DEFENSE HEALTH BOARD
5111 LEESBURG PIKE
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FEB 26 2007

DHB

MEMORANDUM FOR The Assistant Secretary of Defense (Health Affairs)

SUBJECT: DoD Immunization Program for Biological Warfare Defense DHB 2007-01

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 Secretary of Defense October 11, 2006 decision memo disestablished the Armed Forces Epidemiological Board (AFEB) and transferred its functions to the Defense Health Board. The AFEB, as required under DoD Directive 6205.3, and reviews and provides 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 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 March 7th, May 23rd, September 26th, and December 5th 2006, 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 continues to demonstrate progress. 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 war fighter. Based on the updates provided, the structural changes in the DoD medical chemical-biological defense acquisition programs are yielding positive results. Importantly, the milestones for translation of research activities into usable licensed products for medical countermeasures are being achieved, with a few exceptions, at a rate similar to that for commercial pharmaceutical and vaccine development. The Board is 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 bio terrorism 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. In addition, our concern is that this process was also not completed in time for our review with last year's recommendations. This seems to be a potential "crack" in the system that prevents timely and accurate review and subsequent recommendations from the Board. Given the importance of these issues, and 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, the Board believes that a process for timely validation of the threat matrix should be devised and reviewed prior to the Board's annual recommendations.

7. 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 continue to expand research efforts to identify intrinsic risk factors for cardiac complications associated with smallpox vaccine. The Board believes that long-term follow-up regarding outcomes of identified cardiac complications should continue, and the results published in the peer-review literature.

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 continue to consider the threat posed by influenza as an agent of biowarfare and bioterrorism. The Board notes that the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health currently includes avian influenza on its list of potential biological threats. In this regard, the DHB Select Subcommittee on Avian/Pandemic Influenza continues to monitor events surrounding avian influenza and has issued a series of recommendations.

d. Based on presentations regarding the utility, availability, and declining immunogenicity of pentavalent botulinum toxoid vaccines, the Board will issue a separate memorandum regarding recommendations for the use of this vaccine.

8. The above recommendations were unanimously approved.

FOR THE DEFENSE HEALTH BOARD:

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

cc: Surgeon General, Department of the Army
Surgeon General, Department of the Navy
Surgeon General, Department of the Air Force

cf:
Board Members and Consultants
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USD(AT&L)
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Joint Vaccine Acquisition Program
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