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DOD'S MANDATORY ANTHRAX VACCINE IMMUNIZATION PROGRAM FOR MILITARY
PERSONNEL

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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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DOD'S MANDATORY ANTHRAX VACCINE IMMUNIZATION PROGRAM FOR MILITARY
PERSONNEL

THURSDAY, APRIL 29, 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 10:05 a.m., in room 2247, Rayburn House Office Building, Hon. Christopher Shays (chairman of the subcommittee) presiding.

Present: Representatives Shays, Mica, Souder, Terry, Tierney, Allen, and Schakowsky.

Also present: Representative Metcalf.

Staff present: Lawrence Halloran, staff director and counsel; Robert Newman and Marcia Sayer, professional staff members; Jonathan Wharton, clerk; David Rapallo, minority counsel; and Ellen Rayner, minority chief clerk.

Mr. Shays. I would like to call this hearing to order.

The plan to immunize 2.4 million men and women against weaponized anthrax raises legitimate concerns about the safety and efficacy of the current vaccine when used for that purpose on that many people. To address those questions, we asked the General Accounting Office [GAO], to examine the data, supporting safety and efficacy claims and to gauge the impact of good manufacturing practice deviations on vaccine quality.

Their preliminary findings will be discussed today. Based on the GAO study and other information obtained in the course of the subcommittee's investigation, the anthrax vaccine immunization program [AVIP], seems a very broad undertaking built on a very narrow foundation. The one study of safety and efficacy in humans, which was conducted among textile workers in the late 1950's, tested a different vaccine formulation than the one subsequently approved by the Food and Drug Administration [FDA], and used in the AVIP.

Using data on one vaccine to support the approval of another is problematic, particularly when there is no direct marker or correlate of human protection to use in comparing the two vaccines.

Lack of a surrogate for anthrax immunity also means efficacy tests outcomes in animals cannot be extrapolated to humans. The fact that vaccinated monkeys survived exposure to inhaled anthrax longer than guinea pigs or mice suggests, but does not prove, some vaccine protection in man.

Later studies of the FDA-licensed vaccine also show wide variations in adverse reaction rates, suggesting safety issues that may become apparent as usage grows from 200 or 300 people each year to several hundred thousand. There have been no studies of long-term health effects.

Poor DOD recordkeeping prevented any systematic health surveillance of the 150,000 Gulf war troops who took the vaccine. Last year, Congress directed the National Academy of Sciences to study the association between Gulf war veterans' illnesses and wartime exposures, including the anthrax vaccine.

So it may be premature to conclude that the vaccine is as safe and effective for use in a global protection effort as it might be for use by a few thousand mill workers and veterinarians.

Other factors relied upon by DOD to support vaccine safety and efficacy findings have been inflated to better match the scope of the AVI program. DOD relies heavily on FDA approval of the vaccine and FDA regulation of the manufacturer as an indicia of the vaccine's safety and quality. But we now know that approval was based on another vaccine in another time for use in another setting against a different route of exposure.

FDA inspection reports portray an uncharacteristically passive regulator tolerating numerous serious and persistent violations for years at the Michigan production plant, now owned by the BioPort Corp.

The DOD witness at our previous hearing pointed to the ``independent review of the health and medical aspects of the overall program by Dr. Gerard Burrow of Yale University Medical School,' ' but his report entailed no independent analysis of safety and efficacy data.

In a recent letter to the subcommittee, Dr. Burrow clarifies that mischaracterization of his work, saying his charge was only ``general oversight of the vaccination program.' '

The AVIP confronts many active-duty, reserve, and national

guard members with agonizing personal and professional choices. They deserve answers to their questions about the effectiveness and wisdom of this mandatory, invasive forced protection program. They deserve to know the vaccine chosen to meet the preeminent biological threats is as well tested and technologically advanced as the best weapons systems.

They need to be assured claims of AVIP safety are based on more than exaggerated interpretations of inconclusive data, and they need to be assured claims of AVIP effectiveness are based on more than wishful thinking about monkeys.

At this time, I would like to call on our colleague Ms. Schakowsky to see if you have any statement. OK? And Mr. Terry.

I would invite our guest to the committee and invite Mr. Metcalf if he would like to make a statement.

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

[GRAPHIC] [TIFF OMITTED]58959.001

[GRAPHIC] [TIFF OMITTED]58959.002

Mr. Metcalf. I would. Thank you, Mr. Chairman.

I want to thank the chairman and other members of the subcommittee for allowing me to participate in this hearing and express my concerns regarding the safety and effectiveness of the anthrax vaccine. I am deeply grateful that you have been willing to conduct this examination of the Department of Defense's anthrax vaccine immunization program for all military personnel.

I have two outstanding Navy bases in my district. The men and women assigned to carry out the missions of Naval Station Everett and Naval Air Station Whidbey Island are some of our Nation's finest. I want for them the very best in protection, training, equipment, and every advance of science and medicine that is at our disposal.

I understand the grave concerns which have been the catalyst for the anthrax immunization program. I must question, however, the decisions that have been made resulting in the current program. From the time this program was announced, I have had serious reservations.

It is my understanding that we have one source for the anthrax vaccine, and that single source has had significant problems with FDA violations. I also understand that the anthrax vaccine currently being used to vaccinate our active-duty force was produced prior to renovations that are under way at the production facility.

The scientific research upon which FDA based its approval was not conducted to assess protection against a weaponized version of anthrax. Furthermore, the current vaccine was never intended for widespread general use but rather for a very small, targeted population.

The monitoring system for reporting problems has been woefully inadequate.

Those are just a few of the facts that cause me to question the wisdom of this accelerated service-wide program.

I would like to make the committee members aware of the recently published GAO investigation that I requested regarding the presence of squalene antibodies being found in the blood of some sick Gulf war-era veterans.

I asked the GAO to determine if there was any possibility that veterans had received an adjuvant formulation containing squalene and to evaluate the validity of the independent

research being reported. In their response, the GAO revealed the depth of research that had been conducted using experimental squalene adjuvant formulations by both the Department of Defense and National Institutes of Health.

It also confirmed that the independent research is based on sound scientific principles. The integrity of the findings convinced the GAO that this issue needs to be pursued aggressively.

There are many troubling questions that have been raised as a result of GAO's squalene study. Many of you may have seen the investigative articles currently in the press. There have been even suggestions that there could be a relationship to the anthrax vaccine.

I don't know what we will find, but I do know that we have a moral obligation to those who are suffering to stay the course until this mystery is solved.

On behalf of the extraordinary active-duty personnel and veterans in my district, I want to thank you, Mr. Chairman, for the efforts of this committee. You have provided desperately needed leadership on this issue. Your quest for accountability and the truth is an example to all of us.

I am confident that our military force will be stronger as a consequence of this examination of the anthrax vaccine program.

I look forward to working with you on this.

Mr. Shays. Thank you. It is nice to have you here.

Let me just get some housekeeping out of the way.

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.

And I ask further unanimous consent that all witnesses be permitted to include their written statements in the record. And without objection, so ordered.

At this time, I would like to call our first witness. His name is Mr. Kwai Chan, Director of Special Studies and Evaluations, National Security and International Affairs Division, General Accounting Office [GAO].

Thank you. And I believe you are accompanied by Dr. Sushil Sharma. And I will swear in both of you, but, Mr. Chan, I think you are the only one who will be giving testimony.

Mr. Chan. Yes.

[Witnesses sworn.]

Mr. Shays. Note for the record that both have responded in the affirmative.

Mr. Chan, what we are going to do is, we are going to have a green light for 5 minutes, we are going to roll it over for another 5 minutes.

Mr. Chan. OK.

Mr. Shays. And your testimony, obviously, is very important because it sets the stage for the rest of the hearing. So I want to make sure you say everything you need to say.

So, if you are ready, let's begin.

STATEMENT OF KWAI CHAN, DIRECTOR OF SPECIAL STUDIES AND
EVALUATIONS, NATIONAL SECURITY AND INTERNATIONAL AFFAIRS
DIVISION, GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY SUSHIL K.
SHARMA, ASSISTANT DIRECTOR

Mr. Chan. Thank you, Mr. Chairman and members of the subcommittee and Congressman Metcalf. It is, indeed, my

pleasure to be here today. Before I present to you our findings on the safety and efficacy of the vaccine, which we conducted at your request, I want to introduce my colleague, Dr. Sharma, and also I want to acknowledge my staff, Dr. Howard Deshong and Mr. George Bogart in helping me to prepare this testimony.

Let me first discuss the context. As you know, controversy has surrounded the anthrax immunization program since DOD began vaccinating the first of 2.4 million active-duty and reserve members. Some have questioned the safety and efficacy of the vaccine, especially after they learned about the numerous problems FDA found during the inspection of the Michigan facility. Some Gulf war veterans believe that their illnesses might have been caused by anthrax vaccines that they received during the war.

Let me turn to our results. With regards to safety, I have three findings to report. First, the short-term safety of a vaccine was obtained from data collected for licensing and data on subsequent use. The interpretation of pre-licensing data was complicated by a switch from one vaccine to another while the study was under way.

Second, after licensing, this vaccine has been used by a small number of individuals, unlike other vaccines. This number is too small to detect rare and serious adverse events. In the 1970's, FDA did not have an adverse-effect reporting system in place for vaccines. From the available data, we can say that the reported numbers are based on how closely you monitor individuals who receive this vaccine.

As shown in table one on page 7 of my statement--you see a table there--which says that if you do not follow individuals closely after they receive the vaccine, like in a passive system, the number of significant adverse events are significantly lower. And when you monitor individuals closely, then the number rises significantly, this means that the adverse-event reporting system is really dependent on the data you collect, and on the way you collect the data.

Third, the long-term safety of the vaccine has not yet been studied, and, therefore, one cannot conclude that there are no known long-term effects.

In summary, then, concerning vaccine safety, studies have been performed to examine the safety of both original vaccine and the licensed vaccine. These two vaccines were made using different processes and have different data to support their safety.

While these studies identify varying rates of adverse reactions depending on the data-collection mechanism, be they passive or active, they did not question the safety of the vaccine. The long-term safety of the vaccine had not been studied.

With regard to the efficacy of the vaccine, I have three findings to report. First, the only human efficacy study conducted was done on the earlier vaccine, not the licensed vaccine. This study on efficacy was done in 1962 by Brachman. The study demonstrated efficacy against cutaneous anthrax but not inhalation anthrax, which is the current military threat.

In the 1980's, the military collected efficacy data on animals specific to inhalation anthrax. All these studies have supported the view that in those models the vaccine can protect against some anthrax strains, but not all.

Work using monkeys conducted in 1996 show for the first time that non-human primates could be protected against inhalation anthrax. However, in both the guinea pig and the

monkey studies, protection did not correlate with the level antibodies to protective antigen [PA].

More recent work done in 1998, by the military, came to the same conclusion, ``It is unknown what immune mechanisms are important in specific resistance to anthrax. Without a specific and measurable immune correlate of protection, extrapolation of protection data to show that the vaccine is effective for humans, is of questionable value.''

Taking all the evidence into account, it is likely that the vaccine does give some protection. But to what extent, against what amount of anthrax, against which strains, and how long protection last are not known.

In summary, on efficacy, I can say that studies on efficacy of the original and licensed vaccines have been limited to a study of the efficacy of original vaccines for humans and studies of the efficacy of the licensed for animals.

The study on the original vaccine concluded that the vaccine offered protection against cutaneous anthrax. The studies on the licensed vaccine focus on the efficacy of vaccines in protecting animals against inhalation anthrax. These studies, while showing some positive results, may not be extrapolated to humans.

DOD is planning to conduct such correlating studies.

With regards to FDA's inspection of the Michigan facility, we found that until 1993 FDA inspectors did not inspect the part of the facility where anthrax vaccine was made because they were not immunized with anthrax vaccine.

The 1996 and 1998 inspection by FDA of the MBPI facility is one of a series that through the years have been problematic. The Michigan facility has received warning letters and notice of intent to revoke their facility license.

FDA's inspection of the Michigan facility found a number of deficiencies, which fall into two categories. Those that, although serious, might affect only one or a limited number of batches that were produced when the deficiency was extant and those of generic nature that could compromise the safety and efficacy of any or all batches.

The manufacturing plant is currently closed for renovation. Mr. Chairman, this concludes my remarks.

[The prepared statement of Mr. Chan follows:]

[GRAPHIC] [TIFF OMITTED]58959.003

[GRAPHIC] [TIFF OMITTED]58959.004

[GRAPHIC] [TIFF OMITTED]58959.005

[GRAPHIC] [TIFF OMITTED]58959.006

[GRAPHIC] [TIFF OMITTED]58959.007

[GRAPHIC] [TIFF OMITTED]58959.008

[GRAPHIC] [TIFF OMITTED]58959.009

[GRAPHIC] [TIFF OMITTED]58959.010

[GRAPHIC] [TIFF OMITTED]58959.011

[GRAPHIC] [TIFF OMITTED]58959.012

[GRAPHIC] [TIFF OMITTED]58959.013

[GRAPHIC] [TIFF OMITTED]58959.014

Mr. Shays. Would you repeat your last sentence. I was----

Mr. Chan. Yes.

Mr. Shays. Make your last point.

Mr. Chan. The manufacturing plant is currently closed for renovation.

Mr. Shays. Right, but before that.

Mr. Chan. Yes.

Mr. Shays. I just want to be clear on the dates. That is what I was asking my staff. The plant was not inspected until when, thoroughly, by FDA?

Mr. Sharma. The FDA inspectors were visiting the plant and the process has changed over time, but they were not able to enter the facility where they were manufacturing the----

Mr. Shays. Dr. Sharma, I am going to have you get a separate microphone, if you can. I am sorry. I should have asked you to do that before. I apologize to our official reporter.

Yes. You can pull it down and put it in front of you please. Does it reach?

There you go. Thank you, Jonathan.

Mr. Sharma. FDA inspectors had been inspecting the manufacturing facility at routine intervals. However, while they looked at other components of the GMP, they did not enter the manufacturing facility because they were told that they were not immunized.

The first evidence that we found from FDA records was in 1996, when they were told, essentially, that they were immunized and they could enter the facility, and which point in time they uncovered numerous problems.

Mr. Shays. So are we basically saying the anthrax portion was never fully inspected until 1996?

Mr. Sharma. That is correct. The other components of the anthrax production were looked at, at routine intervals such as, you know, where they have the labeling----

Mr. Shays. No. I understand. OK.

Let me start out first by, Mr. Chan, talking about safety. I just want to follow the flow of these questions. So you have responded in part, but I want to make sure I am focused on it.

How different is the licensed vaccine from the earlier version used in the study?

Mr. Chan. The original vaccine was developed in the 1950's by Dr. Wright in Fort Detrick, as I remember. And, the actual license vaccine, MDPH at the time, the Michigan Department of Public Health, was granted a license for a similar vaccine. But I think we found at least there were three differences from the original vaccine.

First, the manufacturing process changed when MDPH took over, and second, the strain of anthrax that Merck used--this is the original license, I mean the original vaccine was produced by Merck. The strain of anthrax that Merck used to grow the original vaccine was changed, and another strain was used to grow the MDPH vaccine.

And finally, to increase the yield of the protective antigen [PA], the ingredient to make the vaccine was changed from the original vaccine.

So, I think we see three different changes made.

Mr. Shays. Do you consider the safety data on the earlier

vaccine relevant to the questionable safety of the licensed vaccine? I mean, how relevant is this issue?

Mr. Chan. I think it is relevant and also is important to understand, back in the 1970's, when the requirement for licensure was purely based on safety. I think that the way that it was done, and later on maybe FDA can expand on this, it is based on the comparison of level of antibody generated, by the two different vaccines.

Mr. Shays. Excuse me a minute. I should be timed, Jon. Sorry.

I am sorry. Make your last point again, please.

Mr. Chan. I am saying that I think the only possible similarity that was produced is really based on the antibody reaction to PA that was generated using the two different vaccines. So, in a way, on the current standard, they are clearly two different vaccines.

Mr. Shays. OK. What basis did you find for the DOD statement that no known long-term side effects are associated with the anthrax vaccine?

Mr. Chan. Well, I think maybe the statement by itself is misleading because in a way I don't believe and we have not found any studies on long-term effects. So if you did not collect the data, certainly there will be no known side effects.

Mr. Shays. When you say you didn't find it, could you just elaborate. I mean, do they exist? Did you make requests of DOD and others?

Mr. Chan. Yes, we have. Yes.

Mr. Shays. And they were not able to provide you any data that would have shown you these studies.

Mr. Chan. Right. We explain that they need to be actively monitoring those people to really determine that, and I may also say that on other vaccines, such monitoring was not done either. But for them to say that there are no long-term side effects, we cannot find any studies to support that statement.

Mr. Shays. At all?

Mr. Chan. No.

Mr. Shays. OK. Did you find any toxicology studies on the vaccine in animals?

Mr. Chan. You want to expand on that?

[Mr. Chan speaks to Mr. Sharma.]

Mr. Sharma. No, not from the earlier work. These were not the requirement----

Mr. Shays. I am going to ask you to speak a little closer to the microphone, and a little more slowly, if you would, Doctor.

Mr. Sharma. It is my understanding, based on the review of DOD documents that they provided to us, a need for such work was suggested in 1996, or around that period, but to the best of our knowledge, such studies has not been conducted.

Mr. Shays. Did you find any animal studies to evaluate any reproductive effects of the vaccine?

Mr. Sharma. No.

Mr. Chan. No.

Mr. Shays. Now, you explained the chart that you had.

Mr. Chan. Yes.

Mr. Shays. But I am to basically infer that if they didn't have followup, then they didn't have reports. But if they had followup, then there were serious side effects associated with the vaccine. Is that correct?

Mr. Chan. What we are saying is the following. If you have

an active data-collection mechanism, that means actually monitor people you can see that both the Pittman study and also the Tripler study, TAMC, the numbers are numerically much higher.

Mr. Shays. OK, now the Pittman study shows 29, and the other study shows 43. Is that 43 out of 536 and 29 out of--oh, this is the percent?

Mr. Chan. The percent. Yes.

Mr. Shays. Now, we are saying that 29 percent had side effects. Is that correct?

Mr. Chan. Systemic, mild side effects, yes.

Mr. Shays. They were fairly mild, and 43 percent had mild side effects in the other study. In Great Britain, it is voluntary?

Mr. Chan. Yes, it is.

Mr. Shays. In France, they don't do it. Their force protection is through protective gear.

Mr. Chan. Yes.

Mr. Shays. In the United States, it is mandatory. In Great Britain, it is voluntary. And in France they don't do it.

Now, in Great Britain we learned that you could improve the anthrax vaccine. In other words, this is an old vaccine that we have now.

Mr. Chan. Yes, sir.

Mr. Shays. And that there would be, they claim, less side effects. But if you did that, wouldn't you have to do a new study to determine if this next-generation vaccine were safe and effective and so on?

Mr. Chan. Yes, you do.

Mr. Shays. So basically what we have is we have a 1950's vaccine, or a 1960's vaccine that could be improved.

Mr. Chan. Sixties. Approved in 1970. Yes.

Mr. Shays. If we did the work to improve it, it would take some time, but then we would have to obviously test it.

Mr. Chan. Correct. As I understand it, first of all, this vaccine, as you know, was licensed in the 1970's. And so improvement can come in many different ways, one of which is really the reduction of number of doses that is required.

Mr. Shays. OK.

Mr. Chan. The six doses plus the booster.

Mr. Shays. Let me just indulge the committee just for two more questions. And let me ask you: Why six shots?

Mr. Chan. Well, we don't know why either. We understood from the beginning that in animal studies, only three shots were required to be done. But in the Brachman study, six shots were imposed. And from then on, it became sort of de facto, the number of shots required were six.

I might add that the Department of Defense is interested in looking and examining why six shots, and could they, in fact, reduce the second of the six shots.

Mr. Shays. Well, let me ask you: Why--what is the claim for the six shots? There has to be some basis for it.

Mr. Chan. I do not believe there is a scientific basis for it, except the Brachman study, of which they selected the six shots dose as the regimen they adopted.

Mr. Sharma. If I may just add to it. I think the way we understand is, the original experiments that were done on mice used the three shots. And then, in the human studies, subsequently, when three shots were used, they found three cases that were infected with anthrax. Two of them had complete series. In one DOD document that they provided to us, it was

stated that the investigator arbitrarily decided to change it to six shots.

And that was the basis for the six shots series. We have not found any other evidence, and that is because there is really no relationship between the level of immunity and the protection. So it is not based on any scientific basis that I know of.

