Statement of Meryl Nass, M.D.

Before the Subcommittee on National Security, Veterans Affairs and International Relations

Christopher Shays, Chairman
Committee on Government Reform, U. S. House of Representatives
April 29, 1999

Congressman Shays, members of the Committee, thank you for inviting me here today to testify about anthrax vaccinations. My goal in this hearing is to provide you with a different prospective than was provided by the Department of Defense physicians and spokesperson regarding the evidence for safety, efficacy, necessity, and possibly even legality, of the anthrax vaccine immunization program.

I would also like to briefly revisit the subject of vaccinations and their possible role in Gulf War Illness. Finally, I hope to leave you with the question of whether illnesses suffered by servicemembers who have received the vaccine in the last 12 months resemble the illnesses suffered by servicemembers following the Gulf War.

Is the vaccine necessary?

At the last hearing on the anthrax vaccine immunization program, Congressman Shays asked, "Why now?" He was told that the threat has recently increased. Has it?

"We have knowledge that as many as ten nations either have or are suspected to have the capability of chemical and biologic warfare.

Susan Bailey, M.D., Assistant Secretary of Defense for Health Affairs, **August 14, 1998**, D.O.D. news briefing

"We have seen the number of nations possessing biological agents increase from four to ten that we know of – there are probably more."

Dr. Thomas J. Welch, Deputy Assistant to the Secretary of Defense for Chemical Matters **July 28, 1988**, Hearing before the Committee on Governmental Affairs of the U.S. Senate.

The Department of Defense was aware of ten nations with biological weapons in 1988. They are still aware of ten nations in 1999.

A central question is whether the vaccine is effective. Will it really work? If anthrax were to be used, will it protect all our soldiers, or the vast majority of our service members? One must look to the animal data. I have compiled all the published guinea pig and mouse experiments in the following three tables. All were immunized with the vaccine service members are currently receiving, termed MDPH, for the Michigan Department of Public Health which manufactured it. One can see varying survival rates from 0-100%, depending upon the strain of anthrax used
and possibly other parameters of the experiment. Survival rates in guinea pigs varied from 23% to 71% when they were exposed to inhaled anthrax. The Ames strain is considered a virulent strain; the Vollum strain, less so.

There is debate about which experimental animals might parallel the human response. One hopes that we are more like guinea pigs than mice, since the best survival rate in mice immunized with the human vaccine and then injected with different anthrax strains was only 10%.

D.O.D. spokespersons claimed that the guinea pig and mouse data should be ignored because the data from monkeys indicates very high survival rates, approaching 95-100%. The question remains, however, whether monkeys do parallel the human response, and how monkeys will respond to more highly virulent anthrax strains, since the monkey experiments cited by D.O.D. used only the Ames strain of anthrax.

Are monkeys more relevant than guinea pigs in assessing anthrax vaccine effectiveness?

1. Many thousands of guinea pigs have been studied, but only 45 monkeys.
2. The potency studies and safety studies done to release lots at the vaccine manufacturer are all performed in guinea pigs.
3. "Since we lack surrogate markers to compare vaccine efficacy between animals and humans, it is still unknown which animal models, if any, resemble the human response to anthrax vaccine."

Bruce Ivins, lead anthrax vaccine researcher at Fort Detrick
"To date, no animal or other potency tests have been demonstrated to be well-correlated with protection of humans. The potency test required for the present vaccine has not been well correlated to efficacy in humans, and it is doubtful that it can be. . ."

"Presently there are no precise serological or other immunological correlates of protection to enable conclusions to be drawn from immunization studies in man. The extrapolation from animal studies to humans likewise is seriously complicated by this fact."

Joint Program Office for Biological Defense meeting 20 October1995. This brings us to the question of whether the vaccine is effective against all anthrax strains. The data we have just reviewed suggests it may not be.

"But fortunately for vaccines, it is difficult to surpass or circumvent the effectiveness of the vaccine. We all know you can develop resistance to antibiotics, for instance, but it's much more difficult to circumvent the vaccine . . <u>This vaccine is thought at this point to be effective against all the strains we know about</u>."

Sue Bailey, M.D., Assistant Secretary of Defense for Health Affairs, August 14, 1998, D.O.D. Press Briefing

D.O.D.'s experts disagree. Two studies at Fort Detrick, in 1986 and 1998, found that 9 and 27 anthrax strains, respectively, killed at least half the immunized guinea pigs injected with these strains.1,2 The strains are all naturally occurring, and were isolates from around the world.

Most of these strains were never tested in monkeys, so no evidence exists that the vaccine will protect monkeys against highly virulent strains.

D.O.D. had other concerns about the vaccine: “Vaccine-induced protection is undoubtedly overwhelmed by extremely high spore challenge.”

From J-4A01206-91 Joint Staff Action Processing Form 16 August, 1991.

1 Little, Stephen F. and Knudsen, Gregory B. “Comparative Efficacy of Bacillus anthracis Live Spore Vaccine and Protective Antigen Vaccine against Anthrax in the Guinea Pig.” Infection and Immunity, May 1986, p. 509-512.

2 Fellows, Patricia et al. “Anthrax Vaccine Efficacy Against B. anthracis Strains of Diverse Geographic Origin.” Presented at International Anthrax Conference. Sept. 1998.

