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THE ANTHRAX VACCINE IMMUNIZATION PROGRAM—WHAT HAVE WE LEARNED?

HEARINGS

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTH CONGRESS

SECOND SESSION

OCTOBER 3 AND 11, 2000

Serial No. 106–249

Printed for the use of the Committee on Government Reform



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THE ANTHRAX VACCINE IMMUNIZATION PROGRAM—WHAT HAVE WE LEARNED?

TUESDAY, OCTOBER 3, 2000

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

The committee met, pursuant to notice, at 11 a.m., in room 2154, Rayburn House Office Building, Hon. Dan Burton (chairman of the committee) presiding.

Members present: Representatives Burton, Morella, Shays, Horn, Hutchinson, Jones, Waxman, Maloney, Norton, Cummings, Kucinich, and Schakowsky.

Staff present: Kevin Binger, staff director; David A. Kass, deputy counsel and parliamentarian; Sean Spicer, director of communications; S. Elizabeth Clay, professional staff member; Gil Macklin, professional staff member and congressional investigator; Robert A. Briggs, clerk; Michael Canty and Toni Lightle, legislative assistants; Josie Duckett, deputy communications director; Scott Fagan, staff assistant; Leneal Scott, computer systems manager; John Sare, staff assistant; Maria Tamburri, assistant to chief counsel; Corinne Zaccagnini, systems administrator; Phil Schiliro, minority staff director; Sarah Despres and David Rapallo, minority counsels; Ellen Rayner, minority chief clerk; and Earley Green, minority assistant clerk.

Mr. SHAYS [presiding]. Good morning. A quorum being present, the Committee on Government Reform will come to order. The hearing will come to order.

I will begin by asking unanimous consent that all Members' and witnesses' written opening statements be included in the record. And without objection, so ordered. I ask further unanimous consent that all articles, exhibits and extraneous or tabular material referred to be included in the record. And without objection, so ordered.

The vulnerability of the Department of Defense Anthrax Vaccine Immunization Program [AVIP], to supply shortages, was one of the major reasons the Government Reform Committee recommended suspending the program 7 months ago. We saw then what DOD only now has been forced to concede, the program is too broad, an undertaking built on too narrow a foundation.

The decision to scale back the AVIP addresses the reality of the current shortage, but fails to confront the fundamental flaw on the program: use of an antiquated medical technology to counter a decidedly modern threat. No program based on the old vaccine can

be sustained. The current producer, the BioPort Corp., has been unable to qualify for a license to make more vaccine.

Their facility is virtually Government-owned already, so there is no reason to believe another Government-owned, contractor operated, GO-CO enterprise, would have any greater success attempting to use the same elaborate, highly regulated, manufacturing process. Why? Because neither BioPort nor DOD is ready to admit the significance of the key FDA inspectional finding first stated in February 1998, and repeated in November 1999: the anthrax vaccine production process is not validated.

That means BioPort lacks data to support the way they conduct key steps in the production process. That in turn means BioPort cannot prove the process is ever the same twice in a row or the vaccine is the same from lot to lot. Validating the anthrax vaccine production process will not be quick and it will not be cheap. When DOD spokesmen blithely describe the company's efforts to work down the list of 30 FDA inspectional findings, they make it sound like a car repair checklist.

DOD seems to believe all BioPort needs to do is tighten a few screws, plug a few leaks, fill out some pesky paperwork and the FDA will be satisfied. In fact, validating a 1950's era vaccine process against current biologic manufacturing standards is more like trying to get an Edsel through modern auto safety and emissions testing. To pass muster will require bending the rules or the expenditure of extraordinary amounts of money, money that could be better applied toward the approval of an improved vaccine.

Without an insured supply of modern anthrax vaccine in hand, continuing to order soldiers, sailors, airmen and marines to start a course of shots they may never finish constitutes in my judgment military malfeasance and medical malpractice. Despite earlier promises to adhere to the FDA approved regimen of 6 shots over 18 months, DOD now admits the shortage means many service members will not be kept on the regime shown to protect humans against anthrax. According to DOD, shots can be delayed up to 2 years before the series has to be restarted.

Now that the program has been reduced to a more reasonable size, what will be the fate of those who are punished for resisting an order that no longer stands? They didn't get a 2-year reprieve. Because DOD placed more faith in BioPort's faulty production estimates than in the intelligence and integrity of those with legitimate questions about the program, hundreds of dedicated, loyal Americans have had their health damaged or their military careers ruined.

Don't they deserve the same deference, even forgiveness, DOD seems so willing to extend to BioPort? No one should doubt the threat is real, as real as the threat of radiological weapons and the threat posed by a myriad of easily obtainable chemical compounds which we have no medical pretreatments. No one should doubt the good intentions motivating this response to the anthrax threat.

But I have come to doubt the judgment, the foresight and the competence of those who chose the wrong approach, persisted in pursuing that approach well after it had become obviously unsustainable, and now can't seem to admit their mistakes and move on.

In the early 1990's, DOD faced a fork in the road to effective force protection and picked the wrong path. Had DOD followed its own assessments of the inadequacies of the current vaccine, they could have focused on obtaining FDA approval of the modern, improved anthrax inoculation needed to meet the real military threat. Instead, they have wasted precious time and money acquiring little more than a false sense of security U.S. troops will be protected against biological warfare.

That time and money should have been spent on modern medical counter-measures and improved protective gear, suits and masks effective against all chemical and biological CB threats.

When confronted over weak CB defenses, including a flawed anthrax vaccine program, some DOD officials retreat to the indefensible position, something is better than nothing. But that false choice glorifies mediocrity as an acceptable force protection standard. U.S. forces deserve the best protection against a growing array of chemical and biological threats. They should not have to risk their lives relying on defective equipment and antiquated vaccines that run out.

We will hear testimony today from many who are involved in and affected by the anthrax vaccine program. Their experience and perspective should help the committee better understand where the AVIP has gone wrong, and where the program needs to go. We welcome their testimony.

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

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Statement of Rep. Christopher Shays
October 3, 2000

The vulnerability of the Department of Defense Anthrax Vaccine Immunization Program (AVIP) to supply shortages was one of the major reasons the Government Reform Committee recommended suspending the program seven months ago. We saw then what DOD only recently has been forced to concede: the program is too broad an undertaking built on too narrow a foundation.

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No program based on the old vaccine can be sustained. The current producer, the BioPort Corporation, has been unable to qualify for a licence to make more vaccine. Their facility is virtually government-owned already, so there is no reason to believe another government-owned, contractor-operated, or GOCO, enterprise will have any greater success attempting to use the same elaborate, highly regulated manufacturing process.

Why? Because neither BioPort nor DOD is ready to admit the significance of the key FDA inspectional finding first stated in February 1998 and repeated in November 1999: the anthrax vaccine production process is not validated.

That means BioPort lacks data to support the way they conduct key steps in the production process. That in turn means BioPort cannot prove the process is ever the same twice in a row, or the vaccine is the same from lot to lot.

Validating the anthrax vaccine production process will not be quick, and it will not be cheap. When DOD spokesmen blithely describe the company's efforts to work down the list of thirty FDA inspectional findings, they make it sound like a car repair checklist. DOD seems to believe all BioPort needs to do is tighten a few screws, plug a few leaks, fill out some pesky paperwork, and the FDA will be satisfied.

In fact, validating the 1950s era vaccine process against current biologic manufacturing standards is more like trying to get an Edsel through modern auto safety and emissions testing. To pass muster will require bending the rules or the expenditure of extraordinary amounts of money - money that could be better applied to the approval of an improved vaccine.

Without an assured supply of a modern anthrax vaccine in hand, continuing to order soldiers, sailors, airmen and Marines to start a course of shots they may never finish constitutes, in my judgment, military malfeasance and medical malpractice.

Despite earlier promises to adhere to the FDA-approved regimen of six shots over 18 months, DOD now admits the shortage means many service members will not be kept on "the only regimen shown to protect humans against anthrax." According to DOD, shots can be delayed up to two years before the series has to be restarted.

Now that the program has been reduced to a more reasonable size, what will be the fate of those who were punished for resisting an order that no longer stands? They didn't get a two-year reprieve.

Because DOD placed more faith in BioPort's faulty production estimates than in the intelligence and integrity of those with legitimate questions about the program, hundreds of dedicated, loyal Americans have had their health damaged or their military careers ruined. Don't they deserve the same deference, even forgiveness, DOD seems so willing to extend to BioPort?

No one should doubt the threat is real; as real as the threat of radiological weapons and the threat posed by a myriad of easily obtainable chemical compounds against which we have no medical pretreatments.

No one should doubt that good intentions motivated this response to the anthrax threat. But I have come to doubt the judgment, the foresight and the competence of those who chose the wrong approach, persisted in pursing that approach well after it had become obviously unsustainable, and now can't seem to admit their mistakes and move on.

In the early 1990s, DOD faced a fork in the road to effective force protection and picked the wrong path. Had DOD followed its own assessments of the inadequacy of the current vaccine, they could have focused on obtaining FDA approval of the modern, improved anthrax inoculation needed to meet the real military threat.

Instead, they have wasted precious time and money acquiring little more than a false sense of security U.S. troops will be protected against biological warfare. That time and money should have been spent on modern medical countermeasures and improved protective gear - suits and masks - effective against all chemical and biological (CB) threats.

When confronted over weak CB defenses, including a flawed anthrax vaccine program, some DOD officials retreat to the indefensible position: "something is better than nothing." But that false choice glorifies mediocrity as an acceptable force protection standard.

U.S. forces deserve the best protection against a growing array of chemical and biological threats. They should not have to risk their lives relying on defective equipment and antiquated vaccines that run out.

We will hear testimony today from many who are involved in, and affected by, the anthrax vaccine program. Their experiences and perspectives should help the Committee better understand where the AVIP has gone wrong, and where the program needs to go. We welcome their testimony.

Mr. SHAYS. At this time, I thank my colleague, Mr. Waxman, for allowing us to begin without his presence, and would now recognize him.

Mr. WAXMAN. Thank you very much, Mr. Chairman.

When this committee took up consideration of the anthrax vaccine report by the National Security Subcommittee last March, I stated that I had several concerns about the Defense Department's program. For that reason, I agreed with many of the report's findings.

I agreed, for example, that the anthrax program was vulnerable to supply shortages and price increase. I also agreed that a reduced shot series potentially could bring down the number of adverse events experienced by service members. And I agreed with proposals to conduct further study on the safety of the vaccine.

I'm pleased to see that the Department of Defense has begun to implement several of these recommendations, such as investigating a reduced shot regimen and soliciting bids for second source contracts. I note, too, that the Institute of Medicine is today convening a conference to assess the safety of the vaccine.

I also said in March that I am not a medical doctor or an intelligence expert. For that reason, I deferred to FDA's assessment of the vaccine's safety and the Defense Department's conclusion about the need to vaccinate members of the armed services. And this remains my view.

At today's hearing, we will hear from several service members who have served this country honorably and their family members who are understandably concerned about the health of their sons and daughters, husbands and wives. Some of these cases are heartbreaking.

Senior Airman Thomas Colosimo, for example, developed multiple cysts on his skull, suffers from repeated blackouts and has been unable to work, travel or do anything unaccompanied since he developed his condition. And Sergeant Kevin Edwards was forced to have a tracheotomy in a helicopter on his way to a hospital in Korea. He has suffered from a terrible skin condition, has lost part of his eyesight, and has even had his tear ducts removed. My heart goes out to these brave individuals. We should be committed to their proper treatment and care and we should honor their service to our country.

Finding what caused these terrible illnesses and injuries can be difficult. As epidemiologists explain, it is often hard to establish a link between a vaccination and an illness that subsequently develops. Statistically, many health problems occur in the general population at or near points in time when individuals receive injections.

It is important, therefore, that we actively gather as much information as possible. We must examine all relevant medical data about the origin and development of conditions in specific cases. We can also compare the prevalence of these conditions among vaccinated populations against those among unvaccinated populations.

A positive step occurred in July 1998, when DOD proposed a program to evaluate, on an individual basis, adverse event reports for the anthrax vaccine. In response, the Department of Health and Human Services convened a group of non-governmental medical experts as the Anthrax Vaccine Expert Committee [AVEC]. AVEC is

unique in that it provides an independent expert assessment of adverse events reported for the anthrax vaccine. And as I understand it, the AVEC has been evaluating cases involving some of the service members here today.

AVEC was not invited to testify about its findings which could have shed more light on this issue. But the expert committee has prepared a description of their origin, function and findings to date. And I would ask unanimous consent to include their summary in the record.

Mr. SHAYS. Without objection, so ordered.

Mr. WAXMAN. In closing, I'd like to thank the chairman for agreeing to the minority request to invite Dr. Alec Walker, an esteemed epidemiologist from the Harvard School of Public Health. Perhaps Dr. Walker can provide some additional context for this issue.

Thank you very much, Mr. Chairman, for convening this hearing and giving our witness an opportunity to make a statement.

[The prepared statement of Hon. Henry A. Waxman follows:]

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STATEMENT OF REPRESENTATIVE HENRY A. WAXMAN

Hearing:
The Anthrax Vaccine Immunization Program — What Have We Learned?

October 3, 2000

Mr. Chairman, when this Committee took up consideration of the anthrax vaccine report by the National Security Subcommittee last March, I stated that I had several concerns about the vaccine program operated by the Department of Defense (DOD). For that reason, I agreed with many of the report's findings.

I agreed, for example, that the anthrax program was vulnerable to supply shortages and price increases. I also agreed that a reduced shot series potentially could bring down the number of adverse events experienced by service members. And I agreed with proposals to conduct further study on the safety of the vaccine.

I am pleased to see that the DOD has begun to implement several of these recommendations, such as investigating a reduced-shot regimen and soliciting bids for second source contracts. I note too that the Institute of Medicine is today convening a conference to assess the safety of the vaccine.

I also said in March that I am not a medical doctor or an intelligence expert. For that reason, I deferred to the assessment of the Food and Drug Administration (FDA) regarding the vaccine's safety and the conclusion of DOD about the need to vaccinate members of the armed services.

This remains my view.

At today's hearing, we will hear from several service members who served this country honorably and their family members who are understandably concerned about the health of their sons, daughters, husbands, and wives.

Some of these cases are heartbreaking:

- Senior Airman Thomas Colosimo, for example, developed multiple cysts on his skull, suffers from repeated black-outs, and has been unable to work, travel, or do anything unaccompanied since he developed his condition.

-more-

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In closing, I would like to thank the Chairman for agreeing to the minority request to invite Dr. Alec Walker, an esteemed epidemiologist from the Harvard School of Public Health. Perhaps Dr. Walker can provide some additional context for this issue.

Thank you.

# #

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

At this time we would recognize Mr. Horn and then I will give up the Chair to the chairman. Mr. Horn, you have the floor. Mr. Horn, do you have an statement?

Mr. HORN. No.

Mr. SHAYS. I recognize at this time the chairman of the Committee, Mr. Burton.

Mr. BURTON. Mr. Chairman, let me just say that I'm going to have to run in and out, because we have some important business with the other committee. So I will stay here and hope you'll retain the Chair while I travel back and forth for a while.

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

Opening Statement

Chairman Dan Burton

Government Reform Committee Hearing

"Anthrax Vaccine Immunization Program – What Have We Learned?"

Tuesday
October 3, 2000
11:00 am

2154 Rayburn House Office Building
Washington, DC

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

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

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

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

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

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

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

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

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

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

- Secretary Cohen stated that before implementing the Anthrax Vaccine Immunization Program, four conditions would be met. One of those conditions was a review of the medical aspects by an "independent expert." The average American would think that he meant an anthrax expert. In March of last year, Dr. Sue Baily, then Assistant Secretary of Defense for Health Affairs, testified to Mr. Shays' subcommittee that "the

safety of our anthrax vaccine immunization program was confirmed by an independent review of the program by Dr. Gerald Burrow, the Special Advisor for Health Affairs for the President of Yale University." As it turns out, Dr. Burrow is a Professor of obstetrics and gynecology. In an April 1999 letter to Mr. Shays, Dr. Burrow admitted that he made it very clear to the Department that he had no expertise in anthrax and that he was conducting the review out of his sense of patriotism. Yet, the Department misrepresented the "independent expert review" to Congress and to its military members and moved forward with the program.

- Lieutenant General Ron Blanck, then the Surgeon General of the Army, testified before the House Armed Services Committee in September of last year. He said that the anthrax vaccine would offer protection against all strains of anthrax. Dr. Arthur Friedlander, a Senior Military Scientist is here today. He authored the only peer-reviewed efficacy study on anthrax. In the 1999 edition of the medical textbook, *Vaccines,* he wrote that the current anthrax vaccine is unsatisfactory for several reasons, including that there is evidence in rodents that the efficacy of the vaccine may be lower against some strains of anthrax than others.

- In regards to genetically modified strains of anthrax, in April of this year, General Blanck told the Senate Armed Services Committee that the Department continues to "hear rumors" about these strains. The fact is that in 1997, Russian scientists published an article about the existence of genetically modified anthrax strains in a British medical journal. The Defense Department played that down in the hearing.

- Mr. Cragin, the Principal Deputy Assistant Secretary of Defense for Reserve Affairs, told Mr. Shays in September of last year that if someone in the National Guard or Reserve is going to resign rather than take the anthrax vaccine, they would not be subject to any penalties. However, the guidance given to Air Force Reserve commanders was not in line with Mr. Cragin's testimony. The Air Force instructed its commanders not to allow transfers of US Air Force Reserve personnel to non-mobility positions in the Reserves unless the individual agreed to take the anthrax vaccine. These reservists were told they would have to

take the vaccine before being transferred, even though the new position was not a part of Phase One vaccine schedule.

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

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

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

seventh of those that served in the Gulf, are being shuffled into psychological evaluations and not being adequately diagnosed and treated.

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

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

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

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

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

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

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

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

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

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

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

The hearing record will remain open until October 18.

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

Mr. SHAYS. Thank you. It's good to have you back.

At this time, Mr. Cummings.

Mr. CUMMINGS. Mr. Chairman, I just wanted to thank you for holding this hearing. I will submit my statement for the record.

[The prepared statement of Hon. Elijah E. Cummings follows:]

Statement
of
Congressman Elijah E. Cummings
Committee on Government Reform Hearing

"The Anthrax Vaccine Immunization Program—What Have We Learned?"

October 3, 2000

Thank you, Mr. Chairman.

The threat of terrorism is critically important to me, my constituents and citizens across this nation. The topic is prevalent in the news and even in entertainment - on TV shows and in movies. The public focus on this issue demonstrates the concern and fear of terrorism that exists today. We must ensure the American people that we have and are continuing to mount an appropriate defense.

The possibility of biological warfare is very real. And the threat of such warfare is not new. A brief look at history demonstrates that chemical and biological warfare has its roots dating back to at least the year 1337 B.C., when plague-ridden cadavers were catapulted over castle walls to spread disease.

With the recent growth of weapons of mass destruction and biological weaponry, it has become very clear that there is an increased need to protect – not only citizens within our borders – but also those who defend our country against outside threats.

There is growing resentment against Americans around the world. I believe that we must do all that we can to ensure the safety of the men and women of our armed services against biological weapons.

The biological weapon, **anthrax**, has become an even greater threat because it is easy to produce, can be stored for long periods of time, and is relatively inexpensive. In fact, anthrax represents the most likely threat to the U.S. and our military personnel. As such, it only makes sense that with the increased threat of biological terrorism that we include the anthrax vaccination and any other biological warfare defense in all of our protection planning.

Through advancement of medical technology, we are attempting to combat the deadly effects of this weapon. Although no vaccine is 100% safe or effective, and cannot possibly protect against all forms of biological

weapons, the Department of Defense views vaccines as one component to protect our military personnel. Specialists at the Department of Defense (DOD), Food and Drug Administration (FDA) and the State Department have tirelessly worked to improve a vaccine created to prevent the lethal consequences of anthrax ingestion. These agencies have made clear that they will continue to monitor the safety of the anthrax vaccination.

Experts at the Centers for Disease Control & Prevention have stated that only one thing has saved more lives than vaccines: clean water. Armed with this information, at this time of year, many Americans are visiting health care professionals to receive their influenza immunizations or "flu shots." We routinely receive this vaccination every year to protect us from influenza. We encourage this vaccine "TO SAVE LIVES."

Like the flu shot, the anthrax vaccination is designed to protect our men and women who put their lives on the line everyday to protect our country and the freedoms of all people. It is our duty, as lawmakers, to ensure that we use all capabilities, including a vaccine, to reach this goal.

I welcome the testimony of our witnesses and commend the Committee for holding this hearing. Thank you.

Mr. SHAYS. Thank you, Mr. Cummings.

Mr. Hutchinson.

Mr. HUTCHINSON. Thank you, Mr. Chairman.

I just want to express my appreciation for this hearing. I actually came here for a couple of reasons, one, to hear my good colleague, Mr. Metcalf, but also to hear my brother, Senator Hutchinson. And I understand that he has been called to a conference meeting and may be unable to be here. But I did want to make sure that his statement was submitted in the record and made a part of it. And he really has a great interest in looking at the Government-owned, contractor operated vaccine production facility and is working to accomplish that or look into that from the Senate side.

I hope that that will be a tangential aspect of this hearing as well. So with that, Mr. Chairman, I yield back.

Mr. SHAYS. Thank you.

At this time, Ms. Schakowsky.

Ms. SCHAKOWSKY. Yes, thank you, Mr. Chairman.

I don't have a statement, but let me just say a few words of thanks to you for holding this hearing, and also to Mr. Metcalf for his leadership on this issue. I was happy to support and sign on to the letter that you sent to the Department of Defense on squalene. And I also appreciate your support in asking for a GAO report on gender differences in our vaccination program and hope that maybe we can get some answers on the status of that issue. So I just want to thank you.

Mr. SHAYS. Thank you very much.

We would ask at this time for unanimous consent that Mr. Jones be allowed to participate in our hearing, both to hear the witnesses, to ask questions. And also I understand that you will be introducing one of the witnesses. So would you like to be recognized now or then?

Mr. JONES. Mr. Chairman, I'll be glad to—the witness that I was asked to introduce will be in the second panel.

Mr. SHAYS. But if you'd like to make a statement, you're more than welcome.

Mr. JONES. I just thank you very much for letting me join this committee as this, I think, is one of the most, when I think about the number of men and women who have left the military over this issue, I think this is extremely important to the national security of this Nation. Thank you.

Mr. SHAYS. Thank you. And I, too, want to thank the chairman for conducting this hearing, and establishing it. And I'm happy to participate in it.

Mr. Metcalf, my understanding is you are going to make a statement and not respond to questions. We won't swear you in for that reason, and then we'll be swearing in our witnesses that follow. You have the floor.

STATEMENT OF HON. JACK METCALF, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WASHINGTON

Mr. METCALF. Thank you, Mr. Chairman, for this opportunity. I share the gratitude of many veterans and military personnel across this Nation for your determined insistence that our men and women in uniform be provided with the best in force protection.

When I began my investigation in 1997, I did so for the veterans and their families who had heard that antibodies to squalene had been discovered in the blood of some sick Gulf war era veterans. I was assured at the time by many that there was nothing to these allegations. But it seemed prudent to me to have the General Accounting Office take a look.

Today, due to a stunning lack of cooperation, we find ourselves with only more questions and only few answers. We must get to the truth.

For that reason, I have issued a report culminating a 3-year investigation into the conduct of the Department of Defense with regard to the possibility that squalene, a substance in vaccine adjuvant formulations not approved by the FDA, was used in inoculations given to Gulf war era service personnel.

According to the General Accounting Office, scientists have expressed safety concerns regarding the use of novel adjuvant formulations in vaccines, including squalene. The report reveals that the FDA has found trace amounts of squalene in the anthrax vaccine. The amount recorded could, and I quote from the report, "boost immune response," according to immunology professor Dr. Dorothy Lewis of Baylor University.

Mr. Chairman I was shocked to learn this week that an FDA spokesperson had dismissed their own findings by declaring that the levels found are inconsequential, that they are naturally occurring and that one would expect to find these levels in any biological vaccine. We've been told for 3 years there is no squalene in anthrax vaccine. Then suddenly we're told, oh, yes, there is, but it's no big deal, it's everywhere. The questions must be asked: have they indeed tested all vaccines for the presence of squalene? If so, at what levels has squalene been detected.

Does that mean the FDA would expect to find squalene in childhood vaccines? If detected, could levels harm a 3-month old?

For years we've been told by the Department of Defense, as the FDA sat by in silent complicity, that they had tested for the presence of squalene and that the anthrax vaccine was found to contain no squalene. Indeed, they have stated repeatedly, the FDA verified that none of the vaccines used during the Gulf war contained squalene as an adjuvant.

Since the FDA's own findings call this statement into serious question, I am calling on you, Mr. Chairman, to initiate an immediate GAO investigation that must ask one vital question: how did squalene get into the anthrax vaccine tested by the FDA?

Scientists who have reviewed my staff's findings agree that this question must be answered. My report states that an aggressive investigation must be undertaken to determine the source of the squalene and the potential health consequences to those who have been vaccinated, both during and after the Gulf war. It again calls for an immediate halt to the current anthrax vaccination immunization program until this issue and the other problems so clearly defined by this committee have been resolved.

My report also documents at length DOD stonewalling attempts to resolve the squalene issue, which led General Accounting Office investigators to document their concerns questioning a pattern of deception, a pattern of deception. The GAO stated that the Depart-

ment of Defense denied conducting extensive squalene testing before the Gulf war, then admitted it after being confronted with the public record.

The GAO revealed that some Department of Defense officials deliberating deployment of the anthrax vaccine expressed, "a willingness to jump out and use everything," in discussing experimental vaccines containing adjuvants not approved by the FDA.

General Accounting Office also found that Peter Collis, the Department of Defense official who headed vaccine efforts, refused to cooperate with them. The report states that the Department of Defense has refused to act in good faith upon the General Accounting Office recommendations to replicate the findings of a test developed by renowned virologist Dr. Robert Garry of Tulane University. Although Department of Defense admitted that they could easily do so. The work of the Tulane researchers has been peer reviewed in a scientific publication of high standing.

Finally, my report states that Congress should take immediate action to review the findings of the General Accounting Office and the Armed Services Epidemiological Board, and provide independent oversight for the immediate implementation of their recommendations. The board recently called on the Department of Defense to engage in close cooperation with Tulane researchers, mirroring the General Accounting Office recommendations from March 1999.

How tragic that we have lost nearly 2 years because the Department of Defense insisted on having their adjuvant expert, who lied to the GAO about his role during the Gulf war, to try to reinvent the wheel instead of cooperating with the Tulane researchers as directed. They have repeatedly expressed their willingness to help find answers to those who are suffering from Gulf war illnesses.

I ask this committee to ensure the recommendations are implemented by those who will guard the integrity of the process and get to the truth. Mr. Chairman, I once again commend you for your courage and leadership. As I am about the leave the Congress, I ask you and the committee to stay the course until the truth is determined and justice is done. Veterans, active service members and their families deployed around the world, are counting on you.

Thank you so very much.

[The prepared statement of Hon. Jack Metcalf follows:]

JACK METCALF
2d District, Washington

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GROUND TRANSPORTATION

COMMITTEE ON SCIENCE
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CHAIR, REPUBLICAN HOUSING OPPORTUNITY CAUCUS

REPUBLICAN POLICY COMMITTEE

Testimony of Congressman Jack Metcalf
Before Hearing of Committee on Government Reform
October 3, 2000

Mr Chairman, I want to thank you for inviting me to testify today on the potential relationship between Gulf War Illnesses and the anthrax vaccinations. I share the gratitude of many veterans and military personnel across this nation for your determined insistence that our men and women in uniform be provided the best in force protection.

I want to make it clear to this committee that when I began this investigation in 1997, I did so in response to the concerns of veterans and their families who had heard that antibodies to squalene had been discovered in the blood of some sick Gulf War-era veterans. My office was assured by other congressional staff that there was nothing to the allegations. It seemed prudent to me to have GAO take a look at the issue, and put it to rest. However, after an investigation that was greatly delayed by a stunning lack of cooperation, we find ourselves with only more questions, and few answers. We must get to the truth.

Indeed, we have an obligation to pursue the truth, wherever it may lead us. To do less would be to act dishonorably toward the dedicated men and women who stand between us and a still dangerous world.

For that reason, I have issued a report culminating a three year investigation into the conduct of the DOD (Department of Defense) with regard to **the possibility that squalene, a substance in vaccine adjuvant formulations not approved by the FDA, was used in inoculations given to Gulf War era service personnel.** According to the GAO (General Accounting Office), scientists have expressed safety concerns regarding the use of novel adjuvant formulations in vaccines, including squalene.

The report reveals that **the FDA has found trace amounts of squalene in the anthrax vaccine. The amounts recorded could "boost immune response**," according to immunology professor Dr. Dorothy Lewis of Baylor University. Mr. Chairman, I was shocked to learn this week that a FDA spokesperson had dismissed their own findings by declaring that the levels found are inconsequential, that they are naturally occurring, and that one would expect to find these levels in any biological vaccine. We've been told for three years there is no squalene in the anthrax vaccine, then suddenly we are told, "Oh yes, its there, but its no big deal-- its everywhere." The questions must be asked: Have they indeed tested all vaccines for the presence of squalene? If so, at what levels has squalene been detected? Does that mean the FDA would expect to find squalene in childhood vaccines? If detected, could the levels harm a three month old?"

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For years we have been told by the Department of Defense, as the FDA sat by in silent complicity, that they had tested for the presence of squalene and that the anthrax vaccine was found to contain no squalene. Indeed they have stated repeatedly, "the FDA verified that none of the vaccines used during the Gulf War contained squalene as an adjuvant." However, on the first page of the letter sent to me by the FDA, they corrected the DOD remark by clarifying that, "neither the licensed vaccines known to be used in the Gulf War, nor the one investigational product known to have been used, contained squalene as an adjuvant in the formulations on file with FDA." Those are two very different statements of the facts.

Therefore, I am calling on you, Mr. Chairman, to initiate an immediate GAO investigation that must ask one vital question: How did squalene get into the anthrax vaccine tested by the FDA? Scientists who have reviewed my staff's findings, agree that this question must be answered.

My report states that an aggressive investigation must be undertaken to determine the source of the squalene, and the potential health consequences to those who have been vaccinated, both during and after the Gulf War. It again calls for an immediate halt to the current Anthrax Vaccination Immunization Program until this issue and the other problems so clearly defined by this committee have been resolved.

My report also documents at length DOD "stonewalling" attempts to resolve the squalene issue, which **led GAO investigators to document their concerns questioning "a pattern of deception**." The GAO stated the DOD denied conducting extensive squalene testing before the Gulf War, then admitted it after being confronted with the public record. The GAO revealed that some DOD officials deliberating deployment of the anthrax vaccine expressed a "willingness to jump out and use everything," in discussing experimental vaccines containing adjuvants not approved by the FDA.

GAO also found that Peter Collis, DOD official who headed vaccine efforts, refused to cooperate with them. The report states that the DOD has refused to act in good faith upon the GAO recommendation to replicate the findings of a test developed by renowned virologist Dr. Robert Garry of Tulane University, although DOD admitted they could easily do so. The work of the Tulane researchers has been peer-reviewed in a scientific publication of high standing.

Finally, my report states that "Congress should take immediate action to review the findings of the GAO and the Armed Services Epidemiological Board, and provide independent oversight for the immediate implementation of their recommendations." **The board recently called on the DOD**

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Mr. Chairman, I want to once again commend you for your courage and leadership. As I am about to leave the Congress, I ask you and the committee to stay the course until the truth is determined and justice is done. Veterans, active service members and their families deployed around the world are counting on you. Thank you so much.

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Mr. SHAYS. Thank you, Mr. Metcalf. You truly will be missed for so many issues. Obviously this is one that you're very focused on, but so many others. And your service has been exemplary.

Thank you for being here.

Mr. METCALF. Thank you.

Mr. SHAYS. We have a panel that is fairly lengthy, and I would invite them to come up basically in the order that we call them. Major John Irelan, Nancy Rugo, Barbara Dunn, Kevin Edwards, Toney Edwards, Senior Airman Thomas J. Colosimo, Joseph Jones, David Ponder, John J. Michels and Dr. Alexander M. Walker. Except for the last two people I have called, I would basically describe this panel as a panel comprised of potential victims of anthrax or related to people who are possible victims.

Major Irelan is the first one. Is he here? Why don't you walk around the front. And you might as well remain standing, because we will be swearing you in.

If I could now invite all of you to stand and raise your right hands, please.

[Witnesses sworn.]

Mr. SHAYS. Thank you. Note for the record that all our witnesses have responded in the affirmative. Please be seated.

Now, it's been my practice to allow people to wander over the 5-minutes, but that's not going to happen with this panel. I think you can understand why. A very important panel, and we appreciate your being here. I would note that our last two witnesses again are, one is an attorney and one is an epidemiologist. It may require, Dr. Walker, I know you're a witness requested on behalf of the minority. Given that you may be responding to a number of issues, I might allow you go over the 5-minutes if that's necessary.

But we'll cover the gamut and I think we'll hear some very important stories. So Major Irelan, you may begin.

STATEMENTS OF MAJOR JON IRELAN, U.S. ARMY, FOREST GROVE, OR; NANCY RUGO, SPOKANE, WA; BARBARA DUNN, IONIA, MI; KEVIN EDWARDS, SAN ANTONIO, TX; TONEY EDWARDS, FAYETTEVILLE, NC; SENIOR AIRMAN THOMAS J. COLOSIMO, ANDREWS AIR FORCE BASE, MARYLAND; JOSEPH JONES, OKLAHOMA CITY, OK; DAVID PONDER, OKINAWA, JAPAN; JOHN J. MICHELS, JR., MCGUIRE WOODS, LLC, MCLEAN, VA; AND DR. ALEXANDRER M. WALKER, PROFESSOR OF EPIDEMIOLOGY, HARVARD SCHOOL OF PUBLIC HEALTH

Major IRELAN. Thank you, sir. I'll try to be concise.

My name is Jon Irelan. I'm a regular Army officer and serving as an advisor to Oregon's Enhanced Infantry Brigade.

One year ago today, while stationed in Dhahran, Saudi Arabia, I received my fourth anthrax vaccine. That's when my problems began. Until that point, I weighed 175 pounds, 5'9", excellent physical condition.

That night, I had a raging fever and my physical condition continued to deteriorate over the next couple of weeks. During that time, I lost facial hair, my testicles shrank to the size of a peanut; the right one, that I could find. I had rapid weight gain, mainly in

the form of subcutaneous fat. I suffered mood swings, had severe groin pain and I lost muscular strength.

I went from a normal workout bench press of 280 pounds to less than 100, and that was in the space of less than 2 weeks.

I made it to Riyadh, to our Joint Aid station on November 4, a flight surgeon diagnosed me as having hypogonadism, and he wrote a referral for me to see a urologist. I did so back in Dhahran at a Saudi medical facility, and he started me on massive doses of testosterone, after screening me for cancers. I soldiered on, came home for Christmas leave with my family, and my family physician was still concerned that they might have missed something. So when I returned to Saudi Arabia, I had some more tests conducted, still there was no other cause identified.

As I got ready to leave Saudi Arabia in May, I visited with a new flight surgeon. He reviewed my records and he noted the strong link between the shot on 1 day and being ill the next. He also directed that I put in a VAERS report at an Air Force medical company, co-located on that same compound. He wrote up the report, I walked over and an Air Force, senior Air Force doctor came out and blocked the report. He scrawled across the back of the page that he did not think they were related, that I needed to see a urologist and if the urologist concurred, then go ahead and file the report.

Had he asked or had he looked at my records, he would have seen that I had been under medical care, specialist's care, for over 6 months.

So when I returned back to the States, I in-processed at Fort Lewis, WA. I visited a very nervous endocrinologist. He never asked any pertinent questions, but focused on discrediting firsthand observations of endocrinologists and flight surgeons. When I left his appointment I went to a urologist and the urology department had a little bit different spin on things. That was when the diagnosis changed from hypogonadism to primary testicular failure. And I was told that something had caused my body to attack the testosterone producing cells in my testicles, and that I would have to take testosterone, in my case, by injection, for the rest of my life.

That's really the short of it, Congressman. The final thing that I would like to add is that I retire next June. I've enjoyed every day of service. I'm very proud of it. I would willingly lay my life down for this country, no problem. But I feel that certain members of the Department of Defense have breached the trust between the soldiers and themselves. No one needs to tell us that this is a dangerous occupation. We understand the associated risks.

But we do not have any protection beyond our elected officials. You are it. You are our last court of appeals.

I and my fellow service members that have been sickened come to you for help. Please do not abandon us.

[The prepared statement of Major Irelan follows:]

STATEMENT BY
JON IRELAN
TO GOVERNMENT REFORM COMMITTEE
HEARING ON ANTHRAX VACCINE IMMUNIZATION PROGRAM – WHAT HAVE WE LEARNED?
OCTOBER 3, 2000
2154 RAYBURN HOUSE OFFICE BUILDING

My name is Jon Irelan.
I am Regular Army Officer assigned to Fort Lewis, Washington with a duty location in Tigard, Oregon. I am serving as an adviser to Oregon's Enhanced Infantry Brigade. I am here today to tell you that I have suffered a severe autoimmune reaction to the Anthrax vaccine.

I have returned to Oregon advisory duties after just completing a remote, one-year unaccompanied tour to the Kingdom of Saudi Arabia. My health problems began while I was stationed in Dhahran, Saudi Arabia after having taken the vaccine.

I arrived in Saudi Arabia on 8 May 1999. My duty location was in Dhahran/Dammam/ Al Khobar area near the Persian Gulf as a member of a three man advisory detachment. When I arrived, I was in excellent physical condition and weighed approximately 175 pounds. I had taken the first three Anthrax shots at Madigan Army Medical Center (Fort Lewis, Washington) before I deployed. However, on 3 October 1999, when I was in Saudi Arabia, I received my fourth Anthrax vaccination (Attach A). By the morning of 4 October, I was sick and started to develop the following symptoms: loss of facial hair, shrunken testicles (to peanut size), rapid weight gain (mainly in the form of subcutaneous fat), mood swings, severe groin pain, a substantial of muscular strength and complete loss of libido.

On 4 November I was able to visit our Joint Aid Station in Riyadh. I walked into the clinic and asked the Physicians Assistant to check me out. He immediately called in the flight surgeon who examined me and diagnosed me as having hypogonadism and wrote a referral to Urology, and ordered an MRI (Attach A). I was sent back out to Dhahran to seek medical attention at a contracted Saudi facility.

At the Saudi facility, the urologist immediately sent me over to their endocrinologist since he found no signs of injury to my testicles. The endocrinologist ordered blood tests to look for indications of brain tumors. Blood tests returned within normal range except in the testosterone area. The endocrinologist started me on heavy doses of oral testosterone. My symptoms quickly vanished. However, both the endocrinologist and I had expected that I would be able to drop down to a lower maintenance dose and eventually no-testosterone at all. We were both wrong. As I would later learn, my testicles were dying.

Several weeks later, while home in the States over Christmas with my wife and two children, I paid a visit to my civilian doctor. I wanted to update him on what was going on with me. Both he and my wife's uncle (a radiologist) were very concerned that the symptoms returned, with a vengeance, at each attempt to reduce my dosage. My doctor asked me to have another MRI to make certain that something had not been over-looked the first time. Back in Saudi Arabia, I had another MRI and a retinal scan in March 2000. Both tests came up negative for brain tumor. About this time, a new flight surgeon examined me when he visited our remote area. He shared my concern over my increasing need for testosterone and requested that the endocrinologist consider returning my dosage back to the original high daily dosage rate since my beard was again thinning and my libido was dead. The Saudi endocrinologist readily agreed and again returned me to the maximum daily dosage.

On 1 May 2000, while I was in Riyadh to out-process, the flight surgeon was reviewing my records to ensure that they were complete for my return to the States and reentry back into the Army Medical system. It was during this meeting that the connection to the Anthrax vaccine was raised by the flight surgeon when he reviewed my shot records. The flight surgeon specifically said that I should never take another Anthrax shot. He directed me to report to a tenant Air Force Medical Company to file a Vaccine Adverse Events

Reporting System (VAERS) report using their terminal (Attach B). However, when I arrived at the medical company, an Air Force Sergeant got very excited, told me to stay put, and he ran from the room. Moments later, an Air Force doctor came in; grabbed my records, read the referring flight surgeon's note and then promptly bent-back the top sheet in my medical records and wrote that he did not believe that there was any connection between my unexplained or "idiopathic" hypogonadism and the Anthrax vaccine, recommended that I first see an urologist and sent me on my way (Attach C). He never even spoke to me nor did he examine me. Had he bothered to read my file, he would have seen that I had been under medical care for this problem for nearly six months. The referring flight surgeon (only a Major himself) was not able to get the report filed.

Later that afternoon, at the close of my exit briefing to my general, I told him that he needed to be aware of the incident at the Medical Company. He became angry himself and asked what he could do to help. He said he was going to personally call the commander at Madigan Army Medical Center to make sure I received care. I told him that I was going to ask the Joint Aid Station to set up referrals at Madigan Army Medical Center for my return to the U.S. The next day, I returned to Dhahran to spend my remaining few days in the kingdom introducing my replacement to my Saudi counterparts. I had two referrals in my hand (for urology and endocrinology). I only had an appointment time for urology. I returned to the U.S. on 7 May 2000.

I traveled from my remote duty location in Oregon to Ft. Lewis, WA for in-processing on 22 May 2000. I had my urology appointment on the afternoon of the following day. My plan was to stay the night and take care of medical issues the 23rd of May before driving back to Oregon. Since I did not have an appointment for endocrinology, only a referral, I drove to Madigan Army Medical Center to see if they might be able to squeeze me in. As I topped the escalator, in the Medical Mall, a voice called my name. The receptionist came out from behind the her desk and said to me, "We've been looking all over for you. Sir, you need to know that the Surgeon General was just here talking about you."

Not quite grasping the significance of her statement, I jokingly replied, "So the fix is in, ha?"
She did not laugh but raised her eyebrows. She instead asked for my medical records and said that I should return at 8:00 am the next morning (23 May 2000).

The following morning I reported as directed. A nervous endocrinologist gave me a cursory examination. His primary attention appeared to be focused upon discrediting the first-hand observations of the two flight surgeons and the endocrinologist who had treated me in Saudi Arabia. He said he could not, of course, tell if I really had those symptoms since I was already being treated for them. I told him that I never diagnosed anything. I simply stood there and real doctors did the diagnosing. He mumbled to himself about what a hot political topic this was. The exam also noted such germane issues as my lack of interest in seeking counseling to quit smoking cigars and the occasional cigarette. He ordered no tests and I must admit, I was happy to leave his company. As I was preparing to leave, the doctor came out into the lobby and gave me a copy of his write-up (Attach D). He then told me that he knew that I was going to urology next and that he would defer to their judgment as to whether I would continue to receive testosterone or whether I would resume the Anthrax injections. After a quick lunch, I returned for my urology appointment. I was prepared for more of the same treatment.

I was seen by a young urologist. He gave me a thorough examination. He asked pertinent questions as he studied my file. As he sat at his desk, with his back to me, he started shaking his head. He turned and said, "Sir, I apologize. You must be extremely frustrated by the care you have received."

Still the naive Infantryman, I thought he was referring to the half-hearted examination I had received at endocrinology hours before. I told him it was OK. I was not expecting much more. The urologist then excused himself and returned with the chief of the urology department. The chief performed his own examination. He said to the other doctor, words to the effect "Screw them, I'm treating him!" He said that I was now his patient. He then told me that I had Primary Testicular Failure and would have to take testosterone for the rest of my life. He said that "something" had caused my body to attack itself and we

may never know why. I didn't press him. This doctor was putting himself in harm's way just to treat me. He apologized for now having to put me through two weeks of no testosterone so that he could "washout" the foreign made medication before starting me on a U.S. made product.

The next two weeks were bad. I lost my beard, suffered terrible chills, hot flashes, muscular weakness, bed-sweats, mood swings and groin pain. Occasionally, ringing ears and blurred vision. Mercifully, on 12 June 2000, I returned to urology submitted to another blood draw for testosterone baseline after a short two-week period. Then I demonstrated to the nurse's satisfaction that I could give myself my own deep-muscular injections of testosterone. I started to feel "normal" again several days later.

I returned to my civilian physician several days later. He is still my primary care provider here in Oregon. He read through my entire medical file and got very upset. He told me that competent medical care could likely have saved my testicles. He said that suspecting Anthrax as a source of autoimmune reaction, to a Saudi doctor, would be like someone walking into a local doctor's office with a rare tropical disease; that doctor is not likely to ever make the connection. When my doctor telephoned some other colleagues, he became concerned that whatever was attacking my testicles could still be attacking something else. They were also puzzled by the absence of other tests that might help to identify the cause of my problem. He was puzzled why I had never been referred to an immunologist. As a former Army physician himself, he wondered why I was not sent to the servicing Army Hospital in Germany aboard the scheduled medical rotator flight at the first diagnosis of potential brain tumor.
I contacted Dr. Meryl Nass, MD with my doctor's concerns and asked her if she was aware of others possessing similar symptoms. She immediately replied saying that she was aware of others with my symptoms and agreed that my physician was correct in his concern about the continued attack on my body. My doctor was totally convinced that I must seek private testing and evaluation at a top civilian medical facility.

I called the VAERS Hotline. There has never been a report filed on my behalf.

Since then, I have sought assistance at a private medical facility. The attending endocrinologist said that I am not exhibiting any other symptoms or signs of autoimmune attack at this time.

I sought assistance through Representative Jack Metcalf's office on 22 July 2000. Congressman Metcalf's office has been assured that a VAERS report will be submitted concerning my own suspected reaction to the Anthrax Vaccine.

I continue to serve in my capacity as an active duty advisor. My retirement date from active duty is 1 June 2001. I am continuing to receive testosterone injections at a rate of once every 12 days or as symptoms start to return. I believe that I will have to take these shots for the rest of my life.

Members of Congress, I appear before you today to tell you that I would willingly lay my life down for the United States of America. I feel that certain members of the Department of Defense have breached the trust that is supposed to exist between soldiers and our leaders. No one needs to tell me that military service is a dangerous occupation and that there are risks associated with that service. But what I wish someone would explain, is why certain civilian and uniformed members of the Department of Defense have been permitted to inflict this unproven investigational drug on my fellow soldiers and why they have been permitted to perpetrate the deceptions and half-truths that surrounds this program.

I and my fellow service members, who have been sickened by the Anthrax vaccine, come to you, our elected representatives, for help.
Please, do not abandon us.

AUTHORIZED FOR LOCAL REPRODUCTION

MEDICAL RECORD | **CONSULTATION SHEET**

REQUEST

	FROM: *(Requesting physician or activity)*	DATE OF REQUEST
UROLOGY	OPM-SANG JAG	3 NOV 99

N FOR REQUEST *(Complaints and findings)*

40 y/o wm c (L) testicular atrophy, hair loss & weight gain, ↓ libido. Please evaluate, free testosterone, ? further evaluation to include MRI.

ISIONAL DIAGNOSIS

hypogonadism

TOR'S SIGNATURE	APPROVED	PLACE OF CONSULTATION	
RICHARD D. BAKER MD USAF, MC, FS		☐ BEDSIDE ☐ ON CALL	☒ ROUTINE ☐ TODAY ☐ 72 HOURS ☐ EMERGENCY

CONSULTATION REPORT

ORD REVIEWED ☐ YES ☐ NO | PATIENT EXAMINED ☐ YES ☐ NO | TELEMEDICINE ☐ YES ☐ NO

(Continue on reverse side)

ATURE AND TITLE		DATE
PITAL OR MEDICAL FACILITY	RECORDS MAINTAINED AT	DEPARTMENT/SERVICE OF PATIENT
TION TO SPONSOR	SPONSOR'S NAME *(Last, first, middle)*	SPONSOR'S ID NUMBER *(SSN or Other)*
ENT'S IDENTIFICATION *(For typed or written entries, give: Name -- last, first, middle; ID no. /SSN or other); Sex; Date of Birth; Rank/Grade)*	REGISTER NO.	WARD NO.

elan, Jon

[redacted]

CONSULTATION SHEET
Medical Record

STANDARD FORM 513 (REV. 4-98)
Prescribed by GSA/ICMR FPMR (41 CFR) 101-11.203(b)(10)

(ATTACH A)

HEALTH RECORD | CHRONOLOGICAL RECORD OF MEDICAL CARE

DATE	SYMPTOMS, DIAGNOSIS, TREATMENT, TREATING ORGANIZATION (Sign each entry)
1 MAY 00	USMTM/OPM - JOINT AND STATION RIYADH, KSA
0800	Clinic Note
	S: 40 y/o male for out-processing first noticed ↓ libido, weight gain, hair loss & ⊙ testicular atrophy, mood swings, groin discomfort
	Eval by endocrine including Normal MRI x 2 revealed ↓ testosterone levels.
	- Unknown reason - post eval pt now on androgel 40g - qid. with good results.
	Today - libido okay, wt loss/change - ↓ subq fat, ∅ hair loss, nl testicular size, ∅ pain
	O: Gen - AAO NAD
	Heart RRR S/M Lung CTA(B) ∅ testicular exam.
	AP Idiopathic hypogonadism - now doing well on androgel, continue. Flu Endocrine on states.
	- ? reaction to anthrax vaccine. Recommend filing VAERS report.
	- recommend ∅ anthrax until Flu & VAERS & endocrine in States.
	David R. Trigg, Maj, USAF, MC, FS AFSC 44F3

PATIENT'S IDENTIFICATION (Use this space for Mechanical imprint)

Irelan, Jon

20/[redacted]

RECORDS MAINTAINED AT:

PATIENT'S NAME (Last, First, Middle Initial)		SEX
RELATIONSHIP TO SPONSOR	STATUS	RANK/GRADE
SPONSOR'S NAME	ORGANIZATION	
DEPART./SERVICE	SSN/IDENTIFICATION NO.	DATE OF BIRTH

CHRONOLOGICAL RECORD OF MEDICAL CARE STANDARD FORM 600 (REV. 5-84) Prescribed by GSA and ICMR FIRMR (41 CFR) 201-45.505

(ATTACH B)

Here for an evaluation 2° to anthrax. Has idiopathic hypogonadism. I do not feel this is related. It should have problem evaluated by urology & then if Urology feels this is a reason we will file a report

Randal Hamric II Col, USAF, MC
44F3 Smith
Family Practice Clinic

(ATTACHED)

MADIGAN ARMY MEDICAL CENTER ENDOCRINE SERVICE
OFFICE 253. 0438 FAX 253.968.0448

/24/2000 9:52:24 AM

ıu were seen today by LTC Curtis Hobbs, MD. You may contact me at 253.968.0438 or by
il <curtis.hobbs@nw.amedd.army.mil>. Remember, contact by email may not afford you
degree of privacy you want.

the beginning of your visit today, you reported that you were taking the following
dications:

DICATION E	DOSE	FREQUENCY	MEDICATION	DOSE	FREQUENCY

ɔu also reported taking the following supplements/herbal products:

asional Motrin or Advil

ease review the instructions and comments listed below. Also note any
ange to the medication listing cited above.

have discussed my findings and recommendations. Here is what I would like you to
:

See the Urologist as scheduled. After that visit consider whether or not you wish
continue to receive testosterone. Recognize that the placebo effect of any
erapy may approach 30%. Consider stopping use of testosterone and seeking further
sessment after a washout period of 4-6 weeks.
Contact your PCM about reassessing your cholesterol.
\void future administration of the anthrax vaccine.
ere are risks to smoking and benefits of smoking cessation. Consider attending
ing Cessation classes. Persons attending formal programs are twice as likely to
tobacco free at 1 year. You must commit to attending 3/4 classes or the all day
turday course held at MAMC. TRICARE schedules for MAMC. McChord patients contact
e clinic at 984-2393. Bremerton catchment area/ Oak Harbor call the Bremerton
val Hospital at 360 475-4853 or 4854.

(ATTACH D)

ADIGAN ARMY MEDICAL CENTER
ersonal Data - Privacy Act of 1974 (PL 93-579)
Printed: 5/24/20 @ 9:51:28

/ISION: MADIGAN AMC, WA
Automated Version of SF600

NDOCRINOLOGY HOBBS, CURTIS J May 24, 2000 0800 VISIT TYPE New Patient BAFA

EF:
1: R/O hypogonadism
)RANCE YES/NO: PCM Dr. Bump

P: 181 / 84 PULSE: 78 RESP: TEMP: HT: 69.0 WT: 205.2 lbs BMI: 30.4 AGE: 40.

LLERGIES: Anthrax vaccine?

EF COMPLAINT: I just returned to CONUS. Hypogonadism. I was in town to inprocess.

Patient interviewed - all available records reviewed. Here to R/O hypogonadism. Patient reports his problems began last fall - was stationed in a remote area of Saudi - had 3 to 4 hours per day to "Do a good work out". One day after PT he noticed groin pain - this lasted about a week. Coincidentally he noticed "An increase in subcutaneous fat". He recalls discussing these symptoms with his bosses wife, a nurse. His symptoms included groin pain, poor libido, increased weight, mood swings, increased subcutaneous fat, shrunken testicles, reduction in body hair, weakness (from bench pressing 280 lbs to under 100). About a week later he was grooming and noticed "I had no facial hair". He then took a shower and, "Couldn't find my left testicle - the right one was a little bitty thing." The pelvic ache continued. The combination of symptoms (duration about 1 month) prompted a visit to his flight surgeon who said, "Something weird is going on here." The patient was told he was developing breasts - he was referred to a Urologist and was sent to SAAH Medical Center. According to the patient, the urologist said, "You don't need to see me - you need an endocrinologist." He was seen on 6 Nov 99 by Dr. Wiam Hussein. Dr. Hussein documented gynecomastia. A series of studies were done (see labs) to include visual fields (normal) and MRI of the sella (normal). At the follow up visit of 16 Nov 99 Dr. Hussein wrote, "Laboratory data revealed NL testosterone levels as well as LH & FSH. Because he is symptomatic will give a trial for few months Androl 160 x 2 wks -> 80 mg. Lose weight (continue diet & exercise)." Patient reports he "Just wanted to know the protocol for dealing with this." He reports his case has "Countrounded everyone". He reports his symptoms cleared with the use of Androl (testosterone undecanoate 40 mg, manufactured by N.V. Organon Oss Holland). Patient was seen on 1 May 00 by Dr. David Trigg - his assessment includes "? reaction to anthrax vaccine. Recommend filing VAERS report." A subsequent entry by Dr. Randal Hamric indicates "I do not feel this [anthrax] is related." Vaccination records indicate anthrax received 17 Feb 99, 26 Mar 99, 18 Apr 99 and 3 Oct 99. A review of his HREC is otherwise remarkable for prior documentation of hypercholesterolemia and recent documentation of systolic HTN. Recorded weights include 6/16/81 (157 lbs), 6/3/88 (170 lbs), 9/30/94 (173 lbs), 11/6/99 (204.6 lbs).

;T MEDICAL
;TORY/PROBLEMS: Pure hypercholesterolemia

ICATIONS:	MEDICATION	DOSE	FREQUENCY	MEDICATION	DOSE	FREQUENCY
	NONE					

Is patient on herbals/supplements? ☐ yes ☒ no
Occasional Motrin or Advil

CUSSION:
Although this patient presented in November 1999 with symptoms suggestive of hypogonadism, the available documentation did not support this diagnosis. The documentation may be incomplete, but what is lable for review indicates normal gonadal function - testosterone was prescribed as part of a therapeutic trial. There is increasing recognition of an "andropause" of sorts - see Tenover JL, Endo & Met Clin NA 27 (4) 1998, 969-987 for discussion of this issue.
cannot determine if this patient's presentation bore any relationship to the administration of anthrax vaccine. To my knowledge, hypogonadism as a consequence of this vaccine has not been reported. Given the ent's close proximity to retirement, it seems appropriate to avoid additional boosters with this vaccine.
he patient's hypercholesterolemia should be reassessed and treated appropriately.
moking cessation is encouraged.
his patient may have systolic HTN - It is also possible that recorded values are inaccurate and reflect use of a cuff too small for this patient. Repeat BP in our clinic using a large cuff was 132/75.

SEE REVERSE OF PAGE FOR social history, family history, hospitalizations/surgeries, physical exam, lab and x-ray, diagnoses at end of visit, and recommendations.

[redacted] IRELAN JON F
7/11/1959 MALE
Spon: IRELAN Self
CS:
Unit: 3/357 INF

W: H: 503-357-2818
CIC: D:
Rank: O-4 MAJ
RR: HANDCARRIED BY PNT

600

Mr. SHAYS. We will be going through everyone and then will be asking questions. Thank you for your extraordinary service to our country.

Ms. Rugo.

Ms. RUGO. Good morning, Mr. Chairman. My name is Nancy Rugo and I am the sister of Sergeant Sandra L. Larson. Today I am here on her behalf, as she passed away June 14, 2000, at the age of 32.

During her illness, before her death, she made it clear to me to do whatever I can on her behalf as she said, if something were to happen to her, she wanted me to help other people. She frantically began researching the causes of her condition, and started to suspect vaccine connection. As her condition worsened, she communicated some of her discoveries with me.

Obviously, something happened, which is why I am here today. And as she requested, I am not going to let this go.

I would like to inform you about my relationship with her, my knowledge of her relationship with the military, and most of all, the events which I believe led to her death.

Sandra and I both grew up in a military atmosphere, as our father was in the Army himself. In fact, she was born while my father was in the Vietnam war. We moved a lot, and my father was in the military for 19 years.

Sandra married a military man, Martin Larson. They met in Tacoma, WA, near the Fort Lewis base. In December 1985 she had her first child, a girl, Megan Marie. Megan is 14 years old today, living with her father in Michigan.

In August 1995 was when Sandra made a decision to enlist in the military. Her reason for enlisting was she wanted to take advantage of receiving a college education, preferably in the medical field. She did her basic training in Fort Campbell. In February 1997, after completing her basic training and getting settled, she gave birth to another girl, McKenzie Marie. Today I am raising McKenzie for her.

McKenzie lived with me during her mother's tour duty in South Korea. And this is where I begin the events to share with you that have led to the last days of her life.

It was the month of April 1998 when Sandra and her daughter were back in Spokane, WA with me. She was preparing for a 1-year tour duty in Camp Stanley, South Korea. She began her 18 month Anthrax program that September 1998 at Camp Stanley. She received her first four of six shots during this stay in Korea and all four vaccines were from Lot 17.

In January 1999, she was granted a 2-week leave to visit me and her daughter in Spokane. I noticed that she did have rashes on her arms at that time and she was very tired. She was assuming she was tired because of work and just needed to catch up on rest.

She also acquired numbness in her arms and was evaluated for what the doctors thought might be carpal tunnel syndrome. She never did object to the vaccines at that time, because she related all these things to nerves and just working hard and it never crossed her mind.

In October 1999, she was relieved of her duties from South Korea and had new orders to relocate to Fort Riley, KS. She was really

excited about coming home. She found a nice home, and they settled, her and her daughter, in Fort Riley. And they called often, and I found them both to be really nicely settled. No one would ever guess that in just 8 months from this date, that she would no longer be here.

March 8, 2000, she received her sixth and final vaccine from Lot 31. I heard about more rashes she noticed on her arms and legs. She was feeling like she was being a bad mother because she was so tired and had no energy. She did express this with military personnel, feeling she was maybe working too hard.

April 7, 2000, in just 4 weeks after that sixth shot, she was admitted into the hospital. Her blood capillaries were bursting, she had no platelets, she had no red or white blood cells and was diagnosed with aplastic anemia. Aplastic anemia is a rare and serious blood disease that occurs from unexplained failure of the bone marrow to produce blood cells.

Her case was extreme, as her symptoms were sudden. This was not a gradual case of aplastic anemia. She was healthy 4 weeks ago, to then have no bone marrow, no platelets. It was as if there was something in her that was killing her immune system, shutting her down.

The doctors could not find a cause, so they diagnosed her as idiopathic aplastic anemia. She was granted a compassionate leave to Fort Lewis, WA, and on April 26th, was at a point where her illness, where infection started to kick in. It looks like I really need to sum this up, so I'm going to have to pass on a lot of the technicalities on here.

I would like to say that on June 2nd, the VA gave her a 130 percent medically retired benefit for her two girls. And on June 14th, she passed away.

In summary, I'd like to say, she joined the military in 1995, transferred to South Korea in 1998. She began the 18 months program, having four of six shots from Lot 17. While she was stationed in South Korea in October 1999, having completed her tour of duty, being transferred to Fort Riley, KS, where she completed her final two vaccines from Lots 44 in September 1999 and Lot 31 in March 2000. April 7, 2000, just 4 weeks after being injected from her sixth shot, she was admitted into the hospital with a serious rare blood disease, aplastic anemia, which is considered an autoimmune disease.

June 14, 2000, 12 weeks after receiving her shot, she was gone. And I really hope that there is an investigation in this squalene. Because the research that I have, if she received contaminated lots or squalene, there's a lot of validation to prove that that's what killed her.

Thank you.

[The prepared statement of Ms. Rugo follows:]

STATEMENT OF
NANCY RUGO
BEFORE THE GOVERNMENT REFORM COMMITTEE
HEARING ON "ANTHRAX VACCINATION IMMUNIZATION PROGRAM – WHAT HAVE WE LEARNED"?
OCTOBER 3, 2000
11:00 A.M., 2157 RAYBURN HOUSE OFFICE BUILDING

Good morning, Mr. Chairman, my name is Nancy Rugo and I am the sister of Sgt. Sandra L. Larson – today, I am here on her behalf as she passed away June 14, 2000 at the age of 32.

During the illness before her death, she made it clear to me to do whatever I can on her behalf if, as she said, *"something were to happen."* She frantically began researching the causes of her condition and started to suspect vaccine connection. As her conditioned worsened, she communicated some of her discoveries and she told me emphatically, "*Nancy, I mean it. Don't let this go.*" Obviously, something happened which is why I am here today. As she requested, I am not going to let this go.

I would like to inform you about my relationship with her, my knowledge of her relationship with the military and most of all the events which I believe led to her death. Sandra and I grew up in a military atmosphere, as our father was in the Army himself, in fact she was born while my father was away in the Vietnam War. Our family moved fairly frequently, living in Europe and the states during his 19-years of service. We grew up to depend on each other, we were more than sisters in our youth, we were best friends. As we matured and grew more independent we always remained dependent upon each other for comfort, advice and most of all we drew from each other strengths and a great motivation in our family and work lives. We use to joke that someday I would be a judge and she would be a 911 Medic or some other extreme, but adventurous, career. She had a great sense of humor, yet she was a strong-willed individual who could set goals and go all out to meet them.

Sandra married at the age of 16 to a military man, Martin Larson. They met in Tacoma, Washington near the Ft. Lewis military base and as he had orders to move to Panama for duty they made the decision to marry so that she could be with him. In December of 1985 she had her first child, a girl, Megan Marie. Megan is 14 years old today, living with her father in Michigan.

In **August of 1995**; she was living with me at my home in Spokane, Washington. She was at a point in her life, at the age of 27 years, where she was looking for direction and purpose. She was contemplating going back to school or work. In reviewing advertisements about how great it would be to join the military and the prospect of receiving a college education, she decided this was for her. She chose the Army, just like our dad, enlisting at a local office in Spokane. She was excited at the prospect of employment and college in return for her service. Sandra was a bit scared about leaving home and weighed the consequences of being away from her family versus the goal of accomplishing a great career with the military. She felt she had made the right choice by enlisting and began her military career in Ft. Campbell Kentucky after completion of her basic training. She immediately enjoyed the military and set her mind on attaining her future college education with hopes of pursuing an education in the medical field.

During her duty in Ft. Campbell in **February of 1997**, Sandra gave birth to another girl, McKenzie Marie. I will never forget the day she called me with the news of her daughter and having a strange feeling overcome me that I just knew that someday I would be raising this little girl. I am. McKenzie lived with me during her mothers tour duty in South Korea and this is where I begin the events to share with you that I believe led to the last days of her life.

It was in the month of **April 1998** when Sandra and her 15-month old daughter, McKenzie, were back in Spokane with me as she was preparing for a one-year tour duty in **Camp Stanley, South Korea**.

She began her 18-month Anthrax program that **September 1998** at Camp Stanley. She received her first 4 of 6 shots during this stay in Korea and all four vaccines were all from Lot 17 (see attachment). In **January of 1999** Sandra was granted a 2 week leave and came back to Spokane to visit with me and her daughter. I immediately noticed changes in her personality – mainly noting she seemed quite exhausted. She shared with me how tired she was; assuming her condition was related to her work duties and the exercise programs she had undergone. I remember coming home from work and she would be fast asleep in bed, and I thought she just needed to catch up on her rest. She had rashes on her arms at that time and told me she thought it was her nerves. While in Korea, she also developed numbness in her arms and was evaluated for what doctors thought might be carpal tunnel syndrome.

She never objected to the many vaccines she had to take while in Korea.

She went back to Korea, unhappy this time, as she did not like leaving her daughter and was afraid she would not have the energy to pass the PE test she would have to take on her return.

In **October of 1999** – Sandra was being relieved of her duties from South Korea and had new orders to relocate to Ft. Riley, Kansas. She was excited about coming home. Once in Ft. Riley she was able to obtain a nice home for herself and McKenzie. They called me often and I found them both to be nicely settled. No one would ever guess that in just 8 months from this date she would no longer be here with us. If only she knew this was all the time she had to spend with her daughter. There are a lot of "*ifs*" in my life now and that is a hard reality for us all.

March 8, 2000– Sandra received her sixth and final Anthrax vaccine, Lot 31. As we were in constant contact, I was to hear about more rashes she had noticed on her arms and legs, just like the rashes I noticed 15 months ago with previous shots. She was feeling like she was "a bad mother" because she was again so very tired and had no energy to do things with her little girl. In fact, she had expressed this with military personnel feeling like she was maybe working too hard.

April 7, 2000 – In just four weeks after that sixth shot, Sandra called me informing me she was not feeling well at all. This time she mentioned she had additional numerous rashes on her arms and legs that we later found out were because blood capillaries were bursting. She was extremely tired and was going to go to the military clinic because she started vaginal bleeding that was "*pouring*" out of her. Apparently once admitted into the clinic, the first thing the doctors did in assuming she had an infection was to do a simple blood test. Upon reviewing this one test, they panicked because they found few, if barely any, blood cells to detect. She had no blood platelets which is what is needed to control bleeding. She was immediately escorted via military ambulance to the nearest capable emergency room, and that was a 2 ½ hour drive to Kansas City Medical Center, a civilian hospital.

April 10, 2000 – Another call from Sandra, this time she was in ICU at Kansas City Medical Center. The doctors had been doing many extreme tests (HIV, Hepatitis, etc) on her to try and figure out what was happening and concluded she had Aplastic Anemia. I was immediately concerned about her and her daughter, who was at the babysitters, and flew to Kansas to do what I could to support her. When I arrived at the hospital, I seriously thought maybe this was all a fluke and she would be fine as we have no family history of this.

Aplastic Anemia is a rare but serious blood disease that occurs from unexplained failure of the bone marrow to produce blood cells. Her case was rather extreme as the symptoms she had were sudden. This was not a gradual case of Aplastic Anemia, she went from a healthy woman just 4 weeks prior to

having no bone marrow, platelets and a extremely low count of red and white blood cells. It was as if there was something in her that was killing her immune system, shutting her down. The doctors could not find a cause and they tested her for everything they possibly could have, so they diagnosed her case as "*Idiopathic Aplastic Anemia.*"

I stayed close to the hospital for two weeks, waiting for the day when all this would stop and she could go home, but things only kept getting worse. The military granted her what is called a "*compassionate leave*" to Ft. Lewis, Washington. I planned on leaving Kansas for Spokane the same time as her transfer but she developed an allergic reaction to one of the most relied upon therapies next to a bone marrow transplant. She would have to stay another week. I stayed long enough for the hospital to at least type me for a possible bone marrow donor. Unfortunately, my sister did not have any bone marrow left in her own body to be typed herself. It was hopeful that a horse serum treatment would cause her body to produce enough bone marrow for them to type, this is what she was allergic to and it never worked.

On **April 26, 2000**, I returned home to Spokane with McKenzie. I kept in contact with my sister on a day to day basis. It was at this point where infections started to kick in, which is the worse thing a Aplastic Anemia patient could have happen. Each of us has white blood cells to fight off infection, but she had none and was to rely on blood transfusions every other day just to keep her going.

May 2, 2000 – Sandra was medically prepared to fly to Ft. Lewis where she would stay at Madigan Army Medical Center. The flight did not go well, and was about the worse thing to happen in her circumstance. The military medic vac plane's cockpit had caught on fire when en route. They had to do an emergency landing at Travis Air Force Base in California. I do not understand how this base became the closet landing as you would assume the route would have had a direction towards Seattle, not California. This base was not equipped to handle her condition and she had to prolong waiting for a much needed blood transfusion. Normally would have one in 2 days but she had to wait 4 days. Because of this, she developed a lung infection called Asperiollous. A normal person such as you and I would have a hard enough time fighting this, but as she did not have her own cells to fight with, this was the worse case scenario for her. They were able to fly her to Ft. Lewis in which she was provided the adequate medical care.

May 20, 2000 – Received a phone call from the ICU physician. I was told I needed to come visit her right away as they did not think she would live through the weekend. I called my parents in Montana and we all drove to Tacoma to be with her. We were told on our arrival that she would not make it through this. They would do all they could to keep fighting, but there was not a chance. The hospital had even started to transplant white donated blood cells directly into her lungs which is an extreme, but hopeful, therapy. My sister was so very ill, she was on a ventilator and her whole body looked as if they had inflated her. She was so scared yet in total denial about leaving, which made it difficult for me to talk to her about her last wishes. She was very angry at everyone, kept saying she was going to get better and had planned on living in Spokane so she could be near me with her daughter.

June 2, 2000 – The VA came to visit with the family while we were at the hospital and said they were in the process to medically retire her as quickly as possible for the benefit of her two girls. They were successful and a great team of help for me at that time. She was granted 130% medically retired benefit.

June 12, 2000 – Sandra went into a coma and I had to return again as I had to make a decision about pulling her off of life support. I was terrified. On June 13, 2000 I arrived at the hospital alone, as I did not want to see anyone but her. She was so far gone already, I felt awful for having her live like this. I sat down with a team of eight doctors to discuss pulling her off and told them I would like to pull her off but I would first like to have her oldest daughter Megan to fly from Michigan as she wanted to say goodbye to her mother while she was still living. This was so stressful, it seemed like everything with

flying her here quickly went wrong, there were flight delays and weather problems, it was almost as if Sandra was trying to avoid having Megan see her like that. By the time Megan's plane arrived in Tacoma, it was after 2 am in the morning on the 14th of June, her mother had already left us two hours prior. Megan was happy to see me and thankful to me for waiting for her, as she knew we were keeping her mother alive for her goodbye. I waited until we got outside the airport to tell Megan that her mother had already left us, her heart had given up. This was so difficult. I called the hospital and told them to keep her in the room and try to clean her up for her daughter's visit, as she insisted on seeing her regardless.

SUMMARY

Sandra Larson joined the military in ***1995***. Was transferred to South Korea in ***1998***, where she began the 18-month Vaccine Program; having four (4) of six (6) shots (lot 17) while stationed in South Korea. In October of ***1999***, having completed her tour duty was then transferred to Ft. Riley, Kansas where she completed her final two vaccines, from lots 44 in September of 1999 and lot 31 in March of ***2000***. April 7, 2000, just four weeks after being injected from her sixth shot, she was admitted into the hospital with a serious rare blood disease, Aplastic Anemia, which could be considered an autoimmune disease. June 14, 2000, twelve weeks after receiving her sixth shot she had deceased.

Attachments
- Vaccine Record
- Physician Evaluation Board Report (June 1, 2000) (Available upon Request)

Two alarming questions I would like an answer to is why, after already showing signs and symptoms after her third shot, was she to partake in more shots? and was she or was she not injected with the experimental Squalene?

Why, when transferring such a seriously ill person, did the military fly the route towards California instead of to Washington State?

In my dealings with the military I was and still am not the least bit satisfied. I have hit a lot of brick walls, have a lot of un-returned phone calls and have received very poor assistance with her causality assistance. The military granted me a Casualty Assistance Officer to work with me on very important paperwork for the girls' benefit. Unfortunately, for me, this person never ever has worked with causality assistance before, in fact we had to go over the instructional booklet together rather blindly. This person was a reserve enlistment officer, an office worker. It turned out that I ended up trying my best to do the appropriate paperwork myself, only to have much of it done wrong, taking a lot of time and more red tape. As far as I know, her husband has yet to receive a gratuity check, which he was suppose to receive during the first week of her death, it has now been 12 weeks. We were told the check was on its way via Fed-Ex in June. Then were told they were waiting for paperwork from us, which we already submitted. Actually, my dealings with the military are quite lengthy and if someone here would like details, please feel free to assist me.

September 28, 2000

My dealings with the VA has been more than great. These people made things easy for me, offering to help where they can and actually accomplishing matters expeditiously.

September 28, 2000

Mr. SHAYS. Thank you, Ms. Rugo. Thank you very much.

Mrs. Dunn.

Mrs. DUNN. Thank you, Mr. Chairman, members of the House Government Reform Committee.

Mr. Chairman and members of the House Government Reform Committee, I'm appearing before you today to at least try to ensure that no other person or family goes through what my family has been through as a result of the Department of Defense BioPort anthrax program. My husband, Richard Dunn, worked for BioPort in Michigan Biologicals since 1992. Dick's job was to care for and monitor animals at BioPort. He was required to take the same vaccine given to our Nation's military personnel.

Dick received 11 doses of the vaccine. The last two were given on April 6th and April 13th, both in his left arm. An autopsy performed in July suggests that the vaccine is a factor, according to our Ionia County medical chief examiner, Dr. Robert Joyce. Dr. Joyce said Dick had an inflammatory response to the vaccine throughout his body.

Immediately after the results of the autopsy were performed, BioPort went on television and said they had no idea Dick ever showed symptoms. BioPort also said the worst reaction they've ever seen were minor headaches and localized pain.

First of all, let me tell you, my husband Dick had more than a headache after his vaccine was given to him in two parts in April. Soon after, he started swelling, left arm, wrist and hands. Dick also had nausea, joint pain, and his left arm was quite hot to touch.

These symptoms never went away. They were no different than any other reaction he had every year, except this time they were much worse.

I understand that these are the same chronic symptoms our military personnel suffered.

On May 11, 2000, the swelling in the left side was much worse, the joint pain was worse, as was his fatigue. My husband seemed much worse than he was the month before.

He went to work on May 13th and called me to say he needed to see a doctor. My husband was put off from work that day. When he would see the BioPort workers compensation doctor in Lansing, he always stopped to see his friends in BioPort. The company knew of his ongoing symptoms, because they were always there to help us with paperwork and would make phone calls to see how he was doing. For that, I'm grateful. He did think of BioPort as his family.

However, when Dick returned to work, he was still swollen, very tired, but was given a release to go ahead and go back to work. He still suffered the joint pain.

Dick died July 7, 2000. That's changed my life and the life of my children forever. This is fact, not fiction. Dick believed in this program, but also wanted it to be a safe program.

I know that BioPort has had a lot of legal troubles, and that you, the Government, have been investigating the company for safety reasons. Only recently did I learn, late in August, BioPort had to recall three products, including the anthrax vaccine, because the wrong expiration date was on the labels.

I don't know what lot or batch of vaccine the company gave my husband. But I do know that a lot of other Americans have been

made sick by this vaccine. That's why I'm here today. Nothing can be done to bring my husband back. But I ask this committee to please rethink this program and make it a safe one.

I hope some day that if any of you need to take this vaccine you have the option of whether to take it or not, and if your option is no, that you have no repercussions from it.

[The prepared statement of Mrs. Dunn follows:]

STATEMENT BY
BARBARA DUNN
TO GOVERNMENT REFORM COMMITTEE
HEARING ON ANTHRAX
OCTOBER 3, 2000

Mr. Chairman and members of the House Government Reform Committee:
I am appearing before you to at least try to ensure that no other person or family goes through what my family has been through as a result of the Department of Defense/BioPort Anthrax Program.
As you know, my husband, Richard Dunn, had worked for BioPort and Michigan Biologic Products Institute, since 1992. Dick's job was to care for and monitor test animals at BioPort, and he was required to take the same anthrax vaccine given to our nation's military personnel.
Dick received 11 doses of the vaccine. The last two were given April 2, 2000 and April 13, 2000, both in the left arm. An autopsy performed in August suggests the vaccine as a factor, according to the Ionia County Chief Medical Examiner Dr. Robert Joyce. Dr. Joyce said Dick had an "inflammatory response" to the vaccine throughout his body.
Immediately after the results of the autopsy were performed, BioPort went on television and said they had no idea Dick had ever shown symptoms. BioPort also said the worst reactions they had ever heard of were minor headaches and localized pains.
First of all, let me tell you that my husband, Dick, had more than a headache after his vaccine was given to him in two parts in April. Soon afterward, he started suffering swelling in his left arm, wrist and hand. Dick also had some nausea, joint pain, and his arm was hot to the touch. These symptoms never went away, and they were no different than the other reactions he had every year, except this time they were much worse. I understand that these are the same chronic symptoms our military people have suffered.
On May 11, 2000, the swelling in the left side was much worse; the joint pain was worse, as was his fatigue. My husband seemed much worse than the month before. He went to work on May 13 and called me to say he needed to see a doctor. Dick was put off from work that day. When he would see the BioPort worker's compensation doctor in Lansing, he always stopped to see his friends at BioPort. His company knew of his ongoing symptoms, because they always helped us with paper work and because of the many calls they made to see how Dick was doing. I am very grateful for that. He did think of them as his family. However, when Dick returned to work, he was still swollen and very tired and still suffered joint pain. Nevertheless, he was given a release to return to work with limitations.
Dick died on July 7, 2000, and that has changed my life and the lives of my children forever. This is fact, not fiction. Dick believed in this program, but also wanted it to be a safe program. I know that BioPort has had a lot of legal troubles and that you, the government, have been investigating the company for safety reasons. Only recently did I learn that in late August, BioPort had to recall three products, including the anthrax vaccine, because the wrong expiration date was put on labels. I don't know what lot or batch of vaccine the company gave Dick,

but I do know that a lot of other Americans have been made sick by the vaccine, and that is why I am here today. Nothing can be done to bring my husband back, but I ask this committee to please rethink this program and make it a safe one. I hope someday that, if any of you need to take this vaccine, you will have an option of whether or not to take it, and that if your option is to say "no," there will not be any repercussions.

Barbara Dunn
611 North Dexter
Ionia, MI 48846

Mr. SHAYS. Mrs. Dunn, thank you. There are many of us who feel that this needs to be a voluntary program and that there should be no repercussions.

Now, it's my understanding, Specialist Edwards, that you are here to answer questions. I know you had an operation on your eyes. And so, I believe that your father, Mr. Edwards, will be reading the statement, is that correct?

Mr. KEVIN EDWARDS. Yes, sir.

Mr. TONEY EDWARDS. Mr. Chairman, members of the committee, good afternoon. My name is Toney Edwards, and I'd like to say, it is indeed a pleasure for me to appear before me today, except for the nature of my testimony. I do, however, very much appreciate the chance to tell my story of multiple medical tragedies in my family.

I have with me today my son, Kevin Edwards, who is currently on active duty and is now assigned to the Medical Hold Co. at Fort Sam Houston, TX, where he has been assigned since November 1998. I hope that the information I will present to you today will help this committee in making recommendations or decisions concerning the safety and future use of the anthrax vaccine.

Before I begin, I would like to give a little information about myself. I'm retired from the U.S. Army. I served approximately 15 years in the 82nd Airborne Division. I served with the 101st Airborne Division in Vietnam. I served in the Berlin Brigade, and I served as a drill instructor at Fort Jackson, SC.

During my tour with the 101st Airborne Division in Vietnam, I was exposed to the herbicide known as Agent Orange, which was used to kill the vegetation in the jungles of Vietnam so that we could have a better opportunity to seek out and destroy the enemy. It was not until later that I learned that the herbicide that I observed being sprayed from military aircraft would ultimately cause the death of many American soldiers, including myself.

I now have prostate cancer as a result of exposure to Agent Orange in Vietnam. I served my country in Vietnam and my life will be cut short as a result of exposure to this toxic chemical, which I was led to believe was harmless and only used to kill vegetation.

My son, Kevin, joined the U.S. Army in August 1994. And after spending some time at Fort Bragg, he was assigned to the Republic of Korea. It is my understanding that the Army's policy that those serving in Korea were required to take a series of anthrax shots. Without objection, without disobeying any orders from his superiors, my son took his first shot, lot No. FAV017, on September 10, 1998, his second shot on September 24, 1998, lot FAV017, and his third shot on October 8, FAV017, in 1998.

On or about November 15, 1998, my son started having headaches and flu-like symptoms and went on sick call at the troop medical center. He was evaluated and given some Actifed and returned to his barracks and again, on November 16, 1998, Kevin again went back to sick call, because his condition had not improved.

He was again examined and was given Motrin and instructed to go back to his barracks. On or about November 17th or 18th, he went back on sick call, because the blisters had begun to form around his mouth, face, neck and back. He was again treated and

returned to the barracks. Records show that at some point between November 15th and November 18th, he was treated for a possible adverse reaction. However, the records do not specify what medical personnel suspected caused the adverse reaction.

On November 19, 1998, Kevin again returned to sick call and subsequently was air evacuated from his station at Camp Carroll to the 121st General Hospital in Seoul, Korea. Some time during the evacuation period, my son lost consciousness, and when he awoke, he had been given a tracheotomy, which was necessary just to save his life.

My wife and I were notified of Kevin's illness on or about November 20, 1998, and when the decision was finally made to fly Kevin to Texas, we flew to Texas to be with him. Kevin was air-evaced to Brooke Army Medical Center on November 25, 1998. We arrived at Brooke Army Medical on November 25th, just short of midnight, and were allowed to see our son the same night.

My daughter, who was already stationed in Texas, arrived at Brooke Army Medical Center before we did. She met us in the hallway and told us to be prepared for an ugly sight. When I first saw my son, I went into a state of shock. I could not believe the condition that he was in. My first thoughts reminded me of my experiences in Vietnam in which I witnessed members of my unit as they were hit by napalm fired from United States aircraft.

Since my son was not involved in any kind of accident involving a vehicle or some type of explosion, I did not expect to see the kind of illness I witnessed when I first saw him. It was hard for me to understand how he could possibly have this type of illness or injury that we witnessed.

After a quick evaluation of his condition, I quickly realized, however, that whatever caused this illness, that my son was very ill and appeared to have a very slim chance of survival. Once we were satisfied that Kevin was out of danger, we returned to Fayetteville and waited for additional information from Brooke Army Medical Center. We arrived back in Fayetteville thinking that we would be kept informed of Kevin's condition.

On April 17, 1999, I mailed a certified letter to the commanding officer at Brooke Army Medical Center, Brigadier General Ogden deWhitt, and asked him if he or a member of his staff would provide me with an update on Kevin's condition. Brigadier General deWhitt did not respond to my letter until October 20, 1999, after I contacted North Carolina Congressman Walter Jones for assistance. And in a letter dated October 20, 1999, Brigadier General deWhitt stated that Kevin's primary diagnosis was staphylococcal scalded skin syndrome [SSS], but that Steven Johnson's Syndrome could not be ruled out.

Brigadier General deWhitt also stated that Kevin should remain at Fort Sam Houston so that his condition could be monitored by the experts at the Army's sold Institute of Surgical Research located at Fort Sam Houston. However, even though the experts at Fort Sam knew of my son's deteriorating eyesight, nothing was done to help him until January 2000, which was 14 months after his hospitalization.

In a memorandum dated November 24, 1999, to Brigadier General deWhitt from Colonel Benjamin Chacko, of the ophthalmology

services at Fort Sam, Colonel Chacko states, "He was sent to the burn ward in November 1999 with acute Steven Johnson's Syndrome, or TENS. His mucus membrane, including his conjunctiva and cornea were acutely affected." Again, in the same memoranda, Colonel Chacko states, "his visual acuity was 20/70 od and 20/40 os. He does have severe photophobia from his chronic keratopathy. Unfortunately, there is no cure to reverse these cicatricial changes."

Even though Kevin's sight continued to get worse from November 1998 through 1999, the experts did not have him seen by a specialist until January 20, 2000. At this time, Brooke Army Medical Center hosted a visiting professor from the University of Florida, Dr. Scheffer Tsang. After examining Kevin, Dr. Tsang made a recommendation that could correct and save some of his vision. I was present when Dr. Tsang evaluated Kevin, and he stated that Kevin's sight would not have gotten to that point if the recommended surgical procedure had taken place earlier.

I'm convinced that my son's illness was caused by the anthrax vaccine. I'm also convinced that my son's case is one of the so-called confirmed cases. This being the case, I ask all members of this committee to take a close look at the evidence that has been presented to you today, in the past, and any that may be presented to you in the future. I urge you to make a recommendation, and I make a bold recommendation that this vaccine be discontinued.

Thank you very much.

[The prepared statement of Mr. Toney Edwards and Mr. Kevin Edwards follows:]

STATEMENT OF
TONEY EDWARDS AND KEVIN EDWARDS
TO
GOVERNEMENT REFORM COMMITTEE
AT HEARING ENTITLED
ANTHRAX VACCINATION IMMUNIZATION PROGRAM – WHAT HAVE WE LEARNED?
OCTOBER 3, 2000
10:00 A.M., 2154 RAYBURN HOUSE OFFICE BUILDING

Mr. Chairman, Members of the Committee, good morning.

My name is Toney Edwards and I would like to say it is indeed a pleasure for me to appear before you today, except for the nature of my testimony, I do, however, ver much appreciate the chance to tell the story of multiple military tragedies in our family.

I have with me today my son, Kevin Edwards, who is currently on active duty and is now in the Medical Hold Company at Brooke Army Medical Center at Ft. Sam Houston, TX. He has been there since November 1998. I hope that the information I provide today will help this committee in making recommendations or decisions concerning the safety and future use of the Anthrax vaccine.

Before I begin, I would like to give a little information about myself. I am retired from the United States Army. I served approximately fifteen years of my career with the 82nd Airborne Division at Fort Bragg, NC. I also served in the 101st Airborne Division in the Republic of Vietnam, the Berlin Brigade and as a Drill Instructor at Ft. Jackson, SC.

During my tour with the 101st Airborne Division in Vietnam, I was exposed to the herbicide known as Agent Orange, which was used to kill vegetation in the jungles of Vietname, so that we could have a better opportunity to see and destroy the enemy. It was not until later that I learned that the herbicide that I observed being sprayed from military aircraft, would ultimately case the death of many American soldiers, including myself. I now have prostate cancer as a result of exposure to Agent Orange, from Vietnam. I have Post Traumatic Stress Syndrome (PTSD) and other illnesses that have made it difficult for me to live a normal life. I feel that these conditions are a result of my Vietnam service. I joined the United States Army from the back woods of Virginia and the Army gave me a life. I served my country in Vietnam and as a result, my life will be cut short due to my exposure to this toxic chemical, which I was led to believe was harmless and only killed vegetation.

My son, Kevin, joined the US Army in August 1994. After spending some time at Ft. Bragg, he was assigned to the Republic of Korea in August 1998. It is my understanding that it is Army policy that those serving in Korea were required to take a series of the Anthrax vaccine. Without objection, and without disobeying any orders from his superiors, my son took his first shot Lot #FAV017 on September 10, 1998, his second

shot of Lot #FAV017 on September 24, 1998 and his third shot of Lot#FAV017 on October 8, 1998.

On or about November 15, 1998, my son started having headaches and flu-like symptoms and went on sick call at the Troop Medical Clinic (TMC). He was evaluated and given some Actifed and was instructed to return to his barracks. Again, on or about November 16, 1998, Kevin again went back on sick call because his condition had not improved. He was again examined and was given Motrin and was instructed to return to his barracks. On or about November 17 or 18, 1998, he went back on sick call because blisters had began forming around his moth, face, neck and back. He was again treated and returned to his barracks. Records show that at some point and time between November 15 and 18, he was treated for possible adverse reaction, however, the records does not specify what the medical personnel suspected caused the adverse reaction. On or about November 19, 1998, Kevin again returned to sick call and was subsequently evacuated by air from his duty station at Camp Carol to the 121st General Hospital in Seoul, Korea. Sometime during the evacuation period, my son lost consciousness and when he awoke, he had been given a tracheotomy, which was necessary just to save his life.

My wife and I were notified on or about November 19, 1998 by the DA of Kevin's serious illness and were told to prepare to come to Korea. On or about November 21, 1998, we were told to be on stand by to go to Ft. Sam Houston, Texas or to the Burn Center in Hawaii. The decision was finally made to fly Kevin to Texas and we prepared to fly to Texas.

Kevin was air evacuated to Brooke Army Medical Center (BAMC) on November 25, 1998. At this time, Kevin and the entire Edwards family would like to take this opportunity to thank the Command at Brooke Army Medical Center and the Command in Korea, who coordinated this flight and the flight crew and medical personnel made the long round-trip flight from Ft. Sam Houston to Korea and returned to bring Kevin home. We would like to offer our special thanks to Dr. Cantenello who made the round trip flight and the person, whom we feel, was the physician who most likely was responsible for saving Kevin's life.

We arrived at Brooke Army Medical Center on November 25, 1998, just short of midnight and were allowed to see our son on the same night. My daughter, who was already in Texas, met my wife and I in the hallway and told us to be prepared for an ugly sight.

When I first saw my son, Kevin, I almost went into a state of shock. I could not believe the condition that he was in. My first thought reminded me of my experience in Vietnam, where I witnessed members of my own unit as they were hit with Napalm fired from US Aircraft.

Since my son was not involved in any kind of an accident involving a car or some type of an explosion, I did not expect to see the kind of illness that I witnessed when I first saw

him. It was hard for me to understand how he could possibly have this type of illness or injury that we witnessed, (SHOW PICTURES) without being involved in some type vehicle accident, a fire or some type of explosion. After quick evaluation of his condition I quickly realized that whatever this was that caused this illness, that my son was vry ill and he appeared to have a slim chance of surviving.

My wife and I and the rest of our family struggled through the next twelve to fifteen days, praying that Kevin would survive this terrible ordeal. Within a few days, we were convinced that through the Grace of God, Kevin would most likely survive this ordeal, but we knew that somehow he would be left scarred and/or disabled for the rest of his life.

As time passed and Kevin was able to communicate with us, I noted that he was very confused about his condition. He appeared to be in a state of shock and disbelief. He was scared and worried about his own survival of his illness. As I questioned him about what he thought caused his illness, he immediately mentioned the Anthrax vaccine.

I knew that the military was inoculating soldiers with the vaccine, and I had heard of some other soldiers complaining about their fear of the vaccine. I had even heard of soldiers who became ill and suspected that their illness was caused by this vaccine. I immediately went to the library at Ft. Sam Houston and began collecting information about this vaccine.

Once we were satisfied that Kevin was out of danger, we started making plans to return home. My wife departed on December 10, 1998 and I departed on December 12, 1998.

We arrived back in Fayetteville thinking that we would be kept informed of Kevin's condition by officials at BAMC. We waited for the next four months, but we did not receive any communication from anyone at BAMC concerning Kevin's condition. On April 17, 1999, I mailed a certified letter to the Commanding Officer of BAMC BG Ogden deWhitt and asked him if he or a member of his staff would provide me with an update of Kevin's condition. I also asked if it would be possible for Kevin to be transferred to Womack Army Medical Center at Ft. Bragg.

BG deWhitt did not respond to my letter until October 20, 1999, after I contacted North Carolina Congressman Walter Jones for assistance. In a letter dated October 20, 1999, BG deWhitt stated that Kevin's primary diagnosis was Staphylococcal Scalded Skin Syndrome (SSSS) but that Steven Johnson' Syndrome could not be ruled out.

BG deWhitt also stated that Kevin should remain at Ft. Sam Houston so that his condition could be monitored by the experts at the Army's sole Institute of Surgical Research located at Ft. Sam Houston, Texas. However, even though the experts at Ft. Sam Houston knew of my son's deteriorating eye sight, nothing was done to help him until January 20, 2000.

In a memorandum dated November 24, 1999 to BG deWhitt, from Colonel Benjamin Chacko, Ophthalmology Service, Colonel Chacko states "he was sent to the Burn Ward in November 1998, with acute Stephen Johnson Syndrome/TENS. His mucus membrane including his conjunctiva and cornea were acutely affected". Again in the same memoranda Colonel Benjamin Chacko states "his visual acuity is 20/70 od and 20/40 os. He does have severe photophobia from his chronic keratopathy. Unfortunately, there is no cure to reverse these cicatrical changes". Even though Kevin's sight continued to get worse from November 1998 through 1999, the experts did nothing to have him seen by more qualified medical personnel until on or about January 20, 2000.

At this time, BAMC hosted a visiting professor from the University of Florida, Dr. Scheffer Tsang. When Dr. Tsang arrived on January 20, 2000, he evaluated Kevin's condition and immediately made recommendations that could correct and/or save some of his vision. I was present when Dr. Tsang visited BAMC and he stated that Kevin's sight would not have gotten to that point if the procedure that he recommended had taken place earlier.

Additional records, that I have obtained, indicate that the command at BAMC reported Kevin's illness as being caused by an adverse reaction to the Anthrax vaccine in excess of one year after the onset of his symptoms. (SHOW EXHIBITS)

Kevin has since that time been sent to the Boston Foundation for Sight, where he has been given special lenses, which has improved his sight. However, he has to frequently change these lenses and use a special lubricant that allows him to see better. His tead ducts have been cut and he can no longer make natural tears. Imagine, being in a position in which you can not even cry.

I was proud of Kevin when he made his decision to join the US Army and serve his country. I supported him in his decision and encouraged him to do so. Due to the manner in which the military has handled Kevin's situation in the past, I would not support any of my relatives who might be considering joining the US Army.

I am convinced that Kevin's illness was caused by the Anthrax vaccine. I am also convinced that my son's case is one of the so-called "confirmed cases". This being the case, I urge all members of the committee members to take a close look at the evidence that has been presented to you today, in the past, and any that may be presented to you in the future, and I urge you to recommend that this vaccine be discontinued.

Thank you very much for allowing us to come before you.

Mr. BURTON [presiding]. Thank you, Mr. Edwards.

Is it Sergeant Colosimo? Airman. I was in the Army.

Mr. COLOSIMO. Mr. Chairman and members of the Committee, I thank you for allowing me the opportunity to speak to you today. My name is Thomas J. Colosimo, and I'm a Senior Airman in the U.S. Air Force.

Please note that any opinions I express are my own and in no way reflect the opinions of the U.S. Air Force.

After I received my first, second and third anthrax shots, I immediately felt pain at the injectionsite. I also had a total of nine cysts that gradually multiplied and increased in size on my scalp. The largest one being the size of a half dollar, and one at the corner of my right eye. The pain got so bad that I went to the base hospital and had the cysts surgically removed.

After each shot, I felt disoriented. I also felt as if a cold were coming on, with headaches, coughing, fatigue and lightheadedness. These symptoms lasted for a few days.

When I received my fourth anthrax shot, the pain at the injectionsite was unbearable. The following day I was sick like the previous three shots. I also started developing a terrible cough that would cause me to gag when I was done. It continued until December when I deployed to Al Jaber, Kuwait, and my condition worsened.

Once there, I started to lose weight rapidly. I lost a total of 50 pounds within the next 3 months. My energy was declining at a rapid pace. The lightheadedness increased to the point of feeling like I was going to pass out. I had night sweats, chills, ear ringing, tremors and severe fatigue. I went to the hospital and spoke with a doctor who sent me to Camp Doha, an Army base nearby, for tests. The results came back normal, and my concerns were dismissed.

I finished the deployment and returned to Hill Air Force Base. I went to the base hospital, disclosed my health concerns, which included increased episodes of vertigo, short term memory loss, shortness of breath, mood swings, confusion, tunnel vision and fatigue. I saw the same doctor that I had seen in Kuwait and suggested that my symptoms were anthrax related. He again minimized my concerns.

My condition continued to worsen, and I started to experience staring spells. I was also getting severe abdominal pains when going to the bathroom, and shin pains that lasted for days for no apparent reason. My ability to concentrate was declining, and forgetfulness was increasing. Memory loss with dizziness was now constant.

The evaluation by several specialists was to no avail. The dizziness was soon followed by daily drop attacks, during which I would collapse wherever I was and which later led to full loss of consciousness. At first, the loss of consciousness only lasted for a few minutes, but as time went on, increased in duration from 30 to 45 minutes, resulting in the inability to speak for about 20 minutes. Several of these episodes included respiratory arrest.

An overwhelming feeling of tiredness occurred prior to these incidents. It was at this time the doctors placed me on an indefinite convalescent leave, and a profile stating no driving or being alone.

Because the Air Force tried to convince me my symptoms were psychosomatic and not life threatening, I had to seek congressional help to seek the medical care I needed. Only with the strong influence and intervention from Representative Peterson and my wife's and mother's involvement did Hill Air Force Base decide to send me to Walter Reed.

Mr. BURTON. If you're having trouble breathing, would you like to take a brief break? Are you all right?

Mr. COLOSIMO. I'm all right, sir.

After 35 days of numerous and extensive tests, Walter Reed diagnosed me with neurocardiogenic syncope, chronic fatigue syndrome, obstructed sleep apnea, anxiety disorder, and situational stress. None of these symptoms predated my first anthrax vaccine.

In fact, I have my narrative summary and patient discharge instruction sheet dated May 13, 2000, my mission diagnosis, anthrax intoxication. I also have a document from the DOD clinical consultant from the anthrax program and advisor to the office of Major General West that my mission to Walter Reed on May 10, 2000 was anthrax related. I have these documents in my possession today.

Walter Reed released me back to Hill Air Force Base and I ended up having no one accept the responsibility for monitoring my illness and medication regimen, because the medical technicians didn't understand my condition and seemed afraid of the congressional advocacy that was involved.

Because of this lack of medical attention, my condition worsened again and I started to develop new systems. I was also left with the responsibility of adjusting my own medication.

Hill Air Force Base then requested a medical review board. The board decided I was fit for duty and I was to return to work, even though I had been told not to drive or to be alone. My profile stated history of syncope, no prolonged standing, climbing, operation of heavy machinery or work with hazardous material, no excessively long shifts or overnight work, no strenuous training or physical fitness requirements, no work on flight line or uncontrolled climate, no deployments, no Government or personal driving. Fit for duty.

At this time, my vision started to fade in and out as with tunnel vision, causing me to fall down stairs and run into walls. I also started to become overly sensitive to household chemicals that never bothered me before, causing me to have episodes of delirium. Because of my increased sensitivity to chemicals and sleep deprivation, I would become delirious, stumble, have slurred speech, my thought process would become unclear, and forgetfulness would be constant. This state of delirium could last for a few minutes to a few days, and I would not remember a thing.

Once again, with the strong and persistent intervention of Representative Peterson and Senator Hatch, and my wife's and mother's involvement, Hill Air Force Base reluctantly returned me to Walter Reed Army Medical Center. I was given less than 1 day's notice and was told I was not allowed to return to the base. It took the Air Force a total of 10 weeks and my falling over 50 times to be returned for treatment.

Since mid-March, I have had over 200 falls. I believe the Air Force is taking a retaliatory posture with me for the congressional

advocacy my family sought for my medical care. But with encouragement of my wife, I am convinced I needed to come forward and tell you my story anyway.

I know of numerous individuals who are sick from the anthrax vaccine. They are afraid to come forward for fear of repetition of the same treatment or lack of that I have sustained. It sickens me that the military leaders have instilled this much fear. I must stand up for what I believe is morally and ethically right. It is for them and others who will soon be sick from this vaccine that I testify before you today.

You leave here whole and intact tonight. I do not. Nor do the other sick victims I represent. Many have symptoms that are far worse than mine, but cannot speak. Many are paralyzed because of fear. Even sadder, many have physical conditions which have been misdiagnosed or under-treated because the optimal method of treatment has been to keep us all separate. What is profoundly disturbing is that wherever two or three sick military gather, anthrax is in the midst of them.