Mr. Shays. Well, we will ask our other witnesses.

And last, does the six-shot anthrax increase or decrease the safety of the vaccine?

Mr. Chan. The safety of the vaccine?

Mr. Shays. Yes. In other words, if you take six--we are talking efficacy and we are talking safety--but in terms of if you do it six times, is it safer or less safe? We don't know? We do know?

Mr. Sharma. Well, we do know that each time you take shots you have more pain. So the more shots you are going to give, you are going to experience more adverse events--at least the probability increases. And this is one of the very strong limitations of the current vaccine. The schedule is too long and heavy on the recipients without any scientific evidence of its needs.

Mr. Shays. Thank you. I appreciate the committee's indulgence. And Ms. Schakowsky.

Ms. Schakowsky. Thank you, Mr. Chairman.

Has the current vaccine ever been studied in humans to determine its protection against inhalation anthrax?

Mr. Chan. No it hasn't.

Ms. Schakowsky. And are you aware of any other vaccines that have been licensed by the Food and Drug Administration without efficacy data to support the intended use in humans?

Mr. Chan. I am not aware of that.

Mr. Sharma. No. I have FDA credentials of this.

Mr. Chan. Yes.

Ms. Schakowsky. Oh, OK. So you just----

Mr. Chan. We are not aware of that.

Mr. Sharma. We are not aware of this.

Ms. Schakowsky. OK. I am wondering if you are--if you do know if the results of the efficacy studies in animals then can be extended and extrapolated to reach conclusions about the efficacy in humans?

Mr. Chan. Well, what we found was that if you use the measure, the so-called antibody, to the PA in animals, that different response in terms immuno-degenecity by species; that is, what we find is that there is no direct correlation to the higher the level antibody implies that you are more likely to be protected among the animals. Although, the best one is really with the monkeys. They are pretty good in terms of that relationship.

We do not have a scientific way to link between animals to humans in terms of a correlation. How does protection correlate in terms of the level antibody to protect the antigens that are there, to the antibody.

So, in a way, DOD is, and certainly CDC, are interested in pursuing and, examining this issue because that would be a real help to science and development of vaccines in the future.

Ms. Schakowsky. The passive monitoring that DOD is doing now, is there any active monitoring going on at all?

Mr. Chan. Yes. In the table, you find the TAMC, 1998, the Tripler, so-called, is active monitoring. This is something that they are doing now, with a small number of vaccinated

individuals.

Ms. Schakowsky. Are these all DOD studies? Is that what you are saying? First of all, mine says page 6 and then it has----

Mr. Chan. I am sorry.

Ms. Schakowsky. There are four columns.

Mr. Chan. Yes.

Ms. Schakowsky. DOD is at the bottom, and it says current monitoring, and it says passive, 223,000.

Mr. Chan. That is right.

Ms. Schakowsky. Are any of those other studies DOD studies or are they all?

Mr. Sharma. They are all DOD studies.

Ms. Schakowsky. They are all DOD studies?

Mr. Chan. Yes.

Ms. Schakowsky. OK. I see.

So, what we are finding here is that passive studies in terms of determining any kind of reactions at all seem to be fairly--not results are reported? Is that what you are saying?

Mr. Chan. The result in DOD, the current monitoring, the last column you find----

Ms. Schakowsky. I am looking at the last column, the passive monitoring.

Mr. Chan. Yes, right. And you find that, the level of so-called reported adverse events is very low in the nature of 0.006 to 0.007.

And the intent of this table is to show that, depending on how you gather your information, you end up with different kinds of numbers.

Ms. Schakowsky. OK.

Mr. Chan. So, in a small way, the Tripler, the TAMC, data, which is also being collected by DOD as well, is an active way to reach and find out, are there adverse events, which is something that DOD is pursuing.

Mr. Sharma. Let me add to--I think it is very well known that the VAERS, which is the system that apparently is in place under FDA--strictly dependent upon the individuals physicians or healthcare providers to report. It has been well agreed that it is a signal system; that is, it tells you that something is happening with this vaccine. It does not tell you how often, with what severity, or does not establish causality. The limitations are very well accepted.

Mr. Shays. Excuse me 1 second. We don't usually have this problem. Are we able to turn it down a little bit?

I am sorry, Dr. Sharma.

Jonathan, we are keeping you busy today, buddy.

Why don't we do this. Why don't you keep talking and we will just ignore the red light, I am sorry to interrupt you.

Mr. Sharma. I think the VAERS system has, as you know, a lot of advantages, but if it is used as a basis to determine absolute numbers, then it is, you know, certainly very misleading. And that is what we are trying to convey. This is a vaccine which, up until 1991, when it first was used on a large scale of 150,000 people during the Gulf war, that was our first opportunity to learn about how this vaccine works on large numbers. But we lost that opportunity. And for the first time, now, we have another opportunity to learn about this vaccine. However, if you are going to rely your safety information based on a passive system, and present that as an absolute number, you will be under-reporting the adverse events.

Ms. Schakowsky. No. When we do polls to determine public opinion, we also have a degree of accuracy. I am wondering in

these other studies, when we talk about, for example the Pittman study, where we had 29 percent saying they had a mild reaction, 14 percent severe or moderate, to what degree of accuracy can we--what can we say in terms of----

Mr. Sharma. These are absolute numbers. You know, it is not like in that particular cohort 29 percent experienced that. There is no confidence interval. It is actually----

Ms. Schakowsky. No. I understand that, but were these, the number vaccinated, the 500 and--the sample, the universe. Was that selected in any kind of scientific way?

Mr. Chan. This is a group that they have. It is not a randomly selected sample. So as a result, the confidence level cannot be provided. I mean, it could be done that way.

Ms. Schakowsky. We don't have any studies that are done that way so that we can----

Mr. Chan. If you want to achieve generalizability, no. We don't have that. A passive system, potentially, could have that because if everybody provided information, then you end up with a census data without sampling. But if people are not encouraged to provide events that they believe are attributable to vaccine and go through the system of reporting, then you will have a very low rate of reporting, as a result.

If you want to do an active monitoring, you can do it by selecting a sample of a few thousand people, and monitoring them over time. The only question is that with vaccine is it difficult, to detect rare events and disease or illness out of this small samples?

Unlike polls, it is always one or zero. But to capture a single event that may occur in a very rare way, then it is difficult. And so you have that conflict.

Mr. Sharma. I think this is a very important point. One of the rare events, Gullain-Barre syndrome, for example, about 1 in 100,000 people, when DOD currently started using this vaccine, and after it was used in about 150,000 people, they had 1 case. So there are these rare events that, even if you monitor a population but if it is small, the likelihood of seeing those events is very, very small, even in the active monitoring system.

Ms. Schakowsky. So what is the best way then for us to determine accurately the side effects, the safety hazards?

Mr. Sharma. There are a number of models one could use, and I think in our discussion with CDC they had provided and discussed with DOD some several options. But let me just talk to you about how it is currently being done by some of the newer vaccines.

One, with Merck, varicella vaccine, they had voluntarily decided to followup 100,000 individuals who are receiving this vaccine for over--at least a start--10 year period. For another vaccine, CDC, under contract, is following about the same number of individuals in four HMO settings. And DOD has an excellent opportunity to monitor because they are all in the system. And there are a number of ways one could do that. And I am sure they are aware of it and would be able to comment on that.

Mr. Chan. I think what we are saying is that if they want to do it, it can be done, without greatly disturbing the system, the way it is right now.

Ms. Schakowsky. Thank you.

Mr. Shays. I would like to call Mr. Terry, but I just want to verify one thing on your chart.

Mr. Chan. Yes.

Mr. Shays. Basically, in the Pittman study, 43 percent had either mild or more severe reaction when you monitored. In the TAMC--and that stands for what, TAMC?

Mr. Chan. Tripler.

Mr. Shays. OK. Right, Army Medical Corps. They had 48 percent when they monitor it.

Mr. Chan. Yes.

Mr. Shays. And now the DOD--current monitoring--they have none. Are they, in fact, monitoring? Can we even put the word ``current'' monitoring? Or is that being a little disingenuous?

Mr. Chan. Well, they have the VAER system, as we said.

Mr. Shays. They have a what?

Mr. Chan. The VAER system, the passive system where people can send in a form.

Mr. Shays. So, do they give out the forms?

Mr. Chan. We have another study looking into that to see how effective that is.

Mr. Shays. OK.

Mr. Chan. But, nevertheless, it is still a passive system.

Mr. Shays. So we don't really even know what kind of monitoring it is, if at all.

Mr. Chan. If you look at footnote E here, it basically shows that right now they are experiencing out of 223,000 vaccines you have 42 reports and so on.

Mr. Shays. No, but my point is they are not basically monitoring.

Mr. Chan. Well, that is what we call data collection is passive. You wait for people to come in and tell you rather than actively go----

Mr. Shays. OK. I don't call that monitoring, with all due respect.

Mr. Chan. Oh. OK. I am sorry.

Mr. Shays. No. You can call it that. I don't call it that.

Mr. Chan. OK.

Mr. Shays. Mr. Terry.

Mr. Terry. Thank you, Mr. Chairman. Some of my questions are in regard to the Michigan production facility. I am reading your statement, for the record and listened to your opening statement and I just need to clarify a little bit of a timetable because it raises some red flags with me.

In your statement, you say that the DOD had inspected the facility, or at least did an inspection in 1992, where it found just a generic statement of deficiencies, including the absence of stability studies. My question is, just to verify the timetable, that study occurred by the DOD in 1992?

Mr. Chan. That is correct.

Mr. Terry. And then, in 1993, the FDA tried to do an inspection and was turned away because they weren't, they didn't have their immunizations. So the inspection didn't occur until 1996. Is that a correct timeline so far?

Mr. Sharma. Yes. I want to qualify it. This is inspection of the manufacturing plant. The FDA has been inspecting very regularly and systematically documenting problems with other components of the production facility. And these problems were very systemic and persistent.

Mr. Terry. OK. But they didn't get the opportunity to get into the plant to do the physical inspection until 1996?

Mr. Sharma. Yes.

Mr. Terry. And that raises my point here. Some red flags were put up in 1992; more should have been put up in 1993, but yet they continued to manufacture and use the vaccine. Correct?

Mr. Sharma. That is correct.

Mr. Terry. Until recently, when they, I guess, voluntarily have closed down the plant for ``renovation''?

Mr. Chan. Right. When we say, inspect the facility, we mean the anthrax production facility because BioPort produces other vaccines as well.

Mr. Terry. Right, and that is what I am focusing on.

Mr. Chan. And so----

Mr. Terry. Well, we aren't having a hearing on those others.

Mr. Chan. I understand. But what I am saying is that FDA had been inspecting them without entering into that particular production site and observing basic systemic problems in terms of the processing for the other stuff as well. So they were noticing those kinds of issues as well.

Mr. Terry. That is part of my point. We had some of these red flags popping up, but yet we went through from 1992 until sometime after 1996 but they were still manufacturing.

Mr. Chan. Right.

Mr. Terry. Right there that raises a concern with me, but the issue then is the safety of the end product. Do the deficiencies that were found then by the FDA in any way affect the safety or the potency of the vaccine?

Mr. Chan. As we stated in terms of vaccine, because it is biologic, it is important that you need to make sure safety is built into the process itself and not just the end product tests. Right now, we are really talking about the end-product test. And DOD had imposed on further supplemental testing after FDA had passed or released a lot.

So they are doing an extensive listing.

Mr. Terry. OK. So I guess----

Mr. Shays. Could the gentleman just yield a second?

Is the answer yes to the question?

Mr. Terry. Yes. That is what I was going to followup with, Chris. I am still not sure if we, if I learned that the safety of the product was jeopardized by these deficiencies. Who are you to trust?

Mr. Chan. I do not know.

Mr. Terry. All right.

Mr. Chan. I can't answer that. But I can tell you that off the lots that have been produced so far, I believe 31 lots-- maybe I'll get the numbers incorrectly--but 8 of those lots have been released and supplementary testing has been done by DOD to release it for vaccination.

And my understanding is that of those remaining lots, as many as 20 lots have been quarantined for further testing. So, it is possible to examine those lots that are going through further testing to determine where the problems lie in terms of the process. That means you go backward to find it. That is possible.

I am not sure that has been done. To examine where did it fail. It could be filtration, it could be something else. But nevertheless, I cannot answer the question as to whether they are safe or not.

Mr. Terry. Well, you had mentioned the lots. I think we could spend a few more minutes dissecting your answer to that, but are there lots that were quarantined? Is this pursued by the FDA?

Mr. Chan. Our understanding is the lots had not passed for release, and have not been supplementary tested by--testing had not been done. So it is awaiting for further testing.

Mr. Terry. Thank you, Mr. Chairman. My time is up.

Mr. Shays. Thank you very much. I'm sorry, Mr. Allen you have the floor.

Mr. Allen. Thank you, Mr. Chairman. Couple of questions. Have there been any studies of the potential effects of the anthrax vaccine when used in combination with other vaccines or other drugs? Any studies that--and a little bit of background. In hearings that this committee held on the effects of Gulf War Syndrome, one of the--you always hesitate to say it--conclusions, but one of the views was that it was a combination of different kinds of chemicals that might be responsible for the various maladies described collectively as the Gulf War Syndrome.

And so, what I am wondering is, it's one thing to test an anthrax vaccine all by itself, but it seems to me that typically our service men and women get a variety of different vaccines. And I would be interested in knowing whether there is any potential for interaction of the anthrax vaccine with others that we should take account of?

Mr. Sharma. To the best of my knowledge, there is one unpublished DOD study, which looked at the interaction effect with botox and anthrax----

Mr. Allen. Between, what was the first?

Mr. Sharma. The botulism toxide vaccine and anthrax. And I will be very happy to provide you for the record our review of that study.

Mr. Allen. OK. Good. I would appreciate receiving that. The other, in the GAO report, you mention the Brachman study claimed that the vaccine gave 93 percent protection against anthrax penetrating the skin, but indicated that the tests on humans with respect to inhalation are--there are too few cases to come to any conclusion.

And in your report, on the next page here, it says that you conclude that testing still needs to be conducted on inhalation anthrax, and you go on to mention some animal studies. How do you do that? How would you do it? What kind of study could be designed or should be designed to determine the efficacy of vaccine against exposure to anthrax by inhalation?

Mr. Chan. Well, in fact DOD is pursuing studies to examine whether there is a correlate--that means define the ingredient that provides protection. They do believe that in animal studies, the protective antigen plays a major factor, but it is not the only factor. So they are looking for other means to examine that, as I understand they are pursuing now in their own research.

Mr. Allen. Other means besides animal studies? Or----

Mr. Chan. No. Looking at animal studies and see how it may be correlated to the human response.

Mr. Allen. I see. OK. Thank you very much.

Mr. Shays. Thank you. I think it is Mark Souder. I think you are next.

Mr. Souder. I am sorry, I read through your testimony. I'm sorry I missed the testimony and the first part of the questions. Are the side effects with this vaccine fairly typical for this serious of vaccine? In other words, the 43 percent in the one study even to have mild, that seemed pretty high, although other studies were lower.

Mr. Chan. Well, I caution, first of all, that the analysis had not been done whether in fact it is directly related to the vaccination itself. So that needs to be done, and then try to attribute it to the vaccine. And then I think one can draw the

conclusion whether it is really caused by the vaccination.

Mr. Souder. Would that be true of other studies of vaccines, however those----

Mr. Chan. Yes, you need to do that because there could be other reasons why it is causing the problem. But those are the kind of observations you would expect. But the degree, in terms of numbers and so on, it appears to be high.

Mr. Souder. What about when it says 'moderate or severe.' What does that mean? In other words, is it--I saw one reference to fevers and chills, or how frequent is that? Does it mean you are debilitated? That you can't ever recover? That you are more prone--you said in your statement that we don't know the long-term impact.

Mr. Sharma. This is very typical of, you know, most bacterial vaccines. You do recover, and what it--the difference between really mild and moderate and severe is discomfort and how it really impacts your functioning. And when you are talking about mild to moderate, this number is high. And, but also you have to recognize this is a very old vaccine, and I think it will be very appropriate for you to ask a PA, what their comment or reaction would be if a newer vaccine would show these numbers. Would it be acceptable to them?

I think they will be a much better position to address the issue.

Mr. Souder. Thank you for doing that question for us. [Laughter.]

I see in the testimony of Dr. Zoon that is coming there is a discussion in her testimony about the anthrax vaccine used on livestock workers, and it said that from this manufacturer, that between 1991 and present, 1.2 million doses were distributed. Have you ever looked at that as to--that's a pretty big universe to see whether there are any side effects in that industry.

Mr. Sharma. Well, let me comment. I think there are two things. We have to make a distinction between the old vaccine and the licensed vaccine or the original vaccine. As far as we know, for the licensed vaccine, post-licensure, approximately 60,000--2,000 doses per year were distributed on average. But we have no information how many individuals were vaccinated. So even if you assume every shot went into a human body, we are talking about over 30 years period, approximately about 60,000 individuals at best.

However, in our discussion with scientists at Fort Detrick, the estimates of the number of people who may have received this vaccine over a 30-year period, range from somewhere between 200 to about 2,000, at the most. And we don't know who those individuals are. There has been no followup. No systematic followup has been done.

So we really--I don't know, you know, the context of, I have not reviewed FDA testimony, but, you know, you have to make a distinction between the old vaccine and the new vaccine.

Mr. Souder. If there was any kind of systematic pattern of at least beyond mild, to moderate, would that not have likely shown up? In other words, in health journals and so on with the distribution.

Mr. Sharma. If the vaccine use is on a very large number of people, you would expect some adverse reactions. But again, you have to recognize the number of people prior to 1998 that were the target group for this vaccine were small. But in general, we would--I would agree with you, if there was somebody who just dropped dead or if a very serious event occurred, it would

have been reported.

Mr. Souder. The symptoms that you described seemed like they could also become confusing. In other words, depending on the delay, you could be uncertain of the symptoms. Could that also make for a reporting problem?

Mr. Chan. Yes. That is why you need to gather information first and minimize the screening process of what you believe to be vaccine-related or not, examine those, and pull out the ones it is not and try to examine further. That is why I am saying there are a number of steps. In here, we are just showing the immediate reaction of the number of adverse events. And I have to qualify those numbers.

Mr. Souder. So there could be many people who don't think it was related to the vaccine and, in fact, it was. Or there could be people in some of these studies who thought it was the vaccine and it wasn't because we haven't gone----

Mr. Chan. That's right. If you have things such as swelling, edema, around the vaccinated site, and you are going to attribute to the vaccine, but other reactions such as fever, you may not be able to attribute to it. Yes.

Mr. Souder. Thank you.

Mr. Shays. Just a small point. You were reading ahead to FDA's testimony. Most of the doses, I make an assumption, after 1991 were not with livestock workers. It was really the war in the Gulf, I believe.

I think you will find that most would be that way, and maybe we will have the FDA clarify that. But that is from their statement on page 11. It is a minor point. But for many years, we didn't have that many people taking the vaccine until the war in the Gulf.

Mr. Mica.

Mr. Chan. Oh, I see. Now I understand. The numbers I was a little surprised by.

Mr. Shays. Yes. No, the statement basically says from 1974 until 1989, approximately 68,000 doses were distributed.

Mr. Chan. I see.

Mr. Shays. In 1990, approximately 268,000 doses were distributed. Between 1991 and the present, we understand that approximately 1.2 million doses were distributed.

Mr. Chan. All right.

Mr. Shays. But we will have that clarified.

Mr. Chan. I understand.

Mr. Shays. Mr. Mica.

Mr. Mica. Thank you, Mr. Chairman. Just a couple of questions. It is my understanding that the only study of the efficacy of the vaccine was performed by the Brachman study?

Mr. Chan. Yes, sir.

Mr. Mica. And it is also my understanding that the study gave the vaccine a 93 percent protection against anthrax penetrating the skin. It said a lower confidence level of 65 percent. Can you explain this lower confidence limit, a 65 percent in this study?

Mr. Chan. I think they had one case of cutaneous anthrax after they received the vaccine. And you have to forgive if I am incorrect with the numbers. Out of a total possible expected number of 13.5 or so, and so if you look at that then the actual protection turned out to be 92.5 percent.

Now, since it is a small sample, they determine what is the uncertainty of that number. And so they end up with the expectation of 92.5 percent protection but with a lower limit of, as low as 60-some-odd percent.

Mr. Mica. Well, I also found----

Mr. Chan. That's against cutaneous anthrax.

