THE ANTHRAX IMMUNIZATION PROGRAM

HEARING

BEFORE THE

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS, AND INTERNATIONAL RELATIONS

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

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THE ANTHRAX IMMUNIZATION PROGRAM

WEDNESDAY, MARCH 24, 1999

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON NATIONAL SECURITY,
VETERANS' AFFAIRS, AND INTERNATIONAL RELATIONS,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2154 Rayburn House Office Building, Hon. Christopher Shays (chairman of the subcommittee) presiding.

Present: Representatives Shays, Ros-Lehtinen, Biggert, Blagojevich, and Schakowsky.

Staff present: Lawrence J. Halloran, staff director and counsel; Robert Newman, professional staff member; Jonathan Wharton, clerk; Cherri Branson and David Rapallo, minority counsels; and Earley Green, minority staff assistant.

Mr. SHAYS. Good morning. I would like to call this hearing to order. This morning we begin the subcommittee's oversight of the Department of Defense, DOD force-wide Anthrax Vaccine Immunization Program [AVIP].

We begin with questions. Why now? Why this vaccine? Why a mandatory program? And why would active duty, reserve and National Guard personnel jeopardize their military careers and even their liberty rather than take the vaccine?

After what has been described as a multi-year and deliberative, but for the most part, closed process, DOD launched the AVIP in 1997, but anthrax was a known threat in the 1991 Gulf war. Vaccine development and acquisition against biological threats have been an explicit element of U.S. force protection policy since 1993.

Yet only now has anthrax been deemed the preeminent threat requiring this additional medical force protection measure unique to that single organism. If, as has been argued, it would be irresponsible, even immoral, not to use the available vaccine, what took so long?

To meet tomorrow's very real threat of biological weapons, cocktails and genetically altered anthrax strains, DOD selected the vaccine approved by the Food and Drug Administration [FDA], almost 30 years ago. It has been described as crude and dated medical technology. The sole production plan is under renovation to address serious failures to follow good manufacturing practices which, in turn, can affect vaccine purity, potency and safety. Is that the best we can do?

The missing element of the mandatory anthrax vaccine program is trust. Radiation testing, Agent Orange, the reckless use of exper-

imental drugs and mysterious Gulf war illnesses have made military men and women understandably distrustful of the Pentagon on medical matters.

Although DOD appears to acknowledge the problem, AVIP brochures and websites still seem heavy handed and one sided, glossing over legitimate concerns about the safety and efficacy of that vaccine, minimizing adverse reaction reports and blaming the internet for fanning dissent.

But it is what they do not find on the Internet that gives many pause. There are no long term studies of anthrax vaccine. Limited use by veterinarians in research since 1970 does not provide the statistical weight to project the vaccine's effect in 2.4 million young men and women. After vaccinating 150,000 Gulf war troops, DOD had a unique pool of subjects to study, but due to poor recordkeeping, no large scale research has been conducted.

So those being ordered to take the vaccine face a profoundly personal choice, whether or not to put something in their bodies they fear may do more harm than good. After military service, the uniform comes off, but the anthrax vaccine stays with you for life. It is just not the commitment many dedicated men and women made to their country when they volunteered for military service.

We arrive at this inquiry after traveling a road that began for many Veterans in the toxic battlefields of the Gulf war where they were exposed to multiple vaccines, experimental anti-nerve agent pills and botulism toxoid vaccine, depleted uranium, low levels of chemical warfare agents, pesticides, oil fire smoke and more. We will follow it until we are sure medical force protection means assuring the long-term health of U.S. forces, not just short-term mission capability.

Again, thanks to all our witnesses for being here today. We look forward to your testimony.

[The prepared statement of Hon. Christopher Shays follows:]

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Statement of Rep. Christopher Shays
March 24, 1999

This morning we begin the Subcommittee's oversight of the Department of Defense (DoD) force-wide Anthrax Vaccine Immunization Program (AVIP).

We begin with questions: Why now? Why this vaccine? Why a mandatory program? And why would active duty, Reserve and National Guard personnel jeopardize their military careers, and even their liberty, rather than take the vaccine?

After what has been described as a multi-year and deliberative, but for the most part closed process, DoD launched the AVIP in 1997. But anthrax was a known threat in the 1991 Gulf War. Vaccine development and acquisition against biological threats have been an explicit element of U.S. force protection policy since 1993.

Yet only now has anthrax been deemed the preeminent threat requiring this additional medical force protection measure unique to that single organism. If, as has been argued, it would be irresponsible, even immoral, not to use the available vaccine, what took so long?

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The missing element of the mandatory anthrax vaccine program is trust. Radiation testing, Agent Orange, the reckless use of experimental drugs and mysterious Gulf War illnesses have made military men and women understandably distrustful of the Pentagon on medical matters. Although DoD appears to acknowledge the problem, AVIP brochures and web sites still seem heavy-handed and one-sided, glossing over legitimate concerns about the safety and efficacy of the vaccine, minimizing adverse reaction reports and blaming the Internet for fanning dissent.

But it's what they don't find on the Internet that gives many pause. There are no long term studies of the anthrax vaccine. Limited use by veterinarians and researchers since 1970 does not provide the statistical weight to project the vaccine's effects in 2.4 million young men and women. After vaccinating 150,000 Gulf War troops, DoD had a unique pool of subjects to study, but due to poor record keeping no large scale research has been conducted.

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We arrive at this inquiry after traveling a road that began for many veterans in the toxic battlefields of the Gulf War, where they were exposed to multiple vaccines, experimental anti-nerve agent pills and botulism toxoid vaccine, depleted uranium, low levels of chemical warfare agents, pesticides, oil fire smoke and more. We will follow it until we are sure medical force protection means assuring the long term health of U.S. forces not just short-term mission capability.

Thanks to all our witnesses for being here today. We look forward to your testimony.

Mr. SHAYS. I would like to acknowledge Ms. Lehtinen.

Ms. ROS-LEHTINEN. Thank you so much, Mr. Chairman. I want to congratulate you for spearheading this effort in Congress, doing these hearings.

As a wife of a Vietnam veteran who had many of his friends subjected to Agent Orange and having our military deny this existence for many years, I want to commend you for being on the cutting edge of this issue and I look forward to hearing from our expert panelists to find out what the proper role of this vaccine is in today's military forces. So thank you, Chris.

Mr. SHAYS. Thank you very much. We have testimony in our first of two panels: Dr. Sue Bailey, Assistant Secretary for Health Affairs, U.S. Department of Defense; accompanied by and I believe will be providing brief comments as well, Lt. General Ronald R. Blanck, U.S. Army; Deputy Surgeon General Todd Fisher, U.S. Navy; Lt. General Charles H. Roadman, II, U.S. Air Force. We welcome all of our witnesses and as is the custom we would invite you to stand to take the oath.

[Witnesses sworn.]

Mr. SHAYS. Thank you. Note for the record that all witnesses have responded in the affirmative and let me say to you Dr. Bailey before recognizing you, that we have very tough questions. We have very real questions to ask, but this committee has not concluded one way or the other about this issue, so we have an open mind and we look forward to your testimony. Thank you.

Dr. Bailey.

STATEMENTS OF DR. SUE BAILEY, ASSISTANT SECRETARY FOR HEALTH AFFAIRS, U.S. DEPARTMENT OF DEFENSE; LT. GENERAL RONALD R. BLANCK, U.S. ARMY; DEPUTY SURGEON GENERAL TODD FISHER, U.S. NAVY; AND LT. GENERAL CHARLES H. ROADMAN II, U.S. AIR FORCE

Dr. BAILEY. Thank you, Mr. Chairman, Ms. Lehtinen, other distinguished members of the committee, anthrax has been identified by the chairman of the Joint Chiefs of Staff as a major threat to American forces. It is lethal. It is easily made and it is easily weaponized. Our mission at Health Affairs is to support force protection through force health protection, specifically that means providing for protection from all sources, including chemical and biological weapons.

The anthrax vaccine is a safe vaccine and it is efficacious, but you should realize that it is not a medical program, that this program is a line commander's program supported by military medicine. It is their responsibility also to provide for the safety of troops and as well, to complete their military mission. Total force anthrax vaccine immunization involved a deliberate and detailed process that resulted in the decision by the Secretary of Defense in May 1998 to immunize the total force. Prior to that in December 1997 a total plan was approved by the Secretary upon four conditions being met. Those conditions were that there was supplemental testing above and beyond that of the production facility and the FDA; that there was a service-wide plan for implementation of the vaccine program as well as communication to our forces, families and those concerned. The third condition was that there was an infor-

mation technology tracking system to allow us an overview and a tracking of each of these immunizations as they were provided, and fourth, that there was an independent review provided. And that if all of these conditions were met, we would proceed with total force vaccination. In fact, all of those conditions were met and we proceeded with total force immunization.

We are deeply committed at the Department of Defense to force health protection. We are proud of the anthrax vaccine immunization program which, as you see, has now provided immunizations for over 223,000 of our troops with very few adverse reactions. At this point the rate is 0.007 percent. That is much lower than most of the vaccine immunization programs that you may be well aware of, those for children and infants, for instance, and for many Americans.

At this point, adverse reactions stand at 42 out of 223,000 individuals and a total of over 600,000 actual immunizations given.

We believe the efforts that we have undertaken, in fact, set the standards as we provide force health protection in a new era of chem-bio weaponization and we are very fortunate to have this vaccine, and in fact, it would be irresponsible were we not using it at this time to protect our troops.

Thank you very much.

[The prepared statement of Dr. Bailey follows:]

ANTHRAX VACCINE IMMUNIZATION PROGRAM

Statement by

Dr. Sue Bailey
Assistant Secretary of Defense for Health Affairs

Submitted to

Subcommittee on National Security,
Veterans Affairs and International Relations
Committee on Government Reform
U.S. House of Representatives

March 24, 1999

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U.S. House of Representatives

Chairman Shays, Representative Blagojevich and Distinguished Committee Members, I very much appreciate this opportunity to appear before your Committee today on one of the Department's most important force health protection efforts – the Total Force Anthrax Vaccine Immunization Program (AVIP). Today I am accompanied by Army Surgeon General Ron Blanck, Air Force Surgeon General Chip Roadman and Navy Deputy Surgeon General Todd Fisher. We will be addressing the decision-making process that led to the implementation of the AVIP program. Although we will be focusing on the medical aspects of the program, I would like to emphasize that this is *not* primarily a medical program. It is a line commanders' program to keep our deployed military personnel safe and prevent combat casualties.

Building upon many lessons learned over the past several years and the Department's strong commitment to force health protection, the AVIP employs a very different and effective approach, incorporating a safe and efficacious vaccine, effective risk communication, extensive immunization tracking, strong command leadership with medical support. As we say often, "anthrax kills; vaccination protects". To date, I am pleased to tell you that 223,000 soldiers, sailors, airmen and marines have received Anthrax immunizations under this program.

As identified by the Chairman of the Joint Chiefs of Staff, anthrax is a major threat to our troops. Anthrax is the primary biological warfare threat faced by U.S. forces. More than 10 countries, including Iraq, have or are suspected of developing this biological warfare capability. Anthrax is the biological weapon most likely to be encountered because it is highly lethal, easy to produce in large quantities, and relatively easy to develop as a weapon.

Further, the nation expects military commanders to do all in their power and authority to employ prudent medical countermeasures in the face of biologic and chemical threats to preserve the safety and well-being of our service personnel as well as to assure a satisfactory completion of their military missions. The Total Force AVIP, a line-managed force health protection program, provides U.S. troops with a much needed measure of protection against a deadly threat.

The Total Force AVIP involved a detailed, deliberative process that culminated in Secretary of Defense Cohen's decision to approve implementation of the program on May 18, 1998.

The deliberative process began with development and implementation of Department of Defense Directive 6205.3, DoD Immunization Program for Biological Warfare Defense, dated November 26, 1993. This directive prescribes the process for addressing requirements for immunization against biological warfare threats against U.S. personnel. A series of discussions within the Department regarding a policy on immunizing US forces against anthrax took place between 1993-1995.

Subsequently, the Chairman, Joint Chiefs of Staff (CJCS) identified anthrax as the primary biological warfare threat to our deployed forces in his Threat Matrix. The CJCS Program Assessment also recommended immunizing the entire force against anthrax. In January 1997, the Deputy Secretary of Defense directed the Assistant Secretary of Defense (Health Affairs) and the Joint Staff to prepare planning guidance to implement anthrax immunizations for US forces.

While in the process of developing the planning guidance, questions arose about the manufacturer, Michigan Biologic Products Institute (MBPI). These questions primarily involved the proposed sale of MBPI by the State of Michigan and also a Food and Drug Administration (FDA) inspection of MBPI in November 1996. The inspection resulted in the FDA directing the manufacturer to take immediate actions to correct facility inspection deficiencies.

Subsequently, a DoD team visited MBPI and determined that the facility had made significant improvements and was moving forward in meeting objectives under its strategic plan for improving its manufacturing facility and processes. Additionally, the State of Michigan assured the Department that the future manufacture of anthrax vaccine would not be adversely affected by sale of the state-owned facility. As a result, the ASD(HA) and Joint Staff again addressed the planning guidance within the Department. After receiving concurrences, the ASD (HA) and Joint Staff incorporated the planning guidance into a Secretary of Defense decision package recommending anthrax immunizations for the total force.

On December 15, 1997, the Secretary of Defense approved the plan for immunization of the total force against anthrax contingent upon the successful completion of four conditions prior to implementation of the program.

(1) supplemental testing, consistent with Food and Drug Administration (FDA) standards, of anthrax vaccine lots in the stockpile to assure their potency, purity, sterility, and general safety

(2) approval of the Services' implementation plans that describe how they plan to administer their respective anthrax vaccine immunization program and communications plans that describe efforts to inform military personnel of the overall program

(3) implementation of a system for fully tracking anthrax vaccinations

(4) review of the health and medical aspects of the program by an independent expert.

On February 3, 1998 due to increasing tensions in his region, the Commander In Chief (CINC) Central Command (CENTCOM) requested acceleration of the total force AVIP for the CENTCOM region. Subsequently, the Deputy Secretary of Defense conditionally approved the CJCS recommendation supporting the CINC CENTCOM request and mandated a final medical review to ensure that the four conditions set by the Secretary of Defense were successfully completed before the program was implemented in the CENTCOM region.

A final medical review, conducted on March 2, 1998, determined that the four conditions specified by the Secretary of Defense had been successfully met for the CENTCOM region.

(1) supplemental testing had been completed on all lots of FDA-licensed anthrax vaccine that would be used in the CENTCOM region

(2)interim automated immunization tracking systems were in place for each service and operational in the CENTCOM region

(3) approved operational plans for administering the anthrax immunization and health risk communications information and briefings were in place in the region

(4) an independent review of the health and medical aspects of the overall program was completed by Dr. Gerard Burrow, Special Advisor for Health Affairs for the President of Yale University, on February 19, 1998.

The Secretary of Defense gave approval for CENTCOM to begin anthrax immunizations in the region on March 2, 1998, with forces assigned or deployed to Southwest Asia (SWA). Immunizations began on March 10, 1998.

On May 18, 1998, Secretary Cohen approved implementation of the Total Force AVIP. As with the Accelerated AVIP for SWA, all four conditions set by Secretary Cohen on December 15, 1997, were met before approval for program implementation was given.

The Total Force AVIP is being implemented in three phases over a seven to eight year period. Under the time-phased implementation plan, forces expected to deploy to high threat areas are the first to be immunized against anthrax. This phase, referred to as Phase I, includes service members and mission essential DoD civilians assigned or deployed to Joint Staff-designated high threat areas in SWA and Korea. Early deploying forces supporting SWA and NWA, to include Active and Reserve Component personnel, constitute Phase II. Phase III will include the remainder of the force, both Active and Reserve Component, and accessions.

Like other immunizations that are required to prepare military personnel for deployment, the anthrax immunization is mandatory. Personnel will be required to have the anthrax immunization unless medically deferred. The authority to direct usage of medical countermeasures constitutes a lawful military order. Why is it essential that the anthrax immunization be mandatory? Military commanders have the responsibility to ensure the health and safety of their troops and to carry out their mission responsibilities. Anthrax is a serious threat. We have a safe and efficacious vaccine. To not use the vaccine constitutes a failure to protect our troops and a risk to carrying out military missions.

Each Service has its own policy for how it will handle Service members who refuse a lawful military order to take the anthrax immunization.

The Department is confident, as is the Food and Drug Administration (FDA), that the FDA-licensed anthrax vaccine is safe and efficacious for its intended use of immunizing the total force against anthrax. The anthrax vaccine has been licensed by the FDA since 1970 and has been recommended for veterinarians, laboratory workers, and livestock handlers in the US for more than 25 years. There have been no long-term side effects reported with the FDA-licensed anthrax vaccine.

Since 1973, USAMRIID has monitored 10,451 injections, or 4605 primary series doses, and 5846 booster doses of FDA-licensed anthrax vaccine administered to USAMRIID laboratory personnel. Short-term reactions were reported to be about 4% for both primary and booster vaccinations (passive data collection). No long-term adverse effects have been reported. As of March 16, 1999, more than 634,000 anthrax immunizations have been given to over 223,000 Service members. To date, there have been 42 Vaccine Adverse Event Reporting System (VAERS) reports submitted to the FDA and CDC (an adverse reaction rate of 0.007 percent). Only 7 service members required hospitalization or experienced loss of duty for more than 24 hours. There was one case of Guillain-Barre Syndrome and that person has subsequently recovered. Compared to other vaccine reaction rates, the anthrax vaccine has a very good safety record. In addition to tracking adverse effects in the overall program, we are also conducting a population-based study at Tripler Army Medical Center, Hawaii, on over 600 military medical personnel (i.e., doctors, nurses, and medical technicians) who have received the anthrax immunization. The survey was specifically designed to derive all possible significant side effects experienced with the anthrax immunization.

The safety of our AVIP was also confirmed by an independent review of the program. Dr. Gerard N. Burrow, who serves as Special Advisor for Health Affairs for the President of Yale University, conducted the review. Dr. Burrow concluded that "the anthrax vaccine appears to be safe and offers the best available protection against wild-type anthrax as a BW agent."

With respect to efficacy, a FDA Advisory Panel stated in 1985 that there is sufficient evidence to conclude that the anthrax vaccine is effective under the limited circumstances for which this vaccine is employed. In a March 13, 1997 memorandum, the FDA confirmed that the pre-exposure administration of the FDA-licensed anthrax vaccine for the prevention of inhalation anthrax is not inconsistent with the current product label. In addition, the Committee on Infectious Diseases, American Academy of Pediatrics (1994), states that "the vaccine is effective in preventing or significantly reducing the occurrence of cutaneous and inhalation anthrax in adults."

Conducting lethal challenge studies in humans is considered unethical and, since there is no study population identified as being at high risk for inhalation anthrax, directly determining the efficacy of the vaccine in humans against aerosol exposure to anthrax spores is not possible. There have been numerous studies of the anthrax vaccine involving animal models. Several studies performed at the USAMRIID have demonstrated the efficacy of the FDA-licensed anthrax vaccine against inhalation anthrax in rhesus monkey challenge studies. These animal studies showed that the FDA-approved anthrax vaccine provided greater than 95% protection against high-dose aerosol challenge with anthrax in the monkey model. Human antibody response to the FDA-licensed vaccine provides further suggestive evidence that the FDA-licensed anthrax vaccine will protect against inhalation anthrax.

To give you a sense as to how we designed the AVIP differently, let me address three major changes from past programs – line commander ownership, risk communication, and tracking of immunizations and adverse effects. The success of this program depends on Line Commanders taking ownership of the program and making sure that their troops are immunized. As always, the medical staff support their line leadership in carrying out the medical aspects of the program. The Line has taken on this responsibility and has been a key to the remarkable success to date. Commanders, including General Shelton, Chairman of the Joint Chiefs of Staff, are often the first to take the shots. They keep track of how their units are doing in getting immunized and make sure the troops get their immunizations on a timely basis. Line Commanders are also involved in communicating the importance of this program to the health of the troops and the achievement of military missions.

With respect to risk communications, again a major change is taking place. For this and future such programs, the troops are being clearly advised up front as to why the vaccination is needed, what vaccination they are receiving, the safety and efficacy of the vaccine, and what potential adverse effects could occur. It is important that the troops understand the benefits as well as the risks, though very low, of Anthrax immunizations. When the program starts in a particular unit, troops are given the opportunity to ask questions and the Commanders and medics work with troops who have concerns about the immunization. Often this is done on an individual and personal basis. In rolling out the program and in its ongoing operation, the Department has used a wide range of communications mechanisms to reach the troops and their families. Briefings, newspapers and handouts have been used extensively. The newest area of communications has been the Internet. Each military service has established Internet web sites to address service member and family concerns regarding the AVIP and its implementation. DoD's DefenseLINK also has an anthrax web site which, with the services' web pages, provides synchronized information to all beneficiaries regarding the anthrax vaccine immunization program.

Tracking who receives vaccinations and any adverse effects is vital to a successful program. Currently, the Services use different interim automated immunization tracking systems (ITS) to record and track the anthrax immunization status of their Service members. The core information is then placed in DoD's central personnel database, the Defense Enrollment and Eligibility Reporting System (DEERS), as the system to track across all Services. These systems are used as management tools to remind Commanders and individuals about their anthrax immunization status (who needs which immunization when) and to keep track of adverse effects. Operational testing of a joint system, Preventive Health Care Application (PHCA), for use at the Service level, has occurred with worldwide deployment beginning this year. To add further emphasis to the importance of tracking immunizations, the Combatant Commands, Joint Staff, and Services began monitoring anthrax immunization status of units assigned to high threat areas as a readiness indicator.

Mr. Chairman, Representative Blagojevich, Distinguished Committee Members, we are deeply committed to protecting the health our forces and are applying the many lessons learned over the past decade. I am proud to say that the Anthrax Vaccine Immunization Program is the culmination of all those efforts and sets the standard for future efforts to protect our troops against the terrible threats of chemical and biological warfare agents. We have a terrible threat. We are fortunate to have a safe and efficacious vaccine. We would be irresponsible if we did not use it to protect our troops.

Mr. SHAYS. Thank you, Dr. Bailey. We will go first to you, General Blanck and then to Surgeon General Fisher and then General Roadman.

General BLANCK. Mr. Chairman, distinguished Members, thank you for the opportunity of appearing to deal with the issues and concerns which I think in your opening comment you summed up very well.

I believe the threat is real. I believe the threat is greater today than it was 2 years ago, 5 years ago, 10 years ago, though it existed then and we have a way to counter the threat and to offer protection to the men and women in uniform and it is the fully FDA approved anthrax vaccine.

Now certainly there are questions and concerns about the vaccine. There must be, because it is not in widespread use. Although it is a very similar vaccine manufactured exactly the same way as tetanus to a very similar organism, has very similar side effects, people know about tetanus and are comfortable with it. By the way, before World War II, tetanus vaccine was also made mandatory for the Armed Forces and during that entire conflict there were only 12 cases of tetanus despite all of the ordnance that was around the wounds suffered by the men and women in uniform.

So this is not something that is particularly new. We know about this vaccine. You alluded earlier to the Gulf war and I think that is particularly pertinent because as Dr. Bailey has described we have learned from the Gulf war. We have learned that even though the vaccine is FDA-approved, we needed supplementary testing so that we knew it met the standards for on top of the FDA approval, safety, sterility, purity and potency and we have done that testing on every lot of vaccine that has been administered to our soldiers.

We knew that we had to have a way of tracking the administration of the vaccine and the individuals who received it, so that we could retrieve the data and so that we knew when the next doses were to be given. I returned on Saturday from Seoul, Korea. While in Seoul, I received my fourth anthrax vaccination and we checked, today, I am in that automated tracking system and so is the sailor who got it with me and the other soldiers who happened to be there for their fourth shot in Korea. So we have that system. It works very well for all three services. And by the way, the sailor was getting his shot in an Army clinic, so it was entered through our system. It goes to the Defense Enrollment Eligibility Reporting System and when he goes on board his ship, the Navy will be able to download that information, see when he needs his fifth immunization, know what lot he got and so forth and so on. So we are doing that very well.

The independent review has already been mentioned. I would like to spend a moment on something that I think we did very poorly in the Gulf war and in following up on health issues and that is risk communication, education, talking to people.

We have tried to do this to the best of our ability and provide information. We have a goal in all of the services that no one gets a needle in their arm without having been educated, having been briefed, often having seen the leadership getting their immunizations first and having had the chance to ask questions and get pertinent and appropriate answers. So we have really taken that very

seriously and I would like, if I might to take 2 minutes and show you a little film clip that has to do with both the education effort, but I think it speaks to safety and I will conclude with the safety.

If I could have the film clip, please.

[Film Clip.]

From the AFRTS News Center in Washington, this is the Two-Minute Report. I am Jim Langdon. On this edition, anthrax.

Even a cute little guy like this could carry the deadly biological agent. That is why Specialist Amber Stanley and the other people who handle animals at the U.S. Army Medical Research Institute of Infectious Diseases have had anthrax vaccination shots. Specialist Stanley has worked at the Institute for more than 2 years. She took her first anthrax shot long before the vaccine became mandatory for all service members.

"I did not mind it, considering the biocontaminant level we were in. I figure at least it would give me a fighting chance if something had happened."

Specialist Stanley says everyone she works with at the Institute has had anthrax vaccination shots.

"I have not met anyone who has had any problems, any health problems, any health risks after taking the shots."

Specialist Stanley has received six anthrax shots so far.

John Kondig probably cannot recall when he took his six anthrax shots. He has been taking the vaccine here at the Institute for more than 30 years.

"I trust it completely. I have no questions about its safety whatsoever."

But he says it is hard to talk about the vaccine's safety to service members who have their minds set against the shots.

"I can understand their feeling, but my personal feeling is that I think they should take the shots as a safety precaution and I do not believe there is anything—there is any danger involved in taking the shots."

A tender arm is the only adverse reaction Mr. Kondig has ever had to anthrax shots. He still runs into people he worked with 30 years ago and says none of them have complained about side effects from the anthrax shots they took.

That is the Two-Minute Report from Washington.

General BLANCK. If we could turn off the tape, please.

Part of the education program, but it speaks to something else. He is one of the individuals who since 1974, having received anthrax, has been followed for long term health effects and we followed those who received over 10,000 of the immunizations over 1,000 individuals to see from 1974 to 1992 if, in fact, there were long term health effects and we found none.

We also have done other studies in groups, for example, at Tripler Army Medical Center to see what the real rate of even minor side effects. As Dr. Bailey has pointed out, we have those that are significant side effects, but somewhere depending on the study between 4 percent and even as high as 30 percent, will have minor local reactions. For example, on my second shot, I developed a nodule at the site of immunization. So there are those kinds of things. But in every study that we have done, in every study that others have done, we have found the rate of adverse effects to be lower than those of other mandatory vaccines. Tetanus comes to mind, Yellow Fever, typhoid, Hepatitis A, Hepatitis B and of course, you know about the DPT that is mandated by most States, in fact, by all States before students start public school, with far greater adverse reactions, or at least the rate of them. We believe this to be a safe vaccine.

As far as efficacy, you know that there has only been one human study and the numbers were in approximately wool sorters. In the group that received the vaccine, none developed inhalation anthrax. In the group that did not receive the vaccine, four did.

The numbers, while significant, still are not large enough to make a great deal of conclusion, though it was at least partially the basis for groups such as the National Academy of Pediatrics, the Food and Drug Administration and others to conclude that this was efficacious against inhalation anthrax. But we went further, of course, and did the animal studies that I think you are aware of. The guinea pig model is not a good one. It does not match our immune system or develop the disease as in humans, so we have used two models that do, one, the rabbit, two, the Rhesus monkey. And in those studies, which I can answer in greater detail, we found the vaccine to be protective in almost all cases, whereas all of the controls died.

That concludes my remarks and I would be happy after the others speak to answer questions.

Mr. SHAYS. Thank you, General Blanck.

Admiral Fisher.

Radm. FISHER. Thank you, Mr. Chairman, distinguished Members. On behalf of Admiral Nelson, I would like to thank you for this opportunity to provide information on the safety and efficacy of the anthrax vaccination immunization program [AVIP].

The Department's decision to vaccinate all Service personnel with the anthrax vaccine was made only after careful validation of the threat of weaponized anthrax and ensuring the vaccine would provide safe and effective protection which you have heard about.

We also in the Navy have great confidence in the safety and the efficacy of the vaccine which has a long history, which you have just heard about again, of safe use with remarkably low incidents of side effects since its start of licensure by the FDA in 1970.

I have received the vaccine and its side effects with me are quite honestly less than what I experienced with the tetanus-typhoid booster, so it is—you know that you got it, but my arm is fine.

Our experience in the Navy has been very positive since we began the anthrax vaccine immunization program in May 1998. As of March 22, over 82,000 Navy and Marine Corps members have been vaccinated, with only 8 reactions reported via the Vaccine Adverse Event Reporting System, the VAERS system. All have been returned to full duty.

Our reporting policy requires a VAERS report be submitted when an individual is placed in quarters for longer than 24 hours, is hospitalized or contamination of the vaccine lot is suspected. However, in our policy message, we emphasize any adverse reaction can be reported and anyone may submit a report, not just the provider.

There may be additional individuals who have experienced some reaction to the vaccine that have not been reported, however, I am confident all of the serious reactions have been reported in our system.

Also, Navy Medical Department personnel are instructed to provide Sailors and Marines this informational brochure before they receive their first anthrax vaccine dose. This includes valuable information about the vaccine and answers to often asked questions, as well as giving the Internet address for the Navy website on anthrax which also then identifies other websites for information.

Our main concern is the safety and welfare of our Sailors and Marines. This is why we are protecting them against the threat of biological warfare, by giving them the anthrax vaccine.

We are fortunate to have a time tested, safe and effective vaccine to provide an important element of the body armor needed to defend our personnel against weaponized anthrax. Anthrax has now joined other immunizations received by our Service men and women to protect against disease threats just as important as wearing a gas mask or carrying a rifle when on the battlefield.

Again, thank you for this opportunity to testify and I would be happy to take specific questions.

Mr. SHAYS. Thank you very much.

General Roadman.

General ROADMAN. Mr. Chairman, members of the committee, thank you for the opportunity to testify today.

I think that in my mind it is clear when it comes to pulmonary anthrax there is one clear simple truth. If you are not vaccinated, if you inhale the spores, you almost certainly will die. As the Air Force Surgeon General, it is my duty to protect the health of our airmen. This duty also requires me to be Air Force's point man in the war to combat diseases which are turned into weapons of mass destruction.

Our greatest and prime biological enemy today is anthrax. And our strongest weapon against it is vaccination.

Now the Air Force so far has immunized about 65,000 people using 200,000 doses and we have had 8, excuse me, 12 total reports in the VAERS system; 7 systemic, which is, of course, fever, muscle aches; and 5 local which is the local induration and redness around the immunization site.

I personally have no doubts or concerns about the vaccine. As a physician, husband and father, I would not ask anybody to do anything I would not do myself. I have completed my anthrax series which is a series of six and you would say well, why are you at six and other people are at four? It looked like, Mr. Chairman, a year prior to the decision we were going to have the anthrax immunization approved and I had started it along with the then Chief of Staff General Fogelman, started it as an issue, once again of confidence and leadership. So I finished my six and I have no worries about its safety and efficacy.

The reason I am convinced of the anthrax vaccine's safety is because the science and the tracking over a long period of time are long standing and credible. This is not a new experimental vaccine.

As you pointed out, it has been FDA licensed for almost 30 years in both the civilian and military population. There has never been a question of effectiveness and safety in its use. What is being questioned is people's perceptions simply because I believe this vaccine is relatively unfamiliar.

It is unfamiliar because we have a generation of people who have forgotten about polio, diphtheria, tetanus, typhoid as major public health issues. And the reason that we have had the luxury of forgetting about those as public issues is because we have had vaccines to be able to deal with them.

In short, I believe that this discussion is being framed incorrectly. It is being framed as fear of an immunization when I believe

we have a weaponized agent that is uniformly lethal and we have an effective immunization and we should not be framing this as fear of the immunization. We should be framing this as fear of the disease itself.

