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DEFENSE VACCINES: FORCE PROTECTION OR FALSE SECURITY?

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTH CONGRESS

FIRST SESSION

OCTOBER 12, 1999

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DEFENSE VACCINES: FORCE PROTECTION OR FALSE SECURITY?

TUESDAY, OCTOBER 12, 1999

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The committee met, pursuant to notice, at 1:15 p.m., in room 2154, Rayburn House Office Building, Hon. Dan Burton (chairman of the committee) presiding.

Present: Representatives Burton, Morella, Shays, Horn, Terry, Waxman, Cummings, Kucinich, and Schakowsky.

Also present: Mr. Jones of North Carolina.

Staff present: Daniel R. Moll, deputy staff director; Mark Corallo, director of communications; David Kass, deputy counsel and parliamentarian; Renee Becker, deputy press secretary; Corinne Zaccagnini, chief information officer; Carla J. Martin, chief clerk; Lisa Smith-Arafune, deputy chief clerk; S. Elizabeth Clay, professional staff member; Robert Briggs, staff assistant; Robin Butler, office manager; Heather Bailey, legislative assistant; Nicole Petrosino, legislative aide; Phil Schiliro, minority staff director; Phil Barnett, minority chief counsel; Sarah Despres and David Rapallo, minority counsels; Ellen Rayner, minority chief clerk, and Jean Gosa, minority staff assistant.

Mr. BURTON. The Committee on Government Reform will be called to order.

Would you raise your right hands, please?

[Witnesses sworn.]

Mr. BURTON. We will have more Members coming. On Tuesdays we usually have Members getting in later, so I apologize for all of our members not being here, but they'll be coming and going.

Good afternoon. A quorum being present, the Committee on Government Reform is called to order; and I ask unanimous consent that all Members' and witnesses' written opening statements be included in the record. Without objection, so ordered.

We're here this afternoon to discuss the development of the U.S. defense vaccine policy. The Subcommittee on National Security, Veterans Affairs, and International Relations chaired by Mr. Shays has conducted a series of hearings looking at the Defense Department's current anthrax vaccine program. The full committee today will examine the overall picture of vaccines for defense.

As part of our ongoing investigation into vaccines we're examining their safety, efficacy, the importance of informed consent, the concerns about vaccine ingredients, purity, and the long-term safety concerns. We're looking into the role of vaccines as a defense

mechanism for biological warfare. Is it viable and appropriate to use vaccines as a defense mechanism? Will it be possible and practical to develop vaccines to protect against all known and potential biological threats?

Much has been said by numerous government officials about the biological warfare threat. We've been told in previous hearings and in testimony prepared for today that, "At least 10 nation states and two terrorist groups are known to possess or have in development a biological warfare capability." Are all these nation states our enemies? How many are confirmed to actually have weapon dispensable anthrax poised and ready to launch?

Intelligence and military officials have testified that it is relatively easy to develop and produce chemical and biological weapons. However, they've also testified that it's much more difficult to successfully deploy chemical weapons. For instance, the Deputy Commander of the Army's Medical Research and Materiel Command testified in 1998 that, "An effective mask casualty producing attack on our citizens would require either a fairly large, very technically competent, well-funded terrorist or state sponsorship."

In March 1999, another expert stated, "The preparation and effective use of biological weapons by potentially hostile states and by non-state actors, including terrorists, is harder than some popular literature seems to suggest."

We've also been told that anthrax is the most likely candidate for a biological warfare threat. What is the basis for that determination? With the aggressive information offensive the Department has launched into its military members and the American public, it's made to sound like the equivalent of the Cuban missile crisis. If that's so, then those who are in harm's way and the American public deserve to know the whole story. A State Department fact sheet on chemical and biological warfare states, "The Department of State has no information to indicate that there's a likelihood of use of chemical or biological agent release in the immediate future. The Department believes the risk of the use of chemical biological warfare is remote, although it cannot be excluded."

There are several issues that need clarification regarding the current anthrax vaccine program, including answering why the United States is the only member of NATO that mandates this vaccine. We have on the screen all of the nations of NATO and their attitude toward mandating the anthrax vaccine, and you'll see the United States is the only one that does that.

The Defense Department would have us believe that the concerns raised about the anthrax vaccine are minor and by a small and vocal group. In fact, on their website, Major Guy Strawder states,

> Much of the hand wringing and bizarre allegations about the vaccine is coming from a vocal minority of people who think the field is where a farmer works and gortex is one of the Power Rangers. Most of these folks have never spent a single moment in harm's way and have no appreciation of what that sacrifice means.

How does that measure up to the following statements that have been sent to us by people in the service?

A Sergeant from Oklahoma says,

> I have served my country with honor and total dedication since 1970. To have this unsafe and unproven vaccine put an abrupt end to my service is a travesty of jus-

tice. I have constantly received excellent appraisals for the past 3 decades and had nothing in mind but to continue receiving these favored appraisals.

We in the military have been told too many false statements about this vaccine. We have been misled about the safety, the long-term effects associated with this vaccine, the proper number of adverse reactions, and the attrition and refusals in our total force. Many will leave the military because of this vaccine and its problems. Many of these folks will give up a career dedicated to service to their country.

Or we have a pilot from Maine who said,

I will be forced out of the Air National Guard and lose my retirement. I have put in 15 good years as a pilot and have enjoyed every one of them. I will not, however, put my health and my future ability to take care of my family on the line for a DOD that refuses to examine their own programs for the safety and cohesion of our military.

Or the F–16 fighter pilot who stated,

I personally have over 22 years of faithful service in the Air Guard. My record is exemplary. I was not planning to retire for at least 2 to 3 years, but the anthrax vaccine program has expedited my retirement plans. The commander of my unit will not allow me to stay in until March 7, 2000, when I will have 3 years time in grade to keep my lieutenant colonel rank into retirement. After almost 23 years of faithful service to my country, I will not be allowed to stay in for the 67 additional days needed to carry lieutenant colonel into retirement, 67 days.

Either the Defense Department is being less than forthcoming about the objections being raised or they have their heads buried in the sand.

A lot of the concerns have been raised about the actual number of adverse events from the anthrax vaccine. The numbers vary greatly—everything from 0.0002 percent reported in the media in February to two-tenths of 1 percent on the package insert to 20 percent, 20 percent, in the one active surveillance currently under way.

We have a slide on this as well. That's the Tripler Med Center study which shows 20 percent.

If the Department is not doing active followup in tracking of health care concerns servicewide, then how will we ever garner an accurate representation of adverse events?

Vice Admiral Richard A. Nelson, Medical Corps Surgeon General, U.S. Navy, stated,

I am aware of the controversy associated with the anthrax vaccine immunization program and the concern our troops have regarding potential side effects. The vaccine is safe. Of over 82,000 marines and sailors inoculated, only eight reactions have been reported via the vaccine adverse reporting system. All have returned to full duty.

In cross-examination, one medic from 29 Palms had no knowledge of the existence of a Vaccine Adverse Event Reporting System form, as adverse event reports are difficult to file when the medical personnel are not even aware that they exist. The Defense Department states that it requires their medical personnel to report all adverse events that cause the loss of duty of greater than 24 hours of hospitalization or hospitalization. Are these the only types of events that are truly adverse? 24 hours? How is it that the Defense Department has been allowed to determine what constitutes a reportable adverse event?

The former FDA commissioner stated that adverse events are dramatically underreported. Only 1 in 10, 1 out of 10, are typically reported. We also know from previous statements made by the De-

fense Department that military reporting is one-seventh—one-seventh of the civilian rate, and we have an attachment up there.

Given these figures, less than 2 of every 100 systemic adverse events are being reported. And for those who have an adverse event, is adequate care being provided? Why is it that many individuals who have been suffering for a very long time with adverse events are still waiting for appointments with appropriate specialists? Or the statement from one Sergeant from Georgia who suffered with memory loss, swelling, dizziness, a rash, muscle twitching, and a month of diarrhea. He said, "The doctors repeatedly ignored my statement that I became sick after taking the anthrax vaccinations." The Master Sergeant from Michigan was told his symptoms showed that he had the flu for an entire year. This diagnosis came from a military doctor who chose only to talk to him and did absolutely no blood work or examination.

And what about plans for more vaccines? Just how many vaccines can one human being safely receive in their lifetime? The Federal Government currently recommends the total of 26 doses of vaccines for children; 26 doses and there you have them. I would like to go into some of the problems my family personally has had with those vaccines. One of my grandchildren is autistic we think maybe as a result of that.

Twenty-six vaccines for children. The typical 20-year career military member can expect an additional 37 doses of vaccinations plus the anthrax and other deployment vaccinations. That would total at least 40 doses over 20 years. There you see the doses we're talking about. There are currently another 18 vaccines in development under the Joint Vaccine Acquisition Program. These are the ones that are planned. And if all the potential biological warfare threats are developed into vaccines, these numbers will skyrocket. Are we going to vaccinate our military to death?

Maybe we need to look at other approaches to dealing with the biological threat. For instance, with good detection equipment and protective gear, the use of products like the orphan drug we just found out about today. We got a call from a company that makes this or has this under review right now and research. The use of products like the orphan pharmacy drug that we have just learned is currently in development that causes the anthrax spores to explode rather than synthesize and can also be used to decontaminate equipment and clothing. Before we start vaccinating everybody, maybe this is an alternative that ought to be looked at and analyzed.

I hope we can find solutions to these issues, get the full story on issues raised and, by doing so, take action to begin to restore trust in the ranks and restore and preserve the careers that have been destroyed.

I just want to say one thing, General West. One of your good friends from Florida, the chairman of the Appropriations Committee, brought to my attention your heroic service to our country. I want you to know that if we get into a heated debate today, that does not take away my respect for you or any of your colleagues

up here at the table. We know of your service to the country and some of the heroic activities you are engaged in, and I want you to know that nothing we say diminishes that.

General WEST. Thank you, sir, but I knew that.

[The prepared statement of Hon. Dan Burton follows:]

Opening Statement

Chairman Dan Burton

Government Reform Committee Hearing

"Defense Vaccines: Force Protection or False Security?"

Tuesday
October 12, 1999
1:00 pm

2154 Rayburn House Office Building
Washington, DC

Good afternoon. We are here this afternoon to discuss the development of the United States' Defense vaccine policy. The National Security Subcommittee chaired by Mr. Shays has conducted a series of hearings looking at the Defense Department's current Anthrax vaccine program.

The Full Committee today will examine the overall picture of vaccines for defense. As part of our ongoing investigation into vaccines, we are examining their safety, efficacy, the importance of informed consent, the concerns about vaccine ingredients, purity, and the long-term safety concerns. We are looking into the role of vaccines as a defense mechanism for biological warfare. Is it viable and appropriate to use vaccines as a defense mechanism? Will it be possible and practical to develop vaccines to protect against all known and potential biological threats.

Much has been said by numerous Government officials about the biological warfare threat. We have been told in previous hearings and in testimony prepared for today that "at least 10 nation-states and two terrorist groups are known to possess, or have in development, a biological warfare capability."[1] Are all these nation-states our enemies? How many are confirmed to actually have weapon-dispensable anthrax poised and ready to launch?

Intelligence and military officials have testified that it is relatively easy to develop and produce chemical and biological weapons. However, they have also testified that it is much more difficult to successfully deploy chemical weapons. For instance, the Deputy Commander of the Army's Medical Research and Materiel Command testified in 1998 that, "an effective mass-casualty producing attack on our citizens would require either a fairly large, very technically competent, well-funded terrorist or state sponsorship." And in March 1999 another expert stated, "the preparation and effective use of biological weapons by potentially hostile states and by non-state actors, including terrorists, is harder than some popular literature seems to suggest.[2]

We've also been told that anthrax is the most likely candidate for a biological warfare threat. What is the basis for that determination? With the aggressive information offensive the Department has launched to its military members and the American public, it's made to sound like the equivalent of the Cuban Missile Crisis. If that is so, then those who are in harms way, and the American public, deserve to know the whole story. A State Department fact sheet on chemical and biological warfare states, "The Department of State has no information to indicate that there is a likelihood of use of chemical or biological agent release in the immediate future. The Department believes the risk of the use of chemical/biological warfare is remote, although it cannot be excluded."[3]

There are several issues that need clarification regarding the current anthrax vaccine program. Including answering why the United States is the only member of NATO that mandates this vaccine? (Attachment)

The Defense Department would have us believe that the concerns raised about the anthrax vaccine are minor and by a "small and vocal group." In fact, on their website, Major Guy Strawder, states, "Much of the hand-wringing and bizarre allegations about the vaccine is coming from a vocal minority of people who think the "field" is where a farmer works and

"Gortex" is one of the Power Rangers. Most of these folks have never spent a single moment in harm's way and have no appreciation of what that sacrifice means"[4]

How does that measure up to the following statements that have been sent to us:

"I have served my country with honor and total dedication since 1970. To have this unsafe and unproven vaccine put an abrupt end to my service is a travesty of justice. I have constantly received excellent appraisals for the past three decades and had nothing in mind but to continue receiving these favored appraisals. We in the military have been told too many false statements about this vaccine. We have been misled about the safety, the long-term effects associated with this vaccine, the proper number of adverse reactions, and the attrition and refusals in our total force. Many will leave the military because of this vaccine and it's problems. Many of these folks will give up a career dedicated to service to their country."[5]

Or the Pilot from Maine who said, "I will be forced out of the Air National Guard and lose my retirement. I have put in 15 good years as a pilot and have enjoyed every one of them. I will not however, put my health and my future ability to take care of my family on the line for a DOD that refuses to examine their own programs for the safety and cohesion of our military."[6]

Or the F-16 fighter pilot who stated, "I personally have over 22 years of faithful service in the Air Guard. My record is exemplary. I was not planning to retire for at least two to three more years but the anthrax vaccine program has expedited my retirement plans. The commander of my unit will not allow me to stay in until March 7, 2000, when I will have three years time and grade to keep my LTC rank into retirement. After almost 23 years of faithful service to my country I will not be allowed to stay in for the 67 additional days needed to carry Lieutenant Colonel into retirement."[7]

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The Defense Department states that it requires their medical personnel to report all adverse events that cause a loss of duty of greater than 24 hours or hospitalization. Are these the only types of events that are truly adverse? How is it that the Defense Department has been allowed to determine what constitutes a reportable adverse event? The former FDA Commissioner, stated that that adverse events are dramatically underreported, only one in ten typically. We also know from previous statements made by the Defense Department that military reporting is one-seventh of the civilian rate. (Attachment) Given these figures, less than 2 of every 100 systemic adverse event are being reported.

And for those who have an adverse event, is adequate care being provided? Why is it that many individuals who have been suffering for a very long time with adverse events, are still waiting for appointments with appropriate specialists? Or the statement from one Sergeant from Georgia who suffered with memory loss, swelling, dizziness, a rash, muscle twitching, and a month of diarrhea, "the doctors repeatedly ignored my statement that I became sick after taking the anthrax vaccinations."[9] And the Master Sergeant from Michigan who was told that his symptoms showed that he had the flu for an entire year. This diagnosis from a military doctor who chose only to talk to him and did absolutely no blood work or examination.

And what about plans for more vaccines? Just how many vaccines can one human being safely receive in their lifetime? The Federal Government currently recommends a total of 26 doses of vaccines for children. (Attachment) The typical twenty-year career military member can expect an additional 37 doses of vaccinations, plus the anthrax and other deployment vaccinations that would total at least 40 doses over twenty years. (Attachment) There are currently another 18 vaccines in development under the Joint Vaccine Acquisition Program. (Attachment) And if all the potential biological warfare threats are developed into vaccines, these numbers will skyrocket. Are we going to vaccinate our military to death?

Maybe we need to look at other approaches to dealing with the biological threat. For instance, with good detection equipment and protective gear, the use of products like the orphan drug that we have just learned is currently in development that causes the anthrax spores to explode rather than synthesize and can also be used to decontaminate equipment and clothing.

I hope that we can find solutions to these issues, get the full story on issues raised, and by doing so, take action to begin to restore trust in the ranks and restore and preserve the careers that have been destroyed.

Witnesses:

Panel I

Sue Bailey, M.D., Assistant Secretary for Health Affairs, Department of Defense.

Cedric E. Dumont, M.D., Medical Director, Office of Medical Services Department of State

Kathryn C. Zoon, Ph.D., Director, Center for Biologics, Evaluation and Research, Food and Drug Administration.

Kwai-Cheung Chan, Director, Special Studies and Evaluation, U.S. General Accounting Office

Panel II

William J. Crowe Jr. (Adm, USN Ret.), Former Chairman, Joint Chiefs of Staff

Major Sonnie Bates, Pilot, USAF

Major Thomas L. Rempfer, Pilot, USAF Reserves

Dr. Jack Melling, Former Director; The Salk Institute, Biologics Development Center and the UK Centre for Applied Microbiology & Research

Mr. Milton Leitenberg, Senior Scholar, Center for International and Security Studies, University of Maryland

John B. Classen, MD, MBA, of Baltimore, Maryland

Neal A. Halsey, MD, Director, Institute for Vaccine Safety, Johns Hopkins University School of Hygiene and Public Health

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[1] Dr. Sue Bailey, Statement before the Government Reform Committee Hearing, Defense Vaccines: Force Protection or False Security?" October 12, 1999.

[2] Mark Gebicke, Director, National Security and Preparedness Issues, General Accounting Office, Before the Subcommittee on Oversight and Investigations, House Transportation and Infrastructure Committee, Hearing on Preparedness Against Terrorist Attacks. June 9, 1999.

[3] http://travel.state.gov/cbw.html Department of State Fact Sheet

[4] Statement of Director of AVIP program in Straighshot newsletter, VOL I, ISSUE #001, JUNE 09, 1999 http://www.anthrax.osd.mil/

[5] Submitted by a Tech Sgt from Oklahoma.

[6] Submitted from an 0-4 from Maine.

[7] Submitted by an F16 pilot in Wisconsin.

[8] Vice Admiral Richard A. Nelson, Medical Corps, Surgeon General, United States Navy, Before the Subcommittee on Defense of the Senate Appropriations Committee on Medical Programs, April 21, 1999.

[9] Submitted by a Sergeant from Georgia who has received three shots to date.



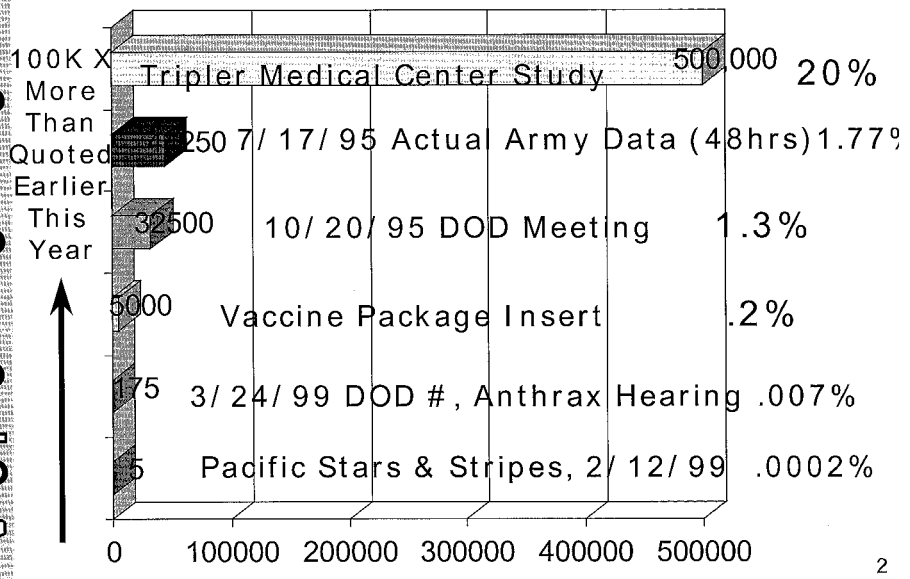
NATO Allies that Mandate Anthrax Vaccine

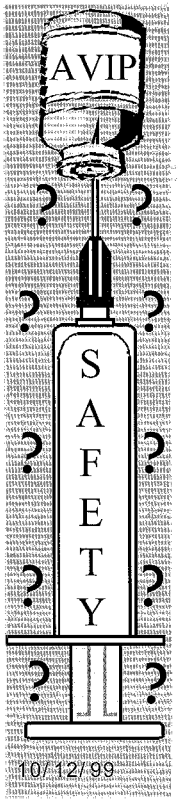
Is the Anthrax Vaccine Mandatory?

Belgium	No	Italy	No
Canada	No	Luxembourg	No
Czech Republic	No	Netherlands	No
Denmark	No	Norway	No
France	No	Poland	No
Germany	No	Spain	No
Greece	No	Turkey	No
Hungary	No	United Kingdom	No
Iceland	(No Military)	United States	Yes



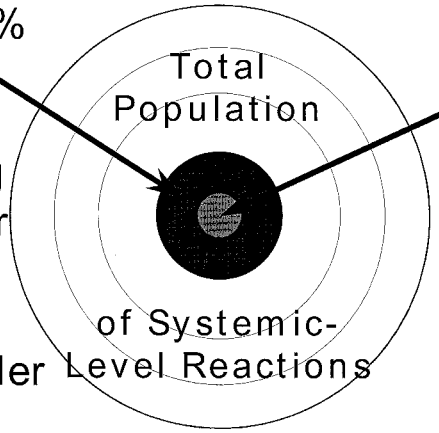
PROJECTED SYSTEMIC REACTIONS FOR 2.5 MILLION SERVICE MEMBERS BASED ON VARIOUS DOD QUOTES





VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) STATISTICS

Only ~10% Actually Reported, According to Former FDA Director David Kessler



Military Reporting Rate is 1/7 that of the Civilian Rate (Swine Flu data)



Childhood Immunization Schedule

Hep B	4 doses
DTaP	5 doses
Td	1 dose
HiB	4 doses
Poliovirus	4 doses
MMR	3 doses
Varicella	2 doses
(Rotavirus)*	3 doses
Total Doses	26 doses

* On temporary hold



20 Years of Shots for Career Military

(Adenovirus)	1
Dose	
Diptheria	3 doses
Influenza	20 doses
Measles	1 dose
Meningococcal disease	1 dose
Mumps*	1 dose
Poliovirus	1 dose
Rubella	1 dose
Tetanus	3 doses
Varicella*	2 doses
Yellow Fever*	3 doses
	37 Doses

*Vaccine Policy Varies Among Military Services



Immunizations for Deployment

for 20 year Career

Anthrax	24 doses
Cholera***	2 doses
Hepatitis A	2 doses
Hepatitis B	3 doses
Japanese Encephalitis	3 doses
(Plague)	3 doses
Rabies	3 doses
Typhoid	Dosage Varies
	40+ doses

*** Seldom used: vaccine offers only short-term protection with painful injection
() Vaccine may not be available due to manufacturing limitations.

10/12/99



Joint Vaccine Acquisition Program

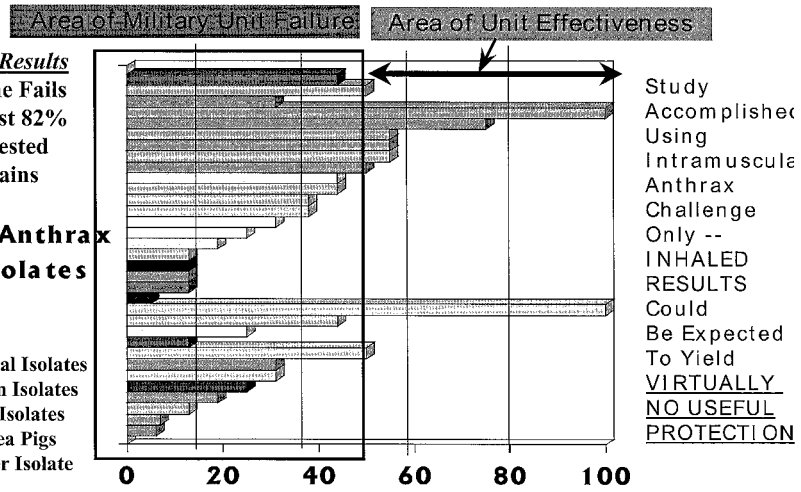
18 Vaccines

Q- Fever Vaccine
Vaccinia Vaccine
Tularemia Vaccine
Botulinum Monovalent Serotype A
Botulinum Monovalent Serotype B
Botulinum Monovalent Serotype C
Botulinum Monovalent Serotype D
Botulinum Monovalent Serotype E
Botulinum Monovalent Serotype F
Botulinum Monovalent Serotype G
Botulinum Polyvalent Serotype A, B, E, F
Ricin Vaccine
Staphylococcal Enterotoxin B Vaccine
Venezuelan Equine Encephalitis (VEE) Vaccine
Combined Venezuelan, Eastern and Western Equine Encephalitis (VEE/ EEE/ WEE) Vaccine
Brucellosis Multivalent Vaccine
Improved Plague Vaccine (Alternate to Existing Product)
Improved Anthrax Vaccine (Alternate to Existing Product)



1998 Ft Detrick Guinea Pig Study

(%Survival Rates of Bioport Vaccine against Anthrax Isolates)



Overall Results

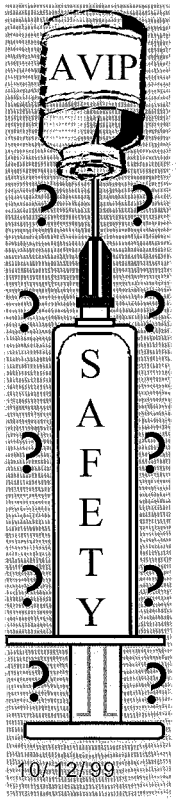
Vaccine Fails Against 82% of Tested Strains

33 Anthrax Isolates

- **21 Animal Isolates**
- **8 Human Isolates**
- **4 Other Isolates**
- **16 Guinea Pigs tested per Isolate**

Study Accomplished Using Intramuscular Anthrax Challenge Only -- INHALED RESULTS Could Be Expected To Yield VIRTUALLY NO USEFUL PROTECTION

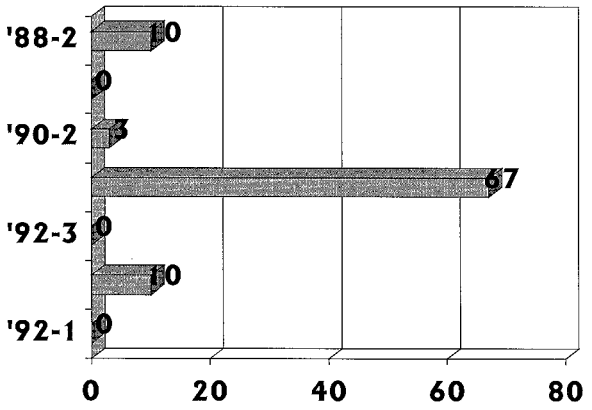
DOD says this guinea pig study against many isolates isn't relevant, yet accepts anthrax vaccine lots from Bioport based on a potency test using only 1 isolate against vaccinated guinea pigs.



Mouse Studies

(%Survival Rates of Bioport Vaccine against Anthrax Isolates)

- Strain denoted by year of test
- Challenge given after 3 doses



***Different Vaccine resulted in 1/3 mice deaths before injection of anthrax spores**

Mr. BURTON. I now recognize Mr. Waxman, the ranking minority member.

Mr. WAXMAN. Thank you, Mr. Chairman.

Today we'll hear testimony about the anthrax vaccine and its use by the Department of Defense. This is a complicated issue with compelling concerns on both sides. Some members of our Armed Services are worried about the safety of the vaccine. This is an understandable and important concern. We need to be constantly vigilant in ensuring that vaccines are as safe as they can be. We must ensure that people are educated about the potential risks of vaccines. We must also carefully monitor the production of vaccines, and we must track all adverse events, treat individuals that suffer side effects, and invest additional research funding to make vaccines even safer and more effective than they are now.

Today I look forward to hearing about how we can improve our performance in some of these areas, but the potential risk of a vaccine is not the only factor to consider. We must also consider the risk of not vaccinating. In the case of childhood vaccines, the risk of not vaccinating is a reemergence of infectious diseases such as polio, measles, or Rubella, diseases we now rarely see in this country.

The chairman had a chart of 20 different diseases—it looked like 20 different diseases—for which immunizations are given. I looked at that list and I thought to myself, thank God we have vaccinations that can prevent those diseases. There were times in our own history and there are places around the world where suffering from those diseases had been a death sentence.

In the case of vaccines against biological weapons, the threat is also severe. The threat of our service members may come in battle or as a result of a terrorist attack. It may come without any warning, without the capability to detect it, and without an opportunity to shield our troops. We are not talking about merely unpleasant but relatively low-risk diseases. If you are infected with anthrax, you die. There is no treatment. All of these risks must be balanced against potential adverse reactions to the vaccine.

On August 3, the committee heard testimony from Antonio Spathe who was diagnosed with an autoimmune deficiency, thyroid disease, anemia, hypoglycemia, depression, hormone imbalance and anxiety disorder after receiving the anthrax and other vaccines. Mr. Spathe's condition is a serious one. Not one person in this room would want someone in their family to be that one in a million individual who suffers serious adverse reactions.

Unfortunately, I think we all know, as Dr. Satcher of the Centers for Disease Control testified at the August 3 hearing, there is no such thing as a perfect vaccine. The decisions facing the Department of Defense are not easy. The risks of anthrax vaccine must be carefully balanced against the risks of not using the vaccine. I believe we should measure these risks using the best scientific and medical evidence available, not inflammatory accusations of unsubstantiated rumors and personal anecdotes. We should base our decisions on a grave, thorough, and extremely critical analysis of all the risks involved.

Before concluding, I would like to note for the record the way in which this hearing was put together and the lack of cooperation the

minority has received from the majority. It is often difficult to learn in advance who the witnesses are going to be and prepare for any hearing. In this case, we did not learn the identity of one witness, Major Rempfer, until this morning.

I recognize that last-minute issues can come up, but I do feel there should be a greater effort to ensure that the minority is informed in advance about these hearings. As a matter of fact, I think the testimony of witnesses has to be submitted 48 hours in advance of their testimony. We should be getting this information in advance so that the minority can prepare for the hearings adequately. We should be approaching these issues of health and safety on a bipartisan basis.

I thank all the witnesses for coming today. I look forward to hearing their testimony, and I yield back the balance of my time.

Mr. BURTON. The gentleman yields back his time.

Do any of the other Members wish to be heard?

Mr. SHAYS. Thank you.

Mr. Chairman, I don't usually have a statement in a full committee hearing, but I would like to place this statement in the record and actually address the chamber here. The recent outbreak of the West Nile encephalitis virus in the Northeast should stand as a warning. Nature's abundant and diverse biological arsenal dwarfs our health surveillance and response capabilities. We're not ready to deter, detect, or treat emerging diseases deployed against us by Mother Nature or by belligerent acts of man.

Responding to a similar warning sounded during the Gulf war, the Department of Defense [DOD] adopted a policy in 1993 setting a new priority on development and acquisition of vaccines to defend against validated biological warfare threats. Today we examine the implications of that policy for the individual war fighter and for the future of the volunteer armed forces.

The forcewide mandatory anthrax vaccine immunization program begun just last year has already raised profound questions about the wisdom, practicality, and necessity of elevating vaccines to the forefront of biological warfare defense. Individual soldiers, sailors, aviators and marines are asking, will these vaccines alone or in combination with the many others planned affect my long-term health? How do I know these vaccines will work against weaponized attack? Will the development of agent-specific vaccines be funded at the expense of collective protective systems, remote detectors, and the physical protective equipment, suits and masks, effective against all biological threats?

Military strategists and scholars are asking, are we responsibly confronting the inevitability of biological attack or surrendering to it out of panic? Does reliance on vaccines betray a lack of confidence in long-standing tenets of force protection, international sanction enforced by treaty, and deterrence backed by the prospect of massive retaliation?

Modern military doctrine dismisses the effectiveness of fixed fortifications against a mobile enemy. Yet in choosing to deploy vaccines against specific biological arguments, we are, in effect, constructing a medical Maginot line. Given the number of possible biological warfare agents, it does not seem practical to build biological barricades in every soldier's body one threat at a time.

Finally, in this important discussion, great care should be taken to maintain the distinction between the military threat and the terrorist threat posed by biological weapons. They are not the same.

Next week the National Security, Veterans Affairs, and International Relations Subcommittee will hold a hearing on the scientific dimensions of the terrorist threat and the thresholds of scale, expense, and technical expertise that differentiates state-sponsored and military biowarfare programs from those posing a greater risk to civilian populations. Mr. Chairman, these hearings can make important contributions to our understanding of critical national security issues.

I appreciate your convening these distinguished panels of witnesses today, and I look forward to their testimony.

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

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Statement of Rep. Christopher Shays

October 12, 1999

The recent outbreak of West Nile encephalitis virus in the Northeast should stand as a warning. Nature's abundant and diverse biological arsenal dwarfs our health surveillance and response capabilities. We are not ready to deter, detect or treat emerging diseases deployed against us by Mother Nature or by terrorist acts of man.

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Individual soldiers, sailors, aviators and Marines are asking: Will this vaccine, alone or in combination with the many others planned, affect my long term health? How do I know these vaccines will work against weaponized attack? Will the development of agent-specific vaccines be funded at the expense of collective protection systems, remote detectors and the physical protective equipment - suits and masks - effective against all biological threats?

Military strategists and scholars are asking: Are we responsibly confronting the inevitability of biological attack, or surrendering to it out of panic? Does reliance on vaccines betray a lack of confidence in longstanding tenets of force protection: international sanction enforced by treaty, and deterrence backed by the prospect of massive retaliation?

Modern military doctrine dismisses the effectiveness of fixed fortifications against a mobile enemy. Yet in choosing to deploy vaccines against specific biological agents, we are, in effect, constructing a medical Maginot Line. Given the number of possible biological warfare agents, it just does not seem practical to build biological barricades in every soldier's body one threat at a time.

Finally, in this important discussion, great care should be taken to maintain the distinction between the military threat and the terrorist threat posed by biological weapons. They are not the same. Next week, the National Security Subcommittee will hold a hearing on the scientific dimensions of the terrorist threat, and the thresholds of scale, expense and technical expertise that differentiate state-sponsored and military biowarfare programs from those posing a greater risk to civilian populations.

Mr. Chairman, these hearings can make important contributions to our understanding of critical national security issues. I appreciate your convening these distinguished panels of witnesses today, and I look forward to their testimony.

Mr. BURTON. Thank you, Mr. Shays. I want to commend you for the work you've been doing on your subcommittee. It's been extraordinary.

Mr. Horn.

Mr. HORN. I'll save my fire for questions.

Mr. BURTON. Save your fire for questions. OK.

Our first panel today, they've already been sworn in because I didn't want them standing too long. Being in the military like I was, I got awfully tired when I used to stand out there for hours and hours, but then I was just an enlisted man.

Dr. Sue Bailey, thank you very much for being with us today. General West, who is a very good friend of Chairman Young, we're very happy to have you here, sir. Colonel Randolph, very nice having you. Dr. Dumont, Dr. Zoon, and Mr. Chan. We really appreciate you being here.

And who do you have with you?

Mr. CHAN. Dr. Charla.

Mr. BURTON. Thank you very much for being here. I would like to let the record reflect the witnesses responded in the affirmative to the oath.

We'll start with Dr. Bailey with an opening statement. We'd like to try to if possible stay within the 5-minute rule because we have a number of people testifying today.

Dr. Bailey.

STATEMENTS OF SUE BAILEY, M.D., ASSISTANT SECRETARY FOR HEALTH AFFAIRS, DEPARTMENT OF DEFENSE; MAJOR GENERAL RANDALL L. WEST, SPECIAL ASSISTANT TO THE SECRETARY OF DEFENSE FOR BIOLOGICAL WARFARE AND ANTHRAX, DEPARTMENT OF DEFENSE; LT. COL. RANDY RANDOLPH, DIRECTOR, ANTHRAX VACCINE IMMUNIZATION PROGRAM AGENCY, DEPARTMENT OF DEFENSE; CEDRIC E. DUMONT, M.D., MEDICAL DIRECTOR, OFFICE OF MEDICAL SERVICES, DEPARTMENT OF STATE; KATHRYN C. ZOON, PH.D., DIRECTOR, CENTER FOR BIOLOGICS, EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION; AND KWAI-CHEUNG CHAN, DIRECTOR, SPECIAL STUDIES AND EVALUATION, U.S. GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY DR. CHARLA

Dr. BAILEY. Chairman Burton, Congressman Waxman, members of the committee, my name is Dr. Sue Bailey. I'm the Assistant Secretary of Defense for Health Affairs for the Department of Defense. I'm very pleased to be here today with General West and Colonel Randolph to speak about our vaccination program for anthrax, and I'd like to submit my written statement and have a very brief oral statement.

Mr. BURTON. Without objection.

Dr. BAILEY. Anthrax is a very deadly organism. It causes cutaneous or inhalation anthrax. It is very stable and can remain viable for years. The incubation period is 1 to 6 days after which, if you have not received the vaccine, you do die. Anthrax is readily weaponized, it is highly lethal, and poses a clear threat in regions where our service personnel are very likely to be deployed.

Under our vaccine immunization program, the number of vaccinations has risen dramatically. We have now given over 1 million of the vaccines. Although local reactions at the injection area itself are not uncommon, they are usually mild and very short-lived. There have been very, very few serious adverse effects, and those are defined as resulting, as you stated, in hospitalization or loss of duty for greater than 24 hours. These cases have all been medically resolved.

The DOD is utilizing a civilian-based FDA system, which is the VAERS reporting system, to document these more serious side effects. Reported reactions are in line with the other commonly prescribed immunizations, including those that you've seen that are for school children here in America. The vaccine, which was licensed by the FDA in 1970, is effective and has an incredibly safe record.

The evidence of vaccine effectiveness against aerosol exposure to anthrax is very persuasive. Although obviously it would be unethical to test human subjects, we are at this point able to say that our animal models using non-human primates have shown that the vaccine is very effective in preventing the disease. Where nearly all of the unvaccinated animals did succumb to an aerosol challenge, we have a vaccine that can protect our troops from this deadly weapon. It would be irresponsible for us to deploy our servicemen and women without using the safe and efficacious vaccine.

I appreciate the opportunity to speak here today and look forward to any questions.

Mr. BURTON. Thank you, Dr. Bailey.

We'll now go to General West.

General WEST. Mr. Chairman, Congressman Waxman, members of the committee, I'm major General West, and I'm honored to appear before you today and hope we can answer your questions about the Department of Defense Anthrax Vaccine Immunization Program.

About 90 gays ago, I was reassigned from the Second Expeditionary Force where I was the Deputy Commander to work in the Office of Secretary of Defense as a Special Advisor for Anthrax and Biological Defense Matters. I was already familiar with the threat and with the vaccine program, but, after taking this assignment, I've spent every working moment reading everything that I could, reviewing all the studies that have been done, looking at the analysis, looking at the test groups and going to the field to talk to our servicemen and women who are taking or expected to take the vaccine.

I also started that effort by going and having a meeting with what might be referred to as the ''know group'' because I wanted to know where they were coming from and what their argument was from the very beginning.

I have to tell you, sir, that I'm more convinced today than I ever have been that what the Department is doing in terms of giving the anthrax vaccine to our servicemen and women is the right and responsible thing to do. I could tell you many stories that I've run into as I traveled about the field and talked with different people about servicemen and women that have taken the vaccine and how well it's worked. I'll limit that in the interest of time to just two.

One is a Staff Sergeant, one of my fellow marines. He's 43 years old. He's in good health. He has no debilitating disease. He has five healthy children. He told me that he would give the anthrax vaccine to his own children if he could. He had his first shot when he was 9 years old living on his father's farm, who is a veterinarian. He feels he made the right choice then and would make the same one again today.

The second account I would share with you is from my own unit at Camp Lejeune. We have a unit there called the Chemical Biological Incident Response Force. Their job is to do consequence management if there should be either a military or a terrorist attack in the United States or somewhere abroad. They are literally a 911 force. They're ready to slide down that pole and go whereever an event might happen. And, God knows, we hope one never does, but if it does, they're ready to go with whatever protective equipment and detection equipment and other things that technology can provide us is available and do the best job they can to contain the devastation that can be caused by an anthrax or another biological or chemical attack.

When they were briefed a three-part brief on the threat, the safety, and the efficacy of this vaccine, all 400-plus members of that unit went down and took their shot. Not one person refused it. Not one person had an adverse reaction that caused him to miss any duty time. Not one of them asked not to take it or complained about taking it afterwards. They understood the threat and they knew that if they went in harm's way and took one deep breath of air contaminated with anthrax spores and wasn't vaccinated that they were going to die. That was motivation for them to take the shot, and that was 1 year before DOD made the shot program mandatory.

Some have argued that if we protect our forces against anthrax that the enemy would simply use another bioweapon. The point I would make here is if the anthrax vaccine serves as a deterrent it will have already accomplished its mission as being the prevention of the use of a catastrophic weapon.

One of the CINCs that asked that all servicemen and women deployed to his theater take the vaccine before they arrive is a commander in chief in the Korean theater. We have service members' families there, and there are many South Koreans that live on that peninsula. If one North Korean airplane with 55 gallon drums of anthrax aerosolized spray flew north of the DMZ about sunset one evening and sprayed that spray from one side of the DMZ to the other with a wind that was blowing at about 30 miles per hour to the south, by the time everyone woke up the next morning, potentially the entire peninsula could risk breathing in air that had been infected with anthrax spores. The deterrent, if it worked, would not only protect our servicemen and women but it would protect the lives of our family members and our allies that might not have been vaccinated even when our servicemen and women are.

Let me take just a moment to talk to the threat.

I believe that there are at least 10 potential adversaries out there who either have weaponized anthrax or are pursuing it. In December 1990, I was in the Persian Gulf. We later learned that Saddam Hussein had anthrax weaponized. He had it deployed on

the battlefield. He had it pointed at our troops, and his commanders had the authority to use it. Deterrents or something worked there, and they never pulled the trigger, and I'm tremendously glad of that, but if he had, we would not have been ready. All of our servicemen and women would not have been vaccinated. I'm afraid many of them would have died.

At least two of our major theaters where our servicemen and women go to work every day go to work under the threat of an anthrax umbrella, meaning that the enemy or a potential adversary has the capability to deliver it and would only have to pull the trigger to do so. We have a vaccine that's FDA approved. It has a proven safety record and we believe a proven efficacy as well. I feel that I would be derelict in my duties if I didn't insist that the servicemen and women that I send to those theaters and other places where it might be used were not vaccinated against the anthrax threat.

The servicemen and women entrusted to me by the mothers and fathers of America are the greatest asset that our Nation has. I would not want to send them there without vaccination.

I wish we had a deterrent that we would know would always work. I wish we had intelligence that would give us advanced warning every time. I wish we had biodetectors that had better sensitivity and we had more of them deployed on the battlefield. I wish we had clothing and equipment that our servicemen and women could wear to protect themselves against a bio or chemical threat and still be able to fight.

But the fact is that we don't. We don't have those things, and they're not in the foreseeable future. The one thing that we do have today that works and we know it works is the anthrax vaccine. The threat is real, and it's now, and I believe we must take the responsible action in protecting our men and women before they deploy in harm's way by giving them the anthrax vaccine.

I can't claim to be an enlisted man now, sir, but I did do 2 years there before I became an officer, so I can understand what you were saying. Thank you.

Mr. BURTON. My respect for you went up just a little bit more, having been an enlisted man myself.

Let me just add one little caveat here, and I think one of the reason's Saddam Hussein didn't use other things was because there was the threat of the possible use of low-yield enhanced radiation tactical nuclear weapons, and I was glad President Bush indicated that was not out of the question and General Schwarzkopf did as well.

Colonel Randolph.

Colonel RANDOLPH. Chairman Burton and distinguished committee members, I'm honored to appear before your committee today and address your questions about the Department of Defense Anthrax Vaccine Immunization Program. We call it AVIP for short.

I'm Lieutenant Colonel Randy Randolph, and I'm the Director of the AVIP agency, which is an organization and office under the Office of the Army Surgeon General.

The AVIP agency is the central source for educational and informational materials on the Anthrax Vaccine Immunization Program. As such, I travel around the Nation, in fact, worldwide,

speaking to service members, family members, as well as spouses and mothers and fathers almost daily.

We manage the AVIP Internet website, which is one of the initiatives to improve our education and our communication with our service members and their family members. Our office manages a toll-free information line, the 1–877–GETVACC line. We also handle numerous daily informational requests from service members, family members, Congress, and the media. We're the focal point for policy coordination for this program and for vaccine distribution and allocation. We not only monitor the services execution through reports from the services but in fact facilitate their execution.

I look forward to answering your questions about this program.

Mr. BURTON. Thank you, Colonel.

I've been out of the service so long I called you major earlier. I didn't see those silver leaves up there. I apologize for that.

[The prepared statement of Dr. Bailey, General West, and Colonel Randolph follows:]

DEFENSE VACCINES:
Part of Total True Force Protection in an Uncertain World

STATEMENT BY
Honorable Sue Bailey
Assistant Secretary of Defense (Health Affairs)

MajGen Randall L. West
Special Assistant to the Under Secretary of Defense, Personnel and Readiness, for Anthrax and Biological Warfare

Lieutenant Colonel Gaston M. Randolph, Jr.
Director, Anthrax Vaccine Immunization Program Agency

Submitted To
HOUSE COMMITTEE ON GOVERNMENT REFORM

FIRST SESSION, 106TH CONGRESS
OCTOBER 12, 1999

NOT FOR PUBLICATION
UNTIL RELEASED BY THE
COMMITTEE ON GOVERNMENT REFORM

INTRODUCTION

Chairman Burton and Distinguished Committee Members, I am honored to appear before your Committee today to address your questions about the Department of Defense (DoD) vaccine immunization program as a component of our biological defense program. I am Dr. Sue Bailey, Assistant Secretary of Defense for Health Affairs. I am accompanied today by Major General Randy West, Special Assistant to the Under Secretary of Defense, for Anthrax and Biological Defense Affairs, and Lieutenant Colonel Gaston M. Randolph, Jr., Director of the Anthrax Vaccine Immunization Program Agency. At your request, our testimony will specifically address the Department's policy involving biological warfare and vaccines, refusal process, personnel education, vaccine safety and surveillance, immunization compliance, and Anthrax Vaccine Immunization Program implementation.

THE THREAT

General - Currently, at least ten nation states and two terrorist groups are known to possess, or have in development, a biological warfare capability. The production of biological warfare agents does not require specialized equipment or advanced technology. When comparing equal amounts of biological and chemical warfare agents, the biological agent is far more potent. Small quantities of biological agents can produce very large numbers of casualties. Biological agents can be delivered through a number of means; including aerial bombs, artillery shells, long-range missiles, agricultural sprayers, and spray tanks carried by aircraft, ships, boats or even cars. Many of the materials and equipment that are used to produce biological warfare agents are available from legitimate sources and intended for other uses such as pharmaceuticals or biopesticides, thus making it difficult to limit, detect or stop the spread of biological warfare technologies and capabilities.

Anthrax Itself - Of all biological warfare agents, anthrax spores are the top choice in biological weapons for "germ warfare." Several of the countries that have or are developing offensive biological warfare capabilities are most likely working with anthrax. Iraq has admitted to producing and weaponizing anthrax. The anthrax accident at Sverdovsk in 1979 illustrated Russia's military research with the organism. Anthrax is many times more lethal than any of the most potent chemical warfare agents, such as VX. It is an infectious disease caused by the bacteria *Bacillus anthracis* and spread by contact with infected animals, handling infected products, eating infected meat, or breathing weapon-dispersed anthrax spores.