Mr. Mica. Your report found the number of individuals who contracted anthrax by inhalation was too low to assess the efficacy of the vaccine against this form. So, my concern is that we don't have that many experiences with human studies. They are fairly limited, and from the information and analysis you have conducted, I am wondering if, again, this forced vaccination is that effective. Do you feel it is that effective and should be continued?

I mean, just basically, based on the reports and the studies that have been done.

Mr. Chan. Well let me answer the first question about why do we say that it is a small number.

When the test was done--the study was done--and published in 1962, it was supplied to four different mills.

Mr. Mica. Right.

Mr. Chan. And the only inhalation anthrax that occurred was in mill A, where there were five of them occur, all in a span of 2 months or so. OK?

And the understanding at the time was that since in the mill itself the air quality was poor, that everybody was exposed to inhalation anthrax. And what the data actually showed, aside from the small number, that anthrax epidemic occurred in one plant and no place else. This would suggest that whatever level of air quality that they were exposed to, including those who did not get vaccinated, end up with inhalation anthrax.

And out of the 1,400, if I remember correctly, some 870 did not get complete vaccinations. So what I am saying is that for that period, a year and a half or so, 5 cases out of 870 people did not end up with inhalation anthrax.

So that is the rate you end up with even if you are unprotected.

Mr. Mica. But what this boils down to, I'm trying----

Mr. Chan. I am sorry.

Mr. Mica. I am trying to get a simple determination, you know, based on the experiments that have been done, the testing of this vaccination. Of course, some of it, as you have said, is in a different setting against different exposures.

The basic question here is, we have several millions of potential folks that may be vaccinated in the future with this, is it that effective? Or are we going through this giving some sort of false security because it may not protect them?

Mr. Chan. Well, potentially, you could. In our statement we state that we believe in fact that it does provide some protection, although the problem, as we discussed before, is about the correlation between animal and human in responding to the challenge.

Mr. Mica. But there hasn't been enough human testing to determine that under different circumstances. Is that correct?

Mr. Chan. Yes.

Mr. Mica. And based on the reactions the folks have had, do you think people should have an opportunity to opt out? Should this be mandatory?

Mr. Chan. I think you are asking a policy question. That's the DOD----

Mr. Mica. Well, no. OK, if you have your kid who is going to serve in the military or you, based on what you know, you have studied this, you are a scientist and have had scientists look at this, would you recommend that folks have the

opportunity to opt out? Or are we using our service men and women as guinea pigs in a big experiment that we are not sure really works?

And also, a concern that I have is that you give them some false sense of security.

Mr. Chan. I am hoping that we all, hopefully, in this hearing we end up agreeing with what the data tell us. And the decision of whether one is vaccinated should be based on a balance between the risk and possible benefits. You are asking a question, does this vaccine have a for the lack of a better word is, have a lot of limitation?

Mr. Mica. I am sorry.

Mr. Chan. A lot of limitation, in the sense that it requires a number of shots over a long period of time. So when you ask the question of forced vaccination--mandatory vaccination, an issue--is if you need an 18-month lead time to fully vaccinate, it is hard for the commander to say I know precisely who is going to go where in the future with the understanding potentially anybody could be there in the future.

And then the second question is that this is really the only solutions they have, potentially. So when will you go?

The third thing I would say is that there are other possible alternatives because vaccination is not the only way to defend against BW agent. You can put masks on; you can basically take antibiotics. Those are other possibilities, and generally we know that, for example, over the next couple of years, both Department of Defense as well as Department of Energy are spending up to \$200 million in terms of detecting both chemical and biological agents, which will help you to speed up the time in detection and respond to an attack.

I am not sure I can answer your question in the very precise way.

Mr. Mica. Are you ready to be vaccinated?

Mr. Chan. If you tell me exactly where to go next year, sir, I would tell you that. As a private citizen, I don't see that threat to myself or my family, but if, in fact, I need to go to a place where I do know the country has this, then I would consider that.

But let me also say there is research done where they examine post-exposure treatments of people, using antibiotics, possibly with this vaccine that, is licensed, there are some promising results with animal studies. So those are other options I can have.

And certainly, as the chairman suggests, that we can also pursue the second-generation vaccine.

Mr. Mica. Thank you. Thank you, Mr. Chairman.

Mr. Shays. Thank you. Mr. Metcalf, do you have a question or two?

Mr. Metcalf. Yes, I do. Thank you, Mr. Chairman.

Mr. Chan, as a result of your concurrent investigations of anthrax and squalene antibodies, have any suspicions been raised about a potential connection between the two? And if so, could you discuss this.

Mr. Chan. I do not know the connection scientifically. I do know that there are soldiers out there who had called us, both Dr. Sharma and myself, with this concern. As you know, our study basically took the positions that we believe DOD should do some research to examine if indeed a valid assay can be developed to determine the presence of the squalene. I think that would really clear up a lot of issues.

Mr. Metcalf. Thank you. That sort of coordinates with my

request for the DOD to do an in-depth investigation on this. If the DOD acted on GAO's squalene report recommendation, do you believe that this would allay the suspicions about a connection between squalene as a presence in a vaccine and the Gulf war illnesses?

Mr. Chan. Well, I think developing a valid assay is just the first step of that. If in fact we find that it cannot be validated, then clearly the associations cannot be pursued. But if in fact you can validate it, indeed you find an antibody, I think a whole set of new questions would be raised.

Mr. Metcalf. Thank you.

Mr. Shays. Thank you. I just have a clarification of a question that Mr. Terry asked, and that is in regards to the process. My understanding is that the process is important when you are developing a vaccine, and I am going to read what you said.

You said, vaccines have three distinguishing features that contrast--this is on page 4 of your testimony--that contrast with those of chemical drugs. First, either they have no clear chemical-defined composition or simple chemical analysis is insufficient for effective characterization. Second, proper evaluation of them, qualitatively or quantitatively, is usually done by measuring their effects in the living organism. Finally, quality cannot be guaranteed from final tests on random samples but only from a combination of in-process tests and production tests and strict controls of the entire manufacturing process.

Isn't it a fact that when you are dealing with biologicals, the process is a very important element to determine both the safety and effectiveness of the vaccine that you are developing?

Mr. Chan. I believe the integrity of the process is a necessary condition, but it is not sufficient to guarantee quality.

Mr. Shays. It is not, but you can take the inverse.

Mr. Chan. Yes, sir.

Mr. Shays. And you can question the quality, and, therefore, you have to raise gigantic concerns about whether the vaccine should be used. Isn't that true?

Mr. Chan. I think that raises the question. Yes.

Mr. Shays. Yes, it does. And just this other point with the Brachman study.

Mr. Chan. Yes.

Mr. Shays. This was in 1955 and 1959, published in 1962. It was in a wool mill. Isn't the problem, we don't know how they were, at what levels they were exposed? We don't know if there was any exposure. We make an assumption that in a wool mill there is going to be some exposure, but don't know what level. It could have been the entire time, it could have been none or minimal exposure to anthrax. Isn't that correct?

Mr. Chan. Yes, that is my one comment I made about inhalation anthrax. The uniqueness of the timing when it all occurred in one place, in one short period of time when epidemic occur, it does not suggest that the other plants have problems with air quality with anthrax spores around.

Mr. Shays. Well, that means something to you. I want to put it in my words, and then tell me if I am inaccurate here.

Mr. Chan. Yes.

Mr. Shays. In my words, we have no control of the threat. First we don't know if the threat was the same to those who had the vaccine and to those who didn't have the vaccine. That is

one point.

But the other point is we don't know what level the threat was. The entire time, there could have been minimal exposure. I mean, there could have been there could not have been. Isn't that correct?

Mr. Chan. Yes, it is.

Mr. Sharma. Let me just answer. We had a meeting on this issue with Dr. Brachman. And we raised this issue, that was there any environmental monitoring done. And his reply was no. In those days, the standards were very different. And then we raised this issue, how do you know that if no disease occurred it was because bales were not contaminated. And he did say to us, that this was one of the very fundamental problems in his study. He did not envision this problem in those days.

But as we discussed, he agreed, that there was no environmental monitoring. They were equating absence of disease with the efficacy of the disease. Indeed, the only time they checked for the contaminant of the bales was when the epidemic occurred. And they did find the bale was contaminated. But they did not look for every single bale that these mills were receiving whether or not----

Mr. Shays. And we don't know what level of contamination--

--

Mr. Sharma. No. There was no monitoring at all.

Mr. Shays. So let's--I could make a summation: One, there was practically none or that there was some, and so this vaccine protects against low-level exposure but that if you had exposure, this study would be meaningless.

I mean, I can infer that?

Mr. Chan. Well, yes. I think, what you might be looking for is sort of a dose response relationship: How many doses you--I believe, in fact, that, you know, with protective antigens, you cannot protect a person ultimately in the sense that you can always overwhelm your immune system by having enough spores and so on. So there is a limit here in terms of the level of protection.

That is why I think it is important to have the self-protection, mask and all the other things that helps. It is really sort of like giving you the first breath. Because if you just sit there and keep on breathing this stuff, you get overwhelmed and can be in trouble as a result.

Yes, you are right. And you are raising a question which we did not, could not address with Brachman's study because we don't know what the level of exposure was, and we really do not know if at higher levels whether the vaccinated individual would be protected or not. I think that is a question.

Mr. Shays. When you say we, you mean generically we, including Mr. Brachman?

Mr. Sharma. That is correct.

Mr. Chan. Including him. Yes.

Mr. Shays. And that is not a criticism of him when he did his study, but it is a criticism of applying this 1950's study to potentially vaccinating 2.4 million Americans who will be ordered and who are being ordered to take it.

Ms. Schakowsky.

Ms. Schakowsky. I just had one question. I was reflecting, Dr. Sharma, on your response to the chairman's question about how we got to six doses. And you said, essentially, that some individual arbitrarily, I think was your word, decided on six doses. I want to go back to that just for a minute. So we have nothing to show that there is any correlation between this

six--these six doses and the efficacy of it, the levels of protection. And nor do we know how this may impact on adverse reactions on the safety--do we know anything about four versus six or one versus six or anything?

Mr. Sharma. You have asked two questions. And the first question is about the multiple dose schedule: We do know that there is a pending IND with FDA which is looking at a reduced-dose schedule. However, one of the problems is we don't know what the level of immunity means in terms of the protection.

There is some animal data that DOD has collected that looks promising, but what they need to do is to do the bridging studies which shows what is the relationship between the level of immunity and protection. And then if they could develop those correlates, then you can overcome this hurdle of, which is the second question, that is how do you extrapolate those results to humans. And that has not been done.

Now, with regard to your second questions on what is the relationship between number of dosages and adverse events, I don't remember exactly, but, yes, there is one place where I have seen on anthrax vaccine where they had looked at the adverse events by number of shots. And they do increase with the frequency of the dose.

Mr. Chan. I think, if I may answer the question a little differently, I think if in fact one can have an IND whereby one can reduce the six shots to even three shots, it would be a tremendous tactical advantage logistically in terms of applying these vaccines, the current licensed vaccine. Because that would mean, instead of requiring 18 months for a full regimen of shots, it would be reduced to 4 weeks.

So the surgeon general of the Army, you know, have been trying to figure out how best to do that. I think they are initiating a study to examine that. And it is significant in that sense.

Ms. Schakowsky. I just want to say that what we don't know is just so overwhelming. And in your answer--in your testimony, it says several studies have shown no direct comparison of immunity and humans to that in monkeys, and the bridging, as you call it, studies that haven't been done and the studies of dosage and how they relate to protection and safety--it is just dramatic, I think.

Thank you.

Mr. Shays. I think we are ready to get to the next panel. Mr. Chan, I appreciate your statement, and I also appreciate your frank answers to our questions. Thank you, and Dr. Sharma.

Mr. Chan. Thank you.

Mr. Shays. And obviously, I appreciate the panel No. 2 and No. 3 for their patience as well.

So at this time, I would call Dr. Katherine Zoon, Director, Center for Biologics Evaluation and Research, Food and Drug Administration, more commonly called FDA, accompanied by Mr. John Taylor, Senior Adviser for Regulatory Policy from FDA. And then we have General Eddie Cain, Joint Program for Biological Defense, Department of Defense, and Dr. Robert Myers, chief operating officer for BioPort Corp.

Welcome them to come and, if you could remain standing just so I could swear you in. As you know, we swear in all of our witness who testify.

Now, let me ask as well. Is there anyone else who might assist you, who you might prefer to answer the question? If they are here, I would prefer they stand up as well so we don't have to swear them in again.

So if they are here, if there is anyone who might--even if you end up not doing it, it is probably better to just get sworn in. That helps us out. And then we will identify you for our recorder if, in fact, you respond to a question.

And if you would, raise your right arms please.

[Witnesses sworn.]

Mr. Shays. Thank you. I recognize all the individuals who stood up as responding in the affirmative. I think it is very important for all of our--we have three people testifying, Dr. Zoon, also General Cain and Dr. Myers, for you to feel that you can give a full statement. And also I have no problem with you responding to anything you have heard. You have been very gracious in listening to the testimony. And you may disagree with it, and you may have some very helpful facts that would allay some of our fears as well.

So, we will start out with Dr. Zoon, then we will go to General Cain, and then we will go to you, Dr. Myers. And I am going to do a 5-minute clock. I am going to switch the clock again another 5 minutes. And we will see if that gives you enough time.

So, at this time, Dr. Zoon.

STATEMENTS OF KATHRYN ZOON, DIRECTOR, CENTER FOR BIOLOGICS EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION; GENERAL EDDIE CAIN, JOINT PROGRAM FOR BIOLOGICAL DEFENSE, DEPARTMENT OF DEFENSE; ROBERT MYERS, CHIEF OPERATING OFFICER, BIOPORT CORP.; AND JOHN TAYLOR, SENIOR ADVISER FOR REGULATORY POLICY, FOOD AND DRUG ADMINISTRATION

Dr. Zoon. Thank you, Mr. Chairman.

Mr. Chairman, members of the committee, and Mr. Metcalf, if he comes back, I am Dr. Kathryn Zoon, Director of the Center for Biologics Evaluation and Research at the Food and Drug Administration. I appreciate the opportunity to discuss the safety and efficacy of the anthrax vaccine currently manufactured by BioPort Corp.

Mr. Chairman, we are aware that some people question the safety and efficacy of the anthrax vaccine. Let me be clear, we believe that for persons at high risk, the licensed anthrax vaccine is safe and effective for the prevention of the often-fatal anthrax disease.

Our confidence in this vaccine is based upon four components. First, the clinical trials and subsequent clinical laboratory experience with the vaccine. In this case, the Brachman trial and the CDC trial, which I will discuss.

Second, ongoing inspections of the manufacturing facility based on our CGMP requirements. Third, our lot release requirements, which are another layer of protection, and fourth, our surveillance of adverse event reports that serve as an early warning system.

We continue all our efforts in all four categories of these areas to help assure that only safe and effective products are on the market.

Anthrax is a highly infectious disease caused by spores of a bacterium known as bacillus anthracis. Untreated cutaneous anthrax infection has a mortality rate of approximately 20 percent. Inhalation anthrax has a mortality rate of 80 to 90 percent or higher.

Mr. Chairman, the only known effective prevention against anthrax disease is the anthrax vaccine. The Centers for Disease Control and Prevention data on reported cases in the United

States indicate a decline from 130 cases per year at the beginning of the century, to zero cases per year in recent years. Use of the anthrax vaccine to immunize people at risk of exposure along with vaccination of animals against anthrax has likely contributed to a favorable decline in anthrax infections.

I will describe the historical efficacy data for you. During the 1950's, Philip Brachman and his colleagues conducted a single-blinded clinical trial involving workers in four mills in northeastern United States. Mill workers were at risk because they routinely handled anthrax-infected animal materials. By comparing the completely vaccinated population versus the placebo population, the authors of the study calculated a vaccine efficacy level of 92.5 percent.

On April 14, 1966, CDC submitted an investigational new drug application for the anthrax vaccine to the Division of Biological Standards, which at that time was part of the National Institutes of Health. Under this IND, the Michigan Department of Public Health manufactured most of the lots of investigational vaccine prepared in a similar, but not identical, manner to the vaccine used in the Brachman study.

Data submitted to the Division of Biological Standards under this IND describe CDC's experience with approximately 7,000 study participants, including textile workers and laboratory workers. On November 10, 1970, the Division of Biological Standards granted a license to the Michigan Department of Public Health for the production of anthrax vaccine.

The data submitted by CDC met the provisions of the Public Health Service Act, which require evidence of safety, purity and potency. After the Division of Biological Standards was transferred from NIH to FDA, a panel review was initiated to verify whether existing data supported the safety and efficacy of biological products. The panel on review of bacterial vaccines and toxoids evaluated all safety and efficacy from the CDC and Brachman trials.

The panel recommended that anthrax vaccine manufactured by the Michigan Department of Public Health be classified as a category one product, meaning it was considered safe, effective and not misbranded.

As the panel concluded, it would be virtually impossible to conduct an efficacy study today as the incidence of naturally occurring anthrax in humans is low and sporadic in occurrence. The safety data base developed by CDC under the IND, however, would be considered a reasonable pre-licensure data base to evaluate such a product today.

The population that has been immunized to date represents individuals who are considered to be at risk for exposure. Approximately 7,000 patients were vaccinated during the CDC clinical trials. While it is not possible to accurately report the precise number of people vaccinated between 1974 and 1989, approximately 68,000 doses were distributed. This is sufficient to vaccinate about 11,000 people.

Deviations from current good manufacturing practices have recently been documented during inspections of the anthrax vaccine manufacturing facility. CGMP's are only one of the several safeguards to assure product quality. Our surveillance includes information from testing and review of manufacturing records, which showed lots of product available for distribution are safe and effective for immunizing individuals at risk.

The anthrax vaccine is subject to lot release. The lot-release program helps assure product safety by providing a quality-control check on product specifications. Each product lot of anthrax vaccine undergoes thorough testing, including purity, potency, identity, and sterility. Manufacturers may release lots only after this testing is documented and reviewed by the FDA.

FDA uses the vaccine adverse-event reporting system, VAERS, to track adverse-event reports possibly associated with licensed vaccines. Any person, including a patient, can file an adverse-event report. Reporting adverse experiences associated with anthrax vaccine is voluntary for healthcare providers and mandatory for the manufacturer. A report does not indicate that the vaccine caused the adverse event, but only that the event occurred soon after the vaccine administration.

From the time VAERS started operating in 1990, until April 1st, 1999, 101 reports of adverse experiences have been received regarding the anthrax vaccine. Of these, 87 were non-serious and 14 were considered serious events. As the number of people immunized with vaccine increased, the number of adverse-event reports may also increase.

Data from the VAERS system can serve as a useful tool in identifying potential problems with the vaccine. Thus far, the reports received on the anthrax vaccine do not signal concerns about the safety of the vaccine.

Mr. Chairman, let me state clearly that we are confident that for persons at high risk, the licensed vaccine is safe and effective for the prevention of anthrax--disease.

I can assure you that FDA will remain vigilant in its oversight.

I appreciate the subcommittee's interest in this very important topic, and I will be happy to answer any questions. Thank you.

[The prepared statement of Dr. Zoon follows:]

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Mr. Shays. Thank you very much.

General Cain. Thank you.

General Cain. Chairman Shays and other distinguished committee members, I am honored to appear before your committee today to address the production and supplemental testing of the Department of Defense, the DOD's, vaccine program. I am Brigadier General Eddie Cain, Joint Program Manager of the Joint Program Office for Biological Defense, and I have served in this position since June 1998.

I have provided the committee with a more detailed written version of my testimony that I would like to submit for the record. Today, I will address the specific questions raised in your letter to Secretary Cohen that are in my area of responsibility.

The Joint Program Office of Biological Defense plays a major role in force protection with DOD by providing detection equipment and medical products to all service members. One aspect of my mission is to provide centralized program management for the advance development and production of all DOD biological defense vaccines, including anthrax vaccine.

This responsibility includes licensing, testing, and stockpiling these biological defense vaccines. As was stated during the March 24th hearing, anthrax is a major biological warfare threat faced by our armed forces. More than 10 countries, including Iraq, have or are suspected of developing a 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 weaponize. If anthrax is used as a biological weapon, disease will most likely occur by inhalation of anthrax spores. Death is the usual outcome once clinical symptoms appear regardless of any post-exposure treatment.

Death from anthrax, however, is preventable by immunization with the licensed vaccine, thereby enhancing force protection. On a personal note, I have received four of the six shots, and I can tell you that I have no reservation about taking the vaccine, and I have had no adverse reaction.

