but not impossible.**
- **"tropic" refers to "ever changing, ever turning, ever mutating; not that it happens to be an infectious, tropical disease.**
- **From the DoD Pest Management Workshop 1995 , it states that for the military to ignore the facts is like an *ostrich sticking its head in the sand(24).***

20.Leishmaniasis & HIV in Gridlock; UNAIDS
21.The Battle; http://fl.mlive.com/news/index.ssf?news/stories/desert501.frm
22. Unclassified doc d. Oct.90
23. Leishmaniasis in the Military; Military Medicine, Vol. 163, Dec.1998
24. DoD Pest Management Workshop 1995

Vision for the Future

- **To properly test Gulf War Veterans and families for Infectious Diseases including Viscerotropic Leishmaniasis by PCR.**
- **To properly recognize and aggressively treat Infectious Diseases known to be affecting Gulf War Veterans, ie; MFI identified, diagnosed and successfully treated by Dr. Garth Nicholson, Bacterial Strep identified, diagnosed and successfully treated by Drs. Hyman and Deming, and Hepatitis C., and the work of David Berg and Hemex.**
- **Immediate treatment and continued surveilence of patients/veterans for resurgence of symptomology and manifestation of leishmaniasis infection.**
- **A developed *sense of urgency by our legislators and sense of duty by our agencies to protect our military, veterans and families and the American Public as a whole.***
- ***Contact The Surface Report at:***
- ***http://www.thesurfacereport.com***

Thank you for your time and attention this afternoon.

Janyce E. Brown IOM August 14, 2000

Janyce E. Brown

September 8, 1998

To Whom It May Concern.

I was a very sick Desert Storm veteran when Doctor Edward Hyman treated me for these sickness, December 14-20, 1994. I attend to you a letter written by me to the "Presidential Advisory Committee on Gulf War Veterans' Illnesses", dated April 11, 1996. In order to detail the various medical problems I was suffering from, similar medical problems my wife has suffered from, how I was treated and helped by Dr. Hyman, and even though my wife has not received Dr. Hyman's full-blown treatment, on occasions she has been helped by him when other doctors did not have a clue as to how to help.

At the time Dr. Hyman treated me, my health was deteriorating at a rapid pace. My mobility was reduced to the use of a cane, with barely enough stamina to even walk. As a matter of fact I had to be wheel-chaired into the hospital. At first when I went to therapy sessions in the hospital, while the treatment was going on I had to be wheel-chaired back and forth. About midway through the treatment, I could finally shuffle enough to walk to therapy and back. This gives you a picture of how bad off I really was at that time, and the improvement began immediately. I honestly believe I would have died within the next couple of years if Dr. Hyman had not given me the treatment he has developed. What is so interesting about my health back then is, two years to a day prior to the Desert Storm War, I ran the Marine Corp Marathon, in Washington, D.C. The first year I ran it in 3 hours and 15 minutes. The next year with a lot less training (about 15 miles a week), I ran it in 3 hours and 15 minutes. After getting sick, I could not even walk one block, without stopping.

Dr. Hyman is able to detect many things through the tests that are not available through studying the blood. It is through the urine that Dr. Hyman was able to detect a bacteria in my body. The bacteria he found was causing all the problems I was experiencing. His method of treatment are very simple, saturate the body with enough antibiotics to eradicate the bacteria. This is done through a blend of IV solutions fed intravenously. This is followed up with several months of medication by mouth in pill form. I am very grateful for the medical intervention I received from Dr. Hyman.

About 2 years ago the number of veterans who died from this sickness were a little over 3,500. Today, that number has increased to over 7,500. One of those was a close friend and fellow comrade by the name of Jackie Belk. Jackie stood about 6 foot 4 inches tall. In his healthier times prior to the Desert Storm Sickness, Jackie could do almost anything he set his mind to. He was an outstanding Heavy Equipment Operator and Mechanic. Simple things like changing the brakes on his truck would only take an hour or two. When he got sick I saw him struggle 4 days trying to change the brakes. Anyone that had ever known Jackie, would see that this was not normal for him. Jackie's story is no different than the many others afflicted with this dreaded disease. He lost his job, and with no means of supporting himself or his family went in the process of slowly losing everything he and his family owned. About a year after Jackie and I attended the Presidential Advisory Committee meeting (April 16, 1996) on Gulf War Illness in Atlanta, Georgia, Jackie Belk passed away.

A while over a month ago, my wife had a bump surgically removed from her breast. While at the doctor's office I met a wife, whose husband had died two weeks prior to that. He too, died of the Desert Storm Sickness. Judging by the age of the wife, I estimated that the young man would have been in his late twenty's or early thirty's.

I am still getting calls from Desert Storm veterans from various parts of the country. These people are very sick, discouraged, and need help. They call me asking if there is hope. All have heard of Dr. Hyman and the treatment he offers. I tell them there is hope. That Dr. Hyman's treatment helped me, and it can help them.

As I mentioned above, my wife has not received Dr. Hyman's full-blown treatment. But a couple of occasions my wife has been prescribed medication by month by him, taking care of bladder problem and infection. Because she has not received the full treatment, her body is not able to eradicate the bacteria that is eating away at her. She is in very poor health. At times she is not able to walk on her own, and by herself, and unable to talk clearly. She has been checked out by many of the finest doctors in Chattanooga, Tennessee. They cannot figure out what her problem is.

I present to you today, several things. The sickness experienced by the Gulf War Veterans is a real sickness and not a post traumatic shock or syndrome. I have the evidence to prove it, other veterans have the liver's, gall bladders and other organ problems to prove it, and the presence of a special type of bacteria. This sickness is not limited to just the veterans. Wives and family members have gotten the sickness from being exposed to the sick veterans. This sickness is not going to go away on its own. Those who are sick will continue to get worse and they eventually die from it. They will have to receive the right medical treatment to get better. I have presented evidence that Dr. Edward Hyman's method works.

The big question is, "What is going to be done for the thousands who are still suffering?" Who is going to make sure they get the right medical attention? Most of them cannot afford the treatment. Because it has gone undetected so long, it is going to take a lot of medical attention to get them taken care of.

The amount of money used by the DOD, the V.A. and other agencies to find out the cause of the sickness/neglect studies could have treated 10,000 sick veterans by now. When is the point where you say enough is enough, these people are sick, it's time to take care of them.

Thomas L. Lane

Patient #1

Dr. Edwin S. Hyman
1515 Poydras Street, Suite 210
New Orleans, LA 70115

Dear Dr. Hyman:

I appreciate the treatment I received from you Dec 15-23, 1992. Because of that treatment, I have virtually gotten back to a normal routine. You in essence gave my life back to me. For that I am very thankful.

The results of that treatment showed up recently, during the annual training I went through at Camp Lejune, March 10-17, 1993. I performed 4 to 5 positions due to lack of personnel. Pulled hard long hours, and was able to hold up marvously. Without the treatment I would not have held up but a couple of days. I was supplied at the standards I had. I owe that to you.

To give you an idea as to what I did, so that you can get an idea of what physical and mental activity was involved, I will give a little details on Camp Lejune. First of all I am department head over the transportation and equipment side of Alpha company. In that respect I am responsible for all the personnel and equipment assigned to us. I planned and was the convoy leader from ISS Huntsville to and from Camp Lejune. I oversaw the transportation for the battalion during AT. I oversaw our project work, which moved in excess of 8,000 cubic yards of material. Debarked the whole battalion to FEX and back. Planned and estimated the Range Safety Project. Tracked upp 40 pieces of equipment. Designed and supervised the raising of LZA holding areas for fuel trucks. Went from 5:00 A.M. to about 8:00 P.M. Non-stop. With about a total of 3 hours sleep per night. Except during 3 days of FEX, during that time I didn't get any sleep.

Again my thanks to you for your dedication to finding out what was wrong with many of us from Desert Storm, and for treating us back to good health. I am truly indebted to you.

Sincerely,
Thomas L. Lane

To whom it may concern.

I am the wife of a Desert Storm Vet. who became sick after his service in the Gulf. For years we had been trying to figure out what this disease is and what could be done to treat it. I had watched as my husband, who is a Registered Nurse and an officer in the USAR, slowly became sick and crippled. He started experiencing rashes, fevers, joint pain and shortness of breath after returning from the Gulf War.

We, as Registered Nurses, have enormous medical resources and access to a variety medical and diagnostic facilities both civilian and military. Even with all of these resources we were stumped by this baffling disease.

I watched as my husband fought the government and this disease, while trying to work and support his family, we have three small boys. He had planned to attend Anesthesia school after the war but was so sick that he couldn't, physically or mentally withstand the rigors of that program and had to defer his educational goals and just concentrate on finding an effective treatment.

His memory, at the time, had deteriorated to the point that was having difficulty with mental skills that he used for years on his job. He couldn't remember doses of drugs that he had used for years, he couldn't remember things that I had told him only hours before, he couldn't read a technical manual without having to reread it several time in order to understand what was being presented. His physical energy level was so low that he couldn't get out of bed for an hour or more after waking up in the morning, he would have to give himself extra time before work so he could get going and work the stiffness out of his joints. He was constantly forgetting simple things and becoming more and more frustrated. He finally heard of Dr Hyman's success with treating Desert Storm illness and was able to participate in this DOD funded study. The results have been dramatic. His memory and cognitive skills have been restored. He applied to and was accepted to Charity Hospital's Xavier Nurse Anesthesiology program and is maintaining a 3.8 GPA. He is still on antibiotics but this is a small price to pay when compared to the dramatic improvement he has experienced.

I just wanted to write this letter to tel. you that this treatment protocol is very effective in the treatment of this disease and that Dr Hyman' treatment has restored hope to a seemingly hopeless situation.

Sincerely
Bonnie S. Koepp RN

Add, please read Thomas Lane's testimony on June 9 1993 before the Subcommittee on Oversight of the Committee on Veterans' Affairs of the U.S. House of Representatives, chaired by Congressman Lane Evans

ABSTRACT

"Living with Leishmaniasis and other Mid-East Diseases since 1990: Devil's or Desert's Revenge? "

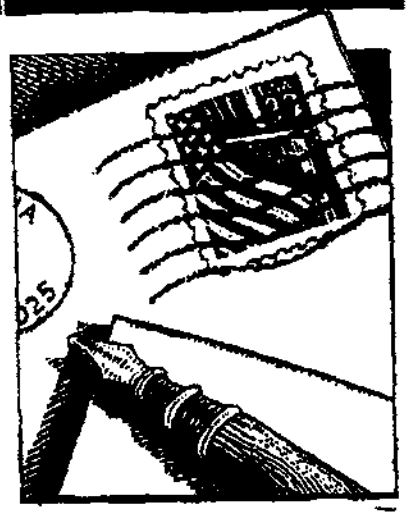
National Gulf War Resources Center GULF ILLNESSES Conference
Atlanta, Georgia, November 8, 1997 ***** K. Murray Leisure, MD, Hershey, PA

Good Samaritan Hospital, Gap Health Services
Infectious Diseases, International, Travel, Persian Gulf Medicine
4th & Walnut Streets, Lebanon, PA 17042. (717) 270-7738. FAX 717-270-7840.

In central PA between 1992 and 1995, we studied 135 tissues collected from 85 unwell Gulf veterans (active duty and reservists) attached to 30 different military groups. Contrary to official reports, many Gulf veterans have real and similar physical diseases even under the microscope. We defined a mucocutaneous, intestinal, and rheumatic DESERT SYNDROME with sinopulmonary and neurocognitive complications using 3 major and 17 minor clinical and pathological criteria since 1992. Diseases in ailing Persian Gulf veterans' tissues include inflammatory bowels seen by colonscopy with microscopic inflammation and eosinophilia, diminutive inflammatory polyps of the gut, unexplained chronic hepatitis, splenomegaly, eosinophilic folliculitis, skin pustules, skin ulcers, asthma, sinusitis, and nose ulcers.

We think many Gulf veterans with this Desert Syndrome acquired one or more infections from the desert because (1) there is a long, 10-week average incubation period for the syndrome, (2) it has flare-ups and a relapsing clinical course, (3) it worsens with prednisone, steroids, alcohol consumption, and pregnancy, all conditions of relative immune suppression, (4) it has been transmitted to some partners and newborns particularly in the early 1990's, and (5) people working in the desert outside of the war months (January - April 1991) and years and desert people not exposed to Anthrax vaccine or any known chemicals or toxins have nevertheless fallen ill with Desert Syndrome. However, no infectious agents were found in spite of extensive evaluations in Persian Gulf veterans except for the desert protozoan parasite *Leishmania tropica*. *L. tropica* grew from 1 axillary lymph node of one veteran in October 1993 and antibodies were present in 2 other veterans with hepatic, splenic, and visceral diseases. One or more new infections difficult to culture on conventional medium might be involved.

VETVOICE



The American Legion Magazine
P.O. Box 1055
Indianapolis, IN 46206

You can also contact us via e-mail directly or through the World Wide Web:

e-mail: tal@legion.org
internet: http://www.legion.org

Doctored Results

THANKS FOR your reports on the Army's Persian Gulf War Health Center. As a physician, I've cared for more than 600 Persian Gulf veterans since Desert Storm in 1991. Many independent professionals with extensive clinical experience like myself remain concerned that government officials still do not appreciate unique physical or medical abnormalities seen in ailing Persian Gulf veterans. At least 10 percent of Gulf veterans developed antibodies or abnormal blood tests to new diseases like viscerotropic leishmaniasis, acquired from sandflies in the Arabian desert. Independent physicians remain concerned about emerging, unknown desert infections and the effects of biological and chemical warfare among today's surviving but ailing Persian Gulf veterans.

The "doctors" in charge of the Defense Department's program are not at all medical specialists. The DoD's Special Assistant in charge of Gulf Illnesses, Dr. Bernard Rostker, has no medical background but a Ph.D. in economics. The Walter Reed Army Hospital Gulf War Health Center is directed by an M.D. psychiatrist, Dr. Charles Engel, who, in conjunction with the National Security Council, focuses on post-combat fatigue and post-traumatic stress disorders. He is not interested in medical diseases or clinical or laboratory abnormalities seen in Gulf War veterans.

Independent, unbiased research and relevant, easy-access medical care are urgently needed for perhaps 200,000-300,000 Persian Gulf veterans with new unexplained illnesses. As documented by a dozen General Accounting Office reports and the 1998 Senate Veterans Affairs Report by Sen. Arlen Specter, R-Pa., it is unclear whether this is possible within today's VA and military medicine organizations.

-- K. Murray Leisure, MD, Infectious Diseases & Epidemiology, Hershey, Pa.

Gulf Veterans' Lesions — Are They Leishmaniasis?

Lesions classified as chronic cutaneous leishmaniasis, typically on hands, face, neck and leg, after returning from Persian Gulf War frontier, were photographed by infectious disease specialist Katherine Murray Leisure, M.D., on military retirement when she examined at the VA Medical Center in Lebanon, Pa., after the Gulf War. Man with these sores is a Navy diver who did not arrive in the Gulf until July '91, four months after hostilities ended; he was never near the war front. Man with leg ulcer worked in desert for one month, October 1990, before Desert Storm.

Veteran with scar (photo right) was plagued by persistent skin eruptions — "Saddam's pox" — and had low platelet counts. Scar is from surgical removal of his spleen. He arrived in Gulf on Jan. 1, 1991, worked amid burning oil fields and became ill three months later.

Leisure classifies these cases clinically as MUMPS: mucocutaneous-mucosal-nasopharyngeal-nasal desert syndrome. Her hypothesis, which has not been confirmed, is that they are caused by parasitic Leishmania species that is transmitted to humans by a sandfly (drawing, top). Promastigote forms of this parasite, which is 2 microns long, swimming forms of the flagella for locomotion, is called a promastigote (below sandfly). It penetrates white cells (macrophages) or other cells, where it is transformed into a life stage called an amastigote (black dots in cell in front of fly). The amastigotes reproduce in human cells. Sandflies ingest these cells when biting humans or other hosts. The leishmania change again into promastigotes; the cycle begins anew.

THE INSTITUTE FOR MOLECULAR MEDICINE

A nonprofit institute dedicated to discovering new diagnostic and therapeutic solutions for chronic diseases

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Huntington Beach,
CA 92649-1041 USA
Tel: (714) 903-2900
Fax: (714) 379-2082

TELEFAX TRANSMISSION COVER SHEET

TO: Wendy Wendler

DATE: 4/1/00

FAX NUMBER: 972-661-0716

No. of PAGES: 7

FROM: Prof. Garth L. Nicolson
President, Chief Scientific Officer and Research Professor
The Institute for Molecular Medicine
Professor of Internal Medicine

MESSAGE:

Dear Wendy,

At the recent NIH Chronic Fatigue Syndrome Coordinating Board in Washington DC, LTC Charles Engel, a psychiatrist and Director of the Gulf War Illness Center at Walter Reed Army Medical Center in Washington DC and Co-Principal Investigator of the VA Cooperative Clinical Study Program #475 (Antibiotic treatment of mycoplasmal infections in Gulf War Illness patients), reported that ~40% of 1,500 GWI patients tested from the 30+ VA and DoD institutions involved in the study were positive for mycoplasmal infections, and of these ~80% were positive for M. fermentans. These data are almost exactly what we previously published (in GWI ~45% positive, >80% M. fermentans, 200 patients) and support our suggested use of antibiotics to treat this condition. Further, Dr. Engel related to the Board that patients in the antibiotic arm of the trial appear to be doing better than the placebo arm, but it will be some time before the trial is complete. Now Dr. Sam Donta of the Boston VA (see S.D. Union article on the trial) and other VA people are trying to take the credit for this after they tried for several years to discredit and stop this line of investigation.

The important thing is that we have developed new diagnostic procedures that can help patients with chronic illnesses, most of whom have chronic infections that cause morbidity. Independent of the cause(s) of their illnesses, chronic infections are a significant problem, because they keep patients from ever recovering (fewer than 8% of chronic illness patients ever recover from their illnesses).
We have developed forensic PCR procedures for the accurate determination of invasive mycoplasmal and other chronic infections, and this may be useful for clinical labs that are struggling with antibody approaches for detecting mycoplasmas. There are millions of patients in the U.S. that are suffering from CFS, FMS, Rheumatoid Arthritis, Autoimmune Diseases, Heart Diseases, Bowel Conditions and other illnesses that have not had effective treatments up until we developed new methods of diagnosing the chronic infections that are commonly associated with these illnesses. Up to one-half of these patients appear to have chronic infections that can be successfully treated.

Sincerely,

Garth L. Nicolson, Ph.D.
President, Chief Scientific Officer and Research Professor
The Institute for Molecular Medicine

IMM Web Site: http://www.immed.org

MEDIA MEMO: ***MAYBE 1 MILLION FAMILIES EXPOSED TO COMMUNICABLE BACTERIA*** 8-2-00

WHO? **Gulf War Veterans, Their Loved Ones, Advocates, Health Scientists & Public Officials,** such as
@ 2:00 pm Sick Gulf Vet's Wife Janyce Brown, c/o 202-479-4000, 810-234-2281 Flint, MI [www.thesurfacereport.com]
Nurse-Navy Cmdr. Julia Dyckman, 717-657-1354, Harrisburg, PA (Testimony to Congress, PAC, etc.)
Fmr. Army Sgt.Major Frank Sauer, West VA (Hyman/Remission Patient, $3+ million Army Study)
@ 2:45 pm Dr. Ed Hyman MD, Pres.-Louisiana Medical Foundation, New Orleans (by speaker phone)
Dr. Ruth McGill MD of Texas & Dr. Larry Plumlee MD of Bethesda, MD (Multiple-Chemical Ills)

WHAT? **Public Meeting, Institute of Medicine-National Academy of Sciences, Committee on *"Identifying Effective Treatments For Gulf War Vets' Health Problems"*** [PGVETS@NAS.EDU]

WHEN? **MONDAY, August 14, 2000, 9am - 6pm** **For Immediate Release - - *10th ANNIVERSARY***

WHERE? Foundry Building - Room 2004, 1055 Thomas Jefferson St. NW (Georgetown), WashDC 20007
[Limited Parking. Metro/Orange Line to Foggy Bottom + N.A.S. Shuttle]
N.A.S.-I.O.M., 2101 Constitution Ave NW (FO 3030B), WashDC 20418, 202-334-1318, fax # 202-334-2939

GULF WAR VETS PLAGUED BY ODD "STREP" GERM

AGENDA:
9:00 am Welcome & Introduction, Dr. Bernard Rosof MD, Committee Chair
9:15 am Treating US Gulf Veterans, Drs. Stephen Hunt MD & Ralph Richardson PhD
10:00 am United Kingdom Gulf Veterans' Health, British Col. John Graham
10:30 am Break – Opportunities for Media Interviews, Photos, Handouts & Other Materials
10:45 am Irritable Bowel Syndrome, Dr. Howard Spiro MD
11:30 am Medically Unexplained Physical Symptoms, Army Col. Charles Engel MD-Psychiatrist
12:15 pm Discussion 12:45 pm Lunch Break & More Media Opportunities
1:30 pm Testimony from Veterans/Others 6:00 pm Closing Discussion & Adjournment

MISSION: Congress directed the Dept. of Veterans Affairs to request that the I.O.M. impanel alleged experts to
1. Identify & describe approaches for assessing treatment effectiveness;
2. Identify illnesses & conditions common among Gulf War Vets, using (only??) DoD/VA Registry data + information in ***published*** articles (raising "peer review" & bias issues re "PhD Pork");
3. Identify ***validated*** (by whom??) models of treatment for these identified conditions & illnesses

KEY PERSONS
a. Dr. Isabel Hoverman MD, Internal Medicine, Austin, TX, 512-459-3149 (Committee)
b. Dr. David Nerenz PhD, Professor, Michigan State University-Flint, 810-232-7000 (Committee)

RULES **10 Minute Presentations** (1-5 pages + exhibits, bibliography, appendix, etc.) allowed afternoon speakers, including Dr. Hyman (semi-retired, age 75, recovering from a recent stroke). [Written deadline, 9/15/00.] Dr. Hyman & his 85-year old associate, Dr. Quentin Deming MD of New Hampshire, headed the only federally funded treatment trial to date that achieved remarkable statistically successful results, wherein all 36 test subjects obtained obvious relief from symptomatology. They used a new patented urine test and a protocol with IV/oral antibiotics that Hyman researched and developed for 30 years, before this conflict in S.West Asia, ironically beginning when S.East Asia produced similar indicators in returning Vietnam War personnel. Yet Hyman wasn't funded to screen and treat the original 3 dozen past a mere 3-week attempt, much less help their possibly contaminated families and friends. Nor was he authorized to assist any other desperately ill Gulf Vets, who already were tested or likely were suffering too from SSB (Systemic Spherical Bacteria, potentially deadly "Strep" & "Staph"). He had proposed a parallel project to confirm suspected communicability among Vets, spouses, offspring, co-workers, other kith and kin. Instead of military transport, the Army insisted that the Louisiana Medical Foundation expend money on airline fares, which might have been used to screen crucial "PointWalker" Cases, in a companion study based on valid empirical evidence. Hyman-tested/untreated Gulf Vets included the late Air Force Col. Don Kline of TX (*7/95) & Army Paratrooper Jason Whitcomb (*9/99) + a pilot/author who now suffers greatly from ALS.

*BUDDY COUNT ***DEATHS AMONG WARTIME THEATER-DEPLOYED TROOPS = "6,584" in Jan. 2000 (DoD)***
After a decade, the Coordinating Board (DoD, VA, HHS) still can't agree on dates & counts. # # #

Treating Gulf War Veterans' Post-Deployment Health Problems

Steve Hunt, M.D.

Ralph Richardson, Ph.D.[1]

Gulf War Clinic

Veterans Administration

Puget Sound Health Care System

Seattle, Washington

[1] University of Washington

Department of Psychiatry & Behavioral Sciences

Gulf War Veterans Statistics

- 696,535 troops deployed
- 535,000 are VA eligible
- More than 225,000 have received outpatient VA care
- More than 25,000 have been admitted to VA medical centers.

Our Clinic

Seattle VA Medical Center Gulf War Clinic

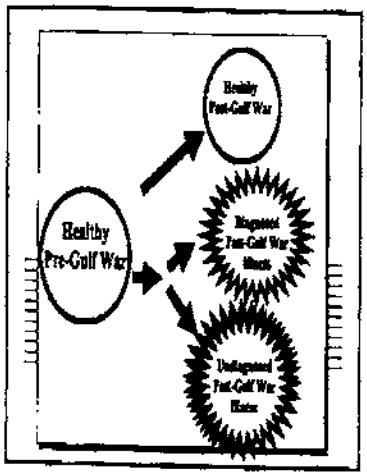
Clinic established 11/94

Staff:

- *Primary care physician
- *Clinical Psychologist
- *Clinic coordinator
- *ARNP women's provider
- *Specialty consultants
- *Support services (PT,dietary, SW, C&P, OT/vocational)

VAPSHCS Gulf War Veterans' Services

1. Primary care evaluation and follow-up clinic-- integrated care/women's program
2. Registry program
3. C&P evaluations
4. Outreach
5. Research

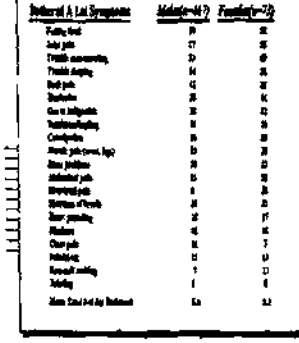


Factors Impacting Health of Gulf War Veterans

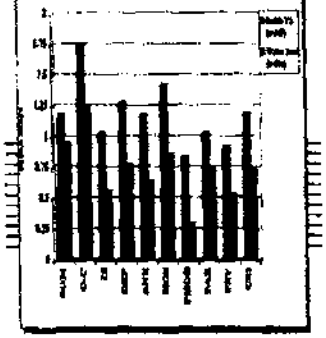
- Disruption in personal/professional/family life
- Abrupt transfer to new environment
- Multiple immunizations
- Exposures
- Anticipation of extended combat
- Field military living conditions
- Psychoemotional stressors(warzone)

Our Patients

Persian Gulf Clinic Veterans Self-Report Symptoms



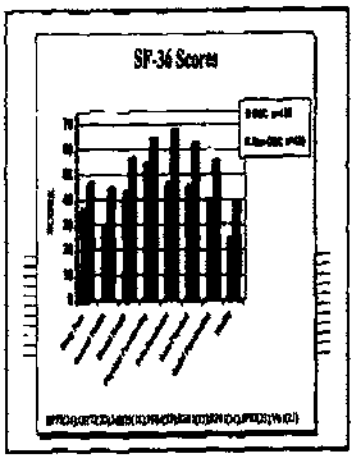
BSI: Gulf War Veterans

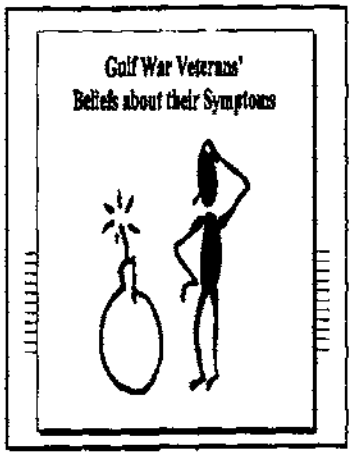


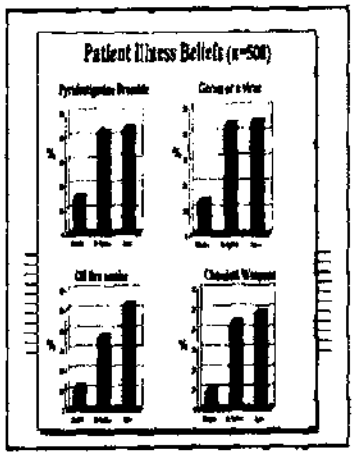
BSI: Gulf War Veterans

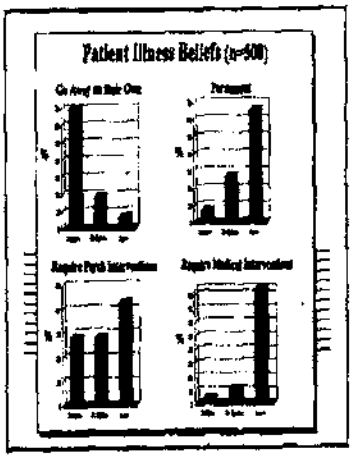
PTSD Checklist Score (PCL)

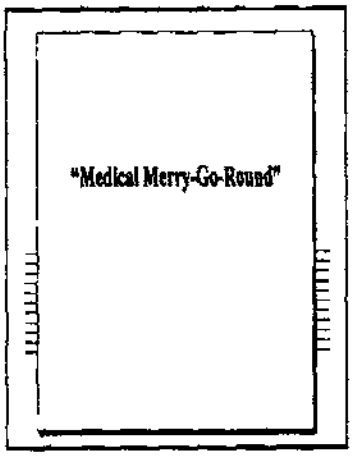
	Males (n=468)	Females (n=73)
Mean Score	30	31
% of cases >50	14 %	15 %

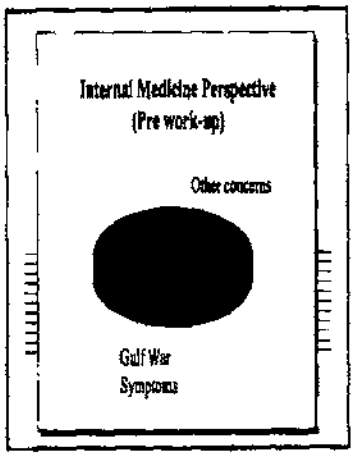

SF-36 Scores

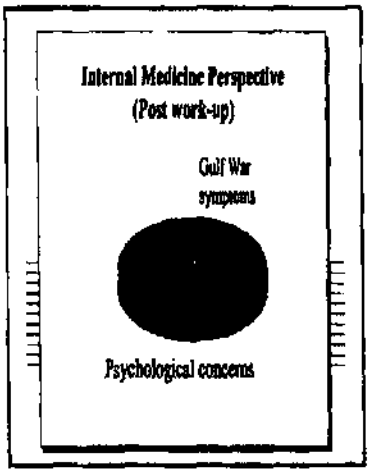

Gulf War Veterans'
Beliefs about their Symptoms

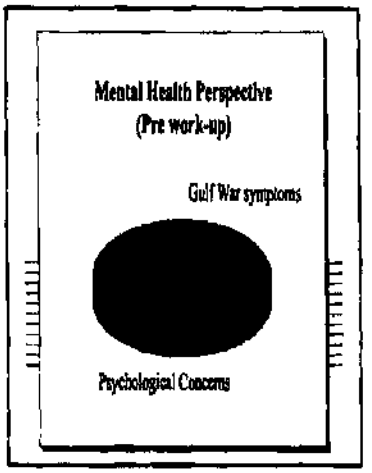

Patient Illness Beliefs (n=508)

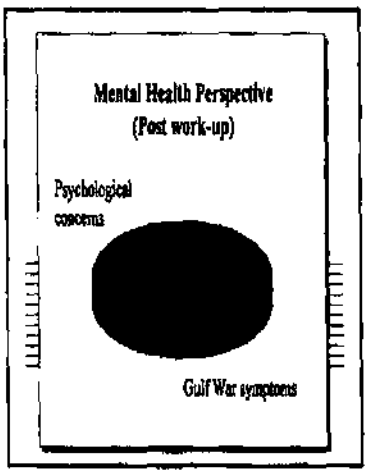

Patient Illness Beliefs (n=508)

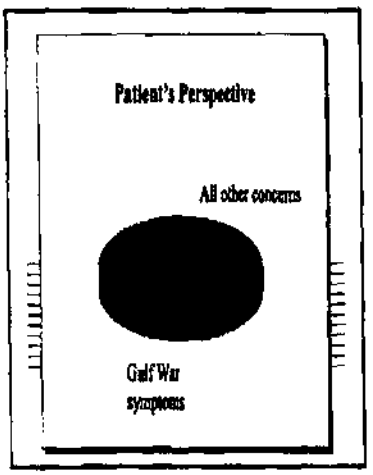

"Medical Merry-Go-Round"

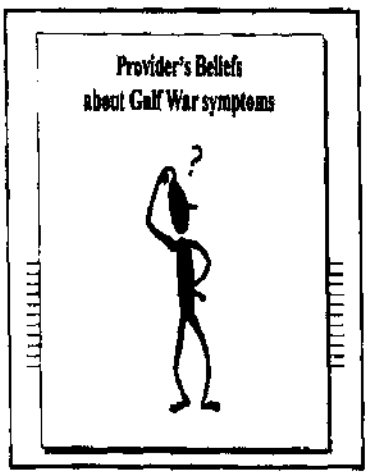

Internal Medicine Perspective
(Pre work-up)
Other concerns
Gulf War
Symptoms

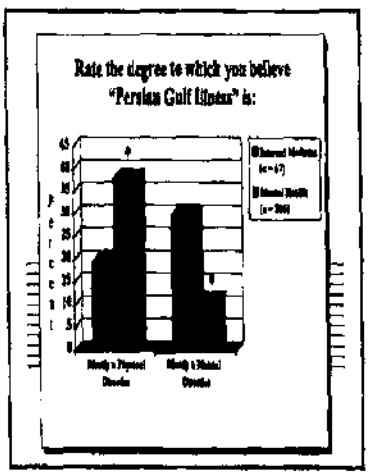

Internal Medicine Perspective
(Post work-up)
Gulf War
symptoms
Psychological concerns

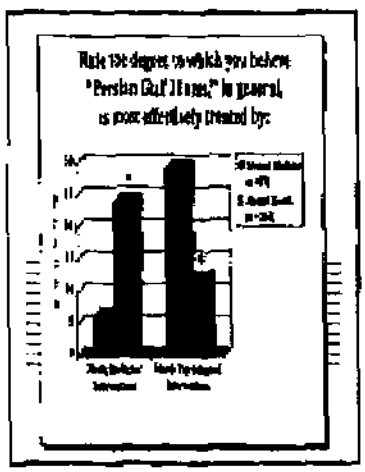

Mental Health Perspective
(Pre work-up)
Gulf War symptoms
Psychological Concerns

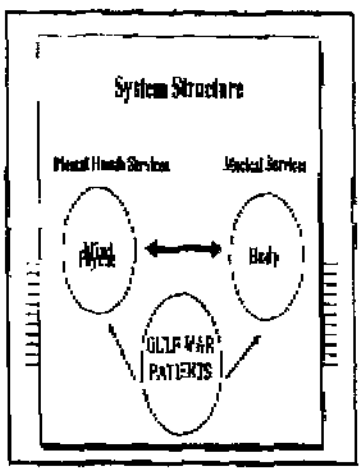

Mental Health Perspective
(Post work-up)
Psychological
concerns
Gulf War symptoms

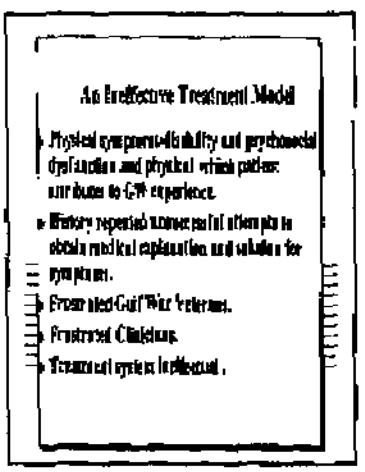

Patient's Perspective
All other concerns
Gulf War
symptoms

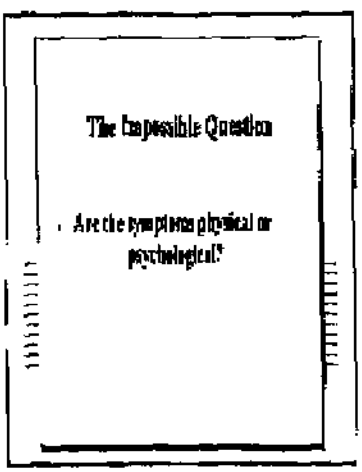

Provider's Beliefs
about Gulf War symptoms

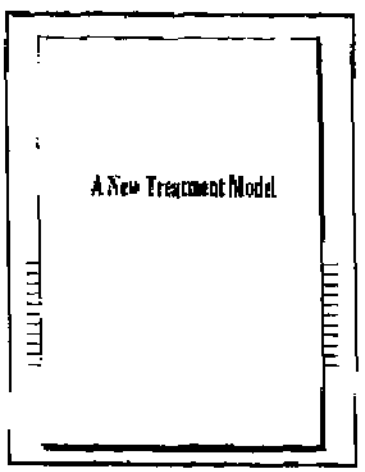

Rate the degree to which you believe
"Persian Gulf Illness" is:

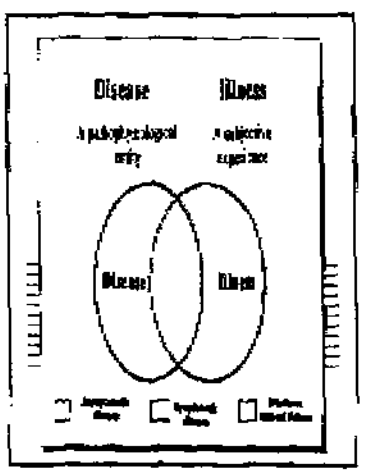

Rate the degree to which you believe "Persian Gulf Illness" in general, is most effectively treated by:


System Structure
Mental Health Services
Medical Services
Allied Physic
Body
GULF WAR PATIENTS


An Ineffective Treatment Model
Frustrated Gulf War Veterans.
Frustrated Clinicians.


The Impossible Question
Are the symptoms physical or psychological?


A New Treatment Model


Disease
Illness
Disease
Illness

Case Presentation

32 year old male infantry scout
In Saudi, Iraq and Kuwait from 8-90 until 7-91

Exposures included multiple immunizations, PB, insect bites, insecticides, chemical alarms, oil fire smoke, fuels, hostile fire , seeing and handling bodies and casualties, dietary changes, sleep deprivation and extreme weather (heat, cold, dampness, sandstorms.

Health in Gulf: brief diarrheal illness

Case Presentation

-Late 1991—sleep disturbance, HA

-Early 1992- discharged from service

-Mid 1993- increasing fatigue, HA, diffuse joint and muscle discomfort, exacerbations of longstanding LBP and RPPS, exertional dyspnea, fluctuating diarrhea & constipation, difficulties with memory and concentration, increasing anger and irritability
-Multiple medical evaluations negative

Case Presentation

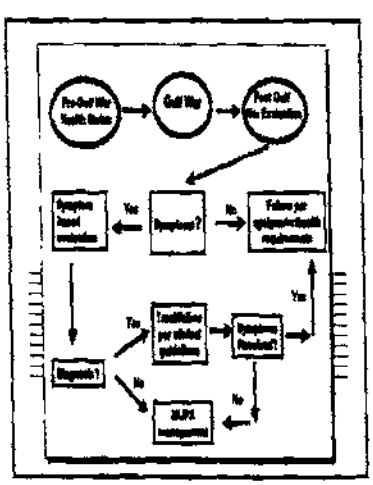
Attitudes, Attributions, Beliefs:

1. That symptoms resulted from nerve agents
   "we knew the Iraqi's had them and were going to use them...alarms were going off all over the place, and there were dead animals everywhere, with no visible signs of what had killed them."
2. Anger, resentment, mistrust
   "...they didn't even admit that there were chemical weapons over there for... how many years?..."
3. Fear of birth defects in children
   (a consequence of a magazine article)

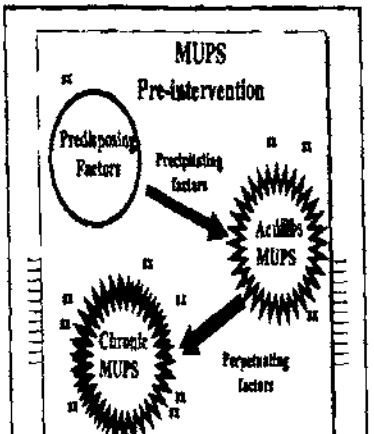
Case Presentation

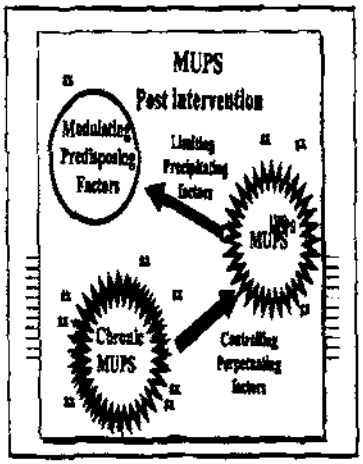
Physical examination:
occipital scalp tenderness, mild generalized muscle tenderness, increased tone lumbar paraspinals

Laboratory results:
Normal UA, CBC/ESR, chemistry panel, TSH, LFT's, hepatitis B/C screen, RF, ANA, CPK 400.
Normal CXR, PFT—mild RAD
GI, Rheumatology and Neuropsychiatric consultation/testing- IBS/FMS



MUPS
Pre-intervention





Medical Management	Self Management
• Acute Symptoms	• Chronic Symptoms
• Professional Responsibility	• Patient Responsibility
• Focus on Causes of Sxs	• Focus on Effects of Sxs
• Goal: eliminate symptoms	• Goal: Increase function
• Procedural	• Education/Motivational

MUPS : Clinical Management

- The question "What is causing my symptoms?" will, for the time being, remain unanswered.
- There will be ongoing consideration of the possibility of identifying and treating specific etiologically established disease.
- It must be understood that environmental or battlefield exposures, physiological stressors and psychological traumas can, individually or in combination, contribute to MUPS.

Case Study
MUPS : Clinical Management
Managing Perpetuating Factors

Social Isolation
regular clinic visits/support group
EBT/vocational rehab

Decreased Activation/Weight gain
EBT/BSP
Dietary counsel

Self Esteem/Self Confidence
above interventions

Financial
vocational rehab training

Coping skills
Identification of personal coping skills

Case Study
MUPS : Clinical Management
Managing Perpetuating Factors (cont)

Illness Beliefs
examine and reformulate illness beliefs in group and in clinic visits

Integrated Medical Care
group co-led by mental health and physical health providers
caution re specialty referral/ close integration

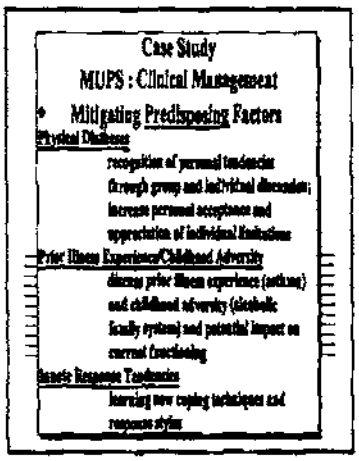
Case Study
MUPS : Clinical Management
Limiting Precipitating Factors

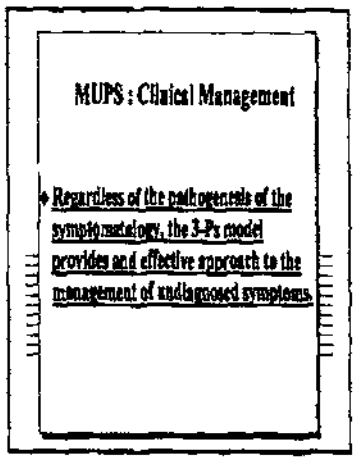
Medical/Psychiatric Co-morbidity
vigilant medical/psychiatric follow-up

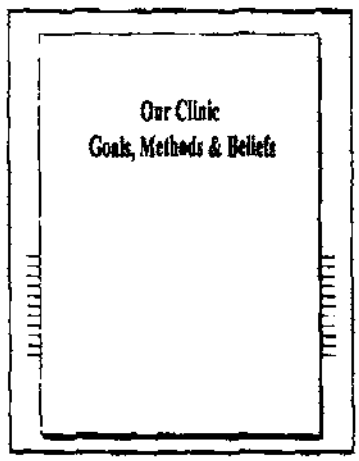
Social/Financial/Occupation stressors
social activation and voc-rehab as above

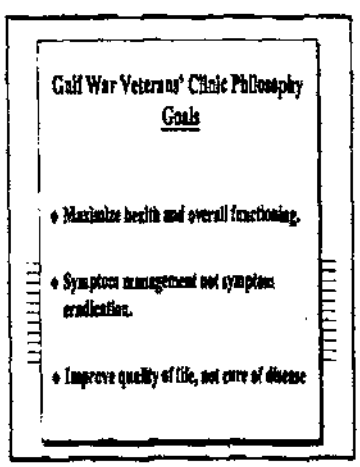
Recurrent Trauma
appropriate occupational track
family/marital counseling

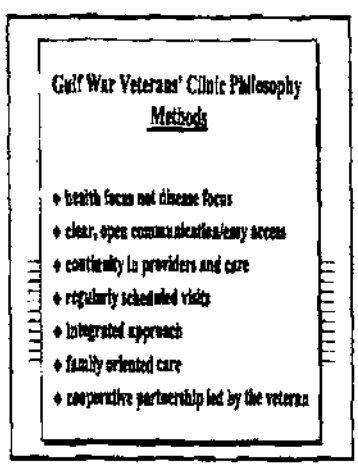
Life Schedule Changes
establish personal, social and vocational structure and schedules (dietary,sleep, recreation, socialization, work/school

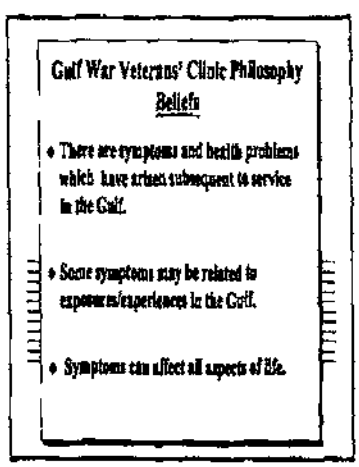

Case Study
MUPS : Clinical Management
♦ Mitigating Predisposing Factors
Physical Distress
recognition of personal tendencies through group and individual discussion; increase personal acceptance and appreciation of individual limitations
Prior Illness Experience/Childhood Adversity
discuss prior illness experience (actions) and childhood adversity (alcoholic family system) and potential impact on current functioning
Chronic Response Tendencies
learning new coping techniques and response styles

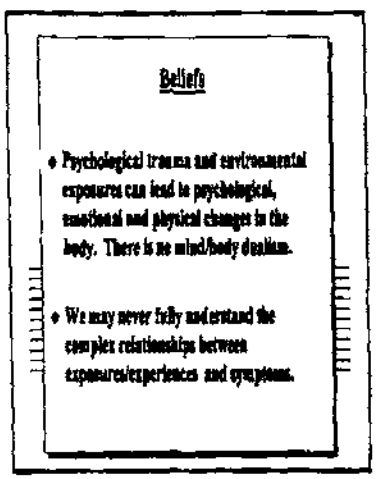

MUPS : Clinical Management
♦ Regardless of the pathogenesis of the symptomatology, the 3-Ps model provides and effective approach to the management of undiagnosed symptoms.

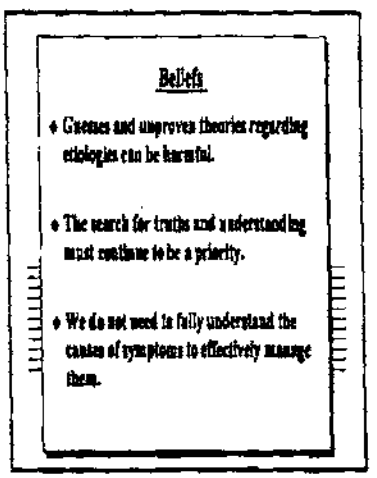

Our Clinic
Goals, Methods & Beliefs

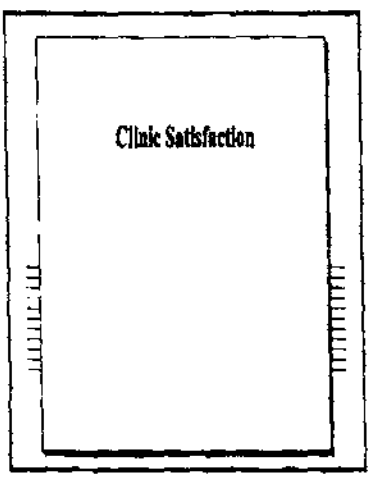

Gulf War Veterans' Clinic Philosophy
Goals
♦ Maximize health and overall functioning.
♦ Symptom management not symptom eradication.
♦ Improve quality of life, not cure of disease

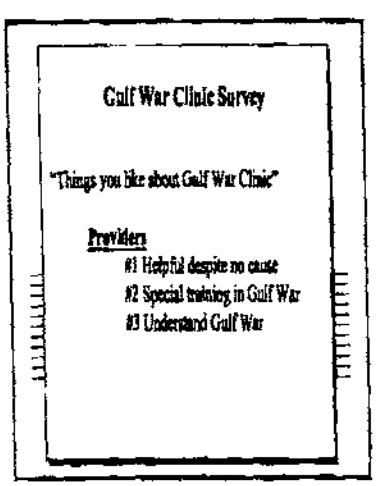

Gulf War Veterans' Clinic Philosophy
Methods
♦ health focus not disease focus
♦ clear, open communication/easy access
♦ continuity in providers and care
♦ regularly scheduled visits
♦ integrated approach
♦ family oriented care
♦ cooperative partnership led by the veteran

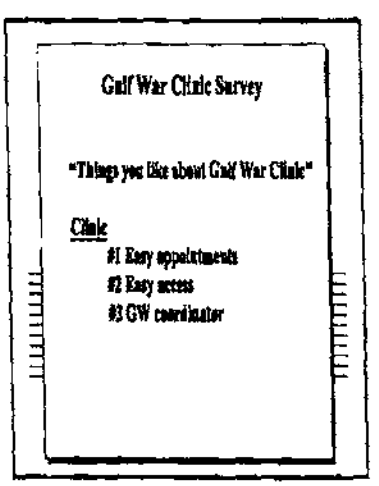

Gulf War Veterans' Clinic Philosophy
Beliefs
♦ There are symptoms and health problems which have arisen subsequent to service in the Gulf.
♦ Some symptoms may be related to exposures/experiences in the Gulf.
♦ Symptoms can affect all aspects of life.

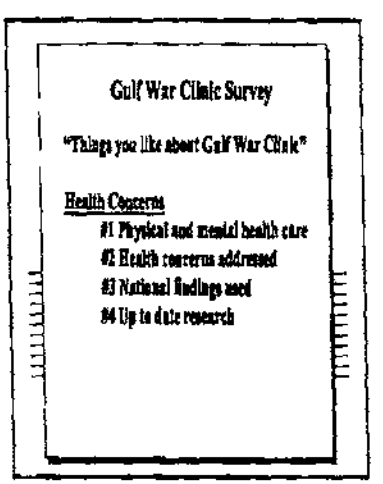

Beliefs
♦ Psychological trauma and environmental exposures can lead to psychological, emotional and physical changes in the body. There is no mind/body dualism.
♦ We may never fully understand the complex relationships between exposures/experiences and symptoms.


Beliefs
♦ Guesses and unproven theories regarding etiologies can be harmful.
♦ The search for truths and understanding must continue to be a priority.
♦ We do not need to fully understand the causes of symptoms to effectively manage them.


Clinic Satisfaction


Gulf War Clinic Survey
"Things you like about Gulf War Clinic"
Providers
#1 Helpful despite no cause
#2 Special training in Gulf War
#3 Understand Gulf War


Gulf War Clinic Survey
"Things you like about Gulf War Clinic"
Clinic
#1 Easy appointments
#2 Easy access
#3 GW coordinator


Gulf War Clinic Survey
"Things you like about Gulf War Clinic"
Health Concerns
#1 Physical and mental health care
#2 Health concerns addressed
#3 National findings used
#4 Up to date research

William E Baumzweiger, M.D. Neurology and Psychiatry
18399 Ventura Blvd. #245
Tarzana, CA 91356
8/14/00

Presentation to the Institute of Medicine: Gulf War Illness--
Its Etiology In Brainstem Dysfunction And Its Treatment

Presented for Dr. Baumzweiger by Ruth McGill, M.D.

The brainstem is a brain organ in which toxic, traumatic, microbial and other impacts can interact in such a way that will cause chronic inflammatory disease. Such disease could immune suppress the victim, causing eventually new and reactivated infections, autoimmunity, and debilitation. The core constellation of signs and symptoms in Gulf War Illness is caused by the simultaneous dysfunction of the nervous system, immune system, and bodily membranes, all negatively impacting on one another. As I indicated to this Institute last year, the disease process appears to be centered in the brainstem. Eventually all parts of the nervous system as well as the immune system manifest the characteristic pathology seen in this illness. The immune system infects the nervous system, and the Nervous System in turn irritates the immune system via Excitotoxicity. (Diagrams)

The pathological process appears to be the result of cumulative effects from multiple wartime environmental insults: low levels neurotoxic gas, toxins from oil well fires, pyridostigmine tablets, insect repellants, "depleted Uranium" radiation, neurotoxic and immunotoxic biological weapons. One researcher counted 33 different potential toxic sources in the War Theater. Even the vaccines the fighters were given may have contributed to the severity of their illness and the diagnostic complexity of this illness.

The treatment of this disorder is complex, but has provided symptomatic relief for over 100 of my patients. It begins with the cooling down of excitotoxically inflamed neurons with Dihydropyridine Calcium Channel blockers or GABA agonists. Ideally, both are used together. Then anti-inflammatories are added to reduce the activity of the arachidonic, leukotrine, and other inflammatory pathways. Then IV immune globulin is used to further stabilize the immune system. IV anti-virals and IV antifungals are given to those patients who are not able to clear microbial fragments out of their neurons and immune cells through the use of oral medications.

After the core neurological and immune inflammatory processes are brought under control, the problems of tachycardia, blood pressure abnormalities, pulmonary dysfunction, pleuritis and pericardial inflammation can then be addressed. The gastrointestinal, musculoskeletal, and other systemic problems associated with this illness can then be treated.

Research studies of Dr. Robert Haley at Southwestern University have confirmed the clinical findings. During a conversation Dr. Haley and I had, Dr. Haley had asked why I thought the brainstem was so central to the process. I pointed out that abnormalities of the Cranial Nerve nuclei were found in all ill Gulf War fighters with this syndrome as well as some ill civilians. His subsequent research into the brainstem has followed from that conversation and confirmed its essential ideas. His group has published two articles on the brainstem in this condition, and a third is coming out shortly.

The clinical findings indicate this disease process invariably involves the spread of very characteristic pathological to the multiple organ systems I have indicated. Many investigators, including myself, have described CNS irritability. Headaches, photophobia, cranial nerve nucleus dysfunction, and even the onset of epilepsy are seen. Dysautonomia is present, manifested by orthostatic tachycardia and night sweats; as well as changes in perspiration. Acoustic dysfunction with loss of hearing at low tones and decreased ability to locate sounds is seen. Vagus nerve dysfunction is seen. Menstrual disorders and thyroid disorders, from defects in pituitary function appear. The appearance of Diabetes, presumably from immune and / or infectious etiologies is common.

Because of Vagal and autonomic dysfunction, digestive and other abdominal symptoms are seen. Dysregulation of control over circulating blood volume and changes in vascular tone with hypotension or hypertension suggest endocrine dysfunction affecting electrolyte balance and the mechanisms of vascular control in the renal system and great vessels. Immune system activation of coagulation is seen.

There is a connection between this neuroimmune disease and it's associated signs of membrane hyperirritability. This irritability is seen in the irritable bowel and reactive airway disease seen in the patients suffering from this illness. Irritability in the musculoskeletal system is frequently seen as well. The membranes of the lungs, heart, bladder, and skin can demonstrate irritability. Clinically explaining this required considerable time researching into and elaborating of concepts as to how patients can develop pathological reactions to normal tissue after neurotoxic / Neurotraumatic, and Neuroinfectious exposure.

The chronic infection / inflammation of the brainstem and other deep brain causes immune suppression. This explains why Gulf War veterans not only have signs of Chemical and Radiation Neurotoxicity, but have signs of high rates of post Gulf War infection from neurotoxic / neurotropic viruses and Mycoplasma. This chronic process also is the cause for the neurobehavioral problems--often mistaken for "psychiatric" diseases such as PTSD or Somatoform Disorders--that these patients demonstrate.

This process can be worsened by further exposure to toxins, solvents, fumes, or subsequent exposures to environmental pathogens. This process can be can be worsened by head injury, especially whiplash. It can become chronic due to infection by neurotoxic microbes, followed by neurodysimmune conflict between immune and neural systems. The result is a vicious cycle of CNS irritability, immune attack on the neurons, and autoimmunity simultaneous with infection by neurotropic / neurotoxic microbes. Along with this vicious cycle, there arises a defect in the ability to utilize oxygen on a tissue level. Membranes begin to break down leading to inflammation in the lining of the lungs and heart. There is loss of energy at a tissue level, with decreased resilience to environmental impacts. These patients cannot tolerate light, loud noise, odors, and foods or drugs. These patients can develop sleep apnea and other forms of insomnia due to the brainstem disorder. They often need mechanical ventilation at night. They develop abnormalities of their SPECT and PET scans due to the Excitotoxic, metabolic and microbial damage. They all require examinations of the antibody levels to immune, neural and microbial antigens. Proper testing will show autoantibdies, immune suppression, and invasion by environmental pathogens. This illness requires very complex workup and treatment.

Appendix

A. Dr. Haley will be happy to provide reprints of the articles that are mentioned.

B. Immune Mechanisms:
1. Prostaglandin Pathway
2. Leukotrine System
3. Mast Cell-Histamine System
4. Tumor Necrosis Factor System
5. Modulation of platelet Serotonin
6. As yet undefined immune modulating pathways.

C. For lack of space, confirmatory data from myself and from Immunosciences Laboratory has not been included, but is available on request

D.The material in this presentation is protected by a pending method patent.

Reviewer #1

MS 070

A computer algorithm offers a comprehensive view of quantitiative bacteriuria

Hyman ES

accepted with minor changes

There is no relationship between what Ed Kass studied and reported 35 years ago and the present day interpretation of his work. Sadly, the interpretation of the meaning of bacteria in the urine, as currently occurs at the bedside, has little or no relation to the evidence. Mistakes are made daily - and sometimes with dire consequences for the patient.

A hurrah for Dr. Hyman. How refreshing is his approach! How simple! and how sensible! It deserves a wide audience, and should be available on the wards for the enlightenment of students and house staff (and those who teach them).

Needless to say this reviewer likes the approach and the message. My concern is: will it be read by the wide audience that should read it? And can the message get across better by improving the manuscript? I struggled with this for a week or two, and could not myself answer it.

Minor Point: lines 1-16.

Would VE and VF not be better written V_E and V_F?

To me, TV means total volume. The abbreviation T is for time (min), and V ises describing the time taken for the bladder to refill after emptying. Would T_R be less confusing?

STATEMENT OF KIRT P. LOVE
GULF WAR RESEARCHER
DIRCTOR OF
DESERT STORM BATTLE REGISTRY
BEFORE THE Institute of Medicine
of the National Academy of Sciences
AUGUST 14, 2000

MISTER CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE:

Physicians are generally able to provide a diagnosis after a single visit with a patient or following the completion of a series of tests. We may see the term "unknown etiology" or "of unknown origin" occasionally associated with the symptom of fever, but very rarely do we see the phrase "undiagnosed illness" reported in the medical chart of a patient. Our veterans' representatives complain that physicians, striving to adhere to standard medical practice, often offer a diagnosis characterized as a "best possible assessment." Because 38 C.F.R. 1 3.317 limits compensation to undiagnosed illnesses, these questionable, perhaps speculative, diagnoses defeat veterans' claims for compensation. We also question how informed VA physicians are regarding the impact of their "assessment" or "diagnosis" on the veteran's ability to be properly compensated by the VA under the provisions relating to compensation for certain disabilities due to undiagnosed illnesses.

Today we respond to charge to the committee's inquiry

1. Identify and describe approaches for assessing treatment effectiveness,

Where H.A.D. is concerned, look at the values of the bone density tests for a real eye-opener.....you will see alot of trends there as well as the A.N.A. and anti-DNA tests, as well as the GGT and ALT/AST tests for liver functions, and Creatine/Creatinin levels in blood and urine analysis that show high protein levels coming from hyperalbuminosis

2. Identify illnesses and conditions common among veterans of the Gulf war

My spinal column is not only deteriorating rapidly, I have a distinct curvature of several Centimeters. Though the conclusion was joint disease, nothing was mentioned concerning the severity of the curvature. I do not have diagnosed arthritis, but I have all the symptoms - pains - degeneration - and osteoplast associated.

3. for these identified conditions and illnesses, identify validated models of treatment.

HAD - Human Adjuvant Disease

The term human adjuvant disease was coined by a Japanese physician who encountered several patients with vague symptoms associated with rheumatic and connective tissue diseases. These patients had had injections into their breasts of mineral oil, silicone oil or other unknown materials for purposes of mammary augmentation.

Based on the erroneous impression that this disease in humans resembles adjuvant arthritis, an experimentally induced disease in rats, the term adjuvant disease was invented. Although adopted by a few investigators in the 1980s, informed physicians or scientists have discredited the term.

http://www.mtdesk.com/alpha2.shtml medical terminology

Coarctation of the aorta ("Coarct")

The aorta is pinched or constricted. This obstructs blood flow to the lower part of the body and increases blood pressure above the constriction.

http://www.americanheart.org/Heart_and_Stroke_A_Z_Guide/conghd.html#as

People with coarctation of the aorta, before and after treatment, are at risk for getting an infection within the aorta or the heart valves (endocarditis) . To help prevent this, they'll need to take antibiotics before certain dental and surgical procedures.

The outlook after surgery is favorable, but long-term follow-up is required. Rarely, coarctation of the aorta may recur. Some of these cases can be treated by balloon angioplasty . The long-term results of this procedure are still being studied. Also, blood pressure may stay high even when the aorta's narrowing has been repaired.

Usually there are no symptoms at birth, but they can develop as early as the first week after birth. A baby may develop congestive heart failure or high blood pressure that requires early surgery. Otherwise, surgery usually can be delayed. A child with a severe coarctation should have surgery in early childhood. This prevents problems such as developing high blood pressure as an adult. *

* Kirt P. Love Director, DSBR
081400 IOM

J Clin Endocrinol Metab 2000 Feb;85(2):692-6

Disturbed neuroendocrine-immune interactions in chronic fatigue syndrome.

Kavelaars A, Kuis W, Knook L, Sinnema G, Heijnen CJ

Department of Pediatric Immunology, Wilhelmina Children's Hospital of the University Medical Center Utrecht, The Netherlands.
a.kavelaars@wkz.azu.nl

[Medline record in process]

The present study was designed to investigate the interaction between neuroendocrine mediators and the immune system in chronic fatigue syndrome (CFS). We examined the sensitivity of the immune system to the glucocorticoid agonist dexamethasone and the beta2-adrenergic agonist terbutaline in 15 adolescent girls with CFS and 14 age- and sex-matched controls. Dexamethasone inhibits T-cell proliferation in healthy controls and in CFS patients. However, the maximal effect of dexamethasone on T-cell proliferation is significantly reduced in CFS patients as compared with controls. The beta2-adrenergic receptor agonist terbutaline inhibits tumor necrosis factor-alpha production and enhances interleukin-10 production by monocytes. Our data demonstrate that the capacity of a beta2-adrenergic agonist to regulate the production of these two cytokines is also reduced in CFS patients. We did not observe differences in baseline or CRH-induced cortisol and ACTH between CFS patients and controls. Baseline noradrenaline was similar in CFS and controls, whereas baseline adrenaline levels were significantly higher in CFS patients.

We conclude that CFS is accompanied by a relative resistance of the immune system to regulation by the neuroendocrine system. Based on these data, we suggest CFS should be viewed as a disease of deficient neuroendocrine-immune communication.

PMID: 10690878, UI: 20152737

My name is Edward S. Hyman, M.D. I am a Fellow of the American College of Physicians I have been in the Private Practice of Internal Medicine for more than 47 years..

Background: My M.D. was from The Johns Hopkins when I was 21. I interned at Washington University under the noted bacteriologist, Dr. W. Barry Wood. After active duty in the Navy, I had a Fellowship and Residency at Stanford, and then spent 2 years in Medicine at Harvard. Then I turned down appointments at Harvard to go into private practice, to see Medicine in the raw before illness such as the Gulf War Illness was divided into categories, which is now the problem.

During these 45 years I have seen thousands of patients from all over the world, referred by physicians or by other patients. Most of these patients had complex medical problems with multiple symptoms which crossed many sub-specialties of Internal Medicine. Many had received the current treatment for illnesses with multiple diagnoses. Many were untreated because the physician did not know how to treat them. Many were sent to Psychiatrists. I found a common cause for the seemingly unrelated illnesses. I was able to help thousands of these who were not helped by other physicians. I found a cause that was common to all of these patients. I developed a method which I refined throughout the years to detect bacteria in the urine. Thus, I have treated patients for 45 years based on my findings in my microscopic examination of their urine. If there is no finding there is no treatment.

My purpose in this phone connection is primarily to answer questions which you may have. Many veterans present know of my successful treatment of Gulf War Illness and a number of them have received the treatment. They can speak for themselves and describe the effect they experienced.

The committee is familiar with my work on this subject. However, I enclose 3 reprints. The previous chairman, Dr. Harold Sox, received ,and I assume read, a manuscript of our results on the Gulf War Illness before the previous meeting of this committee almost a year ago in September of 1999.

The Army and the Veterans Administration are familiar with the work. I presented it to Dr. oshua Lederberg and the members of his Committee in the Pentagon and in detail in June of 1999 to a meeting in the Surgeon General Ronald Blanck's office Both Colonel Engle and Dr. Feussner were present. Many others have visited me in my office laboratory.

They all know that I with 2 well known colleagues, Dr. Quentin Deming retired Chairman of Medicine at the Albert Einstein College of Medicine in New York and William Weiss retired statistician form the FDA, ran a successful placebo controlled, blinded trial which established that the Gulf War Syndrome responds to our antibiotic regimen. The probability that the relief of fatigue we showed could have occurred by chance was less than one in a thousand. The statistics for improvement of quality of life and for relief of headache were equally overwhelming. Pain was also relieved. They know that. Arthralgia goes away.

Most impressively, though we had to use large doses of antibiotics by vein to accomplish this, in our hands there were no significant adverse effects The number of minor ones was the same in the treatment and the placebo groups. The reviewers at Walter Reed were perturbed by a temporary increase of the creatinine kinase in one patient. They misinterpreted this as a liver enzyme. It is not a liver enzyme but is a muscle enzyme. It turned out that this rise was the result of the patient feeling so much better that he suddenly re-instituted heavy muscle training after a long period in which he had done none. His presumed adverse effect was a reflection of improvement.

The implication is surely that this syndrome has a bacterial basis, something that was suggested in about 1912, and is pretty obvious after family members of returning veterans began to experience the same syndromes. That could not result from the veteran having been exposed to chemicals. Sickness due to exposure to chemicals is not contagious. Sickness due to exposure to toxic chemicals is not likely to respond to antibiotics.

The army knows these results. The VA knows these results. We have offered to help them extend the treatment to others. We can not tell you why they have not done so. You will have to ask them. They have said they do not accept our blinding procedure. We think the blinding was highly effective but even if we had used no blinding, a favorable effect on 36 veterans who had sought relief from the Army and VA medical services without success for 5 years should have stimulated them a bit.

Perhaps the most distressing failure of the government to help is shown by the stories of veterans who responded to this treatment. Some of them may be here today. If they were then maintained with benefit by continued oral medication but began to relapse when neither the Army nor the VA would continue to provide a medication which had already been shown to help that particular veteran.

To me the story is inexplicable and sad. No doubt Colonel Engle and Dr. Feussner will offer you explanations which they will consider "scientific". If they or their family had contracted the disease, perhaps each of them would be less unfavorable. Ask the veterans who have been through the program what they think of the explanations.

I will answer any questions now. Most importantly, Colonel Engle and Dr. Feussner have already had their unrestricted time to explain this away, I would be happy to answer their or your further questions. Unless the committee's rules do not allow answers to government statements.

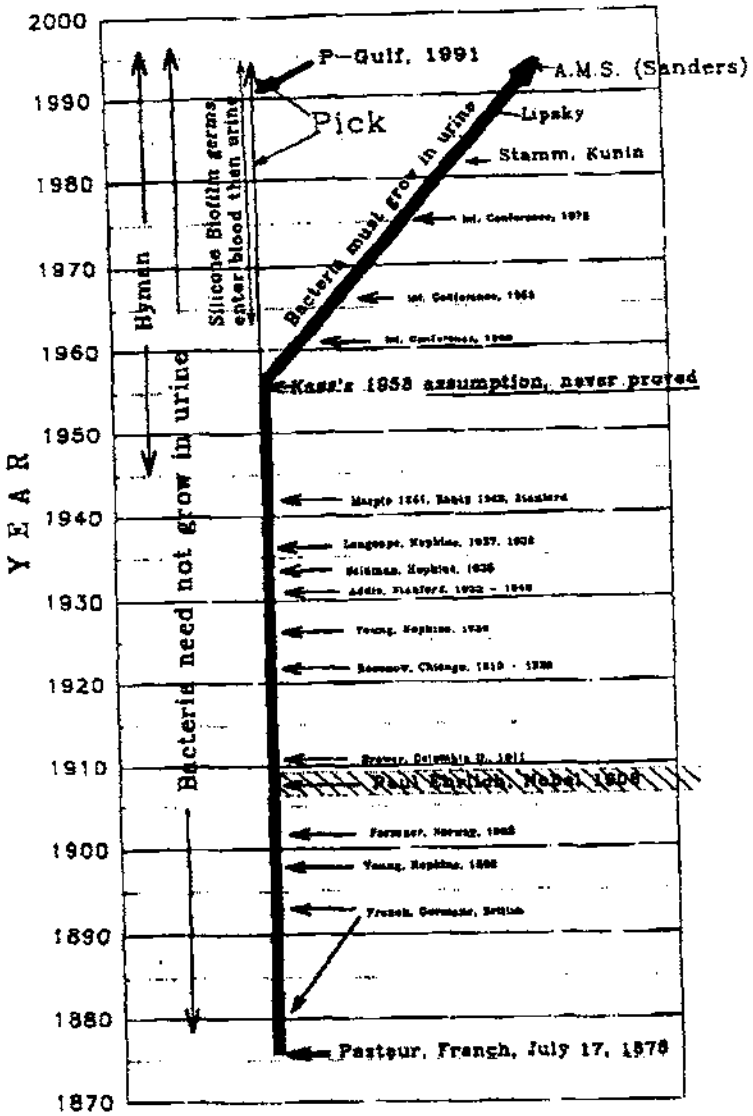
Pertinent references (outside the copying rules):

Hyman, E.S. Improved Microscopic Detection of Bacteriuria. Biotechnic & Histochemistry, 1992 (vol 67):1-8.

Hyman, E.S. Computer Algorithm Offers a Comprehensive View of Quantitative Bacteriuria. Nephron 1993;65:549-558.

Hyman, E,S, A Urinary Marker for Occult Systemic Coccal Disease. Nephron 199;68:314-326.

"Significant" Bacteria in Urine



Ed Hyman

STATEMENT OF VENUS-VAL HAMMACK
GUFL WAR RESEARCHER COODINATOR
FOR THE PERSIAN GULF ERA VETERANS AND
NORTH SHORE VETERANS COUNCILING SERVICE
DESERT STORM BATTLE REGISTRY
BEFORE THE Institute of Medicine
of the National Academy of Sciences
AUGUST 14, 2000

MISTER CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE:

The PGEV, NSVCS AND DSBR believes PGW veterans are significantly disadvantaged in the VA system in terms of medical treatment for and adjudication of claims for undiagnosed illnesses. These results from adherence to standard medical practices, which are inappropriate in this context, combined with a current narrowly-defined VA regulation for undiagnosed illnesses. Simply put, doctors are trained to assess, diagnose, and treat patients for symptoms they experience. Their medical training teaches them to focus on and determine what "disease process" is responsible for making a patient ill. Generally speaking, it is an atypical situation when a physician is unable to provide a diagnosis or probable assessment for an illness he or she encounters; however, "undiagnosed illnesses" are specifically associated with Gulf War Syndrome. To be entitled to compensation under 38 C.F.R. □ 3.317, the illness must remain undiagnosed. Therefore, the standard medical practice of providing a diagnosis for an ill-defined health problem disadvantages PGW veterans seeking compensation under the undiagnosed illness provision.

Physicians are generally able to provide a diagnosis after a single visit with a patient or following the completion of a series of tests. We may see the term "unknown etiology" or "of unknown origin" occasionally associated with the symptom of fever, but very rarely do we see the phrase "undiagnosed illness" reported in the medical chart of a patient. Our veterans' representatives complain that physicians, striving to adhere to standard medical practice, often offer a diagnosis characterized as a "best possible assessment." Because 38 C.F.R. □ 3.317 limits compensation to undiagnosed illnesses, these questionable, perhaps speculative, diagnoses defeat veterans' claims for compensation. We also question how informed VA physicians are regarding the impact of their "assessment" or "diagnosis" on the veteran's ability to be properly compensated by

the VA under the provisions relating to compensation for certain disabilities due to undiagnosed illnesses.

[1] name and describe away/method to determine treatment performance
[2] name illnesses GWV suffer from; name source
[3] name legitimate methods of treatment which improve GWV quality of health

many vets have had specific audivestibular tests or the
Spect SCANS done and analyze those with a technique called statistical therametric mapping, which we now believe is the best way to do that. these people have normal MRIs as people with these other
diseases would have very early in the course. Well, in that case, the next thing you do is -- many things you can do are proton magnetic resonance spectroscopy. Now there are different kinds of spectroscopy.
There are diseases with a normal MRI, the regular MRIs that shows no brain abnormalities, epilepsy. Now you can see abnormality -- chemical abnormalities indicating loss of neurons or inflammation in the emporal lobes that predict epilepsy. And in fact, this is now used to guide the surgeons in order to operate to take out the offending lesion and stop the epilepsy. Yet how can I expect my VA doctor to know this when he does not have access or has not even read the GUIDELINES ON GULF WAR HEALTH (VA Educational document).

The use of Amphetamines are non-catecholamine sympathomimetic amines with CNS stimulant activity. Adderall should be indicated as an integral p.r. of a total GW Veteran's treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in adults with cognitive disorders or behavioral syndrome. characterized by the following group at developmentally inappropriate symptoms: moderate to severe distractibility, short attention span, hyperactivity, emotional liability, and impassivity. The diagnosis of this syndrome should not be made with finality when these symptoms are only of comparatively recent origin. Nonlocalizing (soft) neurological signs, learning disability and abnormal EEG may or may not be present, and a diagnosis of central nervous system dysfunction may be warranted.

many vets have had specific audivestibular tests or the Spect
SCANS done!

GULF WAR VETS 1999

IN SO CALLED GULF WAR CLINIC

DO NOT HAVE SPECIALISTS IN THESE AREAS
TREATING THEM- ONLY COLLECTING
RESEARCH

IMMUNOLOGISTS
TOXOLOGISTS
INDUSTRIAL HYGIENE SPECIALISTS

RESPIRATORY TOXICOLOGIST

NUCLEAR MEDICINE PHYSICIAN WITH
PET OR SPECT EXPERIENCE

BEHAVIORAL TOXICIOLISTS

INFECTIOUS DISEASE SPECIALISTS
TRAVEL MEDICINE SPECIALISTS

REFERRALS TO CIVILIAN DOCTORS OR LABS
ARE TOO -FEW (1 IN 48) requests

Sick Vets Are...

VA Facts: VA Fact sheet:

VA FINALLY FINDS A UNIQUE GULF WAR SYNDROME

After 8 years of government officials repeatedly denying the existence of any new or unique Gulf War syndrome, the Department of Veterans' Affairs has finally concluded--in its own "Nationwide Health Survey of Gulf War Era Veterans"--that, based on data from 11,442 Gulf War veterans and 9,476 non-Gulf War veterans:

"There is a cluster of symptoms unique to Gulf War veterans which could be defined as a new Gulf War Syndrome."

This is the entire conclusion of a short poster entitled "Unique Cluster of Symptoms Among Gulf War Veterans: Cluster Analysis" that was included in the conference proceedings (page 99) but not officially discussed by the VA at the Conference on Federally Sponsored Gulf War Veterans' Illnesses Research held June 23-25, 1999, in Pentagon City, VA.

The study was done by Drs. Han Kang (the VA's chief epidemiologist), Fran Murphy, Clare Mahan, and Kyung Lee in the VA's Central Office and
Drs. Samuel Simmons, Heather Young, and Paul Levine at George Washington University. Its findings replicate and validate those of a more comprehensive factor analysis reported in 1997 by Dr. Robert Haley et al., independent researchers at the Univ. of Texas funded by Ross Perot (see .Haley RW, Kurt TL, Hom J, Is there a Gulf War Syndrome? Searching for syndromes by factor analysis. JAMA 277(3)215-222, 1997).

Dr. Haley presented a paper and several posters himself at this meeting, including a "Confirmatory factory analysis of Haley's three primary Gulf War syndromes in a (N. Texas) VA population of Gulf War veterans."

The VA and Haley both "factored out" the same three symptom clusters or syndromes, although the VA chose to recognize only the most severe,

which it called Neurological (and Haley called Confusion/Ataxia). Both also factored a long list of self-reported exposures, and both found the same one--exposure to nerve gas--factored most significantly with Syndrome 2 (odds ratio of 4.4 compared to those without the syndrome).

Dr. Haley also presented functional MRI data showing brain abnormalities in intracellular chemicals indicative of reduced neuronal and glial cell mass in all three syndromes.

Syndrome 1 abnormalities were focused in the basal ganglia, Syndrome 3 in the pons area of the brain stem, and Syndrome 2 showed abnormalities in both. These areas of the brain are already associated with other chronic neurological disorders like CO poisoning, MS, Parkinsons and Alzheimers.

The VA's "Neurological" Syndrome (#2)
(called Confusion/Ataxia by Haley et al) comprises symptoms of:

Blurred vision
Concentration & memory problems
Irregular heartbeat
Loss of balance & dizziness
Speech difficulty
Sudden loss of strength
Tremors & shaking

The VA claims this cluster was self-reported by 2.4% of the 11,442 deployed veterans (n=277) but only by 0.4% of the non-deployed veterans, among whom it did not factor out as a separate syndrome.

The VA also looked at the relative risk for other medical conditions.
Most significantly, brain seizures were reported by 22.2% of those with this VA Gulf War Syndrome but only 0.4% of the entire population, and neuralgia/neuritis by 32.1% vs. 1.7%.

Unfortunately and unconscionably, now that the VA has finally discovered a Gulf War Syndrome, it has no plans to study it any further.

* The VA says it has no plans to examine or follow any of the 277 cases found in this study--despite its having recently initiated a third and final phase of this same study to conduct extensive physical and laboratory evaluations of 1,000 deployed veterans and their families compared to 1,000 non-deployed. With recruitment and testing scheduled to be conducted through 2002, VA could easily include all those with this "new and unique" Gulf War Syndrome if it cared to do so.

*Nor will VA screen any of the Phase 3 subjects it is selecting for this Gulf War Syndrome, to see if any other cases may be detected, and it has no plans to train its doctors to identify or diagnose this Gulf War Syndrome in their VA Registry examinations.

* Nor does VA have any plans to compensate any Gulf War veterans who may have this syndrome, and it does not even plan to warn them about the greatly increased relative risk they face for neuralgia (RR=18.9) and seizures (RR=55.5) compared to Gulf War veterans without this syndrome. This incredibly high risk of seizures may be contributing to the veterans' higher than expected rate of fatal accidents while driving.

The other two syndromes factored by the VA in the National Health Survey were:

Syndrome 1: Fatigue / Depression
(called Impaired Cognition by Haley et al)

Awaken tired and worn out
Concentration and memory problems
Excessive fatigue
Fatigue >24h after exertion
Feeling anxious, irritable, or upset
Feeling depressed or blue
Sleep difficulty
Sleepiness during daytime

Syndrome 3: Musculoskeletal/Rheumatologic
(called Artho-Myo-Neuropathy by Haley et al)

Back pain/spasms
Generalized muscle aches
Joint aches
Numbness in hands/feet
Swelling in joints
Swelling in extremities

CONGRESSIONAL or SPECIAL CORRESPONDENCE

CMAT: pending
Date: AUG 17 2000

Office of Special Assistant for Gulf War Illnesses
Internal Routing/Tasking Sheet

Coord/ Routing	Position/Organization		Action	Info	Comments
	Special Assistant	(SA)			
6	Deputy Special Assistant	(DSA)	V 8-8	X	
	Executive Assistant to SA	(EA)			
	Executive Assistant to DSA	(EADSA)			
4	☐ Director, Investigation & Analysis _____ (IAD) ☐ DepDir _____ ☐ MED _____ ☐ VDM _____ ☐ C/B _____ ☐ ENV _____ ☐ PAG _____		NWA 22 Aug 00	X	
3	Dir Lessons Learned Implementation	(LLI)		X	by forwarded copy of memo.
2	Dir Public Affairs & Outreach	(PA)		X	
	Dir Medical Outreach & Issues	(MOI)			originator
	Legal Advisor	(LGL)			
5	PM, Gulf War Illnesses Support	(PM)		X	
1	Editorial Review ☐ AMB 2 ☐ Editors _____	(ER)			
	CMAT	(CMAT)			
	Action Management Call 845-8369 X COMEBACK COPY TO: MOI X GET CMAT NUMBER WHEN SIGNED & SENT ☐ READING FILE ☐ THANK YOU FILE X CHRON FILE ☐ ADD TO GulfNEWS				

SUSPENSE:

Prepare reply for signature of:
☐ SA/GWI ☐ SD ☐ DSD ☐ DepSA/GWI

☐ Congress ☐ Oversight ☐ FOIA ☐ OSD ☐ WBM ☐ VSO/MSO ☐ Outgoing
☐ Ltr to SA ☐ IR ☐ E-Mail ☐ OGA ☐ Other ☐ Veteran

KEYWORDS:

05/11/00 Issuance

(125)

CMAT Control #
2000236-0000015

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
FOR
GULF WAR ILLNESSES

AUG 2 1 2000

MEMORANDUM FOR ASSISTANT SECRETARY OF DEFENSE FOR RESERVE AFFAIRS
(MANPOWER & PERSONNEL)
(ATTENTION: (b)(6)

SUBJECT: Proposed Response to Chairman Burton

We understand the magnitude of the effort you are undertaking with the two survey questionnaires to Reserve Component member and spouses, however, we do not concur in the proposed response.

The following actions are recommended for your consideration:

- If it is determined that the best course of action is to not add questions to the surveys as requested by the Chairman, (or if the questionnaires have already been mailed) then state this up front rather than in the final paragraph of the letter.

  If the survey questionnaires have not been mailed, you should state, in terms of time and dollars, the cost of adding the addendum requested by Chairman Burton.

- The second and third paragraphs seem to be overly instructional; they should be rewritten.

- The fourth paragraph brings out anecdotal information whereas what Chairman Burton is proposing is survey research. Your information may be correct, but does not have the strength of survey research.

- (b)(5)

If you decide that you need to include survey questions pertaining to Gulf War illnesses, we will provide assistance. Thank you for the opportunity to review your proposed response.

Michael H. Abreu
COL US Army
Director, Investigation & Analysis

Office of the Assistant Secretary
of Defense for Reserve Affairs
(Manpower & Personnel)

To: Assistant Secretary of Defense for Legislative Affairs
Senior Advisor to DSD for Chemical and Biological Protection
Special Assistant for Military Deployments

From: ODASD(Manpower and Personnel)

Date: August 18, 2000

Subject: Proposed Response to Representative Burton

Enclosed for your coordination is the proposed response to Representative Burton's request to expand the scope of the Reserve component member and spouse surveys to include questions regarding the Anthrax Vaccine Immunization Program and Gulf War Syndrome.

In order to provide a timely response to Representative Burton, your coordination is requested not later the close of business, Monday, August 21, 2000.

Please call (b)(6) or (b)(6) for pick up.

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
1500 DEFENSE PENTAGON
WASHINGTON, DC 20301-1500

RESERVE AFFAIRS

MEMORANDUM FOR SECRETARY OF DEFENSE
DEPUTY SECRETARY OF DEFENSE

THROUGH: UNDER SECRETARY OF DEFENSE (PERSONNEL AND READINESS)

FROM: PRINCIPAL DEPUTY ASSISTANT SECRETARY OF DEFENSE (RESERVE AFFAIRS)
Prepared by: (b)(6) OASD/RA, (b)(6)

SUBJECT: Congressional Inquiry Regarding Reserve Component Survey of Members and Spouses — ACTION MEMORANDUM

PURPOSE: To respond to Representative Burton's request that we postpone implementation of the surveys so that we can include questions regarding the Anthrax Vaccine Immunization Program (AVIP) and Gulf War Syndrome (TAB A).

DISCUSSION: Mail distribution of the first comprehensive survey of Reserve component members and spouses since 1992 began on August 16, 2000. A press release announcing the surveys was issued on August 9, 2000 (TAB B). Over 20,000 surveys had been placed in envelopes and prepared for mailing when Representative Burton's letter was received.

These surveys follow similar surveys in 1986 and 1992, and closely parallel a 1999 survey of active duty personnel and spouses. The surveys are to gather information on a wide range of programs, policies and issues affecting Reserve members and spouses and to provide a longitudinal look at these issues over time. Responses will provide a look at morale, civilian work, economic issues, military training, benefits, impacts of mobilizations, plans to leave or remain in the military and family characteristics.

The type of questions Representative Burton is proposing are not considered appropriate for these surveys. Survey experts advise that it is difficult to ask questions on such matters without first educating the target group. Otherwise, you risk receiving false-positive responses and negatively affecting the reliability of survey analysis. Such questions are best addressed in separate survey efforts. The GAO is conducting a survey specifically addressing the AVIP. If the Congress desires that the Department study the AVIP and Gulf War Syndrome issues in a survey instrument, we shall do so as a separate and focused effort.

Proposed response states the best interests of the Total Force are served by implementing the survey as it is currently printed and that we cannot comply with Representative Burton's request.

COORDINATION: ASD/LA: _____ DSD/CBP: _____ SMD: _____

RECOMMENDATION: Sign memorandum at Tab A.

SECDEF DECISION:

_____ Approved

_____ Disapproved

_____ Other

THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

Honorable Dan Burton
Chairman
Committee on Government Reform
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Thank you for your letter of August 15, 2000, requesting that we postpone dissemination of our Reserve component member and spouse surveys for the purpose of including questions on the Anthrax Vaccine Immunization Program (AVIP) and the Gulf War Syndrome. Since the survey questionnaires have already been printed, you recommended that we develop and include an "insert" to accompany the questionnaire package. You also requested the survey results when complete. We plan to share the results of these surveys with members of the Congress and many other interested individuals and organizations.

We take great care to assure that each DoD-initiated survey methodology adheres to the highest scientific standards and produces statistically valid results. We base many policy decisions on the results of our periodic surveys; therefore, our confidence in these measurement tools must be very high. Scientific method mandates good survey design and response analysis. Reliable survey questions must be tested and evaluated. This takes considerable time, expense and experience. These surveys were carefully designed to follow similar surveys in 1986 and 1992, with many identical questions. Our goal is to develop a longitudinal measure and display of attitudes on continuing and evolving issues over time.

Survey questions are designed to elicit responses that may influence policy decisions; however, it is important to recognize that we do not base all of our policy decisions on survey results. On matters as important as force health protection and readiness, the needs of our military and our country are paramount. DoD implemented the AVIP as a Total Force protection measure against an imminent threat. It is unlikely that we would alter our force protection policy based on the opinions expressed in the survey responses.

Additionally, your comments alluding to growing adverse concerns within the military ranks, dependent community and public at large are not consistent with our data. To the contrary, our data indicates a significant reduction in comments and concerns. We are, in fact, registering more concern from individuals who want to take the vaccine than from those who are opposed.

We regret that we cannot comply with your request to delay the survey for the purpose of adding special questions. In view of the extensive preparations for this survey over the past two years, our existing contractual obligations and the considerable delay in receiving important force-related information

(b)(5)

Sincerely,

TAB A

ONE HUNDRED SIXTH CONGRESS

2000 AUG 16 AM 8:23

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5074
MINORITY (202) 225-5051
TTY (202) 225-6852

August 15, 2000

The Honorable William Cohen
Secretary of Defense
The Pentagon
Washington, DC 20301

Dear Mr. Secretary Cohen:

Pursuant to Rules X and XI of the Rules of the House of Representatives, the Committee on Government Reform has oversight jurisdiction of the Department of Defense (DOD).

It has recently been brought to my attention that the DOD is going to conduct a comprehensive satisfaction survey of military Reserve force personnel and their spouses The surveys will gather information on a wide range of programs, policies and issues affecting Reserve forces personnel and their families. I have reviewed the survey forms and am disappointed that there are no questions surveying the attitudes, opinions or impressions of the Reserve military members or their spouses regarding DOD's Anthrax Vaccine Immunization Program (AVIP). In light of the significant on-going Congressional interest and inquiry regarding the Anthrax vaccine's safety and efficacy, and the growing adverse concerns within the military ranks, dependant community and the public at large, I request that you expand the scope of your survey to include an assessment of the AVIP and the Gulf War Syndrome's impact upon Reserve Component personnel. This survey provides an excellent venue to determine the true impact of both of these programs upon our Reserve forces and their families.

In DOD's August 9, 2000, news release announcing the survey, Mr. Charles Cragin, Principal Deputy Assistant Secretary (Reserve Affairs), stated "...As a department, we must continually strive to do a better job of recognizing and dealing with issues that can adversely affect Reserve component members and their families..." In your statement on December 7, 1997, you said "....to be effective, medical force protection must be comprehensive, well documented and consistent." Surveying DOD's

U11471 /00

reserve component personnel and their spouses regarding AVIP program will demonstrate insightful leadership consistent with the above guidance.

I would like to ask that you postpone implementation of this initiative so you may include questions surveying the AVIP program and impacts of the Gulf War Syndrome concerns. Knowing that the surveys have been printed, I would propose that a survey "insert" be developed to be included in the existing survey packets before they are mailed

Please provide your response by this afternoon, Tuesday, August 15 to my Professional Staff Member, S. Elizabeth Clay. I would like to also request the results of the surveys at their time of completion. If you have any questions, please free to contact Ms. Clay at 202-225-5074.

Thank you for your immediate attention to this matter.

Sincerely,

Dan Burton

Dan Burton
Chairman

Cc: The Honorable Henry Waxman
Chairman, Joint Chiefs of Staff
The Honorable Bernard Rostker
The Honorable Charles Cragin

ONE HUNDRED FIFTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6143

FACSIMILE TRANSMISSION

TO: Secretary Cohen

FROM: T.J. Lightle

PHONE: Voice: (202) 225-5074
Fax: (202) 226-1274

DATE: 8-15-00

FAX NUMBER: (b)(6)

There will be a total of 3 pages, including this page.

COMMENTS: IMPORTANT!

If there are any questions or problems
regarding this transmission, please call the sender
at (202) 225-5074

TAB B

NEWS RELEASE
OFFICE OF ASSISTANT SECRETARY OF DEFENSE
(PUBLIC AFFAIRS)
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DOD TO SURVEY RESERVISTS, SPOUSES

Between August and November 2000, the Department of Defense (DoD) is conducting its first comprehensive satisfaction surveys of military Reserve force personnel and their spouses in eight years. A survey questionnaire is being mailed to 75,000 Reserve and National Guard members. A different questionnaire is being sent to 43,000 spouses. In a first for the Reserves, recipients are able to return the written questionnaires or respond via the Internet.

"The surveys are an important tool because, in recent years, the increased use of the National Guard and Reserve has resulted in many of these personnel spending more time away from their families and full-time civilian employment," said Charles L. Cragin, principal deputy assistant secretary of Defense for Reserve Affairs. "They also face the real possibility of being called to active duty for extended periods, creating some unique quality-of-life concerns."

The surveys will gather information on a wide range of programs, policies and issues affecting Reserve forces members and spouses. Survey responses will provide a comprehensive look at morale, civilian work, economic issues, military training, military benefits and programs, mobilizations and deployments, plans to leave or continue in the military, and member and family characteristics. The effort complements the recently fielded "1999 Surveys of Active Duty Personnel and Spouses."

There are 863,698 personnel serving as Selected Reservists in the seven Reserve forces: the Army National Guard, the Army Reserve, the Naval Reserve, the Marine Corps Reserve, the Coast Guard Reserve, the Air Force Reserve, and the Air National Guard.

The member questionnaire will be mailed to drilling reservists, individual mobilization augmentees, (IMAs) and full-time support personnel. Members up to the rank of O-6 (captain in the Navy and Coast Guard, or colonel in the other services) with at least six months of service, are eligible to be surveyed.

The sample population was determined by component, pay grade, gender, marital status, military occupation, and program status (drilling reservists, full-time support personnel, IMAs). Individuals were selected at random within these groups to ensure adequate sample sizes for subgroups of particular interest. Spouses of members were selected separately from members-sampling was of individuals rather than couples. Consequently, a spouse could be sampled whether or not the member is.

The Office of the Secretary of Defense (Reserve Affairs) will use the findings from these surveys to address reservists' concerns and inform policy officials about unit and family readiness issues, military job satisfaction and mobilization experiences. The information will also be used to respond to queries from Congress, the White House, and the news media. Survey results will be published and available on the World Wide Web by the spring of 2001.

"As a department, we must continually strive to do a better job of recognizing and dealing with issues that can adversely affect Reserve component members and their families," said Cragin. "Our ultimate objective is to craft policies that benefit reservists and, at the same time, protect our national security interests. The empirical data we gain from these surveys is critical to accomplishing this."

For more information, please call the office of the assistant secretary of Defense for Reserve Affairs - Army National Guard Lt. Col. Terry Jones at (703) 695-3620. For more information on the Reserve and National Guard, visit the Reserve Affairs web site at http://raweb.osd.mil.

http://www.defenselink.mil/news/Aug2000/b08092000_bt495-00.html

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2000 Survey of Reserve Component Personnel

Form M

DMDC Survey No. 00-0002M

DEFENSE MANPOWER DATA CENTER
ATTN: SURVEY PROCESSING ACTIVITY
DATA RECOGNITION CORPORATION
5900 BAKER ROAD
MINNETONKA, MN 55345-5987

- Use a blue or black pen, or a pencil.
- Select answers you believe are most appropriate.
- Do not make any marks outside of the response and write-in boxes.
- Please PRINT where applicable.
- Place an "X" in the appropriate box or boxes.

RIGHT	WRONG
X	✓ O

- To change an answer using pen, completely black out the wrong answer and put an "X" in the correct box as shown below.

CORRECT ANSWER	INCORRECT ANSWER
X	■

- To change an answer using pencil, completely erase the wrong answer and put an "X" in the correct box.

ABOUT THIS QUESTIONNAIRE

WHAT IS THE PURPOSE OF THIS SURVEY?

This survey asks about your attitudes and opinions on a wide range of personnel issues in the Reserve components such as morale, well being, and your military plans. This survey will be used to assess programs, policies, and issues affecting Reserve component members and their families. **While no decisions about you alone will be made based on this survey, survey results will influence policy discussions and may result in changes that affect Reserve component members and families.** If you don't respond, your views and the views of other members like you will not be considered in personnel policy reviews and changes.

WHY ME?

You have been selected scientifically to be part of a sample of people who represent members of the Reserve components. Based on your responses and the responses of others, conclusions may be drawn about the views and experiences of Reserve component members overall, and those of demographic subgroups. The validity of these conclusions depends, in part, on receiving enough completed surveys from individuals like you. **The survey results will not be valid if you allow someone else to fill out the survey for you.**

WILL MY SURVEY RESPONSES BE KEPT PRIVATE?

Yes. Under no circumstances will any information about identifiable individuals be released. Your responses will be combined with information from many other members to represent the views and experiences of groups of members. **Do not use any personal, unit, or place names anywhere on this survey.**

PRIVACY NOTICE

In accordance with the Privacy Act of 1974 (Public Law 93-579), this notice informs you of the purpose of the survey and how the findings will be used. Please read it carefully.

AUTHORITY: 10 United States Code, Sections 136, 1782, and 2358.

PRINCIPAL PURPOSE: Information collected in this survey will be used to assess the attitudes and perceptions of Department of Defense and Department of Transportation personnel about programs and policies. This information will help formulate policies that may be needed to improve the working environment.

ROUTINE USES: Reports may be provided to the Secretaries of Defense, Transportation, and the Military Departments, and to the Joint Chiefs of Staff. Findings may be used in reports and testimony provided to Congress. Some findings may be published by the Defense Manpower Data Center (DMDC) or professional journals, or reported in manuscripts presented at conferences, symposia, and scientific meetings. In no case will the data be reported or used for identifiable individuals.

DISCLOSURE: Providing information on this survey is voluntary. There is no penalty if you choose not to respond. However, maximum participation is encouraged so that the data will be complete and representative. Your survey instrument will be treated as confidential. Identifying information will be used only by persons engaged in, and for the purposes of, the survey. Only group statistics will be reported.

I. MILITARY BACKGROUND

1. Of which Reserve component are you a member?

Army National Guard
Army Reserve
Naval Reserve
Marine Corps Reserve
Air National Guard
Air Force Reserve
Coast Guard Reserve
No Reserve component ⇨ **STOP. RETURN SURVEY**

2. How many years have you served in any of the following components? *Mark all that apply. Do not count partial years. Include as Reserve component years:*

- *Time spent mobilized/activated on active duty*
- *Time spent in a full-time active duty program*
- *Time spent in Individual Ready Reserves (IRR)*
- *Time spent as an Individual Mobilization Augmentee (IMA)*

COMPONENT	FULL YEARS
Active Army (USA)	
Army National Guard (ARNG)	
Army Reserve (USAR)	
Active Navy (USN)	
Naval Reserve (USNR)	
Active Air Force (USAF)	
Air National Guard (ANG)	
Air Force Reserve (USAFR)	
Active Marine Corps (USMC)	
Marine Corps Reserve (USMCR)	
Active Coast Guard (USCG)	
Coast Guard Reserve (USCGR)	

3. What is your current paygrade?

E-1	E-6	W-1	O-1/O1E
E-2	E-7	W-2	O-2/O2E
E-3	E-8	W-3	O-3/O3E
E-4	E-9	W-4	O-4
E-5		W-5	O-5
			O-6 or above

4. If you stay in the National Guard/Reserve, when would you expect to be selected for your next promotion to a higher grade?

Does not apply, I do not expect a promotion ⇨ **GO TO QUESTION 6**
Does not apply, I have no opportunities for promotion ⇨ **GO TO QUESTION 6**
I have been selected, but not yet received it
Less than 3 months
3 months to less than 7 months
7 months to less than 1 year
1 year to less than 2 years
2 years or more

5. When would you expect to actually receive your next promotion to a higher grade?

Less than 7 months
7 months to less than 1 year
1 year to less than 2 years
2 years or more
I don't expect to receive it

6. How long have you been in your present unit? *Do not count partial years.*

Less than 1 year
Full years

7. Are you in a different unit now than you were two years ago?

I am no longer in a unit ⇨ **GO TO QUESTION 10**
I was not in a National Guard/Reserve unit two years ago ⇨ **GO TO QUESTION 10**
No, I am in the same unit ⇨ **GO TO QUESTION 10**
Yes, in different unit but in same component
Yes, in different unit in different component

8. Did the following contribute to your changing units? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Was offered a promotion		
b. Promotion was more likely in new unit		
c. Relocated away from previous unit because of civilian job, school, or personal reasons		
d. Previous unit was moved		
e. Went to a unit that was closer		
f. Reorganization within previous unit		
g. Previous unit was closed, deactivated or disestablished		
h. Previous unit moved to another component		
i. Wanted to retrain in a different skill		
j. Thought I would like the job better in new unit		
k. Problems with co-workers or chain of command		
l. Didn't like unit environment		
m. Inadequate administrative support from Reserve or Guard unit/center		
n. Operations Tempo (OPTEMPO) or Personnel Tempo (PERSTEMPO) was too high		
o. Had a new assignment		
p. Was released from active component		
q. Changed Reserve status (e.g., changed from drilling unit to IRR)		
r. Conflict with civilian employment		
s. Mandatory rotation		
t. Family problems		

9. Did you have to retrain in a new skill when you changed units?

No
Yes

10. Have you ever been mobilized or deployed as a member of the National Guard/Reserve?

No ⇨ **IF NO, GO TO QUESTION 16**
Yes

11. Were you mobilized or deployed as a Reservist for the operations listed below? ***Mark "No" or "Yes" for each item. If you mark "Yes" in column A, please indicate whether it was voluntary or involuntary, the deployment's location, and its length. If you mark "No" in column A, go to the next item in column A.***

	A. Were you mobilized or deployed as a member of the National Guard/Reserve for the operations (a-k) listed below?		B. Was your mobilization voluntary or involuntary?		C. Where did you deploy? (Mark one)				D. How long were you mobilized or deployed? Write in number of months. If under 1 month, enter "00". If mobilized/deployed now, write number of months so far.
	No	Yes ⇨	Voluntary	Involuntary	Does not apply, did not deploy	In own state or equivalent (e.g., DC, GU, PR, VI)	To another state or equivalent (e.g., DC, GU, PR, VI)	Outside US	
a. Operation Desert Shield/Storm		⇨							
b. Saudi Arabia (Aug 92-present)		⇨							
c. Centam, Hurricane Mitch Recovery/Rehab		⇨							
d. Operation Restore/Uphold Democracy (Haiti)		⇨							
e. Operation Desert Fox/Iraqi Crisis (SW Asia)		⇨							
f. Operation Joint Forge/Guard/ Endeavor (Bosnia)		⇨							
g. Operation Restore/Continue Hope (Somalia)		⇨							
h. Operation Joint Task Force (Cuba)		⇨							
i. Operation Allied Force (Kosovo)		⇨							
j. Other mobilization or deployment (1) ***Describe:***		⇨							
k. Other mobilization or deployment (2) ***Describe:***		⇨							

12. Are you mobilized/deployed now? ***If yes, indicate the operation in Question 11 for which you are mobilized/deployed.***

No Yes ⇨

IF YES, MARK ONE ⇨

a	d	g	j
b	e	h	k
c	f	i	

If you are currently mobilized/deployed, answer Questions 13-15 about your current mobilization/deployment. If you are not currently mobilized/deployed, answer Questions 13-15 about your most recent mobilization/deployment.

13. Please estimate your (and your spouse's) total income change from all sources as a result of your most recent mobilization or deployment. ***If you (and your spouse) have continuing losses from a business or practice, include those in your estimate.***

Increased $5,000 or more	Decreased $2,500-4,999
Increased $2,500-4,999	Decreased $5,000-9,999
Increased $1-2,499	Decreased $10,000-24,999
No change in income	Decreased $25,000-49,999
Decreased $1-2,499	Decreased $50,000 or more

14. Did the following changes in expenses occur as a result of your being mobilized or deployed? ***Mark "No" or "Yes" for each item.***

	No	Yes
a. Medical expenses increased		
b. Medical expenses decreased		
c. Telephone expenses increased		
d. Household maintenance and car repairs increased		
e. Household maintenance and car repairs decreased		
f. Childcare increased		
g. Mortgage payments declined		

15. What health insurance options did you choose the last time you were mobilized or deployed? ***Mark "No" or "Yes" for each option.***

	No	Yes
a. I kept my private/civilian health insurance		
b. I dropped my private/civilian health insurance		
c. I did not have any health insurance before mobilization/deployment		

16. The questions below are about your preparedness. ***Mark one answer for each item.***

	No	Yes	Not applicable
a. If you are a single parent or are married to a military member, do you have a family care plan?			
b. If you have a family care plan, is it up to date?			
c. Do you have a current written will?			
d. Does anyone currently hold your power-of-attorney?			
e. Do you have life insurance other than SGLI/VGLI?			
f. Have you ever filled out a record of emergency data?			
g. Have you verified/updated your record of emergency data in the past 12 months?			
h. Does your spouse or next-of-kin know where to find your important papers (e.g., will, car registration, checkbook, bank statements)?			

17. Do you plan to elect the Reserve components Survivor Benefit Plan (SBP) when eligible? ***Mark only one.***

- Does not apply, I don't plan to remain until eligible for retirement
- I have already elected to participate
- I have already elected <u>not</u> to participate
- Yes, upon receipt of my 20-year letter
- Yes, when I am 60 years old
- No
- Uncertain, I am not aware of the plan at all
- Uncertain, I don't understand the plan clearly
- Uncertain, I have not made up my mind

18. Have you volunteered for any operations (floats, police actions, training exercises, etc.) for which you were <u>not</u> mobilized or deployed?

- No
- Yes

19. How unlikely or likely is it that you would <u>volunteer</u> for a mobilization or deployment occurring in the next 5 years?

- Very unlikely
- Unlikely
- Neither likely nor unlikely
- Likely
- Very likely

20. How unlikely or likely do you think it is that you, as an individual, will be mobilized or deployed in the next 5 years?

- Very unlikely
- Unlikely
- Neither likely nor unlikely
- Likely
- Very likely

21. How unlikely or likely do you think it is that <u>your unit</u> will be mobilized or deployed in the next 5 years?

- Does not apply, I am not in a Guard/Reserve unit
- Very unlikely
- Unlikely
- Neither likely nor unlikely
- Likely
- Very likely

In this survey, the definition of "military duties" includes deployments, TADs/TDYs, training, military education, time at sea, and field exercises/alerts.

22. In the past 12 months, have you been away from your home overnight because of your military duties? ***Do <u>not</u> include nights spent away from home before out-of-town drills.***

- No ⇨ **IF NO, GO TO QUESTION 24**
- Yes

23. During the past 12 months, how long were you away from your home for the following military duties? ***Add up <u>all</u> nights away from home; assign each night to only one type of military duty.***

	10 months to 12 months	7 months to less than 10 months	5 months to less than 7 months	3 months to less than 5 months	1 month to less than 3 months	Less than 1 month	None
a. Peacekeeping or other contingency operation							
b. Foreign humanitarian assistance mission							
c. Unit training at combat training centers							
d. Counter drug operation							
e. Domestic disaster or civil emergency							
f. Time at sea for scheduled deployments (other than for the above)							
g. Other time at sea (other than for the above)							
h. Joint training/field exercises/ alerts (other than for the above)							
i. Drills or Annual Training/Active Duty Training (ACDUTRA) (other than for the above)							
j. Military education (other than for the above)							
k. Other TADs/TDYs							

24. If you were to be mobilized or deployed for 3 months, how much of a problem would each of the following be for you or your family?

Does not apply
Don't know
A very serious problem
A serious problem
Somewhat of a problem
A slight problem
Not a problem

A. Employer problems at the beginning of the mobilization/ deployment .....
B. Getting the same job back after returning .....
C. Loss of a promotion opportunity .
D. Loss of civilian job .....
E. Demotion in civilian job .....
F. Hostility from supervisor .....
G. Hostility from co-workers .....
H. Would get behind in advances in civilian occupation .....
I. Loss of civilian health benefits during mobilization ...
J. Loss of seniority or job responsibility on civilian job ...
K. Loss of income during mobilization .....
L. Business or professional practice would be damaged (e.g., medical, dental, legal)...
M. Problems for patients, clients, customers .....
N. Other employer problems when you returned to your job .
O. Studies at school or college would be disrupted .....
P. Spouse would need a job but would have trouble finding one .
Q. Increased chances for a marital separation or divorce ..
R. Burden on spouse .....
S. Problems for children .....
T. Problems for other dependents .
U. Childcare .....
V. Other .....

If you marked even a slight problem for "Other," please specify ⇨

25. Have you already experienced any of the problems listed in Question 24 as a consequence of being mobilized or deployed as a member of the National Guard/Reserve?

Does not apply - Have never been mobilized or deployed as a member of the National Guard/ Reserve ⇨ **GO TO QUESTION 28**

No, I have not experienced any problems as a consequence of being mobilized or deployed ⇨ **GO TO QUESTION 28**

Yes

26. Which of the problems listed in Question 24 have you already experienced as a consequence of being mobilized or deployed as a member of the National Guard/Reserve? *Mark all that apply.*

A	F	K	P	U
B	G	L	Q	V
C	H	M	R	
D	I	N	S	
E	J	O	T	

27. Of the problems you marked having experienced in Question 26, which were the most serious? *Print the letters of the most serious problems.*

Most serious problem	2nd most serious problem	3rd most serious problem

II. MILITARY PLANS

28. People participate in the National Guard/Reserve for many reasons. How much have each of the following contributed to your decision to stay in the National Guard/Reserve?

Very great influence
Great influence
Some influence
Little influence
Not at all

a. Serving the country .....
b. Using educational benefits .....
c. Obtaining training in a skill that would help get a civilian job.....
d. Serving with the people in the unit .....
e. Getting credit toward National Guard/Reserve retirement .....
f. Promotion opportunities .....
g. Opportunity to use military equipment .....
h. Challenge of military training .....
i. Needing the money for basic family expenses .....
j. Wanting extra money to use now ...
k. Saving income for the future .....
l. Travel/"get away" opportunities .....
m. Just enjoying the National Guard/Reserve .....
n. Pride in my accomplishments in the National Guard/Reserve .....
o. Amount of enjoyment from military job .....
p. Special and incentive pay.....
q. Reenlistment bonus or continuation pay program .....
r. Required to fulfill an obligation .....

29. Suppose that you have to decide whether to continue to participate in the National Guard/ Reserve. Assuming you could stay, how likely is it you would choose to do so?

Very unlikely
Unlikely
Neither likely nor unlikely
Likely
Very likely

30. If you could stay in the National Guard/Reserve as long as you want, how likely is it that you would chose to serve in the military until eligible for retirement?

Does not apply, I am already eligible for retirement
Very unlikely
Unlikely
Neither likely nor unlikely
Likely
Very likely

31. When you finally leave the National Guard/ Reserve, what paygrade do you think you will have? *Mark one.*

E-1	E-6	W-1	O-1/O1E
E-2	E-7	W-2	O-2/O2E
E-3	E-8	W-3	O-3/O3E
E-4	E-9	W-4	O-4
E-5		W-5	O-5
			O-6 or above

32. When you finally leave the National Guard/Reserve, how many years of service do you expect to have? *Print years of service. If less than 1 year, print "00".*

Full-time active duty National Guard/Reserve program years of service

IRR or Inactive Guard (ING) years of service

Other National Guard/Reserve years of service (in a part-time status)

Active component years of service

III. MILITARY TRAINING

33. Are you currently trained/qualified in your duty Military Occupational Specialty/Designator/Rating/ Air Force Specialty Code (MOS/D/R/AFSC)?

No
Yes

34. Are you currently working in your primary MOS/ D/R/AFSC?

No
Yes

35. Considering all your National Guard/Reserve time on duty in 1999, what percentage of it was spent performing skills related to your primary MOS/D/R/AFSC?

None
1-24%
25-49%
50-74%
75-99%
All

36. Is your current primary MOS/D/R/AFSC the same one you had while on active duty?

Does not apply, I don't have prior active duty service ⇨ **GO TO QUESTION 38**
Yes ⇨ **GO TO QUESTION 38**
No

37. When you joined the National Guard/Reserve, did you have to change your primary MOS/D/R/AFSC and did you want to? *Mark "No" or "Yes" for each item.*

	No	Yes
a. I had to change my MOS/D/R/AFSC.....		
b. I wanted to change my MOS/D/R/AFSC..		

38. In 1999, how many calendar days did you spend in a compensated (pay or points) National Guard/ Reserve status?

Does not apply, I am in a full-time active duty National Guard/Reserve program
None
1-24 days
25-47 days
48 days or more

39. In an average month in 1999, how many unpaid hours, off duty, did you spend on your National Guard/Reserve unit's business?

Does not apply, I am in a full-time active duty National Guard/Reserve program

None *Hours*

40. In an average month in 1999, how many unpaid hours, off duty, did you spend on your professional development in the National Guard/Reserve?

Does not apply, I am in a full-time active duty National Guard/Reserve program

None *Hours*

41. How many nights did you spend away from your home on official military duties in 1999? *Do not include nights spent away from home before out-of-town drills.*

None

Nights

42. How did you attend the 1999 Annual Training/ Active Duty Training (ACDUTRA)?

A few days at a time, several times over the year
A week or more at a time, more than once
All at once
Does not apply, did not attend 1999 Annual Training/Active Duty Training (ACDUTRA)

IV. YOUR MILITARY UNIT

43. Please indicate the category of the Selected Reserve to which you belong. *Mark one.*

Drilling unit Reservist/Traditional Guardsman in a full-time active duty National Guard/Reserve program ⇨ **GO TO QUESTION 50**
Individual Mobilization Augmentee (IMA) ⇨ **GO TO QUESTION 51**

44. How satisfied are you with . . . ?

	Does not apply	Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
a. Training received during your unit drills						
b. Your unit's activities at 1999 Annual Training/ACDUTRA						
c. Opportunities to use your primary MOS/D/R/AFSC skills during unit drills						
d. Opportunities for promotion in your unit						
e. Opportunities for leadership in your unit						
f. Type of weapons or equipment your unit uses during drills						
g. Mechanical condition of the weapons and equipment your unit uses during training						
h. Supervision and direction given during unit drills						
i. Facilities in which you train						
j. Your job						
k. Job security						
l. Workload						
m. Assignment stability						
n. Unit social activities						
o. Work group/co-workers						
p. Acquaintances/friendships						
q. Time required at National Guard/Reserve activities						
r. Your possibility of being mobilized or deployed in the future						
s. Number of recent mobilizations or deployments you have experienced						
t. Not being included in recent mobilizations or deployments						

45. Are you a military technician? *(A military technician provides full-time support as a civilian government employee for administration, training, and maintenance of the unit.)*

No Yes

46. How much of a problem is each of the following for your unit/organization in achieving training objectives?

	Don't know	A very serious problem	A serious problem	Somewhat of a problem	A slight problem	Not a problem
a. Out-of-date equipment/weapons						
b. Poor mechanical condition of equipment/weapons						
c. Being below strength in grades E-1 to E-4						
d. Being below strength in grades E-5 to E-9						
e. Being below strength in grades WO-1 to WO-5						
f. Being below strength in grades O-1 to O-6						
g. Not enough staff resources or time to plan effective training						
h. Poor administrative support						
i. Low attendance at unit drills						
j. Low attendance of unit personnel at Annual Training/ ACDUTRA						
k. Ineffective training during Annual Training/ACDUTRA						
l. Shortage of MOS/D/R/AFSC qualified personnel						
m. Quality of personnel in lower-grade drill positions						
n. Quality of leaders						
o. Inadequate time to plan training objectives						
p. Lack of access to good training facilities and grounds						
q. Lack of good instruction manuals and materials						
r. Lack of supplies, such as ammunition, gasoline, etc.						
s. Lack of spare/replacement parts						
t. Excessive turnover of personnel						
u. Inadequate access to command's operating schedule to plan unit annual training						
v. Uncertainty about future status of unit/organization						
w. Unit reorganizing/restructuring						
x. Inadequate resources to support mission						
y. Inadequate access to computers						
z. Inadequate access to long-term training schedules						

47. About how far do you live from the place where your unit meets/drills?

Less than 50 miles	250-299 miles
50-99 miles	300-349 miles
100-149 miles	350-399 miles
150-199 miles	400 miles or more
200-249 miles	

48. How do you usually get to the place of regular military duty or drills? ***Mark "No" or "Yes" for each item.***

	No	Yes
a. Drive myself		
b. Driven by spouse		
c. Driven by another family member		
d. Car pool		
e. Civilian air transportation		
f. Military air transportation		
g. Public transportation (e.g., bus, taxi)		
h. Walk/bicycle		

49. How long does it usually take you to get from home to the place where your unit meets/drills?

Less than 1/2 hour
1/2 hour to less than 1 hour
1 hour to less than 1 1/2 hours
1 1/2 hours to less than 2 hours
2 hours to less than 4 hours
4 hours or more

50. In general, how would you describe the morale of military personnel in your unit?

Very low	High
Low	Very high
Neither high nor low	

51. In general, how would you describe your morale?

Very low	High
Low	Very high
Neither high nor low	

V. BENEFITS AND PROGRAMS

52. For each family program or service listed, mark its availability to you and your level of satisfaction with the quality of the service/program. ***For each item, mark one response in column A and one response in column B.***

	A. Availability Don't know Not available Off installation only On installation only Both on- and off-installation	B. Satisfaction Very satisfied Satisfied Neither satisfied nor dissatisfied Dissatisfied Very dissatisfied No basis to judge
a. Individual counseling/therapy		
b. Pre-marital programs		
c. Marriage and family counseling/therapy/enrichment		
d. Family support centers		
e. Programs for families with disabled members		
f. Services for families during separation		
g. New parent classes		
h. Single parent programs		
i. Childcare services		
j. Youth/teen programs		
k. Eldercare		
l. Alcohol/drug abuse programs		
m. Spouse employment services		
n. Spouse/child abuse services		
o. Rape counseling services		
p. Crisis referral services		
q. Chaplain services/religious activities		
r. Legal assistance		
s. Financial counseling/management education		
t. Recreational programs		
u. Educational Services Center		
v. Services for single members		

53. During the past 12 months, how often did you and/or your family use the following military on-installation programs, facilities, or services and civilian off-installation programs, facilities, or services? *For each item, mark one response in column A and one response in column B.*

	A. Military On-Installation Program, Facility, or Service	B. Civilian Off-Installation Program, Facility, or Service
	12+ times 6-11 times 3-5 times 1-2 times 0 times Not available	12+ times 6-11 times 3-5 times 1-2 times 0 times Not available
a. Auto, crafts, hobby shops		
b. Bank or credit union		
c. Bowling center or movie theater		
d. Commissary, supermarket, grocery store		
e. Clubs/dance/night clubs		
f. Fitness center/gym		
g. Golf course		
h. Library services		
i. Main exchange/department store		
j. Outdoor recreation areas (campgrounds, picnic areas, beach, stables, etc.)		
k. Outdoor recreation equipment rental		
l. Post office		
m. Recreation center (recreation room, music/TV, game room/amusement machines, etc.)		
n. Recreation lodging/hotels/resorts		
o. Shoppette/mini-mart		
p. Class VI/package store/liquor store		
q. Social activities for single service members (trips, special events, tournaments, etc.)		

54. During the past 12 months, have you used any of the following programs and services? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Adult continuing education/counseling		
b. Tuition assistance programs for college/higher education		
c. Technical/vocational programs		
d. Basic skills education		

55. How much do the following limit your use of the commissary or exchange? *Mark one answer for each row.*

	Completely Very much Somewhat Very little Not at all
Commissary	
a. Prices	
b. Stock	
c. Hours	
d. Distance	
e. The law does not allow more frequent use	
Exchange	
a. Prices	
b. Stock	
c. Hours	
d. Distance	

56. Overall, to what extent do you think you or your family save by using the commissary instead of civilian grocery stores?

- Does not apply, do not use commissary
- Not at all
- Small extent
- Moderate extent
- Large extent
- Very large extent

57. Do you currently use the *EXCHANGE* closest to you?

- No, I don't use an exchange
- No, I use an exchange, but it's not the closest
- Yes, I use the exchange closest to me

58. How long does/would it normally take to get to the exchange closest to you?

- 10 minutes or less
- 11-20 minutes
- 21-30 minutes
- 31-60 minutes
- More than 1 hour
- Don't know

59. Please rate the selection of merchandise at the exchange closest to you.

- Very poor
- Poor
- Average
- Good
- Excellent
- Don't know

60. Please rate the prices at the exchange closest to you compared with prices at other stores in town.

Very poor	Good
Poor	Excellent
Average	Don't know

61. At which Service's exchange do you shop most often?

Does not apply, I do not shop at an exchange
Army and Air Force Exchange Service (AAFES), Post Exchange (PX) or Base Exchange (BX)
Navy Exchange
Marine Corps Exchange

62. What average savings, not considering sales tax, are available at the exchange?

I believe I pay more at the exchange	6-10% savings
No savings	11-20% savings
5% savings or less	More than 20% savings
	Don't know

63. Are your (and your spouse's) shopping privileges limited at exchanges?

No Yes Don't know

64. Can an exchange's merchandise be ordered on the Internet?

No Yes Don't know

65. Are you now using or eligible for educational benefits as a result of military service?

No ⇨ **IF NO, GO TO QUESTION 68**
Yes

66. For which educational benefits are you eligible as a result of your military service?

	Earning eligibility now	Yes, already eligible	No
a. State benefits for National Guard/ Reserve service			
b. Montgomery GI Bill (MGIB) for Selected Reserve			
c. MGIB-Selected Reserve Kicker (A kicker is assistance given to personnel filling critical shortages in skills.)			
d. Active Force benefits (VEAP, MGIB, or tuition assistance)			
e. MGIB-Active Duty Kicker			
f. Tuition assistance (for members of a full-time active duty program)			

67. Which educational benefits are you now using? ***Mark "No" or "Yes" for each item.***

	No	Yes
a. State benefits for National Guard		
b. MGIB for Selected Reserve		
c. Active Force benefits (VEAP, MGIB, or tuition assistance)		
d. ROTC/NROTC scholarship		

68. The National Guard/Reserve components are developing new information materials. Below is a list of topics that might be included. How interested would you be in receiving such materials?

	Very interested	Somewhat interested	Neither interested nor uninterested	Uninterested	Very uninterested
a. Retirement benefits					
b. Survivor Benefit Plan					
c. Family benefits in the National Guard/Reserve					
d. Mobilization information for family members					
e. Montgomery GI Bill for the Selected Reserve					
f. Soldiers/Sailors Civil Relief Act					
g. Dental insurance					
h. Medical insurance					
i. Mobilization preparation for business owners, partners and independent practitioners					
j. Employer-employee relations/rights					

69. Do you have any medical/hospitalization coverage(s)?

No ⇨ **IF NO, GO TO QUESTION 72**
Yes

70. Do you have the following medical/hospitalization coverage(s)? ***Mark "No" or "Yes" for each item.***

	No	Yes
a. Your civilian employer's healthcare plan		
b. Your school's healthcare plan		
c. Your spouse/family member's civilian employer's health plan		
d. Your active duty military healthcare coverage		
e. Your spouse/family member's active duty/retired military healthcare coverage		
f. Veterans' (VA) coverage		
g. Other private coverage		

71. How satisfied are you with the coverage provided by your medical insurance?

Very dissatisfied
Dissatisfied
Neither satisfied nor dissatisfied
Satisfied
Very satisfied

72. If you could buy medical insurance through National Guard/Reserve participation, what is the maximum premium cost you would be willing to pay per month?

Not applicable, I have medical insurance through National Guard/Reserve participation already
Less than $100 per month
$100-149 per month
$150-199 per month
$200-249 per month
$250-299 per month
$300 or more per month

73. How much did you spend on health care services and products (for you and your family) last year? *Include TRICARE/CHAMPUS deductions, enrollment fees, civilian insurance premiums, drugs, co-pays, deductibles, etc. Do not include dental care.*

Don't know
$0-$100
$101-$500
$501-$1,000
$1,001-$1,500
$1,501-$2,500
More than $2,500

74. Is basic dental insurance available to you as a member of the Selected Reserve?

No
Yes

75. Do you have any dental coverage(s)?

No ⇨ **IF NO, GO TO QUESTION 78**
Yes

76. Which of the following dental coverage(s) do you have? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Your civilian employer's dental plan		
b. Your spouse/family member's civilian employer's dental plan		
c. Your active duty military coverage		
d. Your spouse/family member's active duty military coverage (military dental clinic, TRICARE Family Member Dental Plan)		
e. Veteran (VA) coverage		
f. Other private coverage		

77. How satisfied are you with the coverage provided by the civilian dental insurance that you have?

Does not apply, do not have civilian dental insurance
Very dissatisfied
Dissatisfied
Neither satisfied nor dissatisfied
Satisfied
Very satisfied

78. Are you actively considering changing, expanding or getting dental insurance within the next year?

No ⇨ **IF NO, GO TO QUESTION 81**
Yes

79. What is the maximum premium cost you would be willing to pay to enroll yourself in a comprehensive dental plan?

Less than $10 per month
$10-19 per month
$20-29 per month
$30-39 per month
$40-49 per month
$50 or more per month

80. What is the maximum premium cost you would be willing to pay to enroll yourself and your family members in a comprehensive dental plan?

Not applicable
Less than $10 per month
$10-19 per month
$20-29 per month
$30-39 per month
$40-49 per month
$50-59 per month
$60-69 per month
$70 or more per month

VI. INDIVIDUAL AND FAMILY CHARACTERISTICS

81. Are you . . . ?

Male
Female

82. Are you Spanish/Hispanic/Latino? *Mark "No" if not Spanish/Hispanic/Latino.*

No, not Spanish/Hispanic/Latino
Yes, Mexican, Mexican American, Chicano
Yes, Puerto Rican
Yes, Cuban
Yes, other Spanish/Hispanic/Latino

83. What is your race? *Mark one or more races to indicate what you consider yourself to be.*

White
Black or African American
American Indian or Alaska Native
Asian (e.g., Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese)
Native Hawaiian or other Pacific Islander (e.g., Samoan, Guamanian or Chamorro)
Some other race ⇨ ***Please specify***

84. Are you a citizen of the United States? *Mark one.*

Yes, born in the United States
Yes, born in Puerto Rico, Guam, the U.S. Virgin Islands, or the Northern Marianas
Yes, born abroad of American parent or parents
Yes, a U.S. citizen by naturalization
No, not a citizen of the United States

85. Were either of your parents (or guardians) in the military when you were born?

No
Yes, at least one was on active duty
Yes, at least one was a Reservist
Don't know

86. Did you vote in the last local election? In the last presidential election?

A. Last local election
Yes, in person at the polls
Yes, by absentee ballot
No

B. Last presidential election
Yes, in person at the polls
Yes, by absentee ballot
No

87. Which of the following best describes the type of place where you are living now?

In military housing on a base/installation
In a large city (over 250,000)
In a suburb near a large city
In a medium-sized city (50,000-250,000)
In a suburb near a medium-sized city
In a small city or town (under 50,000)
On a farm or ranch
In a rural area but not on a farm or ranch

88. How long have you lived in your present neighborhood?

Less than 1 year
1 year to less than 3 years
3 years to less than 5 years
5 years or more

89. What is the highest degree or level of school that you have completed? *Mark the one answer that describes the highest grade or degree you have completed.*

11th grade or less
12 years of school, no diploma
High school diploma or the equivalent (e.g., GED), not from home schooling
High school diploma or the equivalent (e.g., GED), from home schooling
Some college credit, but less than 1 year
1 or more years of college, but no degree
Associate's degree (e.g., AA, AS)
Bachelor's degree (e.g., BA, AB, BS)
Master's degree (e.g., MA, MS)
Doctoral or professional degree (e.g., PhD, MD, JD)

90. What is the highest school grade or academic degree that you think you will complete in the future? *Mark the one answer that describes the highest grade or degree you think you will complete.*

Does not apply, I don't plan to attend school in the future
11th grade or less
12 years of school, no diploma
High school diploma or the equivalent (e.g., GED), not from home schooling
High school diploma or the equivalent (e.g., GED), from home schooling
Some college credit, but less than 1 year
1 or more years of college, but no degree
Associate's degree (e.g., AA, AS)
Bachelor's degree (e.g., BA, AB, BS)
Master's degree (e.g., MA, MS)
Doctoral or professional degree (e.g., PhD, MD, JD)

91. What kind of civilian school are you currently enrolled in?

Not currently enrolled in civilian school
High school (home schooling)
High school (public or private)
GED completion
Vocational/trade/business or other career training school
Junior or community college (2-year)
Four-year college or university
Graduate/professional school
Other

92. Overall, how much did your family members or others in your life encourage you about entering the National Guard/Reserve? ***Mark one for each item.***

Strongly encouraged
Encouraged
Neither encouraged nor discouraged
Discouraged
Strongly discouraged

a. Father/stepfather/other male guardian .....
b. Mother/stepmother/other female guardian .....
c. Brothers/stepbrothers .....
d. Sisters/stepsisters .....
e. Personal friends .....
f. Teacher(s) .....

93. Have any of your family members or others in your life served in or retired from the military? ***(Include National Guard/Reserve.) Please indicate their current military status. Mark all that apply.***

Retired from the military
Served 8 years or more and separated
Served less than 8 years and separated
Currently serving in the military
Never served in the military

a. Father/stepfather/other male guardian .....
b. Mother/stepmother/other female guardian .....
c. Brothers/stepbrothers .....
d. Sisters/stepsisters .....
e. Personal friends .....
f. Teacher(s) .....

94. Do you have any children aged 10 and older with whom you talk about post-high school options such as jobs and education?

No ⇨ **IF NO, GO TO QUESTION 97**
Yes

95. When you talk with your children about their future do you encourage them to consider the military?

No
Yes

96. When you talk with your children about their future choices, how positive or negative are you about the following?

Very positive
Positive
Neither positive nor negative
Negative
Very negative

a. The military, in general .....
b. Career opportunities in the military .
c. Serving in the military, but not as a career .....
d. Part-time (National Guard/ Reserve) opportunities in the military .....
e. Career opportunities as a civilian Federal government employee .....
f. Career opportunities in the private/civilian sector .....
g. Seeking a college education .....

97. In your opinion, how do the following groups or individuals view your participation in the National Guard/Reserve?

Does not apply
Very favorably
Somewhat favorably
Neither favorably nor unfavorably
Somewhat unfavorably
Very unfavorably

a. Your spouse .....
b. Your children .....
c. Your spouse's relatives .....
d. Your relatives .....
e. Your neighbors .....
f. Your civilian supervisor .....
g. Your civilian co-workers .....
h. Your National Guard/Reserve unit members .....

98. Have you ever used a personal computer (PC)?

No ⇨ **IF NO, GO TO QUESTION 102** Yes

99. Where during the last 12 months have you regularly used a PC? ***Mark "No" or "Yes" for each item.***

	No	Yes
a. Home/residence		
b. Civilian work/office		
c. Guard/Reserve duty station or Armory ...		
d. Installation/ship library		
e. Installation/ship recreation center		
f. Installation/ship education center		
g. Installation/ship family center		
h. Other military location		
i. Other non-military location (for example, public library)		

100. Do you have access to the Internet/World Wide Web?

No ⇨ **IF NO, GO TO QUESTION 102**
Yes

101. From which location do you most frequently access the Internet/World Wide Web? ***Mark one.***

Home/residence
Civilian work/office
Guard/Reserve duty station or Armory
Installation/ship library
Installation/ship recreation center
Installation/ship education center
Installation/ship family center
Other military location
Other non-military location (for example, public library)

102. What is your current marital status? ***Mark one.***

Married
Separated
Divorced ⇨ **GO TO QUESTION 113**
Widowed ⇨ **GO TO QUESTION 113**
Never married ⇨ **GO TO QUESTION 113**

103. How many years have you been married to your current spouse?

Less than one year

Full years married

104. Is your spouse . . . ? ***Mark "No" or "Yes" for each item.***

	No	Yes
a. Working full-time in a Federal civilian job		
b. Working part-time in a Federal civilian job		
c. Working full-time in a civilian job (not Federal)		
d. Working part-time in a civilian job (not Federal)		
e. Managing or working in family business		
f. Self-employed in own business or profession		
g. An unpaid worker (volunteer)		
h. Unemployed and looking for job		
i. Unemployed, not looking for job, but would like employment		
j. Unemployed, not looking for job, and does not want employment		
k. In school		
l. Retired		
m. A homemaker, housewife, househusband		
n. Working multiple jobs		
o. Working temporary job(s)		

105. Does your spouse speak English as his or her main language at home?

No
Yes

106. To what extent do you and your spouse agree on your civilian career plans?

Does not apply, I do not have a civilian job
Strongly disagree
Disagree
Neither agree nor disagree
Agree
Strongly agree

107. To what extent do you and your spouse agree on your military career plans?

Strongly disagree
Disagree
Neither agree nor disagree
Agree
Strongly agree

108. How has your spouse's support for your decision about staying in the military changed in the past year?

Greatly decreased
Somewhat decreased
Has not changed
Somewhat increased
Greatly increased

109. Has your current spouse ever served (past or present) in the U.S. Armed Forces, either on active duty or in the National Guard/Reserve?

No ⇨ **IF NO, GO TO QUESTION 113**
Yes, currently serving on active duty (not a member of the National Guard/Reserve)
Yes, currently a member of the National Guard/Reserve in a full-time active duty status
Yes, currently a member of a drilling unit in the National Guard/Reserve
Yes, currently an IMA, IRR or ING ⇨ **IF IMA/IRR/ING, GO TO QUESTION 111**
Yes, spouse is separated or retired from service ⇨ **IF SEPARATED/RETIRED, GO TO QUESTION 111**

110. Are you presently assigned to the same installation or geographic location as your spouse?

Yes
No, but I expect my spouse will be assigned to this location soon
No, but I expect to be assigned to my spouse's location soon
No, we were unable to get assigned to the same location
No, for other reasons

111. Has your spouse ever been mobilized or deployed as a member of the National Guard/Reserve?

No ⇨ **IF NO, GO TO QUESTION 113**
Yes

112. Was your spouse mobilized/deployed as a Reservist for the operations listed below? *Mark "No" or "Yes" for each item. If you mark "Yes" in column A, please indicate whether it was voluntary or involuntary, the deployment's location, and its length. If you mark "No" in column A, go to the next item in column A.*

	A. Was your spouse mobilized or deployed as a member of the National Guard/Reserve for the operations (a-k) listed below?		B. Was his/her mobilization voluntary or involuntary?		C. Where did he/she deploy? (Mark one)				D. How long was he/she mobilized or deployed? Write in number of months. If under 1 month, enter "00". If mobilized/deployed now, write number of months so far.
	No	Yes ⇨	Voluntary	Involuntary	Does not apply, did not deploy	In own state or equivalent (e.g., DC, GU, PR, VI)	To another state or equivalent (e.g., DC, GU, PR, VI)	Outside US	
a. Operation Desert Shield/Storm									
b. Saudi Arabia (Aug 92-present)									
c. Centam, Hurricane Mitch Recovery/Rehab									
d. Operation Restore/Uphold Democracy (Haiti)									
e. Operation Desert Fox/Iraqi Crisis (SW Asia)									
f. Operation Joint Forge/Guard/ Endeavor (Bosnia)									
g. Operation Restore/Continue Hope (Somalia)									
h. Operation Joint Task Force (Cuba)									
i. Operation Allied Force (Kosovo)									
j. Other mobilization or deployment (1) ***Describe:***									
k. Other mobilization or deployment (2) ***Describe:***									

113. How much of a problem is there for your family when you spend . . . ?

Does not apply
Very serious problem
Serious problem
Somewhat of a problem
Slight problem
Not a problem

a. Time away for weekend drills .
b. Time away for Annual Training/ACDUTRA .....
c. Extra time at National Guard/ Reserve business or activities.
d. Time away for mobilization or deployment .....

For Questions 114-119, "dependents" includes children and anyone else in your family, except your spouse, who has or is eligible to have a Uniformed Services identification card (military ID card) or is eligible for military health care benefits and is enrolled in the Defense Enrollment Eligibility Reporting System (DEERS).

114. Based on the definition following Question 113, do you have legal dependents (not including your spouse)?

No ⇨ **IF NO, GO TO QUESTION 120**
Yes

115. Are arrangements for your dependents who live with you realistically workable for each of the following situations?

Does not apply
Definitely
Probably
Probably not
Definitely not

a. Short-term (less than 30 days) emergency situation such as a mobilization exercise.....
b. Long-term situation such as being mobilized or deployed for 30 days or more.....

116. Do you have a spouse, child, or other legal dependent enrolled in the Exceptional Family Member Program (EFMP) or the Coast Guard Special Needs Program?

No
Yes

117. Do any of your dependents (not including your spouse) have a physical, mental, or emotional condition requiring specialized treatment or care?

No
Yes, dependent requires temporary treatment or care
Yes, dependent requires permanent treatment or care

118. How many children or other dependents do you have in each age group? *Print the number of dependents you have in each age group.*

Less than 1 year old	1 year - under 2 years old	2-5 years old	6-13 years old	14-22 years old	23-64 years old	65 years old or older

119. How many of your children or other dependents in each age group live with you?

Less than 1 year old	1 year - under 2 years old	2-5 years old	6-13 years old	14-22 years old	23-64 years old	65 years old or older

120. Do you have caregiver responsibilities for an elderly family member (such as shopping, home maintenance, transportation, checking on them by phone, finances, and arrangements for care)? *Include family who live with you or live somewhere else.*

No ⇨ **IF NO, GO TO QUESTION 122**

Yes ⇨ **How many?**

121. During the past 12 months, did you lose any time from your military duties due to eldercare responsibilities?

No
Yes

VII. CIVILIAN WORK

122. Are you currently a member of a full-time active duty Reserve program (i.e., Active Guard and Reserve (AGR), Training and Administration of the Reserve (TAR), or Active Reserve (AR))?

No ⇨ **IF NO, GO TO QUESTION 125**
Yes

123. In 1999, did you have a civilian job?

No ⇨ **IF NO, GO TO QUESTION 148**
Yes

124. How interested are you in working in a National Guard/Reserve job that is similar to your civilian job?

Very uninterested
Uninterested
Neither interested or uninterested
Interested
Very interested

125. In your civilian job, do you work as any of the following? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Physician, registered nurse, dentist, optometrist		
b. Pilot/navigator		
c. Information technology professional (computer programmer, systems manager, etc.)		
d. Clergy		
e. Lawyer		

126. Are you currently . . . ? *Mark "No" or "Yes" for each item.*

	No	Yes
a. A member of a full-time active duty program, working an additional civilian job		
b. Working full-time as an Army or Air Force National Guard/Reserve military technician		
c. Working full-time in a civilian job (not military technician)		
d. Working part-time in a civilian job		
e. Employed in a civilian job but not at work due to temporary illness, vacation, strike, layoff, etc.		
f. Managing or working in family business		
g. Self-employed in own business or profession		
h. Unpaid worker (volunteer)		
i. Unemployed and looking for job		
j. Unemployed, not looking for job, but would like employment		
k. Unemployed, not looking for job, and do not want employment		
l. In school		
m. Retired		
n. Homemaker, housewife, househusband		
o. Working multiple jobs		
p. Working temporary job(s)		

127. In 1999, how many weeks were you without a civilian job and looking for civilian work?

Not applicable, I had a civilian job throughout 1999
The entire year

Weeks

128. During 1999, did you do any civilian work for pay? *Answer "Yes" even if you worked only an average of an hour a week as a civilian, or helped without pay in a family business or farm for an average of 15 or more hours per week.*

No ⇨ IF NO, GO TO QUESTION 148
Yes

Questions 129-147 are about your civilian job in 1999. If you had more than one, answer these questions for the one where you worked the most hours per week for most of the year.

129. What kind of business or industry is/was this? *Describe the activity at the location where you were employed. For example: hospital, newspaper publishing, mail order house, auto repair shop, bank. Do not write the name of the company.*

130. What kind of work are/were you doing? *For example: registered nurse, personnel manager, supervisor of order department, auto mechanic, accountant.*

131. What are/were your most important activities or duties at this job? *For example: patient care, directing hiring policies, supervising order clerks, repairing automobiles, reconciling financial records.*

132. Which of the following best describes your civilian employer in 1999? *Mark one.*

Federal government
State government
Local government (including public schools)
Working without pay in family business or farm
Self-employed in own business
Private sector firm with 500 or more employees
Private sector firm with 100-499 employees
Private sector firm with less than 100 employees

133. In 1999, what was your employment status in your primary civilian job? *Mark one.*

Permanent employee
Temporary employee

134. During a typical week, what days do/did you work in your main civilian job? *Mark all that apply.*

Sun Mon Tues Wed Thur Fri Sat

135. In 1999, how many hours per week did you usually work at your main civilian job?

Weekly hours

136. In 1999, how many hours per week did you usually work at all of your civilian jobs?

Weekly hours

137. In 1999, did you ever work more than 40 hours per week at your main civilian job?

No ⇨ IF NO, GO TO QUESTION 140
Yes

138. In 1999, how many weeks did you work more than 40 hours per week at your main civilian job?

Number of weeks

139. In 1999, how were you compensated when you worked overtime (e.g., over 40 hrs. in a week)? *Mark "False" or "True" for each item.*

	False	True
a. Not paid extra for working overtime		
b. Received compensatory time		
c. Paid at my regular pay rate		
d. Paid time-and-a-half		
e. Paid double-time		
f. Paid more than double-time		
g. Received bonus		
h. Received more fees/commission		

140. In 1999, did you have a second civilian job in addition to your primary civilian job?

No ⇨ IF NO, GO TO QUESTION 142
Yes

141. How much did each of the following contribute to your having a second job?

	Completely	Very much	Somewhat	Very little	Not at all
a. Needed additional income to meet basic expenses					
b. Nice to have extra income to use					
c. Saving extra income for future needs					
d. Independence					
e. Self-esteem					
f. Enjoyment of work itself					
g. To gain experience for a non-military second career					

142. In 1999, how often did you lose opportunities for overtime/extra pay because of your National Guard/ Reserve obligations?

Never
Rarely
Occasionally
Frequently
Always

143. Were you self-employed in 1999?

No
Yes ⇨ **IF YES, GO TO QUESTION 146**

144. Which of the following describes how you got time off from your civilian job to meet the following National Guard/Reserve obligations in 1999?

	I used military leave/leave of absence	I used vacation/sick/personal days	Obligation was on day(s) I did not work	Does not apply, I did not attend	Does not apply, no conflict with job
a. Military schooling					
b. Annual Training/ACDUTRA					
c. Required drills					

145. Which of the following best describes how you were paid for the time you took from your civilian job for National Guard/Reserve obligations in 1999?

	Received military pay and full civilian pay	Received military pay and partial civilian pay	Received only military pay	Military obligations were on days I didn't work	Does not apply, I did not attend	Other
a. Military schooling						
b. Annual Training/ACDUTRA						
c. Required drills						

146. How much of a problem is there for your main employer (or for you, if self-employed) when you spend . . . ?

	Very serious problem	Serious problem	Somewhat of a problem	Slight problem	Not a problem	Don't know	Does not apply
a. Time away for required drills							
b. Time away for Annual Training/ACDUTRA							
c. Extra time spent on National Guard/Reserve activities or business							
d. Time away for mobilization or deployment							

147. How similar was your civilian job to your National Guard/Reserve duty?

Does not apply, my civilian job was as a National Guard/Reserve military technician
Very dissimilar
Somewhat dissimilar
Neither similar nor dissimilar
Somewhat similar
Very similar

148. Have you ever been forced to leave college, technical training, apprenticeship training, or any other kind of educational experience because of a mobilization or deployment (voluntary or involuntary)? *Mark all that apply.*

No ⇨ **IF NO, GO TO SECTION VIII on page 20**
Yes, for involuntary duty
Yes, for voluntary duty

149. What type of educational program were you enrolled in? *Mark all that apply.*

College/university (public/state)
College/university (private)
Technical training
Apprenticeship training
Continuing professional education
None of the above

150. Were you able to . . . ? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Obtain a full refund for tuition and/or fees paid for the semester/quarter interrupted by military duty?		
b. Obtain a partial refund for tuition and/or fees paid for the semester/ quarter interrupted by military duty?		
c. Receive credit for course work completed?		
d. Re-enroll, without prejudice, in the same educational institution after performing military duty?		

151. Have you ever participated in computer-based distance learning?

No
Yes

VIII. ECONOMIC ISSUES

The questions in this section address economic issues in the lives of military members and their families. The information will be used to better understand the economic and financial concerns of military members and their families. Although people will have different views on what is or is not personal, most people will consider at least some of the questions to be personal. As with all other questions in this survey, your responses will be held in confidence.

152. Which of the following best describes the financial condition of you (and your spouse)?

Very comfortable and secure
Able to make ends meet without much difficulty
Occasionally have some difficulty making ends meet
Tough to make ends meet but keeping your head above water
In over your head

153. Overall, how do you feel about your family income (that is, all the money that comes to you and other members of your family living with you)?

Very dissatisfied
Dissatisfied
Neither satisfied nor dissatisfied
Satisfied
Very satisfied

154. During the <u>past 12 months</u>, did you (or your spouse) receive any income or financial support from the following sources? *Mark "No" or "Yes" for each item.*

	No	Yes
a. A second job		
b. Alimony		
c. Child support		
d. Supplemental Security Income (SSI)		
e. Unemployment or Workers' Compensation		
f. State-funded childcare assistance		
g. Women, Infants, and Children (WIC)		
h. Food Stamp Program		
i. Head Start Program		
j. Temporary Assistance for Needy Families (TANF)		
k. Medicaid		
l. Other public welfare or assistance		
m. Interest and dividends on savings		
n. Stocks, bonds, or other investments		
o. Pensions from federal, state, or local government employment		
p. Pensions from private employer or union		
q. Veterans benefits or pensions		
r. GI Bill		
s. Social Security or Railroad Retirement		
t. Other sources <u>not</u> including earnings from wages or salaries		

155. What is your total monthly gross (before tax) household income from <u>all sources</u>? *Please include your military earnings, your civilian earnings, your spouse's earnings, and income or financial support from any other source.*

$1-1,000	$6,001-7,000
$1,001-2,000	$7,001-8,000
$2,001-3,000	$8,001-9,000
$3,001-4,000	$9,001-10,000
$4,001-5,000	$10,001 and above
$5,001-6,000	

156. Which of the following best reflects how you use your National Guard/Reserve income? *Mark one.*

To pay bills
On extra things (vacations, niceties, etc.)
Savings and/or investments

157. Do you (or your spouse) <u>pay</u> child support or alimony? *Mark "No" or "Yes" for each item.*

	No	Yes	Does Not Apply
a. You pay child support			
b. Your spouse pays child support			
c. You pay alimony			
d. Your spouse pays alimony			

158. In the past 12 months, did any of the following happen to you (or your spouse)? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Bounced two or more checks		
b. Received a letter of indebtedness (e.g., a letter from a lender to your commanding officer that payment is late)		
c. Had your wages garnished		
d. Fell behind in paying your rent or mortgage		
e. Fell behind in paying your credit card, AAFES, or NEXCOM account		
f. Was pressured to pay bills by stores, creditors, or bill collectors		
g. Had a bill collector contact your unit leader		
h. Pawned or sold valuables to make ends meet		
i. Borrowed money from friends or relatives to help you with a financial difficulty		
j. Borrowed money through an Emergency Loan Assistance Program or a Service Aid Society		
k. Had your utilities (telephone, cable, water, heat or electricity) shut off		
l. Had a car, household appliances, or furniture repossessed		
m. Went bankrupt (declared personal bankruptcy)		

159. What is the average monthly amount of money that you (and your spouse) pay to meet the following expenses? *Please round off amount to the nearest dollar. For example, if your rent is $695.40 per month, enter 0695 in the boxes.*

EXPENSE	MONTHLY COST
a. Rent or mortgage	$ .00
b. Utilities (electric, gas, water, etc.)	$ .00
c. Maintenance (home, yard, etc.)	$ .00
d. Loans/leases on cars, trucks, cycles	$ .00
e. Groceries	$ .00
f. Other	$ .00

160. What is the amount of payments that you (and your spouse) made last month to cover personal unsecured debt? *Include all credit cards, debt consolidation loans, AAFES loans, NEXCOM loans, student loans, and other personal loans. Exclude home mortgage and car loans.*

$0
$1-150
$151-300
$301-450
$451-600
$601-750
$751-900
$901-1050
$1051 and above

161. After the last payment was made on personal unsecured debt, what was the total amount you (and your spouse) still owed? *Include all credit cards, debt consolidation loans, AAFES loans, NEXCOM loans, student loans, and other personal loans. Exclude home mortgage and car loans.*

$0
$1-1,000
$1,001-2,500
$2,501-5,000
$5,001-7,500
$7,501-10,000
$10,001-12,500
$12,501-15,000
$15,001-17,500
$17,501-20,000
$20,001 and above

162. Roughly, what is the total amount of savings you (and your spouse) have? *Please include funds in bank accounts, individual retirement accounts, money market accounts, certificates of deposit, savings bonds, mutual funds, stocks and/or bonds.*

$0
$1-1,000
$1,001-2,500
$2,501-5,000
$5,001-7,500
$7,501-10,000
$10,001-12,500
$12,501-15,000
$15,001-17,500
$17,501-20,000
$20,001-50,000
$50,001-100,000
$100,001 and above

163. Do you rent or own your principal residence?

Rent
Own
Neither, live in government-owned or -leased housing ⇨ **GO TO QUESTION 165**
Neither, live with friends/relatives and pay no costs ⇨ **GO TO QUESTION 165**
Neither, live in other accommodations ⇨ **GO TO QUESTION 165**

164. How long have you rented or owned your current residence?

Less than one year

Full years

IX. FULL-TIME ACTIVE DUTY NATIONAL GUARD/RESERVE

165. Are you a member of a full-time active duty National Guard/Reserve program (i.e., Active Guard and Reserve (AGR), Training and Administration of the the Reserve (TAR), or Active Reserve (AR)?

No ⇨ **IF NO, GO TO QUESTION 173**
Yes

166. In the next year, do you plan to . . . ? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Retire		
b. Leave the National Guard/Reserve (before retiring)		
c. Transfer to an Active component		
d. Transfer to another National Guard/ Reserve component		
e. Become a drilling unit member		
f. Transfer to IMA program		
g. Transfer to Individual Ready Reserve (IRR)/inactive National Guard (ING)		
h. Remain as an AGR/TAR/AR		

167. If you were to leave the AGR/TAR/AR program now and try to find a civilian job, how likely would you be to find a good civilian job?

Very unlikely
Unlikely
Neither likely nor unlikely
Likely
Very likely

168. As of today, how many months have you been assigned as an AGR/TAR/AR to your present post, base or duty station? *Please include any extensions you may have had in the total months assigned.*

Less than one month

Full months

169. How much longer do you expect to be at your present location?

Does not apply, I don't have a specified tour length or I expect to be here indefinitely
Less than 1 month

Full months

170. In all the time you have been in the AGR/TAR/AR program, how many times did you move to a new location because of your permanent change of station (PCS)? *Do not count permanent changes of assignment.*

None ⇨ **IF NONE, GO TO QUESTION 173**

PCS moves

171. For your most recent PCS move, were any of the following a problem?

	Does not apply	Don't know	Very serious problem	Serious problem	Somewhat of a problem	Slight problem	Not a problem
a. Adjusting to a higher cost of living							
b. Moving and setting up a new household							
c. Temporary lodging expenses							
d. Cost of setting up a new residence (curtains, carpeting, paint, etc.)							
e. Transportation costs incurred during move							
f. Finding civilian employment for your spouse or dependents							
g. Continuing your education							
h. Continuing spouse/ dependent education							
i. Transferability of college credits							
j. Finding permanent housing							
k. Finding shopping areas, recreational facilities, etc.							
l. Children adjusting to new environment							
m. Spouse adjusting to new environment							
n. Adjusting yourself to new environment							
o. Medical care for Exceptional Family Program member							
p. Educational facilities for Exceptional Family Program member							

172. In all the time you have been in the AGR/TAR/AR program, how many times did your spouse/ dependents move to a new location because of your permanent changes of station (PCS)?

Does not apply, had no spouse/dependents when I PCS'd

PCS moves

X. MILITARY LIFE

173. Do you perform volunteer work for the National Guard/Reserve, another Defense/Service organization, or for a civilian organization?

No ⇨ **IF NO, GO TO QUESTION 175**
Yes

174. How many hours in an average month do you perform volunteer work for a National Guard/ Reserve, other Defense/Service, or civilian organization? *Answer for each, then go to Question 176.*

a. National Guard/Reserve *Hours*

b. Other Defense or Service group *Hours*

c. Civilian organization *Hours*

175. What prevents you from volunteering? *Mark "No" or "Yes" for each item.*

	No	Yes
a. I do not have time		
b. I am not interested		
c. Location		
d. Times in which activities are scheduled		
e. Lack of childcare		
f. I do not have transportation		
g. I have not been asked		
h. I am physically unable		

176. How do you feel about the amount of time you spend on each activity listed below?

	Does not apply	I spend too much time	I spend about the right amount of time	I don't spend enough time
a. Your civilian job				
b. Family activities				
c. Leisure activities				
d. National Guard/Reserve activities				
e. Community activities				

177. All things considered, how satisfied or dissatisfied are you with each feature of the National Guard/ Reserve listed below?

Not applicable
Very satisfied
Satisfied
Neither satisfied nor dissatisfied
Dissatisfied
Very dissatisfied

a. Basic pay .....
b. Special and incentive pay .....
c. Availability of recruiting/ retention bonuses .....
d. Commissary privileges .....
e. Exchange privileges .....
f. Morale/welfare/recreation privileges .....
g. Retirement pay you would get ...
h. Cost of living adjustments (COLA) to retirement pay .....
i. Other retirement benefits, such as medical care and use of base services .....
j. Educational benefits .....
k. Frequency of moves .....
l. Amount of discipline .....
m. Opportunity to serve your country .....
n. Respect from Active component .
o. Your participation in the National Guard/Reserve .....

178. How much do you agree or disagree with each of the following statements about military life?

Strongly agree
Agree
Neither agree nor disagree
Disagree
Strongly disagree

a. Life in the military is what I expected it to be .....
b. Military personnel in the future will have at least as good retirement benefits as I have .....
c. My military pay and benefits will not keep up with inflation .....

179. How satisfied are you with the following characteristics of the location where you live now? *If you live on an installation, answer for your installation. If you do not live on an installation, answer for your community.*

Does not apply
Very satisfied
Satisfied
Neither satisfied nor dissatisfied
Dissatisfied
Very dissatisfied

a. Climate .....
b. Cost of residence .....
c. Distance to workplace .....
d. Distance to shopping areas ....
e. Distance to recreation areas ...
f. Safety of the area where you live .....
g. Family's ability to handle cost of living .....
h. Availability of military housing ..
i. Quality of military housing .....
j. Availability of civilian housing...
k. Availability of goods and services at the installation or duty station .....
l. Recreational facilities.....
m. Attitudes of local residents toward military families .....
n. Availability of Federal employment for spouse or dependents .....
o. Availability of other civilian employment for spouse or dependents .....
p. Quality of school for dependents .....
q. Availability of medical care for you .....
r. Quality of medical care for you .....
s. Availability of medical care for spouse or dependents.....
t. Quality of medical care for spouse or dependents.....
u. Availability of military family support programs or services ..

180. Would you like to know the results of this survey? *If you are interested in being notified when a brief summary of the results is available on the Web, please print your e-mail address below. This e-mail address will be used for no other purpose than this notification.*

Please print

181. On what date did you complete this survey?

COMMENTS

182. If you have comments or concerns that you were not able to express in answering this survey, please print them in the space provided.

- **PLEASE RETURN YOUR COMPLETED SURVEY IN THE BUSINESS REPLY ENVELOPE. (If you misplaced the envelope, mail the survey to DMDC, c/o Data Recognition Corp., 5900 Baker Road, Minnetonka, MN 55345-5967.)**
- **IF YOU ARE RETURNING THE SURVEY FROM ANOTHER COUNTRY, BE SURE TO RETURN THE BUSINESS REPLY ENVELOPE ONLY THROUGH A U.S. GOVERNMENT MAIL ROOM OR POST OFFICE.**
- **FOREIGN POSTAL SYSTEMS WILL NOT DELIVER BUSINESS REPLY MAIL.**

THANK YOU FOR YOUR TIME AND ASSISTANCE

For Office Use Only

RCS: DD-RA(OT)2067
Exp. 03/31/01

2000 Survey of Spouses of Reserve Component Personnel

Form S

DEFENSE MANPOWER DATA CENTER
ATTN: SURVEY PROCESSING ACTIVITY
DATA RECOGNITION CORPORATION
5900 BAKER ROAD

DMDC Survey No. 00-0002S

- Use a blue or black pen, or a pencil.
- Select answers you believe are most appropriate.
- Do not make any marks outside of the response and write-in boxes.
- Please PRINT where applicable.
- Place an "X" in the appropriate box or boxes.

RIGHT ☒ WRONG ☑ ☐

- To change an answer using pen, completely black out the wrong answer and put an "X" in the correct box as shown below.

CORRECT ANSWER ☒ INCORRECT ANSWER ■

- To change an answer using pencil, completely erase the wrong answer and put an "X" in the correct box.

ABOUT THIS QUESTIONNAIRE

WHAT IS THE PURPOSE OF THIS SURVEY?

This survey asks about your attitudes and opinions on a wide range of personnel issues in the Reserve components such as family well being and use of family programs and services. This survey will be used to assess programs, policies, and issues affecting Reserve component members and their families. **While no decisions about you alone will be made based on this survey, survey results will influence policy discussions and may result in changes that affect Reserve component members and families.** If you don't respond, your views and the views of other spouses like you will not be considered in personnel policy reviews and changes.

WHY ME?

You have been selected scientifically to be part of a sample of people who represent members of the Reserve components. Based on your responses and the responses of others, conclusions may be drawn about the views and experiences of Reserve component spouses overall, and those of demographic subgroups. The validity of these conclusions depends, in part, on receiving enough completed surveys from individuals like you. **The survey results will not be valid if you allow someone else to fill out the survey for you.**

WILL MY SURVEY RESPONSES BE KEPT PRIVATE?

Yes. Under no circumstances will any information about identifiable individuals be released. Your responses will be combined with information from many other spouses to represent the views and experiences of groups of spouses. **Do not use any personal, unit, or place names anywhere on this survey.**

PRIVACY NOTICE

In accordance with the Privacy Act of 1974 (Public Law 93-579), this notice informs you of the purpose of the survey and how the findings will be used. Please read it carefully

AUTHORITY: 10 United States Code, Sections 136, 1782, and 2358.

PRINCIPAL PURPOSE: Information collected in this survey will be used to assess the attitudes and perceptions of spouses of Department of Defense and Department of Transportation personnel about programs and policies. This information will help formulate policies that may be needed to improve the working environment for members and programs for families.

ROUTINE USES: Reports may be provided to the Secretaries of Defense, Transportation, and the Military Departments, and to the Joint Chiefs of Staff. Findings may be used in reports and testimony provided to Congress. Some findings may be published by the Defense Manpower Data Center (DMDC) or professional journals, or reported in manuscripts presented at conferences, symposia, and scientific meetings. In no case will the data be reported or used for identifiable individuals.

DISCLOSURE: Providing information on this survey is voluntary. There is no penalty if you choose not to respond. However, maximum participation is encouraged so that the data will be complete and representative. Your survey instrument will be treated as confidential. Identifying information will be used only by persons engaged in, and for the purposes of, the survey. Only group statistics will be reported.

I. FAMILY MILITARY EXPERIENCE

1. In which National Guard/Reserve component is your spouse? *Mark one.*

- ☐ Army National Guard
- ☐ Army Reserve
- ☐ Naval Reserve
- ☐ Marine Corps Reserve
- ☐ Air National Guard
- ☐ Air Force Reserve
- ☐ Coast Guard Reserve
- ☐ No Reserve component ⇨ **STOP HERE AND RETURN SURVEY**

2. What is your spouse's present paygrade? *Mark one.*

- ☐ E-1
- ☐ E-2
- ☐ E-3
- ☐ E-4
- ☐ E-5
- ☐ E-6
- ☐ E-7
- ☐ E-8
- ☐ E-9
- ☐ W-1
- ☐ W-2
- ☐ W-3
- ☐ W-4
- ☐ W-5
- ☐ O-1/O1E
- ☐ O-2/O2E
- ☐ O-3/O3E
- ☐ O-4
- ☐ O-5
- ☐ O-6 or above
- ☐ Don't know

3. Was your spouse's original decision to join the National Guard/Reserve made before or after you married?

- ☐ Before
- ☐ After

4. Have you ever (past or present) served in the U.S. Armed Forces, either on active duty or in the National Guard/Reserve?

- ☐ No, I have never served ⇨ **GO TO QUESTION 10**
- ☐ Yes, I have served/am serving

5. Are you currently in the U.S. Armed Forces?

- ☐ No, I am retired
- ☐ No, I separated and have no remaining obligation
- ☐ Yes, I am on active duty (not a member of the National Guard/Reserve)
- ☐ Yes, I am a member of the National Guard/Reserve in a full-time active duty program
- ☐ Yes, I am still in the Individual Ready Reserve (IRR) or Inactive National Guard (ING)
- ☐ Yes, I am another type of National Guard/Reserve member (e.g., in a drilling unit, Individual Mobilization Augmentee (IMA), military technician)

6. In which component are/were you? *Mark current component, or last component if separated.*

- ☐ Active Army
- ☐ Army Reserve
- ☐ Naval Reserve
- ☐ Air National Guard
- ☐ Active Marine Corps
- ☐ Active Coast Guard
- ☐ Army National Guard
- ☐ Active Navy
- ☐ Active Air Force
- ☐ Air Force Reserve
- ☐ Marine Corps Reserve
- ☐ Coast Guard Reserve

7. What is/was your highest paygrade? *Mark one.*

- ☐ E-1
- ☐ E-2
- ☐ E-3
- ☐ E-4
- ☐ E-5
- ☐ E-6
- ☐ E-7
- ☐ E-8
- ☐ E-9
- ☐ W-1
- ☐ W-2
- ☐ W-3
- ☐ W-4
- ☐ W-5
- ☐ O-1/O1E
- ☐ O-2/O2E
- ☐ O-3/O3E
- ☐ O-4
- ☐ O-5
- ☐ O-6 or above

8. When you finally leave (or left) military service, how many years of service do you expect to have (or did you have)? *Print years of service. If less than 1 year, print "00".*

- ☐☐ *Full-time active duty National Guard/Reserve program years of service*
- ☐☐ *Individual Ready Reserve (IRR) or Inactive Guard (ING) years of service*
- ☐☐ *Other National Guard/Reserve years of service (in a part-time status)*
- ☐☐ *Active component years of service*

9. If you previously served in the military and you are not currently serving, why did you leave the military? *Mark the one most important reason.*

- ☐ Does not apply, still serving in the military
- ☐ Forced to separate, did not want to leave
- ☐ Did not like the specific military job assignment
- ☐ Did not like the military in general
- ☐ Better civilian job opportunity
- ☐ Left to have or raise child/family
- ☐ Health reason
- ☐ Spouse wanted me to leave
- ☐ Retired
- ☐ Family problems
- ☐ Drills/duty conflicted with civilian job
- ☐ Drills/duty conflicted with family responsibilities
- ☐ Drills/duty conflicted with school
- ☐ Drills/duty conflicted with spouse's military or civilian job
- ☐ Other
- ☐ None of the above

II. INDIVIDUAL AND FAMILY CHARACTERISTICS

10. Are you . . . ?

- ☐ Male
- ☐ Female

11. What age were you on your last birthday?

☐☐ *Years old*

12. Have your parents (or guardians) served in or retired from the military (including the National Guard or Reserve)?

- ☐ No
- ☐ Yes

13. Are you a citizen of the United States? *Mark one.*

- ☐ Yes, born in the United States
- ☐ Yes, born in Puerto Rico, Guam, the U.S. Virgin Islands, or the Northern Marianas
- ☐ Yes, born abroad of American parent or parents
- ☐ Yes, a U.S. citizen by naturalization
- ☐ No, not a citizen of the United States

14. Are you Spanish/Hispanic/Latino? *Mark "No" if not Spanish/Hispanic/Latino.*

- ☐ No, not Spanish/Hispanic/Latino
- ☐ Yes, Mexican, Mexican American, Chicano
- ☐ Yes, Puerto Rican
- ☐ Yes, Cuban
- ☐ Yes, other Spanish/Hispanic/Latino

15. What is your race? *Mark one or more races to indicate what you consider yourself to be.*

- ☐ White
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Asian (e.g., Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese)
- ☐ Native Hawaiian or other Pacific Islander (e.g., Samoan, Guamanian or Chamorro)
- ☐ Some other race ⇨ ***Please specify***

Please print

16. Do you speak English as your main language at home?

- ☐ Yes
- ☐ No, some other language ⇨ ***Please specify***

Please print

17. What is the highest degree or level of school that you have completed. *Mark the one answer that describes the highest grade or degree that you have completed.*

- ☐ 11th grade or less
- ☐ 12 years of school, no diploma
- ☐ High school diploma or the equivalent (e.g., GED), not from home schooling
- ☐ High school diploma or the equivalent (e.g., GED), from home schooling
- ☐ Some college credit, but less than 1 year
- ☐ 1 or more years of college, but no degree
- ☐ Associate's degree (e.g., AA, AS)
- ☐ Bachelor's degree (e.g., BA, AB, BS)
- ☐ Master's degree (e.g., MA, MS)
- ☐ Doctoral or professional degree (e.g., PhD, MD, JD, DVM)

18. What kind of civilian school are you currently enrolled in?

- ☐ Not currently enrolled in civilian school
- ☐ High school (home schooling)
- ☐ High school (public or private)
- ☐ GED completion
- ☐ Vocational/trade/business or other career training school
- ☐ Junior or community college (2-year)
- ☐ Four-year college or university
- ☐ Graduate/professional school
- ☐ Other

19. Have you ever participated in computer-based distance learning?

- ☐ No
- ☐ Yes

20. How long does it normally take to get to the closest military installation?

- ☐ 10 minutes or less
- ☐ 11-20 minutes
- ☐ 21-30 minutes
- ☐ 31-60 minutes
- ☐ More than 1 hour
- ☐ Don't know

21. What is your marital status?

- ☐ Married for the first time
- ☐ Remarried
- ☐ Separated
- ☐ Divorced ⇨ **STOP HERE AND RETURN SURVEY**

22. How many years have you been married to your current spouse?

☐ Less than one year

☐☐ *Full years married*

For Questions 23-27 "dependents" includes children and anyone else in your family, except your spouse, who has or is eligible to have a Uniformed Services identification card (military ID card) or is eligible for military health care benefits and is enrolled in the Defense Enrollment Eligibility Reporting System (DEERS).

23. Based on the definition above, do you and your spouse have a child, children, or other legal dependents?

☐ No ⇨ **IF NO, GO TO QUESTION 39**
☐ Yes

24. How many children or other dependents do you and your spouse have in each age group? *Print the number of dependents you have in each age group.*

Less than 1 year old	1 year-under 2 years old	2-5 years old	6-13 years old	14-22 years old	23-64 years old	65 years old or older

25. Do any of the dependents in Question 24 live with someone other than you?

☐ No ⇨ **IF NO, GO TO QUESTION 27**
☐ Yes

26. With whom do these dependants live? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Spouse	☐	☐
b. Ex-spouse	☐	☐
c. Grandmother and/or grandfather	☐	☐
d. Other relative	☐	☐
e. Friend	☐	☐
f. At school	☐	☐
g. Other non-relative	☐	☐

27. Do any of your dependents have a physical, mental, or emotional condition requiring specialized treatment or care?

☐ No
☐ Yes, dependent requires temporary treatment or care
☐ Yes, dependent requires permanent treatment or care

28. Do you have children under the age of 15 who usually live with you?

☐ No ⇨ **IF NO, GO TO QUESTION 39**
☐ Yes

29. During the last year, who usually took care of your youngest (or only) child while you worked, looked for work, or were in school? *Mark the one arrangement in which the child spent the most hours.*

☐ Does not apply, I was not working, looking for work, or in school ⇨ **IF DOES NOT APPLY, GO TO QUESTION 36**
☐ Spouse cared for child
☐ Child's brother or sister aged 15 or over
☐ Child's brother or sister under 15
☐ Child's grandparent
☐ Other relative of child
☐ Child cares for self
☐ Child was in school or daycare
☐ Other non-relative of child

30. Where was your youngest or only child usually cared for under this arrangement? *Mark one.*

☐ Military daycare center
☐ Nursery or preschool
☐ Child Development Center/daycare center
☐ Elementary or secondary school
☐ Child's home
☐ Licensed family daycare home
☐ Other private home (not licensed)
☐ None of the above

31. During a typical week in the last year, how many hours was your youngest or only child cared for under this arrangement?

☐☐ *Hours per week*

32. During a typical month, how much did you pay for childcare for your youngest or only child? *Please round off to the nearest dollar. For example, if you pay $395.40 per month, you would enter 0395 in the boxes.*

☐ Does not apply, I spend no money on childcare arrangements for my youngest or only child.

$ ☐,☐☐☐ *Dollar amount per month*

33. How many of your dependent children use childcare?

☐☐ *Number of children*

34. What is the total amount that you spend during a typical month on childcare arrangements for all of your children? *Please round off to the nearest dollar.*

☐ Does not apply, I spend no money on childcare arrangements.

$ ☐.☐☐☐ *Dollar amount per month*

35. Approximately how many hours per week does your spouse care for any of your children on a regular basis while you work, look for work, or are in school?

☐☐ *Hours per week*

36. Do you need childcare when your spouse is gone for National Guard/Reserve activities?

☐ No ⇨ **IF NO, GO TO QUESTION 39**
☐ Yes

37. During which of these activities of your spouse do you need childcare? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Weekend drill	☐	☐
b. Annual training/Active Duty Training	☐	☐
c. Mobilization (e.g., deployment, state emergency duty, etc.)	☐	☐

38. What is the total amount that you spent in the last 12 months on childcare arrangements for all of your children when your spouse was gone for National Guard/Reserve activities? *Please round off to the nearest dollar.*

☐ Does not apply, I spent no money on childcare arrangements.

$ ☐.☐☐☐ *Dollar amount last 12 months*

39. Do you have caregiver responsibilities for an elderly family member (such as shopping, home maintenance, transportation, checking on them by phone, finances, and arrangements for care)? *Include family who live with you or live somewhere else.*

☐ No ⇨ **IF NO, GO TO QUESTION 43**
☐ Yes

40. How many elderly family members do you have caregiver responsibilities for?

☐ One
☐ Two
☐ Three or more

41. Do any of these elderly family members live with you?

☐ No
☐ Yes

42. How much care is needed by your elderly family members for whom you have caregiver responsibilities?

☐ No care needed
☐ Small amount of care
☐ Moderate amount of care
☐ Large amount of care
☐ Very large amount of care

III. FAMILY WORK EXPERIENCE

43. Are you currently . . . ? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Working full-time in a civilian job	☐	☐
b. Working part-time in a civilian job	☐	☐
c. Managing or working in a family business	☐	☐
d. Self-employed in your own business or profession	☐	☐
e. An unpaid worker (volunteer)	☐	☐
f. Unemployed and looking for job	☐	☐
g. Unemployed, not looking for job, but would like employment	☐	☐
h. Unemployed, not looking for job, and do not want employment	☐	☐
i. In school	☐	☐
j. Retired	☐	☐
k. A homemaker, housewife, househusband	☐	☐
l. Working multiple jobs	☐	☐
m. Working temporary job(s)	☐	☐

44. To what degree do you and your spouse agree on your career plans?

☐ Strongly disagree
☐ Disagree
☐ Neither agree nor disagree
☐ Agree
☐ Strongly agree

45. To what extent does your paid job(s) conflict with your spouse's National Guard/Reserve job?

☐ Does not apply, I do not have a paid job ⇨ **IF NO PAID JOB, GO TO QUESTION 47**
☐ Not at all
☐ Small extent
☐ Moderate extent
☐ Large extent
☐ Very large extent

46. To what extent does your spouse's National Guard/Reserve job conflict with your current paid job(s)?

☐ Not at all
☐ Small extent
☐ Moderate extent
☐ Large extent
☐ Very large extent

47. Did you have a paid job at any time during 1999?

- ☐ No ⇨ **IF NO, GO TO QUESTION 52**
- ☐ Yes

48. Which of the following best describes your civilian employer in 1999? *Mark one.*

- ☐ Federal government
- ☐ State government
- ☐ Local government (including public schools)
- ☐ Working without pay in family business or farm
- ☐ Self-employed in own business
- ☐ Private sector firm with 500 or more employees
- ☐ Private sector firm with 100-499 employees
- ☐ Private sector firm with less than 100 employees

49. In 1999, how many hours per week did you usually work at your main civilian job?

☐☐ *Weekly hours*

50. Altogether in 1999, what was the total amount you earned from your civilian job or your business, before taxes and other deductions? Include commissions, tips, or bonuses. *Please give your best estimate.*

- ☐ $0
- ☐ $1-1,000
- ☐ $1,001-5,000
- ☐ $5,001-10,000
- ☐ $10,001-15,000
- ☐ $15,001-20,000
- ☐ $20,001-30,000
- ☐ $30,001-40,000
- ☐ $40,001-50,000
- ☐ $50,001-60,000
- ☐ $60,001-70,000
- ☐ $70,001-80,000
- ☐ $80,001-90,000
- ☐ $90,001-100,000
- ☐ Over $100,000

51. How much did each of the following contribute to your decision to work or seek work at a paid job or business?

	Very important	Somewhat important	Not important
a. Need money for basic family expenses	☐	☐	☐
b. Desire for a career	☐	☐	☐
c. Want extra money to use now	☐	☐	☐
d. Want to save money for the future	☐	☐	☐
e. Want independence	☐	☐	☐
f. Enjoy working	☐	☐	☐
g. Want to gain experience for future career	☐	☐	☐

52. How much of a contribution does your spouse's National Guard/Reserve income make toward each of the following items?

	Major	Moderate	Minor	None
a. Meeting basic expenses	☐	☐	☐	☐
b. Extra money to use now	☐	☐	☐	☐
c. Savings for the future	☐	☐	☐	☐

53. To what extent do you and your spouse agree on his/her civilian career plans?

- ☐ Strongly disagree
- ☐ Disagree
- ☐ Neither agree nor disagree
- ☐ Agree
- ☐ Strongly agree

54. To what extent do you and your spouse agree on his/her military career plans?

- ☐ Strongly disagree
- ☐ Disagree
- ☐ Neither agree nor disagree
- ☐ Agree
- ☐ Strongly agree

55. In 1999, did your spouse have a civilian job?

- ☐ No
- ☐ Yes

56. Which of the following best describes your spouse's current military status?

- ☐ A member of the National Guard/Reserve in a full-time active duty program
- ☐ A member of the IRR or ING
- ☐ Other type of National Guard/Reserve member (e.g., drilling unit, IMA, military technician)

57. Is your spouse currently . . . ? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Working full-time in a Federal civilian job	☐	☐
b. Working part-time in a Federal civilian job	☐	☐
c. Working full-time in a civilian job (not Federal)	☐	☐
d. Working part-time in a civilian job (not Federal)	☐	☐
e. Managing or working in family business	☐	☐
f. Self-employed in own business or profession	☐	☐
g. An unpaid worker (volunteer)	☐	☐
h. Unemployed and looking for job	☐	☐
i. Unemployed, not looking for job, but would like employment	☐	☐
j. Unemployed, not looking for job, and do not want employment	☐	☐
k. In school	☐	☐
l. Retired	☐	☐
m. A homemaker, housewife, househusband	☐	☐
n. Working multiple jobs	☐	☐
o. Working temporary job(s)	☐	☐

IV. NATIONAL GUARD/RESERVE PROGRAMS

58. National Guard/Reserve units or centers have programs or activities for family members. For each program/activity listed, mark in column A whether the program/activity was available during the last 12 months. If it was available to you, mark in column B whether you attended or participated in it.

	A. Was it available?			B. Did you attend/participate?			
	Don't know	No	Yes ⇨	No	Yes, once	Yes, twice or more	Don't recall
a. Meetings for families of new members	☐	☐	☐ ⇨	☐	☐	☐	☐
b. Family oriented social events, dinners, athletic programs, bake sales, etc.	☐	☐	☐ ⇨	☐	☐	☐	☐
c. Family oriented information programs about the National Guard/Reserve	☐	☐	☐ ⇨	☐	☐	☐	☐
d. Meetings about mobilization	☐	☐	☐ ⇨	☐	☐	☐	☐
e. Meetings about National Guard/Reserve medical benefits	☐	☐	☐ ⇨	☐	☐	☐	☐
f. Meetings about National Guard/Reserve retirement benefits	☐	☐	☐ ⇨	☐	☐	☐	☐
g. Family support group meetings	☐	☐	☐ ⇨	☐	☐	☐	☐

59. During the past 12 months, how often did you and/or your family members use the following military on-installation programs, facilities, or services and civilian off-installation programs, facilities, or services? *For each item, mark one response in column A and one response in column B.*

	A. Military On-Installation Program, Facility, or Service						B. Civilian Off-Installation Program, Facility, or Service					
	12+ times	6-11 times	3-5 times	1-2 times	0 times	Not available	12+ times	6-11 times	3-5 times	1-2 times	0 times	Not available
a. Auto, crafts, hobby shops	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
b. Bank or credit union	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
c. Bowling center or movie theater	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
d. Commissary, supermarket, grocery store	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
e. Clubs/dance/night clubs	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
f. Fitness center/gym	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
g. Golf course	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
h. Library services	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
i. Main exchange/department store	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
j. Outdoor recreation areas (campgrounds, picnic areas, beach, stables, etc.)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
k. Outdoor recreation equipment rental	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
l. Post office	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
m. Recreation center (recreation room, music/TV, game room/amusement machines, etc.)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
n. Recreation lodging/hotels/resorts	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
o. Shoppette/mini-mart	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
p. Class VI/package store/liquor store	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

60. During the past 12 months, have you used any of the following programs and services? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Adult continuing education/counseling	☐	☐
b. Tuition assistance programs for college/higher education	☐	☐
c. Technical/vocational programs	☐	☐
d. Basic skills education	☐	☐

61. Are you ever eligible to use commissaries and exchanges on military installations?

- ☐ No ⇨ **IF NO, GO TO QUESTION 71**
- ☐ Yes
- ☐ Don't know

62. How much do the following limit your use of the commissary or exchange? *Mark one answer for each row.*

	Completely	Very much	Somewhat	Very little	Not at all
Commissary					
a. Prices	☐	☐	☐	☐	☐
b. Stock	☐	☐	☐	☐	☐
c. Hours	☐	☐	☐	☐	☐
d. Distance	☐	☐	☐	☐	☐
e. The law does not allow more frequent use	☐	☐	☐	☐	☐
Exchange					
a. Prices	☐	☐	☐	☐	☐
b. Stock	☐	☐	☐	☐	☐
c. Hours	☐	☐	☐	☐	☐
d. Distance	☐	☐	☐	☐	☐

63. Overall, to what extent do you think you or your family save by using the commissary instead of civilian grocery stores?

- ☐ Does not apply, do not use commissary
- ☐ Not at all
- ☐ Small extent
- ☐ Moderate extent
- ☐ Large extent
- ☐ Very large extent

64. Do you currently use the *EXCHANGE* closest to you?

- ☐ No, I don't use an exchange
- ☐ No, I use an exchange, but it's not the closest
- ☐ Yes, I use the exchange closest to me

65. How long does/would it normally take to get to the exchange closest to you?

- ☐ 10 minutes or less
- ☐ 11-20 minutes
- ☐ 21-30 minutes
- ☐ 31-60 minutes
- ☐ More than 1 hour
- ☐ Don't know

66. Please rate the selection of merchandise at the exchange closest to you.

- ☐ Very poor
- ☐ Poor
- ☐ Average
- ☐ Good
- ☐ Excellent
- ☐ Don't know

67. Please rate the prices at the exchange closest to you compared with prices at other stores in town.

- ☐ Very poor
- ☐ Poor
- ☐ Average
- ☐ Good
- ☐ Excellent
- ☐ Don't know

68. At which Service's exchange do you shop most often?

- ☐ Does not apply, I do not shop at an exchange
- ☐ Army and Air Force Exchange Service (AAFES), Post Exchange (PX) or Base Exchange (BX)
- ☐ Navy Exchange
- ☐ Marine Corps Exchange

69. What average savings, not considering sales tax, are available at the exchange?

- ☐ I believe I pay more at the exchange
- ☐ No savings
- ☐ 5% savings or less
- ☐ 6-10% savings
- ☐ 11-20% savings
- ☐ More than 20% savings
- ☐ Don't know

70. Are your and your spouse's shopping privileges limited at exchanges?

- ☐ No
- ☐ Yes
- ☐ Don't know

71. Can an exchange's merchandise be ordered on the Internet?

- ☐ No
- ☐ Yes
- ☐ Don't know

72. Have you ever used a personal computer (PC)?

☐ No ⇨ **IF NO, GO TO QUESTION 76**
☐ Yes

73. Where during the last 12 months have you regularly used a PC? ***Mark "No" or "Yes" for each item.***

	No	Yes
a. Home/residence	☐	☐
b. Civilian work/office	☐	☐
c. Guard/Reserve duty station or Armory	☐	☐
d. Installation/ship library	☐	☐
e. Installation/ship recreation center	☐	☐
f. Installation/ship education center	☐	☐
g. Installation/ship family center	☐	☐
h. Other military location	☐	☐
i. Other non-military location (for example, public library)	☐	☐

74. Do you have access to the Internet/World Wide Web?

☐ No ⇨ **IF NO, GO TO QUESTION 76**
☐ Yes

75. From which location do you most frequently access the Internet/World Wide Web? ***Mark one.***

☐ Home/residence
☐ Civilian work/office
☐ Guard/Reserve duty station or Armory
☐ Installation/ship library
☐ Installation/ship recreation center
☐ Installation/ship education center
☐ Installation/ship family center
☐ Other military location
☐ Other non-military location (for example, public library)

76. Do you have any medical/hospitalization coverage(s)?

☐ No ⇨ **IF NO, GO TO QUESTION 79**
☐ Yes

77. Do you have the following medical/hospitalization coverage(s)? ***Mark "No" or "Yes" for each item.***

	No	Yes
a. Your civilian employer's healthcare plan	☐	☐
b. Your school's healthcare plan	☐	☐
c. Your spouse/family member's civilian employer's health plan	☐	☐
d. Your active duty/retired military healthcare coverage	☐	☐
e. Your spouse/family member's active duty military healthcare coverage	☐	☐
f. Veterans' (VA) coverage	☐	☐
g. Other private coverage	☐	☐

78. How satisfied or dissatisfied are you with the coverage provided by your medical insurance?

☐ Very dissatisfied
☐ Dissatisfied
☐ Neither satisfied nor dissatisfied
☐ Satisfied
☐ Very satisfied

79. Do you have any dental coverage(s)?

☐ No ⇨ **IF NO, GO TO QUESTION 82**
☐ Yes

80. Which of the following dental coverage(s) do you have? ***Mark "No" or "Yes" for each item.***

	No	Yes
a. Your civilian employer's dental plan	☐	☐
b. Your spouse/family member's civilian employer's dental plan	☐	☐
c. Your active duty military coverage	☐	☐
d. Your spouse/family member's active duty military coverage (military dental clinic, TRICARE Family Member Dental Plan)	☐	☐
e. Veteran (VA) coverage	☐	☐
f. Other private coverage	☐	☐

81. How satisfied are you with the coverage provided by the dental insurance that you have?

☐ Very dissatisfied
☐ Dissatisfied
☐ Neither satisfied nor dissatisfied
☐ Satisfied
☐ Very satisfied

82. Do you perform volunteer work for the National Guard/Reserve, another Defense/Service organization, or for a civilian organization?

☐ No ⇨ **IF NO, GO TO QUESTION 84**
☐ Yes

83. How many hours <u>in an average month</u> do you perform volunteer work for a National Guard/ Reserve, other Defense/Service, or civilian organization? ***Answer for each, then go to Question 85.***

a. National Guard/Reserve ☐☐ *Hours*
b. Other Defense/Service group ☐☐ *Hours*
c. Civilian organization ☐☐ *Hours*

84. What prevents you from volunteering? ***Mark "No" or "Yes" for each item.***

	No	Yes
a. I do not have time	☐	☐
b. I am not interested	☐	☐
c. Location	☐	☐
d. Times in which activities are scheduled	☐	☐
e. Lack of childcare	☐	☐
f. I do not have transportation	☐	☐
g. I have not been asked	☐	☐
h. I am physically unable	☐	☐

85. Does your local Armory or Reserve unit/center have a family support group (or something similar to a family support group)?

- ☐ No
- ☐ Yes, but not very active
- ☐ Yes, an active family support group
- ☐ Not sure

86. The National Guard/Reserve components are developing new information materials. Below is a list of topics that might be included. How interested would you be in receiving such materials?

	Very interested	Somewhat interested	Neither interested nor uninterested	Uninterested	Very uninterested
a. National Guard/Reserve organization	☐	☐	☐	☐	☐
b. The mission of your spouse's unit	☐	☐	☐	☐	☐
c. The unit's role in mobilization	☐	☐	☐	☐	☐
d. Educational benefits for Reservists	☐	☐	☐	☐	☐
e. Medical benefits for deployed members/dependents	☐	☐	☐	☐	☐
f. Retirement benefits for Reservists	☐	☐	☐	☐	☐
g. Survivor benefits for Reservists	☐	☐	☐	☐	☐
h. Leave and earnings statements	☐	☐	☐	☐	☐
i. Advance schedules for drills and Annual Training/ACDUTRA	☐	☐	☐	☐	☐
j. Family's role in the event of mobilization	☐	☐	☐	☐	☐
k. Family support groups	☐	☐	☐	☐	☐
l. Family counseling	☐	☐	☐	☐	☐
m. Family care plans	☐	☐	☐	☐	☐
n. Defense Enrollment Eligibility Reporting System (DEERS)	☐	☐	☐	☐	☐
o. Dealing with family separations due to mobilization/deployment	☐	☐	☐	☐	☐
p. Dealing with family reunions after mobilization/deployment	☐	☐	☐	☐	☐
q. Soldiers and Sailors Civil Relief Act	☐	☐	☐	☐	☐
r. Uniform Services & Employment Reemployment Rights Act (USERRA)	☐	☐	☐	☐	☐
s. National Committee for Employer Support of National Guard & Reserve	☐	☐	☐	☐	☐

87. How do you feel about the amount of time your spouse spends on each activity listed below?

	Does not apply	Spends too much time	Spends the right amount of time	Doesn't spend enough time
a. Civilian job	☐	☐	☐	☐
b. Family activities	☐	☐	☐	
c. Leisure activities	☐	☐	☐	
d. Community activities	☐	☐	☐	
e. Duty at Armory/Reserve Center	☐	☐	☐	☐
f. National Guard/Reserve Annual Training	☐	☐	☐	☐
g. National Guard/Reserve mobilizations or deployments	☐	☐	☐	☐
h. National Guard/Reserve domestic emergencies	☐	☐	☐	☐

88. How much of a problem for your family is each of the following aspects of your spouse's National Guard/Reserve duty?

	Not applicable	A very serious problem	A serious problem	Somewhat of a problem	A slight problem	Not a problem
a. Time away for weekend drills	☐	☐	☐	☐	☐	☐
b. Time away for Annual Training/ ACDUTRA	☐	☐	☐	☐	☐	☐
c. Extra time spent at National Guard/Reserve	☐	☐	☐	☐	☐	☐
d. Time away from spouse's civilian job due to National Guard/Reserve	☐	☐	☐	☐	☐	☐
e. Effects of National Guard/ Reserve duty on spouse's pay and promotion opportunities in civilian job	☐	☐	☐	☐	☐	☐
f. Time away from children due to National Guard/Reserve duty	☐	☐	☐	☐	☐	☐
g. Time away from you due to National Guard/Reserve duty	☐	☐	☐	☐	☐	☐
h. Drills on special days (e.g., Mothers' Day, Easter)	☐	☐	☐	☐	☐	☐
i. Unscheduled National Guard/ Reserve activities	☐	☐	☐	☐	☐	☐
j. Scheduling family vacations	☐	☐	☐	☐	☐	☐
k. Using vacation time for National Guard/Reserve duty	☐	☐	☐	☐	☐	☐
l. Absence for domestic emergencies (floods, storms, etc.)	☐	☐	☐	☐	☐	☐
m. Absence for mobilization/ deployment (Operation Desert Storm, Haiti, Bosnia, etc.)	☐	☐	☐	☐	☐	☐

89. Has your spouse ever been mobilized or deployed as a member of the National Guard/Reserve?

- ☐ No ⇨ **IF NO, GO TO QUESTION 104**
- ☐ Yes

◆ **90. Was your spouse mobilized/deployed as a Reservist for the operations listed below?** ***Mark "No" or "Yes" for each item. If you mark "Yes" in column A, please indicate whether it was voluntary or involuntary, the deployment's location, and its length. If you mark "No" in column A, go to the next item in column A.***

	A. Was your spouse mobilized or deployed as a member of the National Guard/Reserve for the operations (a-k) listed below?		B. Was his/her mobilization voluntary or involuntary?		C. Where did he/she deploy? (Mark one)				D. How long was he/she mobilized or deployed? Write in number of months. If under 1 month, enter "00". If mobilized/deployed now, write number of months so far.
	No	Yes ⇨	Voluntary	Involuntary	Does not apply, did not deploy	In own state or equivalent (e.g., DC, GU, PR, VI)	To another state or equivalent (e.g., DC, GU, PR, VI)	Outside US	
a. Operation Desert Shield/Storm	☐	☐ ⇨	☐	☐	☐	☐	☐	☐	☐☐
b. Saudi Arabia (Aug 92-present)	☐	☐ ⇨	☐	☐	☐	☐	☐	☐	☐☐
c. Centam, Hurricane Mitch Recovery/Rehab	☐	☐ ⇨	☐	☐	☐	☐	☐	☐	☐☐
d. Operation Restore/Uphold Democracy (Haiti)	☐	☐ ⇨	☐	☐	☐	☐	☐	☐	☐☐
e. Operation Desert Fox/Iraqi Crisis (SW Asia)	☐	☐ ⇨	☐	☐	☐	☐	☐	☐	☐☐
f. Operation Joint Forge/Guard/ Endeavor (Bosnia)	☐	☐ ⇨	☐	☐	☐	☐	☐	☐	☐☐
g. Operation Restore/Continue Hope (Somalia)	☐	☐ ⇨	☐	☐	☐	☐	☐	☐	☐☐
h. Operation Joint Task Force (Cuba)	☐	☐ ⇨	☐	☐	☐	☐	☐	☐	☐☐
i. Operation Allied Force (Kosovo)	☐	☐ ⇨	☐	☐	☐	☐	☐	☐	☐☐
j. Other mobilization or deployment (1) *Describe:*	☐	☐ ⇨	☐	☐	☐	☐	☐	☐	☐☐
k. Other mobilization or deployment (2) *Describe:*	☐	☐ ⇨	☐	☐	☐	☐	☐	☐	☐☐

91. Is your spouse mobilized/deployed now? ***If yes, indicate the operation in Question 90 for which your spouse is deployed.***

☐ No ☐ Yes ⇨

IF YES, MARK ONE ⇨

☐ a ☐ d ☐ g ☐ j
☐ b ☐ e ☐ h ☐ k
☐ c ☐ f ☐ i

If your spouse is currently mobilized/deployed, answer Questions 92 to 102 about his/her current mobilization/deployment.

If your spouse is not currently mobilized/deployed, answer Question 92 to 102 about his/her most recent mobilization/deployment.

92. Did you need family support services during your spouse's most recent mobilization or deployment?

☐ No ⇨ **IF NO, GO TO QUESTION 94**
☐ Yes

93. Were you able to access family support services from/through the military?

☐ No
☐ Yes

94. What health insurance options did you choose the last time your spouse was mobilized or deployed? ***Mark "No" or "Yes" for each item.***

	No	Yes
a. I chose TRICARE as my primary health insurance	☐	☐
b. I kept my private/civilian health insurance	☐	☐
c. I dropped my private/civilian health insurance	☐	☐
d. I used TRICARE as a second payer to my primary health insurance	☐	☐
e. I did not have any health insurance before mobilization/deployment	☐	☐
f. Other ⇨	☐	☐

If you marked "Yes" please specify ⇨ ⇩

Please print

95. Did you file a TRICARE/CHAMPUS medical claim during your spouse's most recent mobilization or deployment?

☐ No ⇨ **IF NO, GO TO QUESTION 99**
☐ Yes

96. Did you need assistance to help you file medical claims during your spouse's most recent mobilization or deployment?

☐ No ⇨ **IF NO, GO TO QUESTION 98**
☐ Yes

97. What level of assistance was available to help you file medical claims?

☐ None
☐ Low
☐ Moderate
☐ High
☐ Very high

98. How satisfied were you with the medical claims processing service you received?

☐ Very dissatisfied
☐ Dissatisfied
☐ Neither satisfied nor dissatisfied
☐ Satisfied
☐ Very satisfied

99. How supportive of families were the following at your location during your spouse's most recent mobilization or deployment?

	Not applicable	Very supportive	Supportive	Neutral	Unsupportive	Very unsupportive
a. Officers in high positions at nearby military installation	☐	☐	☐	☐	☐	☐
b. Personnel at nearby Reserve Center/Armory/Activity	☐	☐	☐	☐	☐	
c. Officers in my spouse's unit	☐	☐	☐	☐	☐	
d. Noncommissioned officers/petty officers in my spouse's unit	☐	☐	☐	☐	☐	
e. Family Service/Support Centers	☐	☐	☐	☐	☐	☐
f. Command representative (e.g., ombudsman)	☐	☐	☐	☐	☐	
g. Civilian community	☐	☐	☐	☐	☐	
h. Other National Guard/Reserve spouses	☐	☐	☐	☐	☐	
i. Friends	☐	☐	☐	☐	☐	
j. Your spouse's civilian employer	☐	☐	☐	☐	☐	☐
k. Your civilian employer	☐	☐	☐	☐	☐	☐

100. Did the following changes in expenses occur as a result of your spouse's most recent mobilization or deployment? *Mark "No" or Yes" for each item.*

	No	Yes
a. Medical expenses increased	☐	☐
b. Medical expenses decreased	☐	☐
c. Telephone expenses increased	☐	☐
d. Household maintenance and car repairs increased	☐	☐
e. Household maintenance and car repairs decreased	☐	☐
f. Childcare increased	☐	☐
g. Mortgage payments declined	☐	☐

101. Were there any changes in income for you or your family during your spouse's most recent mobilization or deployment? *Mark "No" or Yes" for each item.*

	No	Yes
a. Increase in spouse's earnings	☐	☐
b. Increase in my earnings since I worked more hours or took a second job	☐	☐
c. Reduction in spouse's earnings	☐	☐
d. Reduction in my earnings since I was unable to work as much	☐	☐
e. Delays in getting military pay	☐	☐
f. Income from business or practice declined	☐	☐
g. Other increase	☐	☐
h. Other decrease	☐	☐

102. Please estimate your and your spouse's <u>total income change</u> from all sources as a result of your spouse's most recent mobilization or deployment. *If you and your spouse have continuing losses from a business or practice, include those in your estimate.*

☐ Increased $5,000 or more
☐ Increased $2,500-4,999
☐ Increased $1-2,499
☐ No change in income
☐ Decreased $1-2,499
☐ Decreased $2,500-4,999
☐ Decreased $5,000-9,999
☐ Decreased $10,000-24,999
☐ Decreased $25,000-49,999
☐ Decreased $50,000 or more

103. How many times has your spouse been mobilized or deployed since 1992? *If none, print "00".*

☐☐ *Number of times*

104. How many nights did your spouse spend away from your home on official military duties in 1999? *Do not include nights spent away from home before out-of-town drills.*

☐ None

☐☐☐ *Nights*

V. FAMILY ISSUES

105. Which of these community/civilian social services have you or your family used during the past 12 months? ***Mark "Not used" or Used/using" for each item.***

	Not used	Used/ using
a. Individual counseling/therapy	☐	☐
b. Pre-marital programs	☐	☐
c. Marriage or family counseling/ therapy/enrichment	☐	☐
d. Programs for families with disabled members	☐	☐
e. New parent classes	☐	☐
f. Childcare services	☐	☐
g. Youth/teen programs	☐	☐
h. Eldercare	☐	☐
i. Alcohol/drug abuse programs	☐	☐
j. Employment services	☐	☐
k. Spouse/child abuse services	☐	☐
l. Rape counseling services	☐	☐
m. Crisis referral services	☐	☐
n. Chaplain services/religious programs	☐	☐
o. Legal assistance	☐	☐
p. Financial counseling/management education	☐	☐
q. Recreational programs	☐	☐

106. How do you feel about the amount of time you spend on each activity listed below?

	Does not apply	I spend too much time	I spend about the right amount of time	I don't spend enough time
a. Your civilian job	☐	☐	☐	☐
b. Family activities	☐	☐	☐	
c. Leisure activities	☐	☐	☐	
d. Community activities	☐	☐	☐	
e. National Guard/Reserve activities	☐	☐	☐	

107. How unlikely or likely do you think it is that your spouse will be mobilized or deployed in the next 5 years?

- ☐ Very unlikely
- ☐ Unlikely
- ☐ Neither likely nor unlikely
- ☐ Likely
- ☐ Very likely

108. Which of the following would your spouse have to take care of before being mobilized or deployed? ***Mark "No" or "Yes" for each item.***

	No	Yes
a. Dependent care problems	☐	☐
b. His/her personal health problems	☐	☐
c. Family health problems	☐	☐
d. Preparation of emergency data (will, power of attorney, etc.)	☐	☐
e. Financial arrangements	☐	☐
f. Transportation arrangements	☐	☐
g. Civilian job-related arrangements	☐	☐
h. School-related arrangements	☐	☐
i. Vehicle or household maintenance	☐	☐

109. If your spouse were mobilized/deployed for more than 30 days, how likely are you and your family to make use of the following military services?

	Not available	Very likely	Likely	Neither likely nor unlikely	Unlikely	Very unlikely
a. Individual counseling/therapy	☐	☐	☐	☐	☐	☐
b. Marriage or family counseling/ therapy/enrichment	☐	☐	☐	☐	☐	☐
c. Family support centers	☐	☐	☐	☐	☐	☐
d. Programs for families with disabled members	☐	☐	☐	☐	☐	☐
e. Services for families during separation	☐	☐	☐	☐	☐	☐
f. New parent classes	☐	☐	☐	☐	☐	☐
g. Childcare services	☐	☐	☐	☐	☐	☐
h. Youth/teen programs	☐	☐	☐	☐	☐	☐
i. Eldercare	☐	☐	☐	☐	☐	☐
j. Alcohol/drug abuse programs	☐	☐	☐	☐	☐	☐
k. Spouse employment services	☐	☐	☐	☐	☐	☐
l. Spouse/child abuse services	☐	☐	☐	☐	☐	☐
m. Crisis referral services	☐	☐	☐	☐	☐	☐
n. Chaplain services/religious activities	☐	☐	☐	☐	☐	☐
o. Legal assistance	☐	☐	☐	☐	☐	☐
p. Financial counseling/ management education	☐	☐	☐	☐	☐	☐
q. Recreational programs	☐	☐	☐	☐	☐	☐
r. Educational Services Center	☐	☐	☐	☐	☐	☐

110. The questions below are about your family preparedness. *Mark one answer for each item.*

	Don't know	Yes	No
a. Are you currently enrolled or pre-enrolled in the Defense Enrollment Eligibility Reporting System (DEERS)?	☐	☐	☐
b. Does your spouse have a current written will?	☐	☐	☐
c. Does anyone currently hold your spouse's power-of-attorney?	☐	☐	☐
d. Does your spouse have life insurance other than Servicemen's Group Life Insurance (SGLI) or Veterans' Group Life Insurance (VGLI)?	☐	☐	☐
e. Has your spouse ever filled out a record of emergency data?	☐	☐	☐
f. Has your spouse verified/updated his/her record of emergency data in the past 12 months?	☐	☐	☐
g. Do you know where to find important papers (e.g., will, car registration, checkbook, bank statements)?	☐	☐	

111. People participate in the National Guard/Reserve for many reasons. In your opinion, how much have each of the following contributed to your spouse's decision to stay in the National Guard/Reserve?

	Very great influence	Great influence	Some influence	Little influence	Not at all
a. Serving the country	☐	☐	☐	☐	☐
b. Using educational benefits	☐	☐	☐	☐	☐
c. Obtaining training in a skill that would help get a civilian job	☐	☐	☐	☐	☐
d. Serving with the people in the unit	☐	☐	☐	☐	☐
e. Getting credit toward National Guard/Reserve retirement	☐	☐	☐	☐	☐
f. Promotion opportunities	☐	☐	☐	☐	☐
g. Opportunity to use military equipment	☐	☐	☐	☐	☐
h. Challenge of military training	☐	☐	☐	☐	☐
i. Needing the money for basic family expenses	☐	☐	☐	☐	☐
j. Wanting extra money to use now	☐	☐	☐	☐	☐
k. Saving income for the future	☐	☐	☐	☐	☐
l. Travel/"get away" opportunities	☐	☐	☐	☐	☐
m. Just enjoying the National Guard/Reserve	☐	☐	☐	☐	☐
n. Pride in accomplishments in the National Guard/Reserve	☐	☐	☐	☐	☐

112. All things considered, how satisfied are you with each feature of the National Guard/Reserve listed below?

	Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
a. Military pay and allowances	☐	☐	☐	☐	☐
b. Commissary privileges	☐	☐	☐	☐	☐
c. Exchange privileges	☐	☐	☐	☐	☐
d. Morale/welfare/recreation privileges	☐	☐	☐	☐	☐
e. Time required at National Guard/Reserve activities	☐	☐	☐	☐	☐
f. Military retirement pay and benefits	☐	☐	☐	☐	☐
g. Unit social activities	☐	☐	☐	☐	☐
h. Acquaintances/friendships	☐	☐	☐	☐	☐
i. Member educational benefits	☐	☐	☐	☐	☐

113. What is your overall attitude toward your spouse's participation in the National Guard/Reserve?

- ☐ Very unfavorable
- ☐ Somewhat unfavorable
- ☐ Neither favorable nor unfavorable
- ☐ Somewhat favorable
- ☐ Very favorable

114. In your opinion, how do the following groups/individuals view your spouse's participation in the National Guard/Reserve?

	Does not apply	Very favorably	Somewhat favorably	Neither favorably nor unfavorably	Somewhat unfavorably	Very unfavorably
a. Your personal friends	☐	☐	☐	☐	☐	☐
b. Your children	☐	☐	☐	☐	☐	☐
c. Your relatives	☐	☐	☐	☐	☐	☐
d. Your spouse's relatives	☐	☐	☐	☐	☐	☐
e. Your neighbors	☐	☐	☐	☐	☐	☐
f. Your spouse's civilian supervisor	☐	☐	☐	☐	☐	☐
g. Your spouse's civilian co-workers	☐	☐	☐	☐	☐	☐
h. Your spouse's National Guard/Reserve unit members	☐	☐	☐	☐	☐	☐

115. **Would you like to know the results of this survey?** ***If you are interested in being notified when a brief summary of the results is available on the Web, please print your e-mail address below. This e-mail address will be used for no other purpose than this notification.***

Please print

116. **On what date did you complete this survey?** | Y | Y | Y | Y | M | M | D | D |

COMMENTS

117. **If you have comments or concerns that you were not able to express in answering this survey, please print them in the space provided.**

- **PLEASE RETURN YOUR COMPLETED SURVEY IN THE BUSINESS REPLY ENVELOPE. (If you misplaced the envelope, mail the survey to DMDC, c/o Data Recognition Corp., 5900 Baker Road, Minnetonka, MN 55345-5967.)**
- **IF YOU ARE RETURNING THE SURVEY FROM ANOTHER COUNTRY, BE SURE TO RETURN THE BUSINESS REPLY ENVELOPE ONLY THROUGH A U.S. GOVERNMENT MAIL ROOM OR POST OFFICE.**
- **FOREIGN POSTAL SYSTEMS WILL NOT DELIVER BUSINESS REPLY MAIL.**

THANK YOU FOR YOUR TIME AND ASSISTANCE

(126)

CMAT Control #
2000193-0000027

(b)(6)
07/11/2000 09:49 AM

To: (b)(6)
cc:
Subject: Green Sheet Posted by LRS - NonD/DTest 1846, Department of Defense Anthrax Vaccine Program -- FOOD AND DRUG ADMINISTRATION Proposed Testimony

---------- Forwarded by (b)(6) on 07/11/2000 09:50 AM ----------

(b)(6) @osdgc.osd.mil on 07/11/2000 01:45:34 AM

To:
cc: (bcc: (b)(6)
Subject: Green Sheet Posted by LRS - NonD/DTest 1846, Department of Defense Anthrax Vaccine Program -- FOOD AND DRUG ADMINISTRATION Proposed Testimony

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To: (b)(6) @gwillness.osd.mil

DATE: 07/11/00 09:45 AM EST

NonD/DTest 1846
Suspense: 1200, Tuesday, 11 July 2000

We just published an action for which you are either an action, staffing, or information agency. Please log onto the LRS Internet System to access the "Green Sheet." The subject documents are available for you to download and send to other concerned parties within your agency. Also, you will be able to send your comments, etc back electronically. Thanks! LRS

http://www.defenselink.mil/dodgc/lrs

CONGRESSIONAL or SPECIAL CORRESPONDENCE

CMAT: pending
Date: 7/11/00

Office of Special Assistant for Gulf War Illnesses
Internal Routing/Tasking Sheet

Coord/ Routing	Position/Organization		Action	Info	Comments
	Special Assistant	(SA)			
1	Deputy Special Assistant	(DSA)	✓ 7.11		Recommend OK if OSAGWI provide no comment.
	Executive Assistant to SA	(EA)			
	Executive Assistant to DSA	(EADSA)			
	☐ Director, Investigation & Analysis _____ (IAD) ☐ DepDir _____ ☐ MED _____ ☐ VDM _____ ☐ C/B _____ ☐ ENV _____ ☐ PAG _____				
	Dir Lessons Learned Implementation	(LLI)			
	Dir Public Affairs & Outreach	(PA)			
	Dir Legislative Outreach	(LA)			
	Dir Medical Outreach & Issues	(MOI)			
	Legal Advisor	(LGL)			
	PM, Gulf War Illnesses Support	(PM)	Rm		
	Editorial Review ☐ AMB _____ ☐ Editors _____	(ER)			
	CMAT	(CMAT)			
	Action Management Call 845-8369 ☒ COMEBACK COPY TO: [redacted] (b)(6) ☒ GET CMAT NUMBER WHEN SIGNED & SENT ← entire document (including cover routing slip) ☐ READING FILE ☐ THANK YOU FILE ☐ CHRON FILE ☐ ADD TO GulfNEWS				

SUSPENSE:

Prepare reply for signature of:
☐ SA/GWI ☐ SD ☐ DSD ☐ DepSA/GWI

- This a request from General Counsel's office to comment on FDA testimony on anthrax scheduled for July 12. OSAGWI is info and need not respond.
- Dr. Carbella reviewed testimony as did I. Dr. C. provided a good summary (next tab). One DoD issue is raised

☐ Congress ☐ Oversight ☐ FOIA ☐ OSD ☐ WBM ☐ VSO/MSO
☐ Ltr to SA ☐ IR ☐ E-Mail ☐ OGA ☐ Other ☐ Veteran

see p. 17

KEYWORDS:

Quick comment on **proposed testimony of Kathryn C Zoon (CBER, FDA) before Committee on Armed Services, Us Senate, July 12, 2000.**

I don't see anything of immediate concern to OSAGWI (especially if veteran concerns about the anthrax vaccine are currently fielded by AVIP).

The testimony:

- reviews the original human trials and licensure of anthrax vaccine, and specifically mentions data from animal experimentation published last December which expands the number of strains of anthrax for which the vaccine offers protection (p.5)
- comments on the recently published proposed rule that would allow the use of animal data to provide efficacy data to support FDA approval (when human testing is not possible) and notes that comments on this rule are under review by the FDA.
- details the manufacturing facility inspections (both pre-approval and post-approval) and notes the deficiencies in MBPI over the last few years including 11lots of vaccine that were quarantined pending additional information from MBPI about their failure to investigate problems with potency, sterility, and particulate matter. Also notes that MBPI has made improvements and that those lots of vaccine not previously quarantined are safe and effective for the labeled instructions. (The issue of lack of labeling for inhalational anthrax is not mentioned here.). A listing of areas of concern on the most recent inspection (November 1999) is provided (p. 15)
- comments on the VAERS reports of adverse events associated with anthrax vaccine, and notes some 1400 reports of adverse events for some 1.4 million doses distributed. Of these events, 73 were considered serious, but no clear patterns have emerged and that none of these events (except the injection site reactions) can be attributed to the vaccine with a high level of confidence. Vaccine events, of course, will increase as more people receive the vaccine.
- states that the FDA continues to believe the vaccine is safe and effective when used according to approved labeling.
- notes that some DOD personnel had reported that had been told they were fully protected after only three doses and that the FDA had asked DOD last year to investigate this issue (but no DOD reply is included).

TA Cardella MD
Medical Issues
July 11, 2000

DEPARTMENT OF DEFENSE
OFFICE OF GENERAL COUNSEL
LEGISLATIVE REFERENCE SERVICE

Date: July 11, 2000

MEMORANDUM TO: ASD(HA)

INFORMATION FOR: ARMY, NAVY, AF, JCS, USD(P&R), ASD(LA), ASD(PA), IG, GWI, DGC(P&HP), GC

SUBJECT: **LRS DESIGNATOR NonD/DTest 1846, Department of Defense Anthrax Vaccine Program -- FOOD AND DRUG ADMINISTRATION Proposed Testimony**

SUSPENSE: **1200, Tuesday, 11 July 2000**

OMB has requested the views of the Department of Defense on the enclosed subject matter.

ACTION AGENCY: Please review and respond as soon as possible, but before the time noted above. Call in concurrences and short responses. Detailed and elaborate comments can be e-mailed (b)(6) @osdgc.osd.mil) or faxed (b)(6)) to us. When responding refer to the LRS Designator on the Subject line above.

INFORMATION AGENCIES: This referral represents the development of Department of Defense policy on this issue. If it affects your agency, please advise of your interest as soon as possible. Comments will be required by the suspence noted above. If we have no response, we will presume your agency is not adversely affected by this issue.

DO NOT CALL OMB: LRS will consolidate all responses and notify OMB of the Department of Defense response.

Medical:

With regard to our GWI mission, do we have any comment on this proposed testimony by the FDA - Dr. Zoon?

S: NOON 7/11

Return comments to me.

(b)(6)

Designator: NonD/DTest 1846

Agency List — Agencies On Green Sheet

Status	Agency Name
	ARMY - ARMY
Viewed	NAVY - NAVY
	AF - AIR FORCE
	JCS - Joint Chiefs of Staff
Viewed	USD(P&R) - Under Secretary of Defense for Personnel & Readiness
	ASD(HA) - Health Affairs
	ASD(LA) - Legislative Affairs
	ASD(PA) - Public Affairs
	IG - Inspector General, DOD
Viewed	GWI - Special Assistant for Gulf War Illness
	DGC(P&HP) - DGC(Personnel & Health Policy)
	GC - Department of Defense General Counsel

Agency List — Agencies Not on Green Sheet

Status	Agency Name
Viewed	LRS - Legislative Reference Service

LRM ID: MGG3

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

Monday, July 10, 2000

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below

FROM: John D. Burnim (for) Assistant Director for Legislative Reference
OMB CONTACT: Michael Garcia
PHONE: (b)(6) FAX: (b)(6)
SUBJECT: Testimony by Kathryn Zoon, FDA on Department of Defense Anthrax Vaccine Program

DEADLINE: 12:00 Tuesday, July 11, 2000
In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

COMMENTS: This testimony focuses on the Defense Department's anthrax vaccine program. If your agency does not respond by the deadline, this Office may assume that you have no comments.

DISTRIBUTION LIST

AGENCIES:
(b)(6)

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FINAL DRAFT FOR CLEARANCE

STATEMENT

OF

KATHRYN C. ZOON, Ph.D.

DIRECTOR

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

FOOD AND DRUG ADMINISTRATION

BEFORE THE

COMMITTEE ON ARMED SERVICES

UNITED STATES SENATE

JULY 12, 2000

RELEASE ONLY UPON DELIVERY

FINAL DRAFT FOR CLEARANCE

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Kathryn Zoon, Ph.D., Director, Center for Biologics Evaluation and Review (CBER), Food and Drug Administration (FDA or Agency). I appreciate the Committee's interest in the anthrax vaccine and the opportunity for FDA to explain our role in the pre-market review and post-market surveillance of regulated products, and more specifically explain our role with respect the regulation of the Anthrax Vaccine, Adsorbed. In a previous written statement submitted to this Committee on April 13, 2000, we provided a background on anthrax disease, the licensing process for vaccines, and a general explanation of the stages of clinical trials. Let me assure you, as I did in the previous written statement, that we will continue to help ensure that only safe and effective products are marketed and that these products meet high standards of quality in the manufacturing process.

FDA's responsibilities can be divided into pre-approval activities and post-approval activities. With respect to the former, we must help assure that clinical trials are conducted with the utmost regard for protection of human subjects. Clinical trials conducted under Investigational New Drug applications (IND) must be properly designed to ensure the safety of human subjects and to generate meaningful safety and efficacy data used as the basis of FDA's decision on whether to allow product marketing. Products also must be manufactured under conditions that help assure

FINAL DRAFT FOR CLEARANCE

that biologics are safe, pure and potent. FDA makes these determinations during the review of product applications and through on-site inspections.

Once FDA approves a product, we continue to monitor that marketed product to help assure continued safety and effectiveness. For vaccines, this is accomplished though ongoing review of adverse events reported though the Vaccine Adverse Event Reporting System (VAERS), routine inspections and other post-marketing activities. FDA performs routine inspections to verify that manufacturers are following current Good Manufacturing Practice (GMPs) and may perform targeted inspections when there are changes to the manufacturing processes, facility or equipment.

These pre- and post-licensure activities, as they relate to Anthrax Vaccine, Adsorbed and BioPort Corporation, are described below.

CLINICAL TRIALS / ANTHRAX VACCINE

The clinical trials on the anthrax vaccine were conducted by Philip S. Brachman et al. during the 1950's[1] and the Centers for Disease Control (CDC) in the 1960's. The controlled field study by Philip Brachman et al. involved workers in four textile mills in the northeastern United States that processed imported animal hides. This selected population was at risk because the mill

workers routinely handled anthrax-infected animal materials. Prior to vaccination, the yearly average number of human anthrax infection was 1.2 cases per 100 employees in these mills.

For this trial, employees who had not previously contracted anthrax were selected and divided into two groups. The groups were balanced with regard to their age, length of employment, department at the mill, and the particular job they performed. The trial was a single-blinded study, where the participants were not told whether they received the vaccine or placebo. Individuals who did not participate in the controlled study [because they were ineligible (i.e. had a history of prior anthrax) or chose not to receive the injections] also were monitored for anthrax. These individuals were referred to as the observational group.

During the trial, 26 cases of anthrax infection were reported at the mills - five inhalation and 21 cutaneous. Of the five inhalation cases, two individuals had received the placebo, while three individuals were in the observational group. Four of the five people who developed inhalation anthrax died. No cases of inhalation anthrax occurred in anthrax vaccine recipients. Of the 21 cutaneous cases, 15 individuals had received the placebo, three individuals were in the observational group, two individuals were partially immunized and one individual was fully immunized. Based upon a comparison between the populations completely vaccinated versus the populations receiving placebo, the authors calculated a vaccine efficacy level of 92.5 percent.

[1] Philip S. Brachman, M.D., Herman Gold, M.D., Stanley A. Plotkin, M.D., F. Robert Fekety, M.D., Milton Werrin, D.V.M., F.A.P.H.A., and Norman Ingraham, M.D., F.A.P.H.A., Field Evaluation of a Human Anthrax Vaccine, AJPH Vol. 52,632-645, 1962.

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On April 14, 1966, CDC submitted an IND for anthrax vaccine to the Division of Biologics Standards, which was then part of the National Institutes of Health (NIH) and later transferred to FDA (now CBER). Textile employees and laboratory workers were immunized under this IND. The method of preparing this vaccine was similar, but not identical, to the vaccine used in the Brachman et al. study. The vaccines in both studies were based on the immunity induced by the protective antigen (PA). Persons receiving the vaccine made by the two different methods demonstrated similar peak immune responses (antibody concentration) following the initial three doses. A number of lots of investigational vaccine used by CDC under this IND were manufactured by the Michigan Department of Public Health (MDPH), now manufactured by BioPort Corporation (BioPort).

The data submitted to the Division of Biologic Standards described the CDC's experience with approximately 16,000 doses of anthrax vaccine from four lots manufactured at MDPH. These MDPH lots were administered to approximately 7,000 study participants.

The Division of Biologics Standards determined that the data submitted by CDC supported licensure of the vaccine. On November 10, 1970, the Division of Biologics Standards issued a product license to MDPH to manufacture anthrax vaccine.

FINAL DRAFT FOR CLEARANCE

Approved labeling for the anthrax vaccine states that immunization with this product is recommended for individuals who may come in contact with animal products that may be contaminated with *Bacillus anthracis* spores; and for individuals engaged in diagnostic or investigational activities which may bring them in contact with *Bacillus anthracis* spores. It is also recommended for persons at high risk, such as veterinarians and others handling potentially infected animals.

The approved labeling also states that anthrax vaccine is to be administered subcutaneously (injected under the skin). After the initial dose of 0.5ml, further doses of 0.5ml are administered at two weeks, four weeks, six months, 12 months and 18 months, thereafter with yearly boosters.

There are also relevant non-human primate efficacy data. Previously, data had been provided to FDA indicating that anthrax vaccine protects non-human primates against a high challenge dose of inhalation anthrax with the Ames Strain (which is non-homologous, or dissimilar, to the vaccine strain). More recent data on animal efficacy was published in summary form by Arthur Frielander, M.D, et al. in the Journal of the American Medical Association on December 8, 1999. This publication noted that non-human primates had a high level of protection against two or more strains, in addition to the Ames Strain. All three of these strains have been considered by some to be "vaccine resistant." The Department of Defense (DOD) has committed to submit the new data to FDA under an existing IND.

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THE PANEL REVIEW

The Public Health Service Act (PHS Act), under which biologicals such as vaccines are licensed, requires evidence of safety, purity and potency. After the Division of Biologic Standards was transferred from NIH to FDA, expert panels were assigned to review information on biological products, including vaccines that had been on the market prior to the transfer. This external review was initiated in order to verify whether existing data supported the safety and efficacy of marketed biological products.

Biological products were divided into one of six categories. FDA assigned responsibility for initial review and recommendation for all products in these six categories to separate independent advisory panels of outside scientific experts, collectively known as the Advisory Review Panel. The Advisory Review Panel also was charged with advising FDA, in the form of a report, on classification of these products into one of the following categories: Category I - safe, effective and not misbranded; Category II - unsafe, ineffective or misbranded; Category III - insufficient information, further testing required.

Based upon their review of available data, the Advisory Review Panel recommended that the anthrax vaccine manufactured by MDPH be classified as a Category I product and that appropriate licenses be continued based upon substantial evidence of safety and effectiveness of this product. The safety data from the CDC trials and the efficacy data from the Brachman et al.

trials were the basis for these findings. These findings were published in the *Federal Register* on December 13, 1985.

Today, it would be difficult to perform an efficacy study. This is because there are no evident populations where prophylactic vaccine protection against natural exposure to anthrax could be evaluated in a clinical field trial, such as was done in the Brachman et al. study. Specifically, the incidence of naturally occurring anthrax in humans is low and sporadic in occurrence, making identification of a trial target population difficult. Likewise, it would be unethical to perform challenge/protection studies in humans. In this regard, an FDA proposed rule was published in the Federal Register that would allow the use of animal data to provide efficacy data to support FDA approval when scientifically reasonable (Proposed Rule: New Drug and Biological Drug Products; Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against Lethal of Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot Be Conducted, Federal Register 64:53960-70, 1999). Comments on this proposed rule are under review by FDA. Under this proposed rule, human immunogenicity and safety data would still be required.

INSPECTIONS

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is charged with, among other things, helping to assure that drugs marketed in the U.S. are safe and effective, and are

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manufactured in accordance with GMPs. The FD&C Act applies to any human drug for which marketing is sought or which currently is marketed. FDA also is responsible for implementing the provisions of the PHS Act applicable to biological products including vaccines.

FDA conducts "pre-approval inspections" for drugs or "pre-license inspections" for biologics of manufacturing facilities prior to product approval or licensure, and conducts "surveillance inspections" or "GMP inspections" periodically after approval or licensure. For domestic drug manufacturers, the FD&C Act requires registration and surveillance inspections. Inspections may also be performed prior to approval of supplements for major manufacturing changes, on a "for-cause" basis or as part of our bioresearch monitoring program.

BIENNIAL OR GMP INSPECTIONS

Licensed vaccines are regulated under both the FD&C Act and the PHS Act. Vaccines meet the definition of a drug under the FD&C Act, and, therefore, must be manufactured in accordance with the GMP regulations in 21 CFR Parts 210 and 211. As vaccines are also biologics, manufacturers must also comply with applicable regulations in 21 CFR Parts 600 through 680.

Surveillance inspections, also known as a GMP inspections, are generally performed every two years and are more comprehensive in nature, in that multiple products and processes are covered. Once a product is approved or licensed by FDA, ongoing surveillance is needed to determine if

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the product continues to be manufactured in the manner approved in the application. Surveillance inspections focus on licensed products, as opposed to unlicensed products. In the case of vaccines, one or more of a specialized cadre of FDA's Office of Regulatory Affairs investigators and CBER's product specialists known collectively as "Team Biologics" performs these inspections. Team Biologics assumed responsibility for surveillance inspections of vaccines as of October 1, 1999.

The possible outcomes of a surveillance inspection can be much different than a pre-approval inspection. If FDA discovers manufacturing deficiencies while conducting a pre-approval inspection, a possible outcome is that the application or manufacturing supplement may not be approved. If FDA conducts a surveillance inspection and finds deficiencies in the manufacture of products that are currently being marketed, there is a whole range of potential regulatory actions that may occur. These actions include issuing a warning letter or a notice of intent to revoke a license, suspending or revoking a license, filing an injunction against the firm or seizure of product.

There is currently only one FDA-licensed facility for the production of the anthrax vaccine. Michigan Department of Public Health originally operated the facility. In 1996, the facility became known as the Michigan Biologics Products Institute (MBPI), an entity controlled by the State Government of Michigan. Currently, the facility is operated by BioPort based upon the September 1998 transfer of ownership by MPBI to BioPort. In addition to manufacturing

Anthrax Vaccine, Adsorbed, this facility is licensed to manufacture blood derivatives and other vaccines.

FDA has inspected this facility on many occasions during the past decade, identifying a number of deficiencies requiring correction. In particular, FDA conducted a surveillance inspection of MBPI in November 1996. During that inspection, FDA investigators documented numerous significant deviations from the Federal Food, Drug, and Cosmetic Act, FDA's regulations and the standards in MBPI's license. Based upon the documented deviations, FDA issued a Notice of Intent to Revoke letter (NOIR) to MBPI in March 1997. The NOIR letter did not mandate the closure of the facility or lead to seizure of finished product. The letter, however, did state that if MBPI's corrective actions proved to be inadequate, the facility would run the risk of license revocation.

MBPI responded to the NOIR with a "Strategic Plan for Compliance" presented to FDA in April 1997. This plan called for the periodic submission of data to FDA that would serve as evidence of MBPI's progress towards achieving compliance with FDA's regulations. Under the plan, FDA would review this data and then monitor MBPI's progress through follow-up inspections. In February 1998, FDA conducted a follow-up inspection of the MBPI facility to evaluate MBPI's compliance with its strategic plan. It should be noted that this inspection and the November 1996 inspection included blood product and vaccine product facilities in addition to the anthrax vaccine production facility.

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The February 1998 inspection disclosed significant deviations from FDA's regulations. These deviations included, but were not limited to, those related to the manufacture of the anthrax vaccine. In addition, the inspection resulted in a request by FDA that MBPI quarantine 11 lots of anthrax vaccine held in storage, pending review of additional information to be submitted by MBPI (at the time the request was made) regarding the lack of investigations into possible problems with potency, sterility and particulate matter. FDA continues to work closely with BioPort to resolve issues concerning the use of these lots. If satisfactory resolution is not obtained, BioPort has stated that the lots will be rejected. FDA also noted that MBPI had made progress in achieving its compliance goals, but additional work remains in order to correct the deviations related to the manufacture of the anthrax vaccine.

Pursuant to its purchase of the MBPI facility in September 1998, BioPort agreed to abide by the strategic plan and other commitments for corrective actions made by the management of MBPI. It should be noted that MBPI temporarily halted production of anthrax vaccine sublots in January 1998, prior to the sale to BioPort, to begin a comprehensive renovation of the anthrax production facilities. Although there has been a resumption of manufacturing in order to produce lots in support of the license application supplement to include the renovated facility, no lots of anthrax vaccine manufactured in the renovated facility have been released.

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In its most recent GMP inspection of BioPort in October 1998, FDA found continuing improvement. FDA believes that the previously manufactured and CBER released products not presently quarantined by BioPort are safe and effective for the labeled indications. FDA found that the firm had made progress toward meeting objectives under its strategic plan in bringing the facility into full compliance. Based on BioPort's progress to date, FDA is hopeful that the company will continue to demonstrate improvement. We will continue to work closely with BioPort to ensure that the goals outlined in their strategic plan are met.

PRE-APPROVAL INSPECTIONS

When a sponsor submits an application or manufacturing supplement to FDA, the Agency sets an internal review goal to complete the review that may be determined by statute or by goals established in conjunction with the Prescription Drug User Fee Act (PDUFA). The period of time between the receipt of the submission and the final decision by the Agency is called the review cycle. The team of FDA reviewers, which may include a medical officer, microbiologist, statistician, biologist, chemist, and other specialties, examines the clinical, chemistry, and manufacturing controls data along with other data submitted by the sponsor. The review team may decide to request the initiation of a pre-approval or pre-license inspection depending on whether the application meets certain criteria. For biological products, these inspections are performed by CBER staff serve to help ensure compliance with cGMPs; verify or clarify information in the marketing application; possibly observe the actual manufacturing of products;

and/or, evaluate the manufacturer's ability to produce a product that meets FDA standards of quality. The investigator, or the team of investigators, conducting the pre-approval or pre-license inspection, typically focuses on the processes that are specific to the application or manufacturing supplement under review, although there is not always such a clear distinction, given that the same facility, personnel, equipment and procedures may be used to manufacture many products. In some instances there are facilities dedicated to the manufacture of only one product.

When conducting an inspection, the FDA investigator or team typically covers a number of areas including: manufacturing; training; product testing; support systems; and, records. After obtaining a general overview of the facility and operations, the FDA investigator then focuses on problem areas. The scope of the inspection depends on the nature of the inspection and the problems encountered. At the conclusion of the inspection, the FDA investigator issues a Form FDA-483, or Notice of Inspectional Observations, which is a list of significant items observed or that pose a potential problem as noted during inspection. The firm may, if it chooses, immediately start implementing corrections in response to the observations noted by the investigator.

Upon implementing the corrective actions, the firm may notify FDA, typically though a letter to their application, that it believes that adequate corrections have been achieved. FDA reviewers will determine whether the firm's corrective actions are adequate. Prior to the end of the review

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cycle, if the corrective actions pertaining to the manufacturing issues are found to be adequate, and any other information (such as clinical data or statistical data) associated with the submission is found to be adequate, then the application or supplement may be approved.

If the corrective actions appear to be inadequate or have not been implemented prior to the end of the review cycle, or if FDA determines that a follow-up inspection is necessary to verify the corrective actions, FDA will send a complete response letter to the sponsor which means that the application is not approved. If FDA sends such a letter, it is important to understand that FDA's review of an application is a continuing process and the sponsor has the opportunity to once again attempt to correct the manufacturing deviations and any other deficiencies found in the application. The sponsor, once again, may submit information to FDA to start another review cycle. The FDA team may review the amended application or supplement and initiate a follow-up inspection if necessary. It is possible that the application may be approved during a subsequent review cycle.

Due to the rules of confidentiality, the FDA can not generally disclose details of, or even acknowledge the existence of, a pending application unless that information has already become public. In the case of BioPort, there have been press reports, Congressional hearings and information made public by BioPort that have disclosed various aspects of the anthrax vaccine. Because the information has been made public, we can disclose that BioPort does have a pending

supplement for renovations to their anthrax vaccine manufacturing facility. Renovations are assessed by review of a prior approval supplement and by performing a pre-approval inspection.

In order to examine the manner in which BioPort implemented the renovations to the manufacturing facility, FDA conducted an inspection from November 15 through November 23, 1999. At the conclusion of the inspection, BioPort received a Form FDA 483 with observations and possible deviations in some of the following areas: validation, failure to investigate, deviation reporting, aseptic processing, filling operations, standard operating procedures, stability testing, and environmental monitoring. All observations must be addressed adequately before FDA will approve this supplement.

POST-MARKETING ACTIVITIES

LOT RELEASE

Because of the complex manufacturing processes for most biological products, each product lot undergoes thorough testing for purity, potency, identity, and sterility. The anthrax vaccine is subject to lot release. Before a lot of anthrax vaccine can be used, the manufacturer must submit a sample of the vaccine lot and a lot release protocol to the Agency. The lot release documents contain the results of the manufacturer's tests for potency, safety, sterility and any additional assays mandated by their license and a summary of relevant manufacturing details. FDA reviews the manufacturing and testing information provided in the lot release protocol and may elect to perform confirmatory testing on submitted samples. The manufacturer may not

distribute a lot of the product until CBER releases it. The lot release program is one component of FDA's multi-part strategy that helps assure product quality.

VACCINE ADVERSE EVENT REPORTING SYSTEM

Following issuance of an approved license, there is continued post-marketing surveillance of the product by monitoring adverse events, e.g., the Vaccine Adverse Events Reporting System (VAERS). It should be emphasized that it is not always possible to attribute a cause and effect relationship between a reported event and a vaccination. Since the beginning of VAERS operations in 1990, through June 30, 2000, 1404 reports of adverse events associated with use of the anthrax vaccine have been reported to VAERS. FDA understands that from 1990 to 1999, approximately 1,468,000 doses of the vaccine were distributed.

Of those, 73 are considered serious events, which are events considered to be either fatal, life threatening, or resulting in hospitalization or permanent disability. These reports are for diverse conditions, such as hospitalization for severe injection-site reaction, Guillain-Barré syndrome, widespread allergic reaction, aseptic meningitis and multi-focal inflammatory demylinating disease. There are no clear patterns emerging at this time. The remaining reports describe a variety of symptoms, including injection site hypersensitivity, injection site edema (swelling with fluid in tissue), injection site pain, headache, joint pain and pruritus (itching).

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None of these events, except for the injection site reactions, can be attributed to the vaccine with a high level of confidence, nor can contribution of the vaccine to the event reported be entirely ruled out. With the exception of injection site reactions, all of the adverse events noted above occur in the absence of immunization.

While the data gathered from the VAERS system can serve as a useful tool in identifying potential problems, the reports on anthrax vaccine received thus far do not raise any specific concerns about the safety of the vaccine. With all vaccines, as the more people that receive the vaccine increases, so will the numbers of adverse events reported to FDA. Thus, our knowledge of the vaccine will grow accordingly. FDA continues to view the anthrax vaccine as safe and effective for individuals at high risk of exposure to anthrax, when used in accordance with the approved labeling.

THE ANTHRAX VACCINE IMMUNIZATION PROGRAM OF DOD

FDA did not have an official role in the development or operation of the Department of Defense's Anthrax Vaccine Immunization Program, including the AVIP tracking system or the program's adverse event reporting system. In March 1997, DOD briefed FDA about their draft plan for the possible use of the anthrax vaccine to inoculate U.S. military personnel according to

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the FDA approved labeling for six doses administered on a specified schedule over eighteen months. Subsequently, FDA learned that that DOD had formally adopted this plan.

In July 1998, DOD requested that the Department of Health and Human Services organize and coordinate a program to evaluate VAERS reports for the anthrax vaccine. In response to the request by DOD, a group of non-government medical experts was convened by the Health Resources and Services Administration's Vaccine Injury Compensation Program (VICP) in the fall of 1998 as the Anthrax Vaccine Expert Committee (AVEC). AVEC, coordinated by VICP, has met approximately every 3 to 6 weeks since since fall of 1998. These experts have been reviewing all VAERS reports for the anthrax vaccine. Representatives of VICP, FDA, CDC and DOD have attended meetings, and FDA has provided information to assist the committee in its deliberations. AVEC is unique in that it provides an independent civilian expert assessment of adverse events reported for the anthrax vaccine.

Upon learning last year that some DOD personnel reported they had been told that they were fully protected against anthrax after receiving three doses of the anthrax vaccine, both Dr. Jane E. Henney, Commissioner of Food and Drugs, and I, sent letters to DOD. In the letters we asked DOD to expeditiously investigate this matter as we are unaware of any data demonstrating that any deviation from the approved schedule found in the approved labeling will provide protection from anthrax infection.

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CONCLUSION

We appreciate the Committee's interest in the Anthrax Vaccine, Adsorbed and BioPort. Please let me assure you that FDA appreciates the unique situation that DOD's anthrax vaccine immunization program presents to all of the individuals and organizations involved. We continue to believe that the vaccine is safe and effective protection for those individuals at high risk for exposure. We will continue to work with BioPort, as we would with any manufacturer, in an appropriate manner to resolve all situations involving pending submissions and inspectional issues. By manufacturing products in a facility that is operating in a full state of GMP compliance, we can help assure that any product that is released by the company is safe and effective.

Proposed Draft

(b)(6)
06/07/2000 10:48 AM

To: (b)(6)
CC:
Subject: Proposed outline/strawman for responding to Kirt Love's request for 5 unanswered e-mails

Question 3 - also responded to by e-mail
Question 4 - responded to by telephone - (b)(6) - and by e-mail
---------- Forwarded by (b)(6) on 06/07/2000 10:49 AM ----

(b)(6)
06/07/2000 09:07 AM

To: (b)(6) @OSAGWI
CC: (b)(6)
Subject: Proposed outline/strawman for responding to Kirt Love's request for 5 unanswered e-mails

In your telephone conversation with (b)(6) at OSAGWI on June xx, 2000, you stated that of the 139 e-mail requests/questions you had submitted to OSAGWI, xxx were FOIA's and you understood the process and delays, however there were five for which you were still waking on responses. You didn't clarify which five those were, so we have gone through your e-mails and believe we have determined that perhaps the following five are those which you believe have not been answered or were inadequately answered:

Question 1. Your e-mail of February 19, 2000 where you addressed concerns about hepatitis C, vaccines administered in the Gulf and your displeasure with LTG Ronald Blanck.

Answer 1. In our e-mail of (000316) we thought we provided an answer.

Yes, the San Francisco VA has reported a hepatitis C rate of 19% in Viet Nam veterans who seek care there, Them were no other details in the newspaper report as to possible causes of this increased rate. Hepatitis C is higher in people who have receive blood transfusions before testing for hepatitis C began in 1992 [check date], in people using intravenous drugs and in sexual partners of individuals with hepatitis C. It also occurs in individuals without any of the above risk factors. Studies evaluating the rates of hepatitis C in active duty members have shown it is half that of the general population. CDC has published a Morbiii and Mortality Weekly Report (provide date) that indicates there is no evidence of hepatitis C being transmitted through intramuscular injections with immune serum globulin.

Since there were no master records showing who got Vac A or Vac B and indlvidual records were generally not annotated because of local decisions, it is not possible to follow those people today. There is a study to evaluate people known to have had anthrax vaccine with individuals known not to have had anthrax vaccine in the Gulf. A similar study could be done for recipients of the botulinum toxoid vaccine if a log validating vaccination could ba found.

Finally, you are entitled to your opinion about LTG Blanck. He is retiring from the US Army this month and his replacement is yet to be named.

Question 2. Your e-mail of June 4, 2000 refers to your e-mail of April 13, 2000 which requested formal depositions of 15 different groups or individuals.