Anthrax Virulence - Compared to many other pathogens with BW potential, starting cultures of anthrax are relatively easy to obtain. Large quantities of the bacteria can be produced in readily obtainable fermentation vessels. The organism naturally converts to a spore form that can be stored as bulk agent or in filled munitions. When disseminated in air, the spores remain viable much longer than other types of infectious agents. The size of the spores (approximately 1-micrometer) is such that when inhaled, they tend to be retained in the lung. The effects usually are lethal unless rapid diagnosis is made and a combination of appropriate medical measures is administered immediately. One deep breath can inhale enough spores to result in fatality. Initial symptoms begin 1 to 6 days after exposure and mimic cold or flu-like symptoms. Once symptoms occur in the unvaccinated, it is too late for vaccination or antibiotic treatment for those contaminated. If untreated, death follows within 1 to 3 days after symptoms first begin. Lethality for unvaccinated persons who are contaminated and do not receive near term antibiotics approaches 100%.

Anthrax is considered an effective biological weapon because:

- It is lethal if the victim is not treated immediately or prevaccinated.

- Spores can be produced in large quantities using basic knowledge of biology.

- Spores can be stored for years without losing viability.

- Spores can be easily spread in the air by missiles, rockets, artillery, aerial bombs & sprayers.

- There is no effective treatment for unvaccinated inhalational anthrax victims once symptoms are exhibited.

The objective of the Department's Nuclear, Biological and Chemical defense program is to enable our forces to survive, fight and win in an NBC-contaminated environment.

To protect our military personnel against this lethal weapon, the Department of Defense has established a force health protection policy which includes the use of vaccines, where possible, in sufficient time to develop immunity before deployment to high-threat areas. It is also the policy of the United States Government, as delineated in the Executive Order of September 30, 1999 to provide our military personnel with safe and effective vaccines that negate or minimize the effects of biological weapons.

Vaccines to Protect U.S. Military Personnel, 1999

In addition to the routine vaccine needs of healthy adults, U.S. military personnel receive various vaccinations, based on the health threats encountered in their basic military training, occupation, travel and operational areas of employment. Military vaccination schedules are frequently presented to the Armed Forces Epidemiological Board (AFEB), an external panel of distinguished

civilian medical experts for consultation and concurrence. These vaccines are described by category in Table 1.

Vaccines given to all military recruits protect against diphtheria, influenza, measles, meningococcal disease, poliovirus, rubella, and tetanus. Some recruits receive adenovirus, mumps, varicella, and yellow fever vaccines.

In addition, all members receive tetanus-diphtheria toxoids every 10 years and are administered annual vaccines to protect against influenza. However, some members are required to take anthrax, hepatitis A, hepatitis B, Japanese encephalitis, meningococcal, plague, rabies, typhoid, and yellow fever vaccines because of deployment to high-risk areas.

Vaccines given based on occupation, personal risk factors, or personal health status include *Haemophilus influenzae* type b, hepatitis B, Lyme disease, meningococcal disease, pneumococcal disease, rabies, and varicella vaccines.

Table 1 displays the timing and routine schedule of vaccines typically administered to military personnel.

Table 1. Vaccines Typically Administered to Military Personnel, 1999 (U.S. Army, U.S. Navy, U.S. Marine Corps, U.S. Air Force, U.S. Coast Guard)

Timing	Vaccine	Routine Schedule for Basic Immunity **
Recruits:	(Adenovirus)	Single dose
	Diphtheria	Single, every 10 yrs
	Influenza	Annual
	Measles	Single dose
	Meningococcal disease	Single dose
	Mumps *	Single dose
	Poliovirus	Single dose
	Rubella	Single dose
	Tetanus	Single, every 10 yrs
	Varicella *	Two doses
	Yellow fever *	Single, every 10 yrs

During advanced individual training (AIT) and then throughout career (both active-duty and reserve component):	Anthrax (policy in AVIP phase III)	Six-dose series
Routine during career (both active-duty and reserve component):	Diphtheria Influenza Tetanus	Single, every 10 yrs Annual Single, every 10 yrs
Alert forces; when deploying or traveling to high-risk areas (both active-duty and reserve component):	Anthrax (current policy) Cholera *** Hepatitis A Hepatitis B Japanese encephalitis Meningococcal disease (Plague) Rabies Typhoid Yellow fever	Six-dose series Two doses Two doses Three doses Three doses Single dose Three doses Three doses Dosage varies Single, every 10 yrs
Individualized according to occupational or personal needs:	*Haemophilus influenzae* type b Hepatitis B Lyme disease Meningococcal disease Pneumococcal disease Rabies Varicella	Single dose Three doses Three doses Single dose Single dose Three doses Two doses

* Vaccination policy varies among Military Services based on Service needs.

** Booster doses may be required at annual or other intervals to sustain immunity.

*** Seldom used: vaccine offers only short-term protection, with painful injections.

Vaccines listed in parentheses may not be available due to manufacturing limitations.

Adapted from United States Army Regulation 40-562; Navy Bureau of Medicine & Surgery Instruction 6230.15; Air Force Joint Instruction 48-110; Coast Guard Commandant Instruction M6230.4E. Immunizations & Chemoprophylaxis. Washington, DC, 1 November 1995.

Even with this aggressive program to protect our forces, we know we must remain constantly in search of new avenues to combat the ever-emerging biological warfare and infectious disease threats.

Vaccines are under development for a number of validated biological warfare and infectious disease threats to military forces. Included among these are: nine biological disease vaccines being investigated by the Medical Biological Defense Research Program (Staphylococcal Enterotoxins,

Encephalitis viruses, Ricin, Brucellosis, Filoviruses, Othopox viruses, Botulinum Toxin, Plague, and next generation Anthrax vaccine); and five in advanced development at the Joint Vaccine Acquisition Program (Q-Fever, Tularemia, Smallpox, Venezuelan Equine Encephalitis, Botulinum Recombinant Multivalent). In addition, the Military Infectious Disease Research Program currently is investigating vaccines to prevent infections by the following organisms: Malaria (Plasmodium falciparum), Dengue Fever virus, Heptitis E virus, Meningitis (Neisseria Meningitidis Group B), Shigella, Enterotoxigenic Escherichia coli, Campylobacter, and Hantaviruses.

This is only a summary of ongoing research and should not be interpreted as future mandatory vaccine policy. Much work is yet to be done on safety, efficacy, threat, protocol, requirements, etc.

Multi-Dose, Multi-Decade Military Vaccine Safety Studies

Given the number of vaccines presently used and the number under investigation, it is prudent for us to evaluate the safety and efficacy of administering multiple vaccines. We have done that for over forty years.

Research on the health effects of multiple immunizations first appeared in the 1958 *Bulletin of the Johns Hopkins Hospital.* Two follow-on studies appeared in the *Annals of Internal Medicine* in 1965 and 1974 (Peeler, et al., 1958; Peeler, et al., 1965; White, et al., 1974).

These successive studies reported on the health of 99 male laboratory workers at Fort Detrick, Maryland, who were hyper-immunized with multiple vaccines between 1944 and 1971. These workers received 52 to 134 milliliters of vaccines (average: 97 ml) against multiple infections. They also received 6 to 93 microbial skin tests (average: 55 tests) to detect hypersensitivity or immunity to dangerous microorganisms. For comparison, note that the six 0.5-ml doses of

anthrax vaccine in the primary series total 3 ml. These workers received various combinations of immunizations against anthrax, botulism, brucellosis, diphtheria, Eastern equine encephalitis, influenza, plague, poliomyelitis, psittacosis, Q fever, Rift Valley fever, Rocky Mountain spotted fever, smallpox, tetanus, tularemia, typhus, Venezuelan equine encephalitis, Western equine encephalitis, and yellow fever.

The final report concluded: "It is of prime significance that long-term follow-up examination of these intensively immunized men failed to demonstrate any evidence of illness attributable to the immunizations. There is no indication that intensive immunization interfered with the ability to produce adequate antibody titers after antigenic challenge." The authors also noted "These data and the accompanying evaluation of an intensively immunized population provide evidence that no obvious adverse effects result from repeated immunization..." Thus, this group provides reassurance that schedules for routine immunization with a diversity of vaccines should not produce untoward effects merely because of frequency of inoculation.

However, allow me to again clarify that the Department does not plan to administer any additional vaccines without compliance with FDA requirements and when necessitated by existing threats. We are only pursuing prudent, precautionary research and development in response to potential threats.

SAFETY AND EFFICACY OF VACCINES

To ensure that the vaccines administered to our military personnel are safe and effective, the Department of Defense conducts an aggressive, multi-faceted surveillance program. In fact, the safeguards of vaccine administered to DOD personnel meet or exceed every standard for vaccine administration to the civilian population. Our program includes a wide variety of activities that can be grouped into three main scientific method categories: clinical studies of vaccine

recipients; database analysis of vaccine recipient automated medical records; and spontaneous reports.

As the Centers for Disease Control & Prevention (CDC), the Food and Drug Administration (FDA), and trained epidemiologists discovered over time, these methods need to be used in tandem to fully understand whether or not an adverse event was caused by a vaccine or merely coincided in time with the vaccination. Coincidental events are sometimes referred to as temporal (pertaining to or limited in time) associations. Temporal association alone does not prove causation.

A current example of this tandem surveillance is the anthrax vaccine safety program. The Department is using these same three scientific methods to ensure a vaccine that is both safe and effective against all known strains of anthrax pathogen. Anthrax vaccine adsorbed (AVA) has been approved by the FDA for nearly 30 years, and has been reaffirmed by a civilian advisory panel in 1985 and reaffirmed by senior FDA officials in 1999 during previous hearings.

A new long term study, in addition to several already performed, is also underway to determine whether individuals people who received multiple vaccines, including the anthrax vaccine, during their past employment at Ft. Detrick, MD demonstrated any adverse health effects over the long term. A total of 570 study and control volunteers have been enrolled in this case-controlled study that began in 1996. All volunteers signed an approved informed consent document. The study media included a 9-page health history questionnaire, extensive blood tests and urinalysis. The questionnaire queries mental and physical conditions of progeny as well as the health of volunteers. Study end points include symptoms, symptom complexes (including the Gulf War Illness complex of symptoms), diseases, abnormal laboratory and urine tests. Study subjects will be compared to 2-3 race, gender, and age-matched control subjects to determine if any long-term medical effects exist among this unique group of

study subjects. Analysis of the data from the extensive health history questionnaire and numerous laboratory tests is currently in progress.

On August 24, 1999, the Anthrax Vaccine Immunization Program Agency convened a team of medical experts to design a set of studies to assess the long-term safety of the anthrax vaccine, in response to concerns expressed from Service Members, their families and the General Accounting Office. In designing these studies, we have drawn from the accumulated experience of some of the nation's best vaccine researchers at CDC and FDA.

Vaccine Adverse Event Reporting System (VAERS)

The Department of Defense has also been a long-time participant in CDC/FDA national programs aimed at collecting information about adverse events temporally associated with vaccines. DoD has reported to VAERS, since its inception.

A DoD policy memorandum ensuring that Reservists have full access to DoD Medical Treatment Facilities for treatment of adverse events from DoD directed immunizations was signed on July 20, 1999, and clearly outlines patient or provider submission of Form VAERS-1.

Health care professionals, as well as patients themselves, report adverse events after immunization to VAERS. VAERS reports, by definition, will include a combination of events caused by the vaccine and coincidences that are only temporally associated with immunization and have no cause-and-effect relationship with the vaccine.

Naturally, we are most interested in serious adverse events, death, anaphylaxis, hospitalization or prolonged disability, but we are also concerned about reactions at the injection site, often called "local reactions." DoD

encourages our health care professionals to report all adverse events that they consider important and clinically relevant. As with our civilian clinician counterparts, the criteria for reporting a VAERS event are non-restrictive, as a means to encourage reporting.

Education & Communication

The number and variety of vaccines administered to our personnel makes education and communication a high priority. The Department of Defense is committed to fully educating our service members, DoD civilians, DoD civilian contractors and their families on the purpose and value of all its vaccines. One of the most thorough examples of this kind of education is the anthrax vaccination education program. In an unprecedented manner, we use each of the following communications media to accomplish this goal:

◆ A sophisticated anthrax specific website www.anthrax.osd.mil with multiple layers of information and methods for communicating with our Service Member population, their families, and other DOD beneficiaries and concerned members of the American public.

◆ Three Service - specific anthrax websites hyper-linked to all known military and civilian websites discussing anthrax, biological weapons, health care, domestic preparedness, terrorism, VAERS reporting, preventive medicine, infectious disease, and more.

◆ Information sheets (tri-folds) individually tailored for Service Members, Family Members and Civilians. DOD issued Tri-folds to each Service Member receiving the vaccine since administering the first doses in March 1998. The Tri-fold explains the threat of biological weapons, the benefits of anthrax vaccination and the known risks from the vaccine. The Tri-fold is currently under revision to include Reserve Component-specific information on accessing care.

◆ DOD Leaders Briefing required to be given to all Service Members prior to receiving the anthrax immunization. Distributed by each Service and prominently posted on the www.anthrax.osd.mil website.

◆ DOD Health Care Providers Briefing given to all DOD health care providers administering the anthrax vaccine — who then serve as teachers, coaches, mentors for supervisors, commanders, Service Members and their families. Distributed by each Service and prominently posted on the www.anthrax.osd.mil website.

◆ Open House/Speakers Bureau briefings and open educational forums for all Service Members and their families.

◆ A 1.877.GETVACC telephone toll-free information line was implemented on 1 Sep 99.

◆ A variety of anthrax vaccine 'silent training aids'. These highly visible training aids emphasize the key themes of the anthrax threat, safety and efficacy of the vaccine, vaccine dosing schedule, and adverse event reporting.

◆ Armed Forces Information Service news media, local installation print, radio and television news service initiatives.

◆ A state-of-the-art Anthrax Education CD-ROM which provides Service Members, families, supervisors, commanders and health care providers with tailored, multimedia information on the anthrax threat, safety and efficacy of the vaccine, signs, symptoms and prevention of anthrax is in production now.

◆ An Anthrax Vaccine Immunization Program Videotape explaining the threat, safety, efficacy of the vaccine. The video features prominent civilian and

Government scientists and vaccine experts explaining and endorsing the vaccine is also in production.

◆ DOD is currently collaborating with CDC to array this information in the format of Vaccine Information Statements (VIS) that civilian health care providers around the country give America's children, adolescents, and adults during routine vaccinations.

◆ Clinical guidelines for managing adverse events after vaccination were drafted in May 1999, based on a consensus panel of civilian and military physicians experienced both in immunology and the general provision of health care. After a synchronized staffing with the Services, Federal Agencies and other institutions, we will distribute the guidelines worldwide, including posting on the www.anthrax.osd.mil web and all associated, linked health care sites. These guidelines represent DoD's concerted effort to standardize the evaluation and care of people who have adverse events after vaccination against anthrax. It is worth noting that such guidelines have never been developed in the civilian sector.

Administering Vaccines

We realize that no matter how safe a vaccine is or well it is communicated, it is critical to maintain the highest standards in clinical and administrative practices. We do this in variety of ways, including monitoring, documenting, conducting clinical conferences and panels.

Monitoring and Compliance Reporting - Monitoring and compliance using guidelines discussed in the preceding paragraphs are an ongoing quality assurance/quality improvement responsibility of both individual medical treatment facilities and the DOD military health system. Overarching guidance is established in a variety of ways, including standards printed in the joint

immunization instruction, "Immunization and Chemoprophylaxis Regulation" (Army Regulation 40-562, Bureau of Medicine & Surgery Instruction 6230.15, Air Force Joint Instruction 48-110, Coast Guard Commandant Instruction M6230.4E), dated 1 November 1995. This regulation represents the current standard for immunizations and chemoprophylactic practices within the military health system. In addition to this joint regulation, each Service's formal anthrax immunization implementation plan addresses clinical aspects of vaccine administration.

The six shot Anthrax regimen is an excellent example of the requirements of this monitoring and compliance. Using sophisticated information and tracking Service systems, each of the Service immunization tracking systems allows unit leaders to track pertinent individual and unit data from any deployed location. All Service electronic immunization data is ultimately stored in the Defense Eligibility Enrollment Reporting System (DEERS), which serves as the final corporate data repository. In addition to electronically recording anthrax immunizations, each Service employs several redundant paper-based records systems to record immunizations, including the Health Record, the yellow shot record, immunization clinic sign-in logs and other forms.

While the current AVIP Phase 1 focused on immunization of the Active Component, (91% of all service members immunized to date), we are extremely concerned with implementation, tracking, compliance and heath care follow-up of our Reserve Forces. We recognize that the reserve forces will have some special needs as the Department continues its three-phased execution. These challenges include the lack of routine contact with commanders, weekend drill opportunities for immunizations and the concern of Service Member medical follow-up if they have a concern with any expected or unexpected reactions to the vaccine.

Through the AVIP Synchronization Team, supported by the AVIP Agency and working with the ASD (Reserve Affairs), we intend to provide additional services and capabilities to the reserves to ensure their confidence and compliance. Reservists' can receive their vaccinations and follow up medical evaluation as needed at any of our Military Treatment Facilities (MTFs) across the nation. We have begun and have nearly completed implementation of a Federal Strategic Health Alliance for Force Health Protection Initiative that brings together federal agencies and the private sector to increase access to vaccination through internal RC medical assets, DoD Medical Treatment Facilities, the Public Health Service, Veterans Health Administration, and a private contractor, the Arora Group. These resources collectively extend access to care to a provider network of greater than 15,000. A July 1999 Department memorandum reiterates Reserve Component access to DoD Medical Treatment Facilities for treatment of all vaccine adverse events.

The Synchronization Committee will coordinate the phased vaccination of units and locations to better focus our education and communication program and assist commanders, Service Members and their families.

Documentation – In addition to immunization tracking, there are several other quality assurance/quality improvement measures commonly adopted in medical treatment facilities to ensure the highest clinical standards are fulfilled. All clinical encounters (e.g. immunizations administered, sick call visits, hospitalizations, etc.) are documented in the patient's health record. Each dose of anthrax vaccine is recorded in service-specific and DoD-wide tracking systems. The service specific tracking system reports when a Service Member is due the next dose or has been waived or deferred.

Clinical Panels - At the facility level, health care providers use panels called morbidity & mortality committees to discuss and investigate negative outcomes such as death (none of which have been reported from anthrax vaccination).

Medical treatment facilities have pharmacy & therapeutics (P&T) committees to review and encourage reporting of all medication or vaccine related adverse events. Medical treatment facilities submit reports of their quality assurance/quality improvement programs to each Service medical headquarters for corporate review and analysis. To monitor and assure compliance, all Services report any adverse events weekly to their higher medical headquarters.

Refusals

Even with careful monitoring, a strong education and communication program, and the highest vaccine safety standards, some members will choose, by reason of conscience or other motivation, to not participate in an immunization program. A recent example is the Anthrax Vaccine Immunization Program (AVIP).

With the current Directive for all members to participate in the AVIP, some local commanders have had to decide which, of several options available, to take when a person in his or her command refuses to be vaccinated. These options include administrative, non-judicial and/or judicial actions. However, prior to beginning any such action, the Service Member is re-educated and counseled on the nature of that refusal, the threat and the safety and efficacy of the vaccine. Service members are encouraged to speak with a Health Care Provider. Commanders review and take action on each refusal case based on its own merit and the service member's record.

Because the disposition of each case is handled locally, no data is formally collected on personnel, whether active duty, National Guard, reserve or civilian DoD. This permits each commander the opportunity to act independently, without undue outside pressure.

SUMMARY

We believe we have a safe and effective vaccine to respond to a well-documented threat. We are pleased with our recently implemented tracking and documentation system. What we are most proud of, however, is our nation's greatest asset – the service men and women who go in harm's way to preserve our freedom and safeguard our national interests.

We cannot depend on advanced warning of a bio-weapon attack. Bio-detectors, though an important component of our biological-chemical defense strategy, are still in an early state of implementation with many concerns to be worked out. Protective clothing, masks and equipment while available quickly degrades individual and unit performance and is impractical to wear for long periods of time. Imminent death or incapacitation from known biological warfare agents is vaccine preventable. Our personnel deserve our best and fullest protection. It would be a dereliction of leadership and our moral and ethical responsibility not to immunize our service men and women with licensed, safe and effective vaccines.

Mr. BURTON. We'll now go to Dr. Dumont.

Dr. DUMONT. Mr. Chairman and members of the committee, thank you very much for the opportunity to testify before your committee regarding the Department of State's Anthrax Immunization Program. My name is Cedric Dumont. I'm the Medical Director for the Department of State, and the Office of Medical Services is responsible for promoting the health of all the Foreign Service and all our community members overseas.

Mr. Chairman, in the spring of 1998, when it became clear that Iraq had developed a biological weapon capability, the Department of State prepositioned as a precautionary measure anthrax vaccine and antibiotics at our missions located within SCUD range of Iraq. These supplies were stockpiled at these posts with the intent to administer post-exposure vaccination and antibiotics following an attack.

On August 7, 1998, the bombings of our embassies in Nairobi and Dar Es Salaam confirmed that we face a global and multidimensional threat against United States personnel and United States interests overseas and that we can no longer assume that missions outside of SCUD range are at low risk. With the assistance of the emergency security supplemental, we are improving the security of our facilities, employees, and our family members. In addition to physical security upgrades we have implemented a worldwide chemical and biological countermeasures program which includes the Department's voluntary Anthrax Immunization Program.

The program we have initiated, Mr. Chairman, is a voluntary Anthrax Immunization Program that makes the vaccine available to all eligible individuals at our missions overseas, including eligible family members. It is administered on a voluntary basis following strict FDA guidelines.

Mr. Chairman, anthrax as a weapon can be delivered in an aerosolized form by a variety of devices ranging from SCUD missiles to portable dispensers. There is presently no adequate device to detect anthrax in its aerosolized form. It is colorless and odorless. The detection of an anthrax attack will most probably occur days after the event with the appearance of severely, critically ill patients, most of whom we believe would die in the first 72 hours.

The clinical presentation of inhalational anthrax is insidious. Patients may have non-specific, flu-like symptoms; and for the first several days the definitive diagnosis will most probably elude providers and caregivers. Most of these initial cases would succumb to the overwhelming infection.

Animal studies demonstrate that the anthrax vaccine combined with antibiotics can be life-saving if administered within 48 hours of exposure. In the overseas environment, it is very unlikely that exposure can be detected within that timeframe. This is due to the lack of local medical infrastructure at many of our missions. In most cases, local medical providers, technologists, microbiologists and public health officials have neither the training nor the equipment to rapidly detect and identify the anthrax organism.

Like all vaccines, the anthrax vaccine is most effective when used prior to exposure. There has been extensive experience with the administration of this vaccine in veterinarians, animal han-

dlers and laboratory staff, and it is approved by the FDA. Lab studies tell us that in animals the preexposure administration of vaccine is effective against lethal doses of aerosolized anthrax. The vaccine is administered in a six-shot series, and studies suggest that it is protective after the third immunization.

Mr. Chairman, Foreign Service employees and their families serving abroad receive many immunizations throughout their careers in the Foreign Service. When serving overseas, our communities are often exposed to exotic diseases; and when an FDA-approved vaccine is available to protect them against these diseases, such as hepatitis and yellow fever, we offer it to them and to their families.

All our vaccines are administered on a voluntary basis. From our point of view, we consider anthrax as one additional health risk for which there is a protective vaccine. This is a health risk which we believe is worldwide and which is focused on our workplace. One could argue that families are less at risk if the anthrax weapon is targeted against the workplace. We believe that family members are still at risk of exposure, especially at missions where embassy housing is clustered near U.S. Government facilities and where services commonly used by family members are located within the chancery, within the mission.

One of our most difficult challenges is how to protect those individuals who are presently ineligible for the vaccine, those less than 18 or over 65 or pregnant. Recognizing that these individuals are also at risk, the Department of State is engaged in a dialog with the Food and Drug Administration and the manufacturer of the vaccine, BioPort, in exploring the feasibility of providing the vaccine on a voluntary basis to presently ineligible individuals through a Food and Drug Administration approved clinical study. The purpose of the study is to determine the safety and immunogenicity, the effectiveness of this vaccine in those individuals otherwise ineligible.

This concludes my statement, Mr. Chairman. Thank you for the opportunity to testify before the committee.

Mr. BURTON. Thank you, Dr. Dumont.

[The prepared statement of Dr. Dumont follows:]

STATEMENT OF
CEDRIC E. DUMONT, M.D.
MEDICAL DIRECTOR OF THE DEPARTMENT OF STATE
AND OF THE FOREIGN SERVICE

FOR THE

COMMITTEE ON GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES

OCTOBER 12, 1999

Mr. Chairman and Members of the Committee:

Thank you for the opportunity to testify before your Committee regarding the State Department's Anthrax Immunization Program. Specifically, you have asked that I share with the Committee the policy planning process that led to the development of this program and how the Department plans to protect our embassy communities against biological warfare.

Background

In the spring of 1998, when it became clear that Iraq had developed a biological weapon capability, the Department of State deployed as a precautionary measure anthrax vaccine and antibiotics to our missions located within SCUD range of Iraq. These supplies were stockpiled with the intent to administer post exposure immunization and antibiotic treatment following an anthrax attack. Heightened security concerns following the bombings of Nairobi and Dar Es Salaam embassies and the view that we cannot assume posts outside SCUD range are at low risk necessitated that we develop more aggressive and more extensive measures to protect our communities against biological and chemical weapons.

The bombings of our embassies in East Africa on August 7, 1998, confirm that we face a global and multi-dimensional threat against U.S. personnel and interests overseas. With the assistance of the $1.4 billion emergency security supplemental, we are improving the security of our facilities, employees, and dependents. Physical security upgrades are presently underway to enhance the security posture of our diplomatic missions. We have also implemented a worldwide chemical/biological countermeasures program, which includes the Department's voluntary anthrax immunization program.

As you know, anthrax can be delivered in an aerosolized form by a variety of devices, ranging from SCUD missiles to portable dispensers. There is presently no adequate device to detect anthrax in its aerosolized form. This substance is invisible and odorless. A terrorist attack using the anthrax agent can only be detected after the fact. Inhalational anthrax presents with non-specific, flu-like symptoms which progressively worsen over a period of several days. The detection of an anthrax attack could therefore

initially elude medical providers and families. The most probable indication of such an attack would be the sudden appearance of large numbers of critically ill patients, most of whom would die in the first 72 hours. These initial cases would certainly be missed given the clinical similarity of the symptoms of early inhalational anthrax to non-specific respiratory infections or flu-like syndromes.

The administration of antibiotics and anthrax vaccine, if administered within forty-eight hours of exposure can be life saving. In the overseas environment, it is unlikely that exposure would be determined within that time frame. Detection generally would occur only after those who were initially symptomatic succumb to this overwhelming infection. The possibility of early detection in the overseas environment is extremely remote because, clinicians, technologists and microbiologists and public health officials have neither the training nor the equipment to detect anthrax, much less cause to suspect anthrax in their communities. Pre-exposure immunization with the anthrax vaccine would better protect our communities and dramatically reduce the number of casualties in the event of an anthrax attack.

Clinical evidence indicates that the anthrax vaccine is safe and animal testing has clearly demonstrated that the vaccine protects against otherwise lethal doses of inhaled anthrax. The vaccine must be administered in a six-shot series given over 18 months. Studies suggest the vaccine provides effective protection after the third immunization, i.e., six weeks after starting the series. Anthrax vaccine has been administered to several thousand individuals over many years, with no known long-term side effects or evidence of adverse interactions with other immunizations or drugs. Experience with the anthrax vaccine derives from its use in protecting veterinarians, animal handlers and laboratory staff. The vaccine has not been tested for those less than 18 or over 65 years of age or for pregnant women and therefore cannot be administered to these individuals.

State Department Worldwide Anthrax Immunization program

Pre-exposure immunization against infectious diseases is an integral part of Foreign Service life. Our communities are often exposed to exotic infectious agents and pre-exposure administration of vaccines is the most effective means to protect against infectious health risks. Good examples are the hepatitis and yellow fever vaccines. Anthrax exposure, from our point of view, is just one additional health risk. Placed into this context, the anthrax vaccine has been added to the Department's immunization armamentarium. Like all our vaccines, it is offered on a strictly voluntary basis. Aimed at protecting the workplace, this vaccine is offered to eligible individuals overseas. It is administered following strict FDA guidelines. The mobility of the Foreign Service community and the worldwide risk of a biological attack against our missions compel us to make this vaccine available worldwide. Recognizing the limited supplies of the vaccine, we are implementing this program in a stepwise manner, beginning at Posts where we previously pre-positioned the vaccine. As the vaccine becomes more available, we plan on expanding the program to all our missions throughout the world.

Protection of the Ineligible Population

One of the most difficult challenges we face is how to protect those individuals presently ineligible for the vaccine (less than 18 or over 65 years of age or pregnant). The family members of Foreign Service employees while arguably at a lower risk of exposure to anthrax when its target is the work place are still at risk of exposure especially at missions where embassy housing is clustered near USG offices and where services commonly used by family members are located within the chancery (example: commissary, medical services, etc...). Sensitive to this concern, the Department of State is engaged in a dialogue with the Food and Drug administration and the manufacturer of the vaccine, Bioport, in exploring the feasibility of providing the vaccine on a voluntary basis to presently ineligible individuals through a Food and Drug Administration approved clinical investigational new drug (IND) study. The purpose of the IND study is to determine the safety and immunogenicity of the vaccine in those individuals otherwise ineligible.

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This concludes my statement Mr. Chairman. Thank you for the opportunity to testify before the subcommittee. I look forward to answering any questions you may have.

DUMONT TESTIMONY TUESDAY OCTOBER 12, 1999
TALKING POINTS

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE, THANK YOU FOR THE OPPORTUNITY TO TESTIFY BEFORE YOUR COMMITTEE REGARDING THE DEPARTMENT OF STATE'S ANTHRAX IMMUNIZATION PROGRAM.

IN THE SPRING OF 1998, WHEN IT BECAME CLEAR THAT IRAQ HAD DEVELOPED A BIOLOGICAL WEAPON CAPABILITY, THE DEPT OF STATE PRE-POSITIONED AS A PRECAUTIONARY MEASURE ANTHRAX VACCINE AND ANTIBIOTICS AT OUR MISSIONS LOCATED WITHIN SCUD RANGE OF IRAQ. THESE SUPPLIES WERE STOCKPILED AT THESE POSTS WITH THE INTENT TO ADMINISTER POST EXPOSURE VACCINATION AND ANTIBIOTICS FOLLOWING AN ANTHRAX ATTACK.

THE BOMBINGS OF OUR EMBASSIES IN NAIROBI AND DAR ES SALAAM CONFIRMED THAT WE FACE A GLOBAL AND MULTIDIMENSIONAL THREAT AGAINST US PERSONNEL AND INTERESTS OVERSEAS AND THAT WE CAN NO LONGER ASSUME THAT MISSIONS OUTSIDE OF SCUD RANGE ARE AT LOW RISK. WITH THE ASSISTANCE OF THE EMERGENCY SECURITY SUPPLEMENTAL, WE ARE IMPROVING THE SECURITY OF OUR FACILITIES, EMPLOYEES AND FAMILY MEMBERS. IN ADDITION TO PHYSICAL SECURITY UPGRADES, WE HAVE IMPLEMENTED A WORLDWIDE CHEMICAL AND BIOLOGICAL COUNTERMEASURES PROGRAM, WHICH INCLUDES THE DEPARTMENT'S VOLUNTARY ANTHRAX IMMUNIZATION PROGRAM.

THE PROGRAM WE HAVE INITIATED, MR. CHAIRMAN, IS A VOLUNTARY ANTHRAX IMMUNIZATION PROGRAM THAT MAKES THE VACCINE AVAILABLE TO ALL ELIGIBLE INDIVIDUALS AT OUR MISSIONS OVERSEAS INCLUDING ELIGIBLE FAMILY MEMBERS. IT IS ADMINISTERED ON A VOLUNTARY BASIS FOLLOWING STRICT FDA GUIDELINES.

MR. CHAIRMAN, ANTHRAX, AS A WEAPON CAN BE DELIVERED IN AN AEROSOLIZED FORM BY A VARIETY OF DEVICES, RANGING FROM SCUD MISSILES TO PORTABLE DISPENSERS. THERE IS PRESENTLY NO ADEQUATE DEVICE TO DETECT ANTHRAX IN ITS AEROSOLIZED FORM. IT IS COLORLESS AND ODORLESS. THE DETECTION OF AN ANTHRAX ATTACK WILL MOST PROBABLY OCCUR DAYS AFTER THE EVENT, WITH THE APPEARANCE OF LARGE NUMBERS OF CRITICALLY ILL PATIENTS, MOST OF WHOM WOULD DIE IN THE FIRST 72 HOURS. THE CLINICAL PRESENTATION OF INHALATIONAL ANTHRAX IS INSIDIOUS; PATIENTS MAY HAVE NON SPECIFIC FLU-LIKE SYMPTOMS AND FOR THE FIRST SEVERAL DAYS, THE DEFINITIVE DIAGNOSIS WILL MOST PROBABLY ELUDE PROVIDERS AND CAREGIVERS. MOST OF THESE INITIAL CASES WOULD SUCCUMB TO THIS OVERWHELMING INFECTION.

ANIMAL STUDIES DEMONSTRATE THAT THE ANTHRAX VACCINE COMBINED WITH ANTIBIOTICS CAN BE LIFE SAVING IF ADMINISTERED WITHIN FORTY-EIGHT HOURS OF EXPOSURE. IN THE OVERSEAS ENVIRONMENT, IT IS VERY UNLIKELY THAT EXPOSURE CAN BE DETECTED WITHIN THAT TIME FRAME. THIS IS DUE TO THE LACK OF LOCAL MEDICAL INFRASTRUCTURE AT MANY OF OUR MISSIONS; IN MOST CASES, LOCAL MEDICAL PROVIDERS, TECHNOLOGISTS AND MICROBIOLOGISTS AND PUBLIC HEALTH OFFICIALS HAVE NEITHER THE TRAINING NOR THE EQUIPMENT TO RAPIDLY DETECT AND IDENTIFY THE ANTHRAX ORGANISM.

LIKE ALL VACCINES, THE ANTHRAX VACCINE IS MOST EFFECTIVE WHEN USED PRIOR TO EXPOSURE. THERE HAS BEEN EXTENSIVE EXPERIENCE WITH THE ADMINISTRATION OF THIS VACCINE IN VETERINARIANS, ANIMAL HANDLERS AND LABORATORY STAFF AND IT IS APPROVED BY THE FDA. LAB STUDIES TELL US THAT IN ANIMALS, THE PRE-EXPOSURE ADMINISTRATION OF VACCINE IS EFFECTIVE AGAINST LETHAL DOSES OF AEROSOLIZED ANTHRAX. THE VACCINE IS ADMINISTERED IN A SIX SHOT SERIES AND STUDIES SUGGEST THAT IT IS PROTECTIVE AFTER THE THIRD IMMUNIZATION.

MR. CHAIRMAN, FOREIGN SERVICE EMPLOYEES AND THEIR FAMILIES SERVING ABROAD RECEIVE MANY IMMUNIZATIONS THROUGHOUT THEIR CAREERS IN THE FOREIGN SERVICE. WHEN SERVING OVERSEAS, OUR COMMUNITIES ARE OFTEN EXPOSED TO EXOTIC DISEASES AND WHEN A FDA APPROVED VACCINE IS AVAILABLE TO PROTECT THEM AGAINST THESE DISEASES, SUCH AS HEPATITIS AND YELLOW FEVER, WE OFFER IT TO THEM AND TO THEIR FAMILIES. ALL OUR VACCINES ARE ADMINISTERED ON A VOLUNTARY BASIS. FROM OUR POINT OF VIEW, WE CONSIDER ANTHRAX AS ONE ADDITIONAL HEALTH RISK FOR WHICH THERE IS A PROTECTIVE VACCINE. THIS IS A HEALTH RISK WHICH WE BELIEVE IS WORLDWIDE AND WHICH IS FOCUSED ON OUR WORK PLACE. ONE COULD ARGUE THAT FAMILIES ARE LESS AT RISK IF THE ANTHRAX WEAPON IS TARGETED AGAINST THE WORKPLACE; WE BELIEVE THAT FAMILY MEMBERS ARE STILL AT RISK OF EXPOSURE ESPECIALLY AT MISSIONS WHERE EMBASSY HOUSING IS CLUSTERED NEAR USG OFFICES AND WHERE SERVICES COMMONLY USED BY FAMILY MEMBERS ARE LOCATED WITHIN THE CHANCERY (MEDICAL SERVICES COMMISSARY, ETC).

ONE OF OUR MOST DIFFICULT CHALLENGES IS HOW TO PROTECT THOSE INDIVIDUALS WHO ARE PRESENTLY INELIGIBLE FOR THE VACCINE (THOSE LESS THAN 18 OR OVER 65 OR PREGNANT). RECOGNIZING THAT THESE INDIVIDUALS ARE ALSO AT RISK, THE DEPARTMENT OF STATE IS ENGAGED IN A DIALOGUE WITH THE FOOD AND DRUG ADMINISTRATION AND THE MANUFACTURER OF THE VACCINE, BIOPORT, IN EXPLORING THE FEASIBILITY OF PROVIDING THE VACCINE ON A VOLUNTARY BASIS TO PRESENTLY INELIGIBLE INDIVIDUALS THROUGH A FOOD AND DRUG ADMINISTRATION APPROVED CLINICAL INVESTIGATIONAL NEW DRUG (IND) STUDY. THE PURPOSE OF THE IND STUDY IS TO DETERMINE THE SAFETY AND IMMUNOGENICITY OF THE VACCINE IN THOSE INDIVIDUALS OTHERWISE INELIGIBLE.

THIS CONCLUDES MY STATEMENT MR. CHAIRMAN. THANK YOU FOR THE OPPORTUNITY TO TESTIFY BEFORE THE SUBCOMMITTEE. I LOOK FORWARD TO ANSWERING ANY QUESTIONS YOU MAY HAVE.

Mr. BURTON. Dr. Zoon.

Dr. ZOON. Mr. Chairman and members of the committee, I am Dr. Kathryn Zoon, Director, 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.

FDA shares everyone's concern that our military personnel receive safe and effective medical products. Mr. Chairman, we are aware that some people question the safety and efficacy of the anthrax vaccine. Let me be clear. We believe the anthrax vaccine is a safe and effective vaccine in high-risk populations for the prevention of anthrax disease, an often fatal disease, when given as according to the package insert.

Our confidence in this vaccine, like all vaccines, is based upon four components: first, the clinical trials and the subsequent clinical 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 GMP requirements; third, our lot release requirements, which is another layer of protection; and, fourth, our ongoing collection of adverse event reports that serve as an early warning system.

We will continue our efforts in all four of these areas with the anthrax vaccine and all vaccines to assure that only safe products are on the market.

Anthrax is a highly infectious disease caused by spores of a bacterium known as Bacillus anthracis. The only known effective prevention against anthrax is the anthrax vaccine. Use of the anthrax vaccine to immunize people at risk along with vaccination of animals against anthrax has likely contributed to a favorable decline in anthrax infections. The Centers for Disease Control and Prevention data on reported cases of anthrax in the United States indicate a drop from 130 cases per year to zero cases per year in recent years.

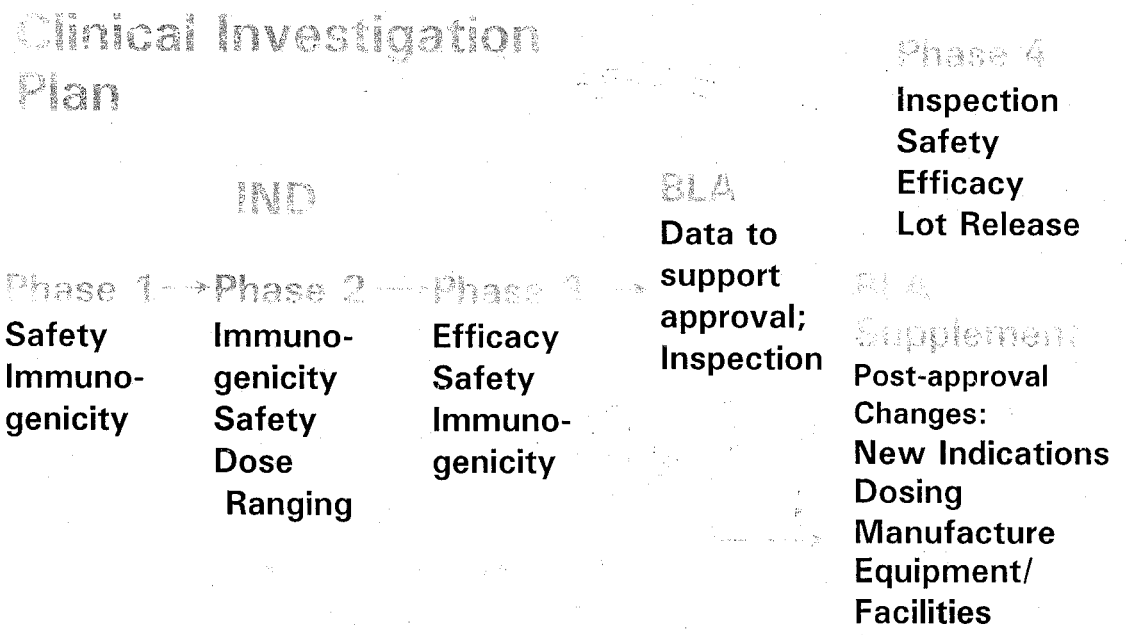
If I could, for the record, I'd like to enter this chart.

Mr. BURTON. Without objection.

Dr. ZOON. Thank you.

[The information referred to follows:]

Stages of Review and Regulation



IND = Investigational New Drug Application; BLA = Biologics License Application

Dr. ZOON. Let me briefly explain the manner in which a vaccine is licensed, and then I will discuss the studies that lead to licensure of the anthrax vaccine. This chart refers to the process, as you can see.

Before a new vaccine can be studied in people, a sponsor must submit an IND, or an Investigational New Drug application, to the FDA. Often we have meetings before the submission of an IND to discuss with the sponsors trial design issues and preclinical information which they should submit.

In addition, in the application, once it's submitted, the sponsor must provide specific information to the FDA. In this process, the IND process which was described, there are three phases in general prior to product approval. However, the distinction between these phases is not absolute.

Phase one trials are focused on basic safety and for vaccines also usually evaluate the immune response solicited by the vaccine. These trials are usually small, generally between 20 and 100 subjects, and they frequently are done in healthy, normal volunteers and may last just several months.

Phase two trials often include several hundred subjects, are often randomized and last anywhere from several months to several years. These usually include individuals who are at high risk for the infectious disease of interest.

Unless severe reactions or a lack of effectiveness surface during the first two phases, the sponsor may decide to perform one or more phase three studies that can include up to several thousand people. These phase three trials are intended to provide the definitive measure of effectiveness as well as continue the evaluation of product safety. The size of the efficacy trial will be affected by the expected incidence of the disease that the vaccine is intended to prevent.

If at the end of phase three trials the sponsor believes that there are adequate data to show the vaccine is safe and effective for its intended use, the sponsor submits a license application to the agency. After licensure, sponsors generally submit samples of each licensed vaccine and results of their own test for purity, potency, safety, and sterility to the agency before the release of each of the licensed vaccine products. In addition, licensed establishments are inspected regularly by the FDA, and there are feedback loops in this process all along the way.

In the interest of time, I would just like to skip and tell you a little bit about the VAERS system. FDA uses the Vaccine Adverse Event Reporting System [VAERS], to track adverse events possibly associated with licensed vaccines. Any person, including a patient, can file a report. Reporting is voluntary for individual health care providers. The vaccine manufacturer, however, must report to the FDA all reports of adverse events of which they are aware.

A VAERS report is not documentation that a vaccine caused an adverse event, but only that an event occurred soon after the vaccine was administered. From the time VAERS started participating in 1990 until October 1, 1999, there have been 425 submitted reports of adverse events associated with the anthrax vaccine. Of those, 29 were considered serious events.

Data gathered from the VAERS system can serve as a useful tool in detecting potential problems with a vaccine, but VAERS reports on anthrax vaccine thus far do not signal concerns about the safety of the vaccine. As more people receive the vaccine, the number of adverse events reported will increase.

Mr. Chairman, again let me state clearly that we are confident that the anthrax vaccine is safe and effective for high-risk adult populations for the prevention of anthrax infection when administered according to the package insert. FDA will remain vigilant in its review of anthrax vaccine adverse events and its oversight of the vaccine manufacturer.

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

Mr. BURTON. Thank you, Dr. Zoon.

[The prepared statement of Dr. Zoon follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

STATEMENT

BY

KATHRYN C. ZOON, Ph.D.

DIRECTOR

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

COMMITTEE ON GOVERNMENT REFORM

U.S. HOUSE OF REPRESENTATIVES

OCTOBER 12, 1999

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Dr. Kathryn Zoon, Director, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA or Agency). I appreciate this opportunity to discuss with you vaccine licensing generally, and specifically, the safety and efficacy of the anthrax vaccine, currently manufactured by BioPort Corporation (the predecessor manufacturer was known as Michigan Biologics Product Institute (MBPI) and prior to that, Michigan Department of Public Health (MDPH)). Let me begin with a brief overview of the process for a vaccine to be licensed.

BACKGROUND

CBER is responsible for evaluating the safety, purity, efficacy and potency of the products we regulate. These products include biological products such as vaccines, products derived from human blood, and many products produced by recent advances in biotechnology. The scope of regulatory responsibility extends to both licensed or approved products and unlicensed products under investigation.

From a regulatory perspective, there are four stages in vaccine development:

1) the pre-Investigational New Drug (IND) stage (before the product is used in people);
2) the IND stage (where human use occurs under limited study conditions);
3) the license application stage for vaccines (where FDA reviews the results of the clinical studies and the manufacturing process); and,
4) the post-licensure stage (following approval of the product for marketing).

Before a new vaccine can be studied in people, a sponsor must submit an IND application to FDA[1]. In the application, the sponsor:

1) describes the composition, source, and method of manufacture of the product and the methods used in testing its safety, purity, and potency;

[1] Sponsors may be individual physicians, a university, a hospital, or a commercial firm, as well as Government agencies, such as the Department of Defense or one of the institutes of the National Institutes of Health.

2) provides a summary of all laboratory and pre-clinical animal testing performed; and,
3) provides a description of the proposed clinical study and the names and qualifications of each clinical investigator.

Once the sponsor submits the IND, FDA has 30 days to review the application to determine whether or not the study may proceed. FDA may prohibit a sponsor from conducting a study for a number of reasons, including when the study volunteers will be exposed to unwarranted risks, by putting the IND on "clinical hold".

The IND process generally is described as having three phases prior to product approval; however, the distinctions between these phases are not absolute. Phase 1 trials are focused on basic safety and, for vaccines, Phase 1 trials also usually evaluate the immune response elicited by the vaccine. These trials are usually small - generally between 20 and 100 subjects - and they frequently are done in healthy "normal volunteers" and may last just several months. Phase 2 trials often include several hundred subjects, are often randomized, and last anywhere from

several months to several years. These trials usually include individuals who are at high risk for the infectious disease of interest. Unless severe reactions or a lack of effectiveness surface during the first two phases, the sponsor may decide to perform one or more Phase 3 studies that can include up to several thousands of people. These Phase 3 trials are intended to provide the definitive measure of effectiveness, as well as continue the evaluation of the product's safety. The size of the efficacy trial will be affected by the expected incidence of disease that the vaccine is intended to prevent. If at the end of Phase 3 trials the manufacturer believes there are adequate data to show the vaccine is safe and effective for its intended use, the manufacturer submits a license application to the Agency.