Protection of the total force against anthrax was initiated by Secretary Cohen in December 1997. One of the conditions required before implementation of the immunization plan was that supplemental testing had to be accomplished to assess sterility, safety, potency, and purity of the vaccine lots in the stockpiles. The FDA has previously released all lots in the stockpile. DOD, however, for added assurance, directed the

Joint Program Office to contract the Michigan Biological Products Institute, now BioPort, to conduct supplemental testing on all lots of anthrax vaccine in the DOD stockpile.

Whereas, BioPort conducts the actual testing, Miretek Systems Inc., a DOD contractor, provides independent oversight of this testing. Miretek staff observes all aspects of the supplemental testing and provides a written report to the Joint Program Office on the acceptability of the testing and test results.

The Joint Program Office then reviews all data prior to releasing any lot for shipment and use. Only those lots in the original stockpile that have passed supplemental testing have been approved for use for immunization.

Supplemental testing began in January 1998. As of April 1999, eight lots have passed all supplemental testing requirements. Detail status of the remaining lots is outlined in my written testimony.

I will now discuss the anthrax vaccine production facility, which is the only FDA licensed manufacturer in the world. Before implementation of the immunization plan and the November 1996 inspection, a DOD task force evaluated the anthrax vaccine capabilities at the facility. It was determined that the facility would require substantial renovation to meet production and FDA regulatory requirements.

Let me reiterate that the decision to renovate the facility was made before the 1996 FDA inspection. Production was stopped in January 1998 to begin the renovations. The physical aspects of the renovation were completed in January 1999. Completion of the renovation also requires validation of the manufacturing equipment and the production process. The process validation includes producing several lots of anthrax vaccine for review by the FDA.

We expect new vaccine to be available by January 2000.

With respect to current vaccine availability, there is sufficient anthrax vaccine to support the Secretary of Defense anthrax immunization program through December 1999. Beyond 1999, both the remaining doses in the stockpile and new vaccine produced in the renovated facility will ensure that DOD has sufficient doses to meet force-protection requirements.

In conclusion, anthrax vaccine is a key element in protecting service members against a lethal threat of anthrax. The DOD will continue to work with BioPort and the FDA to ensure there is a sufficient supply of safe and effective anthrax vaccine.

Mr. Chairman, this concludes my statement. Although I did not address your question regarding adverse reaction reports, I have included a statement in my written testimony from the Office of the Surgeon General regarding this topic.

I am ready to address any questions that may fall in my responsibility at this time.

[The prepared statement of General Cain follows:]

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Mr. Shays. Please summarize that Surgeon General's report. General Cain. In summary, Mr. Chairman, the surgeon general just concluded that it is safe and effective--that the vaccine is safe and effective.

Mr. Shays. That is a real summary. [Laughter.]

I was hoping for a little meat in there, a little detail. Are you prepared to give anything more than that summary?

General Cain. I am not at this time.

Mr. Shays. Dr. Myers.

Dr. Myers. Mr. Chairman and distinguished committee members, my name is Dr. Bob Myers, and I am the chief operating officer of BioPort Corp. And thank you for making my stay here in Washington as pleasant as possible.

I am proud to come before you today and tell you about our experiences as the manufacturer of the first and only routinely used defense vaccine in our country. I am pleased to have this opportunity to personally assure you of our vaccine's safety and effectiveness. Indeed, this vaccine, instead of being criticized, should be welcomed as a safe and effective counter to biological warfare in today's highly threatening global environment.

I have worked for the lab since 1978, when it was owned by the Michigan Department of Public Health. I have been involved in, largely directed, the manufacture of all doses of anthrax vaccine being used in the Department of Defense, by the Department of Defense in its anthrax vaccine immunization program.

Let me be clear at the outset. I don't set policy; I make vaccines. And I am totally committed to providing the very best protection possible against the anthrax threat. BioPort has worked closely with the FDA to license and manufacture a quality vaccine, and we are working closely with the DOD to build and test a stockpile of vaccine that meets their important force-protection requirements.

As you have heard this morning, anthrax is by far the most likely bio-weapon we will face in the near future. The vaccine has been produced in Michigan since the mid-1960's, when the Federal Government came to the Department of Public Health and asked them to develop and produce an anthrax vaccine which was badly needed in the textile industry as well as to protect laboratory workers studying anthrax.

The Michigan lab had a long and outstanding history as one of the leading vaccine developers in the country, had an excellent working relationship with the CDC and the DOD, and last, but by no means least, they were willing to do the work on a vaccine that would protect people against anthrax at a time when there was no interest.

While the anthrax vaccine was licensed in 1970 on the basis of efficacy already presented to you today by FDA, and this was before I started working at the lab, I routinely review

information relating to its safety and effectiveness. So I note the efficacy of BioPort's vaccine was confirmed in 1985 by an expert panel, which found that from 1962 to 1974 no cases--let me repeat, no cases--occurred in fully vaccinated individuals despite continued cases in unvaccinated mill workers.

The FDA panel concluded that the anthrax vaccine is safe and effective.

And let me just point out by example here, in way of answering some questions that may arise--I will start out by saying yearly deaths for the United States for 6 or 7 years, 1990, one; 1991, three; 1992, one; 1993, three; 1994, six; 1995, four; 1996, four.

None of these deaths occurred in vaccinated individuals, and the vaccinated individuals receive either three or five doses. Now, the example that I am describing is an example that is not anthrax, but rabies.

We give five doses of rabies after exposure. Do we know we need to have five doses? No, but when the studies were done, five doses worked. If you don't get vaccinated for rabies, you die after you have been exposed.

Five doses of DTP are given to children between the ages of birth and 5. Would four doses work? While there is some evidence to show that for newer vaccines, perhaps four doses would, and you wouldn't need a fifth.

Why are there six doses for anthrax vaccine? Because six doses work to stop disease, and there haven't been incidences of disease that are large enough since then to study.

Mr. Shays. Let me just make sure I am clear on that. Are you saying in general, Dr. Myers, that six doses is the norm for all vaccines?

Dr. Myers. No I am not. I am saying that five doses for rabies vaccine post exposure works. Nobody wants to take a risk at cutting that back to four. Five doses of DTP are given between birth and 5 years of age. There is some evidence to show that the fifth dose may not be needed, but it is still given. And we know that six doses of anthrax vaccine worked in clinical studies, and since the incidence is so small, no additional studies have been done. Six works; we stay with six.

Mr. Shays. Let me just let you continue, and then I will have you come back.

Dr. Myers. Thank you.

Mr. Shays. Thank you. I am sorry I interrupted you.

Dr. Myers. Thank you.

The FDA and DOD have already spoken to adverse events that have been reported to them. And my written testimony fully covers this topic as well.

I would like to make several additional comments. Let me describe a study that you may not be familiar with. It is a study of about 400 individuals whose reactions were actively solicited after three doses--for each of three doses: Redness, any, 21 percent. Soreness, any, 68 percent. Swelling, any, 11 percent. Arthralgia, any, 16 percent. Fatigue, any, 33 percent. Headache, any, 37 percent. Headache, severe, 2.8 percent. Rash, any, 5.2 percent. Rash, severe, none. Fever, 99.5 degrees Fahrenheit or greater, 2.26 percent.

Seems like a rather high reaction rate. Listen carefully. What is striking is that this was part of a study done with one of the most recently licensed FDA vaccines, a vaccine licensed to protect against lyme disease. But most striking, the reaction rates I just described to you were from the placebo group, not the vaccine.

If you actively solicit reaction rates to injected vaccines, because they use needles, they break the skin, they break nerve fibers, they create inflammation. You will have side reactions. Most will be local. Some will be severe. Generalized reactions can also occur.

I have personally had many doses of the vaccine over the years, more than you, General Cain, and have had nothing worse than the sore arm experienced by many others. If the anthrax vaccine were available for my wife, my children, and my grandson, I would have absolutely no reservation in administering the vaccine to them, including my eldest daughter who is of child-bearing age.

One of the ways the safety and efficacy of vaccines are ensured is through periodic inspections of manufacturing facilities to determine if they are operating in accordance to their license and according to good manufacturing practices.

Our labs have been inspected at least 48 times since 1969, including several recent inspections that reported serious deviations of GMP's. BioPort takes this matter very seriously.

I would like to point out that contrary to the testimony of the GAO, the manufacturing facility was inspected in January 1993. That is the anthrax manufacturing line. It is not a plant. It is not even a building. It is a floor in a building at a campus that has about 20 buildings, most of them two stories or more.

This facility, on the basis of that inspection, was approved in July 1993. Two inspections in 1998, one in February and the other in October, concentrated heavily on the anthrax vaccine, the lots in the stockpile, and related GMP issues. We expect another inspection this summer as part of the FDA's review of our renovated anthrax facility that many have already discussed this morning.

After the February 1998 FDA inspection, we voluntarily quarantined, as a precautionary measure, 10 lots previously released by the FDA. An 11th lot had been quarantined before the inspection. These lots will remain in quarantine until any outstanding issues are resolved to the satisfaction of BioPort and the FDA. If satisfactory resolution is not obtained, the lots will be rejected.

In conclusion, the anthrax vaccine being provided to our troops is safe and effective. It's a typical vaccine. It is not the exception. BioPort is fully committed to making safe and effective vaccine. I am greatly concerned about the unsubstantiated comments made by those who, for whatever reason, are opposed to this important protection against one of the most serious biological threats in the world today.

The anthrax vaccine is an essential component of force protection in our military, and we at BioPort are committed to providing the men and women who serve our country with the highest quality vaccine.

Thank you for the opportunity to be here today. I would be happy to answer any questions you might have.

[The prepared statement of Dr. Myers follows:]

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Mr. Shays. Thank you. Dr. Myers, let me just say, since your company produces the vaccine, that if we ask questions of others and you think something is not stated correctly that even if we did not ask you, I want to make sure that you let us know you want to respond and jump in.

Dr. Myers. Thank you very much. I will.

Mr. Shays. Let me start with you, Dr. Zoon.

Would FDA approve a new anthrax vaccine today based on data from a different vaccine?

Dr. Zoon. FDA would look at the data supplied by the manufacturer and, depending on the data submitted, that possibility exists.

Dr. Myers. If I could just add to that as a manufacturer? There are many vaccines that are licensed without direct efficacy studies in humans. The rabies vaccine, formerly manufactured by the Michigan Department of Public Health, was licensed in 1998--1988--based on post-exposure-simulation studies not exposure in actual field conditions with known rabid animals.

Mr. Shays. OK. I am happy to have you jump in. I just want to pursue the question, and then you are welcome to jump in.

Dr. Myers. I am sorry.

Mr. Shays. Dr. Zoon, is it your testimony that the FDA will approve a new vaccine based on data from a different vaccine? Do they do that?

Dr. Zoon. As I said, Mr. Chairman, we would look at the entire data base----

Mr. Shays. No. That is not what I asked. I want you to answer the question. I asked, can you give me examples of other times that you have done that in the past.

Dr. Zoon. We have approved materials in which study was done with another product, which was developed by a different company, and then there were changes during the initial production--major manufacturing changes during the course of the study.

Mr. Shays. What was that product?

Dr. Zoon. The product was Avenex.

Mr. Shays. And so all the studies were on the old vaccine. And then they were allowed to change it and you approved it based on the studies of the older vaccine?

Dr. Zoon. The pivotal study was done with the original material. Yes.

Mr. Shays. OK. There were studies done afterwards, before you----

Dr. Zoon. There were, there were----

Mr. Shays. Let me just say something. I don't want you to answer quickly, I want you to speak more slowly because this is your field, not mine. And I don't want to get lost.

Dr. Zoon. Right. OK.

Mr. Shays. What I am asking is, did you, before you licensed that product, even though you did the pivotal studies, you said, on an older vaccine, did you continue to do studies

on the new vaccine before you approved it?

Dr. Zoon. The material was continued in other clinical studies.

Mr. Shays. Before you approved it?

Dr. Zoon. That is correct.

Mr. Shays. OK.

Dr. Zoon. However, those studies weren't the pivotal efficacy studies.

Mr. Shays. But the bottom line is you still did studies before you approved it.

Dr. Zoon. We did studies--the material was put in humans. Yes.

Mr. Shays. OK. And has FDA licensed any other vaccine without human efficacy data, and I think Dr. Myers responded. But I want you to respond.

Dr. Zoon. Has FDA--excuse me.

Mr. Shays. Has FDA licensed any other vaccine without human efficacy data?

Dr. Zoon. Efficacy data? I am not prepared to answer that question. I don't have all the information with me today. I would have to go back and look at my records to get back to you on that.

Mr. Shays. But none comes to mind. I realize that there may be many. But none comes to mind right now?

Dr. Zoon. To be honest with you, Mr. Chairman, I focused my concentration on anthrax vaccine for this hearing, and I would be happy to go back and check the records for that.

Mr. Shays. OK. Did you want to make a comment, Dr. Myers?

[Myers indicates he doesn't.]

Mr. Shays. OK. Why did FDA conclude that you needed six shots for anthrax? Dr. Zoon, why did the FDA conclude you needed six shots, not seven, not five, not four. What was the basis, what study was done that showed the six was what you needed to do?

Dr. Zoon. Mr. Chairman, I will answer your question. I wanted to make one clarification for the record, is that the product that I described, Avenex, is a therapeutic, not a vaccine--just to make sure that that is clear.

Mr. Shays. OK. Then let's back up. Tell me a vaccine.

Dr. Zoon. I don't have any other examples here right now.

Mr. Shays. OK. Is there anyone else in FDA here who could tell me of any vaccine that has been approved by, where a study has been done on one and then approved on another? I would be happy to swear you in. I am not saying it doesn't exist. We just want it on the record.

Ms. Goldenthal. I am Karen Goldenthal.

Mr. Shays. Why don't you sit down. And I thank you. And feel free to catch your breath a second. Move that water out of the way, and we are in no rush.

Ms. Goldenthal. I am Karen Goldenthal with FDA.

Mr. Shays. And let me request that you leave your name with the recorder.

Ms. Goldenthal. Certainly.

Mr. Shays. Thank you. Nice to have you here. Thank you.

Ms. Goldenthal. Thank you, Mr. Chairman. The Merck hepatitis A vaccine underwent a very major manufacturing change between the time of the pivotal efficacy trial and the time of approval. And this involved a scale-up and actually change in the procedure of how the hepatitis A virus was grown. So that is an example that comes to mind. And it actually took the sponsor several years to work out all of the issues with the

new manufacturing change.

And then they did a comparison with the material from the efficacy trial.

Mr. Shays. Did they do new studies with the new vaccine?

Ms. Goldenthal. You know, I would have to go back at the file and detail to give you that information, but I believe that they did one study where they looked at the immunogenicity of the new material.

Mr. Shays. I don't know what that last sentence-----

Ms. Goldenthal. The antibody response.

Mr. Shays. OK. Thank you.

Mr. Shays. Let me just ask two more questions here.

Does the FDA require immune correlate protection in an animal model as the basis for extrapolation of efficacy findings to humans?

Dr. Zoon. Excuse me, Mr. Chairman, can you-----

Mr. Shays. We are trying to find--I want to know if you have to find a correlate between what you do in an animal versus its impact on a human being.

Dr. Zoon. There are not good animal models for all studies. However, there are a number for many systems, and with vaccines, often animals are used to look at protection and looking for evidence of correlation with protection as well as human data. And when we can do studies in humans, we also look for correlates of protection.

Mr. Shays. Do you look for them, or do you actually demand that they exist before you license?

Dr. Zoon. In vaccine trials, you had asked earlier about why six doses. In the field of vaccinology, much of it is determined empirically; that means you pick a regimen, you study the regimen.

[Microphone wires knocked out.]

Mr. Shays. Let me just finish my question then. I am sorry.

Dr. Myers, and then I am going to come back for a second round. But if the vaccine is demonstrably safe, why would the company request and receive an indemnification from DOD against the risk of liability due to the possible adverse reactions and failure of the vaccine to convey immunity?

Dr. Myers. The answer to that is the same reason that there is a National Vaccine Injury Compensation Program now. It is to control tort. In 1985, the-----

Mr. Shays. Speak slowly. You are going to get your chance to say everything. I just want to-----

Dr. Myers. I want that 20-minute break. [Laughter.]

Mr. Shays. Yes, sir.

Dr. Myers. I am sorry. In 1985, the price of a dose of DTP vaccine went from 15 cents to \$11 and above because of the tort activity, the litigation that was uncontrolled and unpredictable. I am happy to say now that the cost of a dose of DTP is much, much less as the Federal Government has very wisely funded a program to adjudicate, deliberate, and pay reasonable award to people injured.

There is no such program for anthrax vaccine.

Mr. Shays. OK. But, let me understand. Is it comparable? Why wouldn't you be given the same protection as others? This seems like it is greater protection. I may be wrong.

Dr. Myers. I would welcome and encourage all vaccines to be included in the National Vaccine Injury Compensation Program, but today they are not. And the anthrax vaccine is not included in that program, federally mandated program.

Mr. Shays. You make other products, like tetanus and others

for DOD?

Dr. Myers. That is correct. Not for DOD.

Mr. Shays. OK. But do you have--explain to me--do you have that same exemption?

Dr. Myers. Not from the DOD. We are in the Department of Treasury-administered National Vaccine Injury Compensation Program, and we pay a surcharge; that is, an excise tax, on each dose that is distributed. That funds the program in the case of the rare but possible event that there is injury.

Mr. Shays. OK. Working backward, and then obviously, the seller pays the cost. In other words, am I to infer, trying to answer the question for you, that is your testimony in essence if you are under that program, you would just charge the DOD that much more?

Dr. Myers. I don't have my legal counsel here today, and I think it is a matter for legal counsel to determine whether the choice would be to go with National Vaccine Injury Compensation Program or to continue to pursue indemnification.

Mr. Shays. Well, during this break, I will give you a little bit of a homework assignment. If you would just find out why this seems a bit broader, and I would just love to know why. And maybe there is an explanation. And if you would call your counsel and find out the answer to that.

Dr. Myers. Let me just say--could I complete the answer. At the highest level, this vaccine is getting serious criticism. These hearings have added to that criticism. I think much of that criticism is unfounded.

Mr. Shays. It may be.

Dr. Myers. And I think people would be--anybody who is trying to protect their business would be scared to death of not having indemnification with such loud and unfounded criticism occurring.

Mr. Shays. Well, let me just respond to that because there are two sides to every story. This is a mandatory vaccine. This is not voluntary. This is 2.4 million people, not a few hundred, and this committee and others have every requirement to examine the facts. And I asked a very simple question, and I don't think it is a hard question to answer. And in fact, I think you may have answered it. All I want to know, is this unique for this particular vaccine that gives you an added advantage that didn't exist for others and, if so, why? And if it isn't, then the question is a simple answer and on to the next question.

General Cain, maybe you could respond to why you decided to do this.

General Cain. What was the question?

Mr. Shays. Yes. The question is: The DOD decided to basically give BioPort blanket indemnification, hence risk of liability due to the possibility of adverse reaction or failure of the vaccine to convey immunity. And I need to know why DOD decided to do that? And if you want to think about that and give us an answer when we come back. The question is, have you done it for others as well?

And we will have a 20-minute break. Thank you.

[Recess.]

Mr. Shays. I would like to call this hearing to order. I could ask some more questions, but I am just going to kind of make a comment that hopefully puts this hearing in some context.

I chaired the Subcommittee on Human Resources before I chaired this subcommittee, both in Government Reform. And we

oversaw FDA. We have done a lot of work, the former committee, on Gulf war illnesses. I candidly have suspicions that raise my concerns, but I will first state, I don't know if in the end the military, the DOD, is correct in, one, having this policy. I will say to you that there are soldiers that have do not want to take this vaccine, General Cain.

So I don't know whether they are correct or not. And when I ask these questions, I think we could be in a conflict and our soldiers could be exposed to anthrax and do I want to be the person that somehow moved our Government to not do this?

So there are questions on both sides. In my mind, the jury is out. Where the jury is not out for me is, that given some of our concerns that this is a mandatory program and not a voluntary one. It would seem to me that until some questions are answered, this should be a voluntary program.

So I will obviously acknowledge to myself and for the record that I believe this should be a voluntary program until some questions are answered and that then the military should be required to convince their men and women that it is in their best interest, and then let the men and women of our forces come to some conclusion.

I will also say that one of my problems is that I did not like how the FDA handled pyridostigmine bromide [PB]--I didn't say it correctly, but I can say PB--and that for the use in the military it was a nerve agent, and it was used and licensed for that. And we used it as a prophylactic, which was not the way it was designed for, and I am critical of FDA for, one, being so lax in what they allow the military to do.

The military was supposed to keep records, and it didn't.