We love this Nation and are proud to serve you all. Neither I nor they bear any shame. Shame rests upon a system allowed to become so evil that it's abandoning its own. All it takes is for good people to do nothing. Today is the day a line needs to be drawn, not upon the sand, but upon your soul. You need to say, no more, please stop this insanity.

I want to be among the last sick to testify before you. I was called upon here today to be a token sick person. This is a false perception. In this regard, I am not a singular individual. I am the many who have not lost only their health, but their hope in America.

If I was to imagine an opportunity to testify before Congress in my lifetime, I would certainly prefer it to be on another matter and other circumstances. It has been an honor and a privilege to testify before you anyway, only because I represent thousands and thousands of good people in the military, your spouses, neighbors, friends, sons, and daughters who want to tell you the same thing I am saying to you today, please stop this insanity.

[The prepared statement of Mr. Colosimo follows:]

Statement of Thomas J. Colosimo, SRA, USAF

Before the Committee on Government Reform
U. S. House of Representatives
Dan Burton, Chairman

3 October 2000

Hearing
"The Anthrax Vaccination Immunization Program
What Have We learned?

Mr. Chairman and members of the committee, I thank you for your continued interest in the Anthrax Vaccination Immunization Program (AVIP). I also thank you for asking me to share my personal experiences of adverse reactions to the Anthrax vaccination, and the problems I have encountered while seeking medical care for these vaccine adverse reactions I have incurred in the military. My name is Thomas J. Colosimo, and I am a Senior Airman in the United States Air Force, currently stationed at Andrews Air Force Base, Maryland. Please note that any opinions I express are my own and in no way reflect the opinions of the United States Air Force.

I have served proudly in the Air Force for over nine years. I have had no regrets for my service to my country. During this time I have been deployed to the Middle East eight times to include: Kuwait, Saudi Arabia, and Classified locations. I also have been to twenty other countries. Italy, Germany, Ireland, Tunisia, Chile, Panama, Hungary, Sardinia, Spain, Iceland, Turkey, France, Greece, Canada, Azores, and Egypt just to name a few.

My job was a Nondestructive Inspectionalist. I would inspect aircraft by the use of X-ray, ultrasound, eddy current, bond testing, penetrant, magnetic particle, and oil analysis. By these means I could tell what part of an aircraft or engine was bad or was going to go bad and have it fixed or replaced by specialists before it turned into something catastrophic, such as loss of a pilot or damaging the aircraft. This job was very exciting because whereever the jets went, I went. I enjoyed traveling anywhere the Air Force sent me.

Because of my current health conditions, I am currently in a patient squadron working no more than four hours a day answering phones and taking messages. Because of my current condition, I have trouble performing even these simple tasks. Most of my time is spent going to doctor's appointments or physical therapy.

Before I go into detail about my adverse reactions to the Anthrax vaccination, I'd like to point out that when I was vaccinated, I was not informed of any potential adverse side effects or of the Vaccine Adverse Events Reporting System (VAERS) . There were no hand outs, product inserts, literature, or health questionnaires to read or fill out. I just had to report to immunization, turn in my shot records, and receive the shot. When I voiced my concerns about receiving this

vaccine, I was told failure to comply was punishable under the Uniformed Code of Military Justice (UCMJ). I was uncomfortable with accepting the vaccination, but I complied and put my faith in the system. I received all four shots at Hill Air Force Base, Utah.

I received my first Anthrax shot (lot # 36) on 20 February 1998. I felt a pain in my upper left arm, starting immediately following the injection, confined to the injection site. The day following this immunization, I felt sick, as if a cold were starting. I felt fatigued, lightheaded, and had a headache. A few days later, I developed a cyst on my scalp, which seemed almost insignificant at first, but gradually increased in size. It became noticeable every 2 weeks when getting a hair cut because of the soreness. At the same time a similar lesion developed in the corner of my right eye. At the time, I didn't think much of it and thought they would just go away.

I received my second Anthrax shot (lot # 38) on 15 March 1999, over one year later, even though shot protocol is two weeks between shots 1, 2, and 3. Again I felt immediate pain at the injection site. On the day after the injection, I felt like a cold was coming on with coughing, sneezing, running nose, headache, fatigue, and lightheadedness. Also the cysts that I had originally developed from the first anthrax shot multiplied and increased in size.

I received my third Anthrax shot (lot # 38) on 29 March 1999. Again I felt immediate pain at the injection site, but this time instead of feeling like a cold was starting, I just felt very tired. I was so tired that I slept about 16 hours a day for two weeks. I had no energy. The only thing I wanted to do was go to bed and sleep. By this time I had 9 cysts on my scalp, the largest one being the size of a half dollar, and 1 at the corner of my right eye. The pain I was experiencing from these cysts was unreal. If I were to rate it on a scale of 1 through 10, it would definitely have been a 10. Every time I bumped my head or got a hair cut, it would bring me to tears.

The pain got so bad that I finally went to the base hospital in July 1999 and made an appointment to have the cysts surgically removed. I feared going to the hospital in the first place because I was afraid to find out that something was seriously wrong with me, that these could possibly be tumors. After I had the cysts removed, they were sent for biopsy and were found to be non-cancerous. I didn't think to ask if they were tested for Anthrax, because I didn't relate these symptoms to the Anthrax shot until I received my fourth shot.

I received my fourth Anthrax shot (lot # 24) on 22 September 1999. This time the pain at the injection site was unbearable. While leaving the hospital, I kept my arm at my side because it hurt to move it. I had to sit down a few times because it was hard to catch my breath from the pain. The following day, I was sick. I was fatigued, lightheaded, sneezing, disoriented, and had a headache. I also started developing a terrible cough that would cause me to gag when I was done and continued until December, when I deployed to Al Jaber, Kuwait and my condition worsened.

Once there, I started to lose weight rapidly. Some days I was losing anywhere from 1 to 3 pounds a day. I lost a total of 50 pounds within the next three months. My energy was declining rapidly, the lightheadedness increased to the point of feeling like I was going to pass out. I had night sweats, chills, ear ringing, tremors, and severe fatigue. My sleep alternated from excessive

sleeping one week to insomnia the next week. I went to the hospital and spoke with a doctor who was also from Hill Air Force Base. He ordered several tests for me at Camp Doha, an Army base nearby, and told me the results were "normal" and my concerns were dismissed.

I finished the deployment and returned to Hill Air Force Base 8 March 2000. I went to the Base Hospital to disclose my health concerns, which included increased episodes of vertigo, short term memory loss, shortness of breath, mood swings, confusion, tunnel vision, and fatigue. I expressed that my symptoms might be an adverse reaction to receiving the Anthrax vaccine. The first doctor I saw said I could have had the cysts before I came in the military, that I was probably allergic to milk, and that I was starving myself accounting for the severe weight loss. I was told I could not be evaluated or treated until my medical records were returned from Kuwait. Two weeks later, my medical records arrived – having been hand carried by the physician who treated me in Kuwait. Once they arrived, I was told they were "confidential" and was not allowed to see them. I saw the same doctor that I had seen in Kuwait; he again minimized my concerns.

I was told I was due for my fifth Anthrax shot on 27 March 2000. Because my complaints of malaise were not taken seriously and because I had concerns that all the symptoms I was experiencing were Anthrax related, I decided I couldn't risk taking the next shot.

I was told by the doctors at Hill Air Force Base that my illness was not Anthrax related and that I "had to take the shot." They tried to convince me that my cysts predated my Anthrax series, that the weight loss was a result of a poor diet, and that everything else was psychosomatic. I contacted my Pennsylvania Representative, John Peterson and shot number five was put on hold pending a medical evaluation. Several appointments with area specialists were made, again due to Representative Peterson's intervention.

My condition continued to worsen. I started to experience staring spells. My wife said it took several minutes before I would snap out of it. She said I would have a blank look on my face and talking to me would not help. I was also getting severe abdominal pains when going to the bathroom, shin pains that lasted for days for no apparent reason. My ability to concentrate was declining and forgetfulness was increasing. Memory loss with dizziness was now constant.

The evaluation by several specialists was to no avail, that is - no diagnosis was discerned. The dizziness was soon followed by daily drop attacks and later led to full loss of consciousness. At first the loss of consciousness only lasted for a few minutes, but as time went on, increased in duration from 30 to 45 minutes, resulting in the inability to speak for about 20 minutes. Several of these episodes included respiratory arrests. An overwhelming feeling of tiredness occurred prior to these incidents.

On 30 March 2000 around 1600 hours (4:00 pm), I was at work, pouring water from a pitcher. I blacked-out and fell to the floor. My supervisor immediately called 911 and the paramedics took me to the base hospital. They ran some test and found nothing "out of the norm." My doctor then placed me on a profile stating no driving or working alone and sent me back to work.

The next black out happened on 4 April 2000. I was sitting in the break room at work. The next thing I remember I was laying on the floor in a different room with paramedics all around me. They took me to the Davis County Hospital where I was seen by a neurologist and sent home. He did some lab work and scheduled me for some tests the next day.

The following day I went to the base hospital for more lab work and to get a halter monitor placed on me. I called a co-worker for a ride and went outside to sit on a bench and wait. Witnesses said I got up from the bench, lost consciousness, and fell to the pavement. I woke to find the paramedics with me again and was admitted to Davis County Hospital overnight for more "tests and observation." My halter monitor recorded the incident and showed my heart rate went up to 198 bpm and down to 40 bpm when I blacked out. The neurologist said what I had was Sinus Tachycardia and prescribed heart, sleep, and anxiety medication. I was then put on indefinite convalescent leave.

On 8 April 2000, I was home vacuuming the living room and blacked out. When I came to, my downstairs neighbor, who heard me fall, rushed upstairs to help; he and my wife were yelling and shaking me. They said my eyes were rolled back, eyelids were twitching, my complexion was pale, and I stopped breathing. My wife performed rescue breathing until I came to. It is almost incomprehensible for me to admit to you that these "drop attacks" were becoming "almost normal."

The next day my wife and I went on base to visit with a friend who is in the Air Force Reserves. While visiting with him, I started to feel tired and told them I wanted to go home. While we were walking out to the car, I blacked out. I woke up to an oxygen mask on my face and in the back of an ambulance. I was told I fell face first in the gravel, stopped breathing several times, and had rescue breathing performed on me by a Master Sergeant who was nearby, until the paramedics arrived. I was out for a total of 45 minutes. I was admitted again to Davis County Hospital overnight, with more tests to follow.

The next morning I was taken to Colombia Ogden Regional Medical Center for a tilt table test by Dr. Jones (a Cardiologist). He induced a blackout and said my heart rate went from 60 bpm to 150 bpm to 40 bpm while my blood pressure dropped to 78/38. He diagnosed me with Postural Orthostatic Tachycardia and Chronic Fatigue Syndrome. He gave me an events monitor to wear; this would record what my heart was doing. He stated I would need someone constantly with me because with my loss of consciousness, I would not be able to activate the system. My wife took a family leave of absence from her job to stay with me. I was told I was not allowed to go back to work, drive, or to be alone.

On 6 May 2000, I was out on our balcony. Upon reentering the house, my wife said I looked very pale and disoriented. I had to hold the door to keep myself up and steady. My wife helped me into the recliner and noticed that my eyes were half way open and were rolled back. She said my breathing was slow and deep at first, but got faster and harder. She noticed that the events monitor that I was wearing showed my heart rate had increased from 62 bpm to 220 bpm in a few seconds. She then ran downstairs to get our neighbor to help, but when she returned my chest was "jumping," as though I was having muscle spasms. She then decided to call 911. At

this time I stopped breathing. The operator told my wife to start rescue breathing. On the 10th breath, I started breathing again, and my heart rate had slowed down.

The medics then arrived and put an oxygen mask over my face. They asked if I could hear them and I shook my head "yes." At this time, one of the responders (policeman) walked into the room. He asked my wife if this "was the same guy" they responded to "a few days earlier on Hill Air Force Base." She replied, "yes." He then reached down, grabbed and twisted my nipple and tried to pull me off the floor by it. He told me to sit up, that he "was sick of playing (my) games," that he was "not going to play this game tonight, that (I) was a faker, and that nothing was wrong with (me)." By this time, I was screaming in pain and he dropped me back to the floor. I couldn't speak and I was having trouble catching my breath. He also told my wife that my "doctor at Hill Air Force Base said, (I) was faking it and nothing was wrong with (me)." He repeated this assault again and threatened to repeat it a third time if I didn't respond to him. I was then dragged down three flights of stairs, loaded in an ambulance, taken to the emergency room and kept overnight for observation.

I had 14 more blackouts, most resulting in minor injuries such as scrapes, cuts, scratches, and bruises. Only with the strong influence and intervention from Representative Peterson and my wife's and mother's involvement with the media, did Hill Air Force Base decide to send me to Walter Reed Army Medical Center on 9 May 2000. After 35 days of numerous and extensive test done by Neurology, Cardiology, Infectious Disease, Endocrinology, Gulf War Clinic, Psychiatry, Psychology, ENT, Allergy, and the Sleep Disorder Center, Walter Reed diagnosed me with Neurocardiogenic Syncope, Chronic Fatigue Syndrome, Obstructed Sleep Apnea, Anxiety Disorder, and situational stress. None of these symptoms predated my first Anthrax vaccine.

Informationaly, Neurocardiogenic Syncope is a potentially serious condition that occurs when one's blood pressure drops significantly after standing up, because the muscles around the blood vessels in the legs do not constrict normally. One may feel dizzy with a change of position from laying or sitting to standing. A large decline in blood pressure may cause syncope, the medical term for a sudden, brief loss of consciousness or fainting spell and vision may blur. Low blood pressure upon standing up seems to spring from a failure in the autonomic nervous system. Normally, when a person stands up, there is a reflex constriction of the small arteries and veins to offset the effects of gravity. With Neurocardiogenic compromise - "normal" doesn't happen.

On 13 June 2000, Walter Reed Army Medical Center released me back to Hill Air Force Base with a strong recommendation that I be immediately transferred to Andrews Air Force Base, so I could have intense medical follow up. They also tried to contact my doctors at Hill Air Force Base to establish medical treatment contingency and were repeatedly told "no one was available."

When I returned to Hill Air Force Base, I found out that I had no doctor assigned for my care and no one knew what to do with me. Two weeks went by until I finally met with a doctor who was assigned to me. He told me he was leaving in a few weeks and my "case was too complicated to deal with," so I would "have to wait for another doctor to return from leave." I ended up having no one to accept the responsibility for monitoring my illness and medication

regime because it didn't fall within "the norm." Because of this, my condition worsened and I started to develop new symptoms. I was then left with the responsibility of adjusting my own medications.

On 29 June 2000 around 0100, I got out of bed to get a drink of water and on returning collapsed to the floor. With the help from my wife, I got back into bed. She said I appeared delirious and then at approximately 0230 (2:30 a.m.). I got out of bed. I have no recall of where I was going or why. At approximately 0630 (6:30 am), I returned home. All I remembered was waking up in a parking lot covered in blood, vomit, and urine, not knowing how I got there. The doctor said that my blood pressure dropped so low that I passed out and started to loose control of my extremities.

Hill Air Force Base then requested a Medical Review Board. The Medical Review Board decided that I was "fit for duty" and to return to work along with a profile that stated: "History of syncope- no prolong standing, climbing, operation of heavy machinery, or work with hazardous material, no excessively long shifts(greater than 8 hours) or overnight work, no strenuous training or physical fitness requirements (cycle ergometry), no work on flight line or uncontrolled climate, no deployments, no government or personal driving."

However, my squadron (388th MXS) told me I was still not allowed to return to work and I was to stay at home and wait for orders to Andrews Air Force Base. It was at this time that my vision started to fade in and out as with tunnel vision, causing me to fall down stairs and run into walls. I also started to become overly sensitive to household chemicals that never bothered me before, causing me to have episodes of delirium. My wife said I would get out of bed, usually at night after being around the cat's litter box, oven cleaner or other cleaning products and walk outside and away from our apartment for 6 to 8 hours. She would then call my First Sergeant and the police to help look for me. When I returned or was found, I would go back to bed, wake up the next morning, never remembering a thing.

My wife, my family, and I pleaded with the Air Force that I return to Walter Reed but was denied this again and again. I asked if Hill Air Force Base could at least contact the Walter Reed doctors for advice and possible treatment or testing but was ignored. They promised I would get a doctor at Hill Air Force Base, "soon." I was told weekly that I would be receiving orders "soon" and "it wouldn't be cost effective" to send me sooner if I were getting orders anyway. I used my chain of command including the Base Commander, the Inspector General of the base, the Air Force Inspector General, and the Secretary of the Air Force to no avail. Please be assured, I don't take Congressional advocacy lightly, but I was left with no choice.

Once again with the strong and persistent intervention of Representative Peterson, Senator Santorum, Senator Hatch, and national media exposure caused by my wife and mother, Hill Air Force Base reluctantly returned me to Walter Reed on 8 August 2000, until I got orders to Andrews Air Force Base. I was given less than one days notice and told that I was not allowed to return. It took Hill Air Force Base a total of 10 weeks and my falling over 50 times to be allowed to return for treatment. Since mid March, I have had over 200 falls.

When I arrived at Walter Reed, I was told that they were never notified that I was coming. They admitted me as an inpatient for observation and ran more tests. They adjusted my medications to include: Florinef, Atenolol, Paxil, Lorazepam, Sodium Chloride Tablets, Magnesium Gluconate, Vitamin E, and Vitamin C and continued to observe me. Even with these medications I still get lightheaded, but that is the "best they can do." I received my orders to transfer to Andrews Air Force Base three weeks later on 1 September 2000. I am currently being seen by Walter Reed medical personal on a regular basis.

Because of my increased sensitivity to chemicals and sleep deprivation, I had another episode on Friday, 16 September 2000. My wife said I was delirious, stumbling, had slurred speech, my thought process was unclear, forgetful, and I was in a drunken-like state. She said it was like I had Down's syndrome. By Saturday night my condition worsened. That night, I went to the Base Hospital ER at my family's insistence. They took some urine and blood samples and asked us to wait. Five hours later, the tests results came back "normal" and I was released in the same condition as I arrived, with the recommendation to see my primary physician at Walter Reed Monday morning. This state of delirium lasted until Sunday evening and I don't remember a thing. My doctors at Walter Reed are uncertain what caused this.

While we were at the Emergency Room, our home was entered by the security police and searched. The neighbors told the police we were at the hospital and they called it in to verify it. Once they knew where we were, the police told the paramedics to wait outside. The cops then entered our home through the back door and proceeded to search every drawer, cupboard, closet, and room. They then asked our neighbors if (I) "had a mental problem?" They said "no, he has a medical problem." They asked if (I) "was ever violent with (my) wife?" They also said "no." The police told our neighbors that I "kidnapped (my) wife and was out to hurt her." They also asked if (I) "was on any drugs?" They said that (I) "was on medications." This is clearly harassment and an attempt to discredit my credibility. Ever since I got sick from the anthrax vaccine and acknowledged it as the cause, I have received nothing but hostile retaliation.

Certain Air Force officials who are in charge of reviewing my request for extension and disability have told the doctors at Walter Reed that I am "milking the system" and using my "illness to stay in the military," that I am "a trouble maker" and I "showed it with my mother's and wife's involvement with Congress and the press," that they "were going to make sure any attempts for a medical extension would get denied." My Walter Reed doctors said they needed at least 6 months to do a complete re-evaluation due to the regression that occurred in my health because I received no medical treatment at all from 15 May 2000 through 8 August 2000. They were told by the Air Force two weeks was all they had. My enlistment is up 23 November 2000 and I am being told by my doctors at Walter Reed that I will have to continue taking my current medications for at least a year before they can even consider taking me off of it, even though they are uncertain how I will react without it. I am 28 years old. I was healthy. I had dreams and visions. I did what I was told. I got sick.

I do not understand why the Air Force has abandoned me. Is it because my sickness is associated with the Anthrax shot? My symptoms are not like the flu, where your sick as a dog for a couple of days, then over it. It is hell! You feel good enough to go out and wash the car, then

turn around in 10 minutes and are flat on your face or OK to take a walk, then Boom, laying in the parking lot and forget where you live or how to get help.

I believe the Air Force has taken a retaliatory posture with me for the Congressional advocacy my family sought for my medical care. But it was that or die. I have an illness even I do not understand. I took the Anthrax shots healthy and am now ill. No one is sorrier for this than me. All I wanted through all of this was to receive medical treatment, get better, and press on. But the Air Force has only given me the medical care when forced to. Until Representative Peterson intervened, no one listened.

When I mentioned what happened after taking the Anthrax vaccination to my Air Force doctors, they got defensive. They repeatedly denied that it could be Anthrax. I was even sent to a psychiatrist, but my doctor warned the psychiatrist "be cautious, this patient has questioned the possibility of Anthrax induced problems."

One of the hardest things I've encountered through all of this, is that no one "knows" what is causing my symptoms. I have been to numerous hospitals and seen many doctors, but no one can tell me for certain if I will get better, if this could possibly get worse, or if I'm going to have to live with this for the rest of my life. All they can offer me is medicine to help treat my symptoms. These are only limitedly effective. I continue to get dizzy, fall, sustain confusion and have difficulty speaking at times.

I am scared about the future. What effect is this going to have on my wife and will we be able to have healthy kids someday? What will happen in a year from now, when the doctors take me off the medications? Will I be able to work, drive, and support a family? Will I be able to afford medical insurance with this illness? Who will ever hire me with the current symptoms I have described.

I cannot say what I feel any clearer. I cannot predict what my body will do. I won't likely die as a direct result of the Anthrax shots. It will be more likely due to a fatal injury from a fall. I do not want my wife, mother, and father to stand over my casket and lose all faith in a country I gave 9 years of my life to and pledged to die for. I am now faced with a discharge in November with no disability because the Air Force said I was "fit for duty" and that my condition was neither compensable or ratable. This is incomprehensible.

I am very afraid to testify before you today for fear of reprisal. But with the strength and encouragement of my wife and family, I am convinced that I needed to come forward and tell you my story. I know of numerous individuals who are ill from the Anthrax vaccine that I have seen while I was at Walter Reed, have talked to over the phone, and have received written letters from. They are afraid to come forward for fear of a repetition of the same treatment, or lack of, that I have sustained. They are afraid of losing their job, as well as destroying their career, and not being able to support their families. It sickens me that the military "leaders" have instilled this much fear. I must stand up for what I believe is morally and ethically right. It is for them and others who will soon be sick from this vaccine, that I testify before you today.

Before I conclude, I would like to ask you to think about what a day in my shoes would be like, having an illness that civilian and military doctors do not understand or ignore. Not knowing how your body will react from one second to the next. Going out for a walk and waking up in an ambulance, having your loved ones perform rescue breathing on you and imagining what would happen if you were alone, what it's like not being able to drive, not being able to stand for a period of time, forgetting events and days, blurred vision and dizzy spells when walking, constantly taking numerous medications, and finally not knowing if you'll ever get better or if you'll die from this.

If you suspected that giving any medication or shot to **your** son or daughter would risk hurting them, would **you** hand them that pill or inject them? **I** am someone's son, too.

How can the military be "protected" by a 3rd rate "vaccine?" We do NOT have to sacrifice a few to save the many. I am "the few." Who among you will say I am expendable? I deserve my life, too. Those of us in the military have earned the same rights for consideration and respect you would ask for yourself or that you would demand for someone you love. My family still loves me.

I want to be among the last "sick" to testify before you. I was called upon to be here today to be a "token sick person." This is a false perception. In this regard I am not a singular individual, I am the many who have lost not only their health, but their hope in America.

You leave here tonight whole and intact. I do not ---nor do the 100,000 to 200,000 sick Gulf War and Anthrax Victims I represent. Many have symptoms that are far worse than mine but can not speak. Many are paralyzed because of fear. Even sadder, many have physical conditions which have been misdiagnosed or under treated because the "optimal" method of treatment has been to keep us all separated or label us "psychos". What is profoundly disturbing is that wherever two or three sick military gather---Anthrax is in the midst of them. The "Joes" and "Kristins" I have had the honor to meet are NOT malingerers. NOTHING COULD BE FURTHER FROM THE TRUTH!!

We love this Nation and have been proud to serve you all. Neither I nor they bear any shame. Shame rests upon a system allowed to become so evil that it abandons its own. All it takes is for good people to do nothing. Today is the day a line needs to be drawn, not upon the sand--but upon your soul. YOU need to say, "no more". PLEASE STOP THIS INSANITY!

It has been an honor and privilege to testify before you today ONLY because I represent thousands and thousands of good people...YOUR spouses, neighbors, friends...sons and daughters.

Respectfully submitted,

Thomas J. Colosimo, SRA, USAF

Mr. BURTON. Thank you, Airman Colosimo.

Let me just say that we've sent this message out to the military before, and I see a lot of people here who are probably from the Pentagon. If there is any undue command influence being exerted in order to intimidate any military personnel, there will be very strong congressional action by this committee, and by the entire Congress. You know, I've been getting a lot of stories, we're going to go to Mr. Jones in just a minute, but I've been receiving a lot of stories from people who say they feel intimidated and they will not talk about these problems they're having.

That is unacceptable. I know the military code of conduct. I was in the Army myself. But if something's being done that's wrong, and they're being intimidated to the degree they will not come forward and tell the American people and this Congress the truth, then by golly, that can't be tolerated. And so I want that message to go out to everybody. And to those who are afraid to testify and don't want their names used because of the possible repercussions, let me just say that we will keep their names confidential. We've received over 200 responses to our Web site already from people who have asked us to keep their names quiet, and I'm sure there's thousands more who would like to respond but they're afraid.

But if they respond to us, unless they want us to have them before the committee and have their name used, we will not use it. We're trying to get as much information as possible, so we can come to a logical conclusion and bring this problem to an end.

Mr. Jones.

Mr. JONES. Mr. Chairman, committee, good morning. My name is Joseph Jones, and I served in the military for 3 years, 6 months and 12 days. All I ever wanted to do was be a soldier. This was until I had the anthrax vaccine.

On a training mission in Kuwait, I was told that I might have to take an anthrax vaccine, just in case war broke out. I said OK. I had nothing else to say, I was in the military. The acting sergeant major of the company said that we all had to take the shot. If we refused, we would get a field grade article 15 and the MPs would still hold us down and give us the shot. So you see, either way, we were getting the shot.

I was a good soldier, I did what I was told without question. But if I knew then what I knew now, I would have refused the shot and taken the article 15 along with the consequences for that decision. The consequences I have suffered instead for taking the vaccine have been horrific.

My first three shots resulted in severe headaches, joint pains, chills and fever, vomiting, diarrhea, and weight loss and worsened with each shot. At first, I refused to believe that the anthrax vaccine had anything to do with how I was feeling. Surely, the military would not give me anything that would make me anywhere near this sick.

Within 6 hours after I received my fourth shot, I was sent to the hospital by an ambulance because I had a violent seizure and passed out. I was never admitted to the hospital then or after for observation of the 70 seizures and many separate blackouts which followed. Several times I lost my memory and forgot who my wife was.

I would not wish this on anyone. There have been times I got lost simply because I forgot where I am.

I did not even think about the anthrax vaccine being related to my condition until I read the package insert a few days after the fourth shot. This statement is from the insert itself, that I'll hold up. "Systemic reactions which occur in fewer than 0.02 percent of recipients have been characterized by malaise and lassitude. Chills and fever have been reported in only a few cases. In such instances, immunizations should be discontinued."

Every doctor I knew and saw, I had become ill after each shot, and never once did they discontinue the shot. For this reason, I am ill.

I avoided the fifth and sixth shot because of my reactions to the fourth shot. Fortunately, no one insisted I take any more. No doctor reported my reactions. I had to report them to the FDA myself.

A few months later, I went on medical leave for nearly a year. During that leave, I was either at home in bed or being transported by ambulance or by my wife to the hospital. My seven doctors ordered test after test, but diagnosed nothing.

Today I can no longer function as a productive person in society. I cannot run or do anything that over-exerts my body. It weakens me too much, and it will cause me to have seizures or blackouts.

I'm 24 years old, and like many other young men, I like football and basketball and other sports. But I can't play anywhere like I used to. I don't like the word can't, but I had to get used to using it.

I can only have a job that allows me to set my own hours, because I am sick three times or more a week. I have difficulty getting insurance benefits, because I have to purchase insurance that will take pre-existing injuries, a very expensive option. The military has allotted me only 30 percent medical benefits and 30 percent of my pay. Now, ask yourself, can you live on $554 a month and survive on 30 percent of your medical benefits?

The promise the military made me that the VA would take care of me is a joke. It took a year for me just to receive the VA card. And getting employment takes an act of Congress.

I enjoyed my time in the Army immensely. If I was not sick and I had a choice to reenlist, I would serve my country again in a heartbeat. But now as I know many others who are sick, I would have to rethink that long and hard about joining an organization again that neglects its people.

I can understand why all the soldiers do not want to take the anthrax vaccine. Why would they, if they know they are going to get the same medical treatment that I and all the other soldiers have received. There has been no treatment or admission of problems, just unknown causes of whatever illness the military lists on our medical records.

I believe the military is responsible for my illness because of their carelessness and lack of responsibility in taking care of soldiers, and perhaps the belief that no one would read the vaccine package insert. I'm afraid that this illness will not go away. I'm afraid that the U.S. Government will not acknowledge that I and the other soldiers are sick from the anthrax vaccine.

Last week, we all learned that the FDA found an illegal substance called squalene in the vaccine. The only two lot numbers I got, FAV020 and 30, were both found to contain squalene. Now, I wonder what else holds for my health in the future?

I ask you to help me and all the other soldiers who are sick from this vaccine. Thank you for the time and opportunity.

[The prepared statement of Mr. Jones follows:]

TESTIMONY OF
JOSEPH JONES
BEFORE THE GOVERNMENT REFORM COMMITTEE
HEARING ON "ANTHRAX VACCINATION IMMUNIZATION PROGRAM – WHAT HAVE WE LEARNED"?
ON OCTOBER 3, 2000

Hello my name is Joseph Jones; I served in the military (ARMY) for 3 years 6 months 12 days. I joined the military January 22nd 1996. My first experience in the military was being sent to Atlanta, GA to work as security for the Olympics, and then was assigned to Kelly Hill at Ft. Benning Ga.

I decided in basic training to become the best soldier, to do what I was told and to learn from my leaders. I was recommended for excellence in basic training and leadership skills, and as all-around soldier. I wanted to be the best of the best, I actually enjoyed basic training. In basic training, I did not learn just to become a soldier, I learned to be a team leader, a person that others could trust and look up to. For me, that was important to have the trust of others and to feel the dignity of being a soldier in the United States Army.

All I ever wanted to do was to be a soldier in the Army. I got my chance, and I loved every minute. I actually liked the PT training, the early mornings the strict regime of everything. I was really looking forward to the Kuwait training mission overseas. I excelled in every aspect of training and excelled in every request that was asked of me.

Being in Kuwait was a true experience; it made me appreciate what I had. In Kuwait I was told that I might have to take the Anthrax vaccine just in case war broke out again, I said okay! I had nothing else to say, I couldn't say anything else, and I was in the military. My Sgt. Major for the platoon said "that we all had to take the anthrax shot, if we refused, we would get a field grade Article15 and MP's would still hold us down and give us the shot", so you see; either way I was getting the shot.

I was a good soldier, I did what I was told to do, with out questions. If I knew then what I know now, I would have taken the field Article 15 and refused and would have taken the consequences for that decision. The consequences for taking this vaccine have been horrific. After receiving the Anthrax vaccine my good experience came to a screeching halt. I received the Anthrax vaccine March 17, 1998 in Kuwait, after receiving the 1st vaccine, I had chills, & fever, and became very sick, and it was just like having the flu. I did go to the med. tent and asked to see a Doctor, the PA told me to take Tylenol and get rest. The second shot was on March 31, 1998, I was reluctant to taking the shot due to the illness I experienced with the first shot. I was told I had to take the shot no matter what. I took the vaccine and again experienced the chills and fever and started the direahea and the vomiting, this time it was different than the first, the headaches had increased with

more severe pressure than before. A soldier friend of mine took me to the med. tent due to me being so ill. They told me I had a virus and for me to rest. I was losing weight, losing ground of all my strength. The headache went away to a dull pain after a week or so and I seemed to feel better until the next anthrax shot.

The third shot was on April 14, 1998, I was not feeling well at all, however; I had to take the shot, the illness that had taken my body was the worst flu that I had ever experienced. The headaches and the flu were not going away, the Tylenol was not working.

When I arrived back in the states, I was sick on and off, I was not able to fulfill my duties at work. My Sgt. knew I was sick. He was there in Kuwait with me and knew I had gotten sick after each shot. He gave me time off to be at home when I was sick, or he gave me desk duties.

I refused to believe that the Anthrax vaccine had anything to do with how I was feeling. The military would not give me anything that would make me this sick!!

The fourth shot was on September 22, 1998, I received it at Ft. Benning Ga. This was the same day that I was sent to the Hospital by ambulance due to my becoming very ill and passing out. Two days later the doctors put me on temporary medical leave. I did not realize the Anthrax, was what caused my illness until I had my fourth shot, not until I read the insert that came along with the Anthrax vaccine. (SHOW THE INSERT). I quote from the insert itself "systemic reactions which occur in fewer than 0.2 per cent of recipients have been characterized by malaise and lassitude. CHILLS AND FEVER have been reported in only a few cases. IN SUCH INSTANCES, immunizations should be DISCONTINUED. All adverse reactions thought by a physician possibly to have been related to this product should be directed to the BioPort Corporation (517) 327-1500 during regular business hours and (517) 327-7200 during off hours". The doctors did not report anything; I had to report this to the FDA myself.

You know what I did, I consulted with my physician and he gave me Tylenol, did he stop the shots - NO!! Yes! the military is responsible for my illness. I do believe for their carelessness, their lack of responsibility in taking care of their soldiers, and their ignorance in hoping that no one would read the label.

Every doctor I saw in Kuwait, and here in the states, knew I had become ill with CHILLS AND FEVER AND MALAISE AND LASSITUDE after each shot, and NEVER not once did they discuss with me that this could have been a reason for my illness, nor did they discontinue the vaccine until this was brought to their attention after the 4th shot. I can tell you now, I never received the 5th and 6th series of the vaccine, the military discontinued it.

While I was on medical leave, September 1998, I was either at home in bed or being transported by ambulance, or by my wife to the hospital! I was never admitted to

the hospital, only through the emergency room would I be seen. My doctor ordered test after test and listening, as the doctors found nothing, am I sick? Yes, I'm sick. I was a very healthy person when I entered the military. I can tell you now that my health is far from being good or even fair. The promise the military made to me, that the VA would take care of me, is a joke. The VA has not taken care of me as promised. It took a year for me to just receive the VA card and to get an appointment is an act of congress.

To this day, I've had 70 + seizures and 40 + passing out spells, several of which I have lost my memory and forgot who my wife was! There have been times that I get lost because I forget where I am. I would not wish this on anyone.

Can you tell me, that the anthrax did not make me sick? No! You cannot. You can only go by what I have told you here today.

Everyone knows that taking the flu shot either gives you the flu or prevents you from getting the flu. What is the anthrax supposed to do? Has it prevented me from getting sick, NO, it made me sick. If I was not sick and I had a choice to re- enlist, I would serve my country in heartbeat. But due to the fact that I became ill and I am still suffering from taking the Anthrax vaccine, I would have to rethink that decision.

The military took something of mine, and I want it back. My life, yes, that is a correct statement THEY TOOK MY LIFE, my fun, my activities, my sports, everything that makes me, me, they took away. I cannot run or do anything that overexerts my body I cannot do anything that causes my body to be exerted in any form. I can no longer function as a productive person in today's society and the military has allotted me only 30% medical benefits and 30 % of my pay. Now ask yourselves could you live on 30% of your pay and survive on 30 % of your medical benefits? Would you?

I have to have a job where I can set my own hours, because I am sick 3 times or more a week. I am not able to hold down an 8-5 job and for this, insurance is not a benefit. I have to purchase insurance that will take pre-existing injuries, this is not cheap.

My intent for joining the military was not to become sick. My intent was to join the military and serve my country with all my heart and soul. I'm afraid that this illness will not go away, and I am afraid that the United States government will not acknowledge that I am sick from the Anthrax vaccine.

I'm asking you to help me get my life back, I've taken every medical test the military wants me to take, but cannot afford the test recommended to find out what the true cause is. I ask you to help me and all the other soldiers who are sick from this same illness.

I can understand why all of these soldiers do not want to take the Anthrax vaccine, why would they, if they know they are going to get the same type of medical treatment, that I and all the other sick soldiers have received. There has been no treatment, there has been no acknowledgment of this, and just unknown causes of whatever illness the military list on the records.

When someone asks me about the Anthrax vaccine, I tell them to investigate all avenues and all aspects of the illness this shot has caused. I tell them my story, and recommend them to contact others that are sick as well.

Let me ask you, why would you approve a vaccine to be produced that has the capability of making anyone sick? What are you going to do about helping those of us that have gotten sick from taking the vaccine? And last, if you do approve the vaccine to be continued, are you going to suggest the President and Vice President and everyone sitting before me take the same shots?

In closing, let me ask you a question, would you take this vaccine after hearing my story or would you have some reluctance in taking the vaccine? Would you take this vaccine or would you refuse, knowing it could make you this sick?

I pray that you can have influence on the medical board in San Antonio to upgrade my benefit package.

Thank you for your time,

Joseph Jones

Mr. BURTON. Thank you, Mr. Jones.

Mr. Ponder.

Mr. PONDER. Mr. Chairman and members of the committee, I am thankful for the committee's time and concern regarding the DOD mandatory anthrax vaccination immunization program. I hope that I can provide some insight and understanding to the committee as to how this program has affected me personally and how this program is being carried out in the real world.

My views here and my testimony are my own and not meant to be taken as those of the Navy.

I have been in the Navy for a little over 3 years as a part of the Seabees, which is the construction force of the Navy. I have a wife of 2 years and a son that just turned 1 year old. I am now deployed to Camp Shields, Okinawa, Japan and have been there for almost 7 months.

I am a part of Naval Mobile Construction Battalion 74. We are home ported in Gulfport, MS. As a part of a routine deployment to Okinawa, I was scheduled to go to Pohang, South Korea, as a part of a detachment. I was required to take the anthrax vaccine and I refused it. I would like to explain why and what happened to me as a result.

First I would like to say that I refused the shot after a lot of soul searching, serious thought and inquiry. It was not a snap decision. I am not, as some people have suggested, the pawn of others who for their own reasons, want to stop this program. Quite simply, I was fearful of taking the shot, and nothing I have heard since I first began has reassured me or made me question my decision.

In fact, everything I have learned only makes me more thankful that I did not take this shot. I would like to explain my reasoning for this.

Prior to this, there had already been rumblings about the program and the shot. I had heard and read about people who refused to take it, and I had also read and heard about some of the adverse reactions people had had to the shots. I had heard about a study that showed the presence of squalene antibodies, and the large number of Gulf war veterans who showed signs of Gulf war illness.

During the Gulf war, the DOD had given a number of drugs and vaccines to troops and was testing an experimental anthrax vaccine that contained squalene, a kind of booster for the immune system on cattle. All of this made me very nervous, and I had also read reports of veterans passing illnesses on to their families.

My wife had just had our son in September 1999, and I was scared. Regardless of the source and information, I had some serious questions about the vaccine as my time to take it approached.

After I refused the vaccine, I was told that I would be given Captain's Mast, which under the Uniform Code of Military Justice, I had the right to refuse in favor of a court-martial. I didn't particularly want this, but I knew that I was never going to take the shot, so I refused Captain's Mast in early February, with my unit scheduled to deploy in March to Okinawa.

There were two other people that refused the shot at the same time with me. They elected to take their punishment at Captain's Mast. Punishment for them was 45 days restriction and extra duty,

reduction in rate one pay grade and a half month's pay taken away for 2 months.

The vaccine, as I was told, was a prerequisite to deployment. Despite this, after I refused Mast, I was told that I was going to be going to Okinawa to be court martialed. Something about this didn't seem quite right, so I hired a civilian attorney to represent me, a considerable expense for someone drawing E–4 pay with a wife and a son. There had been two people in our battalion who, about a week earlier, had gone to Captain's Mast on drug charges. They refused mast as well and went to court-martial. They were both kept in Mississippi for their trials.

Now, as my unit prepares to come home, I am told that I will remain in Okinawa for my court-martial, which has been stayed by the Navy and Marine Corps Court of Criminal Appeals. They have agreed to hear my case and my appeal of the judge's ruling that the order to take the shot was lawful.

My being left behind is not a new tactic. A Marine in Okinawa who also refused the shot was left behind by his unit as well, even though no stay has been issued in his case. It is a way for the Navy Marine Corps to get us to give in and take our punishment without a fight. We are left thousands of miles from our home without any support, even from our own units, while the witnesses and other members of the court come home.

Despite this, I will never take the shot. I might eventually do whatever the Navy wants to get home, because I have already been away from my family for more than 6 months. My son recently had his first birthday, but I will not take the shot. I do not believe the order is lawful and I do not believe the vaccine is safe. This Congress passed a law in 1999, after the hard learned lessons of the Gulf war and the use of experimental investigational drugs on troops. That law, 10 U.S.C. 1107, prevents the use of investigational drugs or drugs unapproved for their applied use to be given without a service member's informed consent.

I can assure you that no one has ever asked for, and I have never given, my consent to take this vaccine. What is particularly amazing to me is that the DOD knows that the drug is investigational, but it continues to prosecute people like myself.

In 1996, the predecessor of BioPort filed an investigational new drug application with the FDA. That application was for the anthrax vaccine to be used against an aerosolized challenge and the DOD joined in that application. The application is still pending and has never been withdrawn.

I have learned that there have never been any long terms studies on the effects of this anthrax vaccine. I learned that the company that makes the vaccine still, to this day, cannot get FDA approval because of problems with its production facility, including serious quality control violations that raise questions about what exactly is in these lots of vaccine.

I do not have to detail all the problems to this committee. One only has to pick up the paper, it seems, and at least once a month there is some new revelation about the company, the program or the vaccine that would scare me if I had taken the shot.

The lessons of the Gulf war will be repeated and years from now, we will have people complaining of illnesses and the DOD will not

have answers. This is because the DOD will not admit what is so blatantly obvious to those of us staring down the barrel and who are more concerned about our health than our careers.

The program was and is a bad idea, no matter how well intentioned.

I would like to add a final footnote to my testimony. I was offered, through my attorney, one chance to return home if I agreed to plead guilty for disobeying a lesser order at a lesser forum and accept my punishment. Unless I agree to that, I will, according to my command, be staying in Okinawa for who knows how long. My only regret in all this is the price that my wife and son have had to pay for my decision.

I want to close by thanking my wife and family for their support through this. Thank you.

[The prepared statement of Mr. Ponder follows:]

UNITED STATES MARINE CORPS
Office of the Staff Judge Advocate
Marine Corps Base Quantico
Quantico, VA
22134

5800
TC
01 Oct 2000

From: Petty Officer Third Class David M. Ponder, 404 19 4374
United States Navy
To: Committee on Government Reform

Subj: *WRITTEN TESIMONY FOR THE COMMITTEE ON GOVERNMENT REFORM*

Dear Honorable Members of the Committee,

I am thankful for the Committee's time and concern regarding the Department of Defense mandatory Anthrax Vaccination Immunization Program. I hope that I can provide some insight and understanding to the Committee as to how this program has affected me personally and how this program is really being implemented, out in the "real world", not as it has been discussed in theory by some members of the military establishment in these halls.

I am a Third Class Petty Officer in the United States Navy. I am in the Seabees, the construction force for the Navy. My views here in my testimony are my own and not meant to be taken as those of the Navy.

I have been in the Navy for a little over three years. I have a wife of two years and a son that just turned one year old. I am now deployed to Camp Shields, Okinawa, Japan. I have been here for six months. The way the Seabees work is that you have eight battalions. My battalion is Naval Mobile Construction Battalion 74. We are homeported in Gulfport, Mississippi. Every seven months we make a seven-month deployment. The rotation works that we are deployed to Puerto Rico, go back to homeport, then deploy to Okinawa, and then back to home, each stop being for seven months. When the battalion is deployed there is what is called Details. These are detachments from the main body of the battalion. For instance, this deployment we had details in Atsugi, Sasebo, and Iwakuni, in main land Japan. We also had two in South Korea, one in Chinhae and one in Pohang, the detail which I was to accompany.

My family and I returned from leave and we found out that anybody going to South Korea for any period of time was to receive the Anthrax Vaccine. The Chinhae and Pohang details had to get their first shot on Jan. 12. I went to the medical clinic and told my chief that I wasn't taking the shot. Later that day, my chief and my company commander gave me a written order to take it and I refused that also. There were two other people that refused the shot at the same time. In early February, we went to Captain's Mast. That is another name for non-judicial punishment (NJP). I had been wrestling with the idea of turning that down and requesting a trial by court-martial. The other two elected to take their punishment at Captain's Mast. The punishment for them was 45 days of restriction and extra duty, reduction rate one pay grade, and have half month's pay taken for two months. I opted to go with the court-martial because I did not want to take Captain's Mast and be punished for the same thing six months down the road when this vaccine was ordered again. I knew that I was never going to take the shot.

I would like to explain my reasoning for this. Prior to this, there had already been rumblings about the program and the shot. I had heard and read about people who refused to take it and I had also read and heard about some of the adverse reactions people had had to the shots. I had heard about a study that showed the presence of squalene antibodies in a large number of Gulf War veterans who showed signs of Gulf War Illness. I believe that an article appeared in Newsweek in September 1999, timeframe. The article, and other research I conducted, pointed strongly to the fact that the DoD had given an experimental anthrax vaccine to troops during the Gulf War. People who had received the Gulf War anthrax vaccine and who never went to the Gulf had squalene antibodies in their system. As I understand it, the only way that those antibodies could be present was if squalene had been introduced into the body. During the gulf War, the DoD had given a number of drugs and vaccines to troops and was testing an experimental anthrax vaccine that contained squalene, a kind of booster for the immune system, on cattle. All of this made me very nervous and I had also read reports of veterans passing illnesses on to their families. My wife was pregnant with our son at the time and I was scared. Regardless of the source and information, I had some serious questions about the vaccine as my time to take it approached.

After discussing the matter at some length with my wife and agonizing over the decision, I decided not to take it;

I decided that my family's and my own long-term health were more important than my career in the Navy. At that time, my Navy career appeared to hold a bright future, I had enlisted in the Navy and received advanced promotion to E-4 upon completing my A school as a Seabee. I knew that there would be repercussions for refusing the vaccine, but I never dreamed how dire they would be. I originally had hoped that I would be allowed to part company with the Navy amicably, but that was not to be the case.

After I refused the vaccine, I was told that I would be given Captain's Mast, which, under the Uniform Code of Military Justice, I had the right to refuse in favor of a court-martial. I didn't particularly want this, but I knew that I was never going to take the shot, so I refused Captain's Mast in the late January to early February timeframe, with my unit scheduled to deploy in March to Okinawa. Before the Captain's Mast I had been told by our legal advisor that if I refused Captain's Mast and elected to fight the order at a court-martial, I would more than likely be left in Gulfport. The vaccine, I was told, was a prerequisite to deployment. Despite this, after I refused Mast, I was told that I was going to be going to Okinawa to be court-martialed. Something about this didn't seem right and so I hired a civilian attorney to represent me, a considerable expense for someone drawing E-4 pay with a wife and son. There had been two people in our battalion who, about a week earlier had gone to Captain's Mast on drug charges. They refused Mast as well and went to a court-martial. They were both kept in Mississippi for their trials.

My civilian attorney tried unsuccessfully to prevent the Navy from taking me to Okinawa, but the judge denied our motion. I then was deployed to Okinawa in March and charges were brought against me. Captain Dale Saran, United States Marine Corps, was detailed as my defense attorney. During the time of my court-martial, I have learned a lot about the anthrax vaccine and the anthrax program. None of it has ever given me any reason to question my decision. In fact, everything has only further steeled my resolve and made me absolutely certain of the wisdom of my decision. I would like to detail some of the things that have happened and things that I have learned since this all began.

I have learned that there have never been any long-term studies on the effects of the anthrax vaccine. I learned that the company that makes the vaccine still, to this day, cannot get FDA approval because of problems with its production facility, including serious quality control violations that

raise questions about what exactly is in these lots of vaccine. I do not have to detail all of the problems to this Committee. One only has to pick up the paper, it seems, and at least once a month there is some new revelation about the company, the vaccine, or the program that would scare me if I had taken the shot. It boggles the mind. Some examples:

-- Bioport, the company that makes the vaccine, had to be bailed out by the military to the tune of millions of dollars, and it currently is undergoing criminal investigation for how some of those funds were spent

-- The Secretary of Defense stated that four criteria would have to be met before the program would begin. One of those four criteria was independent review of the program by a civilian expert. As you well know, that civilian medical doctor from Yale, a so-called "expert", turned out to know nothing about anthrax - his specialty involves Obstetrics and Gynecology. In fact, you are already well aware of this because he was asked to testify before congress but declined and will no longer answer questions about his role in the "review"

-- The FDA conducted an inspection of the company's production facility last November and found over forty violations, most of them serious ones in how the vaccine was produced

-- Recently a worker at Bioport's facility died in part because of the vaccine, according to the coroner's report and now the FDA has in fact found squalene in lots of the anthrax vaccine, which the DoD has long denied that were ever there

It would be shocking in the extreme if all of this were new, but unfortunately, for the DoD, it is not. Committees of past Congresses have found these kinds of abuses of servicemembers' basic rights for over fifty years. I urge members of this Committee to read the 1994 Rockefeller report, which details a laundry list of DoD use of members of our Armed Forces servicemembers as guinea pigs, sometimes with pure motives, sometimes not so pure motives. In fact, the one thing that I have learned through all of this is that the order to take the anthrax vaccine is patently illegal because it violates an act of this Congress, a law that was passed specifically because of some of the issues that arise when vaccines are used for purposes other than which they were originally intended.

I am speaking of 10 USC § 1107 and the history behind that law and the hard learned mistakes, which caused this Congress to enact such a law. This and previous congress' experience in investigation Gulf War Illness revealed some startling problems with the DoD's use of two particular drugs during the Gulf war, pyridostigmine bromide (PB) and botulinum toxoid (BT) vaccine. I will not presume to lecture members of this committee about things that they may already have heard, but it seems we have not learned, and the DoD certainly has not learned the lessons from the Gulf. Arguments about the anthrax vaccine's efficacy or safety are really beside the point. A mandatory vaccination program is simply against the law. I provide a brief history only for those who may not be aware of it.

PB was licensed in 1956. The drug was tested safe and effective to work against a particular disease, myasthenia gravis, in a certain quantity, administered in a certain protocol, in a very limited population. That is how specific the license for a new drug must be in order to be approved by the FDA. PB was not licensed to be used as a pretreatment for nerve agents. The DoD asked for and obtained a waiver of the informed consent requirement in order to administer this drug and botulinum toxoid ("BT"), a vaccine. At the time, the PB was to be administered in 30 mg tablets, an amount less than that typically administered to myasthenia gravis patients. (See House Veterans Affairs Subcommittees on Health and Oversight Hearings, 16 Nov 1999, "Possible Health Effects of Pyridostigimine Bromide on Gulf War Veterans."[1]) There were no long-term studies on effects of PB as a pretreatment for nerve gas, but the thought process was that since it had been used on myasthenia gravis patients since 1956 and produced a particular chemical reaction in the body that there should be no cause for concern with using it on soldiers. Unfortunately, this type of linear thinking does not hold true because it assumes linear relationships in the field of medicine. Subsequent experiments have indicated that PB may have severe adverse health effects when withdrawn, or when the patient using it is under heat, stress, and other conditions that were present during the Gulf. Additionally, it may in fact aggravate the effects of other nerve agents, or aggravate the effects of the same nerve agent in non-lethal doses. Of course no one could foresee this at the time, but it provides a lesson for all of us, particularly the military medical establishment, about the necessity for long-term studies when drugs are used for different purposes than they were originally intended. Additionally, the FDA withdrew

[1] The tablets were to be taken 3 times per day; a "typical" myasthenia gravis patient might take 60 mg, 3 times and much more over a long period of time.

the DoD's waiver after the Gulf War and changed the regulations back to what they had always been, requiring a person's (including servicemembers') informed consent before administering such an investigational or experimental drug.

As a result of this experience and previous Congress' inquiry into these areas, 10 USC §1107 was passed to prevent vaccination of someone with an "investigational" drug or a drug "unapproved for its applied use" without their prior informed consent. I can assure you that I have never given my consent nor has it been asked for by the DoD. What is particularly amazing to me is that the DoD knows that the drug is investigational but it continues to prosecute people like me. In 1996, the predecessor of Bioport filed an investigational new drug application with the FDA. One of the reasons for the application was a change to the anticipated route of infection of anthrax for an aerosolized infection. The original anthrax vaccine, the same one that is currently being given to servicemembers, was licensed as a prophylaxis against cutaneous (skin) exposure to the disease. The DoD expects that any weaponized anthrax will be in aerosol form and that is why it joined in the MBPI application and even urged the company to make the change. I have the seen the minutes of meetings between the DoD and MBPI personnel. The DoD knew and has known for quite some time that the current license for the vaccine is only for cutaneous anthrax. Furthermore, FDA regulations state that when such an application is filed, the use of a particular drug for the purposed listed in the application is investigational 30 days after the filing unless the FDA acts otherwise on the application. The President and CEO of Bioport, Mr. Fuad El-hibri, has testified before this Congress that BioPort still has the application pending before the FDA.

The DoD joined in that application and the proposed clinical experiment for the license amendment was to be conducted at Fort Detrick, Maryland. In fact, the clinical protocol required volunteers for this project. Somehow, though, the DoD now mandates that all servicemembers take a vaccine for which it requested volunteers in 1996. At the same time, the DoD comes before Congress and talks about the vaccine as safe and the vaccine's long-term safety record with veterinarians. This is simply not true and doctors have testified before Congress that no long-term epidemiological study or tracking was ever done of these veterinarians or wool workers. Additionally, this is exactly the same kind of thing the DoD said with PB and BT before the Gulf in order to get a waiver from the FDA regulations for those drugs. We now know what a bad idea that was because battlefield use of PB with troops is not the same as

the use of PB in a clinical setting on a limited population. The DoD's AVIP program is a repeat of the DoD's PB and BT biological warfare pretreatment programs. However, this time, the DoD doesn't have a waiver from the FDA, but continues on with the program and prosecutions of those of us who refuse to gamble our long-term health on such a program. This Congress, this country, and veterans of the Gulf War have already learned the lesson the hard way, paying with taxpayer dollars and, in the case of veterans, their health and lives.

It appears as though history will repeat itself because the DoD will not admit what is so blatantly obvious to those of us staring down the barrel and who are more concerned about our health than our careers, the program was and is a bad idea, no matter how well intentioned.

I would like to add a final footnote to my testimony. My command took me to Okinawa because it was necessary for me to be with my unit. My unit is now preparing to return home to our homeport and our sailors to their families . . . except, of course, for me. Because my attorney was able to get a stay of my court-martial for the Navy and Marine Court of Appeals to hear one of our motions, I am being left behind in Okinawa. Meanwhile, all of the witnesses and even jurors of the court-martial will return home to their families while we await the appeals process which could take many more months or even result in dismissal of the case. Even my attorney has changed duty stations to Quantico, Virginia, while I remain behind, to do what, I have no idea. I was offered, through my attorney, one chance to return home if I agree to plead guilty for disobeying a lawful order at a lesser forum and accept my punishment. Unless I agree to that, I will, according to my command, be staying in Okinawa for who knows how long. My only regret in all of this is the price that my wife and son have had to pay for my decisions. I want to close by thanking my wife and family for all of their support through this.

Very Respectfully,

_____

DAVID M. PONDER
PO3 USN

Mr. BURTON. We'd like to have your complete testimony. Do we have copies of that? OK. And if we could get the information on the others that were stationed with you down in Louisiana that were going to be court-martialed for drug charges that were kept there when you went to Okinawa, I'd like to have their names, if you have it, so we can followup on that and find out why they were treated differently than you.

Mr. PONDER. Yes, sir.

Mr. BURTON. Thank you.

Mr. Michels.

Mr. MICHELS. Thank you, Mr. Chairman, distinguished members of the committee, and your staffs. My name is John Michels, Jr. I am a former active duty Air Force officer, 14½ years on active duty, with 9 years following on reserve duty. I spent time as both a flying officer and a judge advocate while on active duty, and I am currently a reserve Lieutenant Colonel and a judge advocate.

I'd like to emphasize again, the committee has a more complete biography in my written statement that I filed with you. I'd like to emphasize again that I am here in my capacity as a private citizen, and not in my capacity as a reserve Lieutenant Colonel or a judge advocate.

Let me make my points directly and initially. The inoculation program as it is currently being administered, that is, with members of the armed forces being forced to submit to vaccinations without first obtaining their informed consent, violates both a Federal statute and a Presidential Executive order. I believe that the orders to take the shots are therefore illegal, the discipline that has been handed out to individuals who refuse to take the shots invalid.

I might add that I worked with Petty Officer Ponder's defense counsel in preparing the defense that was ultimately, we hope, successful, and ultimately will be successful before the Navy Court of Criminal Appeals. I believe that the orders to take the shots are invalid, because the anthrax vaccine absorb, as it is currently being used by the Department of Defense, is an investigational new drug.

My assessment of the vaccine status as an investigational new drug [IND], is based on my review of the manufacturer's IND application in September 1996, which specifically sought IND status for the vaccine for use for inhalation or aerosol anthrax. My opinion on the IND status of the vaccine is also based on the Department of Defense's recent admission that it will not follow the labeling requirements for the vaccine, which means that the vaccine is not only being used for a different purpose for which it was originally licensed, but in a completely different way as well.

And finally, I based my opinion on the recent report that I reviewed late last week indicating that squalene has apparently been found in anthrax vaccine lots, and that squalene antibodies are apparently showing up in some vaccine recipients. I might add, this raises a separate issue under the FDA regulations concerning the production and distribution of an adulterated product, but I don't intend to talk about that today, and it's not in my written statement. I'd be happy to prepare additional information for the committee if it desires.

Mr. BURTON. We would appreciate that.

Mr. MICHELS. OK.

Although the Department of Defense has relied heavily on two letters from FDA officials, and I expect you'll see those today when these folks testify, indicating that the use of the vaccine against the aerosol version of anthrax is not, "inconsistent," with the labeling requirements from a legal perspective, the reliance on those letters is completely misplaced. That is because those letters were not issued as formal FDA opinion letters and because regardless of the contents of the letters, the IND application clearly indicates that the manufacturer believed, in 1996, and again, that application has never been modified or withdrawn, that the product itself, in the opinion of the manufacturer, is not licensed for its current use.

In addition, a Supreme Court decision this spring indicates that the letters such as those relied upon by the Department of Defense are entitled to no deference whatsoever by the courts other than to the extent that they are logically persuasive.

The anthrax vaccination program first came to my attention when it was originally announced in late 1997. At that point, I wondered how long it was going to be before I had to have my shots. I discounted for the most part claims that the vaccine was unsafe, that the program producing the vaccine was mismanaged and unsanitary, that there were substantial misleading statements in the record from various DOD officials about who would approve the vaccine and how it was approved, the medical review of the overall program and the certification of the supplier.

Late in 1999, I was contacted by a colleague, Reserve Major Bruce Smith out of Raleigh, NC, to assist in the defense of an Air Force major, Sonnie Bates. Major Bates is at Dover Air Force Base. He's a pilot who refused to take the anthrax shot. I'm going to summarize here quickly, I don't want to take too much time, and you've got at least one more witness.

The bottom line is this. In 1995, the Army and the manufacturer of that anthrax vaccine decided that they need to seek a modification of the anthrax vaccination license. They went after that by filing an IND application. The committee has a copy of the application, it was submitted with the documents I turned in. That application specifically says, "we are looking to modify the license to get an indication against inhalation anthrax and a changed vaccination schedule," the exact modifications that have been made to the drug at this point.

Once that application is filed, the drug goes into investigational status under FDA regulations. And it stays there until either the investigational process is completed or the investigational application is withdrawn. The statutes that it violates are 10 U.S.C. 1107, and the Executive order issued by President Clinton last fall is Executive Order 13139. Both of those say that you cannot give investigational new drugs to armed forces service members without their informed consent, unless you are willing to certify to the President and get a declaration that the process or the informed consent process is infeasible or that there is an issue of national security present.

There is a way to get around the informed consent requirement. The Department of Defense is well aware of it. Nobody has taken that option.

I want to echo something that Congressman Jones said earlier, then I'm going to wrap up. The effect of this program on the trust and morale of both the active duty, the Reserve and the Guard forces is dramatic. I'm queried on it constantly. There's going to be a conference of Reserve judge advocates out in Denver this weekend. I have already been requested to provide copies of the memorandum I prepared in an effort to elevate this issue. Because there are a lot of folks out there that simply have lost faith, they are concerned that their commanders and the people who supervise those commanders are breaking the faith that they have with their soldiers.

And that's, I think, the real tragedy of this entire program. Thank you, sir.

[The prepared statement of Mr. Michels follows:]

STATEMENT OF JOHN J. MICHELS, JR.

Mr. Chairman, distinguished members of the Committee, I want to thank you for the opportunity to address you today on an issue that I believe directly affects our most important national security resource, the men and women of our Armed Forces. The mandatory anthrax vaccination program, or AVIP, has not only failed in its stated goal of providing adequate protection to all members of the active duty and active reserve forces, but has caused many service members to question whether their civilian and military leadership has their best interest at heart.

For the Committee's information, I would like to provide a brief personal history. I graduated from the United States Air Force Academy in 1977 and attended navigator and electronic warfare officer training. Following an initial assignment to long range reconnaissance aircraft for the Strategic Air Command, I was selected to attend law school under an Air Force program and entered Duke University in 1982. Following law school, I became a member of the Air Force Judge Advocate General's Department and served in various JAG assignments until I left active duty in 1991. Since leaving active duty I have been in private practice with the law firm of McGuireWoods. I am currently a Lieutenant Colonel in the Air Force Reserve. I am testifying in my personal capacity today.

I am not a specialist in medical law, but got involved in the anthrax vaccination issue when a friend asked me to assist him in the representation of Air Force Major Sonnie Bates. You may remember Major Bates as the most senior Air Force officer to refuse the anthrax shot. My colleague, Air Force Reserve Major Bruce Smith and I prepared Major Bates' defense and researched the defenses to the charge of violating a lawful order. Our research uncovered the fact that the manufacturer of the vaccine, Michigan Biologic Products, Inc., filed an

investigational new drug ("IND") application with the Food and Drug Administration ("FDA") for the vaccine in 1996. This fact, when coupled with the legal requirements of 10 U.S.C. § 1107 and Presidential Executive Order ("E.O.) 13139, both of which prohibit administration of an investigational new drug to members of the Armed Forces without their informed consent, renders illegal orders to take anthrax vaccine absorbed ("AVA") shots. The purpose of my testimony today is to explain why orders to take the vaccine are illegal under military law.

I. The Illegal Orders

The key to understanding why the AVA vaccinations are illegal revolves around the status of the vaccine as an IND. The term "IND" is a term of art under FDA regulations and refers to a status given to a substance for which FDA approval is being sought for, among other things, how the substance is used, a change in formulation, a change in route of administration, or repackaging. See 21 C.F.R. § 312 (1999).

The term "IND" also embraces so-called "new" drugs as defined by the FDA itself. See 21 C.F.R. § 312.3(b) (cited in E.O. 13139). A drug is considered a "new" drug, even if it has been in use for years, if there is a proposed change in the use of the product, a change in its formulation or dilution, or changes similar to those required for an IND application.

A variety of court decisions validate FDA's requirement that "new" drugs are not licensed and must seek separate FDA approval. See e.g., Hoffman v. Sterling Drug, Inc., 485 F.2d 132 (3rd Cir. 1973) (marketing a drug previously approved by the FDA for the treatment of malaria as suitable for treating lupus caused the already approved drug to be considered a "new drug" as far as the lupus treatment was concerned); U.S. v. Articles of Drug, etc., 442 F. Supp. 1236 (S.D.N.Y. 1978) (a drug may be considered "new" if there is a change in the dosage, or method of administration or application, or other condition of use prescribed, recommended or

suggested in the labeling of such a drug, even if the drug has previously been approved with a different dosage and for a different purpose). Accordingly, federal statutes, regulations and case law show that even an established and licensed drug such as the AVA that is modified with regard to its dosage regimen or purpose for which it is being offered is an "IND", and therefore covered by the requirements of Executive Order 13139 and 10 U.S.C. § 1107.

A. The AVA has been placed in IND status by its manufacturer in order to receive FDA approval for using the AVA to protect against inhalation anthrax.

The license for the AVA, approved in 1970 by the National Institute of Health, indicates that it was approved as a prophylaxis against anthrax resulting from

> contact with animal products such as hides, hair, or bones which comes from anthrax endemic areas that may be contaminated with *Bacillus anthracis* spores; and for individuals engaged in diagnostic or investigational activities which may bring them into contact with *B. Anthracis* spores... it is also recommended for high risk persons such as veterinarians and others handling potentially infected animals.

Anthrax Vaccine Adsorbed, Package insert, Michigan Department of Public Health ("MDPH"), October 1987.

Because the AVA license contained no specific indication for inhalation anthrax, in 1995 the owner of the vaccine, MDPH, and the United States Army discussed establishing a plan for FDA approval of an inhalation anthrax indication. In October 1995 the Joint Program Manager for the DoD Biological Defense program attended an information meeting prepared by defense contractor Science Applications International Corporation ("SAIC") to discuss a plan. The purpose of the SAIC meeting was to

> provide the Director, Medical Biological Defense Research Program with a project plan to obtain an amendment to the Anthrax Vaccine product license... [to] obtain indication for protection against aerosol exposure.

See Anthrax Vaccine License Amendment Project Plan briefing slides (October 20, 1995).

Documents attached to the briefing slides show clearly that the plan in the fall of 1995 was to get FDA approval to change the immunizational schedule (in this case from a series of six prescribed doses to three doses), and to change the vaccine labeling to reflect that the vaccine was properly administered as protection against pulmonary anthrax. Id.

Minutes of the October 1995 meeting also reflect that the focus of the project was to obtain a label indication change concerning the prevention of pulmonary anthrax. The meeting ended with Brigadier General Walter L. Busbee, Joint Program Manager for Biological Defense, U.S. Army, directing that participants were to continue the process of developing "an option package for initiating and completing amendment to the... anthrax license for: (1) a reduced immunization schedule, (2) immunization by the intramuscular route, and (3) indication for protection against an aerosol challenge." Minutes of the Meeting on Changing the FDA License for the MDPH Anthrax Vaccine to Meet Military Requirements, November 13, 1995. It is worth noting that slides associated with these minutes state that there is "insufficient data to show efficacy against inhalation anthrax." Id.

Less than one year from the date of the briefing, on September 20, 1996, the vaccine manufacturer, MBPI, filed an "initial" Investigational New Drug Application for AVA. The purpose of the application was to "conduct clinical investigations *designed to investigate changes in the approved labeling* for the licensed product. The potential labeling changes would effect a specific clinical indication, route and vaccination schedule for AVA." See Cover Letter, MBPI IND Application, September 20, 1996 (emphasis added). The cover form shows three specific bases for the application, including "inhalation anthrax" exposure.

Of particular note is the Introductory Statement filed with the IND application. In ¶ 3.1 of the Statement, MBPI states

> the ultimate purpose of this IND is to *obtain a specific indication for inhalation anthrax* and a reduced vaccination schedule (emphasis added).

MBPI IND Application.

This IND application by MBPI, which has remained open, unmodified and current, clearly shows that the Army and the manufacturer, MBPI (now Bioport) moved to place the AVA in IND status in order to get a labeling change showing the AVA was effective against aerosol anthrax exposure. The filing of the IND application by MBPI places the AVA in IND status, allowing for FDA-approved clinical testing, as well as interstate transport of the vaccine for testing purposes. As of today, under the FDA regulations the vaccine is an IND for the purposes for which the application was filed, namely, for a change in the labeled use to encompass inhalation anthrax.

The DoD's assertion that, at a later date, the FDA has somehow "approved" the vaccine for inhalation anthrax is factually and legally baseless as will be demonstrated in Section C, infra. However, nothing that various FDA officials say alters the simple fact that the manufacturer, by its application to FDA, squarely placed the AVA in IND status as a preventative against inhalation exposure to anthrax and for a reduced vaccination schedule. This is the key point to understanding why orders to take the shots are illegal: The vaccine is in an IND status for inhalation prophylaxis (and for an altered vaccination schedule), and has been since the manufacturer, at the Army's request, filed its IND application in September 1996.

The Committee should note that DoD does not have the responsibility or the authority to place the AVA in IND status or to take it out of IND status. DoD is not the manufacturer of the

vaccine; only the manufacturer can file the IND application. And, in fact, the manufacturer has done just that and is presumably complying with IND rules.

B. The AVA is an IND because the DoD, as a matter of policy, is not following the licensed vaccine schedule.

In addition to seeking a specific FDA license approval for use against inhalation anthrax, the IND application seeks to modify the licensed vaccination immunization schedule of three subcutaneous injections given two weeks apart, followed by three additional subcutaneous injections given at six, twelve and eighteen months. See MBPI IND Application and AVA package insert (October 1987). Under federal law and FDA regulations, altering the vaccination schedule for the current AVA would be improper, because the deviation from the licensed and approved schedule makes the vaccine a "new" and investigational drug, and also brings it under the aegis of the IND application.

FDA officials, in fact, have advised DoD that

> [I]f the military is interested in using a vaccination time schedule different from the currently licensed schedule for a mass vaccination effort, then informed consent would be appropriate.

February 18, 1997 Memorandum from Dr. Karen L. Goldenthal, an FDA physician responding to a telephone call from Admiral Martin re: Anthrax Vaccine.

Although DoD maintained in court filings as late as last summer that it "specifically follows the FDA approved immunization schedule for the vaccine," it is now a matter of policy that members of the Armed Forces will not be vaccinated on the approved schedule contained in AVA labeling. DoD's public announcements, following the failure of the AVA manufacturer, Bioport, to manufacture vaccine that would pass FDA testing, are clear. The current DoD policy is that soldiers who have received some, but not all, of the shots will not have to repeat the initial sequence of shots, even though they may not receive additional shots for up to two years. The

product label for the AVA specifies an immunization schedule of three injections given two weeks a part followed by additional three injections at six, twelve and eighteen months. DoD's straightforward disregard of the labeling requirements provides further indication of the IND nature of the AVA as it is being used by DoD today. On this basis alone, a court could properly find the FDA to be an IND and subject to the requirements of 10 U.S.C. § 1107 and EO 13139.

C. The FDA letters relied on by DoD to support its position that the AVA is not an IND have no legal effect and are entitled to no deference by the Court.

In an apparent effort to reinforce the untenable position that the AVA is properly licensed, various DoD officials asked FDA representatives to opine on whether the AVA was appropriately used as a prophylaxis against inhalation anthrax.

Unfortunately, none of these letters has any legal viability under the FDA's own regulatory system. Cognizant of the fact that outside entities might place undue reliance on the private informal opinions of FDA staff, the FDA drafted strict requirements for what it refers to as "advisory opinions" that might bind or commit the agency. 21 C.F.R. § 10.85(k) specifically states:

> a statement made or advice provided by an FDA employee constitutes an advisory opinion only if it is issued in writing under this Section. A statement or advice given by an FDA employee orally, or given in writing but not under this Section or § 10.90 is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of the FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

None of the letters relied on by DoD as "proof" that the AVA is not an IND were issued under either of the 21 C.F.R. Sections listed in the regulations. Accordingly, *under FDA regulations* these letters are merely "informal communications" that have absolutely no legal effect. As such, these letters cannot modify the clearly defined legal status of the AVA that

results from the filing of the IND application by MBPI, or by variations in the vaccination schedule currently authorized by various DoD agencies.

Further proof of the letters' limited scope is contained in the recent Supreme Court decision in Christensen, et al. v. Harris County, et al., ___ U.S. ___, 120 S.Ct. 1655, 2000 U.S. LEXIS 3003 (May 1, 2000). The Supreme Court specifically found that agency opinion letters are not entitled to deference by the Court but only to "respect," and then only to the extent that the letters' interpretations are persuasive. Christensen, 2000 U.S. LEXIS 3003 at *19-20. Given that the letters offered by DoD as validation of its position regarding the IND status of the AVA are not agency approved letters, do not incorporate agency approved positions, and fly directly in the face of clear language in an IND application, this Committee should find that these letters are unpersuasive and without legal effect.

Indeed, there could be no other result, given the fact that the letters are totally at odds with the IND application language. It makes absolutely no sense to believe that FDA officials writing in their personal capacity can single-handedly invalidate the regulatory scheme adopted by the FDA to prevent the licensing and interstate movement of Investigational New Drugs. It is clear from the IND application, the use schedule, and the legally invalid FDA letters that DoD's position is untenable. The AVA is an IND. Under federal law and Executive Order it may not be given to members of the Armed Forces without their informed consent.

D. A Federal Statute and a Presidential Order Require Informed Consent From Service Members Prior To The Administration Of The Anthrax Vaccine

A determination that the AVA is an IND renders inescapable the conclusion that service members as a consequence of federal law and service regulations must give their informed consent prior to submitting to vaccinations.

1. The Federal Statute.

10 U.S.C. § 1107 (1999) entitled "Notice of Use of an Investigational New Drug or a Drug Unapproved for its Applied Use" specifically provides:

> (a) Notice Required. - (1) Whenever the Secretary of Defense requests or requires a member of the armed forces to receive an *investigational new drug or a drug unapproved for its applied use*, the Secretary shall provide the member with notice containing the information specified in subsection (d).
>
> (b) Time of Notice. - The notice required to be provided to a member under subsection (a)(1) shall be provided before the *investigational new drug* or *drug unapproved for its applied use* is first administered to the member.
>
> (c) Form of Notice. - The notice required under subsection (a)(1) shall be provided in writing.
>
> (d) Content of Notice. - The notice required under subsection (a)(1) shall include the following:
>
> (1) Clear notice that the drug being administered is an investigational new drug or a drug unapproved for its applied use.
>
> (2) The reasons why the investigational new drug or drug unapproved for its applied use is being administered.
>
> (3) Information regarding the possible side effects of the investigational new drug or drug unapproved for its applied use, including any known side effects possible as a result of the interaction of such drug with other drugs or treatments being administered to the members receiving such drug.
>
> * * *
>
> (e) *Limitation and Waiver. - (1) In the case of the administration of an investigational new drug or a drug unapproved for its applied use to a member of the armed forces in connection with the member's participation in a particular military operation, the requirement that the member provide prior consent to receive the drug in accordance with the prior consent requirement imposed under section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) may be waived only by the President.* The President may grant such a waiver only if the President determines, in writing, that obtaining consent –

(1) is not feasible;

(2) is contrary to the best interests of the member; or

(3) is not in the interests of national security.

(emphasis added).

2. The Order of the President.

On September 30, 1999, the President issued Executive Order 13139, entitled "Improving Health Protection of Military Personnel Participating in Particular Military Operations". EO 13139 provides in pertinent part:

> Sec. 2. Administration of Investigational New Drugs to Members of the Armed Forces.
>
> (a) The Secretary of Defense (Secretary) shall collect intelligence on potential health threats that might be encountered in an area of operations. The Secretary shall work together with the Secretary of Health and Human Services to ensure appropriate countermeasures are developed. *When the Secretary considers an investigational new drug or a drug unapproved for its intended use (investigational drug) to represent the most appropriate countermeasure, it shall be studied through scientifically based research and development protocols to determine whether it is safe and effective for its intended use.*
>
> (b) It is the expectation that the United States Government will administer products approved for their intended use by the Food and Drug Administration (FDA). However, in the event that the Secretary considers a product to represent the most appropriate countermeasure for diseases endemic to the area of operations or to protect against possible chemical, biological, or radiological weapons, but the product has not yet been approved by the FDA for its intended use, the product may, under certain circumstances and strict controls, be administered to provide potential protection for the health and well-being of deployed military personnel in order to ensure the success of the military operation. The provisions of 21 CFR Part 312 contain the FDA requirements for investigational new drugs.
>
> Sec. 3. Informed Consent Requirements and Waiver Provisions.
>
> (a) *Before administering an investigational drug to members of the Armed Forces, the Department of Defense (DoD) must obtain informed consent from each individual unless the Secretary can justify to the President a*

> *need for a waiver of informed consent in accordance with 10 U.S.C. 1107(f). Waivers of informed consent will be granted only when absolutely necessary.*

(emphasis added).

In addition, the provisions of 21 C.F.R. §§ 50, 312 (October 5, 1999) support both the federal statute and the Executive Order by specifically noting situations where the informed consent requirements may be waived. Echoing 10 U.S.C. § 1107, the Regulations note that only the President of the United States may waive the informed consent requirements mandated by his Executive Order and federal law. Waiver is allowed only if one of three preconditions is met – if obtaining informed consent is not feasible; if obtaining informed consent is contrary to the best interests of the recipient; or if informed consent is contrary to national security interests. The President has yet to issue any such waivers, or even initiate action to do so regarding the AVA.

II. The Military Justice System

The Committee has also requested that I provide an overview of the differences between the military and civilian judicial processes as they relate to the anthrax vaccination issue. I will attempt to do so, however, the discussion here obviously will not be exhaustive.

Military offenses that relate to the issue of the AVIP are defined in Articles 90 and 92, which discuss which discuss willful disobedience of lawful commands or orders. Properly promulgated orders and regulations are presumed to be lawful under military law, although the prosecution must establish unlawfulness if the defense is successfully able to raise the issue. Depending on the circumstances, refusal to follow an order may be punished administratively, through non-judicial punishment under the Uniform Code of Military Justice ("UCMJ") or at a court-martial, which may impose a wide variety of sentences up to and including death.

The defenses to a change of refusal to follow a lawful command or order are varied, and can range from lack of authority on the part of the entity giving the order, to overbreadth or unreasonableness. Other potential defenses include justification, necessity, duress, inability or ignorance or mistake. In the case of orders to submit to anthrax vaccination, the most likely defense is that the order conflicts with a statutory right of the person receiving the order, i.e., the right to provide informed consent to the vaccination under 10 U.S.C. §1107, or E.O. 13139. See Manual for Courts – Martial, Part IV, Paragraph 14.c.(2)(a)(iv)(1998).

It is not uncommon for a service member accused of refusing a lawful order to be offered an additional opportunity to comply with the order. Once it has been established that the service member will not comply, a commander may impose punishment either through administrative means or under the UCMJ. This is completely different from the civilian legal system, in which all criminal cases are disposed of in a judicial setting. Administrative punishments can range from reprimands up to and including administrative separation from the Armed Forces, with a service characterization of either an honorable discharge, a general discharge (under honorable conditions), or a discharge under other than honorable conditions.

If a commander believes that administrative sanctions are not sufficient, she may impose punishment under Article 15 of the UCMJ which allows for a relatively quick process in which the commander can impose relatively minor punishments for relatively minor offenses. Typically under an Article 15 proceeding, the commander advises the service member that the service member is believed to have committed an offense under the UCMJ. The service member then responds either in writing or with an oral presentation, or both, to the commander, who then makes the decision whether to impose punishment and to what extent. Maximum punishments are limited given the limited due process nature of the proceeding.

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If a commander feels the offense is substantial, she may decide to press the matter forward to a court-martial. There are three types of court-martial: summary, special and general. Summary court-martial is a simplified, expedited procedure conducted before a commissioned officer who may, but need not be, a lawyer. A service member must consent to a summary proceeding, and is not normally entitled to a detailed defense attorney although he may use civilian counsel. Witnesses are called and the military rules of evidence are in effect, but only enlisted members may be tried by summary court-martial. The maximum punishments are quite limited.

A special court-martial is conducted before either a military judge or a military judge and panel, or jury, of three service members. Trial counsel and defense counsel are appointed to the court and the accused has the right to be represented by a detailed defense counsel or a civilian attorney. Any service member may be tried by a special court-martial for any non-capital offense. The maximum punishments include confinement for six months and forfeiture of two-thirds pay for six months, as well as a bad conduct discharge.

The general court-martial proceeding provides a substantial level of procedural due process. Before convening a general court-martial, the convening authority must order a pretrial investigation and receive a legal opinion as to disposition of the charges. General court-martial may be conducted before a military judge or before a military judge and a panel of at least five members. The only limits upon a sentence that can be imposed by a general court-martial are those limited for each offense in the UCMJ and can include the death penalty, a bad conduct discharge, or a dismissal for officers.

Mr. BURTON. We're well aware of the morale problem with a lot of National Guard units and Reserve units, as well as the active duty. We're working on that as well. We'd like to have any information that you might have, if you could send it to us after you have your meeting out there, where was it, Colorado?

Mr. MICHELS. I'll be happy to provide that to you, sir.

Mr. BURTON. And those citations that you gave us, I don't know if we have those, but if we don't, I'd like to have those so we can followup on those as well.

Mr. MICHELS. Thank you, Mr. Chairman. They're in my written testimony.

Mr. BURTON. OK, thank you.

Dr. WALKER. Mr. Chairman, members, ladies and gentlemen, I feel privileged to address you.

The Soviet dictator, Josef Stalin, said, "A single death is a tragedy, a million deaths are a statistic." I am deeply concerned that Stalin's twisted insight has infected the debate on vaccine safety.

My name is Alec Walker. I study the safety of drugs, vaccines and medical devices. I am a professor of epidemiology at the Harvard School of Public Health. I am also senior vice president for epidemiology at Ingenix Pharmaceutical Services. I hold doctoral degrees in medicine and public health.

Mr. BURTON. Excuse me, Doctor, let me interrupt you. I want to hear all of your testimony, because I'm very interested in it. We will have to recess until Mr. Shays gets back. I'll get back just as quick as I can, because we have a vote on the floor. But we'll be right back.

So we'll stand in recess until the fall of the gavel.

[Recess.]

Mr. BURTON. Dr. Walker, if you would, once everyone regains their seats, if you would start over. I don't think you were too far into your statement. I want to make sure we get all of it. Sorry we had to rush to the floor, but Congressman Shays will tell you that you have to get down there and vote, otherwise they'll throw you out of office.

Dr. Walker.

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I would like to talk about the value of doing population level thinking when we talk about vaccine safety and efficacy. Clinical scientists establish cause and effect by looking at groups of people. Imagine that we vaccinate 100 people who are facing a smallpox epidemic that would be expected to kill a third of them. Suppose

that all of them live. We suspect the vaccine has caused the good outcome.

Whenever we give the vaccine, all live. Whenever we fail to give it, many die. We can say that the vaccine prevents death, and this is an example of statistical reasoning.

Knowledge that comes from groups is the cornerstone of clinical science. It has some important consequences. First of all, we cannot say for any one of the vaccinated people whether the vaccine saved them. After all, most would have survived anyway. This means that we can know a medical fact can be true for groups of people, and at the same time, not know whether it is true for individuals in the group.

The second lesson is that we need scientific methods that talk about whole populations. These are clinical trials, which are experimental studies in man, and epidemiology, which learns from careful observation alone. A scientific study compares a group, such as those who were vaccinated, to a control group of people who were not vaccinated. Using the experience of unvaccinated people helps researchers answer an otherwise impossible question: what would have happened to the vaccinated people if they had not received the vaccine?

We learn about unvaccinated people in general from the control group, and about vaccinees in general from the vaccinated group. We learn about the vaccine by comparing the vaccinated to the unvaccinated groups. This knowledge, which is vital to protecting public health, is not possible if we only compare single individuals.

Scientifically useful groups are defined by an exposure such as a vaccination. The outcomes, good and bad, are enumerated and compared. The rules of evidence in science require these kinds of population comparisons.

By contrast, a group of injured people cannot really tell you about the science behind their injuries. If we know already about a vaccine effect, we can examine an individual to see whether his is a case of vaccine injury. From unusual cases, we can get ideas of what might be studied. However, we cannot usually come to conclusions based on isolated accounts.

Many people in this room have legal training. You are familiar with formal rules of evidence. You also know about the uncertainty of judgments on an individual level. As you consider the problem of vaccine effects, I would ask you to hold tightly to the idea that there are rules of evidence in science, just as in law. In the matter of vaccines, one of the fundamental rules is reliance on a large enough sample, individual cases just do not provide enough information.

Science does not typically draw a conclusion from one man's story, or even groups of stories. For good reasons that are not science, the human sensibility is deeply affected by individual stories. But when it comes to making decisions about what will best protect the most people with the most efficient use of resources, the 6 million are more important than the 1.

We are grateful that there have been no enemy attacks that spread weaponized anthrax. These would have let us test the efficacy of anthrax vaccine against the pathogen for which it was created. Your deliberations on anthrax vaccine will be complicated,

thank God, by the lack of real world experience. Against that backdrop, it will be impossible to weigh risk against benefit.

Let me implore you, nonetheless, to look for risks in a quantitative fashion. Numbers and comparison do not make a good story. But they are your only defense against decisionmaking based more on the emotional circumstances of the few rather than the public health needs of the many.

Thank you for your attention. I'll be happy to take any questions.

[The prepared statement of Dr. Walker follows:]

Evidence for the Evaluation of Vaccine Safety

Alexander M. Walker, MD, DrPH

Senior Vice President for Epidemiology, Ingenix Pharmaceutical Services

Professor of Epidemiology, Harvard School of Public Health

October 3, 2000

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The second lesson is that we need scientific methods that talk about whole populations. These are clinical trials – which are experimental studies in man – and epidemiology, which learns from careful observation alone.

A scientific study compares a group such as those who were vaccinated to a *control group* of people who were not vaccinated. Using the experience of unvaccinated people helps researchers answer an otherwise impossible question. "What would have happened to the vaccinated people, if they had not received the vaccine?" We learn about unvaccinated people in general from the control group, and about vaccinees in general from the vaccinated group. We learn about the vaccine by comparing the vaccinated to the nonvaccinated groups. This knowledge, which is vital to protecting public health, is not possible if we only compare one or two individuals.

Scientifically useful groups are defined by an exposure, such as vaccination. The outcomes, good and bad, are enumerated and compared. The rules of evidence in science require these kinds of population comparisons.

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For good reasons that are not science, the human sensibility is deeply affected by individual stories. But when it comes to making decisions about what will best protect the most people with the most efficient use of resources, the six million are more important than the one.

We are grateful that there have been no epidemics or enemy attacks that spread anthrax. These would have let us test the efficacy of anthrax vaccine. Your deliberations on anthrax vaccine will be complicated, thank God, by the lack of real world experience with the anthrax pathogen. Against that backdrop, it will be impossible to weigh risk

against benefit. Let me implore you, nonetheless, to look for risks in a quantitative fashion. Numbers and comparisons do not make a good story, but they are your only defense against decision-making based more on the emotional circumstances of a few rather than the public health needs of the many.

Thank you for attention. I will be happy to take any questions.

Mr. BURTON. Let me start with you, Dr. Walker. Then I'll yield to my colleague.

How many strains of anthrax are there?

Dr. WALKER. Sir, I'm not here as an expert on anthrax. I'm here as an expert——

Mr. BURTON. Well——

Dr. WALKER [continuing]. Excuse me—on the methods of how one establishes causal relations.

Mr. BURTON. OK, let me ask you a couple of questions. According to my staff, there's at least 27 strains of anthrax, and you're here as an expert witness. How many strains of anthrax will this vaccination, if it is workable, if it does work, will protect the American troops, will it protect them against all of them, one of them or how many?

Dr. WALKER. Sir, I can't tell you that.

Mr. BURTON. You don't have the answer.

Let me ask you, how many controlled studies have been done on the anthrax vaccine?

Dr. WALKER. I'm aware that there have been a number of studies in which there have been followup of safety issues. I have not reviewed those in detail, but I'm aware of them.

Chairman Burton, let me remind you, I'm not here as a defender of the vaccine. I'm here to address methods of proceeding.

Mr. BURTON. You work for a pharmaceutical company as a vice president, do you not?

Dr. WALKER. No, it's not a pharmaceutical company. It's a research arm of a, of United Health Group, which is an HMO company.

Mr. BURTON. Oh, it's an HMO company. I see. Is Harvard receiving any DOD funds for vaccine or biological warfare research, do you know?

Dr. WALKER. Sir, I don't know.

Mr. BURTON. Mr. Ponder, do you know the names of the other two people who were going to be court-martialed—excuse me, Captain, did you have something you wanted to say?

Captain SANES. Sir, I apologize, I'm Petty Officer Ponder's attorney. My apologies.

Mr. BURTON. Do you have the names of those two other people that were to be court-martialed on the drug charges that were not sent to Okinawa?

Mr. PONDER. I do not have them with me right now, sir, but Captain Sanes does. He has them, he knows them.

Mr. BURTON. We'd like to have those, their rank, their serial numbers and where we could get hold of them.

Mr. PONDER. Yes, sir.

Mr. BURTON. Mr. Ponder, how many medications are you now being given by the military?

Mr. PONDER. None right now, sir.

Mr. BURTON. Let me yield to Mr. Shays, I'll come back to my question.

Mr. SHAYS. Dr. Walker, let me ask you this question first, and say to you that you provide a valuable source for us. Because we have heard from a number of witnesses and it's very moving. What I want to thank you for is that you basically are giving us the argu-

ment that we do need to address. And I think it takes frankly some courage to do it, in light of the fact that you are appearing at the same table.

But I do want to say to you, these are not isolated stories. These are countless stories. I'd like to know if any of their stories would be the basis for your statement, if we know already about a vaccine effect, we can examine an individual to see whether his is a case of vaccine injury. From an unusual case, we can get ideas of what might be studied. However, we cannot easily come to a conclusion based on these isolated accounts.

So you've seen, heard some cases. In the process, have you had a sense that some of these cases could be studied?

Dr. WALKER. There are two pieces to this. One is deciding, in the case of an individual, whether or not some injury that he suffered is the result of the vaccine. That presupposes that you know about, the scientific question is, does the vaccine at least sometimes cause these injuries.

What you do in that case is to match up the symptoms, the presentation of the disease and the timing, with what you've established in the past. From Mr. Jones' testimony, it sounded that at least his immediate symptoms were indeed related to the vaccine, but I obviously haven't reviewed his records. The second piece that you can get from individual experience is a way of defining, what is it exactly that I'm looking at. Statistics are not very helpful if they don't count what you're trying to count.

And sometimes, particularly with drug adverse effects and vaccine adverse effects, you have surprises. And you realize that your old way of counting things didn't work. And so you use an individual case to define what the disease entity is you're trying to study, and then you go back to the large population groups to say, well, does this happen more frequently among the vaccinees than the non-vaccinees.

I think that each of the medical stories we've heard today could potentially serve as the basis for that kind of exercise. You say, all right, we have a case of primary testicular failure. Well, we wouldn't have thought to look at that, had we not had this brought to our attention. But now we can look at it, and see, does that occur more frequently in vaccinees than non-vaccinees. And this is how you proceed.

Mr. SHAYS. So the answer would be yes?

Dr. WALKER. The answer would be yes.

Mr. SHAYS. When I hear some of these stories, of course, we've had, our subcommittee on Government Reform has had countless hearings on anthrax. So the thing that I'm aware of that you're not aware of is the extraordinary arrogance of the military. And so you are not necessarily defending the program or opposing it, correct?

Dr. WALKER. That's correct.

Mr. SHAYS. You're just trying to give us some guidance that we have to look at a larger picture. And so I think what you're saying is, if it can be demonstrated, and I think implicit in your statement is, that in the process of saving many, some may or will get hurt.

Dr. WALKER. That's always been the decision around vaccines.

Mr. SHAYS. So it is a given that some people, and it just so happens that through modern technology, all the people that seem to

be hurt by this are coming to us. But I just want to say for the record, there are hundreds and hundreds.

I also want to say for the record, since you're not necessarily aware of it, that we have had military personnel who have said to us that there are no adverse effects and you acknowledge that there will be adverse effects, and that they could be serious. Because that is always the impact of something on such a large scale.

But they have, under oath, said there are no adverse effects. They have also said to us that no one has been forced out of the military, no one has been court-martialed. It just boggles the mind. And I think you also heard Mr. Ponder explain something that is, maybe it would happen in the Soviet Union under Stalin, where they isolate the individual from his family, his support group. No one denies Mr. Ponder is sick, the question is, should he still be allowed to do it, and is there a connection and the military will insist.

Basically, what they're basically doing, in my judgment, is saying that no one gets sick from this. Some could view your testimony as unfriendly to the cause of wanting us to address this. But even if we can't get the military to stop their absurd requirement that this be mandatory, force-wide, even though we can't get them to stop that they don't follow the protocol of six shots, and now have arbitrarily decided, even though they have made a determination, though they requested that this be an investigative drug, they still have a letter from the FDA saying you could still do this, even though the testing wasn't proper. Even though all those things have happened.

They still denied individual servicemen the care they need. And you have supported the fact, by your testimony, in my judgment, that there are going to be some people who are sick, which is, just like an on bended knee requirement, that they find those people and help them. And they deny that there's even those people that exist.

So I'm just trying to say to you that that's the frustration we have. Mr. Ponder has basically been isolated from his family, his friends and his legal counsel. And they are basically, in my judgment, if his testimony under oath is to be believed, requiring him to plead guilty and then he can come home.

So you're not in any way speaking in favor of what I've spoken to, you're just speaking in favor of, and I want to be clear, that when you require a large group to be part of a program, that the benefits clearly may outweigh the costs, but there will be some costs, and they just happen to, some of them may just happen to be before us. Do you want to qualify anything I've said?

Dr. WALKER. There will always be costs. I think we see this in every form of medical treatment. That even the safest ones that there are, there are costs. And it's always a judgment as to what the best thing is to do for the individual in front of you.

With vaccines, unlike, say, antibiotics, the question is much more difficult, because the benefits are in a sense theoretical, as if this person is never exposed to attack, that he's not going to derive any benefit from the vaccine. And so the individuals that you see who have had an adverse effect, in that instance is being laid against

no benefit, just a theoretical benefit that the person had. And that's very unsatisfying.

Mr. SHAYS. Mr. Chairman, could I just have another 5 minutes and then I could finish? Would that be all right? Thank you.

What would you say to someone, if we know that some will have an adverse effect, it could be tiny, but there was some. And you have people who have said, when I took the first shot, I had an adverse effect. I took the second, and you've heard some of the stories here. And by the third time, and maybe it's coincidence, but I was sick the first time, sick the second and sick the third, and I really haven't been sick in between, but maybe I—whatever. You get the gist of my point.

Don't you think there should be some kind of presumption that maybe this person might be that one isolated very small person, statistical individual, that maybe should now have some ability to say now? I mean, we're not talking military ordering. They get court-martialed if they don't take it. But medically speaking, wouldn't that be logical?

Dr. WALKER. I can obviously only speak from the point of view of civilian medicine. I don't know the military.

It's, in the general society, I think it's a bad practice to compel vaccination. People may make mistakes, but I think it's just a violation of fundamental liberties. And it also provides the groundwork for a lot of fear. And there are, you can have this funny mixture of real things and things that aren't imagined, but they are unconnected, suddenly take on a different flavor when the vaccination itself is compelled.

So your question presupposed that the fever and headache actually was a marker of somebody who would go on to have seizures and blackouts and so forth afterwards. I don't know if that connection is true. But that's what you look at. You look at people who have had a particular adverse effect and then you look back at their experience with the vaccination, and compare it to people who didn't have the effect.

Mr. SHAYS. So the bottom line is, though, in a six series, in having six shots, when we start to see adverse effects continue to grow, from a medical standpoint, it would not be unreasonable to say, maybe this is someone who we shouldn't continue requiring to take the vaccine?

Dr. WALKER. In fact, that was commonly what we did with the old pertussis vaccine, that there were children who had had fevers and so forth, they reacted poorly. And they typically got half doses or withheld doses. Nobody knows really whether that affected the safety of the vaccine, but it was common practice.

Mr. SHAYS. I have to tell you, in the entire time we have had a witness, first off, you have been extraordinarily candid on both sides of this issue, you have said to me the most powerful thing that I've heard from a professional. You have said that in the private side, this would be bad practice, to require someone to take a vaccine that they didn't want to take. And you said it would be a violation of fundamental liberties.

And I just thank you for saying that. Because that's the fact. As well as all the other things you admit. Thank you very much.

Mr. BURTON. Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman.

I want to take a moment to thank all of our witnesses for your testimony today. I know it has been quite difficult at times.

Major Irelan, as I listened to your testimony, I kind of got the impression that, well, let me not talk about my impression. Were you satisfied with the military's reaction to your efforts to, No. 1, be diagnosed, and No. 2, receive proper treatment?

Major IRELAN. Congressman, I was trusting. Originally I went back out to Arabia, and I was treated for the symptoms. The Saudi endocrinologist had no idea of what else to look for.

When I got back to the States, I was pretty philosophical about the whole thing, even after having that report blocked by the flight surgeon. And I wrote to my Tennessee Senator, just kind of let him know what's going on. After my experiences up at Madigan Army Medical Center, I got angry, and that's when I started researching around. And when I read the record, I was pretty upset.

No, I was not satisfied with the care from the endocrinology side. I was from the standpoint of the urologist, who was brave enough to treat me as a patient and set the politics aside.

Mr. CUMMINGS. How are you doing now?

Major IRELAN. I'm hanging in there, sir.

Mr. CUMMINGS. I didn't get a chance to hear all the testimony, because I was at another hearing. But the thing that you said that I guess really touched me was when you said that you were willing to die for your country. Even with all of this.

So it must tear at you to be willing to die for this country, but at the same time, feel that you weren't treated right. I mean, I'm just curious.

Major IRELAN. Sir, I'm a grunt. I'm a ground pounder, I don't know much about medicine. The whole time, I've walked up to doctors and said, here I am, you tell me. There is trust. I have to trust my leaders and particularly the medical folks for my care and those of my men.

When a guy shakes and stutters and is concerned about the politics of the entire issue versus looking at me as a patient, that is frightening. It is very unsettling.

Mr. CUMMINGS. How do you address a soldier who comes under you and says, look, major, they want me to take this vaccine and I heard about your situation, and as much as I love my country, I want to be alive to fight for it, I mean, what do you say to somebody like that?

Major IRELAN. Acquaint yourself with the facts. I was ignorant of them until it was actually too late. Went to Mr. Burton's site and started reading the testimony, pored through 120 pages of it, and it sickened me.

A soldier obviously has to make his own value judgment of whether or not that's an order that he could follow. As for myself, given the facts that I have found from testimony, and matter of fact, from this committee, I would not have taken the shots had I known then what I know today.

Mr. CUMMINGS. You're very fortunate, and I want to applaud the chairman for having that on his site. You're very fortunate to have gotten that information. What would you have us do as far as infor-

mation is concerned, and trying to get out the information that you had access to? Or would you have any recommendations?

Major IRELAN. Sir, one recommendation would be to provide, or make sure that information is available to military medical resource tables, just like the Department of Defense's little pamphlet, What Every Service Member or Family Member Needs to Know About the Anthrax Vaccine. So there is a counterpoint, soldiers need to have that access.

It was my father-in-law that actually suggested that I go to the site. I was completely unaware of the issue at hand.

Mr. CUMMINGS. Just one last question, Mr. Chairman. Dr. Walker, and you may have answered this already, every time I go to the doctor, they always ask you your history. They want to know what your father suffered from, your mother, you know, heart disease, whatever. And I'm just wondering, for somebody like Major Irelan, based on what you know, say his son were to take this vaccine. Would you, based upon, I know you don't have all the answers, but if they asked you these questions about regular, routine kinds of things, and reactions, they even ask you about reactions to antibiotics, would you expect, I mean, that his son might go through similar types of reactions?

Dr. WALKER. You take a family history, in this case, to get at genetics. In other words, is there something about the way this person's built, that they inherited, that made them susceptible to a particular disease or a particular adverse event. I'm not aware of research indicating that there's a real familial tendency for these kinds of reactions, but surely some of them must be genetically based.