Answer 2. [legal to provide]

Question 3. Your e-mail of May 11, 2000 where you addressed concerns about Mycoplasma

contamination of anthrax vaccine.

Answer 3. The anthrax vaccine is an FDA approved vaccine. While it is true mycoplasma have been identified as contaminants in tissue cultures. tissue cultures are not used in producing the anthrax vaccine. The US Army dld have an independent organization [name university, I think it was Stanford] test lots of anthrax vaccine produced prior to the Gulf War for mycoplasma and the results were negative. The US Army also took vials of anthrax and introduced mycoplasma into the vial and cultured the vial immediately and every 24 hours to see if the mycoplasma could exist in the vials, Only the culture done immedicately grew mycoplasma, the others grew nothing, proving mycoplasma cannot exist in the anthrax vaccine.

(b)(6) Question 4. [need to get his e-mail about the mystery bunker. I only have the phone call to (b)(that he wanted a copy of the OSAGWI report on the mystery bunker]

Answer 4. We appreciated the information you provided from your first hand experience with explosions involving various bunkers during the post Gulf War period. That information was analyzed by our Preliminary Analysis Group. There was no new information compared to what had already been gathered, and no indication from the date present that there was any release of nerve agent or other toxic substances. OSAGWI only does reports on incidents where there appears to be a possibility of that having occurred.

Question 5. Your e-mail of May 9.2000 where you addressed concerns about the VA referral center in Houston.

Answer 5. OSAGWI is an agency within the Department of Defense. The Houston VA referral center is an agency within the Department of Veterans Affairs. While we both work together to benefit the veteran, OSAGWI has no authority within the Department of Veterans Affairs. We have forwarded your concerns to the Department of Veterans Affairs.

(b)(6)
06/05/2000 07:05 AM

To: (b)(6)

CC:

Subject: Depositions of Gulf War Commanding staff

Kirt Love continues to send numerous letters and emails and call different individuals throughout OSAGWI. His requests include FOIAs, help getting responses from other agencies, and a multitude of demands for other action and information from OSAGWI.

As we've done in the past with other frequent callers/writers, we need to review the status of Mr. Love's correspondence and see if 1) we have responded in a timely and appropriate manner to geniune requests for information, and 2) if the current correspondence is for new information/action, or have already been answered in previous correspondence.

While we have a commitment to assisting veterans in their search for information about the Gulf War, we also have to recognize that them are situations where we have provided as much information/support a8 we am able to provide. As we transition OSAGWI in OSAMD we will be tasked to the max. We need to be very careful how we apply our shrinking resources.

Request we review Mr. Love's status at the next director's meeting by reviewing all previous correspondence and pending requests.

V/R

Forwarded by (b)(6) on 06/05/2000 06:56 AM
(b)(6) on 06/04/2000 09:24:20 PM

Please respond to (b)(6)

To: (b)(6)

cc:

Subject: Depositions of Gulf War Commanding staff

Kirt Love wrote:

I have received no response what so ever, and Ive been told by other OSAQWI etaff this hasnt even been discussed. How far am I from a response to thin, and many other letter* I have sent. Can I have some kind of date you will respond by.

Sincerely
Kirt P. Love
Director, DSBR

(b)(6) @gwillness.osd.mil wrote:

> Your email has been received and
> a response will be provided as soon as
> possible.
>
> Respectfully,
>
> Lt Col (b)(6)
> Director of Public Affair*

Dr. Bernard Rostker, Lt. Col (b)(6), and OSAQWI staff

In multiple conversations with your staff I have requested for a specific intervention into the Gulf War commanding staff, and those with security clearances.

Up till now a large amount of military record* have either been destroyed, altered, ignored, or treated in varying ways to ignore them. Testimony of any personnel ha* been treated as either Congressional, or handled through OSAGWI itself has been pretty much treated as anecdotal. Either way this material is inaccessable by public standards for review. Point, the handling of specific Gulf War testimony that might be medically relevant to Gulf War Illness has been mishandled.

As of April 13, 2000 I specifically request formal depositions of the:

1. CENTCOM staff (1990-1991)
2. C3I Staff (1990 - current)
3. Former Joint Cheifs of Staff(1990 - 1991)
4. Commanding Generals and Staff (1990 - 1991)
5. CIA Intelligence Staff (1990 - 1991)
6. DIA Intelligence Staff (1990 - 1991)
7. FDA and CDC personnel related to vaccine issues (1990 - 1991)
9. NSA personnel handling COMINT and SIOINT materials (1990 - 1991)
9. UNSCOM American Staff (1990 - 1997)
10. NARA personnel handling all Gulf War Record* since 1990
11. DOD Security Review Personnel since 1990

12. General Ronald **Blanck**
13. **Former CIA.Director** John **Deutch**
14. Former President George Bush
15. **Any** personnel with Secret and Top Secret clearances, **as** well **as** personnel in EOD, Black **Ops,** Night operations, end **security** intel positions that **participtaed** during Operation desert **Sheild/Storm** 1990 • 1991.

Since OSAGWI **chooses** to treat **so** much of the **Gulf War as** anecdotal evidence, then having the **sworn** depositione of most **these** persons **should** then et **least support** that fact. However, if fraud and waste **has transpired** then no doubt OSAGWI will **immediately** refute **this avenue** • ince it will prove awkward for them to explain the findings.

I will keep **pushing** this **avenue** with the DOD, DOJ, the QAO, **House,** Senate, OSAQWI, PSOB, until **taping** begins. **I specifically request that OSAGWI** approach the Whitehouse to apply the **executive power** it holds to **begin** these **depositions. That** under the **terms** of **its charter, mandates,** and executive actions it **has** the authority to request this **avenue** of action to resolve the **anecdotal** issues of proper evidence to conclude its **investigation of** the **Gulf War.**

Anything other **then** . ye' from OSAQWI should be treated **as "Obstruction** of **Justice", because** MEDICALLY relevant **material is** ₪ • take.

At this time **this material** should **also** be treated **as** "Perpetuation **of** Evidence" **as** well **as "Perpuation** of Testimony" to **those** that **are** either dying, or lying.

If OSAQWI **has** nothing to hide, **it should welcome this avenue** under the **terms** of **its mission statement** that **cites: "Leave** no stone unturned".

I **await response from** OSAQWI, PSOB, QAO, end any other concerned **parties.** Once **again** I **specifiy,** the **date** is April 13th. 2000 end I **request** a **specific response** from Dr. Bernard **Rostker** concerning this issue.

Sincerely
Kirt P. **Love**
Director, DSBR

(b)(6)
06/07/2000 10:48 AM

To: (b)(6)
CO:
Subject: Proposedoutline/strawman for responding toKirt Love's request for5unanswerad a-mails

Question 3-also responded to by e-mail
Question 4 - responded to by telephone- (b)(6) -and by e-mail
---------- Forwarded by (b)(6) on 06/07/2000 10:49 AM ----------

(b)(6)
06/07/2000 09:07 AM

To: (b)(6)
CC:
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Gulf War Illnesses

Bernard Rostker

CMAT Number: 2000059-E000001 Date Received: 02/27/2000 10:43:06 PM

To: (b)(6)

From:

CC:

Subject: OSAGWI rewriting Gulf War as FICTION

Dear Dr. Rostker and OSAGWI staff

Supposedly OSAGWI has electronic versions of over 6 million records. Yet, in FOIA response 00-F-0366 (Feb 17th 2000) OSAGWI sends me a letter stating there are "NO" records concerning the 1st and 3rd AD demolitions in Iraq and Kuwait during and after the Gulf War.

These "Denial Operations" (demolitions) of the 1st and 3rd AD are on the GulfLINK website, and the rest am deemed Secret and Top Secret at the National Archives CENTCOM and other records sections. These demolitions directly correspond with what my unit witnessed after the War in Southern Iraq/Northern Kuwait.

OSAGWI will not provide me any results concerning the "Mystery Bunker" investigation about my unit, more or less provide or search for othar materials concerning this "Medically relevant" event.

This is much like the letters coming in from USSOC saying there am "No" Spacecom or CINSPACE records from the Gulf War. While the Maxwell AFB kgs directly dispute this fact, and the FROG • SCUD missib tracking data they had. Even the NSA is trying everything it can to "NOT" provide ma relevant SIGINT and COMINT materials of the Gulf War.

The ARMY is now daying the 12 frame refrigerated bunkers and the NAVY/MARINES are denying:

USMCMG

TACC

TAVS

MAGTF

MARDIV materials.

Another appauling event, I get notification that OSAGWI does "NOT" keep trip logs, trip records, or reports(transcripts) on outreach trips to military installations. This means there is "NO" way of confirming contacts or follow ups at "ANY" of these outreaches. This further confirms that the outreach missions are "NOT' to bring home new evidence or provide any hardcopy confirmation of trips efforts.

As I send in these e-mails, OSAGWI has gone into silent running and wont provide responses. Further showing the contempt of the OSAGWI staff for veteran efforts to uncover truths that the OSAGWI staff choose to ignore or rewrite to suite them.

My group expects a response concerning Gen Ronald Blanck and the Anthrax vaccines. My group expects an answer on the Hepatitis C contemination of the ISG/IGG vaccines not only of the Gulf but Vietnam as well, which would account for the High Hepatitis C contamination of the Veteran population (especially in VA Hospitals).

My groups expects responses for everything we posed in e-mails - letters - and oral converstalon with OSAGWI in the last 5 months, as well was as anything even similar to

a question in the last 3 months starting with the materials in the "Security Review Protocols" and carrying on to the "Maxwell AFB Logs" to the e-mails last week.

I could care less if Col Dianne Lawhan and many other OSAGWI staff dislike me or my team. That does not justify ignoring our efforts, considering "WE WERE THERE",

As a tax paying citizen, injured party, and a disabled Gulf War Veteran being denied beneficial medical diagnosis/treatment. I must protest these efforts to disquise events and ignore those of us trying to get to the Heart of the matter.

If OSAGWI is willing to play these games with me and my unit, my team. Then what of those veterans out there with no advocates or the the lack of strength to do more. How many thousands must die to disquise the lack of success in the many failed Gulf War military ventures.

Your department has either destroyed the demolition records of the 1st and 3rd AD or sent them to the National Archives for cold storage. Where are they? Keep in mind, the Archives already responded that 'YOU" have them.

Sincerely

Kirt P. Love

DSBR and Team Associates

CMAT Controlled
Comments:

PAO: Develop response incorporating inputs from Medical, AMB, and Chem Bio.
1)Provide shortsxplanation -again -of the FOIA process. We did a query of the databases for the requested demolition records in the area and timeframe he requested -there were no results. However, we continue to work his other FOIA's, including his request from Frag Orders -which is what he says he found on GulfLINK. (Coordinate with AMB)
2) Coordinate with Chem-Bio on their assessment of his report about demolition of a "mystery bunker."
3) Outreach records
4) His e-mails on anthrax/Gen Blanck/Hepatitis C (2000050-E000009) and Mycoplasma (2000050-E000001) have been forwarded to Health Affairs. Coordinate response on those issues with Medical.
5) Love has again indicated an intent to visit OSAGWI unannounced with media. Need to remind him of the ground rules.

MEDICAL: Please review e-mails 2000050-E000001 and 2000050-E000009 and provide input to PAO on issues raised.

VDM Controlled

Comments:

PAO Controlled

Comments:
rwd - Portion of response dealing with mycoplasma and other medical issues provided by Dr. Kilpatrick.
Response:

Dear Mr. Love:

Thank you for your recent e-mails regarding Gulf War illnesses. This is Bob responding on behalf of Dr. Bernard Rostker, the Special Assistant for Gulf War Illnesses.

In accordance with the law under the Freedom of Information Act, we forward all FOIA requests to the Department of Defense FOIA office. The DoD FOIA office is responsible for coordinating the gathering of information and providing a response. If you have questions on the status of your FOIA requests or a question: on the response, please contact the DoD FOIA office at (703) 697-1180. You may also write directly to:

Directorate of Freedom of Information Act and Security Review
Room 2C757
1157 Defense Pentagon
Washington, DC. 203061155

We have received a number of e-mails from you lately and while we attempt to answer all letters and e-mails in the order we receive them, some questions or requests for assistance take longer to research than others. Additionally, when we receive multiple e-mails, we sometimes combine the answers in one response in order to decrease the time it takes to respond to the sender. If we have not responded to all your questions, please let us know. We try hard to provide a detailed response to every veteran's concerns. The following information is in response to the e-mails we received recently from you.

- You asked about the "mystery bunker." We have examined the information you provided to date and compared it to what we already know. The results of the comparison found no new information. The information was entered in the database, but because the data presents nothing new, no further action is anticipated at this time.

- You also asked about our outreach visits. When we conduct an outreach visit, we receive many questions and requests for assistance from veterans and their families. When and where a request for information or assistance comes from has never been as important as providing timely answers and assistance.

- Your questions or comments about anthrax, Lbutenant General Blanck, Hepatitis C and mycoplasma were forwarded to health Affairs for their Consideration. In response to your e-mail on vaccines, our medical staff provided the following information:

  One of the world's greatest medical advances was the development of vaccines. Lives saved from diseases that caused so much 'death and physical disability is today often forgotten in the United States, where our standard of living, sanitation and national public health efforts have nearly freed our population from these medical terrors. Today, our population tends to be critical of some of the regulations that have allowed them to have this freedom. Vaccines required to

attend public school are sometimes challenged for the good of the one versus the good of the many.

Organized resistance to vaccines has used the Internet to disseminate half-truths, misinformation and blatant lies. People without the understanding of the immunology and physiology of vaccines, or the process by which the Food and Drug Administration (FDA) approves vaccines are often frightened or misled. Tick-borne encephalitis vaccine is an approved investigational New Drug by the FDA. When it was given to troops entering Bosnia in 1996, it was given with informed consent and according to the approved dosing schedule. The 4,000 participants were briefed on the medical threat, the history of safety with this vaccine in Europe, and they chose to participate. There were no negative outcomes as a result of the vaccine administration.

To achieve FDA approval, a vaccine undergoes a rigorous process. This includes testing as an investigational new drug. An investigational new drug is a drug for which a sponsor has applied to the FDA for permission to conduct clinical trials to demonstrate that the drug (or product) produces the desired effect when used by people, technically described as human efficacy testing.

Thus, to gain FDA approval, a vaccine needs to show efficacy for protecting people from the specific disease. That can only be done by giving people an investigational new drug vaccine when they are in an endemic area for a disease and see if they have a lower rate of the disease that people who were not vaccinated. The data from Bosnia were not helpful for this purpose since there was no tick borne encephalitis in any deployed personnel, vaccinated or not

- Anthrax vaccine is FDA approved. The DoD is monitoring all personnel receiving this vaccine today. There continues to be data generated showing that this vaccine is safe to administer to humans. We are providing the optimal protection for our personnel sent where exposure is believed to be a real threat. Data from non-human primates demonstrates that the vaccine provides protection from such an exposure.

- We are unfamiliar with the Muscular Dystrophy vaccine data you quoted as it doesn't apply to the DoD.

- On repeated surveys, the rate of Hepatitis C -- sometimes called HCV -- in military personnel is half the rate of Hepatitis C in the general U.S. population. Them have been reports of hiih rates of Hepatitis C in Viet Nam veterans seeking care in the VA. We know that there am high rates of Hepatitis C in people who had transfusions before testing began on the blood supply in 1992. Hepatitis C rates are also high in individuals who have used IV drugs. Hepatitis C occurs without a history of either transfusion or IV drug use, so more medical evaluation is needed. If there is ever a vaccine for hepatitis C, as there already is for hepatitis A and B, it will start as an investigational new drug before it is granted FDA approval.

- There are DoD and VA programs for individuals who need medical care subsequent to their service in the military. Congress has established the rules. Retirees may be seen in DoD facilities. The VA is available for all others. If their medical problem is service connected, the care is free.

- The BioPort facility, after installing new equipment to produce the anthrax vaccine, is working with the FDA to produce three lots of vaccine that meet the FDA standards. Production was stopped when the production contract expired. This was timed to accommodate the planned renovation of the vaccine production suites as part of D oD's acquisition strategy. The renovation will assure that BioPort remains in compliance with stringent federal manufacturing practices.

  At the request of DoD, each vaccine lot receives supplemental testing before it is used. This testing by the FDA assures the safety, potency, sterility and purity of the vaccine.

  The vaccine has baen safely and routinely administered in the U.S. to at-risk veterinarians, laboratory workers, and livestock handlers since 1970. As with other vaccinations, pain may occur at the site of the injection. Temporary side effects, such as a sore arm, redness, and slight swelling may occur. There are no known long-term side effects, however, when implementing the program, the Secretary of Defense implemented a system to fully track the health status of those receiving the vaccine. In fact, having the program on-tine was one of the requirements before implementing the vaccine program.

- Lieutenant General Ronald Blanck has served with distinction for the last three yearn and nine months. He will be retiring in July 2000 after completing his four year assignment.

- The DoD's Comprehensive Clinical Evaluation Program and the VA's Pemian Gulf Veteran's Registry are still open for all Gulf War veterans and their families. To date, only one in six who served in the Gulf War have availed themselves of this medical evaluation.

- In reference to your e-mail about mycoptasma, our medical staff provided the following information:

  The science of mycoplasma organisms and possible infections is ever expanding. The peopte who work in this field for their life's work find it perplexing and difficult to explain to people who have no background education in science, microbiology or scientific research.

  It begins with the fact that this organism has no rigid cell wall and requims a hypertonic medium to grow In. Then not all mycoplasma am equally easy to culture: in fact most are very difficult. Then, because mycoptasma do not spend most of their time floating freely in the blood stream like other bacteria (staph or strep), they don't produce the usual antibody response in serum. That is why tests like polymerase chain reaction (PCR) am attractive because they am able to detect minute amounts of DNA and replicate it rapidly for a test result. However, PCR does not distinguish if the DNA it detects is alive or dead. The probe for the PCR is a group of amino acids chosen to adhere to a segment of DNA from a mycoplasma which is different from the DNA of other origins in the body, including other species of mycoplasma. It appeam that wherever PCR is used for mywptasma them are positive results.

Does this mean the organisms have always been there and are just now being detected by this new diagnostic technology? That is a philosophiil **question.** Some of the mycoplasma are believed to cause disease (symptoms) in people. Other strains are believed to be commensals (organisms which live in the body and do it no han). If we don't know all the strains of mycoplasma which exist, can we be confident that a PCR test for a known strain could not produce a false positive if it also reacts with an' unknown strain. Basically, not all the information or all the answers are available when it wmes to discussions about mywplasma.

Mycoplasma contamination of cell culture materials is well known because mywplasma species exist in animals and they easily pass through filters used to remove other bacteria with hard walls.

- In previous e-mails, you have made reference to visiting our office and bringing the news media. As we have in the past, we will be happy to meet with you. We will provide a meeting place that is suitable and arrange for our staff to meet with you based on their schedules and availability. We ask in return that provide us with adequate notice so that we are able to make proper arrangements. If the media wish to accompany you, they will need to **contact** the public affairs **office.** This is a standard practice well understood by media professionals.

Again, thank you for this opportunity to respond to your concerns. We hope this information is helpful to you.
000316

PAO Manager Controlled

Comments:
2000 1315 p.m. Incorporated **LtCol** (b)(6) comments. Returned to Dr. Kilpatrick for one last **look** at medical component. bg
2000 0314 p.m. Out for coordination. bg

Medical Controlled

Comments:

Response:

Chemical/Biological Warfare Agents Team Controlled

Comments:

Response:

Gulf War Illnesses

Bernard Rostker

CMAT Number: **1999364-E000001** Data Received: **12/29/99 11:47:37** PM

To: (b)(6)

From:

cc:

Subject: Response to **OSAGWI declass** letter

In this document is the OSAGWI response to

a letter sent a few days ago to OSAGWI and others.

I believe the responding party is Sob Menig

of the Declassification team.

Response:

Dear Mr. Love:

Thank you for your recent e-mail regarding

Gulf War illnesses. My name is (b)(6) and I am

responding on behalf of Dr Bernard Rostker,

the Special Assistant for Gulf War Illnesses.

It would appear from your e-mail that you have

fundamentally misunderstood what we have done

and continue to do at OSAGWI. We have completed

a keywords search of all classified and unclassified

Gulf War records within the Department of Defense.

The keywords selected for the search were determined

to be the most likely to lead to the discovery of

all documents which could provide leads to health

impacts on our veterans.

<<(((b)(starts by attacking ma stating I do not understand

<<the Declassification project and the Security Review

<<Protocols. In fact, I have them posted on my website so

<<everyone can see the KEYWORDS. OSAGWI dint create this

<<list, they follow what was laid down by others further

<<back than themselves. The Army declass team, or should I say:

<<

<<The I-Team

<<The Fast Team

<<The 5-Alpha Team

<<and 200 other known staffers (from Army project)

<<...excluding all otgher branches for sake of simplicity))

<< I asked OSAGWI to post the Security Review Protocols as medically

<<relevant material on GulfLINK of which they flatly opposed.

As this process was completed, documents were scanned to determine relevance. All documents determined to be health related or relevant to the investigation into exposure to hazards have been declassified and posted to GulfLINK.

<<However, sensitive materials that the Army and

<<other opposed was held back. Only the elements

<<already released to the media could not be controlled.

<<A vast amount of material was passed over deliberately

<<as being supposedly deemed "Not medically relevant" or

<<sensitive.

It is physically impossible for our staff to examine every single classified document from the Gulf War. Further, it is not appropriate for every document to be declassified at this time for reasons of national security.

<<They didnt have to, each branch of the service and -subordinates had there own declassification teams.

<<Army, Navy, Air force, Marines, and so on.

<<At this point 99.76% falls under National Security

<<if we go by (b) reconning.

Like you, we are interested in Seeing that all documents relating to the health of Gulf War veterans are declassified.

<<This is absolutely false, the MaxweLL AFB logs as <<well as many other records groups have existed since <<1996. They have known all along and choose to deny. Consequently, every classified documen identified by key word was subjected to human scrutiny before it was rejected for declassification. We continue to work towards the end of declassifying all health-related Gulf War documents and

——ask your help in identifying such———
--classified material.————————

We will evaluate and include new information, as appropriate, in our investigation as it comes available.

<<Again, it has been availabk since December 1996.

<<OSAGWI flat out lies about this. If we dont have it <<out here, then it doesnt exist. Look at the CENTCOM <<logs and how they were handled. OSAGWI and DOD places <<the burden of proof on us, and what we dont know they deny.

We sham your frustration with the present lack of scientifically acceptable explanations for what may be causing the unexplained illnesses of Gulf War veterans. We are sincerely working to provide the answers which our Gulf War veterans need and deserve.

991229

<<I am not frustrated, I am pissed at the total fraud here.

<<OSAGWI needs a E-4 Generator mechanic to help them with

<<the CLASSIFIED records. $100,000,000 in funding and a staff

<<of 200 personnel, and a poor disabled veteran with a few dollars

<<in his pocket is just what they need to resolve this issue

<<I hope I am not the only one (b) has offended.

CMAT Controlled
Comments:

In response to CMAT 1999364-e000001, LTG Vesser has provided the following framework:
Thanks for the email; no intent to offend you: Happy New Year- Y2K has not caused the loss of any documents.
You correctly understand that only a small number of messages deal with the health of GW vets
You rightly indicate much money has been spent on developing and searching data bases to get relevant information
We have learned that messages are not the only source of info- that is why we turn to vets like yourself who can shed light on events messages refer to but do not accurately describe
we call your attention to our methodology to investigate chem incidents. we also call your attention to the redacted publication of chap 11 of the MITRE report and Dr Rostker's comments on it that provide some indication that the messages are often unreliable.
our investigations begin and end with gw vets. Ultimately, they have the knowledge of what actually happened
we ask you to continue to work with us and we solicit your support.

Put this in to a response and I'll run it by LTG Vesser. Shoot for next Tuesday, 4 Jan 00.

VDM Controlled

Comments:

PAO Controlled

Comments:
rwd
Response:

Dear Mr. Love:

Thank you for your recent e-mail regarding Gulf War illnesses. My name is (b) and I am responding on behalf of Dr. Bernard Rostker, the Special Assistant for Gulf War Illnesses.

I regret that our last e-mail offended you because we make a good faith effort to work with all Gulf War veterans in our mutual attempt to successfully determine what is causing the undiagnosed illnesses, We will continue to work with you and all veterans to ensure we have a complete and accurate investigation based on all the facts We expect to have a dialogue about what competing evidence means.

You were correct in pointing out that a great deal of money has been spent in our attempt to provide answers. Our investigations begin and end with Gulf War veterans. A veteran's rank and background has no bearing on the importance of the information they may be able tb provide, We value input of every veteran and know they hold the keys to our being able to answer why many of them are ill.

The changeover to Y2K did not cause the loss of any documents. Preparations were made well in advance to protect the information supporting our investigations.

You also referenced the Maxwell AFB log in your e-mail. We have done a random search of our GulfLINK website for several of the documents from the Maxwell logs and they are still posted them as they have been for some time. The only ones you won't find are those that are still classified. You may choose to disagree with us and the personnel responsible for deciding which documents can and cannot be declassified due to national security. We respect your position on this, but, for the time being, there are documents which will remain unavailable for posting to the website based on their security classification.

We ara interested in seeing that all documents relating to the health of Gulf War veterans are declassified and will work with the appropriate classifying authority towards that end.

We received your request for a meeting and will be glad to host you and the veterans listed on the date and time requested. However, Dr. Rostker is unavailable then and others may not be able to come at the time you requested. We are not always able to bring in the VA or other DoD personnel.

We will be happy to provide the news media with interviews and answer any of their questions. We encourage you to meet with the media before and/or after you visit with us. We do not intend to host them as a part of any business meeting taking place in our offices. They will need to sand any requests for interviews or information through public affairs channels.

Thanks again for your e-mail. We sincerely hope that you will continue to work with us.

000111

PAO Manager Controlled

Comments:
2000 0111 a.m. (b) – Ready for release. VR, bg
2000 0104 p.m. (b) – Ready for consideration and release. VR, bg

Medical Controlled

Comments:

Response:

Chemical/Biological Warfare Agents Team Controlled

Comments:

Response:

Environmental/Occupational Exposures Team Controlled

Comments:

Response:

Medical Planning Issues Team Controlled

Comments:

Response:

Preliminary Analysis Group Controlled

Comments:

Response:

AMB

Comments:

(b)(6)
06/05/2000 07:08 AM

1) Epositions

To: (b)(6) @OSAGWI
cc:
Subject: Depositions of Gulf War Commanding staff

Rich-my apologies for omitting you-its Monday...
---------- Forwarded by (b)(6) on 06/05/2000 07:07 AM ----------

(b)(6)
06/05/2000 06:05 AM

To: (b)(6)

CC:
Subject: Depositions of Gulf War Commanding staff

Kirt Love continues to send numerous letters and emails and call different individuals throughout OSAGWI. His requests include FOIAs, help getting responses from other agencies, and a multitude of demands for other action and information from OSAGWI.

As we've done in the pest with other frequent callers/writers, we need to review the status of Mr. Love's correspondence and see if 1) we have responded in a timely and appropriate manner to geniune requests for information, and 2) if the current correspondence is for new information/action, or have already been answered in previous correspondence.

While we have a commitment to assisting veterans in their search for information about the Gulf War; we also have to recognize that there are situations where we have provided as much information/support as we are able to provide. As we transition OSAGWI in OSAMD we will be tasked to the max. We need to be very careful how we apply our shrinking resources.

Request we review Mr. Love's status et the next director's meeting by reviewing all previous correspondence and pending requests.

V/R

---------- Forwarded by (b)(6) on 06/05/2000 06:56 AM ----------
(b)(6) on 06/04/2000 09:24:20 PM

Please respond to (b)(6)
To: (b)(6)

cc: (b)(6)

Subject: Depositions of Gulf War Commanding staff

Kirt Love wrote:

I have received no response what so ever, and Ive been told by other OSAGWI staff thie hasnt even been discussed. How far am I from a response to this, and many other letters I have sent. Can I have some kind of date you will respond by.

Sincerely
Kirt P. Love
Director, DSBR

(b)(6) pgwillness.osd.mil wrote:

> Your email has been received end
> a response will be provided as soon as
> possible.
>
> Respectfully,
>
> Lt Col (b)(6)
> Director of Public Affairs

Dr. Bernard Rostker, Lt. Col (b)(6) and OSAGWI staff

In multiple conversations with your staff I have requested for a specific intervention into the Gulf War commending staff, and those with security clearances.

Up till now a large amount of military records have either been destroyed, altered, ignored, or treated in varying ways to ignore them. Testimony of any personnel has been treated a.8 either Congressional, or handled through OSAGWI itself has been pretty much treated as anecdotal. Either way this material is inaccessable by public standards for review. Point, the handling of specific Gulf War testimony that might be medically relevant to Gulf War Illness has been mishandled.

As of April 13, 2000 I specifically request formal depositions

of the:

1. CENTCOM staff (1990-1991)
2. C3I Staff (1990 - current)
3. Former Joint Cheifs of Staff (1990 - 1991)
4. Commanding Generals and Staff (1990 - 1991)
5. CIA Intelligence Staff (1990 - 1991)
6. DIA Intelligence Staff (1990 - 1991)
7. FDA and CDC personnel related to vaccine issues (1990 - 1991)
8. NSA personnel handling COMINT and SIGINT materials (1990 - 1991
9. NSCOM American Staff (1990 - 1997)
10. NARA personnel handling all Gulf War Records since 1990
11. DOD Security Review Personnel since 1990
12. General Ronald Blanck
13. Former CIA Director John Deutch
14. Former President George Bush
15. Any pereonnel with Secret and Top Secret clearances, as well as personnel in EOD, Black Ops, Night operations, and security intel positions that participtaed during Operation desert Sheild/Storm 1990 - 1991.

Since OSAGWI chooses to treat so much of the Gulf War as anecdotal evidence, then having the sworn depositions of most these persons should then at least support that fact. However, if fraud and waste has transpired then no doubt OSAGWI will immediately refute this avenue since it will prove awkward for them to explain the findings.

I will keep pushing this avenue with the DOD, DOJ, the GAO, Rouse, Senate, OSAGWI, PSOB, until taping begins. I specifically request that OSAGWI approach the Whitehouse to apply the executive power it holds to begin these depositions. That under the terms of its charter, mandates, and executive actions it has the authority to request this avenue of action to resolve the anecdotal issues of proper evidence to conclude its investigation of the Gulf War.

Anything other than a yes from OSAGWI should be treated as "Obstruction of Justice", because MEDICALLY relevant material is at stake.

At thie time this material should also be created as "Perpetuation of Evidence" as well as "Perpustion of Testimony" to those that are either dying. or lying.

If OSAGWI has nothing to hide, it should welcome this avenue under the terms of its mission statement that cites: "Leave no stone unturned".

I await response from OSAGWI, PSOB, GAO, and any other concerned parties. Once again I specifiy, the date is April 13th. 2000 and I request a specific response from Dr. Bernard Rostker concerning this issue.

Sincerely
Kirt P. Love
Director, DSBR

(b)(6)
05/10/2000 06:57 AM

To: (b)(6)
CC:
Subject: Gulf War Veteran Referral Center . Houston VAMC

(b)(6)

I'm sure you will get this from several sources, but, just in case--looks like one we should put in the **quque.**

---------- Forwarded by (b)(6) on 05/10/2000 06:57 AM ---------
(b)(6) on 05/09/2000 11:54:52 PM

Please respond to (b)(6)

To: (b)(6)

CC:

Subject: Gulf War Veteran Referral Center . Houston VAMC

Dear Dr. **Rostker** and OSAGWI team

After attending the Gulf **War** Vet Referral Center **at** the Houston **VAMC,** I wee **most upset** and disturbed at what I **saw.**

As not to **sound** like the only one, I took down the information from 4 other **Gulf** War Veterans **that attened** the **same** time. Not one **was satisified** from whet I **saw** and heard. These will be available **from** my **website** here shortly. **http://www.gulflink.org**

I noticed for **one,** a large **green** book **at** the **nurses station.** It [illegible] bout 250 **names of** veterans, and the **appoinments scheduled** for them. It seems the only one that the staff **went** to great **care** to write in **was:**
---Psychiatry---
In fact, most this was the only entry.

Houston VA
VA Exam

Knowing that this material is being sent to DOD as a medical study, It seems to me that this is deliberate on DOD/VA's part to show that Gulf War Veterans illness is psychiatric.

Many veterans like myself were falsely baited by doctors to this clinic. I was told the PET and SPECT scans would be available. They were not. In fact, this clinic had nothing new that the other clinics/VAMC's didnt already have. The doctors at the clinic were not very imaginative, and even sarcastic at times. The administrator became defensive and told me I couldnt perform advocacy work while in the room as a patient. They wrote in my records that I talked to other patients, how is that relevant to my medical history.

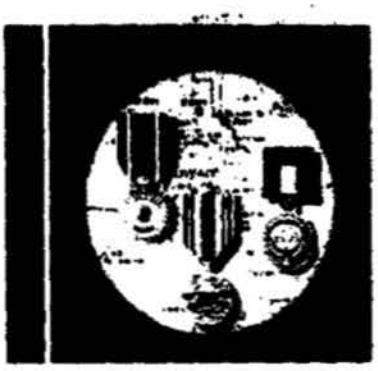
I tried my best to offer ideas, to push research ideas to the doctors. But, found the doctors sticking to old VA dogma. Then the administrator tried to imply somatoform dieorder, of which the final diagnosis did NOT support. In fact, I had a clean bill of MENTAL health. Though physical didnt fare as well.

It is my belief at this time that the Gulf War Referral clinic is deliberately trying to push veterans down the psychiatric hole. People desperate for hope are not getting anything of value, and DOD gets smear reports to make veterans look bad. That this clinic is biased and of very little value to Gulf War veterans who need more extensive medical research. Mostly Endocinological, and Neurological areas, as well as metabolic, and advanced microbial. Last being possible genetic.

If anything the clinic should at least follow the phase II and III CCEP testing procedures to at least pin down some areas not normally tested for.

Either revamp the program or drop it, but continuing as it is now is more than useless. I request a response on the part of OSAGWI to follow this up under the guise of its mission statement. I also request a response from OSAGWI on the center.

Sincerely
Kirt P. Love
Director, DSBR



Office of the Special Assistant for Gulf War Illnesses

CMAT

CMAT Number: 2000132-E000020 Date Received: **05/11/2000**

To: (b)(6)

From:

CC:

Subject: **Mycoplasma** contamination of Vaw A and Vacc B (RAND)

Myc. plasma

Dear Dr. Rostker and OSAGWI Staff

In the past few months more and more studies have shown that mycoplasma strains are much more widespread than previously thought, More hardy and virilant, a variety of biotech agencies as well as other sources find upwards of 30% of diagnostic equipment (such as culture dishes) is contaminated with mycoplasma's. Japanese studies demonstrate a higher rate of infection in the private sector than previously demonstrated, upwards of 50% tested were positive for mycoplasmas.

Though culturing is ineffective, what has been done required a high lipid/cholestrol solution. Many Gulf War Veterans (such as myself) demonstrate hyperlipidemia, possibly creating a ideal enviroment for mycoplasma's that contaminated past vaccines. Both Anthrax/Botulinum Vaccine recipients such as Gulf War veteran Venusval Hammack are positive for both Mycoplasma and Hepatitii C. This is not an issue of careless lifestyle.

Keep in mind that ISG/IGG Hepatitis Vaccines are VIRAL vaccines, and in the mycoplasma CBER report it outlines how viral vaccines are vulnerable to mycoplasma. The ISG/IGG was also one of Michigan Biologics vaccines,

There was NO mycoplasma testing of vaccine's produced my Michigan Biologics during the Gulf War or even recently. In fact, a myriad of viral - bacterial - and fungal elements escaped detection at Michigan Biologics. Since the blood sera (and other items for vaccine production) used to produce these products wasnt screened (essayed) properly, wasnt handled properly, wasnt stored properly, or if defective even destroyed properly.

These are the following products that apply:

Albumin (Human)

Anthrax Vaccine Absorbed

Antihemophilic Factor (Human)

Diptheria and Tetanus Toxoids Absorbed

Pertusis Vaccine Absorbed

Immune Globulin (Human)

Rabies Vaccine Absorbed

Tetanus Toxoid Absorbed

All of these products manufactured by the now infamous Michigan Biologics, or now known as Bioport.

We know that Bioport is still NOT in compliance with license 99 or FDA imposed safety standards, more or less ever has been.

It is looking more and more like the FDA and CDC's lax policies governing Michigan Siiogics may

very well be responsible for the Mycoplasma and

Hepatitis C amoung the veteran population.

In August 20th, 1997 the FDA, RAND, and CBER conferenced called

to discuss the possibility of mycoplasma contamination

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Carolyn Hardegree

Donna Chandler

Jeanne Novak

Brian Malkin

Dr. Golomb

Then a secound call August 27th with Sob Temple.

The

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Stuart Nightingale

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Dennis Myers

Bonnie Lee

Diane Maloney

Nathew Eckel

(See bottom of page for document content material)

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Sincerely

Kirt P. Love

Director, DSBR

(Note: I do expect a response from Mike Kilpatrick and Francis O'Donnell of OSAGWI on this).

This is the FDA/CBER statement of the 8/98 position on mycoplasma:

Fact Sheet Re: Potential Mycoplasma Contamination end Anthrax Vaccine and Botulinum Toxoid Vaccines

Mycoplasma am fastidious organisms which require complex media for growth. They retain only truncated biiynthetic pathways, i.e., they cannot synteaize many intermediate or starting compounds required for growth, and hence they require a complex mixture of nutrients in growth media in order to replicate. The typical mycoplasma growth medium Is composed of beef heart infusion and peptone basal medium which is supplemented with fresh yeast extract and 10-20% horse or fetal calf serum. The more defined, simpler media (minus yeast extract and serum) used for growth

(b)(6)

03/20/2000 03:49 PM

To: (b)(6)

CC: VOM Group

subject: **Kirt Love Call 3/20/00**

Kirt Love call today, **3/20/00,** at **1:00PM.** He **called** to comment on the **email** he received from **OSAGWI** and the PSOB.

Mr. Love said the **OSAGWI email** was garbage because it did not tell him anything he did not already know. He said we **should** have sent him a copy of the report where the explosion incident was investigated. " I wanted a copy of that **report.** Your • ra hiding **information** from **the gulf** war veterans." Mr. Love said the front **office** is not working with him and he will contest it. Also, he stated some individuals are avoiding him, but he refused to name **them.**

Mr. Love said he received a message from the PSOB stating the agenda for the April meeting is set and he can not be accommodated as a speaker during the meeting. Therefore, he has quit **his** job to devote full time to his gulf war efforts. He will visit this **area** during the week of 3-7 **April** and will be all over the place. I asked him if he will **visit** this office and he said he can not tell me that information. He said two **NCOs** are working with him and he will not reveal them.

His web site is scheduled to be up before 1 **April.**

regards

(b)(6)

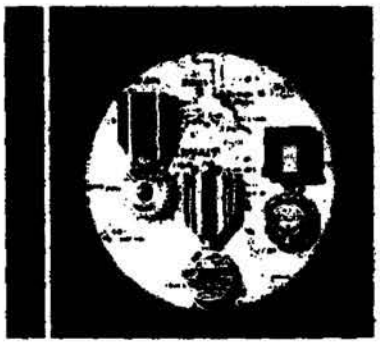
Explosion

(b)(6)

02/28/2000 07:41 AM

To: (b)(6)
cc:
Subject: OSAGWI rewriting Gulf War as FICTION

---------- Forwarded by (b)(6) on 02/28/2000 07:43 AM ----------



Office of the Special Assistant for Gulf War Illnesses

CMAT

CMAT Number: 2000059-E000001 Date Received: 02/27/2000 10:43:06 PM

To: (b)(6)

From:
cc:
Subject: OSAGWI rewriting Gull War as FICTION

Dear Dr. Rostker and OSAGWI staff
Supposedly OSAGWI baa electronic versions of over 6 million records. Yet. in FOIA response 00-P-0366 (Fcb 17th 2000) OSAGWI sends me a letter stating there are "NO" records concerning the 1st and 3rd AD demolitions in Iraq and Kuwait during and after the Gulf War.
These "Denial Operations" (demolitions) of the 1st and 3rd AD arc on the GulfLINK website, and the rest are deemed Secret and Top Secret at the National Archives CENTCOM and other records sections.
These demolitions directly correspond with what my unit witnessed after the War in Southern Iraq/Northern Kuwait.
OSAGWI will not provide me any results concerning the "Mystery Bunker" investigation about my unit,

more or less provide or search for other materials concerning this "Medically relevant" event.

This is much like the letters coming in from USSOC saying there arc "No" Spacecom or CINSPACE records from the Gulf War. While the Maxwell AFB logs directly dispute this fact, and the FROG • SCUD missile tracking data they had. Even the NSA is trying everything it can to "NOT" provide me relevant SIGINT and COMINT materials of the Gulf War.

The ARMY is now daying the 12 frame refrigerated bunkers and the NAVY/MARINES are denying:

USMCMG
TACC
TAVB
MAGTF
MARDIV mateials.

Another appauling event, I get notification that OSAGWI does "NOT" keep trip loge, trip records, or reports (transcripts) on outreach trips to military installations. This means there is "NO" way of confirming contacts or follow ups at "ANY" of these outreaches. This further confirms that the outreach missions are "NOT" to bring home new evidence or provide any hardcopy confirmation of trips efforts.

As I send in these e-mails, OSAGWI has gone into silent running and wont provide responses. Further showing the contempt of the OSAGWI staff for veteran effort. to ""cover truths that the OSAGWI staff choose to ignore or rewrite to suite them.

My group expects a response concerning Gen. Ronald Blanck and the Anthrax vaccines. My group expects a" answer on the Hepatitis C contamination of the ISG/IGG vaccines not only of the Gulf but Vietnam as well, which would account for the High Hepatitis C contamination of the Veteran population (especially in VA Hospitals). My groups expects responses for everything we posed in e-mails • letters • and oral converstaion with OSAGWI in the last 5 months, as well was a.8 anything eve" similar to a question in the last 3 months starting with the materials in the "Security Review Protocols" and carrying on to the "Maxwell AFB Logs" to the e-mails last week.

I could care less if Col Dianne Lawhan and many other OSAGWI staff dislike me or my team. That does not justify ignoring our efforts, considering "WE WBRE THERE". As a tax paying citizen, injured party, and a disabled Gulf War Veteran being denied beneficial medical diagnosis/treatment. I must protest theme efforts to disquise events and ignore those of us trying to get to the Heart of the matter.

If OSAGWI is willing to play these game, with me and my unit, my team. Then what of those veterans out there with no advocates or the the lack of strength to do more. Ho" many thousands must die to disquise the lack of success in the many failed Gulf War military ventures.

Your department has either destroyed the demolition records of the 1st and 3rd AD or sent them to the National Archives for cold storage. Where are they? Keep in mind, the Archives already responded that "YOU" have them.

Sincerely

Kirt P. Love
DSBR and Team Associates

CMAT Controlled
Comments:

VDM Controlled

Comments:

PAO Controlled

Comments:

Response:

PAO Manager Controlled

Comments:

Medical Controlled

Comments:

Response:

Chemical/Biological Warfare Agents Team Controlled

Comments:

Response:

Environmental/Occupational Exposures Team Controlled

Comments:

Response:

(b)(6)
02/21/2000 07:23 AM

To: (b)(6)

CC:
Subject: Failed Vaccine Program - **FDA/CDC issues**

Kit-t Love **email** FYI.

regards

(b)(6) — **Forwarded** by (b)(6) on **02/21/2000** 07:23 AN ———— - - -
(b)(6) on **02/19/2000 07:41:54** PM

Please respond to (b)(6)
To: (b)(6)

cc:
Subject: Failed Vaooine Program - **FDA/CDC issues**

Dear Dr. **Rostker** and **OSAGWI** staff

In the **coming weeks** my group will be **addressing a** variety of problem **areas.** One **area** of concern is the continual **efforts** of DOD to **needlessly experiment** with active duty **soldiers** lives **as** we **speak.**

Surgeon **General Ronald Blanck's** current handling of the Anthrax vaccines is **appauling. If** anything, the General has endangered **soldiers** since before the Gulf **War.** The below article **covers** experimentation policy of MID just with Encephalitis.

What follow up **has** been done on those that received that vaccine, more or **less the** Muscular Dystrophy Vaccine and others of the **Gulf War.** Why is DOD

stonewalling on Hepatitis C contamination of ISG/IGG vaccines and IVIG products. Why is DOD stonewalling on Hepatitis C screening of all soldiers that received ISG before 1996. In several locations and VA hospitals incidence of Hepatitis C is 15%, what of those that have not been screened. Interesting foot note, did not Michigan Biologics (now Bioport) handle Anthrax • Botulinum - and ISG vaccines.

Hasnt the Gulf War veteran community shown how badly DOD handles vaccination programs in the past. Why has DOD drug its heals to follow up the Botulinum Toxoid recipients. Venusval Hammack is one such recipient that is very sick, and yet you have not even conversed with her concerning her health related problems though she is right in front of you. What of those that never deployed that received the vaccine.

As we speak, Anthrax production still does not meet FDA requirements. It is not safe and has side effects. The 10% mortality rate is now slowly being adjusted for by allowing "some" exemptions. In truth the vaccine should be discontinued until its manufacturer complies with FDA guidelines, as well as contamination protocol.

Active duty deserve not only "Informed consent" but truthful explanations of what they are receiving. It should be there. choice.

I openly oppose Surgeon General Ronald Blanck and ask that he be removed from his current position for needlessly endangering soldiers lives. That his involvement with past Vaccines and the Gulf War be much more deeply explored.

There will be a section dedicated to this fact on the pending website: http://www.gulflink.org

Your department needs to follow up in detail ALL vaccine data of the Gulf War. That includes other experimentation currently not • ddrerwd. It needs to actively pursue ALL recipients with very detailed follow up that should be submitted to the FDA and CDC for review. Most importantly, it should seek aggressive treatment for those that have been injured by these vaccines. Not to mention restitution to those that suffered for the DOD's mistakes.

VACCINES
BLANCK
HEPC

Sincerely
Kirt P. Love
DSBR and team

DoD: Encephalitis Vaccine Didn't Threaten Soldiers' Safety

By Douglas J. Gillert
American Force Press Service

WASHINGTON -- Despite Food and Drug Administration claims to the contrary, defense health officials said the use of a vaccine against tickborne encephalitis given to soldiers in Bosnia in 1996 was safe and effective.

Nearly 4,000 American soldiers at high risk volunteered for vaccinations after being briefed on the drug's European history. Some 27 million doses of the vaccine have been given in Europe, where several countries have approved its use. The soldiers signed consent forms before receiving a three-shot series.

Subsequently, there have been no verifiable cases of tickborne encephalitis among U.S. soldiers in Bosnia. In a July 22, 1997, letter to DoD, FDA Commissioner Michael Friedman contended the vaccinations placed the soldiers at risk and violated FDA guidelines for the use of experimental drugs.

Defense officials admitted faulty recordkeeping, but noted the drug was administered under FDA investigational new drug guidelines. Officials said the vaccine was necessary because tickborne encephalitis is endemic to the region and no recognized medical alternative exists. Encephalitis causes inflammation of the brain, leading to paralysis and death.

The Army Medical Research and Materiel Command at Fort Detrick, Md., assessed the vaccine's safety and effectiveness before it was administered to soldiers. The department also has held extensive discussions with the FDA to develop options for allowing DoD to use the best available products to protect deployed soldiers against medical threats and to adapt recordkeeping and other administrative requirements to the operational setting, officials said. However, they admitted a small number (14) of the consent forms were misplaced, as were 242 unused doses of the vaccine. In his letter, Friedman criticized DoD for shortfalls and "significant

deviations" in its administration of the vaccine.

The letter also renewed criticism of the military's administration of investigational new drugs during the Persian Gulf War.In a letter countering Friedman's criticism, Lt. Gen. Ronald Blanck, Army surgeon general, said the vaccination "was given safely" in Bosnia.

The Army ended the vaccination program in September 1997 after no cases of tickborne encephalitis occurred among U.S. troops in Bosnia. Meanwhile, the service adopted environmental control measures and taught the soldiers to take precaution8 against the disease through proper wear of the uniform; treating their skin and uniforms with approved tick repellents; and other measures.

Gulf War Illnesses

Bernard Rostker

CMAT Number. **2000132-E000020** Date Received: **05/1** 112000

To: (b)(6)

From:

cc:

Subject: **Mycoplasma** contamination of **Vacc** A and' Vacc B (RAND)

Dear Dr. Rostker and OSAGWI Staff

In the past few months more and more studies have shown that mycoplasma strains are much more wide spread than previously thought. More hardy and virilant, a variety of biotech agencies as well as other sources find upwards of 30% of diagnostic equipment (such as culture dishes) is contaminated with mycoplasma's. Japaneese studies demonstrate a higher rate of infection in the private sector than previously demonstrated, upwards of 50% tested were positive for mycoplasmas.

Though culturing is ineffective, what has been done required a high **lipid/cholestrol** solution. Many Gulf War Veterans (such as myself) demonstrate hyperlipidemia, possibly creating a ideal enviroment for mycoplasma's that contaminated past vaccines. Both **Anthrax/Botulinum** Vaccine **reciplants** such as Gulf War veteran Venusval **Hammack** are positive for both Mycoplasma and Hepatitis C. This is not an issue of careless lifestyle.

Keep in mind that **ISG/IGG** Hepatitis Vaccines are VIRAL vaccines, and in the mycoplasma CBER report it outlines how viral vaccines are vulnerable to mycoplasma. The **ISG/IGG** was also one of Michigan **Biologics** vaccines.

There was NO mycoplasma testing of vaccine's produced my Michigan Biologics during the Gulf War or even recently. In fact, a myriad of viral • bacterial -and fungal elements escaped detection at Michigan Biologics. Since the blood sera (and other items for vaccine production) used to produce these products wasnt screened (essayed) properly, wasnt handled properly, wasnt stored properly, or if defective even destroyed properly.

These are the following products that apply:

Albumin (Human)

Anthrax Vaccine Absorbed

Antihemophilic Factor (Human)

Diptheria and Tetanus Toxoids Absorbed

Pertusis Vaccine Absorbed

Immune Globulin (Human)

Rabies Vaccine Absorbed

Tetanus Toxoid Absorbed

All of these products manufactured by the now infamous Michigan Biologics. or now known as Bioport.

We know that Bioport is still NOT in compliance with license 99 or FDA imposed safety standards, more or less ever has been.

It is looking more and more like the FDA and CDC's lax policies governing Michigan Biologics may

very well be, responsible for the Mycoplasma and

Hepatitis C amoung the veteran population.

In August 20th, 1997 the FDA, RAND, and CBER conferenced called

to discuss the possibility of mycoplasma contamination

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Diane Maloney

Nathew Eckel

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Sincerely

Kirt P Love

Director, DSBR

(Note: I do expect a response from Mike Kilpatrick and Francis O'Donnell of **OSAGWI** on this).

This is the **FDA/CBER** statement of the **8/96** position on mycoplasma:

Fact Sheet Re: Potential Mycoplasma Contamination and Anthrax Vaccine and **Botulinum** Toxoid Vaccines

Mycoplasma are fastidious organisms which require complex media for growth. They retain only truncated biosynthetic pathways, i.e., they cannot syntesize many intermediate or starting compounds required for growth, and hence they require a complex mixture of **nutrients** in growth media in order to replicate. The typical mycoplasma growth medium is composed of beef heart infusion and **peptone** basal medium which is supplemented with fresh yeast extract and **10-20%** horse or fetal calf serum. The more defined. simpler media (minus yeast extract and serum) used for growth

of eubacteria, such as Bacillus Anthracis or Clostridium botulium, would not be expected to support the growth of mycoplasmas, especially since the bacterial media do not contain serum required as a source of the lipids not synthesized by the mycoplasmas. FDA does not require mycoplasma testing for approved or investigational bacterial vaccines produced with bacterial fermentation media.

Mycoplasmas do not contain a cell wall. Because they do not contain the **murein** found in eubacteria, they are not susceptible to penicillin-derived antibiotics. However, they are generally susceptible to antibiotics such as tetracycline and eythromycin, although antibiotics resistant strains have been described. Because Mycoplasmas are bounded only by a cell membrane (no cell wall), they are sensitive to bacteriostatic agents. The preservatives benzethonium chloride (contained in Anthrax vaccine) and thimerosal (contained in Botulinum Toxoid Vaccine) would be expected to kill any inadvertent mycoplasma organisms. Moreover, the botulinum toxoid vaccine contains inactivated botulinum toxin, which was treated with **.6%** formaldehyde; the vaccine contains **.022%** residual formaldehyde; the Anthrax vaccine contains **.0035%** formaldehyde, used as a stabilizer. Mycoplasmas would be expected to be inactivated by formaldehyde introduced in the manufacture of these two bacterial vaccines.

Mycoplasmas do grow in cell cultures and could potentially

contaminate VIRAL vaccines propogated in tissue cultures, which are frequently grown in media containing animal serum. For this reason, human viral vaccines produced in cell cultures are required by FDA to be tested for mycoplasma contamination. However, this test would not be required from recombinant viral antigens produced in bacterium such as Eschetichia coli. As stated above, mycoplasmas do not grow in bacterial media, and testing of mycoplasma in bacterial vaccines is not warranted. In gact, the preservatives included in the final formulations of the two vaccines specified above would be expected to inhibit mycoplasma growth and would interfere with mycoplasma testing by culture or indicator cell method.

Prepared by FDA/CBER - 8/96

CMAT Controlled
Comments:
pao

VDM Controlled

Comments:

PAO Controlled

Comments:
bg
Response:

Dear Mr. Love:

In your telephone conversation with (b)(6) at OSAGWI in late May this year, you asked a number of questions. This is Barbara, responding on behalf of Dr. Rostker. the Special Assistant for Gulf War Illnesses.

In your conversation with (b)(6) you stated that of the 139 requests/questions you had submitted to OSAGWI, 124 were Freedom of Information Act (FOIA) requests. You said you understood the process and delays, however there were responses to five e-mail inquiries for which you were still waiting. You didn't clarify which five those were, so we have gone through your e-mails and believe we have identified the five you believe were unanswered or inadequately answered.

Question 1. Your e-mail of February 19, 2000, you addressed concerns about hepatitis C, vaccines administered in the Gulf, and your displeasure with LTG Ronald Blanck.

Answer I. In mid-March, we responded to your questions as well as those posed in another e-mail inquiry. We thought we provided an answer.

Yes, the San Francisco VA has reported a hepatitis C rate of 19 percent in Vietnam veterans who seek care there. There were no other details in the newspaper report as to possible causes of this increased rate. Hepatitis C is higher in people who have received blood transfusions before testing for hepatitis C began in1990, in people using Intravenous drugs, and in sexual partners of individuals with hepatitis C. It also occurs in Individuals without any of the above risk factors, Studies evaluating the rates of hepatitis C in active duty members have shown it is half that of the general population. The Centers for Disease Control and Prevention (CDC) published a Morbidity and Mortality Weekly Report (October 16, 1998) that indicates there is no evidence of hepatitis C being transmitted through intramuscular injections with immune serum globulin.

Regarding the anthrax and botulinum toxoid vaccines administered in the Gulf War, no theater-wide master records showing who got "Vac A" or "Vac B" were kept. Although some unit records were annotated, individual records were generally not annotated because of local decisions, thus we are unable to follow every person who received a vaccine.

A study to evaluate people known to have had anthrax vaccine with individuals known not to have had anthrax vaccine in the Gulf is currently under way. A similar study could be done for recipients of the botulinum toxoid vaccine if a log validating vaccination could be found.

Finally, you are entitled to your opinion about LTG Blanck. We is retiring from the US. Army this month and his replacement is yet to be named.

Question 2. Your e-mail of June 4, 2000 refers to your e-mail of April 13. 2000, in which you requested formal depositions of 15 different groups or individuals.

Answer 2. Regarding your request to take depositions of federal and military officials, OSAGWI has no legal authority to order a deposition and is thus unable to assist you. Under Rule 27 of the Federal Rules of Civil Procedure, you may petition a federal district court for permission to take a deposition if you anticipate being a party to a civil action.

Question 3. Your e-mail of May 11, 2000 addresses concerns about Mycoplasma contamination of anthrax vaccine.

Answer 3. The anthrax vaccine is an FDA-approved vaccine. While it is true mycoplasma have been identified as contaminants in tissue cultures, tissue cultures are not used in producing the anthrax vaccine. The US. Army did have an independent organization – Stanford Research International -test lots of anthrax vaccine produced prior to the Gulf War for mycoplasma and the results were negative. The U.S. Army also took vials of anthrax and introduced mycoplasma into the vial and cultured the vial immediately and every 24 hours to see if the mycoplasma could exist in the vials. Only the culture done immediately grew mycoplasma, the others grew nothing, proving mycoplasma cannot exist in the anthrax vaccine.

Question 4. On February 27, 2000, you wrote that OSAGWI wouldn't provide you with any results regarding the "mystery bunker."

Answer 4. As we pointed out in our response sent to you in March this year, we appreciated the information you provided from your first-hand experience with explosions involving various bunkers during the post Gulf War period. That information was analyzed by our Preliminary Analysis Group. What you observed was the destruction of a conventional weapons storage area. We already knew about this destruction and had already interviewed the explosive ordnance disposal personnel who supervised and conducted the operation. Because there was no new information compared to what had already been gathered, and no indication from the data present that there was any release of nerve agent or other toxic substances, no formal report was done. Our office only completes reports on incidents where there appears to be a possibility of chemical warfare agent release having occurred.

Question 5. Your e-mail of May **9, 2000** addresses concerns about the VA referral **center in** Houston.

Answer 5. **OSAGWI** is an agency within the Department of Defense. The Houston VA referral center is an agency within the Department of Veterans Affairs. While we both work together to benefit the veteran, **OSAGWI has** no authority within the Department of Veterans Affiirs. However, we have **forwarded** your concerns to the Department of Veterans Affairs for their consideration and action.
000703

PAO Manager Controlled

Comments:
2000 0620 Bill –This is the coordinated version – with input from Dr. Kilpatrick, (b)(6) (b)(6) Ready for your consideration and release. VR. bg

Medical Controlled

Comments:

Response:

Chemical/Biological Warfare Agents Team Controlled

Comments:

Response:

Environmental/Occupational Exposures Team Controlled

Comments:

Response:

Medical Planning Issues Team Controlled

Comments:

Response:

Preliminary Analysis Group Controlled

Comments:

Response:

AMB

Comments:

Response:

Case Manager Controlled

Comments:

Response:

Dr. Rostker

Comments:

Response:

Attachment:

(b)(6)
04/04/2002 04:11 PM

To: (b)(6) @OSAGWI
cc:

Subject: USACHPPM Health Information Operations Update - 20 March '02

2b please

---------- Forwarded by (b)(6) on 04/04/2002 04:13 PM ----------

(b)(6)
03/20/2002 04:18 PM

To: (b)(6)

cc:

Subject: USACHPPM Health Information Operations Update - 20 March '02
Document is Permanently Archived

FYI

---------- Forwarded by (b)(6) on 03/20/2002 04:22 PM ----------

(b)(6) on 03/20/2002 04:19:51 PM

To:
cc: (bcc: (b)(6))

Subject: USACHPPM Health Information Operations Update - 20 March '02

> Ladies and Gentlemen,
> For your information.
> The USACHPPM Health Information Operations Update provides information
> regarding global medical and veterinary issues of interest to the US Army.
> This information is sent to provide an increased awareness of current and
> emerging health-related issues.
> <<20 Mar 02 HIO update.doc>>
> Very Respectfully,
> LTC (b)(6)
> Deputy Chief of Staff for Operations
> USACHPPM
> DSN (b)(6)

> Comm (b)(6)
> FAX
> email: (b)(6)
>
>
>
>

 - 20 Mar 02 HIO update.doc

(b)(6)
Director, Medical Readiness
Deployment Health Support Directorate
(b)(6)

(b)(6)
Chief, Case Management Assignment Team
Deployment Health Support Directorate
(b)(6)

HEALTH INFORMATION OPERATIONS (HIO) WEEKLY UPDATE

20 March 2002

The HIO Weekly Update provides information regarding global medical and veterinary issues of interest to the United States (US) Army. The weekly update does not attempt to analyze the information regarding potential strategic or tactical impact to the US Army and as such, should not be regarded as a medical intelligence product. Medical intelligence products are available at http://mic.afmic.detrick.army.mil/. The information in the HIO Weekly Update should provide an increased awareness of current and emerging health-related issues. This report and other items of interest are available on the USACHPPM website at http://chppm-www.apgea.army.mil/.

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HOT ISSUES

Anthrax, Cutaneous - Laboratory Worker

A presumptive case of cutaneous anthrax has been identified in Texas in a worker at a private laboratory that is helping CDC process environmental samples from CDC's anthrax investigations. The laboratory where this individual works was able to culture *Bacillus anthracis* from the swab obtained by the worker's private physician. The isolate from this culture was sent to CDC on March 12 and CDC confirmed later that day that the isolate was *Bacillus anthracis*. CDC does not believe that the case poses any risk to public health. The report is at: http://www.cdc.gov/od/oc/media/pressrel/r020313.htm

Anthrax Detector - Sandia National Laboratories

On 6 March, Sandia National Laboratories announced that a patent application had been submitted for a prototype handheld detector under development, which can identify the fatty acid methyl esters (FAME) of anthrax in less than five minutes. The technique works by pre-concentrating airborne particles on a tiny hotplate that vaporizes the fatty acids in bacteria's cell walls to create the FAME that forms a unique fingerprint of the bacteria. A small computer program compares the amount of mass of each ester emitted in the analyzed gases - a process called elution - with already categorized elution peaks indicative of anthrax of other diseases. The report is at http://www.sandia.gov/media/NewsRel/NR2002/anthrax.htm.

Influenza Surveillance – DoD

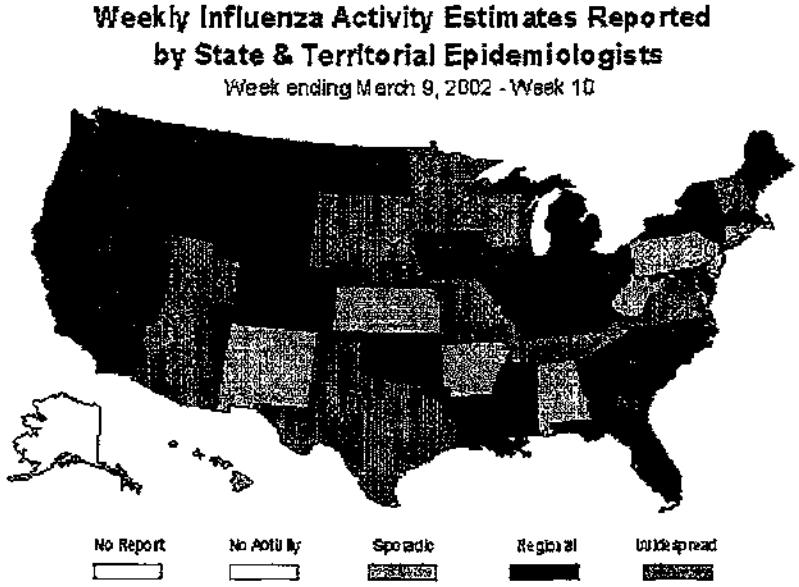
The DoD Worldwide Influenza Surveillance Program is a laboratory-based influenza surveillance program managed by the Air Force. As of 14 March, 474 (20%) of 2,408 submitted specimens have been identified as positive for influenza since the start of the influenza season (29 September): 461 (97%) were influenza A and 13 (3%) were influenza B. Of the 15 influenza isolates identified from NAB Little Creek, Virginia, one-third were influenza B viruses. Army laboratories in San Antonio, TX (BAMC) and Washington DC (WRAMC) identified 23 influenza isolates during the month of February: 21 were influenza A and two were influenza B. Of the 461 influenza A isolates, 92 (20%) have been subtyped, and 86 (93%) were influenza A (H3N2) and 6 (7%) were influenza A (H1N1). Further info, including data from the CDC and international sites, is available at: https://pestilence.brooks.af.mil/Influenza/

Note: Some users may experience difficulty accessing this link directly from this document; if this occurs, copy and paste the hyperlink in your browser address bar.

Influenza Surveillance - US

During week 10 (March 3-9, 2002), 448 (23.5%) of 1,905 respiratory specimens tested by World Health Organization (WHO) and National Respiratory Virus Surveillance System (NREVSS) laboratories were positive for influenza. The overall proportion of patient visits to sentinel physicians for influenza-like illness (ILI) was 2.3%, which is above the national baseline of 1.9%. The proportion of deaths attributed to pneumonia and influenza was 8.8%, which is above the epidemic threshold of 8.3% for week 10. Twelve state and territorial health departments reported widespread influenza activity, 27 reported regional activity, 10 reported sporadic activity, and 1 reported no influenza

activity. Since September 30, 10,081 (15.4%) of 65,494 submitted specimens were positive for influenza. Of the 10,081 isolates identified, 9,865 (98%) were influenza A viruses and 216 (2%) were influenza B viruses. Two thousand seven hundred and eighty-three (28%) of the 9,865 influenza A viruses identified have been subtyped; 2,748 (99%) were H3 viruses and 35 (1%) were H1 viruses. Thirty-six percent of the influenza B isolates reported this season were identified in the Mid-Atlantic region. The CDC classified influenza during the tenth week of the 2002 influenza season as in the map below The current weekly report is at: http://www.cdc.gov/ncidod/diseases/flu/weekly.htm



Picture courtesy of the CDC at: http://www.cdc.gov/ncidod/diseases/flu/weekly.htm

International Conference on Emerging Infectious Diseases - CDC

Conference sessions of the 2002 International Conference on Emerging Infectious Diseases will be available as webcasts following the conference's closing date. Email notification of webcast availability is at http://www.cdc.gov/iceid/program.htm.

Medical Statement - Senate Armed Services Committee

On 13 March, the Assistant Secretary of Defense for Health Affairs and the Executive Director, TRICARE Management Activity, testified before the Personnel Subcommittee of the Senate Armed Services Committee regarding medical issues in President Bush's fiscal 2003 budget request. Highlights of the statement include the following: (1) formation of a high-level working group with DHHS representatives to improve collaboration on defense against biological and chemical terrorism such as IND protocols on smallpox vaccine, pyridostigmine bromide (PB) tablets, botulinum toxoid vaccine, and anthrax vaccine post-exposure with antibiotics; (2) develop and implement a seamless system of electronic healthcare and surveillance data, integrating the entire spectrum from fixed facility systems to field hand-held technology; (3) fully utilize the eight joint ventures established with VA throughout the country and before FY 2005,

transmit/receive computerized patient medical record data to/from VA; (4) perform operational test and evaluation of CHCS II this summer with potential worldwide implementation in third quarter FY02; and (5) deployment of TRICARE Online worldwide later this year following operational testing now underway. TRICARE Online uses the Internet to assist medical beneficiaries in gaining access to the Military Health System by providing information on health, medical facilities, and providers. The testimony is at http://www.senate.gov/~armed_services/e_witnesslist.cfm?id=200.

OB/GYN Devices - FDA Alert

On 14 March, the FDA issued a nationwide/international alert on OB/GYN medical devices manufactured by A&A of Alpharetta, Georgia, which are labeled as sterile but in fact may not have undergone any sterilization process. These products include but are not limited to curettes (flexible and rigid), uterine dilators, endometrial sampling sets, fetal blood samplers, fetal bladder drains, laparoscopy accessories, bone marrow needles, harvesting pumps used in in-vitro fertilization, and aspiration sets. The report is at http://www.fda.gov/bbs/topics/NEWS/2002/NEW00799.html.

USCENTCOM

Medical Statement - Command Surgeon

On 13 March, the USCENTCOM Command Surgeon testified before the Personnel Subcommittee of the Senate Armed Services Committee regarding theater medical support. Highlights of the statement include the following: (1) publication of regional threats by the USACHPPM; (2) publication of detailed medical operations and preventive medicine planning as part of the CINC's OEF campaign plan; (3) issuance of force health protection and medical surveillance guidance and requirements in all deployment orders; (4) issuance of follow up messages on potential threats and specific health issues such as Rift Valley Fever, meningococcal disease, malaria, and TB; (5) institution of sound preventive policies and procedures to address health threat potential posed by detainee operations; and (6) implementation of preventive medicine measures to acquire DNBI rates that are among the lowest of any US armed conflict to date. The testimony is at http://www.senate.gov/~armed_services/e_witnesslist.cfm?id=200.

USEUCOM

Influenza Surveillance – Europe

For week ten, 4-10 March, the EISS reported widespread influenza activity in five countries: Germany, Italy, Netherlands, Norway, and Romania. In general, European clinical morbidity rates were declining or stable; however, increasing rates were observed in four countries: Germany, Poland, Romania, and Sweden. Influenza A, primarily the H3N2 subtype, was dominant in nine countries. Influenza B was dominant in five countries: Belgium, Slovakia, Slovenia, Spain, and Switzerland. For week 10, no cases of influenza A (H1N2) or influenza B/Victoria/2/87-like viruses were reported. The report is at http://www.eiss.org/cgi-files/bulletin_v2.cgi?display=1&code=59&bulletin=59.

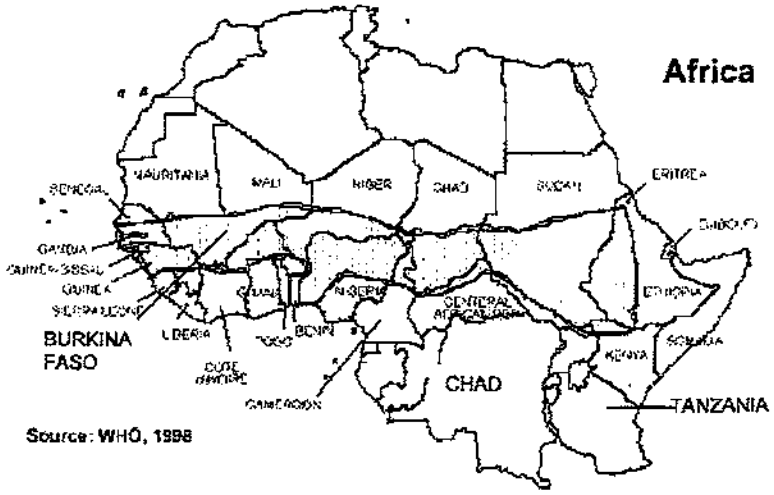
Medical Statement - Command Surgeon

On 13 March, the USEUCOM Command Surgeon testified before the Personnel Subcommittee of the Senate Armed Services Committee regarding theater medical support. Highlights of the statement include: (1) provided contingency medical support to include hospitalization, blood, medical supplies, and patient movement capabilities for USCENTCOM operations, (2) provided forward stabilization of critically injured patients closer to the forward edge of the battle areas than ever before through the use of forward surgical teams in the Balkans and in Nigeria and with planned deployment to Georgia, and (3) instituted the Multinational Integrated Medical Unit initiative in Kosovo, where a medical facility staffed by both Americans and British health care providers provide world-class support to all NATO and coalition forces in the British and American sectors of Operation Joint Guardian. USCENTCOM is using this initiative in Kosovo as a template for coalition medical operations in OEF. The Command Surgeon stated that he believed this type of international and coalition cooperation is the wave of the future. The Command Surgeon also stated that of the OEF patients moved to the Landstuhl Regional Medical Center to date, 75% were due to DNBI and 25% were WIA, which is consistent with operations in the Balkans over the last six years. The testimony is at http://www.senate.gov/~armed_services/e_witnesslist.cfm?id=200.

Meningococcal Meningitis - African Meningitis Belt (AMB)

On 14 March, the CDR Weekly reported a changing pattern in recent years for meningococcal meningitis in the AMB (picture follows). Historically, epidemics in this area would occur in cycles, usually during the dry season (November-June in west Africa and variable in east Africa). In recent years epidemics have flared for two to three consecutive years. The present African meningococcal meningitis pandemic began in 1996 with over 300,000 cases reported to the WHO by the end of 1998. The most affected countries have been Burkina Faso, Cameroon, Chad, Mali, Niger, and Nigeria. In 2001, six countries in the AMB experienced large epidemics: Benin, Burkina Faso, Central African Republic, Chad, Ethiopia, and Niger. Benin reported 6,147 cases including 265 deaths. In addition, Angola, which is outside the belt, reported an outbreak between May and October. Four countries are currently reporting outbreaks, two within the belt (Ethiopia and Burkina Faso) and two outside the belt (Somalia and the Democratic Republic of the Congo). Cases in these outbreaks have been laboratory confirmed as *Neisseria meningitidis* serogroup A, which is the most common

outbreak strain in the AMB. During epidemics, a smaller number of cases are usually reported to be due to serogroup C. Vaccines licensed in the US contain groups A, C, Y, and W135 meningococcal polysaccharides. The vaccine used for routine immunization programs in the UK provides protection for only group C. The report is at http://www.phls.co.uk/publications/CDR%20Weekly/PDF%20files/2002/cdr1102.pdf.



USJFCOM

Allograft-Associated Bacterial Infections - US

On 15 March, the CDC reported that as of 11 March, 26 patients with allograft-associated infections have been identified: 13 with *Clostridium* spp. infection and 14 associated with a single tissue processor. The CDC solicited these reports after the reported death of a recipient of an allograft contaminated with *Clostridium* spp. Sterilization of tissue that does not adversely affect the functioning of tissue when transplanted into patients is the best way to reduce the risk for allograft-associated infections. However, two sterilization methods (ethylene oxide and gamma irradiation) that would eliminate spores have associated technical problems that limit their use in processing of tissues for transplantation. New low-temperature chemical sterilization technologies that kill spores but preserve the biomechanical integrity and function of some allografts are being evaluated. The FDA has released new guidelines for tissue processors at http://www.fda.gov/cber/guidelines.htm#tissval. The CDC report is at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5110a2.htm.

Bacterial Conjunctivitis Outbreak - US College Campuses

On 15 March, the CDC reported an outbreak of conjunctivitis due to an unusual non-typeable strain of *Streptococcus pneumoniae*, which occurred in 574 students over the course of the winter term in mostly undergraduate students at Dartmouth College, New Hampshire. Sensitivity revealed resistance to erythromycin and susceptibility to bacitracin, sulfonamides, and quinolones. A survey of college faculty and interviews

with local childcare centers, schools, ophthalmologists, and primary-care physicians did not identify excessive episodes of conjunctivitis in persons other than college students. School health officials used various media in an effort to educate students, faculty, and staff about ways to reduce transmission to include frequent handwashing and avoidance of shared personal items such as towels, drinking glasses, and other utensils. The student health service also provided all undergraduate students with an alcohol-based antiseptic gel and instructions on proper use for hand antisepsis. Although this method improves hand hygiene in hospital settings, the benefit of antiseptic gel in a community outbreak setting is unknown. The college's winter term ended on 14 March with students departing for spring break. As of 13 March, the student health service continued to report new cases of conjunctivitis. The CDC expressed concern about spread of the conjunctivitis in students crowding popular vacation spots with limited access to handwashing facilities. Between 1 February and 14 March, Princeton University also reported 247 cases of conjunctivitis with preliminary evidence pointing to a bacterial infection. The Princeton University update is at http://www.princeton.edu/Siteware/WebAnnounce.Princeton_Announcements.shtml#1 and the CDC report is at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5110a1.htm.

Cat-Scratch Disease (CSD) in Children - Texas

On 15 March, the CDC reported on an evaluation of medical records for 32 children seen at the Texas Children's Hospital in Houston for CSD, a bacterial infection cause by *Bartonella henselae*. The findings emphasize that although CSD is generally a mild, self-limiting illness, up to 25% of cases have severe systemic illness that can result in protracted hospital stays and lengthy treatments before diagnosis. CSD is a feline-associated zoonotic disease with an estimated annual incidence in the US of 22,000 cases. Although CSD occurs in persons of all ages, the highest age-specific incidence is among children less than 10 years. Infection with CSD is one of the most common causes of chronic lymphadenopathy in children. Serologic testing is the standard method of diagnosis and should be considered for patients who present with adenopathy, fever, malaise, and history of feline contact. A single elevated value for IgG or IgM antibodies is generally sufficient to confirm CSD, because initiation of a humoral immune response generally precedes or is concurrent with symptom onset. The CDC reported that treatment recommendations for *Bartonella*-associated diseases, including CSD, depend on the specific disease presentation. Azithromycin has been shown to hasten resolution of adenopathy associated with CSD. For patients with more severe disease, other antibiotic regimens have been successful, including azithromycin or doxycycline in combination with rifampin or rifampin alone; doxycycline or erythromycin are considered the drugs of choice for bacillary angiomatosis and peliosis. The report is at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5110a4.htm.

Chagas Disease After Organ Transplantation - US

On 15 March, the CDC reported the first recognized US occurrence of *Trypansoma cruzi* infection through solid-organ transplantation. A cluster of three cases occurred due to transplantation of organs from a single donor. Chagas disease is endemic in parts of Central and South America and Mexico, where an estimated 16-18 million persons are infected with *T. cruzi*. Transmission of *T. cruzi* infection by solid-organ transplantation (particularly renal transplants) has been reported in Latin America,

where serologic screening of organ donors and recipients for antibody to *T. cruzi* is standard practice. No test has been licensed for use in the US for screening organ or blood donors. The CDC is coordinating consideration of whether to recommend screening of potential donors for *T. cruzi* infection and, if so, which donors to screen, how to screen, and what to do if the screening tests are positive. The report is at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5110a3.htm.

USPACOM

Medical Statement - Command Surgeon

On 13 March, the USPACOM Command Surgeon testified before the Personnel Subcommittee of the Senate Armed Services Committee regarding theater medical support. Highlights of the statement include the following challenges: (1) vast distance of the theater, which impedes the ability to move medical augmentation into theater when required and the ability to move patients back to definitive care, (2) an aging medical infrastructure with many facilities built during World War II, (3) medical professional shortages, (4) vaccine availability for forward-deployed forces, (5) institution of real time and near real time data streaming and aggregation of joint service medical encounter data, medical facility reports, web-based clinical consultation tools, and an advanced medical disease surveillance system. The testimony is at http://www.senate.gov/~armed_services/e_witnesslist.cfm?id=200.

Antibiotic Residues - Southeast Asia

On 15 March, the Food Standards Agency (FSA) of Northern Ireland reported that the European Commission had issued an alert regarding nitrofuran residues in shrimps and prawns from Southeast Asia (Thailand, Vietnam, Indonesia, India, and Bangladesh). The FSA conducted a retail survey and found that 16 (21%) of 77 samples were positive for nitrofuran residues. Nitrofurans are no longer permitted in the European Union because of health risk concerns. Nitrofurans are mutagens (damage genetic material), and there is concern that they are potentially carcinogenic in humans. The FSA advised against consumption of the affected batches of shrimp and prawns and issued a withdrawal from sale. The FSA has removed the products from the food market. The report is at http://www.food.gov.uk/enforcement/alerts/51574.

USSOUTHCOM

Medical Statement - Command Surgeon

On 13 March, the USSOUTHCOM Command Surgeon testified before the Personnel Subcommittee of the Senate Armed Services Committee regarding theater medical support. Highlights of the statement include: (1) institution of sound preventive policies and procedures to address health threat potential posed by detainee operations, (2) institution of the Emergency Medical Response Program to provide medical training and to assess the capability of host nations to respond to terrorist incidents at US Embassies/Security Assistance Offices, and (3) development of deployable medical teams at JTF Bravo and Roosevelt Roads to provide forward resuscitative surgery. The testimony is at http://www.senate.gov/~armed_services/e_witnesslist.cfm?id=200.

Yellow Fever - PAHO

On 17 March, the PAHO reported provisional totals of reported yellow fever cases for Central and South America as listed in the following table.

Country	2001 Cases	2001 Deaths	2002 Cases (as of 17 Mar 02)	2002 Deaths (as of 17 Mar 02)
Bolivia	4	3	1	1
Brazil	38	19	1	0
Colombia	6	4	1	1
Peru	29	17	5	0
TOTAL	77	43	8	2

Please contact the below-listed POC for suggested improvements and/or comments regarding this report. This report is also available on the USACHPPM website at http://chppm-www.apgea.army.mil/Hioupdate/.

POC (b)(6), DVM, MPH/MCHB-CS-OHD (b)(6)
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ACRONYMNS

ACIP - Advisory Committee on Immunization Practices
AFMIC - Armed Forces Medical Intelligence Center
AFPS – American Forces Press Service
AIDS – Acquired Immunodeficiency Syndrome
APHIS – Animal and Plant Health Inspection Service
BSE – Bovine Spongiform Encephalopathy
CBRN – Chemical, Biological, Radiological, and Nuclear
CDC – Centers for Disease Control and Prevention
CDR – Communicable Disease Report (England)
CHCS - Composite Health Care System
CIA – Central Intelligence Agency
CME - Continuing Medical Education
CONUS – Continental United States
DARPA – Defense Advanced Research Projects Agency, the central research and development organization for the Department of Defense
DHHS – Department of Health and Human Services
DNBI - Disease Non-Battle Injury
DoD - Department of Defense
DOE – Department of Energy
DOS – Department of State
DOT – Department of Transportation
ECG - Electrocardiogram
EISS – European Influenza Surveillance Scheme
EPA – Environmental Protection Agency
ESSENCE – Electronic Surveillance System for the Early Notification of Community-Based Epidemics
EU - European Union
FAO - Food and Agriculture Organization (of the United Nations)
FBI – Federal Bureau of Investigation
FCC - Federal Communications Commission
FDA – Food and Drug Administration
FEMA – Federal Emergency Management Agency
FMD – Foot and Mouth Disease
FSIS – Food Safety Inspection Service
FTC - Federal Trade Commission
GAO – US General Accounting Office
GEIS – Global Emerging Infections System
HACCP – Hazard Analysis Critical Control Points
HIV/AIDS – Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
IAEA – International Atomic Energy Agency
ICBM – Intercontinental Ballistic Missile
ICRC – International Committee of the Red Cross
IDP – Internally Displaced Persons
ILI – Influenza-Like Illness
IND - Investigational New Drug
IRCS – International Red Cross Society
JAMA - Journal of the American Medical Association
JTF – Joint Task Force
K-FOR – Kosovo Forces, a NATO-led international peace enforcement force that entered Kosovo on 12 June 99 under a UN mandate. http://www.kforonline.com/
MMR - Measles, Mumps, and Rubella
MRSA - Methicillin Resistance *Staphylococcus aureus*
NAS – National Academy of Sciences
NATO – North Atlantic Treaty Organization
NCI – National Cancer Institute

NEJM – New England Journal of Medicine
NICHHD – National Institute of Child Health and Human Development
NIH – National Institutes of Health
NIOSH – National Institute for Occupational Safety and Health
NPIC – National Pesticide Information Center
NRC – Nuclear Regulatory Commission
OEF - Operation Enduring Freedom
OIE – World Organisation [sic] for Animal Health
OSHA - Occupational Safety and Health Administration
PA – Protective Antigen
PAHO - Pan American Health Organization: http://www.paho.org
PCBs - Polychlorinated Biphenyls; more info is at EPA: http://www.epa.gov/opptintr/pcb/
PCR – Polymerase Chain Reaction
PHLS – Public Health Laboratory Service
PHS – Public Health Service
PPE – Personal Protective Equipment
RSV – Respiratory Syncytial Virus
TB – Tuberculosis
UK – United Kingdom – England, Northern Ireland, Scotland, and Wales
UN – United Nations
UNHCR – United Nations High Commissioner for Refugees
USAID - United States Agency for International Development
USAMRIID – United States Army Medical Research Institute for Infectious Diseases
USDA – United States Department of Agriculture
USPSTF – United States Preventive Services Task Force
VA - Veteran's Administration
vCJD - variant Creutzfeldt-Jakob Disease
VOA – Voice of America, an international multimedia broadcasting service funded by the US Government
WHO – World Health Organization
WIA - Wounded in Action
WMD – Weapons of Mass Destruction

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Subject: USACHPPM Health Information Operations Update - 15 March '02

> Ladies and Gentlemen,
> For your information.
> The USACHPPM Health Information Operations Update provides information
> regarding global medical and veterinary issues of interest to the US Army.
> This information is sent to provide an increased awareness of current and
> emerging health-related issues.
> <<15 Mar 02 HIO update.doc>>
> Very Respectfully,
> LTC (b)(6)
> Deputy Chief of Staff for Operations
> USACHPPM
> DSN (b)(6)

> Comm (b)(6)
> FAX (b)(6)
> email: (b)(6)
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Deployment Health Support Directorate
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Chief, Case Management Assignment Team
Deployment Health Support Directorate
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USACHPPM
HEALTH INFORMATION OPERATIONS (HIO)
WEEKLY UPDATE

15 March 2002

The HIO Weekly Update provides information regarding global medical and veterinary issues of interest to the United States (US) Army. The weekly update does not attempt to analyze the information regarding potential strategic or tactical impact to the US Army and as such, should not be regarded as a medical intelligence product. Medical intelligence products are available at http://mic.afmic.detrick.army.mil/. The information in the HIO Weekly Update should provide an increased awareness of current and emerging health-related issues.

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HOT ISSUES

Agent Orange - IOM Study

On 27 February, the IOM released a report, "Veterans and Agent Orange: Herbicide/ Dioxin Exposure and Acute Myelogenous Leukemia (AML) in the Children of Vietnam Veterans." The report found inadequate or insufficient evidence that an association exists between exposure to herbicides used in Vietnam or their contaminants and AML in the children of Vietnam veterans. This finding updates an earlier report released on 19 April that found limited or suggestive evidence of an association. The new report is based on a corrected study and other newly reviewed research results. The report is at http://www.nap.edu/catalog/10309.html.

Anthrax Vaccine Adsorbed (AVA) - IOM Study

On 6 March, the IOM released a report, "The Anthrax Vaccine: Is it Safe? Does it Work?" The report concluded that the AVA, as licensed, is an effective vaccine and acceptably safe to protect against anthrax, including inhalational anthrax. The IOM also recommended: (1) studies to determine a quantitative correlation between antibody levels in vaccinated test animals that protect them from bacterial challenge and antibody levels in fully-vaccinated humans so that these correlates can be used to test the efficacy of AVA, (2) DoD support additional studies to determine how long after exposure antibiotics should be given to vaccinated individuals to provide protection, (3) DoD continue support of a CDC study to assess a reduced-dose vaccination schedule with intramuscular administration, (4) future studies continue to include separate analyses for women and men in monitoring and studying health events following vaccination, (5) DoD develop systems to enhance monitoring of later-onset health conditions that might be associated with vaccination, (6) monitoring of AVA be continued in the renovated production facility to assess immunogenicity, stability, and possible adverse events, (7) DoD develop the Defense Medical Surveillance System to regularly test hypotheses that emerge from the Vaccine Adverse Event Reporting System and other sources, (8) DoD evaluate options for longer-term follow-up of possible health effects of AVA and other service-related exposures, (9) DoD expedite research efforts on anthrax disease, the organism, and the vaccine. The report mentioned that DoD should encourage participation in the Millennium Cohort Study, which will follow 140,000 military personnel during and for up to 21 years after their active service to evaluate the health risks of military deployment. The report is at http://www.nap.edu/catalog/10310.html?se_side.

Immunization Safety Review - IOM

On 20 February, the IOM released the report, "Immunization Safety Review: Multiple Immunizations and Immune Dysfunction." The report found that epidemiological evidence did not support a causal relationship between multiple immunizations and an increased risk for infections and for type 1 diabetes. The report also concluded that epidemiological evidence was inadequate to accept or reject a causal relationship between multiple immunizations and risk for allergic disease, particularly asthma. The Committee recommended a continued focus on policy analysis, research, and communication strategy development. The Committee did not recommend a review of the vaccine licensure or immunization schedule for infants based on concerns about immune dysfunction. The report is at http://www.nap.edu/catalog/10306.html.

Influenza A (H1N2) Surveillance - WHO

On 8 March, the WHO reported that between September 2001 and February 2002, influenza A (H1N2) viruses have now been isolated from cases in Canada, Egypt, France, India, Israel, Latvia, Malaysia, Oman, Singapore, the UK, and the US. The 2001-02 influenza vaccine is expected to provide good protection against this virus, as it is a reassortment of the influenza A (H1N1) and (H3N2) strains that are represented in the vaccine. The WHO also reported that existing serological and molecular reagents could be used for identification and characterization of the influenza A (H1N2) viruses. The report is at http://www.who.int/wer/pdf/2002/wer7710.pdf.

Influenza Surveillance – DoD

The DoD Worldwide Influenza Surveillance Program is a laboratory-based influenza surveillance program managed by the Air Force. As of 7 March, 420 (19%) of 2,247 submitted specimens have been identified as positive for influenza since the start of the influenza season (29 September): 415 (99%) were influenza A and 5 (1%) were influenza B. One influenza B virus identified during the past week was of the B/Victoria lineage (NAB Little Creek, VA). The CDC reported last week that the B component of the influenza vaccine for 2001-02 is expected to provide lower levels of protection against viruses of the B/Victoria lineage. Natural immunity to B/Victoria is also expected to be low since this substrain has not circulated for over a decade. The influenza vaccine for 2002-03 will provide protection against the B/Victoria lineage. Of the influenza A isolates, 77 (18%) have been subtyped, and 72 (94%) were influenza A (H3N2) and 5 (6%) were influenza A (H1N1). The first influenza A (H1N2) reassortment strain was identified in a sample from Kunsan, South Korea. Further info, including data from the CDC and international sites, is available at:
https://pestilence.brooks.af.mil/Influenza/

Note: Some users may experience difficulty accessing this link directly from this document; if this occurs, copy and paste the hyperlink in your browser address bar.

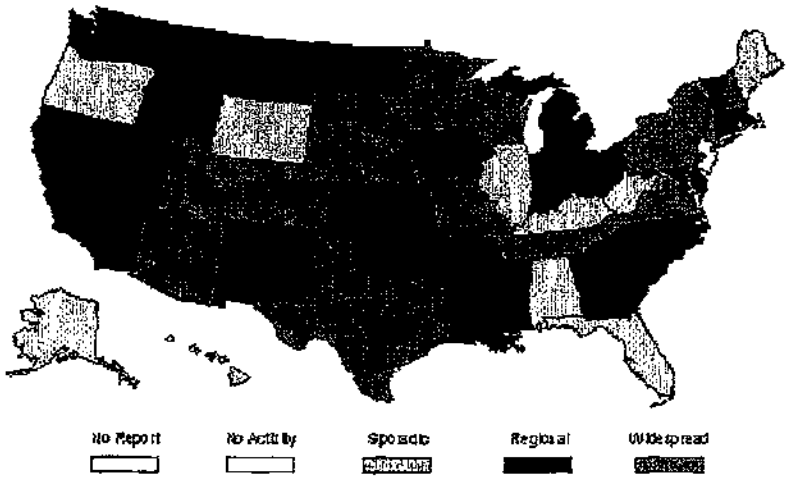
Influenza Surveillance – US

The report for the week ending 23 February (week 8) indicated that during this week overall national visits to physicians for influenza-like illness were 3.5%, which is above the national baseline of 1.9%. Deaths attributed to pneumonia and influenza were 8.1%, which is below the epidemic threshold of 8.3% for this week. For week eight,

laboratory reports indicated 752 (25.9%) of 2,902 respiratory specimens were positive for influenza: 164 influenza A (H3N2), 13 influenza B, and 575 influenza A viruses with unspecified subtype. Since 30 September, 7,499 (13.4%) of 55,876 submitted specimens were positive for influenza: 7,402 (99%) were influenza A and 97 (1%) were influenza B. Of the 7,402 influenza A viruses, 2,188 (30%) were subtyped with the following results: 2,162 (99%) were influenza A (H3) and 26 (1%) were influenza A (H1) viruses. All viruses that have been antigenically characterized (258) were similar to the vaccine strains A/Panama/2007/99 (H3N2), A/New Caledonia/20/99 (H1N1), and B/Sichuan/379/99 (H3N2). The CDC classified influenza during the eighth week of the 2002 influenza season as in the map below. The report is at http://www.cdc.gov/ncidod/diseases/flu/weekly.htm.

Weekly Influenza Activity Estimates Reported by State & Territorial Epidemiologists

Week ending February 23, 2002 - Week 8



Picture courtesy of the CDC at http://www.cdc.gov/ncidod/diseases/flu/weekly.htm.

Childhood Vaccine Shortages - CDC

On 8 March, the CDC reported that *Varicella* vaccine shortages would not be resolved until possibly early summer 2002. The highest incidence of disease is among elementary school aged children. The ACIP recommends all vaccine providers in the US delay administration of the routine childhood *Varicella* vaccine dose from age 12-18 months until age 18-24 months. If the shortage persists after delaying the 12-18 months dose and is of sufficient severity to require further prioritization, then ACIP recommends the following prioritizations (from highest to lowest) for vaccination: (1) healthcare workers, family contacts of immunocompromised persons, adolescents 13 years of age and older, and adults and high risk children (children with HIV and children with asthma or eczema), (2) susceptible children age 5-12 years, particularly children entering school and adolescents aged 11-12 years, and (3) children 2-4 years of age. States may prioritize these categories further.

The measles, mumps and rubella (MMR) vaccine supply shortage is expected to last for 1-3 more months. Two doses of MMR separated by at least a month and administered on or after the first birthday, are recommended for persons who lack adequate documentation of vaccination or other acceptable evidence of immunity. The first dose is recommended at age 12-15 months and the second dose at age 4-6 years. If providers are unable to obtain sufficient MMR vaccine for these recommendations, then ACIP recommends the second dose be deferred. Due to the severity of measles in young children, providers should not delay administration of the first dose. The CDC recommends that records be maintained such that persons who experience a delay in vaccination can be recalled when vaccine becomes available. The report is at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5109a6.htm.

USCENTCOM

Child Malnutrition - Gaza

On 7 March, the UN reported that cases of malnutrition among Palestinian children under five years of age had more than doubled in the past year, which was believed to be due to decreased delivery of relief supplies caused by the economic blockade of the Gaza Strip. According to the report, the World Bank issued a statement indicating that economic collapse remained a real prospect if confrontations in the region continue and that "serious health and environmental problems are emerging." The report is at http://www.reliefweb.int/w/rwb.nsf/6686f45896f15dbc852567ae00530132/ed6c394bff3ddeca85256b75005b9c46?OpenDocument.

Medical Staff Protection Appeals - ICRC

On 7 March, the ICRC issued an appeal to Israeli authorities to take immediate steps to protect medical personnel and conduct a full inquiry into the recent deaths of medical personnel. On 7 March in two separate incidents in Tulkarem, the Israel Defense Forces shot and killed an ambulance driver and a UN employee, who were attempting to aid wounded. A physician inside the Tulkarem ambulance station suffered a leg wound, and shrapnel critically wounded another paramedic as he was trying to evacuate casualties. These latest incidents follow the death on 4 March of the head of the emergency medical service in Jenin and the wounding of five medical staff when Israeli troops shot at their ambulances in the Jenin refugee camp. All ambulances were reportedly marked clearly with the Red Crescent emblem, and the ICRC had cleared their mission in Jenin and Tulkarem with the Israeli authorities. The report is at http://www.icrc.org/icrceng.nsf/8f7eed1263126d254125634d00375313/72f40615d42bd8e8c1256b7600567631?OpenDocument.

Chromated Copper Arsenate (CCA) Spill - Djibouti

On 11 March, the IRIN reported that a four-member UN team and an ecotoxicologist from Switzerland are assessing a CCA spill that occurred in the port of Djibouti in January. The team has determined that five sites have been contaminated and a number of people are under treatment in local hospitals. Also, some domestic animals that entered the site have died. The Djibouti authorities state that they have completed the first phase clean up, which consisted of isolating the contaminated areas and equipment. The second phase may involve isolating the toxic material itself and treating

the contaminated soil, which will likely require international assistance. The report is at http://www.irinnews.org/report.asp?ReportID=24452&SelectRegion=Horn_of_Africa&SelectCountry=DJIBOUTI.

Unidentified Epidemic - Afghanistan

On 8 March, Reuters Health reported the WHO was attempting to evacuate two physicians and six aid workers as well as provide medication to villagers and collect blood samples from the isolated Taiwara village in the Ghor province of central Afghanistan, where 40 people had died of an "unidentified epidemic." The WHO had not been able to gain access to the mountainous location as of the report. The report is at http://www.reutershealth.com/archive/2002/03/08/eline/links/20020308elin021.html.

Weather Implications - Greater Horn of Africa

On 4 March, the IRIN reported on the forecasts developed by the ninth Climate Outlook Forum held in Kenya during mid-February. March to May is the important rainfall season over equatorial areas of the Greater Horn of Africa. The forum predicted normal- to above-normal rainfall during March-May in much of Kenya and Uganda, northern Tanzania, Rwanda, Burundi, southern and central Sudan, western Eritrea, Somalia, and eastern Ethiopia. The positive aspects include normal- to above-normal agricultural and livestock production, adequate water supply for domestic and industrial use, and stable hydroelectric power. The negative aspects include localized flooding, an increase in water-related diseases, especially malaria, soil erosion and landslides, and severe, potentially damaging storms. Potential for an El-Nino type weather system is possible, but modeling systems will be more accurate towards May. In 1997-98 El Nino caused considerable health and economic loss in the region. The forum also predicted below normal rainfall for northern coastal and northwest Kenya, southern Somalia, northeastern Uganda, southern Tanzania, and northern parts of southern Sudan. These regions can expect declining livestock numbers, poor health among pastoralists and their livestock, poor food security and high poverty with increased conflicts over limited water and pasture. Concerns are especially grave in northern Kenya and southern Somalia, where prolonged drought has already caused considerable hardships. The report is at http://www.reliefweb.int/w/rwb.nsf/6686f45896f15dbc852567ae00530132/83b08f0b3bb0d42649256b7300151575?OpenDocument.

Map Courtesy of http://www.lib.utexas.edu/maps/africa/africa_pol01.jpg

Meningococcal Disease (MCD) - Ethiopia

On 8 March the WHO reported that as of 3 March, a total of 2,329 reported cases of MCD (118 deaths) had occurred in Ethiopia since the onset of the outbreak began in September 2001. This is an increase of 1,029 reported cases and 33 deaths since last month. The worst affected region is the Southern Nations, Nationalities and Peoples Region (SNNPR) with 2,022 cases and 89 deaths. Ethiopia issued an appeal for $2.5 million to carry out a mass immunization campaign in five SNNPR priority zones. The report is at http://www.who.int/disease-outbreak-news/2002/march/8amarch2002.htm.

USEUCOM

Ebola / Viral Hemorrhagic Fever - Gabon and Republic of the Congo

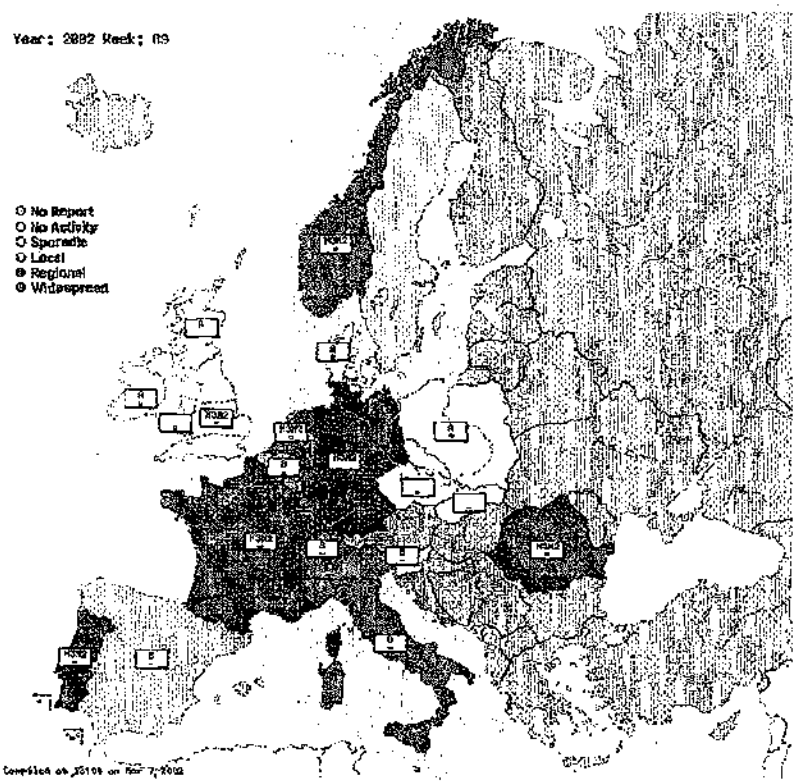
On 6 March, the WHO reported that as of 4 March, the Gabon Ministry of Health had reported 60 confirmed Ebola cases and 49 deaths. This is an increase of 11 confirmed cases and 7 deaths since the last HIO report on 7 February. On 8 March, the *VOA News* reported that the international humanitarian group Doctors Without Borders is sending members to a northeastern area near the town of Mbomo in the Republic of the Congo, where cases have been discovered in recent days. The WHO report is at http://www.who.int/disease-outbreak-news/n2002/march/6march2002.html.

HIV Lookback Denied - England

On 9 March, the British Medical Journal reported that an appeal court ruling last week barred the media from identifying an English health authority that has not contacted former patients of an HIV positive dentist almost a year after learning of his HIV status. No decision has yet been reached on whether to contact dental patients of the dentist, who has now developed AIDS. New official guidelines are expected as early as mid-March regarding the contact and counsel of patients who had invasive procedures performed by HIV positive healthcare workers. Last November, ministers agreed in principle that contact of patients should not be automatic but should be considered on a case-by-case basis. The public interest in preserving the confidentiality of healthcare workers with AIDS is that it would encourage self-reporting of HIV positive status. The report is at http://bmj.com/cgi/content/full/324/7337/564.

Influenza Surveillance – Europe

For week nine, 25 February - 3 March, the EISS reported a decrease in influenza activity across the majority of the European countries. Widespread influenza activity was reported in four countries: Italy, the Netherlands, Norway, and Switzerland. Of these four countries, the weekly clinical morbidity rates were only increasing in the Netherlands. Three networks reported increasing influenza activity with a geographic spread described as sporadic (Poland) or regional (Germany and Romania). Influenza A was dominant in 11 networks of which seven reported the dominant subtype was H3N2; one network reported co-circulation of H1N1 and H3N2. Influenza B was dominant in Belgium, Italy, Slovenia, Spain, and Switzerland. No cases of influenza A (H1N2) or influenza B/Victoria/2/87-like viruses were reported during this week. The report is at http://www.eiss.org/cgi-files/bulletin_v2.cgi?display=1&code=58&bulletin=58



Picture Courtesy of EISS at http://www.eiss.org/cgi-files/bulletin_v2.cgi?display=1&code=55&bulletin=55.

Meningococcal Disease (MCD) - Burkina Faso

On 8 March, the WHO reported that as of 3 March, a total of 1,874 reported cases of MCD (329 deaths) had occurred in Burkina Faso since the outbreak began in December. The districts of Diebougou, Pama, Pissy, and Yako have reached the epidemic threshold. A mass immunization campaign is underway in Diebougou, Pissy, and Yako. The report is at http://www.who.int/disease-outbreak-news/n2002/march/8march2002.html.

Post-Traumatic Stress Disorder - UK Lawsuit

On 9 March, the British Medical Journal reported that nearly 2,000 veterans of combat in Northern Ireland, the Gulf War, the Falklands, and the Balkans, who have been diagnosed with post-traumatic stress disorder and other stress conditions are suing the UK's Ministry of Defense for negligence in failing to prepare them for the horrors of battle, screen out vulnerable individuals, debrief them properly, recognize and treat post-traumatic stress disorder, and help them cope with a return to civilian life. The high court trial is expected to last seven months and to hear evidence from the US, the UK, and Israel. The report is at http://bmj.com/cgi/content/full/324/7337/563.

Third Generation Contraceptive Pill - UK Lawsuit

On 9 March, the British Medical Journal reported that over 100 women and the families of seven dead women filed a compensation claim under the 1987 Consumer Protection Act in the High Court in London against Schering Healthcare (manufacturer of Femodene), Wyeth (Minulet and Tri-Minulet), and Organon Laboratories (Marvelon and

Mercilon). The claim cites independent studies that reportedly show third generation contraceptive pills have more than twice the risk of venous thromboembolism as second-generation predecessors. Studies by the manufacturers show little or no increased risk of venous thromboembolism. The case is scheduled to last five months and will likely generate media interest. The report is at http://bmj.com/cgi/content/full/324/7337/561.

USJFCOM

Joint Task Force Surgeon's Seminar - USJFCOM

On 11-15 March, the eighth annual Joint Task Force (JTF) Surgeon's Seminar will be held for senior medical officers from across DoD. The topics that will be discussed include crisis action planning, force health protection, health service support for all branches of the armed forces, special operations, and for the first time, planning for a homeland security incident. The seminar is designed to better prepare senior medical officers for the role of the JTF surgeon in the joint operational environment. The report is at http://www.jfcom.mil/NewsLink/StoryArchive/2002/pa022502.htm.

Nitrofurans Ban - Food-Producing Animals

On 7 May 02, the extra-label, e.g., topical, use of nitrofuran drugs in food-producing animals will be prohibited because of a public health risk, unless the FDA modifies the rule or extends the comment period. The FDA decision is based on evidence that nitrofuran drugs may induce carcinogenic residues in animal tissues. Systemic use of nitrofurans in poultry and swine has been banned since 1991. A recent (1998) carbon-14 radiolabel residue depletion study by FDA demonstrated that cattle treated with an ophthalmic preparation had residues of the drug present in edible tissues (milk, meat, kidney, and liver). The report is at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-2751-filed.

Psychologists Prescription Authority - New Mexico

On 6 March, the American Psychological Association (APA) reported that New Mexico was the first state to institute a law allowing properly trained psychologists to prescribe psychotropic medications to patients. Psychologists will be given a prescription-training program, which is based on a model used by the DoD to train psychologists in the military to prescribe psychotropic medication for patients. Only a handful of US Army psychologists have completed the rigorous two-to-three year test program and are currently authorized to prescribe medication. The APA report cites that there are only 18 psychiatrists for 72% of the state's residents who live outside of Albuquerque and Santa Fe. The waiting time for a psychiatrist ranges from six weeks to five months in these areas, and 75% of those with mental health disorders are not receiving treatment. Suicide in New Mexico is 75% higher than the national average. The report is at http://www.apa.org/practice/nm_rxp.html.

Tularemia, 1990-2000 - US

On 8 March, the CDC released a report summarizing tularemia cases reported during 1990-2000, which indicated a low level of natural transmission. During this time, 1,368 cases were reported from 44 states, which averaged 124 cases per year. Four states

accounted for 56% of all reported cases: Arkansas (315 cases, 23%), Missouri (265 cases, 19%), South Dakota (96 cases, 7%), and Oklahoma (90 cases, 7%). The age range with the highest incidence was in persons 5-9 years of age and persons over 75 years of age. Males had a higher incidence in all age categories. Of the 936 cases reported with date of onset, 654 cases (70%) reported onset during May-August, but cases were reported during all months of the year. Historically, most cases of tularemia during the summer were related to arthropod bites and during the winter were related to hunters coming into contact with infected rabbit carcasses. Outbreaks of tularemia in the US have been associated with muskrat handling, tick bites, deer fly bites, and lawn mowing or cutting brush. Outbreaks of pneumonic tularemia, particularly in low-incidence areas, should prompt consideration of bioterrorism. The report is at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5109a1.htm.

USPACOM

Agent Orange Conference - Vietnam

On 6 March, the *VOA News* reported that US and Vietnamese scientists had concluded a joint conference in Hanoi and agreed on actions to deal with the effects of the toxic defoliant Agent Orange used by US forces in the Vietnam War. The EPA recently launched a pilot project to improve test methods for detecting Agent Orange and its main toxic ingredient, dioxin at a known Agent Orange hotspot near Danang. Vietnam estimates that nearly one million of its citizens have been affected by the "chemical warfare." The US says no scientific evidence exists to link dioxin to a variety of illnesses, such as birth defects, cancer, and nervous disorders. The US military sprayed nearly 11 million gallons of Agent Orange and other defoliants over Vietnam from 1962 until 1971, when their use was halted after their toxic nature became known. The report is at http://www.voanews.com/article.cfm?objectID=4DC74A0D-3930-4015-89F8E2B68E8B53A2&Title=US%2C%20Vietnam%20End%20Conference%20on%20Agent%20Orange&CatOID=45C9C786-88AD-11D4-A57200A0CC5EE46C.

Earthquake - Philippines

On 5 March, The National Earthquake Information Center reported an earthquake measuring 6.8-magnitude with an epicenter near Mindanao island in the southern Philippines. On 8 March, The Manila Times reported 15 deaths, which were primarily caused by falling debris but included four heart attacks at the height of the tremor. Over 27,000 people fled the coastal areas in fear of tsunamis or tidal waves or an eruption of Mount Parker volcano, neither of which occurred. The Manila Times report is at http://www.manilatimes.net/national/2002/mar/08/top_stories/20020308top7.html.

Leaded Gasoline - Asia

On 7 March, the WHO announced that more than 300 environmental and health experts, who met at the First International Conference on Environmental Risks to Children's Health in Thailand, had called for Asian governments to move quickly to remove lead from gasoline. The experts cited studies in Europe and the US that have shown removal of lead from gasoline had led to reduced levels of lead in children's blood by 90 percent, which in turn led to a 30-40 percent reduction in learning disabilities. The conference attendees also recommended governments should take

measures to eliminate environmental tobacco smoke in public areas and encourage parents to stop tobacco smoking in homes which have children. The report is at http://www.who.int/inf/en/pr-2002-15.html.

USSOUTHCOM

Dengue Fever - Brazil

On 4 March, the CDC reported that 75,000 recent cases (25 deaths) of dengue fever, including about 35,000 (14 deaths) in Rio de Janeiro, have been reported in Brazil through February 2002. Dengue fever is common in Brazil, but these figures represent a significant increase when compared to recent years. Many other countries in South and Central America are also reporting increased dengue activity. The risk for contracting dengue fever is less in rural areas and at altitudes above 4,500 feet. The CDC advised that disease surveillance varies from country to country and that epidemics are not always reported in all countries. The report is at http://www.cdc.gov/travel/other/dengue-brazil-mar2002.htm.

River Blindness - *Onchocerca volvulus*?

On 8 March, *Science Magazine* reported that antibiotic treatment to clear *Wolbachia*, a ubiquitous bacterium that colonizes the nematode *O. volvulus* and thought to be at least partially responsible for river blindness or ocular onchocerciasis, might reduce and prevent the disease. Historically, the disease was thought to be caused by a severe inflammatory response caused by *O. volvulus* microfilaria, which migrated to the eye after transmission from female black fly bites. The disease occurs in Central and South America, Africa, and Yemen. The report is at v. Saint Andre, A, et al. The role of endosymbiotic *Wolbachia* bacteria in the pathogenesis of river blindness. Science 2002 295: 1892-95.

USACHPPM New Products

Irradiated Mail - Web Resource

The anthrax attacks of October 2001 targeted Federal offices and affected mail processed in the Brentwood Postal Facility in Washington, D.C. Other Federal agencies in the Washington area may become targets for this kind of attack, or they may receive mail affected by attacks on other agencies. This website provides a fact sheet and current information on irradiated mail as a countermeasure: http://chppm-www.apgea.army.mil/IrradiatedMail/.

Please contact the below-listed POC for suggested improvements and/or comments regarding this report. This report is also available on the USACHPPM website at http://chppm-www.apgea.army.mil/Hioupdate/.

POC: (b)(6) DVM, MPH/MCHB-CS-OHD, (b)(6)
mailto:(b)(6) @APG.amedd.army.mil

ACRONYMNS

ACIP - Advisory Committee on Immunization Practices
AFPS – American Forces Press Service
AIDS – Acquired Immunodeficiency Syndrome
APHIS – Animal and Plant Health Inspection Service
BSE – Bovine Spongiform Encephalopathy
CBRN – Chemical, Biological, Radiological, and Nuclear
CDC – Centers for Disease Control and Prevention
CDR – Communicable Disease Report (England)
DHHS – Department of Health and Human Services
DoD - Department of Defense
DOE – Department of Energy
DOS – Department of State
EISS – European Influenza Surveillance Scheme
EPA – Environmental Protection Agency
FBI – Federal Bureau of Investigation
FCC - Federal Communications Commission
FDA – Food and Drug Administration
FEMA – Federal Emergency Management Agency
FMD – Foot and Mouth Disease
FSIS – Food Safety Inspection Service
GAO – US General Accounting Office
HIV – Human Immunodeficiency Virus
IAEA – International Atomic Energy Agency
ICBM – Intercontinental Ballistic Missile
ICRC – International Committee of the Red Cross
IDP – Internally Displaced Persons
ILI – Influenza-Like Illness
IOM - Institute of Medicine, part of the National Academy of Sciences
IRCS – International Red Cross Society
IRIN - Integrated Regional Information Networks, part of the United Nations (UN) Office for the Coordination of Humanitarian Affairs (OCHA), a UN humanitarian information unit that may not necessarily reflect the views of the UN or its agencies
NAS – National Academy of Sciences
NATO – North Atlantic Treaty Organization
NCI – National Cancer Institute
NIH – National Institutes of Health
NIOSH – National Institute for Occupational Safety and Health
NRC – Nuclear Regulatory Commission
OIE – World Organisation [sic] for Animal Health
OSHA - Occupational Safety and Health Administration
PCR – Polymerase Chain Reaction
PHLS – Public Health Laboratory Service
PHS – Public Health Service
PPE – Personal Protective Equipment
UK – United Kingdom – England, Northern Ireland, Scotland, and Wales
UN – United Nations
UNHCR – United Nations High Commissioner for Refugees
USDA – United States Department of Agriculture
USPSTF – United States Preventive Services Task Force
VOA – Voice of America, an international multimedia broadcasting service funded by the US Government
WHO – World Health Organization

LTC CMAT Control # 130
2002252-0000006

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TO: (b)(6)
FAX

FROM: (b)(6)
PHONE

Inquiry on Use of Drugs, Vaccines or Toxoids in Pregnant Women During the Gulf War

1. Drugs - Pyridostigmine

   a. Used as a nerve agent pretreatment
   b. Most soldiers received this treatment (200,000 - 300,000)
   c. Drug licensed by FDA for treatment of myasthenia gravis
   d. IND status but waiver of informed consent was obtained from FDA
   e. Number of women given pyridostigmine is unknown.
   f. "Risk benefit determination" is used for use in pregnant women

2. Anthrax Vaccine

   a. FDA Licensed vaccine
   b. Killed vaccine (no living components)
   c. No consent forms needed or used.
   d. Affect on Pregnant women has not been determined (see enclosure)
   e. Estimated 150,000 soldiers given this vaccine but number of women is unknown.

3. Botulinum Toxoid

   a. Toxoid is an inactivated toxin and as such is a dead product.
   b. IND status but waiver of informed consent was obtained from FDA
   c. Given to approximately 8,000 soldiers in the initial assault units.
   d. Unlikely women, let alone pregnant ones, were in such *combat* units.

4. Conclusions.

   a. No pregnant women were sent to the Gulf.
   b. Women who became pregnant after deployment were sent home.
   c. Unlikely that any women were given Botulinum toxoid.
   d. Unknown number of women were given pyridostigmine but no information is known on number or pregnancy status.
   e. Unknown number of women were given anthrax vaccine but no information is known on number or pregnancy status.

Prepared by LTC (b)(6) fax (b)(6) / U.S. Army Medical Research, Development, Acquisition, and Logistics Command (provisional), Pentagon Liaison Office, Rm. 3D425.

CMAT Control #
2002351-0000003

BRIEFING

GAO REPORT ON DOD BIOLOGICAL DEFENSE RESEARCH PROGRAM (BDRP)

GENERAL GORDON R. SULLIVAN
VICE CHIEF OF STAFF
ARMY

1 FEBRUARY 1991

COL GEORGE E. LEWIS, JR.
EXECUTIVE ASSISTANT TO THE ASSISTANT SURGEON GENERAL FOR RESEARCH AND DEVELOPMENT / OTSG LIAISON TO THE ASSISTANT SECRETARY OF THE ARMY (RDA).

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"ARMY FAULTED ON GERM WARFARE RESEARCH"

WASHINGTON POST ARTICLE
29 JANUARY 1991

POST ARTICLE CONFUSES TWO ISSUES

- EFFICACY OF ANTHRAX VACCINE

- GAO REPORT "BIOLOGICAL WARFARE: BETTER CONTROLS IN DOD'S RESEARCH COULD PREVENT UNNEEDED EXPENDITURES" (BDRP)

EFFICACY OF ANTHRAX VACCINE

CURRENT VACCINE

- ARMY DEVELOPED; MANUFACTURED BY MICHIGAN DEPARTMENT OF PUBLIC HEALTH
- REACTIONS MINIMAL AND LOCALIZED; SUBSIDE WITHIN 48 HRS
- EFFICACY GOOD
  - *VACCINE IS SAFE AND EFFECTIVE FOR OCCUPATIONAL EXPOSURES*
  - *THE BEST ANTHRAX VACCINE AVAILABLE FOR U.S. TROOPS*

- CURRENT RESEARCH DIRECTED TOWARD A "PERFECT" VACCINE
- PROTECTION WITH 1 SHOT, "INSTANT" IMMUNITY AND ZERO REACTIONS.

BIOLOGICAL DEFENSE RESEARCH PROGRAM (BDRP)

PURPOSE: "PROMOTE AND MAINTAIN A SOLID NATIONAL DEFENSE POSTURE, IN CONSONANCE WITH NATIONAL POLICY, WITH RESPECT TO POTENTIAL BIOLOGICAL WARFARE THREATS."

- 1972 BIOLOGICAL AND TOXIN WEAPONS CONVENTION PROHIBITS DEVELOPMENT, PRODUCTION AND STOCKPILING OF BIOLOGICAL AND TOXIN WEAPONS.

- 30 MARCH 1976, DOD IDENTIFIED THE DEPARTMENT OF THE ARMY AS THE EXECUTIVE AGENT FOR CHEMICAL AND BIOLOGICAL DEFENSE RESEARCH DEVELOPMENT AND ACQUISITION (DODD 5160.5).

- DOD, THRU BDRP, DEVELOPS MEDICAL COUNTERMEASURES AGAINST BIOLOGICAL WEAPONS ATTACK AND REPORTS ANNUALLY TO CONGRESS IAW PL 91-121 AND PL 91-441.

HISTORY OF GAO SURVEY

- FOLLOWING HEARINGS MAY 1988 THE CHAIRMAN OF SENATE COMMITTEE ON GOVERNMENTAL AFFAIRS REQUESTED THAT GAO DETERMINE WHETHER THE BDRP WAS:
  - DIRECTED AT VALIDATED BIOLOGICAL WARFARE THREAT AGENTS.
  - USED TO DEVELOP MEDICAL PRODUCTS FOR DEFENSE OF U.S. FORCES.
  - COORDINATED WITH OTHER FEDERAL AGENCIES TO AVOID OVERLAP.
- GAO STARTED INVESTIGATION OF BDRP IN SEPTEMBER 1989
- GAO FINAL REPORT FORWARDED TO CHAIRMAN OF SENATE COMMITTEE ON GOVERNMENTAL AFFAIRS ON 27 DECEMBER 1990.
- GAO FINAL REPORT FORWARDED TO DOD 27 JANUARY 1991

GAO REPORT ISSUES

- ARMY WAS GIVEN FUNDS TO BUY APPLES

  ARMY BOUGHT APPLES, AS WELL AS, PINEAPPLES AND CRABAPPLES

- BDRP FUNDS WERE USED TO COUNTER VALIDATED BW THREAT AGENTS, AS WELL AS, POTENTIAL BW THREAT AGENTS (TOXINS AND INFECTIOUS DISEASE AGENTS)

ANCILLARY ISSUES

- WHAT IS A THREAT AGENT? --- ONLY THOSE AGENTS WEAPONIZED?

- WHO DETERMINES WHAT IS A THREAT? --- GAO, AFMIC, AHS, MRDC?

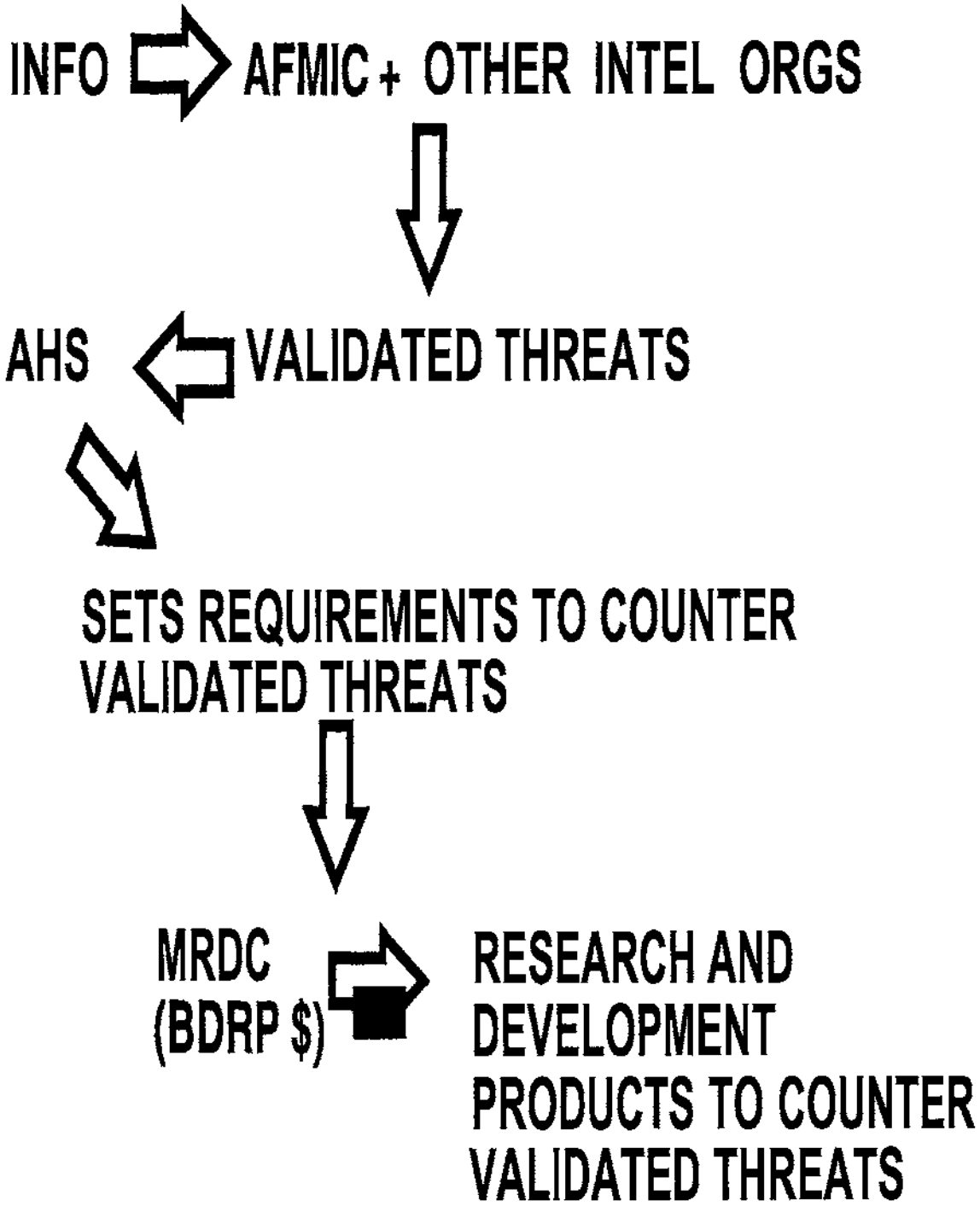
- WHO DETERMINES REQUIREMENTS TO COUNTER THREAT? --- AHS OR MRDC?

- WHO DETERMINES IF THE ARMY R&D EFFORT ADDRESSES THE REQUIREMENTS AND COUNTERS THE THREAT? --- GAO, AHS, MRDC?

- DUPLICATION?

- COORDINATION?

THE "SCHOOL" SOLUTION



GAO ASSERTS THAT

MRDC: DETERMINES WHAT IS A THREAT

MRDC: DETERMINES THE REQUIREMENTS

MRDC: DEVELOPS PRODUCTS TO MEET THE REQUIREMENT

MRDC: DETERMINES IF THE THREAT IS APPROPRIATELY ADDRESSED

THE ROLE OF AFMIC AND AHS ARE MINIMAL

THE ROLE OF MRDC IS MAXIMAL

VALIDATED THREAT VS POTENTIAL THREAT

GAO:

BDRP FUNDS MUST BE SPENT TO COUNTER ONLY VALIDATED THREATS.

ARMY:

BDRP FUNDS SPENT TO COUNTER VALIDATED AND POTENTIAL THREATS

Medical Products Developed Since 1965

Over the past 25 years, the Army completed the development of 10 medical products, costing about $24.6 million. However, 3 of the 10 products did not address validated biological warfare threats. Of the $24.6 million, about $17.1 million, or 70 percent, was spent to develop the 3 products that did not address validated threats. Table 3.1 shows the 10 products developed since 1965.

Table 3.1: BDRP Products Developed Since 1965

Dollars in millions

Product	Fiscal year	Development and initial production costs	Directed at validated threat
Vaccine, Venezuelan equine encephalitis	1966	$0.234	Yes
Vaccine, tularemia	1966	0.242	Yes
Vaccine, eastern equine encephalitis	1968	0.437	Yes
Vaccine, rift valley fever[a]	1969	12.351	No
Vaccine, Venezuelan equine encephalitis	1975	1.138	Yes
Drug, ribavirin	1979	2.702	Yes
Vaccine western equine encephalitis	1984	0.243	Yes
Vaccine, Argentine hemorraghic fever[a]	1986	4.086	No
Vaccine, chikungunya	1986	0.722	No
Vaccine, Q fever	1989	2.479	Yes
Total		$24.634	

[a]The Army used BDRP funds to develop this product, even though this disease is not a biological threat agent but a naturally-occurring, or "infectious," disease that affects large numbers of people in various parts of the world.

Appendix II

Research Conducted by the Army and Other Agencies Involving the Same Biological Agents

Biological agent	Agencies involved	
	National Institutes of Health	Centers for Disease Control
Anthrax	X	
Venezuelan equine encephalitis	X	X
Lassa fever		X
Ebola virus		X
Hemorraghic fever with renal syndrome		X
Congo Crimean hemorraghic fever		X
Dengue fever	X	X
Yellow fever	X	
Alphaviruses	X	
Eastern equine encephalitis	X	
Arboviruses	X	X
Q fever	X	
Tetanus	X	
Plague	X	
Tetrodotoxin	X	
Saxitoxin	X	
Ricin	X	
Brevetoxins	X	
Enterotoxins	X	
Hantaan virus	X	
Arenaviruses	X	
Vaccinia virus	X	
Botulism	X	

GAO RECOMMENDATIONS FOR THE BDRP

- GAO RECOMMENDS THAT SEC ARMY DIRECT MRDC TO:
  - REVIEW ALL ONGOING RESEARCH PROJECTS TO ENSURE THAT THEY ADDRESS VALIDATED BW THREAT AGENTS; DISCONTINUE THOSE THAT DONT
  - ARRANGE FOR INDEPENDENT REVIEWS OF ALL PROPOSED RESEARCH PROJECTS BY AFMIC AND AHS TO ENSURE THAT PROJECTS ADDRESS VALIDATED BW THREAT AGENTS; REPORT RESULTS OF EACH REVIEW TO TSG
  - DISCONTINUE DEVELOPMENT OF ALL PRODUCTS THAT DO NOT ADDRESS A VALIDATED THREAT
- GAO RECOMMENDS THAT THE ARMY AMEND ITS REGULATIONS TO REQUIRE SYSTEMATIC COORDINATION OF MEDICAL BIOLOGICAL RESEARCH WITH OTHER FEDERAL AGENCIES

ARMY RESPONSE TO GAO

- YES, BDRP FUNDS WERE USED TO COUNTERTHE THREAT (VALIDATED AND POTENTIAL)

  TO DO OTHERWISE WOULD PUT OUR BDRP IO-20 YRS BEHIND THE CURRENT THREAT (VALIDATED AND POTENTIAL)

- NO, BDRP EFFORTS ARE NOT DUPLICATING EFFORTS OF OTHER FEDERAL AGENCIES

- YES, WHERE APPROPRIATE, BDRP EFFORTS ARE COORDINATED WITH APPROPRIATE AGENCIES/INSTITUTES/SCIENTISTS/ALLIES

- THE MEDICAL COMPONENT OF THE BDRP IS BEING REVISED AND ADJUSTED, WHERE APPROPRIATE, IN ACCORDANCE WITH THE GAO REPORT AND RECOMMENDATIONS CONTAINED THEREIN

  - THREAT ASSESSMENT AND VALIDATION (AFMIC)
  - REQUIREMENTS PROCESS (AHS)
  - INTERNAL CONTROLS (MRDC)

USACHPPM
HEALTH INFORMATION OPERATIONS (HIO) UPDATE

31 January 2003

The HIO Update provides information regarding global medical and veterinary issues of interest to the United States (US) Army. The update does not attempt to analyze the information regarding potential strategic or tactical impact to the US Army and as such, should not be regarded as a medical intelligence product. Medical intelligence products are available at http://mic.afmic.detrick.army.mil/. The information in the HIO Update should provide an increased awareness of current and emerging health-related issues.

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HOT ISSUES

Blood Test for Lung Cancer May be Possible

28 January - Science Health News reported a blood test that can detect one of the forms of lung cancer before it takes hold may become possible following new Russian research. Alexandr Bazhin of the Belozersky Institute of Physico-Chemical Biology at Moscow State University and colleagues say they have discovered a series of antibody markers that could form the basis of a new screening tool for 'small cell' lung cancer. Cancerous cells are known to express protein 'antigens' that are alien to the body, leading it to produce antibodies that attack them in response. Several studies have shown it is possible to identify the antibodies in the serum of cancer sufferers. In theory, such antibodies could be used as 'markers' for tumors; but in practice, attempts to use individual antibodies as markers have failed. Bazhin and colleagues decided to take advantage of the fact that cancers don't just produce one antigen and antibody reaction, but a whole raft of them. The researchers extracted the antigens from a piece of small cell lung cancer to test for antibodies in people with the same type of cancer. They confirmed previous findings that no antibody, in isolation, can be used to reliably test for the cancer. The problem is that certain antibodies are also found in people with other types of cancer, and some were even found, albeit rarely, in people with no cancer. They report their findings in the February issue of the European Respiratory Journal. View Article

Bush's AIDS Pledge 'Unexpected'

President Bush, under fire from AIDS groups for what they call his neglect of the epidemic, asked Congress in his State of the Union Address to triple AIDS spending in Africa and Haiti to $15 billion over five years. AIDS campaigners and officials, taken by surprise, quickly welcomed the plan though some expressed skepticism and questioned where the money would come from. "I ask the Congress to commit $15 billion over the next five years, including nearly $10 billion in new money, to turn the tide against AIDS in the most afflicted nations of Africa and the Caribbean," Bush said. "This comprehensive plan will prevent 7 million new AIDS infections, treat at least 2 million people with life-extending drugs and provide humane care for millions of people suffering from AIDS and for children orphaned by AIDS," Bush added. On its Web site, the White House said the plan would target Botswana, Ivory Coast, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda and Zambia. View Article

Exercise Like a Drug in Heart Disease, Study Finds

23 January – Reuters reported US researchers say exercise can act like a drug on the blood vessels, reducing the risk of heart disease by literally getting the blood flowing. It works in a surprising way, reducing inflammation, which has recently joined high blood pressure and high cholesterol as a leading known cause of heart disease, the researchers said. The blood stresses the walls of blood vessels as it passes over them, reducing inflammation in a way similar to high doses of steroids. "Inflammation in blood vessels has been linked to atherosclerosis, a hardening of the arteries, and here we see how the physical force of blood flow can cause cells to produce their own anti-inflammatory response," Scott Diamond of the University of Pennsylvania's Institute for Medicine and Engineering, said in a statement. The findings could help explain why exercise works so well to reduce the risk of heart disease, Diamond said. "We're not talking about running a marathon here. We're just talking about getting the blood moving at high arterial levels," he said. View Article

Leanness, Not Diet, May Be Key to Long Life

24 January – Reuters reported dieters got a bit of hope from a study that shows a change in a single gene in mice allows them to eat as much as they want while staying thin -- and live longer. Dr. C. Ronald Kahn of the Joslin Diabetes Center at Harvard Medical School and colleagues genetically engineered a mouse that lacked a gene called fat-specific insulin receptor. This change limited the action of insulin on fat cells. The mice, which they nicknamed FIRKO mice (for fat-specific insulin receptor knock-outs), fed freely without gaining much fat and also lived longer than normal mice. They had 50 to 70 percent less fat, no matter what they ate, and also were less likely to develop diabetes than normal mice. They lived on average 134 days, or 18 percent longer than normal mice. By the age of 30 months half the normal mice had died but 80 percent of the FIRKO mice were still alive. The study is published in the journal *Science*. View Article

Preparing for a Bioterrorist Attack: Legal and Administrative Strategies

01 February – The Journal of Emerging Infectious diseases published an article that proposes and discusses legal and administrative preparations for a bioterrorist attack. To perform the duties expected of public health agencies during a disease outbreak caused by bioterrorism, an agency must have a sufficient number of employees and providers at work and a good communications system between staff in the central offices of the public health agency and those in outlying or neighboring agencies and hospitals. The article proposes strategies for achieving these objectives as well as for removing legal barriers that discourage agencies, institutions, and persons from working together for the overall good of the community. Issues related to disease surveillance and special considerations regarding public health restrictive orders are discussed. View Article

Research May Provide Clue to Ultra Quick Healing

22 January – Canoe Health reported researchers at McGill University in Montreal have found that a growth factor involved in the development of tumors speeds up the healing of wounds. The factor, progranulin, speeds up the body's ability to clean up and repair wounds, a process that is particularly difficult for people with poor circulation such as the elderly and diabetics. "It would be very useful to find ways to promote that process. That's the long-term aim," said Andrew Bateman, lead author on the resulting article, which is being published in the Feb. 1 issue of Nature Medicine. The journal has already published the paper online. View Article

Reusing Water Bottles May Pose Health Risk

26 January – The Toronto Star reported while people may think they're doing a good deed for the environment when they reuse water bottles, researchers say they could be risking their health. Dangerous bacteria and potentially toxic plastic compounds have been found in the types of water bottles typically reused in classrooms and workplaces. A study of water bottles at a Calgary elementary school found bacteria in kids' bottles that would prompt health officials to issue boil-water advisories, had the samples come from a tap. Researchers discovered bacterial contamination in about a third of the samples collected from kids' water bottles at the school. Some samples even showed evidence of fecal coliforms. The bacteria likely came from the kids' hands and mouths over time as they repeatedly used the same bottles without washing them or allowing them to dry. And a study conducted in the United States suggests the kind of thorough washing that could kill bacteria might make the bottles unsafe in another way. Frequent washing might accelerate the breakdown of the plastic, potentially causing chemicals to leach into the water, the study found. View Article

Scientists Discover Natural Antibiotic in Human Gut

27 January – Reuters reported researchers have found a potent antibacterial protein that is made naturally by the human body. The protein, dubbed Ang4, is created by cells in the intestines, according to a study published in the advance online version of the journal Nature Immunology. It is likely that Ang4 normally plays a role in protecting the lining of the intestines. "We showed that Ang4 kills many different types of gut bacteria," said Hooper, a researcher at Washington University School of Medicine in St. Louis, Missouri. "We think that Ang4 is part of the arsenal that use to keep bacteria from getting too close to the intestinal lining and causing damage." Hooper and her colleagues also found that Ang4 was a potent killer of *Listeria monocytogenes*, which has been implicated in recent cases of severe food poisoning. View Article

Too Little, Too Much Sleep Linked to Heart Disease

27 January – MSNBC News reported too little or too much sleep might raise the risk of developing heart disease, according to a study of nearly 72,000 nurses. Women who averaged five hours or less of sleep a night were 39 percent more likely to develop heart disease than women who got eight hours. Those sleeping six hours a night had an 18 percent higher risk of developing blocked arteries than the eight-hour sleepers. And nine or more hours of sleep was associated with a 37 percent higher risk of heart disease. Researchers could not explain the last finding but suggested those women might have slept more because of underlying illnesses. "People should start thinking of adequate sleep not as a luxury but more as a component of a healthy lifestyle," said Dr. Najib Ayas, a sleep disorders specialist who was at Harvard-affiliated Brigham and Women's Hospital in Boston when he led the study. The researchers suggested that getting enough sleep might be nearly as important to heart health as eating right and exercising. And they pointed out a recent poll that found that about one in three Americans has long-term sleep deprivation. The study is published in the Archives of Internal Medicine. View Article

USEUCOM

Angola: 41 New Cases of Tuberculosis

28 January – AllAfrica.com reported at least 141 new cases of tuberculosis were recorded over the last three months in Angola's southern Huila province. This brings the total number of cases to 629, the TB combat supervisor in the province, Pedro Gaspar, said. He mentioned the

massive return of displaced populations to their areas of origin, coupled with scarce food in sanitary units, as the main source of new cases of tuberculosis. With a view to reducing the prevalence in the region, the Public Health Department is considering starting a program to fight against tuberculosis. This will include the upgrading of health workers, diagnosis, prevention and treatment. View Article

Anthrax Outbreak North West South Africa: 50 Admitted to Hospital

26 January – ProMed reported the sixth outbreak of anthrax in the North West Province in 3 months has been reported at Makouspan village in Mooifontein. The first outbreak occurred at villages near the Ramatlabama border with Botswana. Nearly 50 people were admitted to hospital after eating contaminated meat. Edna Molewa, the North West Agriculture MEC, says the provincial government is taking precautions to prevent anthrax from spreading. View Report

Cholera Kills 12 in Mozambique

27 January – New 24 reported a cholera outbreak has killed 12 people and infected hundreds more in northern Mozambique, where floods that have swept away thousands of homes are speeding the spread of the disease. Virginia Saldanha, head of the health department in Sofala province, told Reuters a total of 402 cases had been reported in the past three weeks, but all the deaths had come in the past seven days. Cholera is the latest in a string of disasters to hit the impoverished southern African country, which last week reported the first deaths from starvation amid widespread food shortages. "The disease is spreading rapidly in the northern Cabo Delgado and Nampula provinces. Two people have died from a total of 67 cases reported," Saldanha said. View Article

Kenya: Government Sends Alert On Disease Outbreak

28 January – AllAfrica.com reported the Government of Kenya has issued an alert over the outbreak of communicable diseases across the country. Health Minister Charity Ngilu warned yesterday that parts of the country will experience an outbreak of malaria, cholera, dysentery and diarrhea. She said the outbreak will be occasioned by the change of weather patterns across the country. The Minister said parts of the country affected by the rains are Coast, Rift Valley, Nyanza, North Eastern and parts of Western Province. Ngilu said the government has already distributed the required medicines to all epidemic-prone areas. View Article

Many Austrians May Have High Homocysteine

24 January – Reuters reported as many as one in three Austrians may have high levels of homocysteine, an amino acid suspected of increasing the risk of heart disease, doctors said. This figure, which came from a relatively small study, is much higher than the previous estimate that one in ten Austrians have raised levels of the molecule. "We were not surprised to find that many people had high levels of homocysteine because half of all the deaths in Austria are due to heart and circulatory disease and homocysteine has been associated with these diseases," the head of the study, Dr. Bernhard Zirm, told Reuters Health. "However, we were shocked to find it was as many as one in three," added Zirm. The results of the study support the importance of a healthy lifestyle and a diet that is rich in folic acid, Zirm said. Participants who consumed the least folic acid and vitamins B6 and B12 had the highest homocysteine levels. View Article

Republic of the Congo: Ebola Virus Again Found in Dead Apes

24 January – ProMed reported a chimpanzee was found dead in the remote Odzala National Park of the Republic of the Congo last week. Apollo, the world's best-known gorilla, is missing, and Ebola virus may be the culprit. The alpha male of a 24-member family hasn't been seen since early December 2002, when 2 members of his family were found dead -- along with 3 other endangered western lowland gorillas and several chimps. Less than a year ago, contact with a dead ape was blamed for an Ebola outbreak in the area that killed at least 53 people. Specialists have again found Ebola virus in the dead apes. View Report

Seven People Die of Strange Disease in Ghana

24 January – ProMED reported a strange disease has been spreading across Ghana's Volta Region, leaving 7 people dead, according to a report reaching here from Ghana's capital Accra. The report quoted Nicholas Ahiadorme, chief executive of North Tongu District, Volta Region, as saying that 10 more people suffering from the disease were receiving treatment in the hospitals. He said symptoms associated with the disease, which has mostly affected children, include severe headache, stiff neck, running nose, and violent behaviors. According to the district official, symptoms of the disease were being reported in pockets of settlements in the district. Local medical authorities said that samples of fluids were being analyzed. View Report

UK Troop Food: Poison Suspicions

24 January – Reuters reported British authorities suspect that Islamic militants arrested this month may have been planning to use the deadly toxin ricin to poison the food of a British military base, U.S. officials said. While there was no hard evidence, it was one theory that British investigators were pursuing because one of the suspects arrested worked at a food company, officials said. U.S. authorities are not involved in the case and consider it a British matter, officials said. The New York Times reported that one of the suspects worked for a food preparation company and had been in contact with individuals who worked on at least one British base. Officials told the newspaper that they did not know the identity of the suspect or which base may have been a target. View Article

USCENTCOM

Emergence of Vancomycin-Resistant *E. faecium* in Karachi, Pakistan

26 January – ProMED reported according to a study from Pakistan, vancomycin-resistant enterococcus (VRE) has not been reported previously in Pakistan until vancomycin-resistant *Enterococcus faecium* was isolated from the clinical specimens of 6 patients admitted to the intensive care unit (ICU) and neonatal intensive care unit (NICU) of the Aga Khan University Hospital, Karachi. A total of 10 strains of vancomycin-resistant *Enterococcus faecium* were isolated. All the strains showed high-level resistance to both glycopeptides (vancomycin and teicoplanin) with a vancomycin minimum inhibitory concentration greater than 256 mg/L. All isolates had the vanA gene detected by polymerase chain reaction. The contour-clamped homogeneous electric field (CHEF) pattern demonstrated that all but one of the isolates were of a single clone, suggesting that they were derived from common source. The researchers concluded the use of vancomycin and prolonged hospitalization were common features in all cases investigated. View Report

USNORTHCOM

Agent Orange and a Cancer Are Linked, Study Shows

23 January – The New York Times reported exposure to high levels of Agent Orange, the widely used defoliant in the Vietnam War, is associated with a slight increase in the incidence of a form of leukemia called chronic lymphocytic leukemia, researchers have determined. As a result of the study, the Veterans Affairs Department announced that it would extend benefits to veterans with the disease. The Secretary of Veterans Affairs said the incidents of the cancer among veterans were relatively few, though he estimated that his department would hear from as many as 1,000 new patients a year. Because of the findings, veterans will not have to prove that their illnesses stemmed from Agent Orange exposure. Evidence of military service and a physician's diagnosis will be sufficient. View Article

CDC Releases Guidance for Clinicians on Smallpox Vaccination and Adverse Reactions

28 January – The CDC has released guidelines for clinicians on smallpox vaccination and adverse reactions. This guide is for the evaluation and treatment of patients with complications from smallpox vaccination in the pre-outbreak setting. The guidelines can be found at http://www.cdc.gov/mmwr/pdf/wk/MMWRDispatch1-24-03.pdf

Drug Resistant *Staphylococcus aureus* spreads in L.A.

28 January – ProMed reported there is an outbreak of methicillin resistant *Staphylococcus aureus* [MRSA] in Los Angeles County, California. Although the outbreak seems confined primarily to gay men, doctors say at least one woman contracted the infection, probably from a male sex partner. Because they still know so little about the extent of the outbreak, they can't predict how many people it may eventually affect. The infection, which causes nasty-looking boils, deep abscesses, and widespread surrounding inflammation, has proved impervious to common antibiotics. Although it appears to be spread primarily by skin-to-skin contact, including sex, its origins and precise mode of transmission remain a mystery. Doctors treating it caution that it could also be contracted at health clubs, steam rooms, and other warm, moist environments. "The concern is this organism could spread to and cause disease in the community at large," said Dr. Peter Ruane, an infectious disease specialist in Los Angeles. "It seems to be able to attack normal skin in healthy people." They also found that the strain contains a powerful toxin called Panton-Valentine leukocidin seen in resistant Staph outbreaks in France and in this country. No one knows whether that toxin is responsible for the microbe's ability to break through the skin. The county is sending samples to the CDC for further tests and to see if the same strain has been seen elsewhere. The epidemiologists also have seen the same strain for many months in an ongoing outbreak associated with what they will only describe as a "large institution." That outbreak remains under investigation. View Report

Emerging Pattern of Rabies Deaths and Increased Viral Infectivity

01 February – The Journal of Emerging Infectious diseases published an article that discusses rabies deaths in the United States. Most human rabies deaths in the United States can be attributed to unrecognized exposures to rabies viruses associated with bats, particularly those associated with two infrequently encountered bat species (*Lasionycteris noctivagans* and *Pipistrellus subflavus*). These human rabies cases tend to cluster in the southeastern and northwestern United States. In these regions, most rabies deaths associated with bats in

nonhuman terrestrial mammals are also associated with virus variants specific to these two bat species rather than more common bat species; outside of these regions, more common bat rabies viruses contribute to most transmissions. The preponderance of rabies deaths connected with the two uncommon *L. noctivagans* and *P. subflavus* bat rabies viruses is best explained by their evolution of increased viral infectivity. View Article

FDA: Warning on Asthma Drug Serevent

24 January - The Associated Press reported the FDA warned that some patients using a popular asthma medication are more likely to face life-threatening complications and more likely to die from their symptoms than those who are not taking the drug. Officials emphasized that problems from the drug Serevent were rare, and they said the drug's benefits outweigh the risks. They cautioned that it is dangerous to abruptly stop taking the drug and recommended that concerned patients talk with their doctors. Serevent, an aerosol spray made by GlaxoSmithKline, opens the airwaves to help asthma patients breathe more easily. Patients use it twice a day to prevent attacks. Due to concerns about the drug, Glaxo launched a large study to compare the number of life-threatening experiences, such as intubations and mechanical ventilation, and the number of asthma-related deaths in patients taking the drug vs. the number of such occurrences in patients given a placebo. The study found a greater risk of problems and a greater risk of death among black patients, and found a disparity in deaths among those who were not using a companion drug aimed at controlling inflammation. View Article

Flying SnifferSTAR May Aid Civilians and US Military

23 January – Sandia announced a half-ounce 'sniffer' intended to ride on small aerial drones to detect possible gas attacks on cities and military bases has been created by researchers at Sandia National Laboratories in partnership with Lockheed Martin Corporation. The patented device, which detects nerve gases and blister agents, operates on only half a watt of electrical power, says Sandia researcher Doug Adkins. While other gas monitors exist, "this is small, lightweight, low power, and offers rapid analysis," says Adkins. "Rapid analysis currently is not possible with any other package near this size." Discussions are underway with a US company that produces drone aircraft to include the device among sensors designed to detect biological and radiological threats. The device also has possibilities for use in or near the ventilation systems of buildings, or, with addition of a small pump, on posts surrounding military bases. View Report

Health Data Monitored for Bioterror Warning

27 January – The New York Times reported the government is building a computerized network that will collect and analyze health data of people in eight major cities to secure early warning of a bioterror attack, administration officials say. The Centers for Disease Control and Prevention is to lead the multimillion-dollar surveillance effort, which officials expect to become the cornerstone of a national network to spot disease outbreaks by tracking data like doctor reports, emergency room visits and sales of flu medicine. "Our goal is to have a model that any city could pick up and apply," a senior administration official said of the plan. Officials would not disclose the program's cost or which cities will be involved. In ambition and potential usefulness, the health network goes far beyond an environmental surveillance system, disclosed by the

administration last week that will sniff the air for dangerous germs. The emerging health monitoring network, officials and experts say, will provide information that could save lives if terrorists strike with deadly germs like smallpox or anthrax. In detecting attacks, a head start of even a day or two can greatly lower death rates by letting doctors treat rapidly and prevent an isolated outbreak from becoming an epidemic. View Article

JCAHO Taps Expert Panel to Strengthen Infection Control Standards

22 January – A JCAHO press release reported an expert group of physicians, nurses, risk managers and other health care professionals has been tapped by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to consider and recommend ways in which current JCAHO infection control standards can be strengthened to help prevent the occurrence and devastating impacts of nosocomial infections. The Centers for Disease Control and Prevention (CDC) estimates that more than two million patients annually acquire an infection while hospitalized in U.S. hospitals for other health problems and that 88,000 die as a direct or indirect result of these infections. In addition to the human toll, the CDC reports that efforts to treat these infections add nearly $5 billion to health care costs every year. The 20-member expert panel, which will meet for the first time in February, will be asked both to recommend enhancements to the standards and to suggest ways in which the Joint Commission can better ensure that accredited organizations are truly in compliance with the standards. View Article

Nicotine-Reduced Cigarettes Reach Market

27 January – Newsweek reported the first tobacco CEO to acknowledge smoking is addictive is offering a new cigarette made with genetically modified tobacco that lets smokers choose their level of nicotine. Vector Tobacco Inc. stops short of marketing its Quest cigarettes as a smoking cessation product – a claim that could draw the regulatory attention of the Food and Drug Administration. The cigarettes are, however, designed to allow smokers to cut back on nicotine, the addictive element in tobacco. "The purpose of this product is to help people get to a nicotine-free environment, where they can have zero nicotine in their system. Then they can decide what to do from that point forward," said Bennett LeBow, who runs parent company Vector Group Ltd. The company is spending $15 million on advertising for Quest in seven Mid-Atlantic and Midwest states beginning Monday. It also is funding research at Duke University on how Quest affects smokers' nicotine intake and urge to smoke. Although the company says Quest contains only trace amounts of nicotine, it makes no claims that the cigarette reduces carbon monoxide or the chemicals that increase the risk of cancer heart disease, emphysema and birth defects. View Article

Norovirus Activity; United States, 2002

23 January – ProMed reported during the period June to December 2002, an increased number of outbreaks of acute gastroenteritis (AGE) were reported on cruise ships sailing into U.S. ports (1). In addition, since October 2002, several states have noted an increase in outbreaks of AGE consistent clinically and epidemiologically with norovirus infection, particularly in institutional settings such as nursing homes. Data from CDC indicate the possible emergence of a predominant circulating norovirus strain. View Complete Report

Sarin Responsible For Gulf Syndrome?

24 January – CBS News reported the head of the Veterans Affairs Department said he will ask researchers to investigate possible links between sarin gas and symptoms seen in Persian Gulf War veterans after a study found the nerve gas affected behavior and organ functions in laboratory mice. For years, many scientists have blamed Gulf War Syndrome on stress. Veterans and some researchers, however, attribute the health problems to toxic substances the veterans encountered in the Gulf, including sarin. Others suggest it may be a combination of factors. The Institute of Medicine has been reviewing research of substances considered possible culprits in illnesses suffered by Gulf War veterans. Thus far it has reported that not enough scientific information exists to determine whether exposure to low levels of sarin nerve gas had long-term health effects in people. View Article

Smallpox Vaccine Trial in Children Nixed Because of Supply Outlook

27 January - CIDRAP News reported top federal health officials have turned down a proposal to test the Dryvax smallpox vaccine in small children, but not because of public objections. The trial is no longer needed because the current campaign to vaccinate military personnel and healthcare workers means Dryax won't be available for use in children, officials said. Dryvax has been the foundation of the federal stockpile of smallpox vaccine. The government has about 15 million doses, but the current vaccination effort is expected to use millions of doses in the next several months. The decision not to approve the trial was made by Health and Human Services (HHS) Secretary Tommy Thompson and Food and Drug Administration (FDA) Commissioner Mark B. McClellan. The proposed trial, sponsored by the National Institutes of Health, would have tested Dryvax in standard and diluted concentrations in children aged 2 to 5 years. The decision applies only to this trial and does not rule out future research on smallpox vaccines in children. View Article

Some Troops Freeze Sperm Before Deploying

27 January – USAToday reported some servicemen heading to the Middle East are doing something only modern-day military fighters would consider. They are freezing their sperm before they ship out. Fear of vaccines and possible exposure to chemical and biological agents has prompted at least 80 men in the military to visit laboratories that process and store sperm. Women leaving for the war zone don't have a similar last-minute option because storing eggs has a low success rate, the labs say. The military says there is no data linking mandatory vaccinations, or any other substance soldiers might encounter, and infertility. But thousands of veterans of the Gulf War 12 years ago complained of maladies ranging from recurring headaches and muscle pain to infertility. Many of them attribute their illnesses to a combination of the anthrax vaccine and pollutants, pesticides and chemicals they believe they encountered during the war. View Article

Ten Ohio Horses Dead; Possible Equine Herpesvirus-1 Outbreak

24 January – ProMed reported at least 10 horses have died or have been euthanized at the University of Findlay in Findlay, Ohio, after battling a respiratory and neurologic illness. Preliminary polymerase chain reaction tests completed on tissue samples from affected horses by the Ohio Department of Agriculture Animal Disease Diagnostic Laboratory this morning came back as "presumptive positive" for equine herpesvirus type-1 (EHV-1). Officials from the veterinary services department at the University of Findlay and epidemiologists and scientists

from The Ohio State University are working together to treat at least 11 affected horses with supportive care and to determine the source of infection. View Report

USPACOM

Flu Epidemic Hitting Japan This Winter

26 January – Japan Today reported a flu epidemic has hit Japan, causing nearly 500 schools nationwide to be closed in one week, the most in recent history, health ministry sources said Saturday. The number of flu cases as of 18 January stood around 39,000, with 19,000 of the people coming down with the virus, mainly type-A Hong Kong flu, between 12 January and 18 January according to a recent report by the Health, Labor and Welfare Ministry. By prefecture, Osaka had the most cases with 7,900, followed by Hokkaido, Saitama and Tokyo, the report said, adding that Iwate and Ishikawa had no patients. The sources fear the epidemic will continue to spread. View Article

GM Cheese from Cow Clones

27 January – BBC News reported cows are being modified to produce drugs and improved milk. Scientists in New Zealand have created the world's first cow clones that produce special milk that can increase the speed and ease of cheese making. The researchers in Hamilton say their herd of nine transgenic cows makes highly elevated levels of milk proteins (casein) with improved processing properties and heat stability. Cows have previously been engineered to produce proteins for medical purposes, but this is the first time the milk itself has been genetically enhanced. The scientists hope the breakthrough will transform the cheese industry, and - if widened - the techniques could also be used to "tailor" milk for human consumption. But opponents of GM foods continue to doubt whether such products will be safe. View Article

Rain Brings Relief from Australian Fires

27 January – BBC News reported light rain and cooler temperatures brought relief to firefighters and residents battling fires across Australia, but forecasters warned that temperatures would rise again mid-week. In the country's southeast, where blistering heat over the weekend fueled fires that destroyed up to 20 homes, more than 1,000 people who were evacuated were to return to their homes, although resort towns such as Cooma and Jindabyne remained under threat. But in the northwest, rain over the weekend brought little respite. Rescue workers were grappling with floods on Monday, following heavy tropical rains. And authorities warned that after a month of wild fires in southeast Australia, many blazes were still out of control. Some 80 blazes continue to burn across New South Wales, including one in the Royal National Park bordering the southeastern suburbs of Australia's largest city, Sydney. The fires have been fed by bone-dry conditions, following 10 months of El Nino-aggravated drought. View Article

USSOUTHCOM

New *Aedes* Species Found in Nicaragua

23 January – ProMed reported the Department of Health of Nicaragua announced that it has detected in the north of the country larvae of the mosquito *Aedes albopictus*, also known as "Asian Tiger" and potential transmitter of 23 dangerous diseases. It is the first time they have

detected larvae of this mosquito there. Juan Jose Amador, the director of Epidemiology of the Department of Health, stated that the larvae of the mosquito were discovered in the Potosi municipality in the province of Chinandega, on the frontier with Honduras. He also reported that the mosquito, which transmits diseases like yellow fever, encephalitis, dengue, and West Nile Virus, comes from Asia and has already been detected in Mexico, Belize, Guatemala, and El Salvador. View Report

Please contact the below-listed POC for suggested improvements and/or comments regarding this report. This report is also available on the USACHPPM website at http://chppm-www.apgea.army.mil/Hioupdate/.

POC: (b)(6)
(b)(6)

Approved:
(b)(6)
Chief, Health Information Operations
(b)(6)

(b)(6)
02/05/2003 01:05 PM

To: (b)(6) /OSAGWI@OSAGWI
cc:

Subject: USACHPPM Health Information Operations Update - 31 January 2003

2b please

---------- Forwarded by (b)(6) on 02/05/2003 01:08 PM ----------

(b)(6)
02/05/2003 09:05 AM

To: (b)(6)

cc:

Subject: USACHPPM Health Information Operations Update - 31 January 2003

FYI

---------- Forwarded by (b)(6) on 02/05/2003 09:08 AM ----------

(b)(6) on 01/31/2003 06:27:31 PM

To:

Subject: USACHPPM Health Information Operations Update - 31 January 2003

Ladies and Gentlemen,
For your information.
The Health Information Operations Update provides information regarding global medical and veterinary issues of interest to the US Army. This information is sent to provide an increased awareness of current and emerging health-related issues.
<<31 January HIO Update.doc>>
Very respectfully,
LTC (b)(6)
Deputy Chief of Staff for Operations
US Army Center for Health Promotion
and Preventive Medicine
(b)(6)

 - 31 January HIO Update.doc

(b)(6)
Staff Medical Consultant
Deployment Health Support Directorate
(b)(6)

(b)(6)
Chief, Case Management Assignment Team
Deployment Health Support Directorate
(b)(6)

(133)

CMAT Control #
1999190-0000022

DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
1425 PORTER STREET
FORT DETRICK, MARYLAND 21702-5011

REPLY TO
ATTENTION OF:

MCMR-UIZ-T (70) 29 June 1999

MEMORANDUM FOR Mr. Rich Henriques, Office of the Special Assistant for Gulf War Illnesses, Investigation and Analysis Directorate, 5205 Leesburg Pike, Suite 810 (Skyline 1), Falls Church, VA 22041

SUBJECT: Response to LEAD Report

1. Reference LEAD Report, 11 March 1998, subject: Pesticides.

2. In referenced LEAD Report it is alleged that vaccinations used during the Gulf War "…were made by Jerry Jax (sic) at USAMRID (sic) in horses at his farm. These were never certified to be safe. The firm in Michigan provided only a small portion of the vaccines."

3. In order to answer these concerns, it is first necessary to understand the specifics of vaccination as applied to Operation Desert Shield/Desert Storm (ODS/S). During that conflict, two "anti-biological warfare" vaccines were given to select service members. Approximately 150,000 doses of the Food and Drug Administration (FDA) licensed anthrax vaccine and 8,000 doses of botulinum toxoid were administered.

4. Anthrax vaccine is a commercially available product, licensed by the FDA in 1970. All anthrax vaccine currently used in this country is produced by the Bioport Corporation (formerly the Michigan Department of Public Health [MDPH]). During ODS/S, all lots of this same vaccine were produced by the MDPH. No anthrax vaccine for use in humans is produced or was produced at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID).

5. Botulinum toxoid vaccine is an investigational product (IND) also produced under contract by Bioport. Again, during ODS/S, it was produced by the MDPH. Botulinum vaccine is prepared *in vitro* in a manner somewhat analogous to that used in the manufacture of tetanus toxoid. It is not and was not produced at USAMRIID. Horses play no role in its production.

6. Some confusion may exist because another product, botulism antitoxin, *was* produced (in part) at USAMRIID in horses. Production was accomplished by first hyperimmunizing these horses with botulinum toxoid and then later collecting (via plasmapheresis) the horse serum containing anti-botulinum antibodies. A government contractor then used this horse serum to produce botulism antitoxin. COL Jaax and others at USAMRIID *were* involved in the immunization and plasmapheresis of the horses. Botulism antitoxin is not a vaccine but rather an immunotherapeutic agent designed to be administered only to persons who have already been exposed to botulinum toxin. No antitoxin was used during ODS/S.

7. Point of contact for this memorandum is LTC (b)(6) (b)(6), Operational Medicine Division, (b)(6) or DSN (b)(6)

Gerald W. Parker

GERALD W. PARKER
Colonel, VC
Commanding

CF:
Commanding General, U.S. Army Medical Research and Materiel Command, 504 Scott Street, Fort Detrick, MD 21702-5012

CMAT Control #
1999196-0000004

Directorate for Freedom of Information and Security Review (DFOISR)
Coordination Record

Date: 15-JUL-1999

To: GWI attn (b)(6) EXPEDITE

Case No: 99-C-1075

DESCRIPTION

Number of Pages: 20 Classification: U

Type of Document: STATEMENT Requestor: CLAYPOOL, G

Subject: *ANTHRAX VACCINE IMMUNIZATION PROGRAM*

Source: OSD(LA) Event Date: 21-JUL-1999

Purpose: NATIONAL SECURITY VETERANS AFFAIRS & INTERNATIONAL RELATIONS COMMITTEE

The attached material is forwarded for review and comment in accordance with the following guidelines. Questions concerning this case should be directed to : (b)(6), Rm 2C757, (b)(6), e-mail: (b)(6)@osd.pentagon.mil, unclassified Fax (b)(6)

REVIEWERS: HEALTH AFFAIRS, GWI, JOINT STAFF

A reply is requested by: 16-JUL-1999

CONGRESSIONAL

COORDINATION OFFICE ACTION

To: Directorate for Freedom of Information and Security Review, DFOISR, Room 2C757.
Review by this office in accordance with the guidelines below, result in the following recommendation concerning clearance for publication.

(Check One):

- ☐ No Objection as Received.
- ☐ No Objection Subject to Amendments made by this office (in black pencil). Ammendments and rationale (security and policy) are annotated on page numbers listed below.
- ☐ Objection. Amendments to permit publication are impracticable. Reasons stated below.

(Continue on Reverse side if necessary)

typed name, title and organization | date | signature

Instructions: The policy of the Department of Defense it to authorize and encourage the public release of information concerning the Department of Defense consistent with security requirements, and other exemptions to disclosure under the Freedom of Information Act

Security - Reviewing agencies should identify information known to be classified within the meaning of Executive Order 12958 (DoD Regulation 5200.1R) or information which in the judgement of the reviewing agency warrants classification. In the latter case, it is requested that reasons for this judgement be given and recommendations made for appropriate classification.

Policy - Material originated with the Department of Defense for public release should, in addition, be reviewed for conflict with established policies and programs of the Department of Defense or those of the national government. If change is necessary, reviewing agencies are requested to recommend acceptable substitue language where practicable, or specify needed changes in sufficient detail to permit acceptable revision.

Editorial - Editorial review is not a responsibility of the Directorate for Freedom of Information and Security Review and reviewing agencies should not make editorial corrections. However, obvious errors of fact should be indicated.

RECORD VERSION

DRAFT

ANTHRAX VACCINE IMMUNIZATION PROGRAM

STATEMENT BY

Major General G. Robert Claypool
Medical Corps, United States Army
Deputy Assistant Secretary for Health Operations Policy

Submitted To

SUBCOMMITTEE ON NATIONAL SECURITY,
VETERANS AFFAIRS AND INTERNATIONAL RELATIONS
COMMITTEE ON GOVERNMENT REFORM

FIRST SESSION, 106TH CONGRESS

JULY 21, 1999

DRAFT

NOT FOR PUBLICATION
UNTIL RELEASED BY THE
SUBCOMMITTEE ON NATIONAL SECURITY,
VETERANS AFFAIRS AND INTERNATIONAL RELATIONS

99-C-1075

INTRODUCTION

Chairman Shays, Representative Blagojevich and Distinguished Committee Members, I am honored to appear before your Committee today to address your questions about the Department of Defense (DOD) Anthrax Vaccine Immunization Program (AVIP). I am Major General G. Robert Claypool, Deputy Assistant Secretary for Health Operations Policy. I am accompanied today by Rear Admiral Michael L. Cowan, Deputy Director for Medical Readiness, Joint Staff; Colonel Frederick E. Gerber, Director, Health Care Operations, Office of the Army Surgeon General; and Colonel Renata J. M. Engler, Chief Allergy Immunology Service, Walter Reed Army Medical Center. At your request, our testimony will specifically address AVIP implementation, communication and medical protocols for deferrals and adverse events.

THE BIOLOGICAL WARFARE AGENT ANTHRAX: A CLEAR AND PRESENT DANGER

Our National Security Strategy places our Service Members in a posture of global engagement to **Shape** the international environment; **Respond** to the full spectrum of crises; and **Prepare Now** for an uncertain future. The strategic deployability of our Armed Forces places our men and women at significant risk from the proliferation of biological weapons. Anthrax clearly tops the annual intelligence threat lists from a host of hostile countries known to have stockpiles and the offensive ways and means to deploy anthrax against our forces. Regional, transnational, asymmetric threats and proliferation of biological weapons grows each year. We face a clear and present danger from anthrax.

Death is the predictable outcome of inhalational anthrax in unvaccinated persons. Once clinical symptoms appear, death is assured, despite the most heroic, state of the art, post-exposure medical intervention and treatment given.

The good news is — death from anthrax is vaccine preventable. Immunization with Anthrax Vaccine Adsorbed, licensed as safe and effective by the Food & Drug Administration (FDA) in 1970, provides our men and women with their only chance of survival. Experienced reviewers at the FDA found Anthrax Vaccine Adsorbed (AVA) safe and effective in preventing anthrax in human beings. Furthermore, DOD now has a stockpile of anthrax vaccine enabling us to begin vaccinating our Armed Forces.

KEY IMPLEMENTATION PRINCIPLES: SAFETY, COMMUNICATION, & INDIVIDUALIZED CARE

Chairman Shays, as you requested, my testimony will focus on the DOD's programs to assess and assure the safe delivery of anthrax vaccination. I will review our multi-faceted vaccine safety surveillance programs and discuss our comprehensive communication programs to explain the value of anthrax vaccination to Service Members and their families. Additionally, I will describe our consensus medical protocols for diagnosis, evaluation and disposition of persons who develop physiologic reactions after receiving a dose of anthrax vaccine.

COORDINATED SURVEILLANCE FOR ANTHRAX VACCINE SAFETY

The Department of Defense conducts an aggressive, multi-faceted surveillance program to assess vaccine safety. In fact, the safeguards of vaccine administered to DOD personnel meets or exceed every standard for vaccine administration to the civilian population. Table A clearly outlines over 14 discrete safety initiatives DOD implements compared to those required by Federal programs. Our program includes a wide variety of activities that can be grouped into three main scientific method categories: clinical studies of vaccine recipients themselves; database analysis of vaccine recipient automated medical records; and spontaneous reports. I will summarize each category for you, as well as describe the adverse events that have been reported to either DOD or FDA or both.

Table A: Comparison of Federal Vaccine Safety Programs

	Vaccines for the Civilian Populace	Vaccines for Armed Forces & Essential Civilians
Responsible Parties	- Centers for Disease Control & Prevention (CDC) - Food & Drug Administration (FDA) - other Federal Agencies	- Department of Defense (DOD), Anthrax Vaccine Immunization Program (AVIP)
A. Manufacturing Quality Standards	FDA's Center for Biologics Evaluation & Research (CBER)	- FDA's Center for Biologics Evaluation & Research (CBER) - Collaboration with BioPort to update product labeling ("package insert") with recent experience
B. Clinical Standards	Vaccine Information Statements (VIS)	- Trifold fact sheet (Quad-fold version under development) - VIS based on Quad-fold sheet under development, to mimic CDC VIS format - Education of leadership - Education of troops and families - Quality of health care delivery (e.g., epinephrine availability) - Automated anthrax vaccination registry
C. Vaccine Safety Surveillance		
Clinical Studies		- Clinical immunogenicity trials (different routes of administration, different dosing schedules) - Vaccine-vaccine, vaccine-drug interaction studies - Long-term studies
Database Studies (i.e., large-linked databases)	Vaccine Safety Datalink (VSD) project	Defense Medical Surveillance System (DMSS), Army Medical Surveillance Activity (AMSA)
Spontaneous Reports	Vaccine Adverse Event Reporting System (VAERS)	Vaccine Adverse Event Reporting System (VAERS)
D. External Advisory Panels	Advisory Committee on Immunization Practices (ACIP)	- Armed Forces Epidemiological Board (AFEB) - Anthrax Vaccine External Committee (AVEC)
E. Compensation Programs	Vaccine Injury Compensation Program (VICP) (for damages)	- Military Health Service System (direct care delivery) - Medical retirement process

Each of these scientific methods has advantages and disadvantages. As the Centers for Disease Control & Prevention (CDC), the FDA and trained epidemiologists

over time discovered, these methods need to be used in tandem, to fully understand whether or not an adverse event was caused by a vaccine or merely coincided in time with the vaccination. Coincidental events are sometimes referred to as temporal (pertaining to or limited in time) associations.

DOD follows the convention of CDC, FDA, and the nation's public health and epidemiologic specialists in distinguishing adverse events and adverse reactions. Adverse events are adverse outcomes, for which a cause-and-effect relationship with an exposure (to a medication or vaccine) has not yet objectively been determined. An ***adverse event*** becomes an ***adverse reaction*** once objective evidence is available to establish a cause-and-effect link between an exposure and an adverse outcome. Table B lists some of the criteria proposed many years ago by famed epidemiologist Sir Austin Bradford Hill that help us make the determination of causal association.

Table B: Causal Association Criteria

1. How strong is the association between the exposure and the outcome?
2. What is the quality of the evidence for an association?
3. Is there a dose-response relationship?
4. Is there consistency among several studies?
5. Is there a specific cause for the effect observed?
6. Did the cause exist before the effect occurred?
7. Is the outcome plausible, given what we know about biology?

Adapted from: Rothman KJ, Greenland S. Modern Epidemiology, 2nd ed. Philadelphia: Lippincott-Raven, 1998:24-28.

Let me now review the three scientific method categories of evaluations.

CLINICAL STUDIES

Clinical studies are active studies that have the advantage of compiling data that is valid and reliable. They are expensive and time-consuming. Good clinical studies are often narrowly focused. Great care must be taken in designing clinical studies to avoid pitfalls that epidemiologist experts call *selection bias* and *recall bias*, among others. The challenge is to design a study that eliminates *alternative explanations*. As described below, numerous clinical studies have been conducted on the safety of the anthrax vaccine.

BRACHMAN STUDY

Some of the original safety data on anthrax vaccine was collected through *active monitoring* of vaccine recipients from the Brachman study of 1,330 mill workers in the northeastern United States (*Am J Publ Health* 1962;52:632-45). Brachman showed that *mild local reactions*, consisting of 1 to 2 cm of redness, plus slight local tenderness, occurred in about 30% of recipients. *Moderate* local inflammation (a defensive reaction to irritation) (> 5 cm in diameter), occurred in 4% of recipients. More *severe* local reactions occurred less frequently and consisted of extensive swelling of the forearm, in addition to local inflammation. *Systemic reactions* (reactions beyond the limb into which the vaccine was injected) occurred in fewer than two per thousand (< 0.2%) recipients. These reactions included malaise, and even less frequently, fever and chills.

LICENSURE SAFETY STUDY

Studies on the safety of four lots of anthrax vaccine in the late 1960s, involving approximately 16,000 doses administered to approximately 7,000 people, were submitted in support of vaccine licensure to the National Institute of Health (NIH) Division of Biological Standardization (now the Center for Biologics Research & Review of the FDA) by the Communicable Disease Center (now the Centers for Disease Control & Prevention). With *active querying* and examination of vaccine recipients, *mild local reactions* (<= 3 cm) were reported after 3% to 20% of doses administered. *Moderate reactions* (> 3 cm to < 12 cm) were reported after 1% to 3% of doses. *Severe reactions* (>= 12 cm) were reported after fewer than 1% of doses. *Systemic reactions*, reported in four individuals (fewer than 6 per 10,000 doses), consisted of fever, chills, nausea and general body aches, which resolved spontaneously.

FT. DETRICK MULTI-DOSE SAFETY STUDY

Starting as far back as the 1950s, 99 male laboratory workers at Fort Detrick, Maryland, were followed for up to 25 years, after being vaccinated against multiple diseases, including anthrax. Regrettably, these studies did not include control groups considered adequate by today's standards. While there were some minor elevations in liver and kidney function tests and white blood cell counts in these men (which cannot reliably be distinguished from the simple effects of aging), none of these men developed any unusual diseases or unexplained symptoms that could be attributed to the repeated doses of multiple vaccines [*Annals of Internal Medicine* 1965;63:44-57; 1974;81:594-600; *Bulletin of the Johns Hopkins Hospital* 1958;103:183-98].

SPECIAL IMMUNIZATION PROGRAM SAFETY STUDY

In another clinical study begun in 1973, a study group of 1,590 people working in the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), received 10,451 doses of anthrax vaccine, as part of USAMRIID's Special Immunization Program (SIP). Based on visits to an occupational health clinic (the USAMRIID Special

Immunizations Clinic), 4% of doses resulted in a *local reaction* consisting of redness, induration (an area of hardened tissue), itching, and soft or puffy swelling (edema) at the injection site. *Systemic reactions* of headache, fever, chills, malaise (discomfort, uneasiness), muscle and joint aches occurred after 4 per 1,000 doses. All *local* and *systemic* reactions resolved without any lost time from work, hospitalization or long-term effects. These employees continue to be examined and tested annually for medical conditions since their last visit, yet no diseases or unexplained symptoms have been observed that would not be expected in an unvaccinated group of comparable age and other demographic characteristics.

FT. BRAGG BOOSTER STUDY

In yet another DOD sponsored clinical study, USAMRIID investigators actively assessed the safety of booster doses of anthrax vaccine in 1992-93, given to 486 U.S. Army soldiers at Fort Bragg, North Carolina who had been previously vaccinated against anthrax during the Persian Gulf War 1990-91. Of these soldiers, 21% had local redness and/or swelling in the arm where the booster vaccination was administered. In 5%, the redness and/or swelling was >= 5 cm. No reaction caused lost time from work or hospitalization and all reactions resolved without lasting consequences. One or more *systemic reactions* occurred in 44% of recipients during the first 30 days after vaccination, most commonly muscle aches (30%), malaise (16%), headache (16%), rash (16%), or joint aches (12%). We should note that these troops were engaged in a field exercise at the time of this study. Therefore, the role of the anthrax vaccination cannot reasonably be separated from the rigorous physical exertion (*alternative explanation*) commonly associated with Special Forces field deployments.

CANADIAN SAFETY STUDY

A Canadian sponsored, actively monitored study of vaccine reactions in 576 Canadian Service Members who received anthrax vaccine in 1998 revealed that *mild local reactions* (<= 5 cm) after 9.5% of doses, *moderate local reactions* (> 5 to 12 cm) after 0.5%, with no *severe local reactions* occurring. *Systemic reactions* occurred after 1.4% of doses. Five people developed a fever with or without chills, two reported transient (temporary) indigestion. One vaccine recipient developed a transient nerve disorder. One individual reported having a persistent lump (nodule) at the injection site and multiple nodules at several distant sites, but it is unknown whether those lumps existed unnoticed before the vaccination.

USAMRIID REDUCED DOSE STUDY

In another DOD sponsored pilot study, USAMRIID actively collected safety data during a pilot study to evaluate a reduced schedule for administering the anthrax vaccine (the current protocol requires administration of six doses, given at 0, 2 and 4 weeks and 6, 12 and 18 month intervals with an annual booster). The safety of the standard schedule of the first three doses (0, 2, 4 weeks) into the subcutaneous fat layer under the skin (a subcutaneous injection) was compared to two doses given

subcutaneous and also compared to two injections into the muscle in the upper arm (an intramuscular deltoid injection), in a study totaling 173 people. *Systemic adverse events* were uncommon and their incidence did not differ among the three groups. After the first dose, the side effects noted were headache (14%); malaise (9%); loss of appetite (3%); nausea or vomiting (3%); muscle ache (3%); itching (3%) and low grade fever (3%). Redness and swelling at the injection site occurred more commonly among those given subcutaneous injections, compared to intramuscular injections. Male vaccine recipients developed injection-site reactions less frequently after subcutaneous injection (5% to 32%) than female vaccine recipients (39% to 66%), but the rates were comparably low for both genders when the vaccine was given by intramuscular injection (5% to 7%). Subcutaneous nodules, which resolved spontaneously, were common among recipients of subcutaneous injections, but were not observed among recipients of intramuscular injections. Subcutaneous nodules were usually not noticed by the vaccinee and resolved spontaneously. This pilot study provides compelling evidence that *local adverse events* are less common when the intramuscular route is used to administer anthrax vaccine.

USAMRIID presented these preliminary findings to the FDA in December 1998, showing fewer doses by a less reactive route produce comparable levels of protective antibodies. The FDA requires an additional study of more than 900 anthrax vaccine recipients before it will consider to definitively assert the change in route and schedule is comparably safe and effective as the current route and schedule. This confirmatory trial is being planned at this time, under the sponsorship of the Joint Program Office for Biological Defense.

The difference in injection site reactions between men and women is interesting. The biological explanation for this phenomenon may involve chemicals that transmit signals between cells in the blood or hormonal variations. This is intriguing to biological scientists in both civilian and military health care and needs to be assessed further. The pursuit of answering this question under the support of the AVIP or another agency is the subject of ongoing discussions.

TAMC-600 Study

The next study collecting data on the safety of the anthrax vaccine that I will describe is a prospective, population-based survey conducted at the Tripler Army Medical Center (TAMC), Honolulu, Hawaii. Called the TAMC-600 Study, the survey included 603 TAMC personnel who are physicians, nurses, medics and other medical support personnel who augment U.S. medical forces in Korea in the event of military contingencies. Note that the people surveyed are a highly educated, medically experienced population who would be more able than the norm to describe any adverse events that might occur (and introduces a potential *population bias*). The objectives of this study were to compare the TAMC data to previous studies and to evaluate the TAMC data against spontaneous reports submitted through DOD and FDA channels. Overall, the incidence of *local* reactions, specifically subcutaneous nodules and muscle soreness, are higher than previous surveys or studies, approximately 70% and 65%,

respectively. *Systemic reactions* were not remarkably different from previous clinical experience. About 55% of vaccine recipients reported no *systemic* symptoms; about 20% reported symptoms that they personally judged could be ignored; 15% reported symptoms that affected their activity for a short time but did not limit their ability to perform duties; 8% reported symptoms that affected their activity for a short time that was relieved by self-treatment with nonprescription medication; and fewer than 2% reported that their symptoms were unrelieved by medication and that their ability to perform their duties was limited for a short time. In this group of vaccine recipients, the relative frequency of side effects for each of the first four doses was measured. The frequency of reports of muscle aches was roughly 15%, which represented the most frequently reported *systemic* complaint. The results for all *systemic* complaints did not substantially vary between dose #1, dose #2, dose #3, and dose #4. Muscle aches typically lasted between 7 hours and 3 days. In this group, three spontaneous reports (the FDA Form VAERS-1) were submitted and only one person lost more than one day of work and none were hospitalized.

USAF Vision Study

United States Air Force researchers are finalizing a multicenter pilot study of the effects of anthrax vaccine on visual acuity. The first phase of this study assessed 354 aircrew members vaccinated against anthrax and 363 unvaccinated aircrew members. Vision changes over the course of one year occurred in 12% of vaccinated crewmembers compared to 16% of unvaccinated crewmembers. Additional data are being accrued to increase the precision of this analysis.

Comparison of Anthrax Vaccine with Other US Vaccines

The safety data on anthrax vaccine compare very favorably with safety data for other vaccines licensed in the United States. For hepatitis A vaccine, soreness at the injection site was reported by 56% of adult vaccine recipients. Headache was reported by 14%. For the typhoid polysaccharide vaccine, local tenderness was reported by 98%, pain by 56%, malaise by 24% and headache by 11%. The pneumococcal vaccine has a 71% rate for localized soreness. The recently licensed Lyme disease vaccine produced localized pain in 93% of recipients and fever in 2.5%. The hepatitis B vaccine reports a *local reaction rate* of 17% and a *systemic reaction rate* of 15% in adults.

Each of these nine clinical safety studies alone, as well as all the studies in aggregate (totaling 12,599 people), confirm that the principle *adverse reactions* associated with anthrax vaccine involve the injection site or minor, transient systemic events like malaise or headache. It is important to note all the events that did not occur during the surveillance described above. No deaths occurred following doses of anthrax vaccine, nor any cases of severe allergic hypersensitivity reactions (known as anaphylaxis). The anthrax vaccine clearly has a more favorable side-effect profile, compared to other vaccines commonly used by the civilian population.

Additional Long-Term Study

On July 29, 1999, the Anthrax Vaccine Immunization Program will convene a team of civilian and military medical experts to design a set of studies to assess the long-term safety of anthrax vaccine, in response to requests from Service Members, their families and recommendations of the General Accounting Office. In designing these studies, we will draw from the accumulated experience of some of the nation's best vaccine researchers at CDC, FDA, and civilian universities.

This section summarizes the clinical studies performed to date and those anticipated in the near term. Recall that clinical studies are limited in their ability to detect rare events. Thus, I would like to discuss the next category of scientific study method, database analyses.

Database Analyses

Database studies are active inquiries that can be completed more quickly than clinical studies, if data of interest have already been compiled in electronic databases. Database studies are only as valid and reliable as the quality of the data in the database. They are relatively inexpensive, after the investment in compiling the database is taken into account and they are the one of the best means of assessing rare adverse events.

The Defense Medical Surveillance System (DMSS) is coordinated by the Army Medical Surveillance Activity (AMSA), under the supervision of the U.S. Army Center for Health Promotion & Preventive Medicine (USACHPPM). The DMSS offers the capability to analyze hospitalizations, outpatient visits and other automated records. We intend to use the DMSS to measure the impact of anthrax vaccine, if any, on health outcomes among vaccinated Service Members, to see if it differs from unvaccinated Service Members. Plans are being developed now for more studies of this type, assessing both short-term and long-term questions of vaccine safety, as discussed in the previous sections.

Having discussed the various *active* studies already accomplished and those we are planning, I will now explain our solicitation and analysis of spontaneous reports of *adverse events*, a *passive* form of surveillance.

Spontaneous Reports

Spontaneous reports are unedited reports of individual patient-clinician experiences. But clearly, spontaneous reports are rarely sufficient to assert that the risk of an *adverse event* is higher in a group of vaccine recipients than in a comparable group of unvaccinated people. CDC and FDA agree that spontaneous reports are important for generating signals of issues to address further, but spontaneous reports cannot determine cause-and-effect directly. Spontaneous reports are uncontrolled,

lacking comparison groups. Spontaneous reports are an important part of the national information-gathering effort to assess vaccine safety in general.

VACCINE ADVERSE EVENT REPORTING SYSTEM

The Department of Defense takes advantage of a world class program for collecting spontaneous reports of *adverse events* coincidentally associated with vaccination. This program was developed collaboratively by the FDA and CDC and is called VAERS, the "Vaccine Adverse Event Reporting System".

VAERS is known as a *passive surveillance system*. Passive in this case means VAERS relies on the initiative of health care professionals and patients to report adverse events after immunization. I should note that VAERS reports, by definition, will include a combination of events caused by the vaccine and coincidences that are only temporally associated with immunization and have no cause-and-effect relationship with the vaccine.

Military health care professionals have been instructed repeatedly in multiple media and over many years to report *adverse events*. Naturally, we are most interested in serious adverse events, but we are also interested in reactions at the injection site, what are often called "local reactions." Let me say again, DOD encourages our health care professionals to report all *adverse events* that they consider important and clinically relevant.

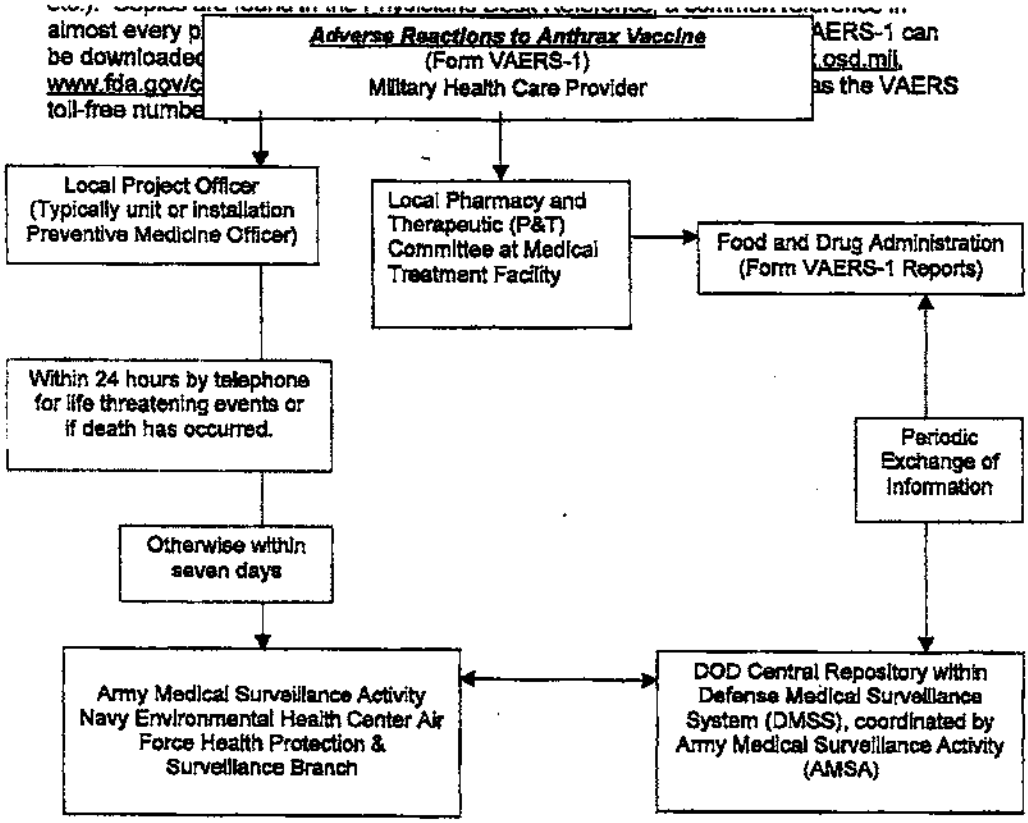
DOD JOINT IMMUNIZATION REGULATION

The duty to report adverse medication events has been codified for many years in the joint immunization instruction (Army Regulation 40-562, Bureau of Medicine & Surgery Instruction 6230.15, Air Force Joint Instruction 48-110, Coast Guard Commandant Instruction M6230.4E, dated November 1, 1995). The joint regulation requires submission of a Form VAERS-1 for all adverse events resulting in more than 24 hours of lost duty time or any period of hospitalization. These requirements represent a higher standard than in comparable civilian community health care settings. VAERS reporting is strictly voluntary for civilian health care providers. DOD VAERS reporting channels are depicted in Figure 1, below.

DOD has have been consistent with CDC instructions to civilian health care professionals for VAERS reports and MedWatch (for reporting adverse events related to medications other than vaccines). Full and complete reporting of VAERS, MedWatch, and their predecessor programs has been the DOD policy for decades.

Copies of Form VAERS-1 are readily available at the pharmacy of every military medical treatment facility, as well as from multiple clinics and departments within the facility (e.g., pediatrics, internal medicine, immunization clinics, emergency department,

Figure 1: DOD Reporting Channels for Adverse Events to Anthrax Vaccine



DOD FORM VAERS-1 INITIATIVES

Additionally, DOD emphasizes/encourages Form VAERS-1 reporting in the following publications/policies/initiatives:

◆ The Apr 99 updated DOD "Force Health Protection Against Anthrax Leaders Briefing", required to be given for all Service Members and DOD Emergency Essential Civilians by supervisors/commanders prior to receiving the anthrax immunization. Slides 12, 13, 14 clearly state for example, for both the AC and RC, "any vaccine associated adverse event may be reported through VAERS by either the patient of provider...in writing or by calling 1.800.822.7869...reporting instructions are available on the Internet at www.fda.gov/cber/vaers.htm."

◆ The Apr 99 updated DOD "Anthrax Vaccine Immunization Program Health Care Providers Briefing", slides 31, 32, 33 provide clear clinical guidelines for VAERS reporting in addition to the guidance provided in the Leaders Briefing above.

◆ DOD Policy Memorandum "Policy for Reporting Adverse Reactions Associated with the Anthrax Vaccine Immunization Program (AVIP)" created 30 Jun 98, issued 21 Apr 99 for Service coordination/implementation outlines clinical protocols and algorithms for submitting VAERS. This policy also requires submission of an "Anthrax Vaccine Adverse Reaction Supplemental Form" in addition to the VAERS.

◆ DOD Policy Memorandum "Ensuring Reservists Have Full Access to Department of Defense (DOD) Medical Treatment Facilities (MTF) for Treatment of Adverse Events from DOD Directed Immunizations" staffed May 99, clearly outlines patient or provider submission of Form VAERS-1. The Memo will be accompanied by a Patient Information 'walk-away' brochure outlining facts about the anthrax vaccine, local and systemic reactions and adverse event reporting options, phone numbers, instructions, Internet access, etc.

◆ DOD Clinical Practice Guidelines for the Management of Anthrax Vaccine Adsorbed Adverse Events, were finalized during the 25-27 May 99 Annual DOD Conference for Biological Warfare Defense Immunizations. Over 150 personnel attended this AVIP Agency sponsored conference from the Services and Interagency participants (CDC, DHHS, Johns Hopkins University, FDA, George Washington University, AFEB, JVAP, CHPPM, USAMRIID, GAO, etc. The Guidelines outline clinical protocols, pre-treatments, specialty referral processes, contraindications, categorization of local and systemic reactions and associated treatment algorithms. The Guidelines clearly outline patient or provider reporting of Form VAERS-1 with all associated phone and Internet access numbers. In addition to normal Service distribution of the Guidelines, they can also be found on the www.anthrax.osd.com web site.

◆ Form VAERS-1 reporting options, sources of information, downloaded copies of the form are a prominent feature of our newly revised anthrax website www.anthrax.osd.mil with separate hot button access to adverse reporting.

◆ The AVIP Agency's 1.877.GETVACC hotline, scheduled for 1 Aug 99 implementation will prominently feature patient or provider reporting of adverse events.

◆ The AVIP Open House/Speakers Bureau effort routinely addresses adverse event reporting, sources of information, etc.

◆ The AVIP Agency continues to encourage advertising VAERS reporting awareness on each of the Services automated Immunization Tracking Systems. The Army's Medical Protection System (MEDPROS) began such advertisements on 7 Jun 99.

◆ The AVIP Agency highlights VAERS reporting in their silent training aids product line in addition to other key themes such as dosing schedule, recording all vaccinations, threat, safety, efficacy, etc.

NON DOD SUBMISSION OF FORM VAERS-1

Individual Service Members or their family members are free to submit VAERS reports directly to FDA if they wish. However, this procedure has a number of disadvantages I would like to make you aware of. First, reports submitted by lay people may not be sufficiently detailed to allow grouping with similar reports causing potentially missed trends. Second, reports that go to FDA first, shared later with DOD, have information redacted. This redaction prevents DOD from categorizing demographic or geographic factors that otherwise helps us assess trends.

As you are well aware, several groups of reports of adverse events associated with anthrax vaccination have been reported Dover Air Force Base, Delaware and the 110th Fighter Wing, Battle Creek, Michigan. In each case, local medical officers redoubled their efforts to assure optimal VAERS reporting at their facilities. Reports from these facilities and all other DOD medical treatment facilities are included in the Form VAERS-1 Summary below.

ANTHRAX VACCINE EXTERNAL COMMITTEE

Once the VAERS reports are received at the central offices, an independent external-review panel we call the Anthrax Vaccine External Committee (AVEC) evaluates each report received. The AVEC represents a special panel of experts commissioned by the AVIP Agency in early 1998 to review and identify any signaling event that would identify problems stemming from the anthrax vaccine. These experts come from the Health Resources & Services Administration (HRSA), a component of the Department of Health & Human Services sponsored Vaccine Injury Compensation Program (VICP). To date, the AVEC has found no problems stemming from the anthrax vaccine. The AVEC uses explicit criteria for attributing causality to adverse events coincidentally associated with anthrax vaccination, based on work begun by the

Canadian Advisory Committee on Causality Assessment (http://www.hc-sc.gc.ca/main/lcdc/web/bid/di/acca_e.html).

FORM VAERS-1 SUMMARY

VAERS reports flow steadily and reliably through our analytic processes. To be consistent, we will report our findings as of July 1, 1999. As of that date, FDA received a total of 215 VAERS reports. Note that the number 215 are the number of Form VAERS-1 submitted. It does not correspond to a number of people in whom an event occurred. Nor does it refer to 215 events, because the same event may have been submitted through duplicate channels on separate pieces of paper by different reporters or advocacy groups encouraging mass reporting. Recognizing that the number 215 properly refers to Form VAERS-1 submitted, we will simply refer to them as 'Reports' or 'VAERS Reports' for the remainder of this discussion.

Of the 215 reports, 174 have been reviewed by the AVEC, up through their most recent meeting on 29 Jun 99. Of these 174 fully reviewed reports, 50 reported *local reactions* at the injection site only; 95 reported various *systemic reactions* only; 29 reported both *local* and *systemic reactions*.

You specifically asked about the frequency of VAERS reports among Service Members in the active (AC) and reserve (RC) components. As of 1 Jul 99, 153 VAERS reports involved AC members, 17 reports involved RC members, and four involved civilians. We report this data with a high degree of confidence although there is no block on Form VAERS 1 to specifically record AC or RC status. You recall that VAERS reports submitted directly to FDA have personal information redacted. These direct FDA submissions limit our ability to fully categorize the AC or RC component of the person reporting. Thus, 88% were from the AC and 10% were from the RC. The reporting rates were 153 reports from the 285,164 AC personnel vaccinated against anthrax (54 reports per 100,000 vaccine recipients). And 17 reports arose from the 26,662 RC personnel vaccinated (64 reports per 100,000 vaccine recipients). The total reporting rate among RC personnel is only slightly higher than among active-duty personnel, a difference that could easily be explained by the slight imprecision of our ability to attribute reports to AC or RC personnel. None of the 17 RC generated involved hospitalization. Six of those 17 reports involved lost duty time. As expected, there is no indication that reservists are burdened with a greater risk of adverse events than their active-duty colleagues.

Eight reports discussed Service Members hospitalized with an illness coincidentally related to anthrax vaccination. Five have recovered completely. Among the five Service Members who recovered, the reports described the events as one case each of *Guillain-Barre' syndrome*, *multiple sclerosis*, *angioedema* involving the left jaw, *aseptic meningitis*, and severe *injection site inflammation*. Three of the eight Service Members hospitalized with an illness coincidental to anthrax vaccination have ongoing conditions: *bipolar psychiatric disorder*, *diabetes mellitus* and *systemic lupus erythematosus*. You will notice that the serious adverse events reported to date are all isolated cases. Only one of each condition was reported, with each condition being an

event that also occurs among unvaccinated people. There are no reports of outbreaks of multiple cases of same disease, other than allergic-type (hypersensitivity) reactions, described below, that are expected with all vaccines and many medications.

The AVEC judged that there was no evidence that the ongoing conditions or the *angioedema* were caused by anthrax vaccination. The AVEC found evidence submitted through VAERS in the case of the alleged *Guillain-Barre' syndrome* was insufficient to reach a conclusion and they are awaiting receipt of additional information. For the cases of *multiple sclerosis*, *aseptic meningitis*, the AVEC judged the events were incompatible with a causal association and unrelated to anthrax vaccination. Notably, the AVEC judged the *injection site inflammation* event as the only case likely caused by the vaccine.

There have been three reports of serious illness coincidentally associated with vaccination that required loss of duty time greater than 24 hours. These reports involved *urticaria* (generalized itching) with hypersensitivity pneumonia, *spondyloarthropathy* (a vertebra joint disease) and *urticaria* with dizziness. The AVEC members judged the cases of *urticaria*, an allergic-type reaction similar to that seen in other vaccine studies, likely caused by the vaccine. The case of aggravation of pre-existing *spondyloarthropathy* was judged to be unclassifiable, not worthy of further review.

The DOD uses a broader definition of serious adverse events, as we cast a broader net than the FDA definition of "serious." Twelve VAERS reports were submitted for Service Members who lost duty time greater than 24-hours, but were not hospitalized. These 12 reports outlined some of the following temporary symptoms: dizziness, nausea, fatigue, diarrhea, double-vision, abdominal pain, "flu"-like symptoms, urticaria, neck stiffness, abdominal cramps, inflammation at the injection site, migraine headache, mood swings and hair loss. Some of these events have been seen in other anthrax vaccine studies and are fully expected. Some are caused by multiple factors. The AVEC judged all these events "not serious".

FORM VAERS-1 RECAPITULATION

To recapitulate, the AVEC reviewed 174 reports; eight reports reflected hospitalization and 15 reflected other "serious" events by either FDA or DOD definition. All the remaining 151 VAERS reports reviewed by the AVEC through 29 Jun 99 were not serious. That is to say, the remaining 151 reports were a mixture of expected skin reactions or transient flu-like symptoms due to the vaccine, or coincidental events the AVEC judged to be unrelated to vaccination.

The eight reports of hospitalization came from eight different geographic locations. Obviously, there is no geographic clustering of adverse events severe enough to warrant hospitalization. Similarly, the 15 other "serious" events by either FDA or DOD definition were not clustered by geographic location.

No VAERS reports were submitted regarding microbial contamination of vaccine lots. When the VAERS reports were compared to the lot of vaccine administered, there were no correlations between lot and number of reports received.

EDUCATION & COMMUNICATION

The Department of Defense is committed to fully educating our Service Member population and their families on the purpose and value of anthrax vaccination in an unprecedented manner. We use each of the following communications media to accomplish this goal:

- A sophisticated anthrax specific website www.anthrax.osd.mil with multiple layers of information and methods for communicating with our Service Member population, their families, other DOD beneficiaries and concerned members of the American public.

- Three Service specific anthrax websites hyper-linked to all known military and civilian websites discussing anthrax, biological weapons, health care, domestic preparedness, terrorism, VAERS reporting, preventive medicine, infectious disease, etc.

- Three Tri-fold information sheets individually tailored for Service Members, Family Members and Civilians. DOD issued Tri-folds to each Service Member since administering the first doses of anthrax vaccine in March 1998. The Tri-fold explains the threat of biological weapons, the benefits of anthrax vaccination and the known risks from the vaccine. The Tri-fold is currently under revision to become a Quad-fold to include RC specific information on accessing care.

- DOD Leaders Briefing required to be given to all Service Members prior to receiving the anthrax immunization. Distributed by each Service and prominently posted on the www.anthrax.osd.mil website.

- DOD Health Care Providers Briefing given to all DOD health care providers who then serve as teachers, coaches, mentors for supervisors, commanders, Service Members and their families. Distributed by each Service and prominently posted on the www.anthrax.osd.mil website.

- Open House/Speakers Bureau briefings and open educational forums for all Service Members and their families.

- A 1.877.GETVACC telephone hotline scheduled for 1 Aug 99 implementation.

- A variety of anthrax vaccine 'silent training aids'. These highly visible training aids emphasize the key themes of the anthrax threat, safety and efficacy of the vaccine, adverse event reporting, etc.

◆ Armed Forces Information Service news media; local installation print, radio and television news service initiatives.

◆ A state of the art Anthrax Education CD-ROM which provides Service Members, families, supervisors, commanders and health care providers with tailored, multimedia information on the anthrax threat; safety and efficacy of the vaccine; signs, symptoms and prevention of anthrax. Under development for over none months, the CD is scheduled for release in Sep 99.

◆ An Anthrax Vaccine Immunization Program Videotape explaining the threat, safety, efficacy of the vaccine. The video features prominent civilian and Government scientists and vaccine experts explaining and endorsing the vaccine. Under development for over six months, the Videotape is scheduled for release 19 Jul 99.

◆ DOD is currently collaborating with CDC to array this information in the format of Vaccine Information Statements (VIS) that civilian health care providers around the country give America's children, adolescents, and adults during routine vaccinations. Our DOD VIS is currently in draft with an expected implementation date of 1 Sep 99.

THE BEST INDIVIDUALIZED CARE

"Consensus Clinical Practice Guidelines For the Management of Anthrax Vaccine Adsorbed Adverse Events" is our DOD written and produced document providing diagnostic and treatment protocols for adverse events coincidentally associated with anthrax vaccine. These Guidelines help individual health care providers who see and treat Service Members in their practice of medicine. The Guidelines enable consistent care and medical work-ups to best serve the individual health needs of Service Members, as well as providing guidance about when to issue medically appropriate waivers or deferrals from further doses of anthrax vaccine.

Clinical Guidelines were issued in draft form in May 1998, based on a consensus panel of civilian and military physicians experienced both in immunology and the general provision of health care. The finalized Guidelines were electronically transmitted to all military medical treatment facilities in early July 1999, as well as being posted on the www.anthrax.osd.mil AVIP website. Guidelines represent DOD's concerted effort to standardize the evaluation and care of people who have adverse events after vaccination against anthrax.

WAIVERS, DEFERRALS AND REPORTING

We define a waiver as a long-term postponement from receiving additional doses of anthrax vaccine. A deferral is a temporary delay, such as during the course of an acute illness, pregnancy or similar short-term condition. Although the Services collaborate in designing the administrative and medical criteria for waivers and deferrals, each Service reports waivers or deferrals according to the needs of the individual Services. The U.S. Army can identify locally and centrally all doses

administered, as well as all administrative and medical waivers and deferrals, in its Medical Protection System (MEDPROS) database. The U.S. Navy and U.S. Marine Corps can identify local doses administered using the Shipboard Non-tactical Automatic Program/Automated Medical System (SNAP/SAMS), but does not collect information about waivers or deferrals. The U.S. Air Force tracks local doses administered, as well as waivers and deferrals, using its Military Immunization Tracking System (MITS). All four services transmit data to the central Defense Enrollment Eligibility Reporting System (DEERS) database.

MONITORING AND COMPLIANCE REPORTING

Monitoring and compliance using guidelines discussed in the preceding paragraphs are an ongoing quality assurance/quality improvement responsibility of both individual medical treatment facilities and the DOD military health system. Overarching guidance is established in a variety of ways, including standards printed in the joint immunization instruction, "Immunization and Chemoprophylaxis Regulation" (Army Regulation 40-562, Bureau of Medicine & Surgery Instruction 6230.15, Air Force Joint Instruction 48-110, Coast Guard Commandant Instruction M6230.4E), dated 1 November 1995. This regulation represents the current standard for immunizations and chemoprophylactic practices within the military health system. In addition to this joint regulation, each Service formal anthrax immunization implementation plan addresses clinical aspects of vaccine administration. Furthermore, we have begun additional programs to train health care providers before the next major expansion of the anthrax vaccine immunization program. In May 1999, the AVIP Agency sponsored the "First Annual DOD Conference for Biological Warfare Defense Immunizations" at Fort Detrick, Maryland, to train clinical experts in anthrax immunization. These trainers will further train and advise medical treatment facilities within their Service specified geographic areas or regions.

DOCUMENTATION

There are several other quality assurance/quality improvement measures commonly adopted in medical treatment facilities to ensure the highest clinical standards are fulfilled. All clinical encounters (e.g. immunizations administered, sick call visits, hospitalizations, etc.) are documented in the patient's health record (HREC). Each dose of anthrax vaccine is recorded in service-specific and DOD-wide tracking systems. The service-specific tracking system reports when a service-member is due the next dose or has been waived or deferred.

CLINICAL PANELS

At the facility level, health care providers use panels called morbidity-&-mortality committees to discuss and investigate negative outcomes such as death (none of which have been reported to date from anthrax vaccination). Medical treatment facilities have pharmacy & therapeutics (P&T) committees to review and encourage reporting of all medication-related adverse events (including those involving vaccines). Treatment

facilities submit reports of their quality assurance/quality improvement programs to each Service medical headquarters for corporate review and analysis. To monitor and assure compliance, all Services report any adverse events weekly to their higher medical headquarters.

INSPECTOR GENERAL STUDY

A DOD inspector general (IG) study begun Nov 98 is still underway to measure compliance with requirements to document anthrax vaccination. Data is still being collected and a final IG report is scheduled for October 1999.

DEPLOYMENT ELIGIBILITY GUIDANCE

Guidance to Service Members, Emergency Essential Civilians and contractor personnel regarding deployment eligibility involving anthrax vaccine is found in each Service anthrax immunization implementation plan; in the DOD Country/Theater Clearance Guide; and the "One Day Policy" issued 30 Mar 99 by the Secretary of Defense establishing a policy requiring anthrax immunization for duty in any of the current high-threat areas of one day duration or more. According to the Service implementation plans for anthrax immunization, DOD force-protection policy states a Service Member will be considered deployable if he or she received the first dose of the six-dose series, regardless of whether or not the series is complete. In those rare instances when an individual is unable to start or continue the anthrax vaccination series due to medical or administrative reasons, as with all DOD vaccines required for worldwide deployment, the Service Member is still deployable, but is the clear exception to the rule. The DOD goal is to receive the first three immunizations (at 0, 2 and 4 weeks) before entry into high threat areas because of the high degree of protective antibodies conferred. This alleviates some of the complexities of having to vaccinate personnel in a high threat area while trying to focus on contingency operations. Anyone unable to comply with vaccination prior to deployment begins or continues the vaccination series upon arrival. Clearly the DOD objective is to begin Total Force vaccinations once the anthrax vaccine stockpile is assured in order to eliminate these deployment confounders.

Our National and Military Security Strategies are founded on a posture of global engagement and emergency response, often requiring no-notice or short-notice deployment of AC and RC units and individuals who deploy, fight and support as teams. DOD is committed to protecting Service Members and Emergency Essential Civilians and contractors with a full anthrax vaccination series. Our program is sufficiently flexible to allow for individual waivers and deferrals when in the individual's best interests, based on objective scientific, clinical expertise and operational requirements.

RESERVE COMPONENT RETENTION

As of July 1, 1999, our records reflect 311,826 Service Members received at least one dose of anthrax vaccine. These include 285,164 members of the AC (91%) and

26,662 members of the RC (9%). Most of the reservists vaccinated to date are in rapid response units, primarily Air Force units. We consider it much too early in the process of vaccinating people in the Reserve Component to assess the effect, if any, of the Anthrax Vaccine Immunization Program on Reserve Component retention.

Isolating the effect of anthrax vaccination on RC retention in a turbulent environment, when so many variables are simultaneously changing, is very difficult to achieve. As you know, Mister Chairman, reserve units are experiencing unprecedented high levels of operations tempo (OPTEMPO), personnel tempo (PERSTEMPO), consolidation of units, changes in missions and equipment (e.g. sea, ground, air major combat platforms), downsizing, deactivations, realignments and other factors. The Assistant Secretary of Defense for Reserve Affairs is currently conducting a series of exit surveys of individuals leaving reserve service to identify trends about which you inquired.

CONCLUSION

DOD conducted serious studies to assess the safety and efficacy of the anthrax vaccine. We have found no serious, long-lasting adverse reactions due to anthrax vaccine. An independent panel of civilian academic experts, from some of America's best clinical institutions confirms our findings. I assure you, the Department of Defense is and will continue to be vigilant in our surveillance for any rare, unexpected reactions to anthrax vaccine. We are committed to fully investigating all allegations against the safety of anthrax vaccine and continuing full and complete disclosure of all risks, based on objective evidence.

We know anthrax kills and vaccination protects. We know death from anthrax is vaccine preventable and that DOD has a safe and effective vaccine to protect its Service Members. Vaccinating men and women we place in harms way to prevent death or serious injury is our moral and ethical duty — a leadership responsibility we perform with full and unfettered confidence.

Thank you for listening. I am now prepared to answer your questions.

(134)

To View or Download MEDCOM Form 700-R,
see below

MEDCOM Reg 40-39

DEPARTMENT OF THE ARMY

HEADQUARTERS, UNITED STATES ARMY MEDICAL COMMAND

2050 Worth Road

Fort Sam Houston, Texas 78234-6000

MEDCOM Regulation

No. 40-39 28 June 1999

Medical Services

ANTHRAX VACCINE ADSORBED (AVA) IMMUNIZATION DOCUMENTATION

Supplementation of this regulation and establishment of forms other than MEDCOM forms are prohibited without prior approval from HQ MEDCOM, ATTN: MCHO-CL.

1. HISTORY. This is the first printing of this publication.

2. PURPOSE. This regulation provides policy and implementing instructions for the use of a new form. This form will document that an individual received information on the Anthrax Vaccine Adsorbed (AVA) and was given the opportunity to ask questions concerning the AVA prior to receiving an AVA immunization at a U.S. Army Medical Command (MEDCOM) military treatment facility (MTF).

3. APPLICABILITY. This regulation applies to individuals who authorize and administer the AVA to Active Duty soldiers, Emergency Essential Civilians (EECs), and other authorized personnel at MEDCOM MTFs.

4. REFERENCES.

a. AR 40-66, Medical Record Administration and Health Care Documentation.

b. AR 40-562/AFJI 48-110/BUMEDINST 6230.15/CG COMDTINST M6230.4E, Immunizations and Chemoprophylaxis.

c. HQDA Letter 40-99-1, The Use of DD Form 2766 and DD Form 2766C.

5. EXPLANATION OF ABBREVIATIONS AND TERMS.

a. Abbreviations.

AVA . . . . Anthrax Vaccine Adsorbed

DD . . . . . Department of Defense (form)

EEC . . . . Emergency Essential Civilian

MEDCOM . . . U.S. Army Medical Command

MTF . . . . military treatment facility

SF . . . . . standard form

b. Terms. See AR 40-66.

6. POLICY.

a. MEDCOM Form 700-R (Anthrax Vaccine Adsorbed (AVA) Immunization Record) will facilitate the documentation of AVA administration. The form will also serve to show that the individual received AVA information and was given the opportunity to ask questions about the AVA prior to receiving the immunization.

b. The form prescribed in this regulation replaces SF 601 (Health Record–Immunization Record) (as prescribed by AR 40-66) only when administering the AVA. All other immunizations will continue to be documented according to

AR 40-562/AFJI 48-110/BUMEDINST 6230.15/CG COMDTINST M6230.4E and HQDA Letter 40-99-1, and the appropriate forms filed according to AR 40-66 and HQDA Letter 40-99-1.

c. MEDCOM Form 700-R is authorized for local reproduction. A copy of this form is located in the back of this regulation.

d. All requirements of AR 40-66, other than those addressed in this regulation, remain in effect.

7. INSTRUCTIONS FOR USE OF THE AVA IMMUNIZATION RECORD. MEDCOM Form 700-R will be completed the first time a soldier, an EEC, or other authorized person receives an AVA immunization. If the immunization series has already been started, the form will be utilized beginning with the next immunization in the series. This form has two sections.

a. Section I, AVA Information Certification. This section will be completed by the individual the first time that the form is utilized. Prior to the administration of the AVA, the provider will give the individual the appropriate AVA information trifold (soldier, family member, or civilian) and ask the individual to read it. Following this, the provider will give the individual the opportunity to ask questions. The provider will then ensure that the individual signs and dates the certification.

b. Section II, Administration of AVA.

(1) The provider (AVA administrator) will fill in the requested data in the "Patient Identification" block and complete the line for the dose being administered. The provider will sign where indicated and add a printed or stamped signature block.

(2) Any AVA immunization previously entered on an SF 601 will be transcribed onto MEDCOM Form 700-R. If data is transcribed, a line will be drawn through the information on the SF 601 and the word "Transcribed" will be written along the line with the date, full name, and rank of the transcribing individual. Superseded forms will not be discarded from the medical record at any time; file the superseded SF 601 according to AR 40-66 and HQDA Letter 40-99-1.

(3) If an automated immunization tracking system printout is available, it may be used in place of section II of MEDCOM Form 700-R. The provider will authenticate the printout by reviewing and signing over a printed or stamped signature block before the printout is placed in the medical record.

c. Filing. File the forms (including any automated printouts) in the medical record together with any existing SF 601 according to AR 40-66. If the individual's medical record contains a DD Form 2766 (Adult Preventive and Chronic Care Flowsheet), attach the forms to the fastener on the right side of the folder.

d. Deployment. After DD Form 2766 is in use, the original DD Form 2766 will be removed from the medical record, and used as a treatment folder when an individual deploys; a copy of the DD Form 2766 will remain in the medical record. The original MEDCOM Form 700-R (or automated printout) will be fastened inside the DD Form 2766 and will accompany the individual to the field; copies will remain in the medical record. Any AVA immunizations given while the individual is deployed may be documented using MEDCOM Form 700-R (or an automated system) at the direction of the

supporting major area command surgeon. The DD Form 2766, the MEDCOM Form 700-R, and any automated printouts will be incorporated into the medical record when the individual returns, and the copies will be removed from the medical record and destroyed.

In order to view Form 700-R, you must have Adobe Acrobat Reader on your computer.
If you do not, *CLICK HERE*
to download Adobe Acrobat Reader.

Then
CLICK HERE
To view or download Form 700-R

The proponent of this publication is the Office of the Assistant Chief of Staff for Health Policy and Services. Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) to Commander, U.S. Army Medical Command, ATTN: MCHO-CL, 2050 Worth Road, Fort Sam Houston, TX 78234-6010.

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ANTHRAX VACCINE ADSORBED (AVA) IMMUNIZATION RECORD

For use of this form see MEDCOM Reg 40-39

SECTION I - AVA INFORMATION CERTIFICATION

1. I have been given an AVA information trifold: ☐ Yes ☐ No

   ☐ What Every Service Member Should Know About the Anthrax Vaccine

   ☐ What Every Family Member Should Know About the Anthrax Vaccine

   ☐ What Every Person Should Know About the Anthrax Vaccine

2. I have been given the opportunity to ask questions about the AVA prior to receiving the immunization.

3. SIGNATURE	4. SSN	5. DATE

SECTION II - ADMINISTRATION OF AVA

DATE GIVEN a	DOSE NUMBER b	DOSING SCHEDULE *(From Day 0)* c	DOSE *(ml)* d	SITE *(left or right arm)* e	MANUFACTURER AND LOT NUMBER f	ADMINISTERED BY *(Printed or stamped signature block)* g
	1	Day 0	0.5			
	2	2 Weeks	0.5			
	3	4 Weeks	0.5			
	4	6 Months	0.5			
	5	12 Months	0.5			
	6	18 Months	0.5			
	Booster	Annual	0.5			
	Booster	Annual	0.5			
	Booster	Annual	0.5			
	Booster	Annual	0.5			
	Booster	Annual	0.5			
	Booster	Annual	0.5			
	Booster	Annual	0.5			
	Booster	Annual	0.5			
	Booster	Annual	0.5			
	Booster	Annual	0.5			
	Booster	Annual	0.5			

PATIENT IDENTIFICATION *(For typed or written entries give: Name (Last, First, Middle); grade; SSN; hospital or medical facility.)*

(135)

CMAT Control #
2000262-0000031

DEPARTMENT OF THE ARMY
HEADQUARTERS, 227TH MEDICAL DETACHMENT
APO NEW YORK 09657

AFVH-XA-227-CO 3 March 1991

MEMORANDUM THRU Commander, 74th Medical Detachment

FOR DCCS, 44th Medical Brigade

SUBJECT: Anthrax Vaccination Program in LBC.

1. On 18 February 1991 the Commander, 227th Medical Detachment, was put in operational control of the anthrax immunization program for the COSCOM personnel who would be remaining in Log Base Charlie (LBC) after the ground offensive began.

2. The following principles guided the effort:

a. Only personnel remaining in the log base would be eligible to receive the anthrax vaccine because the amount of vaccine was llmited and the support personnel in the log bases would be the most likely targets of an anthrax biological attack.

b. Because significant protection from the vaccine is achieved only after the booster shot (2nd shot). priority would be given to giving the vaccine to persons who had already received the initial Immunization.

c. COSCOM would designate the units to be given priority for immunization.

3. On 19 February 1991 contact was made with the COSCOM POC, Major Evans. Coscom priorities were medical units, COSCOM and associated units, Military Police, the 507th CSG, and POL/Quartermaster units.

4. On 20 February the actual immunizations began with the COSCOM compound--HHC COSCOM, 360th C.A. Brigade, 2/4 MMC, and 251st RAOC with injections being given by the 360th medical personnel.

5. Between 20 February and 25 February approximately 2500 persons were immunized with anthrax vaccine Including persons getting their first or second doses. Units included HHC COSCOM, 360th C.B. Brigade, 2/4 MMC, 251st RAOC, 57th Signal Company, 16th MP Brigade, 419th Quartermaster Battalion, 407 Quartermaster, 44th Medical Brigade, 8/158th Aviatlon Battalion, Special Troops Battalion (STB), 7th Transportation Battalion, 185th Transportation Battalion, 70th Ordinance Battalion, the 257th Medical Detachment, and the 590th S&S.

6. An additional 2500 doses of vaccine were provided to the 62d Medical Group and the 85th Medical Battalion to be given to their personnel.

7. On 21 February 1991 an addition 1050 doses of anthrax vaccine arrived at the 32d MEDSOM addressed to Major Curtis of the 502d CRS. Investigation located Major Curtis as the EOC representative at the 507th CGS. He accepted our Invitation to immunize the SUPCOM units for whom the additional vaccine was Intended.

8. Arrangements had been made to return to the units previously visited to provide the second shots. Vaccine was reserved to provide for the booster. Over 2600 doses were scheduled to be given to COSCOM units in LBC between 26 February and 11 March. In addition, over 900 doses of vaccine were scheduled to be given for SUPCOM during the same period.

9. The program stopped on 28 February 1991 when there was no longer a demand for the vaccine the perceived threat having evaporated. This was evidenced by the cancelling of immunizations scheduled for the following 2 days by the 49th MCT, the 25th Signal Battalion, and the 387th Quartermaster Battalion. The first follow-up immunizations were not scheduled to begin until 6 March. The war was over by 1 March 1991.

10. During the days 21-23 February a shot team of medics was provided by the 56th Medical Battalion which was of great help in providing the immunizations. Starting 24 February the 56th no longer provided support because their real mission took precedence--the ground offensive had begun. The rest of the immunizations were given by a shot team consisting of personnel from the 227th Medical Detachment. The 91S's after being trained by the commander filled syringes and the commander gave the injection. This arrangement worked as well as the shot teams previously provided.

11. The program had the following notes of interest:

a. Many units which were scheduled to move north desired to be immunized, but they were not eligible. These included the 34th Medical Battalion, the 47th CSH, and others.

b. Several units which were not eligible to receive the vaccine because they would be forward deployed managed to receive the first dose of the vaccine in January. These included the 5th MASH and the 47th CSH. The immunizing of these units contributed to the inadequate supply of vaccine for those units which were eligible to receive it.

c. There was not enough vaccine to immunize all COSCOM units remaining in LBC. Several commanders repeated contacted the 227th requestlng vaccine only to be informed that there was not enough vaccine and their units would not be receiving it. The most conspicuous of these units were the 25th Signal

Battalion. This unit was scheduled for immunizations only after more vaccine was obtained.

d. Many commanders made the immunization mandatory ensuring high levels of compliance and coverage. Other commanders made it optional which led to only 10-40% of those units actually getting the vaccine.

e. There was a great deal of misinformation about the anthrax-vaccine among the soldiers. Very many thought that the vaccine was NOT FDA approved and was an experimental drug. Many feared drastic systemic side affects. The side effect asked about time and again was sterility.

12. The anthrax immunization program in LBC was a significant success. In seven days over 2500 persons were Immunized, 2500 doses were provided to other medical units to immunize their personnel, and 3500 persons were scheduled to be immunized (mostly second doses).

13. The POC at the 227th Medical Detachment regarding this program is Major Moore, at the 44th Medical Brigade.

RICHARD H. MOORE
MAJ, MC
COMMANDING

(136)

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH VA 220419258

REPLY TO
ATTENTION OF

DASG-HCO

APR 18 2000

MEMORANDUM FOR OFFICE OF THE SECRETARY OF DEFENSE, DEPUTY SPECIAL ASSISTANT FOR GULF WAR ILLNESSES, ATTN (b)(6) (b)(6) 1000 DEFENSE PENTAGON, WASHINGTON, DC 20301-1000

SUBJECT: Request for Security Review

1. Your request for security review and public release of the document titled the Administration of Anthrax Vaccine with 20 attached slides has been completed and cleared for public release.

2. POC this action is (b)(6).

(b)(6)

LTC, MS
NRC STAFF OFFICER

ACTION SUMMARY SHEET

For use of this form, see MEDCOM Correspondence Guide and OTSG Reg 21-51

1. STAFF ACTION FOR: [X] OTSG [ ] MEDCOM

2. SUBJECT
DECLASSIFICATION BEQUEST

3. SUSPENSE DATE

4. DATE
14 Apr 2000

5. SUMMARY OF ACTION *(Briefly describe purpose, discussion/background, and recommendation for the action.)*

PURPOSE. To respond **to a request** by the Special Assistant for Gulf War **Illnesses, Office** of the Secretary of Defense (OSAGWI) review and declassify for public **release** the attached **two** documents: ADMINISTRATION OF BOTULINUM and ADMINISTRATION OF **ANTHRAX** VACCINE. **These** documents **were** previously **released** however were **released** with the wrong attachments.

RECOMMENDATION. Coordinated offices concur/ **nonconcur** with the public release of the above titled documents.

Concur w/declassification of attached Anthrax info only — no knowledge of BotTox.
COL, MS

6. COORDINATIONS

OFFICE SYMBOL	GRADE & LAST NAME	INI	DATE	OFFICE SYMBOL	GRADE & LAST NAME	INI	DATE
DASG-HCO	COL RANDOLPH		14 Apr 00				
DASG-HCO	LTC (b)(6)						

7. MEDCOM REVIEWS / APPROVALS				8. OTSG REVIEWS / APPROVALS			
	GRADE & LAST NAME	INI	DATE		GRADE & LAST NAME	INI	DATE
BR CH				BR CH			
DIV CH				DIV CH			
DIR/OFC CH				DIR/OFC CH			
SGS				ASST EXEC			
XO				EXEC			
CofS				ASG, Ops			
DCHCO				ASG, Per			
DCG				DSG			
CG				TSG			
SGS				SACO			
CSM							
				DISPATCHED			

9. NAME, GRADE. OFFICE SYMBOL, & PHONE NUMBER OF ACTION OFFICER
(b)(6) LTC, DASG-HCO, (b)(6)

10. SIGNATURE
(b)(6)

~~SECRET~~
(This document UNCLASSIFIED when separated from attachments)

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

SPECIAL ASSISTANT
FOR
GULF WAR ILLNESSES

UNCLASSIFIED

MAR 0 8 2000

MEMORANDUM FOR PROJECT OFFICER, OFFICE OF THE SURGEON GENERAL, UNITED STATES ARMY, ATTN: DASG-HCO ((b)(6))

SUBJECT: Declassification Request

This office is preparing Gulf War Illnesses narratives for release to GulfLINK. Therefore, request declassification and clearance for public release of two (2) documents (5 pages) that are attached. If the entire document cannot be declassified, please redact as necessary.

We conducted a search of GulfLINK, and to the best of our knowledge, these documents were not previously declassified/released.

Your response by March 30, 2000 would be greatly appreciated.

My point of contact for this action is (b)(6)

Hale A. Vesser

DALE A. VESSER
Deputy Special Assistant

Attachment(s)
CMAT #2000063-00000 I3
CMAT #2000063-0000014

UNCLASSIFIED

~~SECRET~~
(This document UNCLASSIFIED when separated from attachments)

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CMAT Control #
2000063-0000014

UNCLASSIFIED

Biological warfare is the intentional use of living organisms or their toxic products to cause death, disability or damage in man, animals or plants. The target is man, either by causing his sickness or death, or through limitation of his food supplies or other agricultural resources. Man must wage a continuous fight to maintain and defend himself, his animals and his plants in competition with insects or micro-organisms. The object of BW is to overcome these efforts by deliberately distributing large numbers of organisms of native or foreign origin, or their toxic products, taking full advantage of the ability to utilize more effective methods of dissemination and unusual portals of entry. BW has been aptly described as public health in reverse.

ANTHRAX VACCINATION PROGRAM

BW BACKGROUND

- Threat - Active enemy biowarfare program
- Agents - Anthrax
  - Botulinum toxin
  - Others
- Delivery - Artillary
  - Missiles
  - Aircraft
  - Terrorists

DETECTION AND PROTECTION

- No detection capability
  - Sick soldier the monitor
- Protection
  - Protective mask
  - Pre-exposure vaccination

ANTHRAX

Clinical Presentations

- Cutaneous
- Gastrointestinal
- Inhalation

INHALATION ANTHRAX

- Incubation period - 1 to 6 days
- Initial symptoms
  - Non-specific malaise
  - Low-grade fever
  - Non-productive cough
- Short period of improvement
- Terminal symptoms
  - Abrupt onset of dyspnea, stridor, and cyanosis
  - Tachycardia
  - Rapid progression to shock and death
- Chest X-ray - Wide mediastinum

UNCLASSIFIED

ENCLOSURE (1)

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UNCLASSIFIED

INHALATION ANTHRAX

Treatment

- 16/18 cases fatal with antibiotics alone
- No cases of pulmonary anthrax in vaccinated workers
- Oral ciprofloxacin 1000 mg initially followed by 750 mg twice daily
- Intravenous doxycycline 200 mg initially followed by 100 mg every twelve hours

INHALATION ANTHRAX

Treatment

- Antibiotics alone not protective in monkeys
- Partial vaccination plus antibiotics protective in monkeys
- If anthrax attack suspected, start prophylactic antibiotics.

  Ciprofloxacin 500 mg po bid

  or

  Doxycycline 100 mg po bid
- If confirmed, continue antibiotics for at least four weeks & complete vaccination series

ANTHRAX VACCINE

- Licensed FDA approved vaccine since 1972

  Alum-precipitated protective antigen preparation

  Contains formalin, benzethonium chloride
- Manufactured by Michigan Department of Public Health

ANTHRAX VACCINE

Immunogenicity

- Over 85% with some antibody after 1 dose
- Over 90% seropositive after 3 doses
- Rhesus monkeys with 2 vaccine doses survive large aerosol challenge

ANTHRAX VACCINE

Administration

- Shake the vaccine bottle immediately before use
- Clean the rubber stopper and an area on the backside of the arm with an alcohol pad
- Draw up 0.5cc of vaccine into the syringe
- Administer the vaccine subcutaneously at a 45° angle into the backside of the arm with a 25 gauge needle
- Warn the patient to expect a burning sensation at the vaccine site lasting 1-2 minutes

ANTHRAX VACCINE

Side Effects

- 6% will experience mild local discomfort at the inoculation site
- <1% will have more severe local reaction potentially limiting use of arm for 24-48 hours
- Mild systemic reactions (muscle aches, fatigue, low-grade fever) are uncommon
- Severe systemic reactions are rare
- A few vaccinees will develop small, firm, painless nodules at the injection site that will persist for several weeks

UNCLASSIFIED

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UNCLASSIFIED

ANTHRAX VACCINE

Schedule

- Two doses two weeks apart
- Third dose at least two weeks after second dose when additional vaccine becomes available

Storage

- Vaccine must be kept refrigerated and not frozen
- Avoid excess heat

ANTHRAX VACCINE

Administration

- Vaccine is supplied on ice in blood boxes
- Syringes, needles, and alcohol pads are provided
- Information sheet is provided on the administration of the vaccine
- Vaccine should be administered upon receipt or kept on wet ice or refrigerated

SUMMARY

Anthrax

- Symptoms occur 1-6 days post-exposure
- Fatal for unvaccinated or unprotected soldiers

Anthrax Vaccine

- FDA licensed and safe
- Vaccine provides good protection
- Side effects less severe than typhoid shot

OPERATION DESERT SHIELD

Biological Warfare Threats

Anthrax

Botulism

ANTHRAX

- Spore-forming bacterium
  - Global in distribution
  - Extremely stable
- Fermentation technology allows growth of enormous quantities easily
- Small volumes (several grams) contain tens of thousands of human lethal doses

ANTHRAX

Dissemination

- Readily dispersed covertly by aerosol over hundreds of square miles
- No means of detection available
- Target will not recognize attack until disease occurs (days later)

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ANTHRAX

Disease

- Inhalation anthrax exceedingly rare naturally
- Lethal to >85 % if not immune
- No effective treatment after onset of symptoms

ANTHRAX

Protection

- Physical protection against aerosol = chemical protective mask
- Vaccine available
  - Extensive human experience (> 10,000 vaccinees)
- 3 doses (0, 2, 4 weeks)
  - Some protection after 1 or 2 doses
- Mild - moderate reactions
  - Should not compromise operational capability

UNCLASSIFIED

DEPARTMENT OF THE ARMY
OFFICE OF THE VICE CHIEF OF STAFF
201 ARMY PENTAGON
WASHINGTON DC 20310-0201

CMAT Control #
2000087-0000015

137

1 Encl: AVIP Agency Briefing (Army Briefing)
(1 deleted page omitted)

REPLY TO
ATTENTION OF

DACS-ZB

28 April 1998

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Army Anthrax Vaccine Immunization Program Plan

1. The Secretary of Defense has determined anthrax immunizations are essential to protect the force against this deadly biological warfare agent. Soon the Secretary of Defense will direct us to immunize the force. This program is a command responsibility to execute and ensure our personnel are provided the maximum level of protection possible.

2. The approved Army Anthrax Vaccine Immunization Program Plan is enclosed. Commanders will prepare supporting plans to execute this critical force protection program.

Enclosure

WILLIAM W. CROUCH
General, United States Army
Vice Chief of Staff

ARMY ANTHRAX VACCINE IMMUNIZATION PROGRAM PLAN

REFERENCES: See ANNEX A

1. SITUATION.

a. General.

(1) The Department of Defense (DOD) Anthrax Vaccine Immunization Program (AVIP) is a command responsibility as part of force protection. Commanders are responsible for its implementation, education of their personnel, and tracking of the anthrax immunization series.

(2) DOD Directive 6205.3 sets DOD policy for the use of vaccines for biological defense. The anthrax vaccine meets each of the requirements outlined in this directive.

(3) Program Budget Decision (PBD) 708 provided for the expansion of the anthrax vaccine production base to ensure that adequate amounts of the vaccine are stockpiled and available if needed.

(4) The Joint Program Office for Biological Defense (JPO-BD) will maintain an adequate stockpile of vaccines and defined production capabilities, as determined by the Joint Staff and Services.

(5) The Food and Drug Administration (FDA) approved immunization schedule for this vaccine requires a series of six vaccinations (at 0, 2 and 4 weeks then 6, 12, and 18 months after the first immunization) followed by annual boosters.

(6) Forces deployed in the high threat areas of Southwest Asia and Northeast Asia, and those rotational forces into these areas, will be vaccinated first.

(7) Immunizations will be given to the Total Army force, mission-essential Department of the Army civilians, and mission-essential DOD contract civilians.

(8) DOD policy states that for force protection purposes, a service member will be considered deployable if he/she is enrolled in the six shot series, regardless of whether or not he/she has completed the series. However, it is desirable that all personnel assigned to high threat areas receive their first three shots prior to deployment. In those rare instances when an individual is not able to take or continue the anthrax series due to medical or administrative reasons, he/she is still deployable.

ANNEX K

IMMUNIZATION TRACKING SYSTEM

1. PURPOSE. To provide the concept of operations for Anthrax Automated Immunization Tracking for the Army Anthrax Vaccine Immunization Plan.

2. GENERAL INFORMATION.

a. The Anthrax Vaccine is a 6 shot series administered over a period of 18 months. Primary immunization consists of three subcutaneous injections, 0.5 ml each, given 2 weeks apart (0, 2, 4 weeks) followed by three additional subcutaneous injections, 0.5 ml each, given at 6, 12, and 18 months from the first vaccination. Subsequent booster injections of 0.5 ml at one year intervals are required to maintain immunity.

b. Soldiers that start the vaccination series may leave their duty stations, be deployed and/or be on leave before completion of the series. The Anthrax Immunization Tracking Program will provide visibility of these personnel and their immunization status.

c. A permanent entry will be made to the individual patient's medical record on SF-601, Health Record-Immunization Record, after each dose of Anthrax Vaccine is administered. Entry will include the date of immunization, name of vaccine, lot number and manufacturer of vaccine, series number, dose and route of administration, and name of provider. Immunization will also be noted in Department of Health and Human Services Form PHS 731, International Certificate of Vaccination. Local quality control and quality assurance measures shall be implemented to ensure the accuracy of these entries. Upon deployment, anthrax immunizations will be transcribed onto DA Form 8007.

i.e., IMEDPROS

d. Through the use of an automated immunization tracking system, anthrax vaccine immunization history will be annotated in an individual's data record. Required data elements include: patient name, SSAN, date of immunization, name of vaccine, series number, lot number, manufacturer, dose and route of administration, name of provider, and date next dose due.

3. CONCEPT OF OPERATIONS.

a. The Army will vaccinate forces (active and reserve components) IAW the FDA immunization schedule (6-shot series with annual booster) and DA DCSOPS guidance. DA DCSOPS will prioritize units authorized to receive the vaccine.

b. The Immunization Tracking System the Army will use to track the Anthrax vaccination program is the Force Medical Protection System (MEDPROS). MEDPROS is a subset of the Medical Occupational Data System (MODS). MODS resides on the mainframe computer system at the Pentagon. MEDPROS will become the legacy system to the quad-service immunization tracking system within the Preventive Health Care System (PHCS) in the Composite Health Care System (CHCS) II.

c. A training team from the MEDCOM and ASM Research, (civilian MODS contractors) will provide "train the trainer" courses across the MEDCOM and Army.

(1) Recommended population to be trained is those personnel that will input immunization data at point of service of the immunization ie., immunization clinics, Troop Medical Clinics; and at all levels of Command down through battalion level, those personnel responsible to the Commander to enforce vaccination schedules and keep the Commander informed (Battalion/ Brigade S1s, PSNCOs, etc).

(2) Classes are approximately 4 hours long including orientation, demonstration, and a practical exercise. A classroom with computer terminals is required with no more than two students per terminal. Terminals must be able to access the Wide Area Network (WAN) or have modems to access TSACS.

d. Other Services' military members, Department of Defense Civilian Employees and DOD Contractors may receive their vaccinations at Army MTFs IAW this plan and will be tracked using MEDPROS. Immunizations will be recorded in MEDPROS utilizing the add name function. The MEDPROS system will report anthrax immunization data to DEERS. Other services will gain visibility of their members vaccinated in Army facilities from the DEERS reports. MEDPROS will also read data from DEERS and record the evidence of soldiers receiving anthrax immunizations from another service. DEERS is the central repository for the anthrax immunization data and will provide reports to as required.

