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

27 SEP 2001

AFEB (15-la) 01-06

MEMORANDUM FOR The Surgeon General, Department of The Army

SUBJECT: Medical Risk Assessment of the Biological Threat

1. At the 22-23 May 2001 meeting of the Armed Forces Epidemiological Board (AFEB), the Board was asked to consider use of the Medical Risk Assessment of the Biological Warfare Threat during the 2001 review of the Chairman, Joint Chiefs of Staff Prioritized Biological Warfare Threat List. This assessment is intended to provide a consistent methodology for assessing the medical risk and provide clear medical guidance on the nature of the biological warfare threat. The assessment is intended to supplement the current intelligence-based prioritization of the biological warfare threat and enhance DoD's ability to make medical defense research, development, testing, acquisition and stockpiling decisions.

2. The Board had earlier recommended to the DoD that a medical risk-based analysis was a vital piece of data needed for prioritization of the medical countermeasures program against biological warfare agents. The current prioritization depends primarily on an intelligence-based assessment with no consideration of medical risk-based measures and the operational impact posed by the pathogens which may vary based on the agent characteristics. Upon review and use of the Medical Risk Assessment of the Biological Warfare Threat, the Board makes the following recommendations and observations:

a. WHEN INTEGRATED WITH THE INTELLIGENCE THREAT ASSESSMENT, THE MEDICAL RISK ASSESSMENT METHODOLOGY PROVIDES AN EXCELLENT MEANS TO ANALYZE THE POTENTIAL AND SEVERITY OF AGENTS AS BIOLOGICAL WARFARE THREATS. THE CONCEPTUAL APPROACH IS ENDORSED BY THE BOARD AND SHOULD BE ADOPTED BY THE DOD AS A PROTOTYPE METHODOLOGY TO BE USED IN DEVELOPING A RANK-ORDERED BIOLOGICAL WARFARE THREAT LIST THAT TAKES INTO ACCOUNT THE MEDICAL RISK-BASED MEASURES AND AGENT CHARACTERISTICS.

b. THE BOARD CONCURS WITH THE SCIENTIFIC PANEL CONCERNS AND RECOMMENDATIONS AT APPENDIX E OF THE REPORT, **AND NOTES THAT THE MEDICAL RISK ASSESSMENT METHODOLOGY SHOULD NOT BE USED IN ISOLATION.**

c. THE BOARD RECOMMENDS THE MINOR CHANGES AND CLARIFICATIONS IN PARAGRAPH THREE (3) BELOW BE INCLUDED AS AN ADDENDUM TO THE CURRENT REPORT AND EVALUATED FOR INCLUSION IN FUTURE ITERATIONS OF THE MEDICAL RISK ASSESSMENT OF THE BIOLOGICAL THREAT.

d. THE BOARD RECOMMENDS THAT THIS PROTOTYPE METHODOLOGY BE REVIEWED NO LESS FREQUENTLY THAN EVERY TWO (2) YEARS OR WHENEVER CIRCUMSTANCE MAY WARRANT.

e. THE BOARD COMMENDS THE OFFICE OF THE SURGEON GENERAL, THE MILITARY PANEL MEMBERS, THE SCIENTIFIC PANEL MEMBERS, AND THE BATTELLE EMPLOYEES ENLISTED TO WORK AND ADVISE ON THIS PROJECT. THE MEDICAL RISK ASSESSMENT PANEL MEMBERS ARE OF THE HIGHEST INTERNATIONAL REPUTATION AND REPRESENT SOME OF THE MOST KNOWLEDGEABLE AND OUTSTANDING U.S. MILITARY AND CIVILIAN SCIENTISTS.

3. The following minor changes and clarifications are provided:

a. Table 3: Criteria and Scales - Lethality (a). The case fatality rate is used as the criterion for lethality. The case fatality is the number dead out of the number sick. The mortality rate (the number dead out of the number exposed) would be a better measure for lethality. Under the proposed criteria and scale, if 100 war-fighters were exposed and only one sickened and died, the criteria scale would be 5. If 100 warfighters were exposed and all sickened, but five died, the criteria scale would be 2.

b. Table 3: Criteria and Scales - Lethality (b). The speed of death scale does not seem rational, especially for criteria scales 2-5. The longer the war-fighter is sick and dying, the greater the logistics burden. The scale would seem to be more applicable if the number of days to incapacitation (followed by death) were being measured.

c. Table 3: Criteria and Scales - Effective Dose. Effective dose may not be relevant. The warfighter is either infected or not infected. The criterion should reflect the percentage of those exposed who become ill, given a dose that can be weaponized. This would take into consideration the apparentiinapparent infection ratio. This criterion was eliminated from the final evaluation.

d. Table 3: Criteria and Scales - Morbidity. Severity and duration do not always correspond. One can be severely ill but recover completely. For example, linking

prolonged ICU and permanent disability may not always occur. Severity and duration should be separated as distinct criterion and residual health effects associated morbidity should be clarified; e.g. permanent effects that are not disabling vs. effects that linger but are not permanent.