Safety Considerations

Even if the vaccine was not effective against all anthrax strains, and not against large inoculums of anthrax spores, one might still wish to use it for its residual efficacy if it were perfectly safe. The Department of Defense suggests that, in fact, this is the case. They report only 39 adverse reactions in 550,000 inoculations given. The following table reports these reactions as of February 1999.

However, a variety of other data sources suggest that the rate of adverse reactions used for public consumption grossly underestimates the true rate. A USAMRIID publication reports a rate of systemic reactions of 0.7-1.3%. It also acknowledges the lack of definition of constituents and quantities of material in the vaccine and the significant variation from lot to lot, in the content of PA, as well as all the other components of the vaccine. It further admits that the only published human trial used a different vaccine and had insufficient data to show efficacy against inhalation anthrax.

In fact, three unpublished D.O.D. studies shed some light on the adverse reaction rate for the vaccine:
1. Tripler Army Medical Center (ongoing)
2. Bioport IND Study
3. Fort Bragg Study (Anthrax and Botulinum vaccines used).

1. Tripler Army Medical Center Ongoing Anthrax Vaccine Side Effects Study

* 7.9% of 595 vaccinees reported systemic symptoms after the first inoculation.
* 5.4% stated they could not perform their normal duties due to symptoms.
* 4.2% sought medical care.
* 2.5% lost duty time.
* 2.2% both sought medical care and lost duty time after the first anthrax vaccination.

After the initial three injections, only 3 VAERS reports were filed. The first was on a 35-year-old physician who developed muscle pain, muscle tremors and weakness, and was treated with prednisone. The second was a 38-year-old physician who developed a large local reaction lasting about ten days. The third was a 32-year-old patient with pulmonary sarcoidosis who experienced chest pain, shortness of breath, arthralgias, myalgias, fever and chills for 3 or 4 days beginning thirty minutes after his

first injection.

The author of the initial report on the Tripler study said, “If reported side effects are solely attributable to the anthrax vaccine, one could argue that the vaccine is highly reactogenic.” He also said, “This survey corroborates the relatively high incidence of minor side effects with subcutaneous administration of anthrax vaccine previously observed in this (smaller) cohort study at U.S. AMRIID.”

2. Investigational New Drug Application for Anthrax Vaccine Adsorbed, September 15, 1998

Submitted by Dr. Robert C. Myers, D.V.M., Director, BioPort, to Dr. Carolyn Hardegree, Director, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, FDA

* Blood was collected from volunteers at least monthly for the first year and at 13 months, 18 months, 21 months and 24 months.
* However, information on adverse reactions was only collected for the first 30 days.
* It was an ideal schedule to inquire about possible long-term side effects, but these data were never collected.

The Annual Report (BB-IND 6847 Amendment No. 005) was prepared using preliminary data which were not subjected to quality control review. Additionally, different grouping and scoring criteria were used to sort reactions for the Annual Report and this report. The data presented here were extracted from the statistical database which had undergone a thorough review by the database manager and the statistician.

3. Final Report to the U.S. FDA: Fort Bragg

Protocol: Serologic Response to Anthrax and Botulinum Vaccines
Protocol #FY92-5, M109, Log #A-5747
Principal investigator Lt. Col. Philip R. Pittman, M.D., MPH
United States Army Medical Research Institute of Infectious Diseases
Fort Dietrich, Maryland
Total Number in the Study: 486
Adverse Reaction Profile

Subjective Local Reactions During the First Seven Days of Study in the Right “Anthrax Vaccine” Arm:
* Induration (firmness) 22.3%
* Erythema (redness) 25.2%
Swelling 19.8%

“Evaluation of safety records show that one or more systemic symptoms occurred in 44% of recipients of vaccines within the first seven days after the booster doses.”

Adverse Reaction Profile
Systemic Systems (occurring at any time over the entire 30-day study):
* Alłany systemic symptom 44%

* Headache16.5%
* Illness Feeling16%
* Joint Aches12.6%
* Muscle Aches30%
* Fever ? 100.5? Fahrenheit 2.8%

Systemic Symptoms Occurring >30 days following Anthrax or Botulinum Administration

* AlłAny Symptoms - 3.2%

The third Fort Bragg study looked at persons immunized with anthrax vaccine alone, botulism toxoid vaccine alone, or in the majority of cases, the combination. Therefore, the reaction rates reflect dual vaccination. However, in each of these studies, the rate of systemic reactions is at least 7% and possibly as high as 40%. These rates do not square with the package insert which claims a 0.2% rate of systemic reactions, or the material presented by D.O.D., which claims a rate of 0.007%.

Surely it is clear from these data that the actual reaction rate being experienced by servicemembers inoculated today is grossly underreported. One must ask why, and one must also inquire about the ethical implications of this underreporting. Accurate reporting is essential for the public health. Underreporting on this scale demands the need for oversight on health matters outside D.O.D.

Manufacturing Problems

There has been a significant controversy about manufacturing problems: inability to meet the standards of good manufacturing practices at Michigan Biologic Products Institute, now Bio-Port. The FDA inspection report lists a plethora of violations, yet the Army Surgeon General states repeatedly that the problems only had to do with recordkeeping. Who is telling the truth?