Licensing a new vaccine is only one stage of FDA's oversight of vaccine safety. Following issuance of the license, there is continued post-marketing surveillance of the product by monitoring adverse events, e.g., the Vaccine Adverse Events Reporting System (VAERS), and of the manufacturer's production activities, including compliance with good manufacturing practices. Manufacturers generally

submit samples of each licensed vaccine lot and the results If their own tests for potency, safety, and sterility to the Agency before release of each lot of the licensed product, because of the complex manufacturing processes for most biological products. In addition, licensed establishments are inspected regularly by FDA.

Let me now turn to anthrax.

ANTHRAX DISEASE

Anthrax is a highly infectious disease caused by spores of a bacterium known as *Bacillus anthracis*. These spores resist destruction and may be present in the soil for decades, occasionally infecting grazing animals that ingest the spores. Goats, sheep and cattle are examples of animals that may become infected. Human infection may occur by three routes of exposure to anthrax spores: cutaneous, gastrointestinal, and pulmonary (inhalation). Skin contact with live infected animals, or with the hide, hair or bones of an infected animal may lead to infection of a person's skin, known as cutaneous anthrax infection. This is the most common manifestation of anthrax in humans,

accounting for more than 95 percent of cases. Untreated cutaneous anthrax infection is associated with a death rate estimated to be approximately 20 percent. Eating undercooked or raw, infected meat can cause gastrointestinal anthrax infection. Breathing in airborne spores may lead to inhalation anthrax. Experience has shown that inhalation anthrax has a very high mortality rate, with estimates ranging from 80 percent to 90 percent or higher.

Inhalation anthrax infection has two phases. During the first phase, which occurs within one to five days after inhalation of the spores, the patient has influenza-like symptoms, such as a cough, malaise, fatigue and mild fever. Several days later these symptoms may subside, but are rapidly followed by the second, more severe stage of disease. During the second phase, the patient experiences sudden onset of severe respiratory distress, and sometimes chest pain accompanied by fever. Chest x-rays may show fluid in the lung. Within a day, septic shock and death will likely occur.

Treatment of cutaneous anthrax infection involves administration of antibiotics. In the case of pulmonary anthrax infection, therapy has been of limited benefit, except when given immediately after exposure. Prior to use of the anthrax vaccine, cases of human anthrax infection in the United States were much more prevalent. The only known effective prevention against anthrax is the anthrax vaccine. According to data from the Centers for Disease Control and Prevention (CDC), there were approximately 130 reported cases of anthrax infection per year at the start of this century. In the past decade, there have been no confirmed reports of human anthrax in the United States. It is difficult to assess exactly how much of this dramatic reduction is due to the vaccine, but immunization with the anthrax vaccine of people at risk, along with vaccination of animals against anthrax, have likely contributed to this favorable decline. Elsewhere in the world, human anthrax cases continue to be reported, especially in countries with predominately agricultural economies.

HISTORY OF THE ANTHRAX VACCINE

Philip S. Brachman et al. conducted clinical trials on the anthrax vaccine during the 1950s [2]. This controlled field study involved workers in four mills in the Northeastern United States that processed imported animal hides. This selected population was at risk because the mill workers routinely handled anthrax-infected animal materials. Prior to vaccination, the yearly average number of human anthrax infection was 1.2 cases per 100 employees in these mills.

For this trial, employees who had not previously contracted anthrax were selected and divided into two groups. The groups were balanced with regard to their age, length of employment, department at the mill, and the particular job they performed. The trial was a single-blinded study, in which the participants were not told whether they received the vaccine or placebo. Individuals who did not participate in the controlled study [because they were ineligible (i.e., had a history of prior anthrax) or chose not to receive the injections] were also monitored for

[2] Brachman, P.S., H. Gold, S.A. Plotkin, F.R. Fekety, M. Werrin & N.R. Ingraham. 1962. Field evaluation of a human anthrax vaccine. Am. J. Public Health 52:632-645.

anthrax. These individuals who did not receive vaccine or placebo were referred to as the observational group.

During the trial, 26 cases of anthrax infection were reported at the mills - five inhalation and 21 cutaneous. Of the five inhalation cases, two individuals had received the placebo, while three individuals were in the observational group. Four of the five people who developed inhalation anthrax died. No cases of inhalation anthrax occurred in anthrax vaccine recipients. Of the 21 cutaneous cases, 15 individuals had received the placebo, three individuals were in the observational group, two individuals were partially immunized and one individual was fully immunized. Based upon a comparison between the populations completely vaccinated versus the populations receiving placebo, the authors calculated a vaccine efficacy level of 92.5 percent.

On April 14, 1966, CDC submitted an IND for the anthrax vaccine to the Division of Biologics Standards, which was then part of the National Institutes of Health (NIH), later transferred to FDA. The method of preparing this vaccine was similar, but not identical, to the vaccine used in the

Brachman et al. study. The vaccines in both studies were based on the immunity induced by the protective antigen (PA). Persons receiving the vaccine made by the two different methods demonstrated similar peak immune responses (antibody concentration) following the initial three doses. Textile employees and laboratory workers were immunized under this IND. A number of lots of investigational vaccine used by CDC under this IND were manufactured by the MDPH.

The data submitted to the Division of Biologic Standards described CDC's experience with approximately 16,000 doses of anthrax. This vaccine was administered to approximately 7,000 study participants. Reported local reactions at the immunization site ranged between 3 percent to 36 percent of the initial series of doses, and 3 percent to 33 percent of the booster doses, depending on the lot. Reported mild reactions were 3 percent to 20 percent of all doses. Reported moderate local reactions were 1 percent to 3 percent of doses. Severe reactions were reported for less than 1 percent of doses. Systemic reactions were reported in four cases during the five-year reporting period. These

reactions included fever, chills, nausea and general body aches, and were reported to have been transient.

The Division of Biologics Standards determined that the data submitted by CDC supported licensure of the vaccine. On November 10, 1970, the Division of Biologics Standards issued a product license to MDPH to manufacture anthrax vaccine.

Approved labeling for the anthrax vaccine states that immunization with this product is recommended for individuals who may come in contact with animal products that may be contaminated with *Bacillus anthracis* spores, and for individuals engaged in diagnostic or investigational activities which may bring them in contact with *Bacillus anthracis* spores. It is also recommended for persons at high risk, such as veterinarians and others handling potentially infected animals.

The approved labeling also states that anthrax vaccine is to be administered subcutaneously (injected under the skin). After the initial dose of 0.5ml, further doses of 0.5ml are administered at two weeks, four weeks, six

months, 12 month and 18 months, thereafter, with yearly boosters.

THE PANEL REVIEW

The Public Health Service Act, under which biologics such as vaccines were licensed, required evidence of safety, purity and potency. After the Division of Biologic Standards was transferred from NIH to FDA, expert panels were assigned to review information on biological products, including vaccines that had been on the market prior to the transfer. The review was initiated in order to verify whether existing data supported the safety and efficacy of marketed biological products.

Biological products were divided into one of six categories. FDA assigned responsibility for initial review and recommendation for all products in these six categories to separate independent advisory panels of outside scientific experts, collectively known as the Advisory Review Panel. The Advisory Review Panel also was charged with advising FDA, in the form of a report, on classification of these products into one of the following

categories: Category I - safe, effective and not misbranded; Category II - unsafe, ineffective or misbranded; Category III - insufficient information, further testing required.

Based upon their review of available data, the Advisory Review Panel recommended that the anthrax vaccine manufactured by MDPH be classified as a Category I product and that appropriate licenses be continued based upon substantial evidence of safety and effectiveness of this product. The safety data from the CDC trials and the efficacy data from the Brachman et al. trials were the basis for these findings. These findings were published in the *Federal Register* on December 13, 1985.

Today, it would be difficult to repeat the efficacy studies. This is because there are no evident populations in the United States where prophylactic vaccine protection against natural exposure to anthrax could be evaluated in a clinical field trial, such as was done in the Brachman et al. study. Specifically, the incidence of naturally occurring anthrax in humans is low and sporadic in occurrence, making identification of a trial target

population difficult. Likewise, it would be unethical to perform challenge/protection studies in humans. In addition, human immunogenicity and safety data would be required. The safety database obtained by CDC under the IND would be considered a reasonable pre-licensure database for evaluating a safety study today.

POST-MARKETING EXPERIENCE

Since licensure in November 1970, livestock workers, veterinarians, lab workers and researchers who are at risk for infection have used the anthrax vaccine. The manufacturer provided FDA the following information regarding distribution. From 1974 to 1989, approximately 68,000 doses were distributed. In 1990, approximately 268,000 doses were distributed. Between 1991 and April 1999, we understand that approximately 1,200,000 doses were distributed. We understand additional doses have been distributed since then, however, we do not have final numbers.

It is not possible to give a precise number of persons who received the vaccine prior to use in Operation Desert

Shield and Operation Desert Storm. We estimate that approximately 7,000 subjects received approximately 16,000 doses of the vaccine during clinical trials conducted by the CDC. In addition, between 1974 and 1989, our files show approximately 68,000 doses were distributed. This is sufficient to vaccinate about 11,000 people with the full six-dose regimen of the currently approved anthrax vaccine. It is possible that some doses distributed were not used, or that some individuals did not receive the full course of the vaccine or that some doses were used for annual boosters. Thus, it is not possible to accurately report the precise number of people vaccinated between 1974 and 1989.

According to the CDC, from 1962 to 1974, 27 cases of anthrax occurred in the "at-risk" populations in the United States. Of those, 24 cases occurred in unvaccinated individuals, one case after the person had been partially immunized with one dose of the vaccine and two cases after individuals had been partially immunized with two doses of the vaccine. No documented cases of anthrax were reported for individuals who had received the recommended six doses of the vaccine.

VACCINE ADVERSE EVENT REPORTING - ANTHRAX

With regard to safety data, FDA and CDC jointly operate VAERS. FDA uses this system to track adverse events possibly associated with licensed vaccines. Reporting of adverse events associated with the use of anthrax vaccine is voluntary for individual healthcare providers. The vaccine manufacturer, however, must report to FDA all reports of adverse events of which they are aware.

The report of an adverse event to VAERS is not documentation that a vaccine caused the event, only that the event occurred soon after the vaccine was administered. Doctors and other healthcare providers are encouraged to report serious or unexpected adverse events following vaccination, whether or not they believe that the vaccination was the cause of the adverse event. Since it is difficult to distinguish a coincidental event from one truly caused by a vaccine, the VAERS database contains events of both types.

It should be emphasized that adverse event reports can be made by a health care professional, a patient or anybody

else. If a patient's physician does not file a VAERS report, the patient can do so. FDA encourages individuals to report to VAERS any clinically significant adverse event occurring after the administration of any vaccine licensed in the United States. Reports to VAERS may be made in writing or by calling a toll-free number, 1-800-822-7967. Reporting instructions are available on the Internet at www.fda.gov/cber/vaers.html.

Since the beginning of VAERS' operations in 1990, through October 1, 1999, 425 reports of adverse events associated with use of the anthrax vaccine have been reported to VAERS. Of those, FDA considers 29 serious events. These reports are for diverse conditions, with no clear patterns emerging at this time. Some of these events are described below. The remaining 396 reports describe a variety of symptoms and conditions, including injection site edema (swelling with fluid in tissue), injection site hypersensitivity, rash, headache and fever.

The 29 serious events were reported to have occurred or been diagnosed at times ranging from 45 minutes to four and one half months after vaccination. Some individuals

experienced adverse events following the first dose; others received up to 5 doses before event onset. Most of these individuals reporting adverse events during the current anthrax vaccination program have recovered. Seven patients were hospitalized for severe injection site reactions. One individual experienced a more widespread allergic reaction. One individual was hospitalized with a confirmed case of aseptic meningitis nine days after vaccination. Two individuals experienced Guillain-Barré syndrome. Three weeks after receiving the vaccine, another individual was diagnosed with bipolar disorder and, at last follow-up, has not recovered. One individual experienced signs and symptoms of transverse myelitis. One individual experienced onset of multi-focal inflammatory demyelinating disease and has since clinically recovered. Another individual experienced onset of lupus and, at last follow-up, has not recovered.

None of these events, except for the injection site reactions, can be attributed to the vaccine with a high level of confidence, nor can contribution of the vaccine to the event reported be entirely ruled out. It should be emphasized once again that it is not always possible to

attribute a cause and effect relationship between a reported event and a vaccination. With the exception of injection site reactions, all of the adverse events noted above do occur in the absence of immunization.

While the data gathered from the VAERS system can serve as a useful tool in identifying potential problems, the reports on anthrax vaccine received thus far do not raise any specific concerns about the safety of the vaccine. As more people receive the vaccine, the numbers of adverse events reported will increase. FDA continues to view the anthrax vaccine as safe and effective for individuals at risk of exposure to anthrax.

LOT RELEASE

As mentioned above, because of the complex manufacturing processes for most biological products, each product lot undergoes thorough testing for purity, potency, identity, and sterility. The anthrax vaccine is subject to lot release. FDA reviews the lot release protocols showing results of applicable tests and lot samples are submitted for possible testing by FDA. The manufacturer may not distribute a lot of the **product** until FDA's Center for

Biologics Evaluation and Research releases it. The lot release program is part of our multi-part strategy that helps assure product safety by providing a quality control check on product specifications.

MEMORANDUM OF UNDERSTANDING (MOU) WITH THE DEPARTMENT OF DEFENSE (DoD)

On May 21, 1987, FDA entered into the current MOU with DoD. This replaced the previous MOU signed in 1974. The 1987 agreement established procedures to be followed by DoD and FDA regarding the investigational use of drugs, biologics and medical devices. The MOU affirms that clinical testing of new drugs will be done in accordance with application regulations concerning INDs and IRBs.

The MOU addressed the possibility of a need for expedited review of an IND by FDA to meet DoD requirements concerning National defense considerations. Under the MOU, DoD is responsible for classifying medical research and development as it relates to information that may be made public under Freedom of Information Act regulations. It should be stressed that this agreement, however, does not

allow DoD to perform research on humans without submitting an IND and it requires DoD to comply with all FDA regulations.

FDA's CONSULTATION WITH DoD

REGARDING THE ANTHRAX VACCINE IMMUNIZATION PROGRAM

FDA has not had an official role in the development or operation of the Department of Defense's Anthrax Vaccine Immunization Program, including the AVIP tracking system or the program's adverse event reporting system. In March 1997, DoD briefed FDA about their draft plan for the possible use of the anthrax vaccine to inoculate U.S. military personnel according to the FDA approved labeling for six doses administered on a specified schedule over eighteen months. Subsequently, FDA learned that the DoD plan had been adopted.

In July 1998, DOD requested that CDC, in conjunction with the Health Resources and Services Administration, National Vaccine Injury Compensation Program (VICP), organize and coordinate a program to evaluate VAERS reports for the

anthrax vaccine. In response to the request by DoD, a group of non-government medical experts was convened by the VICP in the fall of 1998 as the Anthrax Vaccine Expert Committee (AVEC). AVEC, coordinated by VICP, has met eight times since 1998. These experts have been reviewing all VAERS reports for the anthrax vaccine. Representatives of VICP, FDA, CDC and DoD have attended meetings, and FDA has provided information to assist the committee in its deliberations. AVEC is unique in that it provides an independent civilian expert assessment of adverse events reported for the anthrax vaccine.

Upon learning that some DoD personnel may be receiving their anthrax vaccine doses significantly later than the FDA approved schedule, both Dr. Jane E. Henney, Commissioner of the Food and Drug Administration, and I, recently sent letters to DoD. In the letters we asked DoD to expeditiously investigate this matter as we are unaware of any data demonstrating that any deviation from the approved intervals of doses found in the approved labeling will provide protection from anthrax infection. We will continue to monitor this issue.

CONCLUSION

Mr. Chairman, we believe the anthrax vaccine is a safe and effective vaccine for the prevention of anthrax disease - an often-fatal disease - when used according to the FDA approved label. Our confidence in this vaccine, like all vaccines, is based upon four components: first - the review of manufacturing and clinical trials and subsequent clinical laboratory experience with the vaccine; second - ongoing inspections of the manufacturing facility; third - our lot release requirements; and fourth - our ongoing collection and analysis of adverse event reports. So far, the data gathered from VAERS reports on anthrax vaccine do not signal concerns about the safety of the vaccine. The Agency will continue to closely monitor and investigate reports of serious adverse events received on all vaccines, including anthrax, to assure that only safe products are on the market.

I appreciate the Committee's interest in this very important topic and would be happy to answer any questions.

Mr. BURTON. Mr. Chan.

Mr. CHAN. Mr. Chairman, members of the committee, I'm pleased to discuss the results of our ongoing examination of the safety and efficacy of the anthrax vaccine.

My testimony is based on previous studies we have conducted to determine the need for a six-shot regimen and annual booster shots; the long- and short-term safety of the vaccine; the efficacy of the vaccine; and the extent to which problems the FDA found in the vaccine production facility in Michigan could compromise the safety, efficacy, and quality of the vaccine. Finally, I will report on studies conducted to determine the effects of the anthrax vaccine on children and pregnant women.

Allow me first to discuss the background of the vaccine. The original vaccine was developed in the 1950's and was first produced on a large scale by the Merck Pharmaceutical Co. In 1962, a study was published on the safety and efficacy of the Merck vaccine against cutaneous anthrax.

In 1970, the Michigan Department of Public Health was granted a license for a similar vaccine that differed from the Merck vaccine in three ways. First, the manufacturing process changed when MDPH took over. Second, the strain of anthrax that Merck used to grow the original vaccine was changed to another strain. Finally, the ingredients used to make the vaccine were changed from the original vaccine.

Now let me turn to the results of our study. With regard to the need for a six-shot regimen and annual booster shot, we did not find any study to determine the optimum number of doses for the current vaccine. For the original vaccine, a three-dose regimen was used initially based on a regimen developed using animals in the 1950's. However, the number of doses was arbitrarily increased to six when three people who received three doses of the vaccine became infected after exposure to anthrax. And the licensed vaccine adopted this schedule. Likewise, although annual boosters are required, the need for annual booster shots has not been evaluated.

With regard to the long-term safety of the vaccine, we found the long-term safety of the licensed vaccine has not been studied. DOD is planning a study to examine this issue.

With regard to short-term safety, one study used only the Merck vaccine and the other used both the Merck and the licensed vaccine. Safety data from the licensed vaccine is difficult to interpret since part of the population used both the Merck and the licensed vaccine. Let me repeat this. The safety data from the licensed vaccine is difficult to interpret since part of the population used both the Merck which is the original vaccine and the licensed vaccine. According to FDA, it is not possible to determine which individuals received which vaccine.

Post-licensure data are limited since FDA did not have the Vaccine Adverse Event Reporting System until 1990, and only a limited number of doses were distributed each year between 1970 and 1998 with the exception of the Gulf war. Approximately 150,000 of United States troops received the anthrax vaccine during the Gulf war, but little information is available since many records were lost. Data collected by Fort Detrick as part of the Special Immuni-

zation Program suggest that women significantly experienced more serious adverse reactions attributable to anthrax vaccine.

Since the mandatory program began, DOD has used an adverse reaction rate based on the number of adverse events it reported to FDA. The FDA system is a passive surveillance system known as VAERS. DOD uses two additional criteria for reporting an event: The individual receiving the vaccine is hospitalized or is on sick leave for more than 48 hours. This fact, combined with data from studies conducted on VAERS, has shown that such systems do not accurately reflect the true incidence of adverse events due to underreporting.

However, DOD has conducted two other studies which used active monitoring where DOD personnel contacted the vaccine recipients directly to find out if they had any adverse reactions. Data from these studies show that not only were there a much higher rate of adverse events, but, additionally, a higher proportion of women reported both local and systemic reactions to the vaccine than their male counterparts. In addition, more than twice the proportion of women reported that they missed one or more duty shifts after their vaccinations than did males.

With regard to efficacy, a 1962 study on the efficacy of the original vaccine concluded that it provided protection to humans against anthrax penetrating the skin and not through inhalation. However, it is important to note that even this protection was not 100 percent.

In 1985, the Federal Register stated that,

> Immunization with this vaccine is indicated only for certain occupational groups. It is recommended for individuals in industrial setting who come in contact with imported animal hides, furs, wool, hair, bristles, and bone meal, as well as laboratory workers involved in ongoing studies on the organism. In general, safety of this product is not a major concern, especially considering its very limited distribution and the benefit-to-risk aspects of occupational exposure in those individuals for whom it is indicated.

In the 1980's, DOD began testing the efficacy of the licensed vaccine in animals, focusing on its protection against inhalation anthrax. The studies showed that the vaccine protected some animals against some strains but not all strains. Furthermore, the level of protection varied for different species, and the results cannot be extrapolated to humans. DOD recognizes that correlating the results of animal studies to humans is necessary and told us that it is planning research in this area. DOD also plans to develop a second generation anthrax vaccine and, as part of this effort, will need to address whether strains of deliberately engineered or naturally occurring anthrax can overcome the protective immunity of such a vaccine.

FDA's inspections of the vaccine production facility in 1996 and 1998 found a number of deficiencies with the Michigan plant. The deficiencies that the FDA identified in its February 1998 inspection fall broadly into two categories: those that might affect only one or a limited number of batches that were produced and those that could compromise the safety and efficacy of any or all batches. The facility was shut down in early 1998 for renovation. A new company, BioPort, which purchased the facility in mid-1998, is addressing these issues.

Finally, you expressed concerns about the effects of the anthrax vaccine on children and pregnant women. The anthrax vaccine is not intended to be administered to children and pregnant women. No studies have been conducted on the vaccine's effects on these groups.

This ends my statement. Thank you.

Mr. BURTON. Thank you, Mr. Chan.

[The prepared statement of Mr. Chan follows:]

United States General Accounting Office

GAO

Testimony

Before the Committee on Government Reform, House of Representatives

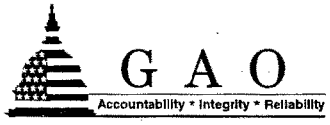
For Release on Delivery
Expected at 1:00 pm, EDT,
Tuesday, October 12, 1999

ANTHRAX VACCINE

Safety and Efficacy Issues

Statement of Kwai-Cheung Chan, Director, Special Studies and Evaluations, National Security and International Affairs Division





GAO/T-NSIAD-00-48

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the results of our ongoing examination of the safety and efficacy[1] of the anthrax vaccine. My testimony is based on previous studies we have conducted to determine (1) the need for a six-shot regimen and annual booster shots, (2) the long- and short-term safety of the vaccine, (3) the efficacy of the vaccine and (4) the extent to which problems the Food and Drug Administration (FDA) found in the vaccine production facility in Michigan could compromise the safety, efficacy, and quality of the vaccine. Finally, I would like to discuss the effects of the anthrax vaccine on children, pregnant women or lactating women.

As you know, concerns have been raised about DOD's anthrax immunization program since DOD began vaccinating its 2.4 million active duty and reserve members in 1998. For example, some active and reserve military personnel have expressed concerns regarding the safety and efficacy of the anthrax vaccine after the FDA found problems during the inspection of the vaccine production facility. In addition, some Gulf War veterans are suffering from unexplained illnesses that they believe might have been caused by anthrax vaccinations received during the war.

[1]Safety means relative freedom from harmful effects to persons affected directly or indirectly by a product that has been prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time. Efficacy is a measure of a

The original anthrax vaccine was developed in the 1950s and was first produced on a large scale by the Merck Pharmaceutical Corporation. After a 1962 study on the vaccine's effect on mill workers, its manufacturing process was changed and the Michigan Department of Public Health took over as the vaccine's producer. This changed vaccine, which is the vaccine being given to U.S. military personnel, was licensed in 1970 by the Division of Biologics Standards, National Institutes of Health. FDA is currently responsible for licensing new vaccines and ensuring vaccine safety.

SUMMARY

No studies have been done to determine the optimum number of doses of the anthrax vaccine. Although annual boosters are given, the need for a six-shot regimen and annual booster shots have not been evaluated.

The long-term safety of the licensed vaccine has not been studied. However, DOD is designing studies to examine the vaccine's long-term effects. Data on the prevalence and duration of short-term reactions to the vaccine are limited but suggest that women experience a higher rate of adverse reactions than men do. FDA's system for collecting data on adverse events associated with the vaccine, which DOD uses, relies on vaccine recipients or their health care providers to

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product's ability to produce a given response. An effective vaccine will provide a certain degree of protection for a certain period of time.

report adverse events.[2] Studies have shown that such systems may not accurately reflect the incidence of events due to underreporting. However, data from two recent DOD efforts to identify the prevalence of adverse events associated with anthrax vaccine show that a higher proportion of women reported both local and systemic reactions to the vaccine than their male counterparts. In addition, more than twice the proportion of women reported that they missed one or more duty shifts after their vaccinations than did males.

A study on the efficacy of the earlier vaccine concluded that it provided protection to humans against anthrax penetrating the skin but did not provide information to determine its effectiveness against inhalation anthrax. In the 1980's, DOD began testing the efficacy of the licensed vaccine in animals, focusing on its protection against inhalation anthrax. The studies showed that the vaccine protected some animals against inhalation anthrax. However, the level of protection varied for different species and the results cannot be extrapolated to humans. DOD recognizes that correlating the results of animal studies to humans is necessary and told us that it is planning research in this area. DOD also plans to develop a second generation anthrax vaccine and, as part of this effort, will need to address whether strains of deliberately engineered or naturally occurring anthrax can overcome the protective immunity of such a vaccine.

[2]Clinical events reported to a passive surveillance system such as FDA's are usually termed adverse events rather than adverse reactions because there is usually insufficient evidence that the vaccine, rather than other health conditions, caused the reported events.

FDA's inspections of the vaccine production facility in 1996 and 1998 found a number of deficiencies. The deficiencies that FDA identified in its February 1998 inspection fall broadly into two categories: those that might affect only one or a limited number of batches that were produced and those that could compromise the safety and efficacy of any or all batches. The facility was shut down in early 1998. A new company, which purchased the facility in mid-1998, is addressing these issues.

Finally, you expressed concerns about the effects of the anthrax vaccine on children, pregnant women, or lactating women. The anthrax vaccine is not intended to be administered to children, pregnant women, or lactating women. No studies have been conducted on the vaccine's effects on these groups.

BACKGROUND

In December 1997, the Secretary of Defense announced that all U.S. forces would be inoculated against the potential use of anthrax on the battlefield. Initial immunization consists of three shots given at 0, 2, and 4 weeks followed by three additional shots given at 6, 12, and 18 months. DOD has recognized that some of the concerns about using the current vaccine might be mitigated in the future through actions such as testing and research and adjustments to the program based on new data.

The inspection process for ensuring vaccine safety is more stringent and complex than for chemical drug because vaccines have three distinguishing features. First, either they have no clearly chemically defined composition, or chemical analysis is extremely difficult. Second, proper evaluation of each batch generally requires measuring their effects in animals. Finally, quality cannot be guaranteed from final tests on random samples but only from a combination of in-process tests, end-product tests, and strict controls of the entire manufacturing process.

From the 1970s until 1998, DOD had been procuring the anthrax vaccine from a facility owned by the State of Michigan, the only facility in the country licensed to produce the vaccine. In 1996 and 1998, FDA identified numerous manufacturing problems at the facility. In response to concerns about the potential loss of anthrax vaccine production, DOD began funding renovation of the facility. Production facilities were shut down in early 1998. In the summer of 1998, the State of Michigan sold the facility to the BioPort Corporation for $25 million. DOD contracts were then transferred to BioPort. BioPort is addressing manufacturing problems.

DATA ON THE NEED FOR SIX SHOTS AND ANNUAL BOOSTERS ARE NOT AVAILABLE

No studies have been done to determine the optimum number of doses of the anthrax vaccine. The immunization schedule of three doses used for the earlier vaccine was based on a regimen developed using animals in the early 1950s. However, the number of doses was arbitrarily increased to six when three people (two at Fort Detrick and one in a private wool mill) who received three doses of the vaccine became infected after exposure to anthrax. In a study of the vaccine's human efficacy published in 1962, a six-dose schedule was used, and the researchers concluded that the vaccine provided protection against anthrax penetrating the skin. The study did not provide enough information to determine whether the vaccine was effective against inhalation anthrax. The license for the vaccine, which was granted in 1970, calls for the six-dose schedule and annual boosters used in the human efficacy study, and DOD has followed this regimen. In September 1998, the manufacturer submitted an Investigational New Drug application to FDA to determine whether the number of shots in the initial schedule could be reduced from six to five.

In November 1971, the Division of Biologics Standards, National Institutes of Health, noted an apparent increase in reports of adverse reactions after individuals received booster shots. The Division considered it advisable to reevaluate the need for annual boosters and possibly the amount of the booster

dose. Although the record is unclear as to whether or not the Division requested the manufacturer to conduct a reevaluation, no such reevaluation has been done to date.

VACCINE SAFETY

The long-term safety of the licensed vaccine has not been studied. However, DOD is designing studies to examine the vaccine's long-term effects.

With regard to short-term safety, data on the prevalence and duration of short-term reactions to the vaccine are limited but suggest that women experience a higher rate of adverse reactions than men. A study on the earlier vaccine's safety was done by Philip Brachman and published in 1962.[2] Brachman reported on 379 subjects that received this vaccine. The study concluded that individual reactions to the vaccine were relatively minor. About 35 percent had local reactions, a figure that varied during the inoculation series. Some recipients developed more severe edema, or swelling, that extended to the mid-forearm or wrist. Two individuals had systemic reactions in addition to the edema. In addition to this study, some data was collected to support licensing of the vaccine but is of limited use because some participants had already received the earlier vaccine and it is not possible to identify who received which vaccine.

[2]P.S. Brachman et al., "Field Evaluation of a Human Anthrax Vaccine," American Journal of Public Health, vol. 52 (1962), pp. 632-645.

Post-licensing data are limited because only a limited number of doses—about 68,000—were distributed by the manufacturer from 1974 through 1989. Also, FDA did not establish its Vaccine Adverse Event Reporting System until 1990. This system, which DOD uses, alerts FDA and the Centers for Disease Control to increases in adverse events. However, it is a passive surveillance system, which means that FDA and the Centers for Disease Control must rely on vaccine recipients or their health care providers to report any adverse events after receiving the vaccine. Studies show that adverse events are reported significantly less frequently with passive surveillance systems than they would be in an active system where vaccine recipients are monitored to find out if they had any adverse effects.

Since DOD's mandatory inoculation program began in 1998, DOD has conducted two efforts to actively collect data on the short-term safety of the vaccine. These data also allow one to examine gender differences in adverse reactions after service-members have received the anthrax vaccine. The first effort, conducted in 1999 by a DOD physician stationed in Korea, was a survey given to service members when they reported for their initial six-dose schedule of shots; it asked questions about their reactions to the previous shot. Results from this effort reflect the researcher's preliminary analysis of the data. The second effort, conducted in 1998-99 at Tripler Army Medical Center, Hawaii, included a survey on adverse reactions to the first three shots when individuals reported for their

fourth shot and later included a follow-up survey on adverse reactions to the fourth shot.

According to the data gathered in both efforts, a higher proportion of females reported reactions to the anthrax vaccine than did their male counterparts. Tables 1 summarizes the rates of all reported reactions to the vaccine in Korea. The data show that a higher proportion of females reported reactions than men (see table 1).

Table 1: Preliminary Data on Gender Differences in the Reported Rate of Adverse Reactions to the Anthrax Vaccine, From Korea Survey (1999)

Dose	Males Percent (number of doses)	Females Percent (number of doses)
First	42.1 (2036)	71.6 (495)
Second	44.4 (1953)	74.0 (474)

Note: This represents a preliminary analysis of the data by the researcher, and at the time of our review, data on reactions to the third shot were not available.
Source: DOD 1999.

The data gathered in Korea also shows that after the first two shots, more than twice the proportion of women than men reported systemic reactions of fever, malaise, or chills than did men (see table 2).

Table 2: Preliminary Data on Gender Differences in Systemic Reactions, From Korea Survey (1999)

Dose number	Fever		Malaise		Chills	
	Male (percent)	Female (percent)	Male (percent)	Female (percent)	Male (percent)	Female (percent)
First	0.9	2.8	6.0	15.6	1.5	5.5
Second	1.7	4.8	7.1	15.4	1.9	4.0

Note: This represents a preliminary analysis of the data by the researcher, and at the time of our review, data on reactions to the third dose were not available.
Source: DOD.

The Tripler survey also demonstrates gender differences in reported reactions (see table 3). These data show that a higher proportion of women reported making an outpatient visit after a vaccination than their male counterparts. In addition, more than twice the proportion of women reported that they missed one or more duty shifts after their vaccinations than did males. In light of the fact no gender specific data were available from the pre-licensure studies, these findings underscore the need for monitoring to better understand the specific effects of this vaccine in different groups.

Table 3: Gender Differences in Reported Local Reactions, Outpatient Medical Visits, and Missed Duty, From Tripler Army Medical Center Survey (1998-99)

Reaction		Dose 1 (percent)	Dose 2 (percent)	Dose 3 (percent)	Dose 4 (percent)
Moderate to severe redness	(m)	17.5	20.4	17.2	31.6
	(f)	49.1	46.9	51.4	39.8
Swelling of lower arm	(m)	9.7	9.5	9.2	7.1
	(f)	13.4	13.5	13.0	8.4
Pain limiting motion of elbow	(m)	9.7	8.7	7.6	7.9
	(f)	17.1	13.5	11.7	8.6
Localized itching	(m)	25.2	25.7	24.5	27.7
	(f)	62.6	60.4	57.9	39.2
Lump or knot	(m)	63.9	64.4	60.5	65.5
	(f)	89.9	87.8	83.6	73.2
Muscle soreness	(m)	66.6	64.7	61.8	60.4
	(f)	79.7	76.4	70.8	61.6
Outpatient medical visit	(m)	5.3	2.0	2.7	[a]
	(f)	10.0	13.8	3.9	
Missed one or more shifts of duty	(m)	2.2	2.0	0.9	[a]
	(f)	5.0	5.1	3.9	

Note: Between 421 and 471 men and between 74 and 83 women responded to each question on the survey.
[a]Data were not available.
Source: DOD.

VACCINE EFFICACY

Studies on the efficacy of anthrax vaccine have been limited to a study of the efficacy of the earlier vaccine for humans, and studies of the efficacy of the licensed vaccine for animals. The only study of the efficacy of the vaccine for humans was performed by Brachman, using the original vaccine. The Brachman study claimed that the vaccine gave 93 percent (and a lower confidence limit of 65 percent) protection against anthrax penetrating the skin. It found that the number of individuals who contracted anthrax by inhalation was too low to assess the efficacy of the vaccine against this form. There has been no specific study of the efficacy of the licensed vaccine in humans. Rather, its efficacy in humans has been inferred from other data, including a reduction in the incidence of anthrax following immunization of at-risk individuals and from animal experiments.

Beginning in the late 1980's, DOD began studying the efficacy of the licensed anthrax vaccine on animals, using guinea pigs, rabbits, and monkeys. All of these studies support the view that in these animals, the licensed vaccine can protect against exposure to some strains of anthrax either by inoculation or inhalation. It is clear, however, that animal species differ in their susceptibility.

Studies of guinea pigs show that some anthrax strains are more or less resistant to vaccines for humans but are protected by the live spore veterinary vaccine.[3]

Research using monkeys showed for the first time that monkeys could be protected against aerosol exposure.[4] However, several studies have shown no direct comparison of immunity in humans to that in monkeys. DOD officials recognize that correlating the results of animal studies to humans is necessary and told us that DOD is planning research in this area. DOD also plans to develop a second generation anthrax vaccine, and as part of this effort, it will need to address whether strains of deliberately engineered or naturally occurring anthrax can overcome the protective immunity of such a vaccine. A variation in virulence among anthrax strains and a variation in relative resistance to vaccine-induced immunity have been observed in experiments on animals. However, the reasons for the variation have not been scientifically proven.

VACCINE MANUFACTURING PROCESS

The quality of a vaccine is closely linked to its manufacturing process, which must be rigorously controlled to ensure that batches of vaccines produced on different occasions are of consistent quality. Accordingly, vaccine production is

[3]P.C.B Turnbull, et al., "Development of antibodies to protective antigen and lethal factor components in humans and guinea pigs and their relevance to protective immunity," Infectious Immunology, vol. 52 (1988) pp.356-363.

[4]B.E. Ivins, et al., "Efficacy of a standard human anthrax vaccine against Baccillus anthracis aerosol challenge in rhesus monkeys," Proceedings of the International Workshop on Anthrax, Salisbury Medical Bulletin, Special Supplement no. 87 (1996) pp.125-126.

very highly regulated to ensure that the products are of consistent quality and safe and effective for the purpose(s) for which regulatory approval was granted. Until 1993, FDA inspectors did not inspect the MDPH facility where the anthrax vaccine was made. According to FDA, access was not granted because its inspectors had not been vaccinated against anthrax. DOD conducted inspections, however, and identified deficiencies during a March 1992 inspection, including the absence of stability studies.

FDA's subsequent inspections of the production facility in 1996 and 1998 found a number of deficiencies. The deficiencies that FDA identified in its February 1998 inspection fall broadly into two categories: those that might affect only one or a limited number of batches and those of a generic nature that could compromise the safety and efficacy of any or all batches. The facility received warning letters from FDA, including one in March 1997 stating its intent to revoke the facility's license. In 1998, the manufacturer closed its plant, which is now being renovated. DOD has directed that supplemental testing for purity, potency, sterility and safety be done on the lots approved by FDA before the current vaccination program began.

EFFECTS OF THE VACCINE ON CHILDREN AND PREGNANT AND LACTATING WOMEN

The anthrax vaccine is not intended to be administered to children, pregnant or lactating women, and consequently no studies have been conducted to determine the specific effects of administering the anthrax vaccine to these groups. Before approving vaccines or drugs for marketing, FDA currently requires the submission of clinical data broken down by (among other things) gender and age. FDA then evaluates these data to determine efficacy and safety for specific subgroups of the general population. In addition, depending on FDA's assessment of clinical data, specific labeling requirements pertaining to potential effects on pregnant women, nursing mothers and pediatric use may also be required. However, the Division of Biologics, National Institutes of Health, which licensed the vaccine in 1970, did not require the submission of data broken down this way.

Mr. Chairman, this concludes my statement. I will be happy to answer any questions you may have.

Contacts and Acknowledgments

For future contacts regarding this testimony, please contact Kwai-Cheung Chan at (202) 512-3652. Individuals making key contributions to this testimony included Sushil K. Sharma, Howard Deshong, Jonathan R. Tumin and Foy Wicker.

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Mr. BURTON. Let me start the questioning. How many strains of anthrax are there, do you know?

Mr. CHAN. As I understand it, the natural strains, there are at least 33 of them at Fort Detrick.

Mr. BURTON. Did your research show how many strains of the anthrax virus or bacteria were going to be dealt with with the inoculations that they're giving to our military?

Mr. CHAN. The vaccine has been tested against guinea pigs, and the results have been varied. I think we found that guinea pigs were protected against 18 strains, but not all strains.

We also tested the vaccine in monkeys against the ames strain, and the results were very promising, but that's the only strain that I know of that DOD tested in monkeys.

Mr. BURTON. It says here, overall results, vaccine fails against nine of the tested strains. There are 33 anthrax strains. Is that accurate?

Mr. CHAN. Yes, that's correct.

Mr. BURTON. Thrirty-three percent of the strains that it was tested against, it failed against 9 of the tested strains.

Dr. BAILEY. I would just like to add, to our knowledge, that the vaccine we are using protects against all known natural strains of anthrax. In fact, the testing—I understand that there were 33 strains tested against guinea pigs and 7 strains with rabbits.

Mr. BURTON. How many were tested on human beings?

Dr. BAILEY. Well, again——

Mr. BURTON. The reason I ask that question—let me just ask. It's been stated by Mr. Chan that you can't—there definitely is a question about the correlation between the animals they tested it upon and human beings. You're talking about guinea pigs and rabbits. There are 33 strains, and we just stated here, according to the overall result from the NATO guinea pig test, it failed against 82 percent of the tested strains. Now, how do you know that it's going to be effective for human beings if it has not been tested on human beings?

Dr. BAILEY. Mr. Chairman, I would like to share with you research that was done years ago with people who were working with wool who had been vaccinated. Among the group that were vaccinated with anthrax vaccine for cutaneous anthrax they were exposed to that frequently, and it showed a high ability to protect. However, there was a natural outbreak of inhalation anthrax; five people died. No one who was vaccinated died. As well, it is unethical for us to test human beings. Therefore, we look to the nonhuman primates who are so similar——

Mr. BURTON. OK. Let me just interrupt here. The inhalation of the anthrax virus has never really been adequately tested, has it?

Dr. BAILEY. That's why I share with you this case in which we demonstrate——

Mr. BURTON. That was——

Dr. BAILEY [continuing]. In the naturally occurring——

Mr. BURTON. That was in the 1950's, and that was regarding people who handled animals—animal skins, hair and so forth, and the vaccine was administered to protect them from having it conveyed through their skin. And you said that some of them died but

none of them died because of the—none died because of the aerosol; is that correct?

Dr. BAILEY. None of them that inhaled the spores died who had been vaccinated. The five who had not been——

Mr. BURTON. How do you know that?

Dr. BAILEY. This is scientific data that we have.

Mr. BURTON. How do you know how many inhaled it? Was it in the air? Did you know that?

Dr. BAILEY. I can get you specifics on that and attach it to the record.

Mr. BURTON. Do you know it was in the air?

Dr. BAILEY. That is what is reported.

I would also like——

Mr. BURTON. No, let me finish. Do you know that it was inhaled?

Dr. BAILEY. That is what is reported. That is in the scientific literature.

Mr. BURTON. Mr. Chan.

Mr. CHAN. I do not agree with that statement. Because when we talked to Dr. Brachman, who wrote the article, he basically said that there was no attempt to measure the level of anthrax spore in the air, and it was done—then he told us something different. Certainly the occurrence of inhalation anthrax did not, first of all, only occur during the crisis where lots of people also were infected with cutaneous anthrax.

Let me state something for you. I hate to use this—the way it's stated appears that there's protection of cutaneous anthrax fully. The study basically said that even under this kind of circumstance, they expect that number of people who are protected it's 92.5 percent with a low confidence of 65 percent. That means that 95 percent of the time, 65 percent to 92.5 percent of the people would be protected against cutaneous anthrax.

And it also stated in the study that there were insufficient number of incidents in the inhalation anthrax to draw the conclusion about the protection, OK? That's what the report says here.

Mr. BURTON. I see my time has expired. I will come back for a second round.

Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman.

It seems to me that there are—this whole question of the hearing boils down to two issues: One, is there a need for the vaccine? And, two, if there is a need, is the vaccine safe and effective?

Let me address the first one first. Let me see whether there's a need for the vaccine.

There are witnesses in panel II that are raising questions about the reality of a threat from anthrax and the need for an anthrax immunization program. General West, what are your views on the threat of an anthrax attack on DOD personnel?

General WEST. Well, Congressman, I certainly hope that there's never an attack. I hope the fact that our forces have been vaccinated and the other things that we can apply against that possibility will be effective. But what we know is that at least 10 of our potential adversaries, and again I hope we never have an adversary, but people we've had disputes with, people that we've been in conflict before, at least 10 of them either have anthrax

weaponized in weapons ready to shoot or they're actively pursuing it.

We also know of at least two terrorist groups that either have it and have tried to use it or are pursuing that capability. As I said in my opening statement, in two of the major theaters, in Korea and in the Persian Gulf, we have servicemen and women that go to work every day in areas where the enemy at any time could deliver an anthrax weapon.

Mr. WAXMAN. Thank you.

I would like to ask this panel then to address the concerns that have been raised about the safety of the vaccine. Dr. Zoon, putting aside concerns about the manufacturer of the vaccine, put aside problems with the implementation of the vaccine program by DOD, would you consider the anthrax vaccine safe if it were properly made and administered?

Dr. ZOON. Yes, sir, I do. Based on the studies originally done on the anthrax vaccine, including the Brackman studies as well as the studies done by the CDC, the adverse event profile in the package insert very much mimics what we are seeing today in terms of the types of adverse events and depending on the population, if the population is a high-risk population, then the risk benefit profile would warrant using the vaccine.

Mr. WAXMAN. Do any of the other members of the panel have additional views they would like to share on the safety question? I understand that Mr.——

Dr. BAILEY. I would just share one additional thing. In looking at the adverse reaction reporting we have, we have 314 that we've reported through VAERS; 17 have had to be hospitalized, but only 5 of those were shown to directly relate to, as best you can determine, to the vaccine, and those were allergic responses.

I would just share with you that the rate that we're seeing as has been indicated is pretty much what we expected. It clearly is in line with other vaccines that are given, diptheria, typhoid, tetanus, the kind of local reactions we see. So we're seeing safety.

Also, we have not had a death. Often, as you know, there are more serious reactions at times to vaccines. We have not had an anaphylactic reaction. We are pleased to report that we feel this is a very safe and efficacious vaccine.

Mr. WAXMAN. Thank you very much, Dr. Bailey.

I understand Mr. Shays' subcommittee held five hearings that focused not on an abstract issue but on the specific details of the manufacturing of the vaccine and on DOD's implementation of its program. Dr. Zoon, can you tell us what the most serious problems are with the manufacturing of the vaccine and whether the manufacturer is taking steps to remedy those problems?

Dr. ZOON. Yes, sir. As stated, the manufacturer had received a Notice of an Intent to Revoke. There were GMP deficiencies, and the manufacturer is currently engaged in remedying those deficiencies.

Mr. WAXMAN. And, Dr. Bailey, could you comment on the most serious problems with DOD's implementation of this program and what steps the agency has taken to remedy these problems?

Dr. BAILEY. These problems in what aspect of the program?

Mr. WAXMAN. In the DOD implementation of the program.

Dr. BAILEY. I assume that's not an acquisition question in terms of BioPort but more a question about the program, actually the clinical aspects of the program.

Mr. WAXMAN. I will tell you what. Let me withdraw that question, because we will probably want to bring it up later for the record.

I couldn't understand this argument, Dr. Chan. You say 82 percent of the strains didn't seem to be affected, and I don't know if that's an accurate statement or not. But what difference would it make? It's almost like saying if you find out a soldier wears a helmet to protect their heads but then they can get shot in the chest, then you would want to make them wear a bulletproof vest. You wouldn't tell them not to wear a helmet any longer, would you?

If it protects against some of the strains of anthrax, isn't that worthwhile? Then we ought to make sure to continue working so that it protects against other strains as well.

Mr. CHAN. I think it makes a lot of sense, unless you want to take it to a limit. For example, if we know what strains Iraqi have and, in fact, DOD had tested the vaccine against that particular anthrax, that is weaponized, I would agree with you, Congressman. But first I think you need to ask them whether they have done that already or not. Let them answer that.

And the second question——

Mr. WAXMAN. You wouldn't want to test it on people?

Mr. CHAN. No, use whatever animal model you want. I don't have any problem with that. But my point is that if they are in existence, 31, 33 different strains that are naturally there, not engineered, then at the very least, we need to test the vaccine against those strains. DOD said, well, we will go to the monkeys model. Try them out and see what happens.

Dr. BAILEY. In fact, I would share with you one of the tests that I think is essential here. We did an aerosol challenge against the Rhesus monkey, and with the Rhesus monkey, when they had received more than two doses, they all survived. Those who had received the vaccine, they survived the aerosol challenge. Again, it's not a human model study. It would be unethical for us to do that.

