



REPLY TO
ATTENTION OF

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258



AFEB

AUG 12 2002

MEMORANDUM FOR

The Assistant Secretary of Defense (Health Affairs)
The Surgeon General, Department of The Army
The Surgeon General, Department of The Navy
The Surgeon General, Department of The Air Force

SUBJECT: Therapeutics Against Biowarfare Agents - 2002-09

1. References:

- a. Memorandum, OASD(HA)/FHP&R, 13 March 2002, Therapeutics Against Biowarfare Agents.
- b. Memorandum, AFEB 00-09, 3 Aug 2000, Antibiotics Against Biowarfare Agents.
- c. Department of Defense Directive 6205.3, "Use Of Investigational New Drugs For Force Health Protection," dated August 1, 2000.

2. The Armed Forces Epidemiological Board (AFEB) annually provides recommendations to the Assistant Secretary of Defense for Health Affairs and the DoD Executive Agent on vaccines and immunization protocols necessary to enhance protection against validated biological warfare threat agents. On March 13, 2002 the AFEB was requested as part of this requirement to also review existing Joint Operational Requirement Documents, progress on specific efforts to obtain new indications for existing therapeutics, and acquisition status of biologics (treatment and prophylaxis) against the current prioritized list of biowarfare agents and finally, to make recommendations on the current status of requirements and suggested priorities.

3. On 21 and 22 May 2002 the AFEB met to consider the biological threat agents designated by the Chairman of the Joint Chiefs of Staff. The Board received briefings on the current intelligence based biological warfare threat, the Medical Biological Defense Research Program, the Joint Vaccine Acquisition Program, and a Medical Requirements Review from the Joint Service Integration Group of the Chemical and Biological (CB) Defense Program. The Board noted that the current intelligence based biological warfare threat list had not been formally validated by the Chairman of the Joint Chiefs of Staff.

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4. The AFEB has previously made recommendations on the most appropriate antibiotics to be used for treatment and prevention of illnesses from biowarfare agents. Some of the antibiotics recommended were not labeled for these indications, thus potentially requiring their use as an investigational new drug (IND) under a protocol which would require written informed consent. Upon making these recommendations, the Board felt that the labeling status should not be a determining factor if there was a clear best option based on other criteria. However, the Board does recognize that it may not be feasible from an operational, logistical, or combat readiness point of view to use drugs under an IND status and the preference is for use of an approved and labeled product whenever possible.

5. To assist with review of the available products, either approved or labeled, as an IND with or without a protocol, or under research and development, the Board worked with the Military Services and produced a matrix listing available vaccines and therapeutics. The recommendations on vaccines, antibiotics and therapeutics are based on this rank ordered matrix. From this review and cognizant of the questions posed to the Board, the Board makes the following findings and recommendations:

a. NO JOINT OPERATIONAL REQUIREMENT DOCUMENTS CURRENTLY EXIST WITH THE GOAL OF OBTAINING NEEDED NEW INDICATIONS FOR EXISTING THERAPEUTICS FOR TREATMENT OR PROPHYLAXIS AGAINST BIOWARFARE AGENTS.

b. OTHER THAN FOR ANTHRAX, LITTLE TO NO PROGRESS HAS BEEN MADE IN OBTAINING NEW INDICATIONS FOR EXISTING THERAPEUTICS.

c. THE ACQUISITION STATUS OF BIOLOGICS (FOR TREATMENT OR PROPHYLAXIS) AGAINST THE CURRENT PRIORITIZED LIST OF BIOWARFARE AGENTS IS FOCUSED EXCLUSIVELY ON VACCINES, WITH TIMELINES FOR AVAILABLE APPROVED AND LABELED PRODUCTS PROJECTED SEVERAL YEARS IN THE FUTURE.

d. THE DOD SHOULD VIGOROUSLY PURSUE EFFORTS TO DEVELOP FDA APPROVED VACCINES AGAINST THE VALIDATED BIOWARFARE AGENTS.