So, yes I have those suspicions that I bring to the table. So, I have questions. Dr. Myers, I have questions that we have only one plant, you are the sole source. I have questions that there may be easy answers to, and then you can feel relaxed and we go on to the next thing.

You know, one is the indemnity, another is, why are we funding the plant. There can be reasons for that. We are not even going to get into that. One thing I can say is that this is not the last hearing. So I don't have to have all my answers now.

But I can say to the FDA, I need to know, because it is unfair for you, Dr. Zoon, for me to expect that you would be able to know other cases where you have handled it the same way. But I have a suspicion that when it comes to the Government, we allow the Government to have one standard and the private sector to have another.

And in my past, I found that to be true. So I want to make sure it is the same standard. And so, would you just explain to me, Dr. Zoon, when you say if a person is at high risk, the vaccine is safe and effective. Why did you use the word high risk?

Dr. Zoon. Because that is what the package insert labeling recommends it for.

Mr. Shays. So, is it not safe and effective for those people who aren't at high risk? So I guess effectiveness is moot, but is it safe?

Dr. Zoon. The vaccine labeling lays out the population for which this vaccine has been recommended. And, in fact, in the labeling, sir, it does say who those populations are. I can review that for you if you would like.

Mr. Shays. No. I just need to know the concept of high risk.

Dr. Zoon. Well, high risk was intended as the data showed from the study-----

Mr. Shays. Why don't you, one, put the document in the record, and then-----

Dr. Zoon. The package insert? I would be delighted to. [The information referred to follows:]

[GRAPHIC] [TIFF OMITTED]58959.054

[GRAPHIC] [TIFF OMITTED]58959.055

Mr. Shays. OK. And then, now, I'm sorry-----

Dr. Zoon. And so in that case, the package insert defines some of the high risk population and makes reference to others, but it discusses the issues surrounding the general population, where it is not recommended.

Mr. Shays. OK. What is left on the table from the GAO's statement is that basically there has been only one study of human beings. And, one, I need to know if that is in fact true. I think, Dr. Myers, you mentioned a study of 400, which I am not really familiar with, but I don't think that was a study related to licensing.

Dr. Myers. That is correct, sir.

Mr. Shays. OK. But what is--all three of you, General Cain as well--what is your reaction to the fact that basically there is one study but that study involved a wool mill that we don't know, as he said, the environment, we don't know the exposure level of anthrax, the disease, in that environment.

One, do you concur with that?

Dr. Zoon first.

Dr. Zoon. I am sorry, can you repeat the question, sir?

Mr. Shays. Yes. I am going to start with you, and I am just going to let Dr. Myers respond.

I want you to respond to the GAO's report. I mean, frankly, if we leave it on the table as it is, it is a pretty strong indictment against the--and I don't think it was intended to be as strong as it was--but in the end, with their response to the questions, they are basically saying they had a study that took place in the 1950's, reported in the early 1960's, and, the Brachman study, that basically had some who were, had the vaccine and some who didn't, and made certain conclusions.

But they made conclusions without knowing the environment and without knowing the exposure to disease. It could, in fact, have been very little exposure. So I just need to let you respond to that.

Dr. Zoon. OK. I would like to just review some of the data that we have. I can't respond to the GAO report because we haven't seen the report. We have just heard this morning, their testimony. We had a meeting prior where some issues were-----

Mr. Shays. But I want you to respond to their testimony. Let's just respond to their testimony. You have heard them.

Dr. Zoon. OK. I would say there are the Brachman studies and then there are the CDC studies, which are the major studies that we are looking at. In the Brachman study, it wasn't-----

Mr. Shays. Was that the only one relating to humans?

Dr. Zoon. No. The CDC study and the Brachman study both involved humans.

Mr. Shays. OK. And the CDC study was when?

Dr. Zoon. The CDC study began in 1966 and lasted until 19-- actually was followed out through probably close to 1974 with some of the followup.

Mr. Shays. OK. Why don't you talk about the Brachman study first?

Dr. Zoon. The Brachman study was a controlled field study. It was single-blinded, means that the individuals who received the vaccine and or placebo, did not know which ones they were getting. And then there was also an observational group that had no treatment.

As was stated, there are four mills in the Northeast in which these studies were done. The incident rate of anthrax back then was about 1.2 cases per 100 employees. So the trial was conducted in that environment.

In looking at the cases of the data from the Brachman study, a number of things were revealed. And as a result of the study--when they looked at the--there were 26 cases of anthrax reported. And, of those, 21 were cutaneous cases; 15 of those cases were in the placebo; one, as stated by the GAO, was in the vaccinated group, and two were in the partially vaccinated group, and three were in the observational group.

Mr. Shays. What is the observational group?

Dr. Zoon. The observational group is the group that received no treatment.

Mr. Shays. OK. But those with placebo received no treatment but thought they were.

Dr. Zoon. Right. That is correct.

Mr. Shays. OK.

Dr. Zoon. So those studies were done in the controlled studies. They monitored adverse events as well as the efficacy to look at the safety and efficacy of the vaccine.

In the CDC study, this----

Mr. Shays. Before you go into that, you didn't answer the question.

Dr. Zoon. Well, I am going through the data. I think that is important.

Mr. Shays. No. I don't want you to go through the data. I want you now to react to the fact that is it true and is that important that the, we don't know the environment, we don't know the level of disease that they were exposed to. Obviously you can't control----

Dr. Zoon. I think there is a little bit of a difference of opinion on that. Our review of the information in this area, suggests that there was environmental monitoring of some--of a certain degree going on. In fact, Dr. Brachman had published a report on the mill and, regarding an inhalation anthrax outbreak, and we would be happy to submit that paper to the record.

[Note.--The information referred to is held in the subcommittee files.]

Dr. Zoon. And in those cases they believe they were looking at what were in the environment in those cases.

Mr. Shays. Well, do they know the level of exposure? They don't. I mean, I think I can say that and I am not even a doctor.

Dr. Zoon. Right. I am just telling you what the information is that is available in the literature, and I think while one can never guarantee what the exposure rate is, there was some information and data regarding what was in the environment, and, in fact, those were published.

Mr. Shays. Then how do you react to Mr. Chan, I think it was him saying that he spoke with Mr. Brachman--Dr. Brachman--and that the doctor acknowledged that they didn't know the environment?

Dr. Zoon. Yes. I am just saying what information we have available, Mr. Chairman.

Mr. Shays. OK. Well you have information that that is what he said.

Dr. Zoon. No. I said that is what was reported in the literature.

Mr. Shays. If you found that the environment--that can't assess the environment, does that make you look at the study differently?

Dr. Zoon. I think it would depend on the context of the whole--one of the things when these studies were done, we do know what the case rate was for that environment at that time as a gestalt, which was about 1.2 cases per hundred employees. We also know that----

Mr. Shays. Dr. Zoon, you don't know at what level they were exposed. You don't know that.

Dr. Zoon. I personally don't know that. Yes.

Mr. Shays. No. But aren't you being a little disingenuous, with all due respect. How would they have determined exposure in 1950?

Dr. Zoon. You have a case rate----

Mr. Shays. Is there someone else who can answer the question? I just want it on the record.

It seems to me, what you would have said is, no, we don't know. And it would seem to me that if you don't know what the environment is, then the study isn't as valid. That would seem to me the straightforward answer to the question.

And I don't know, are we playing a game here?

General Cain. Could I comment?

Mr. Shays. Sure.

General Cain. I think one of the points I have incorrect, and somebody can correct me. It is impossible to do human efficacy testing right now because you have to expose a human to the anthrax virus.

Mr. Shays. I am not arguing that we should do that. I am just taking some question as to why we could claim the study should satisfy, because that is what DOD did, that the study should satisfy us because we did it with humans and then when we look at the study in, hopefully, a relatively intelligent way, we raise questions.

And then there should be answers to them.

Dr. Myers. Mr. Chairman?

Mr. Shays. Yes.

Dr. Myers. Could I comment from a manufacturer's perspective?

Mr. Shays. Sure.

Dr. Myers. Let me give whooping cough as an example. Many times, you don't know----

Mr. Shays. Before you give another example, I am just interested in this. And then believe me, you can give--you can say that is true but it is true in a lot of other cases. I just want to establish----

Dr. Myers. That's true, but it is true in a lot of other cases.

Mr. Shays. No, but is it true? Is it true that we didn't know the environment? I just want to establish that point and then we will get on to the next.

Dr. Zoon. Yes.

Dr. Myers. We knew that goat hair was contaminated with anthrax spores.

Mr. Shays. At what level?

Dr. Myers. I am not sure we knew that level.

Mr. Shays. OK. That is fair. And it may----

Dr. Zoon. Right. But----

General Cain. For me, as a deployed soldier, if I am deployed to an area, and I do know that we have no detection capability to detect or warn at this time, which will tell you to put your mask on. There is nothing out there to tell you. And if I know that in that area there are anthrax spores, the only recourse I have is to have an anthrax vaccine shot.

Mr. Shays. Well, I know, that would be the way you see it, but with all due respect, we need to know that this shot will protect at a level that you would be exposed at. We would need to know that.

And it may have been that in this case that the levels were low and, therefore, this vaccine is effective for low levels, but maybe not at the levels, sir, that you would encounter in warfare.

Dr. Zoon, Dr. Myers I am going to let you----

Dr. Zoon. I just wanted to reaffirm that we did have the historical data on the number of cases of anthrax that the employees got at the mills, and that was the historical data base that in which we were comparing the frequency of anthrax. So, while we don't have the exact levels that were in each bale, and the technology probably didn't even exist for that then, we did have the number of cases----

Mr. Shays. Let me just interrupt you. That is fine. I am not saying that they didn't do their job. I am just saying then let's put it on the record. That's all.

Dr. Zoon. Yes, but we do have the information, sir, that--

--

Mr. Shays. You have historic data: how many and how much.

Dr. Zoon. Yes. We have historic data that there are 1.2 cases of anthrax per 100 employees.

Mr. Halloran. Cutaneous?

Dr. Zoon. I don't have the breakdown, but most of them would be cutaneous.

Mr. Shays. Dr. Myers, you have been very patient. Thank you. And I am happy that--when you talked about rabies, it got my interest. So there may be other things that you want to share.

Dr. Myers. In doing clinical trials for efficacy, I, as a student of those, cannot speak to environmental contamination versus case rate in isolation as a single, as a single item. There are many avenues for the determination of the amount of exposure. A very commonly accepted avenue is the case rate in a population. And that is what was done in this case.

And I was only going to point out, sir, that with whooping cough, we don't know how many organisms our babies breathe when we do tests for whooping cough vaccines. We simply understand the incidence of the disease in the population being studied.

Mr. Shays. Right. The only difference I would say to you, is that we are ordering people to take a vaccine who may be at potential high risk if an enemy exposes them to this disease, but we don't know at what level they would expose us. And I don't think we have any tests that would be able to answer that question.

So I realize we are just----

Dr. Myers. I appreciate that point. I think it is a matter of policy, and it is probably central to the issue: Should vaccination be mandatory? And I am not going to offer an opinion on that other than to say I believe the vaccine works.

And if people are exposed to anthrax by an airborne route, and they are not vaccinated, 9 out of 10 of them will probably die. Some will die even if they are given antibiotic for long-term. On the other hand, if they are vaccinated, I am as confident as we will ever be at this time that most people will survive.

Mr. Shays. Let me, before going to John Tierney, would you just elaborate on rabies. You had mentioned it and I interrupted you.

Dr. Myers. Oh, I had mentioned rabies in that there seems to be some parallels, in fact. If you don't take rabies vaccine after exposure, whether the animal was known rabid or not, and you find out later that the animal was rabid, you will be dead. The disease occurs at a very low rate. As I pointed out in the testimony, one or two deaths, perhaps four deaths, a year. So the contention by the GAO that the disease occurs at such a low rate, therefore you can't tell if it is effective, I guess could be alleged for rabies vaccine, and probably a couple other vaccines as well.

So it seems that, as I listened to the GAO testimony, that the GAO was striving to set apart anthrax vaccine without placing it in context with all other licensed vaccines, with respect to manufacturing, with respect to clinical trials, with respect to post-licensure surveillance, and with respect to the status of the vaccine today.

And last, I would just like to point out that as we grapple with the mandatory immunization issue or policy issue, if you will, for anthrax vaccine, we should also consider the 9 or 10 other vaccines that are given to recruits during basic training and ask the question should those be mandatory as well. And really drill down to the reasons we think they should be mandatory.

There will probably be that there is a reasonable belief that at some point in deployment, or before deployment even, these people will be at risk to diseases that these vaccines protect from. If they get sick, their troop efficiency will be lowered, their unit strength will be lowered. So we vaccinate for hepatitis B for all recruits. These sorts of things.

And I just want to make sure that when we think about anthrax vaccine, we think about it in the context of all vaccines.

Mr. Shays. Yes, the only caveat I would say to you is, sir, that--and this is what we will find out--is the vaccines that our soldiers have that aren't anthrax, have had a history of wide use before they became mandatory?

And this is not a subtle difference. And there is wide use now; whereas, before there wasn't.

Dr. Myers. Could I just make one final comment about that? Most vaccines are licensed on clinical safety trials that aren't that different in magnitude than those done in the 1960's. And it is only after license, and it begins to be used in widespread use that you may or may not detect those kinds of events that occur at the level of 1 in 1 million or 1 in 3 million.

Now, you are never going to get there with a vaccine if it is never in widespread use, and I'll go back to rabies again. Maybe there are 15,000 post-exposure treatments a year. So you might be looking at 15,000 people. But these people believe strongly in that. Just like anthrax, if you are exposed, you die if you don't get vaccine, just like that. They believe that the benefit of taking five doses, not over a year, but five doses over a 28-day period, day 1, 3, 7, 14, and 21 or 28, far

outweigh the risks of developing a lethal disease.

Mr. Shays. That is helpful. Thank you. Mr. Tierney.

Mr. Tierney. Thank you. I only have one. Dr. Myers, is it--
am I accurate in thinking the Department of Defense is now
financing the renovation of some of your facilities?

Dr. Myers. The DOD may want to answer that directly, but
the financing of the renovation is largely funded by
contractual funds from the DOD.

Mr. Tierney. And can you tell me why that is? Why they are
funding a private corporate facility?

Dr. Myers. Well, we are a private corporate facility, but
we are not selling hardly any anthrax vaccine in the private
sector. Our facility capability for making anthrax vaccine is
almost entirely reliant on DOD funds. We are a 6-month-old
company. As we move into the private sector, we believe that
there are possibilities not only for defense vaccines but our
other products as well. And our goal is to become entirely non-
reliant on DOD funding for the defense vaccine sector.

In order to do that, we must be healthy.

Mr. Tierney. So you are telling me that you think
Department of Defense moneys are going into your facilities in
order to help you get healthy. I mean, is that----

Dr. Myers. As long as these moneys are going in and there
was what is called, you may be familiar with this term, GFE,
Government furnished equipment, there are strict regulations
and constraints on the use of that equipment, such that we
can't take Government equipment and make, chug out vaccine, if
you will, and sell it to the private sector. That is just not
legal in this country with GFE.

Mr. Tierney. Doctor, you are the chief operating officer of
the corporation. Are you also a member of the board of
directors?

Dr. Myers. Yes I am, sir.

Mr. Tierney. And are you one of the principals of the
corporation?

Dr. Myers. Will you define principal?

Mr. Tierney. Are you one of the owners of the shares of
stock in the corporation?

Dr. Myers. I am a minority shareholder of a company called
Michigan Biologic Products Inc. And Michigan Biologic Products
Inc. is a minority shareholder of BioPort.

Mr. Tierney. Thank you.

General Cain. Could I comment on that, on DOD perspective?

Mr. Shays. Go ahead.

General Cain. Given that BioPort is the only source
available for the anthrax vaccine, it was imperative that DOD
maintain their viability. The SECDEF immunization program, FDA
inspections, and privatization mandated that DOD put forth an
aggressive effort to maintain industrial capability. In
addition to the routine program management functions, DOD, on a
short-term basis, is providing resources to assist the
manufacturer in achieving full compliance with FDA regulatory
requirements.

A few examples include a transition team that assists in
development of their strategic plan, a regulatory specialist to
oversee the FDA compliance documentation, and a construction
engineer that orchestrated renovation of the production line.

As a result of DOD support, there has been marked
improvement in the facility, and I am confident that in the
near future BioPort will be able to function without our
assistance.

Mr. Tierney. Thank you.

Mr. Shays. Let me ask one point, Dr. Myers, that you were making that I found very interesting. You were suggesting that people had adverse effects in another case where they didn't even have--they were placebos or something?

Dr. Myers. They were placebos. That is correct.

Mr. Shays. It is for the record, and we would look at this. So I just want you to be as precise as possible about it. What are you referring to?

Dr. Myers. The product insert is public knowledge and I would be happy to put it----

Mr. Shays. It's not public knowledge to me, so just put it on the record again.

Dr. Myers. Yes. In the study, approximately 400 individuals were given three doses of a vaccine.

Mr. Shays. Right.

Dr. Myers. And these individuals were actively solicited for the identification of reactions: Did you have a sore arm? Did you have redness? They do this with a diary or a nurse interview, either in person or by telephone. And you find that even for placebo preparation, for the reason I pointed out, you are injecting something with a needle, you are breaking nerve fibers, you are expanding inter-connective--connective tissue within those nerve fibers with that dose.

Mr. Shays. You know, when they give us a shot, they never describe it that way. [Laughter.]

Dr. Myers. I apologize for the detail. [Laughter.]

Mr. Shays. But the bottom line to it is, that what?

Dr. Myers. The bottom line to it is that even with placebo preparations, you have local reactions that are as much as 60 percent. And with general reactions, when asked did you have headache, did you have fatigue, did you have fever, you find that those reaction rates are very high as well, even for preparations that don't contain active vaccine ingredients, the placebo.

Mr. Shays. That would seem to--sorry to interrupt you. That would seem to speak to the issue of the monitoring, the active versus passive monitoring. So I would infer that you are suggesting that if someone was--when the Pittman study in 1997 was done and 29 percent said they had a mild reaction and others had more, 14 percent had a more severe, you might--and yet with DOD, there really is very little response, you would suggest that is just the nature of the shot. And if you asked someone right after a shot, they would respond that way.

Dr. Myers. Yes. And I think there is a further point that I believe in. And that is, just like I know I had a sore arm, because you get a sore arm when you have a vaccine shot into your arm with a needle, that most of the military personnel now understand that. Goodness, they were given vaccines, many vaccines, as basic recruits. They know what an arm feels like after a vaccine, not just anthrax vaccine, but any vaccine.

So probably, it is because they understand the nature of inflammation for a vaccine that is injected that this passive surveillance is so low, not because it is being hidden or they care, or there is a serious problem, it is just that they understand. They are used to getting more shots in the army in basic training than most adults are over several decades. It is no big deal.

Mr. Shays. OK. I knew that needed to be put on the record since we have the other issue, and I am happy to have it put on the record. Let me just ask you, General Cain, and then I think

we will go to the next panel. And then I will certainly ask any of you to make comments.

Mr. Taylor, I would also say that sometimes someone who sits and just listens to questions ends up with the best answers in the end. [Laughter.]

And so I am going to invite you to make any comment you want at the end as well.

This is to you General Cain, how many lots of anthrax vaccine are awaiting the completion of the supplemental testing?

General Cain. What was that again?

Mr. Shays. How many lots of anthrax vaccine are awaiting the completion of the supplemental testing? If that is an answer-----

General Cain. Eight from 31. So-----

Mr. Shays. Eight are finished?

General Cain. Eight are finished.

Mr. Shays. Right. And is that a question that you can answer for us, Dr. Myers?

Dr. Myers. I can answer it.

Mr. Shays. OK. You have that. OK. And I also want to know what went wrong with the potency tests. Is that something you want to answer, Dr. Myers?

Dr. Myers. I can.

Mr. Shays. And then, general, when you are ready, you can answer the first question.

Are you prepared to answer that one?

Dr. Myers. Which one?

Mr. Shays. The question is what went wrong with the potency tests. Can you answer that?

Dr. Myers. Yes.

Mr. Shays. OK. Answer it please.

Dr. Myers. There was an increased level of testing.

Mr. Shays. Speak slowly though.

Dr. Myers. That was required as a result--[laughter as Dr. Myers slows his speech.]

I am having a problem. I guess I am just emphatic. I will try to slow down.

Mr. Shays. No. But this is to your advantage, isn't it? To put it on the record?

Dr. Myers. Yes.

Mr. Shays. OK.