I would also just add in general with vaccines that you're looking for protective antigen response, and really the strain itself is not so essential as the mechanism.

Mr. BURTON. Before I go to Mrs. Morella, let me just say, as I understand it, that was not tested against all 33 strains in the monkey; is that correct?

Dr. BAILEY. That's correct.

Mr. BURTON. Thank you.

Mrs. Morella.

Mrs. MORELLA. Thank you, Mr. Chairman.

I thank the panelists for their presentations, too.

It's interesting, as somebody who was very much involved with having an Office of Research on Women's Health established at the National Institutes of Health, which has been working quite well in including women in protocols and clinical trials, I'm fascinated by our GAO report here which indicates a tremendous disparity in some of the data with regard to gender differences, which says something—I mean, there are big disparities here, and I'm just cu-

rious about what this is saying. Do we need to look at that separately? Would anyone like to extricate from that data something that adds to our base of knowledge of this?

Dr. BAILEY. Mrs. Morella, first of all, I would like to share with you that I've had five of my shots already. I was certainly glad to have done that as I was in the Persian Gulf last year within SCUD range. But I'm confident, in general.

And, again, if a member of my family were in harm's way or in a theatre where I knew that to be a risk, I would certainly want them to have that immunization.

I saw no ill effects. That's beyond the point. The real point is that you're right. We've looked at the data, and we know that there seems to be a higher reaction rate, a local reaction, especially among women, but also in general we're getting a greater response. One of the theories is that women have a stronger immune response, and that may be part of what we're seeing, and I think it would be worth looking at.

But there's a plus to that as well, which means that if, in fact, you have a stronger response, it may be that you have stronger protection as well.

Mrs. MORELLA. I would like to hear from our GAO people, too.

Mr. SHARMA. Let me say a couple of things on this. This is a very significant finding on this vaccine. This vaccine has not been used in large numbers. Although Brachman had some women in his studies—he did not analyze his data on adverse reactions by gender. So we don't know really how this vaccine was going to work on women. However, DOD collected data on its own employees that received the vaccine from 1974 to 1998 found that women had statistically significant higher reaction rate. They had, also, higher lost duty time.

It is correct what Dr. Sue Bailey stated, that it means that women have a better immune system. However, what I would also like to state is that it also calls into question two things.

First of all, we have to ask this question: whether women need the same level of dosing if they have a better, more sophisticated immune system. And I've indicated that for the licensing vaccine, no studies were done to determine the number of doses, the need for the frequency of the booster by gender, so we have no information. This is very significant and alarming. And in our military today, we're going to have more and more women. Right now, there is no protocol to determine what the antibodies levels are.

I think it is important because a point that I wanted to mention earlier in the animal data, one of the things that we found is that antibodies levels which are supposed to be correlated to protection turned out not to be related to protection. In other words, animals that had higher levels of antibodies died than animals that had lower levels. This calls into question, if antibodies levels are not a good measure, then how do we determine what do you need for protection?

So we need to do two types of studies: Are women at higher risk? Is this vaccine or other vaccines in some way impacting the immune system of women? And, second, what is the optimum number of doses for men and women?

Mrs. MORELLA. Would you agree, Dr. Bailey? Did you want to make any statement from FDA's point of view?

Dr. ZOON. Yes, just one comment based on our data from the VAERS system regarding adverse events that have been reported. Although we don't have a denominator for the total number of minor and nonserious and serious reactions totally, other than what's reported to VAERS, our data does suggest that, in terms of the serious reactions, the percentage of the total reports, the percent of serious over the total number of reports to VAERS is the same for men and women, about 7 percent.

Dr. BAILEY. I would certainly agree we need additional research. We have $8 million planned over the next—up until 2005, and I think clearly we need to determine if there indeed is any gender difference.

Mrs. MORELLA. Thank you. I think that's an important point to make. Thank you.

Thank you, Mr. Chairman.

Mr. BURTON. Thank you, Mrs. Morella.

Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

Whoever can answer this—how many biological weapons are there that are actually weaponized and that we might be able to expect could be used aside from anthrax or near weaponized or could easily be weaponized?

General WEST. We would get into a classified area pretty quickly there. I can tell you that several are being pursued. The one that seems to be the force of choice—or the weapon of choice is anthrax. There seem to be more countries pursuing and using that than any other. There are some others that may be possible, but I cannot tell you of any actually that are in the weapons and ready to be shot at this time.

Ms. SCHAKOWSKY. But, General, if it were widely known, as I'm assuming it is, since everything we do is out in the open, that American forces were immunized against anthrax, why would an enemy directing its offense use anthrax if we have this program if there were another weapon of choice?

General WEST. I think there are two parts to that answer, ma'am.

First of all, I mean, anthrax is the weapon of choice for good reason. It's easier to obtain. You can buy the ingredients to grow the culture under the guise of other lawful activities. Once you make it, it's very stable. It lasts for a long time. It's resistant to the elements. It's very tenacious. It's extremely lethal. Some of the other and potential biological weapons are not as stable. They're easily deteriorated by sunlight, by wind, by rain, things like that. They are also easily contaminated. They are also much more dangerous to build.

So particularly on the terrorist side or the smaller nation state side, they may not have the advanced laboratories, they're very dangerous to manufacture and the perpetrator may, in fact, bring harm upon himself.

Ms. SCHAKOWSKY. Does DOD envision at some point in the future that we will attempt to have a vaccination program for every biological weapon?

General WEST. No, ma'am, but what we do is we try to determine as best we can what's being worked on in the world by potential adversaries, what capabilities are there, and we try to do whatever we can to deter that threat. And in some cases that may be vaccine, and in some cases it may be something different. And some of those areas we're already pursuing a vaccine in case they are able to weaponize and in case we think that it's prudent to give such a vaccine. But that takes a while, and we can't get ahead of the FDA there, we can only use one after it was approved for use. But there's work going on in case that came to pass.

Ms. SCHAKOWSKY. Are you concerned, because we are all, of course, interested in deterrence and our ability to maintain our readiness, that we're losing a number of pilots because of their fear of the anthrax vaccine? I mean, if we're talking cost benefit, where does it kick in that we're losing too many of our armed servicemen and people?

General WEST. I'm concerned. I'm concerned about the loss of one single serviceman or woman of a reason for not taking an anthrax shot. I would be remiss as a leader if I wasn't. I wish the problem wasn't out there. I wish that we would have been ahead in the communication effort so that we would have gotten to some of these bases where there have been problems before the people that I assume for their own proper motivations think that it's bad.

But I know that there's a threat out there. And I know that on any given day I may have to send our men and women to operate under the umbrella of that threat. And I couldn't responsibly send them there without using a vaccine that we're convinced is both safe and effective.

Ms. SCHAKOWSKY. Following up on Congresswoman Morella's line of questioning, we had testimony from a woman who was—I know the protocol is that if you are pregnant or suspect that you may be pregnant that you're not required to—that you shouldn't take the vaccine.

However, she was not only not asked if she suspected she was pregnant but there were statements made that implied that women in the Armed Services would just simply say that they suspect that they might and, therefore, unless you were proving that you were pregnant, you were going to take that vaccine. I know that was later denied, and that there was a "he said, she said." But I have no reason to doubt that testimony. I mean, she had no particular motivation, I don't think, to come here and say that.

So I'm concerned that even the protocols that do exist for women in the military are not being followed and that we may be putting some woman at risk, particularly given the little data that we have on the difference and adverse effects on women.

General WEST. I wasn't present for that testimony. But I would agree with you, if that happened, it should not have happened. It would be contradictory to our policy. Every female is supposed to be asked before they take the shot. If they are pregnant, they're excused from taking them. There are no repercussions. They're not required to take the shot if they're pregnant. We don't even want them to.

If that happened, I would like to know about it. We would like to investigate it. If you hear of any other incidents like that, we would like to know about it, because we have——

Ms. SCHAKOWSKY. A lot of incidents of testimony here that is contrary to what is stated DOD policy is on the record for you to observe from people who have come to hearing after hearing after hearing and told us things that we've been then told are not DOD policy that make many of us very concerned about the way this is being implemented.

Thank you.

General WEST. I could add, ma'am, that every one of those is being looked at by the various services' Inspector Generals. We will get to the bottom of every one of those, and we will provide the answers for the record to what we find out.

Mr. BURTON. Thank you, Ms. Schakowsky.

Mr. Shays.

Mr. SHAYS. Thank you.

General West, I know that you sincerely believe that this is a program that we need to pursue. So I don't question your sincerity. But we have an all-volunteer service, and you have a mandatory vaccination program, and you have started a new course. You have decided that, where in the past we would protect and provide vaccinations for what nature may throw at us, the new Army, the new Navy, the new Marines, the new Air Force is that we're going to vaccinate you on the potential threats of terrorists and any military force that may use a biological agent. That's the new voluntary military.

Do you think that will have an impact on our ability to have enlistees and on retention?

General WEST. I don't think it will, if we get our message out that the vaccine is safe and effective. If we convince our young women and men that there is a threat and what we're going to do wouldn't hurt them, there won't be a problem with it. We haven't done that as well as we should. We're trying to get better, and we're going to catch up.

Mr. SHAYS. The problem is that is almost like me saying, trust me, I'm a politician.

General WEST. I would never say that, sir.

Mr. SHAYS. There's enough history of politicians in the military in the past, not you, but the military in the past that would not make people feel very comfortable with your sincerity and my sincerity.

Dr. Bailey, do you believe there is a direct correlation between antibody response to the vaccine and protection from infection?

Dr. BAILEY. The very specific scientific question, and you already heard it addressed here today, it's one of the questions as to whether or not a higher——

Mr. SHAYS. I just want the answer.

Dr. BAILEY. Everything in my scientific background tells me that an antibody response to an antigen does impart immunity and protection.

Mr. SHAYS. Then why isn't DOD tracking antibody titers of vaccinated servicemen and women to see just how much biological body armor they will actually take into battle?

Dr. BAILEY. All of the research at this point indicates that this is efficacious. There clearly are studies which can—we can provide for you and show——

Mr. SHAYS. The military isn't doing this. You are starting a new policy: We are vaccinating for what a terrorist or a military might do. And I'm asking why we aren't starting to gather this information.

Dr. BAILEY. Actually, I think maybe, Colonel Randolph, do you want to respond to that antibody research that has been done? We certainly do look at the body of knowledge that is out there. We do not recreate everything.

Mr. SHAYS. Are you tracking this or are you doing studies? The answer is no. And so the question is, why not?

Dr. BAILEY. Well, you know, one of the concerns is the amount of medical intervention or therapeutics that are done at all that would involve a program, I assume you would suggest that be voluntary to draw blood and to track that.

Again, Colonel Randolph, do you want to add to that in terms of the research or the body of knowledge?

Colonel RANDOLPH. Congressman——

Mr. SHAYS. I need to know why you're not doing it, is the bottom line.

Colonel RANDOLPH. Sir, we don't do titers on military personnel simply because no one does titers on any personnel subsequent to a dose of vaccine. We have to follow the FDA dosing protocol of six doses over 18 months whether we found an antibody titer after two doses or three doses or four doses.

Mr. SHAYS. Yes, Mr. Chan.

Mr. CHAN. I think the chairman noticed my sense of frustration here.

I think, as Mr. Shays said, if we are implementing a policy which is for almost 2.4 million people and potentially even 5 percent have adverse reactions it means 120,000 soldiers are affected and that's significant, if that's the case. It seems to me that we need to be proactively looking for ways to explain the problem to the soldiers so they understand that we care about them.

Now, I just don't understand why we are sticking with six dose schedule. If this is the protocol, and if women are reacting much more adversely than men, and we certainly do not have the original set of data from the Brackman study, explaining the safety of that vaccine, which is in fact not the same vaccine that is being licensed, so there are a lot of unclear unknowns. And I think it needs to be looked into in such a way that we don't stand behind this question of is it safe, is it efficacious because FDA licensed it.

Mr. SHARMA. I would like to add too, there is an additional reason why we should be looking for the antibodies level and that is—we have protocols from other vaccines whereby when people have adverse reactions we check for the antibodies level to determine if they have sufficient levels of antibody that is required and, if they do them you will waive subsequent shots.

Second, when you find that somebody is adversely reacting to a vaccine, we can either increase the time between doses or we can reduce the dose or we also can apply pretreatment. And this body of knowledge about protocol is not new. DOD applies similar proto-

cols to other vaccines. Why it's not being applied to the current vaccine, I do not know.

Mr. SHAYS. Thank you, Mr. Chairman. Mr. Chairman, will we have a chance to ask a second round of questions before we go on to the next panel?

Mr. BURTON. Yes, we will go back for a second round of questions.

Mr. Horn.

Mr. HORN. Thank you, Mr. Chairman.

I wonder if the gentleman on the end, I came in 5 minutes late, would identify himself. Now would you give me the spelling on the name, the gentleman to your left?

Mr. SHARMA. My name is Sushil S-U-S-H-I-L. Last name is Sharma, S-H-A-R-M-A.

Mr. HORN. And you're part of Mr. Chan's staff?

Mr. SHARMA. Yes, I work with him.

Mr. CHAN. He is my colleague.

Mr. HORN. Very good.

Let me just ask this. I was curious when Dr. Dumont said, well, we don't give them to those under 18 or over 65. Now we've had some discussion on the children. Will that policy be changed so that children and seniors over 65 who are abroad—because a lot of these missions aren't State Department missions, they're other agencies. There are military. There's a whole series of people that is in every country we have, and if we should be protecting those individuals, we need to look at people who are over 65. Since I'm over 65, I would have a few concerns if I was in your embassy and you weren't doing it.

Now, if a person asks to do it over 65 or says I want my children done who are in high school, elementary school, under 18, do they get the anthrax vaccine or don't they?

Dr. DUMONT. Congressman, at this point in time, we are just in the beginning of looking at a feasibility——

Mr. HORN. Move that microphone, please, a little closer to yourself.

Dr. DUMONT. Excuse me, again. Congressman, at this point in time, we're concerned with trying to protect in the overseas environment all of those who are not eligible for the vaccine at this point. And so what we're trying to do is we're in the preliminary stage of exploring the feasibility of doing a study for those that are not eligible and that means over 65 but also less than 18.

And so what we could do is do a study that would be FDA approved, but it would involve doing dosing and it also would involve doing blood drawing and assessing titers in that community.

Mr. HORN. What's the evidence in science that says don't give that vaccine to someone over 65?

Dr. DUMONT. To my understanding, and I really would defer to the scientific experts on the FDA side that there is no data, but it's just never been tested and offered to those communities, and that's why there's no information.

Mr. HORN. Well, then we've got an arbitrary standard here. In other words, we've got age discrimination, and there are laws against that, and I don't understand why we have that. Suppose

you're 64½, suppose you're 64 and 11 months, are you not going to give that person the vaccine?

Dr. DUMONT. Again, what we would like to do—and I think we're—we want to protect as many people as we can. We are forced to follow FDA strict guidelines in the administration of this vaccine. If we can make this vaccine available through a study this would be——

Mr. HORN. You're telling me ageism at a point in time is an FDA policy? I think that's silly. Now, unless there's some evidence that people drop over when they get the anthrax shot because they hit 65, I find this unusual and weird. So let's hear it FDA.

Dr. ZOON. Yes, sir. The age in the package insert is based on the studies that were done to support licensure of the vaccine. So the population that was used to show the safety and effectiveness of the vaccine was in that age group, between 18 and 65. To promote vaccines in areas outside that range would be an off-label use of the vaccine.

Now, under some new rules, such as the pediatric rule and some new guidances, looking at special populations now is an important part of them extending medicines to the young and the elderly. The development of the application of existing licensed medicines, can be studied, but they need to be studied under an IND where you have special monitoring of the individuals. To a large degree, many times the very young and the elderly will elicit a different immune response.

So one needs to study the particular agent, in this case the vaccine, to get information and data to assure that the safety and efficacy of that vaccine will be appropriate in those populations.

Mr. HORN. Well, they've picked an arbitrary cohort there, and it seems to me—where's the evidence one way or the other?

Let's deal with women below 18 or women over who might become pregnant some day. It might be 1 month, it might be 1 year, it might be 10 years. I mean, is there any evidence at this point that when you give the anthrax vaccine that 2 years later a woman became pregnant and something deformed the child? Where is the evidence?

Dr. ZOON. At this point in time, no studies have been done to assess that. This particular product is labeled pregnancy category C, which means animal reproductive studies have not been done nor has it been tested in pregnant women, and according to the labeling, this should only be used in pregnant women in extremely high-risk situations where that exposure would be really an imminent hazard.

So the answer to your question is, one can study this in animal models, but it has to be under a properly controlled study with appropriate safeguards, informed consent, et cetera, in order to examine the particular safety and efficacy of any product, including vaccines.

Mr. HORN. OK. And that's because you're following an FDA cohort-type of analysis, is that it?

Dr. ZOON. This would be an IND study, and that population would be studied for the safety and efficacy very closely under an IND with informed consent.

Mr. HORN. Mr. Chairman, I just think sometime maybe the committee would like to get into the FDA regulations on this that they're following, because it sounds to me like it's simple ageism, and I thought we got rid of that 15 years ago in this city. I don't know what happened.

Mr. BURTON. I think the FDA is aware that we will be having a number of hearings involving them.

Before we go to Mr. Terry, let me just say that the immune response that I heard Mr. Chan talking about a while ago varied greatly between individuals of the same age, same gender, everything else. I mean, the amount of immune response varied greatly with the same number of inoculations. And the second thing is you mentioned this stuff was tested—it's not the same shot you're giving today that was tested by Merck, is it? It's a different one, isn't it? I mean, the tests you're talking about were the Merck Laboratories. Has this new shot been tested like the Merck tests were?

Dr. ZOON. Sir, are you addressing me?

Mr. BURTON. Any one of you. You keep referring to this stuff being tested. This is not the same vaccine that Merck tested back in the 1950's. It's a different one. Has this been tested thoroughly?

Dr. ZOON. Let me describe what the situation is. The particular type of anthrax that is used to make the vaccine comes from the vollum strain. That is the parent strain. The Merck vaccine and the current vaccine are both derived from the vollum strain. The original Brachman study used a strain which was slightly different but still derived from the parental strain of vollum.

Now, when the additional studies were done by the CDC, they used some of the Merck vaccine and they also used some of the Michigan vaccine, and over 3,000 individuals got almost completely the Michigan vaccine, and those patients were studied for their safety and comparable immunogenicity levels were observed, and it came from the vollum strain.

Mr. BURTON. Let me interrupt you. You have not tested this vaccine thoroughly? This is not the same vaccine that was tested initially? You've already said there are variations, right?

Dr. ZOON. Yes, I said that the Merck vaccine has some differences, but they're both a variant and avirulent.

Mr. BURTON. I understand. You don't need to—the fact is, it's not the same vaccine and there could be different reactions because of the changes, could there not be?

Dr. ZOON. Well, under the studies that were done, under the IND that supported licensure of the vaccine, that strain was studied for its safety and its immunogenicity.

Mr. BURTON. But it was manufactured differently, was it not?

Dr. ZOON. That other strain was also used in the clinical studies done by the CDC, and it was compared to the original Merck vaccine. Under the FDA Modernization Act that was recently passed, this would not be unusual for it today——

Mr. BURTON. I don't want to belabor this. I want to go to my colleague today. But do either one of you have a response to that?

Mr. SHARMA. I think one of the difficulties in interpreting that data is that we do not know which individual received which vaccine, and the adverse reaction data has not been analyzed by gender and by type of vaccine. We do not know what proportion of the

adverse reaction are specifically attributable to the Merck versus the licensed vaccine from the IND data.

Mr. BURTON. Mr. Terry.

Mr. TERRY. Thank you, Mr. Chairman. Your question and the answers exemplify what I was going to bring up, and that is I'm sitting here and, you know, I only have 7 years of college and about 9 months here, and I haven't learned the languages that I'm hearing here today.

Some of the testimony is confusing with the bureaucratic and scientific-ese that is being exposed. So let me—my questions are not that probing. I just need some clarifications on some of the testimony.

Dr. Bailey, maybe you can help me out here. I'm not accusing you of being the leader of bureaucratic-ese here. You seem to be taking a lead on answering a lot of these types of questions. And again following up on what the chairman brought up in his first questions, there are 33 strains of anthrax, and through this one study that has been discussed almost throughout the hearing today it shows that the current vaccine is only good against, what, 18 percent of the nonstrains? First of all, do you agree with that? It seemed to me in some of your comments that you disagree with that conclusion. Am I correct that you don't agree with that?

Dr. BAILEY. With—I don't know.

Mr. TERRY. The fact that the current vaccine does not inoculate against, what, 82 percent of the known strains?

Dr. BAILEY. It's my understanding that the vaccine we have protects against all known strains. Some of that is because of the data—you were out of the room when I presented some of the data of the studies that were done, animal studies, on the majority or many of those strains. But, more importantly, the antigen antibody response is vaccine theory and scientific theory that we are depending on here and is good science.

Mr. TERRY. So the answer is that the vaccine covers all known strains?

Dr. BAILEY. It does.

Mr. TERRY. General West, do you agree with that?

General WEST. I do, sir. And I certainly don't have the scientific background that Dr. Chan has, but from the limited look that I've taken at it, if you only look at the guinea pig studies, you can go look at guinea pig studies for any of those vaccines that you had on those charts over there, and the data is not nearly as impressive as it is in mice or rabbits or Rhesus monkeys. The tests that we did with all of the strains that have been tested against in the Rhesus monkey model, if they had at least 2 shots, they lived; if they didn't, they died.

Mr. TERRY. Mr. Chan, help me through this now. Have you not incorporated the Rhesus monkey research into your conclusions?

Mr. CHAN. We tried to present them separately. We didn't combine them. What we did look at is the evidence for guinea pigs first, and as we stated 18 out of 33 strains that were tested were found to be efficacious.

Mr. TERRY. What does that mean?

Mr. CHAN. That means it worked.

Mr. TERRY. Thank you.

Mr. CHAN. But with the monkey model, as I stated before, as far as we know, it's only tested against one strain. So my answer is I don't know the efficacy of this vaccine in monkeys against other strains.

Mr. TERRY. Is the one strain, parent strain that is representative of all 33 strains?

Dr. ZOON. The strain that is used to make the vaccine is not virulent, meaning it doesn't cause disease and that's why it's used for the vaccine. It is a particular strain of the organism that has certain characteristics, so it doesn't give the disease you're trying to protect against.

Mr. TERRY. Mr. Chan, are these characteristics inherent to all 33 strains?

Mr. CHAN. I think——

Mr. TERRY. If you can reasonably inoculate focusing on those similarities.

Mr. CHAN. Let me state it differently. If, in fact, that theory is correct, then it should be OK—either it works for all guinea pigs or it doesn't work for all guinea pigs. You know, if it doesn't, then you say, well, whatever the catergorization you're talking about of the Protective Antigen and so on, how come it didn't?

So, as Dr. Sharma just said, when we looked at the animal models, we found that the level of the antibody in those animals does not correlate well with protection. That means it does not imply the higher antibody levels are associated with greater amount of protection. OK.

So it suggests that maybe something else is going on, that's all. I don't know the answer to that.

Mr. TERRY. I only have one more minute, Dr. Bailey, so I want to ask General West one question here. Do we know what strain of anthrax North Korea and Iraq use?

General WEST. We believe that we do. We believe that we've tested for it, and we believe our vaccine will be effective against it. I can't guarantee you that we know everything about them that we would like to know. But based on what we've been able to gather, our vaccine is effective against what they have. And I can't give you all the data on what's been tested, and we tested animals.

Mr. TERRY. Are we testing the vaccine in the general sense that it is your statement that the vaccine works against all 33 strains, or have we done testing with the specific strains that through our intelligence we have found North Korea possesses and Iraq possesses?

General WEST. We could give you for the record how many strains have been tested in each of the animal models. I recollect from the readings that I've done that we tested in the Rhesus monkey model at least four strains. And it was those against all four.

Mr. TERRY. Including what your intelligence has found is used by North Korea and Iraq?

General WEST. Yes, and in our interrogation.

Mr. TERRY. Would you please supply that for the record? That would be helpful.

General WEST. I will, sir.

Dr. BAILEY. Let me just add that the strain—again, I believe you were out of the room—is immaterial in that we're looking at the

antigen antibody response. But I would like to say that USAMRI, the Army Medical Research Institute, in the guinea pig, 33 strains have been tested; in the rabbits 7 strains have been tested; in nonhuman primates, 4 strains have been tested. We believe this vaccine works.

Mr. TERRY. Thank you, Mr. Chairman.

Mr. BURTON. We now have our guest, Mr. Jones, who has sponsored legislation of which many of us have cosponsored dealing with allowing members of the military to have a voice in the decision on whether or not to take the vaccine.

Mr. Jones.

Mr. JONES. Mr. Chairman, thank you, and thank you for allowing me to join your committee today on what I think is a most, most important hearing regarding military and, quite frankly, the readiness of our military.

I would like to, if I may, Dr. Chan, just ask you a yes or no question. Would you agree with General West—I have great respect for—his comment that we know that—10 adversaries that we should be concerned about as it relates to anthrax? Would you say yes or no?

Mr. CHAN. Yes.

Mr. JONES. OK. Let me ask you, Dr. Dumont, would you think a Member of Congress that writes the Secretary of State to ask how she arrived at a policy of whether this should be voluntary or not should get answered back?

Dr. DUMONT. I think you would get an answer back, yes.

Mr. JONES. So you think if the letter was written on August 23rd, sometime before the end of this year, that the Member should receive an answer?

Dr. DUMONT. I can't tell you more than I would think that if the letter was written, that you had sent her the letter, that she would respond.

Mr. JONES. You would be glad if the Member asked you to look into it if—when maybe he should look for an answer.

Dr. DUMONT. Most certainly.

Mr. JONES. I'm asking if you would, please. My name is J-O-N-E-S, and if you would find out when I might get a response to that letter to her.

Let me also—and I'm basing this question on the fact of your response to this committee, and I believe I wrote this down correctly. You argued that the anthrax threat is such that they are compelled—meaning the State Department—to offer the vaccine. Is that somewhat correct to what you might have said?

Dr. DUMONT. That is correct.

Mr. JONES. OK. Let me tell you what I found on the website today, and I'm going to read this for the committee: The Department of State has no information to indicate that there's a likelihood of use of chemical or biological agent released in the immediate future. The Department believes that the risks of the use of chemical, biological warfare is remote, although it cannot be excluded.

Did you know that's on the website?

Dr. DUMONT. Yes, I do, sir.

Mr. JONES. OK. So, therefore, if you don't feel like the likelihood of an attack is imminent so therefore there's some justification for the fact that the State Department says this should be voluntary?

Dr. DUMONT. Congressman, I guess the key piece is that we cannot eliminate the risks completely. And again, as I mentioned in our testimony, is that we believe that, and again I'm coming from the medical background, the information with regard to threat and our missions being at high risk, really comes in from other expertise versus diplomatic security or from the intelligence field.

But the information that I'm given is that our missions overseas are at some risk. And again our point is that if there is a vaccine out there that works and that we can protect our communities, why not offer it to them? Why not make it available to them?

Mr. JONES. Right. And so your decision, because you want to offer this to the employees of the State Department, is that it should be voluntary, not mandated?

Dr. DUMONT. All of our vaccines, sir, under our program are voluntary. We do not have any mandatory vaccines.

Mr. JONES. OK. That's what I needed to know. Even though I have great respect for the men and women in uniform, and particularly from all levels up, that it just amazes me, Mr. Chairman, that this handout—that we have NATO allies that mandate anthrax vaccine and there's only one, and that's America.

Dr. BAILEY. Mr. Jones, may I respond?

Mr. JONES. Yes, ma'am.

Dr. BAILEY. I met with the Minister of Defense from the UK last week, Mr. Spellers, and he told me that, in fact, they would like to have access, but it is a production problem in the UK that prevents them from implementing as aggressive an anthrax vaccine program as we have.

Mr. JONES. Dr. Bailey, as of yet, as far as the government, they have not made a decision to mandate it. It might be what they would like to do or they might be debating whether they should or should not, is that correct, at this time?

Dr. BAILEY. Yes, sir, it's a moot point at this time.

Mr. JONES. OK. Thank you.

Dr. Chan, would you pick up mainly for me, because I'm not on this committee, I am somewhat amazed by Dr. Zoon's answer and that is how the FDA—is this a normal practice that you take the research done by a separate company, even though it relates to the issue, and this issue being anthrax, and they take the data from another company to make a decision to implement a vaccine that was produced by someone other than that company? Is that normal?

Mr. CHAN. I don't think we have found another case like that.

Mr. JONES. Dr. Zoon, would you pick up on that, if that doesn't seem to be a normal course of decisions?

Dr. ZOON. Yes, sir. This is not a unique case. And, in fact, there were data in the license file that used the particular vaccine produced by Michigan at that time in the studies conducted by the CDC. So there were data in the file regarding the material that was manufactured at the Michigan facility in the license application.

Now, in terms of are there other situations where a certain vaccine has modifications during its clinical development and changes are made, the answer is, yes, that does happen.

Mr. JONES. Mr. Chairman, thank you.

Mr. BURTON. Thank you. We really do need to get to the next panel, but I'm going to yield to Mr. Shays. He has a few more questions, and I have a couple more. Then we will go to the next panel.

Mr. Shays.

Mr. SHAYS. Thank you.

Dr. Zoon, what supports the DOD's statement that the anthrax vaccine is effective after three shots?

Dr. ZOON. I think DOD needs to answer that question.

Mr. SHAYS. No, I'm asking you.

Dr. ZOON. I'm not aware of any data that supports its use.

Mr. SHAYS. But you were in this room and you heard the DODs make that statement, correct? I heard it today. And I heard it at other hearings, and it's in their documents. What protocol allows them to make that statement?

Dr. ZOON. The only thing I could say, sir, that the information in the package insert requires the full administration of the vaccine, and that's what it's approved for.

Mr. SHAYS. It's approved for six shots. Is there any data that you have allowed—any protocol that allows this shot to be three shots?

Dr. ZOON. Not to my knowledge.

Mr. SHAYS. OK. Do you have any concern that DOD has said consistently that this is effective after three shots? If we're supposed to trust the DOD and trust me as a politician, what right do they have to make that claim?

No, I'm asking you.

Dr. ZOON. Sir, my——

Mr. SHAYS. You're supposed to oversee what DOD does, and FDA did not do that when we had TB. We didn't keep any records. And we're not going back a few decades. We're in this decade. They didn't do what you required them to do, which is to keep records. You all said you would do a better job at watching what the DOD does now. So I'm asking you that question.

Dr. ZOON. I wrote a letter to the DOD reminding them of what the package insert said regarding the administration of anthrax vaccine. I reminded them, as well as Dr. Henney sent a letter saying that this vaccine should be used according to the schedule on the package insert, which is the six injections plus annual boosters.

Mr. SHAY. They are not allowed to change the protocol?

Dr. ZOON. They can do studies to study whether the three dose regimen has comparable properties using an IND if that is what they choose to do.

Mr. SHAYS. They can do studies?

Dr. ZOON. Yes, they can.

Mr. SHAYS. They have to come back to you, don't they? They have to come back to the FDA in order to gain validity for their claim?

Dr. ZOON. The FDA is responsible for oversight of the manufacture—the DOD, if they were to file an IND to explore that option, FDA would be actively engaged in studies surrounding those studies that would be submitted to the FDA for review.

Dr. BAILEY. Mr. Shays, may I offer some information that I think could be helpful? We have a preliminary report to the FDA for a comparative study to determine the best dose schedule. In fact, by the way, it does look at the antibody response that we discussed earlier.

Mr. SHAYS. That's a request to the FDA?

Dr. BAILEY. Right.

Mr. SHAYS. Have they approved it?

Dr. BAILEY. That has not been approved yet. We asked for further studies.

Mr. SHAYS. Why would you tell your military personnel that they're going to be protected after three doses?

Dr. BAILEY. Sir, the policy is that we follow the regimen dictated by the FDA, and that is the one that we are adhering to.

Mr. SHAYS. You're just playing a game with me. The fact that you made a request to the FDA is meaningless. You have already gone out in the field and told people that they are safe after three, that this is proved to be effective.

Dr. BAILEY. Sir, the human antibody response data shows that the peak antibody level following the first three shots occur at 6 weeks after starting the anthrax vaccine series. That does not mean we move off the protocol, however. There are people, however, they're in harm's way in the Persian Gulf today, and we are doing everything we can to protect them.

Mr. SHAYS. I know you're doing everything you can to protect them, but you have a protocol. You're supposed to keep records, and you're supposed to give six shots, and you have gone out into the field and said because you have determined, not yet approved by FDA, that they are safe after three, that they have——

Dr. BAILEY. No, sir, that's not the case.

Mr. SHAYS. That is the case. Is it not true that in your literature you say that it's been proven to be safe after three? It's been proven?

Dr. BAILEY. No, I'm sorry, we have not proven that. In fact——

Mr. SHAYS. Do you have any documentation that says it's safe after three?

Did you not say it today?

Dr. BAILEY. Yes, sir, I did say it, but that was a study, and we are doing ongoing—we follow the protocol at this point.

Mr. SHAYS. But the problem is, you're following the protocol, but you are telling your military that they are safe after three.

Dr. BAILEY. We're providing them all the protection we possibly can.

Mr. SHAYS. That's a different issue. That's a different issue. That's your judgment. It hasn't been approved by the FDA.

Dr. BAILEY. Yes, sir, because I have sons and daughters out in those areas where we know the risk to be high. I cannot move up the schedule and provide any better protection.

Mr. SHAYS. It's irrelevant whether you have daughters, sons or whatever. You have a legal obligation to follow what the FDA has said, and you have decided to introduce information not yet approved, not yet proven.

Dr. BAILEY. Information I presented today is research information about the rhesus monkey and the challenge that was given

after two, three, four doses and that they survived after that challenge.

I would like for those who are in harm's way to survive as well. I am doing all I can.

Mr. SHAYS. Isn't it true that you have not kept up with the protocol, you have not kept with the schedule? Isn't it true that you have a responsibility to follow a certain period of program for the first shot, the second shot, the third shot, and so on? Isn't it true that you have not kept on schedule with the fourth, fifth, and sixth?

Dr. BAILEY. Sir, it is the policy to follow that schedule and we are tracking that, yes, sir.

Mr. SHAYS. I didn't ask the policy. I asked whether, in fact—the policy means nothing if it's not followed. Isn't it true that you have a deadline, and you have not kept up with the deadline?

Dr. BAILEY. We are at compliance, over 90 percent compliance with that. If someone is 2 days late for a shot, if you feel that that means we're out of compliance, yes, we're out of compliance.

Mr. SHAYS. Dr. Bailey, I don't know ultimately how I am going to come down on this program or how our committee is, but I just want a straight answer. In order to have faith that we can trust you, I just want honest answers. And the honest answer is that you haven't kept up to the schedule, and a simple and honest answer would have been, yes, we have not kept up with the schedule.

You have not abided by what the FDA has said you should abide by; is that not true?

Dr. BAILEY. If being late for an immunization, whether it's your second DPT shot or your third anthrax shot, means you feel we have not kept up with the schedule, of course, with over a million vaccinations, we have not always kept with the schedule, but that is our intent. It is the policy and that is what we are attempting to do.

Mr. SHAYS. Dr. Bailey, intent doesn't cut it. You have to abide by the protocol, and if you don't abide by the protocol, the FDA has a moral obligation, a legal obligation to withdraw your right to use that vaccine.

Your job is to keep up to the schedule or not to do it; isn't that true?

Dr. BAILEY. Well, again, I would go to other vaccines in this country that are also on a schedule. You do not withdraw polio vaccine or DPT because a child is late getting a shot.

Mr. SHAYS. So you've decided on your own that you don't have to abide by the FDA requirements?

Dr. BAILEY. No, sir. I am making every attempt to abide, but with over 340,000——

Mr. SHAYS. Why do you say, no, sir? You just told me that you aren't keeping up with it, and then you used as an excuse that you're not doing it with other vaccines, and you have decided that you were going to do it anyway.

Dr. BAILEY. It is all we have to protect against this deadly threat.

Mr. SHAYS. So the bottom line is that because you believe that this is so important, you are not going to abide by the FDA requirement.

Now, I'd like to ask you, Dr. Zoon, given that fact, what is your requirement?

Dr. ZOON. DOD is not the licensee; DOD is a user. FDA has regulatory control over the licensee, which in this case is BioPort.

Mr. SHAYS. Are you going to withdraw their ability to do this vaccine now that you find that the people who are using it aren't abiding by the protocol?

Dr. ZOON. We have control over the manufacturer, which is BioPort. We don't have control over the users.

Mr. SHAYS. Have you not given DOD the right to use this vaccine?

Dr. ZOON. This is a licensed vaccine. If a physician uses it, or DOD uses it, that does not really fall under our jurisdiction.

Mr. SHAYS. So it's your statement before us now that if DOD doesn't abide by the protocol, you have no responsibility, that you have set out a requirement—who is responsible then? Who is going to make sure that DOD abides by the protocol, if you don't do it?

Dr. ZOON. We don't have the authority.

General WEST. Sir?

Mr. SHAYS. I just want to say, Dr. Zoon, I cannot believe that you have just said under oath that you do not have responsibility to deal with this issue or the authority. You said you don't have the authority.

Dr. ZOON. Yes, that's correct.

Mr. SHAYS. That is your testimony?

Dr. ZOON. We don't have the authority.

Mr. SHAYS. Well, who is going to protect our men and women if you aren't going to do it? Who? Who has the authority?

Mr. BURTON. I don't think you're going to get an answer, Mr. Shays.

General WEST. Could I add to that answer, Mr. Chairman?

Mr. BURTON. General West.

General WEST. Sir, we want to abide by the six-shot protocol. We want to give every one of them on time. There will be cases when a person is due for their second or their third or fourth or fifth or sixth shot, that they will be ill, that they will be pregnant, that they won't show up for drill day, that for some reason they will get an exemption; and we will have to, to follow the FDA protocol, deviate from the exact day on which the shot is due, but we don't want to.

We don't want to stop after three shots. We want to give six shots, and we're going to try to stick to that as best we can. Nobody in DOD has decided that three shots is enough and we're going to stop there. We're not going to do that, sir.

Mr. SHAYS. I honestly don't believe that. I believe that because we have a problem in productivity and production of this, and because there has been such a resistance to take it, that you all have decided to turn away when you get to four and five and just make sure you get up to one, two, and three.

You have decided as a military to do it because you sincerely, sincerely believe that will protect them, you've already told us that, but you don't have the legal right to do that.

General WEST. No, sir, and we know that, and I certainly hope you're wrong. I don't believe that. I believe that we're trying to

stick to it as religiously as we can. In some cases, we fail. Some cases are really good reasons for it.

Mr. SHAYS. I have had six hearings on this and I haven't lost my cool or temper. I've been able to kind of, you know, just look away and just ignore these statements, but it's finally getting to me because, Dr. Bailey, you told us that there has been less of a response than what the label said would be accounted and yet we have Mr. Claypoole saying he expected it would be more, and it's like you say whatever you need to say in order to satisfy the event of the day.

And, Dr. Zoon, for you to say that you have no authority is the most amazing thing I have ever heard at a hearing because the FDA has the obligation, whenever it licenses a drug, to make sure it's used the way the protocol requires, and you don't allow the military or anyone else to deviate from that. That is your requirement.

Mr. BURTON. Let me move on here just a little bit.

We've had hearings on other drugs and we know of doctors and pharmaceutical companies who have had the wrath of the FDA come down upon them because things weren't being used in conjunction with what the FDA specifies as the way it should be done; and that's why I concur with Mr. Shays, because I have heard it before that you do come down on them, you close down companies. You pound them on the head with a meat cleaver, for crying out loud, and yet you say you have no authority over the military.

Let me go on to a couple of questions, because I don't want to debate this endlessly. A lot of the concerns—and this was in my opening statement; a lot of the concerns have been raised about the actual number of adverse events from the anthrax vaccine. The numbers vary greatly. Everything from two ten-thousandths of a percent reported in the media in February, to two-tenths of 1 percent on the package insert, to 20 percent—20 percent in the one active surveillance that's currently under way, the Tripler Medical Center study.

Now, what I don't understand, if the Department is not doing active followup and tracking of health concerns, service wide, then how we will ever garner an accurate representation of the adverse events? I mean, this Tripler Med Center study shows 20 percent side effects, adverse events. Why the disparity in what's in the package and what was in the newspaper?

Dr. BAILEY. May I explain the Tripler study?

Mr. BURTON. Sure.

Dr. BAILEY. That is a study that is under way at this time looking for any kind of adverse reaction. It's with health care workers. They are, in fact, instructed to bring forth any symptom whether they feel it's related to the vaccine or not. Findings were generally encouraging. We're being more proactive and encouraging reporting what may or may not relate to the vaccine.

At the same time, I would also say that the original reports were from the vaccine program when we had at that point not provided the vaccine to that many of our personnel. As we continue the program now and have over a million vaccinations, we are seeing a report which puts it about in line with other vaccines.

Mr. BURTON. Well, Vice Admiral, let us see here, Vice Admiral Richard A. Nelson, Medical Corps Surgeon General, said, "I am aware of the controversy associated with the anthrax vaccine immunization program and the concern our troops have regarding the potential side effects. The vaccine is safe." He said, "Of over 82,000 Marines and sailors inoculated, only eight reactions have been recorded via the vaccine adverse reporting system. All have returned to full duty." But in cross-examination, one medic from 29 Palms had no knowledge of the existence of a vaccine adverse events reporting system form.

Now, how can you know what the percentage of adverse reactions is if the people that are supposed to be on the front lines reporting the adverse reactions don't even know you have a system to do it? I mean, this guy was a medic; he said he had no forms, nothing. He said he had no knowledge of the existence of a vaccine adverse events reporting form, and yet this admiral was saying there were only 7 cases out of 82,000.

Now, if you don't have a reporting system or the forms to report it, how in the heck do you know? Explain that to me. I mean, this guy was a medic up front that was supposed to be giving the inoculations. He was supposed to have a form there that said, here's an adverse reaction, here isn't and so forth. He didn't even have a form, didn't even know about it, and yet you guys can make a categorical statement, there are very minimal, adverse reactions. How could you do that?

Colonel RANDOLPH. Sir, I'd like to make a comment, and I'd like to make a comment based on the fact that I am not a physician, I'm just a soldier, and I think the disparity here can be explained in the way that the FDA and physicians define an adverse reaction versus an adverse event.

A serious adverse reaction is defined by the FDA as death, life-threatening illness, hospitalization or chronic long-term illness. As soldiers and sailors and airmen and Marines, people who are not physicians, what we look at perhaps as a reaction, whether it's serious under this definition or not, is a broader spectrum.

And so the lumps, the bumps that we commonly see and the common side effect profile of this, and other vaccines for that matter, means that what the common soldier like me sees are 30 percent of the minor reactions at the injectionsite—the redness, the swelling, the occasional nodule, and in women, actually about twice that.

Mr. BURTON. Well, Colonel, I appreciate your answer, but that does not address what I am talking about. You have people who are medics who are the front line people giving the shots in many cases. There have been categorical statements made by the military, by this Admiral Nelson and others, saying there are very minimal reactions, and yet the people giving the shots don't know of any adverse reporting system, don't have any adverse reporting forms, don't have anything.

So if there are severe adverse reactions, how do you find out about them if they don't have any way of reporting them?

Colonel RANDOLPH. Sir, we have advertised in our health care providers briefing that every health care provider is supposed to get and then obviously in this one case someone didn't. We have

advertised in all our commanders briefings about the VAERS report. It is on our DOD website exactly how you report an adverse event. In all of our forums, we explain to our people how you file a VAERS 1, and in fact we encourage patients to file, other than a health care provider.

Mr. BURTON. Well, there are an awful lot of military people, I had a young man come into my office this past week. He's a pilot. He's got a family. He said he'd like to be an airline pilot when he leaves. If he doesn't take the shots, he says he won't be able to get a job as an airline pilot because of the kind of discharge he's likely to get, No. 1, and if he does take it and it adversely affects his health, he says he won't be able to get an airline pilot job because it might cause dizziness, not focusing properly with his eyes and all. And he says he's a mess, he doesn't know what to do; and his wife wants him to get out of the military, and he doesn't know what to do.

And that is not an isolated case. Every Member of Congress has had somebody contact them with these same kinds of problems—not just one or two, but many—and these things need to be answered, and the answers have not come forth.

Today, I don't think Mr. Shays feels it and I don't feel it. I don't think Mr. Jones feels it. We simply don't have the answers yet, and so we're probably going to have to look into this further. But the military who defends this Nation needs to know that they're not being unduly jeopardized when they take these shots, and they need to know that the protocol's being followed and everything's being explained thoroughly, and they know what's going to happen. And I don't think anybody in Congress knows, and I don't think anybody in the military really knows, other than maybe those of you who are so-called experts.

Let me just say this, I'd like to, since we're running out of time and want to get to the next panel, we'd like to submit to all of you for the record a number of questions, and we'd like for you to respond to those since we haven't had a chance to get to it.

Dr. Zoon, really quickly.

Dr. ZOON. Yes, I want to have one clarifying point made, Mr. Chairman.

When you said that FDA gives oversight to the pharmaceutical industry, that is absolutely true because they are the individual corporations or sponsors that are regulated by the FDA; and that is true—similar to BioPort for the anthrax vaccine. Certainly, we are concerned about the use of the vaccine, which is why we sent DOD a letter when we found out, actually from members of this committee, about some information.

So we are very much interested in this, but in terms of our authority, our authority is over the people we license or over people manufacturing the vaccine.

Mr. BURTON. So what you're telling Mr. Shays and me and others is that there's a gap there. Once the pharmaceutical company makes the product, and it is given to a doctor or the military or whatever, it's up to them to administer them; and if they don't, there's no way to enforce it.

Dr. ZOON. We can write letters, but that's correct, we don't have the authority.

Mr. BURTON. OK.

Mr. Shays, do you have any final questions?

Mr. SHAYS. Yes, thank you. Who owns BioPort? Does the military have any financial interest in BioPort?

General WEST. No, sir.

Mr. SHAYS. No financial interest at all? They've received no loans, you've built no plant?

General WEST. No, sir.

Mr. SHAYS. The military has not paid for any expenditure at the plant?

General WEST. I am sure that there are things that we have invested in at the plant to make it possible to produce the drug and produce it correctly.

Mr. SHAYS. Well, the answer is, yes, you have invested money in the plant. You are not stockholders in the plant. You are the plant's basic—only customer, practically.

Mr. BURTON. Would the gentleman yield real briefly?

There was an $18.7 million advance that was given to BioPort by the military for what you're talking about.

Mr. SHAYS. Have you put liens on the facility? Is there any obligation there?

Dr. BAILEY. Let me just say that as BioPort is the only manufacturer of the FDA-licensed vaccine, DOD has funded a total of 11 million since 1991 to ensure that continuous supply. We also are providing significant administrative, scientific, technical, and consultative assistance to assure that production is safe.

Mr. SHAYS. Basically, this is a military operation.

Mr. JONES. Would the gentleman yield for just a moment?

Mr. SHAYS. Yes.

Mr. JONES. May I ask Dr. Bailey if it's true, in addition to the $18.7 million that has been advanced, that they have increased the cost of the vaccine from $4-and-something to $10 a shot; is that correct?

You've approved that type of increase; is that correct?

