Terrorism - Anthrax Hearings October 1999

Documents on Terrorism - Anthrax Hearings October 1999

Statement by Kathryn C. Zoon; October 12, 1999
Presentation to the Committee on Government Reform STATEMENT
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INTRODUCTION

Mr. Chairman and Members of the Committee, I am Dr. Kathryn Zoon, Director, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA or Agency). I appreciate this opportunity to discuss with you vaccine licensing generally, and specifically, the safety and efficacy of the anthrax vaccine, currently manufactured by BioPort Corporation (the predecessor manufacturer was known as Michigan Biologics Product Institute (MBPI) and prior to that, Michigan Department of Public Health (MDPH)). Let me begin with a brief overview of the process for a vaccine to be licensed.

BACKGROUND

CBER is responsible for evaluating the safety, purity, efficacy and potency of the products we regulate. These products include biological products such as vaccines, products derived from human blood, and many products produced by recent advances in biotechnology. The scope of regulatory responsibility extends to both licensed or approved products and unlicensed products under investigation. From a regulatory perspective, there are four stages in vaccine development:

the pre-Investigational New Drug (IND) stage (before the product is used in people);

the IND stage (where human use occurs under limited study conditions);

the license application stage for vaccines (where FDA reviews the results of the clinical studies and the manufacturing process); and,

the post-licensure stage (following approval of the product for marketing).

Before a new vaccine can be studied in people, a sponsor must submit an IND application to FDA. In the application, the sponsor:

describes the composition, source, and method of manufacture of the product and the methods used in testing its safety, purity, and potency;

provides a summary of all laboratory and pre-clinical animal testing performed; and,

provides a description of the proposed clinical study and the names and qualifications of each clinical investigator.

Once the sponsor submits the IND, FDA has 30 days to review the application to determine whether or not the study may proceed. FDA may prohibit a sponsor from conducting a study for a number of reasons, including when the study volunteers will be exposed to unwarranted risks, by putting the IND on "clinical hold".

The IND process generally is described as having three phases prior to product approval; however, the distinctions between these phases are not absolute. Phase 1 trials are focused on basic safety and, for vaccines, Phase 1 trials also usually evaluate the immune response elicited by the vaccine. These trials are usually small – generally between 20 and 100 subjects – and they frequently are done in healthy "normal volunteers" and may last just several months. Phase 2 trials often include several hundred subjects, are often randomized, and last anywhere from several months to several years. These trials usually include individuals who are at high risk for the infectious disease of interest. Unless severe reactions or a lack of effectiveness surface during the first two phases, the sponsor may decide to perform one or more Phase 3 studies that can include up to several thousands of people. These Phase 3 trials are intended to provide the definitive measure of effectiveness, as well as continue the evaluation of the product's safety. The size of the efficacy trial will be affected by the expected incidence of disease that the vaccine is intended to prevent. If at the end of Phase 3 trials the manufacturer believes there are adequate data to show the vaccine is safe and effective for its intended use, the manufacturer submits a license application to the Agency.

Licensing a new vaccine is only one stage of FDA's oversight of vaccine safety. Following issuance of the license, there is continued post-marketing surveillance of the product by monitoring adverse events, e.g., the Vaccine Adverse Events Reporting System (VAERS), and of the manufacturer's production activities, including compliance with good manufacturing practices.

Manufacturers generally submit samples of each licensed vaccine lot and the results If their own tests for potency, safety, and sterility to the Agency before release of each lot of the licensed product, because of the complex manufacturing processes for most biological products. In addition, licensed establishments are inspected regularly by FDA. Let me now turn to anthrax.

ANTHRAX DISEASE

Anthrax is a highly infectious disease caused by spores of a bacterium known as *Bacillus anthracis*. These spores resist destruction and may be present in the soil for decades,

occasionally infecting grazing animals that ingest the spores. Goats, sheep and cattle are examples of animals that may become infected. Human infection may occur by three routes of exposure to anthrax spores: cutaneous, gastrointestinal, and pulmonary (inhalation). Skin contact with live infected animals, or with the hide, hair or bones of an infected animal may lead to infection of a person's skin, known as cutaneous anthrax infection. This is the most common manifestation of anthrax in humans, accounting for more than 95 percent of cases. Untreated cutaneous anthrax infection is associated with a death rate estimated to be approximately 20 percent. Eating undercooked or raw, infected meat can cause gastrointestinal anthrax infection. Breathing in airborne spores may lead to inhalation anthrax. Experience has shown that inhalation anthrax has a very high mortality rate, with estimates ranging from 80 percent to 90 percent or higher.

Inhalation anthrax infection has two phases. During the first phase, which occurs within one to five days after inhalation of the spores, the patient has influenza-like symptoms, such as a cough, malaise, fatigue and mild fever. Several days later these symptoms may subside, but are rapidly followed by the second, more severe stage of disease. During the second phase, the patient experiences sudden onset of severe respiratory distress, and sometimes chest pain accompanied by fever. Chest x-rays may show fluid in the lung. Within a day, septic shock and death will likely occur.

Treatment of cutaneous anthrax infection involves administration of antibiotics. In the case of pulmonary anthrax infection, therapy has been of limited benefit, except when given immediately after exposure. Prior to use of the anthrax vaccine, cases of human anthrax infection in the United States were much more prevalent. The only known effective prevention against anthrax is the anthrax vaccine. According to data from the Centers for Disease Control and Prevention (CDC), there were approximately 130 reported cases of anthrax infection per year at the start of this century. In the past decade, there have been no confirmed reports of human anthrax in the United States. It is difficult to assess exactly how much of this dramatic reduction is due to the vaccine, but immunization with the anthrax vaccine of people at risk, along with vaccination of animals against anthrax, have likely contributed to this favorable decline. Elsewhere in the world, human anthrax cases continue to be reported, especially in countries with predominately agricultural economies.

HISTORY OF THE ANTHRAX VACCINE

Philip S. Brachman *et al*. conducted clinical trials on the anthrax vaccine during the 1950s . This controlled field study involved workers in four mills in the Northeastern United States that processed imported animal hides. This selected population was at risk because the mill workers routinely handled anthrax-infected animal materials. Prior to vaccination, the yearly average number of human anthrax infection was 1.2 cases per 100 employees in these mills.

For this trial, employees who had not previously contracted anthrax were selected and divided into two groups. The groups were balanced with regard to their age, length of employment, department at the mill, and the particular job they performed. The trial was a single-blinded study, in which the participants were not told whether they received the

vaccine or placebo. Individuals who did not participate in the controlled study [because they were ineligible (i.e., had a history of prior anthrax) or chose not to receive the injections] were also monitored for anthrax. These individuals who did not receive vaccine or placebo were referred to as the observational group.

During the trial, 26 cases of anthrax infection were reported at the mills - five inhalation and 21 cutaneous. Of the five inhalation cases, two individuals had received the placebo, while three individuals were in the observational group. Four of the five people who developed inhalation anthrax died. No cases of inhalation anthrax occurred in anthrax vaccine recipients. Of the 21 cutaneous cases, 15 individuals had received the placebo, three individuals were in the observational group, two individuals were partially immunized and one individual was fully immunized. Based upon a comparison between the populations completely vaccinated versus the populations receiving placebo, the authors calculated a vaccine efficacy level of 92.5 percent.

On April 14, 1966, CDC submitted an IND for the anthrax vaccine to the Division of Biologics Standards, which was then part of the National Institutes of Health (NIH), later transferred to FDA. The method of preparing this vaccine was similar, but not identical, to the vaccine used in the Brachman et al. study. The vaccines in both studies were based on the immunity induced by the protective antigen (PA). Persons receiving the vaccine made by the two different methods demonstrated similar peak immune responses (antibody concentration) following the initial three doses. Textile employees and laboratory workers were immunized under this IND. A number of lots of investigational vaccine used by CDC under this IND were manufactured by the MDPH.

The data submitted to the Division of Biologic Standards described CDC's experience with approximately 16,000 doses of anthrax. This vaccine was administered to approximately 7,000 study participants. Reported local reactions at the immunization site ranged between 3 percent to 36 percent of the initial series of doses, and 3 percent to 33 percent of the booster doses, depending on the lot. Reported mild reactions were 3 percent to 20 percent of all doses. Reported moderate local reactions were 1 percent to 3 percent of doses. Severe reactions were reported for less than 1 percent of doses. Systemic reactions were reported in four cases during the five-year reporting period. These reactions included fever, chills, nausea and general body aches, and were reported to have been transient.

The Division of Biologics Standards determined that the data submitted by CDC supported licensure of the vaccine. On November 10, 1970, the Division of Biologics Standards issued a product license to MDPH to manufacture anthrax vaccine.

Approved labeling for the anthrax vaccine states that immunization with this product is recommended for individuals who may come in contact with animal products that may be contaminated with Bacillus anthracis spores, and for individuals engaged in diagnostic or investigational activities which may bring them in contact with Bacillus anthracis spores. It is also recommended for persons at high risk, such as veterinarians and others handling potentially infected animals.

The approved labeling also states that anthrax vaccine is to be administered subcutaneously (injected under the skin). After the initial dose of 0.5ml, further doses of 0.5ml are administered at two weeks, four weeks, six months, 12 month and 18 months, thereafter, with yearly boosters.

THE PANEL REVIEW

The Public Health Service Act, under which biologics such as vaccines were licensed, required evidence of safety, purity and potency. After the Division of Biologic Standards was transferred from NIH to FDA, expert panels were assigned to review information on biological products, including vaccines that had been on the market prior to the transfer. The review was initiated in order to verify whether existing data supported the safety and efficacy of marketed biological products.