Unfortunately, the anthrax vaccine has been getting unreasonable criticism in some circles. In particular, there are, in fact, Internet and e-mail programs that I believe are not putting forth all the information that is important. Although their intentions may be good, I believe that these critics build fear unnecessarily about this vaccine.

Yet, it is interesting to note that little is said in the same publications about the devastating disease of anthrax which, by the way, has the same mortality as the Ebola virus. And so we need to put it into context as we are talking about the disease itself.

Truly accurate information, and I believe, Mr. Chairman, you are correct, our obligation is for truly accurate information. I believe it will make it evident that we should fear the disease, and not the immunization.

Now the Air Force, as an expeditionary Air Force, must be ready to deploy any time and that means that in a moment's notice our people must be able to get onto aircraft to execute our mission and they must be fit and healthy. If our country is going to send us into harm's way, we must be equipped with every possible form of protection available. Losing life of even one person when it could be prevented is inexcusable. That is why it is mandatory for all service members to be vaccinated.

In addition to the potential human cost, mass casualties would degrade our military mission, military capability and mission accomplishment. We would not send people into battle without helmets and weapons. So we should also provide the best armor against biological dangers that we can. That armor is immunization.

We recognize that commanders, airmen and family members must become informed about anthrax. We are working hard to educate them through our websites, internal media forum and individual counseling. The Air Force has recently established an Integrated Process Team run by the Assistant Vice of the Air Force to insure a comprehensive approach to the issue involving personnel from across the Air Force. That is medical, line, legal, public affairs and others. It has been framed as a task force looking at the efficiency and effectiveness of the drug. That is absolutely not what this is. It is looking at a large system with a large immunization program and saying are our processes, are our messages, coming across consistently and clear? It is not a deviation by the Chief of Staff at all from believing that we are on the right track. It is an initiative and good management and strong leadership.

I believe that the message of the IPT is clear. The threat is real. Anthrax kills. The vaccine will save your life.

Thank you.

Mr. SHAYS. Thank you, General. Let me ask the first question to you, Dr. Bailey, and then any of you can respond to it.

Why now? Why this program now? Why not 5 years ago? We have known about it for 30 years.

Dr. BAILEY. First of all, we did provide immunization to over 150,000 people in the Gulf during the Gulf war. So this is not something that is new. We also, as you have heard, have tracked immunizations for some time. This is a threat that has increased and that is why now.

Mr. SHAYS. Let me pursue that question in a second. But first, I would like to—I realize I have been derelict in letting you know who else is here. We are joined by Congresswoman Biggert, Judy Biggert from Illinois, and also Janice Schakowsky from Illinois as well, and also the ranking member, Mr. Blagojevich. I would just ask if Mr. Blagojevich would like to make a statement and then we will get back to the questions.

Mr. BLAGOJEVICH. Thank you, Mr. Chairman. Speaking of derelict, as the ranking member, I was a half an hour late. I should confess to obvious dereliction.

I have a statement, and since I was late, rather than hold up the testimony, I will submit this for the record.

[The prepared statement of Hon. Rod Blagojevich follows:]

Opening Statement
Representative Rod Blagojevich, Ranking Member
Subcommittee on National Security,
Veterans Affairs, and International Relations

March 24, 1999

GOOD MORNING, MR. CHAIRMAN. LET ME WELCOME THE WITNESSES FROM THE DEPARTMENT OF DEFENSE WHO ARE HERE TODAY TO DISCUSS D.O.D.'S ANTHRAX IMMUNIZATION PROGRAM. I ALSO WOULD LIKE TO WELCOME THE DISTINGUISHED SERVICE MEMBERS AND THEIR REPRESENTATIVES WHO ARE HERE AND WHO WILL DESCRIBE THEIR CONCERNS ABOUT THE POTENTIAL RISKS INVOLVED WITH THE PROGRAM.

MR. CHAIRMAN, I UNDERSTAND THIS WILL BE THE FIRST OF SEVERAL HEARINGS TO ADDRESS VARIOUS ASPECTS OF THE D.O.D. VACCINATION PROGRAM. I COMMEND THIS EFFORT, AND I LOOK FORWARD TO WORKING WITH YOU IN FULFILLING OUR VALUABLE OVERSIGHT ROLE IN THIS REGARD.

THE THREATS THAT OUR MEN AND WOMEN IN UNIFORM FACE TODAY ARE CLEARLY MORE COMPLEX AND DANGEROUS THAN EVER. UNCONVENTIONAL THREATS -- ESPECIALLY THE THREAT OF BIOLOGICAL WEAPONS -- HAVE CHANGED THE WAY WE VIEW OUR MILITARY MISSIONS AND OUR MEANS OF ACHIEVING THEM.

OUR RESPONSE TO THESE CHANGING THREATS MUST BE TO PROTECT OUR FORCES IN WHATEVER WAY WE CAN. THESE EFFORTS MUST INCLUDE VERY SPECIFIC PHYSICAL PROTECTIONS FOR OUR FORCES, WHICH -- WHEN APPROPRIATE -- INCLUDE INOCULATING OUR FORCES AGAINST DEADLY DISEASES THAT HAVE BEEN WEAPONIZED BY OUR ADVERSARIES.

WITH RESPECT TO THE ANTHRAX PROGRAM, I LOOK FORWARD TO HEARING FROM THE DEPARTMENT OF DEFENSE ABOUT THEIR EFFORTS TO VERIFY THE SAFETY AND EFFICACY OF THE VACCINE. IT SEEMS THERE HAVE BEEN VERY FEW REPORTS OF ADVERSE EFFECTS WITH THE VACCINE ITSELF. I AM VERY CONCERNED, HOWEVER, ABOUT THE PROBLEMS RELATED TO THE MANUFACTURE OF THE VACCINE, ESPECIALLY IN LIGHT OF REPORTS BY THE F.D.A. OF SERIOUS DEFICIENCIES IN THE MANUFACTURING PROCESS AND ITS FACILITIES.

LET ME ALSO SAY THAT I AM SYMPATHETIC TO THE CONCERNS THAT HAVE BEEN EXPRESSED BY SOME OF OUR SERVICE MEMBERS. I AM INTERESTED TO HEAR WHAT YOU VIEW AS THE PRIMARY RISKS OF THE VACCINE, WHAT INFORMATION YOU BASE THESE VIEWS ON, AND HOW YOU BELIEVE YOUR CONCERNS SHOULD BE ADDRESSED.

FINALLY, MR. CHAIRMAN, I KNOW WE ALL AGREE THAT OUR COUNTRY OWES A TREMENDOUS DEBT TO THOSE WHO SERVE IN THE MILITARY. CARING FOR THEIR HEALTH -- BOTH DURING AND AFTER THEIR SERVICE -- REPAYS ONLY ONE SMALL PART OF THAT DEBT. WE HAVE HEARD A LOT ABOUT THE DEFICIENCIES IN THIS AREA IN OUR RECENT HEARINGS WITH THE VETERANS ADMINISTRATION AND THE VETERANS ORGANIZATIONS. AND SO WE MUST BE EVEN MORE VIGILANT THAT THE VACCINES WE GIVE OUR SERVICE MEMBERS TODAY DO NOT RESULT IN ADVERSE HEALTH EFFECTS -- EITHER IN THE SHORT-TERM OR SEVERAL YEARS DOWN THE ROAD.

AGAIN, WELCOME TO OUR WITNESSES. YOUR TESTIMONY IS VERY MUCH APPRECIATED. THANK YOU, MR. CHAIRMAN.

Mr. SHAYS. Thank you. And if I could, let me do some housekeeping.

I ask unanimous consent that all members of the subcommittee be permitted to place any opening statement in the record and that the record remain open for 3 days for that purpose. And without objection, so ordered.

I ask for the unanimous consent that all witnesses be permitted to include their written statement in the record and without objection, so ordered.

And I would invite our other members, if they would like to make a comment before we go back to questioning.

General Blanck.

General BLANCK. Yes. I think there is a combination of factors. One is the increased recognition or assessment of the immediacy of the threat, how serious it is, how likely it is to occur. But I also think it has to do with how seriously we have taken it in the past.

Up until 1990, we faced the Soviet Union and chem-bio was almost in the too hard to do box. We knew that it was there. We did not take it as seriously as we do now with the much more evident threat nations, terrorist groups.

Second reason is, given what I have just described, it was only in the late 1980's that we began a process to increase through the Michigan Biologics Products Institute the production of adequate amounts of vaccine so that we could immunize the whole force. And in fact, we did not have that amount earlier and it is one of the reasons we did not do more immunization in the Gulf in 1990 and so as all of these concerns were discussed and so forth, we came out with the plan that you have heard described in the timing that you know.

General ROADMAN. Yes sir. There are, as you know, 10 nations that we believe or suspect have this capability and I believe there is an increased recognition of the threat, particularly as we look at an asymmetric type of threat in the new world. As you know, the Aum Shirikio experimented with anthrax prior to using sarin in the Tokyo subways. About 9 months ago there was a threat in Las Vegas of an individual to sell anthrax. It did not turn out to be correct. About a year ago, B'nai B'rith here in Washington, DC, received a package stating it was in fact anthrax and there has been a flurry of envelopes going to women's clinics across the country.

I think that as you look at both nation states and as Ron Blanck talked about terrorist groups, most of us who look at this consider it not a question of whether, but when we are exposed to this agent. And I believe that it is therefore our responsibility, particularly as the threat increases to provide maximum force protection.

Mr. SHAYS. Let me just pursue the question. You used 150 of our soldiers, our sailors and their men as well, it was a mixture. Who were the 150,000 who received this vaccine?

General BLANCK. Generally, these were the rear troops, those in ports, airfields. They were not the front line because this will not deter an initiated attack because it takes 2 or 3 days to begin working when symptoms appear. So this is the kind of agent that we felt would be used to cripple the rear, potentially, and so those were the troops that we tended to immunize. Then the decision was in CENTCOM by General Schwartzkopf and his staff.

Mr. SHAYS. You are saying that the impact is not felt immediately. It is felt in a few days?

General BLANCK. That is correct.

General ROADMAN. Mr. Chairman, may I just address that?

Mr. SHAYS. Sure.

General ROADMAN. Because I think we need to paint the picture correctly. The initial symptoms of pulmonary anthrax are flu-like syndrome, where you have a cough, you have muscle aches and low grade fever. And as you would look at an individual you would say you have the flu, unless you suspected that they were exposed to anthrax. The difference between that and the flu is that 3 days later they would be dead. And as a matter of fact, as you look at the accidental release in Sverdkovsk in the then Soviet Union, downwind there—we think up to 100 people downwind who were exposed to a very small release of anthrax and the—if you read the reports, the physicians in the emergency rooms, in the civilian emergency rooms started talking among each other saying are you seeing a lot of flus? And they are saying well yes, we are seeing more flu, but then the following question and are your patients dying? And the fact of the matter is that once people develop symptoms to this, antibiotic treatment in the animal models has been ineffective and that the mortality rate is as we described it.

So it is important to recognize that this is a public health hazard, it is a military mission capability issue.

Mr. SHAYS. Is it not your testimony though you need six shots?

General ROADMAN. You need six shots as required by the FDA for the immunization.

Ron, I think you see after three, you see about 95 percent immunization, but it is still given by the FDA protocol.

Mr. SHAYS. That is 95 percent established by whom?

General BLANCK. By the antibody, demonstrable antibody levels will occur, that we believe offers protection. Certainly, it does in animal models. Actually, in a high percentage after just two shots, 95 percent of patients will demonstrate this antibody response after three.

Mr. SHAYS. And how much time do you have to wait from one shot to the next to the next?

General BLANCK. The protocol is 0, 2 and 4 weeks for the first three shots. So a month.

Mr. SHAYS. Is that what we are doing right now?

General BLANCK. We are doing that and then the fourth shot is at 6 months, fifth is at 12 months, sixth is at 18 months and then there are yearly boosters. Again, this is the protocol established by the FDA on the basis of those earlier trials.

Mr. SHAYS. Now we determined that this would be Army personnel that were not forward engaged? Was this Air Force, Army, Navy?

General BLANCK. All services.

Mr. SHAYS. Were the 150?

General BLANCK. That is correct.

Mr. SHAYS. Now why are you not able to tell us who those 150,000 people are?

General BLANCK. Because the record of their immunization was entered into their medical record, rather than in an automated system that would allow us to track them individually.

Now we have by unit, been able to determine who has been there and in fact, who should have received the immunization and it was on the basis of that information that the National Institutes of Health, Presidential Advisory Committee, Institute of Medicine and so forth did the studies that failed to show any correlation of Gulf related health problems with the administration of the anthrax vaccine. That is what gives us the information and the confidence that the anthrax vaccine was not a cause of these illnesses.

Mr. SHAYS. I am going to go to Mr. Blagojevich, but I am not clear of your answer. My understanding is that we have not taken this 150,000 and seen—made a study exactly of the impact on the 150,000.

General BLANCK. That is correct because we do not know individually who got it. What we have done is taken the information from the comprehensive clinical evaluation program, from the VA studies of those that are ill following their Gulf war service and look to see if there were correlates with the administration of the anthrax vaccine. And it was based on two things. One was their own records or recollection of getting the anthrax vaccine first, and second, on what unit they were in.

Dr. BAILEY. Let me add as far as the tracking goes, that if you remember there were four conditions that Secretary Cohen said. One of them was the tracking. That is one of the overwhelming successful aspects to this program. We can track down to the Social Security number, whether or not you are 2 days late for your immunization. Let me just say everybody sitting at this table are the people responsible for this force health protection mission and all of us have had our anthrax immunizations.

That speaks to the safety, obviously, it is a leadership issue as well. But each of us can tell you that if you are a day late, it is known by our system. We have done an incredibly successful job of tracking every individual and therefore will have long term capability to review retrospectively as well.

Mr. SHAYS. Secretary Cohen told me he is under this program as well.

Dr. BAILEY. Right.

Mr. SHAYS. Mr. Blagojevich.

Mr. BLAGOJEVICH. Thank you, Mr. Chairman. Dr. Bailey, if I can ask you a question or two. The concerns that have been raised about the extension of expiration dates on the vaccine, can you tell us whether the extension of expiration dates has had any effect at all on the safety or efficacy of the vaccine?

Dr. BAILEY. I can. Go ahead, I want to give you some specifics, but go ahead, General Blanck.

Mr. BLAGOJEVICH. Yes, General, that would be great.

General BLANCK. Thank you. If I may, when biologic products are stored, whether they are anthrax vaccine or tetanus vaccine or hepatitis A vaccine, et cetera, they have by FDA regulation a 3-year shelf life. At the end of that 3 years, the vaccine is again tested by the manufacturer, generally, but with the FDA oversight to assure its potency. If the vaccine, in this case, or other biologic

products, still meets their criteria, then it is certified for a further 3 years.

We, in addition to the FDA doing that testing in establishing a new shelf life did the supplemental testing of the safety, sterility, purity and potency, a separate and distinct, actually more than the FDA requires to be absolutely certain that there was no degradation in any way of this product and that it was entirely safe.

Dr. BAILEY. Let me also add that at no time have expired or contaminated lots or vials of vaccine been administered to our service member or shipped by any DOD, by the DOD to any military facilities. That is the answer you specifically need to know, but I wanted to give you some other specifics which is that there was a lot number FAVO20 which was originally approved for release by the FDA in 1994. As General Blanck indicates, expiration dates do come up. In fact, there was an expiration date on that of 1996. The manufacturer requested an extension of the expiration date and they received an FDA expiration date extension until 1999 and that is a common practice.

Mr. BLAGOJEVICH. OK, now these have been tested by lot, right, not by individual vials, is that right?

Dr. BAILEY. By lot.

Mr. BLAGOJEVICH. Can you explain why that is the case?

Dr. BAILEY. That is standard manufacturing and production.

General BLANCK. Well, plus it is tested before it is put in vials. We store it by lot, in bulk.

Mr. BLAGOJEVICH. I have one more question. When Secretary Cohen announced the intention of the Department of Defense to go ahead with total force vaccination, he listed four elements as preconditions. Why were these needed?

Dr. BAILEY. That was to assure the safety and efficacy of the vaccine and that the program was in place in a way that could be monitored. Specifically, you were not in the room, but I know you know the four conditions: supplemental testing and tracking and an implementation program and a communication program to our service members, and finally, independent review. And all of that was accomplished so that Secretary Cohen could be comfortable that we moved ahead with the total force program in the appropriate way.

General BLANCK. If I can add to that, though and this has to do with two things. One are lessons that we have learned from the Gulf war. We are not going to do that again and have that issue. I mean all of us are bound and determined to do everything we can to prevent what went on there and that has to do with recordkeeping and supplemental testing and so forth. But it also has to do with credibility. It also has to do with some of the things that the chairman mentioned as far as atomic testing or Agent Orange or whatever it is that I think has damaged the credibility of the Department substantially. And so we had that independent review. We have the independent testing. We have the FDA approval and so forth and so on, that automated tracking system. We need to make sure that the men and women in the armed forces have that confidence that what they are getting is in, fact, a necessity and will save their lives.

Mr. SHAYS. Thank you very much. Mrs. Biggert.

Mrs. BIGGERT. Thank you, Mr. Chairman. This is probably for Dr. Bailey or General Blanck. You stated in your remarks that there is only one producer of the vaccine which has recently been acquired by somebody else, but it still is one company. Are you comfortable with the fact that there is only one producer?

Dr. BAILEY. I am comfortable at this time that the program that we have developed will provide safe and efficacious vaccine throughout the total force which will take us to the year 2006 and will include total force, active duty and reserves. Yes, we will have safe, efficacious vaccine from that production facility.

In general, I could share with you that I would like to see us less dependent on any specific production capability manufacturing site, with this vaccine or with any vaccine or any medication we may need for force health protection.

Mrs. BIGGERT. Well, there is—it was shut down for a while, renovation and inspection violations?

Dr. BAILEY. It was not shut down because of inspection violations. It was for renovation and in fact, is now beginning production again.

Mrs. BIGGERT. Does the Department of Defense have——

Mr. SHAYS. Could the gentle lady just suspend for a second? Would you elaborate on that answer just a bit as to the purpose it went through renovation? Has the facility not received critical review?

Dr. BAILEY. While not manufacturing anthrax vaccine due to the renovation, a number of deficiencies with the process were cited. Now FDA observes and checks on all of the manufacturing sites of any medications that are provided.

Mr. SHAYS. Right.

Dr. BAILEY. For our forces, as well as other Americans. None of the deficiencies were considered significant enough to warrant plant closure or recall of the anthrax vaccine. In fact, the FDA also found that significant progress had been made toward meeting objectives under its strategic plan for improving its manufacturing facility and processes.

While not required by the FDA, by the way, MPBI has performed supplemental testing as General Blanck indicated.

Mr. SHAYS. Thank you.

Mrs. BIGGERT. To continue then, but were not some of the lots actually quarantined, 11 lots that were quarantined with questions about sterility and potency?

General BLANCK. Yes, absolutely. And in some cases the testing found that, in fact, they were fine and were released by the FDA again to go through our supplemental testing to doubly insure everything.

In at least two cases of which I am aware, we never did release them and destroyed the lot. There was an additional instance where we shipped vaccine to Germany, 200,000 doses and on the basis of one vial having a little sludge in it, ice crystals, that is, we feared the vaccine had been frozen, we destroyed all of them.

We really are trying to bend over backward to make sure that we have an absolutely 100 percent safe product.

Mrs. BIGGERT. When you do further testing is that using it on animals or is that the process that you would determine?

General BLANCK. Yes, it goes through of course the sterility has to do with cultures and the purity with chemical analysis. We know what is in there and then the safety and potency on animal testing.

Mrs. BIGGERT. How do you dispose of anthrax vaccine?

General BLANCK. I am afraid I do not know. I would imagine that would incinerate it. That is the way you generally get rid of biologics.

Mrs. BIGGERT. I was just curious. But the Department of Defense has no interest in the company itself?

Dr. BAILEY. No, absolutely not.

Mrs. BIGGERT. I mean there is no financial or——

Dr. BAILEY. Let me just add, again, we have got answers, but I want you to also have specific answers because we are very confident about this vaccine.

Let me just back up a little bit and give you some details. During a routine, quality control inspection—and by the way, all the vials are checked visually prior to shipment, the manufacturer detected the presence of a gasket or a stopper to the vial, some of the material was in a number of the anthrax vials in a specific lot. All those vials in that lot that contained that material were discarded. Lot release data on that particular lot was subsequently sent to FDA and upon review, FDA did release the lot for use. So again, there is an inert material that had gotten into the vial that was not in the production or the safety of the vaccine or the sterility or purity or efficacy, that there was any concern.

During the February 1998 FDA inspection, and these are routine. They go on continually in vaccine production. The FDA requested they be provided documentation on destruction of the vials that contained the particulate matter. As a good manufacturing practice, the manufacturer quarantined all their remaining vials of that lot pending collection of the documentation required by the FDA. No recall of vaccine of that lot that had been shipped to DOD was instituted by the manufacturer, nor was it requested by the FDA because all vials had been FDA approved before shipment and had been visually checked to insure that none of those had any particulate material.

Mrs. BIGGERT. Just another followup on that. Are there any other companies that have expressed any interest in the manufacture of anthrax?

Dr. BAILEY. Well, in that there are no others interested in providing this vaccine except as is the program that we have outlined here, there have not at this time.

Mrs. BIGGERT. One other question then. What is your judgment that this vaccine will be effective if in case there is a weapons grade where it is needed rather than just because of a country that might have anthrax there.

Dr. BAILEY. Again, we have looked at the immunogenicity of the response, the antibody response to this vaccine and it is very high.

As you heard, in fact, after your second immunization at just 2 weeks, in that first month you have got antibody response, high immunogenicity, so it is very, very effective.

Clearly, there have been for years, as you hear this has been FDA approved vaccines since the 1970's, so we have almost 30 years that show this to be an effective vaccine. In fact, there have

been scientific studies that allowed the FDA to approve the vaccine, starting back as you have heard here with the wool sorters when this was a disease problem in the 1950's and in fact, there have been aerosol challenges which is, of course, of great interest to us because that is how these spores would be weaponized. Those aerosol challenges in Rhesus monkeys show us that, in fact, it is overwhelming protective and that anthrax without the protection is incredibly deadly.

Mrs. BIGGERT. Thank you very much. Thank you, Mr. Chairman.

Mr. SHAYS. Thank you. Before recognizing my colleague from Illinois, Dr. Bailey, do you have in your possession a letter of March 11 that the FDA sent to the Michigan Biologics Products Institute? Do you have it?

Dr. BAILEY. I believe I do.

Mr. SHAYS. I do not want to swallow camels and strain out gnats here, but the FDA issued a letter. I am reading from the Center for Biologics Evaluation Research which is the FDA's division. It has a headline, "FDA warns Michigan Biologics Products Institute of intention to revoke licenses." And it says "The FDA issued a letter to the Michigan Biologics Products Institute, Lansing, Michigan, on March 11, 1997 warning that the Agency will initiate steps to revoke MBPI's established and product licenses unless immediate action is taken to correct deficiencies at the firm." And then further on it goes and says, "An FDA inspection of the MBPI conducted between November 18th and 27th, 1996 documented numerous violations in the following areas: organization and personnel, buildings and facilities, equipment, control of components, drug product containers and closures, production and process controls, laboratory controls and records and reports. Some examples are: failure of the quality control unit to approve or reject all components, drug product containers, closures and in process materials, packaging material, labeling and drug products. Failure to have separate defined areas or other control systems for manufacturing and processing operations. Failure to assure that the equipment used in the manufacturing processing packaging holding of a drug product is appropriate design of adequate size for its intended use and for its cleaning and maintenance. Failure to properly store and handle components and drug product containers and closures. Failure to calibrate instruments, apparatus, gauges and record devices at suitable intervals and failure to record the performance of each step in manufacturing distribution of products." That seems a little more significant than the way I had been led to feel, based on your answer to Mrs. Biggert.

Dr. BAILEY. In fact, there were a number of deficiencies with the manufacturing process that were cited.

Mr. SHAYS. Could you move the microphone a little closer to you and push it down.

Dr. BAILEY. In fact, there were a number of deficiencies with the manufacturing process that were cited.

In February 1998, the FDA inspected the facility, however, and none of the deficiencies were considered significant enough to warrant plant closure or, in particular, any recall of the anthrax vaccine and in fact, the FDA also found that significant progress had

been made toward meeting objectives under its strategic plan for improving the manufacturing facility and processes.

I would also say that we are pleased to report that there has been a renovation of that plant and that many of these things have been taken into account.

Mr. SHAYS. That was the whole point. The implication was that the plant was being renovated to deal with these problems and your implication to us was that you did not need to make those renovations to take care of those problems.

Dr. BAILEY. And the FDA did not require that there was that renovation.

Mr. SHAYS. I know they did not.

Dr. BAILEY. I understand what you are saying.

General BLANCK. The renovation was planned long before these problems were brought to our attention. The 1997 letter had to do with production lines of vaccines other than anthrax. They had not looked at that, though the 1998 inspection, while it acknowledged progress, certainly did continue to find some problems with the anthrax line by which time we had shut it down or Michigan had shut it down.

Mr. SHAYS. The record will show, Dr. Bailey, that your answer was accurate. I mean, we are not disputing the fact that there was not a recall and the plant was not asked to shut down. But I think the record will also show tremendous concern by the FDA revoking a license is not something that is done lightly or suggested that it will be done lightly and there were significant reasons and I am gathering your testimony is that you feel that this has been dealt with?

Dr. BAILEY. I do and I should also state that the JPO is going to testify later on bioport specifically and that I think you can obtain greater information there as that is an acquisition and procurement area, which is outside of my medical purview. I obviously have great concern about safety and efficacy and therefore manufacturing processes.

Mr. SHAYS. Thank you. Thank you for your patience, Congresswoman Schakowsky.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman, and it is really a pleasure to be on this committee and on this subcommittee. Thank you.

I have a number of questions in other areas but I want to followup a little bit on this area of production. Is it true that the Department of Defense is paying for that renovation?

Dr. BAILEY. Again, this is outside the affairs of Health Affairs, and so I would suggest that would more directly be related to JPO and questions referred there. I would be happy to take the question, however, for the record.

Ms. SCHAKOWSKY. I am looking at the brochures that were issued to service members and their families. Under the question, "What if I am pregnant?" this is to service members. "Pregnant women should not receive this vaccine. If you are or believe that you may be pregnant, you should inform your health care provider. The vaccination program will be deferred until the pregnancy is completed." And then further in the one that goes to families, it says, "There is also no scientific evidence to suggest that future preg-

nancies by service members or their spouses will be affected by the use of this vaccine."

First of all, what was the basis for deciding that this was not a vaccine safe for pregnant women?

Dr. BAILEY. There are no vaccines to my knowledge that are recommended to be given or very few, recommended to be given to women who are pregnant. It is generally a safety generalization for women who are pregnant. Although again, there is no evidence at this time that there is any concern to the fetus of a pregnant woman.

It is our policy, however, if anyone is pregnant or feels they may be pregnant, that they step out of line, that they acknowledge that and that their vaccine would be therefore not given until the completion of the pregnancy.

General Roadman, you wanted to——

General ROADMAN. Well, I am an obstetrician so I can talk to that and that is we do not—I can verify, we do not give immunizations just on a basis of common sense of not exposing a fetus to anything external, but there is no scientific evidence to document damage to fetus by vaccines.

General BLANCK. We have had, if I may add, several individuals who received the vaccine at our laboratories become pregnant and have had no problems. This is not a vaccine, again, like tetanus, like any of the other vaccines which have similar constraints on them that would cause any problems during the pregnancy.

The FDA does not do testing of vaccines during pregnancy, as again, a common sense measure, we recommend against giving it.

Ms. SCHAKOWSKY. Well, then in terms of long term effects, have there been any tests on Rhesus monkeys or otherwise on the potential long term adverse effects of the vaccine? Saying that there is no evidence that it is a problem is not quite the same as saying we have data to show that there is, in fact, no problem.

Dr. BAILEY. We have a program underway now, Tripler Army Medical Center, in Hawaii where we are looking at a long term study so that we will be able to track the vaccine that we are giving today. That will be a prospective study to be accomplished over the upcoming years.

General BLANCK. Yes, and we have specifically tracked the individuals since 1974 at our laboratory who have received the over 10,000 immunization doses of the vaccine and as late at 1992 have found no long term health effects. Plus, the Michigan plant has since 1972 distributed over 68,000 doses of the vaccine between the early 1970's to about 1994 and those have gone to Centers for Disease Control to universities to veterinarians working with the organism and so forth.

If there are side effects or long term health effects, it is reported to the FDA. They have no such reports.

Ms. SCHAKOWSKY. You mentioned the CDC. Earlier, it was stated that should someone become ill from anthrax that there really was not any antibiotic protocol that would address that.

The CDC says doctors can prescribed effective antibiotics. Usually, penicillin is preferred, but Erythromycin, tetracycline or another one that I cannot pronounce can also be used. To be effective,

treatment should be initiated early. If left untreated, the disease can be fatal.

So the CDC is saying that should someone contract anthrax that it is treatable.

Dr. BAILEY. In fact, I think that is probably referring to cutaneous and not aerosolized anthrax. Weaponized, aerosolized anthrax, if you are unprotected, without vaccine, you will die within 24 to 36 hours.

Now there are treatments that are undertaken before you have symptoms. If you have symptoms of anthrax and as you have heard here today, by the time we know we have been attacked, people are coming forward with flu-like symptoms. If you have got symptoms, you are going to die 99 out of 100 times regardless of what treatment we would provide.

I would also add that it is very difficult to determine exactly what it is that we are dealing with. In order to even know that it is anthrax, we have to do things like a chest xray. We have to do a gram stain on blood products. By that time, you can imagine if our troops are, in fact, in harm's way and have been attacked, that we have a major combat casualty situation on our hands.

Now we do treat. We will, in fact, treat those with Cipro, Doxycillin, penicillin, but what you are commenting on, I believe, is cutaneous anthrax as reported by CDC.

Ms. SCHAKOWSKY. Do we have any noncompulsory vaccination programs or are all of our programs in the armed services mandatory?

Are there lots of service members who are seeking to be excluded from this program?

Dr. BAILEY. We are, at this time, not specifically tracking, although we are looking at a policy, given our concern about those who may refuse this particular vaccine. However, that is the refusal of a direct order and that is something that is a command issue, dealt with as a line commander issue.

At this point, it is our understanding that we have over 223,000 people that have been immunized with less than 200 who have refused the immunization.

Ms. SCHAKOWSKY. Is it true that in Great Britain that it is an optional program?

Dr. BAILEY. That is true, but it is also true that there are ships at sea in the British Navy where no one is protected, so again, it is a concern of ours that this is a much higher threat than it has ever been before and we do not want to see our sons and daughters going into harm's way unprotected.

Ms. SCHAKOWSKY. Let me ask one other question about this issue of protection. Other than the vaccine, are there other strategies, safeguards that are encouraged, clothing, masks, et cetera?

My concern here is that is there any way in which this vaccination program could be somewhat counterproductive, that is, that will people who are vaccinated feel that they do not need to take other kinds of precautions?

Dr. BAILEY. Let me just share with you that 4 weeks ago I was in the Persian Gulf and I was both on an aircraft carrier at sea and in the desert with our troops and I slept 1 night in a bunkered area and although sitting in the Pentagon there are times where

one would wonder why you may need anthrax immunization, it was no doubt in my mind that I was in harm's way, and that being responsible for all those around me that I was pleased that we had a very robust vaccine program there in the desert and anywhere else where it is considered a high threat.

General BLANCK. If I could add something because I think you are hitting on a very important point and it has to do with other protective measures.

The MOPP gear we have, the protective gear for chemical and biologic, in fact, does protect against not only chemical, but biologic agents such as this. The difficulty is that an enemy would probably use this before the start of hostilities.

For example, as we were building up in the rear areas and that kind of thing, and we would not know it because we do not have real time detectors. By the time we would know about this, it would be far too late to put on those protective measures and certainly this is not something during a buildup that people would be using 24 hours a day. It is very difficult to work in and so forth and so on.

So would they at a time of other threat take, put on this measure even though they had the vaccine, absolutely. Why? Because of other biologic and certainly the chemical agents for which the suit is good protection.