"Although MBPI has had some production problems, mostly due to an aging facility, the FDA has inspected and approved every lot of anthrax vaccine produced there since it was licensed in 1970. The FDA adheres to rigorous standards and would have certainly closed the facility and ordered the destruction of any products that they deemed unsafe."

Ronald R. Blanck, Lt. General, U.S. Army Surgeon General
Letter to the Editor, Belleville News-Democrat 29 May 1998

" . . . Eleven lots of anthrax vaccine were voluntarily quarantined by MBPI as a result of your telephone conversation with the FDA on or about February 27, 1998. During that conversation, the FDA raised concerns about inspectional issues related to potency testing, sterility testing, the presence of particulates in a number of lots of anthrax vaccine.
. . . Please verify in writing that these eleven lots are, and will remain, in quarantine until further notification from the agency."

Kathryn C. Zoon, Ph.D., Director, Center for Biologics Evaluation and Research
Letter to Robert Myers, Director, Michigan Biologic Products Institute, April 28, 1998

The following document, 'Anthrax Vaccine Stockpile Overview,' tells an entirely different story. Of 32

lots subjected to supplemental testing, only six passed. And one on these was found to be unusable after it was shipped to Southwest Asia.

ANTHRAX VACCINE STOCKPILE OVERVIEW
REPORT DATE: July 15 1998

The following document, from D.O.D.'s anthrax vaccine website, confirms the fact that only six lots have passed.

SUPPLEMENTAL TESTING OF ANTHRAX VACCINE

"In December 1997, Secretary Cohen announced plans that would lead to the systemic vaccination of all U.S. military personnel against the biological warfare agent, anthrax. He further stated that the vaccinations would start after several conditions were met. One of those conditions was to conduct supplemental testing, consistent with the Food and Drug Administration's standards, to assure the sterility, safety, potency and purity of the vaccine.

The Joint Program Office for Biological Defense contracted Mitretek Systems, Inc. to oversee and report on this supplemental testing to be performed by the manufacturer. Supplemental testing of the anthrax vaccine stockpile began in January 1998, and is scheduled lot by lot until all are completed at end of calendar year 1998. All lots of vaccine distributed in support of the DoD's Anthrax Vaccine Immunization Program (AVIP) since approval of the Accelerated AVIP in March 1998 have passed supplemental testing.

The supplemental testing results to date are:

Lot FAV017 Successfully completed on 12 Mar 98
Lot FAV019 Successfully completed on 2 Mar 98
Lot FAV020 Successfully completed on 2 Mar 98
Lot FAV030 Successfully completed on 13 Mar 98
Lot FAV034 Successfully completed on 27 Mar 98
Lot FAV036 Successfully completed on 3 Apr 98

Updated: 21 SEP 1998
http://www.defenselink.miłpubs/anthrax/anthrax_memo.html 01/12/99

11 Mar 97 FDA letter to Michigan Biologic Products Institute (MBPI)

* *Series of Inspections with significant deviations in related biologic product lines*
* *Systemic issues in QA/QC & Good Manufacturing Practices (GMP)*
* *Must achieve compliance to prevent license revocation*

Immediate action needed:

* *MBPI commitment to correct w/in 10 days*
* *MBPI comprehensive corrective action planswith milestones & resources w/in 30 days*

Impact (Worst Case):

* *Potential loss of FDA license for Anthrax Vaccine*

* *Derailment of BOT TOX IND contingency licensing initiative*

Department of Defense
United States of America
Possible DoD Supportive Actions – MBPI

Immediate
* Proactive partnership with MBPI, State of Michigan and primary commercial customers
* Assessment Team (assistance in regulatory affairs, QA/QC, technical training)
* Engage FDA (CBER) as requested

Near-Term
* COR staff on-site TDY (facilitate corrective action plan)
* Negotiate contract for facility modernization/expansion
* Transition management to JVAP PMO*

Long-Term
* Transition contract management to DPSC following FDA licensure of new production capability

*Program Management Office for Joint Vaccine Acquisition Program

Is There Evidence for Long-term Vaccine Safety?

D.O.D. says the vaccine has been safely and routinely administered to veterinarians, laboratory workers, and livestock handlers since 1970.
1. The veterinarians and livestock handlers cannot be found, and do not appear to exist.
2. Four hundred to 500 laboratory workers and special operations troops per year have received this vaccine. They have not been screened for adverse effects.
3. Kathryn Zoon, head of the FDA's Center for Biologics Evaluation and Research, pointed out in a May 1998 letter that data on long-term side effects for this vaccine have never been submitted to the FDA. The largest group of people to have received the vaccine prior to 1998 are the Desert Storm veterans, both deployed and non-deployed. There are many with chronic illness in both groups, but the relationship between vaccination and subsequent illness has never been studied in the United States.

Have Fort Detrick workers suffered adverse effects from repeated vaccinations? Anthrax vaccine has been administered to hundreds of workers for over 30 years.The answer is not clear.

Three studies have been published looking for the effects of multiple vaccinations in workers at Fort Detrick: in 1958, 1965, and 1974. None have been published since.