Biological products were divided into one of six categories. FDA assigned responsibility for initial review and recommendation for all products in these six categories to separate independent advisory panels of outside scientific experts, collectively known as the Advisory Review Panel. The Advisory Review Panel also was charged with advising FDA, in the form of a report, on classification of these products into one of the following categories: Category I - safe, effective and not misbranded; Category II - unsafe, ineffective or misbranded; Category III - insufficient information, further testing required. Based upon their review of available data, the Advisory Review Panel recommended that the anthrax vaccine manufactured by MDPH be classified as a Category I product and that appropriate licenses be continued based upon substantial evidence of safety and effectiveness of this product. The safety data from the CDC trials and the efficacy data from the Brachman et al. trials were the basis for these findings. These findings were published in the Federal Register on December 13, 1985.

Today, it would be difficult to repeat the efficacy studies. This is because there are no evident populations in the United States where prophylactic vaccine protection against natural exposure to anthrax could be evaluated in a clinical field trial, such as was done in the Brachman *et al.* study. Specifically, the incidence of naturally occurring anthrax in humans is low and sporadic in occurrence, making identification of a trial target population difficult. Likewise, it would be unethical to perform challenge/protection studies in humans. In addition, human immunogenicity and safety data would be required. The safety database obtained by CDC under the IND would be considered a reasonable pre-licensure database for evaluating a safety study today.

POST-MARKETING EXPERIENCE

Since licensure in November 1970, livestock workers, veterinarians, lab workers and researchers who are at risk for infection have used the anthrax vaccine. The manufacturer provided FDA the following information regarding distribution. From 1974 to 1989, approximately 68,000 doses were distributed. In 1990, approximately 268,000 doses were distributed. Between 1991 and April 1999, we understand that approximately 1,200,000

doses were distributed. We understand additional doses have been distributed since then, however, we do not have final numbers.

It is not possible to give a precise number of persons who received the vaccine prior to use in Operation Desert Shield and Operation Desert Storm. We estimate that approximately 7,000 subjects received approximately 16,000 doses of the vaccine during clinical trials conducted by the CDC. In addition, between 1974 and 1989, our files show approximately 68,000 doses were distributed. This is sufficient to vaccinate about 11,000 people with the full six-dose regimen of the currently approved anthrax vaccine. It is possible that some doses distributed were not used, or that some individuals did not receive the full course of the vaccine or that some doses were used for annual boosters. Thus, it is not possible to accurately report the precise number of people vaccinated between 1974 and 1989.

According to the CDC, from 1962 to 1974, 27 cases of anthrax occurred in the "at-risk" populations in the

United States. Of those, 24 cases occurred in unvaccinated individuals, one case after the person had been partially immunized with one dose of the vaccine and two cases after individuals had been partially immunized with two doses of the vaccine. No documented cases of anthrax were reported for individuals who had received the recommended six doses of the vaccine.

VACCINE ADVERSE EVENT REPORTING - ANTHRAX

With regard to safety data, FDA and CDC jointly operate VAERS. FDA uses this system to track adverse events possibly associated with licensed vaccines. Reporting of adverse events associated with the use of anthrax vaccine is voluntary for individual healthcare providers. The vaccine manufacturer, however, must report to FDA all reports of adverse events of which they are aware.

The report of an adverse event to VAERS is not documentation that a vaccine caused the event, only that the event occurred soon after the vaccine was administered. Doctors and other healthcare providers are encouraged to report serious or unexpected adverse events following vaccination, whether or not they believe that the vaccination was the cause of the adverse event. Since it is difficult to distinguish a coincidental event from one truly caused by a vaccine, the VAERS database contains events of both types.

It should be emphasized that adverse event reports can be made by a health care professional, a patient or anybody else. If a patient’s physician does not file a VAERS report, the patient can do so. FDA encourages individuals to report to VAERS any clinically significant adverse event occurring after the administration of any vaccine licensed in the United States. Reports to VAERS may be made in writing or by calling a toll-free number, 1-800-822-7967. Reporting instructions are available on the Internet at www.fda.gov/cber/vaers.aspl. Since the beginning of VAERS’ operations in 1990, through October 1, 1999, 425 reports of adverse events associated with use of the anthrax vaccine

have been reported to VAERS. Of those, FDA considers 29 serious events. These reports are for diverse conditions, with no clear patterns emerging at this time. Some of these events are described below. The remaining 396 reports describe a variety of symptoms and conditions, including injection site edema (swelling with fluid in tissue), injection site hypersensitivity, rash, headache and fever.

The 29 serious events were reported to have occurred or been diagnosed at times ranging from 45 minutes to four and one half months after vaccination. Some individuals experienced adverse events following the first dose; others received up to 5 doses before event onset. Most of these individuals reporting adverse events during the current anthrax vaccination program have recovered. Seven patients were hospitalized for severe injection site reactions. One individual experienced a more widespread allergic reaction. One individual was hospitalized with a confirmed case of aseptic meningitis nine days after vaccination. Two individuals experienced Guillain-Barré syndrome. Three weeks after receiving the vaccine, another individual was diagnosed with bipolar disorder and, at last follow-up, has not recovered. One individual experienced signs and symptoms of transverse myelitis. One individual experienced onset of multi-focal inflammatory demyelinating disease and has since clinically recovered. Another individual experienced onset of lupus and, at last follow-up, has not recovered.

None of these events, except for the injection site reactions, can be attributed to the vaccine with a high level of confidence, nor can contribution of the vaccine to the event reported be entirely ruled out. It should be emphasized once again that it is not always possible to attribute a cause and effect relationship between a reported event and a vaccination. With the exception of injection site reactions, all of the adverse events noted above do occur in the absence of immunization.

While the data gathered from the VAERS system can serve as a useful tool in identifying potential problems, the reports on anthrax vaccine received thus far do not raise any specific concerns about the safety of the vaccine. As more people receive the vaccine, the numbers of adverse events reported will increase. FDA continues to view the anthrax vaccine as safe and effective for individuals at risk of exposure to anthrax.

LOT RELEASE

As mentioned above, because of the complex manufacturing processes for most biological products, each product lot undergoes thorough testing for purity, potency, identity, and sterility. The anthrax vaccine is subject to lot release. FDA reviews the lot release protocols showing results of applicable tests and lot samples are submitted for possible testing by FDA.

The manufacturer may not distribute a lot of the product until FDA's Center for Biologics Evaluation and Research releases it. The lot release program is part of our multi-part strategy that helps assure product safety by providing a quality control check on product specifications.

MEMORANDUM OF UNDERSTANDING (MOU) WITH THE DEPARTMENT OF DEFENSE (DoD)

On May 21, 1987, FDA entered into the current MOU with DoD. This replaced the previous MOU signed in 1974. The 1987 agreement established procedures to be followed by DoD and FDA regarding the investigational use of drugs, biologics and medical devices. The MOU affirms that clinical testing of new drugs will be done in accordance with application regulations concerning INDs and IRBs. The MOU addressed the possibility of a need for expedited review of an IND by FDA to meet DoD requirements concerning National defense considerations. Under the MOU, DoD is responsible for classifying medical research and development as it relates to information that may be made public under Freedom of Information Act regulations. It should be stressed that this agreement, however, does not allow DoD to perform research on humans without submitting an IND and it requires DoD to comply with all FDA regulations.

FDA's CONSULTATION WITH DoD REGARDING THE ANTHRAX VACCINE IMMUNIZATION PROGRAM

FDA has not had an official role in the development or operation of the Department of Defense's Anthrax Vaccine Immunization Program, including the AVIP tracking system or the program's adverse event reporting system. In March 1997, DoD briefed FDA about their draft plan for the possible use of the anthrax vaccine to inoculate U.S. military personnel according to the FDA approved labeling for six doses administered on a specified schedule over eighteen months. Subsequently, FDA learned that the DoD plan had been adopted.

In July 1998, DOD requested that CDC, in conjunction with the Health Resources and Services Administration, National Vaccine Injury Compensation Program (VICP), organize and coordinate a program to evaluate VAERS reports for the anthrax vaccine. In response to the request by DoD, a group of non-government medical experts was convened by the VICP in the fall of 1998 as the Anthrax Vaccine Expert Committee (AVEC). AVEC, coordinated by VICP, has met eight times since 1998. These experts have been reviewing all VAERS reports for the anthrax vaccine. Representatives of VICP, FDA, CDC and DoD have attended meetings, and FDA has provided information to assist the committee in its deliberations. AVEC is unique in that it provides an independent civilian expert assessment of adverse events reported for the anthrax vaccine.

Upon learning that some DoD personnel may be receiving their anthrax vaccine doses significantly later than the FDA approved schedule, both Dr. Jane E. Henney, Commissioner of the Food and Drug Administration, and I, recently sent letters to DoD. In the letters we asked DoD to expeditiously investigate this matter as we are unaware of any data demonstrating that any deviation from the approved intervals of doses found in the approved labeling will provide protection from anthrax infection. We will continue to monitor this issue.

CONCLUSION

Mr. Chairman, we believe the anthrax vaccine is a safe and effective vaccine for the prevention of anthrax disease – an often-fatal disease – when used according to the FDA approved label. Our confidence in this vaccine, like all vaccines, is based upon four components: first - the review of manufacturing and clinical trials and subsequent clinical laboratory experience with the vaccine; second – ongoing inspections of the manufacturing facility; third – our lot release requirements; and fourth – our ongoing collection and analysis of adverse event reports. So far, the data gathered from VAERS reports on anthrax vaccine do not signal concerns about the safety of the vaccine. The Agency will continue to closely monitor and investigate reports of serious adverse events received on all vaccines, including anthrax, to assure that only safe products are on the market.

I appreciate the Committee's interest in this very important topic and would be happy to answer any questions.