Dr. Myers. During the increased level of testing in the spring of 1998, we found inconsistent results in control vaccine values across several tests with several different dilutions of vaccine. It is a test you know something is not behaving properly when your control vaccine is not behaving properly.

We suspended potency testing, first in the spring of 1998 for a short period of time, and then in the fall of 1998 for a longer period of time while we stepped back to design and evaluate possible sources for the inconsistent results in the potency tests. Those studies have pretty well been completed now. The potency test is behaving again as it should be. And we have assignable causes for the erratic results previously experienced.

Mr. Shays. Thank you. So the first question I wanted to ask, how many lots of anthrax vaccine are awaiting the completion of supplementary testing? The other question I wanted to ask is, are lots produced under conditions FDA found in violation being released without supplemental testing?

So who can answer that question?

General Cain. There are 24, 24 lots right now, that are awaiting supplemental testing.

Mr. Shays. OK.

General Cain. Most of those are, in fact, for potency. The other three, serial D purity, and has been completed in safety. There are three lots that have been quarantined voluntarily by BioPort themselves, 3 of those 24.

Mr. Shays. So this last question? The question is, are lots produced under conditions FDA found in violation being released without supplemental testing?

General Cain. No.

Mr. Shays. Your answer is no?

General Cain. That is no.

Mr. Shays. OK. Is that consistent with everybody else's position? Who would be qualified to answer this besides you, General Cain? Dr. Zoon.

Dr. Zoon. Well, once they have passed the lot release testing and are available and have met all the criteria, they are available for distribution.

Mr. Shays. So, in other words, your initial concern, once it is dealt with, then they are released?

Dr. Zoon. Yes. As long as there are no other, as was reported earlier, there were some lots in quarantine. And those are currently in quarantine because of some observations that we had on inspection. Those observations that we had on inspection need to be investigated by BioPort. Depending on the outcome of those investigations, those lots may or may not be distributed.

Mr. Shays. And then they are reviewed by you before a decision is made?

Dr. Zoon. Yes.

Mr. Shays. OK. Any other final----

Dr. Myers. If I might just add a small point to clarify. When the vaccine is released by the FDA, the DOD pays for the vaccine. So they own it at that point. And we store it onsite for them. The DOD has requested for their vaccine that they already own that supplemental testing be done for 32 lots that were in a stockpile at a point in time. And I just wanted to clarify that is not an activity that is at all directed by the FDA. It is the DOD.

Mr. Shays. OK. Got you. Any other comments before we get to the next panel? Mr. Taylor. Dr. Zoon, we will let you go.

Dr. Zoon. Yes, Mr. Chairman, I just want to correct one fact that, for the record, that FDA did do inspections for anthrax prior to 1996. I think Dr. Myers alluded to one, but there were a number of inspections for the anthrax.

Mr. Shays. On the site seen all parts of the production--I understand that it is part of the building, but it is certainly contained part of the building. Correct?

Dr. Zoon. Right. We were in the production facility several times. Often, though, there was an active manufacturing going on when we were there, but we were actually in the facilities where the anthrax was manufactured, being manufactured.

Mr. Shays. The statistics in the beginning, Dr. Myers, though, you were talking about the FDA being there, not necessarily just for anthrax. Right? We are focusing on anthrax.

Dr. Myers. Well, what I pointed out in my oral testimony was that in January 1993, not so very long ago, the FDA inspected the second floor of the building that is the anthrax

vaccine subplot manufacturing area where fermentation, bacterial culture, and purification is done. That is the isolated part of the facility. They were there, January 1993, because of facility renovation that had recently been completed, which was approved in July 1993.

Mr. Shays. And then----

Dr. Myers. And I am surprised that the GAO didn't have that report.

Mr. Shays. OK, but from 1993 to 1996, did the FDA get into the site?

Dr. Myers. Between 1993 and 1996, did the FDA go to the second floor of this building where the sublots are made?

Mr. Shays. Yes.

Dr. Myers. To my knowledge, they did not during that 3-year period.

Mr. Shays. Right. You know, that shouldn't be. Right? I mean----

Dr. Myers. We, as I said, have received 49 inspections since 19--or at least 48 inspections since 1969. Up until very recently, it has been the agency's position to do one inspection at least once every 2 years for each of three areas: bacterial vaccines and toxoids, viral vaccines, and plasma derivatives.

We have all three types of manufacturing operations; therefore, it could be expected that we would have one and a half or so inspections per year.

Dr. Zoon. If I could just clarify one point, and make one other point. We have had inspectors in there. We have inspectors who were immunized with anthrax vaccine to do the inspection. And they were in there in 1990, looking at it, during the time of Desert Storm, and also in 1993 to look at both the records and looking at some of the areas in the site.

So I just wanted to make sure that the record was corrected.

Mr. Shays. Would you also make sure the record--when did the Army--excuse me, when did the DOD make a determination to have a mandatory policy on anthrax and engage the plant, whether it was mandatory or not? When did that take place? General Cain?

General Cain. I believe in December 1997.

Mr. Shays. And since then, how many times has the plant been inspected?

Dr. Zoon. I didn't hear his comment.

Mr. Shays. Since 1997, December 1997.

Dr. Zoon. Oh, I can give you those numbers. Do you have those, John?

Mr. Taylor. Yes. The facility has been inspected twice, in February 1998 and in October 1998.

Mr. Shays. And, it is not operating now. So----

Mr. Taylor. That is correct. It is not operating right now; however, I believe as Dr. Myers alluded to, we will re-inspect the facility, and once they are up and running, they are right now producing consistency lots with the hope that they will resume full production by the end of the year. And obviously, we will go in and make sure that they are producing the vaccine in compliance with our regulations.

Mr. Shays. Thank you. Is there anything else that any of you would like to say?

Mr. Taylor. Yes, Mr. Chairman, I want to clarify, or address one point that you made after the break. FDA is obviously cognizant and sensitive to the criticism that was

leveled against us in regards to the Gulf war. And I can assure you that we are regulating BioPort and the anthrax vaccine the same way we would regulate any other manufacturer. So I just wanted to address that point.

Mr. Shays. Thank you.

General, I asked you to do--indemnification. I am trying to think of the question that I asked before I left.

General Cain. Yes, I think, why we have a blanket indemnification of BioPort. Two reasons. One, if we had not, it would have added 50 more cents per dose for the vaccines.

Mr. Shays. Right.

General Cain. So, from an economic standpoint, it was smart to do it that way. But more importantly, 2 years ago, when we submitted out interest from industry, not a single industry--manufacturer--wanted to get involved unless there were an indemnification clause.

Mr. Shays. OK. Fair enough. Was there another question that I asked someone else to check out before the break or was that the only question?

OK. I think that was it. Thank you very much. And----

Did you have something you wanted to say, Dr. Zoon. I am sorry.

Dr. Zoon. Yes. I just wanted to assure the chairman that, as FDA, we believe this vaccine is safe and effective for high-risk individuals, but we are committed to being vigilant, in both the review of activities surrounding this vaccine, and vigilant on monitoring the adverse event reports. And we will continue to do so to the best job we can.

Mr. Shays. Thank you very much. Anything else?

Dr. Myers. I just wanted to say that I applaud you and your committee for holding these hearings and for allowing me to be here today to speak as the manufacturer. I think it is very important that you listen to the next panel. I think it is very important that we recognize that there are people who suffered ill effects from the Gulf war. I just want to say that I hope that we concentrate on diagnosing their diseases and adequately funding their care, and that we make certain that we not dwell too long because it would be a disservice to them on the issue of anthrax vaccine because I truly believe it is unfounded.

Mr. Shays. OK. Thank you very much. And I will assure you that you will always have an opportunity if you hear of a hearing and you want to come back and put something on the record, you are more than welcome. [Laughter.]

Thank you very much.

Dr. Myers. Thank you, Mr. Chairman.

Mr. Shays. This time, I am going to ask Dr. Meryl Nass, physician, Freeport, ME; Ms. Randi J. Martin-Allaire, Eaton Rapids, MI; Ms. Roberta Groll, Battle Creek, MI; Mr. David Churchill, Albion, MI; and Mr. Michael Shepard, Savannah, GA, ask them all to come forward and ask them to remain standing so I can swear them in.

It goes Nass, Martin-Allaire, Groll, Churchill, and Shepard.

[Witnesses sworn.]

Mr. Shays. Note for the record that everyone has responded in the affirmative, and one of the advantages of the last panel is--the disadvantage is you have to wait, the advantage is you get to hear other testimony. And I am happy to have you summarize your testimony and speak to the questions that were asked and the answers that were given. Or you can give your testimony, and we are really grateful that you are here. So

thank you.

Dr. Nass, we will start off with you. And we will get the clock. One final note, Jonathan is leaving and is going to work for me in Connecticut. He has done a tremendous job for me, but I think that you probably left yesterday mentally with all of these distractions today. [Laughter.]

Dr. Nass.

STATEMENTS OF MERYL NASS, PHYSICIAN, FREEPORT, ME; RANDI J. MARTIN-ALLAIRE, EATON RAPIDS, MI; ROBERTA GROLL, BATTLE CREEK, MI; DAVID CHURCHILL, BATTLE CREEK, MI; AND MICHAEL SHEPARD, SAVANNAH, GA

Dr. Nass. Thank you. To start off, I wanted to clarify some of the statements made earlier about safety. We have several studies that were presented that looked at adverse effects. But those studies only lasted from 7 days to 30 days following vaccinations. So what we had were short-term effects only. And there is a significant amount of data on that. But it really tells us nothing about what we are interested in, which is, is there chronic illness due to anthrax vaccine?

Now, although none of the studies looked into that, one of them, the IND study, which was just done and submitted by Dr. Myers to FDA, would have been an ideal study to look into long-term effects because they collected blood from service members on at least an every 2-month basis for a period of 2 years, but only inquired about adverse effects over the first 30 days of that study.

Now, when you are wondering what exists that we can look at to try and determine if there is a problem with the vaccine over the long-term, one looks to several cohorts that might be useful. The first, of course, is the workers at Fort Detrick for whom this vaccine was in fact originally developed. There is some obfuscation about this.

But two workers at Fort Detrick died in the 1950's from inhalation anthrax. And it was determined that if Fort Detrick were to continue to do work on offensive biological weapons, they would need to vaccinate their employees so they wouldn't lose them to the diseases they were studying.

And it was for that purpose--this was a high-risk group subject to inhalation anthrax--it was not in any way developed for mill workers or livestock workers who were used as an experimental study group and who were not given the vaccine subsequently. And there was no need for them to have it because they only developed cutaneous anthrax, which is easily treatable with a zero mortality rate with oral antibiotics.

When you look at the Detrick workers, there are actually three studies in existence. These workers were multiply immunized with a number of vaccines. The studies were published in 1958, 1965, I believe, and 1974. They suggest that there were, in fact, some chemical differences in the blood of multiple vaccinees as opposed to controls, suggest that there were some people who developed cancer of the immune system that might have been related to multiple vaccination. But the actual effects of the vaccines were not clear.

Now in the subsequent 25 years, nothing has been published on these employees at Detrick. I don't know whether the Army, for whom they have worked, has done any studies, but this would be very useful to find out.

Another group, obviously, is the Gulf war veterans and the Gulf-era veterans who were non-deployed but vaccinated and

whose only exposure was to vaccines, not necessarily only the anthrax vaccine.

No studies have been done in the United States and published that look at the relationship between anthrax vaccine or multiple bio-warfare vaccines and subsequent Gulf war illness. Now there is data that could be examined to look into this question.

I know Han Kang of the VA has this data. He told me about 4 or 5 months ago that he would try to do the correlations but has told me since that he hasn't had the time.

In England, one study has been published, Catherine Unwin, is the first author, and that did show a statistically significant relationship between vaccination for anthrax alone and multiple vaccinations, and then subsequently onset of Gulf war illness. This was British veterans. It was a study based on recall. The British veterans apparently used some British-made anthrax vaccine, and some United States-made.

We really don't--I don't know how much of which they used, but my suspicion is that at least half of what was administered in England was the American vaccine. And I think that may be supported by some statements that were made earlier, that suggest that 268,000 doses of United States anthrax vaccine were available at the time of the Gulf war.

Certainly studies that look into this for U.S. veterans are critical. One of the reasons we don't have them is the issue of missing records. I have provided a declassified document that suggests that the Army, in fact, does have some immunization records that have been classified, that might help us to relate anthrax vaccine and Gulf illness.

But so far, no one that I know of has access to this data.

Seventh-Day Adventists, in fact, have been asked to participate in a recent study, out of Fort Detrick again. These folks were vaccinated up until the early 1970's and, as far as I know, they were not looked at since. But late last year, in September and October, they were asked to now provide information about any symptoms or disease they may have been diagnosed with in the interim. And when one looks at the survey, they are being asked about symptoms of Gulf war illness.

So it is very interesting. I guess the military hasn't figured out yet whether the vaccine may contribute to Gulf war illness. As far as I know, they have not publicized the existence of this study, but they are interested in finding out.

Is a new epidemic emerging from the current round of vaccinations? I am sorry to say that this does seem to be the case. Both the features of the illnesses that have been reported to me, and the official military response to these illnesses, echo the plight of ill Gulf war vets who remain today without a defined illness and without meaningful approaches to treatment.

Another issue I would like to just touch on is that of legal questions with regard to this vaccine. One of those is whether the vaccine, the order to vaccinate is a lawful order. And I suggest that it may not be, based on the preconditions that Secretary Cohen stipulated at the time he ordered the anthrax vaccine immunization program, several of which do not appear to have been met.

Second, in my looking at the FDA inspection reports between 1993 and 1998, I see the anthrax line only mentioned in the 1998 report. It wasn't mentioned earlier. And the late 1996

report suggests that the Army was performing the anthrax inspections and, therefore, FDA did not have the responsibility to do so. I am not sure that this is supported by the law, which requires FDA to investigate at least every 2 years, and more often if there are problems. And certainly the problems have been well documented at MBPI, now BioPort.

The third and most interesting legal issue is that of whether the currently licensed anthrax vaccine is the only anthrax vaccine to have been given to service members, and if in fact other vaccines may have contributed to illness. An unlicensed vaccine can only be given to a service member if informed consent is obtained. And I have not met a service member or Gulf war vet who tells me that informed consent was sought from them at the time they were vaccinated.

However, this article, written in 1990 by Ernest Takefuji and Philip Russell, who were both administrators at Fort Detrick, suggests that in fact unlicensed anthrax vaccines were administered to service members. And a letter inquiring about this to DOD last year that Mark Zaid and Pat Eddington wrote got an answer that, in fact, the anthrax vaccine mentioned here is not the same anthrax vaccine as the licensed vaccine that service members are currently receiving, suggesting that at least one other has been given.

Dr. Zoon talked about the VAERS reporting and how this produces information about adverse effects suffered shortly after vaccination. I would submit that this is the weakness of the VAERS system. What one really needs is active surveillance over a long period, of a significant enough number of vaccinees to find out whether there is chronic illness. It just doesn't matter what you find out in the first week or the first 30 days if people get over it.

And we are not doing proper surveillance of vaccines if this is all we focus on.

I provided an addendum to my testimony today which asks the general question, is vaccination a good defense against biological warfare? Even if the vaccine were 100 percent effective against all strains of anthrax, which nobody claims, it still would be a porous defense because an enemy would simply choose another biological agent, one that occurs naturally or one created using genetic engineering.

William Patrick, who formerly headed the offensive program at Fort Detrick, had this to say, ``It takes 18 months to develop a weapons-grade biological agent and 10 more years to develop a good vaccine against it.''

I submit that it is impossible to produce vaccines that will keep up with the rate of development of new bio-warfare agents, and that vaccines should clearly not be the first line of defense in this or any case against the threat of biological warfare.

Despite the fact that vaccines are unlikely to provide this defense----

Mr. Shays. We need to get you to----

Dr. Nass. Thank you. May I have 1 minute? Thanks.

Congress appropriated \$322 million in 1997 for the Joint Vaccine Acquisition Program. Its goals are to develop new vaccines for more than 10 known bio-warfare pathogens and administer the vaccine to all U.S. service members. The anthrax program can be regarded as the introduction to this much larger and less well known program.

The FDA has publicly stated that it intends to expedite licensing for these new bio-warfare vaccines.

Are we already embarked on a misadventure that will dwarf the anthrax vaccine program in cost, futility, and medical repercussions? What will it take to call a halt to the current round of vaccinations and, of at least equal importance, what will it take to investigate these illnesses and develop treatment protocols that are serious about getting answers and providing care?

Thank you.

[The prepared statement of Dr. Nass follows:]

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Mr. Shays. Thank you, Dr. Nass. That is very comprehensive and helpful. Thank you.

Now our next three witnesses are civilians who have taken the anthrax vaccine. Is that correct?

Ms. Groll. Correct, sir.

Mr. Shays. And we will start with you, Ms. Martin-Allaire.

Ms. Martin-Allaire. I would like to thank Congress for expressing an interest to the anthrax vaccination immunization program and allowing me the opportunity to speak about my experiences of adverse reactions to the anthrax vaccination and problems seeking medical care I have incurred as a civilian.

My name is Randi Martin and I am a civil service technician at the 110th Fighter Wing Air National Guard Base, located in Battle Creek, MI. I received my first anthrax injection on September 18, 1998, for a volunteer overseas deployment, which was scheduled to deploy on November 11th, 1998. The second injection was administered on October 2nd, and a third on October 16th.

According to my shot record, all injections were from lot FAV030. During this timeframe our base was preparing for an operational readiness inspection, which was scheduled for October 17th to the 23rd, 1998. I felt tired, sluggish, and slow during this timeframe, but associated it to the numerous hours of overtime and stress that comes with any inspection with the military.

On March 14th, 1999, I received my fourth injection. The lot number I received is yet to be determined. The next couple of days after my injection I felt sluggish, tired, and a little disorientated. However, I considered that to be normal with past experiences of inoculations. On March 17th, I realized this was no longer normal. I was so tired I could not get out of bed. My days for the next week consisted of numerous hours of sleeping. I was awakened only to eat.

The following 2 weeks, I attempted going to work a couple of times, but lasted only for a couple of hours each day and then had to leave. The reasons were I was too tired, my head felt like it was going to explode, my abdominal cramping had me doubled-over, or I was just too disorientated.

I began to notice that my memory seemed to be getting worse as I could not remember passwords to programs that I use everyday at my work.

On March 31st I went to the emergency room with the complaints of abdominal cramping, my body was running hot and cold in temperature, a severe headache, shortness of breath, and feeling nauseated. I told the doctor I thought it was a reaction to the anthrax vaccination. The doctor inquired why I was not at a military hospital as they did not know anything about the anthrax vaccination.

I informed him of our situation at our base, where there is no full-time medical physician available. In his willingness to help, he looked through the immunization pamphlets but could find nothing on the anthrax vaccination. This is the second time on the civilian side I have run into this. The doctor called the CDC only to get the answering machine. He left a message, told me to go home and he would call me back when he had an answer.

I left the emergency room with no answers, but at least had a prescription for Motrin. While waiting for a call from the hospital, I was having a conversation with my father. I could not complete sentences without having to stop and gasp for air. I was so winded I literally felt as though I was going to pass out. The hospital called me in about an hour with the number the CDC gave them to give to me.

I called the number but did not catch where I called. I was talking to a woman by the name of Kathy who seemed very nice and wanted to know what my symptoms were. When I started stating them, she interrupted me to say that some of the reactions had not previously been reported as adverse reactions from the vaccine, so she was not going to report some of my symptoms as being any type of adverse reaction.

Her response was I must have caught a virus because symptoms associated with the vaccine last 2 to 3 days and not 2 weeks. I told Kathy of my situation, that doctors were not aware of the anthrax vaccination and did not know what to do for me. Kathy's response was, they haven't heard of the anthrax vaccine? You must live in a small town. Don't they watch TV?

I asked where I called, and she told me the Department of Defense. It then became clear to me how the DOD can state there are few adverse reactions associated with the vaccine. How can you begin a trend of adverse reactions when the DOD states they will not report them?

On April 2nd, our vice wing commander, Colonel Seidel, called a meeting with individuals from the group who received the fourth injection. It was discussed during this meeting that actions were taking place to get us down to Wright Patterson Air Force Base, located in Ohio, the closest military hospital. There seemed to be a lot of legality issues, considering we were civilians and this was a military issue.

Colonel Seidel stated that the soonest we were able to get to Wright Patterson to see a military allergist was April 23rd. However, he was trying to get us in sooner as he found this date to be completely unacceptable.