These studies point out that intensive immunization of experimental animals has been shown to produce delayed adverse consequences, such as amyloidosis, arteritis, multiple myeloma, and other hypersensitivity reactions.

The studies have repeatedly demonstrated abnormalities in the blood of the multiply-immunized when compared with controls. There are increased lymphocytes in the blood, and differences between the

workers and controls in liver and kidney function, serum iron level, and sedimentation rates. The final report had this to say:

"Chronic stimulation of the immunoglobulin-producing system in man is thought to be associated with amyloidosis, plasma cell dyscrasias, and autoimmune diseases. . . Despite cautious extrapolation from animal findings to man, evaluation of these potentially adverse effects remains speculative, because few intensively immunized human populations have been available for study."

The authors concluded, "Nevertheless, the presence of two persons with neoplastic disease oflymphoid origin in the total immunized population by 1970, of approximately 1500 individuals at Fort Detrick, suggests that continued surveillance of the entire group of repeatedly immunized persons is warranted."

White, C. S. et al. "Repeated Immunization: Possible Adverse Effects"
Annals of Internal Medicine. 1974.

What evidence exists regarding Gulf War Illness and anthrax vaccination?

To date, only one study has been published which looks at this question. It examined British Gulf War vets:

"Vaccination against biological warfare and multiple routine vaccinations were associated with this CDC multi-symptom syndrome in the Gulf War cohort."

Catherine Unwin, et al. "Health of U.K. Servicemen who served in Persian Gulf War. "
The Lancet; Volume 353, January 16, 1999.

"Vaccination against plague and anthrax before deployment to the Gulf correlated highly with illnesss. The investigators speculate that these vaccines – more so than the routine ones give to service personnel – had unanticipated effects."

Stephen E. Straus, NIAID, NIH. "Commentary on the Unwin Study". The Lancet, January 16, 1999.

What evidence exists regarding Gulf War Illness and anthrax vaccination?
To date, only one study has been published which looks at this question. It studied British Gulf War vets:

"Vaccination against biological warfare and multiple routine vaccinations were associated with this CDC multi-symptom syndrome in the Gulf War cohort."

Catherine Unwin, et al. "Health of U.K. Servicemen who served in Persian Gulf War. " The Lancet; Volume 353, January 16, 1999.

"Vaccination against plague and anthrax before deployment to the Gulf correlated highly with illnesss. The investigators speculate that these vaccines – more so than the routine ones give to service personnel – had unanticipated effects."

Stephen E. Straus, NIAID, NIH. "Commentary on the Unwin Study". The Lancet, January 16, 1999.

Central to the issue of whether vaccination contributed to or caused Gulf War illnesses is the question of missing immunization records. At the last hearing, Army Surgeon General Blanck reported that anthrax vaccinations had been entered into servicemembers' personal medical records, although they had not been entered in an automated,

centralized format. His assertion runs contrary to the reports of hundreds of veterans who have obtained copies of their vaccination records and find no mention of anthrax in them, even when they were told by medical personnel that anthrax vaccine was being administered.

Where Are the Gulf War Vaccination Records?

From Joint Staff Action Processing Form, Action #J-4A 01206-91 Subject: Freedom Of Information Act request:

"Following Operation Desert Storm, the BW defensive program for D.O.D. has remained properly classified at the SECRET level. The only exception has been the documentation of immunizations into the individual's medical record in order to ensure availability of such information for purposes of epidemiological tracking. All original records and documents used in identifying units and personnel immunized during ODS are still considered classified information.

There are numerous memoranda and decision papers regarding the biological defense program, which while classified, are not responsive to the FOIA request.

Conclusion: Disclosure of the information requested in the detail requested would not be in the D.O.D.'s best interest and could be expected to cause serious damage in the future."

This references ASD (HA) memorandum, "Recording of vaccinations received
in Operation Desert Storm in the medical immunization record (SF601)," 22 July1991

The document cited above suggests that there are central vaccination records that have been classified, which may still exist, and which are likely to help prove whether vaccinations in fact led to Gulf War illness. These records must be found, declassified and shared with ill veterans and the medical personnel who are attempting to care for them.

Treatment studies for Persian Gulf Illnesses currently do not address vaccine injury. Perhaps Congress will see fit to remedy this omission.

Gulf War "Expert Panels"

A series of "expert panels" have been convened to explore the relationship between Gulf War illness and various exposures. Remarkably, none of these panels reviewed actual data regarding the relationship between vaccines and Gulf Illness. Each panel performed a superficial overview of the issue, citing the fact that there were "no known" long-term adverse effects of anthrax vaccination. They neglected to mention that no studies existed, and therefore, there was no data one way or the other.

Is anthrax vaccine a contributor to Gulf War illnesses? Comments by four expert panels

The remarks below were prepared for an interview between DOD spokespeople, and reporters for the program "20/20." I have inserted the comments in Italics to clarify the conclusions of these four panels. The question of whether Gulf War illnesses may be related to anthrax vaccination has certainly not been laid to rest, despite the deliberations of four respected panels, because none of them actually reviewed any data. Nor did they investigate the ways in which anthrax vaccine may be significantly different from the civilian vaccines with which the panelists were more familiar.