Statement by the Honorable Sue Bailey, Major General Randall L. West and Lieutenant Colonel Gaston M. Randolph
Presentation to the Committee on Government Reform
DEFENSE VACCINES:
Part of Total True Force Protection in an Uncertain World
STATEMENT BY
Honorable Sue Bailey - Assistant Secretary of Defense (Health Affairs)
MajGen Randall L. West - Special Assistant to the Under Secretary of Defense, Personnel
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Submitted To
HOUSE COMMITTEE ON GOVERNMENT REFORM
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INTRODUCTION

Chairman Burton and Distinguished Committee Members, I am honored to appear before your Committee today to address your questions about the Department of Defense (DoD) vaccine immunization program as a component of our biological defense program. I am Dr. Sue Bailey, Assistant Secretary of Defense for Health Affairs. I am accompanied today by Major General Randy West, Special Assistant to the Under Secretary of Defense, for Anthrax and Biological Defense Affairs, and Lieutenant Colonel Gaston M. Randolph, Jr., Director of the Anthrax Vaccine Immunization Program Agency. At your request, our testimony will specifically address the Department's policy involving biological warfare and vaccines, refusal process, personnel education, vaccine safety and surveillance, immunization compliance, and Anthrax Vaccine Immunization Program implementation.

THE THREAT

General - Currently, at least ten nation states and two terrorist groups are known to possess, or have in development, a biological warfare capability. The production of biological warfare agents does not require specialized equipment or advanced technology. When comparing equal amounts of biological and chemical warfare agents, the biological agent is far more potent. Small quantities of biological agents can produce very large numbers of casualties. Biological agents can be delivered through a number of means; including aerial bombs, artillery shells, long-range missiles, agricultural sprayers, and spray tanks carried by aircraft, ships, boats or even cars. Many of the materials and equipment that are used to produce biological warfare agents are available from legitimate sources and intended for other uses such as pharmaceuticals or biopesticides, thus making it difficult to limit, detect or stop the spread of biological warfare technologies and capabilities.

Anthrax Itself - Of all biological warfare agents, anthrax spores are the top choice in biological weapons for "germ warfare." Several of the countries that have or are developing offensive biological warfare capabilities are most likely working with anthrax. Iraq has admitted to producing and weaponizing anthrax. The anthrax accident at Sverdovsk in 1979 illustrated Russia’s military research with the organism. Anthrax is many times more lethal than any of the most potent chemical warfare agents, such as VX. It is an infectious disease caused by the bacteria Bacillus anthracis and spread by contact with infected animals, handling infected products, eating infected meat, or breathing weapon-dispersed anthrax spores.

Anthrax Virulence - Compared to many other pathogens with BW potential, starting cultures of anthrax are relatively easy to obtain. Large quantities of the bacteria can be produced in readily obtainable fermentation vessels. The organism naturally converts to a spore form that can be stored as bulk agent or in filled munitions. When disseminated in air, the spores remain viable much longer than other types of infectious agents. The size of the spores (approximately 1-micrometer) is such that when inhaled, they tend to be retained in the lung. The effects usually are lethal unless rapid diagnosis is made and a combination of appropriate medical measures is administered immediately. One deep breath can inhale enough spores to result in fatality. Initial symptoms begin 1 to 6 days after exposure and mimic cold or flu-like symptoms. Once symptoms occur in the unvaccinated, it is too late for vaccination or antibiotic treatment for those contaminated. If untreated, death follows within 1 to 3 days after symptoms first begin. Lethality for unvaccinated persons who are contaminated and do not receive near term antibiotics approaches 100%. Anthrax is considered an effective biological weapon because:

It is lethal if the victim is not treated immediately or prevaccinated. Spores can be produced in large quantities using basic knowledge of biology.

Spores can be stored for years without losing viability.

Spores can be easily spread in the air by missiles, rockets, artillery, aerial bombs sprayers.

There is no effective treatment for unvaccinated inhalational anthrax victims once symptoms are exhibited.

The objective of the Department's Nuclear, Biological and Chemical defense program is to enable our forces to survive, fight and win in an NBC-contaminated environment.

To protect our military personnel against this lethal weapon, the Department of Defense has established a force health protection policy which includes the use of vaccines, where possible, in sufficient time to develop immunity before deployment to high-threat areas. It is also the policy of the United States Government, as delineated in the Executive Order of September 30, 1999 to provide our military personnel with safe and effective vaccines that negate or minimize the effects of biological weapons.

Vaccines to Protect U.S. Military Personnel, 1999

In addition to the routine vaccine needs of healthy adults, U.S. military personnel receive various vaccinations, based on the health threats encountered in their basic military training, occupation, travel and operational areas of employment. Military vaccination schedules are frequently presented to the Armed Forces Epidemiological Board (AFEB), an external panel of distinguished civilian medical experts for consultation and concurrence. These vaccines are described by category in Table 1. Vaccines given to all military recruits protect against diphtheria, influenza, measles, meningococcal disease, poliovirus, rubella, and tetanus. Some recruits receive adenovirus, mumps, varicella, and yellow fever vaccines. In addition, all members receive tetanus-diphtheria toxoids every 10 years and are administered annual vaccines to protect against influenza. However, some members are required to take anthrax, hepatitis A, hepatitis B, Japanese encephalitis, meningococcal, plague, rabies, typhoid, and yellow fever vaccines because of deployment to high-risk areas.

Vaccines given based on occupation, personal risk factors, or personal health status include Haemophilus influenzae type b, hepatitis B, Lyme disease, meningococcal disease, pneumococcal disease, rabies, and varicella vaccines. Table 1 displays the timing and routine schedule of vaccines typically administered to military personnel.

Table 1. Vaccines Typically Administered to Military Personnel, 1999 (U.S. Army, U.S. Navy, U.S. Marine Corps, U.S. Air Force, U.S. Coast Guard)

Timing

Vaccine

Routine Schedule for Basic Immunity **

Recruits:

(Adenovirus)

Diphtheria

Influenza

Measles

Meningococcal disease

Mumps *

Poliovirus

Rubella

Tetanus

Varicella *

Yellow fever *

Single dose

Single, every 10 yrs

Annual

Single dose

Single dose

Single dose

Single dose

Single dose

Single, every 10 yrs

Two doses

Single, every 10 yrs

During advanced individual training (AIT) and then throughout career

(both active-duty and reserve component):

Anthrax

(policy in AVIP phase III)

Six-dose series

Routine during career

(both active-duty and reserve component):

Diphtheria

Influenza

Tetanus

Single, every 10 yrs

Annual

Single, every 10 yrs

Alert forces; when deploying or traveling to high-risk areas

(both active-duty and reserve component):

Anthrax (current policy)

Cholera ***

Hepatitis A

Hepatitis B

Japanese encephalitis

Meningococcal disease

(Plague)

Rabies

Typhoid

Yellow fever

Six-dose series

Two doses

Two doses

Three doses

Three doses

Single dose

Three doses

Three doses

Dosage varies

Single, every 10 yrs

Individualized according to occupational or personal needs:

Haemophilus influenzae type b

Hepatitis B

Lyme disease

Meningococcal disease

Pneumococcal disease

Rabies

Varicella

Single dose

Three doses

Three doses

Single dose

Single dose

Three doses

Two doses

* Vaccination policy varies among Military Services based on Service needs.

** Booster doses may be required at annual or other intervals to sustain immunity. *** Seldom used: vaccine offers only short-term protection, with painful injections. Vaccines listed in parentheses may not be available due to manufacturing limitations. Adapted from United States Army Regulation 40-562; Navy Bureau of Medicine Surgery Instruction 6230.15; Air Force Joint Instruction 48-110; Coast Guard Commandant Instruction M6230.4E. Immunizations Chemoprophylaxis. Washington, DC, 1 November 1995.

Even with this aggressive program to protect our forces, we know we must remain constantly in search of new avenues to combat the ever-emerging biological warfare and infectious disease threats.

Vaccines are under development for a number of validated biological warfare and infectious disease threats to military forces. Included among these are: nine biological disease vaccines being investigated by the Medical Biological Defense Research Program (Staphylococcal Enterotoxins, Encephalitis viruses, Ricin, Brucellosis, Filoviruses, Othopox viruses, Botulinum Toxin, Plague, and next generation Anthrax vaccine); and five in advanced development at the Joint Vaccine Acquisition Program (Q-Fever, Tularemia, Smallpox, Venezuelan Equine Encephalitis, Botulinum Recombinant Multivalent). In addition, the Military Infectious Disease Research Program currently is investigating vaccines to prevent infections by the following organisms: Malaria (Plasmodium falciparum), Dengue Fever virus, Heptitis E virus, Meningitis (Neisseria Meningitidis Group B), Shigella, Enterotoxigenic Escherichia coli, Campylobacter, and Hantaviruses. This is only a summary of ongoing research and should not be interpreted as future mandatory vaccine policy. Much work is yet to be done on safety, efficacy, threat, protocol, requirements, etc.

Multi-Dose, Multi-Decade Military Vaccine Safety Studies

Given the number of vaccines presently used and the number under investigation, it is prudent for us to evaluate the safety and efficacy of administering multiple vaccines. We

have done that for over forty years. Research on the health effects of multiple immunizations first appeared in the 1958 Bulletin of the Johns Hopkins Hospital. Two follow-on studies appeared in the Annals of Internal Medicine in 1965 and 1974 (Peeler, et al., 1958; Peeler, et al., 1965; White, et al., 1974). These successive studies reported on the health of 99 male laboratory workers at Fort Detrick, Maryland, who were hyper-immunized with multiple vaccines between 1944 and 1971. These workers received 52 to 134 milliliters of vaccines (average: 97 ml) against multiple infections. They also received 6 to 93 microbial skin tests (average: 55 tests) to detect hypersensitivity or immunity to dangerous microorganisms. For comparison, note that the six 0.5-ml doses of anthrax vaccine in the primary series total 3 ml. These workers received various combinations of immunizations against anthrax, botulism, brucellosis, diphtheria, Eastern equine encephalitis, influenza, plague, poliomyelitis, psittacosis, Q fever, Rift Valley fever, Rocky Mountain spotted fever, smallpox, tetanus, tularemia, typhus, Venezuelan equine encephalitis, Western equine encephalitis, and yellow fever.

