

COMMENT ON DOCKET NUMBER 1980-0208, FEDERAL DRUG ADMINISTRATION

February 17, 2005

I, Bruce E. Abraham, oppose the administration of the anthrax vaccine to US service members and DOD contract personnel without their informed consent.

I am a US Merchant Marine deck officer soon to be working for a private company on a ship transporting military equipment to the war in Iraq. If the anthrax vaccine is licensed, and the AVIP is resumed, I will be forced to allow myself to be injected with the anthrax vaccine, a substance that has the possibility of ruining the rest of my life. I have been informed that if I decline this injection I will be terminated immediately and blackballed from the industry. This is wrong. The AVA should not be administered without informed consent.

If the Deputy Secretary of Defense has really determined that there is a significant potential for a military emergency involving a heightened risk to United States military forces of an attack with anthrax why haven't the unvaccinated troops and DOD contract personnel been provided with the appropriate antibiotics? Do you think it's because the DOD has determined that there is no anthrax in Iraq?

After reading Docket # 1980N-0208, pages 78281 to 78293 in Federal Register volume 29, number 249, I have the following questions concerning a few sections in the Supplementary Information.

Section IV.A: It states in this section that the Panel based its evaluation of the safety and efficacy of AVA in part on "the Brachman study". This study was conducted in the 1950's. How often does the FDA base its evaluations on such outdated studies? Many advances in the field of medicine have taken place since this time so that even solid data from the past could be reinterpreted in different ways. For such a controversial vaccine, don't you think a new study should be conducted?

Section IV.A: It states in this section that the Panel based its evaluation of the safety and efficacy of AVA on "the Brachman study. I am concerned about the likelihood that the persons involved in these sources are not a representative sample of either the military or DOD contract personnel who have been given AVA or who may be given AVA in the future. What was the personnel make-up of these data sources? It seems likely that the participants were primarily men. Did they include a statistically significant number of both genders, different races, and persons of different weight and of different ages? A vaccine must be made strong enough to be effective in the largest and least sensitive individual while also ensuring the safety of the smallest and most sensitive.

Section IV.A: It states in this section that, "In its proposed determination that the data support the safety and efficacy of AVA, FDA has identified points of disagreement with statements in the Panel report." What are these points of disagreement and how did the FDA deal with them or find them acceptable such that the FDA continued to support the safety and efficacy of AVA?

Section IV.B: It states in this section that "the Brachman study" used an earlier version of the anthrax vaccine. How often does the FDA base the safety and efficacy of a vaccine on the results of studies from a different version of that vaccine? In light of the fact that there have been many reports of adverse reactions to the AVA by military and DOD contract personnel, how can the FDA be sure that the change from the earlier version of the vaccine to the current one did not alter or negate its efficacy?

Section IV.B. Note 5: It states in this section that it would be very difficult, if not impossible, to clinically study (and therefore determine) the efficacy of any anthrax vaccine. Based on this information, how can the Panel and the FDA place the vaccine in Category I, "Licensed biological products determined to be safe and effective and not misbranded"? If the Panel thought it would be difficult or impossible to clinically study (and therefore determine) the efficacy of the anthrax vaccine, how did it determine that it was now possible and acceptable to determine it's safety? The Panel noted that efficacy studies raise ethical considerations. Why is

this a concern for studies, but not for administration, without information or consent, to military and DOD contract personnel?

Section IV.C: It states in this section that the Panel found that the CDC data “suggests that this product is fairly well tolerated with the majority of reactions consisting of local erythema and edema. Severe local reactions and systemic reactions are relatively rare.” The underlined language used by the CDC hardly inspires confidence. Why were more recent GAO reports not a consideration, when their findings included in an active surveillance of adverse reactions, that reaction rates were as high as 84%, with systemic reaction rates as high as 24%?

<http://www.gao.gov/new.items/d02445.pdf> Is there a standard method or standard language by which such recommendations are accepted or is it a subjective process? If there is a standard method and language, what is it?

Section IV.F: It states in this section that, “the labeling seems generally adequate.” This is a very weak endorsement. Either the labeling is adequate or is not. At some point during administration of AVA, the product label was updated to reflect a much greater percentage of adverse reactions than originally printed, more than 100-fold. This is not consistent with the statement that “labeling seems generally adequate.” How was the determination made that the labeling seemed to be generally adequate?

I agree with the Findings in Brief , House Report 106-556, 106th Congress, 2d Session, and would like them included in my comment.

THE DEPARTMENT OF DEFENSE ANTHRAX VACCINE IMMUNIZATION PROGRAM: UNPROVEN FORCE PROTECTION, FOURTH REPORT by the COMMITTEE ON GOVERNMENT REFORM

1. The Anthrax Vaccine Immunization Program, AVIP, is a well-intentioned but over-broad response to the anthrax threat. It represents a doctrinal departure overemphasizing the role of medical intervention in force protection.
2. The AVIP is vulnerable to supply shortages and price increases. The sole-source procurement of a vaccine that requires a dedicated production facility leaves DOD captive to old technology and a single, untested company. Research and development on a second-generation, recombinant vaccine would allow others to compete.
3. The AVIP is logistically too complex to succeed. Adherence to the rigid schedule of six inoculations over 18 months for 2.4 million members of a mobile force is unlikely, particularly in reserve components. Using an artificial standard that counts only shots more than 30 days overdue, DOD tolerates serious deviations from the Food and Drug Administration [FDA] approved schedule.
4. Safety of the vaccine is not being monitored adequately. The program is predisposed to ignore or understate potential safety problems due to reliance on a passive adverse event surveillance system and DOD institutional resistance to associating health effects with the vaccine.
5. Efficacy of the vaccine against biological warfare is uncertain. The vaccine was approved for protection against cutaneous (under the skin) infection in an occupational setting, not for use as mass protection against weaponized, aerosolized anthrax.

Regards,

Bruce E. Abraham