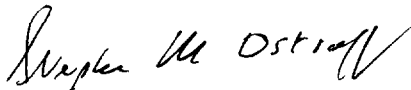
e. RECOGNIZING THE EXTENDED GAP IN THE AVAILABILITY OF APPROVED VACCINES AGAINST BIOWARFARE AGENTS, THE DOD SHOULD INITIATE IMMEDIATE DEVELOPMENT OF JOINT OPERATIONAL REQUIREMENT DOCUMENTS TO: 1) OBTAIN NEW INDICATIONS FOR EXISTING THERAPEUTICS FOR TREATMENT OR PROPHYLAXIS AGAINST BIOWARFARE AGENTS, 2) DEVELOP NEEDED IND APPLICATIONS, 3) DEVELOP NEEDED TREATMENT PROTOCOLS, AND 4) FUND THE RESEARCH NEEDED TO SUPPORT

AFEB (15-1a) 2002-09
SUBJECT: Therapeutics Against Biowarfare Agents

FDA APPROVAL OF DRUGS AND BIOLOGICS FOR THE BIOWARFARE INDICATIONS PREVIOUSLY RECOMMENDED BY THE AFEB.

6. The above recommendations were unanimously approved.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:



STEPHEN M. OSTROFF, M.D.
AFEB, President



JAMES R. RIDDLE, D.V.M., M.P.H.
Colonel, USAF, BSC
AFEB Executive Secretary

3 Encls

1. DoDD 6200.2/6205.3 (Force Health Protection) - Vaccine, Therapeutics, and Prophylaxis
2. Memorandum, OASD(HA)/FHP&R, 13 March 2002, Therapeutics Against Biowarfare Agents
3. Memorandum, AFEB 00-09, 3 Aug 2000, Antibiotics Against Biowarfare Agents.

CF:

Board Members and Consultants (w/o Encls)
USAMRMC (w/o Encls)
USAMRIID (w/o Encls)
USD(AT&L) (w/o Encls)
Joint Vaccine Acquisition Program (w/o Encls)
J4-MRD (w/o Encls)
DASG-HCF (w/o Encls)
JSIG (w/o Encls)
DATSD(CBD) (w/o Encls)
AMEDD(C&S) (w/o Encls)

DISEASE	VACCINE/TOXOID (Rx/Px)	CHEMOPROPHYLAXIS (Px)	CHEMOTHERAPY (Rx)	COMMENTS
Anthrax	Preexposure (Rx) - Treatment (Px) - Postexposure Prophylaxis	(Px) - Postexposure Prophylaxis	(Rx) - Treatment	
FDA Approved & Labeled Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)	Anthrax Vaccine (Preexposure) Bioport vaccine (licensed) 0.5 mL SC @ 0, 2, 4 wk, 6, 12, 18 mo then annual boosters	ciprofloxacin (Px) 500 mg PO bid x 60 days doxycycline (Px) 100 mg PO bid x 60 days Penicillin V Potassium (Px) 500 mg q 6 h x 60 days	ciprofloxacin (Rx) 400 mg IV q 12 h initially then by mouth x 60 days (adult) 15 mg/kg/dose NTE 500mg/dose q12hr x 60 days (pediatric) doxycycline (Rx) 200 mg IV, then 100 mg IV q 12 h Penicillin (Rx) 4 million units IV q 4 h	In an experimental study of monkeys, injection with the anthrax vaccine at 0 and 2 weeks offered complete protection against aerosol anthrax challenge at 8 and 38 weeks and 88% effectiveness at 100 weeks. Anthrax vaccine may cause soreness, redness, itching, swelling, and nodules at the injection site. About 30% of men and 60% of women report these local reactions. For both genders, between 1% and 5% report reactions of 1 to 5 inches in diameter. Serious events, such as those requiring hospitalization, are rare; once per 200,000 doses. Ciprofloxacin and doxycycline prepositioned for deployed forces. PenVK for sensitive organisms only. Once sensitivity data is available then consider switching children to penicillin or amoxicillin. Combined antibiotic regimen may be more effective for treatment. Per AFEB 00-09, first choice for treatment is ciprofloxacin and second choice is doxycycline. Per AFEB 00-09, first choice for post-exposure prophylaxis is ciprofloxacin and second choice is doxycycline.
DoD IRB Approved and/or FDA Accepted IND/Protocol Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)	Anthrax Vaccine (Rx/Px) FDA accepted DoD BB-IND #1081/Contingency Use Protocol for volunteer anthrax vaccination Rx/Px SC @ 0, 2, 4 wk in combination with approved and labeled antibiotics			If unvaccinated, begin initial doses of vaccine under FDA accepted DoD IND/Protocol Implementation guide available for vaccine use IND post exposure w/ antibiotics. CDC has IND to conduct study to investigate reduced dose and IM administration of vaccine. DoD (AVIP) to conduct follow-up reduced dose/IM administration of vaccine under BioPort BB-IND #7281.
No IND/Protocol Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)				JVAP May 2002 projects next generation Anthrax Vaccine baseline IND stockpile quantities obtained FY06. Potential alternates for Rx: gentamicin, erythromycin, and chloramphenicol. CDC treatment protocol for use of Anthrax Human Immune Globulin (AIG).