The final report concluded: "It is of prime significance that long-term follow-up examination of these intensively immunized men failed to demonstrate any evidence of illness attributable to the immunizations. There is no indication that intensive immunization interfered with the ability to produce adequate antibody titers after antigenic challenge." The authors also noted "These data and the accompanying evaluation of an intensively immunized population provide evidence that no obvious adverse effects result from repeated immunization…" Thus, this group provides reassurance that schedules for routine immunization with a diversity of vaccines should not produce untoward effects merely because of frequency of inoculation. However, allow me to again clarify that the Department does not plan to administer any additional vaccines without compliance with FDA requirements and when necessitated by existing threats. We are only pursuing prudent, precautionary research and development in response to potential threats.

SAFETY AND EFFICACY OF VACCINES

To ensure that the vaccines administered to our military personnel are safe and effective, the Department of Defense conducts an aggressive, multi-faceted surveillance program. In fact, the safeguards of vaccine administered to DOD personnel meet or exceed every standard for vaccine administration to the civilian population. Our program includes a wide variety of activities that can be grouped into three main scientific method categories: clinical studies of vaccine recipients; database analysis of vaccine recipient automated medical records; and spontaneous reports.

As the Centers for Disease Control Prevention (CDC), the Food and Drug Administration (FDA), and trained epidemiologists discovered over time, these methods need to be used in tandem to fully understand whether or not an adverse event was caused by a vaccine or merely coincided in time with the vaccination. Coincidental events are sometimes referred to as temporal (pertaining to or limited in time) associations. Temporal association alone does not prove causation.

A current example of this tandem surveillance is the anthrax vaccine safety program. The Department is using these same three scientific methods to ensure a vaccine that is both safe and effective against all known strains of anthrax pathogen. Anthrax vaccine adsorbed (AVA) has been approved by the FDA for nearly 30 years, and has been reaffirmed by a civilian advisory panel in 1985 and reaffirmed by senior FDA officials in 1999 during previous hearings.

A new long term study, in addition to several already performed, is also underway to determine whether individual people who received multiple vaccines, including the anthrax vaccine, during their past employment at Ft. Detrick, MD demonstrated any adverse health effects over the long term. A total of 570 study and control volunteers have been enrolled in this case-controlled study that began in 1996. All volunteers signed an approved informed consent document. The study media included a 9-page health history questionnaire, extensive blood tests and urinalysis. The questionnaire queries mental and physical conditions of progeny as well as the health of volunteers. Study end points include symptoms, symptom complexes (including the Gulf War Illness complex of symptoms), diseases, abnormal laboratory and urine tests. Study subjects will be compared to 2-3 race, gender, and age-matched control subjects to determine if any long-term medical effects exist among this unique group of study subjects. Analysis of the data from the extensive health history questionnaire and numerous laboratory tests is currently in progress.

On August 24, 1999, the Anthrax Vaccine Immunization Program Agency convened a team of medical experts to design a set of studies to assess the long-term safety of the anthrax vaccine, in response to concerns expressed from Service Members, their families and the General Accounting Office. In designing these studies, we have drawn from the accumulated experience of some of the nation’s best vaccine researchers at CDC and FDA.

Vaccine Adverse Event Reporting System (VAERS)

The Department of Defense has also been a long-time participant in CDC/FDA national programs aimed at collecting information about adverse events temporally associated with vaccines. DoD has reported to VAERS, since its inception.

A DoD policy memorandum ensuring that Reservists have full access to DoD Medical Treatment Facilities for treatment of adverse events from DoD directed immunizations was signed on July 20, 1999, and clearly outlines patient or provider submission of Form VAERS-1.

Health care professionals, as well as patients themselves, report adverse events after immunization to VAERS. VAERS reports, by definition, will include a combination of events caused by the vaccine and coincidences that are only temporally associated with immunization and have no cause-and-effect relationship with the vaccine.

Naturally, we are most interested in serious adverse events, death, anaphylaxis, hospitalization or prolonged disability, but we are also concerned about reactions at the injection site, often called "local reactions." DoD encourages our health care professionals

to report all adverse events that they consider important and clinically relevant. As with our civilian clinician counterparts, the criteria for reporting a VAERS event are non-restrictive, as a means to encourage reporting.

Education Communication

The number and variety of vaccines administered to our personnel makes education and communication a high priority. The Department of Defense is committed to fully educating our service members, DoD civilians, DoD civilian contractors and their families on the purpose and value of all its vaccines. One of the most thorough examples of this kind of education is the anthrax vaccination education program. In an unprecedented manner, we use each of the following communications media to accomplish this goal:

u A sophisticated anthrax specific website www.anthrax.osd.mil with multiple layers of information and methods for communicating with our Service Member population, their families, and other DOD beneficiaries and concerned members of the American public.

u Three Service - specific anthrax websites hyper-linked to all known military and civilian websites discussing anthrax, biological weapons, health care, domestic preparedness, terrorism, VAERS reporting, preventive medicine, infectious disease, and more.

u Information sheets (tri-folds) individually tailored for Service Members, Family Members and Civilians. DOD issued Tri-folds to each Service Member receiving the vaccine since administering the first doses in March 1998. The Tri-fold explains the threat of biological weapons, the benefits of anthrax vaccination and the known risks from the vaccine. The Tri-fold is currently under revision to include Reserve Component-specific information on accessing care.

u DOD Leaders Briefing required to be given to all Service Members prior to receiving the anthrax immunization. Distributed by each Service and prominently posted on the www.anthrax.osd.mil website.

u DOD Health Care Providers Briefing given to all DOD health care providers administering the anthrax vaccine — who then serve as teachers, coaches, mentors for supervisors, commanders, Service Members and their families. Distributed by each Service and prominently posted on the www.anthrax.osd.mil website.

u Open House/Speakers Bureau briefings and open educational forums for all Service Members and their families.

u A 1.877.GETVACC telephone toll-free information line was implemented on 1 Sep 99.

u A variety of anthrax vaccine ‘silent training aids’. These highly visible training aids emphasize the key themes of the anthrax threat, safety and efficacy of the vaccine, vaccine dosing schedule, and adverse event reporting.

u Armed Forces Information Service news media, local installation print, radio and television news service initiatives.

A state-of-the-art Anthrax Education CD-ROM which provides Service

Members, families, supervisors, commanders and health care providers with tailored, multimedia information on the anthrax threat, safety and efficacy of the vaccine, signs, symptoms and prevention of anthrax is in production now.

u An Anthrax Vaccine Immunization Program Videotape explaining the threat, safety, efficacy of the vaccine. The video features prominent civilian and Government scientists and vaccine experts explaining and endorsing the vaccine is also in production.

u DOD is currently collaborating with CDC to array this information in the format of Vaccine Information Statements (VIS) that civilian health care providers around the country give America's children, adolescents, and adults during routine vaccinations.

u Clinical guidelines for managing adverse events after vaccination were drafted in May 1999, based on a consensus panel of civilian and military physicians experienced both in immunology and the general provision of health care. After a synchronized staffing with the Services, Federal Agencies and other institutions, we will distribute the guidelines worldwide, including posting on the www.anthrax.osd.mil web and all associated, linked health care sites. These guidelines represent DoD's concerted effort to standardize the evaluation and care of people who have adverse events after vaccination against anthrax. It is worth noting that such guidelines have never been developed in the civilian sector.

Administering Vaccines

We realize that no matter how safe a vaccine is or well it is communicated, it is critical to maintain the highest standards in clinical and administrative practices. We do this in variety of ways, including monitoring, documenting, conducting clinical conferences and panels.

Monitoring and Compliance Reporting - Monitoring and compliance using guidelines discussed in the preceding paragraphs are an ongoing quality assurance/quality improvement responsibility of both individual medical treatment facilities and the DOD military health system. Overarching guidance is established in a variety of ways, including standards printed in the joint immunization instruction, "Immunization and Chemoprophylaxis Regulation" (Army Regulation 40-562, Bureau of Medicine Surgery Instruction 6230.15, Air Force Joint Instruction 48-110, Coast Guard Commandant Instruction M6230.4E), dated 1 November 1995.

This regulation represents the current standard for immunizations and chemoprophylactic practices within the military health system. In addition to this joint regulation, each Service's formal anthrax immunization implementation plan addresses clinical aspects of vaccine administration. The six shot Anthrax regimen is an excellent example of the requirements of this monitoring and compliance. Using sophisticated information and tracking Service systems, each of the Service immunization tracking systems allows unit leaders to track pertinent individual and unit data from any deployed location. All Service electronic immunization data is ultimately stored in the Defense Eligibility Enrollment Reporting System (DEERS), which serves as the final corporate data repository. In addition to electronically recording anthrax immunizations, each Service employs several redundant

paper-based records systems to record immunizations, including the Health Record, the yellow shot record, immunization clinic sign-in logs and other forms.

While the current AVIP Phase 1 focused on immunization of the Active Component, (91% of all service members immunized to date), we are extremely concerned with implementation, tracking, compliance and heath care follow-up of our Reserve Forces. We recognize that the reserve forces will have some special needs as the Department continues its three-phased execution. These challenges include the lack of routine contact with commanders, weekend drill opportunities for immunizations and the concern of Service Member medical follow-up if they have a concern with any expected or unexpected reactions to the vaccine. Through the AVIP Synchronization Team, supported by the AVIP Agency and working with the ASD (Reserve Affairs), we intend to provide additional services and capabilities to the reserves to ensure their confidence and compliance. Reservists' can receive their vaccinations and follow up medical evaluation as needed at any of our Military Treatment Facilities (MTFs) across the nation. We have begun and have nearly completed implementation of a Federal Strategic Health Alliance for Force Health Protection Initiative that brings together federal agencies and the private sector to increase access to vaccination through internal RC medical assets, DoD Medical Treatment Facilities, the Public Health Service, Veterans Health Administration, and a private contractor, the Arora Group. These resources collectively extend access to care to a provider network of greater than 15,000. A July 1999 Department memorandum reiterates Reserve Component access to DoD Medical Treatment Facilities for treatment of all vaccine adverse events.