I couldn't tell a son, you would be in a situation, the problem here is that there's a risk rather than a fact. You don't even know really the level of the risk. And in the case of the vaccine, you're weighing it against, what's the risk that this person's going to be exposed to aerosolized anthrax. And you certainly want to know it. I don't think you could give him just a clear yes, no, without knowing more facts.

Mr. CUMMINGS. It just seems to me that so many people don't seem to have a problem, then you have the ones that do. And it seems to me, and I'm not a doctor, but it seems kind of logical that if he has it, I mean, if my son, if I had gone through what he went through and my son went into the military, I tell you, I would be very reluctant to see him go through the same thing I went through.

Dr. WALKER. I can understand your reluctance. But surely you would think about what risks there were in not taking the vaccine as well. And that's what you have to lay against it.

Mr. BURTON. Thank you, Mr. Cummings.

Dr. Walker, do you believe that the Institute of Medicine is a reliable barometer of whether or not a vaccination is good or bad or if there's been enough research?

Dr. WALKER. It's a human process, but it's one that the Institute of Medicine deliberations certainly give you the best mainstream thinking in a area.

Mr. BURTON. Well, the Institute of Medicine has stated that there is a lack of research to show the anthrax vaccine is safe and

effective for inhalation exposure. And so, you know, that's one of the leading institutions, I guess, as far as advice is concerned and information is concerned. Do you accept that kind of evaluation from them?

Dr. WALKER. It could hardly have been proved safe for inhalation exposure. Because you're not going to do those big, large scale, battlefield style tests. So it can't be proved safe for inhalation exposure.

Mr. BURTON. So there's not been any real strong studies or research? Because they couldn't do it unless they used humans as guinea pigs?

Dr. WALKER. That's exactly the problem.

Mr. BURTON. OK. Let me go to, there was a press release that came out from BioPort. This is one of the things that's troubling. BioPort put this press release out, and it said that they were saddened by the death of Dick Dunn. And they said that Dr. Stephen Coley, the pathologist who conducted the autopsy, called into question the link between the vaccine and his death. Called into question.

And yet if you look at the chief county medical examiner, Dr. Robert Joyce, he said he had an inflammatory response to the vaccine throughout his body. And this is the kind of parsing of words that really bothers me. The county examiner says that there was an inflammatory response to the vaccine throughout his body. And this press release says the vaccine cannot definitely be linked, cannot definitely be linked.

But the boss of this fellow, his boss, says that it was caused, there was an inflammatory response to the vaccine throughout his body.

Let me just ask you a question, Mrs. Dunn, and I know this is a very, very difficult time for you. We appreciate your being here, and we're sorry that you have to go through this after the tragedy you just experienced.

Did you or your husband ever hear of any other BioPort employees that had any trouble with these vaccines from taking them? Any reactions? Do you know of any?

Mrs. DUNN. Yes.

Mr. BURTON. Can you elaborate just a little bit?

Mrs. DUNN. The swelling, the joint pain.

Mr. BURTON. How many others do you know of that had that?

Mrs. DUNN. I don't know, sir.

Mr. BURTON. But he did mention there were others that had that reaction to it?

Mrs. DUNN. Yes.

Mr. BURTON. Were the reactions pretty much restricted to swelling and joint pain, or was there anything more severe than that?

Mrs. DUNN. My husband didn't talk a lot about BioPort. The most he talked was in the last week that he was alive.

Mr. BURTON. Is there anything else you'd like to share with us about what he said that last week?

Mrs. DUNN. No, not at this time.

Mr. BURTON. OK. Major, do you know of anyone else with a similar reaction to what you experienced?

Major IRELAN. Possibly from Dr. Nass, she has mentioned a number of folks, Dr. Meryl Nass.

Mr. BURTON. She would have that information, but she probably wouldn't be able to divulge it without the permission of the patient, I suppose.

Major IRELAN. Possibly, sir.

Mr. BURTON. But there were other cases that she dealt with?

Major IRELAN. Yes, sir.

Mr. BURTON. Do you know of any others besides that?

Major IRELAN. No, sir. I was in a three man detachment in Saudi Arabia, and I'm in an isolated location now.

Mr. BURTON. You're in an isolated location now?

Major IRELAN. I'm part of a little bitty team that advises the National Guard. So I'm not around the major military population centers.

Mr. BURTON. Is that by design? So that you won't be inflaming the situation?

Major IRELAN. No, sir, it has nothing to do with the military trying to keep me away from everybody. It's simply my retirement assignment.

Mr. BURTON. OK. Ms. Rugo, what has DOD done to help with the adverse event evaluation?

Ms. RUGO. The Department of Defense?

Mr. BURTON. Yes. Have they done anything to help with the adverse reaction that your sister had?

Ms. RUGO. I don't believe so.

Mr. BURTON. They haven't talked to you about any of that, or the family?

Ms. RUGO. They have not.

Mr. BURTON. Have you heard of any other anthrax related deaths?

Ms. RUGO. Yes, I have. Just from doing Internet research and finding other Web pages. And I did find a data base of a couple of other deaths. I don't know if it's accurate, but I do know that I have found some.

Mr. BURTON. If I might proceed just a little bit longer here, with the consent of my colleagues.

Mr. Colosimo, I see here this U.S. Air Force active duty Walter Reed medical sheet. And it says that the diagnosis that you had was anthrax intoxication, is that correct?

Mr. COLOSIMO. Yes, sir.

Mr. BURTON. Did they elaborate when they told you that you had anthrax intoxication?

Mr. COLOSIMO. No. In fact, I didn't recognize that until later. I found out much later.

Mr. BURTON. Did the doctors say anything to you out at Walter Reed, saying, you know, this could be anthrax related, or what did they tell you?

Mr. COLOSIMO. They told me my first three shots were most likely anthrax related. They told me my fourth shot was maybe something I was exposed to in Kuwait, or it could be related to the anthrax. But they were uncertain. They gave me a 1-year waiver from the anthrax shot.

But the other document I provided you was one from the chief of allergy. And she stated that my symptoms were anthrax related.

Mr. BURTON. Mr. Edwards, are you aware of anyone else who had reactions to the anthrax vaccine?

Mr. KEVIN EDWARDS. There was another soldier in the medical holding unit who also had blisters in his mouth after receiving his shots. And I have not seen him in about 4 months. But he expressed to me that his reaction was from the vaccine and he also had ocular involvement as well.

Mr. BURTON. His eyes were affected?

Mr. KEVIN EDWARDS. Yes, sir.

Mr. BURTON. Do you remember the fellow's name.

Mr. KEVIN EDWARDS. I have it written down.

Mr. BURTON. We would like to have that, so we can pursue it to see how he's doing.

Are you concerned that minorities are more severely affected by this vaccine than other nationalities or other races?

Mr. KEVIN EDWARDS. It was a question that came into my mind, because he was Hispanic. And I had heard of other cases of people that had had reactions, and most of them were minorities as well. They had not been confirmed, so I don't know for sure if they were from the vaccine. But that was a concern of ours.

Mr. BURTON. What did the military do with your clothing after you had this?

Mr. KEVIN EDWARDS. When I was med-evaced, my personal belongings were placed in plastic bags and quarantined. No one knew what I had, what to do with me, really. So all my personal belongings were just placed in a plastic bag, and that's how I received them.

Mr. BURTON. You got them back that way?

Mr. KEVIN EDWARDS. Yes, sir.

Mr. BURTON. Before you got the vaccinations, were you given any information about possible reactions or any side effects?

Mr. KEVIN EDWARDS. No, sir.

Mr. BURTON. They just said you had to take it?

Mr. KEVIN EDWARDS. Yes, sir.

Mr. BURTON. And how many times did you go to the clinic before you saw a medical doctor?

Mr. KEVIN EDWARDS. I never saw a medical doctor until I was med-evaced from Camp Carroll to 121 hospital.

Mr. BURTON. And how long a period was that from the time you first started experiencing these problems?

Mr. KEVIN EDWARDS. About 5 days. I think I went to the TMC approximately four or five times.

Mr. BURTON. Mr. Edwards, is the military, and you're the father, is the military providing adequate care for your son now, do you think?

Mr. TONEY EDWARDS. At the present time, they are providing care. Obviously he has lost so much of his sight at this point, I'm not sure if it's adequate. I have not, military personnel at Brooke Army Medical Center have not kept me informed of anything in terms of his condition.

Mr. BURTON. But they did say, didn't they, if they had gotten to him sooner, they could have saved his eyesight, or made it a lot better?

Mr. TONEY EDWARDS. Right. That was when they first got the doctor from the University of Florida to come up. By the time they got the doctor from Florida, my son had lost 1 year of his deterioration of his eyesight, before he actually got before an expert.

So I would think that in response to that question that they did not respond as fast as they could have. Perhaps they didn't have the knowledge of what to do. And based on the fact that they said they had to wait on an expert, apparently this is what they did.

However, when I requested that my son be transferred to Fort Bragg Medical Center, General deWhitt convinced me that he had all the experts, and that they were going to take care of him. But he sat there for 1 year, and his eyes stayed infected. And he lost his sight over a year period of time before they got a doctor from the University of Florida to recommend some kind of procedure that would slow down on the loss of sight.

Mr. BURTON. I'm going to yield to Mr. Horn, but let me just say that this general who had no particular medical training said that they had experts there who could take care of your son's eyesight and didn't send him where he could get care.

Mr. TONEY EDWARDS. What he was responding to was when I wrote him a letter asking him to update me on my son's condition. He responded to the letter after Congressman Jones got involved and said that he felt that Kevin needed to stay there at Brooke Army Medical Center where all the experts were. Well, that made me believe that he had all the experts that he needed.

But when it came to treating my son, he didn't have it.

Mr. BURTON. Mr. Horn. Mr. Jones, Mr. Horn has to leave, so we'll get to you as soon as he's through.

Mr. HORN. Thank you, Mr. Chairman. I appreciate all the things that you've told our committee. I just want to ask you a few more, just put your hand up. Did the Food and Drug Administration [FDA], ever contact you, those that were contacted? Now, that's Mrs. Dunn, anyone else ever contacted by the Food and Drug Administration?

So only one of you out of this panel have been contacted by and examined and surveyed, you, Mrs. Dunn. So that sort of disturbs us, to say the least.

Are you all on medication monthly? How many are on medication?

Of those on medication, what's the average amount you have to pay in a month? What about it, Major Irelan?

Major IRELAN. It would come out to $40, right now, a month. Once I leave the military.

Mr. HORN. Who's next?

Mr. KEVIN EDWARDS. I'm not exactly sure how much it would cost, since I get all my medication through the military.

Mr. HORN. So they're not charging you for that?

Mr. KEVIN EDWARDS. No, sir. I do have to buy these drops, sometimes, though. Because our pharmacy does not carry them on their formulary. So from time to time, I'll have to buy them myself, and

they are pretty costly, between $9 and $11 for a box of 30. And I go through a box of these per day.

Mr. HORN. Do you know what that costs, at all?

Mr. KEVIN EDWARDS. For the one box of 30?

Mr. HORN. Right.

Mr. KEVIN EDWARDS. Anywhere between $9 and $11, depending on where you get it.

Mr. HORN. Who's next on medication? Mr. Edwards. Mr. Colosimo.

Mr. COLOSIMO. I'm active duty.

Mr. HORN. So you're OK on covering your costs.

Mr. Johnson.

Mr. JOHNSON. I'm actually out of the military now. Fortunately, I was able to salvage some of my extra pills that I, when I left the military. On average, each pill that I have, Fioronal, costs $37.50, each pill.

Mr. HORN. $37 for each pill?

Mr. JOHNSON. Yes.

Mr. HORN. What is the medication?

Mr. JOHNSON. It's Fioronal, and it's for headaches. It's for migraine headaches. It's laced with a slight bit of cocaine and I don't know what else.

Mr. HORN. Are you on disability?

Mr. JOHNSON. I am on 30 percent disability.

Mr. HORN. Does that cover your medications?

Mr. JOHNSON. At this time, I am not purchasing extra medications, because I have extras. But when I do, it will cover 30 percent of it, not 100 percent.

Mr. HORN. Mr. Jones, medication, how much does it cost you monthly?

Mr. JONES. I'm not on medication, sir.

Mr. HORN. You're still in the service?

Mr. JONES. Yes, sir.

Mr. HORN. Mr. Ponder.

Mr. BURTON. Mr. Horn, Mr. Ponder was in Okinawa. He was brought back here because he wouldn't take the shot and he's under possible court-martial for that purpose, that reason.

Mr. HORN. Well, I think one of our witnesses, maybe Dr. Walker, has said we've got the freedom of privacy and the freedom of person under the constitution. I can't see if you don't want to take it why they should be penalizing you in any way.

Mr. Michels, any medications?

Mr. MICHELS. No.

Mr. HORN. Dr. Walker, you are not injured in this thing, but I take it you did make the statement to Mr. Shays that one shouldn't really be forced to take any medicine.

Dr. WALKER. I did qualify that, that was speaking of civilian practice. I don't have any knowledge of military practice. But in the civilian environment, it would be a mistake.

Mr. HORN. Mr. Colosimo, while you were at Walter Reed, were you seeing other individuals that were ill from anthrax?

Mr. COLOSIMO. I've seen, I don't know if it's just anthrax, I've seen individuals that were ill from the Gulf War Syndrome, who

took the anthrax shot. And there were some that had the same diagnosis that I had.

Mr. HORN. And so they would be what? Given by the military, or would they have to go out and buy it themselves?

Mr. COLOSIMO. They'd have to purchase it themselves.

Mr. HORN. Do you know what that would be?

Mr. COLOSIMO. No, I don't, sir.

Mr. HORN. Well, thank you, you've all given us great testimony. And I regret, Mr. Chairman, I have to be in my office for the chairman of the FCC, and we've got a hearing with it coming up.

Mr. BURTON. OK, Mr. Horn, we appreciate you.

Mr. JONES. Mr. Chairman, I want to thank you. As you know, I'm not a member of your committee, so I thank you and each member of this committee for giving me a little bit of time. I do serve on the Armed Services Committee. And I sit here today, I don't know if I've been to, counting Armed Services and your committee, 10, 8, 9, 10 hearings. And there are two words that come to my mind. And the two words are tragedy and politics.

I think that's what's driving this issue, quite frankly. I look at these men here today, and ladies who have lost loved ones. And I think about the men and women I've seen, both in the full committees and in my office. Most of you know I have three bases in my district, Seymour Johnson Air Force Base, Camp LeJeune Marine, down in Jacksonville and also Cherry Point Marine Air Station. And I think about the fact that men and women who love this Nation, who are in uniform willing to die today for our country, that what a tragedy it is that we have had men and women to be court-martialed or driven out of the military or become ill, as you. And possibly this vaccine has led to a death, I can't say yes or no, I don't know, I'm not an expert.

Then I think about Mr. Edwards who was trying to find out about his son who was seriously ill, near death. And he had to call a Congressman from another district, and the reason for that is because I had been somewhat out front and involved in this issue.

The fact was that it took him almost 1 year to get someone who knew his son's medical situation to communicate with Mr. Edwards and his family to say what their concerns were about what might have caused his illness. Then I think about the fact that the taxpayers of this country are propping up a company named BioPort that cannot even produce the drug. FDA to this point has not even authorized BioPort to produce this drug. That's just an ongoing saga to the tune of about $50 million and more that it's costing the American taxpayers.

That's the politics of it. I don't know why DOD will not admit that we've got a problem and why Secretary Cohen will not ask for a moratorium for a period of time until we as a Congress and they as the Department of Defense can go through this and find out exactly where we are, and is this shot safe, can you say to those in uniform, that yes, it's safe, so those in uniform will not feel like they are guinea pigs.

And to Mr. Ponder, I think it's a tragedy that you or anyone else in uniform would be forced to go to court to say that you are not going to take this shot. Here we have the State Department, whose men and women overseas are on the forefront of a possible terrorist

attack and Mr. Chairman, you know this, and Mr. Cummings knows this also, because you've had that hearing in this committee, their people, it is voluntary whether they want to take it or not.

And if anything, that gives me great trouble as a Member of Congress, quite frankly. Because what I think BioPort saw and the Department of Defense, and I've asked for an inspector general's investigation, quite frankly, it's a year old so far, and within a month or so, they're ready to bring it to a conclusion.

But my concern is the fact that all of a sudden, a decision was made by the Department of Defense, they did not do an adequate job, in my opinion, of informing and educating these men and women in uniform as to the safety of this shot, the necessity of this shot. All of a sudden, it was just mandated by the Secretary of Defense that you will take six shots.

And Mr. Chairman, I think, and Mr. Cummings, I think that is the tragedy of this, quite frankly. Because we as a Nation cannot afford to lose men and women in uniform that want to serve this Nation and to die for this Nation over a vaccine. I've heard a gentleman I have great respect for that is a Marine to say that losing one in uniform over this issue is a tragedy. And I think it is.

And I just want to thank you and this committee for giving me the opportunity to be here. I think quite frankly, that the plus of all this, if there is a plus, is as long as BioPort cannot produce the product, they're running low on inventory. And the best thing to happen to the military, in my opinion, would be that they would not get FDA approval and run out of inventory, then no one would have to take the shot.

But to sit here and see, as I have for 9 or 10 hearings, to see men and women in uniform, America's present and America's future, that are saying that they will either leave the military or they are willing to accept court order within the military and leave under circumstances that they do not desire.

Major Irelan, you said a statement in answer to Mr. Cummings, yes, there is a lot of politics in this whole issue. And to the ladies who have lost loved ones, to Mr. Edwards, whose son, I saw all those photographs of your son when you came to Goldsboro to a town meeting. And Mr. Chairman and members of this committee, there are a lot of people in uniform that are very, very concerned about what the ramifications of this shot might be as it relates to their future.

So I want to thank you. I don't really have questions. I just sat here a while ago listening to everybody. And I just thought, how sad and how tragic it is that we as a Nation, as you said, Major Irelan, your men, and every man and woman in uniform, looks to this Congress to be their protector when there are questions like this.

And quite frankly, I think we as a Congress should demand that the Secretary of Defense put a moratorium on this whole issue until a lot of questions that right now are unanswered can be answered.

Mr. Chairman, I thank you for giving me this time.

Mr. BURTON. Thank you, Representative Jones.

Representative Norton or Representative Cummings.

Mr. CUMMINGS. Just a few more questions, Mr. Chairman.

Mr. Michels, I think you referenced a letter from the FDA, did you get a letter from the FDA?

Mr. MICHELS. Are you referring to the memorandum from Dr. Karen Goldenthal?

Mr. CUMMINGS. Yes.

Mr. MICHELS. In 1997?

Mr. CUMMINGS. Yes.

Mr. MICHELS. I did reference it in my written testimony, yes.

Mr. CUMMINGS. OK. And can you tell us?

Mr. MICHELS. I can read it to you.

Mr. CUMMINGS. If it's not too long.

Mr. MICHELS. No, it's very short. It appears to be an electronic message transmission, it's an inter-office memorandum dated February 18, 1997 from Dr. Karen Goldenthal to Ms. Mary Pendergrast regarding a telephone call from Admiral Martin about the anthrax vaccine. This communication back and forth between these folks was part of the Department of Defense's initial efforts to try to get some kind of authorization from the Food and Drug Administration to go ahead and push forward with a mass vaccination effort even though the drug was in investigational status as a result of the application.

Essentially what DOD was doing was trying to get several people at FDA, one of them Dr. Goldenthal, Dr. Michael Freedman was another one, to give them the OK to say, or to use the vaccine against inhalation anthrax, even though the package and the labeling and the licensing did not specifically say that it was all right to use it as a preventative for aerosolized anthrax.

The upshot, or the import, if you will, of Dr. Goldenthal's message to Ms. Pendergrast concerning Admiral Martin's request for validation is that she said two things. The first thing she said was that she interpreted the vaccine labeling to say that it would be permissive to prevent pulmonary or inhalation anthrax. That was the first thing she said.

The second thing she said, and the reason I cited the memorandum, is that she then goes on to say, however, if the military is interested in using a vaccination time schedule different from the currently licensed schedule for a mass vaccination effort, which, Congressman, is exactly what's happening now, then informed consent would be appropriate.

In other words, if the military deviates from the labeling requirements for a vaccination schedule that is a six shot schedule, every 2 weeks for the first three shots, up to 6 weeks, and then boosters at, I believe it's 6 months, 12 months and 18 months. If they deviate from that six shot regimen, the drug is investigational and they have to get informed consent.

Now, DOD has already announced that they are deviating from the schedule. They are not going to require people to restart their shots if they are in hiatus for up to 2 years. So that sequence is going to be broken.

I guess the question I would be asking the folks who are going to come on the panel after me is, what gives you, what's changed about Dr. Goldenthal's opinion that you don't have to ask for informed consent from the service members now?

Mr. CUMMINGS. Are you defending Mr. Ponder, are you his attorney?

Mr. MICHELS. I am not Mr. Ponder's attorney. I have acted in concert with Mr. Ponder's defense attorney. Basically what I did was send him my memorandum and support materials indicating that I believed the drug was investigational, and that would be a defense to a charge of failure to disobey a lawful order.

Mr. CUMMINGS. And I would take it—are you a lawyer?

Mr. MICHELS. Well, that's actually a matter of opinion, but I've passed the bar, yes, sir. [Laughter.]

Mr. CUMMINGS. I was just wondering, I would take it that when one were to present a case like this, I'm an attorney also, and you have this kind of evidence, things that we've heard here today, it just seems like you'd almost have to, I mean, it would be logical, if you could get it into evidence, to present some of this, is that right?

Mr. MICHELS. That's correct, Congressman. And let me just say, Petty Officer Ponder's case, along with, I believe, it's three others, are up on appeal before the Navy and Marine Corps Court of Criminal Appeal. Those cases are going to be argued up there on this issue, among others. And we're hopeful that we're going to be able to succeed there.

I'll tell you quite frankly, my law firm is taking this as a pro bono effort, this is something I'm trying to do in my spare time. I mean, I'm moving toward setting up a declaratory judgment action, because there are about 300 or 400 people who have taken hits on this program, who have been forced out of the service, who I think were wrongfully separated.

Mr. CUMMINGS. Let me say this, Mr. Chairman. I want to, you know, I had to almost echo the words of Congressman Jones, it's so interesting that when people, so often, when people fall into situations where they're either harmed substantially or they die, sometimes it seems as if we have a tendency to sort of separate them and say, oh, too bad and life kind of goes on.

And the sad part about it is that people are left to suffer, and suffer greatly. When Mrs. Dunn was speaking, I watched the reactions of some of our armed services folks sitting there at the desk. And when she talked about the death of, your husband was it?

Mrs. DUNN. Yes.

Mr. CUMMINGS. I heard Major Irelan talk about how it's quite possible that his death will maybe be in some way related to this, and then I heard Mr. Edward talk about his son. I mean, we're dealing with some very serious issues.

And I just hope, so often what happens is, we've heard these cases, Mr. Chairman, how many, many years later we finally do the right thing and then somebody, first of all, it's almost impossible to even get an apology. But then so many people have died, so many children are left without their mothers and fathers, so many loved ones don't get a chance to celebrate Christmas and Easter with those people. So we have suffered over all of those years.

And I'm just saying, this testimony has been so compelling. I can assure you, we're going to do all we can we can't bring anybody back to life. I wish we could. When I think about the people, the

good men and women like you all who are willing, like Major Irelan said, to lay your lives down, I mean, that's a hell of a statement. I'm willing to die for this country.

The least we can do is try to straighten out this mess. And it is a mess. I don't care how you look at it, it's a mess.

The other thing I think we have to look at, though, at the same time, is, and I'm sure the military will talk about this, and Dr. Walker referred to it, whenever we're dealing with these kinds of issues, I think we have to, there apparently must be some balancing that goes on. What is the threat? How likely is it that this threat is going to be put upon our military folks?

So we've got a lot of questions we have to answer and a lot of things we have to address. But I can tell you one thing. Your lives are precious to us. Your lives are precious. And we want you to live the very best life that you can.

I've often said that we have one life to live, and this is no dress rehearsal. And this so happens to be that life. So hopefully, Mr. Chairman, we can work together in a bipartisan way. And I know Mr. Jones talked about politics. But the fact is, this is a bipartisan effort that I hope we can do something about. And I want to thank you.

Mr. BURTON. Thank you, Mr. Cummings.

We have some votes on the floor and I won't keep this panel any longer. Let me just tell those of you who are on the panel that we will continue to work to try to find as many answers as possible, and we'll try to do what we can to make sure that every member of the military is well informed about vaccines that they have to take, like the one we're talking about. And we're going to try to get this changed to where it's a voluntary effort, or voluntary vaccine.

I know the military has not responded in the affirmative to this, but we're going to keep having these hearings until we force the issue. And those from the military who are on the next panel should be aware of that. And I'd like to also say, anybody that you know, and you will be running across other people who probably have similar problems, be sure to tell them to contact us. We'll keep their confidence. We have a Web site, and we want to make sure we have as much information as possible from every member of the military, male or female, that has had an adverse reaction to the anthrax vaccine.

With that, our hearts go out to those of you who suffered the loss of loved ones or who are suffering now from the effects of the vaccine. And we really thank you for being here.

I'd just like to see, which one of you is getting the eye drops? You're paying $11 a day? Those expenses that you're incurring as a result of your injury that are not being picked up by the military or the Government of the United States, you let me know what they are. Because I'll write a letter to the Defense Department and try to make sure that you're compensated for that. You shouldn't have to pay for that, because it wasn't your fault.

And with that, we stand in recess. We'll be back here in about 10 minutes.

[Recess.]

Mr. BURTON. We will call the next panel. Other members will be back shortly.

[Witnesses sworn.]

Mr. BURTON. Be seated.

I understand there are two opening statements that you wanted to make. Who will be delivering those?

Mr. CRAGIN. I will, on behalf of the Department of Defense. I'm Charles Cragin.

Mr. BURTON. And who else?

Mr. ELENGOLD. I will for the Food and Drug Administration.

Mr. BURTON. All right, why don't we start with Mr. Cragin, and then we'll go to you next.

STATEMENTS OF CHARLES CRAGIN, PRINCIPAL DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR RESERVE AFFAIRS, U.S. DEPARTMENT OF DEFENSE, ACCOMPANIED BY DR. J. JARRETT CLINTON, ACTING ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS; DR. ANNA JOHNSON-WINEGAR, DEPUTY ASSISTANT TO THE SECRETARY OF DEFENSE FOR CHEMICAL AND BIOLOGICAL DEFENSE; MAJOR GENERAL RANDY L. WEST, SENIOR ADVISOR TO THE DEPUTY SECRETARY OF DEFENSE FOR CHEMICAL AND BIOLOGICAL PROTECTION; COLONEL ARTHUR FRIEDLANDER, SCIENCE ADVISOR FOR THE U.S. ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES; AND MARK ELENGOLD, FOOD AND DRUG ADMINISTRATION

Mr. CRAGIN. Thank you, Chairman Burton. On behalf of myself and my colleagues, we appreciate the opportunity to appear before this committee and discuss what we have learned since beginning the Anthrax Vaccine Immunization Program [AVIP].

I'm accompanied today by Dr. J. Jarrett Clinton, the Acting Assistant Secretary of Defense for Health Affairs; Dr. Anna Johnson-Winegar, Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense; Major General Randy L. West, Senior Advisor to the Deputy Secretary of Defense for Chemical and Biological Protection; Colonel Arthur Friedlander, Science Advisor for the U.S. Army Medical Research Institute of Infectious Diseases.

And also joining us are Colonel Randolph, the Director of the Anthrax Vaccine Immunization Program, and Colonel Scovall from the Office of the Navy Judge Advocate General.

The threat of anthrax facing our service men and women today continues to be a lethal threat. And Mr. Chairman, I know you are familiar with the history of Secretary Cohen's decision to vaccinate all U.S. military personnel against anthrax. So I will focus my remarks on our most recent actions and what we have learned concerning AVIP.

Many of our military men and women stationed around the world go to work every day under the threat of a weaponized anthrax attack. Our intelligence tells us the threat to produce and deliver anthrax against our troops in the high threat areas of southwest Asia and Korea is ever present. The colorless, tasteless, odorless, difficult to detect anthrax is one of the few existing biological warfare weapons that can cause swift and almost certain death when an unprotected person is exposed.

For 2½ years we have concentrated on vaccinating those members at greatest risk of exposure to anthrax, particularly those

service members assigned to or deploying to southwest Asia and the Korean peninsula. In phase one of the program, we administered more than 1.9 million doses from our stockpile of safe and effective FDA-licensed vaccine to more than 487,000 individuals.

Our stockpile was originally produced by the Michigan Department of Public Health. The State of Michigan sold the facility to BioPort Corp. in 1998. BioPort is currently working toward FDA biological license application supplemental approval of this new facility. While we work with the FDA toward achieving the approval of the site modifications, we continue to use vaccine from the stockpile of previously manufactured, certified safe and effective FDA licensed vaccine.

The stockpile, however, is currently below the level needed to continue phase one. So we have refocused the scope of our vaccination effort. We now maintain the vaccination program only in the highest threat areas where service members are at greatest risk. Only those U.S. military personnel, emergency essential civilian employees and contractor personnel assigned or deployed on the ground in southwest Asia and Korea for 30 days or more are receiving the vaccine. All other vaccinations will be deferred until we can obtain an assured supply of safe and effective FDA licensed vaccine.

This is not our desired protection level. It is, simply put, all we can accomplish with the available supply. Once this assured supply is available, we will resume phase one and eventually proceed with the subsequent phases to accomplish the vaccination of the entire force. In the meantime, the rest of our force health protection package, including the use of field detectors, protective gear and antibiotics, will remain in place.

Ideally, we would have sufficient vaccine available to vaccinate all of our phase one service personnel according to the Secretary's original schedule. This is not the case, unfortunately, and the Department is managing the risk as optimally as possible, given the current circumstances.

We have learned a great deal in the past few years about the program and our management of it. These lessons will help us better manage the program as we work toward vaccinating the total force in the years to come. Programmatically, the Department has moved toward alternative strategies for vaccine acquisition. We realized that while the current vaccine is the most effective protection available against this lethal weapon, we must continually explore means to improve that protection.

Another critical lesson we have learned is how important it is to communicate clearly and effectively with our service members and their families from the beginning. We underestimated this task, and we shouldn't have. We are now using the Internet and applying communications strategies and tools that more effectively relay information and address the concerns and questions of our service men and women.

These lessons have allowed the Department to better educate, protect and retain highly valuable, active duty and reserve component personnel. Despite our efforts to improve our program, however, the Department still needs FDA licensed vaccine to expand the AVIP and protect the total force. BioPort is the only supplier

of the anthrax vaccine in the United States. Obtaining new production of FDA licensed vaccine as soon as possible is a high priority for the Department.

We are committed to providing the resources necessary to achieve this, and have taken steps to assist BioPort in the submission of their biologic license application to the FDA. First, we provided BioPort with second party consulting and defense contract management oversight to enhance management practice and maximize performance.

Second, we are working to reduce our reliance on BioPort as the only source of FDA licensed anthrax vaccine. We are seeking to identify a second source for manufacturing the anthrax vaccine that can share the product license with BioPort. We have received five expressions of interest thus far, and are analyzing them to determine the cost, schedule and technical feasibility of a second source.

Third, we are restricting further payments to BioPort for only those items deemed allowable to comply with good Government and fiscal practices and congressional direction.

Fourth, the fiscal year 2001 budget includes research funds to develop biological warfare vaccines, to provide protection against multiple biological agents. There is a research program to produce a multi-agent vaccine capable of stimulating immunity against three or more biological warfare agents, utilizing a common platform.

Finally, we have asked for an independent review of the Department's management of vaccine acquisition to ensure that our efforts are credible, consistent and cost effective. We took these steps because our existing stocks of previously manufactured vaccine are not sufficient to sustain the program at its present pace. We are focusing our efforts on the FDA's approval of BioPort's renovated production suite.

There have been many delays, some within and some beyond BioPort's control. Some are related to the inherently complex process of producing biological products. Some are the result of the evolving nature of current manufacturing practices required of a manufacturing facility producing biological agents. Other companies in the vaccine industry are also encountering these challenges. For instance, there are current shortages of the influenza vaccine and also snake anti-venom.

Despite the program's slowdown, we are working with the commanders in chief of the high threat areas to continue to protect as best we can our troops at highest risk. We will accomplish this process consistent with FDA regulations and direction while maintaining our strong focus on safety and protection of our troops.

To date, 13 studies have established the safety of the anthrax vaccine. These 13 studies include collection of both active and passive data from anthrax vaccine recipients. They also include focused and broad based studies and short and long term studies. Results from these studies can be seen on our Web site at www.anthrax.osd.mil. One of the 13 safety studies involves an independent civilian panel review of reports of the Vaccine Adverse Events Reporting System [VAERS]. After 2 years, in which almost 1,200 reports and medical records have been reviewed, the AVIP

continues to report that they have identified no unexpected events and no disease syndromes associated with the anthrax vaccine.

We continue to work hard at making this type of information more available to our service members and their families. We provide through our Web site accurate, fact-based information 24 hours a day. Other more conventional tools include brochures, journal articles, other printed material, training video tapes, silent training aids, a toll-free hotline and e-mail.

All of the AVIP efforts I have discussed require resources. The Department has programmed $74 million between fiscal year 1999 and fiscal year 2005 for the AVIP agency's operating budget. This budget increases across the years as the number of participating DOD personnel and the size of the program increases. Eventually, 2.4 million personnel will be enrolled and sustained once the program completes all three phases of implementation. The Department has funded the program with this in mind.

Mr. Chairman, nearly one-fifth of our service men and women are benefiting from anthrax vaccine protection. That means nearly 500,000 more military members are protected against anthrax today than were protected when our Nation was last involved in hostilities. That is not enough, however. All who serve and defend our Nation deserve to be and should be protected.

We are eager to resume and expand our vaccination efforts to include the total force as soon as an adequate supply of safe and effective FDA licensed vaccine becomes available. We will work diligently with the FDA toward achieving new production, as soon as it is safely practical, and to ensure that the newly produced vaccine remains safe, pure, sterile and potent throughout its shelf life.

Our highest priority has been and will always remain to protect the safety and well being of the men and women who safeguard our country.

Mr. Chairman, that concludes the opening remarks of the Department of Defense representatives.

[The prepared statement of Mr. Cragin follows:]

ANTHRAX VACCINE IMMUNIZATION PROGRAM
Threat, Effectiveness, Safety & Supply

STATEMENT BY

Charles L. Cragin
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(Personnel and Readiness)

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INTRODUCTION

Chairman Burton and Distinguished Committee Members, we appreciate the opportunity to appear before your Committee today to discuss what we have learned since the inception of Anthrax Vaccine Immunization Program (AVIP). I am accompanied today by Dr. J. Jarrett Clinton, Acting Assistant Secretary of Defense for Health Affairs, Dr. Anna Johnson-Winegar, Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense, Major General Randy L. West, Senior Advisor to the Deputy Secretary of Defense for Chemical and Biological Protection and Colonel Arthur Friedlander, Science Advisor for the U.S. Army Medical Research Institute of Infectious Diseases.

LESSONS LEARNED

The anthrax threat facing our servicemen and women is real. And, in an effort to protect them from that threat, the Department implemented the Anthrax Vaccine Immunization Program. To date, we have administered more than 1.9 million doses of safe and effective Food and Drug Administration (FDA) -licensed vaccine to over 487,000 members.

During this period, the Department has learned how to improve its communication with our service members and their families, using the most current technology and applying communication strategies that are more effective in relaying

the information and in addressing the concerns and questions that are very important to our service men and women. In addition, there has been an evolution toward alternative vaccine acquisition strategies. The Department also realizes that, while the current vaccine is the most effective protection available against this tasteless, odorless and colorless lethal weapon, we must continually explore means to improve that protection. The Department has also developed and instituted new administrative and medical exemption policies that enable members to be exempted from the vaccination under certain circumstances. These lessons have allowed the Department to educate, protect and retain highly valuable Active Duty and Reserve members.

BACKGROUND

When Secretary Cohen accepted the recommendation of the Joint Chiefs of Staff to vaccinate all U.S. military personnel against the biological agent anthrax, he did so to protect our men and women in uniform from a colorless, odorless and tasteless aerosolized weapon. Unprotected exposure to anthrax can result in death.

Our intelligence indicates that several countries either have or are attempting to acquire anthrax as a biological weapon. Our intelligence also indicates that the threat of anthrax production and the capacity to deliver it against our troops exists in the high threat areas of Southwest Asia and Korea. This means that many of our military men and women stationed around the world, go to work every day under the threat of a weaponized, anthrax attack. This difficult–to-detect agent is one of the few existing

biological warfare agents that can cause swift and almost certain death when an unprotected person is exposed.

Based on this intelligence, the Department developed a three-phased AVIP implementation plan with the objective of first vaccinating those members at greatest risk of exposure to the biological weapon of anthrax.

For the past two and a half years, we have conducted Phase 1 of the program, vaccinating those military members already assigned or deploying to Southwest Asia and the Korean Peninsula, the two most likely regions where our intelligence collectors believe anthrax could be used against U.S. Forces.

As mentioned before, more than 1.9 million doses of safe and effective, FDA-licensed vaccine have been administered to over 487,000 individuals. While the Committee has expressed an interest in the 442 individuals who have refused to obey a direct order to take the anthrax vaccine, these members only represent less than one-tenth of one percent of those required to take the vaccine.

When the program began, we used vaccine from the stockpile produced by the Michigan Department of Public Health. The state-owned facility and the vaccine license was then sold to a private concern, the BioPort Corporation, in 1998. BioPort has since completed renovations, resulting in an expanded-capability vaccine production suite. It is now working toward FDA Biologic License Application (BLA) supplemental approval

of this new facility. While we work with BioPort toward achieving the approval of the site modifications, we are using vaccine from the stockpile of previously manufactured FDA-licensed vaccine.

However, because the stockpile level is currently below that needed to continue Phase 1 as initially established, we have refocused the scope of our vaccination effort so we can maintain the vaccination program in the areas of the highest threat. Now, only those U.S. military personnel, emergency-essential civilian employees and contractor personnel assigned or deployed on the ground in Southwest Asia and Korea for thirty days or more are receiving the vaccine. All other persons' vaccination doses will be deferred until we can obtain an assured supply of safe and effective, FDA-licensed vaccine. This is not our desired protection level; it is, simply put, all we can accomplish with the available supply. Once this assured supply is available, we will resume Phase 1 and eventually proceed with the subsequent phases to accomplish the vaccination of the entire force. In the meantime, the rest of our force health protection package, including the use of field detectors, protective gear and antibiotics, will remain in place.

Ideally, we would have sufficient vaccine available to vaccinate all of our Phase 1 service personnel according to the Secretary's original schedule. Because this is not the case, the Department is managing the risk as optimally as possible, given the current circumstances.

STEPS TAKEN TO ENSURE FDA APPROVAL OF BIOPORT'S NEW FACILITY

As the Committee is aware, BioPort is the only supplier of the anthrax vaccine in the United States. Attaining new production of FDA-licensed vaccine, as soon as possible, is a high priority for the Department and the Department is committed to providing the resources necessary to achieve this goal. The Department has taken the following steps to assist BioPort in the submission of their BLA to the FDA and to identify additional sites for the production of force health protection vaccines that are vital to national security.

First, second-party consulting and Defense Contract Management oversight has been added to enhance management practices and maximize performance.

Second, we are working to reduce our reliance on BioPort Corporation as the only source of FDA-licensed anthrax vaccine. On June 30, 2000, the Department issued, through the Commerce Business Daily, a "source sought" announcement seeking to identify interest in the pharmaceutical industry in providing a second source for the manufacture of anthrax vaccine. We are exploring the feasibility of another producer sharing the product license with the BioPort Corporation, thus providing DoD a second manufacturing source. Five responses were received and are being analyzed to determine the cost, schedule and technical feasibility of a second source.

Third, we are restricting further payments to BioPort to only those items of expense cost deemed allowable to comply with both good government fiscal practices and Congressional direction. The DoD will be reimbursing costs only if the expenditure is necessary to obtain FDA approval

Fourth, the FY2001 budget includes research funds to develop biological warfare vaccines to provide protection against multiple biological agents. Examples are a next generation anthrax vaccine, a recombinant plague vaccine and a multivalent encephalitis vaccine. While most vaccines are targeted against a single biological warfare agent, there is a research program to produce a multi-agent vaccine capable of stimulating immunity against three or more biological warfare agents, utilizing a common platform. In the commercial market, multi-agent vaccines such as the Measles-Mumps-Rubella vaccine have proven effective against a number of disease-causing agents. These newer multivalent vaccines could serve to advance our long-range strategy to protect our troops against existing and emerging biological agent threats.

Finally, Dr. J. Jarrett Clinton, Acting Assistant Secretary of Defense for Health Affairs and Dr. Hans Mark, Director of Defense Research and Engineering, have been tasked to provide an independent review of the Department's management of vaccine acquisition to ensure that our efforts are credible, consistent and cost effective.

WHY THESE STEPS WERE TAKEN

Because we have reached a point where existing stocks of previously manufactured vaccine are not sufficient to sustain the program at its present pace, we are focusing our efforts on the FDA's approval of BioPort's renovated production suite. There have been many delays, some within and some beyond BioPort's control. Some are related to the inherently complex process of producing biological products. Some are the result of the evolving nature of current Good Manufacturing Practices required of a manufacturing facility that produces biological agents. As you may know, other companies in the vaccine industry are also encountering these challenges.

Despite the program slowdown, we are working with the Commanders-in-Chief of the high threat areas to continue to protect as best we can our troops at highest risk. We will accomplish this process, consistent with FDA regulations and direction, maintaining our strong focus on safety and protection for our troops.

SAFETY SURVEILLANCE

To date, 13 safety studies have established the safety of the anthrax vaccine. These 13 studies have included both the active (solicited) and passive (spontaneously provided) acquisition of data from anthrax vaccine recipients. They have also included focused and broad-based, and short-term and long-term studies.

Results from our studies have already been publicly presented to numerous civilian scientific assemblies and have started appearing in highly respected medical journals, with many more presentations and publications to follow. We have shared raw data with the nation's senior scientists, with members of respected independent advisory panels and with a new panel of independent civilian scientists selected and established by the Department of Health & Human Services. We have collaborated with public health experts at the Centers for Disease Control and Prevention, FDA and leading universities. Pending final publication of the results, we have posted the interim findings from the studies on our web site, for the world to read.

One of the 13 safety studies involves an independent civilian panel review of reports to the Vaccine Adverse Events Reporting System (VAERS). The chief value of VAERS is to look for rare, unexpected events that are temporally associated with the vaccination. At the Department's request, the Department of Health and Human Services convened a civilian panel, the Anthrax Vaccine Expert Committee (AVEC), to review each VAERS report submitted for the anthrax vaccine. After 2 years in which almost 1,200 reports and medical records have been reviewed, the AVEC continues to report that they have identified no unexpected events and no disease syndromes associated with the anthrax vaccine.

COMMUNICATION TOOLS

While we in the Department are aware of the threat and the lethality of the disease, it is imperative that we communicate these facts to our members and their families. To do this, we utilize a variety of avenues, focusing on those methods that are most effective. This has involved using means different from previous education and training programs. The best example of this is the internet. This cost-effective communicator allows us to present fact-based information 24 hours a day. Other more conventional tools being used include brochures, journal articles, other printed materiel, training videotapes, other multi-media products and silent training aids. Silent training aids include items such as message pens, beverage containers and clinical penlights. These durable, timetested objects, commonly used by service members, serve as a continuous reminder of key program messages, contact sources for AVIP information and adverse event reporting.

Because, 2.4 million personnel will ultimately be enrolled and sustained once the program completes all three phases of implementation, the Department has funded the program with this in mind. The DoD has programmed $74 million (FY99 - FY05) for the AVIP Agency's operating budget. This budget increases across the years as the number of participating DoD personnel and the size of the program increases. The annual operating budget includes funding for personnel, equipment, contracts, supplies, travel, conference support, vaccine distribution, quality control and monitoring, education and training, web site development and maintenance, program research and

evaluation, patient outreach, focus group research and the administration of vaccinations through agreements with the U.S. Public Health Service, Department of Veterans Affairs, other Federal Departments/Agencies and the private sector. Each area's expenditures are carefully managed, balancing cost against effectiveness. For example, silent training aids, like the Internet, are another means to effectively offer 24-hour education or training. For $263,704, or 3% of the $8.4M FY00 annual budget, the agency was able to provide message and training information delivery to the force. In addition, by purchasing in bulk, the AVIP Agency saved $30,659 in FY 00. To date, from FY 98, the total silent training aid expenditures have been $304,452.

CONCLUSION

More than 487,000 servicemen and women have received over 1.9 million vaccinations and are today benefiting from this protection. Because of the AVIP, there are many more military members protected against anthrax today, than were protected when our nation was last involved in hostilities. We are eager to resume and expand our vaccination effort to include the total force, as soon as an adequate supply of safe and effective, FDA-licensed vaccine becomes available. We will work diligently with BioPort toward achieving new production as soon as it is safely practical and to ensure that the newly produced vaccine remains safe, pure, sterile and potent throughout its shelf life.

Our highest priority has been, and will always remain, to protect the safety and well-being of the men and women who safeguard our country. To do less would be unacceptable and a serious dereliction of duty and responsibility.

26 Sep 2000

APPELLATE PROCESSES ONGOING WITHIN U.S. NAVY REGARDING ANTHRAX EXTRAORDINARY WRIT CASES

1. There are five anthrax cases in which petitions for extraordinary relief (extraordinary writs) have been filed with the Navy-Marine Corps Court of Criminal Appeals (NMCCA). NMCCA was created by Congress under Article 66, UCMJ, 10 USC 866, with the authority to exercise appellate review over the results of certain courts-martial. These extraordinary writs have been brought pursuant to 28 USC § 1651(a) (the All Writs Act) and military case law which indicates that NMCCA may have authority to act in this matter at this stage.

2. These writs arose out of special courts-martial in which each service member was charged with violating a lawful order that required that he receive an anthrax vaccination.

3. After charges were brought, each service member attempted to challenge at his court-martial the lawfulness of the order in question, and the safety and efficacy of the anthrax vaccination.

4. In each case the military judge conducted a hearing on these preliminary issues. Each judge then ruled that the order to receive an anthrax vaccination was lawful, and that the evidence which the service member sought to introduce regarding the safety and efficacy of the anthrax vaccination was not relevant and therefore inadmissible. These rulings were made pursuant to Rules for Courts-Martial 801((e)(1)(A) and 801(e)(5), which require that the judge rule on questions of law and interlocutory questions arising during trial.

5. In response to these rulings each service member petitioned NMCCA for extraordinary relief under the All Writs Act.

6. Each service member is claiming essentially the same thing: (1) that the military judge erred in determining, as a preliminary matter, that the order to the accused to take an anthrax vaccination was lawful as a matter of law; and (2) that the judge erred in determining that, because the order was lawful, evidence of the alleged dangers of the vaccination was irrelevant and inadmissible.

7. The relief requested by each service member from NMCCA is also effectively the same: (1) reverse the judge's rulings; (2) allow the issue of lawfulness of the order to go to the members of the court-martial (*i.e.*, the jury); and (3) permit the accused to put on evidence of the vaccination's alleged dangers.

8. Of the five extraordinary writs presently pending, one arose in Marine Corps Air Station Miramar, California (*Rose v. DelZompo*), one in Camp Pendleton, California

(*Perry v. Wesley*), and three in Okinawa (*Ponder v. Stone*, *Arroyo v. Stone*, and *Stonewall v. Stone*). In each case the first party named is the charged service member (e.g., *Rose*), and the second party named is the military judge presiding over the court-martial (e.g., *DelZompo*).

9. NMCCA issued stays of the proceedings in all five cases, and directed that the Government show cause why the requested relief should not be granted. The Government has filed its response in all cases except *Stonewall v. Stone* (which was filed with NMCCA on September 25, 2000; the Government's response is not yet due).

10. Additionally, on August 18, 2000, NMCCA specified an issue in *Rose v. DelZompo* asking whether the military judge's interlocutory decision regarding lawfulness was a "usurpation of power." (A usurpation of power has been recognized as one of the grounds potentially warranting a grant of extraordinary relief.)

11. On September 1, 2000, the Government filed its response to the specified issue in *Rose v. DelZompo*. To date this is the only issue that NMCCA has specified in these cases, and the only anthrax-refusal case in which it has done so.

12. Presently, *Rose v. DelZompo* has been set for oral argument, but the originally scheduled date (September 27, 2000) has been canceled due to a scheduling conflict with Lance Corporal Rose's counsel. A new date for argument has not yet been set.

13. After NMCCA decides each of these cases, both the service member and the Government will have the option of asking the United States Court of Appeals for the Armed Forces (CAAF) to review NMCCA's decision. CAAF was created by Congress under Article 67, UCMJ, 10 USC 867, with the authority to exercise appellate review over the results of certain courts-martial which have been reviewed by NMCCA (or one of the other service courts of criminal appeals.) Thus, pursuant to statute and military case law, after NMCCA has acted CAAF would potentially have the authority to act in each case. After CAAF acts, the parties could then petition the United States Supreme Court for review via a writ of certiorari.

14. Given the similarity of the issues in all five cases, it is likely that the cases will be decided the same way. After the appellate courts have decided these extraordinary writs, the cases will be returned to the courts-martial for further proceedings consistent with the appellate courts' decisions.

FY01-05 Biological Warfare Defense Investment

COMMODITY AREA	PROGRAM NAME ($K)	ITEM	FY01	FY02	FY03	FY04	FY05	
BJPO	CRITICAL REAGENTS PROGRAM	BJ5	1133	1140	1145	1136	1170	
BJPO	CRITICAL REAGENTS PROGRAM	JPO210	1911	1914	2007	1849	1903	
BJPO	INTERIM BIO AGENT DETECTOR (IBAD)	BJ5	332	334	336	332	334	
BJPO	JOINT BIO POINT DETECTION SYSTEM (JBPDS)	JP0100	53596	61689	91533	59415	46167	
BJPO	JOINT BIO POINT DETECTOR SYSTEM BLK 2	BJ5	4540	20584	27703	14189	0	
BJPO	JOINT BIO REM EARLY WARNING SYS (JBREWS)	BJ5	0	24676	31081	0	0	
BJPO	JOINT BIO REM EARLY WARNING SYS (JBREWS)	JPO200	0	0	0	34251	36023	
BJPO	LONG RANGE BIO STAND-OFF (XM94) (LR-BSDS)	JPO220	11733	11799	0	0	0	
BJPO	PORTAL SHIELD - AIR BASE / PORT DETECTOR SYSTEM	JPO230	24746	3868	0	0	0	
BJPO	TECHNOLOGY TRANSFER FOR BIO SENSORS	BJ4	6612	10562	15440	20383	11627	
CPSP	BIODETECTION PROGRAM	CP3	2708	3524	6555	1419	0	
CPSP	COUNTERPROLIFERATION SUPPORT (NON-SYSTEM)	CP3	4431	4635	766	2461	5721	
CPSP	CRITICAL REAGENTS PROGRAM	CP3	386	384	0	0	0	
CPSP	INTEGRATED CHEM BIO ATD	CP4	0	0	10526	10536	13187	
CPSP	JOINT BIO REM EARLY WARNING SYS (JBREWS)	CP4	4417	0	0	0	0	
CPSP	JOINT CHEM/BIO UNIVERSAL DETECTOR (JCBUD)	CP3	0	0	0	3783	7624	
CPSP	RESTOPS ACTD	CP3	2688	2873	0	0	0	
CPSP	RESTOPS ACTD	CP4	9730	13539	7654	7567	0	
MBIO	BIOLOGICAL VACCINES	MB4	29694	31691	29873	24860	19465	
MBIO	BIOLOGICAL VACCINES	MB5	24198	57206	68991	42357	33619	
MBIO	BIOLOGICAL VACCINES	JX0005	49795	40430	45649	60834	64031	
TBMD	TECH BASE MEDICAL BIOLOGICAL	TB1	20753	17777	18428	18763	19382	
TBMD	TECH BASE MEDICAL BIOLOGICAL	TB2	21509	30017	31638	22088	22985	
TBMD	TECH BASE MEDICAL BIOLOGICAL	TB3	19980	23063	33154	50328	40819	
TBNM	BASIC RESEARCH (JOINT) **[BIO ESTIMATE]**	CB1	1226	1783	1640	1734	1793	
TBNM	APPLIED RESEARCH (JOINT) **[BIO ESTIMATE]**	CB2	18861	18723	18436	18529	19154	
TBNM	ADV TECH DEV (JOINT) **[BIO ESTIMATE]**	CB3	3018	3847	5232	6445	7078	
	TOTAL		**317997**	**386057**	**447786**	**403259**	**352081**	**1907178**

Mr. BURTON. Thank you.

Mr. Elengold.

Mr. ELENGOLD. Thank you. We have a longer statement for the record, I'll just summarize it.

Mr. BURTON. That's fine, we'll put your whole statement in the record.

Mr. ELENGOLD. Mr. Chairman and members of the committee, I am Mark A. Elengold, Deputy Director for Operations, Center for Biologics Evaluation Research [CBER], of the Food and Drug Administration. I appreciate the committee's interest in the anthrax vaccine absorbed, and the opportunity for FDA to update the committee on the regulatory status of BioPort Corp. and the agency's experience with adverse event reports for the anthrax vaccine.

Accompanying me is Dr. Susan Ellenberg, Director of CBER's Office of Biostatistics and Epidemiology. Let me assure you that we will continue to help assure that only safe and effective products are marketed and these products meet high standards of quality.

There is currently only one FDA licensed facility for the production of anthrax vaccine. The facility was first known as the Michigan Department of Public Health [MDPH], subsequently called the Michigan Biologic Products Institute [MBPI], and is currently known as the BioPort Corp. FDA has inspected this facility on many occasions during the past decade. In particular, FDA conducted a surveillance inspection of MBPI in November 1996. Based upon the documented deviations from current good manufacturing practices [CGMPs], FDA issued a notice of intent to revoke letter to MBPI in March 1997.

In February 1998, FDA conducted a followup inspection of the facility. The February 1998 inspection disclosed continuing significant deviations from FDA's regulations. After BioPort purchased the facility from MBPI in September 1998, FDA inspected the facility in October 1998 and still found deviations but also noted continuing improvement.

In January 1998, MBPI halted production of anthrax vaccine sublots to begin a comprehensive renovation of the anthrax production facility. Although there has been a resumption of manufacturing by BioPort, in order to produce lots in support of the license application supplement for the renovated facility, no lots of anthrax vaccine manufactured in the renovated facility have been submitted to CBER for lot release.

Due to the rules of confidentiality, FDA cannot generally disclose details or, or even acknowledge the existence of, a pending application or supplement, unless that information has already become public. Since press reports and information made public by BioPort have revealed information about anthrax vaccine, FDA can disclose that BioPort does have a pending supplement for renovation of their anthrax vaccine manufacturing facility. BioPort may not release product produced in the renovated facilities until the supplement is approved and each batch has received CBER lot release approval.

In order to examine the manner in which BioPort implemented the renovation for the manufacturing facility, FDA conducted a pre-approval inspection from November 15th through November 23, 1999. At the conclusion of the November inspection, BioPort re-

ceived a Form FDA 483, with observations in the following areas: validation, failure to investigate manufacturing deviations, deviation report, aseptic processing, filling operations, standard operating procedures, stability testing and environmental monitoring. All observations on the Form FDA 483 must be addressed adequately before FDA will approve the supplement.

In addition to inspecting vaccine manufacturers, FDA also monitors adverse events for vaccines and other products. For vaccines, this is accomplished through the Vaccine Adverse Event Reporting System [VAERS]. Generally, VAERS does not establish causality, but is essential to the discovery of potential rare adverse consequences of medical products that may not become evident until large numbers of people have been exposed to them.

Since the beginning of VAERS operations in 1990 through September 15, 2000, 1,561 reports of adverse events associated with use of the anthrax vaccine have been reported to VAERS. FDA understands, based on information from BioPort, that from 1990 to present, approximately 2 million doses of the vaccine have been distributed. Of those reports, 76 are considered serious events, those which are considered fatal, life-threatening, or resulting in hospitalization or permanent disability. These reports are for diverse conditions, such as hospitalization for severe injectionsite reaction and Gullian Barre syndrome, widespread allergic reaction, aseptic meningitis and multi-focal inflammatory demyelinating disease.

There are no clear patterns emerging at this time. The remaining reports describe a variety of symptoms, including injectionsite hypersensitivity, injectionsite edema or swelling, injectionsite pain, headaches, joint pain and itching. None of these diverse events, except for injectionsite reaction, can be attributed to the vaccine with a high level of confidence, nor can contribution of the vaccine to the event report be entirely ruled out. With the exception of injectionsite reaction, all of the adverse events noted above can 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 have not raised any specific concerns about the safety of the vaccine. We appreciate the committee's interest in BioPort and the anthrax vaccine. FDA will continue to work with BioPort as we would with any manufacturer in an appropriate manner to resolve all situations involving pending submissions, inspectional issues and GMP compliance. Additionally, we will continue to monitor the adverse event reports that are submitted through VAERS.

FDA continues to believe that the vaccine is safe and effective protection for those individuals at high risk for exposure to Bacillus Anthracis when used in accordance with the label.

My colleague and I will be happy to answer any questions.

[The prepared statement of Mr. Elengold follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

STATEMENT BY

MARK A. ELENGOLD

DEPUTY DIRECTOR, OPERATIONS

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

FOOD AND DRUG ADMINISTRATION

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

UNITED STATES HOUSE OF REPRESENTATIVES

October 3, 2000

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Mark A. Elengold, Deputy Director, Operations, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA or the Agency). I appreciate the Committee's interest in the Anthrax Vaccine Adsorbed and the opportunity for FDA to update the Committee of the regulatory status of BioPort Corporation (BioPort), and the Agency's experience with adverse event reports for the anthrax vaccine. Let me assure you that we will continue to help ensure that only safe and effective products are marketed and that these products meet high standards of quality.

ANTHRAX DISEASE / ANTHRAX VACCINE

As previously stated before the Committee, anthrax is an infectious disease caused by spores of a bacterium known as *Bacillus anthracis*. Human infection may occur by three routes of exposure to anthrax spores: cutaneous, gastrointestinal, and pulmonary (inhalation). Breathing in airborne spores of anthrax bacterium 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. Prior to the use of anthrax vaccine, cases of human anthrax infection in the United States (U.S.) were much more prevalent. The only FDA approved medical 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.

The clinical trials on the anthrax vaccine were conducted by Philip S. Brachman et al., during the 1950's[1] and CDC in the 1960's. The Michigan Department of Public Health (MDPH) (now BioPort) manufactured four lots of the vaccine used in the CDC study. On April 14, 1966, CDC submitted an investigational new drug (IND) application for anthrax vaccine to the Division of Biologics Standards, which was then part of the National Institutes of Health (NIH) and later transferred to FDA (now CBER). The Division of Biologics Standards determined that the data submitted by CDC supported licensure of the vaccine. On November 10,

[1] Philip S. Brachman, M.D., Herman Gold, M.D., Stanley A. Plotkin, M.D., F. Robert Fekety, M.D., Milton Werrin, D.V.M., F.A.P.H.A., and Norman Ingraham, M.D., F.A.P.H.A., Field Evaluation of a Human Anthrax Vaccine, AJPH Vol. 52,632-645, 1962.

1970, the Division of Biologics Standards issued a product license to MDPH to manufacture anthrax vaccine.

Based upon their review of available data, a 1985 Advisory Review Panel recommended that the anthrax vaccine manufactured by MDPH be classified as a Category I product (safe, effective and not misbranded) and that appropriate licenses be continued based upon substantial evidence of safety and effectiveness of this product. These findings were published in the Federal Register (December 13, 1985, Vol. 50, No. 240 p. 51002-51117).

There are also relevant non-human primate efficacy data. Previously, data had been provided to FDA indicating that anthrax vaccine protects non-human primates against a high challenge of inhalation anthrax with the Ames Strain (which is non-homologous, or dissimilar, to the vaccine strain). More recent data on animal efficacy was published in summary form by Arthur Friedlander, M.D., et al., in the *Journal of the American Medical Association* on December 8, 1999. This publication noted that non-human primates had a high level of protection against two more non-homologous strains, in addition to the Ames Strain. The Department of

Defense (DoD) has committed to submit the new data to FDA under an existing IND.

INSPECTIONS

There is currently only one FDA-licensed facility for the production of the anthrax vaccine. The MDPH originally operated the facility, which then was transferred to the Michigan Biologics Products Institute (MBPI), and finally, in September 1998, the facility was sold to BioPort.

FDA has inspected this facility on many occasions during the past decade, identifying a number of deficiencies requiring correction. In particular, FDA conducted a surveillance inspection of MBPI in November 1996. During that inspection, FDA investigators documented numerous significant deviations from the Food, Drug, and Cosmetic (FD&C) Act, FDA's regulations and current good manufacturing practices (GMPs). Based upon the documented deviations, FDA issued a Notice of Intent to Revoke (NOIR) letter to MBPI in March 1997. The NOIR letter did not mandate the closure of the facility or lead to seizure of finished product. The letter, however, did state that if MBPI's corrective actions proved to be inadequate, the

facility would run the risk of license revocation. MBPI responded to the NOIR with a "Strategic Plan for Compliance" presented to FDA in April 1997.

In February 1998, FDA conducted a follow-up inspection of the MBPI facility to evaluate MBPI's compliance with its strategic plan. The February 1998 inspection disclosed significant deviations from FDA's regulations.

FDA also noted in the February 1998 inspection that MBPI had made progress in achieving its compliance goals, but additional work remains in order to correct the deviations related to the manufacture of the anthrax vaccine. Pursuant to its purchase of the MBPI facility in September 1998, BioPort agreed to abide by the strategic plan and other commitments for corrective actions made by the management of MBPI. During the October 1998 inspection of BioPort, FDA found continuing improvement.

FDA believes that the previously manufactured and CBER released products, not presently quarantined by BioPort, are safe and effective for the labeled indications. FDA found that the firm had made progress toward meeting objectives under its strategic plan in bringing the

facility into full GMP compliance. Based on BioPort's progress to date, FDA is hopeful that the company will continue to demonstrate improvement. We will continue to work closely with BioPort to ensure that the goals outlined in their strategic plan are met.

It should be noted that MBPI halted production of anthrax vaccine sublots in January 1998, prior to MBPI sale to BioPort, to begin a comprehensive renovation of the anthrax production facility. Although there has been a resumption of manufacturing in order to produce lots in support of the license application supplement to include the renovated facility, no lots of anthrax vaccine manufactured in the renovated facility have been released.

Due to the rules of confidentiality, FDA cannot generally disclose details of, or even acknowledge the existence of, a pending application or supplement unless that information has already become public. In the case of BioPort, press reports and information made public by BioPort have disclosed various aspects about anthrax vaccine. Because the information has been made public, FDA can disclose that BioPort does have a pending supplement for renovations to their anthrax vaccine manufacturing facility. BioPort may

not release product produced in the renovated facilities until this supplement is approved. FDA will generally assess manufacturing renovations by a review of a prior approval supplement and by performing a pre-approval inspection.

In order to examine the manner in which BioPort implemented the renovations to the manufacturing facility, FDA conducted a pre-approval inspection from November 15 through November 23, 1999. It should be noted that the November 1999 pre-approval inspection was more focused in scope and purpose from the February and October 1998 surveillance inspections. At the conclusion of the November inspection, BioPort received a Form FDA 483 with observations and possible deviations in some of the following areas: validation, failure to investigate, manufacturing deviations, deviation reporting, aseptic processing, filling operations, standard operating procedures, stability testing, and environmental monitoring. All observations on the Form FDA 483 must be addressed adequately before FDA will approve this supplement.

LOT RELEASE

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. Before a lot of anthrax vaccine can be used, the manufacturer must submit a sample of the vaccine lot and a lot release protocol to the Agency. The lot release documents contain the results of the manufacturer's tests for potency, safety, sterility and any additional assays mandated by their license and a summary of relevant manufacturing details. FDA reviews the manufacturing and testing information provided in the lot release protocol and may elect to perform confirmatory testing on submitted samples. The manufacturer may not distribute a lot of the product until CBER releases it. The lot release program is one component of FDA's multi-part strategy that helps assure products quality.

No lots of anthrax vaccine manufactured in the renovated facility have been released.

VACCINE ADVERSE EVENT REPORTING SYSTEM

Following FDA issuance of an approved license, there is continued post-marketing surveillance of the product by monitoring adverse events. For vaccines, this is accomplished through the Vaccine Adverse Event Reporting System (VAERS), which was initiated in 1990 and is jointly managed by FDA and CDC. VAERS receives reports from vaccine manufacturers, private practitioners, State and local public health clinics, and vaccinees themselves (or their parents or guardians). VAERS accepts all reports of suspected adverse events after administration of any U.S. licensed vaccine to individuals in any age group. Vaccine manufacturers, however, must report to FDA all reports of adverse events of which they are aware.

VAERS is a "passive" surveillance system. This means that it relies on health professionals, patients or guardians to submit reports of adverse reactions following vaccination. (An "active" surveillance system, in contrast, would follow all individuals in a defined population to determine their responses to vaccination.) To encourage reporting of any adverse event suspected of being vaccine-induced, the criteria for reporting to VAERS are non-restrictive. In

effect, the system accepts and includes any report submitted, no matter how tenuous the possible connection with vaccination might seem.

Generally, VAERS does not establish causality but is essential to the discovery of potential rare adverse consequences of medical products that may not become evident until many thousands or millions of people have been exposed to them.

VAERS REPORTS FOR THE ANTHRAX VACCINE

FDA receives adverse event reports on the anthrax vaccine through a system similar to other adverse event reporting systems within the Agency. They are filed directly by health professionals as well as by patients or families. Reporting of adverse events associated with the use of anthrax vaccine is voluntary for individual healthcare providers but, as stated above, the vaccine manufacturer must report to FDA all reports of adverse events of which they are aware. It should be emphasized that adverse event reports can be made by a healthcare professional, a patient or anyone. If a patient's physician does not file a VAERS report, the patient can do so. FDA protects the

confidentiality of patients reporting adverse events. FDA encourages individuals to report to VAERS any clinically significant adverse event occurring after the administration of any vaccine licensed in the U.S. 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 http://www.fda.gov/cber/vaers.html.

CBER handles numerous inquiries from individuals concerning the anthrax vaccine. Individuals who believe they have experienced an adverse reaction are encouraged to report and provide information on filing a VAERS report. Forms are mailed and faxed to individuals upon request and individuals also are referred to FDA's website.

Since the beginning of VAERS operations in 1990, through September 15, 2000, 1561 reports of adverse events associated with use of the anthrax vaccine have been reported to VAERS. FDA understands, based upon information from BioPort, that from 1990 to present, approximately 2,000,000 doses of the vaccine have been distributed.

Of those reports, 76 are considered serious events, which are events considered either fatal, life threatening, or resulting in hospitalization or permanent disability. These reports are for diverse conditions, such as hospitalization for severe injection-site reaction, Guillain-Barré syndrome, widespread allergic reaction, aseptic meningitis and multi-focal inflammatory demyelinating disease. There are no clear patterns emerging at this time. The remaining reports describe a variety of symptoms, including injection site hypersensitivity, injection site edema (swelling with fluid in tissue), injection site pain, headache, joint pain and pruritus (itching).

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. With the exception of injection site reactions, all of the adverse events noted above 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. With all vaccines, as the number of people that receive the vaccine increases, so will the number of adverse events reported to FDA. Thus, our knowledge of the vaccine will grow accordingly. FDA continues to view the anthrax vaccine as safe and effective for individuals at high risk of exposure to anthrax, when used in accordance with the approved labeling.

THE ANTHRAX VACCINE IMMUNIZATION PROGRAM OF DoD

FDA did not have an official role in the development or operation of the DoD's Anthrax Vaccine Immunization Program (AVIP), 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 18 months. Subsequently, FDA learned that DoD had formally adopted this plan.

In July 1998, DoD requested that the Department of Health and Human Services (DHHS) 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 DHHS in the fall of 1998 as the Anthrax Vaccine Expert Committee (AVEC). AVEC has met approximately every three to six weeks since fall of 1998. These experts have been reviewing all VAERS reports for the anthrax vaccine. Representatives of National Vaccine Injury Compensation Program (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.

CONCLUSION

We appreciate the Committee's interest in the Anthrax Vaccine, Adsorbed and BioPort. FDA will continue to work with BioPort, as we would with any manufacturer, in an appropriate manner to resolve all situations involving pending submissions and inspectional issues. By manufacturing products in a facility that is operating in a

full state of GMP compliance, FDA can help assure that any product that is released by the company is safe and effective. Additionally, we will continue to monitor adverse event reports that are submitted through VAERS. FDA continues to believe that the vaccine is safe and effective protection for those individuals at high risk for exposure to *Bacillus anthracis* when used in accordance with the label.

Mr. BURTON. Thank you. Mr. Elengold, how many strains of anthrax are there, do you know?

Mr. ELENGOLD. I could look it up in my notes, Mr. Chairman. But we have Dr. Friedlander, who's an expert in that. And if you don't mind, I'd defer to him.

Mr. BURTON. Sure. How many strains of anthrax are there?

Colonel FRIEDLANDER. Let me say first that in my personal judgment as a physician and a scientist, and based upon working with anthrax, and having taken the vaccine myself for more than 20 years that this vaccine is safe and effective, and it's the best vaccine we have available to protect against this disease.

Mr. BURTON. Thank you, Colonel, for that testimony. But what I'd like to know is, how many strains of anthrax are there?

Colonel FRIEDLANDER. So far as we know, anthrax is very uniform. Isolates appear to be essentially identical.

Mr. BURTON. We were told that there were 27 strains of anthrax. Is that not correct?

Colonel FRIEDLANDER. That's not correct.

Mr. BURTON. There's only one strain of anthrax?

Colonel FRIEDLANDER. No, there are multiple isolates and they're very closely related.

Mr. BURTON. Does the vaccine protect against all of them?

Colonel FRIEDLANDER. All of them that have been tested in the best animal model, yes.

Mr. BURTON. And there has been extensive testing?

Colonel FRIEDLANDER. Yes.

Mr. BURTON. Why is it the Institute of Medicine has stated that there is a lack of research to show the anthrax vaccine is safe and effective for inhalation exposure?

Colonel FRIEDLANDER. I can't answer that without having a much closer look at that.

Mr. BURTON. You're not familiar with their report?

Colonel FRIEDLANDER. I am familiar with the studies that we've done that have shown that it is effective in the best animal models.

Mr. BURTON. In the animal models?

Colonel FRIEDLANDER. Yes.

Mr. BURTON. How many long term studies have there been in human beings?

Colonel FRIEDLANDER. In terms of the studies in humans, it is unethical to do human challenge studies.

Mr. BURTON. So how do you know there's no problem with human beings? You're relying strictly on the animal studies.

Colonel FRIEDLANDER. We have to, because of our inability to do such studies in humans, rely on the best animal models that reflect and are closest to humans.

Mr. BURTON. So there have not been any long term studies on human beings?

Colonel FRIEDLANDER. Unless there was an episode or there were volunteer challenge studies, which would be unethical to perform.

Mr. BURTON. This is Dr. Arthur Friedlander, a senior military scientist, is here today.

Mr. ELENGOLD. That's the Colonel that's just been——

Mr. BURTON. Oh, I'm sorry, Dr. Friedlander, excuse me. You authored the only peer-reviewed efficacy study on anthrax in the 1999

edition of the medical textbook Vaccines. You wrote that the current anthrax vaccine is unsatisfactory for several reasons, including that there is evidence in rodents that the efficacy of the vaccine may be lower against some strains of anthrax than others. Did you write that?

Colonel FRIEDLANDER. Those statements were made in reference to an idealized vaccine, a goal that we are all approaching. The critical, important qualities in terms of the vaccines are its safety and its potency. The vaccine was shown to be safe before licensure. And the best available vaccine is the one that we have.

Mr. BURTON. But you said the current anthrax vaccine, this was in 1999, is unsatisfactory for several reasons, including that there is evidence in rodents that the efficacy of the vaccine may be lower against some strains of anthrax than others. You said—I mean——

Colonel FRIEDLANDER. I believe there is a followon statement in that very sentence that states that in the best animal model, the non-human primate, that the vaccine was effective against all the strains that were tested.

Mr. BURTON. But there was some question about it in the rodents that were tested, I guess.

Colonel FRIEDLANDER. We believe the best animal model that reflects the human is the non-human primate.

Mr. BURTON. But you did have a different result when you dealt with rodents?

Colonel FRIEDLANDER. We don't believe that that's the best model for humans.

Mr. BURTON. I hope you're right. I hope you're right. You've given out a lot of vaccine.

Mr. CRAGIN. Chairman Burton, if I could just correct the record, sir. I think there may have been some confusion in your colloquy with Colonel Friedlander. He was talking about inhalation studies on humans, indicating that of course that would be unethical. You may have been talking about studies relating to reactions to the inoculation of the vaccine on humans.

I just wanted to make sure that at least the record reflected that the colloquy may have been as a result of the confusion.

Mr. BURTON. The study on the primates, with primates, that was through inhalation of the anthrax virus? OK.

Let me ask you a question, Mr. Elengold. You said that they are not producing any vaccine at BioPort now because they have not passed all the requirements at FDA, is that correct?

Mr. ELENGOLD. What I said, Mr. Chairman, was they are not producing any products except, that in order to license a product, we require that a firm manufacture several lots to show that they can do so in GMP and consistently. They have manufactured some lots for that purpose, but none of them have been submitted for lot release.

Mr. BURTON. And they also have to be clean, pure and——

Mr. ELENGOLD. In order for any product to be released from that plant by the FDA, we have to resolve the potency test supplement, which is pending, we have to resolve the facility supplement, which is pending, and then they will have to submit the lots to us for individual lot release, testing, and ultimately lot release.

Mr. BURTON. The vaccine that's being used, or has been used by the military, 2 million shots, I guess, have been administered to 480,000 troops according to the testimony today, was that all manufactured before the current BioPort facility?

Mr. ELENGOLD. That was manufactured before the shutdown for renovation.

Mr. BURTON. And how old are some of those lots?

Mr. ELENGOLD. Some of those lots I believe go back to about 1995.

Mr. BURTON. So they're 5, 6 years old, some of them?

Mr. ELENGOLD. Yes.

Mr. BURTON. Have all those lots been tested by the FDA to make sure that there's no problem with them?

Mr. ELENGOLD. All lots, before they are released, are submitted, the batch records are reviewed, the testing by the manufacturer is reviewed and we then conduct certain tests on them. We do not have the capacity at the Food and Drug Administration to conduct the potency tests.

Mr. BURTON. How did squalene get into any of these lots?

Mr. ELENGOLD. We became aware of that a little over a year ago, after some publications and allegations. At that time, we conduced a second review of all the batch records and manufacturing at BioPort, and could not find any record of squalene in the plant or being used in any production.

To check the allegations, we issued an assignment to our field organization to go out to the DOD depots and pick up both the lots that were mentioned in the Vanity Fair article, which were lots 20 and 30, as well as some other lots that we could find in those facilities. There was no reliable method for testing for squalene, in very, very minute quantities. The smallest methods we could find were in parts per million, a lower level than when it is used as an adjuvant. So we set about and developed our own test method in our laboratories, using our ability to set standards and obtain data on very minute quantities. We found, in lots 20 and 30 between 10 parts per billion and 20 parts per billion.

Now, "none" is a changing term in science, unfortunately. Members of the Congress will remember the debates over the old Delaney amendment, which said that no part of a carcinogen could be in a food. And as science progressed from parts per hundred to parts per trillion, suddenly you were able to find things that were previously believed not there.

Squalene is a naturally occurring substance that is present in every human body as part of the cholesterol processing chain. It's also present in fair amounts in things like olive oil. We found between 10 parts per billion and 20 parts per billion. As used in an adjuvant in the licensed Italian flu vaccine, it is used in levels that are 1 million to 2 million times that level. It is not unreasonable in a fermented product like AVA to expect some of the product in there to contain oils that are naturally occurring. These limits are so small that as I said, until we developed this test, the answer would have been "none."

So based on the information that we looked at and found, and the fact that this is a naturally occurring compound in the human body, these extremely low levels, 1 to 2 millionths of which is prov-

en to be an adjuvant, we decided was within the realm of both "naturally occurring" and "safe."

In addition to that, there is much literature about the safety of squalene as an adjuvant and we can provide some papers from the literature to the committee on that.

Mr. BURTON. So there would be no adverse side effects because they found squalene in any of these batches?

Mr. ELENGOLD. As I said, at the levels of 10 and 20 and 30 parts per billion, we do not believe that there would be any adverse effect, or that it is a different situation from what has occurred from this product from the first day it was produced.

Mr. BURTON. You said you believe that. Can you say categorically there would be no side effects from having squalene?

Mr. ELENGOLD. No, sir.

Mr. BURTON. You can't say that. That was a very long diatribe you just went through, now you're telling me that you can't say categorically that it's not going to cause side effects.

Mr. ELENGOLD. As I said, Mr. Chairman, things in science are constantly evolving and levels of detection go down. I cannot categorically say that a certain test or certain data may become available at some point.

Mr. BURTON. Did the FDA ever tell authorities or anybody that there was no squalene in any of these vaccines?

Mr. ELENGOLD. No, sir.

Mr. BURTON. Nobody ever said that?

Mr. ELENGOLD. Not that I'm aware of.

Mr. BURTON. My staff expert here says that the FDA said that no licensed vaccine in the United States that is being used has squalene in it.

Mr. ELENGOLD. Squalene as an adjuvant, I believe was the entire sentence. Again, we're talking levels of 1 to 2 millions of something that's been found to be effective.

Mr. BURTON. Let me tell you something. I've heard these arguments about all kinds of vaccines. My grandson, I'm sure you've heard me talk about him before. He got nine shots in 1 day and he received something like 40 some times the amount of mercury that is tolerable in a child in 1 day. And he's now autistic.

Now, I've had people say, my gosh, those microamounts of mercury probably wouldn't hurt. But you know, they took mercury off the market when it was in topical dressings, because they didn't want it to leach into individuals. But he's autistic, and they still have mercury in vaccines as well as aluminum and formaldehyde and other things that may cause problems.

So when somebody says something like, you know, we don't believe this, I think we ought to be a little more specific. You just don't know if the squalene in there is causing a side effect, do you?

Mr. ELENGOLD. No, sir.

Mr. BURTON. Thank you.

Now, let me ask you about the amount of vaccine that you have. You have to give these vaccines, as I understand it, over a period of what, about 2 years?

Mr. ELENGOLD. Eighteen months.

Mr. BURTON. Eighteen months. You give one shot and then you give it again in 30 days?

Mr. ELENGOLD. Two weeks.
Mr. BURTON. Two weeks. Then you give another one in?
Mr. ELENGOLD. Four weeks.
Mr. BURTON. That's three. Then you give another one in?
Mr. ELENGOLD. I have to take out my visual aide.
Mr. BURTON. In any event, you've run out of vaccine.
Mr. ELENGOLD. Six months, 12 months and 18 months.
Mr. BURTON. OK. Now, I've been told that the only way for the vaccine to be effective is for you to go through the entire sequence of events. And if you stop somewhere along the line, because you run out of vaccine, then the efficacy of the vaccine is very questionable.

Now, what are you doing with all these people that have not received the entire regime of six vaccines? Do you start all over again? Any of you. Let's say you've given the three shots and you've run out of vaccine.

Mr. ELENGOLD. There is general guidance that is available from the Advisory Committee on Immunization Practices, which is general, not specific to the anthrax vaccine. So I want to stress that.
Mr. BURTON. I understand.
Mr. ELENGOLD. That in cases where it is interrupted for reasons beyond control, that it should be resumed at the point the series was stopped.
Mr. BURTON. Is that true for the anthrax vaccine?
Mr. CRAGIN. Let me ask Dr. Jarrett Clinton, our Acting Assistant Secretary, to also elaborate on that, Mr. Chairman.
Mr. BURTON. Are you related to the President?
Dr. CLINTON. No, I'm not.
Mr. BURTON. It wouldn't make any difference, anyhow, I'm just curious.

Dr. CLINTON. We are following the advice of the Advisory Commission on Immunization Practices at CDC, as referred to by the FDA spokesperson. We are not deviating from the schedule, but we suspend the schedule when the active duty service member who's had the shots leaves the high risk area. We do that because we do not have sufficient vaccine. And as indicated in the opening statement, when we do have sufficient vaccine, we will pick up their schedule where they dropped off.
Mr. BURTON. But you don't start all over again?
Dr. CLINTON. We do not. That's on the basis of the recommendation from the Centers for Disease Control.

One of the powerful things about the immune system is its memory. And we have studies, we don't need to go into great detail here, but basically, when we've had individuals who have only had one or two or three anthrax vaccines, as was the case in the Gulf war, and then follow them up a couple of years later and give them one or two shots, we find that 90 to 100 percent of them respond rapidly to a 100fold increase in their antibodies level, because the immune system remembered that they are to respond again to that.

So all of this is encouraging, that the subjective judgments made by the advisory committee are correct. And that is our plan.

Mr. BURTON. OK, I think you answered my question. You can pick it up where you left off. You don't have to start the whole series over again.

Dr. CLINTON. That's correct.

Mr. BURTON. And it will be just as effective against whatever strains of anthrax that we're talking about.

Dr. CLINTON. That's correct, Mr. Chairman.

Mr. BURTON. And that will be effective against all strains of anthrax?

Dr. CLINTON. Well, that's an interesting question. I think you've already heard some response on it. The anthrax disease works with an agent called PA. And our vaccine is an anti-PA. And any anthrax that has PA in it, we believe theoretically will work.

Mr. BURTON. You believe theoretically?

Dr. CLINTON. Well, in medicine, I can't say always or never. Because things are always changing. But everything we know, everything's that's biologically plausible in terms of even the genetically engineered anthrax, if they engineer to the point that the PA isn't there, then it's no longer anthrax, they've made some other kind of bug.

Mr. BURTON. OK.

Dr. CLINTON. We believe it's biologically plausible that it's effective.

Mr. BURTON. Thank you.

You know, we've been told, and I have a whole host of questions, when my colleagues come, we'll have to let them ask some questions. But we've been told that there are a lot of biological agents that could be used in a battlefield situation to immobilize a potential enemy. You know, they used mustard gas in World War I, I believe, and they've used a lot of other agents. The sophistication of our potential adversaries has grown dramatically, i.e., Saddam Hussein and others.

Are there other potential agents that could be used in lieu of anthrax in a battlefield situation?

Major General WEST. Sir, I think the possibility certainly exists, that there are other biological agents that our potential adversaries either have or are trying to weaponize. What we know is, from our intelligence collection, is that there are several of them that have definitively pursued anthrax, and in some cases, we know they have it. In one case, we know that they deployed it on the battlefield, that they pointed it at our forces, and that their small unit commanders had permission to use it under certain situations.

Fortunately, we have safe and effective protection against that biologic agent. We don't have safe and effective protection against all of them that are possibly out there. But this one, we do. And we truly feel we would be remiss not to use it.

Mr. BURTON. If you are a potential adversary of the United States, and you knew we had a vaccination against anthrax, would you go ahead and produce that kind of a weapon, or would you produce something else to attack our forces?

Major General WEST. What we knew before we started the vaccine program was that they already had it, and they had it in great quantities. We knew that a lot of it had been produced. And we

knew that if we didn't develop protection that they would be inclined to use it, if we got into a battlefield situation.

So we went to the available protection that was there, that the people that our country depends on to say so, consider it safe and effective to use.

Mr. BURTON. I understand, General, but it just seems to me if I were an enemy of the United States and I knew that you had developed a vaccine, if it was effective, and of course there is some question about that, because it's never been fully tested, but I would probably opt for something else in the long term.

Major General WEST. I think it does keep them from using it, sir. There are an awful lot of civilians that will be glad they don't, too, because we have protection.

Mr. BURTON. Do you think we ought to immunize the entire civilian population with this vaccine?

Major General WEST. I think when there's enough vaccine available that civilians that want it should be allowed to take it. And I personally would encourage my family members to take it, if it were available.

Mr. BURTON. You saw the problems with the people who were here today.

Major General WEST. Yes, sir, I did. And I have the same kind of compassion for people that get sick or lose loved ones that you and the rest of the committee do. But when you take a population of half a million people and give them vaccine, some of them are going to go on to get sick. Eventually all of us, and I'm one of those half a million, are going to die. But that doesn't mean that everybody that gets sick or dies that that illness or that death was caused by the anthrax vaccine.

In fact, sir, I think that one of the people that was here today that we spent the most time on, both the military hospital that reviewed his case, a civilian hospital that was called in to consult on that case, and the civilian AVEC review committee, determined that his illness was not related to the anthrax vaccine. And your staff knows that, and we saw it on the wall today. And there was a lot of emotion about that, as though anthrax vaccine caused Mr. Edwards' illness.

Mr. BURTON. You're saying Kevin Edwards was not affected by the vaccine?

Major General WEST. I do not believe he was, sir. Neither do the experts at Brooke Medical facility or the experts at Emory University nor the civilian AVEC review committee. They all believe that it was non-related.

Mr. BURTON. Well, I think that's a matter of conjecture. Mr. Edwards and his father both feel that the onset of the problems he had came shortly after he had the vaccine. And they're convinced otherwise.

Anyhow, we did have another person who testified today and we have his medical records from Walter Reed here. And it says that there's no question that it was anthrax intoxication that caused him his problem.

Major General WEST. Of course, Mr. Colosimo's problem, the doctors do believe, was caused by the anthrax vaccine. And as Dr.

Walker testified, occasionally that happens. It happens in very small numbers, and we wish it didn't happen at all.

Mr. BURTON. We had 10 people up there today.

Major General WEST. Yes, sir.

Mr. BURTON. We had two ladies, one whose sister died and one's husband died. And we have the autopsy and the coroner's report. Then we had these others that had very similar experiences after getting the anthrax vaccine. Do you discount what they said?

Major General WEST. What I would tell you, sir, is that of all the people that were here today, there is only one person that has a medical diagnosis that directly links it to vaccine. And that was only a portion of his medical problems.

There was one other person here today that lost a loved one that one person said could be connected to the vaccine. There are other medical experts who believe it was not.

Mr. BURTON. Believe, believe, believe. But categorically, you can't say that they weren't caused by that. You can't say that about the gentleman that we had up on the screen who suffered dramatically as well and is losing his sight.

But I don't want to get into a big long discussion or argument with you, General. I'd like to ask Mr. Cragin a couple of questions.

You've been serving, I think in an acting capacity over at DOD what, for a couple of years now?

Mr. CRAGIN. In various capacities, yes, Mr. Chairman.

Mr. BURTON. Have you ever been confirmed by the Senate? I'm just curious.

Mr. CRAGIN. I have been confirmed by the Senate in a former capacity.

Mr. BURTON. But not in this current one?

Mr. CRAGIN. Not in the current one.

Mr. BURTON. How come you haven't appeared before them for confirmation?

Mr. CRAGIN. I operate on the premise that the President hasn't chosen fit to nominate me.

Mr. BURTON. Oh, is that the only reason? I was just curious, because I hadn't heard.

Mr. Cragin, I'm intrigued by this so-called evolution to an alterative acquisition strategy. What does that mean?

Mr. CRAGIN. Let me ask Dr. Anna Johnson-Winegar to respond to that question, if you wouldn't mind, Mr. Chairman.

Mr. BURTON. Sure.

Dr. JOHNSON-WINEGAR. Thank you, sir.

As indicated in Mr. Cragin's statement, the Department has initiated some attempts to modify our acquisition strategy, since we admit that being in a situation where there is a single source for the anthrax vaccine is not the most optimal position for the Department.

So the two steps that we have taken, that he indicated, are as follows. First, we advertised in the Commerce Business Daily for second sources, for other vaccine manufacturing companies, other biotechnology companies, other companies who may have an interest in getting into this business, to indicate their interest and willingness to become a second supplier of the current anthrax vaccine adsorbed.

As he indicated, we received five positive responses. We are continuing to evaluate those and will pursue the time, the cost and the other advantages of those.

A second step that we have taken is to initiate efforts to look at a Government owned-contractor operated vaccine production facility, as was referenced in Senator Hutchinson's statement, although he was not here this morning. We have begun the discussions and the planning and the conceptual thinking that would go into that, and would like to consider that as our long-term strategy for vaccine production.

Mr. BURTON. How long has there been an anthrax threat out there by a potential enemy?

Major General WEST. We suspected for a number of years that the Soviet bloc, several members of that bloc, had anthrax capability.

Mr. BURTON. How far back?

Major General WEST. I don't know the exact year, sir. But it's been several years. When we went into the Desert Storm conflict, we believe that Iraq already had it. We didn't know for certain that they had it until after the conflict was over. We reviewed the intelligence and documents and interviewed personnel, and the subsequent peace enforcement investigations were made.

Mr. BURTON. Well, this vaccine was licensed, what, over 30 years ago? How come, with the possible threat of an anthrax attack, has it not been mandated for service people until now?

Major General WEST. I can't tell you that one categorically, either, sir. I can tell you that as the years have gone by, we've become more aware of the threat. Once the Soviet Union dissolved and their scientists and our scientists sat down and talked about some of the things that they have made, we found out that the agent that was most lethal and had been made in the greatest quantities, was anthrax. And we found out some of the places that it had gone. And we found out that some of those places were our potential adversaries, and we wanted to give our service men and women protection.

We don't want to make anybody sick or cause anybody to get deathly ill. But I also don't want to sit in front of you some day after we send a force in harm's way, have them run into an aerosolized anthrax exposure and explain to you why we had hundreds of thousands dead when we had protection available to keep them from dying.

Mr. BURTON. I was in the Army, General, and I understand the hierarchy in the military, the officers want to make sure the rank and file and people who are in combat are going to be protected. But because of the apparent side effects, which cannot be categorically denied here today, it seems to me as our subcommittee report requested in the findings, that every member of the armed services should be fully informed about the possible side effects and they should be able to either accept or reject the vaccine, because they are concerned about the potential side effects.

And it seems to me that because we have never had long term testing, and I understand the reasons why you can't do that, because you haven't had long term testing, it seems to me that until you know more about it than you already do, that the members of

the military ought to be made aware of the possible side effects, and be given some latitude in the decisionmaking process.

And to start talking about court-martialing people or giving them less than honorable discharges because they have not gone along with it, because they feel there's a threat to themselves or their families, and our report does indicate that there's some question about that, even if you don't agree with it, it seems to me that it's a constant drain on personnel. We've lost a lot of people in our reserve units, in our National Guard units. This issue is not going to go away.

And as a result, the morale in many parts of the military is not as high as it ought to be. So I'd just like to say that I think the whole way you're handling this in the military ought to be re-evaluated. It ought to be changed. I know that you're recalcitrant, I know you aren't going to do what we want you to do, even though the Congress, this is supposed to be a civilian government and the Congress is supposed to have some say in what's going on in the military.

But in any event, the Secretary of Defense and the President and everybody said, we're going to go ahead with this. And the bit's in the teeth, and you're going to go ahead with it.

Major General WEST. May I respond?

Mr. BURTON. Yes, I'll let you respond. But I really think that the members of the military ought to have more information, more of a say. I know what you're going to say next, that you've got to have them all inoculated, because you're going into a combat situation, you can't have people half inoculated and half not, because you'll lose half your force, that would be a very difficult thing to control. Is that what you're going to say?

Major General WEST. That would be part of my answer.

Mr. BURTON. I thought so.

Major General WEST. It would be very, very difficult to take care of the half of your force that wasn't vaccinated, and it would keep the half that was vaccinated busy taking care of them when they could be fighting and winning on the battlefield.

Mr. BURTON. Seems to me the only people you'd put in a combat situation were those that, if you thought you had that kind of threat, that would have been inoculated.

But in any event, I don't want to get into a big, long dissertation or argument. We have 5 minutes on the vote, and I've got to go back over there. And I don't want to keep you all day.

Let me just say that we would like to submit to you, Mr. Cragin and Mr. Elengold, all of you, a series of questions. We would really appreciate it if you could answer those as quickly as possible.

We will probably have more hearings on this, but we want to make sure we get as much information from you as possible, so that they'll be productive.

And with that, we want to thank you very much for being here, and we will be submitting questions to all of you. We hope you will respond. You will respond, will you not?

Mr. CRAGIN. We look forward to receiving them, Mr. Chairman.

Mr. BURTON. Thank you.

With that, I ask that my opening statement and other documents that we want to put in the record be put in the record. Without objection, so ordered.

Thank you very much. We stand adjourned.

[Whereupon, at 3:32 p.m., the committee was adjourned, to reconvene at the call of the Chair.]

[The prepared statement of Hon. Tim Hutchinson and additional information submitted for the hearing record follows:]

TIM HUTCHINSON
UNITED STATES SENATOR ● ARKANSAS

Statement

October 3, 2000

Contact: Sue Hensley (202) 224-2358

Senator Tim Hutchinson Testifies on Need for GOCO Vaccine Production Facility

Senator Tim Hutchinson, chairman of the Senate Armed Services Personnel Subcommittee, made the following statement today before the House Government Reform Committee:

"Chairman Burton, Mr. Waxman, members of the Committee, thank you for inviting me to testify this morning. While my efforts in the Senate have not focused on the Anthrax Vaccine Immunization Program with the laser-like focus of the Committee on Government Reform, the excellent body of work you have compiled complements my efforts to change the Department of Defense's vaccine acquisition strategy. You see, it is my belief that the BioPort/anthrax debacle provides lawmakers with an excellent case study, one which illustrates that the Department's present policy of relying on the private sector to provide vaccines critical to the protection of our men and women in uniform is fatally flawed and must be changed. There exists a growing consensus that the Department of Defense must shoulder the responsibility and begin to produce biological warfare vaccines for itself.

In the Early 1990's, in the aftermath of the Gulf War, recommendations were presented to senior Defense Department acquisition officials to fulfill the urgent demands of war-fighters to develop vaccines against biological agents. One of the principal recommendations was for the construction of a Government-Owned, Contractor-Operated (GOCO) vaccine production facility. Detailed and thoughtful studies presented many merits to the GOCO approach. Without listing all of its merits, I will point out that the GOCO option would guarantee the country access to a vaccine supply immune from the foibles of a profit-driven pharmaceuticals industry.

For reasons that remain a mystery to this day, the Defense Department did not elect to pursue the safer, GOCO option. Rather, the Department chose to contract with a private-sector entity we now know as BioPort, for the vaccine against the biological agent anthrax.

Since embarking on this acquisition strategy, events have proceeded as many had feared they would; disastrously. Last summer, the Defense Department awarded the BioPort corporation extraordinary contract relief to a previous contract for the production and vulnerable storage of the anthrax vaccine. The terms of the contract relief reduced the number of doses of vaccine to be produced by one-half, charged the U.S. taxpayer almost three times as much as was originally negotiated, and provided BioPort with an interest-free loan of almost $20 million. BioPort officials have stated that even this may not constitute enough support. I question the fitness of whoever negotiated such a horrendous arrangement on behalf of the American taxpayer.

In July, because of BioPort's continuing troubles, the Department was forced to dramatically scale back the scope of Phase One of the immunization program because the rapid rate of vaccinations threatened to consume the last of the Department's stockpile of FDA approved vaccine. Now, only those personnel who are deployed to high-threat regions, such as the Persian Gulf and the Korean peninsula, will receive vaccinations. As it appears increasingly apparent that neither additional lots of vaccine, nor the new

production line in East Lansing, will receive FDA approval anytime soon even this dramatically reduced effort may completely exhaust the Department's supply of vaccine, leaving our troops vulnerable.

As the Department is preparing to transition into production of the first of more than a dozen new bio-war vaccines developed under the Joint Vaccine Acquisition Program, it was apparent to me that unless we wish to repeat the mistakes of the past, a new acquisition strategy is urgently needed.

Mr. Chairman, my colleagues and I on the Senate Armed Services Committee are making efforts to prevent the Defense Department from continuing to pursue a flawed acquisition strategy. Through oversight hearings and legislative provisions within the National Defense Authorization Bill, we are actively providing the Department with some much needed guidance.

On April 14th, I chaired the second of three Committee hearings on the topic of vaccine production. During that hearing, DOD personnel who had advocated the GOCO route in the early Nineties, and were overruled, were given the opportunity to testify. Their testimony is perhaps the most important the Committee has received all year on this topic.

At a third Committee hearing, conducted in July, the Department announced that it had published a solicitation for a second-source of the Anthrax vaccine. As the Department received only cursory inquiries from the pharmaceutical industry during the required thirty day period, this effort appears to have failed.

In response to the testimony received by the Committee, I drafted Section 221 of the Senate's Fiscal Year 2001 National Defense Authorization Bill. Section 221 requires the Secretary of Defense to conduct a reevaluation of the present vaccine acquisition strategy. The report will include an evaluation of the commercial sector to meet DOD's vaccine requirements and a design for a Government-Owned, Contractor-Operated vaccine production facility.

Section 221 also notes that a significant body of work regarding this topic was assembled in the early 1990's, including Project Badger, which recommended that a GOCO vaccine production facility be constructed at the Pine Bluff Arsenal in my home state of Arkansas.

I fully expect that my provision will be included in the Conference Report that we will soon send to the President for his signature.

In addition to hearings and legislative provisions, I have begun a dialogue with numerous personnel within the Office of the Secretary of Defense. I would be remiss if I did not mention the many productive conversations I have had with the Under Secretary of Defense, Rudy deLeon. Because Secretary deLeon is relatively new to his position and has little ownership over the flawed decisions of the past, he has been very willing to explore alternative acquisition strategies including the solution I favor: construction of a Government-Owned, Contractor-Operated vaccine production facility. As evidence of his commitment to find a solution, vaccine production was the first topic discussed by the Defense Resources Board, which Secretary deLeon chairs, when it met to begin its preparation of the Defense budget submission for Fiscal Year 2001.

I have encouraged Secretary deLeon to include $25 million in the FY02 Defense budget submission for R&D, in addition to $400 million in the next version of the Department's Fiscal Years Development Plan, to cover construction costs. To ensure that funding for this project does not come at the expense of other critically needed bio-defense programs, I will soon meet with the Director of OMB. I am hopeful that I can explore with Mr. Lew ways to increase the top-line of the Defense budget to cover the expense of this project.

Mr. Chairman, I thank you for holding this hearing. For too long DOD has pursued a flawed acquisition strategy that is a disservice to both the American taxpayer and our men and women in uniform. The Department must be weaned from its dependence on the private sector for the provision of critical biological warfare vaccines. I appreciate the opportunity to testify about this important topic, and share with you my efforts, experiences and insights."

WRITTEN SUBMISSION FOR THE RECORD
FOR GOVERNMENT REFORM COMMITTEE HEARING
ON ANTHRAX VACCINE IMMUNIZATION PROGRAM – WHAT HAVE WE LEARNED?
HELD ON OCTOBE 3, 2000
2154 RAYBURN HOUSE OFFICE BUILDING

STATEMENT OF CAPTAIN JAMES GALLAGHER JR., USAF
Sept. 29, 2000

I am a C-5 pilot at Dover AFB, DE. I would like to testify to the Congress to shed light on my personal experience with the anthrax vaccine. I have reported my case to many levels of the chain of command and yet when I look at the official statistics concerning vaccine reactions, my case has never been included. Based on my experience I find fault with numbers reported by the Anthrax Vaccine Expert Committee (AVEC) and I would like to help set the record straight.

I began taking the anthrax vaccine in November 1998. I was very concerned at first with a wide range of information about the vaccine. Ultimately, I decided to trust in our military leaders and the FDA and so I followed my orders to take the shot. By April 1999 the situation had changed and my earlier faith was tested. Several members of my squadron began to suffer from unexplained illnesses and the FDA product approval was questioned with allegations of squalene additives (a point that Congressman Metcalf has recently confirmed). During this time period the Air Force Surgeon General, Lt. General Roadman, visited Dover AFB to address our concerns. He closed his comments with sage advice when he concluded, "It all comes down to a matter of trust." As the numbers of sick coworkers mounted, I found it impossible to put blind faith in my commanders. I wrestled with the decision of whether or not to take the vaccine again. After delaying my fourth shot by three months I was finally ordered to get the shot or face disciplinary action. On 14 September 1999, I chose to take the vaccine and I have regretted that decision every day since.