This is so deadly, not only because of the illness it causes, but because it can be dispersed, it can be spread, we can all be exposed without anybody knowing it until 2 or 3 days later and then it is too late.

Ms. SCHAKOWSKY. Thank you. Thank you, Mr. Chairman.

Mr. SHAYS. Mr. Blagojevich.

Mr. BLAGOJEVICH. Thank you, Mr. Chairman. I would like to get the chronology straight if I possibly can and this is a question for whoever wants to answer it.

The Secretary announced the program in December 1997. He included the four conditions to be met prior to going forward. You stated that he certified these conditions were met the following May 1998. Is that right?

Dr. BAILEY. Yes.

Mr. BLAGOJEVICH. But did you not go ahead before May with the accelerated program for Southwest Asia?

Dr. BAILEY. Yes. In Southwest Asia the concern that the threat had become so great that it was important for us to go ahead and immunize those who were early deployers into that area of high threat.

Mr. BLAGOJEVICH. As I understand it, there is no uniform consistent form of discipline for service members who refuse the vaccine.

Is that a fact?

Dr. BAILEY. Correct. It is a decision that is made service by service.

Mr. BLAGOJEVICH. Is there any risk that individual commanders may discipline differently and cause a disparity that might foster favoritism or in the alternative resentment?

Dr. BAILEY. Again, that is a line command issue and I would ask——

Mr. BLAGOJEVICH. General, could the General address that?

General ROADMAN. With everything under the Uniform Code of Military Justice, it is the line commander, it is the commander on the ground that is in control of that. The line commander is responsible to begin with education, to get the information out to all of the troops. After that information is given and if there is somebody who refuses, particularly in the Air Force, we have medical counseling and if it is a religious issue, counseling by the clergy. If it is not a religious issue, then a direct order is given to get the immunization. And then there is a choice that the individual has about whether to comply with a lawful order or whether to enter the Uniform Code of Military Justice.

This is, in many ways, a good order and discipline issue because in a military you cannot decide which order you are going to obey and which order you are not going to obey. It just does not work that way.

And I have been asked the question well, would not a civilian have a choice of doing that? And the answer is, of course, a civilian would have a choice of doing it. That is what differentiates us from a civilian organization. And the fact of the matter is that we put our people in harm's way and they do not have a choice of where they go and therefore we need to protect them. That is why the local commander is in charge of that because he is responsible for the protection of the troops, as well as the military mission.

I do not believe that as we look at the Uniform Code of Military Justice that there is an issue of favoritism. I cannot talk about the resentment issue because any time you are in trouble, you have a tendency to resent that.

Radm. FISHER. And that is very similar, the same situation in the Navy in regards to the commanding officer on board the ship, the commander of Marines. They have the responsibility for their troops and the authority and responsibility rests in that individual. So whether there is favoritism or not, I have no idea. But I know that the leadership takes this issue very seriously and acts accordingly.

General BLANCK. General Kirwin, when he retired as the Vice Chief of Staff of the Army many years ago, gave a speech that stuck in my mind and it said, it is very interesting that to protect the rights of those in this society, we who wear the uniform give up certain of our rights. It is a term of employment, that, in fact, you follow lawful orders. And you cannot choose which orders to follow as General Roadman said. So this really is not in that sense a medical issue. It really is a command issue, a good order and discipline issue. And in my view, those that choose not to follow the order, have broken their term of employment and should be separated from service. Now with what degree of punishment, that is up to the line commander, but I believe—then they should be where they can make choices and that is as civilians.

Mr. BLAGOJEVICH. One final question. What do you think are the biggest challenges the Department of Defense faces in implementing this vaccination program?

Dr. BAILEY. I think always there is a concern about perception and as you have heard here today this is a safe vaccine that provides us the very best way of protecting our troops when they are

in harm's way. I would be very concerned if the perception and these low numbers of refusals that you hear in an overwhelmingly successful program that is being tracked at the highest possible level to the most minute detail that in some way this program would be adversely affected because it provides us such safety as we attempt to provide the absolute best force health protection available.

Mr. BLAGOJEVICH. Thank you.

Mr. SHAYS. Before we go to our next panel, I would like to get a few answers on the record and have a dialog about a few areas that we have already discussed.

As a doctor, Dr. Bailey, what concerns do you have about the health effects of multiple vaccines administered at the same time?

Dr. BAILEY. We have administered multiple vaccines, I have taken multiple vaccines. It is part of my job to institute policy and provide on-going health protection that often includes providing multiple vaccines and at this time I have no concerns about the vaccines that have been provided or that we are planning to provide for those who deploy.

Mr. SHAYS. So you do not give much credibility to the studies that talk about the cocktail effect of various vaccines?

Dr. BAILEY. I have seen nothing at this time. Now if you are asking am I concerned, every one as well, I think, at this table was involved as you have heard, when we went through the issues that dealt with the medications, pretreatments and protective medicine that was done during the Gulf war.

We are very concerned that we understand exactly what happens to our troops in theater, so that we can assure ourselves that, in fact, there are no long term health risk effects for any of the treatments that we provide to protect our troops.

So am I not concerned at all? I am certainly concerned about those who may be sick who have deployed with the U.S. military, and would want to follow that and have a better ability to track. I am confident that this program you are hearing about today provides us again, with the new standard for allowing us to track that in the future so that we can be absolutely certain from a scientific point of view that we do not have a cocktail effect which could adversely affect someone's long term health.

Mr. SHAYS. How many biological and chemical agents are out there that we have concern about?

Dr. BAILEY. The actual list is a classified list, but clearly——

Mr. SHAYS. What has been printed in the newspaper?

Dr. BAILEY. I will share with you a list that includes some of the things that you have heard about. So again, I think setting the standard here with anthrax is probably one of the most essential aspects of the program you are hearing about today. Clearly——

Mr. SHAYS. Ma'am, I just want an answer——

Dr. BAILEY. Anthrax, plague, small pox, bot tox, ricin.

Mr. SHAYS. And their variations, right? I mean there are different kinds of anthrax? Are there variations to them?

Dr. BAILEY. Well, there are variations to some. Clearly, small pox, there are a variety of what we call orthopoxes. Plague, you can have bubonic plague or pneumonic plague.

Mr. SHAYS. Doesn't the Defense Department list a whole host of biological toxin warfare agents? Isn't there a lot more than what you have mentioned?

Dr. BAILEY. Yes, but I am being very careful to mention those that are specifically not on a list that I may be aware of that are classified, but certainly, there are long lists of biologic agents on the piece of paper that you have in front of you, and by the way, in the world today, which concern me greatly, which are biologic agents that could be weaponized.

Mr. SHAYS. I just want to know the truth. you are expressing your concerns, but I also want there to be some candor between us. When I do not see that candor I begin to suspect. I mean this is a list with a whole number of threats to our soldiers and this is not classified and it is a list that includes probably 50.

Dr. BAILEY. Sir, I do not know exactly what you have on your list, but I would say, of course, there are concerns. But what we are focused on are the assessment of threat risks in a specific area where we may have deployed troops. Those are the assessments we make on a regular basis so we can determine what kind of protection we need to provide against those particular illnesses or disease processes.

Mr. SHAYS. The trouble I am having communicating right now is that we are both aware of a classified list. The classified list includes more than what you have. And we are also aware of—and as soon as we make a xerox copy, we will go through some of that. But it is more than just a few.

Dr. BAILEY. I agree.

Mr. SHAYS. And you talk about anthrax as killing you in 3 days. Some of what is on that list would kill you in less than a day. And it makes me wonder—I do not need to be convinced that anthrax will kill, but I also know there is a whole host of others that will kill.

Dr. BAILEY. Yes sir, but I will take a look at this list, but let me just say that we know Saddam Hussein had vats and production capability and planned for implementation of anthrax as a weapon.

Mr. SHAYS. And we also know he had others.

Dr. BAILEY. Yes.

Mr. SHAYS. Yes, right.

Dr. BAILEY. That is correct.

Mr. SHAYS. But we are not protecting and that a vaccine will not protect.

Dr. BAILEY. And we know——

Mr. SHAYS. And so I am just making the point to you that once we have made the point that anthrax can kill, I can see that, it will kill. And I also can see the fact that if I was ordered to take it, I would probably take it, if I was a soldier.

I do not concede the fact that you have to—and I need to be convinced of the fact, I would like to be convinced of the fact that this has to be in order and that you cannot have 200 people who might decide not to take it and that I wonder what harm is done in that instance and so that is another area to talk about.

But first, just this issue. You are protecting against one deadly substance, one biological agent. There are others.

Dr. BAILEY. Yes sir.

Mr. SHAYS. And when we had pyridostigmine bromide [PB], easier for me to talk about and we ordered every one of our troops to take what was, in effect, for the use it was used—experimental, and we had a requirement from the FDA in order for you to use it in this experimental way that the records be kept, and they were. There is credibility here. And I am happy to know that you are taking recordkeeping. But there is concern among scientists who have respect in their professions that there was a cocktail effect. And you are telling me that you have taken this agent and therefore you are comfortable. That is somewhat interesting, but it does not answer the question. There are people who are concerned about the cocktail effect. It causes me concern that you are not concerned.

Dr. BAILEY. Mr. Chairman, I do not mean to leave the impression that I am not concerned. I clearly would be concerned about any effect which is why I am so pleased we are beginning to track immunizations which as you understand we did not—we were not afforded the ability to do so during the Gulf war. So yes, in fact, I am very concerned that there could be any effect from any of the medical pre-treatments or interventions that we provide and that it could, in fact, affect adversely someone's long term health.

General BLANCK. Mr. Chairman, if I could add briefly. I am aware of at least four studies, most recent of which was published in the Annals of Internal Medicine that has looked at several thousand travelers who have received multiple vaccinations, cocktails, if you will and has not found any long-term health effects, plus we follow our workers, as I described, not only for anthrax, but for exactly that effect because many of our laboratory workers receive not only the FDA approved vaccines, as our soldiers do, but also the experimental vaccines that we are in the process of working on so that we can have some protection for some of these other agents. And we have found in those workers again, no long term health effects. And they are fairly substantial numbers. Certainly not on the hundreds of thousands, but more than 5 or 10. So we are concerned.

Last, I think your point about other agents is exactly right now. Anthrax is probably the easiest to use and as you go down the list, you find them more difficult to use, more limited in their use. It is not to say they would not be used. So it is incumbent on us to develop other additional vaccines, other protective measures, detectors and so forth.

Mr. SHAYS. Thank you. Let me just conclude this part and then I will go to the next line of questioning.

Are we concerned that some of our adversaries have been able to alter anthrax and that the vaccine that we are requiring our troops to take would not be protective?

Dr. BAILEY. We have no evidence at this time of there having been any genetic alteration that would affect the efficaciousness of the anthrax vaccine.

Clearly, that would have to be a concern that could occur as we move ahead in a complex world where there is much going on in terms of DNA and altercations of DNA.

I am pleased to report, however, that there is also no evidence that antibiotic resistant strains are not responsive to our vaccine

as well, so again, we feel comfortable the vaccine we are providing will assure safety.

Mr. SHAYS. It has been—I am sorry, Doctor.

General BLANCK. Well, the Russians have reported that they were able to alter anthrax by genetically engineering it in a way that actually made their vaccine different than ours ineffective.

Mr. SHAYS. And is it not true that some of the soldiers were affected by this themselves? Did they not have some casualties themselves?

General BLANCK. Well, that was from the natural anthrax strain that they were working on that was released, that General Roadman alluded to and there were 100, I do not know, plus or minus——

Mr. SHAYS. Do we know that was a natural strain or not?

General BLANCK. We do. That was a natural strain. It was not a genetically engineered strain.

Now the genetically engineered strain not only was engineered, but it changed its fundamental characteristics and made it unstable. They were never—we are told, we believe, got it out of the test tube. They were not able to do the things with it that you would need to, to weaponize it.

Now we have been trying and trying to get some of what they claim they have, but it is only reports, to see if our vaccine is effective. I would simply say that our vaccine is effective against drug resistance, against all natural strains. Whether it would be against such an altered organism, I cannot say.

Mr. SHAYS. I would just conclude and express the concern that this committee will look at this list.

We are basically having a force protection on one—anthrax, when there are so many others. And it would strike me that our adversaries will just choose another substance. And then we have now—instead of going the direction the French have gone, which is basically dealing their force protection with protective gear which I believe is superior to ours, and learning how to use it and perfect it, so that they can be protected against a whole variety of agents and it is just a concern I have.

I am pleased that we are keeping better records, however.

General ROADMAN. Mr. Chairman, can I? I have reviewed this list and clearly it is a compendium of bacteria and virus. It is a textbook of microbiology. In fact, we do protect against a number of these and as you look at this, you look at Salmonella typhoid, we give immunizations to that. Vibrio cholerae, we give immunizations to that. But much of this has to do with the public health issues and the sanitation of our force and it is important to be able to put these into context and many of these are not stable as anthrax. Now anthrax is a particularly interesting micro organism because it develops spores when it is not in an environment that is conducive to life. And those spores can live for 40 years in the soil. I think, as you know, there is an island north of the UK that was contaminated prior to World War II.

The whole point of that is that anthrax is particularly different from any of these in that it can be laid down by aircraft. It can be put into an aerosolizer, like a fogger and will remain suspended and therefore be aerosolized and not be unstable.

So I think you are correct, there is a whole list of these and there are public health responses. There are also immunizations that we do give, but you cannot look at anthrax and say well, that is the same as Clostridlum perfringens or Vibrio cholerae because they are different organisms.

We believe that anthrax is, in fact, the primary threat that we have. We know that it was weaponized. We were fortunately not exposed to it. It is weaponizable. It is lethal. We have an immunization for it.

Mr. SHAYS. Thank you, General, that is helpful.

Do any of my other colleagues have questions?

Ms. Biggert.

Mrs. BIGGERT. Thank you. There are people in the services who have refused the vaccine. What about in the case of religious reason or that they do not take any drugs at all because of their religion. Is there a discipline for that?

General ROADMAN. No. It is not a disciplinary issue for religious reasons.

Dr. BAILEY. There are several reasons why you are permitted to be excluded like if you are running a high fever, if you are pregnant, if there are religious reasons. But outside of that, it is a lawful order.

Mrs. BIGGERT. Would that be a reason for a transfer from some areas that might be—they might be at risk?

Dr. BAILEY. Absolutely.

Mrs. BIGGERT. And then my other question is as far as multiple vaccines, do we keep records on having this vaccine at the same time that other vaccines are given? Maybe that has been asked. I do not know.

Dr. BAILEY. I happen to have around my neck as I believe—have you got yours as well? The personal information carrier. We have been doing military medicine in many ways in terms of our tracking, the same or through a lot of different wars and deployments. We need to change things. We need to develop this personal information carrier which is smaller than a dog tag and which would let us know what the health concerns were before deployment, during deployment, what occurred during deployment and then post deployment and long term. And that is the information technology that we are seeking and actively involved in and hope to have very soon.

Mrs. BIGGERT. Thank you very much.

General BLANCK. This, by the way, has my immunizations on it. We will begin testing this at Fort Bragg and presumably Bosnia later this year. It also has an ultra sound of a fetus in utero which I assure is not mine, but the point is that it carries an enormous amount of information. It is a 20 megabyte chip.

Mrs. BIGGERT. Thank you very much. Thank you, Mr. Chairman.

Mr. SHAYS. Thank you very much. Is it the intention of DOD to integrate this with the VA because right now——

General BLANCK. Absolutely. Absolutely.

Mr. SHAYS. Thank you very much. I found this panel very helpful and informative. Thank you very much.

I should have asked one thing. Is there anything that any of you would like to say before leaving? I always like to give that option.

Is there any comment that any of you——

Dr. BAILEY. We appreciate the meaningful exchange and I would also share with you, we absolutely appreciate the concerns that you share with us, that we share as well. All of us look for the same end, providing for the defense of this Nation, but also defending those who do so. Thank you.

Mr. SHAYS. Thank you. May I just make a request that someone on your staff stay for the next panel and be able to respond to that, in writing, if there is a need to. Not that you all need to, but just to have someone stay. Thank you very much.

We have testimony from six witnesses our second and last panel and we welcome them. Captain Thomas L. Rempfer, Connecticut National Guard; Major Russell E. Dingle, Connecticut Air National Guard; Private First Class Stephen M. Lundbom, U.S. Marine Corps; Mr. Mark S. Zaid, attorney at law; Colonel Redmond Handy, member, Reserve Officer Association; and Ms. Lorene K. Greenleaf, Denver, CO.

We invite our witnesses. We need 12 chairs. If I could, I would ask you to all stand and we will administer the oath. Thank you.

[Witnesses sworn.]

Mr. SHAYS. We are going to go in that order. I am going to put on the clock and it is going to be 5 minutes. I will let you run over a little bit, but if we can stay close to that it will be appreciated. But frankly your testimony is probably more helpful than the questions we would ask, so we are happy to hear your testimony and we are delighted to have you here. Thank you.

Mr. Rempfer, we are going to start with you.

STATEMENTS OF CAPTAIN THOMAS L. REMPFER, CONNECTICUT NATIONAL GUARD; MAJOR RUSSELL E. DINGLE, CONNECTICUT AIR NATIONAL GUARD; PFC. STEPHEN M. LUNDBOM, U.S. MARINE CORPS; MARK S. ZAID, ATTORNEY AT LAW; COLONEL REDMOND HANDY, RESERVE OFFICER ASSOCIATION; AND LORENE K. GREENLEAF, DENVER, CO

Captain REMPFER. Thank you, sir. Good morning. I want to begin by thanking Congress for all you do to insure America has the best trained, equipped and protected military in the world and I thank the members of this committee for your willingness to thoroughly review the anthrax vaccine immunization program. Given the rapid rate at which the costly program is progressing, I believe timely action by Congress is absolutely critical to insuring that the vaccination policy is truly in the best interests of force protection.

There is an important common bond behind why we are all present today. And that is because we all care about our armed forces. We simply disagree on what form of force protection is best for our troops. Do we achieve it through mandatory vaccines or through other means?

I believe the answer to this question is important because service members are making serious choices about their military careers as a result. Out of respect for the military and my chain of command I am not here today in uniform. My professional dissent on this policy brings me to Congress only after attempting to resolve this issue and my concerns through my chain of command. I believe it

is my duty to speak out against a dangerous doctrinal precedence and the questionable effectiveness presented by the anthrax policy.

We are not speaking out against a vaccine for public health issues. We take a lot of shots. We have always taken them. We are speaking out against vaccines against biological weapons.

As an officer in the Air Force I have obeyed orders for nearly 16 years while serving as a fighter pilot in Korea, Central America, Bosnia and the Middle East. That is what makes my duty today particularly difficult, yet from my earliest training at the Air Force Academy I have also been trained to question orders if they are objectionable. I learned this from officers who lived through the challenges and learned from the lessons of the Vietnam War.

Today, it is not the legitimacy of this order that I question or the officers that are enforcing this Department of Defense directive. Instead, I am questioning the assumptions on which the policy is based and feel that by implying our troops are protected against anthrax we may actually place them in more danger.

The Defense Department acknowledges they did not anticipate a resistance to this program. The resistance is partly based on our self-education process and what we have discovered as a cursory nature of the review that occurred prior to the implementation of the program. Therefore, I hope this recognition warrants a congressionally directed comprehensive review that also answers the following questions.

No. 1, what suddenly mandates the use of this outdated vaccine? Both the capability to weaponize anthrax and the FDA approval for the vaccine have existed for decades. The troops are asking, as you have asked today, why now? No. 2, why force us to take a vaccine that was not intended to combat the inhalation exposure to anthrax and it will be defeated by using different or mutated strains or simply a different pathogen altogether. The body armor that our Department of Defense panel refers to is perceived by many service members as "tin foil armor."

No. 3, why abandon the time tested deterrence doctrine of massive retaliation that was successful in the Gulf war by mandating a force protection measure that may create a facade of force protection, possibly endangering our soldiers?

No. 4, finally, could it be dangerous to erroneously imply to our top military and civilian leaders that our soldiers can withstand a biological attack through defensive posturing? Why have we prudently avoided this path for the proceeding decades? Perhaps it is because we cannot defend against the dynamic nature of this warfare.

After answering these questions I believe you will conclude we can do better than an outdated, marginally effective vaccine that targets only one of many potential biological threats. Instead, I hope Congress will mandate a program that offers real comprehensive force protection based on the logical foundations of intelligence, detection, external protection and medical treatment.

These foundations of force protection rely on a credible willingness to use force. This resolve won the cold war and it won the Gulf war. Abandoning this time tested doctrine and emphasizing the inevitability of biological attack to advocate a defensive anthrax vac-

cination policy may inadvertently result in legitimizing biological warfare.

A monument in Washington, DC, honors America's soldiers by saying "first in war, first in peace, first in the hearts of our country men." Just as that quote impressed me, I am equally encouraged by this committee's decision to keep your service members' interests first by reviewing this program.

The dialog you have initiated today will perform a vital service to this Nation by halting the potentially dangerous doctrinal shift. You can help insure our armed forces readiness by stopping personnel losses. You can also help insure that the armed forces remain an attractive service option for young Americans.

It is my ardent hope that this policy will be reviewed and that mandatory inoculations will be discontinued. This review may find that the cost of the anthrax vaccination policy far outweigh its limited force protection benefits.

Thank you for the opportunity to speak today.

Mr. SHAYS. Thank you, Mr. Rempfer.

Mr. Dingle.

Major DINGLE. Thank you for the opportunity for speaking and while the other gentlemen——

Mr. SHAYS. Excuse me, Mr. Dingle. I am sorry, you need to use that mic. And let me just say something to you. We are doing 5 minutes, but do not feel you have to rush. You can take your time and if you go over 5 minutes, we can deal with that.

Major DINGLE. Thank you for that, sir. It is interesting to listen to the first panel talk and during that short time I wrote four pages of one line notes that I would love to address with corrections and follow on questions, but I will read my opening statement first.

Thank you once again for allowing us and myself to appear today.

Mr. SHAYS. Mr. Dingle, let me just say that you will have an opportunity to go through that. So you can have some peace of mind.

Major DINGLE. Thank you.

Mr. SHAYS. And let me just say to all the witnesses: It is not easy to come and testify before Congress and I think it is particularly difficult when you serve in the government and are testifying. And I know that your superiors recognize that you are doing this in the proper way and that we all respect that. So we know it is discomforting to you, but I would like you to feel at ease because you are welcome here. The committee invited you. We want you here. And the military understands that you are here by our request.

Major DINGLE. Thank you for those words of encouragement. We are, in fact, while I can speak for myself, very apprehensive this morning, but after listening to the first panel we are encouraged that we have been given the opportunity to speak.

I am a Guardsman, a citizen-soldier, a Major and a former Flight Commander in the Connecticut Air National Guard. I have just completed my 10th year of flying A–10's for Connecticut and 17 total years in the service. I will not see an 11th year in Connecticut flying the A–10. I have declined the opportunity to receive the anthrax vaccine and am resigning.

Last September, my unit announced an anthrax vaccination policy that many officers objected to. In response, the wing commander delayed the shot schedule, and formed a team to research the vaccine. I was a key member of that team and in little more than a week the information I gathered presented a compelling argument against the DOD claims of safety and effectiveness. The team presented 15 questions to the commander on October 14th. He forwarded these questions to his superiors. By the end of October and with no answers forthcoming, we were told the anthrax conversation was over and that the shots would commence as scheduled.

Connecticut began the anthrax vaccination program on November 7th. Out lot was using lot FAV030, a lot specifically identified by the FDA as being contaminated in their 1998 inspection report of the Michigan production facility. It became apparent that our use of the chain of command to effect a difference was not working. We felt that public involvement was our last opportunity to get this program reviewed and perhaps halted.

I have been a reluctant participant in this on-going tragedy, but as a Guardsman, I am in a unique position. I have the option to resign when I do not agree with an order. While it would be easy to just walk away and leave this mess for others to deal with, I cannot in good conscience allow this program to go unchallenged.

I am here today to try to highlight the fallacies of the DOD claims of safety and efficacy and to highlight the uncertainty that traditional Guardsmen and Reservists face. The questions we have raised have been distributed to our commander, the news media, all of you and others.

Have our military leaders sought to answer these questions? Have they prepared canned answers just in case you ask them?

While I cannot begin to argue the complex medical issues with these medical experts, the literature available contains clear, unambiguous statements that do not agree with the DOD position. For instance, if the vaccine has been FDA approved and licensed since 1970, why did a former Fort Detrick commander define the vaccine as experimental in a 1990 article? If the vaccine is absolutely safe and effective, why did another Fort Detrick commander conclude that the vaccine was unsatisfactory in a 1994 edition of the medical textbook of Vaccines? If the vaccine is so widely used, why isn't it in the latest Physicians' Desk Reference. The DOD relies on a 1994 American Academy of Pediatrics report that the vaccine is effective against inhaled anthrax, yet the 1997 report by this academy dropped that statement.

While it appears that the DOD is devoting vast amounts of time, money and manpower educating its members about how safe this program is, it is falling short in some key areas. Why isn't the DOD telling members of the military what side effects to be aware of or report? Why are they discounting those who do report side effects and not report those side effects to higher headquarters? Why isn't the VAERS Form available or made known to members?

Mr. SHAYS. What was the last point, why what?

Major DINGLE. I am sorry, I said why is not the VAERS Form available or made known to members?

As citizen soldiers, we all face the uncertainty of medical care should our health be affected while on some sort of military status. We may be soldiers on the weekend, but when Monday rolls around, we are civilians. What happens when a Guardsman reacts to this vaccine on Tuesday or next week or 2 years after she retires? Will the State be forced to pay the medical care of affected unit members? Will their civilian insurance companies pick up the tab or will the Federal Government pay? Will the member face a revolving door of denials and blame games between the VA, the State and the insurance companies? A threat to our personal health, perceived or real, is a critical factor in whether or not we choose to volunteer our bodies in service to our country.

How will this threat affect my civilian job? Should I risk both my military career and my civilian career? These are real and serious questions that many volunteers are asking themselves, the threat and uncertainty of care needs to be addressed.

Finally, the number games that DOD plays need to be challenged. There does not seem to be one set of numbers that DOD is using for public relations. One spokesman says they do not know how many shots were given in Desert Storm. The next has an exact number including an exact number of adverse reactions. Another DOD spokesman reports one number of pilots resigning and having first hand knowledge, I know that number is incorrect. The lack of consistent data is troublesome.

The research and literature is out there. It was performed and written by experts in the field. There can be little doubt that it was accurate when accomplished. If the DOD refutes or interprets these data differently to defend their position, perhaps it is time then to allocate funds to the DOD, perform a proper study of this vaccine in the interest of providing the best protection to our forces.

This controversy is not about the Connecticut Guard, the people seated with me or myself. It is about what is right, not who is right and this is wrong.

I urge the committee to ask the tough questions, to demand forthright answers based on documented evidence, to hold the military accountable for its actions and decisions that affect the health of all of its members including its citizen soldiers.

Thank you so much.

[The prepared statement of Major Dingle and Captain Rempfer follows:]

Written Testimony of Maj. Dingle and Capt. Rempfer, CT ANG

- **Spring 1998**: Flight Surgeon briefed the AVIP. He said that it was a six shot series and very expensive, and that the ANG would have very low priority, so we wouldn't be seeing it at our base for a long time.
- **Spring and Summer 1998**: Research by officers began from Internet sites, and government documents. Officers remained skeptical of reports or stories that did not cite references. We obtained a copy of Senate Report 103-97 (Is Military Research Hazardous to Veterans' Health?; Lessons Spanning Half a Century). It was an official government document that said the vaccine should be considered investigational, and that the government could not rule out the vaccine as a causal factor in Gulf War Syndrome.
- **Late Summer 1998**: We began to develop a roster of pilots to deploy to the Gulf. The DOD guidelines were that you don't require the vaccine unless you're spending more than thirty days in the theater. Most pilots would be going for less than three weeks, so we wouldn't be getting the shots. It became apparent that several officers would not be taking the shot under any circumstances when they did become a requirement, and this word made its way to the command structure.
- **September UTA, 1998**: The wing commander announced a policy regarding anthrax: all officers regardless of mobility status would begin the anthrax shot series in October whether they were deploying to the Gulf or not. Considerable resistance surfaced, so a meeting was held on September 27, 1998. At this meeting the wing commander assured us that those who chose not to get the shot would be treated equally, i.e. a pilot would receive the same punishment as a supply officer, and flying status would not be used as a punishment tool for pilots. We were supplied with basic Xeroxed information regarding the vaccine (Exh. A, B, C)
- **Early October 1998**: Tiger Teams were formed, and for a short time the shots became optional, unless you were scheduled to be in the Gulf for more than 30-days. Maj. Dingle announced his intention to leave the unit at this time, but only after completing his performance report duties, and serving on Tiger Team Alpha. Tiger Team Alpha would research the anthrax vaccine and develop a list of questions for the commander to send to higher HQs. Tiger Team Bravo would research the legal aspects, avenues, and options for guardsman that chose not to take the shot. Maj. Dingle and Capt. Rempfer were the two pilot participants in Tiger Team Alpha. Maj. Dingle performed the bulk of the research and worked very hard to ensure the information presented was factual. Only material including government documents or established publications

were used. The team member's initial list of questions (Exh. D, E) ultimately evolved into the dictated document that was to be no more than two pages (Exh. F). We presented 15 questions with supporting information to the commander. Examples of our documents include the FDA report (Exh. G) showing microbial contamination in the sublots our unit's lot was derived from (FAV 030). (Note: not all our sources were obtained for the original Tiger Team report – yet many additional references are obtained through our research paper at the end of this summary chronologically listing the attachments). I.e. We've included the Dr. Burrow's letter (Exh. H), stating in Enclosure point #2 that the FDA inspection drove supplemental testing. As well, and in contrast, a letter to the editor by Dep. Sec. Of Def. Hamre (Exh. I) contradicts the Dr. Burrows letter by saying the exact opposite. Finally, we asked our wing commander for the supplemental testing results of our lot FAV 030. We were only provided with the '96 paperwork for the original production testing (Exh. K). We pressed for the supplemental testing results and they were never provided.

- **October 1998**: The wing commander subsequently forwarded Tiger Team Alpha's questions to Major General Weaver (Exh. K). We are still waiting for answers. According to the wing commander, the shots were to be delayed until the answers came back, and they would be optional unless you were scheduled to be in the Gulf from more than the thirty days IAW HQs guidance. The wing commander later informed us he actually forwarded a letter up the chain of command to summarize our inputs (Exh. L). His letter reduced our questions to 4, and in the 5th note of the attachment he refers to us as "hard liners", and maintains the unit will be better off when we are gone. At this point we were not very confident answers would be forthcoming.
- **November 1998**: Unit leadership arranged Dr. Huxsoll, Dean of Veterinarian Medicine at LSU to appear at the unit to dispel our concerns. Upon the night of the event all unit members were provided with a guidance sheet of what they could and could not ask (Exh. N). Contrary to the flyer, Dr. Nass was not invited until 8pm the night prior, via a phone message on answering machine to one of the unit members. Maj. Dingle attended the event and wrote a summation of the evening (Exh. O). As well, it was video taped and the video can be obtained from the NGB in DC. Although the NGB taped it and provided it to other ANG units on closed circuit TV, they did not edit it, and ANG members who have watched it have become very concerned with it's content.
- **November UTA 1998**: It became apparent that the answers to the Tiger Team inquiries were not forthcoming, and we were told that the anthrax debate was over, that our questions could not be answered, and that the shots would begin. As well, following our wing commanders' inquiries up the chain of command

as to the rational for the 30-day in country requirement, that requirement was changed to one-day. As a result, 16 vacancies appeared on the deployment list.