Dr. BAILEY. Well, again, we are out of my area, but let me just say that we have a contractual relationship with this organization, and I think that General West should answer that, particularly about pricing.

General WEST. Sir, I think your numbers are correct or very near correct. When we first started buying the vaccine, we were buying it from a facility owned by a State and a university. Part of the overhead for that plant was covered by the State and by the university.

During the process of buying the vaccine from the only supplier that there is in the country, the State of Michigan decided to sell that facility to a private owner. That corporation, once they had to take care of paying the light bill and mowing the grass and a lot of other things, had to increase their cost. We're disappointed that it went up from $4 to $10, but I can tell you that if we compare that to the cost of a lot of other vaccines, it is less than half as much—more than we'd like to pay, but it could be worse.

Mr. BURTON. I ask the gentleman to yield real quickly.

$18.7 million advance, according to what we have here in front of us. So I want to make sure I understand this. They received an

$18.7 million advance and then you also increased, or they increased, the cost per share from $4-and-something to $10. So you not only gave them an advance, but they also received over double, two and a half times the amount of money they were getting per shot to help them cover their expenses?

General WEST. They will, yes, sir, whenever they sell the vaccine. That's been reviewed by the contracts and the legal people, and they did not pay the price that the company asked for. We are paying significantly less than they asked for, but we're paying what the contractual and legal people believe to be a fair and justifiable price.

Mr. BURTON. Two and a half times what they were getting when it was the State of Michigan producing it?

General WEST. That's correct, sir.

Mr. BURTON. Did you have one more question? Because I want to get to the next panel.

Mr. SHAYS. I know that, Mr. Chairman.

Dr. Zoon, you have allowed BioPort to sell this vaccine to the military for a use it wasn't directly tested for. This is being used to combat a weaponized aerosol challenge, and so whereas you have acknowledged that the standard procedure is 65 and older, you weren't technically tested for, but this wasn't technically tested for aerosol. So you have given a lot of leeway to the military BioPort to use this. BioPort is basically funded by the military, and in the quarterly readiness report, at the bottom of this quarterly readiness report, it says, ''Note, soldiers with three or more vaccinations are protected.'' Could you approve that statement by the manufacturer if the manufacturer made that claim?

Dr. ZOON. If the manufacturer wanted to claim three doses were protective and safe, we would have to evaluate the data before adding that to their package insert.

Mr. SHAYS. So you would not allow the manufacturer to make this claim, soldiers with three or more vaccinations are protected, but we're allowing the military—and I'll just conclude, General West, to you.

Bottom line, Dr. Zoon has said she doesn't have the authority. Basically, you're allowed to run this program as you see fit. Then, basically, you don't have to follow the protocol evidently, which is news to me. Today it's news. Why should I feel comfortable that I can trust the military?

You are making a statement that the FDA would not allow a private manufacturer to make. So why should I feel comfortable with the military?

General WEST. It may very well be that we put a statement on the brochure that we shouldn't have put, because it's being interpreted as meaning something different than we implied. The only thing that we mean when we say that is that the research analysis indicates that if you've had at least three shots you have protection against the anthrax virus. We never, ever, sir, planned to stop there. We intend to follow the protocol unless it's changed.

Mr. SHAYS. I know that's your intention, but you're doing something we wouldn't allow the manufacturer to do.

General WEST. We'll take that statement up, sir.

Mr. BURTON. I want to thank the panel. You've been under some pretty heavy grilling today, and we appreciate your patience, and we may be talking to some of you later. And we will be submitting a number of questions to you for the record. Thank you very much.

Our next panel is former chairman of the Joint Chiefs of Staff, Admiral Crowe; Major Bates; Major Rempfer; Dr. Melling; Dr. Leitenberg; Dr. Classen; and Dr. Halsey. Would you all come forward, please. Thank you, gentlemen. Once you all come forward, we want to put everybody under oath as we always do.

I want to thank you for your patience as well. We went much longer on that first panel than we anticipated.

Would you raise your right hands, please.

[Witnesses sworn.]

Mr. BURTON. Have a seat. OK. I think we'll start with the former Chairman of the Joint Chiefs of Staff, Admiral Crowe. We are looking forward to hearing from you, Admiral, and we appreciate you all being here today.

STATEMENTS OF ADMIRAL WILLIAM J. CROWE, JR. (USN RET.); JACK MELLING, BIOLOGICS DEVELOPMENT CENTER, THE SALK INSTITUTE; MILTON LEITENBERG, SENIOR SCHOLAR, CENTER FOR INTERNATIONAL AND SECURITY STUDIES AT MARYLAND; JOHN B. CLASSEN, M.D., MBA; MAJOR SONNIE BATES, PILOT, USAF; MAJOR THOMAS L. REMPFER, PILOT, USAF RESERVES; AND NEAL A. HALSEY, M.D., DIRECTOR, INSTITUTE FOR VACCINE SAFETY, JOHNS HOPKINS UNIVERSITY

Admiral CROWE. Thank you, Mr. Chairman. I answer to both Crowe or Crowe, but I do pronounce it Crowe, and I found one very disturbing thing in the previous testimony. They made an age line of 65. I've taken it at 74. Maybe I should retreat. I'm not sure.

Mr. BURTON. You look much younger.

Admiral CROWE. Mr. Chairman, I've submitted a statement, and with your permission, I will summarize it. This will be highly compressed.

Mr. BURTON. Thank you.

Admiral CROWE. As your invitation requested, my statement reviews in more detail the development of policy during my term as Chairman of the JCS, 1985 to 1989. In the way of background, the President announced in 1969 that we would dismantle our inventory of biological weapons. In 1975, the United States ratified the Biological Weapons Convention.

Clearly, by 1985, we no longer had the option of deterring biological weapons with their own agents. It was the view of the JCS that our conventional and nuclear capabilities offered a high degree of deterrence against hostile governments. Still, we were painfully aware that the Biological Weapons Convention offered no guarantees.

We had evidence that several governments continued to experiment with and to produce biological agents. While our appraisal did not anticipate frequent employment of such weapons, it concluded that, if used, they could reap appalling casualties. We initiated a multifaceted effort to improve our passive defenses. I can de-

scribe this effort in more detail, if you think it necessary, but it is covered in that statement.

During that period, the subject of biological agents had not reached the urgency it enjoys today. We did launch an exploration of the potential role vaccines might play in an antiterrorist effort, but we were primarily seized with the problem of deterring or countering biological attacks on U.S. forces by the military units of hostile governments. It was a deliberate process that received normal funding and did not carry an especially high priority. By the time I retired, we had not fully grappled with the possibility of covert terrorists mounting serious biological challenges.

When I served as Ambassador to Great Britain, the State Department had also not begun to address the problem seriously. In 1998 and early 1999, I headed two accountability review boards to examine the August 1998 embassy bombings in Nairobi and Dar es Salaam. We concluded that although these weapons were not used in these two cases, we concluded that the United States would sooner, rather than later, see terrorist groups turn to biological or chemical agents trying to harm Americans overseas.

Desert Storm, of course, demonstrated that American strength is vastly superior to any conventional forces the Third World might employ. The lesson that came out of that conflict, I believe, was for nongovernment organizations and governments hostile to the United States; it was clear that if they wished to harm our interests, they were going to have to resort to some covert method, more than likely terrorism.

Such groups are extremely difficult to isolate or retaliate against. Ease of concealment and delivery, when coupled with difficulties in detection of agents, severely complicates the retaliation problem. Unquestionably, the threat level is increased because of these developments. My statement examines this subject in some detail.

The anthrax spore, which you've heard a great deal about in the first tranche, is an ideal terrorist biological weapon. I won't go into it because it was examined at some length previously. In fact, the Department of Defense rates anthrax as the No. 1 biological threat today.

As you know, I am a director of BioPort Corp. I'm well aware that the issue of safety has provoked some dispute. BioPort has a deep interest in providing a safe and pure product, and that's exactly what its current owners are bending every effort to produce. The popular press often confuses the issue by mixing up questions of safety and effectiveness, but actually anthrax vaccine has a rather impressive safety record, putting aside the question of effectiveness, starting in the 1960's.

Again, there a number of studies, and I talk about the things that were persuasive to me in my statement. I don't think I should spend time on that since you have explored it at some length already. I will say, though, that I am convinced that the opposition, or rather, that there were some statements about service people that are being rather exaggerated.

In the current program—and I have checked this week with Defense. In the current program, over 340,000 military men and women have taken shots, including myself, and of that, approximately 200 have refused. I also checked with all the personnel or-

ganizations of every service as to whether they were actually seeing vast numbers leave the service or that they were concerned about this problem, and they have no evidence, hard evidence, to support that.

Frankly, there is no question in my mind that we should bend every effort to protect our forces against anthrax attacks. I should note, which came out in the previous hearing, that not one dose of the vaccine has been released without FDA approval and will not be released without FDA approval.

Before closing, I would like to comment on one peripheral issue. It has, on occasion, been rumored that the decision to inoculate all personnel was made to benefit BioPort and, indirectly, to benefit me. If the charge were not so ridiculous, it would be offensive. It outrageously exaggerates my influence. I didn't have that much influence when I was the chairman, much less now.

Let me be completely clear: I never, never solicited any official of the administration to install or promote a mandatory inoculation program. Even the timetable of events firmly refutes the charge. I would of course be happy to elaborate on this. The attempt to link me with the Secretary's decision is pure fantasy.

And that concludes my summary, Mr. Chairman.

Mr. BURTON. Thank you, Admiral Crowe.

[The prepared statement of Admiral Crowe follows:]

Statement of Admiral William J. Crowe, Jr.
To the House Committee on Government Reform
October 12, 1999

Mr. Chairman,

This statement is submitted in response to your letter of 5 October. I believe the subject of force protection and the role vaccine play are important concerns for all Americans.

Your letter specifically requested that I review the background on the development of policy for biological warfare during my tenure as Chairman of the Joint Chiefs of Staff. You no doubt will recall that the President announced in 1969 that we were dismantling our inventory of biological weapons. In 1972, the Biological Weapons Convention (BWC) was completed and in 1975 was ratified by the U.S. Government. The three-year lag period can be attributed to the time it took to destroy the US stock of biological weapons. Throughout, Washington led the international effort to convince nations to forswear biological offensive weapons. The Convention to date has been ratified by 142 signatories. At a special conference held in Geneva in September 1994, the US promoted the development of a legally binding instrument that involved transparency of activities and facilities that could have biological weapons applications. The aim, of course, was to deter violations and enhance compliance with the BWC regime. This issue is still pending.

I served as Chairman, JCS, from 1985 to 1989. In the case of poison gas, our own inventory of these agents served as a deterrent in two world wars. Clearly, by 1985 we no longer had that option in the case of biological weapons. The JCS, however, were not especially uncomfortable with that situation. It was the unanimous view that, from a military perspective, our conventional and nuclear weapons were of sufficient number and quality to assure a reasonable degree of deterrence if foreign governments contemplated the use of such agents against US forces.

That judgment was borne out in Desert Storm. Saddam Hussein had impressive stockpiles of chemical weapons and biological agents. He chose, although faced with defeat in the field, not to employ those weapons. We

know for a fact that he had not been that timid when repressing his Kurdish minority and engaging Iranian units in the 1980's. I am persuaded that Saddam knew that, if he resorted to chemical weapons, it would infuriate all Americans and invite our leaders to retaliate in a devastating fashion.

The JCS during my tenure understood that the Biological Warfare Convention would not necessarily protect us from all biological threats. There was always the possibility of regimes violating the agreement or countries that had not subscribed to the convention producing biological agents. In fact, we had hard evidence that several signatories continued to experiment with and to produce biological agents. Consequently, our security policy embraced a great deal more than merely depending on overt military strength. A vigorous intelligence effort was mounted to improve our ability to locate foreign production facilities, to assess the character of potential agents, and to estimate which foreign militaries might be planning to use such agents in the field.

From this information, a comprehensive threat analysis was compiled incorporating inputs from military commanders, relevant diplomats, and the scientific community. While the appraisal did not anticipate frequent employment of such weapons, it concluded that any possible use could wreak appalling casualties. This conclusion led to a review of our vaccine defenses. Bear in mind every step of this process was widely vetted internally in the US Government and relevant inputs sought.

These conclusions ultimately led to several programs to better prepare our fighting units for dealing with this threat. Protective gear for individual troops was upgraded; BW training was further stressed; the requirements for all equipment, such as tanks, aircraft and ships, to operate in a biological environment were tightened up. In turn, it was recommended that vaccines be developed to counter the effects of specific agents. When dealing with a question such as vaccines that require extensive expertise outside of the Defense Department, a steering group is formed with wide representation from both DOD and relevant outside departments. Their findings are then submitted for consideration at higher levels. It is normal with important initiatives, such as this, for the policy ultimately to be decided by the Secretary of Defense, the National Security Council, and the White House. As I recall, there was little disagreement throughout the process.

We should bear in mind, however, that the subject of biological agents had not reached the urgency that it enjoys today. Anti-toxins had not been used by the military as a matter of course and were not part of the normal routine. We, however, did initiate exploratory probes to determine the feasibility of incorporating such vaccines in the anti-terrorist effort. It was a deliberate and gradual process that received normal funding and not an especially high priority.

There were two fundamental reasons for pursuing this course: (1) if such reasons vaccines were successful in countering biological agents, their use would reduce the nation's vulnerability to biological weapons, and (2) it would save the lives of those exposed to such attacks.

We were primarily seized with the problem of deterring or countering direct attacks on US forces by the military units of hostile governments, i.e., governments we could identify and retaliate against directly in a manner we chose. We had some confidence that we could suitably respond, if any nation elected to employ biological warfare against US personnel. I stress this because the problem of terrorism had not reached the crescendo it has today and that is a problem of another order. By the time I retired ten years ago, we had not fully grappled with the possibility of covert terrorists mounting serious biological challenges.

For example, when I served as the Ambassador to Great Britain (1994-1997), we were increasingly worried about terrorist attacks on overseas installations, but we were almost solely concerned with the threat of small bombs, car bombs, mortars and assassination, not the possibility of terrorists mounting a full fledged biological event.

In late 1998 and early 1999, I headed two Accountability Review Boards to examine the August 1998 embassy bombings in Nairobi and Dar es Salaam. We found a number of discrepancies in the preparedness to survive such catastrophes. In fact, the State Department directives did not address the possibility of biological attacks.

While no biological agents were employed in those two incidents, it was the unanimous opinion of both boards at the conclusion of their deliberations that, sooner rather than later, terrorist groups will turn to biological or chemical agents. In East Africa, the attacks were sponsored by Osama bin Laden, who has impressive resources and who has declared an

Islamic Jihad against Americans wherever they can be found. Such organizations are no longer restricted by national boundaries.

I believe that our rather remarkable "Desert Storm" victory demonstrated to Third World countries that Americans are vastly superior in waging conventional actions. Governments or others who wish to harm our interests will have to look for other ways to confront us. This will, of course, encourage non-government terrorists. It may also lead governments who oppose us to sponsor and employ clandestine terrorists to harm our interests. At this juncture, we are superbly postured to retaliate heavily against governments that provoke us -- and our opponents know that. But sophisticated terrorist groups and covert operations are another matter.

Terrorist groups are configured to strike and then to disperse or disappear. It is difficult to identify them, to locate them, to know where they reside or train. Often they meld back into the larger population of a host country. The "invisibility of the archer" severely complicates defensive or retaliatory efforts. Ease of concealment and delivery, when coupled with difficulties in detection of agents and delays in the appearance of symptoms, makes an assailant extremely difficult to detect and even identify after the fact. There is every likelihood that such tactics will be used more and more in the future. In turn, the military will undoubtedly be called upon to participate heavily in counter-terrorism efforts.

Unquestionably, the overall threat level has increased because of these developments; the Department of Defense rates anthrax as the number one biological threat in the world today. Clearly, this appraisal dramatically reinforces the importance of passive defense measures. I am not privy to the discussions and decisions that are taking place within our government today, but I suspect all the steps I discussed are receiving increased attention. Vaccines are a vital part of this effort. There are a host of new biological agents being developed in laboratories around the world. The problem is amplified by the researchers' ability to alter some agents so that they are more sophisticated, difficult to detect and to counter with anti toxins. The Defense Department has already let contracts to develop counters to the emerging threats. It has also mounted a robust program to build better detection devices for the spectrum of old and new agents.

This does not mean, however, that all agents represent an immediate threat. Each agent must be examined as to availability, difficulty of

production, its lethality and the ease of delivery. Many of the new agents, while exotic, will represent too much of a challenge for terrorists and must be discarded as a likely threat. A few, however, may require genuine attention. Only in those cases will it be necessary to administer an inoculation program. Any decision to administer a particular vaccine would be thoroughly vetted with relevant departments and in particular the health authorities. The threat appraisal will ultimately prioritize the whole list. I believe all of these efforts are worthwhile and must be pursued if we are to keep abreast of emerging developments.

Such a process was employed in the US Government preceding the announcement to inoculate all military personnel with an anthrax vaccine. Since the issues were new, thorny, complicated and politically sensitive, a steering group was formed with representatives from every governmental organization that had an interest. Naturally, the government health agencies were involved and an extensive educational agenda was followed. They were briefed on the experience of other vaccines, on the state of development in the biological sector and on the findings of our intelligence community. The relevant issues were discussed -- more appropriately debated -- before any conclusions were reached. The end product was a recommendation to the Secretary of Defense that all military personnel be inoculated with anthrax vaccine. In every respect it was a deliberate and comprehensive effort.

The US Government considers the anthrax spore to be an ideal terrorist biological agent. It is easy and cheap to produce. It can be deployed widely and easily by the attacker, without disclosing his purpose. More important, it is almost certainly lethal for unprotected humans. The Defense Department reports that at least 10 nations are suspected of having weaponized anthrax.

As you know, I am a director of BioPort Corporation, the firm that supplies the US Government with anti-Anthrax vaccines, and I have a strong interest in its quality. I am well aware that the issue of safety has provoked some dispute.

The vaccine was developed in the United States during the 1950's and 1960's for humans. The FDA approved it in 1970. It is a cell free filtrate produced by a strain of anthrax that does not cause disease. The vaccine contains no whole bacterium, dead or alive. In essence, it is nonpathogenic.

There is no possibility of contracting anthrax disease from this vaccine. Since 1970, it has been safely and routinely administered to at-risk wool mill workers, veterinarians, laboratory workers and livestock handlers in the United States.

The popular press often confuses this issue by mixing up the question of effectiveness and safety. They are distinct issues and should be treated as such. As to safety, the vaccine has been around for a number of years and has compiled an impressive safety record. Time prohibits me from reviewing the plethora of authorities that agree with that conclusion, but I will cite some evidence that I find especially convincing.

At Fort Detrick, Maryland, laboratory workers at the Medical Research Institute of Infectious Diseases have received shots for nearly 30 years without discernible problems. Of 1,700 workers followed for 10 to 25 or more years after anthrax vaccination, none developed any unexplained serious symptoms due to reported doses of anthrax or any other vaccine.

As a requirement for licensure, the safety of the anthrax vaccine was studied between 1965 and 1970 under an approved IND, sponsored by the CDC. During that period, some 16,500 doses of anthrax vaccine were administered. This included the initiation of vaccination of at least 4000 individuals and the administration of approximately 6,500 booster doses. In not one incident was there a safety problem.

Between licensure in 1970 and May 1994, adverse events reported to the Michigan Labs from the 65,000 doses distributed to Persian Gulf recipients were few in number. The adverse events reported were similar in nature to those found during clinical trials of the vaccine and none were associated with chronic or permanent local or systemic effects. In addition, through May 1994, no reports of adverse events were received directly by the Michigan Labs from the approximately 150,000 recipients who received the vaccine during the Persian Gulf conflict. Since then reports have been few in number from the over 1,000,000 does given.

Dr. Susan Ellenberg of the Food and Drug Administration summarized the most recent data from the VAERS adverse vaccine events reporting system of the the FDA and CDC in her July 21, 1999, written testimony before the Subcommittee on National Security, Veterans Affairs and International Relations as follows:

"Since the beginning of VAERS operations in 1990 through July 1, 1999, 215 reports of adverse events associated with the use of anthrax vaccine have been reported to VAERS. Of those, 22 are considered serious events. These reports are for diverse conditions, with no clear patterns emerging at this time." She concluded: "None of these events, except for the injection site reactions, can be attributed to the vaccine with a high level of confidence, nor can contribution of the vaccine to the event reported be entirely ruled out. It should be emphasized once again that it is not always possible to attribute a cause and effect relationship between a reported event and a vaccination. With the exception of injection site reactions, all of the adverse events noted above do occur in the absence of immunization. While the data gathered from the VAERS system can serve as a useful tool in identifying potential problems, the reports on anthrax vaccine received thus far do not raise any specific concerns about the safety of the vaccine."

The program currently in effect has inoculated over 340,000 military men and women. Approximately 200 have refused to receive it according to DOD representatives. Those refusals represent only 1/17 of 1%. I have heard reports that vast numbers are leaving the service as a result. I queried all 4 services and found no evidence this was true.

Surgeon General Satcher has testified and has often said in public statements that the anthrax vaccine is extremely safe. He has been supported by a host of distinguished medical authorities. Incidentally, I have had 4 of the 6 shots myself and I will complete the course next year. Moreover, my understanding is that a military recipient who has a reaction that requires medical attention is taken off the program. There have, of course, been some reactions to the shots. The great bulk of these have been normal reactions to a needle injection, e.g. some swelling, local pain, and perhaps a headache. The DOD has reported 72 cases of serious side effects that required hospitalization or missed duty for greater than a day. Of those only 55 could be attributed to the vaccine and all 55 have returned to duty. Nevertheless, it is noteworthy that DOD has taken the subject seriously and is in the process of commissioning another in-depth study of the vaccine. In all candor, I simply could not find any hard data that suggested the vaccine was systemically unsafe or that reactions exceeded those of other vaccines.

BioPort monitors all reports of any unusual reaction. The company is dedicated "first and foremost" to producing a safe vaccine. Since the takeover of the laboratory in 1998, BioPort has installed an enhanced quality system and made extraordinary efforts to ensure the continued safety and efficacy of the vaccines. I should note in this regard that not a single dose of this vaccine has ever been released without FDA approval.

Frankly, there is no question in my mind that we should bend every effort to protect our forces against anthrax attacks. Believe me, the descriptions of people dying from the anthrax spore are horrifying. It is an agonizing way to die. The effect is very similar to that of the Ebola virus. I suspect if we had had more experience with anthrax deaths, we would better appreciate what the Department of Defense is trying to do.

The argument as to whether the military program should be voluntary or mandatory is outside my purview. I have little desire to enter that argument but, again, I have chosen personally to protect myself by taking the vaccine.

Before closing let me discuss one peripheral issue. It would be naïve of me not to mention some of the vague and rather misinformed criticisms of my association with BioPort. It has on occasion been rumored that the decision to inoculate all service personnel was made to benefit the BioPort Corporation and indirectly me, presumably because of my past associations with the military and the Administration. If this charge were not so ridiculous, it would be offensive. It outrageously exaggerates my influence. I didn't have that much influence when I was Chairman and I certainly don't have it now.

Let me be completely clear. I never, repeat never, solicited any official of this Administration to install or promote a mandatory inoculation program. Secretary Cohen's announcement of the mandatory vaccine requirement was made on May 18, 1998. The Steering Group's deliberations took place many months before this date. Actually, a Washington Post article reported in late 1996 that such a policy was being considered. At the time of the official announcement, the group I was associated with was engaged in a spirited competition with a number of other bidders to privatize the old Michigan Laboratory. The bid winner was not selected until June 1998 and the decision was made by the State of Michigan. The Department of Defense maintained a neutral position throughout this process. Frankly,

the May 18 announcement made the final bidding phase of the competition more intense. The attempt to link me with the Secretary's decision is pure fantasy.

I understand that there are irresponsible web sites run by organizations that oppose the military and/or the vaccine. I would urge the Congress to detach itself from the emotionalism of this debate and not to be deceived or distracted by charges and counter charges that have nothing to do with the real issues. Do vaccines make a worthwhile contribution to the country's defense against biological attacks? Are they reasonably safe to administer to our citizens? My answer is "yes" to both questions.

Admiral William J. Crowe, Jr.

Admiral William J. Crowe, Jr., is a Senior Advisor to GlobalOptions, a crisis management firm based in Washington. Previously, he was the U.S. Ambassador to the United Kingdom of Great Britain and Northern Ireland (1994-97), the Chairman of the President's Foreign Intelligence Advisory Board (1993-94) and the Chairman of the Joint Chiefs of Staff (1985-89). In 1998-1999, he chaired the State Department Accountability Review Boards for the embassy bombings in Dar es Salaam and Nairobi

A native of Oklahoma, Admiral Crowe graduated from the U.S. Naval Academy in 1946. His early naval career was in submarines and he served as the Assistant Naval Attaché to President Dwight D. Eisenhower in 1954-55. Later, as a Rear Admiral, he commanded U.S. Naval Forces in the Persian Gulf.

In 1980, Admiral Crowe was named the Commander in Chief of Allied Forces Southern Europe, the NATO command responsible for Italy, Turkey and Greece, as well as the Mediterranean area. Subsequently, he commanded the U.S. Pacific Command before President Reagan named him the 11th Chairman of the Joint Chiefs of Staff in 1985.

After retirement from the military in 1989, Admiral Crowe was a Counselor at the Center for Strategic and International Studies in Washington and the University Professor of Geopolitics at the University of Oklahoma. His book, "The Line of Fire," was published by Simon and Schuster in 1993. He served on the Boards of Directors of Merrill Lynch, Texaco, General Dynamics, Norfolk & Southern and Pfizer.

Since returning to Washington from his post in London, Admiral Crowe has joined the Boards of Directors of BNFL, Inc., Intervac, L.L.C., Evergreen Holdings, Inc., BioPort Corporation and Kellstrom Industries. He chairs the Advisory Board of the International Program Center of the University of Oklahoma and is a Trustee of Princeton University.

Admiral Crowe holds a Masters degree in Education from Stanford University and a Ph.D. in politics from Princeton University. In 1997-98, he was the Shapiro Visiting Professor of International Affairs at George Washington University. He presently holds the Olin Chair at the U.S. Naval Academy. Admiral Crowe is married to the former Shirley Grennell and they have three children. They reside in Alexandria, VA.

Admiral William J. Crowe, Jr.

Admiral Crowe served from October 1998-January 1999 as the Chairman of two State Department Accountability Review Boards for the Embassy bombings in Nairobi and Dar es Salaam.

He presently serves on the State Department Overseas Presence Advisory Panel.

Admiral Crowe currently holds the Olin Fellowship at the U.S. Naval Academy.

Mr. BURTON. Dr. Melling.

Mr. MELLING. Thank you, Mr. Chairman and members of the committee, for your invitation to present testimony to this committee. My name is Jack Melling, and I am the former director of the Salk Institute Biologicals Facility in Pennsylvania and also the former director and chief executive of the UK's Center for Applied Microbiology Research, which was also involved in defense vaccine work.

Vaccines for defense against biological agents differ from normal public health vaccines in several important ways. First, the effectiveness of defense vaccines cannot be determined by normal human epidemiological trials, due to the rarity of the diseases involved. Animal models are therefore critical to assess efficacy. Such models are limited in their ability to predict what will happen in humans, and in most cases, can at best indicate some possibility of efficacy, but do not allow us to determine if a vaccine will protect 40 percent, 60 percent, 80 percent or whatever in the case of humans.

Nor, in fact, can we predict the human vaccine effectiveness against different levels of biological challenges. I have heard this afternoon also comments about being able to measure antibodies in humans and use that as a predictor. In some cases that is indeed true, but in many cases of infection, the immune response is much more complicated than that which can be measured by a simple antibody response. I believe that a number of the agents that are of concern to us fall in the category of having that complicated an antibody response.

Now, the uncertainty about the level of effectiveness has a number of implications, I believe. First, if vaccines are used, then they should only be one of several protective measures incorporated in a prudent strategy. It also means that if we don't note the level of the effectiveness, then an unknown proportion of vaccine recipients can remain vulnerable. For example, if the vaccine is 60 percent effective, then 4 out of 10 persons remain at risk. Even with 80 percent efficacy, it's one in five. I think this counts as one key argument against a voluntary policy, that is, that it's unacceptable to have a mixture protected and unprotected troops, since even a mandatory policy will leave some people who are vulnerable. It's just that we won't know ahead of time who they are.

And the final implication of the efficacy issue is, certainly for me, that antibiotic administration still remains an ethical essential in the event you know or believe people to have been exposed.

The second way in which these agents differ from normal public health vaccines is in terms of—and I won't dwell on this, as it was discussed earlier—the number, the range and the potential variability of the threats; and taken together, that means that developing, producing, and gaining regulatory approval for a large number of vaccines becomes extremely difficult. I think it also becomes questionable whether in fact the pace of vaccine development, which has to move in accord with regulatory approval, can in fact match the weaponization ability of an aggressor.

The third point is that, unlike diseases which are prevalent in the community where assessing the risk——

Mr. BURTON. Excuse me for interrupting. I just want you to cover that last sentence again, because it seems so relevant. You indicated that keeping pace with the ability of an enemy to produce other biological agents would be difficult. I want to make sure I got that straight.

Mr. MELLING. That is what I said, sir.

You know, our record in developing, producing and monitoring defense vaccines is that in the course of some 30 years we have licensed, I think it is correct to say, in the United States, two vaccines in the defense field. We have licensed two in the UK out of that range of agents; and therefore, if that time scale is indeed appropriate, I think it does mean that vaccines alone as a counter to aggression raise major problems simply because, unfortunately, the balance will tend to be with the aggressor because they can weaponize potentially faster than we can develop approved vaccines.

If I may continue, unlike diseases which are prevalent in the community where assessing the risk of a person acquiring a disease is based on epidemiological data, determining the risks from BW agents depends basically on intelligence assessments, and the basis of these reports is not open to the same kind of debate and scrutiny that we see in the public health field.

In respect of safety, I see no inherent technical reason why defense vaccines should be any less safe than vaccines in general. I would, however, say that because of their specialist nature, because we don't have several firms producing the same vaccine and competing, I think there is a risk that defense vaccines could be stuck in a time warp, and if we are not careful, we could end up with a vaccine equivalent to a bunch of Model T Fords, which were great in their day, but not many people would actually use them today.

And last, I think acceptability is a key issue. Government agencies are heavily involved in research, development, regulatory approval, assessment of disease risks, vaccine procurement, and decisions on use; and therefore, to maintain confidence, it's going to be essential to avoid conflicts of interest, even perceived conflicts of interest, and to clearly demonstrate that especially the regulatory agents treat these vaccines in the same evenhanded way that they do other medicines.

Last, Mr. Chairman, it's my belief that these issues raise serious questions about the feasibility of relying on defense vaccines to protect large numbers of people against numerous disease agents. It is vital that these problems are addressed based on objective and sustainable factual information if we are to properly protect those people on whom we rely for our security.

Mr. Chairman, members of the committee, thank you for your attention, and I'll be happy to answer questions.

Mr. BURTON. Thank you, Dr. Melling.

[The prepared statement of Mr. Melling follows:]

Testimony

Before the Committee on Government Reform

DEFENSE VACCINES: FORCE PROTECTION OR FALSE SECURITY

Issues and Constraints Affecting Vaccine Development, Licensure and Use

Statement of Jack Melling, Former Director; The Salk Institute Biologicals Development Center & The UK Centre for Applied Microbiology & Research

Mr. Chairman and Members of the Committee, thank you for your invitation to present testimony to this committee.

Introduction
The shared goals of all involved in biodefence work are to provide protection which is effective, safe, practical and reliable to those persons who are considered to be at risk from exposure to biological agents in the course of their duties. The current debate is not about the goals, but the means by which they can be achieved. Accordingly I am pleased to contribute to that debate.

Vaccines have proven to be of enormous value in improving public health, but it is the very factors which have underpinned their success in that field which raise questions about the feasibility of bio-defense vaccines for large scale use. There are three factors that need to taken into account to justify vaccine use: vaccine efficacy, vaccine safety and the risk of disease,

Efficacy
Vaccines are not 100% effective in preventing or limiting the impact of infection. Accordingly a vital part of the regulatory approval process is to determine how effective a vaccine is in protecting particular groups of individuals against exposure to a specific microorganism by a certain route. Approval if given is for use under those circumstances that epidemiological studies have shown to be appropriate.

The diseases of concern in relation to defense vaccines are (fortunately) rare and therefore such vaccines cannot be subjected to normal epidemiological evaluation. Accordingly, approval of new vaccines or changes to regimens of production or administration will have to be based on animal models. FDA is now proposing to amend its regulations to permit licensing of some vaccines without requiring human efficacy trials. However, animal species differ one from another in their response to diseases and to vaccines. To extrapolate from an animal model to humans requires an understanding of the disease process and the way in which a vaccine can stimulate those parts of the immune system responsible for protection. The human immune system is highly complex and depending upon the type of disease various parts of that system either singly or in combination come into play. A real understanding of the immune correlates of protection is essential successfully to extrapolate from animals to humans. Although this is possible in the present state of knowledge for simple vaccines such as toxoids where the immune response is well understood it becomes increasingly difficult when more complex immune responses are involved. The timescale for the necessary scientific understanding to be developed is uncertain.

Safety
There is no inherent reason to suggest that defense vaccines may be any less safe than others. It will however be essential that human safety studies both pre- and post licensure are conducted with all the rigor and objectivity applied to normal commercial public health vaccines. This is especially important in view of the role of Government Agencies

in research & development and decisions on regulatory approval, vaccine procurement and vaccine use.

Risk and Benefit
Vaccines like virtually all medical interventions are not 100% safe. No sensible person would undergo a medical procedure unless it is both necessary and the benefits outweigh the possible adverse events. The usual regulatory approval process takes account of the balance between the risk of disease, the safety of the vaccine and the predicted benefit. This balance is not fixed and can change over time. At one time smallpox vaccine was widely administered, but the success of the eradication program meant that continued general vaccination was no longer justified. More recently the success of the polio immunization program has resulted in a position where the, albeit small, number of adverse reactions associated with the live vaccine may no longer be acceptable given the very low risk in developed countries of contracting the disease. In each case it was not the safety or efficacy of the vaccines, but the risk of disease which changed.

In the case of defense vaccines the assessment of risk (that is how likely a person is to be exposed) becomes a issue of intelligence, rather than medical, assessment and thus is not subject to the same peer review process and open debate as is normal for other diseases. It is at present unclear how this assessment could be factored into the approval process.

The number and variability of threat agents
Public health vaccines have had clear and relatively stable disease targets such that even vaccines developed decades ago remain effective today. Where natural variation in the disease organism is an issue, as is the case with influenza, major worldwide programs are devoted to tracking variations and making necessary modifications to the vaccine. Nevertheless, it still takes many months before modified vaccines are brought into use.

There are many potential threat agents. The DOD Joint Vaccine Acquisition Program aims to develop and produce 18 vaccines. The WHO has identified over 30 potential BW agents. Recent reports have suggested that agents may be modified to resist current vaccines thus further compounding the problem of developing, producing, licensing and administering a separate vaccine for each agent. It therefore becomes questionable whether the pace of vaccine development could match the weaponisation ability of an aggressor.

Acceptability
Public health vaccines have achieved wide, although not total, voluntary acceptance. The high level of acceptance is a reflection of people's understanding of the likelihood that they or their families have a significant risk of contracting a disease, their perception of the seriousness of the disease and their faith in their medical advisors and the regulatory system to ensure that any adverse events from receiving the vaccine are outweighed by the benefits. Any loss of confidence can and has resulted in significant reductions in vaccine uptake and resulting increases in disease and the consequences thereof.

Defense vaccine immunization programs involving multiple vaccines and multiple shots are unlikely to gain acceptance unless convincing information about the risks of being exposed to biological agents, any adverse effects of the vaccines and the relative benefits can be made available to vaccine recipients.

Conclusion

Taken together, these issues raise serious questions about the feasibility of using defense vaccines to protect large numbers of people against numerous disease agents.

Mr. BURTON. Dr. Leitenberg. Did I pronounce your name correctly?

Mr. LEITENBERG. As in "light."

Mr. BURTON. Leitenberg. Dr. Leitenberg, I'm sorry. Thank you.

Mr. LEITENBERG. Mister, actually mister.

Mr. BURTON. Mr. Leitenberg.

Mr. LEITENBERG. My role is a bit different. Thank you for permission to present testimony. I am an arms control specialist, not a vaccine specialist, though I was a trained in biochemistry. I began working on chemical and biological warfare problems some 33 years ago, and over that period have gone back to the subject many times, and since 1992 nearly full time. I will discuss three things: first, a review of biological weapon proliferation since the Biological and Toxin Weapons Convention treaty was signed in 1972 and ratified in 1975; then a discussion of the potential for terrorist use in the United States; and last, as a subset on that, because I have done some research on the Aum Shinrikyo, the Japanese group, to tell you what that group was able to do and not to do because, in fact, it's significance is exactly the opposite as it's been portrayed for the last 4 years. It's been both misunderstood and purposefully misrepresented.

First, about the proliferation of biological weapons. The kind of things you would want to know are: Which Nations have sought to have biological weapons? How advanced were their programs? Do we know why they were started? And is there any likelihood of getting any of them to stop?

There are official U.S. Government statements, many of them, stating that in 1972 there were four nations that had these weapons, and in 1989 we said 10, and beginning in 1989 repeated congressional testimony from senior administration officials identified these nations, and you have that summarized in table 1 in my prepared statement. You see that I have grouped them: in the Middle East, Iraq, Libya, Syria, Iran, Egypt. In Southeast Asia, China, North Korea, Taiwan, India with a question mark, and South Korea.

The first two columns are the official U.S. Government sources. There is no official UK government source naming individual countries, but they have said 10. I put in the only official Russian Government source, their foreign intelligence report in 1993, because in fact it said something about North Korea beyond what our own official statements contained.

There were some countries which didn't appear in these statements, though in 1995 both the United Kingdom and the United States said that South Africa had had a biological weapons program. We also believe that Israel has a program, though we don't talk about that because Israel is not "noncompliant." It is not a signatory of the Biological Weapons convention and, therefore, the United States Government does not include Israel in the noncompliance statements. There are also obvious political reasons; we don't discuss it, but that's the formal reason.

All of these countries have offensive biological programs. That does not mean they have deployed usable biological weapons. Anything beyond offensive research is a violation of the treaty and, therefore, not compliance; but you can have offensive research, you

can have experimental production. That's what we call development. You can then have testing of the agent you develop. Then you can weaponize. Then you can produce your stockpiles.

I tried to distinguish those aspects—the U.S. Government has never chosen to do this—which you find in table 2. I tried to extract this information from both the official United States and the official Russian statements, to attempt to distinguish these separate categories. And that's terribly important. We have a habit in official statements, not only of confusing things by lumping those nations that have biological and chemical weapons programs together in one statement—there are administration statements that even include nuclear weapons programs and supply a single number for all together—but we also use the same phrase for all of those different stages in proliferant biological weapons programs.

There's only one statement in the public record, dating 1989 and not dealing with biological weapons, but dealing with chemical weapons, in which official United States statements said that there were 20 countries that had offensive chemical programs, and in that single statement, it said, aside from the United States and Soviet Union, only five or six others had chemical weapons. So that indicated a difference, between 8 and 20, and that's significant.

We don't have anything on the public record which indicates the same thing for biological weapons. So one cannot provide in the public domain, out of the 10 countries that the United States previously identified, and two others which we added in November 1997, raising that number from 10 to 12, but United States officials didn't identify them. I cannot therefore tell you from the public record which or how many of them have biological weapons. There's an attempt to do that in table 2, but beyond that, I can't go further because no one can. If General West can in classified testimony, that's another matter. In the public domain you cannot.

Table 3 was an attempt—and time does not remain to go into that—it was simply to show you that those nations who have made biological weapons don't just make biological weapons. They have either made all three weapons of mass destruction, nuclear, chemical and biological, or at least two, and for biological, and I think in every case after already having made chemical weapons.

Four specific little remarks, and I then have to leave the subject of biological weapons proliferation.

BW isn't new. BW has been around for a while, and all those programs that I named and the U.S. Government has named have been there for about 15 years. These are not new developments.

Second, one country, South Africa, supposedly ended and dismantled its BW program, in the same way as it ended its nuclear weapons program, and that's accepted in the international community.

Now, two things which are important and overlap with the BW terrorist in question. There's no available evidence that the former Soviet laboratories since 1992 have leaked material or personnel to countries of proliferation concern, in other words, those countries listed in table 1. As for the total number of people that left the former Soviet BW laboratories, at least to my knowledge, the U.S. Government thought it knew that number at the end of 1997. It was a small number, and 90 percent of them went to the United States, Western Europe, and Israel. That left a very small portion

for all other places, and some of the other places were not countries of proliferation concern, which left a still smaller fraction.

I want to say something about the Japanese Aum Shinrikyo group, because that's really the event that started everything that's going on now. In March 1995, that group used Sarin, a chemical agent which they had produced, in the Tokyo subway. It killed a dozen people—those are not mass casualties—and it injured a few hundred, not the 5,500 that went to hospitals. It injured a few hundred. The year before, in another Japanese city, the same group killed 7 people and also injured 200 using the same chemical agent.

It was then discovered that the same group had been trying to produce and use biological weapons agents, and that they had tried to disperse such agents nine times in Tokyo and in surrounding areas. That event produced the hearings in the U.S. Senate, by the Committee on Government Operations, at which I also testified in October 1995, and that hearing and its consequences produced all the government decisions since. So that's been the seminal event.

Now the Aum supposedly had been working on two agents, and they're usually said to be the simplest—botulinum toxin which you extract from clostridium botulism, which is food poisoning, which we know of in poor caning, or when people get that in jars, and anthrax. It turns out they were not able to produce either agent, so, of course, their dispersion attempts failed. They were in effect dispersing nothing—water and culture medium. They may, in fact, have grown anthrax, but they had a vaccine strain of anthrax. Therefore, it couldn't make anyone ill. It's probable that the person who was in charge of the program understood that, because that's what he had been able to purchase from a Japanese academic.

They did not have Q fever, so they were not working on Q fever, which has been claimed in the literature and in the Senate report. They did not have Ebola virus. They did not do any genetic engineering. That's a brief summary of what they did and didn't do.

What's important about that? The Aum group had 4 years in which to work. They had the appropriate facilities, two rooms about the size of this hearing chamber. They bought all the right equipment. They had virtually unlimited funds; the estimates go into the hundreds of millions of dollars. They didn't spend that much for BW, but they did spend tens of millions of dollars for it.

They had about a dozen academically trained people, not all in the right discipline, but when you have postgraduate degrees, you in theory know how to learn what you need to know. Nevertheless, they failed in all their BW efforts. That's significant.

The other significant thing is that after I did this research, it was circulated in the U.S. Government and I was told that the U.S. Government knew all this and that everything I had found was the same as the best information that the government had. Nevertheless, no one in the U.S. Government has bothered in 4 years to make public a proper assessment of what the Aum did and was not able to do.

Mr. BURTON. Mr. Leitenberg, we have a number of panelists. Could we go on with the rest of them? I'll come back to you.

Mr. LEITENBERG. Well, the last section was on BW terrorism. Let me just say one more thing.

Mr. BURTON. OK, sure. Go ahead.

Mr. LEITENBERG. The third portion of my presentation was simply to discuss the way the BW terrorist potential is currently understood in the United States. I will leave that aside if you don't have time.

I want to say one thing, however, since my presentation is as an arms controll specialist. My testimony should not be understood as being either pro or con the basic question you're addressing, the military anthrax vaccine initiative, but no arms controller would oppose passive defenses. If our troops are faced with chemical weapons, any arms controller wants to have that antidote inoculation available after U.S. troops would be exposed to chemical weapons. If the forces are exposed, it saves lives; if the forces are not exposed, it's a deterrent. So as a general issue, any arms controller is very much in favor of passive defenses, of which vaccines are one.

So my testimony, whatever it is, should not be understood to bear against that question.

Mr. BURTON. Thank you very much, Mr. Leitenberg.

[The prepared statement of Mr. Leitenberg follows:]

Testimony before the Committee on Government Reform
US House of Representatives, Washington, DC
October 12, 1999

Milton Leitenberg

An Assessment of the Biological Weapons Threat to the United States

Congressmen Burton, Waxman, Members of the Committee. I appreciate the opportunity to present testimony to the committee. Although my professional training was in biochemistry, I am not a vaccine expert. Instead, I have for the past 33 years been occupied in arms control studies and strategic analysis, and repeatedly over the years that has dealt with chemical and biological warfare.

My role here is therefore to provide as accurate a representation as possible of the state of biological weapons proliferation, based on available public sources, and an assessment of its current threat to the United States. That requires me in five minutes to address some four years of gross exaggeration, frequent misinformation, and equally frequent disinformation. My presentation will be divided into three parts:

- a review of the proliferation of biological weapons (BW) since 1972;
- a specific examination of the serious and substantial efforts of the Japanese Aum Shinrikyo religious cult to produce biological weapons. Their four-year effort was a complete failure, and it has been almost universally misrepresented; and
- a discussion of the portrayal of the potential for terrorist use of biological weapons in the United States.

Proliferation of Biological Weapons since 1972

The questions that you should want addressed are:

- How many nations have sought to acquire BW since 1972?
- Which ones?
- How advanced are or were their BW programs?
- Do we have any idea of why these programs were initiated?
- Is there any likelihood that ongoing programs could be reversed and closed down?

Official US government statements repeated for many years that there had been four nations in possession of offensive biological weapons programs in 1972 at the time of the signing of the Biological and Toxin Weapon Convention (BTWC), and that this number had increased to ten by 1989. Beginning in 1989, testimony to Congress by senior US government officials and the annual Non-Compliance statement by the administration to Congress specifically identified these states by name.

Table I

Table 1. States Having BW Programs at Least Approaching Weaponization

	U.S. Government Arms Control Compliance Reports to Congress (1993,1995)	Admirals Brooks,[1] Studeman, Trost (1988,1990,1991); Sec. Cheney, 1990	U.S. and UK Governments (1995)[2]	Russian Federation[3] Foreign Intelligence Report, 1993
Middle East				
Iraq	X	X		
Libya	X	X		X
Syria	X	X		
Iran	X	X		X
Egypt	X			
South/East Asia				
China	X	X		
North Korea		X		X
Taiwan	?	X		
India[4]				?
South Korea				?
Africa				
South Africa			X	
Russia	Ambiguity regarding continuation of offensive program			

1. "Stantement of Rear Admiral Thomas A. Brooks, USN, Director of Naval Intelligence, before the Seapower, Strategic and Critical Materials Subcommittee of the House Armed Services Committee on Intelligence Issues," March 14, 1990, p. 54; "Statement of Rear Admiral William O. Studeman, USN, Director of Naval Intelligence, before the Seapower, Strategic and Critical Materials Subcommittee of the House Armed Services Committee on Intelligence Issues," March 1, 1990, p. 48; "Statement of Admiral C.A.H. Trost, USN, Chief of Naval Operations, before the Senate Armed Services Committee on the Posture and Fiscal year 1991 Budget of the United States Navy," February 28, 1990; "Remarks Prepared for Delivery by the Honorable Dick Cheney, Secretary of Defense, American Israel Public Affairs Committee, Washington, D.C., June 11, 1990," News Release, No. 294-90, p. 4.
2. The South African government claims that its program was disbanded in 1992. Official British government statements refer only to "around 10" nations with "or seeking" BW, but do not name any countries aside from the separate identification of South Africa in 1995.
3. *Proliferation Issues: A New Challenge After the Cold War, Proliferation of Weapons of Mass Destruction*, Russian Federation Foreign Intelligence Report, trans. Joint Publications Research Service JPRS-TND 93-007, March 5, 1993.

