

Opening Statement

Chairman Dan Burton

Government Reform Committee Hearing

**“Anthrax Vaccine Immunization Program – What Have We
Learned?”**

Tuesday

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11:00 am

2154 Rayburn House Office Building

Washington, DC

Good morning. It has been almost one full year since the full committee received testimony regarding the anthrax vaccine program. It's also been seven months since the Committee released the report prepared by the National Security Subcommittee, chaired by Mr. Shays.

In that time, we've continued to see serious adverse events to this vaccine. We have continued to hear about dedicated men and women leaving the armed services over this program. And we've heard of many others who have suffered administrative and judicial punishments for refusing to subject themselves to a vaccine. A vaccine that is being used by the Defense Department for the same indication that Bioport has an Investigational New Drug Application (IND) ongoing with the Food and Drug Administration. The Defense Department is giving this investigational vaccine without informed consent. Doing research on our troops without their knowledge or permission is wrong. I intend to see that someone within the Defense Department is held accountable for this.

The Defense Department chose to ignore the recommendations of the Government Reform Committee. However, one-by-one, our concerns are being proven justified. The Committee raised concerns that a force-wide countermeasure to the threat of weaponized anthrax on the battlefield with a vaccine was unrealistic.

The Defense Department has repeatedly stated to the public and to Congress that anthrax is the number one biological warfare threat to our troops. They may be right. If they truly believe that, then why is it that they've done such a poor job of providing quality suits that will protect against anthrax and other biological and chemical agents; masks that fit properly which will offer protection, and adequate medical protection to our troops?

I continue to believe that this program will not adequately protect our troops in the event of a battlefield use of weaponized anthrax. The Defense Department knows that even if our troops are vaccinated with all six doses of the existing anthrax vaccine, they will not be completely protected. A significant number of men and women will still become sick and die if exposed to the strains of anthrax that this vaccine was designed to protect against.

We also know that there is no existing scientific evidence that this anthrax vaccine will provide any measure of protection against genetically modified strains of anthrax. We know from published scientific articles that genetically modified strains of anthrax do exist. They were produced in the former Soviet Union.

The Committee raised concerns about that the program, as it is structured, was not sustainable. This has proven to be true. On July 17, the Defense Department announced a temporary slowing down of the mandatory force-wide program. At this time, the sole-source manufacturer of the anthrax vaccine (Bioport) has failed to pass FDA inspection to renew manufacturing and distributing the anthrax vaccine.

They have failed inspection, even though taxpayer dollars have been poured into this facility. Last year, the Defense Department offered over twenty million dollars of extraordinary relief to Bioport. Even with this relief, they have not been able to pass inspection.

Additionally, the FDA and the Defense Department are sparing no expense to offer consultants, who at taxpayer's expense, will go to Michigan and help Bioport get their act together and eventually pass inspection.

The Defense Department leadership under this Administration has established a practice of speaking out of both sides of their mouths on these issues. Attached to this statement is a list of questionable statements made by Defense Department and FDA officials. This list shows that on numerous occasions, officials, including those before this committee today, have given different answers depending on who's asking the questions.

For example:

- § Secretary Cohen stated that before implementing the Anthrax Vaccine Immunization Program, four conditions would be met. One of those conditions was a review of the medical aspects by an "independent expert." The average American would think that he meant an anthrax expert. In March of last year, Dr. Sue Baily, then Assistant Secretary of Defense for Health Affairs, testified to Mr. Shays' subcommittee that "the safety of our anthrax vaccine immunization program was confirmed by an independent review of the program by Dr. Gerald Burrow, the Special Advisor for Health Affairs for the President of Yale University." As it turns out, Dr. Burrow is a Professor of obstetrics and gynecology. In an April 1999 letter to Mr. Shays, Dr. Burrow admitted that he made it very clear to the Department that he had no expertise in anthrax and that he was conducting the review out of his sense of patriotism. Yet, the Department misrepresented the "independent expert review" to Congress and to its military members and moved forward with the program.
- § Lieutenant General Ron Blanck, then the Surgeon General of the Army, testified before the House Armed Services Committee in September of last year. He said that the anthrax vaccine would offer protection against all strains of anthrax. Dr. Arthur Friedlander, a Senior Military Scientist is here today. He authored the only peer-reviewed efficacy study on anthrax. In the 1999 edition of the medical textbook, *Vaccines*, he wrote that the current anthrax vaccine is unsatisfactory for several reasons, including that there is evidence in rodents that the efficacy of the vaccine may be lower against some strains of anthrax than others.
- § In regards to genetically modified strains of anthrax, in April of this year, General Blanck told the Senate Armed Services Committee that the Department continues to "hear rumors" about these strains. The fact is that in 1997, Russian scientists published an article about the existence of genetically modified anthrax strains in a British medical journal. The Defense Department played that down in the hearing.
- § Mr. Cragin, the Principal Deputy Assistant Secretary of Defense for Reserve Affairs, told Mr. Shays in September of last year that if someone in the National Guard or Reserve is going to resign rather than take the anthrax vaccine, they would not be subject to any penalties. However, the guidance given to Air Force Reserve commanders was not in line with Mr. Cragin's testimony. The Air Force instructed its commanders not to allow transfers of US Air Force Reserve personnel to non-mobility positions in the Reserves unless the individual agreed to take the anthrax vaccine. These reservists were told they would have to take the vaccine before being transferred, even though the new position was not a part of Phase One vaccine schedule.