- **December UTA 1998**: As a result of the sudden vacancies, and the deployment roster being half full, the unit leadership announced another policy change. All pilots will either take the shots or leave the unit. We were encouraged to leave ASAP, or our fate might be out of our commander's hands. We were also relayed the message by our commanders from our State's TAG, MG Gay, that anyone refusing the vaccine and trying to leave over it, would never work in the military again in any capacity. The policy letter (Exh. P) designates a deadline of the Jan. UTA, and grounds all pilots not in compliance, despite earlier assurances that flying status would not be used as a punishment for refusal. Capt. Rempfer announced his intention to transfer to another military capacity at this time.
- **December 1998**: We gained access to two ANG messages. The first was the ANG message on Force Health Protection Guidelines (Exh. Q). This document prescribes the use of P-tabs for forces, despite our commander's insistence that he'd never make us take them. We felt this was a severe contrast to the way the Anthrax Vaccine Immunization Program (AVIP) was being conducted. As well, we received the ANG message on the AVIP (Exh. R). It specifically stated three phases, where with the most liberal interpretation we would be classified as Phase II. So why the rush to take the vaccine with a Jan. 2000 deadline? We were told it was to get rid of those who could not be relied upon. As a result Capt. Rempfer filed an IG complaint (Exh. S) with the NGB (subsequently he was informed it would not be investigated since it related to DOD policy):
    - I. If you go to a High Threat Area (HTA) for any amount of time, you require the Anthrax vaccination.
    - II. Early deployers have to get the shot by Jan. 2000.
    - III. All others by 2003.
- **Fall of 1998**: We contacted are elected representatives (Exh. T-1, to T-9). We are still waiting for responses from most, and the only initial letters we received maintained they would contact the DOD, or repeated information off the DOD website.
- **January UTA**: Nine pilots decided to not take the vaccine. One had decided in Oct. to transfer to another non-flying position, so he was not included in the numbers. The squadron commander issued a letter confirming the 8 losses (Exh. U). Subsequent to that he reported different numbers to the chain of command, which showed only 2 pilots departed due to the anthrax issue. All

the involved pilots were upset at the misrepresentation and signed, a letter confirming it was the anthrax policy that forced them out of the cockpit (Exh. V). The TAG reported these inaccurate numbers to a congressional interviewer, and Mr. Kevin Bacon reported it in a Pentagon newsbrief.

- **January 1999**: We evolved our original Tiger Team paper into an 11-page research document over time analyzing the myriad of issues of the AVIP (Exh. W). We pressed our concerns again up the chain of command and also posted them on the Internet.
- **February 1999**: As a result, we did obtain 17 detailed answers to our questions from sources outside our chain of command (Exh. X), but were later informed they were merely a draft prepared to answer the questions the Surgeon Generals might face by the 20/20 ABC news representatives. We are adding the answers to the website, despite the fact that they are still in draft form, to try to get the full set of information out to the public. Also, the NGAUS Magazine did an article (Exh. Y) in March dispelling the DOD's myth that the military members that are concerned with the vaccine are simply "misinformed." It specifically says the DOD didn't know our research was conducted professionally and thoroughly, and was well cited.
- **March 1999**: Capt. Rempfer published an Op Ed. in the Baltimore Sun to try to expand the debate on the AVIP. The goal is to help servicemember's, legislators, and Americans understand that the issues with respect to the AVIP are much more complicated than soldiers being scared of a vaccine.

Summary:

1. We feel the DOD's claims of widespread use of the anthrax vaccine are an exaggeration.
2. We feel the DOD's claim of safety and effectiveness is unsubstantiated exaggeration.
3. We feel the DOD is discrediting honest service members that are concerned about a very important force protection issue.
4. We feel the DOD is misrepresenting the numbers to Congress on the losses the AVIP is costing our country.
5. We feel the AVIP needs to be reviewed, and we know that almost every service member who we know feels the same way, even if they've taken the shot.

Good morning. I want to begin by thanking the Congress for all you do to insure America has the best trained, equipped, supported, and protected military in the world.

.herefore, I thank the members of this Committee for their willingness to thoroughly review the DOD Anthrax Vaccine Immunization Program. Given the rapid rate at which this costly program is progressing, I believe timely action by Congress is critical to insuring that the vaccination policy is truly in the best interests of servicemember's force protection, and therefore, our nation's defense.

At this point, I request permission to insert into the public record written testimony detailing Major Dingle's and my experience with the anthrax program.

(Pause)

There is an important common bond behind why we are all present today. It's because we all care about our armed forces. We simply disagree on what form of force protection is best for our troops. Do we achieve it through mandatory vaccines, or through other means? The answer to this question is important, because it is forcing servicemembers to make serious, principled choices about the future of their military careers.

Out of respect for the military and my chain of command, I am not here today in uniform. My professional dissent on this policy brings me to Congress only after attempting to resolve my concerns through my chain of command. I believe it is my duty to continue to speak out against the dangerous doctrinal precedents and questionable effectiveness of the Anthrax Vaccine Immunization Program.

As an Air Force Officer, I have obeyed orders for nearly 16 years while serving as a fighter pilot in the Middle East, Bosnia, Korea, and Central America. However, as an American soldier I have also been trained to question orders if they are objectionable. I learned this at the Air Force Academy from instructors who fought in the Vietnam War.

In this case, it is not the legitimacy of the orders that I question, or the officers enforcing this Department of Defense Directive. Instead, I question the assumptions on which the policy is based, and feel that by implying our troops are protected, we actually place them in greater danger than if they were not vaccinated at all.

The Defense Department acknowledges that they did not anticipate the level of resistance the anthrax vaccination policy has encountered. Resistance to the policy is based partly on the cursory nature of the review that occurred prior to implementation of this program. Therefore, I believe a Congressionally directed, comprehensive review should also answer the following questions:

1. What suddenly mandates the use of this outdated vaccine? Both the capability to weaponize anthrax and the FDA approval for the vaccine have existed for decades. The troops are asking, why now?

2. Why force us to take a vaccine that was not intended to combat inhalation exposure to anthrax, and that will be defeated with mutated strains of anthrax, or simply a different pathogen?

3. Why abandon the time-tested deterrence doctrine of massive retaliation that was successful in the Gulf War by mandating a force protection measure that may create a façade of force protection, endangering our soldiers.

4. Is it dangerous to erroneously imply to our top military and civilian leaders that we can withstand a biological weapons attack through defensive posturing? Why has this been prudently avoided for the preceding three decades?

After answering these questions, I believe you will conclude that we can do better than an outdated, marginally effective vaccine against only one of many potential biological pathogens. Hopefully, Congress will mandate a program that offers real force protection based on four logical foundations of intelligence, detection, external protection, and medical treatment.

These foundations of force protection rely upon a credible willingness to use force. The old phrase, "The best defense is a good offense," was the philosophy that successfully deterred our adversaries during the Cold War. The defensive anthrax vaccination policy may abandon this time-tested doctrine and inadvertently legitimizing biological warfare.

A monument in Washington honors America's soldiers by saying, "First in war, first in peace, and first in the hearts of our countrymen." Just as that quote impressed me, I am equally encouraged by your committee's decision to keep servicemembers interests "First" by reviewing the anthrax vaccination policy.

These issues weigh heavily on my mind, but your actions can turn the corner on this debate. You can perform a vital service to this nation by halting this doctrinal shift. You can insure our armed force's readiness by stopping personnel losses due to this program. And you can help make the armed forces an attractive service option for young Americans.

It is my ardent hope that this review will stop any further mandatory vaccinations until a thorough, unbiased, and scientific review is conducted. This review may find that the costs of the anthrax vaccination policy far outweigh its limited force protection benefits.

I sincerely thank you for the opportunity to testify today.

Subj: **verbal drivel from me!**
. 3/23/99 1:59:56 AM Eastern Standard Time
rom: redingle@ziplink.net (Russell Dingle)
To: TRempfer@aol.com (Buzz Rempfer (E-mail)), ZaidMS@aol.com (Mark Zaid (E-mail)), mnass@igc.apc.org (Meryl Nass (E-mail)), KERNLHANDY@aol.com (Redmond Handy (E-mail))

If you guys don't have enough to read, here's my next and hopefully final whack at doing the testimony thing. Good night and see ya Tuesday. Russ D.

Thank you for the opportunity to appear today. I am Russell Dingle, a citizen soldier, a Major and a former Flight Commander in the CTANG. I have just completed my tenth year flying A-10's for CT. I will not see an eleventh. I have declined the opportunity to receive the anthrax vaccine and am resigning on April 3rd of this year.

Last September my unit announced an anthrax vaccination policy that many officers objected to. In response, the wing commander delayed the shot schedule and formed a team to research the vaccine. I was a key member of that team. In little more than a week the information I gathered presented a compelling argument, against the DoD and its claims of safety and effectiveness.

The team presented 15 questions to the commander on October 14th. He forwarded these questions to his superiors. By the end of October, and with no answers forthcoming, we were told the anthrax conversation was over and that the shots would commence as scheduled.

CT's AVIP began on November 7th. Our unit was using lot FAV030, a lot specifically identified by the FDA as being contaminated in their 1998 inspection of the Michigan production facility.

It was becoming apparent that our use of the chain of command to affect a difference was not working, nor were our attempts t our elected officials involved. We felt that public involvement was our last opportunity to get this program reviewed and perhaps halted.

This has brought me before you today. I have been a reluctant participant in this ongoing tragedy. As a guardsman I am in a unique position. I have the option to resign when I don't agree with an order. While it would be easy to just walk away and leave this mess for others to deal with, I cannot in good conscience allow this program to go unchallenged.

I am here today to try to highlight the fallacies of the DoD claims of safety and efficacy, and the uncertainty that traditional guardsmen and reservists face. The questions we raised have been distributed to our commander, the news media, all of you, and others.

Have our military leaders sought to answer these questions?

Have they developed patent answers just in case you ask them?

I cannot begin to argue complex medical issues with these experts, yet the literature contains clear, unambiguous statements that don't agree with the DoD position. For instance:

If the vaccine has been FDA approved and licensed since 1970, why did a former USAMRIID commander define the vaccine as experimental in a 1990 article?

If the vaccine is absolutely safe and effective, why did a USAMRIID commander conclude that the vaccine was unsatisfactory in a 1994 edition of the medical textbook Vaccines?

If the vaccine is so widely used, why isn't it in the latest PDR?

While it appears that the DoD is devoting vast amounts of time, money, and manpower educating its members about how safe this program is, it is falling short in some key areas.

Why isn't the DoD telling members of the military what side effects to be aware of or report?

..Why are they discounting those who do report side effects and then not report those incidents to higher headquarters?

Why isn't the VAERS form available or made known to members?

As citizen soldiers, part-timers, we all face the uncertainty of medical care should our health be affected while in some sort of military status. We may be soldiers on the weekend, but when Monday roles around we are civilians.

What happens when a guardsman reacts to this vaccine on Tuesday, or next week, or two years after she retires?
Will the state be forced to pay for the medical care of affected unit members?
Will their civilian insurance companies pick up the tab?
Will the federal government pay?
Or will the member face a revolving door of denials and blame games between the VA, the state, and the insurance companies?
A threat to our personal health, perceived or real, is a critical factor in whether or not we choose to "volunteer" our bodies in service to our country. How will this threat affect my civilian job? Should I risk both my military job and my civilian career? These are real and serious questions that many volunteers are asking themselves. This threat and the uncertainty of care needs to be addressed.

And finally, the number games the DoD plays needs to be challenged. There does not seem to be one set of numbers that the DoD is using for public relations. One DoD spokesman says they don't know how many shots were given in Desert Storm, the next spokesman has an exact number, including how many suffered adverse reactions. Another DoD spokesman reports one number of pilots resigning and, having first hand knowledge, I know this number is incorrect. The lack of consistent data is troublesome.

Last year I spent several anxious days contemplating how I should proceed with respect to the anthrax issue. What am I missing, should I risk my health and play the odds, am I letting my country down by quitting; I've never refused an order, now what?

This controversy is not about the CTANG, the people seated with me, or myself. It is about what is right, not who is right. And this is wrong. I urge this committee to ask the tough questions, to demand forthright answers based on documented evidence, to hold the military accountable for its actions and decisions that effect the health of all its members, including its' citizen soldiers.

Thank you.

——————— Headers ———————
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From: Russell Dingle <redingle@ziplink.net>
To: "Buzz Rempfer (E-mail)" <TRempfer@aol.com>,

Mr. SHAYS. Thank you very much, Mr. Dingle.

Mr. Lundbom.

Pfc. LUNDBOM. Thank you, Mr. Chairman, distinguished members of the subcommittee, good morning. My name is Stephen Lundbom. I am originally from Livermore, CA. I am currently serving as a Private First Class, U.S. Marine Corps at 29 Palms, CA. I am here to tell you of my own personal experiences after I decided that I would not accept the mandatory anthrax vaccine. I believe that other Marines—refusers have also shared some or all of my experiences. The views that I express here are my own and not meant to reflect those of the U.S. Marine Corps.

Since this is the first time I have been to Washington, my Dad and I spent Sunday afternoon touring the historical sites such as the Lincoln Memorial, Washington Monument and the Vietnam Veterans War Memorial. At each I saw the words justice, democracy, liberty and independence. These are concepts that this great capital represents to me. They are the things that America is based on and they are the things that our military is sworn to protect and uphold.

I enlisted in the U.S. Marine Corps in June 1997 because I believed in its stated values of pride, honor and dedication. However, when I and other Marines began to ask our commanders questions about the safety and effectiveness of the anthrax vaccine, they responded in ways that in my opinion lacked respect for fundamental legal and democratic rights as citizen soldiers.

Like many Americans of my generation, when I felt a need to learn more about the vaccine, I went first to the Internet. There I quickly learned that there were a number of unanswered questions about this vaccine, particularly as it was being used to protect us from inhalated anthrax spores. I was especially concerned that there was more debate about whether the vaccine would keep us safe if bio weapons were to be used on the battlefield.

The fact that there had been no research on whether the vaccine could cause sterility, birth defects or cancer also worried me, not to mention when we had the opportunity to get educated by our command, questions that were to be answered by the medical officers at the interviews were ceased and questions were stopped. We were no longer allowed to ask any more questions.

When we were called to take the shot, the first in Okinawa, it was not the normal shot procedure. The normal shot procedure that I am familiar with in the Marine Corps is going into a medical facility, a medical personnel having a shot record, a medical personnel having a computer and one medical personnel giving the shot. They were being recorded on computer and on medical record. In this case, the shot was given in a long line with one piece of paper such like this with a list of names and they were highlighted through once they received the shot. No medical records were present at the time of the shot.

Twenty-seven of us announced that they would refuse the shot. After much pressure and many threats, all but five of the initial resisters in my battalion gave in and accepted the vaccination. Like the other four, I was given nonjudicial punishment, Article 15, my sentence was 30 days restriction, 30 days extra duty and a forfeiture of $539 pay which is one half month's pay for 2 months.

Some of the refusers were forced to walk approximately 16 miles each day during the weekends and holidays and many miles other days since the battalion office was a half a mile from the barracks and we had to sign the duty at the location almost every hour from 7 a.m. to 9:45 p.m. When 2 weeks of punishment period had passed, another anthrax vaccine was scheduled and once again I was called in and ordered to take the shot. I was again charged and put up for another nonjudicial punishment. During this Article 15 proceeding Lt. Colonel Stuart Navarre, my Battalion Commander, ordered me to provide him with the phone numbers of my mother's employer, a doctor in general practice back in California. This frightened me because I did not want my refusal to affect my mother's job in any way as she is a nurse. Despite my fear I told Colonel Navarre that I did not believe I had to answer the question like that. He then punished me a second time. This time I received 45 days restriction, 45 days extra duty including signing in the log book every hour and another half month's pay lost for each of 2 months. And this time I received a reduction of rank from Lance Corporal to Private First Class.

To be honest, this constant harassment and punishment wore heavy on my spirit and morale, yet I was able to stick to my resolve not to be vaccinated because of the strong support I received from my wife, who is also a Marine and my family. My fellow refusers were a source of support also.

Finished with our 6 month deployment to Okinawa, my unit returned to 29 Palms, CA where I naively perhaps hoped that my situation might change for the better. Once I completed all my punishment for both nonjudicial punishments, I submitted a request for leave. I was not even allowed to fill out a leave request. My command made it clear that any leave request would be denied. I was told that I could not leave the base because I had refused the anthrax shot and therefore did not deserve to go on leave.

At this point my family and I agreed that I needed outside legal help to help me cope with the unending harassment. My brother had attended an anthrax town meeting which had been sponsored by the G.I.'s Rights group, Citizen Soldier of New York. The event was held in San Diego. My father contacted the Director, Tod Ensign, and he put me in touch with Louis Font, a Boston lawyer who specializes in military defense work. I learned on April 10, 1998 that the Deputy Assistant Judge Advocate General had sent an internal memorandum to all Navy and Marine Corps Judge Advocates. This memo concludes that after punishment for a first refusal, refusal to obey additional orders to be vaccinated for anthrax cannot form the basis for additional convictions of nonjudicial punishment or court martial.

The Marines have violated this attorney's memorandum in my case. I have been doubly punished and now I face a court martial. I believe it is immoral, unethical, illegal and wrong that I have been punished twice at NJP and now face a court martial when the Marine Corps lawyers have been before them and the internal memo that states that this is unlawful.

My father called my Battalion Commander Lt. Colonel Navarre and he said that his hands were tied and he was only following Marine Corps Commandant policies. He said the policy is an NJP

for the first refusal, NJP for the second refusal and a special court martial for the third.

After my attorney explained to me the legal issue, I gladly signed a petition of extraordinary writ which we filed on Monday, March 22, 1999 before the Navy/Marine Corps Court of Criminal Appeals at Washington Naval Yard. It asks that the second NJP be set aside and that no court martial be allowed for this refusal. I ask that Congress investigate whether the Commandant or the Marine Corps has an illegal policy and whether subordinate commanders such as my Battalion Commander are subjecting enlisted men such as myself to multiple punishments as a result of this policy.

It seems to me that the reason for the policy and the reason the Marines are disregarding their own legal memorandum is to keep the number of refusers so low that Congress will be misled in thinking that the compliance is virtually total.

I had never before disobeyed an order and my unblemished record reflects my desire to be a dedicated Marine. I love the Marine Corps and everything it stands for. But when it came time for me to accept this vaccine, I felt in my heart, mind, body and soul that I was doing the right thing by refusing.

I appreciate hearing the testimony of the highest ranking military health authorities who have testified today and it made me respect even more the committee's willingness and desire to hear the point of an enlisted person at the lowest echelon.

Thank you very much for having me testify today. I welcome any questions you may have.

Thank you.

[The prepared statement of Pfc. Lundbom follows:]

THE HOUSE OF REPRESENTATIVES

STATEMENT OF

Private First Class Stephen M. Lundbom

Before the Subcommittee on National Security,

Veterans Affairs, and International Relations

of the Committee on Government Reform

of the House of Representatives

March 24, 1999

Good afternoon, my name is Stephen Michael Lundbom and I am from Livermore, California. I am currently serving as a Private First Class in the United States Marine Corps, at 29 Palms, California.

I am here to tell you of my own personal experiences after I decided that I would not accept the mandatory anthrax vaccine. I believe that other Marine refusers have also shared some or all of my experiences. The views that I express here are my own and are not meant to reflect those of the U.S. Marine Corps.

Since this is the first time I've visited Washington, my dad and I spent Sunday afternoon touring some of the historic sites, such as the Lincoln Memorial, the Washington monument, and the Vietnam Veterans War Memorial. At each, I saw the words "justice", "democracy," "liberty" and

"independence." These are concepts that this great capitol represents to me. They are the things America is based on and they are the things our military is sworn to protect and uphold.

I enlisted in the Marine Corps in June 1997 because I believed in its stated values of pride, honor, and dedication. However, when I and other Marines began to ask our commanders questions about the safety and effectiveness of the anthrax vaccine, they responded in ways that, in my opinion, lacked respect for our fundamental legal and democratic rights as citizen-soldiers.

Like many Americans of my generation, when I felt I needed to learn more about the vaccine, I went first to the internet. Here, I quickly learned that there were a number of unanswered questions about this vaccine, particularly as it was being used to protect us from inhaled anthrax spores. I was especially concerned that there was much debate about whether the vaccine would keep us safe if bio-weapons were to be used on the battlefield. The fact that there had been no research into whether the vaccine could cause sterility, birth defects, or cancer also worried me.

When we were called to take the shot for the first time on Okinawa, twenty-seven of us announced that we would refuse the shot. After much pressure and many threats, all but five of the initial resisters gave in and

accepted vaccination. Like the other four, I was given Non Judicial Punishment (Article 15). My sentence was: 30 days restriction, 30 days extra duty, and the forfeiture of $539.00 pay (one-half months pay for one month). Some of the other refusers were forced to walk approximately sixteen miles each day during the weekend and holidays, and many miles other days, since the battalion office was a half-mile from the barracks and the we had to sign the duty book at that location almost every hour from 7 am to 9:45 pm.

When two weeks of the punishment period had passed, another anthrax vaccination was scheduled and, once again, I was called in and ordered to take the shot. I was again charged and put up for another Non Judicial Punishment. During this Article 15 proceeding Lt. Colonel Stuart Navarre, my battalion commander, ordered me to provide him with the phone number of my mother's employer, a doctor in general practice back in California. This frightened me because I didn't want my refusal to affect my mother's job as a nurse. Despite my fear, I told Colonel Navarre that I didn't believe I had to answer questions like that. He then punished me a second time. This time I received 45 more days restriction, 45 more days of extra duty (including signing the log book every hour) another half months pay

loss for each of two months and a reduction in rank from Lance Corporal to Private First Class.

To be honest, this constant harassment and punishment wore heavy on my spirit and morale. Yet, I was able to stick to my resolve not be vaccinated because of the strong support I received from my wife (who is also a Marine) and my family. My four fellow refusers were a source of support also.

Finished with our six month deployment to Okinawa, my unit returned to Twenty Nine Palms, California where I naively perhaps hoped that my situation might change for the better.

Once I had completed all the punishment from both Non Judicial Punishments I submitted a request for leave. I was not even allowed to fill out a leave request. My command made it clear that any leave requests would be denied. I was told that I could not leave the base because I had refused the anthrax shot and therefore did not deserve to go on leave.

At this point, my family and I agreed that I needed outside legal help to help me cope with the unending harassment. My brother had attended an anthrax town meeting which had been sponsored by the GI rights group Citizen Soldier of New York. The event was held in San Diego. My father

contacted the director, Tod Ensign, and he put me in touch with Louis Font, a Boston lawyer who specializes in military defense work.

I learned that on April 10, 1998 the deputy Assistant Judge Advocate General had sent an internal memorandum to all Navy and Marine Corps Judge Advocates. This memo concludes that after punishment for a first refusal:

> Refusal to obey additional orders to be vaccinated for anthrax cannot form the basis for additional convictions at NJP [Non Judicial Punishment] or courts-martial.

The Marines had violated this attorney's memorandum in my case. I had been doubly punished, and faced a special court.

I believe it is immoral, unethical, illegal and wrong that I have been punished twice at NJP and now face a court-martial, when Marine Corps lawyers have before them the internal memo that states this is unlawful.

My father called my battalion commander, Lt. Col. Navarre, and he said that his hands were tied and that he was only following the Marine Commandant's policy. He said the policy is an NJP for the first refusal, another NJP for the second refusal, and a special court-martial for the third.

After my attorney explained to me the legal issues, I gladly signed a Petition for Extraordinary Writ which we filed on Monday, March 22, 1999, before the Navy/Marine Corps Court of Criminal Appeals at the Washington

Navy Yard. It asks that the second NJP be set aside and that no court-martial be allowed for this refusal.

I ask that Congress investigate whether the Commandant of the Marine Corps has an illegal policy and whether subordinate commanders, such as my battalion commander, are subjecting enlisted men, such as myself, to multiple punishment as a result of this policy. It seems to me that the reason for the policy and the reason the Marine are disregarding their own legal memorandum is to keep the number of refusers so low that Congress will be misled into thinking that compliance is virtually total.

I had never before disobeyed an order and my unblemished record reflects my desire to be a dedicated Marine. I love the Marine Corps and everything it stands for. But when it came time for me to accept this vaccine I felt in my heart, mind, body and soul that I was doing the right thing by refusing it.

I appreciated hearing the testimony of the highest-ranking military health authorities who have testified today and it made me respect even more this Committee's willingness and desire to hear the point of view of an enlisted person at the lowest echelons.

Thank you very much for having me testify today. I welcome any questions you may have.

Mr. SHAYS. Thank you, Mr. Lundbom.

I will go to Mr. Zaid.

Mr. ZAID. Mr. Chairman, distinguished members of the subcommittee, thank you for the opportunity to appear before you and offer my comments on the Pentagon's anthrax vaccination program. My remarks are my own opinion, and not that of my organization, the James Madison Project.

I have been involved in this controversy since April 1998 when I was requested to represent one dozen sailors who were refusing the vaccine aboard the U.S.S. *Independence*. In June 1998, I filed a lawsuit under the Freedom of Information Act for information on the anthrax vaccine and most recently I served as the lead civilian defense counsel for Airman Jeffrey Bettendorf who was the first serviceman to face a court martial for refusing to take the vaccine.

My oral testimony will focus on the circumstances arising when a member of the military refuses the vaccine and the exposure of several significant problems with the Pentagon's policy.

After being retained by the *Independence* sailors, I investigated the prospect of a class action lawsuit in order to halt the program. The planned strategy was to challenge the safety, effectiveness and necessity of the vaccine. Legal research, however, quickly revealed that the likelihood of success was virtually nonexistent. The focus then turned to obtaining information.

The FOIA lawsuit against the Departments of Army, Navy and Air Force and FDA was quite comprehensive. It sought all data that related to the anthrax vaccine. The overwhelming majority of the released documents have never been publicly discussed before today.

Let me first address the legal issues which are actually very straight forward. There is no set policy as to how a refusal will be dealt with, except as any other military discipline problem. Because of the sensitivity surrounding the program, many officers first emphasized counseling and education before imposing punishment. Some, however, resorted to threats of force, although official departmental policies were that no force will be used.

Until recently, the military had been fairly consistent in imposing penalties. Typically, the following would happen. A soldier refuses the vaccine. He is taken to an Article 15, nonjudicial proceeding. He is found guilty, reduced in grade, fined, restricted to ship or base and assigned extra duty. Eventually, he would be administratively discharged. If he had a clean disciplinary record, a general discharge under honorable conditions would likely be approved. In at least two cases that I know of, even where an individual went AWOL, a general discharge was still granted. It was only a matter of time, however, before someone would proceed to a court martial.

Airman Jeffrey Bettendorf who was stationed at Travers Air Force Base in California followed the typical pattern at first. Clean record, wife, child, church going, basic Boy Scout. Unlike prior cases, somewhere in his chain of command someone wanted to set an example and Airman Bettendorf found himself facing a court martial.

The key issue in an anthrax refusal case becomes whether the order to take the vaccine was lawful. The biggest battle is that the

vaccine is FDA approved, therefore the order is presumed valid. From my work on Gulf war syndrome issues, I was aware of theories that the vaccine had been modified in order to hasten or increase its potency. Therefore, our primary defense strategy was that the order was unlawful because the vaccine being used may not have been FDA approved and was therefore experimental. As a matter of law, consent was required.

It was also our position that legal precedent gave us the right to challenge the safety, effectiveness and necessity of the vaccine.

Through discovery we pushed for samples of the vaccine for independent testing. But before we went to trial, the Air Force agreed to accept Airman Bettendorf's earlier request for a discharge and he was processed out of the service under other than honorable conditions.

Airman Bettendorf's case has unfortunately now changed the game plan. Rather than a discharge, refusers will now face much greater prospects for a court martial and once a conviction is obtained, in even one case, a precedent will be set that will be nearly impossible to overcome absent extraordinary circumstances.

Let me now address some very important concerns about the program and I will do so through the Pentagon's own model of myth versus fact.

Myth. The vaccine has been routinely used in the United States since 1970.

Fact. No industry routinely uses this vaccine. Some use can be found among veterinarians and livestock workers, but no evidence of widespread usage exists. And if you ask someone from one of these two fields about use of the vaccine, the typical response is "what vaccine?" In fact, only about 30,000 individuals have received the vaccine since 1970 and relatively few people outside of the military receive a shot per year. The private sector uses between 400 and 500 doses per year. This amounts to perhaps 100 to 300 people per year using the vaccine. The inoculation of 150,000 servicemen during the Gulf war was the first major use of the vaccine in any significant quantity. Six times the number of people were inoculated than had been in 30 years prior.

Myth. There has been no long term side effects from this vaccine or no long term consequences have been demonstrated.

Fact. These statements are totally insupportable. The Defense Department has never researched whether use of the vaccine may result in long term health consequences. In fact, no studies, either in the public or private sector have examined potential long term consequences. The manufacturer's label itself reveals that no cancer or fertility studies have ever been performed. When confronted with these statements of fact, the Pentagon's PR machinery responds "the vaccine has been used for 30 years. It is unethical to conduct tests on humans."

No one is calling for the initiation of tests on humans. Accepting the Pentagon's assertions, however, that the vaccine has been widely used, how difficult would it be to locate a few hundred or maybe a thousand of people who once took the vaccine and after taking into account all the appropriate variables, examine their health. Do they suffer from cancer, leukemia, Alzheimer, any medical malady? Can it be traced to the vaccine? When 2.4 million lives are at stake

there is a moral, if not legal responsibility of the Pentagon to undertake such efforts rather than offer excuses.

Myth. A safe and effective vaccine is available that will protect our forces.

Fact. We have discussed there are some issues of other spores and mutations, so I will not comment more about that.

But withheld from the public's knowledge, until our FOIA lawsuit, was that the Pentagon discovered years ago, it was briefly mentioned earlier, that the current vaccination series of six shots is outdated and unnecessary. In September 1996, the vaccine manufacturer with the approval of the Army filed an initial investigational new drug application with the FDA to reduce the vaccination schedule. The new proposal would be two initial doses with annual boosters as compared to a series of six doses over 18 months.

Despite ample proof of the redundancy of the six shot series, the Pentagon still implemented the current program. By not waiting for FDA approval, the Pentagon cost taxpayers at least an additional $32 million in vaccination costs.

My final comments pertain to the adverse reaction rate. The manufacturing label for anthrax states that systemic reactions occur in fewer than 0.2 percent of recipients and that is characterized by malaise and lassitude. Chills and fever were reported in only a few cases. The real truth, however, has been that systemic reactions among those in the military have been nearly 7 times greater. Internal documentation we obtained revealed that up to 1.33 percent of recipients suffered a systemic reaction. And it is vitally important to understand what is meant by systemic reaction. It is potentially extremely harmful and possibly fatal and while a percentage rate of 1.33 percent may not seem high, when applied to the fact that 2.4 million servicemen will be receiving the vaccine, this means that as many as 32,000 servicemen may suffer serious or fatal reactions.

Reports of systemic reactions such as fever and prolonged muscular weakness have been occurring since the program began. Even more shocking we have heard stories that medical officers have been reluctant or even refused to file adverse reaction reports and that they routinely try to convince the servicemen that what they are suffering has something to do with something else, not the vaccine.

The Pentagon's response has been to distribute, and I do not say this lightly, disinformation by manipulating the statistics and the words. Documents that are now publicly disseminated assert that systemic reactions of 0.2 percent or more are very rare which is contrary to its own reports and more importantly that fever and chill symptoms have been now recategorized as severe local reactions, rather than the systemic that they are. This gives the false impressions that such reactions are common when the fact is such a reaction could be deadly.

Mr. Chairman, it is a sad fact that we regulate industries such as machinery and automobiles far better than we do those that affect what may be placed in our bodies.

The anthrax vaccine currently in use for the military would probably not withstand FDA scrutiny today were it to apply for a license, yet no one seems concerned that we do not know whether

this vaccine is actually a safe product over the long term. No one seems alarmed that the adverse reaction rates exceed the figures supplied by the vaccine manufacturer itself or that the Defense Department has sought to masquerade these ill effects through questionable wording changes.

To be sure, as you said earlier, anthrax is an intensely dangerous biological weapon. It is imperative that we seek out ways to adequately detect the spores before contact and protect ourselves afterward, but the Pentagon's anthrax program represents nothing more than an easy out from the hard task of devoting time and money to developing adequate detection equipment and if possible, efficient vaccines that are truly safe and effective.

The Pentagon has knowingly misled the American people concerning this vaccine. Whether in 20 years from now advanced medical technology will demonstrate the vaccine was either dangerous or safe is anyone's guess, but until we know the full facts, 2.4 million are potentially being placed in harm's way and until the proper studies have been undertaken, the United States should follow the lead of the United Kingdom and implement its anthrax vaccination program as voluntary.

