

**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 Defense Department has publicly acknowledged. Senior Pentagon officials have publicly alleged that those refusing the vaccine have been misinformed, the victims of a paranoid Internet community, or the prey of small groups with agendas. These allegations are false. 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, it appears that fear and dissention has spread throughout the services. 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 strategy was to challenge 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 possibly come from his participation in the experiment.

As a result of Nuremberg, various laws were enacted to ensure that the notion of informed consent was upheld. Federal funding cannot be used by the Department of Defense for research involving a human being unless "the informed consent of the subject is obtained in advance." Safeguards were established to ensure that both Congress and local civilian officials are made aware of any testing of a chemical or biological agent.

The Nuremberg code, in fact, 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), that waived the need for the Defense Department to obtain informed consent. Some believe the FDA was strong-armed into providing such an extreme waiver. 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." The court refused to intervene particularly because the "DoD's decision to use unapproved drugs is precisely the type of military decision that courts have repeatedly refused to second-guess." Even though the Defense Department was also collecting efficacy information while utilizing the experimental drugs under a FDA-waiver of informed consent, the plaintiffs' arguments that unlawful experimentation was being conducted was rejected. "The primary purpose of administering the drugs is military, not scientific. The fact that the DoD will collect information on the efficacy does not transform the strategic decision to use the unapproved drugs in combat into research."

Upon appeal, although the court acknowledged that "deference is owed to the political branches in military matters", it did not agree that "judicial review of the matter here at issue is out of order." Nevertheless, after further review the Court of Appeals deferred to the judgment of the FDA and still dismissed the case.

## **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;
  1. 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.

Alarming, 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 willnilly 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.

### **THE PROBLEMS WITH THE PENTAGONS' AVIP**

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 the 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."

Criticism of the program was inevitable given the Pentagon's history. Questions regarding informed consent, particularly after the horrendous lack of appropriate medical record-keeping experienced during Desert Shield/Desert Storm, and cries of "guinea pigs" were expected from the outset. All the more reason why it is shameful that the anthrax vaccine controversy was not resolved much earlier by the Pentagon.

### **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 low point includes the use of Agent Orange. Both the FDA and the Presidential Advisory Committee on Gulf War Illnesses criticized the Pentagon for its past history of using 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 that 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. Again, the issue is not as much whether any specific historical incident is factually accurate or not, but the credibility, or more precisely lack thereof, of the Pentagon to implement new medical programs. Concern is heightened when the program itself is fraught with controversy, as is the anthrax vaccine.

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

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 has emphasized 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 widespread 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 any significant quantity. In one year, nearly six times 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 inoculation program which has never been seen before in the history of the anthrax vaccine - literally one hundred times more people, each of whom are involuntarily being subjected to the vaccine.

Repeatedly, myself and others have submitted requests for supporting documentation of the Pentagon's assertions that the vaccine is widely used and lacking any long-term ill effects. Invariably a deliberate non-responsive answer is provided with a mere standard citation to the long history of the vaccine with no known reported adverse reactions. Another favorite line is 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. And one that should be properly explored. But no one is calling for the initiation of 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 nearly three decades among veterinarians and live-stock workers. A form of the anthrax vaccine has, in fact, existed in this country for nearly half-a-century. How difficult would it be then to locate several thousand individuals who once took the vaccine and, after taking into account all appropriate variables, examine their health? Do any now suffer from cancer, or leukemia or Alzheimer or any medical malady whatsoever? When 2.4 million lives are at stake, is it not worth the effort to try? Indeed, is it not the lawful or moral responsibility of the Pentagon to undertake such an effort? Yet the Defense Department has not, nor has it shown any willingness to do so. Instead, it offers excuses as it cannot answer the question.

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 have been conducted. 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. That is a dangerous way to operate, particularly when millions of lives are at stake. 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.

There can be no dispute that there is a dearth of studies examining any potential long-term effects of the anthrax vaccine. The important question is why the Pentagon will not admit this fact.

#### **D. Pending IND Application To Modify The Number Of Shots And Intended Use Of The Vaccine Calls Into Question The Necessity Of The AVIP**

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

On September 20, 1996, Michigan Biologic Products Institute ("MBPI"), 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 as 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, and 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 any relevant studies undertaken in support thereof.

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 to affect 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 some way? The Subcommittee should require the Army to provide a more detailed explanation.

## **E. Adverse Side Effects Have Been Significantly Higher Than Reported**

According to the Manufacturer's Label:

Mild local reactions occur in approximately thirty percent of recipients and consist of a small ring of erythema, 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 have even refused to file adverse reaction reports. In fact, they have attempted to convince servicemen that the effects they were encountering had little or nothing to do with the anthrax vaccine.

It is vitally 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 simply geared up their public affairs machine. Suddenly, systemic reactions of 0.2% or more were now labeled as "very rare" and fever and chills became re-categorized as a "severe local reaction". As I do not possess sufficient medical expertise on 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 these types of reactions as systemic and this calls into question the actions and motivations of the Defense Department to assert otherwise.

## **F. Public Remarks Of Pentagon Officials Have Fueled The Debate**

The fault for the growing hysteria that is spreading throughout the military branches must also 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.

Despite realizing at the outset the many problems and criticisms that would arise from a total force inoculation program, the Pentagon nevertheless still has a great deal of work to do and lessons to learn.

## **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 our vaccine, or the use of an entirely different biological or chemical weapon (certainly enough choices exist) for which no adequate vaccine is available. Or, perhaps the Pentagon's decision is intended to merely deflect the weakness of our detection capability and inherent 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. Indeed, the program was so secret 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 have been, of the secrecy during the Gulf War regarding 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 have used any of its known biological weapons, the Defense Department was hoping it would be one of those for which troop vaccinations had been given, rather than one that was not. Following this rationale to its logical conclusion, have we not set ourselves up for potential defeat before even entering battle?

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 examine the real 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.

One thing is clear. Sometimes the lines between myth and fact are blurred. Substantive information regarding the anthrax vaccine represents just such a line.

## CONCLUSION

Mr. Chairman, it is a sad fact that we regulate industries, such as machinery and automobiles, far better than we do those industries that affect what may be placed within our own bodies. The anthrax vaccine currently in use for the 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 questionable 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 anthrax program 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 truly 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 or perhaps safe 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.