DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
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AFEB (15-1a) 2002-06 March 1, 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: Vaccination Program to Protect Against Anthrax

1. During its Winter 2002 meeting, the Armed Forces Epidemiological Board (AFEB) was asked by the Assistant Secretary of Defense for Health Affairs to comment on the possible reintroduction of the Anthrax Vaccine Immunization Program (AVIP) to protect Armed Forces personnel, now that additional Food and Drug Administration (FDA) approved lots of the vaccine have become available. The Board has had a longstanding interest in force protection against biowarfare agents such as anthrax, and in recent years has issued a number of statements concerning use of the vaccine. These previous AFEB statements have supported the use of the vaccine when indicated to protect individuals being deployed to areas where analysis has determined that there is a credible risk of exposure to anthrax.

2. Since these statements were issued, a significant amount of new information has been collected based on the previous experience of the AVIP, which includes studies of short- and long-term safety and side effects associated with vaccination and both basic and applied research studies. The vaccine has also undergone intense scrutiny and review by several independent scientific bodies, including the Institute of Medicine of the National Academy of Sciences. The Board is cognizant of the issues associated with implementation of the total force anthrax immunization program including lack of consensus regarding the risk-benefit ratio, concerns about vaccine safety and efficacy, difficulties tracking vaccine receipt and delivery, and ultimately an inadequate supply of the vaccine that led to a slow-down of the AVIP.

3. The Board is impressed with the degree of diligence that has been given to addressing the concerns and sharing publicly the findings of research efforts, regardless of whether they were supportive of the program. We have seen no data that leads us to conclude that the vaccine is unsafe when administered according to the package insert. The range of reported side effects experienced by recipients of the anthrax vaccine are in line with previously published reports and compatible with similar vaccines. There are no convincing data demonstrating long-term adverse health impacts to recipients of anthrax vaccine, although additional studies are in progress. Data regarding efficacy, particularly against challenge with aerosolized anthrax spores, are less complete because they rely on

animal surrogates and very limited human studies, but there is no reason to believe that the vaccine does not offer valuable added protection to persons from any form of anthrax exposure.

4. The events of Autumn 2001 showed that the intentional use of anthrax can cause significant morbidity, mortality, and disruption of activities. This recent experience is likely to overcome some of the previous opposition to the program should a decision be reached to resume vaccination for personnel in settings where there is a significant risk of exposure to anthrax.

5. The Board recommends the following steps as a means of enhancing the anthrax immunization program:

- **DEVELOP ENHANCED PROGRAMS TO EDUCATE ALL ARMED FORCES PERSONNEL AND THE GENERAL PUBLIC ABOUT THE RISKS AND BENEFITS OF THE VACCINE AND THE REASONS FOR THE PROGRAM.**

- **MAINTAIN THE CURRENT VACCINE TRACKING SYSTEMS AND CONTINUE TO MONITOR FOR ACUTE AND LATENT VACCINE-RELATED MORBIDITY AMONG PERSONNEL WHO RECEIVE THIS VACCINE.**

- **DEVELOP A PROGRAM TO VALIDATE OR AUDIT THE CURRENT VACCINE TRACKING SYSTEMS SUCH THAT RECORDING ERRORS ARE MINIMIZED.**

- **ASSURE THAT MEASURES ARE IN PLACE SO THAT PERSONNEL IN WHOM THE VACCINE IS NOT INDICATED, ESPECIALLY WOMAN WHO ARE PREGNANT OR POTENTIALLY PREGNANT, DO NOT RECEIVE IT.**

- **ASSURE A STEADY AND UNINTERRUPTED SUPPLY OF LICENSED VACCINE TO MEET PROGRAM NEEDS AND MINIMIZE ANY FUTURE DISRUPTION OF PROGRAM ACTIVITIES AND CONTINUE EFFORTS TO DEVELOP ALTERNATE SOURCES FOR VACCINE PROCUREMENT.**

- **THE BOARD STRONGLY ENDORSES ONGOING EFFORTS TO DEVELOP NEW GENERATION ANTHRAX VACCINES THAT ARE POTENTIALLY LESS REACTOGENIC AND COULD REQUIRE LESS**

FREQUENT DOSING TO AFFORD PROTECTION. WE ALSO SUPPORT EFFORTS WITHIN DOD AND THE DEPARTMENT OF HEALTH AND HUMAN SERVICES TO EXPLORE ALTERNATIVE DOSING SCHEDULES AND ADMINISTRATION ROUTES TO MINIMIZE LOCALIZED REACTIONS WITH THE CURRENTLY AVAILABLE VACCINE. SUCH STUDIES WILL HOPEFULLY LEAD TO SIMPLER DOSING SCHEDULES THAT WILL MAKE THE VACCINE MORE ACCEPTABLE TO MILITARY AND OTHER AT RISK PERSONNEL WHILE REDUCING THE COMPLEX LOGISTICAL CHALLENGE OF ADMINISTERING THIS VACCINE TO SUCH A HIGHLY MOBILE POPULATION.

These activities should be part of the criteria used in making decisions about resumption of the anthrax immunization program.

6. The Board is pleased to continue to assist the DoD as it moves forward to develop policies regarding anthrax vaccination and other measures to protect Armed Forces personnel against the threat of biologic weapons of mass destruction.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

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