The Synchronization Committee will coordinate the phased vaccination of units and locations to better focus our education and communication program and assist commanders, Service Members and their families.

Documentation – In addition to immunization tracking, there are several other quality assurance/quality improvement measures commonly adopted in medical treatment facilities to ensure the highest clinical standards are fulfilled. All clinical encounters (e.g. immunizations administered, sick call visits, hospitalizations, etc.) are documented in the patient's health record. Each dose of anthrax vaccine is recorded in service-specific and DoD-wide tracking systems. The service specific tracking system reports when a Service Member is due the next dose or has been waived or deferred.

Clinical Panels -

At the facility level, health care providers use panels called morbidity mortality committees to discuss and investigate negative outcomes such as death (none of which have been reported from anthrax vaccination). Medical treatment facilities have pharmacy therapeutics (PT) committees to review and encourage reporting of all medication or vaccine related adverse events. Medical treatment facilities submit reports of their quality assurance/quality improvement programs to each Service medical headquarters for corporate review and analysis. To monitor and assure compliance, all Services report any adverse events weekly to their higher medical headquarters.

Refusals

Even with careful monitoring, a strong education and communication program, and the highest vaccine safety standards, some members will choose, by reason of conscience or other motivation, to not participate in an immunization program. A recent example is the Anthrax Vaccine Immunization Program (AVIP).

With the current Directive for all members to participate in the AVIP, some local commanders have had to decide which, of several options available, to take when a person in his or her command refuses to be vaccinated. These options include administrative, non-judicial and/or judicial actions. However, prior to beginning any such action, the Service Member is re-educated and counseled on the nature of that refusal, the threat and the safety and efficacy of the vaccine. Service members are encouraged to speak with a Health Care Provider. Commanders review and take action on each refusal case based on its own merit and the service member's record.

Because the disposition of each case is handled locally, no data is formally collected on personnel, whether active duty, National Guard, reserve or civilian DoD. This permits each commander the opportunity to act independently, without undue outside pressure.

SUMMARY

We believe we have a safe and effective vaccine to respond to a well-documented threat. We are pleased with our recently implemented tracking and documentation system. What we are most proud of, however, is our nation's greatest asset – the service men and women who go in harm's way to preserve our freedom and safeguard our national interests.

We cannot depend on advanced warning of a bio-weapon attack. Bio-detectors, though an important component of our biological-chemical defense strategy, are still in an early state of implementation with many concerns to be worked out. Protective clothing, masks and equipment while available quickly degrades individual and unit performance and is impractical to wear for long periods of time. Imminent death or incapacitation from known biological warfare agents is vaccine preventable. Our personnel deserve our best and fullest protection. It would be a dereliction of leadership and our moral and ethical responsibility not to immunize our service men and women with licensed, safe and effective vaccines.

Statement by

Major Thomas L. Rempfer

To

Government Reform and Oversight Committee

U.S. House of Representatives

October 12, 1999

Chairman Burton, Members of the Committee, I open my testimony with the core values of the US Air Force.

"Integrity first, service before self, and excellence in all we do."

I am not here today to speak about the safety and efficacy of the anthrax vaccine. Instead, I am here to discuss another reason for the growing retention problem generated by the anthrax vaccination policy: it is integrity, and its relationship to doctrine.

After exhausting all avenues within my chain of command, and communicating with hundreds of servicemembers over the past year, I have concluded that the root cause of the negative reaction to the anthrax vaccination policy is a sense that the professional standards demanded of military personnel have been consistently violated by those implementing this policy. It is not, as DoD officials assert, simply a failure to educate, but instead a failure to communicate the truth, the whole truth, and nothing but the truth. Here are just a few examples:

First, when the anthrax vaccination policy was announced on December 15, 1997, a senior officer, who refused to be named, told reporters: "It's been licensed since 1970, [and has a] proven safety record. It's been documented." (1)

The whole truth is that in April 1998, Dr. Kathryn Zoon of the FDA stated in a letter that, "data for clinical studies conducted on the long term health effects of taking the anthrax vaccine have not been submitted to the FDA." (2) The Government Accounting Office reiterated this fact on April 30, 1999 (3), and just last week the Army announced they would now conduct such a study. (4)

Next, the Assistant Secretary of Defense for Health Affairs, who is a physician, told Congress on March 24th that "the safety of our AVIP was also confirmed by an independent review of the program." (5) She was referring to a report by a Yale University Medical School professor who was selected by DOD to review the health and medical aspects of the anthrax vaccination policy before its implementation.

The whole truth is that the doctor our DOD repeatedly cited for over a year as their "independent expert" is really an obstetrician and gynecologist. He wrote Congress, upon

being requested to testify last April, that he had informed DoD at the time of the review that he had "no expertise in anthrax." (6) DOD has never acknowledged this admission by their "expert" or explained why they asked an OB/GYN to review a biological warfare immunization program. As a result DOD's independent review is perceived as a sham. (7)

Next, the Assistant Secretary of Defense for Public Affairs speaking about the vaccine in January said, "It's safe and reliable…It works and has no side effects." (8) On June 29th he ridiculed the idea of adverse reactions to the vaccine when he told reporters: "I've had three shots. My hair is growing more robust than ever. I sleep better. I eat better, run farther. It's been nothing but a great experience." (9)

The whole truth is that DOD physicians met at Ft. Detrick, MD, on 25 to 27 May, 1999 to discuss adverse reactions to the vaccine, including the case of an Air Force pilot who developed an auto-immune disorder after receiving the vaccine and had been grounded since November, 1998. (10) On September 30th the Army Surgeon General admitted to 72 cases of adverse reactions that had required hospitalization – while he continued to minimize the risk of the vaccine. (11)

Next, the Assistant Secretary of Defense for Public Affairs has also asserted for months that the number of anthrax refusals is only about 200 servicemembers, inferring no significant impact to readiness. Yet, on September 30th a DoD spokesman finally acknowledged that DoD had made a conscious decision not to track refusals. (12)

The whole truth is that DoD crafted a "no bad news" tracking system that only tracks the administration of shots, but does not track adverse reactions or refusals. The Deputy Secretary of Defense admitted to Congress on September 30th, "he was reluctant to count refusals through a central tracking system because it would undermine command authority." (13) He did not elaborate why telling the truth would undermine the chain of command.

Next, the Assistant Secretary of Defense for Reserve Affairs stated on August 17, 1999: "before Secretary Cohen authorized the use of a single dose, he ordered supplemental testing of the vaccine, doubly ensuring the vaccine's safety and far exceeding any pharmaceutical industry standards. Supplemental testing, combined with the ongoing supervision of the FDA, demonstrates that the vaccine is safe and effective." (14)

The whole truth is that on April 29, 1999, BG Eddie Cain admitted that DoD had suspended the supplemental testing after "inconsistencies" were found in the procedures being used by the manufacturer, Bioport, despite supervision by another DoD contractor hired to oversee the testing. (15) Additionally, the GAO reported that supplemental testing couldn't compensate for a flawed manufacturing process. (16)

Next, the Assistant Secretary of Defense for Reserve Affairs additionally testified to Congress on September 29th, after being reminded he was under oath, that if someone is going to resign over anthrax, "they are certainly not going to be subject to any penalties. This is one of the points of the Guard and Reserve."

The whole truth is that five days later the commander of the 184th Bomb Wing, Kansas Air National Guard, issued a written warning to a B-1 bomber pilot threatening a $500 fine and six months in jail, because the pilot had asked to transfer in lieu of submitting to the vaccine. (17)

Next, the Deputy Secretary of Defense wrote Newsweek Magazine on April 3, 1998 about the anthrax vaccine manufacturer, stating, "no shutdown was ever directed or contemplated as a result of any FDA inspection." (18) Additionally, on August 5, 1999, a senior officer who refused to be named told reporters that a threatened FDA shutdown of the manufacturer's production line was an "urban legend." (19)

The whole truth is that the FDA sent a "notice of intention to revoke" the manufacturer's license on March 11, 1997 after "significant deviations" discovered during previous inspections remained uncorrected. (20) A follow-up FDA report in February 1998 found that, "the manufacturing process for Anthrax Vaccine is not validated." (21) The manufacturer subsequently "voluntarily" suspended anthrax vaccine production. All of the vaccine used on servicemembers to-date was manufactured during the period of repeated significant deviations from FDA manufacturing standards.

Next, in September 1998, the Secretary of the Army wrote a letter indemnifying the anthrax vaccine manufacturer. (22) It stated: "The obligation assumed by [the manufacturer] under this contract involves unusually hazardous risks associated with the potential for adverse reactions in some recipients and the possibility that the desired immunological effect will not be obtained by all recipients." When that letter surfaced in June, DOD called it "a misreading of a routine contracting procedure." (23)

The whole truth is that the last vaccine to receive similar indemnification was the swine flu vaccine in 1976 – a health care fiasco that was supported by the health care community as the anthrax vaccine appears to be today. (24)

Next, the Director of the Air National Guard testified under oath on September 29, 1999 that only one member of the Air National Guard had left over the anthrax vaccine.

