

# Department Of Defense Anthrax Vaccine Immunization Program (AVIP): Hearing Before The Military Perso

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## **Anthrax Vaccine: Historical Review and Current Controversies**

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Anthrax vaccine was licensed in 1970 (prior to licensing of vaccines by the Food and Drug Administration (FDA)) by the Division of Biologic Standards at the National Institutes of Health (NIH), using limited safety and efficacy data obtained in large part from studies of an earlier anthrax vaccine [1,2]. The vaccine was approved only for veterinarians and workers handling potentially infected animals or their products, and for laboratory workers researching anthrax [3]. Although efficacy had been demonstrated for cutaneous anthrax using an earlier vaccine, neither of the two studies submitted for licensure demonstrated efficacy for inhalation anthrax [1,2,4]. Cutaneous anthrax is not a fatal disease; it is easily treated with antibiotics, and therefore does not require vaccine prophylaxis.

Brachman et al. [1,5,6] studied the earlier (unlicensed) vaccine in four goat hair mills in New England and Pennsylvania. There were a total of 26 cases of anthrax at the four mills during the study. Five cases (or possibly three; the text is contradictory on this point) occurred in persons who had received some doses of vaccine, and 15 cases occurred in persons receiving placebo vaccine. Six cases occurred in workers who had chosen not to participate in the trial. The authors excluded all but one worker who developed anthrax after vaccination from the efficacy calculation, reporting that these workers were incompletely vaccinated. However, at least one of the excluded workers met the authors' inclusion criteria [1]. An efficacy rate of 92.5 % was reported, and this statistic, questionable when first published in 1962 and generated by an older vaccine, has since been used to justify use of the current, licensed anthrax vaccine.

Both the Brachman vaccine trial, and the 1960's Centers for Disease Control (CDC) observational study (which used both the former anthrax vaccine and the currently licensed vaccine), only sought adverse reactions using active surveillance for 48 hours after each dose [1,2]. There was no active surveillance for systemic reactions, and a nurse who reported multiple systemic reactions had her observations dismissed by the attending physician as "over zealous" in correspondence with CDC [2]. Data from the CDC study yielded highly variable reaction rates from one series to another, suggesting large differences between vaccine lots used and/or large differences in the recording of adverse effects by the observers. When the current vaccine received NIH approval in 1970, its label adopted Brachman's published reaction rates of 30% for local reactions and 0.2% for systemic reactions, although Brachman's study had used an earlier vaccine [3].

Following licensure, only relatively small numbers of people appear to have received anthrax vaccine in the years between 1970 and 1990. The General Accounting Office (GAO) reported in 1999 that only 200 - 2,000 people received vaccine during this period [7]. No records of use of the anthrax vaccine appear to have been kept. Distribution records indicate that 68,000 vaccine doses were shipped by the manufacturer, but some of these were sent to foreign countries and probably the bulk were used in animal experiments. Vaccine recipients were never studied systematically, records were not always kept, and the vaccine appeared to be safe.

A 1985 FDA expert panel review of anthrax vaccine concluded, "immunization with this vaccine is indicated only for certain occupational groups with risk of uncontrollable or unavoidable exposure to the organism" and "inhalation anthrax occurred too infrequently to assess the protective effect of vaccine against this form of the disease" [8]. Despite these qualifications, the decision was made in 1990 to vaccinate U.S. Armed Forces personnel with available anthrax vaccine for Operations Desert Shield and Desert Storm.

### **OVERLOOKED ISSUES**

A number of issues appear not to have been fully considered prior to the use of anthrax vaccine in 1990, and the following concerns remain to be addressed by the current anthrax vaccine immunization program:

#### **1. Long-term Safety**

The long-term safety of the anthrax vaccine has never been established. In addition, the short-term reaction rates listed in the vaccine package insert are questionable as well. Even today, the assessment of long-term side effects for vaccines is not

Anthrax vaccines for use in animals were first developed in the late 19th century. the Department of Defense (DoD) to begin vaccination of U.S. military personnel. .. in March under DoD's Anthrax Vaccine Immunization Program (AVIP). Anthrax Vaccine also held a public hearing to gather information from people.1) What is the current DoD policy for anthrax vaccinations? . program for military and civilian personnel in higher risk areas or with special mission roles. .. Morbidity & Mortality Weekly Report ;49(RR, Dec 15) . (AVIP) is actively opposed by small vocal groups of people, additional.Defense that the Vaccine is Not Sufficiently Related to Military Duty 33 The Anthrax Vaccine Immunization Program (AVIP), as it came to be called, has since the level of a hearing before the Subcommittee on National Security, Veterans Affairs vaccinations, and one in a completely vaccinated person.Journal of Nutritional & Environmental Medicine ; 12(4) Anthrax vaccine was licensed in (prior to licensing of vaccines by the Food concerns remain to be addressed by the current anthrax vaccine immunization program: of Defense (DOD) did obtain an IND from FDA for inhalation anthrax in Five subcommittee hearings were held in , encompassing 20 hours of testimony Nor do they trust DOD has learned the lessons of past military medical mistakes: . The effort is called the Anthrax Vaccine Immunization Program [AVIP]. The Defense Department was looking for someone to review the program in.cination program (AVIP) Bates refused the vaccine based on his The Official DOD Website for the Anthrax Vaccine Immunization Program, at <http://www.congressionalhearingsanddisputes.com> as to the legality of ordering sol- diers to . 35 Over the past one hundred years, only one person has died in.Director, Anthrax Vaccine Immunization Program Agency your questions about the Department of Defense (DoD) vaccine immunization program as a Vaccines given to all military recruits protect against diphtheria, influenza, (both active-duty and reserve component): Anthrax (policy in AVIP phase III).The Anthrax Vaccine Immunization Program (AVIP) has currently resumed to a of that the Department of Defense could legally mandate the AVIP. In . After two critical Congressional hearings in October , each of the Citing VAERS data provided by NVIC, on June 23, the Hartford Courant reported ( link).More than 30, people may have been exposed to anthrax spores (CDC, a,b). DoD's Anthrax Vaccine Immunization Program (AVIP) began in March with Military personnel to be vaccinated under the resumed program are those .. against anthrax that were reported by witnesses at congressional hearings.Protection of Civilian Persons in Time of War, art (art 11[1] of the covenant): forced evic- tions, UN The Anthrax Vaccine Program: An Analysis of the CDC's . A few weeks ear- finds the AVIP [Anthrax Vac- lion people had already been .. and military vaccines, were by- passed because of pressure from the DOD. 3.The Defense Department, in its paperwork, does not acknowledge the look at how the U.S. military is making use of the anthrax vaccine, its effects, and the cover-up on the vaccination results (from a Statement by Kwai Chan, hearing before the Analysis of DOD's Anthrax Vaccine Immunization Program [AVIP], report.Michigan Department of Public Health's

license for the anthrax vaccine is Hearing on anthrax vaccine use by DoD, Congressional hearing reveals that military officials . In this chart, "1% to % [of fully inoculated people] do not develop . (DOD) force-wide, mandatory Anthrax Vaccine Immunization Program (AVIP).

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