Sorry for going over time, I appreciate the opportunity.

[The prepared statement of Mr. Zaid follows:]

PREPARED STATEMENT OF MARK S. ZAID, ESQ.□
EXECUTIVE DIRECTOR, THE JAMES MADISON PROJECT

BEFORE THE SUBCOMMITTEE ON NATIONAL SECURITY,
VETERANS AFFAIRS AND INTERNATIONAL RELATIONS
COMMITTEE ON GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES

WEDNESDAY, MARCH 24, 1999

"THE PERFORMANCE OF THE ANTHRAX INOCULATION PROGRAM"

Mr. Chairman, distinguished members of the Subcommittee, thank you for the opportunity to appear before you and offer my comments on the growing concern over the military's forced inoculations of our servicemen with the anthrax vaccine. I have been involved with this issue since April 1998, when the first shots were administered to Naval personnel serving in the Gulf region, and I was requested to provide legal counsel to those who were refusing the inoculations aboard the U.S.S. Independence.

Then, in my position as General Counsel for the non-profit organization Veterans for Integrity in Government (VIG), I litigated a Freedom of Information Act case against the government which resulted in the release of thousands of pages of previously unseen documents pertaining to the anthrax vaccine and the Pentagon's vaccination program. Most recently, through The James Madison Project, I served as the lead civilian defense counsel for Airman Jeffrey Bettendorf, who was the first serviceman to face court-martial for refusing to take the vaccine under orders of a superior commissioned officer.

The Pentagon has embarked upon a massive unprecedented public relations' campaign to minimize any potential objections to the vaccination program. Despite these efforts, a tide of dissention is rising among many servicemen and their families. Indeed, it has been far more widespread than the Pentagon has publicly led on. In response, the Pentagon has alleged that those refusing the vaccine are either misinformed, are the victims of a paranoid Internet community, are or the prey of small groups with agendas. Contrary to these allegation, the individuals with whom I have been in contact with have thoroughly researched the issue and have based their decision on a personal, well reasoned and deep-seated desire for preservation of themselves and their loved ones. It is almost certain that in all of the cases a sense of fear contributes to the decision to refuse the vaccine. Regardless of whether the fear is justified, the Pentagon's actions and lack of credibility have led its personnel to make such that choice.

Those refusing have primarily been enlisted personnel under the age of 25. The paucity of protest from more senior rank simply reflects the greater risks and consequences faced by career personnel who oppose official policy. Based on my communications with military personnel, I can assure this Subcommittee that the fear and dissention has spread throughout the services and up the ranks. While it might not always lead to a refusal, it has negatively impacted moral and possibly recruitment as well.

My remarks today will primarily focus on two specific areas: (1) the legal issues that surround this controversy and the options and repercussions involved when a member of the military refuses the vaccine; and (2) the fundamental problems with the Anthrax Vaccination Immunization Program (AVIP) as evidenced by documentation obtained from the government through litigation.

IMPLEMENTATION OF THE AVIP

On December 15, 1997, Secretary of Defense William S. Cohen announced the implementation of a military-wide anthrax immunization plan that had been under review for two years. However, prior to the actual implementation of the program, four conditions were to have been met:

(1) Supplemental testing, consistent with Food and Drug Administration (FDA) standards, to assure sterility, potency and purity of the vaccine;
(2) Implementation of a system to fully track personnel who receive the anthrax vaccine;
(3) Approval of appropriate operational plans to administer the immunizations and communications plans to inform military personnel of the overall program; and
(4) Review of health and medical issues of the program by an independent expert.

These conditions were deemed to have all been met by May 1998. As a result those troops in high-threat areas were ordered to take the vaccine. On May 18, 1998, Secretary of Defense William Cohen approved implementation of the program for the total force.

When the Pentagon first began to administer the vaccine in the Gulf region and reports of the refusals reached the media, I undertook sincere efforts to quietly quash the "mutiny" by requesting a meeting with the appropriate officials of the Department of Defense. I also posed a series of questions regarding the anthrax vaccine. No response was received. Nine days later, as the tension continued to mount on the U.S.S. Independence, I reiterated my request for a meeting and submitted additional questions. I noted that "the decision to inoculate U.S. military personnel with the anthrax vaccine remains an issue that will only continue to escalate into public controversy unless full disclosure is forthcoming from the Department of Defense. Fear, whether founded or not, is running rampant throughout the military system and future refusals of the vaccine are to be expected." Nearly one year later it appears my predictions were unfortunately true. Finally, nearly one month after I submitted my first letter, on May 8, 1998, I received a written response to my questions from Gary A. Christopherson, Acting Assistant

Secretary of Defense.□ The meeting that I requested never occurred. As a result, some colleagues and I explored the option of a class action lawsuit in order to halt the entire vaccination program. The hope was to attack the safety, effectiveness and necessity of the vaccine. Legal research, however, soon revealed that the likelihood of success in federal court was virtually non-existent at best.

A. The Nuremberg Principles On Informed Consent Collapse

Following the end of World War Two, the United States took the lead in ensuring that accountability was attained for the unconscionable and inhuman acts committed by the Nazis. Not only did the United States actively participate in the International Military Tribunal at Nuremberg, but it continued the work on its own for three years through prosecutions of both German and Japanese officials for various war crimes. From the ashes of Nuremberg and the dramatic revelations of the horrific experiments conducted by the Nazis arose a code concerning voluntary consent that has been recognized throughout the world.

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have the legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the

effects upon his health or person which may possible come from his participation in the experiment.

The code was meant to be absolute. In fact, "[t]here is no exception for soldiers or for wartime, and until Desert Shield, the U.S. military had never argued that there should be such an exception." Following the August 1990, invasion of Kuwait by Iraq, the Department of Defense "argued that informed consent under combat conditions was 'not feasible' because some troops might refuse to consent, and the military could not tolerate such refusals because of 'military combat exigencies.'" As a result the FDA issued a new general regulation, rule 23 (d). Not surprisingly, litigation soon ensued.

B. Prior Legal Challenge To The Military's Vaccination Program

Many members of the American public seem to be genuinely surprised to learn that service in the U.S. military comes with a harsh price. Not only is your life placed in jeopardy, but many of the normal constitutional protections afforded to American citizens, and even aliens, disappear.

During the Gulf War a serviceman and his wife sought an injunction to prevent the Department of Defense "from using unapproved drugs on troops taking part in Operation Desert Storm without first obtaining informed consent from the individual military personnel." ADD MORE

"The FDA's position on licensing products produced elsewhere is that they will not commit themselves without seeing the data. Leverage may be needed in the future if this becomes a problem."

C. VIG's Freedom of Information Act Lawsuit

Given the disappointing results of our legal research, the focus turned to obtaining information concerning the anthrax vaccine and the inoculation program. It was now our hope that a concerted effort could be made to convince both the Congress and the American public, through use of the media, of the problems with the Pentagon's vaccination program. In June 1998, I filed a Freedom of Information Act (FOIA) lawsuit against the Departments of Army, Navy and Air Force and the Food & Drug Administration based on requests filed by Patrick G. Eddington, VIG's Executive Director and a former CIA Whistleblower on Gulf War Syndrome.

This comprehensive lawsuit sought the disclosure of all records pertaining to:

(1) the anthrax vaccine;
(2) any studies regarding the anthrax vaccine;
(3) the composition of the anthrax vaccine as administered to U.S. military personnel;
(4) policies governing the discipline of U.S. military personnel who refuse to take the anthrax vaccine;
(5) the Michigan Biologic Products Institute.

The lawsuit, which has essentially concluded, brought about the release of thousands of pages of documents relating to the anthrax vaccine, the majority of which had never been reviewed outside of government channels. Most revealing, however, was what was not disclosed: no evidence that the government has ever attempted to study whether the vaccine is safe over the long-term.

The documentation we obtained reveals some very troubling aspects of the Pentagon's AVIP policy and refutes many of the broad conclusory statements that it offers to justify its actions. I will address specific aspects of concern in more detail later in my testimony.

D. Legal Ramifications Of Refusing The Anthrax Vaccine

No apparent military policy exists governing how anthrax refusers will be dealt with, except to the extent that they should be handled through the appropriate and available administrative and judicial framework governing military discipline in general. In the wake of the initial refusals aboard the U.S.S. Independence, the need to emphasize counseling and education before punishment was highlighted.

Whenever military members are directed to take the initial shot and voice any misgivings, they should be referred to our medical personnel to answer their concerns. If there is still some uncertainty, commanders and first sergeants should get involved in attempting to allay the individual's mistrust. Finally, we should make sure a defense counsel is readily available to answer any additional concerns the individual may have. Only after all available education and counseling type efforts have been exhausted should UCMJ [Uniform Code of Military Justice] action be initiated.

Alarmingly, many servicemen have been and continue to be threatened with forcible inoculation, i.e., they would be tied down, if they did not submit voluntarily, despite Departmental policy that "force should never be used to administer the vaccinations." Indeed, the threat of force convinced many would-be refusers to accept the vaccination.

Ultimately "[a] member refusing vaccination should be issued an order to submit to the vaccination by a superior commissioned officer." If a servicemember refuses the vaccine, the commander has a "full range of options, from taking no action at all to taking administrative action (letters of counseling, letters of reprimand, referral OPR/EPR, etc.) to taking punitive action under the Uniform Code of Military Justice (UCMJ)." Prosecution under the UCMJ will probably take one of two forms. If the order was given by the member's commanding officer, than a charge under UCMJ Article 90(2) will likely be preferred. If someone other than a superior commissioned officer gives the order (i.e., the member's first sergeant or a NCO medical practitioner), action under UCMJ Article 92(2) is more appropriate.

Following refusal the commander can either impose UCMJ Article 15 nonjudicial punishment (NJP) or prefer charges to a general or special court-martial. Article 15 proceedings are meant to address "minor offenses", and punishments include admonition and reprimand, restriction, arrest in quarters, correctional custody, confinement on bread and water or diminished rations, extra duties, reduction in grade and forfeiture of pay.

During the last year the different branches of the military have been fairly consistent in the penalties they have imposed upon those who refuse the vaccination. The typical course of events following a refusal has been a NJP with the imposed sentence including reduction in grade, a forfeiture of pay, restriction to ship or base and assignment of extra duty. Ultimately the service member would be administratively discharged from the military. If the individual had a clean disciplinary history the likelihood was that he would receive, as the vast majority did, a General Discharge under Honorable Conditions. Some who refused that had only a few months left in their tour of duty were permitted to quietly leave without suffering significant administrative punishment. Indeed, even

individuals who went AWOL based solely on their concerns about the vaccine received such a discharge.

As the vaccination program spread throughout the world and more individuals in each branch of the service began to refuse, it was only a matter of time before someone would proceed to a court-martial. Airman Jeffrey Bettendorf, who was stationed at Travis Air Force Base in California, became that unfortunate first person.

On December 1, 1998, Airman Bettendorf refused the vaccine. He was offered an Article 15 for his failure to submit to the anthrax vaccine on December 11, 1998. As the many others who preceded him, he was found guilty and received similar non-judicial punishments; a grade reduction and 45 extra days of duty. Prior to this time A1C Bettendorf had a completely clean disciplinary record. Furthermore, A1C Bettendorf was an outstanding member of his community with a wife and child. He has raised troubled foster teenagers and hosted church groups at his home. Nevertheless, an appeal of that punishment was denied. A1C Bettendorf then experienced the misfortune of having a superior officer who was determined to further punish his alleged defiance to a military order. As a result, following his second refusal of the vaccine on December 30, 1998, charges were preferred against him and a summary court-martial was set for February 1, 1999.

In support of such a charge, the Government must prove four elements:

(1) that the accused received a certain lawful command to submit to the anthrax vaccination;
(2) that, at the time, the order was given by a superior commissioned officer of the accused;
(3) that the accused knew at the time that the officer was his superior commissioned officer; and
(4) that on a date and at a place certain the accused willfully disobeyed the lawful command.

The key element in an anthrax refusal case, and the basis on which A1C Bettendorf's legal defense was conducted, is whether the order was lawful. In discussing a lawful order The Manual for Courts-Martial states:

The order must relate to military duty, which includes all activities reasonably necessary to accomplish a military mission, or safeguard or promote the morale, discipline, and usefulness of members of a command and directly connected with the maintenance of good order in the service. The order may not, without such a valid military purpose, interfere with private rights or personal affairs. However, the dictates of a person's conscience, religion, or personal philosophy cannot justify or excuse the disobedience of an otherwise lawful order.

The test for determining the lawfulness of an order was set forth in U.S. v. Flynn, where the court held that "[t]he order must be: (1) reasonably in furtherance of or connected to military needs; (2) specific as to time and place and definite and certain in describing the thing or act to be done or omitted; and (3) not otherwise contrary to established law or regulation."

The biggest hurdle facing anthrax refusers is that the vaccine allegedly being administered is FDA-approved. Under those circumstances the likelihood, absent extraordinary circumstances and the flexibility to conduct discovery, in securing an acquittal of a serviceman facing an Article 90(2) charge is slim. Orders are presumed to be lawful on their face.

However, at the beginning of the AVIP information had begun to circulate that the anthrax vaccine as administered by the Pentagon was, in fact, not the same FDA-approved vaccine. It had allegedly been modified in some manner in order to strengthen its effect. Therefore, our primary defense in A1C Bettendorf's case, and one that should be utilized alongside any other available defenses in every anthrax refusal court-martial case is that the order is not lawful because it is "contrary to established law or regulation," i.e., the vaccine may not be the same one approved by the FDA. Therefore, the vaccine converts to experimental and as a matter of law and requires the consent of the individual. It was also our defense position that we had every right to present evidence addressing whether the vaccine was safe, effect or even necessary to accomplish a military mission. Ample precedent exists to permit such a defense.

In U.S. v. Chadwell et al., two Marines were tried and convicted by a special court-martial under Articles 90 and 92 for having "willfully disobeyed a lawful order of their superior officer to submit to certain medical treatment, to wit: immunization against smallpox, typhoid, paratyphoid and influenza ..." The Court recognized that "[t]here is no doubt that the legality of an order may be questioned and the courts are required to determine such issue when raised. Individual rights that are protected by the Constitution and statute are not subject to military orders which are arbitrary and unreasonable." Chadwell reiterated a conclusion now more than forty years old held by a prior military court that:

Persons in the military service are neither puppets nor robots. They are not subject to the willynilly push or pull of a capricious superior, at least as far as trial and punishment by court-martial is concerned. In that area they are

human beings endowed with legal and personal rights which are not subject to military order. Congress left no room for doubt about that. It did not say that the violation of any order was punishable by court-martial, but only that the violation of a lawful order was.

Although the Chadwell court did hold that the vaccination order in that case was legal, particularly because the accused did not contest the fact on appeal, most importantly it was noted that the trial court "permitted medical testimony offered by the defense that the shots were unnecessary...." Thus clear precedent exists granting anthrax refusers the ability to challenge the underlying policy of the Pentagon to implement the AVIP.

Therefore, in furtherance of A1C Bettendorf's defense we requested as part of the discovery process samples of the vaccine so that independent testing could be undertaken in order to determine whether or not the Defense Department had modified or altered the vaccine in any way. This request was, of course, refused but before the issue was litigated the Air Force agreed to accept Airman Bettendorf's Chapter 4 request for a discharge and he was processed out of the Air Force under Other Than Honorable conditions.

FALLACIES OF THE PENTAGONS' ASSERTIONS

Much of the blame for the growing hysteria arising from the AVIP must fall on the Pentagon itself. The Defense Department has continually relied on conclusory statements of fact that have little or no basis, set forth misleading information concerning the vaccine, unfairly ridiculed those who have sought to bring to light inconsistencies and problems with the AVIP program and, whether fair or not in these particular circumstances, suffers from a significant lack of credibility.

A. Brief History Of The AVIP

The AVIP is being implemented under the authority of the Secretary of Defense in accordance with DoD Directive, 6205.3, "DoD Immunization Program for Biological Warfare Defense" (November 26, 1993), which established the policy, responsibilities and procedures for stockpiling biological agent vaccines. It also determined which personnel should be immunized and when the vaccines should be administered. The Army serves as the Executive Agency of the AVIP.

The present AVIP calls for a series of six shots over an 18 month period administered in intervals of 0,2 and 4 weeks for the first three shots, and then boosters at 6,12 and 18 months. The original immunization schedule for humans was three doses at 0,2 and 4 weeks "based on a regimen developed for animals." The genesis for a six shot series arose from three immunized workers falling sick in the 1950s which led "an investigator to recommend arbitrarily three more immunizations (6, 12, and 18 months) as boosters."

It has widely been reported that the anthrax vaccine is safe primarily because of the length of time in which it has been available for use. Repeatedly the Defense Department emphasizes that the vaccine has been FDA-approved since 1970, and in use since the 1950s. Moreover, it has been asserted that the vaccine has received wide-spread use throughout the veterinary and livestock communities. This is, however, not entirely accurate. In fact, the vaccine has apparently only been used by approximately 20,000-30,000 people over the last 30-50 years. Outside of the military, relatively few people receive the shot each year.

Indeed, the Defense Department's inoculation of 150,000 servicemen during the Gulf War with the anthrax vaccine, knowledge of which was withheld from most individuals, was the first major use of the vaccine in such quantity. In one year, nearly 6x the number of people were inoculated by the Pentagon than had been in the prior 30 years combined. Despite lacking sufficient tests surrounding the vaccine, particularly regarding its long-term effects, the current AVIP represents a tremendously expanded program which has never been seen before in the history of the anthrax vaccine - 100x more people, each of whom are involuntarily being subjected to the vaccine.

Criticism of the program was inevitable given the Pentagon's history. Issues of informed consent, particularly after the horrendous medical record-keeping experienced during Desert Shield/Desert Storm, and cries of "guinea pigs" were expected from the beginning.

B. History Of Medical Mistreatment And Experimentation Has Fueled Fear

This topic requires very little in the way of introduction. The historical record is not only quite clear, it is despicable. "Examples of use of physicians for governmental purposes include the U.S. military and cold war radiation experiments and the use of investigational drugs on U.S. soldiers in the Gulf War without consent, both done in direct violation of the Nuremberg Code." Another military lowpoint includes the use of Agent Orange.

Both the FDA and the Presidential Advisory Committee on Gulf War Illnesses criticized the Pentagon for its terrible record in using both experimental drugs and vaccines during the Gulf War and exercises in Bosnia. The FDA criticized the Pentagon for "failing to document immunizations in soldiers' permanent medical records and for touting the vaccine in handouts given to troops as 'very safe and extremely effective' when the FDA never authorized such glowing language." The President's Committee went even further and declared the Pentagon "currently is incapable" of handling unapproved drugs. Nor have the concerns regarding the government's predilection to utilize experimental drugs on both military and civilian populations abated.

Of course, vaccines, including anthrax, have been raised as potential contributing causes to the mysterious illness known as Gulf War Syndrome.

C. Pending IND Application To Modify The Number Of Shots And Intended Use Of The Vaccine

Withheld from the public's knowledge until VIG's FOIA lawsuit and, for the most part, until this hearing today, the Pentagon has, at least preliminarily, ascertained that the current AVIP which requires a series of six shots is outdated, unnecessary and perhaps not as effective as a second generation anthrax plan requiring only two shots.

On September 20, 1996, Michigan Biologic Products Institute, the manufacturer of the vaccine, submitted, with the support and encouragement of the Department of the Army, an initial Investigational New Drug (IND) application for Anthrax Vaccine Adsorbed. "The ultimate purpose of this IND is to obtain a specific indication for inhalation anthrax and a reduced vaccination schedule. The new schedule may be two initial doses with annual booster doses, as compared to the licensed six-dose series over 18 months." Despite ample proof from its own studies that the six series shot was essentially redundant, the Pentagon nevertheless initiated the current AVIP in an attempt to inoculate all personnel, even those who realistically will never be at risk, knowing full well that not enough vaccination lots presently exist to accomplish the purpose of the mission. Obviously, of course, by not waiting for the FDA's approval of the IND, the Pentagon's current program has cost taxpayers at least an additional $32 million dollars.

What actions the Pentagon or FDA have taken on this IND is unknown. No other documentation post-dating the IND was obtained through the VIG FOIA litigation. The IND does indicate that its "Comparative Study To Determine the Best Two-dose Schedule and Route of Administration of Human Anthrax Vaccine" was to have begun in Winter 1996 and completed in Winter 1998.

Therefore, this Subcommittee should require the FDA and the Army to provide information concerning the status of the IND and the relevant studies.

Curiously, in a 1990 article entitled "Military Immunizations: Past, Present, and Future Prospects", which was co-written by Drs. Ernest T. Takafuji and Philip K. Russell, both former Commanders of the U.S. Army Medical Research and Development Command at Fort Detrick, it was stated that:

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 ... anthrax.

This characterization of anthrax as "unlicensed" and "experimental" is, of course, in contradiction to the current literature and present posture of the Pentagon and FDA. In response to my request for elaboration as to what this article was referring to, the Defense Department stated:

According to COL Takafuji, a co-author of the referenced article and a previous Commander at the U.S. Army Medical Research and Development Command, the anthrax vaccine referred to in the article is not the FDA-licensed anthrax vaccine, but an experimental second generation anthrax vaccine under development at USAMRIID. The experimental anthrax vaccine is being developed utilizing emerging technologies that should require fewer doses and be more cost-effective to produce and administer.

The Defense Department's response would seem to indicate that the anthrax vaccine referenced in the article refers to the second generation vaccine proposed in the IND, but is it? Setting aside the stringent FDA-requirements now required to obtain a vaccine license or even a change to an existing license, one must question what is truly afoot here. The purpose of the IND is not to change the composition of the vaccine. It is not an attempt to make the vaccine itself stronger. Apparently studies have demonstrated that the six dose regiment now in place is unnecessarily excessive. Therefore, a mere modification of the dose schedule will apparently enable an individual to develop greater immune protection to the anthrax spores. Was the dose modification truly what was being referenced in the article that led two distinguished military medical commanders to term the anthrax vaccine as "unlicensed" and "experimental"? Or has the composition of the vaccine now in use been modified in someway?

The Subcommittee should require the Army to provide a more detailed explanation.

D. No Long Term Studies Of The Effect Of The Vaccine Have Ever Been Conducted And Most Available Studies Are Limited In Scope

The Pentagon has offered the bold assertion that the anthrax vaccine "...." Repeatedly, requests for supporting documentation of this conclusory statement have been presented to the Pentagon. Invariably a non-responsive answer is provided merely citing the long history of the vaccine with no known reported adverse reactions, or that it would be unethical to conduct such tests on humans. Such a response misses the point entirely. Whether use of the vaccine has caused adverse reactions immediately following or shortly after the actual inoculation is a separately valid issue that needs to be explored. And no one is calling for actual human tests to be conducted to determine long-term studies.

It has been the Pentagon's position that the FDA-approved vaccine has been widely used for more than three decades among veterinarians and live-stock workers. How difficult would it be then to locate several thousand of these individuals and examine their health? When 2.4 million lives are at stake, would it not be worth the effort to try? Yet the Defense Department has not, nor has it shown any willingness to do so.

The most revealing aspect of the VIG FOIA lawsuit was what was not disclosed: no studies regarding the long-term safety of the anthrax vaccine. This fact alone unequivocally destroys the Pentagon's assertions that the vaccine has no known long-term health affects. What is amazing is that the

Pentagon has seen fit to implement the AVIP based on very limited information. Its own documents repeatedly refer not to studies that support its assertions that the vaccine is safe and effective, but that none state otherwise. Indeed, the manufacturer's label itself reveals that "[s]tudies have not been performed to ascertain whether Anthrax Vaccine Adsorbed has carcinogenic action, or any effect on fertility." Nor is even the FDA aware of any clinical studies on the long term health effects of the vaccine.

Documentation obtained from the Army through the VIG lawsuit highlights the significant problems facing any real study of the vaccine. In furtherance of the Army's desire to change the dose and usage of the vaccine to protect against inhalation, it was noted that:

It is questionable whether anthrax occurs with sufficient regularity in humans anywhere in the world to allow for meaningful studies to be practically undertaken.

Presently there are no precise serological or other immunological correlates of protection to enable conclusions to be drawn from immunization studies in man.

The demonstration in some animal models that protection with the present vaccine varies across challenge strains further complicates studies and limits the breadth of efficacy claims that can be made.

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.

E. Adverse Side Effects Have Been Significantly Higher According to the Manufacturer's Label:

Mild local reactions occur in approximately thirty percent of recipients and consist of a small ring of erytherna, 1-2 cm in diameter, plus slight local tenderness(1). This reaction usually occurs within 24 hours and begins to subside by 48 hours....

Moderate local reactions which occur in 4 per cent of recipients of a second injection are defined by an inflammatory reaction greater than 5 cm diameter....

More severe local reactions are less frequent and consists of extensive edema of the forearm in addition to the local inflammatory reaction....

Systemic Reactions: Systemic reactions which occur in fewer than 0.2 per cent of recipients have been characterized by malaise and lassitude. Chills and fever have been reported in only a few cases. In such instances, immunization should be discontinued.

The truth, however, has been that systemic reactions have been two to nearly seven times greater than reported by the manufacturer. Although the evidence for these alarming figures arises directly from the Pentagon's own studies, it appears not to have created the type of concern one would normally expect. Indeed, it has been completely ignored and/or intentionally downplayed by military officials. Consider these figures derived from government data obtained through the VIG FOIA lawsuit:

Systemic Reaction Rates	Source of Information
First Shot (1.33%)	USAMRIID, Fall 1990-Spring 1991
First Shot (0.9%)	USAMRIID, 1977-1994
Second Shot (0.6%)	USAMRIID, Fall 1990-Spring 1991
Second Shot (0.4%)	USAMRIID, 1977-1994
Third Shot (0.2%)	USAMRIID, 1977-1994
Boosts (0.5%)	USAMRIID, 1977-1994
MDPH Vaccine (0.7-1.3%)	USAMRIID, 1998

Despite ample evidence that the systemic reaction rate far exceeds the manufacturer's stated limit, the Pentagon nevertheless maintains that only one possible case of a severe systemic reaction has occurred thus far. This is obviously demonstrably false. Indeed, reports of systemic reactions, such as fever and prolonged muscular weakness, have been occurring since the AVIP began. However, military medical officers have been reluctant or refused to file adverse reaction reports or attempted to convince servicemen that the effects they were encountering had little or nothing to do with the anthrax vaccine.

It is important to understand the significance of the systemic reaction rates. These reactions are potentially extremely harmful and possibly fatal. While a percentage rate of 0.7% to 1.33% may not seem high, when applied to the fact that 2.4 million servicemen will be receiving the vaccine under the AVIP, this means that from 16,800 to 31,920 servicemen may suffer serious or fatal reactions to the vaccine; a far cry from the 4,800 individuals who might suffer according to the manufacturer's label. Yet the Pentagon has offered no comments about this alarming and significant discrepancy.

The Department of Defense in its effort to downplay the significance of the number of systemic reactions experienced during their studies geared up their public affairs machine. Suddenly, systemic reactions of 0.2% or more are now labeled as "very rare" and fever and chills became categorized as a "severe local reaction". As I do not possess sufficient medical expertise as to whether fever or chills are more properly labeled as a "severe local reaction" or "systemic", I can not provide further comment on this aspect. However, it is quite obvious that the manufacturer of the vaccine considers the types of reactions that have been reported to various individuals actively monitoring the vaccine program as systemic and this calls in question the actions and motivations of the Defense Department to assert otherwise.

F. Public Remarks Of Pentagon Officials Have Been Ill-Conceived

The fault for the growing hysteria that is spreading throughout the military branches must always lie with several Defense Department and military officials whose public comments have not only been inaccurate or insensitive, but also raise additional concerns. Examples include:

"The side effect percentage is something like .00002 percent, which makes it many times safer, for example, than the diphtheria shots we give our children." Rear Admiral Michael Cowan, medical readiness director on the Joint Staff.

"No third eye has emerged." Secretary of Defense William S. Cohen.

"People are petrified that their penis is going to fall off, yet it is the safest vaccine ever given to American citizens. The polio vaccine was far more dangerous, yet the public lined up for it." General Charles Krulak, MC.

"It just increases your sex drive." Unidentified military doctor to reserve officer.

"It's safe and reliable...It works and has no side effects." Pentagon Spokesman Ken Bacon.

G. Implementation Of The AVIP Raise Significant Policy Questions

The decision to openly publicize the total force inoculation of American troops with the anthrax vaccine should raise questions in many people's minds. What exactly does this program serve to accomplish? Certainly one can genuinely argue that the policy may serve to ensure that our troops are not impeded by any nation or force that chooses to utilize the dangerous anthrax spores, although the Pentagon admits that no nation has ever used anthrax as a weapon.

Then again, one can argue that the public revelation of our force's protection merely serves to encourage the production of a different strain of

anthrax that would not be thwarted by the vaccine, or the use of an entirely different biological or chemical weapon (certainly enough choices exist) for which no adequate vaccine is available or that the Pentagon's decision is meant to merely deflect the weakness of our detection capability and lack of research and development in that area.

As a layperson to military affairs, but one who does routinely become emerged in issues of national security as a result of my law practice, I am particularly perplexed by the absence of an existing explanation justifying why it was so vital during Desert Storm/Desert Shield to maintain an extremely high-level of secrecy surrounding the inoculation of our troops with certain vaccines - to such an extent that many servicemembers still do not know what they were injected with, particularly due to poor record keeping. But yet, now, the Pentagon believes it appropriate to establish an entire public relations protocol to ensure the world knows our troops have been vaccinated against anthrax. The purpose, as I understand it to be, of the secrecy during the Gulf War surrounding certain experimental inoculations - several of which were permitted only through the acquisition of a highly questionable FDA waiver - was to provide our forces a tactical advantage should Iraq choose to utilize a particular biological weapon. In fact, one could reasonable presume that if Iraq were to use any of its known biological weapons, the Defense Department was hoping it would be one of those for which some of our troops were protected against, rather than one that we were not. Following this rationale to its logical conclusion, have we not set ourselves up for potential defeat before even entering battle through implementation of the AVIP?

In responding to the objections and questions that have been raised by servicemembers, their families and concerned Americans regarding the anthrax vaccine, the Pentagon has attempted to label such individuals as part of a "paranoid Internet craze". This unfounded categorization by Defense Department officials to deflect their perceived and apparent lack of adequate response has resulted in the one humorous aspect of this entire issue. While the Pentagon derides those who received their so-termed "misinformation" about the vaccine from the Internet, at the same time it directs those who wish to be responsible researchers to merely examine the truth which, of course, is posted on the Defense Department's Internet site.

Indeed, at this Internet site one will find an elaborate effort to provide answers to the many, many questions raised concerning the safety and effectiveness of the anthrax vaccine. One section in particular deserves mention - Fact vs. Myth. This section represents the Defense Department's attempt to dissuade potential refusers. Based on my research, however, I have developed my own Fact vs. Myth section on the vaccine, one that undoubtedly will not find its way to the Pentagon's website.

MYTH: "Although the manufacturer, Michigan Biologic Products Institute, 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, according to Deputy Secretary of Defense John J. Hamre and military medical officials."
FACT: The FDA does not routinely physically inspect samples.

MYTH: "A safe and effective vaccine is available that will protect our forces."
FACT: New spores have already been developed that will not be effected by the present vaccine.

MYTH: "There have been no long term side effects from this vaccine."

FACT: Totally unsupportable conclusion. The Defense Department has never attempted to research whether or not use of the vaccine has led to long term side effects or other health consequences. In fact, no studies appear to exist, even from the private sector, that examine the potential long term consequences of the vaccine.

MYTH: "This vaccine has been routinely used in the US since 1970, when it was licensed by the Food and Drug Administration."
FACT: With the exception of the military, no industry routinely uses the vaccine. Some use can be found among veterinarians or livestock workers, but no evidence exists demonstrating widespread usage. Only about 30,000 individuals have received the vaccine since 1970, compared with the Pentagon's plan to inoculate over 2.4 million servicemembers. In fact, documentation obtained from the Army through the VIG FOIA litigation reveals that "private sector use of the vaccine is between 400-500 doses per year." Given that the approved FDA dosage schedule is 6 shots, this amounts to less than 100 people per year using the vaccine; a far cry from the perception intentionally created by the Defense Department.