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BT
UNCLAS
SUBJ:CENTCOM AREA OF OPERATIONS: FORCE HEALTH PROTECTION GUIDANCE FOR USEUCOM PE
RSONNEL
REF/A/AFMC MEDIC CD ROM/DI-1810-207-00/JAN00//
AMPN/AFMIC MEDICAL ENVIRONMENTAL DISEASE INTELLIGENCE AND
COUNTERMEASURES (MEDIC) CD ROM//
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AMPN/EUCOM PREVENTIVE MEDICINE HOME PAGE //
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AMPN/DEPLOYMENT HEALTH SURVEILLANCE AND READINESS/4 DEC 98//
REF/D/DOD DIRECTIVE 6490.2/OSD/30AUG97//
AMPN/JOINT MEDICAL SURVEILLANCE//
REF/E/DOD INSTRUCTION 6490.3/07AUG97//
AMPN/IMPLEMENTATION AND APPLICATION OF JOINT MEDICAL SURVEILLANCE
FOR DEPLOYMENTS//
REF/F/OASD(HA) LTR DTD 6 OCT 98//
AMPN/POLICY FOR PRE- AND POST-DEPLOYMENT HEALTH ASSESSMENTS AND
BLOOD SAMPLESREF/G/CDC TRAVEL INFORMATION//
REF/G/CDC/WWW.CDC.GOV/NCIDOD/DVRD/RABIES/PREVENTION&CONTROL/PREVENTL
HTM//
AMPN/RABIES, POST-EXPOSURE PROPHYLAXIS GUIDELINES//
REF/H/MEMO/ASD(HA)/990330//
AMPN/ANNOUNCEMENT AND GUIDELINES FOR TEMPORARY SLOWING AND
FUTURE RESUMPTION OF ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP)//
REF/I/FM 21-10/21JUN00//
AMPN/FIELD SANITATION AND HYGIENE, FIELD MANUAL//
REF/J/DOA MEMO/01OCT98//
AMPN/SANITARILY APPROVED FOOD AMD WATER ESTABLISHMENT FOR ARMED
FORCES PROCUREMENT//
REF/K/DOS/WWW.STATE.GOV/INDEX.HTML//
AMPN/US STATE DEPARTMENT, TRAVEL WARNINGS & CONSULAR INFORMATION
SHEETS//
REF/L/ HTTP://WWW.CIA.GOV/CIA/PUBLICATIONS/FACTBOOK/INDEX.HTML//
AMPN/THECIA WORLD FACT BOOK//
REF/M/MSG/USCINCCENT/181300ZJAN97/CCJ1-XPX//
AMPN/USCINCCENT ROTATION POLICY FOR USCENTCOM AOR//
REF/N/DOC/USCINCCENT/OPORD 97-01A/990415/CCJS//
AMPN/USCINCCENT OPERATIONS ORDER 97-01A//
REF/O/USCINCCENT/301345ZAUG00//CCJ1//
AMPN/USCINCCENT INDIVIDUAL PROTECTION AND INDIVIDUAL/UNIT
DEPLOYMENT//
//
1. THIS MESSAGE PROVIDES FORCE HEALTH PROTECTION (FHP) GUIDANCE

(INCLUDING TRADITIONAL PREVENTIVE MEDICINE RECOMMENDATIONS) FOR ALL USEUCOM PERSONNEL (UNITS AND INDIVIDUAL AUGMENTEES) DEPLOYING TO THE USCENTCOM AOR (AFGHANISTAN, BAHRAIN, DJIBOUTI, EGYPT, ERITREA, ETHIOPIA, IRAN,IRAQ, JORDAN, KAZAKHSTAN, KENYA, KYRGYZSTAN, KUWAIT, OMAN, PAKISTAN. QATAR, SAUDI ARABIA, SEYCHELLES, SOMALIA, SUDAN, TAJIKISTAN, TURKMENISTAN, UNITED ARAB EMIRATES (UAE), UZBEKISTAN, AND YEMEN: AND THE WATERS OF THE ARABIAN GULF, GULF OF OMAN, ARABIAN SEA, GULF OF ADEN, AND RED SEA). PARA 2 PROVIDES PRE-DEPLOYMENT REQUIREMENTS. PARA 3 SPEAKS TO FHP ACTIVITIES DURING THE DEPLOYMENT. PARA 4 OUTLINES POST-DEPLOYMENT REQUIREMENTS, AND PARA 5 PROVIDES DETAILED INFORMATION FOR USE IN HEALTH THREAT/COUNTERMEASURES BRIEFINGS. IT IS IMPERATIVE THAT ALL PERSONNEL UNDERSTAND THE VITAL IMPORTANCE OF THOROUGH DOCUMENTATION OF ALL ASPECTS OF THE FORCE HEALTH PROTECTION AND DEPLOYMENT HEALTH SURVEILLANCE PROCESS.//
//
2. PRE-DEPLOYMENT FHP REQUIREMENTS/PROCEDURES//
2.1. REF M AND N, CONTAIN REQUIREMENTS FOR PERSONNEL DEPLOYING TO THE USCENTCOM AOR FOR 15 DAYS OR MORE FOR OPERATIONS, EXERCISES, OR TEMPORARY DUTY. PERSONNEL TRAVELING TO THE AOR FOR LESS THAN 15 DAYS ARE EXEMPT FROM THESE REQUIREMENTS UNLESS THEY ARE DEPLOYING TO AN AREA DESIGNATED THREATCON D. REGARDING FORCE HEALTH PROTECTION REQUIREMENTS, THIS EXEMPTION APPLIES ONLY TO NBC DEFENSE MEDICAL ITEMS REQUIRED TO BE TRANSPORTED. THIS EXEMPTION DOES NOT APPLY TO PERSONAL IMMUNIZATIONS, HEALTH SCREENING, AND PROTECTIVE MEDICINE COUNSELING. SERVICE COMPONENTS AND MILITARY SERVICES MAY INCREASE THE MINIMUM REQUIREMENTS FOR OPERATIONAL NEED: HOWEVER, THE MINIMUM REQUIREMENTS WILL NOT BE REDUCED WITHOUT PRIOR USCINCCENT APPROVAL. ALL DEPLOYERS, REGARDLESS OF ANTICIPATED LENGTH OF STAY, MUST BE ASSESSED PRIOR TO DEPARTURE AND DETERMINED TO BE MEDICALLY FIT FOR WORLDWIDE DEPLOYMENT, TO INCLUDE:
2.1.1. CURRENT PHYSICAL EXAMINATION OR ASSESSMENT, IAW SERVICE POLICY.//
2.1.2. NO UNRESOLVED HEALTH PROBLEMS (I.E., NO P-4 PROFILE OR LIMITED DUTY STATUS).//
2.1.3. DENTAL CLASS I/II.//
2.1.4. DNA SAMPLE ON FILE WITH THE DOD DNA SPECIMEN REPOSITORY (TELEPHONE (b)(6), DSN PREFIX (b)(6)).//
2.1.5. A HUMAN IMMUNODEFICIENCY VIRUS (HIV) TEST CURRENT WITHIN 12 MONTHS OF DEPLOYMENT (NOTE: A PRE-DEPLOYMENT SERUM SAMPLE WILL BE AUTOMATICALLY ACCOMPLISHED THROUGH THE MECHANISM OF HIV TESTING).//
2.1.6. DEPLOYABLE MEDICAL RECORD UPDATED WITH BLOOD TYPE. MEDICATION/ALLERGIES, SPECIAL DUTY QUALIFICATIONS, IMMUNIZATION RECORD, PRE-DEPLOYMENT HEALTH ASSESSMENT FORM AND SUMMARY SHEET OF PAST MEDICAL PROBLEMS.//
2.1.7. 90-DAY SUPPLY OF PRESCRIPTION MEDICATIONS; REQUIRED MEDICAL EQUIPMENT (GLASSES, HEARING AIDS, ETC); OCCUPATIONAL HEALTH PERSONAL PROTECTIVE EQUIPMENT (RESPIRATORY AND HEARING PROTECTION, DOSIMETERS. ETC).//
2.2. PERSONNEL POTENTIALLY DEPLOYING TO THE USCENTCOM AOR FOR 30 DAYS OR MORE (REPEAT, 30 DAYS OR MORE) MUST COMPLETE THE OASD/HA-APPROVED STANDARDIZED QUESTIONNAIRE DD FORM 2795 (AVAILABLE AT REF B). MEDICAL PERSONNEL MUST REVIEW EACH QUESTIONNAIRE, AND ENSURE APPROPRIATE MEDICAL FOLLOW-UP AS REQUIRED (I.E., RESPONSES DENOTED BY AN ASTERISK). FILE THE ORIGINAL IN THE DEPLOYER'S INDIVIDUAL MEDICAL RECORD, AND IMMEDIATELY FORWARD A COPY TO: ARMY MEDICAL SURVEILLANCE ACTIVITY, ATTN: DEPLOYMENT SURVEILLANCE, BLDG T-20, RM 213 (MCHB-TS-EDM), 6825 16TH ST NW, WASHINGTON DC 20307-5000.//
2.3. THE FOLLOWING IMMUNIZATIONS ARE REQUIRED FOR ALL PERSONNEL DEPLOYING TO THE USCENTCOM AOR:
2.3.1. HEPATITIS A (SERIES COMPLETE, OR DOSE ONE AT LEAST 14 DAYS PRIOR TO DEPARTURE)
2.3.2. TETANUS-DIPHTHERIA (EVERY 10 YEARS)
2.3.3. POLIO (ONE-TIME ADULT BOOSTER OF EITHER IPV OR OPV WITH A TRANSITION FROM OPV TO IPV. AS SOON AS PRACTICABLE)

2.3.4. YELLOW FEVER (EVERY 10 YEARS)
2.3.5. MEASLES (ONE-TIME ADULT BOOSTER IF BORN AFTER 1956)
2.3.6. INFLUENZA (CURRENT VACCINE ADMINISTERED)
2.3.6. TYPHOID (INJECTABLE, EVERY 2 YEARS; ORAL, EVERY 5 YEARS)
2.3.7. MENINGOCOCCAL QUADRIVALENT (EVERY 5 YEARS) MENINGOCOCCAL IS NOT A REQUIREMENT FOR PERSONNEL SERVING EXCLUSIVELY ABOARD NAVAL VESSELS UNLESS THEY WILL BE ASHORE MORE THAN 15 DAYS AT A SINGLE LOCATION.
2.3.8. PER REF H, PERSONNEL (ACTIVE DUTY, RESERVE FORCES, AND EMERGENCY ESSENTIAL DOD CONTRACTORS AND CIVILIANS) ASSIGNED, ON TEMPORARY DUTY OR DEPLOYED ON THE GROUND IN SOUTHWEST ASIA (ARABIAN PENINSULA (INCLUDING BAHRAIN, IRAQ, JORDAN, KUWAIT, OMAN, QATAR, SAUDI ARABIA, UAE, YEMEN, THE RED SEA AND THE PERSIAN GULF)) FOR AT LEAST 30 CONSECUTIVE DAYS, INCLUDING PERSONNEL NEWLY ASSIGNED FOR SUCH A PERIOD AND PERSONNAL AFLOAT ON CONTIGUOUS WATERS WHO HAVE CLEAR POTENTIAL TO BE COMMITTED ASHORE, SHALL RECEIVE ANTHRAX VACCINATIONS UNDER AVIP. VACCINATIONS FOR THESE PERSONNEL MAY BEGIN PRIOR TO ARRIVAL IN THEATER UP TO 45 DAYS PRIOR TO DEPLOYMENT. DURING THE PERIOD OF SLOWED PROGRAM EXECUTION, THIS 30 CONSECUTIVE DAY POLICY WILL REPLACE THE PREVIOUSLY ESTABLISHED "ONE DAY' POLICY. INITIATION OF VACCINE SERIES FOR PERSONNEL OTHER THAN THOSE DESCRIBED ABOVE IS NOT PERMITTED DURING THIS PERIOD OF SLOWED EXEUCTION. DURING THIS SAME TIMEFRAME, SUBSEQUENT VACCINATIONS.FOR PERSONNEL REDEPLOYING FROM THE CENTCOM AOR SHALL BE TEMPORARILY DEFERRED UNTIL DOD PROVIDES FURTHER AVIP GUIDANCE WHEN ADDITIONAL FDA-RELEASED VACCINE IS AVAILABLE.//
2.4. IN ADDITION, THESE IMMUNIZATIONS ARE REQUIRED FOR SELECTED PERSONNEL:
2.4.1. HEPATITIS B (FOR ALL MEDICAL PERSONNEL AND OTHERS AT OCCUPATIONAL RISK OF EXPOSURE TO BLOOD AND BODY FLUIDS SUCH AS MILITARY POLICE, FIREFIGHTERS).
2.4.2. RABIES VACCINE (FOR ALL PERSONNEL AT OCCUPATIONAL RISK OF EXPOSURE IAW SERVICE-SPECIFIC GUIDELINES. NOTE: POST-EXPOSURE PROPHYLAXIS GUIDELINES ARE AVAILABLE AT REF G).
2.4.3. PNEUMOCOCCAL VACCINE (FOR ASPLENIC PERSONNEL).
2.4.4. MALARIA CHEMOPROPHYLAXIS REQUIREMENTS VARY WITH LOCATION WITHIN THE USCINCCENT AOR. UNIT MEDICAL PERSONNEL SHOULD CHECK THE HEALTH RISK ASSESSMENT FOR THE SPECIFIC AREA IN WHICH THEIR UNITS WILL OPERATE.
2.4.5. NBC DEFENSE MEDICAL ITEMS IAW REF M, FOR CONTIGENCY OPERATIONS AND UNIT DEPLOYMENTS OF 15 DAYS OR LONGER, ATROPINE AND 2-PAM AUTOINJECTORS (THREE OF EACH INJECTOR PER DEPLOYING INDIVIDUAL) WILL BE EITHER BULK SHIPPED OR INDIVIDUALLY ISSUED. ADDITIONALLY, UNITS DEPLOYING TO THE ARABIAN PENINSULA WILL BULK SHIP CIPROFLOXIN 500MG TABS (SIX EACH PER DEPLOYING INDIVIDUAL), PYRIDOSTIGMINE BROMIDE (PB) TABS (ONE 18 OR 21 TABLET BLISTER PACK PER DEPLOYING INDIVIDUAL), CANA AUTOINJECTORS (ONE EACH PER DEPLOYING INDIVIDUAL) WITH THE DEPLOYING UNIT. IN THE EVENT OF NO INTRINSIC MEDICAL ELEMENTS, SERVICE COMPONENTS WILL ENSURE ADEQUATE AMOUNTS ARE PREPOSITIONED FOR DEPLOYED FORCES. NO INDIVIDUAL ISSUE OF CANA AND PB TABS IS AUTHORIZED UNTIL DIRECTED.//
2.5. PRE-DEPLOYMENT TUBERCULOSIS (TB) SCREENING. PER REF A, MUST HAVE DOCUMENTATION OF A PPD PERFORMED WITHIN THE PREVIOUS 12 MONTHS. PPD CONVERTERS/REACTORS WILL BE HANDLED IAW SERVICE POLICY. INH PROPHYLAXIS (ALONE) SHOULD NOT DISQUALIFY MEMBERS FROM DEPLOYING.11
2.6. HEALTH THREAT/COUNTERMEASURES BRIEFING. QUALIFIED PERSONNEL MUST INFORM ALL DEPLOYERS OF ANTICIPATED HEALTH THREATS AND RELEVANT COUNTERMEASURES, INCLUDING THE FOLLOWING:
2.6.1. ENDEMIC DISEASES.
2.6.1.1. ACUTE DIARRHEAL DISEASES.
2.6.1.2. CHOLERA.
2.6.1.3. VECTOR-BORNE DISEASES OTHER THAN MALARIA.
2.6.1.4. MALARIA. VARIABLE RISK IN CERTAIN AREAS - REFER TO PARA 2.4.4
2.6.1.5 TUBERCULOSIS.

2.6.1.6. RABIES.
2.6.1.7. SEXUALLY TRANSMITTED DISEASES (STD'S).
2.6.1.8. MENINGOCOCCAL MENINGITIS,
2.6.1.9. SCHISTOSOMIASIS.
2.6.2. ENVIRONMENTAL HEALTH THREATS.
2.6.2.1. TOPOGRAPHY AND CLIMATE.
2.6.2.2. CONTAMINATION AND POLLUTION.
2.6.2.3. DANGEROUS FLORA AND FAUNA.
2.6.3. OCCUPATIONAL HEALTH THREATS.
2.6.4. COMBAT AND DEPLOYMENT-RELATED STRESS.
2.6.5. INJURIES (WORK AND RECREATIONAL).
2.6.6. FOOD AND WATER SAFETY.
2.6.7. FIELD SANITATION AND PERSONAL HYGIENE.
2.6.8. CRIME AND TERRORISM, INCLUDING NUCLEAR, BIOLOGICAL AND CHEMICAL THREATS.
2.6.9. FOOD AND WATER SOURCES: ALL WATER (INCLUDING ICE) IS CONSIDERED NON-POTABLE UNTIL TESTED AND APPROVED BY APPROPRIATE MEDICAL PERSONNEL. NO BULK FOOD SOURCES WILL BE UTILIZED UNLESS INSPECTED AND APPROVED BY U.S. VETERINARY PERSONNEL. COMMANDERS WILL ENSURE THAT THE NECESSARY SECURITY IS IN PLACE TO PROTECT WATER AND FOOD SUPPLY AGAINST TAMPERING. MEDICAL PERSONNEL WILL PROVIDE CONTINUAL VERIFICATION OF QUALITY AND PERIODIC INSPECTION OF STORAGE FACILITIES.//
//
3. FHP REQUIREMENTS/PROCEDURES DURING DEPLOYMENT.
3.1. FOR ANY DEPLOYMENT TO THE USCENTCOM AOR, WITHOUT REGARD TO DEPLOYMENT LENGTH OR LOCATION:
3.1.1. DEPLOYED MEDICAL PERSONNEL AT EACH DEPLOYMENT LOCATION MUST CONDUCT DISEASE NON-BATTLE INJURY (DNBI) SURVEILLANCE FOR THE DEPLOYED POPULATION, USING THE BASIC COLLECTION AND ANALYSIS METHODS SET FORTH IN REF C. DNBI SURVEILLANCE SHOULD BEGIN WITH INITIATION OF HEALTH CARE DELIVERY.
3.1.1.1. THE MAIN REASON FOR TRACKING DNBI RATES IS THEIR VALUE AT THE UNIT LEVEL. SURVEILLANCE PROVIDES A VALUABLE EARLY WARNING SYSTEM FOR DETECTING (AND SUBSEQUENTLY MITIGATING) PROBLEMS WITH UNIT HEALTH AND EFFECTIVENESS.
3.1.1.2. COMMANDER SUPPORT IS ESSENTIAL.
3.1.1.3. DNBI SURVEILLANCE IS NOT REQUIRED IN THE ABSENCE OF DEPLOYED MEDICAL PERSONNEL.
3.1.2. COMMANDERS MUST ENSURE PERSONNEL COMPLY WITH REQUIRED MEDICAL FOLLOW-UP (E.G., CONTINUATION OF THE ANTHRAX VACCINATION SERIES ONCE INITIATED).
3.2. IAW REF C, WHEN THE JCS/EUCOM DEPLOYMENT ORDER IS FOR 30 CONTINUOUS DAYS OR MORE TO A LAND-BASED LOCATION THAT DOES NOT HAVE A PERMANENT US MILITARY MEDICAL TREATMENT FACILITY (MTF), COMMANDERS AND/OR MEDICAL PERSONNEL MUST:
3.2.1. REPORT DNBI SURVEILLANCE DATA (SEE PARA 3.1.1) TO HIGHER HEADQUARTERS USING JCS/EPINATO FORMAT (AVAILABLE AT REF B).
3.2.2. ENSURE SERVICE-SPECIFIC PROCEDURES ARE MAINTAINED FOR APPROPRIATE ARCHIVING OF HEALTH DOCUMENTS AND RECORDS.
3.2.3. CONDUCT SYSTEMATIC OCCUPATIONAL AND ENVIRONMENTAL HEALTH HAZARD SURVEILLANCE. THIS SHOULD INCLUDE:
3.2.3.1. STORAGE, USE, AND DISPOSAL OF HAZARDOUS MATERIALS.
3.2.3.2. ENVIRONMENTAL MONITORING OF AIR, WATER, SOIL, DISEASE VECTORS, AND RADIATION BASED ON ASSESSMENT OF ACTUAL AND/OR POTENTIAL MEDICAL THREATS IN DEPLOYED LOCATIONS.
3.2.4. ENSURE THE INTEGRITY OF FIELD HYGIENE/SANITATION AND OCCUPATIONAL HEALTH AND SAFETY PROGRAMS.
3.2.5. PROCURE AND CONSUME ONLY FOOD AND WATER FROM APPROVED SOURCES.
3.3. THE FORCE HEALTH PROTECTION REQUIREMENTS CAN BE USED AS GUIDANCE FOR FAMILY MEMBERS AND OTHER CATEGORIES NOT PREVIOUSLY MENTIONED. ADDITIONAL IMMUNIZATIONS OR HEALTH SCREENING MAY BE INDICATED AFTER EVALUATING AN INDIVIDUAL'S RISK FACTORS, MEDICAL RECORD AND ASSIGNMENT LOCATION. THESE CONCERNS SHOULD BE ADDRESSED

BETWEEN THE PATIENT AND HIS PRIMARY CARE PROVIDER PRIOR To TRAVELING OVERSEAS.//
//
4. REDEPLOYMENT/POST-DEPLOYMENT FHP REQUIREMENTS/PROCEDURES.
4.1. IAW REF C, FOR PERSONNEL DEPLOYED IN SUPPORT OF US OPERATIONS IN THE USCENTCOM AOR FOR 30 CONTINUOUS DAYS OR MORE TO A LAND-BASED LOCATION THAT DOES NOT HAVE A PERMANENT US MILITARY MTF, THE FOLLOWING MUST BE ACCOMPLISHED.
4.2.1. BEFORE DEPARTING THE DEPLOYMENT LOCATION, REDEPLOYERS RECEIVE A MEDICAL THREAT DEBRIEF AND COMPLETE THE OASD/HA-APPROVED POST-DEPLOYMENT QUESTIONNAIRE DD FORM 2796 (AVAILABLE AT REF B), WITH MEDICAL FOLLOW-UP AS REQUIRED.
4.2.2. CONDUCT TB SCREENING AT HOME STATION WITHIN ONE YEAR OF REDEPLOYMENT (OR SOONEK IAW SERVICE POLICY AND DEPENDING UPON DEGREE OF CONTACT WITH LOCAL POPULATION IN HIGH-RISK AREAS).
4.2.3. COLLECT (IAW SERVICE POLICY) A SERUM SAMPLE FOR HIV TESTING AND STORAGE IN THE SERUM REPOSSTORY, AT HOME STATION.
4.3. MEDICAL PERSONNEL SHOULD SUBMIT ALL LESSONS LEARNED, THROUGH CHANNELS, VIA THE JOINT UNIVERSAL LESSONS LEARNED SYSTEM (JULLS). AFTER ACTION REPORTS SHOULD BE SUBMITTED IAW SERVICE POLICY.
4.4. CONDUCT ADDITIONAL HEALTH ASSESSMENTS AND/OR HEALTH DEBRIEFS IF INDICATED BY HEALTH THREATS OR EVENTS OCCURRING IN THEATER.//
//
5. DETAILED INFORMATION FOR USE IN HEALTH THREAT AND COUNTERMEASURES BRIEFINGS.
5.1. ENDEMIC DISEASES (IAW REF A).
5.1.1. ACUTE DIARRHEAL DISEASES CONSTITUTE THE GREATEST IMMEDIATE INFECTIOUS DISEASE THREAT TO THE FORCE. CHOLERA IS ENDEMIC IN SOME AREAS, AND IS PRIMARILY TRANSMITTED BY INGESTION OF CONTAMINATED WATER. PER REF J, TO COUNTER BOTH OF THESE THREATS: NO FOOD OR WATER (INCLUDING ICE) SHOULD BE CONSUMED UNLESS FIRST APPROVED BY US MILITARY MEDICAL AUTHORITIES; HOWEVER, DEPLOYERS MUST BE EDUCATED THAT IF THEY DO PARTAKE OF LOCAL FARE, EAT ONLY (PIPING) HOT FULLY-COOKED FOODS AND AVOID WARM/COOL/COLD/PARTIALLY- OR UNCOOKED ITEMS; PEELED FRUITS AND VEGETABLES ARE GENERALLY CONSIDERED SAFE, BUT ARE SAFEST WHEN FIRST SANITIZED; EMPHASIZE FIELD SANITATION AND HYGIENE (IAW REF I).
5.1.2. VECTOR-BORNE DISEASES ARE TRANSMITTED BY MOSQUITOES, SAND FLIES, TICKS, LICE, AND FLEAS. MANY VECTORBORNE DISEASES ARE PRESENT IN THE USCENTCOM AOR. SEASONAL VARIABILITY SHOULD BE CONSIDERED. DISEASES INCLUDE MALARIA, TICK-BORNE ENCEPHALITIS, CRIMEAN-CONGO HEMORRHAGIC FEVER, SANDFLY AND WEST NILE FEVERS, RIFT VALLEY FEVER, AND LEISHMANIASIS; THEY CAN SIGNIFICANTLY IMPACT FORCE HEALTH UNLESS PREVENTIVE MEASURES ARE ENFORCED. AVOIDANCE OF VECTORS (24 HRS/DAY) IS KEY, INCLUDING HABITAT AWARENESS, PROPER WEAR OF UNIFORM/OTHER CLOTHING, AND USE OF:
5.1.2.1. INSECT REPELLENT, CLOTHING TREATMENT (PERMETHRIN); NSN 6840-01-278-1336, AEROSOL SPRAY OR IDA-KITS (NSN 6840-01345-0237). ONE CAN TREATS ONE BDU UNIFORM AND ONE MOSQUITO NET (READ LABEL CAREFULLY). AEROSOL SPRAY TREATMENT MUST BE REAPPLIED AFTER (MAXIMUM) 5 WEEKS OR 5 LAUNDERINGS. UNIFORMS TREATED WITH THE IDA-KIT ARE TYPICALLY PROTECTIVE FOR UP TO 6 MONTHS.
5.1.2.2. INSECT REPELLENT, PERSONAL APPLICATION (DEET), NSN 6840-01-284-3982. LOTION APPLIED DIRECTLY TO THE EXPOSED SKIN (AREAS NOT COVERED BY PERMETHRIN-TREATED BDU) PROTECTS AGAINST BITING INSECTS FOR UP TO 12 HOURS PER APPLICATION. MORE FREQUENT APPLICATION MAY BE REQUIRED IN HOT CLIMATES OR HEAVY RAINS.
5.1.2.3. TREATED BDU'S PLUS SKIN REPELLENT PLUS AVOIDANCE DISCIPLINE AFFORD NEARLY COMPLETE PROTECTION.
5.1.3. TUBERCULOSIS. ENDEMIC TO THE USCENTCOM AOR. HIGHEST RISK TO HUMRO PARTICIPANTS.
5.1.4. AVOID ANIMALS. DO NOT KEEP MASCOTS. ANIMALS CAN TRANSMIT VARIOUS DISEASES TO PEOPLE.
5.1.5. SYPHILIS, GONORRHEA, AND OTHER COMMON STD'S ARE PRESENT AT MODERATE LEVELS. HIV IS PRESENT. ABSTINENCE Is THE ONLY WAY TO

ENSURE PREVENTION OF STD'S. IT IS OFTEN IMPOSSIBLE TO DETECT A STD IN A POTENTIAL PARTNER. LATEX CONDOMS SHOULD BE MADE AVAILABLE AND USED BY ALL CHOOSING TO BE SEXUALLY ACTIVE. PROPER USE INCLUDES PLACEMENT PRIOR TO FOREPLAY, USE OF NON-PETROLEUM LUBRICANT TO DECREASE BREAKAGE AND USE OF A NEW CONDOM WITH EACH SEXUAL CONTACT. ENCOURAGE PERSONNEL TO SEEK PROMPT MEDICAL TREATMENT FOR STD SYMPTOMS.
5.1.6.MENINGOCOCCAL MENINGITIS IS PRESENT; HIGHEST RISK TO HUMRO PARTICIPANTS.
5.1.7. SCHISTOSOMIASIS (SNAIL FEVER) LARVAE MAY BE PRESENT IN CONTAMINATED, SNAIL INFESTED BODIES OF FRESH WATER - AVOID WADING OR SWIMMING TO THE EXTENT POSSIBLE. VIGOROUS DRYING OF THE SKIN AFTER EXPOSURE TO SUCH WATER, FOLLOWED IF POSSIBLE BY AN ALCOHOL WIPE-DOWN, CAN HELP PREVENT THE LARVAL PENETRATION OF THE SKIN. SYMPTOMS MAY NOT OCCUR UNTIL 2-6 WEEKS AFTER EXPOSURE AND MAY BE MILD - PHYSICIANS SHOULD BE AWARE OF POSSIBLE EXPOSURES AMONG REDEPLOYING TROOPS.//
5.2. PER REF A, ENVIRONMENTAL HEALTH THREATS.
5.2.1. HEAT INJURIES MAY BE THE GREATEST OVERALL THREAT TO MILITARY PERSONNEL DEPLOYED TO WARM CLIMATES. ACCLIMATIZATION MAY TAKE 10-14 DAYS. ENSURE PROPER WORK-REST CYCLES, ADEQUATE HYDRATION, AND COMMAND EMPHASIS OF HEAT INJURY PREVENTION TO INCLUDE:
5.2.1.1. INSISTING THAT PERSONNEL DRINK ADEQUATE WATER TO PREVENT DEHYDRATION (UP TO ONE AND ONE HALF QUARTS PER HOUR UNDER SEVERE HEAT/WORK CONDITIONS, NOT TO EXCEED TWELVE QUARTS PER DAY).
5.2.1.2. SCHEDULING WORK DURING THE COOLEST TIMES OF THE DAY, AND ESTABLISHING APPROPRIATE WORK-REST CYCLES BASED ON WET-BULB GLOBE TEMPERATURE (WBGT).
5.2.1.3. AWARENESS THAT DIARRHEA, SKIN TRAUMA, DRINKING ALCOHOL, FEVER, OBESITY, OLDER AGE, POOR PHYSICAL CONDITION, AND USE OF CERTAIN DRUGS (E.G., ATROPINE, ANTIHISTAMINES, OR "COLD" MEDICATIONS) INCREASE VULNERABILITY TO HEAT.
5.2.1.4. ENSURING AVAILABILITY AND USE OF INDIVIDUAL PROTECTION SUPPLIES/EQUIPMENT SUCH AS SUNSCREEN, LIP BALM, SUN GOGGLES, ETC.
5.2.2. RISK OF COLD INJURY WILL DEPEND ON THE SPECIFIC REGION, BUT CAN OCCUR IN ANY ENVIRONMENT. HYPOTHERMIA, A LIFE-THREATENING CONDITION, CAN OCCUR AT 55 DEGREES F (AIR TEMPERATURE). RISK OF COLD INJURY INCREASES FOR PERSONS WHO ARE IN POOR PHYSICAL CONDITION, DEHYDRATED, OR WET. COUNTERMEASURES INCLUDE:
5.2.2.1. CLOTHING AND COVER. EXPOSED SKIN IS MORE LIKELY TO DEVELOP FROSTBITE. ENSURE CLOTHING IS CLEAN, LOOSE, LAYERED AND DRY. COVER THE HEAD TO CONSERVE HEAT.
5.2.2.2. HYDRATION AND NUTRITION. PROVIDE WARM FOOD AND BEVERAGES, ESPECIALLY AT NIGHT. INCREASE WATER INTAKE TO 3-6 QUARTS PER DAY. AVOID ALCOHOL. INCREASE FOOD INTAKE TO 4 MRE'S (OR EQUIVALENT) PER DAY.
5.2.2.3. PHYSICAL ACTIVITY. PLAN FOR SHORTENED PERIODS OF SENTRY/GUARD DUTY. SHIVERING IS A WARNING SIGN OF IMPENDING COLD INJURY; INCREASE ACTIVITY, ADD CLOTHING, OR SEEK WARM SHELTER. USE THE BUDDY SYSTEM; OBSERVE ALL PERSONNEL FOR EARLY WARNING SIGNS/SYMPTOMS.
5.2.2. CONTAMINATION OF SURFACE AND GROUND WATER WITH RAW SEWAGE AND INDUSTRIAL WASTES, URBAN AIR POLLUTION AND VEGETABLES CONTAMINATED WITH PESTICIDES POSE LOCALIZED THREATS. CONSULT ENVIRONMENTAL ASSESSMENT AND MEDICAL FOOD INSPECTION PERSONNEL FOR LOCATION-SPECIFIC INFORMATION.
5.2.3. VARIOUS SPECIES OF POISONOUS SNAKES ARE PRESENT. AWARENESS AND AVOIDANCE ARE KEY.//
5.3. ASSUME THAT OCCUPATIONAL HAZARDS WILL NOT SIGNIFICANTLY DIFFER FROM THOSE AT HOME STATION. IF THE JOB AT HOME STATION REQUIRES USE OF PERSONAL PROTECTIVE EQUIPMENT (PPE), SO WILL THE JOB WHILE DEPLOYED.//
5.4. COMMANDERS AND THEIR PEOPLE SHOULD BE AWARE OF COMBAT AND DEPLOYMENT-RELATED STRESS, ITS SIGNS/SYMPTOMS AND HOW TO SEEK HELP FOR THEMSELVES OR THEIR BUDDY. PERSONNEL SHOULD BE COGNIZANT OF

SLEEP DISCIPLINE AND THE IMPACT OF ALCOHOL MISUSE.//
5.5. WORK--AS WELL AS SPORTS AND OTHER RECREATIONAL,--INJURIES ARE SIGNIFICANT CONTRIBUTORS TO NON-EFFECTIVENESS. COMMAND EMPHASIS OF SAFETY AWARENESS Is IMPORTANT.//
5.6. COMMANDER EMPHASIS OF GOOD FIELD SANITATION PRACTICES IS ESSENTIAL IN MAINTAINING FORCE HEALTH, INCLUDING: FREQUENT HANDWASHING; PROPER DENTAL CARE; CLEAN AND DRY CLOTHING (ESPECIALLY SOCKS, UNDERWEAR, AND BOOTS; BATHING WITH WATER FROM AN APPROVED SOURCE). IF A SHOWER IS NOT AVAILABLE, WASH SITES OF PERSPIRATION WITH A WASHCLOTH DAILY. BABY WIPES ARE USEFUL ALTERNATIVES. CHANGE SOCKS FREQUENTLY. FOOT POWDER HELPS PREVENT FUNGAL INFECTIONS.//
5.7. US FORCES SHOULD ALWAYS BE COGNIZANT OF POTENTIAL CRIME AND TERRORISM THREATS, AND TAKE MEASURES TO MINIMIZE PERSONAL AND UNIT VULNERABILITY. CONSULT YOUR FORCE PROTECTION POC FOR DETAILS REGARDING THE USCENTCOM AOR//.
5.7.1. COMMANDERS SHOULD ALWAYS CONSIDER THE POTENTIAL FOR DELIBERATE USE OF NUCLEAR/RADIOLOGICAL, BIOLOGICAL, OR CHEMICAL AGENTS (INCLUDING TOXIC INDUSTRIAL MATERIALS) IN DEPLOYMENT PLANNING AND PREPARATION. MEDICAL COUNTERMEASURES INCLUDE: IMMUNIZATIONS, PPE/MOPP GEAR, BW/CW ANTIDOTES; FOOD, WATER AND ENVIRONMENTAL VULNERABILITY ASSESSMENTS; INCREASED ENVIRONMENTAL SURVEILLANCE AS APPROPRIATE BASED ON INTELLIGENCE REPORTS; DNBI SURVEILLANCE (E.G., INCREASED DNBI COULD BE THE FIRST INDICATION OF A TERRORIST-MEDIATED NBC EVENT).//
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6. POC FOR THIS MESSAGE IS LTC (b)(6), EUCOM/ECJ4-MR, COMMERCIAL PHONE (b)(6), DSN (b)(6) FAX (b)(6) E-MAIL (b)(6) OR (b)(6) THE USCENTCOM POC Is MAJ (b)(6), CCSG, COMMERICAL: (b)(6) DSN (b)(6), EMAIL (b)(6) OR (b)(6), FAX: DSN (b)(6) //
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PAAUZYUW RUcJAcc7199 1281525-UUUU--RHCUAAA RHDIAAA RHHMUNA RHMFIUU
RHRMDAA RUCBACM RUCCBWF RUCJACC RUCJICL RUCJICS RUCJNAV RUCKMEA
RUCQSOC RUCUSTR RUEACMC RUEADWD RUEAHOF RUEAHQA RUEASRT RUEKJCS
RUEOEEE RUEOEGA RUFGCIN RUHEHMS RULSJGA RULYSCC RUMIAAA RUPEUNA
RUWICBE.
ZNR UUUUU
P 0814112 MAY 01
FM USCINCCENT MACDILL AFB FL
TO RUEASRT/COMUSARCENT-CDRUSATHIRD FORT MCPHERSON GA//G-1/G-2/G-3/
G-4/AFRD-MD//
RUHEHMS/COMMARFORPAC//G1/G3/G4/G5/HS//
RHRMDAA/COMUSNAVCENT//N1/N3/N4/SG//
RUCJICS/COMSOCCENT MACDILL AFB FL
RUEOEGA/CJTF KUWAIT
RUEOEEE/CJTF SWA
INFO RHHMUNA/USCINCPAC HONOLULU HI//J1/J3/J4/SG//
RUCBACM/USCINCJFCOM NORFOLK VA//J1/J3/J4/SG//
RUFGCIN/USCINCEUR VAIHINGEN GE//J1/J3/J4/SG//
RUMIAAA/USCINCSO MIAMI FL//SCJ1/SCJ3/SCJ4/SCSG//
RUPEUNA/USCINCSPACE PETERSON AFB CO//J1/J3/SG//
RUCUSTR/USCINCSTRAT OFFUTT AFB NE//J1/J3/SG//
RHCUAAA/USCINCTRANS SCOTT AFB IL//J1/J3/J4/SG//
RUCQSOC/USCINCSOC MACDILL AFB FL//SOCJ1/SOJ3/SOJ4/SOSG//
RUEKJCS/JOINT STAFF WASHINGTON DC//J1/J3/J4/J4-MRD//
RUEACMC/CMC WASHINGTON DC//M&RA/PP&O/I&L//
RHMFIUU/CNO WASHINGTON DC//N1/N093//
RUCCBWF/DEPCHNAVPERS MILLINGTON TN//PERS4/40/4010G/442//
RHDIAAA/HQ ACC LANGLEY AFB VA//SG/DI/DII//
RUEADWD/DA WASHINGTON DC//DAMO-ODO/DASG//
RUEAHQA/HQ USAF WASHINGTON DC//DP/SG//
RUCJNAV/DEPCOMUSNAVCENT MACDILL AFB FL//SG/N1A//
RUHEHMS/COMUSMARCENT//G1/G3/G4//
RUWICBE/CG I MEF//G1/G3/G4/SG//
RUCKMEA/CG II MEF//G1/G3/G4/SG//
RULYSCC/CG III MEF//G1/G3/G4/SG//
RUCJACC/USCINCCENT MACDILL AFB FL//SUPR//
RUEADWD/CSA WASHINGTON DC
RUEAHQA/CSAF WASHINGTON DC
RULSJGA/COMDT COGARD WASHINGTON DC
RHCUAAA/HQ AMC SCOTT AFB IL
RUEAHOF/CDRPERSCOM ALEXANDRIA VA
RUCJICL/COMUSMARCENT HQ'MACDILL AFB FL
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[redacted]
SECTION 1 OF 5
SUBJ:USCINCCENT INDIVIDUAL PROTECTION AND INDIVIDUAL/UNIT DEPLOYMENT
MSGID/GENADMIN/USCINCCENT/CCJ1//
REF/A/DOC/USCINCCENT/CCR 525-8/960911/CCJ3-OG//
REF/B/MSG/USCINCCENT/191341ZDEC98/CCJ1-XPP//
REF/C/MSG/USCINCCENT/181300ZJAN97/CCJ1-XPX//
REF/D/DOC/USCINCCENT/OPORD 97-01A/990415/CCJS//
REF/E/WEB/WWW.FCG.PENTAGON.MIL/FCG/FCG.HTM/DOD 4500.54G, V-1//
REF/F/DOC/USCINCCENT/CCR 381-14/960927/CCJ2-JOCI//
REF/G/MEMO/JCS MSM-251-98/981204//
REF/H/MEMO/ASD(HA)/990330//
REF/I/DOC/AFJI 48-110/AR 40-562/BUMEDINST 6230.15/1 NOV 1995//

REF/K/MSG/USCINCCENT/122011ZJAN00/CCSG//
REF/L/DOC/DODFMR,VOL.7A AND VOL 12//
PAGE 32 RUCJACC7199 UNCLAS
REF/M/DOC/JFTR//
REF/N/DOC/DODI 3020.37//
REF/O/DOC/AFP/10-231/990401//
NARR/REF A IS DEPLOYMENT STANDARD OPERATING PROCEDURES.
REF B IS PREVIOUS VSCINCCENT INDIVIDUAL PROTECTION AND UNIT DEPLOYMENT POLICY MESSAGE,
REF C IS VSCINCCENT ROTATION POLICY FOR USCENTCOM AOR.
REF D IS OPERATIONS ORDER 97-01A.
REF E IS FOREIGN CLEARANCE GUIDE.
REF F IS CENTCOM COUNTER INTELLIGENCE POLICY.
REF G IS IMPLEMENTATION GUIDANCE FOR DEPLOYMENT HEALTH SURVEILLANCE AND READINESS.
REF H IS THE ANNOUNCEMENT AND GUIDELINES FOR TEMPORARY SLOWING AND FUTURE RESUMPTION OF ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP).
REF I IS IMMUNIZATION AND CHEMOPROPHYLAXIS POLICY.
REF J IS FORCE HEALTH PROTECTION (FHP) SUPPORT POLICY FOR USCINCCENT AOR 2.
REF K IS FORCE HEALTH PROTECTION (FHP) SUPPORT POLICY FOR USCINCCENT AOR 1.
REF L IS DEPARTMENT OF DEFENSE FINANCIAL MANAGEMENT REGULATION. REF
PAGE 03 RUCJACC7199 UNCLAS
M IS JOINT FEDERAL TRAVEL REGULATIONS.
REF N IS CONTINUATION OF ESSENTIAL DOD CONTRACTOR SERVICES DURING CRISES.
REF O IS AIR FORCE PAMPHLET/FEDERAL CIVILIAN DEPLOYMENT GUIDE.
RMKS/1. VSCINCCENT AREA OF RESPONSIBILITY (AOR) DEPLOYMENT POLICY IS BEING UPDATED TO REFLECT UPDATES CHANGING FOREIGN DUTY PAY (FDP) TO HARDSHIP DUTY PAY (HDP) AND EXPAND PUBLIC AFFAIRS (PA) GUIDANCE.
2A. REF A PROVIDES REQUIREMENTS THAT MUST BE MET FOR ALL PERSONNEL (UNITS AND INDIVIDUALS) DEPLOYING TO THE USCENTCOM AOR (AFGHANISTAN, BAHRAIN, DJIBOUTI, EGYPT, ERITREA, ETHIOPIA, IRAN, IRAQ, JORDAN, KAZAKHSTAN, KENYA, KYRGYZSTAN, KUWAIT, OMAN, PAKISTAN, QATAR, SAUDI ARABIA, SEYCHELLES, SOMALIA, SUDAN, TAJIKISTAN, TURKMENISTAN, UNITED ARAB EMIRATES [UAE], UZBEKISTAN, AND YEMEN; AND THE WATERS OF THE ARABIAN GULF, GULF OF OMAN, ARABIAN SEA, GULF OF ADEN, AND RED SEA). REF B IS HEREBY SUPERCEDED.
2B. REFS C AND D CONTAIN REQUIREMENTS FOR PERSONNEL DEPLOYING TO THE USCENTCOM AOR FOR MORE THAN 15 DAYS FOR OPERATIONS, EXERCISES, OR TEMPORARY DUTY. PERSONNEL TRAVELING TO THE AOR FOR LESS THAN 15 DAYS ARE EXEMPT FROM THESE REQUIREMENTS UNLESS THEY ARE DEPLOYING
PAGE 04 RUCJACC7199 UNCLAS
TO AN AREA DESIGNATED THREATCON D, THIS EXEMPTION APPLIES ONLY TO MEDICAL NBC DEFENSE ITEMS REQUIRED TO BE TRANSPORTED AND DOES NOT APPLY TO PERSONAL IMMUNIZATIONS, HEALTH SCREENING, AND PREVENTIVE MEDICINE COUNSELING. CENTCOM SERVICE COMPONENTS AND THE MILITARY SERVICES MAY INCREASE THE MINIMUM REQUIREMENTS FOR OPERATIONAL NEEDS, BUT MAY NOT REDUCE THE MINIMUM WITHOUT PRIOR USCINCCENT APPROVAL.
2. UPDATED DEPLOYMENT REQUIREMENTS FOLLOW:
2A. OVERSEAS PROCESSING. PARENT ORGANIZATIONS MUST PROCESS THEIR UNITS/PERSONNEL FOR OVERSEAS MOVEMENT PRIOR TO ARRIVAL IN THE USCENTCOM AOR.
2B. UNIFORM:
2B(1) INDIVIDUALS OR SMALL GROUPS TRAVELING VIA COMMERCIAL AIR OR

CLOTHING DURING TRAVEL PER REF E.
2B(2) THE PRESCRIBED UNIFORM FOR THE USCENTCOM AOR IS THE DESERT CAMOUFLAGE UNIFORM (DCU) WITH CAB (WEARING OF THE MILITARY ISSUED FLOPPY CAP IS A COMMANDER'S PEROGATIVE). IF NOT AVAILABLE THROUGH UNIT SUPPLY CHANNELS, THE BATTLE DRESS UNIFORM (BDU) MAY BE WORN.
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AVIATION PERSONNEL MAY WEAR THE APPROPRIATE UNIFORM FOR THEIR DUTY STATUS, E.G. FLIGHT SUIT. SHIPBOARD PERSONNEL WILL ONLY BE REQUIRED TO WEAR DCU/BDU IF STATIONED ASHORE.
2B(3) EQUIPPING DEPLOYING PERSONNEL IS A RESPONSIBILITY OF THE PARENT ORGANIZATION.
2C. PROTECTIVE MEASURES:
2C(1) ALL PERSONNEL DEPLOYING TO THE USCENTCOM AOR 15 DAYS OR LONGER WILL, AT A MINIMUM, DEPLOY WITH: PROTECTIVE MASK (WITH OPTICAL INSERTS AS REQUIRED), FILTERS (2 EA), GROUND ENSEMBLE (MOPP SUIT) (2 EA), GLOVES W/INSERTS (2 PAIR), OVERBOOTS (2 PAIR), HOOD (2 EA), M-8 AND M-9 PAPER PACK (2 EA), DECON KIT (2 EA), WEB BELT, CANTEEN AND
HELMET. PERSONNEL WILL DEPLOY WITH FLAK VEST IF ISSUED AS PART OF PERSONAL MILITARY EQUIPMENT. AGAIN, THE PARENT ORGANIZATION IS RESPONSIBLE FOR EQUIPPING DEPLOYING PERSONNEL.
2C(2) PRIOR TO DEPLOYING, ALL PERSONNEL MUST BE PROFICIENT IN INDIVIDUAL NBC DEFENSE SURVIVAL SKILLS INCLUDING DEPLETED URANIUM AWARENESS TRAINING AS PRESCRIBED BY SERVICE DIRECTIVES. UNITS MUST BE PROFICIENT IN THE EMPLOYMENT OF UNIT-LEVEL NBC EQUIPMENT.
2C(3) ALL PERSONNEL TRAVELING TO THE AOR IN A CAPACITY IN WHICH
PAGE 06 RUCJACC7199 UNCLAS
THEY BE TRAVELING OFF-BASE WILL
RECEIVE TRAINING FROM THEIR PARENT UNIT/COMMAND ON THE FOLLOWING TOPICS: CULTURAL ASPECTS OF THE COUNTRIES THEY WILL BE WORKING IN, RULES OF ENGAGEMENT, LEVEL ONE ANTI-TERRORISM (AT) MEASURES FOR SELF-PROTECTION (CONDUCTED BY A CERTIFIED LEVEL II AT INSTRUCTOR), FOREIGN INTELLIGENCE AND TERRORISM THREAT AND REPORTING RESPONSIBILITIES PER REF F, MEDICAL THREAT AND
MEDICAL SELF-AID/BUDDY CARE. TRAINING CAN BE EITHER CLASSROOM INSTRUCTION OR REQUIRED READING PRIOR TO TRAVELING TO THE AOR.
2D. WEAPONS: DEPLOYING PERSONNEL MUST BE QUALIFIED PER SERVICE REGULATIONS ON ASSIGNED WEAPONS. AUTHORITY TO DEPLOY WITH WEAPONS WILL BE INDICATED IN APPROPRIATE PLANNING DIRECTIVES, UNIT DEPLOYMENT ORDERS, INDIVIDUAL AUGMENTATION TASKING MESSAGE OR BY SEPARATE USCINCCENT POLICY. (RECOMMENDATION: INCLUDE COMMENTS CONCERNING DOD CIVILIANS AND CONTRACTORS CARRYING WEAPONS.)
2E. FORCE HEALTH PROTECTION: PROVIDES A CONCEPTUAL FRAMEWORK FOR OPTIMIZING HEALTH READINESS AND PROTECTING SERVICE MEMBERS FROM ALL HEALTH AND ENVIRONMENTAL HAZARDS ASSOCIATED WITH MILITARY SERVICE.
2E(1) HEALTH READINESS IS AN ONGOING SERVICE AND SERVICE MEMBER RESPONSIBILITY. IMMUNIZATIONS REQUIRE CURRENCY IN THE FOLLOWING

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CLINICAL AND ADMINISTRATIVE
AREAS:
2E(1)(A). DOD-MINIMUM REQUIREMENTS. PER REF G, ALL DEPLOYING PERSONNEL MUST BE CURRENT IN TETANUS/DIPHTHERIA, HEPATITIS A, MMR/MR, POLIO, INFLUENZA, AND TYPHOID IMMUNIZATIONS.
2E(1)(B) SERVICE-SPECIFIC REQUIREMENTS. ADDITIONAL REQUIREMENTS SPECIFIC TO INDIVIDUAL SERVICES AND TO CERTAIN MILITARY OCCUPATIONS

MAY BE PRESENT. EXAMPLES INCLUDE BUT ARE NOT LIMITED TO HEPATITIS B, VARICELLA, PNUEMOCOCCAL, AND RABIES VACCINES IMMUNIZATIONS.
2E(1)(C) USCINCCENT SPECIFIC REQUIREMENTS. ALL DEPLOYING PERSONNEL MUST BE CURRENT IN YELLOW FEVER AND MENINGOCOCCAL IMMUNIZATIONS. MENINGOCOCCAL IS NOT A REQUIREMENT FOR PERSONNEL SERVING EXCLUSIVELY ABOARD NAVAL VESSELS UNLESS THEY WILL BE ASHORE MORE THAN 15 CONSECUTIVE DAYS AT A SINGLE LOCATION. PER REF H, PERSONNEL (ACTIVE
PAGE 02 RUCJACC7200 UNCLAS
DUTY, RESERVE FORCES, AND EMERGENCY ESSENTIAL DOD CONTRACTORS AND CIVILIANS) ASSIGNED, ON TEMPORARY DUTY OR DEPLOYED ON THE GROUND IN SOUTHWEST ASIA (ARABIAN PENINSULA (INCLUDING BAHRAIN, IRAQ, JORDAN, KUWAIT, OMAN, QATAR, SAUDI ARABIA, UAE, YEMEN, THE RED SEA AND THE PERSIAN GULF)) FOR AT LEAST 30 CONSECUTIVE DAYS, INCLUDING PERSONNEL NEWLY ASSIGNED FOR SUCH A PERIOD AND PERSONNEL AFLOAT ON CONTIGUOUS WATERS WHO HAVE CLEAR POTENTIAL TO BE COMMITTED ASHORE, SHALL RECEIVE ANTHRAX VACCINATIONS UNDER AVIP. VACCINATIONS FOR THESE PERSONNEL MAY BEGIN PRIOR TO ARRIVAL IN THEATER UP TO 45 DAYS PRIOR TO DEPLOYMENT. DURING THE PERIOD OF SLOWED PROGRAM EXECUTION, THIS 30 CONSECUTIVE DAY POLICY WILL REPLACE THE PREVIOUSLY ESTABLISHED "ONE DAY" POLICY. INITIATION OF VACCINE SERIES FOR PERSONNEL OTHER THAN THOSE DESCRIBED ABOVE IS NOT PERMITTED DURING THIS PERIOD OF SLOWED EXECUTION. DURING THIS SAME TIMEFRAME, SUBSEQUENT VACCINATIONS FOR PERSONNEL REDEPLOYING FROM THE CENTCOM AOR SHALL BE TEMPORARILY DEFERRED UNTIL DOD PROVIDES FURTHER AVIP GUIDANCE WHEN AS TO ADDITIONAL FDA-RELEASED VACCINE WILL BE AVAILABLE.
2E(1)(D) COMPONENT COMMANDS WILL REPORT IMMUNIZATION DATA THROUGH SERVICE CHANNELS IAW SERVICE GUIDELINES.
2E(2) THERAPUETIC/CHEMOPROPHYLACTIC MEDICATIONS.
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2E(2)(A) PER REF I, MALARIA CHEMOPROPHYLAXIS REQUIREMENTS VARY WITH LOCATION WITHIN THE USCINCCENT AOR. UNIT MEDICAL PERSONNEL SHOULD CHECK THE HEALTH RISK ASSESSMENT FOR THE SPECIFIC AREA IN WHICH THEIR UNITS WILL OPERATE.
2E(2)(B) MEDICAL NBC DEFENSE ITEMS IAW REF D. FOR CONTINGENCY OPERATIONS AND UNIT DEPLOYMENTS OF 15 DAYS OR LONGER, ATROPINE AND 2-PAM AUTOINJECTORS (THREE OF EACH INJECTOR PER DEPLOYING INDIVIDUAL) WILL BE EITHER BULK SHIPPED OR INDIVIDUALLY ISSUED. ADDITIONALLY, UNITS DEPLOYING TO THE ARABIAN PENINSULA WILL BULK SHIP CIPROFLOXIN 500MG TABS (SIX EACH PER DEPLOYING INDIVIDUAL), PYRIDOSTIGMINE BROMIDE (PB) TABS (ONE 18 OR 21 TABLET BLISTER PACK PER DEPLOYING INDIVIDUAL), CANA AUTOINJECTORS (ONE EACH PER DEPLOYING INDIVIDUAL) WITH THE DEPLOYING UNIT. IN THE EVENT OF NO INTRINSIC MEDICAL ELEMENTS, SERVICE COMPONENTS WILL ENSURE ADEQUATE AMOUNTS ARE PREPOSITIONED FOR DEPLOYED FORCES. NO INDIVIDUAL ISSUE OF CANA AND PB TABS IS AUTHORIZED UNTIL DIRECTED.
2E(3) MEDICAL RECORD. SERVICE POLICIES VARY ON WHETHER THE MEDICAL RECORD WILL ACCOMPANY THE SERVICE MEMBER ON DEPLOYMENT. REGARDLESS, THE FOLLOWING HEALTH INFORMATION MUST ACCOMPANY ALL PERSONNEL (SERVICE MEMBERS AND ALL OTHER DEPLOYING PERSONNEL):
PAGE 04 RUCJACC7200 UNCLAS
2E(3)(A) BLOOD AND RH TYPE.
2E(3)(B) CURRENT MEDICATIONS AND ALLERGIES.
2E(3)(C) SPECIAL DUTY QUALIFICATIONS.
2E(3)(D) IMMUNIZATION RECORD.
2E(3)(E) SUMMARY SHEET OF CURRENT AND PAST MEDICAL AND SURGICAL PROBLEMS.

2E(4) HIV TESTING. SCREENING WILL BE WITHIN THE PREVIous 12 MONTHS PRIOR TO DEPLOYMENT.
2E(5) TUBERCULOSIS SCREENING.
2E(5) (A) MUST HAVE DOCUMENTATION OF A PPD PERFORMED WITHIN THE PREVIOUS 12 MONTHS.
2E(5) (B) PPD CONVERTERS/REACTORS WILL BE HANDLED IAW SERVICE POLICY.
2E(6) DNA SAMPLE. OBTAIN SAMPLE OR CONFIRM PRIOR SAMPLING IS ON FILE. CONTACT THE DOD DNA SPECIMEN REPOSITORY (TELEPHONE (b)(6), DSN PREFIX (b)(6) ; HTTP://AFIP.ORG/OAFME/DNA/INDEX.HTML.
2E(7) ALL PERSONNEL MUST BE ASSESSED AND DETERMINED TO BE MEDICALLY AND PSYCHOLOGICALLY FIT FOR WORLDWIDE DEPLOYMENT. UNRESOLVED HEALTH
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CONDITIONS (INCLUDING BUT NOT LIMITED TO PREGNANCY, PSYCHIATRIC, AND DENTAL CONDITIONS) WHICH RESULT IN A P-3 PROFILE, LIMITED DUTY, OR LIGHT DUTY STATUS, MAY POSE A THREAT TO ALL DEPLOYING PERSONNEL AND MAY HINDER THE OPERATIONAL MISSION AND UNNECESSARILY BURDEN THE IN-THEATER MEDICAL SYSTEM.
2E(7) (A) PHYSICAL EXAMS AND SPECIAL DUTY EXAMS ARE CURRENT IAW SERVICE POLICY AND WILL REMAIN CURRENT FOR THE ANTICIPATED DURATION OF THE DEPLOYMENT.
2E(7) (B) MEDICATIONS. PROVIDE A 90 DAY SUPPLY OF REQUIRED PRESCRIPTION MEDICATIONS TO SERVICE MEMBERS.
2E(7) (C) PRESCRIBED PERSONAL MEDICAL EQUIPMENT. PROVIDE PRESCRIPTION EYEGLASSES (2 GLASSES), PROTECTIVE MASK INSERTS, HEARING AIDS, AND ORTHODONITC EQUIPMENT AS REQUIRED BY THE SERVICE MEMBER.
2E(7) (D) PERSONAL PROTECTIVE EQUIPMENT (PPE). PROVIDE RESPIRATORY AND HEARING PROTECTION, PERSONAL EXPOSURE DOSIMETERS, AND PERSONAL SAFETY EQUIPMENT REQUIRED IN THE PERFORMANCE OF DUTIES ON DEPLOYMENT.
2E(7) (E) DEPLOYABLE COMBAT HEALTH INFRASTRUCTURE PROVIDES ONLY LIMITED AND ROUTINE MEDICAL CARE. THEREFORE, SERVICE MEMBERS DEEMED
PAGE 06 RUCJACC7200 UNCLAS
UNABLE TO COMPLY WITH CENTCOM DEPLOYMENT REQUIREMENTS ON A CONTINUING BASIS AND SERVICE MEMBERS FOR WHOM DEPLOYMENT IS DEEMED A THREAT TO THE INDIVIDUAL OR OTHERS DUE TO DIAGNOSED MEDICAL, MENTAL HEALTH, OR DENTAL CONDITIONS, OR UNRESOLVED MEDICAL, DENTAL, OR MENTAL HEALTH CONDICTIONS ARE CONSIDERED UNFIT FOR DEPLOYMENT. DEPLOYED SERVICE MEMBERS EVIDENCING SUCH CONDITIONS AFTER INITIAL DEPLOYMENT WILL BE RETURNED TO HOME STATION IMMEDIATELY UNLESS AN EXCEPTION IS GRANTED BY'HQUSCENTCOM. REQUEST FOR SUCH EXCEPTION WILL BE FORWARDED THROUGH COMMAND CHANNELS.
2E(8) HEALTH ASSESSMENT. CONDUCT PRE- AND POST- DEPLOYMENT HEALTH ASSESSMENT (DD FORM 2795 AND DD FORM 2796 RESPECTIVELY) IAW REFERENCES G AND J.
2E(9) HEALTH SURVEILLANCE AND PROTECTION DURING DEPLOYMENT. ALL UNITS WILL SUPPORT DISEASE AND ENVIRONMENTAL SURVEILLANCE REQUIREMENTS AND RECOMMENDATIONS PER REFERENCES G AND K.
2E(10) PRE-DEPLOYMENT HEALTH RISK COMMUNICATION. PROVIDE HEALTH INFORMATION TO EDUCATE, TO MAINTAIN FIT FORCES, AND TO CHANGE HEALTH RELATED BEHAVIORS FOR THE PREVENTION OF DISEASE, ILLNESS, AND INJURY DUE TO RISKY PRACTICES AND UNPROTECTED EXPOSURES.
2E(10) (A) GENERAL ISSUES TO BE ADDRESSED. INFORMATION REGARDING

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KNOWN AND SUSPECTED HEALTH RISKS AND EXPOSURES, HEALTH RISK COUNTERMEASURES AND THEIR PROPER EMPLOYMENT, PLANNED ENVIRONMENTAL AND OCCUPATIONAL SURVEILLANCE MONITORING, AND THE OVERALL OPERATIONAL RISK MANAGEMENT PROGRAM.
2E(10)(B) CONTENT. SHOULD INCLUDE, BUT NOT BE LIMITED TO THE FOLLOWING AREAS: OPERATIONAL OR COMBAT STRESS, NUCLEAR, BIOLOGICAL, CHEMICAL THREATS, ENDEMIC INFECTIONS, COMMUNICABLE DISEASES, VECTORBORNE DISEASES, ENVIRONMENTAL CONDITIONS, SAFETY, OCCUPATIONAL HEALTH, ENDEMIC PLANTS, ANIMALS, REPTILES, AND INSECTS HAZARDS.
2E(11) A SIGNIFICANT RISK OF DISEASE CAUSED BY INSECTS AND TICKS EXISTS YEAR-ROUND IN THE AOR. THE THREAT OF DISEASE WILL BE MINIMIZED BY USING THE DOD INSECT REPELLANT SYSTEM AND BED NETS; HTTP://WWW.AFPMB.ORG.
"AGE 02 RUCJACC7201 UNCLAS
2E(11)(A) TREAT UNIFORM WITH PERMETHRIN (INDIVIDUAL DYNAMIC ABSORPTION (IDA) KIT NSN: 6840-01-345-0237 OR AEROSOL SPRAY CAN METHOD NSN: 6840-02-278-1336).
2E(11)(B) APPLY DEET CREAM (NSN: 6840-02-284-3982) TO EXPOSED SKIN (ONE APPLICATION LASTS 6-12 HOURS).
2E(11)(C) WEAR UNIFORM PROPERLY TO MINIMIZE EXPOSED SKIN.
2E(12) FOOD AND WATER SOURCES:
2E(12)(A) ALL WATER (INCLUDING ICE) IS CONSIDERED NON-POTABLE UNTIL TESTED AND APPROVED BY APPROPRIATE MEDICAL PERSONNEL.
2E(12)(B) NO BULK FOOD SOURCES WILL BE UTILIZED UNLESS INSPECTED AND APPROVED BY U.S. VETERINARY PERSONNEL.
2E(12)(C) COMMANDERS WILL ENSURE THAT THE NECESSARY SECURITY IS IN PLACE TO PROTECT WATER AND FOOD SUPPLY AGAINST TAMPERING. MEDICAL PERSONNEL WILL PROVIDE CONTINUAL VERIFICATION OF QUALITY AND PERIODIC INSPECTION OF STORAGE FACILITIES.
2E(13) THE FORCE HEALTH PROTECTION REQUIREMENTS CAN BE USED AS GUIDANCE FOR FAMILY MEMBERS AND OTHER CATEGORIES NOT PREVIOUSLY MENTIONED. ADDITIONAL IMMUNIZATIONS OR HEALTH SCREENING MAY BE INDICATED AFTER EVALUATING AN INDIVIDUAL'S RISK FACTORS, MEDICAL RECORD AND ASSIGNMENT LOCATION. THESE CONCERNS SHOULD BE ADDRESSED
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BETWEEN THE PATIENT AND HIS PRIMARY CARE PROVIDER PRIOR TO TRAVELING OVERSEAS.
2E(14) COMMANDERS WILL VISIBLY AND PROACTIVELY SUPPORT THE DEVELOPMENT, DELIVERY AND DISSEMINATION OF THE HEALTH THREAT COMMUNICATION ALONG WITH THE RECOMMENDED COUNTERMEASURES.
2F. HAND-CARRY PERSONAL ITEMS: AS A MINIMUM, DEPLOYING PERSONNEL MUST HAND-CARRY SEVEN COPIES OF ORDERS, VERIFICATION OF OVERSEAS PROCESSING, ID TAGS (1 SET), MILITARY ID CARD, EMERGENCY DATA CARD, OFFICIAL PASSPORT, AND UPDATED SHOT RECORD. (SEE CENTAF RECOMMENDATION)
2F(1) ID CARDS: PERSONNEL JOINING A UNIT UNABLE TO ISSUE ID CARDS WILL ENSURE THEIR PRESENT CARD DOES NOT EXPIRE DURING THE ANTICIPATED DEPLOYMENT/AUGMENTATION.
2F(2) PERFORMANCE REPORTS: PARENT COMMAND/UNIT SHOULD COMPLETE CHANGE OF DUTY EFFICIENCY AND PERFORMANCE REPORTS FOR AUGMENTEES PRIOR TO DEPARTURE PER APPROPRIATE SERVICE REGULATIONS/DIRECTIVES.
2F(3) SECURITY CLEARANCE: PERSONNEL WILL BE TRANSFERRED IN-STATUS PER APPROPRIATE SERVICE REGULATIONS/DIRECTIVES.
2F(4) ORDERS: ORDERS FOR INDIVIDUAL AUGMENTATION WILL STATE THE

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ULN AND LNR FOR THE POSITION
THE INDIVIDUAL WILL FILL. REMARKS BLOCK WILL STATE THE OPERATION OR CONTINGENCY THE ORDERS SUPPORT, IF GOVERNMENT MESS IS AVAILABLE, IF MESSING IS DIRECTED, AND IF BILLETING IS AVAILABLE.
3. FUNDING:
3A. GENERAL GUIDANCE: ABSENT AUTHORITATIVE CASE-SPECIFIC FUNDING INSTRUCTIONS (SUCH AS MAY BE FOUND IN JOINT STAFF OR USCINCCENT DEPLOYMENT ORDERS) FUNDING WILL REMAIN A COMPONENT/SUPPORTING COMMAND/AGENCY RESPONSIBILITY. SOCCENT, OTHER COMPONENTS, SUPPORTING COMMANDS AND OTHER AGENCIES WILL ABSORB THE FUNDING IMPACTS FOR TASKED RESPONSIBILITIES AND FOR THE TRANSPORTATION AND OTHER COSTS OF THEIR PARTICIPATING PERSONNEL/UNITS/AGENCIES. PARTICIPATING AGENCIES AND DOD ACTIVITIES WILL CAPTURE THEIR INCREMENTAL COSTS FOR REPORTING TO THEIR RESPECTIVE PARENT SERVICE/USSOCOM/PARENT AGENCY AND TO DFAS-DE IAW REFERENCE L, VOLUME 12, CHAPTER 23, PARAGRAPH 2306. FUNDING SHORTFALLS AND RELATED ISSUES/PROBLEMS WILL BE ADDRESSED THROUGH NORMAL SERVICE/AGENCY FUNDING CHANNELS.
3B. SPECIFIC GUIDANCE: SPECIFIC AUTHORITATIVE FUNDING INSTRUCTIONS ARE SITUATIONALLY DEPENDENT AND WILL BE PUBLISHED WHEN NECESSARY
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CASE-UNIQUE ISSUES/REQUIREMENTS ARE IDENTIFIED.
4. ENTITLEMENTS: COMMANDERS WILL LIMIT CROSS MONTH TRAVEL TO IMMINENT DANGER PAY (IDP)
AND COMBAT ZONE TAX EXCLUSION (CZTE) DESIGNATED LOCALITIES WITHIN THE USCENTCOM AOR TO THE
MAXIMUM EXTENT POSSIBLE. ALL REASONABLE MEASURES WILL BE TAKEN TO ENSURE TDY/TAD TRAVEL IS COMPLETED WITHIN A SINGLE MONTH TO PREVENT ABUSE OF RELATED ENTITLEMENTS. MISSION REQUIREMENTS WILL BE USED AS THE ULTIMATE DETERMINING FACTOR IN JUSTIFYING CROSS MONTH TRAVEL.
4A. IDP: A MEMBER IS ENTITLED TO IDP WHEN
HE/SHE IS ON OFFICIAL DUTY IN A DESIGNATED IDP AREA. CURRENTLY THE LAND AREAS WITHIN EGYPT, ETHIOPIA, IRAN, JORDAN, AND PAKISTAN; THE LAND AREAS AND AIR SPACE OF AFGHANISTAN, BAHRAIN, IRAQ, KUWAIT, QATAR, SAUDI ARABIA, SOMALIA, SUDAN, AND YEMEN; AND THE PERSIAN GULF ARE DESIGNATED AS IDP AREAS. IDP IS PAYABLE AT $150.00 PER MONTH. THE AMOUNT Is NOT PRORATED AND THERE IS NO MINIMUM TIME REQUIREMENT. PER REF L (VOLUME 7A), A MEMBER IS NOT CONSIDERED TO BE ON OFFICIAL DUTY IN A DESIGNATED IDP AREA IF THE MEMBER IS IN THE AREA WhILE MERELY TRANSITING (AS DISTINGUISHED FROM PERFORMING OFFICIAL DUTY)
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BY ANY MEANS (INCLUDING VESSEL, AIRCRAFT, AND LAND CONVEYANCE) THE IDP AREA AS A CONSEQUENCE OF TRAVELING BETWEEN TWO POINTS, BOTH OUTSIDE OF THE IDP AREA. WHILE A MEMBER MAY BE REQUIRED TO TRANSIT A DESIGNATED AREA TO GET TO HIS/HER DESTINATION, THE CURRENT DOD POLICY IS THAT THE MEMBER WILL NOT QUALIFY FOR IDP.
4B. CZTE: AREAS THAT ENTITLE MEMBERS
TO CZTE INCLUDE BAHRAIN, KUWAIT, OMAN, QATAR, SAUDI ARABIA, UAE, PERSIAN GULF, RED SEA, GULF OF ADEN, GULF OF OMAN, AND ARABIAN SEA. FOR ENLISTED PERSONNEL, ALL INCOME EARNED IN THE MONTH DURING WHICH ANY TIME IS SERVED IN A COMBAT ZONE IS EXCLUDED FROM INCOME TAX. FOR OFFICERS, PAY EARNED UP TO THE HIGHEST RATE OF PAY PAYABLE TO ANY ENLISTED MEMBER PLUS THE AMOUNT OF HOSTILE FIRE PAY/IDP THAT IS ACTUALLY PAYABLE TO THE OFFICER FOR ANY MONTH DURING WHICH THEY QUALIFY FOR CZTE Is NOT SUBJECT TO WITHHOLDING OF FEDERAL AND STATE
INCOME TAX PER REF L (VOLUME 7A)

4C. HARDSHIP DUTY PAY (HDP) : FORMERLY KNOWN AS FOREIGN DUTY PAY (FDP) OR CERTAIN PLACES PAY. A LIST OF QUALIFIED AREAS CAN BE FOUND IN REF L, CHAPTER 17. EFFECTIVE 1 JAN 2001, HDP-LOCATION (HDP-L) RATES

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PAYABLE TO ALL SERVICE MEMBERS (BOTH OFFICER AND ENLISTED) ASSIGNED TO DESIGNATED HARDSHIP DUTY LOCATIONS WILL BE $50, $100, OR $150 A MONTH. THIS IS A SUBSTANTIAL INCREASE FROM THE PREVIOUS FDP, WHICH WAS LIMITED TO ONLY ENLISTED PERSONNEL AND RANGED IN AMOUNT FROM $8 TO $22.50 PER MONTH. A SERVICE MEMBER PERFORMING TEMPORARY DUTY IN A DESIGNATED AREA IS NOT ENTITLED TO HDP-L DURING THE FIRST 30 DAYS OF CONSECUTIVE SERVICE AT A DESIGNATED LOCATION, HOWEVER, ON THE 31ST DAY, HDP-L IS PAYABLE TO THE MEMBER RETROACTIVE TO THE DATE OF REPORTING FOR DUTY AT THE LOCATION. THIS IS BECAUSE MEMBERS IN THE AREA FOR A SHORT PERIOD DO NOT ENDURE THE SAME RANGE OF PHYSICAL HARDSHIPS AS MEMBERS RESIDING IN THE AREA FOR A LONG-TERM BASIS. THE ASSISTANT SECRETARY OF DEFENSE FOR FORCE MANAGEMENT POLICY (ASD(FMP)) DESIGNATES THE LOCATIONS THAT QUALIFY FOR HDP-L UNDER 37 U.S.C. SECTION 305. DESIGNATED LOCATIONS AND RESPECTIVE RATES WILL

BE PUBLISHED IN REF L, CHAPTER 17.
4D. FAMILY SEPARATION ALLOWANCE (FSA): PAYABLE TO MEMBERS WITH DEPENDENTS AND TO MILITARY COUPLES, REGARDLESS OF DEPENDENCY STATUS, WHO ARE SEPARATED BY GOVERNMENT ORDERS FOR MORE THAN 30 CONSECUTIVE DAYS AT THE RATE OF $100/MONTH. ONLY ONE MEMBER OF A MILITARY COUPLE CAN DRAW FSA AT A TIME. THIS ENTITLEMENT CANNOT BE PAID BEFORE THE 30-DAY QUALIFICATION PERIOD.
5. COMPENSATION: FOR OPERATIONAL OR CONTINGENCY DEPLOYMENTS, THE CINC OR JTF COMMANDER MAY SPECIFY ONE OF THE FOLLOWING THREE TEMPORARY DUTY OPTIONS IAW REF N, U4800:
5A. REGULAR TAD/TDY. THIS IS THE DEFAULT OPTION AND THE CURRENT OPTION BEING UTILIZED IN THE USCENTCOM AOR. PER DIEM ENTITLEMENT IS BASED ON TWO FACTORS, THE AVAILABILITY OF GOVERNMENT QUARTERS AND THE AVAILABILITY OF GOVERNMENT MESS.
5A(1) IF GOVERNMENT QUARTERS ARE AVAILABLE AT THE TAD/TDY LOCATION, THEN THE USE OF GOVERNMENT MESS WILL BE STATED AS ONE OF THE FOLLOWING IN THE ORDERS:
5A(1)(A) USE OF GOVERNMENT MESS IS NOT DIRECTED OR USE OF GOVERNMENT MESS WILL ADVERSELY AFFECT THE MISSION (THE FULL MEAL ALLOWANCE IS PAID, PLUS AN INCIDENTAL EXPENSE OF EITHER $2.00 CONUS

OR $3.50 OCONUS), OR
5A(1)(B) USE OF THE PROPORTIONAL MEAL RATE IS DIRECTED (THE PROPORTIONAL MEAL RATE IS PAID, PLUS AN INCIDENTAL EXPENSE OF EITHER $2.00 CONUS OR $3.50 OCONUS), OR
5A(1)(C) USE OF GOVERNMENT MESS IS DIRECTED. (IF GOVERNMENT MESS IS PROVIDED AT NO COST, THE MEMBER WILL ONLY BE ENTITLED TO AN INCIDENTAL EXPENSE OF $2.00 CONUS OR $3.50 OCONUS. IF GOVERNMENT MESSING IS AVAILABLE AT A COST, THE GOVERNMENT MEAL RATE OF $7.50 PER DAY, PLUS AN INCIDENTAL EXPENSE OF EITHER $2.00 CONUS OR $3.50 OCONUS WILL BE PAYABLE.)
5A(2) IF GOVERNMENT QUARTERS ARE NOT AVAILABLE AT THE TAD/TDY LOCATION, THEN USE OF GOVERNMENT MESS WILL NOT BE DIRECTED (THE FULL MEAL ALLOWANCE IS PAID, PLUS THE INCIDENTAL EXPENSE OF THE LOCALITY CONCERNED).

SECRETARY CONCERNED OR, FOR A JTF, THE CINC OR JTF COMMANDER DETERMINES THAT GOVERNMENT MESS IS ESSENTIAL TO ACCOMPLISH TRAINING AND READINESS. MEMBERS ARE ENTITLED TO RECEIVE THE INCIDENTAL EXPENSE RATE OF $2.00 CONUS OR, IF OCONUS, EITHER THE LOCALITY INCIDENTAL RATE OR $3.50 PER DAY WHEN THE ORDER ISSUING
PAGE 04 RUCJACC7202 UNCLAS
AUTHORITY DETERMINES IT TO BE ADEQUATE FOR ANTICIPATED INCIDENTAL EXPENSES. BAS ENTITLEMENT WILL BE AFFECTED AS INDICATED IN ITEM 6A(3) BELOW.
5C. FIELD DUTY: PAYMENT OF PER DIEM IS NOT AUTHORIZED. EVERYTHING NORMALLY ASSOCIATED WITH PER DIEM IS PROVIDED AT NO CHARGE TO THE MEMBER. IF FIELD DUTY IS DECLARED, BAS ENTITLEMENT WILL BE AFFECTED AS INDICATED IN ITEM 6A(4)(C) AND 6A(4)D BELOW.
6. BASIC ALLOWANCE FOR SUBSISTENCE (BAS): BAS ENTITLEMENTS ARE OUTLINED IN REF L, VOLUME 7A, CHAPTER 25. BAS ENTITLEMENTS WILL BE PAID ACCORDING TO WHICH TEMPORARY DUTY OPTION IS BEING UTILIZED FROM ITEM 5 ABOVE.
6A. REGULAR TAD/TDY: MEMBERS WILL HAVE THEIR BAS ADJUSTED As FOLLOWS:
6A(1) GOVERNMENT MESS DIRECTED OR USED;
6A(1) (A) OFFICERS BAS IS REDUCED BY THE FULL MEAL RATE OF $7.50 PER DAY. (NOTE: OFFICERS ENTITLED TO BASIC PAY ARE NORMALLY ENTITLED TO BAS AT ALL TIMES ON A MONTHLY BASIS.)
6A(1) (B) ENLISTED MEMBERS DRAWING FULL BAS AT THEIR DUTY STATION ARE ENTITLED TO A FULL BAS ALLOWANCE WHILE TAD/TDY BUT WILL HAVE THEIR BAS REDUCED BY THE FULL MEAL RATE OF $7.50 PER DAY,
PAGE 05 RUCJACC7202 UNCLAS
6A(1) (C) ENLISTED MEMBERS DRAWING PARTIAL BAS AT THEIR DUTY STATION ARE ENTITLED TO A FULL BAS ALLOWANCE WHILE TAD/TDY BUT WILL HAVE THEIR BAS REDUCED BY THE FULL MEAL RATE OF $7.50 PER DAY.
6A(2) GOVERNMENT MESS NOT DIRECTED OR NOT AVAILABLE;
6A(2) (A) OFFICERS BAS IS NOT AFFECTED.
6A(2) (B) ENLISTED MEMBERS DRAW FULL BAS DURING THIS PERIOD, REGARDLESS OF THE TYPE OF BAS ENTITLEMENT AT THEIR PERMANENT DUTY STATION.
6B. ESSENTIAL UNIT MESS (EUM): MEMBERS USING EUM AT TAD/TDY LOCATION WILL HAVE THEIR BAS ADJUSTED AS FOLLOWS:
6B(1). OFFICERS BAS WILL BE REDUCED BY THE DISCOUNTED MEAL RATE OF $6.15 PER DAY.
6B(2) ENLISTED MEMBERS ENTITLED TO FULL BAS WILL HAVE THEIR BAS REDUCED BY THE DISCOUNTED MEAL RATE OF $6.15 PER DAY.
6C. FIELD DUTY: FOR BAS PURPOSES ONLY, THIS OPTION IS DIVIDED INTO FIELD DUTY AND TEMPORARY FIELD ASSIGNMENT (TFA).
6C(1). FIELD DUTY, AS USED FOR BAS PURPOSES, IS DEFINED AS ANY MANEUVERS, WAR GAMES, EXERCISES, OR SIMILAR OPERATIONS IN EXCESS OF 180 DAYS WHERE A MEMBER IS SUBSISTED IN A MESS OPERATED BY, OR ON BEHALF OF THE GOVERNMENT, OR WITH AN ORGANIZATION DRAWING
PAGE 06 RUCJACC7202 UNCLAS
FIELD RATIONS.
6C(1) (A). BAS FOR MEMBERS WHEN FIELD DUTY Is DECLARED:
6C(1) (A) (1). OFFICERS WILL BE CHARGED THE DISCOUNTED MEAL RATE OF $6.15 PER DAY.
6C(1) (A) (2). ENLISTED MEMBERS ENTITLED TO FULL BAS PRIOR TO DEPLOYMENT WILL BEGIN DRAWING PARTIAL BAS ON THE DAY ENTERING INTO FIELD DUTY STATUS AND WILL BE CONSIDERED TO BE SUBSISTED IN KIND, UNTIL THEIR RETURN FROM FIELD DUTY.
6C(1) (A) (3) ENLISTED MEMBERS ENTITLED TO PARTIAL BAS PRIOR TO

STATUS AND WILL BE CONSIDERED TO BE SUBSISTED IN KIND.
6C(2). TEMPORARY FIELD ASSIGNMENT (TFA), FOR BAS PURPOSES, IS DEFINED AS ANY MANEUVERS, WAR GAMES, FIELD EXERCISES, OR SIMILAR OPERATIONS OF 180 DAYS OR LESS WHERE A MEMBER IS REQUIRED TO USE MESS PROVIDED BY OR ON BEHALF OF THE GOVERNMENT.
6C(2)(A) BAS FOR MEMBERS WHEN TFA IS DECLARED:
6C(2)(A)(1) OFFICERS WILL BE CHARGED THE DISCOUNTED MEAL RATE OF $6.15 PER DAY.
6C(2)(A)(2) ENLISTED MEMBERS ENTITLED TO FULL BAS WILL CONTINUE TO DRAW FULL BAS AND ARE REQUIRED TO PAY THE DISCOUNTED MEAL RATE OF

UNCLAS
FINAL SECTION OF 5
$6.15 PER DAY.
6C(2)(A)(3) ENLISTED MEMBERS ENTITLED TO PARTIAL BAS WILL CONTINUE TO DRAW PARTIAL BAS AND ARE CONSIDERED TO BE SUBSISTED IN KIND.
6D. THE FOLLOWING WILL BE USED AS GUIDANCE IN MAKING BAS ENTITLEMENT DETERMINATIONS:
6D(1). WHEN MEMBERS OF ONE OR MORE SERVICE PERFORM DUTY UNDER SIMILAR CONDITIONS AT INSTALLATIONS OR ARE ASSIGNED TO ACTIVITIES WITHIN THE SAME AREA, THE COMMANDERS WILL CONFER TO ENSURE UNIFORM DETERMINATIONS ON THE AUTHORIZATION OF BAS. IF COMMANDERS OF MORE THAN ONE SERVICE CANNOT AGREE ON A UNIFORM BAS RATE, THE SENIOR OFFICER WITHIN THE AREA WILL REPORT THE DIFFERENCES, FULLY DOCUMENTED, THROUGH PROPER CHANNELS TO THE SECRETARY OF DEFENSE.
6D(2). WHEN MEMBERS OF MORE THAN ONE SERVICE PERFORM DUTY AT AN INSTALLATION, THE INSTALLATION COMMANDER MAKES THE BAS
PAGE 02 RUCJACC7203 UNCLAS
DETERMINATIONS. SUCH DETERMINATIONS ARE BINDING ON ALL PERSONNEL OF THE DOD PERFORMING DUTY AT THE INSTALLATION.
6E. MILITARY MEMBERS MAY NOT RECEIVE A FULL BAS AND MEALS OR RATIONS AT NO CHARGE FOR THE SAME PERIOD OF SERVICE. MEMBERS IN RECEIPT OF ANY TYPE OF FULL BAS MUST PAY FOR MEALS AND RATIONS. THIS IS A PERSONAL OBLIGATION OF THE INDIVIDUAL. MEALS OR RATIONS MAY BE PAID FOR WITH CASH, BY PAYROLL DEDUCTION, OR BY COLLECTION/REDUCTION OF OTHERWISE ENTITLED TRAVEL PER DIEM. MEALS OR RATIONS PROVIDED BY OR ON BEHALF OF THE GOVERNMENT SHALL BE PAID FOR OR CHARGED AT THE RATE SET BY THE UNDER SECRETARY OF DEFENSE (COMPTROLLER). MEALS FURNISHED BY COMMERCIAL AIR CARRIERS (INCLUDING AIR MOBILITY COMMAND CHARTER FLIGHTS) ARE NOT MEALS FURNISHED BY A GOVERNMENT MESS OR ON BEHALF OF THE GOVERNMENT.
7. PROHIBITED ITEMS: CENTCOM GENERAL ORDER #1A IS IN EFFECT REGARDING ALCOHOL AND PORNOGRAPHIC MATERIAL.
8. MODE OF TRAVEL FOR INDIVIDUAL AUGMENTEES.
8A. ALL PERSONNEL WILL TRAVEL VIA MILAIR OR AMC CARRIER (ROTATOR FLIGHT), UNLESS SPECIFICALLY AUTHORIZED BY USCENTCOM OR A COMPONENT HQ TO TRAVEL VIA COMMERCIAL AIR.
8B. INDIVIDUALS AUTHORIZED TO TRAVEL VIA COMMERCIAL AIR MUST MEET
PAGE 03 RUCJACC7203 UNCLAS
REQUIREMENTS AS IDENTIFIED IN REF E.
9. DEPLOYMENT OF CONTRACTORS PROVIDING DOD ESSENTIAL SERVICES. USE THE GUIDANCE IN REF N.
10. DEPLOYMENT OF EMERGENCY-ESSENTIAL DOD FEDERAL EMPLOYEES. USE THE GUIDANCE PROVIDED IN REF O, AND ENSURE EMPLOYEES CARRY GENEVA CONVENTION CARDS.
11. PUBLIC AFFAIRS (PA) POSTURE PRIOR TO A WARNING ORDER IS

OPERATIONAL SECURITY AND TROOP SAFETY SHOULD ALWAYS BE THE FIRST PRIORITY. UNITS MAY COMMENT ON THEIR PREPARATIONS FOR **DEPLOYMENT** BUT MAY NOT DISCUSS ANY SPECIFIC INFORMATION CONCERNING THE MISSION; E.G. EXACT LENGTH OF DEPLOYMENT, EXACT NUMBERS OF PERSONNEL **OR** EQUIPMENT, ETC. UPON RECEIPT OF A WARNING ORDER, PA POSTURE IS ACTIVE IAW DETAILED PA GUIDANCE PUBLISHED UNDER SEPCOR.

12. THE **USCENTCOM POC'S** ARE: FORCE PROTECTION, CCJS, DSN (b)(6); TRAINING, **CCJ3-NBC,** DSN (b)(6); FORCE HEALTH PROTECTION, CCSG, DSN (b)(6); PERSONNEL PLANS & EXERCISES, **CCJ1-XPX,** DSN (b)(6); PERSONNEL POLICY & ENTITLEMENTS, **CCJ1-XPP,** DSN (b)(6); PUBLIC

AFFAIRS, CCPA, DSN (b)(6); FUNDING/COMPENSATION, CCCO, DSN (b)(6); ESSENTIAL CONTRACTOR SERVICES, CCJ4, DSN (b)(6) AND CCJA, **DSN** (b)(6); DOD EMERGENCY-ESSENTIAL FEDERAL EMPLOYEES, **CCJ1-MPC,** DSN (b)(6) **.//**

BT

#7203

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Received from **AUTODIN** 0815262 MAY 01

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DEPUTY SECRETARY OF DEFENSE
1010 DEFENSE PENTAGON
WASHINGTON, DC 20301-1010

CMAT Control #
2002183-0000003

(140)

JUN 28 2002

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
UNDER SECRETARIES OF DEFENSE
ASSISTANT SECRETARIES OF DEFENSE
GENERAL COUNSEL, DEPARTMENT OF DEFENSE
INSPECTOR GENERAL, DEPARTMENT OF DEFENSE
DIRECTORS OF DEFENSE AGENCIES
COMMANDANT OF THE US COAST GUARD

SUBJECT: Reintroduction of the Anthrax Vaccine Immunization Program (AVIP)

Food and Drug Administration (FDA) approval of the manufacturer's renovated facility restores the availability of anthrax vaccine. FDA has determined that the current anthrax vaccine is safe and effective in protecting against all forms of anthrax infection, a scientific conclusion recently supported by the Institute of Medicine.

Current intelligence assessments indicate that the anthrax threat to Department of Defense (DoD) forces is real. The Department's goal is to protect all forces against anthrax as a part of the Department's Force Health Protection program. Steps are being taken by the Department to ensure protection of U.S. servicemembers and DoD personnel against the threat of anthrax and other potential bioweapon agents, including improved intelligence, detection, and surveillance capabilities, protective clothing and equipment, and new generation vaccines and other medical countermeasures.

At this time, the DoD will resume an Anthrax Vaccine Immunization Program (AVIP) consistent with FDA guidelines and the best practice of medicine, beginning with military personnel, and Emergency-Essential DoD civilians and contractors, at higher risk whose performance is essential for certain mission critical capabilities. Vaccination is mandatory for these personnel, except as provided under applicable medical and administrative exemption policies.

The scope of the AVIP shall encompass personnel assigned to or deployed for more than 15 days in higher threat areas whose performance is essential for certain mission critical capabilities. Near-term AVIP implementation may also include other personnel determined by the Assistant Secretary of Defense for Health Affairs, in consultation with the Chairman of the Joint Chiefs of Staff, to be at higher

risk of exposure to anthrax as conditions change. Vaccinations shall begin, to the extent feasible, 45 days prior to deployment or arrival in higher threat areas.

For personnel who are covered under this new policy, who had previously begun the six shot series but had not completed it, resumption of their vaccination series will begin immediately. For personnel whose six shot series was interrupted, but who are not covered under the new policy, completion of their vaccination series will be deferred until further notice; resumption will begin when feasible, subject to availability of vaccine. Personnel currently being immunized—designated special mission units, manufacturing and DoD research personnel, and Congressionally mandated anthrax vaccine researchers—will continue with their scheduled vaccinations and annual booster shots.

The Under Secretary of Defense for Personnel and Readiness shall issue policy guidance on the medical and administrative aspects of the AVIP. Effective program implementation continues to be the responsibility of the Secretary of the Army as the Executive Agent for the AVIP and the designated senior military officers of the Services.

*** DRAFT – 1/9/03xx****

INTERAGENCY AGREEMENT BETWEEN THE DEPARTMENT OF DEFENSE AND DEPARTMENT OF STATE FOR ANTHRAX VACCINE ADSORBED AND SMALLPOX VACCINE

I. Purpose:

This interagency agreement provides for the Department of Defense (DOD) to transfer to the Department of State anthrax vaccine necessary to protect individuals from potential exposure to *B. anthracis* and smallpox vaccine to prevent the disease caused by variola virus.

Deleted:

II. Authority:

Title 31, United States Code, Section 1535 (the Economy Act).

III. Background:

In order to protect individuals from potential exposure to *B. anthracis*, it is necessary for the Department of State to obtain by interagency agreement a quantity of anthrax vaccine adsorbed ("anthrax vaccine"). DOD has anthrax vaccine it procured from BioPort Corporation. DOD is willing to make the vaccine available to the Department of State.

In order to protect individuals from the disease caused by variola virus, it is necessary for the Department of State to obtain by interagency agreement a quantity of smallpox vaccine (dried, calf-lymph type, *Dryvax*)(hereafter "smallpox vaccine"). Although other forms of smallpox vaccine exist, this document refers only to dried, calf-lymph type, Dryvax. DOD has smallpox vaccine it procured by Interagency Agreement of DATE XX **[Anybody have a copy of the agreement as signed by Jim Hughes? I don't know the date it was signed]** from the Department of Health and Human Services (HHS). Wyeth Laboratories stored, on behalf of HHS and the Center for Disease Control (CDC), the smallpox vaccine doses DOD purchased and which are now made available to the Department of State. Smallpox vaccine is licensed under regulations of the Food & Drug Administration (FDA). DOD is willing to make the smallpox vaccine available to the Department of State.

IV. Description Of Work:

DOD will deliver to the Department of State the quantity of doses of anthrax vaccine and smallpox vaccine required by the Department of State. The number of doses of vaccine to be provided under this agreement shall not exceed 300,000 full-strength doses **[Is this the right number?]** for anthrax vaccine and 20,000 full-strength doses for smallpox vaccine unless this agreement is amended by the parties to specify a new maximum number of doses. In the event of such an amendment, all other pertinent terms of this agreement shall apply.

DOD will deliver to the Department of State or its contractor(s) at locations to be designated by the Department of State the doses of anthrax vaccine and smallpox vaccine required.

For anthrax vaccine, the doses will be in multi-dose vials, each containing 5.2 milliliters of anthrax vaccine. The doses provided will be from vaccine lots licensed and released by the Food and Drug Administration and available for use in accordance with the product labeling. DOD will also provide the Department of State or its contractor(s) with any and all available documentation regarding this vaccine including, but not limited to, its potency and derivation, as well as release and characterization testing information. DOD will also provide the Department of State or its contractor(s) with the name, mail and e-mail address and telephone number of a technical, Program Executive Office for Chemical and Biological Defense (PEO-CBD) scientist who is qualified to answer all of the technical questions of Department of State or its contractor(s). The required material will be sent to Department of State or its contractor(s) as directed by the Department of State Project Officer.

Deleted: Joint Programs

Deleted: JPO-BD)

For smallpox vaccine, the doses will be 20,000 full-strength doses of smallpox vaccine **[Is this the right number?]** as produced and supplied by the manufacturer, consisting of one vial of dried vacuum sealed smallpox vaccine providing 100 doses of vaccine when reconstituted, one diluent syringe (0.25ml), one vented needle and 100 individually wrapped bifurcated needles as a combination package from the manufacturer for use by the Department of State. The 20,000 doses of smallpox vaccine will be provided with intact vacuum in each vial and will be labeled in a manner acceptable to the FDA under standard FDA lot-release procedures.

For both anthrax vaccine and smallpox vaccine, DOD will maintain any DOD-stored doses in a condition ready for prompt shipment within one business day upon request of the Department of State. DOD will be responsible for meeting requirements of the FDA or other prudent requirements for storage conditions for anthrax vaccine and smallpox vaccine. Upon delivery of vaccine to the Department of State, the Department of State assumes this responsibility for the delivered vaccine.

For each dose of anthrax vaccine transferred by DOD to the Department of State, the Department of State shall pay $XX per dose. Payment shall be provided in the manner specified by the liaison officers identified below. Labeling, packaging, and shipping preparation costs will be included in the per-dose price under this paragraph.

For each dose of smallpox vaccine transferred by DOD to the Department of State, the Department of State shall pay $XX per dose. Payment shall be provided in the manner specified by the liaison officers identified below. For all smallpox vaccine provided by DOD to the Department of State under this agreement, DOD will also provide sufficient diluent and needles needed for use of the vaccine. These will be included in the per-dose price under this paragraph.

The Department of State acknowledges that the Department of Defense contract with BioPort Corporation includes a clause providing indemnification under Public Law 85-804 for a wide range of losses that may arise from use of the vaccine purchased under the contract, and provisions regarding Wyeth Laboratories in the DOD-HHS Interagency Agreement of DATE XX. The Department of State further acknowledges its obligation under the Economy Act to reimburse DOD for its actual costs associated with the vaccines provided under this agreement. DOD and the Department of State agree that in the event that BioPort requests indemnification in connection with anthrax vaccine provided to the Department of State under this agreement, or in the event that Wyeth Laboratories requests indemnification in connection with smallpox vaccine provided to the Department of State under this agreement, DOD and the Department of State shall conduct a joint evaluation to determine any further reimbursement due in accordance with the Economy Act for costs incurred by DOD that are attributable to vaccine provided under this agreement. Any such reimbursement shall be subject to the availability of funds. If the Department of State determines it does not have sufficient funds for this purpose, the Department of State shall seek from Congress specific legislation enabling reimbursement of any costs incurred by DOD that are attributable to the Department of State's use of vaccine purchased under this agreement.

IV. Period of Agreement:

This agreement shall terminate three years from the date it is executed by the parties, subject to the availability of funds, unless earlier terminated by either party upon notice to the other party, or unless extended by agreement of the parties.

VI. Project Officers:

For DOD: _____ [What name or names go in here?] Deleted: , JPO-BD

For Department of State:

Anthrax Program:
(b)(6)
U.S. Department of State
2401 E Street, NW
Washington, DC 20522-0102

Smallpox Program
(b)(6)
U.S. Department of State

2401 E Street, NW
Washington, DC 20522-0102

VII. Funding:

Department of State will provide funding to DOD for anthrax vaccine in the amount of $_____ per dose requested. **[What is our full reimbursement charge?]**

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Appropriation number: _____
Common Accounting Number: _____
Object code: _____

Department of State will provide funding to DOD for smallpox vaccine in the amount of $_____ per dose requested. **[What is our full reimbursement charge?]**

Appropriation number: _____
Common Accounting Number: _____
Object code: _____

VIII: Billing Instructions:

Department of State will send payment via direct fund cite to

[Who will handle the money?]5203 Leesburg Pike, Suite 1609
Falls Church, VA 22041-3203
(b)(6)

Deleted: _____, JPO-BD

Deleted: .
Joint Programs Office for Biological Defense ¶

IX. Additional Requirements:

Department of State agrees to use the anthrax and smallpox vaccines in accordance with all requirements of the Food and Drug Administration.

[Note; Our original draft included the following paragraph;

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To promote consistency in government anthrax immunization policy, the Department of State will use the vaccines provided under this agreement to vaccinate only mission essential personnel, unless obtaining written concurrence from the Assistant Secretary of Defense (Health Affairs) to vaccinate other individuals.

State strongly objected to it and deleted it. Policy question for DoD is: Is it OK with DoD that State will be vaccinating adult dependents and DoD is not? A corollary question is whether dependents of military personnel assigned to embassies come

under DoD's policy or DoS's policy? If DoD can live with the fact of different policies, then we need not insist on retaining this paragraph. If not, we should reinsert it and push it back to State, and see if State takes it to the front office or to the White House.]

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Department of State: Department of Defense:

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Deleted: O

Grant Green, Jr.
Under Secretary of State for Management

William Winkenwerder, Jr, M.D.
Assistant Secretary of Defense
(Health Affairs)

Date:

Date:

(b)(6), Lt Col, OASD(HA)

From: Knott, Garland, COL, OASD/HA
Sent: Wednesday, January 15, 2003 12:22 PM
To: (b)(6), Lt Col, OASD(HA)
Subject: FW: Interagency Agreement

(b)(6)

Need your help. See below.

Thanks.

Garland

-----Original Message-----
From (b)(6)@state.gov]
Sent: Wednesday, January 15, 2003 12:15 PM
To: 'Knott, Garland, COL, OASD/HA'
Subject: RE: Interagency Agreement

Garland,
Another question: can you tell me what the paper trail is once A/S Winkenwerder signs the MOU? What I would like to confirm, specifically, is that once an execute order is issued to USAMA to release the doses to State, that we can negotiate quickly the hows and wheres of logistics with that agency. I assume they have complete authority to work those details with us, i.e., it does not become a CINC (or anyone else) issue?
Hope that question makes -- upon re-reading it, I'm not so sure. We are trying to determine the fastest, cleanest route for shipment, that minimizes the number of different hands handling the vaccine (so as to preserve the cold chain, etc.). If USAMA (hope I have that acronym right) can take our doses directly out of existing stockpiles already in the region or nearby, that would be our preference, but I want to make sure that there is only voice speaking to such logistical details. Thanks very much for your assistance.

(b)(6)

Chemical and Biological Countermeasures Working Group
SA-1 Rm. L-301
Tel (b)(6)
Fax
(b)(6)@state.gov

-----Original Message-----
From: Knott, Garland, COL, OASD/HA [mailto:Garland.Knott@ha.osd.mil]
Sent: Wednesday, January 15, 2003 8:57 AM
To: (b)(6)

Subject: RE: Interagency Agreement

(b)(6)

Thank you for your quick action.

Look forward to your reply.

Garland

-----Original Message-----
From: (b)(6) @state.gov]
Sent: Wednesday, January 15, 2003 8:44 AM
To: 'Knott, Garland, COL, OASD/HA'
Cc: (b)(6)
(b)(6)
Subject: RE: Interagency Agreement

Actually, General Counsel's office has put the same request forward to our lawyers, who are working on getting the numbers this morning. (b)(6) of our Legal Advisor's office will pass the numbers to OGC, and copy me and you on her reply.

(b)(6)
Chemical and Biological Countermeasures Working Group
SA-1 Rm. L-301
Tel (b)(6)
Fax
(b)(6) @state.gov

-----Original Message-----
From: Knott, Garland, COL, OASD/HA [mailto:Garland.Knott@ha.osd.mil]
Sent: Wednesday, January 15, 2003 7:50 AM
To: (b)(6)
Cc: (b)(6)
(b)(6)
Subject: Interagency Agreement

(b)(6)

Would you please prove Appropriation numbers, Common Accounting Numbers and Objective Codes for both anthrax and
Smallpox as required in paragraph VII, Funding, of the attached Interagency Agreement between the Department of Defense and Department of State for Anthrax Vaccine Adsorbed and Smallpox Vaccine.

Thank you.

Garland Knott

(b)(6) Lt Col, OASD(HA)

From: Knott, Garland, COL, OASD/HA
Sent: Wednesday, January 15, 2003 6:50 PM
To: (b)(6) Lt Col, OASD(HA)
Subject: RE: HFSC Agenda - 15 Jan 03

(b)(6)

Do we need to get more engaged with this group? I think we do. I see (b)(6) briefing only as the beginning or telling us what we need to do. The real question is, have we made an assessment and developed a solution. The solution or progress toward a solution is what we need to meet our Business Plan Objective. Let me know if there are any meetings that I can accompany you to. I know Tom Kurmel very well, so let me know what I can do to help.

Again, my apology for yesterday, but as you know the vaccine issue has gone high. In fact Dr. Winkenwerder weighed in today and this may reach the Deputy level. Let's reschedule with (b)(6)

Thanks for all your help over the past few days and if you are not out of the office, go home. Anyway, have a good evening and I will see you in the morning.

Garland

-----Original Message-----
From: (b)(6) Lt Col, OASD(HA)
Sent: Wednesday, January 15, 2003 12:09 PM
To: Knott, Garland, COL, OASD/HA
Subject: FW: HFSC Agenda - 15 Jan 03

Sir,
Copy of the brief from (b)(
(b)(

(b)(6) CFAAMA
Lt Col, USAF, MSC
Program Director, Logistics
5111 Leesburg Pike, Sky 4, Suite 901
Falls Church, VA 22041-3258
Voice: (b)(6)
Fax: (b)(6)

-----Original Message-----
From: MERVIS, Stuart [mailto:SMERVIS@lmi.org]
Sent: Wednesday, January 15, 2003 11:10 AM
To: Kurmel, Thom, COL, OASD(HA)/TMA
Cc: robert.hayhurst@ha.osd.mil; ROLON, Luis; DIDURO, John
Subject: RE: HFSC Agenda - 15 Jan 03

Thom, sorry for the late submission but am on the run. Here is my briefing for today's meeting. I will be there promptly at 1240. Thanks and see you there. I will bring 20 copies. Stu

-----Original Message-----
From: Kurmel, Thom, COL, OASD(HA)/TMA [mailto:Thom.Kurmel@tma.osd.mil]
Sent: Tuesday, January 14, 2003 8:18 AM
To: MERVIS, Stuart
Subject: RE: HFSC Agenda - 15 Jan 03

Thanks, we'll put your slides on the common drive here.
Thom

Thom Kurmel
COL, MS, US Army
Director of Facilities Life Cycle Management, TMA
Voice: (b)(6) Cell: (b)(6)

-----Original Message-----
From: (b)(6) @lmi.org]
Sent: Tuesday, January 14, 2003 7:50 AM
To: (b)(6) @tma.osd.mil
Subject: FW: HFSC Agenda - 15 Jan 03

Thom, I sent the below message to (b)(6) - I am on track for tomorrow and will get by short brief to you later today. (b)(6)

-----Original Message-----
From: (b)(6)
Sent: Tuesday, January 14, 2003 7:38 AM
To: (b)(6) OASD(HA)/TMA'
Subject: RE: HFSC Agenda - 15 Jan 03

(b)(6) I have been on the run the past couple of days - I have not forgotten about the briefing. I will send it to you later today and I am on track for attending tomorrow's meeting. (b)(

-----Original Message-----
From: (b)(6)
Sent: Thursday, January 09, 2003 8:47 AM
To (b)(6)
Cc COL, OASD(HA)/TMA
Subject: FW: HFSC Agenda - 15 Jan 03

(b)(6) Here's the agenda Thom mentioned. You will be the speaker at the 1240 - 1255 time slot; Critical Infrastructure (CIP) and Essential Facility Designation.

-----Original Message-----
From: (b)(6) @brooks.af.mil]

Sent: Tuesday, January 07, 2003 6:15 PM
To: (b)(6)
(b)(6)

Subject: HFSC Agenda - 15 Jan 03

All,

Here is the agenda for next the HFSC next Wednesday, 15 Jan 03. As usual, there's a lot to cover..... <<HFSC Agenda 15 Jan 03.doc>>
There are some changes and additions from the draft agenda so please review.

If anyone has any questions or concerns, please contact Col Peterson or me to discuss.

Special notes:

Col Kurmel - Please coordinate time for CARES Update--we can shift slot if necessary

(b)(6) - Please try to locate someone to present on CIP--we can shift schedule if necessary.

(b)(6) - Please note addition of short recap on GAO's Defense Infrastructure Report

(b)(6) - From last HFSC, looking for follow-up on IDIQ $ limits for MILCON A-E fees

(b)(6) - Note addition of AFMS Recap briefing (20 minutes + 5 minute discussion--or so)

(b)(6) - Design and Construction Subc -- status on D&C issues with special emphasis on commissioning, MILCON timeline, and IDIQ sources/capacity

(b)(6) - Note add of O&M funding update

(b)(6) - Note addition of recap on Corps' Policy Memo on MILCON Execution

Thanks,

Bill

WILLIAM C. TWEEDIE, Col, USAF, BSC, PE
Chief, Health Facilities Office-Western Region
AFELM HFO-WR, 333 Market Street, Suite 650
San Francisco, CA 94105-2196
COMM: (b)(6) FAX: (b)(6)
E-mail: (b)(6) brooks.af.mil

(b)(6) **Lt Col, OASD(HA)**

From: Knott, Garland, COL, OASD/HA
Sent: Thursday, January 23, 2003 11:20 AM
To: (b)(6) Lt Col, OASD(HA); Rauch, Terry, COL, OASD(HA)
Subject: FW: DHHS Response to Contingency Planning for Use of IND Product

Importance: High

Terry,

I will move forward unless you say otherwise.

Garland

(b)(6)

Looks like we may have another logistics opportunity to excel.

Would you please read this and give me your assessment. My thoughts are:

The major actions required to make this happen?
Agencies/office that will be involved?
Timeline and milestones with a target for completion?

Can we talk later today or first thing on Friday morning?

Thanks.

Garland

-----Original Message-----
From: Kendrick, Perry, COL, OASD(HA)
Sent: Thursday, January 23, 2003 11:01 AM
To: Knott, Garland, COL, OASD/HA
Subject: FW: DHHS Response to Contingency Planning for Use of IND Product
Importance: High

-----Original Message-----
From: (b)(6) CIV, OSD-POLICY
Sent: Wednesday, January 22, 2003 1:06 PM
To: Kendrick, Perry, COL, OASD(HA)
Subject: FW: DHHS Response to Contingency Planning for Use of IND Product
Importance: High

Perry, this is the email I had seen from (b)(6) on vaccine prepo. I have a voice mail message from (b)(6) to call him on this prepo issue. He seems serious about quick action. I'll let you know what he says when I call him. (b)(6)
-----Original Message-----
From: Adams, David, Col, OASD(HA)
Sent: Friday, January 17, 2003 3:43 PM
To: (b)(6)
(b)(6)

Cc:

Subject: FW: DHHS Response to Contingency Planning for Use of IND Product
Importance: High

Adventis-Pasteur

(b)(6) and Terry:
I spoke with COL Deutsch, the Army fellow at HHS, as well as (b)(6), on the issue of the 20M of AP vaccine that was agreed ("The USG will set aside"). A lot of complexity with this one. You can see at the end of this email string HHS' informal preference not to leave CONUS with this stuff (fine by me, but Dr W. at one time felt that interim staging was pretty critical). To counter his concern, HHS believes they can react quickly enough from the homeland, particularly if the event is in another direction.

The major concerns are related to IND management. Overall, issues I see on first blush include:

Options for set aside:
A. All in CONUS
B. All at one location OCONUS (USAMMCCE, forward of USAMCCE, other)
C. Split (combination of B)
D. Split (east and west)

Policy on use (need to reference the Summary of Conclusions paper):
A. All post-exposure
B. Some potential use pre-exposure

Logistics Support:
A. DoD control in CONUS
B. Via HHS contract in CONUS
C. Combination (HHS ship by their NPS contract mechanisms and we (DOD) control at destination
D. Combination (HHS ship " " " and they contract storage and management somewhere OCONUS
E. DOD control OCONUS

IND issues:
A. Need for PI appointment and "new" IND protocols developed by DOD?
B. Tap into existing IND protocols?
C. Exigency requirements?
D. If looking toward USAMCCE, targeting Landstuhl as a potential location for the PI to be identified from.

Finances:
- Any money exchange required (I understand the whole stockpile was only $12M)

Legal issues:
- Need for an IAA or MOU?

This will need significant work at the med log level of detail; I recommend this as another one for Garland and his bucket, working with the AT&L crowd.

(b)(6)

-----Original Message-----
From: (b)(6) @hhs.gov]
Sent: Friday, January 17, 2003 2:19 PM
To: (b)(6)
Cc:
Subject: DHHS Response to Contingency Planning for Use of IND Product

Through informal coordination with following agencies(organizations),

USAMRMC, USAMMA, USAMMCE, 16th MedLog Bn(Korea), the NPS(CDC) and the FDA., the following recommendations are provided concerning the DoD Contingency Planning for use of the IND Product:

Recommendation:
1. Do not move the IND product in anticipation of an OCONUS requirement. The NPS maintains this product under full compliance of the FDA and has the transportation agreements in place to deliver the product anywhere which would satisfy the post exposure event vaccination requirement.
2. Immediately establish the appropriate Interagency Agreements between the Department of State, the Department of Defense and the Department of Health and Human Services to response and act to meet the contingency requirement.
3. DoD needs to establish an IND protocol for this product in the event this product needs to be exported to support OCONUS contingency operations.

Justification:
1. Regulatory Requirements
a. The regulatory requirements for the IND product should be the deciding factor in making this determination. The NPS is operating under strict FDA requirements for the proper storage and reporting requirements of this IND product. To preposition this product forward would require the site(s) to meet the FDA certification and maintain the stringent protocol to ensure this product remains in compliance of the FDA.
b. The NPS has the response systems in place to respond to the event with the appropriate quantities thereby not potentially jeopardizing more of the product then needed and maintaining maximum flexibility to response to additional simultaneous or sequentially occurring contingencies.

2. Shipping- Customs regulations governs the shipping on an IND product out of the country. The requirements to ship with the intended application for non-US population would require the host nations regulatory approval and customs clearance. Currently, DoD does not have any IND products stored OCONUS specifically for this intended usage. The only IND products are stored for US applications on in support of its operations.
3. Storage Capacity- Not a limiting factor in any scenario. Storage facilities are available for the scenarios discussed (east, west or positioned forward of the central European location). This does not include the additional personnel needed to administer the regulatory requirements of the IND product.
4. Transportation: The NPS has international agreements with commercial carriers for worldwide deployment. These agreements would ensure delivery within 24hrs of receipt of shipment order.
5. Execution Authority:
a. An Interagency Agreement needs to be propositioned to execute a order to deploy this asset for this contingency. This would enable the DoD and DHHS response to be seamless and apportioned to meet the requirement.
b. DoD needs to file an IND for this product in order to execute even under emergency conditions.

COL Mary R. Deutsch
US Army War College Fellow

Department of Health and Human Services
Office of the Assistant Secretary For Public Health Emergency Preparedness
200 Independence Avenue
Washington, DC 20201

Work (b)(6)
Cell
Fax

(b)(6) , Lt Col, OASD(HA)

From: Knott, Garland, COL, OASD/HA
Sent: Friday, January 24, 2003 12:14 PM
To: (b)(6) Lt Col, OASD(HA)
Subject: RE: Interagency Agreement

(b)(6)

This is old business. Nothing further is required.

The agreement between DoD and DOS was completed. AT&L is now the lead on this issue. Because of the emphasis that was generated around this issue, I am surprised that by now Mr. Harvey has not heard through his official channels. This indicates to me that things may not be going as quickly as State expected them to go. I may contact (b)(6) just to keep our relationship on good terms.

But at this point we do not need to do anything further with this issue.

I thank you for your help and apologize that I have not keep you up to date. But things are moving fast and sometimes

Garland

-Original Message-----
From: (b)(6) Lt Col, OASD(HA)
Sent: Friday, January 24, 2003 11:30 AM
To: Knott, Garland, COL, OASD/HA
Subject: FW: Interagency Agreement

Sir,
FYI.
(b)(6

(b)(6)
Lt Col, USAF, MSC
Program Director, Logistics
5111 Leesburg Pike, Sky 4, Suite 901
Falls Church, VA 22041-3258
Voice: (b)(6)
Fax: (b)(6)

-----Original Message-----
From: (b)(6) @eaglegroupint.com]
Sent: Friday, January 24, 2003 11:13 AM
To: (b)(6)
Cc:
Subject: RE: Interagency Agreement

Just a note to mention that Eagle Group has a contract vehicle, a staging facility, the expertise and the experience to support an additional requirement. We could accomplish this by amending our existing vaccination support contracts under LOGJAMSS or by opening a new task order under LOGJAMSS.

I expect to be at USAMMA again, sometime around 10-13 February, to be oriented in packing the EnduroTherm containers. I would be glad to take time to brief you on our capabilities, and our contracting

options at that time. I can do this in Frederick, or at OASD, or both locations.

If we can be part of the solution please contact me at hgeorge@eaglegroupint.com or at 404-766-6760.

(b)(6)

-----Original Message-----
From: Daley, Mike COL USAMMA (b)(6) @DET.AMEDD.ARMY.MIL]
Sent: Friday, January 24, 2003 6:00 AM
To: (b)(6)
Cc:
Subject: RE: Interagency Agreement

LTC (b)(6) I have heard that HHS and/or DOS is involved in supporting a requirement for 20 million doses of smallpox. While we can absorb the relatively small number currently working for DOS with our current manpower, we would not be able to provide distribution and shipping support without manpower augmentation. Please keep this in mind and coordinate with us if HHS approaches you on this issue.

Regarding the current support to DoS, request HA send an official tasker to the Army to support this requirement. We aren't holding up the mission to await the tasker, but technically I should not assume the mission without direction through my chain of command.

Thanks

(b)(6)

-----Original Message-----
From: (b)(6) @ha.osd.mil]
Sent: Thursday, January 23, 2003 8:02 AM
To: (b)(6)
(b)(6)
Cc: (b)(6)
Subject: RE: Interagency Agreement

Good Morning (b)(
Thank you for your quick response! I appreciate the hard work that you and everyone else on the team is doing for us a great deal.

Have a great day and stay warm!
(b)(6)
(b)(6)
Lt Col, USAF, MSC
Program Director, Logistics
5111 Leesburg Pike, Sky 4, Suite 901
Falls Church, VA 22041-3258
Voice (b)(6)
Fax: (b)(6)

-----Original Message-----
From: (b)(6)
[mailto: (b)(6) @DET.AMEDD.ARMY.MIL]
Sent: Wednesday, January 22, 2003 10:12 AM
To: (b)(6)
Cc:
Subject: RE: Interagency Agreement

Sir,
Concerning the impending shipments of Smallpox vaccine from DoD to DoS. I have heard that the IAA agreement has been signed so the action now moves away from PEO-CBD and to MILVAX ,and USAMMA. I have been in contact with (b)(6) to discuss the shipping details. Broadly they are:

1. Appointed DoS representative will gain access to USAMMA's secure automated vaccine ordering webpage by requesting a logon and password. After this is accomplished that DoS individual can input orders for delivery to DoS locations. Registration will require identification of the ordering representative by a DoS official via written authentication (email is appropriate).

Requests for Smallpox Vaccine should be submitted online via the USAMMA Distribution Operations Center (DOC) secure website. Upon selecting the smallpox Vaccine Request Form option vaccine requestors are required to complete a registration process. Upon registration approval an account will be established for the user. The requestor should then go directly to the USAMMA DOC secure website via a link provided to them in email. If the requestor has previously registered they should go directly to the USAMMA DOC secure website via the link provided.

2. Once the order is received the USAMMA DOC contacts the receiving unit and coordinates directly with them to ensure POCs are notified of the incoming shipment and to ascertain appropriate reefer space.

Shipping: Smallpox vaccine shipped from the CDC is packaged in a shipping container with a digital monitor (TempTales®) to document shipping temperature. Follow all package instructions. Remove vaccine from shipping container, inspect, and place vaccine in an approved storage refrigerator promptly after receipt. Return monitor to the U.S. Army Medical Materiel Agency (USAMMA) as instructed. Do not release vaccine to end-user until authorized by USAMMA. For more information go to http://www.usamma.army.mil.

Storage: Like most vaccines, smallpox vaccine must be stored in the refrigerator at 2 to 8° C (36 to 46° F). DO NOT FREEZE. If smallpox vaccine is exposed to temperatures above or below this level for > 1 hour, contact USAMMA at DSN (b)(6) (b)(6). Smallpox vaccine, like most vaccines, can tolerate short exposures to other temperatures without degradation. USAMMA provides guidance on unusual storage conditions or distribution emergencies.

3. After the vaccine is received the USAMMA DOC walks the receiving units through procedures involving temp monitors and commercial carriers designed to ensure quick release of the vaccine for use.

4. During the entire process the ordering POC can access shipping progress by logging on to USAMMA's webpage which links to the commercial carriers worldwide tracking network. Using the airway bill number provided by USAMMA the receiving unit and requestor can track the movement of the vaccine as it nears its destination.

5. Finally the receiving unit is faxed an official release certificate that assures the user of the vaccines potency.

This process is the same for smallpox and anthrax vaccines.

I will be happy to answer more specific questions as they come up.

(b)(6)

MAJ, MS
Pharmacy Consultant to the USAMMA Commander &
Deputy Director, Distribution Operations,
Anthrax Vaccine Immunization Program (AVIP)
Attn: MCMR-MMO
1423 Sultan Drive, Suite 100
Fort Detrick, MD 21702
Tel: (b)(6) DSN: (b)(6)
Cell: (b)(6)
Fax: DSN: (b)(6)
E-mail: (b)(6) @amedd.army.mil

-----Original Message-----
From: Daley, Mike COL USAMMA
Sent: Wednesday, January 15, 2003 3:40 PM
To: (b)(6) MAJ USAMMA
Subject: FW: Interagency Agreement

(b)(6)

Need you to lay out the simple step by step of how State will order, to include what needs to be done before they can order, e.g.,

1. DoD HA provides documentation to PEO-CBD and USAMMA on number of vials available to State.
2. State provides documentation identifying who their ordering officials are.
3. Ordering officials access the USAMMA web site to request registration.
4. USAMMA validates authority of individual with document provided in step 2 and registers ordering official.

etc, etc.

Provide this to LTC (b)(6), cc to me.

Thanks

(b)(6)

-----Original Message-----
From: (b)(6) Lt Col, OASD(HA)
[mailto:(b)(6) @ha.osd.mil]
Sent: Wednesday, January 15, 2003 12:56 PM
To: (b)(6)
(b)
Cc:
(b)(
Subject: RE: Interagency Agreement

(b)(and All,
Thanks for the help! Once the MOA is signed, it is our opinion that DoS will want the vaccine ASAP and will need to know the steps for transferring the vials to them. Does HA have to go through the PEO-CBD, CDC, etc. as well? Any thoughts is appreciated. (b)(6)
(b)(6)

Lt Col, USAF, MSC
Program Director, Logistics
5111 Leesburg Pike, Sky 4, Suite 901
Falls Church, VA 22041-3258
Voice: (b)(6)
Fax: (b)(6)

-----Original Message-----
From: (b)(6) LTC JRCAB
[mailto:(b)(6) @DET.AMEDD.ARMY.MIL]
Sent: Wednesday, January 15, 2003 12:45 PM
To: (b)(6)
(b)(6
Cc:
(b)
Subject: RE: Interagency Agreement

(b)(6)

USAMMA Cdr is COL Mike Daley.
Mr. (b)(6) is his POC for Interagency Agreements (or at least was last time I dealt with an IA issue).
MAJ (b)(6) is the Chief of the USAMMA Distribution Operations Center that will be responsible for working out shipment details.

All are cc'd on this response.

(b)(6)
-----Original Message-----
From: (b)(6) Lt Col, OASD(HA)
(b)(6) @ha.osd.mil]
Sent: Wednesday, January 15, 2003 12:32 PM
To (b)(6) LTC JRCAB
Subject: FW: Interagency Agreement

(b)(6)

Who can I forward this to in USAMMA please?
(b)(6

(b)(6)
Lt Col, USAF, MSC
Program Director, Logistics
5111 Leesburg Pike, Sky 4, Suite 901
Falls Church, VA 22041-3258
Voice: (b)(6)
Fax: (b)(6)

-----Original Message-----
From: Knott, Garland, COL, OASD/HA
Sent: Wednesday, January 15, 2003 12:22 PM
To: (b)(6) Lt Col, OASD(HA)
Subject: FW: Interagency Agreement

(b)(6)

Need your help. See below.

Thanks.

Garland

-----Original Message-----
From: (b)(6) @state.gov]
Sent: Wednesday, January 15, 2003 12:15 PM
To: 'Knott, Garland, COL, OASD/HA'
Subject: RE: Interagency Agreement

Garland,
Another question: can you tell me what the paper trail is once A/S Winkenwerder signs the MOU? What I would like to confirm, specifically, is that once an execute order is issued to USAMA to release the doses to State, that we can negotiate quickly the hows and wheres of logistics with that agency. I assume they have complete authority to work those details with us, i.e., it does not become a CINC (or anyone else) issue?
Hope that question makes -- upon re-reading it, I'm not so sure. We are trying to determine the fastest, cleanest route for shipment, that minimizes the number of different hands handling the vaccine (so as to preserve the cold chain, etc.). If USAMA (hope I have that acronym right) can take our doses directly out of existing stockpiles already in the region or nearby, that would be our preference, but I want to make sure that there is only

voice speaking to such logistical details. Thanks very much for your assistance.

(b)(6)

Chemical and Biological Countermeasures Working Group
SA-1 Rm. L-301
Tel: (b)(6)
Fax
(b)(6) @state.gov

-----Original Message-----
From: Knott, Garland, COL, OASD/HA
(b)(6) @ha.osd.mil]
Sent: Wednesday, January 15, 2003 8:57 AM
To: (b)(6)
Subject: RE: Interagency Agreement

(b)(6)

Thank you for your quick action.

Look forward to your reply.

Garland

-----Original Message-----
From: (b)(6) @state.gov]
Sent: Wednesday, January 15, 2003 8:44 AM
To: 'Knott, Garland, COL, OASD/HA'
Cc: (b)(6)
(b)(
Subject: RE: Interagency Agreement

Actually, General Counsel's office has put the same request forward to our lawyers, who are working on getting the numbers this morning. (b)(6)
(b)(6) of our Legal Advisor's office will pass the numbers to OGC, and copy me and you on her reply.

(b)(6)

Chemical and Biological Countermeasures Working Group
SA-1 Rm. L-301
Tel: (b)(6)
Fax
(b)(6) @state.gov

-----Original Message-----
From: Knott, Garland, COL, OASD/HA
(b)(6) @ha.osd.mil]

Sent: Wednesday, January 15, 2003 7:50 AM
To: (b)(6) @state.gov'
Cc: (b)(6)
(b)
(6)
Subject: Interagency Agreement

(b)(6)

Would you please prove Appropriation numbers, Common Accounting Numbers and Objective Codes for both anthrax and Smallpox as required in paragraph VII, Funding, of the attached Interagency Agreement between the Department of Defense and Department of State for Anthrax Vaccine Adsorbed and Smallpox Vaccine.

Thank you.

Garland Knott

DHHS/DoD/DoS Agreement on Use of and Prepositioning of an IND Product in CONUS and OCONUS

Background:
We are currently drafting a MOA between DoD, DoS, & DHHS to transfer a specific amount of DoD anthrax/smallpox vaccines over to the DoS in order to protect individuals from exposure to B. anthracis and smallpox vaccine to prevent the disease caused by variola virus. Also, we are discussing the requirement to preposition 20M of Adventis-Pasteur vaccine in the event of a WMD event.

Options:

1. Preposition all of the vaccines in CONUS
2. Preposition all vaccines in one location in OCONUS? Or do we preposition in other OCONUS locations to protect Europe, Far East, & Middle East?
3. Split combination of all at one location
4. Split the stock between the East and West

General Questions/Remarks:

1. Review the IA between the three departments mentioned above and see what guidance or agreement is in place regarding the use of an IND?
2. Advice from legal?
3. What guidance is out there concerning the safeguarding and shipment of an IND?
4. Certain levels of certification are required for the proper storage of IND's. What is the guidance? Will the proper manpower be contracted for 24/7 to meet any emergency needs?
5. Tracking/reporting requirements?
6. What are our current stockage levels? If classified, please respond using cypernet to COL Knott?
7. What size population does our current stockage cover? Current location of our stockage?
8. If we transport IND stock to OCONUS and an event suddenly creates a need for the material to be returned back to CONUS what is the mechanism setup to allow this transfer? Where would the shipment enter CONUS? Vulnerabilities?

(b)(6) **Lt Col, OASD(HA)**

From: Daley, Mike COL USAMMA (b)(6) @DET.AMEDD.ARMY.MIL]
Sent: Friday, January 24, 2003 6:00 AM
To: (b)(6)
Cc:
Subject: RE: Interagency Agreement

LTC (b)(6), I have heard that HHS and/or DOS is involved in supporting a requirement for 20 million doses of smallpox. While we can absorb the relatively small number currently working for DOS with our current manpower, we would not be able to provide distribution and shipping support without manpower augmentation. Please keep this in mind and coordinate with us if HHS approaches you on this issue.

Regarding the current support to DoS, request HA send an official tasker to the Army to support this requirement. We aren't holding up the mission to await the tasker, but technically I should not assume the mission without direction through my chain of command.

Thanks

(b)(6)

-----Original Message-----
From (b)(6) @ha.osd.mil]
Sent: Thursday, January 23, 2003 8:02 AM
To: (b)(6)
Cc:
Subject: RE: Interagency Agreement

Good Morning (b)(
Thank you for your quick response! I appreciate the hard work that you and everyone else on the team is doing for us a great deal.

Have a great day and stay warm!
(b)(6)

(b)(6)
Lt Col, USAF, MSC
Program Director, Logistics
5111 Leesburg Pike, Sky 4, Suite 901
Falls Church, VA 22041-3258
Voice: (b)(6)
Fax: (b)(6)

(b)(6)

-----Original Mes
From: (b)(6)
Sent: Wednes
To: (b)(6)
Cc:
Subject: RE

1Y.MIL]

Sir,
Concernin
I have hea

es away from PEO-

CBD and to MILVAX ,and USAMMA. I have been in contact with (b)(6) to discuss the shipping details. Broadly they are:

1. Appointed DoS representative will gain access to USAMMA's secure automated vaccine ordering webpage by requesting a logon and password. After this is accomplished that DoS individual can input orders for delivery to DoS locations. Registration will require identification of the ordering representative by a DoS official via written authentication (email is appropriate).

Requests for Smallpox Vaccine should be submitted online via the USAMMA Distribution Operations Center (DOC) secure website. Upon selecting the smallpox Vaccine Request Form option vaccine requestors are required to complete a registration process. Upon registration approval an account will be established for the user. The requestor should then go directly to the USAMMA DOC secure website via a link provided to them in email. If the requestor has previously registered they should go directly to the USAMMA DOC secure website via the link provided.

2. Once the order is received the USAMMA DOC contacts the receiving unit and coordinates directly with them to ensure POCs are notified of the incoming shipment and to ascertain appropriate reefer space.

Shipping: Smallpox vaccine shipped from the CDC is packaged in a shipping container with a digital monitor (TempTales®) to document shipping temperature. Follow all package instructions. Remove vaccine from shipping container, inspect, and place vaccine in an approved storage refrigerator promptly after receipt. Return monitor to the U.S. Army Medical Materiel Agency (USAMMA) as instructed. Do not release vaccine to end-user until authorized by USAMMA. For more information go to http://www.usamma.army.mil.

Storage: Like most vaccines, smallpox vaccine must be stored in the refrigerator at 2 to 8° C (36 to 46° F). DO NOT FREEZE. If smallpox vaccine is exposed to temperatures above or below this level for > 1 hour, contact USAMMA at DSN (b)(6) (b)(6) Smallpox vaccine, like most vaccines, can tolerate short exposures to other temperatures without degradation. USAMMA provides guidance on unusual storage conditions or distribution emergencies.

3. After the vaccine is received the USAMMA DOC walks the receiving units through procedures involving temp monitors and commercial carriers designed to ensure quick release of the vaccine for use.

4. During the entire process the ordering POC can access shipping progress by logging on to USAMMA's webpage which links to the commercial carriers worldwide tracking network. Using the airway bill number provided by USAMMA the receiving unit and requestor can track the movement of the vaccine as it nears its destination.

5. Finally the receiving unit is faxed an official release certificate that assures the user of the vaccines potency.

This process is the same for smallpox and anthrax vaccines.

I will be happy to answer more specific questions as they come up.

majg

(b)(6)

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO ATTENTION OF

AFEB (15-1a) 99-5

25 May 1999

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

SUBJECT: Armed Forces Epidemiological Board Recommendations for Biological Warfare Vaccines

In accordance with DOD Directive 6205.3, "DOD Immunization Program for Biological Warfare Defense," the Armed Forces Epidemiological Board (AFEB) met on 24 May 1999 at the Institute for Defense Analyses, Alexandria, VA to review vaccines available to protect against the validated biological warfare (BW) threat agents.

2. After review of the Biologic Threat Matrix and the above directive, the AFEB makes the following comments and recommendations:

a) THE AFEB CONTINUES TO STRONGLY ENDORSE THE CURRENT DOD ANTHRAX VACCINE IMMUNIZATION PROGRAM. FURTHER, THE BOARD RECOMMENDS THAT DOD AGGRESSIVELY PURSUE CLINICAL INVESTIGATIONS NECESSARY TO REVISE AND/OR ACCELERATE THE CURRENT ANTHRAX VACCINATION SCHEDULE (ACCELERATED SCHEDULE, FEWER DOSES, IM VS. SC ADMINISTRATION, ETC.).

b) REGARDING THE USE OF VACCINES AND BIOLOGICS TO PROTECT AGAINST BW AGENTS, THE AFEB RECOMMENDS THAT THE PRIORITIZATION FOR VACCINE DEVELOPMENT, AND THE USE OF RESOURCES BE DIRECTED IN THE FOLLOWING MANNER:

TIER I (INTENT: HIGHEST PRIORITY TO RAPIDLY ACCELERATE AND IMMEDIATELY ESTABLISH VACCINE PRODUCTION CAPABILITY). AGENTS LISTED UNDER TIER I INCLUDE SMALLPOX, PLAGUE, ANTHRAX, AND STAPHYLOCOCCAL ENTEROTOXIN B.

TIER II (INTENT: HIGH PRIORITY CANDIDATES FOR VACCINE DEVELOPMENT AS SOON AS POSSIBLE). AGENTS INCLUDE RICIN, BOTULINUM, TULAREMIA, HEMORRHAGIC FEVERVIRUSES, ENCEPHALITIS VIRUSES, Q FEVER, ❑ RUCELLOSIS, AND SHIGELLOSIS.

TIER III (INTENT: WARRANTS FURTHER RESEARCH AND CLOSE OBSERVATION FOR SCIENTIFIC DEVELOPMENTS OR VALIDATED NEW

THREATS THAT WOULD MOVE IT INTO TIER I OR TIER II). ALL OTHER BIOLOGIC AGENTS.

c) THE BOARD STRONGLY FELTTHAT A COMPLETERESPONSE TO THE VALIDATED BIOLOGIC WARFARE THREAT MATRIX INVOLVES MORE THAN VACCINE RECOMMENDATIONS PERSE. THEREFORE, WE RECOMMEND AREVIEW OF DOD DIRECTIVE 6205.3, AND THATIT BE REVISED WITH ATTENTION TO THE FOLLOWING ISSUES:

1) THE BOARD RECOGNIZES THAT PRIORITIZATION OF BW THREATS IS CURRENTLY ONLY INTELLIGENCE-BASED, WITH NO CONSIDERATION OF MEDICAL RISK-BASED MEASURES. THE BOARD STRONGLY FELT THAT A MEDICAL RISK ANALYSIS IS A VITAL PIECE OF DATA NEEDED FOR PRIORITIZATION OF ADMINISTERING AND DEVELOPING NEWVACCINES. SUCHINPUT WILL INSURE THAT THE PROPER NUMBER OF DOSES ARE RECOMMENDED FOR STOCKPILING, (FOR USE IN DOD PERSONNEL, ESSENTIAL CIVILIANS, CONTRACTORS, ETC.). FORMAL MEDICAL RISK-ANALYSES SHOULDBE CONDUCTED FOR ALL VALIDATED AGENTS. PRIORITY SHOULD BE GIVEN TO A HIGHLY TRANSMISSIBLE SCENARIO SUCH AS SMALLPOX.

2) THE BOARD HIGHLY RECOMMENDS A REVIEW OF THE CURRENT DOD VACCINE STOCKPILINGNUMBERS THAT WOULD TAKE INTO ACCOUNT HIGH-RISK POPULATIONS, AND COMMUNICABILITY OF THE BW AGENT. THIS IS ESSENTIAL TO DECISIONS ABOUT NUMBERS OF DOSES OF VACCINE AND RESOURCE USE.

3) THE SOARD RECOMIENDSTHATA REVIEW OF TEMPORARY/INTERIM COUNTERMEASURES BE PERFORMED SUCH AS TAKING INTO ACCOUNT FACTORS SUCH AS TREATMENT AVAILABILITY, PRE.VERSUSPOST-EXPOSURE PROPHYLAXIS, AND STOCKPILING OF CURRENTLY AVAILABLE PHARMACEUTICALS, AS WELL AS PRIORITIES FOR PHARMACEUTICAL R&D AGAINST VALIDATED BIOLOGIC WARFARE THREATS.

4) THE BOARD RECOMMENDS A FORMAL REVIEW OF THE EFFECTIVENESS OF CURRENT MEDICALSURVEILLANCE AS AN "EARLY DETECTOR" FOR EXPOSURETO BIOLOGIC WARFARE AGENTS.

AFEB (15-1a) 99-5
SUBJECT Armed Forces Epidemiological Board Recommendations for Biological Warfare Vaccines

5) THE BOARD RECOMMENDS A FORMAL REVIEW OF THE RAPID DIAGNOSTICS AVAILABLE TO SUPPORT MEDICAL SURVEILLANCE AS AN EARLY DETECTOR FOR EXPOSURE TO BIOLOGIC WARFARE AGENTS.

d) THE BOARD ENDORSES, AND URGES RAPID DEPLOYMENT OF THE PLANNED JOINT TRI-SERVICE SOFTWARE PROGRAMS CAPABLE OF RECORDING AND REPORTING ADMINISTRATION OF ANY DOSE OF VACCINE (LICENSED OR IND) ADMINISTERED TO DOD PERSONNEL.

e) LASTLY, THE BOARD RECOMMENDS THAT HIGH QUALITY EDUCATION AND MARKETING PROGRAMS BE DEVELOPED FOR EACH VACCINE DEPLOYED AGAINST BIOLOGIC WARFARE AGENTS AND RECOMMENDED FOR USE IN DOD PERSONNEL. IDEALLY, THIS WOULD BE DEVELOPED BY EXPERTS BOTH INSIDE AND OUTSIDE OF THE DOD.

3. The above recommendations were unanimously by the Board.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

DENNIS M. PERROTTA, PH.D.
President, AFEB

GREGORY A. POLAND, M.D.
Chairman Disease Contro. Committee

BENEDICT M. DIN.EGA, COL, MC, USA
AFEB Executive Secretary

CF:
The Surgeon General, Army

DRAFT

MEMORANDUM

Mycoplasma

To: Gen. Ronald Blanck , Surgeon General of the Army
From: Beatrice Golomb, M.D., Ph.D., and Ross Anthony, Ph.D. RAND
Date: February 9, 1999
Subject: Testing for Mycoplasma in Anthrax Vaccine

Overview

RAND is conducting a series of literature reviews on the possible relation of exposures to illness in Persian Gulf War (PGW) veterans, for the Office of the Special Assistant for Gulf War Illnesses (OSAGWI). As part of this research, RAND conducted literature reviews on both vaccinations and infectious diseases. Dr. Beatrice Golomb's review of vaccinations found no hypotheses of special concern relative to the anthrax vaccine, except one loose end concerning mycoplasma that could be easily resolved with additional research.

Mycoplasma has been proposed as a plausible cause of illness in some PGW veterans. Contamination of the anthrax vaccine has also been suggested as a possible source of mycoplasma infection in ill PGW veterans. Simple research could exclude this possibility. (The conventional microbiological wisdom is that mycoplasma would not grow in the anthrax vaccine medium, and if it did grow it would be killed by the stabilizer and preservative is most likely true; however this has not been empirically tested.)

Background - Results of Literature Review

The extensive literature review pertaining to immunizations concludes that there is no specific evidence favoring any of a set of theories that propose to link vaccines to illness. (Such theories include, for instance, multiple immunizations; adjuvant disease; shifts in cytokine profiles; and nonadjuvant effects of aluminum). However there is room for residual concern regarding the theory that mycoplasma could be a cause of illness. The theory that anthrax vaccine could serve as a repository for mycoplasma has been denigrated, as the conventional microbiological wisdom is that mycoplasma would not grow in the anthrax vaccine medium, and if it did grow it would be killed; however the theory has not been empirically refuted.

The Mycoplasma Evidence

Although it is not the purpose of this memo to evaluate the claims that mycoplasma could be a cause of illness among some Gulf War veterans, sufficient evidence has been presented that the issue is being further researched in DoD and the VA. Evidence adduced in favor of mycoplasma as a possible cause of illness in PGW veterans includes:

- Mycoplasma infection is consistent with several characteristics of illness including a) variable latency to illness, b) development of "similar" illness in family members, c) reports of resolution of symptoms in response to long-term anti-mycoplasma antibiotics, d) properties of the organism potentially compatible with production of symptoms like those of PGW veterans

- Mycoplasma has been found with increased frequency in some ill PGW veterans compared to controls by two independent investigators (See and Nicolson) using PCR in both cases, supplemented by an non-validated technique (nucleoprotein gene tracking) by one investigator.

Mycoplasma and the Anthrax Vaccine

Mycoplasma are common laboratory contaminants, and thus testing for mycoplasma occurs in viral vaccines, which require use of nutritionally rich media for their production. However, vaccines such as the anthrax vaccine are not routinely tested because more nutritionally impoverished media are used that are presumed inhospitable to growth of mycoplasma. Concerns regarding vaccine contamination have targeted anthrax, as the only "new" vaccine used in the PGW (except botulinum toxoid vaccine, which was used by too few troops to be a significant contributor to illness).

Mycoplasma are presumed unlikely to be able to survive in the anthrax vaccine. Although mycoplasma are fastidious and would be presumed not to grow in the chemically defined, cell-free medium of the anthrax vaccine, it has not been shown that they cannot survive in this medium. Also it is assumed that the formaldehyde (stabilizer) and benzethonium chloride (preservative) would kill any mycoplasma that accidentally contaminated the vaccine, but again no tests were identified that demonstrate these agents were tested to prove they do kill mycoplasma.

All evidence we have supports the conventional wisdom except one paper was identified in which mycoplasma was tested for and found in anthrax vaccine (Alshawe, A. and G. Alkhateeb (1987). "Test of Iraqi Anthrax vaccine with other vaccines." *J Biological Sciences Research* 17(1): 1-16). In this 1987 study, mycoplasma contamination was detected, however this was an Iraqi anthrax vaccine whose production may differ substantially from that in the US.

Recommendation on Additional Research

Although the conventional wisdom that mycoplasma could not survive in the anthrax vaccine because there is not the required media and/or the stabilizer and preservative would kill any such mycoplasma are most likely correct, to the best of our knowledge, no one has ever tested the vaccine to rule out this possibility. In order to extinguish (or support) any concerns regarding the possibility that mycoplasma could have been spread as a contaminant in the anthrax vaccine, additional studies could be performed. Although the basics of such studies -- test of the activity of benzethonium chloride and formaldehyde against mycoplasma and a test of mycoplasma viability in the vaccine itself – are clear, we would suggest two or three experts in the field be called together to help design research to close out this issue.

NOT PART OF THE MEMO – (b)(6) Present thinking – Checking this FOR (b)(6) Only

(b)(6) Suggested Research Design that would need to be looked at by others

In order to extinguish (or support) concerns regarding the possibility that mycoplasma could have been spread as a contaminant in the anthrax vaccine, two series of studies are advised:

Study A: Test of activity of benzethonium chloride and formaldehyde against mycoplasma:
Employ serial dilutions of:

1. Benzethonium chloride;
2. Formaldehyde
3. Combinations of both; to determine what concentrations are needed to kill mycoplasma

Several species of mycoplasma should be employed in the serial dilution testing of each agent. These should include:

1. Mycoplasma fermantans incognitus,
2. Mycoplasma pneumoniae
3. Ureaplasma urealyticum, and
4. Mycoplasma arthritides.

Test the result by:

1. Attempting to culture the product for mycoplasma (using a mycoplasma-friendly medium),
2. Passaging the product through a susceptible species of animal to demonstrate or preclude viability, looking for illness (where relevant); and ability to recover mycoplasma from the animal using PCR, and
3. Including controls in both instances: in these controls the mycoplasma species without formaldehyde and benzethonium are similarly 1. cultured and 2. passaged through animals.

Study B: Test of mycoplasma viability in the vaccine itself:
Mycoplasma (of each of the species named above) should be added to the anthrax vaccine itself and to each of several control vehicles (including saline and a mycoplasma-favorable medium) in increasing concentrations, and tests should be performed for viable mycoplasma – including:

1. Culturing the result in a mycoplasma-favorable medium, and
2. Injecting mycoplasma sensitive species with the product and following the animals for illness (where relevant) and for ability to recover mycoplasma using PCR.

Anthrax Vaccine Immunization Program Related Research
Vaccine Healthcare Center Network Component

SUMMARY: Study Protocol for Evaluation of Outcomes Related to Current Practices of Clinical Alternative Anthrax Immunization Strategies in the Setting of Adverse Events

Introduction

In 1998, because of the concern that military personnel could be at heightened risk of exposure to weaponized anthrax, the Department of Defense (DoD) initiated a program to vaccinate approximately 2.4 million active duty military personnel and selected reserves with anthrax vaccine adsorbed (AVA). However, the anthrax vaccination program met with resistance from some members of the military and scientific communities because of concerns about vaccine safety, dosing regimens, effectiveness against inhalation anthrax, and vaccine production. Concerns about long term disabling illness temporally associated with anthrax vaccine administration have continued to impact adversely on trust in the vaccine program. In addition, distrust of the validity of the Vaccine Adverse Events Reporting System for detection and characterization of rare adverse events plus the occupational requirement for immunization strictly adherent to the current package insert instructions have challenged the trust of some service member as well as health care providers in relation to the overall program in that alternative management strategies are needed to maintain career viability. Congressional hearings regarding the anthrax vaccine immunization program stressed the need for greater efforts toward establishing the safety and validity of continued and/or alternative immunization strategies in the face of certain adverse events. Applying allergy-immunology adverse drug reaction management principles, the Department of Defense developed clinical guidelines for possible management of certain anthrax vaccine related adverse events. (See Attachment #1 and #2)

Current limitations for the development of these studies include the fact that an absolute level of anti-protective antigen (anti-PA) antibody has not been defined as protective versus non-protective for inhalation anthrax. It is proposed however, like the currently ongoing FDA approved dose reduction, route change study, to use non-immunologic inferiority as measured by anti-PA antibody as a marker of a successful alternative vaccine strategy for those patients with prior adverse events.

Study Purpose

In response to this Congressional mandate, the Department of Defense Vaccine Healthcare Center Network and National Immunization Program(NIP)/National Center for Infectious Diseases at CDC have developed a research agenda to study the safety and efficacy of alternative anthrax vaccine administration strategies for patients with prior adverse events by:

1) Characterizing and standardizing the case definitions for adverse events including those where vaccine related causality cannot be proven or disproved at this time;
2) Determining the outcomes of alternative clinical management approaches to anthrax vaccine related adverse events as outlined in the clinical guidelines for vaccine related adverse events diagnosis and management;
3) Validating the alternative clinical management approaches to anthrax vaccine associated adverse events through the measurement of anti-PA antibody and correlating responses to existing data as the gold standard of non-immunologic inferiority.

Anthrax Vaccine Immunization Program Related Research
Vaccine Healthcare Center Network Component

The DoD Vaccine Healthcare Center (VHC) Network research agenda, in collaboration with the NIP/CDC, addresses these issues using a multifaceted approach that is being conceived, managed, and closely coordinated within the Department of Defense and the NIP/CDC. As part of this research agenda that addresses safety, the VHC plans to conduct a long-term follow-up study of service members with a prior history of an anthrax vaccine related adverse event who received subsequent doses of vaccine either following the package insert instructions or with an alternative strategy to include pretreatment with anti-inflamrratory and/or analgesic therapies.

To this purpose, the Walter Reed National Vaccine Healthcare Center is developing a draft study protocol for the purpose of identifying and evaluating service members with prior adverse events who have had continued dosing of vaccine or who are in need of additional dosing under current guidelines. If clinical symptoms are persistent, the VHC will provide and document complex, multi-specialty diagnostic and therapeutic case management of the problems and contribute this information to the existing VAERS system as follow-up VAERS submissions. For the individuals where the adverse event has resolved but is of significant concern to the affected individual, their family or their healthcare provider, the benefit-risk ratio for continued immunization versus permanent medical exemption will be carefully reviewed by the VHC staff in collaboration with Walter Reed allergy-immunology adverse drug reaction management committee. Balanced risk communication will be provided in order to obtain clinical (rather than research protocol) informed consent from the individual for continued immunization challenge and what the options are. The healthcare provider in collaboration with the patient will select the optimum management strategy based on the individual patient assessment.

Enrollment in the research protocol will allow for anti-PA antibody measurement before and after the treatment option and will include long-term follow-up of outcomes and subsequent dosing with anthrax if the outcome is favorable. In addition to providing insights into the potential association of AVA with long-term adverse effects, particularly as related to rare adverse events that are reproducible with repeated vaccine dosing, the results of this study may suggest plausible areas for follow-up research into the causal pathways of any long-term adverse events that may be attributable to receipt of AVA.

The clinical value of outcomes data that can be used in future counseling of options to individuals with adverse events cannot be overemphasized. In the context of penicillin allergy, there is widespread clinical consensus about how to approach benefit-risk counseling of patients in relation to penicillin challenge and/or desensitization despite the history of an adverse event/hypersensitivity reaction. No such clinical consensus exists for vaccine related immunization health care. These efforts will enable the development of a data collection network in relation to experience with occupationally needed vaccines such as anthrax and this type of clinical management challenge. In addition, future refinement of clinical guidelines based on evidence rather than clinical empiricism is an additional goal that will strengthen trust in vaccine safety and clinical immunization health care in general.

Example of Patient Counseling Data Requirements: "Thirty patients like you with your type of adverse event received additional doses of anthrax vaccine by this route and/or with this pretreatment and had no significant adverse event and/or had a normal or unchanged quality of life 1 year later."

Materials and Methods

Study Group Definitions

Based on the current clinical guidelines for non-iive (including anthrax) vaccine related adverse events diagnosis and management, patients will be enrolled based on the adverse event category with expanded considerations broadly including also the following categories:

1. No reaction but medically related high anxiety regarding anthrax vaccine dose risks
   - Example: patient with strong family history of collagen vascular disease
   - Example: patient with a prior history of adverse events to other vaccines and continued high anxiety despite extensive clinical counseling
2. Moderate local reactions with short term systemic symptoms and high anxiety related to next dose
3. Large local reactions > 120 mm diameter
4. Other local reactions with high anxiety related to next vaccine dose
5. Systemic symptoms temporally associated with vaccine with high anxiety related to next dose
   a. Subcategories are currently under development in collaboration with the AVEC and other consultant groups

Patients will be recruited through the evolving outreach efforts of the Vaccine Healthcare Center Network and the DoD network of military allergy-immunology consultants who are frequently involved with referrals related to the safety of continued immunization. Other specialist networks within DoD, particularly the neurologists and otolaryngologist, will also be involved in the outreach to capture rare adverse events temporally related to anthrax vaccine. There is a need to involve the Veterans Administration and the TRICARE network since many service members, particularly reservists, receive their care in these sites rather than military treatment facilities.

Among the feasibility challenges in the development of this type of protocol is the fact that case matched control groups are not easily generated. Particularly as related to large local reactions and subcutaneous nodules, other vaccines clearly do not have this problem since aluminum hydroxide containing vaccines are not and should not be administered by the subcutaneous route. Our understanding of the rarer systemic adverse events with other vaccines is also limited and it is possible that if resources and manpower permit, a similar outreach could be developed for other non-live vaccines as a control group for the anthrax investigation.

One set of control groups that can be incorporated into the protocol includes patients with no **prior large local reaction (< 50 mm** diameter local reaction) and **no prolonged systemic symptoms (> 96** hours) with at least I dose of prior anthrax vaccine for monitor anti-PA pre and 3-4 weeks subsequent vaccine dosing along with symptom tracking by diary and written response to screening questionnaire. The complexity factor with significant resource implications is the fact that with the restart of the anthrax vaccine program, dose **2, 3, 4,** etc within the standard series will be highly variably delayed. Correcting for each dose number in

the series and the time delay variable remains a statistical challenge. Proposed ranges for each dose number is outlined below:

- On-time to package insert + 2-4? Weeks
- 4- 12 weeks (1-3 months) later than scheduled dose
- 13-26 weeks (>3 to 6 months) later than scheduled dose
- 27-52 weeks (>6 to 12 months) later than scheduled dose
- > 52 weeks (> 1 year) later than scheduled dose
- 53-104 weeks (1-2 years)
- 105-156 weeks (2-3 years)
- 157-208 weeks (3-4 years)
- > 4 years

Outcome Measures

In the first stage of this proposed study, retrospective review of anthrax vaccine related medical exemptions would be used to further refine, in collaboration with the VAERS and AVEC (Anthrax Vaccine Executive Committee) reviewing process, the clinical guidelines and adverse events case definitions. The clinical guidelines will be used as a starting point and potentially new symptom complexes may be identified, particularly in collaboration with the Clinical Immunization Safety Assessment or CISA centers of excellence project development with similar goals to the DoD Vaccine Healthcare Center Network.

Those patients identified with ongoing or prolonged (>90 days) adverse symptoms temporally associated with anthrax vaccine immunization will undergo careful assessment as to quality of life and degree of functional impairment using the following tools:

- SF-36 quality of life measurements
- Subtle cognitive dysfunction and chronic fatigue syndrome-like complaints present some unique challenges for quantified assessment. The staff of the Walter Reed Allergy-Immunology and Neurology Departments are currently actively investigating cognitive impairment detection through modifications of the SF-36 that are under development in relation to the human immunodeficiency virus patient studies.

At least one annual quality of life follow-up evaluation will be completed on all enrollees with continued annual evaluation for at least 4 years for those with chronic persistent complaints. One of the challenges in these types of studies is the issue of inter-current illness and stresses such as deployment, which may cloud the data interpretation. Active efforts are ongoing to try to identify potential control groups with the collaboration of the Deployment Health Center at Walter Reed Army Medical Center.

Additional outcomes to be measured in relation to patients with prolonged adverse events temporally related to anthrax immunization are currently being developed in relation to the specific type of adverse event category. It should be understood that clinical practice assumptions during the anthrax vaccine immunization program from 1998 through 2001 included the following desirable end points for successful clinical management of an individual with an adverse event related to anthrax vaccine immunization:

- Documentation of protective immunity (when and if a specific marker is validated) or non-immunologic inferiority of immune response as a correlate of protection and

eliminating the need for additional vaccine doses at the time of visit – not available to clinicians to date but the type of approach to other vaccine related adverse events considered desirable for developing trust in a program;

- With patient informed consent (clinical rather than research) despite potential risk of additional vaccine doses, additional doses of vaccine given with no serious adverse event – considered a drug challenge under controlled conditions because the benefit-risk considered favored a challenge from both the patient and provider perspective;
- With patient informed consent (clinical rather than research), additional doses of vaccine given with adverse event severity reduced or eliminated through alternative vaccination strategy (intramuscular route, reduced dose at one injection site, intradermal, etc.) and/or concomitant treatments such as anti-inflammatory (oral and/or topical) and/or analgesic therapjj.

From the service member and healthcare provider perspective, the ability to develop a safe and effective strategy for immunization (active or passive for the future) that reduces oreliminates serious side effects and achieves "immune protection" to allow forfull occupational function with no restrictions despite possible medical exemption from further vaccine doses is the goal for providing comprehensive positive clinical support to a mandated immunization program.

- Example: non-immunologic inferiority of anti-PA antibody post vaccine = successful alternative vaccination for the individual patient with recommendation for a medical waiver in terms of occupational fitness for deployment despite a medical exemption for additional dosing at the given point in time.

If warranted by the findings of the initial studies, we may then conduct subsequent studies to evaluate the occurrence and magnitude of excess risks of specific clinically verified diagnostic endpoints and/or laboratory studies (e.g., examination of serologic markers of autoimmunity or genetic predisposition).

Statistical Analyses

All clinical symptoms associated with persistent or prolonged adverse events will be individually coded (ICD-9) so that symptom frequency in the population of patients can be analyzed in terms of frequency and clustering as related to the type of adverse event, the vaccine dose number where symptoms occurred, gender and other measures of demographic features ifsufficient data is available (such as ethnicity). Particularly reproducible reactions with repetitive dosing of vaccine will be analyzed for consistency of symptoms and duration of symptoms. We will use descriptive statistics (e.g., means, frequency distributions, etc.) to characterize study participants by vaccine doses, concomitant vaccine or other drug exposures, and by the various demographic factors and potential confounders.

Differences in the outcome measures among different groups of patients with continued immunizations by alternative strategies will be analyzed as both continuous measures using parametric statistics (e.g., t-tests to evaluate exposure group mean differences on selected cognitive function test scores) and as dichotomous indicators using nonparametric tests (e.g., contingency tables and Chi-square statistics to evaluate differences across reaction types plus treatment groups in the prevalence of specific diagnostic endpoints), as appropriate. Geometric mean anti-PA antibody levels in different alternative vaccine strategies groups, if the groups

contain adequate numbers of patients, will be compared to historical data available with the standard vaccine schedule and route as well as data, as it becomes available, from the dose reduction and route change study.

Additional statistical approaches are being investigated regarding still to be defined outcomes measures.

Protection of Human Subjects

The fact is that allergy-immunology and adverse drug reaction management practices have included alternative strategies for immunizations using off label approaches **and** validating outcome through measurement of an immunologic marker correlating to potential **efficacy**. The anthrax vaccine immunization program is one of the few vaccine programs where no validating measurement was available to clinical practitioners yet alternative practices were used in order to preserve career viability of service members. The likely benefits to the individual participants are great in that unlike current clinical practice, under protocol at least some measure of validating a clinical intervention through measurement of anti-PA antibody would be made available. Non-immunologic inferiority as an end-point for the current dose reduction route change study should also be acceptable for individual patients as an end point for adequate reduction of risk from mortality/morbidity related to inhalation anthrax exposure. The current program results in clinical pressures to continue immunizing individuals who are probably hyper-responders to the vaccine and who may have extremely high titers of anti-PA and should be allowed to continue their full deployment status within the Department of Defense despite lesser number of doses of vaccine. Since women may be at increased risk for hyper-response to multiple vaccine dosing, this protocol could be of particular benefit to women suffering adverse events such as very large local reactions, already known to correlate to higher levels of anti-PA antibody.

From a human use and ethics perspective, this study could not require blinding of choice of alternative strategies. Rather, the focus is on validation and documentation of outcomes of existing clinical practices. In that context, patients who feel that they cannot continue the vaccine due to risk of serious side effects, would be exempted from further vaccination per medical exemption guidelines. However, they would be followed long term in order to determine if there is a change of acceptance of **further** vaccination as more knowledge becomes available about the long term safety of continued immunization despite an adverse event. The risks to participants are limited to the small risk of disclosure of personal information and the risk of becoming upset or stressed as a result of the evaluation process. However, the study results will provide **NIP/CDC, DoD,** public health professionals, the US Congress, and military service personnel with valuable information on validating alternative management strategies following an anthrax vaccine related adverse event. To minimize these risks and to assure the privacy and confidentiality of each participant, we will follow a thorough informed consent process, and the Vaccine Healthcare Center Network will safeguard all data collected during the conduct of these studies from unauthorized disclosures to the fullest extent possible in accordance with applicable statutes.

Study Advisory Panel

Anthrax Vaccine Immunization Program Related Research
Vaccine Healthcare Center Network Component

Prior to the commencement of this study, the Clinical Advisory Committee for the Vaccine Healthcare Center Network (to be chartered under Health Affairs) in conjunction with representative expert input will convene to review this proposed study protocol and to make recommendations on the overall study design and approach, selection and interpretation of tests and standards/criteria to be applied. Since there are occupational implications for the outcomes, consideration will be given to including other advisory members and/or groups. Furthermore, we will reconvene this panel (or one with a similar composition) periodically during the conduct of this study and analysis of the results to offer the VHC/NIP advice in managing the study, disseminating the results, and, if warranted, designing and conducting subsequent follow-up studies.

Study Timeline and Costs

Since many of the adverse events are rare and in the process of definition standardization, and since the development of a vaccine healthcare center network within the Department of Defense is just beginning, this study will be conducted over the next 5 years as an ongoing endeavor to build confidence in the anthrax vaccine immunization program and provideclinical data on long-term outcomes for adverse vaccine related reaction management, particularly when alternative clinical management strategies are used. Collaborations such as the Brighton Collaboration for international standardization of vaccine related adverse events and enhanced VAERS data mining for signal detection are critical to the future of clinical diagnosis and therapeutic management strategies for vaccine related adverse events. We have not yet estimated the detailed cost of conducting this proposed study.

Additional Research Initiatives Proposed for the Vaccine Healthcare Center Network

Prospective Evaluation of Modified Administration Strategies

Outlined below is a possible approach to standardizing from existing clinical practice the clinical management response strategies for prior adverse events related to anthrax vaccine immunization for a prospective study:

1. Delay next shot if anti-PA antibody level is non-immunologically inferior to 1 month post 1 year dose data, recheck titers in 1 year, stratify to groups outlined below.
2. If anti-PA antibody is below 2 STD of mean for 1 month post 1 year dose, patients will be stratified as follows:
   - Administer a dose of anthrax vaccine with no pretreatment
   - Administer a dose of anthrax SQ with pretreatment of the injection site with topical steroid at the time of injection plus/-NSAID & antihistamine
   - Administer anthrax vaccine dose in divided doses at 2 sites SQ
   - Administer anthrax vaccine dose IM with NO pretreatment
   - Administer anthrax vaccine dose IM withNSAID+AH pretreatment
   - Administer anthrax vaccine dose SQ with 1000 mg of Tylenol PO 1 hour prior to and for 3 doses at 8 hour intervals after the vaccine
   - Administer anthrax vaccine dose IM with 1000 mg of Tylenol PO 1 hour prior to and for 3 doses at 8 hour intervals after the vaccine

Anthrax Vaccine Immunization Program Related Research
Vaccine Healthcare Center Network Component

Monitors:

1. Rates of large local reactions (> 50 mm diameter erythema &/or induration's)
2. Systemic symptoms tracking for 30 days and comparison of groups
3. Anti-PA antibody levels pre and 4-6 weeks post vaccination

Other Topics of Clinical Research Related to the Anthrax Vaccine Immunization Program

1. Cytokine Responses to Anthrax Vaccine by the Intramuscular versus Subcutaneous Route

2. Persistent Fatigue in Patients with Adverse Events Temporally Associated with Anthrax Vaccine and/or Multiple Immunizations: Defining Patterns of Immune Response Compared to Normals

3. Defining Patterns of Persistent Neurological Symptoms Temporally Associated with Anthrax Vaccine or Immunization Exposures

Research Proposals from the VHC Network Initiatives

Background Hypotheses

Hypotheses

1. Large local reactions related to anthrax vaccination are preventable with topical corticosteroid therapy at the time of immunization.

2. Severe large local reactions associated with anthrax vaccination are preventable by pretreatment with topical steroids and non-sedating antihistamines.

3. Topical corticosteroids do not interfere with measurable immune response to PA antigen.

4. Anthrax vaccine related headaches are preventable with acetaminophen therapy 1000 mg at the time of the shot and continuing for 24 hours after vaccine administration.

5. Systemic symptoms associated with anthrax vaccine immunization can be prevented by pretreatment with non-steroidal anti-inflammatory therapy plus high dose acetaminophen therapy.

Anthrax Vaccine Immunization Program Related Research
Vaccine Healthcare Center Network Component

For Information Only:

Clinical protocols with the Department of Defense as related to the anthrax vaccine immunization program must be carefully reviewed in relationship to ethical and perceptual "experimenting with uniformed service members" concerns. The Vaccine Healthcare Center Research initiatives must work within those considerations and concerns and can therefore not participate in certain types ofresearch related to the vaccine. For example, the dose reduction route change study was ruled to not be acceptable for implementation with service members. The discourse that follows is the type of discussions that are going on with research designs in general and when a placebo arm is acceptable.

The Ethics of Placebo Studies – Notes from USUHS

> Dr. L runs a clinical research center. Recently he was invited to participate in an 8 week study of a new investigational drug for the treatment of asthma. This new medication has been shown to have promising effects in the laboratory, and is now to be tested in hutnans. The protocol that was devised involves comparing this new drug to placebo in a group of uncontrolled moderate asthmatics that are currently being treated only with inhaled beta-agonists. Dr. L was concerned when he received the protocol, and was not sure he should participate in a study where some uncontrolled moderate asthmatics will be treated with a placebo. He telephoned the study organizers to find out what was the rationale behind the use of a placebo. They responded that by using a placebo arm the study could be performed using many fewer subjects. In addition, they stated that they felt that the subjects enrolled would not have a significantly poor outcome from being treated with a placebo for the 8 weeks of the study.

This vignette highlights an ongoing concern of many-the ethical implications of and appropriate of use of placebo arms in clinical studies. Recently the New England Journal of Medicine contained an article by Drs. Ezekial Emanuel and Franklin Miller discussing the "ethics of placebo" (*N Engl J Med.* 2001. 345(12):915-8.). Because this is an important issue not only in our specialty, but also in all of medicine, we have summarized their comments below. As is the case with all of these ethical discussions, we provide this as a means to stimulate discussion.

In this article, the authors start by defining the two extreme views, which they call "placebo orthodoxy" and "active-control orthodoxy." The "placebo orthodoxy" includes those individuals who argue for a placebo arm in all studies. This stance argues that placebo arms are needed to ensure the validity of a study, or to prove that a new treatment is efficacious-even when it is no more efficacious than current therapies, but may have fewer side effects, The authors dissect this stance and point out its shortcomings. In particular, they note that the ethical use of placebo controls has never been clearly stated. In a pair of articles, Ellenberg and Temple (Ann Intern *Med.* 2000. 133:455-463 and 464-470.) argue that placebo controls are ethical provided that only temporary discomfort without any "permanent adverse consequences" are suffered by the participants. In the New England Journal article this idea is dismissed since it allows for "intolerable suffering on the part of study participants." To further make their case, Drs. Emanuel and Miller describe the placebo-controlled trials of ondansetron(*N Engl J Med.* 1990.

322:810-6.; *Semin Oncol. 1992.* 19:67-71.; and *Ann Intern Med.* 1993. 118:407-13.), where subjects were allowed to suffer emesis without treatment rather than being given metoclopramide (the then-current standard of care). Clearly, they state, "these trials were unethical." Thus, in some cases placebo controlled trials are not appropriate.

The so-called "active-control orthodoxy" also has significant flaws. These individuals feel that all clinical experiments must be designed to compare the new drug tothe currently available therapies. As such, this group feels that the question that should be asked of a new therapeutic is, is it any better than what we already have? Supporting this line of thinking is the latest Declaration of Helsinki, which states, "The benefits, risks, burdens, and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods." However, as the authors point out, this anti-placebo approach has significant problems. One consists of the assumption that by not using a placebo arm. the study is automatically on higher ethical ground. This, as the authors point out, is clearly not the case, as it is unethical to perform a study that is scientifically fatally flawed because of the lack of a placebo arm. There are additional concerns that are raised by not using a placebo arm. Assuming the difference in response to conventional treatment versus the study medication is smaller than the difference between placebo and the study drug, then a larger number of subjects must be enrolled in the study to produce a statistically reliable result. The authors then go through a calculation showing that in several cases, the lack of a placebo arm could potentially put more subjects at risk of an inferior treatment. Finally, the assumption that all placebo arms are unethical assumes that their use will lead to significant harm and suffering. Indeed, this is not always the case. The authors give the example of a treatment for baldness or headaches—two conditions, where "clinicians frequently do not treat such ailments..." As a result, those subjects in the placebo arm are not being exposed to undue harm and suffering.

The authors, having poked holes in both of the extreme views, argue for a more moderate approach to the use of placebos. They state that placebo arms are unethical "if effective, life-saving, or at least life-prolonging treatment is available" and if the placebo treated subjects were "substantially more likely to suffer serious harm" than the treatment arm. However, if the risk of harm or severe discomfort is minimal, then the use of a placebo would be considered appropriate. Additionally, the authors argue that in situations where there is increased risk to the placebo arm, but this risk is similar to what would be experienced without the use of the placebo arm, then, again, the use of placebos is justified. Situations where the use of a placebo would be appropriate include "a high placebo-response rate," when the study "condition is typically characterized by a waxing-and-waning course, frequent spontaneous remissions.. ." and when "existing therapies are only partly effective or have very serious side effects.. .or.. .an equivalence trial would have to be so large that it would reasonably prevent..completion of the study." In all of these situations, the use of a placebo would still only be acceptable if "the placebo group should not be substantially more likely than those in the active-treatment group to die; to have irreversible morbidity or disability or to suffer other harm; to suffer reversible but serious harm; or to experience severe discomfort." The authors conclude their article with a discussion of the use of the pros and cons of using placebos in chronic stable angina.

Currently there is still much disagreement on the appropriate use of placebo arms in clinical trials. We hope that this discussion will help provide information for further exploration of this important issue.

The Ethics Committee provides these discussions as a -way to open. a dialogue on the various ethical issues that confront our specialty on a daily basis. These issues are often quite complex and do not have simple "right" or "wrong" solutions. The articles are meant as a way to highlight the various issues that are involved. in these ethical dilemmas, they should not be viewed as the Ethics Committee or the Academy's particular stance on an issue.

The National Academies
INSTITUTE OF MEDICINE

Committee to Assess the Safety and Efficacy of the Anthrax Vaccine

Second Meeting
January 29-30, 2001

Room 2004
The Foundry Building
1055 Thomas Jefferson Street, NW
Washington, DC

Meeting Objectives

- Review several completed studies of anthrax vaccine safety and efficacy
- Evaluate knowledge of vaccine components
- Define needs for additional information gathering
- Plan future meetings

Agenda

Monday, January 29, 2001

9:30 Breakfast

10:00 Closed Session

12:00 **Open Session**

A review of some of the studies of the anthrax vaccine

12:00 The CDC Observational Study
Dr. Juli Clifford
Center for Biologics Evaluation and Research, FDA

12:30 Components of the Anthrax Vaccine Absorbed and Contrast with Merck Vaccine
Dr. Robert Myers
Bioport Corporation

1:00 Working Lunch- provided

1:30 Field Evaluation of a Human Anthrax Vaccine
Dr. Stanley Plotkin

2:00 Ft. Detrick Multi-Dose, Multi-Vaccine Safety Studies
Dr. Phillip Pittman
U.S. Army Medical Research Institute for Infectious Diseases

2:30 Ft. Detrick Special Immunization Program
Dr. Phillip Pittman

3:00 Ft. Bragg Booster Study
Dr. Phillip Pittman

3:30 **Break**

3:45 Reduced Dose/Route of Administration Pilot
Dr. Phillip Pittman

4:15 Defense Medical Surveillance System Data
Dr. Mark Rubertone
U.S. Army Center for Health Promotion and Disease Prevention

4:45 **Adjourn Open Session**

5:00 **Commence Closed Session**

Tuesday, January 30

Open Session

8:00 Breakfast

8:30 U.S Forces in Korea Survey
Dr. Ken Hoffman
Military and Veterans Health Coordinating Board

9:00 Status of the Anthrax Vaccine Research Portfolio
Dr. John. Grabenstein
Anthrax Vaccine Immunization Program Agency

9:30 **Adjourn Open Session**

IOM Mtg 29 Jan

Diniega, Benedict, COL, OASD/HA

From: Jennings, Gerald, COL, OASD/HA
Sent: Tuesday, January 09, 20016:39 AM
To: Diniega, Benedict, COL, OASD/HA
cc: (b)(6)
Subject: RE: IOM Committee to Assess the Safety and Efficacy of the Anthra x Vaccine: Meeting Announcement

Ben, See below. Dr. Clinton had asked for you to cover and report. Let me know if a problem. Jerry.

-----Original Message-----
From (b)(6)
(b)(6)
Sent: Monday, January 08, 20015:57 PM
To: Jennings, Gerald, COL, OASD/HA
Cc: Diniega, Benedict M COL OTSG
Subject: RE: IOM Committee to Assess the Safety and Efficacy of the Anthra x Vaccine: Meeting Announcement

For the open sessions, yessir, absolutely. I'm still waiting for a schedule of when the open and closed sessions will be. I'll keep you informed.

(b)(6)

-----Original Message-----
From: Jennings, Gerald, COL, OASD/HA (b)(6) @ha.osd.mil]
Sent: Monday, January 08, 200116:51
To (b)(6)
Subject: RE: IOM Committee to Assess the Safety and Efficacy of the Anthra x Vaccine: Meeting Announcement

(b)(6 can someone from HA attend? Thanks. Jerry.

-----Original Message-----
From: (b)(6)
(b)(6)
Sent: Monday, January 08, 200110:44 AM
To: (b)(6)
Cc:
(b)
(6)
Subject: FW: IOM Committee to Assess the Safety and Efficacy of the Anthra x Vaccine: Meeting Announcement

FYI, I'm awaiting the Committees request for support.

v/r (b)(6)

-----Original Message-----
From: Anthrax Vaccine Safety and Efficacy Study (b)(6) @nas.edu]
Sent: Friday, 05 January, 2001 17:02
To: Anthrax Vaccine Safety and Efficacy Study
Subject: IOM Committee to Assess the Safety and Efficacy of the Anthrax Vaccine: Meeting Announcement

The IOM Committee to Assess the Safety and Efficacy of the Anthrax Vaccine will hold its second meeting on January 29-30th, at the Foundry Building in Washington, D.C. The agenda for the meeting is currently under development, but will address some of the studies that have assessed the safety or efficacy of the anthrax vaccine. The agenda will include sessions open to the public, tentatively scheduled for the afternoon of the 29th. An agenda for the meeting will be distributed to this list as soon as possible.

For more information about this study, visit:
http://www4.nationalacademies.org/cp.nsf/8314f46c8196eda98525657100556a57/76dcdf87db8e2f7e8525691b0044c473?OpenDocument

Regards,

The IOM Anthrax Vaccine Safety and Efficacy Study

The National Academy of Sciences (NAS), Institute of Medicine (IOM) report, "Protecting Those Who Serve: Strategies to Protect the Health of Deployed U.S. Force. "

A. BACKGROUND.

1. In 1996 Deputy Secretary of Defense asked the National Academy of Sciences (NAS) to advise the Department of Defense on a strategy to better protect the health of US troops in future deployments. Over a two-year period, the NAS sponsored, through its Institute of Medicine (IOM), four different study groups that evaluated 1) assessment of health risks; 2) detecting exposures to harmful agents; 3) physical protection and decontamination; and 4) medical protection, treatment, and records. Upon completion and publication of the results of those studies, the NAS empanelled a committee for a third year to shape the most important findings and recommendations of the first four studies into a long-term strategy.

2. The report asserts that the Department has made few concrete changes at the field level in implementing previously identified recommendations for protecting the health of deployed forces. The committee judged the extent of implementation of these recommendations to be, thus far, unacceptable. The committee concluded that immediate action is called for to avoid both unnecessary risks to service members and jeopardizing future missions.

B. POSITIONS.

The DOD has made much progress in addressing the medical deficiencies noted in this report. In the 10 years since the Gulf War, the U.S. military has learned much about preventive medicine, risk communication, and health care from dealing with Gulf War health issues and from caring for troops deployed to Somalia, Rwanda, Haiti, Bosnia, and Kosovo. To improve the health of military personnel and veterans, it has been necessary to learn from both the successes and the mistakes of military medicine. These lessons continue to be incorporated into new policy and programs, which are fundamentally changing how the DOD addresses the health care needs, particularly those needs related to deployment, of military personnel.

C. QUESTIONS AND ANSWERS.

1. **Question:** What has the Department's done to address the medical deficiencies noted in the report?

Proposed Response: The DOD has promulgated specific policy addressing many of the lessons learned from the Gulf War deployment. In 1996, OASD(HA) directed establishment of the Defense Medical Surveillance System and the Armed Forces serum repository. In 1997, OASD(HA) promulgated DOD Directive 6490.2, "Joint Medical Surveillance" and DOD Instruction 6490.3, "Implementation and Application of Joint Medical Surveillance for Deployments," outlining the policy for assessment and communication before and during deployment of significant health threats and corresponding medical prophylaxis, immunization and other unit and individual countermeasures for the Area of Operations. In 1999 OASD(HA) established DOD Deployment Health Research and Clinical Centers. Major Force Health Protection initiatives of these Centers include the national surveillance for birth defects among DOD beneficiaries, the Millennium Cohort Study, Post-Deployment Health Clinical Practice Guidelines, and the Recruit Assessment Program. The principal objective of the Millennium Cohort Study is to evaluate the impact of military deployments on various measures of health

over time including medically unexplained illnesses and chronic diseases such as cancer, heart disease, and diabetes. The clinical practice guidelines will enhance the ability of health care providers to identify, communicate with, and manage patients with deployment health concerns. If successful, the Recruit Assessment Program will initiate a longitudinal health record for military personnel at accession and provide comprehensive, baseline health data on military recruits.

2. **Question:** Has the Department done anything to address combat stress?

Proposed Response: Combat Stress Control (CSC) is an ongoing and critically vital issue to the Department. The DOD Directive 6490.5, "Combat Stress Control" was signed in February of 1999. It mandates that:

- CSC policies shall be implemented throughout the Department of Defense;
- Service CSC consultants shall meet periodically;
- Leadership aspects of combat stress prevention shall be emphasized;
- CSC units shall train with operational organizations;
- BICEPS principles (Brevity, Immediacy, Centrality, Expectancy, Proximity, Simplicity)
- Members experiencing CSRs shall be managed within the unit;
- Misconduct be handled through UCMJ; and
- CSR casualty rates be collected discretely from neuropsychiatric and DNBI data.

DOD CSC units have been very active in Somalia, Haiti, Kosovo, Bosnia, and on numerous other humanitarian missions. Information pamphlets on handling dead bodies and other stresses are available on the Army mental health website (Armymentalhealth.com) and from CHPPM.

3. **Question:** What is the Department's approach to documenting all deployment medical encounters?

Proposed Response: The DOD, through the Theater Medical Information Program (TMIP), is aggressively pursuing the development and implementation of information systems which will assist us in gathering mission-critical medical information throughout an individual service member's deployment. TMIP will support the collection and monitoring of immunizations, ambulatory care, diagnosis, treatment, radiation/occupational health, and blood management. Furthermore, TMIP will electronically transmit and aggregate these data to a theater database at the Joint Task Force Commander level for use in detecting disease and illness clustering where overt exposure histories do not exist as well as provide the data for and medical command and control at the deployed medical facility level. Funding for TMIP has been approved and the first component, which equates to the military computerized patient record for deployed forces, will begin field-testing in second quarter FY01, with full deployment commencing in FY02.

D. FOR ADDITIONAL INFORMATION: Mr. Ronald Richards, Acting DASD (Health Operations Policy, OASD(HA); Office Number: (b)(6) Home Number: (b)(6) (b)(6) E-mail Address: (b)(6) @ha.osd.mil

Date: December 15, 2000

Diniega, Benedict, COL, OASD/HA

From: (b)(6), LtCol, OASD/HA
Sent: Tuesday, January 16, 20013:58 PM
To: Diniega, Benedict, COL, OASD/HA
Subject: **FW:** IOM Committee to Assess the Safety and Efficacy of the Anthrax Vaccine: Meeting Announcement

FYI

-----Original Message-----
From: Anthrax Vaccine Safety and Efficacy Study (b)(6) nas.edu]
Sent: Friday, January 05, 2001 5:02 PM
To: Anthrax Vaccine Safety and Efficacy Study
Subject: IOM Committee to Assess the Safety and Efficacy of the Anthrax Vaccine: Meeting Announcement

The IOM Committee to Assess the Safety and Efficacy of the Anthrax Vaccine will hold its second meeting on January 29-30th, at the Foundry Building in Washington, D.C. The agenda for the meeting is currently under development, but will address some of the studies that have assessed the safety or efficacy of the anthrax vaccine. The agenda will include sessions open to the public, tentatively scheduled for the afternoon of the 29th. An agenda for the meeting will be distributed to this list as soon as possible.

For more information about this study, visit:
http://www4.nationalacademies.org/cp.nsf/8314f46c8196eda98525657100556a57/76dcdf87db8e2f7e8525691b0044c473?OpenDocument

Regards,

The IOM Anthrax Vaccine Safety and Efficacy Study

146

U.S. Department
of Transportation
Federal Aviation
Administration

800 Independence Ave., S.W.
Washington, D.C. 20591

OCT 15 1999

Office of the Army Surgeon General
ATTN: AVIP Agency (LtCol(P) Randolph)
Skyline 5
5111 Leesburg Pike
Falls Church, VA 22041-3258

Dear Colonel Randolph:

This is in response to a request that I inform you of Federal Aviation Administration policy regarding the eligibility for medical certification of civilian pilots who have been immunized with anthrax vaccine.

In accordance with an informal policy recently established by the Federal Air Surgeon, individuals who have been immunized with the anthrax vaccine are not disqualified from performing civilian airman duties so long as they do not experience significant adverse side effects that would otherwise be considered disqualifying.

I trust that this information is helpful. If you need something further, please let me know.

Sincerely,

Jon L. Jordan, M.D.
Federal Air Surgeon

(147)

2000109-0000009

May 23, 2000

MEMORANDUM FOR RECORD

1. The following document was reviewed by the OSAGWI Legal Advisor and cleared for public release:

CMAT #2000109-0000009 - Department of Health and Human Services letter dated Nov 26, 1999 with three enclosures to Congressman Dan Burton, reference anthrax vaccine.

2. Point of contact for this action is the undersigned at (b)(6) (b)(6).

(b)(6)

CMAT

(b)(6)

OSAGWI Legal Advisor

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 26 1999

The Honorable Dan Burton
House of Representatives
Washington, D.C. 20015

Dear Mr. Burton:

Thank you for your interest in the anthrax vaccine. This is in response to your letter dated November 3, 1999, co-signed by three of your colleagues, to Dr. Jane E. Henney, Commissioner of the Food and Drug Administration (FDA or the Agency). You raised a number of issues related to the pending license supplement application of BioPort Corporation to produce the anthrax vaccine. Ms. Jarilyn Dupont of my staff has had several conversations with Mr. John Weaver of your staff, on November 12 and November 17, 1999, concerning the status of this response. As was explained to Mr. Weaver, the response provided below is based on information available under the Freedom of Information Act (FOIA) and FDA implementing regulations.

Inspections

As you know, BioPort Corporation, (previously known as Michigan Department of Public Health or Michigan Biologics Products Institute), holds a license to manufacture Anthrax Vaccine Adsorbed. FDA has inspected this facility on many occasions during the past decade, identifying a number of deficiencies requiring correction. Your statement that the anthrax vaccine-specific portion of the manufacturing facility was not physically inspected in 23 years is not accurate. A review of inspection reports from 1972 to 1998 shows that Anthrax Vaccine Adsorbed was covered as part of the inspection on 12 separate occasions either by record review, observation of manufacturing areas or interviews with engineering and manufacturing staff. This information was contained in the written testimony of Dr. Kathryn C. Zoon, Director, Center for Biologics Evaluation and Research (CBER), before the Committee on Government Reform, Subcommittee on National Security, Veterans Affairs and International Relations, on April 29, 1999. In response to Members' questions, Dr. Zoon also stated that FDA did conduct inspections for the anthrax vaccine prior to 1996.

90N-0302

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C163 /ANS

Product Testing and Specifications

FDA agrees that products must be consistently manufactured to meet specifications prior to product approval. FDA review does include product characterization. Because of the complex manufacturing process for most biological products, each lot of the product undergoes thorough testing for purity, potency, and sterility. Manufacturers may release lots of product only after testing is documented. FDA may require lot samples and protocols showing results of applicable tests to be submitted for review and possible testing by the Agency. The anthrax vaccine manufactured by BioPort is subject to lot release, under which a manufacturer may not distribute a lot of product until CBER releases it. The lot release program is part of FDA's multi-part strategy that helps assure biological product safety by providing a quality control check on product specifications.

Anthrax Vaccine Adsorbed Indications

Dr. Zoon's testimony before the Committee on Government Reform on October 12, 1999, stated that the indication is based on risk. She did not state that the anthrax vaccine is indicated only for individuals at risk for cutaneous exposure to anthrax, nor that the use is for a "limited" population. The labeling for the anthrax vaccine product is enclosed. The labeling for Anthrax Vaccine Adsorbed does not mention route of exposure (e.g., cutaneous), per se. Use of the vaccine for protection against both cutaneous and inhalation anthrax exposure is not inconsistent with the labeling for Anthrax Vaccine Absorbed.

The term "paucity of data," used in the 1997, letter to Dr. Stephen Joseph, then Assistant Secretary of Defense for Health Affairs, from Dr. Michael A. Friedman, then FDA Lead Deputy Commissioner, is used to describe the relatively few reported cases of inhalation anthrax in the efficacy trial. Requiring the anthrax vaccine to be returned to an investigational new drug (IND) status will not generate more human efficacy data, as inhalation anthrax in humans is not amenable to study, due to the low incidence and sporadic occurrence of disease in natural settings. It should be noted that in the United States, in this century, only 18 human cases of inhalation anthrax have been reported (Brachman, P.S. Inhalation anthrax. *Ann N Y Acad Sci* 353:83-93, 1980). This low incidence of naturally occurring inhalation anthrax since introduction of the vaccine makes it impossible to duplicate the findings in the Brachman and the Centers for Disease Control and Prevention (CDC) surveillance data of the 1950's to early 1970's. In the past several years, the Department of Defense (DOD)

In the past several years, the Department of Defense (DOD) has concluded that the threat of biological attack is great enough that troops should be considered part of the high-risk population for which this vaccine is an appropriate prophylactic measure. (This information was provided to Chairman Dan Burton, in a response to an August 11, 1999, letter seeking information on vaccines.) You may wish to contact DOD to discuss its risk assessment.

There is presently no basis for concluding that the anthrax vaccine, a licensed product, when used in accordance with current labeling, should be used pursuant to an IND application or, as requested in your letter, that FDA "place the anthrax vaccine back under IND status."

Data to Support Indications and Administration Schedule

There is a misperception that no clinical or scientific studies have been conducted to support the current Anthrax Vaccine Adsorbed-dosing schedule. The currently licensed anthrax vaccine administration schedule was used in the Brachman efficacy trial and CDC IND.

The Brachman et al. trial was used to support the licensure of the anthrax vaccine. This trial was a single-blinded, well-controlled trial conducted in four United States textile mills processing imported goat hair with an 'exposed, susceptible, supervised population." The average incidence of anthrax prior to the study was 1.2 cases per 100 employees per year. The dose administration schedule was the same as the currently licensed vaccine dose administration schedule: 0, 2 and 4 weeks; 6, 12, and 18 months, followed thereafter by annual boosters. Of the 1,249 mill workers, 909 individuals participated in the controlled part of the study. Individuals who received neither vaccine nor placebo served as an unvaccinated observational control. A total of 26 anthrax **cases** occurred during the trial: 21 cutaneous cases and five inhalation cases (four fatal). Of these 26 cases, three (all cutaneous) occurred in anthrax vaccine recipients. One **case** occurred after two doses, one case occurred 13 months after the third dose (fourth dose not given), and one case occurred five months after the third dose. Five cases of inhalation anthrax occurred at one site (the Manchester, New Hampshire goat hair processing plant) during the trial. Two of the inhalation cases were in the placebo group and three inhalation cases were in the unvaccinated group. **No cases of *inhalation anthrax occurred in anthrax vaccine recipients.***

The efficacy level of 92.5 percent, as presented in the major publication of the efficacy trial (Brachman, et. al., 1962 Field evaluation of a human anthrax vaccine. *Am J* Public Health. 52:632-645) includes anthrax cases in the vaccine and placebo groups and is not limited to cutaneous anthrax cases. The efficacy of the anthrax vaccine in this study was calculated to be 92.5 percent. This calculation (92.5 percent) is sometimes erroneously presented as the vaccine efficacy against cutaneous anthrax.

Following the 1957 trial and the five cases of inhalation anthrax in placebo and unvaccinated individuals, the Manchester, New Hampshire goat hair processing plant vaccinated all employees against anthrax (starting in December 1957). The case rate in this plant fell from 8.2 cases per year prior to 1957 to 0.4 cases per year from December 1957 to June 1966, the latter consisting of four cutaneous cases. In July 1966, an employee (unvaccinated) of an adjacent facility (metal fabricator shop) died from inhalation anthrax. The source of the agent was thought to be the adjacent goat hair processing plant. In a follow-up investigation by CDC (January 30 - February 6, 1967), environmental sampling of both facilities identified *B. anthracis* inhalation anthrax (LaForce FM et al.: Epidemiologic study of a fatal case of inhalation anthrax. *Arch* Environ Health 18:798-*805*, 1969).

Under CDC IND, approximately 16,000 doses of the vaccine were administered to approximately 7,000 study participants who were at risk for anthrax. These doses were administered according to the same six-dose schedule that is the approved dosing schedule today.

Furthermore, in CDC surveillance data (1962-1974), 27 cases of anthrax occurred in 'at-risk" industrial settings: *24* cases in unvaccinated individuals, one case after one dose of vaccine and two cases after two doses of vaccine. No cases of anthrax were reported in individuals who received all six doses of anthrax vaccine.

It is interesting to note that CDC publication, *Biosafety in Microbiological and Biomedical Laboratories 4th Edition* (1999), states that laboratory associated cases of anthrax have not been reported in the United States since the late 1950s when the human anthrax vaccine was introduced. Before that date, numerous cases of laboratory associated anthrax, occurring primarily at facilities conducting anthrax research, were reported.

Additional Findings Supporting Anthrax Vaccine Adsorbed

The Public Health Service Act, under which biologicals such as vaccines were licensed in 1970, requires evidence of safety, purity and potency. After the Division of Biologic Standards was transferred from the National Institutes of Health to FDA, expert panels were assigned to review information on biological products, including vaccines that had been licensed prior to the transfer. The review was initiated in order to assess the safety, effectiveness and labeling of products licensed prior to July 1, 1972. Based upon their review of available data, the Advisory Review Panel recommended that marketing of Anthrax Vaccine Adsorbed manufactured by Michigan Department of Public Health be allowed to continue based upon substantial evidence of safety and effectiveness of the product. The safety data from CDC IND, as well as the efficacy data from the Brachman et al. trial, and CDC surveillance data (1962-1974) from "at-risk" industrial settings were the basis for these findings. These findings were published in the Federal Register of December 13, 1985.

Furthermore, data from a well-controlled monkey study has become available since the time of the 1985 Panel report. The efficacy of the Anthrax Vaccine Adsorbed licensed for use in humans also was tested in rhesus monkeys challenged by an aerosol of virulent Bacillus *anthracis* spores. The data from this study suggests vaccine efficacy against inhalation anthrax. It should be noted that monkeys are quite similar to humans with regard to the clinical course and pathological findings following inhalation anthrax.

While these studies cannot prove that the vaccine would be 100 percent effective in a terrorist or wartime situation, they are the only known data on pre-exposure protection currently available against inhalation anthrax.

DOD Vaccine Administration Schedule

In the September 29, 1999, letter to Dr. Sue Bailey, Assistant Secretary of Defense Health Affairs, Dr. Kathryn C. Zoon, Director, CBER, stated in the final paragraph, "We reiterate our previous statement made to DOD on December 16, 1997, that FDA approval of the anthrax vaccine is based on the six-dose regime found in the approved labeling. Because we are unaware of any data demonstrating that any deviation from the approved intervals of doses found in the approved labeling will provide protection from anthrax infection, we strongly recommend that the Anthrax Vaccine Immunization Program follow FDA-approved schedule." Similar information was included in a letter dated

September 28, 1999, to Dr. Sue Bailey from Dr. Jane E. Henney. Copies of both of these letters are enclosed.

DOD has conducted a pilot study, under a BioPort IND, to evaluate several dosing schedules and routes of administration for the anthrax vaccine. This pilot study used full informed consent. The pilot study evaluated anti-protective antigen antibody levels in vaccines. One purpose of the pilot study was to evaluate the feasibility of eliminating the week two dose as well as to evaluate differences between the subcutaneous and intramuscular routes of administration. This pilot study was intended to select a dosing schedule(s) for further evaluation in a larger, comparative, statistically definitive study to potentially support a change in the label. In December 1998, DOD met with FDA representatives to discuss such a study. To date, DOD has not yet submitted a definitive study protocol to evaluate and potentially support a change in the dosing schedule for the anthrax vaccine.

Product Expiration Dating

The expiration date of a biological product may be changed pursuant to Title 21, Code of Federal Regulations (CFR) 5610.50, Date of Manufacture, which states in part that the date of manufacture shall be the date of initiation by the manufacturer of the last valid potency test. As stated in 21 CFR §610.53 (b), the dating period for a product shall begin on the date of manufacture, as prescribed in section 610.50. A valid potency assay is required prior to an extension of dating. The expiration date is based on the last valid potency assay.

BioPort's License Application

The content of license applications under FDA review, including the number and characterization of lots, are not releasable under FOIA. Please be assured, however, that FDA will not approve an application until a manufacturer demonstrates that a product can be consistently manufactured under current good manufacturing practices (cGMPs) to meet product specifications. Lots manufactured to support a license application or supplement cannot be sold without approval of the application or supplement and remain subject to FDA lot release requirements as described above.

Proposed rule

In response to your comments on the proposed rule for animal studies, FDA agrees that there needs to be a scientifically verifiable extrapolation from animal data. FDA's Proposed Rule, "New Drug and Biological Drug Products; Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot Be Conducted," was published in the October 5, 1999, Federal Register. The docket is open for comment until December 20, 1999. Your letter will be forwarded to the docket so that your comments regarding the proposed rule can be entered into the docket for consideration. After the comment period has closed, FDA will review the comments and determine the appropriate next step in the process. At this time, there is no date for publication of a final rule.

We trust this information responds to your concerns. If you have further questions, please let us know. A similar response has been provided to your co-signers.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

3 Enclosures
"Package Labeling for Anthrax Vaccine Adsorbed"
"September 28, 1999 letter to Dr. Sue Bailey, Assistant Secretary of Defense Health Affairs, from Dr. Jane E. Henney, Commissioner, FDA"
"September 29, 1999, letter to Dr. Sue Bailey, Assistant Secretary of Defense Health Affairs, Dr. Kathryn Zoon, Director, CBER"

cc: Dockets Management Branch

Congress of the United States

Washington, DC 20515

November 3, 1999

The Honorable Jane E. Henney, M.D.
Commissioner
Food and Drug Administration
14-7 1 Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Henney:

We are writing to express our serious concerns regarding the pending license supplement application of BioPort to produce the anthrax vaccine. We strongly urge that each of the items contained in the letter be fully addressed and a response provided to us prior to the approval of BioPort's license supplement application.

As you are aware, in 1997 the Department of Defense mandated the implementation of a force-wide Anthrax Vaccine Immunization Program (AVIP). Since the announcement of this plan to inoculate all 2.4 million members of our Armed Services, FDA documented deficiencies in the manufacturing process have caused widespread and persistent concerns regarding the safety of the vaccine.

Of particular concern is that despite the licensure of the anthrax vaccine in 1970, 23 years passed before your agency physically inspected the anthrax-specific portion of the manufacturing facility. In testimony before the House Government Reform Committee, Dr. Zoon, the Director of FDA's Center for Biologics Evaluation and Research, indicated that two inspections of the production facilities in 1997 and 1998 revealed significant deviations from the Federal Food, Drug, and Cosmetic Act, FDA's regulations, and the standards in the Michigan Biological Product Institute (MBPI) license. Inspection reports of the production facilities following its purchase by BioPort revealed some progress but many remaining deviations. In large part, the significant ongoing deviations prompted the company to close the facility for remodeling rather than face the likelihood of FDA revoking their license.

Given the documented deviations from approved practices in the manufacturing process, it is imperative that the FDA follow it's own prescribed regimen of thorough testing for purity, potency, identity, and sterility. As a prerequisite for approval of the license supplement, the testing must reveal lot-to-lot consistency for the vaccine. Included within the testing requirements, the FDA must ensure lot-to-lot consistency for the antigen level. FDA mandated lot-to-lot consistency will ensure we can accurately measure the efficacy of the vaccine. The lack of clinical data detailing the relationship between antigen levels and the amount of protection provided argues strongly for greater vaccine consistency data so correlates of

No. 99-7003

immunity can be studied. In that regard, please provide information on the status of FDA's request of BioPort to characterize the vaccine. Any failure to characterize the vaccine must preclude the approval of the license supplement application.

We also urge that the FDA place the anthrax vaccine back under Investigational New Drug (IND) status. As Dr. Zoon testified before the Government Reform Committee, the MBPI vaccine was licensed for use by a limited population of individuals at risk for coetaneous exposure to anthrax through infected animals or animal products. The December 13, 1985 Federal Register and the FDA approved package inserts indicate: "Since the risk of exposure to anthrax infection in the general population is slight, routine immunization is not recommended." However, the Department of Defense, in its implementation of the AVIP, is performing a large-scale inoculation for protection against inhalation anthrax. The scope of the vaccination program and the form of exposure anticipated by DoD were not addressed in the initial license. A March 13, 1997, letter from Dr. Michael Friedman, FDA Lead Deputy Commissioner, to Stephen Joseph, then Assistant Secretary of Defense for Health Affairs, acknowledged the "paucity of data regarding the effectiveness of the anthrax vaccine for prevention of inhalation anthrax." This lack of significant data strongly suggests the need for further study under IND status.

Additionally, the data submitted for licensure of initial vaccine did not include scientifically valid support for the current dosing structure. GAO stated that no studies have been conducted to determine the optimum number of doses of the anthrax vaccine. Although annual boosters are recommended, the need for a six-shot regimen and annual booster shots has not been evaluated. There is also no clinical data to accurately conclude that the prescribed regimen provides a consistent level of protective antigen to be efficacious against inhalation anthrax. A September 29, 1999 letter from Dr. Zoon to Dr. Sue Bailey, the Assistant Secretary of Defense for Health Affairs indicated that there is lack of data on the impact of deviations from the approved vaccine regimen. Prior to the approval of the license supplement application, the FDA must scientifically verify the clinical data supporting the six-dose regimen. We would like to be apprised of FDA's plans to accomplish this goal and be provided the clinical data supporting the correlation between the dosage and anti-body levels.

We are also requesting the status of FDA's proposed rule regarding the use of animal data to support claims of human efficacy. Human efficacy information for the current license and the license supplement application is based overwhelmingly upon the application of data from animal anthrax vaccinations and exposure. However, there have been great discrepancies between various animal models regarding the efficacy of the anthrax vaccine. We acknowledge and support the moral argument against human testing to determine the efficacy of the vaccine. At the same time, we must ensure there is a scientifically verifiable extrapolation from animal data that can be applied to humans. It is our understanding the proposed rule would attempt to establish protocols to provide that information. If that rule has not been approved, we would like

Should you have any questions regarding this letter, please do not hesitate to contact us or any member of our staffs. Please provide this information by November 18. Thank you for your consideration of these serious matters. We look forward to your prompt reply.

Sincerely,

Walter B. Jones
Member of Congress

Dan Burton
Member of Congress

Benjamin A. Gilman
Member of Congress

Christopher Shays
Member of Congress

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

September 28, 1999

Sue Bailey, M.D.
Assistant Secretary of Defense
Health Affairs
1200 Defense Pentagon
Room 3E346
Department of Defense
Washington, D.C. 20301-1200

Dear Dr. Bailey:

It was a pleasure meeting with you on August 24 to discuss issues of mutual concern. Subsequent to our meeting, Dr. Kathryn Zoon, Director of FDA's Center for Biologics Evaluation and Research, advised me of additional information that she reviewed related to anthrax vaccination for our military troops.

Dr. Zoon has reviewed information from congressional sources that some troops may not be receiving the vaccine in accordance with the schedule found in the approved labeling. As you are aware this schedule is the only regimen shown to be effective in protecting humans against anthrax and is the only schedule approved by FDA. I have asked Dr. Zoon to communicate our concerns on this important matter to you directly. Thank you in advance for your prompt attention to this.

Sincerely,

Jane E. Henney, M.D.
Commissioner of Food and Drugs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20852-1448

SEP 2 9 1999

Sue Bailey, M. D.
Assistant Secretary of Defense
Health Affairs
1200 Defense Pentagon
Room 3E346
Department of Defense
Washington, DC 20301-1200

Dear Dr. Bailey:

On December 16, 1997, Food and Drug Administration (FDA) officials met with the Department of Defense (DOD) officials to discuss DOD's Anthrax Vaccine Immunization Program (Am). During that meeting, Dr. Ed Martin acting Assistant Secretary of Defense, Health Affairs, briefed Dr. MichaelFriedman, Lead FDA Deputy Commissioner on DOD's plan to implement anthrax vaccinations of the U.S. military forces. As part of that briefing, Dr. Martin emphasized that the anthrax vaccine immunization program would not vary from the FDA approved labeling.

Recently, it has come to the agency'sattention through congressional sources, that some troops may not be receiving the vaccine in accordance with the schedule found in the approved labeling. AS you know, the approved anthrax labeling states thatfull immunization involves six (6) doses administered over 18 months to complete the primary series. Labeling calls for doses of the vaccine to be administered, following the first dose, at 2 and 4 weeks, 6 months, 12 months and 18 months, with yearly boosters thereafter. This schedule is the only regimen shown to be effective in protecting humans against anthrax and is the only schedule approved by FDA. Data received by FDA from congressional sources indicate that a number of reserve and active military personnel are receiving their anthrax vaccine doses significantly later than the FDA approved schedule.

WC reiterate our previous statement made to DOD on December 16, 1997 that FDA approval ofth: anthrax vaccine is based on the six-dosereginen found inthe approved labeling. Because we are unaware ofany data demonstrating that any deviation from the approved intervals ofdoses found in the approved labeling will provide protection from anthrax infection, WC strongly recommend that the Anthrax Vaccine Immunization Program follow the FDA approved schedule. We wouldlike to hear from you as soon as possible regarding *this* important *matter.*

Sincerely yours,

Kathryn C. Zoon, Ph.D.
Director
Center for Biologics Evaluation
and Research

ANTHRAX VACCINE ADSORBED

DESCRIPTION

Anthrax Vaccine Adsorbed is a sterile product made from filtrates of microaerophilic cultures of an avirulent, noncapsulated strain of *Bacillus anthracis* which elaborates the protective antigen during the growth period. The cultures are grown in a synthetic liquid medium and the final product is prepared from the sterile filtered culture fluid. The potency of this product is confirmed according to the U.S. Food and Drug regulations (21 CFR 620.23): Additional Standards for Anthrax Vaccine Adsorbed. The final product contains no more than 2.4 mg aluminum hydroxide (equivalent to 0.83 mg aluminum) per 0.5 cc dose. Formaldehyde, in a final concentration not to exceed 0.02%, and benzethonium chloride, 0.002%, are added as preservatives.

CLINICALPHARMACOLOGY

Anthrax Vaccine Adsorbed is used in man to promote increased resistance to *Bacillus anthracis* by active immunization (1,2).

INDICATIONS AND USAGE

Immunization with Anthrax Vaccine Adsorbed is recommended for individuals who may come in contact with animal products such as hides, hair, or bones which come from anthrax endemic areas and may be contaminated with *Bacillus anthracis* spores; and for individuals engaged in diagnostic or investigational activities which may bring them into contact with *B. anthracis* spores (1-5). It is also recommended for high risk persons such as veterinarians and others handling potentially infected animals. Since the risk of exposure to anthrax infection in the general population is slight, routine immunization is not recommended.

If a person has not previously been immunized against anthrax, injection of this product following exposure to anthrax bacilli will not protect against infection.

CONTRAINDICATIONS

A history of a severe reaction to a previous dose of anthrax vaccine is a contraindication to immunization with this vaccine.

WARNINGS

1. Any acute respiratory disease or other active infection is generally considered to be adequate reason for deferring an injection.
2. Persons receiving cortico-steroid therapy or other agents which would tend to depress the immune response may not be adequately immunized with the dosage schedule recommended. If the therapy is short termed, immunization should be delayed. If the therapy is long termed, an extra dose of vaccine should be given a month or more after therapy is discontinued.

PRECAUTIONS

1. *General:* Epinephrine solution, 1:1000, should always be available for immediate use in case an anaphylactic reaction should occur, even though such reactions are rare.
2. *Carcinogenesis, Mutagenesis, Impairment of Fertility:* Studies have not been performed to ascertain whether Anthrax Vaccine Adsorbed has carcinogenic action, or any effect on fertility.
3. *Pregnancy:* PREGNANCY CATEGORY C. ANTHRAX VACCINE ADSORBED
   Animal reproduction studies have not been conducted with Anthrax Vaccine Adsorbed. It is also not known whether Anthrax Vaccine Adsorbed can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Anthrax Vaccine Adsorbed should be given to a pregnant woman only if clearly needed.
4. *Pediatric Use:* This antigen should be administered only to healthy men and women from 18 to 65 years of age because investigations to date have been conducted exclusively in that population.

ADVERSE REACTIONS

Local Reactions: Mild local reactions occur in approximately thirty per cent of recipients and consist of a small ring of erythema, 1-2 cm in diameter, plus slight local tenderness(1). This reaction usually occurs within 24 hours and begins to subside by 48 hours. Occasionally, the erythema increases to 3 to 5 cm in diameter. Local reactions tend to increase in severity by the 5th injection and then may decrease in severity with subsequent doses.

Moderate local reactions which occur in 4 per cent of recipients of a second injection are defined by an inflammatory reaction greater than 5 cm diameter.

These may be pruritic. Subcutaneous nodules may occur at the injection site and persist for several weeks in a few persons. A moderate local reaction can occur if the vaccine is given to anyone with a past history of anthrax infection.

More severe local reactions are less frequent and consist of extensive edema of the forearm in addition to the local inflammatory reaction.

All local reactions have been reversible.

Systemic Reactions: Systemic reactions which occur in fewer than 0.2 per cent of recipients have been characterized by malaise and lassitude. Chills and fever have been reported in only a few cases. In such instances, immunization should be discontinued.

DOSAGE AND ADMINISTRATION

Dosage

Primary immunization consists of three subcutaneous injections, 0.5 mL each, given 2 weeks apart followed by three additional subcutaneous injections, 0.5 mL each, given at 6, 12 and 18 months(1).

If immunity is to be maintained, subsequent booster injections of 0.5 mL of anthrax vaccine at one year intervals are recommended.

Administration

1. Use a separate sterile needle and syringe for each patient to avoid transmission of viral hepatitis and other infectious agents.
2. Shake the bottle thoroughly to ensure that the suspension is homogeneous during withdrawal. The rubber stopper should be treated with an appropriate disinfectant and allowed to dry before inserting the needle.
3. This preparation must be given subcutaneously after cleansing the overlying skin with an antiseptic.
4. Follow the usual precautions to avoid intravenous injection.
5. After withdrawing the needle, the injection site may be massaged briefly and gently to promote dispersal of the vaccine.
6. The same site should not be used for more than one injection of this vaccine.
7. Do not syringe-mix with any other product.
8. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED

Anthrax Vaccine Adsorbed is supplied in 5 mL vials containing 10 doses each.

STORAGE

THIS PRODUCT SHOULD BE STORED AT 2 TO 8°C (35.6 to 46.4°F). Do not freeze. Do not use after the expiration date given on the package.

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These recommendations are prepared by the Michigan Department of Public Health only for the guidance of the physician. They do not replace the experience and judgment of the physician, who should be familiar with the recent pertinent medical literature before administering any biologic product.

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April 4, 2000

Memorandum:

From: Cathy Liverman and Carolyn Fulco

Subject: Institute of Medicine report, *An Assessment of the Safety of the Anthrax Vaccine: A Letter Report*

We are pleased to enclose a copy of the Institute of Medicine report, *An Assessment of the Safety of the Anthrax Vaccine: A Letter Report*, recently completed by the IOM Committee on Health Effects Associated with Exposures During the Gulf War. This report provides an assessment of the peer-reviewed literature on the safety of the anthrax vaccine. The report was released Tuesday, April 4th.

If you have any questions about the report, please call Cathy Liverman, (202) 334-3986 or Carolyn Fulco, (202) 334-3312.

2101 Constitution Avenue, NW, Washington, DC 20418 *Phone* (202) 334 2039 *Fax* (202) 334 2939 national-academies.org

An Assessment of the Safety of the Anthrax Vaccine

A Letter Report

Committee on Health Effects Associated with
Exposures During the Gulf War

INSTITUTE OF MEDICINE
Washington, D.C.

An Assessment of the Safety of the Anthrax Vaccine

A Letter Report

March 30, 2000

Major General Randall L. West, USMC
Special Advisor for Biological Defense Affairs
Under Secretary of Defense for Personnel and Readiness
Department of Defense
4000 Defense Pentagon
Washington, DC 20301-4000

Dear General West:

In February of this year, the Department of Defense (DoD) requested that the Institute of Medicine (IOM) provide a report on the safety and efficacy of the anthrax vaccine that could be used to answer questions raised by Congress. The IOM has agreed to undertake this comprehensive study, which will require approximately 24 months to complete. The questions include the types and severity of adverse reactions, including gender differences; long-term health implications; efficacy of the vaccine against inhalational anthrax; correlation of animal models to safety and effectiveness in humans; validation of the manufacturing process; definition of vaccine components in terms of the protective antigen and other bacterial products and constituents; and identification of gaps in existing research.

Because of immediate concern over anthrax vaccine safety issues, the IOM offered to draw relevant information from an ongoing study of Gulf War exposures funded by the Department of Veterans Affairs. The opportunity to provide limited information relating to the safety of anthrax vaccine is possible due to the ongoing work of the IOM Committee on Health Effects Associated with Exposures During the Gulf War, which was tasked with conducting literature reviews on six Gulf War exposures (including the anthrax vaccine). This committee began its work in January 1999, and it is scheduled to provide its report in August of this year. With the agreement of the Department of Veterans Affairs, the IOM was able to produce this letter report that summarizes the committee's literature review on the safety of the anthrax vaccine. This information, while very narrowly focused, may be helpful now to Congress, the DoD, and others before the IOM begins its comprehensive assessment of the anthrax vaccine. Although DoD requested the IOM's consideration of safety and efficacy, the current IOM committee was not tasked with issues of vaccine efficacy. The report that follows therefore addresses only the limited peer-reviewed literature on the safety of the anthrax vaccine.

The committee evaluated the primary peer-reviewed literature and did not draw conclusions from the secondary literature (e.g., reviews). Publications that were not peer reviewed had no evidentiary value for the committee, and they were not used as a basis for conclusions about the degree of association between an exposure and a health effect. The ability of the IOM to conduct the more comprehensive study of the anthrax vaccine requested by the DoD assumes that the significant body of work that has been conducted by the DoD on this subject will be released for publication in peer-reviewed scientific journals.

INTRODUCTION

Currently there are two types of anthrax vaccine available for human use: a live attenuated spore vaccine that has been tested and used widely in the countries of the former Soviet Union (Shlyakhov and Rubinstein, 1994) and protective-antigen vaccines that were developed in the United States and the United Kingdom in the 1950s using filtrates of attenuated strains of the anthrax bacillus. Protective antigen, one of the three toxin proteins produced by the anthrax bacillus, is the protective component of the British and U.S. vaccines, which differ in their method of production and in the strains of the bacillus used (Ibrahim et al., 1999). The committee decided to base its conclusions solely on studies of the protective-antigen vaccines because the live attenuated spore vaccine differs substantially in terms of composition, reactogenicity, and potential residual virulence.

The U.S. anthrax vaccine, which was used in the Gulf War and is currently still in use, was granted product licensure on November 10, 1970. In 1985, a Food and Drug Administration (FDA) advisory panel reviewing the status of bacterial vaccines and toxoids categorized the anthrax vaccine in Category 1 (safe, effective, and not misbranded) (FDA, 1985). The current dosing schedule is 0.5 ml administered subcutaneously at 0, 2, and 4 weeks and 6, 12, and 18 months, followed by yearly boosters. It is estimated that 68,000 doses of the U.S. anthrax vaccine were distributed from 1974 to 1989; 268,000 doses in 1990; and 1.2 million doses from 1991 to July 1999 (Ellenberg, 1999). The exact number of people who received the vaccine is not known. The following sections provide a synthesis of the available peer-reviewed studies.

ANIMAL STUDIES

Few studies have explicitly looked for adverse health effects of the protective-antigen anthrax vaccine in animals. In a study by Wright and colleagues (1954), 25 rabbits were administered five 0.5-ml intracutaneous injections of anthrax vaccine on alternate days. The rabbits were sacrificed 23 days later. Complete autopsies including gross and microscopic examination of all organs revealed no adverse effects. In studies conducted in nonhuman primates, no remarkable local or systemic reactions were seen (Darlow et al., 1956; Ivins et al., 1998). Few meaningful conclusions regarding adverse effects in humans can be drawn from the animal studies of the vaccine; the primary goal of the majority of those studies has been to determine the vaccine's efficacy.

HUMAN STUDIES

There are only a few published peer-reviewed studies examining the safety of the anthrax vaccine in humans. The studies discussed below, with the exception of the Ft. Detrick studies, administered only the anthrax vaccine and were not intended to examine the effects of multiple vaccinations. The committee notes a recent literature review (Demicheli et al., 1998) on anthrax vaccine studies conducted according to the Cochrane Collaboration guidelines for systematic reviews of health care interventions. Only the Brachman study (described below) met the Cochrane criteria for prospective randomized or quasi-randomized studies of a protective antigen anthrax vaccine.

Short-Term Studies

During the development of the anthrax vaccine, several studies examined adverse reactions in humans. These studies used early versions of the culture filtrate (protective-antigen) vaccine. Wright and colleagues (1954) described the reactions of 660 persons who received a total of 1,936 injections. They found that 0.7% of the vaccinated subjects reported systemic reactions—typically consisting of mild muscle aches, headaches, and mild-to-moderate malaise lasting 1 to 2 days. Significant local reactions—typically swelling (5–10 cm in diameter) and local pruritus (itching)—were reported for 2.4% of the injections. The incidence of local reactions increased with the number of previous injections. Two additional early studies also showed low rates of mild, brief local reactions (Darlow et al., 1956; Puziss and Wright, 1963). There is no long-term follow-up reported on the subjects in these studies.

Brachman Study

Brachman and colleagues (1962) conducted the only randomized clinical trial of vaccination with a protective-antigen anthrax vaccine. Although the vaccine used in this study was similar to the vaccine currently available in the United States in that it was a protective-antigen vaccine, the manufacturing process has since changed and a different strain of anthrax bacillus is now used (GAO, 1999a).

The clinical trial was conducted among 1,249 eligible workers[1] at four goat hair processing mills in which some raw materials were contaminated by the anthrax bacillus. After the initial series of three injections, the study had to be terminated at the largest mill, which employed nearly half of the subjects, because of an outbreak of inhalation anthrax that required the immunization of all employees. At the remaining mills, 480 participants completed the series of injections (230 of whom were randomized to active vaccination and 250 of whom were randomized to receive placebo injections) and 81

[1]Employees who had a previous case of anthrax were not eligible for the study. Of the 1,249 eligible participants, 340 refused to participate in the study.

participants did not complete the series of injections.[2] The study subjects did not know whether they had received the active vaccine or placebo; the article does not state whether the investigators were also blinded.

The report of the study does not always clearly distinguish the results in the three mills for the 480 subjects who completed the vaccination series from the 81 subjects who did not complete the series. Neither does it clearly distinguish the results for the 480 subjects in the three mills who completed the series from results for the subjects from the largest mill who had been randomized, received the initial injections, and were partially evaluated prior to the mill's withdrawal from the study.

The participants were examined 24 and 48 hours following each vaccination to assess both local and systemic reactions to the vaccine. There was no report of subsequent active or passive surveillance for possible adverse effects beyond 48 hours after each vaccination (there was further monitoring for the vaccine's efficacy, however). The typical reaction is described as a ring of erythema (1–2 cm in diameter) at the injection site, with local tenderness that lasted 24–48 hours. Some subjects (a number was not given) reported more extensive edema, erythema (>5 cm in diameter), pruritus, induration, or small painless nodules at the injection site (lasting up to several weeks). Twenty-one persons had moderate local edema that lasted up to 48 hours. Three individuals had edema extending from the deltoid to the mid-forearm (in one case, to the wrist) that dissipated within 5 days. The only systemic reactions were reported in two individuals (0.9% of the actively vaccinated subjects), who experienced "malaise" lasting 24 hours following vaccination. The study notes that three individuals who received the placebo (0.1% alum) had mild reactions.

Long-Term Studies

The committee located only one published series of studies that discussed long-term follow-up of individuals who received multiple vaccinations, including the anthrax vaccine, due to the nature of their employment. A group of employees at Fort Detrick, Maryland, were followed for an average of 25 years to investigate the potential subclinical effects of intensive vaccination.[3] The participants underwent physical examinations and/or laboratory testing in 1956 ($n = 93$), 1962 ($n = 76$), and 1971 ($n = 77$) (Peeler et al., 1958, 1965; White et al., 1974).

No clinical sequelae attributable to intense long-term immunization could be identified in this cohort. None of the subjects suffered unexplained clinical symptoms requiring them to take sick leave that could be attributed to the vaccination program. There was some evidence of a chronic inflammatory response, as characterized by certain laboratory

[2]The authors state that there was a gradual decline in participation in the study, partly because of changes in the nature of the textile business and partly because some of the employees withdrew from the program.

[3]Prior to 1956, all 99 persons had been vaccinated against botulism, tularemia, Rocky Mountain spotted fever, Q fever, plague, typhus, psittacosis, and Eastern, Western, and Venezuelan equine encephalitis; in addition, 95 of the subjects were also immunized against smallpox, 37 against brucellosis, 28 against anthrax, and 25 against diphtheria. By 1962, 72 of the 76 study subjects had been vaccinated against anthrax (in addition to other vaccinations) (Peeler et al., 1958, 1965).

test abnormalities: elevated levels of hexosamine, an acute-phase reactant, and polyclonal elevations in levels of gamma globulins. These changes cannot necessarily be attributed to the vaccinations, as the workers studied were occupationally exposed to a number of virulent microbes. However, the studies did not report any clear adverse clinical consequences, such as neoplasms, amyloidosis, or autoimmune diseases.

This series of longitudinal clinical studies had several shortcomings. There was no comparison cohort and no random sampling of the employees. Therefore, the results may not be applicable to a broader population. Further, the outcomes may be due in part to the healthy worker effect, since the subjects were selected for the intensity and length of their immunization history, and individuals who left employment were not considered. Thus, the studies may have inadvertently focused on the most resilient individuals. Moreover, it would be difficult, if not impossible, to attribute adverse effects to any one vaccine, since the study subjects received multiple vaccines.

Non-Peer-Reviewed, Unpublished Information

The committee reviewed summaries of data from the Vaccine Adverse Event Reporting System (VAERS).[4] We did not, however, review the individual VAERS forms submitted by health care providers, people receiving the vaccination, family members, or others. VAERS data are useful as a sentinel for adverse events but are limited in their usefulness for assessing the rate or causality of adverse events since the information may be underreported, incomplete, or duplicative and may not always have been confirmed by medical personnel (IOM, 1994). From its inception in 1990 through July 1, 1999, there have been 215 VAERS reports regarding anthrax vaccination (Ellenberg, 1999). The majority of the reports describe local or systemic symptoms including injection site edema, injection site hypersensitivity, rash, headache, and fever. Twenty-two of the VAERS reports are considered serious events and were described as occurring (or being diagnosed) from 45 minutes to 4½ months after the vaccination. The reports of serious events include severe injection site reactions, a widespread allergic reaction, a case of aseptic meningitis, an onset of lupus, an onset of inflammatory demyelinating disease, a diagnosis of bipolar disease, and two cases of Guillain-Barré syndrome (Ellenberg, 1999). FDA and CDC are responsible for monitoring the VAERS data to detect unusual trends and occurrences of adverse health effects. That monitoring assists the FDA and CDC in responding appropriately to adverse events. In recent congressional testimony, FDA stated that "the reports on the anthrax vaccine received thus far do not raise any specific concerns about the safety of the vaccine" (Ellenberg, 1999).

Additionally, there are a number of unpublished studies with data on the safety of the anthrax vaccine (Table 1). However, these studies are either ongoing or have not been published in the peer-reviewed literature, and they were therefore not considered in the committee's conclusions regarding the strength of the evidence for associations with adverse health outcomes. In its full report, the committee uses these studies in determining

[4]VAERS is a passive surveillance system that is overseen jointly by the Centers for Disease Control and Prevention (CDC) and the FDA. Reports may be sent in to VAERS at any time following vaccination.

its recommendations for future research directions. The studies are currently described only in secondary sources (e.g., reviews, congressional testimony, and reports from the General Accounting Office). The publication of these studies would substantially increase the available body of information on which conclusions regarding health effects can be made.

TABLE 1. Unpublished and Ongoing Studies of the Anthrax Vaccine

Study	Brief Description
Licensure Safety Study	Data submitted in support of the application for licensure describes approximately 7,000 persons who received approximately 16,000 doses
Special Immunization Program Safety Study	Follow-up study on 1,590 workers at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) who received 10,451 doses since 1973
Ft. Bragg Booster Study	An assessment of the safety of booster shots given to 486 male military personnel who had received initial anthrax vaccinations during the Gulf War
Canadian Forces Safety Survey	Active monitoring of 576 persons in the Canadian military who received the anthrax vaccine in 1998
USAMRIID Reduced Dose and Route Change Study	Pilot study involving 173 persons who received a reduced dose schedule or vaccination via a different route (intramuscular)
Tripler Army Medical Center Survey	Survey of 603 health care personnel who were vaccinated at Tripler Army Medical Center in 1998–1999
U.S. Air Force Vision Study	A comparison of visual acuity in 354 vaccinated aircrew members with 363 unvaccinated aircrew personnel
Korea Survey	Survey of military personnel at the time they received subsequent doses of the vaccine

SOURCES: Claypool, 1999; GAO, 1999b.

Conclusions on Human Studies

There is a paucity of published peer-reviewed literature on the safety of the anthrax vaccine. The committee located only one randomized peer-reviewed study of the type of anthrax vaccine used in the United States (Brachman et al., 1962). However, the formulation of the vaccine used in that study differs from the vaccine currently in use. The series of Ft. Detrick studies shows no clinical sequelae from multiple vaccinations, including the anthrax vaccination, over 25 years of intermittent observation in a highly selected cohort. However, there was no active surveillance for chronic symptoms in these studies, which raises the possibility of underreporting of symptoms.

The published studies have found transient local and systemic effects (primarily erythema, edema, or induration) of the anthrax vaccine. There have been no studies of the anthrax vaccine in which the long-term health outcomes have been systematically evaluated with active surveillance. That is not unusual, however, as few vaccines for any disease

have been actively monitored for adverse effects over long periods of time. The committee strongly encourages the development of active monitoring studies that evaluate long-term safety in recipients of the anthrax vaccine.

The committee concludes that in the peer-reviewed literature there is inadequate/insufficient evidence to determine whether an association does or does not exist between anthrax vaccination and long-term adverse health outcomes. This finding means that the evidence reviewed by the committee is of insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an association between the vaccine and a health outcome in humans. Reviewing the large body of results that have not yet been published would enable more definitive conclusions about the vaccine's safety. The committee strongly urges the investigators conducting studies on the safety of the anthrax vaccine to submit their results to peer-reviewed scientific journals for publication. The proposed IOM study to evaluate the safety and efficacy of the anthrax vaccine will be able to examine a more extensive literature, as the DoD has agreed to make its studies of the vaccine available.

To date, published studies have reported no significant adverse effects of the vaccine, but the literature is limited to a few short-term studies. The committee's findings are best regarded as an early step in the complex process of understanding the vaccine's safety, which began with the vaccine's licensure in 1970 and the 1985 FDA advisory panel finding that categorized the anthrax vaccine as safe and effective. Active long-term monitoring of large populations will provide further information for documenting the relative safety of the anthrax vaccine.

Sincerely,

Institute of Medicine Committee on Health Effects
Associated with Exposures During the Gulf War

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NOTICE: Preparation of this report was approved by William Colglazier, Executive Officer of the National Research Council, on behalf of its Governing Board, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the Committee on Health Effects Associated with Exposures During the Gulf War, which are responsible for the report, were chosen for their special competences and with regard for appropriate balance.

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Additional copies of this letter report are available in limited quantities from the Division of Health Promotion and Disease Prevention, Institute of Medicine, 2101 Constitution Avenue, N.W., Washington, DC 20418. The full text of this letter report is available on line at **www.nap.edu/readingroom.**

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Printed in the United States of America

The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The image adopted as a logotype by the Institute of Medicine is based on a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

INDEPENDENT REPORT REVIEWERS

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the Institute of Medicine in making the published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. The committee wishes to thank the following individuals for their participation in the review of this report:

Donald A. Henderson, Johns Hopkins University
Richard Johnston, University of Colorado
Joyce Lashof, University of California, Berkeley
Robert Miller, (retired) National Cancer Institute
Gregory Poland, Mayo Clinic and Foundation
Hugh Tilson, University of North Carolina at Chapel Hill
Mary Wilson, Mount Auburn Hospital, Cambridge, MA

While the individuals listed above have provided constructive comments and suggestions, responsibility for the final content of this report rests solely with the authoring committee and the Institute of Medicine.

149

CMAT # 2000010-0000028

KEYWORDS:
LETTER FROM (b)(6) - RESPONSE TO ANTHRAX FACT MYTH VS FACK STORY BY TOM CUNNINGHAM IN DECEMBER 1999 ISSUE OF SOLDIER MAGAZINE.

(b)(6)

FOR:
(b)(6)

FROM:
(b)(6)

December 27, 1999

Soldier Magazine: FEEDBACK, Soldiers, 9325 Gunston Road, Ste S108, Fort Belvoir, Virginia 22060-5581.

Sir,

This is my response to your Anthrax Fact MYTH vs. FACT story by Tom Cunningham in DECEMBER 1999 issue of Soldier Magazine.

In this article one of the "Myths" concerning the anthrax vaccine was that;

"MYTH: The anthrax vaccine causes cancer, steritlity, miscarraiages and birth defects."

"Fact: There is no evidence to support these allocations. In more that 200 years of experience, no vaccine has ever been shown to cause cancer. No inactived vaccine ever invented (such as anthrax) has been shown to cause reproductive health problems – not sterility, not miscairaiges, not birth defects.

In fact, national experts specifically recommend vaccination during pregnancy for women who are vulnerable to tetanus, influenza or meningococci."

"There are no known long-term side effects to the anthrax vaccine".

I tend to strongly disagree with these statements of fact that are reported in this article! FACT: on 13 JAN 91 again on 5 FEB 91 (Desert Shield, Saudia Arabia) I and others in my unit received "VAC A" and VAC A2" respectfully (the anthrax vaccine). On FEB 6, I woke up had red urine all day. I finally got to a clinic that night that could analyze my urine. It contained red blood cells to numerous to count (RBCs TNTC). They pumped four bags of intrevenious fluids (4 liter) into me until it was clear again. Then they let me go without an explination of what caused this problem.

FACT: When I returned from Desert Shield/Desert Storm (D/S x 2) my wife and I decided to start our family. When things did not develop as planned in a timely manner (6 months) we started to seek medical assistance. After 7 years of infertility treatment (thouseands of my dollars spent, countless tests, procedures, and disappointments) we finally adopted two wonderful children from Russia in 1997 and 1998.

FACT: During that process I was informed that my sperm was positive for "anti-sperm anti-bodies". As explained by our doctor, the circulatory/immune system does not know that you have a reproductive system unless the biological barrier is somehow breached by it. Then the white blood cells (infection/invader killers) that accompany the red ones develop an anti-body to combat the invaders it detects. Thus, my sperm became the invaders in my body to be targeted and destroyed by the white blood cells, a kind of fratricide played out in my body! Thus, we could not have children of our own. Sometime in my past this must have happened to develop this anti-body. In retrospcet, I believe the "VACC A" shots that caused some kind of break down between my renal (kidneys) and circulatory systems (that was evident in my urine), also happen between my reproductive system and circulatory systems at this same time. Thus, indirectly the vaccines caused sterility to occure in me. Nothing else in my past explains this occurance!

Coincidentally, another soldier in my unit who received these vaccinations shots also, returned with me from D/S x2 with hopes of adding to his family. He and his wife already had a boy and happened to get pregnant shortly after our return. But, the child's heart never fully developed, upon being born and it only lived for minutes. What caused that coincidental birth defect?"

I do not know what happened to my body or why, nobody will or can explain it to me. They would not even write in my shot record that this was the anthrax vaccination that I received, just "VACC A", when I insisted that something had to go in there. We were told in rumor style that it was the anthrax vaccine. Maybe you are right and I got something else that only a lab rat should get and the anthrax vaccine is all right? However, I do know the consequences of the "VACC A" shots that I got are farther reaching that the Federal Government is willing to admit. "FACT" given this article of yours, or maybe I was one of the lab rats that helped make the current vaccine safe? Or maybe it needs more testing and test subjects? We will probably never know. But, here are two cases of "known long-term side effects to the anthrax vaccine". So, how am I suppose to believe that this vaccine is safe from the ones that I have already had? How am I suppose to morally support letting my soldiers receive this vaccine?

I don't trust you to report the truth about this subject, only what the Army wants soldiers to hear. I don't trust the Army to protect me or my soldiers with this vaccine and would rather take my chances on having another DS/DS x2 style war (without exposure to biohazards) than getting another secret vaccine. Especially one that I've had before with a bad reaction, or one the government is unwilling to admit the total risks involved. And, don't tell me that the vaccines that I got in D/S x2 don't count and I have to start all over again! If those shot's weren't good enough, then something is really wrong with this "story" of yours! Get it straight before you give it to me or my soldiers, and tell the Army to do the same.

Sincerely,

(b)(6)

(150)

DEPARTMENT OF DEFENSE
OFFICE OF GENERAL COUNSEL
LEGISLATIVE REFERENCE SERVICE

Date: September 29, 2000

MEMORANDUM TO: ASD(HA)
STAFFING FOR: ARMY, NAVY, AF, JCS. USD(P&R), GWI
INFORMATION FOR: ASD(LA), ASD(PA), IG, DGC(P&HP), GC

SUBJECT: LRS DESIGNATOR **NonD/DTest** 1883, Anthrax Vaccine Adsorbed -- HEALTH & HUMAN SERVICES **(HSS)** OVERSIGHT TESTIMONY

SUSPENSE: 1200, Monday, 2 October 2000

OMB has requested the views of the Department of Defense on the enclosed subject matter.

ACTION AGENCY: Please advise upon receipt of name of action officer and phone number. Please review and respond by the suspense date or request an extension. OSD agency comments require DGC coordination. Please advise us in advance if comments will he provided.

STAFFING AND INFORMATION AGENCIES: Please review the enclosed request and respond appropriately. If staffing agencies do not respond by the suspense dote or request an extension. we will assume you have no interest. Information agencies need not respond unless comments are necessary. OSD agency comments require DGC coordination. Please advise us in advance if comments will be provided.

DO NOT CALL OMB: LRS will consolidate all responses and notify OMB of the Department of Defense response.

2000280-0000009

STATEMENT BY

Mark A. Elengold

Deputy Director (Operations)

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

FOOD AND DRUG ADMINISTRATION

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

UNITED STATES HOUSE OF REPRESENTATIVES

October 3, 2000

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Mark A. Elengold, Deputy Director (Operations), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA or the Agency). I appreciate the Committee's interest in the Anthrax Vaccine Adsorbed and the opportunity for FDA to update the Committee of the regulatory status of BioPort Corporation (BioPort), and the Agency's experience with adverse event reports for the anthrax vaccine. Let me assure you that we will continue to help ensure that only safe and effective products' are marketed and that these products meet high standards of quality.

ANTHRAX DISEASE / ANTHRAX VACCINE

As previously stated before the Committee, anthrax is an infectious disease caused by spores of a bacterium known as *Bacillus anthracis*. Human infection may occur by three routes of exposure to anthrax spores: cutaneous, gastrointestinal, and pulmonary (inhalation). Breathing in

airborne spores of *anthrax* bacterium may lead to inhalation anthrax. Experience has shown that inhalation anthrax has a very high mortality rate, with estimates ranging from 80 percent to 90 percent or higher. Prior to the use of anthrax vaccine, cases of human anthrax infection in the United States were much more prevalent. The only FDA approved medical prevention against anthrax is the anthrax vaccine. According to data from the Centers for Disease Control and Prevention (CDC), there were approximately 130 reported cases of anthrax infection per year at the start of this century.

The clinical trials on the anthrax vaccine were conducted by Philip S. Brachman et al. during the 1950's' and CDC in the 1960's. The Michigan Department of Public Health (MDPH) (now BioPort) manufactured four lots of the vaccine used in the CDC study. On April 14, 1966, CDC submitted an investigational new drug (IND) application for anthrax vaccine to the Division of Biologics Standards, which was then part of the National Institutes of Health (NIH) and

[1] Philip S. Brachman, M.D., Herman Gold, M.D., Stanley A. Plotkin, M.D., F. Robert Fekety, M.D., Milton Werrin, D.V.M., F.A.P.H.A., and Norman Ingraham, M.D., F.A.P.H.A., Field Evaluation of a Human Anthrax Vaccine, AJPH Vol. 52,632-645, 1962.

later transferred to FDA (now CBER). The Division of Biologics Standards determined that the data submitted by CDC supported licensure of the vaccine. On November 10, 1970, the Division of Biologics Standards issued a product license to MDPH to manufacture anthrax vaccine.

Based upon their review of available data, a 1985 Advisory Review Panel recommended that the anthrax vaccine manufactured by MDPH be classified as a Category I product (safe, effective and not misbranded) and that appropriate licenses be continued based upon substantial evidence of safety and effectiveness of this product. These findings were published in the Federal Register (December 13, 1985, Vol. 50, No. 240 p.51002-51117).

There are also relevant non-human primate efficacy data. Previously, data had been provided to FDA indicating that anthrax vaccine protects non-human primates against a high challenge of inhalation anthrax with the Ames Strain (which is non-homologous, or dissimilar, to the vaccine strain). More recent data on animal efficacy was published in summary form by Arthur Friedlander, M.D., et al. in the *Journal of the American Medical Association* on December 8.

1999. This publication noted that non-human primates had a high level of protection against two more non-homologous strains, in addition to the Ames Strain. The Department of Defense (DoD) has committed to submit the new data to FDA under an existing IND.

INSPECTIONS

There is currently only one FDA-licensed facility for the production of the anthrax vaccine. The MDPH originally operated the facility, which then was transferred to the Michigan Biologics Products Institute (MBPI), and finally, in September 1998, the facility was sold to BioPort.

FDA has inspected this facility on many occasions during the past decade, identifying a number of deficiencies requiring correction. In particular, FDA conducted a surveillance inspection of MBPI in November 1996. During that inspection, FDA investigators documented numerous significant deviations from the Food, Drug and Cosmetic (FD&C) Act, FDA's regulations and current good manufacturing practices (GMPs). Based upon the documented deviations, FDA issued a Notice of Intent to Revoke (NOIR)

letter to MBPI in March 1997. The NOIR letter did not mandate the closure of the facility or lead to seizure of finished product. The letter, however, did state that if MBPI's corrective actions proved to be inadequate, the facility would run the risk of license revocation. MBPI responded to the NOIR with a "Strategic Plan for Compliance" presented to FDA in April 1997.

In February 1998, FDA conducted a follow-up inspection of the MBPI facility to evaluate MBPI's compliance with its strategic plan. The February 1998 inspection disclosed significant deviations from FDA's regulations.

FDA also noted in the February 1998 inspection that MBPI had made progress in achieving its compliance goals, but additional work remains in order to correct the deviations related to the manufacture of the anthrax vaccine. Pursuant to its purchase of the MBPI facility in September 1998, BioPort agreed to abide by the strategic plan and other commitments for corrective actions made by the management of MBPI. During the October 1998 inspection of BioPort, FDA found continuing improvement.

FDA believes that the previously manufactured and CBER released products, not presently quarantined by BioPort, are safe and effective for the labeled indications. FDA found that the firm had made progress toward meeting objectives under its strategic plan in bringing the facility into full GMP compliance. Based on BioPort's progress to date, FDA is hopeful that the company will continue to demonstrate improvement. We will continue to work closely with BioPort to ensure that the goals outlined in their strategic plan are met.

It should be noted that MBPI halted production of anthrax vaccine sublots in January 1998, prior to MBPI sale to BioPort, to begin a comprehensive renovation of the anthrax production facility. Although there has been a resumption of manufacturing in order to produce lots in support of the license application supplement to include the renovated facility, no lots of anthrax vaccine manufactured in the renovated facility have been released.

Due to the rules of confidentiality, FDA can not generally disclose details of, or even acknowledge the existence of,

a pending application or supplement unless that information has already become public. In the case of BioPort, press reports and information made public by BioPort have disclosed various aspects about anthrax vaccine. Because the information has been made public, FDA can disclose that BioPort does have a pending supplement for renovations to their anthrax vaccine manufacturing facility. BioPort may not release product produced in the renovated facilities until this supplement is approved. FDA will generally assess manufacturing renovations by a review of a prior approval supplement and by performing a pre-approval inspection.