Four different panels: The Institute of Medicine, The Presidential Advisory Committee, The Department of Veteran's Affairs, and the National Institutes of Health have investigated the cause of Persian Gulf Illness (PGI) and concluded that the anthrax vaccine does not explain the long-term, chronic effects associated with PGI.

None of these four panels actually studied the incidence of PGI in vaccinated versus non-vaccinated Gulf War troops. NO data has been published in the open literature on this issue in the Untied States. The one published study to look at British veterans' vaccination status at the time of the Gulf Way, and its correlation with subsequent development of PGI, was published in the Lancet January 16, 1999. (British troops received US-made anthrax vaccine, as well as anthrax vaccine produced in England.) This study, whose first author was Catherine Unwin, showed a statistically significant association between vaccination (for anthrax as well as multiple vaccinations) and PGI. The collected for the VA on PGW veterans should allow this type of comparison as well, but has not been published.

The Presidential Advisory Committee (PAC) on Gulf War Illnesses Final Report, December 1996: p. 114, states: "The committee concludes it is unlikely that health effects reported by Gulf War veterans today are the result of exposure to the Botulinum toxoid or anthrax vaccines, used alone or in combination.

Again, the committee concluded this on the basis of what is known about vaccines in general, and without reviewing actual incidence data. What did the PAC Special Report, which followed the FinalReport, say about DoD's vaccination policy?

"As determined by FDA, DoD's use of TBE vaccine during Operations Joint Endeavor/Joint Guard has violated federal regulations pertaining to investigational products on several accounts, including: record keeping failures; failure to monitor fully the study's progress; failure to ensure the protocol was followed so safety and efficacy can be assessed; promotion of safety and efficacy for the investigational product; and failure to obtain Institutional Review Board approval of informed consent documents. FDA also expressed uncertainty about whether there had been a violation of Army record keeping and documentation requirements, which mandate that servicemembers' permanent records accurately reflect TBE immunizations."

Health Consequences of Service During the Persian Gulf War: Recommendations for Research and Information Systems, Institute of Medicine (IOM), 1996: P. 55, 2nd paragraph: concerning adverse interactions due to multiple exposures. "All of these possible drug interactions (and others not mentioned) cause acute and short-term problems. The committee knows of no evidence of any chronic

effect."

The Persian Gulf Experience and Health, NIH Technology Assessment Workshop Panel. JAMA, August 3, 1994-Vol 272, No. 5, p.391-395: P. 394 vaccines: general discussion including botulinum and anthrax vaccines. "No long-term adverse effects have been documented."

A Working Plan for Research on Persian Gulf Veterans' Illnesses. Department of Veterans Affairs, November 1996: P. 26, 4.1.6 vaccines: "Both vaccines (anthrax and botulinum toxoid) have been used for many years without adverse effects. All three (IOM, PAC, and the Defense Science Board) review panels stated that no long-term adverse effects have been documented or would be expected. Further study of the potential adverse effects of vaccines in this population is not recommended by any of the three panels, nor is it endorsed in this plan."

The three quotes from three panels above are examples of an interesting phenomenon. If you never look for something, you are sure never to find it. These three panels noted that there was a lack of evidence of long term adverse effects. But no study of long term adverse effects was ever published; nor were such effects ever collected and submitted to FDA, according to Kathryn Zoon (Zoon, KC. Letter from the Director of the FDA Center for Biologics Evaluation and Research to Patrick Eddington. FDA via FOIA. April 28, 1998).

DOD was the owner of the equipment used to produce the vaccine, the employer of virtually all vaccine recipients, and the employer of health care workers administering and monitoring vaccinations. No meaningful postmarketing surveillance appears to have ever been performed, with the exception of the standard passive VAERS reporting system. Even after reports of severe illness in Persian Gulf War veterans, the relationship between vaccination and illness has never been subjected to statistical analysis in the United States. Yet there do exist immunization records for thousands of veterans, and surveys using veteran recall of vaccine could also be done. So yes, there is no evidence of long-term adverse effects, but the 1974 study of multiply vaccinated persons at Fort Detrick did not exclude the real possibility of such effects, and also acknowledged that they do occur in animal models.

Where do the GWI expert panels get their information?

Every reference cited by the PAC is to a DOD briefer (Philip Russell being a former Commander at Fort Detrick; the others are current employees). No peer reviewed literature is cited. Side effects of the vaccine are minimized. The issue of multiple vaccines given together is trivialized, with no review of the existing literature on the topic. The committee claims its conclusions are "based on available evidence" but cites none.

Presidential Advisory Committee on Gulf War Illnesses: Final Report
Anthrax and Botulinum Toxoid Vaccines

Anthrax vaccine. In 1970, FDA licensed anthrax vaccine to protect civilian workers against possible infection by anthrax bacteria. Since 1967 and before the Gulf War, more than 20,000 inoculations have been routinely administered to at-risk populations, including laboratory personnel who work with the bacteria that causes anthrax, persons in industries that work with animal hides and wool (which can be

a source of anthrax infection), and veterinarians who com in contact with anthrax-infected animals.