e. Table 3: Criteria and Scales - Persistence. The important variable is the duration of time that the risk continues. Criterion 5 should read "Potentially becomes endemic – effective indefinitely INCLUDING effective through vectors." For instance, an infectious agent such as cholera would fit criterion 5 excepting for the phrase "and effective through vectors." Cholera is not spread through vectors, but one would assume the criteria is intended for all agents potentially being evaluated.

f. Table 3: Criteria and Scales - Communicability. The "aerosol – droplet – contact – standard precautions" scale is not intuitive. A communicability scale is more objectively measured by the percent of second generation infections engendered under field conditions. None of the current criteria take into consideration an arthropod-borne infectious agent, for instance. Additionally, ease of infectivity is not clearly addressed. Ease of infectivity is addressed somewhat at the bottom of page 3 and in the criterion "effective dose," however some agents are easily disseminated while others may have more specific routes of infection, both in primary and secondary infections. Additionally, the medical effect may also depend on the route of infection.

g. Table 3: Criteria and Scales - Identification & Diagnosis. The difficulty and delay until time of diagnosis is the deciding element here. The difficulty and delay in getting unidentified specimens to a reference lab seem to determine the extreme as far as difficulty of diagnosis. "Lab in CONUS" may not be the deciding factor so much as the delay in getting the specimen to a lab to analyze it. Further, "lab in CONUS" implies that the infection occurred outside the United States. A domestic terrorism incident could occur to soldiers in the United States. For clarity, scale 4 should correspond to sending lab specimens to a reference laboratory requiring a delay of diagnosis and increased difficulty with logistics. Scale 3 should refer to use of a laboratory distant from the incident but not a reference laboratory.

h. To allow broader acceptance of the Medical Risk Assessment of the Biological Threat, further clarification on agent assignment to risk variables (e.g. E, H, M, and L) in Table 6: FM 100-14 Risk Management Matrix and Table 8: BW Agent Risk Management Matrix, is needed.

i. On page 3 of the report, reference is made to a "two-tiered" set of generic criteria. "Tier 1" is defined, but the definition of "Tier 2" must be inferred. One must assume "Tier 2" corresponds to criteria in Table 2 on page 4.

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4. To evaluate the medical risk assessment methodology for other agents, an exercise with rabies virus was conducted. Rabies virus has infected a series of laboratory workers and spelunkers by aerosol. If rabies were weaponized, it would be placed between Lassa and saxitoxin, a seemingly appropriate placement.

	Raw score	Weighted score
Morbidity	5	.33
Communicability	1	.oo
Lethality (a)	5	.09
Post-exposure (Post)	5	.08
Persistence	3	.04
Post-exposure (Pre)	2	.02
Lethality (b)	3	.05
Identification (Dx)	3	.03
TOTAL WEIGHTED SCORE		.64

5. The above recommendations and observations 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.
Lt Col, USAF, BSC
AFEB Executive Secretary

3 Encls
1. Memorandum, 22 May 2001, Medical Risk Assessment of the Biological Warfare Agent Threat
2. Final Report on Medical Risk Assessment of the Biological Warfare Threat
3. AFEB Recommendation 00-7, 3 August 2000, "Comments and Recommendations Concerning the JCS BW Threat List for 2000"

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CF
The Acting Assistant Secretary of Defense (Health Affairs)
The Surgeon General of the Navy
The Surgeon general of the Air Force
Board Members and Consultants (wo/encls)
USAMRMC (wo/encls)
USAMRIID (wo/encls)
USD (AT&L) (wo/encls)
Joint Vaccine Acquisition Program (wo/encls)
J4-MRD (wo/encls)
DASG-HCF (wo/encls)

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
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REPLY TO
ATTENTION OF

DASG-HCF

2 MAY 2001

MEMORANDUM FOR PRESIDENT ARMED FORCES EPIDEMIOLOGICAL BOARD
ATTN: DR. F. MARC LAFORCE, M.D., 5109 LEESBURG PIKE,
FALLS CHURCH. VA 22041-3258

SUBJECT: Medical Risk Assessment of the Biological Warfare Agent Threat

1. Reference memorandum, AFEB, 25 May 1999, subject: Armed Forces Epidemiological Board Recommendations for Biological Warfare Vaccines.

2. I am pleased to forward you the Medical Risk Assessment of the Biological Warfare (BW) Threat (Encl) for use during the 2001 review of the Chairman, Joint Chiefs of Staff (CJCS) Prioritized Biological Warfare Agent Threat List. LTC Debra Schnelle, my NBC Defense Staff Officer, has prepared a briefing for your 22-23 May 2001 meeting to review the project and explain the methodology.

3. I look forward to the outcome of your deliberations. I am confident the product will provide a consistent methodology for assessing the medical risk and provide clear medical guidance on the nature of the BW threat. It will supplement the current intelligence-based prioritization of the BW threat and enhance our ability to make intelligent medical defense research, development, testing, acquisition and stockpiling decisions.

4. My point of contact for this action is LTC Debra D. Schnelle, DASG-HCF, (703)-681-8185, Email: debra.schnelle@otsg.amedd.army.mil.

Encl

JAMES B. PEAKE, M.D.
Lieutenant General
The Surgeon General