

Doctors for Disaster Preparedness
STATEMENT FOR THE RECORD

Submitted by

DOCTORS FOR DISASTER PREPAREDNESS

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Hearings on

U.S. DEPARTMENT OF DEPARTMENT OF DEFENSE
ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP)

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Doctors for Disaster Preparedness is a national organization of physicians and scientists founded in 1983. We are dedicated to increasing public awareness of threats from both man-made and natural disasters, and to promoting life-saving preparedness including homeland defense.

We recognize a serious threat of biological and chemical warfare, as well as the potential for use of other weapons of mass destruction. The Department of Defense has responded to this threat by implementing the Anthrax Vaccine Immunization Program (AVID) to inoculate 2.4 million military personnel.

But the threat is not limited to military personnel engaged in warfare. Last year, the CDC received reports of a series of bioterrorist threats of anthrax exposure to domestic civilian targets. These were in the form of letters purportedly contaminated with the bacillus, or in telephone threats about contaminated ventilation systems.

Because of the potential exposure of civilians, we are concerned that the Anthrax Vaccine Immunization Program will be expanded to other diseases or contaminants, and used as a model for the mandatory vaccination of civilian children as well as adults.

The Assistant Secretary for Defense for health Affairs, Dr. Sue Bailey, states that the AVID is "not primarily a medical program." Yet the DOD is administering to our soldiers a medical procedure which raises the following scientific and medical concerns:

1. VACCINE NO SUBSTITUTE FOR OTHER PROTECTIONS

Because of the wide diversity of agents that could be used, no single vaccine or combination of vaccines and antidotes is sure to be effective: thus, there is no substitute for shelter and adequate protective gear. We believe that both military and civilian populations should have access to the type of NBC shelters that are standard in Swiss homes.

2. LACK OF CLINICAL STUDIES

While anthrax has long been recognized as a serious threat, having been weaponized by a number of potential adversaries, currently available anthrax vaccine falls far short of optimal. The anthrax vaccine was licensed in 1970 on the basis of one published study, with only five inhalation cases.

Animal studies have shown survival rates as low as 4% and as high as 100% after anthrax challenge. A 1994 Staff Report for the Committee on Veterans Affairs is quoted as saying that **"its [the vaccine's] safety, particularly when given to thousands of soldiers in conjunction with other vaccines, is not well established"** (*Lancet* 351:657, 1998, quoting a ProMED-mail posting). The one U.S. producer, Michigan Biologic Products Institute (now Bioport Corp.), would have closed last year except for a last-minute plea by the Pentagon, because of serious concerns about its manufacturing practices.

3. MEDICAL EFFICACY IN DOUBT

Textbooks of military medicine and *The Medical Letter* (40:52-53, 1998) state that the anthrax vaccine is "safe and effective." The British secretary of state for defence was vaccinated on camera in an effort to convince service personnel and the public of the vaccine's safety. However, several epidemiologists at the

University of Bristol described the state of current thinking as one of "clinical equipoise" and recommended randomizing troops to receive or not receive vaccine (*Br Med J* 316:1322, 1998).

Certainly, there is a need to develop a better vaccine. Harrison's Principles of Internal Medicine states: "*The current vaccines are impure and chemically complex, elicit only slow-onset protective immunity, provide incomplete protection, and cause significant adverse reactions.*"

4. VACCINE NO DEFENSE AGAINST NEW STRAINS OF ANTHRAX

The vaccine is not completely protective against all natural strains of *Bacillus anthracis*. An additional threat in the context of biological warfare is the potential use of genetically engineered strains, against which both vaccine and antibiotics may be ineffective (*CMAJ* 158:633, 1998). Russian scientists have already produced vaccine resistant strains

5. POTENTIAL IMPACT ON IMMUNE SYSTEM & LINK TO GULF WAR SYNDROME

Anthrax vaccine has been suggested as a possible cause for the Gulf War Syndrome. While evidence that anthrax vaccine alone can cause such a syndrome has not been forthcoming, it is possible that the combination of agents may have induced unexpected adverse changes in the immune response. Additionally, pertussis vaccine may have been administered as an adjuvant to increase the immune reactions to other vaccines, especially anthrax (Jamal GA: "Adverse Drug React" *Toxicol Rev* 17:1-17, 1998). There is a report that the anthrax-pertussis combination induced "severe loss of condition and weight" in animals (*Nature* 390:3, 1997).

6. POOR RECORD KEEPING & FOLLOW UP STUDIES

Fear and mistrust are fueled by poor record-keeping about chemical exposures and vaccines in the Gulf War. There are no adequate records of recipients of special immunizations not in general use (anthrax and botulinum) (Wegman DH

et al.: Am J Epidemiol 146:704-711, 1997). The British defence ministry has also admitted that "medical record-keeping in the Gulf was not satisfactory," according to researcher Alan Silman of the University of Manchester (Nature 384:604, 1996). Moreover, "the MOD [ministry of defence] suffers from an excessive culture of secrecy" (Nature 390:3- 4, 1997).

7. EXPANSION OF MANDATORY VACCINES TO CIVILIAN SECTOR

The questions raised about adverse reactions due to vaccine cocktails are highly pertinent in the civilian sector, now that such a large number of vaccines are mandated for administration to children, with exclusion from school and even charges of child neglect or abuse as penalties for noncompliance.

RECOMMENDATIONS & CONCLUSION

Because of the limited efficacy of the anthrax vaccine, prevention of exposure with shelters and protective gear remains indispensable. In addition to improved vaccines with limited toxicity, the Department of Defense should consider more advanced and less invasive tools, such as decontamination agents.

For example, a material developed by D. Craig Wright of Novavax, Inc, which may be able to rapidly destroy a wide variety of dangerous bacteria and viruses, including anthrax spores. The material, called BCTP, is made from water, soybean oil, Triton X 100 detergent, and the solvent tri-n-butyl phosphate. Laboratory mice and rats thrive when fed the material. Rapid inactivation of anthrax bacteria and spores combined with low toxicity could make BCTP a promising candidate as a broad-spectrum post exposure decontamination agent.

In summary, better passive protection measures and expanded research into vaccines are urgently needed. At present, mandatory vaccination of all troops with the available anthrax vaccine has raised a number of well-founded concerns that should be addressed openly. Our organization is available for any questions or concerns of this committee.