MYTH: The anthrax vaccine is effective against inhalation anthrax.
FACT: The Defense Department bases its assertion purely on limited and predominantly unpublished and non-peer reviewed studies. The anthrax vaccine presently being produced was never specifically designed to protect against inhalation anthrax, although that is not to say it is ineffective. The still-pending IND which was submitted in 1996 seeks to change the label of the vaccine to include inhalation protection as an intended use. Obviously it would be unethical to conduct experiments on humans in order to demonstrate effectiveness of the vaccine. However, one would hope the military would at the very least seek independent and more detailed reviews of its experiments on non-human primates, or other appropriate animals, before relying on such a conclusory assertion.

CONCLUSION

Mr. Chairman, it is a sad fact that we regulate industries governing machinery and automobiles far better than we do those industries that affect what may be placed within our bodies. The anthrax vaccine currently in use for our military probably would not withstand FDA scrutiny were it submitted for approval today. Yet no one seems concerned that various unknowns exist that go to the heart of whether this vaccine is actually a safe product over the long term. And no one seems alarmed that the adverse reaction rates far exceed the figures supplied by the vaccine manufacturer itself, or that the Defense Department has sought to masquerade these ill effects through wording changes.

To be sure anthrax is an intensely dangerous biological weapon. It is imperative that we seek out ways to adequately detect the spores before contact and protect ourselves after. But the Defense Department's AVIP represents nothing more than an easy out from the hard task of devoting time and money to develop adequate detection equipment and, if possible, efficient vaccines that are safe and effective.

The Defense Department has knowingly misled the American people concerning this vaccine. Whether twenty years from now advanced medical technology will demonstrate that the anthrax vaccine was, in fact, dangerous is anyone's guess. But until we know the full facts surrounding the safety, effectiveness and necessity of the anthrax vaccine, 2.4 million people are potentially being placed in harm's way for possibly no legitimate reason. Until then the United States should follow the lead of the United Kingdom, and restore some semblance of our cherished constitutional rights to our brave and honorable servicemembers and implement the vaccination program as voluntary.

If continued unchecked and unchallenged, the Defense Department's actions to involuntarily vaccinate its total force may serve as a prelude to forced civilian vaccinations, and the stripping of many of our protected civil liberties. This specific debate is best left to another day and another hearing, but the potential repercussions of what is now transpiring merits our immediate attention.

Thank you for the opportunity to present my views on this matter.

The James Madison Project (JMP), 1501 M Street, N.W., Suite 1175, Washington, D.C. 20005. Tel. No. (202) 785-3801; Fax No. (202) 223-4826; E-Mail: JaMadPro@aol.com. JMP is a Washington, D.C.-based non-profit organization with the primary purpose of educating the public on issues relating to intelligence gathering and operations, secrecy policies, national security and government wrongdoing. JMP also handles litigation under the Freedom of Information and Privacy Acts, including representation of news organizations, journalists, authors, intelligence officers, whistleblowers or others who allege harm at the hand of a government, foreign or domestic, in matters involving intelligence, national security and government accountability issues. The views expressed by Mr. Zaid are his own and do not necessarily reflect the views of any organization or entity with which he is or has been affiliated. A biographical sketch is attached.

News Release, Office of Assistant Secretary of Defense (Public Affairs), December 15, 1997, "Defense Department to Start Immunizing Troops Against Anthrax, available at http://www.defenselink.mil.

The Joint Program Office for Biological Defense contracted with Mitretek Systems, Inc. to fulfill the first condition and perform independent evaluation of supplemental testing. The process began in January 1998, and was scheduled to have been completed in November 1998. See Memorandum for Secretary of Defense from Assistant Secretary of Defense (Health Affairs), May 1, 1998 (copy on file with the Subcommittee and the author). Although the memorandum indicates that the initial lots passed supplemental testing, none of the test results have been publicly released. Conditions two and three were sufficiently completed by mid-Spring 1998. The independent review referenced in condition four was conducted by Dr. Gerard N. Burrow, Special Advisor for Health Affairs for the President of Yale University, and completed on February 19, 1998. His findings, discussed in more detail later, appear to merely reflect a review of the literature provided by the Pentagon and some telephone inquiries. No evidence suggests Dr. Burrow was aware of the multitude of problems associated with the manufacturing process, the unusually high rate of systemic reactions or the possibility that the Department of Defense may have modified the existing vaccine. This Subcommittee may wish to consider contacting Dr. Burrows to further explore the extent of his actual knowledge of the AVIP and how that might have effected his decision.

Memorandum from The Secretary of Defense, "Implementation of the Anthrax Vaccination Program for the Total Force," May 18, 1998 (copy on file with the Subcommittee and the author); see also News Release, Office of Assistant Secretary of Defense (Public Affairs), "Total Force Anthrax Vaccination Decision Announced,"
May 22, 1998, available at http://www.defenselink.mil.

Letter dated April 13, 1998, from Mark S. Zaid, Esq. to Honorable William S. Cohen, attached at Exhibit "1".

Letter dated April 22, 1998, from Mark S. Zaid, Esq. to Honorable William S. Cohen, attached at Exhibit "2".

Id. at 2.

Letter dated May 8, 1998, from Gary A. Christopherson to Mark S. Zaid, Esq., attached at Exhibit "3".

THE NAZI DOCTORS AND THE NUREMBERG CODE, HUMAN RIGHTS IN HUMAN EXPERIMENTATION 2 (George J. Annas & Michael A. Grodin, eds., 1992).

Annas, George J., Changing the Consent Rules for Desert Storm, 326 The New England Journal of Medicine 770, 770 (1992).

Id. (citation omitted).

21 C.F.R. § 50.23 (d)(1990).

Interestingly, in planning a change to the current anthrax vaccination program, BG Walter L. Busbee, Joint Program Manager for Biological Defense, informed those in attendance at a meeting that "the DoD position is 'soldiers are citizens first;' and whatever studies are formulated, the have to be done with this concept in mind. Soldiers have the same Constitutional rights as other citizens." Memorandum for See Distribution, "Minutes of the Meeting on Changing the Food and Drug Administration License for the Michigan Department of Public Health (MDPH) Anthrax Vaccine to Meet Military Requirements," November 13, 1995, at 3 (copy on file with the Subcommittee and the author). Were this truly the case, this Congressional hearing would not be necessary.

John Doe et al. v. Louis Sullivan et al., 756 F.Supp. 12, 13 (D.D.C. 1991).

Memorandum for Record, "Third Tri-Service Task Force (Project Badger) Meeting, October 18, 1990, at 2-3 (copy on file with the Subcommittee and the author). "Project Badger" was apparently a Desert Shield endeavor to ensure that certain experimental vaccines, including those that became the subject of Doe v. Sullivan, were accelerated through production and implementation in time for Desert Storm. The various minutes of the Task Force meetings were obtained through VIG's FOIA litigation.

Veterans for Integrity in Government v. Department of the Army et al., Civil Action No. 98-1649 (D.D.C. June 29, 1998)(RWR).
The FDA was specifically tasked for more detailed information concerning, but not limited to, anthrax licensing data, lot production, labeling, any memoranda's of understanding between the FDA and Defense Department, proposed rules governing informed consent and biological warfare vaccine production.

Memorandum for all ACC Staff Judge Advocates, BG William A. Moorman, USAF, Staff Judge Advocate, dated May 6, 1998 (copy on file with the Subcommittee and author). The document also notes that the military "must be highly sensitive to the concerns of the military member, particularly after the DESERT SHIELD/STORM controversy over immunization." Id.

Memorandum from Deputy Assistant Judge Advocate General (Criminal Law) to All Navy and Marine Corps Judge Advocates, April 10, 1998, at 3 ("JAG Memo"). There seems to be a great deal of confusion throughout the branches over whether force should be threatened or utilized, at least at the Command level on the ground. While it is the military's position that "Commander's have authority to order involuntary medical treatment of soldiers in cases where such treatment is deemed militarily necessary," see Unclassified Memorandum, "Refusal of Soldiers

to be Vaccinated Against Anthrax," July 17, 1998, attached at Exhibit "4', various branches, such as the Navy, have explicitly declared that, as a matter of policy, force will not be used. Id. Indeed, the decision to avoid the use of force appears to be departmental policy. See AVIP, Program Review for the Deputy Secretary of Defense, August 1998 ("Force Should Never Be Used To Administer The Vaccinations"), attached at Exhibit "5". Nevertheless, reports of threats - most likely for intimidation purposes - still continue to be received. See Sean D. Naylor, Fighting the anthrax vaccine: AWOL soldier faces discharge over the shots, Army Times, Aug. 17, 1998.

Over the last year I have been contacted by many servicemembers throughout the different branches of service who informed me of initial wide-spread refusals. Follow-up communications revealed, however, that many servicemen reluctantly consented to the vaccine following threats of severe punishment or even forcible inoculations. The Pentagon has significantly downplayed the actual number of initial refusals by only reporting those who were actually disciplined.

JAG Memo, supra note #, at 3; See Order to Take Anthrax Vaccination, September 30, 1998, attached at Exhibit "6".

"Air Force Approach to Anthrax Immunizations," undated, at 3 ("Air Force Approach")(copy on file with the Subcommittee and the author).

Article 90(2) states in relevant part that "[a]ny person subject to this chapter who ... willfully disobeys a lawful command of his superior commissioned officer ... shall be punished...."

Article 92(2) states in relevant part that "[a]ny person subject to this chapter who ... having knowledge of any other lawful order issued by a member of the armed forces, which it is his duty to obey, fails to obey the order ... shall be punished as a court-martial may direct."

It is important to note that this applies only to active-duty personnel and not reservists of national guardsmen. Members of these organizations can simply quit prior to punishment being imposed. The true test of the military's ability to withstand the growing dissent against the anthrax vaccine will depend on the actions taken by the reserve and guard units. Already several units have almost become non-deployable, particularly because of pilots refusing the vaccine. See Eddington, Patrick G., Contamination fears drive reservists who refuse vaccine, Army Times, Jan. 18, 1999, at 10, attached as Exhibit "7" ("Eddington").

Manual for Courts-Martial, Part V, paragraph 5(c)(1)-(8)(1998 ed.).

As the AVIP calls for a series of six shots, three of which are to be administered within a one month period, servicemen have faced the prospect of disobeying repeated orders to take the vaccine. Many servicemen have been punished more than once for refusing essentially the same order, apparently in contradiction to established policy. "Refusal to obey additional orders to be vaccinated for anthrax cannot form the basis for additional convictions at NJP or courts-martial." JAG Memo, supra note #, at 3, citing U.S. v. Greene, 8 M.J. 796 (NCMR 1980). See also Manual for Courts-Martial, Part V, paragraph 1(f)(1)-(3)(1998 ed.)(prohibiting double, increased and multiple punishments). Documentation obtained by VIG through its FOIA lawsuit reveal that a disparity of policy among the branches. See USCENTCOM Anthrax Debate sheet, July 31,1998 (commenting on differences between Air Force and Navy), attached as Exhibit "8".

"The discharge can be characterized as honorable, general or under other than honorable conditions, depending upon the circumstances surrounding the member's service." Air Force Approach, supra note #, at 4.

This is based on information received from individual servicemembers whom I have represented or maintained communications.

A1C Bettendorf rejected the summary court-martial forum on January 30, 1999, and on February 1, 1999, the charge was referred to a Special Court-Martial. Following my appearance in the case on February 12, 1999, we were scheduled to proceed to a court-martial on March 16, 1999. In the interim, following increased efforts to obtain additional discovery materials, an expressed intention by the defense team to investigate the vaccine itself and extensive national publicity, A1C Bettendorf was granted an administrative discharge under Other Than Honorable Conditions.

Part IV, paragraph 14(c)(2)(a)(iii)(1998 ed.).

34 M.J. 1183 (AFCMR 1992).

Id. at 1188.

Unger v. Ziemniak, 27 M.J. 349 (C.M.A. 1989).

One theory that emerged was that the vaccine had been spiked with squalene as an adjuvant to enhance the immune response. Report of the Special Investigation Unit on Gulf War Illnesses, Senate Committee on Veterans' Affairs 123 (1998).

We also argued that A1C Bettendorf had the right to present evidence concerning his views of the vaccine's safety, effectiveness and necessity in any sentencing phrase in order to mitigate any punishment. The Government conceded that A1C Bettendorf had the right to make a sworn or unsworn statement regarding how his state of mind had been effected by information he had compiled about the vaccine, but opposed the introduction of any evidence subsequently obtained.

36 C.M.R. 741 (1965).

Id. at 742.

Id. at 749.

U.S. v. Milldebrandt, 8 USCMA 635 (1958)(citation omitted).

Id. at 748.

Id. at 750.

According to the manufacturer, the final product should contain no more than 2.4 mg aluminum hydroxide (equivalent to 0.83 mg aluminum), 0.02% of formaldehyde and 0.0025% of benzethomium chloride, per 0.5 ml dose. IND at 002.

See Steven Lee Myers, Airman Discharged for Refusal to Take Anthrax Vaccine as Rebellion Grows, New York Times, Mar. 11, 1999. A1C Bettendorf's final discharge disposition was, therefore, more harsh than many of the refusers who preceded him. However, facing a possible penalty of six months in jail, he had earlier filed for such a discharge in order to avoid the court-martial. Nevertheless, A1C Bettendorf's cases raises valid concerns for the consistency in the

treatment of refusers. In 1995, when the Defense Department implemented its DNA-identification program, several UCMJ cases arose after servicemembers refused to submit to blood and tissue sampling. An Air Force technical sergeant who refused was found guilty at a special court-martial of an Article 92 violation and sentenced to grade reduction and 14 days hard labor. However, he submitted a request for voluntary discharge, which was accepted, and he received an honorable discharge. See Undated document "Air Force Approach to Anthrax Immunizations" at 3 (copy on file with the Subcommittee and the author).

Memorandum for See Distribution, "Minutes of the Meeting on Changing the Food and Drug Administration License for the Michigan Department of Public Health (MDPH) Anthrax Vaccine to Meet Military Requirements," November 13, 1995, at 2 (copy on file with the Subcommittee and author).

Id.

CITE

Dr. Bradford Smith, a veterinary professor at UC-Davis, was interviewed by CNBC, the airing of which occurred on March 22, 1999, and stated he knew of few veterinarians that were taking the vaccine. Contrary to the Pentagon's repeated assertions, he expressly denied that it was used by the veterinarian community on a routine basis.

Interestingly, despite likely having the second largest force contingent in the Gulf region, the British goverhment's anthrax vaccination program is entirely voluntary. See Warren Richey, A vaccination war erupts in military, The Christian Science Monitor, Jan. 28, 1999 (noting that 70 percent of British military personnel have declined the vaccine).

Anthrax Vaccine License Amendment Project Plan, "Information Briefing for Joint Program Manager, DoD Biological Defense, SAIC, October 20, 1995, at 18 (copy on file with Subcommittee and the author).

Editorial, Legacies of Nuremberg: Medical Ethics and Human Rights, 276 JAMA 1682, 1683 (Nov. 27, 1996)(citations omitted). See also Final Report, Advisory Committee on Human Radiation Experiments (1995)(conducted extensive inquiry into the history of government-sponsored human radiation experiments that occurred between 1944 and 1974).

See Fatal Flaws: How the military misled Vietnam veterans and their families about the health risks of Agent Orange, San Diego Union Tribune, Nov. 1, 1998.

Patrick Pexton, Pentagon Can't Be Trusted With Experimental Drugs, Navy Times, Feb. 16, 1998

Id. With respect to the AVIP, because of past deficiencies, Senator John D. Rockefeller IV stated that "[w]hile this may be the only reasonable choice at this point, I am doubtful about DoD's ability to do it properly." Deborah Funk, Vaccinations: Senate Warns DoD To Get It Right, Navy Times, Mar. 30, 1998.

Deborah Funk, Military Proposes Use Of Experimental Drugs At Home, Navy Times, Oct. 27, 1997. Included within the Defense Department's proposal was an anthrax vaccine post-exposure treatment. Id. See also Patrick Pexton, Pentagon Can't Be Trusted With Experimental Drugs, Navy Times, Feb. 16, 1998 (FDA "pointed out an underlying inability for the Defense Department to carry out its obligations" for handling experimental substances).

See Declan Barber, Admission on Gulf War vaccines spurs debate on medical records, 390 Nature 3 (Nov. 6, 1997)(British confirmed that pertussis vaccine combined with anthrax vaccine). The Presidential Advisory Committee on Gulf War Veterans' Illnesses concluded that "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." Final Report, The Presidential Advisory Committee on Gulf War Veterans' Illnesses 114 (1996). Despite this finding, doubts and suspicions remain.

An IND is "required for the clinical evaluation of an unlicensed product or for an unapproved use of a licensed product, such as a new indication, dose, or route of administration." Anthony, Bascom F. and Sutton, Ann, The Role of the Food and Drug Administration in Vaccine Testing and Licensure, NEW GENERATION VACCINES 1188 (2d ed. 1997).

According to Dr. Walter Brandt, Science Applications International Corporation (SAIC), amending the license is the responsibility of MDPH since it currently holds the license and interacts with FDA. Although the Defense Department may actually develop the scientific data to support the amendment, "MDPH must agree with and present the plan to the FDA for their concurrence...the DoD must fully support the MDPH in this effort through a formal agreement." Memorandum for See Distribution, "Minutes of the Meeting on Changing the Food and Drug Administration License for the Michigan Department of Public Health (MDPH) Anthrax Vaccine to Meet Military Requirements," November 13, 1995, at 3 (copy on file with the Subcommittee and the author).

Investigational New Drug Application, "Anthrax Vaccine Adsorbed (AVA)", submitted by Michigan Biologic Products Institute, September 20, 1996, at 001 attached at Exhibit "#" (complete copy on file with the Subcommittee and the author). Additionally, the interval between immunization may be changed as well from two weeks to four weeks. CITE. Why the Army waited until 1996 to have MDPH pursue FDA approval for a reduced series program is unknown. The Pentagon has stated that it was experimenting with a second generation anthrax vaccine of this nature before 1990. See "Department of Defense Responses to Questions From Mr. Mark S. Zaid, Attorney At Law" at 3-4, attached at Exhibit "#".

Nearly four years ago, Colonel Arthur Friedlander, Chief, Bacteriology Division, U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID), commented at a meeting to discuss the planned vaccination dose schedule change that "there is no evidence to indicate that six does are necessary to protect humans against anthrax infection." Memorandum for See Distribution, "Minutes of the Meeting on Changing the Food and Drug Administration License for the Michigan Department of Public Health (MDPH) Anthrax Vaccine to Meet Military Requirements," November 13, 1995, at 2 (copy on file with the Subcommittee and author)(emphasis added).

In April 1998, the cost of a single dose of the vaccine was $4.44. Memorandum from General William W. Crouch, U.S. Army, Vice Chief of Staff, dated April 28, 1998 with Questions and Answers Appendix at E-26 (copy on file with Subcommittee and author). If implemented the IND would appear to require only three shots within an 18 month period. The $32 million dollar figure is derived from the cost per single shot (3x) multiplied by the 2.4 million servicemen. Of course, this figure does not take into account that transportation, storage and administration costs would also be saved.

Internal Army documentation obtained through the VIG FOIA lawsuit intimates that the FDA will take 5-6 years to make a final decision on modifying the vaccine. Memorandum for See Distribution, "Minutes of the Meeting on Changing the Food and Drug Administration License for the Michigan Department of Public Health (MDPH) Anthrax Vaccine to Meet Military Requirements," November 13, 1995, at 4 (statement of COL Hurst, Office of the Deputy Assistant to the Secretary of Defense - Chemical/Biological Matters)(copy on file with the Subcommittee and author). Given the alleged seriousness, according to the Pentagon, of the impending threat, one must question why perhaps a waiver was not sought as during the Gulf War and perhaps why the process takes so long. More importantly, the extreme length of time apparently necessary to merely change the vaccination schedule and projected use - nothing that effects the actual composition or production of the vaccine itself - raises serious questions concerning whether the original vaccine would be approved were it submitted today. In fact, licensure of the vaccine was approved by the FDA in 1970, based merely on one clinical efficacy trial published in 1962. See Letter dated April 28, 1998, to Patrick G. Eddington, Executive Director, Veterans for Integrity in Government, from Kathryn C. Zoon, Ph.D., Director, Center for Biologics Evaluation and Research, FDA, at 1, attached as Exhibit "#". Unfortunately, evidence of efficacy was not required for licensure of biologics until after 1972. See Anthony, Bascom F. and Sutton, Ann, The Role of the Food and Drug Administration in Vaccine Testing and Licensure, NEW GENERATION VACCINES 1186 (2d ed. 1997).

Id. at 021 attached at Exhibit "#". The study, which was to have been undertaken in Ward 200, Medical Division, U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Frederick, Maryland, was to involve at least two hundred military and/or civilian volunteers. Id. at 030A-032 attached at Exhibit "#".

4 Infectious Disease Clinics of North America 156 (1990)(emphasis added).

See "Department of Defense Responses to Questions From Mr. Mark S. Zaid, Attorney At Law" at 4, attached at Exhibit "#".

These assertions were espoused as recently as March 22, 1999, by Lt. General Kevin Kiley, Assistant Surgeon General, USAF, when he appeared on a nationally-television program on CNBC.

The only document released that discusses long-term safety was a two page Information Paper dated November 23, 1994 that merely glosses over the potential future risks posed by the vaccine. It summarily concludes "[t]here is no scientific data to indicate a long term safety-risk associated with the use of the Anthrax vaccine." See Exhibit "#". Of course, this conclusion is to be expected given that no such data has ever been collected. One would think the Pentagon would be responsible enough to concern itself with the collection of such data given the breadth to which it is implementing the AVIP over vocal objections. Nor have any relevant studies concerning the anthrax vaccine presumably been withheld due to classification concerns. VIG was notified that the only studies withheld on grounds of national security dealt with production and technological issues. Should any relevant classified materials exist, the government then illegally withheld such documentation from VIG. For a list of those studies released to VIG, see Exhibit "#".

Aside from the potential long-term effects, another concern that has arisen is the effect of the anthrax vaccine when combined in close proximity with other vaccines. Concerns over "vaccine soup" have been of particular interest to those researching potential causes of Gulf War Syndrome. A limited study conducted at

Fort Bragg and Fort Detrick revealed that the combination of the anthrax and botulinum vaccines did produce "mild and moderate reactions", as well as a "few serious side effects." Memorandum for Dr. Edward Martin, Principal Deputy to the Assistant Secretary of Defense (Health Affairs) from BG Russ Zautchuk, U.S. Army Medical Research and Materiel Command, July 19, 1995, at 2 (copy on file with the Subcommittee and the author). But once again the Army was more willing to rely on the fact that computer databases searches and telephone inquiries revealed that "no studies have reported on interactions between anthrax vaccine and other pharmaceuticals" rather than actually perform such studies. Id. at 1.

□"Anthrax Vaccine Adsorbed", F-483 100M 10/90 (rev. 10/87), attached as Exhibit "#" ("Manufacturer's Label").

□. See Letter dated April 28, 1998, to Patrick G. Eddington, Executive Director, Veterans for Integrity in Government, from Kathryn C. Zoon, Ph.D., Director, Center for Biologics Evaluation and Research, FDA, at 2, attached as Exhibit "#".

□Undated briefing page, U.S. Army (copy on file with the Subcommittee and author).

□Id.

□Id.

□Id.

□Id. at 2-3. Reports have been made of servicemen experiencing adverse effects, such as fever, following inoculation with the vaccine, but that military medical personnel refused to discontinue the vaccinations.

□See Exhibit "#".

□Anthrax Vaccination Reactions, Primary Series, Special Immunizations Clinic, USAMRIID, Ft. Detrick, MD, 1977-94, June 1994 (Unpublished Data), attached as Exhibit "#".

□Id. REFERS TO fn 61.

□Anthrax Vaccination Reactions, Primary Series, Special Immunizations Clinic, USAMRIID, Ft. Detrick, MD, 1977-94, June 1994 (Unpublished Data), attached as Exhibit "#".

□Anthrax Vaccination Reactions, Primary Series, Special Immunizations Clinic, USAMRIID, Ft. Detrick, MD, 1977-94, June 1994 (Unpublished Data), attached as Exhibit "#".

□Anthrax Vaccination Reactions, Primary Series, Special Immunizations Clinic, USAMRIID, Ft. Detrick, MD, 1977-94, June 1994 (Unpublished Data), attached as Exhibit "#".

□USAMRIID Briefing Slide, 1998, at Exhibit "#".

□Executive Summary dated 11 June 1998, "Possible Anthrax Vaccine Related Reaction", at Exhibit "#".

In its brochure "What Every Soldier, Sailor, Airman and Marine Should Know About The Anthrax Vaccine", attached as Exhibit "#"), which is made available to servicemen in each branch, the Defense Department attempts to minimize the concerns of the anthrax vaccine by comparing adverse reaction rates with the typhoid and influenza vaccines. The document notes that less than 1% of those who receive the anthrax vaccine should experience fever. Thus it would clearly appear fever is to be considered a systemic reaction. Indeed, in an apparently unpublished report, obtained through VIG's FOIA lawsuit, in which Dr. Phillip R. Pittman, Chief, Special Immunizations Branch, USAMRIID, served as the Principal Investigator, low-grade fever was characterized as a "[m]oderate systemic reaction". "Anthrax and Botulinum Vaccines: Antibody Prevalence and Immune Response to Boost(s) in Military Personnel Initially Vaccinated During Operations Desert Shield/Desert Storm", March 21, 1995, at 9 (copy on file with Subcommittee and the author). Furthermore, in response to concerns raised by the Vice Chairman, Joint Chiefs of Staff, over the safety of the anthrax vaccine, the Assistant Secretary of Defense (Health Affairs), Dr. Stephen C. Joseph, submitted a memorandum dated July 25, 1995, that described systemic reactions as being "characterized by chills, fever, and general malaise." Memorandum for Vice Chairman, Joint Chiefs of Staff, "Anthrax Vaccine", July 25, 1995, at 1, attached at Exhibit "#". Finally, in a Program Review prepared for the Deputy Secretary of Defense in August 1998, it was noted that four systemic reactions to the vaccine had occurred, and that systemic was defined to encompass malaise, chills and fever and anaphylaxis. See AVIP, Program Review for the Deputy Secretary of Defense, August 1998, attached at Exhibit "#".

At the initial trials that led to FDA approval of the anthrax vaccine, "four cases resulted in systemic reactions, defined as chills and fever (2 cases), fever only (one case), and illness with general aching for 24 hours (1 case)." Memorandum for Deputy Secretary of Defense from Stephen C. Joseph, M.D., M.P.H., Assistant Secretary of Defense (Health Affairs), undated, at 8 (copy on file with Subcommittee and the author). In light of the clear evidence that fever constitutes a systemic reaction, the obvious effort by the Defense Department to convince its personnel and the public otherwise is deplorable.

GulfNEWS, November 1998, at 3. Since 1989, $830 million dollars has been paid out to 1100 diphtheria claims under a special no-fault federal vaccine court. Washington Post Magazine, Aug. 30, 1998, at 14.

Washington Post, Oct. 30, 1998.

San Diego Union Tribune, date unknown.

Quote conveyed to me by former reserve officer who refused anthrax vaccine.

Pentagon Press Conference, date unknown.
According to recently declassified documents obtained through VIG FOIA lawsuit, the Defense Department believed in 1991, that the release of any information under FOIA concerning the use of vaccine for botulinum on servicemembers stationed in the Persian Gulf during Desert Shield and Desert Storm "would be very valuable to present and potential adversaries. The disclosure of detailed information such as the number of individuals vaccinated, quantities of vaccine produced, etc., would interfere with our ability to respond rapidly in the future to the now identified chronic shortages in the industrial base." See Joint Staff Action Processing Form, Freedom of Information Request #3106 (91-FOI-1267), August 1, 1991, at 2 (copy on file with the Subcommittee and the author). The document concluded that "[d]isclosure of the information requested,

in the detail requested, would not be in the DOD's best interest and could be expected to cause serious damage in the future." Id.
□Air Force Policy Letter, Anthrax Update, August 1998 Edition at 1, attached as Exhibit "#".

□Eddington, Patrick G., Contamination fears drive reservists who refuse vaccine, Army Times, Jan. 18, 1999, at 10, attached as Exhibit "#".

□News Release, Office of Assistant Secretary of Defense (Public Affairs), December 15, 1997, "Defense Department to Start Immunizing Troops Against Anthrax, at 3, available at http://www.defenselink.mil.

□Deb Riechmann, Russian Version Of Anthrax Can Thwart U.S. Vaccine/Unknown If Iraq Has Deadly Strain, Navy Times, Mar. 2, 1998; Bradley Graham, Dose of Explanation comes with Anthrax Shots, Washington Post, Oct. 30, 1998. Additionally, military experiments upon guinea pigs demonstrated that the present anthrax vaccine provided little or no protection against certain strains of anthrax. See MDPH-PA Vaccine Efficacy Data, USAMRIID, 1992 (copy on file with the Subcommittee and the author).

□Memorandum from General William W. Crouch, U.S. Army, Vice Chief of Staff, dated April 28, 1998 with Questions and Answers Appendix at E-24 (copy on file with Subcommittee and author). Documents distributed throughout the services also assert that "no long term consequences have been demonstrated. "What Every Soldier, Sailor, Airman and Marine Should Know About The Anthrax Vaccine" at 2, attached as Exhibit "#". While accurate on its face, the statement is misleading. Not one study has been conducted to determine the long-term effects of the anthrax vaccine.

□Id. at 1. See also News Release, Office of Assistant Secretary of Defense (Public Affairs), December 15, 1997, "Defense Department to Start Immunizing Troops Against Anthrax, at 2, available at http://www.defenselink.mil ("It has been widely used in the United States since the early 1970s....").

□James W. Crawley, Military Seeks To Ease Fear Of Anthrax Vaccine, San Diego Union-Tribune, Feb. 9, 1999. This relatively low number is likely due to the fact that "human anthrax is rare in the United States, with only four cases between 1979 to 1988." Operational Requirements Document for Improved Anthrax Vaccine (IAV), U.S. Army Medical Materiel Development Activity, March 1995, at 1 (copy on file with Subcommittee and the author).

□Memorandum from General William W. Crouch, U.S. Army, Vice Chief of Staff, dated April 28, 1998 with Questions and Answers Appendix at E-23 (copy on file with Subcommittee and author).

□Nevertheless, according to a staff report prepared for the Senate Committee on Veterans' Affairs, the "vaccine should ... be considered investigational when used as protection against biological warfare." Is Military Research Hazardous To Veterans' Health? Lessons Spanning Half A Century, Staff Report, Committee on Veterans' Affairs, U.S. Senate, 103d Cong., 2d Sess. 15 (1994).

Mr. SHAYS. Mr. Zaid, I am not a great fan of class action suits, but your questions were very provocative. Before I go to Mr. Handy, I just want to be clear, it is your testimony that only between 100 and 300 people in the United States in the private sector take this vaccine, a year?

Mr. ZAID. Based on documentation and reports and I believe I think that dosage came from an article in the San Diego Union Tribune, it indicated and I believe it refers to the private sector, that between 400 and 500 doses per year are used which given the FDA approved six shot series, I would presume that is only of 100 to 200 or 300 people.

Mr. SHAYS. Even if you were off by 1,000——

Mr. ZAID. We are talking about a very, very small number.

Mr. SHAYS. Mr. Handy, I am going to get right to you, I just will say that this is the first of many hearings and I found myself wanting to ask a question based on what you said of our previous panel, but we are going to have FDA in front of us and we are going to nail some of this down. And we will try to do it fairly quickly.

Mr. Handy.

Colonel HANDY. Thank you, Mr. Chairman. I sincerely appreciate the committee's inviting me to discuss my concerns about the policy. I am grateful this important issue is receiving serious review. Before proceeding, I would ask the committee to enter my written testimony in the record, along with supporting documents which I will provide in full shortly after the hearing.