The day I took my fourth dose of the anthrax vaccine I began to feel extremely fatigued. My daily pattern became going home every night and falling asleep at 7:00 PM. I would wake up 11 hours later and still feel tired throughout the day. Four days after that shot, the pain started in my hands and wrists. I began to experience pains whenever I would use my hands for any purpose, no matter how small. Flying airplanes through this pain became difficult and so I knew I needed help. After a three-month process of visiting a rheumatologist, immunologist, and endocrinologist I was finally diagnosed with Hashimoto's thyroiditis, an autoimmune disorder. After being sick for several months, the best thing to happen to me was to find a name for my disease. I now take a pill every day and all of my symptoms have been alleviated. I will require medication every day for the rest of my life but at least the pain and fatigue are gone.

Ironically, having a name for my problem is why I feel compelled to report my condition to this committee. The origin of my symptoms can be traced to the day when I took my fourth anthrax shot. I was concerned before taking this shot, so I had an extensive blood screening a month prior to my fourth vaccination. These test results were all normal to include an Anti Nuclear Antibody (ANA) screening, a general test for the presence of autoimmunity. Just a month after being vaccinated, my blood tested positive for ANA and showed high levels of thyroid antibodies. Despite this evidence suggesting causality, let me be the first to tell you that this does not prove a causal relation. Hashimoto's thyroiditis, and for that matter all autoimmune disorders, has NO KNOWN cause. Last week in a briefing I was told that the AVEC has determined that only one person from Dover AFB has suffered a serious reaction to the anthrax vaccine. I have personally seen five other people from my base become afflicted with autoimmune disorders, which will affect them for the rest of their lives. In all cases the symptoms begin shortly after anthrax vaccinations. Capt. Michelle P. also suffered through autoimmune thyroiditis and pernicious anemia. A reserve Lt. Col. Jay L. and his chief engineer suffer from rheumatoid arthritis. Another reservist suffers from what could be lupus. A flight engineer in my squadron, SSgt. Mike M. spent 78 days hospitalized in Walter Reed after contracting Chronic Inflammatory Demyelinating Polyneuritis. We all suffer from autoimmune disorders where our bodies for some reason can no longer tell the difference between germs and self; and so our immune systems attack assorted body parts with varying results. All of us suffer from diseases of unknown origin, yet the DOD is convinced that the anthrax vaccine could not possibly be a causal factor.

Shouldn't we all be alarmed at this rate of illness in a military unit, the likes of which none of my colleagues has EVER experienced? In a May 1999 briefing, our head flight surgeon, Lt. Col. Luna, stated that in his entire career he had only treated 5 autoimmune patients and if he should ever encounter five such patients on one base that we could bet he would get to the bottom of it. Instead what I perceive from the medical community is that my case and the others have been bagged, tagged, and shelved. There is no known cause to what ails me and so it must not be anthrax related. No one is searching for a cause to all this illness. I am not a doctor, so I don't have access to extensive medical resources. However, I have been able to research my medical condition on my own time and have found some interesting insights. A study by Dr. Y. Shoenfeld and A. D. Cohen in 1996[1] and another by Dr. Noel R. Rose in 2000[2] suggest that there is perhaps a link between vaccines and autoimmunity but that more research is necessary. In a Feb 2000 study Dr. Shoenfeld and Dr. A. Aron-Maor state that, "the temporal relationship [between vaccination and onset of autoimmune disorders] (i.e. always 2-3 months following immunization) is impressive"[3]. The state of modern medicine may never prove beyond a shadow of doubt what happened to me and my fellow soldiers but I do believe that I know one of the unknown causes of autoimmunity and that is the anthrax vaccine.

My message for you is that the AVEC numbers you see reflect only a small fraction of the people who are sick from this vaccine. GAO stated that the VAERS system only captures 1 to 3% of vaccine reactions[4]. After a VAERS report is submitted it is scrutinized to a point where the final numbers capture only a fraction of the true picture. The end result is then presented to the National Command Authority and the troops as the best information we have about anthrax vaccine safety. Is it any wonder that these numbers show the safest vaccine ever fielded? Our leaders will only make decisions that are as good as their information. Our troops are left to match these numbers with what they see around them, their sick friends and coworkers. General Roadman had it right when he said it was all a matter of trust and that is the real casualty of the current reporting system. At our last anthrax education briefing our commander presented us with the 'real facts' about anthrax reactions straight from the AVEC. After the brief he opened the floor for questions and TSgt. Dave summed it all up best. He said that he would follow orders and take the vaccine but he did not want to and would not if given the choice; he said that you can say whatever you want about the vaccine but he did not trust any of it.

<<SIGNED>>

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Author's note: Some names edited for privacy

References:

[1] Cohen AD, Shoenfeld Y, "Vaccine-induced autoimmunity", Journal of Autoimmunity, Dec 1996; Vol 9 No. 6, 699-703

[2] Rose NR, "Immunologic Hazards Associated with Vaccination of Humans", Journal of Autoimmunity, Feb 2000, Vol 14, No. 1

[3] Shoenfeld Y, Aron-Maor A, "Vaccination and Autoimmunity-'vaccinosis': A Dangerous Liaison?", Journal of Autoimmunity, Feb 2000, Vol 14, No. 1

[4] House Government Reform Committee Report on AVIP

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary
for Legislation

Washington, D.C. 20201

Mr. David Rapallo
Professional Staff Member
Committee on Government Reform
#512 Ford Office Building
U.S. House of Representatives
Washington, D.C. 20515

Mr. Rapallo:

Please find attached, per the minority staff's request, a fact sheet on the Anthrax Vaccine Expert Committee (AVEC). The committee operates under the Health Resources and Services Administration (HRSA), with funding and various HHS liaison representatives as described in the summary. HRSA prepared the attached information. Please call me with any questions concerning this information or the sample attachment.

Sincerely,

Jack Mitchell

Jack Mitchell
Office of the Assistant Secretary for Legislation

In June 1998, to help ensure an objective evaluation of anthrax vaccine safety, the Surgeon General of the United States Army requested the creation of an independent civilian panel to provide ongoing medical assessment of adverse events reported to the Vaccine Adverse Event Reporting System (VAERS) following anthrax vaccination. The Department of Health and Human Services (DHHS) accepted this responsibility and moved to create the Anthrax Vaccine Expert Committee (AVEC), a panel of private sector physicians and scientists with expertise in vaccines and vaccine adverse events. The work of AVEC is supported with liaison representatives from HRSA, FDA, CDC, and DoD. AVEC is charged with the responsibility for conducting causality assessments of anthrax vaccine adverse event reports submitted to VAERS. AVEC also looks for signals of possible trends in the reviewed material. AVEC is tasked with preparing written summaries of their findings for regular publication in the peer reviewed medical literature. AVEC also provides its findings with regard to the need for additional research and/or surveillance. AVEC is not an advisory committee.

The membership of AVEC has included civilian medical experts in diverse fields such as rheumatology, immunology, virology, general internal medicine, pediatrics, and neurology. Also included are scientific vaccine experts in the fields of statistics and epidemiology. The medical experts are responsible for the assessment of the causal relationship between the anthrax vaccination and the adverse event. AVEC members are not government employees. They are compensated for their time and efforts through a contract with the Department of Health and Human Services. The first year of this project was funded by HRSA with money transferred to HRSA under a MOU from the National Vaccine Program Office in CDC. The second year was funded by HRSA with money transferred to HRSA under a MOU from DoD. Future years will be funded in the same way as the second year.

To maintain confidentiality, patient identifiers (name, address, telephone number, and birth date except for the year of birth) are redacted from all forms by the VAERS contractor before they are forwarded for AVEC review.

One of the first tasks completed by AVEC was the creation of a case assessment form onto which the AVEC medical reviewer could abstract information from the VAERS material related to causality (see tab 1 for a copy of the current case assessment form). If more medical information is needed, AVEC seeks follow-up information on the case through the VAERS contractor. The AVEC medical reviewer develops a preliminary opinion concerning the causal relationship between the anthrax vaccination and each adverse event reported. The reviewer's preliminary assignment of causality is reviewed by all the medical experts on AVEC at periodic phone conferences and agreement is reached on how each question on the case assessment form will be scored. AVEC members who are not physicians (epidemiologist, statistician) and liaison members do not vote on how the case assessment form is scored.

The assessment of causality employs a scale defined by the World Health Organization. A "very likely/certain" causal relationship is assigned to an event that occurred at a plausible time and has no reasonable alternate explanation. A rating of "probable"

applies when the event occurred at an appropriate time and it seems unlikely that it could be attributed to concurrent diseases or exposures. A classification of "possible" is assigned if the event could also be explained by concurrent disease or exposure. A score of "unlikely" is given if the event occurred after the vaccination but other factors appear to be the likely cause. An event whose time of onset was not compatible with vaccination or where there is a definite alternate cause was scored as "unrelated". Cases with insufficient information to rate causality were labeled as "unclassifiable".

Information from the case assessment forms and original VAERS reports are coded and keyed into an ACCESS database. In addition, the ACCESS database was merged with a VAERS database provided by the FDA that contains COSTART (Coding Symbols for Thesaurus of Adverse Reaction Terms) codes for all reported signs and symptoms. Denominator data regarding persons given anthrax vaccine was obtained from the Defense Medical Surveillance System (DMSS). These databases are being organized to produce the raw data needed for the publication of AVEC's findings in the medical peer reviewed literature.

DoD figures show that 1,859,506 doses of anthrax vaccine have been administered to 463,027 people as of August 30, 2000. As of October 2nd, 2000, AVEC has reviewed 1,170 VAERS forms , of which 17 were duplicates, for a total of 1,153. The total number of VAERS forms received by the VAERS contractor is 1,511 reports. 341 VAERS forms are currently being processed and are awaiting AVEC review.

After each meeting the AVEC has concluded that no significant signals of previously unknown or unsuspected adverse events were noted. An AVEC subcommittee, consisting of committee members, is currently reviewing all reports of Guillain Barre Syndrome reported to VAERS after Anthrax vaccine. The subcommittee is also reviewing cases of paresthesia reported after the vaccine. A report will be presented to the full AVEC. The AVEC is also preparing a manuscript for peer reviewed medical publication on the results generated from the first year of AVEC review. It is anticipated that the manuscript will be completed by the end of the year.

AVEC is modeled on the Advisory Committee on Causality Assessment in Canada. It is proving to be a novel and useful tool for the evaluation of vaccine safety here in the United States.

Anthrax Vaccine Expert Committee - Case Assessment Form

VAERS #:

1. Vaccine(s): Anthrax Dose #: Lot #: Vaccine(s): Dose #: Lot #:

1.1 Adequate Information: O Yes O No

1.2 Primary Reason / Event for reporting:

1.2a Time period to onset of symptoms and signs after vaccination: Duration

1.3 Type of Event: O Local O Systemic O Both Outcome O Recovered O Improving O Chronic

2. The questions below are related to the primary reason / event for reporting:

		< 1%	1 - 5 %	> 5%
2.1 Frequency of occurrence of the adverse event:	NPR* O	Rare O	Intermediate O	Common O

2.2 Similar events known to occur with other disease:		O Yes	O No	
2.3 Event is known to be related to the vaccine:		O Yes	O No	
2.4 Event is explainable by the biological properties of the vaccine:		O Yes	O No	O Unknown
2.5 Contributing factors (VAERS# 7,18,19):		O Yes	O No	O Unknown
2.6 a. Patient had similar symptoms in the past following Anthrax vaccine:	O N/A	O Yes	O No	O Unknown
b. Patient had similar symptoms in the past following vaccination:	O N/A	O Yes	O No	O Unknown
c. Patient had similar symptoms in the past *not* following vaccination:	O N/A	O Yes	O No	O Unknown
2.7 Concomitant or preceding condition (VAERS# 7,18,19,21):	O Rel*	O Yes	O No	O Unknown
2.8 Concomitant or preceding drug therapy (VAERS# 13,14,17):		O Yes	O No	O Unknown

2.9 Vaccine-event interval compatible with the event (VAERS# 10,11):
O N/A O Typical O Compatible O Incompatible O Unknown

* **NPR:** not previously reported to VAERS **Rel:** assessment of causality to be done in context of primary reason / event for reporting

3. Conclusion with regard to the primary reason for reporting:

3.1 The causal relation or association is:
O Very likely - certain O Probable O Possible O Unlikely O Unrelated O Unclassifiable

3.2 Possible New Entity O Yes O No 3.3 Insufficient Data O Yes O No

3.4 The case would benefit from a second review: O Yes O No

3.5 Additional data needed: O Yes O No If Yes, specify:

4. Comments:

5. Recommendations:

Revised 19 Jan 99

Metcalf Report on the Potential Role of Squalene in Gulf War Illnesses

Prepared by the office of
Congressman Jack Metcalf
September 27, 2000

JACK METCALF
2ND DISTRICT, WASHINGTON

COMMITTEE ON TRANSPORTATION AND INFRASTRUCTURE
SUBCOMMITTEES:
AVIATION
GROUND TRANSPORTATION

COMMITTEE ON SCIENCE
SUBCOMMITTEE:
ENERGY AND ENVIRONMENT

Congress of the United States
House of Representatives
Washington, DC 20515–4702

COMMITTEE ON BANKING AND FINANCIAL SERVICES
SUBCOMMITTEES:
HOUSING
FINANCIAL INSTITUTIONS
DOMESTIC AND INTERNATIONAL MONETARY POLICY

CHAIR, REPUBLICAN HOUSING OPPORTUNITY CAUCUS

REPUBLICAN POLICY COMMITTEE

Statement of Congressman Jack Metcalf
Subcommittee on National Security, Veterans Affairs, and International Relations
September 27, 2000

Mr Chairman, I want to thank you for the opportunity to once again be a small part of your courageous effort to answer questions regarding Gulf War Illnesses and vaccines used by our military personnel. Your determination to move forward and find answers has provided vital leadership for this Congress on this critically important issue.

Indeed, we have an obligation to pursue the truth, wherever it may lead us. To do less would be to act dishonorably toward the dedicated men and women who stand between us and a still dangerous world.

For that reason, I have issued a report culminating a three year investigation into the conduct of the DOD (Department of Defense) with regard to **the possibility that squalene, a substance in vaccine adjuvant formulations not approved by the FDA, was used in inoculations given to Gulf War era service personnel.** According to the GAO (General Accounting Office), scientists have expressed safety concerns regarding the use of novel adjuvant formulations in vaccines, including squalene.

The report reveals that **the FDA has found trace amounts of squalene in the anthrax vaccine. The amounts recorded are enough to "boost immune response**," according to immunology professor Dr. Dorothy Lewis of Baylor University. Therefore, my report concludes that, Mr Chairman, you are absolutely correct in demanding an immediate halt to the current AVIP (Anthrax Vaccination Immunization Program).

My report further states that an aggressive investigation must be undertaken to determine the source of the squalene, and the potential health consequences to those who have been vaccinated, both during and after the Gulf War.

The report also documents at length DOD "stonewalling" attempts to resolve the squalene issue, which **GAO investigators characterized as "a pattern of deception**." The GAO stated the DOD denied conducting extensive squalene testing before the Gulf War, then admitted it after being confronted with the public record. The GAO revealed that DOD officials deliberating deployment of the anthrax vaccine expressed a "willingness to jump out and use everything," in discussing experimental vaccines containing adjuvants not approved by the FDA.

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JACK METCALF
2D DISTRICT, WASHINGTON

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GAO also found Peter Collis, DOD official who headed vaccine efforts, refused to cooperate with them. The report states that the DOD has refused to act in good faith upon the GAO recommendation to replicate the findings of a test developed by renowned virologist Dr. Robert Garry of Tulane University, although DOD admitted they could easily do so. The work of the Tulane researchers has been peer-reviewed in a scientific publication of high standing.

Finally, my report states that "Congress should take immediate action to review the findings of the GAO and the Armed Services Epidemiological Board, and provide independent oversight for the immediate implementation of their recommendations." **The board called on the DOD to engage in close cooperation with the Tulane researchers.**

Congress must get to the bottom of the labyrinth that has become known as "Gulf War Illnesses." Mr Chairman, you have been in the forefront of this effort. As I am about to leave the Congress, I just want to once again commend you for your courage in this leadership role. Please stay the course. Veterans, active service members and their families deployed around the world are counting on you. Thank you so much.

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Executive Summary

Congressman Jack Metcalf has issued a report culminating a three year investigation into the conduct of the DOD (Department of Defense) with regard to **the possibility that squalene, a substance in vaccine adjuvant formulations not approved by the FDA, was used in inoculations given to Gulf War era service personnel.** According to the GAO (General Accounting Office), scientists have expressed safety concerns regarding the use of novel adjuvant formulations in vaccines, including squalene.

The report reveals that **the FDA has found trace amounts of squalene in the anthrax vaccine. The amounts recorded are enough to "boost immune response**," according to immunology professor Dr. Dorothy Lewis of Baylor University. Therefore, the report concludes that immediate action should be taken to halt the current AVIP (Anthrax Vaccination Immunization Program). It further states that an aggressive investigation must be undertaken to determine the source of the squalene, and the potential health consequences to those who have been vaccinated, both during and after the Gulf War.

The report also documents at length DOD "stonewalling" attempts to resolve this issue, which **GAO investigators characterized as "a pattern of deception**." The GAO stated the DOD denied conducting extensive squalene testing before the Gulf War, then admitted it after being confronted with the public record. The GAO revealed that DOD officials deliberating deployment of the anthrax vaccine expressed a "willingness to jump out and use everything," in discussing experimental vaccines containing adjuvants not approved by the FDA.

GAO also found Peter Collis, DOD official who headed vaccine efforts, refused to cooperate with them. The report states that the DOD has refused to act in good faith upon the GAO recommendation to replicate the findings of a test developed by renowned virologist Dr. Robert Garry of Tulane University, although DOD admitted they could easily do so. The work of the Tulane researchers has been peer-reviewed in a scientific publication of high standing.

Finally, the report states that "Congress should take immediate action to review the findings of the GAO and the Armed Services Epidemiological Board, and provide independent oversight for the immediate implementation of their recommendations." **The board called on the DOD to engage in close cooperation with the Tulane researchers.**

Congressman Metcalf believes it is clearly within the oversight responsibility of the Congress to get to the bottom of the labyrinth that has become known as "Gulf War Illnesses." **We have an obligation to pursue the truth, wherever it may lead us**. To do less would be to act dishonorably toward the dedicated men and women who stand between us and a dangerous world, willing to die if necessary to defend our nation.

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The Request For Investigation

- **August 29, 1997 Congressman Jack Metcalf requested the General Accounting Office (GAO) investigate reports that the presence of antibodies for squalene had been discovered in the blood of some sick Gulf War-era veterans.** The assay (test) being used to detect the antibodies had been developed at Tulane University by Dr. Robert Garry, world renowned virologist.(Appendix 1)

  At the time of Congressman Metcalf's request, the research by Drs. Garry, Asa and Cao had not yet been published in a peer-reviewed scientific journal. Their work, "Antibodies to Squalene in Gulf War Syndrome," was published in the February 2000 issue of *Experimental and Molecular Pathology*. (Appendix 2)

  NOTE: Squalene is a component of adjuvant formulations used in some experimental vaccines but not in any licensed vaccines. Squalene is found in shark liver oil, some vegetable oils, and the human liver and can also be manufactured through chemical engineering. (GAO/NSIAD-99-5).

Section One
The Investigation: A Pattern of Deception

- **September 1997 - March 29, 1999 General Accounting Office (GAO) investigators initiated their study and completed the report "GULF WAR ILLNESSES: Questions About the Presence of Squalene Antibodies in Veterans Can Be Resolved"** (GAO/NSIAD-99-5). The investigation was significantly slowed by government officials withholding or presenting incomplete information, ***leading GAO investigators to document their concerns questioning a "pattern of deception."*** (1) The following six dated entries are found in the background material for the GAO report. They illustrate the pattern of deception that clouded the investigation.

  November 14, 1997 GAO entrance conference with Department of Defense (DOD) officials. GAO notes state,
  1) "They said DOD had not performed or sponsored any research on synthetic or natural squalene or squalane until after the Gulf War. The sponsorship was through two CRADAs [Cooperative Research and Development Agreement]. However, they could not tell us who the CRADA's were with, what stage they were in, or what tests had been performed.
  2) "Squalene was used in two experimental adjuvants, after the war and involving fewer than 100 subjects. These were for HIV and Malaria vaccines. They said NIH had also used in some of their research protocols. DOD officials also stated that DOD was involved after animal testing stage." (2)
  In background papers, GAO investigators stated, "However, GAO found evidence of several other studies in our searches of publication databases, references and articles. ***Various DOD officials gradually acknowledged on a piece meal basis that their clinical research had started before the war,*** *that they had conducted 5 clinical studies with squalene and had planned a sixth, that the size of these studies was increasing and now has involved 572 human subjects, and that some of these studies were purely their own investigational New Drug (IND) Studies.* ***Moreover they had conducted numerous animal studies, particularly to develop a modern vaccine for anthrax. In fact, in most cases they only admitted to conducting research after we had discovered it in public records. On three occasions people attending a meeting did not report their own research on squalene adjuvants."*** *(3)*

  December 10, 1997 GAO entrance conference with Food and Drug Administration (FDA) officials. GAO investigators noted that it was a very productive meeting and recorded:

1) "The purpose of developing new adjuvants, even though alum is safe, is to use fewer inoculations, get a better response, and to check unconquered antigens. Earlier adjuvant ran into problems in animal testing... Most of DOD's work has been with Ribi Detox for malaria. **Their person most interested in developing own adjuvants at WRAIR** [Walter Reed Army Institute of Research] **is Carl Alving.**
2) "Allied had concerns about the quality of our vaccines. Michigan had some manufacturing problems.
3) "Karen is sure DOD used plague vaccine. They pushed it. She confirmed that squalene was used in placebos.
4) "FDA testing of drugs and vaccines: Good Manufacturing Practices inspection every 2 years. Test each lot released. No routine random sample. For bot tox [botulism toxoid] they also checked for safety and sterility, but not the makeup of the compound. DOD should have reserve samples. Required to have them for each lot. **Squalene should not be there**." (4)
NOTE: See Appendix 25 regarding the discovery by FDA in 1999 of trace amounts of squalene found in limited testing of Anthrax Vaccine, Adsorbed in the lots tested.

March 30, 1998 **GAO interview with Donald Burke, Director of AIDS research for DOD during the Persian Gulf War.** GAO recorded, "Burke said he was involved with AIDS trials at time of war and purposely chose not to get involved in BWD [biological weapons defense] issues at that time... In his AIDS work he experimented with MF59 [an adjuvant containing squalene] because alum was destructive to HIV proteins. He has had good cooperation with NIH [National Institutes of Health]. He recounted various studies, including a large one with 300 subjects getting MF59. . . He suggested we talk to . . . Carl Alving about DOD adjuvant research." (5))
GAO investigators noted, "Don Burke the former director of DOD's HIV research and Debbie Birx, the current director disagreed on the existence of a large early HIV trial with squalene with over 600 volunteers. She said he was thinking of an NIH trial. However, NIH reported no trials of that magnitude. (6)

April 6, 1998 **GAO interview with Dr. Carl Alving, DOD's top adjuvant researcher.** GAO stated,
1) **"Alving opened by saying he didn't know anything about Operations Desert Storm and Desert Shield (ODS) and the vaccines that were used. He is a researcher, and an expert, but not in the policy loop**.
2) "GAO pressed why he was not consulted about gulf war inoculations given his world class expertise. He admitted that just prior to gulf war he was asked if he could develop an anthrax vaccine on a crash basis. He stated that WRAIR has manufacturing capability, Ft. Detrick does not. He could have done it in 3-6 months but never received a follow on phone call to formally authorize the work. If asked, he could have done it but would have recommended MF59 for anthrax because Chiron had the manufacturing capacity and the desire to market it. Ribi, Chiron and Hunter

were the adjuvant leaders at the time. . . He was subsequently asked again (by DOD?) to develop an anthrax vaccine using liposomes, but it and all others. . . tested failed to protect monkeys with a single shot, which he thought was an absurd criteria. But he thought commercial considerations may have driven the criteria.
3) "He also said that as the world's foremost expert on lipids he knew quite a bit about cholesterol and its precursor, squalene. He doubted that a vaccine with squalene would produce a meaningful antibody response.
4) "Analysis: Overall, the commercial links appear to be crucial to the course of DOD vaccine R&D" (7))
GAO investigators recorded the following observation in a section titled, DOD officials were less than forthcoming about their role in Gulf War vaccine decision making: *"Carl Alving, DOD's top adjuvant researcher was not included in our meetings at WRAIR where he worked, nor even mentioned as someone we should interview. However, both NIH and FDA had said he was the person at DOD most involved with adjuvants. We subsequently met and while he acknowledged that he was probably the army's best expert on adjuvants, he at first denied having any role in the gulf war vaccine deliberations. After Kwai Chan left, Sushil Sharma pressed him on this, asking how could it be that they would discuss these issues without their principle expert. He then remembered that he had been called by someone from the army's biological warfare defense program at USAMRID [United States Army Medical Research Institute of Infectious Diseases], who asked if he could develop a new, more potent anthrax vaccine on a crash basis to use in the Operation Desert Shield. He worked on it and thought he could do it, but no one ever called him back. He wouldn't say who called from USAMRID or why he just didn't return the call."* (8))

April 19, 1998 Interview with Dr. Anna Johnson-Winegar, Director Environmental and Life Sciences, key participant in the tri-service committees advising on the science and vaccine production issues.
1) "Project Badger. [Tri-Service Task Force established prior to the Gulf War, (9/90) to investigate ways to increase production of biological warfare vaccines.] Badger was a discussion about the scientific issues involved in improving troop vaccine coverage. Discussions were wide-ranging and interesting, e.g. nonspecific immune enhancements, but there was not much data. Carl Alving was our in-house adjuvant expert, and a participant in our discussion. [Dr. Alving first told GAO he did not have any role in the gulf war vaccine deliberations, then minimized his involvement.] We discussed using liposomes, but they didn't have enough. You have to go to war with what you have, not novelties that don't have your full confidence.
2) " Adjuvants discussion and recommendations. Discussion of adjuvants was limited. Its one thing to discuss interesting phase 1 research, quite another to apply it to short term shortages. In the long run they can be of potential use. But scientific inference doesn't lead to immediate military operations. Some in the group were willing to jump out and use everything. (She refused to say who.) Our group advised

the Surgeon General who in turn worked with the JCS. There was not any data on what happens to people getting the anthrax and botulism vaccines at the same time. But we had to do it.

3) "Safety issues. There was little discussion of long term safety issues. They were thinking short term and immediate. Generally inactive vaccines don't have a problem. They used inactive antigens. But there were a lot of discussions regarding GMP [Good Manufacturing Practice] issues. For instance, they had trouble finding the exact same fermenter. Getting approval for a new one could take FDA 30 months. They went ahead started production with it and got retroactive approval. Anthrax vaccine is stable for up to 20 years if kept at right cool temperature." (DI-9)

NOTE: In a DOD Badger document File 120396_sep96_decls10_0002.txt, Subject: Desert Shield Biological Warfare HOC Working Group, the following statement is found:

"It was reported that the individuals from logist___ USAMRIID, were expected back from theater today with the ___ anthrax and botulinum vaccines, antitoxin, ribavirin and centoxin. While in theater the items were under refrigeration; however, there was a report that the refrigerator failed to operate for a period of time and possibly these items were damaged. The items will be re___ to USAMRIID and a determination made with regard to the disposition." (Appendix 3)

GAO notes state, "Anna Johnson-Winnegar played a major role in Project Badger, leading the effort seeking the urgent assistance of vaccine manufacturers. She sat in on most of the Project Badger meetings addressing BW defenses. Our interview with her revealed several contradictions. At first she said they had limited discussion about adjuvants, but then added that discussions were wide ranging and interesting, e.g. nonspecific immune enhancements, but there was not much data to base a decision. Alving, she said, was their in-house adjuvant expert, and a participant in their discussions. Some in the group felt is was one thing to discuss interesting Phase 1 research, quite another to apply it to short term shortages, ***but others were willing to jump out and use everything. She declined to tell us who advocated pushing forward the use of experimental vaccines.*** *" (10)*

April 23, 1998 **GAO meeting with General Ronald Blanck, Surgeon General of the Army, a discussion on the deliberations, decision making of DOD on vaccine production and administration for the Persian Gulf War.** GAO summarized Gen Blanck's recollection:

1) "One manufacturer, Michigan for both botulism and anthrax vaccine. We had a fair amount of anthrax vaccine but only a small amount for botulism (BT). However, we found Iraqis might have F and G strains so we contracted with Porton to make them. To best of his knowledge none were administered. We got it but didn't use it. Everything we used was from Michigan. Salk at Swiftwater had the capacity to help produce, but got nothing from them. He got NIH to approve NCI use.

2) "Novel Adjuvants Use. Blanck recalled no discussion of boosting immunogenicity with novel adjuvants. He was certain nothing was added to the products at Michigan. They decided to not do anything outside of the FDA. The anthrax vaccine used alum as an adjuvant.
3) "Who else should GAO interview. We should talk to Winnegar and Collis as planned. **Collis headed oversight for Badger and vaccine efforts**..." (11)

The following GAO statement summarized the failed attempts to interview Peter Collis. ***"Peter Collis, the chairman of the tri-service task force, Project Badger, repeatedly declined to talk to us.*** *First he said he could not meet unless he had the classified project summary to ensure his recall was accurate. We said we could provide those. Then he said as a civilian without a clearance he could not look at the notes. [GAO could proceed with process to obtain a temporary clearance for him.] Then he called declining one last time saying he really didn't know much. However, the Project Badger notes clearly show him to be at the hub of all the discussions, and that he conducted the briefings about the committees recommendations."* (12)

- **September 11, 1998** **GAO exit Conference with DOD officials.** GAO investigators record:
1) "We presented a summary our principal findings of our job on Squalene and Gulf War Illnesses, 713014. DOD officials stated that **if the independent researchers have developed a good test for squalene antibodies, there was no reason to wait for publication. The researchers could share it with DOD and they could cooperate on further research and development concerning squalene and Gulf War illness**. This could be done through a CRADA which would protect the rights of the independent researchers. DOD would like to validate the test, particularly its specificity.
2) " DOD officials again acknowledged that they had the know how to develop such an assay and could have tested for squalene antibodies but did not... They stated that DOD could do the screening for antibodies to squalene for veterans who are ill along with a larger battery of tests, but they would have to think through the health administration consequences because they didn't want to do screening if they were not prepared to act on the results. Colonel Takafuji concluded that the questions raised by the independent researchers are going to come back to DOD." (13)

Section Two
The Stonewalling and Obfuscation

- **March, 1999** **GAO presented to Metcalf their findings (GAO/NSIAD-99-5).** GAO recommended DOD not wait for the peer-review and publication process, but take immediate action to: **"conduct research designed to replicate or dispute the independent research results** that revealed the presence of squalene antibodies in the blood of ill Gulf War-era veterans." Surprisingly, DOD's comments regarding the GAO recommendations, contained in the report, **accused GAO of being "scientifically and fiscally irresponsible," even though their own officials had stated there was no reason to wait for publication**. (14) The GAO report stated, "Safety concerns have been cited regarding the use of novel adjuvant formulations in vaccines, including squalene, and the associated adverse reactions. It has also been suggested that the safety of vaccines containing these formulations must be evaluated in conservative ways." (GAO/NSIAD-99-5 Page 3)

- **May 13, 1999** **Congressman Metcalf wrote Secretary of Defense William Cohen challenging DOD's refusal to carry out the GAO recommendations, and encouraging DOD to get to the truth by doing the research necessary to validate or dispute the Tulane test results.** (Appendix 4)

- **May 24, 1999** **Dr. Carl Alving called Dr. Robert Garry of Tulane, and indicated his "purely scientific" interest in Dr. Garry's work.** Dr. Alving also asked to review a draft of the manuscript on anti-squalene antibodies which was subsequently published. Dr. Garry agreed to fax him a copy of the *in progress* work for his personal review, requesting that he not circulate the copy. **Dr. Garry was not made aware of Dr. Alving's intent to circulate the paper and publicly subject it to scathing reviews as published on the DOD website prior to publication.** (Appendix 5)

- **May 25, 1999** **Dr. Russell Wilson of Autoimmune Technologies, Tulane's exclusive licensee for the anti-squalene antibodies technology, sent a letter to Dr. Carl Alving sharing information, and offering to provide information regarding the ASA (anti-squalene antibody) assay and research with DOD.** (Appendix 6)

- **May 28, 1999** **Dr. Sue Bailey, Assistant Secretary of Defense for Health Affairs, provided GAO the DOD's final response to the March, 1999 report.** She stated, "Our position and the concerns expressed in our comments to the draft report have not changed . . . The test methods proposed by the investigators at Tulane University need to be reviewed and validated by other scientists." ***DOD would not take action until the peer-reviewed publication process was complete.*** (Appendix 7)

- **Summer 1999** **An anonymously written DOD memo was obtained by the defense team representing five young Marines at Twenty-Nine Palms who were being court-martialed for their refusal of the anthrax vaccine.**
The six page document entitled, "Issues Relating to Antibodies to Squalene" was a scathing review by Dr. Carl Alving and Dr. Matyas of the unpublished work of Dr. Garry and his colleague Dr. Pamela Asa. It discussed the phone calls of May 24 and 25 between Dr. Alving and Drs. Garry and Wilson. With absolutely no proof, it accused Drs. Garry and Asa of an apparent anti-military agenda. **It concluded by stating "There is an obvious need for independent in-house research by the Army to examine the issues and implications, if any, of antibodies to squalene." Attached was a chart detailing a three year study, with a total cost of $1,260,834.00**. (Appendix 8)

- **July 23, 1999** **Dr. Bailey responded to Metcalf's May 13, 1999 letter to Secretary Cohen**. Once again she commented, " The Department's position and concerns have not changed from those published as Appendix VI of the GAO report." (Appendix 9)

- **September 27, 1999** **Metcalf letter to Secretary Cohen.** Metcalf replied, " . . . because of your department's years of research in this area, I ask that you reconsider and proceed with the GAO recommendations. Your current position of waiting for the completion of the peer review and publication process does not recognize the vast amount of research that the DOD has already accomplished regarding adjuvant formulations containing squalene. **The men and women who served honorably and are suffering from Gulf War Illnesses deserve truthful answers and *immediate action*.**"(Apdx. 10)

- **October 25, 1999** **Because of DOD's refusal to cooperate with GAO recommendations, Congressman Metcalf asked for congressional intervention.** With the help of Congressman George Nethercutt, the House Report to H.R. 2561, the Fiscal Year 2000 Department of Defense Appropriations Bill, included language instructing DOD to develop and/or validate the assay to test for the presence of squalene antibodies. This legislative action was signed into law by the President on October 25. (Appendix 11)

- **November 5, 1999** **Metcalf received a reply to his September 27 letter from Secretary Cohen**. While stating: "The Department's position has been consistent and remains unchanged," he went on to inform Congressman Metcalf that **a DOD investigator** has been funded to "pursue a study to determine the feasibility of developing a test for antibodies to squalene." (Appendix 12)
Although Secretary Cohen did not identify the DOD investigator, GAO discovered that DOD had awarded the study to Dr. Carl Alving. The project was not designed to replicate or dispute theTulane findings as had been recommended by GAO, but to develop a different means of testing for antibodies to squalene. (Appendix 13)

- **January 2000** **DOD provided some members of Congress a report titled, "Development and Validation of an Assay to test for the Presence of Squalene Antibodies."** It stated, "This Report has been prepared in response to a requirement of the 106th Congress, House of Representatives, Report 106-244, 2000 Department of Defense Appropriations Bill." It acknowledged that DOD had funded a DOD researcher to "determine the feasibility of developing a test for antibodies to squalene." **It did not suggest a collaborative effort with Dr. Garry and his colleagues at Tulane to save valuable time for those who are suffering from Gulf War Illnesses, even though the researchers at Tulane had expressed their willingness to assist.** (Appendix 14)

- **January 31, 2000** **Congressman Metcalf was joined by nine colleagues requesting DOD do an objective analysis** of "Antibodies to Squalene in Gulf War Syndrome" - the peer-reviewed article published in the February 2000 issue of *Experimental and Molecular Pathology* by Drs. Asa, Cao and Garry. **The question from Congress was clear, "Given the published article, it seems prudent to use the assay if it could help sick Gulf War era veterans. Do you agree?"** (Appendix 15)

- **February 25, 2000** **Congressman Metcalf sent a strong letter to Secretary Cohen asking for immediate action to remove misleading information from the DOD's official Anthrax Vaccination Inoculation Program (AVIP) website regarding the peer-reviewed, published article on squalene antibodies.** Earlier in the week, the information had been discovered, prior to receipt of the DOD's official reply to the January 31 letter. (Appendix 16)

- **February 28, 2000** **The official DOD response to the January 31 letter was delivered to Congressman Metcalf's office**. *Most of the information provided was based on a review of the early draft*, not the published study which included significant changes. The half-page critical analysis of the peer-reviewed article was anonymously written, with no indication of the author's professional credentials to conduct and provide the review. **DOD did not address the congressional question regarding the potential use of the assay to help sick Gulf War era veterans.** (Appendix 17)

- **March 3, 2000** **Congressman Metcalf challenged Secretary Cohen to halt the obfuscation campaign that DOD was waging concerning the issues surrounding antibodies to squalene research. Metcalf provided ample evidence to demonstrate his conclusion.**. (Appendix 18)

- **March 27, 2000** **On behalf of Secretary Cohen, Dr. Sue Bailey responded to Congressman Metcalf's February 25 and March 3 letters.** She acknowledged needed modifications on the DOD AVIP website to more objectively reflect the Tulane research. She also informed Metcalf that the Armed Forces

Epidemiological Board (AFEB) would convene a subcommittee of experts to review and critique the published article in response to Congressman Metcalf's March 3 letter. (Appendix 19)

- **June 2000** **An exchange of letters in Experimental and Molecular Pathology. Dr. Carl Alving and Dr. John Grabenstein submitted a critique of the Tulane research, and Drs. Asa, Cao and Garry co-authored the response**. The journal Editorial Note made the following statement: "New findings require confirmation within the bounds of comparability. This is as true for methodology as it is for the data produced from a particular study. This exchange of letters ...relates to methodology. **Drs. Alving and Grabenstein offer no data against the conclusions of Asa et al.** (Appendix 20)

- **August 10, 2000** **Congressman Metcalf was presented the DOD 'objective analysis' of the article "Antibodies to Squalene in Gulf War Syndrome" by an Armed Forces Epidemiological Board subcommittee of experts.** They concluded unanimously that the research reported in the paper does not support its claim that the laboratory test created by Dr. Garry at Tulane may identify persons ill with Gulf War Syndrome. **However, on the last page of the report, they state, " Whatever the paper's flaws and since the AFEB cannot exclude the remote possibility that the authors have identified a laboratory means of distinguishing persons with possible Gulf War Syndrome (GWS) from all others, replicability becomes the major unresolved issue...Therefore we recommended that a suitable test of replicability be done in cooperation with the authors..."** They go on to state, **" ... we are trying to ... get quickly and inexpensively to a more meaningful bottom line: does the ASA assay clearly, reliably and unequivocally distinguish people with GWS from all others, and, if so, with what specificity and sensitivity?"** (Appendix 21)

Section Three
FDA Testing Reveals Squalene in Anthrax Vaccine

For over a year, the DOD has been contracting with SRI International to test for squalene in vials of the anthrax vaccine preparations which have been and are being given to military personnel. For some time, DOD documents have made two claims regarding squalene:
1) The FDA verified that none of the vaccines used during the Gulf War contained squalene as an adjuvant; and
2) they have found NO squalene in their testing of anthrax vaccine lots. *(Appendix 13 and 22) Documents on the DOD AVIP website from SIR International confirm their tests revealed no squalene in the anthrax vaccine sent to them for analysis. (Example: Appendix 23)*

- **January 31, 2000** **Congressman Metcalf wrote the FDA asking them to confirm the following DOD statement made to Congress, "The FDA verified that none of the vaccines used during the Gulf War contained Squalene as an adjuvant."** (Appendix 24)

- **March 20, 2000** **The FDA responded to Congressman Metcalf and provided their official position.** "In fact FDA did verify to the Senate Special Investigations Unit on July 23, 1997, in a telephone conversation with Committee staff of the SIU, not with DOD, **that neither the licensed vaccines known to be used in the Gulf War, nor the one investigational product known to have been used**, contained squalene as an adjuvant in the formulations on file with FDA."

Most importantly, the FDA closed their letter with the following statement: "Very limited testing of Anthrax Vaccine, Adsorbed, conducted by CDER in 1999 determined that there were only trace amounts of squalene in the lots tested ... *(Appendix 25)*

- **Dr. Dorothy Lewis of Baylor College of Medicine sent a letter to Congressman Metcalf explaining that the test used by FDA which found low levels of squalene in Anthrax vaccine samples is a "much more sensitive technique" than the one used by DOD.** ***(Why would DOD use a less sensitive test procedure?)***

  Dr. Lewis determined, ***"The real issue is whether squalene in parts per billion was added to the vaccine preparations given to the military, as well as whether this concentration of squalene could alter the immune response."***

  While acknowledging the need for research to respond to the findings, she stated, ***"it is possible that very small amounts of a biologically active product could induce an immune response, either to the molecule itself or it could boost immune responses to other agents in the mixture."*** (Appendix 26)

CONCLUSION

1. Despite numerous denials by the Department of Defense, FDA has found squalene in the Anthrax Vaccine in limited testing. This vaccine is still being forced upon our active military duty personnel. Immediate action must be taken to halt the current AVIP (Anthrax Vaccination Immunization Program) until this matter is resolved. Aggressive research must be undertaken to determine the source of the squalene, if it could alter the immune response, and the potential health consequences to those who have been vaccinated, both during the Gulf War, and as a result of the mandatory, force-wide AVIP.

2. The recommendation of the Armed Forces Epidemiological Board subcommittee that, "...a suitable test of replicability be done in cooperation with the authors..." mirrors the findings of the GAO over eighteen months ago— "DOD should conduct research designed to replicate or dispute the independent research results that revealed the presence of squalene antibodies in the blood of ill Gulf War-era veterans."

3. Congress should take immediate action to review the findings of the GAO and the Armed Services Epidemiological Board, and provide independent oversight for the immediate implementation of their recommendations. The Department of Defense has wasted years in their determined effort to stonewall this issue. The researchers at Tulane are willing to work with DOD to pursue answers for those suffering from Gulf War Illnesses. Within a few months, and for a small investment of money, important knowledge will be acquired that may offer real hope. For the men and women who honorably serve this nation, there is no valid reason for further delay.

All footnotes are references to General Accounting Office (GAO) background working documents for GAO final report "Gulf War Illnesses: Questions About the Presence of Squalene Antibodies in Veterans Can Be Resolved, (GAO-NSIAD-99-5)March 1999.

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14. DI-13

Bolding and italics added for emphasis.

Appendices can be requested from the office of:

Congressman Jack Metcalf
1510 Longworth House Office Building.
Washington, D.C. 20515

Phone: 202.225.2605

JACK METCALF
2ND DISTRICT, WASHINGTON
COMMITTEE ON
TRANSPORTATION
AND INFRASTRUCTURE

Appendix 1

COMMITTEE ON BANKING
AND FINANCIAL SERVICES

CHAIR, REPUBLICAN HOUSING
OPPORTUNITY CAUCUS

Congress of the United States
House of Representatives
Washington, DC 20515–4702

August 29, 1997

Mr. James F. Hinchman.
Acting Comptroller General
U.S. General Accounting Office
441 G. Street NW
Washington DC 20548

Dear Mr. Hinchman:

My office has been contacted by several veterans and other constituents concerned about recent reports that the presence of antibodies for synthetic squalene has been discovered in blood samples of some Gulf War veterans.

I would like to request that you do a preliminary investigation into these reports. It is important that Members of Congress be fully informed of the facts surrounding this issue. If I can be of further assistance, please feel free to contact either myself, or Norma Smith in my Everett office.

Thank you for your attention to this matter.

Sincerely,

Jack Metcalf

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GAO
United States
General Accounting Office
Washington, D.C. 20548

National Security and
International Affairs Division

November 14, 1997

The Honorable Jack Metcalf
House of Representatives

Dear Representative Metcalf:

This letter confirms our intent to provide you with information pursuant to your August 19, 1997 request that we conduct a preliminary investigation in reports that antibodies for synthetic squalene have been discovered in blood samples of some Gulf War veterans. Norma Smith of your Everett, Washington office provided us with background regarding your request in conversations on August 29 and September 9, 1997.

Due to the complexity of issues addressed in you August 29 letter, we need to proceed with a separate design phase to examine what preliminary evidence exists for these allegations. The objectives of the study will address the following issues:

- Has DOD ever performed or sponsored any research on synthetic or natural squalene or squalane;
- was synthetic squalene used as an adjuvant in any developmental drugs and/or vaccines;
- are there any pharmaceutical firms involved in the development and production of drugs using squalene in any form;
- what tests have been done regarding its safety, efficacy and effectiveness;
- have our troops or DOD civilian personnel ever been given squalene in any form. If yes, for what purpose and under what circumstances?

The design phase will be completed by January 15, 1998. We will remain in contact with your staff, and by the end of January, we will provide you with a projected completion date for the total study. If you have any questions regarding this work, please contact me at (202) 512-3092, or my Assistant Director, Sushil Sharma, at (202) 512-3460.

Sincerely yours,

Kwai-Cheung Chan
Director
Special Studies and Evaluation

Appendix 2

Experimental and Molecular Pathology 68, 55–64 (2000)
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Antibodies to Squalene in Gulf War Syndrome

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Received September 23, 1999

Gulf War Syndrome (GWS) is a multisystemic illness afflicting many Gulf War-era veterans. The molecular pathological basis for GWS has not been established. We sought to determine whether the presence of antibodies to squalene correlates with the presence of signs and symptoms of GWS. Participants in this blinded cohort study were individuals immunized for service in Desert Shield/Desert Storm during 1990–1991. They included 144 Gulf War-era veterans or military employees (58 in the blinded study), 48 blood donors, 40 systemic lupus erythematosus patients, 34 silicone breast implant recipients, and 30 chronic fatigue syndrome patients. Serum antibodies to squalene were measured. In our small cohort, the substantial majority (95%) of overtly ill deployed GWS patients had antibodies to squalene. All (100%) GWS patients immunized for service in Desert Shield/Desert Storm who did not deploy, but had the same signs and symptoms as those who did deploy, had antibodies to squalene. In contrast, none (0%) of the deployed Persian Gulf veterans not showing signs and symptoms of GWS have antibodies to squalene. Neither patients with idiopathic autoimmune disease nor healthy controls had detectable serum antibodies to squalene. The majority of symptomatic GWS patients had serum antibodies to squalene. © 2000 Academic Press

INTRODUCTION

The illnesses afflicting men and women who served in the military conflict in the Persian Gulf during 1990–1991 remain ill-defined. A constellation of symptoms including fatigue, rashes, headaches, arthralgias, myalgias, lymphadenopathy, diarrhea, memory loss, autoimmune thyroid disease, increased allergies and sensitivities to environmental elements, and neurological abnormalities collectively referred to as Gulf War Syndrome (GWS) have been described in veterans from this conflict (Persian Gulf Veterans Coordinating Board, 1995; Grady *et al.*, 1998; Fukuda *et al.*, 1998; Unwin *et al.*, 1999; Coker *et al.*, 1999). A symptom-based case definition of GWS has recently been described (Fukuda *et al.*, 1998). While GWS patients in general do not suffer from classic rheumatic diseases, the signs and symptoms are reminiscent of entities, such as arthralgias, fibromyalgia, lymphadenopathy, autoimmune thyroid disease, chronic fatigue syndrome, malar rashes, and musculoskeletal signs and symptoms associated with various autoimmune conditions and exposure to silicone, an organic material developed, in part, to be used as an immunological adjuvant for vaccines (Ismail *et al.*, 1999; Straus, 1999; Hyams *et al.*, 1996). Many, if not most, of these signs and symptoms are caused, promoted, or modulated by cytokines (Dinarello, 1988; Akiro *et al.*, 1990), further details of which are beyond the scope of this paper. Serological abnormalities including hypergammaglobulinemia and abnormal serum proteins have been reported in 45% of GWS patients (Grady *et al.*, 1998). A variety of possible explanations for GWS have been proposed. The Persian Gulf Veterans Coordinating Board addressed the issues of possible chemical and biological

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weapons to account for these illnesses (Persian Gulf Veterans Coordinating Board, 1995). Haley *et al.* (1997) grouped various reported symptoms into six different syndromes based upon self-reported possible exposure to chemicals in the Persian Gulf. It has been suggested that a combination of chemical and biological weapons exposure may account for GWS illnesses. Abou-Donia *et al.* (1996) examined the acute effects of pyridostigmine bromide and organophosphate exposure in chickens and suggested that the toxicity observed may be similar to that suffered by Gulf War veterans. Another explanation for GWS is that it is posttraumatic stress syndrome (Hyams *et al.*, 1996).

It has also been suggested that GWS may be due to exposure to biological weapons, dysregulation of the immune system (Rook *et al.*, 1998), or imbalance in the TH1/TH2 ratio, either as an adverse reaction to the intense vaccination schedule or as a result of exposure to biological agents in the Persian Gulf (Rook *et al.*, 1998).

Gulf War veterans and attendant civilian personnel received a variety of immunizations in preparation for possible deployment to the Persian Gulf theater. A similar intensive vaccination regimen was also used in British troops (David *et al.*, 1997). Epidemiological studies indicate that multiple vaccinations or vaccination against biological warfare agents are the factors with the highest correlation with GWS symptomatology (Unwin *et al.*, 1999).

We have identified a group of GWS patients who served in American and British military forces or worked as civilian employees to the U.S. military or their contractors during Desert Shield/Desert Storm in the Persian Gulf, 1990–1991. These patients served in all branches of the military and received the required immunizations. They served throughout the Persian Gulf, including on ships of the U.S. Navy not in combat or exposed to environmental toxins at ground level. We have found antibodies to squalene, an experimental immunological adjuvant, in a high percentage of these GWS cases.

MATERIALS AND METHODS

Patients were admitted to the study based upon service in the United States or the United Kingdom military or as civilian employees of the U.S. military or their contractors in the Persian Gulf during 1990–1991. Patients became aware of the study via the Internet and word of mouth with other veterans and were enrolled consecutively on a voluntary basis. No fees were paid by the subjects or to the subjects who participated in this study. Inclusion were individuals who fit the recently proposed case definition for GWS (Fukuda *et al.*, 1998) and others without GWS symptoms. Service occurred in Desert Shield/Desert Storm, Operation Provide Comfort (in northern Iraq where there were no chemical weapons), CENTCOM in Saudi Arabia, Kuwait, Camp 4 (front lines), and medical units in various locations in Saudi Arabia. Some were in theater for months. Others were evacuated due to illness after as little as 36 h after arrival and before the war commenced. We tested deployed personnel who served in various parts in theater during the war, but were and are not sick. We tested patients referred to as nondeployed veterans, those immunized for duty in the Persian Gulf, but who did not leave the United States or were deployed elsewhere. None participated in NIH experimental vaccination trials. Although our positive control subjects had participated in such trials and were known to have received squalene-containing adjuvant reactions. Further controls had idiopathic autoimmune disease or silicone breast implants or were healthy subjects with no stigmata of autoimmune disease.

Patient records and histories were obtained from the Gulf War-era participants. Board-certified rheumatologists, neurologists, and endocrinologists made all diagnoses. Compilation of data, including commercial lab results, was done by chart review by one investigator (P.B.A.) and was reviewed by board-certified rheumatologists.[2] Serum samples from study participants were collected by laboratory personnel via standard phlebotomy procedures using vacutainer tubes and butterfly needles and were stored at −20°C until they were shipped to Tulane University School of Medicine in New Orleans. Samples from Gulf War-era veterans were blinded. The identities or exact number of samples from each category was not made available to the Tulane laboratory until after completion of the diagnostic testing. All samples were tested twice under the same conditions. Results from all samples in both tests were consistent. At the end of the study, patient data were matched with the outcome of the anti-squalene antibody (ASA) assay and results were tabulated.

Anti-squalene Antibody Assay

The ASA assay measures the binding of serum immunoglobulin (IgG) to squalene immobilized on nitrocellulose. It is similar in format to the antipolymer antibody (APA) assay

[2]Dr. D. Kevin Asa, M.D., Memphis, Tennessee; Dr. Michaela Fetni, Johns Hopkins University, Baltimore, Maryland.

for partially polymerized acrylamide (Tenenbaum *et al.*, 1997). Seropositivity on the APA assay has been shown to correlate with severe musculoskeletal signs and symptoms present in a subset of silicone breast implant recipients (Tenenbaum *et al.*, 1997). For the blinded study, squalene (>99% purity) was diluted 10-, 100-, 1000-, and 10,000-fold in distilled water, applied to nitrocellulose membranes, and allowed to air-dry. The nitrocellulose membranes were then cut into 4-mm-wide strips, placed in 20-well trays, and rinsed in wash buffer (Tris-buffered saline containing 0.3% polyoxyethylene sorbitan monolaurate and 0.005% thimerosal, pH 7.4). The strips were incubated in 2 ml blocking buffer (Tris-buffered saline containing 5% powdered instant milk, 4% goat serum, and 0.008% thimerosal, pH 7.4) for 45 min prior to the addition of 5 μl of patient sera (1:400 dilution) followed by a further 90-min incubation. This dilution factor was chosen based upon the very strong antibody responses found in GWS patients. All incubations and washes were carried out at room temperature on a rocking platform. The blocking buffer was then removed and the strips were washed with washing buffer (three times for 5 min each). After the strips were washed, 2 ml of blocking buffer containing biotin conjugated to goat anti-human IgG (Kirkengaard & Perry Laboratories, Gaithersburg, MD), diluted 1:1000, was added. After a 60-min incubation, the strips were again washed as above, and 2 μl of blocking buffer containing avidin-conjugated horseradish peroxidase (Jackson ImmunoResearch, West Grove, PA), diluted 1:500, was added. Following another 60-min incubation, the strips were washed, as above, and 2 ml of detection-buffered saline containing 30% methanol, 0.6 mg/ml 4-chloro-1-napthol, 0.03% hydrogen peroxide; pH 7.4) was added. The reaction was allowed to proceed for 15 min and was stopped by rinsing the strips in distilled water. The strips were allowed to air-dry for visual scoring on a scale of 0 to +4.

Statistical Analysis

The strength of binary relationships was tested using χ^2 tests of independence. This protocol was a feasibility study. Accordingly, no power studies were performed.

RESULTS

Primary Studies

To ascertain that our assay could detect antibodies to squalene, we had positive controls who were two subjects who had volunteered to participate in a vaccine trial at the NIH involving the use of a squalene-containing adjuvant (Table 1). Subsequent to vaccination, they developed a multisystem disorder similar to that of Persian Gulf veterans. Their symptoms are listed in Table 2.

TABLE 1
Squalene Reactivity of NIH Vaccine Trial Participants

Patient	Doses of squalene	[illegible]
A	1	
B	2	

Patient A received a single injection and became ill within 3 weeks, with signs and symptoms including arthritis, fibromyalgia, lymphadenopathy, photosensitive rashes, fatigue, headaches, and fasciculations. This patient had lower than normal acetylcholinesterase and histological evidence of IgG-mediated demyelinization. The NIH vaccine study code was broken; only adjuvant containing squalene had been administered as a placebo. This patient was weakly positive for ASA. Patient B went through the complete experimental vaccination protocol before manifesting a similar set of signs and symptoms and was +3 for ASA.

Fukuda and co-workers (1998) have reported that individuals deployed to the Persian Gulf who became ill have a chronic multisystem disease. The cohort of GWS patients in our study have many signs and symptoms of autoimmune connective tissue and neurological disease with arthritis (94%), fibromyalgia (94%), lymphadenopathy (94%), rashes (94%), weakness (86%), fatigue (81%), chronic headaches (78%), and memory loss (72%) as the most frequent symptoms (Table 3).

It should be noted, however, that most patients did not have

TABLE 2
Symptoms Which Appeared after a Single Adjuvant Injection

Arthritis
Fibromyalgia
Lymphadenopathy
Rashes
Photosensitive rashes
Malar rashes
Chronic fatigue
Chronic headaches
Fasciculations
Lymphocytic infiltrates around vascular tissue
IgG-mediated demyelinization
Lower than normal levels of acetylcholinesterase

TABLE 3
Symptoms and Diagnostic Lab in GWS Patient Groups

	D-S (%)	D-W (%)	ND-S (%)	UK-D (%)
Arthritis	94	0	100	100
Fibromyalgia	94	8	100	100
Lymphadenopathy	94	0	100	100
Rashes	94	0	100	100
Photosensitive rashes	25	0	75	100
Malar rashes	17	0	63	100
Chronic fatigue	81	33	100	100
Chronic headaches	78	0	100	100
Abnormal body hair loss	19	0	38	33
Nonhealing skin lesions	42	0	63	66
Aphous ulcers	36	0	63	66
Dizziness	47	8	100	66
Weakness	86	17	100	66
Memory loss	72	25	100	66
Seizures	14	0	50	66
Mood changes	72	0	63	100
Neuropsychiatric problems	44	0	88	66
+FANA	20	0	50	Unknown
Anti-dsDNA	14	0	Unknown	Unknown
Low C3 and C4	14	0	Unknown	Unknown
Anti-thyroid	14	0	Unknown	Unknown
Anemia	14	0	50	Unknown
Elevated ESR &/or CRP	25	0	75	Unknown
SLE	17	0	50	Unknown
MS	3	0	Unknown	Unknown
ALS	8	0	0	0
Raynaud's phenomenon	42	0	75	66
Sjogren's syndrome-	8	0	Unknown	33
Chronic diarrhea	36	0	63	66
Night sweats	36	0	88	66
Low grade fevers	39	0	88	66

Note. D-S, deployed, sick (N = 38); D-W, deployed, well (N = 12); ND-S, nondeployed, sick (N = 8); UK-D, deployed, sick, UK (N = 3).

an optimal workup for connective tissue and neurological autoimmune diseases because of the limited resources in the Veterans' Administration hospitals or military hospitals. Nevertheless, all patients reported here meet the case definition recently established (Fukuda *et al.*, 1998). In agreement with a prior study (Grady *et al.*, 1998), some of these GWS patients also had abnormal laboratory values, including positive antinuclear antibodies (ANA;17%), anti-dsDNA (14%), low C3 and C4 (14%), anemia (14%), anti-thyroid microsomal antibodies (14%), and elevated ESR and/or CRP (22%). A minority of symptomatic patients met diagnostic criteria for classical autoimmune diseases, including Sjogren's syndrome (8%), multiple sclerosis (3%), ALS (8%), and systemic lupus erythematosus (17%).

Likewise, military personnel from the United Kingdom have shown the same array of signs and symptoms as those from the United States. Their signs and symptoms included arthritis (100%), fibromyalgia (100%), lymphadenopathy (100%), rashes (100%), chronic fatigue (100%), chronic headaches (100%), and memory loss (66%). Laboratory data are not unavailable for this group. They also had malar rashes, Raynaud phenomenon, and sicca syndromes. Thus, our cohort represents a subset of veterans that displays manifestations of GWS. The severity of symptoms in our cohort can be explained by a self-selection bias in that the patients volunteered for our study.

Persons activated to deploy who were vaccinated, but did not deploy for a variety of reasons, had an array of signs and symptoms with even higher frequencies of arthritis (100%), fibromyalgia (100%), lymphadenopathy (100%), rashes (100%), weakness (100%), fatigue (100%), chronic headaches (100%), and memory loss (100%) (Table 3). The nondeployed individuals had higher rates of dizziness (100%), seizures (50%), and neuropsychiatric abnormalities (88%). The number in this group was small, and these differences were not statistically significant. Laboratory values for the nondeployed individuals with GWS were abnormal, with positive ANA (50%), anemia (50%), and elevated ESR and/or CRP (75%).

In contrast, abnormal signs, symptoms, and laboratory values were rare in the cohort of Gulf War-era veterans who considered themselves well and upon examination did not have debilitating health problems. They reported some signs and symptoms, but their illnesses were not multisystemic (Table 3). The signs and symptoms reported included fibromyalgia (8%), chronic fatigue (33%), weakness (17%), memory loss (25%), and thyroid disease (8%). None reported positive laboratory values for autoimmune processes or were so diagnosed.

Musculoskeletal signs and symptoms are more common in females than males, and autoimmune diseases are predominantly found in females in ratios ranging from 8:1 to 14:1 (Michet *et al.*, 1985; Geirsson *et al.*, 1994). We wished to determine why predominantly male military personnel, both deployed and nondeployed, initially found fit for duty during the war, would develop signs and symptoms common to autoimmune diseases. Many studies have shown that adjuvants used to enhance vaccine efficacy can induce autoimmune disease (Zamma, 1983; Lorentzen *et al.*, 1995; Madzhidov *et al.*, 1986; Kleinau *et al.*, 1995). Thus, we sought whether GWS patients who received immunizations had antibodies to an immunological adjuvant. Squalene was chosen as it has been used in many experimental vaccine adjuvant formulations since 1987. A variation of a previously

described assay, one which measures the binding of serum antibodies to low-molecular-weight polymers (Tenenbaum *et al.*, 1997), was used in the current study. This immunological assay, similar in format to Western immunoblotting, quantitates the binding of antibodies to squalene immobilized on nitrocellulose (Fig. 1). Serum samples were tested blindly. We found that GWS patients who deployed had ASA responses ranging in intensity from +1 to +4. Most of the sick Gulf War veterans had +2 and +3 reactivity to squalene at a serum dilution of 1:400. One individual had an especially strong reaction rated as +4. A high majority (95%) of symptomatic deployed individuals with GWS were positive on the ASA assay (Fig. 2A).

Interestingly, all sick veterans who did not deploy but had received immunizations as preparation for deployment also had antibody reactivity to squalene. In contrast, none of the persons deployed to the Gulf who thought of themselves as well were ASA positive.

Other Studies

Squalene is an organic polymer, with some antigenic epitopes which might be shared with other organic polymers, acting as immunostimulants. Antibodies to silicone and partially polymerized acrylamide (the antigen in the antipolymer assay) were weakly positive in fewer than 10% of the symptomatic Gulf War-era veterans. Four patients with musculoskeletal signs and symptoms and exposure to silicone breast devices were tested to see if antibodies to squalene were present; none were reactive (see below). To determine if antibodies to squalene occurred in idiopathic autoimmune diseases, samples were taken from patients who had defined autoimmune diseases, both rheumatic and neurologic, but none were reactive. To determine if healthy individuals from the general public might have antibodies to squalene, we tested members of the general public. Again, none showed antibody reactivity (Table 4).

In a broader unblinded antibody-screening study, antibodies to squalene were studied in larger groups of individuals (Fig. 2B). Blood samples of Gulf War veterans from different medical centers were tested for ASA. This group contained a high percentage of ASA-positive individuals (63%). The samples included were not segregated according to their clinical status and included healthy controls. Squalene is in some cosmetic products, so we tested to determine if antibodies were present in the general population. Samples of blood from blood banks indicated only 5% antibody reactivity to squalene and the reactions were much less intense (Fig. 1). To determine if antibody to squalene was a marker for autoimmune disease processes, tests were conducted on blood samples from patients with systemic lupus erythematosus. This group had 10% ASA weakly positive reactivity (Fig. 2B). Patients suffering from chronic fatigue syndrome have some of the signs and symptoms of GWS patients, but showed only 15% weak reactivity. Prior studies have shown that most individuals exposed to silicone breast devices with

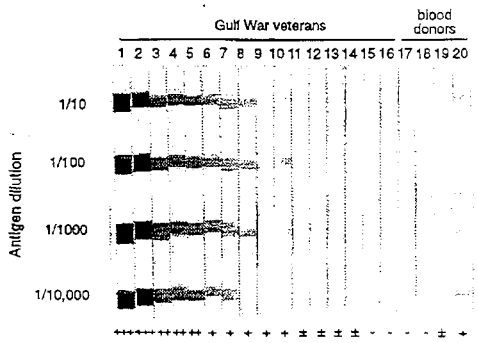

FIG. 1. Antisqualene antibody responses in representative Gulf War Syndrome patients and blood donors.

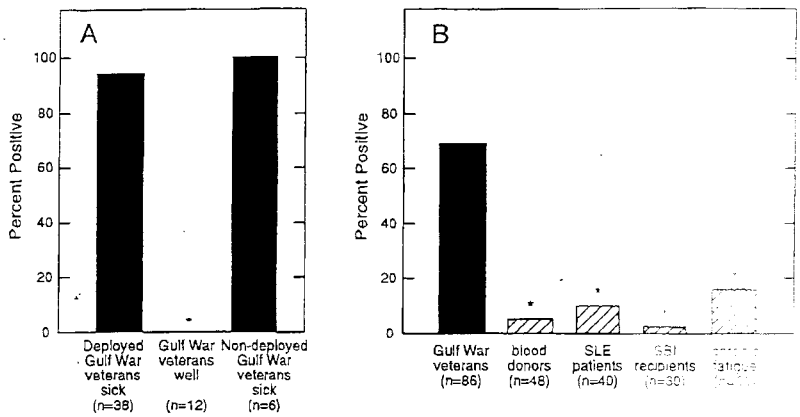

FIG. 2. Antisqualene antibody responses in Gulf War Syndrome patients, blood donors, systemic lupus erythematosus (SLE) patients, chronic fatigue syndrome patients, and symptomatic silicone breast implant (SBI) recipients. (A) Blinded samples. *, $P < 0.001$ compared to percentage positive in well Gulf War veterans by χ^2 test. (B) Unblinded samples. *, $P < 0.001$ compared to percentage positive in Gulf War Syndrome patients.

severe musculoskeletal signs and symptoms have serum antibodies reactive to a synthetic polymer (polyacrylamide) (Tenenbaum *et al.*, 1997). Both silicone and acrylamide, like squalene, are potent immunological adjuvants (Naim *et al.*, 1997; Nicholson *et al.*, 1996; Yoshida *et al.*, 1994; Sergott *et al.*, 1986). Therefore, we tested for cross-reactive antibodies to squalene in serum from patients exposed to SBI. Only 10% of this group were weakly positive for antibodies to squalene (Fig. 2B), confirming the results with the smaller sample in the blinded portion of the study.

TABLE 4
Squalene Antibodies—Blinded Study Patient Groups

Patient group	ASA reactivity (%)
D-S	95
D-W	0
ND-S	100
UK-D	100
Breastimplants	0
NIH vaccine participants	100
Idiopathic autoimmune disease	0
Healthy general public	0

Note. D-S, deployed, sick ($N = 38$); D-W, deployed, well ($N = 12$); ND-S, nondeployed, sick ($N = 8$); UK-D, UK deployed, sick ($N = 3$); NIH vaccine trial patients ($N = 2$).

DISCUSSION

The illnesses afflicting military veterans and civilians who served in the Persian Gulf in 1990–1991 have remained clouded in confusion and controversy. Several recent studies have indicated that the Gulf War-era patients are suffering from a chronic multisystemic illness, but with a continuum of signs and symptoms not within the definitions of "classic" rheumatic diseases or other specific disorders (Fukuda *et al.*, 1998; Ismail *et al.*, 1999; Straus, 1999). In some, onset of illness occurred within a few weeks after receiving immunizations. This includes personnel never deployed due to illness. It also included some who did deploy, but were in theater for as little as 48 h before being sent home before the war began because of severe joint and muscle pain and neurological problems. Other Gulf War veterans became ill

years after the war, but showed illnesses similar to those who became ill soon after vaccination. The variability of expression of symptoms and severity may be due to individual immune responses genetically regulated by the histocompatibility complex (Lorentzen *et al.*, 1995; Madzhidov *et al.*, 1986).

Our results suggest that ASA reactivity is a marker for the signs and symptoms of GWS. Finding serum antibodies to squalene in Gulf War patients is unexpected, and the basis for the presence of these antibodies remains unclear. ASA are not a general marker for autoimmune disease due to their absence in idiopathic autoimmune patients and rarity in patients with other, presumed environmentally induced, autoimmune diseases. The signs and symptoms of our Gulf War patients are similar to those of a subset of female patients following exposure to silicone. Some individuals with silicone exposure suffer from many of the multisystem symptoms, viz, arthralgias, myalgias, lymphadenopathy, and neurological disorders prevalent in GWS patients in the current study (Bridges *et al.*, 1993; Brautbar *et al.*, 1995; Wolford, 1997). Symptomatic silicone breast implant recipients also have high levels of antibodies to synthetic polymers (Tenenbaum *et al.*, 1997) and to silicone,[3] but did not have high prevalence of ASA.

It has been suggested that abnormal immune responses may be involved in GWS (Rook *et al.*, 1997). Immunological adjuvants have the generally desirable property of eliciting cell-mediated immunity and antibodies when administered with an antigen. They may also cause a more generalized and indiscriminate stimulation of the immune system and disrupt the balance of immune self-regulatory mechanisms, which may lead to autoimmune disease (Zamma, 1983; Lorentzen *et al.*, 1995; Madzhidov *et al.*, 1986; Kleinau *et al.*, 1995). Squalene has been used extensively as an adjuvant in animal models to induce autoimmune diseases (Lorentzen, 1999; Beck *et al.*, 1976; Kohashi *et al.*, 1977; Garrett *et al.*, 1985; Whitehouse *et al.*, 1974; Yoshino *et al.*, 1994). Cytokines are mediators of immunological regulation and inflammatory responses (Van der Meide *et al.*, 1996), and increased cytokine levels are associated with the development of autoimmune disease in established rodent models of autoimmunity (Fitzpatrick *et al.*, 1996). Squalene has been shown to induce increased levels of interleukin-5 (IL-5), IL-6, and interferon-γ (Valensi *et al.*, 1994). Several different adjuvants have been demonstrated to produce or exacerbate autoimmune diseases in experimental models. Adjuvant-induced arthritis is a well-characterized autoimmune disease induced in rats and other species (Zamma, 1983; Lorentzen *et al.*, 1995; Madzhidov *et al.*, 1986; Kleinau *et al.*, 1995). The disease process in adjuvant-induced arthritis is complex, affecting multiple organ systems. For example, a cachetic syndrome (Rofe *et al.*, 1996) and testicular dysfunction (Clemons *et al.*, 1998) have been associated with adjuvant-induced arthritis. Uveitis, a T-cell-mediated intraocular inflammatory disease, can also be induced by adjuvants (Petty *et al.*, 1996). Neurological disease can be the result of immunological mechanisms, including autoimmunity (Rogers *et al.*, 1996; Tebin *et al.* 1996; Hemperat *et al.*, 1995; Wucherpfennig *et al.*, 1990; Cross *et al.*, 1991; Bansal *et al.*, 1994), and neurological symptoms are commonly seen in autoimmune diseases (McNicholl *et al.*, 1994; Zapone *et al.*, 1993; Moll *et al.*, 1993).

All pharmacology is controlled toxicology. Although not approved by the Food and Drug Administration for human use, squalene has been used as an adjuvant in experimental vaccines against a variety of pathogens, including *Bacillus anthracis* (Ivins *et al.*, 1994), *Plasmodium falciparum* (Hoffman *et al.*, 1994), and herpes simplex virus (Burke *et al.*, 1994). Effectiveness of adjuvants has been shown to parallel toxicity defined as the initiation of autoimmune disease processes (Zamma, 1983; Koga *et al.*, 1986). Adjuvants should not produce reactions at injection sites, be pyrogenic, or induce anterior uveitis, arthritis, or other protean autoimmune processes (Allison *et al.*, 1991). A study using squalene as an adjuvant in influenza vaccine reported moderate to severe local and systemic reactions in humans (Keitel *et al.*, 1993). The participants suffered induration, erythema, lymphadenopathy, fever, chills, nausea, and dizziness symptoms which lasted for several days. Another squalene-containing adjuvant was used with gp120 in a human immunodeficiency virus vaccine, where it induced severe systemic and local reactions in 15 of 30 vaccinees (Kaefer *et al.*, 1996). Similarly, in a study of simian immunodeficiency vaccine in macaques, squalene was used as an adjuvant, and the animals developed anti-human-cell antibodies and autoimmune-like symptoms (Vaslin *et al.*, 1992). Future studies should determine whether or not ASA have a role in these pathological processes.

Squalene is a naturally occurring molecule absorbed from food and synthesized as a precursor for cholesterol, myelin, and hormones. This synthesis occurs within the hepatocytes and is further processed into cholesterol in the endoplasmic reticulum (Stamellos *et al.*, 1993). Fecal analysis indicates that about 60% of dietary squalene is absorbed (Strandberg *et al.*, 1990). Dietary squalene is absorbed through lymphatic vessels after being cyclized to sterols during transit through

[3]Cao, Yan *et al.*, unpublished observations.

the intestinal wall (Tilvis *et al.*, 1983). It is processed into chylomicrons by the epithelial cells of the small intestines. It becomes a lipid droplet covered by β-lipoprotein containing triglyceride and cholesterol ester. This increases serum levels of free and esterified methyl sterol contents. About 90% of absorbed squalene is in lipoproteins, appearing in chylomicrons and VLDL, suggesting that removal of dietary squalene may indicate metabolism of intestinal lipoproteins (Gylling *et al.*, 1994).

Squalene is a nonsteroid precursor of cholesterol. Reports have indicated that high titers of autoantibodies to cholesterol, once considered to be a poorly immunogenic molecule, could be generated by immunization with liposomes containing cholesterol and lipid A as adjuvant (Swartz *et al.*, 1988; Alving *et al.*, 1991; Dijkstra *et al.*, 1996). Injection of either silicone gel or silicone oil intraperitoneally also resulted in high titers of autoantibodies to cholesterol (Alving *et al.*, 1996). The silicone component serves as an adjuvant as well as initiating the autoimmune process. The high titers were IgM with relatively low titers of IgG to cholesterol (Dijkstra *et al.*, 1996; Alving *et al.*, 1996). The specificity of these antibodies was to cholesterol and structurally similar sterols containing a 3β-hydroxyl group. Anticholesterol binding activity was significantly diminished if the 3β-hydroxyl domain was altered by oxidation, substitution, epimerization, or esterification (Dijkstra *et al.*, 1996). It has been reported that naturally occurring autoantibodies have been detected in humans (Alving *et al.*, 1989), but these were much lower in titer than those produced with either lipid A or silicone.

Several facts argue against our assay detecting cross-reactive antibodies to cholesterol instead of antibodies specific for squalene. First, squalene is neither a sterol nor does it have a 3β-hydroxyl group. The respective molecular structures, internal molecular bonding, charge distribution, and antigenic epitopes are different. Second, if high-titer autoantibodies to cholesterol that are cross-reactive with squalene are normal, we should see no difference between our various patient groups. The GWS patients and NIH positive control patients are very distinct in their strong IgG antibody reactivity to squalene. Third, if silicone alone can generate antibodies to cholesterol and these are cross-reactive to squalene, we should see high antibody reactivity to squalene in patients exposed to silicone in addition to the GWS and NIH patients. This did not occur.

In the course of these studies, we examined two volunteers for a vaccine trial at the NIH involving squalene as adjuvant. They developed a multisystem disease similar to that seen in Persian Gulf veterans subsequent to their participation in the trial. One received a single injection and became ill within a few weeks with signs and symptoms including arthritis, fibromyalgia, lymphadenopathy, photosensitive rashes, fatigue, headaches, and fasciculations. This individual had lower than normal acetylcholinesterase, histological evidence of lymphocytic infiltrates around vascular tissue, and IgG-mediated demyelinization. After this NIH vaccine study code was broken, it was found that only adjuvant squalene had been administered as placebo. This patient was weakly positive for ASA. Another patient who went through the whole experimental protocol before manifesting a similar set of signs and symptoms was 3+ positive for ASA.

Multiple vaccinations and vaccination against biological warfare agents are the factors with the highest correlation with GWS symptomatology (Unwin *et al.*, 1994). It is important to note that our laboratory-based investigations do not establish that squalene was added as adjuvant to any vaccine used in military or other personnel who served in the Persian Gulf War era. Several investigators have speculated that GWS is the result of either exposure to chemicals, chemical weapons, or to biological agents encountered in the Persian Gulf (Persian Gulf Veterans Coordinating Board, 1995; Abou-Donia *et al.*, 1996; David *et al.*, 1997; Haley,1997). However, such exposure would likely have immediate effects and many Gulf War veterans were [illegible] months or years after the military conflict. Many of these GWS patients have improved on treatment regimens prescribed by their personal physicians, rheumatologists, and neurologists, namely the immunosuppressives used for classical rheumatological conditions.[4] These treatments have included steroids, methotrexate, hydroxychloroquine, and cytoxan. Such treatments would have no effect on subjects exposed to chemical weapons. If GWS was due to an exogenous infectious agent, the immunosuppressive regimens used would likely result in an exacerbation of the symptoms. This did not occur. The molecular pathology of GWS must be defined before its etiology can be assigned. We present here evidence of an immune factor based upon the adjuvancy of squalene. Further studies are required to define the role of ASA, if any, in the pathogenesis of GWS.

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[4]Asa, P.B. *et al.*, unpublished observations.

REFERENCES

Abou-Donia, M., Wilmarth, K., Jensen, K., Oehme, F., and Kurt, T. (1996). Neurotoxicity resulting from coexposure to pyridostygmine bromide, deet, and permethrine. Implications of Gulf War chemical exposures. *J. Toxicol. Environ. Health* **48**, 35–56.

Akira, S., Hirano, T., Taga, T., and Kishimoto, T. (1990). Biology of multifunctional cytokines: IL6 and related molecules (IL1 and TNF). *FASEB J.* **4**, 2860–2867.

Allison, A., and Byars, N. (1991). Immunological adjuvants: Desirable properties and side effects. *Mol. Immunol.* **28**, 279–284.

Alving, C. R., and Swartz, G. M., Jr. (1991). Antibodies to cholesterol, cholesterol conjugates and liposomes: Implications for atherosclerosis and autoimmunity. *Crit. Rev. Immunol.* **10**, 441–453.

Alving, C. R., Swartz, G. M., Jr., and Wassef, N. M. (1989). Naturally occurring autoantibodies to cholesterol in humans. *Biochem. Soc. Trans.* **17**, 637–639.

Alving, C. R., Wassef, N. M., and Porter, M. (1996). Antibodies to cholesterol: Biological implication of antibodies to lipids. *Curr. Top. Microbiol. Immunol.* **210**, 181–185.

Bansal, A., Abdul Karim, B., Malik, R. A., Goulding, P., Pumphrey, R. S., Boulton, A. J., Holt, P. L., and Wilson, P. B. (1994). IgM ganglioside GM1 antibodies in patients with autoimmune disease and neuropathy, and controls. *J. Clin. Pathol.* **47**, 300–302.

Beck, F. W., and Whitehouse, M. W. (1976). Modifications in the establishment of allergic encephalomyelitis (EAE) in rats: An improved assay for immunosuppressive drugs. *Agents Actions* **6**, 460–467.

Brautbar, N., Campbell, A., and Vojdani, A. (1995). Silicone breast implants and autoimmunity: Causation, association, or myth? *J. Biomater. Sci. Polym. Ed.* **7**, 133–145.

Bridges, A. J., Cooley, C., Wang, G., Burns, D. E., and Vasey, F. B. (1993). A clinical and immunological evaluation of women with silicone breast implants and symptoms of rheumatic disease. *Ann. Intern. Med.* **118**, 929–936. [see comment].

Burke, R., Goldbeck, C., Ng, P., Stanberry, L., Ott, G., and Van Nest, G. (1994). Influence of adjuvant on the therapeutic efficiency of a recombinant genital herpes vaccine. *J. Infect. Dis.* **170**, 1110–1119.

Clemons, J., and Brout B. (1989). Testicular dysfunction in the adjuvant-induced arthritic rat. *J. Androl.* **10**, 419–421.

Coker, W. J., Bhatt, B. M., Blatchley, N., and Graham, J. T. (1999). Clinical findings for the first 1000 Gulf War veterans in the Ministry of Defence's medical assessment programme. *BMJ* **318**, 290–294.

Cross, A., and Raine, C. (1991). Central nervous system endothelial cell–polymorphonuclear cell interaction during autoimmune demyelinization. *Am. J. Pathol.* **139**, 1401–1409.

David, A., Ferry, S., and Wessely, S. (1997). Gulf War illness. *BMJ* **314**, 239–240.

Dijkstra, J., Swartz, G. M., Jr., Raney, J. J., Aniagolu, J., Toro, L., Nacy C. A., and Green, S. J. (1996). Interactions of anti-cholesterol antibodies with human lipoproteins. *J. Immunol.* **157**, 2006–2013.

Dinarello, C. A. (1988). Biology of interleukin 1. *FASEB J.* **2**, 108–115.

Fitzpatrick, J., Koh, J., Hartwell, D., Beller, D., and Levine J. S. (1996). Dysregulated cytokine expression in vivo in predisposed and autoimmune-prone MLR mice. *Autoimmunity* **23**, 217–229.

Fukuda, K., Nisenbaum, R., Stewart, G., Thompson, W. W., Robin, L., Washko, R. A., Noah, D. L., Barrett, D. H., Randall, B., Herwaldt, B. L., Mawle, A. C., and Reeves, W. C. (1998). Chronic multisymptom disease affecting Air Force veterans of the Gulf War. *J. Am. Med. Assoc.* **280**, 981–988.

Garrett, I. R., Whitehouse, M. W., Vernon Roberts, B., and Kerrigan, P. M. (1985). Ambivalent properties of gold drugs in adjuvant-induced polyarthritis in rats. *J. Rheumatol.* **12**, 1079–1082.

Geirsson, A., Steinsson, K., Gudmundsson, S., and Sigurdsson, V. (1994). Systemic sclerosis in Iceland: A national epidemiological study. *Ann. Rheum. Dis.* **53**, 502–505.

Grady, E. P., Carpenter, M., Koenig, C., Older, S., and Bartolfarino, D. F. (1998). Rheumatic findings in Gulf War veterans. *Mil. Med.* **158**, 367–371.

Gylling, H., and Miettinen, T. A. (1994). Postabsorptive metabolism of dietary squalene. *Atherosclerosis* **106**, 169–178.

Haley, R. W. (1997). Is Gulf War syndrome due to stress? The influenza reexamined. *Am. J. Epidemiol.* **146**, 695–703.

Haley, R. W., and Kurt, T. L. (1997). Self-reported exposure to neurotoxic chemical combinations in the Gulf War. A cross-sectional epidemiologic study. *J. Am. Med. Assoc.* **277**, 231–237.

Hoffman, S., Eaelman, R., Bryan, J. P., Schneider, I., Davis, J., Sedegran, M., Gordon, D., Church, P., Gross, M., and Silverman, C. (1994). Safety, immunogenicity, and efficacy of a malaria sporozoite vaccine administered with monophosphoryl lipid A, cell wall cytoskeleton of mycobacteria, and squalene as adjuvant. *Am. J. Trop. Med. Hyg.* **51**, 603–612.

Honnorat, J., Trouillas, P., Thivolet, C., Aguera, M., and Petit, M. (1995). Autoantibodies to glutamate decarboxylase in a patient with cerebellar atrophy, peripheral neuropathy, and slow eye movement. *Arch. Neurol.* **52**, 462–468.

Hyams, K. C., Wignall, S., and Roswell, R. (1996). War syndromes and their evaluation: From the U.S. Civil War to the Persian Gulf War. *Ann. Intern. Med.* **125**, 398–405.

Ismail, K., Everitt, B., Blatchley, N., Hull, L., Unwin, C., David, A., and Wesseley, S. (1999). Is there a Gulf War syndrome? *Lancet* **353**, 179–182.

Ivins, B., Fellows, P., Fix, L., Estep, J., Farchaus, J., Friedlander, A., and Gibbs, P. (1995). Experimental anthrax vaccines: Efficacy of adjuvants combined with protective antigen against aerosol *Bacillus anthracis* spore challenge in guinea pigs. *Vaccine* **13**, 1779–1783.

Keefer, M., Graham, B. S., McElrath, M. J., Matthews, T. J., Stablein, D. M., Corey, L., Wright, P. F., Lawrence, D., Fast, P. E., Weinhold, K., Hsieh, R. H., Chernoff, D., Dekker, C., and Delio, R. (1996). Safety and immunogenicity of Env 2-3, a human immunodeficiency virus type 1 candidate vaccine, in combination with a novel adjuvant, MTP-PE/MF-59. *AIDS Res. Hum. Retroviruses* **12**, 683–693.

Kousek, W., Couch, R., Bond, N., Adair, S., Van Nest, G., and Dekker, C. (1992). Pilot evaluation of influenza virus vaccine (FLUV) combined with adjuvant. *Vaccine* **11**, 909–913.

Kleinau, S., Lorentzen, J., and Klareskog, L. (1995). Role of adjuvants in turning autoimmunity into autoimmune disease. *Scand. J. Rheumatol. Suppl.* **101**, 179–181.

Kobashi, O., Pearson, M., Beck, F. J., and Alexander, M. (1977). Effect of oil composition on both adjuvant induced arthritis and delayed hypersensitivity to purified protein derivative and peptidoglycans in various rat strains. *Infect. Immun.* **17**, 244–249.

Koga, T., Kakimoto, K., Hirofuji, T., Kotani, S., Sumiyoshi, A., and Saisho, K. (1986). Muramyl dipeptide induces acute joint inflammation in the mouse. *Microbiol. Immunol.* 30, 717–723.

Lorentzen, J. C. (1999). Identification of arthritogenic adjuvants of self and foreign origin. *Scand. J. Immunol.* 49, 45–50.

Lorentzen, J. C., Olsson, T., and Klareskog, L. (1995). Susceptibility to oil-induced arthritis in the DA rat is determined by MHC and non-MHC genes. *Transplant. Proc.* 27, 1532–1534.

Madzhidov, U. V., Blandova Z. K., and Madzhidov, A. V. (1986). Genetic control of sensitivity to experimental adjuvant arthritis in mice of inbred lines. *Bull. Exp. Biol. Med.* 102, 74–76. [in Russian]

McNicholl, J., Glynn, D., Mongey, A., Hutchinson, M., and Bresnihan, B. (1994). A prospective study of neurophysiologic, neurologic, and immunologic abnormalities in systemic lupus erythematosus. *J. Rheumatol.* 21, 1061–1066.

Michet, C., McKenna, C., Elveback, L., Kaslow, R., and Kurland, L. (1985). Epidemiology of systemic lupus erythematosus and other connective tissue diseases in Rochester, Minnesota, 1950 through 1979. *Mayo Clin. Proc.* 60, 105–113.

Moll, J., Markusse, H., Pijnenburg, J., Vecht, C., and Henzen-Logmans, S. (1993). Antineuronal antibodies in patients with neurological complications of primary Sjogren's syndrome. *Neurology* 43, 2574–2581.

Naim, J. O., Ippolito, K. M., and Van Oss, C. J. (1987). Adjuvancy effect of different types of silicone gel. *J. Biomed. Mater. Res.* 37, 534–538.

Nicholson, J., Jr., Hill, S. L., Frondoza, C. G., and Rose, N. R. (1996). Silicone gel and octamethylcyclotetrasiloxane (D4) enhances antibody production to bovine serum albumin in mice. *J. Biomed. Mater. Res.* 31, 345–353.

Persian Gulf Veterans Coordinating Board. (1995). Unexplained illnesses among Desert Storm veterans. A search for causes, treatment, and cooperation. *Arch. Intern. Med.* 155, 262–268.

Petty, R., Johnston, W., McCormick A., Hunt, D., Rootman, and J., Rollins, D. (1989). Uveitis and arthritis induced by adjuvant: Clinical, immunological, and histological characteristics. *J. Rheumatol.* 16, 400–405.

Rofe, A., Philcox, J., Haynes, D., and Coyle, P. (1994). Wasting in adjuvant-induced arthritis and its relationship to plasma zinc, copper, and liver metallothionein. *Agents Actions* 42, 60–62.

Rogers, S., Twyman, R., and Gahring, L. (1996). The role of autoimmunity to glutamate receptors in neurological disease. *Mol. Med. Today* 2, 76–81.

Rook, G. A., and Zumla, A. (1997). Gulf War Syndrome: Is it due to a systemic shift in cytokine balance towards a Th2 profile? *Lancet* 349, 1831–1833.

Rook, G.A., and Zumla, A. (1998). Is the Gulf War Syndrome an immunologically mediated phenomenon? *Hosp. Med.* 59, 10–11.

Sergott, T. J., Limoli, J. P., Baldwin, C. M., Jr., and Laub, D. R. (1985). Human adjuvant disease, possible autoimmune disease after silicone implantation: A review of the literature, case studies, and speculation for the future. *Plast. Reconstr. Surg.* 78, 104–114.

Stamellos, K. D., Shackleford, J. E., Shechter, I., Jiang, G., Conrad, D., Keller, G.A., Krisan, S. K. and (1993). Discoordinate regulation of squalene synthase in rat hepatic cells. Biochemical and immunological evidence. *J. Biol. Chem.* 268, 12825–12836.

Strandberg, T. E., Tilvis, R. S., and Miettinen, T. A. (1990). Control of the variables of cholesterol during squalene feeding in humans: Comparison with cholestyramine treatment. *J. Lipid Res.* 31, 1937–1943.

Straus, S. E. (1998). Bridging the gulf in war syndrome. *Lancet* 353, 162–163.

Swartz, G. M., Gentry, M. K., Amende, L. M., Blanchette-Mackie, E. J., and Alving, C.R. (1988). Antibodies to cholesterol. *Proc. Natl. Acad. Sci. USA* 85, 1902–1906.

Tekin, S., Aykut, C., Ozgun, S., and Aktas, S. (1996). The role of autoimmunity in vascular dementia. *Dementia* 7, 91–96.

Tenenbaum, S. A., Rice, J. C., Espinoza, L. R., Cuellar, M. C., Polmak, D. R., Sander, D. M., Williamson, L. L., Haselip, A. M., Dinkel, G. S., and Tesser, J. R. (1997). Use of antipolymer antibody titers in recipients of silicone breast implants. *Lancet* 349, 449–450.

Tilvis, R. S., and Miettinen, T. A. (1983). Absorption and metabolic fate of dietary 3H-squalene in the rat. *Lipids* 18, 223–225.

Unwin, C., Blatchley, N., Coker, W., Ferry, S., Hotopf, M., Hull, L., Ismail, K., Palmer, I., David, A., and Wessely S. (1999). Health of UK servicemen who served in Persian Gulf War. *Lancet* 353, 169–178.

Valensi, J., Carlson, J., and Van Nest, G. (1994). Systemic cytokine profiles in BALB/c mice immunized with trivalent inactivated vaccine containing MF-59 oil emulsion and other advanced adjuvants. *J. Immunol.* 153, 4029–4039.

Van der Meide, P., and Schellekens, H. (1996). Cytokines and the immune response. *Biotherapy* 8, 243–249.

Vaslin, B., LeGrand, R., Vogt, G., Roques, P., Stoeckel, P., Sala, M., and Dormont, D. (1992). Purified inactivated SIV vaccine: Comparison of adjuvants. *Int. Conf. AIDS* 8, [Abstract No. PoA2227].

Whitehouse, M. W., Orr, K. J., Beck, F. W., and Pearson, C. M. (1974). Freund's adjuvants: Relationship of arthritogenicity and adjuvanticity in rats to vehicle composition. *Immunology* 27, 311–333.

Wolford, L. (1997). Temporomandibular joint devices: Treatment factors and outcomes. *Oral Surg. Oral Med. Oral Pathol. Oral Radiol. Endod.* 83, 143–149.

Wucherpfennig, K., and Weiner H. L. (1990). Immunological mechanisms in chronic demyelinating diseases of the central and peripheral nervous system. *Res. Publ. Assoc. Res. Nerv. Ment. Dis.* 68, 105–116.

Yoshida, S. H., Teuber, S. S., German, J. B., and Gershwin, M. E. (1994). Immunotoxicity of silicone: Implications of sulfur balance towards adjuvant activity. *Food Chem. Toxicol.* 32, 1089–1100.

Yoshino, S., and Yoshino, J. (1994). Recruitment of pathogenic T cells to synovial tissues of rats injected intraarticularly with nonspecific agents. *Cell. Immunol.* 158, 305–313.

Zamma, T. (1983). Adjuvant-induced arthritis in the temporomandibular joint in rats. *Infect. Immun.* 39, 1291–1299.

Zanone, M., Peakman, M., Purewal, T., Watkins, P., and Vergani, D. (1993). Autoantibodies to nervous tissue structures are associated with autonomic neuropathy in type I (insulin-dependent) diabetes mellitus. *Diabetologia* 36, 564–569.

Appendix 3

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Page: 0002
Total Pages: 4

Subject: DESERT SHIELD BIOLOGICAL WARFARE HOC WORKING GROUP

Unit: OTSG

Parent Organization: HSC

Box ID: BX003203

Folder Title: MINUTES OF THE DESERT SHIELD BIOLOGICAL WARFARE

Document Number: 1

Folder SEQ #: 159

UNCLASSIFIED

protective. A second challenge of these animals, withoi additional antibiotic prophylaxis, found them to be susci to anthrax exposure. The animals who had previously reci e

6. (U) BW Vaccines, Botulinum Antitoxin and IND Drugs Theater.

a. COL Tomlinson reported on an outbreak of foodbor: botulinum in Cairo, Egypt, and that a quantity of the bo@ antitoxin from theater was shipped to Egypt. LTC McKee there were approximately 80 cases; with 15 of these resu in death. The outbreak was believed to be associated wi@ under cooked fish. He also reported individuals from CD, to Egypt to investigate the outbreak and took antitoxin 1 them. LTC McKee stated that in addition to the Army's a: CDC's antitoxin, antitoxin was also supplied by a Europe, manufacturer. Since several sources of antitoxin were u some individuals may have received several doses of diff, antitoxin, evaluation of the efficacy of the Army produc be difficult at best. LM Ld

b. It was reported that the individuals from logist USAMRIID, were expected back from theater today with the anthrax and botulinum vaccines, antitoxin, ribavirin and centoxin. While in theater the items were under refrigeration; however, there was a report that the refrigerator failed to operate for a period of time and possibly these items were damaged. The items will be re to USAMRIID and a determination made with regard to the disposition. I

7. (U) Documentation of Vaccine Usage in Theater.

2D DISTRICT, WASHINGTON

COMMITTEE ON TRANSPORTATION AND INFRASTRUCTURE
SUBCOMMITTEES:
AVIATION
GROUND TRANSPORTATION

COMMITTEE ON SCIENCE
SUBCOMMITTEE:
ENERGY AND ENVIRONMENT

Appendix 4

Congress of the United States
House of Representatives
Washington, DC 20515–4702

COMMITTEE ON BANKING AND FINANCIAL SERVICES
SUBCOMMITTEES:
HOUSING
FINANCIAL INSTITUTIONS
DOMESTIC AND INTERNATIONAL MONETARY POLICY

CHAIR, REPUBLICAN HOUSING OPPORTUNITY CAUCUS

REPUBLICAN POLICY COMMITTEE

May 13, 1999

The Honorable William S. Cohen
Secretary of Defense
The Pentagon
Washington, DC 20301-1010

Reference: "Questions About the Presence of Squalene Antibodies in Veterans Can Be Resolved. GAO, March 1999

Dear Secretary Cohen:

On March 29, 1999, the General Accounting Office released the report I had requested regarding squalene antibodies in veterans suffering from Gulf War Illnesses. As DOD prepares its response to the final report issued by the GAO, I am requesting answers to a number of questions that remain outstanding.

In the report DOD commented, "There is no basis for believing that Gulf War-era veterans were exposed to squalene-containing vaccines. The DOD has indicated that no experimental vaccines with squalene containing adjuvants had been used in U.S. troops during the Gulf War." (Page 23)

Contrary to the above assertion, the GAO report did not implicate the Department of Defense. Rather, the report concluded it would be prudent for DOD to "review the independent research that researchers report has revealed the presence of squalene antibodies in the blood of ill gulf War-era veterans, and conduct its (DOD) own research designed to replicate or dispute these results." (Pg 8-9)

1. DOD officials told the GAO, that DOD could develop an assay for detecting antibodies to squalene, and a sample testing could be done for a small investment. Will the DOD reassess their former position, and aggressively pursue this first step? Determining if the antibodies are present is vitally important. If they are present, then the process to ascertain the significance of that finding can begin.

2. If the DOD is concerned that it does not have the resources, or that it would require a lengthy period of time (over six months) to conduct an initial investigation, is there a reason why you cannot send a team of experts to Tulane University where the research has been done to validate or dispute its integrity?

3. In light of the missing shot records of so many of our Gulf War-era veterans, is it possible to determine absolutely that they did not receive any vaccine formulations containing squalene during or prior to the Gulf War? Is this conclusion based solely on the statement of the vaccine manufacturer?

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(202) 225-2605

EVERETT OFFICE:
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(425) 252-3188
(800) 562-1386

BELLINGHAM OFFICE:
322 NO. COMMERCIAL, #203
BELLINGHAM, WA 98225
(360) 733-4500

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The DOD stated in its response, "The assay for anti-squalene antibodies developed by the independent researchers has not been validated through peer review or publication in the scientific literature . . . Data obtained from a methodology that has not been validated have significant potential to harm or mislead Gulf War veterans through the medical misinformation the data may support." (Page 23)

The researchers at Tulane have made clear their willingness to work with DOD. Time is critical for thousands of sick Gulf War-era veterans who continue to suffer and have been waiting the last seven years for help. The truth cannot harm or mislead Gulf War veterans. You have the capability to validate or dispute the methodology.

However, not getting to the bottom of this perplexing problem will no doubt continue to have serious ramifications. I am sure you are aware of the growing concern among active military members regarding the current anthrax vaccination program. Reports of serious adverse reactions are increasing. The oversight hearing of the Subcommittee on National Security, Veterans Affairs, and International Relations on April 29, 1999, revealed troubling testimony. Members of the Michigan Air National Guard are suffering significant health consequences following their anthrax vaccinations. During the hearing, the GAO raised a number of critical questions regarding the safety and efficacy of the anthrax vaccine. Combined with the squalene issue, these factors are escalating a climate of distrust. Inaction, while waiting for the lengthy peer review process, will only exacerbate this disturbing situation.

4. Confirmation exists that several active duty personnel recently inoculated have tested positive for antibodies to squalene. Several publications have alleged a potential connection between anthrax vaccinations and squalene. Therefore, is it not in the best interest of the United States active duty forces to immediately take action to determine the facts and potential health consequences?

This situation provides the DOD an extraordinary opportunity to demonstrate our nation's committment to the honorable men and women who serve our country. Thank you for your assistance. I look forward to your personal reply.

Sincerely,

Jack Metcalf

Jack Metcalf

Appendix 5

Tulane University Medical Center

SCHOOL OF MEDICINE
Department of Microbiology & Immunology SL38
1430 Tulane Avenue
New Orleans, Louisiana 70112-2699
(504) 587-2027 Fax: (504) 584-1994
E-mail: rgarry@tmcpop.tmc.tulane.edu

Robert F. Garry, Ph.D.
Professor

8/14/00

RE: Note to file regarding conversation with COL Carl R. Alving, M.D.

To whom it may concern:

On or about May 24, 1999 I received an unsolicited telephone call at my office from COL Carl R. Alving, M.D. Dr. Alving, whose work on lipids and adjuvants I was somewhat familiar with, indicated that he had a scientific interest in the work on squalene antibodies conducted by Drs. Pamela Asa and Yan Cao and myself.

Dr. Alving indicated that his interest in my studies was "purely scientific" and that he wished to get more information because of his interest in the general area of lipids, antibodies and adjuvants. This was plausible because of Dr. Alving's prior work in this general area. The conversion, which lasted from about 45 minutes, was almost entirely scientific and covered a broad range of topics related to anti-lipid antibodies.