On April 7th, the first group of four left Battle Creek Air National Guard Base at 7:45 a.m. to Wright Patterson to see the military allergist. During my examination, the allergist examined my ears, eyes, nose, and throat, felt my abdomen, checked my reflexes, and examined my VAERS report. I received a chest x ray at my request. I was told I was fine. During this time, the allergist was aware of my symptoms. The allergist stated in my medical record that I had a local reaction and to followup with my civilian doctor. Subsequently, two civilian physicians that I have seen so far know nothing about this vaccination. We returned to our base at 11:30 p.m. still with many questions and no answers.

April 14th in the morning I was feeling very ill. I had abdominal cramping, a headache, and was feeling extremely nauseous. I went in at 8 a.m. to inform my boss that I was leaving ill. The response was that I needed to watch my sick leave as I was in the hole. My sick leave available balance seemed to be the only concern, even though she was previously made aware of the problems I was experiencing from the vaccination.

My position at work requires you to be multi-task orientated. Since coming back to work, I am unable to accomplish this. I can now only do one task at a time, as it takes every bit of concentration to focus on just the task at hand. One month after the injection, I am still having continuous headaches, which medication no longer has any effect on. I am still having abdominal cramping; I am still feeling nauseous; I am experiencing memory problems; and I am continuously tired. I cannot walk up a flight of stairs without becoming winded. My joints are achy when they are bent for longer than a couple of minutes. I have extreme lower back pains, and just recently have developed back spasms. I have

gained nearly 20 pounds in 1\1/2\ months. I have absolutely zero tolerance for anybody or for anything. I do a lot of typing at my job. Normally I can type 75 words per minute. Now if I type more than 5 minutes, I find myself needing to stop as all of my fingers seem to tighten. I am only 25 years old and this should not be happening. I was off work for nearly a month with the only explanation being I have caught some kind of a mysterious virus that no one can explain or yet detect.

I was on antibiotics at the time I received my fourth injection, and was never asked if I was on any type of medication or antibiotics. A VAERS form was never shown to us or offered. We found our own VAERS form on the internet, filled it out ourselves, and sent it forward. I never even knew a VAERS form existed, and I have been in the military for 8 years. I have recently learned that our base clinic was never aware of a VAERS form due to the fact that it is not a military form. The lack of knowledge for a mandated program that has been displayed by the ``key personnel'' has been completely appalling.

The medical treatment that was given down at Wright Patterson to myself was nothing short of get her in and get her out. The Department of Defense's response of not reporting some of my reactions I find very troubling. Due to the fact that I was cutoff from the DOD, I never even finished stating all of my symptoms.

I have found the situation I am in puzzling, that consideration on what to do if a technician or Guardsman becomes sick was never taken. This seems like an important step missing considering it is now mandatory for military personnel, active duty or civilian.

There seems to be no answers to my questions on why I am feeling the way that I am feeling. The only responses are the vaccine is safe, has been routinely used for 30 years, and will protect me in bio-warfare. My concerns from this vaccination are legitimate concerns. If reactions get worse after each injection, with what I have experienced on the fourth injection, what am I going to have to look forward to on the fifth injection? The sixth? The annual boosters? Why are my symptoms being categorized as local, which consists only of swelling from the elbow to the shoulder and a sore arm when there are clearly more reactions involved? How many other soldier's reactions are being classified lower than what they really are? There are too many unanswered questions associated with this program. And there are too many vague responses.

I am neither a medical physician nor a scientist; however, I feel I am the most qualified to know what is going on with my own body. I know what my health is now as opposed to where it was before I started taking the anthrax injections. There is a massive difference, and there is something wrong.

Thank you.

[The prepared statement of Ms. Martin-Allaire follows:]

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Mr. Shays. Thank you very much. That is a very powerful statement. And I am sorry for what you have encountered. At least information should be available to you.

Ms. Groll.

Ms. Groll. Mr. Chairman and members of the committee, I sincerely thank you for your interest in the anthrax vaccine immunization program and for allowing me to testify today on the effects and obstacles I have faced since starting this vaccine program. Please note that any opinions I express are my own and in no way reflect the opinions of the Michigan Air National Guard or those of my superior officers.

I am currently a technical sergeant in a civil service GS-9 management and systems analysis, assigned to the 110th Logistics Squadron, Battle Creek, MI. I received my first of the anthrax series on September 18th in preparation for a possible voluntary deployment to Qatar. The deployment was voluntary, and the vaccine was a prerequisite to the deployment. I acted on blind faith in the Department of Defense, my superiors, and trusted in the individuals I felt qualified to administer the vaccine.

Following the first two shots of the series, I noticed I was extremely fatigued and nauseous; however, during the same period of time I was working numerous hours in preparation for an upcoming operational readiness inspection. I attributed the symptoms to the extra hours and stress, not to the vaccine.

On October 16th, I receive No. 3 of the inoculation series. Coincidentally, this inoculation coincided with the beginning of the ORI. The third inoculation not only enhanced the same symptoms, but I also noticed I was becoming increasingly short-tempered, emotional, nauseous, experienced loss of appetite, and achy joints. Once again I attributed this to the stress and the long hours of our inspection.

For the following month, my health continued to become progressively worse, until finally I sought medical attention on November 12. I was then placed on antibiotics and antidepressants for chronic fatigue.

On March 14, I was notified that our clinic was waiting for our group to report to the clinic for our fourth anthrax vaccination. Upon our arrival at the clinic, the medical personnel were quite agitated and appeared unorganized. For the first time, I felt apprehensive about receiving this or any other vaccine. We questioned the medical staff as to why we were receiving our shot early. We were told that it was OK as long as we received it within a 24-hour window.

We were given our inoculation and sent to the holding area. While waiting to be released, I noticed that my shot record indicated the date of inoculations as March 16th. This was March 14th. I compared my records with the other individuals present and theirs also reflected the 16th.

Sergeant Martin questioned Major Jermeay on why the date read the 16th. He appeared upset, collected our shot records, and disappeared. When he returned with our shot records, the dates had been changed to reflect the date of inoculation as March 15th. It is still the 14th.

We once again questioned him on this, and we were told the date was within the 24-hour period recommended by DOD so that it was OK. My shot records also indicate that I have received all four lots from lot FAV030, which would indicate that my final inoculation to be from an expired vaccine.

Mr. Shays. Excuse me a minute.

[Pause in testimony while chairman confers.]

Ms. Groll. That evening I started to feel ill: chills, fever, and nausea. My symptoms increased over the next few days to include headache, dizziness, diarrhea, and abdominal pain. On Wednesday, March 17, as non-commissioned officer in charge of the base honor guard, I was rendering services--honors at a memorial service for a former member of the U.S. Air Force. During the memorial service, I developed tremors and dizziness. I went home immediately following the services. The next few days were again spent in bed.

By Friday, March 19, my symptoms had increased to include shortness of breath. Once again I sought medical attention. During the medical evaluation, I stated that I had received my fourth anthrax inoculation on Sunday, March 14th. My physician immediately ordered blood work, urinalysis and referred me to an infectious disease and pulmonary specialist. Upon consultation with him, he in turn referred me to neurologist for my tremors and advised me that I was having an adverse reaction to the vaccine and that I needed to inform my supervisors so they could complete the necessary paperwork. He also advised me not to have any further vaccinations.

Later that day I informed my supervisor, the first link in my chain of command, what I had been told by my doctor. He in turn passed it up the chain. The following day, March 24th, I received a phone call at home from my supervisor stating the information had been passed along to the chief of supply, the Group commander, and also to the senior medical technician. He further requested that I call senior master sergeant Keller as he indicated that she was confused as to why the clinic would need to complete forms, the VAERS forms.

He further stated that I should not have to use my civilian leave for this illness since it was related to the military and that the clinic, in his opinion, should be completing a line-of-duty investigation.

He also informed me that he had discussed the situation with Lieutenant Colonel Allen and that he would have our squadron commander, Major Karen Dvorak, research the issue once she returned from Texas on March 30th.

I feel it is important to recognize at this time that we as a group were placed on annual training order for each of our inoculations with the exception of the fourth inoculation, which we were in unit training assembly status. We were told originally that we needed to be on military status to receive the vaccine. This is in case we had an adverse reaction----

Mr. Shays. Let me say that you are trying to accommodate us by reading fairly quickly, and so I realize that you--you can slow down just a spec, but it is very interesting testimony.

Ms. Groll. Thank you, sir.

We were told that we needed to be in military status to receive the anthrax vaccine. In case we had an adverse reaction to the inoculation, the military would be responsible for our medical care.

On April 7, I was scheduled for a 1 o'clock appointment with Colonel Dr. Garramone from Wright Pat Air Force Base. Dr. Garramone questioned me thoroughly concerning my symptoms and performed what I thought to be a thorough examination, including a pulmonary exam. I feel it is important to note that out of the 11 individuals that were examined by the medical personnel at Wright Patterson Air Force Base, I was the only one Colonel Garramone examined.

Colonel Garramone recommended that I be examined by a

neurologist and personally escorted me to the neurology clinic. However, they were unable to see me until the next day at 8 a.m. Colonel Garramone then telephoned Battle Creek at 2 p.m. and talked with Lieutenant Colonel Barker, support group commander, requesting that I be allowed to remain until the following day to be examined by the neurologist and to have further blood and urinalysis work completed.

By 4:45 p.m., the others had completed their examinations and their laboratory work. However, we were still waiting for a decision from Battle Creek on if we could stay for further testing the following morning. It was inevitable that--obvious, that supervision could not make that decision.

Between 4:45 and 5:15, Colonel Garramone made the decision that he was going to send us home. He prescribed a pain medication and completed an Air Force form, form 422, a physical profile, indicating that I had a possible neurological reaction to the anthrax vaccine and to also rule out fibromyalgia.

He talked further with Colonel Seidel and informed him, since he was sending us home, that I needed to be followed up with a military neurologist. We arrived home in Battle Creek at 11:30 that night very exhausted. It was very apparent that very little preparation had gone into preparing us for this trip.

The remaining few weeks since my fourth inoculation had consisted of several more doctor visits, all civilian, and numerous diagnostic tests being performed. As of this writing, I have worked 19 hours since March 17th, 1999, and have used close to 400 hours of my civilian leave overall due to what I feel is due to the anthrax vaccination.

I am still suffering chronic fatigue, shortness of breath, memory loss, weight loss, mood swings, abdominal pain, occasional nausea, and diarrhea, and tremors in my right arm.

Today, I have not been notified of if or when I will be scheduled up for the followup with a military neurologist that was recommended on April 7th by Colonel Garramone at Wright Pat.

I am not, and would never profess to be, a qualified medical professional; however, I do feel as though I am in touch with my own body and I know that something is wrong. I have taken my career seriously, devoting 14 years of my life playing a role in the defense of our great Nation. Throughout my tenure with the 110th Fighter Wing, I have always been amongst the first to volunteer to support the mission, always challenged myself to go above and beyond what is required of my position.

Unceasingly devoting numerous hours to the base honor guard and to other community service events. However, the events of the past few weeks have tarnished my faith in my unit and in the Department of Defense. I feel as though I have been misinformed and betrayed by the same country I seek to defend.

It is my impression through my own research that the anthrax vaccination immunization program belongs to and the success lies with the line commanders, yet, whenever a question has been addressed to our commander, they have repeatedly gone unanswered. Furthermore, I find it extremely disheartening that the only superior officer within my unit who has shown any concern for us whatsoever has been Colonel Roger Seidel. The response, lack of knowledge, and inaccurate recordkeeping from the medical squadron has been deplorable.

I consider trust, integrity, and accountability to be a vital link between all leadership and employees. Is it possible

that leadership is not taking an active role in these three values? Is it possible that this is why service men and women are choosing to defy a lawful order and not to be inoculated with the anthrax vaccine?

I personally was very hesitant to testify in this hearing today for fear of reprisal. It is only through the encouragement of my family and friends that I was convinced that I need to come forward with my experiences. The reality is that numerous individuals are becoming ill following the anthrax vaccine. Numerous individuals are afraid to come forward for fear of reprisal, loss of income, inability to support their families.

It is for my fellow members of the services that I testify before you today. I pray that others will also have the strength now to come forward.

I again thank you for the honor and privilege of testifying before you today. I ask that the subcommittee seriously considers as a minimum, a moratorium on the anthrax vaccination program until all questions concerning safety and health of our service men and women are answered.

Thank you.

[The prepared statement of Ms. Groll follows:]

[GRAPHIC] [TIFF OMITTED]58959.116

[GRAPHIC] [TIFF OMITTED]58959.117

[GRAPHIC] [TIFF OMITTED]58959.118

[GRAPHIC] [TIFF OMITTED]58959.119

Mr. Shays. Thank you, Ms. Groll.

Let me just comment on both the testimonies we have heard. We could make an assumption that you are typical of many others that are suffering, or we could make an assumption that you are the exception to the rule. But in either case, you are, once you agree to take on the mission, required by your Government to take these vaccines.

Ms. Groll. Correct.

Mr. Shays. This is really a message that we will convey to the DOD, you need to be assured that every need that you have is addressed and that if, in fact, like the statistics say, there will be some who will suffer. A vast majority won't, if the statistics are right. And you tend to be the very few under their view that are suffering. You shouldn't go under this kind of experience. You should be--your every concern should be addressed.

And I apologize that it hasn't been as a member of the Government.

Ms. Martin-Allaire. May I add something?

Mr. Shays. You may add something and then we will get to Mr. Churchill. Yes. Why don't you put the microphone right next to you.

Ms. Martin-Allaire. I just wanted to add, being as how you were talking about numbers, that there were 12 at our base that got this injection, starting back on September 18th, and out of the 12, there were 9 of them that had very bad, adverse reactions.

Mr. Shays. That is very helpful to know. Thank you.

Mr. Churchill.

Mr. Churchill. Mr. Chairman and subcommittee members, thank

you for allowing me to testify today. I am here today under my first amendment right, and this testimony does not reflect anything against the U.S. Air Force and the Michigan Air National Guard.

I work for the Michigan Air National Guard as a civil service technician. I am a technical sergeant for the Air National Guard and also I have served on active duty my first 3 years of service. I have served in the U.S. Air Force in some capacity for the past 17 years this December.

I have volunteered for numerous trips, including Southern Watch both in 1994 and 1996, and I volunteered for this trip that we were talking about to Qatar last November. As a prerequisite for this Qatar trip, 10 other civil service technicians along with two traditional Guardsmen were required to receive several anthrax vaccinations before we were allowed to go, the same vaccinations which brings me here today to testify about.

I would now like to testify before you about the medical complications that I have experienced, complications that I believe are directly attributed to the anthrax vaccination that I received. Mr. Chairman and subcommittee members, we have no full-time medical doctors at our unit. This being the case, we had to turn to the civilian medical community.

A little background on me. I have studied karate for quite a few years and I am an avid speed walker and do numerous activities to stay in shape. However, I have noticed since I received my fourth injection on March 14 that, when I went to my karate class, I have no stamina. I just thought I was out of shape. I spent the next 2 days after I did my class, which is a 2-hour karate class, trying to recuperate.

Anything as far as sitting for a period of time, then standing, my legs ache, my joints in my hips, knees, and ankles crack and snap. I have a pain in my lower back, which comes and goes, I have found blisters inside my mouth. The last one I wasn't sure what it was. So I pinched it with my fingers and filled my hand with blood.

I have little red bumps all over my body, mostly concentrating on my torso. My skin will turn red and hot at any time, but then I will get chills. My hands and feet sweat excessively, and I have a tightness in my chest that comes and goes. My hands have little bumps under the skin, and the skin around my fingers is peeling off, including the palms of my hands. I have been having sinus troubles with a lot of drainage in the morning, sometimes with a blood-like mixture. And I have and continue to experience memory loss, irritability, and shortness of attention span and abdominal cramping.

I am not tolerable of the cold weather. My hands and fingers hurt extremely when they are cold. I have also found that my skin sunburns now under very little exposure.

On about March 27th, I received a medical questionnaire from Dr. Meryl Nass and it raised concerns. I was told from Dr. Nass about the vaccination adverse events recording system forms on the Internet. She suggested that I fill it out immediately and fax it to the CDC. I then scheduled myself for an appointment to find out if these things I was feeling could have anything to do with the fourth injection.

On March 29th, I went to my physician for an answer to my symptoms. The doctor's words were, it is not anthrax, you would be incapacitated and on the floor. We know nothing about this vaccine. The military gave you the shot, the military needs to find out what is wrong with you.

March 31st we had a meeting with our squadron commander, Major Dvorak. We were told that it was impossible for a line-of-duty orders without a physician's recommendation. And concerns of the lot number and the dates were addressed as administrative errors. The shot records would be collected, and the right information would be annotated on the shot records. Along with the shot records, the other major concern was that those individuals that were being treated by civilian doctors would have to sign a medical-release form for the clinic so that they could obtain the information that the civilian doctors had accumulated.

With no concern of personal health being taken, I was stunned at what I was being told. I decided to become proactive, and started calling as many people as I could to see who would be interested in helping us. I could not believe this many people were sick with no concern being displayed to the well-being, other than fixing administrative errors.

At 3 o'clock on that same day, I sent an email to Senator Carl Levin's office and House Representative Nick Smith with concerns of individual health and care for our unit. At 5 o'clock, Tech Sergeant Groll and I met with Colonel Seidel, the vice commander, and discussed the following issues: No. 1 was the people and their health; No. 2 was the clinic; and No. 3 was the commander's concern.

On April 6th, I was informed that Martin, Groll, Stewart, and myself would be going to Wright Patterson Air Force Base on the 7th to see an allergist. We were to make sure that we turned in a copy of the VAERS form to the clinic before we left so that they could input the information into the military immunization tracking system. When we arrived at--when we arrived, we checked into the allergy department.

The doctor looked over my VAERS and took down my symptoms. He then checked me out pretty thoroughly and asked me if I had been near any animals in Qatar. He then told me he was going to order my blood drawn, a urinalysis, and a chest x ray. I was told after review of my blood, urinalysis, and chest x rays that I was OK.

On April 13th, Tech Sergeant LaMore and Staff Sergeant Frank went to Wright Patterson also. The doctor told Tech Sergeant LaMore and stated in his medical record that he was having a systemic reaction. The doctor recommended after the next injection, if the same symptoms occur, to cease the rest of the series. Tech Sergeant LaMore has been the only person diagnosed with the systemic reaction although he had the same symptoms as the rest of the individuals involved.

Some individuals, in fact, had worse reactions.

We are told people at high levels of the Guard that they are working on issues such as us using our civilian and technician sick and annual leave, our insurance payments, to include some high-cost prescriptions that my insurance does not pay for. There are a number of us that are getting our blood taken to have it sent for testing for squalene.

I hope these symptoms can be diagnosed and treated. These symptoms because I do not know if they are short-term, long-term, or treatable. Will they affect any of my future children? Or will they affect any of my family members?

In talking to Lori Greenleaf and Meryl Nass and others that have much more time and sources in this, they tell me there is a cure for the way that I feel. I cannot believe that I have received more information from people that have no interest in me other than the concern for another human being. This is

appalling to me, considering my 17-year commitment to the U.S. Air Force and the Air National Guard.

I have taken more sick leave from work in the past 4 months than I have over the last 3 years. This statement is very true for just about all of the individuals involved in this situation. I ask that you please keep pursuing the truth into this vaccination. The information is there. There are just too many questions that nobody can answer at this time.

I again thank you, Mr. Chairman, subcommittee members. I will accept any questions at the end of this testimony.

[The prepared statement of Mr. Churchill follows:]

[GRAPHIC] [TIFF OMITTED]58959.120

[GRAPHIC] [TIFF OMITTED]58959.121

[GRAPHIC] [TIFF OMITTED]58959.122

[GRAPHIC] [TIFF OMITTED]58959.123

[GRAPHIC] [TIFF OMITTED]58959.124

[GRAPHIC] [TIFF OMITTED]58959.125

Mr. Shays. Thank you, Mr. Churchill. I hope that you are finding that you are getting a better response now than you were getting. Are you finding that?

Ms. Groll. No, sir.

Mr. Shays. OK. We will address that.

Mr. Shepard. Excuse me, nice to have you here, sir.

Mr. Shepard. Good afternoon, Mr. Chairman. Thank you for your indulgence. I am going to be as short as possible, but I really think the message I have is really important and needs to be heard in its entirety.

Mr. Shays. Well, that is why you are here.

Mr. Shepard. My name is Sergeant Michael Shepard. My family and I are residents of Potter County. That is in the 5th Congressional District in rural north-central Pennsylvania. Congressman John Peterson represents us. I am currently finishing a 4-year enlistment as a military intelligence analyst in the U.S. Army. I am proud of my service and deeply respect the military and the great freedom it defends everyday.