The whole truth is that eight pilots from the Connecticut ANG resigned or transferred specifically because of the anthrax vaccine, as did seven pilots in the Wisconsin ANG who are now grounded while awaiting out-processing. Four days after this testimony denying attrition, 22 of 50 pilots in the Tennessee ANG unit in Memphis quit – along with 38 other servicemembers. These are just a few examples of the current attrition and pale in comparison to the expected losses to a program just beginning in the reserves.

Finally, the Secretary of Defense has stated that he would be "derelict" in his duty if he did not mandate use of the anthrax vaccine. (25)

The whole truth is that weaponized anthrax has been available since World War II and the anthrax vaccine has been available since 1970. Additionally, the GAO has testified that, "the nature and magnitude of the military threat of biological warfare has not changed since 1990." (26) Accepting the Secretary's statement means that every other Secretary of Defense in the post-Cold War era has been derelict for not mandating the vaccine.

Framing the anthrax vaccination as a moral imperative has precluded an intellectually honest debate about this policy and has resulted in punishment of those who question it. (27)

Analysis:

These ten lapses of our core values are merely the beginning in the unraveling of the truth. They have placed military commanders at all levels in an untenable position: either implement a questionable policy or sacrifice their careers. Consequently, the anthrax vaccine policy has turned into a biological loyalty test. The anthrax vaccine is no longer a health policy. Instead, it has become an issue of "good order and discipline" and the ability of the military's leadership to impose its will on subordinates. Loyal servicemembers now must express their fealty to the chain of command by submitting to the vaccine. For those who don't, there is arbitrary discipline – incarceration and court-martial for some, dismissal and disgrace for others. (28)

Each of these examples demonstrates a breakdown of intellectual honesty, which is the linchpin of integrity and doctrine. Without honesty doctrine is merely dogma. Congressman Shays has referred to the anthrax vaccination policy as a "medical Maginot Line." (29) It requires the tacit cooperation of our adversaries to use the only biological agent against which we have invasively defended ourselves. It requires our adversaries to not use chemical agents at all. It requires our adversaries to attack only the one percent of Americans who are vaccinated. Recognizing the logical long-term implications of this façade of force protection (30), former deputy director of the Soviet biological weapons programs, Dr. Ken Alibek, told the Joint Economic Committee of Congress that: "In the case of most military and all terrorist attacks with biological weapons, vaccines would be of little use." (31) Further, he recently stated: "We need to stop deceiving people that vaccines are the most effective protection and start developing new therapeutic and preventive approaches and means based on a broad-spectrum protection." (32)

Servicemembers have discovered an acute dichotomy between what defense officials are telling Congress and the information readily available in government documents, Congressional testimony, medical research and news reports. (33) This contrast creates an ethical dilemma for servicemembers whose core values require the questioning of immoral orders. Consequently, out of our respect for the Constitutional imperative of civilian control of the military we have reluctantly and repeatedly asked Congress to intercede and stop the corrosive impact the anthrax vaccination policy is having on our nation's military. If Congress is not proactive in response to DOD's absence of intellectual honesty, the unfortunate reality is that those members of the all-volunteer military who do embody its core values will simply leave.

I close with an excerpt from The Soldier and the State, by noted Harvard military scholar, Samuel Huntington. He rhetorically asked, "what does the military officer do when he is ordered by a statesman to take a measure which is militarily absurd when judged by professional standards and which is strictly within the military realm without political

implications?" Huntington answered, "the existence of professional standards justifies military disobedience." (34)

Our professional standards have been made very clear: Integrity first, service before self, and excellence in all we do. Therefore, I believe I would be derelict in my duty if I did not take this opportunity to express my adamant professional dissent toward the Anthrax Vaccine Immunization Policy. As well, it would be unconscionable for me not to seek redress for all servicemembers, dedicated to the profession of arms, who have been inexorably drawn into this professional military dilemma. Mr. Chairman, I offer sincere thanks to you for looking out for our nation's servicemembers.

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Statement by Neal A. Halsey M.D.
Statement of
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Before the Committee on Government Reform
U.S. House of Representatives
October 12, 1999

My name is Dr. Neal Halsey. I am a pediatrician specializing in the study of infectious diseases and vaccines at the Johns Hopkins University School of Public Health. Thank you Mr. Chairman for the opportunity to provide this committee with my perspective on the important issue of vaccine safety. I have had the opportunity to care for children who have suffered from each of the infections that can be prevented through vaccination. I have also cared for children who have developed serious adverse reactions to vaccines. These experiences, coupled with my research over 27 years, have resulted in my current focus of

interest on vaccine safety and the founding of the Institute for Vaccine Safety at Johns Hopkins University. My objective, and I believe the objective of most people in this room, is to ensure that both children and adults receive the safest vaccines possible to protect them against serious infectious diseases.

I have had the opportunity to review the written testimonies of Drs Harold Margolis, Samuel Katz, and David Satcher in their appearances before this committee and Congressman Mica's subcommittee. These witnesses have detailed the enormous benefits from immunizations and I agree with their statements. Therefore, I will not reiterate the benefits of vaccines in my testimony today, but I will be happy to address any questions regarding this issue.

Since this committee has expressed concern about possible conflicts of interest I provide the following information. I have never owned stock from any vaccine company or any other corporation. My retirement account is in mutual funds. I own no patents and I have no vested interest in any specific vaccine made by any company. My salary is generated from teaching and research grants and contracts, including studies to evaluate vaccine safety issues supported by the World Health Organization, the US Agency for International Development, the Food and Drug Administration and the manufacturer of Lyme disease vaccine. The Institute for Vaccine Safety has received support from individuals concerned about vaccine safety, and in 1997 and 1998 we received unrestricted educational grants from several vaccine manufacturers.

I have served on the Advisory Committee for Immunization Practices for the Centers for Disease Control and Prevention (CDC) and the Committee on Infectious Diseases of the Academy of Pediatrics (AAP). During my tenure on the advisory committees to the CDC and the AAP, I was a strong advocate for changes in policy to encourage the use of the safest vaccines possible, including the change to use of inactivated polio vaccine and acellular pertussis vaccines. I no longer serve on these committees and I appear before you today representing myself and the Institute for Vaccine Safety.

I was asked to comment on three issues: the number of vaccines children receive, combination vaccines and diabetes. I am not concerned about the number of vaccines children receive, and I look forward to the availability of several other vaccines that will help us prevent serious infections and cancer. The human immune system is remarkable in its capacity to respond to millions of different antigens. Children are exposed to many thousands of bacteria, fungi and viruses beginning at the moment of birth. In the first few months of life the human immune system responds to many foreign antigens from these organisms. Each bacterium contains hundreds of different antigens including carbohydrates, fatty substances, proteins, RNA and DNA. Children develop antibodies to 17 different proteins in one common bacterium (Moraxella catarrhalis) and a strep throat infection results in immune responses to 25-50 different antigens1. Some new highly effective vaccines are made using only one or two bacterial antigens. For example, Haemophilus influenzae type b vaccines, or Hib as they are commonly called, contain only a single bacterial antigen attached to a protein. Children immunized with these vaccines

are protected against meningitis and sepsis caused by the Haemophilus influenzae type b organism.

Therefore, the immune systems of children who receive this vaccine are exposed to far fewer antigens than children naturally infected with the bacterium. Since all children would be exposed to the bacterium if they were not immunized, the use of the Hib vaccine actually reduces the burden on the immune system. Questions have been raised about the benefits and problems associated with administering several vaccines at the same time or combining vaccines in the same syringe. There are factors that can limit the ability to combine vaccines and there are theoretical concerns that have been reviewed in detail in a workshop sponsored by the FDA, the National Vaccine Program Office, CDC and NIH2. These factors are taken into account in the FDA review of combination products. Numerous studies have been conducted to evaluate the safety and effectiveness of vaccines administered simultaneously or in the same syringe. Several efforts to produce new combined vaccines have not been successful, but those vaccines that have been approved by the FDA have been carefully evaluated and found to be safe and effective. Experts serving on advisory committees for the CDC and the AAP review the data from these studies prior to making recommendations for general use.

Children benefit from combined vaccines because they are protected against several different diseases with a single injection, thereby reducing pain and discomfort from multiple injections. If we did not have combined vaccines, children would need to be brought to physician's offices or clinics far more often, perhaps even weekly during the first few months of life in order to protect them against serious infections. The use of combined vaccines can simplify the immunization process and record keeping for parents, physicians and public health officials3.

Recently, concerns have been raised about the amounts of thimerosal preservative and other products in some vaccines. Manufacturers, the FDA, the CDC and the AAP have responded rapidly to these concerns to make new products available that reduce infant's exposure to these components. I anticipate that further steps will be taken in the near future to eliminate these concerns. The use of combination products reduces the total exposure to these components and theoretical concerns about these issues.

If vaccines that are currently given in combination were separated and administered at separate visits,children would be left unprotected against some diseases for varying periods of time. As we learned a decade ago with the resurgence of measles in this country, leaving children unprotected even for a few weeks or months can lead to epidemics and unnecessary suffering and deaths. We do not need to learn the same lessons over again.

I know that Congressman Burton is concerned about combining measles, mumps, and rubella vaccines in the same syringe. This issue was raised first in the United Kingdom by Dr. Andrew Wakefield. Dr. Wakefield's unfortunate statements at a press conference about separating measles mumps and rubella vaccines were based upon theory, not fact. Part of this theory was based upon his studies of children with inflammatory bowel disease. His

original studies suggesting persistent measles infection in the inflamed intestinal tissue have not held up to careful review by investigators at the University of Connecticut and in Japan where his findings were not replicated4-6. A review by highly qualified professionals in the United Kingdom found no evidence of a causal association between autism and MMR7. Autism is a complex disease and there undoubtedly are several factors that contribute to children acquiring this unfortunate disorder. Unraveling the complex etiology will require research into the basic causes by highly qualified scientists. We do know that encephalitis is one of the factors that pre-disposes children to autism. All three of the diseases prevented by the MMR vaccine, measles, mumps and rubella, can cause encephalitis. We would not want to leave children unprotected against these diseases for even a short period of time. The routine use of MMR has resulted in the prevention of many thousands of cases of congenital rubella syndrome, a recognized cause of autism. I support the continued use of the combined measles, mumps and rubella vaccines as the safest and most effective means to protect children against these diseases.