In order to examine the manner in which BioPort implemented the renovations to the manufacturing facility, FDA conducted a pre-approval inspection from November 15 through November 23, 1999. It should be noted that the November 1999 pre-approval inspection was more focused in scope and purpose from the February and October 1998 surveillance inspections. At the conclusion of the November inspection, BioPort received a Form FDA 483 with observations and possible deviations in some of the following areas: validation, failure to investigate,

manufacturing deviations, deviation reporting, aseptic processing, filling operations, standard operating procedures, stability testing, and environmental monitoring. All observations on the Form FDA 483 must be addressed adequately before FDA will approve this supplement.

POST-MARKETING ACTIVITIES

LOT RELEASE

Because of the complex manufacturing processes for most biological products, each product lot undergoes thorough testing for purity, potency, identity, and sterility. The anthrax vaccine is subject to lot release. Before a lot of anthrax vaccine can be used, the manufacturer must submit a sample of the vaccine lot and a lot release protocol to the Agency. The lot release documents contain the results of the manufacturer's tests for potency, safety, sterility and any additional assays mandated by their license and a summary of relevant manufacturing details. FDA reviews the manufacturing and testing information provided in the lot release protocol and may elect to perform confirmatory testing on submitted samples. The manufacturer may not

distribute a lot of the product until CBER releases it. The lot release program is one component of FDA's multi-part strategy that helps assure products quality.

No lots had been released since November 1999

VACCINE ADVERSE EVENT REPORTING SYSTEM

Following FDA issuance of an approved license, there is continued post-marketing surveillance of the product by monitoring adverse 'events. For vaccines, this is accomplished through the VAERS system, which was initiated in 1990 and is jointly managed by FDA and CDC. VAERS receives reports from vaccine manufacturers, private practitioners, State and local public health clinics, and vaccinees themselves (or their parents or guardians). VAERS accepts all reports of suspected adverse events after administration of any U.S. licensed vaccine to individuals in any age group. Vaccine manufacturers, however, must report to FDA all reports of adverse events of which they are aware.

VAERS is a "passive" surveillance system. This means that it relies on health professionals, patients or guardians to submit reports of adverse reactions following vaccination. (An 'active" surveillance system, in contrast, would follow all individuals in a defined population to determine their responses to vaccination.) To encourage reporting of any adverse event suspected of being vaccine-induced, the criteria for reporting to VAERS are non-restrictive. In effect, the system accepts and includes any report submitted, no matter how tenuous the possible connection with vaccination might seem.

Generally, VAERS does not establish causality but is essential to the discovery of potential rare adverse consequences of medical products that may not become evident until many thousands or millions of people have been exposed to them.

VAERS REPORT FOR THE ANTHRAX VACCINE

FDA receives adverse event reports on the anthrax vaccine through a system similar to other adverse event reporting systems within the Agency. They are filed directly by

health professionals as well as by patients or families. Reporting of adverse events associated with the use of anthrax vaccine is voluntary for individual healthcare providers but, as stated above, the vaccine manufacturer must report to FDA all reports of adverse events of which they are aware. It should be emphasized that adverse event reports can be made by a healthcare professional, a patient or anyone. If a patient's physician does not file a VAERS report, the patient can do so. FDA protects the confidentiality of patients reporting adverse events. FDA encourages individuals to report to VAERS any clinically significant adverse event occurring after the administration of any vaccine licensed in the United States. Reports to VAERS may be made in writing or by calling a toll-free number, 1-800-822-7967. Reporting instructions are available on the Internet at http://www.fda.gov/cber/vaers.html.

CBER handles numerous inquiries from individuals concerning the anthrax vaccine. Individuals who believe they have experienced an adverse reaction are encouraged to report and provide information on filing a VAERS report. Forms

are mailed and faxed to individuals upon request and individuals also are referred to FDA's website.

Since the beginning of VAERS operations in 1990, through September 15, 2000, 1561 reports of adverse events associated with use of the anthrax vaccine have been reported to VAERS. FDA understands, based upon information from BioPort, that from 1990 to present, approximately 2,000,000 doses of the vaccine have been distributed.

Of those reports, 76 are considered serious events, which are events considered either fatal, life threatening, or resulting in hospitalization or permanent disability. These reports are for diverse conditions, such as hospitalization for severe injection-site reaction, Guillain-Barré syndrome, widespread allergic reaction, aseptic meningitis and multi-focal inflammatory demyelinating disease. There are no clear patterns emerging at this time. The remaining reports describe a variety of symptoms, including injection site hypersensitivity, injection site edema (swelling with fluid in tissue), injection site pain, headache, joint pain and pruritus (itching).

None of these events, except for the injection site reactions, can be attributed to the vaccine with a high level of confidence, nor can contribution of the vaccine to the event reported be entirely ruled out. With the exception of injection site reactions, all of the adverse events noted above occur in the absence of immunization.

While the data gathered from the VAERS system can serve as a useful tool in identifying potential problems, the reports on anthrax vaccine received thus far do not raise any specific concerns about the safety of the vaccine. With all vaccines, as the number of people that receive the vaccine increases, so will the number of adverse events reported to FDA. Thus, our knowledge of the vaccine will grow accordingly. FDA continues to view the anthrax vaccine as safe and effective for individuals at high risk of exposure to anthrax, when used in accordance with the approved labeling.

THE ANTHRAX VACCINE IMMUNIZATION PROGRAM OF DoD

FDA did not have an official role in the development or operation of the DoD's Anthrax Vaccine Immunization Program (AVIP), including the AVIP tracking system or the program's adverse event reporting system. In March 1997, DoD briefed FDA about their draft plan for the possible use of the anthrax vaccine to inoculate U.S. military personnel according to the FDA-approved labeling for six doses administered on a specified schedule over 18 months. Subsequently, FDA learned that DoD had formally adopted this plan.

In July 1998, DoD requested that the Department of Health and Human Services (DHHS) organize and coordinate a program to evaluate VAERS reports for the anthrax vaccine. In response to the request by DoD, a group of non-government medical experts was convened by DHHS in the fall of 1998 as the Anthrax Vaccine Expert Committee (AVEC). AVEC has met approximately every three to six weeks since fall of 1998. These experts have been reviewing all VAERS reports for the anthrax vaccine. Representatives of VICP, FDA, CDC and DoD

have attended meetings, and FDA has provided information to assist the committee in its deliberations. AVEC is unique in that it provides an independent civilian expert assessment of adverse events reported for the anthrax vaccine.

CONCLUSION

We appreciate the Committee's interest in the Anthrax Vaccine, Adsorbed and BioPort. FDA will continue to work with BioPort, as we would with any manufacturer, in an appropriate manner to resolve all situations involving pending submissions and inspectional issues. By manufacturing products in a facility that is operating in a full state of GMP compliance, FDA can help assure that any product that is released by the company is safe and effective. Additionally, we will continue to monitor adverse event reports that are submitted through VAERS. FDA continues to believe that the vaccine is safe and effective protection for those individuals at high risk for exposure to *Bacillus anthracis* when used in accordance with the label.

(b)(6) @osdgc.osd.mil on 10/01/2000 01:36:33 AM

To:
cc: (bcc: (b)(6))

Subject: Green Sheet Posted by LRS NonD/DTest 1883, Anthrax Vaccine Adsorbed -- HEALTH & HUMAN SERVICES (HSS) OVERSIGHT TESTIMONY

To: (b)(6) @gwillness.osd.mil

DATE: 10/01/00 09:36 AM EST

NonD/DTest 1883
Suspense:1200, Monday, 2 October 2000

we just published an action for which you are either an action, staffing, or information agency. Please log onto the LRS Internet System to access the "Green Sheet." The subject documents are available for you to download and send to other concerned parties within your agency. Also, you will be able to send your comments, etc back electronically. Thanks! LRS

http://www.defenselink.mil/dodgc/lrs

Designator: NonD/DTest 1883

Agency List — Agencies On Green Sheet

Status	Agency Name
Commented	ARMY - ARMY
Viewed	NAVY - NAVY
	AF - AIR FORCE
Viewed	JCS - Joint Chiefs of Staff
Commented	USD(P&R) - Under Secretary of Defense for Personnel & Readiness
Viewed	ASD(HA) - Health Affairs
	ASD(LA) - Legislative Affairs
	ASD(PA) - Public Affairs
	IG - Inspector General, DOD
Commented	GWI - Special Assistant for Gulf War Illness
Viewed	DGC(P&HP) - DGC(Personnel & Health Policy)
	GC - Department of Defense General Counsel

Agency List — Agencies Not on Green Sheet

Status	Agency Name
Viewed	DA&M - Director, Administration and Management
Viewed	LRS - Legislative Reference Service

Comment Submited for
LRS Designator: NonD/DTest 1883

Date/Time:	10/02/00 04:34:50
Agency:	GWI - Special Assistant for Gulf War Illness
User:	(b)(6)
Comment Type:	No Comment
Comments:	OSAGWI/MR/MD has no comments.

LRM ID: RJP378

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

Friday, September 29, 2000

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below

FROM: Ingrid M. Schroeder (for) Assistant Director for Legislative Reference
OMB CONTACT: Robert J. Pellicci
PHONE: (b)(6) FAX: (b)(6)
SUBJECT: HEALTH & HUMAN SERVICES Oversight Testimony on the Anthrax Vaccine Adsorbed

DEADLINE: NOON Monday, October 2, 2000
In accordance with OMB Circular A-19, OMB requests the views of Your agency on the above subject before advising on its relationship to the program of the President. Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go' provisions of Title XIII Of the Omnibus Budget Reconciliation Act of 1990.

COMMENTS: Hearing is before the House Committee on Government Reform on Tuesday, October 3rd.

DISTRIBUTION LIST

AGENCIES:
29-DEFENSE - (b)(6)
83-National Security Council - (b)(6)
95-Office of Science and Technology Policy -(b)(6)

EOP:
(b)(6)

Office of the Special Assistant to the Secretary of Defense **for** Gulf *War Illnesses, Medical Readiness, and* **Milita** *y Deployments*

CMAT #: Pending

Date:

Action Tasking II Internal Routing Sheet

		Action	Info	Comments
	Special Assistant (SA)			
	Deputy Special Assistant (DSA)			
	Executive Assistant to SA (EA)			
	Executive Assistant to DSA (EADSA)			
	☐ **Director, Investigation & Analysis** ___(IAD) ☐ C/B __ ☐ ENV __ ☐ PAG __ ☐ VDM __			
	Dir Lessons Learned Implementation (LLI)			
	Dir Public Affairs & Outreach (PAO)			
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	Legal Advisor (LGL)			
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	Editorial Review (ER)			
	☐ COMEBACK COPY TO: (b)(6) AMB ☒ GET CMAT # WHEN SIGNED ☐ READING FILE ☒ CHRON FILE			

SUSPENSE:

Prepare reply for signature of:

☐ Special Assistant ☐ Deputy Special Assistant

☐ **Congress**	0 Oversight	0 FOIA	☐ OSD	☐ WBM	☐ VSO/MSO	☐ Outgoing
☐ Ltr to SA	0 IR	0 E-Mail	0 OGA	0 Other		☐ veteran

KEYWORDS:

09/07/00 Issuance

(151)

CMAT Control #
1999138-0000029

William Y. Ellis
Chief, Department of Chemical Information
Division of Experimental Therapeutics
Walter Reed Army Institute of Research
Washington, DC 20307-5100

7 May 1999

Dear Sir:

This letter reports our preliminary findings on the determination of squalene in vials of an anthrax vaccine preparation.

Three vials of ANTHRAX VACCINE ADSORBED, Manufactured By MICHIGAN DEPARTMENT OF PUBLIC HEALTH, Lansing, Michigan, 48909, U.S. License No. 99, LOT FAV020, EXP 6 FEB 99, were received on 23 April 1999.

We have developed a sensitive, rapid assay method for squalene using high performance liquid chromatography. The assay specificity is based on chromatographic retention time and on the uv absorption characteristics of the analyte. The method sensitivity is ~0.7 nanogm squalene/10 microL injection, based on squalene in 2-propanol. The method linearity is 0.7 nanogm to 225 nanogm/10 microL injection with r^2 =.999, also based on squalene in 2-propanol. The method is currently undergoing validation.

We find no measurable amount of squalene in the vials. If any squalene were present, it would be less than 70 nanogm per 0.5 milliL vaccine preparation, which volume is the label dose.

We will prepare and submit our final report as soon as the study is completed.

Sincerely yours,

Peter Lim, Ph.D.
Principal Investigator
Catalysis and Anal. Chem. Dept.
Pure and Applied Phy. Chem. Div.

Ronald J. Spanggord, Ph.D.
Assistant Principal Investigator
Catalysis and Anal. Chem. Dept.
Pure and Applied Phy. Chem. Div.

SRI International
333 Ravenswood Ave. • Menlo Park, CA 94025 • (650) 859-2000

(152)

21917
1999055-0000044

CMAT Control #
1999141-0000029

Dear Staff. (Updated) 2 March 99

Since the last report I sent into you, my condition has worsened a bit. I have copies of all my medical records since this started so I guess you could say I am one of the fortunate ones. I have recommended to others that I know to the same and send in a VAERS form to you. I have encouraged others who were with me and who have been experiencing similar symptoms to mail in their forms. I am not the only one who is experiencing problems.

I have migraines now, accompanied by sensitive hearing. I have had bouts of dizziness, tightness of chest, numbness on my scalp, face, throat, and shoulder blades. I am happy to say that they have dramatically dropped since the one set but still occur daily. I still have sleep disorders, I'm either real tired or I can't sleep. Memory problems still bother me as do situations requiring cognitive processes. I have a feeling my system maybe reacting to a meningitis vaccination (MGC) I was given on 27 Jan 99. I thought I had enough problems already. I have had one case last Friday (29 Feb 98) were my hands swelled up and down, my joints tightened up on me (especially my legs and hip joints) and I had a very tight chest accompanied by numbness of my head, neck, lower jaw and tongue. My doctor says I passed out for a bit. Fortunately, our TMC (Troop Medical Clinic) is right next door to my building. I have noticed times were my semen burns. I have also noticed a big change in my sex drive.

The doctor who is treating me tends to thinks I have Fibromyalgia. I have had a problem with low B12 back in November and December time frame. he placed me on B12 injections for a month. My initial results was 170 compared to the 425 results taken a month later. I have recently found out that my last test puts me in the 500's range. Doctor is not ruling out a B12 deficiency yet and has scheduled me for a Shilling's test. I understand that the two have similar overlapping symptoms. I do suffer from tender points on my feet, joints and limbs that tend to favor Fibromyalgia.

I am currently being seen by Neurology at Ft. Gordon, Ga. MRI's show that I need surgery to remove a bone spur in my neck. This may or may not fix the problem I am being told.

I have enclosed a list of symptoms that have occurred since Nov. 98, as I am sure I have left something out. Thank you for all your help and assistance. I look forward to hearing from you again at the soonest.

respectfully,
(b)(6)

(b)(6) [redacted]

(b)(6) [redacted]

21917
1999055-0000044

Adverse Reactions, Symptoms, Time course

1. Rash on bottom of both feet. Looked like I stepped on a pin cushion. Resembled small red spots/dots

2. Pain in right wrist muscle twitching upper right arm approximately 1.5 months accompanied by diarrhea. Diarrhea stopped approximately 1 month after return from Kuwait.

3. Slight numbness, pins and needless sensation in right hand accompanied with muscle twitching in upper right arm at approximately 2 months. Pain in left ankle making it difficult to sleep.

4. Increasing pain, swelling, numbness, and tingling in right hand, fingers and wrist at approximately 2.5 months. Hand and arm feels weak. Pain in left ankle and foot which comes and goes. Toes achy.

5. Slight numbness, pins and needless sensation in left hand, finger tips, and wrist at approximately 3 months. Difficulty sleeping due to pain and numbness in both wrists and hands.

6. Weakness, Tingling and pain in both forearms, hands, wrists and joints at 4 months. Treated for Carpal Tunnel Syndrome. x 2 months. Sent to Physical Medicine for Nerve Conduction tests 11 Sept 98. Test show nerve conduction is normal.

7. Muscles soreness, numbness in both hands, wrists forearms, joints, legs and feet that comes and goes. Pain and numbness increasing as of 8 Nov 98. Diagnosis as stated to be Rheumatoid arthritis. Blood tests show that Rheumatoid factor is negative. fatigue present most of the time. Short term memory problems noticed. Refereed to Rheumatology.

Symptoms since 8 Nov 98

A	Night sweats.
A	Insomnia
A	Chronic fatigue
AW	Heat Flashes
A	Sore Feet, Knees and Joints
AW	Tight/Heavy chest (increase)
A	Increased Short term memory problems (forgetting home address, names, numbers)
A	Difficulty concentrating
AW	Head aches
A	Difficulty walking (limping, sore tender and achy ankles)
AW	Increase in numbness to toes hands and joints
AW	Swelling of hands and feet. (hands swell and become splotchy looking)
A	Mood swings
AW	Migraine headaches (mainly on the left side. Eye feels likes it' being pushed out)
A	Burning sensation in extremities that comes and goes.
A	Blurred vision in left eye (Eye exam show no abnormality, pain due to migraine)
A	Increased lack of quality sleep
A	Brain fog upon waking
A	Burning semen/painful intercourse
AW	Dry mouth
A	Change in sexual performance and stamina
AW	Dizziness and disorientation (fainting)
AW	Sore throat since Attach on 29 Feb 99 Better now but scratchy (2 March 99)
A	Muscle and joint pain especially during either cold or damp weather
AW	Numbness of scalp, face, neck, and shoulders (Seizure like spells which last roughly 5 to six hours in duration) Less severe as of 25 Feb 99.
A	Acne/sores
A	Constipation/hemroids

Dear (b)(6),

I appologize for the addded confussion. I totally confussed myself. I wil try another another stab at it. A= Atnthrax, M=MGC, W=worsening of symptoms! I think I have it this time.

AW Night sweats
AW Insomnia
A- AW Chronic fatigue/weakness
AW Heat Flashes
AW Sore Feet, Knees and Joints
A-MW Tight/Heavy chest (increase)
AW Increased Short term memory problems (forgetting home address, names, numbers)
AW Difficulty concentrating/thinking
AW-M Head aches
A-AW Difficulty walking (limping, sore tender and achy ankles/feet)
AW-M Increase in numbness and aches in toes hands and joints
AW-M Swelling of hands and feet. (hands swell and become splotchy looking)
AW Mood swings
AW-M Migraine headaches (mainly on the left side. Eye feels likes it' being pushed out)
AW Burning sensation in extremities/nerves that comes and goes.
AW Blurred vision in left eye which comes and goes(Eye exam shows no abnormality, Blurring due to migraine)
AW Increased lack of quality sleep
AW Brain fog upon waking
AW Burning semen/painful intercourse
AW-M Dry mouth
AW Change in sexual performance and stamina
AW-M Dizziness, disorientation, Lightheadedness
M Fainting
M Sore throat since Attach on 29 Feb 99 Better now but scratchy (2 March 99)
AW Muscle and joint pain especially during either cold or damp weather changes
M Numbness of scalp, face, neck, back and shoulders (Seizure like spells which last roughly 5 to six hours in durationand make me feel really weak and spaced out. The episodes Feel they run from my upper body straight to my hips and leg muscles. The weakness feels like a numbing, sapping senasation when I am walking. Less severe as of 25 Feb 99. Still occure daily.
AW Acne/sores
AW Constipation/hemroids

(b)(6) I tried to be a little clearer on some of the intems listed. I want this to accuratly reflect what's been going on with me.

I hope this does it. You were right, the way I had it it looked as if there were no changes. I was wrong. The numbness in my head, and upper body took on a whole new side of this after the MGC shot. I have notices an increase in the way my hands and feet swell also. Like I mentioned, the weather changes really give me problems.

I mentioned to my Doctor that I don't feel like me anymore. The eye thing, the memory, and the symptoms seem to have changed from what they were. That may sound silly but it's true. I am not the same guy I was a year ago and it's so frustrating that I want to scream. I hope and pray that I don't get any worse. I have about had it with Doctors telling me , "There's not much we can do about it!"

Again, thank you for all your help and concern. Please keep me informed of your findings and any addvice you may have concerning my situation.

Please let me know if I an be of any further help or assistance. May God bless all of you!
Respectfully,(b)(6)

May 10, 1999

This is a long email on a very important issue. As some of you may know there is a major controversy brewing over the Department of Defense's policy to immunize the entire U.S. military against the perceived biological threat of anthrax. Please review some of the below material and reply to U.S. Representative Christopher Shays (Chairman of the Subcommittee on National Security, Veterans Affairs, and International Affairs) calling for an immediate end to the anthrax vaccination immunization program: rep.shays@mail.house.gov

There is evidence to suggest that the DOD has controlled all access to information regarding the vaccine, its production, distribution and administration, reporting of side effects, and care of persons having side effects. The DoD has already immunized over 100,000 [230,000] troops and has plans to immunize all 2.4 million servicemembers. Systemic side effects may occur in at least 7% of recipients. That has the potential of seriously harming 168,000 servicemembers! Even the DoD admits that a .7-1.3% of systemic side effects which translates into 16,800 to 31,920 casualties when applied to the total U.S. force. The cost benefit analysis of long term care provided to casualties of the AVIP clearly necessitates its immediate end. Adverse symptoms plaguing vaccine recipients include fever, chills, headaches, malaise, chronic fatigue, dizziness, memory loss, cognitive disturbance, sleep disorders, blackouts, and seizures. These side effects mirror

those of
thousands of Gulf War Veterans suffering from a form of auto-immune disease.
Perhaps even more frightening are prospects for routine inoculations to protect citizens from a perceived terrorist threat. When will the vaccinations end?

Collection of data regarding the efficacy of the Michigan Department
of Public Health (MDPH) vaccine clearly does not mandate its use as a protection against inhalation anthrax. Recent [pending] publication of Dr. Asa and Dr.
Garry's molecular biology studies of veterans receiving the MDPH vaccine in
1998 indicate the existence of anti-bodies to squalene, an adjuvant possibly used by the DOD to boost the efficacy of the vaccine (Vanity Fair May 1999). The FDA has not approved squalene and use of such an
adjuvant would be a violation of servicemembers' rights.

On March 24, 1999 and April 29, 1999 the U.S. House Subcommittee on
National Security, Veterans Affairs, and International Relations held hearings on the safety and efficacy of the vaccine. The entire April 29th
hearing including expert testimony by an anthrax specialist can be viewed at:
http://www.house.gov/reform/ns/hearings

The General Accounting Office's (GAO) independent studies of the vaccine and
Dr. Meryl Nass's testimony are most insightful. The testimony of victims of
this program and a review of their systemic side effects is heard under panel
3. The testimony of Mr. Groll, Mr. Churchill, and Mrs. Martin-Allaire during
the committee hearing on April 29th is further proof of the toxicity of the
vaccine and its side effects. These cases were not reported via the Vaccine
Adverse Event Reporting System (VAERS) form and submitted to the FDA because
military medicine intervened collecting and in some instances modifying their
records.

Highlights from the hearing are as follows:

"The nature and magnitude of the military threat of biological warfare has
not changed since 1990. . .(pg3)
A 1991 Army document noted that "it would be scientifically incorrect to assume that this (licensed) vaccine would be totally efficacious under different circumstances, that is, beyond the parameters of the study design
[not for protection against inhalation anthrax]. Pg8
We conclude that . . . testing still needs to be conducted on inhalation anthrax. pg8
-Director, Special Studies and Evaluations, National Securities Division, GAO

"To date, no animal or other potency tests have been demonstrated to be well
correlated with protection of humans. The potency test required for the present vaccine has not been well correlated to efficacy in humans, and it is
doubtful that it can be." -Joint Program Office for Biological Defense 20
Oct 1995

"Vaccine-induced protection is undoubtedly overwhelmed by extremely high spore challenge."
- Joint Staff Action Processing Form 16 August 1991

"Evaluation of safety records show that one or more systemic symptoms occurred in 44% of recipients of vaccines within the first seven days after
the booster doses."
-Final Report to the U.S. FDA: Fort Bragg, Serologic Response to Anthrax and
Botulism Vaccines

In each of these studies [3 unpublished DoD studies uncovered] the rate of
systemic reactions is at least 7% and possibly as high as 40%. These rates
do not square with the package insert which suggest a 0.2% rate of systemic
reactions, or the material presented by the DoD, which suggests a rate of
.007%. Surely it is clear from these data that the actual reaction rate being experienced by servicemembers inoculated today is grossly underreported...

There is no good evidence for vaccine safety, efficacy or necessity.

DoD may
have illegally used unapproved vaccines on servicemembers in the past, and
has not demonstrated that the order to vaccinate is a lawful order.
Persian
Gulf illness appears to be related, at least in part, to anthrax
vaccination.
DoD had obfuscated the causal role of vaccines by classifying
immunization
records and controlling the deliberations of expert panels. Current
servicemembers are now falling ill from the same disease.
- Dr. Meryl Nass, MD Internal Medicine. Member, Federation of American Scientists Working Group on Biological Weapons Verification. Noted
Anthrax
Vaccine expert.

"I acted on blind faith in the Department of Defense, my superior and
trusted
individuals I felt were qualified to administer the vaccine. . .
Following
the first two shots of the series I noticed that I was extremely
fatigued and
nauseous. . . . The third inoculation not only enhanced the same symptoms
but
I also noticed that I was becoming increasingly short tempered
emotional,
nauseous, experienced loss of appetite, and achy joints. . . I started
to
feel ill, chills, fever, and nausea. My symptoms had increased to
include
headache, dizziness, diarrhea, and slight abdominal pain. [After the
4th
inoculation] my husband took me to the emergency room due to severe
abdominal
and back pain, dizziness, and headaches. After 7 hours and numerous
tests I
was returned home with more tests and follow-ups scheduled. Once again
received another diagnosis for my mystery illness. I've taken my career
seriously devoting 14 years of my life playing a role in the defense of
our
great nation. . . I feel as though I have been misinformed and betrayed
by
the same country I seek to defend. -Technical Sergeant Roberta
Groll,
Battle Creek, Michigan

The Honorable Christopher Shays

Subcommittee On National Security, Veterans Affairs, and International Relations
RHOB Room B-372
Washington, D.C. 20515
(202) 225-2548

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21 917
1999055-0000044

Question for Gulf War Syndrome team

1. GAO report on Squalene and recent Anthrax Safety hearing as of 29 April 99

2. Congressman Shays opening statement April 29.

3. Product Warning Insert Systemic reactions.

4. Soldiers who report these reactions are being told it's all in their heads. Soldiers continue to get sick. Soldiers are not aware of the symptoms nor are they being told of the VAERS forms.

5. DOD reports of low adverse reactions and the program's success. Hmmm, According to recent hearing many are finding that the reactions are deliberately being ignored. Shot records are missing data and in many cases there is no Documentation listed.

6. Vaccine is based on an entirely different Vaccine.

7. Dr Burros states that his report entailed no independent analysis of safety and efficacy data. This was one of the four Cornerstones of Our commander and chief's Guidance.

8. Colonel Handy's testimony - Senate report 103-97 Lt. General Blanck's states, "The anthrax vaccine should continue to considered as a potential cause for undiagnosed illnesses in Persian Gulf Personnel.

9. Squalene report completed by GAO , DR. Shushil Sharma.

10. I am charged with accomplishing the mission and looking out for the health and welfare of my soldiers. How can I do that when the people who treat my soldiers are turning a deaf ear to

their reports? For the last two days I have heard nothing but you need to come forward. You need to let us know what's happening. I stand here before you and like many, We are telling you but you're not listening.

11. What about the soldiers who did not deploy and are getting sick now? What are you doing for them?

DMMC Control # (153)
2003169-0000052

Directorate for Freedom of Information and Security Review (DFOISR)
Coordination Record

SECURITY REVIEW

June 18, 2003

To: ~~OSA/GWI~~ DHSD 845-8369

Case Number: 03-S-1516

FOR PICKUP BY LTC

Number of Pages: 45 **Classification:** U

Type of Document: ARTICLE **Requestor:** SMITH, TYLER

Subject: THE POSTWAR HOSPITALIZATION EXPERIENCE OF GULF WAR VETERANS PARTICIPATING IN US HEALTH REGISTRIES

Source: DEPARTMENT OF THE NAVY **Event Date:**

Purpose: PUBLIC RELEASE

The attached material is forwarded for review and comment in accordance with the following guidelines. Questions concerning this case should be directed to : (b)(6), Rm.2C757, (b)(6), e-mail: (b)(6) @dfoisr.whs.mil, unclassified Fax (b)(6)

NOTE: Intended for future publication in the Journal of Occupational and Environmental Medicine.

Please advise if reviews required other than:
HA OSA/GWI

A reply is requested by: 02-JUL-2003

COORDINATION OFFICE ACTION

To: Directorate for Freedom of Information and Security Review, DFOISR, Room 2C757.
Review by this office in accordance with the guidelines below, result in the following recommendation concerning clearance for publication.

Check One:

☑ **No Objection as Received.**

☐ **No Objection Subject to Amendments** made by this office (in black pencil). Ammendments and rationale (security and policy) are annotated on page numbers listed below.

☐ **Objection.** Amendments to permit publication are impracticable. Reasons stated below.

(Continue on Reverse side if necessary)

COL John Goodwin

(b)(6) JUN 2 3 2003 John W Goodwin

phone number date signature

Department of Defense
Deployment Health Support
5113 Leesburg Pike, Suite 901
Falls Church, VA 22041-3226
Official Business

Instructions: The policy of the Department of Defense it to authorize and encourage the public release of information concerning the Department of Defense consistent with security requirements, and other exemptions to disclosure under the Freedom of Information Act

Security - Reviewing agencies should identify information known to be classified within the meaning of Executive Order 12958 (DoD Regulation 5200.1R) or information which in the judgement of the reviewing agency warrants classification. In the latter case, it is requested that reasons for this judgement be given and recommendations made for appropriate classification.

Policy - Material originated with the Department of Defense for public release should, in addition, be reviewed for conflict with established policies and programs of the Department of Defense or those of the national government. If change is necessary, reviewing agencies are requested to recommend acceptable substitue language where practicable, or specify needed changes in sufficient detail to permit acceptable revision.

Editorial - Editorial review is not a responsibility of the Directorate for Freedom of Information and Security Review and reviewing agencies should not make editorial corrections. However, obvious errors of fact should be indicated.

DEPARTMENT OF THE NAVY
NAVAL HEALTH RESEARCH CENTER
POST OFFICE BOX 85122
SAN DIEGO, CA 92186-5122

MAY - 9

IN REPLY REFER TO
5721
Ser 00/089
1 May 03

From: Commanding Officer, Naval Health Research Center, San Diego
To: Chief, Bureau of Medicine and Surgery (MED-00P)
Via: Chief, Bureau of Medicine and Surgery (M2B), 2300 E St NW, Washington, DC 20372-5300

Subj: REQUEST FOR PUBLICATION CLEARANCE, PUBLIC AFFAIRS PROGRAM

Ref: (a) BUMEDINST 5721.3
(b) BUMED ltr 5721, Ser 26B/00U0484 of 22 Sep 01

Encl: (1) BUMED 5721.3 Clearance for Publication Form with NHRC Report 03-10, "The Postwar Hospitalization Experience of Gulf War Veterans Participating in US Health Registries" (Jimenez/B Smith/GC Gray/et al.)

1. **FORWARDED FOR REVIEW AND APPROVAL** per references (a) and (b). The report in enclosure (1) has been reviewed by this command. Upon approval, enclosure (1) will be submitted to Journal of Occupational and Environmental Medicine for publication consideration. The DoD Assurance number is 31283.

2. The report does contain sensitive information.

M. Duk

M. DUKOVICH
Acting

IR-5-1576

DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
2300 E STREET NW
WASHINGTON DC 20372-5300

IN REPLY REFER TO

5721
Ser M2B/03U0072
23 May 03

FIRST ENDORSEMENT on NAVHLTHRSCHCEN ltr 5721 Ser 00/089 of 1 May 03

From: Chief, Bureau of Medicine and Surgery
To: Chief, Bureau of Medicine and Surgery (M00P)

Subj: REQUEST FOR PUBLICATION CLEARANCE, PUBLIC AFFAIRS PROGRAM

1. In accordance with references (a) and (b), the manuscript, enclosure (1) to basic correspondence, "The Postwar Hospitalization Experience of Gulf War Veterans Participating in US Health Registries", has been reviewed by this directorate.

2. Since the material is potentially sensitive (Gulf War Illness) it is forwarded for M00P review. Recommend the material be approved for submission for publication in the "Journal of Occupational and Environmental Medicine" (US).

3. M2 point of contact is Mr. Ken Wimmer at 202-762-0474.

C D Forcino

C. D. FORCINO
By direction

Copy to:
NAVHLTHRSCHCEN (w/o attachments)

Clearance for Publication or Presentation

Section (1) to be completed by researcher or submitter

Author(s) Name, Command, and Rank: Tyler C. Smith, MS, Dinice L. Jimenez, BS; Besa Smith, MPH; Gregory C. Gray, MD, MPH; Tomoko I. Hooper, MD, MPH; Gary D. Gackstetter, DVM, MPH, PhD; Jack M. Heller, PhD; Nancy A. Dalager, MS; Han K. Kang, DrPh; Kenneth C. Hyams, MD, MPH; and Margaret A.K. Ryan, MD, MPH

Title of Work: The Postwar Hospitalization Experience of Gulf War Veterans Participating in US Health Registries

Purpose/Forum: (Check all appropriate)

_____Presentation __X__Journal article

_____Book ____Other (Please Explain

Name, Place, Dates of Presentation/Journal Title/Book Publisher: Journal of Occupational and Environmental Medicine

Synopsis of the Manuscript/article/research paper in laymen's terms:

Although the US military experienced relatively low combat casualty rates during the Gulf War, there has been concern that exposures occurring during the war may have resulted in postwar morbidity among Gulf War veterans. The Department of Veterans Affairs (VA) and the Department of Defense (DoD) initiated clinical registries to provide systematic health evaluations for self-referred Gulf War veterans. As of September 1999, more than 100,000 of the nearly 700,000 Gulf War veterans had enrolled in one or both of the Gulf War health registries. The authors used Cox's proportional hazards modeling to investigate and identify the significant associations between registry participation and postwar hospitalization. These findings support the hypothesis that registry participants were more likely to have postwar morbidity than veterans who chose not to enroll in the health registries.

Review Findings	Action/Comments
____ Higher review not required by BUMEDINST 5721.1D	OIC/CO authorized to approve. If uncertain about sensitivity of a subject, contact BUMED Public Affairs Office at (202) 762-3218.
_____ Animal Use _____ Human Use _____ Foreign Journal	Following command review, forward to BUMED for review and approval or disapproval
_____ AIDS/HIV __X__ Persian Gulf Illness _____ Controversial/Sensitive	Following command review, forward to BUMED for review and approval or disapproval. If higher review is required, BUMED will coordinate with appropriate commands
_____ Potential Media Interest	If uncertain about sensitivity of a subject, contact BUMED Public Affairs Office at (202) 762-3218.

Coordinator's Name, Command, and Telephone Number
LT Sheri Parker, USN, Public Affairs Officer, Naval Health Research Center, Comm/DSN 619-557-4688

Enclosure (1)

The Postwar Hospitalization Experience of Gulf War Veterans Participating in US Health Registries

Tyler C. Smith, MS; Dinice L. Jimenez, BS; Besa Smith, MPH; Gregory C. Gray, MD, MPH; Tomoko I. Hooper, MD, MPH; Gary D. Gackstetter, DVM, MPH, PhD; Jack M. Heller, PhD; Nancy A. Dalager, MS; Han K. Kang, DrPh; Kenneth C. Hyams, MD, MPH; and Margaret A.K. Ryan, MD, MPH

Abstract word count: 131

Text word count: 3,714

From the Department of Defense Center for Deployment Health Research at the Naval Health Research Center, San Diego, CA (T.C.S., D.L.J., B.S., M.A.K.R.); the Department of Epidemiology, College of Public Health at the University of Iowa, Iowa City, Iowa (G.C.G.); the Department of Preventive Medicine and Biometrics at the Uniformed Services University of the Health Sciences, Bethesda, MD (T.I.H, G.D.G); Deployment Environmental Surveillance Program at US Army Center for Health Promotion and Preventive Medicine, Aberdeen Proving Ground, MD (J.M.H.); Environmental Epidemiology Service, Department of Veterans Affairs, Washington, DC (N.A.D., H.K.K.); and Office of Public Health and Environmental Hazards, Department of Veterans Affairs, Washington, DC (K.C.H.).

This represents report 03-10, supported by the Department of Defense, under work unit no. 60002. The views expressed in this article are those of the authors and do not reflect the official policy or position of the Department of the Navy, Department of the Army, Department of Defense, or the US Government. Approved for public release; distribution unlimited.

This research has been conducted in compliance with all applicable Federal Regulations governing the protection of human subjects in research (Protocol #31283).

Corresponding author: Tyler C. Smith, DoD Center for Deployment Health Research, P.O. Box 85122, Naval Health Research Center, San Diego, CA 92186-5122; telephone (619) 553-7593; fax (619) 553-7601; e-mail: Smith@nhrc.navy.mil

Running head: Gulf War Registry Participant Postwar Hospitalization

Abstract

Although the US military experienced relatively low combat casualty rates during the Gulf War, there has been concern that exposures occurring during the war may have resulted in postwar morbidity among Gulf War veterans. The Department of Veterans Affairs (VA) and the Department of Defense (DoD) initiated clinical registries to provide systematic health evaluations for self-referred Gulf War veterans. As of September 1999, more than 100,000 of the nearly 700,000 Gulf War veterans had enrolled in one or both of the Gulf War health registries. The authors used Cox's proportional hazards modeling to investigate and identify the significant associations between registry participation and postwar hospitalization. These findings support the hypothesis that registry participants were more likely to have postwar morbidity than veterans who chose not to enroll in the health registries.

Key words: occupational exposure, environmental exposure, morbidity, hospitalization, symptoms, clinical evaluation, Persian Gulf syndrome, military medicine, veterans

Since returning from the Gulf War in August 1991, more than 100,000 of the 697,000 US military personnel who served in the Gulf have enrolled in the Department of Veterans Affairs (VA) and/or the Department of Defense (DoD) health registries.[1] Some of these veterans have reported symptoms and illnesses that may be a result of exposures during the war,[2-4] although morbidity rates during the war due to combat as well as disease non-battle injuries were lower than in previous major conflicts.[5] Public and veteran concern has prompted extensive research on Gulf War veterans' health during the decade following the war,[6] though etiologies for the increased symptom reporting and clear case definition remain elusive. Epidemiological studies have found no evidence to suggest excess morbidity among Gulf War veterans, as measured by hospitalizations in active duty members within 2 years of the Gulf War,[7] hospitalizations among members who did not seek care at DoD treatment facilities,[8] hospitalizations for select diagnoses,[9] mortality due to diseases,[10-12] or birth defects among live births in active duty members within 2 years of the Gulf War.[13] Other epidemiological studies focusing on the health impact of specific war-time exposures compared potentially exposed and nonexposed Gulf War veterans but found no excess in hospitalizations for those personnel possibly exposed to the smoke from Kuwaiti oil well fires,[14] nor those personnel possibly exposed to nerve agents released as a result of munitions demolitions at Khamisiyah, Iraq.[15, 16] Efforts to group symptoms or conditions into a unique

syndrome in Gulf War era veterans have largely shown that the same kinds of symptoms and illnesses occur in both Gulf War and nondeployed veterans,[17-21] although a recently published report suggests that there may be a cluster of symptoms consistent with neurological impairment that is unique to Gulf War service.[22] In addition to these studies, there have been numerous studies demonstrating that Gulf War veterans are more likely to self-report symptoms[17, 23-27] and adverse pregnancy outcomes[28] than their military peers.

In response to concerns about environmental and occupational exposures during the Gulf War, the VA initiated the Gulf War Health Examination Registry on November 4, 1992, and the DoD initiated the Comprehensive Clinical Evaluation Program on June 7, 1994.[29-35] Both health registries offered a systematic medical evaluation, including basic laboratory tests and additional sophisticated diagnostics, to Gulf War veterans who elected to participate. As of September 1999, 70,385 participants had enrolled in the VA registry and 32,876 participants had enrolled in the DoD registry.

In a 2002 report, combined VA and DoD registry data based on more than 100,000 active duty, National Guard, and Reserve veterans, were examined to identify potential occupational factors and wartime exposures that may influence subsequent health care-seeking behaviors.[1] Those most likely to elect to participate in a registry included older veterans, female veterans, veterans possibly exposed to oil well fire smoke,[14] veterans possibly exposed to the

demolition plume from Khamisiyah,[15] Reserve and National Guard, Army veterans, and veterans in the theater of operations during intense combat periods. Investigation of DoD primary occupational specialties found that the broad categories of craftworkers, health care providers, and infantry, gun crews, and seamanship (combat) specialists, were more likely to enroll in the registries.[1] The 2002 report provided insight into factors that may influence health care-seeking behaviors but did not answer the question of whether the Gulf War registries were enrolling those veterans that were the most ill. This study documents objective outcomes based on the examination of participants' hospitalization experiences after the war but prior to enrolling in one of the health registries.

Methods

Study Population

The study population included all regular active-duty military personnel who were deployed to the Gulf War theater for one or more days during the Gulf War deployment period, August 1, 1990, through July 31, 1991. Reserve and National Guard personnel were not included in this investigation because their access to military hospitals is limited to their time while in an active-duty capacity. Demographic and deployment data for Gulf War veterans were provided by the Defense Manpower Data Center, Monterey Bay, California, and reflected

military status as of August 1, 1991. These data included gender, marital status, date of birth, race/ethnicity, home state of record, military service branch, DoD primary occupational specialty (10 major groups defined by the DoD Occupational Conversion Manual),[36] military pay grade, date of separation from military service, Gulf War deployment history, and dates of entry and exit in theater. Additionally, as in previous reports,[1, 7, 14] hospitalization data from all DoD hospitals from July 31, 1989, to August 1, 1990 were aggregated and linked by an individual unique identifier to our study population to create a prewar hospitalization indicator. This variable denoted whether an individual was hospitalized during the 12 months prior to the start of the war in January 1991.

Environmental Exposure Data

Upon withdrawal from Kuwait, the Iraqi Army ignited over 600 oil wells, producing massive clouds of smoke.[37] In response to health and environmental concerns, the US Army Center for Health Promotion and Preventive Medicine, in collaboration with the National Oceanic and Atmospheric Administration/Air Resources Laboratory, estimated 24-hour unit exposures to concentrations of oil well fire smoke particulate matter. These meteorological and diffusion modeling data were then overlaid onto troop location data using a geographic information system to produce troop unit exposure estimates.[14]

Although there was no evidence that Iraq used chemical weapons against coalition forces during the Gulf War,[38] in June 1996 the DoD announced that the United Nations strongly suspected that rockets equipped to carry chemical weapons had been destroyed in March 1991 by US forces near Khamisiyah, Iraq. This prompted meteorological and dispersion modeling of the possible release of sarin and cyclosarin to model estimated hazard areas. These data were overlaid onto troop location data to identify those personnel possibly exposed to nerve agents from the destruction of Khamisiyah in March 1991. In 1999, a comparison of the hospitalization experiences among those potentially exposed and unexposed suggested that veterans who may have been exposed to the hazard areas were not suffering increased postwar morbidity from ultralow or subclinical nerve agent exposure.[15] In December 2000, the Office of the Special Assistant for Gulf War Illnesses released a much more detailed report[39] to augment its original 1997 case narrative.[40] This report was followed by a final report in April 2002, identifying 101,752 Gulf War veterans as having been possibly exposed in the hazard areas created by the destruction of munitions at Khamisiyah.[41] A more precise model of particulate matter distribution at Khamisiyah was obtained after revision of meterologic models, a reduction in estimates of nerve agents released, the combination of both sarin and cyclosarin toxicity levels (instead of sarin alone), the inclusion of atmospheric removal mechanisms (e.g., dilution, deposition, and degradation), and updated unit location information and personnel

data. This updated model resulted in generally smaller geographic exposure estimates than were originally predicted. Using the revised list of personnel who were possibly exposed to the modeled daily hazard areas, we created an exposure variable for use in our analyses.

In addition to the possible environmental exposures, there have been concerns that vaccines given to troops during the Gulf War may have contributed to excess morbidity either individually, in conjunction with other vaccines, or when administered under stressful conditions.[42-44] Although data on immunizations were very sparse for the period of the Gulf War, we have included a variable indicating those who were documented to have received vaccinations against botulinum toxin or anthrax.

Gulf War Health Registry Data

The Gulf War Health Examination Registry (VA Registry) initiated by the VA on November 4, 1992, was a voluntary registry devoted to veterans and their families who were deployed to the Gulf War and who had separated from active duty or who were Reserve or National Guard members during the conflict. The objective of the VA Registry was to provide clinical examinations, including both laboratory tests and physician referrals, to further evaluate symptoms reported by veterans during their initial physical examinations.[1, 32, 33, 45]

The Comprehensive Clinical Evaluation Program (DoD Registry) initiated by the DoD on June 7, 1994, was also a voluntary registry offered to Gulf War veterans and their families who remained on active duty, retired from career service, became civilian DoD employees, or served full-time in the Reserves or National Guard. The objective of the DoD Registry was to provide systematic clinical evaluations for the diagnosis and treatment of medical conditions occurring subsequent to service in the Gulf War theater.[1, 29-31, 46] To ensure equal opportunity for care, the program was initiated worldwide at 184 military health care facilities located in 39 states, 8 foreign countries, and 2 territories.

Study Outcomes

To assess postwar morbidity prior to registry enrollment, hospitalizations were evaluated from August 1, 1991, to June 6, 1994. Probability of hospitalization for "any cause" and hospitalization with a diagnosis in each of 14 broad *International Classification of Diseases, 9th Revision, Clinical Modification* (ICD-9-CM) diagnostic categories was examined.[7, 47] Investigation of individual diagnoses within the broad diagnostic categories focused on the 5 most frequent 3-digit diagnostic codes from each of the diagnostic categories yielding the highest relative risks. Additionally, we chose to examine specific ICD-9-CM diagnoses that have previously been of concern to Gulf War veterans.[9, 15, 48] Hospitalizations were scanned in chronological order and diagnostic fields were

scanned in numeric order for the diagnostic codes of interest. Only the first hospitalization meeting outcome criteria was counted for each veteran.

Statistical Analyses

After descriptive investigation of population characteristics, analyses were performed to assess the significance of associations between the outcome (hospitalization) and demographic, exposure, deployment, and registry participation variables. An exploratory analysis was developed to further assess variables of interest for significant associations and possible confounding, while simultaneously adjusting for all other variables in the model. Using regression diagnostics, collinearity among variables was assessed. Additionally, multiplicative interaction was investigated by introducing cross-product terms into the model.

Cox's proportional hazards time-to-event modeling methods were used to compare the postwar hospitalization experience of participants in Gulf War health registries to the experience of those Gulf War veterans not participating in the registries, while accounting for attrition from active-duty service over the near 3-year follow-up period. Follow-up time was calculated from August 1, 1991, until hospitalization, separation from active-duty service, or June 6, 1994, whichever

occurred first. The saturated Cox regression model was reduced by a manual backward stepwise elimination approach, removing those variables that were not independently associated at an alpha cutoff level of 0.05.

Statistical analyses producing adjusted risk ratios (RRs) and associated 95% confidence intervals (CIs) were performed using SAS® software (Version 8.0, SAS Institute, Inc., Cary, NC). Cumulative probability of hospitalization as a function of time was graphed after stratification by registry enrollment status.

Results

Exposure, demographic, and deployment data were available for 546,522 active-duty Gulf War veterans who were deployed to the Gulf theater for one or more days during the war and remained on active duty for at least one day between the dates of August 1, 1991, and June 6, 1994 (table 1). Of these veterans, 69,189 (12.7%) registered in either the DoD or VA health registries. The Registry population consisted of 94% men, 52% younger than 26 years of age, 53% married, 89% enlisted personnel, 67% white, 47% Army, and 26% combat specialists. Sixty-four percent of the Registry population were considered most likely exposed to the oil well fire smoke plumes from the Kuwaiti oil well fires, and more than 13% were considered potentially exposed to hazard areas created by the demolition of rockets that may have contained nerve agents at Khamisiyah (table 1). Based on the only known documentation, 0.4% of the Registry

population was given the anthrax vaccine and 0.1% was vaccinated against the botulinum toxin.

Initial analyses indicated that registry participation, gender, marital status, home state, age, prewar hospitalization, military pay grade, race/ethnicity, service branch, occupational category, Khamisiyah hazard area exposure, oil well fire smoke exposure, and vaccine status were significantly associated with a person being hospitalized using an alpha cutoff level of 0.05 (table 2). Regression diagnostics to evaluate pairwise correlations and the variance inflation factor suggested a slight multicollinearity between age, marital status, and pay grade; and potential exposure to hazard areas created by Khamisiyah munitions destruction and being in-theater between February to April 1990. Further investigation suggested the removal of the variable for the time period of February to April 1990. There were no other significant influences found between the parameters in the model. As a result, all remaining variables were included in the model analyses.

Using Cox regression to simultaneously adjust for all variables in the model, registry participation was significantly associated with postwar hospitalization (RR, 1.43; 95% CI, 1.40 to 1.46) (table 3). The corresponding plots of cumulative probability of hospitalization by participation status remained stable through time although with a noticeable divergence suggesting an increase in the probability of hospitalization for registry participants (figure 1) that is not

associated with a temporal bias. Other covariates that were significantly associated with postwar hospitalization included female gender (RR, 1.55; 95% CI, 1.51 to 1.59), personnel 31 years or older when compared with those younger than 22 years old (RR, 1.12; 95% CI, 1.10 to 1.15), Army personnel when compared with Navy and Coast Guard (RR, 1.36; 95% CI, 1.33 to 1.39), personnel with a non-US or unknown home state (RR, 1.07; 95% CI, 1.03 to 1.10), enlisted personnel when compared with officers (RR, 1.50; 95% CI, 1.46 to 1.55), personnel with a prewar hospitalization (RR, 1.66; 95% CI, 1.62 to 1.70), and those people receiving *Botulinum* toxoid vaccination (RR, 1.43; 95% CI, 1.12 to 1.82) (table 3). Participating personnel in the occupational category of craftsmen were slightly more likely to be hospitalized compared to the combat specialist category (RR, 1.07; 95% CI, 1.03 to 1.12). Health care workers were also more likely to be hospitalized compared to the combat specialist category (RR, 1.27; 95% CI, 1.23 to 1.31) (table 3).

Additional statistical modeling was performed for each of the 14 major diagnostic categories using registry nonparticipants as the reference group (table 4). These analyses indicated a positive association between registry participation and postwar hospitalization in each of the 14 major ICD-9-CM categories. The associations varied in magnitude, with the largest measure being in the category of nervous system diseases (RR, 1.72; 95% CI, 1.59 to 1.85) and the smallest measure of association being in the category of blood diseases (RR, 1.21; 95% CI,

1.09 to 1.34). Modeling was performed on the 5 most frequent 3-digit diagnoses from each of the 5 diagnostic categories yielding the highest relative risks (table 5). All but 2 of these 25 models suggested a positive association between postwar hospitalization and registry participation.

Further modeling was performed on 6 specific diagnoses of interest to Gulf War veterans (table 6). In these analyses, participants in the health registries were more likely to have been hospitalized for mononeuritis (RR, 2.03; 95% CI, 1.73 to 2.37), asthma (RR, 1.93; 95% CI, 1.61 to 2.32), fibromyalgia (RR, 2.52; 95% CI, 1.65 to 3.84), and malignant neoplasms (RR, 1.44; 95% CI, 1.16 to 1.79) than their non-registry participant peers.

Discussion

Although the overall incidence of morbidity and mortality were lower in the Gulf War than in previous conflicts,[49, 50] concern over the deployment causing long-term morbidity among Gulf War veterans has persisted over the past decade. Soon after the end of the war, veterans began reporting symptoms of physical conditions, such as fatigue, headaches, joint pain, skin rash, shortness of breath, sleep disturbances, difficulty concentrating, and forgetfulness.[51, 52] In response to veterans' concerns, both the VA and DoD initiated Gulf War health registries. After media coverage and extensive outreach programs, about 1 in 7 veterans had

volunteered to participate in either registry by September 1999. There has been conjecture that because enrollment was open to all, registry participants may not represent the most ill veterans. Since registry participation has been considered an indicator of Gulf War-related morbidity, it was important to validate this assumption with objective data like hospitalization experiences.

During the 3-year postwar follow-up period, 19.2% of registry participants were hospitalized compared to 12.6% of registry nonparticipants. After adjusting for all other demographic, exposure, and occupational variables, registry participants were 1.4 times more likely to have a postwar hospitalization than registry non-participants (95% CI, 1.40 to 1.46). Demographic risk factors associated with postwar hospitalization have been well documented in previous reports.[7, 8, 14, 15] Our findings were consistent with those previous reports, in that associated factors included female gender, older age, pre-war hospitalization, enlisted status, white race, and Army service. Also consistent with previous studies on objective exposure data,[14, 15] those who were exposed to oil well fire smoke (RR, 0.95; 95% CI, 0.93 to 0.98) and those who were presumed exposed to nerve agents at Khamisiyah were not at increased risk for hospitalization compared to those not exposed (RR, 0.99; 95% CI, 0.96 to 1.01) in multivariable modeling. Additionally, as was found in a similar study on the association between anthrax vaccination and hospitalization,[53] there was no increased probability of hospitalization for those with a documented history of anthrax

vaccination compared to those without a documented history of anthrax vaccination. It is interesting that troops who were documented as being vaccinated against botulinum toxin had an increased probability of hospitalization compared to those not receiving the vaccination (RR, 1.43; 95% CI, 1.12 to 1.82). However, it should be noted that data regarding these militarily unique immunizations during the Gulf War of 1991 are incomplete, and these findings should be viewed with caution.

Our investigation of postwar hospitalization risk for broad categories of DoD primary occupational codes applied the category of infantry, gun crews, and seamanship specialists as the reference group because these personnel are more likely to be in combat roles. Personnel in this category included combat and military operations leaders, infantrymen, aircraft crew members, weapons specialists, demolition experts, Special Operations forces, and combat engineers. When compared with this group, health care workers were at increased risk of postwar hospitalization (RR, 1.27; 95% CI, 1.23 to 1.31). Although this group is generally not on the front lines of combat, this finding is consistent with other reports of increased probability of hospitalization in this occupational category.[8, 14, 15]

Investigation of hospitalizations for 14 diagnostic categories found all to be positively associated with registry participation. The 5 highest measures of association were observed in the categories of nervous system diseases (RR, 1.72;

95% CI, 1.59 to 1.85), musculoskeletal system diseases (RR, 1.70; 95% CI, 1.64 to 1.76), symptoms, signs, and ill-defined conditions (RR, 1.69; 95% CI, 1.59 to 1.80), respiratory system diseases (RR, 1.62; 95% CI, 1.53 to 1.72), and mental disorders (RR, 1.43; 95% CI, 1.36 to 1.52) (table 5). These results were similar to the most common major diagnostic categories found in the health registries: mental disorders, respiratory disorders, skin conditions, and musculoskeletal diseases.[34]

Modeling of the 5 most frequent 3-digit diagnostic codes from each of the diagnostic categories yielding the greatest relative risks were examined, and 23 of the 25 models showed a positive association between hospitalization and registry participation (table 5). The highest measures of association for postwar hospitalization and registry participation from each of these categories included migraine (RR, 2.46; 95% CI, 1.96 to 3.07), other forms of ischemic heart disease (RR, 1.89; 95% CI, 1.48 to 2.42), asthma (RR, 1.93; 95% CI, 1.61 to 2.32), other disorders of bone and cartilage (RR, 1.73; 95% CI, 1.55 to 1.93), and symptoms involving respiratory system and other chest symptoms (RR, 2.03; 95% CI, 1.81 to 2.28). The most common diagnoses in the nervous, circulatory, and respiratory system categories were consistent with the most common diagnoses found in the same categories in the registries.[34] However, for the category of musculoskeletal system diseases, back pain and nonspecific joint pain were the most common diagnoses in the registries. These differed from the most common hospitalization

diagnoses, which included disorders of the bone, cartilage, synovitis, and internal derangement of the knee. This suggests that hospitalizations were more likely to be associated with acute injury and that registry diagnoses reflected chronic conditions that were more difficult to diagnose.

These analyses have a number of limitations that should be considered. A study period of only 3 years may not be long enough to adequately capture hospitalizations for long-term health problems. The use of hospitalization as a measure of morbidity limits our investigation to only severe health problems, and use of military hospital data limits the capture of hospitalization experiences to only military facilities. Immunization data included only documented vaccinations and present only sparse data for investigation during the 1991 era. Lastly, although extensive efforts were made to accurately model potential exposure to oil well fire smoke and Khamisiyah nerve agents, acquiring precise individual level exposure data is challenging, and presumed exposures should be viewed with some caution.[1, 15]

Despite these limitations, our study has a number of strengths. Objective hospitalization data are considered to be very complete for active-duty military personnel because they have ready access to DoD medical facilities and seldom seek medical care outside the DoD system. The large study population provided adequate statistical power to detect even small differences, and proportional hazards modeling allowed for relative risk estimates while simultaneously

adjusting for many covariates and varied length of follow-up. Additionally, the model demonstrated increased probability of hospitalization for demographic, occupational, and exposure covariates that were consistent with those of other postwar hospitalization studies, suggesting model reliability.[7, 14, 15, 54]

In summary, we defined an objective measure of post-Gulf War morbidity in relation to enrollment in the DoD and VA Gulf War registries. Based on objective data, registry participants were more likely to be ill prior to registry enrollment when illness was defined by postwar hospitalization for any cause, for all of the 14 diagnostic categories, for 23 of the 25 specific diagnoses, and for 4 of the 5 specific diagnoses of high interest. These findings suggest that Gulf War registry participants, as a group, may have experienced more ill health than nonparticipants after the war and before the registries were established.[34, 55] Whether sick Gulf War veterans were overly encouraged to enroll, or that being hospitalized was predictive of enrollment, these findings would refute arguments that registry enrollees, overall, were well veterans seeking only to document concern about future health problems. Our results serve to strengthen analyses that use registry participation as a marker of ill health among Gulf War veterans.

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Table 1. Exposure, Deployment, and Demographic Characteristics of Active-Duty Veterans Deployed to the Gulf War, in Relation to Gulf War Registry Participation

Variable	Total population n (%) (N=546,522)	Registry participants n (%) (N=69,189)	Nonparticipants n (%) (N=477,333)
Oil well fire			
Not exposed	54,289 (9.9)	2,356 (3.4)	51,933 (10.9)
Undetermined	142,589 (26.1)	10,462 (15.1)	132,127 (27.7)
Exposed	349,644 (64.0)	56,371 (81.5)	293,273 (61.4)
Khamisiyah plume			
Not under plume	474,109 (86.7)	52,551 (75.9)	421,558 (88.3)
Under plume	72,413 (13.3)	16,638 (24.1)	55,775 (11.7)
Vaccine			
No vaccine and unknown	544,053 (99.5)	68,727 (99.3)	475,326 (99.6)
Botulinum toxoid	409 (0.1)	57 (<0.1)	352 (<0.1)
Anthrax	2,060 (0.4)	405 (0.6)	1,655 (0.4)
Gender			
Male	513,367 (93.9)	63,486 (91.8)	449,881 (94.2)
Female	33,155 (6.1)	5,703 (8.2)	27,452 (5.8)
Home state			
Northwest	71,497 (13.1)	9,044 (13.1)	62,453 (13.1)
Northeast	200,717 (36.7)	25,056 (36.2)	175,661 (36.8)
Southeast	106,316 (19.4)	15,864 (22.9)	90,452 (18.9)
Southwest	116,710 (21.4)	14,150 (20.4)	102,560 (21.5)
Non-US/ unknown	51,282 (9.4)	5,075 (7.3)	46,207 (9.7)
Age at time of deployment (y)			
<22	147,892 (27.0)	16,019 (23.2)	131,873 (27.6)
22-25	133,816 (24.5)	15,331 (22.1)	118,485 (24.8)
26-31	140,407 (25.7)	17,821 (25.8)	122,586 (25.7)
>31	124,407 (22.8)	20,018 (28.9)	104,389 (21.9)
Prewar hospitalization			
No	508,761 (93.1)	62,871 (90.9)	445,890 (93.4)
Yes	37,761 (6.9)	6,318 (9.1)	31,443 (6.6)
Marital status			
Single	257,926 (47.2)	29,027 (41.9)	228,899 (47.9)
Married	288,596 (52.8)	40,162 (58.1)	248,434 (52.1)

Military pay grade			
Commissioned officer	52,618 (9.6)	3,980 (5.8)	48,638 (10.2)
Enlisted	486,230 (89.0)	63,953 (92.4)	422,277 (88.5)
Warrant officer	7,674 (1.4)	1,256 (1.8)	6,418 (1.3)
Race/ethnicity			
White	363,199 (66.5)	41,751 (60.3)	321,448 (67.3)
Black	129,629 (23.7)	20,698 (29.9)	108,952 (22.8)
Hispanic	21,961 (4.0)	2,603 (3.8)	19,358 (4.1)
Other	31,733 (5.8)	4,158 (6.0)	27,575 (5.8)
Branch of service			
Navy and Coast Guard	140,972 (25.8)	4,949 (7.2)	136,023 (28.5)
Army	255,494 (46.7)	51,841 (74.9)	203,653 (42.7)
Marines	82,818 (15.2)	8,112 (11.7)	74,706 (15.6)
Air Force	67,238 (12.3)	4,287 (6.2)	62,951 (13.2)
Attrition during the study period			
Not separated	282,371 (51.7)	34,404 (49.5)	250,909 (52.3)
Separated	264,151 (48.3)	35,036 (50.5)	228,970 (47.7)
Occupational category			
Electronic equipment repair	45,135 (8.3)	4,065 (5.9)	41,070 (8.6)
Infantry, gun crews	140,243 (25.7)	18,426 (26.6)	121,817 (25.5)
Communications/ intelligence	55,570 (10.2)	7,531 (10.9)	48,039 (10.1)
Health care	28,110 (5.1)	4,146 (6.0)	23,964 (5.0)
Other technical	11,564 (2.1)	1,854 (2.7)	9,710 (2.0)
Administration	60,984 (11.2)	8,362 (12.1)	52,622 (11.0)
Electrical/ mechanical repair	109,856 (20.1)	12,548 (18.1)	97,308 (20.4)
Craftsmen	19,363 (3.5)	2,207 (3.2)	17,156 (3.6)
Service & supply handlers	53,551 (9.8)	7,479 (10.8)	46,072 (9.7)
Nonoccupational and missing	22,146 (4.0)	2,571 (3.7)	19,575 (4.1)
Time period in theater			
August-October 1990			
Not in theater	251,879 (46.1)	28,944 (41.8)	222,935 (46.7)
In theater	294,643 (53.9)	40,245 (58.2)	254,398 (53.3)
November 1990–January 1991			
Not in theater	133,181 (24.4)	10,693 (15.5)	122,488 (25.7)
In theater	413,341 (75.6)	58,496 (84.5)	354,845 (74.3)
February-April 1991			
Not in theater	74,854 (13.7)	3,020 (4.4)	71,834 (15.1)
In theater	471,668 (86.3)	66,169 (95.6)	405,499 (84.9)
May-July 1991			
Not in theater	337,603 (61.8)	41,412 (59.8)	296,191 (62.1)
In theater	208,919 (38.2)	27,777 (40.2)	181,142 (37.9)

Table 2. Characteristics of Active-Duty Veterans Deployed to the Gulf War in Relation to Postwar Hospitalization Experience 1991-1994

Variable	Hospitalized n (%) (N=73,218)	Not Hospitalized n (%) (N=473,304)	*p*-value*
Registry status			<.0001
Registry nonparticipant	59,906 (81.8)	417,427 (88.2)	
Registry participant	13,312 (18.2)	55,877 (11.8)	
Oil well fire			<.0001
Not exposed	6,859 (9.4)	47,430 (10.0)	
Undetermined	19,923 (27.2)	122,666 (25.9)	
Exposed	46,436 (63.4)	303,208 (64.1)	
Khamisiyah plume			<.0001
Not under plume	62,423 (85.3)	411,686 (87.0)	
Under plume	10,795 (14.7)	61,618 (13.0)	
Vaccine			<.0001
No vaccine and unknown	72,799 (99.4)	471,254 (99.6)	
Botulinum toxoid	67 (0.1)	342 (0.1)	
Anthrax	352 (0.5)	1,708 (0.4)	
Gender			<.0001
Male	66,099 (90.3)	447,268 (94.5)	
Female	7,119 (9.7)	26,036 (5.5)	
Home state			<.0001
Northwest	9,159 (12.5)	62,338 (13.2)	
Northeast	26,491 (36.2)	174,226 (36.8)	
Southeast	15,052 (20.6)	91,264 (19.3)	
Southwest	15,762 (21.5)	100,948 (21.3)	
Non-US/ unknown	6,754 (9.2)	44,528 (9.4)	
Age at time of deployment (y)			<.0001
<22	18,717 (25.6)	129,175 (27.3)	
22-25	15,993 (21.8)	117,823 (24.9)	
26-31	18,475 (25.2)	121,932 (25.8)	
>31	20,033 (27.4)	104,374 (22.0)	
Prewar hospitalization			<.0001
No	65,289 (89.2)	443,463 (93.7)	
Yes	7,920 (10.8)	29,841 (6.3)	
Marital status			<.0001
Single	32,285 (44.1)	225,641 (47.7)	
Married	40,933 (55.9)	247,663 (52.3)	
Military pay grade			<.0001

Commissioned officer	6,163 (8.4)	46,455 (9.8)	
Enlisted	65,854 (90.0)	420,376 (88.8)	
Warrant officer	1,201 (1.6)	6,473 (1.4)	
Race/ethnicity			<.0001
White	48,319 (66.0)	314,880 (66.5)	
Black	18,265 (24.9)	111,364 (23.5)	
Hispanic	2,500 (3.4)	19,461 (4.1)	
Other	4,134 (5.7)	27,599 (5.8)	
Branch of service			<.0001
Navy and Coast Guard	16,384 (22.4)	124,588 (26.3)	
Army	38,298 (52.3)	217,196 (45.9)	
Marines	9,665 (13.2)	73,153 (15.5)	
Air Force	8,871 (12.1)	58,367 (12.3)	
Attrition during the study period			<.0001
No separation	43,806 (59.9)	239,256 (50.6)	
Separated	29,367 (40.1)	234,093 (49.5)	
Occupational category			<.0001
Electronic equipment repair	5,348 (7.3)	39,787 (8.4)	
Infantry, gun crews	17,634 (24.1)	122,609 (25.9)	
Communications/ intelligence	7,136 (9.8)	48,434 (10.2)	
Health care	5,373 (7.3)	22,737 (4.8)	
Other technical	1,707 (2.3)	9,857 (2.1)	
Administration	8,717 (11.9)	52,267 (11.0)	
Electrical/ mechanical repair	13,765 (18.8)	96,091 (20.3)	
Craftsmen	2,713 (3.7)	16,650 (3.5)	
Service & supply handlers	7,306 (10.0)	46,245 (9.8)	
Non-occupational and missing	3,519 (4.8)	18,627 (3.9)	
Time period in theater			
August-October 1990			0.4054
Not in theater	33,640 (45.9)	218,239 (46.1)	
In theater	39,578 (54.1)	255,065 (53.9)	
November 1990 – January 1991			0.2817
Not in theater	17,726 (24.2)	115,455 (24.4)	
In theater	55,492 (75.8)	357,849 (75.6)	
February-April 1991			0.2763
Not in theater	9,934 (13.6)	64,920 (13.7)	
In theater	63,284 (86.4)	408,384 (86.3)	
May-July 1991			0.0174
Not in theater	44,938 (61.4)	292,665 (61.8)	
In theater	28,280 (38.6)	180,639 (38.2)	

* *p*-value based on a chi square test of association.

Table 3. Adjusted Risk Ratios and 95% Confidence Intervals for "Any Cause" Postwar Hospitalization Among Regular Active-Duty Registry Participants in Department of Defense or Veterans Administration Registries, August 1, 1991, to June 6,1994

Variable	Number of subjects	Number (%) Hospitalized	RR*	95% CI*	*p*-value
Registry status					<0.0001
Registry nonparticipant†	477,333	59,906 (12.6)	-	-	
Registry participant	69,189	13,312 (19.2)	1.43	(1.40, 1.46)	
Oil well fire					0.1273
Not exposed†	54,289	6,859 (12.6)	-	-	
Undetermined	142,589	19,923 (14.0)	1.01	(0.98, 1.04)	
Exposed	349,644	46,436 (13.3)	0.95	(0.93, 0.98)	
Khamisiyah plume					0.0051
Not under plume†	474,109	62,423 (13.2)	-	-	
Under plume	72,413	10,795 (14.9)	0.99	(0.96, 1.01)	
Vaccine					0.0001
No vaccine and unknown†	544,053	72,799 (13.4)	-	-	
Botulinum toxoid	409	67 (16.4)	1.43	(1.12, 1.82)	
Anthrax	2,060	352 (17.1)	1.03	(0.92, 1.14)	
Gender					<0.0001
Male†	513,367	66,099 (12.9)	-	-	
Female	33,155	7,119 (21.5)	1.55	(1.51, 1.59)	
Home state					0.1387
Northwest†	71,497	9,159 (12.8)	-	-	
Northeast	200,717	26,491 (13.2)	1.01	(0.99, 1.04)	
Southeast	106,316	15,052 (14.2)	1.03	(1.00, 1.06)	
Southwest	116,710	15,762 (13.5)	1.06	(1.03, 1.08)	
Non-US/ unknown	51,282	6,754 (13.2)	1.07	(1.03, 1.10)	
Age at time of deployment (y)					<0.0001
<22†	147,892	18,717 (12.7)	-	-	
22-25	133,816	15,993 (12.0)	0.95	(0.92, 0.97)	
26-31	140,407	18,475 (13.6)	0.92	(0.89, 0.94)	
>31	124,407	20,033 (16.1)	1.12	(1.10, 1.15)	
Prewar hospitalization					<0.0001
No†	508,761	65,298 (12.8)	-	-	
Yes	37,761	7,920 (21.0)	1.66	(1.62, 1.70)	
Marital status					0.0038
Single†	288,596	32,285 (12.5)	-	-	

Married	257,926	40,933 (14.2)	0.98	(0.96, 1.00)	
Military pay grade					<0.0001
Commissioned officer†	52,618	6,163 (11.7)	-	-	
Enlisted	486,230	65,854 (13.5)	1.50	(1.46, 1.55)	
Warrant officer	7,674	1,201 (15.7)	1.23	(1.15, 1.31)	
Race/ethnicity					<0.0001
White†	363,199	48,319 (13.3)	-	-	
Black	129,629	18,265 (14.1)	0.88	(0.87, 0.90)	
Hispanic	21,961	2,500 (11.4)	0.73	(0.70, 0.76)	
Other	31,733	4,134 (13.0)	0.92	(0.89, 0.95)	
Branch of service					<0.0001
Navy and Coast Guard†	140,972	16,384 (11.6)	-	-	
Army	255,494	38,298 (15.0)	1.36	(1.33, 1.39)	
Marines	82,818	9,665 (11.7)	1.13	(1.10, 1.16)	
Air Force	67,238	8,871 (13.2)	1.07	(1.04, 1.10)	
Occupational category					0.7936
Infantry, gun crews†	140,243	17,634 (12.6)	-	-	
Electronic equipment repair	45,135	5,348 (11.9)	0.89	(0.86, 0.92)	
Communications/ intelligence	55,570	7,136 (12.8)	0.90	(0.88, 0.93)	
Health care	28,110	5,373 (19.1)	1.27	(1.23, 1.31)	
Other technical	11,564	1,707 (14.8)	0.99	(0.94, 1.04)	
Administration	60,984	8,717 (14.3)	0.92	(0.90, 0.95)	
Electrical/ mechanical repair	109,856	13,765 (12.5)	0.91	(0.89, 0.93)	
Craftsmen	19,363	2,713 (14.0)	1.07	(1.03, 1.12)	
Service & supply handlers	53,551	7,306 (13.6)	0.99	(0.97, 1.02)	
Nonoccupational and missing	22,146	3,519 (15.9)	1.06	(1.02, 1.10)	
Time period in theater August-October 1990					0.0006
Not in theater†	251,879	33,640 (13.4)	-	-	
In theater	294,643	39,578 (13.4)	1.02	(1.01, 1.04)	

*RR = adjusted risk ratio; CI = 95% confidence interval.

†Reference category.

Table 4. Adjusted Risk Ratios for Postwar Hospitalizations in Major 3-Digit ICD-9-CM* Categories Among Regular Active-Duty Gulf War Veterans in Department of Defense and Veterans Administration Registries, August 1, 1991, to June 6, 1994

ICD-9-CM Codes*	Major Diagnostic Categories	Nonparticipants (N=477,333)	Registry Participants (N=69,189)	
		N (%) Hospitalized	N (%) Hospitalized	RR† (95% CI)
001-139	Infection and parasitic	4,665 (1.0)	1,074 (1.6)	1.36 (1.27, 1.45)
140-239	Neoplasms	2,827 (0.6)	731 (1.1)	1.43 (1.31, 1.55)
240-279	Endocrine, nutritional, and metabolic diseases	3,024 (0.6)	662 (1.0)	1.33 (1.22, 1.46)
280-289	Blood diseases	1,994 (0.4)	496 (0.7)	1.21 (1.09, 1.34)
290-319	Mental disorders	8,245 (1.7)	1,703 (2.5)	1.43 (1.36, 1.52)
320-389	Nervous system diseases	3,294 (0.7)	935 (1.4)	1.72 (1.59, 1.85)
390-459	Circulatory system diseases	3,813 (0.8)	1,055 (1.5)	1.57 (1.46, 1.69)
460-519	Respiratory system diseases	6,549 (1.4)	1,557 (2.3)	1.62 (1.53, 1.72)
520-579	Digestive system diseases	12,188 (2.6)	2,616 (3.8)	1.35 (1.29, 1.41)
580-629	Genitourinary system diseases	5,457 (1.1)	1,424 (2.1)	1.43 (1.34, 1.52)
680-709	Skin diseases	3,147 (0.7)	646 (0.9)	1.35 (1.24, 1.48)
710-739	Musculoskeletal system diseases	14,893 (3.1)	4,080 (5.9)	1.70 (1.64, 1.76)
780-799	Symptoms, signs, ill-defined	5,497 (1.2)	1,572 (2.3)	1.69 (1.59, 1.80)
800-999	Injury and poisoning	12,423 (2.6)	2,588 (3.7)	1.30 (1.24, 1.36)

**International Classification of Diseases, Ninth Revision, Clinical Modification.*

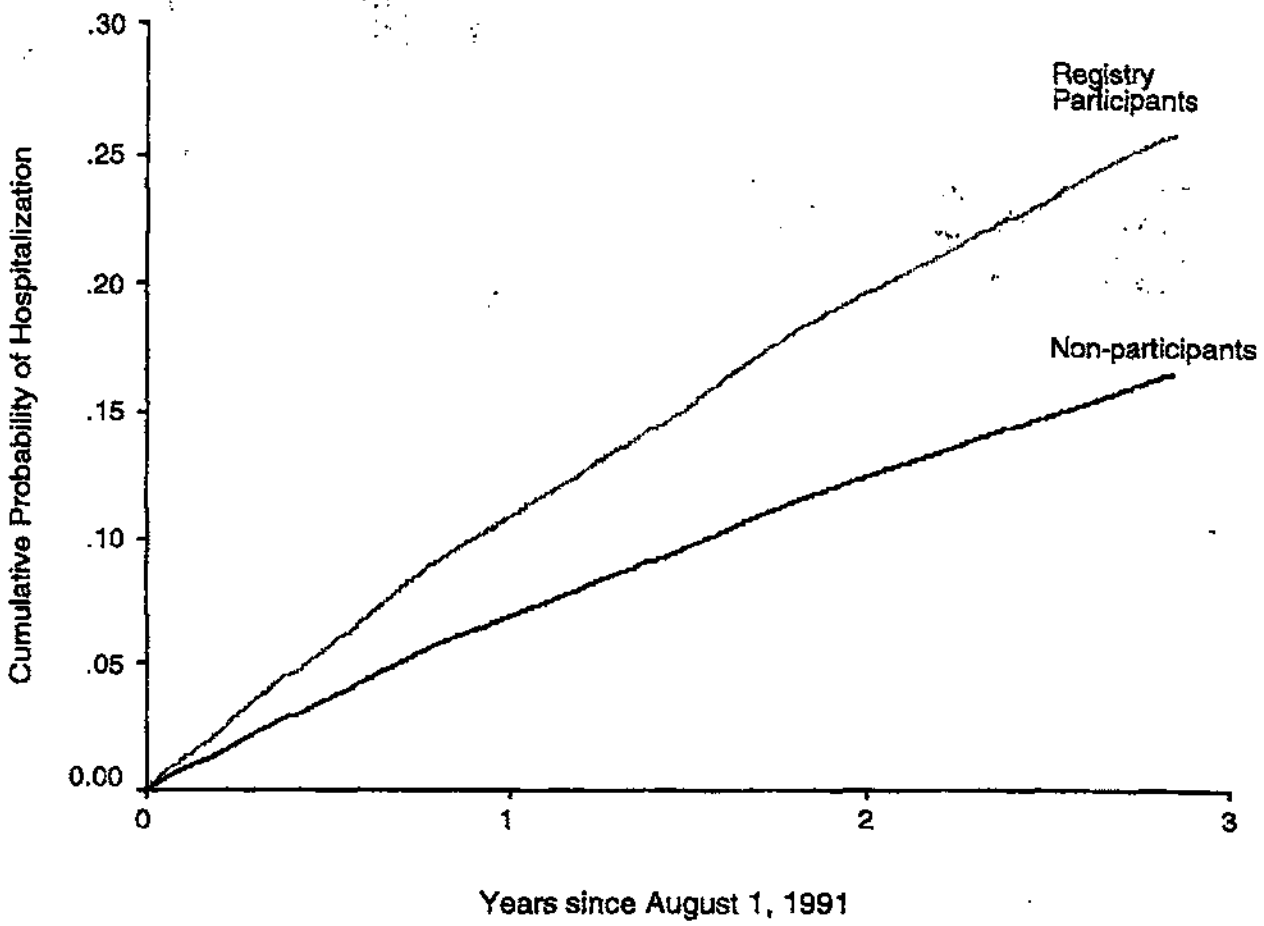
[1]RR = adjusted risk ratio; CI = 95% confidence interval.

Table 5. Adjusted Risk Ratios for the 25 Most Frequent 3-Digit Diagnostic Codes From the 5 Diagnostic Categories Yielding the Highest Relative Risks Among Regular Active-Duty Gulf War Veterans in Department of Defense and Veterans Administration Registries, August 1, 1991, to June 6, 1994

ICD-9-CM Category*	Diagnoses	Nonparticipants (N=477,333)	Registry Participants (N=69,189)	
		N (%) Hospitalized	N (%) Hospitalized	RR† (95% CI)
Diseases of the nervous system: 320-389				
354	Mononeuritis of upper limb and mononeuritis multiplex	429 (0.1)	147 (0.2)	2.06 (1.68, 2.53)
346	Migraine	284 (0.1)	132 (0.2)	2.46 (1.96, 3.07)
355	Mononeuritis of lower limb	272 (0.1)	100 (0.1)	2.08 (1.63, 2.66)
378	Strabismus and other disorders of binocular eye movement	185 (<0.1)	30 (<0.1)	0.98 (0.65, 1.46)
385	Other disorders of middle ear and mastoid	174 (<0.1)	33 (0.1)	1.32 (0.89, 1.95)
Diseases of the circulatory system: 390-459				
401	Essential hypertension	1,130 (0.2)	335 (0.5)	1.51 (1.33, 1.73)
455	Hemorrhoids	636 (0.1)	201 (0.3)	1.53 (1.29, 1.81)
427	Cardiac dysrhythmias	466 (0.1)	106 (0.2)	1.47 (1.17, 1.84)
456	Varicose veins of other sites	395 (0.1)	72 (0.1)	1.36 (1.05, 1.77)
414	Other forms of ischemic heart	303 (0.1)	102 (0.2)	1.89 (1.48, 2.42)

	disease					
Diseases of the respiratory system: 460-519						
470	Deviated nasal septum	1,771	(0.4)	376	(0.5)	1.71 (1.52, 1.92)
478	Other diseases of upper respiratory tract	1,189	(0.3)	287	(0.4)	1.89 (1.64, 2.17)
474	Chronic disease of tonsils and adenoids	961	(0.2)	186	(0.3)	1.61 (1.36, 1.90)
473	Chronic sinusitis	745	(0.2)	188	(0.3)	1.78 (1.50, 2.12)
493	Asthma	487	(0.1)	181	(0.3)	1.93 (1.61, 2.32)
Diseases of the musculoskeletal system: 710-739						
717	Internal derangement of knee	4,630	(1.0)	1,170	(1.7)	1.61 (1.51, 1.72)
727	Other disorders of synovitis and tenosynovitis	2,448	(0.5)	705	(1.0)	1.61 (1.47, 1.76)
718	Other derangement of joint	2,094	(0.4)	558	(0.8)	1.71 (1.55, 1.88)
733	Other disorders of bone and cartilage	1,633	(0.3)	454	(0.7)	1.73 (1.55, 1.93)
726	Peripheral enthesopathies and allied symptoms	1,241	(0.3)	372	(0.5)	1.73 (1.53, 1.95)
Symptoms, signs, and ill-defined conditions: 780-799						
780	General symptoms (eg, sleep disturbance, drowsiness)	1,000	(0.2)	314	(0.5)	1.99 (1.73, 2.28)
786	Symptoms involving respiratory	1,264	(0.3)	451	(0.7)	2.03 (1.81, 2.28)

Figure 1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Cumulative Probability of Hospitalization
Registry Participants
Non-participants
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2
3
Years since August 1, 1991

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2522
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SUBADDRESS	
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PGS. SENT	1
RESULT	OK

DMMC Control #
2003169-0000052

Directorate for Freedom of Information and Security Review (DFOISR)
Coordination Record

SECURITY REVIEW

June 18, 2003

To: ~~OSA/GWI~~ DHSD 845-8369

Case Number: 03-S-1516

FOR PICKUP BY LIZ

Number of Pages: 45 Classification: U

Type of Document: ARTICLE Requestor: SMITH, TYLER

Subject: THE POSTWAR HOSPITALIZATION EXPERIENCE OF GULF WAR VETERANS PARTICIPATING IN US HEALTH REGISTRIES

Source: DEPARTMENT OF THE NAVY Event Date:

Purpose: PUBLIC RELEASE

The attached material is forwarded for review and comment in accordance with the following guidelines. Questions concerning this case should be directed to: Mr. ARTHUR HORN, Rm 2C757, 697-3078, e-mail: arthur.horn@dfoisr.whs.mil, unclassified Fax 693-7341.

NOTE: Intended for future publication in the Journal of Occupational and Environmental Medicine.

Please advise if reviews required other than:
HA OSA/GWI

A reply is requested by: 02-JUL-2003

COORDINATION OFFICE ACTION

To: Directorate for Freedom of Information and Security Review, DFOISR, Room 2C757.
Review by this office in accordance with the guidelines below, result in the following recommendation concerning clearance for publication.

Check One:

☑ **No Objection as Received.**

☐ **No Objection Subject to Amendments** made by this office (in black pencil). Ammendments and rationale (security and policy) are annotated on page numbers listed below.

☐ **Objection.** Amendments to permit publication are impracticable. Reasons stated below.

(Continue on Reverse side if necessary)

Col John Gardner 703 578 8524 JUN 23 2003 John W Gardner

phone number date signature

Department of Defense
Deployment Health Support
5113 Leesburg Pike, Suite 901

(154)

11/17/00 FRI 14:52 FAX (b)(6) DFOI&SR CMAT Control # 2000325-0000003

DEPARTMENT of DEFENSE

Directorate for Freedom of Information and
Security Review, Room 2C757
1155 Defense Pentagon
Washington, DC 20301-I 155

Facsimile Transmittal

17 Nov 00

To: **OSA/GWI**

Organization: Attn: (b)(6)
Office Phone: (b)(6)
FAX Number:

From: (b)(6) **Navy Division,**
DFOISR/WHS/DOD

Phone: (b)(6)
FAX:

Total Pages Transmitted (including cover sheet): 7

Comments:

(b)(6),

Enclosed is a Navy security review request for an abstract intended for future presentation. If approved, the abstract will be presented to the Military Veteran's Coordination Board at the Conference on Illnesses among Gulf War Veterans, Alexandria, VA, 24-26 Jan 01 (SR case: 00-S-0813). A copy of our SD Form 373 is also provided for your review response. Please call *me* if you have any questions regarding this case. Tbank you for your assistance!

(b)(6)

Deputy, Navy Division
DFOISR/WHS/DOD

Directorate for Freedom of Information and Security Review (DFOISR) 01-S-0813
Coordination Record

SECURITY REVIEW

November 17, 2000

To: OSA/GWI 845-8369
Case Number: 01-S-0813

Number **of Pages:** 1 **Classification:** U
Type of Document: ABSTRACT **Requestor:** SATO, PAUL
Subject: DOD-WIDE SURVEILLANCE FOR "S-HEALTH REQUIRING HOSPITALIZATION POTENTIALLY ASSOCIATED WITH ANTHRAX IMMUNIZATION: 1998 DATA
Source: OPNAV Event Date: 24-JAN-2001
Purpose: CONFERENCE

The attached material is forwarded for review and comment in accordance with the following guidelines. Questions concerning this case should be directed to : (b)(6) Rm.2C757, (b)(6) e-mail: (b)(6) @osd.pentagon.mil, unclassified Fax (b)(6)

NOTE: Abstract intended for presentation to the Military Veteran's Coordination Board: Conference on Illnesses among Gulf War Vets.

Please advise If **reviews** required other **than:**
HA ARMY OSA/GWI P&R

A reply is requested by: **04-DEC-2000**

COORDINATION OFFICE ACTION

To: Directorate for Freedom of Information and Security Review, DFOISR, Roam 2C757.
Review by this office in accordance with the guidelines below, result in the following recommendation concerning clearance for publication.

Check One:

☐ **No Objection as Received.**

☐ **No Objection Subject to Amendments** made by this office (in black pencil). Ammendments and rationale (security and policy) are annotated on page numbers listed below.

☐ **Objection.** Amendments to permit publication are impracticable. Reasons stated below.

(Continue on Reverse side if necessary)

typed name, title and organization | phone number | date | signature

Instructions: The policy of the Department of Defense it to authorize and encourage the public release of information concerning the Department of Defense consistent with security requirements, and other exemptions to disclosure under the Freedom of Information Act

Security - Reviewing agencies should identify information known to be classified within the meaning of Executive Order 12958 (DoD Regulation 5200.1R) or information which in the judgement of the reviewing agency warrants classification. In the latter case, it is requested that reasons for this judgement be given and recommendations made for appropriate classification.

Policy - Material originated with the Department of Defense for public release should, in addition, be reviewed for conflict with established policies and programs of the Department of Defense or those of the national government. If change is necessary, reviewing agencies are requested to recommend acceptable substitue language where practicable, or specify needed changes in sufficient detail to permit acceptable revision.

Editorial - Editorial review is not a responsibility of the Directorate for Freedom of Information and Security Review and reviewing agencies should not make editorial corrections. However, obvious errors of fact should be indicated.

DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
2300 E STREET NW
WASHINGTON DC 20372-5300

IN REPLY REFER TO

5721
Ser 26B/00U0585
24 Oct 00

FIRST ENDORSEMENT on NAVHLTHRSCHCEN ltr 5721 Ser 00/312 of 17 Oct 00

From: Chief, Bureau of Medicine and Surgery
To: Chief, Bureau of Medicine and Surgery (MED-00P)

Subj: REQUEST FOR PRESENTATION CLEARANCE, PUBLIC AFFAIRS PROGRAM

1. In accordance with reference (a), the presentation, enclosure (1) of reference (b), "DOD-Wide Surveillance for Ill-Health Requiring Hospitalization Potentially Associated with Anthrax Immunization: 1998 Data", has been reviewed by this division.

2. The presentation does contain sensitive material (Anthrax) and is, therefore, forwarded for MED-00P review and approval. Recommend that it be approved for presentation at the Military and Veteran's Coordination Board: Conference on Illnesses among Gulf War Veterans, Alexandria, VA, 24-26 January 2001.

3. My point of contact is Mr. (b)(6) at (b)(6).

R. K. LEBLANC
By direction

copy to: NAVHLTHRSCHCEN (w/o attachments)

01-S-0813

DEPARTMENT OF THE NAVY
NAVAL HEALTH RESEARCH CENTER
POST OFFICE BOX 85122
SAN DIEGO, CA 92186-5122

IN REPLY REFER TO
5721
Ser 00/312
17 Oct 00

From: Commanding Officer, Naval Health Research Center, San Diego
To: Chief, Bureau of Medicine and Surgery (MED-OOP)
Via: Chief, Bureau of Medicine and Surgery (MED-26), 2300 E St NW, Washington, DC 20372-5300

Subj: REQUEST FOR PRESENTATION CLEARANCE, PUBLIC AFFAIRS PROGRAM

Ref: (a) BUMEDINST 572 1.3

Encl: (1) BUMED 572 1.3 Clearance for Presentation Form with NHRC Presentation "DOD Surveillance for Ill-Health Requiring Hospitalization Potentially Associated with Anthrax Immunization: 1998 Data" (Sato/Smith/Reed/ et al.)

1. FORWARDED FOR REVIEW AND APPROVAL. Enclosure (1) has been reviewed by this command and is forwarded, per reference (a). Upon approval, enclosure (1) will be presented at the Military and Veterans' Coordinating Board: Conference on Illnesses among Gulf War Veterans: A Decade of Scientific Research, to be held 24-26 January 2001 in Alexandria, Virginia.

2. The presentation contains sensitive information.

THOMAS J. CONTRERAS, JR.

2000-178

Clearance for Publication or Presentation

Section (1) to be completed by researcher or submitter

Author(s) Name, Command, and Rank:
Paul A. Sato, MD. MPH; Tyler Smith. MS; Robert Reed, MS: Linda Wang, BS; Neal Halsey, MD; and Phillip Pittman, MD, MPH

Title of Work: DOD-WIDE SURVEILLANCE FOR ILL-HEALTH REQUIRING HOSPITALIZATION POTENTIALLY ASSOCIATED WITH ANTHRAX IMMUNIZATION: 1998 DATA

Purpose/Forum: (Check all appropriate)

____X Presentation ____Journal article

____Book ____Other (Please Explain

Name, Place, Dates of Presentation/Journal Title/Book Publisher:
Military and Veteran's Coordinating Board: Conference on Illnesses among Gulf War Veterans: A Decade of Scientific Research. Alexandria. VA, Jan 24-26.2001.

Synopsis of the Manuscript/article/research paper in laymen's terms:

The dangers posed to the US military by anthrax as a biological weapon prompted the Department of Defense (DoD) to initiate mandatory immunization of all US militarypersonnel with anthrax vaccine in 1998. This program is currently being implemented.To date, over 500 service members have declinedanthrax immunization, despite the consequences that may result. Concern about long-term severe and/or permanent adverse effects of the vaccine appear to have been the important reasons for refusal, although no long-term anthrax vaccine associated adverse events are either known or expected. CDHR has developed a multi-year study to monitor for potential long-term, severe, anthrax immunization adverse events, if any. These studies add to existing work by the services, the Food and Drug Administration, and the Centers for Disease Control and Prevention.

Review Findings	Action/Comments
____ Higher review not required by BUMEDINST 5721.1D	OIC/CO authorized to approve. If uncertain about sensitivity of a subject. contact BUMED Public Affairs Office at (b)(6)
___ Animal Use ____ Human Use ____ Foreign Journal	Following command review, forward to BUMED for review and approval or disapproval
____ AIDS/HIV	
Persian Gulf Illness	
X Controversial/Sensitive	Following command review, forward to BUMED for review and approval or disapproval. If higher review is required. BUMED will coordinate with appropriate commands
X Potential Media Interest	If uncertain about sensitivity of a subject. contact BUMED Public Affairs Office at (b)(6)

Coordinator's Name, Command. and Telephone Number
LCDR (b)(6) MC, USN, Public Affairs Officer, Naval Health Research Center. Comm/DSN (b)(6)

ENCLOSURE (/)

DOD-WIDE SURVEILLANCE FOR ILL-HEALTH REQUIRING HOSPITALIZATION POTENTIALLY ASSOCIATED WITH ANTHRAX IMMUNIZATION: 1998 DATA

Paul A. **Sato** [1], Tyler C. **Smith** [1], **Robert** J. Reed [1], Linda Wang', Neal A. Halsey [2], **Phillip** R. **Pittman** [3]

DoD Center for Deployment Health Research(**CDHR**), Naval Health Research Center [1], San Diego, CA; Johns Hopkins University, Baltimore, MD[2]; US Army Medical Research Institute of Infectious Diseases, Fort**Detrick**, MD [3]

PRINCIPAL AUTHORS **EMAIL** ADDRESS:
Sato@nhrc.navy.mil

Introduction: The dangers posed to the US military by anthrax as a biological weapon prompted the Department of Defense (**DoD**) to initiate mandatory immunization of all US military personnel with anthrax vaccine in 1998. This program is currently being implemented. To date, over 500 service members have declined anthrax immunization, despite the consequences that may result. Concern about long-term severe. **and/or** permanent adverse effects of the vaccine appear to have been the important reasons for refusal, although no long-term anthrax vaccine associated adverse events are either known or expected. CDHR has developed a multi-year study to monitor for potential **long-term**, severe, anthrax immunization adverse events, if any. These studies add to existing work by the services, the Food and Drug Administration, and the Centers for Disease Control and Prevention.

Hvuothesis: Examining hospitalization rates in anthrax immunized as compared to **nonimmunized** service members on active duty (AD) identifies potential long-term adverse events associated with anthrax vaccine.

Procedures: Data on hospitalization in military medical treatment facilities, and on anthrax immunization status of service members, are accessed through centralized data repositories. By matching and linking data systematically **over** time from these sources, we obtained adjusted 1998 **hospitalization** rates in anthrax immunized compared to the **nonimmunized**. Comparisons within 14 selected International Classification of Diseases, Ninth Revision, Clinical Modification, diagnostic categories were made. A multivariable explanatory model generated adjusted risk ratios for hospitalization, immunized compared to nonimmunized, after adjustment for covariates found to be influential.

Results: Adjusted risk ratios by diagnostic category**were** either significantly less than 1.0 or included 1.0 within their 95 percent confidence intervals.

Conclusions: Anthrax immunized service members were at equal or lesser risk of ill-health requiring hospitalization in 1998, the **first** year of the **DoD** anthrax immunization program.

This research was supported by US Amy Medical **Research** and **Materiel** Command under **AIBS** no. 990261.

REGISTRATION INSTRUCTIONS

1. Gulf War Veterans' Illnesses Researchers who plan to submit abstracts must complete the Abstract Submission Form and return it with their abstract to the SAIC Frederick office by October 30.2000.
2. All participants MUST complete the Advance Registration Form and return it to the SAIC McLean office by December 15.2000.

ABSTRACT SUBMISSION FORM

Illnesses among Gulf War Veterans: A Decade of Scientific Research

DEADLINE FOR SUBMISSION: OCTOBER 30, 2000

1. ABSTRACT TO BE PRESENTED BY:

First Name, Initial, Lost Name: Paul A. Sato		
Institution/Affiliation: DoD Center for Deployment Health Research, Naval Health Research Center		
Title: Senior Medical Epidemiologist		Degree/Rank: MD, MPH
Address: NHRC	P.O. Box 85122	Bldg 322
city: San Diego	state: CA	Zip: 92186-5122
Daytime Phone(s): (b)(6)	Fax: (b)(6)	E-mail: (b)(6) @nhrc.navy.mil

2. ABSTRACT TITLE: NATIONAL STUDY O[redacted]: PARTIAL RESULTS FROM A REPRESENTATIVE SURVEY OF 1991-ERA MILITARY VETERANS

3. TOPIC *(Select the topic that best fits your poster/platform presentation):*

- X Epidemiology
- _ Treatment
- _ Toxicology
- ___ Other
- ___ Force Health Protection/Prevention/Surveillance
- ___ Psychological/Psychosocial
- ___ Neurological/Neuropsychological/Neurobiology of Stress

4. PRESENTATION PREFERENCE *(Check one only)*:

	Only	Preferred
Platform	-	-
Poster	X	___
No Preference	-	-

5. BIOSKETCH ATTACHED? X YES ___ NO

Complete the Abstract Submission Form and the Abstract Template included on the enclosed computer disk. Return both files along with your Curriculum Vita or Biosketch:

Shannon Smith
SAIC, Abstract and Conference Coordinator
5340 Spectrum Drive, Suite N
Frederick, MD 21703

Phone: (b)(6)
Fax:
E-mail: [redacted]@us-frederick.mail.saic.com

11/21/00 08:55 FAX (b)(6) OSAGWI/MR/MD 001

****
*** TX REPORT ***
****

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Office of the Special Assistant for **Gulf War** Illnesses,
Medical Readiness and Military Deployments
5113 Leesburg Pike. Suite 901
Falls Church, Virginia 22041
(b)(6)
Fax: (b)(6)

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SUBJECT:

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

Directorate for Freedom of Information and Security Review (DFOISR)
Coordination Record

SECURITY REVIEW

01-S-0813

November 17, 2000

To: OSA/GWI 845-8369
Case Number: 01-S-0813

Number of Pages: 1 **Classification:** U
Type of Document: ABSTRACT **Requestor:** SATO, PAUL
Subject: DOD-WIDE SURVEILLANCE FOR ILL-HEALTH REQUIRING HOSPITALIZATION POTENTIALLY ASSOCIATED WITH ANTHRAX IMMUNIZATION: 1998 DATA
Source: OPNAV **Event Date:** 24-JAN-2001
Purpose: CONFERENCE

The attached material is forwarded for review and comment in accordance with the following guidelines. Questions concerning this case should be directed to: (b)(6), Rm.2C757, (b)(6), e-mail (b)(6) @osd.pentagon.mil, unclassified Fax (b)(6)

NOTE: Abstract intended far presentation to the Military Veteran's Coordination Board: Conference on Illnesses among Gulf War Vets.

Please advise If reviews required other than:
HA ARMY OSA/GWI P&R

A reply is requested by: 04-DEC-2000

COORDINATION OFFICE ACTION

To: Directorate for Freedom of information and Security Review, DFOISR, Room 2C757.
Review by this office in accordance with the guidelines below. result in the following recommendation concerning clearance for publication.

Check One:

☒ **No Objection as Received.**

☐ **No Objection Subject to Amendments** made by this office (in black pencil). Ammendments and rationale (security and policy) are annotated on page numbers listed below.

☐ **Objection.** Amendments to permit publication are impracticable. Reasons stated below.

(Continue on Reverse side if necessary)

Patricia L. O'Donnell

typed name, title and organization	phone number	date	signature
COL Frank O'Donnell Dir, Medical Readiness	OSAGWI/MR/MD (b)(6)	11/20/00	

Instructions: The policy of the Department of Defense it to authorize and encourage the public release of information concerning the Department of Defense consistent with security requirements, and other exemptions to disclosure under the Freedom of Information Act

Security - Reviewing agencies should identify information known to be classified within the meaning of Executive Order 12958 (DoD Regulation 5200 1R) or information which in the judgement of the reviewing agency warrants classification. In the latter case, it is requested that reasons for this judgement be given and recommendations made for appropriate classification.

Policy - Material originated with the Department of Defense for public release should, in addition, bc reviewed for conflict with established policies and programs of the Department of Defense or those of the national government. If change is necessary, reviewing agencies are requested to recommend acceptable substitue language where practicable, or specify needed changes in sufficient detail to permit acceptable revision.

Editorial - Editorial review is not a responsibility of the Directorate for Freedom of Information and Security Review and reviewing agencies should [redacted] However, obvious [redacted] of fact [redacted] be indicated.

SD [redacted] 373 (AUTOMATED), MAR [redacted] [redacted] EDITIONS ARE OBSOLETE

Rec'd

CMAT Control # (155)
2003044-0000024

DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420

In Reply Refer To: 12

DEC 11 2000

The Honorable J. Jarrett Clinton, M.D.
Acting Assistant Secretary of Defense
Health Affairs
1200 Defense Pentagon
Room 3E1082
Washington, DC 20301-1200

Dear Dr. Clinton: Jarrett

You are cordially invited to attend the Conference on Illnesses among Gulf War Veterans: A Decade of Scientific Research. The conference will be held at the Hilton Alexandria Mark Center in Alexandria, Virginia. Sessions will begin the morning of January 24th and end the afternoon of January 26th. The preliminary meeting agenda can be found on pages 6 and 7 in the enclosed registration booklet.

The purpose of the Conference is to bring together, in a common forum, researchers, clinicians, veterans, veterans' groups, and government officials concerned about Gulf War veterans' illnesses in order to:

- Provide an opportunity for researchers to present and exchange study results;
- Provide an opportunity for veterans and veterans' groups to learn about ongoing research and to interact directly with researchers, clinicians, and government officials;
- Provide an opportunity to inform executive and legislative branches of the government about research and clinical initiatives related to the Gulf War that should be considered for future deployments;
- Inform clinicians of current practices for the treatment of Gulf War veterans' illnesses and the latest research findings and their potential impact on clinical care;
- Learn from recognized experts about overarching research areas as they relate in the etiology, diagnosis, and treatment of Gulf War veterans' illnesses;
- Encourage communication, cooperation, and collaboration among researchers, clinicians, and veterans; and
- Evaluate the implication of research on Gulf War veterans' illnesses: current state-of-the science and lessons learned.

The Honorable J. Jarrett Clinton, M.D.

In addition to the regularly scheduled program, there will be a Public Availability Session on Thursday, January 24th, from 5:15 – 6:45 p.m. This session is designed to give veterans and interested members of the public an opportunity to discuss their concerns and questions with scientists currently researching Illnesses among Gulf War Veterans. All registered conference participants are invited to participate.

We would be delighted and honored if you could attend the conference. If you are unable to attend, you may designate a member of your staff to attend in your place. If possible, please have a member of your staff confirm your attendance at the meeting with Ms. Sandra Carlson, Science Applications International Corporation, who can be reached at 301-228-3114. The registration fee will be waived should you, or your designee, decide to attend. A copy of the registration booklet is enclosed.

We look forward to seeing you at the conference.

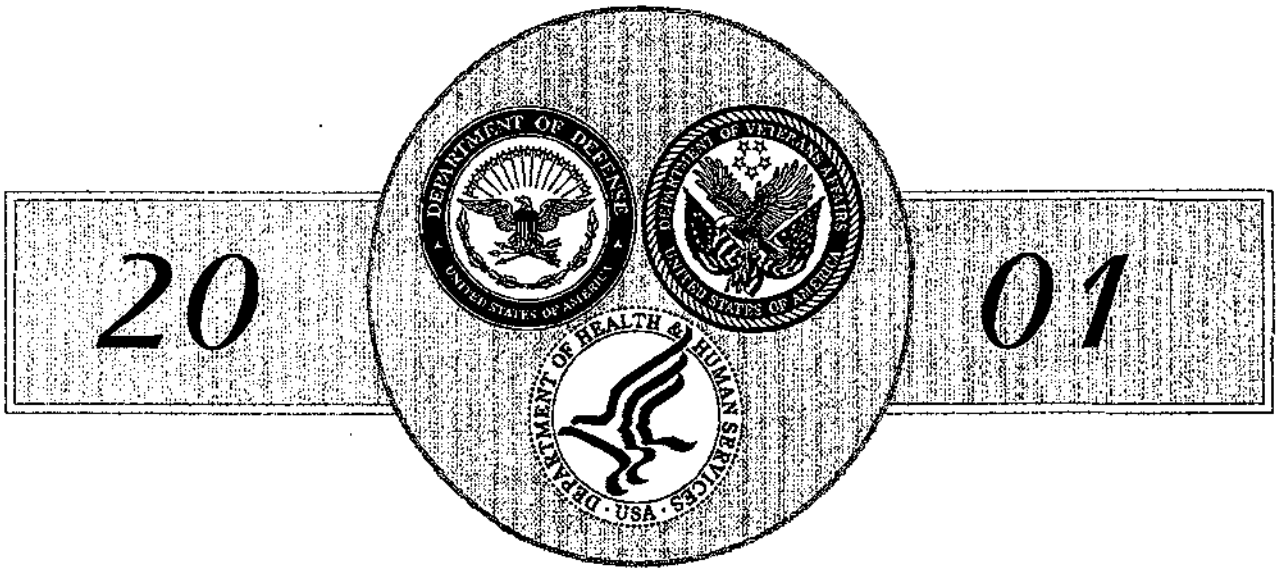
Sincerely,

John R. Feussner, M.D., M.P.H.
Chief Research and Development Officer

Enclosure

DR MAZZUCHI,
DR CLINTON AT TRICARE CONFERENCE. SOME OF YOUR FOLKS INVOLVED. DO YOU WANT TO GO?

The Research Working Group:
Military and Veterans Health Coordinating Board



Conference on Illnesses among Gulf War Veterans: A Decade of Scientific Research

Hilton Alexandria
Mark Center
Alexandria, Virginia
January 24-26, 2001

Call for Abstracts and Registration Booklet

Military and Veterans Health Coordinating Board

September 5, 2000

Department of Defense

Department of Veterans Affairs

Department of Health and Human Services

Dear Colleagues:

You are cordially invited to attend the Conference on Illnesses among Gulf War Veterans: A Decade of Scientific Research to be held in Alexandria, Virginia, January 24-26, 2001. The Conference will be held at the Hilton Alexandria Mark Center. Sessions will begin the morning of January 24th and end the afternoon of January 26th.

The purpose of the Conference is to bring together, in a common forum, researchers, clinicians, veterans, veterans groups, and government officials concerned about Gulf War Veterans' Illnesses in order to:

- Provide an opportunity for researchers to present and exchange study results;
- Provide an opportunity for veterans and veterans' groups to learn about ongoing research and to interact directly with researchers, clinicians, and government officials;
- Provide an opportunity to inform executive and legislative branches of the government about research and clinical initiatives related to the Gulf War that should be considered for future deployments;
- Inform clinicians of current practices for the treatment of Gulf War veterans' illnesses and the latest research findings and their potential impact on clinical care;
- Learn from recognized experts about overarching research areas as they relate in the etiology, diagnosis, and treatment of Gulf War veterans' illnesses;
- Encourage communication, cooperation, and collaboration among researchers, clinicians, and veterans; and
- Evaluate the implication of research on Gulf War veterans' illnesses: current state-of-the-science and lessons learned.

If you are an active federally sponsored researcher in this area, we ask that you consider submitting an abstract on your research for consideration as a platform or poster session. A platform presentation would be approximately 10-15 minutes in length. If you are interested, please use the enclosed abstract submission form. Please note that **abstracts must be received by close of business, October 30, 2000.**

If you plan to attend the Conference, please complete the attached registration materials and RSVP as directed in the booklet.

We look forward to seeing you at the conference.

John R. Feussner, M.D.
Chief Research and Development Officer
Department of Veterans Affairs
Washington, DC

About the Meeting

The objectives of the Conference on Illnesses among Gulf War Veterans: A Decade of Scientific Research are to bring together, in a common forum, researchers, clinicians, veterans, veterans groups, and government officials to:

- ✓ Provide an opportunity for researchers to present and exchange study results;
- ✓ Provide an opportunity for veterans and veterans groups to learn about ongoing research and to interact directly with researchers, clinicians, and government officials;
- ✓ Provide an opportunity to inform executive and legislative branches of the government about research and clinical initiatives related to the Gulf War that should be considered for future deployments;
- ✓ Inform clinicians of current practices for the treatment of Gulf War veterans' illnesses and the latest research findings and their potential impact on clinical care;
- ✓ Learn from recognized experts about overarching research areas as they relate in the etiology, diagnosis, and treatment of Gulf War veterans' illnesses;
- ✓ Encourage communication, cooperation, and collaboration among researchers, clinicians, and veterans; and
- ✓ Evaluate the implications of research on Gulf War veterans' illnesses: current state of the science and lessons learned.

This conference is sponsored by the Department of Defense (DoD) with planning and execution done under the auspices of the Research Working Group of the Military and Veterans Health Coordinating Board. The continuing medical educational activity is a collaborative effort with the Office of Employee Education of the U.S. Department of Veterans Affairs, Washington, DC.

Format

A mix of renowned scientists, physicians, and health care providers will address the audience during the Keynote and Plenary sessions. In the afternoon, key leaders in the field will preside over Thematic Platform Sessions with presentations drawn from submitted abstracts that specifically highlight the work of Gulf War veterans' illnesses researchers. Additional abstracts of Gulf War veterans' illnesses researchers will be displayed as posters during poster sessions. Clinical Sunrise Symposiums will be held on Thursday and Friday mornings and a special Clinician Session will be held on Friday afternoon.

Call for Abstracts

Abstracts must be received by October 30, 2000.

Abstract Information

Investigators are invited and federally sponsored investigators are encouraged to submit an abstract for consideration for presentation at the Conference on Illnesses among Gulf War Veterans: A Decade of Scientific Research. Because research sponsored by the federal government is a major focus of this meeting, priority consideration for presentations will be given to those scientists receiving federal funds for Gulf War veterans' illnesses research. The Technical Planning Committee (TPC) will review all abstracts. The committee reserves the right to return (or not publish) abstracts that it feels do not meet basic standards of scientific rigor or quality. However, it is the intention of the planning committee to publish all acceptable abstracts, regardless of whether the abstract was selected for presentation. The following instructions are to assist you in preparing your abstract. ***Submission of an abstract does not constitute registration for the meeting.*** The text of your scientific abstract (1-page limit) will be published in proceedings that will be made available at the time of the meeting. All abstracts must be electronically submitted to Science Applications International Corporation (SAIC) by October 30, 2000.

Abstracts must describe in a succinct manner the purposes and results of the research so that the quality, originality, and comprehensiveness of the work can be evaluated by the TPC. The abstract should contain a title, author's name and affiliation, followed by a single-spaced abstract, and contract acknowledgement. It is generally accepted that the first author of an abstract will be its presenter. Each abstract must contain and abstract section headings must identify (a) an introduction indicating the purpose of the study; (b) hypothesis to be tested; (c) a brief description of pertinent experimental procedures; (d) a summary of the results to date; and (e) conclusions. Titles should be indicative of the content of the abstract. Enclosed please find a IBM-formatted computer disk that contains an electronic abstract submission form and abstract template for your convenience.

Call for Abstracts (cont.)

The TPC requests that authors select a topic that best describes their abstract. The topics serve as a guide in the selection and grouping of abstracts for particular sessions. Topics are listed on the Abstract Submission Form, included on the disk provided. All submitted abstracts will be reviewed by the TPC, which will ultimately determine placement. Acceptance letters and presentation guidelines will be sent to presenters at the end of November. A sample abstract from the 1999 Conference is provided on page 5.

Instructions for Electronic Submission of Abstracts

1. *Submission Form*.....A completed Abstract Submission Form must accompany each abstract. You will find the Abstract Submission Form as an electronic file on the Abstract Submission Disk. You must include the full name, address, fax, telephone, and electronic mail addresses of the presenter as well as topic and presentation choices on this form.

2. *Curriculum Vitae or Biosketch*.....Attach an electronic version of your curriculum vitae (CV) or a brief biosketch onto the disk provided for the mail submission or attach the electronic file to your e-mail submission. The CV or biosketch file must be in PC format or a version of Macintosh software version 7.5 or higher.

3. *Abstract Format*.....The scientific abstract must contain the title (bold, all caps), complete names of authors (bold, initials caps), and affiliations (initial caps, unbolded), followed by the single-spaced abstract. Use font "Times New Roman" size "11." The electronic template is compatible with PC and Mac utilities; however, the Macintosh must be running system software version 7.5 or higher and support Apple PC exchange in order to read and write to a PC disk.

4. *Titles*.....Titles should be indicative of the content of the abstract. All words necessary to identify the subject matter should be included in the title. Periods (not dashes or other punctuation) should be used to separate two-part titles; titles must be in all capital letters and bolded. Abbreviations are not permitted.

5. *Text* .....Use font "Times New Roman" and size "11." (Do not type text of abstract in all capitals. Do not modify the electronic template. Place figures and tables within the text. Legends should be beneath the figures or tables.) On the text pages, begin single-spaced typing one line below the top blue outline. Skip one line between paragraphs. Paragraphs should be flush to the left-hand margin.

6. *Section Headings*.....*As referenced above*, each abstract must contain and abstract section headings must identify (a) an introduction indicating the purpose of the study; (b) hypothesis to be tested: (c) a brief description of pertinent experimental procedures; (d) a summary of the results, to date; and (e) conclusions. *Abstracts that do not follow this format may be rejected without further consideration.*

7. *Acknowledgement*.....Include complete contract acknowledgement at the bottom of the page. Please identify the source of your funding (e.g., VA Merit Review, DoD contract, NIH) as well as the appropriate grant, contract or project number.

8. *Abbreviations*.....Abbreviations may be used in the text of the abstract if they are defined at their first mention in the text.

9. *Length*.....Do not exceed 1 page.

10. *Disk or E-mail Submissions*.....Authors are asked to submit their abstracts either by mail or e-mail so that the organizers have all abstracts electronically. Please see the directions for e-mail and mail submission listed below.

    Abstract submission via Mail: All investigators have been sent a 3 1/2" IBM formatted disk containing both a MS Word template for your abstract as well as the Abstract Submission Form. Type your abstract directly onto the template provided, complete the Abstract Submission Form, and attach the CV or biosketch. Please make sure to label the disk with your name and phone number and mail it to: Shannon Smith, Abstract and Conference Coordinator, SAIC, 5340 Spectrum Drive, Suite N, Frederick, MD 21703-7357.

    Abstract submission via E-Mail: All investigators have been sent a 3 1/2" IBM formatted disk containing both a MS Word template for your abstract as well as the Abstract Submission Form. Type your abstract directly onto the template provided, complete the Abstract Submission Form, and attach the CV or biosketch. E-mail documents to: abstract.coordinator@us-frederick.mail.saic.com. Please label the e-mail heading or disk with the author's last name, and title of presentation.

11. *Abstract confirmation*.... Investigators who have e-mailed their abstracts to SAIC will receive a confirmation e-mail to acknowledge receipt within 1 week. Investigators who have mailed their abstract on the computer disk will receive confirmation within 2 weeks. If you have not received a confirmation within 2 weeks, please contact Shannon Smith at 301-228-3148 or abstract.coordinator@us-frederick.mail.saic.com.

Sample Abstract

PAIN SENSITIVITY IN PATIENTS WITH FIBROMYALGIA (FM) PART II: EXPECTANCY EFFECTS ON PAIN MEASUREMENTS

F. Petzke[1], D.J. Clauw[1] and R.H. Gracely[2]

Department of Medicine, Georgetown University Medical Center[1], and NIDR, National Institutes of Health, Bethesda[2], MD

Introduction: Fibromyalgia is characterized by chronic widespread pain, tenderness and increased sensitivity to various sensory stimuli. Some have suggested that hypervigilance or increased "expectancy", and not physiological factors, may cause the change in somatosensory perception in this and related conditions. One method of assessing the role of expectancy in sensory testing paradigms is to present stimuli in both an ascending and random fashion. In ascending paradigms, where the individual can anticipate the next stimulus, expectancy is felt to play a role in symptom reporting, whereas this effect is eliminated in random paradigms.

Hypothesis: The concurrent use of ascending and random testing paradigms will identify some FM subjects who over-report pain in ascending paradigms (relative to the value obtained in random testing), and these subjects will have certain psychological and clinical characteristics.

Procedures: Pressure pain sensitivity was assessed in 42 [illegible] with FM and 27 age and gender matched HC. Both ascending (0.45-kg increments up to 4.54 kg [ASC]) and random (7 stimuli repeated twice in random order [RAN]) rectangular pressure stimuli to the thumbnails of 5-sec duration were used. Pain intensity (PI) was recorded with a combined numerical/analog descriptor scale and reported as area under curve. Tenderness (dolorimetry [DM], clinical pain intensity (Short form McGill [MG]), depression (Beck depression inventory [BDI]) and symptom report (Brief Symptom Inventory [BSI]) were assessed concurrently.

Summary of Results: As a group both HC and FM were more sensitive to the random than to the ascending pressure stimuli (HC: 16.3±2.4 *vs.*41.6±5.9 [PI-AM], p<.0001 and FM: 52.5±5.0 *vs.* 72.0±4.6, p<0.0001). The ratio of RAN/ASC was significantly lower in the group of FM patients (1.64±0.2 *vs.*3.78±0.8, p<.017) because of a subset of subjects with high expectancy (ASC>RAN). The FM patients were divided into two groups (RAN/ASC<1.1 = "high expectancy" [HE] and RAN/ASC >1.1 = "low expectancy [LE]). Only 9 (21%) had HE, and compared to LE these subjects reported significantly more clinical pain (MG scales: p<0.04-.001), more tenderness (DM pain threshold: 1.07±.013 *vs.*1.5±.01, p<.012), and higher somatic depression scores (BDI: 12.2±1.3 *vs.* 5.9±0.6, p<.02). BSI scores were not significantly different between HE and LE.

Conclusions: An increased pain response to the ascending (relative to the random) testing paradigm identifies a subgroup of FM patients with more severe disease, and/or an increased tendency to report pain and/or symptoms. These findings need to be extended and tested in the general population.

Individuals performing this study were supported in part by DAMD grants 17-96-1-6042 and 17-97-1-7361, and the Veteran's Administration

Preliminary Meeting Agenda

Tuesday, January 23, 2001

3:00 p.m. — 6:00 p.m.
Registration — *East Lower Foyer*

4:00 p.m. — 6:00 p.m.
Poster Board Setup — *Terrace Ballroom*

Wednesday, January 24, 2001

8:00 a.m.
Registration — *East Lower Foyer*

8:00 a.m. — 9:00 a.m.
Continental Breakfast Available — *East Lower Foyer*

8:00 a.m. — 4:00 p.m.
Poster Board Setup — *Terrace Ballroom*

Plaza Ballroom B

9:00 a.m. — 9:10 a.m.
Welcome — Kelley A. Brix

9:10 a.m. — 9:40 a.m.
Keynote Address — John R. Feussner

9:40 a.m. — 11:20 a.m.
Ongoing Longitudinal Follow-up Studies of Gulf War Veterans
(Moderator: Gregory C. Gray)
- Susan P. Proctor
- Howard M. Kipen
- Bradley N. Doebbeling
- Simon Wessely

Question and Answer Session

11:20 a.m. — 11:35 a.m.
BREAK

11:35 a.m. — 1:00 p.m.
Alternate Approaches to Case Definitions: Is There a Gulf War Syndrome?
(Moderators: K. Craig Hyams & Timothy R. Gerrity)
- William Reeves
- Simon Wessely
- Bradley N. Doebbeling
- Gregory C. Gray
- Peter Spencer

Question and Answer Session

1:00 p.m. — 2:30 p.m.
LUNCH BREAK

2:30 p.m. — 5:30 p.m.
Concurrent Platform Sessions

5:30 p.m. — 7:30 p.m.
Poster Session and Reception — *Terrace Ballroom*

Thursday, January 25, 2001

7:00 a.m. — 9:00 a.m.
Continental Breakfast Available — *East Lower Foyer*

7:00 a.m. — 8:25 a.m.
Clinical Sunrise Symposium I
(Moderator: Charles C. Engel)

Clinical Practice Guidelines: Health evaluation and screening for individuals presenting in primary care at risk for deployment related conditions.
- Oded Susskind

Clinical Practice Guidelines: Diagnosis and treatment strategies for patients with chronic multi-symptom illnesses (Chronic Fatigue Syndrome and Fibromyalgia).
- Daniel Clauw

Plaza Ballroom B

8:30 a.m. — 10:10 a.m.
Results of Neuropsychological Research of Gulf War Veterans
(Moderator: Drue H. Barrett)
- Peter Spencer
- Roberta F. White
- Joseph Barrash
- Anthony David

Question and Answer Session

10:10 a.m. — 10:25 a.m.
BREAK

10:25 a.m. — 12:30 p.m.
State of the Science Review: Potential Exposures to Sarin, Pyridostigmine Bromide, Anthrax Vaccine and Botulinum Toxoid
(Moderator: Barry W. Wilson)

12:30 p.m. — 2:00 p.m.
LUNCH BREAK

2:00 p.m. — 5:00 p.m.
Concurrent Platform Sessions

5:15 p.m. — 6:45 p.m.
Public Availability Session

(This session is designed to give veterans and interested members of the public an opportunity to discuss their concerns and questions with scientists currently researching Illnesses among Gulf War Veterans.)

Participating Officials and Scientists to Date:
- Mark Brown
- Charles C. Engel
- Michael E. Kilpatrick
- Simon Wessely
- Barry W. Wilson
- Roberta F. White

Preliminary Meeting Agenda (cont.)

Friday, January 26, 2001

7:00 a.m. — 9:00 a.m.
Continental Breakfast Available — *East Lower Foyer*

7:15 a.m. — 8:30 a.m.
Clinical Sunrise Symposium II
(Moderator: Steven C. Hunt)

Treatment Trials: Exercise/Behavioral Therapy (EBT) and Antibiotic Treatment (ABT). Preliminary lessons learned from controlled trials of treatments for the symptoms of undiagnosed illnesses in Gulf War veterans.
- Don Salisbury

Depleted Uranium (DU): Overview of the Baltimore Depleted Uranium Follow-up Program, and of the expanded DoD/VA program.
- Melissa A. McDiarmid

Plaza Ballroom B

9:00 a.m. — 9:45 a.m.
Force Health Protection: Strategies to Protect Deployed Forces
(Moderator: Rick Riddle)
- Robert G. Claypool
- John Moxley

9:45 a.m. — 10:00 a.m.
BREAK

10:00 a.m. — 11:40 a.m.
New Initiatives on Medical Surveillance
- K. Craig Hyams
- Gregory C. Gray
- Charles C. Engel
- Margaret A.K. Ryan
- Mark Rubertone

Combat Stress Control
- Elspeth Cameron Ritchie

Question and Answer Session

11:40 a.m. — 1:00 p.m.
LUNCH BREAK

1:00 p.m. — 4:30 p.m.
Clinical Session: Gulf War Veterans' Illness Demonstration Projects
(Moderator: Artie Shelton)

4:30 p.m.
Meeting adjourns

Preliminary Presenters to Date

Joseph Barrash, Ph.D.
Co-Director, Benton Neuropsychology Laboratory, Department of Neurology, University of Iowa College of Medicine

Robert G. Claypool, M.D.
Executive Director, Military and Veterans Health Coordinating Board, U.S. Department of Veterans Affairs

Daniel Clauw, M.D.
Associate Professor of Medicine, Georgetown University Medical Center

Anthony David, M.D.
Professor of Cognitive Neuropsychiatry, Department of Psychological Medicine, Institute of Psychiatry, Guy's, King's & St. Thomas's School of Medicine, London U.K. and Institute of Psychiatry

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Director and Senior Scientist, Center for Research on Occupational and Environmental Toxicology, Oregon Health Sciences University

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Research Director, Boston Environmental Hazards Center; Director of Clinical Neuropsychology Boston Veterans Administration Medical Center

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Bart Kuhn
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Barry W. Wilson, Ph.D.
Professor of Environmental Toxicology and Avian Sciences, University of California at Davis

Speaker Information/Presentation Format

Audiovisual Guidelines for the Keynote and Plenary Sessions: Sessions will be presented in double projection. Both a slide projector system and a computer with an LCD projection system will be provided in the Plaza Ballroom. Speakers must bring either one set of 35-mm slides or a disk for this purpose. OVERHEAD PROJECTORS WILL NOT BE AVAILABLE. Slides/images will be projected on two separate screens, one on each side of the presenters' platform.

Speakers should plan to arrive at the meeting room approximately 15 minutes before the session begins to give their slide carousels to the projectionist. A speaker ready room with audiovisual equipment will be available for preparation of presentations. Staff members will be available to assist you. If you plan to bring your presentation on disk, we ask that you give it to a staff member at the Speaker Registration Booth or in the Speaker Ready Room as soon as you arrive at the meeting.

Audiovisual Guidelines for the Concurrent Afternoon Platform Sessions: A single slide projector and a computer with an LCD projection system will be provided in the Concurrent General Platform Sessions. PIs whose abstracts are selected as Platform Presentations in the General Sessions must bring one set of slides or a disk for this purpose.

Computer Disk Format

If you plan to use the LCD projection system, your presentation must be on an IBM PC-compatible floppy diskette, CD-ROM, or Zip drive and must be in Microsoft Office 97 format (Word, PowerPoint, or Excel).

Slide Preparation

All slides should be duplicates, not originals, in case of loss or damage. Slides should be thumb-spotted by placing a mark in the upper right-hand corner of the slide when it is loaded properly in the slide tray, and numbered in the proper sequence. Use standard horizontal format. Vertical and super slides should be avoided. Extra slide carousels will be available. It is approximately 100 feet from the projection screens to the last row of the plenary conference room, so please plan your font sizes accordingly.

Poster Session Setup

PIs whose abstracts are selected for presentation at the meeting must have their posters assembled and ready for display in the Terrace Ballroom by 4:00 p.m., January 24, 2001. Poster boards will be available for setup between 4:00 p.m. and 6:00 p.m. on January 23 and 8:00 a.m. and 4:00 p.m. on January 24. Poster assignment numbers will be displayed in front of the exhibit hall as well as listed in the Program Booklet. Posters are to remain on display until 7:00 p.m., January 25. All materials must be removed by 12:00 noon on January 26. Please refer to the "Poster Format Guidelines."

Instructions for Poster Presentations

Abstracts scheduled for presentation in poster sessions will be grouped by topic, numbered, and listed in the final program.

Posters should be readable by reviewers 5 feet away. The message should be clear and understandable without oral explanation. Illustrations, labels, etc., must be attached to the poster board with thumbtacks, which will be available in the poster area. Do not write on the poster boards.

Please leave space in the upper left-hand corner of the poster board for a poster number. This number will be on your poster board when you arrive. A copy of your extended abstract should be posted to the right of the poster board number. A label indicating the extended abstract title, author, and the affiliation should be placed at the top of the poster board, to the right of the abstract. A label listing the funding source(s) must be displayed in the lower right corner of the poster board.

Poster Format Guidelines

The poster board surface area is 3′ 8″ high and 7′ 6″ wide (approximately 110cm x 230cm). The following guidelines have been prepared to help improve the effectiveness of poster communication.

1. Initial Sketch: Plan your poster early. Focus your attention on a few points. Try various styles of data presentation to achieve clarity and simplicity. Does the use of color help? What needs to be expressed in words? Suggest headlines and text topics.

2. Rough Layout: Enlarge your best initial sketch, keeping the dimensions in proportion to the final poster (see diagram). Ideally, the rough layout should be full size. A blackboard is a convenient place to work. Print the title and headlines. Indicate text by horizontal lines. Draw rough graphs and tables. This will give you a good idea of proportions and balance. If you are working with an artist, show him or her the poster layout. Ask associates for comments. This is still an experimental stage.

3. Final Layout: The artwork is complete. The text and tables are typed but not necessarily enlarged to full size. Now ask, is the message clear? Do the important points stand out? Is there a balance between words and illustrations? Is there spatial balance? Is the pathway through the poster clear?

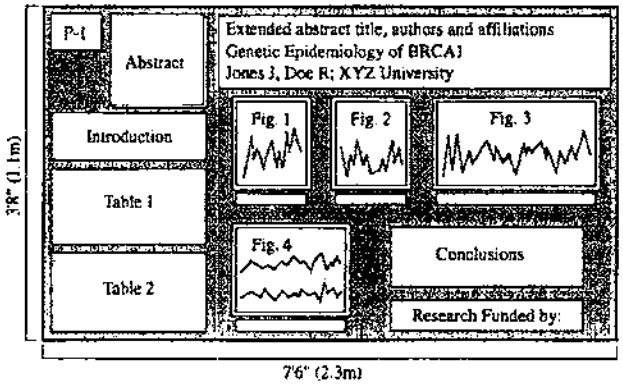
Speaker Information/Presentation Format (cont.)

4. Balance: The figures and tables should cover slightly more than 50% of the poster area. If you have only a few illustrations, make them large. Do not omit the text, but keep it brief. Be sure every illustration has a brief caption. The poster should be understandable without oral explanation.

5. Typography: Avoid abbreviations, acronyms, and jargon. Use a consistent type of style throughout. Use large type, for example, ORATOR. An 8 1/2" x 11" sheet of paper photostatically enlarged 50% makes the text readable from 5 feet.

6. Eye Movement: The movement (pathway) of the eye over the poster should be natural—down the columns or along the rows. Size attracts attention. Arrows, pointing hands, numbers, and letters can help clarify the sequence.

7. Simplicity: The temptation to overload the poster should be resisted. More material may mean less communication.



Logistical Information

Meeting Location
Hilton Alexandria Mark Center
5000 Seminary Road
Alexandria, Virginia 22311
(703) 845-1010

Hotel Accommodations
A block of hotel rooms has been reserved at the Hilton Alexandria Mark Center at the Government per diem rate for Washington DC ($118.00 plus tax). To make reservations participants must contact the Hilton directly at (703) 845-1010, by December 24, 2000. Be sure to identify yourself as a participant in the Illnesses among Gulf War Veterans' Meeting in order to receive this special rate. Reservation requests made after December 24 will be accepted on a space available basis only.

Registration
All participants must register by completing the enclosed Registration Form. Please return the form with your registration fee by December 15 to obtain the reduced registration rate. Registrations received after December 15 and on-site registration will be accepted at the late fee amount of $225. Registration confirmations will be sent either by e-mail or fax within 2 weeks of receiving payment.

Registration by December 15 = $175
Registration after December 15 = $225

The registration fee provides (1) admittance to all scientific and poster sessions, (2) continental breakfast each morning, Wednesday through Friday, (3) AM and PM refreshments concurrent with the Technical Program sessions, and (4) one copy of the conference Proceedings plus all conference materials. Advance registration is encouraged. The sole intent of the registration fee is to promote, enhance, and facilitate technical discussions and long-term professional relationships/ collaborations in Gulf War Veterans' Illnesses Research.

On-Site Registration
On-Site Registration will take place outside of the Plaza Ballroom in the Lower Foyer on Tuesday, January 23 from 3:00 p.m. to 6:00 p.m. and will begin again on Wednesday, January 24 at 8:00 a.m.

Continuing Education Credits
Continuing Medical Education (CME) credits for Physicians and Continuing Education Units (CEU) for Nurses will be provided through the Veterans Affairs for this meeting.

The VA Employee Education System (EES) is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians. The EES also is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation.

Continuing education hours will be determined and noted within the final agenda. A certificate of attendance will be awarded to participants and accreditation records will be on file at the VA EES.

In order to receive continuing education credit, participants must attend 100% of the program and complete an evaluation. A sign-in sheet for continuing education will be available at the registration table each morning for those persons desiring continuing education. An EES representative will be available to answer questions and provide assistance. Each physician and nurse should claim only those hours of credit that he/she actually spent in the educational activity.

Logistical Information (cont.)

The EES must ensure balance, independence, objectivity, and scientific rigor to all EES-sponsored educational activities. The intent of this disclosure is not to prevent faculty with a significant financial or other relationship from presenting materials, but rather to provide the participant with information on which they can make their own judgements. It remains for the participant to determine whether the faculty/writers/ authors interests or relationships influence the materials presented with regard to exposition or conclusion. When an unapproved use of a FDA-approved drug or medical device, or an investigational product not yet FDA approved for any purpose is mentioned, EES requires disclosure to the participants.

Air and Ground Transportation

The Hilton Alexandria Mark Center is located approximately 7 miles from Reagan National Airport and 20 miles from Washington Dulles International Airport. The hotel provides complimentary shuttle transportation to and from Reagan National Airport, the Pentagon, and Pentagon City Mall/Metro every hour from 6: 00 a.m. until 11:00 p.m., daily. To arrange shuttle service, you must call the hotel at (703) 845-1010. Vans are equipped for en-route check-in. The taxi fare from Dulles International Airport to the hotel is approximately $30. Garage parking for overnight guests is $5.00 daily and $8.00 for those attending during the day only.

Driving Directions

From Downtown Washington, DC

Take I-395 South toward Richmond. Follow for 7 miles to Exit 4, Seminary Road West. Continue one block to the Hilton on the left.

From the South (Richmond)

Take I-395 North to I-395 exchange toward Alexandria and Washington, DC. Take Exit 4, Seminary Road West. Continue one block to the Hilton on the left.

From the North (Baltimore)

Take I-95 South to Virginia. Take exit I-395 North toward Washington, DC. Take Exit 4, Seminary Road West. Continue one block to the Hilton on the left.

From Dulles Airport

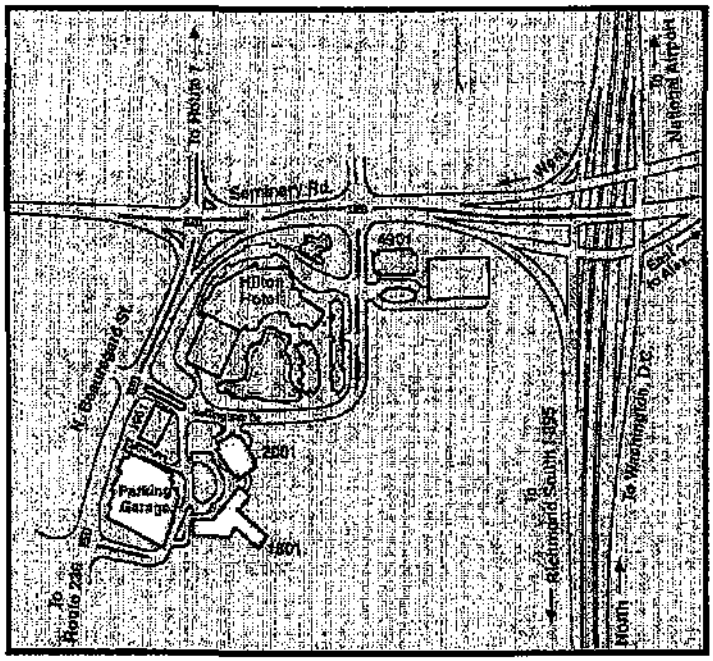
Take Dulles Access Road to I-495 South toward Richmond. Take I-395 North toward Washington, DC (left exit). Take Exit 4, Seminary Road West. Continue one block to the Hilton on the left.

Lunch

Lunches are not provided during the meeting. Two restaurants, the Plaza Café and Halyards, are located in the lower lobby of the hotel. Additional restaurants are located within walking distance of the hotel.

Special Assistance

In compliance with the Americans with Disabilities Act, the conference organizers and the Hilton Alexandria will make all reasonable efforts to accommodate disabled persons with special requirements. Please contact Ms. Sandra Carlson (301-228-3114) or Ms. Shannon Smith (301-228-3148) if you require special assistance.



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Sample Abstract

PAIN SENSITIVITY IN PATIENTS WITH FIBROMYALGIA (FM) PART II: EXPECTANCY EFFECTS ON PAIN MEASUREMENTS

F. Petzke[1], D.J. Clauw[1] and R.H. Gracely[2]

Department of Medicine, Georgetown University Medical Center[1], and NIDR, National Institutes of Health, Bethesda[2], MD

Introduction: Fibromyalgia is characterized by chronic widespread pain, tenderness and increased sensitivity to various sensory stimuli. Some have suggested that hypervigilance or increased "expectancy", and not physiological factors, may cause the change in somatosensory perception in this and related conditions. One method of assessing the role of expectancy in sensory testing paradigms is to present stimuli in both an ascending and random fashion. In ascending paradigms, where the individual can anticipate the next stimulus, expectancy is felt to play a role in symptom reporting, whereas this effect is eliminated in random paradigms.

Hypothesis: The concurrent use of ascending and random testing paradigms will identify some FM subjects who over-report pain in ascending paradigms (relative to the value obtained in random testing), and these subjects will have certain psychological and clinical characteristics.

Procedures: Pressure pain sensitivity was assessed in 42 [illegible] with FM and 27 age and gender matched HC. Both ascending (0.45-kg increments up to 4.54 kg [ASC]) and random (7 stimuli repeated twice in random order [RAN]) rectangular pressure stimuli to the thumbnails of 5-sec duration were used. Pain intensity (PI) was recorded with a combined numerical/analog descriptor scale and reported as area under curve. Tenderness (dolorimetry [DM], clinical pain inventory (Short form McGill [MG]), depression (Beck depression inventory [BDI]) and symptom report (Brief Symptom Inventory [BSI]) were assessed concurrently.

Summary of Results: As a group both HC and FM were more sensitive to the random than to the ascending pressure stimuli (HC: 16.3±2.4 *vs.*41.6±5.9 [SEM], p<.0001 and FM: 52.5±5.0 *vs.* 72.0±4.6, p<0.0001). The ratio of RAN/ASC was significantly lower in the group of FM patients (1.64±0.2 *vs.*3.78±0.8, p<.017) because of a subset of subjects with high expectancy (ASC>RAN). The FM patients were divided into two groups (RAN/ASC<1.1 = "high expectancy" [HE] and RAN/ASC >1.1 = "low expectancy [LE]). Only 9 (21%) had HE, and compared to the LE these subjects reported significantly more clinical pain (MG scales: p<0.04-.001), more tenderness (DM pain threshold: 1.07±.013 *vs.*1.5±.01, p<.012), and higher somatic depression scores (BDI: 12±1.3 *vs.* 5.9±0.6, p<.02). BSI scores were not significantly different between HE and LE.

Conclusions: An increased pain response to the ascending (relative to the random) testing paradigm identifies a subgroup of FM patients with more severe disease, and/or an increased tendency to report pain and/or symptoms. These findings need to be extended and tested in the general population.

Individuals performing this study were supported in part by DAMD grants 17-96-1-6042 and 17-97-1-7361, and the Veteran's Administration

SAIC LSO(Frederick) Fax:1-301-698-6188 Jan 8 '01 12:43 P.02

FOR LTC Paul Smith — (703) 681-0022

The Research Working Group:
Military and Veterans Health Coordinating Board

Conference on Illnesses among Gulf War Veterans: A Decade of Scientific Research

Hilton Alexandria
Mark Center
Alexandria, Virginia
January 24-26, 2001

Program and Abstract Book

MEETING AGENDA

Tuesday, January 23, 2001

3:00 - 6:00 PM	REGISTRATION	*East Lower Foyer*
4:00 - 6:00 PM	POSTER BOARD SET-UP	*Terrace Ballroom*

Wednesday, January 24, 2001

8:00 AM	REGISTRATION Continental Breakfast Available	*East Lower Foyer*
8:00 AM - 4:00 PM	POSTER BOARD SET-UP	*Terrace Ballroom*

Plaza Ballroom

9:00 AM - 1:30 PM	**PLENARY SESSION**	Chair, Kelley A. Brix
9:00 AM	Welcome	Kelley A. Brix
9:10 AM	Keynote Address: Gulf War Research: Science, Policy, and Politics	John R. Feussner
9:40 - 11:25 AM	*Ongoing Longitudinal Follow-up Studies of Gulf War Veterans ◆ Moderator, Gregory C. Gray*	
9:45 AM	Longitudinal Follow-up of Gulf War Veterans: The Devens Cohort Study	Susan P. Proctor
10:05 AM	Longitudinal Examination of Symptom Patterns among Gulf War Registry Veterans	William K. Hallman
10:25 AM	Solving Challenges in Longitudinal Research on Gulf War Illnesses	Bradley N. Doebbeling
10:45 AM	View from the United Kingdom	Simon Wessely
11:05 AM	Questions and Answers	
11:25 AM	BREAK	
11:45 AM - 1:30 PM	*Alternate Approaches to Case Definitions: Is There a Gulf War Syndrome? ◆ Moderators, K. Craig Hyams and Timothy R. Gerrity*	
11:55 AM	CDC Air Force Study: Development of a Working Case Definition	Drue H. Barrett
12:05 PM	Criteria for a Valid Case Definition	Robert W. Haley
12:15 PM	Is There a Gulf War Syndrome? Round 3	Simon Wessely
12:25 PM	Approaches to Case Definition in The Iowa Study Syndrome Analysis	Bradley N. Doebbeling
12:35 PM	Factor Analysis of Self-Reported Symptoms: Does It Identify a Gulf War Syndrome?	James D. Knoke
12:45 PM	Single and Multiple Symptom-Based Case Definitions Describe Persistent Unexplained Illnesses in Gulf War Veterans	Peter Spencer
12:55 PM	Questions and Answers	
1:30 - 3:00 PM	LUNCH BREAK	

Meeting Agenda (cont.)

3:00 - 5:10 PM	**CONCURRENT PLATFORM SESSIONS**	
3:00 - 3:10 PM	**SESSION A: EPIDEMIOLOGY I** Co-Chairs: Bradley N. Doebbeling and Han K. Kang	*Beech A & B*
3:10 - 3:35 PM	**Health Services Utilization Five Years Post Gulf War** ◆ Bradley N. Doebbeling	
3:35 - 4:00 PM	**Health Care Utilization and Disability of Gulf War Era Women** ◆ Tomoko R. Sampson	
4:00 - 4:20 PM	**BREAK**	
4:20 - 4:45 PM	**Prospective Follow-up of Health Status in Gulf War Veterans and Era Controls** ◆ Margaret D. Voelker	
4:45 - 5:10 PM	**Spatial Analysis (Using GIS Techniques) of Gulf War Troop Location Data in Relationship with Symptom Reports** ◆ Susan P. Proctor	
3:00 - 3:10 PM	**SESSION B: TOXICOLOGY I** Co-Chairs: Mark Brown and James Romano	*Plaza I*
3:10 - 3:35 PM	**Sarin-Induced Increase in Blood-Brain Barrier (BBB) Permeability Is Augmented by Co-Exposure with Stress, Pyridostigmine Bromide (PB), DEET, and Permethrin in Rats** ◆ Mohamed B. Abou-Donia	
3:35 - 4:00 PM	**Effects of Inhalation Exposure to Low Levels of Sarin in Fischer 344 Rats** ◆ Rogene F. Henderson	
4:00 - 4:20 PM	**BREAK**	
4:20 - 4:45 PM	**Neuroimmune Effects of Subclinical Doses of Sarin: Sarin Suppresses T Cell Responsiveness through the CNS** ◆ Mohan L. Sopori	
4:45 - 5:10 PM	**Depleted Uranium Fragments Cause Soft Tissue Sarcomas in the Muscles of Rats** ◆ Fletcher F. Hahn	
3:00 - 3:10 PM	**SESSION C: TREATMENT** Co-Chairs: Daniel J. Clauw and Simon Wessely	*Plaza II*
3:10 - 3:35 PM	**Measurement of Tenderness in Gulf War Veterans: What Does It Tell Us?: Results from the VA Cooperative Study #470** ◆ Daniel J. Clauw	
3:35 - 4:00 PM	**Physical Functional Status and Its Relationship to Common Symptoms of Chronic Multisymptom Illnesses in Gulf War Veterans: Results from the VA Cooperative Study #470** ◆ David A. Williams	
4:00 - 4:20 PM	**BREAK**	
4:20 - 4:45 PM	**Predicting Costs of VA Health Care for Gulf War Veterans** ◆ M. Jan Tackett	
4:45 - 5:10 PM	**Doxycycline Therapy of Mycoplasma Positive Veterans with Gulf War Illness** ◆ Sam T. Donta	
3:00 - 3:10 PM	**SESSION D: NEUROLOGICAL, NEUROPSYCHOLOGICAL, NEUROBIOLOGY OF STRESS** Co-Chairs: Timothy R. Gentry and Karl Friedl	*Plaza III*
3:10 - 3:35 PM	**Effects of Pyridostigmine Bromide on Physiology and Performance in Humans** ◆ Mary R. Cook	

MEETING AGENDA (CONT.)

3:35 - 4:00 PM	**Side Effects of Low-Dose Pyridostigmine Bromide Are Not Related to BCHE Genotype or Enzyme Inhibition** ◆ Mary R. Cook	
4:00 - 4:20 PM	BREAK	
4:20 - 4:45 PM	**Heart Rate Variability in Ill Gulf War Veterans, Fibromyalgia Patients, and Healthy Controls** ◆ Timothy R. Gentry	
4:45 - 5:10 PM	**Abnormal Circadian Variation in Autonomic Nervous System Activity in Ill Gulf War Veterans** ◆ Robert W. Haley	
5:30 - 7:30 PM	**POSTER SESSION AND RECEPTION**	*Terrace Ballroom*

Thursday, January 25, 2001

8:00 - 9:00 AM	**Continental Breakfast**	*East Lower Foyer*
7:30 - 8:45 AM	**CLINICAL SUNRISE SYMPOSIUM I:** **Clinical Practice Guidelines ◆ Moderator, Charles C. Engel**	*Beach A&B*
	Post Deployment Health Evaluation and Management	Oded SussKind
	Diagnosis and Treatment Strategies for Patients with Chronic Multi-Symptom Illnesses	Daniel J. Clauw

Plaza Ballroom

9:00 AM - 12:30 PM	**PLENARY SESSION**	
	Results of Neuropsychological Research of Gulf War Veterans ◆ Moderator, Drue H. Barrett	
9:05 AM	**Summary of Five Years of Neuropsychological Research of Gulf War Veterans at the Portland Environmental Hazards Research Center**	Daniel Storzbach
9:25 AM	**Neuropsychological Functioning in Persian Gulf War Veterans: Studies from Boston Environmental Hazard Center**	Roberta F. White
9:45 AM	**Assessment of Cognitive Dysfunction in Gulf War Veterans: The Iowa Gulf War Case-Validation Study**	Joseph Barrash
10:05 AM	**A Controlled Study of Neuropsychological Functioning and Mood Disorders in U.K. Veterans in the Gulf War**	Anthony S. David
10:25 AM	**Questions and Answers**	
10:40 - 10:55 AM	BREAK	
10:55 AM	***State of the Science: Potential Exposure to Sarin, Pyridostigmine Bromide, Depleted Uranium, and Vaccines ◆ Moderator, Barry W. Wilson***	
11:00 AM	**The Nerve Agent Release at Khamisiyah Pit**	Michael Abreu
11:40 AM	**Report of the Institute of Medicine Committee on Health Effects Associated with Exposures Experienced during the Persian Gulf War**	Harold C. Sox
12:20 PM	**Questions and Answers**	
12:30 - 2:00 PM	LUNCH BREAK	

MEETING AGENDA (CONT.)

2:00 - 4:35 PM	**CONCURRENT PLATFORM SESSIONS**	
2:00 - 2:10 PM	**SESSION E: EPIDEMIOLOGY II** Co-Chairs: Michael B. Kilpatrick and John T. Graham	*Beech A&B*
2:10 - 2:35 PM	**Anthrax Vaccination and Self-Reported Symptoms, Functional Status, and Medical Conditions in the National Health Survey of Gulf War Era Veterans and Their Families** ◆ Clare M. Mahan	
2:35 - 3:00 PM	**Histopathologic Study of Skin Biopsies in Gulf War Veterans: The Kuwait Registry, AFIP** ◆ Charles S. Specht	
3:00 - 3:20 PM	**BREAK**	
3:20 - 3:45 PM	**How Many Veterans are Affected by Gulf War-Related Health Problems? A Review of Population-Based Estimates** ◆ Lea Steele	
3:45 - 4:10 PM	**The Gulf Veterans' Medical Assessment Programme (GVMAP) London (UK) - A Case Series of 3,000 Cases** ◆ Harry A. Lee	
4:10 - 4:35 PM	**The Impact of Military Deployments on Health: A Comparison of the Post Deployment Hospitalization Risk between U.S. Veterans of the Gulf War and Veterans of Subsequent Peacekeeping Missions to Bosnia and Southwest Asia** ◆ Bess Smith	
2:00 - 2:10 PM	**SESSION F: TOXICOLOGY II** Co-Chairs: Barry W. Wilson and Mark Brown	*Plaza I*
2:10 - 2:35 PM	**Interaction of DEET, Permethrin, and Pyridostigmine with Cholinergic Receptors and Cholinesterases** ◆ Richard K. Gordon	
2:35 - 3:00 PM	**Systemic Pyridostigmine Suppresses Inflammatory Cytokines Released after Topical Permethrin and DEET Exposure** ◆ Nancy A. Monteiro-Riviere	
3:00 - 3:20 PM	**BREAK**	
3:20 - 3:45 PM	**Running and Restraint Stress Fail to Influence Pyridostigmine-Induced Acetylcholinesterase Inhibition in Rat Brain** ◆ Carey N. Pope	
3:45 - 4:10 PM	**Low Level Effects of Pyridostigmine Bromide and Delayed Neuropathy Organophosphates in Experimental Animals** ◆ Barry W. Wilson	
2:00 - 2:10 PM	**SESSION G: PSYCHOLOGICAL/PSYCHOSOCIAL** Co-Chairs: Roberta F. White and Charles C. Engel	*Plaza II*
2:10 - 2:35 PM	**Who Believes They Have Gulf War Syndrome?** ◆ Trudie Chalder	
2:35 - 3:08 PM	**Neuropsychological Functioning in Danish Gulf War Veterans** ◆ Susan P. Proctor	
3:00 - 3:20 PM	**BREAK**	
3:20 - 3:45 PM	**The Impact of Sexual Assault and Harassment on Posttraumatic Stress Disorder among Deployed Persian Gulf Veterans** ◆ Erick K. Ishii	

TOX

MEETING AGENDA (CONT.)

3:45 - 4:10 PM	**Fatigue, Pain, Cognitive Symptoms and Mental Health-Related Functioning among Gulf Vets with Chronic Multisymptom Illnesses: Results from the VA Cooperative Study #470** ◆ Charles C. Engel	
4:10 - 4:35 PM	**Are Veterans Seeking VA Primary Care as Healthy as Those Seeking Department of Defense Primary Care? A Look at Gulf War Veterans' Symptoms and Functional Status** ◆ Ralph D. Richardson	
2:00 - 2:10 PM	**SESSION II: FORCE HEALTH PROTECTION/ PREVENTION/SURVEILLANCE** Co-Chairs: Brian J. Balough and Craig Postlewaite	*Plaza III*
2:10 - 2:35 PM	**Induction and Detection of Antibodies to Squalene** ◆ Carl R. Alving	
2:35 - 3:00 PM	**Comparison of Psychological Health Assessments for Soldiers Deploying to Kosovo with and without Deployment Experience** ◆ James W. Ness	
3:00 - 3:20 PM	**BREAK**	
3:20 - 3:45 PM	**Characteristics of Army Personnel Remaining in the National Guard Six Years after Gulf War Deployment: A Descriptive Analysis** ◆ Susan P. Proctor	
3:45 - 4:10 PM	**DoD-Wide Surveillance for Ill-Health Requiring Hospitalization Potentially Associated with Anthrax Immunization: 1998 Data** ◆ Paul A. Sato	
4:10 - 4:35 PM	**Post-Combat Syndromes from 1900: An Intra- and Inter-War Comparison** ◆ Edgar Jones	
5:15 - 6:45 PM	**PUBLIC AVAILABILITY SESSION** (This session is designed to give veterans and interested members of the public an opportunity to discuss their concerns and questions with scientists currently researching Illnesses among Gulf War Veterans.) Participants: ◆ Mark Brown ◆ Simon Wessely ◆ Charles C. Engel ◆ Roberta F. White ◆ Michael E. Kilpatrick ◆ Barry W. Wilson	*Magnolia Room*

Friday, January 26, 2001

8:00 - 9:00 AM	**Continental Breakfast**	*East Lower Foyer*
7:15 - 8:55 AM	**CLINICAL SUNRISE SYMPOSIUM II:** ◆ Moderator, Stephen C. Hunt	*Beech A&B*
7:20 - 8:05 AM	**Medical Surveillance Results in DU-Exposed Gulf War Veterans**	Melissa A. McDiarmid
8:05 - 8:50 AM	**A Review of the VA Gulf War Registry Program**	Don Salisbury
	A Model of the Clinical Management of Symptoms	Ralph D. Richardson & Stephen C. Hunt

CMAT Control # (156)
2001103-0000037

THEDEPUTYSECRETARYOFDEFENSE
WASHINGTON, D.C. 20301-1000

17 JUL 2000

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
UNDER SECRETARIES OF DEFENSE
ASSISTANT SECRETARIES OF DEFENSE
GENERAL COUNSEL, DEPARTMENT OF DEFENSE
INSPECTOR GENERAL, DEPARTMENT OF DEFENSE

SUBJECT: Temporary Slowing and Future Resumption of Anthrax Vaccine Immunization Program (AVIP)

On May 18, 1998, Secretary Cohen, based on the recommendations of the Chairman and Members of the Joint Chiefs of Staff, directed implementation of the AVIP for the total force to protect against the very real threat of anthrax as a biological weapon. Since then more than 455,000 personnel have received vaccinations. We now face an unexpected delay in the availability of vaccine supplies approved by the Food and Drug Administration (FDA) as safe and effective. We must therefore execute an orderly, temporary slowing of the AVIP until additional FDA-approved vaccine becomes available. The following actions shall be taken:

1. The current scope of the AVIP shall be maintained in the areas of highest threat, Southwest Asia and Korea. Personnel assigned or deployed on the ground in these areas for at least 30 days, including personnel newly assigned for such a period and personnel afloat on contiguous waters who have potential to be committed ashore, shall continue under the AVIP. Vaccinations for these personnel should begin prior to arrival in theater and may commence up to 45 days prior to deployment. All vaccinations will be provided consistent with the FDA-approved vaccination schedule. During this period of slowed program execution, the 30 day policy described above will replace the previously established "one day" policy.

2. Effective immediately, initiation of the vaccine series for personnel other than those described in paragraph 1 above under the AVIP total force program shall be deferred during this period of slowed execution.

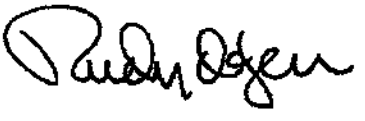
3. The Secretary of the Army, as Executive Agent of the AVIP, shall issue instructions to recover from units worldwide, to the extent feasible, unopened vials of vaccine that can be redirected for use as authorized above by units assigned or deployed to the designated high threat areas.

4. With respect to vaccine supplies for which the Executive Agent determines that redirection to the high threat areas is not feasible, units are authorized to use the remaining vaccine on hand to continue the normal six-vaccination series as long as supplies last for personnel who have previously begun the series. DoD policies on medical and administrative exemptions remain in effect. With the exception of highest risk personnel described in paragraphl above and this use of supplies on hand, next scheduled doses for other personnel shall be deferred until additional vaccine is available. At that time personnel for whom vaccinations were deferred will resume vaccinations consistent with guidance from the Center for Disease Control and Prevention Advisory Committee on Immunization Practices and consultation with the FDA.

5. Informational materials provided topersonnel during this period of slowed program implementation shall, in addition to addressing benefits, side effects, and other medical information, specifically advise personnelof the current status of the program and its effect on dosage schedules.

6. The Executive Agent, working in conjunction with other elements of the Department of Defense, as appropriate, shall: (a) take all appropriate steps to seek to restore the supply of safe and effective anthrax vaccine for the resumption of the full-scale AVIP not later than January 2001 and for the long-term maintenance of the program; and (b) during the period of limited vaccine supply, establish in coordination with the Assistant Secretary of Defense (Health Affairs) contingency arrangements to assure the availability of vaccine for post-exposure treatment in contextsof both military operations and support for domestic agency emergencyresponse.

The AVIP is a necessary and successful program. It shall be fully resumed as soon as possible. In the meantime, the other pillars of our Force Health Protection Program--protective gear, biological agent detectors and antibiotic treatment--willhelp protect personnel at risk. Programs to educate and inform personnel about the biological agent threat and the safety and effectiveness ofanthrax vaccine will continue during this period of slowed implementation and upon full program resumption.



CMAT Control #
2001103-0000039
(157)

OFFICE OF THE DEPUTY SECRETARY OF DEFENSE

1010 DEFENSE PENTAGON
WASHINGTON, DC 20301-1010

27 Nov 00

MEMORANDUM FOR VICE CHIEF OF STAFF, ARMY

SUBJECT: Additional Temporary Slowing and Future Resumption of the Anthrax Vaccine Immunization Program (AVIP)

Faced with the continued delay in the availability of Food and Drug Administration (FDA) released anthrax vaccine, we must further reduce consumption of vaccine until additional FDA-released anthrax vaccine becomes available. Effective immediately, the Deputy Secretary of Defense has directed that the area of execution as defined in the July 17, 2000 DEPSECDEF memorandum, subject: Temporary Slowing and Future Resumption of Anthrax Vaccine Immunization Program (AVIP), is redefined from Southwest Asia and Korea to only Southwest Asia (Boots-on-Ground SWA Plus Option). All other slowdown criteria directed in the July 17, 2000 policy remain in effect. This policy has been coordinated with the Joint Staff, applicable CINCs, and the SECDEF.

Request you notify the other Services' AVIP Senior Military Officials of this decision, and direct Services' implementation through execution messages as soon as possible to enable the earliest implementation.

Randall L. West
Major General, USMC
Senior Advisor to the
Deputy Secretary of Defense for
Chemical and Biological Protection

GWI, MR, MD (158) INFO

SECRETARY OF DEFENSE CORRESPONDENCE ROUTING SLIP

Action Agency: **ASD (PUBLIC AFFAIRS)**
Action Required: APPROPRIATEACTION
Coordinate With:.

Remarks: *IDENTICAL INVITE TO SECDEF- REFERENCE **U13671-01**. POSTMARKED **08/03/01**.*

Special Instructions:

Suspense Date: **August/22/2001**	Routing Date: **August/9/2001**	OSD CONTROL #: **U13672-01**

INFORMATION DISTRIBUTION

CMAT Control #
2001240-0000038

OFFICE

DEPUTY SECRETARY OF DEFENSE
EXECUTIVE SECRETARY
UNDER SECRETARY FOR PERSONNEL & READINESS
ASD (Health Affairs)
SECRETARY OF THE ARMY
EXECUTIVE SECRETARY REAR

July 31, 2001

OFFICE OF THE
SECRETARY OF DEFENSE

2001 AUG -9 PM 2:27

Mr. Paul **Wolfowitz**
Deputy Secretary of Defense
1010 Defense Pentagon
Washington D.C., 20301-1000

Mr. wolfowitx:

You are cordially invited to attend a rally organized to present facts concerning the use of the Anthrax Vaccine Absorbed (AVA) on the men and women of the US Armed Forces.

A colleague, Robin Hawes, and myself are sponsoring the even on September **15th**, 2001 **from** 12:00 p.m. – 3:00 p.m. on the front steps of the state capitol located in Lansing, Michigan. Your presence is **respectfully** requested as a participant in a panel discussing the Anthrax Vaccine Immunization Program **(A.V.I.P)**. Additional panel members will include: Dr. Meryl **Nass,** former USAF Major Sonnie Bates, former USAF COL Redmond Handy, and other current and former members of the Armed Forces who have had severe reactions to the Anthrax vaccine such as former USAF Senior Airman Tom Colosimo and former USA Major John **Irelan.**

Personally, I was in the military for nine years. My career came to a halt due to the AVIP. I received four shots of the series **from** late 1998 until early 1999. **After** the fourth shot, I began to notice symptoms ranging **from** chronic fatigue, vertigo, migraines, achy joints/muscles, to **short**-term memory loss. I was still experiencing these symptoms at the time my **fifth** shot came due. My chain of command was insistent I receive my **fifth** shot. I refused due to my previous reactions. As a result, I wasultimately discharged with an "Honorable" discharge.

We are offering you the opportunity to share with the American public and the media, your views of the program and its impact on America's Armed Forces. Your presence is important in order that an open and honest forum can be achieved. By inviting and advertising the presence of both sides, we will allow a public airing of **both** the concerns of the troops as well as the position of the Defense Department. Press releases are going to be made to a variety of mainstream television and print media to maximize coverage.

For planning purposes, it would be helpful and appreciated to receive a prompt response to our invitation as soon as possible **from** you or a representative of your office. I have enclosed a copy of our brochure for review. If an **official** request through a public affairs department in the Pentagon is required, please provide me with this information as soon as possible as well. I thank you in advance for your consideration.

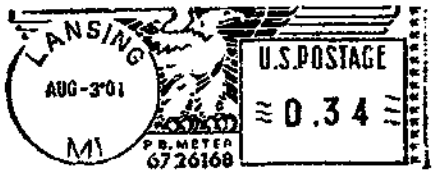
Sincerely,

Randi Allaire

Encl: Brochure

U13672/01

Randi Allaire
708 South **Pennsylvania** Ave.
Lansing, MI 48912



Mr.. Paul **Wolfowitz**
Deputy Secretary of Defense
1010 Defense Pentagon
Washington **D.C.,** 20301-1000

20301+1000

Hosted by: Ms. Randi Allaire & Mrs. Robin Hawes (formerly Smith-Groll)

Ms. Randi Allaire

Ms. Robin Hawes

Ms. **Allaire** belonged to the Armed Services for nine years, and was a member of the 110" Fighter Wing, Air National Guard, MI, for her remaining 3½ years in service. She received her 4th shot in March of 1999, **and** became very ill with symptoms ranging from short-term memory loss, vertigo, chronic fatigue, migraines, shortness of breath and **aching** joints/muscles. She received no medical treatment **from** the military, only denials. Due to her continuing illness, she **refused** the 5th shot, and was ultimately discharged under Honorable Conditions. She has testified in **front** of Congress, and has devoted her spare time to helping and supporting service members with the same challenges.

Ms. Hawes **belonged** to the Armed Forces with over 14 years of service. She was a member of the 110th Fighter Wing, Aii National Guard, Battle Creek, MI. She received her 4th anthrax **vaccination** in March of 1999. Following the vaccination she became extremely ill with symptoms ranging **from tremors** in her right arm, chronic fatigue, migraines, rashes, vertigo, shortness' of breath, abdominal cramping and memory loss. Because of her illness, the National **Guard** Bureau medically disqualified her from continued military service. Subsequently she was discharged from the 110th Fighter Wing. **Robin** is a mother of four, and has also testified in front of Congress.

Speakers & Special Guests

Dr. Meryl Nass
MAJ **(Former) Sonnie** Bates
LTC (Retired) Redmond Handy
SRA **(Former)** Tom Colosimo
MAJ Jon Irelan

- ***Other special speakers to be announced at the event***

Biographies

Dr. Meryl Nass - Dr. Nass is a practicing physician in her civilian occupation. She has been actively researching the **anthrax** vaccination for over ten years, and is considered an expert in this field. By default, she has become an activist against the A.V.I.P. She has testified numerous times before congress and the House **Sub**-Committee. Her testimonies are yet to be **refuted** by the Department of Defense. For more information about Dr. **Nass,** please visit her **website** at:
http://www.anthraxvaccine.org

SRA (former) Tom Colosimo– SRA Tom Colosimo has had over 700 blackouts since receiving the Anthrax Vaccine. He has extreme chemical sensitivity where **almost** any chemical will send him into a delirium episode. The Air Force awarded him a mere 64% disability. Currently he is unemployable. At this time, he has been rated by Social. ***Security*** as being 100% disabled, and now waits a decision from the Veteran's Administration (VA). To find out more information about Tom, please visit his **website** at:
http://www.tomcolosimo.com

MAJ (Former) Sonnie Bates - MAJ Sonnie Bates was transferred to Dover Air Force Base (APB) in August of 1999. He was the Chief **Operations** and Analysis Branch for the 436th Operations Group. **MAJ** Bates began noticing **severe** side effects in the pilots of the unit who had received the **Anthrax** Vaccination and began his own investigation of the cluster. 252 **questionnaires** were sent to the pilots **of** Dover APB. 139 were completed and returned. The reactions he discovered among this group ran parallel with Gulf War Syndrome (GWS).
MAJ Bates **then** refused to receive the Antbrax Vaccine. He was ultimatcly discharged Honorable Under General Conditions, despite his exemplary record and accomplishments. To learn more about MAJ Bates and the information he has discovered through research, visit his **website** at http://www.majorbates.com

Remember the warning **from** President Eisenhower's farewell address: ***"Only an alert and knowledgeable citizenry can compel the proper meshing of the huge industrial and military machinery of defense with our peaceful methods and goals, so that security and liberty may prosper together."***

SUPPORT OUR TROOPS!
Help Stop the Experimentation being conducted on our Soldiers!
ANTHRAX-NO!

Biographies Cont'd

MAJ Jon Irelan – MAJ Jon Irelan received four anthrax vaccinations. After receiving his 4th vaccination,, he began to develop loss of facial hair, severe loss of testosterone, rapid weight gain, mood swings, severe groin pain, a substantial loss of muscular strength and severe fatigue. Military physicians refused to connect his symptoms to the anthrax vaccine. A report recording symptoms was never even filed- by the military on his behalf.

COL. (Retired) Redmond Handy - a vocal critic of the military's mandatory Anthrax Vaccination Immunization Policy (A.V.I.P.). He founded the National Organization of Americans Battling Unnecessary Service member Endangerment (NO ABUSE), After extensive research, and meeting those ill from the shots, Mr. Handy retired in protest from his Pentagon position as a full bird Colonel in the Air Force Reserve. He has testified before the House National Security Subcommittee and the House Armed Services Personnel Subcommittee. Mr. Handy has helped vaccine victims legitimately avoid further shots, obtain Congressional assistance, and receive shot-related disability rulings from the Veteran's Administration. As an expert witness, he has discussed the vaccine's problems on many national and local media forums and has written several articles.

How You Can Help

Ben Franklin has been credited as saying, "Justice will not be served until those who are unaffected are as outraged as those who are." Until the public becomes outraged at the unethical treatment of our national heroes who keep the world safe for democracy, experiments like the A.V.I.P will continue. **This program is only the beginning as the Pentagon has 18 new biowarfare vaccines under development, along with an HIV/AIDS shot** Our men and women of the Armed Forces are not second-class citizens to be used as guinea pigs. You can: 1. Seek state legislation that prohibits National Guard commanders from using experimental medicines. 2. Write and call your Representatives and Senators and demand better for our fighting force. 3. If our elected Government officials cannot provide better for our soldiers, demand and vote for an official who will! 4. And when you have an opportunity, please thank a veteran for preserving our rights of free speech and voting power.

For farther information on the Anthrax Vaccine:
http://www.anthraxvaccine.org
http://www.majorbates.com
http://www.enter.net/~jfsorg
http://www.jamesmadisonproject.org
http://www.anthraxvaccine.net
http://www.dallasnw.quik.com/cyberella

For further information on organizations to become a member of in protecting our troops, contact: rollingresistance@home.com

BECOME INVOLVED! Together we can help ensure the safety of this nation and those who defend it..

ROLLING RESISTANCE

2001

National Gathering to Support American Citizens in Uniform Suffering from the Pentagon's Anthrax Vaccine

Victims and Experts Discuss Corruption & Consequences

Come Find Out What The Pentagon Doesn't Want You To Know

Sign an FDA petition to destroy quarantined vaccine stock

September 15, 2001
12:00 p.m. – 3:00 p.m.
Lansing, Michigan
Steps of the State Capitol

(Live band beginning at 11:30 am.)

Sponsored in part by: The Anthrax Vaccine Network (AVN) &The National Organization of Americans Battling Unnecessary Servicemember Endangerment (NO ABUSE)

CMAT Control # (159)
2002035-0000025

BP

Memorandum

DATE: September 20, 1999

TO: Secretary Cohen
Deputy Secretary Hamre
Gen. Shelton
Under Secretary de Leon

FROM: Ken Bacon

RE: Gulf War illness and Anthrax

cc: Bob Tyrer, Dr. Bailey, Dr. Rostker, Ms. Berkowsky

I want to call your attention to a development in' our continuing work on Gulf War Illness and a planned press announcement that could have implications for the anthrax vaccination program.

In mid October Bernie Rostker plans to announce the results of a Rand Corp. review of literature about pyridostigmine bromide, which was given to about 200,000 soldiers during the Gulf War to protect them against **soman**, a nerve agent. The review concludes that "PB cannot be ruled out as a possible contributor to the development of unexplained or undiagnosed illness in some PGW veterans." Any hint that a **DoD** sponsored review fails to rule out a connection between a treatment administered by the military and Gulf War Illness symptoms is likely to stir new opposition to anthrax vaccine, even though there is no scientific connection between PB and the vaccine.

Bernie has built considerable credibility for the department by commissioning similar Rand reports and announcing their results, The reports are then reviewed by the Institute of Medicine, as this one will be. However, earlier reports on oil well fires and depleted uranium concluded that there wasn't a likely link to Gulf War Illness symptoms. This report will be news because it doesn't rule out a connection between PB use and those symptoms.

Sue Bailey's team has some concerns about the methodology used in the review of medical literature, and these could be discussed during the briefing. However, we all agree that we must release the report, explain the findings and call for additional research. Health Affairs and the VA will also have to deal with questions about the report's implications for treatment of GWI. One problem is that there are no good records on who got PB and whether they took it as **instructed**—three tablets a day.

We have told the NSC what our plans are, and the staff is on board. Everybody agrees that you should probably send a memo to President Clinton giving him a heads up before we make the announcement.

To comply with a new law, the White House is about to issue an executive order outlining the steps that the President must take to waive informed consent for the use of a investigation new drug, which PB is when used to protect against **soman**. The NSC is aware of announcement and is figuring out the implications for the timing of the executive order.

In addition, Personnel and Readiness is currently reviewing **DoD's** policy for the future use of PB. The announcement must also be coordinated with the press briefing. There is general agreement that PB is the only way to protect troops against **soman**. However, there is no public evidence that Iraq weaponized **soman** before, during or after the Gulf War.

Some staffers on the Hill and veterans representatives have been briefed on preliminary versions of the report. The press knows that it is coming and is beginning to wonder if we are sitting on the report. Bernie and I believe strongly that we must get the report out relatively soon, but we can't move until we resolve issues such as the proper research response, how to support veterans who took PB and the timing of the executive order.

I recommend that your key staff members discuss this report and apprise you of the impact that it could have on various GWI investigations and on the anthrax program.

294

CMAT Control #
2000074-0000018

(160)

28

(b)(6)
09/27/99 03:20 PM

To: (b)(6)

cc:

Subject: My notes from NGWRC 4th annual meeting

I attended this session on Sep 20 and 21. The opening ceremony included a color guard (out of shape and practice), the Pledge of Allegiance and the National Anthem. Opening comments by (b)(6) and (b)(6) were pleasant.

I attended a session on VA Vet Centers. (b)(6) spoke of her experiences in the Gulf at a medical station with 11 doctors. She was apparently a social worker and currently works as a Team Leader at a VA clinic in New Orleans with patients with PTSD. She was there for Desert Shield, Storm, Farewell and Calm. She stated it is difficult to do group therapy with GW vets; they prefer individual therapy. She related the war was stressful. At her location there were 50-60 scuds a day. She stated their activity in the Gulf was the opposite of all of their training to stay in small groups and keep a low profile. They were in large groups. 3000 sleeping side by side on mats with no privacy, even to shave. She talked about a SGT talking to her while she was in a shower, surprised he knew it was her until she realized he was tall and could see her over the walls. She said there were 1500 accidental deaths. (I talked with her afterwards and asked where she got the numbers. She said they were hers and she believed them because that is how many body bags she issue out.) She said the vaccines caused concerns, especially the anthrax vaccine because it was not tested in the States and nobody wanted it. She said the oil well fires were "mystical", but people were always in soot. Of the 366 in her unit 8 have already died since returning from the Gulf. She spoke about a 23yo SGT who lost all his hair, developed respiratory problems and then died. There were a lot of reports about rapes. She said nobody did anything. She talked to her CO who then after her interviews with women who were raped medically evacuated them. A major issue for her was that nothing was done when people did "crazy" things, particularly people she had worked with for 9 years. Her examples were men ejaculating on women's tents and in their beds. For the homecoming the question was, " Who goes first?" She said this created a great deal of stress. Her battalion commander (a Col) had a nervous breakdown. Officers were falling apart and not leading. Another Col committed suicide by shooting himself in the head with a 9mm gun. Her question was "How do you tell his wife and children he did that?" She said the "visible" troops went home first - those around Washington DC. They had to "look pretty" with new uniforms. The parades were not for the GW vets. They were overdone, the American public and government making up for the way they treated the Viet Nam vets. Those who came after the "War" was over were the ones who participated in the parades. Those there Jan 17-Feb 28 did not participate. People were not given awards because the time was so short, even though they deserved them. The reserves had no jobs when they got home. Many just never got "back up". College students couldn't remeber. They had nightmares and flashbacks, headaches, flu symptoms. All they wanted was a good life again. People asked her how she could go to war and leave her 18 month old son with her husband. She learned she didn't have a problem with that. It was her patriotic duty, why she was in the reserves. The people asking the questions were the ones with a problem. She closed by saying the Vet Center is keeping the promise to help the vets make adjustments and live their lives.

The next session was on Health Care and Advocacy. (b)(6) started by restating the goals of the NGWRC: To find out why Gulf War veterans are sick. To be sure Gulf War veterans receive care. To be sure Gulf War veterans receive compensation for their disabilities. To be sure DoD never repeats the mistakes of the Gulf War. He said it is important that peole call their legislators, inform them of various press releases and to magnify the intensity of the advocacy.

Bill Frasure (Viet Nam Veterans group) said that he works on the Hill. He wanted to "shoot straight". Issues of Gulf War vets are dropping off the interest scale on the Hill. The PSOB just confirms what Rostker says and "we all know what Rostker says, everybody is fine". There are a lot of ends to wrap up. The fight is not over.

Robert Newman (just call me Bob) spoke next. He is the aide to Christopher Shays. He gave a subcommittee update. They have been working since March 96. There have been 14 hearings. Their major report was accepted with 18 recommendations. HR 4036 was passed on to the Byrd act and incorporated into the Omnibus Bill - The Presumption for service connection for exposures to "toxins" "they" determined were there. The IOM must develop "linkage" to the illnesses. The VA will be updating the IOM work regularly. They got IND's to require approval by the President if a "waiver" of informed consent is requested. The GAO is to study the effectiveness of the coordinating board's research. 1. The amount of money spent. 2. The projected money to be spent, including OSAGWI. 3. The productivity (objectives being met). 4. The relationship of the coordinating board and OSAGWI. 5. The OSAGWI contract management. He stated the OSAGWI is spending more than half the dollars allocated for research. And he wants to look into the relationship between OSAGWI and RAND since Dr Rostker worked there previously. No coordinating board assessment of its research has been published. The hearing will raise eyebrows. They are pushing a bill to allow disabled vets to receive part of the frozen Iraqui assets. Anthrax vaccination should be considered as a cause of the illnesses. They are concerned about the side effects of the anthrax vaccine and the fact there are no medical exemptions. The DoD resists reporting of adverse effects. Why do females have twice the rate of side effects compared to males? The anthrax program was launched before the four criterea Secretary Cohen listed were met. The criterea are still not met today. DoD should still approve a new vaccination schedule. This vaccine is not the vaccine that was approved in the 1970's. That one was for wool sorters disease strain of anthrax. There are many delayed casualties of the Gulf War.

(b)(6) talked about needing to advocate for health care. The spouses who served are too sick. She entered the spouse and children program at the VA but was not happy with it. Need to be professional. Attend the spouses appointments. Ask questions.

(b)(6) said the number of VA doctors and VA clinics is dropping. New patient numbers are down. Need to ask why. The short form to apply for VA benefits to medical care is important. They need new studies in the VA that are real programs. The VA is opening up referals to Houston. Reports from vets is that nothing is new, even with the referal. They do the same old tests. Some get new medications that cause new problems. She is advocating the Patients Bill Of Rights. Every patient should be assigned a primary care physician, have the right for consults to specialists, and must show up for appointments, be professional, but be persistent. The updated Self Help Guide has the symptom list and shows the diagnostic code for undiagnosed illness. Loss of interest on the Hill means they need more effort. Use the VSO's for faster action with the VA. She knows that all the records of vaccinations in the Gulf are stored at FORCECOM at Ft McPherson. How can DoD say there are no records of shots in the Gulf when the did a study at Ft Bragg on the response to second booster of anthrax and bot tox in 496 soldiers?

In the Oil Well Fire Pollution session (b)(6) spoke first. He said the environmental monitoring began in March 1991 with a report on April 3, 1991. RAND is portrayed as an independent, yet the DoD report refers to the RAND report. This is circular logic. He then talked about particulates, with 260 micrograms per meter cubed being the limit for solid particulate material. The PM10 limit is 50 micrograms per meter cubed (3.5 micron sized). The ATSDR states particulates cause burning eyes, nasal discharge and cough. An Emergency Room in Kuwait City reported many increased visits during the oil well fires, with heart disease, GI disease and emphysema. In 1991 there was a plan to do further monitoring, use weather planes and evaluate people. Now DoD says there are no medical records. Was the plan done? There was no report of sampling form military bases near oil well fires, like Camp Freedom. DoD has skewed the data by averaging in data collected after all the fires were out. In Phoenix PM10 particles are 66% soil, but PM2.5 particles are 16% soil and 57% combustion products. Health effects occur from exposure to particles - DoD and RAND say the oil well fires exposures had no health effects. The EPA says PM2.5 easily reach the lungs. Damage to the lungs leads to secondary heart damage. There are chemical attached to particulate material; that should be a concern. He's been waiting for months on FOIA's for data on the oil well fires from DoD and RAND. The RAND and DoD oil

well fire papers are unacceptable and incomplete.

(b)(6) spoke next. He said he is an engineer who has become a self-taught expert on petroleum product toxicity. He started with "Why are we ignoring the obvious?" There was diesel fuel exhaust that everybody breathed. There were many petroleum products in addition to the oil well fires. Troops were unprotected. Soot - DoD says there is "no risk". Oil Rain - troops inhaled oil, swallowed oil and had it on their uniforms constantly. If you paint oil on mice they get cancer - this is published. Oil goes through the skin and lungs into the body. There has been no discussion of lipoid pneumonia. Inflammatory diseases occur as the result of petroleum toxicity. Cancer is the result of carcinogens in soot and oil. The exposure data from DoD ignores air inversions, plume touch downs which occurred for days and the Shmal winds in the summer. The measurements were taken in the summer. Troop exposure was maximum in the winter. There are no inversions in the summer. The Shmal winds blow coarse sand and fine soot. The fires were reduced in numbers when the measurements were taken and the wells were at lower pressure when measurements were done. The CHPPM Risk Assessment is invalid because it did not use oil rain and oil fumes (exhaust, etc). Superfund methods were used. These are not valid for massive smoke and petroleum mist and rain. The 11th ACR was in Kuwait June 10 to September 20 1991. Their theater medical records were destroyed in the Doha fire. They are having medical problems similar to Gulf War veterans. Lipoid pneumonia can occur with inhalation, ingestion or just through the skin. Symptoms are wheezing, cough and progressive loss of lung function. DoD smoke screens were shown to cause problems. The list of diseases misdiagnosed when lipoid pneumonia is correct include cerebral palsy, rheumatiod arthritis, ALS and progressive muscular dystrophy. There is a need for research to look for lipoids in lung, spleen, liver and lymph nodes. Computerized tomography could help. Pulmonary lavage is probably too late. Biopsy is possible. Treatment includes oral and inhaled steroids and nutritional support. Repeat pulmonary function studies must be done to see progressive lung loss. The OBVIOUS is oil well fires and petroleum are the causes of Gulf War Illnesses. Aeromatic compounds go into fat in the skin and on exposure to light cause rashes. This explains the rash problem. (b)(6) has said the oil field workers have had no problems. He is the medical consultant for the petroleum industry; of course he says there are no problems. The oil fighters spent hours each day cleaning their skin with special solvents. He supposes the firefighters had and used protective equipment. (b)(6) stood up and said he was told 20% of Kuwaites have chronic illnesses when he was a visiting professor in Kuwait. (b)(6) ended by saying the heavy metals in diesel exhaust and oil fires is not significant.

(b)(6) from the IOM discussed their evaluation of exposures. He said the study is based on the Agent Orange model. In Phase I they will evaluate 3-4 exposures (PB, Sarin, Anthrax and Bot Tox Vaccines and DU). In Phase II they will evaluate 3-4 more exposures. In Phase III there will be 2-3 year updates. Mid August 2000 their report is due. Science will drive the conclusions, not politics. All work they do will be open to public access. He gave their web site and e=mail address.

(b)(6) gave the VA update. He said this is a good news story. They have directed $134M on 145 projects. There are 5 demonstration projects ongoing in the VA, a DU medical evaluation program and two treatment protocols. The five demonstration projects include the Boston VA's health problems related to sleep. Snoring leads to poor sleep which leads to debilitation. Surgery and drugs seem to correct the snoring. Any veteran can get a DU urine test now that they are doing the DU military occupational hazard program. The two treatment trials are EBT (exercise-behavior modification trial) and ABT (antibiotic treatment). The latter is an attempt to "check this out" There is no proof that Mycoplasma fermentans incognitus is causing the diseases.

THAT ENDED DAY ONE. I WILL DO DAY TWO TOMORROW.

(162)

CMAT Control #
1999273-0000009

(b)(6)
09/28/99 04:25 PM

To: (b)(6)

cc:
Subject: Notes from NGWRC meeting in Las Vegas

(b)(6) presented an update from CDC. The Iowa study is a CDC project. Veterans from Iowa were contacted by phone and questioned regarding their health and symptoms. The follow-up program is evaluating those who reported asthma symptoms, compared to Gulf War veterans without asthma symptoms and non-GW persons with asthma. Another project is trying to define Gulf War Illnesses ((b)(6) in New Jersey). They are doing a telephone survey of health in 1161 Gulf War vets in the New Jersey area as well as 1200 Air Force personnel and a new group of 3000. The SF-36 is the form being used for symptoms and for psychological measures the BSI and CIDI-SF are being used. Another project is looking at cognitive function and symptom patterns (b)(6) in Boston). Brain activation patterns are being measured with a function MRI while the subject is doing testing of memory. From these data they will develop a case definition and then replicate the work in Danish troops. She discussed a project using logical analysis of data (a statistical package) to review previous data and see if there are any patterns or clustering. The CDC conference in Feb-Mar directed by (b)(6) was discussed as obtaining broad public input for future research. The four working groups were Pathophysiology, Assessment, Treatment and Prevention. The report is intended to be placed on the internet when complete - anticipated date is by the end of October 1999.

(b)(6) from CDC discussed his study of Air National Guard who reported symptoms in Pennsylvania. He started by saying if one looks at a population with symptoms/disease now, there are four possibilities as to why it exists. First, there could have been an epidemic (exposure or outbreak) during the Gulf War and we now are looking at the residual. Second, there could have been an event which causes delayed symptoms/disease (he cited birth defects as an example). Third, there could have been an event which has a latent period before it causes disease/symptoms (he cited cancer). Fourth, the symptoms/disease being looked at today has nothing to do with the Gulf War. (b)(6) said that everybody seems to forget the possibility of the fourth event. He then said that all clinical investigations should start with a case series to characterize the patients, followed by a population survey to look for clusters of illness and then a case-control study should be done. Case series only verify an illness exists and characterize it. The Pennsylvania study used four groups - the group that complained about illnesses present, another Pennsylvania Air Force group that did not complain about illnesses, and two Florida groups (one Air Force special forces and another Air Guard group). The data were evaluated in a common sense approach--assuming an event would affect 25% of the personnel and symptoms should be three times greater in those exposed-- and a statistical approach--using factor analysis. In this study, both methods agreed. Fatigue, mood and cognition related symptoms and musculoskeletal symptoms were the predominate features and have been called the CDC case definition. They looked for at least one chronic (6 months or greater) symptom from two or more categories. In Gulf War veterans 39% had mild/moderate symptoms and 6% had severe symptoms. In nondeployed veterans 14% had mild/moderate symptoms and 0.7% had severe symptoms. The greatest "risk factor" was being enlisted and the second "risk factor" was being female. CDC did thorough physical examinations and all CDC test known for viruses, parasites and bacteria. There were no physical findings noted and all laboratory testing was normal. The symptoms of Gulf War Illnesses closely relate to those symptoms of PTSD and Chronic Fatigue Syndrome. (b)(6) spoke up and said sick Gulf War veterans just want to get treatment, not to be "studied". Another veteran asked how (b)(6) could say all the CDC tests were normal when (b)(6) and (b)(6) are doing tests that show something abnormal. (b)(6)

responded that there are three options. One - he is right and they are wrong. Two - he is wrong and they are right. Three - they are all wrong. He went further to say that (b)(6) has an excellent reputation as a scientist. However, as he recognizes, he has developed a new test and until it can be reproduced in the hands of other scientists it should not be accepted as correct. He gave an example of a test another scientist had put forward that proved to be false.

In the session on Gulf War Vaccines (Anthrax) and Pesticides (b)(6) spoke first. She stated that she has been responsible for adding vaccines to the agenda for investigations. She has documents that show greater numbers of veterans were vaccinated with anthrax (150,000) and botulinum toxoid (8000), however she did not give numbers or what are the documents. (b)(6) said that she treats patients and is not able to tell them what was the exposure responsible for making them ill. She recommends the book "Ostler's Web" to help them deal with their dilema. Gulf War Illnesses is plagued by reluctance on the part of DoD and the VA. This problem needs work which can be done quickly, easily and with little expense. She stated her reputation has been besmirched by DoD, she believes because she consulted for the government of Cuba. She determined that cyanide poisoning was the problem. She suggested that it was a deliberate effort, perhaps. Cuba called in experts in chem-bio epidemics. They sent MD's door to door to examine all who were sick. They started treatment trials before the cause was known - at least 10 different programs. They did studies on all the sick people including looking at spinal fluid and doing nerve biopsies. She didn't talk about establishing research protocols or getting informed consent. She stated the French are not sick and they were not vaccinated and did not take PB. The US vaccinated people who did not deploy. DoD says there are no studies comparing those who got anthrax or other vaccines to those who did not because there are no records. (b)(6) has copies of orders for "classification" of vaccine records. The British study showed an association between Gulf War Illnesses and plague and anthrax vaccines and finishes saying these vaccines must have had "unanticipated affects". She went on to say the DoD used Seventh Day Adventists as "guinea pigs" for their vaccines program but did no studies on these people for long term effects. DoD has used the GWI symptom list for other studies. Now it is time to find out if vaccines cause GWI. She believes that each lot of anthrax vaccine is different. She suspects that they have been redating the lots of vaccine since 1970 without testing. Some lots are 20 years old. The VAERs reports are not being honestly done. In 1997 at USAMRIID the systemic reactions were 1% and the local reactions were from 2.4-3.9% for a total of 5.7%, not the 0.017% DoD is advertising today. She showed a slide of problems with the anthrax vaccine. The components are unidentified. There is no filtering done. The variation in the PA can be as much as 40 times different. In 1998 thre was a study with a 20% systemic reaction rate. At Ft Bragg the systemic reactions occurred in 44%. At Tripler 8% are having systemic reactions with the first dose and 48% are having systemic reactions with the fourth dose. DoD says there are no long term studies and won't release the information to the GAO. She knows which lot is the "problem" lot. It is cited in the GAO report on anthrax. How many vets are sick after the shots. The DoD won't say. She knows "10% are chronically ill". Six of 31 lots tested were acceptable. Those unacceptable are just relabelled. (b)((b)(6) then interrupted her to allow time for the other speakers. (b)(6) put up her website for correct information : anthraxvaccine.org She closed with saying there are many unlicensed vaccines, including anthrax at Ft Detrick. There is legal recourse if people are treated with these vaccines without informed consent. The fight is ongoing.

(b)(6) spoke next. He was in the Air National Guard, but recently transferred to the Air Force Reserve to avoid having to take the anthrax vaccine. He is tracking all the pilots and air crew who are doing the same thing. They want to continue serving their country and doing what they love - fly airplanes. He says DoD has a Mantra : The anthrax vaccine is safe, effective and FDA approved. An independent review of the vaccine program was ordered by Sec Cohen, but never done. An OB-GYN doctor did the review and in a letter said it was " a review done for a friend". The plant has been closed and is not producing vaccine. The FDA is reviewing the plant - the process for production is not yet approved. There is military necessity the DoD says. Even USAMRIID says no about effectiveness of the vaccine against all types of anthrax that might be made. The GAO says the supplemental testing was flawed. DoD assured a tracking system, but there has been dismal compliance. There is no tracking of attrition due to the vaccine. 20-27 of 40 pilots in the New York Guard are leaving because of the vaccine. Recently with tropical storm Floyd there was a power outage that led to loss of temperature control of a shipment of anthrax vaccine that spared the base from giving the vaccine. There

are a dozen additional BW vaccines to be produced.

Mr Todd Ensign spoke next. He is the author of "Metal of Dishonor". He started saying there has been no civilian involvement in the investigations into illnesses in Gulf War veterans. He made some disparaging remarks about RADM Mayo reflecting the DoD position by saying "I'm not here to look at the past but to prepare for the future". He talked about a person who was strapped down and given his anthrax shot and others who have been threatened with the same. DoD needs to understand we won't give up our human rights. This anthrax vaccine is just part of a huge plan. There are 14 other BW vaccines being prepared. Clinto just approve a $1.4B program to combat BW terrorism, covering it with saying the first part is for police training. He said everybody should read the book "Biohazard" by Ken Alebek, a Soviet expert who defected. It says they were working on genetic alterations to anthrax. Smallpox is the biggest threat and this nation is not vaccinated today and only a couple million doses of vaccine exist. It is ridiculous to use the anthrax vaccine, it won't protect against all strains of anthrax. The British are saying the vaccine is not protective. It is criminal what the government is doing. Perhaps we should "inspect" Ft Detrick. "I'm sure they are just doing defensive work". Why does nobody want to do a study of anthrax vaccinees versus nonvaccinated? The PAC was political posturing of science, as shown by its stance on DU when they say no long term effect. The problem is that there has been no independent scientist allowed to provide input. The New York Times just ran a report of sailors who did deck sanding in 1965 (1200 sailors) who were diagnosed with sarcoidosis. Now they are finding the diagnosis was wrong. It is silicosis. DoD still has it wrong with the diagnoses they are making.

(b)(6) spoke next. He is an entomologist who is an expert on pesticides. He said there is no safe insecticide. Millions of uniforms were treated with permethrin at a dose 60-120 times higher than is used in the cotton fields, and they don't use minimal doses there. There are long term health effects. DoD has directed its research in the wrong directions. Insecticides should be used as treatment, not as prophylaxis. DoD has "minds that won't learn". There were no mosquitos in the winter, but permethrin was used all during the war. Chelation therapy won't help those with insecticide poisoning since it is stored in the fat. The person must get rid of all body fat.

(b)(6) then talked. He was introduced by (b)(6) as a person who has devoted 3-4 years on DU research. It was predicted by DoD before the war that DU dust was the biggest threat. In July 1990 there is a memo discussing the fear of loss of this weapon because of problems. DoD refused to use Doug Rokke's DU training program developed in 1994. No radiac meters were used, as shown in his film, with medics testing the wounded patient before providing treatment. Memos during the war cautioned that after-action reports should play down the problems with DU so as not to jeopardize retaining it as a weapon. Arlene Hudson is an author of the RAND DU report. She worked at RAND as an OSAGWI staff member. Is RAND really "independent"? Just as DoD did with Agent Orange, they are saying nobody was exposed to "enough" DU to have medical problems. But there was no testing to say how much they were exposed to. Even those wounded were not tested. There were other weapons used in the Gulf War, too. We need to obtain a presumption of exposure to enough DU to cause medical problems. RAND didn't even review the AFFRI report showing cancer. The PSOB is having a Department of Energy expert review the RAND DU paper. Tell me this is not conflict of interest. Peducah is where DoD stores its DU, and we know about the workers at that plant. DOE plans to recycle DU. If they sell it to an arms manufacturer, DOE says they no longer are responsible, the Nuclear Energy Commission has responsibility over the public use. At Oakridge there was an autopsy done on a worker that showed uranium in the bones. Funding was pulled by the government before that work could be published. DoD is not "independent" Neither is DOE. He stated he got to give 2 1/2 hours of testimony to the PSOB. He dismantled the DoD position, put holes in the DoD position. He provided his critique of the OSAGWI DU report. In July Rudman praised RAND and discredited AFFRI. In August the PSOB said there was not enough exposure to DU to cause the undiagnosed illnesses. Why are they not saying if DU is responsible for the other 80% of sick veterans who have a diagnosed illness?

(b)(6) spoke next. He was an E-2 tank crewman with the 24th Infantry. On March 2, 1991 they were on a mop up mission, attacking fleeing Iraquis. One of their tanks was destroyed. It caught fire. They pulled the crew members out and put four DU rounds through the tank. Four days later the tank was returned to Saudi. He was diagnosed with skin cancer. The doctor said there was no scientific basis to detemine cause and effect from his Gulf War exposures. Nobody told this unit about DU. They had no thought of risk from the damaged tank. They did not change their clothes or

shower for 3-4 weeks. They received no medical follow-up. All members of his unit dispersed when they returned to CONUS. He doesn't know their health. There are contaminated areas out there. Troops are in them today. Children and adults in the area are in them. Contamination is concentrated at the run off sites. There is a major civilian impact. He did not join the Army to kill children. DU was used in Kosovo. While DU is a force multiplier, we need to ban DU now.

(b)(6) spoke next. He cited Dr Rostker's speech to the Americal Legion in 1998 as an example of DoD protecting the use of DU. He claimed the DU evaluation program is not looking at the lung effect of DU exposure. He pointed to (b)(6) as a vet with a tumor in his arm who is left out of the statistics. In April of 1999 Gen Blanc said they were using urine to test for DU exposure. The urine test is not effective to measure inhalation/ingestion exposure. OSAGWI should remove its DU report. There are no medical studies of children born to DU exposed members. In Nov 1998 RADM Steinman of the PSOB said the OSAGWI DU report was premature. There are falsehoods being used. It is said the 144th had urine testing and all 27 tested negative. Only 12 returned the testing kits with urine. The DoD and VA are now requiring the urine to meet specific levels for all three isotopes in DU or it is called negative. There are many studies on stress. There are only two studies on DU and they are in rats. In April 1999 Gen Blanc changed the Army policy to exempt soldier from the regulation for medical evaluation when exposed to DU. (b)(6) wrote a memo to OSAGWI saying their DU report is wrong. Rudman in July 1999 said there should be more research on DU and chemicals. I would question the integrity of Rudman and the PSOB because their first meeting on July 16,17 1998 was secret and there was no transcript. FOIA only got us a copy of the OSAGWI briefing slides. In June 1995 AR-4014 was change to not effect troops during mobilization. Tens of thousands were exposed to DU, only 33 have been tested. The 22nd SUPCOM logs indicate no medical testing was offered for DU. (b)(6) only made two other entries in the log about DU. Doha was a PR nightmare. There were medical log entries, but numbers 71-104 are missing. DU assessments being done now are just guesses. We want research now on DU and the DU exposed veterans. We have been abandoned by the government.

(b)(6) spoke next. In 91 he was in a vehicle (Bradley) struck with two DU penetrators. He was never told it was DU. His child had to go to the emergency room right after he returned and brought all his gear into the house. He was discharged in Nov 91. His wife had a miscarriage in Dec 91. In March 92 his father asked him about DU exposure. His son now has blisters on his hands and feet. In 94 he was tested at the Baltimore VA. Whole body counts were done but he was told the results could not be used. They were repeated. He still has the fragments taken out of him and recently they still "pegged" the meter on a geiger counter. Questions were then asked. How much DU is 20 micrograms? RAND says exposures were 1-2 milligrams; this is unreasonable. DoD says 2 DU rounds will give a 24 mg exposure. Lead sheets are not being used in the OSAGWI report. We need a presumption that DU is causing the illnesses. (b)(6) then continued. What was the tumor? Was it DU related? He said he got the tumor in his bone. He thinks it was caused by DU. He smoked cigarets that were with him in the Bradley and pieces of shrapnel would fall out as he smoked. He lived in the vehicle for weeks. The OSAGWI DU report is "Bogus". On urinalysis there are mutations of bacteria from the DU. The VA is doing "other" types of testing on the urine. Why are only 33 in the program? Is this DoD "Looking forward, not back (RADM Mayo"? Now DoD says 113 were in or on vehicles hit with DU. Six Bradleys were buried. The rest were shipped back and 20 were decontaminated in a special building. The Army can't find any DU in Kuwait, but journalists can find it in Iraq. Many were killed on 5 ton trucks that were hit. What happened to the Marine vehicles? They were taken to KKMC and the 144th assessed them. RADCON didn't come until mid March to check for contamination. They said all contaminated vehicles were Army. They received no education on DU. 85% of DU was shot by A-10's. Some was shot by Harriers. The rest was shot by tanks. A tank was rejected to be taken back for a memorial for public access because it would be a health and safety risk. There is a lot of uncertainty about DU. Only the Pentagon is certain. Ships were loaded with these vehicles which were said to be "all clean". Looking inside you could see body parts and dust. There had to be exposures at unloading sites, too. This affected civilians in CONUS. Soldiers were never told what was being fired by what side. Many brought back Iraqi souveniers. The only female to test positive for DU with no wounds is here. She is a "stumper". Her exposure had to be through inhalation or through the skin. Information never got to medical. The training film that was not released shows medics treating the wounds from DU while wearing "disposable clothing". There was never disposable clothing on the battlefield.

That concludes what I heard. There were usually about 80 people present in the combined sessions. At least 10 were media and it appeared that 20 or so were from the government (DoD, VA, PSOB).

CMAT Control #
1999273-0000011

(163)

(b)(6)
09/30/99 12:45 PM

To: (b)(6)

cc:
Subject: Update -- 29 Sept. Hearing on the Anthrax Program

FYI

---------- Forwarded by (b)(6) on 09/30/99 12:44 PM ----------

(b)(6) on 09/30/99 11:03:52 AM

To: (b)(6)
cc: (bcc (b)(6)
Subject: Update -- 29 Sept. Hearing on the Anthrax Program

Friends, Family, Concerned Citizens, & DoD Reps;

I observed the 5th AVIP (Anthrax Vaccine Immunization Program) hearing yesterday in Washington. I was glad to be present and reassured myself that all the concerned citizens embroiled in this dilemma are questioning this policy for all the right reasons: Duty, Honor, Country. Let me share a few of the highlights of the hearing from the best of my recollection:

-- Congressman Shays Chaired the forum and emphasized that the compliance review of the AVIP is required due to the "paucity" of tracking data that emerged out of the Gulf War Illness ordeal with respect to vaccine administration. Over an intriguing four hour hearing he concluded that it appeared the DoD was constructing a "medical Maginot Line" with the AVIP.

-- Congressman Burton, Chairman of the Gov. Reform and Oversight Comm. also joined the Congressional Subcomm. team, and informed the attendees that his own full committee would be holding a hearing on the 12th of Oct. to review the anthrax program. He offered tough questions and I anticipate a challenging hearing in the full committee.

-- Congressman Souder from IN attended and was a reputable confirmation of the testimony of LTC Tom Heemstra, IN ANG, first military commander worldwide to stand up to this policy for his troops in asking for a genuine, but belated, thorough review of this initiative. Ltc Heemstra's command was taken away as a result of his questions about the anthrax program. Mr. Souder later added that he felt the DoD was "digging in" over this issue and was "defending the anthrax program rather than defending the troops." Rep. Souder also added that Officers are speaking out against this vaccine policy while they've never spoken out against any other vaccine, and he asked, 'while there are many reasons to get out of the military today, why give them another?'

-- Additional testimony was provided by Maj. Cheryl Hansen, MD USAFRs; Capt. David Panzera, NY ANG; and TSgt William Mangieri. All of these servicemembers focused on the possible attrition to their home units once

faced with vaccination in the near future. Testimony maintained, and is back up by current units that are being tested by the policy, that 25 to 60% of pilots in the Air Reserve Component will hang up their flight suits in lieu of being injected with a suspect vaccine. The senior DoD leadership appears to be in complete denial mode over this reality.

-- The Asst. Sec. of Def. for Reserve Affairs, Mr. Cragin, led the opposite panel, and testified that their is no attrition trend due to this program (this is because only about 1% of aircrew in the reserves have been subjected to vaccination to date). He implied that all current attrition is normal based on an 18% average annual ANG turnover rate (this is not an aircrew statistic and is simply DoD spin). He emphasized the DoD is only in phase one of the program which corresponds with recent reports from the field that commanders are discontinuing prematurely inoculating any longer in advance of phase two requirements to hold off resignations. One of these bases is Stewart ANG Base in Newburgh, NY. In his testimony the Asst. SecDef admitted he had just visited the base. During this visit he was allegedly informed of the potential loss of over 50% of their pilots. A couple days later their shot deadline was canceled.

-- The Director of the Air National Guard, MG Weaver, also testified that there has been only one (1) servicemember that is a known refuser. At that point several servicemembers in attendance glanced at eachother wondering if we were the "one." MG Weaver later went on to say during an interview that a "few" Wisconsin pilots had "walked" over the vaccine issue directly refuting his previous testimony. He added that he would give this vaccine to his infant daughter despite the fact that FDA approved this vaccine only for 18-65 year olds. The Chairman took exception with this blind faith in the program and maintained that the Director would be a "fool" to offer an adult vaccine to a child.

-- Col. Dougherty, the Surgeon General of the National Guard Bureau also testified. In his only notable delivery he refused to give a "yes" or "no" answer to Congressman Shays' question as to whether or not the anthrax vaccine was effective against all strains of the virus. On the third query by the Chairman he finally maintained, 'we believe so.'

-- As a summary I'd like to review a few of the inconsistencies highlighted by this hearing compared to what servicemembers are experiencing throughout the country:

1. Our ANG Director, MG Weaver, emphasized that we've lost only one ANG member due to the anthrax vaccination policy. This is despite that fact that CT lost 8 pilots nine months ago exclusively due to this vaccination policy. This is a matter a the congressional record. As well 7 pilots were lost in the WI ANG, and all the remaining states have yet to be put on record because this program is just beginning in the Air Reserve Components.

2. All DoD Panel members were required by the chairman to specifically testify under oath that they are aware of NO commanders in the field that are telling their people that anthrax cannot be attributed as the casual factor in resigning. They assured the Chairman that there is no pressure in the units throughout the Guard and Reserve to hide anthrax as a reason for resigning.

3. All DoD Panel members were also required to testify under oath that No commanders are implying to their troops that they'll be punished if they use anthrax as a reason for getting out. The DoD panelists went on to say on the Congressional record that any guardsman can leave the force over the anthrax vaccine without any retribution or retaliation because they are citizen

soldiers (Ref. Panel Two Oral Q&A testimony, 29 Sept. '99, for the House Subcommittee on National Security, House Rayburn Office Bldg.).

4. Mr. Cragin's claims that there is no attrition trend caused by anthrax vaccination, and people are leaving, not due to refusing the vaccine, but for other reasons such as equipment or ops tempo concerns where challenged by Congressman Shays. The Chairman put the Asst. Sec. of Def. for Reserve Affairs on notice to reconcile his claims based on his other public statements that the Air Line Pilot's Assoc. Medical staff is so swamped with inquiries by pilots that they had to create a website to deal with the concerns (see: <A HREF="http://www.aviationmedicine.com/anthrax.htm#anti">http://www.aviationmedicine.com/anthrax.htm#anti</A>) Of course what they don't tell you is that the 3 Flight Docs have a military or government background (see: <A HREF="http://www.aviationmedicine.com/staff.htm">http://www.aviationmedicine.com/staff.htm</A>). Additionally Panel Two's testimony claimed commanders in the field are being "challenged" by their pilots which also, according to Congressman Shays, did not corresponding to the Asst. SecDef's testimony.

-- Finally, I hope to reiterate that the servicemembers concerned with the implementation of the AVIP are speaking out not only due to the disregard of their health rights, but also because they are asking for a commonsense and comprehensive approach to force protection. I feel it is our military obligation and duty. The chasm between the research that is readily available to servicemembers in Congressional GAO testimony, the Consolidated Federal Register, and Senate Reports puts into question the DoD's claims of safety, efficacy and military necessity. Additionally, as these proceeding progress a great divide is also growing between what servicemembers see happening in the field versus the message senior DoD official offer to Congress under oath. I continue to be encouraged at the speed in which this review is progressing compared to any previous military medical controversy.

-- To see some recent coverage on this hearing and the others see this weblink:
<A HREF="http://www.courant.com/news/special/anthrax/index.stm">http://www.courant.com/news/special/anthrax/index.stm</A>

(b)(6)

164

(b)(6)
02/10/2003 07:46 AM

To: (b)(6)
cc:

Subject: Gulf Deployment

Please put into the system for answer. Thanks.

---------- Forwarded by (b)(6) on 02/10/2003 07:48 AM ----------

(b)(6) on 02/09/2003 01:25:45 PM

To: (b)(6)
cc:

Subject: Gulf Deployment

Mr. Kilpatrick

I have to question the fact that many of the same drugs and vaccines that were given to the vets of the Gulf War deployment of 1990/1991, are again being utilized as pre-treatments to the possible exposures. I realize that the DOD would like to have the ability to be able to send the troops of the United States to war with the knowledge that they will be protected from exposures of chemicals and biological agents, however the illnesses of the veterans of the initial deployments in 1990/1991 should be enough of a learning tool to tell us that these are not good forms of treatment.

I realize that many research trials have been conducted to date and the FDA has given approval to utilize these methods, although how can they be utilized knowing the outcome of health effects on the soldiers? We are aware of the possible exposures in the area just as we knew in the previous battle, but why would one believe that soman is to be the choice of chemical exposures when they have proven to have chemicals that are much more volatile than this agent? The PB anthrax vaccine, and others are known to cause problems especially in combination with other chemical agents whether DEET, other vaccines, chemical agents, biological agents, etc. The research has been done on many of these very agents in the past and the fact that the combination of chemicals has been ignored is justification to not be handing this out to the very people that will be risking life and limb to defend the United States.

The Anthrax alone when being given to soldiers in other areas comes with an information packet plainly stating that this should not be given to anyone planning pregnancy in a specific time period, any medications must be reviewed prior to being given this vaccine, this tells us that this vaccine should not be given in conjunction with other chemicals and yet the troops are given multiple vaccines and PB as well as being exposed to any chemical that remains alive in the Gulf Area of operations.

How can the DHSD say that these are safe to give to the troops and quote research trials? How can you possibly re-create the actual environment of the war of 1991 when their were many reported chemicals that were detected and unable to be named at the time of detection? This in itself says that there are more exposures and additional cause for not further risking the lives of our troops to unknown health hazards due to the possibilities of the same hazards being repeated 12 years later.

I would think having seen the volume of ill veterans that have commented on the risks this would have been reviewed more thoroughly and the troops would be given at the very least facts from the vets of past deployment and the opportunity to decline the pre-treatments that have been offered.

How can this type of thing continue to happen in today's world? Our troops have been utilized for years as

"test rats" for medications, vaccines and the like this has to be stopped.
My husband is a victim of the last war's pretreatment and has been debilitated for many years, having many ailments none of which have been diagnosed as somatic disorders, he was a vital healthy man at the time of deployment, now at 35 he is unable to walk more than a few feet at a time, his brain scans show massive holes in his brain and his liver is showing signs of shutting down, granted this may not seem unusual for some but considering that he had no health problems prior to his service I can honestly say this is the cause, what is being done? Nothing! He receives pain medications, and anti inflammatory medications. And a battle for the compensation that he was told he would be entitled to if he became ill during service. Many of the veterans of the initial deployment have the same type of ailments and have been ignored saying this was made up or the list of ailments was available to the public and the belief is that the vets "developed" ailments after they realized there were others that may get compensation, but the facts are these people would much rahter make the real money they made prior to the illness having debilitated them than have to try to live on the pittance of veterans compesation, if they are able to win the battle and get their 100% disability awarded before they pass away.
The research that has been done on the vaccines and pills, and bilogical agent and chemical agent exposure is done seperately and in what I am sure is a sterile environment, how can you possibly duplicate the environment of the Iraq War when you can not possibly be able to move the area of operations to your labs etc?
The fact that there were unknown agents in the area when the SCUDS were being deployed and the oil fires were burning is in itself reason to pause and re-think the meds and vaccines that are being utilized today and then.
Knowing the health problems of the vets in the 1991 war should be enough to at least make the dept's take heed and halt this practice unless 1. the troops choose willing to take the meds and vaccines knowing all possible risks 2. any threat of disciplinary actions has been removed should the troop choose to not participate in the treatment. All vets should be garanteed compensation and medical benefits should they suffer repercussions due to the meds and vaccines in addition to any other exposures whether they are known or unknown agents.
Yes I realize this creates a problem financially for the United States, however the fact that the veteran has the same problems on a personal level is as much an issue as it would be in that instance for the United States. Many vets from the previous war now are homeless, or has suffered from undue financial problems due to their health from their deployment and this is also taxing to the United States by way of reducing the trust the people have in the military to take care of the veterans when they are in need to no fault of their own short of signing to defend the United States.
Where is the data that shows these pre-treatments are safe when given in conjunction with other medications and vaccines? Where is the data showing the need to expose the vets to this pretreatment? Why choose to pretreat for Soman when we have the data showing that Iraq has sarin, and cyclo sarin capabilities and had this prior to the 1991 war? Where is the data showing that the pre-treatment for soman and anthrax will not react in a volatile manner if exposed to another form of chemical that is known to be in the region admittedly sold to them by companies in the United States and or our allies?
I am very interested in hearing the answers and seeing the data that is available to the public on these topics, what precautions are being taken for the troops of today that weren't taken in the war of 1991. We knew in the 1980's that this country would deploy chemicals and that many of these chemicals had a half life of not only years but thousands and millions of years and yet the troops in the 1991 time frame were sent there unprepared for what they had to face in the way of illnesses. How can we say that todays troops are any more prepared?
Admittedly, the NBC gear is not up to what the standards should be, as was certainl the case during the initial deployments.
In what way has the chemical alarms been improved? How are the troops in the field supposed to know if they have been chemically exposed, the tankers and mechanics that were not in an area of great numbers were unable to have the benefits of chemical alarms. They had no way of being treated medically should they have a need during recovery missions etc. How has this changed for the troops of today?
I look forward to hearing from your office in these matters.
I have many additional questions that I will forward to your mail box soon.
Thank You (b)(6)

(b)(6)

(b)(6)
Deputy Director
Deployment Health Support Directorate
(b)(6)

DEPARTMENT OF DEFENSE
5113 LEESBURG PIKE, SUITE 901
FALLS CHURCH, VIRGINIA 22041-3226

DEPLOYMENT
HEALTH SUPPORT

MAR 2 0 2003

(b)(6)

Dear (b)(6)

In a recent e-mail you raised several questions about conditions that have been investigated as possible contributing causes of Gulf War illnesses. In the context of current military deployments to the Middle East, you questioned whether policies regarding such things as vaccines and protective gear had changed since the time of your husband's military service. We have enclosed a detailed response to your questions that addresses the issues you raised in your e-mail. Also enclosed is a printout of the anthrax vaccine information statement issued by the Centers for Disease Control and Prevention (CDC), also available online at: *http://www.cdc.gov/nip/publications/VIS/default.htm#anthrax*

The CDC's position states no precaution for delaying childbearing after vaccination; recommends vaccinating a pregnant woman possibly exposed to anthrax in some cases; and, under certain conditions, approves giving the anthrax vaccine at the same time as other vaccines.

In your e-mail, you expressed concern that research into Gulf War illnesses fails to take into account the interactions of combinations of factors. There are actually several government-sponsored studies that examine possible interactions that may be causing the illnesses in Gulf War veterans. For example, one study is examining the possible physiological and neurobehavioral effects from exposure to pyridostigmine bromide, fuels, and DEET. Another is looking into the possible neurophysiologic and neuropathologic effects of low-level exposures to sarin, pyridostigmine, pesticides, and botulinum toxoid. For more information you may wish to examine *The Annual Report to Congress on Research into Gulf War Veterans' Illnesses*, available on line at: *http://www.va.gov/resdev/pgulf98/gwrpt98.htm.*

During the course of our investigations, many veterans recalled stories of Scud missile attacks. Some believed they had been subjected to chemical or biological warfare agents in these attacks. There is no evidence that Iraq used any chemical or biological warfare agents during the Gulf War. All Scud missile debris recovered in the Kuwait theater of operations and Israel indicated the use of high explosive warheads only. In addition, although Iraq was thought to have tested chemical and biological warheads with the Scud missile before the war, it is now believed there were key technical problems they had not solved that could have precluded its use. The threat of massive retaliation from the U.S. also appears to have deterred Saddam Hussein from employing any chemical or biological weapons. In July 2000, we released an information paper on Iraq's Scud Ballistic Missile Program. I have enclosed a copy or you can find it on line at: *http://www.gulflink.osd.mil/scud_info/*

Thank you for the opportunity to address your concerns. We hope this information is useful to you.

Sincerely,

Michael E. Kilpatrick, M.D.
Deputy Director

Enclosures

Response To Questions From September 20, 2002, Meeting

NBC equipment and protective gear:

You can find a listing and descriptions of nuclear, biological and chemical detection equipment in the Army's inventory at: *http://www.sbccom.army.mil/products/nbc.htm* Samples of the information papers are attached. You can obtain more information on this issue by contacting the Headquarters' Public Affairs Office at: *public.affairs@sbccom.apgea.army.mil*

Headquarters' Address: Commander
U.S. Army Soldier & Biological Chemical Command
ATTN: AMSSB-PA
5183 Blackhawk Road, Bldg. E5101, Rm. 225
Aberdeen Proving Ground, MD 21010-5424

Documenting immunizations, including the FDA approved anthrax vaccine:

- DoD policies require the documentation of all immunizations given to servicemembers. For deployments, the JCS requires immunizations to be recorded on the abbreviated medical record (DD Form 2766), supplemented as necessary by the pocket immunization record (PHS 731) and service-specific forms.
- The individual services have fielded electronic immunization tracking systems:
  - The Army uses its Medical Protection System to electronically record immunizations of its servicemembers.
  - The Navy uses its Shipboard Automated Medical System to electronically record immunizations of its servicemembers, then forwards this information through the Naval Medical Information Management Center to the Defense Eligibility Enrollment Reporting System (DEERS).
  - The Air Force uses its Complete Immunizations Tracking Application to record immunizations given at both medical facilities and field locations, and indicates good success with all component members.

There are initiatives to combine or link the data from these systems for both personal and population health purposes through DEERS, the Composite Health Care System and the Theater Medical Information Program.

Possible exposure of personnel and families to contaminated equipment:

No evidence exists of exposure of non-deployed military members or deployed members' families to biological and chemical contaminants from equipment returning from the Gulf War.

Chemical Agent Resistant Coating (CARC)

Military regulations and standard operating procedures require conformance to and compliance with public law and national consensus standards for the hazard communication program. DoD Instruction 6050.5, the Department of Defense Hazard Communication Program, outlines responsibilities and procedures for a comprehensive hazard communication program that includes training for DoD personnel in potential occupational health hazards. Department of Defense personnel are to be informed of safe work practices and are to be trained in the selection, use, and availability of personal protective equipment (PPE) to prevent injuries and illnesses. It states that it is Department of Defense policy to protect personnel from the adverse effects of workplace hazardous materials and waste, to reduce chemically related injuries and illnesses, and to establish and maintain a standardized hazardous materials information system. Each service and component is required to establish and maintain hazard communication programs that conform to the requirements of DoD Instruction 6050.5 and comply with the Occupational Safety and Health Administration hazard communication requirements.

Dormancy of biological and chemical agents in the Persian Gulf region:

The Department of Defense subject matter experts have completed extensive research on the various biological and chemical agents that are believed to be in the inventory of potential adversaries in the region. They have good data on the dormancy of these agents. The U.S. Army Center for Health Promotion and Preventive Medicine is responsible for and will conduct the appropriate monitoring and testing in the areas our servicemembers will be deployed.

Data available to veterans and their families on studies concerning exposures and effects:

All the information we have concerning possible exposures to veterans of the Gulf War is posted on the GulfLINK web site, to include associated government funded research.

OSHA standards in place in Desert Shield/Storm:

Occupational Safety and Health Administration standards do not apply to a combat theater. Manufacturers place warnings on the materials and liquids used to clean equipment that warn an individual of the dangers of exposure without proper equipment or improper use of these materials. It is the responsibility of the unit officers and NCOs to ensure their servicemembers know, understand, and follow these safety precautions.

Policies to ensure non-deployed servicemembers are not exposed to battlefield contaminants:

There is no indication that non-deployed servicemembers or family members were exposed to harmful battlefield contaminants. If there is any indication that deployed personnel and their equipment were exposed to chemical or biological weapons, the appropriate decontamination procedures will be accomplished. Additionally, personnel will be provided medical treatment and the follow-on health care and monitoring based on the type of exposure.

Samplings currently being conducted in Persian Gulf Region:

The U.S. Army Center for Health Promotion and Preventive Medicine is responsible for environmental surveillance. An information paper on their program is enclosed. You can obtain more information from their web site at: *http://chppm-www.apgea.army.mil/desp/pages/despinfo.htm*

Smoke from burning oil wells, space heaters, etc., and veterans' health:

We have found no evidence to change the findings of our oil well fires environmental exposure report, nor the Institute of Medicine's findings that oil well fires did not cause, contribute or significantly impact veterans' long-term health.

Military regulations related to environmental exposures:

DoDD 6490.2, DoDI 6490.3 and JCSMCM-0006-02 are Department of Defense Regulations that relate to environmental exposures.

VAERS:

The Assistant Secretary of Defense (Health Affairs) and all of the service Surgeons General have emphasized the importance of following the policy already in place for reporting vaccine adverse events. When adverse events occur at the treatment facility, medical care providers must ensure that the report is forwarded. When an adverse event occurs after the patient has departed the treatment facility, it is up to that individual to ensure the information gets reported. When administering vaccinations, medical care providers should be briefing the recipient on what to expect and what they should do if there is an adverse event.

Storage of pre-deployment blood samples:

Pre-deployment blood samples are stored in such a manner that an individual's specimen can be retrieved for testing if necessary. If a servicemember's health is believed to have been impacted adversely by a deployment, the sample is available to medical care providers to assist in that servicemember's diagnosis and treatment.

Squalene:

The Department of Defense has looked into the issue of squalene and, unless new information is discovered, believes it has been adequately addressed. DoD has funded research on this topic and studies are still under way.

Release of documents in reference to the destruction of nuclear reactors and bio-chemical bunkers under the Freedom of Information Act (FOIA):

FOIA provides exemptions on the release of information based on a variety of reasons. If there are documents that relate to the incidents referred to above, the information that falls into an

How many Gulf War veterans were medically discharged? Died?

We are unable to determine how many Gulf War veterans were medically discharged. The Social Security Administration identified 9,113 Gulf War veterans who have died.

SPECT Scans:

Medical care providers will recommend a SPECT scan if clinically indicated. These scans are not done routinely because the utility of SPECT scans is still the subject of research. Until indications for these scans are clearer, routine use of this procedure as a screening test, which involves exposing the patient to radiation, should only be done as part of an approved research study where participants give their informed consent.

Are sufficient force health protection measures in place?

The Department of Defense believes that the force health protection policy, training and protective measures in place are sufficient to protect our servicemembers.

Planned destruction of CCEP and Gulf War Registry original evaluation documents:

We are unaware of any plan to destroy original Comprehensive Clinical Evaluation Program (CCEP) or Gulf War Registry evaluation records. The CCEP evaluation records are already being archived at the National Archives and Records Administration.

U.S. Army Medical Research and Material Command research solicitation:

We recommend you contact the U.S. Army Medical Research and Material Command Public Affairs Office at (301) 619-2736 for information on their research program. The request to provide all the document titles associated with DOEHR must be submitted under the Freedom of Information Act (FOIA) to the Department of Defense FOIA office. Their address is:

Directorate of Freedom of Information Act and Security Review
Room 2C757
1157 Defense Pentagon
Washington, D.C. 20301-1155

Has Dr. Kilpatrick read Doug Rokke's address at the Fall Congressional/Coalition Leadership Breakfast?

Dr. Kilpatrick has not read Doug Rokke's address at the Fall Congressional/Coalition Leadership breakfast. Our organization was unaware of the address and has not received a copy of text.

SHAD

All the information we have available on the Deseret Test Center Project SHAD/Project 112 is posted to our DeploymentLINK Web site. The site is updated as soon as we have new information. The URL for the site is: *http://deploymentlink.osd.mil/current_issues/shad/shad_intro.shtml*

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Recommendation to conduct a study of Gulf War veterans who received anthrax vaccine versus control group that did not:

We will forward this recommendation to the research working group.

Leishmaniasis:

DoD-funded research into diagnostic methods and treatment for leishmaniasis continues today as it has for decades. Please refer to the Medsearch Web site for research projects funded since the Gulf War. The URL is: *http://www.gulflink.osd.mil/medsearch/*

Military researchers' work in this area is a modest, but important, part of global research efforts directed against the various forms of leishmanial disease, which threaten large portions of the world's population outside the United States. Military interest in leishmaniasis has historically reflected concerns about this threat to deployed US forces. Unfortunately, standards for the diagnosis and treatment of leishmaniasis have not changed dramatically since 1991.

Research into the development of a serological test for leishmanial infection has so far failed to yield a new, practicable test. In the absence of such a test, laboratory confirmation of the diagnosis depends upon either microscopic examination of biopsy material or a positive culture of a biopsied lesion or organ. Walter Reed Army Institute of Research investigators have found that an investigational test using PCR methodology has shown great promise in diagnosing cutaneous disease.

In underdeveloped parts of the world without sophisticated medical care, the diagnosis of cutaneous leishmaniasis is often made on clinical grounds, without the use of supplementary testing. The principal treatments used around the world for the more serious forms of leishmaniasis consist of pentavalent antimony and Amphotericin B. The latter has recently been approved by the FDA for treatment of visceral leishmaniasis. Research into new treatments, including possible oral and topical medications, has identified several new, promising drugs.

Plum Island and mycoplasma development for biological warfare purposes:

There was no program to develop mycoplasma as a biological weapon. The history of Plum Island in New York includes information that the U.S. Army Chemical Corps had been planning an animal disease research laboratory there in the early 1950's. At the completion of all construction work on May 26, 1954, the Chemical Corps' Plum Island new facility was officially deactivated, without ever having been used.

The United States Department of Agriculture (USDA) was designated to receive the transfer of Plum Island in 1952, about the time the Chemical Corps was initiating the laboratory building process. On July 1, 1954, the Army officially transferred Plum Island to the USDA. The new Animal Disease Laboratory building 101 compound was dedicated on Sept. 26, 1956. All of the buildings renovated by the Chemical Corps from 1952-54 were occupied by the new Plum Island Animal Disease Center (PIADC). In October 1991, all operation and maintenance activities

were privatized, transferring to a contractor (under USDA supervision) all personnel involved in these activities. Currently the operation and maintenance of the PIADC are conducted through a contract with LB&B Associates, Inc., headquartered in Columbia, Maryland.

Pesticide Exposures:

The Department of Defense has instituted changes in training and the use of pesticides. Pesticide use and misuse have not been ruled out as possible causes of some of the symptoms and illnesses experienced by some Gulf War veterans. Research continues.

CDC Conference report on Carbon Monoxide Exposure:

The Centers for Disease Control and Prevention (CDC) have information on carbon monoxide exposure on their web site at: *http://www.cdc.gov/nceh/airpollution/carbonmonoxide/default.htm*

Nerve Agent Exposures:

The Department of Defense has acknowledged that some Gulf War veterans were possibly exposed to low levels of chemical agents and that it is not clear what the long-term health implications are for this possible exposure. Research continues in this area.

Milk Factory:

This has been looked into and there was no evidence to indicate that any further investigation was necessary. For more information, see the CIA's report, *Intelligence Update: Chemical Warfare Agent Issues During the Persian Gulf War: http://www.cia.gov/cia/publications/gulfwar/cwagents/cwpaper1.htm*

Patient Treatment by DoD, VA and Civilian Doctors:

We recognize that the Department of Defense could have done better in handling the illnesses experienced by Gulf War veterans. An effort has been made to better educate and sensitize our medical care providers to the problems Gulf War veterans have experienced. As a result the following actions have occurred.

- The National Defense Authorization Act for Fiscal Year 1999 authorized the Secretary of Defense to "...establish a center devoted to a longitudinal study to evaluate data on the health conditions of members of the Armed Forces upon their return from deployment on military operations for the purposes of ensuring the rapid identification of any trends in diseases, illnesses, or injuries...."

- The goal of the three DoD centers is "...to improve our ability to identify, treat, and minimize or eliminate the short- and long-term adverse effects of military service on the physical and mental health of veterans."

- The Deployment Health Research Center has been directly engaged with the VA in the IOM-recommended Millennium Cohort Study to evaluate whether deployment-related

exposures are associated with post-deployment health outcomes. It also manages the national DoD Birth Defects Registry.

- The Deployment Health Clinical Center has been a leading proponent for developing post-deployment health evaluation and management clinical practice guidelines, which have recently been implemented throughout the DoD and VA health systems.

- The Deployment Health Surveillance Center is the DoD proponent for the identification of and response to medical threats associated with deployments and, most recently, acts of terrorism.

Rescue Workers:

The Centers for Disease Control (CDC) are looking into health issues concerning the rescue workers and personnel who worked in buildings in the vicinity of the World Trade Center at the time of the attack. You can obtain information on this issue from the CDC web site at: *http://www.cdc.gov/niosh/emres01.html*

West Nile Virus:

According to the Centers for Disease Control and Prevention, West Nile virus is spread by the bite of an infected mosquito, and can infect people, horses, many types of birds, and some other animals. Most people who become infected with West Nile virus will have either no symptoms or only mild ones. However, on rare occasions, West Nile virus infection can result in severe and sometimes fatal illnesses. There is no evidence to suggest that West Nile virus can be spread from person-to-person or from animal-to-person except as recently occurred in this country through blood transfusion or organ transplantation. If you would like more information Virus, visit the CDC web site at: *http://www.cdc.gov/ncidod/dvbid/westnile/qa/overview.htm*

Several of the attendees at the meeting asked questions concerning Department of Veterans Affairs' issues to include benefits, service-connected disabilities, VA training VACOLS, GWVIS availability to researchers, benefits and health care associated with SHAD, and veteran studies. All of these questions have been referred to the VA for response.

Responses to issues from December 10, 2002 Meeting

Leishmaniasis and Endemic Diseases Issue:

The US Army Center for Health Promotion and Preventive Medicine, the Navy Environmental Health Center, the Air Force Institute for Environmental Safety and Occupational Health Risk Analysis, as well as the Armed Forces Pest Management Board, and other organizations, have devoted significant resources to identifying vector-borne illnesses in various parts of the world and describing methods for how US servicemembers can avoid contracting these illnesses. These organizations have developed a variety of tools to teach individual servicemembers, as well as preventive medicine personnel, how to avoid the transmission of a variety of diseases endemic to the region in which they are deployed.

Reference documents have been created for multiple audiences. Detailed, technical documents are readily available on the Internet and on CD-ROMs for preventive medicine personnel and pest management personnel who provide training and guidance on the identification, prevention, and treatment of vector-borne illness such as malaria, leishmaniasis, and other diseases. Examples of these training materials include technical guides, disease vector profiles, service doctrine and guidance, etc.

The other training documents include short, easy-to-read, staying healthy guides designed for use by individual servicemembers. Over 15 regional and country guides have been developed, for areas such as Afghanistan and Pakistan, as well as Central Asia. The guides provide a variety of useful information, including an overview of the region, disease threats, and ways to avoid injury and illness. In addition, the guides provide guidance on using the DoD Insect Repellent System to reduce the risk of contracting vector-borne diseases. The guides also recommend the use of permethrin-treated bed nets and using DEET repellents. A generic, staying-healthy guide recommends frequent washing of hands, especially after using the latrine and prior to eating.

Deployed preventive medicine units routinely conduct entomological surveillance efforts to ensure early warning and control of disease vectors, as well as nuisance pest populations.

Although cases of cutaneous leishmaniasis can be expected among American forces in Afghanistan, none has been identified so far. A handful of cases of cutaneous disease are identified each year among troops stationed in Kuwait. Leishmaniasis is transmitted to humans through the bite of an infected sandfly. It is not directly contagious from person to person.

Standards for the diagnosis and treatment of leishmaniasis have not changed dramatically since 1991. Research into the development of a serological test (antibody test) for leishmanial infection has so far failed to yield a new, practicable test. In the absence of such a test, laboratory confirmation of the diagnosis depends upon either microscopic examination of biopsy material or a positive culture of a biopsied lesion or organ. Walter Reed Army Institute of Research investigators have found that an investigational test using PCR methodology has shown great promise in diagnosing cutaneous disease. In underdeveloped parts of the world without sophisticated medical care, the diagnosis of cutaneous leishmaniasis is often made on clinical grounds, without the use of supplementary testing.

Personal hygiene issues centered on any deployments to Persian Gulf Region and research data on safety of DEET and permethrin:

DoD policy recommends the use of the repellents DEET and permethrin, as directed on the label, in order to minimize the risk of contracting vector-borne diseases such as malaria, leishmaniasis, and other endemic diseases depending on the location of the deployment. DEET has been used by the military since 1957 as its standard repellent. It is effective against a wide variety of arthropod species, including mosquitoes, biting flies, fleas, ticks, and chigger mites. It has been used by millions of civilians for over 40 years and has an excellent safety record. However, there have been isolated reports of harmful effects associated with its use.

DoD currently recommends the use of the 33% extended duration formulation (NSN 6840-01-284-3892). This formulation has been available since 1990. The US Environmental Protection Agency (EPA) issued a fact sheet on DEET in 1998 and a Re-registration Eligibility Decision document on DEET (including information on health risks and environmental risks) in 1998. Also, in 1998, EPA reported that 225 DEET products were registered for use as aerosol and non-aerosol sprays, creams and lotions, stick, foams, and toweletts. Product concentrations ranged from 4% to 100% active ingredients. EPA states that "DEET generally is of low acute toxicity, and, based on the available toxicological data, the Agency believes that the normal use of DEET does not present a health concern to the general U.S. population ...."

Permethrin is the most recent addition to the arsenal of personal protective repellents and is the most effective clothing impregnant available. Its primary mode of action is contact toxicity, particularly against crawling arthropods, chigger mites, fleas, and lice. It also acts as a contact repellent to mosquitoes. Most of these vectors are capable of transmitting disease to personnel.

The available scientific literature on DEET and permethrin is vast. Interested parties are encouraged to refer to the forthcoming Institute of Medicine literature review on pesticides (expected to be released in January 2003) and A Review of the Scientific Literature as it Pertains to Gulf War Illnesses, Volume 8: Pesticides issued by RAND.

Current guidance recommends that commanders emphasize good field sanitation practices to maintain force health. Field sanitation practices include personal hygiene activities such as frequent hand washing, bathing, and dental care. Another guidance document for a recent deployment described the importance of hand washing and provided instructions for the construction, use, and maintenance of a hand-washing station.

During a deployment, individual servicemembers are instructed to take steps to protect themselves from biting insects. Such personal protective measures include: 1) Applying a thin coat of long-lasting DEET insect repellent to all exposed skin; 2) Applying permethrin clothing repellent to your BDUs and letting it dry prior to putting it on; 3) Wearing the uniform properly. These three steps comprise the "DoD Repellent System" and provide soldiers with maximum protection against vector-borne diseases.

Other personal protection activities include treating the bednetting with permethrin, avoiding the use of perfumes or colognes, and washing and inspecting your body for insects and bites daily.

In October 2001, the US Army added a task entitled "Practice Individual Preventive Medicine Countermeasures" to its Soldiers' Manual of Common Tasks, which contains critical common tasks. The newly added task includes proper and timely hand washing. Effective hand washing practices should mitigate DEET and permethrin exposures.

Chem/Bio suits issue:

The process to identify existing inventories was robust and extensive. Everything possible has been done to find and identify Isratex BDOs around the world.

- The Defense Logistics Agency notified its depot system to discontinue issuance of the suits to the services of the Isratex BDOs that were being stored in its warehouses. They determined that all of them were in Albany, GA. The depot identified all Isratex BDOs in its possession and segregated them from other chemical protective clothing. These stocks were marked with yellow "police" tape and easily identifiable placards.

- We believe that the Services and DLA have identified all Isratex BDOs that still exist and that the 250,000 that cannot be accounted for have been consumed and disposed of.

- The tracking information is provided to Congress on an annual basis in the Chemical and Biological Defense Program, Annual Report to Congress. The April 2002 report was provided to Congress and is available on-line.

Armed Forces Institute of Pathology (AFIP) issue:

AFIP has published its policy on support to individuals on its web site. The policy clearly states the criteria for submitting a request. "The AFIP accepts cases from both civilian and military sources throughout the world. Cases are generally accepted only from pathologists or clinicians who are functioning as pathologists. However, AFIP recently began accepting cases on a limited basis submitted directly from patients with prior coordination." The web site location for this information is: *http://www.afip.org/Departments/repository/submit.html*

AFIP's main web site address is: *http://www.afip.org/index.html*
For their mission and a list of services: *http://www.afip.org/Departments/repository/index.html*

ANTHRAX VACCINE

WHAT YOU NEED TO KNOW

1 What is anthrax?

Anthrax is a serious disease that can affect both animals and humans. It is caused by bacteria called *Bacillus anthracis*. People can get anthrax from contact with infected animals, wool, meat, or hides. In its most common form, anthrax is a skin disease that causes skin ulcers and usually fever and fatigue. Up to 20% of these cases are fatal if untreated.

When *B. anthracis* is inhaled, as when used as a biological weapon, it is much more serious. The first symptoms may include a sore throat, mild fever and muscle aches. But within several days these symptoms are followed by severe breathing problems, shock, and often meningitis (inflammation of the brain and spinal cord covering). Once symptoms appear, this form of anthrax is almost always fatal, despite treatment with antibiotics.

2 What is anthrax vaccine?

Anthrax vaccine protects against anthrax disease. The U.S. vaccine does not contain actual *B. anthracis* cells and it does not cause anthrax disease. Anthrax vaccine was licensed in 1970.

Based on limited but convincing evidence, the vaccine protects against both cutaneous (skin) and inhalational anthrax.

3 Who should get anthrax vaccine and when?

People 18 to 65 years of age potentially exposed to large amounts of *B. anthracis* bacteria on the job, such as laboratory workers.

Military personnel who may be at risk of anthrax exposure from weapons.

The basic vaccine series consists of 6 doses.

- The first three doses are given at two-week intervals.
- Three additional doses are given, each one 6 months after the previous dose.

Annual booster doses are needed for ongoing protection.

If a dose is not given at the scheduled time, the series does not have to be started over. Resume the series as soon as practical.

Anthrax vaccine may be given at the same time as other vaccines.

4 Some people should not get anthrax vaccine or should wait

Anyone who has had a serious allergic reaction to a previous dose of anthrax vaccine should not get another dose.

Anyone who has recovered from cutaneous (skin) anthrax should not get the vaccine.

Pregnant women should not be routinely vaccinated with anthrax vaccine. This is merely a precaution. There is no evidence that the vaccine is harmful to either a pregnant woman or her unborn baby. Vaccination *may* be recommended for pregnant women who have been exposed, or are likely to be exposed, to anthrax.