¹ USAMMA-HHS reciprocal support agreement for access to the National Pharmaceutical Stockpile.

² Rank ordered matrix with recommended interventions listed in order of optimal choice.

DISEASE <i>Botulinum Toxins</i>	VACCINE/TOXOID (Rx/Px) Preexposure (Rx) - Treatment (Px) - Postexposure Prophylaxis	CHEMOPROPHYLAXIS (Px) (Px) - Postexposure Prophylaxis	CHEMOTHERAPY (Rx) (Rx) - Treatment	COMMENTS
FDA Approved & Labeled Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)				Skin test for hypersensitivity before equine antitoxin administration. CDC has limited quantities of trivalent equine antitoxin for serotypes A, B, E. A, B is licensed by Connaught; and E is a CDC IND Product. CDC trivalent equine antitoxin (CDC IND #6750), A,B, E.
DoD IRB Approved and/or FDA Accepted IND/Protocol Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)	Pentavalent Toxoid (Preexposure) FDA Accepted DoD BB-IND #3723/Laboratory Use Protocol for pentavalent toxoid (serotypes A – E), 0.5 ml deep SC @ 0, 2 & 12 wk, then yearly boosters DoD IRB Approved Contingency Use Protocol to be submitted to BB-IND #3723,CDC#161 (06/02) (CDC BB-IND #161: SIP program administered under this IND)		Heptavalent Equine Despeciated Antitoxin (Rx) FDA accepted DoD BB-IND #7451/ Treatment Use Protocol for heptavalent equine despeciated antitoxin for serotypes A-G: 1 vial (10 mL) IV Botulinum Immune Globulin (First Flight) (Rx) FDA accepted DoD BB-IND #3703/ Treatment Use Protocol for Botulinum Immune Globulin (BIG), F(ab') ₂ , Heptavalent, Equine Whole IgG (Human) Pentavalent (Rx) FDA accepted DoD BB-IND #1332/ Treatment Use Protocol for Botulism Immune Globulin Pentavalent (Human) (A-E)	
No IND/Protocol Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)	Pentavalent Toxoid (Preexposure) DoD pentavalent toxoid Contingency Use Protocol awaiting DoD IRB approval (06/02); will be submitted to FDA under BB-IND 3723		Heptavalent Equine Despeciated Antitoxin (Rx) Botulinum Immune Globulin (First Flight) (Rx) Whole IgG (Human) (Rx) DoD IND #7451,3703,1332/ Umbrella Emergency Use Protocol awaiting DoD IRB approval. (06/02); will be submitted to FDA under new IND	JVAP May 2002 projects rBotulinum Bi-valent (AB) IND stockpile quantities obtained FY06.

DISEASE <i>Plague</i>	VACCINE/TOXOID (Rx/Px) Preexposure (Rx) - Treatment (Px) - Postexposure Prophylaxis	CHEMOPROPHYLAXIS (Px) (Px) - Postexposure Prophylaxis	CHEMOTHERAPY (Rx) (Rx) - Treatment	COMMENTS
FDA Approved & Labeled Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)			gentamicin (Rx) doxycycline (Rx) 200 mg IV then 100 mg IV bid, until clinically improved then 100mg PO bid for total of 10-14 d doxycycline (Rx) 100 mg PO q 12 h x 5-7 d continued at least 2 d after afebrile Streptomycin (Rx) 2 grams daily in 2 divided doses IM. A minimum of 10 days of therapy is recommended Tetracycline (Rx) 1-2 grams divided in two or four equal doses continued at least 2 d after afebrile	Greer inactivated vaccine (FDA licensed) is no longer available. Gentamicin - Approved indication, no dosage information provided. Standard dose in subjects with serious infections and normal renal function is 3mg/kg/day in 3 divided doses (q8h). Doxycycline is not the recommended treatment.
DoD IRB Approved and/or FDA Accepted IND/Protocol Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)				
No IND/Protocol Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)		doxycycline (Px) 100 mg PO bid x 7 d or duration of exposure ciprofloxacin (Px) 500 mg PO bid x 7 d Tetracycline (Px) 500 mg PO qid x 7 d	gentamicin (Rx) 5mg/kg or IV once daily x 10 - 14 d ciprofloxacin (Rx) 400mg IV q 12 h until clinically improved then 750 mg PO bid for total of 10 -14 d doxycycline (Rx) 200 mg IV, then 100 mg IV bid, until clinically improved then 100mg PO bid for total of 10-14 d. Tetracycline (Rx) 1-2 grams divided in two or four equal doses continued at least 2 d after afebrile.	Per AFEB 00-09, first choice is gentamicin and second choice is ciprofloxacin. Per AFEB 00-09, first choice for post-exposure prophylaxis is doxycycline and second choice is ciprofloxacin. Chloramphenicol for plague meningitis. 25 mg/kg IV, then 15 mg/kg qid x 14 d Alternate Rx: trimethoprim-sulfamethoxazole JVAP May 2002 projects plague vaccine IND stockpile quantities obtained FY08.