I am here today only as a private citizen. I am not speaking on behalf or in any official capacity on behalf of the Department of Defense, the Air Force or the Reserve Officers Association which selected me as its most outstanding individual Air Force Reservist in the Nation in 1996.

I am a Colonel in the Air Force Reserves, promoted just last summer. Last fall, the Air Force selected me for a 4-year full-time military position in the Pentagon. I elected not to pursue that job. Right now I am seriously considering early retirement which will mean a voluntary reduction in rank and pay to Lt. Colonel. Why would I forego the remainder of my career in protest over a shot I will not even face for several years? I care deeply about the integrity of my DOD employer and my service, but I am thoroughly dismayed by a tidal wave of information and abuse which is causing widespread damage to the dignity and the devotion of our Nation's defenders.

Mr. Chairman, my hope is that the deception stops here. Let me be specific about just some of the disturbing information which is causing reactions in the ranks. First, key experts consider vaccines a useless defense against biological warfare.

Second, major medical journals give no credence to the claims that anthrax vaccine will work against inhaled vaccine in particular.

Third, and this is important, Fort Detrick studies show the anthrax vaccine has an 82 to 100 percent failure rate. The DOD is ignoring their own data.

Fourth, as already mentioned, the Joints Staff may be developing as many as 50 or more other vaccines which could provide addi-

tional sources of misery for our dedicated soldiers, sailors and airmen.

Fifth, nearly 50 documented types of side effects already occur with this vaccine.

Sixth, few think of challenging the statement that the vaccine is FDA approved, but as Mark Zaid just pointed out, we wonder and have heard that it would not be approved using today's standards.

Last, and perhaps most ominous, the DOD intends to increase its role in State biological disasters according to several reports. In other words, if this prospect materializes, the DOD may also abandon informed consent principles and proper procedures in the civilian community.

I feel this policy must be addressed early before any more damage is done to morale, recruiting, retention and combat effectiveness. We are potentially witnessing the slow, but systematic dismantling of a yet formidable total force with balanced contributions from the Guard and Reserve. An Air Force Reserve pilot recently remarked, "For the past 2 months, I do not know if I am coming or going. Being in the Reserves these days is like being on active duty full time. Our guys have been making a lot of sacrifices to do this job. We have reached the breaking point and the anthrax issue is basically the last straw."

Mr. Chairman, I would like to humbly suggest several useful congressional actions regarding this specific vaccine and DOD practices in general. First, I believe it would be most beneficial for the Congress to require DOD to cease its baseless marketing claims of the vaccine as safe and effective. Also, perhaps a funding moratorium could be imposed on the vaccine program and money could be used to study its ramifications so that both military and civilian doctors understand how to treat all 50 side effects.

Although a catastrophic reaction has not occurred yet, people have been hospitalized and the close friends and relatives of our soldiers, sailors and airmen already consider this situation totally unacceptable.

Finally, I would ask the committee to require DOD to develop regulations and policies that would treat individual service members with respect on medical matters. I would suggest those policies include full medical workups prior to inoculations, allergic reaction assessments, the right of informed consent on questionable vaccines, FDA approved or not, full disclosure of risks and side effects by a non-DOD paid expert, and the right to exercise personal, religious beliefs to decline questionable vaccines regardless of church affiliation or stated written doctrine.

I believe the era of the mandatory use of questionable vaccines must be terminated for the health of the force. Our allies who do not do this to their soldiers also do not have Gulf war syndrome or they have addressed their mistakes and offered voluntary vaccines.

Mr. Chairman, I am sure that every member of the Armed Forces will be grateful for your support and care in this matter. I thank you very much for the opportunity to testify.

[The prepared statement of Mr. Handy follows:]

STATEMENT ON ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP)
Redmond H. Handy, Colonel, USAFR

PREPARED FOR THE HOUSE OF REPRESENTATIVES
Committee on Government Reform
Subcommittee on National Security, Veterans Affairs, and Intn'l Relations
March 24, 1999

INTRODUCTION

Mr Chairman, I sincerely thank the committee for inviting us to discuss the Pentagon's mandatory anthrax vaccine policy. It is truly a privilege for us to participate in this matter of critical importance to our national security.

I believe this policy is harmful to our national defense capabilities. I believe that common sense and logic must prevail in addressing biological warfare threats. I do not believe this policy meets those criteria. I have spent a significant amount of time during the past year giving thought to the impacts of this policy on our hard-working and dedicated volunteer force. The more I researched the more uncomfortable I became. The objectionable issues with this policy are many, and I would like to simply outline them for the committee in the form of preliminary findings.

EFFECTS OF MISGAUGING THE BIOWARFARE THREAT

Produces Fear Out Of Proportion To Actual Threat
- Daniel Greenberg wrote recently "While a gullible press echoes its frightening warnings, there are no independent assessments of the potential for terrorist attacks."
- Literature reviews indicate the potential for biological attack remains small and incalculable
- DOD descriptions of biowarfare as "not a matter of if, but when", suggests 100% probability
- Vaccine package indicates routine immunization is not recommended; low risk in population

Other National and International Effects
- Vaccine policy erodes 1972 Biological Weapons Convention; encourages biological arms race
- Sends message that US expects anthrax to be used
- Deemphasizes massive retaliation response threat which worked in Desert Storm
- Vaccine failure threatens unit effectiveness and survival and risks public outrage

VACCINE EFFECTIVENESS

Vaccines are Useless Against Bioterrorist Threats
- Bill Patrick, probably the nation's foremost expert on germ warfare who directed offensive biological programs at Ft Detrick in the 1960s, has **no confidence in vaccines as a defense**
  - -- He says it takes only 18 months to develop a germ, but 10 years to develop a vaccine
  - -- Smart adversaries choose a different germ or modify an old one to defeat the vaccine
- **Vaccines could never keep up** with the possible anthrax permutations, variations of other biological agents, combinations of agents, stronger doses, and genetically-engineered germs.

Anthrax Vaccine Already Proven Ineffective By The Army's Own Tests
- Ft Detrick guinea pig experiments in 1986 and 1998 showed dismal efficacy results.
  - -- In the 1998 study, the anthrax vaccine failed to provide survival rates of 50% (the military definition of unit effectiveness) in 27 of 33 different anthrax isolates. **(an 82% failure rate!)**
  - -- Even worse, 12 of those isolates killed 75-96% of the vaccinated pigs.
  - -- Similar **mice studies indicate a 90-100% failure rate** for this vaccine.

DOD Discarding Relevant Reports and Data To Claim AVIP Effectiveness
- DOD basing use of the vaccine on rhesus monkey and rabbit trials showing 90%+ survival
  - -- DOD states pig and mice studies are less relevant
- Are these studies thrown out for a myriad of other medical assessments for similar reasons?
- Journal of the American Medical Association says **data is lacking** for inhalation efficacy claim
- Senate Staff Report 103-07 says **efficacy against inhaled anthrax is "unknown".**

HEALTH AND SAFETY

Although I understand a separate hearing is scheduled by the committee to address this area with medical professionals, I would like to relate discoveries to the level of my understanding gained from research and discussions with several civilian and medical professionals familiar and directly involved with this issue.

Anthrax Vaccine Parallels Government Swine Flu Vaccine Mistakes
- Several analyses of swine flu vaccine shows **disturbing similarities** to anthrax vaccine
  - -- 1 Ft Dix swine flu death caused scare because of 1918-19 pandemic (450K died)
  - -- Inoculation decision made regardless antibiotics (also suggested for anthrax, but not available in '18-'19 to fight the actual bacterial pneumonia cause of many deaths)
  - -- Center for Disease Control unable to estimate probability of epidemic occurrence
  - -- Severity could also not be predicted
  - -- No serious side effects anticipated for the swine flu vaccine, even though untested
  - -- 3-24-76 meeting to decide program implementation characterized as a "staged event"
  - -- Field trials yielded depressing efficacy results, many adverse reactions
  - -- Swine flu program vaccinated 2X as many as ever before for a single season virus **(2.5 million military receiving anthrax vaccine is 17X as many as in the Gulf War)**
  - -- Military reactions to the shot were reported at substantially and suspiciously lower rates
  - **-- Deaths/severe reactions halted program; 4,000 nerve damage claims over 12 years**

Relevant Gulf War Illness Information
- Senate Staff Report 103-97 indicates **43% of Gulf War troops had vaccination side effects**
- Same report indicates **anthrax vaccine is possible contributor to Gulf War Syndrome**

FDA Vaccine Approval Process, Inspection Reports And Warning Letters to Manufacturer
- Approved in 1970 based on study of only 26 textile workers in the 1950s
- Approved 2 years before FDA began requiring efficacy demo—**wouldn't be approved today**
- FDA Warning Letters sent to the manufacturer in 1995 & 1997 **(threatened to revoke license)**
- Feb 20, 1998, scathing FDA report lists 53 categories of discrepancies, 31 subcategories

FDA Vaccine Approval Process, Inspection Reports & Warning Letters to Manufacturer (Con't)
- The plant is now shut down for renovation, but DOD is still using the current vaccine supply
- Retests of all lots only overseen by DOD contractors—manufacturer actually did the retesting
- **Initially, 22 of 30 lots failed retest; those cleared are still causing serious reactions**

Problems with Systemic Reactions to the Vaccine (Requiring Shots be Discontinued)
- **DOD figures**--.0002% systemic reaction (**5 out of 2.5M** service members should stop the shot)
- Vaccine package insert claims a .2% reaction rate (5000 out of 2.5M members should stop)
- Two Ft Detrick studies show up to a 1.3% reaction rate **(32,500 members could be affected)**
- Documented cases exist of shots continuing after systemic reactions--violates insert instructions
- **Documented reactions to the anthrax vaccine** from the FDA's Vaccine Adverse Event Reporting System include the following: Tremors -- trembling or shaking; Somnolence -- state of being drowsy); Syncope -- loss of consciousness resulting from insufficient blood flow to the brain; Bradycardia -- slow heart rate; Dyspnea - difficult or labored breathing; Pharyngitis – inflammation of the throat; Rhinitis -- inflammation of the mucous membrane of the nose (allergy-type); Cellulitis -- inflammation of connective tissue; Purpura/Thrombopenia – hemorrhage of blood into the skin/decrease in the number of blood platelets; Stomatitis – inflammation diseases of the mouth; Angioedema -- an allergic skin disease; Photophobia – painful sensitiveness to strong light; Meningitis -- life threatening illness caused by bacterium Urticaria – hives; Paresthesia -- a sensation of pricking, tingling, creeping on the skin associated with injury of a sensory nerve; Pruritis -- localized or generalized itching due to irritation of sensor nerve endings from organic or psychogenic causes; Edema -- an abnormal excess accumulation of serous fluids in connective tissue or in a serous (thin, watery constitution) cavity; Vasodilation -- widing of the lumen (blood vessels); Alopecia -- loss of hair (baldness); Arthralgia -- Pain in one or more joints; Asthenia -- loss or lack of strength Lymphadenoma -- (1) lymphoma (2) Hodgkin's Disease; Myalgia -- pain in one or more muscles; Hypokinesia -- decreased muscular movement
- **Other reactions that don't need translation**: Agitation, Amnesia, Diarrhea, Dizziness, GI Distress, Headache, Insomnia, Chest pain, Sweating, Weight loss, Injection Site Reaction, nausea, rash, vomiting, pain at injection site, chills, fever, mass at injection site, headache, cough, allergic reaction, visual field defect, abdominal pains, abnormal stool, previous reaction, ulcer in mouth. **Nearly 50 different types of reactions have occurred.**

ALLIES EXPERIENCE WITH THE VACCINE

- French: Didn't vaccinate in the Gulf War; their military members don't have GWS
- British: Admit mistakes in Gulf; offered a voluntary vaccine; program stopped
- Israelis: Don't have a mandatory vaccine policy either; relying on antibiotics
- Canadians: Had mandatory vaccine policy; recently stopped because of supplies/controversy

SUPPORT FOR THE PROGRAM

- U. S. TalkSpot Radio Program Survey shows 83% AGAINST this forced vaccination program
- Army Times Publishing Company poll showed 77% AGAINST
- British voluntary anthrax vaccine program - 73% DECLINED

REACTIONS AND IMPACTS ON THE GUARD AND RESERVE

Background
- Reservists couldn't turn to military facilities, the VA or their civilian health care providers for accurate diagnosis or treatment of vaccine side-effects from shots administered in the Gulf War
- Thousands of Gulf War shot records were lost or did even not reflect shots were administered
- The Reserve Officer's Association challenged DOD on Gulf War Syndrome (GWS) in 1997
  -- Their resolution urged Congress to provide appropriations to pay for GWS problems
- **This vaccine is creating fresh wounds and deep resentment less than a decade after GWS**

Medical Issues
- Reservists personally know people who contracted Gulf War Syndrome
- Even severe health problems occurring on active duty are sometimes treated with skepticism
- **Both civilian and military doctors seem to lack accurate/important information, especially on how the vaccine might generate the 50 different side-effects and how to treat them.**

Personal, Family and Women's Issues
- Reservists are concerned about what they might pass on to nursing babies or future children
- Reserve women might be concerned they can't start a family during 18 month initial shot series
- Are pregnant reservists going to be kept out of theater or deployed "exposed" without shots **(Active duty pregnant women are not reassigned back to states - unprotected in theater?)**
- Reservists are concerned that everyone is given the vaccine regardless of individual medical conditions (such as allergies which might trigger an immune system response) or interactions with other medications they are taking (package insert does not address)
- **Health risks jeopardize civilian income; reservists can't afford vaccine side-effects!**

Professional Objections/Issues
- Strategic Lift aircrews especially take a myriad of shots already, what's next?
- Senior aircrew inclined to retire; loss of leadership (5000 flying hours, instructor pilots)
- Younger pilots have less to lose with the military, a lot to lose when just signing on with airline
- Policy is creating tension in units
- Increases turnovers (one unit had 50% turnover in past 3 years, hadn't had in previous 10 years)

CIVILIAN ISSUES

Administration Won't Use Current Vaccine on Civilian Population Which Is Also At Risk
- Oklahoma City, Atlanta Olympics and New York City Trade Center bombings—civilian targets
- 50+ anthrax threats across country in last several months; *None* against the military
  -- Who are the hoaxers? Who's behind them?
- Administration official has said **"Vaccinating civilians is another thing entirely and we don't think we want to do that with the vaccines currently available."**
- All military will absorb a risky product, while most of America *may* get better protection
- What sense does it make to allow civilians and contractors to remain "exposed" while working side by side with "protected" military members

LIMITATION ON FREEDOM OF RELIGION

- DOD provides a religious reason for not taking the vaccine, implying ethical and moral issues
- Policy requires religious objection based on recognized church doctrine against ALL vaccines
- No religion, unless it is a self-destructive cult, would approve injecting questionable substances
- This limitation is a step too far in limiting freedom of religion and could evoke a public outcry
- Doesn't allow for private religious beliefs; must be recognized church-going individual
- **National survival is not dependent on religious objections to questionable vaccines**

FINANCIAL INTERESTS IN VACCINES WARRANT FURTHER INVESTIGATION

- Vaccine market potential increased with recent tax, patent and litigation changes
- Allegations of corruption over the vaccine plant sale; Michigan lawmakers outraged
- Administration meeting on vaccine stockpiling plan included those who would gain financially

IMPLICATIONS FOR THE FUTURE

- $322M budgeted for new biological vaccines compared to $115M for 121 GWS Studies
- DOD has requested FDA waivers in handling civilian disasters; wants greater involvement
  - -- Plans to use some of the same experimental drugs and vaccines used in Gulf War
  - -- Seeking broad authority waive requirements such as keeping track of who gets what drugs, proper labeling, monitoring side effects, and informing patients of complications before they give consent

CONCLUSION

As you can see, I believe there are many disturbing issues here. Lawful orders must not include controversial policies created from waivers to medical standards established at such great cost by the Greatest Generation. I urge continued focus on this vaccine until a voluntary policy is established which is respectful of the legitimate concerns of the men and women who pledge their lives to this nation's freedom. I thank the committee for this opportunity to testify.

Mr. SHAYS. Thank you, Mr. Handy. Ms. Greenleaf. I am sorry, we need to give you that mic and then we can move the yellow papers and you can put it in front of you a bit. Thank you.

Ms. GREENLEAF. Thank you, Mr. Chairman, and members of the committee. I am privileged to appear before you to present a personal viewpoint on the anthrax vaccination policy adopted by the Department of Defense. The position I present today is not only my own, but it is shared by concerned parents, spouses, family members and friends of military personnel who are unfortunate and often unwilling participants in a policy which is believed to be misleading to military personnel and the American public.

Our views are neither radical nor unfounded, nor are our sons and daughters and spouses troublemakers as implied by government officials who are in charge of either implementing the policy or presenting an acceptable public relations position to the general public and the media.

Needless to say that people who have refused the vaccine are volunteers and in some cases come from families who have a history of military service. These men and women are often well-trained, intelligent and articulate. They are truly, in many cases, the best and brightest of their generation, trained in nuclear technology, air combat and flight, and constitute a cross section of the fields of training and study offered by the military. Yet faced with an order to take the vaccine without reasonable answers to reasonable questions, these men and women have been borne to pressure and coercion of the military authorities. They have suffered reduction in rank, reduction in pay, restriction of liberty and dismissal from the service, all because they refuse to accept the assurances of the authorities that the vaccine is safe and effective.

The DOD points to the numbers and says look at how many people support our policy. What they do not tell you is that many personnel cannot afford to say no, cannot afford to take a reduction in grade and pay and as a result are pressured into subjecting themselves to the needle.

There is more resistance out there to this policy than the numbers support. Unfortunately, the military sidesteps the issues of the safety and efficacy of the vaccine with its dictate, it is an order. We do not stand against this policy without medical support. Drs. Meryl Nass and Victor Sidel, two prominent physicians in the United States, have expressed similar doubts in articles written for various scientific and medical journals. The policy has had a negative effect on U.S. military preparedness and expertise. The recent resignations of Connecticut Air National Guard pilots cost the U.S. Government the skill and training of fighter pilots who had a history of service and were willing to continue to put their lives on the line in Iraq or other unfriendly combat zones. Two U.S. Navy nuclear trained personnel aboard a nuclear aircraft carrier were recently disciplined and dismissed from the service for failure to take the vaccine. More trained and qualified personnel are on the horizon asking for answers. The answers are not forthcoming.

And the response of the military is to take these well-trained men and women, refuse them answers and discharge them for insubordination. All this in a context of concern among the military's

own recruiting commands that the military cannot attract or keep qualified people.

Look at what is happening to these young people and ask yourselves why is there reluctance of younger people to join our armed forces? I am the mother of a young sailor who has completed his service. My son took the vaccines and I am upset that the military has indifferently cast aside questions of its safety. I am upset that the quality control questions on the production of the vaccine have remained unanswered. I am further upset that my son, as well as all military personnel have possibly been inoculated with a vaccine the safety of which is a big concern and which may not even work.

To subject our men and women of the armed forces to a vaccine which is possibly unsafe, unreliable and ineffective is to subject all such personnel to a misguided impression that the vaccine will protect them from all strains of anthrax regardless the manner of exposure. It is an Alice-in-Wonderland approach to a problem. It is one shared by me and thousands of men and women all over this country.

On behalf of myself, my family and on behalf of the men and women who have had the courage to stand up to this misguided policy, I thank you for the opportunity in allowing me to speak today.

[The prepared statement of Ms. Greenleaf follows:]

WRITTEN TESTIMONY
AVIP HEARING
3/24/99
LORENE GREENLEAF

Testimony of Lorene Greenleaf
AVIP Hearing 3/24/99

I begin this written testimony by thanking the Committee for giving me the opportunity to express my concerns regarding the Anthrax Vaccination Policy. I write this statement on behalf of thousands of concerned military troops and family members.

As the mother of an Honorably discharged Navy veteran who was coerced into taking anthrax inoculations in the spring of 1998, we have serious concerns related to the safety, efficacy, and necessity of the anthrax vaccine. My son was inoculated with vaccines that were in violation on the FDA inspection report of 2/98 as being "expired" and only tested for potency rather than safety and sterility. (See attachments 1, 2)

Out of fear for my son's health, I began searching for information on the anthrax vaccine, submitting Freedom of Information Act requests to the FDA, Dept. of the Army, and the Michigan production facility. (See attachment 3) After reviewing information obtained, I made several phone calls to the DOD, FDA, and MBPI regarding statements made by FDA inspectors in some reports, (See attachment 4) and found these conversations very troubling. (See attachment 5)

I then became very active speaking with the media, therefore my name has become familiar among military troops as someone to contact for factual information regarding the vaccine. In the past year, I have responded to thousands of requests for information from military troops and family members. (See attachment 6)

These brave young men and women have been accused of gathering false information from the Internet, when in fact, most are obtaining information I have accumulated through FOE requests. This information is forwarded via email upon their request. When this information hits a military base or ship, it spreads like wildfire.

These concerns are justified however, these troops are being punished (in many cases more than once for the same offense), (See attachment 7) financially strapped due to reduction in rank, (See attachment 8) discharged under less than honorable conditions, harassed, and threatened. Some have gone as far as going AWOL to avoid forced inoculation. Most have impeccable service records, and are not looking for a way out of the military, they are only looking out for their health. The military is losing some of America's finest. (See attachment 9)

Unfortunately, I have also had several reports of soldiers who have become ill shortly after receiving anthrax inoculations. (See attachments 10,11) In most cases these symptoms are tightness in chest, severe headaches, bloody diarrhea, rashes and vomiting. Some more severe than others, and these symptoms reportedly worsen with each dose. In reviewing the Vaccine Adverse Event Reporting System report obtained from the FDA, I find these reactions have not been reported. (See attachment 12) Many of these sick soldiers have requested that an adverse event report be filed, only to be turned down by

Testimony of Lorene Greenleaf
AVIP Hearing 3/24/99

the military medical facility. (See attachment 13) I have responded to several requests to mail VAERS forms to soldiers suffering what they believe to be adverse reactions to the vaccine. The military medical facilities are not following this critical procedure, and most are unaware that this can be done themselves.

Studies show that anthrax vaccine alone is not sufficient if exposure occurs, anti-biotic treatment must begin immediately. Is our military prepared for a situation like this, and would our soldiers be able to seek medical treatment immediately if exposure occurred in the middle of a battlefield?

Many are receiving 1 or 2 inoculations before the expiration of their active duty enlistment term. These soldiers do not have the opportunity to complete the inoculation series while on in-active status. Is it necessary to partially inoculate these troops? And, would they need to begin the series again if called back to active duty in a wartime situation?

Finally, in my communications with thousands of service members, I expect the refusal and resigning numbers to continue growing. Is our military prepared for this kind of loss?

Thank you very much for your time.

Mr. SHAYS. You all have made a very valuable contribution and have given us areas to focus in on as a committee that we will not fully get into today, but we will get into. When I come to my questioning, Mr. Dingle, I am going to allow you to go through that list and just give me reactions. But I am going to, at this time, recognize my colleague from Illinois, Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. I just as a group want to say about your testimony that I do not think anyone who is listening to the testimony could doubt one, its sincerity or two, the real commitment that you have to our armed services and that you are—your strong belief in your commitment and as good Americans. So I just wanted to say that that came through to me strong and clear. And that there is clearly a difference of opinion here.

I wanted to ask you if we really know, is it Colonel Handy? You said that there has been no catastrophic occurrence. And given the large numbers of people that have currently had the anthrax vaccine, do you not think that there is something reassuring about that?

Colonel HANDY. Reassuring that the catastrophic event, some kind of catastrophic event has not occurred?

Ms. SCHAKOWSKY. Yes.

Colonel HANDY. When you look at the number of people who will be vaccinated and the risk that is involved with the numbers, eventually 2.5 million people, I find it unusual that we are jumping from in the Gulf war, 150,000 to 2.5 million based on shaky grounds. That is a 17 fold increase in the number of vaccinations that will be given compared to the largest number given previously. I think the risk would be extremely large, in that case, that there certainly is a greater chance, a much greater chance that that could happen.

I also think that given the situation where we have had people in the hospital already, and if you look through the 50 reactions so far, you find some that are kind of disturbing, blackouts, for one. There is one that Lorene mentions on a case that is being reviewed now where there was a behavioral, a severe behavioral problem that occurred with a person who has not had any behavioral problems apparently in his life.

Ms. SCHAKOWSKY. So essentially, you are not comforted. You say that there are—in your view, there is enough evidence that multiplied many times that there could—I am wondering if any of you would say that there is an acceptable level of adverse reaction or if we have to seek out a vaccine where there is none at all.

Mr. ZAID. Congresswoman, obviously, we are at somewhat of a disadvantage of answering what is predominantly a medical question, but obviously you have reactions to vaccines, almost every type of vaccine invariably produces some sort of reaction. That is not the issue.

The issue in this case is the extent of the adverse reactions and the level of it, particularly being that the adverse reactions being seen amongst our troops are up to seven times greater than what the manufacturer and the FDA have essentially approved. And that should be alarming yet I have only seen it downplayed in all public comments. I would love to hear a public comment from the Pentagon in reaction to that. I have seen much of their internal

documentation. Their internal documentation, I can tell you, and I have provided it to the subcommittee, differs from what they have said publicly and as to how they have categorized adverse reactions and the rate of adverse reaction. And if I might, with respect to what you asked for Colonel Handy, there is another story down below the surface that really has not come out to the public. Now those of us that have worked on the issue have been aware of it because we speak very often to family members and service members. The level of opposition has been much greater than has been publicly acknowledged by the Pentagon. It just has not reached the level of punishment.

There were times where I would receive a call and be told that units had 200 people initially trying to refuse the vaccine. Ultimately, it only dwindled down to a few, typically because some were persuaded often they read the information. They felt that they were content enough to take the vaccine. Most cannot refuse because of their level of seniority. They cannot give up the salary. They cannot deal with the possibility of losing a career in the military for this. Some have been threatened. We have had many reports of threats. It is not a widespread policy, but I can tell you it has occurred. We had situations like in Ms. Greenleaf's son's case where opposition to the initial shot occurred, punishment occurred, but then the soldier consented to the vaccine. Those numbers are not being counted.

The real impact upon the military will not be coming from those on active duty. It will come from the Reserve and the National Guard units. We have had almost two, at least two units, for example, Connecticut and at Travis Air Force Base, where the Guard units just up and quit as we have heard, and almost become nondeployable. Now they did not, but we have not just mechanics—my client at Travis Air Force Base repaired equipment—we are talking pilots quitting over this. That is where the impact will be and we have not really seen the true extent as to how the Guard units will react.

Ms. SCHAKOWSKY. I am a little disturbed by that route of argument as well, saying that because members of the armed services have objected to an order then therefore it is by definition our obligation to rethink that order. I mean one certainly would not want to argue that in a combat situation if there was some resistance to going into combat.

So what is it about this that makes it unique that because there have been refusals, more perhaps than you say there are, then we have to rethink our policy?

Mr. ZAID. That is true. There is a grave danger to refusing a lawful order. Under military law, there is an ability to challenge even the lawfulness of an order. Many times I would presume it probably fails. In this circumstance, I think a lot of the reaction certainly comes from a lack of credibility in the Pentagon from past problems. The chairman mentioned some of them earlier. That is not necessarily a reason why to create serious doubts, but that has certainly fueled fear amongst service members.

The true impact comes from when you consider some of the policy implications and again, some of the issues the chairman raised, why anthrax? In fact, internal documentation we obtained in the

lawsuit demonstrated that during the Gulf war when another FOIA requester had asked for similar information on vaccinations, the Pentagon said we cannot release this information. It is harmful to our interests because we would be telling our enemies how many people we vaccinate, what we are vaccinating them against, and what is our stockpile of vaccines. That was back in 1991. The reasoning was if a biological or chemical weapon is going to be used against you, you do not want to tell your enemy that you are vaccinated against that because hopefully they will use something that you are vaccinated against, rather than being hit by something else.

So now from a policy standpoint, I am not a military strategist, but this is fueling a lot of growing fear particularly among the family members. Why publicize this? Would not, as the chairman suggests, our enemies just shift over to another weapon. That is one of the issues. It is a very in-depth process, obviously.

Ms. SCHAKOWSKY. And a number of those questions, I think, are medical questions and the FDA may be able to shed some light on that. I am glad that the chairman said we will have an opportunity there.

I wanted to get into some of the pressure tactics that were used and not at length. I am just concerned, you said that there were five others or five of you total who ultimately refused. Were these kinds of pressure tactics kind of standard operating procedure where you were? Have you heard of others? So when we get these numbers of refusals, are they skewed based on those kinds of tactics—those pressure tactics?

Pfc. LUNDBOM. Ma'am, in my situation, we were pretty isolated. We were on the island of Okinawa, Japan, so we did not really know about any what the other—how other units were handling the situations, but with us, before the shots even came up to be taken, the command took initiative and asked who has doubts about this? Who is confused about this? When they saw the alarming number of people stand up and say well, I really do not want to take this vaccine, including many number of people who were soon to be getting out of the military who would not be allowed to finish the cycle of 18 months. They had classes after classes, counseling and then when we started getting rumors cycled through what the punishments might be: time in prison, up to 2 years, we were told; dishonorable discharges; threatened that you will ruin your military career, you are going to ruin any chance of a successful civilian career. This scared a lot of people because we have people in the unit that have wives, children and other family members that they need to take care of. So this scared a lot of people and when the shots finally came around to it, they pretty much had no choice, but to take the vaccination. And when we were in the theater, when we were told we were going to have the opportunity to ask questions, at first they told us their information that they had and then once they came around to us asking questions, the people answering the questions may have been just a little underskilled in the field, they might not just have had the knowledge, but they could not answer the questions. And with that, the congregation of military personnel became heated and they were quite distraught

and the command halted questions. They stopped questioning and that was it. No more questions. You are taking the shot.

Ms. SCHAKOWSKY. Thank you. Did anyone else want to respond to that?

Ms. GREENLEAF. I would like to make a comment. Dr. Sue Bailey, I believe it was, Dr. Bailey said that there had only been eight adverse reactions reported to the FDA on the vaccine. I have the current VAERS report. You will find that in my written testimony. There have been 84 reported with 6 hospitalization and 2 life-threatening situations. The military medical facilities are doing a horrible job of reporting these adverse reactions. These people are being told they have got the flu, go lie down, you will be OK in a few days. After receiving the inoculations these symptoms start within hours. My son is now suffering adverse reactions from the vaccine and we had to complete the VAERS form ourselves, the military did not do this.

Ms. SCHAKOWSKY. Thank you.

Captain REMPFER. I did have one thing to add if you don't mind. I think myself and Major Dingle, as fighter pilots, seek out root causes for problems. Personally, I have witnessed a very unfortunate event in my unit, one that I think is going to occur in many units across the country in our reserve components and that is the implementation of this policy. As fighter pilots, we tend to look for root causes. I do not think our units are to blame. I think the policy is to blame. I think that many believe and all the questions that are arising show that the policy to be hard to defend. There are many inconsistencies.

I would like to point out just a couple more of the inconsistencies that were disturbing to us and caused us to make these major decisions in our careers. The long-term studies that the Department of Defense maintains by this committee's opening statements concurs are in question, as well, the widespread use. Of late, there was an article in the National Guard Association Magazine that talked about the National Bovine Ranchers Association. They had no knowledge of this vaccine.

Even a comment by Ms. Bailey earlier today, she mentioned that there were 634,000 troops that had taken the vaccine. That number is widely inflated. I think what she meant to say was doses, but I guess my question as a service member is why are we creating a number concerning doses in order to try to create the impression of a greater sample size that is being inoculated? It comes down to trust. These are issues of trust. We are not in a combat situation, but when we are in a combat situation that is a vital element of our ability to perform.

Another example, we had a disagreement earlier about whether or not the FDA had forced the close down of the plant. The Department of Defense continues to maintain, there has been letters to the editor that maintain that the FDA did not cause that. But Dr. Burroughs in his letter, he was sanctioned by the Department of Defense to do a study, agrees and it is in our written testimony that the shut down was due to the FDA

As far as numbers go, most of us feel like the first initial step would be an optional policy so we can continue to sort through the program and the potential problems that there are. It is creating

problems out in the field. We are allowing pregnant individuals not to take the shot. We are allowing religious refusers not to take the shot and if the refusers of the vaccine on other grounds are so few, that perhaps they can be included as well, while we continue to study the issue.