There is no reason to delay childbearing after either the man or the woman gets anthrax vaccine.

Vaccines, including anthrax vaccine, are safe to give to breast-feeding women.

5 What are the risks from anthrax vaccine?

Getting anthrax disease is much more dangerous than any risk from the vaccine.

Like any medicine, a vaccine is capable of causing serious problems, such as severe allergic reactions. The risk of anthrax vaccine causing serious harm, or death, is extremely small.

Mild Problems

- Soreness, redness, or itching where the shot was given (about 1 out of 10 men, about 1 out of 6 women)
- A lump where the shot was given (about 1 person out of 2)
- Muscle aches or joint aches (about 1 person out of 5)
- Headaches (about 1 person out of 5)
- Fatigue (about 1 out of 15 men, about 1 out of 6 women)
- Chills or fever (about 1 person out of 20)
- Nausea (about 1 person out of 20).

Moderate Problems

- Large areas of redness where the shot was given (up to 1 person out of 20).

Severe Problems

- Serious allergic reaction (very rare - less than once in 100,000 doses).

As with any vaccine, other severe problems have been reported. But these events appear to occur no more often among anthrax vaccine recipients than among unvaccinated people.

There is no evidence that anthrax vaccine causes sterility, birth defects, or long-term health problems.

Independent civilian committees have not found anthrax vaccination to be a factor in unexplained illnesses among Gulf War veterans.

6 What if there is a moderate or severe reaction?

What should I look for?

Any unusual condition, such as a severe allergic reaction or a high fever. If a severe allergic reaction occurred, it would happen within a few minutes to an hour after the shot. Signs of a serious allergic reaction can include difficulty breathing, weakness, hoarseness or wheezing, a fast heart beat, hives, dizziness, paleness, or swelling of the throat.

What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell your doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your health care provider to file a Vaccine Adverse Event Reporting System (VAERS) form if you have *any* reaction to the vaccine. Or call VAERS yourself at **1-800-822-7967** or visit their website at **http://www.vaers.org.**

7 How can I learn more?

- Ask your doctor or other health care provider. They can give you the vaccine package insert or suggest other sources of information.

- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-2522** (English)
  - Call **1-800-232-0233** (Español)

  - Visit the CDC's website at **http://www.cdc.gov/ncidod/dbmd/diseaseinfo/anthrax_g.htm**

- Contact the U.S Department of Defense (DoD):
  - Call **1-877-438-8222**
  - Visit the DoD website at **www.anthrax.osd.mil**

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Disease Control and Prevention
National Immunization Program

CMAT Control #
2003041-0000019

(165)

"Rauch, Terry, COL, OASD(HA)" (b)(6) @ha.osd.mil> on 02/10/2003 12:50:43 PM

To: (b)(6)
cc:

Subject: FW: Hearing Papers

Ed: See below - I've typed in POCs next to the topic.

T

-----Original Message-----
From: (b)(6)
Sent: Monday, February 10, 2003 12:17 PM
To: (b)(6)
(b)(6)
Subject: Hearing Papers
Importance: High

We are beginning to prepare Dr. Winkenwerder for Congressional Oversight hearings in the near future. In order to facilitate this preparation, we are requesting that you provide information papers on the below subjects. A sample format is attached; the "key messages" should be a description of the message that Dr. Winkenwerder should be prepared to communicate to Congress; please keep any background or factual information in the "facts" section of the paper.

Please submit papers to me (please copy (b)(6) no later than 1200, Wednesday, February 19th.

Papers that were previously submitted for Secretary Rumsfeld or Dr. Chu's hearing preparation are highlighted in yellow and are attached. Please resubmit these in the requested format and include any additional or updated information as appropriate.

Please call or email me with any questions or concerns.

Thank you.

V/R.
(b)(6)
Force Health Protection (DHS) — (b)(6)
Anthrax (Ben) — (b)(6)
Adenovirus (Ben) — (b)(6)
DoD Role in Homeland Defense (Stew)
Smallpox (Ben) (b)(6)
SHAD (DHS) —
Gulf War Illness (ALS Study) (DHS) — (b)(6)
Pre and Post Deployment Health Assessments (DHS) — (b)(6)
Environmental Surveillance (DHS) — (b)(6)
Depleted Uranium (DHS) — (b)(6)
Pyridostigmine Bromide (Sal) —
Iowa Army Ammunition Plant (IAAP) (DHS???) — (b)(6)

<<Sample.doc>> <<SecDef Smallpox.doc>> <<Force Health Protection.doc>>
<<PB.doc>> <<Project112 SHAD Info Paper.doc>> <<Anthrax.doc>>

(b)(6)
Office of the Assistant Secretary of Defense (Health Affairs)

TRICARE Management Activity
(b)(6)

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 - Pre-PostDeployAssess.doc

 - SecDef Smallpox.doc

 - Force Health Protection.doc

 - PB.doc

 - Project112 SHAD Info Paper.doc

 - Anthrax.doc

PRE- AND POST-DEPLOYMENT HEALTH ASSESSMENTS

KEY MESSAGE:

The DoD continues to develop a program to assess the health of servicemembers before and after they deploy to determine deployability of these individuals, allow for health interventions they may require, and track changes in their health status that may result from exposures and experiences during deployment. This program is to be part of a larger plan for standardized, longitudinal, and comprehensive health surveillance of military personnel. Fully implemented, this program is intended to be of benefit for both individual and population health.

FACTS:

- Following the Gulf War, it was apparent that the health status of deploying and redeploying service members had not always been determined or documented. This may have contributed to the difficulty in determining health status changes attributable to deployment.

- Beginning with the Bosnia deployment (1996) and formalized the following years by directives, instructions, and policy statements (DoDD 6490.2 (1997), DoDI 6490.3 (1997) and DoD-HA (1998)), the DoD implemented the use of standardized forms to be administered to service members as they deploy and when they return.

- Completed health assessment forms are to be placed in the individual service members' health records with copies forwarded to the Army Medical Surveillance Activity for data entry and subsequent analysis.

- There is currently a low rate of return of completed forms and substantial concern as to whether forms administered immediately before and after deployments will be able to capture information suitable for all intended purposes.

(b)(6) M.D./DHSD, (b)(6) February 20, 2002

DoD Smallpox Vaccination Program

Message: The DoD Smallpox Vaccination Program is underway with few adverse events.

1) *(Good news story)* The President announced the DoD Smallpox Vaccination Program on 13 Dec 02, and DoD began vaccinating smallpox response teams and health care teams in mid-December 2002. Vaccination of designated deployed personnel began in early January 2003.

2) *(Bad news story)* Although the program is making good progress, some of the anticipated adverse events have occurred.

- Two significant adverse events are being evaluated. Vaccinia immune globulin was not required to treat either one. Only one required hospitalization. Both service members are recovering.

Possible Questions:

1. When do you expect the DoD program to be completed?

- **We cannot give you our exact timelines for security reasons, but we can assure you that we will vaccinate all designated personnel as soon as possible.**

2. Has there been any deaths due to vaccination.

- **No.**

3. Has the virus in the smallpox vaccine (vaccinia virus) been accidentally transferred to any contacts of vaccine recipients?

- **No.**

COL Benedict Diniega/OASD(HA/FHP&R) (b)(6)

FORCE HEALTH PROTECTION (FHP) – HOW ARE WE DOING BETTER SINCE THE GULF WAR?

MESSAGE:

- The DoD has applied medical lessons learned from the Gulf War to many programs to help protect the health of military personnel before, during, and following deployments.
- Force Health Protection Strategy: DoD has developed a Force Health Protection strategy that promotes the health of servicemembers before deployment, protects personnel during deployment, and provides treatment for deployment-related health conditions. The ASD(HA) with support of the Joint Staff and the Military Services is developing individual medical readiness standards and developing a new Force Health Protection directive to institutionalize our emphasis on force health protection.

FY04 Program/Budget Impact:

- None noted at this time

Issues:

- The DoD instituted a deployment health surveillance program that includes pre-and post-deployment health assessments, which validate individuals' medical readiness to deploy and address health concerns upon their return; individual serum specimens maintained in the DoD Serum Repository; and improved occupational and environmental health surveillance programs that help protect service members' health during deployment. The ASD(HA) is developing streamlined deployment health assessments, implementing an interim system like the Theater Medical Information Program for medical surveillance, and establishing a management structure for comprehensive medical surveillance needs, along with comprehensive policies for deployment occupational and environmental health surveillance.
- The DoD has established three deployment health centers (for health surveillance, health care, and health research) that focus on the prevention, treatment, and understanding of deployment health concerns, including development of a post-deployment health clinical practice guideline.
- The DoD has improved health risk communication through the provision of regionally-specific medical intelligence, environmental risk assessments, medical threat briefings, outreach programs, and deployment web sites.
- The DoD coordinates with the VA on deployment health concerns through a DoD/VA Deployment Health Working Group.
- The DoD is developing the Composite Health Care System II and the Theater Medical Information Program to create electronic medical records and improve deployment medical record-keeping. The ASD(HA) is working with the Military Services to develop an improved process for incorporating individual servicemember medical records from deployments into permanent health records.

COL John Gardner (b)(6) , DHSD, January 22, 2003

PYRIDOSTIGMINE BROMIDE (PB)

MESSAGE:

- The DoD must always balance the risks of war, to include the potential for use of deadly nerve agents such as soman, with the possible side effects from drugs such as PB. Currently, PB is thought to be an essential part of the medical protection our troops have for soman, which is extremely lethal. However, PB does have known short-term side-effects, such as diarrhea, and some veterans remain concerned that hypotheses regarding long term effects have not been disproved. We must continue our efforts to improve how we protect our troops against deadly nerve agents.
- Providing the best protection to our troops sometimes involves balancing several issues. The benefits of pyridostigmine far outweigh the risks.

FY 2004 Program/Budget Impact:

- In the U.S., PB is classified as an "investigational new drug" (IND) for this medical purpose. PB was widely used during the Gulf War under special procedures approved by the FDA. After the Gulf War, concerns have been expressed as to whether PB may have contributed to Gulf War veterans' illnesses. Most reviews do not consider PB a likely cause but a Rand report concluded that medical research to date has not ruled out some hypotheses of PB as a possible contributor.
- DoD has funded over $20 million for research concerning the safety and efficacy of PB as a nerve agent pretreatment adjunct. Data from some of these studies was submitted to the FDA for approval of PB under the newly established animal efficacy rule.
- Evidence of the effectiveness of PB as a pre-treatment for soman was based solely on animal studies.

Issues:

- DoD has pre-positioned several million doses of pyridostigmine bromide (PB), labeled as an (IND), as a nerve agent pretreatment against soman.
- Soman is an extremely lethal nerve agent, confirmed or strongly suspected to be in the arsenal of a number of potential adversaries. Standard treatments for other nerve agents must be administered within two minutes of exposure to soman to be effective. There is currently no effective pre-treatment approved by the FDA for exposure to this agent. However, the results of animal tests suggest that use of PB as a pretreatment adjunct, coupled with standard post-exposure treatments, may be protective. PB is approved by the FDA as safe and effective treatment of certain neuromuscular disorders, but has not been approved in the U.S. for marketing as a nerve agent pre-treatment.
- On January 6, 2003, the Department submitted a New Drug Application (NDA) to the Food and Drug Administration (FDA) for approval of PB for this indication.

PROJECT 112/SHIPBOARD HAZARD AND DEFENSE

MESSAGE:

- From 1962 to 1973, the Deseret Test Center conducted a series of chemical and biological warfare vulnerability tests in support of Project 112. Project SHAD (Shipboard Hazard and Defense) was a subset of that program.
- The DoD conducted Project 112/SHAD tests primarily using substances believed to be safe in place of chemical or biological warfare agents to simulate the dispersion of harmful agents in a chemical or biological attack.
- A few veterans have expressed concern that they may have been exposed to harmful substances during these classified tests.
- At the request of the Department of Veterans Affairs, the Department of Defense has been actively pursuing declassification of relevant medical information from all planned chemical and biological tests in Project 112. DoD investigators are searching through classified technical documents archived in various locations to identify reports about Project 112/SHAD testing.
- DoD is committed to providing the VA with the medically relevant information it needs to settle benefits claims as quickly and efficiently as possible and evaluate and treat veterans who were involved in those tests.
- Congress has directed completion of the DoD's investigation by the end of the summer and publication of an interim and final report.

Issues:

- Congress provided no specific funding for the Project 112/SHAD investigation, or for the required reports.
- Project 112/SHAD investigations and reporting should be completed in FY03, so there are no issues for FY04.

(b)(6), DHSD, January 22, 2003

ANTHRAX VACCINE IMMUNIZATION PROGRAM

MESSAGE:

- Current intelligence assessments indicate that the anthrax threat to DoD forces is real.
- The Department's goal is to protect all forces against anthrax as a part of the Department's Force Health Protection program.
- Current scope of the immunization program encompasses personnel assigned to or deployed for more than 15 consecutive days in higher threat areas whose performance is essential for certain mission critical capabilities.
- After an exhaustive review, the National Academy of Sciences concluded that anthrax vaccine is effective against all forms of anthrax and is as safe as other vaccines commonly given to adults.
- Anthrax vaccine is a critical component in our arsenal against bioterrorism.

FY 2004 Program/Budget Impact:

- Present funding supports current and estimated future needs.
- Budget and Program Data ($ in millions)

	Prior Yr (FY02)	Current (FY03)	Budget (FY04)	FYDP (FY05-09)	Total
DHP[1]	14.4	16.1	16.8	90.9	138.2
Army Procurement[2]	49.5	42.7	63.3	290.8	446.4

[1] Funds the Army's AVIP Agency Operations
[2] Funds vaccine procurement- transfer from Chemical and Biological Defense Program

Issues:

- Anthrax is readily weaponized and highly lethal. It poses a clear threat as demonstrated by the anthrax terror attacks in the fall of 2001.
- Since March 1998, the Department of Defense has protected its personnel against anthrax weapons by means of the Anthrax Vaccine Immunization Program. To date, more than 2 million doses of anthrax vaccine have been given to more than 565,000 Service Members.
- Current policy requires mandatory protective vaccination of selected personnel who are assigned to or deployed to designated higher-threat areas.
- DoD is working with the Department of Health and Human Services and other federal agencies to develop a next generation anthrax vaccine that is expected to offer a more user-friendly regimen than the current vaccine which requires six shots with yearly boosters.

02/10/03 13:36 FAX (b)(6) OSAGWI/MR/MD 001

****
*** TX REPORT ***
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Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 2/10/03 1:33:55 PM

TO: ***CDR*** (b)(6) ***FROM:*** (b)(6)

ORGANIZATION: FHP/R

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v/r

Congressional Oversight Hearing
Key Messages

1 DoD Smallpox Vaccination Program (SVP

2 DoD Anthrax Vaccine Immunization Program (AVIP)

3 Pyridostigmine Bromide

4 DoD Adenorvirus Vaccine Status

5 Deployment Health Assessments

6 DoD Support to Homeland Defense Activities

7 DoD Medicine's Role in Homeland Defense

8 VA-DoD Contingency Hospital System in Homeland Defense

9 IOWA Army Ammunition Plant (IAAP) Exposure Study

10 Depleted Uranium

11 Environmental and Health Effects From Depleted Uranium (GU) Use On The Battlefield

12 Environmental Surveillance Capabilities In Support of Force Health Protection Requirements

13 Improved Depleted Uranium Training

14 Medical Follow-Up Of Veterans With The Highest Depleted Uranium Exposures

15 DoD-VA Cooperation On Project 112/SHAD Testing

DOD SMALLPOX VACCINATION PROGRAM (SVP)

KEY MESSAGE:

Because of the threat of bioterrorism and biological warfare using smallpox, and the need to preserve the capabilities of our Armed Forces to respond globally to any contingency, the President decided to vaccinate select DoD personnel against smallpox. The program is making good progress. As expected, some of the anticipated adverse reactions have occurred. These vaccine recipients are receiving quality medical care for treatment of these reactions, and routine monitoring for adverse events continue.

FACTS:

- The President announced the DoD Smallpox Vaccination Program on 13 Dec 02.
- DoD began vaccinating smallpox response teams and health care teams in mid-December 2002.
- Vaccination of designated deployed and deploying personnel began in early January 2003.
- To date, over 8,000 military healthcare personnel on medical response teams and over 110,000 of deployed/deploying military personnel have been vaccinated.
- Three vaccine recipients have developed significant reactions to the vaccine; all three recovered and have returned to duty. No vaccine recipient has required treatment with vaccinia immune globulin (VIG).
- To date, there has been no deaths due to smallpox vaccination.
- Active and passive surveillance for adverse events continue. Adverse events are monitored by a joint CDC and DoD Data Management and Safety Board (DMSB) on a regular basis.

Prepared by: COL B.M. Diniega/FHP&R/(b)(6) /Input from MILVAX/February 11, 2003

ANTHRAX VACCINE IMMUNIZATION PROGRAM

KEY MESSAGE:

The Department of Defense resumed its Anthrax Vaccine Immunization Program (AVIP) in June 2002 to protect our Armed Forces against the clear and present threat from the biowarfare agent anthrax. The current scope of this program encompasses military personnel and emergency-essential DoD civilians and contractors deploying for more then 15 consecutive days in higher threat areas. The National Academy of Sciences' Institute of Medicine concluded that anthrax vaccine is effective against all forms of anthrax and is as safe as other vaccines commonly given to adults. Since March 1998 to present over 2.5 million doses have been administered with no unexpected patterns of adverse events detected. The DoD Anthrax Vaccine Immunization Program is a critical force health protection program that facilitates maximum flexibility of the warfighter, and thus ensuring mission accomplishment.

FACTS:

- Current intelligence assessments indicate that the anthrax threat to DoD forces is real. Anthrax is the easiest biowarfare agent to produce and weaponize, and the spores are highly lethal. The anthrax terror attacks in the fall of 2001 demonstrated the lethality, yet also provided practical experience in the post-exposure treatment of anthrax infection.

- The National Academy of Sciences concluded that anthrax vaccine is effective against all forms of anthrax and is as safe as other vaccines commonly given to adults. To date, 18 human safety studies and 7 independent scientific panels have affirmed the safety and efficacy of the anthrax vaccine.

- Over 2.5 million doses of anthrax vaccine have been given to over 711,000 service members.

- The anthrax vaccine has been licensed by the U.S Food and Drug Administration (FDA), without interruption, since 1970. Concerns about deficiencies in meeting current Good Manufacturing Practices (cGMP) were resolved to the satisfaction of the FDA. On January 31, 2002, the FDA granted the Bioport Corporation full approval to resume distribution of the U.S.-licensed anthrax vaccine.

- DoD in conjunction with the Department of HHS and other federal agencies are conducting research on a next generation anthrax vaccine and a reduced-dose/changed route of administration regimen for the current anthrax vaccine.

FY 2004 Program/Budget Impact:

- Present funding supports current and estimated future needs.

- Budget and Program Data ($ in millions)

	Prior Yr (FY02)	Current (FY03)	Budget (FY04)	FYDP (FY05-09)	Total
DHP[1]	14.4	16.1	16.8	90.9	138.2
Army Procurement[2]	49.5	42.7	63.3	290.8	446.4

[1] Funds the Army's AVIP Agency Operations

[2] Funds vaccine procurement- transfer from Chemical and Biological Defense Program

PYRIDOSTIGMINE BROMIDE

KEY MESSAGE: The Department of Defense (DoD) has pre-positioned, for force health protection purposes, several million doses of pyridostigmine bromide (PB) as a nerve agent pretreatment against soman. Soman is an extremely lethal nerve agent, confirmed or strongly suspected to be in the arsenal of a number of potential adversaries. Standard treatments for other nerve agents must be administered within two minutes of exposure to soman and even then are not very effective. The results of animal tests suggest that use of PB as a pretreatment adjunct, coupled with standard post-exposure treatments, may be protective. On February 5, 2003, the Food and Drug Administration approved the use of PB as a pre-treatment against soman.

FACTS:

- In the U.S., PB was classified as an "investigational new drug" for this medical purpose. PB was widely used during the Gulf War under special procedures approved by the FDA. In the aftermath of the Gulf War, concerns were expressed as to whether PB may have contributed to Persian Gulf War Veterans' Illnesses. Reviews conducted by the Institute of Medicine and the Presidential Advisory Committee on Gulf War Veterans' Illnesses did not consider PB a likely cause, but a Rand report concluded that medical research to date had not ruled out some hypotheses of PB as a possible contributor. The Rand report was the subject of further independent review by the Armed Forces Epidemiology Board and the Institute of Medicine. The AFEB stated that the shortcomings of the RAND report "are so profound as to render the Document scientifically too weak for use in policy development." The IOM indicated that there was insufficient evidence to determine whether an association does or does not exist between PB and long-term adverse health effects.

- DoD has funded over $20 million for research concerning the safety and efficacy of PB as a nerve agent pretreatment adjunct. Data from some of these studies was submitted to the FDA for approval of PB under the newly established animal efficacy rule.

- Evidence of the effectiveness of PB as a pre-treatment for soman was based solely on animal studies because it is unethical to expose people to lethal nerve agents in order to test the effectiveness of a drug.

- On January 6, 2003, the Department submitted a New Drug Application (NDA) to the Food and Drug Administration (FDA) for approval of PB for this indication.

- On February 5, 2003, the FDA approved PB for use as a pretreatment against Soman Nerve Agent Pretreatment (Soman Nerve Agent Pretreatment, Pyridostigmine, SNAPP).

Prepared by: (b)(6) FHP&R, (b)(6)

DOD ADENOVIRUS VACCINE STATUS

KEY MESSAGE:

Adenovirus is a military significant respiratory disease that particularly infects military trainees in recruit training camps resulting in respiratory infection, increased burden to the health care system, and lost training time. The military Services required recruits to be vaccinated with adenovirus vaccine Type 4 and 7 between 1980 until 1999 when vaccine supplies were depleted. The company which made the adenovirus vaccine went out of business in 1996. DoD has contracted with another company to re-manufacture adenovirus vaccine.

FACTS:

- Adenovirus vaccines Type 4 and 7 (both oral) were licensed in 1980.
- Army, Navy, and Marine recruits were routinely vaccinated on entry to recruit training camp from 1980 until vaccine supplies were depleted in 1999.
- The manufacturer (Wyeth) ceased producing adenovirus vaccines in 19XX, and the last shipment of vaccine to DoD was in 1996.
- In September 2001, the US Army Medical Research and Materiel Command, awarded a contract to Barr Laboratories, Inc for the remanufacture of the adenovirus types 4 and 7 vaccines.
- In May 2002, Barr completed an agreement with Wyeth to transfer the manufacturing technology, adenovirus master seeds, and human cell cultures to grow the viruses.
- Barr has broken ground at their Forest, VA facility. Construction of the manufacturing facility will be completed in June 2003, and all equipment will be installed by August 2003.
- Barr estimates that 5 years is needed to accomplish development, clinical trials, FDA approval, and establish production capabilities. Upon review of the timelines, no significant cost-effective acceleration of the program could be identified.

Prepared by: COL B.M. Diniega/FHP&R/(b)(6) /Input from USAMRMC/February 13, 2003

DEPLOYMENT HEALTH ASSESSMENTS

KEY MESSAGE: Congress directed DoD to establish a system to assess the medical condition of deployed service members, including pre-deployment and post-deployment medical examinations and records of deployment-related health services and events.

FACTS: DoD compliance with above Congressional direction includes the following:

- Pre-Deployment Health Assessments.
  - Deploying personnel receive individual health assessments that are documented on DD Form 2795, Pre-Deployment Health Assessment.
  - These assessment forms include eight questions on health status and concerns. The forms are reviewed by medical personnel and a decision is rendered on the service member's medical deployability or non-deployability and appropriate referral for treatment of any identified health problems.
  - Individual pre-deployment health assessments further include reviews of required immunizations and other protective medications/measures, personnel protective and medical equipment, DNA and serum (HIV) samples (saved in the DoD Serum repository), dental classification, and briefings on deployment-specific health threats and countermeasures.
- Post-Deployment Health Assessments.
  - Redeploying personnel receive individual health assessments that are documented on DD Form 2796, Post-Deployment Health Assessment.
  - These assessment forms include six questions on health and exposure concerns. The forms are reviewed by medical personnel and positive responses result in a review of deployment health records and appropriate referral for follow-up care.
  - Follow-up health care is also available through military and VA providers using the jointly-developed Post-Deployment Health Clinical Practice Guideline, which has been designed specifically for addressing deployment-related health concerns.
  - The post-deployment health care process is managed by the DoD Deployment Health Clinical Center (DHCC) located at Walter Reed Army Medical Center. The DHCC is a "center of excellence" for post-deployment health care that provides clinical guidance, training, and tools (website: www.pdhealth.mil).
- Recordkeeping.
  - The original deployment health assessment forms should be placed in the service member's permanent medical record. Copies of the forms should be sent to the Army Medical Surveillance Activity, where the forms are scanned and the data entered into the Defense Medical Surveillance System for archiving and analysis.
  - Documentation of all health treatment provided during a deployment, as well as any notable environmental and occupational exposure information, should be placed in individual service member medical records. Deployment exposure records should have the capability of being linked to health records.
  - Rosters of deployed personnel are required to be created and maintained, along with information on the deployed unit of assignment and deployment location(s).

Prepared by: (b)(6) DHSD, (b)(6) February 11, 2003

INFORMATION PAPER

February 12, 2003

Subject: Department of Defense Support to Homeland Defense Activities

Background

The task of supporting civil authorities in a time of crisis is not a new mission for DoD. The U.S. military has a long history of providing support and assistance to domestic civil authorities during emergencies and other instances of national concern. For example, the military has assisted relief agencies during natural disasters such as hurricanes and earthquakes.

US Northern Command

The command's mission is homeland defense and civil support, specifically is:

- to conduct operations to deter, prevent, and defeat threats and aggression aimed at the United States, its territories, and interests within the assigned area of responsibility; and
- as directed by the President or Secretary of Defense, to provide military assistance to civil authorities including consequence management operations.

USNORTHCOM plans, organizes, and executes homeland defense and civil support missions, but has few permanently assigned forces. The command will be assigned forces whenever necessary to execute missions as ordered by the President.

USNORTHCOM responds to requests for federal military support from a Lead Federal Agency in a time of national crisis following an incident. In such a crisis, when requested by a Lead Federal Agency and approved by the Secretary of Defense, USNORTHCOM will support the civilian Lead Federal Agency designated to be in charge of the event – usually the Federal Bureau of Investigation (FBI) for Crisis Management or the Federal Emergency Management Agency (FEMA) for Consequence Management. The mission of USNORTHCOM is to provide command and control for deploying DoD consequence management assets in order to reduce the effects of the incident, save and preserve lives, and restore critical services.

Response Process

The process involves the Federal government, local fire, police and emergency medical services, called the First Responders, that will activate Mutual Aid Agreements to bring in surrounding local first responders. Should the local assets be overwhelmed, then the

State responds by providing the governors National Guard assets. Neighboring State Governors help each other through Emergency Management Assistance Compacts (EMAC). Should regional assets be overwhelmed, the Federal Government would assist under the Federal Response Plan. 28 different agencies, which include DoD, have signed this plan which is an agreement on how the entire federal capability will be brought to bear on a disaster. Should any of these agencies need additional assistance, DoD could be called upon to respond, mission permitting. The Secretary of the Defense will direct, via an EXECUTION ORDER, US Northern Command to provide assets to assist FEMA at the disaster site who will deploy an advanced team.

DoD Medical Capabilities

DoD brings significant medical capabilities to the table. These include: field hospitals, specialized medical augmentation teams, field laboratory diagnostic capabilities, medical evacuation, public health, vector control, patient tracking, veterinary support, medical supply support, and mass casualty care. Additionally, we have our fixed medical treatment facilities located around the nation that have inpatient nursing and medical expertise. Specific medical tasks include triage and stabilization, health and risk assessment, and other life sustaining and supporting measures.

Finally, under the Federal Response Plan (FRP), Executive Support Function 8, we have a robust bed expansion capability that can be activated subsequent to a disaster of this magnitude called the National Disaster Medical System. The NDMS is a joint Federal, State, and local mutual aid organization for a coordinated medical response in time of war, national emergency, or major domestic disaster resulting in a mass casualty situation. NDMS is the response to supplement health and environmental health services at the disaster site. Patients are evacuated to designated locations throughout the United States for casualties that cannot be treated locally. They are then placed in a national network of hospitals that have agreed (through signed MOUs) to accept patients in the event of a major disaster. The DoD is a primary Federal agency responsible for administering the NDMS. Other agencies sharing responsibilities with the DoD are the DHS, FEMA, and the DVA. NDMS is activated by the ASD(HA) *in support of military contingencies* when casualties exceed the combined capabilities of the VA/DoD Contingency Care System. The *Assistant Secretary for Public Health Emergency Preparedness (ASPHEP) may activate NDMS in response to a domestic conventional disaster*. Under the latter circumstances, DoD Components will participate in relief operations to extent compatible with U.S. national security interests, when authorized.

In summary, DoD medical capabilities are available to support consequence management efforts, when authorized through the RFA process, mission permitting.

Prepared by: CDR (b)(6), OASD(Health Affairs), (b)(6)

INFORMATION PAPER

February 12, 2002

SUBJECT: DoD Medicine's Role in Homeland Defense

Key Points

- The Federal Response Plan (ESF #8) spells out Federal health and medical service provisions to supplement State and local resources in response to public health and medical needs following a major disaster or emergency (to include a WMD event) within the CONUS. The National Disaster Medical System (NDMS) is integral to this function. (**TAB A** depicts DoD and agencies' roles for all ESFs).

- NDMS is a joint Federal (DoD, FEMA, DHS, and VA), State, and local mutual aid organization for a coordinated medical response in time of war, national emergency, or major domestic disaster resulting in a mass casualty situation. The Office of Emergency Response (OER) currently manages the program through the Assistant Secretary for Public Health and Emergency Preparedness (ASPHEP) (*a recent change from the Assistant Secretary of Health, HHS*) under the new Under Secretary for Emergency Preparedness and Response, Department of Homeland Security (DHS) (effective 01 Mar 2003).

- Activation: **DoD Directive 3020.36, "Assignment of National Security Emergency Preparedness (NSEP) Responsibilities to DoD Components,"** November 2, 1988 and **DoD Directive 6010.22, " National Disaster Medical System,"** January 21, 2003 both state that the NDMS is activated by the ASD(HA) *in support of military contingencies* when casualties exceed the combined capabilities of the VA/DOD Contingency Care System. In accordance with the **Federal Response Plan (FRP) 9230.1-PL**, the *ASPHEP may activate NDMS in response to a domestic disaster (note: as mentioned above, recently changed from ASH to ASPHEP. An adjustment to the FRP language needs to be made to reflect this change)*. Under the latter circumstances, DoD components will participate in relief operations to extent compatible with U.S. national security interests, when authorized.

- Public Law 107-296 "Homeland Security Act of 2002" (*Signed into Law*)

  - The position of ***Assistant Secretary for Public Health Emergency Preparedness*** is transferred to the new DHS under the Under Secretary for Emergency Preparedness and Response.

  - The Office of Emergency Response (OER) will manage the day-to-day operations of the NDMS in collaboration with its four (4) partners.

- OER coordinates the operations of the NDMS and any other emergency response activities within the Department of Homeland Security and other issues that are related to bioterrorism or public health emergencies.

- All other functions of the NDMS will continue as they exist today, pending further changes by the four (4) partners . MOUs, the Federal Response Plan, and aforementioned directives are still applicable.

Prepared by: CDR (b)(6) OASD(HA), (b)(6)

EXECUTIVE SUPPORT FUNCTIONS (ESFs) of THE FEDERAL RESPONSE PLAN

AGENCY / ESF #	1 Transportation	2 Communications	3 Public Works and Engineering	4 Firefighting	5 Information and Planning	6 Mass Care	7 Resource Support	8 Health and Medical Services	9 Urban Search and Rescue	10 Hazardous Materials	11 Food	12 Energy
USDA	S	S	S	P	S	S	S	S	S	S	P	S
DOC		S	S	S	S		S			S		
DOD	S	S	P	S	S	S	S	S	S	S	S	S
DOEd					S							
DOE					S		S	S		S		P
HHS			S		S	S		P	S	S	S	
HUD						S						
DOI		S	S	S	S					S		S
DOJ					S			S	S	S		
DOL			S				S		S	S		
DOS	S									S		S
DOT	P				S		S			S		S
TREAS	S				S		S					
VA			S			S	S	S				
AID								S	S			
ARC					S	P		S			S	
EPA			S	S	S			S		P	S	
FCC		S										
FEMA	S	S		S	P	S	S	S	P		S	
GSA	S	S			S	S	P	S			S	
NASA					S		S		S			
NCS		P			S		S	S				S
NRC					S					S		S
OPM							S					
SBA					S							
TVA	S		S									S
USPS	S					S		S				

P = Primary Agency: Responsible for Coordination of the ESF
S = Support Agency: Responsible for Supporting th Primary Agency

TAB A

INFORMATION PAPER

February 12, 2003

SUBJECT: The VA DoD Contingency Hospital System in Homeland Defense

Key Points:

- The VA-DoD Health Resources Sharing and Emergency Operations Act (Pub. L. 97-174) was enacted on May 4, 1982 which gave the VA a new mission: to serve as the principal health care backup to DoD in the event of war or national emergency that involves armed conflict. In addition to the contingency mission, this public law amended Title 38, United States Code (U.S.C.), in order to promote greater peacetime sharing of health care resources between VA and DoD.

- In response to the 1982 law, a Memorandum of Understanding (MOU) was executed between the Secretary of Defense and the Administrator of Veterans Affairs (presently the Secretary of Veterans Affairs), specifying each agency's responsibilities under the law. More specifically, plans have been developed jointly by VA and DoD to implement Public Law 97-174 by establishing a VA/DoD Contingency Hospital System as reflected in the Veterans Health Administration Handbook 0320.1 of May 1, 1997.

- Activation of the system is made when the Secretary of Defense determines that DoD needs VA medical care resources because of a military conflict or another type of national emergency. The Secretary of Defense then notifies the Secretary of Veterans Affairs, in writing, of any need for medical care contingency support. Finally, the Secretary of Veterans Affairs commits VA to provide support and communicates this commitment to the Secretary of Defense in writing.

- Overall policy is that VA will provide DoD with maximum bed availability in the specific contingency bed categories within 72 hours of activation of the VA-DoD Contingency Hospital System. In order to accomplish this, VA could arrange for care of for some of its patients at civilian hospitals (subject to Presidential approval), if necessary.

- Currently, the Commander, US Joint Forces Command (JFCOM) has overall responsibility to ensure integrated CONUS medical operations. Consequently, JFCOM has in place the Integrated CONUS Medical Operations Plan (ICMOP) that coordinates all CONUS medical assets in support of DoD casualties. ICMOP is supported by the VA/DoD Contingency Hospital System Plan. Deliberations are ongoing between U.S Northern Command (NORTHCOM) and JTFCOM as to which combatant command will manage this function. Recent indicators are that this activity will transfer to USNORTHCOM once they are fully operational capable (FOC) on 01 October 2003.

Prepared by: CDR (b)(6) OASD(HA), (b)(6)

IOWA ARMY AMMUNITION PLANT (IAAP) EXPOSURE STUDY

KEY MESSAGE:

In response to 2000 and 2001 legislation (Sec. 1078, 106-398 and Sec 8172, 107-117) DoD acted to identify past and current IAAP DoD workers and notify them of possible hazardous exposures. DoD security policies have been reviewed and the workers are being provided guidance to facilitate their ability to discuss radioactive and other hazardous exposures with appropriate officials including health care providers.

As directed, the DoD developed a health study of the IAAP workers. US Army Center for Health Promotion and Preventive Medicine (USACHPPM) contracted with the College of Public Health at the University of Iowa (UI), which is conducting a study of Department of Energy (DOE) employees at the IAAP. As part of the Phase I of the study, the UI has identified over 35,000 previous IAAP workers to date and anticipates identifying an additional 3,000 workers. The health study protocol has received Human Subjects Institutional Review Board (IRB) approval. The USACHPPM is reviewing the study protocol to ensure it is scientifically sound, and will coordinate with the UI researchers to ensure they make all necessary changes.

The Armed Forces Epidemiology Board, the DOE Beryllium Institutional Review Board, and an independent academic group will conduct the external peer review of the study as part of USACHPPM's approval process to ensure the study is both ethically and scientifically sound.

FACTS:

The Iowa Army Ammunition Plant, a DoD conventional munitions assembly facility, has operated continuously from 1945 to present. From 1948 to 1975, the Department of Energy (DOE) assembled, modified, tested, and disassembled nuclear weapons within the IAAP plant complex. Some cross-over of DoD workers to the DOE facility reportedly occurred during the years when the nuclear weapons facility operated.

Senator Harkin (D-Iowa), sponsored legislation in 2000 and 2001 (Section 1078 of Public Law 106-398 and Section 8172 of Public Law 107-117) directing the Secretary of Defense to identify past and current IAAP DoD workers and notify them of possible exposures. The legislation further directed the Secretary of Defense to review policies that may prevent or discourage former defense nuclear weapons workers from discussing radioactive and other hazardous exposures with appropriate officials to include health care providers. The OSD-ATL (Nuclear matters) was required to report to congressional defense committees on the DoD plan for accomplishing these directives. The report was submitted in August 2002.

The 2002, DoD Appropriations Bill also earmarked $1M DHP funds for a health study of past and current IAAP DoD workers, including contractors and subcontractors. The

study was intended to provide an evaluation for DoD workers similar to that prescribed by Congress for past DOE workers at the plant (1993 legislation, Section 3162 of Public Law 102-484).

The USACHPPM received the $1M in FY02 and contracted with UI to conduct the DoD study. This same agency is conducting the DOE study at the IAAP. IU will identify and notify past and current DoD IAAP workers during Phase I of the study. FY02 funding was transferred to UI on September 19, 2002. Additional congressional funding ($1M) was appropriated for fiscal year 2003 (H.R.5010, Senate Report 107-213). Congress mandated in the 2003 bill that all workers be screened for beryllium.

The study will identify and notify all current and former IAAP conventional weapons workers, inquire about their exposures to hazardous substances, conduct job exposure assessments, collect and analyze mortality data, request responses to health questionnaires, and conduct medical examinations to determine health outcomes related to workplace exposures.

The IAAP Workers are also concerned about the potential for exposure to radiation and chemicals present in the ammunition plant. Preliminary review of records indicates that IAAP conventional weapons workers may have been exposed to silica, beryllium, solvents, explosives, epoxies, heavy metals, and fibrogenic dusts.

The UI is contracting with American Ordinance to provide all industrial hygiene and medical surveillance program data.

The UI received Human Subjects Institutional Review Board approval to proceed on August 14, 2002. The UI submitted a final study protocol to USACHPPM on October 18, 2002.

The contentious issue related to the study protocol involves the use of the beryllium lymphocyte proliferation test to identify workers exposed and sensitized to beryllium. The test has a positive predictive value of approx 50% in asymptomatic workers and may falsely identify beryllium illness.

The USACHPPM's proactive risk communication strategy addresses the importance of and need for fair and balanced media coverage.

The study protocol states that future research use of and access to data collected during the study will be afforded to and approved by the DoD.

DEPLETED URANIUM (DU)

KEY MESSAGE:

Depleted Uranium (DU) is the superior heavy metal for defeating enemy armored vehicles and for defending US armored vehicles. The United Nations Environment Programme, the World Health Organization, European Commission, the United Kingdom Royal Society, and the United Kingdom Ministry of Defense evaluated areas in the Balkans where DU was used. Common conclusions were that no widespread environmental contamination and no health impact on the local population or deployed personnel is expected.

FACTS:

- Depleted uranium's density, high melting point, high tensile strength, pyrophoric properties, and ability to self sharpen as it penetrates a target make it favorable for use in weapons.
- Like any heavy metal, DU has chemical toxicity properties that, in high doses, can cause poisoning and health effects. Radioactivity of DU is 40 percent lower than that of natural uranium.
- The Institute of Medicine found limited/suggestive evidence of **no** association between DU exposure and lung cancer or clinically significant renal dysfunction.
- Reviews of literature on health effects of natural uranium or DU by the US Department of Health and Human Services and the RAND Corporation support the conclusion that DU is unlikely to be the cause of undiagnosed symptoms in Gulf War veterans.
- The Baltimore Veterans Affairs Medical Center has been monitoring approximately 60 Gulf War veterans involved with DU friendly fire incidents. Approximately 20 in this group still have DU fragments in their bodies. While they have higher than normal urine uranium levels, none have adverse health effects due to the chemical or radiological properties of DU.
- Individuals with normal urine uranium levels now are unlikely to develop any DU-related toxicity in the future, regardless of what their DU exposure may have been in the Gulf War.
- The US Army has completed a $5M+ test to measure DU aerosol levels and residue after DU rounds strike Abrams tanks and Bradley fighting vehicles. The USACHPPM will complete a $2M Health-Affairs-funded DU health risk assessment by September 30, 2003.
- DU training continues as troops deploy to SWA.
  - The Army's DU training policy is that all soldiers will receive DU awareness training (Tier I) with additional specialized training provided to those with occupation specialties that involve battle damage assessment and repair and maintenance of tracked and wheeled vehicles (Tier II) and to officer and enlisted Chemical soldiers (Tier III).

- The Marine Corps uses a three-level DU training program. Both the Marines and Navy use a Service-specific variant of the Army's DU Awareness Training video.

- The Air Force program requires personnel on mobility status to receive DU awareness training and has incorporated DU awareness guidance in the Nuclear, Biological, and Chemical handbook carried by all deploying personnel.

- The US Army Medical Command has provided updated DU awareness training to military caregivers in DoD and the Veterans Administration by means of a training video. The video is distributed to medical units worldwide.

- Recent DU Events of Note

  - At the request of USCENTCOM, LTC Melanson, DU Consultant to the Army Surgeon General, briefed Saudi officials in October 2002 on the hazards of DU and addressed their concerns about DU buried in Saudi Arabia following the Gulf War.

  - At the request of USCENTCOM, a subject matter expert from the US Department of Health and Human Services' Agency for Toxic Substances and Disease Registry recently provided an overview of the Agency's Toxicological Profile for Uranium at a meeting in Saudi Arabia.

  - At the request of the Kuwaiti government, the International Atomic Energy Agency recently completed an evaluation of the environmental impact of DU used in Kuwait during the Gulf War. IAEA officials have informally indicated that their findings are consistent with UNEP findings in the Balkans (no widespread contamination and no significant impact to the environment).

  - In the event of renewed hostilities in SWA, the Army has fielded a new 25mm DU round for the Bradley Fighting Vehicle. This round was not available during Gulf War in 1991.

(b)(6)

DHSD

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February 13, 2003

ENVIRONMENTAL AND HEALTH EFFECTS FROM DEPLETED URANIUM (DU) USE ON THE BATTLEFIELD

KEY MESSAGE:

Depleted Uranium (DU) is the superior heavy metal for defeating enemy armored vehicles and for defending US armored vehicles. In response to public concerns about possible health effects in areas where DU was used in combat, the United Nations Environment Programme, the World Health Organization, European Commission, the United Kingdom Royal Society and the United Kingdom Ministry of Defense evaluated areas in the Balkans where DU was used. Common conclusions were that no widespread environmental contamination and no health impact on the local population or deployed personnel is expected.

FACTS:

- Depleted uranium's density, high melting point, high tensile strength, pyrophoric properties, and ability to self sharpen as it penetrates a target make it particularly favorable for use in weapons.
- Like any heavy metal (uranium, lead, tungsten, etc.), DU has chemical toxicity properties that, in high doses, can cause poisoning and health effects. Radioactivity of DU is 40 percent lower than that of natural uranium.
- The Institute of Medicine found limited/suggestive evidence of no association between DU exposure and lung cancer (below 0.200 Sieverts cumulative internal dose) or clinically significant renal dysfunction. The study stated that there were inadequate or insufficient data to determine whether an association exists between exposure to uranium and a variety of health conditions, including lymphatic cancer, bone cancer, nervous system disease, nonmalignant respiratory disease, and other health outcomes (e.g., gastrointestinal disease).
- Reviews of literature on health effects of natural uranium or DU by the Department of Human Services' Agency for Toxic Substances and Disease Registry and the RAND Corporation support the conclusion that DU is unlikely to be the cause of undiagnosed symptoms in Gulf War veterans.
- The Baltimore Veterans Affairs Medical Center has been monitoring approximately 60 Gulf War veterans involved with DU friendly fire incidents. Approximately 20 in this group still have DU fragments in their bodies. While they have higher than normal urine uranium levels, none have adverse health effects due to the chemical or radiological properties of DU.
- The US Army has completed a $5M+ Capstone test to measure DU aerosol levels and residue after Abrams tanks and Bradley fighting vehicles are struck by DU rounds. USACHPPM/Battelle are scheduled to complete a $2M OSD(HA) funded DU health risk assessment by September 30, 2003.
- Iraq maintains that DU munitions used in the Gulf War caused severe health and environmental damage in Iraq and has raised the issue with the UN Security Council.

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February 13, 2003

ENVIRONMENTAL SURVEILLANCE CAPABILITIES IN SUPPORT OF FORCE HEALTH PROTECTION REQUIREMENTS

KEY MESSAGE:

As a result of significant improvements over the past several years in the anticipation, identification, evaluation, and control of potentially hazardous environmental exposures to our Servicemembers while deployed, an enhanced level of Force Health Protection is being afforded to DoD active duty, civilians, and contractor personnel. The U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM), in its role as the DoD lead agent for occupational and environmental surveillance, continues to exert a strong leadership role in this area, most notably by its leadership on the Joint Environmental Surveillance Work Group (JESWG).

FACTS:

- The Department of Defense Directive 6490.2 and Instruction 6490.3 (both published in 1997) and the Joint Staff Memorandum, MCM-0006-02 (Feb 2002) all address deployment medical surveillance including the requirement for occupational and environmental health surveillance. These documents provide sufficient policy and guidance to require the military services and commanders to use standardized procedures for assessing health readiness and conducting health surveillance, including environmental surveillance, in support of all joint deployments. Servicemembers deploying for Operation Enduring Freedom and the current crisis in SW Asia are covered by the detailed requirements for occupational and environmental surveillance included in the CJCS memorandum.

- Environmental surveillance improvements since the Gulf War include (1) pre-deployment environmental health site evaluations utilizing greatly enhanced medical intelligence identifying environmental threats including industrial activity hazard assessments; (2) more comprehensive ambient air, soil, and water health risk assessments with improved documentation during deployment with improved sampling equipment; (3) a sound risk management program to control adverse exposures whenever possible, and (4) better-quality medical surveillance both during and after deployment to detect any illnesses due to environmental exposures.

- A retrospective analysis of environmental surveillance activities in Bosnia (Operation Joint Forge) and Bosnia-Herzegovina (Operations Joint Endeavor and Operation Joint Guard) have been the most comprehensive of any U.S. Forces' deployment to date.

- This surveillance has been conducted primarily by deployed military preventive medicine detachments from the Air Force, Navy, and Army, including the U.S. Army 520th Theater Army Medical Laboratory (TAML) and personnel from the USACHPPM. The Air Force, followed by the Army, and now the Navy (in-progress) have tailored their preventive medicine (PM) assets to deploy based on the specific theater PM requirements, thus greatly reducing associated logistical footprints.

- The Joint Environmental Surveillance Working Group (JESWG) reviews, develops, and recommends functional aspects of environmental health surveillance policy for consideration by the Joint Preventive Medicine Policy Group developed an Occupational and Environmental Health Surveillance (OEHS) White Paper. The White Paper identifies numerous areas for which policy opportunities to be pursued. DASD (FHP&R) recently provided approval to DHSD to pursue six of these opportunities during FY 03: (1) further enhancement of joint occupational and environmental surveillance operations; (2) clarification of the roles of service preventive medicine units relating to chemical, biological, radiological, nuclear, and high explosive (CBRNE) agents; (3) establishment of additional OEHS training requirements; (4) obtaining DDR&E's support for additional OEHS science and technology RDT&E; (5) enhancement of health risk communication procedures, including the publishing of a DoD Health Risk Communication Manual for use during deployments; and (6) improved documentation of occupational and environmental exposures in service personnel medical records. A major portion of this effort will include revisions of the DoD 6490.2 and DoDI 6490.3 both of which are currently in-progress.

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FHP&R/DHSD

(b)(6)

February 11, 2003

IMPROVED DEPLETED URANIUM TRAINING

KEY MESSAGE:

The DoD recognizes that it is essential that all military personnel receive training on the possible medical hazards of depleted uranium (DU). The DoD and the Services need to ensure that all deployable personnel know what DU is, how it is used, how they might encounter it on the battlefield, the hazard it presents, and how to prevent or minimize personal exposures.

FACTS:

- The Gulf War was the first offensive and defensive use of DU in combat, but only personnel on platforms using DU were trained. In early 1999, a tri-Service DU working group met and made recommendations for total force training. Today, each of the Services use a tiered DU awareness training program. The DoD and VA healthcare providers have seen and have available a DU training video.

- The Army is the lead agency in DoD for defining DU's hazard potential and for providing guidance and training pertaining to exposure to DU on the battlefield.

- The Army's policy is that all soldiers will receive DU awareness training (Tier I) with additional specialized training provided to those with occupation specialties that involve battle damage assessment and repair and maintenance of tracked and wheeled vehicles (Tier II) and to officer and enlisted Chemical soldiers (Tier III). The DU training program, fielded in July 1999, focuses on force health protection and operational effectiveness. On October 28, 2002, the Army added a new Tier IV DU awareness training for Bradley Fighting Vehicle personnel.

- Each of the four tiers of the Army's DU training program is supported by a training support package available to all units from the Army Chemical School at Ft. Leonard Wood, MO.

- The Marine Corps also uses a similar tier approach for their DU training program. Both the Marines and Navy use a Service-specific variant of the Army's DU Awareness Training video.

- The Air Force program calls for all personnel on mobility status to receive DU awareness training and has incorporated DU awareness guidance in the Nuclear, Biological, and Chemical handbook carried by all deploying personnel.

- The US Army Medical Command has provided updated DU awareness training to military caregivers in DoD and the Veterans Administration by means of a training video. The video is distributed to medical units worldwide.

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DHSD

(b)(6)

February 13, 2003

MEDICAL FOLLOW-UP OF VETERANS WITH THE HIGHEST DEPLETED URANIUM EXPOSURES

KEY MESSAGE:

The highest exposure to depleted uranium (DU) during the Gulf War occurred during friendly fire incidents in which DU munitions fired from US tanks struck US combat vehicles. Soldiers riding in or on these vehicles may have been exposed to DU by fragments embedded in their bodies, inhalation and ingestion of DU particles, and wound contamination. The Baltimore VA Medical Center began a voluntary program to monitor these DU-exposed veterans in 1993. While many of these veterans have medical problems resulting from their physical injuries, the medical evaluators report that none are sick from DU's chemical or radiological toxicity.

FACTS:

- Depleted uranium is a heavy metal (1.7 times as dense as lead) by-product of the uranium enrichment process and is 40% less radioactive than natural uranium.
- The major health concerns associated with DU relate to its chemical properties as a heavy metal rather than to its radioactivity. Very high exposure and absorption of uranium can cause kidney (renal) harm.
- The VA evaluates veterans in this voluntary program every two years to determine if their exposure to DU is affecting their health.
- In 1998, DoD and VA recommended urine uranium evaluations for veterans exposed to DU while working in contaminated vehicles for extended periods. Urine uranium tests were also made available to any Gulf War veteran who wanted one.
- Elevated urine uranium levels occur primarily in those veterans with DU fragments in their bodies. No significant relationship was found between kidney function and urine uranium values in the program participants.
- Individuals with normal urine uranium levels now are unlikely to develop any DU-related toxicity in the future, regardless of what their DU exposure may have been in the Gulf War.
- Individuals with elevated levels of urine uranium ten years after the Gulf War have not developed kidney abnormalities or any other uranium-related adverse outcome.
- The DU Medical Follow-up Program will continue to monitor those individuals with elevated urine uranium levels to enable early detection of any adverse health effects due to their continued exposure to embedded DU fragments.
- These findings are consistent with assessments conducted by the World Health Organization, United Nations Environment Programme, European Commission, European Parliament, United Kingdom Royal Society, and United Kingdom Ministry of Defense. No widespread environmental contamination and no health impact on the local population or deployed personnel are expected.

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February 13, 2002

PROJECT 112/ SHIPBOARD HAZARD AND DEFENSE (SHAD)

KEY MESSAGE:

From 1962 to 1973, the Deseret Test Center, headquartered at Fort Douglas, Utah, conducted a series of chemical and biological warfare vulnerability tests in support of Project 112. Project SHAD was a subset of that program. The DoD conducted tests in support of Project 112 using primarily substances believed to be safe to simulate the dispersion of chemical or biological warfare agents during an attack. A few veterans have expressed concern that they may have been exposed to harmful substances while participating in these classified tests. At the request of the VA, the DoD is actively declassifying medically relevant information concerning all tests conducted by the Deseret Test Center in support of Project 112.

FACTS:

- DoD investigators have searched classified technical documents located at various locations to identify reports about the Project 112 testing.
- The Army, as executive agent declassifies medically relevant information while ensuring that national security information remains protected.
- Unclassified personnel and operational records held at the National Archives are used to identify test participants.
- Investigators have identified 134 planned Project 112 tests:
  - 62 tests were cancelled.
  - 46 tests were conducted.
  - The status on 26 tests is still being investigated.
- Information, to include participant names, has been provided to VA on 42 of the conducted tests.
- The FY 2003 Authorization Act mandated status reporting to Congress, but provided no funding.
- DHSD expects to complete investigation efforts by June 2003.

Prepared by: (b)(6), J.D.,DHSD, (b)(6)

DOD-VA COOPERATION ON
PROJECT 112/SHAD TESTING

KEY MESSAGE:

The departments of Defense (DoD) and Veterans Affairs (VA) are cooperating in developing information on past chemical and biological tests to assist veterans making benefits claims. Specifically, the DoD is providing medically relevant information to the VA regarding tests planned and directed by the Deseret Test Center,

FACTS:

- In August 2000, the VA asked the DoD for help in obtaining information needed to clarify claims information from servicemembers who believed they might have been exposed to harmful substances during their participation in a series of tests known as Shipboard Hazard and Defense (SHAD).

- The VA claims experts requested that DoD identify what types of substances veterans might have been exposed to, where, and when they may have been exposed. The biological or chemical warfare agents or simulants used, dates of the tests, and which vessels and/or units participated are key to determine if there should be a concern today.

- The DoD began an investigation to collect medically relevant information associated with these tests to respond to the VA's request. The process has been painstaking. Paper and microfilm records have been carefully reviewed, important bits of information pieced together and added to a list of materials, which then had to go through the Pentagon's declassification process. DoD passes all medically relevant information on each test to the VA, to include both ship-based and land-based testing.

- In the course of the investigation, DoD investigators discovered that SHAD was a part of a larger testing program, Project 112, directed by the Deseret Test Center at Ft. Douglas, Utah, between 1962 and 1973. In the mid-1960s, the Deseret Test Center moved to Dugway P
Deseret Test Center closed in 1973.

- This investigation has required the close cooperation of the VA, the Coordinating Board, the Assistant Secretaries for Manpower and Reserve Navy, and elements of the Office of the Secretary of Defense. The Under S worked to expeditiously declassify needed documentation.

- At least 16 members of Congress have forwarded inquiries on behalf of con 112/SHAD tests. In late 2002, Congress directed that the DoD complete it of summer 2003. In 2002, Congress passed Public Law 107-314 requirin month report outlining the DoD investigation plan and progress. The fir 2003.

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DHSD
(b)(6)
January 22, 2003

CMAT Control # (1166)
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Diniega, Benedict, COL, OASD/HA

From: Advisory Committee for Immunization Practice (b) @cdc.gov]
Sent: Thursday, December 06, 20019:27 AM
To: (b)(6)

cc:

Subject: CLOSED ACIP MEETING -Anthrax


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THE FULL E-MAIL

An emergency meting of the **ACIP** will take place via conference call on Friday, December 7, 2001 from **3:30pm-5:30pm** Eastern Time. This is a CLOSED **ACIP** meeting. Participants are limited to those included in this e-mail. Participants must be Federal Employees or Special Government Employees and have signed and returned the confidentiality statement.

Attached is the confidentiality statement in wordperfect and in microsoft word. Please sign this statement and return it to me by 3:00 PM Eastern Time today. This form MUST be completed before you can participate in the call. You may FAX it to me at (b)(6) . Please note the exchange is (b)(6)

PLEASE REMEMBER
DO NOT have anyone in the room during the conference call unless they are an appointed member of **ACIP** or a Federal employee and have signed the **confidentialitiy** agreement.

DO NOT use a speaker phone

DO NOT use a cell phone

DO NOT use a portable phone

CONFERENCE CALL INFORMATION

TIME: **3:30pm - 5:30** pm
PHONE NUMBER (b)(6)
LEADER: (b)(6)
PASSCODE: (b)(6)

At entry, you will be put on a hold line with music. All parties will be connected at one time. If you are disconnected, you will not be able to reconnect.

Thank you

(b)(6)

MEETING ANNOUNCEMENT
ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

Advisory Committee on Immunization Practices
Conference **Call**
December 7, 2001
1:30 pm - 4:30 pm Eastern Time

1.30 Welcome Disclosure by Committee Members		Dr. J. Modlin (Chair, ACIP) Dr. D. Snider (CDC, OD)
1:45 Update on vaccine supply -- PCV7 and DTaP	Discussion	Mr. Dean Mason (NIP, ISD)
2: 15 Recommendations for use of PCV7 in response to the shortages	Presentation Discussion Vote	Dr. Gary Freed (Univ.. Mich.) Dr. David Johnson (ACIP Member) Dr. Ben Schwartz (NIP,ESD) Dr. Chris Van Beneden (NCID) Dr. Cyndy Whitney (NCID)
3:15 Recommendations for use of DTaP in response to the shortages Delay of 4"dose of DTaP	Presentation Discussion Vote	Dr. Kris Bisgard (NIP, ESD)
3:45 Update on current status of Joint Statement on thimerosal		Dr. Roger Bernier (NIP, OD)
4: 15 Public Comment		
4:30 Adjourn		

A conference call of the Advisory Committee on Immunization Practices is Friday, December 7, 2001 at 1:30 PM Eastern time.

To access the teleconference participants should dial you must dial (b)(6) (b)(6) **International callers should dial** (b)(6) **To be connected to the call, you will need to provide the attendant with the pass code** (b)(6) **and leader name,** (b)(6) **You will then be automatically connected to the call.**

Please note the

DAY - Friday, December 7
TIME - **1:30PM - 4:30PM** Eastern Time
PHONE NUMBER - (b)(6) **- THIS IS** A NEW **PHONE NUMBER**
International callers (b)(6)
LEADER NAME: (b)(6)

TRANSACTION REPORT

Transmission
Transaction(s) completed

NO.	TX DATE/TIME	DESTINATION	DURATION	PGS.	RESULT	MODE
556	DEC. 6 09:41	(b)(6)	0' 00' 22"	001	OK	N ECM

Confidentiality Agreement

Given the sensitive nature and public health and national security implications of the anthrax issue, the members of the ACIP, participants of the anthrax working group, and others attending the ACIP meeting on Friday, December 7, 2001, agree that by their participation in this matter they will be subject to the confidentiality restrictions of 45 CFR § 73.735307. You are prohibited (1) from communicating any non-public information provided to the working group or to the committee regarding this issue and (2) from disclosing the deliberations of the working group and committee, unless specifically approved to do so by the Centers for Disease Control and Prevention. I understand that this obligation does not apply to any information that has been published or was publicly known prior to my participation in this matter.

Please return a signed copy of this document to (b)(6) (fax).

Accepted (b)(6)

(b)(6)

Printed name

Date: 12/6/01

Confidentiality Agreement

Given the sensitive nature and public health and national security implications of the anthrax issue, the members of the ACIP, participants of the anthrax working group, and others attending the ACIP meeting on Friday, December **7, 2001,** agree that by their participation in this matter they will be subject to the confidentiality restrictions of 4.5 CFR § 73.735307. You are **prohibited** (1) from communicating any non-public information provided to the working group or to the committee regarding this issue and (2) from disclosing the deliberations of the working group and committee, unless specifically approved to do so by the Centers for Disease Control and Prevention. I understand that this obligation does not apply to any information that has been published or was publicly known prior to my participation in this matter.

Please return a signed copy of this document to (b)(6) at (b)(6) (fax).

Accepted: (b)(6)

Signature

(b)(6)

Printed name

Date: 12/6/01

Diniega, Benedict, COL, OASD/HA

From: Baken, Denise, COL, OASD/HA
Sent: Thursday, December 06, 20013:49 PM
To: Diniega, Benedict, COL, OASD/HA; (b)(6)
cc: Driscoll, Robert, COL, OASD/HA
Subject: Draft AVIP program resumption memo

AVIP Resumption Memo.doc

Gentlemen,

Attached is my first stab at a resumption memo. We sent it to OGC, Joint Staff and AVIP for a "good scrutizining" If you would, please make comment so I can incorporate your concerns/ideas as well.

Thanks
Denise

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
UNDER SECRETARIES OF DEFENSE
ASSISTANT SECRETARIES OF DEFENSE
GENERAL COUNSEL, DEPARTMENT OF DEFENSE
INSPECTOR GENERAL, DEPARTMENT

SUBJECT: Resumption of the Anthrax Vaccine Immunization Program (AVIP)

On June 8, 2001, the Deputy Secretary of Defense directed a third orderly temporary slowing of the Anthrax Vaccine Immunization Program until additional Food and Drug Administration approved anthrax vaccine became available. During this interim period, vaccinations have been limited to personnel in designated special operations units, individuals in the manufacturing process and researchers participating in congressionally mandated research projects. However, FDA approved anthrax vaccine is expected to become available by second quarter fiscal year 2002. We will therefore begin to execute an orderly expansion of the program. To achieve this orderly expansion, the following actions shall be taken:

1. The scope of the AVIP shall be expanded to include all personnel assigned or deployed on the ground in the high threat areas of Southwest Asia and Korea. Personnel assigned or deployed to these areas for at least 30 days, including personnel newly assigned for such a period and personnel afloat on contiguous waters who potential to be committed ashore, shall be included in this expansion. Vaccinations for these personnel shall begin prior to arrival in theater and may commence up to 45 days prior to deployment. All vaccinations will be provided consistent with the FDA-approved vaccination schedule. Personnel in these categories, whose vaccination series was interrupted because of the temporary slowing, will resume their vaccinations at the point of deferment and continue the series consistent with the FDA-approved vaccination schedule. This resumption will be administered in accordance with guidance from the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices and in consultation with the FDA.

2. The Assistant Secretary of Defense for Health Affairs shall issue policy guidance on the medical aspects of this resumption for areas to include, but are not limited to, vaccine administration, dosing schedule, medical screening before immunization and medical and administrative exemptions. This policy shall be in accordance with guidance from the Centers for Disease Control and Prevention and in consultation with the FDA.

3. The Secretary of the Army, as Executive Agent of the AVIP, shall issue instructions to distribute vaccine, to the extent possible, to support this program expansion. If redirection to the high threat areas is not feasible, the

Executive Agent shall determine appropriate alternate means to support the orderly program resumption.

4. Informational materials shall be provided to all personnel during this expansion period addressing the benefits, side effects, and other medical information. These materials shall specifically address the status of the program and any potential effects of the deferred dosage schedules.

5. The Executive Agent, working in conjunction with other elements of the Department of Defense, shall, take appropriate steps to determine the threat potential faced by all later deploying personnel to identify the priority for resuming the AVIP for these members.

The AVIP is a necessary and vital part of the Department's Force Health Protection program, offering members the best protection available against a known threat. Programs to educate and inform personnel abut this and other biological and chemical warfare agents will continue during this period of program resumption.

Diniega, Benedict, COL, OASD/HA

From: Advisory Committee for Immunization Practice (b)(6)
Sent: Thursday, December 06, 2001 1052 AM
To: (b)(6)
cc:
Subject: ACIP Conference CALLS for December 7

Please note that the closed ACIP meeting on Anthrax is in addition to the already scheduled meeting on PCV7, DTaP, and Thimerosal. That meeting on PCV7, DTaP, and Thimerosal will begin at 1:30 and it will be open to the public. Hopefully, we will be able to end this meeting by 3:30. The meeting on anthrax scheduled for 3:30 is a closed meeting. The information to connect to this meeting is different and should not be shared with anyone.

Diniega, Benedict, COL, OASD/HA

From: (b)(6) LTC OTSG
Sent: Thursday, December 06, 20011:12 PM
To: Benedict Diniega'
Subject: FW: Anthrax immunizations

fyi
-----Original Message-----
From: (b)(6) @bethesda.med.navy.mil]
Sent: Thursday, November 15, 2001 1:56 PM
To: (b)(6)
Subject: Anthrax immunizations

COL Friedlander and LTC (b)(6),

I wanted to thank you both for your assistance in developing my recommendations for the Capitol. Without directly dragging either of you into the maelstrom I've made it known that I'm talking to as many subject experts as possible! I just sent the attached letter to ADM Eisold, knowing that it will probably be given to Senator Daschle for consideration. I expect this will not be smooth sailing because of the political ramifications of my recommendations. Although the letter is long I would appreciate it if you would take a look at it and see if my rationale, as written in the letter, makes sense to you.

Thanks again,
(b)(6)

<<DaschleAnthraxVax.n01.doc>>
CDR (b)(6)
Chief, Infectious Disease Service
Director, Nat'l Capitol Consortium Infectious Diseases Program
National Naval Medical Center
8901 Wisconsin Avenue
Bethesda, MD 20889-5600
(b)(6)
FAX: (b)(6)

Diniega, Benedict, COL, OASD/HA

From: (b)(6) @cdc.gov]
Sent: Thursday, December 06, 200112:02 PM
To: (b)(6)

Subject: FW: Agenda for 12 noon EST call December 6

PEP vaccine.doc

> -----Original Message-----
> From: (b)(6)
> Sent: Thursday, December 06, 200111:55 AM
> To: (b)(6)
> (b)(6)
> Cc: (b)(6)
> (b)(6)
> Subject: RE: Agenda for 12 noon EST call December 6
>
>
>
> -----Original Message-----
> From: (b)(6)
> Sent: Thursday, December 06, 200110:39 AM
> To: (b)(6)
> Cc:
> (b)(6)
>
> Subject: RE: Agenda for 12 noon EST call December 6
>
> Current issue (PEP vaccine) and some data (pathproph).
> **<<PEP vaccine.doc>>**
> -----Original Message-----
> From: (b)(6)
> Sent: Thursday, December 06, 200110:15 AM
> To: (b)(6)
> Cc:
> (b)(6)
> Subject: Agenda for 12 noon EST calf December 6
>
> Proposed agenda
>
> Opening and statement of purpose of meeting
>
> Review of current issues
>
> New data:
>
> Compliance issues
>
> Potential dose via 'envelope"
>
> Review of previous ACIP recommendations

>
> Update on vaccine supply
>
> Discussion
>
>
> (b)(6) will be on the call to take the Workgroup through
> these issues.
>
> (b)(6)

National Naval Medical Center
Infectious Disease Service
8901 Wisconsin Avenue
Bethesda, MD 208894600
(b)(6) FAX:(b)(6)
(b)(6) @bethesda.med.navy.mil

15 NOV 2001

From: Chief, Infectious Disease Service
To: Attending Physician, United States Capitol

Subj: RECOMMENDATIONS FOR US **CAPITOL** INDIVIDUALS EXPOSED TO ANTHRAX

Admiral Eisold:

1. As we have discussed previously, I feel the final recommendations for the care of the Capitol patients may need to be more conservative than the general recommendations in the CDC guidelines. There are particular aspects of this case, as well as animal studies, which I feel must be considered. I have briefly outlined a few of the points that I would like to make from these studies.

2. Studies in non-human primates demonstrate that when animals are exposed to aerosols of anthrax spores and have antibiotic therapy initiated 24 hours after exposure, they are prevented from developing disease. Although protection from anthrax for the 30 days of prophylaxis was demonstrated, these monkeys did not develop *B. **anthracis*** antibodies in response to their exposure. Five of 29 animals developed fatal inhalation anthrax 6-28 days after stopping antibiotics.'Earlier primate studies have demonstrated the persistence of viable *B. anthracis* spores in the mediastinal lymph nodes for at least 100 days after exposure (at 75 days after exposure an estimated 0.5 to 1 .O % of the originally retained spores were recoverable but at 100 days there were only "traces" detectable). [2] Death of one animal 98 days after spore inhalation was found in another **study.**[3] Viable *B. anthracis* were noted in the lungs of all the apparently healthy monkeys that were sacrificed 55-84 days after exposure in an additional **study.**[4]

3. Although similar research has not been performed in humans it is expected that patients who are exposed to inhaled *B. anthracis* spores and have prompt initiation of antibiotic prophylaxis will not develop protective antibodies. Because of the persistence of spores, **DoD** recommendations (as well as earlier CDC recommendation?) have always included immunization as part of the post-exposure plan. The rationale was that antibiotic prophylaxis ensured protection against germinating spores until anthrax immunization associated antibodies were sufficient to enhance effective immune scavenging of any persistent spores.

4. Current CDC guidelines for post-exposure prophylaxis do not include the use of anthrax vaccine and recommend 60 days of antibiotic prophylaxis.[6] These recommendations are based on the 1979 experience in Sverdlovsk where an estimated 2 grams of anthrax spores were released over the city leading to 96 human cases of anthrax, the last of which occurred 43 days after the release of the spores.[7]

5. My greatest concern has been that there is evidence of high level exposure in Senator Daschle's staff. All 13 of the individuals in Hart Room 612 had positive nasal swabs; many of the culture plates were entirely covered with Bacillus *anthracis* colonies at 12- 18 hours after plating. Although variability in sampling technique makes quantitative interpretation of nasopharyngeal swabs impossible, we can be sure that these heavy, early growths of anthrax are not indicative of a minor exposure.

6. Earlier this year, the Canadian Defence Research Establishment Suffield performed the study most germane to the US Capitol situation. [8] In order to provide a realistic evaluation of the efficiency and risk of transmission of anthrax spores from opening a letter, a carefully planned simulation was performed. Spores of the related, but non-pathogenic, *Bacillus globigii* were used to simulate anthrax. The study was done with 0.1 g and 1 .O g of spores placed in a standard envelope and opened in a 10 x 18-ft office. There were significant amounts of spores aerosolized within seconds, >99% of which were in the 2.5 to 10 µm size range. A person remaining in the room for 10 minutes could inhale an estimated 480 LD_{50}s from a 0.1 g envelope and 3080 LD_{50}s from a 1 .O g envelope. "In addition, the aerosol would quickly spread throughout the room so that other workers, depending on their exact locations and the directional air flow within the office, would likely inhale lethal doses."

7. Although there is no way to prove the level of exposure that actually occurred in Senator Daschle's office, evidence supports that there may have been very high levels of spores, possibly as high (or higher) than in the Canadian study. The deaths in Sverdlovsk were believed to have occurred after a release of 2 grams of spores over an entire city. The letter in Senator Daschle's office was estimated to have a similar weight of spores released into the confines of a few rooms. The conditions in the Hart Building are far closer to the Canadian study than to the Sverdlovsk release.

8. If we presume over time that inhaled spores are progressively cleared by the immune system to some level at which there is no significant risk of developing clinical disease, then the size of the initial inoculum is obviously critical. It is likely that the inoculum of most individuals exposed in the Sverdlovsk release was significantly less than the exposure of some individuals in Senator Daschle's office. If the 2.0-gram release over Sverdlovsk was responsible for deaths as long as 43 days after exposure then the relatively higher inoculum in Senator Daschle's office may be associated with disease beyond the 60 days of prophylaxis recommended by the CDC. Again, in referring to the animal data if ~ 1% of spores initially inhaled are present at 60 days this may be insignificant if your inoculum size was on the order of 1-10 LD_{50}. At the other extreme, if you have 1% of spores persistent after inhalation of 3000 LD_{50}s then the individual may have retention of many times the number of viable spores needed to develop inhalation anthrax.

9. In conclusion, the critical aspect of this exposure is the inoculum size. I feel there are two ways in which this can be addressed, both of which are more conservative than current CDC guidelines:
    a. I recommend we consider offering anthrax immunization to the subset of patients who were likely to be most heavily exposed. This would include only those individuals in the rooms with positive nasal swab (rooms **610, 612, 613** and 509). The only additional patient I would include would be the Capitol policeman who was in the hallway in the **5th** floor but was nasal culture positive. (He grew one colony of *Bacillus anthracis* at *42* hours, indicative of a much lower level of exposure than in the offices, this does NOT warrant recommending vaccine to all the individuals who walked through the same hallway.) Antibiotic therapy could be halted 28 days after immunization is complete.
    b. If immunization cannot be performed, than therapy should be continued for a total of 90 days (for the same subset of individuals as above). This would allow for the clearance of more spores from the heavily exposed patients and further decrease the likelihood of developing disease. There is always some risk of developing anthrax after even prolonged antibiotics are discontinued, halting after 60 days of therapy on 14 December risks patients leaving the area for the holidays and becoming inaccessible to adequate medical care. Ninety days of therapy would end on Sunday, 13 January 2002 after the holiday traveling period so patients can be followed in the OAP and aggressively managed in the unlikely event that someone develops clinical anthrax.

10. I recognize that these recommendations have implications far beyond Capitol Hill. Although the situation at Brentwood is different than in the Hart, the only deaths that occurred were from Brentwood and that cannot be ignored. Some of the same points I made for the Capitol are likely to be true for postal employees. I also recognize that some of the nations best Public Health authorities have produced the CDC guidelines, my credentials and experience do not approach those of these policy makers and I do not take lightly making recommendation that go beyond their guidance. As such, I have had numerous discussions with colleagues from the NIH, USAMRIID, **WRAIR,** NMRC and the metro DC Infectious Diseases community about our situation. These experts support me in my recommendations and are prepared to discuss them with you or other officials if necessary. Ultimately, we have responsibility as the clinicians working with these patients to be their advocates and to provide the best medical answer. In my opinion anthrax immunization is the best medicine.

11. I appreciate your consideration of my recommendations and am available, as always, to discuss them with you at your convenience.

(b)(6)

Commander, Medical Corps, US Navy

1. Friedlander AM, Welkos SL, Pitt MLM, et al. Postexposure prophylaxis against experimental inhalation anthrax. J Infect Dis 1993;167: 1239-42
2. Henderson DW, Peacock S, Belton FC. Observations on the prophylaxis of experimental pulmonary anthrax in the monkey. J Hyg 1956; 54:28-36
3. Glassman HN. Discussion - Industrial Inhalation Anthrax. Bacteriol Rev 1966; 30:657-659
4. Gochenour WS, Sawyer WD, Henderson JE, et al. On the recognition and therapy of Simian woolsorter's disease. J. Hyg 1963; 61:317-322
5. CDC. Bioterrorism Alleging Use of Anthrax and Interim Guidelines for Management- United States, 1998; 48:69-74
6. CDC. Update: investigation of bioterrorism-related anthrax and interim guidelines for exposure management and antimicrobial therapy, October 2001. MMWR 2001;50:909-919.
7. Meselson M, Guillemin J, Hugh-Jones M, et al. The Sverdlovsk Anthrax Outbreak of 1979. Science 1994; 266:1202-1208
8. Koumikakis B, Armour SJ, Boulet CA, et al. Risk Assessment of Anthrax Threat Letters. Defence Research Establishment Suffield 2001; Technical Report TR-2001-048 (Draft form)

Diniega, Benedict, COL, OASD/HA

From: (b)(6)
Sent: Wednesday, December 05, 2001 2:56 PM
To: (b)(6)
cc:
Subject: Dec. 7 ACIP meeting - NEW INFORMATION

Phone Number: (b)(6) -- Please note this is a new phone number
International callers: (b)(6)
Conference Name: ACIP Meeting
Leader Name: (b)(6)

Advisory Committee on Immunization Practices Conference Call
Friday, December 7, 2001
1:30 pm - 4:30 pm Eastern Time

AGENDA
1:30 Welcome Dr.
J. Modlin (Chair, ACIP)
Disclosure by Committee Members Dr. D.
Snider (CDC, OD)

1:45 Update on vaccine supply -- PCV7 Discussion Mr.
Dean Mason (NIP, ISD)
and DTaP

2:15 Recommendations for use of PCV7 Presentation Dr. Gary
Freed (Univ.. Mich.)
in response to the shortages Discussion
Dr.David Johnson (ACIP member)
Vote Dr.
Ben Schwartz (NIP, ESD)
Dr.
Chris Van Beneden (NCID)
Dr.
Cyndy Whitney (NCID)

3:15 Recommendations for use of DTaP in Presentation Dr.
Kris Bisgard (NIP, ESD)
response to the shortages Discussion
Delay of 4th dose of DTaP Vote

3:45 Update on current status of Joint statement on thimerosal — Dr. Roger Bernier (NIP, OD)

4:15 Public Comment

4:30 Adjourn

>

Diniega, Benedict, COL, OASD/HA

From: (b)(6)
Sent: Wednesday, December 05, 20012:54 PM
To: (b)(6)

cc:

Subject: NEW MEETING INFORMATION FOR ACIP

This message is specificly for ACIP members and staff who will be connected to the call.

PLEASE NOTE:

If you are on this list, to assure you will connected to the conference call on an interactive line, you will be connected to a subconference line. You will be connected to the main conference call as a group. PLEASE call 10 minutes before 1:30. If you can not call early, please have someone call for you, and connect using your name to assure you are connected correctly. In order for this to work, I must know by 12:OO noon tomorrow, December 6th, if you will or will not participate. You may have already confirmed, but I still need you to respond yes or no to this e-mail. If you have any questions, please give me a call at (b)(6). Thank you.

(b)(6)

Phone Number: (b)(6) --- Please note this is a new phone number
International callers: (b)(6)
Conference Name: ACIP Meeting
Leader Name: (b)(6)

AGENDA

1:30 Welcome Dr.
J. Modlin (Chair, ACIP)
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Kris Bisgard (NIP, ESD)
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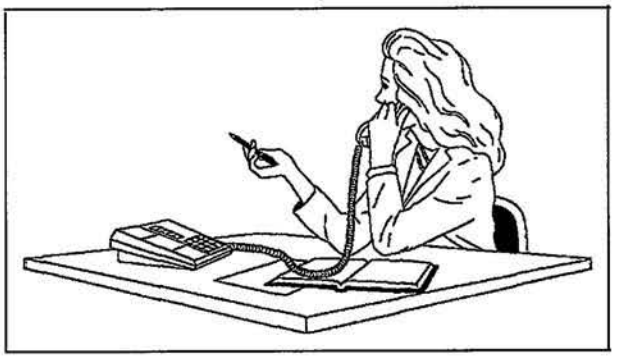
Roger Bernier (NIP, OD)
statement on thimerosal

4:15 Public Comment

4:30 Adjourn



DATE: November 16, 2001

TO: ACIP Members, Ex Officios, and Liaisons
Members of the Public

FROM: Program Analyst, ACIP (b)(6)

SUBJECT: Open Conference Call Meeting of the Advisory Committee on Immunization Practices

A conference call of the Advisory Committee on Immunization Practices is scheduled for Friday, December 7, 2001 at 1:30 PM Eastern time. The conference call agenda will include a discussion of the use of pnemnococcal conjugate vaccine (PCV-7) and diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) in response to shortages of PCV-7 and DTaP, and use of pediatric vaccines containing thimerosal.

To access the teleconference participants should dial you must dial (b)(6) International callers should dial (b)(6). To be connected to the call, you will need to provide the attendant with the pass code (b)(6) and leader name, (b)(6) You will then be automatically connected to the call.

If you have a problem during your conference, you may press *0 at anytime to signal the attendant.

Please note the
DAY - Friday, December 7
TIME - 1:30PM - 4:30PM Eastern Time
PHONE NUMBER (b)(6)
International callers (b)(6)
LEADER NAME (b)(6)

Thank you.
(b)(6)

Diniega, Benedict, COL, OASD/HA

From: (b)(6)
Sent: Friday, November 16, 200111:33 AM
To: (b)(6)

Subject: OPEN CONFERENCE CALL - **ACIP** Meeting

A conference call of the Advisory Committee on Immunization Practices is scheduled for Friday, December 7, 2001 at **1:30** PM Eastern time. The conference call agenda will include a discussion of the use of pneumococcal conjugate vaccine (PCV-7) and diphtheria and tetanus toxoids and acellular pertussis vaccine **(DTaP)** in response to shortages of PCV-7 and **DTaP,** and use of pediatric vaccines containing thimerosal.

To access the teleconference participants should dial you must dial (b)(6) International callers should dial (b)(6) To be connected to the call, you will need to provide the attendant with the pass code (b)(6) and leader name, (b)(6). You will then be automatically connected to the call.

If you have a problem during your conference, you may press ***0** at anytime to signal the attendant.

Please note the DAY - Friday, December 7
TIME - **1:30PM - 4:30PM** Eastern Time
PHONE NUMBER - (b)(6)
International callers - (b)(6)
LEADER NAME (b)(6)

Diniega, Benedict, COL, OASD/HA

From: (b)(6)
Sent: Thursday, December 06, 2001 1:36 PM
To: (b)(6)

Subject: FW: PCV7 shortage materials


Sp_PCV7_shortage_ACIP3.doc


Sp_PCV_immunogenicity.doc


Sp_ACIP_shortage_recs.ppt

These documetns aree for the ACIP conference call on Friday at 1:30. They include 1) the draft recommendations; 2) the figures that I will use during the conference call; and 3) a table of immunogenicity of various regimens.

> Thanks.
>
> Ben
>
> <<Sp_PCV7_shortage_ACIP3.doc>> <<Sp_ACIP_shortage_recs.ppt>>
> <<Sp_PCV_immunogenicity.doc>>

Pneumococcal conjugate vaccine use in a setting of vaccine shortage: Updated Recommendations of the Advisory Committee on Immunization Practices (ACIP)

Pneumococcal conjugate vaccine was licensed on February 17, 2000 and ACIP recommendations for use of this vaccine were published in the MMWR on October 6, 2000 (1). Currently, about 1.5 million doses are needed per month to meet demand, with the manufacturer estimating that -90% is used for the 4-dose infant vaccination series and -10% for catch up vaccination.

Because of the rapid increase in demand and problems with production, there have been back-orders for public sector vaccine during most of 2001. The situation deteriorated in August when issues related to facilities and product testing limitations at the manufacturer's productions sites halted distribution for several weeks. On Sept 14, CDC published recommendations for vaccination in the setting of a shortage that was anticipated to be brief (2). However, in September only -700,000 doses were distributed (47% of demand given a 4-dose infant schedule) and in October only -600,000 doses were distributed (40% of demand). Current projections for vaccine distribution by the manufacturer are ~ 1.2 million doses per month from November, 2001, through March, 2002 (86% of demand), and -2 million doses per month from April 2002 through mid-year (142% of demand). Based on these data, if pneumococcal conjugate vaccine demand remains unchanged, a shortage situation in some practices likely will continue into the second half of 2002.

Because of the critical supply situation, the need to meet ongoing demand, and the importance of replenishing stocks at State health departments for distribution to vaccine providers, ACIP has made revised recommendations to limit pneumococcal conjugate vaccine use until supplies are adequate. Two key principles underlie these recommendations. First, providers should conserve vaccine supply by decreasing the number of doses administered to healthy infants rather than leaving some children in the group recommended for vaccination completely unprotected. Second, changes in pneumococcal conjugate vaccine use and ordering practices should be made by all providers, regardless of the current vaccine supply in their own practice. Concerted effort is needed to assure that vaccine is available as widely as possible for all young children.

1. High risk children less than 5 years of age should continue to be vaccinated as recommended by ACIP in October 2000 (1). The high risk group includes children with sickle cell disease and other hemoglobinopathies; anatomic asplenia; chronic disease including chronic cardiac or pulmonary disease and diabetes mellitus; CSF leak; HIV infection; immunocompromising conditions; immunosuppressive chemotherapy or long-term systemic corticosteroids use; and those who have received a solid organ transplant.

2. Healthy infants and children <24 months old should receive a decreased number of pneumococcal conjugate vaccine doses based on the age at which vaccination is initiated and the provider's estimate of vaccine supply in their practice (Table). Providers should vaccinate according to the moderate or severe shortage schedule based on their estimates

of pneumococcal conjugate vaccine availability in their practice. If, based on the size of their birth cohort and their recent vaccine supply experience, providers estimate a shortfall of <25%, the schedule for a moderate shortage would be recommended. If estimates suggest a greater shortfall, the severe shortage schedule would be recommended. In settings where reductions in vaccine use greater than the estimated 46% for a severe shortage schedule are needed, providers should set priorities for infant vaccination depending on assessment of risk, temporarily deferring those at lowest risk. Demographic risk factors for invasive infections include African-American or American Indian descent (1). Exposure risk factors include not breastfeeding and attendance at out-of-home child care (3).

Limited data support a recommendation for a 2-dose schedule among infants; however, this regimen is preferred to vaccinating some children with 3-doses and leaving others unprotected. Efficacy data from a randomized controlled trial pre-licensure suggest that 1 or 2 doses of pneumococcal conjugate vaccine are protective during the 2-month interval before the next dose with a point estimate of 86% efficacy but a 95% confidence interval that includes zero (4). Immunogenicity data show increases in antibody titer following 2 doses for all vaccine serotypes except 6B (5). For all serotypes, 2 doses of conjugate vaccine is likely to increase antibody avidity and induce immunological memory that is boosted by subsequent antigenic exposure. Acceptable 2-dose regimens include vaccination at 2 and 4 months, 2 and 6 months, or 4 and 6 months of age. The main advantage of regimens that begin at 2 months of age is earlier provision of protection (Figure). Immunogenicity may be improved by increasing the interval

between doses and vaccinating at 2 and 6 months of age or by vaccinating at 4 and 6 months of age. "Carrier priming" has been documented with the CRM_{197} *Haemophilus influenzae* type b conjugate vaccine (6) but this impact has not been evaluated for pneumococcal conjugate vaccine. Although immunogenicity would be greater if pneumococcal conjugate vaccination were deferred until after 6 months of age (e.g., administered at 7 and 9 months), this regimen which would leave younger infants unprotected and require additional vaccination visits.

3. Providers should maintain a list of children for whom conjugate vaccine has been deferred so that it can be administered when the supply situation allows. The highest priority for vaccination among children who have been deferred is infants vaccinated with only 2-doses. Infants who have received 3 doses and are eligible for their fourth dose would be a second priority group.

4. Pneumococcal polysaccharide vaccine currently is not licensed or recommended for children <2 years old. Although unpublished data suggest that administration of this vaccine at 15-18 months of age may significantly boost antibody levels among children primed with 3 doses of conjugate vaccine (unpublished data, R. Daum), this study did not use the currently licensed conjugate preparation. ACIP recommends that further studies be done to evaluate the immune response to a polysaccharide vaccine booster dose among children who are 12-15 months of age.

CDC has an ongoing reporting system for invasive pneumococcal disease following pneumococcal conjugate vaccine. Because data are limited regarding the long-term efficacy of a 3-dose conjugate vaccine regimen for young infants, we ask all providers to report vaccine failures to this system. Information regarding this study can be found at http://www.cdc.gov/nip under the Health Care Professionals tab. For questions contact the Duty Officer, Respiratory Diseases Branch, CDC (Phone: 404-639-2215; Fax: 404-639-3970).

References

1. CDC. Preventing pneumococcal disease among infants and young children: recommendations of the Advisory Committee on Immunization Practices. MMWR 2000; 49(RR-9): 1-35

2. CDC. Notice to readers. Decreased availability of pneumococcal conjugate vaccine. MMWR. 2001;50:783-4.

3. Levine OS, Farley M, Harrison LH, Lefkowitz L, McGeer A, Schwartz B. Risk factors for invasive pneumococcal disease in children: a population-based case-control study in North America. Pediatr 1999;103:E28.

4. Black, S, Shinefeld H, Fireman B, et al. Efficacy, safety, and immunogenicity of heptavalent pneumococcal conjugate vaccine in children. Pediatr Infect Dis J 2000; 19: 187-95.

5. Rennels MB, Edwards KM, Keyserling, HL, et al. Safety and immunogenicity of heptavalent pneumococcal vaccine conjugated to CRM197 in United States infants. Pediatrics 1998; 104:604- 11.

6. Granoff DM, Rathore MH, Holmes SJ, et al. Effect of immunity to the carrier protein on antibody responses to *Haemophilus influenzae* type b conjugate vaccines. Vaccine 1993;11(Suppl 1):S46-51

Table. Recommendations for pneumococcal conjugate vaccine use among healthy children in moderate and severe shortage settings. The vaccine schedule for no shortage (shaded) is included as a reference to prior ACIP recommendations; providers should not use the no shortage schedule, regardless of their own vaccine supply situation, until the national shortage is ameliorated.

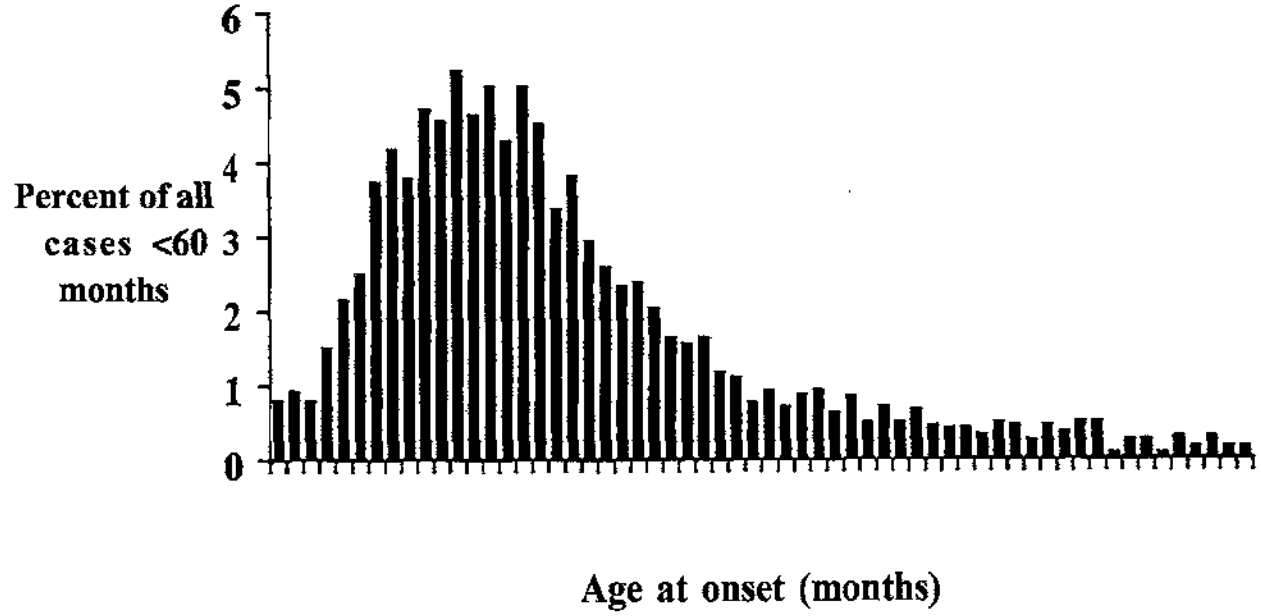
Age of first PCV7 vaccination	**No shortage (ACIP** statement, Oct. 2000)	**Moderate shortage** (shortfall estimated at **<25%** of doses)	**Severe shortage** (shortfall estimated at **≥25%** of doses)*
<6 months	2, 4, 6, and 12-15 months	2, 4, and 6 months (defer 4th dose)	2-doses at 2 month interval in 1st 6 months of life (defer 3rd and 4th doses)
7- 11 months	2-doses at 2 month interval; 12-15 month dose	2-doses at 2 month interval; 12- 1.5 month dose	2-doses at 2 month interval (defer 3rd dose)
12-23 months	2-doses at 2 month interval	2-doses at 2 month interval	1 dose (defer 2nd dose)
≥24 months	1 dose should be considered	No vaccination	No vaccination
Reduction in vaccine doses used**		21%	46%

* See text for recommendations when a provider estimates a shortfall of >50% of doses.

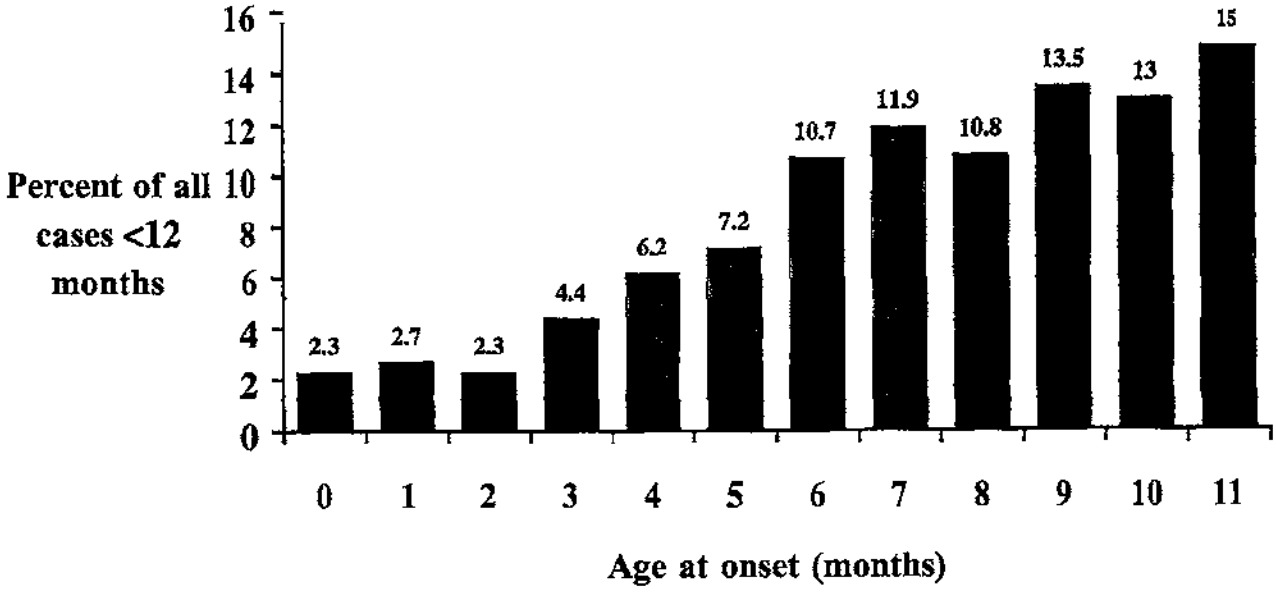
** Assumes that 85% of vaccine is administered to healthy infants beginning vaccination at <7 months of age; 5% is administered to high risk infants beginning vaccination at <7 months of age and 10% is administered to healthy children beginning vaccination at 7 to 24 months of age. Actual vaccine savings will depend on a provider's own vaccine use.

Figure. Proportion of invasive pneumococcal infections by month of age among children <60 months old (Figure A) and <12 months old (Figure B). Results of population-based active surveillance, 1998-99 (CDC, unpublished data).

A.



B.



Immunogenicity of pneumococcal conjugate vaccine among U.S. infants and children by dose and age of vaccination. Data from both the licensed product and pre-licensure studies with a higher antigen concentration are included as there was no significant difference in titer by antigen concentration. Values in bold are included in the product package insert.

				Range EIA GMC (µg/ml)							
Age and Schedule	Number of Studies	N Range	Total N	4	6B	9V	14	18C	19F	23F	NOTES
2,4,6 Schedule											
Pre Vaccine (2 mo)	6	32-159	1130	0.05/0.12	0.31/0.53	0.12/0.28	0.18/0.38	0.09/0.27	0.28/0.65	0.11/0.29	Includes Daum et al. 2µg & 5µg doses
Post Dose #1	1	47	47	Not done	0.12	Not done	0.19	0.32	0.66	0.07	Includes Daum et al. 5µg dose only
Post Dose #2	2	47-90	137	1.48	0.19/0.26	0.44	1.69/1.97	0.74/1.36	2.20/2.62	0.32/0.51	Daum et al. 5µg doses & Rennels et al.
Post Dose #3	5	47-159	1011	1.32/2.03	1.22/3.62	0.98/1.80	3.42/5.83	1.24/2.76	1.46/3.9	1.24/2.54	Includes Daum et al. 2µg & 5µg doses
	1	31-88	118	1.46/1.47	2.18/4.70	1.52/1.99	4.60/5.05	2.16/2.24	1.39/1.54	1.48/1.85	Kaiser Efficacy DTP/DTaP
Catch Up 7 - 11 mo (7,9,12-18mo)											
Post Dose #2	2	37-38	107	2.33/3.80	3.66/4.83	2.04/2.38	4.69/5.83	1.86/2.24	1.96/2.15	1.93/2.80	
Catch Up 12-17 mo											
Post Dose #2	2	25-30	55	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible] Native Americans (-59%)
Catch Up 18-23 mo											
Post Dose #1	2	33-48	78	1.62/2.91	0.44/0.80	0.89/2.12	0.45/0.72	1.49/1.65	0.96/1.31	0.69/1.50	Includes Native Americans. (-59%)
Post Dose #2	2	45-54	97	3.36/6.85	3.71/4.92	1.80/3.86	6.48/6.69	2.65/3.42	3.17/3.86	2.71/2.75	Includes Native Americans. (-54%)

Daum RS, Hogerman D, Rennels MB, et al. Infant immunization with pneumococcal CRM_{197} vaccines: effect of saccharide size on immunogenicity and interactions with simultaneously administered vaccines. *J Infect Dis* 1997;176:445-55.

Rennels MB, Edwards KM, Keyserling HL, et al. Safety and immunogenicity of heptavalent pneumococcal vaccine conjugated to CRM_{197} in United States infants. *Pediatrics* 1998;101:604-11.

Shinefield HR, Black S, Ray P, et al. Safety and immunogenicity of heptavalent pneumococcal CRM_{197} conjugate vaccine in infants and toddlers. *Pediatr Infect Dis J* 1999;18:757-63.

Black S, Shinefield H, Fireman B, et al. Efficacy, safety and immunogenicity of heptavalent pneumococcal conjugate vaccine in children. *Pediatr Infect Dis J* 2000;19:187-95.

Wyeth Data on File (F. Malinoski personal communicatio

Recommendations for Pneumococcal Conjugate Vaccine Use in the Setting of a Vaccine Shortage

Report of the ACIP Working Group

Outline

- Key issues in developing recommendations
- Summary of draft recommendations
- Discussion
- Vote

Key Issues in Developing Recommendations

- Predicting the supply situation
- Response to Sept. 14 CDC recommendations
- Flexibility for practices based on their own vaccine supply
- Availability of data supporting reduced dose schedules
- Evaluation of alternate 2-dose schedules among young infants
- Role of pneumococcal polysaccharide vaccine

Recent and Predicted Supply Situation

- Based on the ACIP recommended schedule, demand is ~1.5 million doses per month
- In September and October supply was <50% of demand based on the 4-dose infant schedule
- From Nov. 2001 to Mar. 2002 distribution of ~1.2 million doses per month is predicted
- From Apr to June 2002, distribution of ~2 million doses per month is predicted
- If vaccine distribution was equitable and all providers adhered to a 3-dose infant schedule the shortage would be ameliorated by mid-2002.

Response to the Sept. 14 Recommendations

- Provider survey by Dr. Freed

Flexibility for Practices Based on Their Own Vaccine Supply?

- Vaccine supply is uneven
  - The need to conserve vaccine differs between practices and States
- Changing vaccine ordering or distribution is difficult
- Providers are likely to have a practice rather than a population perspective.
- Options for recommendations
  - Flexibility of no change to a 2-dose schedule
  - Limited flexibility of a 3-dose or 2-dose schedule
  - No flexibility; same recommendation for all practices

Availability of Data Supporting Reduced Dose Schedules

- Limited
- Key issues include...
  - Efficacy (NCK trial 86% point estimate before next dose for 1 or 2 doses with 95% CI overlapping 0)
  - Duration of protection (no data)
  - Priming and memory (likely for 2-doses but no data)
  - Impact on NP carriage (occurs with 3-doses but no data on 2-doses in infants)

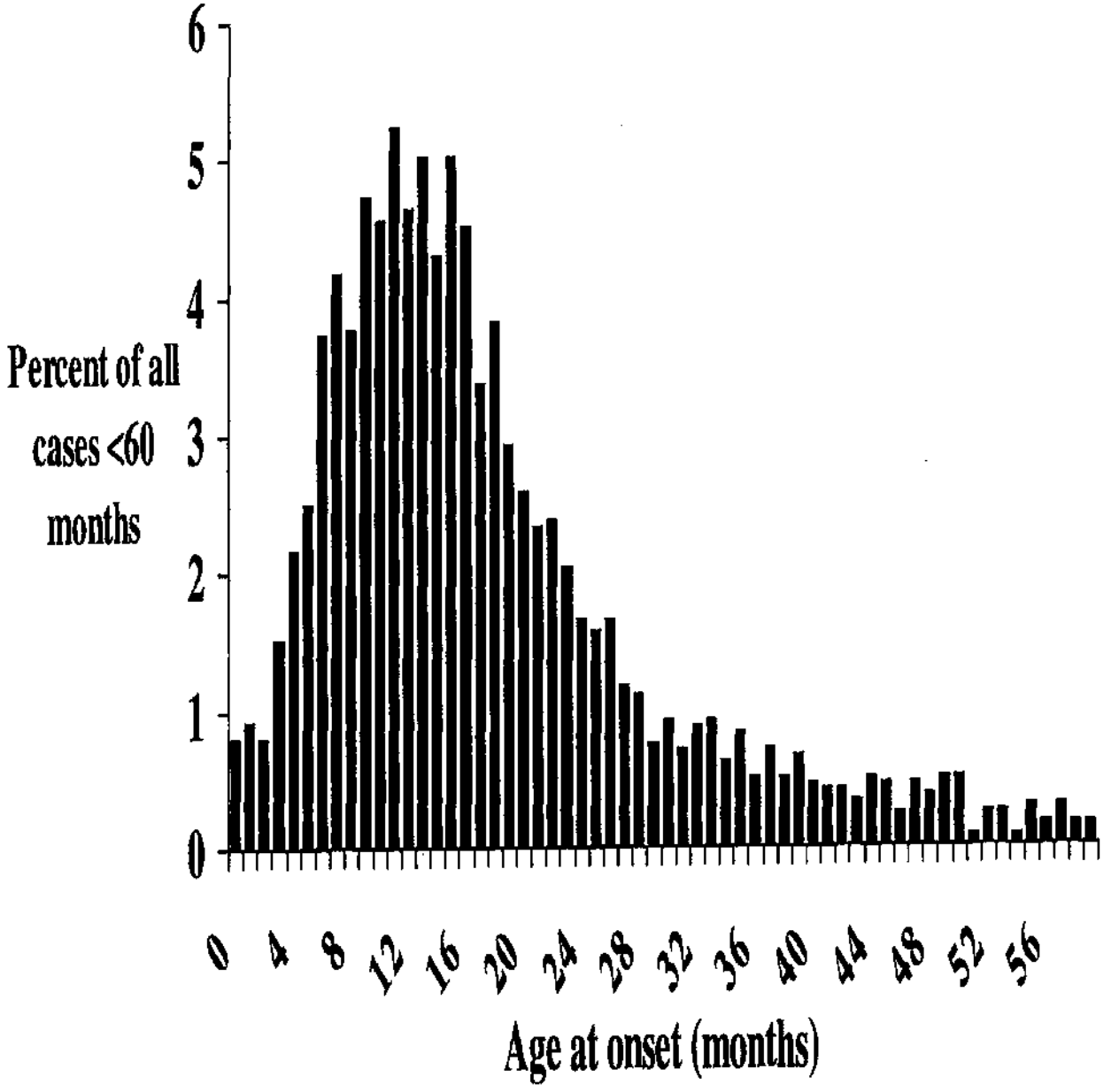
Immunogenicity of Reduced Dose Regimens

- Infants <6 months old
  - Post 2nd dose at 2 & 4 months, no increase in GMC for type 6B and small increase for 23F
  - Post 3rd dose, GMC >1 ug/ml for all vaccine types
- Infants 7-11 months old
  - Post 2nd dose, GMC >1ug/ml for all vaccine types
- Children 12-23 months
  - Post 1st dose, GMC increases for all types but may be <1ug/ml and is least for type 6B
  - Post 2nd dose, GMC >2ug/ml for all vaccine types

Options for Alternate 2-Dose Schedules Among Young Infants

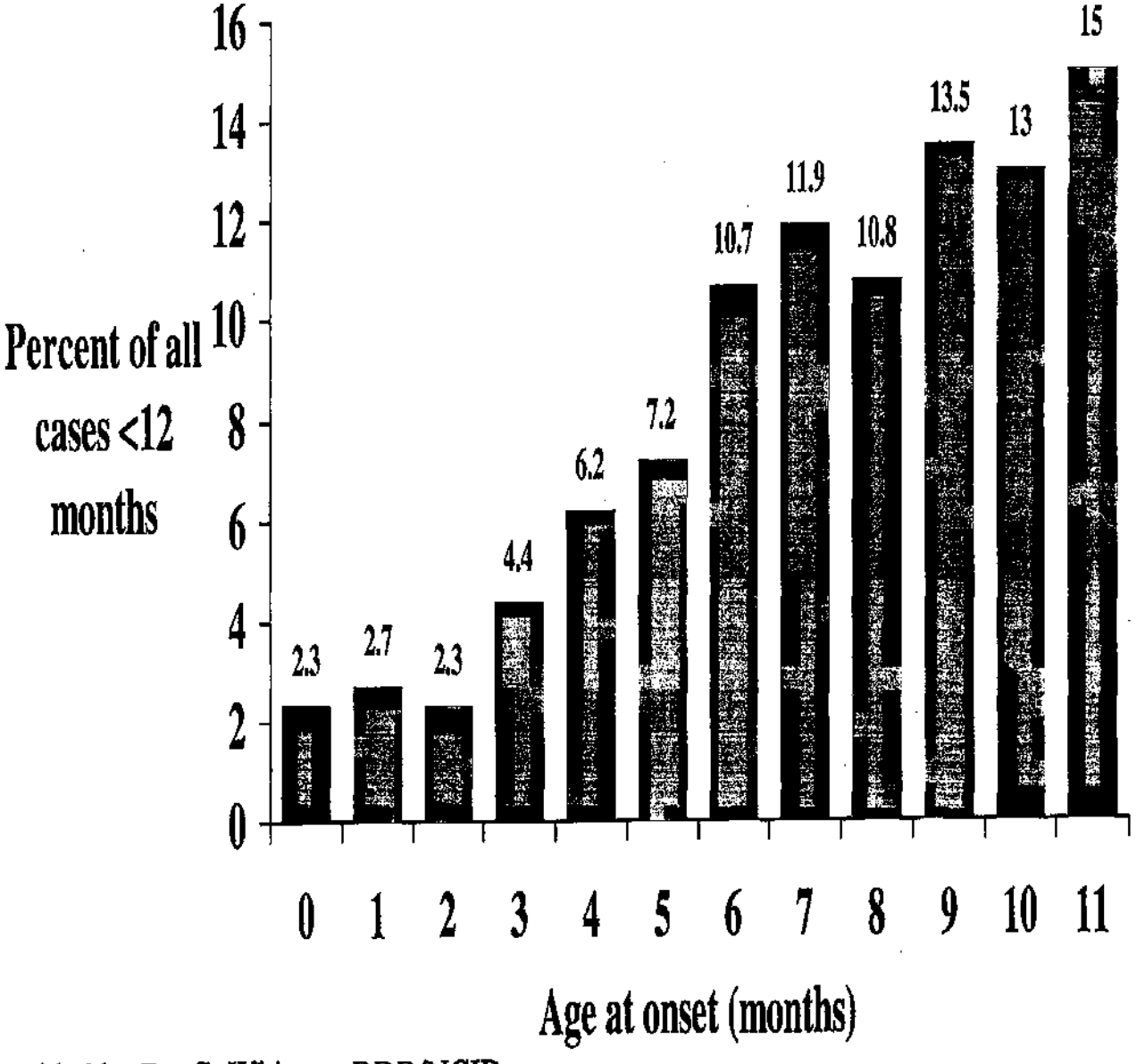
- 2-doses in the first 6 months of life
  - 2 & 4 months: early protection, least immunogenicity
  - 2 & 6 months: early protection, perhaps better immunogenicity
  - 4 & 6 months: perhaps better immunogenicity, perhaps carrier priming
  - Schedule may be dictated by vaccine availability rather than provider choice
- 2-doses at 7 & 9 months of age: good immunogenicity, lack of early protection, need for additional visits

Age Distribution of Invasive Pneumococcal Disease In Children <60 Months 1998 and 1999, Active Bacterial Core Surveillance



Provided by Dr. C. Whitney, RDB/NCID

Age Distribution of Invasive Pneumococcal Disease in Children <12 Months in the U.S. 1998 and 1999, Active Bacterial Core Surveillance



Provided by Dr. C. Whitney, RDB/NCID

Role of Pneumococcal Polysaccharide Vaccine

- Licensed for persons >2 years old
- Recommended for high risk persons >2 years old
- May boost antibody levels among primed infants (3-doses) when given in 2nd year of life (15-18 months)
- Limited supply and no Federal contract
- WL vaccine contains thimerosal

Draft Recommendation Highlights

- Key principles
  - Reduced doses per child is preferable to not vaccinating some children for whom vaccine is recommended
  - Changes in vaccine use and ordering practices should be made by all providers
- Providers have flexibility for reduced dose schedules based on vaccine supply
- Infants should be vaccinated in the 1st 6 months with flexibility regarding timing
- Pneumococcal polysaccharide vaccine should be studied but is not recommended for a 2nd year dose

Diniega, Benedict, COL, OASD/HA

From: (b)(6) LTC OTSG (b)(6) @otsg.amedd.army.mil]
Sent: Friday, February 15, 2002 2:23 PM
To: Randolph, Gaston M COL OTSG (b)(6) @ha.osd.mil'
Cc: (b)(6)
Subject: Planning for release of IOM report
Importance: High

I just got off the phone with (b)(6) DrPH, staff coordinator for the IOM cmte on safety and efficacy of anthrax vaccine. She indicated that IOM President (b)(6) and Dr. Winkenwerder had chatted, which will set in motion a release schedule something like the following -- DRAFT -- DRAFT

DRAFT

Fri 22 Feb - IOM provides "final" report to DoD for security review (b)(6)

Mon 25 Feb - DoD returns results of security review to IOM

Tue 26 Feb - IOM delivers official report to DoD, the sponsor. DOD may ask questions or ask for clarification of specific points.

The report would be marked "Prepublication proof copy - embargoed until official release on March 6."

DoD will probably get ~ 50 copies.

IOM party: (b)(6) perhaps IOM senior leaders

Questions:

where: AVIP Agency suggests in Pentagon, 3E1082

who: Dr. Winkenwerder? (b)(6) HA staff, (b)(6) others

when: When is Dr. W free that day?

Tue 26 Feb - DHHS Secretary Thompson asked IOM to be kept him informed of major developments generally, so IOM would like to deliver the report to senior DHHS people later in the same day as they deliver it to DoD. Could involve Asst Secy for Health Eve Slater, D.A. Henderson, or others at that level.

Tue 26 Feb - IOM would deliver either a briefing about the report or the report to Congressman Nethercutt, "champion" of the IOM review on Capital Hill. This is apparently an IOM tradition and would be "hard not to do."

Tue 5 Mar - IOM releases embargoed report to key press

Wed 6 Mar - public release with press conference. Event open to public but only press may ask questions. DoD may attend (sitting quietly in back).

Press conference conducted by cmte chair Strom, plus 2 to 5 other committee members.

Questions:

where: possibly in the "Green Building," Wisconsin Avenue, north of Georgetown

when: TBA

Afterward: typos and other minor errors can be fixed, then the report goes to the National Academy Press. Roughly 11 weeks later, DoD will get ~ 500 copies.

Please advise how to plan for 26 Feb...

v/r (b)(6)

(b)(6)
Deputy Director for Clinical Operations
Anthrax Vaccine Immunization Program Agency
U.S. Army Medical Command
5111 Leesburg Pike (Suite 401)
Falls Church, VA 22041-3258
(b)(6) Fax (b)(6) Beeper (b)(6)

Anthrax Vaccine -- 18 safety studies, involving > 500,000 vaccine recipients, plus concurrence of six independent civilian reviews, with ongoing surveillance. Spend some time reading the details at http://www.anthrax.mil.

Subscribe to a weekly mailing on the AVIP - http://www.anthrax.mil/temp/listsubscribe.asp

Toll-free Question & Answer Service: 877-GET-VACC.

Diniega, Benedict, COL, OASD/HA

From: (b)(6) @cdc.gov]
Sent: Wednesday, October 24, 2001 4:00 PM
To: (b)(6)
cc:
Subject: **FW: CDC** Conference Bridge Confirmation

-----Original Message-----
From (b)(6)
Sent: Wednesday, October 24, 2001 3:07 PM
To (b)(@CDC.GOV
Subject: CDC Conference Bridge Confirmation

MEETME RESERVATION

Host Name: BIOTERRORISM

Subject:

Participants:

Conference Date: 25-OCT-01

Conference Time: 10:00 AM Eastern

09:00 AM Central

08:00 AM Mountain

07:00 AM Pacific

Conference Duration: 02:00 Hours

Conference Size: 20 Port(s)

Bridge Telephone Number: (b)(6)

Conference Code: (b)(6)

==========

Thank you using CDC Conference Bridge. Please review this confirmation for accurateness. If you need to make a change, please hit reply to this email or call (b)(6)

Alternate Bridge Telephone Numbers for NON-FEDERAL PARTICIPANTS ONLY!

If your bridge telephone number is (b)(6)
If your bridge telephone number is

Diniega, Benedict, COL, OASD/HA

From: (b)(6) @cdc.gov]
Sent: Wednesday, October 24, 20016:52 PM
To: (b)(6)
cc:
Subject: RE: Emergency reconvening of the ACIP Bioterrorism Working Group to address anthrax vaccine issues

(b)(6) would like to focus the ACIP on these four issues:

Prioritization of populations for pre-exposure anthrax vaccination
- based on current epidemiology &
- potential wider scale threat

Recommendations for anthrax vaccine studies in pediatric populations

Recommendations for further clarification of relative efficacy of 60 day antibiotic post-exposure prophylaxis vs at least 30 days of antibiotics + 3 doses of anthrax vaccine

Potential use of hyperimmune serum for adjunctive therapy for life-threatening anthrax disease

Thanks, (b)(6)

> -----Original Message-----
> From: (b)(6)
> Sent: Wednesday, October 24, 200111:51 AM
> To: (b)(6)
> Cc:
> (b)(6)
> Subject: Emergency reconvening of the ACIP Bioterrorism Working Group
> to address anthrax vaccine issues
>
> (b)(6) and (b)(6) Thank you for agreeing to pursue an urgent reconvening
> of the working group to address critical issues regarding the anthrax
> vaccine.
>
> In addition to the official members, these were the "adjunct" members that
> were extremely helpful and probably should be included again:
> (b)(6)
>
> I think it would be advisable to include a member from the Johns Hopkins
> team as well. That would best be (b)(6), I think.
>
> (b)(6 Can you send to (b)(6) and (b)(6) please the contact information
> for these individuals? Also, to address the questions below from (b)(
> (b)(6) the members will need to be brought up to speed on the CDC
> research program. Can you send to all members the description of the AVRP
> research activities?
>
> (b)(6) Please send all the email addresses for the official members to

> (b)(6)
>
>
> Critical issues to be addressed:
>
> 1. CDC and partners are prepared to begin a 43 month human trial to
> evaluate AVA change of route (SC! to IM) and dose reduction (6 down to as
> few as 3).
> Is this the right study to do under the current circumstances?
> Should this study be modified in some way to address more urgent
> issues?
> Is there a way to accelerate the change in route and dose reduction?
> This could have a remarkable impact on costs and usefulness of AVA,
> and projection of vaccine needs.
> Should we include a pediatric arm of some kind? Maybe an open label
> three dose regimen - 0, 2 wks and 6 or 12 months.
> Should we include rPA in head-to-head comparisons with AVA in adults
> &/or children?
>
> 2. Similarly, CDC and partners have already began non-human primate
> studies to identify immunologic correlates of protection?
> Is this the correct use of these animals & infrastructure under the
> current circumstances?
> What is the relative priority of these studies vs nhp studies to
> clarify antibiotics alone vs antibiotic + vaccine for PEP?
> Do we have current US capacity to do these relatively large nhp
> studies (i.e., immune correlates and PEP issues) simultaneously?
> Assuming that we should continue with nhp studies to identify
> immunologic correlates of protection, should we include rPA along with AVA
> in these studies?
>
> 3. What is the licensing strategy for rPA? This is critical to define in
> regard to any discussions of timelines for development.
> Will an rPA based vaccine be required to be shown non-inferior to
> the currently licensed AVA 6 dose SQ regimen based on immunogenicity?
>
> 4. Should we immediately design and initiate nhp studies to resolve the
> question of benefit from antibiotic + vaccine vs antibiotics alone?
> From our perspective, this information drives critical questions
> regarding addition of vaccine to the NPS. Since committments have already
> been made for some level of anthrax preparedness based on antibiotics
> alone, once we are able to make a decision on use of vaccine - calculation
> of need for the stockpile will be relatively straight forward.
>
> 5. Should we submit an IND for use of our pooled hyperimmune anti-AVA sera
> for use as therapy for human disease? As I mentioned on the phone, we
> have this reagent and it may be useful in treating some of the cases we
> are currently seeing. I would appreciate thoughts *on* this.
>
> 6. I think for rapid movement on many of these issues, we need to have a
> FDA CEBR person detailed to CDC for some period of time - maybe 3 months,
> to help expedite collaboration on the myriad of IND, protocol, and
> manufacturing issues.
>
> Also, considerations for expanded immunization recommendations in light of
> the current threat.
>
> Thank you.
>
> (b)(6) DVM, MPH, DSc
>
> Chief, Zoonoses Unit
> Meningitis and Special Pathogens Branch
> DBMD, CDC MS-C09

> 1600 Clifton Rd.
> Atlanta, GA 30333
> Tel: (b)(6)
> Fax:
> Email: (b)(6)
>
>

Diniega, Benedict, COL, OASD/HA

From: (b)(6) @cdc.gov]
Sent: Thursday, October 25, 20018:48 AM
To: (b)(6)
cc:
Subject: Anthrax vaccine
Importance: High

(b)(6) attached are my comments appended on top of (b)(6) (his are in red, mine in blue). I'll send the tables separately.

(b)(6)

DRAFT

Date:
To: The Deputy Secretary, DHHS
THRU: Acting Assistant Secretary for Health, DHHS
From: (b)(6) M.D. Chair DHHS Anthrax Scientific and Technical Feasibility Team
Subject: Options, Issues and Recommendations for Response to Anthrax

Background: The purpose of this memorandum is to summarize the scientific and technical feasibility (supply, development and procurement) of a biomedical response to a major act of anthrax bioterrorism in the United States of America, and to provide recommendations for your consideration.

Anthrax is not a communicable disease and outbreaks of the disease will, therefore, be locally limited. However there are now expanding potential target populations for deploying such a vaccine for certain segments of the civilian population. For example, laboratorians handling potentially contaminated specimens and decontamination teams. It seems likely that the number of groups for whom vaccine might become indicated may increase in the coming weeks and months. In addition, although the science is limited, it is widely believed from animal studies that post exposure immunization may shorten the needed duration for antibiotic prophylaxis after exposure. Recent events ~~have~~ required us to consider the expanding possibilities associated with widespread release of anthrax and to identify plans for immediate, intermediate and longer-term response. Recent events ~~have shown~~ that the dissemination of anthrax spores can be accomplished and limiting our focus to site containment cannot be a long-term strategy. Two biomedical options for the control of anthrax are available, antimicrobial therapy and vaccines. The primary response to anthrax exposure has been antimicrobials, which have been used both inprophylactic and therapeutic-m. ~~These include~~ Ciprofloxacin is explicitlyflicensed for post-exposure prophylaxis), whereas penicillin~~,~~ and doxycycline and generally licensed for treatment of anthrax infection. Several other classes of licensed antimicrobials have shown activity against anthrax, in vitro.

> Presently, there is no licensed vaccine available for civilian use and only limited quantities are available as an investigational drug. Currently, Bioport is the only producer of licensed anthrax vaccine and has a sole contract to provide vaccine to the military. The manufacturer has had difficulty in complying with current good manufacturing practices but is nearing the end of a series of steps that are likely to bring it into compliance such that the Food and Drug Administration can release licensed vaccine for use soon. This vaccine has not been tested in children. Licensed in 1970. t~~T~~he vaccine ~~that has been most widely~~ used in the U.S. is made from cell-free cultured filtrates of an attenuated strain of anthrax. Known as AVA, i is produced by BioPort Corporation, Lansing, Michigan. The current stockpile is owned by the U.S. Department of Defense-. The vaccine requires 6 doses over a period of 18 months for maximal protection, according to the FDA-approved product labeling. New data that will be available soon may permit pre-exposure immunization employing as few as 4 doses. The predominant antigen associated with this vaccine is known as the protective antigen (PA) and second generation vaccines have been focused on attaining these purified antigens through recombinant DNA technology (rPA). To date, no rPA vaccines have been tested in humans.

Assignment: The Secretary requested the establishment of an Anthrax Scientific and Technical Feasibility (see attached list) to do the following:

- Determine the scientific and technical feasibility to ~~make available of assure~~ing vaccine and/or appropriate therapy would be available to all ~~that~~ who would need it; and
- Develop a set of options and recommendations for accomplishing this purpose.

Conclusion:

The work group recommends that the decision to acquire anthrax vaccine for civilian use be made and that on-going capacity to produce a vaccine inventory be maintained.

Immediate (widespread attack between present to one month): The options are limited. For the immediate term, antibiotics will need to remain the primary tool for response. In addition to continuing to provide courses of antibiotic treatment, limited supplies of AVA (10,000 doses) can be made available for use forin pre-exposure prohylaxis of those who are considered at greatest risk based on the current epidemiologic situation. In addition, the military is willing to permit the Department acquire a lot of 209,000 doses of vaccine that could be deployed immediately as part of the National Pharmaceutical stockpile. There are several options for the use of this vaccine: 1) mail handlers working in the vicinity of automated sotting equiopment C-500,000 individuals) 2) for protection of some of the first responders in a selected high risk urban settina where an attack might be focused (this population may be as large as 9.8 million firefighters, policemen and other first response individuals). 3) post-exposure prophylaxis (in combination with antibiotics) as well as being offered to those at immediate risks, (e.g. workers in a taraeted facility, laboratory workers and decontamination experts) as a prophylactic. Or 4) held in reserve until there is better understanding of who the greatest risks are. The work grouop favors.....[my preference would be #4]. Use of masks (e.g. N95) for low-density potential contamination sites should also be considered.

Intermediate response (one month to 1 year): Additional doses of AVA can be made available as the circumstance dictate. The DoD has agreed that ~3 million does that are being held in resrve could be labeled and final testing accomplished within the next week. This vaccine would remain the property of the military but it has been agreed it could be deployed for the civilian population if the situation warranted this. There are an additional xxxxxdoses of recently produced licenseable vaccine that the military plans to distribute to their forces as soon as it is released by the FDA. In addition, there are xxxxxdoses that may be deployable are further review by the FDA with Bioport; this review is underway and should be completed with in xxxxdays. The work aroup is exploring with DoD, the **FDA** and ?Bioport the feasibility of expanding their production capacity both by increasing their production capabilities and by subcontracting to another producer. It is unclear how much of this additional vaccine would be distributed between the DoD and the DHHS. Expected production in this time period is xxxxxxxxxx(current capacity) to xxxxxxxx(expanded capacity).~~made available~~manufactured.

X Longer-term response (1 year to 6 years): Opportunities to provide sufficient vaccine (AVA and/or rPA) to protect the U.S. population is feasible. In addition to the currently licensed anthrax vaccine, the technology exists to produce a more refined anthrax vaccine by means that can be rapidly scaled up if more vaccine was needed. Therefore, in addition to obtaining access to vaccine produced by the current technology, the work group recommends that the new technology be explored immediately **as an** interim and longer-term solution **to** obtaining and **maintaining anthrax** vaccine for the **civilian** population. Obstacles to developing vaccines by these technologies **have been** hampered by intellectual property issues between Federal departments.

X In addition to vaccine, therapeutic modalities (e.g. antitoxin) could be developed. The work group recommends that these modalities be rapidly developed and deployed.

Expansion of the classes of **antimicrobials** available for use against anthrax, both prophylactically and therapeutically, could also occur.

Recommendations: The DHHS Anthrax Scientific and Technical Feasibility Team recommends that immediate efforts be directed to pursuing the multiple approaches required for the immediate and intermediate response. These include:

- Purchase of available AVA vaccine from the military. This will require indemnification ~~from~~ by DHHS and use of the vaccine under IND.
- Expansion of the supply of first line antibiotics.

X Additional therapeutic modalities for the treatment of inhalation anthrax (e.g. antitoxin derived from previously immunized individuals) could be rapidly developed. The work group recommends that these modalities be rapidly developed and deployed.

X As the epidemiology of illnesses and exposure evolves, the numbers of doses of vaccine needed for the civilian population will become clearer. Until that time, the capacity to produce large amounts of potentially licenseable vaccine needs to be created as quickly as feasible.

- Development of revised guidelines for the distribution and use of masks and antibiotics.
- Development of guidelines for the storage and use of limited supplies of AVA vaccine.
- Accelerate the human evaluation of rPA.
- Accelerate the evaluation of additional classes of antimicrobials

Longer term

- Expand discussions with BioPort, as well as other manufacturers with respect to their ability to produce AVA for civilian use. This will require negotiations with DOD.
- Expand human testing of rPA vaccines
- Expand evaluation of therapeutic approaches to include novel antitoxins and monoclonal antibodies

Diniega, Benedict, COL, OASD/HA

From: (b)(6) @cdc.gov]
Sent: Thursday, October 25, 20018:57 AM
To: (b)(6)
cc:
Subject: RE: Anthrax vaccine
Importance: High

some comments on the tables

Goal	Approach	Pros	Cons	Considerations:
Immediate Response Present -1 month	APPROACH #1: Use existing lots of vaccine under IND status 10,000 doses for pre-exposure prophylaxis highest risk groups. Acquire 209,000 deployable doses for National Pharmaceutical stockpile. Ready 3 million doses in order to assure they are deployable.	3-6 million doses available in multiple lots. Probably adequate for first responders and limited attack. Favorable scientific reviews from ACIP, AFEB, Cochrane Collaboration, Working Group on Civilian Biodefense, other independent civilian panels	Different lots produced under different conditions. Not all vaccine lots licensable. History of concern with use of this vaccine (organized antivaccine movement). Limited testing in children, pregnant women, elderly and immune suppressed populations. Pre-exposure approach requires 6 doses over 18 months for maximum response, according to the FDA-approved product labeling. Post-exposure requires at least 3 doses in conjunction	Indemnification for civilian populations remains an issue. Must address issue of secured and deployable storage. Immediate need to label lots for IND use. Target population to vaccinate must be identified. Must ascertain potential requests from allied nations. National Academy of Sciences/Institute of Medicine Committee on Safety & Efficacy of Anthrax Vaccine (the "Strom committee") nearing completion of 2-year review

			with antibiotic treatment.	
Goal	**Approach**	**Pros**	**Cons**	**Considerations:**
Immediate Response cont. Present -1 month	APPROACH #2: Expand potential list of useful antibiotics by testing: • Other quinolones • Erythomycin • Clindamycin • Extended spectrum penicillins • 0th. Macrolides • Aminoglycosides • Vancomycin	Expands clinicans' treatment options. Expands potential manufacturers/suppliers. Allows flexibility to use individually or in combination to treat possible antibiotic strains.	Most not licensed for post-or pre-exposure treatment of anthrax. For many, efficacy not established.	For those showing effect, must be tested in animal models with aerosol exposure.
	APPROACH #3: Acquire and Use hyperimmune serum for adjunctive therapy of advanced anthrax disease.	Potential to neutralize toxin. Historical use and benefit. Limited supportive animal efficacy data [if true.. . .] Limited material currently available. [is any material available????]	None	Could only be used under IND.

Goal	Approach	Pros	Cons	Considerations:
Intermediate response 1-12 months	APPROACH #1: Expand production of AVA vaccine under contract with BioPort.	Additional stocks of licensable vaccine would be available.	Security threat of only one manufacturer.	• DoD contracted with BioPort for the entire available supply~~is under sole contract to DOD and~~. P production of AVA vaccine for civilian use would need to be negotiated in the short term, although the DoD contract permits civilian sales beyond the contracted needs of the U.S. military. • There is a finite production capacity and trained personnel through BioPort. A ~~and~~ although expansion is possible, production of AVA for the entire civilian population is not possible in the intermediate term. Product indemnification needs to be provided.
	APPROACH #2: Expand production of AVA vaccine under contract with other vaccine manufacturers.	Increased capacity to manufacture potentially licensable vaccines.	~~Manufacturers~~ Other manufacturers have no production ~~record~~ experience with this particular product.	Intellectual property would need to be transferred (e.g., shared license or contract operation).

Goal	Approach	Pros	Cons	Considerations:
Intermediate response cont. 1-12 months	APPROACH #3: Accelerate development of alternative anthrax vaccines (e.g. rPA)	Pilot lot of vaccine already produced through DOD/DHHS collaboration, The bulk vaccine could be vialed and clinically evaluate~~dion~~ within the intermediate term. Multiple approaches to rPA development are underway (e.g. single and double mutants) Easy, reliable and safe technology. Purity of product. Scale-up is simple. Multiple potential manufacturers. Potential advantages for immunologic response to vaccination. [We don't understand what this entry refers to. Some scientists feel that going to rPA alone may be "overpurifying" the vaccine. if other cellular or	Animal studies of rPA are encouraging but human trials have yet to be performed. Human efficacy trials can never be performed.	Intellectual property ownership of this approach is unclear.

capsular components have
immunologic value]

Goal	Approach	Pros	Cons	Considerations:
Intermediate response cont. 1-12 months	APPROACH #4: Accelerate prophylactic and therapeutic options for pre- and post-exposure anthrax by implementing activity screening and small animal and primate testing of antimicrobial alternative choices for Cipro penicillin and doxycyline and development and testing of monoclonal and polyclonal antibody products.	Generate data on effectiveness and duration of treatment to guide public health decisions.	None	

Goal	Approach	Pros	Cons	Considerations:
Long-term response (over 12 months)	Produce sufficient vaccine to neutralize threat nationally and internationally. • Select best vaccine • Expand its production • Expand testing to include all segments of the population	If needed, will allow immunization of population. Insures multiple manufacturers for future needs. Security of multiple manufacturing sites.	For new vaccine, little data on efficacy and duration of response in humans. Less safety data will be available, compared to the 18 existing human studies with earlier formulations of anthrax vaccine.	Indemnification for civilian population remains an issue. New products will require expanded animal and clinical trials. Must address issue of secure storage of stockpile. Combination of post-exposure treatment with antibiotics must be studied.

Diniega, Benedict, COL, OASD/HA

From: (b)(6)

Sent: Wednesday, October 24, 200110:26 PM

To: (b)(6)

cc:

Subject: RE: DHHS Anthrax Sci /Tech Feasibility Team

(b)(6), thanks for the opportunity to review your drafts. Comments of the AVIP Agency (Office of the Army Surgeon General) are attached using "Track Changes." I'll also fax these to (b)(6) Let me know if you would prefer a different number.

I've also taken the liberty of attaching our bibliography and review of 18 human safety studies, in case that would help jump-start your work.

We have a wide variety of professional, medical resources at our website: http://www.anthrax.osd.mil. I'd be happy to help you navigate it if you would like. We also have a wealth of lay-language materials, which are often harder to write!

Best regards, (b)(6)

(b)(6)
Deputy Director for Clinical Operations
Anthrax Vaccine Immunization Program Agency
US. Army Medical Command
5111 Leesburg Pike (Suite 401)
Falls Church, VA 22041-3258
(b)(6) Fax (b)(6) Beeper (b)(6)

Anthrax Vaccine -- 18 safety studies, involving > 500,000 vaccine recipients, plus concurrence of six independent civilian reviews, with ongoing surveillance. Any questions? Spend some time reading the details at http://www.anthrax.osd.mil.

Subscribe to a weekly mailing on the AVIP - http://www.anthrax.osd.mil/temp/listsubscribe.asp

Toll-free Question & Answer Service: 877-GET-VACC

-----Original Message-----
From: (b)(6) @niaid.nih.gov]
Sent: Wednesday, October 24, 2001 5:42 PM
To: (b)(6)
(b)(6)
Subject: RE: CDC Conference Bridge Confirmation

Attached is a draft of the memo and approaches for the timeframes that were discussed I realize that you have had limited time to look at this. I would suggest that you spend time digesting/improving these documents with a goal of submitting back to me (via email) tomorrow 9 a.m. any changes you want. I will develop a second draft and resend by noon. (b)(...can you do another bridge 19ine fore tomorrow

-----Original Message-----

From: (b)(6) @cdc.gov]
Sent: Wednesday, October 24, 2001 2:50 PM
To: (b)(6)
(b)(
Subject: FW: CDC Conference Bridge Confirmation
Importance: High

for the 5:30 call - please pass on to the appropriate people

-----Original Message-----
From: (b)(6)
Sent: Wednesday, October 24, 2001 2:46 PM
To (b)(6)
Subject: FW: CDC Conference Bridge Confirmation
Importance: High

Below is your bridge line.

-----Original Message-----
From: (b)(6) @cdc.gov]
Sent: Wednesday, October 24, 2001 2:47 PM
To: (b)(6)
Subject: CDC Conference Bridge Confirmation

MEETME RESERVATION

Host Name: (b)(6) CALL

Subject:

Participants:

Conference Date: 24-OCT-01

Conference Time: 05:30 PM Eastern

04:30 PM Central

03:30 PM Mountain

02:30 PM Pacific

Conference Duration: 02:00 Hours

Conference Size: 15 Port(s)

Bridge Telephone Number: (b)(6)

Conference Code: (b)(6)

Thank you using CDC Conference Bridge. Please review this confirmation for accurateness. If you need to make a change, please hit reply to this **email** or call (b)(6)

Alternate Bridge Telephone Numbers for NON-FEDERAL PARTICIPANTS ONLY!

If your bridge telephone number is (b)(6) dial (b)(6)
If your bridge telephone number is dial

ANTHRAX: SCIENTIFIC EVIDENCE REGARDING EFFECTIVENESS & SAFETY
1 October 2001

*- core article

The Disease Anthrax

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Detailed Safety Review of Anthrax Vaccine Adsorbed
19 October 2001
Compiled by the Anthrax Vaccine Immunization Program (AVIP) Agency
US Army Medical Command, Falls Church, Virginia

To date, 18 human studies have assessed the safety of anthrax vaccination. These studies, some stretching back almost 50 years, reported adverse events after vaccination in varying degrees of detail. The following sections report the design characteristics of these studies, the number of men and women participating, and their specific findings.

Among the studies described below, one of two vaccine formulations was used. The Brachman study and the early Fort Detrick studies used anthrax vaccine manufactured according to the original 1950s formula developed at Fort Detrick, Maryland (sometimes called the "Merck vaccine"). Research on this vaccine has been repeatedly accepted by the Food & Drug Administration (FDA) as relevant to the understanding of the safety profile of the current anthrax vaccine, developed in the 1960s.

In the 1960s, the production process for anthrax vaccine was improved to increase the concentration of the active ingredient, known as "protective antigen" (increasing the vaccine's potency), and to decrease the amount of other bacterial components in the vaccine (e.g., proteins called edema factor or lethal factor), thus increasing purity. This purer, more potent vaccine, manufactured in Lansing, Michigan, was licensed by the National Institute of Health (NIH) in 1970. Responsibility for vaccine regulation migrated from NIH to the Food & Drug Administration in 1972. FDA reaffirmed the anthrax vaccine license in 1985 (Fed Reg 1985;50:51002-117 http://www.anthrax.osd.mil/SiteFiles/articles/Indexclinical/Fed_register.htm). Additional information regarding the transition was published in 1962 (Wright GG, Puziss M, Neely WB. *Journal of Bacteriology* 1962;83:515-22).

The CDC observational study involved people who received either the original vaccine or the improved vaccine, or both. The other studies described below used anthrax vaccine manufactured according to the improved 1960s formula, the same vaccine used in the United States today.

SUMMARY:

Anthrax vaccine prevents anthrax. Anthrax vaccine does not prevent other health problems. This is evident in the similar rates of hospitalization among Service Members vaccinated or unvaccinated against anthrax (section Q).

Like all vaccines, anthrax vaccine can cause soreness, redness, itching, swelling, and lumps at the injection site. About 30% of men and 60% of women report injection-site reactions of 1" or smaller diameter, usually lasting only a few days. Lumps at the injection site can persist a few weeks, but eventually go away. For both genders, between 1% and 5% report moderate reactions of 1 to 5 inches in diameter. Larger reactions occur after about one in a hundred vaccinees.

Beyond the injection site, from 5% to 35% will notice rashes (16%), headaches (14% to 25%), joint aches (12% to 15%), malaise (6% to 17%), muscle aches (3% to 34%), nausea (3% to 9%), chills (2% to 6%), fever (1% to 5%). Again, these symptoms usually go away after a few days.

The vaccine's March 1999 product labeling ("package insert") indicates that systemic effects occur in 0.2% of vaccine recipients. This value of 0.2% is unusually low, compared to other vaccines and compared to modern data collection with the licensed anthrax vaccine. The low value probably reflects a "threshold effect" of counting only cases of substantial adverse events, in contrast to mild adverse events.

To monitor rare or unexpected adverse events associated in time to any vaccine, DOD health-care providers have participated in the Vaccine Adverse Event Reporting System (VAERS), since its inception in 1990. In addition, each VAERS report involving anthrax vaccine is reviewed by an independent panel of civilian physicians. Between fall 1998 and the present, this panel has detected no patterns of unexpected adverse events related to anthrax vaccination.

There are no known long-term patterns of side effects from the anthrax vaccine, based on an ongoing series of studies at Fort Detrick, Maryland, and elsewhere. Reports in this series were published in 1958, 1965, and 1974.

Despite the extensive body of knowledge regarding the safety of anthrax vaccine, safety monitoring continues, as is prudent for all vaccines and medications.

Details of each study appear on following pages. The 18 studies include:

Group I: Studies from 1950s into the Present

A. The Brachman Study (pivotal field trial evaluating safety and efficacy).

B. The CDC Observational Study (the follow-on open-label study between the Brachman study and vaccine licensing in 1970).

C. Fort Detrick Multi-Dose, Multi-Vaccine Safety Studies (evaluations of Army laboratory workers vaccinated hundreds of times with dozens of vaccines).

D. Fort Detrick Special Immunization Program (SIP) Safety Study (continuation of the previous study among more workers into modern times).

Group II: Studies from the 1990s, Data Collection by Survey

E. Fort Bragg Booster Study (evaluation of additional doses of anthrax vaccine among soldiers vaccinated several years earlier during the Persian Gulf War).

F. USAMRIID Dose-Reduction / Route-Change Study (study of anthrax vaccine administered by two different injectable routes of administration).

G. Canadian Forces Safety Survey (study of Canadian Service Members).

H. TAMC-601 Survey (study of adverse events after anthrax vaccination of medical personnel at Tripler Army Medical Center).

I. U.S. Forces Korea Vaccination Series (study of adverse events among personnel there).

J. Reports involving Anthrax Vaccine Submitted to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS) and Evaluated by the Anthrax Vaccine Expert Committee.

K. ROTC Cadets at **Fort Lewis, Washington**

Group III: Studies from the 1990s, Database Analyses

L. USAF Air Combat Command Study, Langley Air Force Base (study of outpatient medical care among Air Force personnel after return from Southwest Asia).

M. Fort Stewart, Georgia, Reproductive Health Study

N. Reproductive Outcomes of the Wives of Male Soldiers Vaccinated Against Anthrax (Preliminary Report)

0. USAF Vision Study (a study of visual acuity among vaccinated and unvaccinated air crew members).

P. Army Aviator Flight Physical Examination Study, Aviation Epidemiology Data Register

Q. Defense Medical Surveillance System (comparison of hospitalization and outpatient visit rates for those vaccinated and unvaccinated against anthrax).

Group IV: Other Studies

R. Mycoplasma Study

Group I: Studies from 1950s into the Present

A. The Brachman Study

Citation: Phillip S. Brachman, Herman Gold, Stanley A. Plotkin, F. Robert Fekety, Milton Werrin, Norman R. Ingram. Field evaluation of human anthrax vaccine. *American Journal of Public Health 1962;* volume *52:* pages *632-45.*
http://www.anthrax.osd.mil/site_files/articles/indexclinical/brachman.pdf

Investigators: Epidemiologists at the Communicable Disease Center (Atlanta), the Johns Hopkins Hospital (Baltimore), and the Philadelphia Department of Public Health.

Period of Observation: 1955 to 1959

Participants: 1,249 people total, gender unspecified, of whom 379 received anthrax vaccine. At least 3 of the 26 cases of anthrax detected in this study occurred in women.

Vaccine Studied: Fort Detrick formulation

Study Design: Randomized, placebo-controlled trial of anthrax vaccine among mill workers in New Hampshire and Pennsylvania who processed raw imported goat hair.

Findings: "The typical reaction was mild and did not cause any interruption of work."

(a) Injection-site ("local") Reactions:

Mild local reactions, consisting of 1 to 2 cm of redness, plus slight local tenderness, occurred in ~ 30% of recipients within 24 hours after vaccination. Itching was noted less commonly. "In general, all signs and symptoms disappeared within the next 24 to 48 hours. In many of the cases, this minimal degree of local reaction would not have been noticed by the inoculee had not his arm been examined at 24 and 48 hours after inoculation."

Moderate local inflammation (a defensive reaction to irritation) (> 5 cm in diameter), occurred in 4% of recipients.

Large local reactions occurred less frequently and consisted of extensive swelling of the forearm, in addition to local inflammation. "Three individuals experienced edema extending from the deltoid to the mid-forearm and, in one case, to the wrist, with a definite collection of fluid in the bursa of the elbow. This extensive edema disappeared within three to five days."

(b) Events Beyond the Injection Site ("systemic"): Brachman, et al., did not differentiate between nonserious and serious events. Systemic events occurred in fewer than two per thousand (< 0.2%) recipients, including "...two individuals who experienced, along with the edema-producing local reactions, some malaise of 24 hours'duration."Even less frequently, fever and chills were noted.

(c) Events or effects by gender: Brachman, et al., did not differentiate between men and women in describing adverse events.

(d) Length of time to resolution: Brachman reported no adverse events persisting beyond five days, except that A few inoculees developed small, firm, painless nodules at the site of injections which persisted for several weeks."They also noted "Half of these edema-producing reactions were maximum at 24 hours, and the remainder at 48 hours."

B. The CDC Observational Study

Citation: FDA Panel on Review of Bacterial Vaccines & Toxoids: Food & Drug Administration. Biological products; Bacterial vaccines and toxoids; Implementation of efficacy review. *Federal Register 1985;* volume 50: pages 51002-I 17. http://www.anthrax.osd.mil/Site_Files/articles/Indexclinical/Fed_register.htm

Investigators: Data collected under DBS-IND#180 by the Center for Disease Control (CDC), Atlanta. Data submitted to the National Institute of Health (NIH) Division of Biologics Standardization (DBS) to support the license application for anthrax vaccine. NIH granted this license in 1970. In 1972, responsibility for vaccine regulation migrated from NIH to the Food & Drug Administration (FDA).

Period of Observation: 1962 to 1972

Participants: about 7,000 people, gender unspecified, involving about 16,000 doses of anthrax vaccine. At least 227 of these people received 10 or more annual booster doses.

Vaccine Studied Mixture of people receiving the Fort Detrick formulation and the Lansing formulation

Study Design: Observational study assessing use of vaccine in industrial high-risk settings. Side-effect data was collected on vaccinees, but not on any control subjects. At the same time, CDC collected and analyzed reports of cases of anthrax disease from around the United States (which recorded 24 cases of anthrax in unvaccinated people, but no cases in vaccinated people).

Findings: "Local reactions are typically mild.... Only a few systemic reactions with marked chills and fever have been recorded. All reactions reported have been self-limited." "Severe local reactions and systemic reactions are relatively rare."

(a) Injection-site ("local") Reactions:
Mild local reactions ($\leq$ 3 cm) were reported after 3% to 20% of doses administered.
Moderate reactions ($>$ 3 cm to $<$ 12 cm) were reported after 1% to 3% of doses.
Large reactions ($\geq$ 12 cm) were reported after fewer than 1% of doses.

(b) Events Beyond the Injection Site ("systemic"): Report authors did not differentiate between nonserious and serious events. Systemic reactions, reported in four individuals (fewer than 6 per 10,000 doses), consisted of fever, chills, nausea and general body aches, which resolved spontaneously.

(c) Events or effects by gender: Report authors did not differentiate between men and women in describing adverse events.

(d) Length of time to resolution: Authors did not report persistent adverse events.

C. Fort Detrick Multi-Dose, Multi-Vaccine Safety Studies

Citation: Richard N. Peeler, Leighton E. Cluff, Robert W. Trever. Hyper-immunization of man. *Bulletin of the Johns Hopkins Hospital 1958;* volume 103: pages 183-98.
Investigators: Scientists at the Johns Hopkins University (Baltimore)
Period of Observation: 1944 to 1956 (mean: 10.4 years)
Participants: 99 men (range: *28* to *65* years old, mean: 40.1 years), 0 women, 99 people total, recipients of multiple immunizations against anthrax, botulism, brucellosis, diphtheria, Eastern equine encephalitis, influenza, plague, poliomyelitis, psittacosis, Q fever, Rift Valley fever, Rocky Mountain spotted fever, smallpox, tetanus, tularemia, typhus, Venezuelan equine encephalitis, Western equine encephalitis, and yellow fever, totaling 36 to 74 milliliters of vaccines, plus multiple skin tests to detect hypersensitivity to microbial antigens. [For comparison, note that the six doses of anthrax vaccine in the primary series total 3 ml.]

* * *

Citation: Richard N. Peeler, Paul J. Kaduli, Leighton E. Cluff. intensive immunization of man: Evaluation of possible adverse consequences. *Annals of Internal Medicine* 1965; volume 63: pages 44-57.
http://www.anthrax.osd.mil/Site_Files/articles/INDEXclinical/anthraxlibrary/Intensive.pdf.
Investigators: Scientists at the Johns Hopkins University (Baltimore)
Period of Observation: 1944 to 1962 (mean: 15.3 years)
Participants: 76 men (subset of 99 reported above), who received 42 to 102 ml of vaccines (mean: 74 ml)

* * *

Citation: Charles S. White III, William H. Adler, Virginia G. McGann. Repeated immunization: Possible adverse effects: Reevaluation of human subjects at 25 years. *Annals of Internal Medicine* 1974; volume 81: pages 594-600.
http://www.anthrax.osd.mil/Site_Files/articles/INDEXclinical/anthraxlibrary/Repeated.pdf.
Investigators: Scientists at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, Maryland
Period of Observation: 1944 to 1971
Participants: 97 men (subset of 99 reported above), who received 52 to 134 ml of vaccines (mean: 97 ml), plus 6 to 93 skin tests (mean: 55), compared to 26 age- and gender-matched, unvaccinated control subjects
Vaccine Studied: Mixture of people receiving the Fort Detrick formulation and the Lansing formulation

Study Design: Cohort study, occupational setting. The third study included a small control group.
Findings: While there were some minor elevations in liver and kidney function tests and white blood cell counts in these men, none of these men developed any unusual diseases or unexplained symptoms that could be attributed to the repeated doses of multiple vaccines.
(a) Injection-site ("local") Reactions: Not the subject of these studies.
(b) Events Beyond the Injection Site ("systemic"): Several laboratory abnormalities were noted (including elevated white blood cell counts and elevated liver function tests). Many of these abnormalities were transient and not detected in the 1974 study.

"It is of prime significance that long-term follow-up examination of these intensively immunized men failed to demonstrate any evidence of illness attributable to the immunizations. There is no indication that intensive immunization interfered with the ability to produce adequate antibody titers after antigenic challenge."

The 1974 study concluded, "These data and the accompanying evaluation of an intensively immunized population provide evidence that no obvious adverse effects result from repeated immunization. .. Thus, this group provides reassurance that schedules for routine immunization with a diversity of vaccines should not produce untoward effects merely because of frequency of inoculation."

(c) Events or effects by gender: Not applicable.

(d) Length of time to resolution: Not applicable, long-term health effects sought but no hazard found.

D. Fort Detrick Special Immunization Program (SIP) Safety Study

Citation: Pittman PR, Gibbs PH, Cannon TL, Friedlander AM. Anthrax vaccine: Short-term safety experience in humans. Full manuscript accepted by *Vaccine*, estimated publication late 2001.

Investigators: Scientists at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, Maryland

Period of Observation: 1973 to 1999

Participants: 1,249 men, *334* women, *1,583* people total, who received 10,722 doses of anthrax vaccine from 32 separate vaccine lots, assessed at the USAMRIID Special Immunizations Clinic (its occupational-health clinic). Of this group, 273 people received 10 or more doses of anthrax vaccine, and 46 people received 20 or more doses.

Vaccine Studied: Lansing formulation

Study Design: Cohort study of repeatedly vaccinated laboratory workers, with data based on visits to an occupational health clinic (the USAMRIID Special Immunizations Clinic).

Findings: All local and systemic events resolved without extended time lost from work, hospitalization or long-term effects. These employees continue to be examined and tested annually for medical conditions since their last visit, yet no diseases or unexplained symptoms have been observed that would not be expected in an unvaccinated group of comparable age and other demographic characteristics.

(a) Injection-site ("local") Reactions: 3.6% of doses resulted in a local reaction consisting of redness, induration (an area of hardened tissue), itching, and soft or puffy swelling (edema) at the injection site. The most common were erythema and/or induration (3.2%). Most people who reacted to a dose of anthrax vaccine received subsequent doses without problems. But people who reported an injection-site reaction were more likely to report a local reaction to a later dose. Injection-site reactions were grouped into three categories: < 5 cm (2"), 5 to 12 cm (2 to 5"), and > 12 cm (5").

(b) Events Beyond the Injection Site ("systemic"): Systemic reactions of headache, fever, chills, malaise (discomfort, uneasiness), muscle or joint aches occurred after 1 per 100 doses. The most common of these were headache (0.4%), malaise (0.4%), and fever (0.1%). One hundred systemic events noted above were classified as nonserious.

One serious systemic event was reported in this study, a woman who developed multiple sclerosis. [Background: About 10,000 people are diagnosed with multiple sclerosis each year in the United States.] Her case resolved in 6 weeks and she returned to duty, without recurrence of her disease. All other systemic events resolved without extensive time lost from work, hospitalization or long-term effects.

(c) Events or effects by gender: Women noted both local (i.e., erythema, induration, edema, swollen lymph nodes, lumps) and systemic events (i.e., headache, fever, dizziness, hives) more commonly than men. Women reported more injection-site reactions for each of the magnitude categories. Adverse events were reported by 0.1% *to* 2% of men and 0.1% to 6% of women. People < 40 years old reported adverse events more often than those 40 years or older.

(d) Length of time to resolution: All local and nonserious systemic events resolved without extensive time lost from work, hospitalization or long-term effects.

Group II: Studies from the 1990s, Data Collection by Survey

E. Fort Bragg Booster Study

Citation: Pittman PR, Hack D, Mangiafico J, Gibbs P, McKee KT Jr., Eitzen EM, Friedlander AM, Sjogren MH. Antibody response to a delayed booster dose of anthrax vaccine and botulinum toxoid. Manuscript at journal, undergoing peer review.

Investigators: Scientists at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, Maryland

Period of Observation: 1992 to 1994

Participants: 495 men, 0 women, 495 people total, U.S. Army special mission soldiers at Fort Bragg, North Carolina

Vaccine Studied: Lansing formulation

Study Design: USAMRIID investigators actively assessed the safety of booster doses of anthrax vaccine, given to soldiers previously vaccinated against anthrax and botulism during the Persian Gulf War of 1990-91. All 495 were assessed for vaccine safety; 279 were assessed for immunogenicity. Some received an anthrax vaccine booster alone, although most received booster doses of both anthrax vaccine and botulinum toxoid.

Findings: No adverse event caused lost time from work or hospitalization and all reactions resolved without lasting consequences.

(a) Injection-site ('local') Reactions:

None: Of these soldiers, 67% to 74% reported no redness or swelling.

Mild: 16% to 28% had local redness and/or swelling in the arm where the booster vaccination was administered, less than 5 cm in diameter.

Moderate: In 4.7% to 9.3%, the redness and/or swelling was $\geq$ 5 cm.

Large: Three soldiers (0.6%) developed redness or swelling > 12 cm in diameter.

(b) Events Beyond the Injection Site ('systemic'): One or more systemic reactions occurred in 26% to 45% of recipients during the first 30 days after vaccination, most commonly muscle aches (23% to 31%), fever (8% to 20%), malaise (7% to 17%), headache (9% to 17%), rash (0% to 17%), or joint aches (7% to 13%). We should note that these troops were engaged in a field exercise at the time of this study. Therefore, the role of the anthrax vaccination cannot reasonably be separated from the rigorous physical exertion commonly associated with field deployments.

(c) Events or effects by gender: Not evaluable.

(d) Length of time to resolution: No adverse event caused lost time from work or hospitalization and all reactions resolved without lasting consequences.

F. USAMRIID Dose-Reduction / Route-Change Study

Citation: Technical report provided to the Food & Drug Administration.
Pittman PR, Kim-Ahn G, Pifat DY, Coonan K, Gibbs P, Little S, Pace-Templeton JG, Myers R, Parker GW, Friedlander AM. Anthrax vaccine: Safety and immunogenicity of a dose-reduction, route comparison study in humans. Full manuscript accepted by *Vaccine,* estimated publication late 2001.

Investigators: Scientists at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, Maryland

Period of Observation: 1998 (enlarged study in planning, coordinated by the CDC)

Participants: 109 men, 64 women, 173 people total

Vaccine Studied: Lansing formulation

Study Design: USAMRIID actively collected safety data during a pilot study to evaluate a reduced schedule for administering the anthrax vaccine. The safety of anthrax vaccination was studied in three cohorts of people: (1) some got the standard schedule of the first three doses (0, 2, 4 weeks) into the subcutaneous layer ½" under the skin, (2) others received two doses given subcutaneously, (3) a third cohort received two injections into the muscle in the upper arm, about 1" below the surface. All these volunteers gave informed consent for the procedure.

Findings: This study provides evidence that local adverse events are less common when the intramuscular route is used to administer anthrax vaccine, compared to the subcutaneous route.

(a) Injection-site ("local") Reactions: Redness and swelling at the injection site occurred more commonly among those given subcutaneous injections, compared to intramuscular injections. Male vaccine recipients developed injection-site swelling (induration) less frequently after subcutaneous injection (3% to 19%) than female vaccine recipients (38% to 75%), but the rates were comparably low for both genders when the vaccine was given by intramuscular injection (1.4% to 2.2%). Subcutaneous nodules, which resolved spontaneously, were common among recipients of subcutaneous injections (24% of men, 63% of women), but were not observed among recipients of intramuscular injections (0% for both men and women).

(b) Events Beyond the Injection Site ("systemic"): Systemic adverse events were uncommon and their incidence did not differ among the three cohorts. After the first three doses, the side effects noted were headache (7% to 17%); malaise (4% to 10%); loss of appetite (0% to 9%); nausea or vomiting (2% to 6%); muscle ache (2% to 7%); itching (0% to 3%) and low grade fever (0% to 3%). All of these reactions were graded as nonserious; none were serious events.

(c) Events or effects by gender: Male vaccine recipients developed injection-site swelling (induration) less frequently after subcutaneous injection (3% to 19%) than female vaccine recipients (38% to 75%), but the rates were comparably low for both genders when the vaccine was given by intramuscular injection (1.4% to 2.2%). Subcutaneous nodules, which resolved spontaneously, were common among recipients of subcutaneous injections (24% of men, 63% of women), but were not observed among recipients of intramuscular injections (0% for both men and women).

(d) Length of time to resolution: Not specifically described, but temporary duration was common, as in other studies.

G. Canadian Forces Safety Survey

Citation: Canadian Forces Medical Group. Letter from Assistant Chief of Staff Operations to Canadian Clinical Trials and Special Access Programme, 15 October 1999.
Investigators: Canadian military physicians, Canadian Forces Medical Group, Ottawa
Period of Observation: February to May 1998
Participants: 576 people total, gender unspecified, members of three Canadian Forces units deployed to the Persian Gulf during Operation Determination who received 1,676 doses of anthrax vaccine (1, 2, or 3 doses per person)
Vaccine Studied. Lansing formulation

Study Design: Actively monitored study of adverse events after anthrax vaccination.
Findings:

(a) Injection-site ("local") Reactions:
Mild (1 to 5 cm): after 4.4% of doses, reported by 12.7% of recipients
Moderate (> 5 to 12 cm): after 0.2% of doses, reported by 0.5% of recipients
Large: none reported

(b) Events Beyond the Injection Site ("systemic"): Systemic reactions occurred after 2.2% of doses, reported by 5.7% of recipients. Reported systemic events included headache (13 reports), flu-like gastrointestinal symptoms (9), fever with or without chills (5), foul taste in mouth (3), and neurologic symptom (1, temporary, not considered serious). Two individuals reported heartburn after each of three vaccine doses. . One individual reported a persistent lump (nodule) at the injection site and multiple nodules at several distant sites, but it is unknown whether those lumps existed unnoticed before the vaccination. One medical officer noted several cases of fever and chills, with or without malaise; in all cases these events resolved within 2 to 5 days.

(c) Events or effects by gender: Not described

(d) Length of time to resolution: In all cases except the persistent nodule, these events resolved within 2 to 5 days.

H. TAMC-601 Survey

Citation: Centers for Disease Control & Prevention. Surveillance for adverse events associated with anthrax vaccination - U.S. Department of Defense, 1998-2000. *Morbidity & Mortality Weekly Report* 2000;49(Apr 28):341-5. Reprinted in *JAMA* 2000;283:2648-9. http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/mm4916a1.htm.

Wasserman GM, Pittman PR, Grabenstein JD, Rubertone MV, and colleagues. Analysis of adverse events after anthrax vaccination in US Army medical personnel. Full manuscript for publication nearing completion.

Investigators: Preventive Medicine Division, Tripler Army Medical Center (TAMC), Honolulu, Hawaii

Period of Observation: 1998 to *2000*

Participants: 416 men, 185 women, *601* people total; physicians, nurses, medics and other medical-support personnel who augment U.S. medical forces in Korea in military contingencies. Mean age 29.9 years.

Vaccine Studied. Lansing formulation

Study Design: Prospective, population-based, self-reported survey. The people surveyed are a highly educated, medically experienced population, more able than the norm to describe adverse events and with more ready access to care than other populations.

Findings: Regardless of gender, most adverse events after vaccination were mild and self-limited. The results for all systemic complaints did not substantially vary between dose #1, dose #2, dose #3, and dose #4.

(a) Injection-site ('local') Reactions:

Mild, redness < 5 cm (35% to 40%). Women reported more localized itching (39% to 63%), compared to men (25% to 28%). Women developed more subcutaneous nodules (73% to 90%), compared to men (61% to 66%).

Moderate, redness 5 to 10 cm (20% to 25%).

Large, redness >10 cm (5% to 10%). Moderate to large injection-site reactions were more common among women (40% to 51%) than among men (17% to 32%). Women reported more swelling of the lower arm (8% to 14%), compared to men (7% to 10%)

(b) Events Beyond the Injection Site ('systemic'): Women reported muscle soreness more often (62% to 80%), compared to men (60% to 67%). About 20% of men and women reported symptoms that they personally judged could be ignored; 15% reported symptoms that affected their activity for a short time but did not limit their ability to perform duties; 8% reported symptoms that affected their activity for a short time that was relieved by self-treatment with nonprescription medication; and fewer than 2% reported that their symptoms were unrelieved by medication and that their ability to perform their duties was limited for a short time. From 1.5% to 2.7% of women and 1.2% to 2.1% of men reported systemic events leading to limitation of performing duties.

(c) Events or effects by gender: Individual injection-site and systemic events occurred more frequently among women than men, but events in both genders were similar in resolving on their own over the course of a few days without residual consequences. Between 4% and 14% of women had an outpatient medical visit, compared to 2% to 5% of men. From 4% to 12% of women and 2% to 6% of men reported they could not perform a duty for a short period after vaccination.

(d) Length of time to resolution: Muscle aches typically lasted between 7 hours and 3 days.

I. U.S. Forces Korea Vaccination Series

Citation: Centers for Disease Control & Prevention. Surveillance for adverse events associated with anthrax vaccination - U.S. Department of Defense, 1998-2000. *Morbidity & Mortality Weekly Report (MMWR)* 2000;49(Apr 28):341-5. Reprinted in *JAMA* 2000;283:2648-9. http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/mm4916a1.htm.

Hoffman K, Costello C, Menich M, Grabenstein JD, Oaks H, Engler RJM. Using a patient-centered structured medical note for aggregate analysis: Determining the safety profile of anthrax vaccine at a mass immunization site. Manuscript at journal, undergoing peer review.

Investigators: Department of Preventive Medicine, 121st General Hospital, Seoul, Republic of Korea

Period of Observation: 1998 to 1999

Participants: 2,214 men, 610 women, 2,824 people total

Vaccine Studied: Lansing formulation

Study Design: Systematic recording of self-reported surveys when personnel returned for subsequent doses of anthrax vaccine.

Findings: Regardless of gender, almost all reported events were localized or minor, self-limited, and did not lead to impairment of work performance.

(a) Injection-site ("local") Reactions: Women reported lumps more frequently (50% to 62%) than did men (21% to 29%).

Mild (redness < 5 cm): Women (12% to 14%), men (7% to 8%)

Moderate (redness 5 to 12 cm): Women (11% to 13%), men (4% to 5%)

Large (redness > 12 cm): Women (2% to 4%), men (0.4% to 1%)

(b) Events Beyond the Injection Site ("systemic"): Itching was reported by 20% to 37% of women and 6% to 8% of men. Fever was reported by 2% to 4% of women and 1% of men. Chills were reported by 3% to 6% of women and 1% to 2% of men. Malaise was reported by 8% to 15% of women and 4% to 7% of men. Overall, 0% to 1.9% reported that their work activity had been limited to some extent or were placed on limited duty. From 0% to 1 .1% reported losing one or more days of duty; 0.4% to 1.7% consulted a clinic for the reaction. One individual was treated in an emergency room (analyzed under VAERS, below).

(c) Events or effects by gender: Overall, 60% to 68% of women and 32% to 40% of men reported at least one adverse event after the first or second doses of anthrax vaccine.

(d) Length of time to resolution: Almost all reported events were localized or minor, self-limited, and did not lead to impairment of work performance.

J. Reports involving Anthrax Vaccine Submitted to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS) and Evaluated by the Anthrax Vaccine Expert Committee

Citation: Centers for Disease Control & Prevention. Surveillance for adverse events associated with anthrax vaccination - US. Department of Defense, 1998-2000. *Morbidity & Mortality Weekly Report (MMWR)* 2000;49(Apr 28):341-5. Reprinted in *JAMA* 2000;283:2648-9. http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/mm4916a1.htm.

Sever JL, Brenner AI, Gale AD, Lyle JM, Moulton LH, West DJ. Safety of anthrax vaccine: A review by the Anthrax Vaccine Expert Committee (AVEC) of adverse events reported to the Vaccine Adverse Event Reporting System (VAERS). Manuscript at journal, undergoing peer review.

Investigators: Civilian medical experts convened by US Department of Health & Human Services (DHHS). Health Resources & Services Administration

Period of Observation: 1990 to present. Data collection and analysis ongoing

Participants: 1,563 vaccine recipients reflected in 1,652 VAERS reports (1,623 when duplicates are omitted), as of October 2, 2001

Vaccine Studied: Lansing formulation

Note: The most detailed information on VAERS reports is maintained by the Food & Drug Administration (FDA) *and the Centers for Disease Control & Prevention (CDC). The following analysis is based on VAERS information made available to the DoD. Questions involving more detailed analyses should be referred to DHHS.*

Study Design: DoD relays all reports (whether initiated by vaccinee, guardian, health-care provider, or any other source) of adverse events after any vaccination to VAERS. The VAERS staff seeks additional medical records, if needed, and follows subjects of these reports to gather information about symptom resolution.

At the request of DoD, the Department of Health and Human Services (HHS) established an Anthrax Vaccine Expert Committee (AVEC) in October 1998 to review VAERS forms related to anthrax vaccine. The AVEC independently reviews all anthrax vaccine-related reports received by VAERS. The AVEC meets every 3 to 6 weeks, along with representatives of DoD, CDC, FDA, and HHS, to review all the new anthrax adverse events reports submitted in the interim. The AVEC reviews the quality of the submitted information, evaluates the reported event in the context of expected and unexpected adverse events to vaccines, and assesses the cause-and-effect relationship of the event with the anthrax vaccine. The AVEC also looks for any clinically significant patterns in the aggregate data.

Findings: To date, the AVEC reports that it has found nothing unexpected in the side-effect profile of anthrax vaccine. The chairman of the AVEC stated, "Based on the review of these adverse events, it is apparent that it is safe to continue the anthrax vaccine immunization program of the Department of Defense and it is appropriate to continue to monitor the vaccine adverse events reports and review the safety of the vaccine on an ongoing basis."

As of October 2, 2001, the independent AVEC reviewed 1,623 unique VAERS reports related to anthrax vaccination. The 1,623 reports were grouped into three main categories, based on effect on the vaccine recipient's functional status: hospitalization, loss of duty $\geq$ 24 hours, and other (reports involving neither hospitalization nor loss of duty $\geq$ 24 hours).

Fifty-seven of the 1,623 reports involved hospitalization. The civilian panel found that 10 of the 57 "very likely/certainly" or "probably" were caused by anthrax vaccine. All ten involved allergic, inflammation reactions at the injection site.

For background, the other 47 hospitalizations (those not categorized as "very likely/certainly" or "probably" caused by anthrax) vaccine involved the following diagnoses (update needed):

Abdominal pain (1-"unclassifiable" according to AVEC)
Acute encephalitis (1 -"unrelated")
Angioedema (1 -"unrelated")
Aplastic Anemia (1- "unclassifiable")
Atrial fibrillation (1 -"unlikely," 1-"unclassifiable")
B-cell lymphoma involving CNS (1 -"unrelated")
Bipolar psychiatric disorder (1--"unclassifiable," 1-"unrelated")
Blackout episode (1 -"unrelated")
Cardiac arrest (1-"unrelated")
Cardiomyopathy with atrial fibrillation (1-"unlikely," 1-"unrelated")
Diabetes mellitus, insulin-requiring (1-"unclassifiable")
Diabetes mellitus, non-insulin-requiring (1-"unrelated")
Dysesthesias (T1 and below) (1 -"unclassifiable")
Dyspnea (2-"unclassifiable")
Endocarditis with perirectal abscess (1-"unrelated")
Fatigue and injection-site inflammation (1-"possible")
Febrile illness (1 -"unrelated")
Guillain-Barre syndrome (GBS, 3-"unclassifiable," 2-"unrelated")
Idiopathic thrombocytopenic purpura (ITP, 1-"unclassifiable")
inflammation over olecranon process (1-"unrelated")
Liver abscess with *E. coli* septicemia (1-"unrelated")
Intestinal surgery (appendectomy) (1 -"unrelated")
Meningitis, aseptic (1-"unrelated")
Meningitis, viral (1-"unclassifiable")
Meningitis, unspecified (1-"unrelated")
Multiple sclerosis (1-"unlikely")
Neurological symptoms (facial weakness, slurred speech) (1-"unlikely")
Neutropenia, fever (2-"unclassifiable")
Pemphigus vulgaris (1-"unlikely")
Progressive paralytic neurologic disease (1-"unlikely")
Rash (1 -"possible")
Scleritis bilaterally (1 -"unrelated")
Seizure (1 -"unrelated")
Syncope (1 -"unrelated")
Systemic lupus erythematosus (1-"unlikely")
Toxic epidermal necrolysis syndrome (1 -"unrelated")
Viral-like syndrome (2-"unrelated")

Another 161 reports involved loss of duty $\geq$ 24 hours (but did not involve hospitalization); the civilian panel found that 89 of the 161 certainly or probably were caused by anthrax vaccine. These 89 reports described injection-site reactions (52 reports), various rashes (9), acute allergic reactions (9), viral-like symptoms (9), itching (2), gastroenteritis (2), muscle aches (2), bronchiolitis obliterans (1), tingling sensation (1), photophobia (1), and swollen lymph nodes (1). Some reports described multiple symptoms.

The balance of the 1,623 reports, 1,405, involved neither hospitalization nor loss of duty $\geq$ 24 hours. All were reviewed by the AVEC, which found no patterns of unexpected adverse events.

* * *

Separate analyses performed by the Anthrax Vaccine Immunization Program (AVIP) Agency indicate there has been no clinically meaningful correlation between anthrax vaccine and reports of adverse events involving hospitalization (all 57 reports) or loss of duty $\geq$ 24 hours (all 161 reports) based on (a) geographic clustering, (b) vaccine lot (manufacturing batch), or (c) Active- vs. Reserve Component status.

No VAERS reports have been submitted regarding microbial contamination of vaccine vials.

(c) Events or effects by gender: A separate analysis performed by the Anthrax Vaccine Immunization Program (AVIP) Agency indicate that there has been no correlation between anthrax vaccine and reports of adverse events involving hospitalization (for any cause, not just reports judged by the AVEC to be caused by the vaccine), based on gender.

(d) Length of time to resolution: Based on information available to the Anthrax Vaccine Immunization Program (AVIP) Agency (some of which includes records with information redacted by the FDA), all personnel described by VAERS reports judged by the AVEC to be "very likely/certainly" or "probably" caused by anthrax vaccine have recovered or are recovering.

K. ROTC Cadets at Fort Lewis, Washington

Citation: Gunzenhauser JD, Cook JE, Parker ME. Acute side effects of anthrax vaccine in ROTC cadets participating in advanced camp, Fort Lewis, 2000. *Medical Surveillance Monthly Report* 2001;7(5):9-11. http://amsa.army.mil/1MSMR/2001/v07_n05.pdf.

Investigators: Preventive Medicine Service, Madigan Army Medical Center, Fort Lewis, Washington

Period of Study: Summer 2000

Participants: 73 cadets attending Advance Camp for the Reserve Officer Training Corps (ROTC) with orders for follow-on training in Korea.

Vaccine Studied: Lansing formulation

Study Design: 25 cadets who inadvertently received a 1 -ml dose of anthrax vaccine for their first dose were contrasted with 48 cadets who received the proper 0.5-ml volume.

Findings:

(a) Injection-site ('local') Reactions: The most common symptom was sore arm, reported by 67% of cadets, regardless of first dose received. The next three most common symptoms occurred more commonly in the double-dose group: redness-39% vs. 19%, lump-44% vs. 29%, swelling-50% vs. 19%.

(b) Events Beyond the Injection Site ('systemic'): Of nine specific symptoms queried, similar proportions of double- and standard-dose cadets reported one or more symptoms. However, 44% of double-dose and 26% of standard-dose cadets reported three or more symptoms. Seventeen percent of double-dose cadets and 7% of standard-dose cadets reported decreased performance after the second anthrax vaccination. One cadet who received a doubled first dose attended sick call with a chief complaint of feeling feverish and was returned to duty. There were no hospitalizations, ER visits, or missed training related to vaccination.

(c) Events or effects by gender: Not analyzed by gender.

(d) Length of time to resolution: All reactions to the vaccine were mild and self-limited. None affected cadet training.

M. Fort Stewart, Georgia, Reproductive Health Study

Citation: Wiesen AR, Littell CT. Relationship between anthrax vaccination and pregnancy, birth, and adverse birth outcome among women in active service with the US Army. Manuscript at journal, undergoing peer review.

Investigators: Department of Preventive Medicine, Winn Army/Community Hospital, 3rd infantry Division, Fort Stewart and Hunter Army Air Field, Georgia

Period of Study: January 2000 to March 2001

Participants: All 4,092 active-duty women aged 17 to 44 years old, assigned to either Fort Stewart and Hunter Army Air Field

Vaccine Studied: Lansing formulation

Study Design: Cohort study of all active-duty women, 17 to 44 years old, assigned to either Fort Stewart and Hunter Army Air Field, evaluating likelihood and outcomes of pregnancy, contrasting 3,136 women vaccinated against anthrax and 962 unvaccinated women.

Findings:

(a) Conception: 384 of the 3,136 vaccinated women became pregnant, compared to 129 of 962 unvaccinated women, statistically equivalent proportions.

(b) Giving Birth: 276 births resulted from 381 vaccinated women followed to term, compared to 77 births resulting from 101 unvaccinated women followed to term, statistically equivalent proportions.

(c) Birth Defects: The adjusted odds ratio for low birth weight and vaccination was 1.3 (95% confidence interval 0.2, 6.4), meaning no statistically significant elevation. The adjusted odds ratio for structural abnormalities of cosmetic or surgical significance and vaccination was 0.7 (95% confidence interval 0.2, 2.3), meaning no statistically significant elevation. The adjusted odds ratio for *any* adverse birth outcome and vaccination was 1.2 (95% confidence interval 0.5, 2.9), meaning no statistically significant elevation.

(d) Length of time to resolution: Not applicable, long-term health effects sought but no hazard found.

Group III: Studies from the 1990s, Database Analyses

L. USAF Air Combat Command Study, Langley Air Force Base

Citation: Rehme PA, Williams R, Grabenstein JD. Ambulatory medical visits among anthrax vaccinated and unvaccinated personnel after return from southwest Asia. Manuscript at journal, undergoing peer review.

Investigators: USAF Air Combat Command, 1st Aerospace Medicine Squadron, Langley AFB, Virginia

Period of Observation: 1998 to 1999

Participants: 3,390 vaccinated men, 655 vaccinated women, *4,045* total vaccinated personnel; compared to 962 unvaccinated men, 170 unvaccinated women, 1,132 total unvaccinated personnel, 5,177 people total, USAF personnel deployed to Southwest Asia between January and September 1998

Vaccine Studied: Lansing formulation

Study Design: Electronic records of anthrax vaccination were linked with electronic records of ambulatory medical visits among vaccinated and unvaccinated personnel who had returned from Southwest Asia in the previous 6 months.

Findings: No statistically significant associations between anthrax vaccination and any ambulatory diagnosis were found. These diagnoses included allergy, arthropathy, circulatory, dermatological, digestive, endocrine, headache/neurological, hearing, infectious/parasitic, injuries, mental health, musculoskeletal, nasal, neoplastic, ocular, reproductive, respiratory, sleep disorders, urinary, unexplained illness, or more than one diagnosis. In addition, vaccination status did not cause any statistically significant elevation in ambulatory visits for 16 specific diagnoses (e.g., autoimmune disease, thyroid disorder, infertility, dizziness/syncope, tinnitus).

(a) Injection-site ("local") Reactions: Not applicable.

(b) Events Beyond the Injection Site ('systemic'): No effects observed.

(c) Events or effects by gender: No difference in findings when men and women are considered separately. No gender effects observed.

(d) Length of time to resolution: Not applicable, no hazard found.

N. Reproductive Outcomes of the Wives of Male Soldiers Vaccinated Against Anthrax (Preliminary Report)

Citation: None yet, report in progress. Wojcik B, Abbott CA. Reproductive health outcomes in spouses and neonates of anthrax-vaccinated male soldiers.

Investigators: Center for Health Education & Studies, Army Medical Department Center & School

Period of Study January 1998 to August 2000

Participants: 237,022 active-duty Army male soldiers married to civilian women, contrasting 68,267 wives of anthrax-vaccinated men and 168,755 wives of anthrax-unvaccinated men. Pregnancy-related hospitalizations occurred as follows: 5,153 women hospitalized with 17,909 diagnoses in the vaccinated group and 28,117 women hospitalized with 89,108 diagnoses in the unvaccinated group. Further analysis evaluated 4,425 deliveries to wives of anthrax-vaccinated men and 22,802 deliveries to wives of anthrax-unvaccinated men.

Vaccine Studied: Lansing formulation

Study Design: Electronic records of anthrax vaccination were linked with electronic personnel records and electronic medical records of obstetric and gynecologic outpatient visits and hospitalizations. First, cohorts of anthrax-vaccinated and unvaccinated men were defined. From these cohorts, a smaller secondary set of cohorts of their wives was defined. Paternity of the husband for the offspring was assumed.

Findings:

(a) Rates of various hospitalizations did not differ significantly between the wives of anthrax-vaccinated men and the wives of anthrax-unvaccinated men.

Condition (ICD-9 code)	Fraction of Wives, Vaccinated Group	Fraction of Wives, Unvaccinated Group	Statistical Finding
Menstrual disorders (626)	0.8%	0.6%	p=0.09
Infertility (628)	0.2%	0.2%	p=0.55
Ectopic pregnancy (630-633)'	0.7%	0.6%	p=0.16
Complications of labor (660-69)	28.5%	28.2%	p=0.50
Normal pregnancy (V22)	0.2%	0.2%	p=0.13
High-risk pregnancy (V23)	0.8%	0.9%	p=0.37

(b) Outcomes of delivery did not differ significantly between the wives of anthrax-vaccinated men and the wives of anthrax-unvaccinated men.

Birth Outcome	Deliveries Among Vaccinated Group	Deliveries Among Unvaccinated Grp	Statistical Finding
Single live born	98.8%	98.4%	p=0.21
Single stillborn	0.3%	0.5%	
Twins, both live born	0.9%	1.1%	
Twins, both stillborn	0.0% (n=0)	0.0% (n=5)	
Length of stay $\geq$ 4 d	8.0%	8.4%	

(c) Length of time to resolution: Not applicable, long-term health effects sought but no hazard found.

0. USAF Vision Study

Citation: Gibson RL, Hinten SR. Study of the effects of anthrax immunization on vision. Institute for Environment, Safety, & Occupational Health Risk Analysis, Brooks Air Force Base, Texas. Full manuscript for publication nearing completion.

Investigators: Force Health Protection and Surveillance Division, Institute for Environment, Safety, & Occupational Health Risk Analysis (IERA/RSRH). Personnel were seen by Aeromedical Consult Service, United States Air Force School of Aerospace Medicine.

PHASE I

Period of Observation: 1998 to 1999

Participants: 178 case subjects with vision change (161 men and 17 women) and 1,803 control subjects without vision change (1,744 men and 59 women), 1,981 people total, USAF aircrew members, deployed worldwide

Vaccine Studied: Lansing formulation

Study Design: Aviators who suffered a change in vision sufficient to jeopardize flying status were enrolled as cases, with ten age-matched controls identified from automated records of physical examinations. Next, the vaccination status of cases and controls were determined from the anthrax vaccination database.

Findings: Seventeen of 95 cases (18%) had received at least one dose of anthrax vaccine, compared to 451 of 1,060 control aviators (43%). The resulting odds ratio of 0.30 (95% confidence interval: 0.18 to 0.52) provides evidence that vaccination is not associated with vision change. Technically, the value less than one (with a confidence interval that excludes one) implies that vaccination is protective against vision change, but such a phenomenon is not biologically plausible.

(a) Injection-site ("local") Reactions: Not applicable.

(b) Events Beyond the Injection Site ("systemic"): Vaccination is not associated with vision change.

(c) Events or effects by gender: Not applicable, no effect observed.

(d) Length of time to resolution: Not applicable, long-term health effects sought but no hazard found.

PHASE II

Period of Observation: 1998 to 1999

Participants: 448 case subjects with vision change and 510 control subjects without vision change, 958 people total, USAF aircrew members, deployed worldwide

Vaccine Studied: Lansing formulation

Study Design: Medical records with pairs of physical examination data were collected that recorded changes in visual acuity. Next, the vaccination status of cases and controls were determined from the anthrax vaccination database.

Findings: 109 of 448 aviators (24.4%) with visual acuity change had been vaccinated against anthrax, compared to 134 of 510 (26.3%) of aviators without visual acuity change. The resulting odds ratio of 0.90 (95% confidence interval: 0.68 to 1.20) provides evidence that there is no association between anthrax vaccination and changes in visual acuity.

(a) Injection-site ("local") Reactions: Not applicable.

(b) Events Beyond the Injection Site ("systemic"): Vaccination is not associated with vision change.

(c) Events or effects by gender: Not applicable, no effect observed.

(d) Length of time to resolution: Not applicable, long-term health effects sought but no hazard found.

P. Army Aviator Flight Physical Examination Study

Citation: Mason KT, Grabenstein JD, McCracken LR. Hearing loss after anthrax vaccination among US Army aircrew members. Manuscript at journal, undergoing peer review.
Mason KT, Grabenstein JD, McCracken LR. US Army Aviation Epidemiology Data Register: Physical findings after anthrax vaccination among US Army aircrew members. Technical report, October 2001.

Investigators: Aviation Epidemiology Data Register, US Army Aeromedical Activity, US Army Aeromedical Center, Fort Rucker, Alabama (www.rucker.amedd.army.mil)

Period of Study: 1998 to *2000*

Participants: 3,356 matched pairs of anthrax vaccinated and unvaccinated aircrew members (6,712 personnel), matched by gender, race, age, class of flying duties and service component.

Vaccine Studied: Lansing formulation

Study Design: Matched pairs were contrasted for the presence of hearing loss, defined as a > 15 decibel hearing loss in any frequency in any ear when comparing the audiology examination before and after the first anthrax vaccination date of vaccinated personnel

Findings:

(a) Among the 3,356 matched pairs, 83 pairs had a hearing loss in both the vaccinated and unvaccinated individual, whereas 2,439 pairs had no hearing loss in either the vaccinated and unvaccinated individual. In 429 pairs, the unvaccinated individual had a hearing loss, but the vaccinated person did not. In 405 pairs the converse was true: the vaccinated individual had a hearing loss, but the unvaccinated person did not. Thus, the odds ratio for hearing loss due to vaccination is 0.94 (95% confidence interval: 0.82, 1.09), meaning that anthrax vaccination is unrelated to hearing loss.

(b) Similarly, no significant elevations in the rates of the following conditions were detected in matched-pairs analysis:

weight loss or gain of 20 pounds or more
hypertension $\geq$ 140190 or began taking antihypertensive medication
abnormal change in blood pressure
abnormal hematocrit
intraocular hypertension $\geq$ 21 or began taking medication for glaucoma
stereopsis greater than 40-second arc
abnormal stereopsis
loss of vision of 1 or more Snellen lines
loss of vision of 2 or more Snellen lines
loss of vision of 3 or more Snellen lines
development of proteinuria, glycosuria, or hematuria
fasting blood sugar > 115 or diagnosis of diabetes mellitus

(d) Length of time to resolution: Not applicable, long-term health effects sought but no hazard found.

Q. Defense Medical Surveillance System (comparison of hospitalization rates for selected diagnoses before and after introduction of Anthrax Vaccine Immunization Program)

Citation: Lange JL, Lesikar SE, Brundage JF, Rubertone MV. Screening for adverse events following anthrax immunization using the Defense Medical Surveillance System. Full manuscript for publication nearing completion.

Investigators & Design: The Defense Medical Surveillance System (DMSS) is a longitudinal, relational database of personnel and demographic data, augmented with military experience and medical event data for active-duty personnel in each of the military services. The DMSS is coordinated by the Army Medical Surveillance Activity (AMSA, www.amsa.army.mil), a component of the US Army Center for Health Promotion & Preventive Medicine (USACHPPM, http://chppm-www.apgea.army.mil).

Period of Study. 1998 to 2001

Vaccine Studied: Lansing formulation

I. *TRENDS OVER TIME*

[Note: graphics available at
http://www.anthrax.osd.mil/Site_Files/articles/INDEXclinical/safety_reviews.htm*]*

The rate of hospitalization for any cause among Service Members assigned to US Forces Korea shows a steady decline since 1993, despite introduction of the hepatitis A vaccination program in 1996 and the anthrax vaccination program in 1998. These data are especially meaningful, given that all military personnel in Korea received anthrax vaccine between August 1998 and November 2000. The evidence shows that there has not been an increase in hospitalizations in a theater where all Service members were vaccinated against anthrax and all hospitalizations are recorded electronically.

The rate of death due to illness for any cause at any location among active-duty Service Members has stayed steady or declined slightly, despite introduction of a hepatitis A vaccination program in 1996 and the anthrax vaccination program in 1998.

The rates of hospitalization for diagnoses alleged to be related to anthrax vaccination (including leukemia, Guillain-Barre syndrome, erythema multiforme, thyroid disorders, multiple sclerosis, lupus erythematosus, and aortic aneurysm) are essentially unchanged since 1993, despite introduction of a hepatitis A vaccination program in 1996 and the anthrax vaccination program in 1998.

Analysis of trends over time is helpful, but not as meaningful a comparison as when the health experiences of vaccinated and unvaccinated Service Members are contrasted directly. Such analyses appear in the next section.

II. *DIRECT COMPARISONS OF VACCINATED & UNVACCINATED PEOPLE*

[Note: graphics available at
http://www.anthrax.osd.mil/Site_Files/articles/INDEXclinical/safety_reviews.htm*]*

The most scientifically powerful evidence for the safety of this vaccine comes from the Defense Medical Surveillance System, which establishes that anthrax-vaccinated and - unvaccinated personnel are hospitalized and visit outpatient clinics at basically the same rates, both overall and for each organ system of the body. For example, one per 35

anthrax-vaccinated people is hospitalized each year, compared to one per 28 unvaccinated people hospitalized per year. Anthrax-vaccinated personnel are as healthy (and as sick) as unvaccinated personnel.

Automated records of immunization and hospitalization were linked electronically. This analysis consisted of 757,540 person-years of experience in the anthrax-vaccinated group and 3,430,459 person-years experience in the anthrax-unvaccinated group. A person-year is analogous to a man-hour. Effectively, it is the experience of one person followed for one year of time. Two people followed for 6 months each also constitutes a person-year.

Rates of hospitalization for each of 14 major diagnostic categories among anthrax vaccine recipients were contrasted with Service Members (SMs) who have not received anthrax vaccine. The rate of hospitalization for each of the 14 major diagnostic categories was the same for SMs vaccinated or unvaccinated against anthrax. These categories include Blood and Blood Formation, Circulatory, Digestive, Endocrine / Immunology / Metabolic, Genitourinary-Female, Genitourinary-Male, Infectious Disease, Mental Health, Musculoskeletal / Connective Tissue, Neoplasms, Nervous System, Respiratory, Skin, Injury or Poisoning, and Ill-Defined Conditions.

The accompanying table shows the rate of hospitalization for each category per 100,000 Service Members per year, differentiating people vaccinated or unvaccinated against anthrax. The next column shows the ratio (the unadjusted ratio) of these two rates. If the rates between two groups are the same, the ratio is one.

The column labeled "adjusted ratio" uses the standard statistical method known as regression to remove the effects of age, gender, rank, deployment, service, ethnicity, previous hospitalization, calendar year, and occupation. Statistical adjustment simplifies the comparison to just the effect of the vaccine, holding other effects constant, providing an apples-to-apples comparison. The adjusted ratio is a more specific measure of the relationship between anthrax vaccination and hospitalization.

To account for the inherent variability in measures such as these, the 95% confidence interval is provided. The 95% confidence intervals (CIs) are the range of values within which the true value would lie 95% of the time, if you repeated the analysis multiple times. The 95% CIs shown are for the adjusted rate ratios. For a rate ratio to find a "statistically significant elevation," the confidence interval would have to be entirely above 1.00.

* Finding: Assessing 14 broad categories of hospitalization, rate ratios for vaccinated active-duty Service Members are comparable to SMs unvaccinated against anthrax. None of the rate ratios is elevated. The rates of hospitalization are essentially the same for vaccinated and unvaccinated Service Members. [Details appear in the graphic.]

Within these 14 broad categories of hospitalization, specific diagnoses are of interest. Another accompanying table shows the rates of hospitalization for various disorders alleged to be associated with anthrax vaccination. The accompanying table shows data for lymphatic cancers (such as leukemia), thyroid disorders, multiple sclerosis, Guillain-Barre syndrome, disorders of the ear, asthma, ulcers or gastritis, joint problems (arthropathies), diffuse disorders of connective tissue (e.g., lupus erythematosus), heart rhythm, or complications of surgery or medical care not elsewhere classified. As with the major categories above, no rate ratio is elevated for vaccinated active-duty Service Members, compared to SMs unvaccinated against anthrax.

* Finding: Again, none of the rate ratios is elevated for vaccinated active-duty Service Members, compared to SMs unvaccinated against anthrax. The rates of hospitalization are essentially the same for SMs vaccinated or unvaccinated against anthrax. [Details appear in the graphic.]

Similarly, rates of outpatient medical visits (ambulatory visits) for each major diagnostic category among anthrax vaccine recipients was contrasted with Service Members (SMs) who have not received anthrax vaccine.

* Finding: None of the rate ratios is elevated for vaccinated active-duty Service Members, compared to SMs unvaccinated against anthrax. The rate of outpatient visits for each major diagnostic category was comparable for SMs vaccinated or unvaccinated against anthrax. [Details appear in the graphic.]

Again, within these broad categories of outpatient medical visits, specific diagnoses are of interest. Another accompanying table shows the rates of outpatient visits for various disorders alleged to be associated with anthrax vaccination. The accompanying table shows data for thyroiditis, hypothyroidism, multiple sclerosis, Guillain-Barre syndrome, visual disturbances, vertigo, asthma, migraine, rheumatoid arthritis, lupus erythematosus, heart rhythm, atherosclerosis, diabetes mellitus, testicular dysfunction, ulcerative colitis, erythema multiforme. As with the major categories above, none of these rate ratios is elevated for vaccinated active-duty Service Members, compared to SMs unvaccinated against anthrax.

* Finding: None of the rate ratios is elevated for vaccinated active-duty Service Members, compared to SMs unvaccinated against anthrax. The rates of outpatient medical visits are essentially the same for SMs vaccinated or unvaccinated against anthrax. [Details appear in the graphic.]

For a third analysis, only incident hospitalizations and outpatient medical visits were considered. Incident visits are defined here as the first visit for a given diagnosis, regardless of inpatient or outpatient setting. This approach removes some practice-pattern differences that exist across the wide range of military treatment facilities around the globe, as well as removing the effect of repeat visits for the same diagnosis. Incident analysis emphasizes the number of people with a diagnosis, with less focus on the number of visits they experienced. Again, for each major diagnostic category among anthrax vaccine recipients was contrasted with Service Members (SMs) who have not received anthrax vaccine.

* Finding: None of the rate ratios is elevated for vaccinated active-duty Service Members, compared to SMs unvaccinated against anthrax. The rate of incident visits for each major diagnostic category was comparable for SMs vaccinated or unvaccinated against anthrax. [Details appear in the graphic.]

Once again, within the broad categories, we analyzed the same specific diagnoses.

* Finding: As with the major categories above, none of these rate ratios is elevated for vaccinated active-duty Service Members, compared to SMs unvaccinated against anthrax. The rates of outpatient medical visits are essentially the same for SMs vaccinated or unvaccinated against anthrax.

Gender-Specific Effects: When these analytic approaches are repeated looking at men and women separately, we again find that

a. anthrax-vaccinated women are hospitalized and have outpatient medical visits at the same rates as unvaccinated women.

b. anthrax-vaccinated men are hospitalized and have outpatient medical visits at the same rates as unvaccinated men.

Group IV: Other Studies

R. Mycoplasma Study

Citation: Hart MK, DelGiudice RA, Korch GW. Absence of Mycoplasma contamination in anthrax vaccine. Full manuscript accepted by *Emerging Infectious Diseases,* estimated publication late 2001.

Investigators: US Army Medical Research Institute of infectious Diseases and National Cancer Institute.

Period of Study: 2000

Participants: Laboratory study. No human subjects. Twenty vials of anthrax vaccine from four lots retrieved from eight military clinics across the United States. The vials were divided into two matched sets and sent to both the National Cancer Institute for live mycoplasma organisms by culture in anaerobic SP-4, anaerobic DM-1, and aerobic M-CMRL media. Charles River Tektagen (Malvern, PA) tested the second set for mycoplasma DNA by polymerase chain reaction (PCR) assay.

Vaccine Studied: Lansing formulation

Study Design: Laboratory analysis of the presence of mycoplasma in anthrax vaccine, and the ability of containers of anthrax vaccine to support the growth of mycoplasma bacteria [a putative cause of illness among Gulf War veterans].

Findings:

(a) Contents of vials of anthrax vaccine were cultured in three media at several dilutions, but mycoplasma did not grow.

(b) To test the ability of mycoplasma to survive in the vaccine, 154 million colony-forming units of live *Mycoplasma fermentans* were intentionally placed into vaccine vials, mixed, incubated, and sampled 24, 48, and 72 hours later. Inactivation of mycoplasma by the preservatives in the vaccine was rapid, as no growth was detected from any of the samples taken at any time point.

(c) Testing for the presence of mycoplasma DNA produced negative results for all 10 lots evaluated.

Goal	Approach	Pros	Cons	Considerations:
Immediate Response Present -1 month	APPROACH #1: Use existing lots of vaccine under IND status	3-6 million doses available in multiple lots. Probably adequate for first responders and limited attack. Favorable scientific reviews from ACIP, AFEB, Cochrane Collaboration, Working Group on Civilian Biodefense, other independent civilian panels	Different lots produced under different conditions. Not all vaccine lots licensable. History of concern with use of this vaccine (organized antivaccine movement). Limited testing in children, pregnant women, elderly and immune suppressed populations. Pre-exposure approach requires 6 doses over 18 months for maximum response, according to the FDA-approved product labeling. Post-exposure requires at least 3 doses in conjunction	Indemnification for civilian populations remains an issue. Must address issue of secured and deployable storage. Immediate need to label lots for IND use. Target population to vaccinate must be identified. Must ascertain potential requests from allied nations. National Academy of Sciences/Institute of Medicine Committee on Safety & Efficacy of Anthrax Vaccine (the "Strom committee") nearing completion of 2-year review

			with antibiotic treatment.	
Goal	**Approach**	**Pros**	**Cons**	**Considerations:**
Immediate Response cont. Present -1 month	APPROACH #2: Expand potential list of useful antibiotics by testing: • Other quinolones • Erythomycin • Clindamycin • Extended spectrum penicillins • 0th. Macrolides • Aminoglycosides • Vancomycin	Expands clinicans' treatment options. Expands potential manufacturers/suppliers. Allows flexibility to use individually or in combination to treat possible antibiotic strains.	Most not licensed for post-or pre-exposure treatment of anthrax. For many, efficacy not established.	For those showing effect, must be tested in animal models with aerosol exposure.
	APPROACH #3: Use hyperimmune serum for adjunctive therapy of advanced anthrax disease.	Potential to neutralize toxin. Historical use and benefit. Limited supportive animal efficacy data [if true...] Limited material currently available. {is any material available????}.	None	Could only be used under IND.

Goal	Approach	Pros	Cons	Considerations:
Intermediate response 1-12 months	APPROACH #1: Expand production of AVA vaccine under contract with BioPort.	Additional stocks of licensable vaccine would be available.	Security threat of only one manufacturer.	• DoD contracted with BioPort for the entire available supply~~is under sole contract to DOD and~~. P production of AVA vaccine for civilian use would need to be negotiated in the short term, although the DoD contract permits civilian sales beyond the contracted needs of the U.S. military. • There is a finite production capacity and trained personnel through BioPort. A ~~and~~ although expansion is possible, production of AVA for the entire civilian population is not possible in the intermediate term. Product indemnification needs to be provided.
	APPROACH #2: Expand production of AVA vaccine under contract with other vaccine manufacturers.	Increased capacity to manufacture potentially licensable vaccines.	~~Manufacturers~~ Other manufacturers have no production ~~record~~ experience with this particular product.	Intellectual property would need to be transferred (e.g., shared license or contract operation).

Goal	Approach	Pros	Cons	Considerations:
Intermediate response cont. 1-12 months	APPROACH #3: Accelerate development of alternative anthrax vaccines (e.g. rPA)	Pilot lot of vaccine already produced through DOD/DHHS collaboration. The bulk vaccine could be vialed and clinically evaluated~~ion~~ within the intermediate term. Multiple approaches to rPA development are underway (e.g. single and double mutants) Easy, reliable and safe technology. Purity of product. Scale-up is simple. Multiple potential manufacturers. Potential advantages for immunologic response to vaccination. {We don't understand what this entry refers to. Some scientists feel that going to rPA alone may be "overpurifying" the vaccine. if other cellular or	Animal studies of rPA are encouraging but human trials have yet to be performed. Human efficacy trials can never be performed.	Intellectual property ownership of this approach is unclear.

	capsular components have immunologic value		

Goal	Approach	Pros	Cons	Considerations:
Intermediate response cont. L-12 months	APPROACH #4: Accelerate prophylactic and therapeutic options for pre- and post-exposure anthrax by implementing activity screening and small animal and primate testing of antimicrobial alternative choices for Cipro penicillin and doxycyline and development and testing of monoclonal and polyclonal antibody products.	Generate data on effectiveness and duration of treatment to guide public health decisions.	None	

Goal	Approach	Pros	Cons	Considerations:
Long-term response (over 12 months)	Produce sufficient vaccine to neutralize threat nationally and internationally. • Select best vaccine • Expand its production • Expand testing to include all segments of the population	If needed, will allow immunization of population. Insures multiple manufacturers for future needs. Security of multiple manufacturing sites.	For new vaccine, little data on efficacy and duration of response in humans. Less safety data will be available, compared to the 18 existing human studies with earlier formulations of anthrax vaccine.	Indemnification for civilian population remains an issue. New products will require expanded animal and clinical trials. Must address issue of secure storage of stockpile. Combination of post-exposure treatment with antibiotics must be studied.

DRAFT

Date:
To: The Deputy Secretary, DHHS
THRU: Acting Assistant Secretary for Health, DHHS
From: Anthony S. Fauci, M.D. Chair DHHS Anthrax Scientific and Technical Feasibility Team
Subject: Options, Issues and Recommendations for Response to Anthrax

Background: The purpose of this memorandum is to summarize the scientific and technical feasibility (supply, development and procurement) of a biomedical response to a major act of anthrax bioterrorism in the United States of America, and to provide recommendations for your consideration.

Recent events have required us to consider the expanding possibilities associated with widespread release of anthrax and to identify plans for immediate, intermediate and longer-term response. Recent events ~~have shown~~ that the dissemination of anthrax spores can be accomplished and limiting our focus to site containment cannot be a long-term strategy. Two biomedical options for the control of anthrax are available, antimicrobial therapy and vaccines. The primary response to anthrax exposure has been antimicrobials, which have been used both inprophylactic and therapeutic uses. ~~These include~~ Ciprofloxacin is explicitly (licensed for post-exposure prophylaxis), whereas penicillin, and doxycycline and generally licensed for treatment of anthrax infection. Several other classes of licensed antimicrobials have shown activity against anthrax, in vitro.

Licensed in 1970, t~~T~~he vaccine ~~that has been most widely used~~ in the U.S. is made from cell-free cultured filtrates of an attenuated strain of anthrax. Known as AVA, it is produced by BioPort Corporation, Lansing, Michigan. The current stockpile is owned by the U.S. Department of Defense~~military~~. The vaccine requires 6 doses over a period of 18 months for maximal protection, according to the FDA-approved product labeling. The predominant antigen associated with this vaccine is known as the protective antigen (PA) and second generation vaccines have been focused on attaining these purified antigens through recombinant DNA technology (rPA). To date, no rPA vaccines have been tested in humans.

Assignment: The Secretary requested the establishment of an Anthrax Scientific and Technical Feasibility (see attached list) to do the following:

- Determine the scientific and technical feasibility to make available& ~~assur~~ing vaccine and/or appropriate therapy would be available to all that who would need it; and
- Develop a set of options and recommendations for accomplishing this purpose.

Conclusion:

Immediate (widespread attack between present to one month): The options are limited. For the immediate term, antibiotics will need to remain the primary tool for response. In addition to continuing to provide courses of antibiotic treatment, limited supplies of AVA can be made available for use in post-exposure prophylaxis (in combination with antibiotics) as well as being offered to those at immediate risks, (e.g. laboratory workers and decontamination experts) as a prophylactic. Use of masks (e.g. N95) for low-density potential contamination sites should also be considered.
Intermediate response (one month to 1 year): Additional doses of AVA can be made ~~available~~manufactured.
Longer-term response (1 year to 6 years): Opportunities to provide sufficient vaccine (AVA and/or rPA) to protect the U.S. population is feasible. Expansion of the classes of antimicrobials available for use against anthrax, both prophylactically and therapeutically, could also occur.

Recommendations: The DHHS Anthrax Scientific and Technical Feasibility Team recommends that immediate efforts be directed to pursuing the multiple approaches required for the immediate and intermediate response. These include:

- Purchase of available AVA vaccine from the military. This will require indemnification ~~from~~ by DHHS and use of the vaccine under IND.
- Expansion of the supply of first line antibiotics.
- Development of revised guidelines for the distribution and use of masks and antibiotics.
- Development of guidelines for the storage and use of limited supplies of AVA vaccine.
- Accelerate the human evaluation of rPA.
- Accelerate the evaluation of additional classes of antimicrobials

Longer term

- Expand discussions with BioPort, as well as other manufacturers with respect to their ability to produce AVA for civilian use. This will require negotiations with DOD.
- Expand human testing of rPA vaccines
- Expand evaluation of therapeutic approaches to include novel antitoxins and monoclonal antibodies

(169)

Diniega, Benedict, COL, OASD/HA

From: Friedlander, Arthur M COL USAMRIID (b)(6) @DET.AMEDD.ARMY.MIL]
Sent: Saturday, November 17, 2001 5:25 PM
To: (b)(6)

Subject: RE: How Anthrax Vaccine Works

(b)(6) It's difficult to put on one slide but I suggest the following:
Just say that the vaccine contains PA as indicated with the yellow circle, and eliminate that it comes from the bacteria as you have drawn it with filtering. The human makes antibodies to PA and it binds to the PA as you indicate and blocks the PA+LF and PA+EF from binding to human target cell and thus prevents damage. It may be better to discuss as it is hard to relay in print. In general, the arrow from bacteria to vaccine should be eliminated. Just have it leading to PA, LF and EF. Maybe we can talk on Monday.

(b)(

From: (b)(6)
Sent: Saturday, November 17, 2001 2:06 PM
To: (b)(6)
(b)(6)

Subject: How Anthrax Vaccine Works

<<File: 111501 IDIV Brief-Animated Slide.ppt>>
Our exceptional AVIP team developed this PowerPoint slide to explain how AVA works. Would you all please murder-board it for us?

Please make your recommendations for improvement specific, so we know what change you suggest.

thx, (b)(6)

-----Original Message-----
From: (b)(6)
Sent: Thursday, November 08, 2001 3:04 PM
To: (b)(6)
(b)(6)

Subject: POC Contact List

All,

This is a new POC/AVIP Contact list. Please review and if we need to make any updates just email me your changes and I will update the list for all.

Thank you.

R/(b)(6)

CMAT Control #
2002136-0000001

170

(b)(6)
05/16/2002 07:32 AM

To: (b)(6)
cc:

Subject: FW: Jason Nietupski Case

For your info, the VA changes disability rating for adverse responses to vaccines. See below.

VR,
(b)(6)

FYI.

-----Original Message-----
From: (b)(6) CIV, OASD/HA
Sent: Wednesday, May 15, 2002 3:17 PM
To: (b)(6)
(b)(6)
Subject: FW: Jason Nietupski Case

Interesting message from (b)(6)

-----Original Message-----

(b)(5)

- ~max0003.PDF

(b)(6)
Deputy for Public Affairs and Outreach
Deployment Health Support Directorate
(b)(6)

2003126-000001

(b)(6)
06/06/2002 08:49 AM

To: (b)(6) @OSAGWI
cc:

Subject: FW: Jason Nietupski Case

2b e-mail please

---------- Forwarded by (b)(6) on 06/06/2002 09:52 AM ----------

(b)(6)
05/16/2002 07:32 AM

To: (b)(6)
cc:

Subject: FW: Jason Nietupski Case

For your info, the VA changes disability rating for adverse responses to vaccines. See below.

VR,
(b)(6)

FYI.

-----Original Message-----
From: (b)(6) CIV, OASD/HA
Sent: Wednesday, May 15, 2002 3:17 PM
To: (b)(6)
(b)(6)
Subject: FW: Jason Nietupski Case

Interesting message from (b)(6)

(b)(5)

(b)(5)

 - ~max0003.PDF

(b)(6)
Deputy for Public Affairs and Outreach
Deployment Health Support Directorate
(b)(6)

(b)(6)
Chief, Case Management Assignment Team
Deployment Health Support Directorate
(b)(6)

DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF GENERAL COUNSEL
TEL (b)(6)
FAX

FACSIMILE TRANSMITTAL SHEET

TO: (b)(6)	FROM: (b)(6) Deputy General Counsel
COMPANY: DOD/OGC	DATE: 5/14/2002
FAX NUMBER: (b)(6)	TOTAL NO. OF PAGES INCLUDING COVER: 6
PHONE NUMBER:	SENDER'S REFERENCE NUMBER:
RE: Anthrax-vaccination opinion	YOUR REFERENCE NUMBER:

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

(b)(– Our opinion interprets "injury" as used in 38 U.S.C. §101(24) as including adverse reactions to injections of the anthrax vaccine. It remains for the VA Regional Office with jurisdiction over this claim to attribute the veteran's current disability to this injury and assign an appropriate disability rating, but the path is now clear for it to do so.

This is being designated a "precedent opinion" so that, by virtue of 38 U.S.C. §7104(c) and 38 C.F.R. §14.507(b), it is also binding on all other VA claims-adjudication personnel.

Thanks for bringing this to our attention. - (b)(6)

Department of Veterans Affairs

Memorandum

Date: May 14, 2002

From: General Counsel (022)

VAOPGCPREC 4-2002

Subj: Meaning of "Injury" for Purposes of Active Service – 38 U.S.C. § 101(24) NIETUPSKI, Jason M. (b)(6)

To: Director, Compensation and Pension Service (21)

QUESTION PRESENTED:

Whether a former member of the Army Reserve who received two anthrax inoculations during inactive duty training and who alleges suffering from chronic fatigue and chronic Lyme-like disease as a result of these inoculations may be considered to have been disabled by an injury in determining whether the member incurred disability due to active service.

DISCUSSION:

1. The claimant had active duty service in the United States Army from May 29, 1995, to June 18, 1999, and was then assigned to the Army Reserve. In preparation for a required two-week tour of duty in Korea, the claimant received three anthrax inoculations,[1] the first two of which were received while on inactive duty training on February 12 and March 11, 2000. The claimant received the third inoculation on March 25, 2000, while in civilian status. The claimant was deployed to Korea from April 10, 2000, to April 24, 2000. The claimant has filed a claim with the Department of Veterans Affairs (VA) seeking service connection for chronic fatigue and chronic Lyme-like illness claimed to have resulted from the anthrax inoculations.

2. Pursuant to 38 U.S.C. §§ 1110 and 1131, service-connected disability compensation may be paid for disability resulting from injury suffered or disease contracted in line of duty "in the active military, naval, or air service." Section 101(24) defines the term "active military, naval, or air service" as including "active duty, any period of active duty for training during which the individual concerned was disabled or died from a disease or injury incurred or aggravated in

[1] The Department of Defense (DoD) mandated anthrax vaccinations for all service members and DoD civilian employees assigned or deployed to high-threat areas. Memorandum of Under Secretary of Defense, Change of Anthrax Vaccine Immunization Program (AVIP) Operational Procedure, March 30, 1999. The Anthrax Vaccine Adsorbed (AVA) involves 6 subcutaneous injections over an 18-month immunization schedule and annual booster doses. Institute of Medicine, *The Anthrax Vaccine: Is It Safe? Does It Work?* at 5 (2002).

line of duty, and any period of inactive duty training during which the individual concerned was disabled or died from an injury incurred or aggravated in line of duty." (Emphasis added.) Thus, in the case of inactive duty training, only if the individual suffered an "injury" during such service can disability resulting from such service provide a basis of eligibility for disability compensation.

3. The question of what constitutes an "injury" for purposes of section 101(24) must be considered in light of three previous General Counsel opinions in which we analyzed the distinction between "injury" and "disease" under that statute. One such opinion, VAOPGCPREC 86-90 (O.G.C. Prec. 86-90), concerned whether a heart attack sustained following heavy exertion while on inactive duty training was an injury within the meaning of section 101(24). Medical evidence in that case indicated that the heart attack was the result of coronary artery disease, which existed prior to the training period, although the event may have been precipitated by physical exertion. On those facts, we concluded that the claimant's heart attack was not caused by an injury, but rather was attributable to disease.

4. In VAOPGCPREC 86-90, we examined the medical cause of the heart attack. We noted the consensus among medical specialists that excessive effort and strain cannot damage a normal heart and concluded that the heart attack was the result of a disease process. We further concluded that Congress intended to exclude "nontraumatic incurrence or aggravation of a disease process, and that manifestations of cardiovascular disease, such as heart attacks of nontraumatic origin, fall within the excluded class of disability, i.e., do not constitute injuries under the statute." In *Brooks v. Brown*, 5 Vet. App. 484, 487 (1993), *aff'd*, 26 F.3d 141 (Fed. Cir. 1994), the United States Court of Veterans Appeals concluded that VAOPGCPREC 86-90 is consistent with the governing statutes and Congress' policy reflected in those statutes. We note that the focus of our holding in VAOPGCPREC 86-90 was clearly on the non-traumatic nature of the cause of the heart attack. We may assume that a heart attack caused by a traumatic external event that is independent of a disease process, *e.g.*, an electric shock, may be considered an injury.

5. VAOPGC 6-86 (3-27-86) followed and relied upon what was formerly Op. G.C. 1-81 (subsequently reissued and redesignated as VAOPGCPREC 86-90). [2] Although VAOPGC 6-86 is not precedential, it illustrates how the opinion now

[2] The VA General Counsel opinion originally designated as Op. G.C. 1-81 was published on May 19, 1981. This opinion was reissued as a precedent opinion on July 18, 1990, and redesignated as VAOPGCPREC 86-90 (O.G.C. Prec. 86-90).

3.

Director, Compensation and Pension Service (21)

designated VAOPGCPREC 86-90 has been applied. In VAOPGC 6-86, we determined that a claimant who received an influenza vaccination by injection while on inactive duty training and subsequently developed Guillain-Barre syndrome did not incur a disability resulting from an injury for purposes of section 101(24). Referencing what is now VAOPGCPREC 86-90, we reasoned that the term "injury" denotes harm from external trauma, while the term "disease" refers to some type of internal infection or degenerative process. The opinion cited several sources for the proposition that the term "trauma" commonly refers to the application of external force or violence. We further reasoned that, under modern medical practice, the routine insertion of a hypodermic needle into the body is not commonly considered to involve application of external force or violence that is characteristic of injury. However, we recognized that an injection could be considered to have caused a traumatic injury if contact with the needle caused lasting nerve or tissue damage.

6. Most recently, in VAOPGCPREC 8-2001, we held that an individual who suffers from post-traumatic stress disorder (PTSD) as a result of a sexual assault that occurred during inactive duty training may be considered disabled by an "injury" for purposes of section 101(2) and (24). This conclusion was based upon the analysis of the preceding General Counsel opinions indicating that "injury" refers to the results of an external trauma rather than a degenerative process and the fact that, according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, of the American Psychiatric Association, at 427 (diagnostic criterion A), a diagnosis of PTSD requires experiencing a traumatic event.

7. The concept exemplified by these VA General Counsel opinions is that "injury" refers to the results of an external trauma, rather than a degenerative process. While, as noted in VAOPGC 6-86, "trauma" frequently is defined with reference to external force or violence, the term may commonly be considered to encompass injury to living tissue caused by an extrinsic agent. *Webster's Ninth New Collegiate Dictionary* 1256 (1990). In this regard, we believe that consideration of the nature of vaccines is helpful in resolving the issue of whether introduction of a vaccine into the body may constitute trauma for purposes of determining the nature of harm resulting from the vaccine.

8. A vaccine is a suspension of attenuated or killed microorganisms or of antigenic proteins derived from them. Dorland's Illustrated Medical Dictionary 1787 (28th ed. 1994). Vaccines artificially induce the immune system to produce antibodies that will attack invading organisms and prevent disease. National Institute of Allergy and Infectious Diseases, *How Vaccines Work, available at* http://www.niaid.nih.gov/daids/vaccine/how.htm. Although vaccines and mass

immunization programs have been extremely successful in protecting the public health against dangerous diseases, "available data indicate that some vaccines are associated with rare but serious adverse effects." *The Anthrax Vaccine: Is It Safe? Does It Work?* at 85. An adverse event following a vaccination may be either local or systemic. *Id.* at 86. The duration of these events may be acute or chronic, and adverse health effects may range from mild to severe. *Id.*

9. The foregoing discussion indicates that inoculation with a vaccine involves the introduction of a foreign substance into the body and that, while the substance is intended to and generally does have a beneficial effect, adverse reactions, sometimes of a severe nature, may result. Further, based on the above discussion, we believe that the term "injury" in section 101(24) may be interpreted to include harm not only from a violent encounter but also from exposure to a foreign substance, such as a vaccine. We recognize that in our non-precedential opinion VAOPGC 6-86 we concluded that harm resulting from an influenza vaccination would not be considered to have resulted from an injury. However, VAOPGC 6-86 focused on harm caused by the "routine insertion of a hypodermic needle into the body" and on the absence of external force or violence, rather than on the introduction of an extrinsic agent to body tissue. We believe the common understanding of the concept of "trauma," which is recognized as the cause of "injury," encompasses a broader definition than the one applied in VAOPGC 6-86 and that such broader definition includes serious adverse effects on body tissue or systems resulting from introduction of a foreign substance. Thus, an adverse reaction to a vaccination may be considered an "injury" as that term is used in 38 U.S.C. § 101(24).

10. This conclusion is consistent with VAOPGCPREC 86-90, in which the harm suffered (a heart attack) did not result from an external force or substance, but rather from a pre-existing disease. This conclusion is also consistent with VAOPGCPREC 8-2001, in which we recognized that a condition (in that case PTSD) that has characteristics of a disease may be considered to be the result of an injury, where it resulted from an external assault.

HELD:

If evidence establishes that an individual suffers from a disabling condition as a result of administration of an anthrax vaccination during inactive duty training, the individual may be considered disabled by an "injury" incurred during such training as the term is used in 38 U.S.C. § 101 (24), which defines "active military, naval, or air service" to include any periods of inactive duty training during which the individual was disabled or died from an injury incurred or aggravated in line of duty.

5.

Director, Compensation and Pension Service (21)

Consequently, such an individual may be found to have incurred disability in active military, naval, or air service for purposes of disability compensation under 38 U.S.C. § 1110 or 1131.

Tim S. McClain

Tim S. McClain

(b)(6)
02/28/2002 02:06 PM

To: (b)(6) @OSAGWI
cc:

Subject: RE: Gulf War anthrax vaccinees

2b please

---------- Forwarded by (b)(6) on 02/28/2002 02:09 PM ----------

(b)(6)
02/04/2002 04:19 PM

To: (b)(6) @OSAGWI
cc: @OSAGWI

Subject: RE: Gulf War anthrax vaccinees
Document is set for Permanent Archival

See (b)(6) comment. We may already have the list of vaccinees.

---------- Forwarded by (b)(6) on 02/04/2002 04:21 PM ----------

(b)(6) on
02/04/2002 04:21:04 PM

To: (b)(6) @OSAGWI
cc: (b)(6)

Subject: RE: Gulf War anthrax vaccinees

Many thanks for this information, (b)(6) It will be very useful as we plan our strategy on this thing.

(b)(6) told me that he had, in fact, forwarded a copy of this very same file (alpha roster(s)) to the OSAGWI several years ago (?1997). Therefore, it should exist somewhere in your archives. Let me know if for some reason it can't be located, and I'm sure (b) would be happy to resend.

(b)(6)

-----Original Message-----
From: (b)(6) @deploymenthealth.osd.mil
(b)(6)
Sent: Monday, February 04, 2002 12:40 PM
To: (b)(6)
Subject: Re: Gulf War anthrax vaccinees

(b)(6)

See below. (b)(6) works in our office.

(b)(6)

---------- Forwarded by (b)(6) on 02/04/2002 12:42 PM ----------

(b)(6)

02/04/2002 10:27 AM

To: (b)(6) @OSAGWI
cc: (b)(6)

Subject: Re: Gulf War anthrax vaccinees (Document link: (b)(6)

Sir,

Per our discussion, the technical part of this relatively simple. We do have access to internal and external government and commercial databases that would allow us to develop likely current address information if we were requested to do so. This would require approval of an official request from AMEDD or the sponsoring government office. The request would need to include an explanation of what the information would be used to accomplish and verification that the requesting office will protect the information per the Privacy Act. The requestor would also be required to cover any costs involved in developing the address information, e.g., per individual charges for retrieving address information from a commercial vendor.

We note with interest the mention of an alpha roster of personnel given Anthrax vaccine in the Gulf. As you know, this organization is in possession of several Anthrax rosters. Whether or not they end up requesting our assistance, we would be very interested in obtaining a copy of their roster to compare with our holdings.

(b)(6)
Chief, Case Management Assignment Team
Deployment Health Support Directorate
(b)(6)

(b)(6)
Director, Medical Readiness
Deployment Health Support Directorate
(b)(6)

 - att1.htm

(b)(6)
Director, Medical Readiness
Deployment Health Support Directorate
(b)(6)

(b)(6)
Chief, Case Management Assignment Team
Deployment Health Support Directorate
(b)(6)

Office of the Special Assistant to the Deputy Secretary of Defense

for Gulf War Illnesses

(800)-754-2132 fax 703-578-8501
email: brostker@gwillness.osd.mil

(ELD)

Mission of the Special Assistant

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DOD adopts doctrine, policy and procedures to reduce risks for troops in the future.

Post War

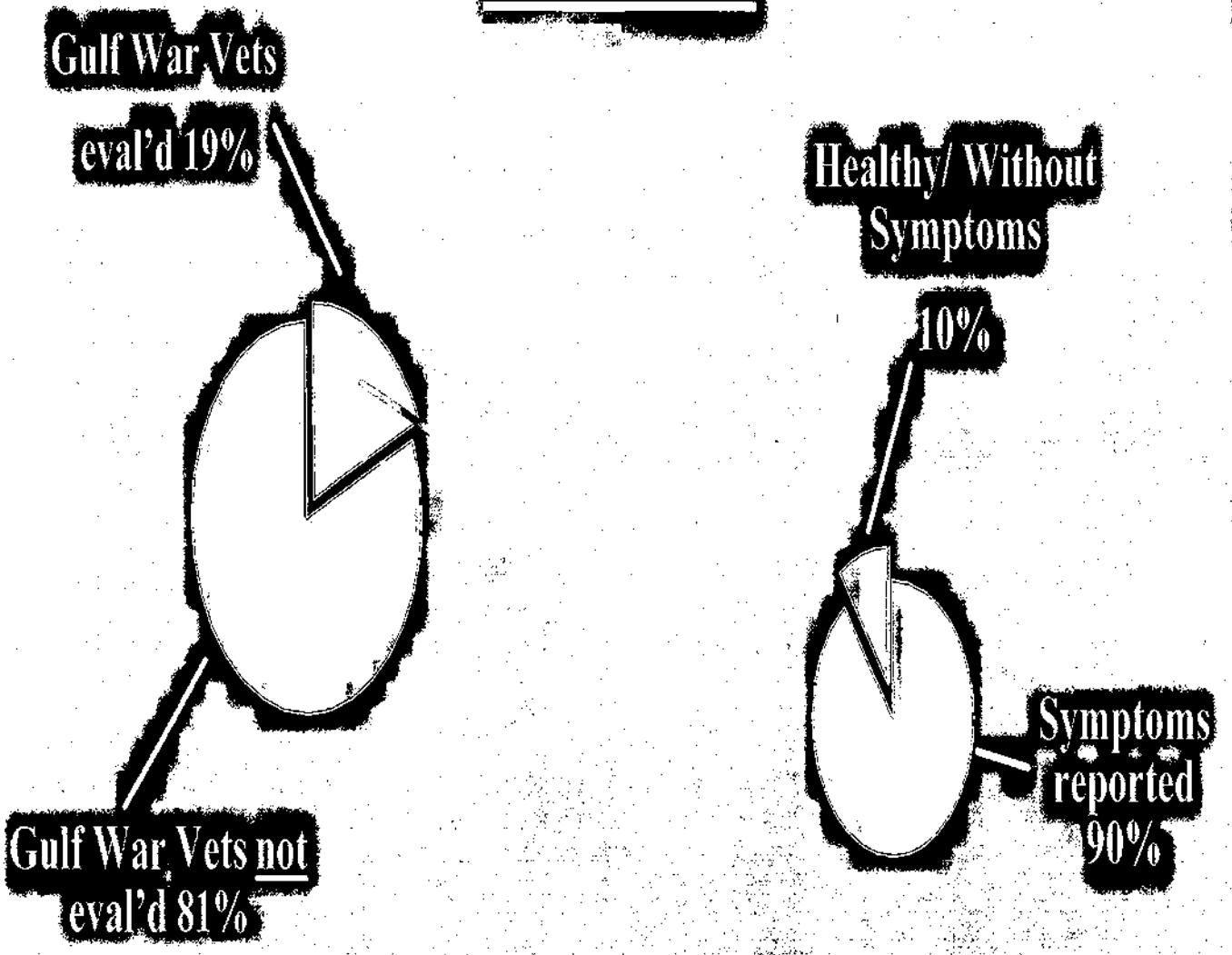
Shortly after re-deployment, many individuals in a few units reported common symptoms

- Aching joints
- Headaches
- Rashes
- Sleep disorders
- Diarrhea
- Hair loss
- Memory loss
- Fatigue

Confounding Issues

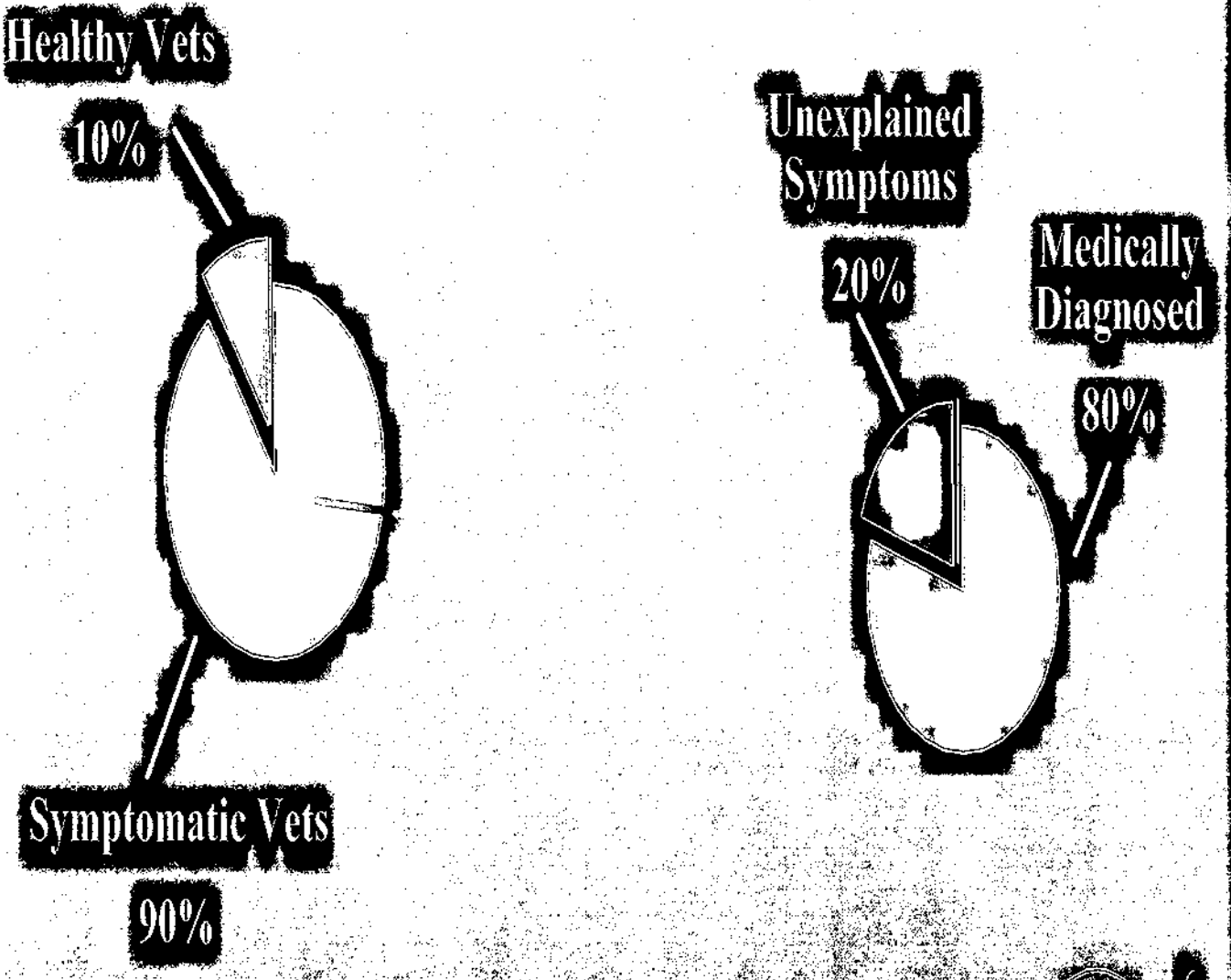
- No clustering
- No symptom consistency
- Variable onset
- No longitudinal evaluation
- As yet - no new disease or links between exposures and symptoms

Evaluation Distribution of 697,000 CCEP/VA



Diagnosis Distribution of Evaluated Veterans

CCEP/VA



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Healthy	10% - 11,494
Symptomatic (Sick)	90% - 103,450
Medically explained and treatable	80% - 82,760
Medically unexplained	20% - 20,690

As of Oct'99

*Comprehensive Clinical Evaluation Program (CCEP) and Dept. of Veteran's Affairs Registry, programs to provide health care to soldiers and veterans.

Looking for Causes

The Dirty Battlefield

- What Iraq may have done to us.
  - Oil Well Fires, Stress
- What the environment may have done to us.
  - Sand, Infectious diseases, bad food and water
- What we may have done to ourselves.
  - Pesticides, Pyridostigmine Bromide, Low levels of CW agent, DU
- Challenges in the future range from low-tech pariah states to the revolution in military affairs.

OSAGWI Investigations

- **Chemical/biological warfare:**
  - Focus in 1997; 16 papers
  - Watershed is Khamisiyah

- **Environmental:**
  - Focus in 1998
    - Oil well fires, pesticides, depleted uranium (DU)

DU Exposure Issues

- Radiation
- Heavy metal toxicity
- Consequences of exposure
- Reproductive effect
- Contamination of theater

Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Collect pre-deployment blood sample
- Verify HIV test is current
- Verify Immunizations up to date
- Verify current physical exam
- Complete Health questionnaire

Deployment

- Routine disease/injury reporting
- Forward medical laboratory
- Immunization tracking
- Environmental monitoring

Post Deployment

- Collect blood sample
- Medical debriefs
- Complete health questionnaire
- Screening exams as needed

Anthrax Vaccine

- What is Anthrax?
- Vaccine is safe and necessary
  - FDA Licensed in 1970
  - Used for many years to protect textile mill workers
  - Recommended by Centers for Disease Control (CDC):
    - Workers occupationally exposed to anthrax (labs, mills)
    - Treatment of anyone exposed to anthrax aerosols
    - Only known pretreatment and protection against exposure

Anthrax Vaccine

- DoD Policy - mandatory for total force
  - Phased implementation
- Phase I - SWA and Korea (now)
- Phase II - Early deploying forces to SWA and Korea (now)
- Phase III - Total force (early 2000's)
- Vaccine series:
  - 0, 2, 4 weeks; then 6, 12, 18 months; annual booster
- Reported reactions (1 Oct 99 per DoD/Health Affairs):
  - 1,147,349 doses, 211 adverse reactions=0.018%
    - 155 systemic reactions, 56 local reactions
- DoD anthrax web site: www.anthrax.osd.mil

Myths versus Reality

Cover up	Open process & oversight
Not listening	Solicit eyewitness reports
Destroy records	Found missing records
20,000 veterans dead	6,186 veterans dead
No assistance to vets	Evaluation and care
"Syndrome"	More than 40 illnesses
CW or DU cause	Many possible causes
Brass doesn't care	Force Protection efforts
	Tough choices
	Cultural changes

Summary

- Work continues: "leave no stone unturned"
- We rely on Gulf War veterans:
  - To give us leads
  - To check our accuracy
- We rely on you:
  - To ensure GW vets get proper testing and treatment
  - To dispel myths and demand facts

Obtaining Help and Information

- Comprehensive Clinical Evaluation Program (CCEP)
  - 1-800-796-9699
- Veterans Affair registry program
  - 1-800-749-8387
- Town Hall
  - Thursday, November 4, 1999, Infantry Hall (Bldg. 4) at 1900 hrs
- Displays
  - P.X., Infantry Hall, and Martin Army Community Hospital
- Contact managers

Office of the Special Assistant for Gulf War Illnesses

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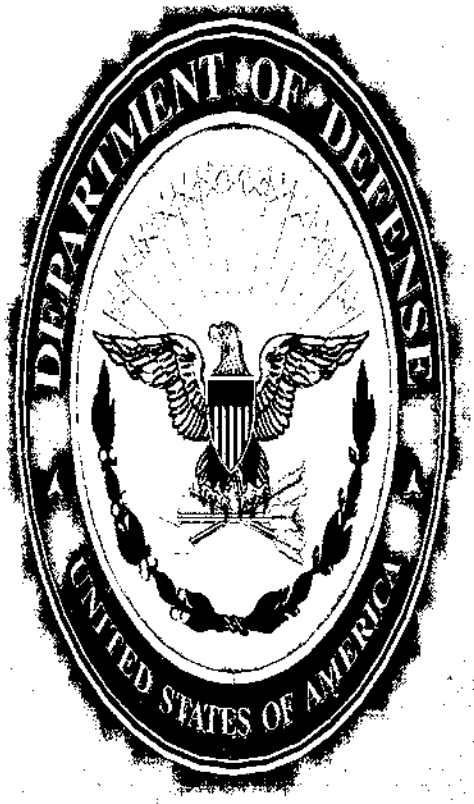

for Gulf War Illnesses

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(173)

Briefing Overview

- Organization - Mission Statement
- Why should I care?
- Symptoms and Illnesses
- Looking for causes
- Gulf War Lessons Learned
- Force Health Protection
- Obtaining help and information

Special Assistant for Gulf War Illnesses

Dr. Bernard Rostker

- Appointed November 12, 1996 by the Deputy Secretary of Defense
- 180 team members

Mission of the Special Assistant

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DOD adopts doctrine, policy and procedures to reduce risks for troops deploying now and in the future.

Why Should I Care?

- Lessons from the Gulf War about dirty battlefields.
- You must protect yourself against hazards.
- You will be working with or leading Gulf War vets.
- You will probably deploy overseas.
- You are responsible for force protection.

Who Served in the Gulf War

697,000 U.S. service members

Army	348,000	50%
Navy	160,000	23%
Marine	105,000	15%
Air Force	84,000	12%

259,000 Coalition Forces

U.S. Deaths

Battle deaths	148
Non-battle deaths	224
Hospitalizations	Over 27,000

Post War

Shortly after re-deployment, many individuals in units reported common symptoms

- Joint pain
- Headaches
- Sleep disorders
- Depression
- Fatigue
- Memory loss
- Rash
- Muscle pain

Physician Message Sent

"Your laboratory, x-ray and physical exams results are normal."

Patient Messages Received

"There's nothing wrong with you!"

"It's all in your head!"

"You're faking these symptoms!"

Confounding Issues

- No clustering
- No symptom consistency
- Variable onset
- No long term study
- As yet - no new disease or links between exposures and symptoms

Looking for Causes

The Dirty Battlefield

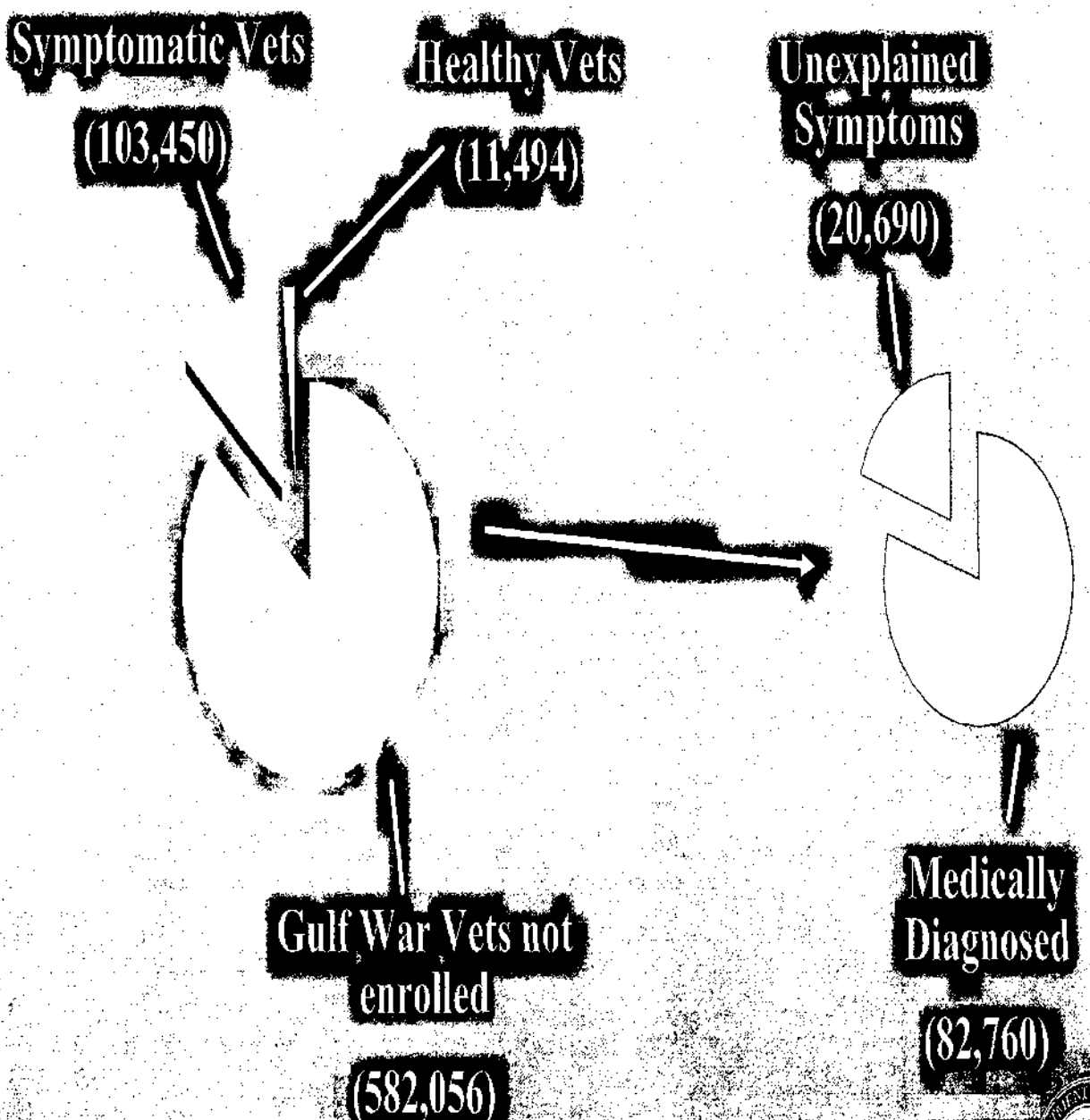
- What Iraq may have done to us.
  - Oil Well Fires, Chem/Bio threat
- What the environment may have done to us.
  - Sand, Insects, Infectious diseases
- What we may have done to ourselves.
  - Pesticides, Pyridostigmine Bromide
- Challenges in future conflicts and humanitarian deployments.