During the course of our conversation, Dr. Alving shared some of his recent studies on anti-cholesterol antibody with me. At that time, I was only vaguely familiar with those studies. Dr. Alving offered the opinion that the anti-squalene antibodies might be a subclass of the anti-cholesterol antibodies. I replied that this might be worth looking into.

Dr. Alving also asked to review a draft of the manuscript on anti-squalene antibodies which was subsequently published in ***Experimental and Molecular Pathology***. I agreed to fax him a copy of the *in progress* work for his personal review. Because the work had not yet been accepted for publication, I asked that he not circulate the copy.

At no time was I made aware that Dr. Alving's intent was to circulate our paper and subject it to the scathing reviews subsequently published on the DoD website prior to publication and in abbreviated form as a letter to the editor of *Experimental and Molecular Pathology* .

Robert F. Garry

Robert F. Garry, Ph.D.
Professor

Appendix 6

Autoimmune Technologies, LLC
144 Elks Place, Suite 1402
New Orleans, Louisiana 70112
Telephone: (504) 529-9944 Facsimile: (504) 568-0634
E-mail: rwilson@communique.net

May 25, 1999

Col. Carl Alving, M.D.
Department of Membrane Biochemistry
Walter Reed Army Institute of Research
Building 40, Room 1022
Washington, DC 20307-5100

Dear Dr. Alving:

It was a pleasure talking with you today. As we discussed, I am enclosing two reprints and a copy of a manuscript that deal with our work on anti-polymer antibodies. I would appreciate any comments or questions that you might have concerning our work.

In regards to the anti-squalene antibody assay, I mentioned to you that Tulane University Medical Center has filed for patent protection concerning the use of anti-squalene antibodies in evaluating Gulf War Syndrome. As Tulane's exclusive licensee for this technology, we would be happy to discuss information regarding the assay and our research with you. If you need additional information or have any questions, please contact me.

By the way, I wanted to mention to you that I have read many of your papers concerning liposomes and toxins. My dissertation project, many years ago, concerned the cloning of exotoxin A from *Ps. aeruginosa*, and after our phone conversation, I remembered reading your paper on the interaction of diphtheria toxin and phospholipids. Again, it was a pleasure talking with you today, and I look forward to talking with you soon.

Sincerely,

Russell B. Wilson

Russell B. Wilson, Ph.D.
President

enclosures

Appendix 7

THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

28 MAY 1999

Mr. Kwai-Cheung Chan
Director, Special Studies and Evaluations
National Security and International Affairs Division
U.S. General Accounting Office
Washington, DC 20548

Dear Mr. Chan:

This is the Department of Defense (DoD) response to the General Accounting Office (GAO) final report, GAO/NSIAD-99-5, "GULF WAR ILLNESSES: Questions About the Presence of Squalene Antibodies in Veterans Can Be Resolved," dated March 29, 1999 (GAO Code 713014/OSD Case 1711).

The Department acknowledges receipt of the final report and inclusion of the DoD response to the draft report as Appendix VI. We acknowledge the extensive changes that GAO made to the report based on the published DoD response and the other comments and annotations to the draft report, which we had provided to GAO separately.

Our position and the concerns expressed in our comments to the draft report have not changed. The clinical significance and origin of antibodies to squalene, if their existence is corroborated, remain unknown. The test methods proposed by the investigators at Tulane University need to be reviewed and validated by other scientists. Finally, no vaccines with squalene-containing adjuvants were used in U.S. troops during the Gulf War.

The Department continues to solicit and fund research designed to better understand and treat the health problems of Gulf War veterans. Requests for research proposals are published as Broad Agency Announcements in the Commerce Business Daily and are readily available to interested civilian and Federal investigators. We encourage investigators, including those at Tulane University, to submit research proposals that further our understanding of illnesses among Gulf War veterans. Our commitment to civilian and Federal researchers and to Gulf War veterans is to the support and funding of high quality research, which is best assured when all decisions on research funding are based on a process of rigorous, competitive, and independent peer review of all research proposals.

Sincerely,

Dr. Sue Bailey

Appendix 8

ISSUES RELATING TO ANTIBODIES TO SQUALENE

Background

Recently, Pamela B. Asa, Ph.D. (of Memphis, TN) and Robert F. Garry (of Tulane University, New Orleans, LA) have been quoted in the popular press as claiming that a higher percentage of sick Gulf War veterans than healthy Gulf War veterans, or than normal blood donors, have antibodies to squalene in their blood. Squalene is a naturally-occurring, oil (a molecule that is in the category of fats and lipids) that is widely distributed in large quantities in the human body, and that has been proposed for use as a commercial adjuvant for increasing the potency of vaccines. Based on the claims by Drs. Asa and Gary, numerous accusations have been leveled at DoD. These include (among others) the allegation that the U.S. Army spiked the anthrax vaccine with squalene as an adjuvant during the Gulf War, and the claim that antibodies to squalene are responsible for the symptoms observed in sick Gulf War veterans.

A detailed investigation of numerous issues relating to squalene and squalene antibodies has been made by the U. S. Army Medical Research and Material Command (USAMRMC) and the Walter Reed Army Institute of Research (WRAIR). The commanding general of USAMRMC, MG John Parker, personally telephoned Dr. Garry, and also assigned COL Carl R. Alving, M.D. (Colonel, U. S. Medical Corps) to call Dr. Garry and to investigate the technical aspects of squalene and antibodies to squalene. COL Alving, who is Chief of the Department of Membrane Biochemistry at WRAIR, has had more than 30 years of research and clinical experience in studying the biochemistry and immunology of lipids, fats, and oils, and is internationally recognized for his research and clinical experience with lipids and oils as adjuvants for vaccines. He is also one of the world's foremost experts in the study of antibodies to lipids. The comments that follow result from this investigation.

Conversation with Dr. Garry

On Monday 24 May 1999 COL Alving and one of his staff members, Gary R. Matyas, Ph.D. (another expert in biochemistry, lipids, antibodies to lipids, immunology, and oil-based adjuvants), called Dr. Garry to discuss Garry's method of measuring antibodies to squalene. Based on the telephone conversation, at the present time the results claimed by Drs. Asa and Garry that have been made in the popular press have not even been minimally validated by scientific peer review. According to Dr. Garry, an attempt has been made Dr. Asa and him (together with Yan Cao, M.D. of Tulane) to achieve at least some measure of scientific peer acceptance by submitting a paper for publication in the Journal of the American Medical Association. However, to date, this effort has not been successful. Dr. Garry faxed a copy of the manuscript (that was marked as being a "revised" version) to COL Alving. Dr. Garry stated that the manuscript had somehow been published without his permission on the internet and that because of the publicity he doubted that it would be published as a scientific peer-reviewed paper.

Analysis of the purported assay for antibodies to squalene

When Garry was asked to provide a detailed standard operating procedure for detecting antibodies to squalene, he said that the complete details were given in the manuscript that he faxed. However, COL Alving and Dr. Matyas found literally dozens of important technical and theoretical flaws in the assay that was faxed by Dr. Garry. Many of these were fatal flaws. Although many of the flaws that were detected by Alving and Matyas require a detailed technical knowledge of such assays, some can be explained rather simply, as shown below.

First, the conclusions are entirely based on faulty, nonscientific, circular reasoning. Positive results in an unproven assay that has not been previously validated to detect antibodies against an antigen cannot then be used be used as scientific proof that antibodies to the antigen exist in an unknown sample. The assay must first be validated by independent means. In scientific terms, it would be said that there were ***no validated positive controls***.

Second, the assay is notable for its **lack of negative controls**. There is no control in which the human serum containing the presumed antibodies is omitted. There is no control in which the avidin-conjugated horse radish peroxidase is omitted. Finally in a new unproven assay it is essential to prove specificity of the assay. There is no evidence that the assay is not simply measuring nonspecific IgG molecules that are not antibodies to squalene but nonspecifically stick to squalene. Although IgG molecules were detected in the assay with second antibodies to human IgG, there were no controls to show that second antibodies to other normal serum proteins (e.g., albumin, fibrinogen, alpha 2 macroglobulin, complement, etc.) could not also have have been detected. The entire assay may be completely due to nonspecific binding of squalene to IgG molecules that are not actually antibodies.

Third, the unknown human serum samples were **tested only at a single very high dilution** (a dilution of 1/400). Most assays for naturally-occurring antibodies, particularly antibodies to lipids, start at a much higher concentration of serum, typically a dilution of 1/50. Thus, the Garry method would be expected to miss the presence of all of the antibodies that would be detected at a higher concentration of serum. In fact, it is possible that at a higher concentration of serum 100% of normal blood donors might give positive results. [When this was pointed out to Dr. Garry, he admitted that a much higher percentage of positives in normal serum might have been detected with more concentrated serum.] A further drawback of the use of only a single dilution of serum rather than a series of dilutions, is that there is a no way to obtain a titer, i.e., a quantitative measure of the degree of activity in the sample. Titers are routinely obtained in measurement of antibody levels, and the absence of quantitation in the Garry assay prevents any meaningful comparison between unknown serum samples.

Fourth, no specificity controls were run to determine if the antibody binds to other structurally related compounds, such as cholesterol. Although Dr. Garry verbally stated that the antibodies did not bind to squalane (the fully hydrogenated analog that lacks double bonds), there was no evidence of any specificity whatsoever in the manuscript that was sent for peer review. One can only wonder why such important information would

be left out of the first description of an unproven assay that purports to measure specific antibodies.

As stated earlier, numerous other important and fundamental flaws were detected in the assay. This can only lead to the conclusion that even if the paper is ultimately published in its present form, there will continue to be, at the least, considerable controversy over the scientific validity of the assay and the conclusions derived from the assay.

Commercialization of Dr. Garry's assay

On Tuesday, 25 May 1999 COL Alving and Dr. Matyas had a detailed telephone conversation with Dr. Russell Wilson, President of Autoimmune Technologies, L.L.C. (New Orleans, LA). This was done because Dr. Garry had indicated that, even in the absence of peer-reviewed scientific validation, the patent rights to the technology for measuring antibodies to squalene had been exclusively licensed by Tulane University for commercial development by this company. Dr. Wilson confirmed that Drs. Garry and Asa are listed as coinventors on the patent for the assay that has been exclusively licensed by Autoimmune Technologies. This was further confirmed in a letter dated 25 May that was shipped to COL Alving by Dr. Wilson. According to Dr. Wilson, the company does not currently have any type of kit or other product that can be purchased for detecting antibodies, but is in the process of developing a product. Dr. Wilson stated that the company is working on an "ELISA-based version" of the assay. If this is true, then it might represent still another assay that has not been validated in a normal scientific manner.

Financial conflict of interest of Drs. Asa and Garry

The exclusive licensing of the above patent application, on which Asa and Garry are coinventors, to Autoimmune Technologies establishes an obvious, and highly disturbing, economic motive to achieve widespread testing for profit. In the absence of such testing for antibodies to squalene, the exclusive license to Autoimmune Technologies would be worthless. Furthermore, Dr. Wilson stated, and the faxed manuscript confirmed, that Autoimmune Technologies also provides professional financial support for Dr. Garry at Tulane in the form of a grant. Although the issue was not investigated in depth with Dr. Garry or Wilson, it is likely that Drs. Asa and Garry also stand to benefit personally from commercialization of the patent. The financial benefits that would accrue to Drs. Asa and Garry, both professionally and personally, therefore create an obvious conflict of interest that, at a minimum, could be expected to color their scientific objectivity.

Anti-military agenda of Drs. Asa and Garry

It is disturbing to note that the strongest thrust of the above manuscript by Asa, Cao, and Garry, that is based on an unvalidated and unproven assay, is apparently directed to trying to convince sick Gulf War veterans that their illnesses are due to the presence of antibodies to squalene. There is an apparent agenda to convince veterans who put their lives on line in the Gulf War, that such antibodies were actually caused by their Gulf War experience. From the quotations in the popular press it is clear that there is also an agenda by some to claim that the antibodies were

induced by the alleged secret use of squalene as an adjuvant in the anthrax vaccine. To his credit, when asked about this, Dr. Garry stated that he did not believe that the antibodies were caused by any conspiracy to spike the anthrax vaccine with squalene. Instead, he apparently adhers to an alternative, but also unproven, theory that some constituent of the anthrax vaccine exhibits structural homology with squalene, a phenomenon sometimes referred to as molecular mimicry, and that the antibodies were induced by the anthrax vaccine in this manner. None of this is proven. No such structural homolog has ever been identified. This is an untested theory that has no basis whatsoever in fact. The only evidence, if it were viewed as such, is the unvalidated and unproven assay of Garry that purports to detect higher levels of antibodies to squalene in sick Gulf War veterans than in the normal population. The apparent anti-military agenda of Drs. Asa and Garry is a clear factor that could color their scientific results. Because of this, the Army could be made vulnerable by exclusive reliance on collaboration with Dr. Garry or Autoimmune Technologies. There is an obvious need for independent in-house research by the Army to examine the issues and implications, if any, of antibodies to squalene.

Antibodies to lipids are not new or unique: Antibodies to cholesterol in normal human sera

The concept of the presence of antibodies to lipids in human serum is not a new idea. COL Alving is particularly well-known for having discovered that 100% of normal human sera contain naturally-occurring antibodies to cholesterol. This observation was first made in 1988 and has been independently confirmed in the peer-reviewed literature. COL Alving has even created and patented a monoclonal antibody to cholesterol, and the clone is on deposit in the American Type Culture Collection. It has been proposed that naturally-occurring antibodies to cholesterol in humans actually serve a useful and beneficial function in helping to remove low density lipoprotein cholesterol (so-called "bad" cholesterol) from the blood. Because squalene is a precursor and building block for cholesterol in the human body, and is structurally very similar to cholesterol, it is the opinion of COL Alving that so-called antibodies to squalene might actually be antibodies to cholesterol that are cross-reacting with squalene. Thus it is possible that the apparent antibodies to squalene, per se, do not exist but rather are antibodies to cholesterol that have beneficial effects. When this was raised as an issue by COL Alving in his conversation with Dr. Garry, it was obvious that Dr. Garry was completely unaware of the scientific literature that exists on antibodies to cholesterol. When informed of the antibodies to cholesterol, Dr. Garry agreed that the purported antibodies that he observed might very well represent antibodies that react with cholesterol.

Pert Chart for Completion of Studies on Antibodies to Squalene

	99		FY00				FY01				FY02				FY01			
	$154,792		$509,256				$596,786				$493,606				$230,398			
Milestones	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	
Development and Testing of ELISA Assay for Antibodies to Squalene																		
Evaluation and Development of Other Assays for Antibodies to Squalene																		
Development of a Positive Control Antibody to Squalene																		
Large Scale Production of a Positive Control Antibody to Squalene for Use in Assays																		
Testing of Normal Human Serum for Antibodies to Squalene by ELISA																		
Testing of Normal Human Serum for Antibodies to Squalene by Other Methods																		
Development of a High Volume Throughput ELISA for the Measurement of Antibodies to Squalene in Serum																		
Development of a High Volume Throughput Assay Using an Alternative Method for the Measurement of Antibodies to Squalene in Serum																		
Testing of Gulf War Veterans for Antibodies to Squalene																		
Determination of Specificity of Antibodies to Squalene																		
Biological Significance of Antibodies to Squalene																		

SUMMARY BUDGET SQUALENE ANTIBODY TASK

Milestones	FY 99				FY 00				FY 01			
	Materials	Personnel	Overhead	Total	Materials	Personnel	Overhead	Total	Materials	Personnel	Overhead	Total
Development and Testing of ELISA Assay for Antibodies to Squalene	10,000	41,280	5,128	56,408	0	41,280	4,128	45,408	N/A	N/A	N/A	N/A
Evaluation and Development of Other Assays for Antibodies to Squalene	10,000	32,960	4,296	47,256	10,000	98,800	10,888	119,768	N/A	N/A	N/A	N/A
Development of a Positive Control Antibody to Squalene	13,520	32,960	4,648	51,128	45,080	98,880	14,396	158,356	N/A	N/A	N/A	N/A
Large Scale Production of Positive Control Antibody to Squalene for Use in Assays	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	15,000	0	1,500	16,500
Testing of Normal Human Serum for Antibodies to Squalene by ELISA and Other Methods	N/A	N/A	N/A	N/A	20,000	37,440	5,744	63,184	10,000	12,480	1,248	24,728
Development of a High Volume Throughput ELISA for the Measurement of Antibodies to Squalene in Serum	N/A	N/A	N/A	N/A	15,000	57,600	7,260	79,860	N/A	N/A	N/A	N/A
Development of a High Volume Assay Using an Alternative Method for the Measurement of Antibodies to Squalene in Serum	N/A	N/A	N/A	N/A	10,000	28,800	3,830	42,630	10,000	28,800	3,830	42,630
Testing of Gulf War Veterans for Antibodies to Squalene	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	70,000	37,440	10,744	118,184
Determination of Specificity of Antibodies to Squalene	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	40,000	131,840	17,184	189,024
Biological Significance of Antibodies to Squalene	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	55,133	131,840	18,697	205,670
Total	33,520	107,200	14,072	154,792	100,080	363,888	46,296	509,256	200,133	342,600	54,253	596,786

Total Cost for First Three Years $1,260,834

Appendix 9

THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

RECEIVED
JUL 2 3 1999

JUL -2 1999

Honorable Jack Metcalf
United States House of Representatives
Washington, DC 20515-4702

Dear Representative Metcalf:

This is in reply to your letter to Secretary Cohen regarding the United States General Accounting Office (GAO) report, GAO/NSIAD-99-5, "GULF WAR ILLNESSES: Questions About the Presence of Squalene Antibodies in Veterans Can Be Resolved." Thank you for your letter and for your concern for the health and welfare of military members and veterans.

The Department's position and concerns have not changed from those published as Appendix VI of the GAO report. The clinical significance and origin of antibodies to squalene, if their existence is corroborated, remain unknown. The test methods proposed by the investigators at Tulane University need to be reviewed and validated by other scientists. Finally, no vaccines with squalene-containing adjuvants were used in U.S. troops during the Gulf War.

Learning the clinical significance and origin of antibodies to squalene is a more important first step than knowing if such antibodies exist in a given person or group of persons. Well-designed laboratory and animal studies must precede studies in humans to answer these questions.

The forum for validating or disputing the integrity of medical research findings or clinical hypotheses is through subjecting one's work to peer review by scientists through presentation at scientific meetings and publication in peer-reviewed scientific publications. The assay for anti-squalene antibodies, which independent researchers at Tulane University developed, has not been validated at other laboratories nor have their methods and findings been subjected to broad peer review. A draft manuscript reporting the Tulane scientists' methods and findings was provided to the Research Working Group of the Persian Gulf Veterans' Coordinating Board. The Research Working Group is currently evaluating the work, will review other available literature, and will produce a White Paper on the significance of the unpublished findings.

No vaccines with squalene-containing adjuvants were used in U.S. troops during the Gulf War. There was no mention in Gulf War era documents that the DoD ever considered producing or using a vaccine that would not comply with the Food and Drug Administration's requirements for a licensed product or a product in an investigational new drug status. For several years, however, one of the scientists on the Tulane report has speculated that an autoimmune response to a vaccine adjuvant may be the cause of illnesses among Gulf War veterans. The initial speculation was that vaccines given to service members during the Gulf War contained squalene

as an adjuvant. Subsequently, the speculation was that Gulf War era service members received an experimental anti-HIV vaccine containing squalene without their knowledge.

Only recently has the speculation, as presented in the lay press, shifted to theories of adjuvants containing squalene in the anthrax vaccine. The anthrax vaccine did not and does not contain squalene. We are extremely confident of that statement; however, to reassure our service members and the public we have begun testing existing anthrax vaccine lots for the presence of squalene. The independent civilian laboratory conducting the test reports that no squalene was detectable in any vials from the six anthrax vaccine lots that have been tested to date.

The Tulane scientists have been encouraged to submit a research proposal in response to existing DoD broad agency announcements requesting proposals for Gulf War illnesses-related research. If and when the independent researcher or any other scientist submits for funding a research proposal for further studies of the alleged finding of antibodies to squalene, the DoD will ensure that the proposal receives a fair evaluation by the independent scientific review panel, which assesses all such proposals. The Department of Veterans Affairs (VA), Office of Research and Development, also has encouraged the Tulane investigators to identify a VA researcher as a collaborator and submit a proposal for funding. Since VA has an intramural research program and does not award funds to non-VA scientists, such collaboration could allow for the submission of a research proposal to VA's investigator-initiated Merit Review Program in the Medical Research Service for possible merit-based funding. The Tulane investigators have indicated to VA officials that they intend to do this.

Our commitment to civilian and Federal researchers and to Gulf War veterans is to the support and funding of high quality research, which is best assured when all decisions on research funding are based on a process of rigorous, competitive, and independent peer review of all research proposals.

Sincerely,

Dr. Sue Bailey

Appendix 10

JACK METCALF
2D DISTRICT, WASHINGTON

COMMITTEE ON TRANSPORTATION AND INFRASTRUCTURE
SUBCOMMITTEES:
AVIATION
GROUND TRANSPORTATION

COMMITTEE ON SCIENCE
SUBCOMMITTEE:
ENERGY AND ENVIRONMENT

COMMITTEE ON BANKING AND FINANCIAL SERVICES
SUBCOMMITTEES:
HOUSING
FINANCIAL INSTITUTIONS
DOMESTIC AND INTERNATIONAL MONETARY POLICY

CHAIR, REPUBLICAN HOUSING OPPORTUNITY CAUCUS

REPUBLICAN POLICY COMMITTEE

Congress of the United States
House of Representatives
Washington, DC 20515–4702

September 27, 1999

The Honorable William S. Cohen
Secretary of Defense
The Pentagon
Washington, DC 20301-1010

Dear Secretary Cohen:

I was deeply disturbed by the response I received from Dr. Sue Baily regarding my letter to you dated May 13, 1999. I had requested that the Department of Defense (DOD) reconsider its answer to the General Accounting Office (GAO) in regards to their investigative report (GAO/NSIAD-99-5, "GULF WAR ILLNESSES: Questions About the Presence of Squalene Antibodies in Veterans Can Be Resolved," dated March 29, 1999) on the presence of squalene antibodies in some sick Gulf War-era veterans. Unfortunately, her letter of refusal only raised additional concerns about DOD's unwillingness to aggressively pursue answers for those suffering from Gulf War Illnesses.

One of the things most troubling to me over the past months, is the misinformation that DOD continues to provide publicly regarding this issue. The Tulane study demonstrates that ill Gulf War-era veterans have statistically distinct antibody levels to squalene when compared to other population groups. Various sources within DOD continue to assure the public and military members that squalene is naturally occurring in the human body and is found in over-the-counter items. Are you alleging that those who use these over-the-counter products containing squalene have similar antibody levels to sick Gulf War-era veterans being tested? If so, on what evidence are you basing your conclusion? How can we know unless we have an assay that is reliable? Is it not disingenuous for DOD to make such statements while avoiding the significant research it has done and continues to pursue in the area of adjuvant and vaccine development, and the potential use of squalene as an adjuvant component?

The recommendations of GAO are based on the sound belief that the first step in determining the significance of the Tulane results is to review the assay being used to produce the finding. The assay being used at Tulane is a variant of the common Western blot assay used routinely by the scientific community. If it is validated, then the work can begin to discover the clinical significance for those who are suffering. DOD has the scientists and resources to conduct a timely review that is inexpensive, expands on the research already conducted, and responds to the veterans who have waited over seven years for answers.

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While expressing assurance that DOD did not use adjuvants containing squalene during the Gulf War, Dr. Bailey closes her letter by encouraging the Tulane scientists to submit a research proposal. Why on the one hand has DOD been absolutely unyielding in their refusal to cooperate with GAO recommendations (for the DOD to conduct its own research designed to replicate or dispute the findings), while on the other, encouraging a formal research proposal on the very study we have repeatedly asked DOD to review?

In light of these events, I am requesting a complete review of DOD's work on squalene to date. Surely the DOD's research on experimental vaccines using adjuvant formulations containing squalene has provided data and meaningful insight regarding the consequences of their use. What research has been done by your department to assess the adverse health effects of these adjuvants? Did the trials include an 'adjuvant-only' test group to provide data regarding its safety? I am asking that you provide a clear picture for Congress and the public, of your work regarding adjuvant formulations so that rumor can be dispelled and replaced with fact.

Once again, because of your department's years of research in this area, I ask that you reconsider and proceed with the GAO recommendations. Your current position of waiting for the completion of the peer review and publication process does not recognize the vast amount of research that the DOD has already accomplished regarding adjuvant formulations containing squalene. The men and women who served honorably and are suffering from Gulf War Illnesses deserve truthful answers and *immediate action.*

I look forward to your personal reply.

Sincerely,

Jack Metcalf

Appendix 11

H.R. 2561
Dept of Defense Appropriations Bill 2000
Title VI
Report of the Comm on Appropriations 280

mittees by no later than January 31, 2000 on actions taken in the military health system to establish a systematic program for early detection and prevention of cervical cancer using the most modern and up to date screening methods.

GULF WAR ILLNESS

The Committee concurs with the findings of a recent GAO report on squalene antibodies and is concerned by the Department's reluctance to test for squalene antibodies since squalene is a potential contributing factor in illnesses of veterans of the Persian Gulf War. The Secretary of Defense is directed to develop and/or validate the assay to test for the presence of squalene antibodies. A report detailing the proposals to carry out this requirement shall be submitted to the Committee by January 1, 2000.

COMPUTER BASED MODELING IN HEALTH CARE

The Committee believes that computer based modeling and simulation capabilities may assist military health planners to assess the cost, access and quality impacts of reengineering delivery processes, delivery of protocols, and insertion of technology before committing vital resources. The Committee urges the Department to consider these management tools.

CHEMICAL AGENTS AND MUNITIONS DESTRUCTION, ARMY

Fiscal year 1999 appropriation	$780,150,000
Fiscal year 2000 budget request	1,169,000,000
Committee recommendation	781,000,000
Change from budget request	−388,000,000

COMMITTEE RECOMMENDATIONS

PROGRAM REDUCTIONS

The Army requested $1,169,000,000 for Chemical Agents and Munitions Destruction, Army. The Committee recommends $781,000,000, a decrease of $388,000,000. Of the decrease, $4,500,000 is taken with prejudice against program management consultants. Of the funds available, $75,303,000 shall be transferred to the Federal Emergency Preparedness Program to provide off-post emergency response and preparedness assistance to the communities surrounding the eight continental United States chemical storage and disposal sites.

The Chemical Agents and Munitions Destruction Program, Army mission is to safely destroy all U.S. chemical warfare munitions and related materiel while ensuring maximum protection of the public, personnel involved in the destruction effort, and the environment. The Committee commends the Army for its efforts in destroying chemical munitions in a safe manner. As of March 17, 1999, over 13.5 percent, or 4,259 tons, of the stockpile has been destroyed. Currently there are two sites operational and five sites in the design phase. Despite the fact that two additional sites are on hold until completion of the Assembled Chemical Weapons Assessment Demonstration, the Committee is hopeful that the U.S. will meet the deadline of April 2007 for the destruction of chemical munitions as called for by the Chemical Weapons Convention.

Signed into law
10/25/99

Appendix 12

THE SECRETARY OF DEFENSE
WASHINGTON, DC 20301

NOV 08 1999

NOV 3 1999

Honorable Jack Metcalf
House of Representatives
Washington, DC 20515-4702

Dear Jack:

Thank you for your letter on the Department's position regarding the U.S. General Accounting Office report "Gulf War Illnesses: Questions about the Presence of Squalene Antibodies in Veterans Can be Resolved" (GAO/NSIAD-99-5).

We share your concern about troubling misinformation on this issue. The Department's position has been consistent and remains unchanged. Squalene was not used as an adjuvant in the anthrax vaccine. DoD gave no vaccines with squalene-containing adjuvants to U.S. troops deploying to the Gulf War. The Food and Drug Administration has verified that none of the vaccines used during the Gulf War contained squalene as an adjuvant. DoD contracted with an independent laboratory that verified that the anthrax vaccine does not contain squalene.

We asked the Tulane investigators to submit an application for research funding to validate their testing, but they did not. Our commitment to non-Government and Federal researchers and to Gulf War veterans is to support and fund research on potential causes of illnesses in Gulf War veterans. DoD is interested in looking at whether illnesses in service members are associated with antibodies to squalene. To do this, we need a scientifically proven test for squalene antibodies to assess whether Gulf War veterans have antibodies to squalene, hence our reason for pursuing additional research. In response to a DoD solicitation for research on illnesses among Gulf War veterans, a DoD investigator who is a nationally recognized expert in antibodies to cholesterol and other lipids, has been funded to pursue a study to determine the feasibility of developing a test for antibodies to squalene.

To date, the Tulane investigators have not succeeded in publishing their work in the medical literature. A draft of the Tulane paper was provided to the Research Working Group (RWG) of the interagency Persian Gulf Veterans' Coordinating Board. I have asked the RWG to provide you with a copy of its review of the draft Tulane paper. The review will contain the additional information on squalene that you requested.

Sincerely,



TOTAL P.02

Title: Antibodies to Squalene
Project #: DoD-100
Agency: DoD
Study Location: Walter Reed Army Institute of Research (WRAIR), Forest Glen, MD
Project Status: Ongoing
Principal Investigator: Colonel Carl Alving, MD
Start Date: 1999
Completion Date: 2001
Phone: 301-319-9611

OVERALL PROJECT OBJECTIVE: Establish an effective means of testing for antibodies to squalene and determination of whether such antibodies are present in the blood of sick Gulf War veterans.

SPECIFIC AIMS: See objective.

METHODOLOGY: Clinical (immunologic) research.

EXPECTED PRODUCTS (MILESTONES): Establishment of appropriate testing method(s) for squalene antibodies and determination of whether such antibodies are present in a sample of ill Gulf War veterans.

STATUS/RESULTS TO DATE: The ELISA assay development is complete and control monoclonal antibodies have been successfully developed.

PUBLICATIONS: none to date

NOTES:

1. Colonel Alving submitted this proposal to the U.S. Army Medical Research and Materiel Command (USAMRMC) in FY99 under the Broad Agency Announcement (BAA) for Gulf War Illnesses Research projects.

2. An independent scientific peer review of Colonel Alving's proposal recommended that initial studies be limited to that part of the proposal directed toward induction of squalene antibodies. The peer review panel stated, "If antibodies to squalene cannot be induced, the subsequent studies proposed should not be initiated." The panel's final recommendation was, "...that only the first year of the proposal be funded until more information is provided on the experimental design and more importantly on whether or not antibodies to squalene exist."

3. The USAMRMC's Military Operational Medicine Research Program provided adequate funding to WRAIR to accomplish this objective. The funded project comprises five specific tasks to be completed by the end of FY00:

a. Develop and test ELISA assay for antibodies to squalene.

b. Evaluate and develop other assays for antibodies to squalene.

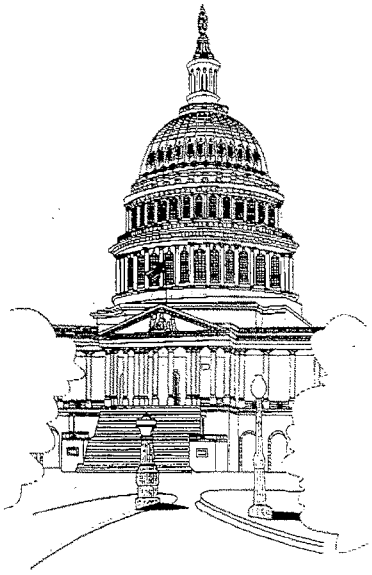
c. Develop a positive control antibody to squalene.

d. Large scale production of positive control antibody to squalene for use in assays.

e. Test normal human serum for antibodies to squalene by ELISA and other methods.

REPORT TO CONGRESS

GULF WAR ILLNESS



Development and Validation of an Assay to Test for the Presence of Squalene Antibodies

Executive Summary

This Report has been prepared in response to a requirement of the 106th Congress, House of Representatives, Report 106-244, 2000 Department of Defense Appropriations Bill:

> The Committee concurs with the findings of a recent GAO report on squalene antibodies and is concerned by the Department's reluctance to test for squalene antibodies since squalene is a potential contributing factor in illnesses of veterans of the Persian Gulf War. The Secretary of Defense is directed to develop and/or validate the assay to test for the presence of squalene antibodies. A report detailing the proposals to carry out this requirement shall be submitted to the Committee by January 1, 2000.

A May 1999 *Vanity Fair* article, "The Pentagon's Toxic Secret," alleged that the Department of Defense possibly used "an illicit and secret anthrax vaccine" on its own soldiers.[31] According to a Vanity Fair news release, "the licensed formula for...anthrax vaccine may have been altered, without formal FDA approval, to contain an experimental, and potentially dangerous, additive," squalene, that reportedly "causes incurable diseases in lab animals and may be the cause of some cases of Gulf War syndrome." The *Vanity Fair* article went on to suggest that the modified anthrax vaccine "may be part of the stockpile now being administered in the wake of the DoD's December 1997 decision to immunize 2.4 million people in the armed services against anthrax." A NewsWatch Associate editor presented an opposing review of the allegations entitled "Vanity Scare" in May 1999.[32]

On March 29, 1999, Congressman Jack Metcalf announced the release of a General Accounting Office (GAO) report, which he had requested, regarding squalene antibodies in veterans suffering from Gulf War illnesses. The GAO Report, "Gulf War Illnesses: Questions about the Presence of Squalene Antibodies in Veterans Can be Resolved" (GAO/NSIAD-99-5) recommended that DoD "conduct research designed to replicate or dispute the unpublished independent research results that revealed the presence of squalene antibodies in the blood of ill Gulf War-era veterans."[33]

In its investigations of illnesses among Gulf War veterans, the Senate Special Investigations Unit (SIU) found no credible information indicating that vaccines used during the Gulf War contained squalene.[38] In its report, the SIU stated that according to the Food and Drug Administration (FDA), squalene can be contained in a vaccine due to two different processes: 1) as an adjuvant, which is an agent to enhance the immune response; or 2) in minute quantities in vaccines manufactured using eggs, since eggs are rich in squalene and cholesterol. The FDA verified that none of the vaccines used during the Gulf War contained squalene as an adjuvant.

To investigate the squalene hypothesis, a scientifically proven test for squalene antibodies is needed to assess whether Gulf War veterans have antibodies to squalene. In response to a DoD solicitation for research on illnesses among Gulf War veterans, a DoD investigator and nationally recognized expert on antibodies to cholesterol and other lipids submitted a research proposal to determine the feasibility of developing a test for antibodies to squalene.

The funded research project to determine whether antibodies to squalene exist has five main objectives:

1) Development and validation of an ELISA assay for antibodies to squalene.
2) Evaluation and potential development of other assays for antibodies to squalene.

3) Development of a positive control antibody to squalene.
4) Production of the positive control antibody to squalene for use in the assays.
5) Testing of normal human serum for antibodies to squalene by ELISA and other methods.

The DoD funded study should provide adequate scientific evidence to resolve the issue of whether squalene antibodies exist and can be detected in human serum.

Background

Squalene is a relatively simple, linear hydrocarbon. It is a naturally occurring molecule in the human metabolic process that synthesizes cholesterol.[1] Squalene is present in human sebum and cell wall structures. Squalene is also a component of shark liver oil, some vegetable oils, and plant and animal cell membranes.[2] It is licensed by the FDA as a dietary supplement in the United States and is listed in the *Physicians' Desk Reference*. Squalene is used commercially in the cosmetic industry and in sunscreen products.[3]

Epidemiological studies of breast and pancreatic cancer in several Mediterranean populations have demonstrated that increased dietary intake of olive oil is associated with a small decreased risk or no increased risk of cancer, despite a higher proportion of overall lipid intake. Experimental animal model studies of high dietary fat and cancer also indicate that olive oil has either no effect or a protective effect on the prevention of a variety of chemically induced tumors. As a working hypothesis, it is proposed that the high squalene content of olive oil, as compared to other human foods, is a major factor in the cancer risk-reducing effect of olive oil. Experiments in vitro and in animal models suggest a tumor-inhibiting role for squalene.[4] In addition, studies using squalene in combination with low-dose pravastatin have demonstrated combination therapy significantly reduces total cholesterol and LDL cholesterol and increases HDL cholesterol to a greater extent than either drug alone.[5]

Squalene is one of several components of adjuvant formulations in a variety of vaccines.[6] One common formulation is MF59. MF59 is a safe, practical, and potent adjuvant for use with human vaccines.[7] Toxicology studies in animal models and Phase I-III studies in humans have demonstrated the safety of MF59 with HSV, HIV, and influenza vaccines.[7-17] Hilhers, et al, concluded that reactogenicity and stability but not adjuvanticity of synthetic sulfolipo-polysaccharide/squalane/water formulations depended on the molecular weight of synthetic sulfolipo-polysaccharide and that synthetic sulfolipo-cyclodextrin/squalane/water is a promising non-mineral oil adjuvant as it combines strong adjuvanticity (i.e. better than the mineral oil-based adjuvant presently applied) with low reactogenicity and good stability.[18]

However, Lorentzen has reported that the cholesterol precursor squalene (C30H50), through nonspecific activation of the immune system, can precipitate arthritis in rats. Using arthritis-prone rat strains to search for disease-triggering factors among molecules which initially induce innate defense reactions rather than specific immune responses, Lorentzen reported on the potential for endogenous lipids to precipitate arthritis.[19] In addition, there is evidence that in some instances squalene has a negative effect on the nervous system.[20-21]

Pamela B. Asa, Ph.D., an unaffiliated molecular biologist from Memphis, Tennessee and Yan Cao, M.D. and Robert F. Garry, Ph.D., from Tulane University, New Orleans, Louisiana have theorized that illnesses afflicting veterans of the Gulf War are an atypical connective tissue disease (an autoimmune disease) resulting from use of the vaccine adjuvant, squalene.[22-23] These investigators have reportedly developed an immunoassay for detecting anti-squalene antibodies and used the assay to test blood serum samples from various patient and control groups.

To investigate this hypothesis, DoD has funded a scientific program which will answer several major questions. Initially, the research staff will determine if antibodies to squalene exist and if an assay can be developed to detect and quantify these antibodies. In addition, an animal model will be used to induce anti-squalene antibodies to use as positive controls to characterize anti-squalene antibodies in

humans. If a positive antibody response to squalene can be induced in mice, then normal human serum can be tested for possible antibodies to squalene. Next, the research program will focus on qualitative detection of squalene and development of a chemical assay. Finally, the research program will examine the biological implications of antibodies to squalene.

Discussion

Pamela B. Asa, who has worked in the area of rheumatology and silicone-gel breast implants, presented a theory in 1995 of "human adjuvant disease" and its possible link to Persian Gulf War (PGW) Veterans' Illnesses. She theorized that silicone adjuvant (an agent added to a vaccine to increase antigenic response) was responsible for PGW veterans developing "human adjuvant disease."[24] A scientific review prepared by an independent non-governmental medical expert on September 13, 1995 of Dr. Asa's "Report on Gulf War Syndrome" found the basic hypothesis and supporting evidence presented was based on a series of erroneous assumptions and unsupported conjectures.[25] A similar review by the Medical, Chemical and Biological Defense Research Program found the basic hypothesis and supporting evidence presented by Dr. Asa were flawed or inaccurate.[26] Available information also strongly argues against Dr. Asa's hypothesis:

> All vaccines used during the Gulf War have a long history of safety and all, except BotTox that was used under an Investigational New Drug (IND), were licensed by the FDA at the time of the Gulf War.
>
> Since the standard immunization series is given to individuals in basic and advanced training, only a relatively small number of additional vaccines were given during deployment to the Persian Gulf, and the previous use of these vaccines has not resulted in problems similar to those reported by GW veterans.
>
> All vaccine lots are individually licensed for safety and efficacy. The vaccines used, therefore, are unlikely to be contaminated or of low quality.
>
> The only adjuvant used in the vaccines given to Gulf War personnel was alum. Alum is an FDA-approved adjuvant with a long history of safety. It has been given to millions of people worldwide without significant problems. No experimental adjuvants were used by the military.
>
> There are no reports of alum causing human adjuvant disease or any other chronic disease.
>
> There are no reports of chronic inflammatory responses at the sites of immunization with vaccines containing alum as would be expected if human adjuvant disease were to occur.
>
> Several recent studies have failed to show any association between silicone-gel implants and increased incidence of connective tissue disease. There is little supporting evidence, other than anecdotal reports, that silicone-gel implants cause an increase in connective tissue diseases or human adjuvant disease.

Dr. Asa's current work focuses on the presence of antibodies to squalene in a cohort of 142 Gulf War-era veterans or military employees. She theorizes that "Gulf War Syndrome" manifests a spectrum of signs and symptoms similar to that of other atypical connective tissue diseases and that most "Gulf War Syndrome" patients have serum antibodies to squalene, an immunological adjuvant. The study protocol attributes the hypotheses to findings in one (1) patient from a NIH-sponsored trial using squalene as an adjuvant.[22] The findings of the current unpublished work apparently originate from samples collected under this protocol. It is unknown if informed consent was obtained from individuals submitting samples for testing or if an Institutional Review Board (IRB) reviewed and approved the research protocol. Review of the draft manuscript indicates the basic hypothesis and supporting evidence presented as flawed or inaccurate. The findings from the study must be interpreted with caution as flawed methodology including biased sample selection and potential cofounders weaken any potential association. The following information also strongly argues against the current hypothesis:

> If in fact antibodies to squalene are present in Gulf War veterans, the clinical significance of finding these antibodies in humans is unknown. Squalene is normally present in humans as part of the body's production of

cholesterol. In addition, it is found in human sebum (skin oils) and plant and animal cell membranes. Antibodies to cholesterol in humans are common.

There may be alternative explanations for the reported laboratory findings, including: detection of naturally occurring squalene; cross-reaction with compounds similar to squalene; elevated levels of squalene due to a known or unknown disease process causing human illnesses, or; laboratory error or contaminant.

If in fact anti-squalene antibodies are present in the blood of Gulf War-era veterans, this is not sufficient to establish an association of squalene or squalene antibodies with any illness(es) among Gulf War veterans.

The assay for anti-squalene antibodies, which independent researchers at Tulane University developed, has not been validated at other laboratories nor have their findings been subjected to minimal peer review through publication in the scientific literature.

The only adjuvant used in the vaccines given to Gulf War personnel was alum. Alum is an FDA-approved adjuvant with a long history of safety. It has been given to millions of people worldwide without significant problems. No experimental adjuvants were used by the military.

The anthrax vaccine given to service members during the Gulf War and subsequently did not and does not contain squalene.

The Army Surgeon General has verified that the anthrax vaccine was never produced at any alternate production facilities in the U.S. during the Gulf War, and anthrax vaccine production at the Michigan Biologic Products Institute (MBPI, now BioPort) never contained squalene. Stanford Research Institute, International has recently completed verification testing for squalene on 6 lots of anthrax vaccine and verified that no squalene was detectable in any of the vials.

There are no data demonstrating increased rates of autoantibodies in ill Gulf War veterans.

Unfortunately, we cannot be sure that the theorists actually detected antibodies to a synthetic squalene adjuvant in the veterans they tested. They reportedly used a variation of a previously described assay.[27] This technique was used to claim findings of the first evidence from a blinded study of the existence of a laboratory marker that correlates with the severity of local and systemic complications in silicone breast implant recipients. The assay in question detects antibodies, not to silicone, but to a synthetic polymer whose characteristics have not been fully described. In subsequent letters to the editor, many noted the methodological flaws in the study, argued that since the antibody is not against silicone, there was no reason to suppose the implants had anything to do with the symptoms or antipolymer antibody assay test results, and noted that the investigators had reported similar high seroactivity in fibromyalgia patients.[28] A Committee named by the Institute of Medicine (IOM) recently reported that a careful study of all the evidence indicates that women with silicone breast implants are no more likely to develop chronic disease than women without the implants. The IOM Committee did not address antipolymer antibodies; however, they stated that "The clinical significance of a recently described antipolymer antibody test is unclear, although the polymer in question is not silicone or silicon containing, and it is extremely unlikely that it measures an antisilicone antibody."[29]

Dr. Garry and Tulane University reportedly received a U.S. patent in 1997 for an assay that could detect antibodies to polymers, of which squalene is one. In a letter from Dr. Garry to DoD, Re: Anti-Squalene Antibodies, dated May 7, 1999, Dr. Garry informed DoD that Tulane University Medical Center had applied for a patent on the use of anti-squalene antibodies in assessing Gulf War Syndrome. Dr. Garry also informed DoD that Tulane was the sole owner of the intellectual property provided in the letter of May 7, and that DoD should share the data only with those who have a specific need to know. In this letter, Dr. Garry reviewed the specifics of the anti-squalene antibody assay, or ASA Assay, that measures the binding of serum immunoglobulins to squalene.

The Office of the Army Surgeon General (OTSG) requested an update in early May 1999 on investigations, tests, and projects to investigate allegations regarding squalene in the anthrax vaccine and plans for developing an assay for squalene antibodies.[30] In the update, the Army stated that all lots of the anthrax vaccine released by DoD would be tested and that current testing to date by Stanford Research Institute, International confirmed that no squalene was detectable in any of the vials. The FDA is doing additional testing. Dr. Garry provided the manuscript outlining the details of his proposed assay to OTSG for review. It was the opinion of COL Alving and Dr. Matyas that there were "dozens of important technical and theoretical flaws" in the assay-many described by COL Alving as "fatal flaws." Dr. Garry had informed COL Alving and Dr. Matyas that, "even in the absence of peer-reviewed scientific validation, the patent rights to the technology for measuring antibodies to squalene had been exclusively licensed by Tulane University for commercial development by a company called, Autoimmune Technologies, L.L.C." Dr. Garry was unaware of the scientific literature that exists on antibodies to cholesterol. When informed of the antibodies to cholesterol by COL Alving, Dr. Garry "agreed that the purported antibodies that he observed might well represent antibodies that react with cholesterol."

Excerpts of the GAO report entitled, "Gulf War Illnesses: Questions about the Presence of Squalene Antibodies in Veterans Can be Resolved" stated that independent researchers had developed a test based on a Western blot assay and had detected antibodies to squalene in the blood of sick Gulf War veterans. If the description of the test described in the GAO report is accurate, there are some technical points that would seem to invalidate such a test:

> Squalene is a non-charged long chain hydrocarbon that would not be expected to migrate on a gel such as required in a Western blot assay.
>
> Because squalene lacks charge, it would not be expected to transfer to nitrocellulose as is done in a Western blot assay.

On March 29, 1999, Congressman Jack Metcalf (Washington) announced the release of a GAO report, which he had requested, regarding squalene antibodies in veterans suffering from Gulf War illnesses. The GAO Report, "Gulf War Illnesses: Questions about the Presence of Squalene Antibodies in Veterans Can be Resolved" (GAO/NSIAD-99-5) recommended that DoD "conduct research designed to replicate or dispute the independent research results that revealed the presence of squalene antibodies in the blood of ill Gulf War-era veterans."[31] The GAO did not comment on the ethical conduct of the research including a requirement for informed consent and IRB review of the protocol. The GAO did note that Chiron and Ribi ImmunoChem reported that their squalene adjuvant formulation had been tested on over 9,000 and 1,000 human subjects, respectively.

The clinical significance of finding antibodies to squalene is unknown. Squalene is normally present in humans as part of the body's production of cholesterol. It is found in human sebum (skin oils) and plant and animal cell membranes. The scientific work that has been done on squalene's role in human health and disease notes the positive effects of dietary squalene on cancer prevention and cholesterol regulation and the safety and efficacy of squalene as a vaccine adjuvant. There may be alternative explanations for the reported laboratory findings, including: detection of antibodies to cholesterol;[32a-27] detection of antibodies to naturally occurring squalene; cross-reaction with compounds similar to squalene; elevated levels of squalene due to a known or unknown disease process causing human illnesses, or; laboratory error or contaminant.

The assay for anti-squalene antibodies developed by independent researchers at Tulane University has not been minimally validated through publication in the scientific literature. The investigators have

reportedly submitted a manuscript to a peer-reviewed medical journal; to date, however, this effort apparently has not been successful.

Since the Gulf War, squalene has been a component of vaccines undergoing testing by the Walter Reed Army Institute of Research (WRAIR). Volunteers received the vaccines in well-controlled studies that followed FDA regulations. Squalene is one of several components of the adjuvants found in each of two vaccine products undergoing testing by WRAIR. Pharmaceutical grade squalene is used to produce the oil emulsion used in these vaccine products. The exact compositions of the adjuvant in these vaccines are proprietary and belong to DoD Cooperative Research and Development Agreement (CRDA) partners. Development, evaluation, and FDA approval for the use of these adjuvant systems has been conducted by DoD CRDA partners and WRAIR. The two vaccines are investigational products for the prevention of malaria and human immunodeficiency virus (HIV) infection. Information on the study on the HIV vaccine has not yet been published and is considered proprietary information. Information on the study involving the malaria vaccine has been published in the scientific literature.[35]

Prior to its use in humans, the vaccines containing the emulsion underwent extensive FDA-mandated Good Laboratory Practices repeat dose toxicology studies involving rodents, rabbits, guinea pigs and nonhuman primates. The details of these studies (four volumes) were filed with the FDA as part of the IND application. The studies revealed anticipated inflammatory responses surrounding the site of injection. No gross changes were observed. No laboratory abnormalities were found.

Conclusion

Allegations of an ongoing conspiracy by the media and others is troubling. Squalene is not a foreign substance. It is normally present in the human body in large quantities because it is a precursor to the biosynthesis of cholesterol in the liver. The DoD funded study should provide adequate scientific evidence to resolve the issue of whether squalene antibodies exist and if they can be detected in human serum. Since squalene is being used as an adjuvant in some newer generation vaccines, this question becomes of interest not only to the military but also to the general public. Previously, these investigators were able to demonstrate antibodies to cholesterol. Squalene may not be immunogenic by itself, but under certain circumstances antibodies to the compound may arise. Although antibodies to cholesterol and possibly squalene occur naturally, this does not necessarily mean they have an adverse effect.

This research proposal was submitted in response to a competitive solicitation for proposals. The proposal was peer reviewed independent of the Department, by the American Institute of Biological Sciences, and received a high scientific merit score. Programmatic review was accomplished by the Department and the Research Working Group of the Persian Gulf Veterans Coordinating Board. Based on the results of this research, further studies can be pursued, if appropriate, to look at the existence of these antibodies in Gulf War veterans and their correlation to disease.

1) Mayes P.A., Cholesterol Synthesis, Transport, & Excretion, Harpers Biochemistry, 24 ed. 271-283
2) Christian, M.S. Final Report on the Safety and Assessment of Squalane and Squalene. J. Amer Coll Toxicol., 1:37-56 1982
3) Christian, M.S. Final Report on the Safety and Assessment of Squalane and Squalene. J. Amer Coll Toxicol., 1:37-56 1982
4) Newmark HL, Squalene, olive oil, and cancer risk: a review and hypothesis, Cancer Epidemiol Biomarkers Prev 1997 Dec;6(12):1101-3
5) Chan P, Tomlinson B, Lee CB, Lee YS, Effectiveness and safety of low-dose pravastatin and squalene, alone and in combination, in elderly patients with hypercholesterolemia, J Clin Pharmacol 1996 May;36(5):422-7
6) Vogel F.R. and Powell, M.F. A Compendium of Vaccine Adjuvants and Excipients, Vaccine Design, 1994
7) Ott G, Barchfeld GL, Chernoff D, Radhakrishnan R, van Hoogevest P, Van Nest G; MF59. Design and evaluation of a safe and potent adjuvant for human vaccines, Pharm Biotechnol 1995;6:277-96
8) Minutello M, Senatore F, Cecchinelli G, Bianchi M, Andreani T, Podda A, Crovari P, Safety and immunogenicity of an inactivated subunit influenza virus vaccine combined with MF59 adjuvant emulsion in elderly subjects, immunized for three consecutive influenza seasons, Vaccine 1999 Jan;17(2):99-104
9) Cataldo DM, Van Nest G, The adjuvant MF59 increases the immunogenicity and protective efficacy of subunit influenza vaccine in mice, Vaccine 1997 Nov;15(16):1710-5
10) O'Hagan DT, Ott GS, Van Nest G, Recent advances in vaccine adjuvants: the development of MF59 emulsion and polymeric microparticles, Mol Med Today 1997 Feb;3(2):69-75
11) Keefer CM, Graham BS, McElrath MJ, Matthews TJ, Stablen DM, Corey L, Wright PF, Lawrence D, Fast PE, Weinhold K, Hsieh R, Chernoff D, Dekker C, Dolin R, Safety and Immunogenicity of Env 2-3, a Human Immunodeficiency Virus Type 1 Candidate Vaccine, in Combination with a Novel Adjuvant, MTP-PE/MF59. Aids Research and Human Retroviruses, 199612(8): 683-693
12) Belshe RB, Gorse GJ, Mulligan MJ, Evans TG, Keefer MC, Excler JL, Duliege AM, Tartaglia J, Cox WI, McNamara J, Hwang KL, Bradney A, Montefiori D, Weinhold KJ, Induction of immune responses to HIV-1 by canarypox virus (ALVAC) HIV-1 and gp120 SF-2 recombinant vaccines in uninfected volunteers, AIDS 1998, 12:2407-2415
13) Straus SE, Wald A, Kost RG, McKenzie R, Langenberg AGM, Hohman P, Lekstrom J, Cox E, Nakamura M, Sekulovich R, Izu A, Dekker C, Corey L, Immunotherapy of Recurrent Genital Herpes with Recombinant Herpes Simplex Virus Type 2 Glycoproteins D and B: Results of a Placebo-Controlled Vaccine Trial, The Journal of Infectious Diseases, 1997;176:1129-34
14) Langenberg AGM, Burke RL, Adair SF, Skulovich R, Tigges M, Dekker CL, Corey L, A Recombinant Glycoprotein Vaccine for Herpes Simplex Type 2: Safety and Efficacy, Annals of Internal Medicine, 15 June 1995;122:889-898
15) Lambert JS, McNamara J, Katz SL, Fenton T, Kang M, VanCott TC, Livingston R, Hawkins E, Moye J, Borkowsky W, Johnson D, Yogev R, Duliege AM, Francis D, Gershon A, Wara D, Martin N, Levin M, McSherry G, Smith G, Safety and Immunogenicity of HIV Recombinant Envelope Vaccines in HIV-Infected Infants and Children, Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology, 1998, 19:451-461
16) Wang JB, Adler SP, Hempfling S, Burke RL, Duliege AM, Starr SE, Plotkin SA, Mucosal Antibodies to Human Cytomegalovirus Glycoprotein B Occur following both Natural Infection and Immunization with Human Cytomegalovirus Vaccines, The Journal of Infectious Diseases 1996

17) 174:387-92; Ashley RL, Crisostomo FM, Doss M, Sekulovich RE, Burke RL, Shaughnessy M, Corey L, Polissar NL, Lengenberg AGM, Cervical Antibody Response to a Herpes Simplex Virus Type 2 Glycoprotein Subunit Vaccine, The Journal of Infectious Diseases 1998;178:1-7
18) Hilgers LA, Lejeune G, Nicolas I, Fochesato M, Boon B , Sulfolipo-cyclodextrin in squalane-in-water as a novel and safe vaccine Adjuvant, Vaccine 1999 Jan 21;17(3):219-28
19) Lorentzen JC, Identification of arthritogenic adjuvants of self and foreign origin, Scand J Immunol 1999 Jan;49(1):45-50
20) Gajkowska B, Smialek M, Ostrowski RP, Piotrowski P, Frontczak-Baniewicz M, The experimental squalene encephaloneuropathy in the rat, Exp Toxicol Pathol 1999 Jan;51(1):75-80
21) Smialek M, Gajkowska B, Ostrowski RP, Piotrowski P, Experimental squalene encephaloneuropathy in the rat, Folia Neuropathol 1997;35(4):262-4
22) Asa, Pam, Protocol for Study of Gulf War Illnesses
23) Asa PB, et al. Gulf War Syndrome pathology is associated with serum antibodies to an immunological adjuvant, squalene. Unpublished
24) The Possible Role of Vaccine Adjuvants in Persian Gulf War Veterans' Illnesses, March 1996, http://www.gulflink.osd.mil
25) Independent Non-Governmental Medical Expert, Scientific Review, Report on Gulf War Syndrome by Dr. Pam Asa, September 13, 1995
26) U.S. Army Medical Research and Material Command, Medical Chemical and Biological Defense Research Program, Review of Report on Gulf War Syndrome by Dr. Pam Asa, Synopsis of Hypothesis Proposed, 13 October 1995
27) Tenenbaum, SA, et al, Use of antipolymer antibody assay in recipients of silicone breast implants, *Lancet* 1997; 349: 449-54
28) *Lancet* 1997; 349: 1170-1173
29) Safety of Silicone Breast Implants, 1999, Institute of Medicine
30) Information Paper, OTSG-HCO, 27 May 1999, Investigation into Allegations of Squalene in Anthrax Vaccine
31) Matsumoto, G., The Pentagon's Toxic Secret, Vanity Fair, May 1999, 82-98
32) Butterworth, T. NewsWatch Spotlight, 11 May 1999
33) GAO Report, Gulf War Illnesses: Questions about the Presence of Squalene Antibodies in Veterans Can be Resolved, GAO/NSIAD-99-5
34) Alving, C.R., et al, found most human sera tested contain naturally occurring IgG and IgM autoantibodies that react with crystalline cholesterol
35) Alving, Carl R., Swartz, Glen M. and Wasseff, Nabila M., Naturally occurring autoantibodies to cholesterol in humans, Biochemical Society Transactions, 629th Meeting, London, Vol 17; 637-639
36) Alving, Carl R., Swartz, Glen M. Antibodies to Cholesterol, Cholesterol Conjugates, and Liposomes: Implications for Atherosclerosis and Autoimmunity, Critical Reviews in Immunology, Vol 10, Issue 5; 1991:441-453
37) Swartz GM, Gentry MK, Amende LM, Blanchette-Mackie EJ, Alving CR, Antibodies to cholesterol, Proc. Natl. Acad. Sci. Vol 85, pp. 1902-1906, March 1998, Immunology
38) Report of the Special Investigation Unit on Gulf War Illnesses, 1998, page 123

39) Jose A. Stoute, Moncef Slaoui, D. Gray Heppner, Patricia Momin, Kent E. Kester, Pierre Desmons, Bruce T. Wellde, Nathalie Garcon, Urszula Krzych, Martine Marchand, W. Ripley Ballou, Joe D. Cohen, A Preliminary Evaluation of a Recombinant Circumsporozoite Protein Vaccine against Plasmodium Falciparum Malaria, *The New England Journal of Medicine* – January 9, 1997 – Volume 336, Number 2

Appendix 15

COMMITTEE ON TRANSPORTATION AND INFRASTRUCTURE
SUBCOMMITTEES:
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GROUND TRANSPORTATION

COMMITTEE ON SCIENCE
SUBCOMMITTEE:
ENERGY AND ENVIRONMENT

Congress of the United States
House of Representatives
Washington, DC 20515–4702

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CHAIR, REPUBLICAN HOUSING
OPPORTUNITY CAUCUS

REPUBLICAN POLICY COMMITTEE

January 31, 2000

The Honorable William S. Cohen
Secretary of Defense
The Pentagon
Washington, DC 20301-1010

Dear Secretary Cohen:

We are writing to ask for an objective analysis of "Antibodies to Squalene in Gulf War Syndrome" - an article that has just been published in the February 2000 issue of *Experimental and Molecular Pathology*.

This peer-reviewed article found anti-squalene antibodies in a very high percentage of sick Gulf War-era veterans. As a bio-marker for the disease process involved in Gulf War Illnesses, the assay/blood test cited in the study could provide a vital diagnostic tool. We hope this will quickly lead to improved medical treatments for many who are suffering.

Many who have heard about this issue are anxious to understand the ramifications, especially those veterans and their families whose lives sadly have been directly affected. We certainly acknowledge the need for further research. However, that should not preclude a vigorous examination of the immediate benefits this study may provide medical practitioners treating those who suffer from Gulf War Illnesses.

The House passed version of the Fiscal Year 2000 Defense Appropriations Bill included report language instructing the Department of Defense to develop and/or validate the assay to test for the presence of squalene antibodies. This action was taken in response to DOD unwillingness to cooperate with the March 1999, General Accounting Office recommendation [NSIAD-99-5].
It reflected our firm belief that the integrity of the assay was the first step in finding answers.

Now that this study has been peer-reviewed and published, we need to take the next step and build on established science. An internal review by the same individuals within the DOD who were unwilling to cooperate for months does not constitute the kind of science that those who sacrificed for this nation deserve. Given the published article, it seems prudent to use the assay if it could help sick Gulf War era veterans. Do you agree?

We look forward to hearing from you by March 1, 2000. We thank you for your commitment and efforts on behalf of our Gulf War-era veterans.

Sincerely,

Jack Metcalf

Norm Dicks

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Norm Dicks

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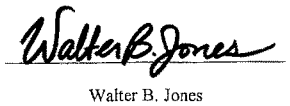
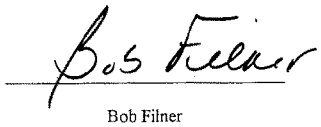
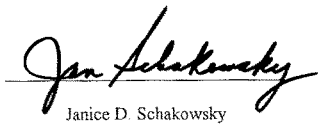


Walter B. Jones



Bob Filner



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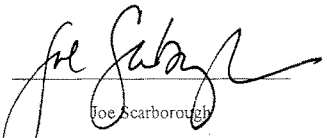
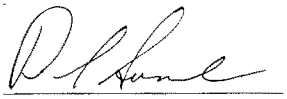
Lane Evans



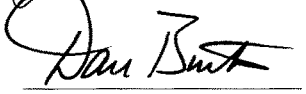
Ron Paul



Joe Scarborough



Bernard Sanders



Dan Burton

Appendix 16

JACK METCALF
2D DISTRICT, WASHINGTON

COMMITTEE ON TRANSPORTATION AND INFRASTRUCTURE
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Congress of the United States
House of Representatives
Washington, DC 20515–4702

COMMITTEE ON BANKING AND FINANCIAL SERVICES
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REPUBLICAN POLICY COMMITTEE

via facsimile 703-697-9080 - FINAL COPY

February 25, 2000

The Honorable William S. Cohen
Secretary of Defense
The Pentagon
Washington, DC 20301-1010

Dear Secretary Cohen:

I am exasperated and deeply disturbed by the Department of Defense's addition to its Anthrax Vaccination Inoculation Program (AVIP) website in the "Q & A" section under the heading "Production Issues" and the title "Accusations - Squalene."

On January 31, 2000, nine of my colleagues and I sent you a letter requesting an objective analysis of "Antibodies to Squalene in Gulf War Syndrome" - an article that had just been published in the February 2000 issue of *Experimental and Molecular Pathology* - a respected scientific peer-review journal. The letter represented our hope that DOD would seize the opportunity to do the kind of serious, scientific review that those who serve and sacrifice for our nation deserve.

Instead, a review of the AVIP website shows that DOD has chosen to do a hit-piece, dismissing "Antibodies to Squalene in Gulf War Syndrome" with the wildly expansive claim that "conclusions derived from the test results have **NO** scientific basis" (emphasis added). The marines, airmen, sailors and soldiers who access this site are not provided the courtesy of a rebuttal from the internationally respected scientist who developed the assay used in the research.

I am dismayed you would allow this posting to the website before you fully respond to the letter sent on January 31. DOD's action certainly reinforces the letter's concern regarding the inappropriateness of an internal review by the same individuals within DOD who have been unwilling to cooperate for nearly a year.

Additional information in this section is also troubling in its incompleteness. One section outlines "What does the U.S. Senate say about squalene?". Unfortunately, the site neglects to state that the 1998 conclusions made by the Senate Special Investigations Unit were made prior the GAO investigation, prior to the gathering of additional scientific data and more recently, findings in the House of Representatives.

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Page two--The Honorable William S. Cohen--February 25, 2000:

How can the DOD expect to regain the seriously eroded trust of its military personnel if misrepresentations posted on your official website are allowed to go unchallenged? Please take immediate action to remove the inappropriate and misleading response from DOD's information page, and do what is right - an objective analysis of the merits of this study.

Sincerely,

Jack Metcalf

Jack Metcalf
House of Representatives

cc: Representative Norm Dicks
Representative Walter Jones
Representative Bob Filner
Representative Janice Schakowsky
Representative Lane Evans
Representative Ron Paul
Representative Joe Scarborough
Representative Bernard Sanders
Representative Dan Burton

Appendix 17

THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

FEB 28 REC'D

FEB 24 2000

Honorable Jack Metcalf
House of Representatives
Washington, DC 20515

Dear Representative Metcalf:

Thank you for your letter asking for an objective analysis of Antibodies to Squalene in Gulf War Syndrome – an article published in the February 2000 issue of *Experimental and Molecular Pathology*. Prior to publication of the article, the Research Working Group (RWG) of the interagency Persian Gulf Veterans' Coordinating Board had objectively reviewed the work of Dr. Asa and her colleagues. We look forward to the scientific dialog and additional research that will now go forward as a result of long awaited publication of this data. I have enclosed the RWG review, our Report to Congress in response to the Fiscal Year 2000 Defense Appropriations Bill report language, and a review of the published article.

As you know, we have encouraged and awaited publication by these scientists ever since Dr. Asa first presented her theory on "human adjuvant disease" and its possible link to Persian Gulf War (PGW) veterans' illnesses. Prior to speculation about squalene, Dr. Asa theorized that silicone adjuvant (an agent added to a vaccine to increase antigenic response) was responsible for PGW veterans developing "human adjuvant disease."

The Department published in the February 10, 1999 Commerce Business Daily a specific request for research proposals on "Interactions Of Drugs, Biologics And Chemicals In Service Members In Deployment Environments," supporting our research on illnesses among Gulf War veterans. This preceded the recommendation of the General Accounting Office to pursue research in this area. In response to this solicitation, a research proposal was submitted to develop and validate an assay to test for the presence of squalene antibodies. This proposal received a high independent scientific review merit score, was funded, and the research is ongoing.

We wholeheartedly agree that the integrity of the assay is the first step in finding answers. Our commitment to Gulf War veterans is to support and fund quality research. This is best assured when all decisions on research funding are based on a process of rigorous, competitive, and independent peer review of all research proposals. We are committed to responsible and aggressive pursuit of research that will further our understanding of illnesses among Gulf War veterans and prevent similar illnesses following future deployments.

Sincerely,

Dr. Sue Bailey

Enclosures:
As stated

Scientific Manuscript: "Antibodies to Squalene in Gulf War Syndrome"

The study, by Drs. P. B. Asa, Y. Cao and R. F. Garry, appeared in the February 2000 issue of Experimental and Molecular Pathology. The paper by Asa and colleagues presents data obtained by using an immunological assay that reportedly can detect previously unknown antibodies against squalene, a relatively simple, linear hydrocarbon that is a naturally occurring molecule in humans, animals and plants. Squalene is normally found in cell membranes in humans and is one of the building blocks for producing cholesterol.

Summary: Using this novel assay, the authors' report finding anti-squalene antibodies in a high percentage of "Gulf War Syndrome" patients. The antibody test developed at Tulane University Medical Center is called the Anti-Squalene Antibody Assay, or ASA Assay. Tulane has a patent pending on the ASA Assay, and Autoimmune Technologies LLC, a New Orleans biomedical company, has licensed the rights to the ASA Assay from Tulane.

The published research reportedly included both blinded and unblinded studies. In the blinded study, the ASA Assay was reportedly used to test blood samples from 56 individuals who were in active military service or who were civilian employees of the U.S. armed forces or their contractors during 1990-1991. Most, but not all, of the members of this group were reportedly deployed to the Persian Gulf theater of operations. The group comprised 38 deployed individuals who were ill, 12 deployed individuals who were healthy, and 6 non-deployed individuals who were ill. The results of the blinded study showed that 95% of the deployed sick individuals tested positive, none of the deployed healthy individuals tested positive, and 100% of the non-deployed sick individuals tested positive for anti-squalene antibodies.

In the unblinded study, the ASA Assay was used as a screening tool to gather further data. Blood samples from 86 additional individuals who were in active military service or who were civilian employees of the U.S. armed forces or their contractors during 1990-1991, including healthy individuals, were tested, and 69% of them tested positive. Because squalene is used as an ingredient in some cosmetics, 48 samples from blood banks were tested to see if the antibodies were present in a larger segment of the general population. Of these, 5% tested positive. To see if the antibodies were a marker for other autoimmune disease processes, 40 samples from patients with systemic lupus erythematosus were tested. Of these, 10% tested positive. Because patients with chronic fatigue syndrome have many symptoms similar to those of "Gulf War Syndrome" patients, 30 chronic fatigue patients were tested. Of these, 15% were positive.

The research also included a small adjunct study in which two individuals who had previously volunteered to participate in a vaccine trial in which squalene was an adjuvant in the vaccine were tested for the presence of anti-squalene antibodies. Both subjects tested positive. These two were the only patients in the research group who had a known exposure to squalene from vaccines.
The conclusion reached as a result of this research study is that most patients in the study groups who are ill with "Gulf War Syndrome" have serum antibodies to squalene while most other people do not. The clinical significance of the presence of the antibodies, however, is still not known, and while it is possible that the antibodies play a role in the disease process itself, the study does not explore the mechanisms involved in developing the antibodies.

Critical analysis: It is unknown if informed consent was obtained from individuals submitting samples for testing or if an Institutional Review Board (IRB) reviewed and approved the research protocol.

The authors claim to create a novel assay that detects antibodies to squalene. The authors however, do not use valid positive or negative controls. There are no positive controls (i.e., sera previously proven to contain antibodies to squalene) to validate the argument that the assay can detect antibodies to squalene. For positive controls, the authors cite only results obtained using this novel assay on two individuals reportedly vaccinated once and thrice with a squalene-containing adjuvant in a clinical trial sponsored by the National Institutes of Health. The authors provide no preimmunization results to demonstrate that the presumptive anti-squalene activity in the so-called positive controls was not present before immunization with the squalene adjuvant.

Fundamental to interpretation of novel assay data are negative controls. Such negative controls are critical to prove that the assay is not detecting artifacts (extraneous, cross-reacting substances). The authors have no negative control in which the human serum containing the presumed antibodies is omitted; there is no negative control in which the avidin-conjugated horse radish peroxidase is omitted; there is no negative specificity control for nonspecific binding of IgG, i.e., for normal IgG molecules sticking nonspecifically to squalene.

A further criticism of the paper is the authors use of only a single dilution of serum, rather than a series of dilutions. Without using this technique, there is a no way to obtain a titer, i.e., a quantitative measure of the degree of activity in the sample. The test results were scored at +++, ++, +, +/-, and -, raising the possibility that at high concentrations most normal sera might give a positive result; and the total absence of antibodies in a "normal" population must be regarded with some suspicion. If "squalene antibodies" or derivatives are associated with "Gulf War syndrome," one may expect titers to parallel severity of symptoms. The paper gives no evidence of this.

The assay by Asa and colleagues remains an unvalidated and unproven assay.

Appendix 18

JACK METCALF
2d District, Washington

COMMITTEE ON TRANSPORTATION AND INFRASTRUCTURE
SUBCOMMITTEES:
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COMMITTEE ON BANKING AND FINANCIAL SERVICES
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CHAIR, REPUBLICAN HOUSING OPPORTUNITY CAUCUS

REPUBLICAN POLICY COMMITTEE

via facsimile 703-697-9080

March 3, 2000

The Honorable William S. Cohen
Secretary of Defense
The Pentagon
Washington, DC 20301-1010

Dear Secretary Cohen:

Please intervene to halt the obfuscation campaign Department of Defense officials seem intent on conducting concerning the issues surrounding antibodies to squalene research. Monday, February 28, 2000, I received a response to the letter I had sent to you. Nine of my colleagues in the House of Representatives joined me to request that DOD do an objective analysis of "Antibodies to Squalene in Gulf War Syndrome" -- an article recently published in the February 2000 issue of *Experimental and Molecular Pathology*.

DOD's letter, authored by Dr. Sue Bailey, avoids providing Congress a clear and direct answer to our request. The following excerpts illustrate my concerns with DOD's official reply.

1. In paragraph one, Dr. Bailey states that she has enclosed the Research Working Group (RWG) review. She does not mention that the RWG reviewed an early draft of the study, provided to them as a professional courtesy. The text of the final peer-reviewed article contains some significant changes. Members of Congress asked for an objective analysis of the peer-reviewed article. It is difficult to understand why Dr. Bailey chose to include a review not based on the published scientific article, unless her goal was confusion rather than clarity.

2. Also provided as an attachment, and referenced in paragraph one, is a review of the published article. I was dismayed that Dr. Bailey would provide this brief summary with no indication of the author's name or professional credentials to conduct and provide such a review. My colleagues and I stated clearly, "An internal review by the same individuals within the DOD who were unwilling to cooperate for months does not constitute the kind of science that those who sacrificed for this nation deserve." A half-page critical analysis, anonymously written, is not an appropriate response to the congressional request.

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3. Dr. Bailey continues in paragraph two by making a reference to an early theory that is completely irrelevant to our request. Dr. Asa's early and *confidential* correspondence with DOD regarding potential cause was motivated by concern for those suffering from Gulf War Illnesses. DOD must encourage researchers to explore hypotheses rather than setting them up for public criticism, if we are going to solve the mystery of Gulf War Illnesses. The congressional inquiry's focus is the peer-reviewed study and the assay used to detect the antibodies. Dr. Bailey's reference is an unnecessary distraction from the facts.

4. Dr. Bailey's third paragraph attempts to portray DOD as proactive in developing and validating an assay to test for the presence of squalene antibodies prior to the GAO recommendations. Nothing could be further from the truth:

A. DOD's response to the GAO accused them of being "scientifically and fiscally irresponsible" for suggesting that DOD conduct research to dispute or validate the independent research findings. DOD's position was clear: until the peer-review and publication process by the private scientists was completed, it would not consider action that could provide answers to those suffering from Gulf War Illnesses. (GAO/NSIAD-99-5)

B. When DOD was interviewed by GAO during the investigation, its spokespersons acknowledged DOD had the know-how to develop such an assay and could have tested for squalene antibodies but did not.

C. When Dr. Bailey provided DOD's final comments to the GAO report, she stated, "Our position and the concerns expressed in our comments to the draft report have not changed." (DOD letter to the GAO dated May 28, 1999)

D. It was only after the U.S. House of Representatives took action and instructed DOD to cooperate with the GAO recommendations that Congress received notice from DOD of its funding of related research. This confirmatory research is being conducted by a DOD researcher. *(House of Representatives Report 106-244, Department of Defense Appropriations Bill, 2000)*

In light of these facts, it is disturbing that Dr. Bailey would construct paragraph four in such a way as to revise the sequence of events, and in doing so, misrepresent DOD's consistent position prior to legislative action.

In closing, Dr. Bailey states, "We are committed to responsible and aggressive pursuit of research that will further our understanding of illnesses among Gulf War veterans and prevent similar illnesses following future deployments." Unfortunately, something vital is missing from her statement: treatment and answers for those who are suffering. It is not acceptable to ask sick Gulf War-era veterans and their families to wait decades for endless research projects which do not generate help and treatment for those suffering. The consequences of this failed policy approach are all too clear to Congress, the American public, and especially the veterans exposed to and sickened by Agent Orange during the Vietnam War.

Our request to you on January 31, 2000 was straightforward and simple: determine if the assay used in the peer-reviewed, published study could be utilized as a diagnostic tool to help sick Gulf War era veterans. I would greatly appreciate your personal assistance to insure that DOD provide the objective analysis initially requested, including identification of those who are providing the analysis and their

professional credentials.

Thank you.

Jack Metcalf

Jack Metcalf
House of Representatives

cc: Representative Norm Dicks
Representative Walter Jones
Representative Bob Filner
Representative Janice Schakowsky
Representative Lane Evans
Representative Ron Paul
Representative Joe Scarborough
Representative Bernard Sanders
Representative Dan Burton

Appendix 19

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

MAR 27 REC'D

Honorable Jack Metcalf
United States House of Representatives
Washington, DC 20515-4702

Dear Congressman Metcalf:

Thank you for your recent letters on the Anthrax Vaccine Immunization Program's website and on the information I provided to you as requested in your inquiry of January 31, 2000. To address your request for additional objective analysis of this article, I have asked the Armed Forces Epidemiological Board to convene a subcommittee of experts to review and critique this work. I will provide you with this critique and, as requested, the curricula vitae of the reviewers. In addition, the National Academy of Sciences, Institute of Medicine (IOM), is assessing the role squalene may play as a cause of illnesses among Gulf War veterans and reviewing the work of Dr. Asa and her colleagues. The IOM expects to publish a report in August of this year.

The Department has considered your comments and suggestions regarding the Anthrax Vaccine Immunization Program's website. On March 10, 2000, the portion of the website describing the antibody test developed by Dr. Asa and colleagues was modified to read as follows: "Whether or not this test has any clinical meaning will be settled by medical experts over time. For now, it is sufficient to recognize the conclusions of the authors: "It is important to note that our laboratory-based investigations do not establish that squalene was added as adjuvant to any vaccine used in military or other personnel who served in the Persian Gulf War era.""

Our commitment to Gulf War veterans is unwavering. All known, testable hypotheses concerning illnesses among Gulf War veterans have been or are being pursued through our program of basic science research. All decisions on research funding are based on a process of rigorous, competitive, and independent peer review. We are committed to responsible and aggressive pursuit of research that will further our understanding of illnesses among Gulf War veterans and prevent similar illnesses following future deployments.

Sincerely,

Dr. Sue Bailey

Dr. Sue Bailey

Appendix 20

Experimental and Molecular Pathology 68, 196–198 (2000)
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LETTERS TO THE EDITOR

To the Editor:

A recent article in this journal by Asa *et al.* (2000) purports to measure serum antibodies to squalene. The paper fails to establish the validity of the test. The essential flaws involve selection of proper positive controls and proper negative controls, quantitative methods, and selection of study populations.

The authors hypothesize that antibodies are induced by "the adjuvancy of squalene," such that injection of squalene could elicit antibodies to squalene. One approach might be to inject squalene into an experimental animal to determine *first* whether the injection can induce the purported antibodies and *second* whether the assay can detect the induced antibodies. Antibodies induced by injection, if they exist, could then serve as a positive control for the unvalidated assay.

The assay describes no positive controls that actually validate the assertion of detecting antibodies to squalene. Such positive controls would consist of comparable serum samples demonstrated to contain anti-squalene antibodies after injection with squalene.

The authors assert that they have positive controls, in the form of two human subjects previously injected with a squalene-containing placebo during a clinical trial at the National Institutes of Health. However, the authors provide no preinjection results to establish that intentional injection of squalene led to antibodies to a substance already present in the body.

The assay also lacks elementary negative controls routinely run in enzyme-linked immunoassays. Such negative controls are required to prove that the assay is not detecting cross-reacting substances. In a new, unproven assay that claims to detect a novel antibody, one must prove specificity. There were no negative controls in which the human serum containing the presumed antibodies was omitted or in which the avidin-conjugated horseradish peroxidase was omitted. There is no evidence that the assay was not simply measuring other IgG molecules with nonspecific binding to squalene. This could be easily accomplished by substituting an oil molecule similar to squalene. An excellent negative control would be squalane, the fully hydrogenated form of squalene.

The unknown human serum samples were tested only at a single dilution (1:400). Most assays for naturally occurring antibodies, particularly antibodies to lipids, start at a higher concentration of serum, typically a dilution of 1:50. Thus, the method of Asa *et al.* could miss the presence of antibodies detectable at a higher concentration of serum. It is possible that normal blood donors could give positive results at a higher concentration of serum.

A further drawback of using only a single dilution of serum, rather than a series of dilutions, is that there is no way to obtain a quantitative measure of the degree of activity in the sample. Titers are routinely obtained when antibody levels are measured. The absence of quantitation in this assay weakens meaningful comparisons between unknown serum samples from subjects accrued in a nonrandom manner.

Figure 1, said to show "antisqualene antibody responses," is particularly flawed. In this figure, unspecified quantities of squalene were added as aqueous dilutions of 1:10, 1:100, 1:1000 and 1:10,000 for impregnation of nitrocellulose. No explanation is provided for how an oil such as squalene, not soluble in water, could be diluted in water by the published methods. Further, a washing solution containing polyoxyethylene sorbitan monolaurate could have detergent-like qualities that could remove squalene. Despite the extensive dilutions of the squalene, there is no evidence of a dilution curve (assessing each strip vertically), regardless of whether the antibody reactions were rated as 3+, 2+, or 1+. This suggests that nonspecific binding of serum immunoglobulin may have occurred.

The conclusions of Asa and colleagues, purporting to correlate anti-squalene with Gulf War illnesses, in our opinion, rely on circular logic. Positive results with an assay not previously validated to detect antibodies cannot be used as scientific proof that antibodies to the antigen exist in samples of unknowns. It is premature to proceed directly to testing

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serum samples from healthy people and sick people before conducting the fundamental validation steps.

The critique offered here is not meant to imply that antibodies to squalene do not or cannot exist. As pointed out by the authors, extensive work demonstrates that antibodies to cholesterol, a molecule for which squalene serves as a precursor, are found in virtually all normal human sera. A recent report proposes that naturally occurring antibodies to cholesterol may serve a vital physiologic function in helping regulate low-density lipoprotein metabolism in humans (Alving and Wassef, 1999).

REFERENCES

Alving, C. R., and Wassef, N. M. (1999). Naturally occurring antibodies to cholestero.. A new theory of LDL cholesterol metabolism. *Immunol. Today* **20**, 362–366.

Asa, P. B., Cao, Y., and Garry, R. F. (2000). Antibodies to squalene in Gulf War Syndrome. *Exp. Mol. Pathol.* **68**, 55–64. doi:10.1006/exmp.1999.2295.

Carl R. Alving

Walter Reed Army Institute of Research
Silver Spring, Maryland 20910

John D. Grabenstein

U.S. Army Medical Command
Falls Church, Virginia 22041

This letter is doi:10.1006/exmp.2000.2314

Reply

To the Editor:

Alving and Grabenstein declare that our methods "do not establish the validity of the test." They are mistaken and have made a number of false assumptions about our methods and about which experiments were and were not performed to validate the anti-squalene antibody (ASA) assay. We also strongly disagree that animal work must precede human studies.

Our study (1) is the first description of anti-squalene antibodies in humans. Replicating our results in an animal model may well be useful for studying the possible role of ASA in Gulf War Syndrome (GWS), but is not a prerequisite by any standards we (or the peer reviewers of our manuscript) are aware of for establishing the validity of an immunoassay. For example, it was not essential to demonstrate antinuclear antibodies (ANA) in animals to develop a useful ANA assay for human autoimmune disease. Moreover, there is no assurance that small animals or even primates would respond immunologically to a squalene challenge. Production of ASA may require conjection with or coexposure to additional substances or an autoimmune process not readily reproduced in an animal model.

It would also be unethical to inject squalene, a substance that has a 25-year history of causing both autoimmune rheumatological disease and neurological disease (Lorentzen, 1999; Grajkowska *et al.*, 1999), into humans to see if we could raise antibodies to it.

The ASA assay, a variation on the well-characterized Western blot assay, was validated by standard approaches used in immunoassay development. Alving and Grabenstein assert that "the assay lacks negative controls." However, each of the "elementary" negative controls they suggested, as well as many other controls, was in fact performed. The descriptions of these simple tests were not included in our paper for brevity. Assays in which either human serum or avidin-conjugated horseradish peroxidase was omitted gave no reaction. It should be noted that the reagents we used are precisely the same stringently validated reagents used to detect human antibodies to human immunodeficiency virus in commercially available Western blot assays. Squalane, a molecule similar to squalene, also gave no reaction in this assay. Furthermore, preincubation of positive human sera with squalene (but not squalane or other oils) blocked the assay in a dose-dependent manner. Squalene did not block another immunoassay, the HIV Western blot, further confirming the validity of the ASA assay.

Alving and Grabenstein are incorrect in their assumption that "the samples were tested at only a single dilution." In the process of optimizing the ASA assay, samples were tested at varying dilutions between 1:25 and 1:4000. 1:400 was determined to be the optimal dilution.

We did not indicate that squalene was soluble in water. Squalene, like many oils, can be finely dispersed in water and diluted as indicated. Western blot-style immunoassays differ from other types of immunoassays. Titers are not routinely obtained in Western blot-style immunoassays. At lower serum dilutions, some normal donors do react on the

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ASA assay. This is to be expected and does not change the conclusions stated in our paper in any way.

Alving and Grabenstein assert that "a washing solution containing polyoxyethylene sorbitan monolaurate could have detergent-like properties that could remove squalene." This speculation is directly refuted by the results we presented. The ASA assay is similar in format to Western immunoblotting, in which proteins are tightly bound to nitrocellulose strips simply by drying. A similar method was used to apply squalene to the nitrocellulose strips used in the ASA assay. For this molecule, as with proteins in Western blots and nucleic acids in Southern and Northern blots, hydrostatic and other interactions with nitrocellulose are strong enough to resist removal by a weak detergent.

It is extremely unlikely that our results can be explained by "nonspecific binding of serum immunoglobulin." If this were the case, then similar or higher percentages of healthy donors or autoimmune patients (many of whom were hypergammaglobulinemic) would have detectable binding of serum antibodies in the ASA assay compared with GWS patients (ASA *et al.*, 2000). As this was not observed, the use of sera from these appropriate control populations further validates the ASA assay.

The ASA assay was rigorously validated by standard immunological methods prior to testing of serum samples from healthy and sick individuals. Circular logic was not used, and we stand firmly by the conclusions of our manuscript.

REFERENCES

Asa, P. B., Cao, Y., and Garry, R. F. (2000). Antibodies to squalene in Gulf War Syndrome. *Exp. Mol. Pathol.* 66, 55–64. doi: 10.0006/exmp.1999.2295.

Gajkowska, B., Smialek, M., Ostrowski, R. P., Piotrowski, P., and Fronczak Baniewicz, M. (1999). Experimental squalene encephaloneuropathy in the rat. *Exp. Toxicol. Pathol.* 51, 75–80.

Lorentzen, J. C. (1999). Identification of arthritogenic adjuvants of self and foreign origin. *Scand. J. Immunol.* 49, 43–50.

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This letter is doi:10.1006/exmp.2000.2315

Editorial Note

New findings require confirmation, within the bounds of comparability. This is as true for methodology as it is for the data produced from a particular study. This exchange of letters from the Office of the Surgeon General, United States Army, and the authors of "Antibodies to squalene in Gulf War Syndrome," *Exp. Mol. Pathol.* 68, 55–64 (2000), relates to methodology. Drs. Alving and Grabenstein offer no data against the conclusions of Asa *et al.*

The exchange will be judged by the scientific community on its merits, as all such matters should be. We point out only that Asa *et al.* are correct in their reply when they note that Western blot methods do not routinely measure relative titers, although some laboratories may report an intensity grade from the bands produced (e.g., 1+ to 4+).

The Editors

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Letter
Carl R. Alving, John D. Grabenstein
Experimental and Molecular Pathology, Vol. 68, No. 3, Jun 2000, pp. 196-197 (doi:10.1006/exmp.2000.2314)

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Appendix 21

THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

AUG 10 REC'D

AUG 2 2000

Honorable Jack Metcalf
House of Representatives
Washington, DC 20515-4702

Dear Representative Metcalf:

I am pleased to provide you with the objective analysis that you requested for the article "Antibodies to Squalene in Gulf War Syndrome," published in the February 2000 issue of *Experimental and Molecular Pathology*. The Armed Forces Epidemiological Board convened a subcommittee of experts to review and critique this article and the attached response was unanimously endorsed and approved by the Board.

I hope we have answered the questions raised in your letter. Thank you for your interest in the health of Gulf War veterans.

Sincerely,

J. Jarrett Clinton, MD, MPH
Acting Assistant Secretary

Attachment:
As stated

cc:
Special Assistant for Gulf War Illnesses

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH VA 22041-3258

AFEB (15-1a) 00-6 11 July 2000

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Armed Forces Epidemiology Board (AFEB) Recommendations Regarding Review of the Paper, "Antibodies to Squalene in Gulf War Syndrome by P. B. Asa, Y. Cao and R. F. Garry."

1. The AFEB was tasked by the Department of Defense (Health Affairs) to conduct an objective analysis of the above paper following a request by Congressman Jack Metcalf to Health Affairs.

2. A Special Subcommittee was formed to review the paper. Results of the review and the paper were distributed to the rest of the Board prior to the AFEB meeting. The Subcommittee's findings were presented to the whole Board at the AFEB Meeting held 28-29 February 2000 at Fort Sam Houston, Texas. After discussions and several additional reviews, the report was finalized.

3. The AFEB has thoroughly reviewed the paper by Dr. Asa and colleagues who describe a laboratory test they feel may identify individuals ill with "Gulf War Syndrome." The following is a summary of the findings:

a. THE RESEARCH REPORTED IN THIS PAPER DOES NOT SUPPORT THIS CLAIM.

b. THE PAPER CONTAINS NUMEROUS SHORTCOMINGS, SEVERAL OF THEM SERIOUS, THAT COMBINE TO INVALIDATE THE AUTHORS' CONCLUSIONS.

c. IT REMAINS UNCLEAR IF THE ASSAY ACTUALLY MEASURES ANTIBODIES TO SQUALENE, AS THE AUTHORS ASSERT; THE ASSAY MAY MEASURE SOMETHING ELSE OR THEIR FINDINGS MAY BE A NON-SPECIFIC CHEMICAL REACTION.

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AFEB (15-1a) 00-6 11 July 2000

SUBJECT: Armed Forces Epidemiology Board (AFEB) Recommendations Regarding Review of the Paper, "Antibodies to Squalene in Gulf War Syndrome by P. B. Asa, Y. Cao and R. F. Garry."

4. The Board unanimously endorses and approves the above findings and the enclosed report. Details of their findings can be found in the enclosed report.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

F. MARC LAFORCE, M.D.
AFEB President

BENEDICT M. DINIEGA
Colonel, USA, MC
AFEB Executive Secretary

3 Encls
1. Report
2. Tasking Letter
3. CVs

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BvetMed Msc MRCVA
LCol Maureen Fensom, CFMS

REVIEW OF THE PAPER

ANTIBODIES TO SQUALENE IN GULF WAR SYNDROME
by PB Asa, YCao and RF Garry

published in
***Experimental and Molecular Pathology*, Volume 68, pp 55-64 (2000)**

A REPORT FROM
THE ARMED FORCES EPIDEMIOLOGICAL BOARD
JUNE 22, 2000

SUMMARY OF FINDINGS

The Armed Forces Epidemiological Board has thoroughly reviewed the paper by Dr. Asa and colleagues who describe a laboratory test they feel may identify persons ill with "Gulf War Syndrome." The AFEB has concluded unanimously that the research reported in this paper does not support this claim. The paper contains numerous shortcomings, several of them serious, that combine to invalidate the authors' conclusions. It remains unclear if the assay actually measures antibodies to squalene, as the authors assert; the assay may measure something else, or their findings may be a non-specific chemical reaction.

BACKGROUND

The Armed Forces Epidemiological Board (AFEB) was tasked by the Department of Defense (Health Affairs) to conduct an objective analysis of the above captioned paper by Asa *et al.* The tasking letter is enclosed.

A special subcommittee[1] of the AFEB was formed to initiate the task. The Special Subcommittee read the above captioned paper by Asa *et al.* The subcommittee fully discussed its impressions, questions and concerns, and developed a consensus document. The chair of the subcommittee then formally presented the subcommittee's findings to the entire AFEB[2] which had been supplied with the paper and the consensus document in advance of the meeting. After input from the entire AFEB, this final report is offered to the requester by the AFEB president.

FINDINGS

The AFEB reviewed the paper with great interest. However, the AFEB found the paper to contain a large number of scientific flaws, some of which are extremely grave. These flaws invalidate to an almost complete degree the conclusions regarding squalene and the implications that proceed from them. The major flaws include the following:

Controls: Despite assertions and disclaimers in the paper, there are no valid controls.

- For a valid positive control, one needs serum previously proven to contain antibodies to squalene; only this can validate that the assay can detect antibodies to squalene. What the authors use as and assert is a positive control are two sera from individuals reportedly vaccinated (either once or three times) with an NIH trial vaccine containing squalene. The authors provide no pre-vaccination data to demonstrate that the activity detected in their assay was not present before vaccination with a squalene adjuvant.
- Negative controls are essential to prove that the assay is not detecting something other than anti-squalene antibodies. Missing are controls which omit serum containing the presumed antibodies or which omit the avidin-conjugated horse radish peroxidase. Also missing is a negative specificity control to rule out non-specific binding of normal IgG molecules to squalene.

Blinding: It is unclear if the researchers were blind as to illness/wellness status of study participants.

- The paper asserts at several points that this is a blinded study, but it remains possible that the critical element of knowing the illness/wellness status or category may have been known, even if, as the paper states, "...The identities or exact number of samples from each category were not made available..."

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[1] S-Music, Chair; E Barrett-Connor, P Landrigan, Members; *curricula vitae* attached per written request of Congressman Metcalf to Defense Secretary Cohen, as "...objective analysis...including identification of those who are providing the analysis and their professional credentials."

[2] During the 30-31 May 2000 meeting of the AFEB at Ft. Detrick, MD.

- Thus, the authors' assertions, that they did not know which subjects had "Gulf War Syndrome" and which did not, are not convincing. If the authors knew which blood samples came from Gulf War veterans, this could have biased their interpretation of their test findings.

Specificity: Does the ASA Assay actually measure antibodies to squalene?

- In this type of blotting experiment, one normally demonstrates specificity of the reaction by blocking (or adsorbing) the antibody with the antigen (in solution). This is not demonstrated.
- Hence, it is not possible to know what the ASA assay detects. It is a Western-blot type assay, and is either positive (+) or negative (–). Since the paper describes it being used in only one dilution of patient serum (1:400), it seems the assay can determine only whether "something" was detectable or not, and this "something" is not presently definable.
- Antibodies to squalene, or to any other substance for that matter, should be detectable across a range of concentrations, so antibody assays are normally constructed to demonstrate this, the most common form today being an enzyme-linked immunoassay (ELISA). The actual level or concentration of antibody, ranging from undetectable to just detectable through high concentration, should have medical/biological correlations and implications, with some threshold point that correlates with the development of symptoms or disease.
- Nitrocellulose is a highly reactive substance that binds many materials. The paper does not show that the squalene deposited on the membrane is actually still there at the end of the assay. For example, one could imagine that squalene could "block" the nitrocellulose membrane long enough to protect the "dot" from the milk treatment and then be washed out, as polyoxyethylene sorbitan laurate is a detergent that could remove a lipid like squalene. This could leave a naked spot of nitrocellulose to react with some other protein.
- If this were a valid assay it should work with another substrate (other nylon membranes, like Immobilon).
- Given the relationship between squalene and cholesterol, do these sera react with cholesterol? The authors raise the question but don't answer it.
- Can one actually raise antibodies, deliberately, to squalene? It is a common component of cells and should be present in amounts that would swamp out any squalene-specific antibodies.

Dose response: None is apparent.

- In the figures of the Asa *et al* paper, there is no obvious dose response in relation to the amount of antigen (squalene) deposited on the nitrocellulose membrane.
- A dose-response should be seen with respect to antigen and antibody concentration; neither is shown.

CONCLUSIONS

In summary, the clear failure to provide positive controls and negative controls as well as unambiguous blinding, invalidates the authors' ability to argue for the meaningfulness of their test and any conclusions they might draw from these results. This is true even before one gets to the more technical issue of the specificity of the ASA assay.

Therefore, the AFEB has little confidence that the patent-pending ASA assay actually measures antibodies to squalene, though we cannot entirely eliminate this possibility.

Whatever the paper's flaws and since the AFEB cannot exclude the remote possibility that the authors have identified a laboratory means of distinguishing persons with possible Gulf War Syndrome (GWS) from all others, replicability becomes the major unresolved issue. The AFEB recognizes the difficulties inherent in defining a possible case of GWS since there is no standardized case definition. However, the AFEB feels that the symptom list in the Asa *et al* paper is a good potential starting point, and that, for example, cases might be selected from tertiary referral centers for GWS such as the one at Walter Reed, with controls from a civilian, non-exposed workforce. Therefore we recommend that a suitable test of replicability be done in cooperation with the authors and with attention to the following design elements:

- selection of participants - cases and control subjects - by an independent *ad hoc* body or committee, chaired by a tenured academic from a well-known medical research institution
- establishing clear *a priori* selection and exclusion criteria for cases and for controls
- serological testing done in a secure and absolutely blind manner with strict chain of custody rules and documentation in place
- a sufficient number of subjects to have statistical power to detect a true difference, if one exists, with 80% likelihood and with a 5% chance or less of finding a difference due to random chance alone.
- a study design with at least two arms – testing done as in the paper by the people who have licensed this patent-pending technique, versus testing done by one or more lipid laboratories using more standard antibody techniques such as enzyme-linked immunoassay to detect antilipid antigens

We wish to be clear that we are not discussing a study to validate whether the ASA assay can detect antibodies to squalene. Rather, we are trying to leap over this intermediate obstacle and get quickly and inexpensively to a more meaningful bottom line: does the ASA assay clearly, reliably and unequivocally distinguish people with GWS from all others, and, if so, with what specificity and sensitivity? Many caveats and qualifiers would have to be in place to assure meaningfulness, and the preceding bulleted list can (and probably should) be usefully expanded and further refined to help assure that any ensuing serological study be definitive.

The AFEB is extremely doubtful that the assay reported by Asa *et al* is a valid or accurate test for illness among Gulf War veterans. However in an effort to leave no stone unturned in evaluating veterans' complaints, the AFEB feels it may be worthwhile to repeat the study, using appropriate scientific methods as outlined above. This recommendation should definitely not be considered an endorsement of the paper by Asa *et al* that we have herewith reviewed.

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

09 MAR

MEMORANDUM FOR EXECUTIVE SECRETARY, ARMED FORCES EPIDEMIOLOGICAL BOARD

SUBJECT: Objective Analysis of Article "Antibodies to Squalene in Gulf War Syndrome"

I request that the Armed Forces Epidemiological Board (AFEB) convene a subcommittee and review and provide OASD(HA) with an objective analysis of the attached article, "Antibodies to Squalene in Gulf War Syndrome" published in the February 2000 issue of *Experimental and Molecular Pathology*. Congressman Jack Metcalf requested this objective analysis. Congressman Metcalf would also like the curriculum vitas of the reviewers.

OASD(HA) will provide Congressman Metcalf with this critique and the curriculum vitas of the reviewers when complete. Please provide this review NLT 15 May 2000. To assist in this review, I have attached an extensive review of the work on squalene as a cause of illnesses among Gulf War veterans by the interagency Research Working Group of the Persian Gulf Veterans Coordinating Board prior to publication of the article and previous correspondence with Congressman Metcalf's office on this topic.

My point of contact is James R. Riddle, LtCol, USAF, BSC, (703) 681-1703, fax (703) 681-3655, or email james.riddle@ha.osd.mil.

