DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
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AFEB

AUG 2 2 2005

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: DoD Immunization Program for Biological Warfare Defense AFEB 2005-06

1. References:

a. Department of Defense Directive 6205.3, "DoD Immunization Program for Biological Warfare Defense," dated November 26, 1993.

b. Department of Defense Directive 6200.2, "Use Of Investigational New Drugs For Force Health Protection," dated August 1, 2000.

c. Memorandum, OASD(HA)/FHP&R, March 13, 2002, Therapeutics Against Biowarfare Agents.

d. Memorandum, AFEB 2002 - 09, August 12, 2002, Therapeutics Against Biowarfare Agents.

2. The Armed Forces Epidemiological Board (AFEB) meets annually as required under DoD Directive 6205.3 to provide recommendations to the Assistant Secretary of Defense for Health Affairs and the DoD Executive Agent on protocols necessary to enhance protection against validated biological warfare threat agents. Specifically, DoD Directive 6205.3 requires that "on an annual basis the President of the Armed Forces Epidemiological Board (AFEB) shall identify to the Assistant Secretary of Defense for Health Affairs vaccines available to protect against validated biological warfare threat agents, and recommend appropriate immunization protocols."

3. On 21-22 March 2005, the Board met to consider the biological threat agents designated by the Chairman of the Joint Chiefs of Staff and to discuss appropriate medical countermeasures. The Chairman of the Joint Chiefs of Staff validated threat list was last formally updated in September 2002. The Board received briefings on the Chairman's threat list, the use of investigational new drugs in the combatant theater, and updates on the medical biological defense research program and the advanced development of chemical and biological medical countermeasures. In addition, the Board received an extensive presentation on the status of the

military vaccines program (MILVAX) highlighting the execution of policies for administration of biowarfare countermeasure vaccinations.

4. The transition of biological countermeasure research to the Defense Threat Reduction Agency Board is producing impressive results. The scope and quality of the ongoing research activities, as presented to the Board, gives reasonable assurance that substantial progress is being made toward enhanced protection of the future Warfighter. Based on the updates provided, the structural changes in the DoD medical chemical-biological defense acquisition program are yielding positive results. For the first time in several years, the milestones for translation of research activities into usable licensed products for medical countermeasures are being achieved at a rate similar to that for commercial pharmaceutical and vaccine development. The Board is very pleased with these results.

5. The biowarfare countermeasure matrix provided for the Board's review is excellent and serves as an example of successful interagency collaboration. The programmatic architecture that facilitated the matrix's development also allows for periodic updates. This document should significantly assist the Department of Defense and other agencies involved in biowarfare and bioterrorism protection.

6. The Board remains concerned that the scheduled validation process for the Chairman's threat list has not yet been completed. While uncertainties regarding international biological threat assessments are expected to remain, the Board believes sufficient information is available to complete the updating process and hopes that a revised threat list will shortly be available.

7. The Board is very concerned that the legal proceedings involving anthrax vaccine have substantially impaired the Department's ability to protect military service members against this important biowarfare threat. Based on its comprehensive review of the scientific literature, it is the Board's view that anthrax vaccine adsorbed, USP (*BioThrax*, BioPort Corporation) is safe and effective in preventing anthrax disease in humans regardless of the route of infection. Continued availability of this vaccine is deemed vital to national security.

8. The Board commends the Department of Defense for its impressive smallpox vaccine adverse events surveillance and research efforts. The results of the Department efforts and those of the Centers for Disease Control and Prevention have greatly enhanced scientific knowledge regarding the use of this vaccine and the frequency of adverse events, and helps to assure the successful delivery of vaccine to the American public should it be needed. The Board particularly commends MILVAX and the Vaccine Healthcare Centers for their leadership role in this area.

9. Based on the information provided, the Board makes the following recommendations:

a. The Department should continue threat-based policies for the use of biowarfare countermeasures. The Board does not endorse the expansion to full force vaccination programs for anthrax and smallpox vaccines under the current threat conditions. Rather, vaccination strategies that focus on deployments to high-threat theaters of operations should remain the basis for decisions about the need for pre-exposure vaccination against biowarfare threats.

b. The Board recommends that the Department expand research efforts to identify intrinsic risk factors for cardiac complications associated with smallpox vaccine. While follow-up for vaccinia-associated cardiac injury cases has revealed little or no long term health effects, the mechanism involved in the development of acute cardiac injury among the relatively small number of servicemembers affected is worthy of further study. The Board believes it is likely that focused immunological and proteomic research could identify predictive biological markers for cardiac injury and potential new treatment options. Long-term follow-up regarding outcomes of identified cardiac complications should continue.

c. Based on the history of pandemic influenza, international concerns regarding avian influenza (H5 N1) in Asia, recent laboratory errors involving the distribution of highly virulent strains of the virus, and the technological advances in genetic reengineering, the Board encourages the Department to consider the threat posed by influenza as an agent of biowarfare and bioterrorism. The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) currently includes avian influenza on its list of potential biological threats.

10. The above recommendations were unanimously approved.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

GREGORY A. POLAND, M.D.
AFEB, President

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Board Members and Consultants
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