OSAGWI Investigations

- Chemical/biological warfare:
  - Chemical warfare agent - Khamisiyah incident
- Environmental:
  - Depleted uranium (DU), Oil well fires, Pesticides
- Medical issues and lessons learned:
  - Vaccines, PB, records, policy
    - "Cocktail" effect

Diagnosis Distribution/697,000 Deployed

CCEP/VA Participants



Proactive Measures - You

- Recognize and contend with potential hazards:
  - Improve intel notification
  - Train all personnel
  - Reduce adverse effects of and stress from potential exposures
  - Understand the environment and culture before deploying
- Improve feedback and cross talk

Proactive Measures - Your Unit

- Improve expedient demolition of munitions
- CW/BW detection: earlier with fewer false positives
- Improve operational and medical records handling
- Adapt for the future
  - Retain individual unit locations and records
  - DU training
  - Improved medical surveillance
  - Force health protection

Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Pre-deployment serum sample
- Verify HIV test in last 12 months
- Immunizations
- Verify current physical exam
- Health questionnaire

Deployment

- Routine disease/injury reporting
- Forward medical laboratory
- Immunization tracking
- Environmental monitoring

Post Deployment

- Collect serum sample
- Medical debriefs
- Complete health questionnaire
- Screening exams as needed

Future Equipment

- Personal Information Carrier (PIC)
- Biological Integrated Detection System (BIDS)
- Automatic Chemical Agent Alarm (ACADA)
- Medic Cam - Tele medicine

Anthrax Vaccine

- What is Anthrax?
  - Bacteria
  - Easily obtained, stored and weaponized
  - Deadly - (skin vs inhaled exposure)
- Vaccine is safe and necessary!
  - FDA Licensed in 1970
  - Used for many years to protect textile mill workers
  - Recommended by Centers for Disease Control (CDC):
    - Workers occupationally exposed to anthrax (labs, mills)
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Bottom Line

- Gulf War Veterans key for our work
- You must protect yourself on the Dirty Battlefield
- Anyone deployed to South West Asia is eligible for CCEP *(family members included)*
- Don't tough it out - Get signed up and evaluated
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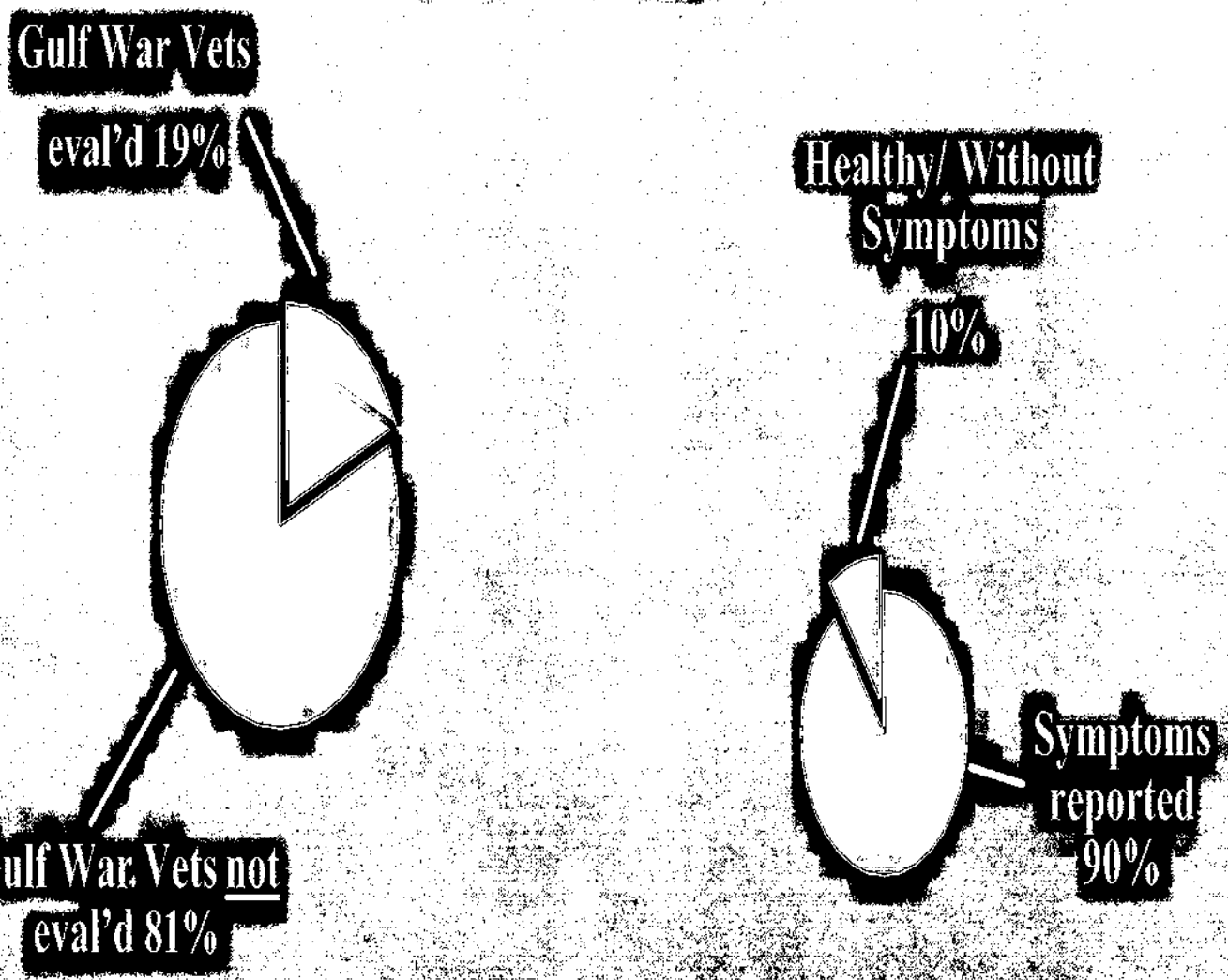
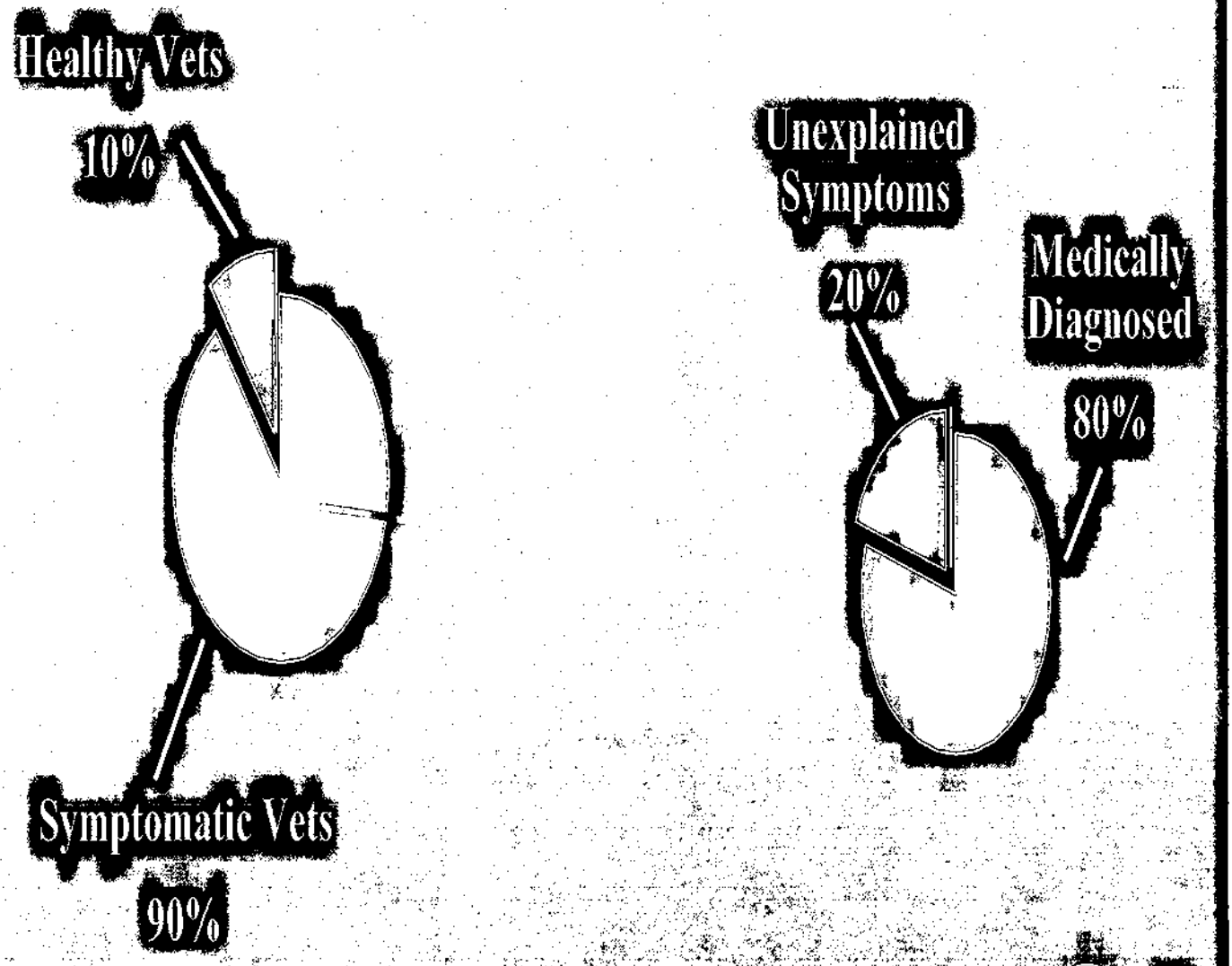


Office of the Special Assistant for Gulf War Illnesses

Diagnosis Distribution of Evaluated Veterans

CCEP/VA



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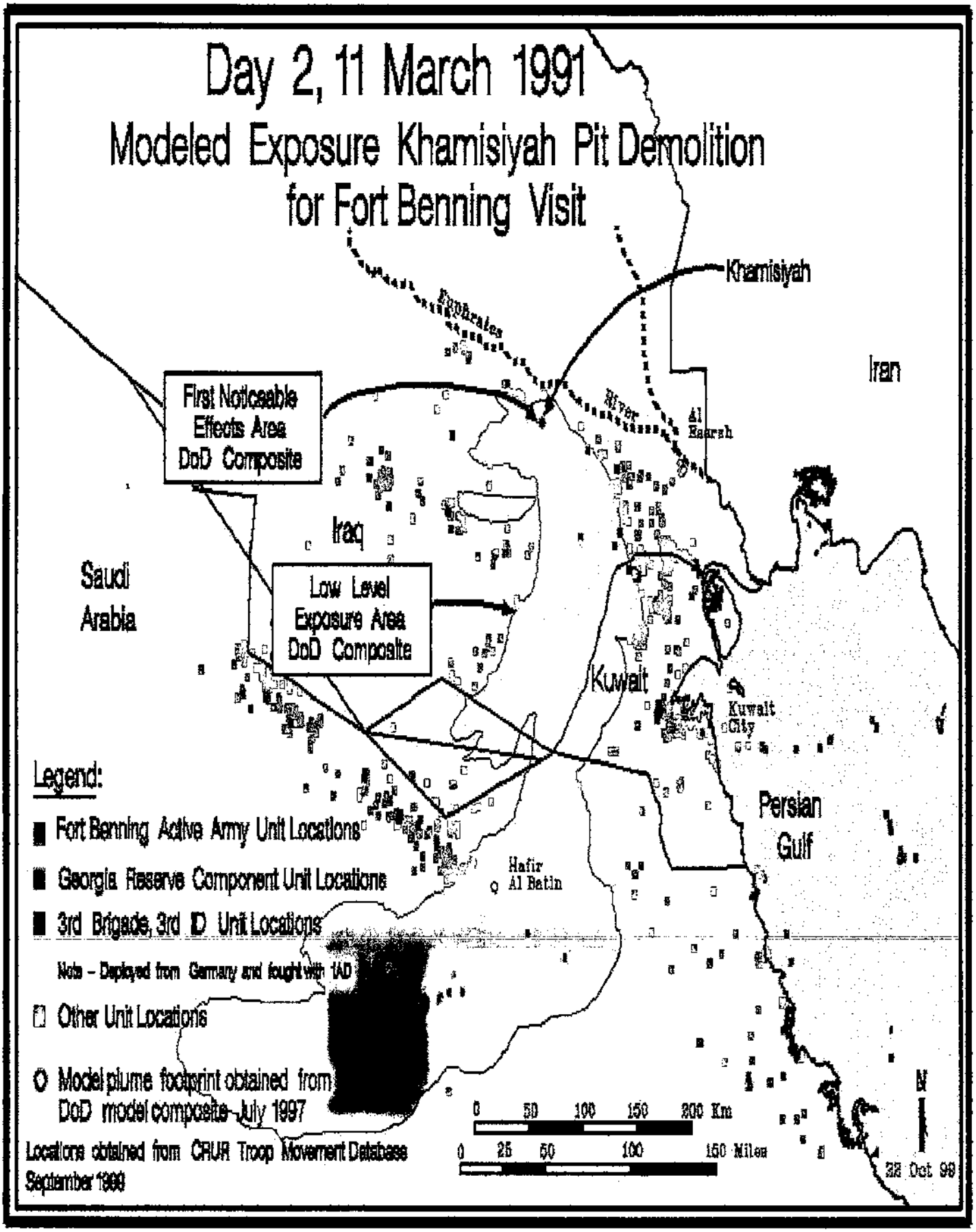
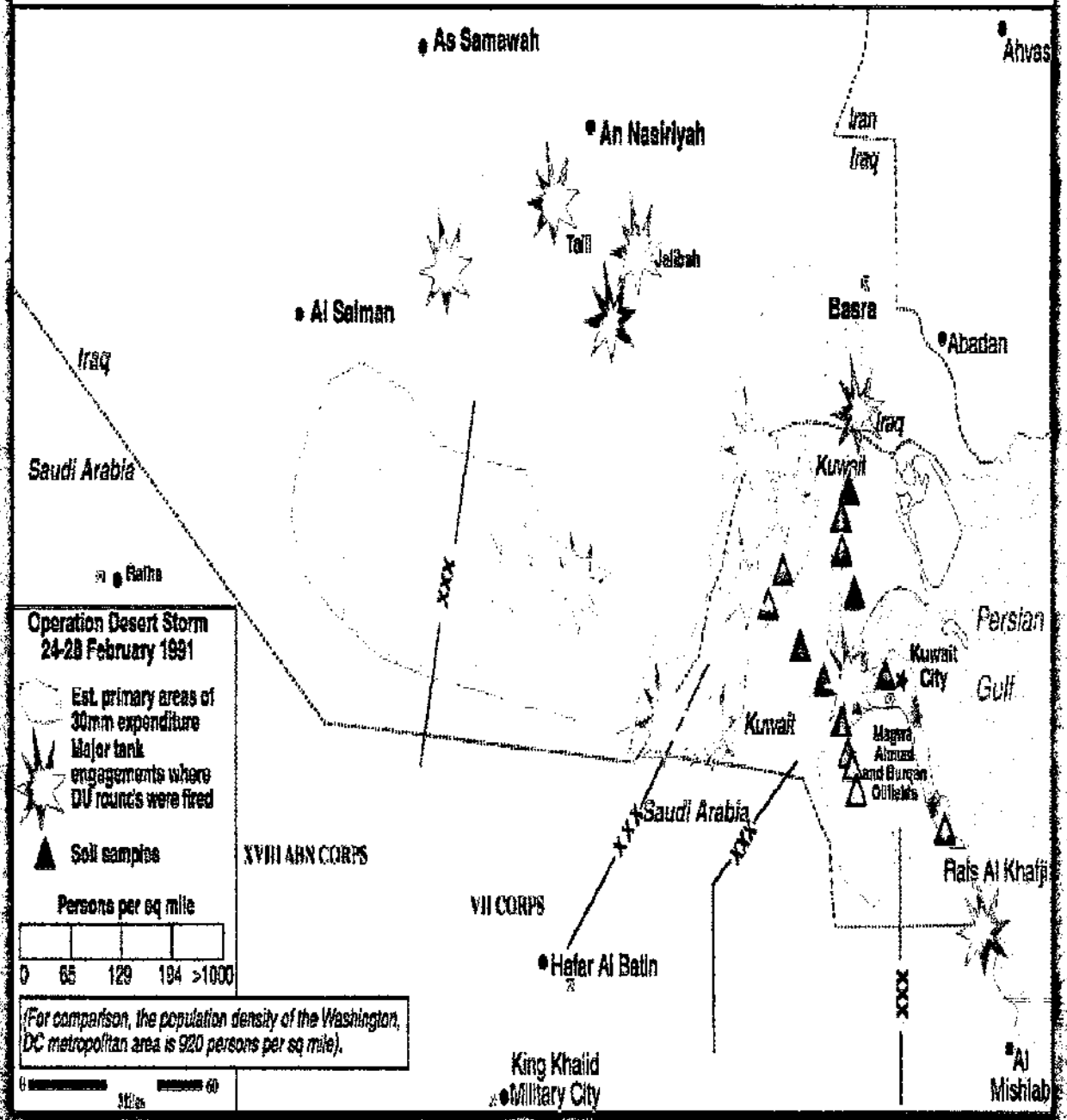

Day 2, 11 March 1991
Modeled Exposure Khamisiyah Pit Demolition
for Fort Benning Visit
Khamisiyah
Euphrates River
Al Basrah
Iran
First Noticeable Effects Area DoD Composite
Iraq
Saudi Arabia
Low Level Exposure Area DoD Composite
Kuwait
Kuwait City
Persian Gulf
Hafir Al Batin
Legend:
Fort Benning Active Army Unit Locations
Georgia Reserve Component Unit Locations
3rd Brigade, 3rd ID Unit Locations
Note - Deployed from Germany and fought with 1AD
Other Unit Locations
Model plume footprint obtained from DoD model composite July 1997
Locations obtained from CRUR Troop Movement Database September 1990
0 50 100 150 200 Km
0 25 50 100 150 Miles
N
22 Oct 99

Primary Areas of DU Expenditure



Investigator's Message Sent

"The symptoms described were not consistent with symptoms associated with exposure to chemical warfare agents or depleted uranium."

Veteran's Messages Received

"You're wrong!"

"You can't possibly be sick because of this!"

DU Exposure Issues

- Radiation
- Heavy metal toxicity
- Consequences of exposure
- Reproductive effect
- Contamination of theater

DU Awareness Training

- Current CTT Task (031-503-1017)
- Better information is now available
  - Chemical toxicity vice radioactivity
  - Continue the mission
  - Respiratory protection for extended exposure
- Training support packages being updated
  - Includes updating the common task & GTA
  - Additional training for specialists
- Use existing training management system

OSAGWI Investigations

- Medical issues and lessons learned:
  - Focus in 1999
    - Vaccines, PB, records, policy
    - DU training
    - Managing hazards

Proactive Measures - You

- Recognize and contend with potential hazards:
  - Improve intel notification
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Operational Lessons - Your Unit

- Improve expedient demolition of munitions
- CW/BW detection: earlier with fewer false positives
- Relate CW to operational and medical records
- Adapt for the future
  - Retain individual unit locations and records
  - DU training
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Pre-deployment

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Back-up Slides

Identifying Possible Causes

- Normal disease rate
- Linking hazards and illnesses
  - Research
  - New disease paradigm

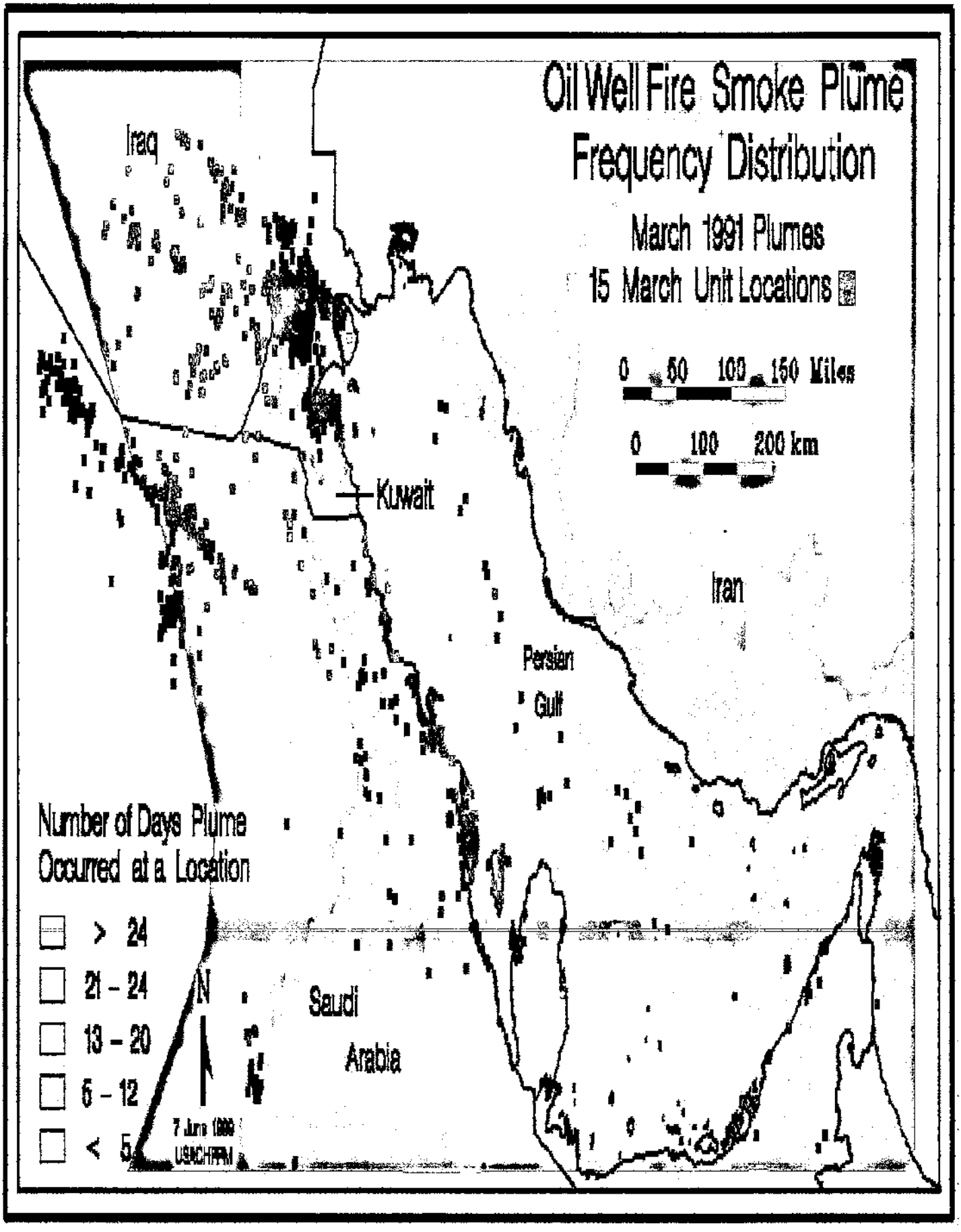
Symptoms

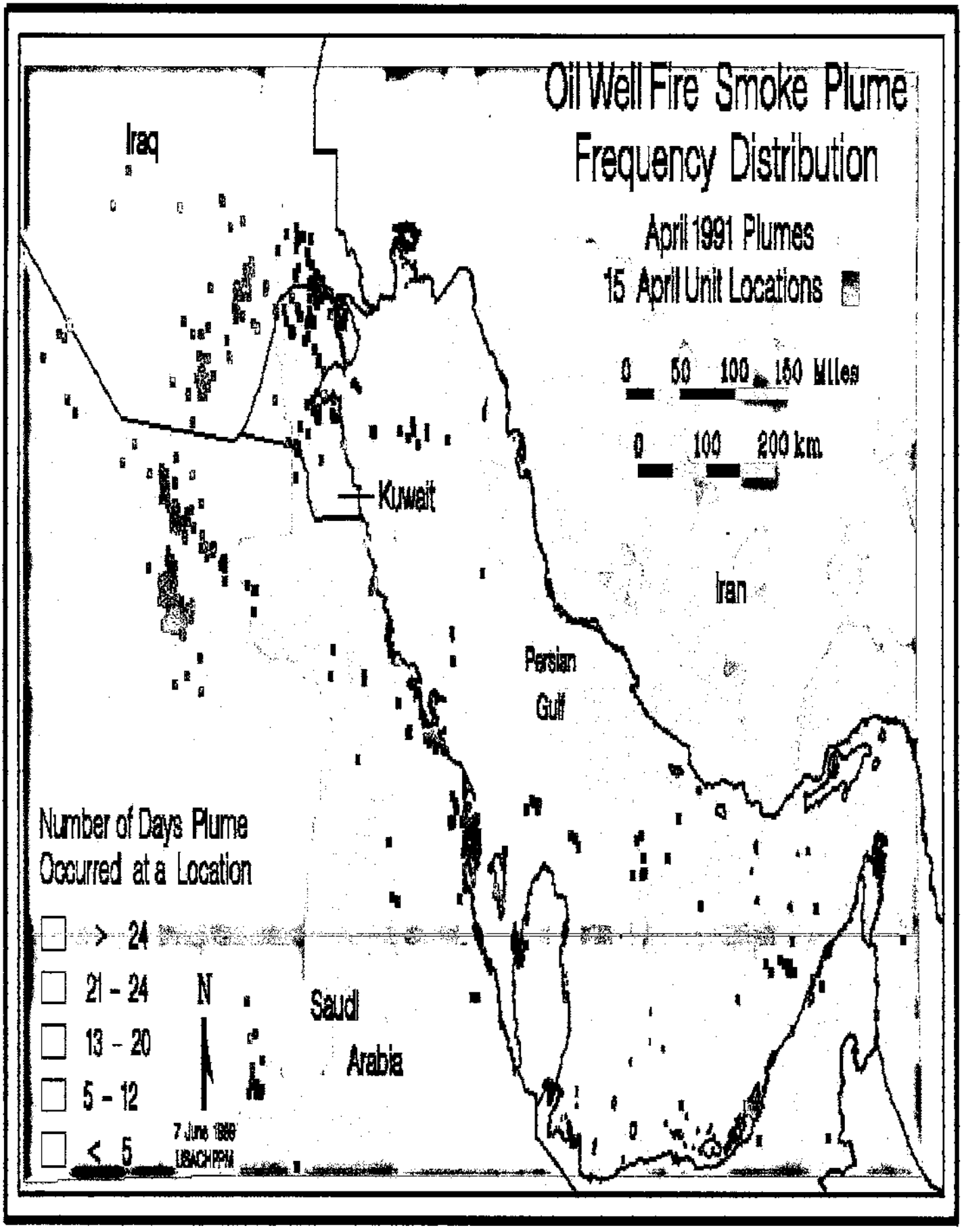
- Tiredness
- Rashes
- Headaches
- Muscle aches
- Joint pains
- Abdominal pain
- Diarrhea
- Hair loss
- Memory loss
- Sleep disturbance
- Depression
- Concentration problems

Hazards

- Chemical warfare agent
- Pesticides
- Vaccines
- Pyridostigmine bromide
- Stress
- Biological warfare agent
- Oil well fires
- Depleted uranium
- Infectious disease
- "Cocktail" effect

30+ offered as possible causes


Oil Well Fire Smoke Plume
Frequency Distribution
March 1991 Plumes
15 March Unit Locations
0 50 100 150 Miles
0 100 200 km
Iraq
Kuwait
Iran
Persian
Gulf
Saudi
Arabia
N
Number of Days Plume
Occurred at a Location
> 24
21 - 24
13 - 20
6 - 12
< 5
7 June 1999
USACHPPM


Oil Well Fire Smoke Plume
Frequency Distribution
April 1991 Plumes
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Iraq
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Medical Training for Line Leaders

- Wellness Requirements = Mission Success
  - Routine examinations, vaccinations
  - Force Health Protection
  - Anthrax Vaccination
- Normal Disease Rates - Garrison or Deployment
  - Diarrhea
  - Sports injuries
  - Cancer, heart attacks, diabetes, etc.

Operational Lessons - You

- Recognize and contend with potential hazards:
  - Improve intel notification.
  - Train all personnel.
  - Reduce adverse effects of and stress from potential exposures.
  - Understand the environment and culture before deploying.
- Improve feedback and cross talk.

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Army	348,000	50%
Navy	160,000	23%
Marine	105,000	15%
Air Force	84,000	12%

259,000 Coalition Forces

Who Served in the Gulf War

Gender	
Men	93%
Women	7%
Component	
Active	83%
Reserve/National Guard	17%
Community	
Officer	10%
Enlisted	90%

<26 years old - 55%; 26-35 years old - 32%; > 35years old - 13%

Medical Support

Largest emergency health care system since WWII

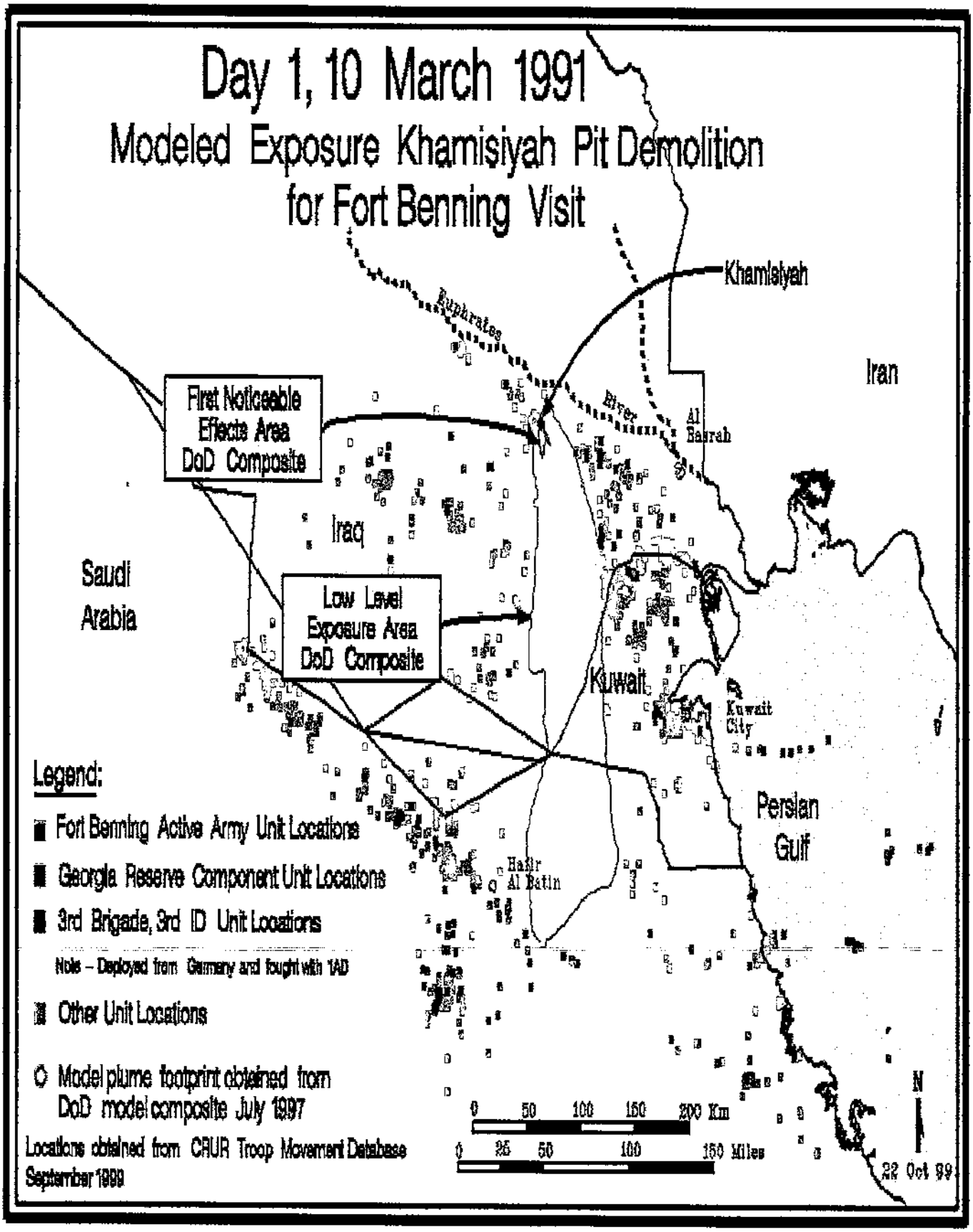
- 41,000 medical personnel
- 18,000 beds
- 2 hospital ships
- 63 combat zone hospitals

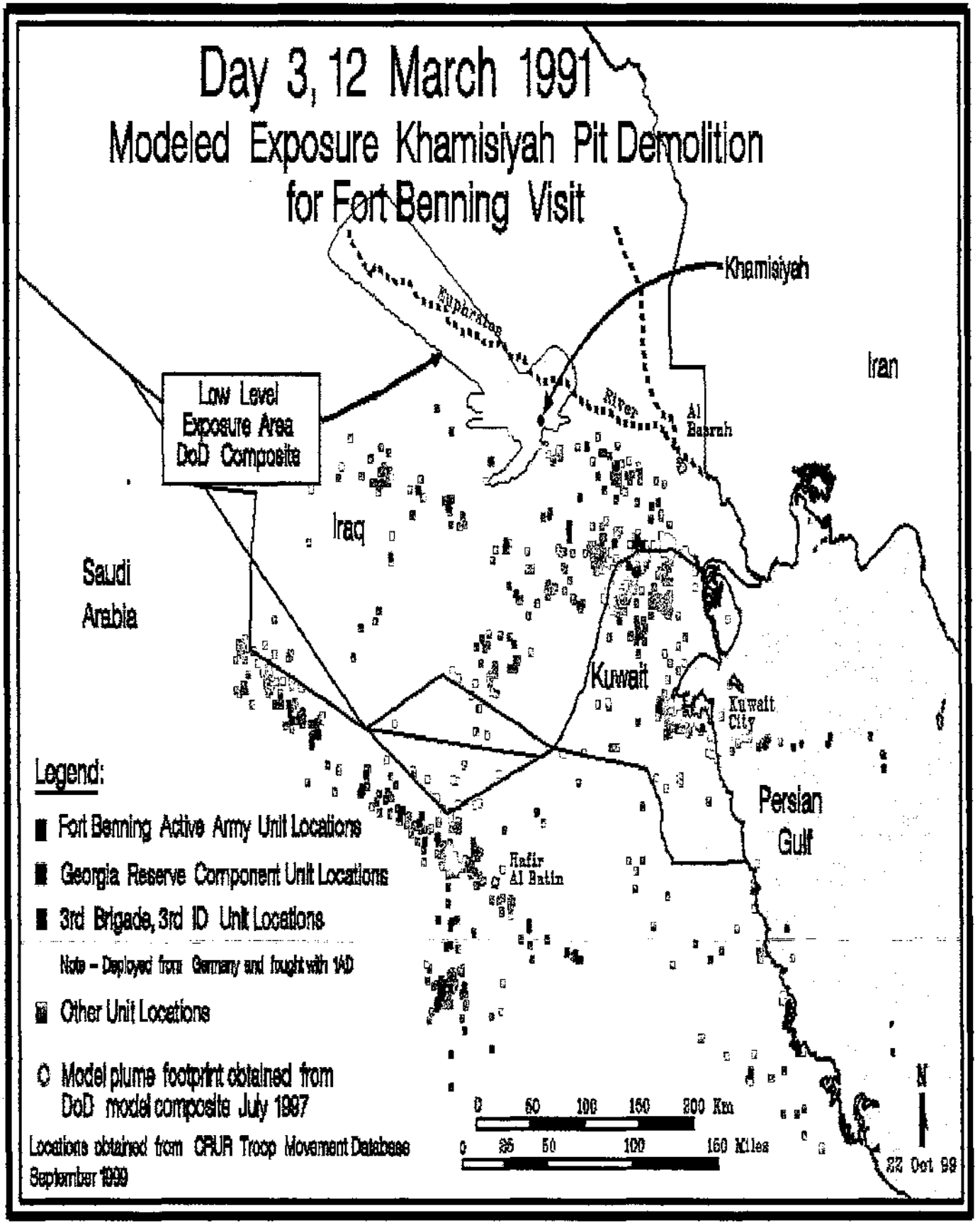
Possible Causes

- Normal disease rate
- New disease paradigm
- Research
- Black camel

Future Equipment

- Personal Information Carrier (PIC)
- Biological Integrated Detection System (BIDS)
- Automatic Chemical Agent Alarm (ACADA)
- Medic Cam - Tele medicine


Day 1, 10 March 1991
Modeled Exposure Khamisiyah Pit Demolition
for Fort Benning Visit
Khamisiyah
Euphrates River
Iran
Al Basrah
First Noticeable Effects Area DoD Composite
Iraq
Saudi Arabia
Low Level Exposure Area DoD Composite
Kuwait
Kuwait City
Persian Gulf
Hafir Al Batin
Legend:
Fort Benning Active Army Unit Locations
Georgia Reserve Component Unit Locations
3rd Brigade, 3rd ID Unit Locations
Note – Deployed from Germany and fought with 1AD
Other Unit Locations
Model plume footprint obtained from DoD model composite July 1997
Locations obtained from CRUR Troop Movement Database September 1999
0 50 100 150 200 Km
0 25 50 100 150 Miles
N
22 Oct 99


Day 3, 12 March 1991
Modeled Exposure Khamisiyah Pit Demolition
for Fort Benning Visit
Khamisiyah
Euphrates River
Tigris River
Iran
Low Level
Exposure Area
DoD Composite
Iraq
Saudi
Arabia
Kuwait
Kuwait
City
Persian
Gulf
Hafir
Al Batin
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N
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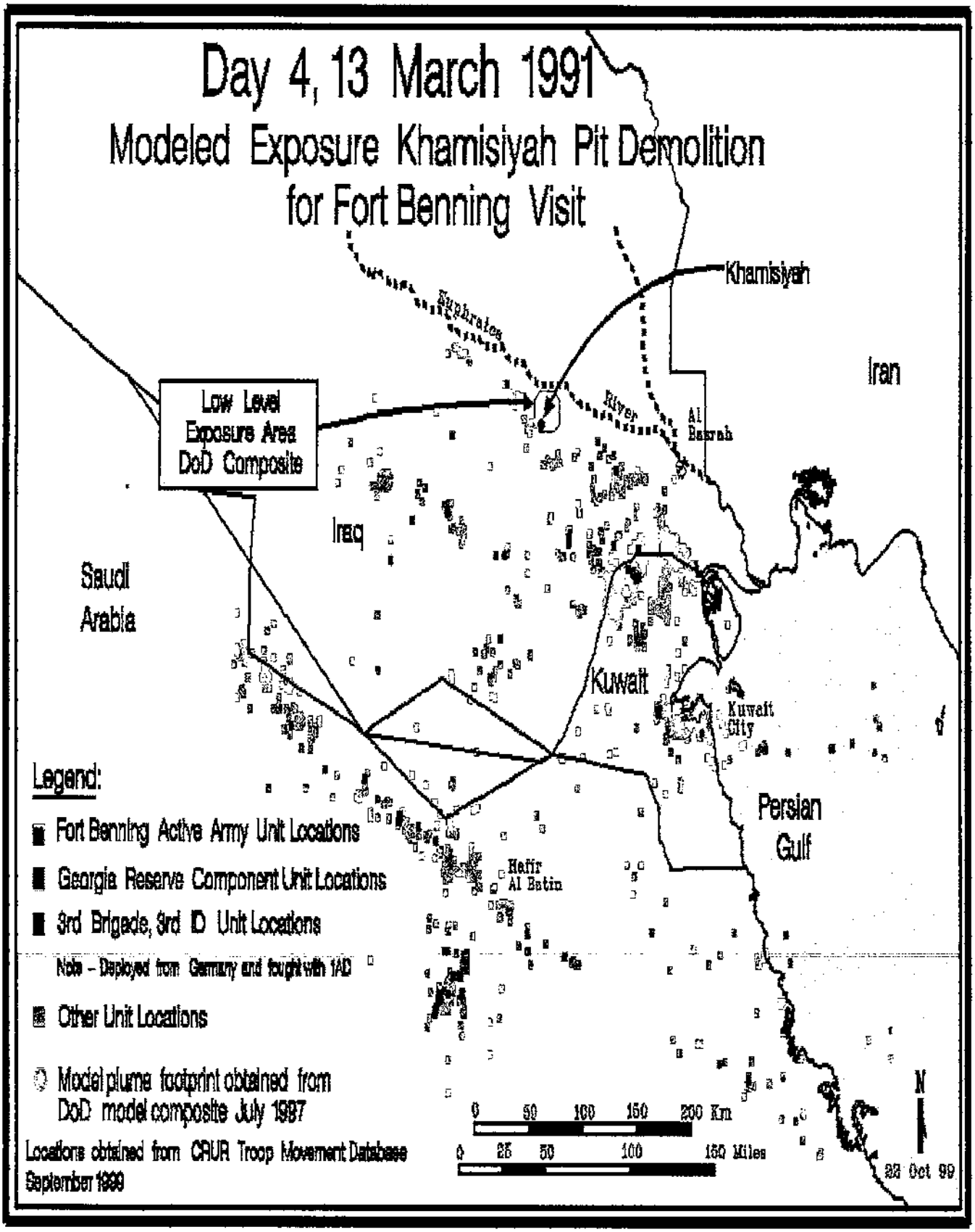
Day 4, 13 March 1991
Modeled Exposure Khamisiyah Pit Demolition
for Fort Benning Visit
Khamisiyah
Euphrates
River
Iran
Low Level
Exposure Area
DoD Composite
Al
Basrah
Iraq
Saudi
Arabia
Kuwait
Kuwait
City
Persian
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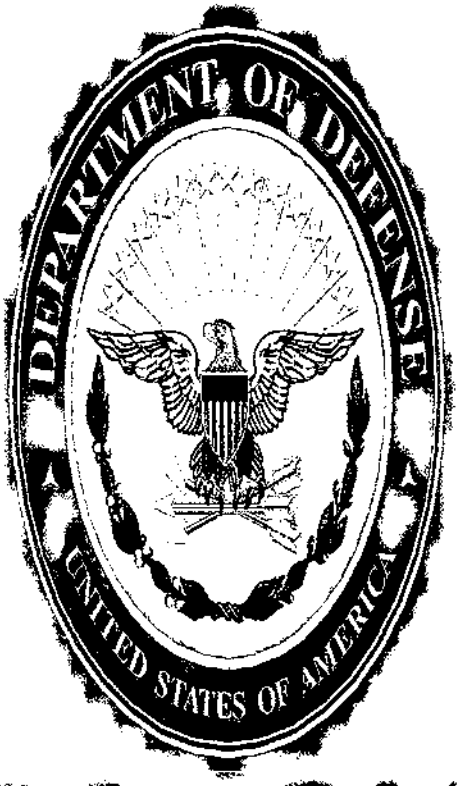
September 1999
0 50 100 150 200 Km
0 25 50 100 150 Miles
N
22 Oct 99

Summary

- Work continues: "leave no stone unturned"
- We rely on Gulf War veterans:
  - To give us leads
  - To check our accuracy
- We rely on today's force -- including you:
  - To ensure GW vets get proper testing and treatment
  - To apply lessons learned to the future

Office of the Special Assistant to the Secretary of Defense



for Gulf War Illnesses, Medical Readiness and Military Deployments

800-497-6261 fax 703-578-8501

email: brostker@gwillness.osd.mil

Briefing Overview

- Mission Statement
- The Gulf War
- Post Gulf War Issues
- Searching for answers
- Lessons Learned
- Force Health Protection
- Bottom Line
- Obtaining help and information

Vision of Special Assistant for Gulf War Illnesses, Medical Readiness, and Military Deployments

- The Department of Defense recognizes the right of those involved in deployments to receive information that enables them to make informed judgements about their health.
- We will develop and disseminate such information in a relevant and timely fashion.
- We will work with others in the Defense Department to incorporate lessons from previous deployments to foster the well-being of deployed forces.

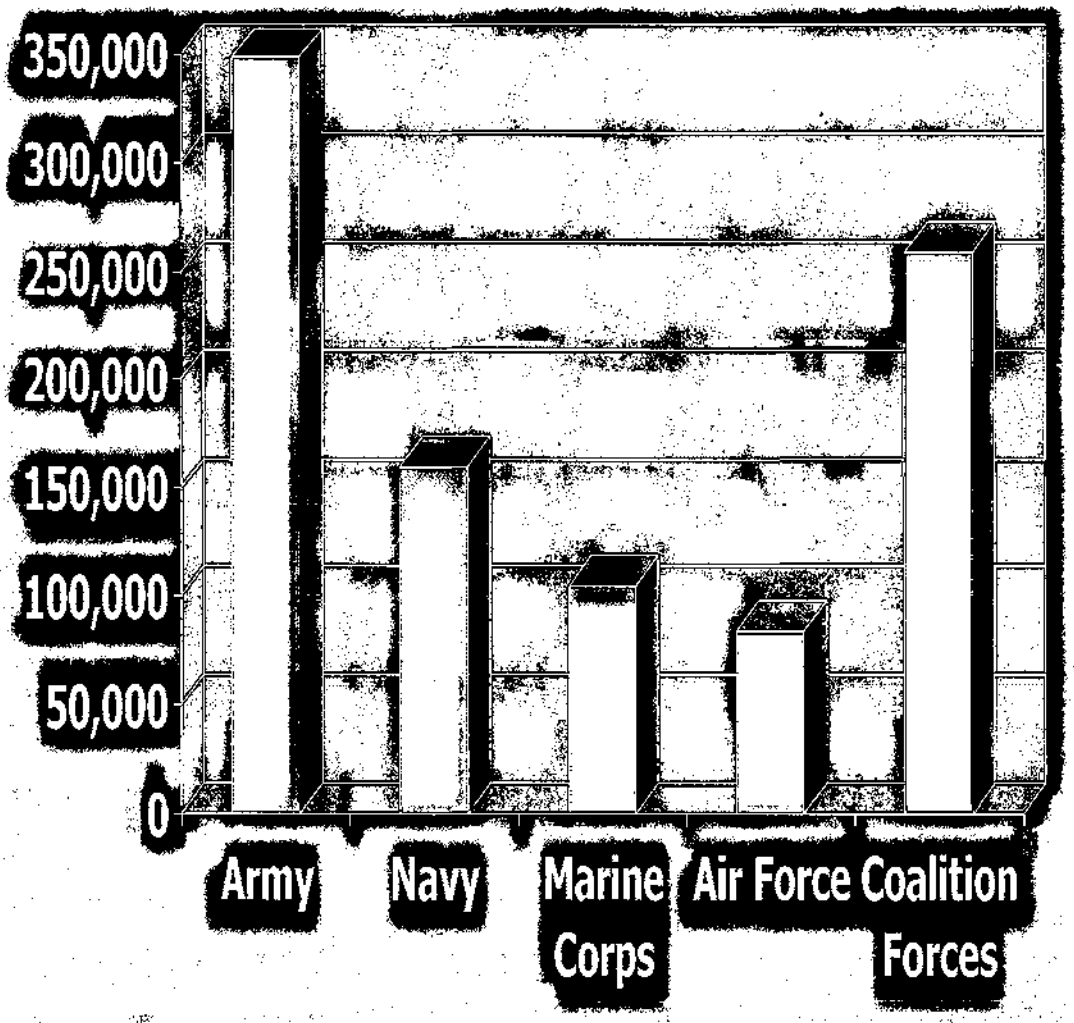
Gulf War Illnesses Mission

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DOD adopts doctrine, policy and procedures to reduce risks for troops in the future.

Why Should I Care

- Lessons from the Gulf War about dirty battlefields
- You must protect yourself against hazards
- You will be leading Gulf War vets
- You are responsible for force protection
  - What are the dangers of the dirty battlefield?
  - How good are our detectors and MOPP gear?
  - How do we determine if we are exposed?
  - Will attacking enemy CW/BW stockpiles put us at risk?

Gulf War Theater Forces



697,000 U.S. service members

Office of the Special Assistant

1 in 7 Veterans Reported Symptoms Since The War

Most frequently reported symptoms

- Joint pain
- Headaches
- Sleep disorders
- Depression
- Fatigue
- Memory loss
- Rash
- Muscle pain

Communication Breakdown

- Veterans with real health problems
- Healthcare professionals unable to provide answers
- Government slow to recognize the reality of problems

Confounding Issues

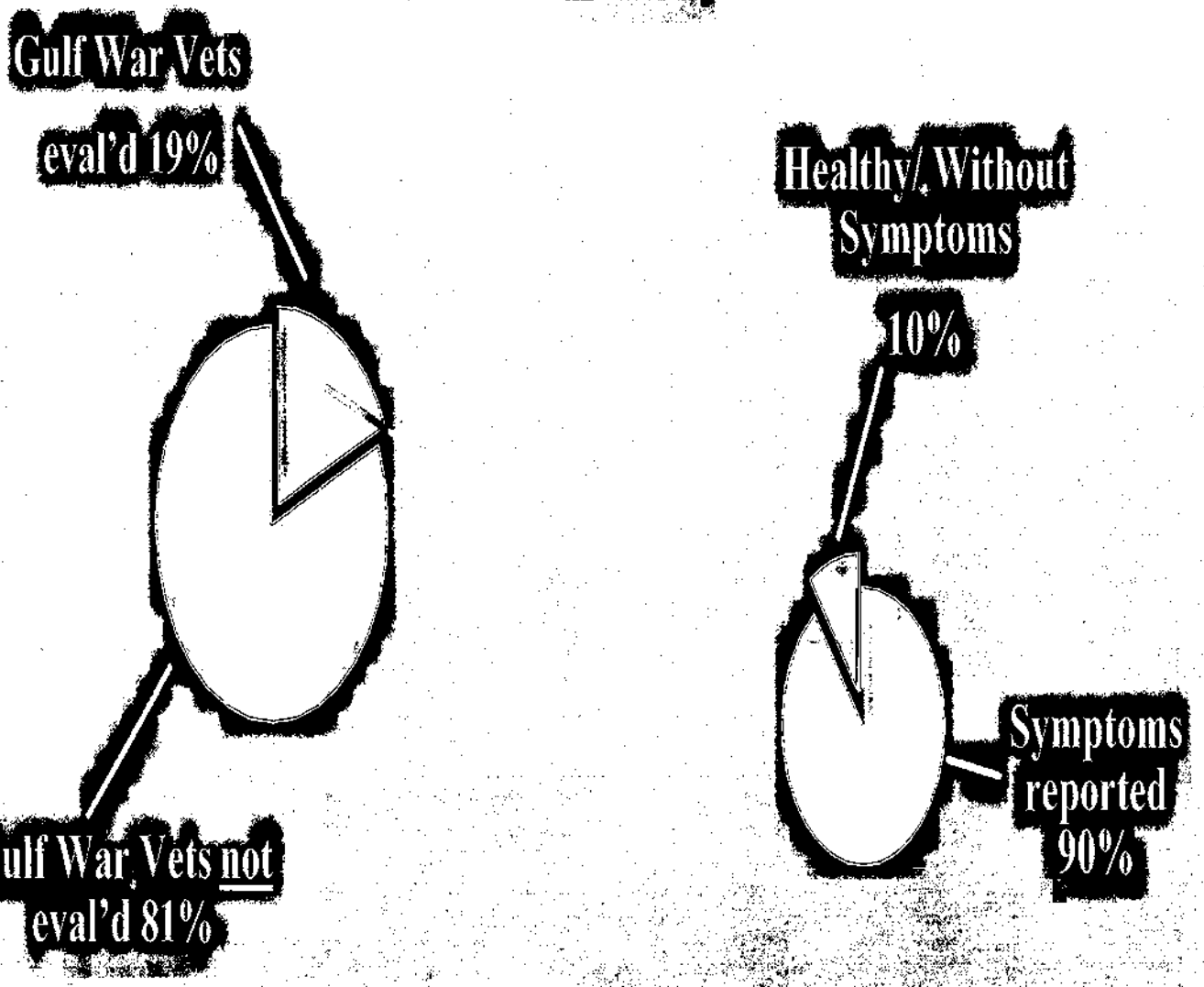
- No clustering
- No symptom consistency; variable onset
- No new disease or links between exposures and symptoms
- No long term study

Taking Care of Service Members

- **DoD Comprehensive Clinical Evaluation Program**
  - Gulf War vets (active, Guard/Reserve, retired)
  - Active service member deployed to SWA since war ended
  - Family members
  - Civilian employees
- **VA Persian Gulf Registry**
  - Gulf War vets (left service prior to retirement)
  - Service members deployed to SWA and left service before retirement
  - Evaluation for family members
- **Available to *all* service members deploying to South West Asia**
  - Most people evaluated can be treated

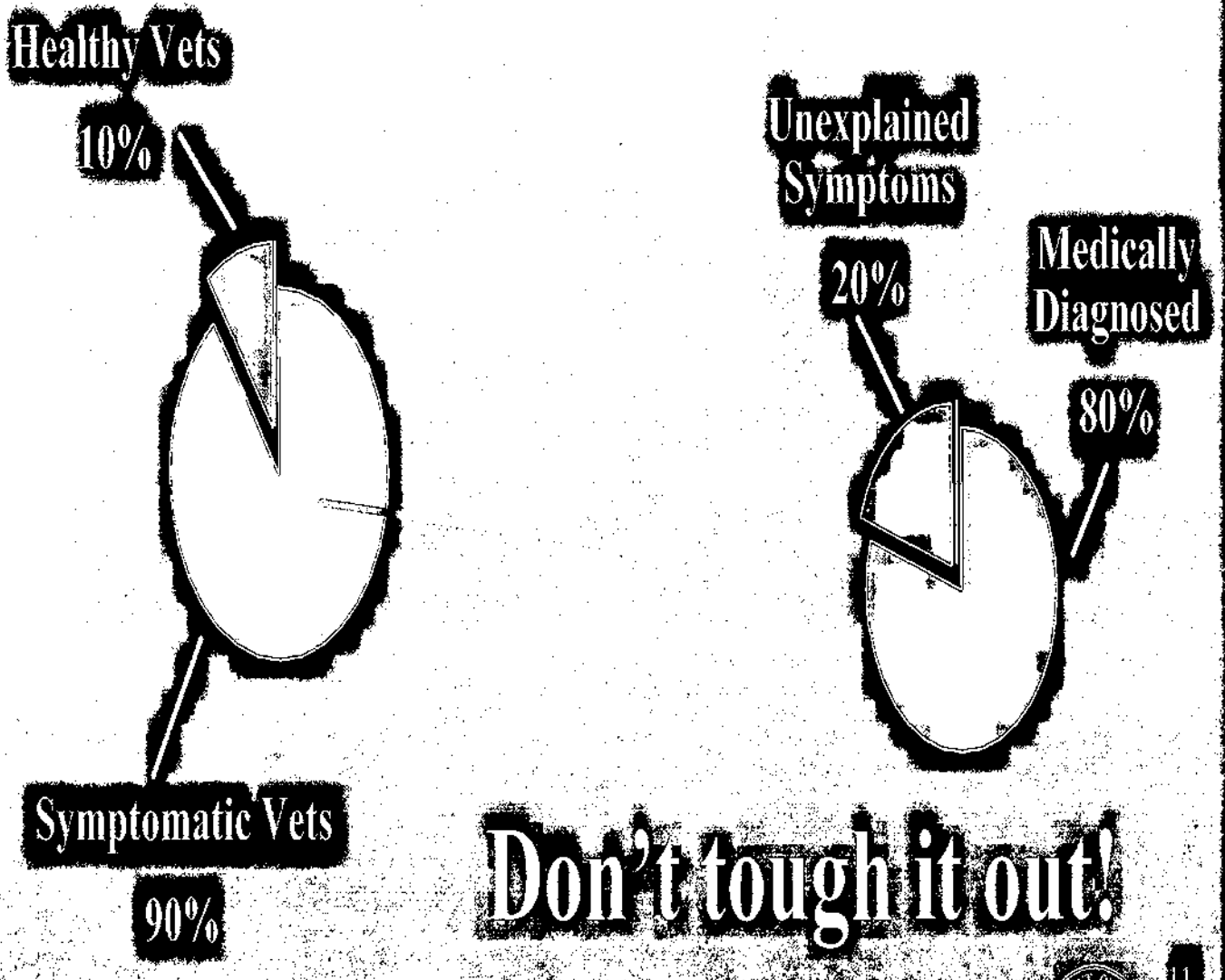
Don't Tough It Out!

Evaluation Distribution of 697,000 CCEP/VA



Diagnosis Distribution of Evaluated Veterans

CCEP/VA



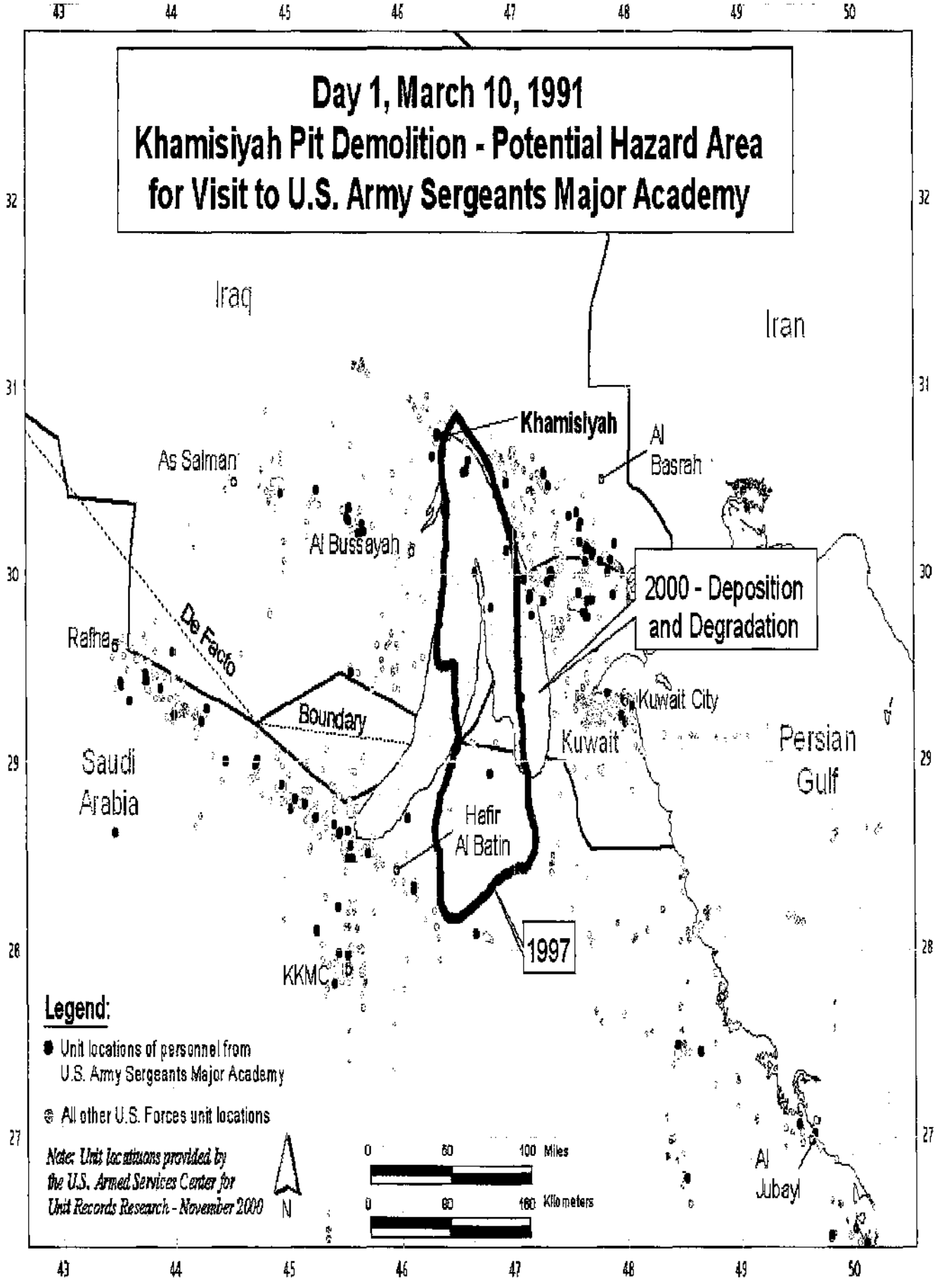
Don't tough it out!

OSAGWI Investigations

- Chemical/biological warfare:
  - Chemical warfare agent - Khamisiyah incident
    - 99,000 vets notified in 1997
- Environmental:
  - Depleted uranium (DU), Oil well fires, Pesticides, CARC Paint, Particulates
    - Science doesn't support DU or Oil Well fires as causes
    - Still examining pesticides
- Medical issues:
  - Vaccines, PB, records, policy
- Persian Gulf War Veterans Coordinating Board-Scientific Research
  - 190+ studies sponsored by DoD, HHS & DVA
  - Science shows no exposure cause or effect relationship yet!

Why Remodel 1997 Work On The Khamisiyah Pit Release?

- Improved models as a result of scientific review
- Both dispersion models consider deposition for each agent modeled
- Applied agent degradation where known
- CIA source terms revised to lower amounts
- Toxicity of cyclosarin included
- Improved troop location data
- Depict where M8A1 detectors would have alarmed


Day 1, March 10, 1991
Khamisiyah Pit Demolition - Potential Hazard Area
for Visit to U.S. Army Sergeants Major Academy
43
44
45
46
47
48
49
50
32
31
30
29
28
27
Iraq
Iran
Khamisiyah
Al Basrah
As Salman
Al Bussayah
2000 - Deposition and Degradation
Rafha
De Facto
Boundary
Saudi Arabia
Kuwait City
Kuwait
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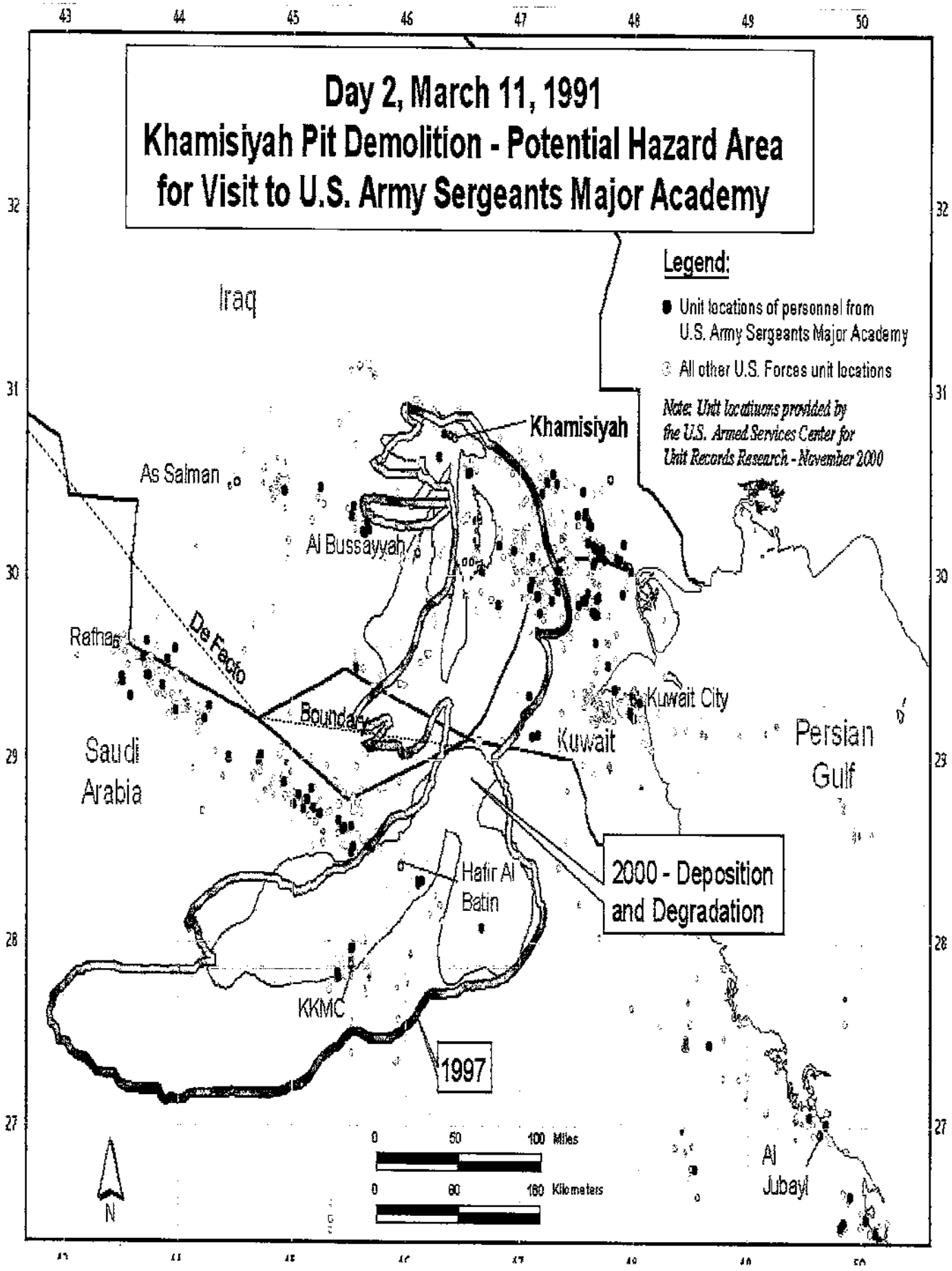
Hafir Al Batin
1997
KKMC
Al Jubayl
Legend:
Unit locations of personnel from U.S. Army Sergeants Major Academy
All other U.S. Forces unit locations
Note: Unit locations provided by the U.S. Armed Services Center for Unit Records Research - November 2000
N
0 50 100 Miles
0 80 160 Kilometers


Day 2, March 11, 1991
Khamisiyah Pit Demolition - Potential Hazard Area
for Visit to U.S. Army Sergeants Major Academy
Legend:
Unit locations of personnel from U.S. Army Sergeants Major Academy
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Iraq
Khamisiyah
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De Facto Boundary
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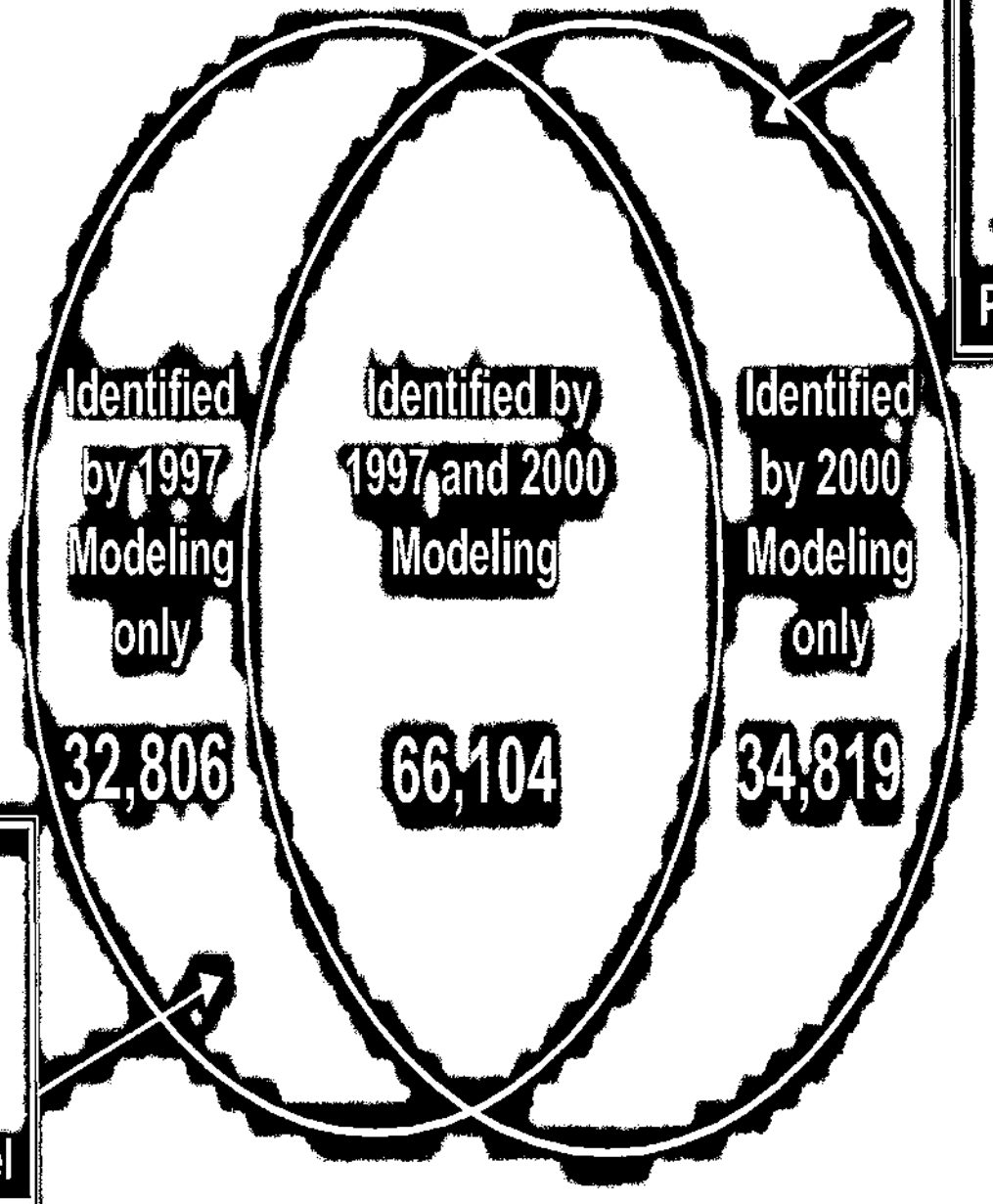
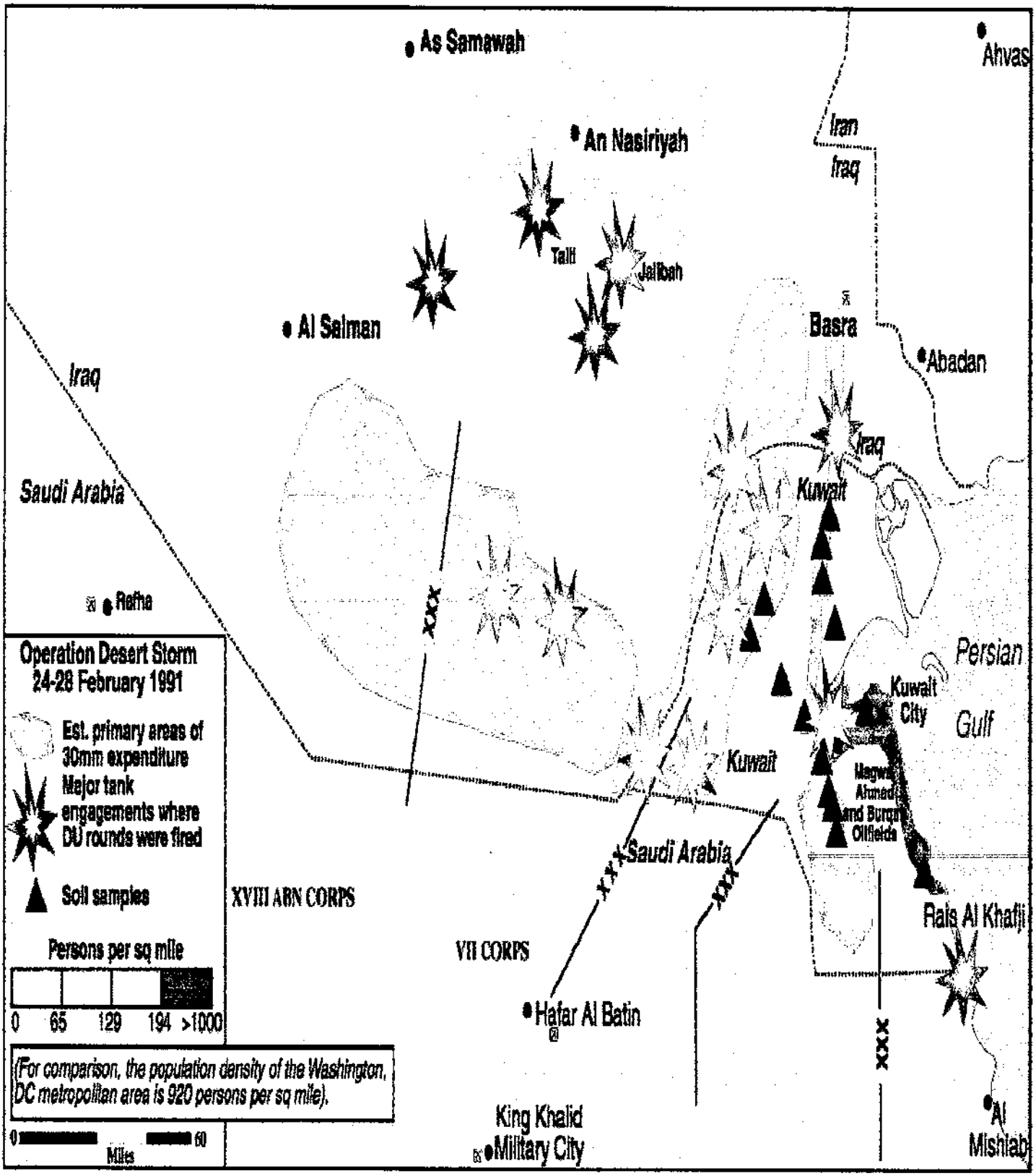
Kuwait City
Kuwait
Persian Gulf
Hafir Al Batin
2000 - Deposition and Degradation
KKMC
1997
Al Jubayl
0 50 100 Miles
0 80 160 Kilometers
N
43 44 45 46 47 48 49 50
32 31 30 29 28 27

1997-2000 Khamisiyah Possible Exposure Population



Primary Areas of DU Expenditure



Gulf War Investigation Results

- Poor intelligence about Iraq's CW/BW weapons
- Not enough vaccines and no explanation given
- Limited environmental survey
- Information about nerve agent pre-treatment (PB) wasn't given to troops
- Inadequate training about DU or CW detectors
  - Training could have averted unnecessary exposure to DU and anxiety resulting from false alarms
- *Veterans re-deployed and left service without thorough medical exam or debrief*

What the Gulf War Experience Taught Us

- Commanders need to have *greater sensitivity* to non-traditional risks on the modern battlefield
- The demands of Force Health Protection require a *proactive approach*
- The key to maintaining trust and credibility with servicemembers and their families is *responsive communication*
- Commanders should be *risk managers*, rather than consequence managers

Leaders Must Manage Risk to Protect Health

Applying Lessons Learned

You

- Train self and others to recognize and avoid hazards
- Improve feedback and cross talk
- You are your own best health advocate

Your Unit

- CW/BW detection:earlier with fewer false positives
- Create, relate and save operational, NBC, and medical records
- Adapt to reduce risks and train to reduce future risks such as DU
- Debrief to explain what happened
- Monitor service members' health & environment

Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Collect pre-deployment blood sample
- Verify HIV test is current
- Verify Immunizations up to date
- Verify current physical exam
- Complete Health questionnaire

Deployment

- Routine disease/injury reporting
- Forward medical laboratory
- Immunization tracking
- Environmental monitoring

Post Deployment

- Collect blood sample
- Medical debriefs
- Complete health questionnaire
- Screening exams as needed

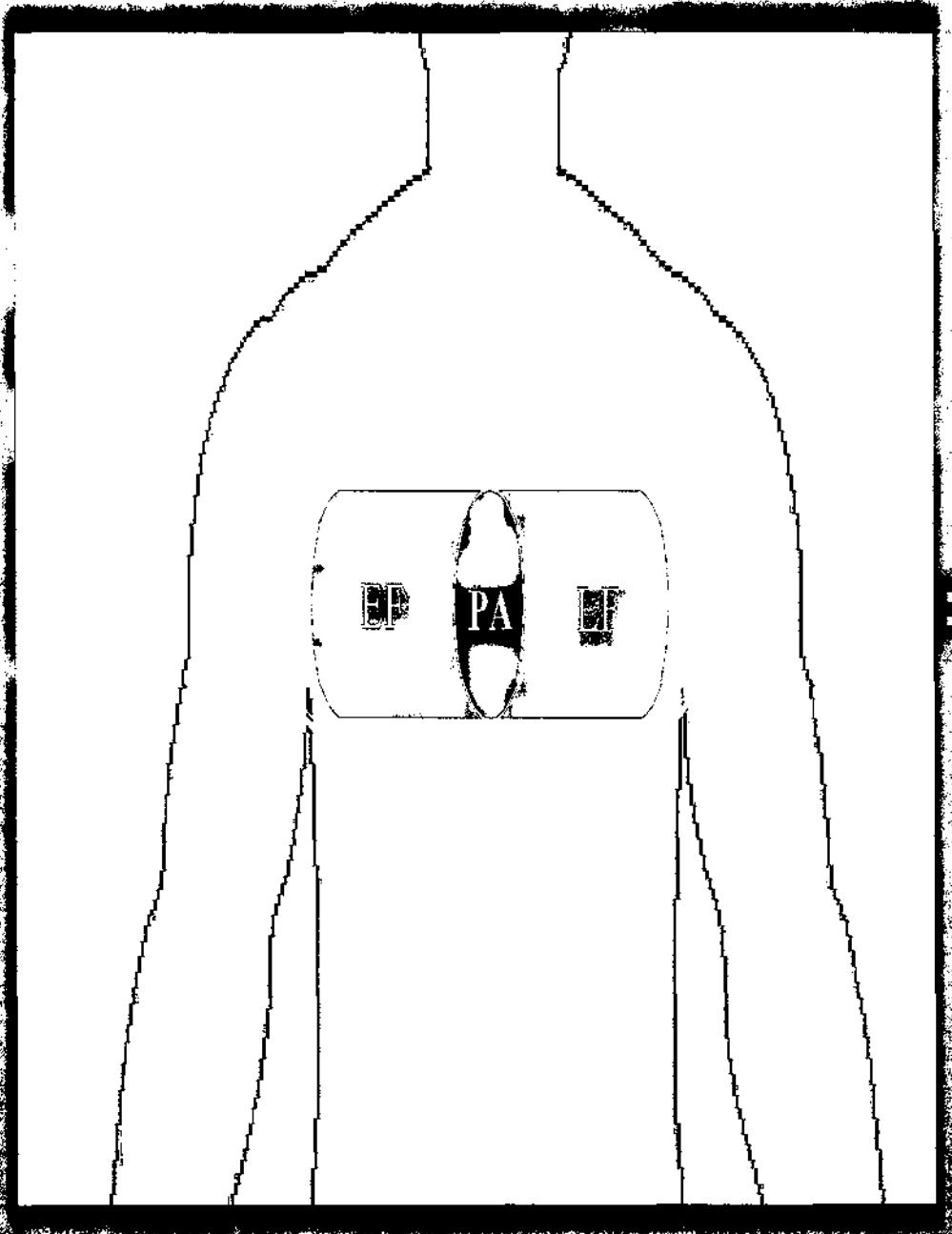
You are your own best health advocate!

Anthrax

- Inhalation anthrax is deadly
- Biological warfare agent of choice:
  - Cheap and easy to produce
  - Can be dispersed in air by a variety of methods
  - Odorless, colorless, tasteless, difficult to detect
  - Flu-like symptoms early, rapid deterioration, and death
- MOPP 4 prevents exposure
- Antibiotics work before symptoms appear

Vaccination against anthrax is critical for your protection

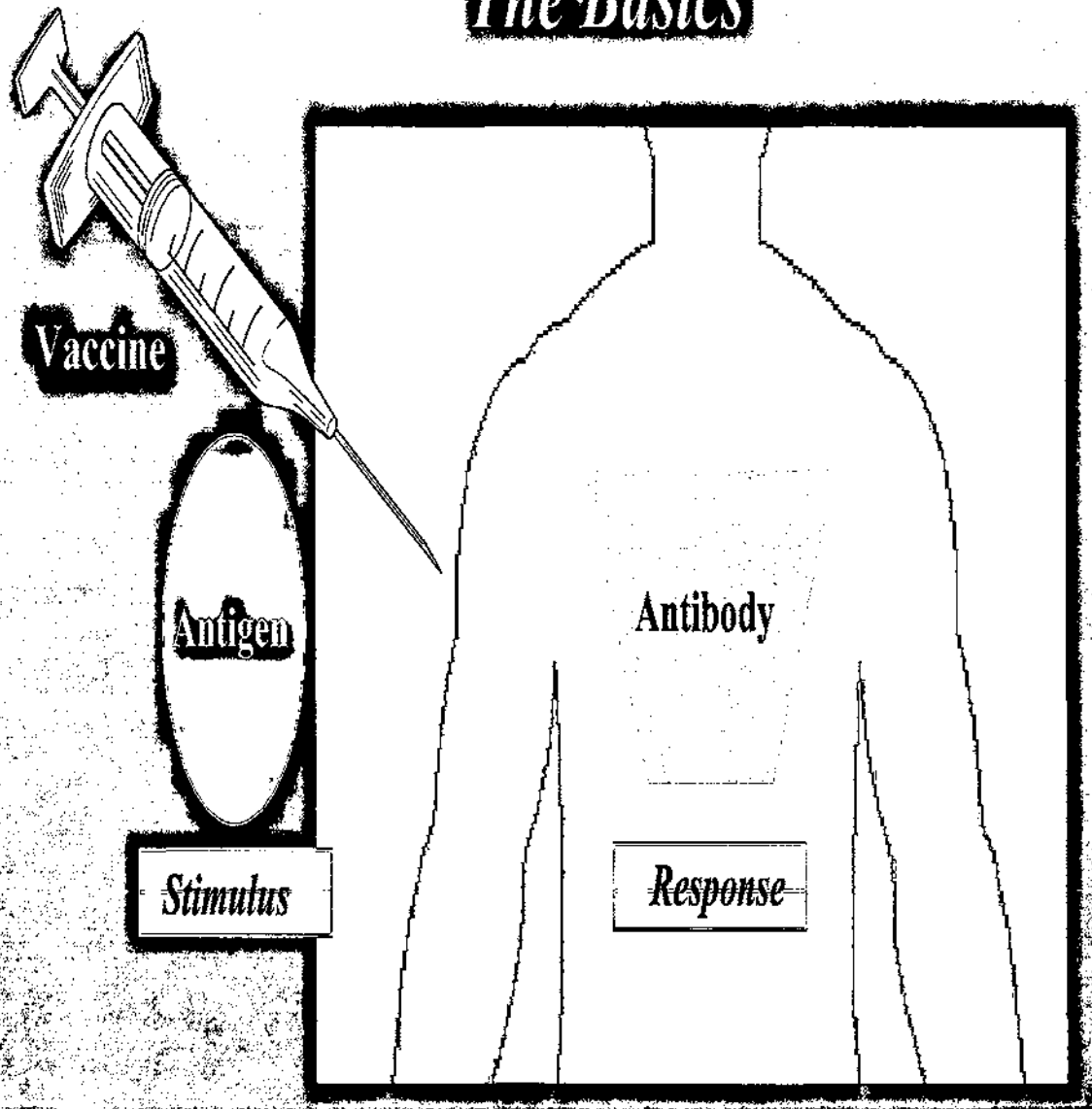
ANTHRAX BACTERIA ATTACK



= Death

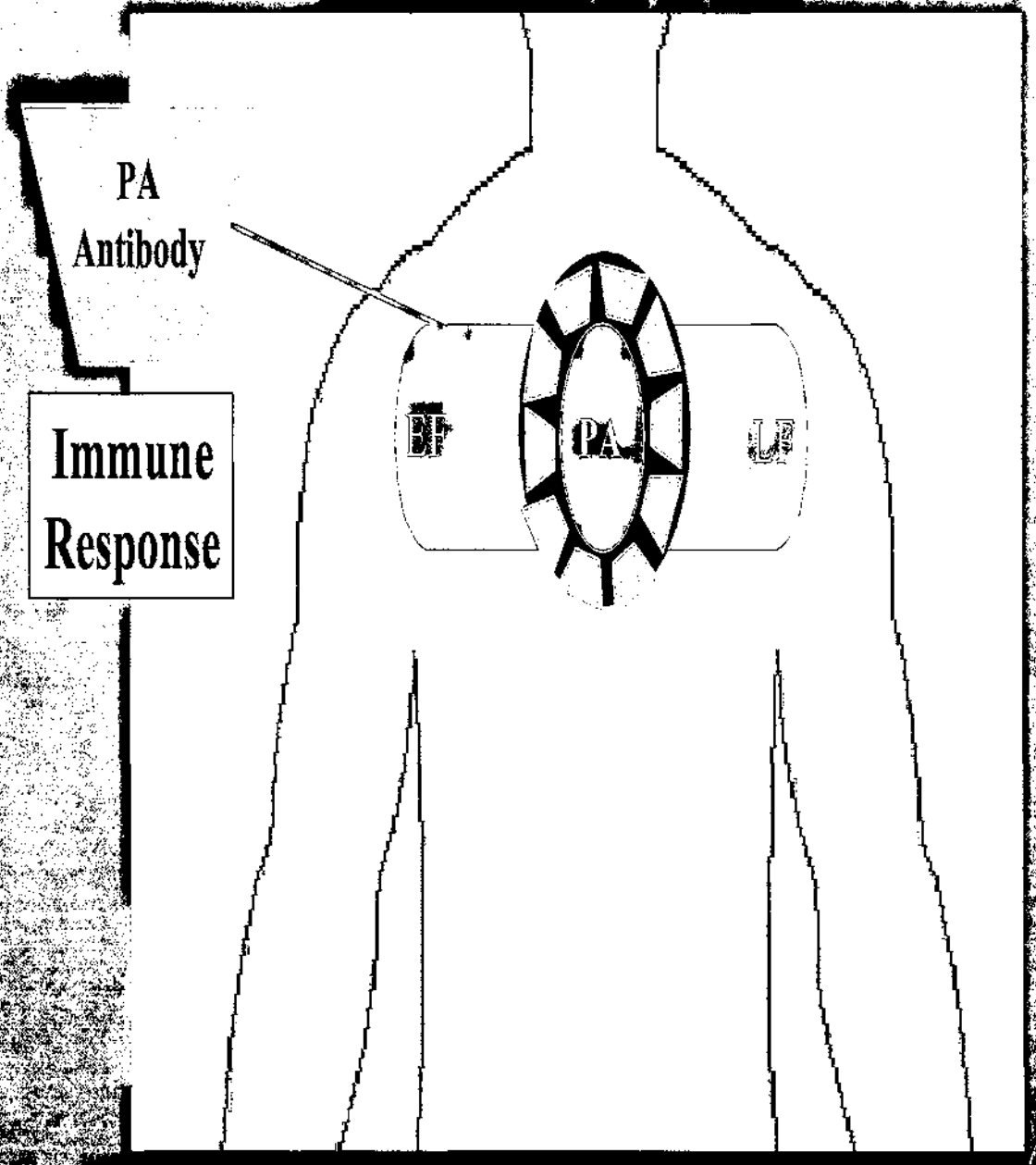
IMMUNE SYSTEM ACTIVATION BY VACCINE

The Basics



AFTER ANTHRAX VACCINE

Antibodies at Work



Anthrax Vaccine Program

- Licensed by the FDA since 1970
- Dosing schedule is six doses over 18 months
  - 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster
- Shortages in stockpiled doses require temporary slowdown of AVIP
  - No new vaccine available from renovated facility until FDA approves [new vaccine lots] safety and effectiveness
  - Vaccinations continue for service members assigned or deployed at least 30 days in highest threat areas
  - Next scheduled doses for those not in high threat areas will be deferred until sufficient doses are available

(877) GET-VACC DSN: 761-5101

www.anthrax.osd.mil

www.aviationmedicine.com

Pyridostigmine Bromide

- Threat - Soman is deadly nerve agent
- PB is the only known pretreatment against Soman.
  - Auto injectors alone will not save you
- Issues have been raised about PB
  - Further research is ongoing
- Only President can authorize its use without informed consent

Myths versus Reality

Cover up	Open process & oversight
Not listening	Solicit eyewitness reports
Destroy records	Found missing records
20,000 veterans dead	6,686 veterans dead
No assistance to vets	Evaluation and care
"Syndrome"	Normal spectrum of illnesses known
CW or DU cause	Evaluating many possible causes
Brass doesn't care	Force Protection efforts
	Tough choices
	Cultural changes

Bottom Line

- Lessons learned from the Gulf War affect today's doctrine and deployments
- Leaders must manage risk to protect health
- Everyone is responsible for force protection
- You are your own best health advocate
- Vets should not tough it out; get examined
- Vaccination against anthrax protects you

Obtaining Help and Information

GWIMRMD Veterans' Hotline
800-497-6261

Comprehensive Clinical Evaluation Program
800-796-9699

Veterans Affairs Persian Gulf Registry Program
800-749-8387

http://www.gulflink.osd.mil

Office of the Special Assistant to the Secretary of Defense

for Gulf War Illnesses, Medical Readiness and Military Deployments

800-497-6261 fax 703-578-8501

email: brostker@gwillness.osd.mil

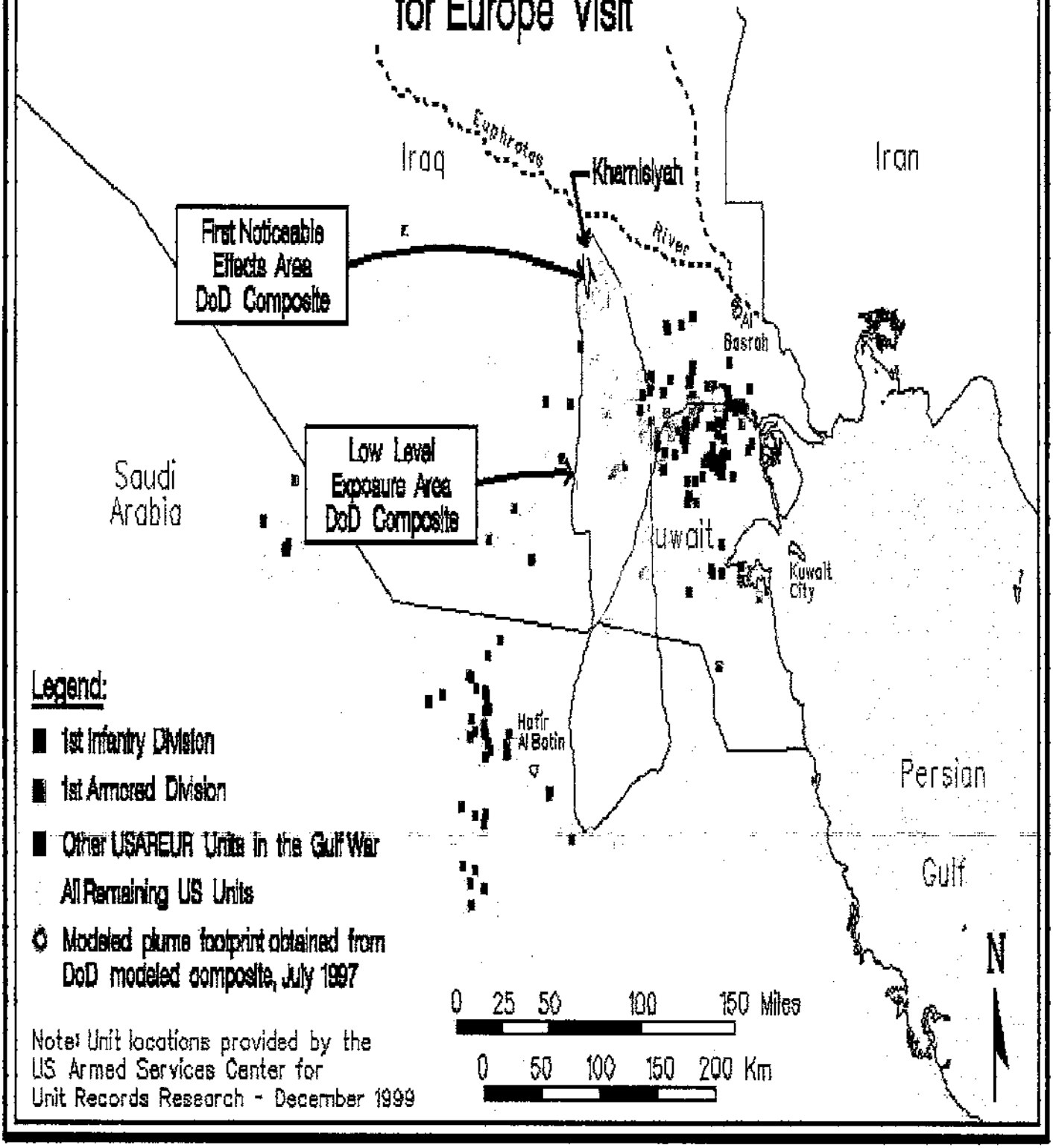
Back-up Slides

A National Effort

- **OVERSIGHT:** Presidential, 7 Congressional Committees, VSOs, Veterans, the Media
- **INVESTIGATIONS:** IGs, GAO, SIU
- **DoD:** ASDs, Special Assistants, DIA, the Surgeons General
- **OUTSIDE AGENCIES:** CIA, VA, HHS, GWVCB, CDC
- **DECLASSIFICATION:** CIA, DIA, and the Services
- **TECHNICAL PROJECTS:** Dugway, Edgewood, Picatinny, CHPPM, Think tanks, outside experts

Day 1, 10 March 1991

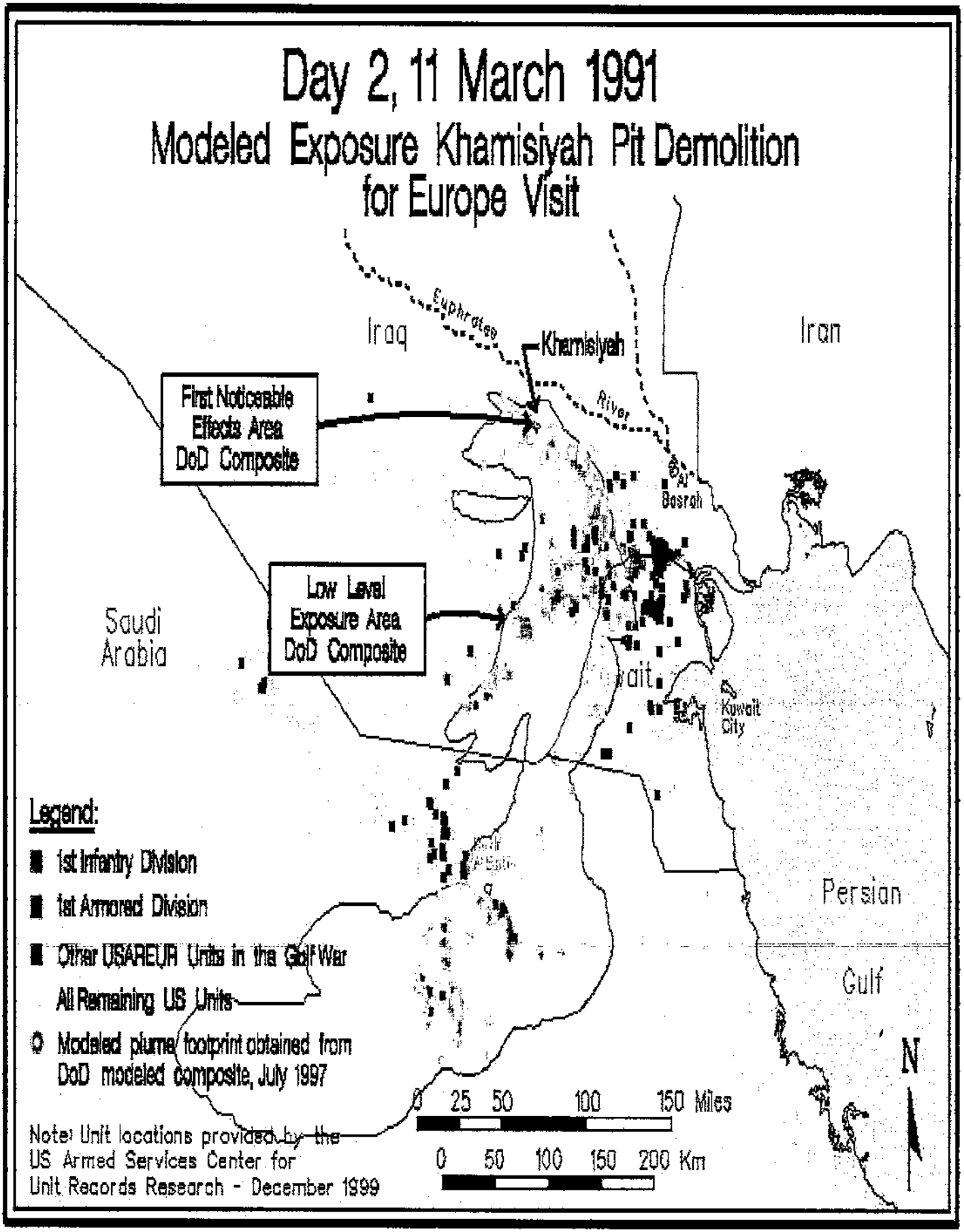
Modeled Exposure Khamisiyah Pit Demolition for Europe Visit



Legend:

- 1st Infantry Division
- 1st Armored Division
- Other USAREUR Units in the Gulf War
- All Remaining US Units
- Modeled plume footprint obtained from DoD modeled composite, July 1997

Note: Unit locations provided by the US Armed Services Center for Unit Records Research - December 1999


Day 2, 11 March 1991
Modeled Exposure Khamisiyah Pit Demolition for Europe Visit
Iraq
Khamisiyah
Iran
Euphrates River
First Noticeable Effects Area DoD Composite
Low Level Exposure Area DoD Composite
Al Basrah
Saudi Arabia
Kuwait City
Persian Gulf
N
Legend:
1st Infantry Division
1st Armored Division
Other USAREUR Units in the Gulf War
All Remaining US Units
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0 25 50 100 150 Miles
0 50 100 150 200 Km
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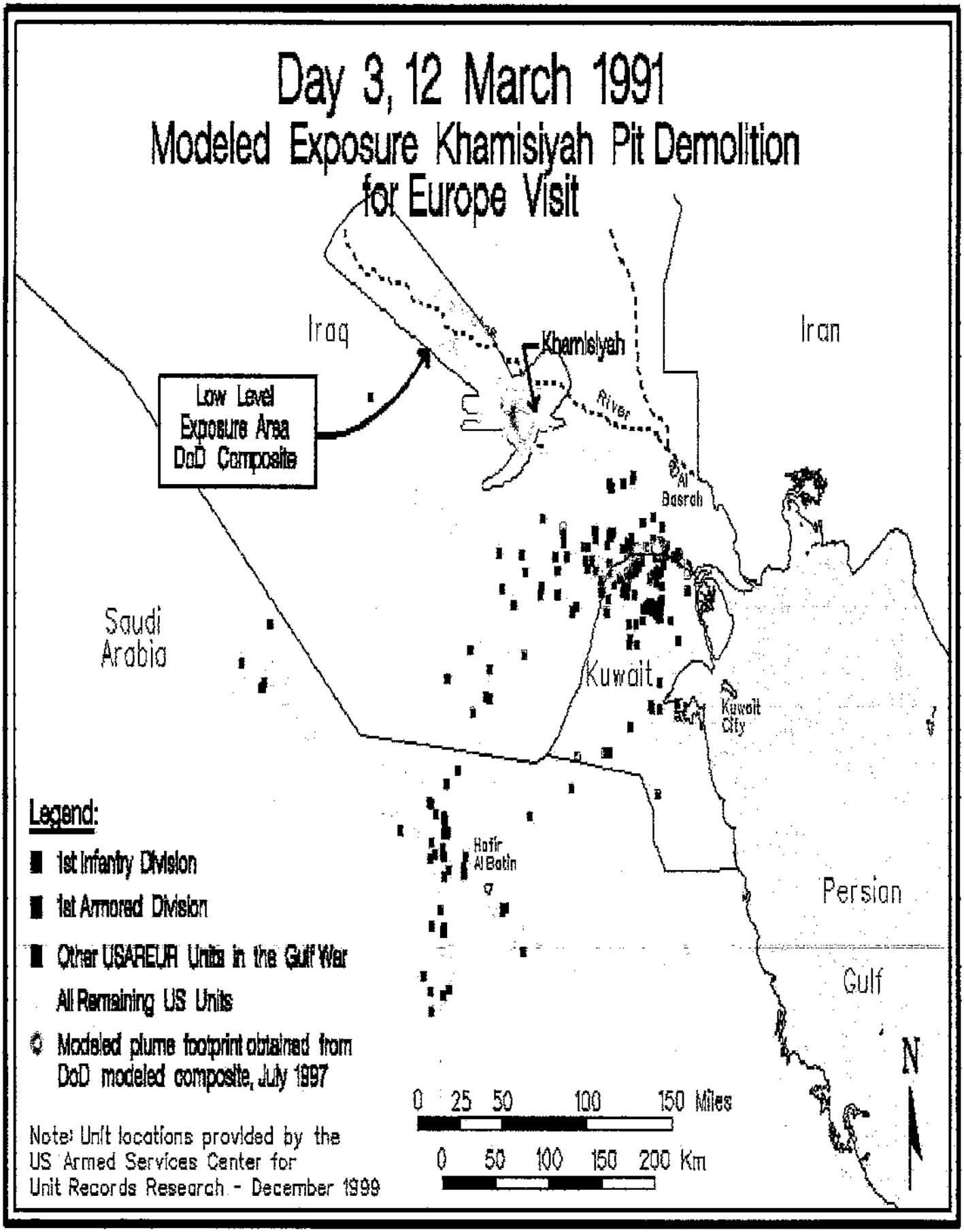
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Iraq
Iran
Khamisiyah
River
Low Level Exposure Area DoD Composite
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Kuwait
Kuwait City
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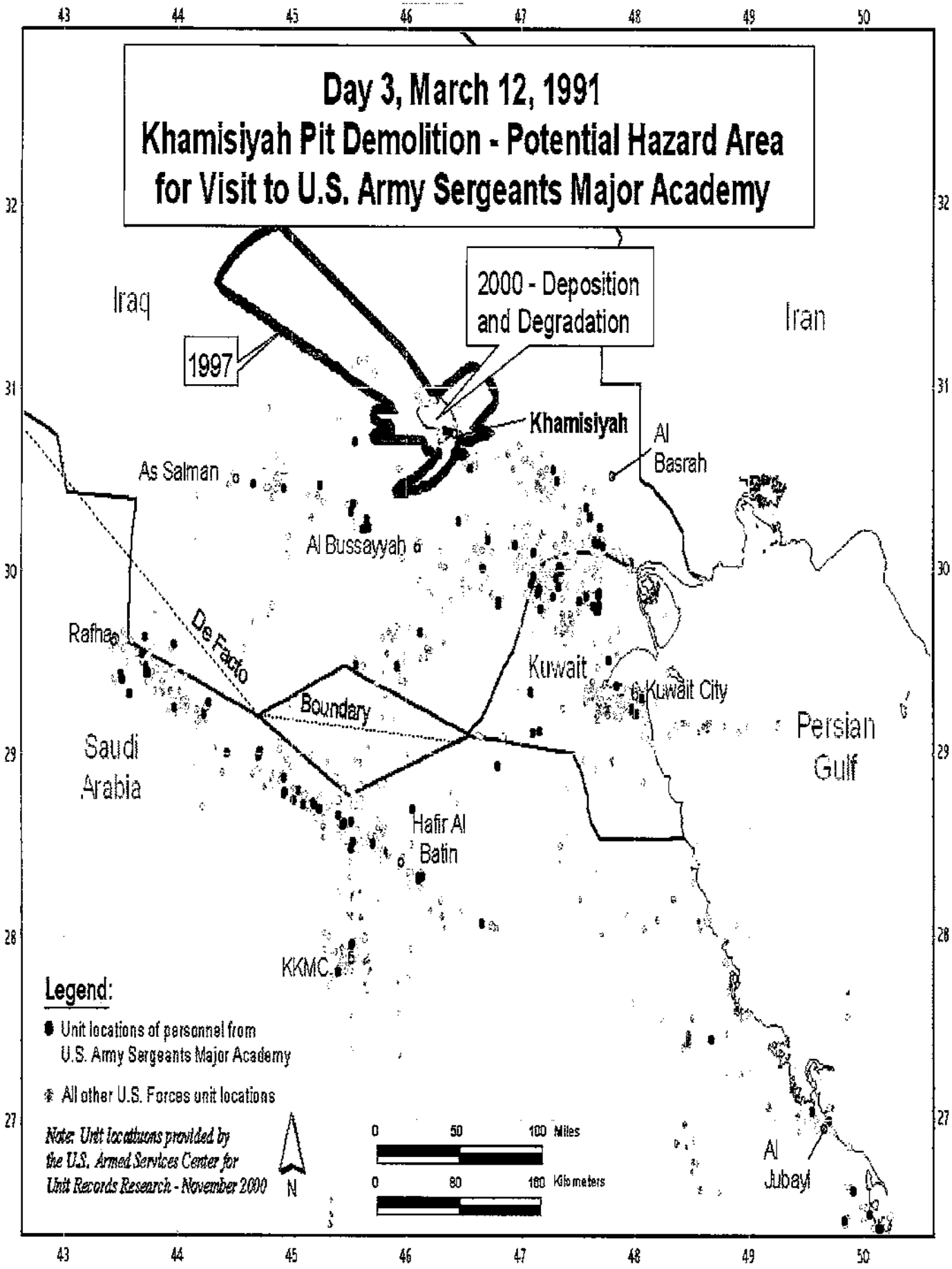
Day 3, March 12, 1991
Khamisiyah Pit Demolition - Potential Hazard Area
for Visit to U.S. Army Sergeants Major Academy
2000 - Deposition and Degradation
1997
Iraq
Iran
Khamisiyah
Al Basrah
As Salman
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All other U.S. Forces unit locations
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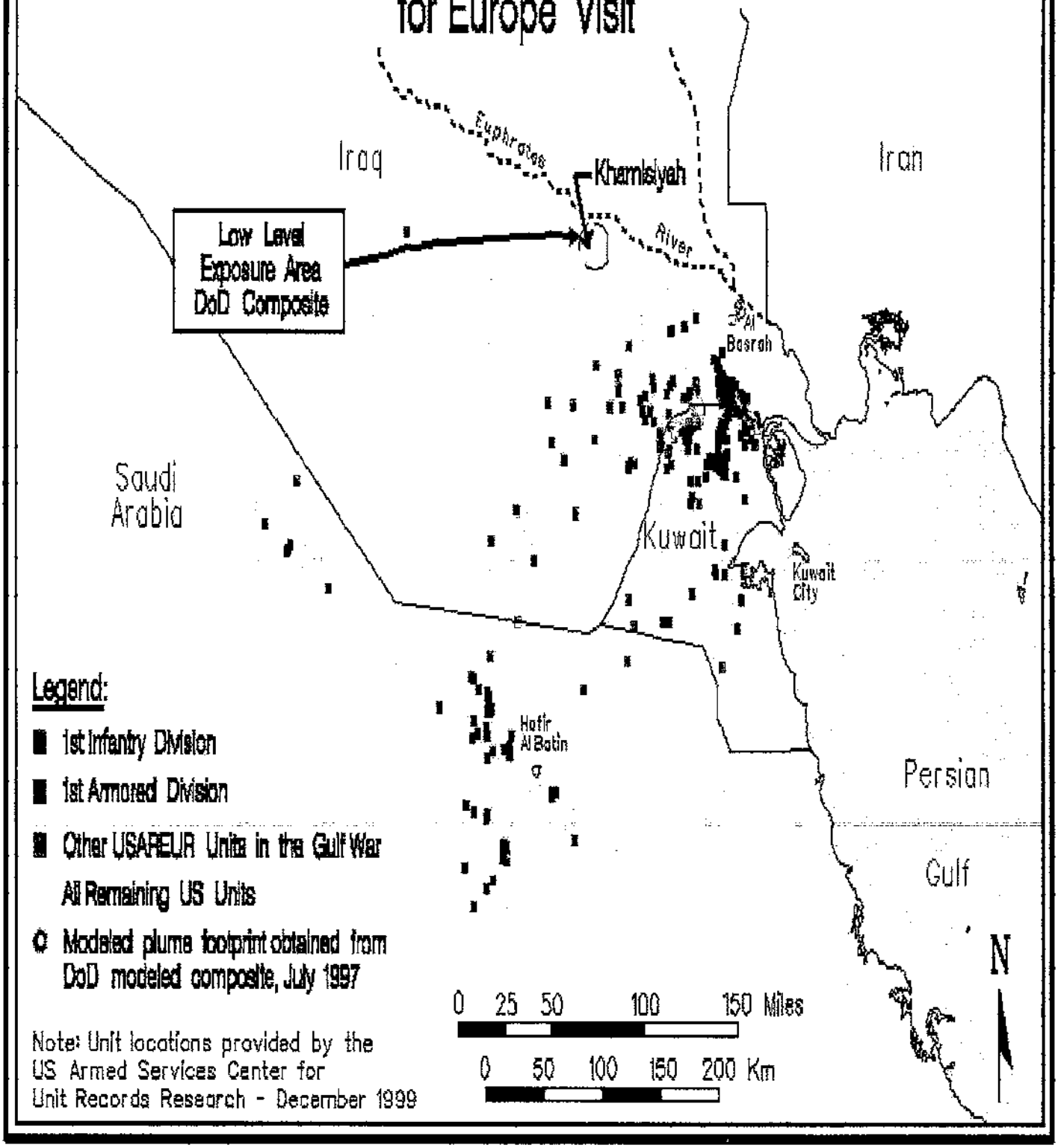
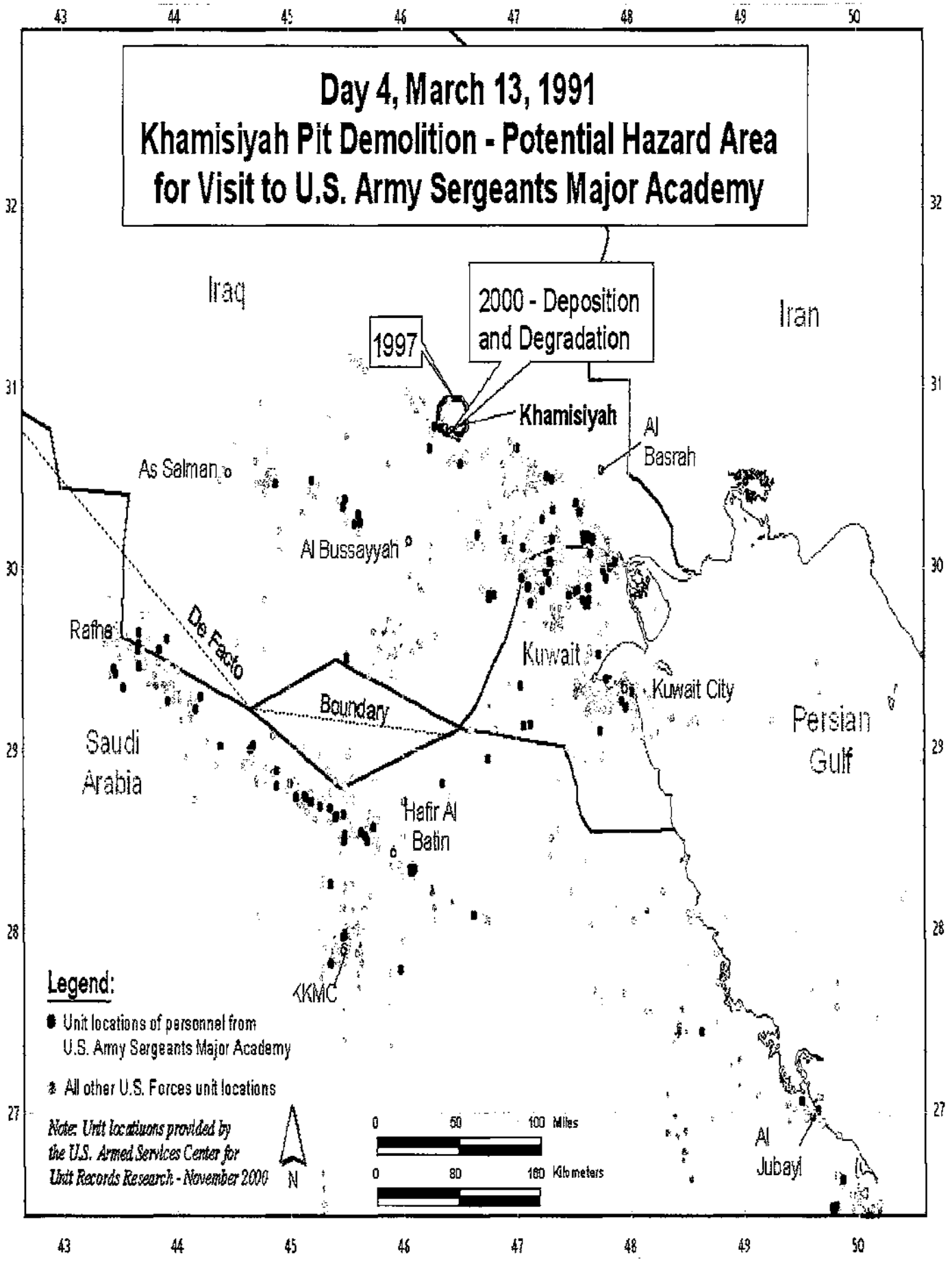
N
0 50 100 Miles
0 80 160 Kilometers
43 44 45 46 47 48 49 50
32 31 30 29 28 27

Day 4, 13 March 1991

Modeled Exposure Khamisiyah Pit Demolition for Europe Visit




Day 4, March 13, 1991
Khamisiyah Pit Demolition - Potential Hazard Area
for Visit to U.S. Army Sergeants Major Academy
Iraq
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1997
2000 - Deposition and Degradation
Khamisiyah
Al Basrah
As Salman
Al Bussayyah
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Kuwait
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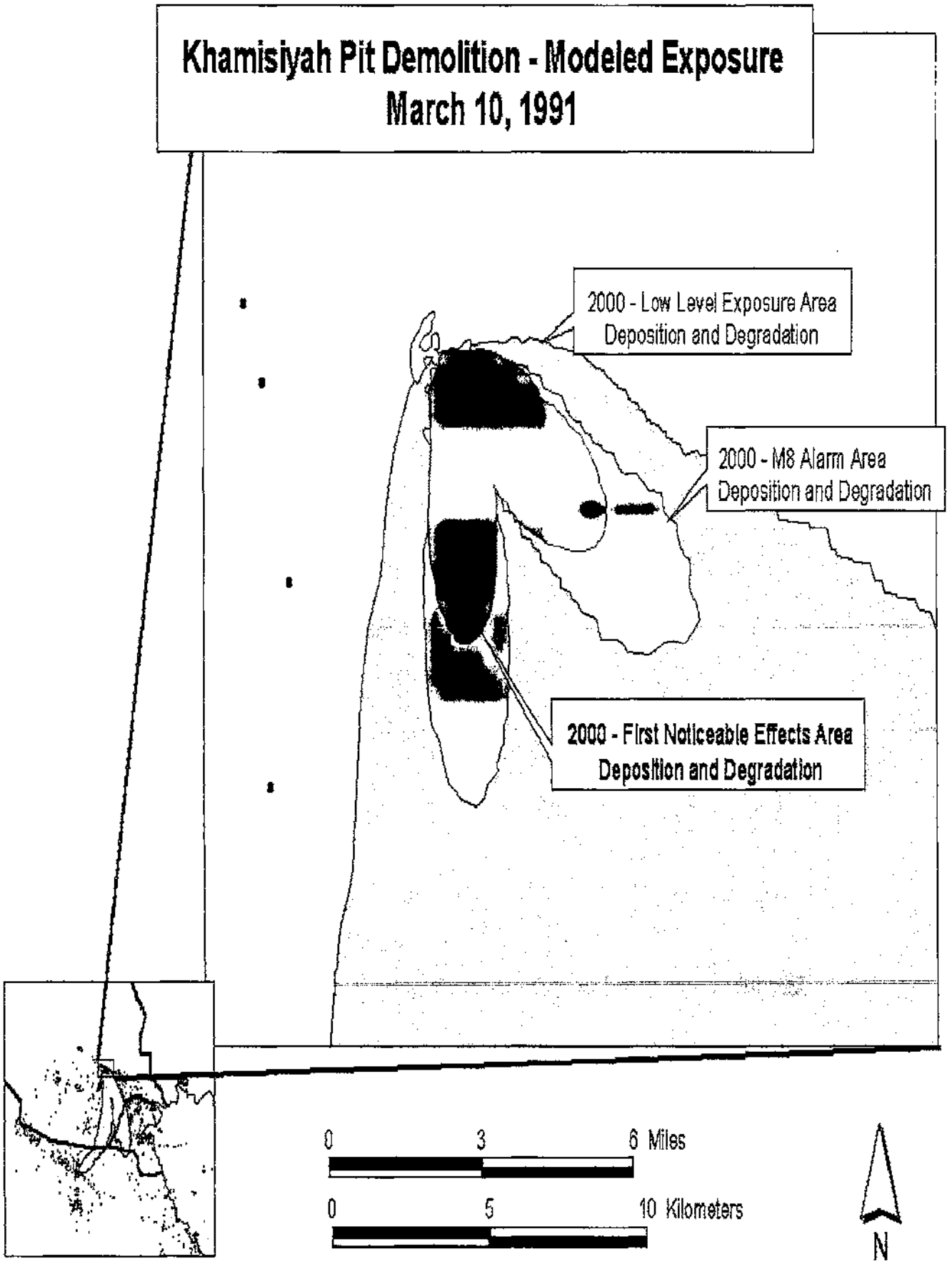
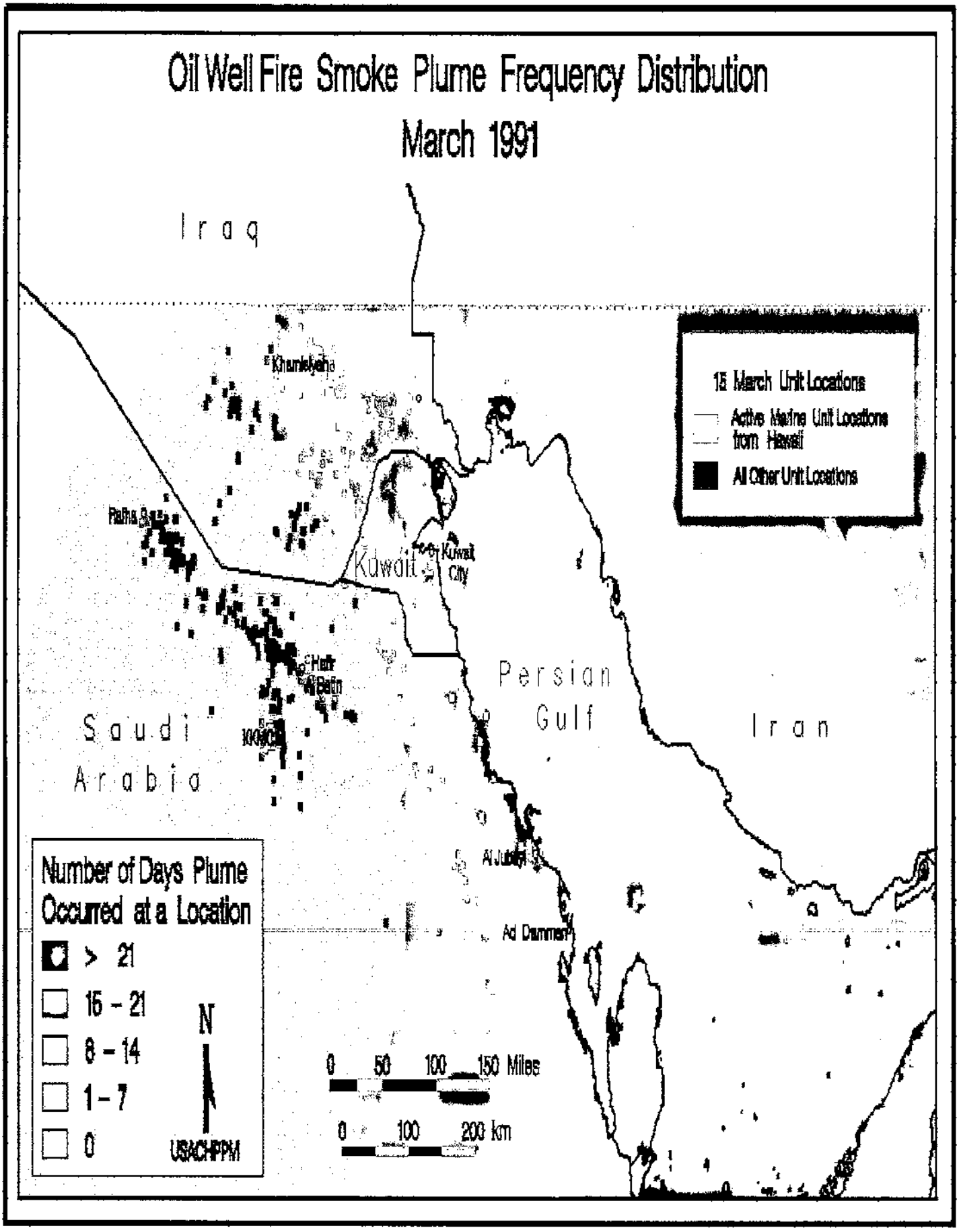

Khamisiyah Pit Demolition - Modeled Exposure
March 10, 1991
2000 - Low Level Exposure Area
Deposition and Degradation
2000 - M8 Alarm Area
Deposition and Degradation
2000 - First Noticeable Effects Area
Deposition and Degradation
0
3
6 Miles
0
5
10 Kilometers
N


Oil Well Fire Smoke Plume Frequency Distribution
March 1991
Iraq
Khurmaylah
Kuwait
Kuwait City
Persian Gulf
Iran
Saudi Arabia
Hafr Al Batin
Al Jubail
Ad Dammam
15 March Unit Locations
Active Marine Unit Locations from Hawaii
All Other Unit Locations
Number of Days Plume Occurred at a Location
> 21
15 - 21
8 - 14
1 - 7
0
N
USAFETAC/PPM
0 50 100 150 Miles
0 100 200 km

DU Exposure Issues

- Radiation
- Consequences of exposure
- Heavy metal toxicity
- Reproductive effect
- Contamination of theater

Anthrax

- Anthrax - an offensive BW agent
  - Inhalation anthrax is highly lethal
  - Easy to develop and weaponize
  - Remains viable for long periods
  - At least seven potential adversaries suspected of researching, developing and/or weaponizing anthrax.
- We have a safe and effective vaccine

Vaccination against anthrax is critical for your protection

Anthrax Vaccine Program

- Licensed by the FDA since 1970
  - Safely administered in the U.S. to at-risk veterinarians, laboratory workers, and livestock handlers
- Shot schedule: 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster

1-877-GET-VACC

DSN: 761-5101

www.anthrax.osd.mil

www.aviationmedicine.com

Conclusions about PB

- We cannot rule out pyridostigmine bromide as a contributor to increased health symptoms in Gulf War veterans.
- Further research is needed to determine the effectiveness of the current dose of PB against Soman.
- Additional research about safety and effectiveness of PB for humans is needed.

A New Reality -- The Dirty Battlefield

- What enemy may do to us
  - Chemical/Bio threat, Man made environmental hazards (Oil Well Fires)
- What the environment may do to us
  - Infectious diseases, insects, environmental risks (desert, jungle)
- What we may do to ourselves
  - Pesticides, Stressors, Investigational New Drugs, PB

Current and future conflicts and humanitarian deployments have and will have these challenges

Leadership

- Unit Leaders rarely understood their central role in risk management (especially risk communication) to non-traditional threats
- If unaddressed, perceptions and fears can produce unanticipated consequences
- Staff response to exposure risks and events lacked coordination and cohesion
- Unity of effort problematic among Medical, Safety, and Line staffs

LEADERS MUST MANAGE RISK TO PROTECT HEALTH

Office of the Special Assistant to the Deputy Secretary of Defense

for Gulf War Illnesses

(800)-754-2132 fax 703-578-8501

email: brostker@gwillness.osd.mil

Mission of the Special Assistant

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DOD adopts doctrine, policy and procedures to reduce risks for troops in the future.

Post War

Shortly after re-deployment, many individuals in a few units reported common symptoms

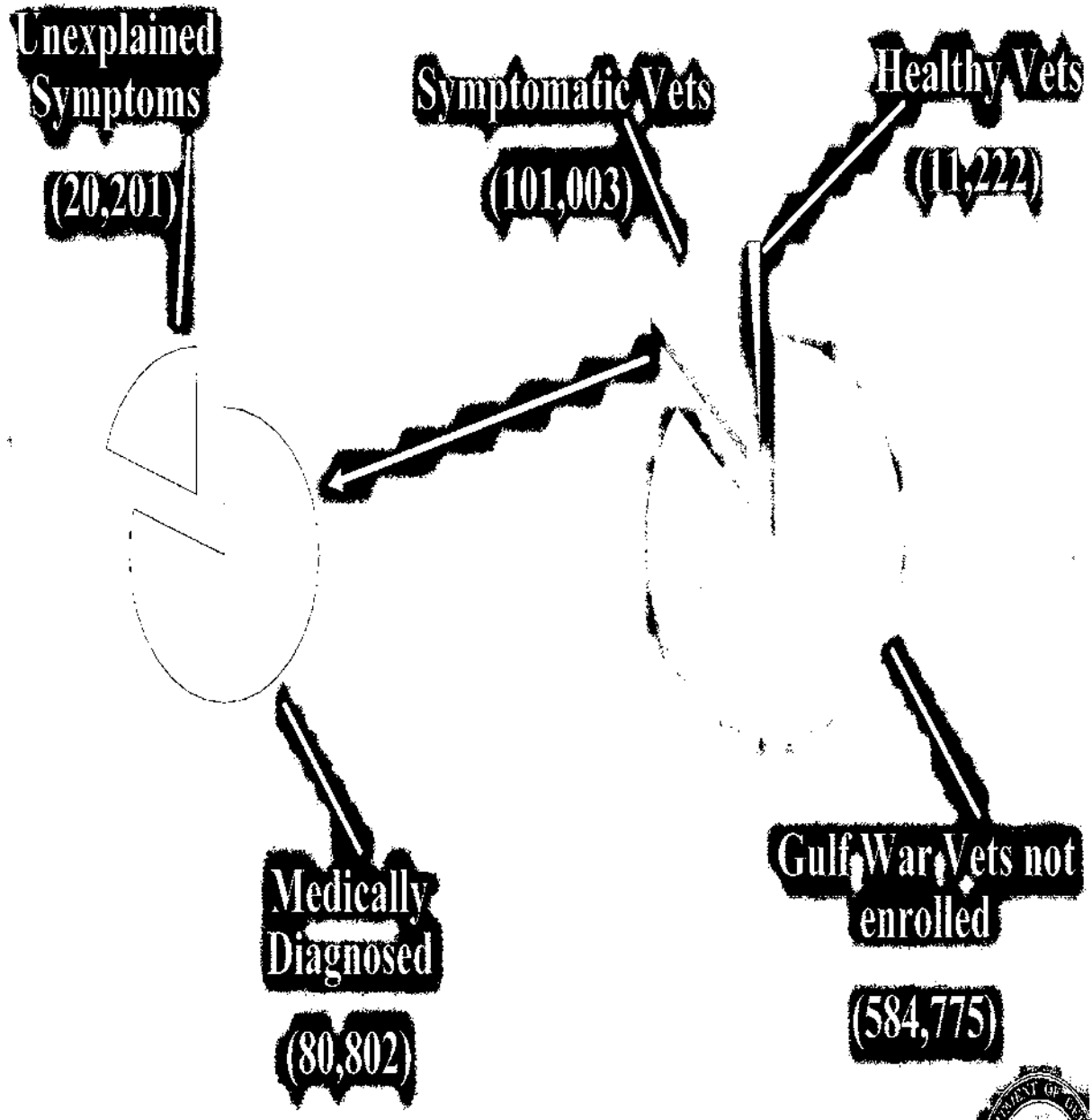
- Aching joints
- Headaches
- Rashes
- Sleep disorders
- Diarrhea
- Hair loss
- Memory loss
- Fatigue

Confounding Issues

- No clustering
- No symptom consistency
- Variable onset
- No longitudinal evaluation
- As yet - no new disease or links between exposures and symptoms

Diagnosis Distribution/697,000 Deployed

CCEP/VA Participants



Looking for Causes
The Dirty Battlefield

- What Iraq may have done to us.
  - Oil Well Fires, Stress
- What the environment may have done to us.
  - Sand, Infectious diseases, bad food and water
- What we may have done to ourselves.
  - Pesticides, Pyridostigmine Bromide, Low levels of CW agent, DU
- Challenges in the future range from low-tech pariah states to the revolution in military affairs.

OSAGWI Investigations

- Chemical/biological warfare:
  - Focus in 1997; 16 papers
  - Watershed is Khamisiyah
- Environmental:
  - Focus in 1998
  - Oil well fires, pesticides, depleted uranium (DU)

DU Exposure Issues

- Radiation
- Heavy metal toxicity
- Consequences of exposure
- Reproductive effect
- Contamination of theater

Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Pre-deployment serum sample
- Verify HIV test in last 12 months
- Immunizations
- Verify current physical exam
- Health questionnaire

Deployment

- Routine disease/injury reporting
- Forward medical laboratory
- Immunization tracking
- Environmental monitoring

Post Deployment

- Collect serum sample
- Medical debriefs
- Complete health questionnaire
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Anthrax Vaccine

- What is Anthrax?
- Vaccine is safe and necessary
  - FDA Licensed in 1970
  - Used for many years to protect textile mill workers
  - Recommended by Centers for Disease Control (CDC):
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    - Treatment of anyone exposed to anthrax aerosols
    - Only known pretreatment and protection against exposure

Anthrax Vaccination Program

- Phase I - SWA and Korea (now)
- Phase II - Early deploying forces to SWA and Korea (8/99)
- Phase III - Total force (early 2000's)
- 288,360 vaccinated - 891,260 doses (June 99)
- 79 adverse reactions = 0.009% (June 99)
  - 44 systemic reactions, 35 local reactions
- Complete supplemental testing on vaccine prior to release
- Plant renovation completed.
- DoD anthrax web site: www.defenselink.mil/specials/Anthrax

Myths versus Reality

Cover up	Open process & oversight
Not listening	Solicit eyewitness reports
Destroy records	Found missing records
20,000 veterans dead	5,773 veterans dead
No assistance to vets	Evaluation and care
"Syndrome"	More than 40 illnesses
CW or DU cause	Many possible causes
Brass doesn't care	Force Protection efforts
	Tough choices
	Cultural changes

Summary

- Work continues: "leave no stone unturned"
- We rely on Gulf War veterans:
  - To give us leads
  - To check our accuracy
- We rely on you:
  - To ensure GW vets get proper testing and treatment
  - To dispel myths and demand facts

Obtaining help and information

- Comprehensive Clinical Evaluation Program (CCEP)
  - 1-800-796-9699
- Veterans Affair registry program
  - 1-800-749-8387
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  - Thursday, June 24th at the Town Hall, Community Center
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(11)

Pentagon Mobilizes: Special Assistant for Gulf War Illnesses

Dr. Bernard Rostker

- Appointed November 12, 1996 by the Deputy Secretary of Defense
- 180 team members

Mission of the Special Assistant

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
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Why Should I Care?

- Lessons from the Gulf War about dirty battlefields.
- You must protect yourself against hazards.
- You will be working with or leading Gulf War vets.
- You will probably deploy overseas.
- You are responsible for force protection.

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	Cultural changes

U.S. Deaths

Battle deaths	148
Non-battle deaths	224
Hospitalizations	27,000

Post War

Shortly after re-deployment, many individuals in a few units reported common symptoms

- Aching joints
- Diarrhea
- Headaches
- Hair loss
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- Fatigue

Physician Message Sent

"Your laboratory, x-ray and physical exams results are normal."

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"There's nothing wrong with you!"

"It's all in your head!"

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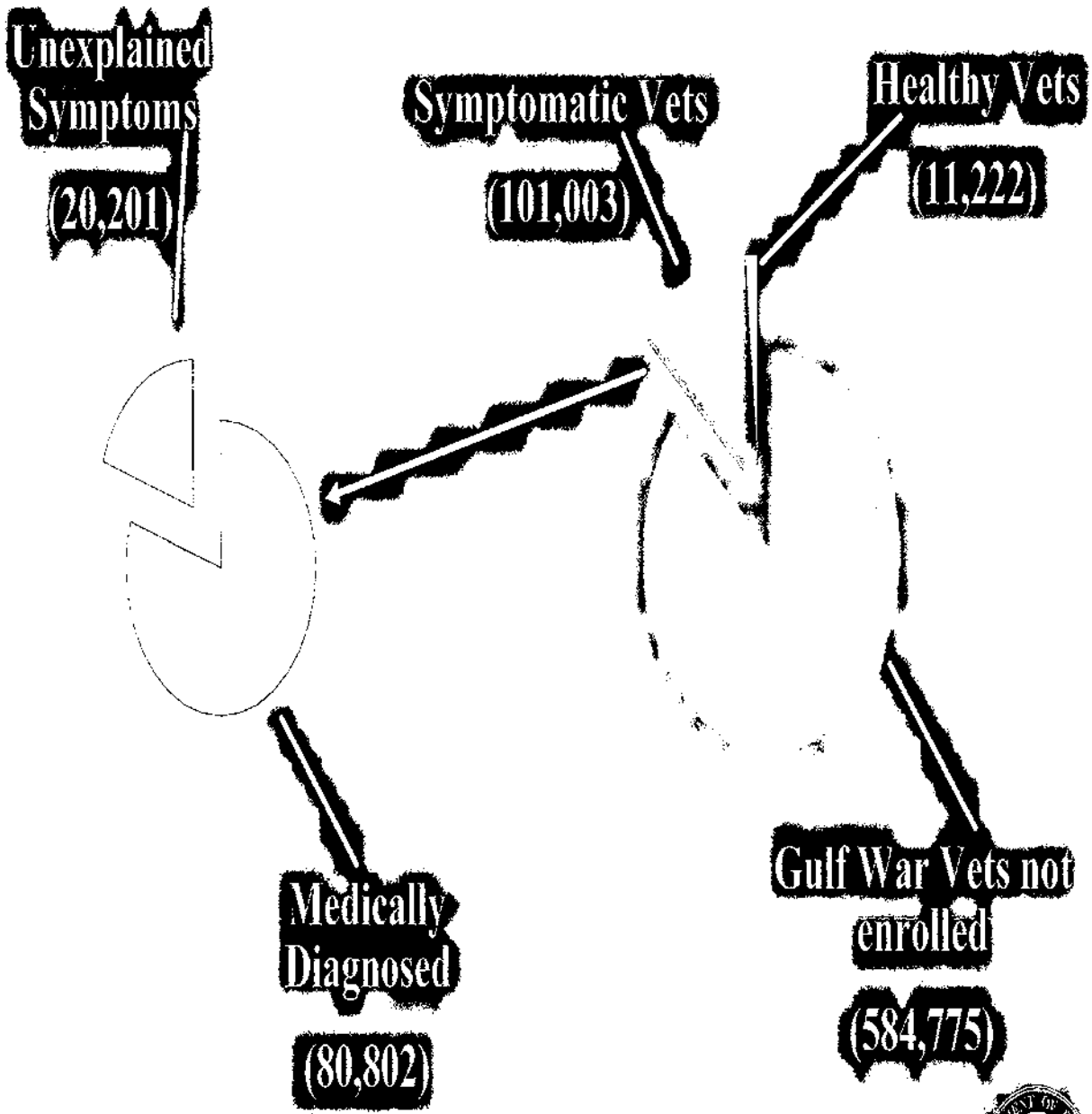

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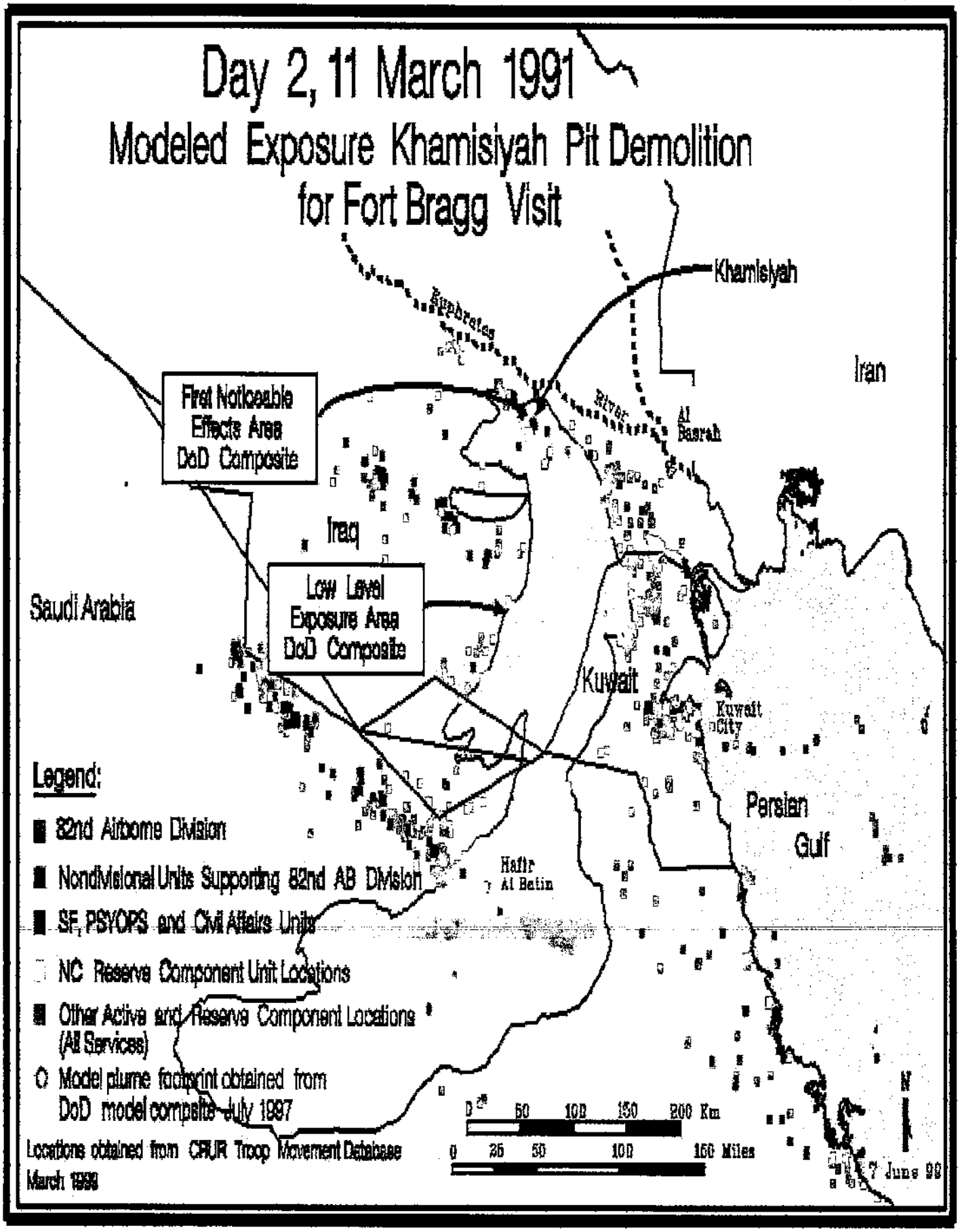
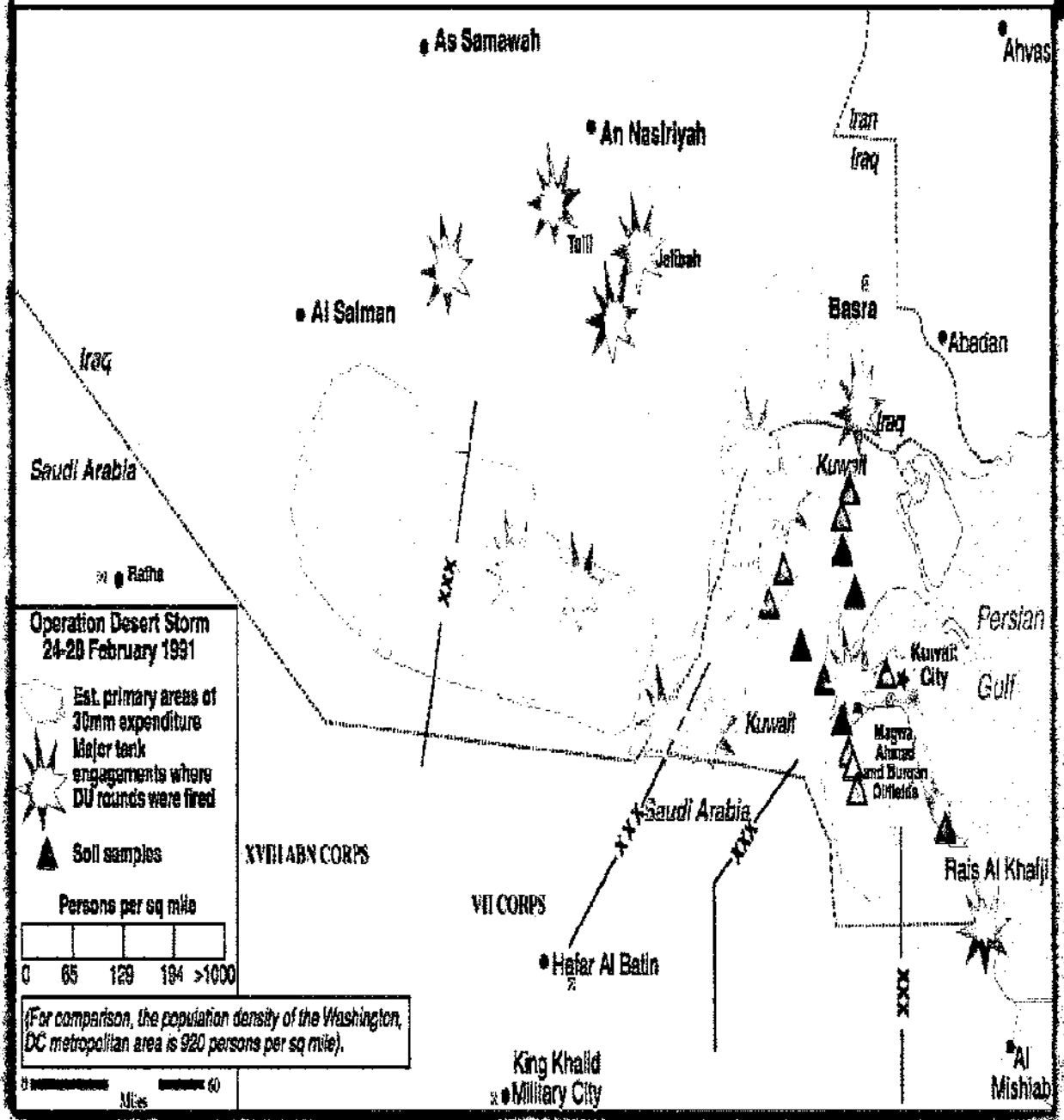

Day 2, 11 March 1991
Modeled Exposure Khamisiyah Pit Demolition
for Fort Bragg Visit
Khamisiyah
Euphrates
River
Iran
Al Basrah
First Noticeable Effects Area DoD Composite
Iraq
Low Level Exposure Area DoD Composite
Saudi Arabia
Kuwait
Kuwait City
Persian Gulf
Hafir Al Batin
Legend:
82nd Airborne Division
Non-Divisional Units Supporting 82nd AB Division
SF, PSYOPS and Civil Affairs Units
NC Reserve Component Unit Locations
Other Active and Reserve Component Locations (All Services)
Model plume footprint obtained from DoD model compsite July 1997
Locations obtained from CRUR Troop Movement Database March 1998
0 50 100 150 200 Km
0 25 50 100 150 Miles
N
7 June 99

Primary Areas of DU Expenditure



Investigator's Message Sent

"The symptoms described were not consistent with symptoms associated with exposure to chemical warfare agents or depleted uranium."

Veteran's Messages Received

"You're wrong!"

"You can't possibly be sick because of this!"

DU Exposure Issues

- Radiation
- Heavy metal toxicity
- Consequences of exposure
- Reproductive effect
- Contamination of theater

DU Awareness Training

- Current CTT Task (031-503-1017)
- Better information is now available
  - Chemical toxicity vice radioactivity
  - Continue the mission
  - Respiratory protection for extended exposure
- Training support packages being updated
  - Includes updating the common task & GTA
  - Additional training for specialists
- Use existing training management system

OSAGWI Investigations

- Medical issues and lessons learned:
  - Focus in 1999
    - Vaccines, PB, records, policy
    - DU training
    - Managing hazards

Proactive Measures - You

- Recognize and contend with potential hazards:
  - Improve intel notification
  - Train all personnel
  - Reduce adverse effects of and stress from potential exposures
  - Understand the environment and culture before deploying
- Improve feedback and cross talk

Operational Lessons - Your Unit

- Improve expedient demolition of munitions
- CW/BW detection: earlier with fewer false positives
- Relate CW to operational and medical records
- Adapt for the future
  - Retain individual unit locations and records
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  - Force health protection

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- Contact managers

Bottom Line

- Gulf War Veterans key for our work
- You must protect yourself on the Dirty Battlefield
- Anyone deployed to South West Asia is eligible for CCEP
- Don't tough it out - Get signed up and evaluated
- You are your best health advocate
- Apply these lessons learned

Office of the Special Assistant for Gulf War Illnesses

CONTACT NUMBERS

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Back-up Slides

Identifying Possible Causes

- Normal disease rate
- Linking hazards and illnesses
  - Research
  - New disease paradigm

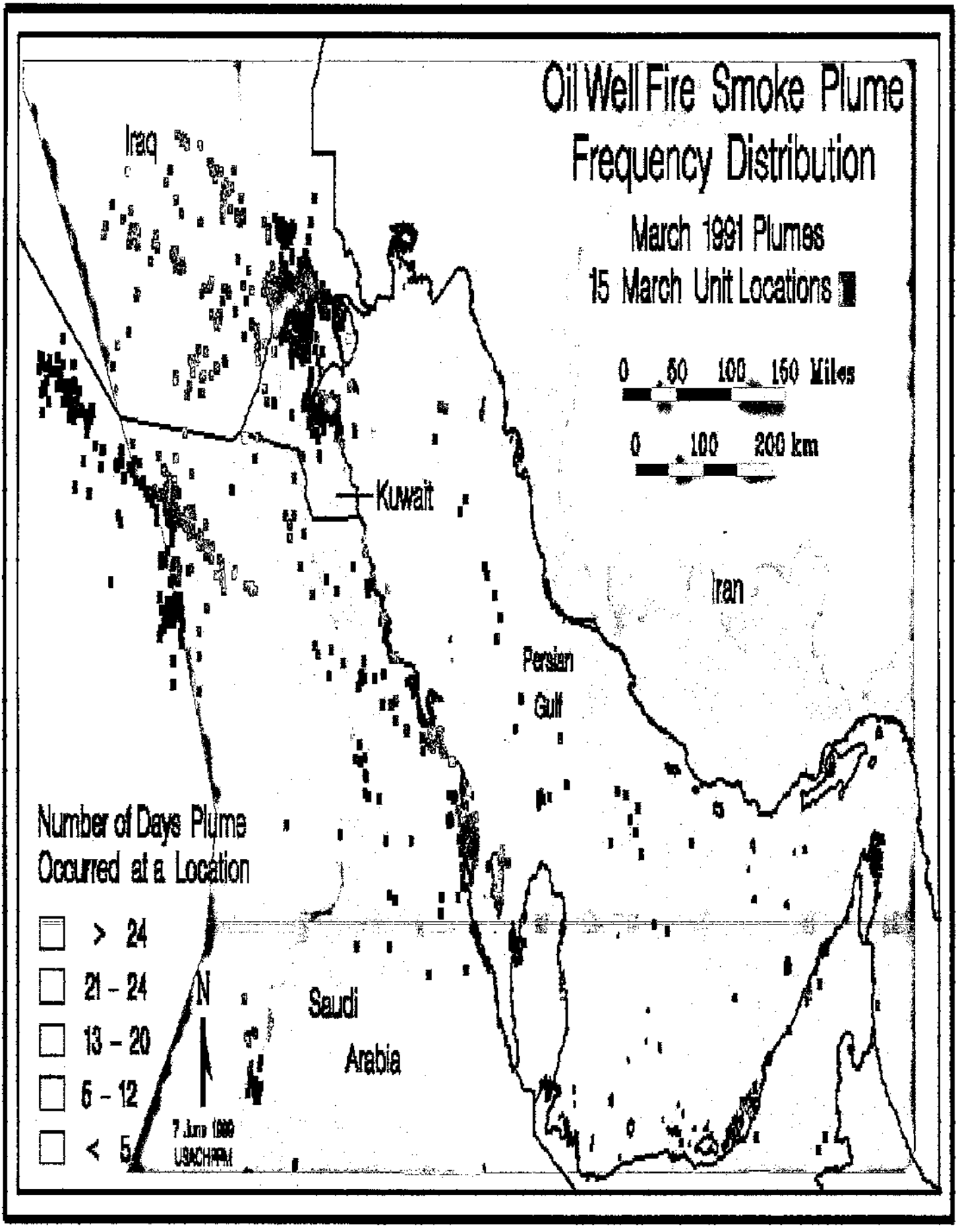
Symptoms

- Tiredness
- Rashes
- Headaches
- Muscle aches
- Joint pains
- Abdominal pain
- Diarrhea
- Hair loss
- Memory loss
- Sleep disturbance
- Depression
- Concentration problems

Hazards

- Chemical warfare agent
- Pesticides
- Vaccines
- Pyridostigmine bromide
- Stress
- Biological warfare agent
- Oil well fires
- Depleted uranium
- Infectious disease
- "Cocktail" effect

30+ offered as possible causes


Oil Well Fire Smoke Plume
Frequency Distribution
March 1991 Plumes
15 March Unit Locations
0 50 100 150 Miles
0 100 200 km
Iraq
Kuwait
Iran
Persian
Gulf
Saudi
Arabia
Number of Days Plume
Occurred at a Location
> 24
21 - 24
13 - 20
6 - 12
< 5
N
7 June 1999
USACHPPM

Medical Training for Line Leaders

- Wellness Requirements = Mission Success
  - Routine examinations, vaccinations
  - Force Health Protection
  - Anthrax Vaccination
- Normal Disease Rates - Garrison or Deployment
  - Diarrhea
  - Sports injuries
  - Cancer, heart attacks, diabetes, etc.

Operational Lessons - You

- Recognize and contend with potential hazards:
  - Improve intel notification.
  - Train all personnel.
  - Reduce adverse effects of and stress from potential exposures.
  - Understand the environment and culture before deploying.
- Improve feedback and cross talk.

Who Served in the Gulf War

697,000 U.S. service members

Army	348,000	50%
Navy	160,000	23%
Marine	105,000	15%
Air Force	84,000	12%

259,000 Coalition Forces

Who Served in the Gulf War

Gender	
Men	93%
Women	7%
Component	
Active	83%
Reserve/National Guard	17%
Community	
Officer	10%
Enlisted	90%

<26 years old - 55%; 26-35 years old - 32%; > 35years old - 13%

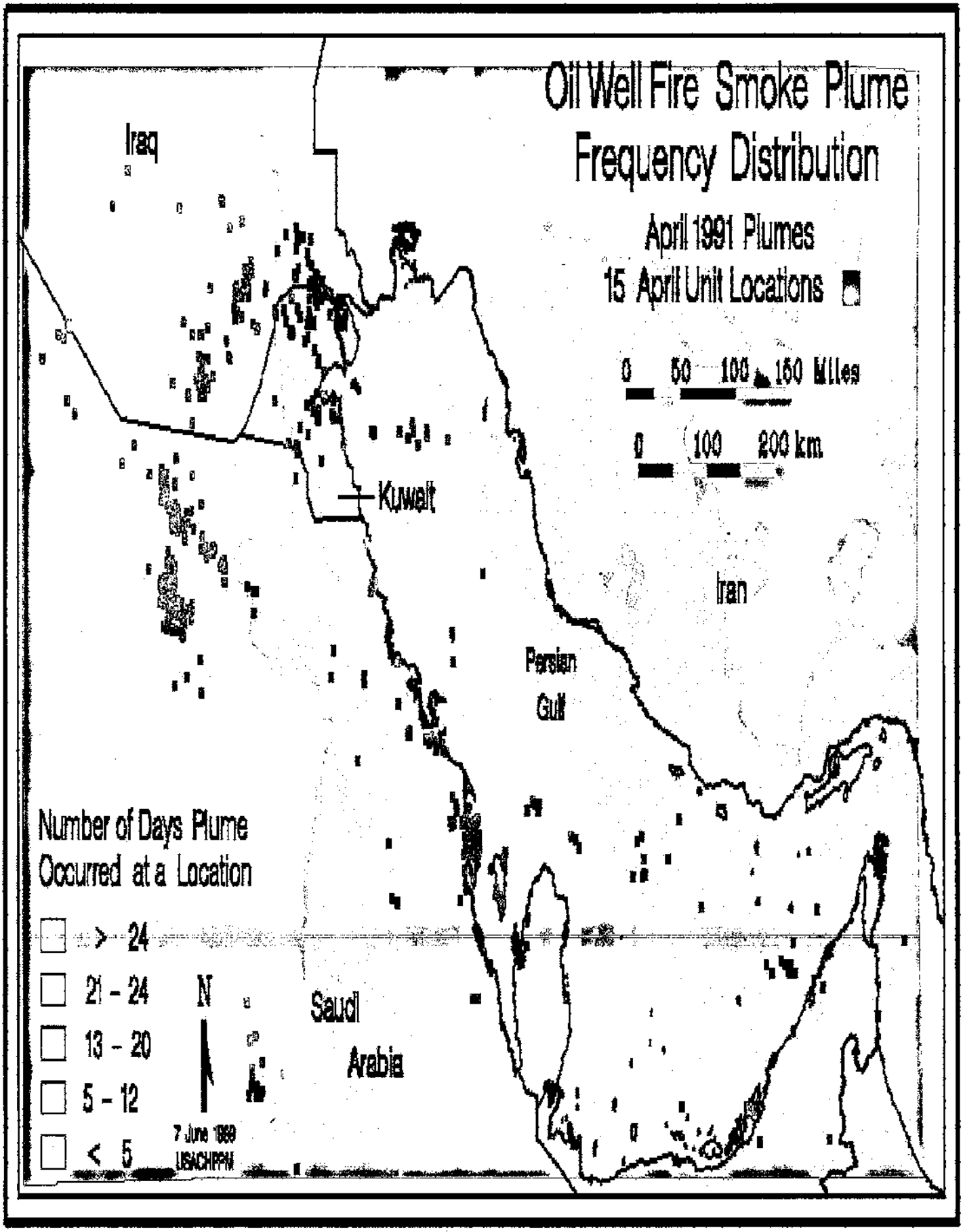
Medical Support

Largest emergency health care system since WWII

- 41,000 medical personnel
- 18,000 beds
- 2 hospital ships
- 63 combat zone hospitals

Possible Causes

- Normal disease rate
- New disease paradigm
- Research
- Black camel


Oil Well Fire Smoke Plume
Frequency Distribution
April 1991 Plumes
15 April Unit Locations
0 50 100 150 Miles
0 100 200 km
Iraq
Kuwait
Iran
Persian
Gulf
Saudi
Arabia
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Occurred at a Location
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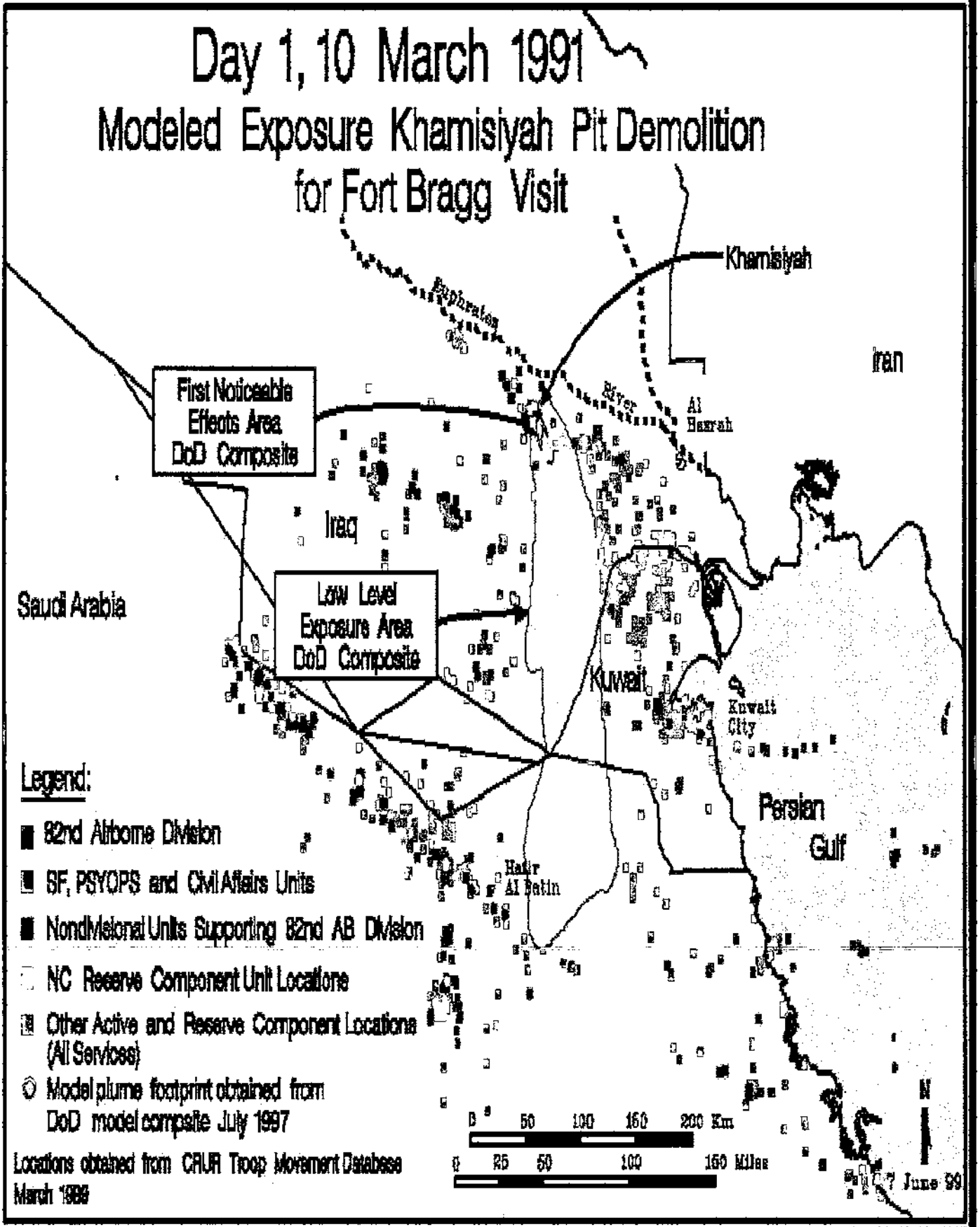
7 June 1999
USACHPPM

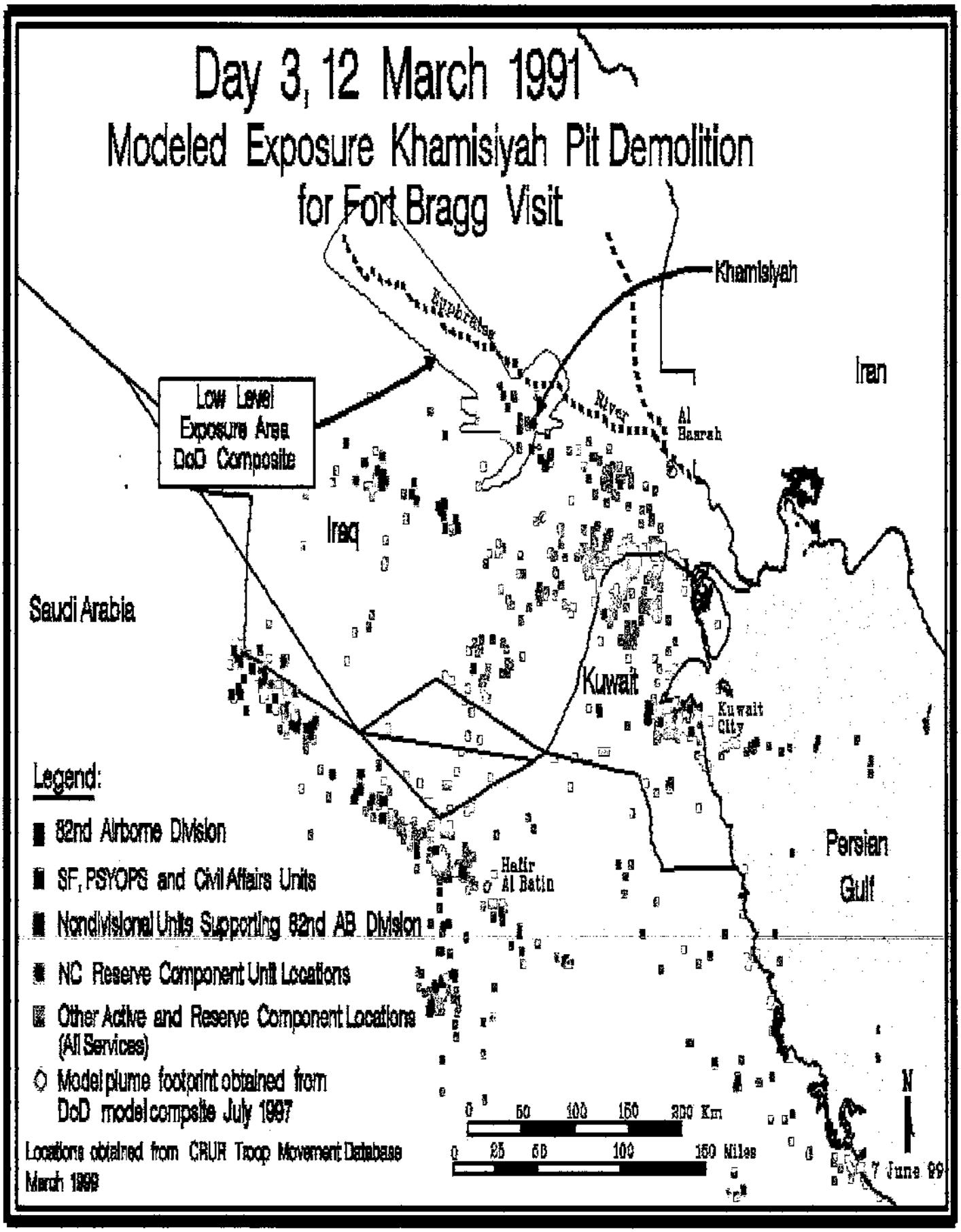
Future Equipment

- Personal Information Carrier (PIC)
- Biological Integrated Detection System (BIDS)
- Automatic Chemical Agent Alarm (ACADA)
- Medic Cam - Tele medicine

Day 1, 10 March 1991

Modeled Exposure Khamisiyah Pit Demolition for Fort Bragg Visit




Day 3, 12 March 1991
Modeled Exposure Khamisiyah Pit Demolition
for Fort Bragg Visit
Khamisiyah
Euphrates River
Iran
Low Level
Exposure Area
DoD Composite
Al
Basrah
Iraq
Saudi Arabia
Kuwait
Kuwait
City
Persian
Gulf
Hafir
Al Batin
Legend:
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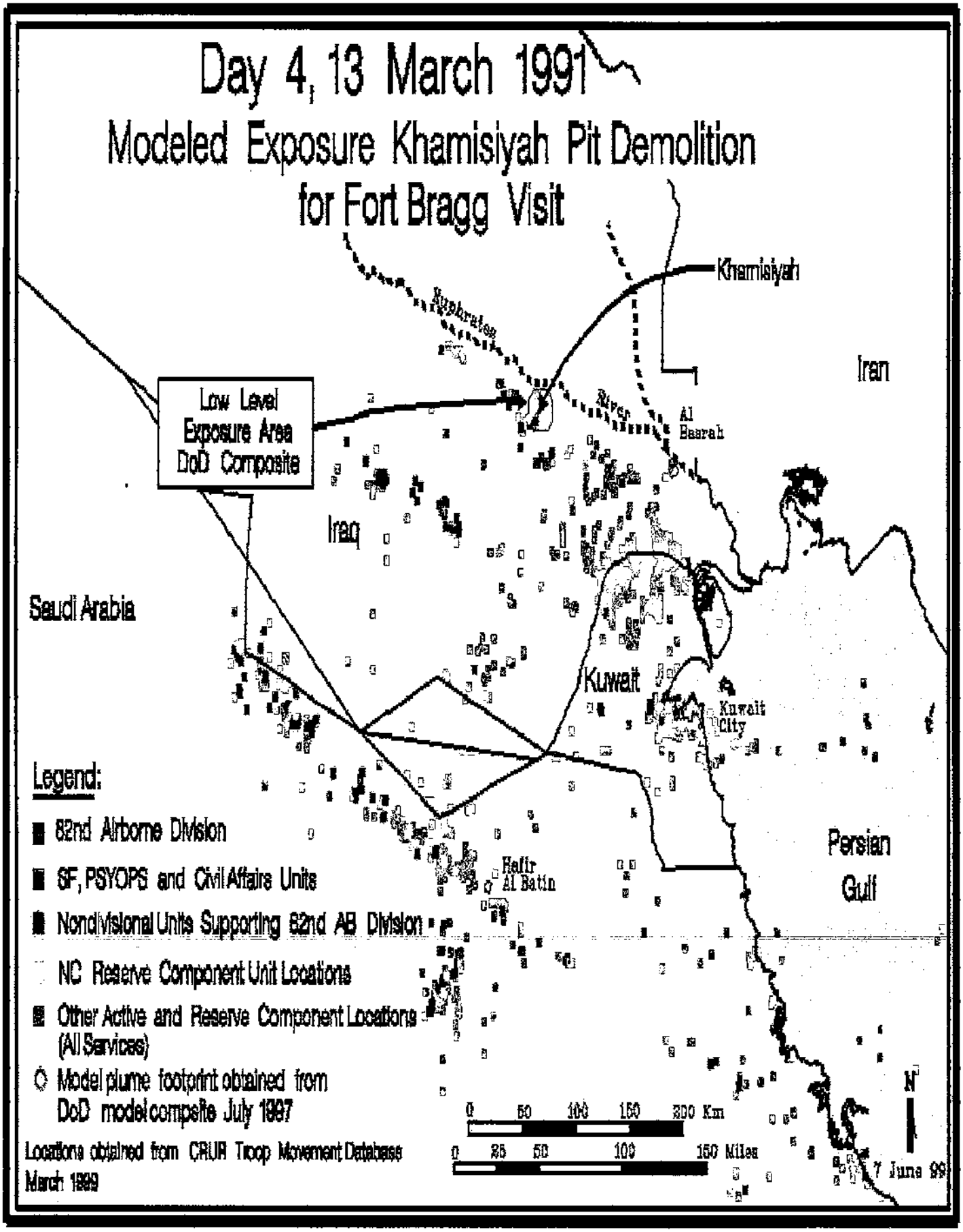
Day 4, 13 March 1991
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Khamisiyah
Iran
Low Level
Exposure Area
DoD Composite
Iraq
Saudi Arabia
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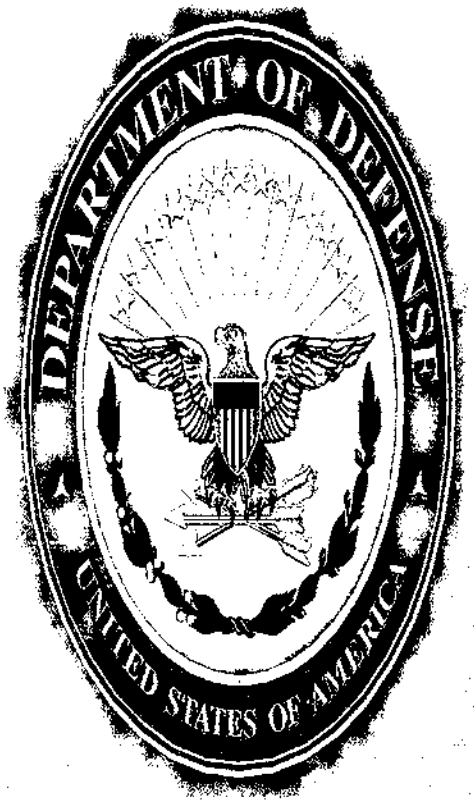
Summary

- Work continues: "leave no stone unturned"
- We rely on Gulf War veterans:
  - To give us leads
  - To check our accuracy
- We rely on today's force -- including you:
  - To ensure GW vets get proper testing and treatment
  - To apply lessons learned to the future

Office of the Special Assistant to the Deputy Secretary of Defense



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(82)

Briefing Overview

- Organization - Mission Statement
- Why should I care?
- Symptoms and Illnesses
- Looking for causes
- Gulf War Lessons Learned
- Force Health Protection
- Obtaining help and information

Special Assistant for Gulf War Illnesses

Dr. Bernard Rostker

- Appointed November 12, 1996 by the Deputy Secretary of Defense
- 180 team members

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- Sleep disorders
- Depression
- Fatigue
- Memory loss
- Rash
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- What the environment may have done to us.
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- What we may have done to ourselves.
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- Challenges in future conflicts and humanitarian deployments.

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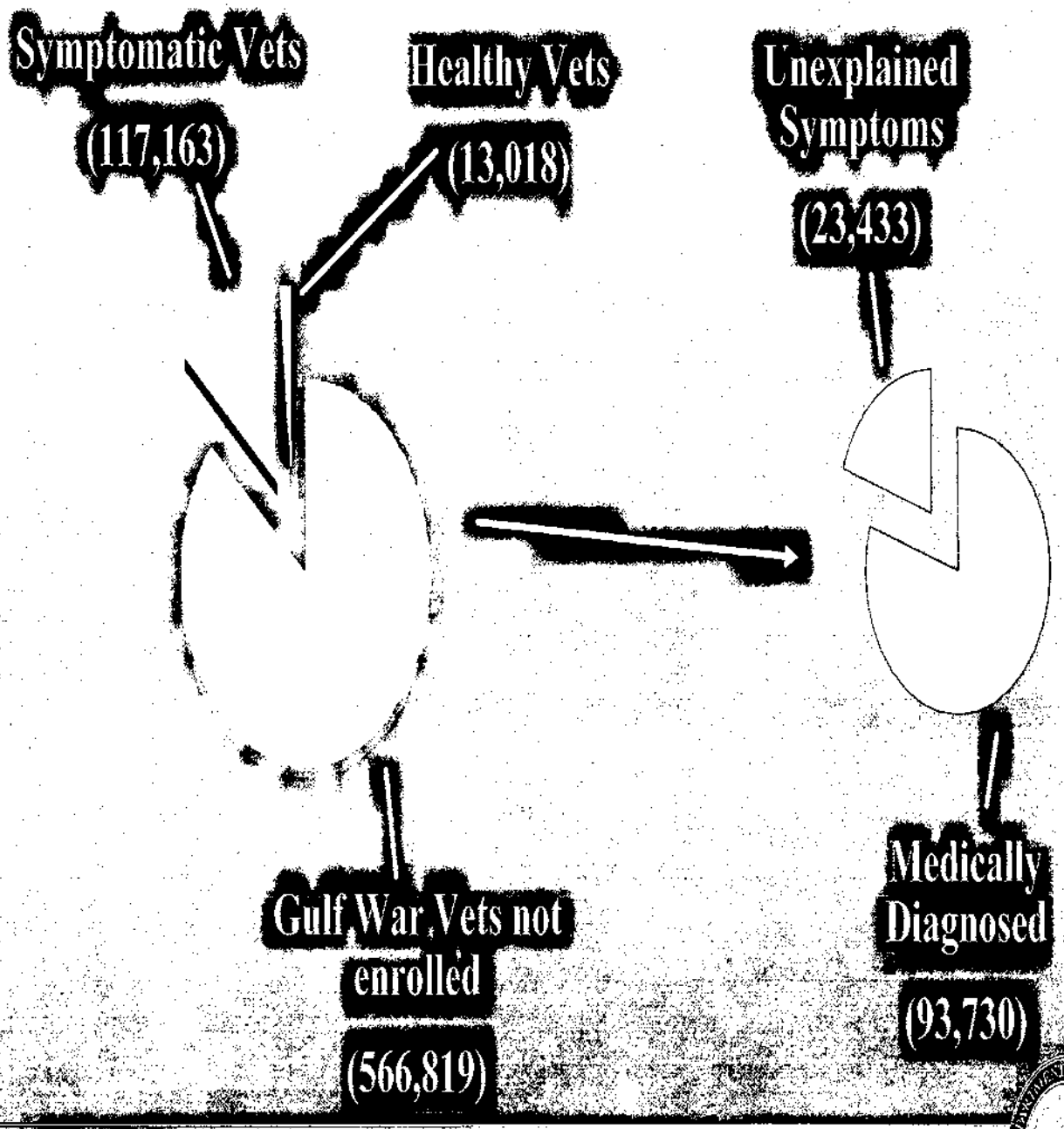

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  - Deadly - (skin vs inhaled exposure)
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  - Used for many years to protect textile mill workers
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    - Workers occupationally exposed to anthrax (labs, mills)
    - Treatment of anyone exposed to anthrax aerosols
    - Only known pretreatment and protection against exposure

Anthrax Vaccine

- DoD Policy - mandatory for total force
  - Phased implementation
- Phase I - SWA and Korea (now)
- Phase II - Early deploying forces to SWA and Korea (8/99)
- Phase III - Total force (early 2000's)
- Vaccine series:
  - 0, 2, 4 weeks; then 6, 12, 18 months; annual booster
  - 1,147,349 doses, 211 adverse reactions=0.018% (01 Oct 99)
    - 155 systemic reactions, 56 local reactions

- DoD anthrax web site: www.anthrax.osd.mil

Obtaining help and information

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  - Thursday, Oct 21 at the McMahon Theater, 1900hrs
- Displays
  - P.X., Commissary and Evans Army Community Hospital
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Bottom Line

- Gulf War Veterans key for our work
- You must protect yourself on the Dirty Battlefield
- Anyone deployed to South West Asia is eligible for CCEP *(family members included)*
- Don't tough it out - Get signed up and evaluated
- You are your best health advocate
- Apply these lessons learned

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(21)

Briefing Overview

- Organization - Mission Statement
- Why should I care?
- Symptoms and Illnesses
- Looking for causes
- Gulf War Lessons Learned
- Force Health Protection
- Obtaining help and information

Special Assistant for Gulf War Illnesses

Dr. Bernard Rostker

- Appointed November 12, 1996 by the Deputy Secretary of Defense
- 180 team members

Mission of the Special Assistant

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DOD adopts doctrine, policy and procedures to reduce risks for troops deploying now and in the future.

Why Should I Care?

- Lessons from the Gulf War about dirty battlefields.
- You must protect yourself against hazards.
- You will be working with or leading Gulf War vets.
- You will probably deploy overseas.
- You are responsible for force protection.

Who Served in the Gulf War

697,000 U.S. service members

Army	348,000	50%
Navy	160,000	23%
Marine	105,000	15%
Air Force	84,000	12%

259,000 Coalition Forces

Who Served in the Gulf War

MALE	93%
FEMALE	7%
ACTIVE	83%
RESERVE/NATIONAL GUARD	17%
OFFICER	10%
ENLISTED	90%

< 26 years old - 55%; 26-35 years old - 32%; > 35 years old - 13%

Medical Support

Largest emergency health care system since WW II

41,000 medical personnel

•18,000 beds

- 2 hospital ships

- 63 combat zone hospitals

source: CENTCOM Publications - Commander-in-chief US CENTCOM "Desert Shield/Desert Storm Facts, Figures, Quotes and Anecdotes 7 AUG 90-11 APR 91," prepared by CENTCOM PAO

Medical Support

- 27,000 hospitalizations in theater
- 8,000 medical evacuations
- ????? outpatient visits

U.S. Deaths

Battle deaths	148
Non-battle deaths	224

Post War

Shortly after re-deployment, many individuals in units reported common symptoms

- Aching joints
- Headaches
- Rashes
- Sleep disorders
- Diarrhea
- Hair loss
- Memory loss
- Fatigue

Office of the Special Assistant for Gulf War Illnesses

Physician Message Sent

"Your laboratory, x-ray and physical exams results are normal!"

Patient Messages Received

"There's nothing wrong with you!"

"It's all in your head!"

"You're faking these symptoms!"

Confounding Issues

- No clustering
- No symptom consistency
- Variable onset
- No long term study
- As yet - no new disease or links between exposures and symptoms

Looking for Causes

The Dirty Battlefield

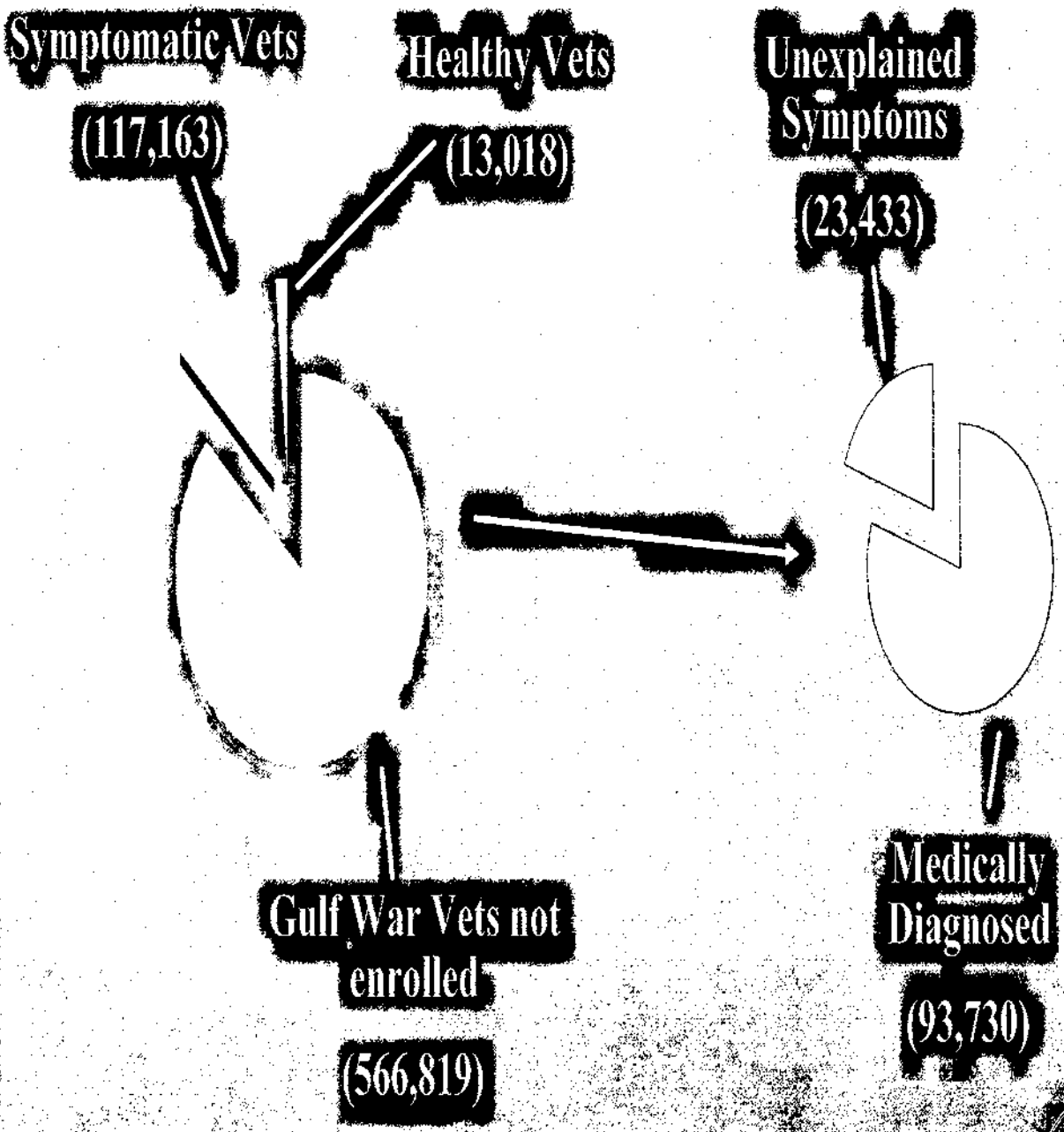
- What Iraq may have done to us.
  - Oil Well Fires, Chem/Bio threat
- What the environment may have done to us.
  - Sand, Insects, Infectious diseases
- What we may have done to ourselves.
  - Pesticides, Pyridostigmine Bromide
- Challenges in future conflicts and humanitarian deployments.

OSAGWI Investigations

- **Chemical/biological warfare:**
  - Chemical warfare agent - Khamisiyah incident
- **Environmental:**
  - Depleted uranium (DU), Oil well fires, Pesticides
- **Medical issues and lessons learned:**
  - Vaccines, PB, records, policy
    - "Cocktail" effect

Diagnosis Distribution/697,000 Deployed

CCEP/VA Participants



Epidemiology Studies

	Deployed (%)	Non-Deployed (%)
Medical separation (Aug 91 - Dec 93)	2.20	2.56
Hospitalizations (Aug 91 - Sep 93)	21.6	21.6
Hospitalizations unexplained illnesses (Aug 91 - Apr 96)	1.21	1.27
Birth Defects (Aug 91 - Sep 93)	7.45	7.59
Mortality (Aug 91 - Sep 93)	.025	.023

Proactive Measures - You

- Recognize and contend with potential hazards:
  - Improve intel notification
  - Train all personnel
  - Reduce adverse effects of and stress from potential exposures
  - Understand the environment and culture before deploying
- Improve feedback and cross talk

Proactive Measures - Your Unit

- Improve expedient demolition of munitions
- CW/BW detection: earlier with fewer false positives
- Improve operational and medical records handling
- Adapt for the future
  - Retain individual unit locations and records
  - DU training
  - Improved medical surveillance
  - Force health protection

Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Pre-deployment serum sample
- Verify HIV test in last 12 months
- Immunizations
- Verify current physical exam
- Health questionnaire

Deployment

- Routine disease/injury reporting
- Forward medical laboratory
- Immunization tracking
- Environmental monitoring

Post Deployment

- Collect serum sample
- Medical debriefs
- Complete health questionnaire
- Screening exams as needed

Future Equipment

- Personal Information Carrier (PIC)
- Biological Integrated Detection System (BIDS)
- Automatic Chemical Agent Alarm (ACADA)
- Medic Cam - Tele medicine

Anthrax Vaccine

- What is Anthrax?
  - Bacteria
  - Easily obtained, stored and weaponized
  - Deadly - (skin vs inhaled exposure)
- Vaccine is safe and necessary!
  - FDA Licensed in 1970
  - Used for many years to protect textile mill workers
  - Recommended by Centers for Disease Control (CDC):
    - Workers occupationally exposed to anthrax (labs, mills)
    - Treatment of anyone exposed to anthrax aerosols
    - Only known pretreatment and protection against exposure

Anthrax Vaccine

- DoD Policy - mandatory for total force
  - Phased implementation
- Phase I - SWA and Korea (now)
- Phase II - Early deploying forces to SWA and Korea (8/99)
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- Vaccine series:
  - 0, 2, 4 weeks; then 6, 12, 18 months; annual booster
  - 1,147,349 doses, 211 adverse reactions=0.018% (01 Oct 99)
    - 155 systemic reactions, 56 local reactions

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Shortly after re-deployment, many individuals in a few units reported common symptoms

- Aching joints
- Headaches
- Rashes
- Sleep disorders
- Diarrhea
- Hair loss
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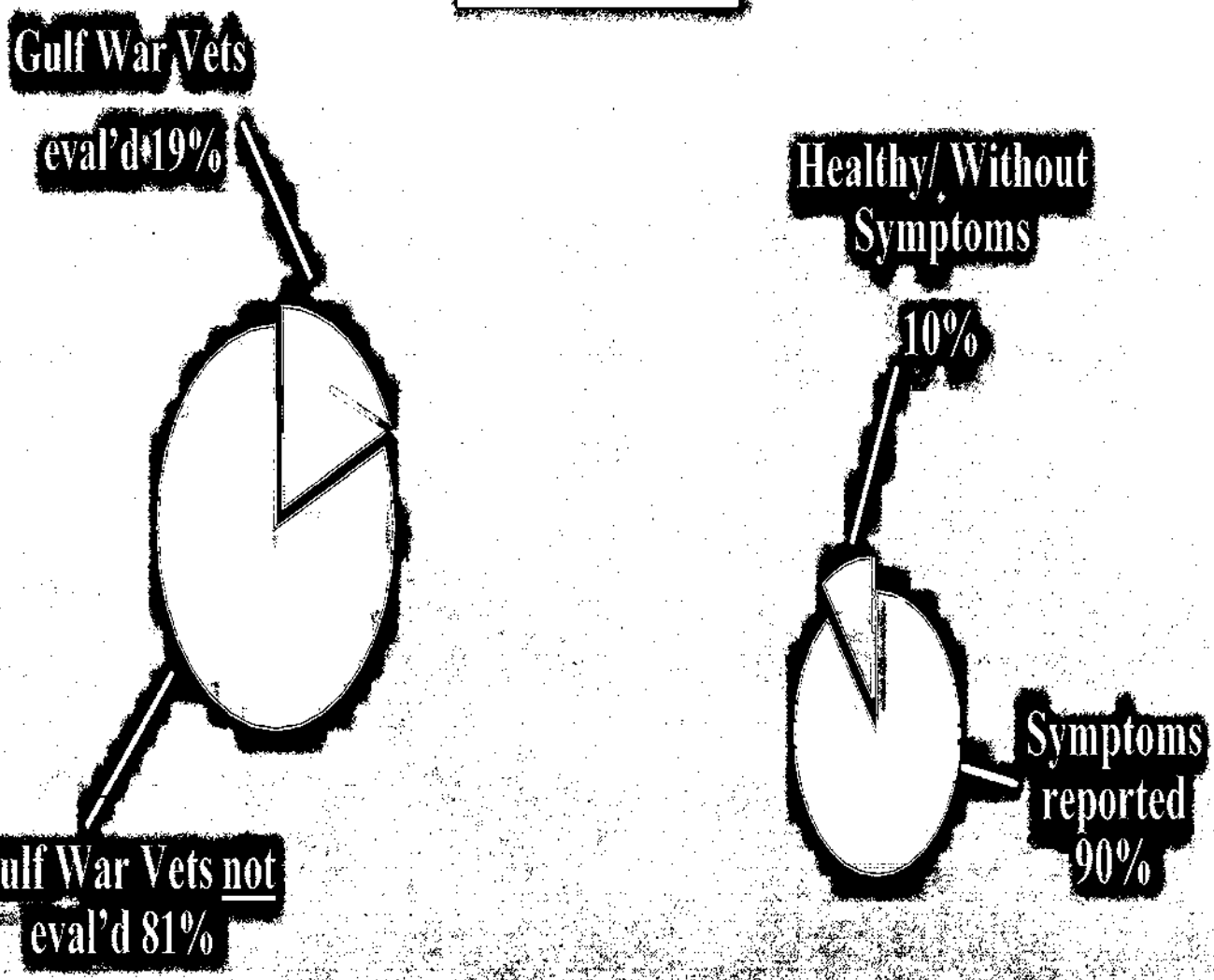
Evaluation Distribution of 697,000 CCEP/VA



Diagnosis Distribution of Evaluated Veterans

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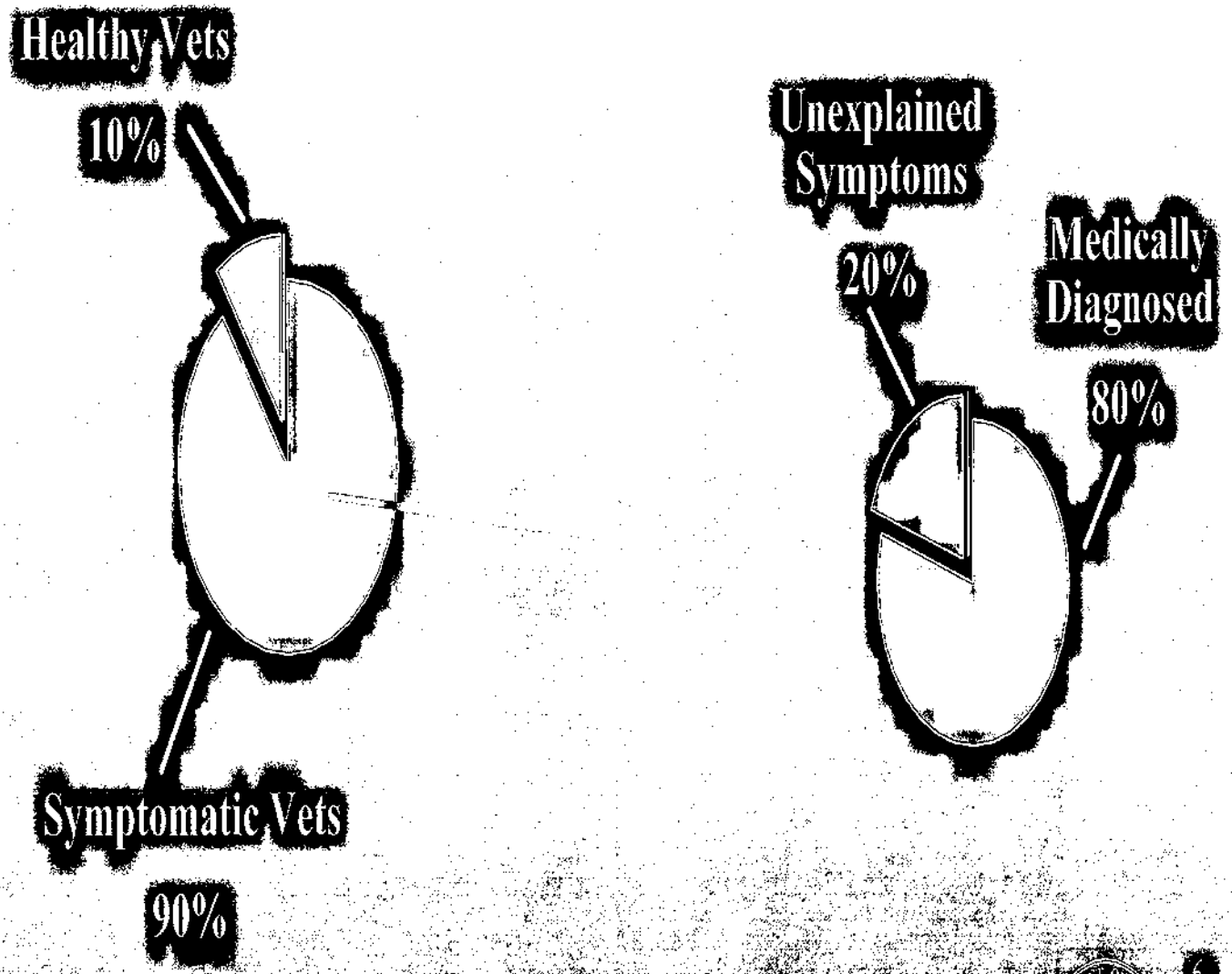

Diagnosis Distribution

130,181 participants — **CCEP/VA***

Healthy	10% - 13,018
Symptomatic (Sick)	90% - 117,163
Medically explained and treatable	80% - 93,730
Medically unexplained	20% - 23,433

As of Sep'99

*Comprehensive Clinical Evaluation Program (CCEP) and Dept. of Veteran's Affairs Registry, programs to provide health care to soldiers and veterans.

Looking for Causes

The Dirty Battlefield

- What Iraq may have done to us.
  - Oil Well Fires, Stress
- What the environment may have done to us.
  - Sand, Infectious diseases, bad food and water
- What we may have done to ourselves.
  - Pesticides, Pyridostigmine Bromide, Low levels of CW agent, DU
- Challenges in the future range from low-tech pariah states to the revolution in military affairs.

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- Chemical/biological warfare:
  - Focus in 1997; 16 papers
  - Watershed is Khamisiyah
- Environmental:
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DU Exposure Issues

- Radiation
- Heavy metal toxicity
- Consequences of exposure
- Reproductive effect
- Contamination of theater

Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Collect pre-deployment blood sample
- Verify HIV test is current
- Verify Immunizations up to date
- Verify current physical exam
- Complete Health questionnaire

Deployment

- Routine disease/injury reporting
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Myths versus Reality

Cover up	Open process & oversight
Not listening	Solicit eyewitness reports
Destroy records	Found missing records
20,000 veterans dead	6,186 veterans dead
No assistance to vets	Evaluation and care
"Syndrome"	More than 40 illnesses
CW or DU cause	Many possible causes
Brass doesn't care	Force Protection efforts
	Tough choices
	Cultural changes

Summary

- Work continues: "leave no stone unturned"
- We rely on Gulf War veterans:
  - To give us leads
  - To check our accuracy
- We rely on you:
  - To ensure GW vets get proper testing and treatment
  - To dispel myths and demand facts

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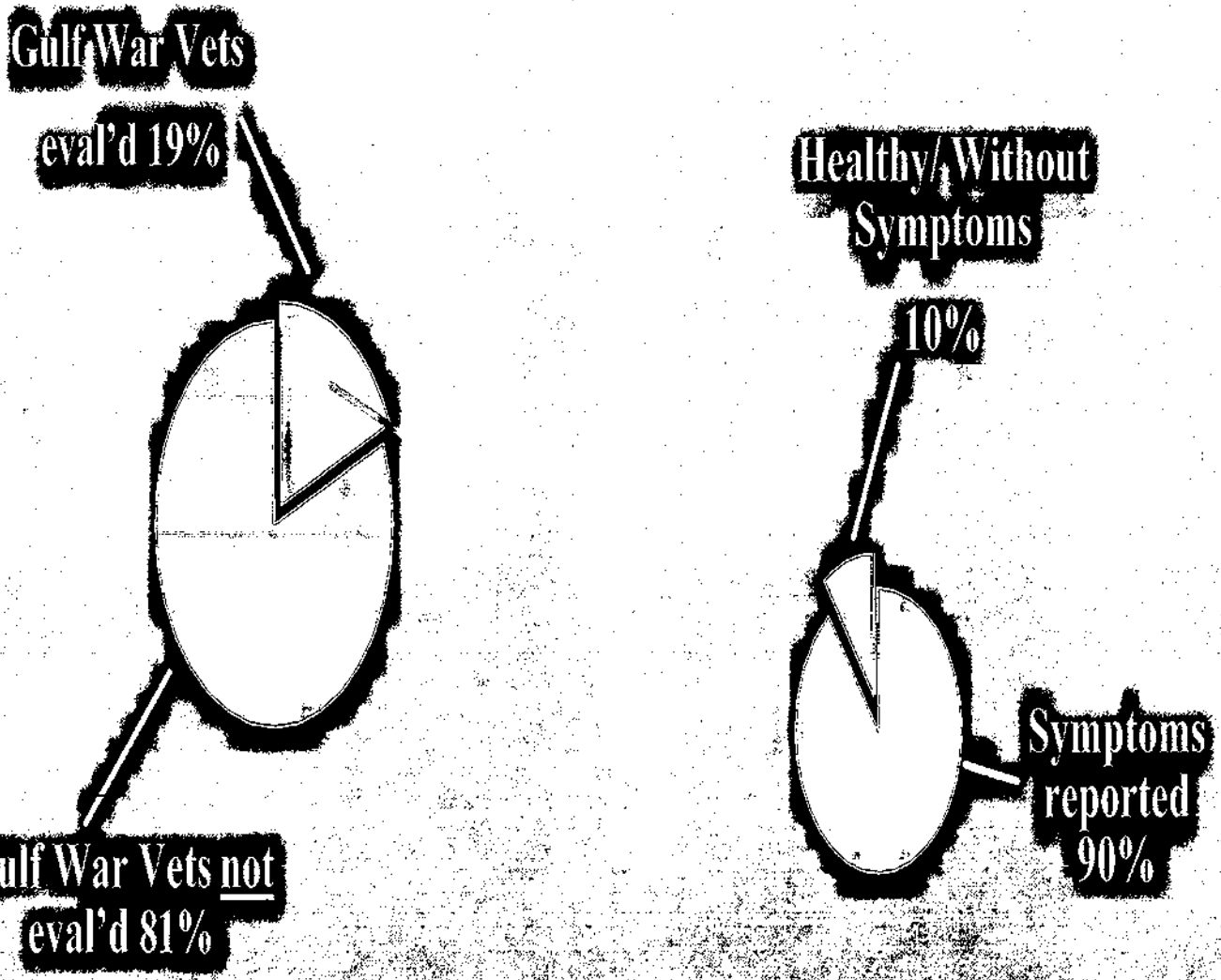

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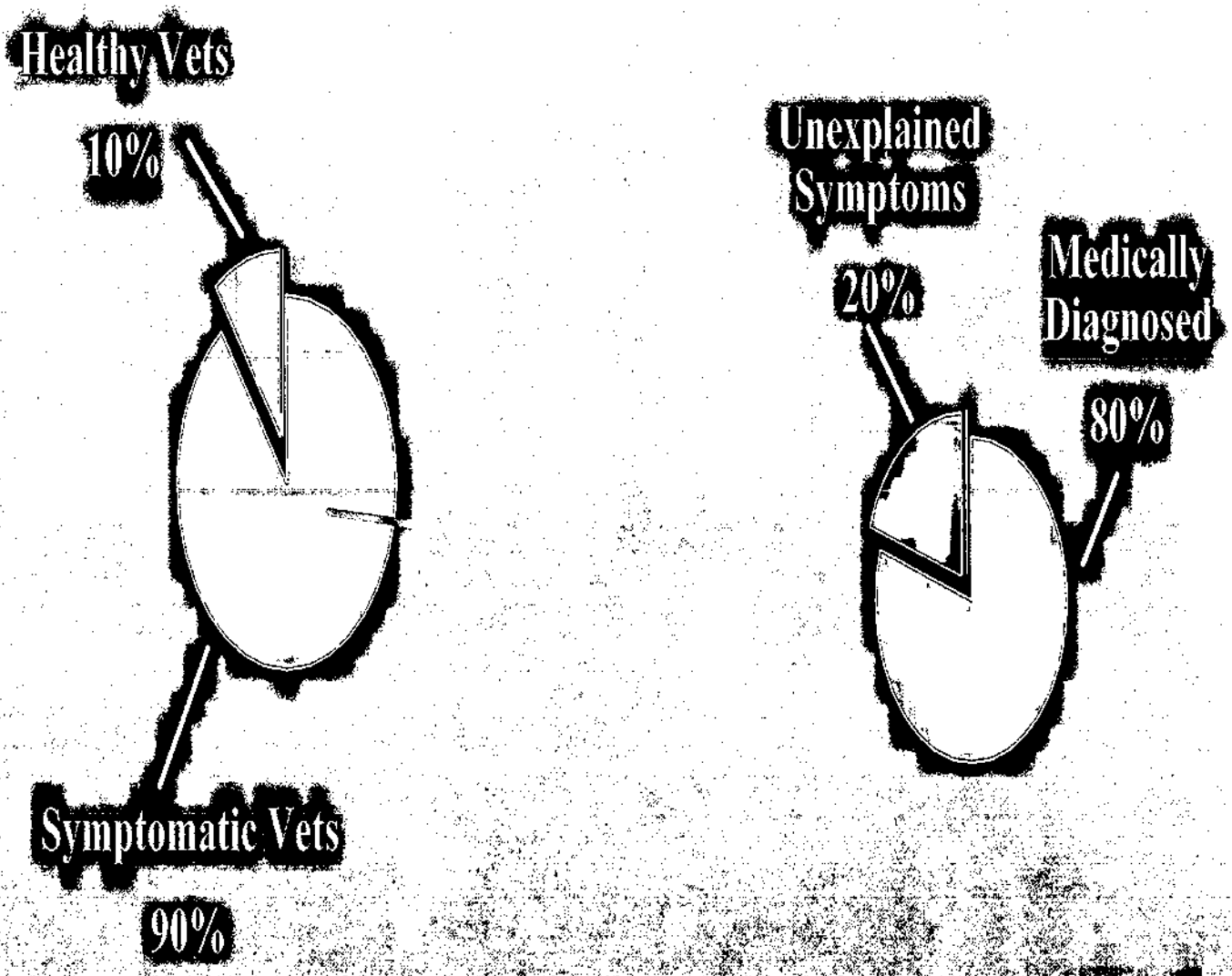

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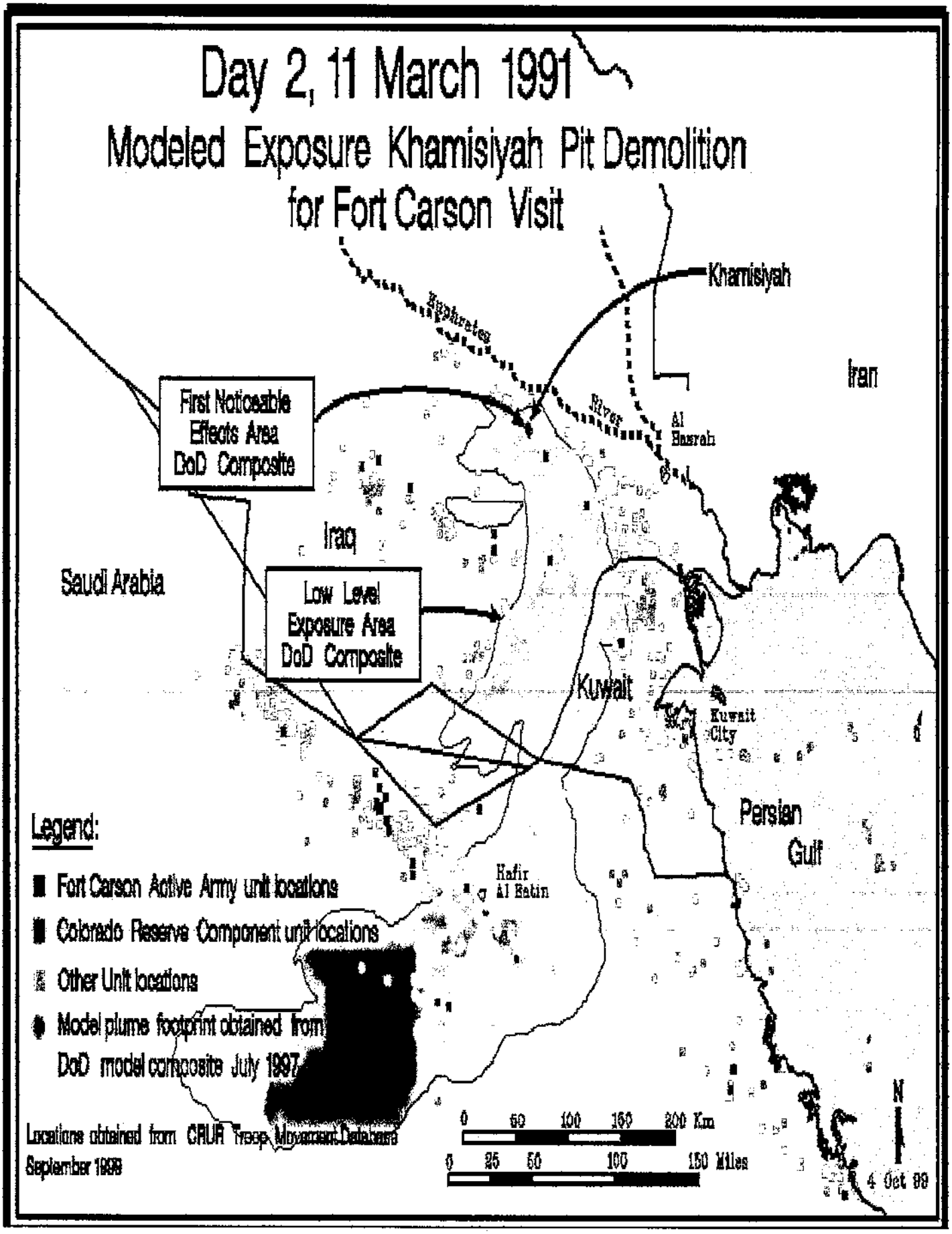
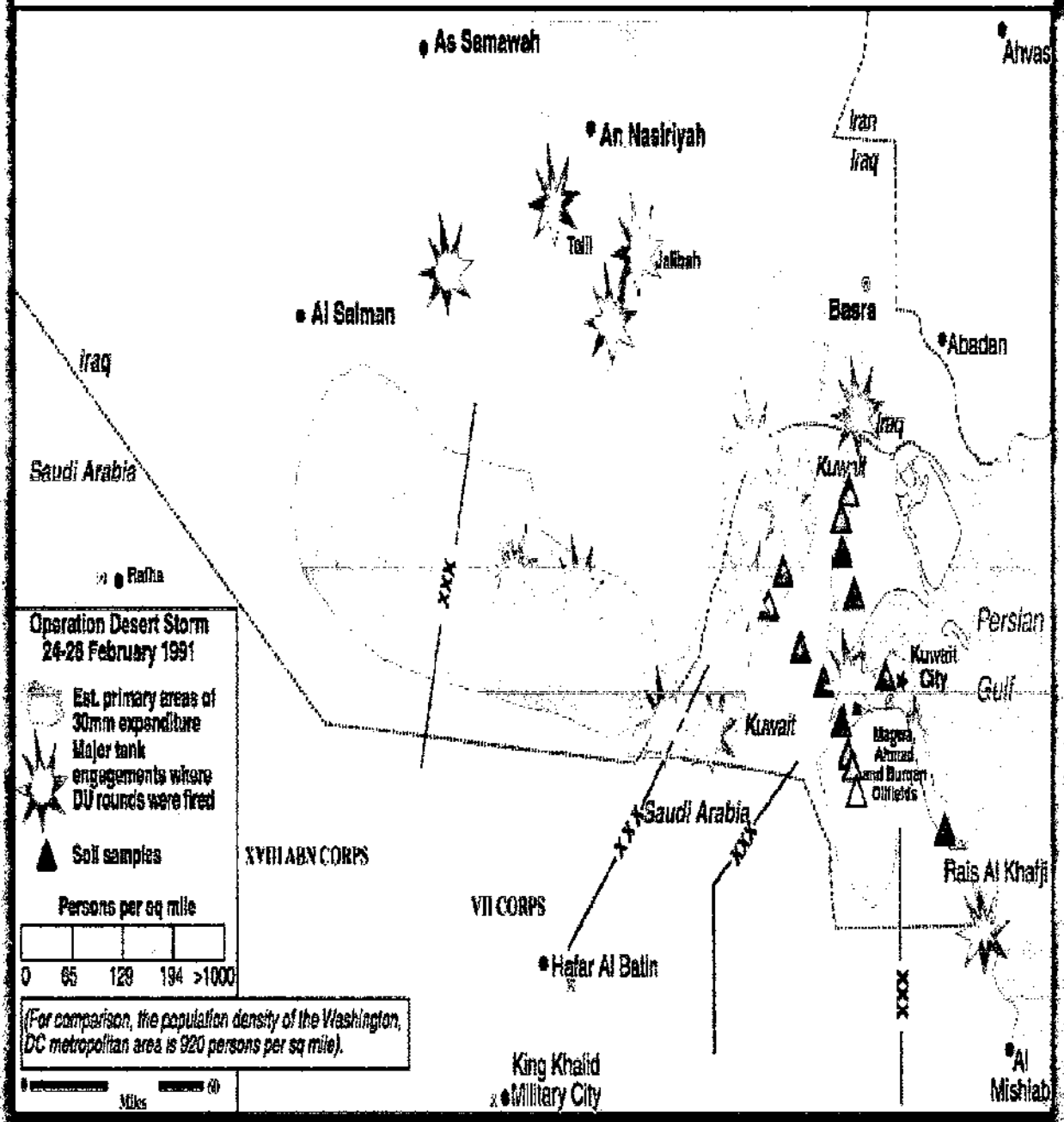

Day 2, 11 March 1991
Modeled Exposure Khamisiyah Pit Demolition
for Fort Carson Visit
Khamisiyah
Euphrates
River
Iran
Al
Basrah
First Noticeable
Effects Area
DoD Composite
Iraq
Saudi Arabia
Low Level
Exposure Area
DoD Composite
Kuwait
Kuwait
City
Persian
Gulf
Hafir
Al Batin
Legend:
Fort Carson Active Army unit locations
Colorado Reserve Component unit locations
Other Unit locations
Model plume footprint obtained from
DoD model composite July 1997
Locations obtained from CRUR Troop Movement Database
September 1998
0 50 100 150 200 Km
0 25 50 100 150 Miles
N
4 Oct 99

Primary Areas of DU Expenditure



Investigator's Message Sent

"The symptoms described were not consistent with symptoms associated with exposure to chemical warfare agents or depleted uranium."

Veteran's Messages Received

"You're wrong!"

"You can't possibly be sick because of this!"

DU Exposure Issues

- Radiation
- Heavy metal toxicity
- Consequences of exposure
- Reproductive effect
- Contamination of theater

DU Awareness Training

- Current CTT Task (031-503-1017)
- Better information is now available
  - Chemical toxicity vice radioactivity
  - Continue the mission
  - Respiratory protection for extended exposure
- Training support packages being updated
  - Includes updating the common task & GTA
  - Additional training for specialists
- Use existing training management system

OSAGWI Investigations

- Medical issues and lessons learned:
  - Focus in 1999
    - Vaccines, PB, records, policy
    - DU training
    - Managing hazards

Proactive Measures - You

- Recognize and contend with potential hazards:
  - Improve intel notification
  - Train all personnel
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  - Understand the environment and culture before deploying
- Improve feedback and cross talk

Operational Lessons - Your Unit

- Improve expedient demolition of munitions
- CW/BW detection: earlier with fewer false positives
- Relate CW to operational and medical records
- Adapt for the future
  - Retain individual unit locations and records
  - DU training
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Back-up Slides

Identifying Possible Causes

- Normal disease rate
- Linking hazards and illnesses
  - Research
  - New disease paradigm

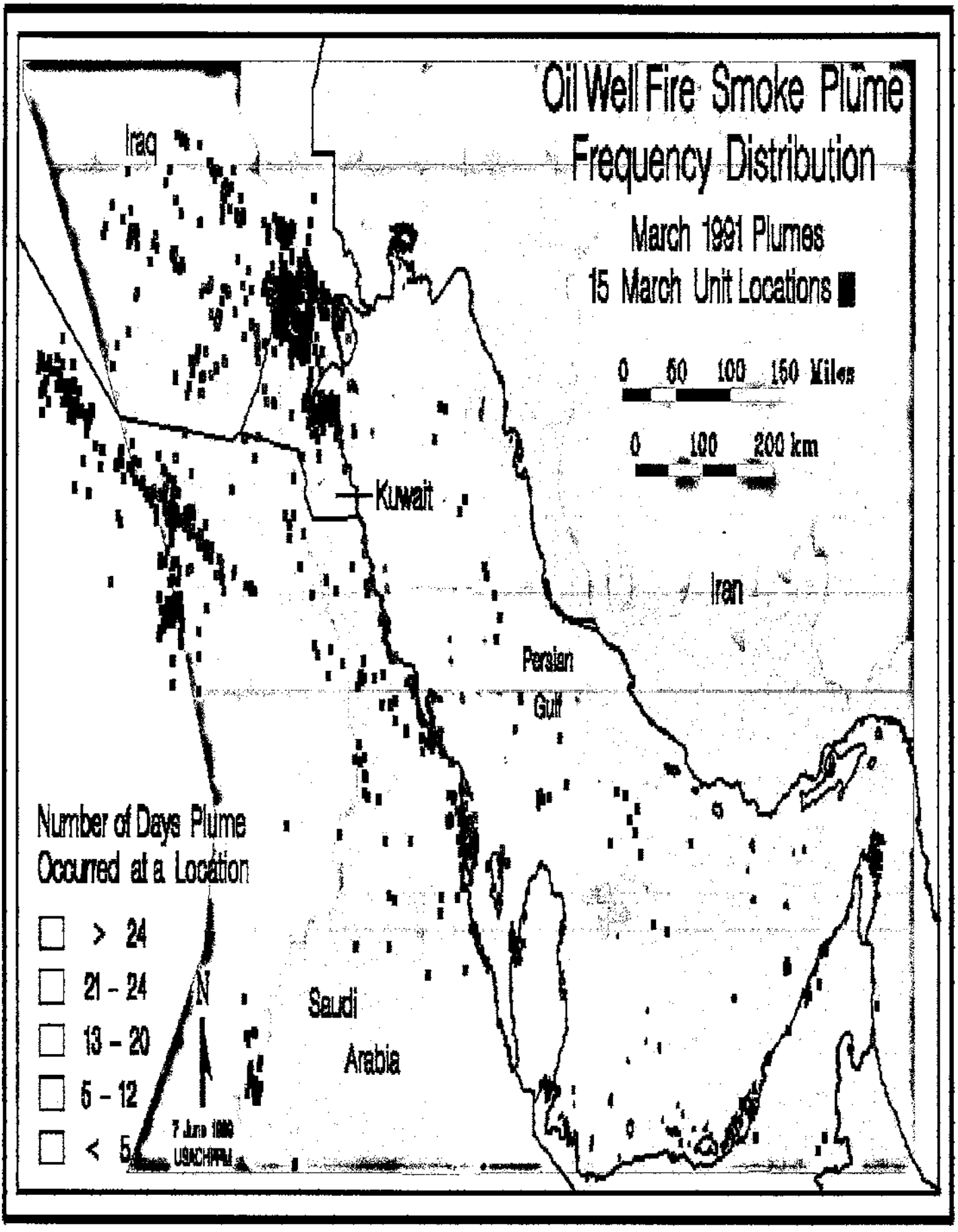
Symptoms

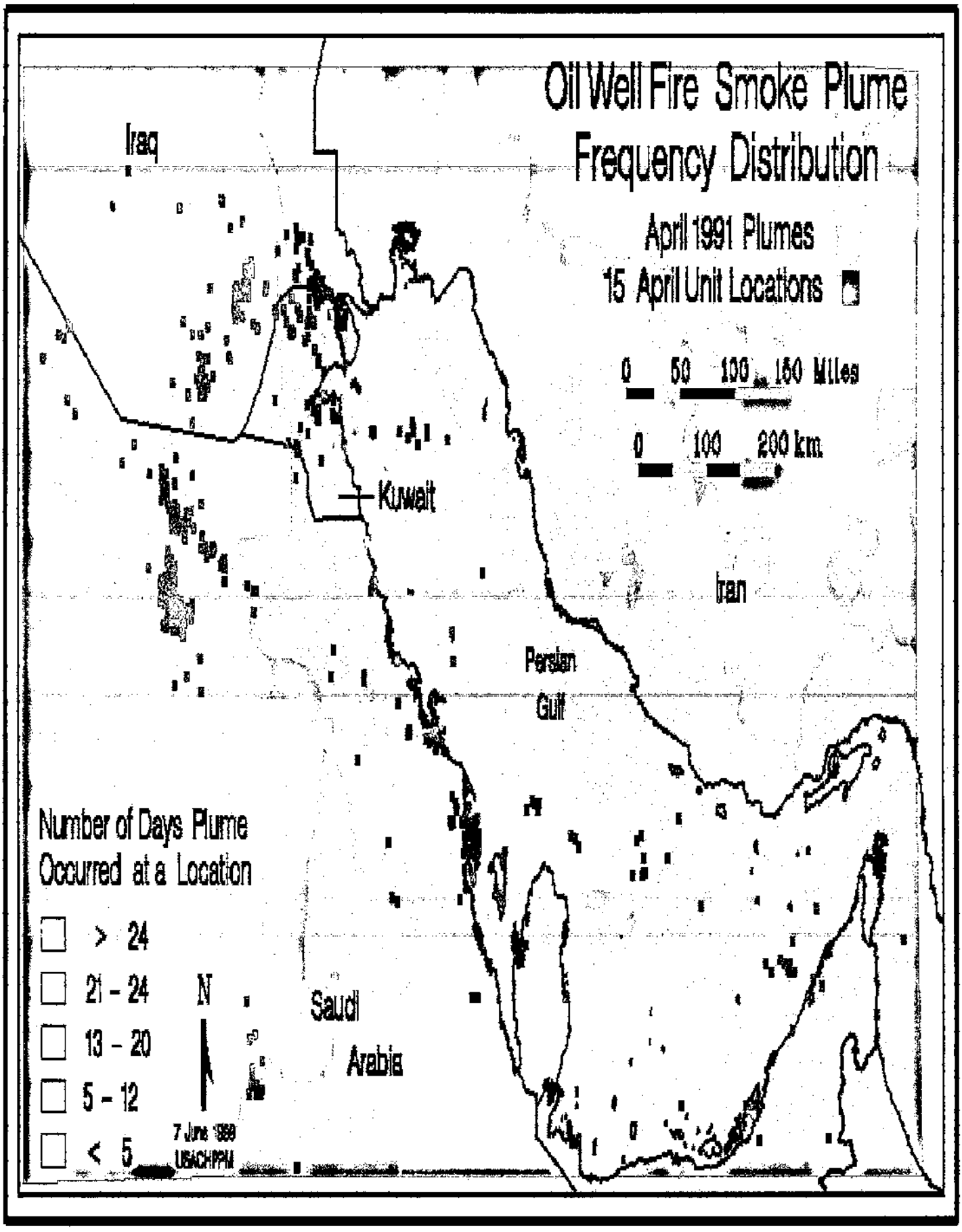
- Tiredness
- Rashes
- Headaches
- Muscle aches
- Joint pains
- Abdominal pain
- Diarrhea
- Hair loss
- Memory loss
- Sleep disturbance
- Depression
- Concentration problems

Hazards

- Chemical warfare agent
- Biological warfare agent
- Pesticides
- Oil well fires
- Vaccines
- Depleted uranium
- Pyridostigmine bromide
- Infectious disease
- Stress
- "Cocktail" effect

30+ offered as possible causes


Oil Well Fire Smoke Plume
Frequency Distribution
March 1991 Plumes
15 March Unit Locations
0 50 100 150 Miles
0 100 200 km
Iraq
Kuwait
Iran
Persian
Gulf
Saudi
Arabia
N
Number of Days Plume
Occurred at a Location
> 24
21 - 24
13 - 20
5 - 12
< 5
7 June 1991
USAFCHPPM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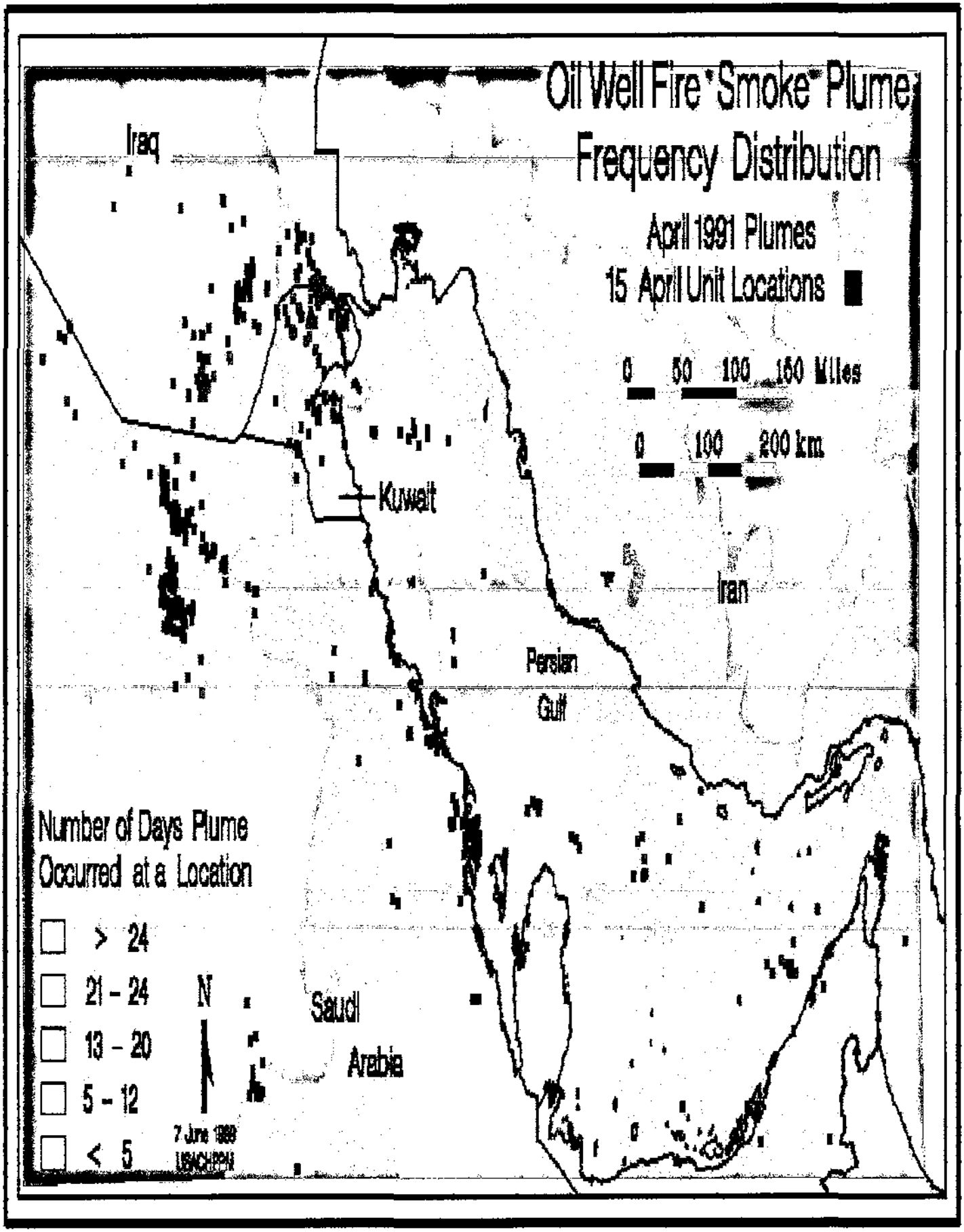
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Medical Training for Line Leaders

- Wellness Requirements = Mission Success
  - Routine examinations, vaccinations
  - Force Health Protection
  - Anthrax Vaccination
- Normal Disease Rates - Garrison or Deployment
  - Diarrhea
  - Sports injuries
  - Cancer, heart attacks, diabetes, etc.

Operational Lessons - You

- Recognize and contend with potential hazards:
  - Improve intel notification.
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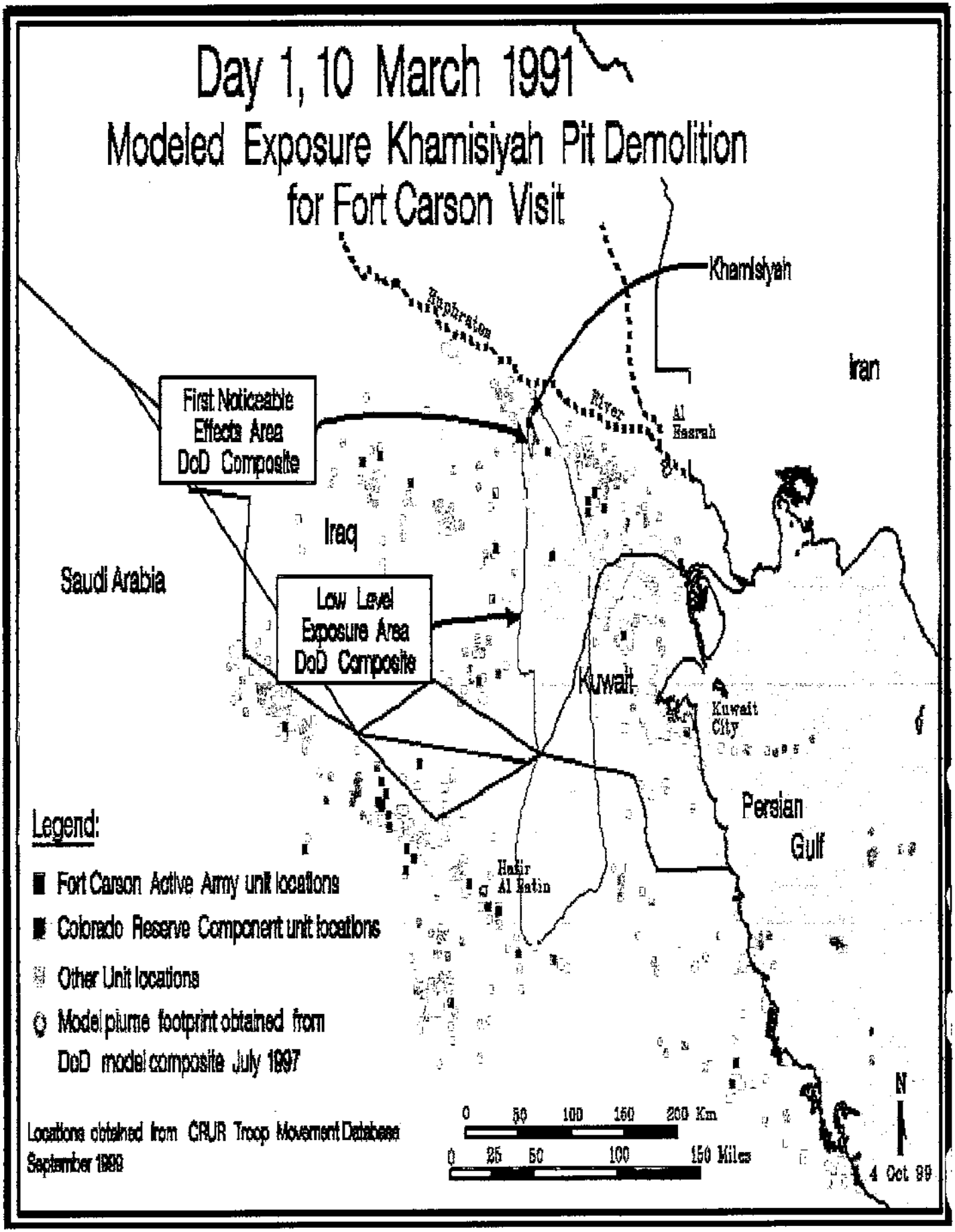
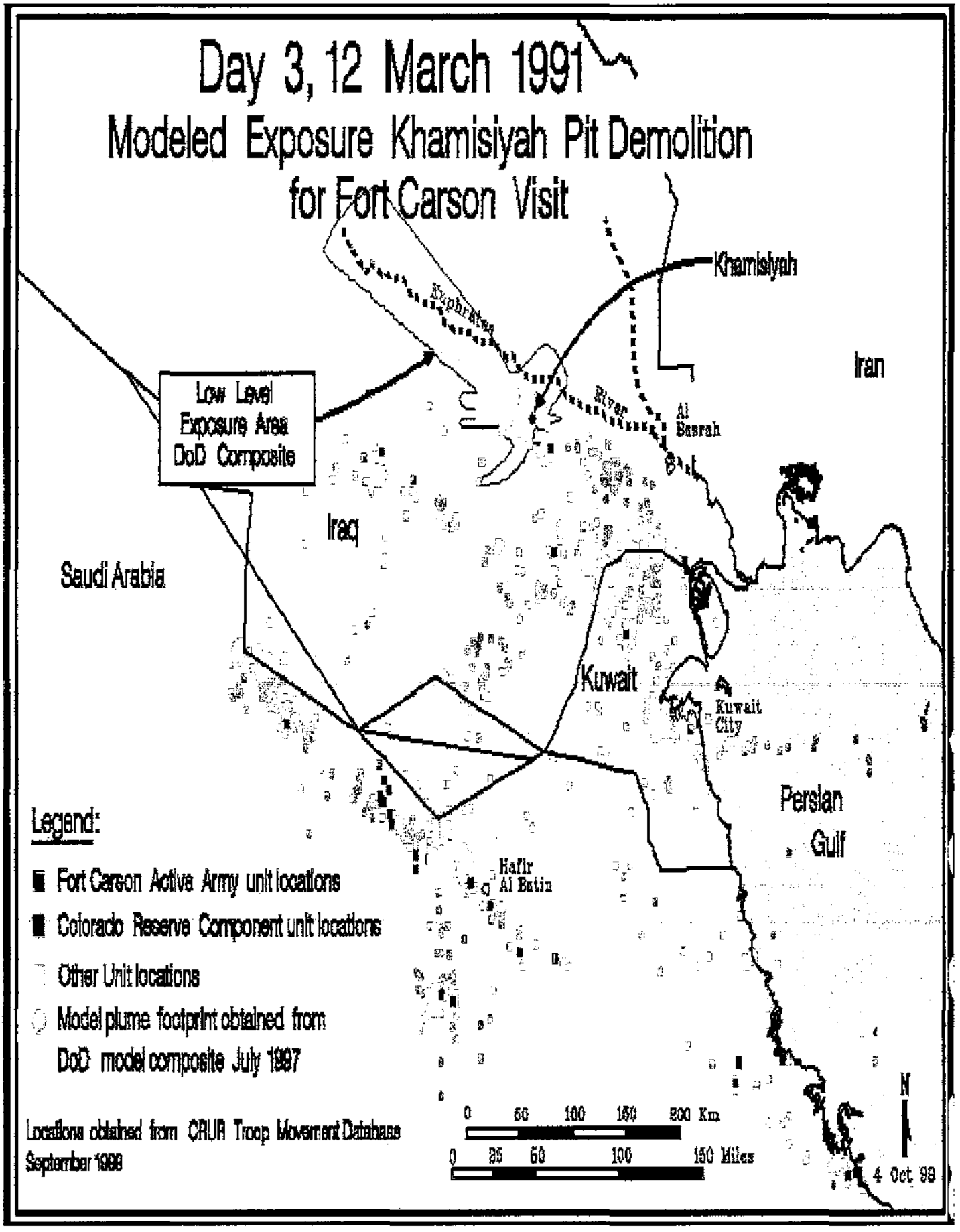
- Automatic Chemical Agent Alarm (ACADA)
- Medic Cam - Tele medicine


Day 1, 10 March 1991
Modeled Exposure Khamisiyah Pit Demolition
for Fort Carson Visit
Khamisiyah
Euphrates
River
Iran
Al
Basrah
First Noticeable
Effects Area
DoD Composite
Iraq
Saudi Arabia
Low Level
Exposure Area
DoD Composite
Kuwait
Kuwait
City
Persian
Gulf
Hafir
Al Batin
Legend:
Fort Carson Active Army unit locations
Colorado Reserve Component unit locations
Other Unit locations
Model plume footprint obtained from
DoD model composite July 1997
Locations obtained from CRUR Troop Movement Database
September 1999
0 50 100 150 200 Km
0 25 50 100 150 Miles
N
4 Oct 99


Day 3, 12 March 1991
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for Fort Carson Visit
Khamisiyah
Euphrates
River
Low Level
Exposure Area
DoD Composite
Iraq
Iran
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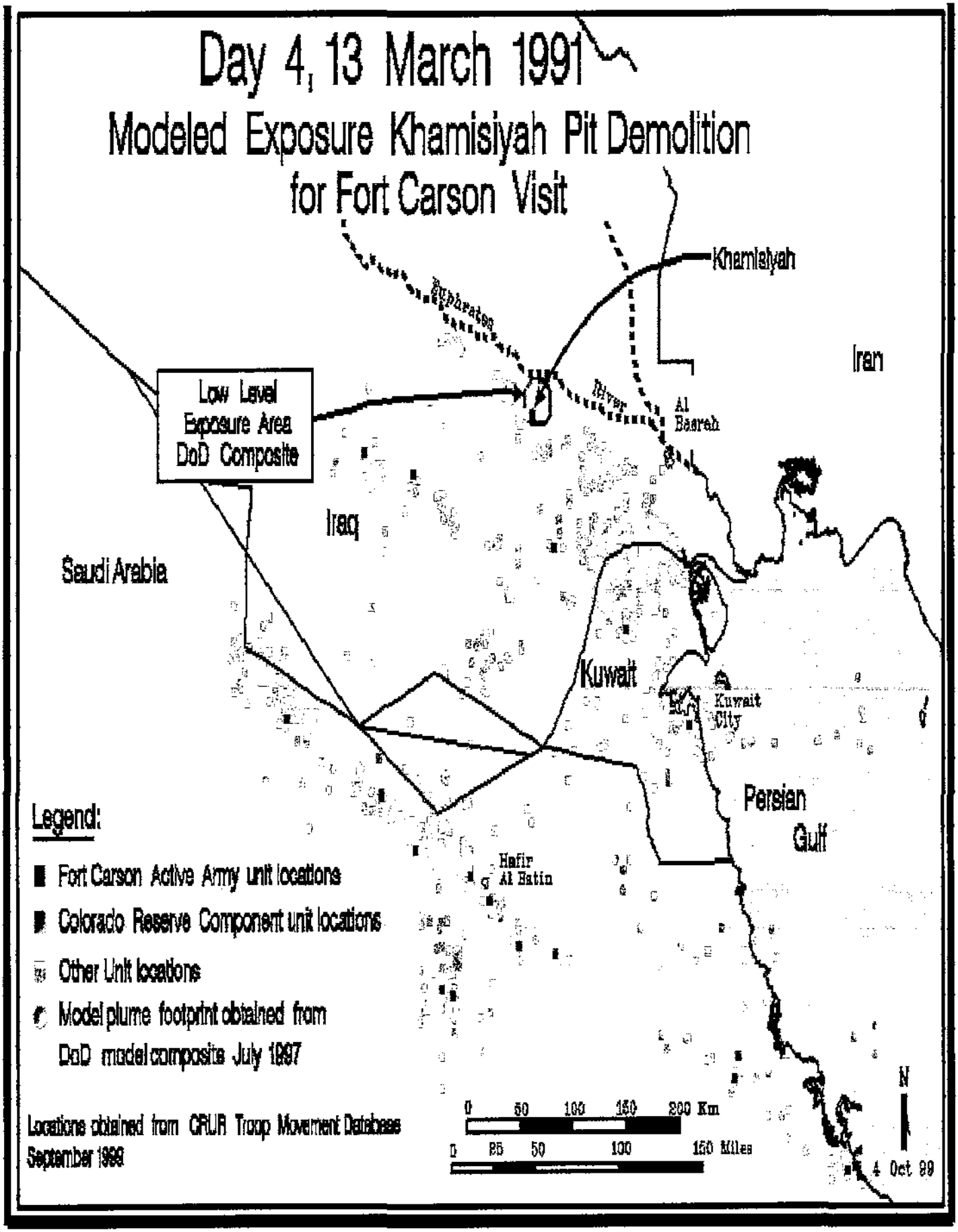
Day 4, 13 March 1991
Modeled Exposure Khamisiyah Pit Demolition
for Fort Carson Visit
Khamisiyah
Euphrates River
Iran
Low Level
Exposure Area
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Summary

- Work continues: "leave no stone unturned"
- We rely on Gulf War veterans:
  - To give us leads
  - To check our accuracy
- We rely on today's force -- including you:
  - To ensure GW vets get proper testing and treatment
  - To apply lessons learned to the future

Office of the Special Assistant to the Secretary of Defense

for Military Deployments

DSN 761-1078 fax 703-578-8501

email: brostker@gwillness.osd.mil

Office of the Special Assistant for Gulf War Illnesses

(81)

Briefing Overview

- Mission Statement
- The Gulf War
- Post Gulf War Issues
- Searching for answers
- Lessons Learned
- Force Health Protection
- Bottom Line
- Obtaining help and information

Our Mission

- Realistically gain the information for those involved in deployments for them to make informed decisions about their health.
- Investigate to understand and explain illnesses in Gulf War veterans.
- Establish a proactive, reactive and interactive communication program to provide this information.
- Develop relationships with DoD organizations to foster implementation of lessons learned.
- Partner ASD Health Affairs in representing DoD with non-DoD organizations including the Military Veterans Health Coordinating Board.