DISEASE <i>Ricin Toxin</i>	VACCINE/TOXOID (Rx/Px) Preexposure (Rx) - Treatment (Px) - Postexposure Prophylaxis	CHEMOPROPHYLAXIS (Px) (Px) - Postexposure Prophylaxis	CHEMOTHERAPY (Rx) (Rx) - Treatment	COMMENTS
FDA Approved & Labeled Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)				Inhalation: supportive therapy G-I : gastric lavage, superactivated charcoal, cathartics. IND #6181 withdrawn 8/12/96.
DoD IRB Approved and/or FDA Accepted IND/Protocol Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)				
No IND/Protocol Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)				JVAP May 2002 lists Ricin vaccine in tech base and projects ricin vaccine IND stockpile quantities obtained FY08.

DISEASE <i>Encephalitis Viruses</i>	VACCINE/TOXOID (Rx/Px) Preexposure (Rx) - Treatment (Px) - Postexposure Prophylaxis	CHEMOPROPHYLAXIS (Px) (Px) - Postexposure Prophylaxis	CHEMOTHERAPY (Rx) (Rx) – Treatment	COMMENTS
FDA Approved & Labeled Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)				Supportive therapy: analgesics and anticonvulsants prn.
DoD IRB Approved and/or FDA Accepted IND/Protocol Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)	<p>VEE Live Attenuated Vaccine (Preexposure)</p> <p>FDA Accepted DoD BB-IND #142/ Laboratory Use Protocol for VEE TC-83 live attenuated vaccine: 0.5 mL SC x1 dose</p> <p>VEE Inactivated Vaccine (Preexposure)</p> <p>FDA Accepted DoD BB-IND #914/ Laboratory Use Protocol for VEE C-84 vaccine: (formalin inactivated TC-83), 0.5 mL SC for up to 3 doses</p> <p>EEE Inactivated Vaccine (Preexposure)</p> <p>FDA Accepted DoD BB-IND #266/ Laboratory Use Protocol for EEE inactivated vaccine: 0.5 mL SC at 0 & 28 d</p> <p>WEE Inactivated Vaccine (Preexposure)</p> <p>FDA Accepted DoD BB-IND #2013/ Laboratory Use Protocol for WEE inactivated vaccine: 0.5 mL SC at 0, 7, and 28 d</p>			<p>VEE vaccine manufactured in 1965. Live, attenuated vaccine, with significant side effects. 25%-35% of recipients require 2-3 days bed rest. Time to develop immunity – 8 weeks. Must be given prior to EEE or WEE (if administered subsequent, antibody response decreases from 81% to 67%).</p> <p>VEE TC-83 reactogenic in 20%. No seroconversion in 20%. Only effective against subtypes 1A, 1B, and 1C. VEE C-84 vaccine used for non-responders to VEE TC-83.</p> <p>WEE vaccine manufactured in 1991. Antibody response is poor, requires 3-dose primary (one month) and 3-4 boosters (one month apart). Primary series antibody response in 29%, 66% after four boosts. Time to develop immunity – six months.</p> <p>EEE manufactured in 1989. Antibody response is poor, requires 3-dose primary (one month) and 1-2 boosters (one month apart). Primary series yields antibody response in 77%; 5%-10% of non-responders after boosts. Time to immunity – 3 months.</p> <p>EEE and WEE inactivated vaccines are poorly immunogenic. Multiple immunizations are required.</p>
No IND/Protocol Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)				Multivalent VEE vaccine advanced development funded through FY04.