Although active long-term safety surveillance is not generally part of the FDA vaccine licensing process, the FDA encourages U.S. health care providers and the law requires manufacturers to report serious adverse reactions for all licensed vaccines (53). FDA has not received data that raise concerns about the safety of the anthrax vaccine.

Historical data for short-term health effects of the anthrax vaccine indicate up to six percent of recipients experience mild discomfort, including tenderness, redness, swelling or itching at the inoculation site for up to 72 hours. Fewer than one percent experience a more severe local reaction that potentially limits the use of the arm for one to two days.

Systemic reactions, e.g., fever, malaise, are uncommon (about 0.0 percent). 102, 103

According to DOD, medical monitoring and surveillance conducted during the Gulf War found the expected short-term side effects of anthrax vaccines occurring at approximately the historical rates.53. A single hospitalization for a vaccination site infection was reported. DOD points out that precise information about all possible short-term side effects is unknown, however, because of difficulties in collecting such data during and after the Gulf War.

53. Eitzen, E., U.S. Army Medical Research Institute of Infectious Disease, Fort Detrick, unpublished report to Presidential Advisory Committee on Gulf War Veterans' Illnesses, October 1995.

102. Johnson-Winegar, A., Director, Medical, Chemical, and Biological Defense Research, U.S. Army Medical Research, U.S. Army Medical Research Development Command, testimony before the Presidential Advisory Committee on Gulf War Veterans' Illnesses staff, May 1996.

103. Johnson-Winegar, A., Director, Medical, Chemical, and Biological Defense Research, U.S. Army Medical Research, U.S. Army Medical Research Development Command, testimony before the Presidential Advisory Committee on Gulf War Veterans' Illnesses staff, December 1995.

Health effects of multiple vaccines. The human immune system has evolved the capability to deal with thousands of foreign substances, to sort them out, and to regulate immune response. Humans live among a vast population of hostile microorganisms, and vaccinations --even multiple, vaccinations – are a small part of total immune stimulation. Individual vaccines can cause adverse effects, but several studies of the effects of giving multiple vaccinations at one time have found no adverse effects associated with the practice. Research on this issue continues, but based on available evidence, the Committee believes it is unlikely that multiple vaccines are responsible for illnesses reported today by Gulf War veterans. 202, 219, 268.

What do we conclude about the risks of vaccines to Gulf War veterans? The Committee concludes it is unlikely that health effects reported by Gulf War veterans today are the result of exposures to the BT or anthrax vaccines, used alone or in combination.

202. Pittman, P.R., "Anthrax and Botulinum Vaccines: Antibody Prevalence and Immune Response to a Booster Dose in Military Personnel Initially Vaccinated During Desert Shield/Desert Storm: Preliminary Report," in review for submission to U.S. Food and Drug Administration to supplement

BB-IND3723, March 1995.

219. Russell, P.K., Department of International Health, Johns Hopkins University, testimony before the Presidential Advisory Committee on Gulf War Veterans' Illnesses, April 1996.

268. U.S. Army, Medical Research Institute of Infectious Diseases, Protocol: (Retrospective) Assessment of the Health of Workers Formerly Employed at Fort Detrick, MD, P. R. Pittman, Principal Investigator, September 1996.

I recently discovered the existence of an interesting D.O.D. study, initiated in September 1998. Seventh-day Adventists, who had participated in "Project Whitecoat" in the 1950's through the 1970'--they had been volunteer guinea pigs for the biological warfare program at Fort Detrick -- had received anthrax vaccination as well as other vaccinations during their tenure at Fort Detrick. Now, 25 years after the program ended, Detrick researcher Col. Philip Pittman, a principal investigator in other anthrax vaccine studies, has approached these Adventists to learn more about possible long-term effects of their stay at Fort Detrick earlier. What was the Department of Defense looking for? It appears they are seeking evidence of a Gulf War-type illness in these volunteers. The symptoms they are inquiring about are as follows:

Seventh Day Adventist Follow-Up Study, Conducted by Lt. Col. Philip R. Pittman

The data will be used "in developing a body of knowledge about whether there are any long-term effects of these immunizations." (Caree Van Linden, USAMRIID Public Affairs, 10/2/98)

24 Below is a list of common symptoms. The are associated with a wide of conditions. Please carefully review each symptom and answer with the **one answer** that best applies to you.

Difficulty sleeping
* Never a problem
* Minor or infrequent problem
* Occasionally a problem
* Regular, but not serious, problem
* Constant or serious problem
* Major or disabling problem

Fatigue
* Never a problem
* Minor or infrequent problem
* Occasionally a problem
* Regular, but not serious, problem
* Constant or serious problem
* Major or disabling problem

Joint aches and pains
* Never a problem
* Minor or infrequent problem
* Occasionally a problem

* Regular, but not serious, problem
* Constant or serious problem
* Major or disabling problem

Headaches
* Never a problem
* Minor or infrequent problem
* Occasionally a problem
* Regular, but not serious, problem
* Constant or serious problem
* Major or disabling problem

Unexplained Rashes
* Never a problem
* Minor or infrequent problem
* Occasionally a problem
* Regular, but not serious, problem
* Constant or serious problem
* Major or disabling problem

Muscle aches
* Never a problem
* Minor or infrequent problem
* Occasionally a problem
* Regular, but not serious, problem
* Constant or serious problem
* Major or disabling problem