Gulf War Theater

- August 1990 to July 1991
- 697,000 US service members
- More then 27,000 hospitalizations
- 148 battle deaths
- 224 non-battle deaths

1 in 7 Veterans Reported Symptoms Since Return

Most frequently reported symptoms

- Joint pain
- Headaches
- Sleep disorders
- Depression
- Fatigue
- Memory loss
- Rash
- Muscle pain

Communication Breakdown

- Veterans with real health problems
- Healthcare professionals unable to provide answers
- Government slow to recognize the reality of problems

Confounding Issues

- No clustering
- No symptom consistency; variable onset
- No new disease or links between exposures and symptoms
- No long term study

Taking Care of Service Members

- **DoD Comprehensive Clinical Evaluation Program**
  - Gulf War vets (active, Guard/Reserve, retired)
  - Active service member deployed to SWA since war ended
  - Family members
- **VA Persian Gulf Registry**
  - Gulf War vets (left service prior to retirement)
  - Service members deployed to SWA and left service before retirement
  - Evaluation for family members
- **Available to *all* service members deploying to South West Asia**

Don't Tough It Out!

OSAGWI investigations

- Chemical/biological warfare:
  - Chemical warfare agent - Khamisiyah incident
    - 99,000 vets notified
- Environmental:
  - Depleted uranium (DU), Oil well fires, Pesticides
    - Science doesn't support DU, particulates or Oil Well fires as causes.
    - Still examining pesticides
- Medical issues:
  - Vaccines, PB, records, policy
- Scientific research under PGVCB
  - 180 studies sponsored by DoD & DVA and HHS
  - No cause and effect relationship so far

Investigation Results

- Gulf War
  - Poor intelligence about "Iraq"s CW/BW weapons
  - Information about vaccines & PB wasn't given to troops
  - Inadequate training about DU or on limitations of FOX vehicle, M8A1 alarm and M256 kit
  - *Veterans re-deployed and left service without thorough medical exam or debrief*

The Dirty Battlefield

- What enemy may do to us
  - Chemical/Bio threat; Man made environmental hazards (Oil Well Fires)
- What the environment may do to us
  - Infectious diseases, insects, environmental risks (desert, jungle)
- What we may do to ourselves
  - Pesticides, Stressors, Accidents & Investigational New Drugs

Current and future conflicts and humanitarian deployments have and will have these challenges

Applying Lessons Learned

You

- Train self and others to recognize and avoid hazards
- Improve feedback and cross talk
- You are your own best health advocate

Your Unit

- Create, relate and save operational, NBC, and medical records
- Monitor service member's health & environment
- Post deployment debrief

Force Health Protection

- Pre-deployment
  - –Medical screening/surveillance and briefings
- Deployment
  - –Record keeping
  - –Monitor Environment and personnel
- Post Deployment
  - –Medical screening and Unit debriefing

Anthrax

- Anthrax - an offensive BW agent
  - Inhalation anthrax is highly lethal
  - Easy to develop and weaponize
  - Remains viable for long periods
- We have a safe and effective vaccine

Vaccination against anthrax is critical for your protection

Anthrax Vaccine Program

- Licensed by the FDA since 1970
- Dosing schedule: 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster
- Shortages in stockpiled doses require temporary slowdown of AVIP

1-877-GET-VACC DSN: 761-5101

www.anthrax.osd.mil

www.aviationmedicine.com

Pyridostigmine Bromide

- Threat - Soman is deadly nerve agent
- PB is the only known pretreatment against Soman.
  - Auto injectors alone will not save you
- Issues have been raised about PB
  - Further research is ongoing
- Only President can authorize its use without informed consent

Bottom Line

- Lessons learned from the Gulf War affect today's doctrine and deployments
- You will deploy on missions
- Everyone is responsible for force protection
- You are your own best health advocate
- Don't tough it out; get examined

Obtaining help and information

- SA/MD Veteran's Helpline (800) 497-6261

- Comprehensive Clinical Evaluation program (800) 796-9699

Local CCEP contact here

- Veterans Affairs Persian Gulf registry program (800) 749-8387

http://www.gulflink.osd.mil

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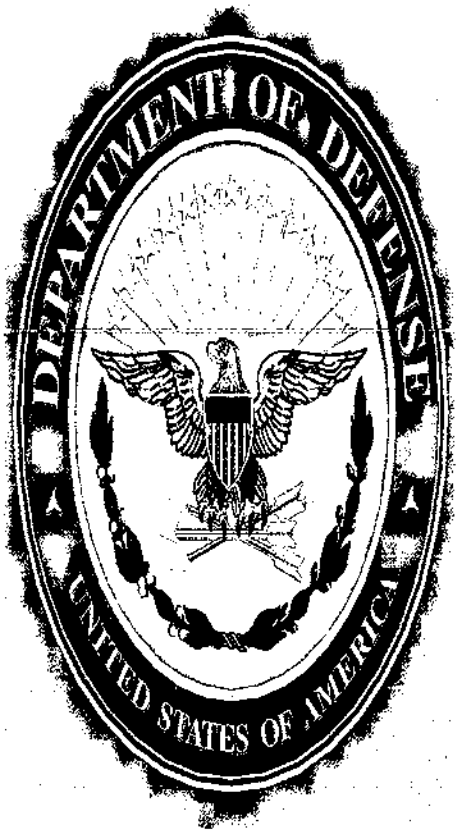
Office of the Special Assistant to the Deputy Secretary of Defense



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- Investigate to understand and explain illnesses in Gulf War veterans
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- Lessons from the Gulf War about dirty battlefields.
- You must protect yourself against hazards.
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    - Training could have averted unnecessary exposure to DU and anxiety resulting from false alarms
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Applying Lessons Learned

You

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- Improve feedback and cross talk
- You are your own best health advocate

Your Unit

- Monitor service member's health & environment
- Maintain adequate field expedient demolition SOP
- CW/BW detection: earlier with fewer false positives
- Create, relate and save operational, NBC, and medical records
- Adapt to reduce risks and train to reduce future risks such as DU

Force Health Protection- A Joint Concept

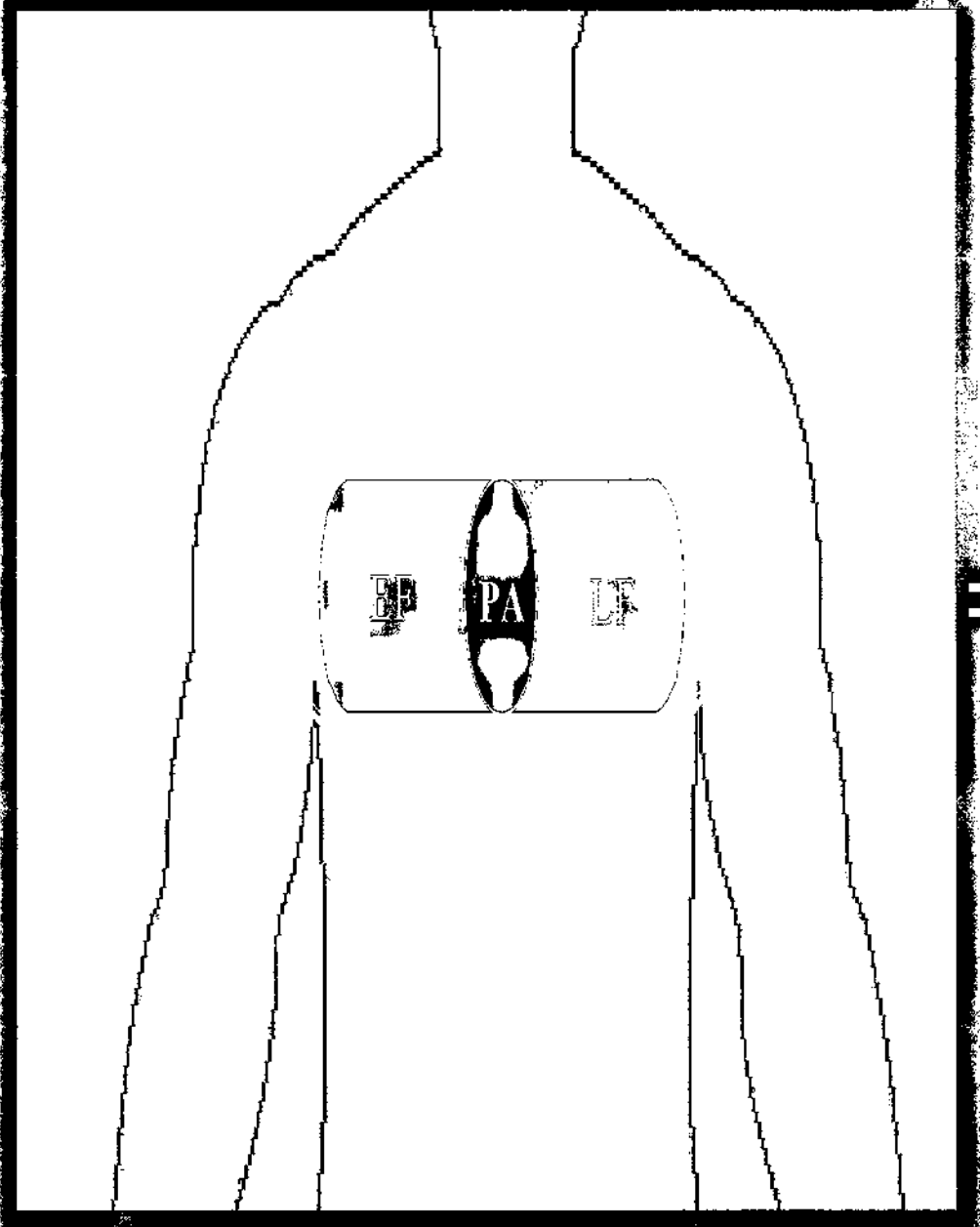
- Medical screening/surveillance
- Record keeping - Personal information carriers
- Integrate Force Health Protection into operational requirements
- Follow up to deployment

Anthrax

- Inhalation anthrax is deadly
- Biological warfare agent of choice:
  - Cheap and easy to produce
  - Can be dispersed in air by a variety of weapons
  - Odorless, colorless, tasteless, difficult to detect
  - Flu-like symptoms early, rapid deterioration, and death

Vaccination against anthrax is critical for your protection

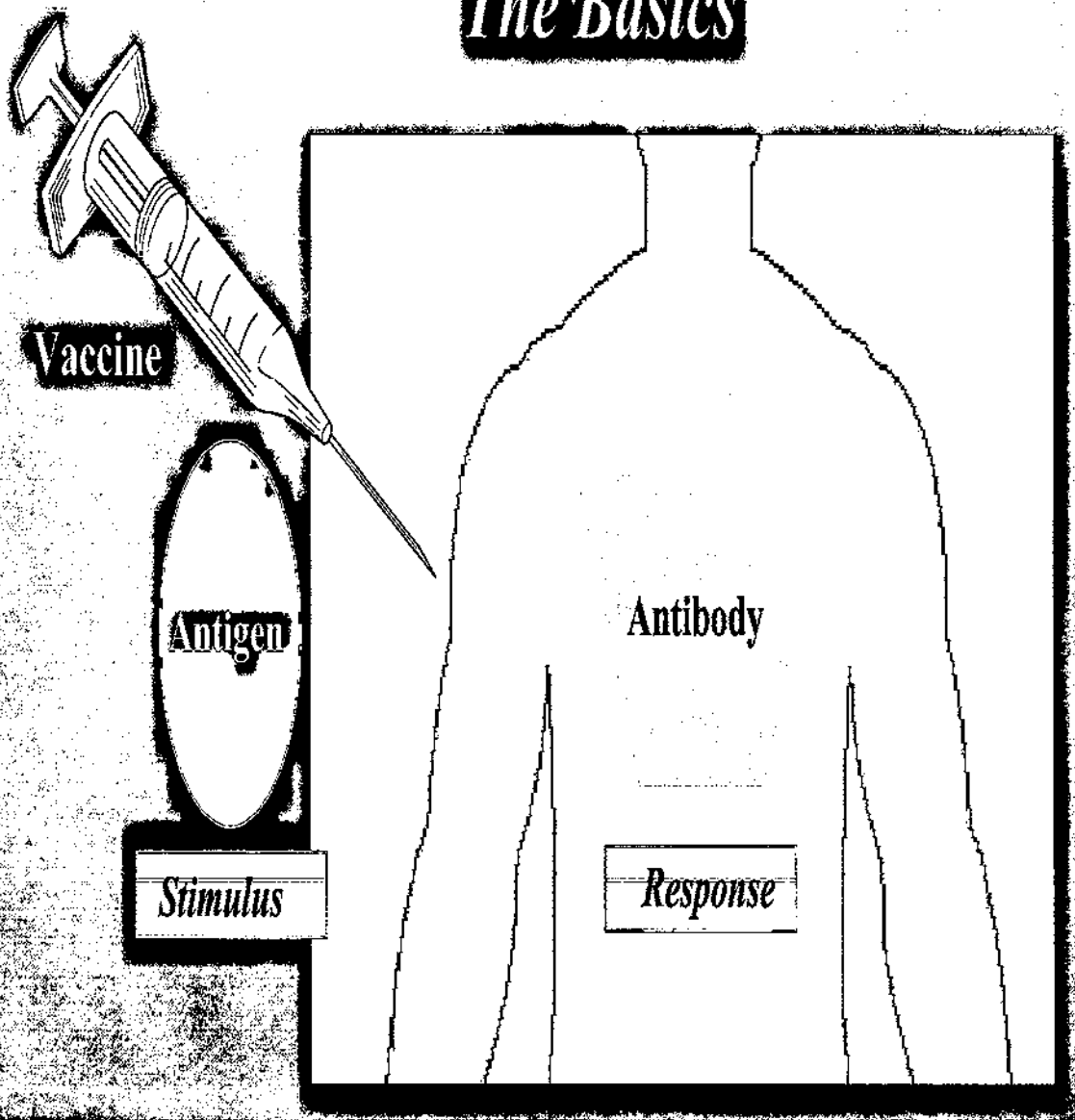
ANTHRAX BACTERIA ATTACK



= Death

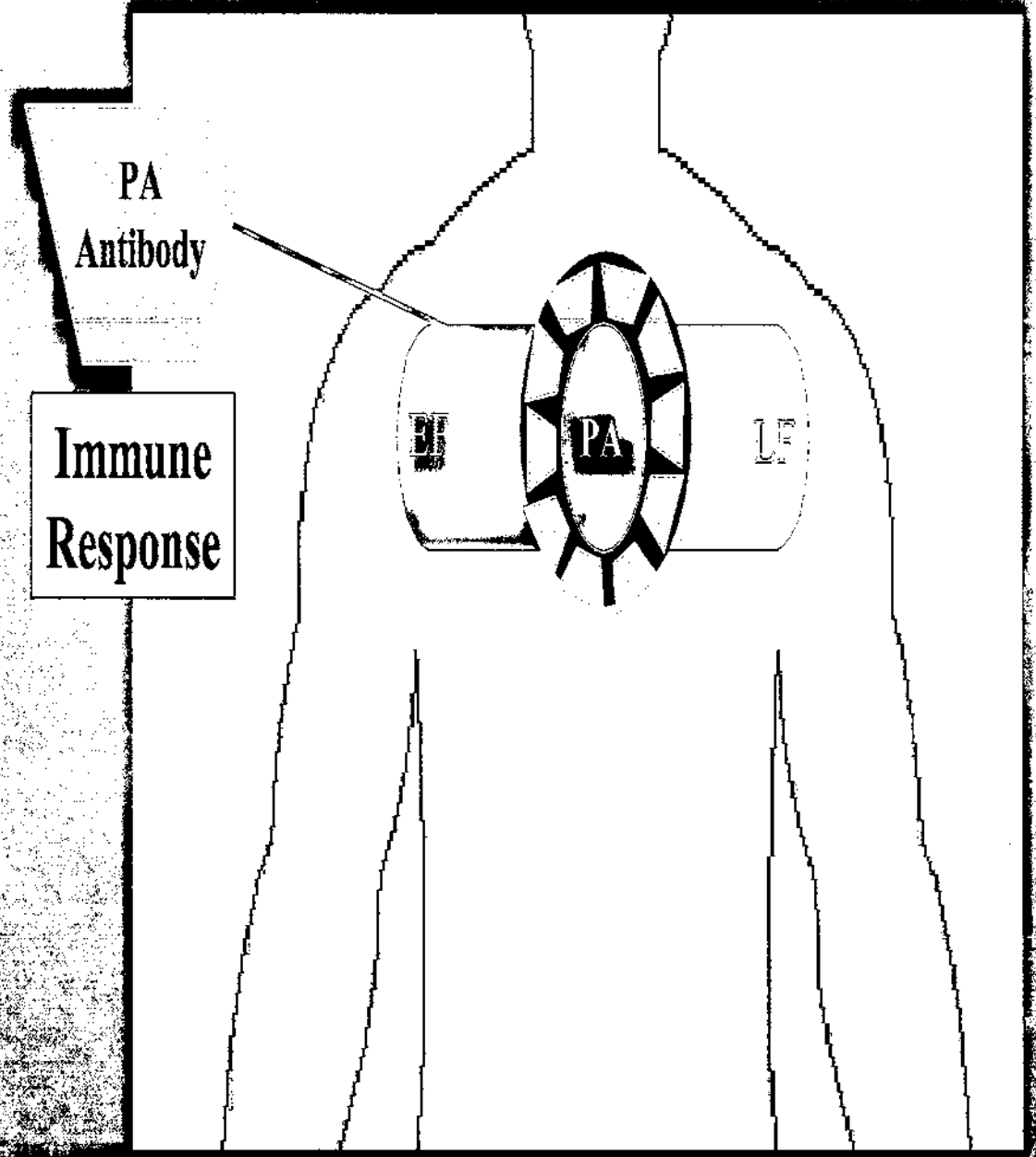
IMMUNE SYSTEM ACTIVATION BY VACCINE

The Basics



AFTER ANTHRAX VACCINE

Antibodies at Work



Office of the Special Assistant for Gulf War Illnesses

Anthrax Vaccine Program

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Bottom Line

- Lessons learned from the Gulf War affect today's doctrine and deployments
- You will deploy on missions
- Everyone is responsible for force protection
- You are your own best health advocate
- Don't tough it out; get examined

Obtaining help and information

- Comprehensive Clinical Evaluation program

  Comm: 06371-86-8340

  DSN: 486-8340

- Veterans Affair Persian Gulf registry program

  Local U.S. consular office or 1-800-749-8387

- Hotline for OSAGWI DSN: 761-1078

http://www.gulflink.osd.mil

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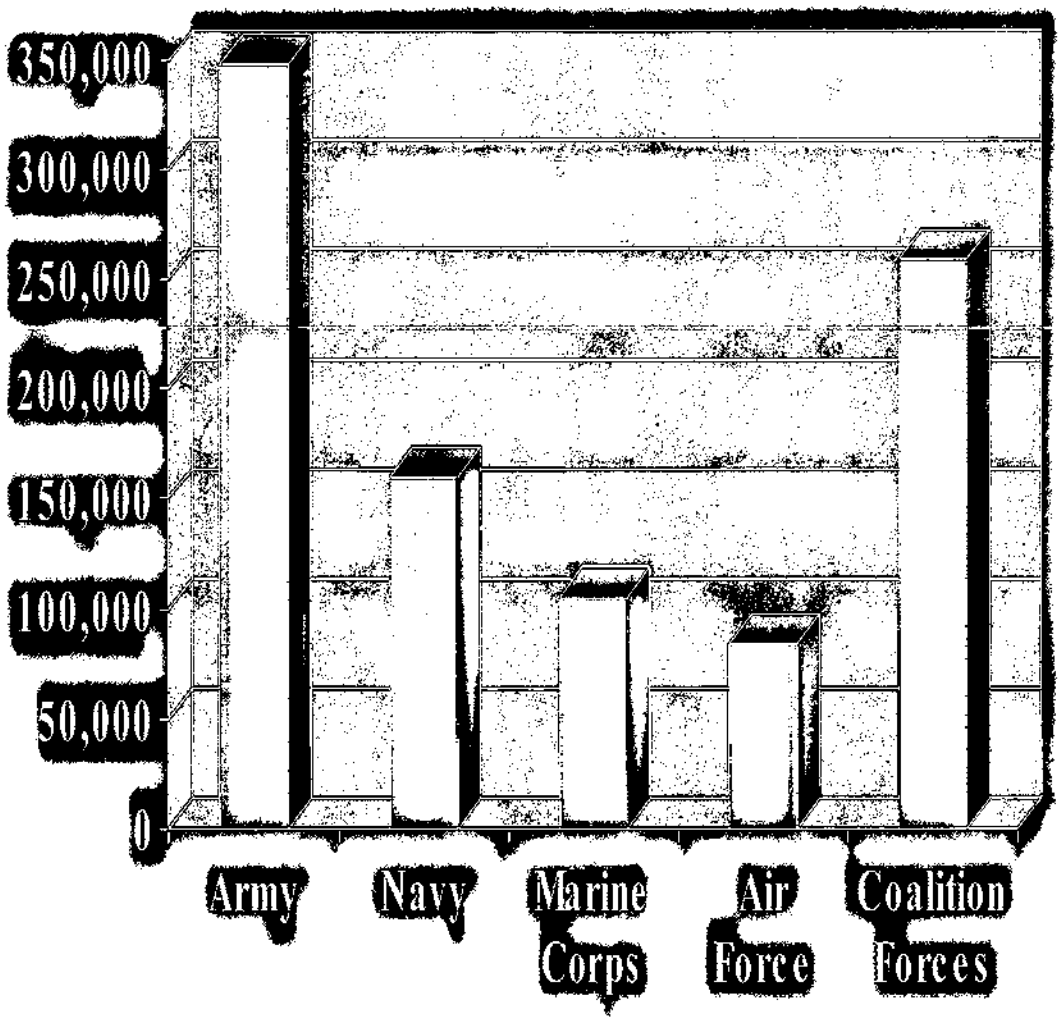
Gulf War Theater Forces

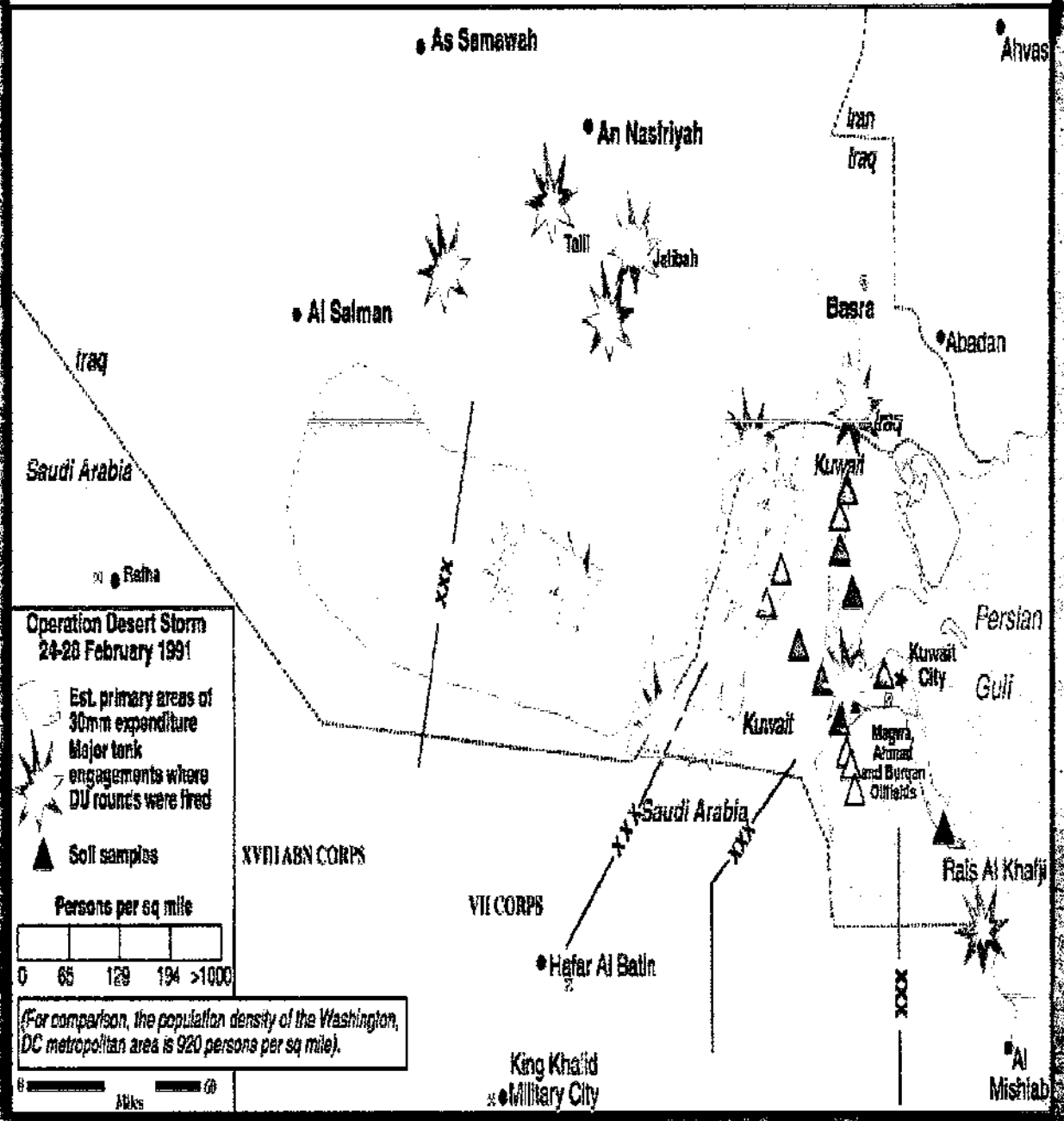


697,000 U.S. service members

DU Exposure Issues

- Radiation
- Consequences of exposure
- Heavy metal toxicity
- Reproductive effect
- Contamination of theater

Primary Areas of DU Expenditure



Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Collect pre-deployment blood sample
- Verify HIV test is current
- Verify Immunizations up to date
- Verify current physical exam
- Complete Health questionnaire

Deployment

- Routine disease/injury reporting
- Forward medical laboratory
- Immunization tracking
- Environmental monitoring

Post Deployment

- Collect blood sample
- Medical debriefs
- Complete health questionnaire
- Screening exams as needed

You are your own best health advocate!

RAND study on PB drew on Comprehensive Sources

- ~10,000 Titles
- ~6,000 Abstracts
- ~2,000 Documents Read
- ~1,000 Citations
- ~80 Interviews
- Documents declassified by British

Conclusions about PB

- We cannot rule out pyridostigmine bromide as a contributor to increased health symptoms in Gulf War veterans.
- Further research is needed to determine the effectiveness of the current dose of PB against Soman.
- Additional research about safety and effectiveness of PB for humans is urgently needed.

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A National Effort

- **OVERSIGHT:** Presidential, 7 Congressional Committees, VSOs, Veterans, the Media
- **INVESTIGATIONS:** IGs, GAO, SIU
- **DoD:** ASDs, Special Assistants, DIA, the Surgeons General
- **OUTSIDE AGENCIES:** CIA, VA, HHS, GWVCB, CDC
- **DECLASSIFICATION:** CIA, DIA, and the Services
- **TECHNICAL PROJECTS:** Dugway, Edgewood, Picatinny, CHPPM, Think tanks, outside experts

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Office of the Special Assistant for Gulf War Illnesses

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Myths versus Reality

Cover up	Open process & oversight
Not listening	Solicit eyewitness reports
Destroy records	Found missing records
20,000 veterans dead	6,186 veterans dead
No assistance to vets	Evaluation and care
"Syndrome"	More than 40 illnesses
CW or DU cause	Many possible causes
Brass doesn't care	Force Protection efforts
	Tough choices
	Cultural changes

Taking Care of Service Members

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Day 2, 11 March 1991

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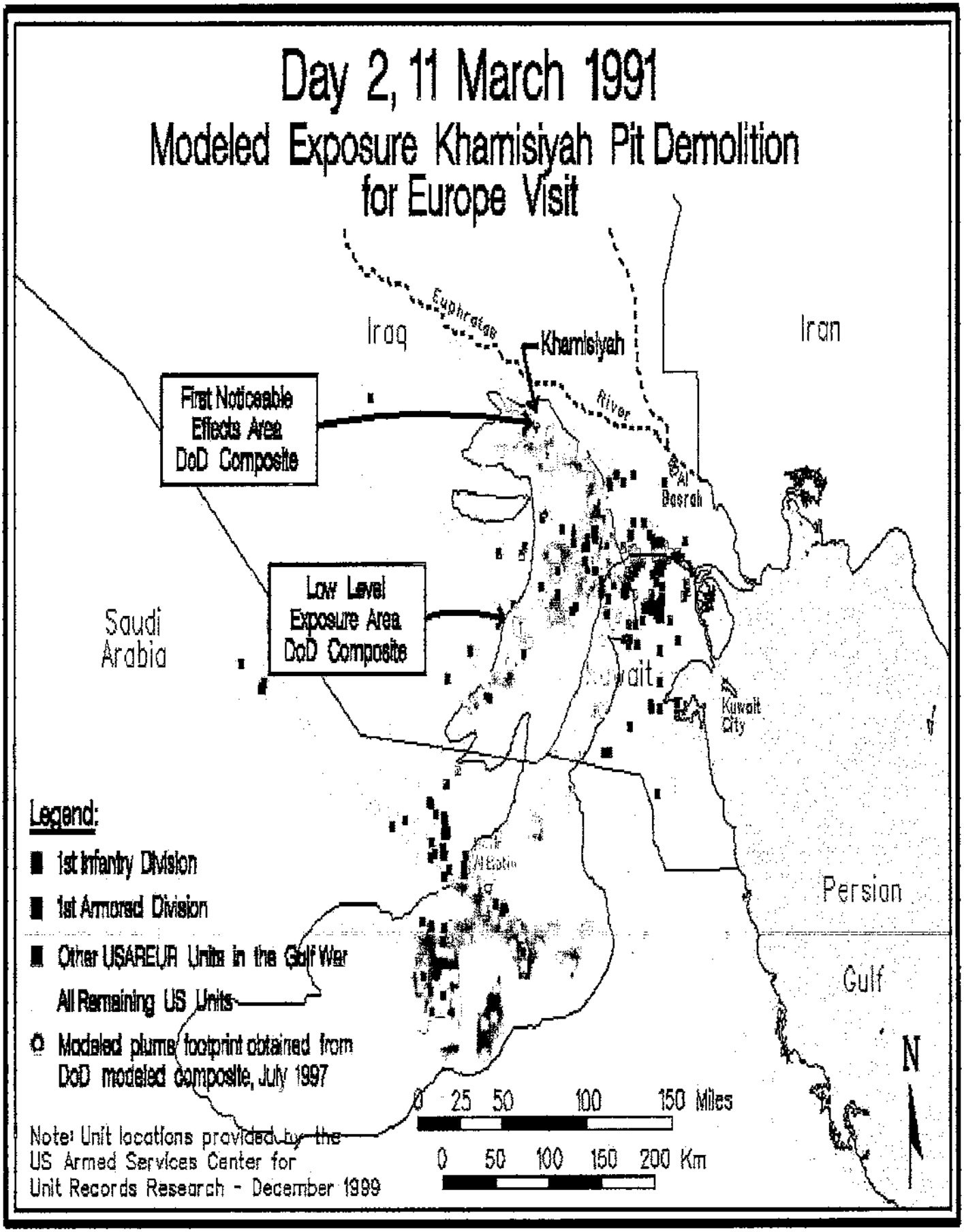

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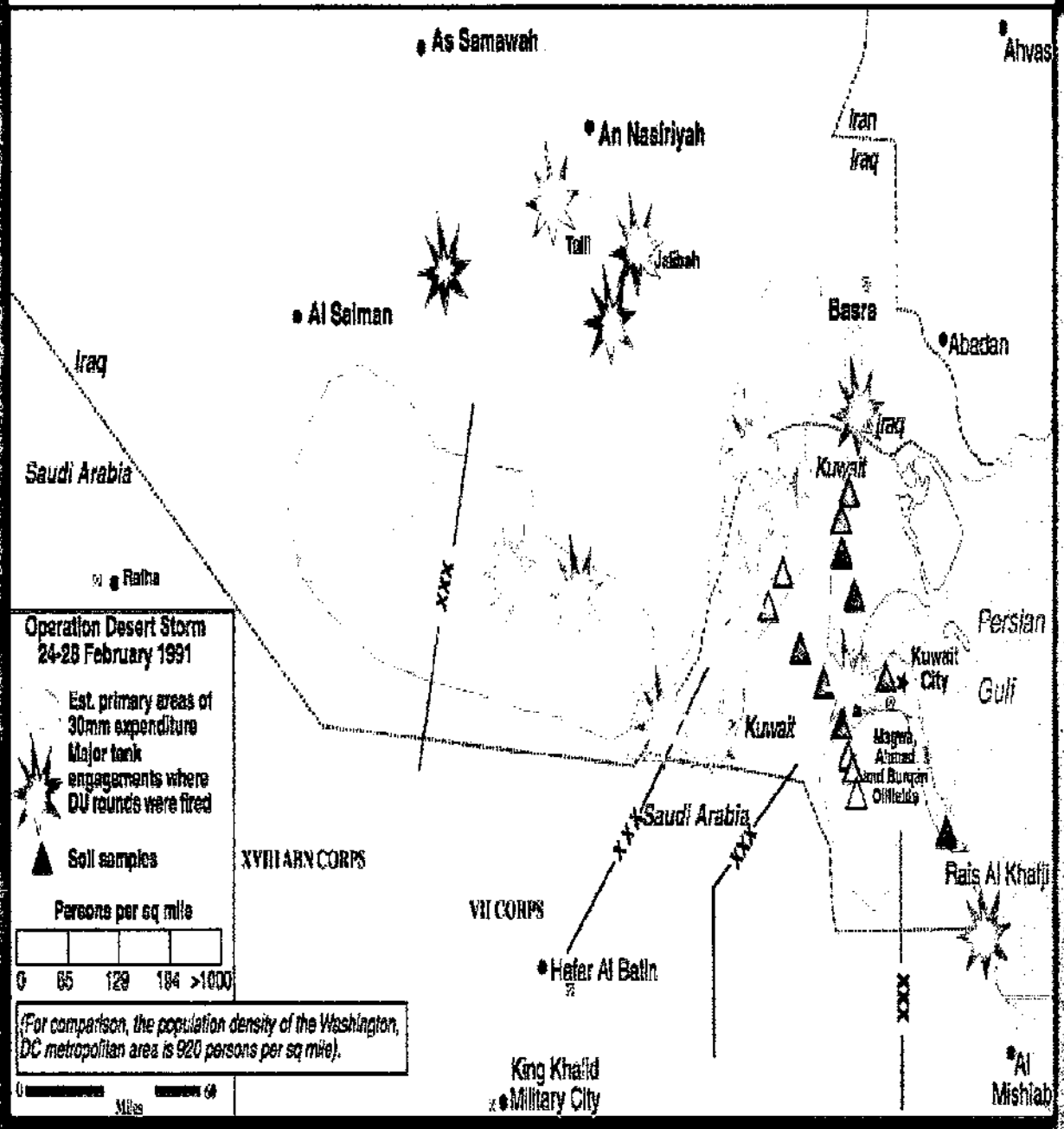

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  - Flu-like symptoms early, rapid deterioration, and death
- MOPP 4 prevents exposure
- Antibiotics work before symptoms appear

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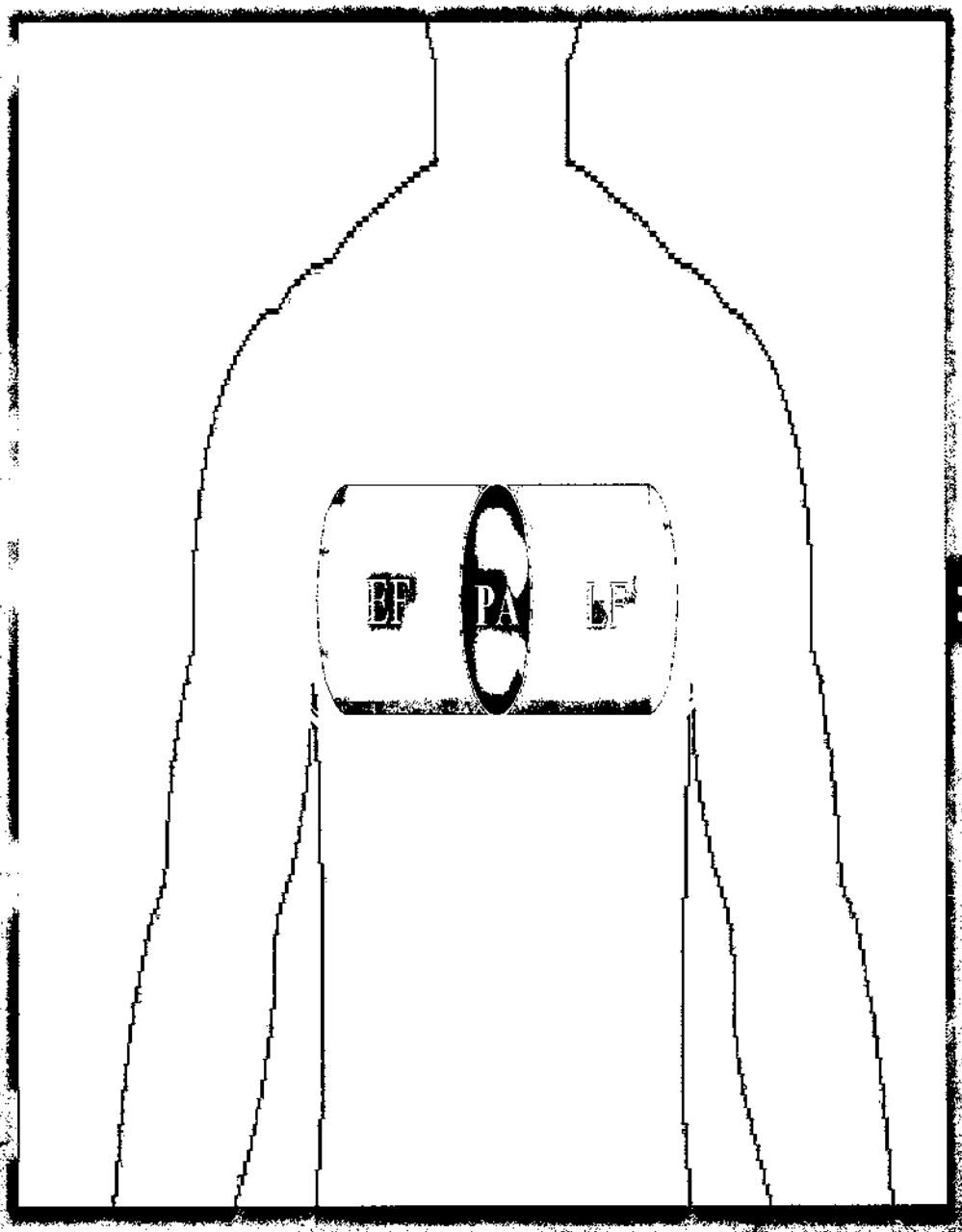

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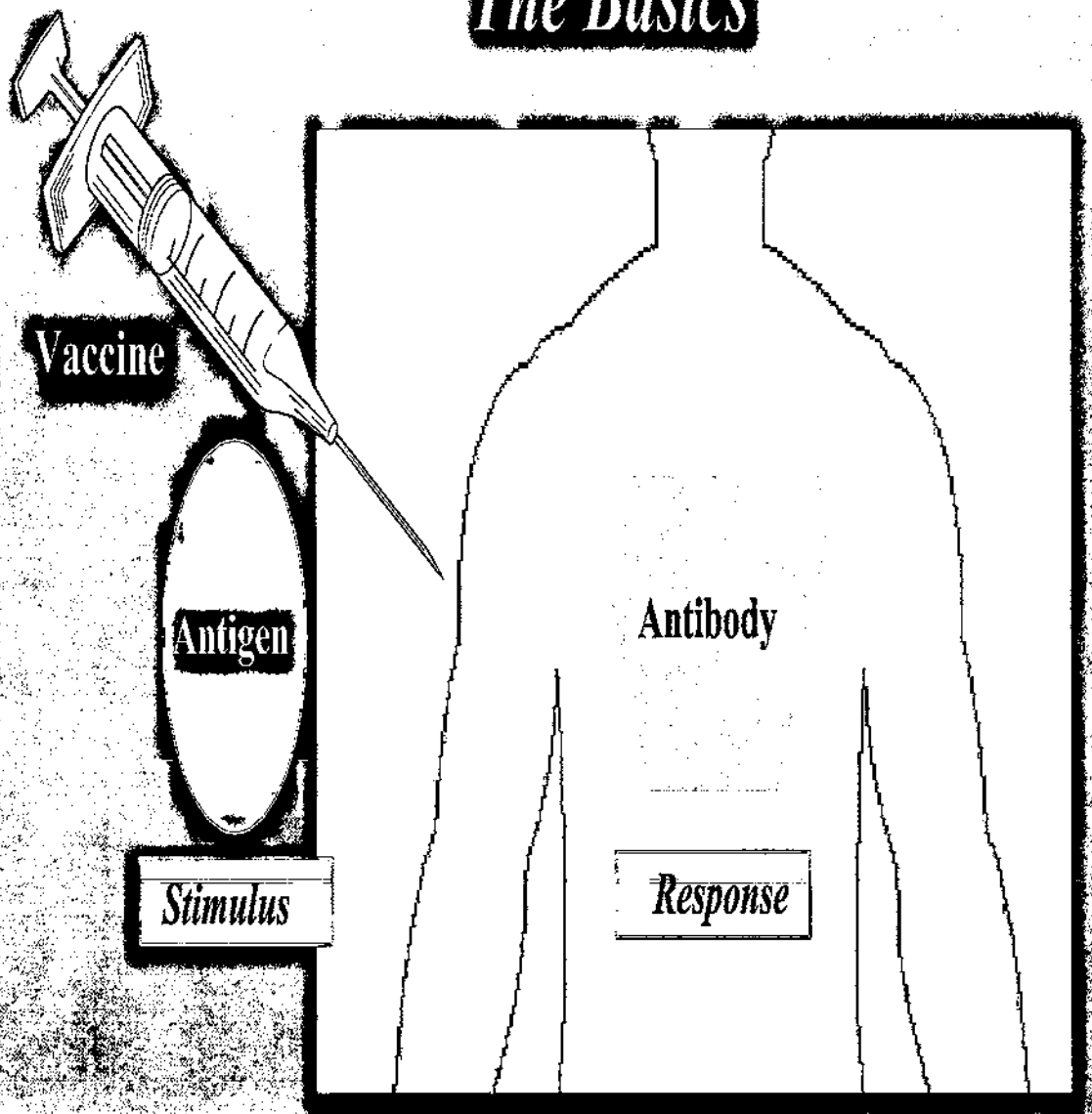

AFTER ANTHRAX VACCINE

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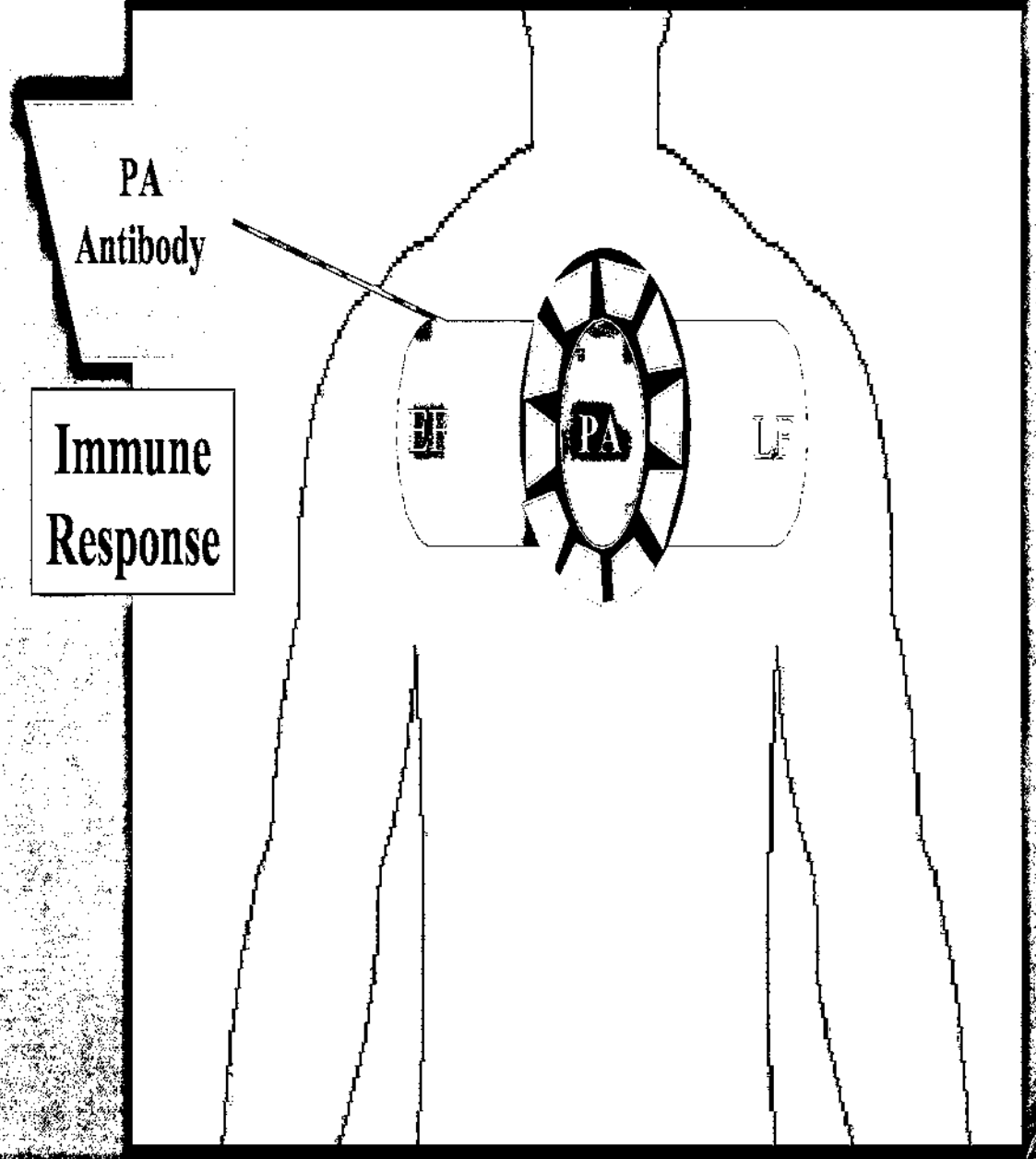

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DSN: 761-5101

www.anthrax.osd.mil

www.aviationmedicine.com

Pyridostigmine Bromide

- Threat - Soman is deadly nerve agent
- PB is the only known pretreatment against Soman.
  - Auto injectors alone will not save you
- Issues have been raised about PB
  - Further research is ongoing
- Only President can authorize its use without informed consent

Bottom Line

- Lessons learned from the Gulf War affect today's doctrine and deployments
- You will deploy on missions to dirty areas
- Everyone is responsible for force protection
- You are your own best health advocate
- Don't tough it out; get examined
- Vaccination against anthrax protects you

Obtaining help and information

- **Comprehensive Clinical Evaluation program**

  Comm: 06371-86-8340

  DSN: 486-8340

- **Veterans Affair Persian Gulf registry program**

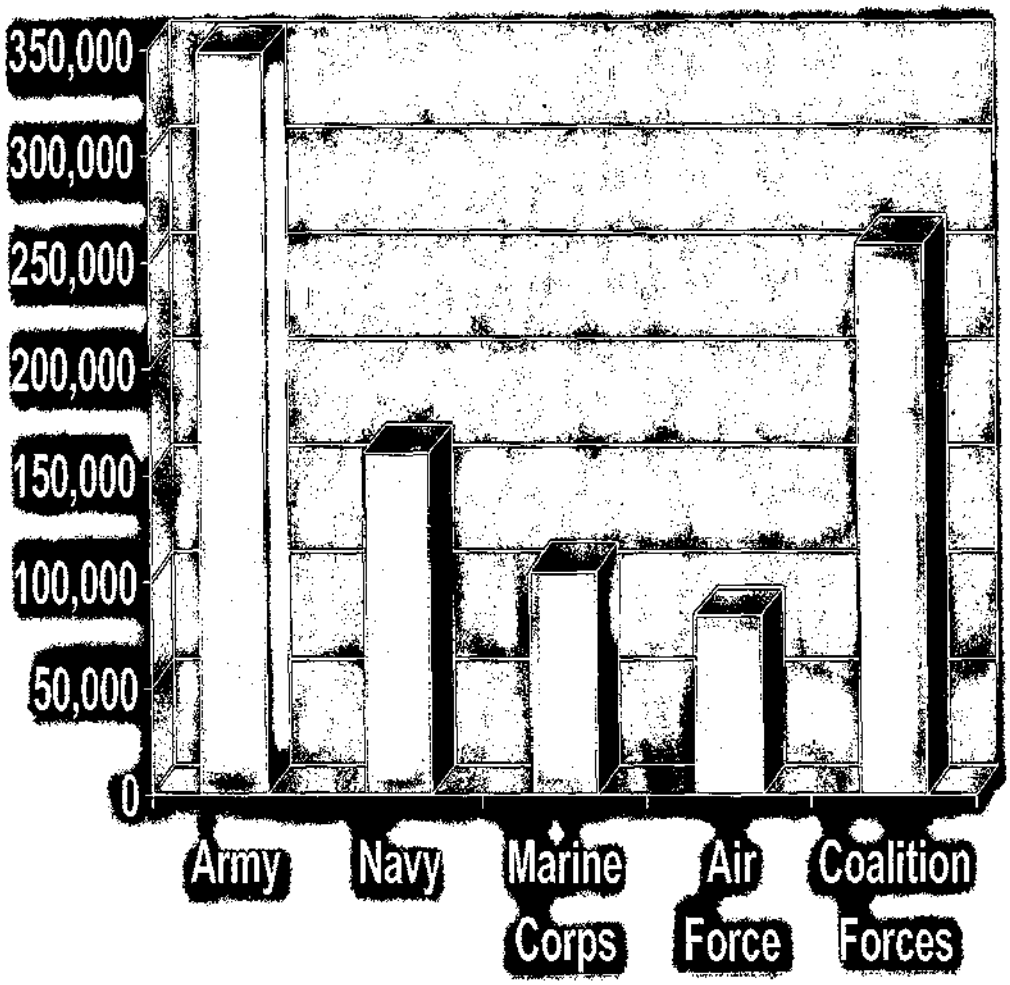
  Local U.S. consular office or 1-800-749-8387

- **Hotline for OSAGWI** **DSN: 761-1078**

http://www.gulflink.osd.mil

Back-up Slides

Gulf War Theater Forces



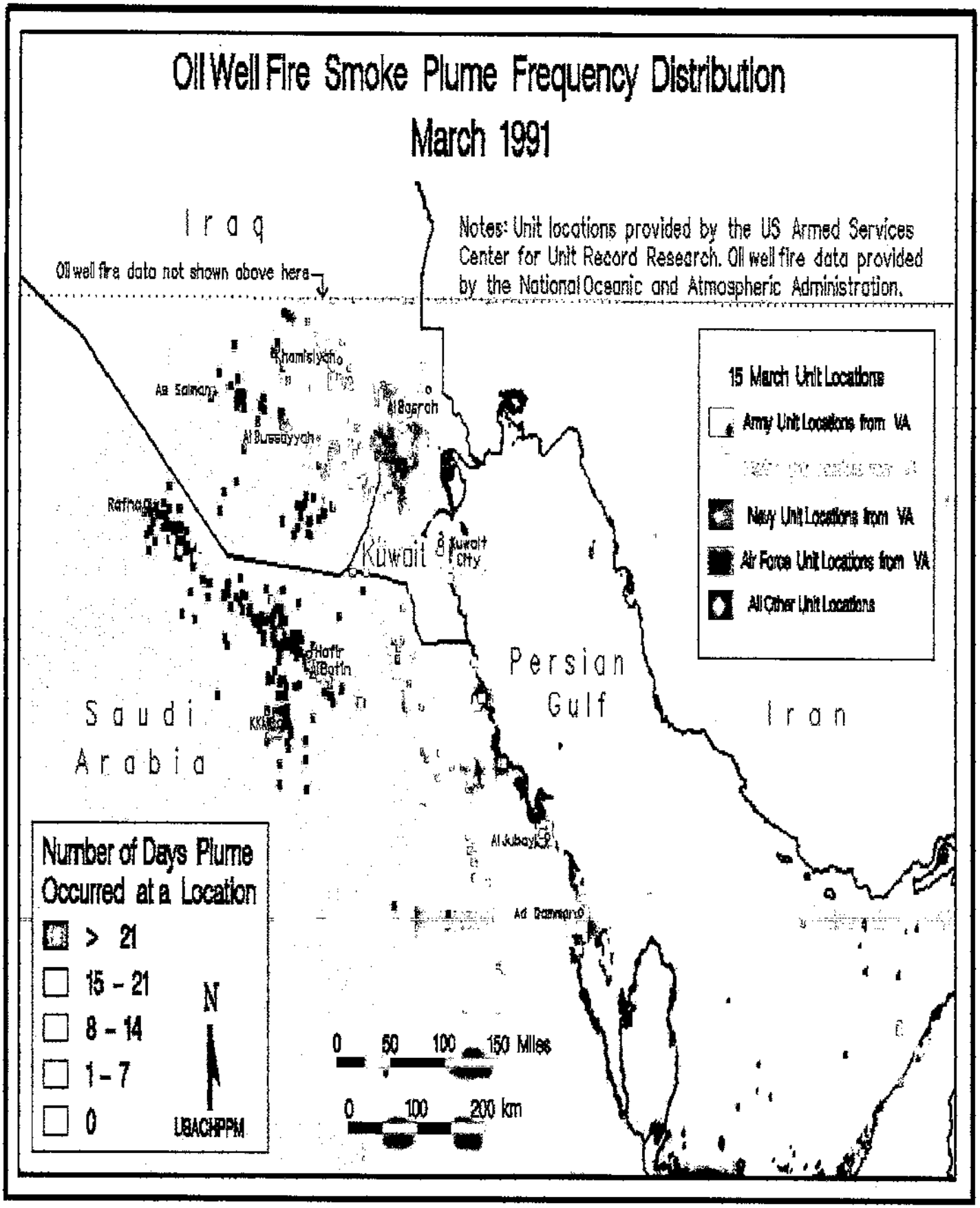
697,000 U.S. service members

DU Exposure Issues

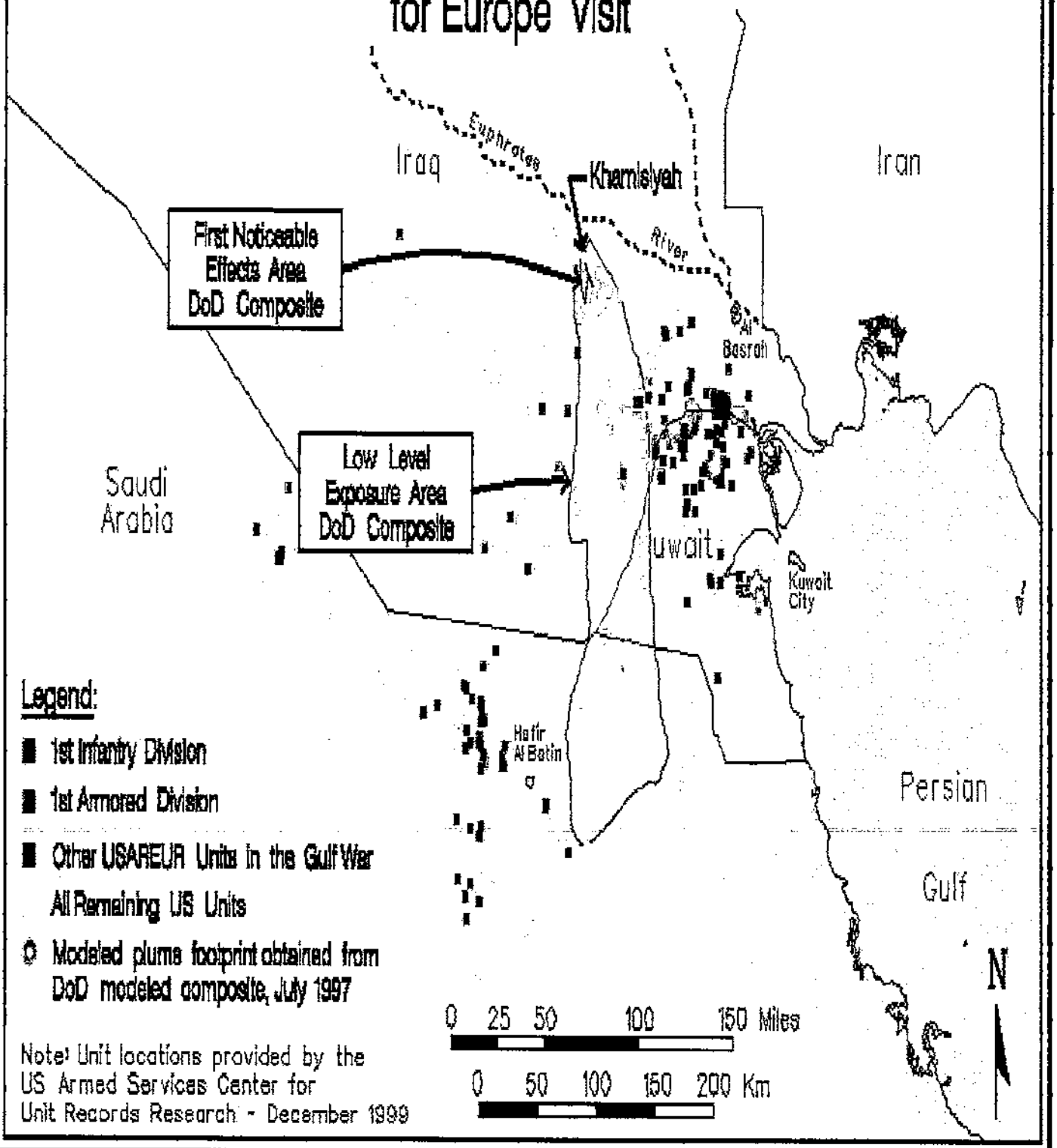
- Radiation
- Consequences of exposure
- Heavy metal toxicity
- Reproductive effect
- Contamination of theater

Conclusions about PB

- We cannot rule out pyridostigmine bromide as a contributor to increased health symptoms in Gulf War veterans.
- Further research is needed to determine the effectiveness of the current dose of PB against Soman.
- Additional research about safety and effectiveness of PB for humans is urgently needed.


Oil Well Fire Smoke Plume Frequency Distribution
March 1991
Iraq
Oil well fire data not shown above here
Notes: Unit locations provided by the US Armed Services Center for Unit Record Research. Oil well fire data provided by the National Oceanic and Atmospheric Administration.
15 March Unit Locations
Army Unit Locations from VA
Navy Unit Locations from VA
Air Force Unit Locations from VA
All Other Unit Locations
Kuwait
Kuwait City
Persian Gulf
Iran
Saudi Arabia
Number of Days Plume Occurred at a Location
> 21
15 - 21
8 - 14
1 - 7
0
N
USACHPPM
0 50 100 150 Miles
0 100 200 km

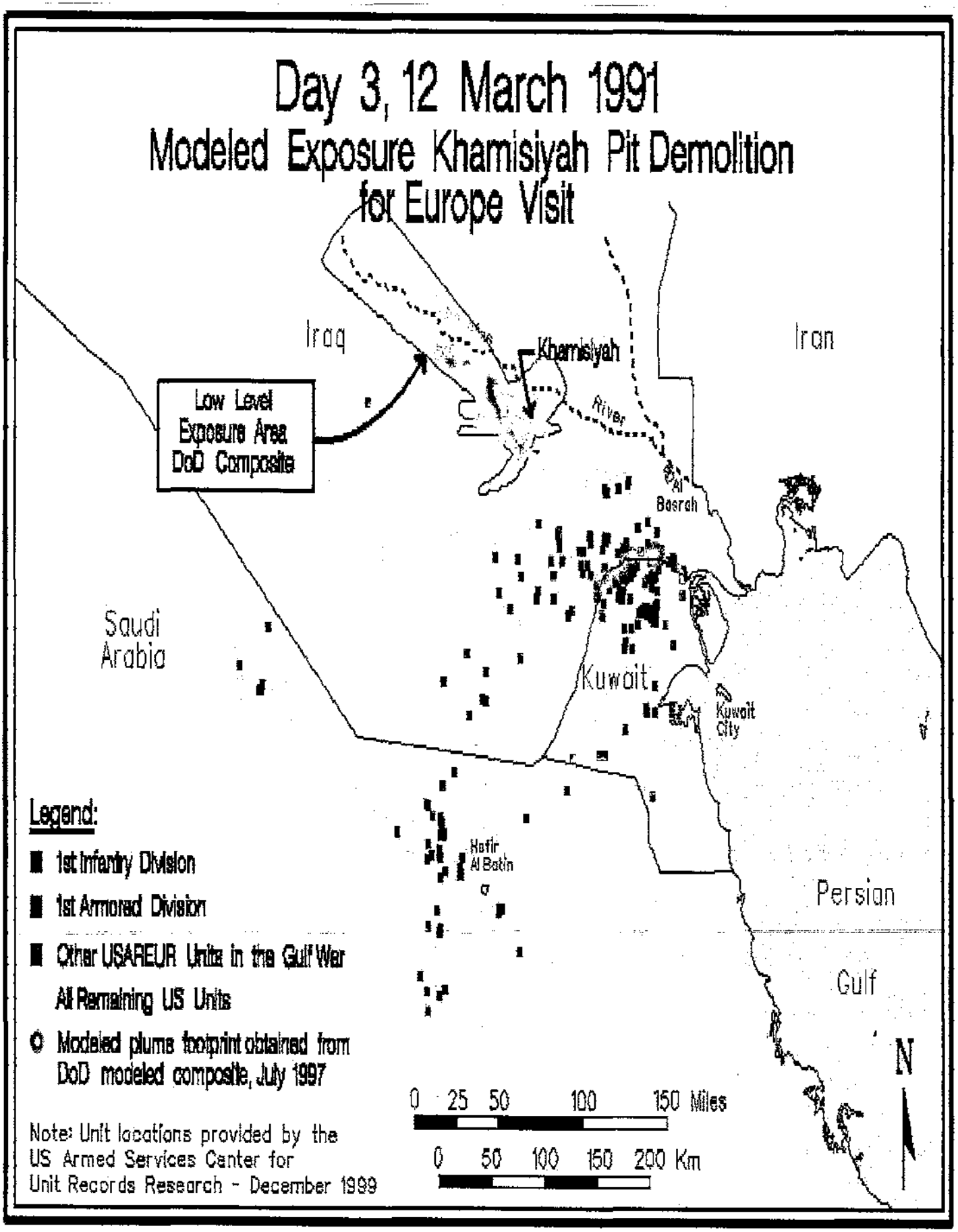
Day 1, 10 March 1991
Modeled Exposure Khamisiyah Pit Demolition for Europe Visit



Legend:

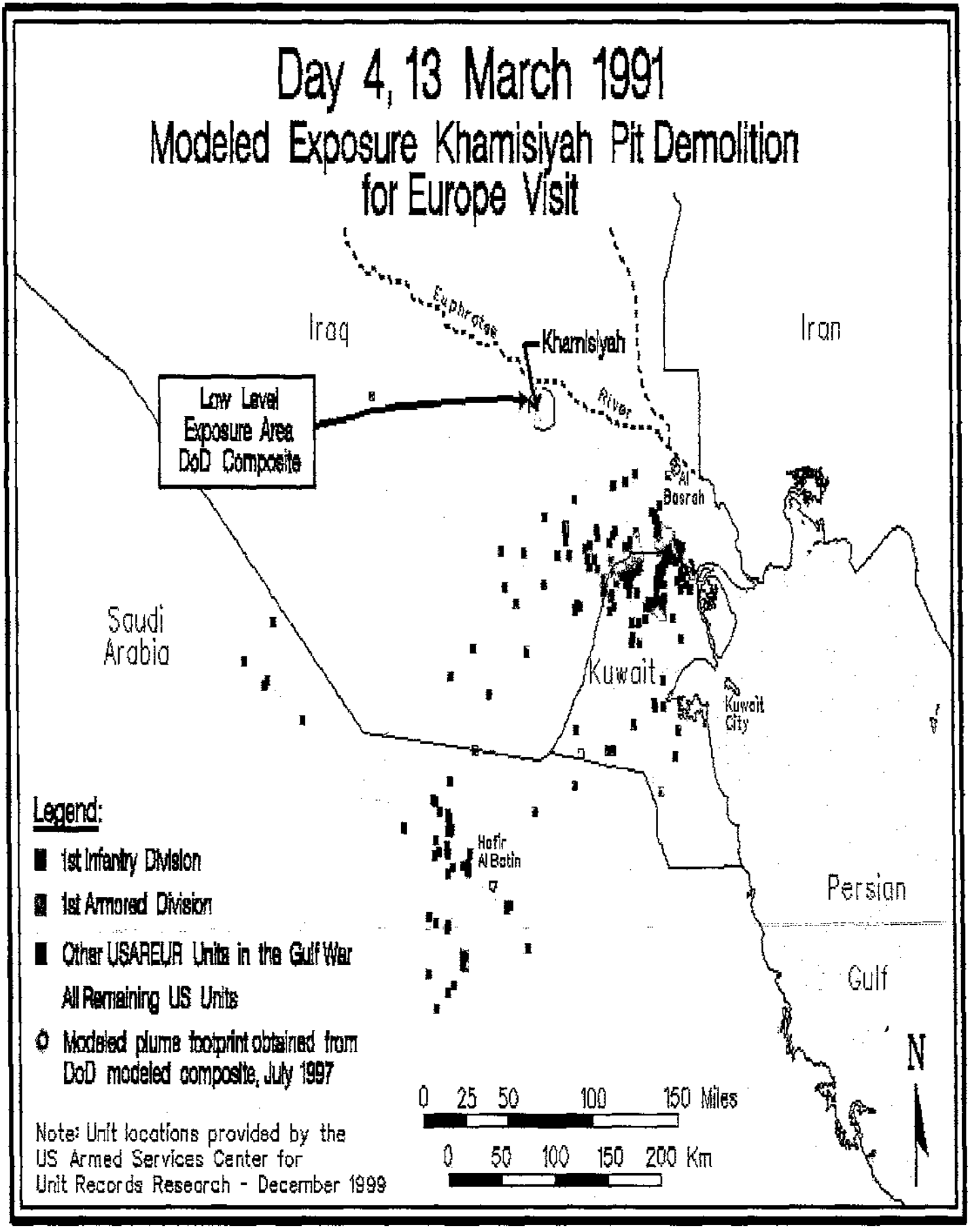
- 1st Infantry Division
- 1st Armored Division
- Other USAREUR Units in the Gulf War
- All Remaining US Units
- Modeled plume footprint obtained from DoD modeled composite, July 1997

Note: Unit locations provided by the US Armed Services Center for Unit Records Research - December 1999


Day 3, 12 March 1991
Modeled Exposure Khamisiyah Pit Demolition for Europe Visit
Iraq
Khamisiyah
Iran
Low Level Exposure Area DoD Composite
River
Al Basrah
Saudi Arabia
Kuwait
Kuwait City
Hafir Al Batin
Persian
Gulf
N
Legend:
1st Infantry Division
1st Armored Division
Other USAREUR Units in the Gulf War
All Remaining US Units
Modeled plume footprint obtained from DoD modeled composite, July 1997
0 25 50 100 150 Miles
0 50 100 150 200 Km
Note: Unit locations provided by the US Armed Services Center for Unit Records Research - December 1999

Day 4, 13 March 1991

Modeled Exposure Khamisiyah Pit Demolition for Europe Visit



Office of the Special Assistant to the Secretary of Defense

for Gulf War Illnesses, Medical Readiness, and Military Deployments

800-497-6261 fax (703) 578-8501

email: brostker@gwillness.osd.mil

Briefing Overview

- Mission Statement
- The Gulf War
- Searching for Answers
- Lessons Learned
- Force Health Protection
- Bottom Line
- Obtaining Help and Information

Vision of the Special Assistant for Gulf War Illnesses, Medical Readiness, and Military Deployments

- The Department of Defense recognizes the right of those involved in deployments to receive information that enables them to make informed decisions about their health
- We will develop and disseminate such information in a relevant and timely fashion
- We will work with others in the Defense Department to incorporate lessons from previous deployments to foster the well-being of deployed forces

Gulf War Illnesses Mission

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DOD adopts doctrine, policy and procedures to reduce risks for troops in the future.

Gulf War Theater

- August 1990 to July 1991
- 697,000 US service members
- More than 27,000 hospitalizations
- 148 battle deaths
- 224 non-battle deaths

1 in 7 Veterans Reported Symptoms Since the War

Most frequently reported symptoms

- Joint pain
- Headaches
- Sleep disorders
- Depression
- Fatigue
- Memory loss
- Rash
- Muscle pain

Communication Breakdown

- Veterans with real health problems
- Healthcare professionals unable to provide answers
- Government slow to recognize the reality of problems

Confounding Issues

- No clustering
- No symptom consistency; variable onset
- No new disease or links between exposures and symptoms
- No long term study

Taking Care of Service Members

- **DoD Comprehensive Clinical Evaluation Program**
  - Gulf War vets (active, Guard/Reserve, retired)
  - Active service member deployed to SWA since war ended
  - Family members
  - DoD civilians
- **VA Persian Gulf Registry**
  - Gulf War vets (left service prior to retirement)
  - Service members deployed to SWA and left service before retirement
  - Evaluation for family members
- **Available to *all* service members deploying to South West Asia**

Don't Tough It Out!

OSAGWI Investigations

- Chemical/biological warfare:
  - Chemical warfare agent - Khamisiyah incident
    - 99,000 vets notified
- Environmental:
  - Depleted uranium (DU), Oil well fires, Pesticides
- Medical issues:
  - Vaccines, PB, records, policy
- Scientific research under PGVCB
  - 180+ studies sponsored by DoD, DVA, & HHS
  - No cause and effect relationship shown so far

Investigation Results

- Gulf War
  - No offensive CW/BW use
  - Not enough vaccines and no explanation given
  - Limited environmental surveys
  - Information about nerve agent pre-treatment (PB) wasn't given to troops
  - Inadequate training
    - *Veterans returned home and left service without thorough medical exam or debrief*

The Dirty Battlefield

- What enemy may do to us
  - Chemical/Bio threat, man-made environmental hazards (oil well fires)
- What the environment may do to us
  - Infectious diseases, insects, environmental risks (desert, jungle)
- What we may do to ourselves
  - Accidents, pesticides, investigational new drugs, PB

Current and future conflicts and humanitarian deployments have and will have these challenges

Applying Lessons Learned

- Train self and others to recognize and avoid hazards
- Monitor service member's health & environment
- Improve feedback and cross talk
- Know your equipment strengths and weaknesses
- Create, relate and save operational, NBC, and medical records
- Adapt to reduce risks and train to reduce future risks such as DU

Force Health Protection

- Pre-deployment
  - Medical screening/surveillance and briefings
- Deployment
  - Record keeping
  - Monitor environment and personnel
- Post Deployment
  - Medical screening and unit debriefing

Anthrax

- We have a safe and effective vaccine
- Anthrax - an offensive BW agent
  - Inhalation anthrax is highly lethal
  - Easy to develop and weaponize
  - Remains viable for long periods

Vaccination against anthrax is critical for your protection

Anthrax Vaccine Program

- Licensed by the FDA since 1970
- Dosing schedule: 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster
- Shortages in stockpiled doses require temporary slowdown of AVIP

(877) GET-VACC DSN: 761-5101

www.anthrax.osd.mil

www.aviationmedicine.com

Pyridostigmine Bromide

- Threat - Soman is deadly nerve agent
- PB is the only known pretreatment against Soman
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Bottom Line

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- You will deploy on missions
- Everyone is responsible for force protection
- You are your own best health advocate
- Vets should not tough it out; get examined

Obtaining Help and Information

GWIMRMD Veterans' Helpline

(800) 497-6261

Comprehensive Clinical Evaluation Program

(800) 796-9699

Veterans Affairs Persian Gulf Registry Program

(800) 749-8387

TAMC CCEP

(808) 433-4531

http://www.gulflink.osd.mil

Outreach team

- Town Hall
  - 1900, Thursday, Oct 5, Richardson Theater, Bldg. 500, Fort Shafter
- Displays
  - TAMC, Hickam AFB, Pearl Harbor, MCBH-Kaneohe Bay, Schofield Barracks
- Contact managers

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Back-up Slides

Myths versus Reality

Cover up	Open process & oversight
Not listening	Solicit eyewitness reports
Destroy records	Found missing records
20,000 veterans dead	6,686 veterans dead
No assistance to vets	Evaluation and care
"Syndrome"	More than 40 illnesses
CW or DU cause	Many possible causes
Brass doesn't care	Force Protection efforts
	Tough choices
	Cultural changes

A National Effort

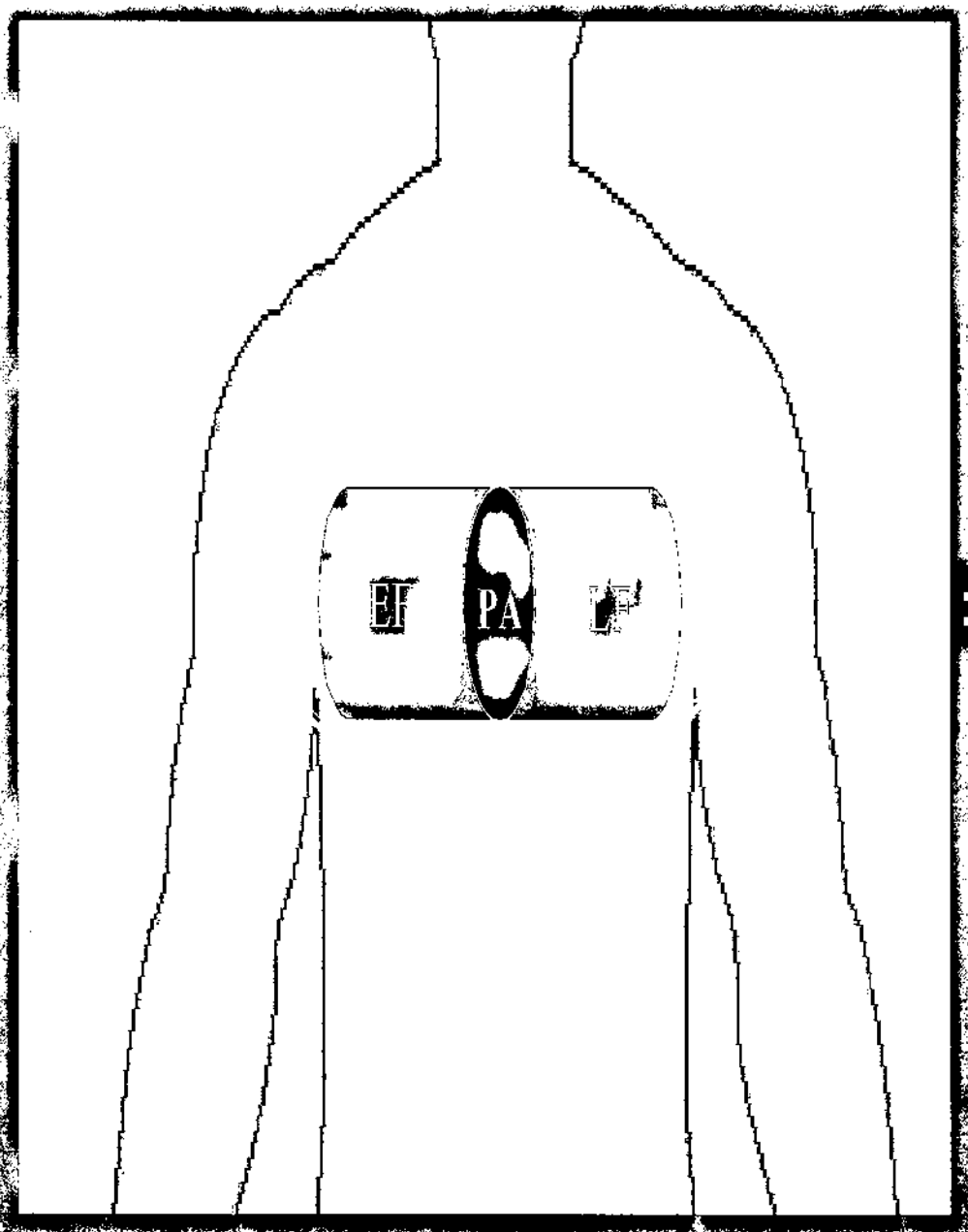
- **OVERSIGHT:** Presidential, 7 Congressional Committees, VSOs, Veterans, the Media
- **INVESTIGATIONS:** IGs, GAO, SIU
- **DoD:** ASDs, Special Assistants, DIA, the Surgeons General
- **OUTSIDE AGENCIES:** CIA, VA, HHS, GWVCB, CDC
- **DECLASSIFICATION:** CIA, DIA, and the Services
- **TECHNICAL PROJECTS:** Dugway, Edgewood, Picatinny, CHPPM, Think tanks, outside experts

Anthrax

- Inhalation anthrax is deadly
- Biological warfare agent of choice:
  - Cheap and easy to produce
  - Can be dispersed in air by a variety of weapons
  - Odorless, colorless, tasteless, difficult to detect
  - Flu-like symptoms early, rapid deterioration, and death
- MOPP 4 prevents exposure
- Antibiotics work before symptoms appear

Vaccination against anthrax is critical for your protection

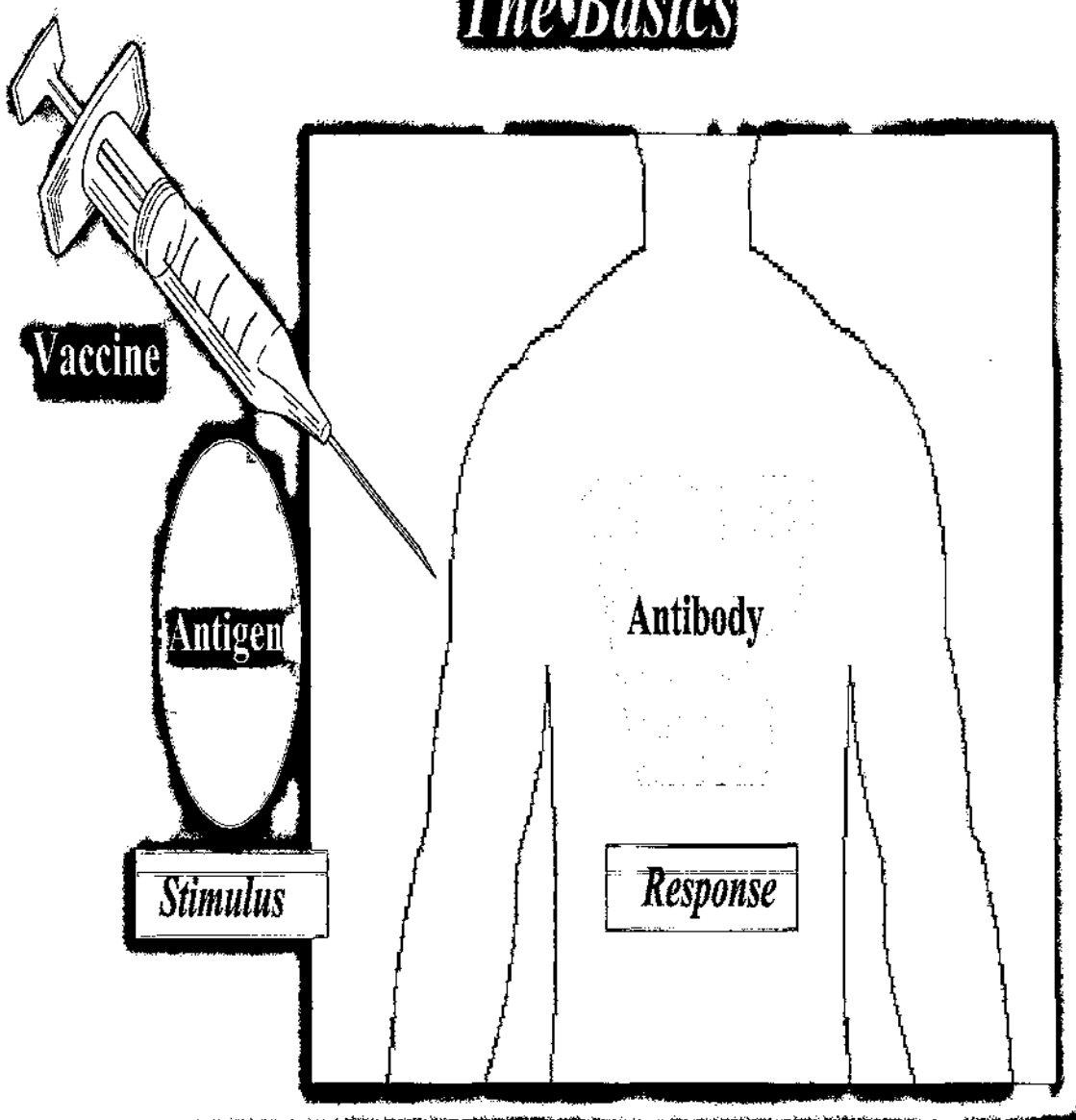
ANTHRAX BACTERIA ATTACK



= Death

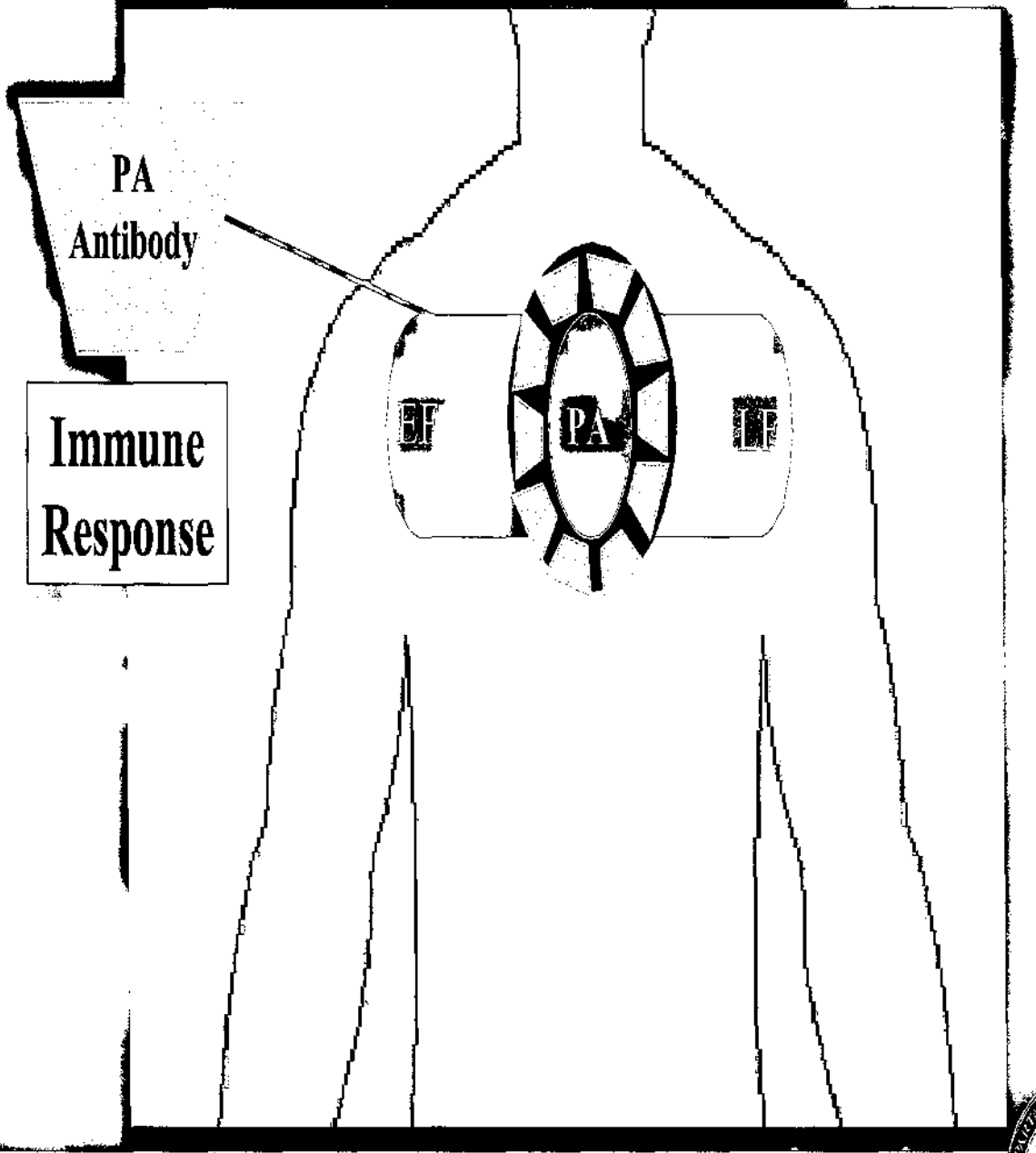
IMMUNE SYSTEM ACTIVATION BY VACCINE

The Basics



AFTER ANTHRAX VACCINE

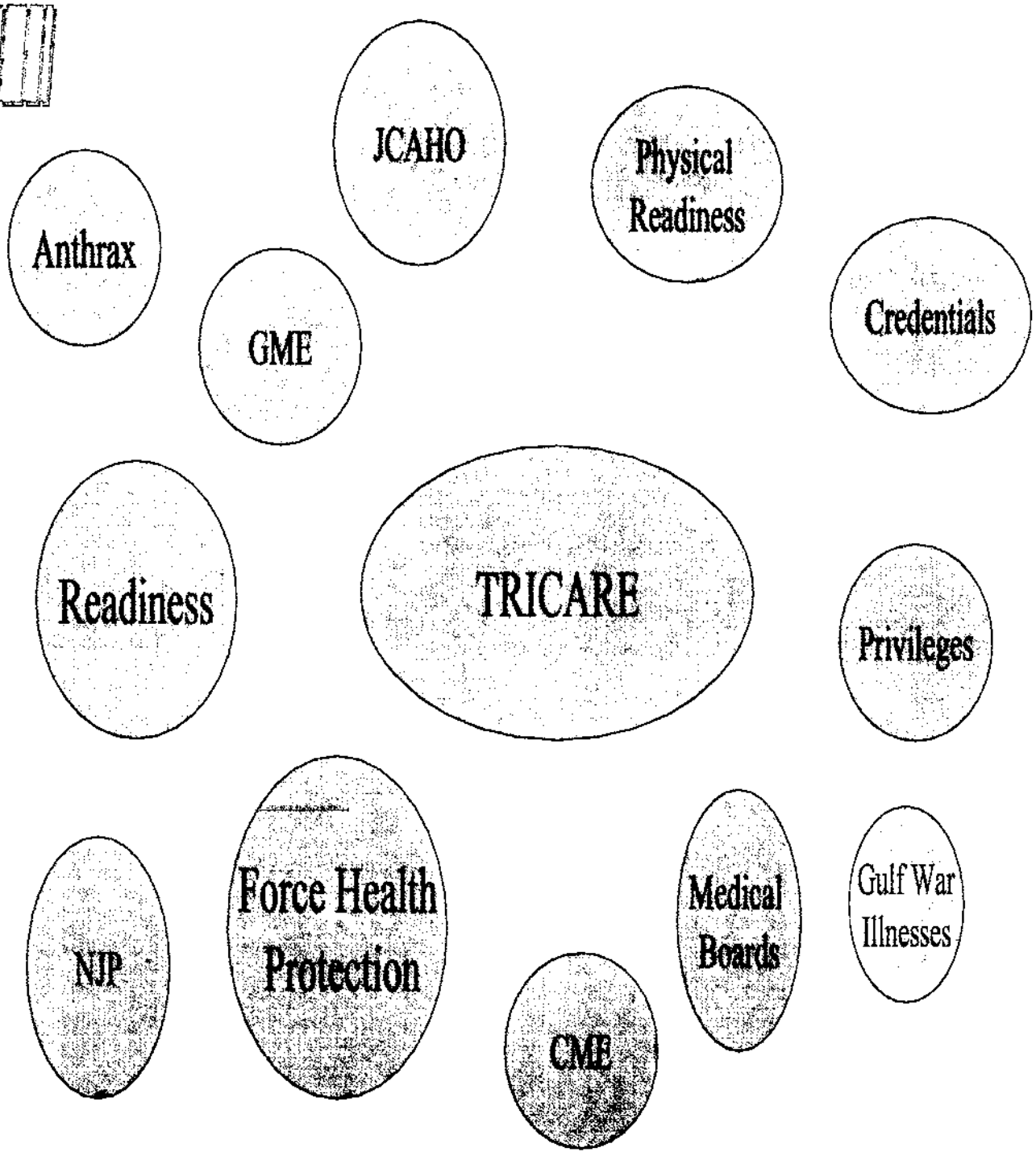
Antibodies at Work

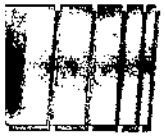


Office of the Special Assistant

Office of the Special Assistant to the Secretary of Defense for Gulf War Illnesses, Medical Readiness, & Military Deployments

Michael E. Kilpatrick MD, FACP
Medical Readiness
703-578-8510 fax 703-578-8501
email: mkilpatr@gwillness.osd.mil

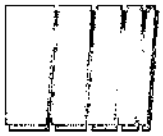

JCAHO
Physical Readiness
Anthrax
GME
Credentials
Readiness
TRICARE
Privileges
Force Health Protection
NJP
Medical Boards
Gulf War Illnesses
CME



Special Assistant

Dr. Bernard Rostker

- Appointed November 12, 1996 by the Deputy Secretary of Defense
- 180 team members



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- Ensure DoD adapts doctrine, policy and procedures to reduce risks for troops in the future.

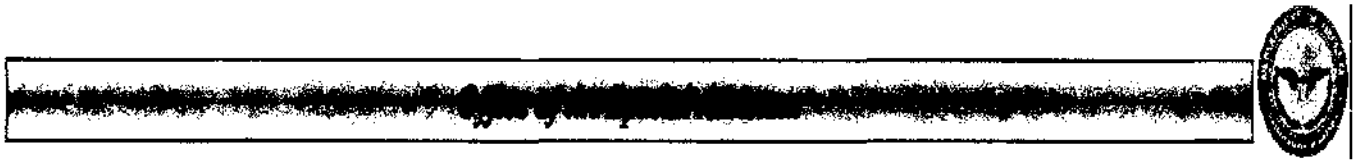
Who Served in the Gulf War

697,000 U.S. service members

ARMY	50%
NAVY	23%
MARINE	15%
AIR FORCE	12%

259,000 Coalition Forces

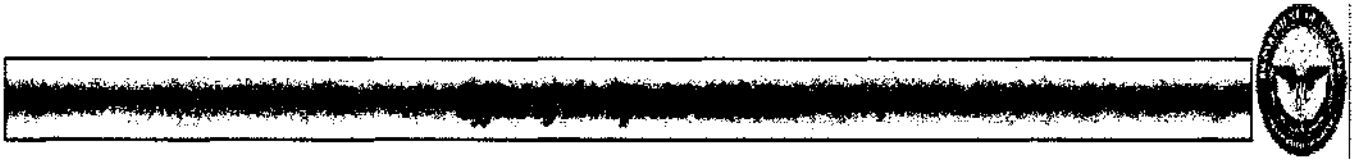
Source: Presidential Advisory Committee on Veterans Illnesses, Final Report

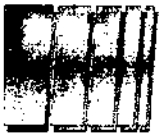


Who Served in the Gulf War

MALE	93%
FEMALE	7%
ACTIVE	83%
RESERVE/NATIONAL GUARD	17%
OFFICER	10%
ENLISTED	90%

< 26 years old - 55%; 26-35 years old - 32%; > 35 years old - 13%



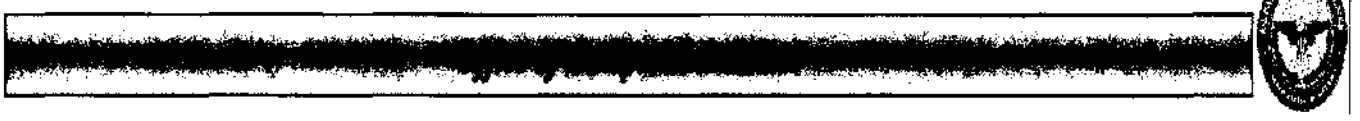


Medical Support

Largest emergency health care system since WW II

- 41,000 medical personnel
- 18,000 beds
  - 2 hospital ships
  - 63 combat zone hospitals

source: CENTCOM Publications - Commander-in-chief US CENTCOM "Desert Shield/Desert Storm Facts, Figures, Quotes and Anecdotes 7 AUG 90-11 APR 91," prepared by CENTCOM PAO



Medical Support

- 27,000 hospitalizations in theater
- 8,000 medical evacuations
- ????? outpatient visits

U.S. Deaths

Non-Battle	224
Battle	148

Symptoms

Tiredness

Rashes

Headaches

Muscle aches

Joint pains

Abdominal pain

Diarrhea

Hair loss

Memory loss

Sleep disturbance

Depression

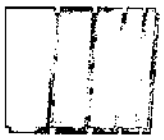
Concentration problems

Medical Evaluations

- Comprehensive Clinical Evaluation Program (CCEP)

Total Participants	56,091	
Decline examination	15,948	
Examined		40,143
- Veterans Affairs Registry -examined		79,710
Total Examined		**119,853**

Source: OASD (Health Affairs) 31 Aug 00 VA Registry 25 Jul 00



Diagnosis Distribution

Categories	CCEP (%)	VA Registry (%)
Healthy	10	12
Symptomatic	90	88
Medically explained	80	80
Medically unexplained	**20**	**20**

Physician Message Sent

"Your laboratory, x-ray and physical exams results are normal."

Patient Messages Received

"There's nothing wrong with you!"
"It's all in your head!"
"You're faking these symptoms!"

Epidemiology Studies

	Deployed (%)	Non-Deployed (%)
Medical separation (Aug 91 - Dec 93)	2.20	2.56
Hospitalizations (Aug 91 - Sep 93)	21.6	21.6
Hospitalizations unexplained illnesses (Aug 91 - Apr 96)	1.21	1.27
Birth Defects (Aug 91 - Sep 93)	7.45	7.59
Mortality (Aug 91 - Sep 93)	.025	.023

Possible Causes

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

DEPLETED URANIUM

PYRIDOSTIMINE BROMIDE

INFECTIOUS DISEASES

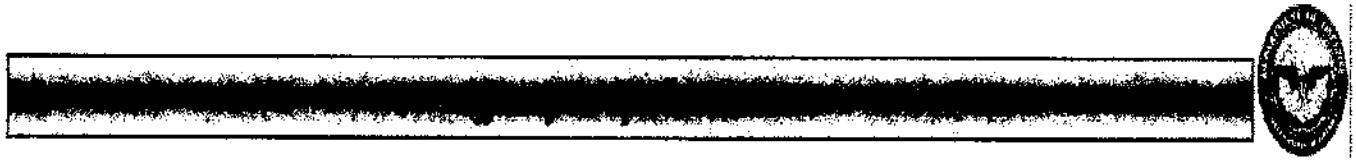
STRESS

COCKTAIL EFFECT

Lessons Learned

CHEMICAL WARFARE

- 14,000 M8 units
- False Positives
- In and out of MOPP, no explanations
- Alarms turned off
- No need to know
- Brain Damage

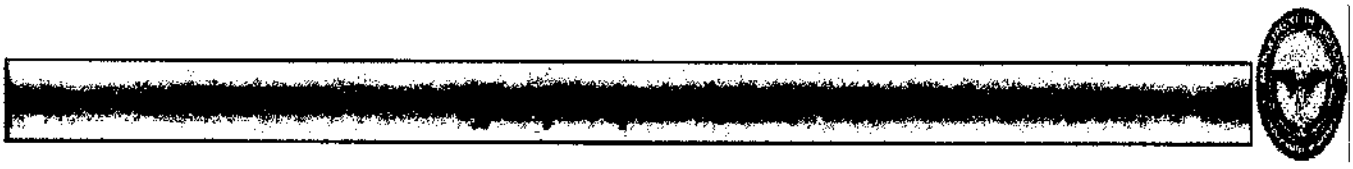


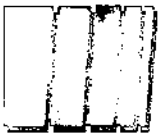
Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

- Navy Forward Laboratory
- No positive cultures





Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

- DEET, permethrin, organophosphates
- Unapproved items: flea collars, SNIP

Lessons Learned

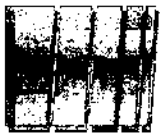
CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

- Soot, ash, black cloud
- No information
- EPA monitoring March 91
- Particulates, no toxic fumes



Lessons Learned

CHEMICAL WARFARE

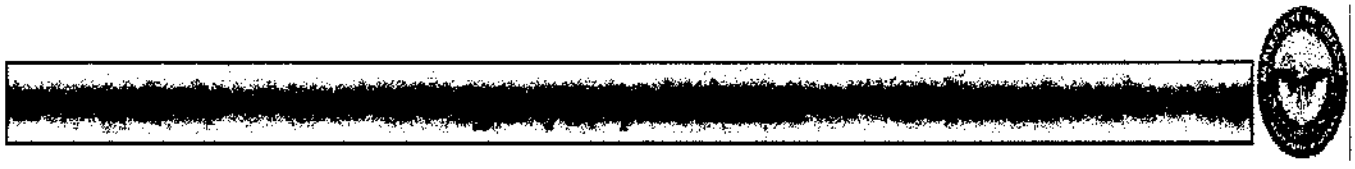
BIOLOGICAL WARFARE

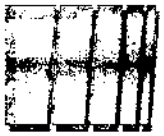
PESTICIDES

OIL WELL FIRES

VACCINES

- Vaccines "secret"
- No records
- No explanations
- Squalene





Lessons Learned

CHEMICAL WARFARE

PESTICIDES

VACCINES

BIOLOGICAL WARFARE

OIL WELL FIRES

DEPLETED URANIUM

- Tank armor, penetrators
- No training
- Heavy metal, proximal tubule
- Surveillance of most exposed

Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

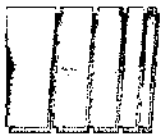
OIL WELL FIRES

VACCINES

DEPLETED URANIUM

PYRIDOSTIGMINE BROMIDE

- Soman prophylaxis
- Not FDA approved use
- Recognized side effects
- Medical confusion
- No explanations, no records
- Varied protocols



Lessons Learned

CHEMICAL WARFARE

PESTICIDES

VACCINES

PYRIDOSTIGMINE BROMIDE

BIOLOGICAL WARFARE

OIL WELL FIRES

DEPLETED URANIUM

INFECTIOUS DISEASES

- 12 malaria, 32 leishmaniasis
- Diarrhea, URI's
- *Mycoplasma fermentans incognitus*

Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

DEPLETED URANIUM

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INFECTIOUS DISEASES

STRESS

- NO DoD policy that "stress is the cause of symptoms"
- CNN, communications home
- Uncertainties
- Profiles are stress of chronic disease
- PTSD rate lower than Vietnam
- Stress can amplify already existing symptoms

Lessons Learned

CHEMICAL WARFARE

PESTICIDES

VACCINES

PYRIDOSTIGMINE BROMIDE

STRESS

BIOLOGICAL WARFARE

OIL WELL FIRES

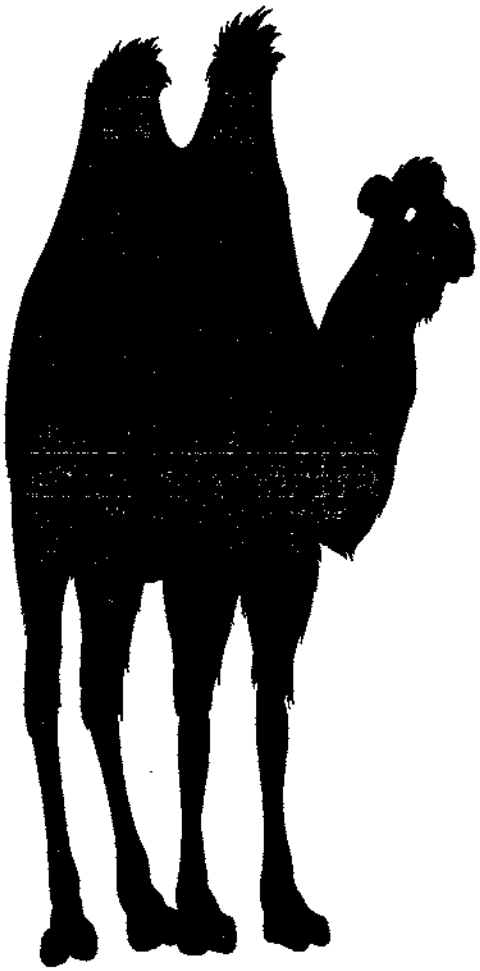
DEPLETED URANIUM

INFECTIOUS DISEASES

COCKTAIL EFFECT

- No scientific evidence yet

THE BLACK CAMEL



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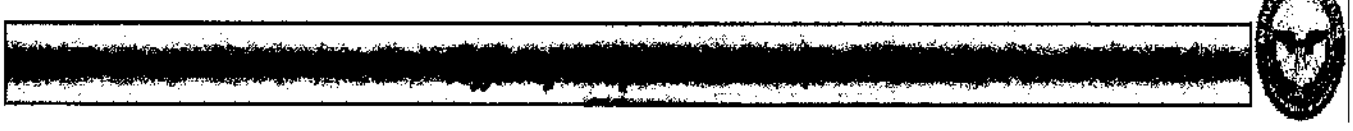
Possible Causes

- Normal disease rate
- New disease paradigm - a Black Camel



Major Lesson Learned from the Gulf War

DoD Does Not Deal Well With Non-Traditional Issues

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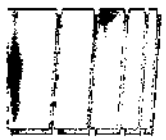
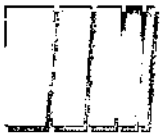


Deployments

- Unexpected and rapid personnel movement
- Personal and family hardships
- Stress in the field
  - Missile attacks
  - Chem-bio attacks
  - Witnessing death/atrocities
  - Harsh Living Conditions
  - Foreign cultures
  - Racial/ethnic hatred
- Inadequate communication
- No answers to questions after returning



Force Health Protection

Predeployment

Health Promotion
Immunizations Current
Health Assessment Surveys
Medical Threat Briefing
Environmental Threat

Deployment

Environmental & Medical Surveillance
Food and Water Inspections
Industrial/Occupational Surveillance
Forward Deployed Labs
Host Nation Medical Support
Combat Stress Teams

Post Deployment

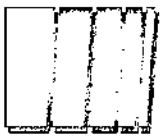
Health Assessment Surveys
Medical Debriefings
Medical Surveillance
Risk Communication

Risk Communication

1. Allow Ventilation
2. Determine Underlying Concern
3. Empathy
4. Conclusion Soundbite
5. Facts (2)
6. Next Steps

Art of Medicine

1. Ask open-ended questions
2. Chief complaint
3. Managed similar problems
4. Diagnosis
5. Lab, physical findings
6. Treatment, next appointment



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CONTACT NUMBERS

Department of Defense's - CCEP	800-796-9699
VA Persian Gulf Registry	800-749-8387
Department of Defense's Incident Reporting Line	800-497-6261
GulfLINK	*www.gulflink.osd.mil*

Michael E. Kilpatrick MD, FACP

phone 703-578-8510 fax 703-578-8501

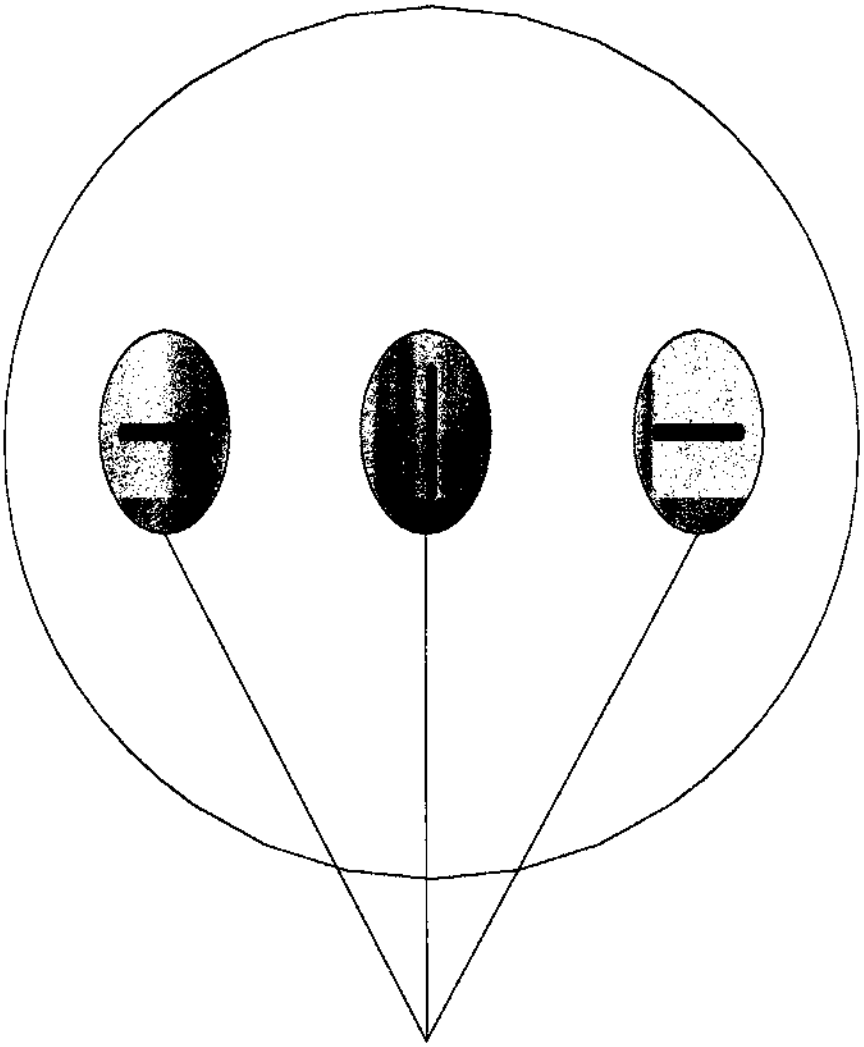
email: mkilpatr@gwillness.osd.mil

Anthrax

- We have a safe and effective vaccine
- Anthrax - an offensive BW agent
  - Inhalation anthrax is highly lethal
  - Easy to develop and weaponize
  - Remains viable for long periods
  - At least seven potential adversaries suspected of researching, developing and/or weaponizing anthrax.

Vaccination against anthrax is critical for your protection

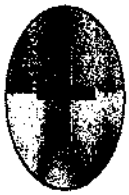
Anthrax Bacteria

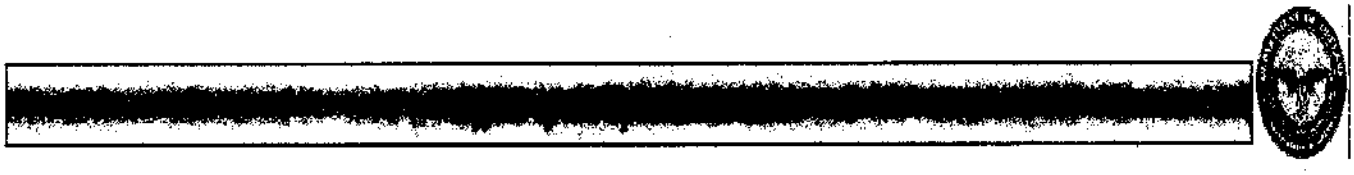


Toxins

Anthrax Bacteria

Toxin
Combination

 = Death

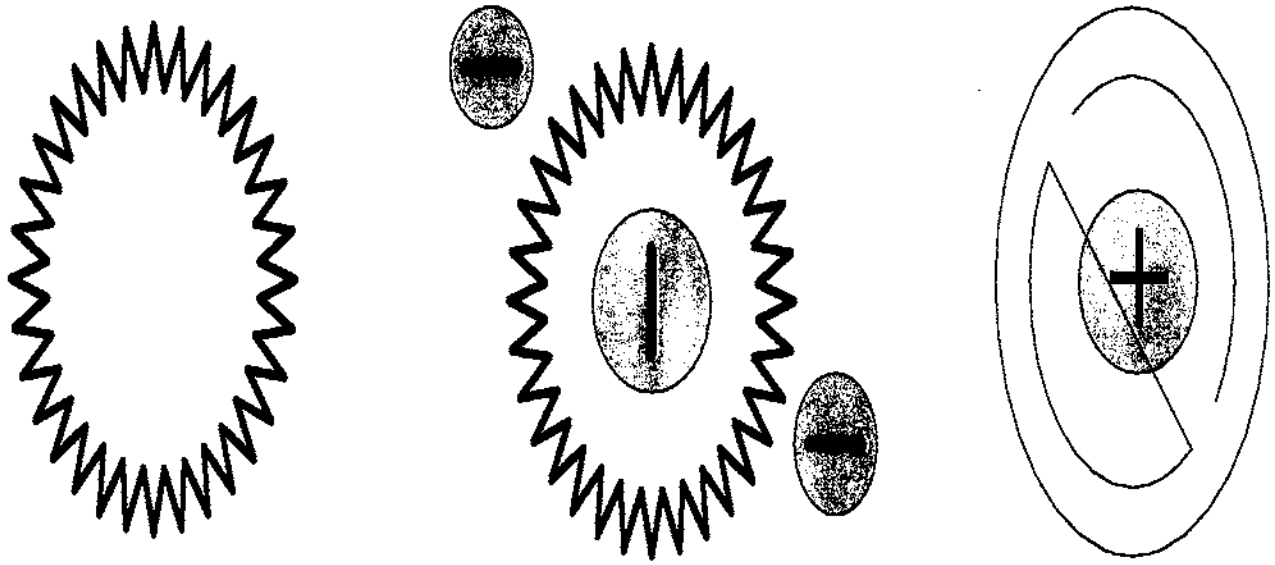


Anthrax Vaccine

Produces

Attacks
Toxin

PROTECTS



Medical Personal Information Center (PIC)

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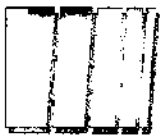


Where Do We Go From Here?

- Concept - Deployment Medicine Clinics
  - Connected to all deployment sites
  - Source for pre and post deployment information
  - Information for family members
- Concept - Education on Vaccines
  - Start updating electronic record entrance
  - Validate accuracy with leave/bonus requests
  - Internet linkage to CDC for recommendations
- Concept - ????

Understanding Today's Military Member

- 55% are married
- 46% have children
- 40% of the 1.3 million children are < 6 years old
- 6% are single parents
- 8% care for elder parents
- 14% are women

Concerns of the Deployed Member

- Importance of the mission
- Recognition by others of his/her role
- Ability to express fears/concerns/problems to leadership
- Recognition for performance

Successful Mission

- Knew why I was there and agreed
- Knew what to do
- Knew how to do it
- Had what I needed to do it
- Did it well
- Was appreciated for my contribution
- Returned proud I had been there

Office of the Special Assistant to the Secretary of Defense

for Gulf War Illnesses, Medical Readiness, and Military Deployments

800-497-6261 fax (703) 578-8501

email: brostker@gwillness.osd.mil

Briefing Overview

- Mission Statement
- The Gulf War
- Searching for Answers
- Lessons Learned
- Force Health Protection
- Bottom Line
- Obtaining Help and Information

Vision of the Special Assistant for Gulf War Illnesses, Medical Readiness, and Military Deployments

- The Department of Defense recognizes the right of those involved in deployments to receive information that enables them to make informed decisions about their health
- We will develop and disseminate such information in a relevant and timely fashion
- We will work with others in the Defense Department to incorporate lessons from previous deployments to foster the well-being of deployed forces

Gulf War Illnesses Mission

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DOD adopts doctrine, policy and procedures to reduce risks for troops in the future.

Gulf War Theater

- August 1990 to July 1991
- 697,000 US service members
- More than 27,000 hospitalizations
- 148 battle deaths
- 224 non-battle deaths

1 in 7 Veterans Reported Symptoms Since the War

Most frequently reported symptoms

- Joint pain
- Headaches
- Sleep disorders
- Depression
- Fatigue
- Memory loss
- Rash
- Muscle pain

Communication Breakdown

- Veterans with real health problems
- Healthcare professionals unable to provide answers
- Government slow to recognize the reality of problems

Confounding Issues

- No clustering
- No symptom consistency; variable onset
- No new disease or links between exposures and symptoms
- No long term study

Taking Care of Service Members

- **DoD Comprehensive Clinical Evaluation Program**
  - Gulf War vets (active, Guard/Reserve, retired)
  - Active service member deployed to SWA since war ended
  - Family members
  - DoD civilians
- **VA Persian Gulf Registry**
  - Gulf War vets (left service prior to retirement)
  - Service members deployed to SWA and left service before retirement
  - Evaluation for family members
- **Available to *all* service members deploying to South West Asia**

Don't Tough It Out!

OSAGWI Investigations

- Chemical/biological warfare:
  - Chemical warfare agent - Khamisiyah incident
    - 99,000 vets notified
- Environmental:
  - Depleted uranium (DU), Oil well fires, Pesticides
- Medical issues:
  - Vaccines, PB, records, policy
- Scientific research under PGVCB
  - 180+ studies sponsored by DoD, DVA, & HHS
  - No cause and effect relationship shown so far

Investigation Results

- **Gulf War**
  - **No offensive CW/BW use**
  - **Not enough vaccines and no explanation given**
  - **Limited environmental surveys**
  - **Information about nerve agent pre-treatment (PB) wasn't given to troops**
  - **Inadequate training**
  - ***Veterans returned home and left service without thorough medical exam or debrief***

The Dirty Battlefield

- What enemy may do to us
  - Chemical/Bio threat, man-made environmental hazards (oil well fires)
- What the environment may do to us
  - Infectious diseases, insects, environmental risks (desert, jungle)
- What we may do to ourselves
  - Accidents, pesticides, investigational new drugs, PB

Current and future conflicts and humanitarian deployments have and will have these challenges

Applying Lessons Learned

- Train self and others to recognize and avoid hazards
- Monitor service member's health & environment
- Improve feedback and cross talk
- Know your equipment strengths and weaknesses
- Create, relate and save operational, NBC, and medical records
- Adapt to reduce risks and train to reduce future risks such as DU

Force Health Protection

- **Pre-deployment**
  - Medical screening/surveillance and briefings
- **Deployment**
  - Record keeping
  - Monitor environment and personnel
- **Post Deployment**
  - Medical screening and unit debriefing

Anthrax

- We have a safe and effective vaccine
- Anthrax - an offensive BW agent
  - Inhalation anthrax is highly lethal
  - Easy to develop and weaponize
  - Remains viable for long periods

Vaccination against anthrax is critical for your protection

Anthrax Vaccine Program

- Licensed by the FDA since 1970
- Dosing schedule: 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster
- Shortages in stockpiled doses require temporary slowdown of AVIP

(877) GET-VACC DSN: 761-5101
www.anthrax.osd.mil
www.aviationmedicine.com

Pyridostigmine Bromide

- Threat - Soman is deadly nerve agent
- PB is the only known pretreatment against Soman
  - Auto injectors alone will not save you
- Issues have been raised about PB
  - Further research is ongoing
- Only President can authorize its use without informed consent

Bottom Line

- Lessons learned from the Gulf War affect today's doctrine and deployments
- You will deploy on missions
- Everyone is responsible for force protection
- You are your own best health advocate
- Vets should not tough it out; get examined

Obtaining Help and Information

GWIMRMD Veterans' Helpline
(800) 497-6261

Comprehensive Clinical Evaluation Program
(800) 796-9699

Veterans Affairs Persian Gulf Registry Program
(800) 749-8387

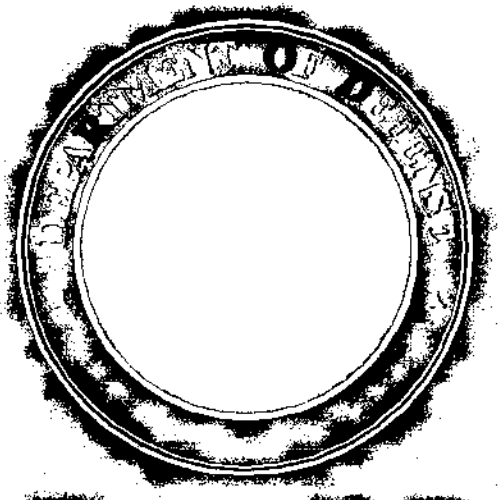
TAMC CCEP
(808) 433-4531

http://www.gulflink.osd.mil

Outreach team

- Town Hall
  - 1900, Thursday, Oct 5, Richardson Theater, Bldg. 500, Fort Shafter
- Displays
  - TAMC, Hickam AFB, Pearl Harbor, MCBH-Kaneohe Bay
- Contact managers

Office of the Special Assistant to the Secretary of Defense



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Back-up Slides

Myths versus Reality

Cover up	Open process & oversight
Not listening	Solicit eyewitness reports
Destroy records	Found missing records
20,000 veterans dead	6,686 veterans dead
No assistance to vets	Evaluation and care
"Syndrome"	More than 40 illnesses
CW or DU cause	Many possible causes
Brass doesn't care	Force Protection efforts
	Tough choices
	Cultural changes

A National Effort

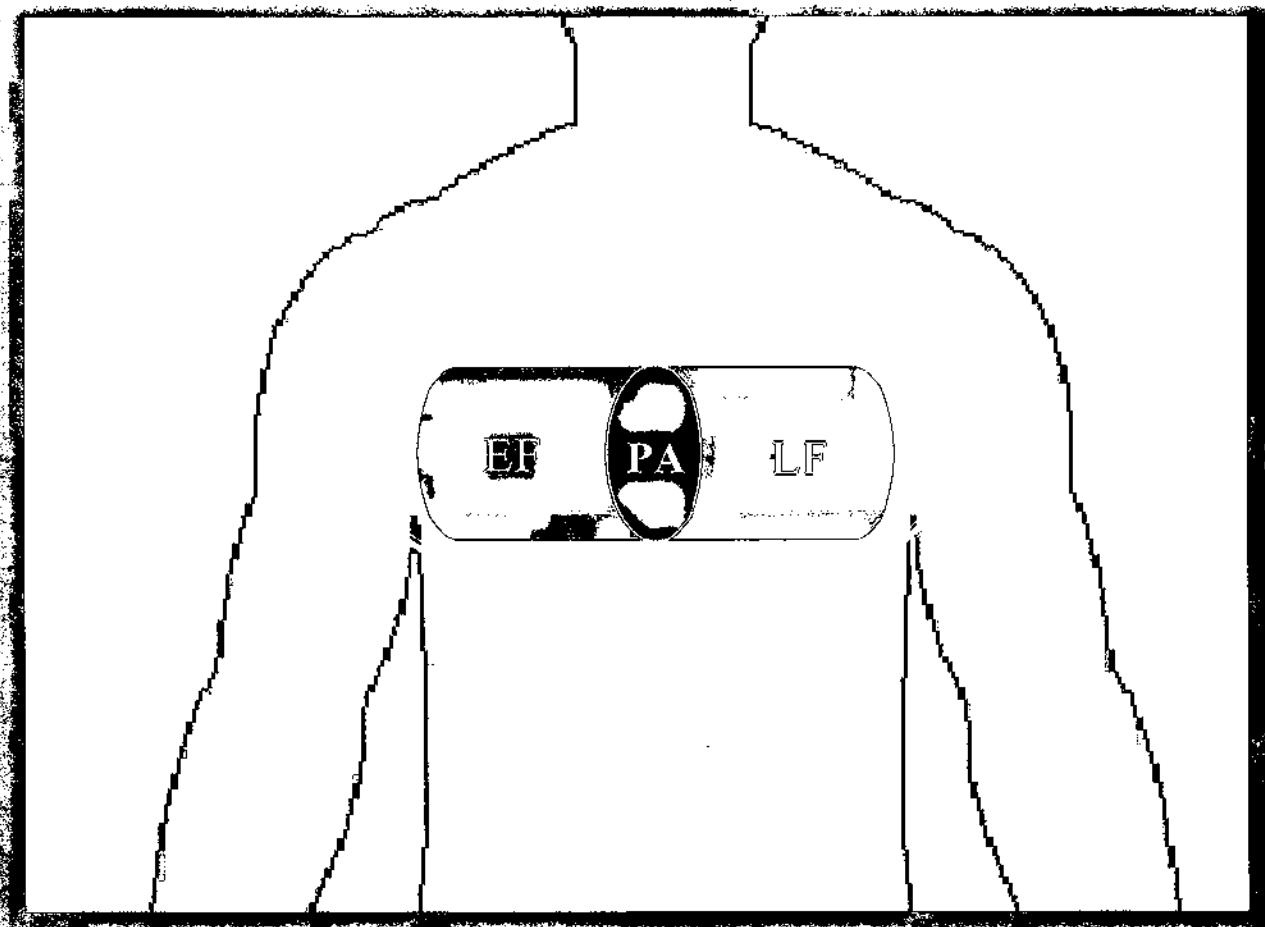
- **OVERSIGHT:** Presidential, 7 Congressional Committees, VSOs, Veterans, the Media
- **INVESTIGATIONS:** IGs, GAO, SIU
- **DoD:** ASDs, Special Assistants, DIA, the Surgeons General
- **OUTSIDE AGENCIES:** CIA, VA, HHS, GWVCB, CDC
- **DECLASSIFICATION:** CIA, DIA, and the Services
- **TECHNICAL PROJECTS:** Dugway, Edgewood, Picatinny, CHPPM, Think tanks, outside experts

Anthrax

- Inhalation anthrax is deadly
- Biological warfare agent of choice:
  - Cheap and easy to produce
  - Can be dispersed in air by a variety of weapons
  - Odorless, colorless, tasteless, difficult to detect
  - Flu-like symptoms early, rapid deterioration, and death
- MOPP 4,prevents exposure
- Antibiotics work before symptoms appear

Vaccination against anthrax is critical for your protection

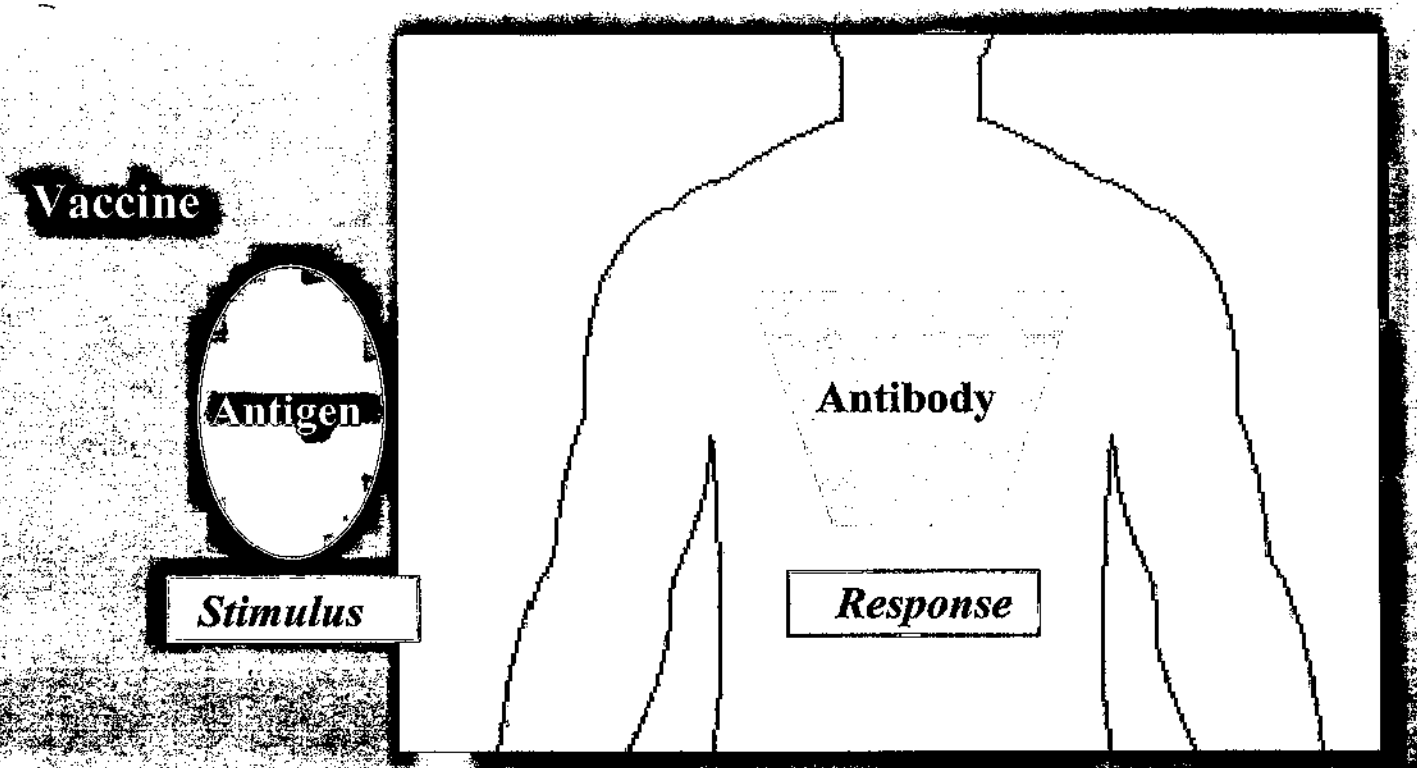
ANTHRAX BACTERIA ATTACK



= Death

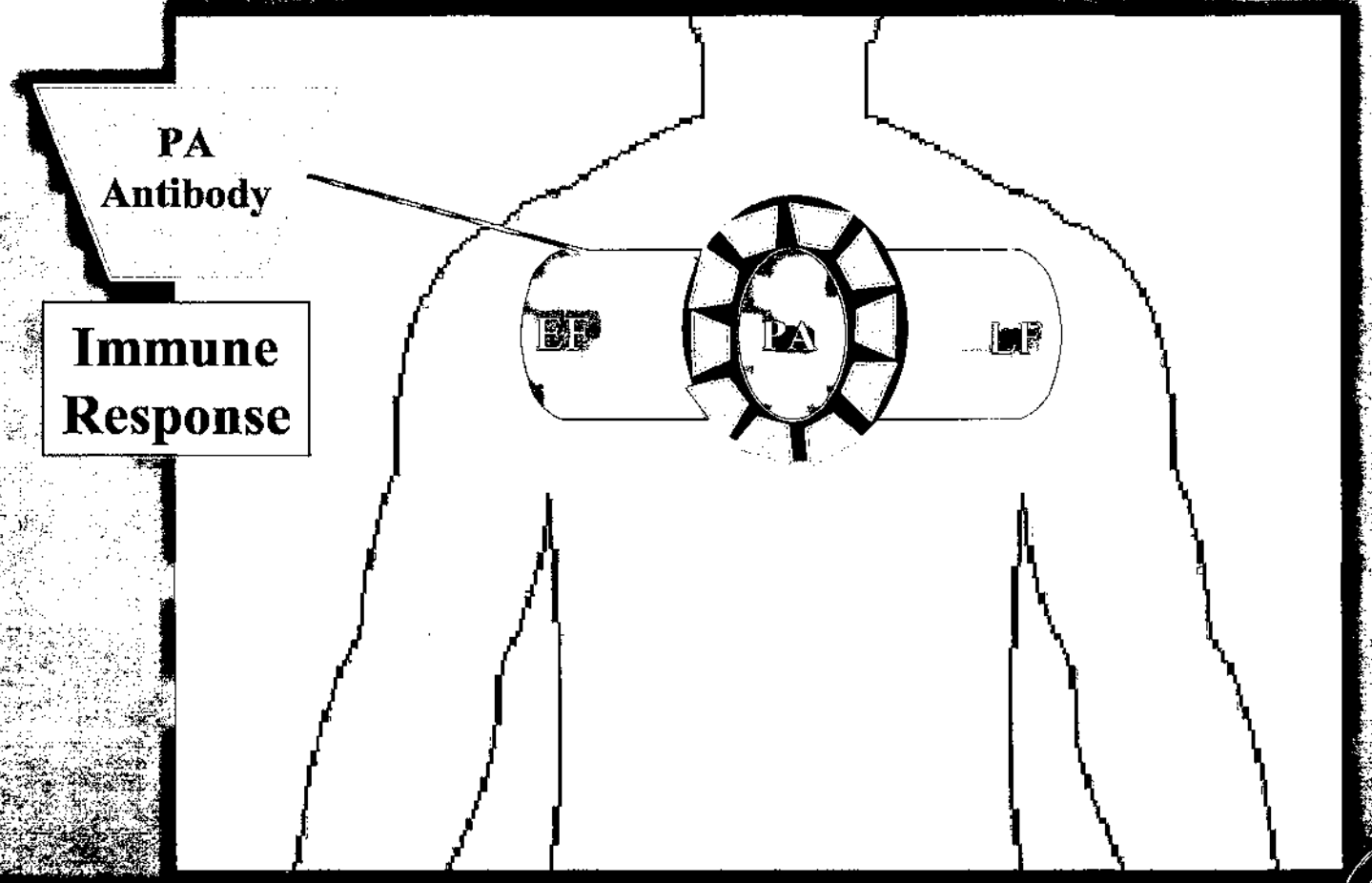
IMMUNE SYSTEM ACTIVATION BY VACCINE

The Basics



AFTER ANTHRAX VACCINE

Antibodies at Work



Office of the Special Assistant

Office of the Special Assistant to the Secretary of Defense for Gulf War Illnesses, Medical Readiness, & Military Deployments

Francis L. O'Donnell
Colonel, Medical Corps, United States Army
Director, Medical Readiness
703-845-3374 fax 703-578-8501
email: fodonnel@gwillness.osd.mil

JCAHO

Physical Readiness

Anthrax

GME

Credentials

Readiness

TRICARE

Privileges

NJP

Force Health Protection

Medical Boards

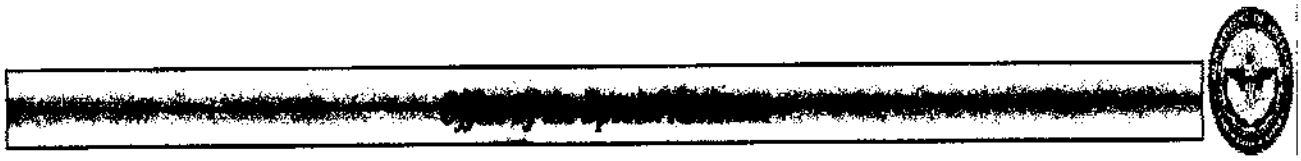
Gulf War Illnesses

CME

Special Assistant

Dr. Bernard Rostker

- Appointed November 12, 1996 by the Deputy Secretary of Defense
- 180 team members



Gulf War Illnesses Mission

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DoD adapts doctrine, policy and procedures to reduce risks for troops in the future.

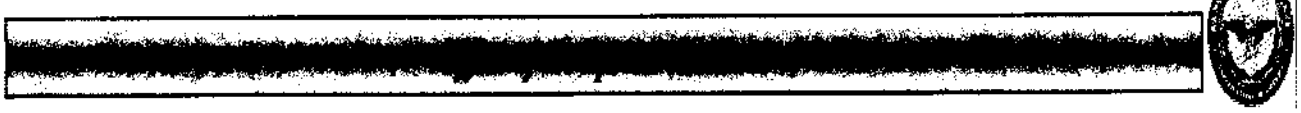
Who Served in the Gulf War

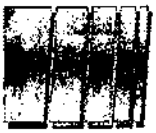
697,000 U.S. service members

ARMY	50%
NAVY	23%
MARINE	15%
AIR FORCE	12%

259,000 Coalition Forces

Source: Presidential Advisory Committee on Veterans Illnesses, Final Report

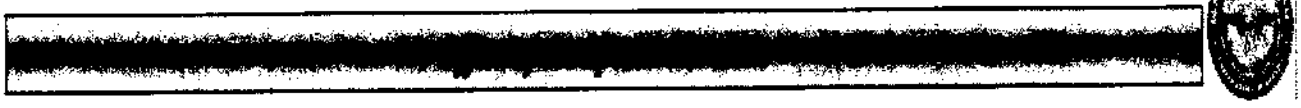




Who Served in the Gulf War

MALE	93%
FEMALE	7%
ACTIVE	83%
RESERVE/NATIONAL GUARD	17%
OFFICER	10%
ENLISTED	90%

< 26 years old - 55%; 26-35 years old - 32%; > 35 years old - 13%

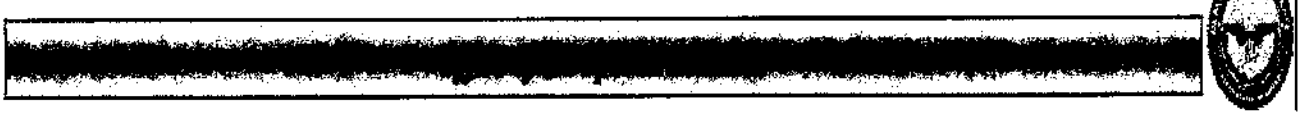


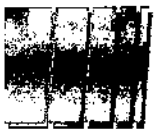
Medical Support

Largest emergency health care system since WW II

- 41,000 medical personnel
- 18,000 beds
  - 2 hospital ships
  - 63 combat zone hospitals

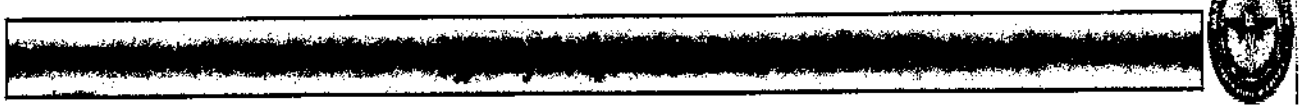
source: CENTCOM Publications - Commander-in-chief US CENTCOM "Desert Shield/Desert Storm Facts, Figures, Quotes and Anecdotes 7 AUG 90-11 APR 91," prepared by CENTCOM PAO

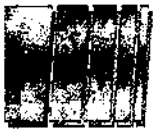




Medical Support

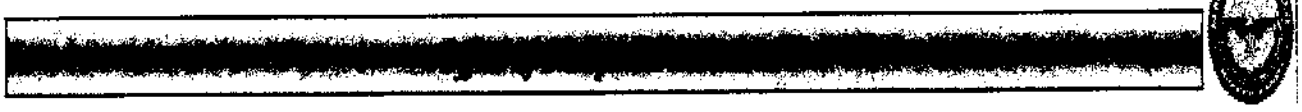
- 27,000 hospitalizations in theater
- 8,000 medical evacuations
- ????? outpatient visits





U.S. Deaths

Non-Battle	224
Battle	148



Symptoms

Tiredness

Rashes

Headaches

Muscle aches

Joint pains

Abdominal pain

Diarrhea

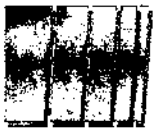
Hair loss

Memory loss

Sleep disturbance

Depression

Concentration problems

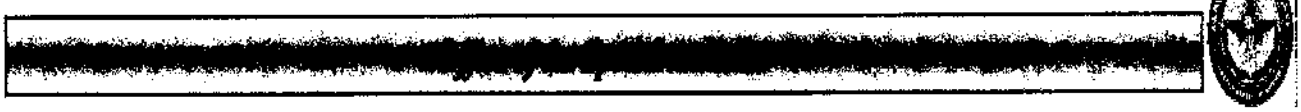


Medical Evaluations

- Comprehensive Clinical Evaluation Program (CCEP)

Total Participants	56,091
Decline examination	15,948
Examined	40,143
♦ Veterans Affairs Registry -examined	79,710
Total Examined	**119,853**

Source: OASD (Health Affairs) 31 Aug 00 VA Registry 25 Jul 00



Diagnosis Distribution

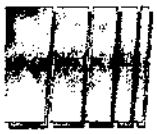
Categories	CCEP (%)	VA Registry (%)
Healthy	10	12
Symptomatic	90	88
Medically explained	80	80
Medically unexplained	**20**	**20**

Physician Message Sent

"Your laboratory, x-ray and physical exams results are normal."

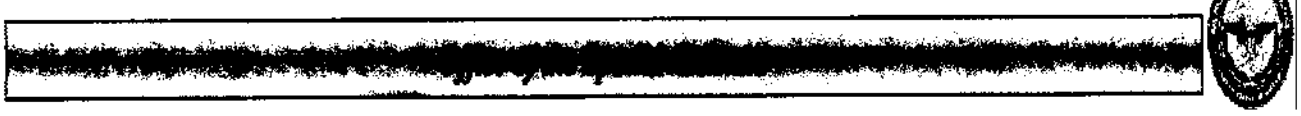
Patient Messages Received

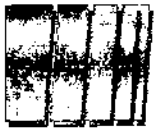
"There's nothing wrong with you!"
"It's all in your head!"
"You're faking these symptoms!"



Epidemiology Studies

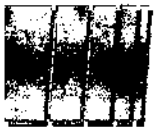
	Deployed (%)	Non-Deployed (%)
Medical separation (Aug 91 - Dec 93)	2.20	2.56
Hospitalizations (Aug 91 - Sep 93)	21.6	21.6
Hospitalizations unexplained illnesses (Aug 91 - Apr 96)	1.21	1.27
Birth Defects (Aug 91 - Sep 93)	7.45	7.59
Mortality (Aug 91 - Sep 93)	.025	.023





Possible Causes

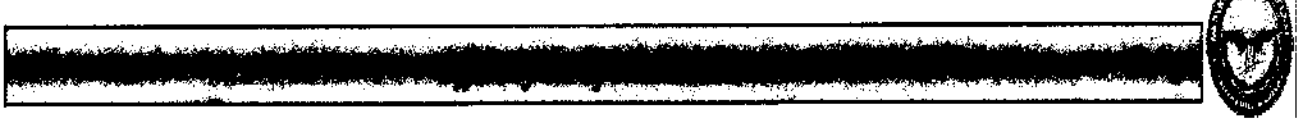
CHEMICAL WARFARE	BIOLOGICAL WARFARE
PESTICIDES	OIL WELL FIRES
VACCINES	DEPLETED URANIUM
PYRIDOSTIMINE BROMIDE	INFECTIOUS DISEASES
STRESS	COCKTAIL EFFECT

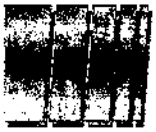


Lessons Learned

CHEMICAL WARFARE

- 14,000 M8 units
- False Positives
- In and out of MOPP, no explanations
- Alarms turned off
- No need to know
- Brain Damage



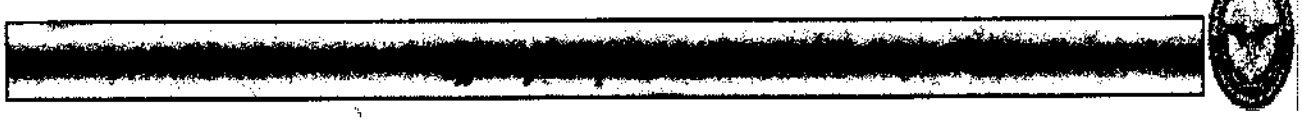


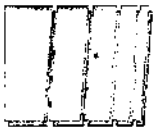
Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

- Navy Forward Laboratory
- No positive cultures





Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

- DEET, permethrin, organophosphates
- Unapproved items: flea collars, SNIP

Lessons Learned

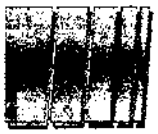
CHEMICAL WARFARE

PESTICIDES

BIOLOGICAL WARFARE

OIL WELL FIRES

- Soot, ash, black cloud
- No information
- EPA monitoring March 91
- Particulates, no toxic fumes



Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

- Vaccines "secret"
- No records
- No explanations
- Squalene

Lessons Learned

CHEMICAL WARFARE

PESTICIDES

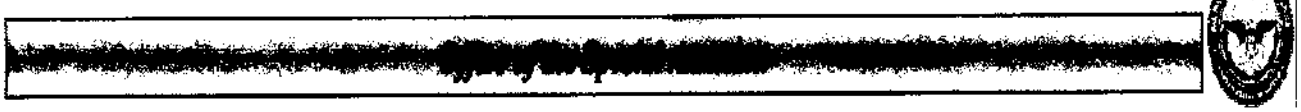
VACCINES

BIOLOGICAL WARFARE

OIL WELL FIRES

DEPLETED URANIUM

- Tank armor, penetrators
- No training
- Heavy metal, proximal tubule
- Surveillance of most exposed



Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

DEPLETED URANIUM

PYRIDOSTIGMINE BROMIDE

- Soman prophylaxis
- Not FDA approved use
- Recognized side effects
- Medical confusion
- No explanations, no records
- Varied protocols

Lessons Learned

CHEMICAL WARFARE

PESTICIDES

VACCINES

PYRIDOSTIGMINE BROMIDE

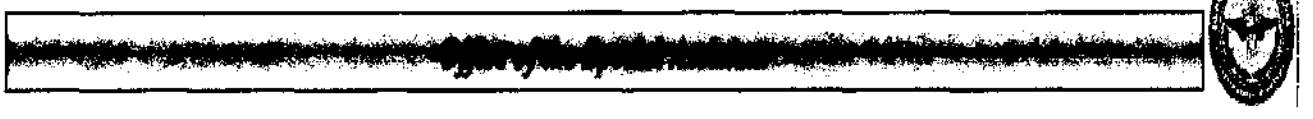
BIOLOGICAL WARFARE

OIL WELL FIRES

DEPLETED URANIUM

INFECTIOUS DISEASES

- 12 malaria, 32 leishmaniasis
- Diarrhea, URI's
- *Mycoplasma fermentans incognitus*



Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

DEPLETED URANIUM

PYRIDOSTIGMINE BROMIDE

INFECTIOUS DISEASES

STRESS

- NO DoD policy that "stress is the cause of symptoms"
- CNN, communications home
- Uncertainties
- Profiles are stress of chronic disease
- PTSD rate lower than Vietnam
- Stress can amplify already existing symptoms

Lessons Learned

CHEMICAL WARFARE

PESTICIDES

VACCINES

PYRIDOSTIGMINE BROMIDE

STRESS

BIOLOGICAL WARFARE

OIL WELL FIRES

DEPLETED URANIUM

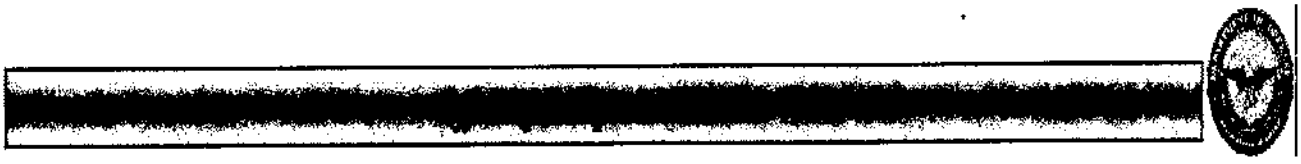
INFECTIOUS DISEASES

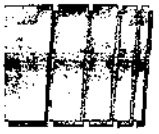
COCKTAIL EFFECT

- No scientific evidence yet

Possible Causes

- Normal disease rate
- New disease paradigm - a Black Camel





Major Lesson Learned from the Gulf War

DoD Does Not Deal Well With Non-Traditional Issues

Deployments

- Unexpected and rapid personnel movement
- Personal and family hardships
- Stress in the field
  - Missile attacks
  - Chem-bio attacks
  - Witnessing death/atrocities
  - Harsh Living Conditions
  - Foreign cultures
  - Racial/ethnic hatred
- Inadequate communication
- No answers to questions after returning

Understanding Today's Military Member

- 55% are married
- 46% have children
- 40% of the 1.3 million children are < 6 years old
- 6% are single parents
- 8% care for elder parents
- 14% are women

Force Health Protection

Predeployment

Health Promotion
Immunizations Current
Health Assessment Surveys
Medical Threat Briefing
Environmental Threat

Deployment

Environmental & Medical Surveillance
Food and Water Inspections
Industrial/Occupational Surveillance
Forward Deployed Labs
Host Nation Medical Support
Combat Stress Teams

Post Deployment

Health Assessment Surveys
Medical Debriefings
Medical Surveillance
Risk Communication

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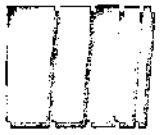

Risk Communication

1. Allow Ventilation
2. Determine Underlying Concern
3. Empathy
4. Conclusion Soundbite
5. Facts (2)
6. Next Steps

Art of Medicine

1. Ask open-ended questions
2. Chief complaint
3. Managed similar problems
4. Diagnosis
5. Lab, physical findings
6. Treatment, next appointment

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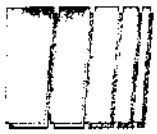
CONTACT NUMBERS

Department of Defense's - CCEP	800-796-9699
VA Persian Gulf Registry	800-749-8387
Department of Defense's Incident Reporting Line	800-497-6261
GulfLINK	*www.gulflink.osd.mil*

COL Francis L. O'Donnell MC, USA

phone 703-845-3374 fax 703-578-8501

email: fodonnel@gwillness.osd.mil

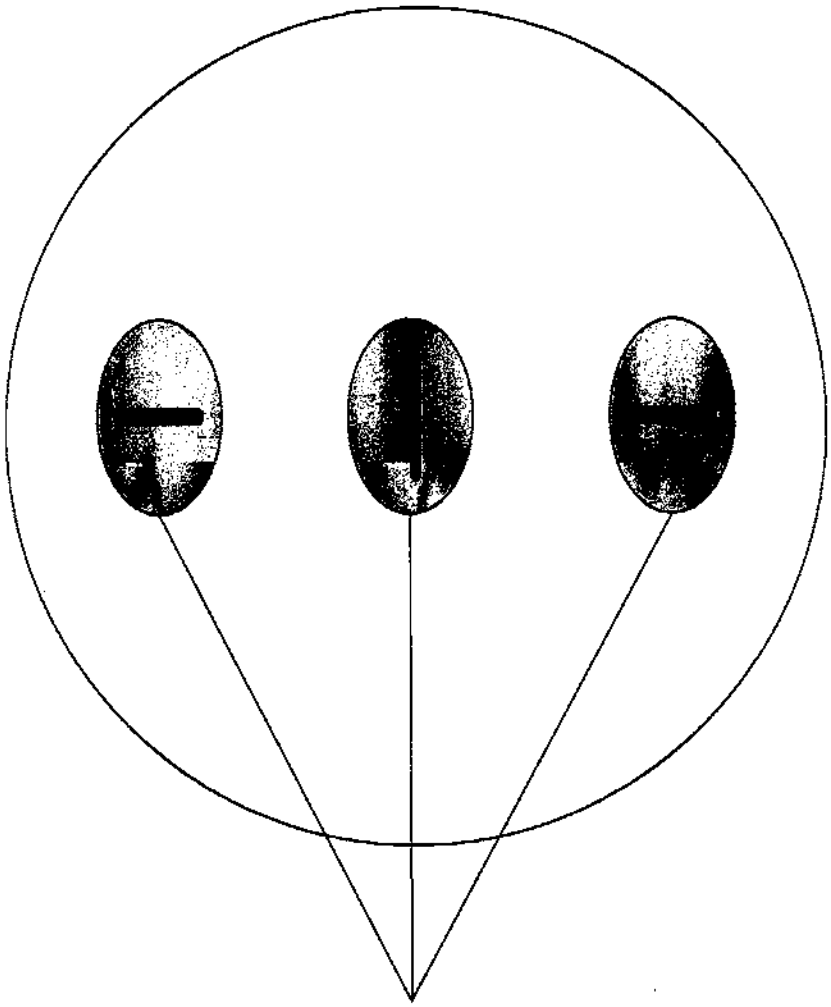


Anthrax

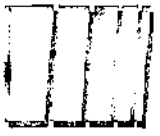
- We have a safe and effective vaccine
- Anthrax - an offensive BW agent
  - Inhalation anthrax is highly lethal
  - Easy to develop and weaponize
  - Remains viable for long periods
  - At least seven potential adversaries suspected of researching, developing and/or weaponizing anthrax.

Vaccination against anthrax is critical for your protection

Anthrax Bacteria

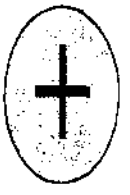


Toxins



Anthrax Bacteria

Toxin Combination



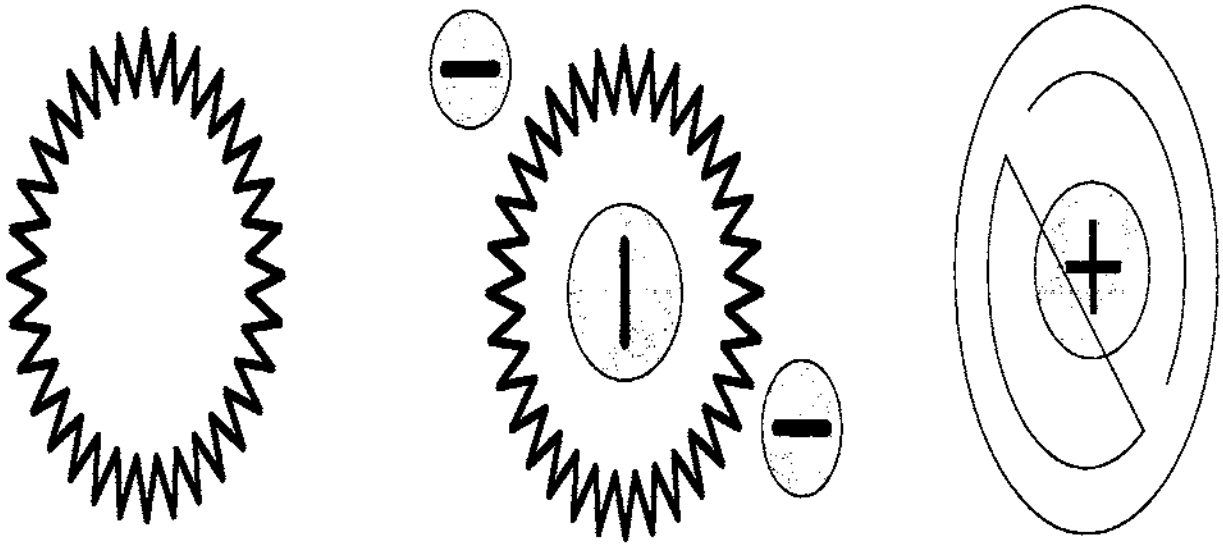
= **Death**

Anthrax Vaccine

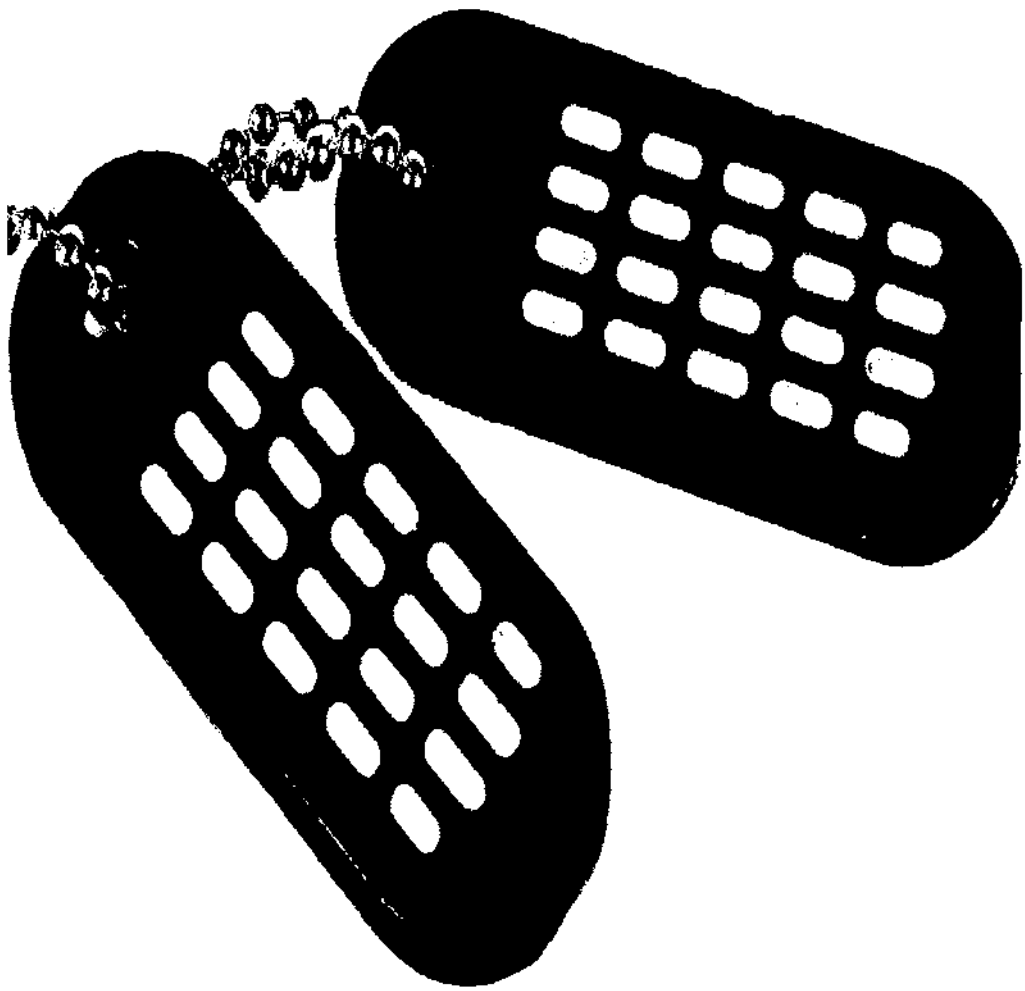
Produces

Attacks Toxin

PROTECTS



Medical Personal Information Center (PIC)



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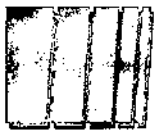
Where Do We Go From Here?

- Concept - Deployment Medicine Clinics
  - Connected to all deployment sites
  - Source for pre and post deployment information
  - Information for family members
- Concept - Education on Vaccines
  - Start updating electronic record entrance
  - Validate accuracy with leave/bonus requests
  - Internet linkage to CDC for recommendations
- Concept - ????

Concerns of the Deployed Member

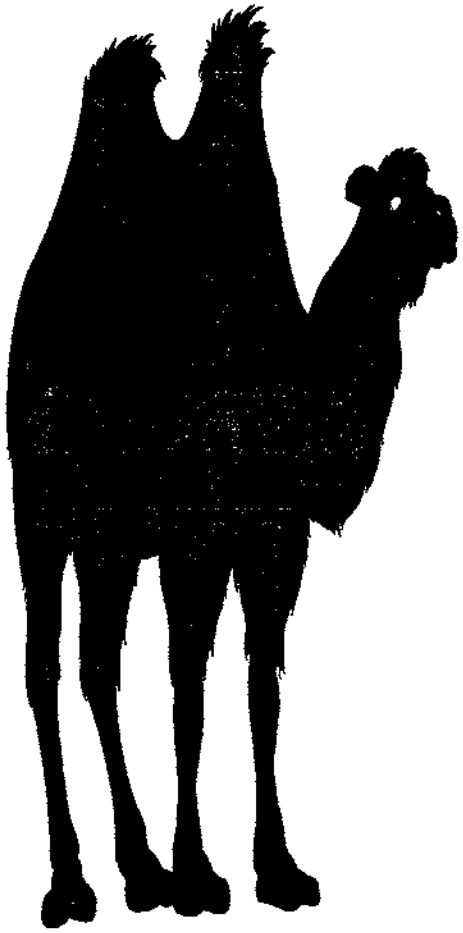
- Importance of the mission
- Recognition by others of his/her role
- Ability to express fears/concerns/problems to leadership
- Recognition for performance



Successful Mission

- Knew why I was there and agreed
- Knew what to do
- Knew how to do it
- Had what I needed to do it
- Did it well
- Was appreciated for my contribution
- Returned proud I had been there

THE BLACK CAMEL



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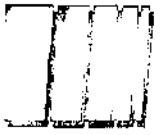
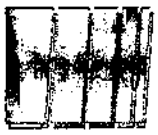


Distribution of CCEP Diagnoses by Major ICD-9 Categories

	Primary (%)	All Dx (%)
• Musculoskeletal	19.6	20.8
• Symp., Signs, IDC	17.4	19.0
• Psychological	17.3	14.8
• V-Codes	10.1	6.0
• Respiratory Sys.	6.5	5.9
• Digestive	6.1	7.3
• Skin	5.9	6.5
• Nervous System	5.5	5.9

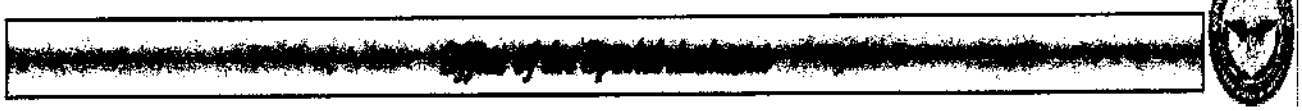
Distribution of CCEP Diagnoses by Major ICD-9 Categories (cont)

	Primary (%)	All Dx (%)
• Infections	2.6	3.0
• Circulatory Sys.	2.5	2.8
• Endocr.-Metab.	2.3	2.7
• Genitourinary	1.3	1.8
• Injury-Poisoning	0.9	1.1
• Neoplasms	0.9	0.9
• Blood	0.6	0.9



Musculoskeletal / Conn. Tissue

• Pain in Joint	5.5 %
• Osteoarthrosis	3.6 %
• Back Pain and other Back Disorders	2.8 %
• Disord. of Tendons, Muscle Attachments	1.6 %
• Other Disorders of Soft Tissue	1.4 %
• Disc Disorders	1.0 %
• Knee Derangements	0.4 %



Symptoms, Signs, Ill Defined Cond.

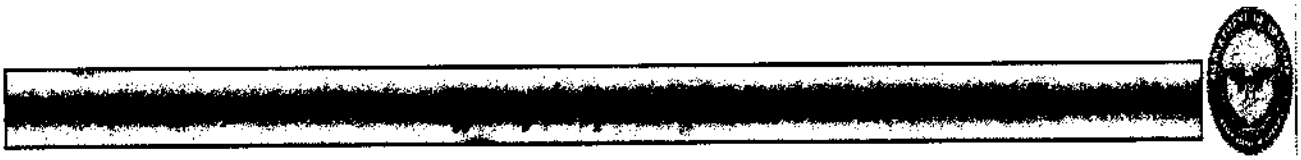
• Malaise, Fatigue	4.2 %
• Sleep Disturbances	3.3 %
• General Symptoms and Hyperhidrosis	1.9 %
• Symp. Of Respiratory Sys. And Chest	1.6 %
• Symptoms involving the Skin	1.1 %
• Alterations of Consciousness, Awareness	0.6 %
• Abdom. Pain, Various Locations	0.4 %
• Symptoms of Digestive System	0.4 %

Psychological

• Depressive Disorder	2.9 %
• Neuroses	2.8 %
• Prolonged PTSD	2.6 %
• Affective Disorders	1.8 %
• Adjustment Reactions	1.2 %
• Sleep Disorders	0.6 %
• Organic Brain Syndromes, Various	0.5 %

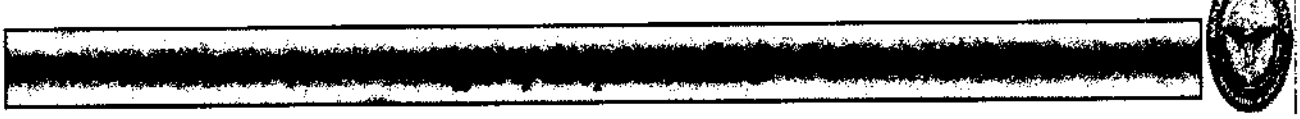
Respiratory Tract

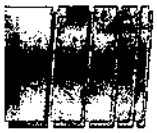
- Asthma 2.2 %
- Allergic Rhinitis 1.5 %
- Chronic Upper Respir. Inflammation 1.5 %



Healthy

- Feared complaint, no diagnosis 8.0 %
- Routine general medical examination 0.9 %



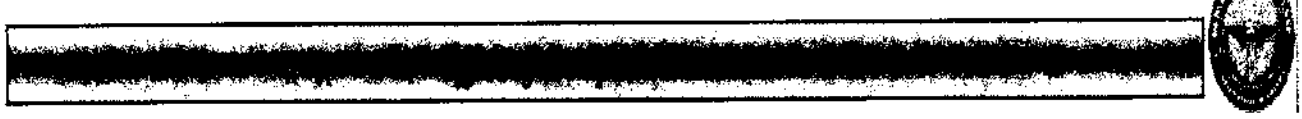


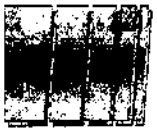
Gastrointestinal

- Irritable Colon 1.5 %
- Esophageal Reflux 1.3 %
- Enteritis and Colitis 0.6 %

Integument

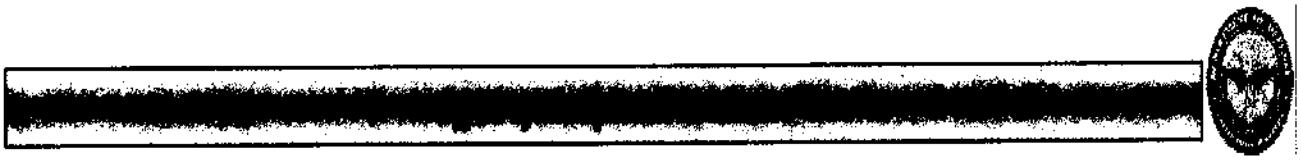
- Alopecia, hirsutism, other dis. of hair 1.3 %
- Fungus infections of skin 1.3 %
- Contact dermatitis, other eczema 1.2 %
- Urticaria, various types 0.5%





Headache

• Tension Headache	3.1 %
• Migraine	2.9 %
• Headache	2.5 %



Other

- Hypertension, essential 1.2 %
- Lipoid Metabolism Disorders 0.6 %
- Hearing Loss 0.4 %
- Hypothyroidism 0.4 %

Office of the Special Assistant to the Secretary of Defense

for Gulf War Illnesses, Medical Readiness and Military Deployments

800-497-6261 fax 703-578-8501

email: brostker@gwillness.osd.mil

(81)

Briefing Overview

- Mission Statement
- The Gulf War
- Post Gulf War Issues
- Searching for answers
- Lessons Learned
- Force Health Protection
- Bottom Line
- Obtaining help and information

Vision of Special Assistant for Gulf War Illnesses, Medical Readiness, and Military Deployments

- The Department of Defense recognizes the right of those involved in deployments to receive information that enables them to make informed decisions about their health.
- We will develop and disseminate such information in a relevant and timely fashion.
- We will work with others in the Defense Department to incorporate lessons from previous deployments to foster the well-being of deployed forces.

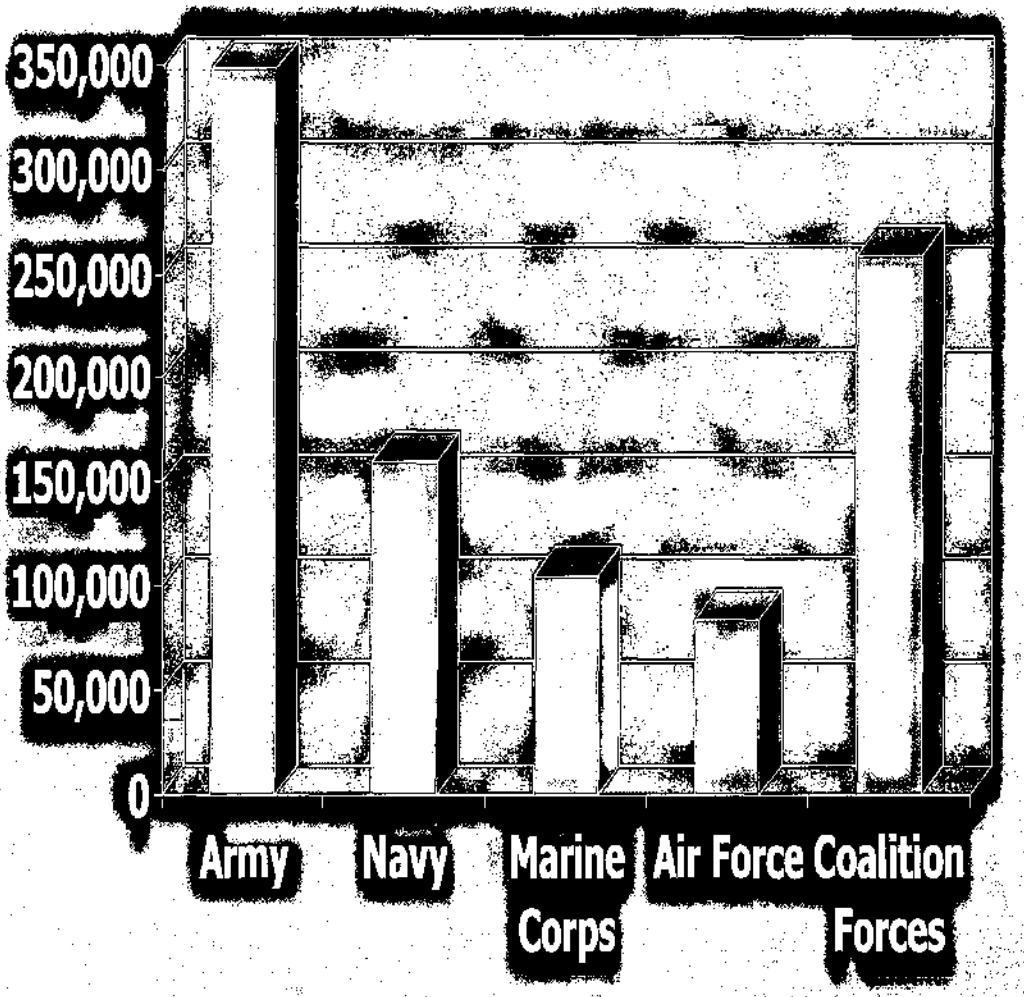
Gulf War Illnesses Mission

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DOD adopts doctrine, policy and procedures to reduce risks for troops in the future.

Why Should I Care

- Lessons from the Gulf War about dirty battlefields
- You must protect yourself against hazards
- You will be leading Gulf War vets
- You are responsible for force protection
  - What are the dangers of the dirty battlefield?
  - How good are our detectors and MOPP gear?
  - How do we determine if we are exposed?
  - Will attacking enemy CW/BW stockpiles put us at risk?

Gulf War Theater Forces



697,000 U.S. service members

Office of the Special Assistant

1 in 7 Veterans Reported Symptoms Since The War

Most frequently reported symptoms

- Joint pain
- Headaches
- Sleep disorders
- Depression
- Fatigue
- Memory loss
- Rash
- Muscle pain

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Communication Breakdown

- Veterans with real health problems
- Healthcare professionals unable to provide answers
- Government slow to recognize the reality of problems

Confounding Issues

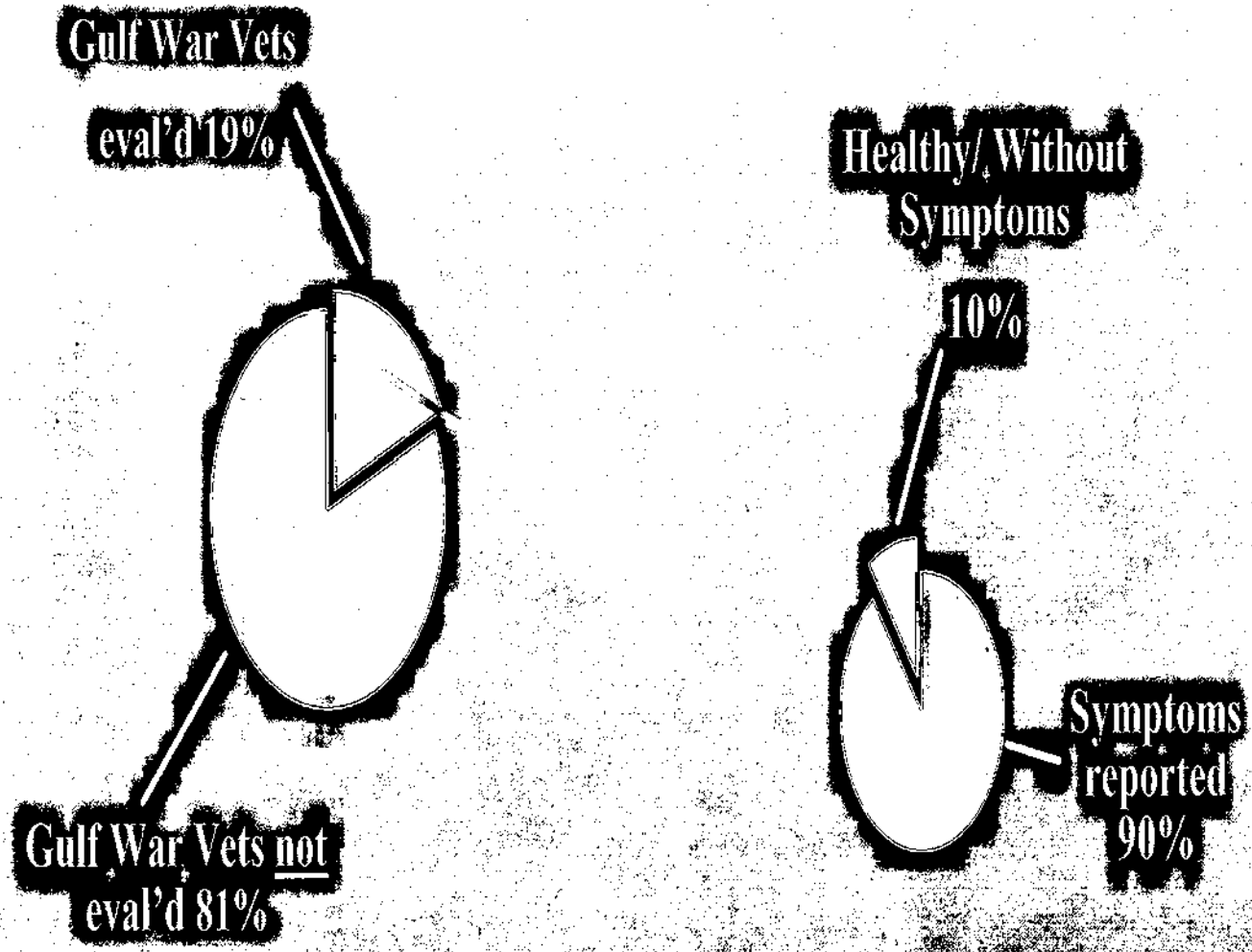
- No clustering
- No symptom consistency; variable onset
- No new disease or links between exposures and symptoms
- No long term study

Taking Care of Service Members

- DoD Comprehensive Clinical Evaluation Program
  - Gulf War vets (active, Guard/Reserve, retired)
  - Active service member deployed to SWA since war ended
  - Family members
  - Civilian employees
- VA Persian Gulf Registry
  - Gulf War vets (left service prior to retirement)
  - Service members deployed to SWA and left service before retirement
  - Evaluation for family members
- Available to *all* service members deploying to South West Asia
  - Most people evaluated can be treated

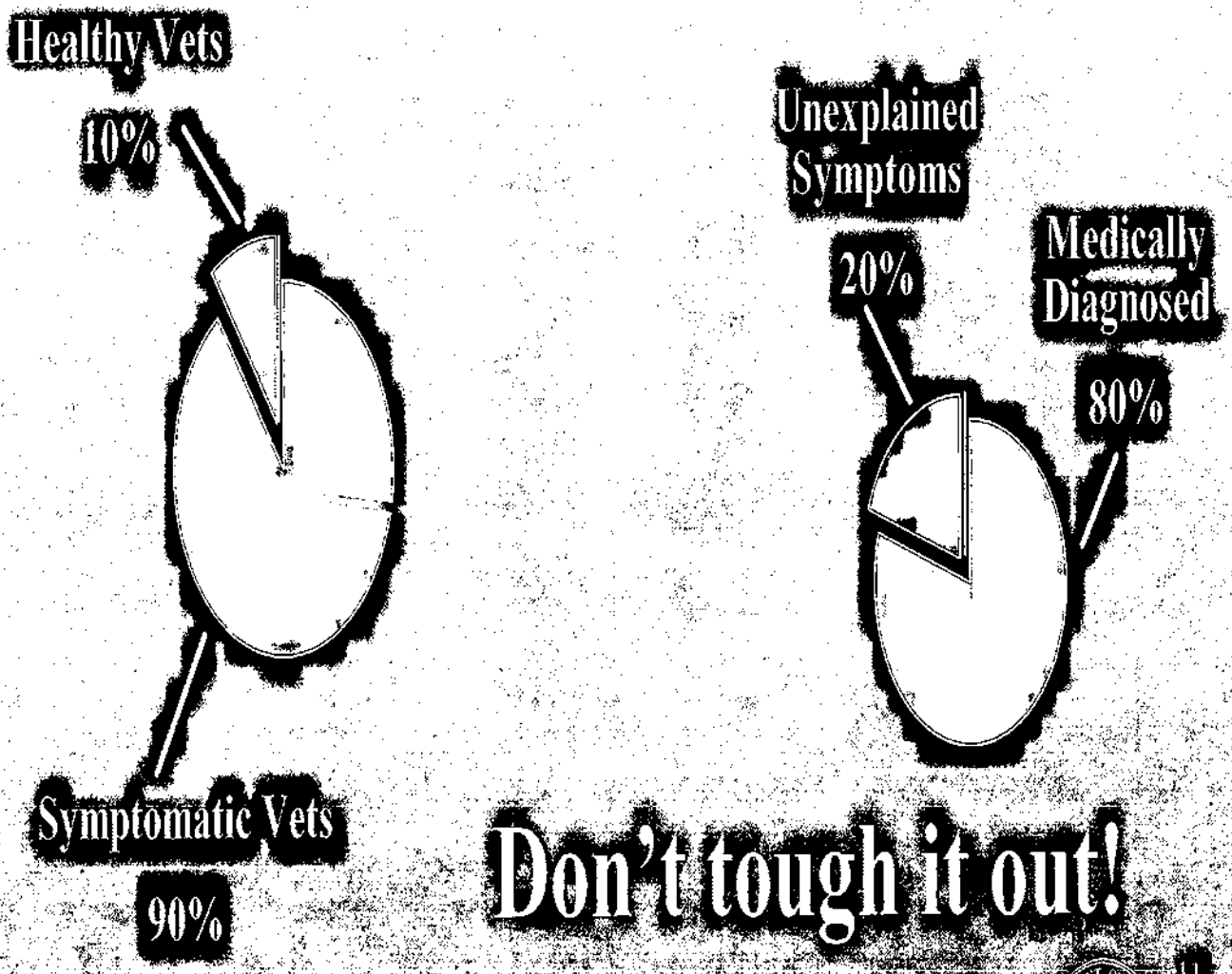
Don't Tough It Out!

Evaluation Distribution of 697,000 CCEP/VA



Diagnosis Distribution of Evaluated Veterans

CCEP/VA



Don't tough it out!

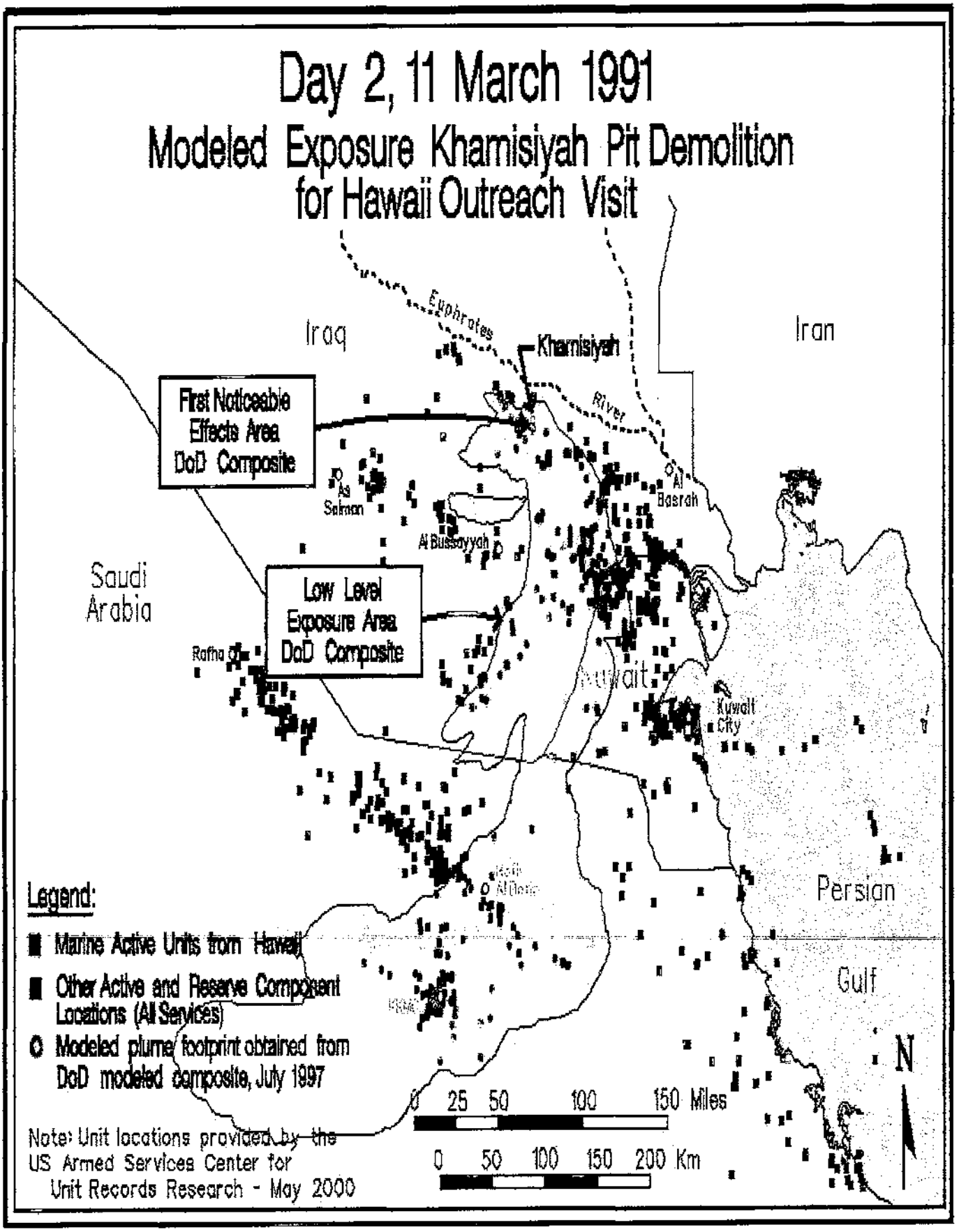
Office of the Special Assistant

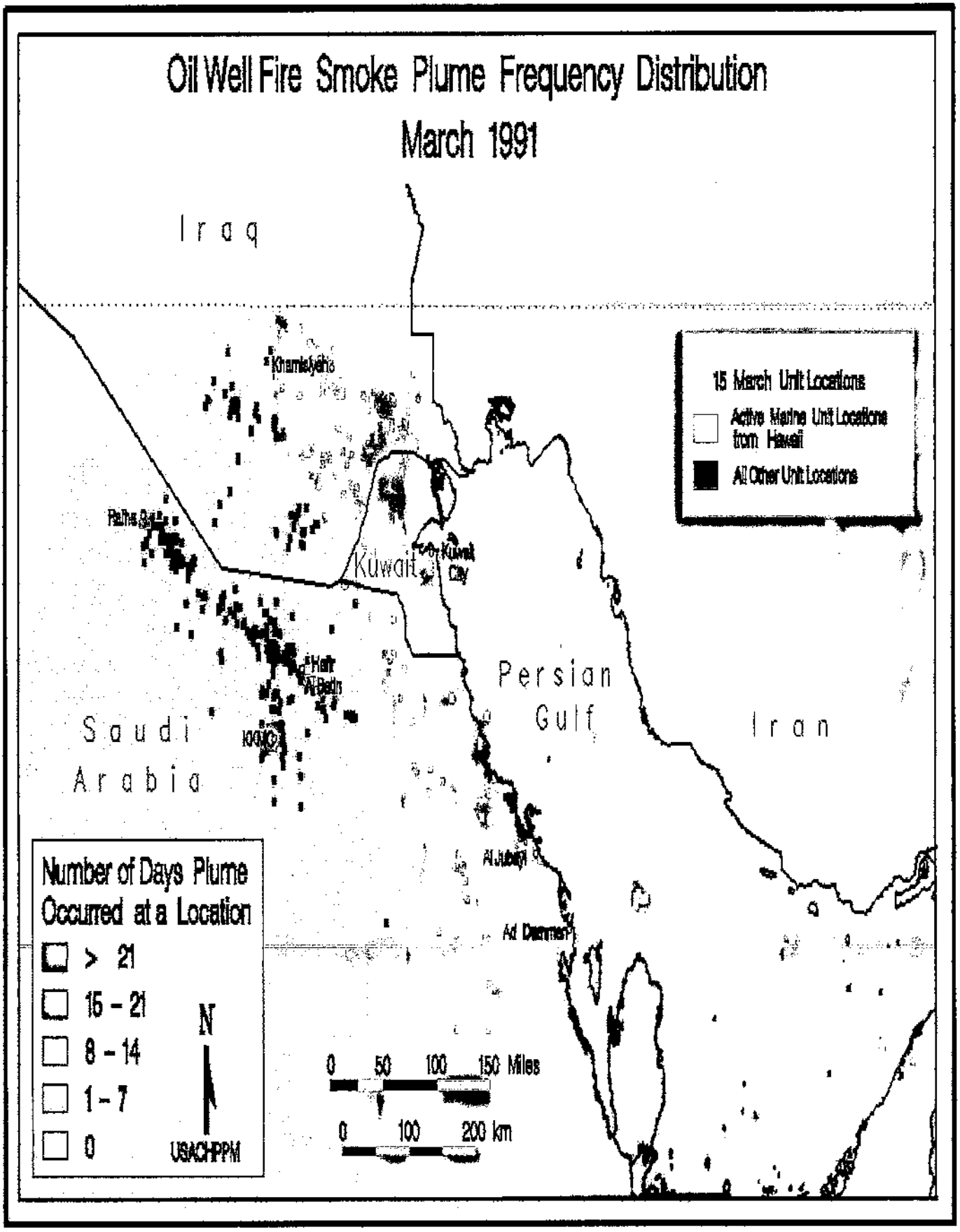
OSAGWI Investigations

- Chemical/biological warfare:
  - Chemical warfare agent - Khamisiyah incident
    - 99,000 vets notified
- Environmental:
  - Depleted uranium (DU), Oil well fires, Pesticides
    - Science doesn't support DU or Oil Well fires as causes
    - Still examining particulates and pesticides
- Medical issues:
  - Vaccines, PB, records, policy
- Persian Gulf War Veterans Coordinating Board-Scientific Research
  - 180+ studies sponsored by DoD, HHS & DVA
  - Science shows no exposure cause or effect relationship yet!

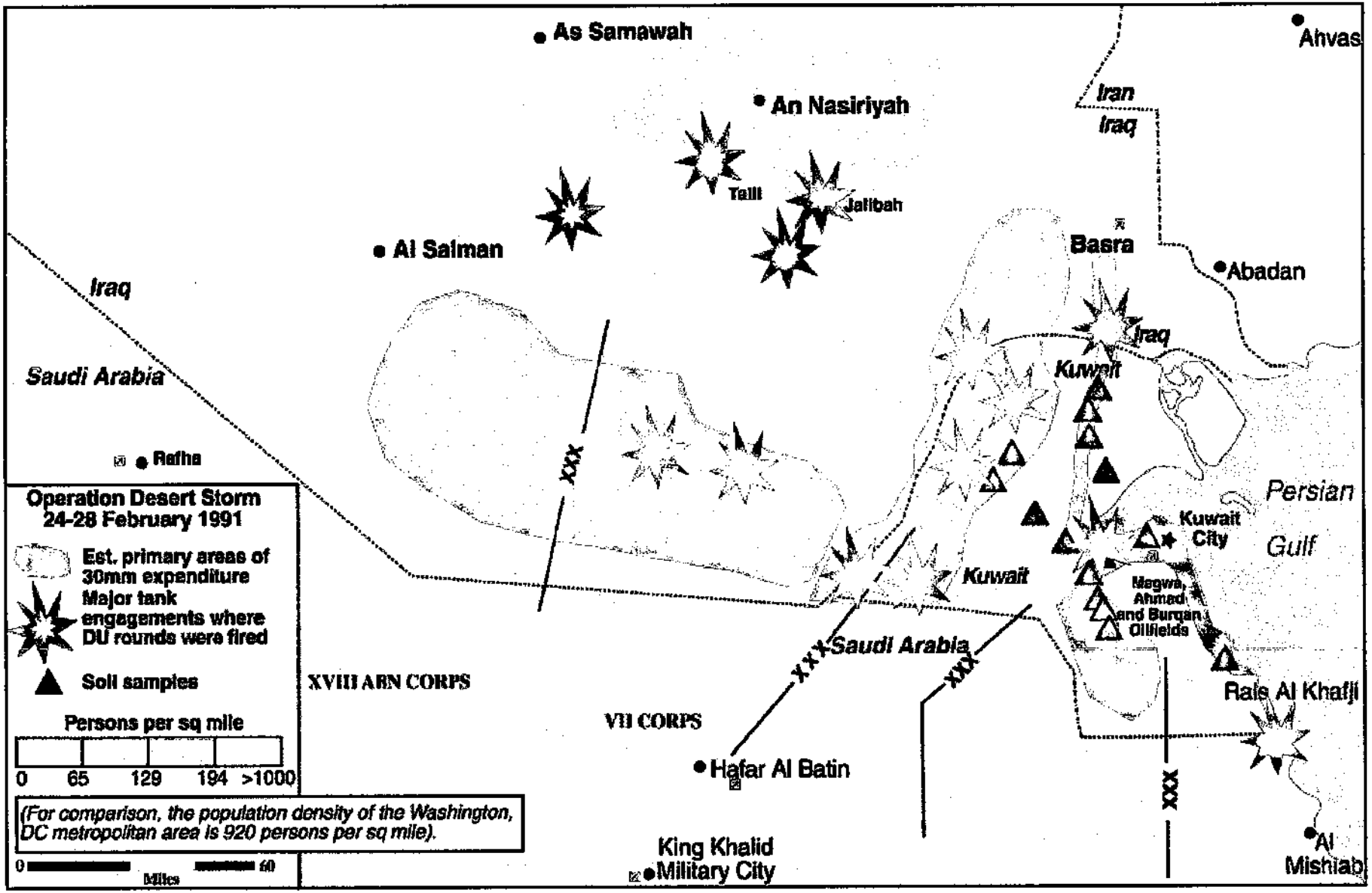
A New Reality =
The Dirty Battlefield

- What enemy may do to us
  - Chemical/Bio threat, Man made environmental hazards (Oil Well Fires)
- What the environment may do to us
  - Infectious diseases, insects, environmental risks (desert, jungle)
- What we may do to ourselves
  - Pesticides, Stressors, Investigational New Drugs, PB
  - Current and future conflicts and humanitarian deployments have and will have these challenges


Day 2, 11 March 1991
Modeled Exposure Khamisiyah Pit Demolition
for Hawaii Outreach Visit
Iraq
Iran
Euphrates River
Khamisiyah
First Noticeable Effects Area DoD Composite
Low Level Exposure Area DoD Composite
Ras Salman
Al Busayyah
Al Basrah
Saudi Arabia
Rafha
Kuwait
Kuwait City
Persian Gulf
Legend:
Marine Active Units from Hawaii
Other Active and Reserve Component Locations (All Services)
Modeled plume footprint obtained from DoD modeled composite, July 1997
0 25 50 100 150 Miles
0 50 100 150 200 Km
N
Note: Unit locations provided by the US Armed Services Center for Unit Records Research - May 2000


Oil Well Fire Smoke Plume Frequency Distribution
March 1991
Iraq
Kuwait
Kuwait City
Persian Gulf
Iran
Saudi Arabia
Khamisiyah
Hafr Al Batin
Al Jubail
Ad Dammam
15 March Unit Locations
Active Marine Unit Locations from Hawaii
All Other Unit Locations
Number of Days Plume Occurred at a Location
> 21
15 - 21
8 - 14
1 - 7
0
USACHPPM
N
0 50 100 150 Miles
0 100 200 km

Primary Areas of DU Expenditure



DU Exposure Issues

- Radiation
- Consequences of exposure
- Heavy metal toxicity
- Reproductive effect
- Contamination of theater

Gulf War Investigation Results

- Poor intelligence about Iraq's CW/BW weapons
- Not enough vaccines and no explanation given
- Limited environmental survey
- Information about nerve agent pre-treatment (PB) wasn't given to troops
- Inadequate training about DU or CW detectors
  - Training could have averted unnecessary exposure to DU and anxiety resulting from false alarms
- *Veterans re-deployed and left service without thorough medical exam or debrief*

Applying Lessons Learned

You

- Train self and others to recognize and avoid hazards
- Improve feedback and cross talk
- You are your own best health advocate

Your Unit

- CW/BW detection:earlier with fewer false positives
- Create, relate and save operational, NBC, and medical records
- Adapt to reduce risks and train to reduce future risks such as DU
- Debrief to explain what happened
- Monitor service members' health & environment

Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Collect pre-deployment blood sample
- Verify HIV test is current
- Verify Immunizations up to date
- Verify current physical exam
- Complete Health questionnaire

Deployment

- Routine disease/injury reporting
- Forward medical laboratory
- Immunization tracking
- Environmental monitoring

Post Deployment

- Collect blood sample
- Medical debriefs
- Complete health questionnaire
- Screening exams as needed

You are your own best health advocate!

Anthrax

- Anthrax - an offensive BW agent
  - Inhalation anthrax is highly lethal
  - Easy to develop and weaponize
  - Remains viable for long periods
  - At least seven potential adversaries suspected of researching, developing and/or weaponizing anthrax.
- We have a safe and effective vaccine

Vaccination against anthrax is critical for your protection

Anthrax Vaccine Program

- Licensed by the FDA since 1970
- Dosing schedule is six doses over 18 months
  - 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster
- Shortages in stockpiled doses require temporary slowdown of AVIP
  - No new vaccine available from renovated facility until FDA approves [new vaccine lots] safety and effectiveness
  - Vaccinations continue for service members assigned or deployed at least 30 days in highest threat areas
  - Next scheduled doses for those not in high threat areas will be deferred until sufficient doses are available

(877) GET-VACC DSN: 761-5101

www.anthrax.osd.mil

www.aviationmedicine.com

Pyridostigmine Bromide

- Threat - Soman is deadly nerve agent
- PB is the only known pretreatment against Soman.
  - Auto injectors alone will not save you
- Issues have been raised about PB
  - Further research is ongoing
- Only President can authorize its use without informed consent

Conclusions about PB

- We cannot rule out pyridostigmine bromide as a contributor to increased health symptoms in Gulf War veterans.
- Further research is needed to determine the effectiveness of the current dose of PB against Soman.
- Additional research about safety and effectiveness of PB for humans is needed.

Bottom Line

- You will deploy on missions to dirty areas
- Everyone is responsible for force protection
- Evaluating PB and pesticides as contributors to GW vets' symptoms
- Lessons learned from the Gulf War affect today's doctrine and deployments
- You are your own best health advocate
- Vets should not tough it out; get examined
- Vaccination against anthrax protects you

Obtaining Help and Information

GWIMRMD Veterans' Helpline
(800) 497-6261

Comprehensive Clinical Evaluation Program
(800) 796-9699

Veterans Affairs Persian Gulf Registry Program
(800) 749-8387

TAMC CCEP
(808) 433-4531

http://www.gulflink.osd.mil

Outreach team

- Town Hall
  - 1900, Thursday, Oct 5, Richardson Theater, Bldg 500, Fort Shafter
- Displays
  - TAMC, Hickam AFB, Pearl Harbor, MCBH-Kaneohe Bay, Schofield Barracks
- Contact managers

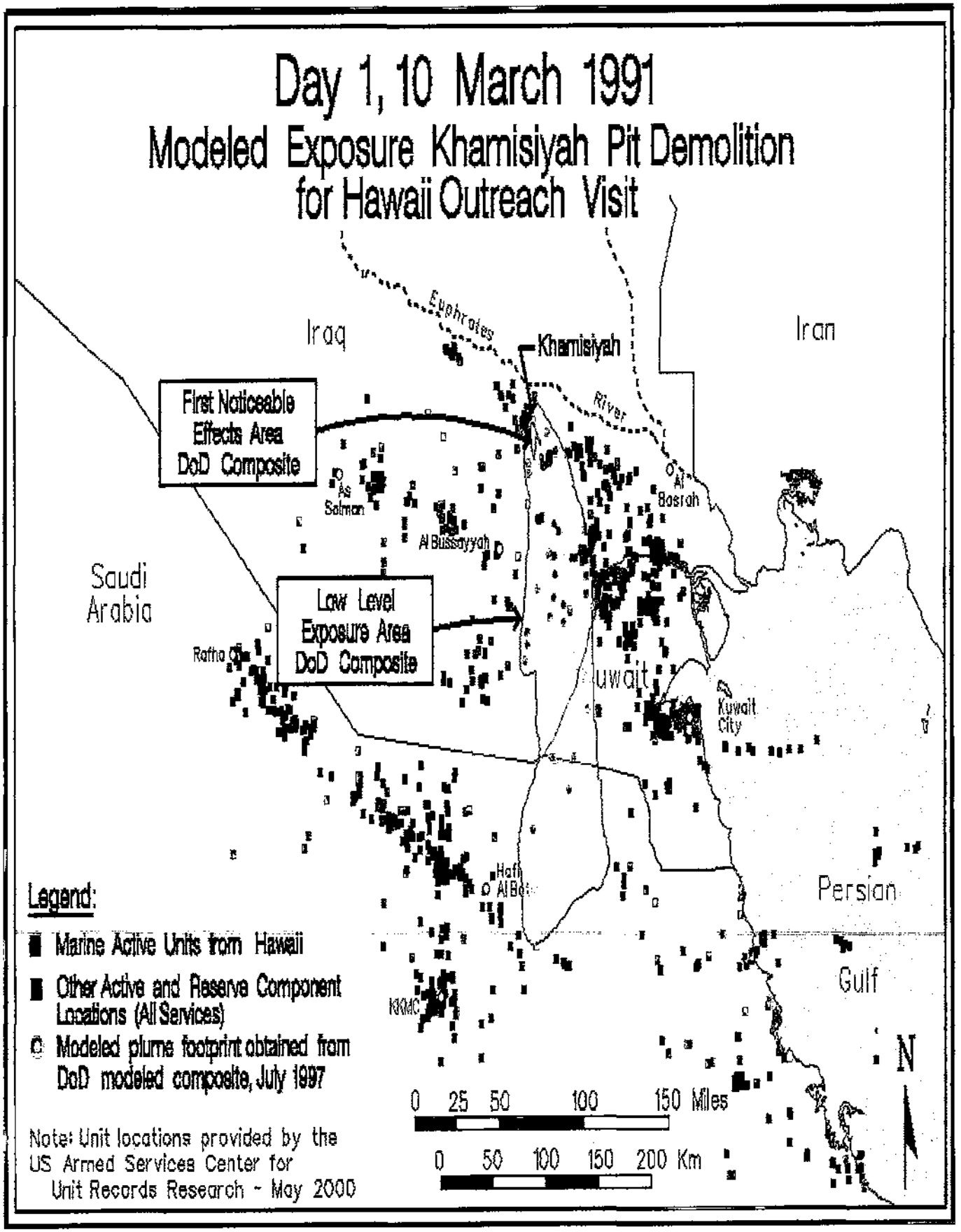
Back-up Slides

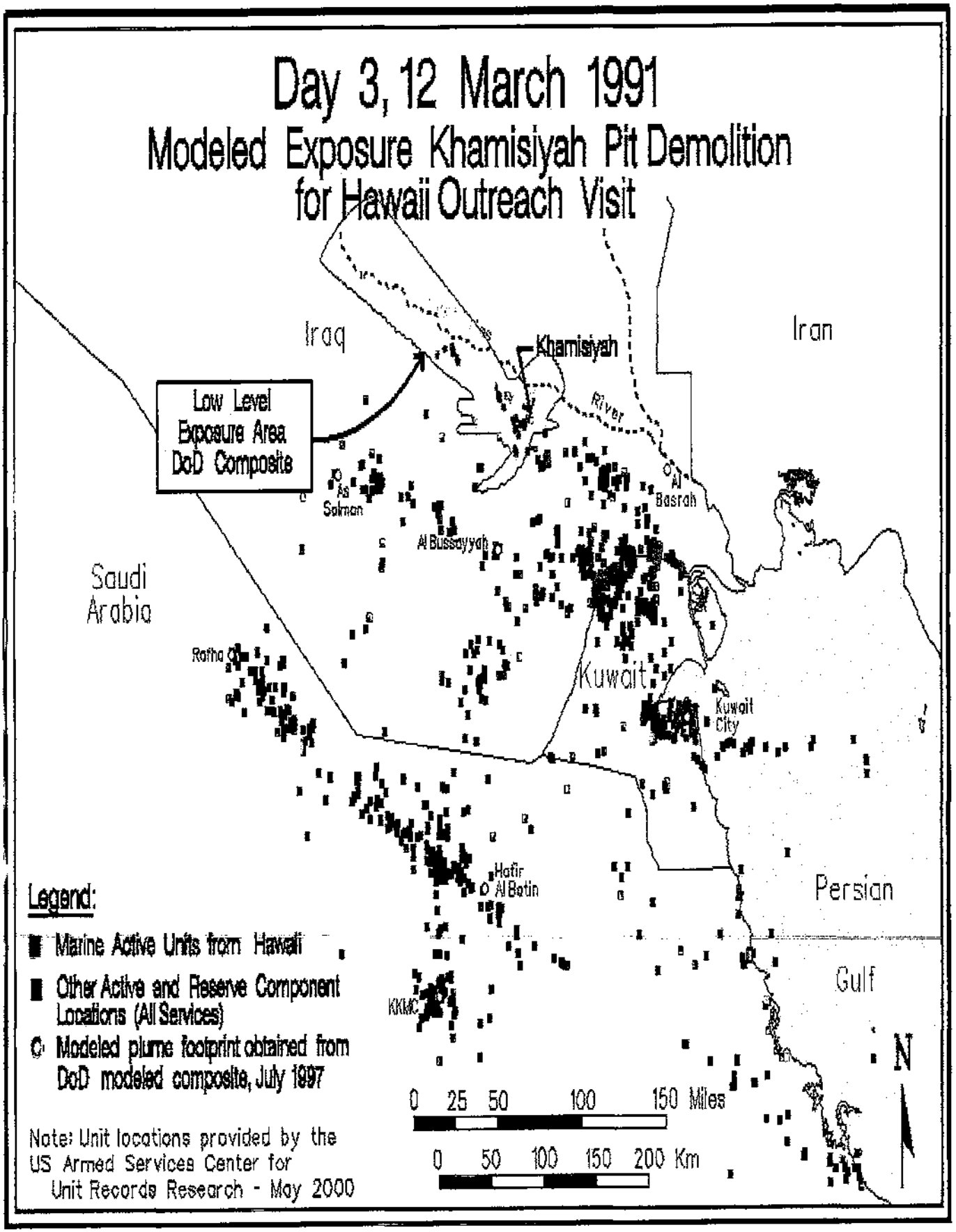
Myths versus Reality

Cover up	Open process & oversight
Not listening	Solicit eyewitness reports
Destroy records	Found missing records
20,000 veterans dead	6,686 veterans dead
No assistance to vets	Evaluation and care
"Syndrome"	Normal spectrum of illnesses known
CW or DU cause	Evaluating many possible causes
Brass doesn't care	Force Protection efforts
	Tough choices
	Cultural changes

A National Effort

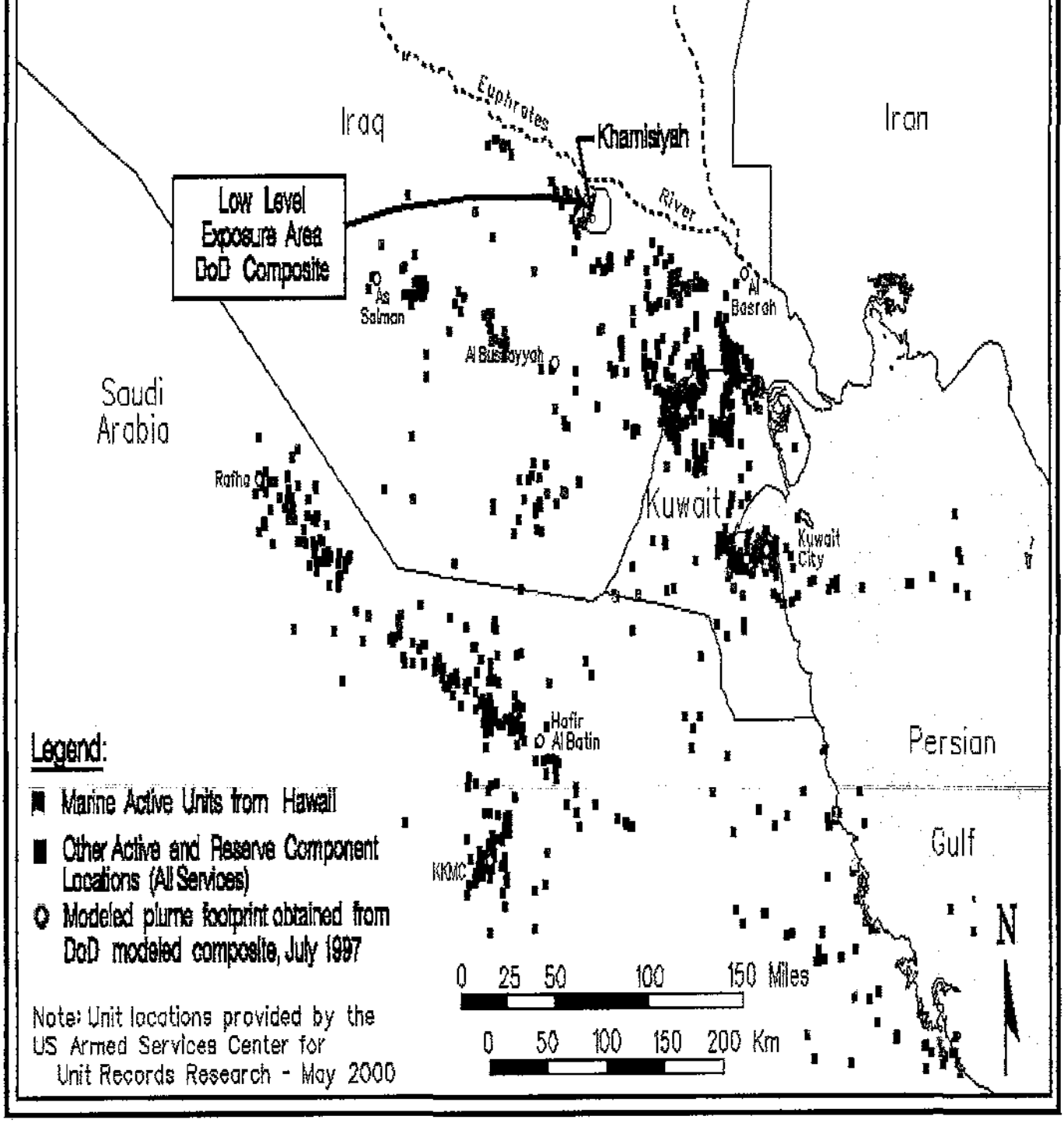
- **OVERSIGHT:** Presidential, 7 Congressional Committees, VSOs, Veterans, the Media
- **INVESTIGATIONS:** IGs, GAO, SIU
- **DoD:** ASDs, Special Assistants, DIA, the Surgeons General
- **OUTSIDE AGENCIES:** CIA, VA, HHS, GWVCB, CDC
- **DECLASSIFICATION:** CIA, DIA, and the Services
- **TECHNICAL PROJECTS:** Dugway, Edgewood, Picatinny, CHPPM, Think tanks, outside experts


Day 1, 10 March 1991
Modeled Exposure Khamisiyah Pit Demolition
for Hawaii Outreach Visit
Iraq
Iran
Euphrates
Khamisiyah
River
First Noticeable Effects Area DoD Composite
As Salman
Al Basrah
Al Bussayyah
Saudi Arabia
Low Level Exposure Area DoD Composite
Kuwait
Kuwait City
Persian
Gulf
Legend:
Marine Active Units from Hawaii
Other Active and Reserve Component Locations (All Services)
Modeled plume footprint obtained from DoD modeled composite, July 1997
Note: Unit locations provided by the US Armed Services Center for Unit Records Research - May 2000
0 25 50 100 150 Miles
0 50 100 150 200 Km
N


Day 3, 12 March 1991
Modeled Exposure Khamisiyah Pit Demolition
for Hawaii Outreach Visit
Iraq
Khamisiyah
Iran
Low Level
Exposure Area
DoD Composite
As
Salman
Al Basrah
Al Bussayyah
Saudi
Arabia
Ratha
Kuwait
Kuwait
City
Hafir
Al Batin
Persian
Gulf
KKMC
Legend:
Marine Active Units from Hawaii
Other Active and Reserve Component
Locations (All Services)
Modeled plume footprint obtained from
DoD modeled composite, July 1997
Note: Unit locations provided by the
US Armed Services Center for
Unit Records Research - May 2000
0 25 50 100 150 Miles
0 50 100 150 200 Km
N

Day 4, 13 March 1991

Modeled Exposure Khamisiyah Pit Demolition for Hawaii Outreach Visit

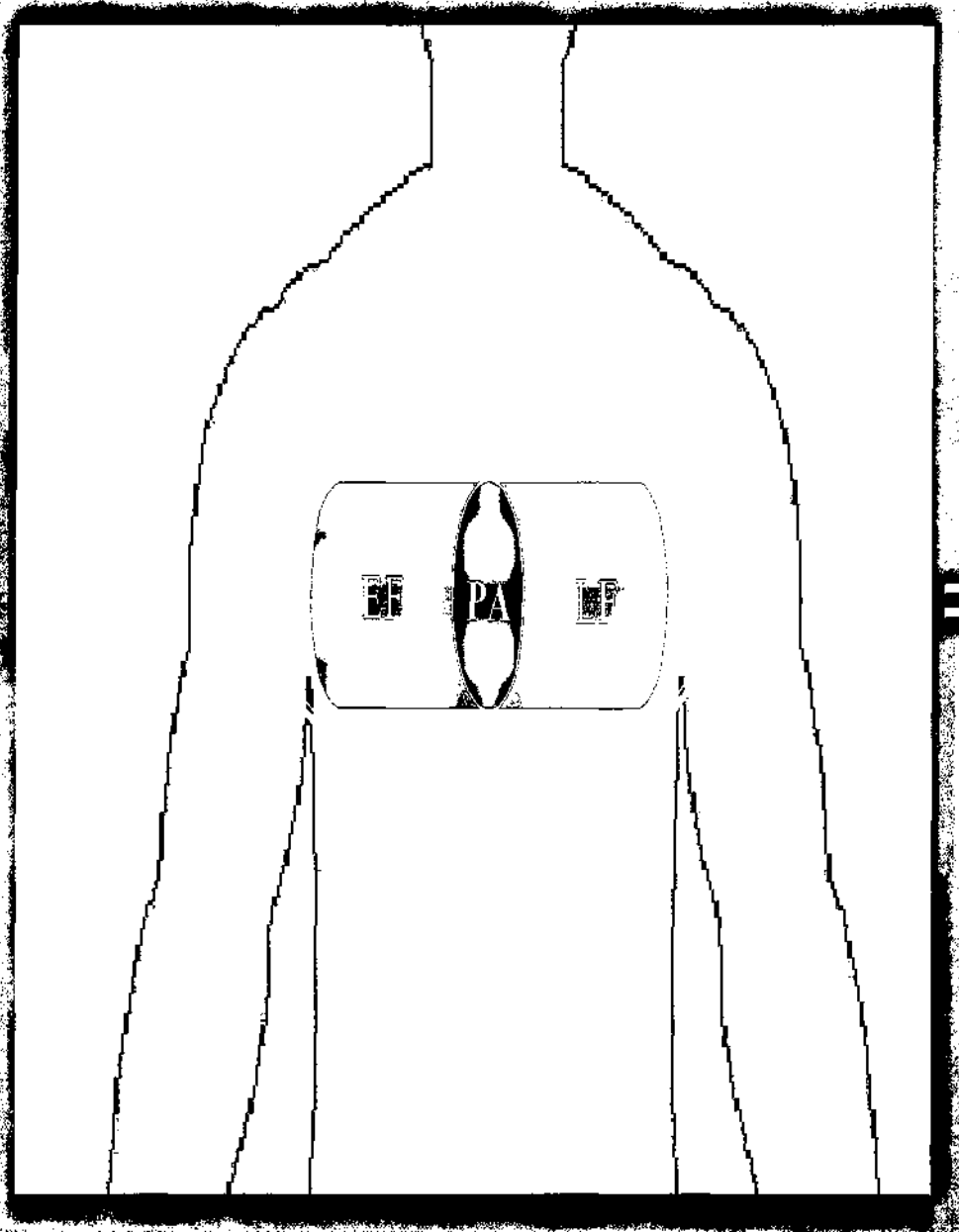


Anthrax

- Inhalation anthrax is deadly
- Biological warfare agent of choice:
  - Cheap and easy to produce
  - Can be dispersed in air by a variety of methods
  - Odorless, colorless, tasteless, difficult to detect
  - Flu-like symptoms early, rapid deterioration, and death
- MOPP 4 prevents exposure
- Antibiotics work before symptoms appear

Vaccination against anthrax is critical for your protection

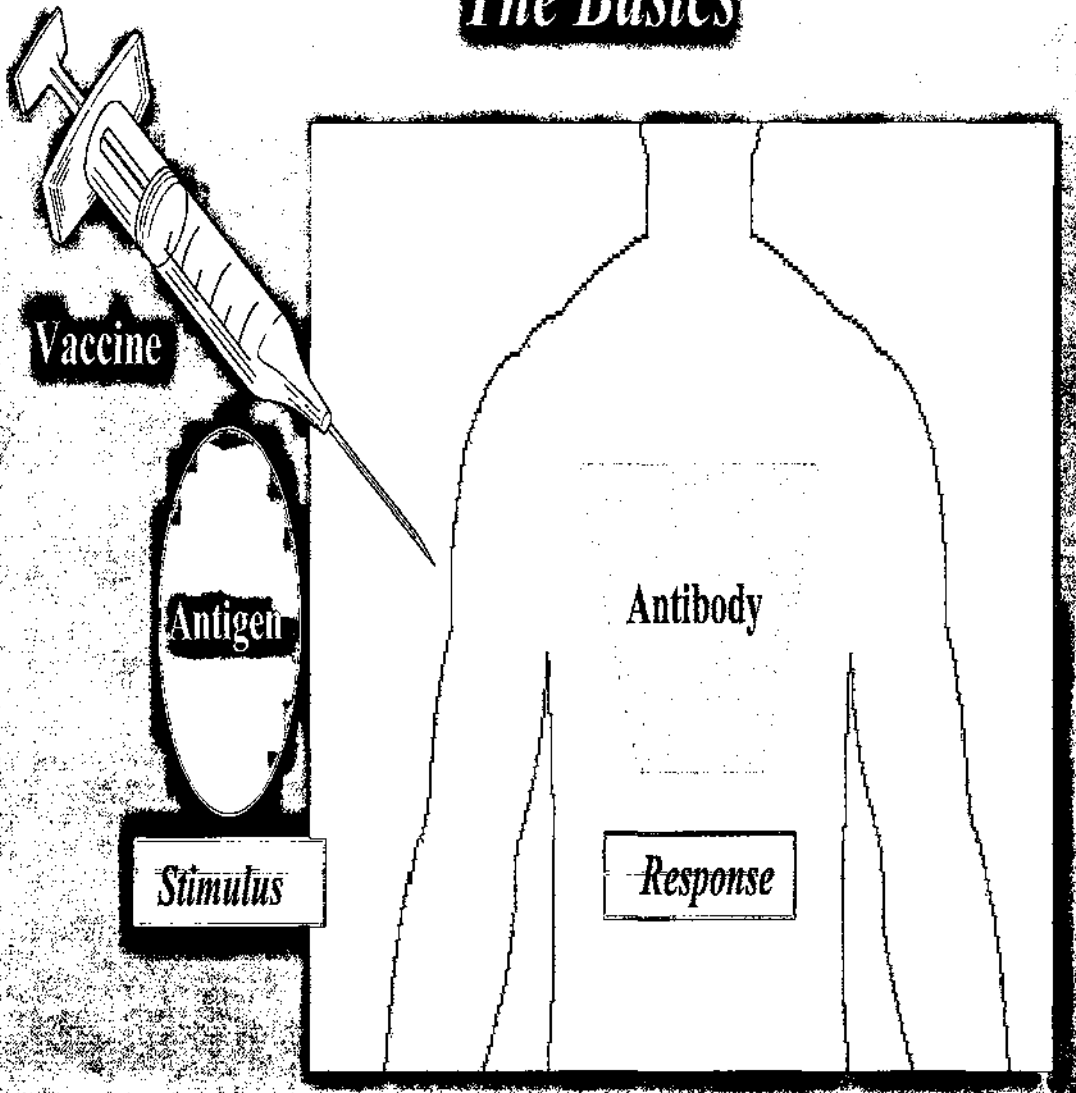
ANTHRAX BACTERIA ATTACK



= Death

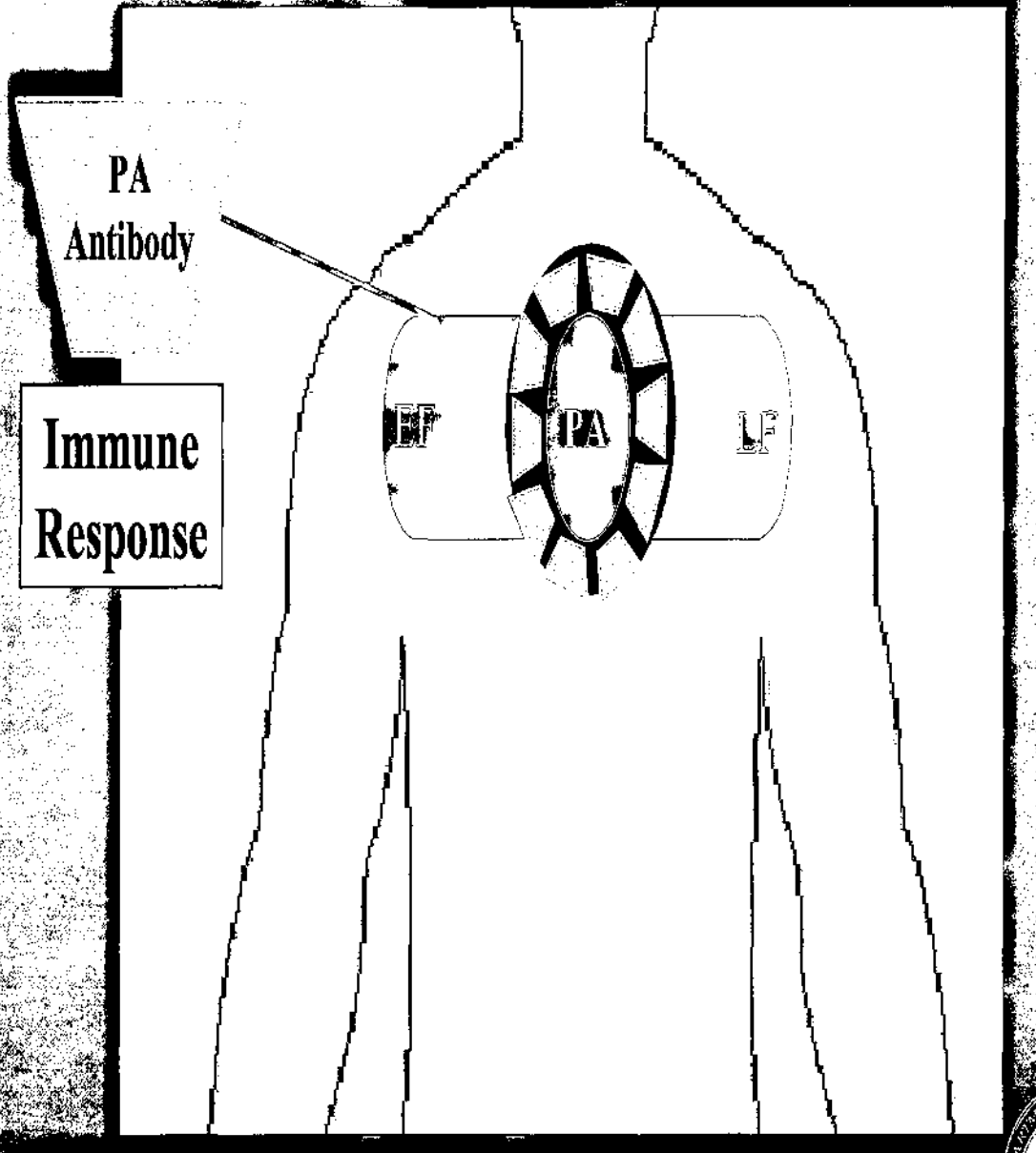
IMMUNE SYSTEM ACTIVATION BY VACCINE

The Basics



AFTER ANTHRAX VACCINE

Antibodies at Work



Office of the Special Assistant

Anthrax Vaccine Program

- Licensed by the FDA since 1970
  - Safely administered in the U.S. to at-risk veterinarians, laboratory workers, and livestock handlers
- Shot schedule: 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster

1-877-GET-VACC
DSN: 761-5101
www.anthrax.osd.mil
www.aviationmedicine.com

Office of the Special Assistant to the Deputy Secretary of Defense

for Gulf War Illnesses

(800) 754-2132 fax 703-578-8501
email: brostker@gwillness.osd.mil

Briefing

- Organization - Mission Statement
- Why is this important to you
- Symptoms and Illnesses
- Looking for causes
- Gulf War - Lesson Learned
- Force Health Protection
- Obtaining help and information

Special Assistant for Gulf War Illnesses

Dr. Bernard Rostker

- Appointed November 12, 1996 by the Deputy Secretary of Defense
- 180 team members

Mission of the Special Assistant

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DOD adopts doctrine, policy and procedures to reduce risks for troops deploying now and in the future.

Myths versus Reality

Cover up	Open process
Not listening	Solicit eyewitness reports
Destroy records	Significant oversight
20,000 veterans dead	5,773 veterans dead
No assistance to vets	Evaluation and care
"Syndrome"	More than 40 illnesses
CW or DU cause	Many possible causes
Brass doesn't care	Force Protection efforts
	Tough choices
	Cultural changes

Why is this important to you?

- Lessons from the Gulf War about dirty battlefields.
- You must protect yourself against hazards.
- You will be working with or leading Gulf War vets.
- You will probably deploy overseas.
- You are responsible for force protection.

Who Served in the Gulf War

697,000 U.S. service members

Army	348,000	50%
Navy	160,000	23%
Marine	105,000	15%
Air Force	84,000	12%

259,000 Coalition Forces

U.S. Deaths

Battle deaths	148
Non-battle deaths	224
Hospitalizations	27,000

Post War

Shortly after re-deployment, many individuals in units reported common symptoms

- Aching joints
- Headaches
- Rashes
- Sleep disorders
- Diarrhea
- Hair loss
- Memory loss
- Fatigue

Physician Message Sent

"Your laboratory, x-ray and physical exams results are normal."

Patient Messages Received

"There's nothing wrong with you!"

"It's all in your head!"

"You're faking these symptoms!"

Confounding Issues

- No clustering (similar symptoms / varied experiences)
- No symptom consistency (similar experiences / varied symptoms)
- Variable onset (from right after return to present)
- No long term study
- As yet - no new disease or links between exposures and symptoms

Looking for Causes

The Dirty Battlefield

- What Iraq may have done to us.
  - Oil Well Fires, Combat hazards, Chem/Bio threat
- What the environment may have done to us.
  - Sand, Insects, Infectious diseases
- What we may have done to ourselves.
  - Pesticides, Pyridostigmine Bromide
- Challenges in future conflicts and humanitarian deployments.

OSAGWI Investigations

- Chemical/biological warfare:
  - Chemical warfare agent - Khamisiyah incident
- Environmental:
  - Depleted uranium (DU), oil well fires, pesticides
- Medical issues :
  - Vaccines, PB, records, policy
- Lessons Learned
  - Identify opportunities to learn
  - Affect doctrine, policy, procedures, and training

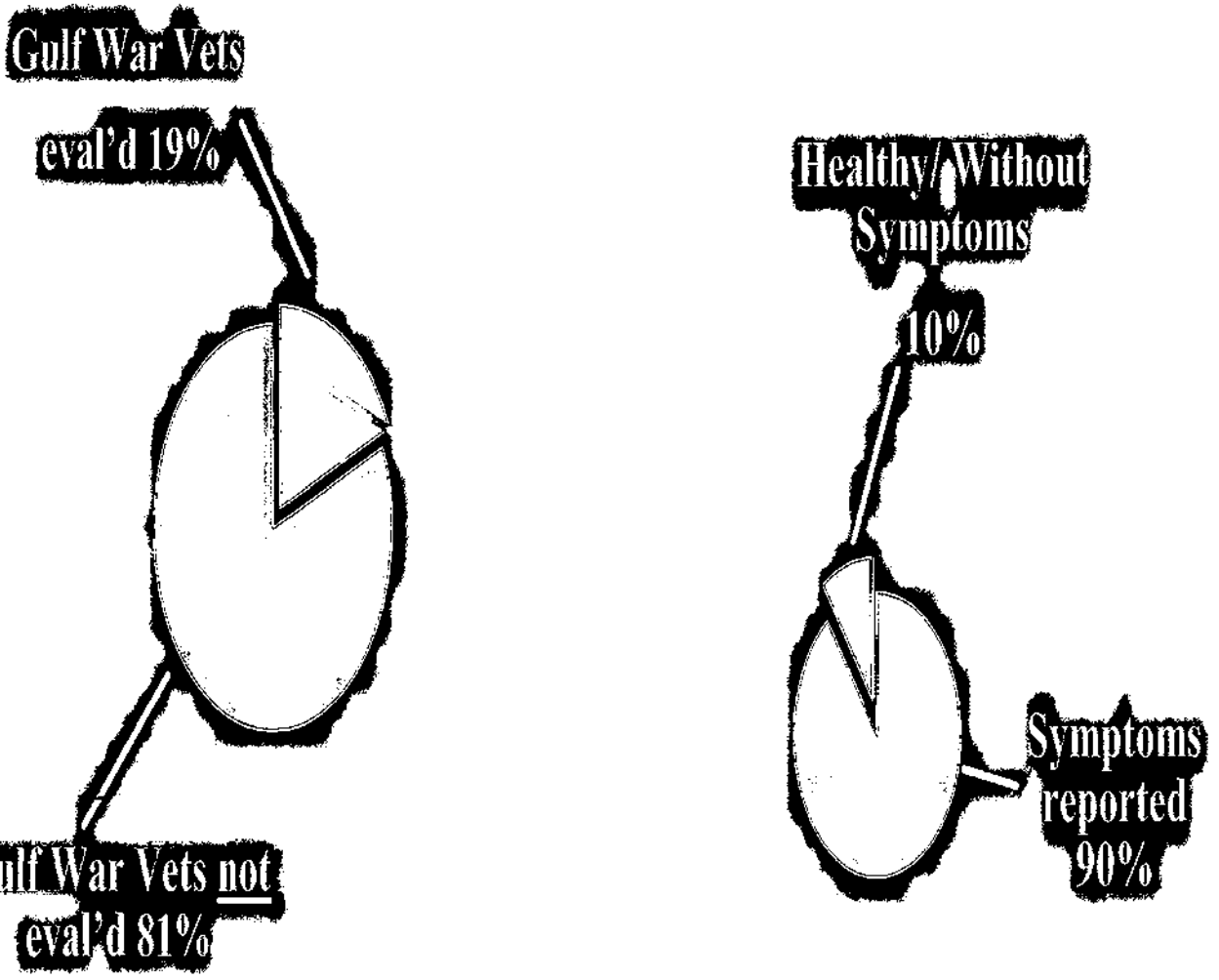
Potential Exposure Hazards

- Chemical war agent
- Pesticides
- Vaccines
- Pyridostigmine bromide
- Stress
- Biological warfare agent
- Oil wells fires
- Depleted uranium
- Infectious disease
- "Cocktail" effect

30+ offered as possible causes

Evaluation Distribution of 697,000

CCEP/VA



Diagnosis Distribution of Evaluated Veterans

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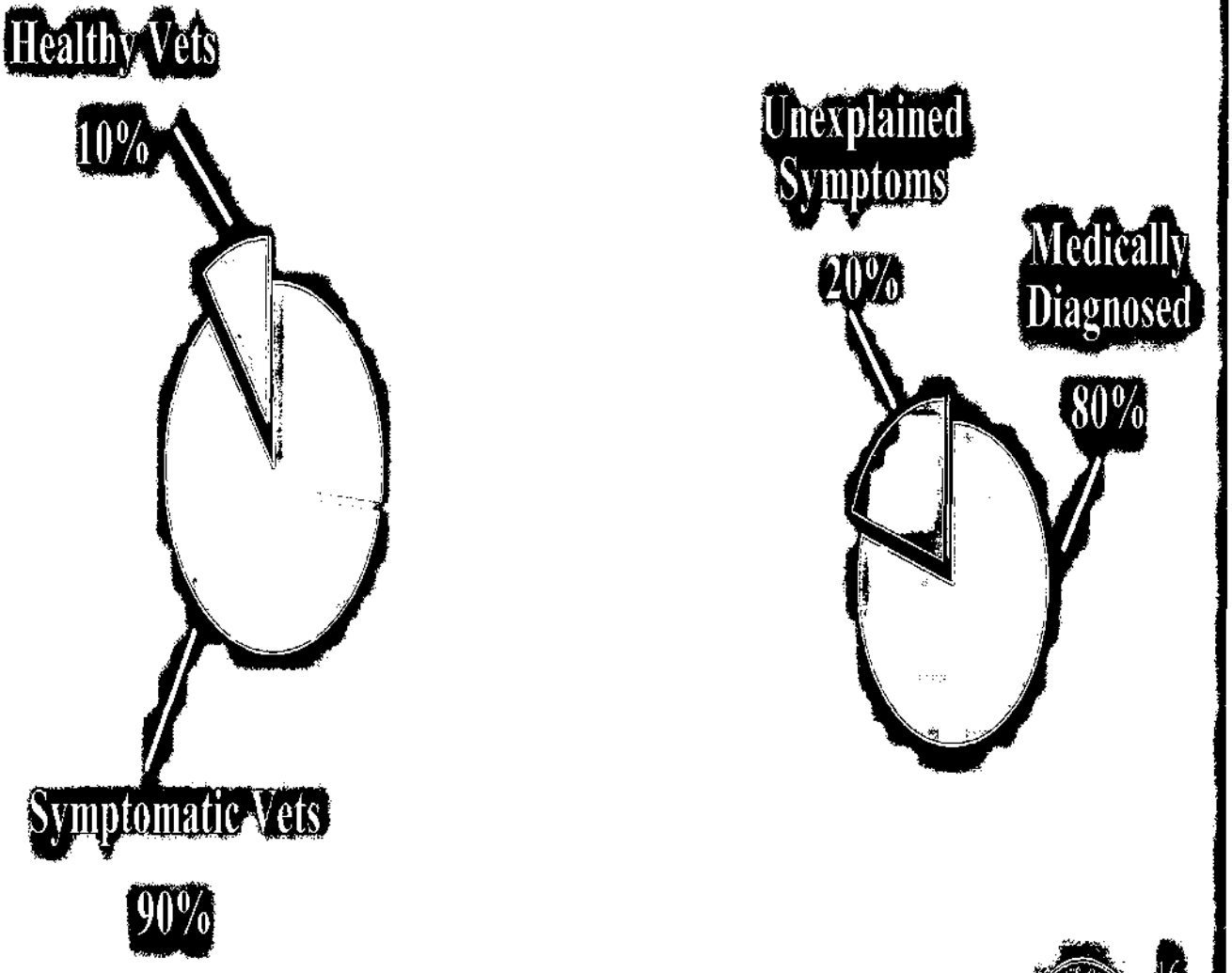

Diagnosis Distribution

129,159 participants	CCEP/VA*
Healthy	10% - 12,916
Symptomatic (Sick)	90% - 116,243
Medically explained and treatable	80% - 92,994
Medically unexplained	20% - 23,249

As of 31 Jul '99

*Comprehensive Clinical Evaluation Program (CCEP) and Dept. of Veteran's Affairs Registry, programs to provide health care to soldiers and veterans.

Proactive Measures - You

- Recognize and contend with potential hazards:
  - Improve intel notification.
  - Train all personnel.
  - Reduce adverse effects of and stress from potential exposures.
  - Understand the environment and culture before deploying.
- Improve feedback and cross talk.

