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

REPLY TO
ATTENTION OF

JUL 19 2002

AFEB (15-1a) 2002-08

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

1. References:

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

b. Memorandum, AFEB 94-07, 3 Aug 1994, Biological Warfare Vaccines.

c. Memorandum, AFEB 96-04, 8 Nov 1996, Recommendation for Biological Warfare (BW) Vaccines.

d. Memorandum, AFEB 99-05, 25 May 1999, Armed Forces Epidemiological Board Recommendations for Biological Warfare Vaccines.

e. Memorandum, AFEB 00-07, 3 Aug 2000, Armed Forces Epidemiological Board (AFEB) Comments and Recommendations Concerning the JCS BW threat List for 2000.

f. Memorandum, AFEB 01-05, 27 Sep 2001, DoD Immunization Program for Biological Warfare Defense.

g. Memorandum, AFEB 01-06, 27 Sep 2001, Medical Risk Assessment of the Biological Threat.

2. On 21 and 22 May 2002 the Armed Forces Epidemiological Board (AFEB) met to consider the DoD Immunization Program for Biological Warfare Defense as required by Department of Defense Directive 6205.3, "DoD Immunization Program for Biological Warfare Defense," dated November 26, 1993. Specifically, the AFEB is tasked to identify to the Assistant Secretary of Defense for Health Affairs (ASD(HA)) vaccines available to protect against biological threat agents designated by the Chairman of the Joint Chiefs of Staff, and recommend appropriate immunization protocols.

3. The Board received briefings on the current intelligence based biological warfare threat, the Medical Risk/Threat Matrix, the Medical Biological Defense Research Program, and the Joint Vaccine Acquisition 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.

4. Although there has not been an updated and approved Chairman of the Joint Chiefs of Staff Validated Threat List for 2002, there have been significant changes in the availability of vaccines to protect against biological warfare threat agents since the AFEB last reviewed this issue in 2001. These include a greater supply of licensed anthrax vaccine (adsorbed) (AVA) and an acceleration of efforts to develop a sufficient stockpile of licensed vaccinia (smallpox) vaccine. Previous AFEB recommendations on administration of anthrax vaccine remain current. Two previously licensed smallpox vaccines are now available, Dryvax® made by Wyeth and the Aventis Pasteur vaccine, however both would currently have to be administered under investigational new drug (IND) protocols because of changes in diluent composition (Dryvax®) and testing for potency and sterility (Aventis Pasteur vaccine). Recent studies have demonstrated that Dryvax® can undergo a fivefold dilution and still produce "take" rates, which indicate a successful immunization, equivalent to full strength vaccine. New generation cell-culture derived smallpox vaccine is being procured by the Department of Defense and Department of Health & Human Services, but is not currently available or licensed.

5. In June 2002, the Advisory Committee on Immunization Practices (ACIP) recommended against routine smallpox vaccination of U.S. civilians due to the perceived low threat, the known complication profiles of the vaccine, and the readily available option for postexposure prophylaxis. However, the ACIP did endorse preexposure vaccination of designated smallpox response teams that would be called upon to respond to a smallpox incident, and medical and emergency response personnel at risk of coming into early contact with a smallpox case.

6. Because of these changing circumstances, including a changing threat assessment, the AFEB endorses the development of policies and contingency plans for use of smallpox vaccine in military personnel. While these policies should be consistent with ACIP recommendations, the Board recognizes that there are unique features within the military, especially concerning circumstances where postexposure prophylaxis would not be feasible from an operational, logistical, or combat readiness point of view that should be considered. In addition, the side effect profiles from smallpox vaccine are likely to be lower in military personnel since they are repeatedly screened for immune-compromising conditions that predispose to complications from smallpox vaccine. Therefore, DoD policies are likely to diverge from those used in the civilian sector. Regarding smallpox vaccine, the Board makes the following recommendations:

a. UNTIL LICENSED PRODUCT IS AVAILABLE, ANY USE OF INVESTIGATIONAL SMALLPOX VACCINE SHOULD BE DONE ON A VOLUNTARY BASIS WITH FULL INFORMED CONSENT UNLESS ADMINISTERED PER 10 U.S.C. 1107.

b. PREFERENCE SHOULD BE GIVEN TO THE USE OF LICENSED OVER UNLICENSED PRODUCT WHENEVER POSSIBLE.

c. THE DOD SHOULD MOVE TOWARDS DEVELOPMENT OF A STOCKPILE, OR READY ACCESS TO SUPPLIES OF LICENSED SMALLPOX VACCINE AND VACCINIA-IMMUNE GLOBULIN ADEQUATE FOR FULL-FORCE PROTECTION IF NECESSARY.

d. CONSISTENT WITH ACIP POLICY, THE DOD SHOULD IDENTIFY SMALLPOX RESPONSE TEAMS, MEDICAL EVACUATION PERSONNEL AND DESIGNATED MEDICAL CARE FACILITIES THAT WOULD HANDLE SMALLPOX CASUALITIES AND DEVELOP POLICIES FOR PRE- AND POST-EXPOSURE VACCINATION.

e. THE DOD SHOULD DEVELOP POLICIES THAT MINIMIZE THE POTENTIAL FOR SECONDARY TRANSMISSION OF VACCINIA FROM VACCINATED PERSONNEL.

f. THE DOD SHOULD IDENTIFY CIRCUMSTANCES, E.G. SPECIAL FORCES PERSONNEL AND DEPLOYMENTS WHERE THREAT ASSESSMENTS INDICATE A POTENTIAL HIGHER RISK OF SMALLPOX EXPOSURE, IN WHICH POST-EXPOSURE PROPHYLAXIS WOULD EITHER NOT BE FEASIBLE OR (DUE TO THE KNOWN LOCAL SIDE EFFECTS OF THE VACCINE) MIGHT DEGRADE OPERATIONAL READINESS, AND DEVELOP OPTIONS FOR PRE-EXPOSURE PROPHYLAXIS OF THESE PERSONNEL. OF NOTE, SMALLPOX PROTECTION REQUIRES ONLY A SINGLE DOSE OF VACCINE AND GENERALLY OCCURS WITHIN 7-DAYS OF ADMINISTRATION, MAKING A JUST-BEFORE DEPLOYMENT OPTION POSSIBLE.

g. THE DOD SHOULD DEVELOP TRACKING SYSTEMS FOR ADMINISTRATION OF VACCINE AND THE OCCURRENCE OF COMPLICATIONS AND SIDE EFFECTS FROM ANY USE OF THE SMALLPOX VACCINE IN MILITARY PERSONNEL.

7. The above recommendations were unanimously approved.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

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