Many hypotheses about causal factors have been offered to explain the increasing incidence of autism and diabetes. Statements made about hepatitis B vaccines before Congressman Mica's subcommittee on May 18,1999 have been refuted by letters submitted to the committee by the State Epidemiologist of New Hampshire and the Director-General of Health of New Zealand. Also, the study in Finland referred to by Dr. Classen was published in the British Medical Journal and reveals no evidence of any effect from Hib vaccination on the risk of diabetes8. The increasing incidence of diabetes, autism, and other medical conditions for which no specific etiology has been identified parallels the increase in many other factors such as the use of wireless communications, computers, and fast food restaurants. One could easily hypothesize that these factors or many other changes in our lifestyles contributed to the increases in these diseases, but there is no scientific evidence to support these ideas. Two workshops have been conducted to investigate the possible link between childhood diabetes and vaccines, one at the Institute for Vaccine Safety and the other at the National Institutes of Health9,10. The conclusions from both inquiries revealed no scientific evidence to support the hypothesis that vaccines cause diabetes. There are studies indicating the selective use of some vaccines early in life can prevent diabetes in animals, but to date, studies in humans have not confirmed this finding. Additional studies are in progress and other research is needed to identify methods for preventing this important cause of disease.

The history of medicine is filled with stories of physicians and others who have been quick to claim that they have the answers to complex medical problems based on inadequate studies. Just as people should not be misled by promises of cures from fake medications, we should not mislead people with false villains to blame when unexpected illnesses occur. The parents of children with diabetes, autism and other disorders that we do not fully understand deserve answers as to why this happened to their child. These answers should be based on sound scientific inquiries. Congress should support increased funding for research to identify the basic causes of these disorders.

Identifying the safest possible vaccines is a process; there are no absolutes. We must constantly reassess vaccines using appropriate experts and make adjustments when indicated. This situation is similar to safety evaluation of other products such as automobiles. Modifications are constantly being made in automobile design to improve safety. These efforts require constant study, reassessment, and innovation through a competitive marketplace. Hepatitis B vaccine has been the target of several anti-vaccination groups. Hepatitis B vaccine prevents acute and chronic liver disease and this vaccine is the first successful cancer preventing vaccine. I hope that this committee would encourage the development of other cancer preventing vaccines through objective scientifically based inquiries. Promoting unproven hypotheses and hearsay about vaccine safety could have a negative effect on the willingness of vaccine manufacturers to invest the large amount of resources necessary to develop new vaccines that will protect our children against cancer and other serious diseases.

The primary message I would like to convey to this committee is that decisions about vaccine safety should be based on good science, not hypotheses, opinion, individual beliefs, or observations. Federal agencies responsible for vaccine safety and major universities have procedures to assure high quality scientific research and reviews of vaccine safety issues. Congress should be concerned about vaccine safety and should provide sufficient resources to assure that the best possible science is conducted to assist with development of vaccine policy.

Assuring the safest possible vaccines requires constant vigilance and periodic reviews of all vaccines. Rapid advances in biotechnology are being made that have created new tools for developing and evaluating vaccines. We need highly qualified scientists who are on the cutting-edge of their fields to be conducting reviews of new and existing vaccines. Therefore, it is disconcerting to learn that the research budget for the agency responsible for approving vaccines, the Center for Biologics and Evaluation Research (CBER) of the FDA, has been cut to one-third of the level that it was just five years ago. You cannot expect an agency to do its job effectively if you deprive the scientists of research support. If this committee is truly concerned with assuring that the safest possible vaccines are used for children and adults, I urge you to investigate this issue and restore funding for vaccine safety research. The NIH, CDC, and FDA should be queried to determine the funding needed to support all aspects of vaccine safety research.

Thank you for the opportunity to share my views on these subjects. I will be happy to answer any questions.

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Attachments:

The Institute for Vaccine Safety Diabetes Workshop Panel. Childhood immunizations and type 1 diabetes: summary of an Institute for Vaccine Safety Workshop. Pediatr Infect Dis J 1999;18(3):217-22. (not included in this document)

Karvonen M, Cepaitis Z, Tuomilehto J. Association between type 1 diabetes and Haemophilus influenzae type b vaccination: birth cohort study. BMJ 1999;318(7192):1169-72. (not included in this document)

Statement of

Admiral William J. Crowe, Jr.

Before the

House Committee on Government Reform

October 12, 1999

Mr. Chairman,

This statement is submitted in response to your letter of October 5. I believe the subject of force protection and the role vaccine play are important concerns for all Americans.

Your letter specifically requested that I review the background on the development of policy for biological warfare during my tenure as Chairman of the Joint Chiefs of Staff. You no doubt will recall that the President announced in 1969 that we were dismantling our inventory of biological weapons. In 1972, the Biological Weapons Convention (BWC) was completed and in 1975 was ratified by the U.S. Government. The three-year lag period can be attributed to the time it took to destroy the US stock of biological weapons. Throughout, Washington led the international effort to convince nations to forswear biological offensive weapons. The Convention to date has been ratified by 142 signatories. At a special conference held in Geneva in September 1994, the US promoted the development of a legally binding instrument that involved transparency of activities and facilities that could have biological weapons applications. The aim, of course, was to deter violations and enhance compliance with the BWC regime. This issue is still pending.

I served as Chairman, JCS, from 1985 to 1989. In the case of poison gas, our own inventory of these agents served as a deterrent in two world wars. Clearly, by 1985 we no longer had that option in the case of biological weapons. The JCS, however, were not especially uncomfortable with that situation. It was the unanimous view that, from a military perspective, our conventional and nuclear weapons were of sufficient number and quality to assure a reasonable degree of deterrence if foreign governments contemplated the use of such agents against US forces. That judgment was borne out in Desert Storm. Saddam Hussein had impressive stockpiles of chemical weapons and biological agents. He chose, although faced with defeat in the field, not to employ those weapons. We know for a fact that he had not been that timid when repressing his Kurdish minority and engaging Iranian units in the 1980's. I am persuaded that Saddam knew that, if he resorted to chemical weapons, it would infuriate all Americans and invite our leaders to retaliate in a devastating fashion.

The JCS during my tenure understood that the Biological Warfare Convention would not necessarily protect us from all biological threats. There was always the possibility of regimes violating the agreement or countries that had not subscribed to the convention producing biological agents. In fact, we had hard evidence that several signatories continued to experiment with and to produce biological agents. Consequently, our security policy embraced a great deal more than merely depending on overt military strength. A vigorous intelligence effort was mounted to improve our ability to locate foreign production facilities, to assess the character of potential agents, and to estimate which foreign militaries might be planning to use such agents in the field.

From this information, a comprehensive threat analysis was compiled incorporating inputs from military commanders, relevant diplomats, and the scientific community. While the appraisal did not anticipate frequent employment of such weapons, it concluded that any

possible use could wreak appalling casualties. This conclusion led to a review of our vaccine defenses. Bear in mind every step of this process was widely vetted internally in the US Government and relevant inputs sought.

These conclusions ultimately led to several programs to better prepare our fighting units for dealing with this threat. Protective gear for individual troops was upgraded; BW training was further stressed; the requirements for all equipment, such as tanks, aircraft and ships, to operate in a biological environment were tightened up. In turn, it was recommended that vaccines be developed to counter the effects of specific agents. When dealing with a question such as vaccines that require extensive expertise outside of the Defense Department, a steering group is formed with wide representation from both DOD and relevant outside departments. Their findings are then submitted for consideration at higher levels. It is normal with important initiatives, such as this, for the policy ultimately to be decided by the Secretary of Defense, the National Security Council, and the White House. As I recall, there was little disagreement throughout the process.

We should bear in mind, however, that the subject of biological agents had not reached the urgency that it enjoys today. Anti-toxins had not been used by the military as a matter of course and were not part of the normal routine. We, however, did initiate exploratory probes to determine the feasibility of incorporating such vaccines in the anti-terrorist effort. It was a deliberate and gradual process that received normal funding and not an especially high priority.

There were two fundamental reasons for pursuing this course: (1) if such reasons vaccines were successful in countering biological agents, their use would reduce the nation's vulnerability to biological weapons, and (2) it would save the lives of those exposed to such attacks.

We were primarily seized with the problem of deterring or countering direct attacks on US forces by the military units of hostile governments, i.e., governments we could identify and retaliate against directly in a manner we chose. We had some confidence that we could suitably respond, if any nation elected to employ biological warfare against US personnel. I stress this because the problem of terrorism had not reached the crescendo it has today and that is a problem of another order. By the time I retired ten years ago, we had not fully grappled with the possibility of covert terrorists mounting serious biological challenges.

For example, when I served as the Ambassador to Great Britain (1994-1997), we were increasingly worried about terrorist attacks on overseas installations, but we were almost solely concerned with the threat of small bombs, car bombs, mortars and assassination, not the possibility of terrorists mounting a full fledged biological event.

In late 1998 and early 1999, I headed two Accountability Review Boards to examine the August 1998 embassy bombings in Nairobi and Dar es Salaam. We found a number of discrepancies in the preparedness to survive such catastrophes. In fact, the State Department directives did not address the possibility of biological attacks.

While no biological agents were employed in those two incidents, it was the unanimous opinion of both boards at the conclusion of their deliberations that, sooner rather than later, terrorist groups will turn to biological or chemical agents. In East Africa, the attacks were sponsored by Osama bin Laden, who has impressive resources and who has declared an Islamic Jihad against Americans wherever they can be found. Such organizations are no longer restricted by national boundaries.