John F. Mazzuchi

John F. Mazzuchi, Ph.D.
Deputy Assistant Secretary of Defense
Clinical and Program Policy

Attachments:
As Stated

CURRICULUM VITAE

I. PERSONAL DATA

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II. EDUCATION

Institution	Date	Major/Minor Courses	Degree
University of London; London School of Hygiene and Tropical Medicine	1975-1976	Tropical Public Health	Diploma
Centers for Disease Control and Prevention – Atlanta, GA	1972-1973	Preventive Medicine	Resident
University of Maryland School of Medicine; Baltimore, MD	1966-1970	Fellow in Infectious Disease; Assistant Resident in Internal Medicine; Junior Assistant Res in Internal Medicine; Intern in Internal Medicine	Fellow, Resident, Intern
University of Maryland School of Medicine; Baltimore, MD	1962-1966	Doctor of Medicine	MD
George Washington University Washington, DC	1962	Invertebrate zoology and entomology	BS
George Washington University Washington, DC	1961	Liberal arts	AA

III. MERCK/MRL EMPLOYMENT HISTORY

Title	From – To
Director, Report Evaluation and Safety Surveillance Worldwide Product Safety and Epidemiology Department Merck Research Laboratories, Blue Bell, PA	May 1999 to present

IV. NON-MERCK EMPLOYMENT HISTORY

Title	From - To
Medical Epidemiologist Division of Women's and Children's Health, Department of Health and Human Services; State of North Carolina; Raleigh, NC	June 1998 to May 1999
Chief, Occupational and Environmental Epidemiology Division of Epidemiology, Department of Health and Human Services; State of North Carolina; Raleigh, NC	November 1996 – May 1998
Senior Regional Advisor for the Caucasus and Embassy Physician; United States Agency for International Development and American Embassy; Tbilisi, Republic of Georgia	1995 - 1996
Administrator, Division of Preventive Medicine and State Epidemiologist; then State Health Officer (last 6 months) Department of Health, State of Wyoming; Cheyenne, WY	1991 - 1994

Director, Global EIS Program; CDC, USPHS; Atlanta, GA	1986 - 1990
Deputy Director, Global EIS Program; CDC, USPHS; Atlanta, GA	1983 - 1986
Staff Epidemiologist, Policy Unit Population, Health and Nutrition Department, World Bank; Washington, DC	1982 – 1983
Deputy Director; Field Services Division, Atlanta, GA	1977-1982
Assistant Director; Field Services Division, Atlanta, GA	1976-1977
Full Time Internal Student, CDC Career Development; University of London, School of Hygiene and Tropical Medicine	1975 – 1976
Smallpox Eradication Advisor; Dacca, Bangladesh	1973 – 1975
Epidemic Intelligence Service Officer; Florida Department of Health and Rehabilitative Services; Jacksonville, FL	1971 – 1973

V. ACADEMIC EXPERIENCE

Instructor, Division of Infectious Diseases; University of Maryland School of Medicine; Baltimore, MD	1970 – 1971

VI. ADDITIONAL TRAINING

Source	Date	Type	Certification
American Management Association	1980	3 week course	Yes
Oak Ridge Nuclear Facility: Response to Nuclear Disaster	1992	1 week course	Yes

VII. SOCIETY MEMBERSHIPS and OTHER PFOFESSIONAL EXPERIENCES

Member, Armed Forces Epidemiology Board, US Department of Defense; 1998 to present
Georgian Academy of Sciences of Preventive Medicine and Human Ecology; 1996
Fellow, American College of Preventive Medicine; 1979
Diplomate, American Board of Preventive Medicine; 1978
Fellow, Royal Society of Hygiene and Tropical Medicine; 1975
Chairman, Scientific Advisory Committee; 1989-1991
Member, Scientific Advisory Committee, Caribbean Epidemiology Center (PAHO),
Port of Spain, Trinidad and Tobago; 1988-1991
Consultant, Assessment of Health Needs, USAID Assessment Team, Sultanate of Oman, 1980
WHO Epidemiological Services Consultancies:
Indonesia, 1979; Indonesia, Burma, Bangladesh, 1978; Republic of Korea, 1977
Post-liberation Nutrition Survey, CDC Assessment Team, Bangladesh; 1972
Research Physician, Infectious Diseases Hospital, University of Chile, Santiago, Chile; 1970
Attending Physician, Cholera Hospital, Pakistan-SEATO Cholera Research Laboratory; Dacca, East Pakistan; 1967-1968

VIII. HONORS

US Public Health Service Meritorious Service Medal - 1997
US Public Health Service Outstanding Service Medal - 1985
US Public Health Service Commendation Medal - 1979

IX. PUBLICATIONS

1. Music, S. I., Wenzel, R. P., Libonati, J. P., Snyder, M. J., Hornick, R. B., Woodward, T. E; Induced Human Cholera (abstract), Journal of Clinical Investigation, 49:69-70a, June 1970
2. Hornick, R. B., DuPont, H. L., Music, S. I., Snyder, M. J., Libonati, J. P.; Investigations into the Pathogenesis of Diarrheal Diseases, Trans Am Clin Climatol Assoc, Oct 26;82:141-7 1970.
3. Clyde, D. F., Miller, R. M., Music, S. I., McCarthy, V. C.; Prophylactic and Sporontocidal Treatment of Chloroquine-Resistant Plasmodium Falciparum from Viet Nam, American Journal of Tropical Medicine and Hygiene, 20:1-5, January, 1971.
4. Music, S. I., Fine, E.M., Togo, Y; Zoster-Like Disease in the Newborn due to Herpes Simplex virus, New England Journal of Medicine, 284:24-26, January 7, 1971.
5. Hornick, R. B., Dupont, H. L., Music, S. I., Snyder, M. J., Libonati, J. P.; Investigations into the Pathogenesis of Diarrheal Diseases, Trans AM Clin Climatol Assoc, 82: 26 October 1970.
6. Hornick, R. B., Music, S. I., Wenzel, R. P., Cash, R., Libonati, J. P., Snyder, M. J.; Woodward, TE; The Broad Street Pump Revisited: Response of Volunteers to Ingested Cholera Vibrios, Bull NY Acad Med, 47 (10): October, 1971.
7. Termini, B. A., Music, S. I.; The Natural History of Syphilis: A Review, South Med J., 65 (2): February, 1972.
8. Snyder, M. J., et al; Trimethoprim-sulfamethoxazole in the Treatment of Typhoid and Paratyphoid Fevers, J Infect Dis 128:Suppl:734-7: November, 1973.
9. Music, S. I., Howell, J. T., Brumback, C. L.; Red Tide, Its Public Health Implications, JFMA 60(11): November, 1973.
10. Cash, R. A., Music, S. I., Libonati, J. P., Snyder, M. J., Wenzel, R. P., Hornick, R. B.; Response of Man to Infection with *Vibrio cholerae*. I. Clinical, Serologic, and Bacteriologic Responses to a Known Inoculum, J. Infect Dis 129 (1): January, 1974.
11. Hattwick, M. A. W., Rubin, R. H., Music, S. I., Sikes, R. K., Smith, J. S., Gregg, M. B.; Postexposure Rabies Prophylaxis with Human Rabies Immune Globin, JAMA, Vol 227: 407-410: Jan. 28, 1974.
12. Cash, R. A., Music, S. I., Libonati, J. P., Craig, J. P., Pierce, N. F., Hornick, R. B.; Response of Man to Infection with *Vibrio cholerae*. II. Protection from Illness Afforded by Previous Disease and Vaccine, J. Infect Dis 130 (4): October, 1974.
13. Cash, R. A., Music, S. I., Libonati, J. P., Schwartz, A. R., Hornick, R. B.; Live Oral Cholera Vaccine: Evaluation of the Clinical Effectiveness of Two Strains in Humans, Infect Immun 19(4): Oct., 1974
14. Snyder, M. J., Gonzalez, O., Palomino, C., Music, S. I., et al: Comparative Efficacy of Chloramphenicol, Ampicillin, and Co-Trimoxazole in the treatment of Typhoid Fever. The Lancet, 2 (7966): 1155-7, Nov 27, 1976.
15. Music, S. I.: Surveillance, chapter in Guidelines for Analysis of Communicable Disease Control Planning in Developing Countries, International Health Planning Methods Series, Office of International Planning Methods Series, Office of International Health, USPHS, 1979 DHEW Publication No. (PHS) 79-50080.
16. Thacker, S. B., Music, S. I., Pollard, R. A., Berggren, G., Boulos, C., Nagy, T., Brutus, M., Pamphile, M., Ferdinand, R. O., Joseph, V. R.; Acute Water Shortage and Health Problems in Haiti, Lancet, 1:471-473, March 1, 1980.
17. Music, S. I.: The Role of Epidemiology in Helping CDC Improve Public Health. Annales Istituto Superiore di Sanitá, 21(4): 431-4, 1985.
18. Schwartz, B., Al-Tobaiqi, A., Al-Ruwais, A., Fontaine, R. E., A'ashi, J., Hightower, A. W., Broome, C. V., Music, S. I.; Comparative Efficacy of Cephtriaxone and Rifampicin in Eradicating Pharyngeal Carriage of Group A *Neisseria meningitidis*, Lancet, 1:1239-42, June 4, 1988.
19. Music, S. I.: Schultz, M. G.: Field Epidemiology Training Programs, New International Health Resources, JAMA, Vol 263, No 24:3309-3311, June 27, 1990.
20. Simonsen, L., Khan, A. S., Gary, H. E. Jr., Hanson, C., Pallansch, M. A., Music, S., Holman, R. C., Stewart, J. A., Erdman, D. D. Arden, N. H., Arenberg, I. K., Schonberger, L. B.; Outbreak of Vertigo in Wyoming: Possible Role of an Enterovirus Infection. Epidemiol Infect 117(1):149-57, August, 1996.
21. Music, S. I., Khetsuriani, N.: Epidemiology Bulletin, Ministry of Health, Republic of Georgia. Vol 1, Nos. 1-6:1-120, January – June 1996. (Though listed officially as *CDC Advisor* my actual role was to first do and then train others in how to do every step from conception and writing through publication and distribution of the first six monthly issues of this official publication of the Georgian government. These are available in English via Internet and the CDC homepage on SANet: http://www.sanet.ge/cdc/index.html.

22. Music, S. I., Georgia's public-health problems. Ltr to the Editor in Lancet, 348 (9043), Dec 21, 1996.
23. Smith, C. G., Music, S. I.: Pfiesteria in North Carolina: The Medical Inquiry Continues. NC Medical Journal, 59(4), Jul-Aug 1998.
24. Furney, W., Music, S. I., Wiley, J.: North Carolina Childhood Asthma Management Initiative: A Summary of the Summary Report. NC Medical Journal, 60(4), Jul-Aug 1999.
25. Music, S.I.: The Elimination of Preventable Asthma: Lessons from Smallpox. NC Medical Journal, 60(4), Jul-Aug 1999.
26. Khetsuriani, N., Music, S., Deforest, A., Sutter, R.W.: Evaluation of a Single Dose of Diphtheria Toxoid Among Adults in the Republic of Georgia, 1995: Immunogenicity and Adverse Reactions. Journal of Infectious Diseases 181 (Suppl 1):S208-S212, February 2000.

CURRICULUM VITAE

NAME:	BARRETT-CONNOR, Elizabeth Louise
WORK ADDRESS:	University of California, San Diego School of Medicine Department of Family and Preventive Medicine, 0607 La Jolla, California 92093-0607
HOME ADDRESS:	6423 Avenida Cresta La Jolla, California 92037-6514
BIRTHPLACE: & DATE:	Evanston, Illinois April 8, 1935
MARITAL STATUS:	Married, James D. Connor, M.D. 3 children
COLLEGE:	Mount Holyoke College, South Hadley, Massachusetts, 1952-1956 - Zoology
MEDICAL SCHOOL:	Cornell University Medical College, New York City, 1956-1960 - Medicine
INTERNSHIP:	University of Texas, Southwestern Medical School, Dallas, Parkland Memorial Hospital, 1960-1961
RESIDENCY:	University of Texas, Southwestern Medical School, Dallas, Parkland Memorial Hospital, 1961-1963
	University of Miami, School of Medicine, Jackson Memorial Hospital, Infectious Diseases, 1963-1964
POST-DOCTORAL:	London School of Hygiene & Tropical Medicine 1964-1965 – D.C.M.T., Diploma in Clinical Medicine of the Tropics
	University of Minnesota, Minneapolis, 1967 (3-week course) Advanced Epidemiology - Certificate
	Johns Hopkins University, Bar Harbor, Maine, 1968 (2-week course) Genetics - Certificate

September, 99

FELLOWSHIPS:

Medical Student Fellowship in Public Health and Preventive Medicine, Cornell University Medical College, 1958
Louisiana State University Interamerican Program in Central America, Summer 1962
National Institutes of Health Post-Doctoral Fellowship, London School of Hygiene and Tropical Medicine, 1964-5
Fulbright Award (declined), 1964

DEGREES:

B.A., Mount Holyoke College, 1956
M.D., Cornell University, 1960
D.C.M.T., London School of Hygiene and Tropical Medicine, 1965

FACULTY APPOINTMENTS:

University of Miami, School of Medicine
Instructor of Medicine, 1965-1968
Assistant Professor of Medicine, 1968-1970

University of California, San Diego School of Medicine
Assistant Professor of Community Medicine and Medicine, 1970-1974
Associate Professor of Community and Family Medicine and Medicine, 1974-1981
Chief, Division of Epidemiology 1974-present
Professor of Family and Preventive Medicine and Medicine, 1981-present
Acting Chair, Department of Community and Family Medicine, 1981-1982
Chair, Department of Family and Preventive Medicine, 1982-1997

HONORS, NAMED LECTURESHIPS, AND VISITING PROFESSORSHIPS:

Frederick Murgatroyd Prize, London, 1965
Invited Participant, Bicentennial Colloquium of the New York Hospital, 1971
Invited Participant, Meeting Commemorating the 25th Anniversary of Dr. Donald W. Seldin's Chairmanship of the Department of Internal Medicine, The University of Texas, Dallas, 1977
Invited Participant, Symposium on the Advances in Diabetes Epidemiology, Colloquium Inserm, NIH, OMS. Abbaye de Fontevraud, France, May 3-7, 1982
Kaiser Award for Excellence in Teaching, University of California San Diego, School of Medicine, 1982

Living Legacy Award, Women's International Center, San Diego, California, March 6, 1984
Alexander D. Langmuir Lecture, Centers for Disease Control, Atlanta, April , 1985
Honorary Doctor of Science Degree, Mount Holyoke College, South Hadley, Massachusetts, May 26, 1985
Doctor of the Year Award, San Diego Health Care Association, San Diego, November 18, 1985
Katharine Boucot Sturgis Lecture, American College of Preventive Medicine, Atlanta, April 5, 1986
Kelly West Memorial Lecture/Award, American Diabetes Association, Indianapolis, June 6, 1987
Merit Award, National Institute of Aging, July, 1987 –1996
Visiting Professor, Royal Society of Medicine, London, May 1989.
John Rankin Lecture, Madison, Wisconsin, October 20, 1989
Don McLeod Memorial Lecture, Halifax Nova Scotia, February 9, 1990.
Member, Institute of Medicine, 1991
Elizabeth Blackwell Lecture, Rochester, Minnesota, September 18, 1991
The Lila Wallace Visiting Professorship, The New York Hospital/Cornell Medical Center, March 4-5, 1992
The Donald P. Shiley Visiting Lectureship, Scripps Clinic and Research Foundation, San Diego, March 13, 1992
Outstanding Educator Award, Association of Teachers of Preventive Medicine, March 22, 1992
Leonard M. Schuman Lecture, University of Michigan, Ann Arbor, July 28, 1993
Wade Hampton Frost Lecture, American Public Health Association, San Francisco, October 25, 1993
Joe Stokes Lecture Research Seminar, Grand Rounds, Boston, November 11, 1993
University of California, San Diego, Faculty Research Lecturer Award, March 10, 1994
James D. Bruce Memorial Award, American College of Physicians, April 21, 1994
Soroptimist International of La Jolla Award, Making a Difference for Women, Health, June 7, 1995
Ancel Keys Lectureship, American Heart Association Scientific Sessions, November 13, 1995
American Heart Association, Elizabeth Barrett-Connor Research Award in Epidemiology and Prevention for Investigators In Training, November 14, 1995
UCSD Chancellor's Associates Faculty Excellence Award in Research, January 31, 1996
Honorary Doctor of Medicine Degree, University of Utrecht, The Netherlands, March 26, 1996
Honorary Doctor of Medicine Degree, University of Bergen (Norway), August 3, 1996
The Florence Mahoney Lecture on Aging, National Institures of Health, September 25, 1996
Arthur Gordon Visiting Professor, University of California, Los Angeles, October, 1996
American Heart Association Council on Epidemiology and Prevention, Distinguished Service Award, November 12, 1996

The Donald P. Shiley Visiting Lectureship, Scripps Clinic and Research Foundation, March, 1997
The Cleveland Clinic Foundation Department of Cardiology Visiting Professor, June, 1997
John Cassell Memorial Lecture, Society for Epidemiologic Research, 30th Annual Meeting, June 12, 1997
Clinical Service Award, Society for the Advancement of Women's Health Research, June 24, 1997.
Raine Distinguished Visitor's Award, The University of Western Australia, October 26 - November 5, 1997
Distinguished Lecturer in Geriatrics, Duke University Medical Center, J January 29-30, 1998
13th Annual Harry S. Feldman Lecture, American Epidemiologic Society (AES) Meeting, Harvard Medical School, March 26, 1998
Award of Meritorious Achievement of the American Heart Association, Dallas, Texas, June 26, 1998
Women's Health Hero Award – American Health for Women, New York, September, 1998
Woman in Science Award – American Medical Women's Association, New Orleans, November, 1998
Nathan J. Kiven Oration and Brownwide Grand Rounds, The Miriam Hospital and Brown University,Rhode Island, April 9, 1998
Alvin L. Schultz Visiting Professor of Internal Medicine, Minneapolis, October 20, 1998
Visiting Professor, Brigham and Women's Hospital, Boston, Massachusetts, November, 1998
National Institutes of Health Award for Outstanding Work in Gender Differences in Osteoporosis, March, 1999
Heath Clark Lectureship, London School of Hygiene and Tropical Medicine, London, England, March, 1999
Invited Participant, Controversies and Dilemmas in Endocrinology, Royal College of Physicians of Edinburgh, Scotland, March, 1999

GRANTS:

National Institutes of Health, Lipid Research Clinic, Veterans Administration Hospital, La Jolla, California, 1970-1989 .
Janssen Drug Study Fund, 1976-1978.
National Institutes of Health, Peripheral Arterial Disease Grant #HL22255-01, April 1, 1978, - November 30, 1980.
American Heart Association, California Affiliate, Grant-in-Aid, #80-S114, July 1, 1980 - June 30, 1981.
National Institute of Arthritis, Diabetes, Digestive & Kidney Diseases, Epidemiology of Diabetes in an Adult Community #1 RO1 AM31801, July 1, 1983 - June 30, 1988.

UCSD/SDSU Teaching Nursing Home Project. #NIA AG03990-01A1, May 1, 1984 - April 30, 1989.

National Institutes of Health, National Heart, Lung and Blood Institute, PHS HL34591, Endogenous Sex Hormones & Cardiovascular Disease Risk in Men, April 1, 1986 - March 31, 1987.

American Heart Association California Affiliate, Orange County Chapter Grant-in-aid-Dietary Factors, Blood Pressure and Cardiovascular Disease. #85-S116, July 1, 1986 - December 31, 1988.

Weight Watchers - Analyzing in Detail Extensive Database with Regard to Obesity and Heart Disease, January 1,1987 - December 31, 1989.

National Institute of Health - National Institute of Aging- Study of Risk Factors for Osteoporosis in the Elderly. #NIH/NIA 1 R37 AG07181-01, UCSD #90-6518, August 1, 1987 - July 31, 1992 (Merit Award).

National Institute of Health - Postmenopausal Estrogen/ Progestin Interventions (PEPI). #NIH 1001- HL40207-01, UCSD #90-6500. September 3, 1987 - August 31, 1992.

University of California Academic Geriatric Resource Program-Interdisciplinary Geriatrics Fellowship Program. #87SD-C2D-2-01, July 1, 1987 - June 30, 1988.

National Institute of Diabetes and Digestive and Kidney Diseases - Epidemiology of NIDDM and IGT in an Adult Community. UCSD #88-5256, July 15, 1988 - June 30, 1990.

American Association of Retired Persons.- The Effects of Husbands' Retirement on Their Wives. UCSD #87-6259, January 1, 1988 - December 31, 1988.

National Institute of Health, NHLBI - LRC Follow-up Study--CPPT and Prevalence. UCSD #6947, June 29, 1971 - September 30, 1991.

National Institute of Health, NIA - Alzheimers Disease Research Center Competitive Supplement. UCSD #89-6638, August 17, 1990 - March 31, 1994.

National Institute of Health - Predictors of Cardiovascular Disease in the Elderly. UCSD #90-6070, January 1, 1991 - December 31, 1991.

National Institute of Health, NIDDK - Epidemiology of NIDDM and IGT in an Adult Community. UCSD #91-6083, December 1, 1991 - November 30, 1996.

National Institute of Health - Epidemiology of NIDDM and IGT Supplement. UCSD #92-6591, June 1, 1992 - February 28, 1993.

National Institute of Health, NIA - Study of Risk Factors for Osteoporosis

in the Elderly (Osteo II). UCSD #91-6122. August 1, 1992 - July 31, 1997. (Merit Award)

Merck, Sharp and Dohme, Fracture Intervention Trial (FIT). UCSD #92-5548, October 1, 1991 - March 31, 1997.

National Coffee Association, "Coffee/Caffeine/Bone Mineral Density". UCSD #92-6164, February 1, 1992 - January 31, 1993 (no cost extension August 31, 1993).

Solvay Pharmaceuticals - A Double-Blind, Parallel Group Study of the Effects of Estratest H.S. vs. Premarin in Surgically Menopausal Women. UCSD #92-6838. June 1, 1992 - May 31, 1995.

Wyeth-Ayerst, Heart & Estrogen/Progestin Replacement Study (HERS). UCSD #91-5180. October 8, 1992 - December 31, 1998.

National Institute of Health, NHLBI - Postmenopausal Estrogen/Progestin Interventions (PEPI). UCSD #92-5242. August 1, 1992 – July 31, 1994.

Weight Watchers. Sex hormones, obesity and diabetes in older women. UCSD #93-7168. November 1, 1993 - October 31, 1994.

National Institutes of Health, NIDDK. NIDDM Primary Prevention Trial. UCSD #94-5368, July 1, 1994 to June 30, 2001. (Co-PI)

National Institute of Health, NHLBI, Postmenopausal Estrogen-Progestin Intervention (PEPI) Safety Followup Study, N01-HV-48136, June 15, 1994 to December 14, 1997.

National Institute of Health, NHLBI, Postmenopausal Estrogen-Progestin Intervention (PEPI) Safety Followup Analysis Study, N01-HV-48136, August 1, 1994 to July 31, 1997.

Lilly Research Laboratory. Comparison of Raloxifene HCL and Placebo in the Treatment of Postmenopausal Women with Osteoporosis. UCSD #95-5368, November 1, 1994 to October 31, 1999.

Wyeth-Ayerst Laboratories. A Randomized, Double-Blind Placebo & Active Controlled, Parallel, Multicenter Study to Assess the Safety & Efficacy of 3 1/2 Day Combinations of 17B-Estradiol Norethindrone Acetate Transderma Delivery Systems for Relief of Menopausal Vasomotor Symptoms & Reduction of Endometrial Hyperplasia. UCSD#97-9150. May 27, 1997 to April 30, 1999.

Osteometer Meditech A/S. Bone Mineral Content & Density in the Forearm, Speed of Sound, & Boradband Ultrasound Attenuation in the Calcancus: Normal Range in US Caucasian Females & Males, 20-80 years of age. UCSD #98-9010. June 15, 1997 to December 31, 1997.

Osteometer Meditech A/S. Forearm Mineral Density in the Normal Caucasian Female Population in the Calcancus: Normal Range in US Caucasian Females & Males, 20-80 Years of Age. UCSD 97-9099. December 15, 1997 to January 31, 1997.

Merck & Co. A 5-Year, Double-Blind, Randomized, Placebo-Controlled Extension Study to Examine the Long-Term Safety & Efficacy of Oral Alendronate In Postmenopausal Women Who Previously Received Alendronate in Conjunction with the Fracture Intervention Trial (FLEX) UCSD #98-9051. January 3, 1998 to October 30, 2003.

National Institutes of Health, Soy Health Effects (SHE). 1RO1 HL57790-01, April 1, 1997 to March 31, 2000.

National Institutes of Health/NIDDK, Diabetes Primary Prevention Program (DPP). 5UO1 DK48339-04, September 10, 1994 to June 30, 2001.

National Institutes of Health, Comparison of Medical and Surgical Treatment for Abnormal Uterine Bleeding Post-Menopausal Women (Ms?). September 30, 1996 to September 29, 2001.

Eli Lilly & Co. Raloxifene Hydrochloride or Placebo in Postmenopausal Women At Risk for Major Cardiovascular Events. UCSD #98-9146. September 4, 1998 – September 30, 2005.

National Institutes of Health, NIA. Gender Differences in Osteoporosis (OSTEO III) UCSD #98-6285. December 1, 1998 to November 30, 2002.

National Institutes of Health, Osteoporotic Fractures in Men (MR.OS). UCSD #98-6088. December 10, 1998 to November 30, 2003.

MEDICAL QUALIFICATIONS:

Licensure, Florida, 1965
Licensure, California, 1970 (#C-32076)
Diplomate, American Board of Internal Medicine, 1968
Diplomate, National Board of Medical Examiners

PROFESSIONAL SOCIETY MEMBERSHIPS:

Fellow, American College of Physicians (Publications Committee, 1988-90)
Fellow, Council on Cardiovascular Epidemiology, America Heart Association (Chair, 1989)
Fellow, Royal Society of Health
Fellow, American College of Preventive Medicine
Fellow, American College of Nutrition
Fellow, The Royal Society of Medicine
Member, American Venereal Disease Association (Vice-President, 1977-1978)
Member, American Federation for Clinical Research
Member, Association of Teachers of Preventive Medicine (Board of Directors, 1987-90)
Member, Infectious Disease Society of America

Member, International Epidemiological Association
Emeritus Member, American Society of Tropical Medicine and Hygiene
Member, Society for Epidemiologic Research (President, 1983)
Member, Association for Practitioners in Infection Control
Member, California Academy of Preventive Medicine
Member, Western Association of Physicians
Member, American Epidemiological Society (President, 1993-94)
Member, American Diabetes Association
Consultant, Veterans Administration Hospital, Miami, 1969
Consultant/Lecturer in Internal Medicine (Infectious Diseases), U.S. Naval Hospital, San Diego, 1970-85
Consultant, Mercy Hospital, San Diego, 1970-85
Consultant, American Medical Association Department of Drugs, Chicago, 1976
Member, Hospital Infection Control Committee, University Hospital, San Diego, 1970-1972 (Chairman 1975-1977)
Member, Hospital Infection Control Committee, Veterans Administration Hospital, La Jolla, 1971-85
Member, Research Committee, Zoological Society of San Diego, 1978-86
Member-at-Large, Research Peer Review Sub-Committee, American Heart Association, California Affiliate, 1977-1981
Member, Advisory Committee for Genetic Disorders, California Department of Health, 1974-1975
Ad hoc member, Study Section, Center for Disease Control, Atlanta, 1971-1972
Member, Expert Advisory Committee, Food & Drug Administration, Rockville, 1972-1977
Member, Advisory Council on Immunization Practices, Center for Disease Control, Atlanta, 1973-1977
Member, Preventive Medicine and Public Health Test Committee, National Board of Medical Examiners, Philadelphia, 1974-1980 (Chair, 1977-1980)
Member, Epidemiology Working Group, National Commission on Arthritis and Musculoskeletal Diseases, Boston, 1975-1976
Ad hoc Member, National Institute of Allergies and Infectious Diseases Committee, HEW/NIH, 1977
Member, Consultant Task Force for the Study of Health in Egypt and Future U.S. Development Assistance
Alternatives, National Institute of Medicine, 1978
Member, National Institute of Allergies and Infectious Diseases

Committee, 1978-1982
Member, American Tropical Medicine Delegation to China, American Society of Tropical Medicine and Hygiene, 1978
Member, The American Geriatrics Society, 1987-present
Member, Medical Research and Development Advisory Panel, Review Group Concerned with Parasitic Diseases, Walter Reed Army Institute of Research, Department of the Army, 1979-1982
Member, Special Consultants to Department of Defense Overseas Medical Research Laboratories, US Department of Defense, 1980
Consultant, Task Force, Institute of Medicine, Division of International Health, Health in Egypt: Recommendations for U.S. Assistance, January, 1979
Member, Core Faculty, Annual Seminars on Epidemiology of Cardiovascular Disease, American Heart Association, 1978-present
Member, California Medical Association Scientific Advisory Panel; Preventive Medicine and Public Health, 1982-present
Member, American Epidemiological Society Membership Committee 1987-present
Member, Advisory Committee, Role of BCG Vaccinations in the United States, Research Foundation, 1983-1985
Member, (San Diego) Mayor's Task Force for Acquired Immunity Deficiency Syndrome (AIDS), 1983-1985
Member, Epidemiology Research Unit, University of Texas, 1983-1986
Member, National Advisory Committee on Vital and Health Statistics, May 30, 1984 - February 28, 1987
Member, American Public Health Association, Epidemiology Section, (Chair, 1989-91)
Member, European Diabetes Epidemiology Study Group, 1984- present
Member, NHANES III Advisory Committee (FACEB), 1985
Member, Preventive Medicine Residency Advisory Committee, San Diego (Chair, 1985)
Member, Epidemiology and Biometry Program Working Group, Subcommittee of the Clinical Applications and Prevention Advisory Committee (CAPAC), National Heart, Lung, and Blood Institute, Bethesda, Maryland, 1985-1987
Member, Burroughs-Wellcome Fund/American College of Preventive Medicine Pharmacoepidemiology Award Advisory Committee, 1986-1989
Member, San Diego Foundation for Medical Care, 1986-present
Member, Resource Advisory Committee on the Epidemiology of the

Chronic Diseases of Aging of the National Archives of Computerized Data on Aging, 1988-1994
Member, Technical Advisory Committee for Diabetes Translation and Community Control Programs, Centers for Disease Control, February 6, 1989 - June 30, 1991.
Member, International Epidemiological Association (North American Councillor, 1990-present)
Member, International Scientific Committee for the 3rd International Conference on Preventive Cardiology, 1989-1990
Member, U.S. Army Research and Development Advisory Committee, Ft. Detrick, Frederick, Maryland 1990-1993
Member, International Society and Federation of Cardiology, Section of Epidemiology, 1990-present
Member, National Heart, Lung, and Blood Institute Task Force on Hypertension 1990-93
Member, National Diabetes Advisory Board, National Institutes of Health, 1990-1994
Member, The Royal Society of Medicine, 1992-present
Member, Advisory Board of the HERITAGE Study, 1992-present
Member, Faculty, WHO Postgraduate Seminar on Diabetic Epidemiology (Krakow, Poland), 1992
Member, Data and Safety Monitoring Board, Women's Health Initiative, 1993-present
Member, Faculty of International Society & Federation of Cardiology Teaching Seminar 1993-present
Councilor, Western Association of Physicians, 1994-97
Member, Human Subjects Program Review Committee, UCSD, 1994-present
Member, The New York Academy of Sciences, 1995-present
Member, Scientific Advisory Board, Ostex International, Inc., 1995-present
Member, Raloxifene Advisory Board, Eli Lilly and Company, 1995-present
Member, American Federation for Aging Research, National Scientific Advisory Committee, 1996
Member, Membership Committee, Institute of Medicine, 1996-1999
Member, Armed Forces Epidemiology Board, 1996 -
Member, Advisory Council, National Instiurte of Aging-1996-
Member, Advisory Council, National Institute of Aging, 1997 –
Board of Directors, North American Menopause Society, 1997-
National Institues of Health/Women's Health Initiative: Data and Safety Monitoring Board, 1997-

Member, Editorial Board, American Journal of Preventive Medicine, 1998-
Sigma Xi – The Scientific Research Society, 1998 –
Member, National Lipid Education Council, 1998-
Member, Science Advisory Board, County of San Diego, 1999-
Member, Medical Committee, Royal Netherlands Academy of Arts and Sciences, 1999-
Member, Endocrine Society, 1999-

REVIEWER:

Annals of Internal Medicine, 1974-present
Review of Respiratory Diseases, 1974-present
New England Journal of Medicine, 1974-present
Journal of American Medical Association, 1975-present
Public Health Reports, 1975-1985
Emergency Medicine, 1975-1980
Western Journal of Medicine, 1975-present
American Journal of Tropical Medicine and Hygiene, 1979-present
Arthritis and Rheumatism, 1981-present
American Journal of Epidemiology, 1981-present
Reviews of Infectious Diseases, 1982-present
Arteriosclerosis, 1984-present
Circulation, 1985-present
Journal of Chronic Disease, 1982-present
Preventive Medicine, 1988-present
International Journal of Gynecology & Obstetrics, 1994-present

EDITORIAL BOARDS:

American Journal of Epidemiology
American Journal of Infection Control, 1981-1986
American Journal of Preventive Medicine
Annals of Epidemiology
Annals of Internal Medicine, 1979-82
Cardiovascular Risk Factors, 1995-present (Member of Advisory Board)
Circulation
International Journal of Epidemiology
Journal of Clinical Investigation (Consulting Editor), 1995-1997
Reviews in Clinical Gerontology
Sexually Transmitted Diseases, 1977-81
The Women's Letter
Menopause

November 1999

CURRICULUM VITAE

Name: Philip J. Landrigan, M.D., M.Sc., D.I.H.
SSN: 022-32-0504

Born: Boston, Massachusetts, June 14, 1942

Wife: Mary Florence

Children: Mary Frances
Christopher Paul
Elizabeth Marie

Education:

High School:	Boston Latin School, 1959
College:	Boston College, A.B. (magna cum laude), 1963
Medical School:	Harvard - M.D., 1967
Internship:	Cleveland Metropolitan General Hospital, 1967-1968
Residency:	Children's Hospital Medical Center, Boston, (Pediatrics), 1968-1970
Post Graduate:	London School of Hygiene & Tropical Medicine, 1976-77 Diploma of Industrial Health (England), 1977 Master of Science in Occupational Medicine, University of London (with distinction), 1977

Positions Held:

Current:
Mount Sinai School of Medicine, Ethel H. Wise Professor of Community and Preventive Medicine and Chairman of the Department of Community and Preventive Medicine, 1990-Present.
Mount Sinai School of Medicine, Director, Division of Environmental and Occupational Medicine, Department of Community and Preventive Medicine, 1985-Present.
Mount Sinai School of Medicine, Professor of Pediatrics, 1985-Present.

Previous:
U.S. Environmental Protection Agency, Senior Advisor to the Administrator on Children's Health and the Environment, 1997-1998.
National Institute for Occupational Safety and Health, Director, Division of Surveillance, Hazard Evaluations and Field Studies, 1979-1985.
Centers for Disease Control, Chief, Environmental Hazards Activity, Cancer and Birth Defects Division, Bureau of Epidemiology, , 1974-1979.
Centers for Disease Control, Director, Research and Development, Bureau of Smallpox Eradication, 1973-1974.
Centers for Disease Control, Epidemic Intelligence Service (EIS) Officer, 1970-1973.

Adjunct Positions:

University of Washington School of Public Health and Community Medicine, Clinical Professor of Environmental Health, 1983 - Present.
Harvard Medical School, Visiting Lecturer on Preventive Medicine and Clinical Epidemiology, 1982 - Present.
Harvard School of Public Health, Visiting Lecturer on Occupational Health, 1981 - Present.
University of Cincinnati, Department of Environmental Health, College of Medicine, Assistant Clinical Professor of Environmental Health, 1981 - 1986.
London School of Hygiene and Tropical Medicine, Visiting Fellow, TUC Institute of Occupational Health, 1976 - 1977.
Harvard Medical School, Clinical Instructor in Pediatrics, 1969 - 1970.

Memberships:

American Academy of Pediatrics, Fellow
Society for Epidemiologic Research, Member
American Public Health Association, Member
Occupational Health Section, Chair, 1989-90
Royal Society of Medicine, Elected Fellow
International Commission on Occupational Health, Member
Scientific Committee on Epidemiology
American College of Epidemiology, Fellow
Board of Directors, 1990 - 1993.
American Epidemiological Society, Elected Member
Collegium Ramazzini, Fellow
President, 1997-present
Herman Biggs Society, Member
New York Academy of Sciences, Fellow
New York Occupational Medicine Association, Member
Board of Directors, 1988 - 1990.
American College of Occupational and Environmental Medicine, Fellow
New York Academy of Medicine, Elected Fellow
Physicians for Social Responsibility, Member
Board of Sponsors, 1994-95; Board of Directors 1996-1999

Specialty Certifications:

American Board of Pediatrics - 1973
American Board of Preventive Medicine:
General Preventive Medicine - 1979
Occupational Medicine - 1983

Awards and Honors:

Institute of Medicine, National Academy of Sciences, Elected to membership, 1987
U.S. Department of Health, Education and Welfare ,Volunteer Award, 1973
U.S. Public Health Service, Career Development Award, 1976
Centers for Disease Control, Group Citation as Member of Beryllium Review Panel, 1978
U.S. Public Health Service, Meritorious Service Medal, 1985
New York Committee for Occupational Safety and Health, Annual Honoree, 1985
New England College of Occupational and Environmental Medicine, Harriet Hardy Award, 1993
United Brotherhood of Carpenters, William Sidell Presidential Award, 1995
American Public Health Association, Herbert L. Needleman Medal and Award for Scientific Contributions and Advocacy on Behalf of Children, 1995.
International Association of Fire Fighters, Occupational Health and Safety Award, 1995
Physicians for Social Responsibility, Broad Street Pump Award in Environmental Health, 1996
Mayo Clinic, Department of Pediatrics, Amberg-Heimholtz Lecturer in Pediatrics, 1998
International Society for Occupational and Environmental Health, Vernon Houk Award, 1998
Centers for Disease Control and Prevention, Langmuir Memorial Lecturer, 1999
American College of Preventive Medicine, Katherine Boucot Sturgis Award, 1999
Mothers & Others for a Livable Planet, Award for Advocacy on Behalf of the Health of Children, 1999
Earth Day New York, Award for Excellence in Environmental Medicine, 1999

Visiting Professorships:

University of Tokyo, Visiting Professor of the Faculty of Medicine, September 1989
University of Tokyo, Visiting Professor of the University, July 1990
University of Cape Town Medical School, Visiting Professor, Department of Community Health, March 1992
Medical College of Pennsylvania, Catherine Boucot Sturgis Visiting Professor in Community and Preventive Medicine, March 1992
National University of Singapore, Visiting External Examiner in Occupational Medicine, 1994
Duke University Medical School, Visiting Professor, NIEHS Clinical Training Program in Environmental Medicine, 1995

Committees:

The White House
Presidential Advisory Committee on Gulf War Veterans' Illnesses, 1995-1996.

American Academy of Pediatrics
Committee on Environmental Hazards, 1976 - Present. Chairman, 1983-1987.

National Research Council

National Academy of Sciences, Assembly of Life Sciences. Board on Toxicology and Environmental Health Hazards, 1978-1987; Vice-Chairman, 1981-1984.

National Academy of Sciences, Assembly of Life Sciences, 1981-1982; Commission on Life Sciences, 1982-1984.

Institute of Medicine, Committee for a Planning Study for an Ongoing Study of Costs of Environment-Related Health Effects, 1979-1980.

National Academy of Sciences, Panel on the Proposed Air Force Study of Herbicide Agent Orange, 1979-1980.

National Academy of Sciences, Committee on the Epidemiology of Air Pollutants, Vice-Chairman, 1984-1985.

National Academy of Sciences, Committee on Neurotoxicology in Risk Assessment, 1987-1989.

National Academy of Sciences, Committee on the Scientific Issues Surrounding the Regulation of Pesticides in the Diets of Infants and Children, Chairman, 1988-1992.

National Academy of Sciences, Board on Sustainable Development, 1995-1998.

National Institutes of Health/U.S. Public Health Service

National Institutes of Health, Study Section on Epidemiology and Disease Control, 1986-1990.

National Institute of Environmental Health Sciences, Third Task Force for Research Planning in the Environmental Health Sciences; Chairman, Subtask Force on Research Strategies for Prevention of and Intervention in Environmentally Produced Disease, 1983-1984.

National Institute for Occupational Safety and Health, Board of Scientific Counselors, 1995-1997.

State and Local Government

State of New York, Governor's Blue Ribbon Committee on the Love Canal, 1978-1979.

State of New Jersey, Meadowlands Cancer Advisory Board, Chair, 1987-1989.

State of New York, Asbestos Advisory Board, Chair, 1987 - Present..

State of New York, New York State Advisory Council on Lead Poisoning Prevention, Chairman, 1993 - Present.

City of New York, Mayor's Lead Paint Poisoning Advisory Committee, 1991-1993.

State of New York, Public Health Priorities Committee, 1996.

State of New York, Health Research Science Board, 1997 - Present.

Academic

Harvard School of Public Health, Occupational Health Program, Residency Review Committee, 1981-1983; Chairman, 1981.

New York Academy of Medicine, Working Group on Housing and Health, 1987-1989; Chairman, 1989.

Association of University Programs in Occupational Health and Safety, 1985 – Present; President, 1986-1988.

New York Lung Association, Research and Scientific Advisory Committee, 1986-1989. Board of Directors, 1987-1990.

Milbank Memorial Foundation, Technical Board, 1986-1988.

Mickey Leland National Urban Air Toxics Research Center, National Advisory Committee, 1994-1995.

Cornell University, Dean's Advisory Council in Veterinary Medicine, 1996-1997.

International Organizations

World Health Organization. Contributor to the WHO Publication: "Guidelines on Studies in Environmental Epidemiology" (Environmental Health Criteria, No. 27), 1984.
International Agency for Research on Cancer, Working Groups on Cancer Assessment, October 1981 and June 1986. (IARC Monographs No. 29 and No. 42).

Environmental Organizations

INFORM, Board of Directors, 1991 - Present.
Environmental Health Foundation, Board of Directors, 1993 - Present.
Colette Chuda Environmental Fund, Scientific Advisory Committee, 1994 - Present.
Children's Health Environment Coalition, Board of Directors, 1996 - Present.
Children's Environmental Health Network, Board of Directors, 1995 - Present.

Labor Unions

United Automobile Workers (UAW) - Chrysler Corporation, Joint Scientific Advisory Committee, Member, 1990 - Present.
United Brotherhood of Carpenters, National Health and Safety Fund, Medical Advisory Committee, 1990 - Present; Chairman, 1994 - Present.
International Association of Fire Fighters, John Redmond Foundation, Medical Advisory Committee, 1989 - Present.
International Brotherhood of Teamsters, National Health and Safety Advisory Committee, 1994 - Present.
George Meany Center for Labor Studies, Board of Trustees, 1994-1997.

Other Organizations

Health Insurance Plan (HIP) of Greater New York, Board of Directors, 1992-1994.
American Legion, Science Panel, Chairman, 1988 - Present.

Editorial Boards:

Editor-in-Chief: *American Journal of Industrial Medicine*, 1992 - Present; Consulting Editor, 1979-1992.
Editor-in-Chief: *Environmental Research*, 1987-1994.
Consulting Editor: *Archives of Environmental Health*, 1982 - Present.
Editorial Board: *Annual Review of Public Health*, 1984-1990.
Senior Editor: *Environmental Research*, 1985-1987.
Editorial Board: *American Journal of Public Health*, 1987 - Present.
Editorial Board: *New Solutions*: A Journal of Environmental and Occupational Health Policy, 1990 - Present.
Editorial Board: *The PSR Quarterly*: A Journal of Medicine and Global Survival, 1990-1994.
Editorial Board, *Journal of Public Health Management and Practice*, 1995-1996.

National Service:

United States Public Health Service, Commissioned Corps, 1970-1985. LCDR (04) to CAPT (06).
United States Naval Reserve, Medical Corps, 1996 - Present.
LCDR (0-4) 1996-98; CDR (0-5) 1 April, 1998 - Present.

Appendix 22

ACCUSATIONS-- SQUALENE

1. What is squalene?

Squalene is a naturally occurring substance found in plants, animals, and humans. It is manufactured in every human body as part of the process of making cholesterol and hormones. Squalene is also found in a variety of foods, cosmetics, health supplements, and over-the-counter medications. (Links to commercial squalene sources)

Squalene has been used as an adjuvant (a substance used to improve the body's response to a vaccine) in some investigational vaccines manufactured in the U.S., including vaccines to protect against HIV disease. Squalene is approved by European health agencies for use in an influenza vaccine. Whatever the arguments for or against squalene as a vaccine adjuvant, the fact is that none of the vaccines that were administered to U.S. troops during the Gulf War contained squalene as a vaccine adjuvant. This includes the anthrax vaccine, which does not contain squalene and never has contained squalene. The FDA has licensed only aluminum salts (e.g., aluminum hydroxide, aluminum phosphate, aluminum potassium sulfate) as adjuvants.

The Department of Defense (DoD) has never exposed any military member or civilian to any squalene-containing investigational product without the person's informed consent, abiding by FDA regulations. The DoD has conducted five human clinical trials using investigational vaccines containing squalene (investigational vaccines for the prevention of malaria and HIV infection) in FDA-approved vaccine studies. Two of the malaria vaccine studies involving a total of 17 human volunteers were conducted before or during the Persian Gulf War. Although it is unlikely, some of these subjects may have been involved in the Gulf War. Nevertheless, these investigational vaccines were part of FDA-approved studies that followed FDA guidelines for the use of investigational vaccines, including the informed consent of the participants.

2. Did DoD have anthrax vaccine tested for the presence of squalene?

Yes, and the vaccine was found to contain no squalene. To determine whether squalene was present in the anthrax vaccine, the DOD recently contracted with an independent civilian laboratory, Stanford Research Institute (SRI) International of Menlo Park, California, to test for the presence of squalene in every lot of the anthrax vaccine released to DOD. SRI International tested 14 lots of anthrax vaccine and formally reported that no squalene was detected in any of the 14 lots. The test they used is sensitive enough to detect the squalene naturally present in the oil in a human fingerprint. The DOD will test all other lots of anthrax vaccine in the stockpile when the allegations arose. Graphic images of the test results are posted at http://www.anthrax.osd.mil/Site_Files/lot_documents/lot_documents_menu.htm.

3. Has DoD ever requested that MBPI change the formula for licensed anthrax vaccine or develop a new anthrax vaccine to include squalene?

No. DoD never requested MBPI to change the formula for the licensed vaccine or to develop a new anthrax vaccine with any adjuvant, including squalene.

4. What are the facts behind the accusations about squalene?

In their effort to explain the health problems of some Gulf War veterans, a few investigators have theorized, and the press has amplified their theories, that a vaccine adjuvant may have caused an autoimmune disease in veterans. A recent *Vanity Fair* article "The Pentagon's Toxic Secret" (May 1999) alleges that the DoD possibly used "an illicit and secret anthrax vaccine" on its own soldiers. The writer's interpretation and presentation of the facts regarding the Department's use of anthrax vaccine are speculative, inflammatory, and wrong. His allegations and the reported "clinical evidence" are not new. Since 1997, reports in the *Washington Times* and its magazine *Insight on the News* have made similar allegations regarding an experimental "anti-HIV vaccine."

The investigators cited in the Vanity Fair and Insight on the News articles (Pamela Asa, Ph.D., Memphis, TN and Robert Garry, Ph.D., Tulane University School of Medicine, New Orleans, LA) report that they have developed and patented a test for anti-squalene antibodies. Autoimmune Technologies, LLC, of New Orleans, has an exclusive license on the use of the test. With their test the investigators report that they have detected anti-squalene antibodies in the blood of ill Gulf War veterans. Their method was published in the February 2000 issue of the journal "Experimental and Molecular Pathology." Whether or not this test has any clinical meaning will be settled by medical experts over time. For now, it is sufficient to recognize the conclusions of the authors: "It is important to note that our laboratory-based investigations do not establish that squalene was added as adjuvant to any vaccine used in military or other personnel who served in the Persian Gulf War era."

5. What did the GAO say about squalene testing and what are DoD researchers doing?

The U.S. General Accounting Office (GAO) has released a report "Gulf War Illnesses: Questions about the Presence of Squalene Antibodies in Veterans Can be Resolved" (GAO/NSIAD-99-5). The Department of Defense disagreed with the GAO's opinion that "the first step is to determine the extent to which they [antibodies to squalene] are present in a larger group of sick Gulf War-era veterans."

To investigate the squalene hypothesis, a scientifically proven test for squalene antibodies is needed to assess whether Gulf War veterans have antibodies to squalene. In response to a DoD solicitation for research on illnesses among Gulf War veterans, a DoD investigator and nationally recognized expert on antibodies to cholesterol and other lipids submitted a research proposal to determine the feasibility of developing a test for antibodies to squalene. The funded research project to determine whether antibodies to squalene exist has five main objectives: 1) Development and validation of an enzyme-linked immunosorbant assay (ELISA) for antibodies against squalene. 2) Evaluation and potential development of other assays for antibodies to squalene. 3) Development of a positive control antibody to squalene. 4) Production of the positive control antibody to squalene for use in the assays. 5) Testing of normal human serum for antibodies to squalene by ELISA and other methods. This study should provide adequate scientific evidence to resolve the issue of whether squalene antibodies exist and can be detected in human serum. Only if this kind of preliminary evidence indicates that it is possible to create and measure anti-squalene antibodies can one contemplate the next step. The next step would be to determine whether the presence of anti-squalene antibodies differs between two groups. For example, one might want to compare (1) deployed vs. nondeployed veterans, (2) veterans with vs. without symptoms attributed to Gulf War illnesses, or (3) some other comparison. These steps will take a couple years to work through.

The proper first step is to show that the test measures what the test claims to measure. Further, the medical significance and the origin of antibodies to squalene, even if their existence is corroborated, remain unknown. Without such information, Gulf War veterans get only speculation about the meaning of the test result and its implication for their health. Gulf War veterans deserve objective evidence and recommendations based on sound science.

6. What does the U.S. Senate say about squalene?

In its investigations of illnesses among Gulf War veterans, the Senate Special Investigations Unit (SIU) found no credible information indicating that vaccines used during the Gulf War contained squalene (1998, page 123). In its report, the SIU stated that according to the Food and Drug Administration (FDA), squalene can be contained in a vaccine due to two different processes: 1) as an adjuvant, which is an agent to enhance the immune response; or 2) in minute quantities in vaccines manufactured using eggs, since eggs are rich in squalene and cholesterol. The FDA verified that none of the vaccines used during the Gulf War contained squalene as an adjuvant.

Appendix 23

GIF image 674x900 pixels http://www.anthrax.osd.mil/Site_Files/lot_documents/SQUALENE/SQUA020.gif



William Y. Ellis
Chief, Department of Chemical Information
Division of Experimental Therapeutics
Walter Reed Army Institute of Research
Washington, DC 20307-5100

7 May 1999

Dear Sir:

This letter reports our preliminary findings on the determination of squalene in vials of an anthrax vaccine preparation.

Three vials of ANTHRAX VACCINE ADSORBED, Manufactured By MICHIGAN DEPARTMENT OF PUBLIC HEALTH, Lansing, Michigan, 48909, U.S. License No. 99, LOT FAV020, EXP 6 FEB 99, were received on 23 April 1999.

We have developed a sensitive, rapid assay method for squalene using high performance liquid chromatography. The assay specificity is based on chromatographic retention time and on the uv absorption characteristics of the analyte. The method sensitivity is ~0.7 nanogm squalene/10 microL injection, based on squalene in 2-propanol. The method linearity is 0.7 nanogm to 225 nanogm/10 microL injection with $r^2 = .999$, also based on squalene in 2-propanol. The method is currently undergoing validation.

We find no measurable amount of squalene in the vials. If any squalene were present, it would be less than 70 nanogm per 0.5 milliL vaccine preparation, which volume is the label dose.

We will prepare and submit our final report as soon as the study is completed.

Sincerely yours,

Peter Lim, Ph.D.
Principal Investigator
Catalysis and Anal. Chem. Dept.
Pure and Applied Phy. Chem. Div.

Ronald J. Spanggord, Ph.D.
Assistant Principal Investigator
Catalysis and Anal. Chem. Dept.
Pure and Applied Phy. Chem. Div.

SRI International
333 Ravenswood Ave • Menlo Park, CA 94025

JACK METCALF
2D DISTRICT, WASHINGTON

COMMITTEE ON TRANSPORTATION AND INFRASTRUCTURE
SUBCOMMITTEES:
AVIATION
GROUND TRANSPORTATION

COMMITTEE ON SCIENCE
SUBCOMMITTEE:
ENERGY AND ENVIRONMENT

Appendix 24

Congress of the United States
House of Representatives
Washington, DC 20515–4702

COMMITTEE ON BANKING AND FINANCIAL SERVICES
SUBCOMMITTEES:
HOUSING
FINANCIAL INSTITUTIONS
DOMESTIC AND INTERNATIONAL MONETARY POLICY

CHAIR, REPUBLICAN HOUSING OPPORTUNITY CAUCUS

REPUBLICAN POLICY COMMITTEE

January 31, 2000

Jane E. Henney M.D., Commissioner
Food and Drug Administration
Room 1555
5600 Fishers Lane
Rockville, MD 20857

re: Department of Defense (DOD)
Report To Congress: Gulf War Illness
"Development and Validation of an Assay
To Test for the Presence of Squalene Antibodies"

Dear Commissioner Henney:

In its report provided to Congress this month, the DOD made the following statement in its Executive Summary: "The FDA verified that none of the vaccines used during the Gulf War contained Squalene as an adjuvant."

Unfortunately, the DOD report did not provide a site reference for their statement. Please provide copies of the written documents in which your verification was provided to the DOD.

Specifically, please provide answers to the following questions:

1. What vaccines were tested?
2. What lot numbers of those vaccines were tested?
3. Who did the testing?
4. Where was the testing done?
5. What specifically was being looked for during the testing?
7. Were any additional adjuvants identified during the testing?

Please respond within 14 days. Thank you for your attention to this matter.

Sincerely,

Jack Metcalf

Jack Metcalf

cc: Kathryn c. Zoon, Ph.D.

WASHINGTON OFFICE:
1510 LONGWORTH HOB
WASHINGTON, DC 20515
(202) 225-2605

EVERETT OFFICE:
2930 WETMORE AVENUE, #9E
EVERETT, WA 98201
(425) 252-3188
(800) 562-1385

BELLINGHAM OFFICE:
322 NO. COMMERCIAL, #203
BELLINGHAM, WA 98225
(360) 733-4500

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Appendix 25

DEPARTMENT OF HEALTH & HUMAN SERVICES

MAR 22 RECD
RECEIVED
Food and Drug Administration
Rockville MD 20857
MAR 28 2000

MAR 20 2000

The Honorable Jack Metcalf
House of Representatives
Washington, D.C. 20515-4702

Dear Mr. Metcalf:

Thank you for your letter dated January 31, 2000, addressed to Dr. Jane E. Henney, requesting information from the Food and Drug Administration (FDA) concerning squalene and vaccines used during the Gulf War. We apologize for the delay in responding.

Your letter referenced a Department of Defense (DOD) Report to Congress which you indicated had included the statement that "The FDA verified that none of the vaccines used during the Gulf War contained squalene as an adjuvant." Your letter requested both that verification to DOD and responses to a number of questions. FDA was unfamiliar with the DOD report you cited. On March 9, Ms. Jarilyn Dupont of my staff discussed this with Ms. Norma Smith of your district office and she provided FDA with the DOD Executive Summary referred to in your letter. In reviewing the DOD Executive Summary, it appears that the statement DOD made was in reference to a statement contained in a report from the Senate Special Investigation Unit (SIU) of the Senate Veterans' Affairs Committee which conducted a comprehensive review of Gulf War illnesses. That report indicated that the FDA verified that none of the vaccines used during the Gulf War contained squalene as an adjuvant. (*Report of the Special Investigation Unit on Gulf War Illnesses*, page 123, footnote 331).

In fact, FDA did verify to the Senate Special Investigations Unit on July 23, 1997, in a telephone conversation with Committee staff of the SIU, not with DOD, that neither the licensed vaccines known to be used in the Gulf War, nor the one investigational product known to have been used, contained squalene as an adjuvant in the formulations on file with FDA. FDA also has provided this information, and the information provided below, to the General Accounting Office (GAO) as part of an audit on squalene and Gulf War illness.

Currently, the only adjuvant in licensed vaccine formulations are aluminum compounds. Squalene, an intermediate in the

biosynthesis of cholesterol, is not approved for use as an adjuvant in licensed vaccines. Vaccines are not routinely tested for the presence or absence of squalene by the manufacturer or by FDA's Center for Biologics Evaluation and Research (CBER). Manufacturers perform specific tests as outlined in their license application. The tests for Anthrax Vaccine Adsorbed include Sterility, General Safety, Potency, Aluminum, Formaldehyde, and Benzethonium Chloride. Samples for the Anthrax lots and corresponding protocols containing the test results are submitted to CBER. CBER has the option to perform additional testing on lots submitted for lot release.

Very limited testing of Anthrax Vaccine, Adsorbed, conducted by CBER in 1999 determined that there were only trace amounts of squalene in the lots tested. After an article appeared in the May 1999 issue of Vanity Fair entitled "The Pentagon's Toxic Secret," CBER tested in its laboratories the two lots mentioned in the article (FAV020 and FAV030) for squalene. Three other Anthrax lots (FAV038, FAV043, FAV047) and two other lots of other bacterial vaccines (Wyeth Diphtheria and Connaught Tetanus) containing alum adjuvants were randomly selected for comparative purposes. Due to the inability to detect trace amounts of squalene parts per million, CBER developed a test to detect the substance in parts per billion. The trace amounts of squalene were determined by gas chromatography with flame ionization detection. The squalene content of the lots was determined to be in the level of low parts-per-billion and was comparable to levels determined in three other lots of the anthrax vaccine and the other biological products that were tested. In addition to squalene, lots FAV020 and FAV030 were also tested for aluminum, formaldehyde and benzethonium chloride.

We trust this information responds to your concerns. If we may be of any further assistance, please contact us again.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
of Legislation

BAYLOR
COLLEGE OF
MEDICINE

Department of Immunology
One Baylor Plaza, BCMM-M929
Houston, TX 77030-3498
Tel: 713-798-6054
Fax: 713-798-3700

September 22, 2000

Congressman Jack Metcalf
2930 Wetmore Avenue, Suite 9-E
Everett, WA 98201

Dear Congressman Metcalf:

As you know, squalene is not approved for use as an immune adjuvant, however, there is evidence that very small amounts of the Anthrax Vaccine given to Gulf War participants contained this compound.

The tests done by SRI International were performed using a fairly sensitive technique called High Pressure Liquid Chromatography(HPLC). This technique is commonly used to find trace chemicals of drugs in a test specimen compared to a control specimen. However, as I understand this case, a much more sensitive test using gas chromatography, which instead of examining the test specimen as a liquid, vaporizes it which makes it a much more sensitive technique, found low levels of squalene in Anthrax vaccine samples.

The real issue is whether squalene in parts per billion was added to the vaccine preparations given to the military, as well as whether this concentration of squalene could alter the immune response.

More research needs to be done to answer these questions, but it is possible that very small amounts of a biologically active product could induce an immune response, either to the molecule itself or it could boost immune responses to other agents in the mixture. In any case, the discrepancy between the SRI test and that done by CBER needs to be investigated.

Sincerely,

Dorothy E. Lewis

Dorothy E. Lewis, Ph.D.
Associate Professor of Immunology

DEL/tfs

THE ANTHRAX VACCINE IMMUNIZATION PROGRAM—WHAT HAVE WE LEARNED?

WEDNESDAY, OCTOBER 11, 2000

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

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

Present: Representatives Burton, Gilman, Morella, Shays, Ros-Lehtinen, Horn, Souder, Terry, Chenoweth-Hage, Norton, Cummings, Kucinich, Tierney, and Schakowsky.

Also present: Representatives Shimkus and Jones.

Staff present: Kevin Binger, staff director; David A. Kass, deputy counsel and parliamentarian; Thomas Bowman, senior counsel; S. Elizabeth Clay and Gil Macklin, professional staff members; Robert A. Briggs, clerk; Robin Butler, office manager; Michael Canty and Toni Lightle, legislative assistants; Josie Duckett, deputy communications director; Scott Fagan and John Sare, staff assistants; Leneal Scott, computer systems manager; Corinne Zaccagnini, systems administrator; Sarah Despres and David Rapallo, minority counsel; Ellen Rayner, minority chief clerk; and Earley Green, minority assistant clerk.

Mr. BURTON. Good morning. A quorum being present, the Committee on Government Reform will come to order.

I ask unanimous consent that all Members' and witnesses' written opening statements be included in the record.

Without objection, so ordered.

I ask unanimous consent that all articles, exhibits and extraneous or tabular material referred to be included in the record.

Without objection, so ordered.

During last week's hearings, we heard from four men whose lives have been forever changed while serving in the military and taking the anthrax vaccine. Tom Collossimo, John Irelan, Kevin Edwards and Joseph Jones may never fully recover from their current health conditions. And yet, all except one of these men, who were very healthy prior to receiving the anthrax vaccine, are being told there is no evidence to prove the vaccine is connected to their illnesses. I believe one of them during dinner last week had a seizure, did he not? He had a seizure. Did he have to be taken to the hospital? No.

Since our hearing, one of these men—I guess it is in my statement here—since our hearing, this gentleman had a grand mal sei-

zure and another fell as a result of his medical condition and required five stitches.

Major General West sat here last week and told us that several groups of experts reviewed Kevin Edwards' medical information and determined that the anthrax vaccine was not the cause of his illness. What he failed to share with the committee was that the documentation provided for the evaluation of Kevin's condition was incomplete.

Of the nine key questions on the form the Anthrax Vaccine Expert Committee evaluated, six were marked unknown. I find it troubling that this expert committee would rule out the possibility that the anthrax was linked to an adverse event when they did not have information on 60 percent of the key questions.

Last week, we also heard from two individuals who lost loved ones in the last year. Nancy Rugo's sister was certain the anthrax vaccine caused her illness and impending death. Mrs. Barbara Dunn's husband worked at Bioport and received 11 anthrax vaccine shots. After each dose, he suffered an adverse reaction. The Bioport physician was so concerned about Mr. Dunn's previous reactions that the dose he received was split in half and the halves delivered a week apart.

Yet the Defense Department believes the individuals who testified last week and their loved ones were not injured by the anthrax vaccine.

Last week Mr. Charles Cragin testified before our National Security, Veterans Affairs, and International Relations Subcommittee that because they are volunteers, no individual who is in the Guard or Reserve was going to be subjected to any penalties. Today we will hear from three individuals the truth of what is really happening in the field and how it is affecting military readiness.

Lt. Colonel Tom Heemstra was a commander and pilot for the 163rd Fighter Squadron in Fort Wayne, IN. While significantly lower numbers have been reported up the chain of command, Colonel Heemstra is aware of 21 pilots leaving the 163rd Squadron. To date, two of these pilots chose to return to the unit and were forced to take the vaccine as a show of loyalty. So far, 14 replacements have been hired. Many of these replacements require extensive training to be ready to fly the F–16.

Colonel Heemstra was grounded, forced out as commander and forced into retirement. All of these actions ended an exemplary 20-year military career that began at the Air Force Academy.

Captain Dan Marohn, also an F–16 fighter pilot in the 163rd Fighter Squadron, refused to submit to the anthrax vaccine. As a result, he was given the choice between a court martial and an Article 15 non-judicial punishment. He was fined and threatened with a jail sentence. Many others who did not have commitments simply resigned. Others transferred to non-deployment positions to finish their time until retirement.

Pat Ross, an Air Force Academy graduate, spent 16 years as a fighter pilot in active duty in the Air Force and 3 years in the Air National Guard. He was the squadron commander of the 172nd Fighter Squadron in Battle Creek, MI. The 172nd Squadron was told to take the vaccine or leave the unit. The staff judge advocate told his squadron that if they refused to take the shot, they would

be discharged with a less than honorable discharge. While the deadline to take the vaccine was postponed and no pilot has yet been ordered to take the vaccine, 15 pilots resigned or left the unit.

Because of Secretary Cohen's decision to mandate the anthrax vaccine, we have lost a substantial number of pilots and aircrew members. These pilots and aircrew members are essential to our military readiness. They are the backbone of every military operation. Without our Air National Guard and Reserve, the U.S. military would be unable to respond to any national security threat or emergency.

The Air Force estimates that it takes about 9 years and almost $6 million to train and develop a fully qualified and experienced aviator. The General Accounting Office is providing results of their survey of Guard and Reserve pilots and aircrew members. I hope everybody listens to their report today, especially those at the Pentagon and the military. They learned that the adverse events for those who have taken the vaccine were much higher than has been reported to this committee. They learned that there is little support for a vaccine approach to biological warfare protection.

Twenty-five percent of the pilots and aircrew members of the Guard and Reserve who were surveyed have transferred to another unit, left the military, or moved to inactive status. Anthrax was the main reason for one-fourth of these departures.

What is more disturbing is that another 18 percent of these individuals plan to leave the service in the next 6 months; 61 percent of those individuals stated that the anthrax vaccine was the main reason. So whether the Defense Department wants to admit it or not, with a potential loss of 43 percent of our Guard and Reserve pilots and aircrew members, we have a serious readiness problem.

The written testimony provided by the Defense Department is a regurgitation of previous statements and completely ignores the topic of this hearing, readiness and retention. They state that for men and women who choose to serve their country, they do so in the knowledge that service is an honor. They go on to State that failure to provide protection against anthrax would be a dereliction of duty.

Was the Department's failure to provide functional masks and suits a dereliction of duty? Is the Department's failure to fully inform the troops of the risks and benefits of the vaccine prior to the vaccination a dereliction of duty?

When under scrutiny, the Department's first action was to attack the veracity and integrity of the accusers and their data. When the men and women in our Armed Services, individuals who have volunteered to give their lives to protect this country if necessary, questioned Secretary Cohen's program, these men and women were portrayed by the Defense Department as malingerers.

The Defense Department has insulted the honor and integrity of anyone who has dared question the anthrax vaccine program. We have had numerous Air Force Academy graduates testify before the committee. I wonder how many malingerers manage to graduate from the Air Force Academy?

It is clear that the anthrax vaccine program is the wrong approach to protecting our troops. We will hear today from Dr. Stephen Porter, the president and chief executive officer of Virtual

Drug Development, Inc. He will offer another approach to providing force protection, a pre-exposure antibiotic.

It is important that the Defense Department aggressively develop other means to protect our forces. We need functional protective suits and masks that are not defective and that will offer real protection for both biological and chemical threats. We need effective detection equipment, and our strongest protection against anthrax or any other biological and chemical threat is a strong defense ready to respond to any threat or emergency.

The hearing record will remain open until October 25.

I now recognize my good friend, Mr. Kucinich, sitting in for the minority ranking member, Mr. Waxman.

Mr. KUCINICH. Thank you for holding this hearing. I think the question is well put as to whether or not this FBI program has——

Mr. SHAYS. Is the gentleman's mic on?

Mr. KUCINICH. Testing. It is. Thank you very much, Mr. Chairman.

Mr. SHAYS. Maybe you could start over.

Mr. KUCINICH. I want to thank the Chair for holding this hearing. I think the Chair's concern here is well taken. The American people need to know whether or not this vaccination program is affecting the readiness of our Armed Forces. In particular, we need to know why members of the Armed Forces are not supporting this particular—the troops do not support this program because of concerns about adverse reactions.

I think the questions that are being raised here in the committee are important and serious, and I look forward to the testimony of the witnesses.

Mr. BURTON. Thank you, Mr. Kucinich. Mr. Shays, do you have an opening statement?

Mr. SHAYS. I do, Mr. Chairman. One year ago, the National Security Subcommittee, which I chair, held a hearing on the impact of the Anthrax Vaccine Immunization Program [AVIP], on Reserve component readiness, retention and morale. The Department of Defense [DOD], position then was essentially one of blissful ignorance. DOD had no data on how many National Guard and Reserve members were leaving due to concerns over the vaccine, had only the vaguest plans to collect any data on the question, but concluded nevertheless the impact of the controversial program was negligible. Those are their words.

My dictionary defines negligible as "so small or unimportant or of so little consequence as to warrant little or no attention." It appears DOD continues to believe the problem can be ignored, despite abundant and growing evidence of opposition to the anthrax vaccine effort.

Today, we will discuss new data supporting the conclusion many reached long ago: The AVIP is having a substantial, detrimental impact on Reserve component readiness, retention and morale. The implications of the General Accounting Office [GAO], findings cannot be difficulties missed, diminished or defined away. Critical elements of Reserve component units are being rendered unready to perform their missions, and that lack of readiness is directly attributable to the AVIP.

This data can be of no surprise to the DOD. The purposeful, and I stress, the purposeful failure, to gather information cannot excuse the consistent effort to mislead, misinform, and ignore readily available evidence of the program's drain on readiness. I, for one, am tired of the official dissembling on this issue. We want the truth. We want the truth. To the extent DOD acknowledges any Reserve component attrition to the anthrax program, blame is placed on inadequate communication of the threat and the response. But the survey results we will hear today point to a genuine lack of trust in the product, not the packaging. It will take more than a revamped Web site to address the legitimate concerns of those being asked to risk their civilian livelihoods in a force protection experiment, and that is what this is, an experiment.

Behind these numbers are loyal, dedicated and skilled men and women who want to serve their Nation. They deserve to be heard.

Mr. Chairman, I thank you for holding these hearings. I thank you for the hearing we had last week. But I want to say, my committee has had a number of hearings on this issue, and I sincerely believe the military is being blatantly untruthful to us. I believe this program is destroying our readiness. I believe that it must stop.

Mr. BURTON. I thank the gentleman from Connecticut. I want to say, the committee has held a number of hearings, but he has done yeoman service to this country and to the committee with his subcommittee chairmanship by really working on this. I really appreciate your hard work.

I would like for the witnesses to stand now to be sworn.

[Witnesses sworn.]

Mr. BURTON. We have Mr. Heemstra, Mr. Marohn, Mr. Ross and Dr. Porter. Let's start with Mr. Heemstra. We will go right down the line here. We would like for you, if you can, to keep your comments to 5 or 6 minutes. But if you run over, we will be lenient. But try to be as concise as you can. We want to hear your whole story.

STATEMENTS OF TOM HEEMSTRA, LEXINGTON, KY; DAN MAROHN, PLYMOUTH, IN; PAT ROSS, BATTLE CREEK, MI; AND R. STEPHEN PORTER, VIRTUAL DRUG DEVELOPMENT, INC., BRENTWOOD, TN

Mr. HEEMSTRA. First, thank you on behalf of the backbone of our military force, the Enlisted Corps, and many of our 2.4 million troops who do not, I repeat, do not support this anthrax shot program. I speak for them, because they cannot risk their career to speak out, but they thank me almost every day.

Thank you for the opportunity to address you. Focusing on Fort Wayne, the 163rd Fighter Squadron, in terms of readiness, retention and morale. My qualifications: I testified before the subcommittee in September last year. My background, a 20-year military career beginning at the Air Force Academy, where I received the best honor, ethics and leadership training available anywhere in the world. My career is highlighted by an opportunity to serve at Fort Wayne as the 163rd Fighter Squadron Commander.

Many Guard and Reserve pilots sent you a message when they voted with their feet. We lost 260 pilots, from 12 percent of the

units so far, which means we will lose 2,100 if this shot program continues. That will be $10 billion lost in training cost for a $130 million shot program, plus invaluable combat experience gone.

DOD is either in denial or a coverup operation. In September, their answer under oath was "only one quit from the Guard because of the shot," despite signed affidavits and testimony before Congress of eight resignations from Connecticut, and at that time seven pilots chose to leave at Madison. I estimated we would lose 15 to 20 at Fort Wayne. Within 1 week, 22 left from Memphis and decided not to take the biological oath of loyalty to this shot program. Plus 30 were lost at McChord, 20 at McGuire, 60 at Dover, and 50 at Travis. Wow. Wow.

Let's not argue numbers any more. How about names, real people, faces, that I clearly see of my men who gave up on trusting their leadership and voted with their feet. Their names are represented by the coded initials on the graphic to protect their privacy in their followon careers. Can we have that graphic, please?

These are the men who are gone. Twenty-one. Note the leadership at Fort Wayne falsely reported to GAO and the media that only 9 left, versus the 21 that are really missing. Two of these changed their mind, came back and agreed to take the shot reluctantly. But then, after the shot policy changed, the leadership offered to give them special permission, a waiver, to now violate current DOD policy and give them the shot anyway.

If I could have the next slide, please.

If DOD or Fort Wayne wants to argue or fudge the numbers again, let's look at it another way, who they had to hire to replace the departed. They hired 14. Notice they still have five vacancies. But out of those 14, many were at various stages of flying currencies and qualifications, requiring some to attend formal F–16 schools, and, as I said, they still have five vacancies. Needless to say, a rebuilding program. Plus, two of the top three flying leadership positions are being filled and have been for most of the last 2 years with officers who are not even flying.

For a real world deployment to Saudi Arabia, they had to get six pilots from two other bases in order to fulfill their obligation. Now, imagine this happening on a grand scale nationally, and you will get a picture of what I was trying to tell the subcommittee last September and warn my leadership of at Fort Wayne.

Finally, the troops thank you for your courage, integrity and leadership on this issue. America's sons and daughters needed a voice in Washington. You heard, you listened, you acted to protect them and spoke the truth, despite whatever political, economic and career pressures you faced. The exact opposite approach and behavior from DOD has eroded, if not destroyed, their trust in military leadership. And rightfully so. DOD misled you, the Congress, the GAO, the American people and their own troops. They have betrayed the trust of us all. Webster defines that as treason.

The arrogance of power and the abuse of power seemingly have elevated them above the truth and above the law, causing them to use an experimental, adulterated drug for an off label use on a large scale vaccination program, violating FDA protocol in administering it, while the FDA discovered a substance not approved in

the vaccine, which DOD also denied, and then calling us conspiracy theorists or Internet malcontents.

Further, they coerced, intimidated, threatened and punished in order to enforce this program. Reference my written testimony and chronology up through the present date, and my colleagues' testimony dating back to the Connecticut eight pilots.

One of my pilots, Captain Dan Marohn, sitting next to me, was even threatened with jail time after the policy was changed and he was no longer required to take the shot. They punished me by forcing my resignation as Squadron Commander before I testified. After I testified, they illegally grounded me. They damaged my personnel file and performance reports and forced me into retirement now, against my wishes, and in direct contrast to what the Headquarters Air Reserve Personnel Center says and documents.

These actions clearly violate Whistleblower Protection laws, Title 10, U.S. Code, DOD Directive 7050.6 and Article 92 of the UCMJ. These offenses and punishments are inconsistent with Assistant Secretary of Defense Cragin's declaration under oath that people in the Guard would not be punished for resigning and not taking the shot.

On January 2, I filed an Inspector General report with the Secretary of Defense's office citing these violations, and have been largely ignored for the better of 6 months. Perhaps the Attorney General would enforce the laws that our DOD has ignored.

If DOD had listened to your committee when you called for a halt to the program, we would not have experienced the upheaval at Fort Wayne and Battle Creek. If they had listened 6 months ago, when you inferred that it was an illegal order, we would be well on our way to restoring the faith, trust and integrity our military institution absolutely requires, and out of that comes good order and discipline.

If the lessons learned from the Rockefeller Report had not been ignored after the Gulf war, this abuse of power might have been checked. And if only we had received support from your colleague, the chairman of the Personnel Subcommittee, who went on record twice saying that DOD is using this vaccine in a manner other than it was what approved for, we might have ended the abuse. The FDA's term for that off-label use is "investigational," and that requires informed consent by law. This was a lost opportunity to be a watchdog and a defender of our military troops.

But we now know the recipe for executing an illegal order and the results that follow: First, pick a bad policy that ignores U.S. law, FDA regulations, the historical and ethical lessons of Nuremburg, Agent Orange and radiation testing, that ignores basic human rights, congressional declarations of unlawful, ignores sick and injured people, Gulf war illness, improper influence and corruption in the acquisition process, and that ignores lack of testing and quality control standards consistent with historical failure of the program and lack of proven necessity, and then apply it on a massive, grand scale; add fear, intimidation, coercion, punishment, greed, careerism; throw more money into it, add politics to it, put it in the hands of some powerful, and the result is a travesty.

I actually predicted the results of this policy failure last September when I said we will lose 1,000 to 2,000 pilots. We are on sched-

ule to lose 2,100 if this program continues. I said we will lose 25 to 60 percent of our pilots at Fort Wayne, and we lost 55 percent. I said we will have sick people. Many of these will remain secretly sick to protect their careers. I said we will have a breakdown in trust. Correction, I should have said meltdown. I also said we are the guinea pigs. We know it, and so do you, and now the FDA has proved it.

What can be done? Three things. No. 1, restore faith in the system. Protect your troops with legislation, since military careerism won't. Halt this program immediately based on its grandiose failure.

No. 2, establish a process for safe acquisition of necessary, proven by the threat, force protection measures that will be effective and with full FDA oversight, regulatory authority and accountability for all vaccinations so we never go down this road again.

And, No. 3, completely restore through funding, medical assistance and blanket immunity, all who were injured by this program, physically, medically, and occupationally, in their professional military careers. Please protect our military against future abuses of power.

[The prepared statement of Mr. Heemstra follows:]

TESTIMONY OF TOM HEEMSTRA
TO GOVERNMENT REFORM COMMITTEE
HEARING ON ANTHRAX
OCTOBER 11, 2000

Distinguished Members of Congress, Ladies and Gentlemen:

First, I thank you for the opportunity to address you on the Lessons Learned from the Anthrax Vaccine Immunization Program, focusing specifically on Ft. Wayne—the 163rd Fighter Squadron, in terms of readiness, retention, and morale. My qualifications and testimony are based on a 20 year military career: I graduated from the Air Force Academy at the very beginning of my career, where this country graciously provided me an outstanding opportunity for an education. The Academy in essence is a leadership laboratory, that includes the finest values, ethics, and honor training anywhere in the world. Towards the end of my career, I was fortunate to serve at Ft. Wayne as the F-16 Fighter Squadron Commander, the highlight of a wonderful career.

Second, I sincerely thank you, this time, especially on behalf of the backbone of our military force-our enlisted corps, and many of our 2.4 million troops who do NOT support this anthrax shot program. How do I know I speak for these troops? Not a month, week, or sometimes even a day go by that I am not thanked for fighting this battle for them--because they have no choice but to risk a court-martial for disobeying this order, an order you have also found to be illegal. And according to a USA poll last summer, 83% of Americans think anthrax should be a voluntary vaccine.

As you are aware, many pilots have resigned or transferred out of flying positions, leaving the Air National Guard and Air Force Reserves. About 260 pilots, from 12% of the units so far, which makes a total estimate of about 2100 pilots lost if the shot program continues. **Over ten billion dollars** in training costs could walk out the door. When I testified to this Committee on 29 Sep 99, I estimated we would lose 1000-2000 pilots due to anthrax. My projection has proven to be true and right on track. Unfortunately, DOD leadership, to protect their own careers, will no doubt still be in denial over this issue. In Sep their answer under oath was "only one had quit from the Guard because of the shot" despite signed affidavits and testimony before Congress of 8 resignations from Connecticut. And at that time 7 pilots had chosen to leave at Madison. I estimated 15-20 would leave Ft. Wayne. Within one week 22 left from Memphis and chose not to submit to the "biological oath of loyalty". Plus, 30 were lost at McChord, 20 at McGuire, 60 at Dover, and over 50 at Travis from the USAFR. WOW!

But let's not argue numbers anymore since they have been manipulated: their's vs.ours. How about names, real people, faces I picture clearly of my men who gave up on trusting their leadership and voted with their feet? Their names below are represented by coded initials on the graphic to protect their privacy and their follow-on careers.

GONE

1. FTRC
2. RAHB
3. WDMD
4. STHJ
5. HEPT
6. HAJF
7. EPTU
8. GAPT
9. AWGR
12. WMJY
13. BJDE
14. JDMH
15. MAGD
16. MACC
17. PTRM
18. AJTY
19. WWCI
20. DBNR
21. ECBH

***Keep in mind the leadership at Ft. Wayne **falsely reported** to GAO and the media that only 9 pilots left because of the shot. They know as I do, and many could testify, their numbers are false.

2 of these 21 pilots listed changed their minds, came back and agreed to take the shot. However, then DOD policy changed. They were not forced to take the shots. However, please note the leadership at Ft. Wayne offered to get "special permission, a waiver" to violate current DOD policy, "inventing" their own policy again, to allow them to give these 2 pilots the shot—presumably out of revenge, definitely out of control.

If DOD or Ft. Wayne wants to "fudge" the numbers again, let's look at it another way: who they had to hire to replace the departed.

REPLACEMENTS

1. RAMF
2. BADJ
3. CHJN
4. CECB
5. JEDF
6. LAGF
7. DHJD
8. CJLV
9. RJMK
10. DMRL
11. TDRO
12. DIMF
13. MPVR
14. WBBP
15. **VACANT**
16. **VACANT**
17. **VACANT**
18. **VACANT**
19. **VACANT**

Note the 5 **VACANCIES after they had to hire 14 new pilots, all at various stages of flying currencies, & qualifications—some requiring attendance at formal F-16 school. The experience and cohesiveness of this fighter squadron were demolished and they are now on a rebuilding program. Plus, the top 2 flying leadership jobs have been essentially unfilled for the last 11/2-2 yrs by noncurrent pilots. Ft.Wayne's flying leadership has been virtually nonexistent, compared to the way a fighter squadron should be run.

1. Wing Commander—filled
2. Operations Group Commander—VACANT of a current F-16 pilot since 25 Feb 99: 11/2 years.
3. Squadron Commander—VACANT of a current F-16 pilot since 18 Nov 98: 2 years.

Imagine this happening on a grand scale, nationally, and you will get a picture of what I was trying to warn my leadership at Ft. Wayne and your committee of last summer. Also noteworthy: approximately 10 other pilots, in addition to the 21 who resigned or transferred, said at one time they would **not** take the shot, then later changed their mind after agonizing over a very tough choice. Only 2-3 pilots are known to have wanted to take the shot.

Thirdly, the troops thank you for your courage, integrity, and leadership in researching and taking a stand on this issue. America's sons and daughters needed a voice in Washington. You heard, you listened, you acted to protect them, and spoke the truth despite whatever political, economic, or career pressures you faced. The exact opposite approach and behavior from DOD on this issue has eroded, if not destroyed trust in our military leadership. Rightfully so: DOD misled you, the Congress, the GAO, the American people, and their own troops. **They have betrayed the trust of us all.**

The arrogance of power, and the abuse of power seemingly have elevated them above the truth and above the law, causing them to use an experimental, adulterated drug for an off-label use, on a large scale vaccination program, violating FDA protocol in administering it, while the FDA discovered a substance not approved in the vaccine recipe, which DOD also denied, and then calling us conspiracy theorists and internet malcontents.

Further, they coerced, intimidated, threatened and punished in order to enforce this program, reference my written testimony/Chronology up thru the present date, and my colleagues testimony dating back to the Connecticut 8 pilots. Specifically, they threatened to put one of my outstanding pilots in jail, Capt Dan Marohn sitting by my side, as well as punishing me by a forced resignation as a Commander, an illegal grounding, damaging my personnel file and performance reports, and forcing me into retirement now against my wishes and in direct contrast to the official documents of the Headquarters Air Reserve Personnel Center (HQ ARPC) which I have here and offer as evidence of their punishment mentality. **These actions clearly violate Whistle Blower Protection Laws, Title 10 US Code, DOD Directives 7050.6 and Article 92 of the UCMJ**. These offenses and punishments follow Asst Secretary of Defense Cragin's declaration under oath that people in the Guard would not be punished for resigning and not taking the shot. In Jan I filed an Inspector General complaint with the Secretary of Defense's Office citing these violations, and have been largely ignored for the better of 6 months. Perhaps the Attorney General would enforce the laws our DOD has ignored.

If DOD had listened to your Committee, when you you inferred that it was an illegal order, we would not have experienced upheaval at Ft. Wayne and Battle Creek. If they had listened 6 months ago, when you declared it an illegal order we would be well on our way to restoring the faith, trust, and integrity our military institution absolutely needs to have. Out of that comes good order and discipline. If the Lessons Learned from the Rockefeller Report had not been ignored after the Gulf War, the abuse of power might have been checked. If only we had received support from your colleague, the Chairman of the Personnel Subcommittee who went on the record twice, once in a Congressional joint subcommittee meeting last November, saying DOD is using the vaccine in a manner

it was not approved for, we might have ended the abuse. The FDA's term for off-label use is: "investigational" and that requires informed consent by law. This was a lost opportunity to be a watchdog and defender of our military troops.

We now know the recipe for executing an illegal order and the results that follow. Take a bad policy:

that ignores US law, FDA regulations, the historical and ethical lessons of Nurmburg, Agent Orange, and radiation testing,

that ignores basic human rights, Congressional declarations of "unlawful", sick and injured people, Gulf War Illness, improper influence/corruption in the acquisition process,

that ignores lack of testing and quality control standards, consistent historical failure of the program, lack of proven necessity;

then apply it on a massive, grand scale;

add fear, intimidation, coercion, punishments, greed, careerism,

throw more ($$$) money into it,

add politics, and put it in the hands of some powerful people:

the result—a travesty!

I accurately predicted the results of this policy failure last September when I said:

We will lose 1000-2000 pilots. We're on schedule to lose 2100 if the program continues.
We will lose 25-50% of our pilots. We lost 53-58% at Ft. Wayne.
We have sick people. Many of these will remain secretly sick to protect their careers.
We will have a breakdown of trust. My fault, I should have said **meltdown**!
I also said: We're the guinea pigs. We know it. And so do you. Now the FDA proved it.

What can be done?

1. Restore faith in the system. Through legislation and your influence with colleagues protect your troops, since military careerism won't. Halt the program immediately based on its grandiose failure.
2. Establish a process for safe acquisition of necessary force protection measures that will be effective with full FDA oversight, regulatory authority, and accountability for all vaccinations so we never go down this road again.
3. Completely restore through funding, medical assistance, and blanket immunity all who were injured by this program: physically/medically and occupationally in their professional military careers.

Please protect our military against future abuses of power.

CHRONOLOGY

(dates are accurate to the best records and recollections of multiple witnesses)

OUTLINE OF EVENTS AT THE 163 FIGHTER SQUADRON
CONCERNING THE ANTHRAX VACCINE

Mar 99 Squadron members learn and research more about the vaccines potential negative affects and mandatory compliance. We are put on an artificial deadline for an "invented" base policy to be vaccinated on Aug, 9 months early. Tension is high and time is short to find out about safety of the shot. I traveled to Maine to meet with Dr. Meryl Nass, a civilian anthrax expert, to research, study, and enlist her help.

17 Apr 99 In accordance with DOD's goal of educating our people about the shot and with the full knowledge of our leadership at Ft. Wayne, I invited Dr. Nass to visit Ft. Wayne and educate our people. The Wing CC's order prevented her from coming on base. I was then told educating the troops meant telling them DOD's versions of the facts. I questioned whether this was "censoring the truth" and questioned our responsibility as trustees of their health to find out the truth, but was ridiculed. The meeting with Dr. Nass lasted 5 hours, 20 pilots attended and 30 enlisted personnel. All who attended were convinced by the facts to avoid the shot, and convinced that DOD had been less than truthful.

Apr-Jul 99 The Indiana Assistant Adjutant General for the Air National Guard from State Headquarters made an indirect threat to my career saying: "you should have fired the son-of-a-b____ five years ago when you had the chance". He was referencing a time when I previously exercised my Constitutional rights as a "citizen-soldier". As a Whistle Blower I informed Congress of the money waste and deceit of American taxpayers in trying to take away fighters from Ft. Wayne and replace them with tanker aircraft, in the interest of saving money under the Bottom Up Review. The truth came out on this issue and the fighters remained at Ft. Wayne. However, this punishment mentality frames the behavior of the base leadership. Three pilots, myself included, were punished by grounding for 3 months for exercising our Constitutional rights.

5 May 99 After several meetings with the leadership questioning the legality of the order, and the unethical, unsafe, and 'ineffectiveness on the battlefield' aspects of the shot; I recognized our military leaders lack of interest. Pilots were criticized for their lack of patriotism, lack of commitment, disloyalty, and distrust in the system. Participation in the operational flying for part-timers began to seriously drop off. I then contacted several Congressmen in person, spending a week in Washington to try to inform them of the severe potential impact of this shot on the health and safety, retention and readiness, and the negative impact on morale. I spoke with Congressmen as a civilian, a "citizen-soldier" in an unofficial role, not representing my unit, and in civilian attire.

26 May 99 Stop Loss goes into effect as a result of the war and pilots are not allowed to resign. This causes serious concern with pilots potentially being forced to take an unsafe, ineffective, unproven shot that could threaten their civilian airline careers and the future health and security of their families.

May-Jun 99 I was given a 'gag order' to cease discussions about the anthrax vaccination on base. I complied with this directive as much as possible by not initiating any conversations, and minimizing or diverting any that were initiated by the troops, and by not impacting the mission.

Jul-Aug 99 All Commanders at the base were "encouraged" to take the shot. Here, I was questioned whether I would support the shot policy. I clarified the current DOD shot policy as "not being required until just prior to deployment", for us, then, it would not be required until around Feb 2000. Since safety was being investigated and hearings were being conducted in Washington, I stated "in light of these questions I was uncomfortable taking the shot". I was told we would then need another Squadron Commander. I then asked if it was better for me to resign or be fired. I was asked to resign as Squadron Commander. I was told my performance reports would **not** reflect negatively if I resigned vs. being fired. Note: I had not and never have refused to take the shot, but merely said, based on the current DOD policy and negative safety reports, and ongoing hearings in Congress, I was "uncomfortable at this time" taking it so early, and conflicting with DOD policy. This new base shot policy, where taking the shot 9 months early was encouraged for Commanders, was certainly targeted at me-to coerce me into taking it, to manipulate compliance base wide and end my negative stance toward this policy, to silence the critic, or make it possible to remove me because this new base shot policy was **not applied uniformly** to all commanders. Not all were specifically asked to take the shot, not all did take the shot. However, I was the only one fired, or forced to resign. This action had a negative affect on morale and made many pilots angry at the punishment mindset of our leadership. Prior to resigning I attempted to have two of my pilots promoted. The Wing Commander would not promote them if they were not going to take the shot, which still had not been ordered. So these pilots still had not made their decisions, nor were they required to so early. Pilots were told they could be easily replaced by rental pilots. One of our crew chiefs became sick from the shot, kept a diary, was not offered a VAERS form from the clinic, and was finally told his illness is from a pre-existing condition and not from the shot. However, that was not what he believed about his illness. The base leadership was not informed initially about this sick person, for a long period of time because of distrust, future career worries, and knowing the tendency of DOD to dismiss these cases without helping the sick individual. Others are sick even today on the base, but are fearful to speak up because of how it will negatively affect their career. Finally, on 14 Jul our sick crew chief reported to the base clinic.

Sep 99 After this punishment of forced resignation for not complying with an encouraged policy, that coincides with an unlawful order", the Congressional Committee on Government Reform invited me to testify on 29 Sep 99 which I did.

24 Nov 99 After flying 3 sorties that week and one that day, Wed morning, the day before Thanksgiving, I was scheduled to fly with the Wing Commander in the afternoon. After my first flight the Ops Group Commander asked me if he could talk to me, was very nervous and said I was grounded. The only reason offered was stress. Although, there was no unusual stress affecting my performance and my performance was excellent

as witnessed by several that week in air-air (kill of blue air as red air in a handcuffed scenario) and air-ground (excellent bomb scores). I even flew a single-ship sortie. No other reason besides stress was offered for my grounding, and this was never documented. Many witnesses will verify how arbitrary and mean-spirited this grounding was due to my public stand on the anthrax issue and testifying to Congress in Sep vs. my flying performance or emotional/mental health. **This retaliatory and reprisal action violates Whistleblower Laws, Title 10 US Code, Section 1034, DOD Directives 7050.6 Military Whistleblower Protection, and Article 92 UCMJ**. My protected disclosures and communications with Congress were always in a civilian or "citizen-soldier" status, and never in uniform or representing my military unit. In fact, prior to testifying I inquired with Mr. Larry Halloran of the Congressional staff, whether I would need a protective subpoena because I had been already punished once, being forced to resign. Now I was being punished again by an arbitrary and unwarranted grounding.

4 Dec 99 We all received a letter from the Indiana Adjutant General called the "verbal order" to take the shot with no date, or timeline on it and no specifics as to how refusers would be treated if they still had a commitment to the Guard.

2 Jan 00 Because of the illegal reprisal actions and punishment I had been exposed to for exercising my Constitutional rights, I filed an Inspector General complaint with the Secretary of Defense Office and informed the Operations Group Commander.

Jan 00 Many pilots were shocked and surprised to find they had been grounded early in January because "someone" believed they would not take the shot when it was projected to become mandatory on Feb 13, the date we expected to receive the written order to take the shot. A letter was mailed on 7 Jan informing them that their decision was needed by 8 Jan. Of course, this letter was not received in the mail until after our decision was already required. Many were caught off guard since the December order did not have any dates/timeframes associated with it and many of us wanted to know then what to expect. We asked but received no specific answers. Considering the secrecy, surprise, and grounding a month earlier than necessary, it seemed to be an attempt to coerce and manipulate people, short notice, into taking the shot, or at least make a decision once again earlier than required in order to keep flying. The number of names on the no-shot list was approximately 21. The press was told there were only 9. The base also misled the press saying, "these pilots are not grounded" (although that terminology was good enough for the pilots). They were told the pilots were just not allowed to fly right now!

13 Feb 00 All personnel had to take the shot or resign/transfer. I decided to transfer and discussed this the Ops Group Commander. He and the personnel office were unprepared for how to do this and the paperwork required. So I informed him at the same meeting I would retire, since I was within 120 days of the Adjutant General's "120 day window" and that was the recommendation of my Area Defense Council. I emphasized several times I had no intention of ever disobeying an order.

1Apr-4May00 The squadron deployed to Saudi Arabia without enough pilots to do the mission. Six (6) pilots from 2 other bases, Terre Haute and Syracuse helped us with our real world deployment by providing these pilots.

07 May 00 My retirement papers were filled out for me without consulting me and I was asked to sign in an attempt to coerce me out at the earliest opportunity. Since the shot policy could change and I was still earning retirement points for a good 20th year, and I still had an IG complaint pending with little action; I was unsure if I was even legal to retire/resign. So, I refused to sign. In another attempt to punish me, I found my performance reports in my personnel file had been negatively written despite assurances to the contrary if I would resign rather than be fired as Squadron Commander. Specifically, I was cited for not yet obeying by 4 Dec a verbal order to take the shot. This negative "4 Dec" comment not only fell outside the reporting period that expired on 1 Nov for that particular performance report, but also by Nov 1, we still had not been ordered to take the shot. This blatant punishment to end my career should not have been placed in my performance report. Also, there is no mention in my performance report of me being the Squadron Commander, an elite position that should have been rightfully recognized.

1 Jun 00 I hand-delivered a letter of resignation and transfer request to the Academy Liaison Officer program which I was already doing as an additional duty. By the time I got off the plane back in Cincinnati a few hours later, I had a call from Ft. Wayne telling me they were not going to approve my resignation/transfer because I would not be within the 120 day window (Wrong! Order to take the shot: 13 Feb + 120 days = 12 Jun.) I immediately called the Wing Commander and was assured they would coordinate for my transfer to take place, possibly to the Inactive Ready Reserve. I expressed my concern and belief that the Inactive Ready Reserve transfer was incorrect and would possibly hurt my ability to smoothly transfer to the Academy LO job because it might force a re-application. (I was already active and did not want to go in an "inactive" status, and perhaps a refusal, since I had been punished twice now and transfers were generally being handled negatively throughout the Air Force Reserves because of the shot program and DOD's punishment mindset. This might jeopardize or delay my eventual retirement if the transfer paperwork messed up credit for good years etc.) It should have been a simple parallel type transfer since I was already doing the job as an additional duty the last 5 years. I was assured it would be properly handled.

7 Jun 00 I received a threatening letter from the Ops Group Commander dated 25 May. The letter contained several misstatements and deceptive points trying to rewrite history, which I corrected in a letter dated 12 Jul. The letter threatened Administrative Action for disobeying a lawful order of not taking the shot. Since I had taken care of this before the 3 Jun deadline (according to the 25 May letter) to comply with the shot, by hand-delivering my transfer/resignation, I should have been okay.

14 Jun 00 Received a letter from the Wing Commander and forms to sign transferring to the Inactive Ready Reserve contrary to what I believed was correct and best, since I just wanted to transfer laterally to the Academy Liaison Officer job.

27 Jun 00 I went to Ft Wayne and found out it was the Base Commander (who's actions have been legitimately suspect in another pilot's case) who had coordinated, supposedly with the Academy, for my transfer to the Inactive Ready Reserves. I immediately called the Academy and was told emphatically not to transfer to the Inactive Ready Reserve. I confirmed it with her and asked if I should talk to anyone else. They said I could call ARPC in Denver. So, I immediately did. He said the same thing. Do NOT transfer to the Inactive Ready Reserve, it will only cause a big mess. I queried also about a Stop-Loss program for LO's and was told that no transfers were being approved until 1 Oct. I asked if this applied to the Guard. He said to call my base personnel office. So, I immediately did and was given the same answer: No transfers would be approved until Oct 1. At this point I realized my career was being negatively manipulated again by a Base Commander, who as a supervisor of the personnel office should have known better. Because of this I could not sign the new paperwork sent to me by the Wing Commander. Why were they pressing me to transfer when it would not be approved prior to 1 Oct? Why were they putting me in an Inactive Ready Reserve status after I specifically had suggested it probably was not proper and the Academy confirmed it?

17 Jul 00 The base receives a change in the shot policy. It is no longer required if troops will not be on the ground in a high-threat area more than 30 days.

20 Jul 00 The Ops Group Commander asked me what I wanted to do: transfer or retire? Knowing the transfer option as designed by them was a trap, and considering the threats, intimidation, coercion, punishment, harassment, and discrimination I had already received, and after already trying to transfer twice and retire a previous time, I chose to retire once again; of course under duress, not wanting to really do this, and not knowing DOD had changed the shot policy, but knowing I am not getting fair cooperation, and I am frustrated and tired of being harassed and deceived. The Ops Group Commander said he would personally escort me to the base personnel office to make sure I signed. Once there, the retirement form instructions said to call ARPC before filling it out. I suggested we should probably do that to the visible disappointment and grudging agreement of the personnel assistant and my Ops Group Commander. Planning initially to retire on 5 Aug, ARPC then told me I could not retire before 20 Sep 00, 60 days from now. Knowing I now had bought some time to do the transfer paperwork correctly, or the possibility of a change in the vaccination policy as they ran out of un-quarantined anthrax vaccine like we told them would happen in Congressional hearings, I signed the papers for 20 Sep with my Commander overlooking to make sure I signed them. As I signed I considered writing a comment about duress on the form and asked the personnel assistant the purpose of one of the blank blocks on the form, but was told it was not allowed for my purposes. So I signed without noting duress on the form but knowing I still had options to prevent execution of my retirement. NOTE: I was not informed that on 17 Jul 00, 3 days prior to me being coerced to sign, the base had received a change to the shot policy not requiring me to take the shot or to transfer or retire. This policy change was never briefed in detail on the base, but largely glossed over. Many had to do their own research to find the documents and details that covered the change.

Jul-Aug 00 Two pilots who initially chose not to take the shots, changed their mind and came back to fly. They had to agree to take the shot. However because the shot policy changed they were not forced to take it. In a vindictive manner though, they were both told the leadership could "request special permission, a waiver to give them the shot," contrary to DOD policy.

3 Aug 00 Informed now the policy had changed, I went to the personnel office to withdraw my retirement papers. I was told by both an enlisted person and an officer, I would need a letter approved by the Ops Group Commander and the Wing Commander with their approval before I could change my mind on retirement. Knowing this was probably not true, nor was it the counsel they had given a previous retiree, I very specifically questioned each of them. "Is there any written guidance or regulations that cover this situation?" They both said "No". Suspicious of such an absolute answer from an organization that lives and breathes by regulations, and suspicious of their motives influenced by the Base Commander from an office that already tried to hurt my career by transferring me to the Inactive Ready Reserve, and to avoid more resistance from the base, I immediately called ARPC. They confirmed my suspicions of base personnel when I asked what was required to withdraw my retirement papers. They said what I was told was not true. All that was needed was a letter to ARPC from me. I verified it to be sure, and asked if a fax was okay. They said it was okay. They said my base had not yet projected me out, so it will be easy to take care of and it will be like it never happened (like I had never submitted my retirement papers.) I immediately wrote a fax and sent it, quoting the conversation. I also sent a certified copy of the same letter on 7 Aug to ARPC.