I am here to speak for what I believe is a silent majority in the armed forces on the anthrax vaccine immunization program. At this point, I want to make it clear for the record that my opinions on this issue are not tied in any way to the possibility of me being deployed. I am not on deployment orders, have not been in the past year, and do not intend to be deployed in the near future. However, I am prepared to deploy at a moment's notice.

Furthermore, my service record is impeccable at this time. I have never been accused of misconduct, given non-judicial punishment, or even given a negative counseling statement. My record demonstrates achievement far and beyond my peers in such a short period. These statements are to totally disarm the suggestions that have been made or will be made in the future regarding my motivation or my fellow soldiers' motivation who oppose the AVIP.

My testimony today expresses my convictions and is not intended to reflect or represent the Army's policies or views. My comments regarding safety and efficacy today are meant to

communicate the situation that faces the average enlisted soldier. My credibility does not lie in what I know about science, but what I know about soldiers.

We have heard opposing views regarding the safety of this vaccine on several fronts. The first, no long-term studies available. The second, the nature of the FDA approval. The third, serious questions regarding the production facility. Fourth, the current reactions of the service members. And fifth, circumstantial evidence linking vaccinations, possibly anthrax, to Gulf war illnesses.

In addition, the efficacy of the vaccine has been debated in regards to it being developed for cutaneous anthrax exposure.

The exacerbating element of the AVIP is the shrinking credibility of the DOD. Since your last hearing, the Army has changed its AVIP brochure to retract its claim that veterinarians routinely use this vaccine. In addition, the publication of the investigation in Vanity Fair on the anthrax vaccine's possible tie to Gulf war illnesses has further damaged the DOD's credibility, even if you dismiss half of the article as sensationalism.

Finally, the military's heavy-handed tactics for producing a ``successful'' program have been brought to light by the reversal of the decision--or it is in limbo now--regarding PFC Lundbom's, you recall from your last hearings, discharge. It was announced here in your committee hearing and then changed when he returned to his unit.

Any service person that has completed basic training recognizes that the DOD's claims to this committee and the congressional staff, which it is vociferously lobbying, that this vaccine is, ``as important as carrying a rifle or gas mask'' or is a vital piece of ``body armor,'' as you heard in the first hearing, are quizzical at best. In fact, aren't these claims troubling when you consider that these senior leaders are expecting us to believe that the crude technology of the 1950's and 1960's is the body armor, my body armor of the next millennium?

Is this the best we can do as the most modernized military in the world? Why aren't we researching and developing the best protective gear that combines a more effective protective mask with protective clothing that allows for more flexibility to accomplish the mission?

If we are this concerned with an imminent attack, we need to make it the highest priority to obtain the best protective equipment and tightly control the national stock so that we are always ready to go to war.

In light of these real concerns, I believe the information available to soldiers and the lack of candor exhibited by DOD officials when pointedly questioned on the information leaves the enlisted soldier two options. The soldier can blindly trust the DOD and accept the shots at his own risk, or refuse the shots and accept the current contextualization of this act as disobeying an order.

If this were all an academic discussion, then it would certainly be intriguing at this point. However, even as we speak, men and women in uniform are facing very serious and difficult choices that have long-term consequences just like this vaccine.

You see, this issue is about class too. Most members of an all-volunteer force are from the middle and lower classes of society. This service is generally comprised of citizens from

urban and rural America, rural districts just like my own. These people are barely paying their bills with their paychecks.

Place yourself in the boots of a 23-year-old PFC who is a single mother struggling to get by on her salary and additional assistance. She has followed the AVIP issue until it is her turn. She is faced with these very serious, legitimate, and real questions regarding the effects on her health on the one hand and loss of her livelihood, educational benefits, and loss of an honorable characterization of her loyal service to the U.S. Army on the other.

What does the specialist who is getting married this summer do? He needs leave in June and he needs the GI bill to provide for his wife and family. What about the soldier who has three kids and 10 years in service, like most enlisted soldiers, barely making ends meet and cannot even imagine a fine, let alone the loss of rank. These personnel may initially refuse, but after continual threats and consideration of their future, will yield to the harassment and submit their bodies because of a dollar bill.

In my personal experience, I am aware several initial AVIP refusers who were threatened with military punishments and then complied with the program. Every soldier I speak to has reacted substantially to these shots, with several suffering diarrhea, abdominal cramps, malaise, flu-like symptoms, including fever, headache, and, in some cases, vomiting.

In addition, local swelling has lasted longer than any shot they have ever taken. It is a big deal.

Some soldiers' arms have stayed swollen for over 2 weeks. I asked these soldiers about using the VAERS forms. They did not know it existed and were not issued one when vaccinated. Nor were these soldiers briefed on how to report the actions or the importance of reporting these reactions for the very success of this program.

In essence, you are not getting the truth: ``Passive monitoring,' ' is being generous.

At my level, my observations on the impact of this program as you asked me as a first-line supervisor include the following. First, soldiers overwhelmingly distrust the DOD on this issue because of the available information. Second, soldiers put their career, livelihood, and educational benefits before their legitimate concerns for their health.

Third, soldier morale and trust in our leadership is suffering due to the obvious steamrolling over legitimate concerns and questions. They will continue to do so if this program is allowed to continue unabated, and if future vaccination programs follow this particular model, this will affect retention in both direct and indirect ways.

Fourth, soldiers are confused with the sudden paranoia about NBC attacks in the public and private sector. The defense establishment has known about weaponized anthrax and other elements since at least 1990 if not long before. The threat has always been real, but taking action for action sake does not help the situation. It seem more like a Band-Aid than strategy. Those of us at the lowest echelons in the intelligence community have taken time to pause because we are confused. The nation of Israel, arguably the greatest enemy of our current adversaries in the Gulf region, is not scrambling like the United States to inoculate their civilians and soldiers. They have protective equipment ready for use if necessary.

And the fifth is 200,000-plus compliant service persons are

not an endorsement of the AVIP. The silent majority does not want to take these shots based on the legitimate concerns that were present before this committee investigation began and still have not been answered by this probe.

Soldiers are not disputing that they are in the armed forces and must respect the orders of superiors. Trust and respect work both ways. In times of peace, the military must train as they fight in order to be confident that in the day of battle each soldier will understand their duty and will execute without question upon order.

However, let us make sure we keep the AVIP in context. You were told in your first hearing that soldiers, ``cannot choose which order to follow.' Very true. But how do you expect soldiers to trust the orders of their superiors on the day of battle when, during peace, they poorly plan and execute programs like this one.

To add injury to insult, they attempt to convince the American people and us that this 1950's technology is my, ``body armor,' and is important as my gas mask for attacks of biological-chemical cocktails.

Soldiers are not fooled and I hope you will not be either.

This issue will affect me personally in the near future. I do not want to risk my personal health for this program that is extremely suspect, at best, in light of the current information available. There are legitimate concerns as we have outlined them.

I have contacted both Senators and my Congressman, John Peterson, regarding the issue. I am not aware of any written policy regarding service personnel with less than 18 months. When I am forced to choose whether to take the shots in June, I will have only 10 months left in the Army. Even if I suspend critical analysis of the situation and blindly trust the DOD and take the shots, I will have no recourse if it causes my family or I future problems--health problems. This is because of the legal precedent of the early 1950's commonly referred to as the Feres doctrine.

The doctrine has held that the Government is not liable for the effects of military service. The lawsuits stemming from birth defects in children of Gulf war veterans have been dismissed based on the Feres doctrine in the past 2 years.

The most I could hope for if I take the shots and suffer future health problems is treatment from the Department of Veterans Affairs, if my income is low enough. Therefore, in light of the current information, I do not feel compelled to comply with the AVIP.

The consequences of not complying, if I do not comply, will likely be demotion, fines, and threats of a prejudicial discharge. I do not want to face these consequences; however, I will do so if I am forced to. I will do it not only for me but also for my fellow service members and citizen soldiers in my congressional district that are without a voice.

The majority of service personnel in my unit and, if surveyed, the entire military do not want to take the vaccine. The majority of a volunteer force is from the lower portions of our society in terms of affluence. This means that the majority of service personnel cannot take the financial hardship of fines. In addition, a discharge that is not honorable will take away the soldier's GI bill, which is why many young Americans of modest means join the military service, a promise of access to education to build a brighter tomorrow for themselves and their families.

In my opinion, with so many questions outstanding at this time, it is wrong, even immoral, to force service personnel into choosing between these alternatives. It is time for Members of Congress, especially Members representing districts like mine, to step forward, take a principled stand, and ask that this program be halted, made voluntary, or, at minimum, suspended until the deliberative bodies of the U.S. House and Senate complete their reviews of the AVIP and report their findings.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Shepard follows:]

[GRAPHIC] [TIFF OMITTED]58959.126

[GRAPHIC] [TIFF OMITTED]58959.127

[GRAPHIC] [TIFF OMITTED]58959.128

Mr. Shays. Thank you, Mr. Shepard.

Mr. Shepard--I am going to refer to him as Mr. Shepard. You are in uniform but you are testifying as a private citizen? Is that correct?

Mr. Shepard. I am testifying--I can testify as a member of the Service with the invite that you gave me. I checked with legal counsel. And testifying as an enlisted person as well as a private citizen----

Mr. Shays. You are in uniform and you are a sergeant. Correct?

Mr. Shepard. Yes, sir.

Mr. Shays. OK. Let me just say to you that I would not want you to in any way infer from these hearings that it would be our recommendation that you not comply based on your orders. This would be clearly a personal decision, and I would respect your personal decision. But I just want to make sure that you wouldn't feel false cover by coming to this committee and then taking that stand and inferring--because I have concerns about it being mandatory and voluntary, and maybe concerns that go deeper than that, that I not mislead you.

Mr. Shepard. I appreciate that, Mr. Chairman. I recognize it is a personal choice and all the personal consequences that may follow will fall upon my head.

Mr. Shays. Well, your statement was very articulate and extremely well thought out and impressive, as were all the testimony.

I am just going to say it again, and that is, we are trying to determine whether this is the right policy for the military. We are trying to determine whether we can feel comfortable that the anthrax vaccine is safe. We are trying to determine whether or not--how we want to weigh in on this.

The one thing I feel pretty convinced about is, given what I know, that it should be voluntary and that you shouldn't be, Mr. Shepard, placed in the situation you feel placed in.

And the other thing I know is that we don't even have to get into a debate on the issues that we heard from Ms. Martin-Allaire and Ms. Groll and Mr. Churchill about the fact that you have taken the vaccine and you do know your bodies, you know how you felt before, and you know how you felt afterwards. And you shouldn't be left in this vacuum, trying to fend for yourself. Your employer, your government should be by your side, helping you in every way, and you shouldn't even have even a speck of feeling somewhat deserted and betrayed.

And if nothing else, I certainly would want to weigh in on that side of it. I am going to just ask any of you--your testimonies are pretty comprehensive, they are fairly consistent. In the case of Ms. Allaire, Ms. Groll, and Mr. Churchill, you are also making a statement besides the fact that you do not feel well. And you describe symptoms that are quite similar. You are making the statement that others you work with are encountering the same problem.

Out of how many? If you would, Ms. Martin-Allaire. Why don't you move that microphone over a little bit further.

Dr. Nass, you kind of got us into this whole issue, but I am just going to focus on those that have been on the firing line right here as----

Ms. Martin-Allaire. In our group this past time, around in September, there was 12 of us that started receiving the shots.

Mr. Shays. And how many are not--are feeling the effects?

Ms. Martin-Allaire. There was nine.

Mr. Shays. Nine out of 12.

Ms. Groll. Sir?

Mr. Shays. Yes.

Ms. Groll. I think it is important to note too that we are the first, we are the, say, guinea pigs. But they have called us the guinea pigs, too. We are the first ones at our base to receive the shots. We are the first group of individuals to receive them.

Mr. Shays. It kind of makes you wonder too though if you don't have a batch that is not up to the level it should be. Well, we will be pursuing that as it relates to the 12 of you.

Mr. Churchill, you are not part of the same----

Mr. Churchill. Yes, sir.

Mr. Shays. So you are three of the nine? OK.

Mr. Churchill. Also, I would like to make mention that on Tuesday, before we came down here, I had called our clinic because I wanted to get a copy of my VAERS form that I sent to the CDC. And there is a lot of debate about these VAERS forms that they are taking their numbers from.

When I called our senior health technician at our clinic, I had referred to if I had my copies still in my medical records before I went to Wright Patterson, and she said yes. And I had questioned if I could get a copy of that form from her, and she said sure. Well, I in turn had mentioned what had happened to the other forms that were filled out for all the other individuals that were sent to Wright Patterson, being all 12 of us, and she said she still had them and the only ones that were probably sent out she didn't know what to do with them still, other than she had inputted the information into the military immunization tracking service. But she never forwarded them to anybody else.

So they are still sitting in our unit since they were filled out the second week in March.

Ms. Groll. The only VAERS forms that the CDC has received have been from the three of us, and that is because we independently either faxed them or I personally mailed mine. And I have a confirmation. I included that as part of my written testimony from VAERS that they received my vaccine. The rest of the individuals that counted on the clinic to forward them on, it has never happened.

Mr. Shays. Tell me what you think the significance is of the misdating, that it was just carelessness or intentional?

Ms. Groll. What was the question?

Mr. Shays. The misdating of the shots.

Ms. Groll. I personally feel it was intentional. As I stated in my statement, sir, that it is their impression, and it is also out on I believe it is the DOD Web site, there's a 24-hour window. By giving us the shot on Sunday, and this an impression, sir, and an opinion of my own----

Mr. Shays. I understand. That is what I am asking for.

Ms. Groll. By giving it to us on Sunday, we were on annual, in UTA status. So we were in a military status. To get it in the middle of the week, when we were supposed to receive it, they would have had to once again put us on orders and also to bring in a physician. And they didn't want to have to do this. That is why the decision was made at--we didn't even receive our shots until almost----

Mr. Shays. I am sorry. I don't understand the significance of why they would have to have a physician--I mean what is----

Ms. Groll. They would have to bring someone in because we do not have any full-time nurses or physicians at the base.

Mr. Shays. But how does the misdating exempt them from that?

Ms. Groll. Because they gave it to us 2 days early while we were in a military status.

Mr. Shays. Oh, I see. So the implication was that it was done while you were----

Mr. Churchill. We were on drill status on the weekend.

Ms. Groll. Right. They needed to give it to us in a military status, otherwise it would have cost them significant amount of money. As when we were sent to Wright Patterson, we were also sent to Wright Patterson and we had to take annual leave from our civilian side. As a GS employee, we had to take annual leave, and they sent us to Wright Patterson in a non-paid duty status.

Mr. Shays. That is interesting.

Ms. Groll. We sit before you very broken.

Mr. Shays. What is that?

Ms. Groll. We sit before you very broken and frustrated.

Mr. Shays. Yes. I know.

Ms. Martin-Allaire. Sir, can I add something to that too?

Mr. Shays. Sure.

Ms. Martin-Allaire. On the dates of the shot records, I have since during all of this time, contacted the Pentagon and asked them what the requirements were on if you could be given the shots early. And if you can, you know, whatever. And the response that I got back from the Pentagon was that you can't even get the shot 24 hours early.

Mr. Shays. See, the problem for us in Government, you know, on this side, is that we are told, that this is what the need is, this is how we do it, and it sounds a lot more efficient than the real-life story of how you encounter it. And it sounds a little more, when you have those who are involved in implementing it, they--you get the sense that it has a little bit more feeling and compassion to it than the kind of experiences that each of you have put on our congressional record.

Mr. Shepard, tell me what--summarize what is motivating you to be so out-front here?

Mr. Shepard. I had--Mr. Chairman, I had no intentions of being out front. My conversation with your staff indicated that my strategy was to keep my concerns close to my vest until I had to make this very personal decision. I was collecting information in regards to this issue. I wanted to find out what this committee was doing so I could give the pertinent

information to my elected representatives.

So in that process, my concerns, as indicated here, were communicated with your staff and thus they obviously conferred with you and issued an invite to me.

I had a decision to make at that point, whether to stay private or to go public.

Mr. Shays. No. I realize that we asked you to be here. So--
--

Mr. Shepard. Right. Well----

Mr. Shays. I want the record to state that. You came at our request.

Mr. Shepard. The reason being, the reason I am speaking is because I have, quite frankly, I have a limited ability to withstand the financial punitive measures, and if I decide to make that decision, I will have the ability to weather that type of storm. Ninety-nine point nine percent of the people that I am speaking--that I work with cannot--that is the first thing, that they can't even deal with these legitimate concerns that are here because of the dollar bill that they need to pay their next paycheck with.

Mr. Shays. You know, your reference to paying the next paycheck, our committee oversees the defense and intelligence community and State Department for waste, fraud, and abuse. We don't pass laws. We investigate, make recommendations, and then work very hard to have the committees of jurisdiction make changes to the statute or the appropriators fund the money.

But one of the things that we are looking at is the working conditions of our military. Why we don't have the recruitment success that we have had? Why are we not having people re-enlist?

And one of the things that has been a real eye-opener for me is the pay scale that so many of our men and women have to abide by and live by. So it is very poignant for you to----

Mr. Shepard. You will get the type of compliance that you have been--that has been reported to you if you deal with what everybody understands, including the DOD, and obviously Congress deals with it, money.

And obviously, at the lower rungs of society, at the lower levels of affluence as I have indicated, that in an all-volunteer force you are going to get socio-economically, you can contextualize not wanting this shot and then refusal as disobeying an order. That speaks volumes because the other side has nothing to speak.

Mr. Shays. Well, I have been very impressed with the men and women that I have seen in our service, at all levels of command. But it really gives you cause with your kind of testimony.

Dr. Nass, what is your reaction to what you have heard? Let me just say to all of you, I am going to kind of close this up because I think your statements speak volumes and now it will be our job to personally follow, in particular, the four of you as you sort this out. And we will try to do our best to help and also, given that you are 9 out of 12, it sort of gives us a pocket to look at. It will tell us a lot.

I want you to make sure, if I don't say this to you later, that you feel very willing to be back in touch with our committee, and, if you are not satisfied, and I know you will be, but if you are not, with what the committee is doing, to call my office personally. And let me know that personally.

Dr. Nass.

Dr. Nass. I am not quite sure what question you are asking.

Mr. Shays. Well, I am asking you a very general one. You gave a testimony in the beginning. Were you surprised by what you heard? Do you think this is typical? Do you have any----

Dr. Nass. Yes.

Mr. Shays. OK. So I am just asking for a general but not long answer to the question.

Dr. Nass. Based on purely anecdotal evidence, which is all that exists, reports of probably from 50 to 100 people, some who filled out questionnaires and some who only wrote me a little bit about their symptoms, I believe that the syndrome that these three people have described is fairly typical, although they may be more severe than most.

From what I know, there are two lots in particular, each lot being approximately 200,000 doses, that have caused the majority of symptoms and that those people who report to me also--when they are ill and they survey other people who receive vaccine at the same time that they did, they find that a large number of those people also seem to be having chronic symptoms----

Mr. Shays. Yes. Let me interrupt a second to say: Are you told the lot numbers when you are given the shot?

Ms. Groll. It is indicated in our shot records, sir. And I believe--I know I did, I submitted copies of my shot record. And they are all FAV030 is what it is recorded.

Mr. Shays. OK. We will trace that. I am sorry.

Dr. Nass. So, anyway, what I hear is that 020 and 030 are the major problems. But we know that only six or eight lots passed testing. We don't know how many of those lots have actually been used. So there may only be four lots that have been used and whatever.

It may be that, you know, when the generals say they haven't had any adverse effects, I believe them. And I hear from some people on board ship that hardly anyone has had an adverse effect, and then on another ship everybody has had an adverse effect. So I think what we need is active surveillance, which has not yet taken place.

I don't know what the numbers will be in the end. You know, it is hard to even say how many people are suffering severe symptoms from Gulf war illness, although over one-seventh of those who went to the Gulf have reported problems.

It is impossible to say at this point how widespread this is going to be, but I--I mean I have a list from one base where 38 names were given to me of people who are ill.

So----

Mr. Shays. Well, that is a helpful way to kind of wrap this up. And I would like to acknowledge and thank Dr. Myers for staying and listening to this testimony. I frankly think that is a fine thing for you to have done.

And with that, we will, unless there is any other comment. And I would welcome any other comment. We will call this hearing adjourned.

[Whereupon, at 2:17 p.m., the subcommittee was adjourned.]