I believe that our rather remarkable "Desert Storm" victory demonstrated to Third World countries that Americans are vastly superior in waging conventional actions. Governments or others who wish to harm our interests will have to look for other ways to confront us. This will, of course, encourage non-government terrorists. It may also lead governments who oppose us to sponsor and employ clandestine terrorists to harm our interests. At this juncture, we are superbly postured to retaliate heavily against governments that provoke us -- and our opponents know that. But sophisticated terrorist groups and covert operations are another matter.

Terrorist groups are configured to strike and then to disperse or disappear. It is difficult to identify them, to locate them, to know where they reside or train. Often they meld back into the larger population of a host country. The "invisibility of the archer" severely complicates defensive or retaliatory efforts. Ease of concealment and delivery, when coupled with difficulties in detection of agents and delays in the appearance of symptoms, makes an assailant extremely difficult to detect and even identify after the fact. There is every likelihood that such tactics will be used more and more in the future. In turn, the military will undoubtedly be called upon to participate heavily in counter-terrorism efforts.

Unquestionably, the overall threat level has increased because of these developments; the Department of Defense rates anthrax as the number one biological threat in the world today. Clearly, this appraisal dramatically reinforces the importance of passive defense measures. I am not privy to the discussions and decisions that are taking place within our government today, but I suspect all the steps I discussed are receiving increased attention. Vaccines are a vital part of this effort. There are a host of new biological agents being developed in laboratories around the world. The problem is amplified by the researchers' ability to alter some agents so that they are more sophisticated, difficult to detect and to counter with anti toxins. The Defense Department has already let contracts to develop counters to the emerging threats. It has also mounted a robust program to build better detection devices for the spectrum of old and new agents.

This does not mean, however, that all agents represent an immediate threat. Each agent must be examined as to availability, difficulty of production, its lethality and the ease of delivery. Many of the new agents, while exotic, will represent too much of a challenge for terrorists and must be discarded as a likely threat. A few, however, may require genuine attention. Only in those cases will it be necessary to administer an inoculation program. Any decision to administer a particular vaccine would be thoroughly vetted with relevant departments and in particular the health authorities. The threat appraisal will ultimately prioritize the whole list. I believe all of these efforts are worthwhile and must be pursued if we are to keep abreast of emerging developments.

Such a process was employed in the US Government preceding the announcement to inoculate all military personnel with an anthrax vaccine. Since the issues were new, thorny, complicated and politically sensitive, a steering group was formed with representatives from every governmental organization that had an interest. Naturally, the government health agencies were involved and an extensive educational agenda was followed. They were briefed on the experience of other vaccines, on the state of development in the biological sector and on the findings of our intelligence community. The relevant issues were discussed -- more appropriately debated -- before any conclusions were reached. The end product was a recommendation to the Secretary of Defense that all military personnel be inoculated with anthrax vaccine. In every respect it was a deliberate and comprehensive effort.

The US Government considers the anthrax spore to be an ideal terrorist biological agent. It is easy and cheap to produce. It can be deployed widely and easily by the attacker, without disclosing his purpose. More important, it is almost certainly lethal for unprotected humans. The Defense Department reports that at least 10 nations are suspected of having weaponized anthrax.

As you know, I am a director of BioPort Corporation, the firm that supplies the US Government with anti-Anthrax vaccines, and I have a strong interest in its quality. I am well aware that the issue of safety has provoked some dispute.

The vaccine was developed in the United States during the 1950's and 1960's for humans. The FDA approved it in 1970. It is a cell free filtrate produced by a strain of anthrax that does not cause disease. The vaccine contains no whole bacterium, dead or alive. In essence, it is nonpathogenic. There is no possibility of contracting anthrax disease from this vaccine. Since 1970, it has been safely and routinely administered to at-risk wool mill workers, veterinarians, laboratory workers and livestock handlers in the United States.

The popular press often confuses this issue by mixing up the question of effectiveness and safety. They are distinct issues and should be treated as such. As to safety, the vaccine has been around for a number of years and has compiled an impressive safety record. Time prohibits me from reviewing the plethora of authorities that agree with that conclusion, but I will cite some evidence that I find especially convincing.

At Fort Detrick, Maryland, laboratory workers at the Medical Research Institute of Infectious Diseases have received shots for nearly 30 years without discernible problems. Of 1,700 workers followed for 10 to 25 or more years after anthrax vaccination, none developed any unexplained serious symptoms due to reported doses of anthrax or any other vaccine.

As a requirement for licensure, the safety of the anthrax vaccine was studied between 1965 and 1970 under an approved IND, sponsored by the CDC. During that period, some 16,500 doses of anthrax vaccine were administered. This included the initiation of

vaccination of at least 4000 individuals and the administration of approximately 6,500 booster doses. In not one incident was there a safety problem.

Between licensure in 1970 and May 1994, adverse events reported to the Michigan Labs from the 65,000 doses distributed to Persian Gulf recipients were few in number. The adverse events reported were similar in nature to those found during clinical trials of the vaccine and none were associated with chronic or permanent local or systemic effects. In addition, through May 1994, no reports of adverse events were received directly by the Michigan Labs from the approximately 150,000 recipients who received the vaccine during the Persian Gulf conflict. Since then reports have been few in number from the over 1,000,000 does given.

Dr. Susan Ellenberg of the Food and Drug Administration summarized the most recent data from the VAERS adverse vaccine events reporting system of the the FDA and CDC in her July 21, 1999, written testimony before the Subcommittee on National Security, Veterans Affairs and International Relations as follows:

"Since the beginning of VAERS operations in 1990 through July 1, 1999, 215 reports of adverse events associated with the use of anthrax vaccine have been reported to VAERS. Of those, 22 are considered serious events. These reports are for diverse conditions, with no clear patterns emerging at this time." She concluded: "None of these events, except for the injection site reactions, can be attributed to the vaccine with a high level of confidence, nor can contribution of the vaccine to the event reported be entirely ruled out. It should be emphasized once again that it is not always possible to attribute a cause and effect relationship between a reported event and a vaccination. With the exception of injection site reactions, all of the adverse events noted above do occur in the absence of immunization. While the data gathered from the VAERS system can serve as a useful tool in identifying potential problems, the reports on anthrax vaccine received thus far do not raise any specific concerns about the safety of the vaccine."

The program currently in effect has inoculated over 340,000 military men and women. Approximately 200 have refused to receive it according to DOD representatives. Those refusals represent only 1/17 of 1%. I have heard reports that vast numbers are leaving the service as a result. I queried all 4 services and found no evidence this was true.

Surgeon General Satcher has testified and has often said in public statements that the anthrax vaccine is extremely safe. He has been supported by a host of distinguished medical authorities. Incidentally, I have had 4 of the 6 shots myself and I will complete the course next year. Moreover, my understanding is that a military recipient who has a reaction that requires medical attention is taken off the program. There have, of course, been some reactions to the shots. The great bulk of these have been normal reactions to a needle injection, e.g. some swelling, local pain, and perhaps a headache. The DOD has reported 72 cases of serious side effects that required hospitalization or missed duty for greater than a day. Of those only 55 could be attributed to the vaccine and all 55 have returned to duty.

Nevertheless, it is noteworthy that DOD has taken the subject seriously and is in the process of commissioning another in-depth study of the vaccine. In all candor, I simply could not find any hard data that suggested the vaccine was systemically unsafe or that reactions exceeded those of other vaccines.

BioPort monitors all reports of any unusual reaction. The company is dedicated "first and foremost" to producing a safe vaccine. Since the takeover of the laboratory in 1998, BioPort has installed an enhanced quality system and made extraordinary efforts to ensure the continued safety and efficacy of the vaccines. I should note in this regard that not a single dose of this vaccine has ever been released without FDA approval.

Frankly, there is no question in my mind that we should bend every effort to protect our forces against anthrax attacks. Believe me, the descriptions of people dying from the anthrax spore are horrifying. It is an agonizing way to die. The effect is very similar to that of the Ebola virus. I suspect if we had had more experience with anthrax deaths, we would better appreciate what the Department of Defense is trying to do.

The argument as to whether the military program should be voluntary or mandatory is outside my purview. I have little desire to enter that argument but, again, I have chosen personally to protect myself by taking the vaccine.

Before closing let me discuss one peripheral issue. It would be naïve of me not to mention some of the vague and rather misinformed criticisms of my association with BioPort. It has on occasion been rumored that the decision to inoculate all service personnel was made to benefit the BioPort Corporation and indirectly me, presumably because of my past associations with the military and the Administration. If this charge were not so ridiculous, it would be offensive. It outrageously exaggerates my influence. I didn't have that much influence when I was Chairman and I certainly don't have it now.

Let me be completely clear. I never, repeat never, solicited any official of this Administration to install or promote a mandatory inoculation program. Secretary Cohen's announcement of the mandatory vaccine requirement was made on May 18, 1998. The Steering Group's deliberations took place many months before this date. Actually, a Washington Post article reported in late 1996 that such a policy was being considered. At the time of the official announcement, the group I was associated with was engaged in a spirited competition with a number of other bidders to privatize the old Michigan Laboratory. The bid winner was not selected until June 1998 and the decision was made by the State of Michigan. The Department of Defense maintained a neutral position throughout this process. Frankly, the May 18 announcement made the final bidding phase of the competition more intense. The attempt to link me with the Secretary's decision is pure fantasy.

I understand that there are irresponsible web sites run by organizations that oppose the military and/or the vaccine. I would urge the Congress to detach itself from the emotionalism of this debate and not to be deceived or distracted by charges and counter

charges that have nothing to do with the real issues. Do vaccines make a worthwhile contribution to the country's defense against biological attacks? Are they reasonably safe to administer to our citizens? My answer is "yes" to both questions.