Fevers
* Never a problem
* Minor or infrequent problem
* Occasionally a problem
* Regular, but not serious, problem
* Constant or serious problem
* Major or disabling problem

Tremors or uncontrollable shaking
* Never a problem
* Minor or infrequent problem
* Occasionally a problem
* Regular, but not serious, problem
* Constant or serious problem
* Major or disabling problem

Depression
* Never a problem
* Minor or infrequent problem

* Occasionally a problem
* Regular, but not serious, problem
* Constant or serious problem
* Major or disabling problem

Memory Loss
* Never a problem
* Minor or infrequent problem
* Occasionally a problem
* Regular, but not serious, problem
* Constant or serious problem
* Major or disabling problem

Abdominal Pain
* Never a problem
* Minor or infrequent problem
* Occasionally a problem
* Regular, but not serious, problem
* Constant or serious problem
* Major or disabling problem

Feeling sick or 'not right'
* Never a problem
* Minor or infrequent problem
* Occasionally a problem
* Regular, but not serious, problem
* Constant or serious problem
* Major or disabling problem

Is A New Epidemic Emerging?

Most important to the discussion we're having today is the question of whether servicemembers currently being vaccinated are developing chronic, adverse effects from the anthrax vaccination. Because we do not have long-term data from prior to the current immunizations, it is essential that servicemembers be studied now to see whether there are one or more common disease syndromes emerging in servicemembers who report illness. I have had an unusual role to play in trying to discern whether this is the case. As a publicly-known expert on the anthrax vaccinations, I have been contacted by 50-100 servicemembers who report a variety of symptoms. I have not had the opportunity to examine these people, but many have filled in detailed questionnaires for me regarding their symptoms, and some have sent copies of their medical records. Fortunately, you will be hearing from some of them today.

I am sorry to report that the illness symptoms described to me are remarkably similar, and also mimic the symptoms reported by numerous ill Gulf War veterans. This illness resembles Chronic Fatigue Syndrome, with fatigue, sleep disturbance and cognitive deficits. There is a significant component of headache, muscle pain and joint pain, along with respiratory and abdominal complaints. In addition, many servicemembers report neurologic symptoms including sensory neuropathies and widespread autonomic dysfunction. Many report sensory hypersensitivity, and some chemical sensitivity. Their

symptoms often worsen after the six month (4th) booster vaccination.

The predominant initial symptoms are:

* Abdominal cramping
* Diarrhea (sometimes bloody)
* Fever
* Chills
* Headaches
* Malaise
* Respiratory distress

Later, persisting symptoms have included:

* Chronic fatigue
* Dizziness
* Joint and muscle pain
* Headaches
* Memory loss/cognitive disturbances
* Sleep disorders
* Peripheral sensory neuropathies
* Intermittent abdominal pain
* Intermittent diarrhea
* Chest pains
* Recurring rashes
* Blackouts or seizures

The majority of complaints of illness have been associated with vaccination using lots 020 and 030. Each lot contains approximately 200,000 doses.

Anthrax vaccine is composed of an uncharacterized mix of bacterial products. Concentrations of these materials vary significantly from lot to lot. Because the constituents of this vaccine have never been defined, it is impossible to establish purity. It is also unknown whether any vaccine components cause adverse effects.

Because many ill servicemembers remain on active duty and are trying to stay in the military, their names and medical records cannot be provided. They are attempting, unsuccessfully, to receive appropriate medical care within the military. This is difficult when the existence of a post-vaccination syndrome is being denied by D.O.D.

Both the features of their illness, and the official response to it, echo the plight of ill Gulf War veterans, who remain without a defined illness, and without meaningful approaches to treatment.

Legal Issues

Unfortunately, the discussions we are having today have significant legal implications. Servicemembers who have refused the vaccine have faced a variety of punishments, including court

martial. Some of those who have become ill subsequent to the Gulf War, or to the recent rounds of vaccinations, feel they may have been given unapproved vaccines which are not licensed by the FDA, and which D.O.D. had no legal right to use. They are interested in seeking redress, if they can demonstrate such vaccines were administered to them.

The following article suggests that in fact, one or more unapproved anthrax vaccines has been given to servicemembers.

"Military Immunizations: Past, Present and Future Prospects," written by a former Fort Detrick Commander, states that unlicensed anthrax vaccine has been used.

"LIMITED USE VACCINES AND PRODUCTS

Limited use vaccines and products are defined as those ***unlicensed*** **experimental vaccines**, toxoids, and immunoglobulins that have been developed against specific military threats associated with high morbidity. These products would be used in specific contingency situations. Some of the limited use vaccines could be considered to be experimental deployment vaccines, since they are directed against serious region-specific endemic diseases. Limited use vaccines include Venezuelan equine encephalitis, Eastern equine encephalitis, Western equine encephalitis, Rift Valley fever, tularemia, Q fever and ***anthrax***. Botulinum toxoid (types A through E) is also included in the category of limited use products."

Ernest T. Takefuji, M.D., MPH, and Philip K. Russell, M.D., from Military Immunizations: Past, Present And Future Prospects, Infectious Disease Clinics of North America, March 1990, Page 156.