DISEASE <i>Tularemia</i>	VACCINE/TOXOID (Rx/Px) Preexposure (Rx) - Treatment (Px) - Postexposure Prophylaxis	CHEMOPROPHYLAXIS (Px) (Px) - Postexposure Prophylaxis	CHEMOTHERAPY (Rx) (Rx) - Treatment	COMMENTS
<p><i>Tularemia</i></p> <p>FDA Approved & Labeled</p> <p>Preexposure</p> <p>Treatment (Rx)</p> <p>Postexposure Prophylaxis (Px)</p>			<p>Streptomycin (Rx) 1-2 grams daily IM in divided doses x 7-14 days until patient is afebrile for 5-7 days</p> <p>doxycycline (Rx) 100 mg PO q 12 h x 5-7 d continued at least 2 d after afebrile</p> <p>doxycycline (Rx) 200 mg IV, then 100 mg IV q 12 h</p> <p>Tetracycline (Rx) 1-2 grams divided in two or four equal doses continued at least 2 d after afebrile</p>	<p>Streptomycin is not the recommended treatment, is in limited supply and may be difficult to obtain.</p>
<p>DoD IRB Approved and/or FDA Accepted IND/Protocol</p> <p>Preexposure</p> <p>Treatment (Rx)</p> <p>Postexposure Prophylaxis (Px)</p>	<p>Live attenuated vaccine (Preexposure)</p> <p>FDA Accepted DoD BB-IND #157/ Laboratory Use Protocol for live attenuated vaccine: single 0.1ml dose by scarification</p>			<p>Vaccine manufactured in 1964. Vaccine cannot be used because of FDA "clinical hold". FDA requires study report of 35 years of clinical trials. FDA unlikely to review new protocols.</p>
<p>No IND/Protocol</p> <p>Preexposure</p> <p>Treatment (Rx)</p> <p>Postexposure Prophylaxis (Px)</p>		<p>ciprofloxacin (Px) 500 mg PO q 12 h for 14 d</p> <p>doxycycline (Px) 100 mg PO bid x 14 d</p> <p>Tetracycline (Px) 500 mg PO qid x 14 d</p>	<p>gentamicin (Rx) 3-5 mg/kg/d IV x 10-14 d</p> <p>ciprofloxacin (Rx) 400 mg IV q 12h until improved, then 500 mg PO q 12 h for total of 10 - 14 d</p> <p>ciprofloxacin (Rx) 750 mg PO q 12 h for 10 - 14 d</p>	<p>Per AFEB 00-09, the first choice for treatment is gentamicin and second choice is ciprofloxacin.</p> <p>Per AFEB 00-09, first choice for post-exposure prophylaxis is ciprofloxacin and second choice is doxycycline.</p> <p>JVAP May 2002 projects tularemia vaccine IND stockpile quantities obtained FY05.</p>

DISEASE	VACCINE/TOXOID (Rx/Px)	CHEMOPROPHYLAXIS (Px)	CHEMOTHERAPY (Rx)	COMMENTS
<i>Smallpox</i>	Preexposure (Rx) - Treatment (Px) - Postexposure Prophylaxis	(Px) - Postexposure Prophylaxis	(Rx) – Treatment	
FDA Approved & Labeled Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)				
DoD IRB Approved and/or FDA Accepted IND/Protocol Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)	Dryvax (Preexposure) Dryvax (1:1) CDC BB-IND#9829/ Contingency Use Protocol for vaccination in response to act of Bioterrorism Dryvax (1:1) CDC BB-IND#9829/ Laboratory Use Protocol TSI (Salk) Vaccine (Preexposure) TSI (Salk) Vaccine DoD BB-IND #4984/ No Protocol			
No IND/Protocol Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)	Dryvax (Preexposure) Dynport Vaccine (Preexposure) DoD JVAP IND. Acambis/Acambis-Baxter (Preexposure) CDC/DHHS IND. Dryvax (Postexposure) Dryvax (1:1) DoD IND/ Contingency Use Protocol awaiting DoD IRB approval (06/02); will be submitted to FDA under new IND		VIG (Vaccinia Immune Globulin) (Rx) FDA Accepted DoD BB-IND #8429/ Treatment Use Protocol for disseminated vaccinia for laboratory workers: VIG 0.3-0.6 ml/kg infusion Treatment/Emergency Use Protocol for VIG to treat deployable forces for disseminated vaccinia awaiting DoD IRB approval (06/02); will be submitted to FDA under BB-IND #8429 Cidofovir 5 mg/kg infusion (Rx) Cidofovir Treatment/Emergency Use Protocol for smallpox treatment awaiting DoD IRB approval (06/02); will be submitted to FDA under new IND Cidofovir Treatment/Emergency Use Protocol for disseminated vaccinia treatment to be submitted to the USAMRIID Human Use Committee (06/02); will be submitted to DoD IRB; will submit under previous cidofovir IND	Dryvax - Wyeth calf lymph vaccinia vaccine 100 dose vials undiluted: 1 dose by scarification. Greater than 97% take after one dose within 14 days of administration. Contraindications include pregnancy, history of eczema or the presence of active skin diseases, and immunodeficiency. Potential complications include encephalitis and generalized vaccinia. It is estimated up to one death (up to five deaths per million in unvaccinated adults) and 74 complications occur per million vaccinations in the general population. Dryvax is effective up to 4 days post exposure. Pre and post exposure vaccination recommended if > 3 years since last vaccine JVAP May 2002 projects Vaccinia, Cell Culture Derived vaccine IND stockpile quantities obtained FY03.