§ In May of this year, Mr. Cragin sent a letter to thirty-five members of Congress in response to concerns about the program. He suggested an endorsement of the Anthrax Vaccine Immunization Program by the American Public Health Association by referencing a communicable diseases manual published by the Association. The fact is that the Association adopted a policy statement in 1999 urging the Defense Department to delay any further immunization against anthrax using the vaccine, or to at least make it voluntary. The policy statement was issued because of the controversy in the medical literature about the efficacy of the vaccine, the lack of valid monitoring of its potential adverse effects, and the stance taken by the United Kingdom and other allies that the receipt of the vaccine remains voluntary among their troops. The Defense Department was aware of this policy statement and chose to misrepresent the position of the nation's largest public health association.

Today we will hear from two of our colleagues, Senator Tim Hutchinson, who sits on the Senate Armed Service Committee, and Congressman Jack Metcalf. Congressman Metcalf released a report last week that he will present to the Committee. It outlines the discovery that the anthrax vaccine does indeed contain squalene – an adjuvant. Prior to this discovery, the FDA has indicated that no licensed vaccine contained squalene. This topic has been of particular concern because the Defense Department has repeatedly denied that the vaccine contained squalene. I intend to get to the bottom of this issue.

We have received numerous reports of adverse effects from the anthrax vaccine. Oftentimes, we hear that the illnesses are not taken seriously. One individual was diagnosed with the flu – for over eighteen months. Individuals suffering with Gulf War Syndrome, suffering physical symptoms that mirror what we are seeing with anthrax injuries, are being given psychological evaluations and sent home. The Veterans Administration has been directed to provide our Gulf War Veterans with adequate medical care. I am disturbed to learn that these men and women, over one seventh of those that served in the Gulf, are being shuffled into psychological evaluations and not being adequately diagnosed and treated.

Last week the media broke the news of the death of a Bioport employee after receiving his eleventh dose of the anthrax vaccine. His wife, Mrs. Barbara Dunn, is joining us today. We are also being joined by Nancy Rugo, whose sister became ill after receiving the anthrax vaccine and eventually died. Mrs. Rugo is now raising her sister's three year old daughter. On behalf of the Committee, I'd like to express our condolences to Mrs. Dunn and Ms. Rugo.

Major Jon Ireland will share with us his heart-wrenching story of suffering tremendous life altering injuries from the anthrax vaccine. No man should suffer the devastation of hypogonadism.

Kevin Edwards, a Specialist in the Army, is accompanied by his father Toney today. They will share the story of Kevin suffering a dramatic reaction while in Korea that he feels is related to the vaccine.

Senior Airman Thomas Collosimo and Mr. Joseph Jones are both joining us today to talk about similar adverse reactions. They both have suffered repeated black outs and loss of consciousness. Mr. Jones was recently medically discharged with only a thirty percent disability. A thirty percent disability makes no sense. He cannot drive, or work to the capacity he needs in order to provide for his family and pay for his medications.

Earlier this year, Petty Officer, David Ponder, an E-4 in the Navy was shipped to Okinawa. We were told he had to stay with his battalion for the court martial. We were told that he had to stay with the commanding officer who knew his record and with his colleagues so they could testify.

He asked to have his case heard in the United States, where he could hire a civilian lawyer. Instead the Navy forced him to go to Okinawa, where he would be isolated from his family. When David asked a civilian lawyer to come to Okinawa and represent him, he was told he would have to pay fifty thousand dollars up front for the attorney to leave the rest of his cases and fly to Okinawa. Fifty thousand dollars on an E-4's salary.

I think the real reason he was shipped so far from home was they wanted to isolate him. He is facing court martial charges after refusing to take the anthrax vaccine. His case is one of six currently being reviewed by the Navy Appellate Court. After testifying David must return to Okinawa even though his battalion is returning to Gulf Port, Mississippi this coming week. His commanding officer has returned to the United States. His defense counsel has transferred back to the United States. Yet the Navy, that told Congress that David must stay in his battalion, has been unable to tell us if David will be allowed to return to the United States with his battalion or whether the Navy plans to keep him in Okinawa. After weeks of asking, the Navy has been unable to tell David if he gets to return to the United States with his battalion.

Mr. John Michels is an attorney with the McGuire Woods law firm in McLean, Virginia. He is also an Air Force Reserve lawyer, and assisted in Major Sonnie Bates' defense. His testimony will detail why the order to take the anthrax vaccine is **not** a lawful order.

Dr. Alexander Walker, Senior Vice President for Epidemiology, Ingenix Pharmaceutical Services and a Professor of Epidemiology, at the Harvard School of Public Health is testifying on behalf of the Minority.

We will also be hearing from the Food and Drug Administration and the Department of Defense.

We have a long hearing scheduled today. The issues of adverse events are too important to rush, so I have scheduled a second hearing next week to focus solely on military readiness and retention issues.

The hearing record will remain open until October 18.

I now recognize the ranking minority member, Mr. Waxman, for his opening statement.