These statements additionally noted that some of the states listed were signatories of the BTWC. Israel, South Africa, and North Korea, however, were never mentioned or listed; Israel and North Korea are not signatories to the BTWC, and hence are not in "non-compliance." However, US administrations believed that all three countries maintained offensive BW programs. In November 1997, the Director of the US Arms Control and Disarmament Agency (ACDA) increased the US estimate to 12 nations (in the course of a statement to negotiating states to the BTWC in Geneva), although the additional two states have never been identified by US officials.

The number is therefore twelve, and not sixteen, seventeen, or eighteen, as are sometimes found in the press. These are offensive programs, which the BTWC prohibits, but it does not in all cases mean regular production of biological weapon agents, the storage of stockpiles, or the possession of weapons. Official US or British government statements have further been confounded by the inclusion of caveats such as "suspected", "developing" or "capable of". We have only one example in the public record of what the scale of these differences may be, and that statement is ten years old and pertained to chemical weapons. At the same time as US government officials were routinely saying that "about 20" nations had chemical weapons "capability," the Director of ACDA told the Senate Foreign Relations Committee on January 24, 1989, that apart from the US and the USSR "...no more than a handful, five or six" actually possessed a stockpile of chemical weapons." An accurate understanding has been further complicated, and continues to be so, as in statements by official US government spokesmen in 1997 and 1998, that provide a single number grouping together nations with biological or chemical weapon programs.

On the other hand, statements of denial by various nations carry very little credibility in this field. The USSR did not admit to possessing chemical munitions until 1987. Indian officials denied for decades that their country possessed chemical munitions; they even claimed that their government had never so much as considered obtaining them. This past year, under the terms of being a signatory to the Chemical Weapons Convention, India declared its chemical weapons stocks. The Iraqi government, of course, lied for years about its production and possession of biological weapons stocks and delivery systems, and every indication is that they continue to lie about it.

As to how far offensive national BW programs have been carried out by different states, Table II shows the relevant bits of information available in the US Non-Compliance documents, and in the 1993 Russian Foreign Intelligence Report.

Table II

It should be noted that the latest available US Department of Defense issues of Proliferation: Threat and Response (April 1996 and November 1997) do not indicate specific BW agent production for either Iran or for North Korea. Neither has testimony at the unclassified level by the Directors of the CIA or DIA in 1998 and 1998.

As for the motives for national BW development programs, Table III indicates that every nation that has embarked on an offensive BW program has also sought or has produced either chemical weapons or nuclear weapons, or both.

Table 2

BIOLOGICAL WEAPONS: OFFENSIVE PROGRAMS, TO THE DEGREE KNOWN IN THE MIDDLE EAST

STATE	Offensive R&D	TESTING	PRODUCTION	Stockpiling	Alleged Use
IRAQ	YES	YES	YES	YES	
IRAN	YES		Small		
SYRIA	YES				
EGYPT	YES		In the Past	In the Past	
LIBYA	YES		Small		
ISRAEL	YES	Probably	Probably		
OTHERS					
SOUTH AFRICA	In the Past	?	In the Past	In the Past	
NORTH KOREA	YES	YES*	YES*		
USSR	YES	YES	YES	In the Past	(possible)
CHINA	YES	YES	YES	In the Past	

Table III

There are several important additional points that should be noted in this section:

- None of the national BW programs cited above are new. They all date back about 15 years or more.

- One, South Africa's (which apparently was responsible for low-level BW use outside its own borders), was discontinued, as was the South African nuclear weapons program, immediately prior to the end of the apartheid government.

- There is no available evidence of the transfer of BW agent cultures from the former USSR or from Russian laboratories since 1992 to other countries of BW proliferation concern.

- There has also been minimal dispersion of researchers from former Soviet BW facilities to countries of concern. The total number of such individuals who emigrated from Russia (as of late 1997) was small, and of those, 90 percent became employed in the United States, Western Europe or Israel. That leaves a very small number who moved to other countries, and some of those countries were also not of BW proliferation concern.

The Effort of the Aum Shinrikyo group in Japan to Produce Biological Weapons Agents

In March 1995, members of a Japanese religious cult, the Aum Shinrikyo, were responsible for releasing the chemical agent Sarin in the Tokyo subway. They had produced the Sarin themselves, and their act killed thirteen people and injured several hundred (not 5,500, which was the number of people that arrived at hospitals.) They had also used Sarin undetected in June 1994 in another Japanese city, in an incident that produced seven deaths and injured 200. It was subsequently discovered that the group had attempted to produce biological agents between 1990 and 1994 and to disperse what they had produced on nine occasions in Tokyo and other nearby areas, to no effect.

The Tokyo subway event led to the US Senate Hearings in October 1995 held by the Committee on Government Operations, under Senators Roth and Nunn, which in turn catalyzed the train of decisions, programs and funding to counter the potential use of weapons of mass destruction in the United States. The public discussion in the United States for the past four years has, however, been overwhelmingly relegated to biological weapons, and "bioterrorism." The experience of the Aum group in its efforts to produce biological agents is particularly important for several reasons, but it has been continually misinterpreted and misrepresented to mean precisely the opposite of what the experience demonstrated.

First, as to what the group's capabilities were and what they did do:

- They had virtually unlimited funds to procure appropriate equipment, which they did through front companies they had established.

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First, as to what the group's capabilities were and what they did do:

- They had virtually unlimited funds to procure appropriate equipment, which they did through front companies they had established.

- They had adequate facilities, and four years in which to work undisturbed.

- They had about a dozen people with graduate training, not all in the appropriate disciplines, but with the kind of academic training which in theory should lead one to understand how to go about learning what one needs to know.

- They had attempted to buy assistance and technology in the USSR to aid their efforts to produce both chemical and biological weapons, and despite the expenditure of several million dollars, they came away empty-handed. This last point is particularly important as one real-world reference point relating to the frequently expressed fear of the likely ease of procuring such information from unemployed or poorly-salaried former Soviet experts.

Second, concerning what the Aum group was able to achieve or not achieve:

- They attempted to produce two biological agents, Botulinum Clostridium, to obtain Botulinum toxin, and anthrax, both of which are constantly stated to be easy to do. They failed to produce either, and so of course their efforts to "disperse" these also failed. In fact, they could not have produced any infective anthrax since they had obtained a culture of a non-virulent, denatured vaccine strain of the organism.

- They did not have any Q-fever cultures, and therefore they were not "working with" that organism (contrary to various reports). They had attempted to purchase a Q-fever culture from a Japanese academic researcher, but were rebuffed, which is again of particular significance.

- They did not have samples of the Ebola virus, contrary to various reports, though it does appear that they had hoped to obtain them.

- Finally, they did not do any "genetic engineering," also contrary to some further misreporting.

There are two important points to be made. First, the Aum experience was a real, serious example, not the constant hypothetical evocations of unqualified, untrained "terrorists" being able to produce biological agents in "kitchens," "garages," "bathtubs," and "home beer brewery kits." Despite the expenditure of substantial time, effort, money and some requisite talent, their efforts totally failed. Second, it is my understanding that classified US government evaluations of the efforts of the Aum group to produce biological agents are the same as the information I have provided above, which was obtained in the course of a few weeks of research. Despite this, no member of any agency of the US government has seen fit to provide a more proper public assessment of the lessons of this experience.

The Potential of Terrorist Use of Biological Weapons in the United States

This subject has been characterized for four years by ignorance, hype, and gross exaggeration. The clichés that one hears without end as if the speaker were referring to the next

morning's sunrise: "It is not a matter of whether, just when...;" "The nation will face within five years...," are no better than daydreaming. Five years since the Aum efforts of 1990 to 1994 have already passed. When terrorist acts which could be relatively easily achieved, such as aircraft hijackings or product tamperings first appeared as terrorist mechanisms, the rate of these events increased sharply year by year within five years.

There are numerous authoritative-sounding statements declaring the supposed ease of preparing biological agents by novices -- the bathtubs, bathrooms, kitchens, and garages, and the media has repeated them ad nauseum. Such claims are nonsense. However, such exaggeration is also not a neutral commodity. It unquestionably stimulates what it is supposedly warning against. Stressing, or claiming, the ease, effectiveness, great danger, likelihood, proximity, expectancy, of BW, as in Secretary of Defense Cohen's notorious Washington Post Op-Ed of November 26, 1997, is more likely to induce and to stimulate interest and consideration of attempts to produce BW by other parties, either states or non-state groups.

Instead, what we have seen are many hundreds of hoaxes. Hoaxes are not BW, they are not "anthrax," and they are not "BW events." Nor are they terrorist consideration of the use of BW (or as phrased in the Defense Science Board Summer Study of 1997, demonstrations of "...the breadth of weaponry available" to terrorist groups), and they should not be counted in statistical compendia as such. A hoax is a hoax, and nothing else.

Two brief, but more expert assessments were provided to Congress early in 1999. John Lauder, Special Assistant to the Director of Central Intelligence for Proliferation told the House Permanent Select Committee on Intelligence on March 3, 1999, that "...the preparation and effective use of BW by both potentially hostile states and by non-state actors, including terrorists, is harder than some popular literature seems to suggest." And Col. David Franz, then the Deputy Commander of the US Army's Medical Research and Materiel Command told the Senate Intelligence Committee that BW terrorism is difficult to carry out, and that it would require a "...large well-funded terrorist program or state sponsorship."

As for state-sponsored BW terrorism, here again there are real-world reference points. The US Department of State releases an annual list of states that support terrorist groups. For ten years, this list has included four countries that the US government also states to have offensive biological (and chemical) weapons programs: Iraq, Iran, Syria, and Libya. There is no record of any of these countries supplying biological (or chemical) weapons or even technical expertise to any of the terrorist groups that they support. Most experts believe that if these nations ever do use biological agents for covert terrorist purposes, they will do so by using their own nationals to carry out the task, and not by handing the materials to ad hoc affiliated groups.

On April 29-30, 1999, a meeting was held in Washington under the auspices of the Chemical & Biological Arms Control Institute to more carefully examine the plausibility of potential terrorist use of BW. Well-informed consultants to US government agencies repeatedly pointed out that no threat analysis of this subject -- an examination of potential actors and potential feasibilities -- had ever been prepared inside the US government. Instead, contractors had produced vulnerability analyses, scenarios of effects that would follow release of a BW agent. Those systematic studies that have surveyed relevant events over the past 50 or 100 years uniformly predict that the most likely event will be, as they have in the past, the use of easily

available off-the-shelf chemicals, individual poisonings, or the use of the most simply prepared toxins, such as ricin.[1] A terrorist use of a BW agent is best characterized as an event of extremely low probability, which might -- depending on the agent, its quality and its means of dispersion -- produce high mortality (or economic damage if it is an anti-plant or anti-animal agent). To date, apparently a single person has died in the United States since 1900 due to terrorist use of biological or chemical agents. One might, for reasonable context, compare this to the official estimates released only a few weeks ago, indicating that thousands of people in the US die or are injured per year due to food poisoning.[2]

An Added Note on the DOD Anthrax Vaccine Initiative

My testimony is not and should not be interpreted as being in opposition to the Department of Defense's anthrax vaccine initiative. Others will speak to the degree of its specific efficacy, but anyone interested in stemming biological, or chemical, weapons proliferation would argue in support of passive defenses, of which vaccines against specific BW agents are one example. No one would argue, in principle, against supplying US military personnel with antidotes against nerve gases, which are designed to be used following battlefield exposure to nerve gases, despite some degree of risk that the use or inappropriate use of these entails. If US military personnel were ever exposed to nerve gases, in combat or by means of sabotage, then the antidote is available and its use would save extremely large numbers of lives. If the event never happens, the availability of the antidote, or by analogy in the case of biological agents, the vaccine, as well as other passive defensive measures, nevertheless serves as an important deterrent against enemy use of the agent against US forces.

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[1]See the compendium produced by Dr. Seth Carus for the National Defense University, Bioterrorism and Biochrimes: The Illicit Use of Biological Agents in the 20th Century, August 1998; contracted studies by Harvey McGeorge for US government agencies; "An Unlikely Threat," Jonathan B. Tucker and Amy Sands, Bulletin of the Atomic Scientists, 55:4 (July-August 1999), pp. 46-52. See also, Lois Ember, "Combating the Threat," Chemical and Engineering News, July 5, 1999, pp. 8-17.

[2]Five thousand deaths, 325,000 hospitalizations, and 76 million illnesses per year due to food poisoning: "Food-Related Illness and Deaths in the United States," Emerging Infectious Diseases, September-October 1999, pp. 607-625.

Milton Leitenberg, Senior Fellow, Center for International and Security Studies, School of Public Affairs, University of Maryland

A brief curriculum vitae is attached. My first publications on the subject of biological weapons appeared in 1967, and I was one of a team of authors that produced the six-volume study, The Problem of Chemical and Biological Warfare, published between 1971 and 1973 in London and Stockholm. Between 1992 and 1999, I have published fifteen papers dealing with biological weapons, for the most part concerning the BW program of the former USSR and Russia.

Mr. BURTON. Dr. Classen.

Dr. CLASSEN. My name is Bart Classen. I am a physician and an immunologist. Thank you very much, Mr. Chairman and committee members, for inviting me to speak.

I oppose mandatory anthrax vaccination. This vaccine has not undergone proper testing and will increase the recipient's risk of autoimmune diseases, including diabetes. My research involves studying the long-term effects of vaccines on autoimmune disease, including diabetes.

I started working with this anthrax vaccine 8 years ago. The vaccine was approved for marketing in 1970 without a single controlled clinical trial. I know of no controlled clinical trial performed since approval. This is documented in the FDA letters enclosed in my written testimony. My animal studies indicate that even low doses of the anthrax vaccine caused significant immune stimulation, and the effect is additive with other vaccines such as diptheria, tetanus and pertussis. The results indicate immunization starting in the first month of life can prevent autoimmune diseases. However, immunization starting after 2 months increases the risk in both humans and animals.

My work with the anthrax vaccine involves starting immunization in the first month of life. However, based on similarity with other vaccines I have worked with, I would expect that it would increase the risk of autoimmunity, including diabetes in recipients, including humans.

Published data supports an association between military vaccines and an increased risk of diabetes. A very high rate of insulin-dependent diabetes exists in the Navy. Those entering the Navy have a similar rate to the general population. However, after being in the military for several years, their rate of diabetes exceeds the rate reported for the general population. In Sweden, where all men are drafted, but women traditionally aren't drafted into the military, the rate of diabetes prior to the draft is about the same in men and women. After the draft, however, when the men receive the vaccines, their rate is about twice that of women between the ages of 20 and 34. By contrast, in the U.S. Navy where men and women receive the same vaccines, their rate of diabetes is about the same.

This suggests that military vaccines may be doubling the risk of diabetes in the recipients. Based on my work with vaccines and diabetes, I estimate the anthrax vaccine may cause diabetes in 1 out of every 1,000 recipients and some form of chronic adverse event in 1 in every 200 recipients. These effects may not occur until 4 years or more after immunization.

I can give numerous examples where employees of the U.S. Public Health Service lacked commitment to medical science and instead appeared to be furthering their careers by acting as propaganda officers to support political agendas pertaining to vaccines. In one case, I can demonstrate that employees of a foreign government who are funded and working closely with the U.S. Public Health Service submitted false data to a major medical journal.

The true data indicated that the vaccine was dangerous. However, the false data indicated that there was no risk. An employee of the NIH, who manages large vaccine grants, jointly published a

misleading letter about the subject with one of these foreign civil servants.

In May, the U.S. Public Health Service assured Congressman Mica's subcommittee that the hepatitis B vaccine was safe. Weeks later, the U.S. Public Health Service, however, changed its hepatitis B vaccination policy because there was too much mercury in the vaccine. It's hard to imagine that they didn't know a problem existed when they tried to convince Congressman Mica that the vaccine was safe.

I have several recommendations that are discussed in my testimony. However, I think the most important is that there's a need to hire a special prosecutor to determine if public health officials are following the laws enacted to ensure safety of vaccines, and if public health officials, along with manufacturers, are misleading the public about the safety of these vaccines.

France investigated the actions of its own public health officials and found that they had not followed the law in ensuring the safety of biological products. After imprisonment of several public health officials in France, France now has a leadership position in ensuring vaccine safety as demonstrated by their discontinuation of the routine hepatitis B immunization program for school-age children in France.

Simple improvements with vaccine technology may lead to over a 50 percent reduction in insulin-dependent diabetes and other autoimmune diseases.

I want to thank you very much for the opportunity to speak. This ends my testimony.

Mr. BURTON. Some of the things you brought up there are very interesting. I'd maybe like to talk to you a little bit more about this later, Dr. Classen.

[The prepared statement of Dr. Classen follows:]

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October 12th, 1999

The Honorable Dan Burton, Chairman
U.S. House of Representatives
Committee on Government Reform
Washington, DC 20515

Dear Chairman Burton and committee members,

Thank you for the opportunity to present my views on this important issue. I oppose mandatory anthrax vaccination of military personnel based on safety concerns revealed by my own research. This vaccine has not under gone proper safety testing and along with other vaccines will increase the rate of autoimmune diseases including diabetes in military personnel. The anthrax vaccine will cause medical and financial hardships to its recipients. Currently many do not develop the vaccine induced autoimmune diseases until after leaving the military and are not properly compensated because they do not suspect that their disease is related to their military service or the military denies it is related.

My research involves studying the long term effect of vaccines on autoimmune diseases including diabetes. I began working with the anthrax vaccine over 8 years ago. The product I used was produced by the Michigan Department of Health which is the same product being given to US military personnel. During my studies with the vaccine I did an literature review of the vaccine which included retrieving documents on the vaccine from the FDA as part of the freedom of information act. Enclosed are four letters from the FDA/Public Health Service (Exhibits dated 2/6/1969; 2/10/1969; 9/30/1969; 11/2/1970) which clearly reveal that the anthrax vaccine was approved for marketing without the manufacturer performing a single controlled clinical trial. It is impossible to demonstrate safety and efficacy without performing a clinical trial and the FDA was aware of this but approved the vaccine for marketing anyway. I am not aware of any proper clinical trials with this anthrax vaccine being performed after marketing commenced so strong consideration should be made for removing the vaccine from the market until proper clinical trials are performed.

I studied the ability of the vaccine to stimulate the immune system in ways unrelated to its protective effects against anthrax. These experiments involved using the anthrax vaccine to alter the risk of autoimmune diabetes in the rodents. The data, which has been published in 2 separate papers (*Autoimmunity, 24: 137-145, 1996*; *Autoimmunity*, 27(3): 135-139, 1998), showed that even low doses of the anthrax vaccine caused significant stimulation of the immune

system. I attribute this strong effect to the many different immunologically active molecules in the vaccine including the aluminum adjuvant. The vaccine is made from an unpurified filtrate from bacteria grown in culture media and thus contains many different molecules which can stimulate the immune system.

My published animal studies indicate that immune stimulatory effect of the anthrax vaccine is additive with other vaccines such as the diphtheria, tetanus and pertussis vaccine. The results of my studies indicated that immunization starting in the first month of life can prevent autoimmune disease including diabetes however immunization starting after 2 months increases the risk both in humans and animals. My work with anthrax vaccine involved giving it in the first month of life however, based on its similarity to other vaccines I have studied, it would be expected to increase the risk of autoimmunity including diabetes when given to adults. This conclusion is supported by a number of human population studies (*Infectious Diseases in Clinical Practice*, 6: 449-454, 1997). I have discontinued research on using the anthrax vaccine for preventing diabetes based on the risks of giving it to large number of people.

The risk of autoimmunity following immunization of military personnel has been suspected for years but few studies have been performed. Studies were done on Finnish military personnel after receiving vaccines during basic training *(Acta Pathol. Microbiol. Scand. 56:478-479,1962; Proceedings of the Society for Experimental Biology and Medicine 124(1):229-233, 1967).* The authors showed that many of the people receiving the vaccines developed an autoantibody called rheumatoid factor and were thus at increased risk for developing autoimmune arthritis. The authors state "it is suggested that among apparently healthy persons there are a few with varying degrees of a tendency to form rheumatoid factor in connection with antigen stimulation (*Acta Pathol. Microbiol. Scand. 56:479,1962).*" Supporting studies have indicated that 0.3% of military recruits develop arthritis acutely post immunization in boot camp however this figure may be low based on the rates of arthritis following single vaccines *(Annals of the Rheumatic Diseases 52(12) 843-4, 1993).*

I have done some preliminary work in military populations looking for an increased risk of diabetes following immunization, unfortunately the military lacks a sufficient infrastructure to properly evaluate the risk of immunization. Several papers have been published indicating that there is a very high risk of insulin dependent diabetes in the navy *(American J. Epidemiology 138:984-987, 1993)* and diabetes in the air force *(Aviation, Space, and Environmental Medicine 66: 1175-1178).* The risk seems to increase with the time in the military. The paper on insulin dependent diabetes in the navy shows that those under 20 who enter the military have a similar rate of diabetes to those of similar age in the general US public *(Diabetes Care 16:841-842, 1993)* but those in their 30s, and who presumably have been in the military for several years, the rate of diabetes exceeds the age specific rate in the general population. Data from Sweden also suggests that the military vaccines may be leading to an increased risk of diabetes. In Sweden traditionally almost all men, but not women were drafted and received vaccines. The incidence

of diabetes in Sweden is about the same in men and women prior to the age of the draft, 18. However, the incidence of diabetes is about twice as high in men then women between the age of 20 and 35 (*International Journal of Epidemiology 21:352-358, 1992).* By contrast in the US navy between the ages of 17 to 34 white women have a 25% higher rate of insulin dependent diabetes then white men. These data support a causal relationship of vaccines on diabetes in the military.

My data indicates that a single vaccine such as the anthrax vaccine may cause one case of insulin diabetes per 1,000 people immunized (*Infectious Diseases in Clinical Practice*, 6: 449-454, 1997). The delay between vaccination and the development of diabetes may be delayed 3 to 10 years or more. Immunization of 2.5 million recruits may cause 2,500 people to develop insulin dependent diabetes. Insulin dependent diabetes is just one potential adverse event and the cumulative long term rate of chronic adverse events may be 5 times as high or 1 chronic adverse event per 200 persons immunized.

I am greatly concerned about the safety of the anthrax vaccine and other vaccines. It is clear to me that the government's immunization policies, both the military and civilian, are driven by politics and not by science. I can give numerous examples where employees of the US Public Health Service lack a commitment to medical science and instead appear to be furthering their careers by acting as propaganda officers to support political agendas. In one case I can demonstrate that employees of a foreign government, who were funded and working closely with the US Public Health Service, submitted false data to a major medical journal. The true data indicated the vaccine was dangerous however the false data that was submitted indicated there was no risk. An employee of the NIH who manages large vaccine grants jointly published an misleading letter about the subject with one of these foreign civil servants. As you are aware it is illegal to falsify data from research funded by the US government.

In May employees of the US Public Health Service assured Congressman Mica's subcommittee that the hepatitis B vaccine was safe. Weeks later the US Public Health Service changed its hepatitis B immunization policy because there was too much mercury in the vaccine. It is hard to imagine they did not know a problem existed when they tried to convince Congressman Mica that the vaccine was safe. Employees of the CDC did preliminary studies which supported my data that the hepatitis B vaccine was linked to an increased risk of diabetes. In a follow up study they changed the study design by adding unorthodox mathematical coefficients "fudge factors" to substantially reduce the true risk of diabetes associated with vaccination and now their data would make it appear that the vaccine is safe. Even their new data however indicates those receiving the hepatitis B vaccine starting after 2 months of life may be at a 50% increased risk of diabetes compared to those receiving it at birth. The real tragedy is that our research indicates that technology is available to make vaccines much safer but public health officials are hindering the development of safer technology by denying there are safety problems with existing products. These actions are also preventing individuals from receiving the compensation they are entitled to.

I have several recommendations. First, there is a need to hire a special prosecutor to determine if public health officials are following the laws enacted to ensure vaccines are safe and if public health officials along with manufacturers are misleading the public about the safety of these products. France investigated the actions of its public health officials and found they had not followed the law in ensuring the safety of biological products. After the imprisonment of several public health officials in France, government employees have taken a leadership position in vaccine safety as demonstrated by their discontinuing school age hepatitis B vaccination.

Proper safety studies looking at the long term effects of vaccines on diabetes and other autoimmune diseases need to be done before the anthrax or any other vaccine is promoted for wide spread use. The public needs to be warned about the increased risk of diabetes and other autoimmune diseases associated with vaccines. Private citizens need access to government database so they can perform independent safety studies on vaccines. Successful enactment of these changes will allow improvements in vaccination which could lead to over a 50% reduction in insulin dependent diabetes and other autoimmune diseases.

In closing I am opposed to mass immunization of with the anthrax vaccine because of the inevitable rise in autoimmune diseases as a result of immune stimulation with this vaccine and secondly the questionable efficacy. Thank you for the opportunity to speak.

Sincerely,

John Barthelow Classen MD

John B. Classen

UNITED STATES GOVERNMENT

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

Memorandum

To File

TO : Dr. Margaret Pittman, Chief, LBP M. P.

DATE: February 6, 1969

Ref. No. 67-70

FROM : Ad Hoc Committee

SUBJECT: Michigan Department of Health Anthrax Vaccine, Evaluation of Clinical Data submitted under on January 22, 1969

As requested, we have reviewed the clinical data contained in letter of January 22, 1969 and its attached report. Our comments are as follows:

1. The lack of cases of anthrax in an uncontrolled population of approximately 600 persons in the Talladega mill can hardly be accepted as scientific evidence for efficacy of the vaccine. There is no indication of the frequency or the detail with which the bacteriological studies on goat hair were conducted during this period. We do not question that there might be up to 10 cases of expected anthrax per 600 workers, but without evidence of actual exposure in this mill during this time, and the apparently unpredictable incidence and distribution of anthrax in various mills (see Fig. 1, Brachman et al, Am. J. Pub. Hlth 52:632, 1962), the assumption of efficacy appears speculative.

2. It was noted that site of inoculation reaction rates were higher, presumably due to closer follow-up. The nature and degree of reactions is not well defined.

3. The results from the agar gel precipitin inhibition (AGPI) technique are not clear. We cannot evaluate the data without details for performing and interpreting the test.

4. It would be helpful if any stored human sera from the earlier study with the could be compared by the AGPI technique with sera from persons receiving the Michigan product. Since no simultaneous animal potency comparison of and Michigan products has been possible, this would provide at least some evidence of a comparable response in man.

John C. Feeley, Ph. D.

Charles R. Manclark, Ph. D.

Joseph P. O'Malley, M. D.

Robert W. Kolb

HELP ELIMINATE WASTE HEW COST REDUCTION PROGRAM

000098

UNITED STATES GOVERNMENT

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

Memorandum

Concur [signature] 2-10-69

TO : Dr. Sam T. Gibson, Assistant Director, L & I DATE: February 10, 1969

Ref #067-70

FROM : Chief, LBP and
Chairman, Ad Hoc Committee

SUBJECT: Michigan Department of Health: Application for license for Anthrax Vaccine

On June 21, 1968 the Ad Hoc Committee recommended that license be granted following publication of Additional Standards: Anthrax Vaccine. It was noted also that clinical data establishing efficacy of the product had not been submitted and that data be requested from NCDC.

No comments were received on the Proposed Notice of Rule Making published December 14, 1968, and it is understood that these standards have been forwarded with request for publication in the Federal Register.

The progress report of submitted January 22, 1969 failed to provide supporting clinical efficacy data. See memorandum of February 6, 1969. Apparently no study designed to obtain the appropriate data has been planned. Safety data appear to be satisfactory.

Michigan has filed with the Division all required information and material for license except the results of an adequately controlled clinical investigation that establishes efficacy. No cases of anthrax have occurred among vaccinees. Laboratory data have been submitted that show that the product does have specific ability to protect guinea pigs. Therefore, it is recommended that license be granted and that NCDC be requested to obtain data with a view to determine human efficacy of the product.

[signature]
Margaret Pittman, Ph. D.

HELP ELIMINATE WASTE HEW COST REDUCTION PROGRAM

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UNITED STATES GOVERNMENT
Memorandum

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

10-1-69

TO : Dr. Sam T. Gibson, Assistant Director, L & I DATE: September 30, 1969

Ref. No. 67-70

FROM : Margaret Pittman, Ph. D., Chief, LBP
Chairman, Ad Hoc Committee

SUBJECT: Michigan Department of Public Health, visit by Dr. George R. Anderson and Dr. J. R. Mitchell

Anthrax Vaccine
(DBS personnel: Drs. J. C. Feeley and M. Pittman)

The recent information submitted by NCDC and Ft. Detrick for DBS was discussed. It was emphasized that the epidemiological study did not provide control data, whereby the effectiveness of the vaccine could be evaluated. The fact that the vaccine has been used in a number of textile mills and that there has been no case of Anthrax was substantive but not conclusive evidence of efficacy.

It was also noted that Michigan Lot 3 was more reactive than one lot prepared by Ft. Detrick and one lot prepared by
With gel diffusion tests it was demonstrated that the first two lots induced antibodies that were lower in titer and of shorter duration than did product. However, the first two lots were fractionated antigens and a true comparison could not be made.

Michigan Lot 2 now in current use was less reactive than Lot 3. Lot 7 will be put into use by the end of this year.

Dr. Anderson was informed that all requirements for filing the application for Anthrax Vaccine had been fulfilled but that license could not be issued until the Additional Standards: Anthrax Vaccine had been published. A nontechnical block was delaying their publication. Dr. Anderson was appreciative of the information.

HELP ELIMINATE WASTE HEW COST REDUCTION PROGRAM

UNITED STATES GOVERNMENT
Memorandum

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

TO : Reference No. File 67-70

DATE: *November 2, 1970*

FROM : Chairman, Ad Hoc Committee

SUBJECT: Michigan State Department of Health: Anthrax Vaccine Adsorbed

This brings up to date matters concerning the application for license.

1. On October 28, 1970, Additional Standards: Anthrax Vaccine Adsorbed were published. The Committee had previously recommended license on publication of the Standards. The appropriate documents are attached. See Item 3 below.

2. Since the Committee recommended that license be issued on publication of the Standards, a progress report on ; has been received. It covered the period from August 1, 1969 to October 15, 1970. Vaccine was distributed to 14 investigators; 3,127 injections in primary series and 1,323 booster injections had been made. It was reported that the reactivity of the vaccine had remained relatively constant over the 4-year period.

   It was also reported that (1) Lot 2 (prepared in 1966) was used only from August 1, 1969 to October 1, 1969 and (2) Lot 7 (prepared in 1968) had satisfactory potency 9/25/69 but had decreased in potency when tested October 1970. This information indicates that a watch must be kept on the stability of the product.

3. Letter of notification. At the time the license is sent to the mfr it is recommended that the following be requested:

   (1) A complete set of labeling including the package enclosure.

   (2) The latest potency tests of Lots 2 and 7 reported in the IND from the Center for Disease Control suggest that the product may not be stable through the dating period of one year (5°C, 2 years). It is advised (a) that available data be organized and forwarded to the Division and (b) that a schedule be provided for the collection of additional data that may be indicated.

   (3) Since the samples submitted in support of license contained 0.0933% and 0.1307% aluminum, subsequent lots should contain not less than 0.4 mg aluminum per single human dose.

Margaret Pittman, Ph. D.

HELP ELIMINATE WASTE HEW COST REDUCTION PROGRAM

Mr. BURTON. Major Bates.

Major BATES. Mr. Chairman, members of the committee, I thank you for the opportunity today to speak here on this critical issue. I'm a C–5 pilot, newly assigned to Dover Air Force Base. Two months ago I arrived at Dover in high spirits, excited about the new challenges that lie ahead. However, within the first few weeks I became aware of some very disturbing facts. I learned that people were suffering, and I have an attachment here to run down this list of suffering.

A captain on active duty, pilot, has been grounded for several months. She was healthy before receiving the vaccine—suffers from autoimmune disorder, has sustained thyroid damage and has testified before Congress.

Another captain, active duty C–5 pilot, has been grounded for several months after taking the fourth shot. He was healthy before receiving the vaccine, and he developed cysts on numerous places on the inside and outside of his body, to include his heart. He has undergone surgery to remove the cysts and was hooked up to an IV for 6 weeks. He says the medical group is working on a waiver to get him back on flying status, even though he still has a cyst around his heart. He is afraid for his future. He is afraid he will never fly again in the military or civilian community. He said the flight doctor did eventually hand him a VAERS report and told him she was going against her instructions to do so, but she thought he should fill one out anyway.

Another major, pilot, C–5 pilot, is being treated for an autoimmune disorder.

Another major, active duty C–5 pilot, has been grounded for several months. He was healthy before receiving the vaccine. He has been suffering crippling bone joint pain and ringing of the ears. The pain is so bad he can't climb into the airplane. He has been battling the various infections continuously during the past several months and has developed new allergies in the past month. He's been in physical therapy for the last 3 months with no progress.

Staff sergeant, active duty C–5 flight engineer, after the fourth vaccine began to experience diverse symptoms which included chronic bone joint pain, chronic fatigue and a loss of ability to concentrate. He's been cross-trained into another, less demanding career field.

Tech sergeant, active duty flight engineer, has been grounded for 8 months after receiving the vaccine. He's experienced eight seizures. Other symptoms include crippling bone joint pain, memory lapses, ringing of the ears, dizziness, and inability to concentrate.

Tech sergeant, active duty flight engineer, grounded for 4 months after the vaccine, being treated at Walter Reed.

Master sergeant, retired, C–5 flight engineer. During his retirement ceremony just a couple of weeks ago, the squadron commander described him as becoming very ill in the last several months of his service and not being able to fly, and I found out that he had diabetes.

Staff sergeant, active duty C–5 loadmaster. He was healthy, 33 years old, until receiving the vaccine September 1998. Since then he's suffered from pneumonia, chronic pneumonia, more than once, memory loss, severe bone joint pain, dizziness, and hearing prob-

lems. The recent bone scan revealed lesions on his ribs, spine, and pelvis. They're treating him for skeletal tuberculosis, although the doctors are still puzzled. He's been grounded since February.

Staff sergeant, active duty loadmaster on C–5. He experienced chronic bone joint pain after receiving the vaccine. Said his arms frequently go numb. He filed a VAERS report. He's been grounded for so long the medical group asked him about a medical discharge, but he's not interested. He's been on active duty for 17 years and he wants to try to keep his pension.

Tech sergeant, active duty loadmaster, healthy prior to receiving the vaccine, first shot September 1998, 33 years old. Started having severe sinus problems, bone joint pain in October, started having memory lapses in December, and he described these memory lapses as, why am I standing in this room. He didn't know how he got there. And there's more than one testimony like that.

He was on convalescent leave during February following a surgery and told by the squadron supervision to get up to the base now and get your third anthrax vaccine. He had a friend drive him up there because he couldn't drive. He was uncomfortable to get the shot since he was on antibiotics and he had just come off a steroid IV 2 days prior. He described the condition to the med tech. The med tech gave him the shot anyway, to receive the fourth shot on March 10th, and then 2 days after that has thyroid damage. He says he will be on thyroid medicine the rest of his life. He's been grounded since February. The VAERS report the base completed for him had incorrect data on it he found out. His home phone was incorrect, and they said he was not on medication when he received the vaccines so he filled out one on his own.

Airman, first class, active duty mission control specialist. She was healthy prior to the vaccine. After the second shot she started experiencing episodes of vertigo, ringing in the ears, and memory lapses. She has had five vertigo episodes. She describes them as being so severe she can't walk. The vertigo has ceased since the vaccine stopped and she is on a waiver not to receive anymore anthrax vaccine until her health improves. She said the anthrax issue is one reason why she plans on not reenlisting.

And by the way, we have more than one of those anthrax waivers after people have had a couple of shots until their health improves or for a period of a year depending on how the letter is written.

And I'd like to talk about one other person I wasn't planning on talking about because they're not in my squadron. It was the anaphylactic shock incident we had earlier this year. We have had one. The first panel said there hasn't been one. The chief of the immunization clinic at Dover had an anaphylactic shock experience. They are now putting her on antiallergy medicines, so she can maybe get the shot in the future I was told by the chief flight surgeon.

All these people have three things in common. They've all received the anthrax vaccine; they're all healthy prior to the vaccine; and they're all, except for the antephialtic shock, in my squadron. I've never seen anything like this before. I've been to five bases, to include Dover. If the Ninth Squadron health figures were the norm, then 101,000 troops would be suffering from this.

Excuse me. I'm getting a little shaken up here.

Our leadership seems to be desensitized, and that is not an attack on my chain of command. I believe there are people so close to this issue, they are so deep in the woods, they can't see the forest.

I'm a new guy. I've got a fresh set of eyes, and I can see the forest. It is as if it were snowing in the summer, and nobody wants to acknowledge it.

I'll close by saying I don't have any physical evidence. I don't have the resources for that. I don't have any physical evidence to link the anthrax vaccine to the illness, but I would like to close with a quote by who was then Senator William S. Cohen about drawing conclusions during the 1974 debate relating to the impeachment of President Nixon. "If you went to sleep on the ground outside here and woke up with fresh snow on the ground, certainly you would reasonably conclude that snow had fallen during the night even if you did not see it." I couldn't agree more. I would like to close by thanking you and the committee for allowing me to testify today.

Mr. BURTON. Thank you, Major Bates. I know that you and Major Rempfer had to take some risk to come here today. We appreciate that, and we'll do our dead-level best to make sure you're treated fairly. We appreciate your bravery in coming forth.

[The prepared statement of Major Bates follows:]

PREPARED STATEMENT OF SONNIE G. BATES, MAJOR, USAF

PREPARED FOR THE HOUSE OF REPRESENTATIVES

Committee on Government Reform

12 Oct 99

INTRODUCTION

Mr. Chairman, it is truly an honor to appear before your committee and to be given the opportunity to testify. I am a major on active duty in the United States Air Force. I am here today in response to your invitation seeking my views and experiences with regards to the AVIP. The views expressed in my testimony are my own and not meant to be taken as those of the DOD or the Air Force.

I have longed to be an Air Force pilot since the age of four, when I first saw the Thunderbirds perform at an air show. This life long dream kept me focused throughout high school, college, and flight school. I now have a wife and three kids. My youngest child, Seth, is autistic, which makes my conviction on this issue even stronger. Because Seth may need my support when he is an adult, I am committed to do everything in my power to sustain a long and healthy life.

When I received orders to go to Dover AFB I was aware that the anthrax vaccine might be required for mobility status. In fact, during my out-processing at Randolph AFB, I went to the immunization clinic to get all my shots for worldwide service. I expected to get the anthrax vaccine on that day. However, the technician said I did not need the anthrax vaccine for worldwide service and if Dover AFB required it, then I would get it there. This is an important point because I am describing how I did not have the concerns about the anthrax vaccine until after I witnessed the sickness at Dover AFB.

UNUSUAL ILLNESSES AT DOVER AFB

I was previously stationed at DAFB for three years (Nov 1993-Dec 1996); no unusual rates of illnesses were evident during my tenure. However, within the first week after reporting for duty this past August, I learned of several people who had strange illnesses. Everyone I spoke with linked their problem to the anthrax vaccine, since they were healthy before receiving the shot. This concerned me so I asked about the anthrax vaccine program during my first meeting with the squadron commander. He seemed very open and objective about the issue and recommended I do my own research if I have any concerns. He did confirm that this was a mandated program and reminded me of the consequences of those who refuse it.

My research began by talking to people that were grounded. (See Attachment 1 - List of People With Unusual Illnesses) As such, I have found that 12 people, in my squadron

alone, have unusual or disabling illnesses that did not exist prior to the anthrax vaccine and the causes are unknown. My conversations with these individuals bring to light obvious health and safety concerns. Medically diagnosed conditions of thyroid damage, liver damage, external and internal cysts (including cysts around the heart), autoimmune disorders, crippling bone/joint pain, seizures, memory loss, vertigo, and inability to concentrate have been documented. In addition, there are as many as 60 cases of such unusual illnesses at DAFB, a statistic recently confirmed by an official that testified before your subcommittee earlier this year. The common denominator in these cases is that all those suffering were inoculated with the anthrax vaccine. It defies logic to ignore the anthrax vaccine as causal in a majority, if not all, of these illnesses.

In all my life I have never seen sickness in this magnitude, especially in a group of people that should be physically fit for battle. Something is wrong. It's as if it is snowing in the summer and no one wants to acknowledge it.

This is not the military that I know. Physical fitness and soldiering go hand in hand. Until now, in my 13 years of service, at five different bases, I have witnessed only one person become afflicted with a serious and unusual illness. If my squadron health figures represented the norm, then approximately 4.4 percent of our military force would be disabled due to these strange illnesses. I hope there are not 101,000 active duty, reserve, and guard troops currently disabled with strange illnesses. If a local community or neighborhood had over 4 percent of their population effected by undefined illnesses, I am sure the people would be demanding answers.

Last week, I again expressed my concern to my squadron commander and he sent me to the Area Defense Council. They told me that a precedent had been set in that I might not be afforded the opportunity to put on a defense if I refuse the vaccine. The attorney said that they may try to make an example of me because of my rank and I may have to serve up to two years in prison. When I told my wife this she began to cry. After five military moves in thirteen years, and all the sacrifices she has made, how could I look at her without an answer? No one wants answers to this bizarre situation more than I do.

LACK OF MEDICAL SUPPORT

Aircrew members are afraid they will be grounded and then not cared for properly by our medical staff. One pilot in our squadron told me a doctor used the term "malingerer" when describing her slow recovery process. Nothing could be more insulting to this officer who has suffered from an autoimmune disorder and thyroid damage after she received the anthrax vaccine.

Our flight surgeons appear to have marching orders not to investigate the cause of all these illnesses. The company line from the medical field is, "I do not know what caused the illness, but I do know it wasn't from the anthrax vaccine". The only person in the medical community that had the conviction and integrity to come forward was our patient advocate. He claims, "[he] has been ostracized by the medical community." He now is adversely paying for his belief in what the AF calls "The Core Values".

One flight surgeon told me that there have been 62 VAERS reports filed, but he believes some of them are sympathetic. Maybe the doctors do not understand that our crewmembers, especially our enlisted, need to fly to keep from losing their flight pay. Therefore, the idea of grounding oneself for sympathetic reasons just does not make sense.

RISK MANAGEMENT IN THE MILITARY

Safety issues must be addressed. Many people at this base are experiencing symptoms, which impede their performance to a degree that may be hazardous. Memory loss, dizziness, and an inability to concentrate, to the acute degree that these people describe, are dangerous symptoms in a soldier's line of work. One pilot described his short-term memory loss as "not remembering a conversation that took place twenty minutes earlier." At the time, this pilot was on flying status. This type of memory lapse problem could lead to catastrophe in aviation.

I am willing to accept the understood risks associated with military service. These risks are normally considered to be direct, with the results being realized fairly soon after the action taken. Typical examples are getting injured or killed on the job, during an exercise, or in actual combat. One of the more glamorous Air Force examples of accepting risk is the test pilot mission. However, how many young people will desire to be like Chuck Yeager when they realize the "new age" risks might include taking part in medical research without their consent.

I have been trained to manage risks to avoid undue harm. I do believe in the military structure, and the importance of following lawful orders. Congress should draft legislation to require a soldier's consent to participate in medical research.

MISREPRESENTATION OF THE ANTRHAX VACCINE

The office of the Secretary of Defense Anthrax Vaccine web page states, "Since 1970, it has been safely and routinely administered to at-risk wool mill workers, veterinarians, laboratory workers, and livestock handlers in the United States." However, I have found that civilian doctors and veterinarians, in general, do not have experience with this vaccine and do not know how to acquire it. I have personally called numerous civilian veterinarian and medical doctors to see what they know about the anthrax vaccine. Not one, including the Chief Veterinarian for the State of Delaware, had ever received or administered the anthrax vaccine, nor do they know how to acquire it.

HELMET ANALOGY

Some leaders have used the analogy of comparing the anthrax vaccine to a helmet. And they say it would be a dereliction of duty to send troops into battle without the helmet and/or the anthrax vaccine. This argument is misleading. I have a helmet; it is called a chemical warfare suit.

FDA APPROVAL

The FDA approval is not an issue for me. A hamburger may be FDA approved, but if the processing plant is negligent, the consumer may pay with his life.

POSSIBLE CONTAMINATION OF THE ANTHRAX VACCINE

There is an on-going controversy over the sterility and purity of the anthrax vaccine. The February 1998 FDA inspection report states;

> "Of the 6 sublots contaminated in September and October 1997, 4 were contaminated with B. anthracis, one with Bacillus cereus and one identified only as Bacillus species. The firm initiated investigations into these contaminations (97DAV42, 97DAV53, 97DAV49, 97DAV52 and 97DAV64; I did not investigate one of the six lots). It was determined by the firm that, other than technician error (in reference to the contamination in sublots AV636 and AV637), a change in filters due to the previous filter being discontinued, was the cause of the contamination with B. anthracis in several sublots. All sublots which were made with these filters in place were quarantined until all release testing was finished and QA released the sublots. As an [example], the deviation report for sublot AV646 is included (Exhibit 9B)

In Dr. Meryl Nass' 30 Sep 99 Written testimony to the House Armed Services Committee, she writes;

> "Included with this testimony are charts detailing the lots in the MBPI stockpile, the dates of release, and some of the supplemental testing issues that have led to their quarantine. The statements previously cited by Dr. Gilbreath and Gen. Cain indicate that not all lots have been, or were intended to be, supplementally tested."

Dr. Nass' 15 page testimony referenced above along with the FDA's 79 page report, reveal compelling evidence that the current vaccine out in the field may be suspect to contamination.

WHY I AM AGAINST THIS ANTHRAX VACCINE

- It is a common denominator to the unusual illnesses at our base.
- It is not available to the public – gives the appearance of being experimental.
- Congressional Staff Report 103-97 says, "Although the results of this study suggest the vaccine might protect against anthrax that has been sprayed, it is not sufficient to prove that anthrax vaccine is safe and effective as used in the Persian

Gulf. The anthrax vaccine should therefore be considered investigational when used as a protection against biological warfare"

- The product insert states, "Studies have not been performed to ascertain whether Anthrax vaccine absorbed has carcinogenic action, or any effect on fertility."
- Dr. Kwai Chan testified on 29 April 1999, "The long-term safety of the vaccine has not yet been studied."
- I am concerned about the vaccine being contaminated.
- I do not believe the AVIP mandate is a lawful order. There must be a law that prevents un-consented tampering with my body.
- The risk is too great. If I lose my health, I am no good to my country and I become an extra burden to my family.
- I believe it is wrong to inject anyone against his or her will, especially with a drug that has not been used by the general public.
- Religious reasons. However, the current Air Force policy states that you must be against all vaccines to request a religious waiver. I believe the Air Force has over-stepped its authority on this sub-issue. (See attachment – Stance of the United Methodist Church)

NEED FOR STANDARD PROCESS FOR THOSE WHO REFUSE

There is even controversy over the process for those refusing this vaccine. A naval officer in California is given a swift HONORABLE discharge, while others are spending time in jail and receiving less than honorable discharges. Has the DoD admitted guilt by giving the naval officer an honorable discharge for refusing this vaccine? There are several other examples of inconsistencies across the nation. As I explained earlier, I might face a two-year prison sentence. I DO NOT WANT A DISHONORABLE DISCHARGE. I DO NOT WANT AN HONORABLE DISCHARGE. I WANT AN HONORABLE MILITARY.