Thank you for your time, ma'am.

Ms. SCHAKOWSKY. Thank you.

Mr. SHAYS. Let me start with you, Mr. Dingle, and ask how you reacted to the first panel. You wanted to make some comments and I would welcome that and I would welcome any other of you making any comments to what you heard in our first panel.

Major DINGLE. Thank you for this opportunity and it may be a little disjointed as I bounce around a little bit and I am not going to go through all of them.

The DOD, panel 1, along with other staff presented a very nice full color presentation for you. One of those large posters was the 42 adverse reactions. General Blanck indicated that he had a nodule and therefore an adverse reaction. I would like to know if he was 1 of those 42, as was General Fisher. He said the side effects of his shots were less than those of other shots that he has received. Are his adverse reactions part of that 42?

Mr. SHAYS. We will find that out. That is a good question.

Major DINGLE. That is a fair question. That needs to be asked.

Mr. SHAYS. You are making me regret you were not on the panel asking questions.

Major DINGLE. Dr. Bailey said that the anthrax was identified, right at the beginning of her opening statement was that it was a critical issue. I was curious to know when that was identified. Was it identified in 1996? 1986? 1976? Also, that number of 42—let me go back to that again. I know of six in Connecticut alone. I have no idea if they have been reported or not up the chain of command. So that is some of the number stuff that I think needs to be—and once again, Mr. Zaid commented on that at length, the numbers game.

If you will give me a couple of seconds to review my notes.

Mr. SHAYS. Sure. In fact, I would be happy to have you review your notes and if you want me to call on somebody else, you can come back.

Major DINGLE. Thank you.

Mr. SHAYS. Does anybody else want to react to the first panel? Mr. Handy.

Colonel HANDY. There was another figure mentioned that the reaction rate was 0.047 percent. That is quite an increase if you just do the math. According to what was accorded earlier in publications throughout the Department of Defense, for instance, the Capital Flyer, Admiral Cowan was noted as saying it was 0.0402 percent. That means the decimal place goes over 2 more points which really gets to be beyond the scope of believability because if you take the 0.0402 percent times the 2.5 million in service that will get the shot, you are saying that only five members in the service will have systemic reactions. So the 0.047 percent, now is 175 if you do the math. Again, 0.047 percent means you move the decimal place over again 2 points. And as we have heard in testimony, the vaccine insert says it is 0.2 percent. That translates to 5,000 serv-

ice members who will get systemic level reactions. Fort Detrick studies as Mark Zaid pointed out, at 1.3 percent, again moving the decimal place over 2 digits, gives as many as 32,000. So the figures are all over the map and it causes a great deal of credibility problems in our opinion.

Mr. SHAYS. Any other observations?

Pfc. LUNDBOM. Actually, I would like to kind of put a few questions out there, if I may, Mr. Chairman. On page 1 of Dr. Sue Bailey's testimony, she—paragraph 2 in about the middle of it, she says, "Extensive immunization tracking, strong commander leadership with medical support", I want to question the command leadership and with the medical support on the lower levels in such like battalions and platoons and squads where people are actually getting vaccinated. We do not all just go to a big hospital at the Pentagon and get overseen.

With my experience of watching all the members in my unit stand in a big long line and get vaccinated without their medical records on hand, and then having our name just simply highlighted through a paper and it is supposed to be put into records later, well, we had members that were on a rifle detail who were going to miss their third shot. It goes first shot, spend 2 weeks, second shot, another 2 weeks, and then third shot. Well, they were on a rifle detail and they could not make their third shot. So they were going to go documentate that they were going to take their shot later than what FDA had approved it for. When they went down to do that, they had found that the first two shots had not been documented inside their medical records. So I just wanted to throw that question out.

Mr. SHAYS. Had not been documented?

Pfc. LUNDBOM. Had not been documented, sir. And also another question thing on the testimony because on page, at about the middle of the page where it says Secretary Cohen approved to implement on May 18, 1998 and again toward the right hand side of the top paragraph below that it says over a 7 to 8 year period, well, that was true when they put it at 2006 to complete the program, but since they bumped it up to 2003 to my understanding. And I just wanted to throw that question out there also. Thank you.

Mr. SHAYS. Any other observations, Mr. Dingle?

Major DINGLE. If you have the moment and please indulge me, maybe about 10 points and I do not necessarily want to generate all the discussion over it. I would just like to enter them in the record as possibly a question for follow up for other investigations.

I will do it chronologically from the beginning of the first panel's testimony. General Blanck stated that guinea pigs were not a good model for studying the effects of the anthrax, especially the aerosolized. If so, why is the most recent study presented, which was presented in September 1998 conducted by Dr. Ivins from Fort Detrick. Their animal was the guinea pig. Why are they spending money on studies using animals that are not conducive. I am not sure—I think there is some problems with using monkeys and stuff, but apparently you do not have those ethic problems with whether it is rabbits or guinea pigs. So their most recent publicly presented study involves the use of the animals they say is not a good model.

General Fisher said, talked about the criteria for filling out a VAERS form was 24 hours off of duty or hospitalization. I have talked with the folks at CDC/FDA that run the VAERS program and that is absolutely different from the folks there and what they would like to see reported. Any reaction whatsoever should be reported and its use basically is that of a post-marketing surveillance program to build the data base for any and all drugs and vaccines, not just the anthrax vaccine, obviously. So I am curious to know why the military definition for a VAERS report, generating a VAERS report is so different than the rest of the society?

General Blanck also stated that he was impressed by a former, I believe general officer, what he said a few years ago that soldiers give up rights when you wear the uniform. I would like to know specifically which rights we give up when we took the oath to serve our country. I do not remember reading or accepting any abrogation of my rights.

Dr. Bailey spoke later on of the threat risks.

Mr. SHAYS. Could I just ask—I do think you give up some. Maybe it is a definition of rights.

Major DINGLE. I am not sure how the term was used, but I would just be interested——

Mr. SHAYS. The military can tell you when to go to bed and when to wake up, when to get up and a lot of things they can tell you to do they cannot tell me to do.

Major DINGLE. Point well taken. I just thought it was a very strong statement. I was not sure that that statement—it stuck in my mind. I thought it can be discounted or whatever you want.

Additionally, later on Dr. Bailey talked about when we were discussing the 50 or so biological agents on the piece of paper there and why we were not, the DOD was not working to protect its members against those threats. She talked about the need for threat risks are made for specific areas in the world and with Iraq being a sensitive one at the moment. Connecticut has lost a quarter of its pilots due to this measure and they will be deploying later next week for a tour in Kuwait.

Mr. SHAYS. How many pilots are we talking about total?

Major DINGLE. Nine pilots have declined to take the vaccine. Eight will eventually be leaving the unit to my knowledge. One is——

Mr. SHAYS. Out of how many?

Major DINGLE. At the time that our take it or leave policy was enacted it was 35 pilots to my knowledge on the base.

So while we have left, being forced out of the military and a career of service because of this policy, either right now or very shortly another Guard unit will be deploying to Northern Watch flying over the same enemy or flying over the same country, Iraq, as we are going to and they do not even know how to spell anthrax at their base. It has not been brought up. It has been mentioned. Those people will be deploying to that area and they have not even addressed this issue yet.

Mr. SHAYS. Mr. Dingle, let me just ask a question that would gnaw me if I did not ask. Your unit is being deployed.

Major DINGLE. Yes sir.

Mr. SHAYS. Is there some logic—can I make an assumption. And how would you counter this assumption that some would find this a convenient way to be deployed? In other words, they can blame it on anthrax and therefore not have to take this assignment.

Major DINGLE. He wants to respond, but I am not really sure what you are asking.

Mr. SHAYS. Sure. What I am asking is this. Your unit is being deployed at an active duty, correct? Is that correct?

Captain REMPFER. We are not being activated. We will be put on active duty orders. We are not being activated, but we are supplementing the forces that are over in the area of responsibility. I for one was on the deployment list, along with many of the other pilots.

Mr. SHAYS. Let me just ask you for the record and we will just take the best answer you have. Could some use this as a means for not being deployed? Blame it on anthrax and therefore be reassigned or be able to resign?

Let me ask you this first question. Do you have the ability to resign from this duty for any other reason?

Major DINGLE. Yes sir. We could walk away from our citizen soldier responsibilities, but we do not choose to do that. This is the issue that came in the way of our service.

Mr. SHAYS. Let me put it this way. Let me take my time here. Your unit is being deployed where?

Major DINGLE. Kuwait, sir.

Mr. SHAYS. It is going to Kuwait in a theater that is pretty hot. In your case, Mr. Dingle, and I believe the sincerity of all of you. I am not questioning your sincerity, but I want to put on the record by your refusal to take anthrax, you are not going to be going to Kuwait, correct. Is that true for both of you?

Major DINGLE. That is correct, sir.

Captain REMPFER. Yes sir.

Mr. SHAYS. If you did not want to go to Kuwait, would you be able to not go for another reason, just simply say I am getting out or would you not have to go to Kuwait because you have signed up for a certain period of time?

Major DINGLE. Sir, this is a—the way the Guard and Reserve works, to the best of my knowledge and——

Mr. SHAYS. Sure.

Major DINGLE. I am just a fighter pilot, but I do not want to slight my military knowledge in all other areas, but it is voluntary. You can volunteer to go on the deployment or not. Most people sign up to go on these deployments. So there are people that have just declined to not participate in this. It is not—depending on the seriousness of the deployment or the area of the world, people's personal civilian careers, what is going on in their civilian jobs, people either volunteer for deployments or not. It is not a case of everybody goes. In order to make a whole unit go, and make it mandatory and an order to go, I believe that Congress has to activate the unit.

Mr. SHAYS. OK. That is your knowledge and it may be the accurate one.

Captain REMPFER. Sir, and for the record, if I may.

Mr. SHAYS. Sure.

Captain REMPFER. I was on the deployment roster. I was ready and willing to go and so were most of the other gentlemen that have left the unit as a result of this policy. I personally spent 122 days in Kuwait last winter on two back to back deployments and I was more than willing to go again.

Mr. SHAYS. I hear you.

Captain REMPFER. I personally have been in touch with many Guardsmen and Reservists around the country. Many agree after self-educating themselves on this policy and looking into the issues revolving around it, that this could stand in the way of their continuing to serve. It has just begun in the Guard Reserve and we are already seeing the losses.

Mr. SHAYS. One of my fears is that the seven—or is it eight—who are basically refusing to take anthrax and therefore will not be deployed. And if they leave the service it will be recorded as they are not necessarily liking the pay or you are not liking some other thing and that we need to—it would be interesting to see how the eight of you will be recorded by the military.

Captain REMPFER. And sir, I think that is very important that we record it properly. That we attribute the losses appropriately. Unfortunately, both the unit and the Department of Defense mistakenly reported only two pilots actually being lost from the unit due to anthrax. In fact, it was all eight pilots that are transferring out of the unit that have been lost to anthrax. We put a letter together to that effect. We included it in our written testimony and we feel it is most important that we attribute it appropriately.

Mr. SHAYS. Now will both of you give up flying or will you be flying somewhere else? The nodding does not get recorded.

Major DINGLE. Sorry about that. That makes the cameras, but not the tape. If this program turned around tomorrow, we have been told that we are no longer welcome in our unit. I do not anticipate any unit asking us to fly for them now or in the future no matter what the outcome of this policy is, so I have resigned to the fact that I am going to hang up my G-suit and never fly for the U.S. military again.

Mr. SHAYS. Do you fly commercially? Do you fly professionally?

Major DINGLE. Yes sir.

Mr. SHAYS. What do you fly?

Major DINGLE. I fly Boeing airplanes.

Mr. SHAYS. You, sir?

Captain REMPFER. McDonnell Douglas airplanes, sir.

Mr. SHAYS. But it is a different kind of activity, is it not?

Major DINGLE. Absolutely. It is a totally different type of flying.

Mr. SHAYS. So you are giving up a real love, are you not?

Major DINGLE. Yes sir. It is in fact, the military flying is how I got into it and the commercial flying is a secondary endeavor that occurred later.

Mr. SHAYS. Thank you. Yes sir.

Captain REMPFER. And if I may, sir, I think it is a very important distinction to turn around that citizen soldiers are leaving the service of their country in order to concentrate on their families or civilian professions. I would like to turn that right back around and say the reason we are serving is because we want to serve our country and if our families are important to us and our civilian ca-

reers are so important to us, we have been for a long time making a sacrifice to serve and we wanted to continue to do so.

Mr. SHAYS. Thank you. I know I have just been focusing on the two of you because I wanted to clarify termination here, but I want you to react to Mr. Lundbom's story and tell me how it is different from yours because it is different.

Major DINGLE. It is absolutely different, sir. He is active duty and is under the U.S. Code Title 10, I believe, I am not sure the Marines, but the active duty, UCMJ. We are, technically, we are militiamen. And unless we have been federalized by the President, we work for the State, for the Governor. We come under a completely different set of UCMJs and we basically wear a couple of different hats and today I am a civilian. When I go and I am on some sort of military pay status, that is when I put on my hat.

Mr. SHAYS. Tell me how you react to his story. It is different in terms of how he interacted with his superior officers?

Major DINGLE. To me, it is really disheartening to hear that type of story. As an officer, I think all officers, and we do agree, I will even agree with the Surgeon General that taking care of our folks is a top priority in all of the decisions and things that we do. So it is disheartening to hear stories of this kind of treatment.

Captain REMPFER. And if I may, I would like to implore everyone to go back to the root cause of what might be causing the challenges to the UCMJ and what might be putting this great burden on the field commanders out there in the country. It is the anthrax policy and the controversies that revolve around it.

Mr. SHAYS. Let me conclude this part and then I am going to recognize the ranking member of the committee. We have 27 boxes that basically we have gotten from the Joint Program Office. We have gone through about 5 of the 27 boxes. And one of the documents I have before me is titled "Procurement of Anthrax Vaccine Single Source Versus Additional Site" and it just kind of speaks in one way to a point you made, Mr. Zaid. It has facts A, B, C and then 1, 2, 3 under C and then it has 4 under C and then D and then E says, "the original license for AVA, anthrax, was supported by efficacy data obtained in a very small study of humans working in the wool sorting industry during the 1950's and 1960's. More stringent FDA regulatory requirements for a vaccine produced by another manufacturer would likely require the development of a surrogate efficacy model. This is high risk because no model currently exists."

The implication is that the FDA standards today are quite different than they are 30 years ago.

Mr. ZAID. That is right.

Mr. SHAYS. And that we are not quite sure how the FDA would view this vaccine today.

Mr. ZAID. I believe I recall that document, as a matter of fact. The 1970 approved version was based on a 1962 clinical data study that was submitted, just one. It was not until 1972 that the FDA changed their requirements for biological vaccinations to make more stringent standards for efficiency studies and effectiveness studies. When Desert Shield started, and I provided some of this documentation to you and I can give you even more, there was a task force put together called Project Badger that looked into get-

ting enough vaccinations for everyone in time for Desert Storm. And at this early date, even 10 years ago, the Pentagon knew that the current series that the FDA had approved was unnecessary. In fact, the history of it was that in the 1950's a worker arbitrarily decided six doses was appropriate. And I will tell you, everything I saw is from Defense Department documentation. This is all from internal government documentation provided to us in the FOIA lawsuit.

They tried to rush through to get the vaccinations. They approached countless laboratories. The problem was the FDA and, in fact in one document they indicate that if they are going to have a problem with the FDA, they are going to have to put some pressure on them and that is where the waiver came from.

Mr. SHAYS. Let me just conclude my statement and then recognize Mr. Blagojevich. I made an assumption that I brought to the table even before we had testimony from the first panel that this vaccine was in widespread use in the private sector. Your number of 300 to 400, even if it was 3,000 to 4,000, compared to what I thought it was, is a big surprise to me. So it will be interesting to nail down that number.

Mr. ZAID. The reason why there is only one major manufacturing plant is that it is not a cost-effective, profitable vaccine because nobody is using it besides the military. And it is very tough to manufacture in the sense that for spore-like vaccinations, you are not able to manufacture other types of vaccines in the same vicinity. So it is very expensive, not cost per dose, but if you are going to make it your livelihood, you better have a good customer, like the Defense Department, who all of a sudden wants to vaccinate 2.4 million people.

Mr. SHAYS. Thank you. Mr. Blagojevich.

Mr. BLAGOJEVICH. Thank you, Mr. Chairman. Private Lundbom, I am going to be looking at you here on this question, but anybody is free to answer the question and if feel you can go lower than Private First Class, Private Lundbom, do not answer this question. We were given a briefing by the Department of Defense prior to this hearing. At that briefing, they provided us with a status report on the number of adverse reactions to the VAERS reporting system. We have that right here. This printout was from February of this year and it shows that the Army reported 22 adverse reactions. The Navy reported 5. The Air Force reported 11 adverse reactions. But the Marines list no adverse reports.

The question to you, Private, or anyone else, is do you believe this is a result of pressure by commanders, especially in the Marines not to report adverse effects?

Pfc. LUNDBOM. First of all, I have extreme respect for the U.S. Marine Corps and for my command. Looking into the situation and the punishment that I received, and to respond to the comments you made about losing rank again, I have received new information just now from Congresswoman Ellen Tauscher that my court martial has been dropped now and by my merit they are granting me an Admin. Separation under General with Honorable Conditions. But to answer your question——

Mr. BLAGOJEVICH. Maybe you should not answer the question in view of that, Private, why do not we just ask someone else. We do not want to get you in trouble.

Mr. SHAYS. Let me just say this to you. With respect to the military, they have cooperated with us and they respect your testimony and I know that you are saying that in good faith. But I just want it clearly understood. I do not think anything of ill will will come your way by being honest with us and being respectful of the service that you love.

Pfc. LUNDBOM. I can answer the question that is not in any disrespect. With the Marine Corps, as far as I am concerned, and this is a personal opinion, the Marine Corps is the best fighting unit in the U.S. military, but I am a little biased because I am part of that branch. But sitting where I sit, we have so much pride in ourselves and what we do and I think when say we complain about something, complain about an effect, a Marine to himself, unless you are in a lot of pain, does not even worry about complaining about it because it is no big deal. That is the way I think most Marines feel. That is not the way they are told to feel. That is just the way they feel. And I think that is why the reports are so low, just because it is in our heads, it is in our hearts.

Mr. BLAGOJEVICH. You are tough Marines.

Pfc. LUNDBOM. We are tough and we stick it out. And if it was something serious, I am sure they would have reported it, if they felt like their health was in danger like long term sickness or something like that, but with just nodules on the arms and sore arms. People have told me, my arm is sore. My arm has been sore for a week, but they do not feel like it takes precedence to report it just because they do not feel it is necessary.

Mr. BLAGOJEVICH. OK, so based on what you have seen, Private, or what you have not seen, in other words, you have not seen any indication that any commanders in the Marine Corps are putting pressure on any of you guys not to come forward.

Pfc. LUNDBOM. No. No pressure.

Mr. BLAGOJEVICH. OK, thank you very much, Private. Good luck to you.

Ms. GREENLEAF. I really feel like the medical facilities are not instructed on what to do and when to report these adverse reactions. I am aware of several cases where the service member went into the medical facility with a rash, vomiting, bloody diarrhea and they were just told they have the flu. I am not sure that they are aware that this needs to be done.

Colonel HANDY. Congressman, I might also mention that I looked at the swine flu vaccine debacle in the 1970's and the Journal of the American Medical Association had an article on that where they reported that the rate of adverse reaction reports from the military were seven times fewer than that in the civilian population and I do not know what the causes were, but it was an interesting phenomenon. So there is perhaps precedence there, perhaps due to the culture.

Mr. BLAGOJEVICH. Right, more cultural than any kind of purposeful cover-up. Does anybody else want to address that?

Mr. ZAID. I think that is right from a command level. I certainly am not aware of either any of my clients or any of the service men

or their families that have contacted me that anyone is being threatened to not report adverse reactions. There is a mentality among the military that unless, as the private said, you are truly suffering, do not say anything. I certainly have received reports that medical personnel have down-played, as Ms. Greenleaf has said, the significance of what our reactions to something, whether or not it is related to the vaccine, I certainly do not know, but within a point in time sufficiently close in proximity to the vaccination that one would think the military medical personnel might want to explore a little further. But they are telling people that they are not going to file an adverse reaction report. That is occurring. I am not saying it is widespread, but there have been at least isolated reports of that.

Mr. BLAGOJEVICH. Thank you.

Mr. SHAYS. We are going to conclude, but I welcome any of you having a closing statement, any observation you want to make. Is there anyone?

Mr. ZAID. Yes sir. Can I just say just a couple of things in response to some comments made on the first panel real quick and I can meet with your staffers at a later date about this.

A couple of things that had been said. Coming from the standpoint in at least the spring of 1998 when I was very much involved on a more global scale when more in the Persian Gulf were being vaccinated, many of those from the Independence that were contacting me and the John Stennis, were not having notations placed into their personal medical records. Now that might have changed. I hope and I am sure it is better now. What is significant about that—though let us go back to the four conditions that were supposed to have been met before the program was implemented and that was a key facet of it—was that there had to be adequate medical recordkeeping. There was not, at least in the initial few months. And I would encourage the committee. I think I attached it as exhibit 2. The independent evaluation of the vaccine. I dare say it is a document that you or I could write very easily by doing public research of available literature. There was no independent testing or independent evaluation of this vaccine. And I will leave it to you just to read the document and you can come to your own conclusion on that.

Much of the data that has been the basis for the Pentagon's decision is unpublished, and let me just say finally in response to one thing Dr. Bailey had said about the cocktail mix which you know from your Gulf war syndrome interest has been a significant factor. There was a memorandum, and I have given it to your committee, authored for Dr. Edward Martin in 1995, who was the principal Deputy to the Assistant Secretary of Defense—I do not know if that was Dr. Bailey at the time—from Brigadier General Ross Zautchuk at the U.S. Army Medical Research and Material Command. And it said that a limited study was conducted at Fort Bragg and Fort Detrick and revealed that the combination of anthrax and botulinum vaccine did produce mild and moderate reactions as well as a few serious side effects. So the government has data that is inconsistent with what is being publicly reported to our servicemen, the public and I dare say to the Congress.

Mr. SHAYS. Thank you.

Colonel HANDY. Mr. Chairman, just a couple of quick items. It gets to a question that Ms. Schakowsky asked about what is different about this particular program or vaccine and I think two areas are worth exploring and I know you are going to have a hearing on the doctrinal area and I think that is critical because we keep hearing the idea that this threat, the biological warfare threat, and in particular, the anthrax threat, it is not a matter of if, but when. This is the kind of mentality that occurred also in the swine flu vaccine problem.

The fact is the literature review and even during that situation showed that the risk was extremely small. The literature review now says the same thing. It is also incalculable. The problem with the phrase, "it is not a matter of if, but when" suggests that there is a 100 percent probability that there will be an anthrax attack and that all service members will be affected. Therefore, we must vaccinate all service members. I think there is a patent fallacy in attempting to create that kind of logic and I will appreciate the results of that investigation.

The other thing that really gets to her question about the differences as to why this program is different. For most of I would think, the members of the service, having 25 shots for one particular vaccine over a 20 year career is an amazing difference. That is what we are really talking about. With the standard vaccines that our members have to have when they come in the service or even that they get for deployment and especially the pilots get a lot of those, this is still a significant increase and in most people's minds that is an imposing threat that is probably suspected to be more probable than an actual anthrax attack. And I think that is a big difference.

Mr. SHAYS. Very interesting. Would anyone else like to make a comment?

Major DINGLE. I would just like to thank you once again for the opportunity to speak before the panel.

Mr. SHAYS. Let me just say, you all have been very interesting and very helpful and very sincere. You have served your country in various ways that are quite significant and you have taken a stand in something you believe in and I really respect that from all of you and I thank you for coming. Stay in touch.

[Whereupon, at 1:05 p.m., the subcommittee was adjourned.]

[Additional information submitted for the hearing record follows:]

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ANTHRAX VACCINE IMMUNIZATION PROGRAM

Statement by

Jane M. Orient, M.D.
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Submitted to:

Subcommittee on National Security,
Veterans Affairs and International Relations

Committee on Government Reform
U.S. House of Representatives

April 1, 1999

It has also been alleged by witnesses before this committee that adverse reactions are underreported. Long-term risk is unknown: appropriate studies have not been performed, and record-keeping has been inadequate.

INFORMED CONSENT MUST BE OBSERVED EVEN BY MILITARY

No consent can be informed if the information is based on science that violates fundamental precepts of honesty and integrity and lacks a proper research design that can disprove the hypothesis of safety if indeed there are significant adverse effects.

As pointed out by Grodin and Annas (authors of an article on legacies of Nuremberg for medical ethics and human rights, published in JAMA in 1996 [276:1682-1683]), the entire point of informed consent in combat is "not to prevent soldiers from obtaining whatever protection may be afforded them by an investigational agent that has not been adequately tested, but rather, it is to give them the choice of whether they think the 'protection' is worth the risks of adverse effects" (Grodin MA, Annas GJ: JAMA 277:712-713, 1997).

RECOMMENDATIONS

While the spotlight is on the military, we would also like to draw the committee's attention to the increasing demands for mandatory vaccination of civilians, even without the exigencies of war or the demands of military discipline. At a time when "patient's rights" are the focus of so much concern, we must not lose sight of the right to refuse a medical treatment as well as to refuse to participate in an experiment (or the functional equivalent thereof). Access to information necessary to reach a truly informed, independent judgment is also essential.

The military and scientific community should give consideration to the development and use of a newer, more effective vaccine. Several are in late-stage development which are more effective than the current vaccine but do not cause toxicity as reported by the Army's own Bacteriology Division at the Army Medical Research Institute of Infectious Diseases at Ft. Detrick, Maryland (*Journal of Biological Chemistry*, 264[32]:19103-7, 1989).

A careful examination of the nation's vaccine policies, with respect to both military and civilian populations, is overdue. Some issues are scientific, to be sure, but basic constitutional rights and fundamental premises of medical ethics are also at stake.

The Association of American Physicians and Surgeons stands ready to work with this committee to help ensure the safety and well-being of our citizens and soldiers.

The Association of American Physicians and Surgeons is a nationwide organization of physicians of all specialties, dedicated to the practice of private medicine under the traditional ethical code of Hippocrates since 1943. Dr. Orient, AAPS Executive Director, is nationally-recognized author of medical textbooks, such as The Art and Science of Bedside Diagnosis, Assistant Clinical Lecturer, Internal Medicine, University of Arizona College of Medicine and a board-certified internist. She is also President of Doctors for Disaster Preparedness.

The Association of American Physicians and Surgeons respects the need of our military forces to maintain order and discipline as well as to protect our troops to the best of their ability and judgment. We also recognize the threat of biological warfare.

Because of this threat, the U.S. military plans to vaccinate 2.4 million personnel against anthrax, including more than a million "citizen-soldiers" who are members of the National Guard and Reserves. A number of soldiers are risking court martial rather than accept the vaccine because of concerns about safety. Some believe it may be related to the Gulf War Syndrome.

On the other hand, some civilians are asking questions about how to obtain the vaccine because they wish to protect themselves against a highly fatal disease, which has unquestionably been weaponized by many possible antagonists.

As scientists, we are concerned with limited testing before approval of vaccine and the lack of subsequent clinical trials, the limited efficacy of the vaccine and the adverse effects on patients, both systemic and localized.

For the purposes of this statement, we will focus on the ethical implications of these concerns. The question of mandatory vaccination of all forces against anthrax raises a number of questions of medical ethics and constitutional rights:

- adherence to the Nuremberg Code;
- scientific integrity;
- and the expansion of forced vaccinations to the civilian population.

NUREMBERG CODE IS BASED ON INFORMED CONSENT

The Nuremberg Code was promulgated by four American judges acting under the authority of the U.S. military, following American rules of procedure. The key principle is the requirement for informed, voluntary consent by the individual subject of experimentation. The Code makes no exceptions for members of the

military or the exigencies of war.

Although U.S. law has not made authoritative use of the Nuremberg Code, the guidelines adopted by the National Institutes of Health in the mid-1950s were based on the "ten commandments" of Nuremberg, and provided that **"[e]very volunteer must give his full consent to any test, and he must be told exactly what it involves."**

During the Persian Gulf War, the FDA granted a waiver permitting the use of pyridostigmine bromide and anti-botulinum vaccine, without consent. This was the first instance in which an official government agency officially sanctioned the direct violation of the Nuremberg Code (see Milner CA: "Gulf War guinea pigs: is informed consent optional during war?" *Journal of Contemporary Health Law and Policy* 12:199-229, 1996).

ANTHRAX VACCINE: TREATMENT OR EXPERIMENTATION?

A distinction must be made between treatment and experimentation. It may be asserted that anthrax vaccine (unlike pyridostigmine bromide as used in the Gulf War or anti-botulinum vaccine) constitutes "treatment," or that it is not experimental because of being declared safe and effective by the FDA.

In fact, the anthrax vaccine was licensed by the FDA before efficacy studies were required. Its efficacy against inhalational anthrax has been questioned. Moreover, it is likely that an adversary would use a strain (possibly genetically engineered) against which the vaccine is not effective (see Ivins BE, Welkos SL: "Recent advances in the development of an improved, human anthrax vaccine." *European Journal of Epidemiology* 4:12-19, 1998). British epidemiologists suggested that troops be publicly randomized to receive active vaccine or placebo, clearly implying that many consider the vaccine to be experimental (Ness AR, Harvey I, Gunnell D, Smith GD: "All troops sent to Gulf should be randomised to receive anthrax vaccination or placebo." *British Medical Journal* 316:1322, 1998).

SAFETY OF VACCINE IN QUESTION

The safety of the vaccine is in dispute. One issue is reported serious deficiencies in the manufacturing process or in the "updating" of expired lots. The systemic reaction rates reported in the government's own data have been as high as 1.33%. Consider that a risk of 1 in 100,000 is considered to be of regulatory concern for "involuntary" (public) risk and 1 in10,000 for "voluntary" (occupational) risk. (The risk of systemic vaccine reaction, for comparison, is 1,330 in 10,000, or 13,300 in 100,000, or 133,300 in 1 million.)

STATEMENT FOR THE RECORD

Submitted by

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Hearings on

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

March 24, 1999

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

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

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

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

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

1. VACCINE NO SUBSTITUTE FOR OTHER PROTECTIONS

Because of the wide diversity of agents that could be used, no single vaccine or combination of vaccines and antidotes is sure to be effective: thus, there is no substitute for shelter and adequate protective gear. We believe that both military and

civilian populations should have access to the type of NBC shelters that are standard in Swiss homes.

2. LACK OF CLINICAL STUDIES

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

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

3. MEDICAL EFFICACY IN DOUBT

Textbooks of military medicine and *The Medical Letter* (40:52-53, 1998) state that the anthrax vaccine is ``safe and effective." The British secretary of state for defence was vaccinated on camera in an effort to convince service personnel and the public of the vaccine's safety. However, several epidemiologists at the University of Bristol described the state of current thinking as one of ``clinical equipoise" and recommended randomizing troops to receive or not receive vaccine (*Br Med J* 316:1322, 1998).

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

4. VACCINE NO DEFENSE AGAINST NEW STRAINS OF ANTHRAX

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

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

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

6. POOR RECORD KEEPING & FOLLOW UP STUDIES

Fear and mistrust are fueled by poor record-keeping about chemical exposures and vaccines in the Gulf War. There are no adequate records of recipients of special immunizations not in general use (anthrax and botulinum) (Wegman DH et al.: Am J Epidemiol 146:704-711, 1997). The British defence ministry has also admitted that ``medical record-keeping in the Gulf was not satisfactory," according to researcher Alan Silman of the University of Manchester (Nature 384:604, 1996). Moreover, ``the MOD [ministry of defence] suffers from an excessive culture of secrecy" (Nature 390:3-4, 1997).

7. EXPANSION OF MANDATORY VACCINES TO CIVILIAN SECTOR

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

RECOMMENDATIONS & CONCLUSION

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

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

toxicity could make BCTP a promising candidate as a broad-spectrum post exposure decontamination agent.

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

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