A number of servicemembers are now awaiting court martial for their refusal to submit to anthrax vaccination. Is the order to vaccinate a lawful order? Given all the questions that have been raised today, one wonders whether D.O.D. has the right to order a vaccine of questionable efficacy and dubious safety to be administered, willy-nilly, to 2.4 million service members.

Secretary of Defense William Cohen established four pre-conditions before he would approve the anthrax vaccination program. Were Secretary Cohen's four pre-conditions for approval of the anthrax vaccination program actually met?

If not, was the order to vaccinate a lawful order?
1. Secretary Cohen asked for an **independent expert** to review and approve the program.

Gerard Burrow, M.D., is a maternal-fetal thyroid expert at Yale University. Anthrax vaccine is not approved for use in pregnancy, nor in children under 18. He therefore has no experience with the vaccine, and has never published any papers on anthrax, infectious disease, or biological warfare.

How was he chosen to review this program? Is his independence as illusory as his expertise?

1. Secretary Cohen asked for supplemental testing, consistent with Food and Drug Administration standards, to assure sterility, safety, potency and purity of the vaccine.

Sterility – three of the eleven quarantined lots in April 1998 failed due to sterility testing. The February

1998 inspection also noted that several sublots which had failed sterility testing were used in the production of lots.

Safety -- Safety can only be judged by long-term follow up of people who have received the vaccine. Until now, such follow up has never been accomplished.

Potency -- Of the eleven lots quarantined by FDA on April 28, 1998, seven failed potency testing. Some of these had previously passed potency tests. Because MBPI retested lots until they achieved a pass on potency testing, this is no surprise.

Purity – "The vaccine is composed of an undefined crude culture supernatant adsorbed to aluminum hydroxide. There has been no quantification of the protective antigen content of the vaccine or of any of the other constituents, so the degree of purity is unknown."

Dr. Arthur Friedlander, MC Colonel and head of Bacteriology at Fort Detrick's USAMRIID [Brachman PS and Friedlander AM: Anthrax. In Plotkin SA and Mortimer EA (eds): Vaccines, ed 2. Philadelphia, WB Saunders, 1994, pp. 729-739.]

Addendum to the testimony of Meryl Nass, M.D.

Committee on Government Reform, Subcommittee on National Security, Veteran's Affairs and International Relations

Hearing on Anthrax Vaccine Safety, April 29, 1999

As a general principle, is vaccination a good defense against biological warfare?

What if the vaccine was 100% effective against all natural strains of anthrax, which nobody claims? An enemy would simply choose another biological agent: one that occurs naturally or one created using genetic engineering. The Defense Advanced Research Projects Agency (DARPA) identified 65 naturally-occurring biological and toxin warfare agents directed against humans: there exist vaccines for less than ten of these. "It takes 18 months to develop a weapons-grade (biological) agent, and ten more years to develop a good vaccine against it."

William Patrick, former head of the Biowarfare Program, Fort Dietrich, New York Times, November 3, 1998. "The plethora of real and constructible microbial pathogens, and the numerous ways in which exposure to them can occur, makes development of agent and root-specific defenses both foolish and futile."

J. Jacobsen, M.D., "Biologic Warfare Testing", Committee on Armed Services, House of Representatives, May 3, 1988 "One cannot overstate our inability to deal with novel agents. . . [To] unprepared public health authorities who know nothing of the weapon's origins, its structure, its pathogenic mechanism and transmission, the task of producing a vaccine or drug and doing it very rapidly is almost impossible . . . Today the number of potential agents has multiplied to the point where it is no longer possible to plan or respond with defenses. There is no public health or medical strategy." Robbins, M.D., "Biologic Warfare Testing", Committee on Armed Services, House of Representatives, May 3, 1988

Despite the fact that vaccines are unlikely to provide a robust defense against known biological agents and are even less likely to provide a defense against novel, genetically engineered agents, Congress appropriated $322 million in 1997 for the Joint Vaccine Acquisition Program. Its goals are to develop new vaccines for more than ten known biowarfare pathogens and administer the vaccines to all US servicemembers.

The anthrax vaccine immunization program can be regarded as the introduction to this much larger, and less well-known, program. FDA has stated publicly that it will expedite licensing for these biowarfare vaccines.

Are we already embarked on a misadventure that will dwarf the anthrax vaccine program in cost, futility, and medical repercussions?

In summary, there is no good evidence for vaccine safety, efficacy or necessity. D.O.D. may have illegally used unapproved vaccines on servicemembers in the past, and has not demonstrated that the order to vaccinate is a lawful order. Persian Gulf illness appears to be related, at least in part, to anthrax vaccination. D.O.D. has obfuscated the causal role of vaccines by classifying immunization records and controlling the deliberations of expert panels. Current servicemembers are now falling ill from the same disease.

What will it take to call a halt to the current round of vaccinations?

Equally important, what will it take to investigate these illnesses and develop treatment protocols that are serious about getting answers and providing care?

The smoke and mirrors have to go!

I would like to conclude by thanking the Committee again for allowing me to present this testimony. I would be happy to supply supporting documents and any other information that may shed light on the considerable questions which remain unresolved regarding the anthrax vaccine.