CONCLUSION

Our leadership seems desensitized to the illnesses at our base. The anthrax program appears to be taking precedence over the people. Make the vaccine voluntary and see how many people really believe in it.

Congressional investigations have uncovered several examples of how the military has experimented on its own people (Congressional Staff Report 103-97). Congress must put

a stop to this. A line has to be drawn on how far the military can go when it comes to tampering with a person's health.

How will this issue affect potential new recruits if the situation is not corrected? Most new recruits understand and are willing to accept the risks of being injured or killed while accomplishing the mission of the Air Force. However, most people would steer away from a military career if they thought they might be subject to medical research without their consent. At the rate the guard and reserves are losing people, I am sure the recruiting offices are faced with an extraordinary challenge to fill these open positions.

On September 29, 1999 the committee was told that there was not a retention problem. However, 60 reserve pilots have quit at Dover AFB alone. I have confirmed this with long time friends in the reserves and by calling the operations officer and asking if there were any vacancies.

I feel fortunate that we are early enough in this program for Congress to take appropriate and timely action. It is amazing how before the anthrax vaccine people at this base did not suffer from undefined illnesses. Although evidence linking Dover's unusual illnesses to the anthrax vaccine is circumstantial, I would like to end with a 1974 quote by the then Senator William S. Cohen about drawing inferences properly, during a debate relating to the impeachment of President Nixon **"If you went to sleep on the ground outside here, and woke up with fresh snow on the ground, certainly you would reasonably conclude that snow had fallen during the night even if you did not see it."** I couldn't agree more.

Again, I thank you for giving me this opportunity to testify

Sonnie Bates, Maj, USAF

ATTACHMENT 1 - LIST OF PEOPLE WITH UNUSUAL ILLNESSES
(Asterisk indicates individual has allowed me to release their name upon request)

The following is a list of people that I have first hand knowledge of that are suffering from diverse illnesses at Dover Air Force Base

Personnel with strange illnesses in the 9th Airlift Squadron

* Captain xxxxxxxxxxxx – Active Duty C-5
Has been grounded for several months. She was healthy before receiving the anthrax vaccine. Suffers from autoimmune disorder. Has sustained thyroid damage.

* Captain xxxxxxxxx– Active Duty C-5 Pilot
Has been grounded for several months after taking the fourth shot. He was healthy before receiving the anthrax vaccine. He developed cysts on numerous places on the inside and outside of his body, to include his heart. He has undergone surgery to remove some of the cysts and was hooked up to an IV for six weeks. He says the medical group is working on a waiver to get him back on flying status, even though he still has the cysts around his heart. He is afraid for his future. He is afraid that he will never fly again in the military or as a civilian. He said the flight doctor did eventually hand him a VAERs report and told him that she was going against her instructions to do so, but she thought he should fill one out anyway.

Major XXXXXX – Active Duty C-5 Pilot
Being treated for an autoimmune disorder.

* Major xxxxxxxxxx – Active Duty C-5 Pilot
Has been grounded for several months. He was healthy before receiving the anthrax vaccine. He has been suffering from crippling bone/joint pain and ringing in the ears. The pain is so bad he cannot climb the steps to get into the airplane. He has been battling various infections continuously during these past several months and has developed new allergies in the past one month. Has been in physical therapy for three months with no improvements.

Staff Sgt xxxxxxxxxxxxx– Active Duty C-5 Flight Engineer
After the fourth vaccine he began to experience diverse symptoms, which included chronic bone/joint pain, chronic fatigue, and a loss of ability to concentrate. He has been cross-trained into another, less demanding career field.

Technical xxxxxxxxx – Active Duty C-5 Flight Engineer
Has been grounded for eight months after receiving the vaccine. Has experienced eight seizures. Other symptoms include crippling bone/joint pain, memory lapses, ringing in the ears, dizziness, and an inability to concentrate.

ATTACHMENT 1 – continued

Technical Sgt xxxxxxxxxxxxxxxxxx - Active Duty C-5 Flight Engineer
Has autoimmune disorder.

Master Sgt (ret) xxxxx – Retired C-5 Flight Engineer
During his retirement ceremony the squadron commander described how he became ill and was grounded during his last months of service.

Staff Sgt XXXXXXX – Active Duty C-5 Loadmaster
He was healthy until receiving the anthrax vaccine. Now he suffers from tuberculosis of the bones.

* Staff Sgt xxxxxxxxxxx – Active Duty C-5 Loadmaster
He experienced chronic bone/joint after receiving the vaccine. He said his arms frequently go numb. Filed a VAERS report. He has been grounded for so long the medical group has questioned him about a medical discharge. However, he is not interested in a medical discharge because he has been in the military for over 17 years and does not want to lose his pension.

* A1C xxxxxx – Active Duty Mission Control Specialist
She was healthy prior to the anthrax vaccination. After the second shot she started experiencing episodes of vertigo, ringing of the ears, and memory lapses. She has had five vertigo episodes, described as being so severe that she couldn't walk. The vertigo has ceased since the vaccine has stopped and she is on a waiver to not receive any more anthrax vaccine until her health improves. She said that the anthrax issue is one reason why she plans on not re-enlisting.

Reserves

Captain XXXXXXX - Reserve C-5 Pilot
Since receiving the vaccine, he has experienced headaches, dizzy spells, short-term memory loss, and bed spins. These symptoms lasted for about a month. He has received a waiver so that he doesn't have to take the vaccine for another year. The medical group ruled out a brain tumor. Oddly enough, before a brain tumor was ruled out and after the dizziness stopped, he was allowed to fly.

3rd Airlift Squadron
Captain XXXXXXX – Active Duty C-5 Pilot
Became very ill after receiving the vaccine and experiencing short-term memory loss. He also said that his wife had recently become extremely ill. An Electro Dermal Scan revealed heavy traces of anthrax in his blood. His wife's blood also showed traces of anthrax.

Attachment 2 – Congressional Testimony by Major Bates

STANCE OF THE UNITED METHODIST CHURCH

The Air Force has taken a stance on denying requests for waivers based religious objections, unless the religious organization does not accept all vaccines. This is an unjust policy. According to the Book of Discipline of the United Methodist Church, Copyright 1992, page 97, paragraph 72k:

> "Physical and mental health has been greatly enhanced through discoveries by medical science. It is imperative, however, that governments and the medical profession carefully enforce the requirements of the prevailing medical research standard, maintaining rigid controls in testing new technologies and drugs utilizing human beings. The standard requires that those engaged in research shall use human beings as research subjects only after obtaining full, rational, and uncoerced consent."

There has been no research on the long-term health effects of the anthrax vaccine. The Department of Defense is currently studying the adverse affects of the vaccine, which puts the drug in research status. Congressional Staff report 103-97 states the following when addressing the animal studies conducted on this vaccine:

> "Although the results of this study suggest the vaccine might protect against anthrax that has been sprayed, it is not sufficient to prove that anthrax vaccine is safe and effective as used in the Persian Gulf. The vaccine should therefore be considered investigational when used as a protection against biological warfare."

Therefore, any member of the United Methodist or other church with similar bylaws should be able to request a waiver from this vaccine based on religious objection.

BIOGRAPHY

MAJOR SONNIE G. BATES

Major Sonnie G. Bates is a newly assigned C-5 pilot at Dover Air Force Base. He was commissioned through the Reserve Officer Training Corps program in June 1986 and entered the Air Force in September of that same year. He has over 3,000 hours flying experience in the T-37B Primary Trainer and the C-5 Galaxy Strategic Airlifter.

EDUCATION
1986 Bachelor of Science in Math, Northern Kentucky University, Highland Heights, KY
System Safety Management Course, University of Washington, College of Engineering
Certified Level One Program Manager, Aeronautic Systems Center, Wright-Patterson AFB, OH
Squadron Officer School, Maxwell AFB, AL

ASSIGNMENTS
T-37 Instructor Pilot, Vance AFB, OK; 1986-1989
T-37 Flight Examiner, Detachment Commander, Grissom AFB, IN; 1989-1993
C-5 Aircraft Commander, 436th APS Flight Commander, Dover AFB, DE; 1993-1996
C-17 System Safety Program Manager, Wright-Patterson AFB, OH; 1996-1998
T-37 Pilot Instructor Training Flight Commander, Randolph AFB, TX; 1998-1999
C-5 Aircraft Commander, Dover AFB, DE; Current

AWARDS AND DECORATIONS
Meritorious Service Medal with oak leaf cluster
Air Force Commendation Medal with oak leaf cluster
Air Force Achievement Medal

OTHER ACHIEVEMENTS:
Instructor Pilot of the Quarter in three organizations - 5th FTS, 559th FTS, 12th OG
Company Grade Officer of the Quarter in three organizations - 3rd AS, 436th APS, 436th OG
AMC Air Freight Operation of the Year, 1996
Aircrew Safety Award of Distinction - 12th Flying Training Wing, 19th Air Force, and AETC

EFFECTIVE DATES OF PROMOTION:
Second Lieutenant - June 14, 1986
First Lieutenant - June 15, 1988
Captain - July 26, 1990
Major - April 1, 1998

Mr. BURTON. Major Rempfer.

Major REMPFER. Thank you, Chairman Burton, members of the committee.

I open my testimony with the core values of the United States Air Force: "Integrity first, service before self, and excellence in all we do."

I've served our Nation faithfully and honorably for 12 years as an officer, 4 prior to that as an Air Force Academy cadet. I've flown F–16's and F–117's and most recently A–10's for our Nation's Air Force, and I intend on serving for many years to come.

I'm not here to speak about the safety of the vaccine or the efficacy. Instead, I'm here to discuss another reason for the growing retention problem generated by the Anthrax vaccination policy. Its integrity and its relationship to this policy and how it extends to doctrine. After exhausting all avenues within my chain of command and communicating with hundreds of service members for the past year, I've concluded that the root cause of the negative reaction to the anthrax vaccination policy is a sense that the professional standards demanded of military personnel have been consistently violated by those implementing this program. It is not, as DOD officials assert, simply a failure to educate the troops. Instead, it is a failure to communicate the truth, the whole truth, and nothing but the truth, and I'll offer up a few examples.

First, when the Anthrax vaccination policy was announced on December 15, 1997, a senior officer who refused to be named told reporters, "It's been licensed since 1970 and has a proven safety record. It's been documented."

The whole truth is that in April 1998, Dr. Catherine Zoon of the FDA stated in a letter that, "clinical studies conducted on the long-term health effects of taking the anthrax vaccine have not been submitted to the FDA." The Government Accounting Office reiterated this fact on April 30, 1999, and just recently the Army has announced that they will now conduct a study.

Next, the Assistant Secretary of Defense for Health Affairs, who is a physician, also told Congress on March 24 that, "The safety of our AVIP was also confirmed by an independent review of the program." She was referring to a report by a Yale University medical professor who was selected by DOD to review the health and medical aspects of the anthrax vaccination policy before its implementation. This is one of the four mandates by the Secretary of Defense.

The whole truth is that the doctor our DOD repeatedly cited for over a year as their independent expert is really an obstetrician and gynecologist. He wrote Congress, upon being requested to testify last April, that he had informed the DOD at the time of the review that he had no expertise in anthrax. DOD has never acknowledged this admission by their "expert" or explained why they asked an OB/GYN to review a biological warfare immunization program. As a result, by service members the DOD's independent review is considered to be a sham.

Finally, the Assistant Secretary of Defense for Public Affairs has also asserted for months that the number of refusals is only about 200 service members, inferring no significant impact to readiness. Yet on September 30th a DOD spokesman finally acknowledged that the DOD has made no effort to track refusals.

The whole truth is that the DOD has carefully crafted a ''no bad news'' tracking system that only tracks the administration of the shots but does not track adverse reactions or refusals. The Deputy Secretary of Defense admitted to Congress on September 30 he was reluctant to count refusals through a central tracking system because it would undermine command authority. He did not elaborate why telling the truth would undermine the chain of command.

I have seven additional examples of contradictory statements by DOD and senior officials that elaborate on this concern of service members. One is from the Assistant Secretary of Defense for Public Affairs, two from the Assistant Secretary of Defense for Reserve Affairs, one from the Deputy Secretary of Defense, one from the Secretary of the Army, one from the Director of the Air National Guard, and one from the Secretary of Defense. I can hold those off until later, and they are included in my written testimony unless you would like me to elaborate at this time.

Mr. BURTON. Major Rempfer, I think we'll get to those after a bit. I really appreciate the research that you've done on this, and we will have those for the record. We will look at those.

Major REMPFER. And so, to conclude, I would just like to say that these three lapses and the others that I've included are merely the beginning of the unraveling of the truth. They have placed the military commanders at all levels in an untenable position, either implement a questionable policy or sacrifice their careers. Consequently, the anthrax vaccination policy has turned into a biological loyalty test.

The anthrax vaccine is no longer perceived by the troops as a health policy. Instead it's become an issue of good order and discipline. Loyal service officers must now show their loyalty to the chain of command by submitting to the vaccine. For those who don't, there is arbitrary discipline, incarceration and court marshal for some, dismissal and disgrace for others. And some are merely asked to leave and keep quiet.

Each of these examples demonstrates a breakdown of intellectual honesty, which is the linchpin of integrity and doctrine between commanders and their troops. Without honesty, doctrine is merely dogma, as Congressman Shays referred to with the ''medical Maginot Line'' concept today. Doctrine would require the tacit cooperation of our adversaries to use the only biological agent against which we have invasively defended ourselves. It requires our adversaries to not use chemical agents at all. It requires our adversaries to attack only the 1 percent of Americans who are vaccinated.

Recognizing the long-term logical implications of this facade of force protection, Dr. Ken Alibek, the former deputy director of the Soviet biological weapons program, told the Joint Economic Committee of Congress that, ''In the case of most military and all terrorist attacks with biological weapons, that seems to be of little use.''

Further, he recently stated, ''We need to stop deceiving people that vaccines are the most effective protection and start developing new therapeutic and preventive approaches and means based on broad-spectrum protection.''

I think that's what your service members are asking for as well. Service members have discovered an acute dichotomy between

what defense officials are telling Congress and the information readily available in government documents, congressional testimony, medical research, and news reports. This contrast creates an ethical dilemma for service members whose core values require the questioning of immoral orders.

Consequently, out of respect for the constitutional imperative of civilian control of the military, we have reluctantly and repeatedly asked for Congress to intercede and stop the corrosive impact the anthrax vaccination policy is having on our Nation's military. If Congress is not proactive in response to the DOD's absence in this case, the unfortunate reality is that those members of the voluntary military who are tying to embody these core values simply leave.

I'll close with an excerpt from the Soldier and the State by noted Harvard military scholar Samuel Huntington. He rhetorically asked, "What does the military officer do when he is ordered by a statesman to take a measure which is militarily absurd when judged by professional standards?" Huntington answered, "The existence of professional standards justifies military disobedience."

Our professional standards have been made very clear to us: Integrity first, service before self, and excellence in all we do. I believe I would be derelict in my duty if I did not take this opportunity to express this professional dissent. As well, it would be unconscionable for me not to seek redress for all the service members that have been affected by it, that are dedicated to the profession of arms and who have inextricably been drawn into this professional military dilemma.

Mr. Chairman, thank you for listening to us today and looking out for the interest of service members.

Mr. BURTON. Thank you, Major.

[The prepared statement of Major Rempfer follows:]

Statement by

Major Thomas L. Rempfer

To

Government Reform and Oversight Committee
U.S. House of Representatives

October 12, 1999

Chairman Burton, Members of the Committee, I open my testimony with the core values of the US Air Force.

"Integrity first, service before self, and excellence in all we do."

I am not here today to speak about the safety and efficacy of the anthrax vaccine. Instead, I am here to discuss the reason for the growing retention problem generated by the anthrax vaccination policy: it is integrity, and its relationship to doctrine.

After exhausting all avenues within my chain of command, and communicating with hundreds of servicemembers over the past year, I have concluded that the root cause of the negative reaction to the anthrax vaccination policy is a sense that the professional standards demanded of military personnel have been consistently violated by those implementing this policy. It is not, as DoD officials assert, simply a failure to educate, but instead a failure to communicate the truth, the whole truth, and nothing but the truth. Here are just a few examples:

First, when the anthrax vaccination policy was announced on December 15, 1997, a senior officer, who refused to be named, told reporters: "It's been licensed since 1970, [and has a] proven safety record. It's been documented."[1]

- The whole truth is that in April 1998, Dr. Kathryn Zoon of the FDA stated in a letter that, "data for clinical studies conducted on the long term health effects of taking the anthrax vaccine have not been submitted to the FDA."[2] The Government Accounting Office reiterated this fact on April 30, 1999[3], and just last week the Army announced they would now conduct such a study.[4]

Next, the Assistant Secretary of Defense for Health Affairs, who is a physician, told Congress on March 24th that "the safety of our AVIP was also confirmed by an independent review of the program."[5] She was referring to a report by a Yale University Medical School professor who was selected by DOD to review the health and medical aspects of the anthrax vaccination policy before its implementation.

- The whole truth is that the doctor our DOD repeatedly cited for over a year as their "independent expert" is really an obstetrician and gynecologist. He wrote Congress, upon being requested to testify last April, that he had informed DoD at the time of the review that he had "no expertise in anthrax."[6] DOD has never acknowledged this admission by their "expert" or explained why they asked an OB/GYN to review a biological warfare immunization program. As a result DOD's independent review is perceived as a sham.[7]

Next, the Assistant Secretary of Defense for Public Affairs speaking about the vaccine in January said, "It's safe and reliable...It works and has no side effects."[8] On June 29th he ridiculed the idea of adverse reactions to the vaccine when he told reporters: "I've had three shots. My hair is growing more robust than ever. I sleep better. I eat better, run farther. It's been nothing but a great experience."[9]

- The whole truth is that DOD physicians met at Ft. Detrick, MD, on 25 to 27 May, 1999 to discuss adverse reactions to the vaccine, including the case of an Air Force pilot who developed an auto-immune disorder after receiving the vaccine and had been grounded since November, 1998.[10] On September 30th the Army Surgeon General admitted to 72 cases of adverse reactions that had required hospitalization – while he continued to minimize the risk of the vaccine.[11]

Next, the Assistant Secretary of Defense for Public Affairs has also asserted for months that the number of anthrax refusals is only about 200 servicemembers, inferring no significant impact to readiness. Yet, on September 30th a DoD spokesman finally acknowledged that DoD had made a conscious decision not to track refusals.[12]

- The whole truth is that DoD crafted a "no bad news" tracking system that only tracks the administration of shots, but does not track adverse reactions or refusals. The Deputy Secretary of Defense admitted to Congress on September 30th, "he was reluctant to count refusals through a central tracking system because it would undermine command authority."[13] He did not elaborate why telling the truth would undermine the chain of command.

Next, the Assistant Secretary of Defense for Reserve Affairs stated on August 17, 1999: "before Secretary Cohen authorized the use of a single dose, he ordered supplemental testing of the vaccine, doubly ensuring the vaccine's safety and far exceeding any pharmaceutical industry standards. Supplemental testing, combined with the ongoing supervision of the FDA, demonstrates that the vaccine is safe and effective."[14]

- The whole truth is that on April 29, 1999, BG Eddie Cain admitted that DoD had suspended the supplemental testing after "inconsistencies" were found in the procedures being used by the manufacturer, Bioport, despite supervision by another DoD contractor hired to oversee the testing.[15] Additionally, the GAO reported that supplemental testing couldn't compensate for a flawed manufacturing process.[16]

Next, the Assistant Secretary of Defense for Reserve Affairs additionally testified to Congress on September 29th, after being reminded he was under oath, that if someone is going to resign over anthrax, "they are certainly not going to be subject to any penalties. This is one of the points of the Guard and Reserve."

- The whole truth is that five days later the commander of the 184th Bomb Wing, Kansas Air National Guard, issued a written warning to a B-1 bomber pilot threatening a $500 fine and six months in jail, because the pilot had asked to transfer in lieu of submitting to the vaccine. [17].

Next, the Deputy Secretary of Defense wrote Newsweek Magazine on April 3, 1998 about the anthrax vaccine manufacturer, stating, "no shutdown was ever directed or contemplated as a result of any FDA inspection."[18] Additionally, on August 5, 1999, a senior officer who refused to be named told reporters that a threatened FDA shutdown of the manufacturer's production line was an "urban legend."[19]

- The whole truth is that the FDA sent a "notice of intention to revoke" the manufacturer's license on March 11, 1997 after "significant deviations" discovered during previous inspections remained uncorrected.[20] A follow-up FDA report in February 1998 found that, "the manufacturing process for Anthrax Vaccine is not validated."[21] The manufacturer subsequently "voluntarily" suspended anthrax vaccine production. All of the vaccine used on servicemembers to-date was manufactured during the period of repeated significant deviations from FDA manufacturing standards.

Next, in September 1998, the Secretary of the Army wrote a letter indemnifying the anthrax vaccine manufacturer.[22] It stated: "The obligation assumed by [the manufacturer] under this contract involves unusually hazardous risks associated with the potential for adverse reactions in some recipients and the possibility that the desired immunological effect will not be obtained by all recipients." When that letter surfaced in June, DOD called it "a misreading of a routine contracting procedure."[23]

- The whole truth is that the last vaccine to receive similar indemnification was the swine flu vaccine in 1976 – a health care fiasco that was supported by the health care community as the anthrax vaccine appears to be today.[24]

Next, the Director of the Air National Guard testified under oath on September 29, 1999 that only one member of the Air National Guard had left over the anthrax vaccine.

- The whole truth is that eight pilots from the Connecticut ANG resigned or transferred specifically because of the anthrax vaccine, as did seven pilots in the Wisconsin ANG who are now grounded while awaiting out-processing. Four days after this testimony denying attrition, 22 of 50 pilots in the Tennessee ANG unit in Memphis quit – along with 38 other servicemembers. These are just a few examples of the current attrition and pale in comparison to the expected losses to a program just beginning in the reserves.

Finally, the Secretary of Defense has stated that he would be "derelict" in his duty if he did not mandate use of the anthrax vaccine.[25]

- The whole truth is that weaponized anthrax has been available since World War II and the anthrax vaccine has been available since 1970. Additionally, the GAO has testified that, "the nature and magnitude of the military threat of biological warfare has not changed since 1990."[26] Accepting the Secretary's statement means that every other Secretary of Defense in the post-Cold War era has been derelict for not mandating the vaccine. Framing the anthrax vaccination as a moral imperative has precluded an intellectually honest debate about this policy and has resulted in punishment of those who question it.[27]

Analysis:

These ten lapses of our core values are merely the beginning in the unraveling of the truth. They have placed military commanders at all levels in an untenable position: either implement a questionable policy or sacrifice their careers. Consequently, the anthrax vaccine policy has turned into a biological loyalty test. The anthrax vaccine is no longer a health policy. Instead, it has become an issue of "good order and discipline" and the ability of the military's leadership to impose its will on subordinates. Loyal servicemembers now must express their fealty to the chain of command by submitting to the vaccine. For those who don't, there is arbitrary discipline – incarceration and court-martial for some, dismissal and disgrace for others.[28]

Each of these examples demonstrates a breakdown of intellectual honesty, which is the linchpin of integrity and doctrine. Without honesty doctrine is merely dogma. Congressman Shays has referred to the anthrax vaccination policy as a "medical Maginot Line."[29] It requires the tacit cooperation of our adversaries to use the only biological agent against which we have invasively defended ourselves. It requires our adversaries to not use chemical agents at all. It requires our adversaries to attack only the one percent of Americans who are vaccinated. Recognizing the logical long-term implications of this façade of force protection[30], former deputy director of the Soviet biological weapons programs, Dr. Ken Alibek, told the Joint Economic Committee of Congress that: "In the case of most military and all terrorist attacks with biological weapons, vaccines would be of little use."[31] Further, he recently stated: "We need to stop deceiving people that vaccines are the most effective protection and start developing new therapeutic and preventive approaches and means based on a broad-spectrum protection."[32]

Servicemembers have discovered an acute dichotomy between what defense officials are telling Congress and the information readily available in government documents, Congressional testimony, medical research and news reports.[33] This contrast creates an ethical dilemma for servicemembers whose core values require the questioning of immoral orders. Consequently, out of our respect for the Constitutional imperative of civilian control of the military we have reluctantly and repeatedly asked Congress to intercede and stop the corrosive impact the anthrax vaccination policy is having on our

nation's military. If Congress is not proactive in response to DOD's absence of intellectual honesty, the unfortunate reality is that those members of the all-volunteer military who embody its core values will simply leave.

I close with an excerpt from *The Soldier and the State,* by noted Harvard military scholar, Samuel Huntington. He rhetorically asked, "what does the military officer do when he is ordered by a statesman to take a measure which is militarily absurd when judged by professional standards and which is strictly within the military realm without political implications?" Huntington answered, "the existence of professional standards justifies military disobedience."[34]

Our professional standards have been made very clear: Integrity first, service before self, and excellence in all we do. Therefore, I believe I would be derelict in my duty if I did not take this opportunity to express my adamant professional dissent toward the Anthrax Vaccine Immunization Policy. As well, it would be unconscionable for me not to seek redress for all servicemembers, dedicated to the profession of arms, who have been inexorably drawn into this professional military dilemma.

Mr. Chairman, I offer sincere thanks to you for looking out for our nation's servicemembers.

Chronology and Information Paper on the US Servicemember's Anthrax dilemma:

http://www.dallasnw.quik.com/cyberella/Anthrax/Chron_Info.html

References:

[1] http://www.defenselink.mil/news/Dec1997/x12181997_x1215mfp.html
[2] Dr. Kathryn Zoon, FDA Director of Biologics Evaluation and Research, 28 Apr 1998, at http://www.dallasnw.quik.com/cyberella/Anthrax/Zoon4_98.html
[3] http://www.house.gov/reform/ns/hearings/testimony/mrchan4-30.htm
[4] http://www.defenselink.mil/news/Oct1999/n10071999_9910074.html
[5] http://www.house.gov/reform/ns/hearings/testimony/testimonybailey.htm
[6] http://www.dallasnw.quik.com/cyberella/Anthrax/Burrow_4_99.htm
[7] http://www.dallasnw.quik.com/cyberella/Anthrax/Editorial2.html
[8] http://www.defenselink.mil/news/Jan1999/n01221999_9901222.html
[9] DOD press briefing, 29 Jun 99, http://www.defenselink.mil/news/Jun1999/t06301999_t0629asd.html
[10] http://www.dallasnw.quik.com/cyberella/Anthrax/FtDetrick5_99.html
[11] http://www.washingtonpost.com/wp-srv/aponline/19990930/aponline174510_000.htm
[12] http://www.defenselink.mil/news/Sep1999/t09301999_trfg-930.html
[13] http://www.washingtonpost.com/wp-srv/aponline/19990930/aponline174510_000.htm
[14] http://www.defenselink.mil/news/Aug1999/n08171999_9908176.html
[15] http://www.house.gov/reform/ns/hearings/testimony/cain4-30.htm
[16] http://www.house.gov/reform/ns/hearings/testimony/mrchan4-30.htm
[17] Letter from Commander, 184th Bomb Wing, Col Edward A. McIlhenny dated 4 Oct 1999 (submitted to committee)

[18] http://www.defenselink.mil/other_info/newswkedit.html
[19] http://www.defenselink.mil/news/Aug1999/x08051999_x0805ant.html
[20] http://www.dallasnw.quik.com/cyberella/Anthrax/Mar97.html
[21] http://www.defenselink.mil/news/Aug1999/x08051999_x0805ant.html
[22] http://www.dallasnw.quik.com/cyberella/Anthrax/Mem_D_98.html
[23] http://www.defenselink.mil/news/Jul1999/n07021999_9907022.html
[24] Kreisher, Otto, "Maker of anthrax shot seeks bailout", San Diego Union-Tribune, July 1, 1999
[25] http://www.defenselink.mil/news/Mar1999/n03101999_9903103.html
[26] http://www.house.gov/reform/ns/hearings/testimony/mrchan4-30.htm
[27] Graham, Bradley, "Air Force Censures Vaccine Critic," Washington Post, August 2, 1999
[28] http://www.dallasnw.quik.com/cyberella/Anthrax/Chron_Info.html
[29] Shays, Christopher, Rep (R-CT), House Government Reform Subcommittee on National Security, fifth hearing on AVIP, September 29, 1999
[30] http://www.house.gov/reform/ns/hearings/testimony/written_testimony_of_maj.htm
[31] Statement by Dr. Kenneth Alibek before the Joint Economic Committee of Congress Wednesday, May 20, 1998
[32] http://www.emergency.com/1999/alibek99.htm
[33] http://www.dallasnw.quik.com/cyberella/Anthrax/refute.html
[34] Huntington, Samuel P., *The Soldier and the State*, pg. 77

Mr. BURTON. Dr. Halsey.

Dr. HALSEY. My name is Dr. Neal Halsey. I'm a pediatrician specializing in the study of infectious diseases and vaccines at the Johns Hopkins University School of Public Health. I thank you, Mr. Chairman, for the opportunity to provide this committee with my perspective on the important issue of vaccine safety.

I've had the opportunity to care for children who have suffered from each of the infections that can be prevented through vaccination. I've also cared for children who have developed serious adverse reactions to vaccines. My objective, and I believe the objective of most people in this room, is to ensure that both children and adults receive the safest vaccines possible to protect them from serious infectious diseases.

I've had the opportunity to review the written testimonies of Drs. Harold Margolis, Samuel Katz, and David Satcher in their appearances before this committee and Congressman Mica's subcommittee. These witnesses have detailed the enormous benefits from immunizations, and I agree with their statements. Therefore, I will not reiterate the benefits of vaccines in my testimony today, but I will be happy to answer any questions regarding this issue.

I was asked to comment on three issues: one, the number of vaccines that children receive; second, combination vaccines; and, third, diabetes. I am not concerned about the number of vaccines that children receive, and I look forward to the availability of several other vaccines that will help us prevent serious infections and cancer.

The human immune system is remarkable in its capacity to respond to millions of different antigens. Children are exposed to many thousands of bacteria, fungi, and viruses beginning at the moment of birth. Exposure to a single bacteria stimulates an immune response to 17 to 50 different proteins.

Some new vaccines, such as the Haemophilus influenzae, or Hib vaccine as it's called, contain only one or two bacterial antigens. Therefore, children immunized with this vaccine are exposed to fewer antigens than naturally infected children, and immunized children are protected against meningitis and sepsis.

Recently, concerns have been raised about the amount of thimerosal, a mercury containing preservative, and other products in some vaccines. Manufacturers, the Food and Drug Administration, the CDC, and the American Academy of Pediatrics have responded rapidly to these concerns to make new products available and reduce infants' exposures to these components. I anticipate that further steps will be taken in the near future to eliminate these concerns. The use of combination products reduces the total exposure to these components and theoretical concerns about these issues.

Children benefit from combined vaccines because they're protected against several different diseases with a single injection, thereby reducing pain and discomfort. If vaccines that are currently given in combination were administered at separate visits, children would be left unprotected against some diseases for varying periods of time. As we learned a decade ago with the resurgence of measles in this country, leaving children unprotected even for a few weeks or months can lead to epidemics and unnecessary

suffering and deaths. We do not need to learn those same lessons over again.

I know that you, Mr. Chairman, are concerned about combining measles, mumps, and Rubella vaccines in the same syringe. The studies and theories that were raised by Dr. Andrew Wakefield have not held up to careful review by investigators in this country, in Japan, and at his own institution in the United Kingdom.

We know that encephalitis predisposes children to autism. All three of the diseases prevented by the MMR vaccine, measles, mumps, and Rubella, can cause encephalitis. We would not want to leave children unprotected against these diseases for even a short period of time. I support the continued use of the combined measles, mumps, and Rubella vaccines as the safest and most effective means to protect children against these diseases.

With regard to diabetes, there have been two workshops that have been conducted to investigate the possible link between childhood diabetes and vaccines. One was held at the Institute for Vaccine Safety at Johns Hopkins and the other at the National Institutes of Health. The conclusions from both inquiries have revealed no scientific evidence to support the hypothesis that any vaccine causes diabetes. I will append to my testimony the conclusions of one of those workshops and provide a summary of the other one.

The history of medicine is filled with stories of physicians and others who have been quick to claim that they have answers to complex medical problems based on inadequate studies. Just as people should not be misled by promises of cures from fake medications, we should not mislead people with false villains to blame when unexpected illnesses occur.

The parents of children with diabetes, autism, and other disorders that we do not fully understand deserve answers as to why their child developed these diseases. These answers should be based on sound scientific inquiries. Congress should support increased funding for research to identify the basic causes of these disorders.

Identifying the safest vaccines is a process, and there are no absolutes. Promoting unproven hypotheses and hearsay about vaccine safety could have a negative effect on the willingness of vaccine manufacturers to invest the large amount of resources necessary to develop new vaccines that will protect our children against cancer and other serious diseases.

Congress should be concerned about vaccine safety and provide sufficient resources to assure that the best possible science is conducted to assist with the development of vaccine policy. We need highly qualified scientists who are on the cutting edge of their fields to be conducting reviews of new and existing vaccines. Therefore, it is disconcerting to learn that the research budget for the agency responsible for approving vaccines, the Center for Biologics and Evaluation Research of the FDA, has been cut to one-third the level that it was just 5 years ago. If this committee is truly concerned with assuring that the safest possible vaccines are used for children and adults, I urge you to investigate the issue and restore funding for vaccine safety research. You should also query the other agencies to determine the funding needed to address other aspects of vaccine safety.

Thank you for the opportunity to share my views on these subjects. I've provided a much more detailed statement, including references, for the record. I would be happy to answer any questions.

Mr. BURTON. Thank you very much, Doctor.

[The prepared statement of Dr. Halsey follows:]

Statement of Neal A. Halsey M.D.
Professor of International Health and Pediatrics
Johns Hopkins University
Director, Division of Disease Control
Director, Institute for Vaccine Safety
Department of International Health
Johns Hopkins University School of Public Health
Before the Committee on Government Reform
U.S. House of Representatives
October 12, 1999

My name is Dr. Neal Halsey. I am a pediatrician specializing in the study of infectious diseases and vaccines at the Johns Hopkins University School of Public Health. Thank you Mr. Chairman for the opportunity to provide this committee with my perspective on the important issue of vaccine safety. I have had the opportunity to care for children who have suffered from each of the infections that can be prevented through vaccination. I have also cared for children who have developed serious adverse reactions to vaccines. These experiences, coupled with my research over 27 years, have resulted in my current focus of interest on vaccine safety and the founding of the Institute for Vaccine Safety at Johns Hopkins University. My objective, and I believe the objective of most people in this room, is to ensure that both children and adults receive the safest vaccines possible to protect them against serious infectious diseases.

I have had the opportunity to review the written testimonies of Drs Harold Margolis, Samuel Katz, and David Satcher in their appearances before this committee and Congressman Mica's subcommittee. These witnesses have detailed the enormous benefits from immunizations and I agree with their statements. Therefore, I will not reiterate the benefits of vaccines in my testimony today, but I will be happy to address any questions regarding this issue.

Since this committee has expressed concern about possible conflicts of interest I provide the following information. I have never owned stock from any vaccine company or any other corporation. My retirement account is in mutual funds. I own no patents and I have no vested interest in any specific vaccine made by any company. My salary is generated from teaching and research grants and contracts, including studies to evaluate vaccine safety issues supported by the World Health Organization, the US Agency for International Development, the Food and Drug Administration and the manufacturer of Lyme disease vaccine. The Institute for Vaccine Safety has received support from individuals concerned about vaccine safety, and in 1997 and 1998 we received unrestricted educational grants from several vaccine manufacturers.

I have served on the Advisory Committee for Immunization Practices for the Centers for Disease Control and Prevention (CDC) and the Committee on Infectious Diseases of the Academy of Pediatrics (AAP). During my tenure on the advisory committees to the CDC and the AAP, I was a strong advocate for changes in policy to encourage the use of the safest vaccines possible, including the change to use of inactivated polio vaccine and acellular pertussis vaccines. I no longer serve on these committees and I appear before you today representing myself and the Institute for Vaccine Safety.

I was asked to comment on three issues: the number of vaccines children receive, combination vaccines and diabetes. I am not concerned about the number of vaccines children receive, and I look forward to the availability of several other vaccines that will help us prevent serious infections and cancer. The human immune system is remarkable in its capacity to respond to millions of different antigens. Children are exposed to many thousands of bacteria, fungi and viruses beginning at the moment of birth. In the first few months of life the human immune system responds to many foreign antigens from these

organisms. Each bacterium contains hundreds of different antigens including carbohydrates, fatty substances, proteins, RNA and DNA. Children develop antibodies to 17 different proteins in one common bacterium (*Moraxella catarrhalis*) and a strep throat infection results in immune responses to 25-50 different antigens[1]. Some new highly effective vaccines are made using only one or two bacterial antigens. For example, *Haemophilus influenzae* type b vaccines, or Hib as they are commonly called, contain only a single bacterial antigen attached to a protein. Children immunized with these vaccines are protected against meningitis and sepsis caused by the *Haemophilus influenzae* type b organism. Therefore, the immune systems of children who receive this vaccine are exposed to far fewer antigens than children naturally infected with the bacterium. Since all children would be exposed to the bacterium if they were not immunized, the use of the Hib vaccine actually reduces the burden on the immune system.

Questions have been raised about the benefits and problems associated with administering several vaccines at the same time or combining vaccines in the same syringe. There are factors that can limit the ability to combine vaccines and there are theoretical concerns that have been reviewed in detail in a workshop sponsored by the FDA, the National Vaccine Program Office, CDC and NIH[2]. These factors are taken into account in the FDA review of combination products. Numerous studies have been conducted to evaluate the safety and effectiveness of vaccines administered simultaneously or in the same syringe. Several efforts to produce new combined vaccines have not been successful, but those vaccines that have been approved by the FDA have been carefully evaluated and found to be safe and effective. Experts serving on advisory committees for the CDC and the AAP review the data from these studies prior to making recommendations for general use.

Children benefit from combined vaccines because they are protected against several different diseases with a single injection, thereby reducing pain and

discomfort from multiple injections. If we did not have combined vaccines, children would need to be brought to physician's offices or clinics far more often, perhaps even weekly during the first few months of life in order to protect them against serious infections. The use of combined vaccines can simplify the immunization process and record keeping for parents, physicians and public health officials[3].

Recently, concerns have been raised about the amounts of thimerosal preservative and other products in some vaccines. Manufacturers, the FDA, the CDC and the AAP have responded rapidly to these concerns to make new products available that reduce infant's exposure to these components. I anticipate that further steps will be taken in the near future to eliminate these concerns. The use of combination products reduces the total exposure to these components and theoretical concerns about these issues.

If vaccines that are currently given in combination were separated and administered at separate visits,children would be left unprotected against some diseases for varying periods of time. As we learned a decade ago with the resurgence of measles in this country, leaving children unprotected even for a few weeks or months can lead to epidemics and unnecessary suffering and deaths. We do not need to learn the same lessons over again.

I know that Congressman Burton is concerned about combining measles, mumps, and rubella vaccines in the same syringe. This issue was raised first in the United Kingdom by Dr. Andrew Wakefield. Dr. Wakefield's unfortunate statements at a press conference about separating measles mumps and rubella vaccines were based upon theory, not fact. Part of this theory was based upon his studies of children with inflammatory bowel disease. His original studies suggesting persistent measles infection in the inflamed intestinal tissue have not held up to careful review by investigators at the University of Connecticut and in Japan where his findings were not replicated[4-6]. A review by highly qualified

professionals in the United Kingdom found no evidence of a causal association between autism and MMR[7]. Autism is a complex disease and there undoubtedly are several factors that contribute to children acquiring this unfortunate disorder. Unraveling the complex etiology will require research into the basic causes by highly qualified scientists. We do know that encephalitis is one of the factors that pre-disposes children to autism. All three of the diseases prevented by the MMR vaccine, measles, mumps and rubella, can cause encephalitis. We would not want to leave children unprotected against these diseases for even a short period of time. The routine use of MMR has resulted in the prevention of many thousands of cases of congenital rubella syndrome, a recognized cause of autism. I support the continued use of the combined measles, mumps and rubella vaccines as the safest and most effective means to protect children against these diseases.

Many hypotheses about causal factors have been offered to explain the increasing incidence of autism and diabetes. Statements made about hepatitis B vaccines before Congressman Mica's subcommittee on May 18,1999 have been refuted by letters submitted to the committee by the State Epidemiologist of New Hampshire and the Director-General of Health of New Zealand. Also, the study in Finland referred to by Dr. Classen was published in the British Medical Journal and reveals no evidence of any effect from Hib vaccination on the risk of diabetes[8]. The increasing incidence of diabetes, autism, and other medical conditions for which no specific etiology has been identified parallels the increase in many other factors such as the use of wireless communications, computers, and fast food restaurants. One could easily hypothesize that these factors or many other changes in our lifestyles contributed to the increases in these diseases, but there is no scientific evidence to support these ideas. Two workshops have been conducted to investigate the possible link between childhood diabetes and vaccines, one at the Institute for Vaccine Safety and the other at the National Institutes of Health[9,10]. The conclusions from both inquiries revealed no scientific evidence to support the hypothesis that vaccines cause

diabetes. There are studies indicating the selective use of some vaccines early in life can prevent diabetes in animals, but to date, studies in humans have not confirmed this finding. Additional studies are in progress and other research is needed to identify methods for preventing this important cause of disease.

The history of medicine is filled with stories of physicians and others who have been quick to claim that they have the answers to complex medical problems based on inadequate studies. Just as people should not be misled by promises of cures from fake medications, we should not mislead people with false villains to blame when unexpected illnesses occur. The parents of children with diabetes, autism and other disorders that we do not fully understand deserve answers as to why this happened to their child. These answers should be based on sound scientific inquiries. Congress should support increased funding for research to identify the basic causes of these disorders.

Identifying the safest possible vaccines is a process; there are no absolutes. We must constantly reassess vaccines using appropriate experts and make adjustments when indicated. This situation is similar to safety evaluation of other products such as automobiles. Modifications are constantly being made in automobile design to improve safety. These efforts require constant study, reassessment, and innovation through a competitive marketplace. Hepatitis B vaccine has been the target of several anti-vaccination groups. Hepatitis B vaccine prevents acute and chronic liver disease and this vaccine is the first successful cancer preventing vaccine. I hope that this committee would encourage the development of other cancer preventing vaccines through objective scientifically based inquiries. Promoting unproven hypotheses and hearsay about vaccine safety could have a negative effect on the willingness of vaccine manufacturers to invest the large amount of resources necessary to develop new vaccines that will protect our children against cancer and other serious diseases.

The primary message I would like to convey to this committee is that decisions about vaccine safety should be based on good science, not hypotheses, opinion, individual beliefs, or observations. Federal agencies responsible for vaccine safety and major universities have procedures to assure high quality scientific research and reviews of vaccine safety issues. Congress should be concerned about vaccine safety and should provide sufficient resources to assure that the best possible science is conducted to assist with development of vaccine policy.

Assuring the safest possible vaccines requires constant vigilance and periodic reviews of all vaccines. Rapid advances in biotechnology are being made that have created new tools for developing and evaluating vaccines. We need highly qualified scientists who are on the cutting-edge of their fields to be conducting reviews of new and existing vaccines. Therefore, it is disconcerting to learn that the research budget for the agency responsible for approving vaccines, the Center for Biologics and Evaluation Research (CBER) of the FDA, has been cut to one-third of the level that it was just five years ago. You cannot expect an agency to do its job effectively if you deprive the scientists of research support. If this committee is truly concerned with assuring that the safest possible vaccines are used for children and adults, I urge you to investigate this issue and restore funding for vaccine safety research. The NIH, CDC, and FDA should be queried to determine the funding needed to support all aspects of vaccine safety research.

Thank you for the opportunity to share my views on these subjects. I will be happy to answer any questions.

References:

1. Institute of Medicine (US). Immunologic Reactions. In: Stratton KR, Howe CJ, Johnston Jr., RB, editors. Adverse Events Associated with

Childhood Vaccines: Evidence Bearing on Causality. Washington DC: National Academy Press; 1994. p. 63.

2. Williams JC, Goldenthal KL, Burns DL, Lewis Jr. BP, editors. Combined Vaccines and Simultaneous Administration: Current Issues and Perspectives. Vol 754. New York: New York Academy of Sciences; 1995.
3. Advisory Committee on Immunization Practices, American Academy of Pediatrics and the American Academy of Family Physicians. Combination Vaccines for Childhood Immunization. Pediatrics 1999;103(5):1064.
4. Iizuka M, Masamune O. Measles vaccination and inflammatory bowel disease [letter; comment]. Lancet 1997;350(9093):1775.
5. Liu Y, van Kruiningen HJ, West AB, Cartun RW, Cortot A, Colombel JF. Immunocytochemical evidence of Listeria, Escherichia coli, and Streptococcus antigens in Crohn's disease. Gastroenterology 1995;108(5):1396-404.
6. Iizuka M, Nakagomi O, Chiba M, Ueda S, Masamune O. Absence of measles virus in Crohn's disease [letter]. Lancet 1995;345(8943):199.
7. Taylor B, Miller E, Farrington CP, Petropoulos MC, Favot-Mayaud I, Li J, Waight PA. Autism and measles, mumps and rubella vaccine: no epidemiological evidence for a causal association. Lancet 1999;353(9169):2026-29.
8. Karvonen M, Cepaitis Z, Tuomilehto J. Association between type 1 diabetes and Haemophilus influenzae type b vaccination: birth cohort study. BMJ 1999;318(7192):1169-72.
9. The Institute for Vaccine Safety Diabetes Workshop Panel. Childhood immunizations and type 1 diabetes: summary of an Institute for Vaccine Safety Workshop. Pediatr Infect Dis J 1999;18(3):217-22.
10. Jefferson TO, Rabinovich R, Tuomilehto J. Vaccines and their real or perceived adverse effects. BMJ 1999; 318: 1487.

Attachments:

- The Institute for Vaccine Safety Diabetes Workshop Panel. Childhood

immunizations and type 1 diabetes: summary of an Institute for Vaccine Safety Workshop. Pediatr Infect Dis J 1999;18(3):217-22.

- Karvonen M, Cepaitis Z, Tuomilehto J. Association between type 1 diabetes and Haemophilus influenzae type b vaccination: birth cohort study. BMJ 1999;318(7192):1169-72.

Mr. BURTON. I share your concern about the cut in funding for that research regarding the safety of vaccines. I think that's extremely important.

I hope nobody that's followed our hearings believes that I and members of this committee don't believe that vaccines are absolutely necessary. I think they're the reason that we have the highest quality of life and health of any nation in the history of mankind.

However, in my family, my granddaughter received a hepatitis B shot, and 6 hours later she was not breathing. Now, that does cause a little bit of concern.

My grandson received the shots that you referred to, a perfectly healthy young man who is going to be 6 foot 10, according to his doctor, his pediatrician, when he grows up. I want him to be in the NBA so he can support me. He's autistic, and there was no manifestation of anything like that prior to him getting these shots. So I think more research needs to be done.

I would like to ask you one question, however. Do you receive any funding or any kind of research grants or anything of that type from any pharmaceutical companies?

Dr. HALSEY. Yes, I have received in the past year funding for research on Lyme disease vaccine, the safety of Lyme disease vaccine in children.

Mr. BURTON. From what company?

Dr. HALSEY. That is from SmithKline Beecham, the only manufacturer of Lyme disease vaccine.

Mr. BURTON. I just wanted to know if you had any funds being received from the pharmaceutical companies.

Dr. HALSEY. Could I address the point you made, just briefly?