Proactive Measures - Your Unit

- Improve expedient demolition of munitions
- CW/BW detection: earlier with fewer false positives
- Relate CW to operational and medical records
- Adapt for the future
  - Retain individual unit locations and records.
  - DU training
  - Improved medical surveillance
  - Force health protection

Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Collect pre-deployment blood sample
- Verify HIV test is current
- Verify Immunizations up to date
- Verify current physical exam
- Complete Health questionnaire

Deployment

- Routine disease/injury reporting
- Forward medical laboratory
- Immunization tracking
- Environmental monitoring

Post Deployment

- Collect blood sample
- Medical debriefs
- Complete health questionnaire
- Screening exams as needed

Equipment Improvements

- Personal Information Carrier (PIC)
- Biological Integrated Detection System (BIDS)
- Automatic Chemical Agent Alarm (ACADA)
- Medic Cam - Tele medicine

Anthrax Vaccine

- What is Anthrax
  - Bacteria
  - Easily obtained, stored,and weaponized
  - Deadly - (skin exposure vs inhaled exposure)
- Vaccine is safe and necessary
  - FDA Licensed in 1970
  - Used for many years to protect textile mill workers
  - Recommended by Centers for Disease Control (CDC):
    - Workers occupationally exposed to anthrax (labs, mills)
    - Treatment of anyone exposed to anthrax aerosols
    - Only known pretreatment and protection against exposure

Anthrax Vaccine

- DoD Policy - mandatory for total force
  - Phased implementation
- Phase I - SWA and Korea (now)
- Phase II - Early deploying forces to SWA and Korea (now)
- Phase III - Total force (early 2000's)
- Vaccine series:
  - 0, 2, 4 weeks; then 6, 12, 18 months; annual booster
- Reported reactions (11 Aug 99 per DoD/Health Affairs):
  - 1,047,553 doses, 148 adverse reactions=0.014%
- DoD anthrax web site: www.anthrax.osd.mil

Obtaining Help and Information

- Comprehensive Clinical Evaluation Program (CCEP)
  - 1-800-796-9699
- Veterans Affair registry program
  - 1-800-749-8387
- Town Hall
  - Thursday, August 26 at Haszard Auditorium at 1900
- Displays
  - P.X. and Ireland Army Community Hospital
- Contact managers

Bottom Line

- Gulf War Veterans key for our work
- Apply lessons learned
- You must protect yourself on the Dirty Battlefield
- Anyone deployed to South West Asia is eligible for CCEP *(family members included)*
- Don't tough it out - Get signed up and evaluated
- You are your best health advocate

Office of the Special Assistant for Gulf War Illnesses

CONTACT NUMBERS

Department of Defense's - CCEP	800-796-9699
VA Persian Gulf Registry	800-749-8387
Department of Defense's Incident Reporting Line	800-472-6719
OSAGWI Contact Managers	800-497-6261

www.gulflink.osd.mil

Office of the Special Assistant to the Deputy Secretary of Defense

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(800) 754-2132 fax 703-578-8501
email: brostker@gwillness.osd.mil

(1)

Briefing Overview

- Organization - Mission Statement
- Why should I care?
- Symptoms and Illnesses
- Looking for causes
- Gulf War Lessons Learned
- Force Health Protection
- Obtaining help and information

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Post War

Shortly after re-deployment, many individuals in units reported common symptoms

Joint pain	49%	Fatigue	47%
Headaches	39%	Memory loss	34%
Sleep disorders	32%	Rash	31%
Depression	23%	Muscle pain	21%

Physician Message Sent

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Confounding Issues

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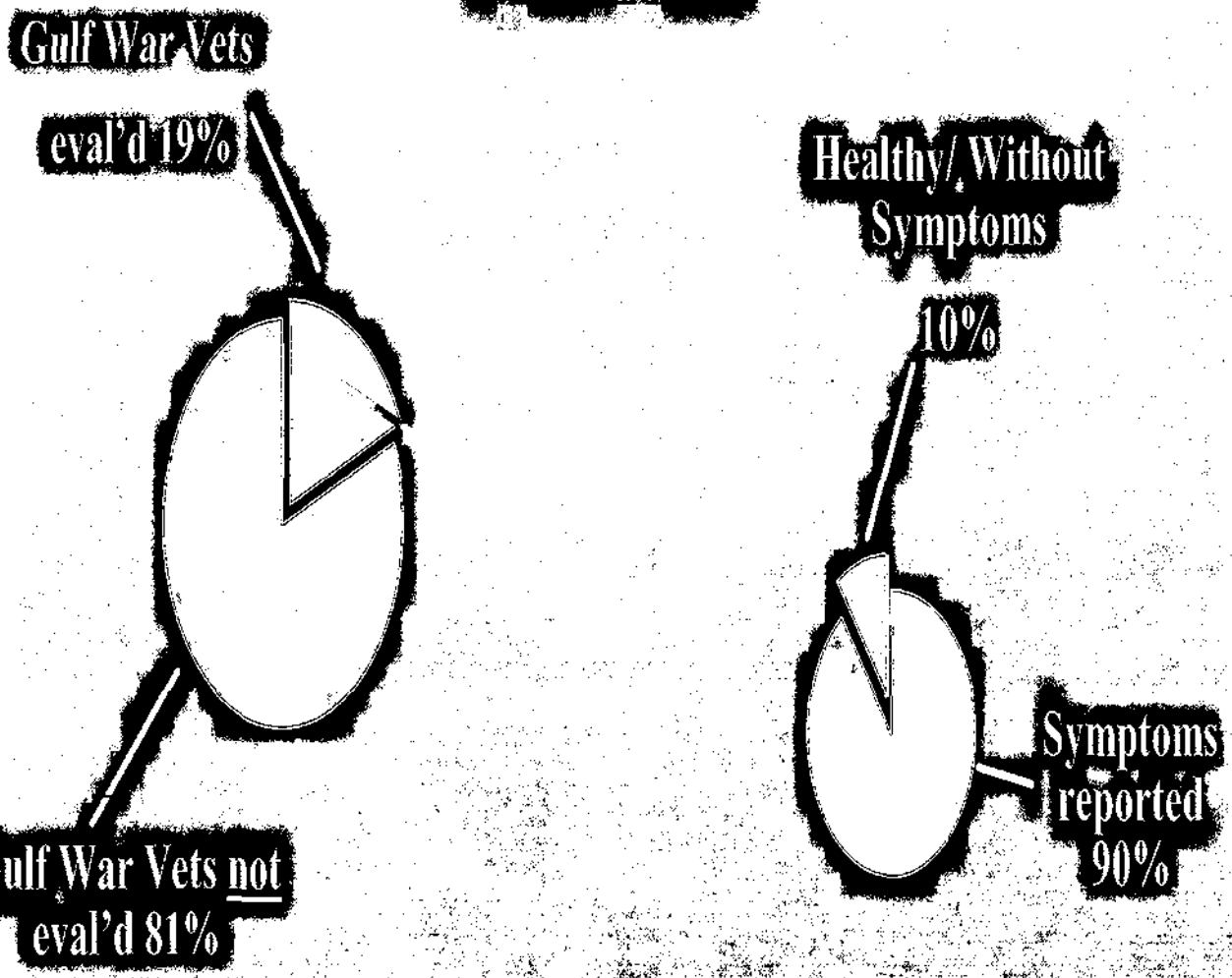

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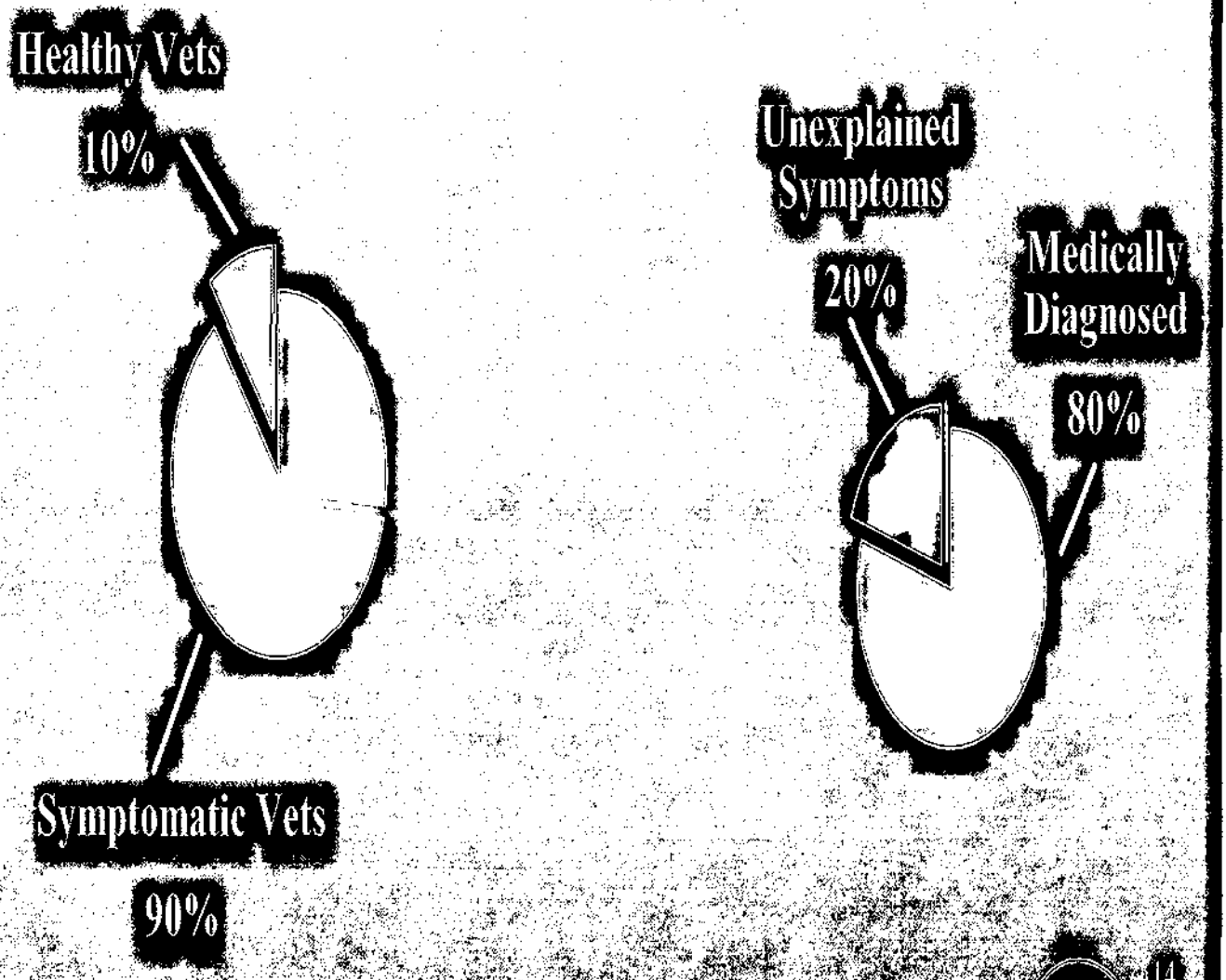

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  - Retain individual unit locations and records
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  - Improved medical surveillance
  - Force health protection

Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Collect pre-deployment blood sample
- Verify HIV test is current
- Verify Immunizations up to date
- Verify current physical exam
- Complete Health questionnaire

Deployment

- Routine disease/injury reporting
- Forward medical laboratory
- Immunization tracking
- Environmental monitoring

Post Deployment

- Collect blood sample
- Medical debriefs
- Complete health questionnaire
- Screening exams as needed

Future Equipment

- Personal Information Carrier (PIC)
- Biological Integrated Detection System (BIDS)
- Automatic Chemical Agent Alarm (ACADA)
- Medic Cam - Tele medicine

Anthrax Vaccine

- What is Anthrax?
  - Bacteria
  - Easily obtained, stored and weaponized
  - Deadly - (skin vs inhaled exposure)
- Vaccine is safe and necessary!
  - FDA Licensed in 1970
  - Used for many years to protect textile mill workers
  - Recommended by Centers for Disease Control (CDC):
    - Workers occupationally exposed to anthrax (labs, mills)
    - Treatment of anyone exposed to anthrax aerosols
    - Only known pretreatment and protection against exposure

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- DoD Policy - mandatory for total force
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Obtaining help and information

- Comprehensive Clinical Evaluation Program (CCEP)
  - 1-800-796-9699
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Bottom Line

- Gulf War Veterans key for our work
- You must protect yourself on the Dirty Battlefield
- Anyone deployed to South West Asia is eligible for CCEP *(family members included)*
- Don't tough it out - Get signed up and evaluated
- You are your best health advocate
- Apply these lessons learned

Office of the Special Assistant for Gulf War Illnesses

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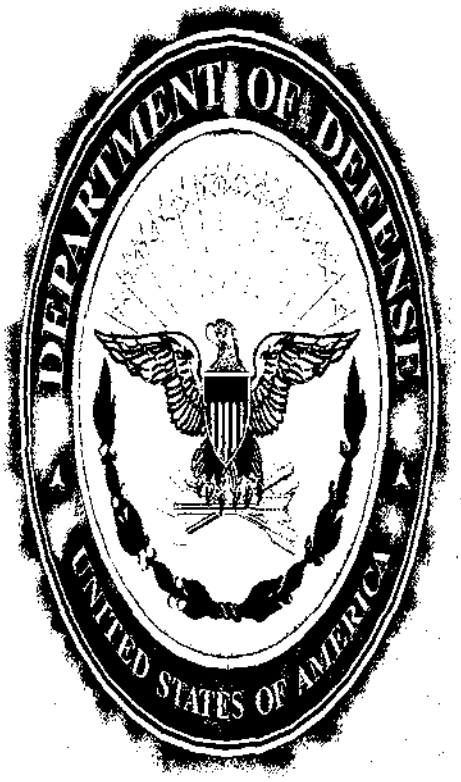

for Gulf War Illnesses

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email: brostker@gwillness.osd.mil

Pentagon Mobilizes: Special Assistant for Gulf War Illnesses

Dr. Bernard Rostker

- Appointed November 12, 1996 by the Deputy Secretary of Defense
- 180 team members

Mission of the Special Assistant

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DOD adopts doctrine, policy and procedures to reduce risks for troops in the future.

Why Should I Care?

- Lessons from the Gulf War about dirty battlefields.
- You must protect yourself against hazards.
- You will be working with or leading Gulf War vets.
- You will probably deploy overseas.
- You are responsible for force protection.

Myths versus Reality

Cover up	Open process & oversight
Not listening	Solicit eyewitness reports
Destroy records	Found missing records
20,000 veterans dead	5,773 veterans dead
No assistance to vets	Evaluation and care
"Syndrome"	More than 40 illnesses
CW or DU cause	Many possible causes
Brass doesn't care	Force Protection efforts
	Tough choices
	Cultural changes

U.S. Deaths

Battle deaths	148
Non-battle deaths	224
Hospitalizations	27,000

Post War

Shortly after re-deployment, many individuals in a few units reported common symptoms

- Aching joints
- Headaches
- Rashes
- Sleep disorders
- Diarrhea
- Hair loss
- Memory loss
- Fatigue

Physician Message Sent

"Your laboratory, x-ray and physical exams results are normal."

Patient Messages Received

"There's nothing wrong with you!"

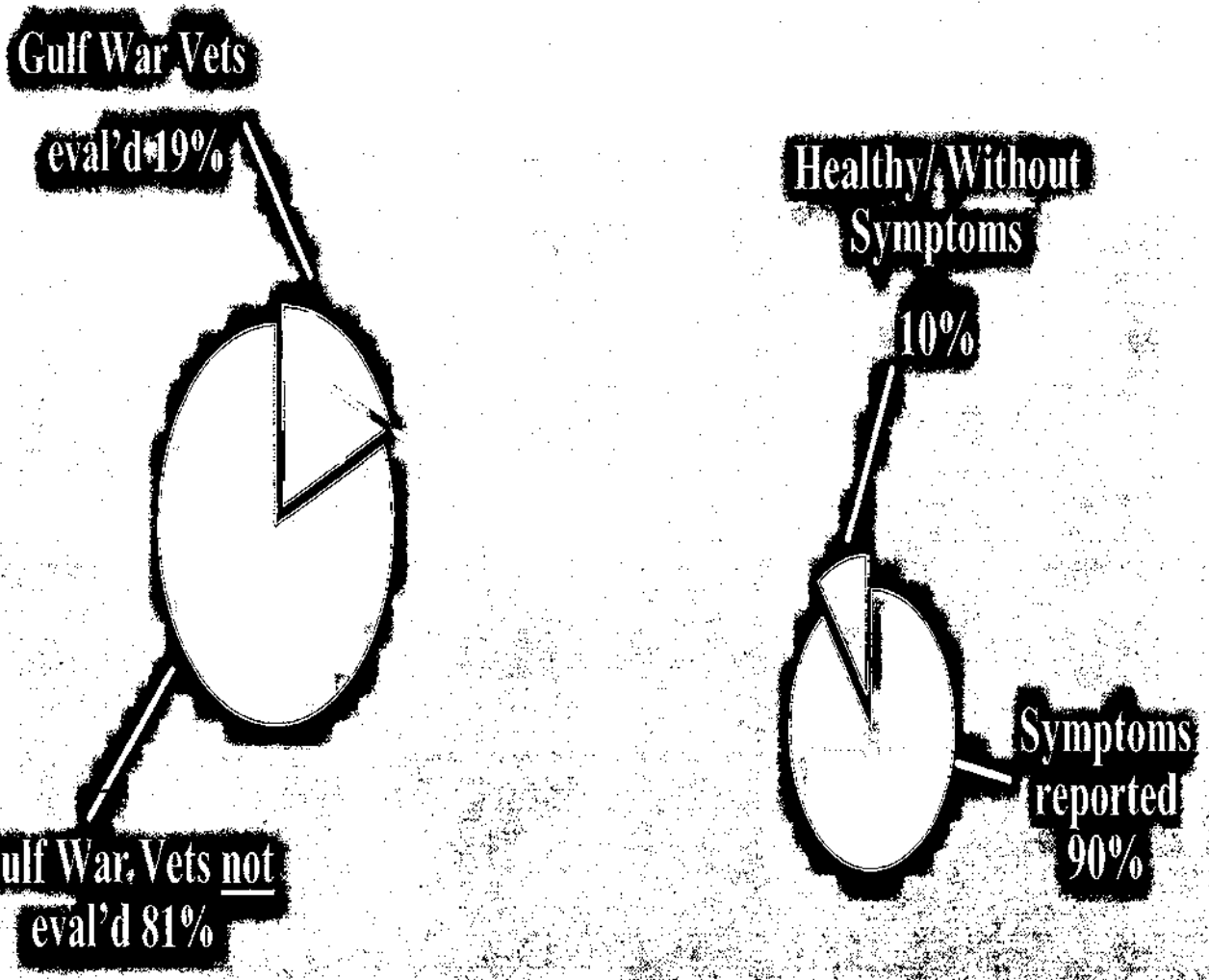
"It's all in your head!"

"You're faking these symptoms!"

Confounding Issues

- No clustering
- No symptom consistency
- Variable onset
- No longitudinal evaluation
- As yet - no new disease or links between exposures and symptoms

Evaluation Distribution of 697,000 CCEP/VA



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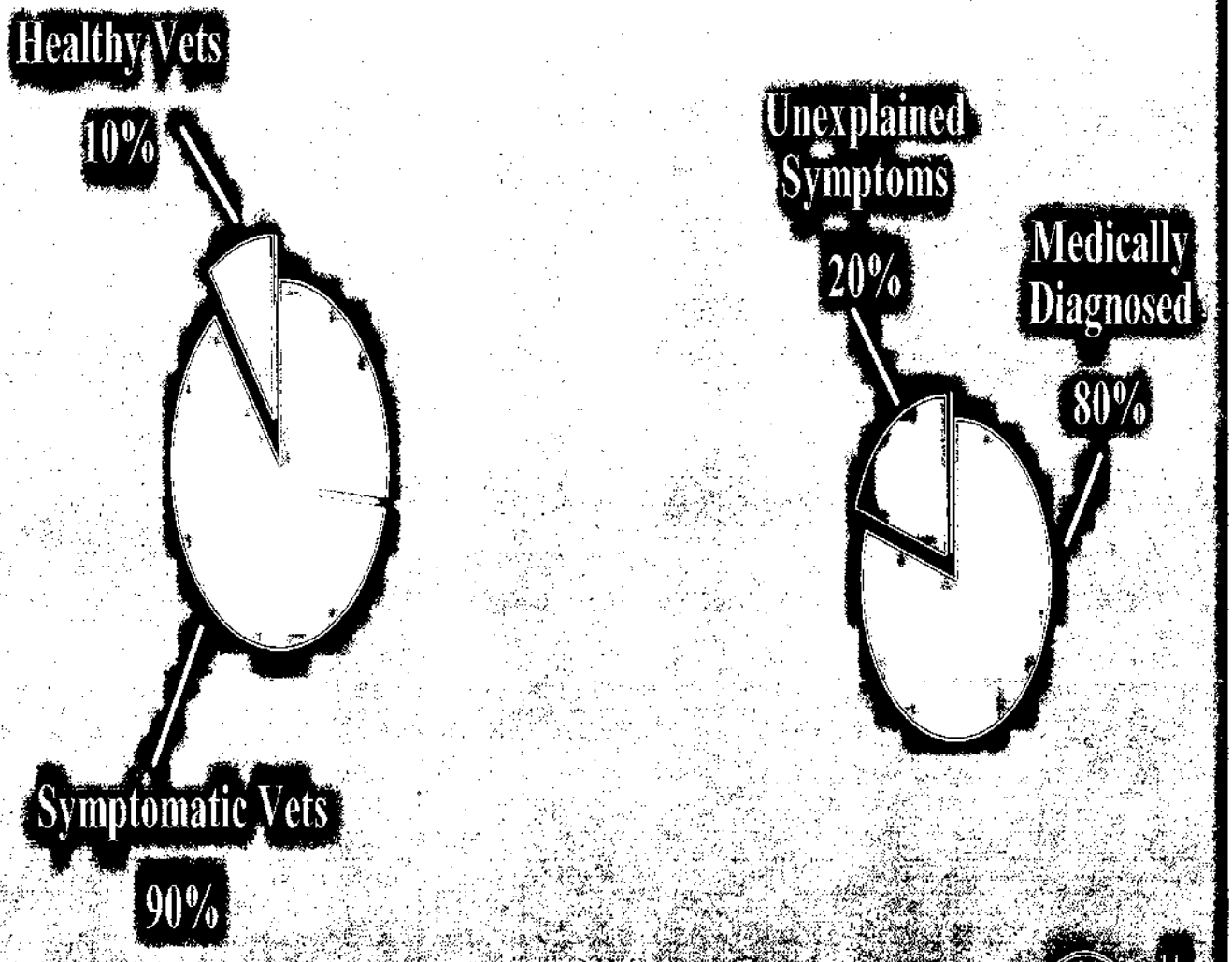

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129,159 participants	CCEP/VA*
Healthy	10% - 12,916
Symptomatic (Sick)	90% - 116,243
Medically explained and treatable	80% - 92,994
Medically unexplained	20% - 23,249

As of 31 Jul '99

*Comprehensive Clinical Evaluation Program (CCEP) and Dept. of Veteran's Affairs Registry, programs to provide health care to soldiers and veterans.

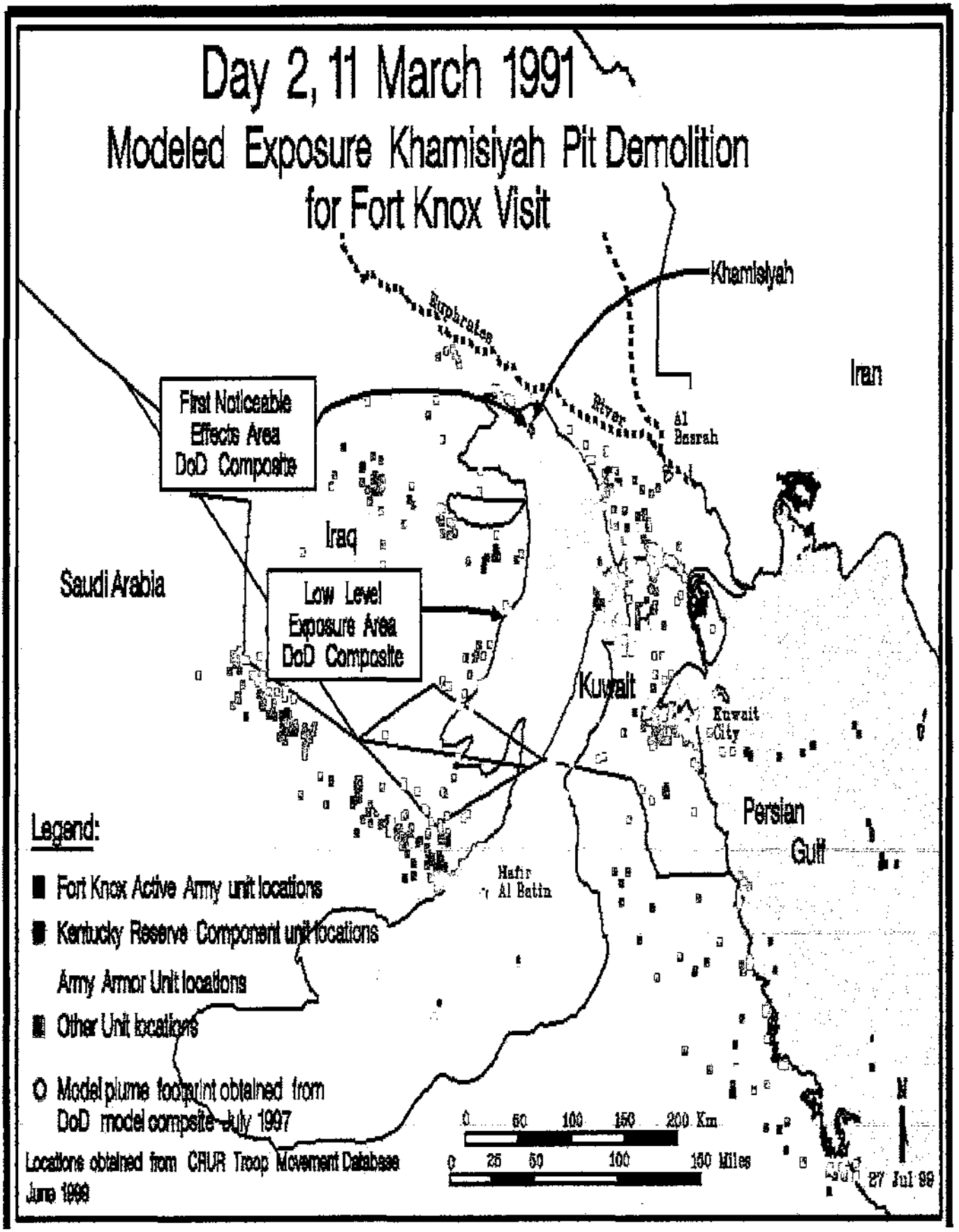
Looking for Causes

The Dirty Battlefield

- What Iraq may have done to us.
  - Oil Well Fires, Stress
- What the environment may have done to us.
  - Sand, Infectious diseases, bad food and water
- What we may have done to ourselves.
  - Pesticides, Pyridostigmine Bromide, Low levels of CW agent, DU
- Challenges in the future range from low-tech pariah states to the revolution in military affairs.

OSAGWI Investigations

- Chemical/biological warfare:
  - Focus in 1997; 16 papers
  - Watershed is Khamisiyah
- Environmental:
  - Focus in 1998
  - Oil well fires, pesticides, depleted uranium (DU)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Euphrates
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Iran
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0 25 50 100 150 Miles
N
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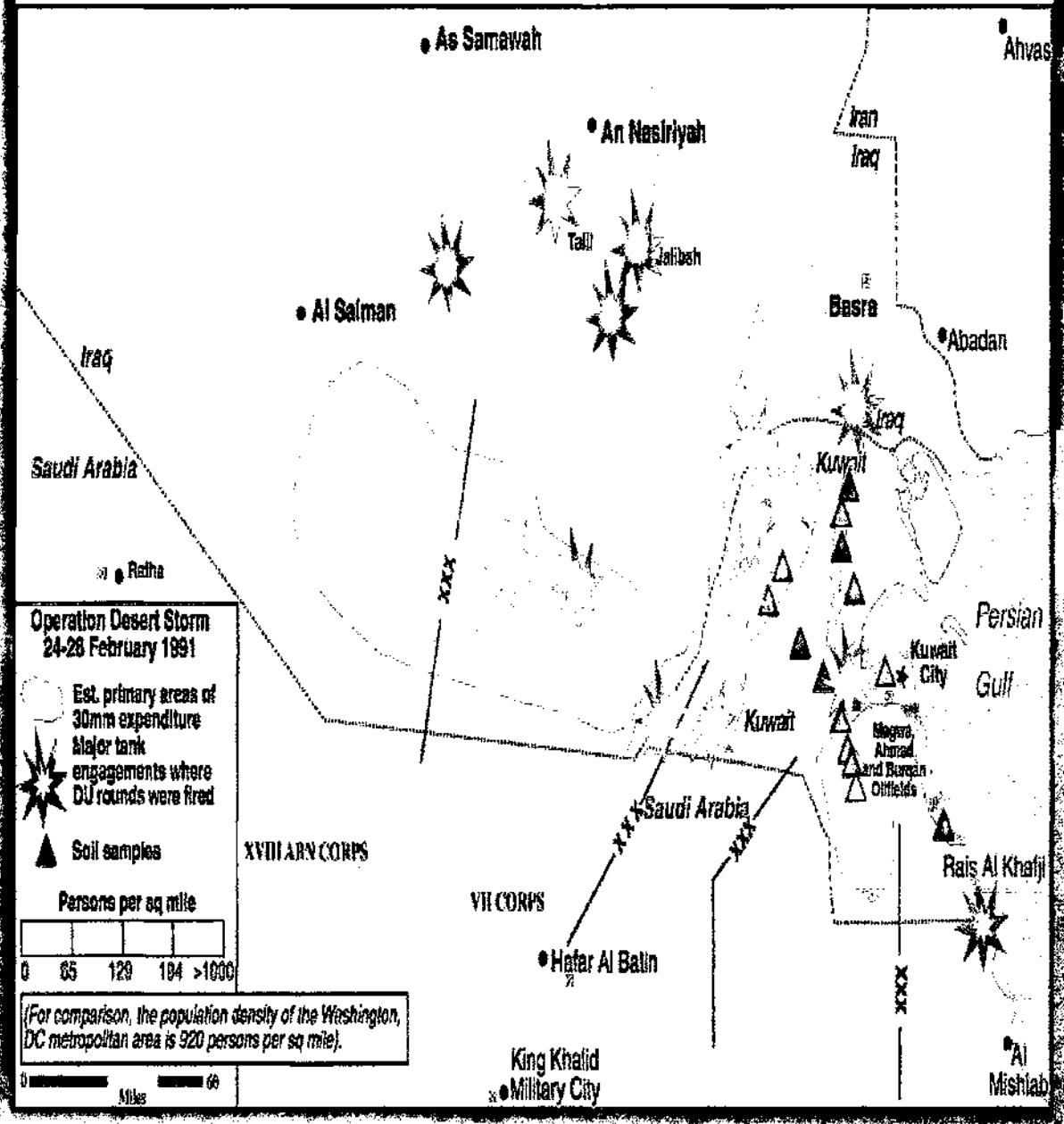
Primary Areas of DU Expenditure



Investigator's Message Sent

"The symptoms described were not consistent with symptoms associated with exposure to chemical warfare agents or depleted uranium."

Veteran's Messages Received

"You're wrong!"

"You can't possibly be sick because of this!"

DU Exposure Issues

- Radiation
- Heavy metal toxicity
- Consequences of exposure
- Reproductive effect
- Contamination of theater

DU Awareness Training

- Current CTT Task (031-503-1017)
- Better information is now available
  - Chemical toxicity vice radioactivity
  - Continue the mission
  - Respiratory protection for extended exposure
- Training support packages being updated
  - Includes updating the common task & GTA
  - Additional training for specialists
- Use existing training management system

OSAGWI Investigations

- Medical issues and lessons learned:
  - Focus in 1999
    - Vaccines, PB, records, policy
    - DU training
    - Managing hazards

Proactive Measures - You

- Recognize and contend with potential hazards:
  - Improve intel notification
  - Train all personnel
  - Reduce adverse effects of and stress from potential exposures
  - Understand the environment and culture before deploying
- Improve feedback and cross talk

Operational Lessons - Your Unit

- Improve expedient demolition of munitions
- CW/BW detection: earlier with fewer false positives
- Relate CW to operational and medical records
- Adapt for the future
  - Retain individual unit locations and records
  - DU training
  - Improved medical surveillance
  - Force health protection

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Back-up Slides

Identifying Possible Causes

- Normal disease rate
- Linking hazards and illnesses
  - –Research
  - –New disease paradigm

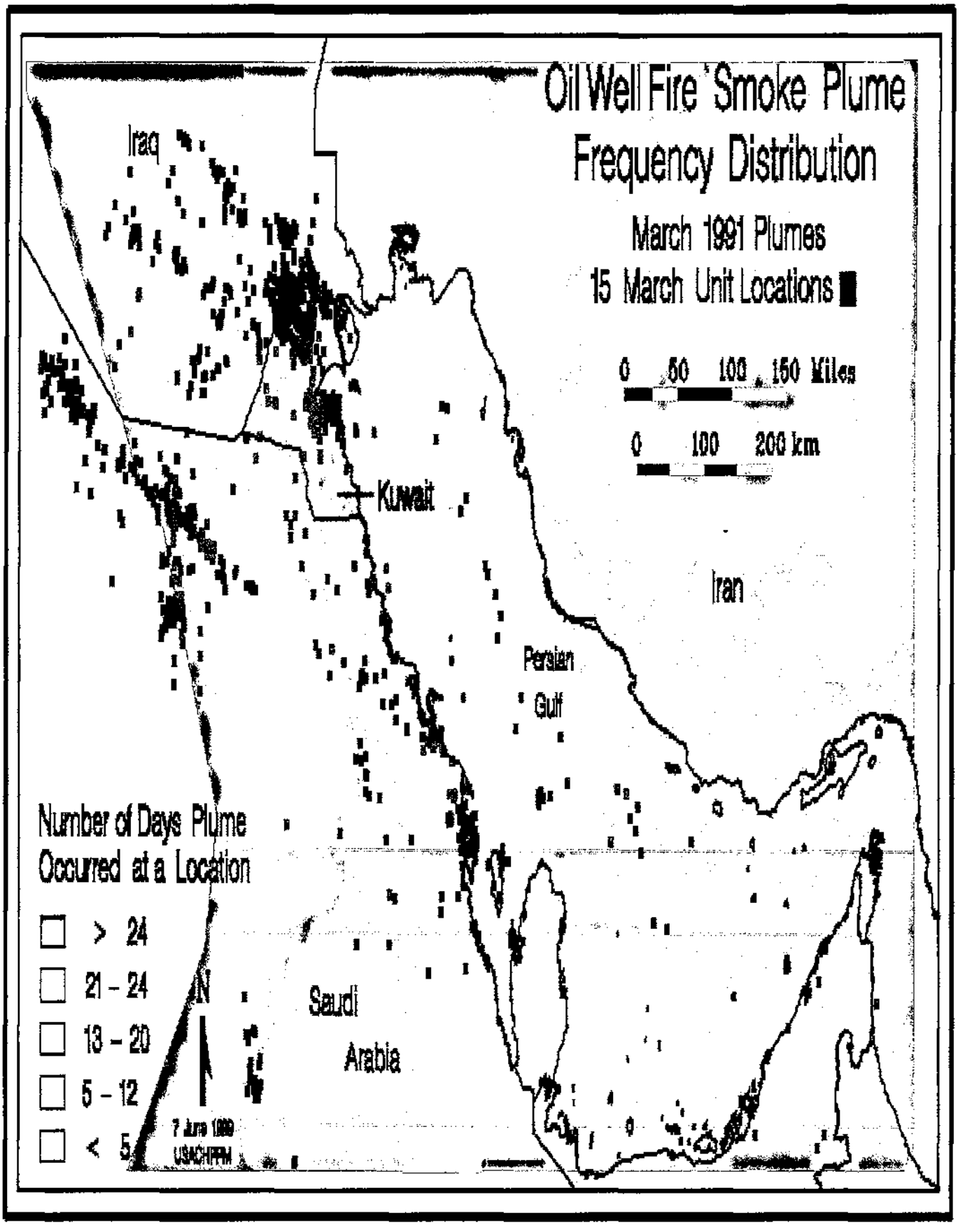
Symptoms

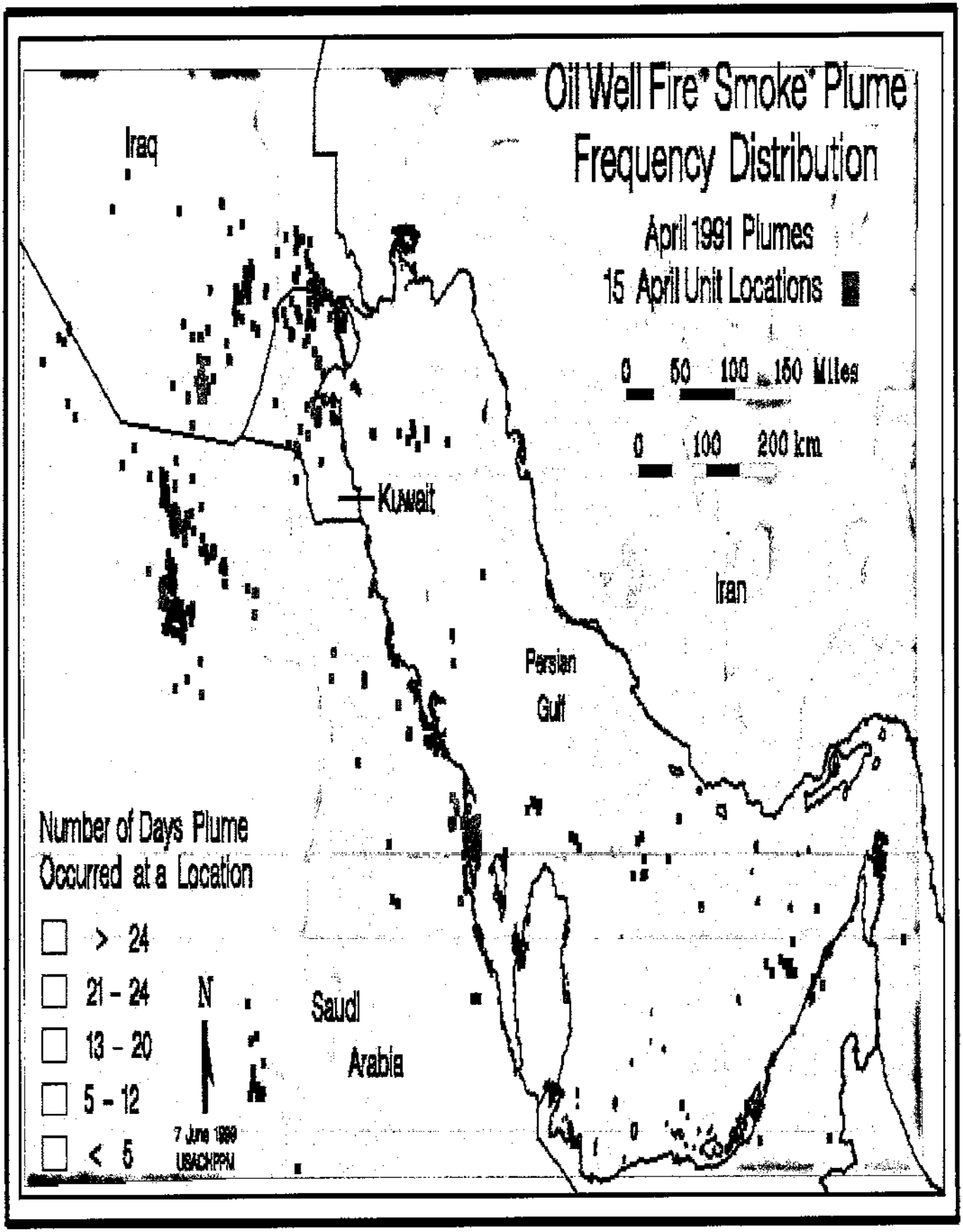
- Tiredness
- Rashes
- Headaches
- Muscle aches
- Joint pains
- Abdominal pain
- Diarrhea
- Hair loss
- Memory loss
- Sleep disturbance
- Depression
- Concentration problems

Hazards

- Chemical warfare agent
- Pesticides
- Vaccines
- Pyridostigmine bromide
- Stress
- Biological warfare agent
- Oil well fires
- Depleted uranium
- Infectious disease
- "Cocktail" effect

30+ offered as possible causes


Oil Well Fire Smoke Plume
Frequency Distribution
March 1991 Plumes
15 March Unit Locations
0 50 100 150 Miles
0 100 200 km
Iraq
Kuwait
Iran
Persian
Gulf
Saudi
Arabia
Number of Days Plume
Occurred at a Location
> 24
21 - 24
13 - 20
5 - 12
< 5
N
7 June 1999
USACHPPM


Oil Well Fire* Smoke* Plume
Frequency Distribution
April 1991 Plumes
15 April Unit Locations
0 50 100 150 Miles
0 100 200 km
Iraq
Kuwait
Iran
Persian
Gulf
Saudi
Arabia
Number of Days Plume
Occurred at a Location
> 24
21 - 24
13 - 20
5 - 12
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N
7 June 1999
USAFCKPPN

Medical Training for Line Leaders

- Wellness Requirements = Mission Success
  - Routine examinations, vaccinations
  - Force Health Protection
  - Anthrax Vaccination
- Normal Disease Rates - Garrison or Deployment
  - Diarrhea
  - Sports injuries
  - Cancer, heart attacks, diabetes, etc.

Operational Lessons - You

- Recognize and contend with potential hazards:
  - Improve intel notification.
  - Train all personnel.
  - Reduce adverse effects of and stress from potential exposures.
  - Understand the environment and culture before deploying.
- Improve feedback and cross talk.

Who Served in the Gulf War

697,000 U.S. service members

Army	348,000	50%
Navy	160,000	23%
Marine	105,000	15%
Air Force	84,000	12%

259,000 Coalition Forces

Who Served in the Gulf War

Gender	
Men	93%
Women	7%
Component	
Active	83%
Reserve/National Guard	17%
Community	
Officer	10%
Enlisted	90%

<26 years old - 55%; 26-35 years old - 32%; > 35years old - 13%

Medical Support

Largest emergency health care system since WWII

- 41,000 medical personnel
- 18,000 beds
- 2 hospital ships
- 63 combat zone hospitals

Possible Causes

- Normal disease rate
- New disease paradigm
- Research
- Black camel

Future Equipment

- Personal Information Carrier (PIC)
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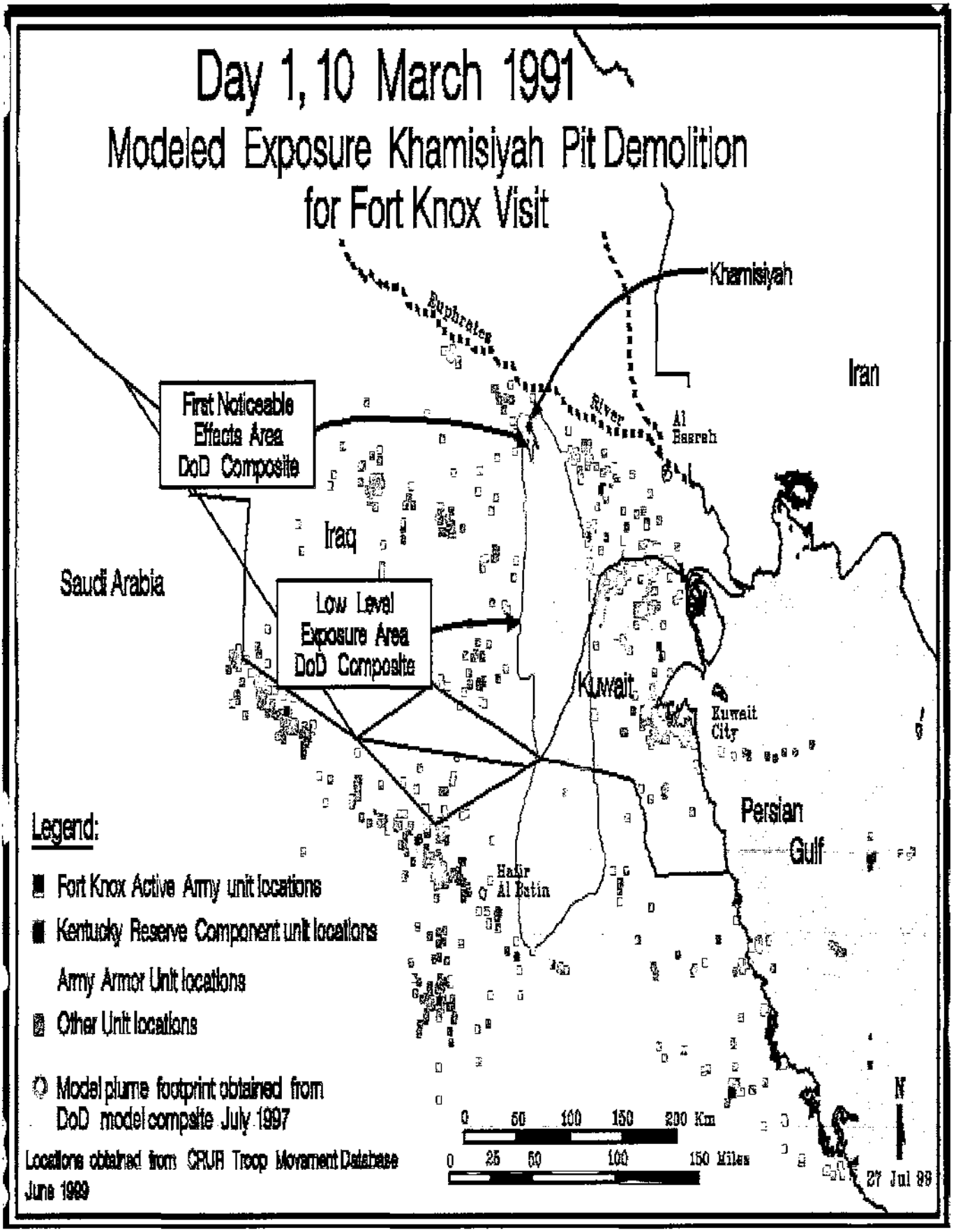
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for Fort Knox Visit
Khamisiyah
Euphrates
River
Iran
Al
Basrah
First Noticeable
Effects Area
DoD Composite
Iraq
Saudi Arabia
Low Level
Exposure Area
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Kuwait
Kuwait
City
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Gulf
Hafr
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Legend:
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Model plume footprint obtained from
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0 50 100 150 200 Km
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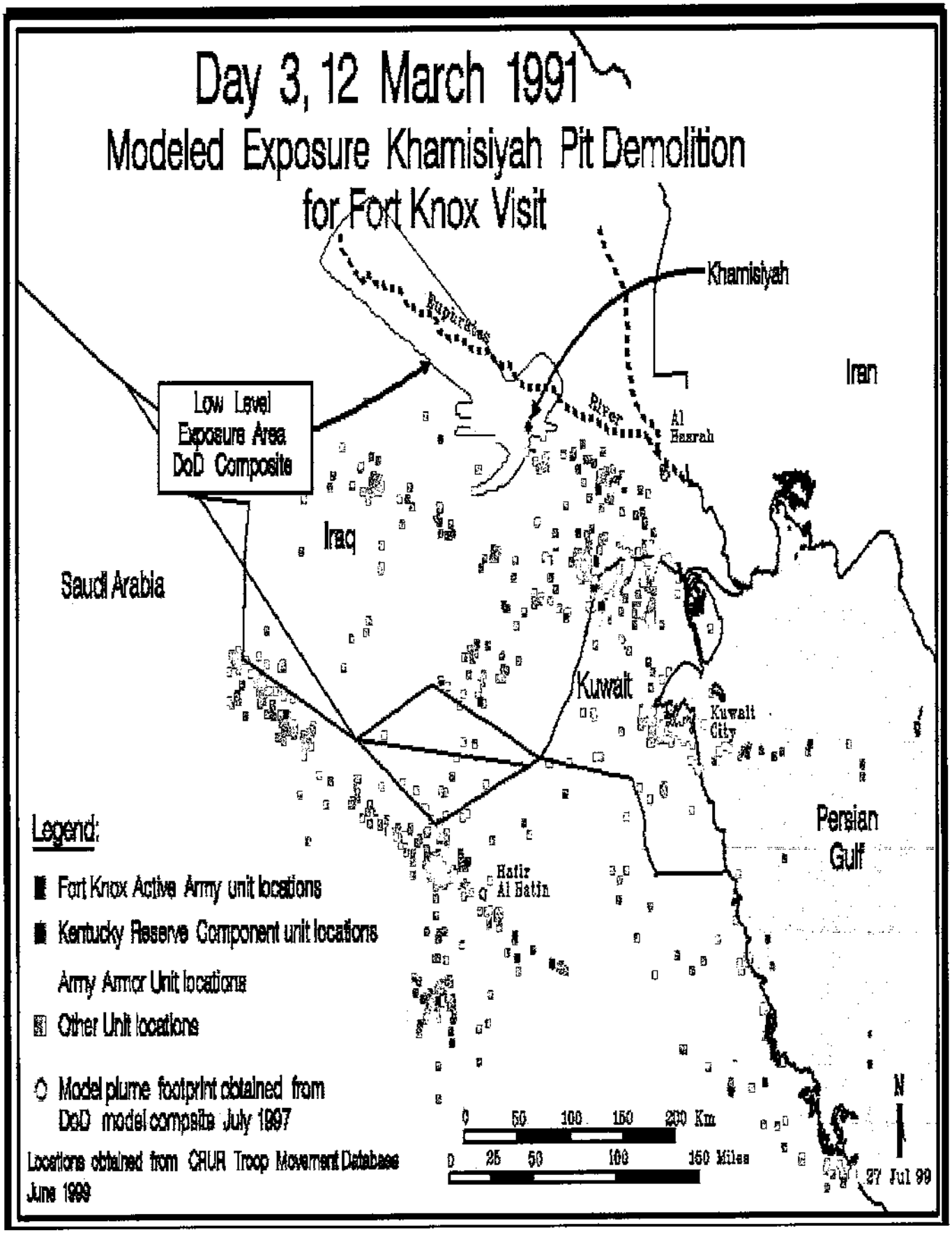
N
27 Jul 99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Modeled Exposure Khamisiyah Pit Demolition
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Euphrates
River
Iran
Low Level
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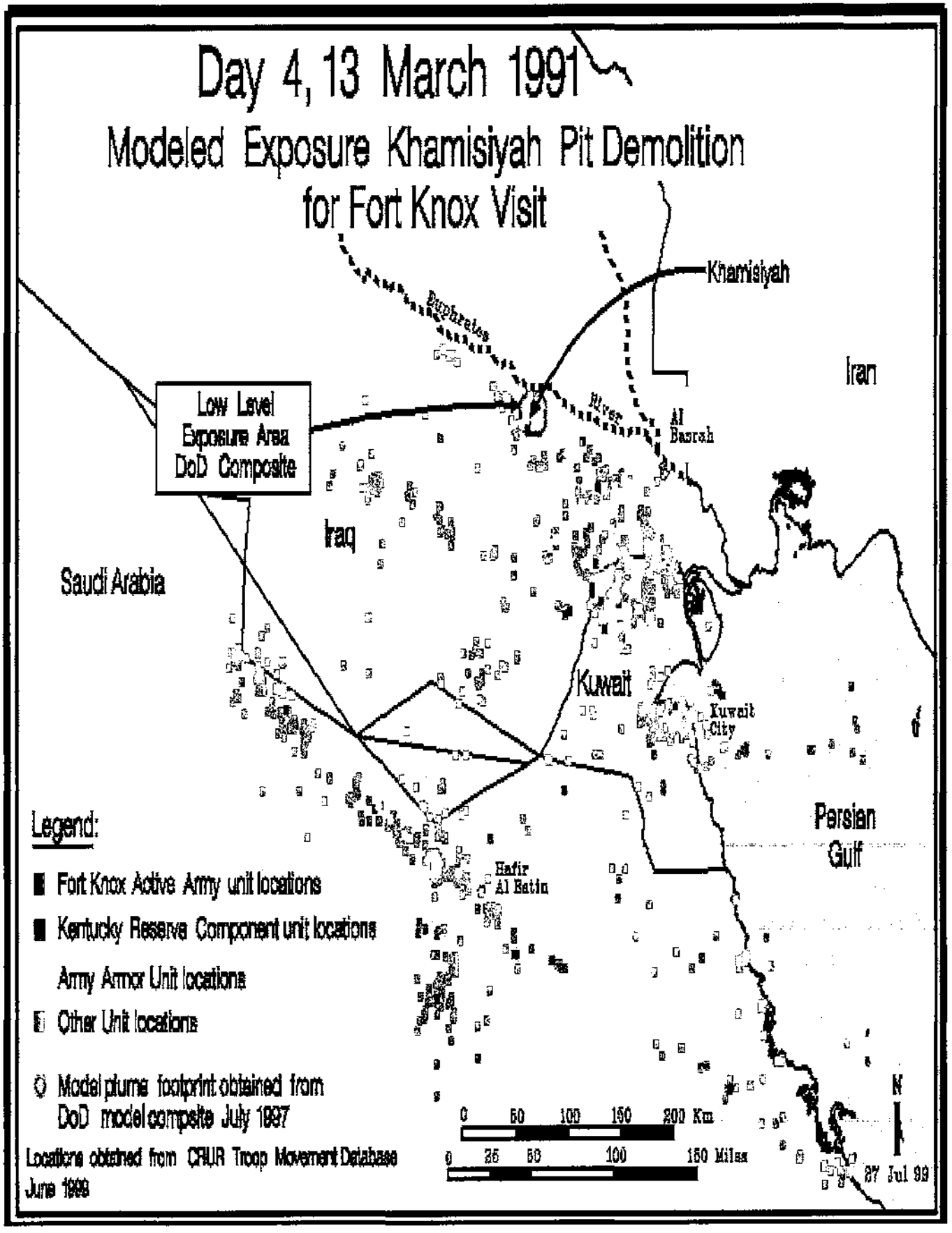
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Summary

- Work continues: "leave no stone unturned"
- We rely on Gulf War veterans:
  - To give us leads
  - To check our accuracy
- We rely on today's force – including you:
  - To ensure GW vets get proper testing and treatment
  - To apply lessons learned to the future

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Mission of the Special Assistant

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DOD adopts doctrine, policy and procedures to reduce risks for troops in the future.

Post War

Shortly after re-deployment, many individuals in a few units reported common symptoms

- Aching joints
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- Rashes
- Sleep disorders
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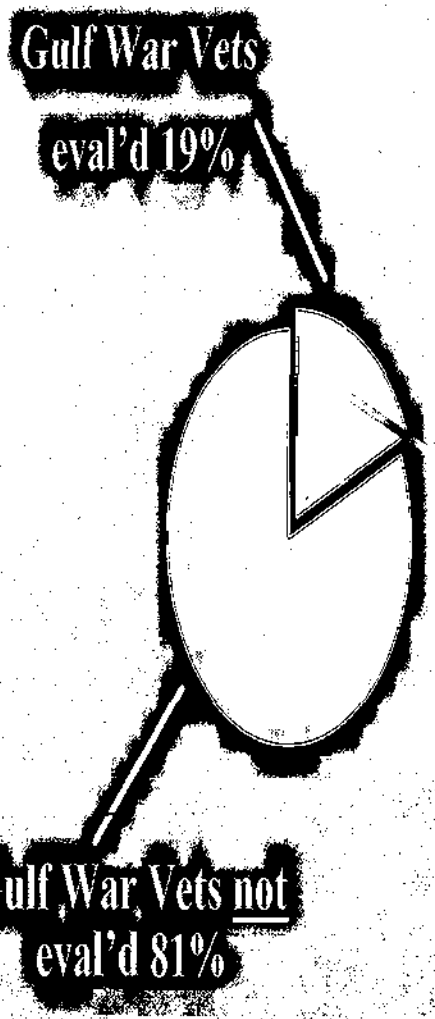

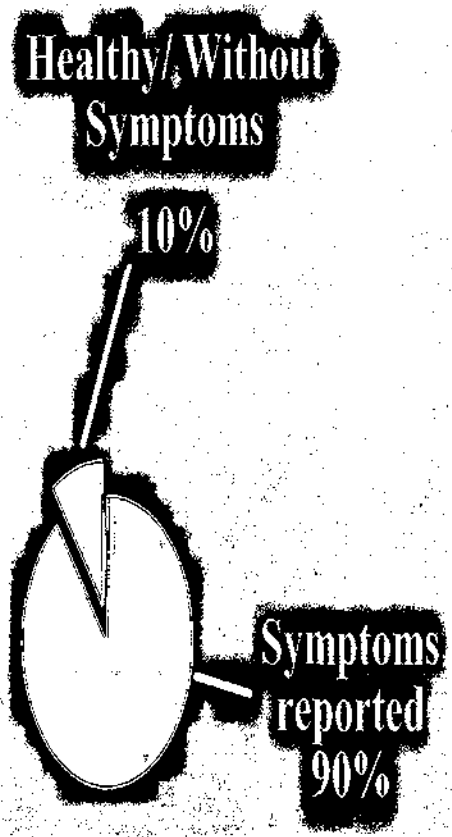

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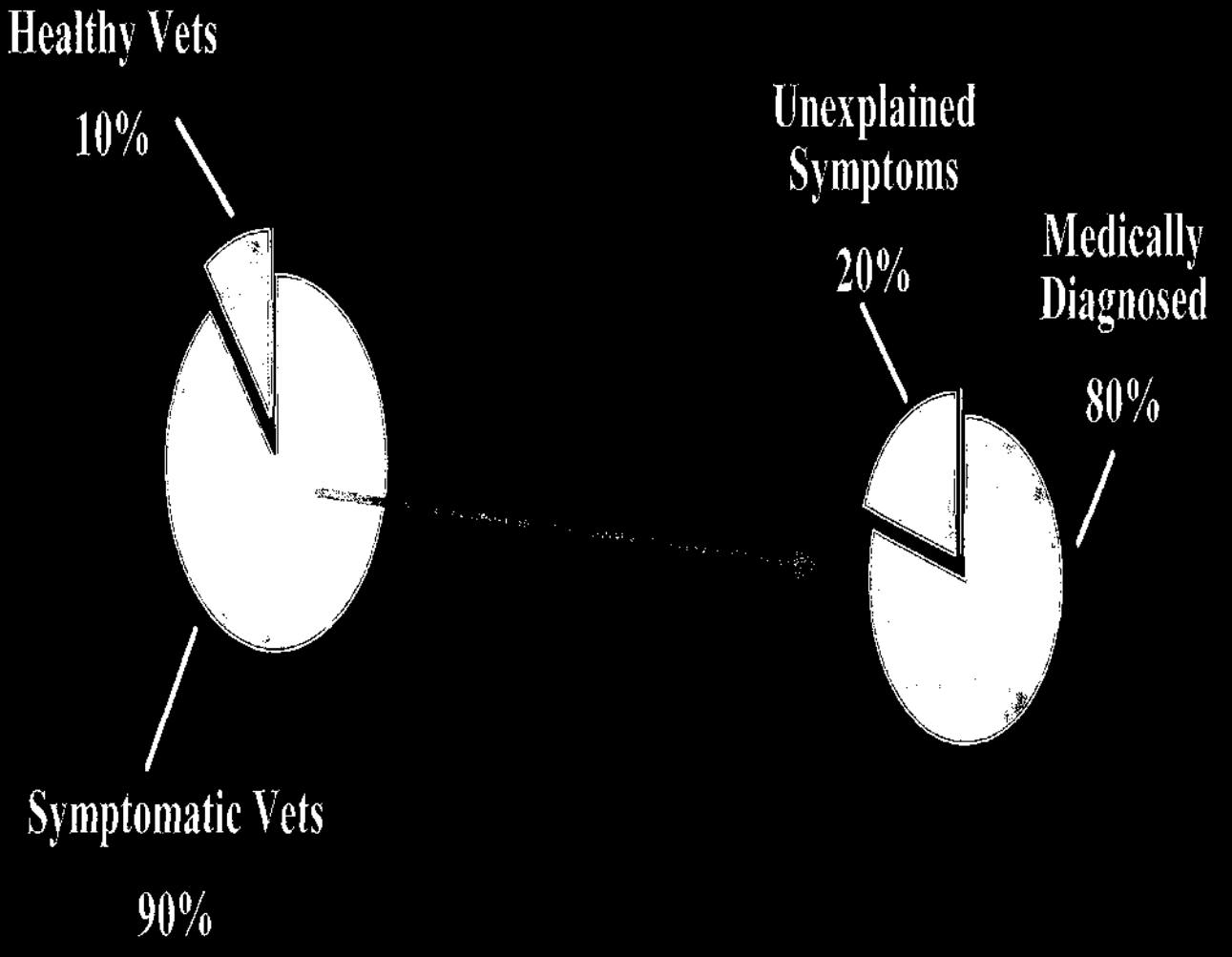

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  - To ensure GW vets get proper testing and treatment
  - To dispel myths and demand facts

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(161)

Briefing Overview

- Mission Statement
- The Gulf War
- Post Gulf War Issues
- Searching for answers
- Lessons Learned
- Force Health Protection
- Bottom Line
- Obtaining help and information

Our Mission

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain illnesses in Gulf War veterans
- Ensure DOD adopts doctrine, policy and procedures to reduce health risks for troops deploying now and in the future

Why Should I Care?

- Lessons from the Gulf War about dirty battlefields.
- You must protect yourself against hazards.
- You will be leading Gulf War vets.
- You are responsible for force protection.
  - What are dangers of dirty battlefield?
  - How good are our detectors and MOPP gear?
  - Will our counter-fire put us at risk?
  - What are likely patterns of dispersion?
  - How do we determine if we are exposed?
  - What if my fighting vehicle is hit with DU?

Gulf War Theater

- August 1990 to July 1991
- 697,000 US service members
- More then 27,000 hospitalizations
- 148 battle deaths
- 224 non-battle deaths

1 in 7 veterans reported symptoms since re-deployment

Most frequently reported symptoms

- Joint pain
- Headaches
- Sleep disorders
- Depression
- Fatigue
- Memory loss
- Rash
- Muscle pain

and many others

Confounding Issues for Doctors

- No clustering
- No symptom consistency; variable onset
- No new disease or links between exposures and symptoms
- No long term study

Doctor - Patient - Government Communication Breakdown

- Veterans with real health problems
- Healthcare professionals unable to provide answers
- Government slow to recognize the reality of problems

Taking Care of Service Members

- DoD Comprehensive Clinical Evaluation Program
  - Gulf War vets (active, Guard/Reserve, retired)
  - Active service member deployed to SWA since war ended
  - Family members
- VA Persian Gulf Registry
  - Gulf War vets (left service prior to retirement)
  - Service members deployed to SWA and left service before retirement
  - Evaluation for family members
- Available to *all* service members deploying to South West Asia
  - Most people evaluated can be treated

Don't Tough It Out!

Investigations

- Chemical/biological warfare:
  - Chemical warfare agent - Khamisiyah incident
    - 99,000 vets notified
- Environmental:
  - Depleted uranium (DU), Oil well fires, Pesticides
    - Science doesn't support DU or Oil Well fires as causes.
    - Still examining particulates and pesticides
- Medical issues:
  - Vaccines, PB, records, policy
- Scientific research
  - 145 studies sponsored by DoD, DVA & HHS
  - Multiple exposures

A New Reality – The Dirty Battlefield

- What enemy may do to us
  - Chemical/Bio threat, Man made environmental hazards (Oil Well Fires)
- What the environment may do to us
  - Infectious diseases, insects, environmental risks (desert, jungle)
- What we may do to ourselves
  - Pesticides, Stressors, Investigational New Drugs, PB

Current and future conflicts and humanitarian deployments have and will have these challenges

Investigation Results

- Gulf War
  - Poor intelligence about Iraq's CW/BW weapons
  - Not enough vaccines and no explanation given
  - Limited environmental survey
  - Information about nerve agent pre-treatment (PB) wasn't given to troops
  - Inadequate training about DU or on limitations of FOX vehicle, M8A1 alarm and M256 kit
    - Training could have averted unnecessary exposure to DU and anxiety resulting from false alarms
  - Veterans re-deployed and left service without thorough medical exam or debrief

Applying Lessons Learned

You

- Train self and others to recognize and avoid hazards
- Improve feedback and cross talk
- You are your own best health advocate

Your Unit

- Monitor service member's health & environment
- Maintain adequate field expedient demolition SOP
- CW/BW detection: earlier with fewer false positives
- Create, relate and save operational, NBC, and medical records
- Adapt to reduce risks and train to reduce future risks such as DU

Force Health Protection-
A Joint Concept

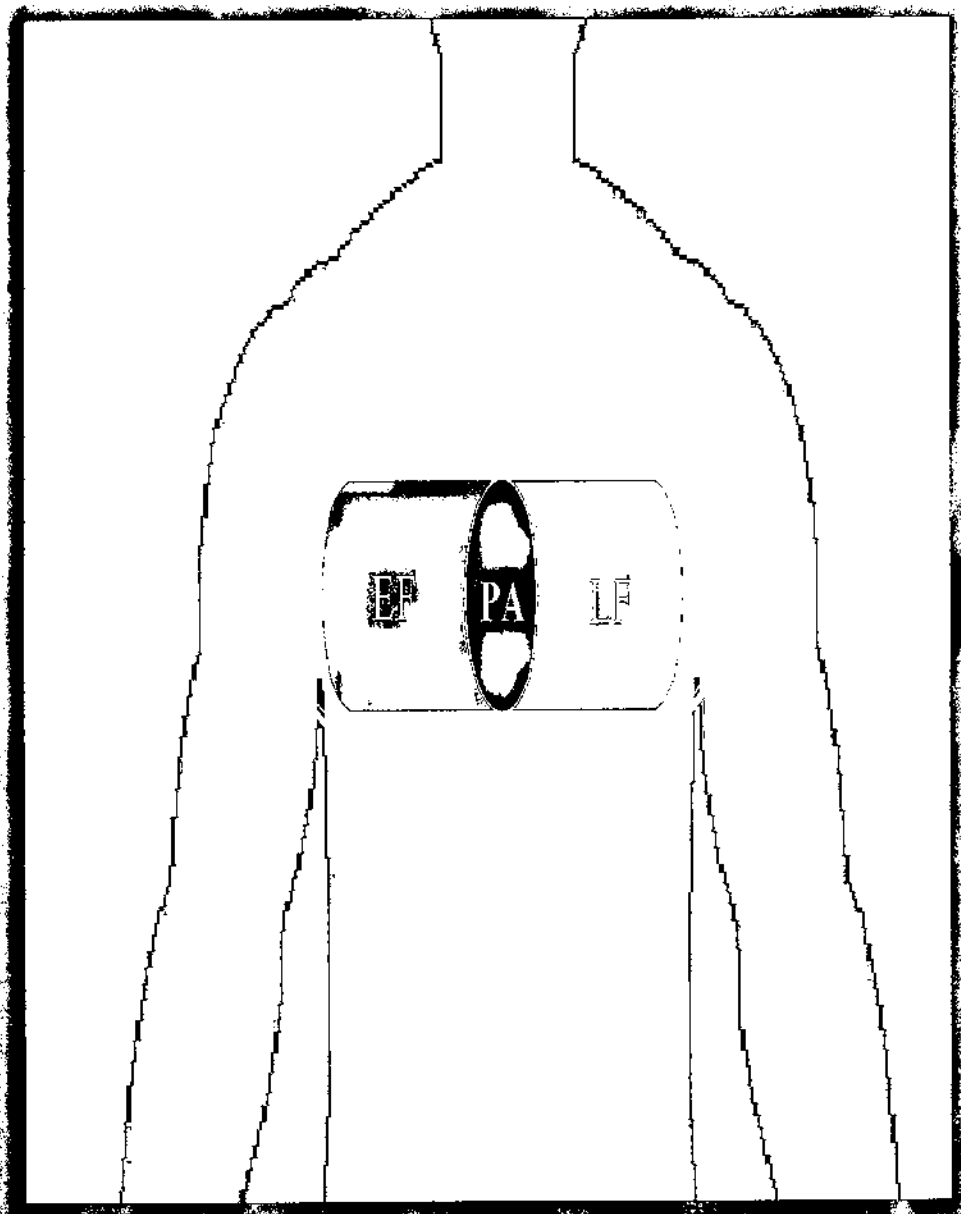
- Medical screening/surveillance
- Record keeping - Personal information carriers
- Integrate Force Health Protection into operational requirements
- Follow up to deployment

Anthrax

- Inhalation anthrax is deadly
- Biological warfare agent of choice:
  - Cheap and easy to produce
  - Can be dispersed in air by a variety of weapons
  - Odorless, colorless, tasteless, difficult to detect
  - Flu-like symptoms early, rapid deterioration, and death

Vaccination against anthrax is critical for your protection

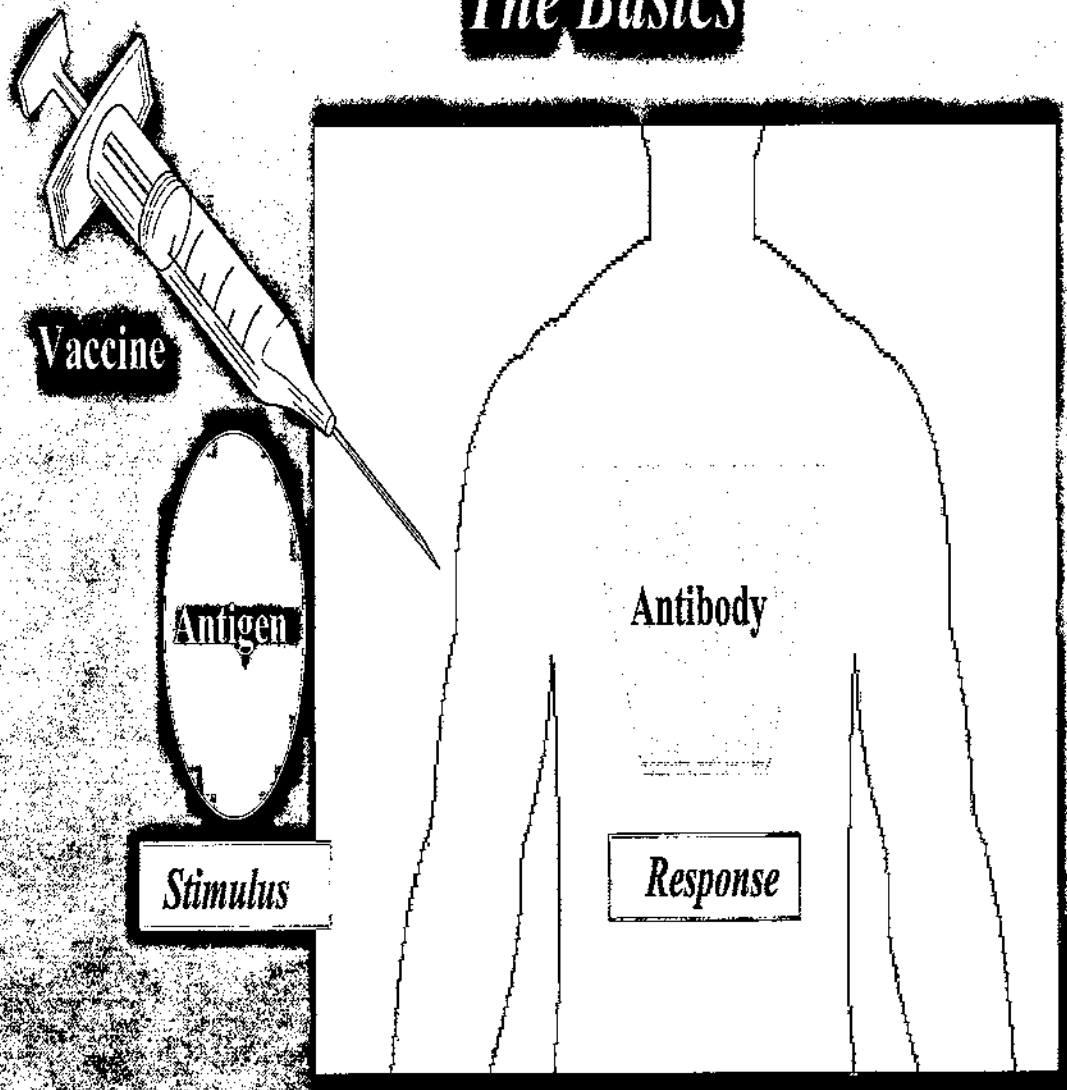
ANTHRAX BACTERIA ATTACK



= Death

IMMUNE SYSTEM ACTIVATION BY VACCINE

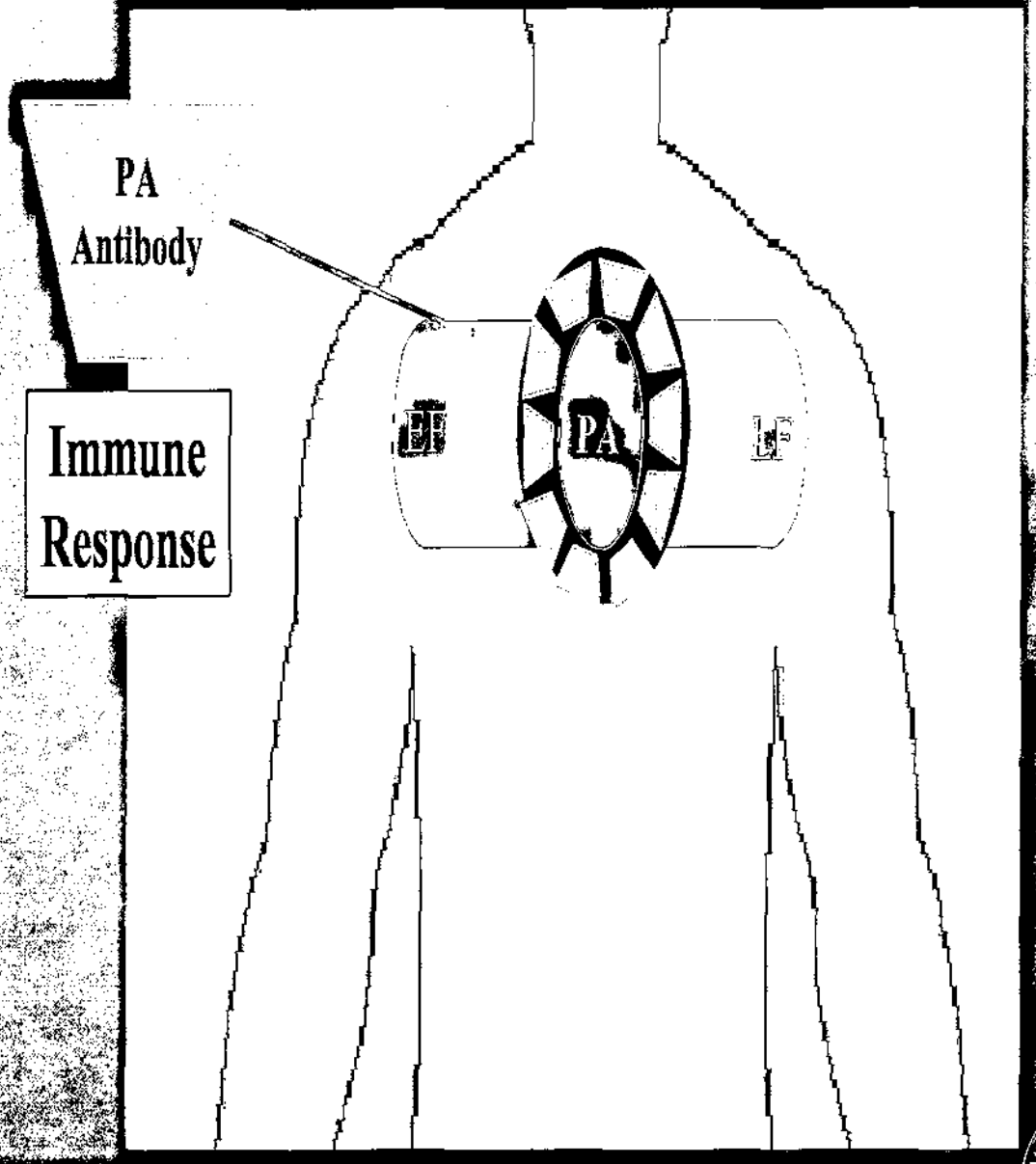
The Basics



Office of the Special Assistant for Gulf War Illnesses

AFTER ANTHRAX VACCINE

Antibodies at Work



Office of the Special Assistant for Gulf War Illnesses

Anthrax Vaccine Program

- Licensed by the FDA since 1970
  - Safely administered in the U.S. to at-risk veterinarians, laboratory workers, and livestock handlers
- Shot schedule: 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster

1-877-GET-VACC
www.anthrax.osd.mil
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Pyridostigmine Bromide

- Threat - Soman is deadly nerve agent
- PB is the only known pretreatment against Soman.
  - Auto injectors alone will not save you
- Issues have been raised about PB
  - Further research is ongoing
- Only President can authorize its use without informed consent

Bottom Line

- Lessons learned from the Gulf War affect today's doctrine and deployments
- You will deploy on missions
- Everyone is responsible for force protection
- You are your own best health advocate
- Don't tough it out; get examined

Obtaining help and information

- Comprehensive Clinical Evaluation program (CCEP) 1-800-796-9699
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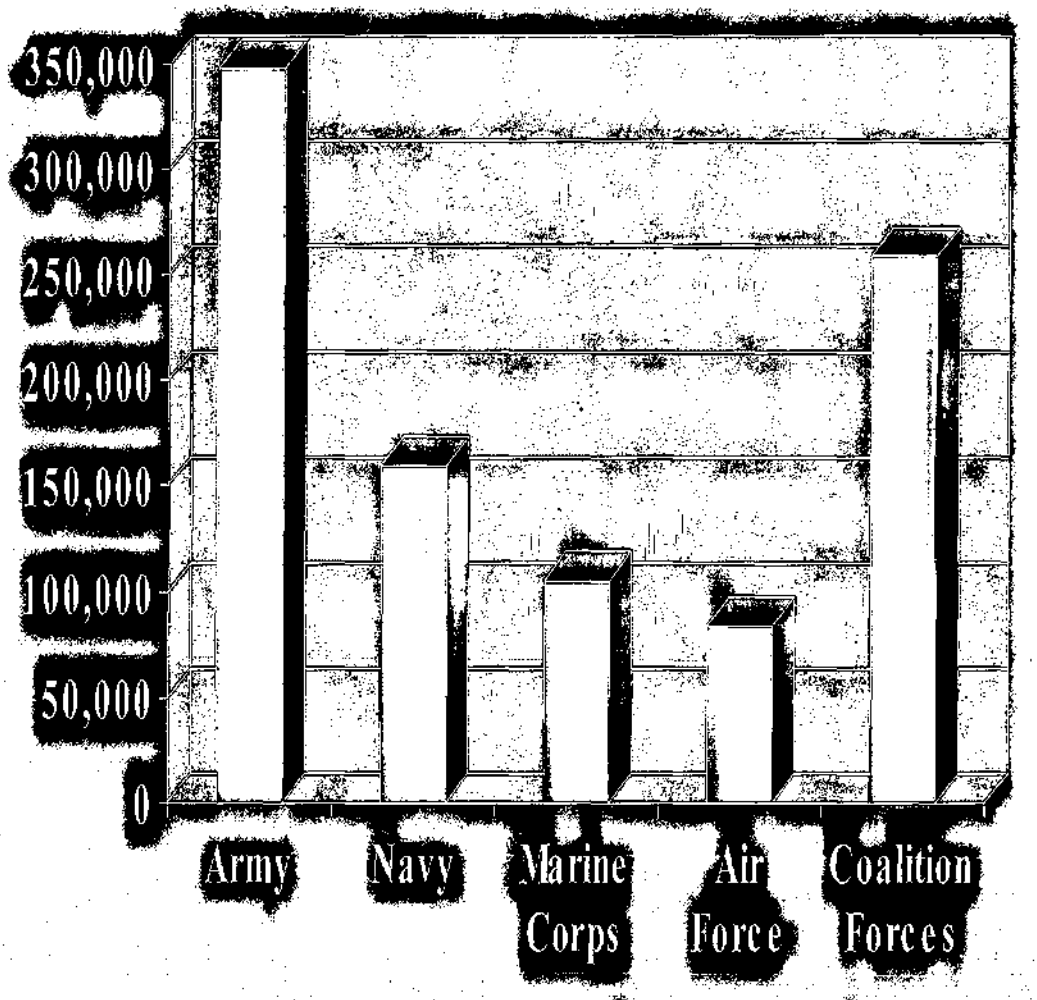
http://www.gulflink.osd.mil

Office of the Special Assistant to the Deputy Secretary of Defense

for Gulf War Illnesses

DSN 761-1078 fax 703-578-8501
email: brostker@gwillness.osd.mil

Gulf War Theater Forces

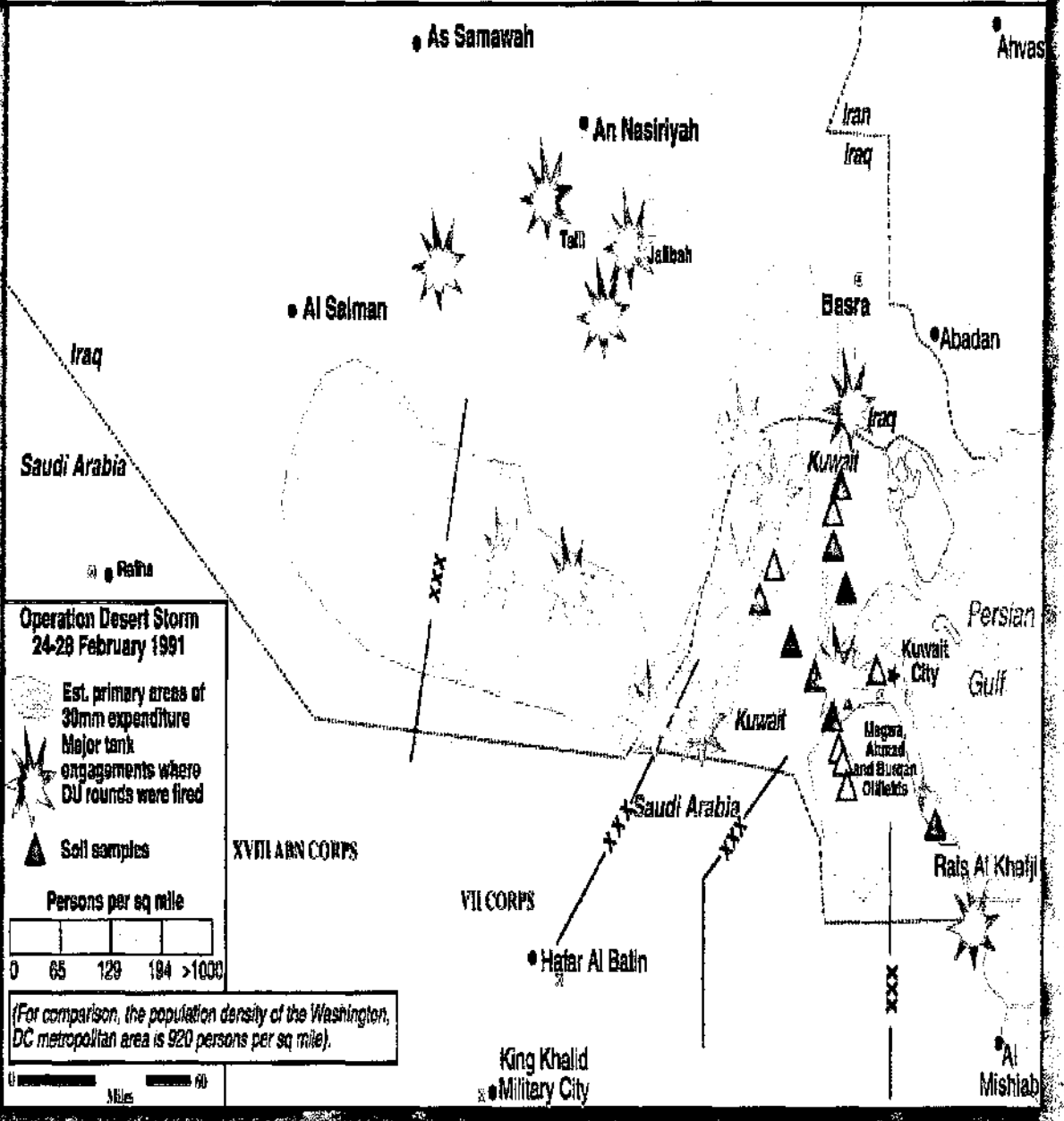


697,000 U.S. service members

DU Exposure Issues

- Radiation
- Consequences of exposure
- Heavy metal toxicity
- Reproductive effect
- Contamination of theater

Primary Areas of DU Expenditure



Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Collect pre-deployment blood sample
- Verify HIV test is current
- Verify Immunizations up to date
- Verify current physical exam
- Complete Health questionnaire

Deployment

- Routine disease/injury reporting
- Forward medical laboratory
- Immunization tracking
- Environmental monitoring

Post Deployment

- Collect blood sample
- Medical debriefs
- Complete health questionnaire
- Screening exams as needed

You are your own best health advocate!

RAND study on PB drew on Comprehensive Sources

- ~10,000 Titles
- ~6,000 Abstracts
- ~2,000 Documents Read
- ~1,000 Citations
- ~ 80 Interviews
- Documents declassified by British

Conclusions about PB

- We cannot rule out pyridostigmine bromide as a contributor to increased health symptoms in Gulf War veterans.
- Further research is needed to determine the effectiveness of the current dose of PB against Soman.
- Additional research about safety and effectiveness of PB for humans is urgently needed.

Office of the Special Assistant to the Deputy Secretary of Defense

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(125)

Briefing Overview

- Mission Statement
- The Gulf War
- Post Gulf War Issues
- Searching for answers
- Lessons Learned
- Force Health Protection
- Bottom Line
- Obtaining help and information

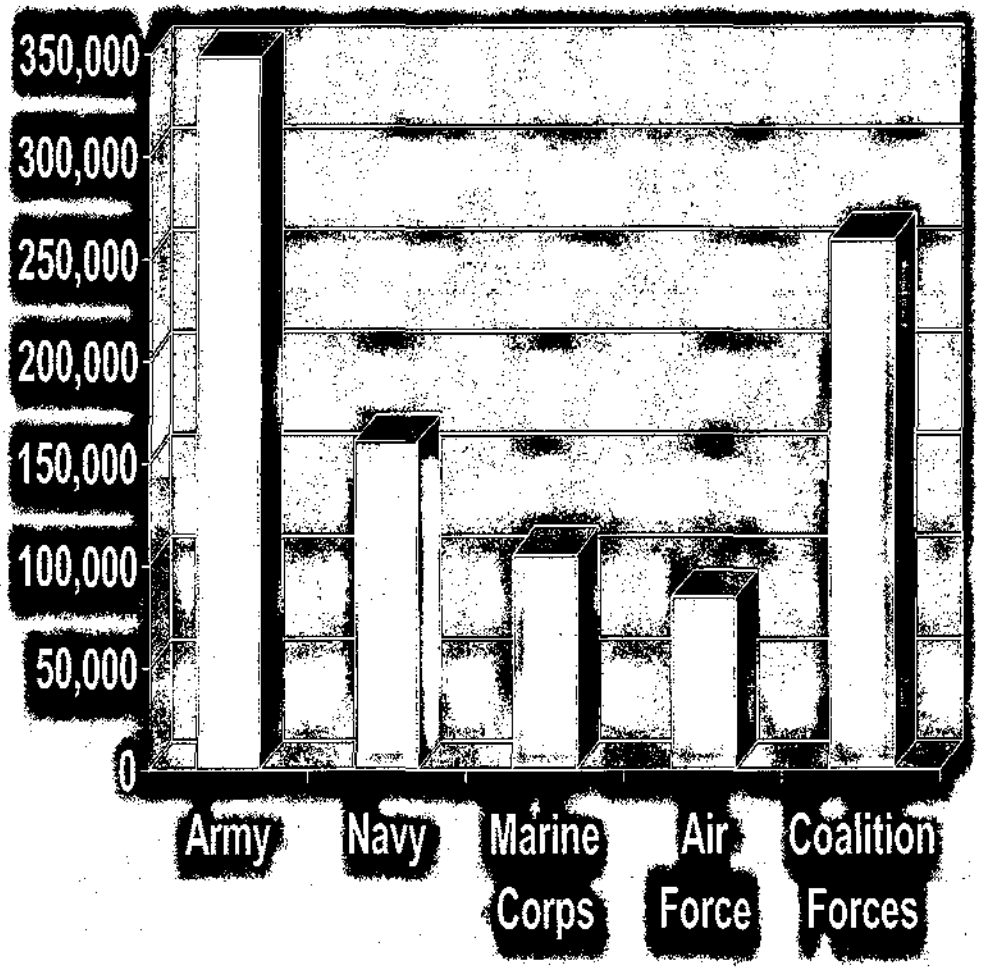
Our Mission

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain illnesses in Gulf War veterans
- Ensure DOD adopts doctrine, policy and procedures to reduce health risks for troops deploying now and in the future

Why Should I Care

- Lessons from the Gulf War about dirty battlefields
- You must protect yourself against hazards
- You will be leading Gulf War vets
- You are responsible for force protection
  - What are the dangers of the dirty battlefield?
  - How good are our detectors and MOPP gear?
  - How do we determine if we are exposed?
  - Will our counter-fire put us at risk?
  - How do we identify captured CW/BW?
  - What if my fighting vehicle is hit with DU?

Gulf War Theater Forces



697,000 U.S. service members

Gulf War Theater

- August 1990 to July 1991
- 697,000 US service members
- More then 27,000 hospitalizations
- 148 battle deaths
- 224 non-battle deaths

1 in 7 Veterans Reported Symptoms Since Re-deployment

Most frequently reported symptoms

- Joint pain
- Headaches
- Sleep disorders
- Depression
- Fatigue
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- Muscle pain

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- No clustering
- No symptom consistency; variable onset
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- No long term study

Doctor - Patient - Government Communication Breakdown

- Veterans with real health problems
- Healthcare professionals unable to provide answers
- Government slow to recognize the reality of problems

Myths versus Reality

Cover up	Open process & oversight
Not listening	Solicit eyewitness reports
Destroy records	Found missing records
20,000 veterans dead	6,584 veterans dead
No assistance to vets	Evaluation and care
"Syndrome"	More than 40 illnesses
CW or DU cause	Many possible causes
Brass doesn't care	Force Protection efforts
	Tough choices
	Cultural changes

Taking Care of Service Members

- **DoD Comprehensive Clinical Evaluation Program**
  - Gulf War vets (active, Guard/Reserve, retired)
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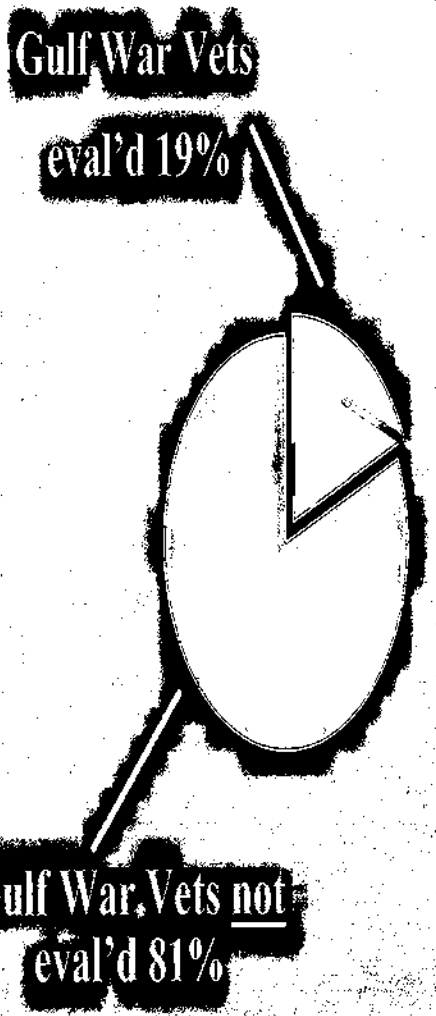
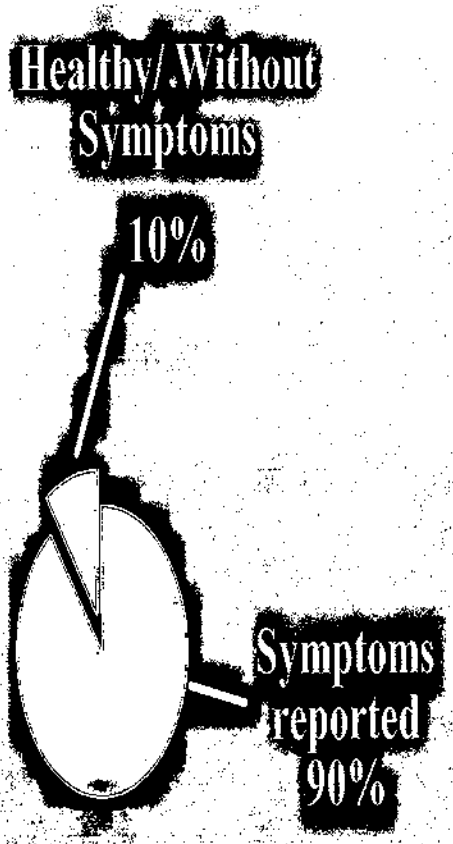
Don't Tough It Out!

Evaluation Distribution of 697,000 CCEP/VA

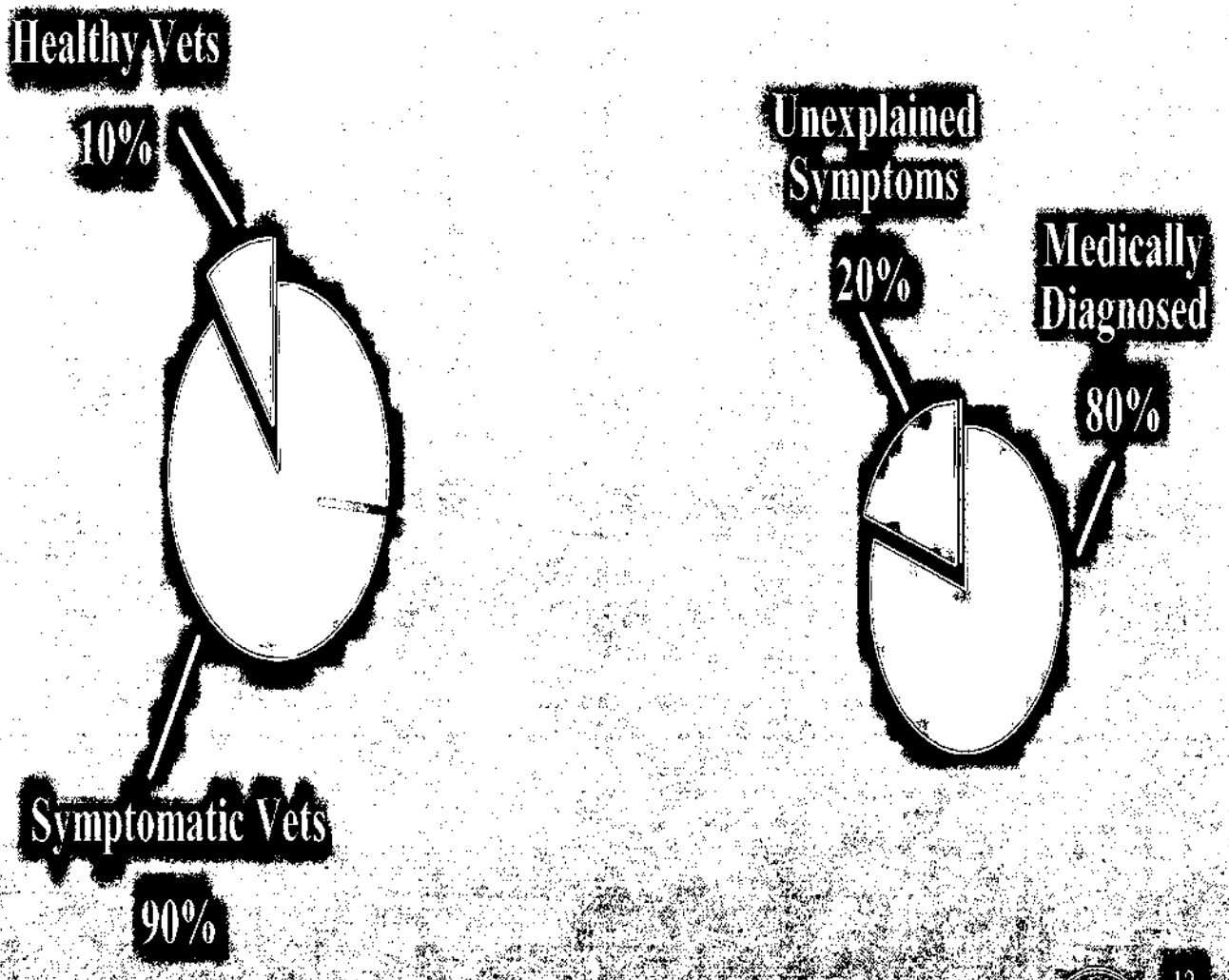




Office of the Special Assistant for Gulf War Illnesses

Diagnosis Distribution of Evaluated Veterans

CCEP/VA



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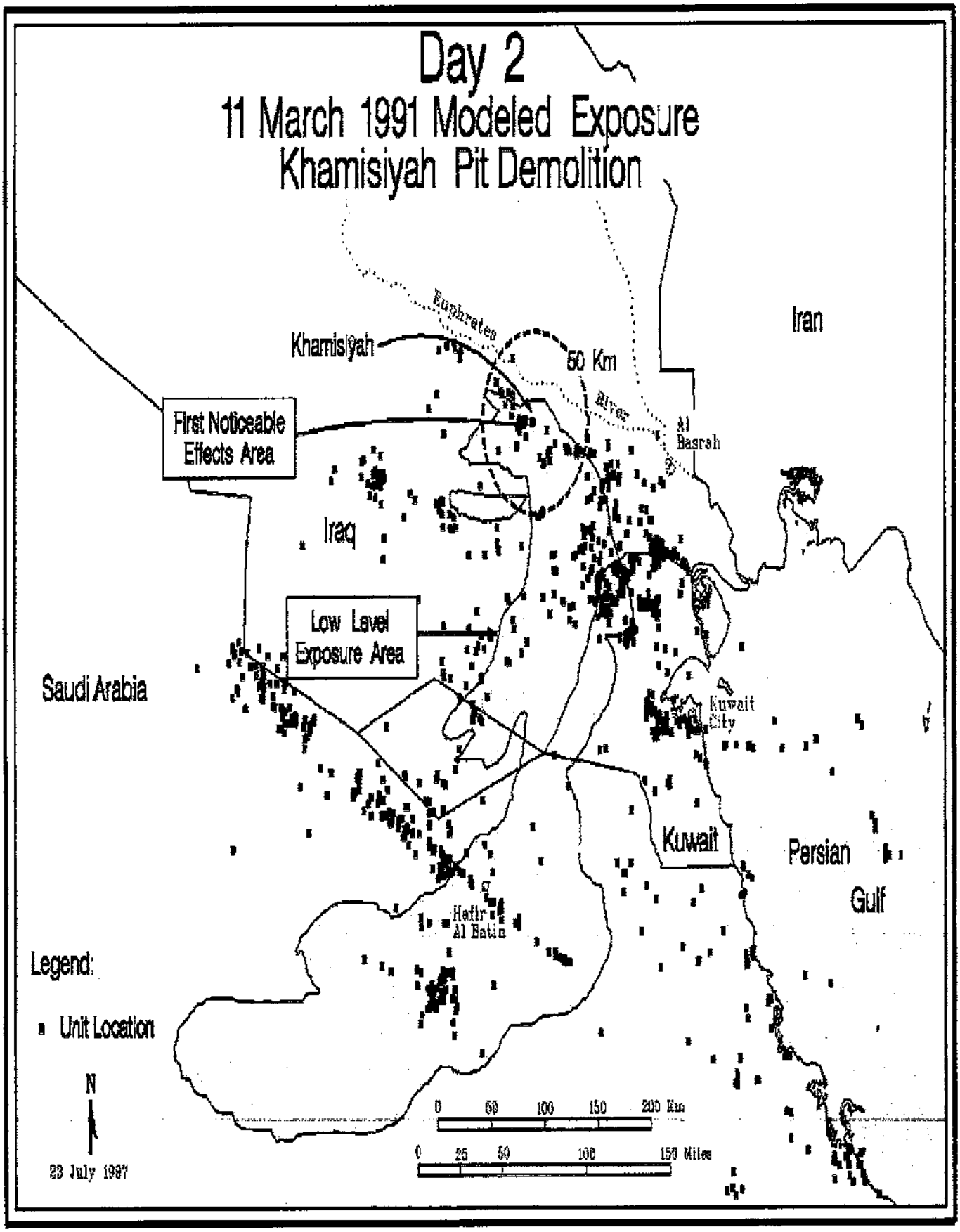
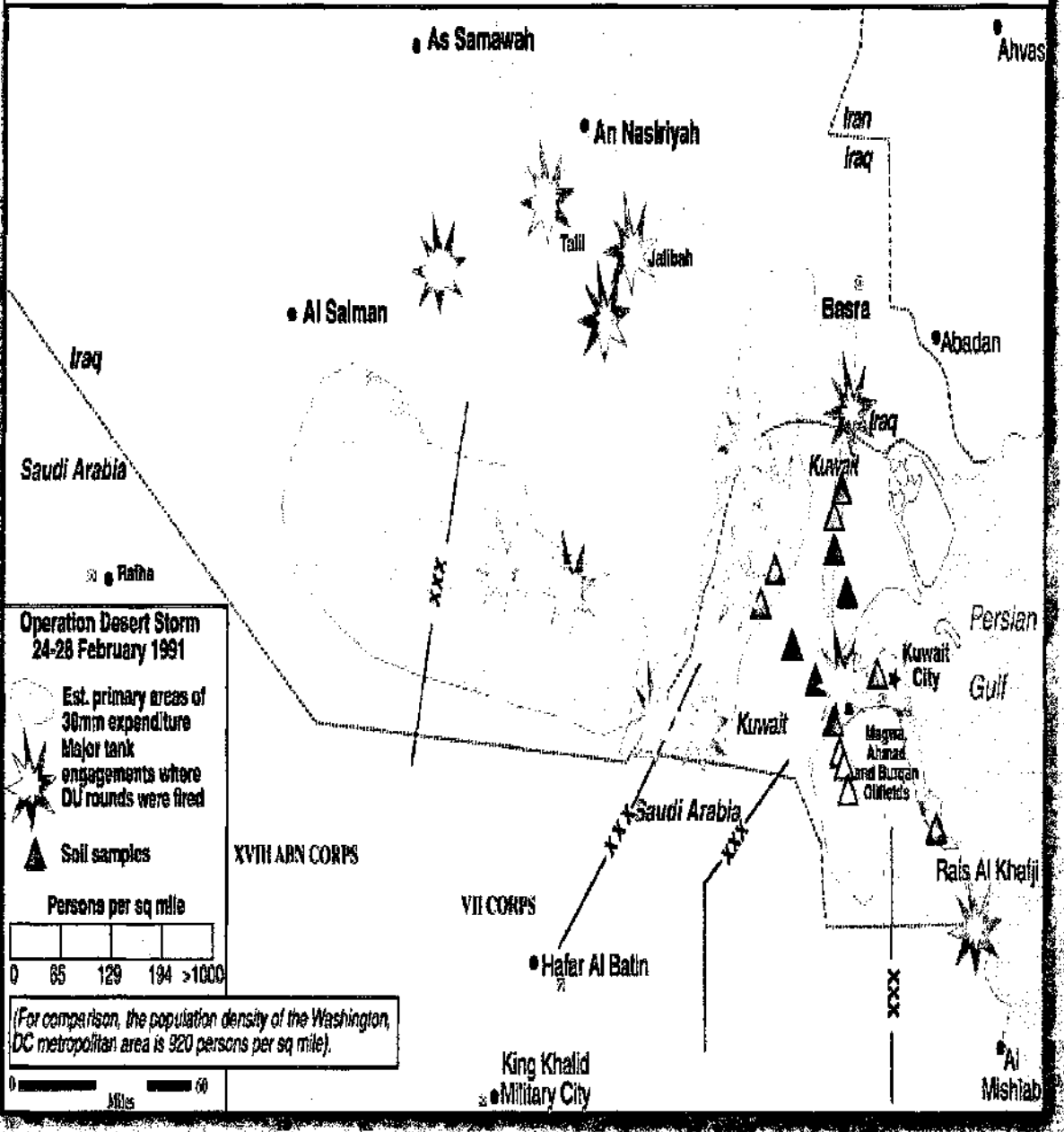

Day 2
11 March 1991 Modeled Exposure
Khamisiyah Pit Demolition
Euphrates
Khamisiyah
50 Km
River
Iran
Al Basrah
First Noticeable Effects Area
Iraq
Low Level Exposure Area
Saudi Arabia
Kuwait City
Kuwait
Persian Gulf
Hafir Al Batin
Legend:
Unit Location
N
23 July 1997
0 50 100 150 200 Km
0 25 50 100 150 Miles

Primary Areas of DU Expenditure



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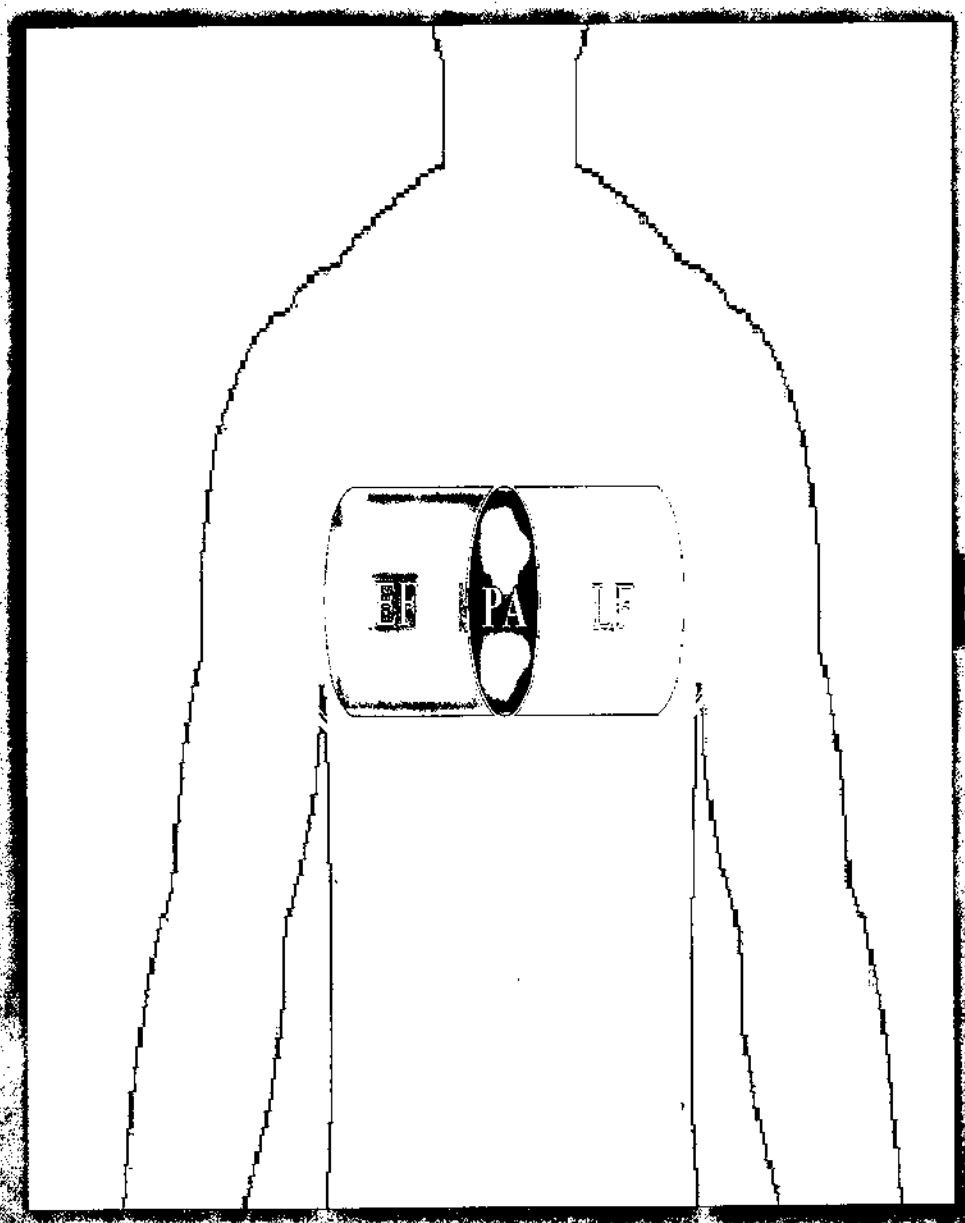
  - Odorless, colorless, tasteless, difficult to detect
  - Flu-like symptoms early, rapid deterioration, and death
- MOPP 4 prevents exposure
- Antibiotics work before symptoms appear

Vaccination against anthrax is critical for your protection

ANTHRAX BACTERIA ATTACK



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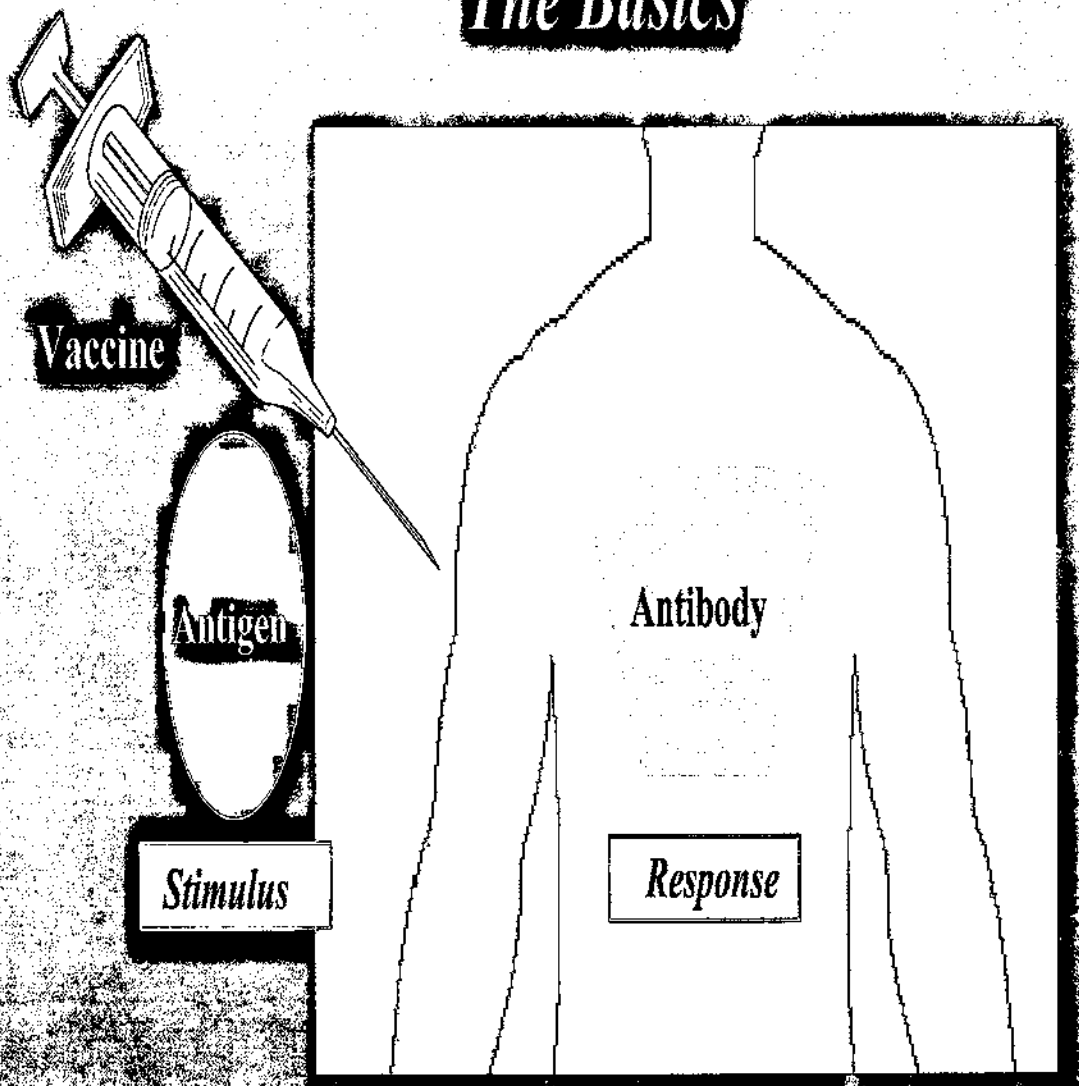
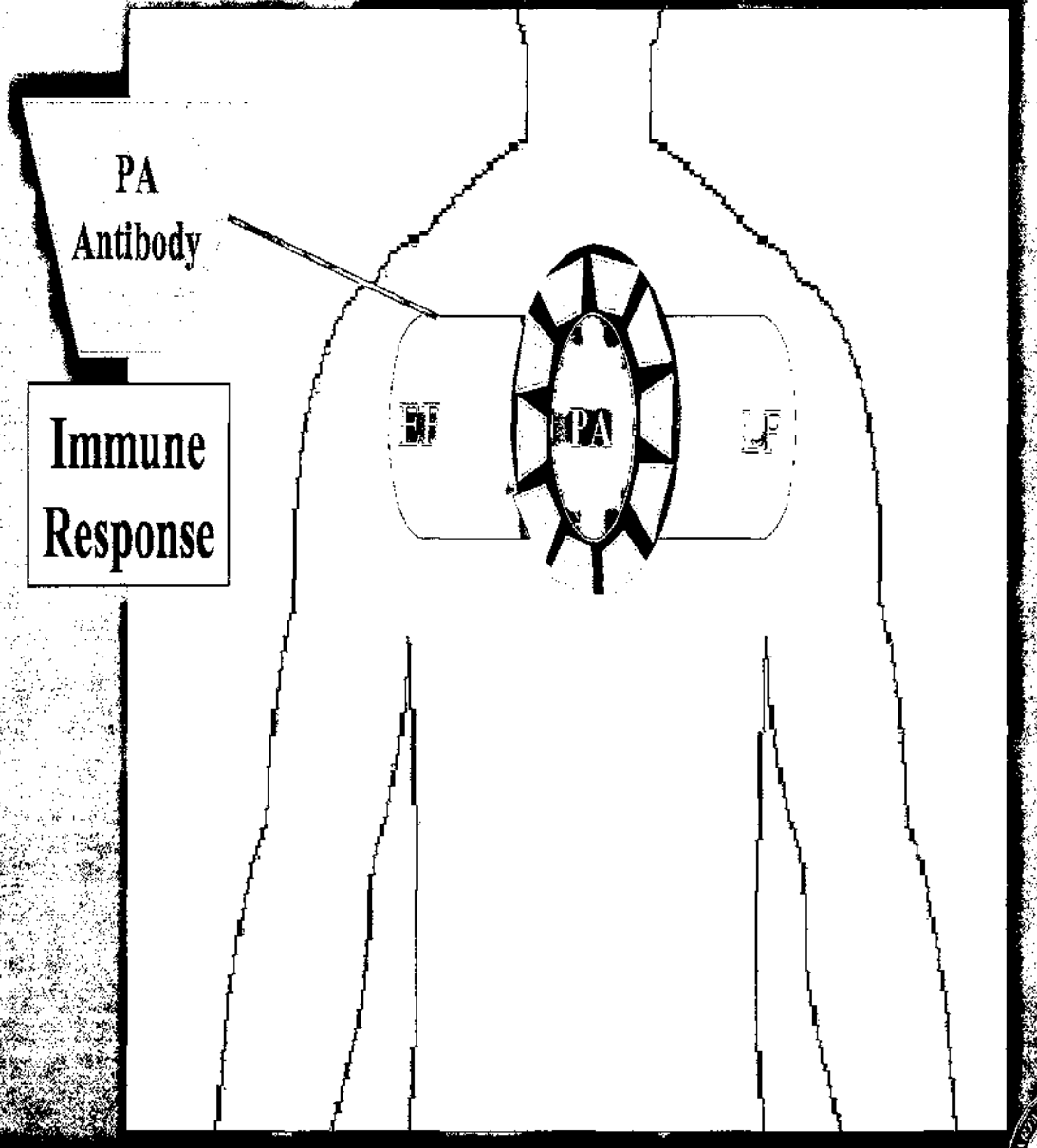
IMMUNE SYSTEM ACTIVATION BY VACCINE

The Basics



AFTER ANTHRAX VACCINE

Antibodies at Work



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www.aviationmedicine.com

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  - Auto injectors alone will not save you
- Issues have been raised about PB
  - Further research is ongoing
- Only President can authorize its use without informed consent

Conclusions about PB

- We cannot rule out pyridostigmine bromide as a contributor to increased health symptoms in Gulf War veterans.
- Further research is needed to determine the effectiveness of the current dose of PB against Soman.
- Additional research about safety and effectiveness of PB for humans is urgently needed.

Bottom Line

- Can not rule out PB, pesticides, or particulates
- Lessons learned from the Gulf War affect today's doctrine and deployments
- You will deploy on missions to dirty areas
- Everyone is responsible for force protection
- You are your own best health advocate
- Don't tough it out; get examined
- Vaccination against anthrax protects you

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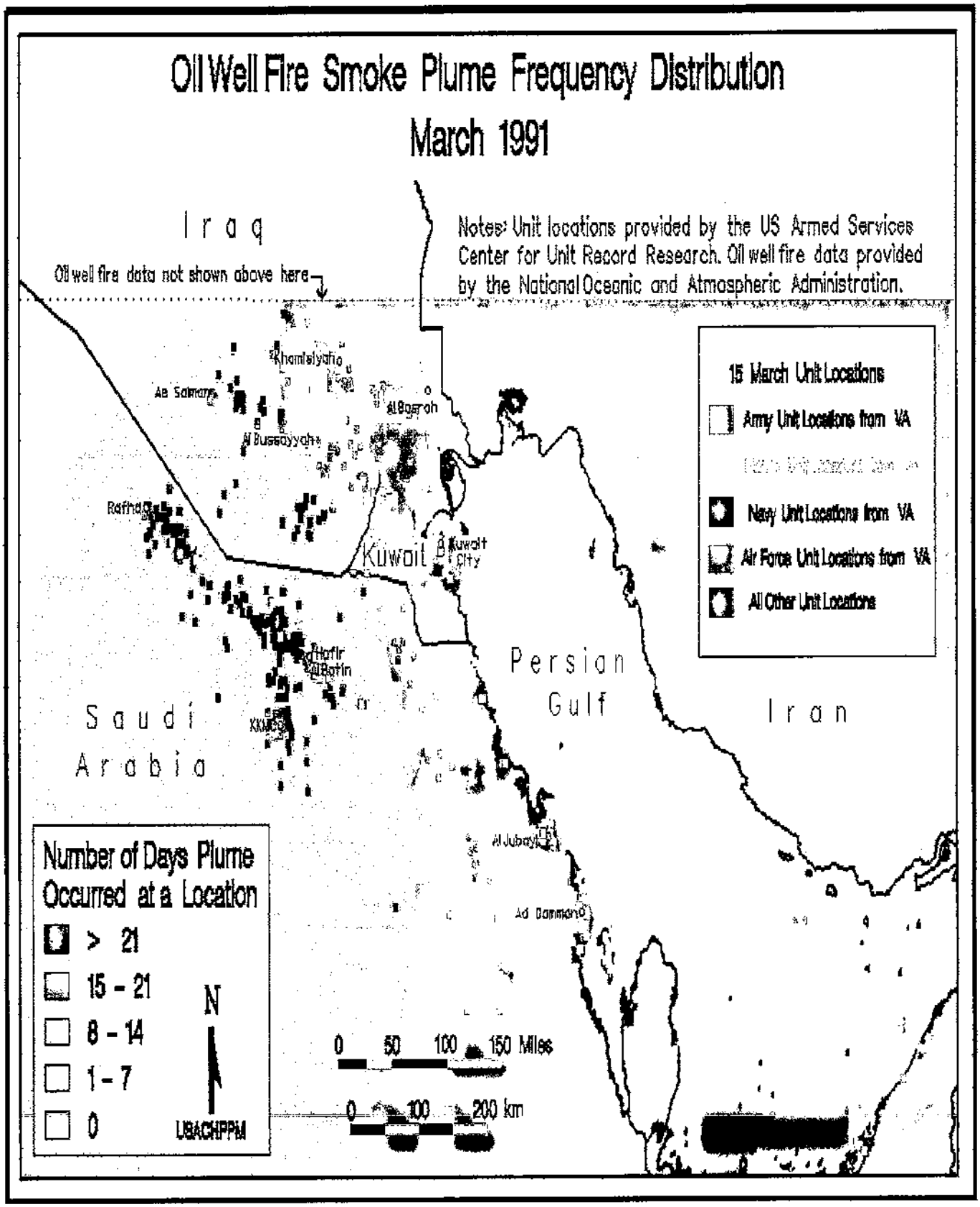
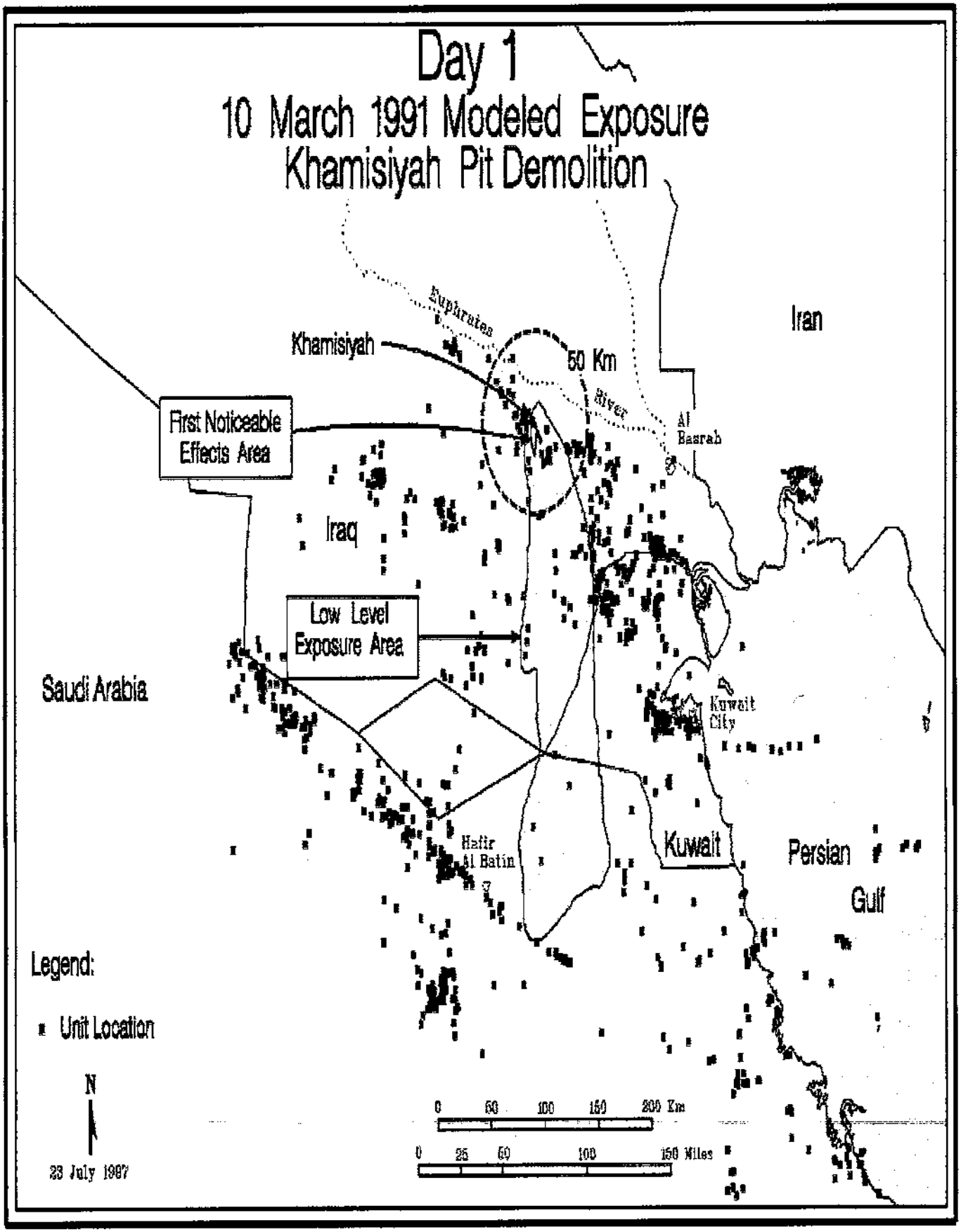
Back-up Slides

A National Effort

- **OVERSIGHT:** Presidential, 7 Congressional Committees, VSOs, Veterans, the Media
- **INVESTIGATIONS:** IGs, GAO, SIU
- **DoD:** ASDs, Special Assistants, DIA, the Surgeons General
- **OUTSIDE AGENCIES:** CIA, VA, HHS, GWVCB, CDC
- **DECLASSIFICATION:** CIA, DIA, and the Services
- **TECHNICAL PROJECTS:** Dugway, Edgewood, Picatinny, CHPPM, Think tanks, outside experts


Oil Well Fire Smoke Plume Frequency Distribution
March 1991
Iraq
Oil well fire data not shown above here
Notes: Unit locations provided by the US Armed Services Center for Unit Record Research. Oil well fire data provided by the National Oceanic and Atmospheric Administration.
15 March Unit Locations
Army Unit Locations from VA
Navy Unit Locations from VA
Air Force Unit Locations from VA
All Other Unit Locations
Khamisiyah
Ar Salman
Al Busayyah
Al Basrah
Rafha
Kuwait
Kuwait City
Hafr Al Batin
Khafji
Saudi Arabia
Persian Gulf
Iran
Al Jubayl
Ad Dammam
Number of Days Plume Occurred at a Location
> 21
15 - 21
8 - 14
1 - 7
0
N
UBACHPPM
0 50 100 150 Miles
0 100 200 km


Day 1
10 March 1991 Modeled Exposure
Khamisiyah Pit Demolition
Euphrates
River
Khamisiyah
50 Km
First Noticeable
Effects Area
Low Level
Exposure Area
Iraq
Iran
Al
Basrah
Saudi Arabia
Kuwait
City
Kuwait
Persian
Gulf
Hafir
Al Batin
Legend:
Unit Location
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23 July 1997
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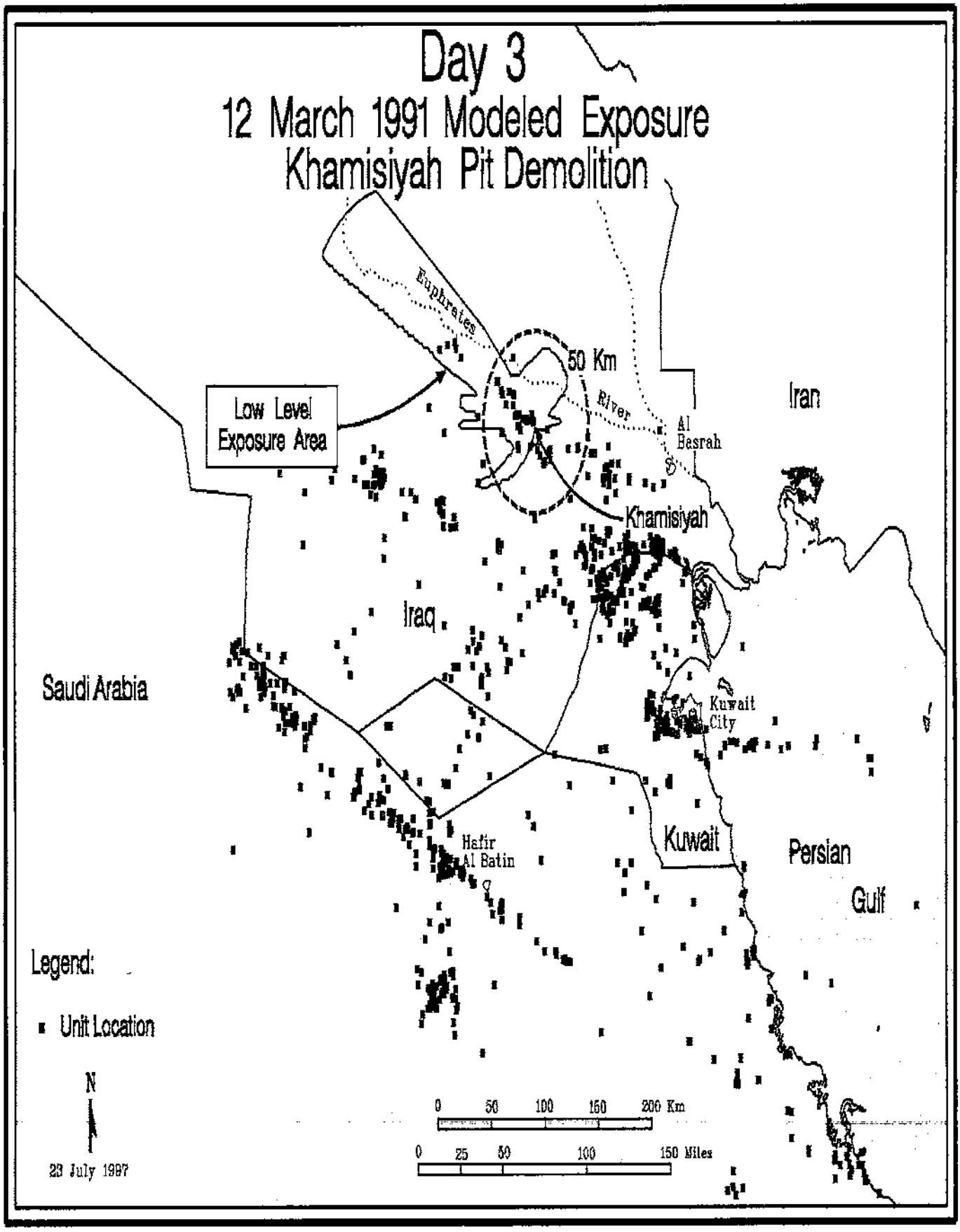
Day 3
12 March 1991 Modeled Exposure
Khamisiyah Pit Demolition
Euphrates
50 Km
River
Low Level
Exposure Area
Iran
Al
Basrah
Khamisiyah
Iraq
Saudi Arabia
Kuwait
City
Hafir
Al Batin
Kuwait
Persian
Gulf
Legend:
Unit Location
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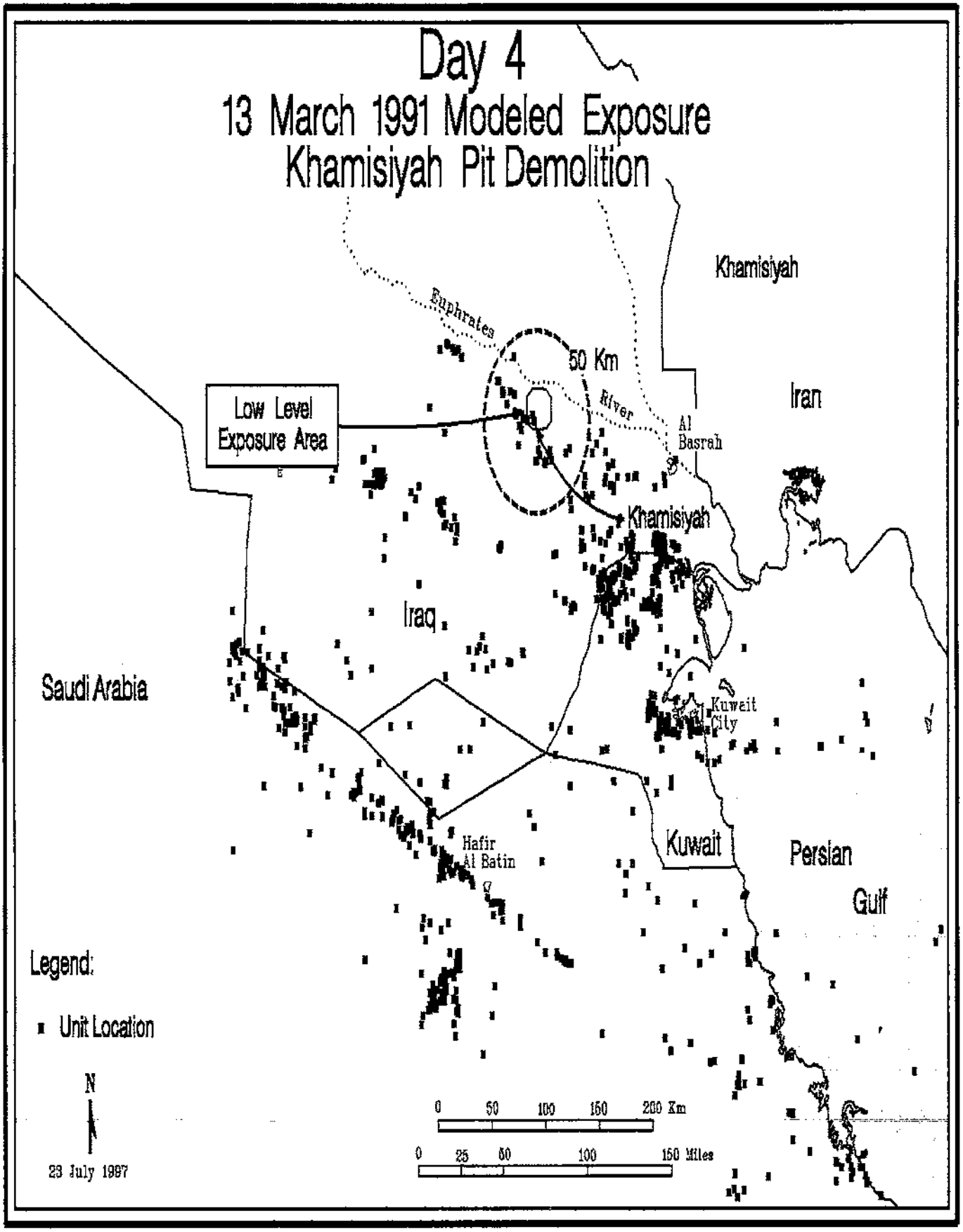
Day 4
13 March 1991 Modeled Exposure
Khamisiyah Pit Demolition
Khamisiyah
Euphrates
50 Km
River
Iran
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Al
Basrah
Khamisiyah
Iraq
Saudi Arabia
Kuwait
City
Hafir
Al Batin
Kuwait
Persian
Gulf
Legend:
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23 July 1997
0 50 100 150 200 Km
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Office of the Special Assistant to the Secretary of Defense

for Gulf War Illnesses, Medical Readiness, and Military Deployments

(703) 497-6261 fax (703) 578-8501

email: brostker@gwillness.osd.mil

Briefing Overview

- Mission Statement
- The Gulf War
- Searching for Answers
- Lessons Learned
- Force Health Protection
- Bottom Line
- Obtaining Help and Information

Vision of the Special Assistant for Gulf War Illnesses, Medical Readiness, and Military Deployments

- The Department of Defense recognizes the right of those involved in deployments to receive information that enables them to make informed decisions about their health
- We will develop and disseminate such information in a relevant and timely fashion
- We will work with others in the Defense Department to incorporate lessons from previous deployments to foster the well-being of deployed forces

Gulf War Illnesses Mission

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DOD adopts doctrine, policy and procedures to reduce risks for troops in the future.

Gulf War Theater

- August 1990 to July 1991
- 697,000 US service members
- More than 27,000 hospitalizations
- 148 battle deaths
- 224 non-battle deaths

1 in 7 Veterans Reported Symptoms Since the War

Most frequently reported symptoms

- Joint pain
- Headaches
- Sleep disorders
- Depression
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- Veterans with real health problems
- Healthcare professionals unable to provide answers
- Government slow to recognize the reality of problems

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- No clustering
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    - 99,000 vets notified
- Environmental:
  - Depleted uranium (DU), Oil well fires, Pesticides
- Medical issues:
  - Vaccines, PB, records, policy
- Scientific research under PGVCB
  - 180+ studies sponsored by DoD, DVA, & HHS
  - No cause and effect relationship shown so far

Investigation Results

- Gulf War
  - No offensive CW/BW use
  - Not enough vaccines and no explanation given
  - Limited environmental surveys
  - Information about nerve agent pre-treatment (PB) wasn't given to troops
  - Inadequate training

= *Veterans returned home and left service without thorough medical exam or debrief*

The Dirty Battlefield

- What enemy may do to us
  - Chemical/Bio threat, man-made environmental hazards (oil well fires)
- What the environment may do to us
  - Infectious diseases, insects, environmental risks (desert, jungle)
- What we may do to ourselves
  - Accidents, pesticides, investigational new drugs, PB

Current and future conflicts and humanitarian deployments have and will have these challenges

Applying Lessons Learned

- Train self and others to recognize and avoid hazards
- Monitor service member's health & environment
- Improve feedback and cross talk
- Know your equipment strengths and weaknesses
- Create, relate and save operational, NBC, and medical records
- Adapt to reduce risks and train to reduce future risks such as DU

Force Health Protection

- Pre-deployment
  - Medical screening/surveillance and briefings
- Deployment
  - Record keeping
  - Monitor environment and personnel
- Post Deployment
  - Medical screening and unit debriefing

Anthrax

- We have a safe and effective vaccine

- Anthrax - an offensive BW agent
  - Inhalation anthrax is highly lethal
  - Easy to develop and weaponize
  - Remains viable for long periods

Vaccination against anthrax is critical for your protection

Anthrax Vaccine Program

- Licensed by the FDA since 1970
- Dosing schedule: 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster
- Shortages in stockpiled doses require temporary slowdown of AVIP

(877) GET VACC DSN: 761-5101

www.anthrax.osd.mil

www.aviationmedicine.com

Pyridostigmine Bromide

- Threat - Soman is deadly nerve agent
- PB is the only known pretreatment against Soman
  - Auto injectors alone will not save you
- Issues have been raised about PB
  - Further research is ongoing
- Only President can authorize its use without informed consent

Bottom Line

- Lessons learned from the Gulf War affect today's doctrine and deployments
- You will deploy on missions
- Everyone is responsible for force protection
- You are your own best health advocate
- Vets should not tough it out; get examined

Obtaining Help and Information

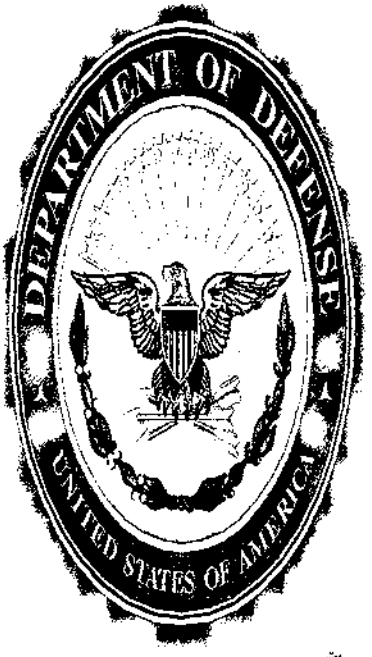
- OSAGWI/MR/MD Veterans' Helpline
  (800) 497-6261

- Comprehensive Clinical Evaluation Program
  (800) 796-9699

- Veterans Affairs Persian Gulf Registry
  (800) 749-8387

http://www.gulflink.osd.mil

Office of the Special Assistant to the Secretary of Defense



for Gulf War Illnesses, Medical Readiness, and Military Deployments

(703) 578-8500 fax (703) 578-8501

email: brostker@gwillness.osd.mil

Back-up Slides

Myths versus Reality

Cover up	Open process & oversight
Not listening	Solicit eyewitness reports
Destroy records	Found missing records
20,000 veterans dead	6,584 veterans dead
No assistance to vets	Evaluation and care
"Syndrome"	More than 40 illnesses
CW or DU cause	Many possible causes
Brass doesn't care	Force Protection efforts
	Tough choices
	Cultural changes

A National Effort

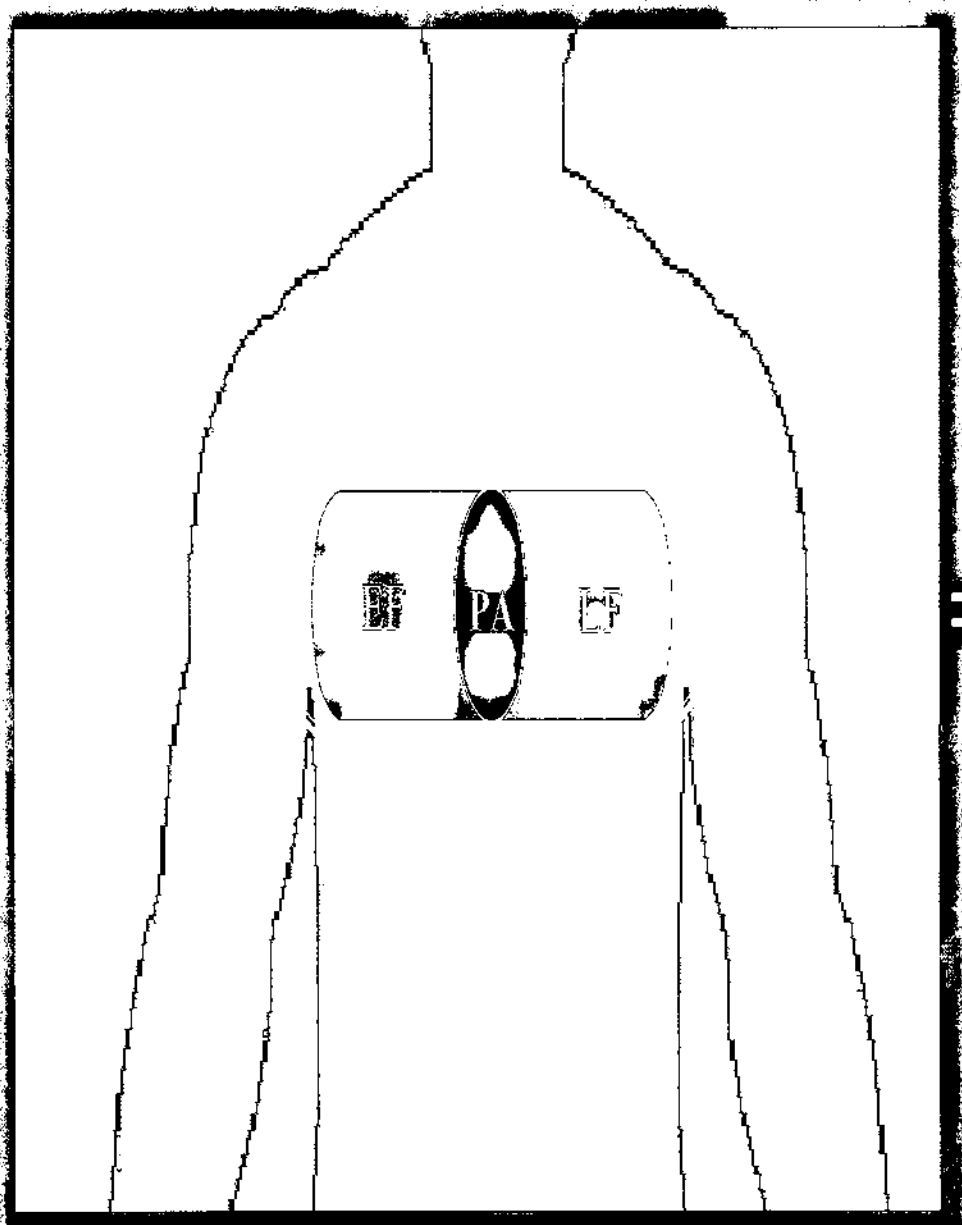
- **OVERSIGHT:** Presidential, 7 Congressional Committees, VSOs, Veterans, the Media
- **INVESTIGATIONS:** IGs, GAO, SIU
- **DoD:** ASDs, Special Assistants, DIA, the Surgeons General
- **OUTSIDE AGENCIES:** CIA, VA, HHS, GWVCB, CDC
- **DECLASSIFICATION:** CIA, DIA, and the Services
- **TECHNICAL PROJECTS:** Dugway, Edgewood, Picatinny, CHPPM, Think tanks, outside experts

Anthrax

- Inhalation anthrax is deadly
- Biological warfare agent of choice:
  - Cheap and easy to produce
  - Can be dispersed in air by a variety of weapons
  - Odorless, colorless, tasteless, difficult to detect
  - Flu-like symptoms early, rapid deterioration, and death
- MOPP 4 prevents exposure
- Antibiotics work before symptoms appear

Vaccination against anthrax is critical for your protection

ANTHRAX BACTERIA ATTACK



= Death

24

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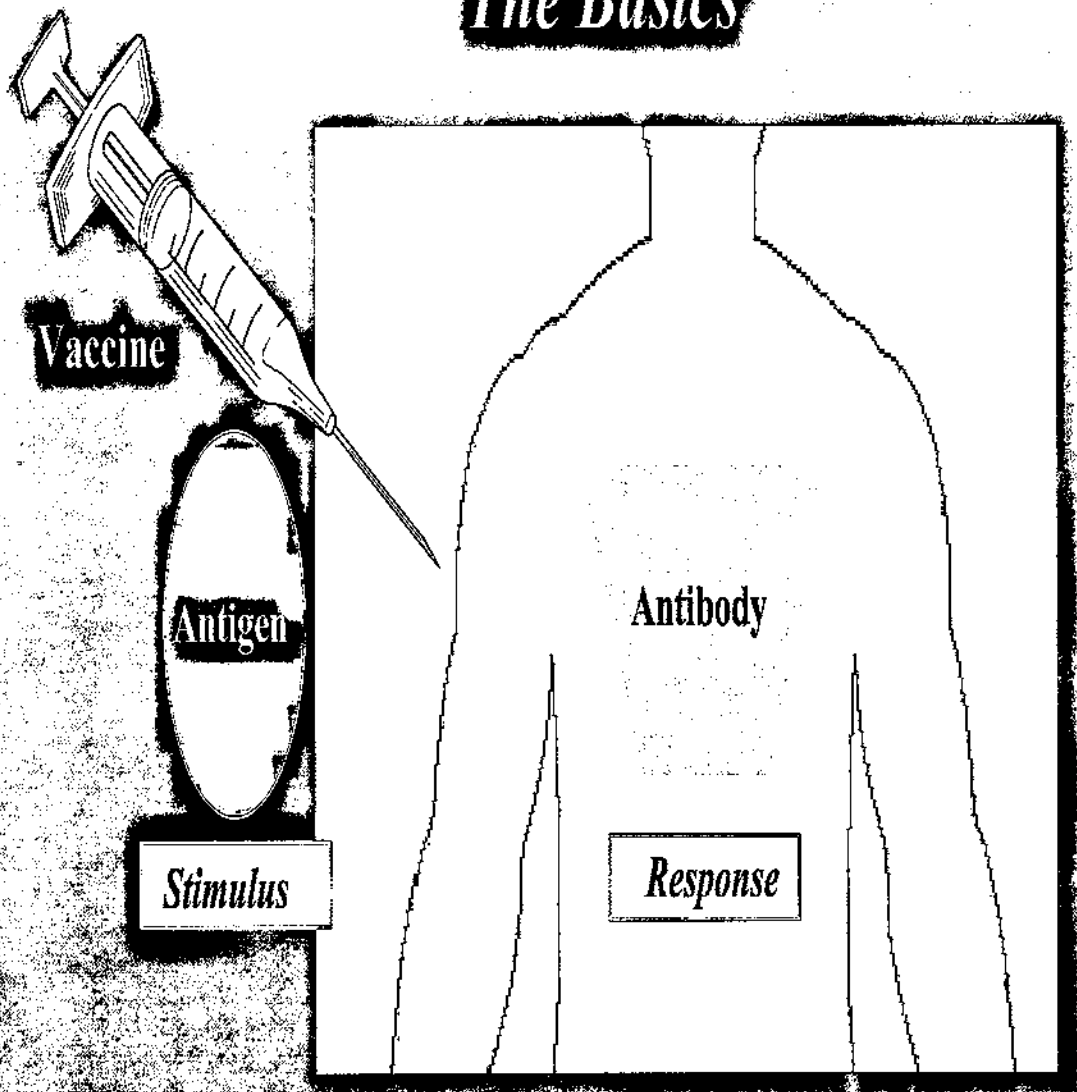
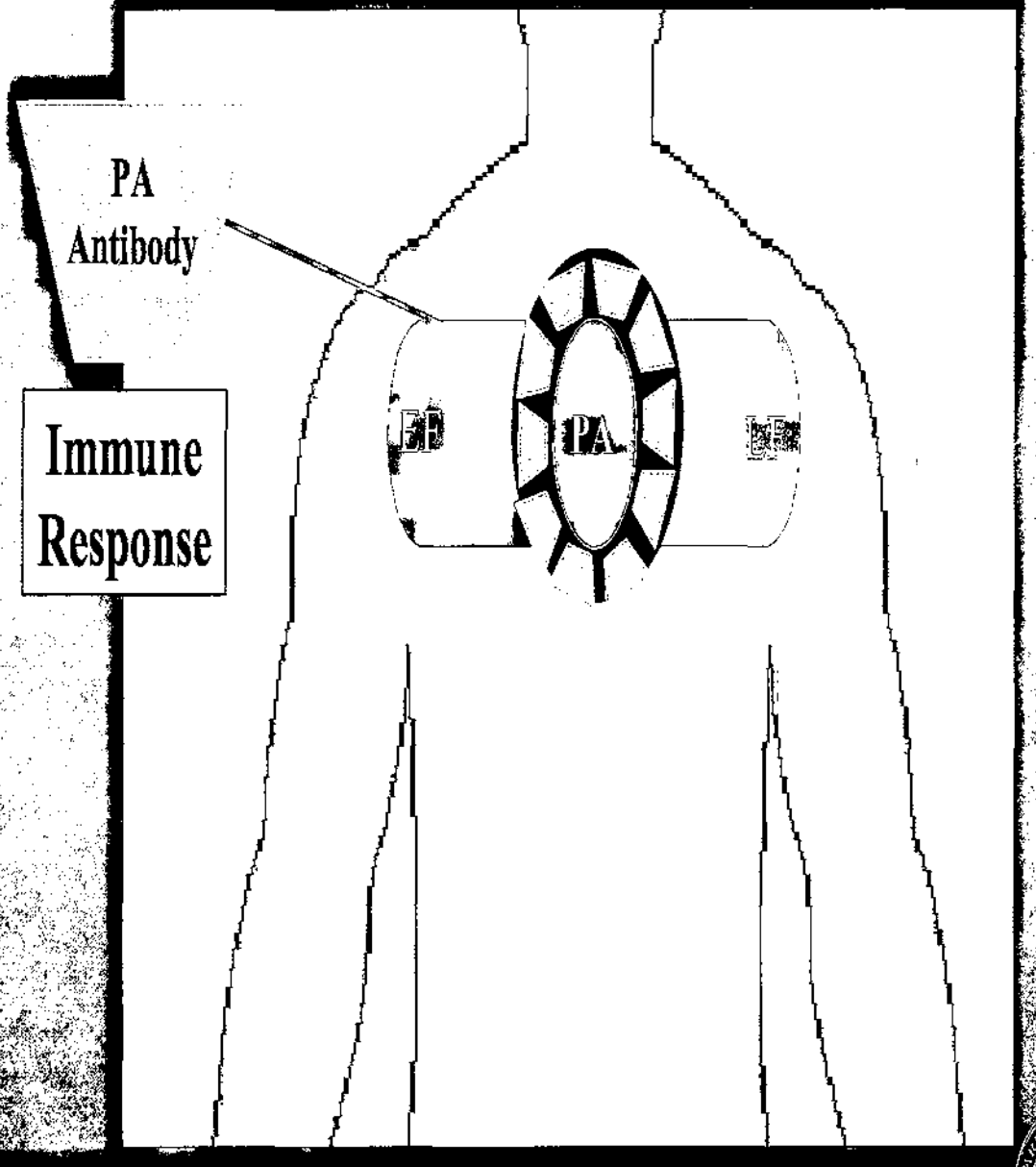
IMMUNE SYSTEM ACTIVATION BY VACCINE

The Basics



AFTER ANTHRAX VACCINE

Antibodies at Work



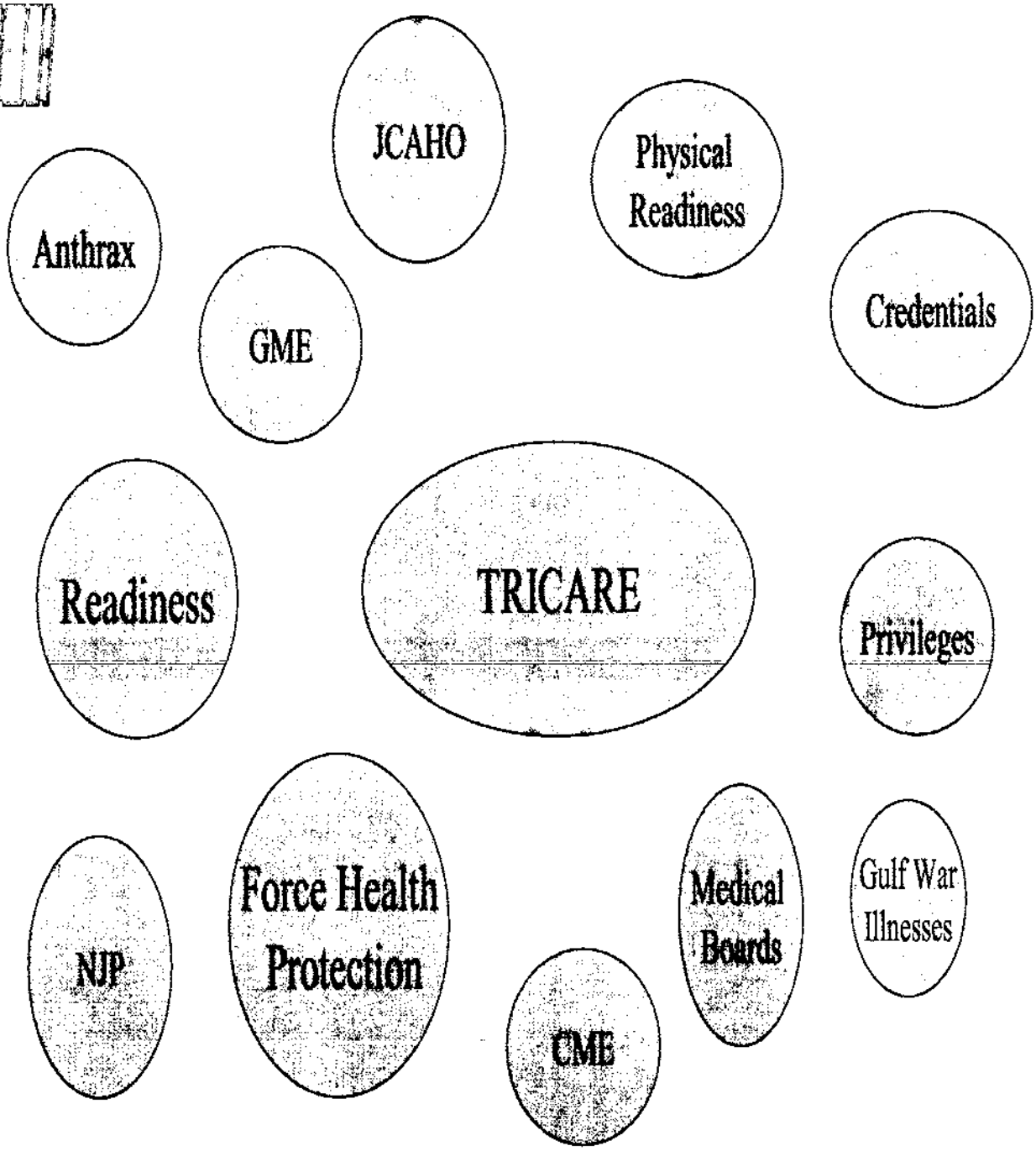
Office of the Special Assistant to the Secretary of Defense for Gulf War Illnesses, Medical Readiness and Military Deployments

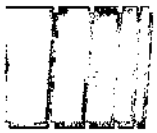
Michael E. Kilpatrick MD, FACP

Medical Outreach and Issues

703-578-8510 fax 703-578-8501

email: mkilpatr@gwillness.osd.mil


JCAHO
Physical Readiness
Anthrax
GME
Credentials
Readiness
TRICARE
Privileges
Force Health Protection
NJP
Medical Boards
Gulf War Illnesses
CME



Special Assistant

Dr. Bernard Rostker

- Appointed November 12, 1996 by the Deputy Secretary of Defense
- 180 team members

Gulf War Illnesses Mission

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain Gulf War illnesses: "leave no stone unturned"
- Ensure DoD adapts doctrine, policy and procedures to reduce risks for troops in the future.

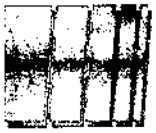
Who Served in the Gulf War

697,000 U.S. service members

ARMY	50%
NAVY	23%
MARINE	15%
AIR FORCE	12%

259,000 Coalition Forces

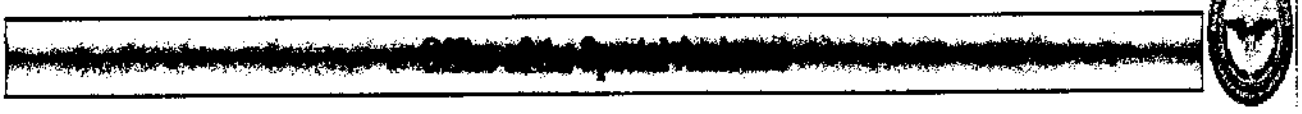
Source: Presidential Advisory Committee on Veterans Illnesses, Final Report



Who Served in the Gulf War

MALE	93%
FEMALE	7%
ACTIVE	83%
RESERVE/NATIONAL GUARD	17%
OFFICER	10%
ENLISTED	90%

< 26 years old - 55%; 26-35 years old - 32%; > 35 years old - 13%



Medical Support

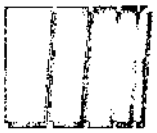
Largest emergency health care system since WW II

- 41,000 medical personnel
- 18,000 beds
  - 2 hospital ships
  - 63 combat zone hospitals

source: CENTCOM Publications - Commander-in-chief US CENTCOM "Desert Shield/Desert Storm Facts, Figures, Quotes and Anecdotes 7 AUG 90-11 APR 91," prepared by CENTCOM PAO

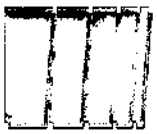
Medical Support

- 27,000 hospitalizations in theater
- 8,000 medical evacuations
- ????? outpatient visits



U.S. Deaths

Non-Battle	224
Battle	148



Symptoms

Tiredness

Rashes

Headaches

Muscle aches

Joint pains

Abdominal pain

Diarrhea

Hair loss

Memory loss

Sleep disturbance

Depression

Concentration problems

Medical Evaluations

- Comprehensive Clinical Evaluation Program (CCEP)

Total Participants	55,883	
Decline examination	15,899	
Examined		39,984
Veterans Affairs Registry -examined		79,710
Total Examined		**119,694**

Source: OASD (Health Affairs) 28 Jul 00 VA Registry 25 Jul 00

Diagnosis Distribution

Categories	CCEP (%)	VA Registry (%)
Healthy	10	12
Symptomatic	90	88
Medically explained	80	80
Medically unexplained	**20**	**20**

Physician Message Sent

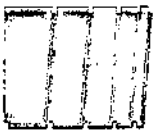
"Your laboratory, x-ray and physical exams results are normal."

Patient Messages Received

"There's nothing wrong with you!"
"It's all in your head!"
"You're faking these symptoms!"

Epidemiology Studies

	Deployed (%)	Non-Deployed (%)
Medical separation (Aug 91 - Dec 93)	2.20	2.56
Hospitalizations (Aug 91 - Sep 93)	21.6	21.6
Hospitalizations unexplained illnesses (Aug 91 - Apr 96)	1.21	1.27
Birth Defects (Aug 91 - Sep 93)	7.45	7.59
Mortality (Aug 91 - Sep 93)	.025	.023



Possible Causes

CHEMICAL WARFARE	BIOLOGICAL WARFARE
PESTICIDES	OIL WELL FIRES
VACCINES	DEPLETED URANIUM
PYRIDOSTIMINE BROMIDE	INFECTIOUS DISEASES
STRESS	COCKTAIL EFFECT

Lessons Learned

CHEMICAL WARFARE

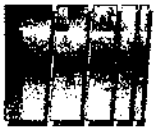
- 14,000 M8 units
- False Positives
- In and out of MOPP, no explanations
- Alarms turned off
- No need to know
- Brain Damage

Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

- Navy Forward Laboratory
- No positive cultures



Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

- DEET, permethrin, organophosphates
- Unapproved items: flea collars, SNIP

Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

- Soot, ash, black cloud
- No information
- EPA monitoring March 91
- Particulates, no toxic fumes

Lessons Learned

CHEMICAL WARFARE

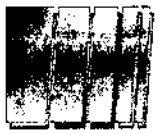
BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

- Vaccines "secret"
- No records
- No explanations
- Squalene



Lessons Learned

CHEMICAL WARFARE

PESTICIDES

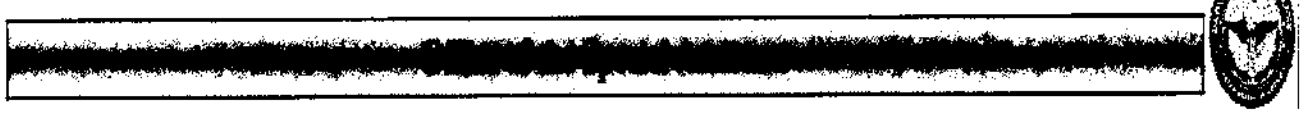
VACCINES

BIOLOGICAL WARFARE

OIL WELL FIRES

DEPLETED URANIUM

- Tank armor, penetrators
- No training
- Heavy metal, proximal tubule
- Surveillance of most exposed



Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

DEPLETED URANIUM

PYRIDOSTIGMINE BROMIDE

- Soman prophylaxis
- Not FDA approved use
- Recognized side effects
- Medical confusion
- No explanations, no records
- Varied protocols

Lessons Learned

CHEMICAL WARFARE

PESTICIDES

VACCINES

PYRIDOSTIGMINE BROMIDE

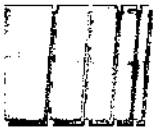
BIOLOGICAL WARFARE

OIL WELL FIRES

DEPLETED URANIUM

INFECTIOUS DISEASES

- 12 malaria, 32 leishmaniasis
- Diarrhea, URI's
- *Mycoplasma fermentans incognitus*



Lessons Learned

CHEMICAL WARFARE

BIOLOGICAL WARFARE

PESTICIDES

OIL WELL FIRES

VACCINES

DEPLETED URANIUM

PYRIDOSTIGMINE BROMIDE

INFECTIOUS DISEASES

STRESS

- NO DoD policy that "stress is the cause of symptoms"
- CNN, communications home
- Uncertainties
- Profiles are stress of chronic disease
- PTSD rate lower than Vietnam
- Stress can amplify already existing symptoms

Lessons Learned

CHEMICAL WARFARE

PESTICIDES

VACCINES

PYRIDOSTIGMINE BROMIDE

STRESS

BIOLOGICAL WARFARE

OIL WELL FIRES

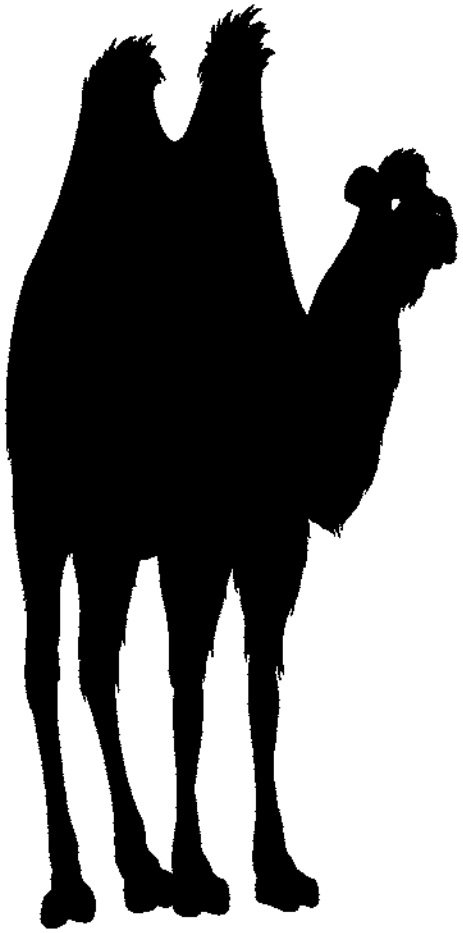
DEPLETED URANIUM

INFECTIOUS DISEASES

COCKTAIL EFFECT

- No scientific evidence yet

THE BLACK CAMEL



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Possible Causes

- Normal disease rate
- New disease paradigm - a Black Camel

Major Lesson Learned from the Gulf War

DoD Does Not Deal Well With Non-Traditional Issues

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Deployments

- Unexpected and rapid personnel movement
- Personal and family hardships
- Stress in the field
  - Missile attacks
  - Chem-bio attacks
  - Witnessing death/atrocities
  - Harsh Living Conditions
  - Foreign cultures
  - Racial/ethnic hatred
- Inadequate communication
- No answers to questions after returning

Force Health Protection

Predeployment

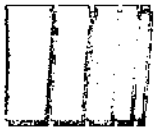
Health Promotion
Immunizations Current
Health Assessment Surveys
Medical Threat Briefing
Environmental Threat

Deployment

Environmental & Medical Surveillance
Food and Water Inspections
Industrial/Occupational Surveillance
Forward Deployed Labs
Host Nation Medical Support
Combat Stress Teams

Post Deployment

Health Assessment Surveys
Medical Debriefings
Medical Surveillance
Risk Communication



Risk Communication

1. Allow Ventilation
2. Determine Underlying Concern
3. Empathy
4. Conclusion Soundbite
5. Facts (2)
6. Next Steps

Art of Medicine

1. Ask open-ended questions
2. Chief complaint
3. Managed similar problems
4. Diagnosis
5. Lab, physical findings
6. Treatment, next appointment

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CONTACT NUMBERS

Department of Defense's - CCEP	800-796-9699
VA Persian Gulf Registry	800-749-8387
Department of Defense's Incident Reporting Line	800-497-6261
GulfLINK	*www.gulflink.osd.mil*

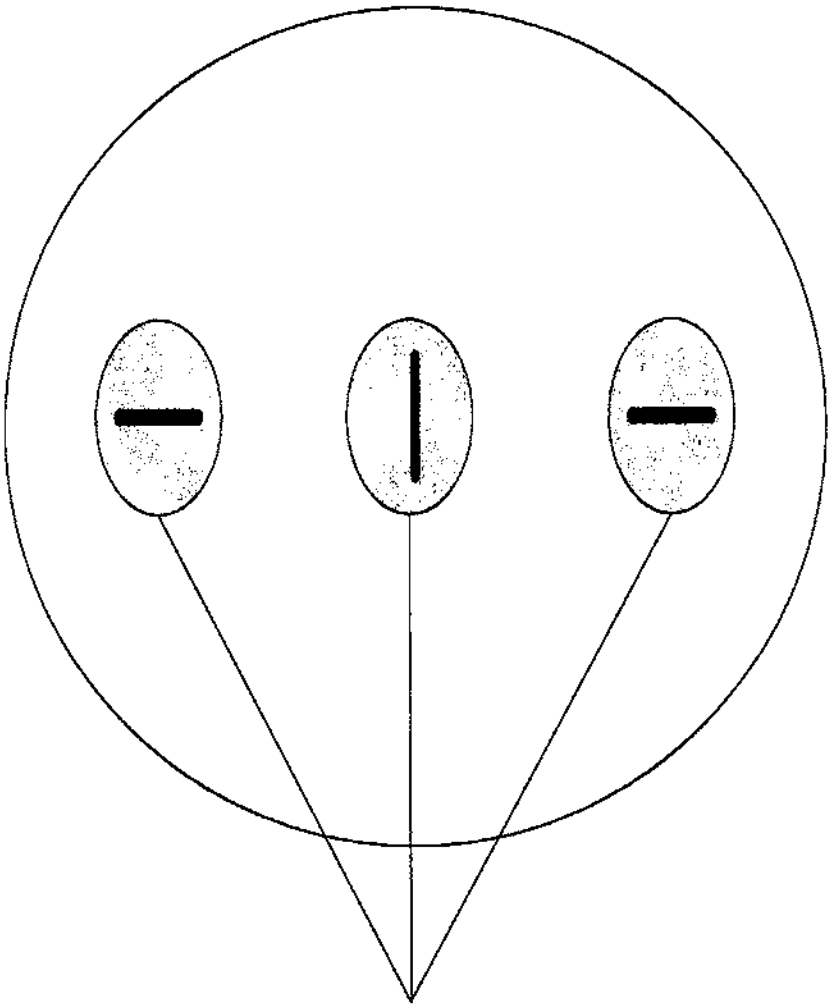
Michael E. Kilpatrick MD, FACP
phone 703-578-8510 fax 703-578-8501
email: mkilpatr@gwillness.osd.mil

Anthrax

- We have a safe and effective vaccine
- Anthrax - an offensive BW agent
  - Inhalation anthrax is highly lethal
  - Easy to develop and weaponize
  - Remains viable for long periods
  - At least seven potential adversaries suspected of researching, developing and/or weaponizing anthrax.

Vaccination against anthrax is critical for your protection

Anthrax Bacteria



Toxins

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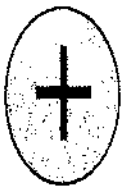
Anthrax Bacteria

Toxin Combination

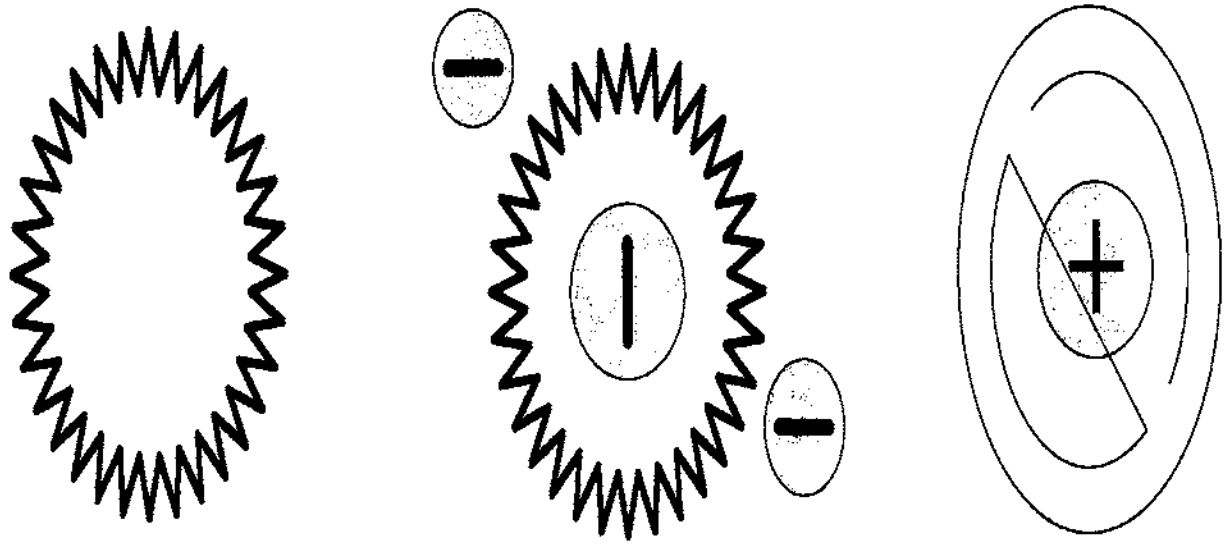
 = **Death**

Anthrax Vaccine

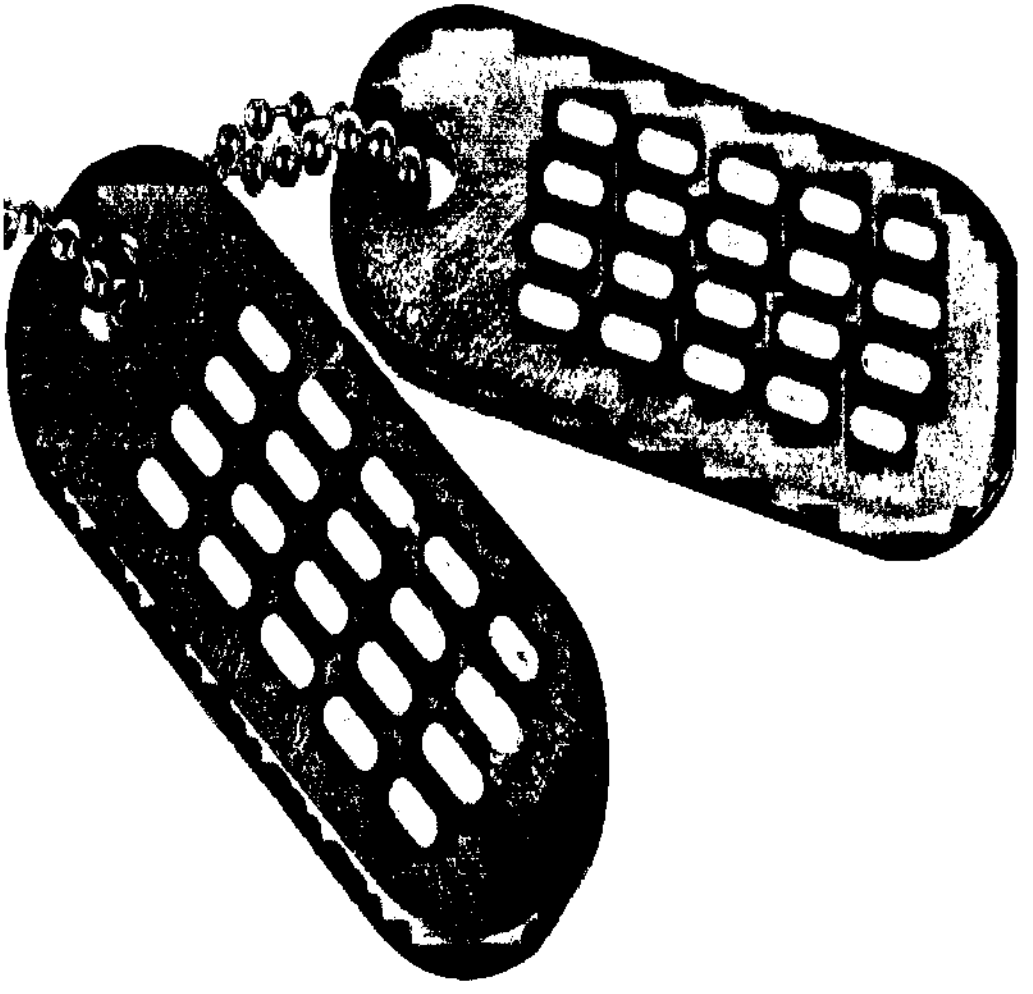
Produces

Attacks Toxin

PROTECTS



Medical Personal Information Center (PIC)



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Where Do We Go From Here?

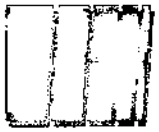
- Concept - Deployment Medicine Clinics
  - Connected to all deployment sites
  - Source for pre and post deployment information
  - Information for family members
- Concept - Education on Vaccines
  - Start updating electronic record entrance
  - Validate accuracy with leave/bonus requests
  - Internet linkage to CDC for recommendations
- Concept - ????

Understanding Today's Military Member

- 55% are married
- 46% have children
- 40% of the 1.3 million children are < 6 years old
- 6% are single parents
- 8% care for elder parents
- 14% are women

Concerns of the Deployed Member

- Importance of the mission
- Recognition by others of his/her role
- Ability to express fears/concerns/problems to leadership
- Recognition for performance



Successful Mission

- Knew why I was there and agreed
- Knew what to do
- Knew how to do it
- Had what I needed to do it
- Did it well
- Was appreciated for my contribution
- Returned proud I had been there

Office of the Special Assistant to the Secretary of Defense

for Gulf War Illnesses, Medical Readiness, Military Deployments

(800) 497-6261 fax 703-578-8501
email: brostker@gwillness.osd.mil

Briefing Overview

- Mission Statement
- The Gulf War
- Searching for answers
- Lessons Learned
- Force Health Protection
- Bottom Line
- Obtaining help and information

Vision of the Special Assistant for Gulf War Illnesses, Medical Readiness, and Military Deployments

- The Department of Defense recognizes the right of those involved in deployments to receive information that enables them to make informed decisions about their health.
- We will develop and disseminate such information in a relevant and timely fashion.
- We will work with others in the Defense Department to incorporate lessons from previous deployments to foster the well-being of deployed forces.

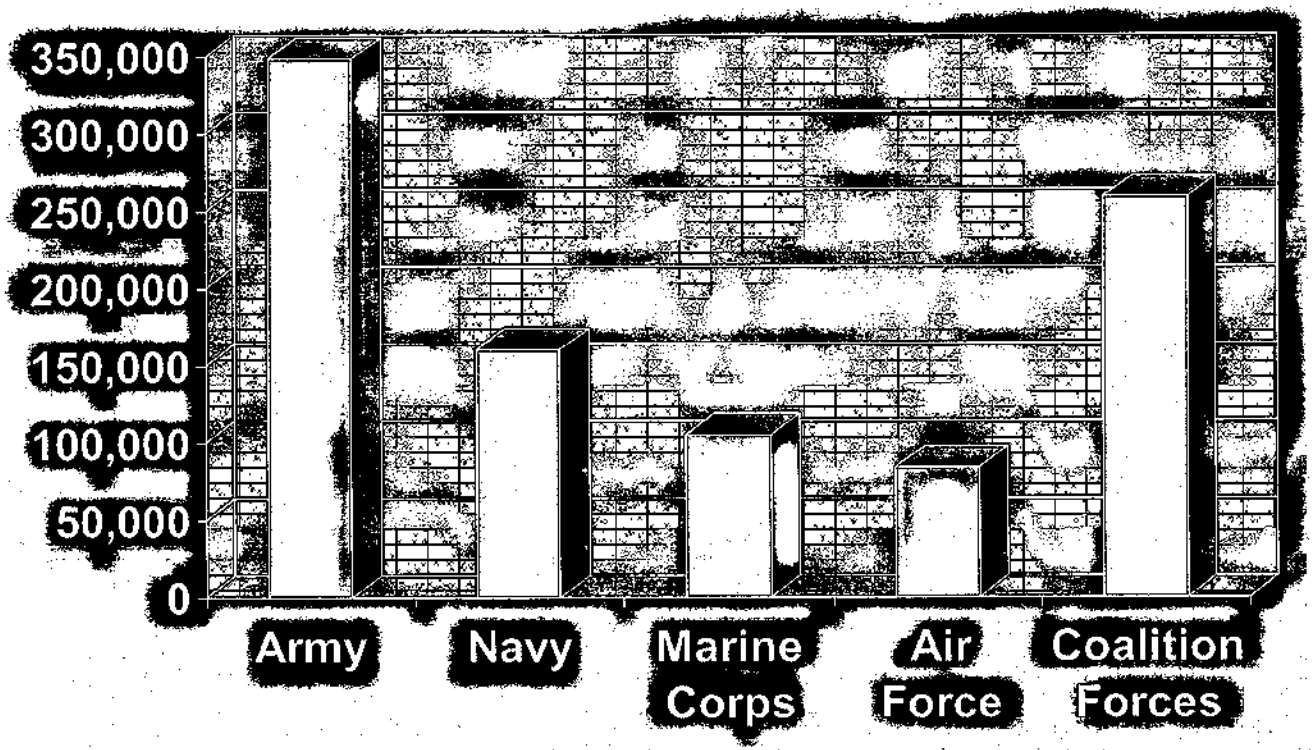
Gulf War Illnesses Mission

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate to understand and explain illnesses in Gulf War veterans
- Ensure DoD adopts doctrine, policy and procedures to reduce health risks for troops deploying now and in the future

Why Should I Care

- Lessons from the Gulf War about dirty battlefields
- You must protect yourself against hazards
- Deployment leadership is everyone's responsibility
- Help is available

Gulf War Theater Forces



697,000 U.S. service members

1 in 7 Veterans Reported Symptoms Since the War

Most frequently reported symptoms

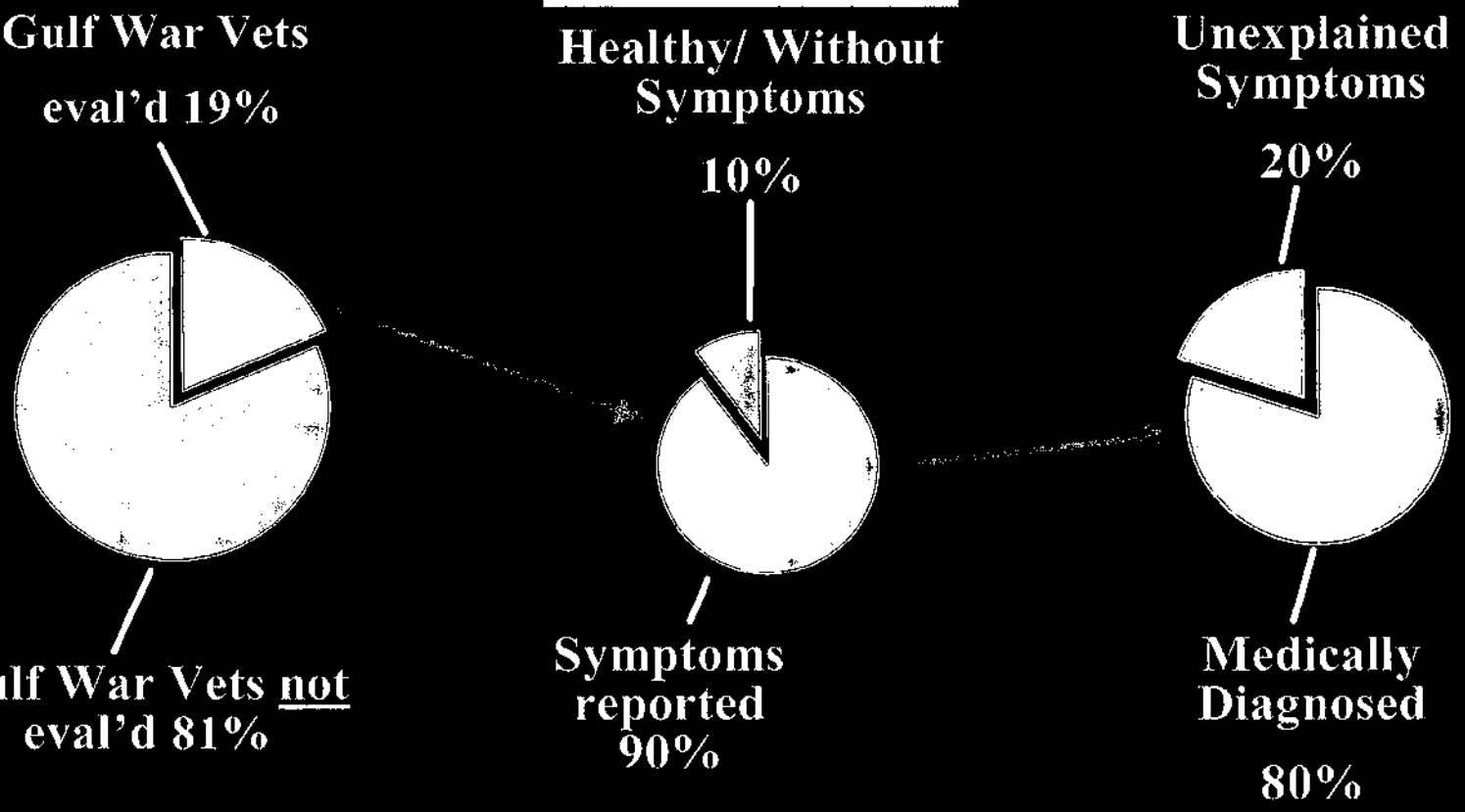
- **Joint pain**
- **Headaches**
- **Sleep disorders**
- **Depression**
- **Fatigue**
- **Memory loss**
- **Rash**
- **Muscle pain**

Taking Care of Service Members

- DoD Comprehensive Clinical Evaluation Program
  - Gulf War vets (active, Guard/Reserve, retired)
  - Active service member deployed to SWA since war ended
  - Family members
- VA Persian Gulf Registry
  - Gulf War vets (left service prior to retirement)
  - Service members deployed to SWA and left service before retirement
  - Evaluation for family members
- Available to *all* service members deploying to South West Asia
  - Most people evaluated can be treated

Evaluation Distribution of 697,000

CCEP/VA



Don't Tough It Out

OSAGWI Investigations

- Chemical/biological warfare:
  - Chemical warfare agent - Khamisiyah incident
    - 99,000 vets notified
- Environmental:
  - Depleted uranium (DU), Oil well fires, Pesticides
    - Science doesn't support DU or Oil Well fires as causes.
    - Still examining particulates and pesticides
- Medical issues:
  - Vaccines, PB, records, policy
- Scientific research under PGVCB
  - > 180 studies sponsored by DoD, DVA, & HHS
  - No cause and effect relationship so far

A New Reality =
The Dirty Battlefield

- What enemy may do to us
  - Chemical/Bio threat, man-made environmental hazards (oil well fires)
- What the environment may do to us
  - Infectious diseases, insects, environmental risks (desert, jungle)
- What we may do to ourselves
  - Accidents, pesticides, investigational new drugs, PB

Current and future conflicts and humanitarian deployments have and will have these challenges

Investigation Results

- Gulf War
  - No offensive CW/BW use
  - Not enough vaccines and no explanation given
  - Limited environmental survey
  - Information about nerve agent pre-treatment (PB) wasn't given to troops
  - Inadequate training
  - *Veterans re-deployed and left service without thorough medical exam or debrief*

Applying Lessons Learned

- Train self and others to recognize and avoid hazards
- Monitor service member's health & environment
- Improve feedback and cross talk
- Know your equipment strengths and weaknesses
- Create, relate and save operational, NBC, and medical records
- Adapt to reduce risks and train to reduce future risks such as DU

Force Health Protection

Pre-deployment

- Verify DNA sample on file
- Collect pre-deployment blood sample
- Verify HIV test is current
- Verify Immunizations up to date
- Verify current physical exam
- Complete Health questionnaire

Deployment

- Routine disease/injury reporting
- Forward medical laboratory
- Immunization tracking
- Environmental monitoring

Post Deployment

- Collect blood sample
- Medical debriefs
- Complete health questionnaire
- Screening exams as needed

You are your own best health advocate!

Anthrax

- Anthrax - an offensive BW agent
  - Inhalation anthrax is highly lethal
  - Easy to develop and weaponize
  - Remains viable for long periods
  - At least seven potential adversaries suspected of researching, developing and/or weaponizing anthrax.
- We have a safe and effective vaccine

Vaccination against anthrax is critical for your protection

Anthrax Vaccine Program

- Licensed by the FDA since 1970
- Dosing schedule is six doses over 18 months
  - 0, 2, 4 weeks, 6, 12, 18 months, plus annual booster
- Shortages in stockpiled doses require temporary slowdown of AVIP
  - No new vaccine available from renovated facility until FDA approves BioPort's license application
  - Vaccinations continue for service members assigned or deployed at least 30 days in highest threat areas
  - Next scheduled doses for those not in high threat areas will be deferred until sufficient doses are available

(877) GET-VACC DSN: 761-5101

www.anthrax.osd.mil

www.aviationmedicine.com

Pyridostigmine Bromide

- Threat - Soman is deadly nerve agent
- PB is the only known pretreatment against Soman.
  - Auto injectors alone will not save you
- Issues have been raised about PB
  - Further research is ongoing
- Only President can authorize its use without informed consent

DU Exposure Issues

- Radiation
- Consequences of exposure
- Heavy metal toxicity
- Reproductive effect
- Contamination of theater

Bottom Line

- You will deploy on missions to dirty areas
- Everyone is responsible for force protection
- Lessons learned from the Gulf War affect today's doctrine and deployments
- You are your own best health advocate
- Don't tough it out; get examined

Obtaining help and information

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- Comprehensive Clinical Evaluation Program
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http://www.gulflink.osd.mil

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Myths versus Reality

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Not listening	Solicit eyewitness reports
Destroy records	Found missing records
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No assistance to vets	Evaluation and care
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CW or DU cause	Many possible causes
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	Tough choices
	Cultural changes

A National Effort

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- **INVESTIGATIONS:** IGs, GAO, SIU
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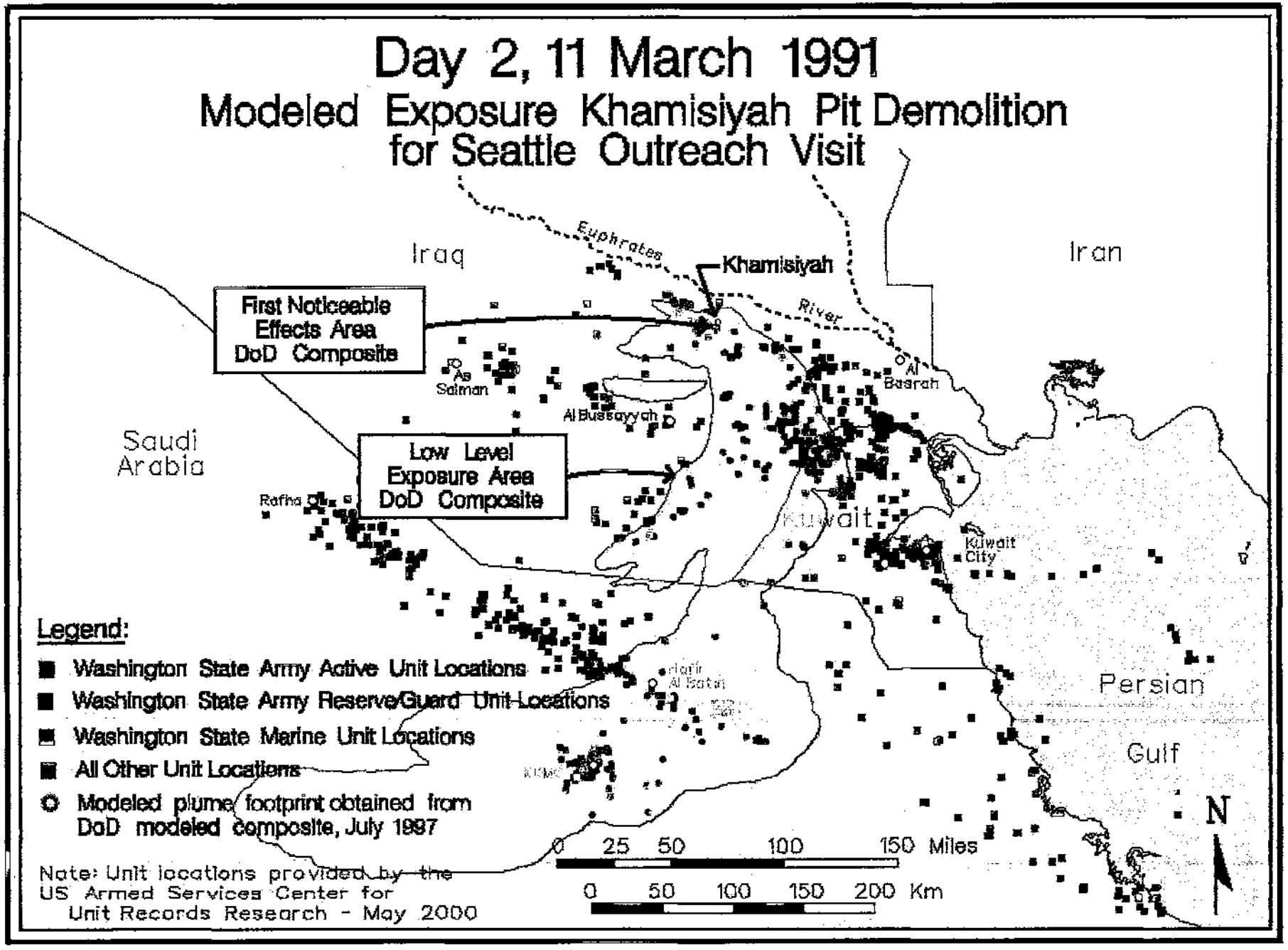
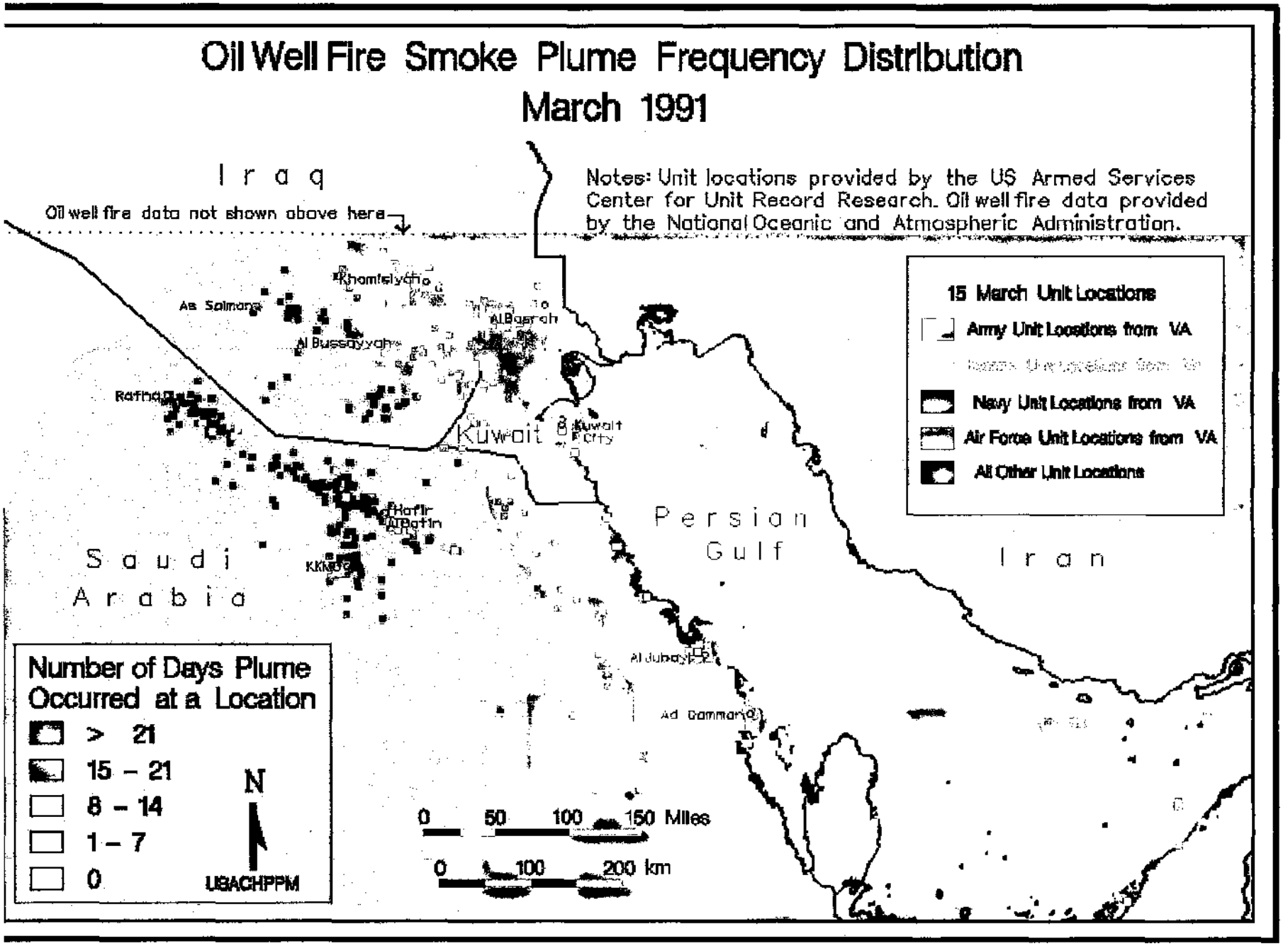
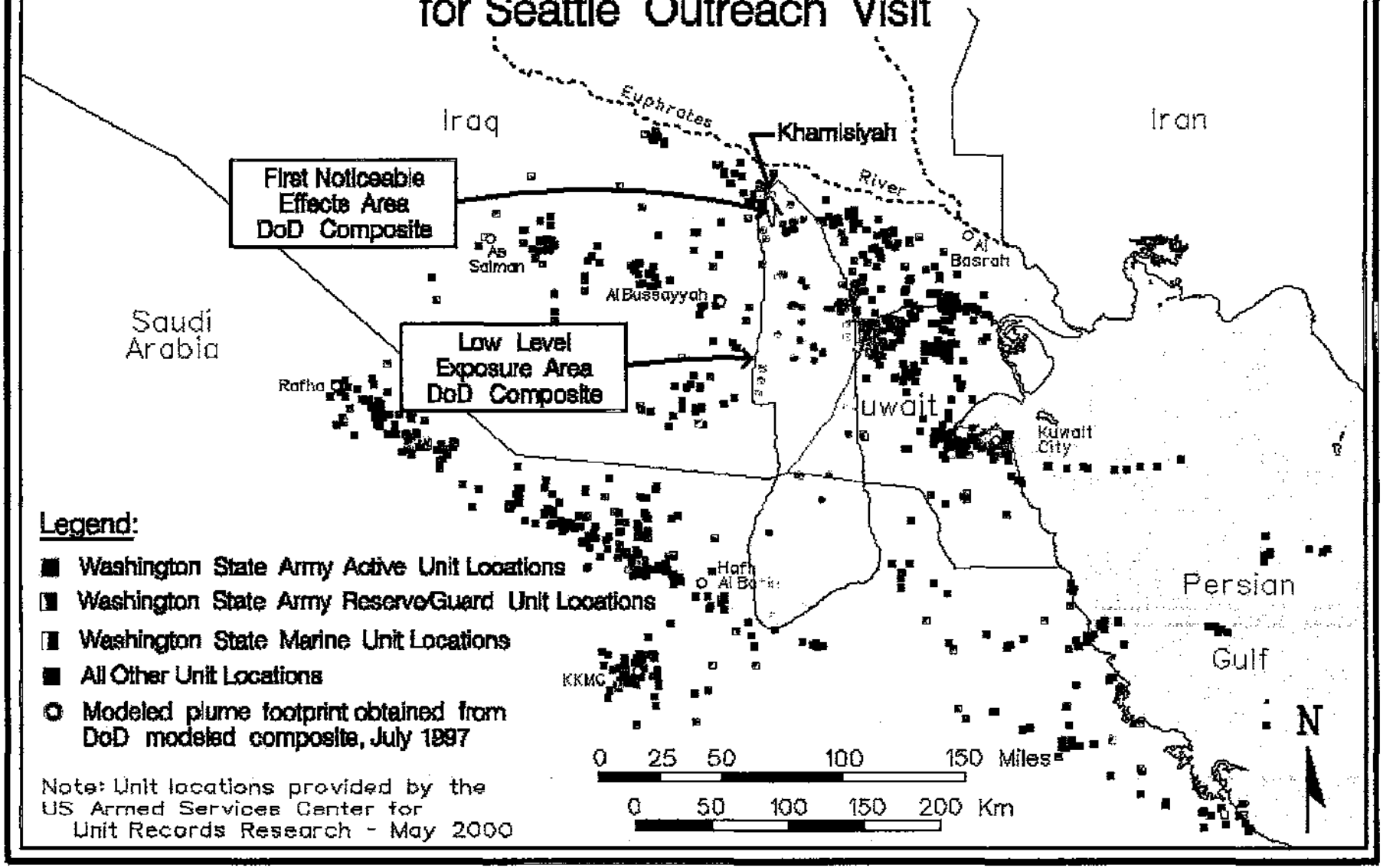

Day 2, 11 March 1991
Modeled Exposure Khamisiyah Pit Demolition
for Seattle Outreach Visit
Iraq
Iran
Euphrates River
Khamisiyah
First Noticeable Effects Area DoD Composite
As Salman
Al Busayyah
Al Basrah
Saudi Arabia
Low Level Exposure Area DoD Composite
Rafha
Kuwait
Kuwait City
Persian Gulf
Legend:
Washington State Army Active Unit Locations
Washington State Army Reserve/Guard Unit Locations
Washington State Marine Unit Locations
All Other Unit Locations
Modeled plume footprint obtained from DoD modeled composite, July 1997
Note: Unit locations provided by the US Armed Services Center for Unit Records Research - May 2000
0 25 50 100 150 Miles
0 50 100 150 200 Km
N


Oil Well Fire Smoke Plume Frequency Distribution
March 1991
Iraq
Oil well fire data not shown above here
Notes: Unit locations provided by the US Armed Services Center for Unit Record Research. Oil well fire data provided by the National Oceanic and Atmospheric Administration.
15 March Unit Locations
Army Unit Locations from VA
Navy Unit Locations from VA
Air Force Unit Locations from VA
All Other Unit Locations
Kuwait
Kuwait City
Persian Gulf
Iran
Saudi Arabia
As Salmani
Al Bussayyah
Al Basrah
Hafir Al Batin
Al Jubayl
Ad Dammam
Number of Days Plume Occurred at a Location
> 21
15 – 21
8 – 14
1 – 7
0
N
0 50 100 150 Miles
0 100 200 km
UBACHPPM

Day 1, 10 March 1991

Modeled Exposure Khamisiyah Pit Demolition for Seattle Outreach Visit



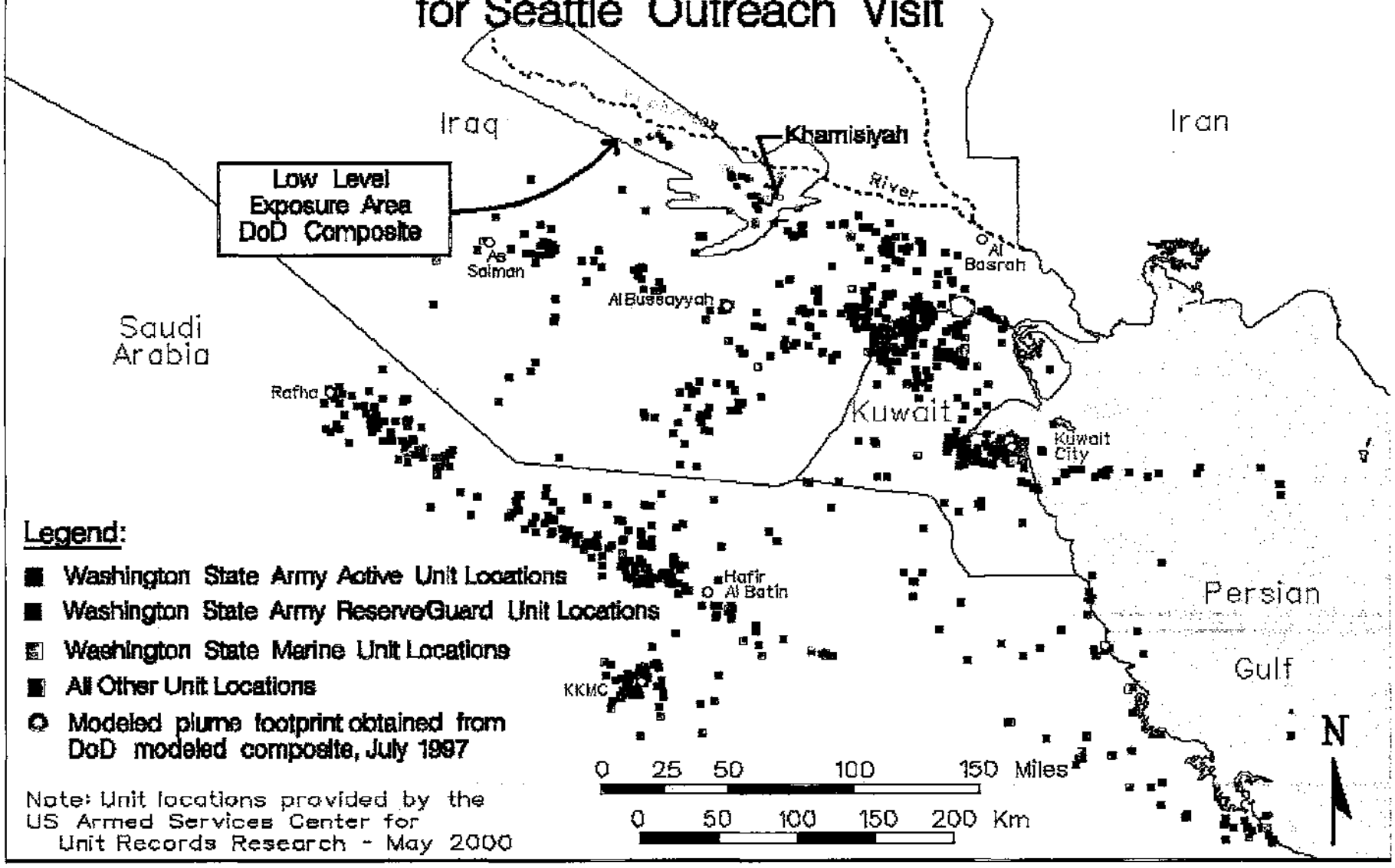
Legend:

- Washington State Army Active Unit Locations
- Washington State Army Reserve/Guard Unit Locations
- Washington State Marine Unit Locations
- All Other Unit Locations
- Modeled plume footprint obtained from DoD modeled composite, July 1997

Note: Unit locations provided by the US Armed Services Center for Unit Records Research - May 2000

Day 3, 12 March 1991

Modeled Exposure Khamisiyah Pit Demolition for Seattle Outreach Visit



Legend:

- Washington State Army Active Unit Locations
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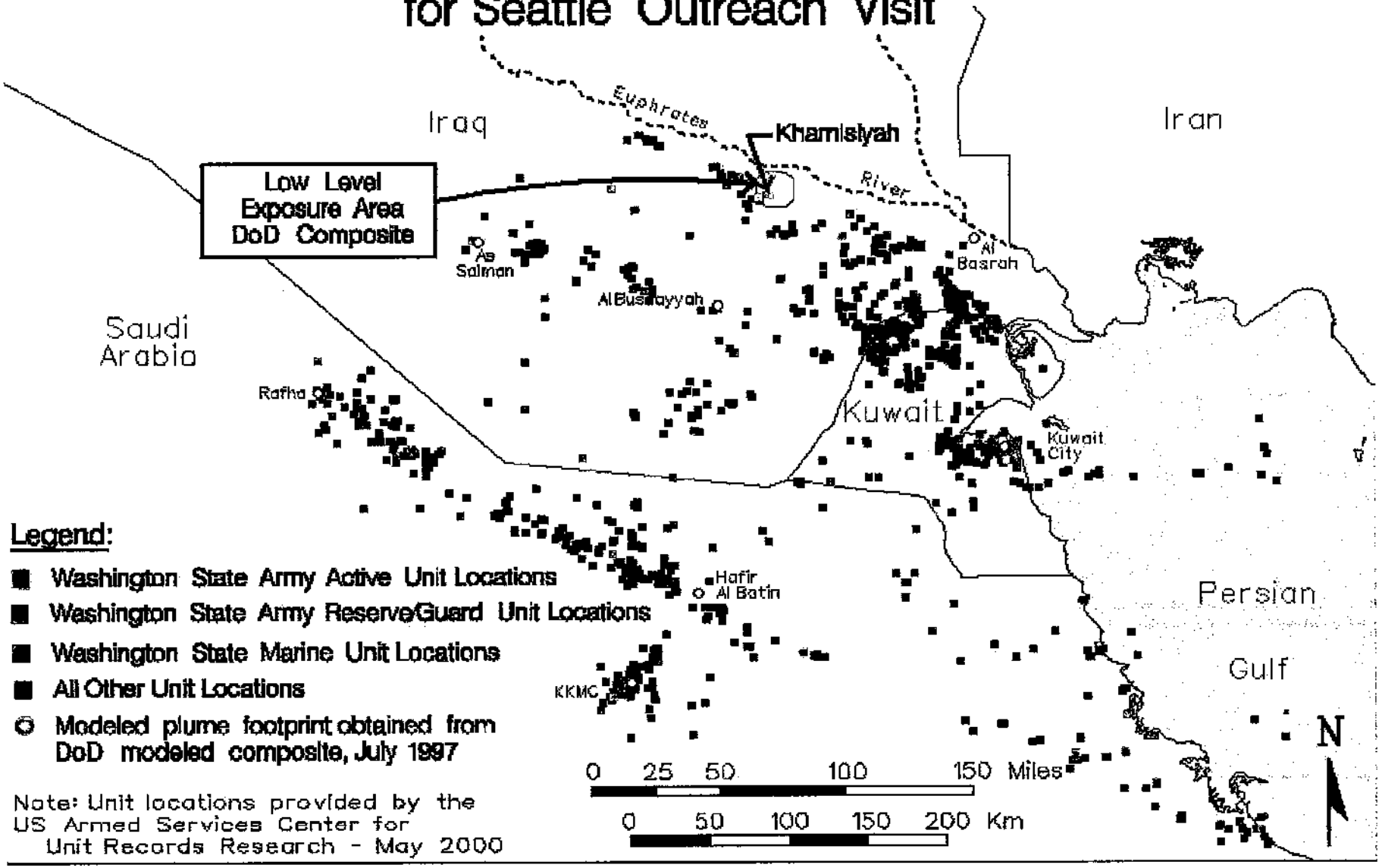
- Washington State Marine Unit Locations
- All Other Unit Locations
- Modeled plume footprint obtained from DoD modeled composite, July 1997

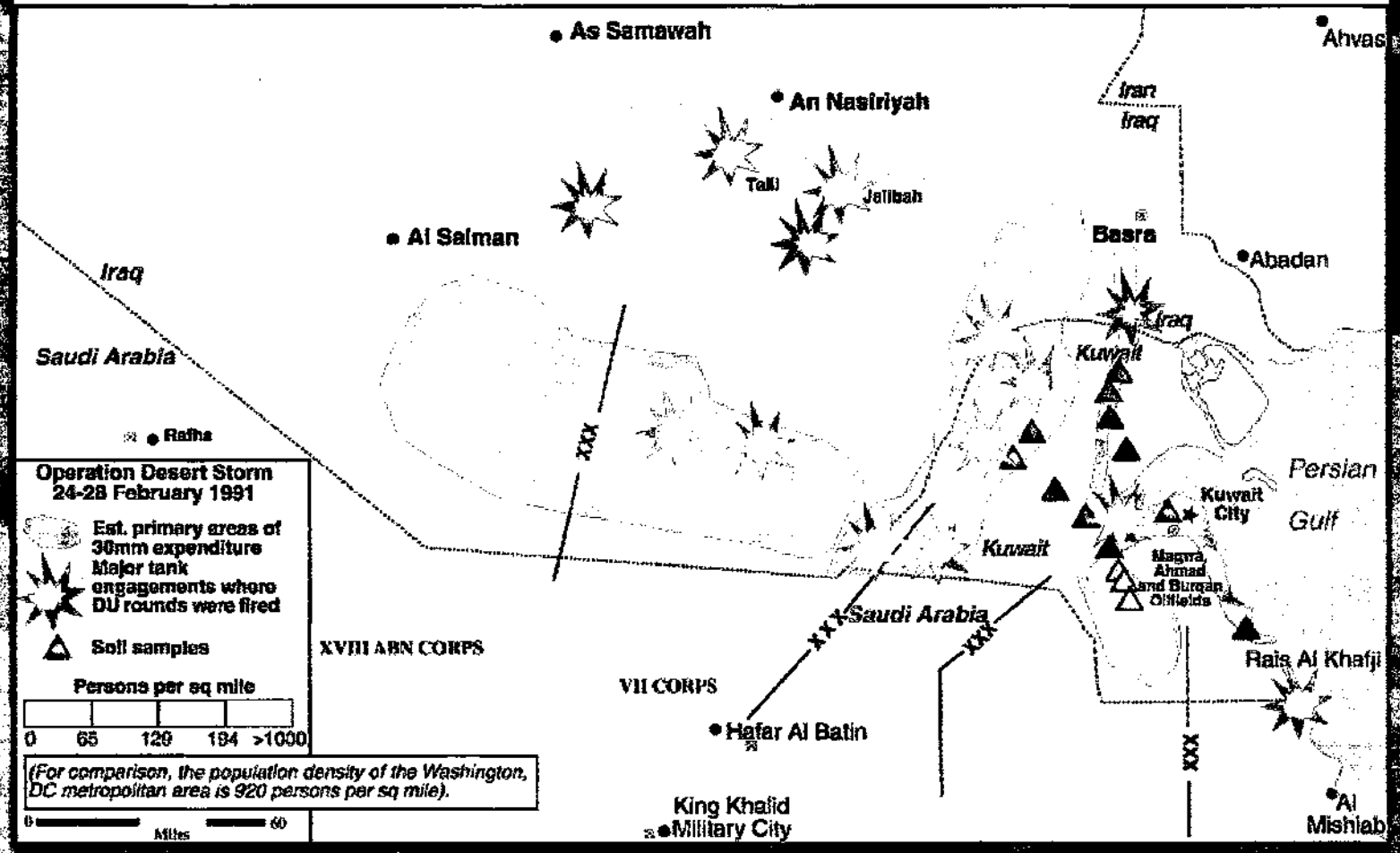
Note: Unit locations provided by the US Armed Services Center for Unit Records Research - May 2000

Day 4, 13 March 1991

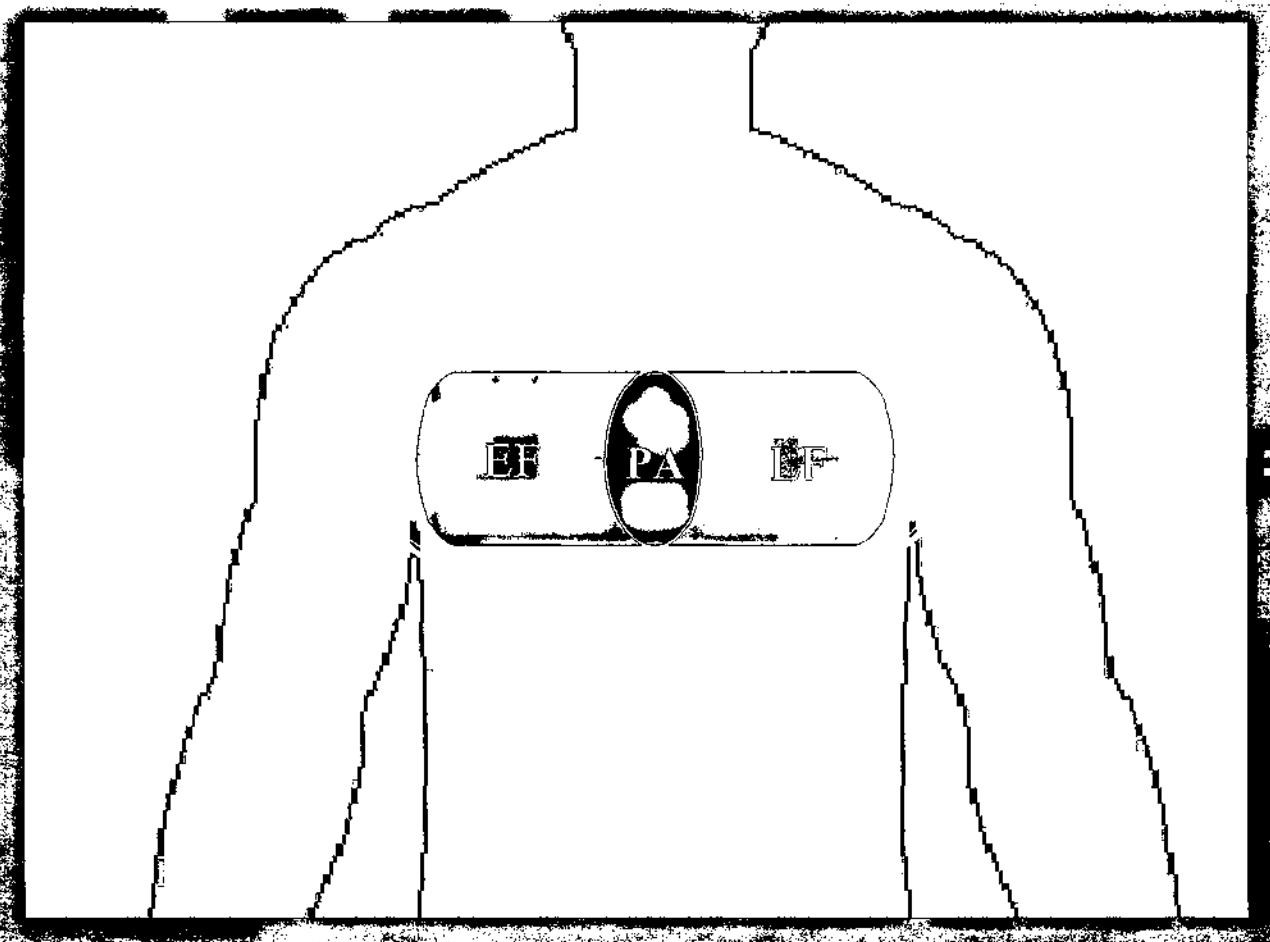
Modeled Exposure Khamisiyah Pit Demolition for Seattle Outreach Visit



Primary Areas of DU Expenditure



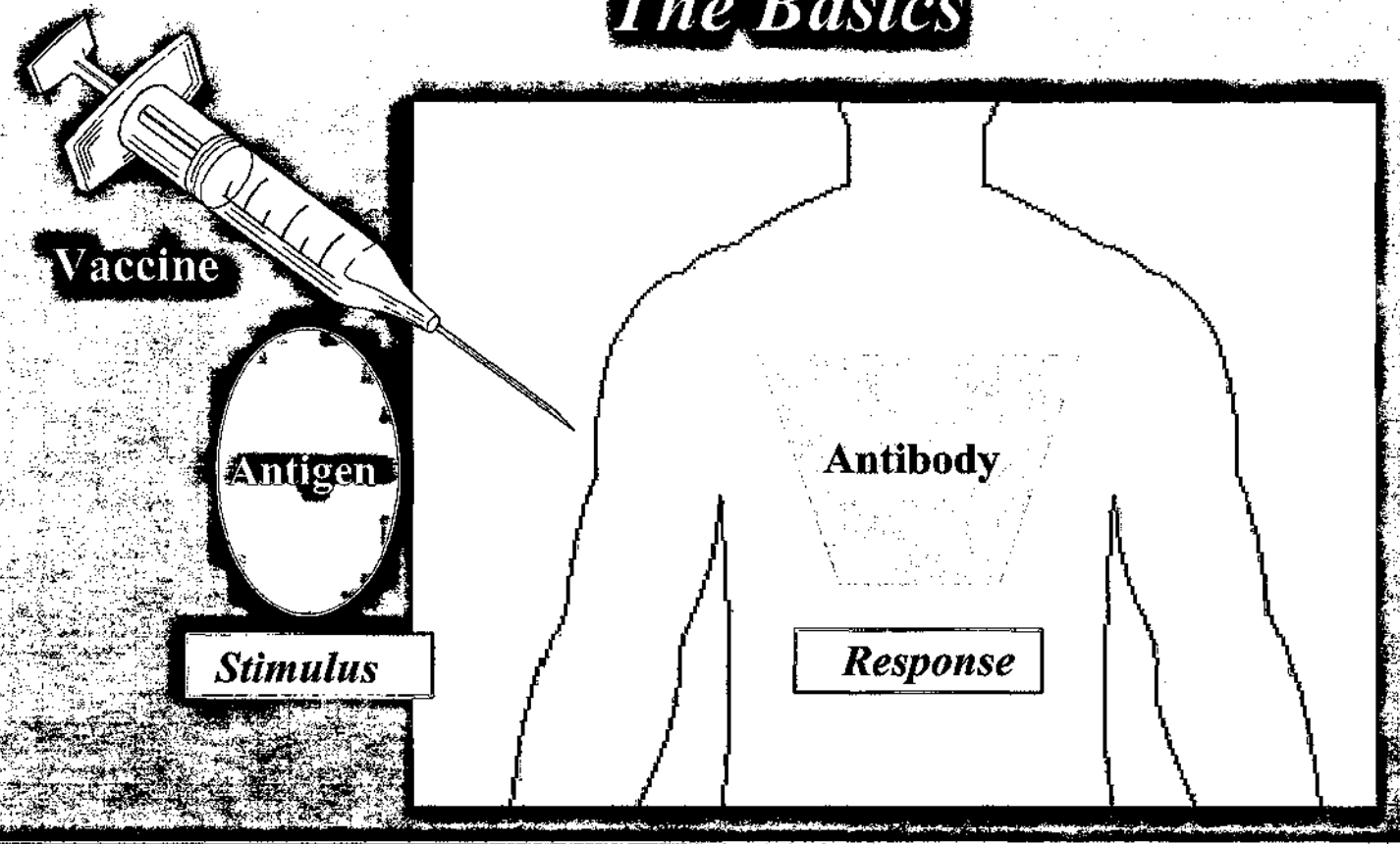
ANTHRAX BACTERIA ATTACK



= Death

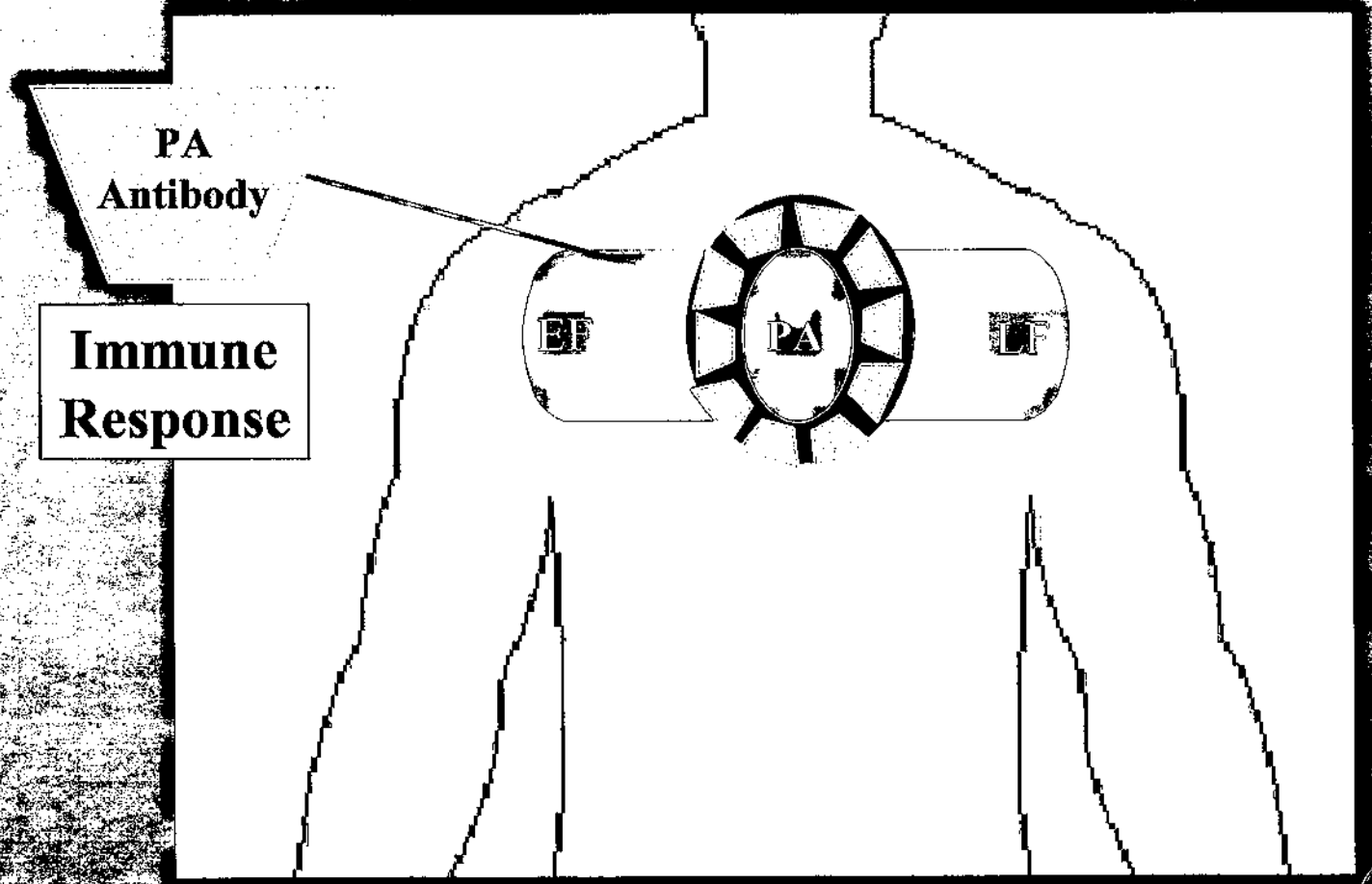
IMMUNE SYSTEM ACTIVATION BY VACCINE

The Basics



AFTER ANTHRAX VACCINE

Antibodies at Work



Gulf War Theater

- August 1990 to July 1991
- 697,000 US service members
- More then 27,000 hospitalizations
- 148 battle deaths
- 224 non-battle deaths

Confounding Issues for Doctors

- No clustering
- No symptom consistency; variable onset
- No new disease or links between exposures and symptoms
- No long term study

Doctor – Patient – Government Communication Breakdown

- Veterans with real health problems
- Healthcare professionals unable to provide answers
- Government slow to recognize the reality of problems

Need for SAMD

- DoD slow to recognize Agent Orange, GW Illnesses.
- DoD learned when vets talk, we should listen.
- DoD obligation to take care of serving veterans.
- DoD must learn what causes vets' symptoms
- DoD determined to learn lessons so it never happens again.

Conclusions about PB

- We cannot rule out pyridostigmine bromide as a contributor to increased health symptoms in Gulf War veterans.
- Further research is needed to determine the effectiveness of the current dose of PB against Soman.
- Additional research about safety and effectiveness of PB for humans is urgently needed.

Office of the Special Assistant to the Secretary of Defense

for Gulf War Illnesses, Medical Readiness, and Military Deployments

(703) 497-6261 fax (703) 578-8501

email: brostker@gwillness.osd.mil

(171)

Briefing Overview

- Mission Statement
- The Gulf War
- Searching for Answers
- Lessons Learned
- Force Health Protection
- Bottom Line
- Obtaining Help and Information

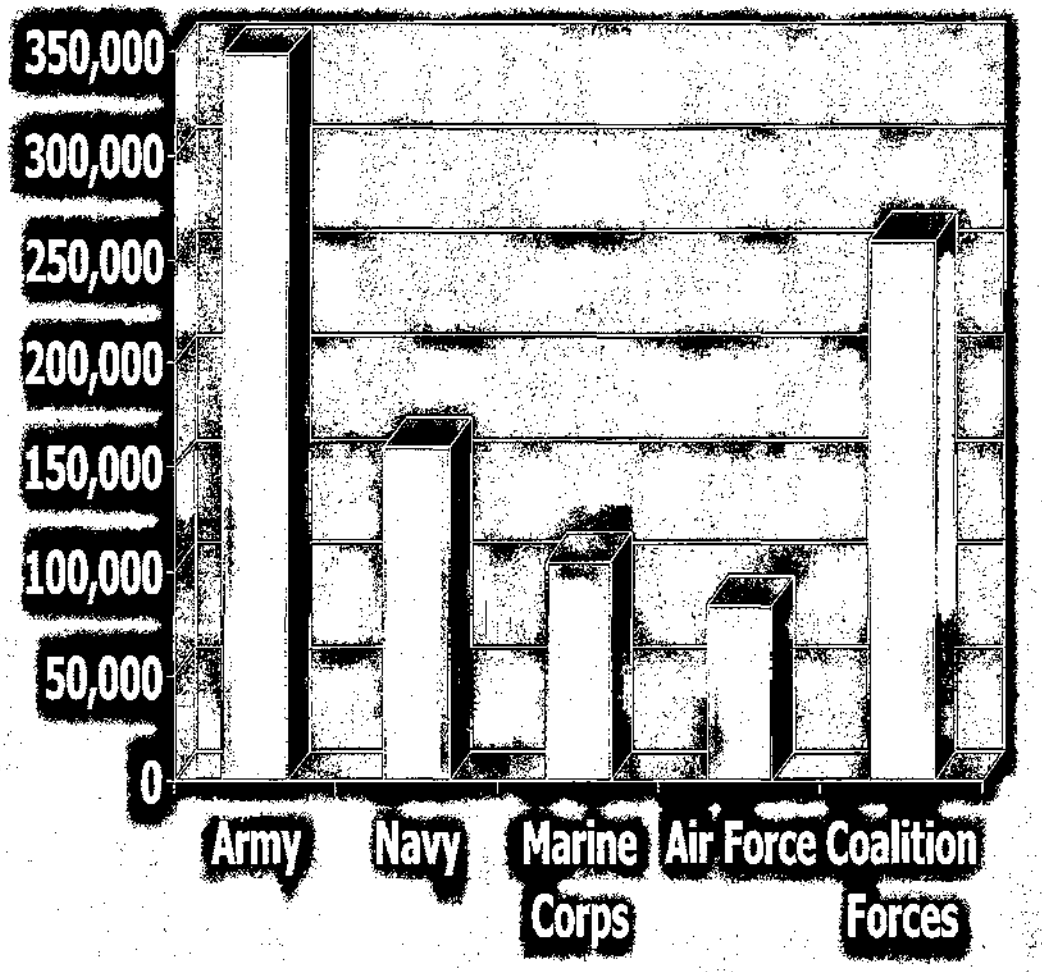
Our Mission

- Ensure Gulf War veterans are properly cared for: "people are our first concern"
- Investigate and explain illnesses in Gulf War veterans
- Ensure DOD adopts doctrine, policy and procedures to reduce health risks for troops deploying now and in the future

Vision of the Special Assistant for Gulf War Illnesses, Medical Readiness, and Military Deployments

- The Department of Defense recognizes the right of those involved in deployments to receive information that enables them to make informed decisions about their health
- We will develop and disseminate such information in a relevant and timely fashion
- We will work with others in the Defense Department to incorporate lessons from previous deployments to foster the well-being of deployed forces

Gulf War Theater Forces



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Office of the Special Assistant

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1 in 7 Veterans Reported Symptoms Since the War

Most frequently reported symptoms

- Joint pain
- Headaches
- Sleep disorders
- Depression
- Fatigue
- Memory loss
- Rash
- Muscle pain

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Taking Care of Service Members

- DoD Comprehensive Clinical Evaluation Program
  - Gulf War vets (active, Guard/Reserve, retired)
  - Active service member deployed to SWA since war ended
  - Family members
  - DOD civilians
- VA Persian Gulf Registry
  - Gulf War vets (left service prior to retirement)
  - Service members deployed to SWA and left service before retirement
  - Evaluation for family members
- Available to *all* service members deploying to South West Asia

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Force Health Protection

- Pre-deployment
  - Medical screening/surveillance and briefings
- Deployment
  - Record keeping
  - Monitor environment and personnel
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- Inhalation anthrax is deadly
- Biological warfare agent of choice:
  - Cheap and easy to produce
  - Can be dispersed in air by a variety of weapons
  - Odorless, colorless, tasteless, difficult to detect
  - Flu-like symptoms early, rapid deterioration, and death
- MOPP 4 prevents exposure
- Antibiotics work before symptoms appear

Vaccination against anthrax is critical for your protection

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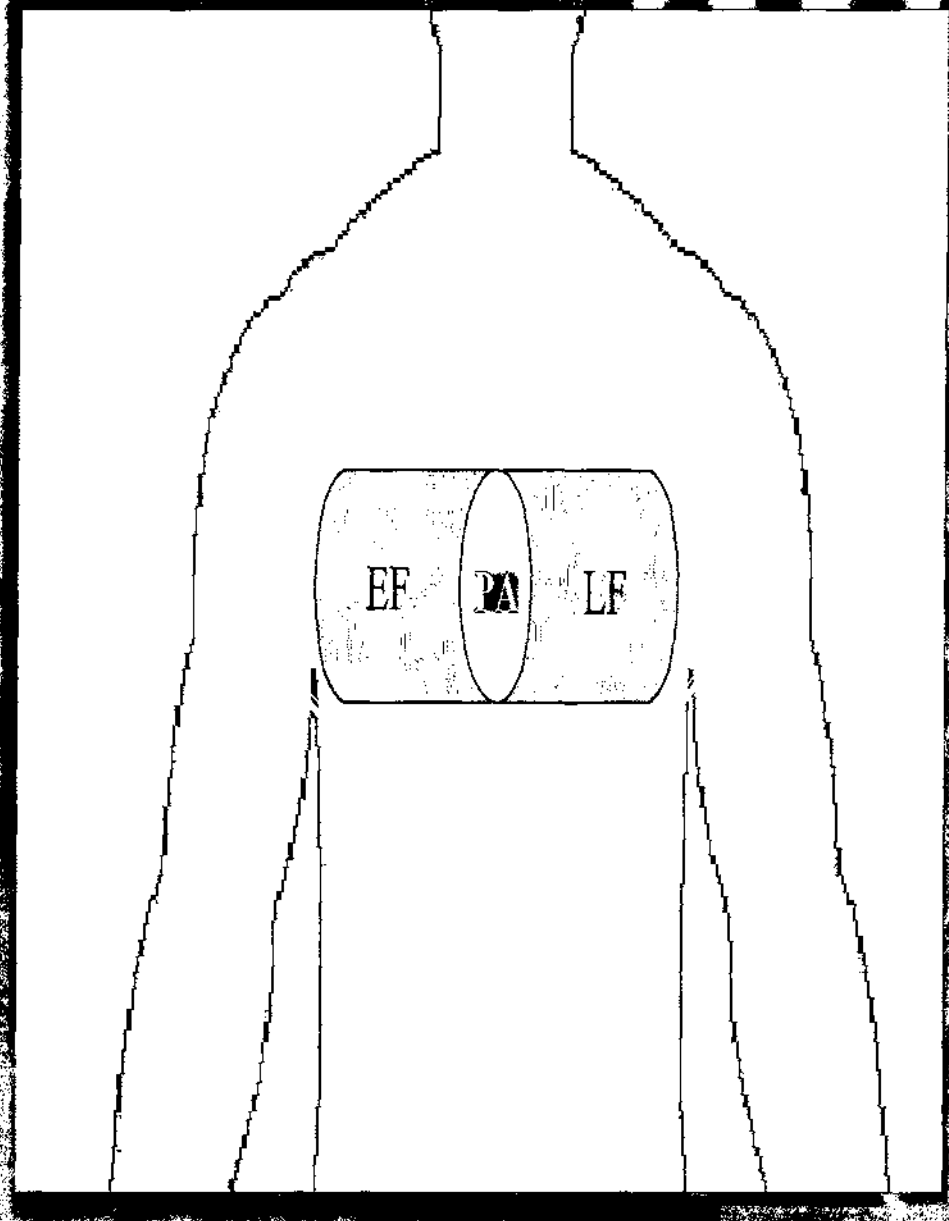

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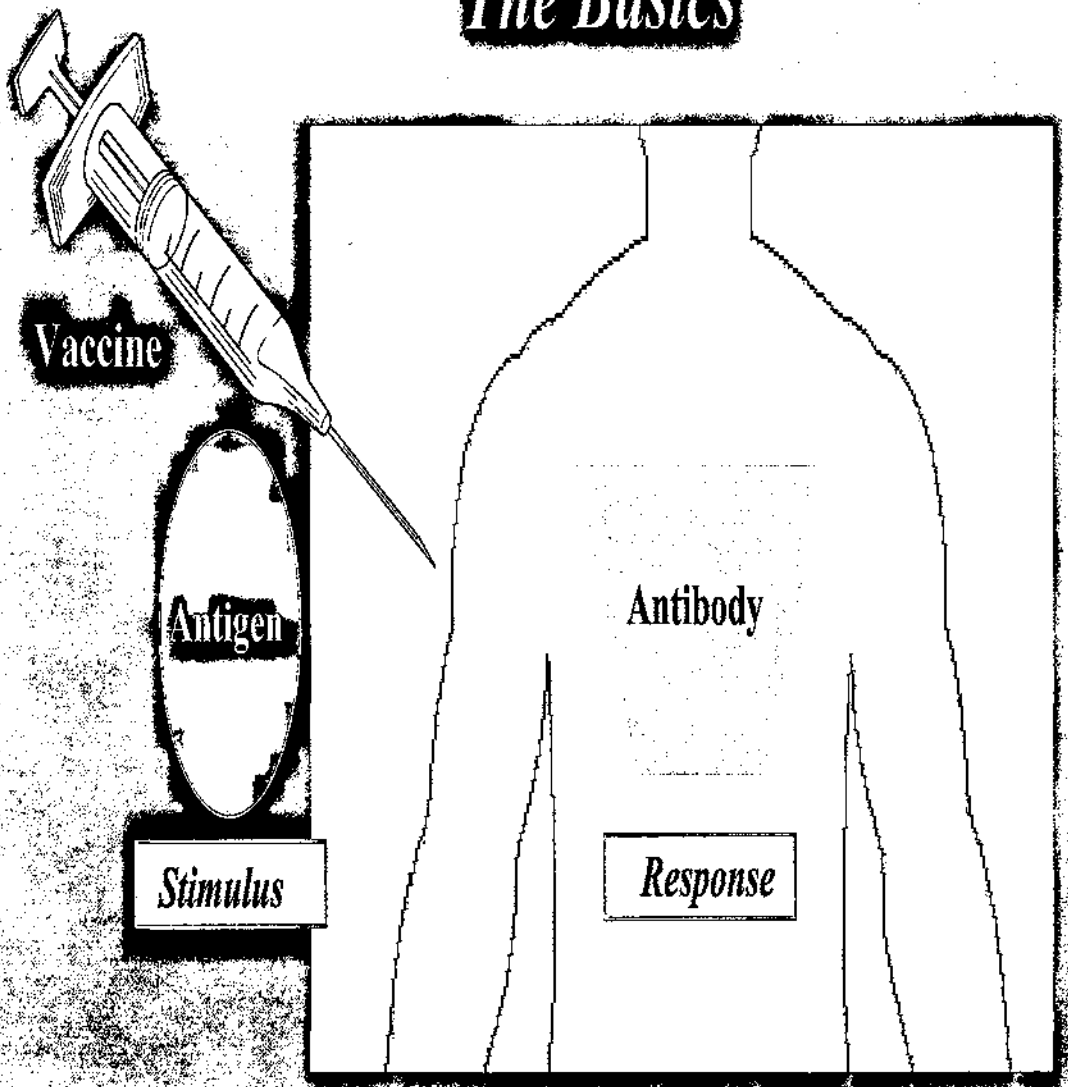

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