DISEASE <i>Staphylococcus Enterotoxins</i>	VACCINE/TOXOID (Rx/Px) Preexposure (Rx) - Treatment (Px) - Postexposure Prophylaxis	CHEMOPROPHYLAXIS (Px) (Px) - Postexposure Prophylaxis	CHEMOTHERAPY (Rx) (Rx) - Treatment	COMMENTS
FDA Approved & Labeled Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)				Ventilatory support for inhalation exposure.
DoD IRB Approved and/or FDA Accepted IND/Protocol Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)				
No IND/Protocol Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)				JVAP May 2002 projects Staphylococcal Enterotoxin Vaccine IND stockpile quantities obtained FY09.

DISEASE <i>Marburg/Ebola</i>	VACCINE/TOXOID (Rx/Px) Preexposure (Rx) - Treatment (Px) - Postexposure Prophylaxis	CHEMOPROPHYLAXIS (Px) (Px) - Postexposure Prophylaxis	CHEMOTHERAPY (Rx) (Rx) - Treatment	COMMENTS
FDA Approved & Labeled Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)				Aggressive supportive care and management of hypotension very important. Human antibody used with apparent beneficial effect in uncontrolled human trials.
DoD IRB Approved and/or FDA Accepted IND/Protocol Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)				AHF Candid #1 vaccine (x-protection for BHF) (IND) RVF inactivated vaccine (TSG IND 365) TSG IND 4307 Live attenuated MP 12 vaccine Ribavirin (CCHF/Lassa/KHF) (TSG IND #16666 30 mg/kg IV initial dose; then 16 mg/kg IV q 6 h x 4 d; then 8 mg/kg IV q 8 h x 6 d
No IND/Protocol Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)				Passive antibody for AHF, BHF, Lassa fever, and CCHF. JVAP May 2002 lists Marburg and Ebola vaccine in tech base and projects IND product obtained in FY09 and FY12 for Marburg and Ebola respectively.

DISEASE <i>Q Fever</i>	VACCINE/TOXOID (Rx/Px) Preexposure (Rx) - Treatment (Px) - Postexposure Prophylaxis	CHEMOPROPHYLAXIS (Px) (Px) - Postexposure Prophylaxis	CHEMOTHERAPY (Rx) (Rx) - Treatment	COMMENTS
FDA Approved & Labeled Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)			doxycycline (Rx) 100 mg PO q 12 h x 5-7 d continued at least 2 d after afebrile doxycycline (Rx) IV 100mg IV q12h Tetracycline (Rx) 1-2 grams divided in two or four equal doses continued at least 2 d after afebrile	Per AFEB 00-09, the first choice for treatment is doxycycline.
DoD IRB Approved and/or FDA Accepted IND/Protocol Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)	Inactivated Whole Cell Vaccine (Preexposure) FDA Accepted DoD BB-IND #610/ Laboratory Use Protocol for Inactivated Whole Cell Vaccine: Single 0.5 ml s.c. injection; SIP protocol			Q-Fever vaccine manufactured in 1970. Significant side effects if administered inappropriately; sterile abscesses if prior exposure/skin testing required prior to vaccination. Time to develop immunity – 5 weeks.
No IND/Protocol Preexposure Treatment (Rx) Postexposure Prophylaxis (Px)		doxycycline (Px) 100 mg PO bid x 5 d (start 8-12 d post-exposure) Tetracycline (Px) 500 mg PO qid x 5 d (start 8-12 d post-exposure)		Per AFEB 00-09, first choice for post-exposure prophylaxis is doxycycline.