I think it's the No. 1 issue that people have trouble understanding, from the testimony that I heard from this panel, from what I heard on the earlier panels, and from what I just heard from you. The science of causality assessment is not understood by most people, and I think we need to do a better job of educating as to how we do determine that something that occurs following a vaccine, a drug, or a food is or is not caused by that problem. We must have good science to say that either there's a very specific test that can be done, which is the case with some situations with adverse events to vaccines, such as live virus vaccines, or you must demonstrate a difference in risk.

Mr. BURTON. I have to ask other questions, but that's one of the reasons why we're having all of these hearings.

We had the DPT shot. There's been substantial information coming to us from doctors and others that there were side effects that could have resulted in autism; and the DPAT shot, which is a substitute, has been on the market for some time. It's much safer. Everybody knows that, and yet they're still using the DPT shot. We're trying to find out why that's the case, among other things, but we're looking into the things you're talking about.

Let me go to Major Bates here, real quickly. How many people are in your squadron?

Major BATES. 270, sir.

Mr. BURTON. Of the 270, how many did you say have had these kinds of problems?

Major BATES. Twelve, sir.

Mr. BURTON. Twelve out of 270.

Major BATES. About 4.4 percent.

Mr. BURTON. Did you have any others that refused the shot?

Major BATES. Yes, sir. There was an airman a few months ago that was discharged with less than honorable conditions. He's the only active duty member at our base that I'm aware of.

However, the new group of pilots—and not just pilots, the new group of people that come in the summer, usually we do a lot of moves in the summer, none of us have received the vaccine yet. When we walk around the halls and talk to each other, everybody looks both ways. They say, man, I don't want this vaccine. I hope the Congress stops it. That's what the new people say. But, of course, we have to wait to see when it comes time to roll up the sleeve where they stand on that.

Mr. BURTON. I've had a couple of flight engineers and pilots come in and talk to me about this. They've indicated the same consternation that you have.

Major Rempfer, how many people do you have in your squadron?

Major REMPFER. The squadron I was in prior to transferring over to the U.S. Air Force Reserves, my situation was I didn't want to disobey the order, and we were—it was made very clear to us that—leave the unit if you're not planning on taking the shot. So I've done that. There's a pattern all across the country of that occurring in many bases.

In my squadron, we had approximately 32 A–10 fighter pilots, and 8 of us ended up choosing to leave the unit in lieu of accepting the vaccine. And there was an additional couple of individuals that chose to take non-mobility positions within the unit.

Mr. BURTON. They were no longer in flight status.

Major REMPFER. That's very true. They were in mobility slots, but they chose to go ahead and allow themselves to be grounded and not fly anymore. That was the ultimatum. We're going to ground you and process you out of the unit.

Mr. BURTON. Of those who had the shots, were there any adverse side effects that you know of?

Major REMPFER. I don't think there have been any VAERS forms filed in the unit. I'm not aware of any at least. But our informal communications with all our friends who still remain in the unit are that many of them felt like they had adverse reactions. Nobody reported, and they back us up 100 percent.

Mr. BURTON. Why did they not report it? Did they say whether they were afraid of losing their flight status?

Major REMPFER. I think most folks are reluctant to do it because most of them also hold FAA certifications as well.

Mr. BURTON. They'd like to be pilots in commercial aircraft after they——

Major REMPFER. In my case, in this unit most of them are commercial airline pilots.

Mr. BURTON. I see. You're in the reserves?

Major REMPFER. Yes, sir.

Mr. BURTON. Admiral Crowe, during your career was there ever discussion for the need to use the anthrax vaccine to protect our troops against a biological attack?

Admiral CROWE. Mr. Chairman, I retired in 1989; and in my statement I went through some of the measures that we took in the JCS. But the question of toxin or anti-toxin and terrorism, et cetera, really had not—the urgency had not developed to that point. We were just beginning to explore the potential of this problem but not individual vaccines, et cetera.

Mr. BURTON. Let me just ask one more question, and I'll go to Mr. Shays. You state that you had no contact with the Defense Department in negotiations with regard to the BioPort contract. Have you had any communications with anyone in the Department or the Pentagon since your retirement?

Admiral CROWE. First of all, I didn't say in regard to the contract. I said in regard to the decision to make inoculations—mandatory inoculations.

Mr. BURTON. Did you have contact with them or talk to anybody at the Department of Defense about the BioPort company or what——

Admiral CROWE. I did after it became a BioPort company but not at the policy level. This was at the working level. And I wrote a letter to Secretary Cohen after we became a company to point out some of the problems we would be experiencing with foreign sales, et cetera.

Mr. BURTON. Did you ever talk to them about anything like the financial problems the company was having and the need for additional funding?

Admiral CROWE. I had one contact where I said that, if that is true, we want the U.S. Government to be in on it, and all the records would be accessible to them at BioPort. That was all that was said. I really had very few conversations on this subject with anybody in the Defense Department.

Mr. BURTON. There was $18.4 million that was advanced because the company was in difficulty. I just wondered if you ever talked about that.

Admiral CROWE. I'm aware of that. That, incidentally, is a contract that's been signed, but it's not been forwarded yet.

Mr. BURTON. But did you discuss that with anybody, sir?

Admiral CROWE. Not within the Department. No, I did not, sir.

Mr. BURTON. Thank you.

Mr. Shays.

Mr. SHAYS. Thank you.

Admiral, I wasn't going to get into this because there are so many issues that concern me more, but I'm surprised that you actually had retired a good number of years before you started working for BioPort.

Admiral CROWE. Yes. I was retired about 5 years, and then I was Ambassador for 3 years, and I retired again.

Mr. SHAYS. I didn't know that, because I hadn't paid much attention to the issue. I thought you had left sooner. It's clear, though, you joined this facility, this operation, because you had value to add to it.

Admiral CROWE. I think that's correct, yes.

Mr. SHAYS. It's also clear to me that you sincerely must believe that this potentially is an important business to be in because you believe it is a serious problem?

Admiral CROWE. Well, I thought terrorism—I had a great deal of experience with that in England, and also these two boards I was on—I felt that, No. 1, terrorism was a coming threat. They need more attention to it. And, No. 2, that it was a business that didn't engage in offensive weapons. It was not engaged in killing people. It was engaged in a passive defense, and I thought it was necessary for the military to have that kind of thing.

Mr. SHAYS. Thank you.

Dr. Halsey, I may have sounded that my mind is made up more than I think it is on this issue. I am leaning toward a voluntary program until DOD and BioPort get their act together before it becomes mandatory. But I would really appreciate—and I'm not practicing the lawyer's creed of knowing the answer to the question before I ask it, so I would be very interested in knowing what your answer is. And that is what should be the role of the FDA as it relates to the oversight? This is a very interesting——

Dr. HALSEY. I can speak from my experience as a practitioner and with my experience serving with the Academy of Pediatrics in an advisory committee capacity, and I believe that what Dr. Zoon stated is correct and applies not just to the military but it applies to the practice of medicine everywhere.

The military is a little different in that it is part of the Federal Government, and that may change things certainly from your perspective, but there are many instances when people are obligated to, because of the science that's out there, to do some things with—drugs is much more common, vaccines I don't favor at all—to do things that are slightly different than what the package labeling says.

From the pediatrician's perspective, our biggest frustration is that many drugs and vaccines are not tested in children adequately. This has been addressed recently by Congress in a law which I've forgotten the name of that requires more testing in pediatric patients so that we do know how we can use these effective products in them. But the FDA cannot govern the day-to-day practice of medicine of physicians.

I am not prepared at all to speak about the military. My service has been with the Public Health Service, a branch of the military, but——

Mr. SHAYS. Would BioPort, though, be allowed to claim that the vaccine is proved to be effective after three——

Dr. HALSEY. Again, that's a regulatory issue, but my understanding is that any advertising——

Mr. SHAYS. I don't understand your answer, that's a regulatory issue. This is something you get involved in all the time.

Dr. HALSEY. Yes, I am involved in it. But I'm not the FDA, and I can't speak for the FDA, but I'll tell you what my understanding is.

Mr. SHAYS. Let me ask you, do you have any—can you answer honestly? There's not—nobody has anything over you, do they?

Dr. HALSEY. No, nobody has anything over me at all at this time.

Mr. SHAYS. I just want to know your expertise. And we have certain rules that apply to one group. Should it apply to the DOD?

Dr. HALSEY. The question, as I understand it, should—does FDA have regulatory authority over BioPort's advertising——

Mr. SHAYS. Let me ask you this.

Dr. HALSEY. Let me try to answer.

Mr. SHAYS. No, I can tell you exactly the question. Should a company that has been given a license be able to advertise that the drug will do something that the license doesn't give approval for?

Dr. HALSEY. No. And the FDA does have authority over advertising by companies.

Mr. SHAYS. And promotional material and so on.

Dr. HALSEY. Correct.

Mr. SHAYS. So if BioPort was doing this, you have a problem. You would have a problem with them claiming that it is efficacious after three when their license says and they only have the documentation to be licensed for six.

Dr. HALSEY. I believe that the answer is yes to your question.

I would have to say that my understanding of the response from—and I've forgotten the General's name who is responding—is that it is their effort to try to get all six doses in, but they have looked at the immune response after three doses, and there is evidence of an immune response which they believe will provide some protection, may not be all the protection. But I don't believe there was a state—the response that I heard was that there wasn't any conscious effort to say that's all you need, that they're trying to do that. But they recognize that, gee, maybe we get some protection after three rather than six. That's my understanding.

Mr. SHAYS. Why did you want to make that point? That wasn't my question, but why did you want to make that point?

Dr. HALSEY. Well, I believe there's a difference between——

Mr. SHAYS. You sound like you're an apologist for the military.

Dr. HALSEY. I'm no apologist for anybody—the military, the FDA or vaccines in general.

Mr. SHAYS. That's exactly what they said. But I want to know who watches the military, who protects our soldiers, our sailors, our pilots? Whose role——

Dr. HALSEY. I can't answer that question. I think you have to—you have better access to the people who can answer who watches over the military. I think you do.

Mr. SHAYS. That's true. And, because of that, I have a gigantic problem with what I'm hearing. Because the FDA basically has given the military the ability through the license of BioPort to use a vaccine in a way that is new, an aerosol type of exposure, not tested for. We're letting them do that, and we're saying, though, you've got to follow the practice. They've said to the military that you need to follow the protocol. But now I learn today they don't have the authority to back up that requirement.

So I'm asking you, as someone who is very close and is concerned about vaccines, I want to know who should do it and then tell me what I should do. You said it's up to me, so what should I do about it?

Dr. HALSEY. If you believe there was false advertising taking place by someone in the Federal Government, then I think you have a right or an obligation to try to determine if that is true or not. Now, I can't speak to whether it's true, because I haven't seen any of this material.

Mr. SHAYS. But this is what I'm trying to understand. What I'm trying to understand is, you said, this is my responsibility, so I'm going to exercise it. I need to know whether or not we should ignore the licensing procedures, the six shots, and go with new studies that haven't yet been accepted by the FDA as valid for the licensing of the product.

Dr. HALSEY. Based on everything that I've heard here today and my previous reading, I think everybody in the military would be happy if there were additional studies that——

Mr. SHAYS. Could a private company get away with saying to FDA we would like to follow it? We would be happy if we could, but we can't follow the protocol? That's a good enough answer?

Dr. HALSEY. A company that manufactures the vaccine cannot advertise such things without approval by the FDA, but a private physician or a health maintenance organization or such can actually do some things with drugs or vaccines that are not exactly in accord with what is in the package label.

Mr. SHAYS. And they've been given this right by the FDA. The military has been given this right by the FDA, correct?

Dr. HALSEY. I don't believe that that's who grants that. I believe—I don't know the law in this situation. I do know the practice of medicine.

Admiral CROWE. I think he was talking about private doctors.

Mr. SHAYS. Pardon me, sir? I didn't hear what you said.

Admiral CROWE. I said I think he was talking about private doctors.

Mr. SHAYS. Yes. It's a wonderful circumstance that we have right now. Basically, we're supposed to trust the military—and I wonder why, based on past experience, whether it was Agent Orange, whether it was people my office has had to help that have been exposed to radiation—we're supposed to trust the military to do the right thing, and now we have a program where we had 300 people, give or take, a year who got the vaccine, and they were tested under one type, and now we have a circumstance where it's to be used as a prophylactic from exposure by a terrorist or a military organization through aerosol spraying, and we now have 2 million plus who are going to get this vaccine, and we're supposed to trust the military to govern itself.

And I made the assumption when I walked into this hearing that the FDA was in fact going to make sure its protocol was maintained, and in fact the FDA wrote the military and said, you haven't kept up with your schedule. And if they didn't have that authority, I wonder why they even bothered to write the letter. I mean, I just thought they had that authority.

Mr. BURTON. Can I come back to you in just a moment?

Mr. SHAYS. Just to make one point.

I'm not comfortable with generals practicing medicine, and I'm not comfortable with doctors planning wars, and, frankly, I'm not comfortable with doctors planning war doing medicine. I'm not comfortable with doctors planning wars, I'm not comfortable with politicians planning wars or doing medicine. This was an area—I was eager to get into it, but I basically see we have no one watching the military, and they have no basis in which to say, trust us, based on past experience.

Mr. BURTON. I'll come back to you in just a moment if you have further questions, Congressman Shays. Let me just ask a couple of questions, and that will do it for me.

Dr. Melling, I want to go back to something you said in your opening statement. I think it's extremely important that everybody who may be paying attention to this hearing understand it. You said in your opinion that if we start—and I may be paraphrasing what you said—but if we start inoculating people against things like anthrax, that the potential enemies who would use anthrax as a weapon would see that, and there are a number of things that they could use to counter that, other biological weapons which they undoubtedly would do. I mean, why would they attack us with anthrax if they knew that nobody was going to get it? They would go to somebody else. Is that what you were saying?

Mr. MELLING. It wasn't precisely that, but I do agree with the comment that you made. I think what I was really saying was that the time it takes to develop vaccines and take them through the approval process is long. This is true not just for defense vaccines, it's true for commercial products. Because an aggressor is not constrained by the need for regulatory approvals, ethical considerations and all the rest of it, I think the pace at which they could move is likely to be faster than the pace at which we can defend through vaccine development.

Mr. BURTON. While we're going through the process of developing and passing through FDA and the other agencies the anthrax vaccine, they knowing what we're doing, would say, why should we concentrate on perfecting this weapon when we can perfect another one very quickly?

Mr. MELLING. Yes.

Admiral CROWE. May I make a comment?

First of all, if we succeed in doing it, that would be progress. In other words, we convince terrorist organizations not to use anthrax against us. That's the purpose of this whole thing. What it would do, you're absolutely right, it would go to other weapons. We feel that when you get into more sophisticated forms of biological warfare, that's not as easy for the terrorist to wage, and it causes him big problems.

Mr. BURTON. How many biological agents are there that could be used?

Admiral CROWE. Probably three or four. In the next 10 years, there will be even more maybe. But whether they're practical for terrorist use severely limits the number, and anthrax is one of the easiest for them to make. We would like very much if they reached the conclusion they couldn't attack us with anthrax.

Mr. BURTON. The only concern that I have is that with the Internet and all the new technologies we're seeing develop very, very rapidly, it seems to me in the not-too-distant future they'll be able to move more quickly with these agents than they have in the past, and to try to vaccinate against all of them is going to be very difficult. I think the point that Dr. Melling is making is that they can move faster because they have no restrictions than we can in producing a vaccine.

Admiral CROWE. But their resources are limited to certain things.

Could I make a comment in this regard, Mr. Chairman? You asked me to talk about development of policy. One of the things you have got to be aware of is when the Secretary of Defense makes the decision to do these sorts of things, there are lots of pressures that act on him. They have the same kind of testimony you're having. They try and look at the pros and cons. They try to look at the entire spectrum. But I don't get any feeling in these hearings that his problems are being considered.

One of his major problems is that he is in command of several million men. He is given a lot of information that says anthrax vaccine will work in many, many cases. It's not flawless. There will be some reaction, et cetera. I would just like to imagine a hearing where, if we didn't use the anthrax vaccine and all of a sudden our forces are hit with it and several thousand people in this country are killed by anthrax, then we'd have a real hearing on why we had a vaccine that wasn't used and didn't save those people. That would be a real situation.

Mr. BURTON. There's no question that we believe that the troops ought to be protected, and I think everybody here agrees with that. What we're asking is has there been proper testing? Have we been very straight with the military personnel about the side effects of all this? And should there be informed consent?

I was in the military, too, and if I thought there was a real chance that I might be incapacitated for life by taking a vaccine, even though I might be more at risk if I went into combat and had to face that, I think I might make a different kind of choice. I think that's what a lot of these people are talking about.

I want to ask you, Major Bates, quickly one thing. Were you threatened at all if you refused to take the shot, that you'd be court-martialed and incarcerated?

Major BATES. Yes, sir.

Mr. BURTON. Tell me exactly what they said to you.

Major BATES. I spoke with my squadron commander, told him I was very uncomfortable with this. He reiterated the policy. If I didn't take the vaccine, I would be court-martialed. There were no other options. I asked him about a religious waiver. He said, no chance.

Mr. BURTON. They told you flat out you'd be court-martialed and probably incarcerated for up to 2 years?

Major BATES. He sent me to the area defense counsel after he told me I would be court-martialed. I went to the area defense counsel; and they said, because of your rank, you have the chance of spending up to 2 years in prison.

Mr. BURTON. That's the same case for your colleagues in the military who might refuse to take this.

Major BATES. Yes, sir.

Mr. BURTON. There's no way that we could really tell how many people who don't want to take it or feel they might be in jeopardy because of the threat of prosecution or dishonorable discharge.

Major BATES. Yes, sir. And one female naval officer has been released from the military with an honorable discharge. I would like to see this kind of lack of consistency across the country with the military corrected.

Mr. BURTON. What you would like to see, if military personnel says, OK, we don't want to take this shot because we think it's a risk to me and my future, rather than to having face a court-martial that they just be able to be discharged if they want to do that?

Major BATES. Yes, sir. And if you don't mind, I don't want a dishonorable discharge from the military.

Mr. BURTON. Under honorable——

Major BATES. I don't want an honorable discharge from the military. I want an honorable military.

Mr. BURTON. You want an honorable military.

Major BATES. Yes, sir.

Mr. BURTON. OK. Very good.

What about in the reserves?

Major REMPFER. In the reserves and the guard, as a matter of fact, the Assistant Secretary of Defense of Reserve Affairs testified on September 29th, after he was reminded that he was under oath by Congressman Shays, that, "If someone is going to resign over anthrax, they are certainly not going to be subject to any penalties. This is one of the points of the guard and reserve." And, unfortunately——

Mr. BURTON. That was before Congressman Shays' subcommittee?

Major REMPFER. Yes, sir. Unfortunately, the whole truth is that, 5 days after that, the commander of the 184th Bomb Wing in Kansas for the Air National Guard issued a written warning and a letter of reprimand to a B–1 bomber pilot threatening a $500 fine and 6 months in jail because the pilot had asked to transfer out of the unit in lieu of submitting to the vaccine. And we have similar contradictory occurrences compared to Mr. Cragin's testimony.

In the U.S. Air Force reserves they've recently, again just after that hearing, come down with a policy that says anybody who's essentially refused the anthrax vaccine is not going to be allowed to transfer.

Mr. BURTON. Let me ask just one more question, and I'll yield back to you, Mr. Shays.

Dr. Classen, you're the only one who has really come out and said categorically that this vaccine being administered would cause and could cause side effects, including diabetes. On what do you base that?

Dr. CLASSEN. Based on extensive animal studies and human studies with vaccines. We find that when you stimulate the immune system you're going to get an increased risk of autoimmune diseases, including diabetes. There is a lot of substantial evidence, including related literature and interferons as well.

Mr. BURTON. Was that just because of this one vaccine or any vaccine?

Dr. CLASSEN. It's any vaccine, practically. If you stimulate the immune system, you stimulate macrophages cells. You release interferons. You are going to increase the risk of——

Mr. BURTON. Is it greater with the anthrax vaccine or vaccines of that type?

Dr. CLASSEN. I can't say that for sure. Aluminum maginate probably is not a good thing to have. It stimulates certain cells. Six

doses is probably not as good as having two or one dose. So there are some problems with the anthrax vaccine.

Also, anthrax vaccine is made from a filtrate which is an unpurified sort of material, as opposed to certain vaccines that may just have a specific amino acid or specific protein. The anthrax is less pure, and so that would tend to stimulate the immune system as well.

Mr. BURTON. Thank you.

Mr. Shays.

Mr. SHAYS. Thank you.

Dr. Melling, you made—in point one of your statement you said the effectiveness of defense vaccines cannot be determined by normal human epidemiological trials due to the rarity of diseases involved. Animal models, therefore, are critical to assess efficacies. Such models are limited in their ability to predict what will happen in humans and in most cases can best indicate some possibility of efficacy but do not allow us to determine if a vaccine will protect 40, 60, or 80 percent or whatever of humans, nor can we predict the human vaccine effectiveness against different levels of challenge. Is that, your view, generally accepted or if I ask Dr. Halsey would he disagree with that?

Mr. MELLING. I believe that my view is one that is generally accepted; and, in fact, this has been traditionally, I think, one of the reasons agencies both here and other countries have required human epidemiological trials before they actually license vaccines in order to demonstrate efficacy.

Unfortunately, our detailed knowledge of the human immune system is still limited, and this has meant the number of vaccines where we can make an accurate prediction of human efficacy solely based on animal studies is also equally limited. This really is the problem we're wrestling with.

I think we've heard and certainly I've personally done work on animal models relating to anthrax, the guinea pig model that was referred to earlier, and what we see is different animals respond in different ways. It doesn't mean that the vaccine will not protect humans.

In fact, I'll answer the question you haven't asked me, but I do believe it has some protective effect in humans. What I can't estimate is the level of that protective effect, and that's why I personally would not wish to rely solely on the vaccine, that I would look at one of several measures.

It's interesting, the Institute of the U.K. that I used to direct, we have people working on anthrax. They were all vaccinated, but we took great care that, if they were working with the organism, they were also protected by other containment measures, and there was no way we'd be able to rely solely on the vaccine.

Mr. SHAYS. Thank you.

Dr. Halsey, what is your sense of that?

Dr. HALSEY. Well, I think all of us would prefer to have epidemiologic studies proving efficacy for any vaccine prior to it being licensed, but I do understand the difficulty in this situation where the disease is so rare that it virtually is impossible to do that study. I mean—and the other way in which we sometimes can learn an enormous amount is through human volunteer challenge

studies, but I don't think anybody wants to do that with this organism, just as we are not doing that with HIV vaccines. It's too dangerous to do that.

Now, I can't say that it might not be done under some circumstances, but then you must depend upon the animal data and you look for a correlation with protection. And that correlation with most vaccines is antibody, but that is not the only measure of an immune response, and for many other vaccines there are other factors which we are not very good at measuring which are associated with protection.

Mr. SHAYS. Dr. Leitenberg.

Mr. LEITENBERG. I just want to clarify one thing.

During World War II, the natural mode of infection by BW agents in the natural world was not through aerosol inhalation. The "breakthrough,"—unfortunate breakthrough—in the World War II United States-U.K.-Canadian BW program was to discover aerosol dissemination of BW agents. You cannot expect to have aerosol BW agents being tested against a human population. That's impossible. That's really at the crux of your conundrum, and what you've been asking for. You can't do that in the United States.

Mr. SHAYS. Let me ask you, Admiral Crowe, did we ever provide anthrax to any of our Middle East allies or adversaries?

Admiral CROWE. I think we did. I know that some other countries in Desert Storm received it, but I think most of that was furnished by U.K.

Mr. SHAYS. I mean before that. For instance, did we ever give Saddam Hussein anthrax?

Admiral CROWE. I'm not aware of that. I don't think so.

Mr. SHAYS. Mr. Leitenberg.

Mr. LEITENBERG. I think what you're asking about for that is Iraq was able to obtain from the type culture collection in the United States some of their anthrax cultures.

Admiral CROWE. But that was not a government——

Mr. LEITENBERG. That was certainly inadvertent, and that was a universal practice. Such international supply has now been tightened up enormously, subsequent to the discovery that that's where some of Iraq's cultures came from. Iraqi strains of anthrax were also obtained from other sources, but some were obtained from the United States type culture collection, yes.

Mr. SHAYS. Mr. Classen, any of the questions I asked, did you want to respond to?

Dr. CLASSEN. The only issue I guess that really I want to address is the previous panel where you kept saying you're not getting a straight answer. You know, that is what really gets my blood boiling, too, is that we just don't—when you confront these people, which are public health officials, they just aren't upfront, I believe, and they're not doing their job. I think they're looking after their career. They are career government people who are going to say what they say to improve their career.

And I think that the real problem here is that there's no downside. You don't have to obey the laws. You just do what you have to do to promote your career, and then there's no repercussions.

I think that is why we need a special prosecutor to come in and to look in fact and see are these people in the public health service,

are they obeying the laws and the legislation that Congress has enacted to ensure safety of biological products.

And I think if you look at France, France did that. I think they sent four public health officials to jail. They clearly were looking after their own careers and not abiding by the laws. In doing so, they jeopardize the health of the public. And I think that clearly that's what's going on here, and I think we really need some changes in that regard.

Mr. SHAYS. Mr. Chairman, I just have a few more questions, not long.

I would like to put in the record a letter received—excuse me, a copy of a letter that Sue Bailey, the Assistant Secretary of Defense, received; and it's stamped September 29, 1999. It's from Kathryn Zoon, and it's three paragraphs. I'll read the last paragraph.

> We reiterate our previous statement made to DOD on December 16, 1997, that FDA approval of the anthrax vaccine is based on the six-dose regimen found in the approved labeling. Because we are unaware of any data demonstrating that any deviation from the approved intervals of doses found in the approved labeling will provide protection from anthrax infection, we strongly recommend the anthrax vaccine immunization program follow the FDA-approved schedule. We would like to hear from you as soon as possible regarding this matter.

[The information referred to follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 29 1999

Food and Drug Administration
Rockville MD 20852-1448

Sue Bailey, M D.
Assistant Secretary of Defense
Health Affairs
1200 Defense Pentagon
Room 3E346
Department of Defense
Washington, DC 20301-1200

Dear Dr. Bailey:

On December 16, 1997, Food and Drug Administration (FDA) officials met with the Department of Defense (DOD) officials to discuss DOD's Anthrax Vaccine Immunization Program (AVIP). During that meeting, Dr. Ed Martin acting Assistant Secretary of Defense, Health Affairs, briefed Dr. Michael Friedman, Lead FDA Deputy Commissioner on DOD's plan to implement anthrax vaccinations of the U.S. military forces. As part of that briefing, Dr. Martin emphasized that the anthrax vaccine immunization program would not vary from the FDA approved labeling.

Recently, it has come to the agency's attention through congressional sources, that some troops may not be receiving the vaccine in accordance with the schedule found in the approved labeling. As you know, the approved anthrax labeling states that full immunization involves six (6) doses administered over 18 months to complete the primary series. Labeling calls for doses of the vaccine to be administered, following the first dose, at 2 and 4 weeks, 6 months, 12 months and 18 months, with yearly boosters thereafter. This schedule is the only regimen shown to be effective in protecting humans against anthrax and is the only schedule approved by FDA. Data received by FDA from congressional sources indicate that a number of reserve and active military personnel are receiving their anthrax vaccine doses significantly later than the FDA approved schedule.

We reiterate our previous statement made to DOD on December 16, 1997 that FDA approval of the anthrax vaccine is based on the six-dose regimen found in the approved labeling. Because we are unaware of any data demonstrating that any deviation from the approved intervals of doses found in the approved labeling will provide protection from anthrax infection, we strongly recommend that the Anthrax Vaccine Immunization Program follow the FDA approved schedule. We would like to hear from you as soon as possible regarding this important matter.

Sincerely yours,

Kathryn C. Zoon, Ph.D.
Director
Center for Biologics Evaluation
and Research

Mr. SHAYS. I read this letter and made an assumption, and I started to smile as I read it. I didn't realize when she said recommend, it wasn't a joke. She was recommending it. And one of the things that—instead of requiring it.

And one of the things that I just think is of interest to me is that the bottom line from this hearing, I've learned something that I clearly should have known before, but bottom line is the—this program run by the military does not have to follow the protocol and that the FDA does not have to make them follow the protocol. And so that the military says they're trying to follow the program. They don't have to. And we have no one I guess who can make them do it, I guess, unless Congress.

Clearly, one of the recommendations that I'm going to recommend to our subcommittee is that we not allow a government agency to administer drugs without there being some outside source or organization or institution that is there to protect from the misuse of a potential drug.

I'll yield back.

Mr. BURTON. The gentleman yields back his time.

Mr. Leitenberg.

Mr. LEITENBERG. Since I previously answered "yes" to your question, Congressman Shays—you had asked did the United States ever provide anthrax to Iraq—and I really shouldn't have answered an unqualified "yes." The U.S. Government didn't give the Iraqi Government anything. An institution in Iraq was able to obtain the culture from the type culture collection. That's really a better answer.

Mr. SHAYS. It is a better answer. There's always speculation that in this battle between Iran and Iraq that we were helping Iraq, and I appreciate your answer.

Mr. BURTON. Mr. Waxman.

Mr. WAXMAN. Thank you very much, Mr. Chairman.

I think that the FDA position is that they don't regulate the practice of medicine. They approve a product that is presented to them by the manufacturer to be safe and effective in order to get their approval, and then I don't think FDA has ever been the appropriate agency to go and police how medicine is practiced by government or nongovernmental agencies. So I think that point you raise is an interesting one, but I'm trying to think it through.

Off the top of my head, I find it very difficult to expect the FDA should have to deal with that burden. And then if you take the position that no government program can be run unless it follows the protocols you're making an assumption that the Department of Defense has not followed the protocols, and I'm not convinced of that, although I am convinced that they didn't do what they should have done in monitoring. And it's upsetting that they didn't because they have a captive audience, so to speak, where they should have been monitoring any adverse reactions. But I don't think they would admit to the conclusion you've reached, that they weren't going to give all the shots required.

Mr. SHAYS. Would the gentleman yield?

Mr. WAXMAN. Sure.

Mr. SHAYS. The challenge I have is I'm wondering if this is the practice of medicine when in fact we have our soldiers who are basically ordered by the superior officers to take a particular drug.

Mr. WAXMAN. I think you raise a good point—if I could take back my time, I think you raise a very good point.

I was responding to FDA's responsibility, but we as a government have a responsibility, if our young men and women are going to be required to take a vaccine, to make sure that it's administered to them in a way that's proper and will protect them and if there are adverse effects that we know about them.

I think we need to know more about adverse effects. There are all sorts of pharmaceutical products that we don't know about because we rely on the self-reporting of a lot of the companies, sometimes voluntarily, particularly in the area of medical devices, and we need to know more.

Let me just ask a few questions unless I get more time.

Dr. Halsey, Dr. Classen has described his theory that vaccines cause various diseases such as childhood diabetes. I understand NIH conducted a workshop in May 1998 to address Dr. Classen's claim; is that correct?

Dr. HALSEY. Yes, that is correct. And I had mentioned in my testimony that there were two workshops. We also conducted one at the Institute for Vaccine Safety at Johns Hopkins. Both workshops concluded that no vaccines have been shown to cause diabetes in humans.

I would add part of where some of the confusion has occurred is that there is work in at least four different laboratories with animals predisposed to get diabetes, and you can prevent diabetes in those animals with some vaccines given very early in life. Dr. Classen has done some of those studies, but it is inappropriate to move from that to then say that you can cause diabetes with vaccines. There is no evidence to support that statement.

Mr. WAXMAN. I have a statement from the National Institutes of Allergy and Infectious Diseases which reported on the meeting, and this summary expressed the following findings: "the consensus was that existing studies in humans do not indicate an increase in Type 1 diabetes attributable either to any vaccine or to the timing of vaccine administration."

So the summary says this was a consensus. Do you agree with these findings and, if so, why?

Dr. HALSEY. I agree completely with those findings. We could go through all of the data and the problems that occurred with the methods and the logic that were presented by Dr. Classen, but I think you would have to give me 15 minutes to say that. But basically, you cannot use what we call ecologic data, temporal trends that are occurring, to draw a conclusion about causality assessment.

The most telling evidence is in a clinical trial that was done in Finland, and those data were published. I will provide the committee with the final publication of that study, which clearly demonstrated in a randomized trial of Hemophilus influenza vaccine, that there was no difference between the two groups, it was a random chance that there would be a slight difference in numbers, but they're basically identically the same in children that got multiple

doses early in life versus a single dose later in life. And it's very convincing data.

Mr. WAXMAN. Thank you very much. I see the time is running out, but Admiral Crowe, I wanted to thank you for being here on such short notice and making yourself available to the committee. I know you had to shuffle around your schedule. I want to thank you for raising that issue of your relationship to BioPort, the anthrax vaccine manufacturer. There have been a lot of rumors floating around; you addressed it head on in your statement.

Some of these rumors are on the Internet. Several members of the Armed Services Committee suggested last week that you may have benefited improperly from inside information when you joined BioPort. And you just said that's absolutely not true; is that correct?

Admiral CROWE. Yes, sir. I sometimes think the Internet is more dangerous than taking the vaccine.

Mr. WAXMAN. You stated that anyone could have bid on the purchase of the Michigan facility with the full knowledge of DOD's planned vaccination program; isn't that correct?

Admiral CROWE. I'm sorry, would you say that again?

Mr. WAXMAN. Anybody could have bid on the purchase of the Michigan facility and had the knowledge about DOD's planned vaccination program?

Admiral CROWE. Oh, yes. That was public knowledge as early as 1996.

Mr. WAXMAN. And did other companies compete for that contract?

Admiral CROWE. They all knew about that. They all competed in that environment. They were all aware of it. Secretary Cohen's announcement, of course, in May, which was an official one, formal one, intensified the competition, but it didn't bring anything new to the debate.

Mr. WAXMAN. I'm pleased that you set the record straight and people should have known that.

Admiral CROWE. Thank you.

Dr. CLASSEN. Can I set the record straight on my own research, if that's possible?

Mr. WAXMAN. It's OK with me, let me find out what the chairman wants to do, because my time is up.

Mr. BURTON. Let me followup on that very quickly.

Mr. SHAYS. Can I ask a question, Mr. Chairman? We don't have any time restraints do we? We just have three members here.

Mr. BURTON. No, we don't. I would like to ask a question or two. Henry is welcome to ask questions. I would never stop Henry.

Admiral Crowe, it's my understanding that in September of—what year was that, 1998—the BioPort company was formed, and the papers were filed with the secretary of state, I guess, in Michigan who formed BioPort; and within 30 days of the filing of those papers, BioPort had the government contract. And during that interim period, you became a member of the board; is that correct?

Admiral CROWE. I became a member of the board because BioPort completed the transaction.

Mr. BURTON. But it was a 30-day period within about a month or so?

Admiral CROWE. The contracts were already set, and that was part of the agreement with the State of Michigan they would go on with the new owner.

Mr. BURTON. Before you became a part of BioPort, did you have any contact over——

Admiral CROWE. We had nothing to do with the contracts.

Mr. BURTON. Did you have any contact at all with the Department of Defense about the company at all?

Admiral CROWE. I visited the GPO office with my CEO 1 day. The State of Michigan, during the process of the negotiations, wanted to ensure—and this applied to all of the bidders, not just to BioPort—to ensure that if they won the bid, that the Defense Department would express some sense that it could accept their ownership of the firm. And all the bidders had to do that with the Defense Department, and that's what we did.

The negotiations——

Mr. BURTON. But you were the one that talked to them about that?

Admiral CROWE. Well, I went with the meeting where we asked them to answer this question. They didn't answer it in the meeting, they wrote a letter later, but——

Mr. BURTON. Did any of the other bidders, to your knowledge, have people who had been formerly high officials in the Pentagon?

Admiral CROWE. Certainly members of the government and the military.

Mr. BURTON. But high up in the Pentagon?

Admiral CROWE. Not that I know of, no, sir.

Mr. BURTON. OK.

Dr. Classen, you didn't have a chance to respond to the comments that Dr. Halsey was making regarding Mr. Waxman's questioning.

Dr. CLASSEN. Right, I would like to make the record straight.

There were two meetings to discuss vaccines and diabetes. The first was Dr. Halsey's meeting. That was a meeting that was funded by several vaccine manufacturers. My understanding is that that they fund Dr. Halsey's institute on safety, hundreds of thousands of dollars. I called the public health school and asked them particularly what vaccine manufacturers were funding this meeting.

It was not an objective meeting. Before the data was even presented, Dr. Halsey attacked me for being on TV regarding this issue, and that was clearly inappropriate since the data should have been discussed before his conclusions were made, but his conclusions were made beforehand.

He asked the panel, from what I was told, to sign a consensus statement essentially denouncing my findings. The panel absolutely refused to sign a consensus statement that denounced my findings. Therefore, I don't think there's any way you can say there's consensus if people would refuse to sign a consensus statement.

However, in his publication that he did on this meeting, there were numerous false information in this publication including the statement that there was consensus.

Mr. WAXMAN. Excuse me, Dr. Classen, you're talking about Dr. Halsey, but the National Institute of Allergy and Infectious Diseases had a meeting.

Dr. CLASSEN. Right, I'm going to discuss that.

Mr. WAXMAN. They had a consensus at their meeting from what I understand from their summaries.

Dr. CLASSEN. They did not have a vote. I mean, how can you say there's a consensus without some type of formal vote? It would be like saying, OK, this is——

Mr. WAXMAN. This isn't a report from Dr. Halsey, this is a report from the NIAID, and they say the consensus was that existing studies in humans do not indicate an increase in Type 1 diabetes attributable either to any vaccine or to the timing of vaccine administration.

Dr. CLASSEN. That's exactly why I'm so upset, and I talked to Mr. Shays about this. I mean, they're not being honest. They didn't have a vote. The only vote they had, from my understanding, was at Dr. Halsey's meeting where they in fact refused to sign a consensus statement. Then they had somebody go up in front of them, in front of this meeting saying, we have come to consensus, good day.

There was no vote. You can't have a consensus unless you take a poll and find out what's going on.

And the same day that Dr. Halsey is talking about was, in fact, his data from Finland where in fact the investigators submitted false data. This data was in fact funded in part by the United States Government; they submitted false data to the British Medical Journal. They did not include their sources of funding, that partially funded this study. In fact, the British Medical Journal then—as a neutral party, the British Medical Journal reported—whereas in the process of reporting these investigators to an ethics committee on ethics in publication in the UK—so it's a complicated issue and the people weren't always telling the truth.

And in fact——

Mr. WAXMAN. Excuse me. If people disagree on a scientific issue, is that not telling the truth if they disagree with the conclusions?

Dr. CLASSEN. It's not a consensus.

Mr. WAXMAN. You're saying one thing, somebody else says another thing. If they disagree with you, are they liars?

Dr. CLASSEN. No, but it's not a consensus. If they say there is a consensus, then there had better be a consensus.

Mr. WAXMAN. The National Institute of Allergy and Infectious Diseases says there was a consensus. You say there wasn't a consensus?

Dr. CLASSEN. Absolutely.

Mr. WAXMAN. Then we have a disagreement on that point.

Dr. CLASSEN. OK.

Mr. WAXMAN. Thank you, Mr. Chairman.

Mr. BURTON. I'm not sure this is going to be resolved today. I'm sure that you and Dr. Halsey have strong differences which we can't resolve. But I would like to have information from both of you that we can put into the record on your positions which we can't go into because of time constraints today.

Do you have some more?

Mr. SHAYS. Mr. Chairman, I apologize for extending this. There are different people here I would love to get their answers; and some of the answers I don't think I will like, but I want them on the record.

My fear is, and maybe I don't need to be afraid of this, but my fear is that we are entering a whole new area of—and I address this to you, Admiral Crowe, and, Dr. Halsey.

Admiral, my understanding is that you obviously believe there is the threat of biological, chemical, and potentially nuclear threat. I believe—I happen to believe that; I think we share that.

My sense is that you have gotten involved in this area because you believe this is an area that you are doing good; as you said earlier.

Admiral CROWE. I originally thought that, yes.

Mr. SHAYS. The question I have is, though, do you see that this is just the first of many vaccines that we will take as a prophylactic against the terrorists or attack by a military force?

Admiral CROWE. I don't know that I'm competent to answer that question. I don't foresee it specifically.

Mr. SHAYS. You are competent because I'm asking from your military background. Your military background said this was an area you should get involved in.

Admiral CROWE. Yes.

Mr. SHAYS. But I did make the assumption that you weren't just getting in for anthrax.

Admiral CROWE. Military history would suggest that in this challenge and many others that there will be movement in the weapons themselves and counterweapons.

Mr. SHAYS. And that the way to protect our military is through a vaccine?

Admiral CROWE. We will look at that.

Incidentally——

Mr. SHAYS. Don't run away too quickly here.

We're opening the door; this is a whole new approach for the military?

Admiral CROWE. Absolutely.

Mr. SHAYS. And I gathered from you that you believed this is a very positive development.

Admiral CROWE. That you could get protection from a vaccine?

Mr. SHAYS. And that we would go down that road.

I don't view it as positive.

Admiral CROWE. When you say "go down that road," I would agree with the comment made that it should be one of many steps.

Mr. SHAYS. OK. So this would be, the same logic that applies to anthrax could apply to some of the other threats?

Admiral CROWE. Possibly.

Mr. SHAYS. Because when you say to us, because I think about this, I mean if I have a role that makes this a voluntary process, and then there isn't some circumstance where anthrax is used, you know, that would be a pretty horrible thing to live with.

But you could say that about almost any threat?

Admiral CROWE. Yes.

Mr. SHAYS. And so I can't think that way. I have to kind of take myself out of that, you know, that consequence.

Dr. Halsey, do you see this as a positive development? I mean, are you concerned that we could have a military—drawing the military and get not only so many vaccines for natural potential, you know, Mother Nature, but also what your enemy may do, we're going—you're going to get 10 or 15 vaccines in the course of your service?

Dr. HALSEY. Well, I don't think that I or probably anybody else here wants to pretend that they can predict what will happen in the field of bioterrorism over the next decade or two with regard to what organisms might occur. Just from an infectious disease standpoint and a history of infectious disease, the military have had to be out front with routine immunization of troops against so many other organisms which we don't normally use for the general public.

I personally am more comfortable knowing that should there be a bioterrorism event that we at least have some troops who are not going to be susceptible to the organism and who will be available to help defend the country in any way they can.

So I see it as a positive development, because it does look to me as though anthrax is a very real risk.

Mr. SHAYS. So this just may be the beginning. And I don't say that other than just to say this may be just the beginning, correct?

Dr. HALSEY. Certainly. But I don't want to predict the future.

Mr. SHAYS. OK. Then do you not think it makes sense that if we are going to go down that route that there be some ability to monitor and regulate how the military does this?

Dr. HALSEY. Certainly everybody needs oversight. And I would agree with what I think you're saying, in that there should be some oversight of this process. Who that is, I don't know, but you're in a much better position to determine who that might be.

There is the Armed Forces Epidemiologic Board which has in the past provided a lot of this coordination, but I don't know the oversight mechanisms.

Mr. SHAYS. The DOD acknowledges they're not in technical compliance. They are trying to comply. But even their definition of "compliance" is, if they miss within 30 days, they're still in compliance.

So we have got this double challenge; one is, first, to acknowledge that they're not even within their 30 days past date, but even their writing a rule that basically says they're in compliance if they're 30 days late.

Doesn't that tell you something about how the DOD is approaching their effort to live up to the protocol, and forgetting—I'm not talking about the whole issue of getting involved in medicine. I'm just talking about abiding by the protocol.

Dr. HALSEY. I probably am not qualified to speak, because I don't know the precise protocol that they're following and what windows of time that they provide opportunities for people to meet the requirements of the protocol. And I think you should address that to the military.

Mr. SHAYS. If a protocol says you're supposed to have a shot and—six shots, and it gives the exact dates of time within a certain period, I'm asking—this is your area of expertise.

Dr. HALSEY. I will be glad to respond.

And I think it's very evident to me as a pediatrician that has been concerned about vaccination of children that we do have guidelines that call for precise ages at which those vaccines are given. But, unfortunately, there are many children in this country, in spite of having very conscientious parents, who don't get those vaccines at exactly the time that we recommend them—2, 4, and 6 months. We don't call them delinquent unless they go at least a month beyond the time that is recommended and then we consider them behind.

So the principle of setting up some guidelines like that is widespread in immunization.

Mr. SHAYS. OK, thank you.

Thank you, Mr. Chairman.

Mr. BURTON. These people look like they're getting hungry.

Mr. SHAYS. Don't give up here. Let's pursue this.

Mr. BURTON. I can handle it, if you can, Henry. Go ahead.

Mr. WAXMAN. Thank you, Mr. Chairman.

Admiral Crowe, as a military proposition, if you've got a possible enemy with a new weapon, you want to figure a way to counter that new weapon.

Admiral CROWE. Yes.

Mr. WAXMAN. And what we're talking about is a vaccine that can, we would hope, be able to counter a terrorist activity.

Admiral CROWE. Hopefully.

Mr. WAXMAN. I'm sort of surprised that we wouldn't be pleased that we have such an opportunity.

Admiral CROWE. That was my original approach. I thought the country would be—would welcome this.

Mr. WAXMAN. I have my doubts about the strategic defense initiative, because it's very expensive and I don't know whether it will be effective. And I tend to think that one of the dangers would be not a nuclear weapon sent by a missile but a nuclear weapon being brought in by a terrorist. I suppose the answer to that would be, well, you don't leave your troops vulnerable to that attack.

Is that the way you would look at that, or how would you respond to that?

Admiral CROWE. There are many ways to deliver the weapon, it's a multifaceted problem, and it's a very serious threat.

Mr. WAXMAN. So bioterrorism can be multifaceted as well?

Admiral CROWE. Yes, as well.

Mr. WAXMAN. You try to figure out, as best you can, how to do that?

Admiral CROWE. Actually, we do a variety of things. We do a great many things besides this to try to protect our men, our equipment from—to live in a biological environment. One of the things that we should consider about this vaccine is, we discuss the military aspects today, but it also should be—if it's successful, and we can refine it so that it is, it should probably be administered to civilians at some point. If we ever have an anthrax scare on this country, there is going to be a great demand for it on the civilian market.

Mr. SHAYS. Would you like to advertise in the hearings?

Admiral CROWE. I find that sort of upsetting, not comfortable.

Mr. WAXMAN. I'm not sure if I agree with that, because I know that the larger the population that we immunize, the greater the chance of risks.

Admiral CROWE. OK.

Mr. WAXMAN. And I think that, as Mr. Shays indicated, we have a responsibility wherever our people are taking risks. Especially if the government is telling them to take those risks, we have to be very responsible and cautious to be sure that it's a risk that is a prudent one for us.

Admiral CROWE. I will say one thing. If I was exposed to anthrax, I sure would like to have this kind of protection and I do have it.

Mr. WAXMAN. And I would agree with you there. Thank you very much. I know you've been on for hours, and I had another committee hearing, so I'm coming in fresh. But I thank you, Mr. Chairman, for being so indulgent of me and the members of the panel.

Mr. BURTON. No problem, Mr. Waxman.

Did you have anything else, Mr. Shays?

Mr. SHAYS. No, thank you.

Mr. BURTON. I want to thank you very much. You've been patient. And you gentlemen in the military, if you have any undue pressure, I hope you will contact my office and maybe we can help. We will do our best to help you out.

Thank you very much. We stand adjourned.

[Whereupon, at 5:40 p.m., the committee was adjourned.]

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