5 Aug 00 Since I was no longer retiring and had this confirmed with ARPC and because the shot was no longer required, one of our other pilots and I together informed the Ops Group Commander we would like to fly F-16s and stay in the squadron. He said concerning the shot, that it was not a change in policy, even though the policy had changed. Now the shot was not required if we were not going to be on the ground in a high-threat area more than 30 days and now we should be allowed to come back and fly. He said we would have to agree to take the shot (even though this would violate current DOD policy) like 2 other pilots who changed their minds and decided to come back and fly, (even though they were not required to take the shot). He then offered to get "special permission, a waiver" so we too could take the shot, directly counter to DOD policy in order to harass the 2 of us who wanted to continue our military flying careers.

18 Aug 00 ARPC sent me a confirmation (and left a phone message saying that my retirement was withdrawn.) ARPC also faxed the base to let them know I had withdrawn my retirement papers and Ft. Wayne must gain me back into their system.

20 Sep 00 I faxed a letter to my Ops Group Commander. Since my retirement was withdrawn with ARPC sending me confirmation documents, I requested to be reinstated as a pilot and reinstated as Squadron Commander.

26 Sep 00 I went to Ft. Wayne to report for duty, my last drill of the fiscal year. The Ops Group Commander informed that I was now retired and "that my 20 Sep 00 fax was the first anyone at the base knew anything about me wanting to continue my career" apparently ignoring the documents and witnessed conversations I had with him personally and with 2 personnel at the personnel office. So, after informing him, my immediate supervisor and commander, the base personnel office, then ARPC HQ Personnel, I was told I had not gone through proper channels. I was also told ARPC considered me retired.

27 Sep 00 I informed Congressman Souder's office of this latest form of punishment that ended my career, prematurely and in a very negative fashion.

2 Oct 00 I contacted HQ ARPC to find out their version of my status. They say I am still in, and the base must "gain" me back into their system. Ft. Wayne seems intent on punishment and keeping me out. At this point a court of law, a positive Inspector General investigation and resolution, or maybe a good 'ole-fashioned act of Congress may be required to correct this situation.

11 Oct 00 What next?! Following my testimony before you today I will be ready for the next round.

Mr. BURTON. Thank you, Mr. Heemstra. We have been joined by a number of our colleagues. I think Chairman Gilman did have an opening statement. Do any others have opening statements? Would you raise your hand if you have a comment you would like to make. If not, we will recognize the chairman of the International Relations Committee, Mr. Gilman, and then we will get back to the witnesses.

Mr. GILMAN. Thank you very much, Mr. Chairman. I regret I was delayed. I had to open up our International Relations Committee that is examining our peacekeeping missions abroad and the policies involved therein, and I will have to return to that committee. But I want to thank you, Chairman Burton, for convening this morning's important hearing to review the Department of Defense mandatory anthrax vaccination program's effect on readiness.

I want to thank subcommittee Chairman Shays, who has conducted an ongoing investigation with regard to this program.

This morning we will be hearing, in addition to the pilots who are before us from the Reserves, the General Accounting Office, which is ready to report the preliminary result from their study, a study that I joined with our chairman in requesting. The GAO study examined the vaccine program's effect on morale and retention in our Reserves and National Guard units, and when this issue was first brought to our attention last year, brought to my attention by service personnel in my own congressional district, where we have a significant Air National Guard unit that flies our C–5's around the world, I feared that Air, Guard and Reserve pilots would be leaving the service in droves, rather than receive the shots, just as the gentleman before us now has indicated.

As we will see this morning, this has happened throughout our Nation. I fully expect that the Department of Defense will continue to maintain its official position that the program has not had any detrimental effect on readiness.

Throughout the life of the program, the Pentagon has maintained a "see no evil" approach to personnel separations. It is an unbelievable approach. Instead of examining the facts, they are trying to bury the facts. The reality is that we have a volunteer military that is heavily dependent on Guard and Reserve personnel for rapid deployment of forces overseas, as well as for sustained theater air operations. Without Reserve and Guard pilots, further deployments can literally not get off the ground.

Many of the pilots who have left come from vital C–5 transport units. Had the vaccine been implemented at Stewart Air Force Base near my congressional district, more than half of the pilots were prepared to resign. I mention that from information, direct information that I have received.

When combined with the situation at Travis and Dover Air Force Bases, the Air Force airlift capabilities would have been severely impacted.

The public relations campaign being waged by the Pentagon refutes this. The official message is that the majority of troops are taking the vaccine with only a small minority of disgruntled individuals refusing. It bears noting, however, that the Pentagon only lists active duty shot refusers in their public estimates. National Guard and Reserve members have been fully ignored.

From the evidence I have reviewed, each National Guard base that begins to implement the vaccination program suffers attrition among its pilots that has been consistently averaging between 20 to 40 percent. This is not rumor, it is reality. Yet it is a reality that the Pentagon apparently refuses to accept.

Irrespective of this, however, is the fact that our military, with its current quality of life problems, coupled with an unparalleled rate of deployment under the administration, cannot afford to continue losing highly qualified personnel from its Reserve and National Guard units. Regrettably, this fact does not appear to be a consideration of the current administration, which still maintains that any potential benefit of the program far outweighs the possible costs involved and its implementation.

It is my opinion that while this program began with good intentions, it was initiated in a hasty matter before a proper amount of research on the efficacy and safety of the vaccine was completed. Moreover, the Pentagon has gone to great lengths to avoid getting a true picture of the number of adverse reactions and the impact that it has had on readiness. It would not be unfair to say that DOD officials have also engaged in the sustained pattern of deception regarding their testimony before Congress on this issue. Having served as a member of Representative Shay's subcommittee in the 105th Congress during his investigation of the Gulf war illness issue, I learned to view testimony from the Pentagon with a healthy dose of cynicism. I was pleased to see that the subcommittee report reached many of the same conclusions which led me to introduce legislation to halt this program until further study of the safety and effectiveness of the vaccine had been completed.

Moreover, while the Armed Services Committee chose not to act upon my legislation, the language calling for independent studies was included in the fiscal year 2000 defense appropriations conference report. I might add that today we have the defense authorization before us in the full Congress, and, you know, this kind of approach can affect our overall approach to what the Defense Department needs and we want to support the Defense Department in their needs. But I am going to ask our officials in the Defense Department who are in charge of this program to truly examine the facts and make certain we are moving in the right direction.

I was pleased to see that the General Accounting Office and the Food and Drug Administration have chosen so far to take an independent critical look at both the program, its effect on readiness and the manufacturing process behind the vaccine, a process that leaves a lot to be desired.

It also bears mentioning that throughout this process, DOD officials have taken pains to avoid responding to the charges leveled in the report approved by this committee with anything beyond the official boilerplate response. Not once, to my knowledge, has anyone from DOD questioned the science behind the criticisms of this program.

Furthermore, DOD claims, especially those relating to the number and percentage of systemic adverse reactions, increased after intense scrutiny was placed on the program. These issues have made reaching an effective solution to the problem extremely difficult.

I cannot understand also the loss of records, pertinent records, with regard to this situation. DOD has been unable to provide medical records that we have requested saying they have been lost someplace, lost despite the confidentiality of some of those records.

Once again, Chairman Burton, thank you for convening what I consider a very important hearing, important to our reserves, important to the security of our Nation.

Mr. BURTON. Thank you, Chairman Gilman.

Mr. Souder, did you have an opening statement?

Mr. SOUDER. Yes, I would like to make a few comments, and ask that this statement be inserted in the record.

Mr. BURTON. Without objection.

Mr. SOUDER. This has been of particular concern to me because the Fort Wayne Air base has clearly been one that has been talked about nationally because we had some people of courage who stood up early on. I met with people from other bases as well. But in many cases, they did not speak out or as many would speak out as they did in Fort Wayne.

But I want to make a couple of general points as well. As Lt. Colonel Heemstra pointed out in his testimony, in his chronology here, part of our problem in Fort Wayne and part of my problem as a Congressman is I am worried I am going to get a retaliation and get my base transferred.

Colonel Heemstra has been through this once before, where they made an illogical attempt to move the F–16 base out of Fort Wayne. I would argue that even with this problem and with the Federal Government making it more difficult to retain pilots, if this base is not in Fort Wayne and instead goes to a less populated area, they would not have even been able to replace the pilots that were replaced in Fort Wayne because you need a populous area with which to attract pilots who are working in another job.

So not only is Lt. Colonel Heemstra concerned about retaliation, I am concerned about retaliation in my district for speaking out early on and saying this should have been voluntary and I had deep questions.

Second, one of the challenges that is faced by the local commanders in Fort Wayne is they also want to keep the base there. They are trying to figure out how to keep their units staffed, they are trying to do their duty as officers. That has been compounded by a poor decision by the Federal Government. I am one trying to work through both sides. I have a full base there of people who have been trying to implement the program that is ill conceived, but their duty is they believe to implement that program. They have at least tried to keep track of those health cases where they have had problems, and they are doing the best they can with competing demands, both at the grass roots level from their employees, and from the national system as a whole that is demanding the anthrax shots.

Third, in addition to the people that have been referred to here, let me just say I have talked to many individuals, they catch me at church, they catch me at soccer events, airports, pilots who have stayed in, personnel who have stayed in, who are scared. Part of the reason they are scared is they saw what happened in the Gulf war and may have actually been complicated by anthrax shots

there, and their concerns are if they have other jobs, if they are pilots in other places and doing this as a volunteer service, if later on we learn that anthrax had effects on their ability to get health insurance, is the government going to stand behind them?

There is no clear evidence right now that the government is going to in fact stand behind them or acknowledge there are problems. The fact is, none of us really know for sure what the impact of this anthrax is combined with other shots.

We hear some cases, and there appear to be some problems, we don't know how wide and extensive it is, and data is still coming in. But when I had a young pilot of 28 who came to me and said I have three kids, my income is working for, I forget whether it was United or USAir, an airline, he said can you guarantee me if something happens I am not going to lose my health insurance later on or lose my primary source of income?

What can I tell him? Of course not. We are the Federal Government. We don't guarantee anything down the road. It is a very difficult situation for those young pilots whose lives are at risk.

Sometimes it seems right now that the government is more concerned about the risk aversion for the government than a risk aversion for the very people who have decided to defend our Nation, and that is backward. It has happened in the anti-terrorism area where we seem to be so worried about somebody getting blamed that we overreact sometimes because we are worried more about blame protection and future lawsuits to the Federal Government.

So I want to thank the individuals who stood up. This has been a very difficult process for all of us. I hope that we would change our standard and say that if we don't expect civilian members of our government to be forced to take this shot, if we could not have this pass an FDA test, then why in the world would we have those volunteers who are willing to sacrifice for our country have to have this mandatory test?

I yield back.

Mr. BURTON. Thank you, Mr. Souder. Do other Members have an opening comment or statement they would like to make?

If not, we will return to the panel. We go to Mr. Marohn. I am not using your rank correctly, you are a Lt. Colonel?

Mr. HEEMSTRA. Yes.

Mr. BURTON. And you are——

Mr. MAROHN. Captain.

Mr. BURTON. I was an enlisted man, so I have to show deference to you guys.

Mr. MAROHN. My testimony today is emblematic of what is occurring to thousands of U.S. military personnel with regard to the AVIP. I come here today to speak for all those men and women in uniform who wonder when they awaken each day, whether they have in effect been made into guinea pigs by a Nation for which they would have freely given their lives to protect and defend.

I come here today to speak for those who reluctantly submitted to a controversial immunization because they felt they had no other option.

I was an F–16 aviator at the 163rd Fighter Squadron at Fort Wayne, IN. My performance reports, my awards and decorations

and my leadership assignments all indicate I was an excellent pilot and officer. In civilian life I am a pilot for a major airline.

My pilot training carried with it a service commitment that would not allow me to resign prior to the completion of that commitment. When I refused to submit to the vaccine, I was grounded, given the choice between a court martial or Article 15, and fined, threatened with 329 days in jail if I did not pay that fine. Many others also refused the immunization. Most were able to resign. Some transferred to other assignments to complete their military careers and retire. But those of us under service commitments could only comply or face the most severe punishment.

After being made aware we would have to submit to the vaccine and listening to Dr. Meryl Nass make her presentation in the spring of 1999, we felt compelled to step up our research on the vaccine and the implementation of the program. We learned that there were real and valid concerns about safety and quality control methods of the lab that produces it, and we learned that many in our military are living in fear, as mentioned by all of you.

They feel they have no choice but to keep quiet and take the shot, because their commanders will not listen anyway, and if the commander is willing to take a stand against the program, he or she too runs the risk of punishment and/or dismissal.

Careerism over good leadership and integrity is eroding our military. Every day more and more military people are losing trust in the institutions and the Nation that they have taken an oath to defend. My own case is illustrative.

On December 5, 1999, our squadron received the verbal order to comply. The policy letter was ambiguous as to what action would be taken against those under commitment that refused. A letter requesting clarification was equally ambiguous. In the first or second week of January 2000 I received a call from my Ops Group commander asking if I was going to take the shot. I told him that I probably would not take it, but I would give him my final decision by February 13, the deadline to decide. About that time, I received a written order to comply dated January 8, 2000. The order said that violating the order may result in punishment.

On or about January 9, anyone that had not given an affirmative response to take the shot was grounded. Please make a note, this was a full month before the deadline. I was told this action was taken to "save our resources for the guys that are going to take the shot and deploy."

Please note that this occurred while—I already said that. On February 13 I did not submit to taking the shot. Later in the month in a conversation with my Ops Group commander, I was asked to reconsider. He also told me at that point that my case would be decided by the Indiana State Adjutant General, not by commanders at Fort Wayne.

On June 7th, I received a letter from the Assistant Adjutant General for Air ordering me to appear in his office on June 24. Another pilot with a commitment who also refused the shot called to tell me he had received the same letter. When I reported as ordered, after meeting with the Judge Advocate, my appointed legal counsel told me that I was going to be charged with failure to obey the order of a superior officer and would be offered a court martial

or an Article 15. After he explained the meaning and ramifications of each, I felt I had no choice but to accept the Article 15. I left Headquarters with an Article 15, a fine of two-thirds of 1 month's base pay, which was suspended for 30 days, and a feeling I had just somehow been railroaded into something that should not have happened.

Less than a month later, a slowdown at the anthrax immunization program became known to a few people on the base. Within days of this temporary slowdown, two pilots rehabilitated and agreed to take the shot to return to flight status. Because of the current policy, they are not required to take the shot, but were asked to volunteer to take it to show good faith. Both declined, stating policy, and were allowed to continue to fly.

The memo directing the slowdown was dated July 17th. On September 8 I received a letter from State Headquarters that I was in violation of the suspension of the fine for not taking the shot before July 24th, 7 days after the slowdown of the program. Nonetheless, I was to make arrangements to deliver the fine to my commander or face incarceration in the county jail for 1 day for each dollar of the $329 fine.

I asked for and was granted time to discuss with counsel whether my punishment would be affected by the change. After explaining the circumstances, my legal counsel suggested that I write my commanders asking for a total review of my punishment and asking them to rescind the Article 15 and the fine. I am still waiting for a response.

The AVIP has had a negative affect on our base. Morale is low and will be slow to rebuild. The squadron suffered a huge vacuum of experience, with a mass exodus of pilots who put their military careers second to principle.

Looking beyond my own base, I ask where will we be in the future when it is time for others to deploy and more personnel take the same stand? Like me, they signed on the dotted line to give their lives for their country in battle, not for poorly thought out, badly implemented and totally unnecessary policy that puts their livelihood and perhaps life at risk. And if the sacrifice of my military career prevents even one more person from falling ill to the shot, it will have been worth the pain and suffering.

I feel as many do that leadership is in denial over the effects of this shot. People are suffering from real afflictions after receiving it. How many more people have to suffer before the leadership takes notice?

Instead of simply saying their symptoms are not related to the vaccine and would have arisen whether they took the shot or not, we need to apply scientific methods to determine the real cause and effect.

In conclusion, the Anthrax Vaccine Immunization Program has already resulted in the loss of more personnel than the very thing it was designed to protect them against. The program deserves your urgent attention and concern.

Thank you.

[The prepared statement of Mr. Marohn follows:]

Testimony of ***Captain Daniel Wayne Marohn***

To the Government Reform Committee
Hearing on Anthrax Vaccination Immunization Program:
What Have We Learned?
October 11, 2000 10 a.m.

This testimony is not just an account of what has happened to me, personally, but a reflection on what is occurring to thousands of military members in the United States. I come here today to speak for all of those who live day to day wondering if they have been made into proverbial "guinea pigs" by an institution that they trusted with, and would have given, their lives for. I come here today to speak for those that reluctantly submitted to a controversial vaccination because they felt they had no other option.

I am not here to slander or assassinate anyone's character. My testimony will neither embellish nor contain false information or half-truths. My intention is to convey to you the effects that the Anthrax Vaccination Immunization Program (AVIP) is having on our troops on a day to day basis.

I was an F-16 pilot at the 163 Fighter Squadron in Fort Wayne, Indiana. I had pursued a pilot slot at Fort Wayne for 5 years before being selected "off the street"--a civilian with no previous military flying experience. I was known as a hard worker, a good pilot, and a quality officer—which my performance reports and awards and decorations reflect. I was a 4-ship flight lead, qualified in all squadron missions, part of the initial cadre of Night Vision Goggle (NVG) pilots, and was selected to upgrade to instructor pilot (IP). I had also been in charge of the training shop as a full-time guard technician before I resigned to take employment at a major airline.

When I refused to submit to the AVIP, I was grounded, given the choice between a court-marshal or an Article 15, fined and threatened with 330 days in jail if I did not pay the fine. Many others, not only in our squadron, but in the Wing as well, did not submit to the order to take the vaccine. Most resigned. Some transferred to finish out to retirement. But a few of us were under commitments from training and had no option but to face punishment as directed by the Adjutant General of the State of Indiana.

The chronology of events that led to my testifying today is this:

In March of 1999, we were made aware that we would deploy as part of the Air Expeditionary Force (AEF) and would have to take the anthrax vaccine. Some of our pilots learned, through the grapevine, that several pilots in Connecticut had resigned over concerns about the vaccine. Closely eyeing the ensuing controversy, we felt compelled to seek out all information that we could find relating to the vaccine.

On 17 April 1999, over a drill weekend, Dr. Meryl Nass, an acknowledged civilian expert on anthrax, gave a presentation and explained her thoughts and concerns on the vaccine and the AVIP. It must be noted that she was not allowed on base and our flight surgeons were encouraged not to attend her briefing. No fewer than 50 people from the base attended—over half of those were enlisted personnel. After her briefing we felt compelled to step up our research on the vaccine and the implementation of the program.

Our squadron received the verbal order to comply with the AVIP on 05Dec99. The policy letter was too ambiguous concerning what action would be taken against those of us under a commitment that refused the shot. Three of us wrote a letter to our Ops Group commander (OG/CC) requesting clarification. The response letter, dated 20Dec99, still did not make clear if we would face punishment or not.

In the first or second week in January 2000, I received a call from my OG/CC telling me that he need to know if I was planning on taking the shot. I told him that I would probably not take it, but I would give him my final decision by 13Feb00, the deadline to decide. About that time, I received the written order to comply, which was dated 08Jan00. The order, once again, said that violating the order "may" result in punishment.

On or about 09Jan00, anyone that had not give a response leaning toward the affirmative was grounded. I was told that this action was taken to "save our resources for the guys that are going to take the shot and deploy." This occurred about a month prior to the deadline.

13Feb00--I did not submit to taking the shot.

Later that month, in a conversation with the OG/CC, I was asked to reconsider my decision. He also told that whatever happened to us would be decided by State not Fort Wayne—The Adjutant General's (TAG) decision. I told him that in light of the current state of the program and the controversy surrounding it, it was too much of a risk to my health. As a commercial pilot, my livelihood depended on my medical certificate. If anything should medically disqualify me, that would be the end of a very good career not to mention that it would be devastating to my family.

On 07Jun00, I received a letter from the Assistant Adjutant General for Air (AG/Air) ordering me to appear in his office on 24Jun00. No specific reason was given, but I gathered it was in regard to my refusal to take the shot. The other pilot with a commitment that refused the shot called to tell me he had received the same letter later that day.

The two of us reported as ordered on 24Jun00. As we were waiting, our appointed legal counsel showed up and introduced himself. In talking with him we found out that he did not know for sure what the meeting was about, but had been called to be present. He briefly met with the JAG and came in to tell us that we were going to be charged with failure to obey the order of a superior officer and would be offered the choice of a court-marshal or an Article 15. Having only limited knowledge of either one we asked if he could explain the meaning and ramifications of each. He asked the JAG and AG/Air if he could have some time with us before we reported. They agreed. After a lengthy conversation I reported, was read the charges against me, and asked to decide. Still not having a clear picture of how accepting one over the other would affect me, I asked for, and was given, more time with counsel. After more discussion, I felt I had no choice but to accept the Article 15. I left HQ with an Article 15, a fine of 2/3 one month's base pay (suspended for 30 days) and the feeling that I had, somehow, I had just been railroaded into something I shouldn't have been. The other pilot opted for the same punishment for the same reasons.

20Jul00—One of the girls in Operations, whose specialty is airfield management, receives an e-mail from an airfield management information distribution contact, containing the memo calling for the slow down of the AVIP due to shortages. Because

she is under no obligation to disseminate the memo, she sends it only to a few people whom she thinks might be interested. Nothing else involving the slowdown is ever mentioned on base other than what people heard in news publications. Within days of this "temporary slowdown", 2 pilots "rehabilitate" and agree to take the shot and return to flight status. Because of the current policy they are not required to take the shot, but are asked to volunteer to take the shot so our squadron can attempt to get a waiver. Both decline—stating current policy guidelines—and continue to fly.

On 08Sep00 I received a letter from State HQ stating that I was in violation of the suspension of the fine for not taking the shot before 24Jul00 (8 days after the program slowdown memo was dated). Therefore, I was to make arrangements to deliver the fine to my commander or face incarceration in the county jail for one day for each dollar of the fine ($329.12).

On 10Sep00, I asked my SQ/CC and OG/CC if I could have some time, before I paid the fine, to discuss with legal counsel if my punishment would be affected by the policy change. The OG/CC agreed.

I finally was able to speak to my legal counsel on 26Sep00 about my situation. I explained that on 17Jul00 the program became such that unless I deployed to SWA for more than 30 days, I was not eligible to receive the shot and 2 pilots were now flying without having taken it. Since I had until 24Jul00, would this affect my punishment. He said it was an interesting case, but he didn't know. He suggested that I write my commanders asking for a total review of the punishment and asking for them to rescind the Article 15 and the fine. To date, I am still waiting to hear a response.

The AVIP has had a negative effect on our base as a whole. Moral is low and will be slow to rebuild. It left a huge vacuum of experience with the mass exodus of pilots that put their military career second to principle. But looking beyond our unit, where will we be in the future when it's time for others to deploy and more personnel make the same stand? People may question my patriotism and my fitness as an officer for refusing to obey the order to take this vaccine, but I signed on the dotted line to give my life for my country in battle, not for a poorly thought out, badly implemented, and totally unnecessary policy. I am, however, more than willing to fall on my sword and sacrifice my military career, even for those that criticize me, if it prevents one more person from falling ill to this shot.

Many in our military are living in fear. Here are some quotes that most of our ranking officials will not hear: "They are fearful of being forced to put something in their bodies that may cause a chronic medical condition that our government will probably refuse to accept responsibility for." "What can I do? If I say no I'll be forced out and have to start all over again in an entry-level position. With fifteen years in I can't afford it so I'm stuck." "Yeah, I really trust our government on this one. I get the same warm fuzzy when I think about their radiation and LSD experiments. I bet their statistics were right on track with those guys, too." "This whole thing is so stupid. I'm not even going to (SWA) and I have to take the shot. Like someone's really going to anthrax Ft. Wayne, Indiana. What a waste."

Many feel they have no choice but to shut up and take the shot, because none of their commanders will listen anyway. Troops with a leader willing to take a stand against this program will be short one good commander. Careerism over good leadership and

integrity is eroding our military. Everyday more and more troops lose trust in our institution.

Our leadership has been living in denial over the effects of this shot. People are suffering from real afflictions after having received it. We keep hearing how statistically they would have developed these symptoms regardless of having taken the shot. How many more have to suffer before the numbers finally add up? People are being told these afflictions are not related to the vaccine and they have been reading too much about it on the Internet. I, along with all of those that have been told this, would like to see the scientific methods used to determine such unequivocal diagnosis.

In conclusion, the Anthrax Vaccination Immunization has already resulted in the loss of more personnel than the very thing it was designed to protect them against.

Mr. BURTON. Thank you, Captain. We have been joined by Congressman Shimkus, and he has an introduction to make.

Mr. SHIMKUS. Thank you, Mr. Chairman. I appreciate the opportunity to introduce the next witness. As a veteran and a West Point grad, this issue is very important to me. But the next witness is a 1981 graduate of the United States Air Force Academy, originally assigned at an A–10 squadron at Myrtle Beach, and then as an instructor pilot, then flew F–15's in Okinawa, then a tour as an instructor pilot, a tour in the Pentagon, left the active Air Force and commanded the A–10 Squadron, National Guard, Battle Creek, MI, and flew in Kosovo.

But, more importantly, he is the husband of my sister, my brother-in-law, someone I have great respect for. With that, I would like to welcome Pat here to testify to this committee. I left my committee to come listen to the testimony. Mr. Chairman, I appreciate the courtesy you have extended me.

Mr. BURTON. Thank you, Congressman. Does it create any problems in the family that you went to West Point and he went to the Air Force Academy?

Mr. SHIMKUS. Well, we know that the Army Air Corps was first, so it is not really a big problem for us.

Mr. BURTON. Is it Captain Ross?

Mr. ROSS. It is Lt. Colonel Ross.

Mr. BURTON. You are recognized.

Mr. ROSS. The Army-Air Force game has not been played yet this year.

Good morning, Mr. Chairman, and members of the committee. I am here at the request of the committee to highlight the loss of combat mission ready pilots and aircrew caused by the Department of Defense Anthrax Vaccine Immunization Program. I believe I am qualified to address this subject based on my graduation from the Air Force Academy, my 16 years as a fighter pilot in the active duty Air Force, and my 3 years in the Air National Guard.

Most recently, I was the Squadron Commander of the 172nd Fighter Squadron, Battle Creek, MI, flying the A–10 Thunderbolt II. During my tenure as squadron commander, I was honored to respond, with my squadron, to a Presidential selective Reserve call-up in support of Operation Allied Force over Kosovo. For our efforts, the 172nd Fighter Squadron was recently honored as the outstanding Air National Guard Fighter Squadron of 1999 by both the National Guard Association of the United States and the Air Force association.

However, less than a few months after earning these awards, I was directly involved in the process that played out over a 6 to 8-month period resulting in the loss of almost 50 percent of the combat pilots in my unit. I will not only address these losses, but the ongoing punishment and coercion of the members of the Air National Guard who have refused to voluntarily submit to the anthrax vaccination, particularly at Battle Creek, MI.

In the interest of saving time, I will not list here the chronology of events and policy changes that my unit went through from September 1999 until today. Rather, I refer you to my written testimony and the previous testimony to this committee by Major Russell Dingell and Major Thomas Rempfer in March and October

1999, concerning the loss of 25 percent of the combat pilots in the Connecticut Air National Guard. With an almost uncanny accuracy, that same chronology, coercion, threats of punishment and lack of integrity witnessed by the Connecticut officers occurred at Battle Creek exactly 1 year later.

The bottom line for my squadron, as directed by the 110th Fighter Wing commander, was you either volunteer to take the anthrax vaccine or you must leave the unit. The 110th Fighter Wing staff judge advocate stated that any member who refused to take the shot would be administratively discharged with a less than honorable discharge.

To this day, not one pilot at Battle Creek has ever been ordered to take the anthrax vaccine. While the threatened deadline changed several times from January to March 2000, pilots began resigning, transferring or stating their intent to retire as early as November 1999. When the final retirement is effective at the end of the year, 15 pilots will have been coerced to leave the unit in order not to disobey an order that was never given.

Add to those losses two current members of the 172nd Fighter Squadron who are grounded and are being threatened with punitive action, the same as Captain Marohn has testified, simply for not volunteering to take anthrax vaccinations that are now no longer required by DOD policy. That brings the total number of pilots that the American taxpayer spent millions of dollars to train and whose Operations Desert Storm and Allied Force combat experience cannot be replaced, to 17 pilots at Battle Creek.

The effects of the anthrax vaccine program on my unit are, unfortunately, not unique. As I stated earlier, the Connecticut Air National Guard lost eight pilots. Other losses in the Air National Guard include 21 pilots of the Indiana Air National Guard that Colonel Heemstra talked about, 7 pilots of the Wisconsin Air National Guard, 22 pilots from the Tennessee Air National Guard, and 19 pilots from the Oklahoma Air National Guard. Losses in the Air Force Reserve include 58 pilots from Travis Air Force Base, CA, 60 pilots at Dover Air Force Base, DE, 30 pilots at McChord Air Force Base, WA, and 20 pilots at McGuire Air Force Base, NJ.

These losses, totaling over 260 pilots, at over $1 billion in training costs alone, are from just 12 percent of the units in the Air National Guard and the Air Force Reserve. That is an almost tenfold negative return on the total cost of the AVIP program to date. None of these losses have been reported to the Congress, as was directed to Major General Weaver by Representative Shays during testimony to his subcommittee in September 1999. In addition, Assistant Secretary of Defense Cragin also testified that no one would be punished if they chose to leave the Guard or Reserve. Not only are two members of the Michigan Air National Guard being punished, but, as you have heard, also two members from the Indiana Air National Guard who were threatened with jail time.

While I have focused on pilots of the Air National Guard and Air Force Reserve today, I would be extremely and deeply remiss if I did not mention the men and women noncommissioned officers who are being punished as well. As the backbone of our Armed Forces, these men and women are the true strength of the U.S. military.

In many cases, they are bearing the brunt of the illnesses, administrative punishments, fines and less than honorable discharges.

Why have all these individuals left the Air National Guard and Air Force Reserve rather than take the anthrax vaccine? I believe it simply boils down to one word, trust. They feel they can no longer trust the leadership when they say the vaccine is safe and effective. They feel they can no longer trust the leadership if they should become ill due to the vaccine that they will be taken care of by the country they are prepared to give their life for. They feel they can no longer trust the leadership when they are told to get educated, research the issues and then make their own personal decision, with no retribution. The actions of the leadership are in direct conflict with their statements to the troops, and to Congress.

Morale has always been crucial to providing the overwhelming margin of victory for our Armed Forces during the conflicts that we have fought and won throughout our history. The Anthrax Vaccine Immunization Program is having an extremely adverse effect on morale and retention, and for the good of the U.S. Armed Forces, the program should be halted until the concerns of the Congress are satisfactorily addressed and a safe and effective source of vaccine can be assured.

On behalf of the men and women who keep this great country of ours free, I thank you again, Mr. Chairman and members of the committee, for your concern.

[The prepared statement of Mr. Ross follows:]

PAT ROSS
TESTIMONY BEFORE
GOVERNMENT REFORM COMMITTEE
OCTOBER 11, 2000
10:00 A.M., 2157 RAYBURN

Good morning Mr. Chairman and members of the committee. I am here at the request of the committee to highlight the loss of combat mission ready pilots and aircrew caused by the Department of Defense Anthrax Vaccine Immunization Program. I believe I am qualified to address this subject based on my graduation from the United States Air Force Academy, my 16 years as a fighter pilot in the active duty Air Force, and my 3 years in the Air National Guard. Most recently, I was the Squadron Commander of the 172nd Fighter Squadron, Battle Creek, Michigan, flying the A-10 Thunderbolt II. During my tenure as Squadron Commander, I was honored to respond, with my squadron, to a Presidential Selective Reserve Call-up in support of Operation Allied Force over Kosovo. For our efforts, the 172nd Fighter Squadron was recently honored as the Outstanding Air National Guard Fighter Squadron of 1999 by both the National Guard Association of the United States and the Air Force Association. However, less than a few months after earning these awards, I was directly involved in the process that played out over a six to eight month period resulting in the loss of almost 50% of the combat pilots in my unit. I will not only address these losses, but the on-going punishment and coercion of members of the Air National Guard who have refused to voluntarily submit to receiving the anthrax vaccination, particularly at Battle Creek, Michigan.

In the interest of saving time, I will not list here the chronology of events and policy changes that my unit went through from September of 1999 until today. Rather, I refer you to my written testimony and the previous testimony to this committee by Major Russell Dingle and Major Thomas Rempfer in March and October 1999, concerning the loss of 25% of the combat pilots in the Connecticut Air National Guard. With an almost uncanny accuracy, that same chronology, coercion, threats of punishment and lack of integrity witnessed by the Connecticut officers, occurred at Battle Creek, exactly one year later. The bottom line for my squadron, as directed by the 110th Fighter Wing Commander, was you either volunteer to take the anthrax vaccination or you must leave the unit. The 110th Fighter Wing Staff Judge Advocate stated that any member, who refused to take the shot, would be administratively discharged with a Less than Honorable discharge. To this day, not one pilot at Battle Creek was ever ordered to take the anthrax vaccine. While the threatened deadline changed several times from January to March 2000, pilots began resigning, transferring or stating their intent to retire, as early as November of 1999. When the final retirement is effective at the end of this year, 15 pilots will have been coerced to leave the unit in order not to disobey an order that was never given. Add to those losses two current members of the 172nd Fighter Squadron who are grounded, and are being threatened with punitive action, simply for not volunteering to take the anthrax vaccinations that are no longer required by DOD policy. That brings the total number of pilots, that the American taxpayers spent millions of dollars to train, and whose Operations Desert Storm and Allied Force combat experience cannot be replaced, to 17 pilots at Battle Creek.

The effects of the anthrax vaccine immunization program on my unit are, unfortunately, not unique. As I stated earlier, the Connecticut ANG lost 8 pilots. Other losses around the Air National Guard include 21 pilots of the Indiana Air National Guard, 7 pilots of the Wisconsin Air National Guard, 22 pilots from the Tennessee Air National Guard and 19 pilots from the Oklahoma Air National Guard. Losses in the Air Force Reserve include 58 pilots from Travis AFB, California, 60 pilots at Dover Air Force Base, Delaware, 30 pilots at McChord AFB, Washington and 20 pilots at McGuire AFB, New Jersey.

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While I have focused on the pilots of the Air National Guard and Air Force Reserve today, I would be deeply remiss if I did not mention the men and women Non-Commissioned Officers that have also been coerced into leaving or are being punished as well. As the backbone of our Armed Forces, these men and women are the true strength of the United States military. In many cases, they are bearing the brunt of the illnesses, administrative punishments, fines and less than honorable discharges.

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Morale has always been crucial to providing the overwhelming margin of victory for our Armed Forces during the conflicts we have fought and won throughout our history. The anthrax vaccine immunization program is having an extremely adverse effect on morale and retention, and for the good of the United States Armed Forces, the program should be halted until the concerns of the Congress are satisfactorily addressed, and a safe and effective source of vaccine can be assured.

On behalf of the men and women who keep this great country of ours free, I thank you again, Mr. Chairman, and members of the committee, for your concern.

September 1998: 12 members of the 110th Fighter Wing (FW) receive the first anthrax vaccinations at the base to deploy voluntarily to Qatar.

November 1998: 110th FW personnel deploy to Qatar.

January 1999: 8 combat pilots from the Connecticut Air National Guard (ANG) resign rather than take the anthrax vaccine.

March 1999: 9 of the 12 110th FW members report being ill following their 4th anthrax vaccination in the six shot series. Information concerning the existence of their illness is kept quiet from the remainder of the 110th Fighter Wing. Discussions begin concerning the future participation of the 172nd Fighter Squadron (FS) in the upcoming Aerospace Expeditionary Force (AEF) 7 deployment in the summer of 2000.

May 1999: 15 pilots and over 150 other personnel from the 110th FW respond to a Presidential Selective Reserve Call-up (PSRC) and deploy to Trapani AB, Italy in support of Operation Allied Force/Noble Anvil. Members from the Massachusetts and Idaho ANG combine with the Michigan ANG to form the 131st Expeditionary Fighter Squadron, the only ANG fighter unit called up to perform combat operations over Kosovo.

July 1999: Personnel and aircraft redeploy from Operation Allied Force having flown more than 800 hours of combat operations around the clock in Kosovo.

August 1999: Chief of Staff of the Air Force, General Ryan, states the Air Force needs time to reconstitute forces following Operation Allied Force. Questions arise as to the timing of the start of the AEF cycle and 172nd FS participation following the deployment to Kosovo. Information suggests the deployment cycle may slip up to six months.

September 1999: Air Force announces the start of the AEF cycle will begin as scheduled on 1 Oct 1999. ANG Wing Commanders meet in Omaha, NE to discuss participation of all units in the AEF cycle. Massachusetts, Idaho and Michigan commanders try to remove their units from deploying in the summer of 2000 due to the operations tempo from Operation Allied Force and the anticipated effects on retention of beginning the anthrax vaccinations in their units. Wing commanders from Maryland, Connecticut and Pennsylvania do not want their units to be substituted since they had just returned from duty in Operation Southern Watch (SWA) from February-April 1999. MI ANG and VA ANG F -16 units not assigned to specific AEFs volunteer to augment MI, ID and MA ANG A-10 units in AEF 7 to reduce the number of pilots required from the A-10 units.

September UTA, 1999: All 172nd FS pilots are informed of the upcoming AEF 7 deployment and the requirement for the anthrax vaccinations in order to participate. Participation in the deployment will be voluntary since there will not be a PSRC as with Operation Allied Force, as directed by MGen Weaver. Required number of pilots and specific dates of deployment are not known, but it is anticipated each pilot will spend two weeks in theater. Augmentation by the F-16 units is announced and a volunteer sign-up sheet is posted.

October 1999: Representatives of the VA ANG F-16 unit visit the deployment location in SWA and determine the mission is "beneath them". They complain to ANG HQ and are moved from AEF 7 to AEF 8, with deployment now to Operation Northern Watch (ONW), no longer requiring their unit to receive the anthrax shots. MI ANG F-16 unit follows suit. Meetings begin to formulate the schedule to accomplish all training requirements for the deployment. Deployment date for the 110th FW is determined to be August 2000. The Operations Group and Logistic Group Commanders formulate dates for the beginning of the anthrax vaccinations. January 2000 Unit Training Assembly (UTA) is targeted to coincide with the beginning of Department of Defense (DOD) Phase II implementation of the Anthrax Vaccine Immunization Program (AVIP).

October UTA, 1999: 172nd FS pilots are informed that the unit must now provide the entire requirement for pilots and aircraft for AEF 7. This will require all of the 36 pilots at Battle Creek to volunteer for the deployment and be required to take the anthrax vaccinations. Morale plummets on the news. Sign-up sheet contains no volunteers.

November 1999: Operations Group commander sends every pilot a letter informing them of the requirement for all pilots to begin anthrax shots in January 2000. Questions arise concerning the ability of pilots to resign rather than disobey an order to take the shots. All full-time pilots are told they are expected to participate or leave the unit. Pilots are told those without commitments have until January UTA to decide before being ordered. Those pilots with commitments will have no choice but to take the shot or disobey an order to do so. Those who disobey the order will be reprimanded and discharged administratively with a Less than Honorable discharge. Pilots requested information to explain the program and rumors of potential illnesses to unit members caused by the shots. They are told no information concerning any potentially sick individuals at Battle Creek, MI can be provided due to privacy concerns. Mistrust of the leadership begins to take root. The first 172nd FS pilot resigns. Two DOD speakers are scheduled to speak at the December UTA. Volunteer sign-up sheet is taken down with three names on it.

December UTA 1999: The Operations Group commander informs all pilots that in order to have the correct amount of vaccine on hand for the January UTA, they must formally make their decision to take the shot by the end of the weekend. Chaos erupts because of the gravity of the decision required in such a short time frame. 172nd FS Commander intervenes to the 110th FW commander to delay the mandatory order to allow time for the pilots and spouses to digest the briefings of the weekend. Wing Commander is informed of the possibility of up to 50 % of the pilots leaving. Wing Commander contradicts the Operations and Logistics Group commanders and delays the requirement for mandatory

shots until after all education briefings are completed, March 2000 UTA. All pilots and their spouses attend briefings by Dr. Rhys-Jones and USAF doctor from Wright-Patterson AFB, OH. 110th FW Vice Commander and 110th Staff Judge Advocate give a briefing concerning the responsibility of the military to provide for the member and families in the unlikely event that a member should develop an illness after taking the anthrax vaccine. He stated the military would accept responsibility for care after a line-of-duty (LOD) determination confirmed the vaccine in fact caused the symptoms. After questions from many spouses, he admitted that none of the members of the unit currently claiming illness from the vaccine were given LOD status. He refused to answer further questions concerning the sick members again citing privacy concerns. Many pilots made their decisions to leave following this briefing. Two more pilots immediately request transfers to the Air Force Reserve. Further education briefings are scheduled for the February 2000 UTA.

January UTA 2000: Failure of the Bioport plant renovations to win FDA approval causes the DOD to delay implementation of Phase II of the AVIP. 10 pilots voluntarily begin the anthrax vaccine shot series. Wing Commander directs all requests for transfer, resignations or retirements can only be approved by him and no longer by the unit commanders. Resignations will not be approved for any one, only transfers to the Individual Ready Reserve or to other non-flying Reserve jobs. Retirement requests will not relieve the requirement to begin the shot series unless the retirement will be effective before August 2000, the deployment date. All Squadron commanders are informed they will be required to take the shots in order to remain in their command positions. Operations Group Commander reminds pilots that in order to have the proper number of vaccine doses available for the now mandatory date of March 2000, as directed by the Wing Commander, decisions must be in writing by the end of the February UTA. 172nd FS Commander has personnel technicians determine exactly who has commitments to the ANG and discovers only 5 out of 36 pilots have any commitments. Those pilots are told they have no choice but to take the shot at the March UTA or be grounded, reprimanded and administrative discharge proceedings begun for a Less than Honorable discharge for refusing an order to take the shot. Two more pilots request a transfer to the Reserves.

January 10, 2000: 172 FS Commander informs the Operations Group Commander of his resignation. Discussions occur concerning the announcement timing and the effect on the remainder of the pilots who still have not made their decision. The decision to delay announcement until after the education briefings during the February UTA is reached to lessen the chances of pilots leaving due to the Squadron Commander's decision. Announcement for a replacement will be made then.

January 2000: News of the Squadron Commander's resignation spreads throughout the unit. Pilots invite Dr. Meryl Nass to speak in order to get a non-DOD point of view on the issues. All pilots who had not started the anthrax shot series attend the briefing along with the unit Flight Surgeon and Public Affairs officer, who were sent by the base leadership.

February UTA 2000: DOD briefings occur for the entire 110th Fighter Wing. Unit Flight Surgeon speaks and answers questions concerning the Dr. Nass briefing. Wing Commander speaks to pilots concerning the retirement and transfer policy. He states that if a pilot is not going to volunteer for the unit deployment, and take the anthrax shots, then he must leave the unit. He backs down on requiring retirements to be effective prior to the deployment date of August 2000, but states requests to retire must be received prior to March UTA. 172nd FS Commander speaks to pilots and announces his resignation officially. Five pilots request transfer to the Reserves bringing the total to 11. Four pilots eventually file for retirement by the end of CY2000. The Operations Group Commander is fired with no explanation.

March UTA 2000: 9 of the remaining 11 pilots begin the anthrax vaccination shot series. NO PILOT IN THE 110TH FIGHTER WING WAS EVER ORDERED TO TAKE THE SHOTS. A new 172nd FS Commander is appointed. Harassment begins for the two pilots who do not voluntarily begin the shot series. They are told they will not be allowed to go on the winter deployment to Tucson, AZ. Their request to participate in an exercise in Thailand was initially denied because it was determined to be "too good a deal", but they were later allowed to attend after protesting their punishment to the new Operations Group commander.

April 2000: GAO arrives to interview unit concerning anthrax program and effect on morale. Only the former Squadron Commander is available from the 11 pilots who left the unit. The four pilots requesting retirement are interviewed.

July 2000: Both pilots who did not volunteer to begin the anthrax shot series were grounded by the new 172nd FS Commander for "not volunteering for a voluntary deployment." They were told they would be assigned to the Intelligence section in a non-flying capacity, required to return all of the flying uniforms and would be given administrative General discharges. The SJA subsequently tells them they cannot be given General discharges, "because they have done nothing wrong." DOD announces a change in AVIP policy due to shortage of FDA approved and tested vaccine. Individuals deploying to "high threat areas" for less than 30 consecutive days no longer require the anthrax vaccination.

August 2000: The 172nd Fighter Squadron deploys in support of AEF 7. Due to the losses because of the AVIP, pilots from other ANG units, the Reserves and active duty Air Force, augment them. One of the active duty pilots arrives in theater without having taken any anthrax vaccinations. Both grounded 172nd FS pilots officially volunteer with the Wing Commander for the second rotation of the deployment. Their request is denied. They file an IG complaint with the ANG IG for being punished for no reason other than they "did not comply with the squadron commander's wishes and volunteer for a voluntary deployment."

September 2000: Aircraft and personnel return from AEF 7 deployment. 172nd FS receives awards from the Air Force Association and the National Guard Association of the United States as the Outstanding Air National Guard unit of 1999 for their combat

operations in Kosovo in support of Operation Allied Force. 172nd FS pilots that received the anthrax shots feel betrayed, now that the DOD policy has changed. Many of the pilots that left the unit, rather than disobey an order that was never given, feel they were coerced into ending their careers for no reason.

Mr. BURTON. We have been joined by Mr. Cummings and Ms. Norton of D.C. Do either of you have any comments to make at the outset?

No questions right now. We will proceed with Dr. Porter.

Dr. PORTER.

Dr. PORTER. Thank you, Mr. Chairman, distinguished members. May I have slide 1. I have several graphics, and I have also entered the testimony of an extensive proposal in addition to the prepared text.

VDDI focuses on pharmaceutical product opportunities where general proof of principle has already been established in pre-clinical or early human testing, and where the products will have novel or significant potential advantages over currently available products on the market. VDDI pursues early stage products qualifying for fast track approval, primarily in cancer, cardiovascular disease and infectious disease.

Mr. BURTON. Dr. Porter, it is going to be hard for us to follow you, so if you could pull the microphone a little closer and take your time reading that so we can follow you.

Dr. PORTER. VDDI pursues early stage products qualifying for fast-track approval, primarily in cancer, cardiovascular disease and infectious disease. As the name suggests, VDDI utilizes a virtual business model.

Graphic 2, please. Virtual drug development entails a small core group of employees responsible for strategic management, regulatory strategy and financial control; outsourcing of all noncore business functions, including manufacturing, preclinical and clinical development.

Slide No. 3, please. Global strategic resources and Internet-based enabling technology, and the use of electronic data capture and data submission to regulatory authorities. By adopting this model, VDDI believes it can reduce total drug development and program costs by at least 25 percent and development times by 50 percent.

Slide 4, please. As the graphics demonstrates, we have a core team of employees and individuals that work on an outsourcing of noncore business functions through manufacturing and preclinical and clinical development.

Graphic 6, please. In principle, a vaccine for anthrax is a good and necessary part of a complete protection package against anthrax, but the present vaccine program has suffered from a number of problems including, in military parlance, collateral damage or friendly fire casualties. Providing effective interdiction for persons threatened with exposure to anthrax endospores must remain a national priority. Despite numerous animal studies, the efficacy in humans of the AVA vaccine in the face of inhalational anthrax remains in serious doubt.

Practical issues surrounding providing the vaccine to those in need of it also constitutes a real problem. The rapid progress and fatal nature of this disease, the vague early symptoms and the distinct possibility of human-engineered multiple antibiotic resistance suggests traditional antibiotic intervention may be of limited utility. More importantly, recent knowledge of the cloning of additional virulence factors, for example, toxins from other bacteria, into the B. anthracis raises the possibility that the nature and pathogenesis

of the disease can be manipulated to the point of rendering our current interdiction strategies impotent. Clearly, new ways to block the disease state at its earliest stages, before dissemination and production of its lethal toxin, represent an exploitable and potentially valuable addition to our abilities to combat this disease.

I pose several questions. Would the utility of a novel prophylactic antibiotic regimen that provides active protection against all forms of anthrax, natural and engineered, be a useful addition to our treatment armamentarium against this bioweapon? Vaccines function by initiating the development of host antibodies that will quickly recognize B. anthracis or a component of its protein toxin. Unfortunately, it may be relatively easy for the enemy to genetically alter the surface of proteins. This also occurs naturally, without intervention by man, that these antibiotics recognize, thereby making vaccine treatment ineffective; or to use molecular biological techniques to insert the virulence genes into a different bacterium. More importantly, recent knowledge of the cloning of additional virulence factors—parenthetically, toxins from bacteria, cereolysin AB, into the B. anthracis host—raises the possibility that the nature and pathogenesis of the disease can be manipulated to the point of rendering our current interdiction strategies impotent.

In addition, wouldn't the ability to use a technology that would allow for the near immediate deployment of our troops and personnel be of strategic and practical advantage over an immunization schedule that requires months to be deemed as possibly effective?

Wouldn't the ability to deploy and store a small molecule treatment regimen that is stable in field conditions offer advantages over a regimen that requires refrigeration?

Wouldn't the ability to offer a rapid scale-up and production of an alternative prophylactic and/or treatment confer significant advantages over an immunization program?

Next graphic. Thank you.

The University of Alabama and VDDI created an NAD synthetase technology that is mature and ready for optimization. The key to the success of this program will be a discovery program that can create a pharmaceutical product that has appropriate stability, absorption, metabolism and safety profiles that allows its use in animal experimentation and then human experimentation. The NAD synthetase enzyme is an essential enzyme for gram-positive bacteria, including methicillin-resistant staph aureus, vancomycin-resistant Enterococcus faecium, and coagulation aureus staphylococcus. This NAD synthetase is a ubiquitous enzyme that is found in both eukaryotes and prokaryotes cell lines, and we have distinct differences between the human and the bacteria forms of this enzyme.

Next slide. Through a structure based directed Small Molecule Development Program and a platform technology, DARPA has funded $6 million of this development program and as a result, we have shown some excellent in vitro activity to date.

Next. This is a structure of NAD synthetase enzyme with one of the congeners interdicted into that enzyme showing how and where it interferes with the activity of the enzyme.

Next. This is a life cycle of the B. anthracis endospore going from the bottom left to the top. The spore outgrows, it requires NAD

synthetase as a critical enzyme for further growth to the form the vegetative stage form, and at that stage, the exotoxins are released, and that is where most of the human damage occurs. The NAD synthetase molecule is putatively stated to inhibit both the early stage and the later stage of outgrowth of the B. anthracis organism.

Next slide. These micrographs show the inhibition of the B. subtilis as a surrogate to B. anthracis using one of the analogs in a concentration-dependent manner, destroying both the vegetative and the spore forms of the organism.

Next. Work done by USAMRIID showing several analogs against virulent and nonvirulent strains of the anthracis shows a concentration of MIC 100 micromoles per ML, showing significant activity against the Ames strains.

Next. Following the completion of this early work, a formal preclinical development program will optimize the doses, institute allometric scaling, and characterize the safety in at least two animal models and complete the anthrax efficacy, dose response and pharmacokinetic profiling in animals. A formal Investigational New Drug application will be submitted to the FDA and it is proposed that two volunteer studies will be conducted: a single-dose, dose escalating safety, a tolerance study, a pharmacokinetic phase I clinical trial, to be followed by a multi-dose safety tolerance and PK phase I clinical trial. These studies will be correlated with information gained from preclinical animal safety data and correlated with efficacy of the human trial experience. Since it is unethical to conduct anthrax interdiction trials in humans, surrogates of plasma and tissue concentrations obtained from animal interdiction studies will be used as correlates and inferences for the human experience.

The Food and Drug Administration has recently proposed regulations for the development of new drugs to be used against lethal or permanently disabling toxic substances, including agents that may be used in biological warfare. This is published in the Federal Register, Volume 64, No. 192, October 1999, entitled "Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot Be Conducted." The recent approval of Ciprofloxacin for B. anthracis treatment partially validates this approach.

In collaboration with PPD Discovery, and the University of Alabama, VDDI will develop a preclinical and clinical strategy in accordance with these new regulations and will discuss the strategy with the FDA at a pre-IND meeting to be scheduled.

In summary, the specific design of our lead compounds, in conjunction with our preliminary in vitro and in vivo data suggest that the lead compounds have minimum inhibitory concentrations against B. anthracis that are quite acceptable. The lead compounds have minimum inhibitory concentrations against MRSA, VREF, and vancomycin-resistant E. faecalis that is good or better than clinically proven antibiotics. Some of the lead compounds show specificity against gram-positive but not gram-negative strains, thus reducing some adverse effects of clinically approved antibiotics. Some of the lead compounds show excellent activity against virulent and attenuated strains of B. anthracis. The mechanism of

action of the compounds is specific to prokaryotic cells and thus leading to significant safety profile for clinical use.

The product development issues that remain to be resolved include development of parenteral agents, development of orally active agents, and development of a relatively long half-life product.

DARPA has supported the initial funding for this program at $6 million. USAMRIID has supported the early synthetic chemistry and in vitro studies with several strains of B. anthracis and has just agreed to refund $300,000 for this work to the University of Alabama. VDDI has received an NIH R43 SBIR phase I grant for $135,000. Additional support is requested from the Department of Defense and will be used to complete the synthetic chemistry and initiate the preclinical development program. Specifically, $2 million is needed immediately and will be spent as allocated by the time and resources as outlined in the extensive protocol and proposal that have been submitted with testimony. Additional funds necessary to complete this development program and their respective utilization are shown in table 1, which I do not have a graphic of, but is submitted in testimony. A greatly detailed time scale and deliverable assessment for this program is also included with the proposal.

In summary, I submit the enclosed program outline for the development and commercialization of a novel oral pharmaceutical as testimony before your committee. I removed proprietary and sensitive information from that formal proposal. I thank you, committee members and Mr. Chairman.

[The prepared statement of Dr. Porter follows:]



TESTIMONY OF
STEPHEN PORTER
TO THE GOVERNMENT REFORM COMMITTEE
ON OCTOBER 11, 2000
10:00 A.M., 2154 RAYBURN

VDDI was formed in order to capitalize on the opportunity to develop early stage pharmaceuticals. The Company licenses attractive product development opportunities from academic institutions, biotech firms and pharmaceutical companies. VDDI focuses on pharmaceutical product opportunities where general proof-of-principle has already been established in pre-clinical or early human testing, and where the products are novel and offer significant potential advantages over those currently in the market or in development. VDDI pursues early-stage products qualifying for fast track approval, primarily in cancer, cardiovascular disease and infectious disease. As its name suggests, VDDI utilizes a virtual business model. Virtual drug development entails: (i) a small core group of employees responsible for strategic management, regulatory strategy, and financial control, (ii) outsourcing all non-core business functions, including manufacturing preclinical and clinical drug development, (iii) global strategic resources and internet based enabling technology, and (iv) electronic data capture and data submission to regulatory authorities. By adopting this model, VDDI believes it can reduce total drug development program costs by at least 25% and development times by up to 50%.

In principal, a vaccine for anthrax is a good and necessary part of a complete protection "package" against anthrax, but the present vaccine program has suffered from a number of problems. Providing effective interdiction for persons threatened with exposed to anthrax endospores must remain a national priority. Despite numerous animal studies, the efficacy in humans of the AVA vaccine in the face of inhalational anthrax remains in serious doubt. Practical issues surrounding providing the vaccine to those in need of it also constitute real problems. The rapid progress and fatal nature of this disease, the vague early symptoms and the distinct possibility of human-engineered multiple antibiotic resistance suggests traditional antibiotic intervention may be of limited utility. More importantly, recent knowledge of the cloning of additional virulence factors (*e.g.*, toxins from other bacteria) into the *B. anthracis* host raises the possibility that the nature and pathogenesis of the disease can be manipulated to the point of rendering our current interdiction strategies impotent. Clearly, new ways to block the disease state, at its earliest stages --before dissemination and production of its lethal toxin-- represent an exploitable and potentially valuable addition to our abilities to combat this disease.

Questions:

Would the utility of a novel prophylactic antibiotic regimen that provides active protection against all forms of anthrax natural and engineered, be a useful addition to our treatment armamentarium against this bioweapon?

Vaccines function by initiating the development of host antibodies that will quickly recognize *B. anthracis* or a component of its protein toxin. Unfortunately, it may be relatively easy for the enemy to genetically alter the surface of proteins (this also occurs naturally, without intervention by man) that these antibodies recognize, thereby making vaccine treatment ineffective; or to use molecular biological techniques to insert the virulence genes into a different bacterium. More importantly, recent knowledge of the cloning of additional virulence factors (*e.g.*, toxins from other bacteria, cereolysin ab) into the *B. anthracis* host raises the possibility that the nature and pathogenesis of the disease can be manipulated to the point of rendering our current interdiction strategies impotent.

Wouldn't the ability to use a technology that would allow for the near immediate deployment of our troops and personnel be of strategic and practical advantage over an immunization schedule that requires months to be deemed as possibly effective?

Wouldn't the ability to deploy and store a treatment regimen that is stable in field conditions, offer advantages over a regimen that requires refrigeration.

Wouldn't the ability to offer very rapid scale up and production of an alternative prophylactic and/or treatment regime confer significant advantages over an immunization regimen?

The UAB NADs technology is mature and ready for optimization. The key to success will be a discovery program that creates a pharmaceutical product, which has appropriate stability, absorption, metabolism, and safety profiles to allow its use in animal experimentation. Following completion of this work, a formal preclinical development program will optimize the doses; institute allometric scaling; characterize the safety in at least two animal models; and complete the anthrax efficacy, dose response, and pharmacokinetic (PK) profile in animal. Then, a formal Investigational New Drug (IND) application will be submitted to the FDA, and two normal volunteer studies will be conducted: a single-dose, dose-escalating safety, tolerance, and PK Phase I clinical trial, to be followed by a multi-dose safety, tolerance, and PK Phase I clinical trial. These studies will be correlated with information from preclinical (animal) safety, PK and efficacy with the human trial experience. Since it is unethical to conduct anthrax interdiction trials in humans, surrogates of plasma and tissue concentrations obtained from animal interdiction studies will be used as correlates and inferences of the human experience.

The Food and Drug Administration has recently proposed regulations for the development of new drugs to be used against lethal or permanently disabling toxic

substances, including agents that may be used in biological warfare (published in the Federal Register Vol. 64, No.192, (Oct. 1999: "Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot Be Conducted). The recent approval of Ciprofloxacin for *B. Anthracis* treatment partially validates this approach.

In collaboration with PPD Discovery, and The University of Alabama, VDDI has developed a preclinical and clinical strategy in accordance with these new regulations, and will discuss this strategy with the FDA at a pre-IND meeting to be scheduled.

In summary, the specific design of our lead compounds, in conjunction with our preliminary in vitro and in vivo data suggest that:

- The lead compounds have minimum inhibitory concentrations (MIC) values against *B. Anthracis* that are quite acceptable.
- The lead compounds have minimum inhibitory concentrations (MIC) values against *MRSA* and vancomycin resistant *Enterococcus faecium* and *E. faecalis,* that is as good or better than clinically approved antibiotics
- Some of the lead compounds show specificity against gram positive, but not gram negative strains, thus reducing some adverse effects of clinically approved antibiotics
- Some of the lead compounds show excellent activity against virulent and attenuated strains of *B. anthracis.*
- The mechanism of action of the compounds is specific to prokaryotic cells, thus leading to a great safety profile for clinical use.

Product development issues that remain to be resolved include:

- Development of parenteral agents;
- Development of orally active agents; and
- Development of a relatively long half-life product.

DARPA has supported the initial funding for this program ($6 Million). USAMRIID supported the early synthetic chemistry and *in vitro* studies with several strains of *B. anthracis* and has just agreed to refund $300,000 for this work performed. VVDI has received an NIH R43 SBIR Phase I grant for $135,000. Additional support is requested from the Department of Defense and will be used to complete the synthetic chemistry and initiate the preclinical development program. Specifically $2 Million is needed immediately, and will be spent as allocated by the time and resources as outlined in the enclosed Proposal. Additional funds necessary to complete this development program and their respective utilization are shown in summary format in Table 1. A greatly detailed timescale and deliverable assessment for this program is also included in the proposal.

Table 1

Stage of Project	Estimated Duration	Estimated Cost
Synthetic Chemistry	12-24 wks	$860,000.00
Drug Lead Profiling	30 days	$300,000.00
Pre-IND Meetings (2)	90 days	$67,250.00
Preclinical Drug Development	16 months	$2,738,400.00
IND Filing	4 weeks	$150,000.00
Clinical Drug Development	20 months	$2,475,000.00
Nonclinical Drug Development	2.5 yrs	$2,700,000.00
NDA Filing	6 weeks	$650,000.00
Manufacturing	4 yrs	$5,000,000.00
Administrative and Project Management	4yrs	$2,250,000
Total		**$16,990,341.00**

I submit the enclosed program outline for the development and commercialization of a novel oral pharmaceutical as testimony before your committee "The Anthrax Vaccine Immunization Program: What Have we Learned?" Oct 11th. I have removed proprietary and sensitive information, however, the essential elements of this proposal remain for consideration and review by this committee.



Proposal for the Development of A Novel Pharmaceutical for Anthrax

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VDDI

I. EXECUTIVE SUMMARY

Anthrax represents the single greatest biological warfare threat, according to many military and counterterrorism planners. Anthrax has been regarded as a possible agent of biowarfare or bioterrorism for almost a century. The inhalational form of the disease is considered the most likely clinical entity resulting from the intentional use of an aerosolized preparation of the spores of *Bacillus anthracis*. Historically, penicillin has been the drug of choice to treat inhalational anthrax, but survival is poor once clinical signs and symptoms are present. Mortality in inhalational anthrax is 80-100% in patients infected with penicillin-susceptible *B. anthracis* who receive appropriate treatment. The possibility of the use of a penicillin-resistant strain in an intentional attack has been raised. *For a discussion of epidemiology, microbiology, pathogenesis, clinical manifestations, prevention, and treatment of this infection, the reader is referred to reviews by Pile et al. [1], Dixon et al. [2] and Inglesby [3].*

Among the Category A biological agents, inhalational anthrax is somewhat unique in that there was an outbreak of this infection in 1979 among the human population of Sverdlovsk, former USSR. This outbreak, considered the result of an accident at a military microbiology facility, is one of the few opportunities for systematic study of human disease resulting from any category A agent [4,5].

The goal of this research effort is to develop drugs that can treat or prevent infection from *B. anthracis*. The Center for Biophysical Sciences and Engineering at The University of Alabama at Birmingham (UAB-CBSE) has identified a novel enzyme target, NAD synthetase (NADs), which is critical for the outgrowth of germinating spores and vegetative life cycle of *B. anthracis [6]*. The CBSE has determined the structure of this enzyme and used structure-based drug design and structure-directed combinatorial synthesis to develop new generation antibiotics that will specifically prevent anthrax spore outgrowth and also inhibit the vegetative growth of anthrax, if infection has already occurred.

Ideally, troops would take a tablet each morning, thereby protecting them from anthrax spores developing into the vegetative form, resulting in release of exotoxins and other sequalae of the infection. However, even if already infected the product would inhibit the infectious agent, the vegetative growth of *B. anthracis*. In addition, it should be noted that NADs is an essential enzyme for all bacteria. Thus, the developments of compounds that inhibit this enzyme have the capability of providing protection against a broad spectrum of spore forming and gram-positive bacteria. In fact, we have already demonstrated that our initial lead compounds are effective against other gram-positive bacteria including, including antibiotic resistant strains such as methicillin resistant *Staphylococcus aureus (MRSA)* and vancomycin resistant *Enterococcus faecium* and *E. faecalis*

The development program for a NADs inhibitor was previously funded by DARPA for a period of three years. During that time UAB-CBSE isolated and purified *Bacillus subtilis* and *E. coli* NADs, crystallized the enzymes and determined their three-dimensional

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structures (very similar for both bacterial species) using x-ray crystallography. The structure was used to guide the development of new pharmaceuticals to specifically inhibit the biological action of this enzyme by blocking its active site. At present, UAB-CBSE has designed, synthesized and tested compounds that have been demonstrated to inhibit both the outgrowth of germinating anthrax spores and the vegetative growth of anthrax (testing was performed at USAMRIID). This is an entirely new antibacterial drug target and a unique mode of antibacterial drug action that promises to be particularly effective against *B. anthracis*, since it is well established that inhibiting two steps in a sequential biological pathway leads to synergistic, not additive effects. The same compounds have also been shown to be effective against other spore forming bacteria as well as bacteria such as *S. aureus* (multiple strains), *Enterococcus faecium*, *Enterococcus faecalis*, *E. coli*, *M. catarrhalis*, *S. hemolyticus*, *S. agalactiae*, and *S. pneumoniae*. Furthermore, we have tested compound toxicity in whole cells and in mice with extremely promising results. Preliminary data from ongoing efficacy trials also looks promising but further optimization is required to improve bioavailability for oral administration, ensure a sufficiently long plasma half-life and other pharmaceutical elegance issues. Although further optimization of the compounds is necessary, UAB-CBSE, PPD Discovery and VDDI are optimistic that they can produce a viable, clinically approved compound within three years. In summary, UAB-CBSE and VDDI have a detailed plan, as outlined below, including all development and clinical testing required for FDA approval with a total estimated cost of $15-20 million.

II. Specific Aims

Anthrax, according to many military and counterterrorism planners, represents the single greatest biological warfare threat. The long-term goal of this research effort is to discover, characterize, and develop oral and intravenous drugs that can prevent prophylacticaly or treat infection from *B. anthracis*. A novel enzyme target, critical to the germination/outgrowth and vegetative life cycle of *B. anthracis*, has been identified and thus should be an effective point for inhibiting both the vegetative and spore forms of anthrax. Not only is NADs a new antibacterial drug target, but also it is unique by virtue of its requirement for two essential steps in the life cycle of a bacterium. This represents a totally new approach to highly effective antibacterial drugs.

Nicotinamide adenine dinucleotide (NAD) plays a vital role in many biological processes, including being a cosubstrate for hydride transfer, such as DNA recombination and repair, and numerous oxidation-reduction reactions. NADs is present in all prokaryotes[1] and eukaryotes[2]; however, the eukaryotic enzyme is a multisubunit protein with little homology to the prokaryotic form. Furthermore, unlike prokaryotes, eukaryotic amidotransferases contain two distinct domains, which may or may not belong

[1] An organism of the kingdom Prokaryotae, constituting the bacteria and cyanobacteria, characterized by the absence of a nuclear membrane and by DNA that is not organized into chromosomes.

[2] A single-celled or multicellular organism whose cells contain a distinct membrane-bound nucleus.

to the same polypeptide subunit. A glutamine amide-transfer domain confers the ability to use glutamine as a nitrogen source, whereas a synthetase domain provides specificity and is involved in the transfer of ammonia to the substrate. Most prokaryotes require ammonia and are not able to utilize glutamine as a source of nitrogen, since they do not contain a glutamine amide-transfer domain. This suggests that NADs inhibitors can be designed selectively to target prokaryotic cells, without affecting eukaryotic cells, thus reducing any toxicity associated with human use. Furthermore, our NADs inhibitors are selective against gram-positive bacteria but not gram-negative bacteria. Therefore, these compounds may not be associated with disruption of the normal intestinal flora, as are the currently available antibiotics.

Inhibitors developed against the NADs effectively prevent both the outgrowth of germinating spores and the vegetative growth of *B. subtilis* and *B. anthracis*. The innovative elements of the proposed research are (1) the utilization of a totally new antibacterial drug target; (2) the fact that this new drug target is required for two separate but essential steps in the life cycle of *B. anthracis*, offering synergistic effects that should provide extremely effective drugs; and (3) the identification of NADs inhibitors that have the potential and the necessary drug development attributes to become therapeutic agents. The preliminary results presented in this proposal were obtained by the principle subcontractor (UAB-CBSE). This data suggest a very promising commercial opportunity for developing NADs inhibitors into pharmaceuticals for both military and civilian use. The goals for this program, presented below, are measurable milestones.

The purpose of the proposed research program is to:

- Use combinatorial chemistry and rational drug design to synthesize additional NADs inhibitors;
- Employ pharmacological screening to determine the biological activity of the synthesized model NADs inhibitors; to be used for oral (p.o.) and intravenous (i.v.) administration;
- Apply an *in vitro* (Caco-2 cells) intestinal absorption model to evaluate the deliverability of the biological active inhibitors;
- Rationally direct the synthetic chemistry program for the optimization of NADs inhibitors to provide both acceptable *in vivo* biological activity against anthrax and other characteristics critical for successful drug development;
- Complete synthetic scale up and GMP manufacturing including:
    - Development of efficient GMP-compliant synthetic scheme
    - Development of GMP-compliant final drug product formulation
    - Development and validation of analytical methods for in-process controls, chemical characterization, and release specifications for identity, potency, and purity of the drug substance
    - Selection and full characterization of a reference standard
    - Scale up of synthesis and production of 2.0 kg of drug substance
    - Establish stability program for the drug substance

  - Development and validation of analytical methods for in-process controls, chemical characterization, and release specifications for identity, potency, and purity of the drug product
  - Establish stability program for the drug product
- Conduct preclinical and clinical pharmacokinetics (PK), efficacy and safety studies.
- This program will be carried out for a compound that can be administered via both oral and intravenous routes. If it is not possible to find one compound that can be administered by both routes, two compounds will be developed, one for oral administration and a second for intravenous administration.
- File an IND with at least one month of stability on drug substance; and
- Conduct a clinical strategy as single and multiple-dose (30 day) safety, tolerance and PK studies prior to NDA filing and apply for approval with the FDA.

Anthrax

A World Health Organization report estimated that 3 days after the release of 50 kg of anthrax spores along a 2-km line upwind of a city of 500,000 population, 125,000 infections would occur, producing 95,000 deaths [7]. This number represents far more deaths than predicted in any other scenario of agent release. Moreover, it has been estimated [8] that an aerial spray of anthrax along a 100-km line under ideal meteorologic conditions could produce 50% lethality rates as far as 160 km downwind. Finally, the United States chose to include anthrax in the now-defunct offensive biological weapons program of the 1950s, and the Soviet Union and Iraq also admitted to possessing anthrax weapons. An accident at a Soviet military compound in Sverdlovsk in 1979 resulted in at least 66 deaths due to inhalational anthrax, an inadvertent demonstration of the viability of this weapon [9]. See Appendix I for further discussion.

III. COMMERCIAL DEVELOPMENT PROGRAM

An oral and intravenous antibiotic regimen that would kill both the spore outgrowth phase ("dark spores") and vegetative stage of *B. anthracis* would have several therapeutic advantages over immunologic approaches, which include:

- Vaccines can be difficult to store, deploy and administer and troops tend to fear their administration and their effectiveness;
- Vaccines function by initiating the development of host antibodies that will quickly recognize *B. anthracis* or a component of its protein toxin. Unfortunately, it may be relatively easy for the enemy to genetically alter the surface of proteins (this also occurs naturally, without intervention by man) that these antibodies recognize, thereby making vaccine treatment ineffective [10]; or to use molecular biological techniques to insert the virulence genes into a different bacterium.
- Our lead drugs specifically inhibit the active site of NADs, an enzyme critical for the germination and viability of *B. anthracis*. It would be extremely difficult for

the enemy to genetically alter the catalytic site region of the protein because doing so would most likely adversely affect its normal biological function;

- The compounds as designed can be extremely stable, thus they could be stored (at room temperature) for long periods of time; and
- The compounds as designed will offer protection against antibiotic resistant strains of *B. anthracis* as well as other gram-positive bacteria and their antibiotic resistant strains.

The UAB NADs technology is mature and ready for optimization. The key to success will be a discovery program that creates a pharmaceutically elegant product, which has appropriate stability, absorption, metabolism, and safety profiles to allow its use in animal experimentation (the product developability stage). Following completion of this work, a formal preclinical development program will optimize the doses; institute allometric scaling; characterize the safety in at least two animal models; and complete the anthrax efficacy, dose response, and pharmacokinetic (PK) profile in rabbits and monkeys. Then, a formal IND will be submitted, and two normal volunteer studies will be conducted: a single-dose, dose-escalating safety, tolerance, and PK Phase I clinical trial, to be followed by a multi-dose safety, tolerance, and PK Phase I clinical trial. See Appendix II for Project outline and Gant Chart up to IND.

IV. REGULATORY STRATEGY

The Food and Drug Administration has recently proposed new regulations for the development of new drugs to be used against lethal or permanently disabling toxic substances, including agents that may be used in biological warfare (published in the Federal Register Vol 64, No.192, (Oct. 1999: "Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot Be Conducted).

VDDI has developed a preclinical and clinical strategy in accordance with these new regulations, and will discuss this strategy with the FDA at a pre-IND meeting to be scheduled for the fall of 2000.

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V. NADs Inhibitor Drug Development Plan

Drug Development Plan for NADs Inhibitor against B. Anthracis

Outlined below is the Drug development plan from Discovery to FDA submission.

1. Drug Discovery Stage
   - A. Synthesis of Discovery Leads using Combinatorial Chemistry and Rational Drug Design
   - B. High Throughput Enzyme Inhibition Screening against NADs, HTS for enzyme inhibition, and Antibacterial Screening(MIC)
2. Screening And Profiling Of Lead Compounds (Multiple Discovery Leads)
   - A. Preliminary Analytical and Bioanalytical Method Development
   - B. Preliminary Formulation Evaluation for Clinical Route of Administration
   - C. *In Vitro* (Caco-2) Drug Delivery for Transport across Gastrointestinal Membranes
   - D. *In Vitro* and *In Vivo* Pharmacology Assessment against Anthrax and Other Targets
   - E. *In Vitro* Toxicology and Metabolism Assessments
   - F. Preliminary Pharmacokinetics (PK) in Rodent Model (2-3 discovery leads)
   - G. Single-Dose Toxicology (2-3 discovery leads)
3. Preclinical and Nonclinical Drug Development Stage (Single Drug Candidate)
   - A. Formulation Evaluation, Preparation, and Characterization, including Stability
   - B. Analytical Chemistry Methods Validation for Content and Impurity Profiling
   - C. Bioanalytical Chemistry Method Validation to Support Toxicology Studies
   - D. IND/NDA-Directed Toxicology Studies, including Safety Pharmacology; Genotoxicity; Local toxicity Acute, Subchronic, Chronic, and Reproductive Toxicology; and Carcinogenicity
   - E. PK and Bioavailability in Toxicology Animal Species and for Allometric Scaling
   - F. Drug Metabolism and ADME, including Mass Balance, Metabolite Profiling and Identification, Tissue Distribution, and Toxicology Support
   - G. Efficacy Evaluation in Anthrax-Exposed Animal (Rabbit and Nonhuman Primate) Models
   - H. Preparation and Submission of IND, including Phase Ia and Ib Clinical Protocols, Investigator's Brochure, and Clinical Drug Development Plan
4. Clinical Drug Development Stage
   - A. Intravenous Single- and Multiple-Dose Phase I Safety and Tolerance Studies, including human PK
   - B. Oral Single- and Multiple-Dose Phase I Safety and Tolerance Studies, including human PK
5. Manufacturing
   - A. Raw Materials, Including Identification of Critical Components and Shelf-Life
   - B. Scale Up and Engineering, Including Identification and Validation of Processes
   - C. Documentation Generation of CMC Sections of IND and NDA
   - D. Drug Substance, Including Characterization and Specification Requirements
   - E. Definitive (Shelf-Life) Stability for Drug Substance and Drug Product
   - F. Packaging, Labeling, and Package Insert

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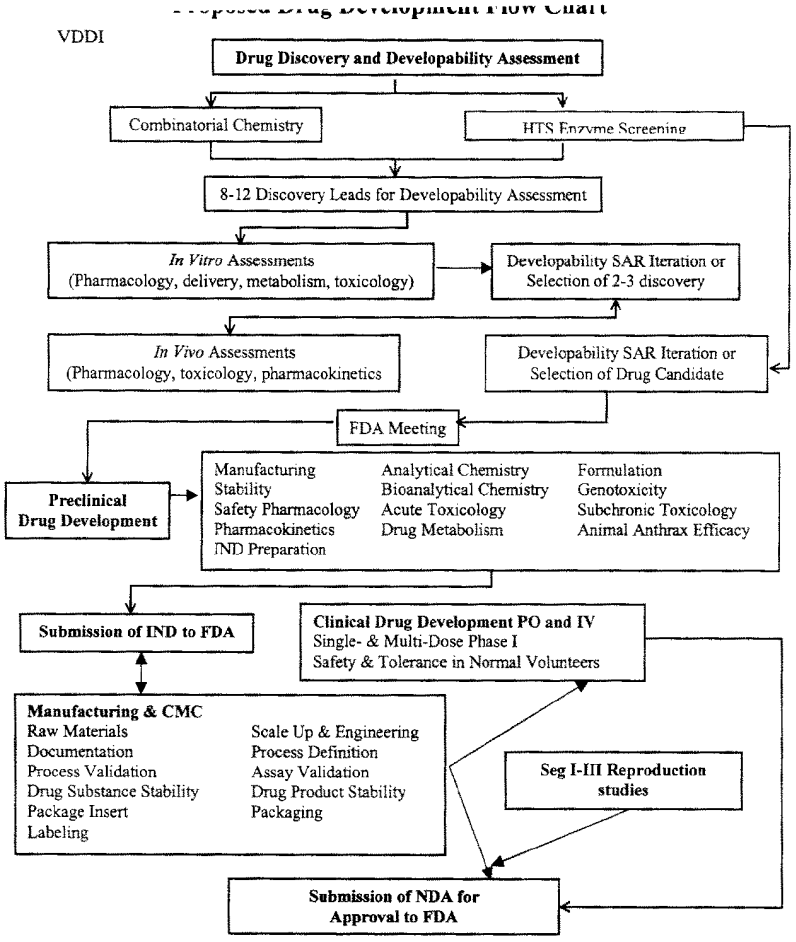

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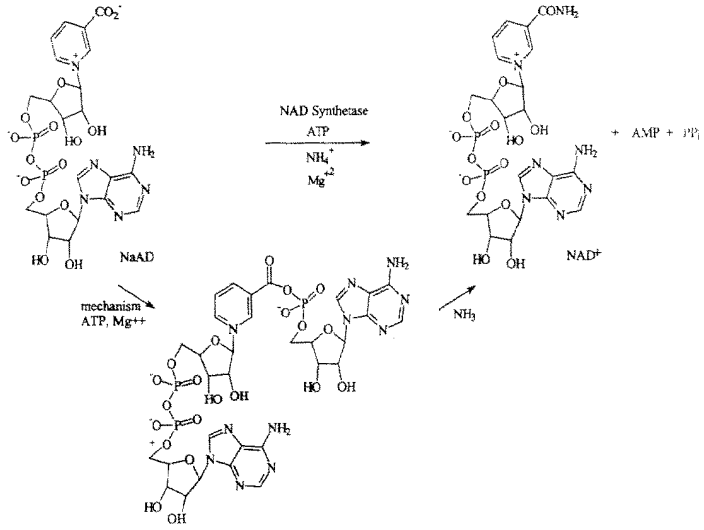
VDDI

Synthetic Chemistry Program

Background/Previous Work

The enzyme NADs, as summarized below, catalyzes the conversion of nicotinic acid adenine dinucleotide (NaAD) into nicotinamide adenine dinucleotide (NAD). This is a simple chemical change of a carboxylic acid to a carboxamide, but several very large molecules are utilized to accomplish this change. These include not only NaAD but also adenosine triphosphate (ATP). These become joined during the enzyme reaction to form the adenosine monophosphate (AMP) adduct of NaAD, which subsequently reacts with



ammonia to provide the product NAD. Thus the binding site of NADs must be very large to accommodate the NaAD-AMP intermediate. Our x-ray crystallography results show, in fact, that this binding site is long and linear, with a "canyon" in the surface of the enzyme homodimer at one end, near the dimer interface, and a buried "cave" at the other end that reaches well into the interior of one of the enzyme subunits. ATP binds in the "cave" end, and NaAD binds in the "canyon" end such that the ends are in close proximity for chemical reaction.

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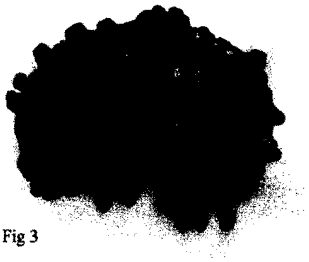
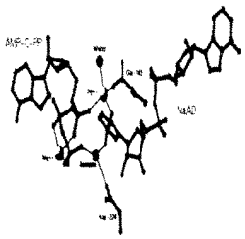


Fig 3

A coupled enzyme assay was developed to monitor the rate of NAD production in the reaction catalyzed by NADs. This assay uses excess alcohol dehydrogenase to catalyze the NAD-dependent oxidation of acetaldehyde from ethanol. The rate of NADH production is monitored at 340 nm by absorbance and is stoichiometrically related to NAD formation by NADs. Using this coupled assay, the enzyme kinetics of each substrate was determined. The velocity of NAD formation as a function of ATP NaAD and NH_3 concentrations have been performed. These data were analyzed by steady-state Michaelis-Menton kinetics to determine Michaelis constants (Km) and maximum velocities (Vmax) as well as interaction parameters between substrates. The kinetic parameters for the NADs catalyzed reaction are given below in Table 1. The accompanying figure is derived from the UAB-CBSE x-ray structure, illustrating some key interactions in the active site of the enzyme.

Table 1. Steady-State Kinetic Parameters

Substrate	Km (mM)
MgATP	0.120
NaAD	0.082
NH3	10



Our approach to the rapid development of drug-like inhibitors of NADs combined the tools of structure-based drug design and "structure-targeted" combinatorial chemistry. The steps are summarized below:

- Obtain multimilligram quantities of pure target protein.
- Crystallize and obtain high-resolution structure of target protein
- Identify "lead" compounds (by computer modeling, database mining, combinatorial chemistry, and high throughput screening)
- Obtain high-resolution structure of lead compound-protein complex.
- Carry out computer modeling and new compound design.
- Perform "targeted" combinatorial synthesis to rapidly explore structure-activity relationships.
- Perform high throughput biological assays.

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- Perform additional in vitro and in vivo studies on most promising compounds, including toxicity.

UAB-CBSE have completed these steps and have identified approximately 50 different lead compounds which possess exciting activities for preventing the outgrowth of germinating *Bacillus* spores, and which also prevent the vegetative growth of *Bacillus* and other gram-positive bacteria, including antibiotic-resistant strains.

UAB-CBSE is now pursuing the iterative cycle of structure-based drug design that, when coupled with targeted combinatorial synthesis, should rapidly provide potent, selective inhibitors with clinical potential.

As summarized above UAB-CBSE have already accomplished the most difficult part of new drug development for a new biological target; namely, identifying useful "lead compounds" and obtaining the structure in complex with the enzyme active site. The approach that we took to reach this stage of development is summarized below.

Since the NADs-binding site is so large, it is unlikely that a single molecule capable of occupying most of the site will be useful as a drug. (The most commonly used drugs have molecular weights less than 500 to provide reasonable opportunities for absorption and distribution throughout the body). Furthermore, the natural substrates were not attractive as lead molecules because of their chemical complexity and difficulty of synthetic modification; additionally, charged organophosphate compounds do not readily undergo diffusion across membranes, making development of an oral drug of this type unlikely. Instead, we utilized computerized modeling, database mining, and combinatorial chemistry for the development of totally novel lead compounds that possess desired drug-like properties.

In this approach UAB-CBSE chose to identify small molecule inhibitors specific for NADs subsites (smaller areas within the large catalytic site). The small molecules would then be synthetically joined to form "dimers" that should exhibit dramatically enhance binding affinity.

The best inhibitors of NADs were very effective antibacterial agents against the vegetative growth of *B. anthracis*, *B. subtilis*, and other gram-positive bacteria including MRSA and vancomycin-resistant *E. faecalis* and *E. faecium* (VREF). Furthermore, these compounds blocked the outgrowth of germinating *B. subtilis* and *B. anthracis* spores; they thus attack two separate steps in the life cycle of spore-forming bacteria. This approach offers a unique advantage over conventional antibiotic approaches since it is well recognized that the inhibition of two steps within a linear biological pathway leads to synergistic, not additive effects. The MIC values in these antibacterial assays were typically 0.40-10 μg/mL, which was as good or better than many clinically used antibiotics (run as positive controls) for susceptible strains and, unlike the clinical antibiotics, these compounds maintained equivalent effectiveness against resistant strains.

VDDI

Preliminary In Vitro And In Vivo Data

Summary of in vitro data and discussion

MIC data is shown in Tables 2A, 2B, and 3 illustrate the very potent antibacterial activity of our NAD synthetase inhibitors. Table 2A illustrates, for selected compounds, the very potent activity against *B. subtilis*, a spore-forming gram-positive bacterium like *B. anthracis*. Table 2A also illustrates the selectivity of these inhibitors for gram positive over gram-negative bacteria.

Drs. John Ezzell and Joany Jackman (USAMRIDD) performed preliminary *in vitro* antimicrobial (MIC) activity in Mueller Hinton plates against *B. anthracis* Ames strain spores. A representative series of compounds is summarized in Table 2b.

Table 2A. MIC Values (μg/mL) for Selected NADs Inhibitors.

Compound	*Bacillus subtilis* (ATCC 9372) [Gram +]	*Staphylo-coccus aureus* (ATCC 29213) [Gram +]	*S. aureus*, MRSA[a] (ATCC 33593) [Gram +]	*Pseudo-monas aeruginosa (ATCC 27853)* [Gram -]	*Salmonella enteritidis (ATCC 13076)* [Gram -]
270	6.2	1.6	3.1	>50	>50
409	1.6	3.9		>50	>50
939	3.5	3.1		>50	>50
940	2.5	6.2		>50	>50
948	6.2	4.7		>50	>50
949	3.1	3.9		>50	>50
951	1.6	2.3	2.3	>50	>50
953	3.5	6.2		>50	>50
1074	1.6				
1108	3.1	9.4	3.1	>50	>50
1197	0.39	0.39		>25	>25
Rifampin	1.5				
Methicillin		1.0 (16)[b]	32		
Vancomycin	0.39	1.6			

[a]MRSA = methicillin-resistent *Staphylococcus aureus.*

Table 2B.
MIC_{100} Lead Compounds
against *B. anthracis*

VDDI

Compound Number	MIC (μg/mL) Vegetative Growth	LD_{50} (IP) (mg/kg) in Animal	LD/MIC
951	1.6	156	97.5
409	1.6	62.5	39.1
274	1.6	125	78.1
270	6.3	62.5	9.9
940	31	62.5	2.0

Table 3 illustrates the broad activity of our NADs inhibitors against a range of bacteria. As can be seen, the addition of plasma to selected MIC incubation samples causes a greater than 10-fold decrease in antibacterial activity, with the MIC increasing from 5 to >50 μg/mL. This could be due to tight protein binding between the compound and serum albumin. Many drugs bind to plasma proteins, and such binding can be beneficial. Excessively tight binding, however, provides too little free drug for adequate distribution to tissues and therefore lowers efficacy.

Alternatively, the increase in the MIC may be due to rapid degradation of the compounds by plasma esterases. Analogs of some of our lead compounds have ester constituents that may lend themselves to rapid metabolism by tissue, blood cell or liver esterases. In this case, a markedly shortened plasma half-life will lead to a shortened duration of activity against the bacterial targets. However, we already have demonstrated that the chemical transformation of the ester linkage to an amide, which is not susceptible to serum esterases, maintains full enzyme inhibition activity. But this issue will be further addressed in developmental work described under the Goals section below.

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Table 3. MIC values (μg/mL) for NAD Synthetase Inhibitors Against a Variety of Bacteria

Compound →	Linezolid	Vancomycin	UAB1108	UAB1174	UAB1182	UAB1186	UAB1197	UAB270	UAB409	UAB951
S. aureus 1095	3.13	0.78	3.13	3.13	6.25	3.13	3.13	6.25	3.13	3.13
S. aureus 1095 +SERUM	3.13	1.56	>100	100	>100	>100	>100	>100	>100	>100
S. aureus 1146	3.13	0.39	1.56	0.78	1.56	1.56	1.56	1.56	1.56	1.56
S. aureus 1146 +SERUM	3.13	0.78	>100	25	>100	>100	25	>100	100	>100
S. epidermidis 1034	1.56	3.125	1.56	0.78	1.56	3.13	0.78	1.56	1.56	1.56
S. pneumoniae 1193	0.78	≤0.20	>100	3.13	100	50	12.5	25	12.5	25
S. pneumoniae 1175	1.56	0.39	>100	6.25	>100	>100	12.5	25	12.5	25
S. pyogenes 1068	0.78	0.39	>100	3.13	>100	>100	6.25	25	12.5	25
S. pyogenes 0203	0.39	0.2	25	0.78	50	50	0.78	6.25	3.13	6.25
E. faecalis 1085	1.56	1.56	3.13	1.56	6.25	3.13	3.13	3.13	3.13	6.25
E. faecalis 1085 +SER	1.56	6.25	>100	100	>100	>100	>100	>100	>100	>100
E. faecium 1022	1.56	>100	1.56	1.56	3.13	1.56	1.56	1.56	1.56	1.56
E. faecium 1022 +SER	1.56	>100	>100	100	>100	>100	>100	>100	>100	>100
E. coli 1086	12.5	>100	12.5	6.25	12.5	12.5	100	12.5	25	>100
E. coli 1051	>100	0.39	25	3.13	6.25	3.13	25	3.13	6.25	12.5
K pneumoniae 0031	>100	>100	>100	3.13	>100	>100	>100	>100	>100	>100
E. cloacae 1042	>100	>100	>100	>100	>100	>100	>100	>100	>100	>100
E. aerogenes 1018	>100	>100	>100	>100	>100	>100	>100	>100	>100	>100
P. aeruginosa 0104	>100	>100	>100	>100	>100	>100	>100	>100	>100	>100
P. mirabilis 1049	>100	>100	>100	>100	>100	>100	>100	>100	>100	>100
H. influenzae 0131	12.5	100	50	25	>100	>100	100	100	6.25	>100
H. influenzae 1100	12.5	>100	>100	50	>100	>100	>100	>100	12.5	>100
M. catarrhalis 0040	6.25	100	6.25	3.13	6.25	12.5	50	6.25	12.5	25
M. catarrhalis 1055	25	100	6.25	3.13	3.13	12.5	25	12.5	6.25	50

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Cytotoxicity data

Cell-based assays for cytotoxicity to mammalian cells have also been performed on these candidates and reveal that they are much less toxic to mammalian cells (the cytopathic concentration causing 50% cell death (CC_{50}), in a human lymphoma cell assay, was greater than 1000 μM (500 μg/mL) for some examples). This suggests a favorable therapeutic index (Figure 8). With MICs in the nM range and overt cell toxicity seen at concentrations in excess of 1000 uM we are reasonably assured of the relative low toxicity of these compound as compared

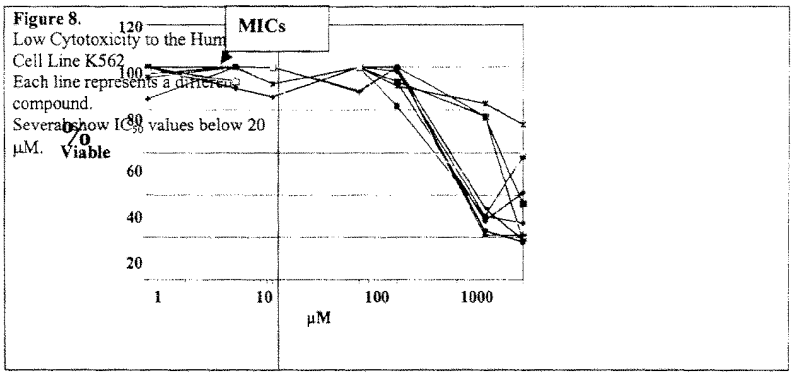

Figure 8.
Low Cytotoxicity to the Human
Cell Line K562
Each line represents a different
compound.
Several show IC_{50} values below 20
μM.

Previous Experience Summary

In summary, the specific design of our lead compounds, in conjunction with our preliminary in vitro and in vivo data suggest that:

- The lead compounds have MIC values against *MRSA* and vancomycin resistant *Enterococcus faecium* and *E. faecalis,* that is as good or better than clinically approved antibiotics
- Some of the lead compounds show specificity against gram positive, but not gram negative strains, thus reducing some adverse effects of clinically approved antibiotics
- Some of the lead compounds show excellent activity against virulent and attenuated strains of *B. anthracis.*
- The mechanism of action of the compounds is specific to prokaryotic cells, thus leading to a great safety profile for clinical use.

Product development issues that remain to be resolved include:

- Development of parenteral agents
- Development of orally active agents
- Development of a relatively long half-life product

The approaches we will take to resolving these issues are discussed in the Goals section below.

▪

Goals for developing clinical candidates.

UAB-CBSE and PPD Discovery will conduct a parallel development program in which preclinical candidates are identified for both parenteral and oral routes of administration. Of course, a single agent may result which is suitable for both routes.

(a) Our best enzyme inhibitors have IC_{50} values of about 10 μM. We intend to improve this activity by 10-100 fold. Such an enhancement in enzyme inhibition should translate into administration of lower doses, which should minimize toxicity. This would also minimize potential problems related to limited water solubility (see below). (b) Our *in vitro* antibacterial studies reveal that addition of serum to selected MIC incubation samples causes greater than a ten-fold decrease in antibacterial activity (MIC goes from <5 - >25 μg/mL). This effect is often due to excessive protein binding between the drug and serum proteins. (Alternatively, point (c) below may be involved.) This is a greater loss of activity as compared to typical clinically used antibiotics exposed to serum. Many useful drugs bind to plasma proteins, and such binding can be beneficial. However, excessively tight protein binding provides too little free drug for adequate distribution to tissues and efficacy. *The extent of protein binding will be decreased.* (c) Current compounds contain an ester linkage in the tether. Such a linkage may be susceptible to cleavage by serum esterases. *If these compounds act as substrates for serum esterases, we will modify the ester linkage (change to sterically hindered ester, amide, ether, etc.).* (d) Our existing antibacterial compounds are excessively hydrophobic on one end of the dimer, which limits their water solubility to about 1 mM. *We will improve water solubility by 10 to 100-fold.*

These goals will be accomplished using the following approaches, all which take advantage of our knowledge of the catalytic site and our experience with combinatorial synthesis of these structural classes. (a) *Enhance potency.* Based on existing lead compound structures and our knowledge of the catalytic site, we will prepare compound libraries to rapidly explore structure-activity relationships in order to enhance potency of inhibition and decrease toxicity. As examples, we will include electron-donating and electron-withdrawing groups on the aromatic rings, explore steric bulk on both ends of the dimer, include conformational constraint in the tether (phenyl or cyclopropyl within linker, etc.), and evaluate polar and nonpolar substituents (including variations in steric bulk) in all regions of the structure. This approach will rapidly identify optimum structural components in each region of the inhibitor. (b) *Decrease protein binding.* The

observation that addition of serum to antibacterial assay broths results in a dramatic decrease in antibacterial effects for lead compounds suggests that excessive protein binding (to serum proteins) is problematic. Since more polar compounds may be expected to exhibit lessened protein binding, we will evaluate selected compounds from goal (a) above that exhibit good enzyme inhibitory activity and in vitro antibacterial activity, and contain extra polar substituents, in an *in vitro* protein binding assay to select those which have diminished protein binding affinity. (c) *Reduce activity as substrates for serum esterases.* If observed to be a general problem, as mentioned above, we will modify the ester linker in the tether. Among numerous possibilities are modifications to amides, ethers, sterically hindered esters, ketones, ureas, etc. We recently synthesized an amide-linked analog, which maintains comparable activity as an inhibitor of *B. subtilis* NAD synthetase. (d) *Increase water solubility.* Current compounds have limited water solubility (about 1 mM). This property should be improved to facilitate formulation of iv or acrosolization solutions. As in goals (a) and (b), we will accomplish this by using combinatorial chemistry to ascertain which regions of the lead compounds can tolerate the addition of polar substituents (e.g., alcohols, amines, amides, ethers, etc.), without a significant decrease in activity or increase in toxicity.

Regarding new compound library generation, the goals are to prepare small, discrete parallel compound libraries that evaluate effects of different substituents on the hydrophobic end of the dimer, and on the hydrophobic linker chain. We anticipate that medium polarity substituents on the hydrophobic aryl moiety (amides, esters, ethers, hydroxyalkyl, etc.) should increase water solubility and decrease protein binding. Similarly, ether or amino linkages in the linker chain, or polar substituents (as side chains), should also have the same effect. We also will explore effects of electron-withdrawing and electron-donating groups on the aromatic ring. Substitution effects on the aryl ring and the linker will first be explored separately, and further iterations will be subsequently performed to determine if favorable effects are additive in the same molecule. Compounds with enhanced potency may result, and the SAR data that is generated will be useful in further optimization of potency, if necessary. Protein crystal structures will be determined for complexes of the best inhibitors, and the results used to design next generation libraries.

The synthetic approaches will be modeled after those that we have developed for preparing the first 1,400 compounds. These methods employ solution phase parallel synthesis and have been designed to provide discrete library members with high final purity (≥ 80%). All parallel synthetic reactions are monitored by TLC, and sequestering resins) are used where appropriate to improve purities. Occasionally, filtration through flash silica on vacuum manifolds is performed to remove very polar or very nonpolar contaminants. All intermediates and products are evaluated for purity and integrity using LC/MS; and about 10% of all products undergo additional purity evaluation using internal NMR standards to confirm purity estimates provided by LC/MS. Compounds which show good activity as enzyme inhibitors are resynthesized singly and carefully purified to confirm activity and provide quantities for additional biological evaluation.

Development of orally active agents. We also intend to develop orally active inhibitors of NAD synthetase as antibacterial agents that are highly effective against anthrax. To do so we will pursue three different approaches. (a) Develop an uncharged "prodrug" form that is converted into the biologically active, positively charged form after oral absorption. (b) Identify good inhibitors that do not contain a permanent positive charge, since permanently charged molecules will normally not permeate through cell membranes by passive diffusion. (c) Using our now extensive knowledge of the NADs catalytic site, develop totally new, uncharged structural classes as NAD synthetase inhibitors.

(a) Orally active prodrug. The most direct approach to orally bioavailable NAD synthetase inhibitors is to develop an uncharged, prodrug form of the positively charged antibacterial agent. The prodrug form, since it is not permanently charged, would undergo oral absorption but in plasma or tissues or the bacterial cell would be metabolically converted to the permanently charged, active form. *Note that development of an optimized charged drug, as discussed above, is first necessary to fully take advantage of the prodrug approach.* (The prodrug is simply a "delivery form" of the active compound, and the latter needs to be fully optimized for efficacy, pharmacological properties, and minimum toxicity).

Based upon literature precedent, we plan to pursue several strategies for prodrug development. Each is summarized below.

(b) Develop active compounds which lack a permanent positive charge. Our major strategy for this goal is to develop new compounds which are positively charged at physiological pH, but which equilibrate with the uncharged form to provide good bioavailability. This should satisfy the requirement of the enzyme binding site for a full positive charge but permit membrane permeability and oral bioavailability via the equilibrating uncharged form.

Role of PPD Discovery in preclinical candidate development. This contract organization contains a variety of scientific expertise and capabilities including synthetic organic chemistry, combinatorial chemistry, an in-house combinatorial compound library, and experience carrying out preclinical studies and solving drug development problems. Their role regarding medicinal chemistry, when needs cannot be efficiently met by the UAB Laboratory of Medicinal & Combinatorial Chemistry, may include (a) the resynthesis of synthetic intermediates and products to expedite target compound production, (b) the synthesis of analogs to enhance SAR studies, (c) the synthetic scale-up of compounds needed in greater quantity for animal studies, and (d) the GMP synthesis of compounds when needed for preclinical studies. In addition to advice from external scientific consultants, this group may also be asked to provide input regarding structural solutions to problems encountered during preclinical development. These procedures will insure that good ideas are promptly generated and prioritized to move compounds forward. Standard toxicological studies for preclinical development will be conducted and coordinated by PPD Discovery.

Chemistry Manufacturing Controls (CMC).

Upon synthesis of the bulk Active Pharmaceutical Ingredient (API) at least the following studies will be undertaken as a portion of the CMC section of the plan. All procedures will be performed according to FDA cGMP and ICH guidelines currently in effect at the time. It is anticipated that the API will be formulated as both an oral (PO) and intravenous (IV) product. Studies will be performed in parallel in order to accelerate the timing of the program.

The preliminary analytical methods will be transferred and validated in order to assist in formulation, dissolution, stability, and dose analysis studies. Methods will be assessed for specificity, sensitivity, linearity, accuracy, precision, reproducibility and ruggedness.

The API will be formulated for oral (PO) and intravenous (IV) routes of administration. For PO administration the API may be formulated as either a capsule (hard gel) or tablet. For IV administration, it is preferred that the API is formulated as a readily injectable sterile solution. If this is not possible, the API will be formulated as a lyophilized product suitable for reconstitution immediately prior to use. Formulation processes will consider excipient incompatibilities and all other standard procedures. PO formulations will be assessed for blending, particle size, homogeneity, dissolution rates, etc.. IV formulations will be assessed for homogeneity, particle size, appearance, particulate matter, pH, clarity, etc. Formulations will be assayed for impurities using a suitable method.

IV formulations will be evaluated for materials incompatibilities. This will include container/closure, tubing and injection device incompatibilities.

The bulk API will be assessed for stability. Drug substance will be assayed using accelerated conditions and various storage conditions (temperature, humidity). Since the drug product is intended for use under battlefield conditions, stability studies will stress extreme conditions. Photostability studies will be conducted. The bulk API will be evaluated for stability under forced degradation conditions.

The formulated API (both PO and IV products) will be subjected to accelerated stability studies similar to those described above. In the event the IV formulation is found to be unstable in solution, it may be necessary to consider reformulating the product as a lyophilized substance that would be reconstituted immediately prior to use. In this event, studies similar to those describe above would be performed. However, the sterile formulated API would be lyophilized in suitable container/closure systems, and studies would be performed upon the lyophilized substance.

Following development of suitable PO and IV formulations, the formulated API will be placed on long-term stability studies of up to 2 years. Stability of the API will be assessed at 0, 1, 3, 6, 9, 12, 18, 21 and 24 months..

Preclinical and Nonclinical Development Program

Preliminary pharmacokinetic studies, metabolite stability, metabolite identification and metabolite induction/inhibition studies will be conducted early in the process of identifying lead compounds. Therefore, these data will be available for the lead compounds before those compounds are taken into the formal preclinical safety and efficacy program.

Following completion of the CMC section the following preclinical studies will be performed to assess the safety and efficacy of the API. All procedures will be conducted according to testing facility standard operating procedures and the US FDA Good Laboratory Practice Regulations currently in effect (21 CFR, Part 58). Also, they will comply with OECD Principles of Good Laboratory Practice and the Japanese Good Laboratory Regulations (Notification 313 of the Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, Japan, effective March 31, 1982; and revised by Notification No. 870, effective October 5, 1988) as well as the Guidelines for Toxicity Studies of Drugs Manual (published by Yakuji Nippo, Ltd., January, 1991). The program safety and efficacy will be proven in 2 (or 3) animal species infected with B. anthracis and that this strategy is in accordance with that in the Federal Register Vol 64, No.192 (Oct. 1999: "Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot Be Conducted) This strategy will be discussed with FDA at the pre-IND meeting. The most rapid pre-Investigational New Drug (IND) toxicity program would likely involve 90 days studies with 2-week satellite of breakout studies in a rabbit and primate species. A thorough investigation of the dose-response relationship in these studies would normally be sufficient to establish doses for chronic toxicity studies, which could begin immediately. Therefore, it would be possible for chronic safety data in animals (6-12 months) to be available at NDA filing without prolonging the timeline beyond that required for the clinical trials.

Table 4 Outline of Preclinical Development Plan to Support the Submission of the IND

Primary Pharmacology Studies	
	In vitro studies including MICs
	In vivo anthrax interdiction study in the rabbit
	In vivo anthrax interdiction study in the primate
Safety and Efficacy Pharmacology Studies	
	Receptor Binding panel
	CNS pharmacology
	Cardiovascular pharmacology
	Respiratory pharmacology
	Efficacy Pharmacology Studies
	Single and multiple dose studies in rat
	Single and Multiple dose in Rabbit Multiple dose in macaque primates
Toxicology Studies	
	Genetic Toxicology studies
	Local irritation studies
	Acute IV toxicity (rat and at least one nonrodent species) with toxicokinetics and 14-day satellite phase
	Acuto PO toxicity (rat and at least one nonrodentspecies) with toxicokinetics and 14-day satellite phase
	90 Day IV toxicity (rat and at least one nonrodent species) with toxicokinetics and 14-day satellite phase
	90 Day PO toxicity (rat and at least one nonrodent species) with toxicokinetics and 14-day satellite phase
ADME	
	Single and repeat dose pharmacokinetic studies
	Mass balance study

Additional nonclinical studies that will be conducted concurrently with clinical develop include reproductive toxicology studies in rat and rabbit, chronic toxicology studies, and carcinogenicity studies. Tissue distribution studies, metabolite identification and pharmacokinetic studies of major metabolites will also be conducted during this phase.

The study of NADs to prevent inhalational anthrax will performed in a non-human primate (macaque) model; this will be supported by *in vitro* data assessing the activity of NADs against *B. anthracis*. The pharmacology of NADs in the macaque will be correlated with that of in human populations. See Appendix II for greater detailed discussion on the preclinical and clinical timelines

Clinical Development Program

Following discussion and approval from the FDA the clinical development program will consist of two normal volunteers studies. These studies will correlate information from preclinical safety, PK and efficacy with the human trial experience. Since it is unethical to conduct anthrax interdiction trials in humans surrogates of plasma and tissue concentrations obtained from animal interdiction studies will be used as correlates and inferences of the human experience.

Phase Ia

Normal volunteers will be recruited to evaluate safety PK and maximal tolerated dose of the i.v. and the p.o. compounds. Single i.v. and p.o. doses will be administered to each of two cohorts of 36 normal volunteers after an overnight fast. Serial PK blood samples will be drawn along with blood and urine collections for safety chemistry and hematologic studies. Plasma and tissue (skin blister) concentrations of the NADs compounds will be correlated with PK data derived from preclinical studies.

Phase IB

After completion of the results of the Phase Ia study, two doses regimens, high and low, will be selected for the i.v. and the p.o. dosing. Two multi-dose normal volunteer studies will be designed. Daily doses will be administered to each of two cohorts of 36 normal volunteers for 14 days i.v. and 30 days p.o. Serial PK blood samples will be drawn along with blood and urine collections for safety chemistry and hematologic studies. Plasma and tissue (skin blister) concentrations of the NADs compounds will be correlated with PK data derived from preclinical studies.

Budget and Timelines

DARPA has supported the initial funding for this program ($6 Million). USAMRIID supported the *in vitro* studies with several strains of *B. anthracis* and has just agreed to refund $300,000 for this work performed. VVDI has received an NIH R43 SBIR Phase I grant for $135,000. Additional support is requested from the Department of Defense and will be used to complete the synthetic chemistry and preclinical development program. Specifically, $2 Million is needed immediately, and will be spent as allocated by the time and resources as outlined in this Proposal. A detailed timescales and deliverable assessment of this program is shown below See Appendix II

A gross summary of the multi-year budget is shown in Table 5 below. Details of manufacturing cost, selected efficacy trials (anthrax interdiction) and FDA mandated studies necessitate an approximation at this time. Diligence and site visits are ongoing for these aforementioned programs.

Table 5

Stage of Project	Estimated Duration	Estimated Cost
Synthetic Chemistry	12-24 wks	$860,000.00
Drug Lead Profiling	30 days	$300,000.00
Pre-IND Meetings (2)	90 days	$67,250.00
Preclinical Drug Development	16 months	$2,738,400.00
IND Filing	4 weeks	$150,000.00
Clinical Drug Development	20 months	$2,475,000.00
Nonclinical Drug Development	2.5 yrs	$2,700,000.00
NDA Filing	6 weeks	$650,000.00
Manufacturing	4 yrs	$5,000,000.00
Administrative and Project Management	4yrs	$2,250,000
Total		$16,990,341.00

VI. APPENDIX I ANTHRAX

Anthrax

Background. Anthrax is one of the great infectious diseases of antiquity. The fifth and sixth plagues from the Bible's book of Exodus may have been outbreaks of anthrax in cattle and humans, respectively. The "Black Bane," a disease that swept through Europe in the 1600s causing large numbers of human and animal deaths, was likely anthrax. In 1876, anthrax became the first disease to fulfill Koch's postulates (i.e., the first disease for which a microbial etiology was firmly established), and 5 years later, in 1881, the first bacterial disease for which immunization was available [11]. Large anthrax outbreaks in humans have occurred throughout the modern era -- more than 6,000 (mostly cutaneous) cases occurred in Zimbabwe between October 1979 and March 1980[12], and 25 cutaneous cases occurred in Paraguay in 1987 after the slaughter of a single infected cow[13].

A World Health Organization report estimated that 3 days after the release of 50 kg of anthrax spores along a 2-km line upwind of a city of 500,000 population, 125,000 infections would occur, producing 95,000 deaths[7]. This number represents far more deaths than predicted in any other scenario of agent release. Moreover, it has been estimated[8]that an aerial spray of anthrax along a 100-km line under ideal meteorologic conditions could produce 50% lethality rates as far as 160 km downwind. Finally, the United States chose to include anthrax in the now-defunct offensive biological weapons program of the 1950s, and the Soviet Union and Iraq also admitted to possessing anthrax weapons. An accident at a Soviet military compound in Sverdlovsk in 1979 resulted in at least 66 deaths due to inhalational anthrax, an inadvertent demonstration of the viability of this weapon[9].

Anthrax is caused by infection with *B. anthracis*, a gram-positive spore-forming rod. The spore form can survive in the environment for many decades. Certain environmental conditions appear to produce "anthrax zones", areas wherein the soil is heavily contaminated with anthrax spores. Such conditions include soil rich in organic matter (pH <6.0) and dramatic changes in climate, such as abundant rainfall following a prolonged drought. Partly because of its persistence in soil, anthrax is a rather important veterinary disease, especially of domestic herbivores. Vultures may mechanically spread the organism in the environment Anthrax zones in the United States closely parallel the cattle drive trails of the 1800s[14].

Anthrax spores lend themselves well to aerosolization and resist environmental degradation. Moreover, these spores, at 2-6 microns in diameter, are the ideal size for impinging on human lower respiratory mucosa, optimizing the chance for infection. A bioterrorist who attempts to use it as a weapon will face issues in the manufacture and delivery (avoiding clumping into larger particles) of anthrax spores in this particular size range. The milling process imparts a static charge to small anthrax particles, making them more difficult to work with and, perhaps, enabling them to bind to soil particles[15]. This, in part, may account for the relatively low secondary aerosolization potential of anthrax,

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as released spores bind to soil, clumping in particles therefore substantially larger than 6 microns. This clumping tendency, together with a high estimated 50% infectious dose (ID_{50}) of 8,000-10,000 spores might help explain the rarity of human anthrax in most of the Western world, even in areas of high soil contamination.

The Disease. Most endemic anthrax cases are cutaneous and are contracted by close contact of abraded skin with products derived from infected herbivores, principally cattle, sheep, and goats. Cutaneous anthrax is readily recognizable, presents a limited differential diagnosis, is amenable to therapy with any number of antibiotics, and is rarely fatal. While common in parts of Asia and sub-Saharan Africa, cutaneous anthrax is very rare in the United States; the last case was reported in 1992[16]. Inhalational anthrax, also known as woolsorters' disease, has been an occupational hazard of slaughterhouse and textile workers; immunization of such workers has all but eliminated this hazard in Western nations. As a weapon, however, anthrax would likely be delivered by aerosol and, consequently, be acquired by inhalation. A third type of anthrax, acquired through the GI route (e.g., consuming contaminated meat) is exceedingly rare but was initially offered by Soviet scientists as an explanation for the Sverdlovsk outbreak.

Inhalational anthrax begins after exposure to the necessary inoculum, with the uptake of spores by pulmonary macrophages. These macrophages carry the spores to tracheobronchial or mediastinal lymph nodes. Here, *B. anthracis* finds a favorable milieu for growth and is induced to vegetate. The organism begins to produce an antiphagocytic capsule and at least three proteins, which appear to play a major role in virulence. These proteins are known as edema factor, lethal factor, and protective antigen. These toxins result in necrosis of the lymphatic tissue, which in turn causes the release of large numbers of *B. anthracis*. The organisms gain access to the circulation, and an overwhelming fatal septicemia rapidly ensues. At autopsy, widespread hemorrhage and necrosis involving multiple organs is seen.

Inhalational anthrax generally occurs after an incubation period of 1 to 6 days[17]. During the Sverdlovsk outbreak, however, spontaneous cases arose as late as 43 days after the assumed release date[9]. Such unexplained late cases have potentially serious implications for post-exposure treatment and management of victims of aerosol exposure. After the incubation period, a nonspecific flu-like illness ensues, characterized by fever, myalgia, headache, a nonproductive cough, and mild chest discomfort. A brief intervening period of improvement sometimes follows 1 to 3 days of these prodromal symptoms, but rapid deterioration follows; this second phase is marked by high fever, dyspnea, stridor, cyanosis, and shock. In many cases, chest wall edema and hemorrhagic meningitis (present in up to 50% of cases[18]) may be seen late in the course of disease. Chest radiographs may show pleural effusions and a widened mediastinum, although true pneumonitis is not typically present. Blood smears in the later stages of illness may contain the characteristic gram-positive spore-forming bacilli. Death is universal in untreated cases and may occur in as many as 95% of treated cases if antibiotic therapy is begun more than 48 hours after the onset of symptoms.

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While early recognition of anthrax is likely to require a heightened degree of suspicion, the diagnosis is supported by gram-positive bacilli in skin biopsy material (in the case of cutaneous disease) or in blood smears. A preponderance of gram-positive bacilli in swabs of the nares or in appropriate environmental samples might support a diagnosis of anthrax where intentional release is suspected. Chest radiographs exhibiting a widened mediastinum in the proper setting of fever and constitutional signs and in the absence of another obvious explanation (such as blunt trauma, deceleration injury, or post-surgical infection) should also lead to a diagnosis of anthrax. This finding is only likely to occur late in the course of disease. Confirmation is obtained by culturing *B. anthracis* from blood.

Disease Management. While endemic strains of *B. anthracis* are typically sensitive to various antibiotics, including penicillin G, antibiotic-resistant strains do (on rare occasion) occur naturally[19] and can be readily isolated in laboratories. For this reason, as well as the convenience of twice-daily dosing, many experts consider ciprofloxacin (400 mg intravenously (I.V.) q 12 h) the drug of choice for treating victims of terrorism or warfare. Doxycycline (100 mg I.V. q 12 h) is a possible alternative, although rare doxycycline-resistant strains of *B. anthracis* are known. These recommendations are based solely on *in vitro* data and data from animal models[20]; no human clinical experience with these regimens exists. In cases of endemic anthrax, or where organisms are known to be susceptible, penicillin G (2 million units I.V. q 2 h or 4 million units I.V. q 4 h) is recommended.

Post-exposure prophylaxis against anthrax may be achieved with oral ciprofloxacin (500 mg orally q 12 h) or doxycycline (100 mg orally q 12 h), and all persons exposed to a bioterrorist incident involving anthrax should be administered one of these regimens at the earliest possible opportunity. In cases of threatened or suspected release of anthrax, chemoprophylaxis can be delayed 24 to 48 hours, until the threat is verified. Chemoprophylaxis can be discontinued if the threat is found to be false. Levofloxacin and ofloxacin would be potential alternatives to ciprofloxacin. In addition to receiving chemoprophylaxis, exposed persons should be immunized. On the basis of animal data (wherein an appreciable number of unvaccinated primates died when antibiotics were withdrawn after 30 days of therapy)[21], chemoprophylaxis is best continued until the exposed persons have received at least three doses of vaccine (thus, for a minimum of 4 weeks). If vaccine is unavailable, some recommend that chemoprophylaxis be continued for 8 weeks[22,23]. The available vaccine is given in a pre-exposure regimen at 0, 2, and 4 weeks, and at 6, 12, and 18 months. Persons at continuing risk for exposure should receive yearly boosters. Exposed persons should receive at least three doses (at 0, 2, and 4 weeks), assuming no further exposure is likely, before discontinuing chemoprophylaxis.

On July 28, 2000, the FDA's Anti-Infective Drug Products Advisory Committee unanimously recommended the approval of Cipro® for inhalational anthrax (post-exposure) based on the available scientific data and consideration of the special circumstances surrounding the potential use of the drug.

VDDI

The recommended adult dose of Cipro® for post-exposure inhalational anthrax is 500 milligrams given orally twice a day. The recommended pediatric dose of Cipro® for post-exposure inhalational anthrax is 15 mg/kg given orally twice a day. The adult intravenous dose is 400 mg twice a day; the pediatric intravenous dose is 10 mg/kg twice a day. Treatment with ciprofloxacin should begin as soon as possible after exposure. The Drug should be administered for a total of 60 days.

The most common adverse drug reactions observed with the use of ciprofloxacin include nausea, vomiting, diarrhea, abdominal pain, rash, headache, restlessness. In patients who have received ciprofloxacin for 60 days or longer, no new or unexpected adverse reactions were identified compared to patients receiving shorter approved regimens.

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VII. Appendix II Project Deliverables and Timelines

Inserted is a detailed analysis of the timeline and deliverables for this program from Preclinical to NDA

INSERT MS Project DoD IND-DNA Gantt

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VIII. REFERENCES

1. Pile et al., Anthrax as a potential biological warfare agent, Arch Intern Med 158: 429-34; Mar 9, 98.
2. Dixon TC, Meselson M, Guillemin J, Hanna, PC. Anthrax. 341(11) N. Engl J. Med. 1999;341:815-26.
3. Inglesby TV, Henderson DA, Bartlett JG, Ascher MS, Eitzen E, Friedlander AM, Hauer J, McDade J, Osterholm MT, O'Toole T, Parker G, Perl TM, Russell PK, Tonat K Anthrax as a biological weapon: medical and public health management. Working Group on Civilian Biodefense. JAMA 1999 May 12;281(18):1735-45
4. Abramova et al, Pathology of inhalational anthrax in 42 cases from the Sverdlovsk outbreak of 1979, Proc Natl Acad Sci USA 90: 2291-94 March 1991
5. Meselson et al, The Sverdlovsk anthrax outbreak of 1979, Science 266: 1202-08; Nov 18,94.
6. Brouillette WJ, Muccio DD, Jedrzejas M, Brouillette CG, Singh RK, Kearney JF, Devedjiev Y, Cristofoli W, DeLucas LJ, Garcia JG, and Schmitt L. "Methods of Synthesizing and Screening Inhibitors of Bacterial NAD Synthetase Enzyme, Compounds Thereof, and Methods of Treating Bacterial and Microbial Infections with Inhibitors of Bacterial NAD Synthetase Enzyme," U. S. Provisional Patent Application 60/097,880, Aug. 25, 1998; PCT/US99/00810, January 14, 1999; PCT/US99/14839, June 30, 1999.
7. Report of a WHO group of consultants. Health aspects of chemical and biological weapons. Geneva: World Health Organization 1970; 97-9.
8. Science Applications International Corporation. Effectiveness of medical intervention against battlefield levels of *Bacillus anthracis*. 1993.
9. Meselson M, Guillemin J, Hugh-Jones M, Langmuir A, Popova I, Shelokov A, Yampolskaya O, et al. The Sverdlovsk anthrax outbreak of 1979. Science 1994; 266:1202-7.
10. Pomerantsev AP, Staritsin NA, Mockov YuV, Marinin LI Expression of cereolysine AB genes in Bacillus anthracis vaccine strain ensures protection against experimental hemolytic anthrax infection. *Vaccine* 1997 Dec;15(17-18):1846-50.
11. Pasteur L, Chamberlain C-E, Roux E. Compte rendu sommaire des experiences faites a Pouilly-le-Fort,pres Melun, sur la vaccination charbonneuse [French]. Comptes Rendus des seances De L'Academie des Sciences 1881; 92:1378-83.
12. Turner M. Anthrax in humans in Zimbabwe. Cent Afr J Med 1980; 26:160-1.
13. Harrison LH, Ezzell JW, Abshire TG, Kidd S, Kaufmann AF. Evaluation of serologic tests for diagnosis of anthrax after an outbreak of cutaneous anthrax in Paraguay. J Infect Dis 1989; 160:706-10.
14. Coker PR, Smith KL, Hugh-Jones ME. Anthrax in the USA. Proceedings of the Third International Conference on Anthrax, Plymouth, England, September 7-10, 1998:44 [abstract].
15. Sidell FR, Patrick WC, Dashiell TR, editors. Jane's Chem-Bio Handbook. Alexandria (VA): Jane's Information Group; 1998; 229-44.
16. Centers for Disease Control and Prevention. Summary of notifiable diseases, United States, 1997. MMWR Morb Mortal Wkly Rep 1998; 46:74.

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17. Brachman PS, Friedlander AM. Anthrax. In: Plotkin & Mortimer, editors. Vaccines. Philadelphia (PA):W.B. Saunders; 1994; 730.
18. Abramova FA, Grinberg LM, Yampolskaya OV, Walker DH. Pathology of inhalational anthrax in 42 cases from the Sverdlovsk outbreak of 1979. Proc Natl Acad Sci U S A 1993; 90:2291-4.
19. Lightfoot NF, Scott RJD, Turnbull PCB. Antimicrobial susceptibility of *Bacillus anthracis.* Salisbury Medical Bulletin Suppl 1990; 68:95-8.
20. Kelly DJ, Chulay JD, Mikesell P, Friedlander AM. Serum concentrations of penicillin, doxycycline, and ciprofloxacin during prolonged therapy in rhesus monkeys. J Infect Dis 1992; 166:1184-7.
21. Friedlander AM, Welkos SL, Pitt MLM, Ezzell JW, Worsham PL, Rose KJ, et al. Post-exposure prophylaxis against experimental inhalation anthrax. J Infect Dis 1993; 167:1239-42.
22. Centers for Disease Control and Prevention. Bioterrorism alleging use of anthrax and interim guidelines for management-United States, 1998. MMWR Morb Mortal Wkly Rep 1999; 48:69-74.
23. FDA briefing package anti-infective drug products Advisory committee meeting July 28, 2000 Supplemental New Drug Applications 19-537, 19-847, 19-857, 19-858, 20-780 CIPRO (ciprofloxacin), Bayer Corporation Pharmaceutical Division, for post-exposure prophylaxis of clinical disease from inhaled *B. anthracis.*

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GONE

1. FTRC
2. RAHB
3. WDMD
4. STHJ
5. HEPT
6. HAJF
7. EPTU
8. GAPT
9. AWGR
12. WMJY
13. BJDE
14. JDMH
15. MAGD
16. MACC
17. PTRM
18. AJTY
19. WWCI
20. DBNR
21. ECBH

***Keep in mind the leadership at Ft. Wayne **falsely reported** to GAO and the media that only 9 pilots left because of the shot. They know as I do, and many could testify, their numbers are false.

2 of these 21 pilots listed changed their minds, came back and agreed to take the shot. However, then DOD policy changed. They were not forced to take the shots. However, please note the leadership at Ft. Wayne offered to get "special permission, a waiver" to violate current DOD policy, "inventing" their own policy again, to allow them to give these 2 pilots the shot—presumably out of revenge, definitely out of control.

If DOD or Ft. Wayne wants to "fudge" the numbers again, let's look at it another way: who they had to hire to replace the departed.

PLACEMENTS

1. RAMF
2. BADJ
3. CHJN
4. CECB
5. JEDF
6. LAGF
7. DHJD
8. CJLV
9. RJMK
10. DMRL
11. TDRO
12. DIMF
13. MPVR
14. WBBP
15. **VACANT**
16. **VACANT**
17. **VACANT**
18. **VACANT**
19. **VACANT**

Note the 5 **VACANCIES after they had to hire 14 new pilots, all at various stages of flying currencies, & qualifications—some requiring attendance at formal F-16 school. The experience and cohesiveness of this fighter squadron were demolished and they are now on a rebuilding program. Plus, the top 2 flying leadership jobs have been essentially unfilled for the last 11/2-2 yrs by noncurrent pilots. Ft.Wayne's flying leadership has been virtually nonexistent, compared to the way a fighter squadron should be run.

1. Wing Commander—filled
2. Operations Group Commander—VACANT of a current F-16 pilot since 25 Feb 99: 11/2 years.

Squadron Commander—VACANT of a current F-16 pilot since 18 Nov 98: 2 years.

Virtual Drug Development, Inc.
A New Value Proposition

R. Stephen Porter, Pharm.D., MRCP
President, CEO
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www.virtualdrugdevelopment.com



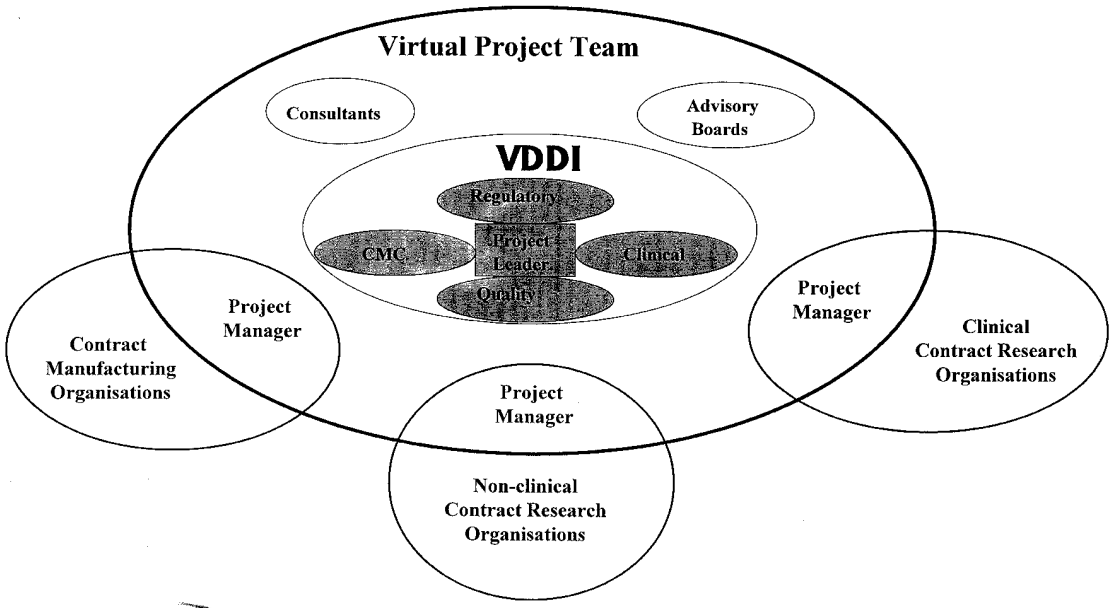
Executive Summary

- VDDI is a specialty pharmaceutical company utilizing global and cost-effective strategies to acquire, develop, license, and commercialize novel pharmaceutical products.
- VDDI represents a new value proposition that streamlines traditional drug development using an array of enabeling technologies.

"Virtual" vs. Traditional Drug Development

- Investment in intellectual capital, not bricks and mortar.
- Global access to product development expertise.
- Internet backbone allowing 24/7/365 development efforts.
- Expedited decision cycles, no bureaucratic drag.

VDDI's Virtual Drug Development Model



NAD Synthetase Program:
B. Anthracis Infectious Diseases

NAD Synthetase is an Attractive Target

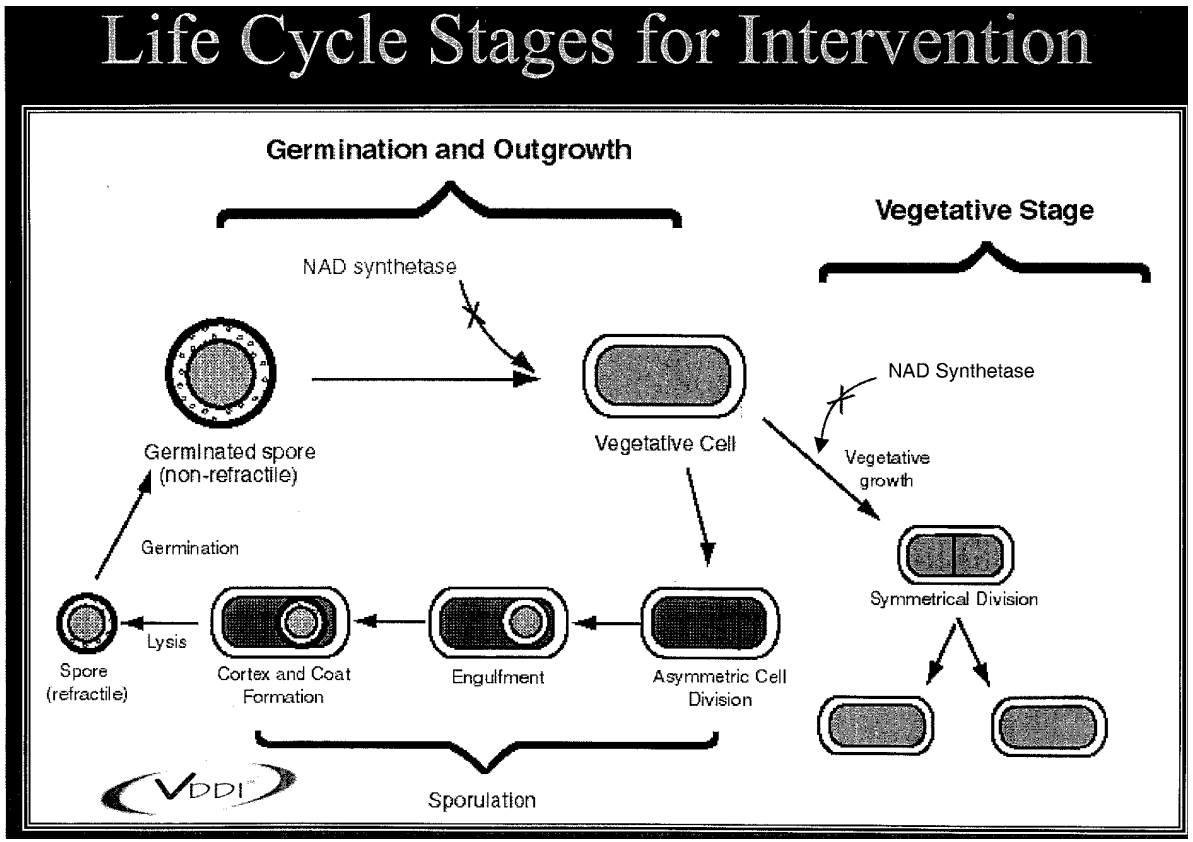
- An essential enzyme for gram positive (MRSA, VREF, CNS) bacteria and for fungal growth
  - Mutants impaired in NAD synthetase activity are non-viable, therefore functional mutation assumed impossible.
  - The bacterial enzymes are highly homologous, however the human enzyme is very different (10X larger molecular weight) with different substrate requirements.

NAD Synthetase Inhibitor

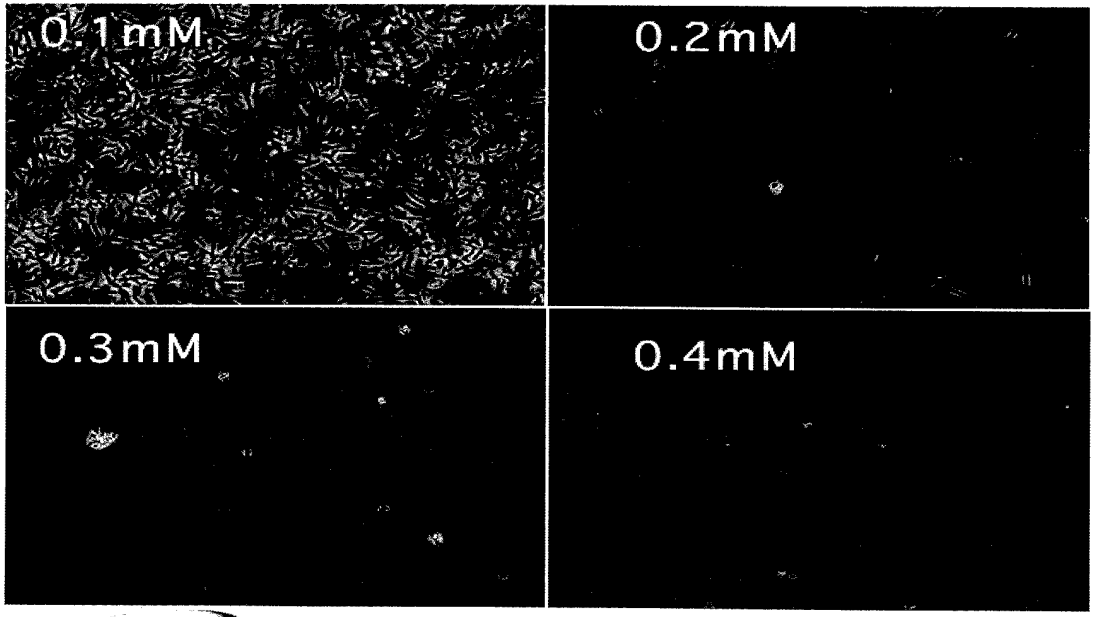
- Structure-based and "targeted" small molecule drug.
- Platform technology with applications for resistant infections.
- DARPA funding in excess $6 Million.
- Excellent in-vitro activity.

binding site
binding site

Life Cycle Stages for Intervention



Inhibition of B. subtilis by WAC1-89



MIC$_{100}$ Lead Compounds against B. anthracis

Compound	Strain	MIC$_{100}$ (μM)
WAC 1-89	Ames	167
	Sterne	167
	Delta Ames	83
409	Ames	3
270	Ames	3
274	Ames	3

VDDI Approach to Commercialization

- SBIR Grant Filed 12-15-99 Approved $136,000.
- FDA Approval of regulations facilitating Bio-Weapons Initiatives.
- Three species toxicology program with allometric scaling.
- Rabbit & Rhesus monkey interdiction (BSL3-4).
- Two human NL subject PK studies with surrogate correlation to animal data [Plasma/ tissue].
- Commercialization est. costs $17-20 Million.

Mr. BURTON. Dr. Porter, one of the problems I have is understanding a foreign language that I have never studied. I have absolutely no idea what you just said.

Dr. PORTER. I take that as a compliment, I guess.

Mr. BURTON. Well, I guess you could take it that way, but what I would like for you to do, Dr. Porter, if you could, because I think probably other Members have some questions about what you just said, could you very briefly give us a snapshot of what you are talking about; what, in effect, you just said in layman's language?

Dr. PORTER. The use of a rapidly deployable oral antibiotic that would be used as a prophylactic regimen during a period of engagement in the theater of war with exposure to biological weapons, particularly B. anthracis.

Mr. BURTON. So it could be used in a battlefield situation prior to contact with the enemy when you thought they might be using an anthrax-type weapon.

Dr. PORTER. That is the premise. I think most people in infectious disease research and people who work in Third World countries understand the use of prophylactic antibiotics, including tetracycline or ciprofloxacin as a means of preventing zoonotic disease exposure.

Mr. BURTON. Thank you very much. We have been joined by Mr. Walter Jones who has been very active in this. Have we been joined by any other Members? Ms. Schakowsky has joined us. Do you have any opening comments, Ms. Schakowsky?

If not, we will now go to questions. Let me start, if it is all right, with those of you—Mr. Shays was the first one here. Mr. Shays, you have been very active in this investigation from day 1. Would you like to wait?

Mr. SHAYS. I will pass.

Mr. BURTON. OK. Let me start with Mr. Heemstra. I think you probably covered this already, but do you feel that you have been retaliated against because of your testifying last year before this subcommittee?

Mr. HEEMSTRA. Yes, sir, very directly. I testified to the subcommittee on September 29. On, I think it was November 24 or 25, I was grounded arbitrarily after I had been flying, you know, as a normal F–16, current, ready-to-go-to-war pilot. An arbitrary reason was that stress was affecting me, and I have many, a multitude of witnesses that will testify otherwise, that stress was having no effect on my performance.

Mr. BURTON. You have already talked about a number of the squadrons around the country that have been adversely affected by this program. I think one of the things that all of the Members ought to be aware of, and maybe you could explain this, is the impact on our readiness. A lot of people look at the Reserve as something that comes as a secondary part of any kind of military engagement.

Would you explain how important it is that the Reserves be militarily ready and how that figures into the overall equation if we go into a conflict?

Mr. HEEMSTRA. Yes, sir. Increasingly, the Guard is being called up to help the active duty and relieve them on some of the deployments that have been going on. So as much as every year and a

half, it seems that we are being called up to deploy to real world locations. In our case we had to get help from other units because we faced the anthrax shot. But increasingly, we are called upon. And if we are going to lose another 2,000 pilots—I understand from a briefing I received at the Air Force Academy a year ago that we are already 2,000 pilots short nationwide—so if we lose another 2,000 because the shot program continues, that will be 4,000 out of about a 14,000-strong pilot force that they would like to have. That is a huge chunk.

Mr. BURTON. So the Reserves around this country are an absolute, essential, immediate part of any defense program.

Mr. HEEMSTRA. Yes, sir. Not only are we called upon to go do those things, we are just as current and ready and experienced to go do those jobs, even though we only do it, many of us, in a part-time role.

Mr. BURTON. Mr. Marohn, why is it, Captain, that you just did not simply resign?

Mr. MAROHN. I was not allowed to, due to my commitment.

Mr. BURTON. How long was your commitment?

Mr. MAROHN. I believe it was for 7 years. My commitment is up this coming May 20.

Mr. BURTON. This May 20. So your commitment is up May 20.

Mr. MAROHN. Yes, sir.

Mr. BURTON. And yet they said they were going to fine you $300-some or 300-some days in jail.

Mr. MAROHN. That is correct.

Mr. BURTON. The DOD stated in their testimony that they have taken steps to utilize tools that more effectively relay information. How did your unit find out about the most recent slowdown of the AVIP, and is this normally how important information is disseminated to units?

Mr. MAROHN. It was just happenstance that they found out, and it was only disseminated to really just a few select individuals.

Mr. BURTON. So they didn't sit down with the unit and just go through the whole thing and give you a complete story of how this thing was going to play out?

Mr. MAROHN. No, they did not.

Mr. BURTON. Just a few individuals knew how it, by word of mouth, it passed through the unit?

Mr. MAROHN. One of our ladies that deals with airfield management received a message just through happenstance, like I said that, hey, here is something, if you are interested; you know, tell whoever. Which she only disseminated the e-mail to people that she thought might be interested, those that were reluctant to take the shot, and obviously myself. I was very interested in hearing that. That is how I learned of the slowdown program.

Nothing was ever called by any of the commanders in any of the commanders calls to tell everybody on a wide scale, hey, this is what is going on with the program right now.

Mr. BURTON. So you really didn't have the complete information that you and the rest of your unit needed?

Mr. MAROHN. Correct.

Mr. BURTON. Mr. Craigen said before this committee that Reservists were not going to be punished if they decided not to take the shot. How is that different from what you experienced?

Mr. MAROHN. Totally different.

Mr. BURTON. So what he said before the committee was not accurate?

Mr. MAROHN. Well, I am sitting here today wondering whether, you know, if I pay this fine or not, whether I am going to go to jail. I have an Article 15 on my record right now. So I would say that that would be an accurate assessment.

Mr. BURTON. We need to talk to Mr. Craigen again about that.

Mr. Ross, you stated in your testimony that in only nine Guard units, representing 12 percent of the air National Guard, 260 pilots chose to leave the Guard instead of taking the vaccine. Do you agree with the statement of the DOD when they say that documented losses from such cases are a very small minority?

Mr. ROSS. No, Mr. Chairman. Obviously, I think the numbers that were cited before, anywhere from 25 to 50 percent of the units, is more accurate. Just as Colonel Heemstra testified, this was not an unknown happening that was going to come on our unit. Once we got back from Kosovo last year, we knew that we were going to face this situation. I informed my boss and his boss, the one commander, that I anticipated that our unit would be no different from any other unit. There was no reason to think it wouldn't; 25 to 50 percent had been the running number in these units that preceded us. Battle Creek has not been one of the leading units due to our timing, so we could sit back and watch these other nine units. So we had the luxury, if you will, of seeing the experience and knowing that 25 to 50 percent was more accurate.

Mr. BURTON. So when the military comes before this committee or one of our subcommittees and they tell us that it is a very small minority, that is blatantly false?

Mr. ROSS. Yes, Mr. Chairman, in my opinion.

Mr. BURTON. Article 134 of the Military Code and Article 107 says that false official statements—and I presume a statement to the Congress of the United States would be considered a false statement if it is under oath—can result in a court-martial. So officers from the Pentagon that come over here and tell us one thing and then the facts say something else, they are in violation of the Military Code of Conduct, right?

Mr. ROSS. Yes, Mr. Chairman, I believe they could be.

Mr. BURTON. I understand that lying is punishable under Article 134 and is punishable by dismissal, forfeiture of all pay and allowances, including retirement, and incarceration.

OK. I think I have gone through—let me just go through, Dr. Porter, just a couple more questions. Are any of you commercial pilots?

Mr. HEEMSTRA. Yes.

Mr. ROSS. Yes.

Mr. MAROHN. Yes.

Mr. BURTON. You are all commercial pilots? Can you tell me real quickly if you know of any pilots who are in the Guard who have experienced dizziness or any side effects that may affect their ability to fly a commercial aircraft?

Mr. HEEMSTRA. Yes, sir, I do. I have heard of several incidents and of course those people don't want—obviously need to protect their careers.

Mr. BURTON. I understand that. But, you know, everybody in America ought to be concerned about this. The Congress people at this dais, we all fly back and forth to our districts or someplace in the country almost every week. The people in this room, people across the country, put their lives in the hands of pilots every week. And if they are getting vaccinations that impair their ability to fly a plane that is carrying passengers in this country, then that goes beyond just military preparedness and the military problems that can be incurred in a conflict.

You are telling me that some of the pilots that have received the anthrax vaccine have had side effects that include dizziness and other things that could impair their ability to fly a commercial aircraft.

Mr. MAROHN. Sir, one of our pilots, after receiving the shot, was in the middle of a trip with his airline, and had to be removed from that trip because he was so sick.

Mr. BURTON. What kind of sickness did he incur?

Mr. MAROHN. He had slight dizziness, but more importantly, he had broken out in a cold sweat, feverish conditions, aches, and an unknown rash that had occurred. But it had wiped him out physically to the point where he was unable to perform his duty as a pilot.

Mr. BURTON. So the copilot had to take over?

Mr. MAROHN. They reassigned another pilot to that.

Mr. BURTON. How long after the shot did that take place, do you recall?

Mr. MAROHN. I don't recall.

Mr. ROSS. Mr. Chairman, I have also had some experience with that with a few of the pilots in my unit that did take the shot. Again, as was stated before, most of them are reluctant to come forward with any kind of a reaction. I will say that, you know, the folks that I know, to their credit, that the pilots do know the responsibility of flying sick, and will request to be removed from their trip or not even go on their trip and report in sick.

The one instance that I can think of was one of the pilots had a numbing in his arm that he got the shot in that persisted for a fairly long time. He was understandably reluctant to say anything about it, and in between, he was on the schedule where he was taking shots every 2 weeks, so he was basically not with his airline for that first week and he was waiting to see if his arm would, in fact—the feeling would come back in his arm.

So I think you will find that it is a very hard subject to approach a pilot out there, but you are absolutely correct in the effect. I don't know of any pilots that would knowingly fly sick, but this does affect their job as you say, and they then have to either come off the trip in the middle of a trip such as Captain Marohn said or report sick for the trip.

Mr. BURTON. I understand and I appreciate that, and I am sure they are very concerned about not only their safety but the safety of their passengers. But that does not alter the fact that if they are in the middle of a flight and experience dizziness or something that

impairs their ability to get that plane to the ground safely, that it could, in effect, endanger not just themselves, but a whole host of people.

Mr. ROSS. Yes.

Mr. BURTON. Mr. Cummings, would you like to ask some questions?

Mr. CUMMINGS. Thank you very much, Mr. Chairman. I have a few questions here.

Last week, we had another hearing on this same subject, and the testimony was troubling and it was—it made me feel very uncomfortable as to what the military might be doing with regard to this vaccine. We had some people who came in and talked about how their relatives died and they linked it to the vaccine. I want to make it clear that all of us up here, no matter what side of the aisle we sit on, are concerned about our military. Our military makes it possible for us to enjoy the freedom that we enjoy.

So in that light, I just want to ask a few questions.

Now, Mr. Ross, when the chairman asked you about the military coming up after you all testifying, and having contrary testimony to what you have stated, I am just wondering, might the difference—and I am certainly not here to defend the military, but I am just curious—might the difference be that they get—there is something called exit interviews, is that right? I mean something where you talk about——

Mr. ROSS. Yes, Congressman.

Mr. CUMMINGS. OK. And just listening to what I have heard here this morning, I take it that sometimes those exit interviews may not always be accurate, out of fear?

Mr. ROSS. Yes. And I went through this period with my pilots in discussing this with them about exit interviews and being truthful. There are two viewpoints on this. A number of my guys wanted to be very activist, if you will, and make sure that they knew that they were leaving for the anthrax vaccine, and I did not discourage that. On the other side, as their commander, I also told them, at least at my unit, that the wing commanders, you know, if you were going to be disobeying an order, that there were serious consequences on that. So we tried to lead turn, the very thing you are talking about, and not forcing any action that did not need to go to that level.

Consequently, on the exit interview then, when these individuals—as the commander I would get the first exit interview, and then my boss, and ultimately his boss, and that was the wing commander. A number of pilots—and I think that it would be fair to say that my unit would say to the 15 pilots that have left, that they did not all leave because of the anthrax vaccine. The way they will justify that is they will say it was not the No. 1 thing they left for, and I do not disagree with that. There are a number of pressures and other things on the Guard and Reserve in the first place, besides this shot. But certainly, when they come up and they say, you take the shot by this date or not, then it is somewhere in the factoring of the timing of that shot.

So I think that you will find, and I think the GAO reported this, at least when they came to Battle Creek and they interviewed ev-

erybody that left, that the No. 1 reason may not have been anthrax with a certain individual; but if you look, it was the No. 2 reason.

Mr. CUMMINGS. I think that if you were to look at people in the military, the ones I have gotten to know, they, most of them, love their careers.

Mr. ROSS. Absolutely.

Mr. CUMMINGS. So I think you can put one and one together and come up with the right conclusions. But in the exit interviews, is it normally more than one reason?

Mr. ROSS. It varies with individuals, but there is usually cited, I would say, from one to three reasons. Again, one of the things that we did not know at the time as we were going through this was, there was a distinct fear amongst the pilots, even the ones leaving, that if they said they were leaving for anthrax, that they would somehow be punished.

Mr. CUMMINGS. Might we have situations where none of the three reasons—or the reasons were anthrax? In other words, I am talking about whatever documentation—you know——

Mr. ROSS. It is possible; it is possible.

Mr. CUMMINGS. What I am trying to get to is that I don't want—I saw where the chairman was going, and he talked about criminal violations and things of that nature with regard to these military officers that are going to be testifying in a few minutes. And as an attorney and one who is concerned about those kinds of issues, I don't want them to be set up so that when they come up here and testify, they are basing their testimony on documents, and then somebody says oh, we caught them.

Mr. ROSS. I understand that.

Mr. CUMMINGS. I just wanted to see if we could just clarify, you know, what happens in that process. But the bottom line is, and if you will just allow me just a second, Mr. Chairman, I think what you have said is so important in that we should be concerned about the real reasons why people are leaving our military. We should be. That is very, very important. At the same time, I think it helps that if the people who are in charge know, I mean, and have knowledge as to why they are leaving, that is one thing; but if they don't have knowledge, that is another thing. I guess that is what I am trying to point out.

Mr. ROSS. Congressman, I think on the GAO survey you will find also that you have to be asked the question in order to respond yes or no to it. So I think that that is also part of the problem here. I know when guys interviewed with me, exiting, what questions I asked. But I also know, having filled out surveys as recently as last month, that I was sent by the Department of Defense as a Reservist, there was not one question in that survey as to why I had left my previous job due to the anthrax vaccine. It wasn't even covered in the survey and the survey was some 75 questions long.

So I think you have to ask the question.

Mr. CUMMINGS. Thank you very much.

Mr. BURTON. The question was not even in the survey?

Mr. ROSS. No, not at all. And my wife received one as a spouse also, and there was nothing in her survey either.

Mr. BURTON. I think Mr. Souder was next. Mr. Souder.

Mr. SOUDER. Thank you, Mr. Chairman. A couple of basic questions for the record.

Colonel Heemstra, what percentage of the pilots in Fort Wayne work in the airline industry?

Mr. HEEMSTRA. I would say it is about three-quarters, about 75 percent.

Mr. SOUDER. Because I wanted to reiterate Chairman Burton's point. We talk about Passenger Bill of Rights. Part of the Passenger Bill of Rights ought to know the status of their pilots, and I know that in the private expressions to me from the pilots in Fort Wayne, that there was a lot of concern that if the airlines get overjumpy, they may not employ people in the Guard, and this is a primary method of employment for people in the Guard. So one of the difficulties of us even having hearings like this is, it complicates recruiting and other things for the Guard, and yet the people have a right to know that. It is a very difficult balance.

If you were—as I have met with different people in the Department of Defense and in the Guard. One of the problems is that they are trying to make decisions, to followup on Mr. Cummings' point, on the data that exists in front of them. And this data is at best mixed, and for multiple reasons, all of which are legitimate: career, punishment, keeping future options, we are not getting a full data base.

How would you address that problem if you were in command at the Department of Defense? In other words, how would you get this accurate data?

Mr. HEEMSTRA. I think it is important to be in touch with your troops and that gets down to the grass-roots level. So GAO's survey was certainly helpful. And I met with the team before they came out to Fort Wayne and hit the bases that they interviewed, and we tried to find ways to get the real data up to you. That is probably the best way that I can think of. But as Colonel Ross was telling Mr. Cummings, in exit interviews you are not always asked the question. And also, to protect their careers, because many of these people transferred, they don't want to say that it was anthrax, because then that is going to affect their future careers.

Mr. SOUDER. So the No. 1 thing is they ought to be seeking the truth through the questions, trying to track the data; when they give the shot, make sure there is a health register that is clear for everybody as to the after-effects. And if it is in dispute—for example, we have one case in Fort Wayne where not a pilot, but a technician who initially said he was going to take the test, and volunteered and went in to take the test, has had medical complications ever since that point, that it isn't showing up, partly because they are in dispute whether the medical complications came from the shot. But we ought to have some sort of an inventory of every single shot and whether there is even a dispute as to whether the followup is there. I sense that in Fort Wayne, that is becoming done more, and hopefully around the country, but you can't do a see-no-evil, hear-no-evil thing in trying to address this.

I have another kind of general opinion that I think it is important to get on the record. When we started working with the antiterrorism issue about 3 years ago in the subcommittee that Chairman Shays now is head of, one of the trips with now Speaker

Hastert, we went over to the Middle East, and we were at Prince Sultan and Incirlik. We met with the people who, several of the inspectors who at that point had been kicked out of Iraq, and one thing that became clear in talking to base commanders is that the blame game is partly what is driving this policy right now.

In other words, everybody is afraid of having some sort of a terrorist attack when they are in command, and the punishment of several individuals in a symbolic way at Khobar Towers where we went to visit has made our commanders so jumpy that they are, in my opinion, skipping steps that normally would have been taken in vaccines and other antiterrorism things, because they are afraid of being blamed, and it has complicated our ability to address this whole question.

Now, one thing that I hear from the Guard, which is a legitimate concern—I favor voluntary for the Guard, the Guard did not sign up in the same way, even though they are used the same way as regular military—there is a concern that the Guard and the Reserves would be treated as second rate if somehow you are voluntary and the regular military is not.

Do any of you share that concern, or can we, in fact, have a difference even though you are going into the same arena? It is interesting to me that apparently the Department of Defense personnel, based on the same Embassies and the same areas, do not have to mandatorily take the shot. Department of State employees do not have to take the shot, even if they are based in the Middle East; it is voluntary. There clearly are some gradations.

Do you have any concerns that it could hurt the image of the Guard and Reserve if you are voluntary and the regular military is not?

Mr. HEEMSTRA. I think it is perfectly valid that they are treated differently since they are different, and many of us have civilian airline careers. For example, I have to have an FAA physical every 6 months to fly international, so if I had symptoms from the shot, I would have to decide whether to be truthful on that and let my doctor know, or not. So, there are some circumstances for Guard and Reserve pilots that are obviously different than active duty. But I think now that the policy has been slowed down where you are not required to get the shot if you are not going to be there on the ground more than 30 days, well, as Guard and Reserve pilots, we never go anywhere more than 30 days, because then we lose our full-time employee benefits through our airlines. So that usually—that policy now is very effective, I think.

Mr. SOUDER. Mr. Chairman, may I ask one question of Mr. Ross?

Mr. BURTON. Yes, and if you would, I would like you to yield to me after you ask that question.

Go ahead.

Mr. SOUDER. Mr. Ross, one of the concerns with the way the anthrax vaccine was developed was that they don't have FDA approval and that, in fact, we have concerns that it is not being cross-tested.

In your proposed method, would that be FDA-approved and would it be cross-tested?

Dr. PORTER. I think you meant the question to Dr. Porter.

Mr. SOUDER. Yes, I am sorry.

Dr. PORTER. We expect full compliance with the FDA regulations for approval of this product, and the unique difference that we offer is that because of the regulations that have recently been promulgated in the Federal Register, that we can fast track this approval through an abbreviated program that would be much different than a typical antibiotic development schedule.

Mr. SOUDER. Would it be studied as to its cross-impact with other vaccinations that the forces are taking?

Dr. PORTER. It would not necessarily be required to be tested against adjunctive vaccines, but we would like to see that work accomplished in animal studies for sure, not in humans.

Mr. SOUDER. Thank you. I yield to the chairman.

Mr. BURTON. His time has expired, but I really want to ask one quick question.

The people on active duty who are flying who have a 3- or 4-year obligation, or there is 1 year left on their obligation to serve in the military, that are pilots, would they not have the same concerns? Because when they leave the service, many of them want to become airline pilots and it has to do with their future incomes as well. Would they not be concerned about this as well?

Mr. HEEMSTRA. Yes, Mr. Chairman, they would be concerned if they had any symptoms, and those probably would be detected in the rigorous physicals that they have done by the airlines before they get their job. So they would probably be screened out and wouldn't even get hired.

Mr. BURTON. The reason I ask that is, GAO has not surveyed the active military, but I think a logical person would assume that the same concerns that you fellows have and the other people in the Reserve have, the active duty people would have because of the long-term problems that they might face.

Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. I have just a few questions. I want to, once again, express my discomfort with the way that our members of the armed services have been treated by the Department of Defense. My husband is a pilot, a general aviation pilot. My experience with pilots is that they want to fly. They are not looking for reasons to not fly or making up symptoms of things that would disqualify one from being able to fly. So I listened carefully when pilots came to other hearings and gave reasons for their decisions and the pain that they felt, personal, emotional pain from not being able to fly, in addition to the symptoms that they connected to anthrax.

But what bothers me, and Representative Souder described it, is that we are not somehow seeking the truth, that is how it feels to me; that in all of our hearings we have heard that there have been no long-term studies, there have been precious few short-term studies, there have been problems with the manufacturer, with the product that has been developed, and on and on and on.

I have to tell you, and I have said this before, my initial response to this, my gut feeling before the hearings started, was "be a man, roll up your sleeve, take the shots, that is the rule." And increasingly, as I have heard what has happened, I feel less and less convinced of that, particularly because it doesn't seem as if we are any

further along now with answers. Yet, we seem to be further along with a fairly punitive approach.

Mr. Ross, in some ways I think you answered the question. When we look at the findings in the GAO report, what you are saying and what others have said is that there is a possibility that reasons that were given other than anthrax because even after leaving, there could be some retribution. What could that be? What kind of risk is perceived?

Mr. ROSS. As Colonel Heemstra said, most of the transfers, short of a retirement from an individual, is transferring into the Air Force Reserve or into another job that is not a—a job that does not require the deployment. In most cases, in all cases at my unit, it was transferring to jobs, those that did stay either in the Air Force Reserve or into the National Guard, to non-flying jobs. So the concern is that there would be some sort of tracking or some sort of way to continue retribution on an individual who has chosen to leave the current flying position they are in, but they want to continue their service in the National Guard or in the Air Force Reserve.

Very few—in fact, at my squadron, at my base, the wing commander would not accept anyone's resignation outright. No one was allowed to do anything other than transfer into the individual Ready Reserve of the Air Force Reserve, or retire. So if you wanted to resign, you had to first transfer to the Air Force Reserve and then resign from there. I surmised that that was because then there would not be the record of a resignation from my unit. That would be dealt with with the Air Force Reserve.

Mr. BURTON. Ms. Schakowsky, would you yield for just a moment?

Ms. SCHAKOWSKY. Yes.

Mr. BURTON. One of the things—and you brought this up, and that is why I would like to at this time maybe give you a little information. We wrote a letter to the Department of Defense. They sent out two surveys, one to the active duty Reservists and one to their wives. It is a very voluminous document. There is not one question about the Gulf War Syndrome or about anthrax in here; and when we said, why don't you add an addendum to this so that that can be factored into the equation as to why these people are leaving, they wrote back and said they would not do that.

So your question about the right questions being asked, the two surveys that were started to be sent out in August of this year, none of them, none of the questions referred to the Gulf War Syndrome or anthrax, and that is one of the major reasons, according to these gentlemen and others, that they are leaving the Reserves. So the Pentagon evidently does not want to know and they are not asking the question.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. Let me just say that the responses to your inquiry as to why those questions weren't included seem fairly unsatisfactory to me. We have systems that are supposedly designed to track information, like the VAERS system, but again testimony that we have heard suggests that people are discouraged from using systems.

Could I just ask one more question?

Could it be that there is somehow an overstatement or exaggeration, or misperception of the retribution that could occur? Could it be more attributable perhaps to a rumor mill, you know how those things can get started, or to what extent are we looking at reality here from members of our armed services?

For anyone to answer.

Mr. HEEMSTRA. Well, I think a great example is being threatened to be put in jail. I think a great example is that my performance reports were tarnished, I was grounded illegally after testifying before you, and then finally forced to retire. So if you put something on your form that says that you transferred because of anthrax, and as Colonel Ross was saying, many of these people didn't have the option to retire. There are maybe 1 or 2 out of 20 even have the years in to retire, so most transferred. So when you go into the inactive Reserve, the reason I left was because of anthrax; when you try to come back in maybe to finish up your years, they are going to say well, you disobeyed a lawful order and your record is already tarnished anyway.

So I don't think it is an exaggerated threat at all. I think many are still hopeful that—we know that it is a slow process—but that Washington will shake things up and get this thing straightened out and it will go away, and then they would like to come back in and still serve their country and still fly.

Ms. SCHAKOWSKY. Thank you.

Mr. BURTON. Thank you, Ms. Schakowsky, and thank you for yielding.

Mr. Horn.

Mr. HORN. Thank you, Mr. Chairman.

Some of these questions should go to General West and General Weaver, but I won't be able to get here, so perhaps we can ask them the same thing and get their response in the record.

I am curious; to your knowledge, those of you on panel one here, the degree to which it goes up the hierarchy, both in terms of—let's say in the Army equivalent—I realize you are in the Air Force, but the wing or the regiment and so forth. How far up did it go to require vaccination of officers above you, and how about the technicians? So what was the criteria that you had to follow on your base for the people above you?

Mr. MAROHN. Sir, everybody that was in a deployable AFSC was required by our State to take the shot. Commanders were encouraged to take it to give the troops a sense of safety, I guess, and when Colonel Heemstra did not do that before the deadline, he was punished; unfairly, in our mind. But we were all required to take the shot, all the way from the enlisted——

Mr. HORN. Did that go up on the air staff and the Joint Chiefs? Did they take it?

Mr. MAROHN. I believe so.

Mr. HORN. How about the technicians? You never know where they are going to be under fire, but you need them.

Mr. MAROHN. All of the technicians were, I guess, requested to be in the front of the line, so to speak.

Mr. HORN. So was anybody left out of that hierarchy?

Mr. MAROHN. Not that I am aware of. Only the people that were in a nondeployable AFSC.

Mr. HEEMSTRA. Sir, just to pick back up on that, there were reports that there was a unit—and I don't have this verified yet—in New York that, I guess they were required to take the shot. Supposedly 90 percent of them put in resignation papers, so they were going to lose 90 percent of their pilots. That would have totally shut down the unit, and we were told that the National Guard Bureau allowed them to not have to take the shot. So I am not sure what exemption they were granted. You know, maybe because they weren't going to be on the ground in the threat areas for a certain period of time, or what. But somehow, I think maybe somebody was treated differently in this process and the Guard Bureau might have been involved in that. And we don't have it verified; I am sorry.

Mr. HORN. Well, that is interesting, because obviously they know that they can't fly very much if you don't have the technicians available, and they know they can go out for civilian occupations at three or four times what the Air Force is paying them.

The Gulf War Syndrome was mentioned. That would be out of people in the 1990's. How about Agent Orange? Anybody still around from the Vietnam War on the technician side? Did you ever have any of that? Because that was another one the Pentagon covered up and denied for years, finally getting around to it, and that is why this sort of gets to me when I see this kind of situation happen.

As was said, trust is what you have to have of the command above you, and if that trust breaks down, that is a real fault. And that is why I would be curious to have the generals reply to that, as to what were the exceptions and why were they excepted in the case of the Air Guard. And perhaps General Weaver can perhaps put that in the record, Mr. Chairman.

Mr. BURTON. Does that conclude your questioning, Mr. Horn?

Mr. HORN. I would like General Weaver, who is director of the International Guard, what exceptions were made and under what conditions that you didn't have to take the anthrax vaccination. Apparently there were exceptions.

Mr. BURTON. We will ask that that question be answered.

Mrs. Morella, I believe you are next.

Mrs. MORELLA. Thank you, Mr. Chairman. I think this is a very important continuation of the hearings that you have had on this issue, because there is just no doubt that this whole concept of the readiness of our military, and since the announcement of the mandatory vaccination program in 1997, growing numbers of military personnel, particularly the Guard and Reservists, are choosing to resign rather than take the anthrax vaccine. Many of them are confronted, as you have stated in your testimony, with the option, take the vaccine or leave the service; or there are recriminations that may occur.

Unfortunately, too many are choosing to leave. This is what we have seen in the GAO report. Questions about safety, efficacy, and the necessity of the anthrax vaccine program.

So I just think that we have a responsibility to make sure that trust is there; because obviously, if the anthrax vaccine is safe and can effectively combat the threat of anthrax for our military, the Pentagon has failed to convince the very people that they are try-

ing to protect. And I think that is what we want to get at. There are serious questions that have been raised, and this panel has helped to forward those questions to us, legitimate questions that have to be addressed in order to ensure our military receive the answers that we do need.

I guess having heard—and I thank you for coming before us, you are very courageous to give us your stories, but I would like to direct questions to Dr. Porter, because Dr. Porter seems to be pointing out that maybe there is an alternative that should be strongly considered. It appears as though your antibiotic for protection against biological weapons is one that would really assist. It also appears as though you already have—in your testimony you said, I think, you got $4 million as a start? When I look at your chart, ultimately, over a 4-year period we give you $16 million?

Dr. PORTER. We are asking for an additional almost $17 million to complete the development program through the approval processes, and $2 million immediately.

Mrs. MORELLA. $2 million right away.

Dr. PORTER. And $6 million has already been allocated through DARPA over a period of time to UAB.

Mrs. MORELLA. I know there have been a few questions asked of you about this. It sounds as though this is really on a go, a go path. And from what I think I heard you say to someone else, FDA is also going to be involved with looking at an approval process? Where are you? Do you have competition? What do you think you could do with this?

Dr. PORTER. As far as we understand, there is no competition relative to the target. There is "alternative antibiotics" that are available, but we think we have a unique advantage relative—vis-a-vis to the previous work done at USAMRIID and some of the mechanistic activity of the compound. We think that we have a compound that is a small molecule that is a pretty well-defined drug development process through the regulatory agencies. The FDA will be integral in the "buying in," if you will, of our development scheme. We think there has been a road map for that relative to the recent approval of ciprofloxacin, Cipro, which is a drug well known to the military for the use in this indication, and also they are currently stockpiling that compound. We think we have an advantage relative to the fact that this compound, as we are designing it, will have a much more narrow spectrum; therefore, an obligatory lack of some the broader-spectrum antibiotic side effect profiles that Cipro represents.

Mrs. MORELLA. Do you see it as a substitute for the anthrax vaccine?

Dr. PORTER. Our premise is that you have 2 to 8 hours before your body recognizes the anthrax, grows it out and then releases the toxin. The white cells that are found in your body, engulf the organisms that is the spore. Our premise is that if you were there before those spores were resident in the body, that those white cells would immediately be involved in the killing process if there is antibiotic resident within the body. You need to take this antibiotic for up to 60 days, because some of these spores can live almost in a dormant fashion within the lungs for 60 or more days, and this is well known and well described in animal trial work.

Mrs. MORELLA. Is General Weaver going to say that he thinks you are on the right path?

Dr. PORTER. I can't speak for General Weaver. We have had discussions with Dr. Anna Johnson-Wagener, we have submitted a formal proposal to them almost a month ago relative to this process. As I said, they should have been aware of the work done by USAMRIID and the funding that was associated with that. They have helped facilitate the repayment of certain funds to UAB, which we thank them for. But we think that we offer a viable alternative approach that could be—in relatively short order, provide a solution to the deployment and distribution and safety profile of a compound that would be used to prevent the toxic reactions to these biological weapons.

Mrs. MORELLA. Your timetable is what, about 4 years?

Dr. PORTER. About 4 years, correct.

Mrs. MORELLA. If I could just briefly ask you, gentlemen, if you have any comments about this possible alternative vaccine and what you think we should be doing in the meantime? What suggestions do you have for us? Any of you who would like to venture. It doesn't even have to be about that vaccine. I mean, do you think that we should right now say forget mandating voluntary? Because I know in some instances it is mandatory, in others it is voluntary, but it appears to be mandatory.

Mr. HEEMSTRA. Well, the new drug sounds hopeful, so I think we wouldn't have the attrition results that we are experiencing now and the readiness problems that we are having. So I think safety has been the No. 1 issue for the pilots that have left. And I think if we had had a voluntary shot program, we probably would have had maybe 10 percent, maybe 20 percent that would have taken the shot, similar to the British who have a voluntary shot program from what I understand. So I think a voluntary shot would fix things right now. And like I said, for the Guard and Reserve, with the policy the way it is now, not requiring it for if you are not going to be on the ground more than 30 days, that is going to save some of the retention problems that we were having before that.

Mrs. MORELLA. Do Mr. Marohn or Mr. Ross want to add anything to that?

Mr. MAROHN. I think anything other than what we have right now would be much better.

Mrs. MORELLA. You think a moratorium right now?

Mr. MAROHN. I think if this drug were proven safe and it was well documented, then I would not have a problem taking something like that.

Mr. ROSS. I agree, Congresswoman. At least a moratorium right now until the issues that have been raised by the committee are addressed. That, as a minimum, would help in the short term. I do think that Colonel Heemstra talked about in his testimony, too, some long-term suggestions so that, you know, the next vaccine down the road does not fall into the same category. Again, I think we get back to trust at that point.

Mrs. MORELLA. Thank you.

Thank you, Mr. Chairman.

Mr. BURTON. Thank you, Mrs. Morella. Chairman Gilman, I understand you have a question.

Mr. GILMAN. Thank you. I will be brief. Just, Dr. Porter, you say it is going to take you about 4 years to develop your vaccine?

Dr. PORTER. It is an antibiotic. Yes, that is the timetable for the negotiations. The FDA will further define that time scale.

Mr. GILMAN. What should be done or could be done in the interim period to prevent this present vaccine that has so many problems from being utilized? What can the military do to make some sort of a temporary method of providing a proper vaccine?

Dr. PORTER. Well, they have a whole basket of defense processes, including interdiction, physical interdiction, clothing. Also antibiotics are routinely part of their retinue against bioweapons, including ciprofloxacin as a treatment regimen, and I think they could help explore the use of that as a prophylactic regimen, although it has worked on animals in that regard.

Personally, in my opinion, I do not have direct obligatory knowledge of all of the problems associated with the vaccine, but my personal opinion is I think broad-based deployment is not the issue. I think a voluntary use or a use with the highest risk of exposure among the military personnel would be a prudent approach, and perhaps a moratorium on the other uses of the vaccine until further safety has been tested.

Mr. GILMAN. Did you have an opportunity to examine the present vaccine that is being utilized?

Dr. PORTER. Only what is in the public domain. Only the information available to the members of this committee.

Mr. GILMAN. Based upon your information from the public domain, what is your assessment of the present vaccine?

Dr. PORTER. My assessment, it is probably not much different than most vaccines. It has that attendant risk, usually in the 1 percent range, and that risk is well-known and a risk-benefit program for certain disease states of other uses to immunological approaches to infectious diseases.

I think in this particular case those risks may have to be balanced against the benefits associated with the program. I have no real opinion as to whether this should be taken from the market, for example, but I do feel it fits with many other vaccines relative to its safety profile, as far as percentage of adverse events.

Mr. GILMAN. Thank you, Mr. Chairman.

Mr. BURTON. Mr. Jones, thank you for visiting with us today.

Mr. JONES. Thank you.

I am going to be brief, because I know we want to get to the next panel. But I must say I want to compliment you and this committee.

Two weeks ago, on the Armed Services Committee, we held a hearing regarding readiness; and we had the Joint Chiefs. I asked the question of all three—Navy, Marine and Air Force—are your pilots getting enough time in the cockpit to be combat ready? The answer from each one, Mr. Chairman, was no. So my point is, if we are having Reserve pilots that are leaving the Reserves because of this vaccine, then this readiness problem is going to really be serious next year if we are still holding these hearings, because we have got a problem now.

What I would like to ask Mr. Heemstra, Mr. Marohn and Mr. Ross, when—after Secretary Cohen made the decision to mandate

this shot, how long after that order to mandate the shot did you start becoming concerned? Do you remember the first couple of months after you heard that this was going to be an order that you and the Guard would have to take this shot? Mr. Heemstra.

Mr. HEEMSTRA. Congressman, I think the order went out late 1997. We didn't start hearing much about it until the spring of 1998. So it was around March. Right away, we got some civilian help from Dr. Nass.

Mr. JONES. So initially, when the decision was made, there was no effort to educate you or your unit as to why this shot was necessary and how the Department of Defense felt this shot was safe. Did you not have any type of education process?

Mr. HEEMSTRA. Yes, there was no formal education on that. It was just us doing research ourselves via the Internet and getting Dr. Nass to come, and then we started hearing what DOD said the story was.

Mr. JONES. Mr. Marohn, the same question to you, sir.

Mr. MAROHN. The only education we got on the vaccine came at the time when we were given the verbal order in December 1999. That is when the program of educating us on this was really begun. Otherwise, we had sought out information on our own.

Yes, they did bring somebody on the base to try to let us know the safety of it, but what we were hearing was contrary to what we had found on our own.

Mr. JONES. Mr. Ross.

Ms. ROS-LEHTINEN. At Battle Creek, we were a little bit further down the line of units that got this. Although we did have about a year after Secretary Cohen mandated the program in the fall of 1998, we had about 12 enlisted members of the unit volunteer to support a deployment to the Middle East. Those individuals were vaccinated. Some have testified to Congressman Shays' committee as to their illnesses.

We knew somewhat in 1998, after that first year when these individuals were starting to report sick, that something would eventually occur. We were unable to get any answers from the leadership at our base. They flatly refused to talk about any individuals being sick, and they were handling that case for another year. So it was not until the unit returned from Kosovo at the end of Operation Allied Force in September 1999 that we focused on the fact that we were going to have to take this shot within the next 6 to 8 months.

Education from the Department of Defense then began in December 1999. So almost 2 years after the mandate.

Mr. JONES. Yes, sir, Colonel?

Mr. HEEMSTRA. Yes, sir. The education that was provided was after we talked with Dr. Nass initially there. They brought somebody in from the University of Colorado, a doctor who was an expert on vaccines, so it was about an hour or hour and 15 minute lecture. He spent the first close to 40 or 45 minutes talking about vaccines and how great they were and then the last 20 minutes on the anthrax. So it was obvious that their education attempt was just propaganda. The biggest example of that would be somebody asked him a question about different strains of anthrax, and he was taken off guard and didn't really realize there were different

strains of anthrax and didn't answer the question very well. So we were more educated than he was concerning anthrax.

Mr. JONES. Let me ask each one of you, knowing that you still have friends that are in the Reserves in these squadrons and you have conversations with them from time to time, do you anticipate—I mean this for each one—do you anticipate some of your friends are saying to you we are probably not going to stay in much longer if they are going to mandate this shot? Are you hearing that, or is that not——

Mr. HEEMSTRA. Yes, sir, I have been directly told by some of the guys that have taken the first three shots they will not take any more shots. So their careers are very short-lived.

Mr. MAROHN. Sir, I was a technician leading up to this. I was hired by a major airline in July 1999 shortly before we were going to be required to take it. I was going to be the only person that would resign as a technician over this because I felt so strongly about it.

Most of other technicians that stayed on board and received the shot are I don't think as willing now to continue to take part in the program, and I know of two specifically that are seriously considering and actively pursuing a different career. So far, they have yet to fill my position from a year and a half ago as the training officer because they cannot get anybody in there that wants to not only give time, which they got out of the active duty for, they want to spend time with their families now, while the fact of deploying every year, more mission capabilities being added to our squadron and now this, I don't think people are going to continue to stand for it. I think you will see a lot more exit of pilots, especially technician pilots, in the future.

Mr. JONES. Mr. Ross.

Mr. ROSS. I definitely think, Congressman, you will find that since my unit has returned now from their AEF commitment No. 7, they took their three shots to get over there, the program is in the current hold position that it is, they will not be required to take any more shots, but in the interim here I think you will see another three or four who have felt that they now did their duty and are ready to leave. Then, once again, when the shots are started back up, some of those folks, as Colonel Heemstra said, not take the fourth shot.

Mr. JONES. Thank you, Mr. Chairman.

Mr. BURTON. Mr. Shays. I want to thank Mr. Jones for his interest in this and his work on this. He has been working on it for a long time. Good fellow.

Mr. SHAYS. Mr. Jones is a real hero on this issue, and I really thank him for participating in this hearing.

Mr. Chairman, I particularly thank you. Our subcommittee has attempted to look at this issue, but we have needed your stature and the stature of the full committee to get a little deeper. I also appreciate your participation in the hearings at the subcommittee level.

Mr. Heemstra, you are Mr. Heemstra now, but when you came before us, you were a Lieutenant Colonel, is that correct?

Mr. HEEMSTRA. Yes, sir. I think my status is in question. I was forced to sign my retirement papers. I signed them about 60 days

ago—I wasn't aware that the policy had changed 3 days prior to signing them, because, as we said before, the base did not want that information out that the policy had changed. When I found out, I withdrew my retirement papers with the Headquarters Personnel. I have documents saying my papers were withdrawn. So I should be still in. However, Fort Wayne does not acknowledge or recognize these official documents, so they say I am out. So I have no idea what my status is.

Mr. SHAYS. They say you are Mr. Heemstra. You believe you are still Lieutenant Colonel. When you came before the committee, you were Lt. Colonel.

Mr. HEEMSTRA. Yes, sir.

Mr. SHAYS. That was on Wednesday, September 29th.

When you opened your testimony, you said, I humbly submit these views, which are shared by the majority, not as a rebel to change policy but as a servant and a civilian soldier interested in examining this policy and the best interests of my Nation and my former troops.

You also went on to say, as you know, we are the guinea pigs. We know we are the guinea pigs. You know we are the guinea pigs. As one Senator shockingly told us a few months ago, you signed on the dotted line when you joined, giving up those rights of ordinary citizens, so roll up your sleeve and obey orders.

We may have sure rendered these rights to our superiors, but it was into their care and their trusteeship to take care of those rights.

You said a lot of other things that day.

At that hearing, Mr. Burton asked a question of Mr. Cragin, and Mr. Burton said, well, let me go forward with the rest of these questions, and then he can answer if he would like. From 1996 to 1998, the Air Force lost 369 pilots in that 2½ to 3 year period. It is estimated this year it could reach as many as 340 in 1 year when the paperwork is processed in September. Many tracking the numbers have remained mute because of what happened to Deborah J. Aigen, an Air Force pediatric nurse, who in a letter to the military newspaper Stars and Stripes raised concerns about the vaccine's side effects and so forth. Is that also a figment of someone's imagination?

Mr. Cragin: Would you—I am going to ask General Weaver. I have his facts and figures in front of me, Mr. Chairman, but I would prefer to have you hear from General Weaver since I am looking at his attrition numbers for the last 5 years.

Now, Mr. Weaver starts to answer the question. And then he says, our retention rate—and we are the busiest Reserve component force of all the Reserve component forces. In fact, 75 percent of the Reserve component forces called up for Kosovo were Air National Guardmen and women. We have the best retention rate in the Air National Guard of all services, over 90 percent.

Talking personally, personally to all the commanders, to include the 122nd, there are challenges with explaining, with discussing as they are with the members of their unit on the anthrax issue. But when it really gets down to it, we have 10,700 people inoculated for anthrax in the Air National Guard, with one known refusal documented.

He was trying to give the impression that when it comes to anthrax, there was only one.

That is almost 10 percent of our force. Now, there is a lot of anecdotal evidence out there about all these pilots leaving the force when they are forced to do so. Well, we already have 10,000 individuals voluntarily taking anthrax shots, some of which right now are in the combat operation in Northern Watch. So when I hear all these other figures about these mass resignations and what not, they are just not there.

That is what General Weaver said.

Now, we asked General—I asked General Weaver, I would make a request that any person who leaves the Reserve or National Guard be specifically asked if any anti-anthrax vaccine was a factor in their decision and to what extent it was; and then I said, I will followup and see that it is done.

General Weaver: Yes, sir, I will do that. Yes, sir, I will do that.

Then we see questionnaires sent out to our military, not even asking the question about anthrax. And then when the chairman says please ask the question about anthrax, they say, no.

Now, in the hearing you had last week, Mr. Chairman, which was an extraordinary hearing, you again had victims. Mr. Heemstra, Mr. Marohn and Mr. Ross, you are victims, and all the people you serve with are victims, in my judgment. They are also brave military personnel who wanted to serve their country under the trusteeship that you have in the military.

Mr. Chairman, you had one, two, three, four, five, six, seven, eight, nine individuals who testified, in addition to Dr. Alexander Walker at the request of the minority. Now, Dr. Alexander Walker is a professor of epidemiology, Harvard School of Public Health, and he made the point to us, almost like the military, it is a concept of acceptable loss. You do a vaccine, there are going to be some people who have an adverse effect, which was in essence to say all these people may be before you who you, Congressman Shays, may think of as victims, but they may be just the very few, the very few with acceptable loss.

Now, the interesting thing is that we know they don't represent—those witnesses last week did not represent that. In other words, the totality of those who may have been perceived as victims.

I want to ask each of you, do you know anyone who has taken the shot who has had adverse side effects?

Mr. Heemstra.

Mr. HEEMSTRA. Yes, sir, I know several at the base, that some are secretly sick and will not come forward, some that even in their family situation have not made it a known fact that they have taken the shot.

Mr. SHAYS. Mr. Marohn.

Mr. MAROHN. Yes, sir, I do. I know of several. I know that one of the men in our life support is currently under review, and they are seriously looking at the shot as a causal effect in his current medical condition. They are also reviewing his discharge.

Mr. SHAYS. Mr. Ross.

Mr. ROSS. Yes, Congressman. I would say I personally know in the neighborhood of 15 individuals that are still at the base. Some

of the individuals at Battle Creek that I know personally testified to your subcommittee, and you have had their testimony in the record from Battle Creek.

Mr. SHAYS. Thank you.

Now, Dr. Alexander Walker at one point said there will always be costs. This is in the transcript of last week dated Tuesday, October 3rd. There will always be costs. I think we see this in every form of medical treatment. That even the safest ones, that there are—there are costs, and it is always a judgment as to what the best thing is to do for the individual in front of you. With vaccines, unlike antibiotics, the question is much more difficult, because the benefits are in a sense theoretical, as if this person is never exposed to attack, then he is not going to derive any benefit from the vaccine. So the individual that you see, who has had adverse effect, in that instance is being laid against no benefit, just a theoretical benefit that the person had, and that is very unsatisfying.

Then he goes on to say—excuse me—and I asked him, don't you think there should be some kind of presumption that maybe this person might be that one isolated, very small person, statistical individual that maybe should have some ability to say no? I mean, we are not talking military order. I mean, we are not taking the military order. They get court-martialed if they don't take it. But, medically speaking, would that be logical?

And the question that preceded was, if someone had an adverse effect, couldn't we make an assumption that they were that, in the words of Dr. Walker, the few who had a statistical negative effect with that anthrax and then should they be asked to take the second, third, fourth, fifth or sixth shot?

Mr. Walker: I can obviously only speak from the point of view of civilian medicine. I don't know the military. It is in the general society. I think it is a bad practice to compel vaccination. People may make mistakes, but I think it is just a violation of fundamental liberties.

Now, this was the witness intended to boost up what the military was doing. Then he said it also provides the groundwork for a lot of fear.

Then he continues, so your question presupposes that the fever and headache was actually a marker of someone who would go on to have seizures and blackouts and so forth afterwards?

I don't know if that connection is true, but that is what you look at. You look at people who have had a particular adverse effect, and then you look back at their experience with the vaccination and compare it to the people who don't have the effect.

So then I said—Mr. Shays: So the bottom line is in a six series, having six shots, when we start to see adverse effects continue to grow, from a medical standpoint, it would not be unreasonable to say maybe this is someone who we shouldn't continue requiring to take the vaccine?

Dr. Walker: In fact, that was commonly what we did with the old pertussis vaccine, that there were children who had fevers and so forth, they reacted poorly, and they typically got half doses or withheld doses. Nobody knows whether that affected the safety of the vaccine, but it was common practice, and obviously so—I added the obviously so.

I would like, Mr. Chairman, to just conclude by asking that we submit for the record these two—without objection, I request that——

Mr. BURTON. Without objection.

Mr. SHAYS [continuing]. These two surveys, and what I consider an obnoxious letter, but let me just not paraphrase it that way, a letter from Mr.—let me make sure I am getting it correct, Dr. Rosker.

Mr. BURTON. Without objection.

Mr. SHAYS. Excuse me, sorry to hold you up. It is from Bernard Rosker, August 25, 2000, and it was addressed to Dan Burton, chairman of the committee.

Mr. BURTON. Without objection.

Mr. SHAYS. Then I would just like to also ask that—we had written Mr. Cragin and Dr. Weaver a letter of—General Weaver, I am sorry—November 3rd. I would like that letter—we were expressing concern about the accuracy of information provided by you to the Subcommittee on National Security and so on, when he said, "but when it really gets down to it, we have had 10,700 people inoculated for anthrax in the Air National Guard with one known refusal documented." We would like our letter put in the record and Dr. Weaver's response to us, and that was dated November 10, 1999; and also the letter to Honorable Charles Cragin of October 7th, and then his response of October 21st.

Mr. BURTON. Without objection.

Mr. SHAYS. Thank you, Mr. Chairman.

Mr. BURTON. Thank you very much.

[The information referred to follows:]

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November 3, 1999

MG Paul A. Weaver, Jr.
Director, Air National Guard
1411 Jefferson Davis Highway
Arlington, VA 22202

Dear General Weaver:

I am concerned about the accuracy of information provided by you before the Subcommittee on National Security, Veterans Affairs, and International Relations. In your sworn testimony before the Subcommittee on September 29, 1999, you made the following statement:

"But when it really gets down to it, we have had 10,700 people inoculated for anthrax in the Air National Guard with one known refusal documented." (unofficial transcript, pages 118-119)

The Subcommittee has reason to believe the above statement is inaccurate. Please provide an explanation of your statement, including identification of the individual who refused the inoculation and a copy of the document wherein the refusal is recorded.

Further, we have become aware that in response to a question from the field regarding this matter, you indicated it was understood that you were referring to individuals "with a commitment" as contrasted to those who had no commitment. We find nothing in the hearing transcript that so limits your description of the documented "refusal". Please explain this apparent discrepancy.

Please send your reply before 5 p.m., Wednesday, November 10, 1999, to the Subcommittee office, Room B-372 Rayburn House Office Building, Washington, D.C. 20515

Sincerely,

Christopher Shays
Chairman

cc: Rep. Dan Burton
Rep. Henry Waxman
Rep. Mark Souder
Rep. Rod Blagojevich

DEPARTMENTS OF THE ARMY AND THE AIR FORCE
NATIONAL GUARD BUREAU
1411 JEFFERSON DAVIS HIGHWAY
ARLINGTON, VA 22202-3231

November 10, 1999

Office of Policy and Liaison

The Honorable Christopher Shays
United States House of Representatives
1126 Longworth House Office Building
Washington, DC 20515

Dear Representative Shays:

Thank you for your November 3, 1999 letter and the opportunity to clarify my testimony before your September 29, 1999 hearing.

My reference to the 10,700 people inoculated for anthrax refers to the number of personnel in the Air National Guard who, at the time of my testimony, had begun the anthrax immunization series. With respect to the "one known refusal documented," I was referring to Technical Sergeant Marquerite Jett, who is a member of the 115th Fighter Wing, Wisconsin Air National Guard. Sergeant Jett volunteered for a deployment, received the first two immunizations, and because of migraine headaches, refused to take the third immunization.

At the time of your hearing, I had thought non-judicial punishment against Sergeant Jett had been initiated as a result of refusing, despite being ordered. However, this is not correct in that her case is currently on hold pending a further medical review. My characterization of "the one known refusal" was based on the Air National Guard defining a refusal as "a member who has a requirement to receive the immunization and refuses to take the immunization after receiving a direct order to do so." This order is given only after the member receives education and counseling by medical, legal and command authorities. To date, we have no record or knowledge of any member refusing a direct order to be immunized.

I should point out that in the Air National Guard, in lieu of receiving the immunization, a member might simply request separation or retirement if his or her service obligation or commitment has been fulfilled. As you know, several have done so. While all separating or retiring members are encouraged to complete voluntary exit surveys, there is no mandatory requirement to do so. The Department of Defense is currently considering whether or not to specifically track anthrax refusals and if they determine it to be appropriate, the Air National Guard will follow suit.

I trust you will find this information to be useful.

Sincerely,

PAUL A. WEAVER, JR.
Major General, USAF
Director, Air National Guard

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October 7, 1999

The Hon. Charles L. Cragin
Principal Deputy Assistant Secretary
Reserve Affairs
1500 Defense Pentagon
Washington, D.C. 20301-1500

Dear Mr. Cragin:

Your testimony on September 29 raised certain questions not addressed during the hearing on the impact of the anthrax vaccine program on reserve component units. Pursuant to the Subcommittee's oversight jurisdiction, and in order to insure a complete and accurate record on these important issues, please provide written responses to the following requests:

1. In your testimony, despite portraying the retention and readiness impact of the anthrax program as negligible, you nevertheless described conversations "with the commanding officers of many of the units that have been experiencing personnel challenges regarding anthrax ...." Please provide the unit designations, locations and commanding officers' names and telephone numbers for the conversations referenced in your testimony. Please also describe the nature (resignations, transfer requests, information requests, etc.) and extent (numbers and percent of unit authorized and current strength) of the personnel challenges attributable to the anthrax program in each unit.

2. The Subcommittee has received an unconfirmed report that you were provided detailed information about a substantial number of pending resignations and transfer requests attributable to the anthrax vaccine program during your visit to Stewart Air Force Base, Newburg, New York earlier in September. Please provide a detailed description (and copies of documents, if any) of all information

conveyed to you in any form during your visit to Stewart Air Force Base regarding actual or potential impacts on unit retention or readiness attributed to the anthrax vaccine program.

3. Please describe the extent of your knowledge and involvement in the formulation of the Air Force Reserve "Interim Anthrax Policy" which states, in part, "For those members who submit an AF FM 1288 or other request for reassignment (letter, memo, etc.) after having been scheduled or directed to take the anthrax immunization; the commanders may not approve those reassignment requests."

Please provide your response before 5 p.m. Thursday, October 15, 1999 to the Subcommittee office, B-372 Rayburn House Office Building, Washington, D.C. If you or your staff have any questions about this request, please contact me or Lawrence Halloran, Subcommittee Staff Director and Counsel.

Sincerely,

Christopher Shays
Chairman

cc: Rep. Dan Burton
Rep. Henry Waxman
Rep. Mark Souder
Rep. Rod Blagojevich



OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1500

RESERVE AFFAIRS

21 OCT 1999

Honorable Christopher Shays
Chairman
Subcommittee on National Security
Veterans Affairs, and International Relations
Committee on Government Reform
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This is in response to your letter of October 7th, which requested further information and clarification regarding my testimony of September 29th. As per discussions between our offices, the October 15th deadline was extended until today.

At your request, I am submitting the following information: a detailed summary of the conversations, subsequently referenced in my testimony, with commanding officers of several Reserve units; information regarding my trip to Stewart Air Force Base; and information regarding the extent of my knowledge of and involvement in the formulation of the Air Force Reserve "Interim Anthrax Policy."

Summary of Conversations with Guard and Reserve Commanding Officers

Conversation with Brigadier General Peter K. Sullivan, Commander, 512 Airlift Wing (AFRC), Dover AFB, DE 302-677-5120

Gen Sullivan reported that the main challenges regarding anthrax protection were related to information and communication. While he stated that some of his personnel had "lingering doubts" about the program, the big concern, from his perspective, was not anthrax but the unreliability of the C-5 aircraft that his personnel were tasked to fly. Repeated breakdowns and shortage of parts were affecting morale. Anthrax vaccination was just one more requirement. He indicated concern about how all the requirements helped add to "frustration of mission." Gen Sullivan also speculated about additional force protection requirements that may be coming over the horizon, and the need to ensure good communications and educational efforts for those requirements if they appear. He expressed frustration over his ability to explain the threat of weaponized anthrax to his personnel—the clear threat we face should make the rationale for the shots apparent. He said we needed to do a better job of explaining the threat. About anthrax, he said, "it's another requirement...just too many requirements." He shared some concerns, which he characterized as short-term, about retention and admitted that both anthrax and, more generally, "mission turbulence" were contributing to personnel

Conversation with Colonel Martin M. Mazick, Commander, 439 Airlift Wing (AFRC) Westover ARB, MA 413-557-3588

Col Mazich reported that things were in pretty good shape in his unit. Only two personnel, one engineer and one pilot, have left as a result of anthrax concerns. Four others have left the unit due to retirement or transfer to the Air Reserve Personnel Center. While he reported no readiness concerns, he did express some frustration over an "inundation of requirements." On anthrax, he said that some personnel who had taken the shots developed "bruising" at non-shot locations, which was "inexplicable." He reported no recruiting issues as a result of the anthrax protection program. High optempo and perstempo were major factors in recruiting and retention. Additionally, 5 airplanes were undergoing T-tail repairs and were not able to fly. In sum, "extraneous issues" were putting strains on his people, but they remained "able to do the job."

Conversation with Lieutenant Colonel Michael L. Leeper, Vice Commander, 137 Airlift Wing (ANG), Oklahoma City, OK 405-686-5222

Col Leeper and I discussed the Air Expeditionary Force (AEF) concept and its implementation. His wing is scheduled to perform AEF duties around Christmas time—175-225 personnel are scheduled to deploy in support of the AEF. He expressed concerns about being able to meet that requirement on a volunteer basis, partly as a result of "anthrax hysteria." He estimated that he would lose 9 to 14 line pilots, the majority of whom were leaving for reasons unrelated to anthrax, including perstempo, optempo, and family concerns. He also reported that Dr. Meryl Nass had recently visited the area at the invitation of the technician's union. Nass, who is a harsh critic of the anthrax protection program, reportedly told a group of reservists that [paraphrase]: "if you don't take the shot and get into a threat area, you're going to die."

Trip to Stewart Air Force Base, September 15, 1999

You also requested information regarding a report received by the committee which claimed that I was provided with detailed information about a substantial number of pending resignations and transfer requests attributable to the anthrax vaccine program during my visit to Stewart Air Force Base on September 15, 1999.

During a meeting with Wing officials, at which I was accompanied by Major General Raymond Rees, Vice Chief, National Guard Bureau, and Brigadier General Craig McKinley, Deputy Director, Air National Guard, Lt Col Mark White, the 105th Wing's operations group commander, gave me a list detailing pending resignations and retirements.

I attach a copy of that list, which indicated that 21 personnel were due to retire or resign as of January 1, 2000. Of these, 17 had listed anthrax as their reason for doing so.

Subsequent conversations with Brigadier General Thomas P. McGuire, Jr., commander, 105 Airlift Wing at Stewart AFB, Newburgh, NY (914-563-2001), indicated

challenges. However, he was clear in his assessment that readiness was at acceptable levels.

Conversation with Colonel Alan M. Mitchell, Commander, 446 Airlift Wing (AFRC), McChord AFB, WA, 253-984-5526

Col Mitchell reported that it had been "a turmoil filled summer"—not as a result of anthrax but because of the wing's conversion from C-141 aircraft to the C-17. Even before the anthrax protection program began, the wing had projected personnel losses among aircrews of up to 40% as a result of the stresses and strains caused by the conversion. Today, in the wake of the anthrax program, that forecast remains accurate. Furthermore, retention challenges are reflected mostly in the same group of airmen who have expressed concern over anthrax. In other words, those being most affected by the conversion are also those most vocal about anthrax. The 26 personnel the wing is losing because of anthrax concerns are "already replaced." Col Mitchell reported that it had "not impacted our readiness." We have, he said, "different faces" performing the same mission. Overall, he reported that the trust factor was damaged—a lot of little issues have weakened the bonds. He also reported that pilots "no longer need the furlough insurance" offered by reserve duty—the civilian economy is booming and drawing people away. Among those who are leaving, most have not identified anthrax on their 1288s—indeed many have referenced family and civilian job stresses as the reasons for leaving. Col Mitchell reported that those leaving the unit would be held in a non-participatory status for six months while their jobs were filled by others who are new to the wing. He expressed the view that the anthrax program "came on us too fast"—a clear reference to communication challenges. But he also said that there were still people trickling back to the wing to take the shot. The biggest lesson learned, according to Col Mitchell, was that, "Guys aren't hearing about the threat."

Conversation with Colonel Walter L "Buster" Burns, Commander, 103 Fighter Wing (ANG), Bradley, CT 860-292-2526 ***(Active duty officer in charge of an ANG wing)*

Col Burns reported that his unit has 20 personnel listed as overdue and 1 on medical deferral. All those overdue were overdue for their fourth shots, and thirteen of those were scheduled for their fourth shots in early October. He also reported that 3 NCOs had taken 3 of the 6 six shots, as required by the FDA protocol, but had recently said they would stop taking the shots. Col Burns attributed this action to elevated expectations that Congress would soon stop the program. Col Burns was explicit in his assessment that he had no readiness concerns related to anthrax. He stated that his greatest challenges came as a result of the recent presidential call-up of reservists for air operations over Kosovo. He also said that the greatest need was to "get the threat briefing out to the troops." He said, "I do not have issues related to anthrax affecting readiness."

that almost all of those who had said they were resigning because of the anthrax shots have now rescinded their resignations. This may be due in whole or in part to the fact that anthrax vaccinations at Stewart were postponed in the wake of power outages during Hurricane Floyd. Gen McGuire speculated that the resignations might be resubmitted in May, when the program resumes at Stewart. In addition, Gen McGuire reported that anthrax continued to be a challenge but that they were working on new communications and outreach efforts. He also said that anthrax was one of many concerns at his base, including optempo and the reliability of C-5 aircraft.

Air Force Reserve "Interim Anthrax Policy"

With respect to my knowledge of and involvement with the formulation of the Air Force Reserve "Interim Anthrax Policy," I was aware that the Air Force Reserve leadership was considering such a policy but had no involvement in its formulation.

Thank you for your continuing interest in our efforts to protect our personnel from the very real and growing threat of weaponized anthrax. As I indicated during your hearing, we firmly believe that we have a moral obligation to give our service members the protection they need from this lethal threat.

Sincerely,

Charlie Cragin

Charles L. Cragin
Principal Deputy Assistant Secretary

Enclosure:
As stated

RESIGNATIONS/RETIREMENTS THROUGH 1 JAN 00

PILOTS

ANTHRAX	17
OTHER	4
TOTAL	21

ANTHRAX PILOT LOSSES (17)

- EVALUATOR PILOTS 1
- AERIAL REFUELING INSTRUCTOR PILOTS 4
- AERIAL REFUELING AIRCRAFT COMMANDER 3
- AIRCRAFT COMMANDERS 6
- COPILOTS 3

FLIGHT ENGINEERS

ANTHRAX	2

PILOT PROJECTION 1 JAN 00

FULL TIME PILOTS

AUTHORIZED: 12
ASSIGNED: 9

-3

GUARDSMEN PILOTS

AUTHORIZED: 48
ASSIGNED: 25

-23

TOTAL PILOTS

AUTHORIZED: 60
ASSIGNED: 34

-26

% MANNING FOR PILOTS ***57%***

PER AFI 11-2C-5V 1 JANUARY 1999

FLYING HOURS NEEDED TO UPGRADE TO C-5 AIRCRAFT COMMANDER:

TOTAL FLYING TIME	*C-5 FLYING TIME*
2000	200
1600	400
1400	600

Mr. BURTON. If there are no further questions of this panel, I want to thank you very much for coming back. We appreciate your standing up on this issue. I know it has caused you some problems. Hopefully, we will get this thing resolved; and maybe, the good Lord willing, we will get you back to flight status one of these days.

Dr. Porter, thank you for the education. Thank you very much. I am learning more every day.

With that, we will now have the next panel come forward.

The next panel is Mr. Chan of the GAO and General West and those accompanying them. If there is going to be testimony given by others than Mr. Chan and Mr. West, we would like those to stand so they can be sworn.

Would any of the witnesses like to take a 5-minute break before we start the panel?

Generals, would you like to take a quick break before we start the panel? We may be here for some time.

Mr. Chan, you and the folks from GAO, would you like to take a 5-minute break?

The cameraman? Just to show you that we do care about the media once in a while, we will take a 5-minute break. We will be right back. This is for you.

What network are you from? CBS. Just tell CBS that we do care about you guys, once in a while.

[Recess.]

Mr. BURTON. If we could have the witnesses come to the table and stand, please.

[Witnesses sworn.]

Mr. BURTON. We will start I guess like we did the last panel, at the left. Mr. Chan, are you ready with some kind of opening statement——

Mr. CHAN. Yes, sir.

Mr. BURTON [continuing]. From the GAO?

Mr. CHAN. Yes, sir.

Mr. BURTON. OK, Mr. Chan, proceed.

STATEMENTS OF KWAI-CHEUNG CHAN, GENERAL ACCOUNTING OFFICE; AND MAJOR GENERAL RANDALL L. WEST, USMC, SENIOR ADVISOR TO THE DEPUTY SECRETARY FOR CHEMICAL AND BIOLOGICAL PROTECTION, ACCOMPANIED BY MAJOR GENERAL P.A. WEAVER, JR., ANG, DIRECTOR, AIR NATIONAL GUARD

Mr. CHAN. Mr. Chairman and members of the committee, it is my pleasure to be here today to discuss the preliminary results of our ongoing work on the impact of the DOD's anthrax vaccine immunization program on the Air National Guard's and Air Force Reserve's retention of trained and experienced personnel.

Specifically, I am going to report today on, one, the impact of the vaccination program on retention; two, the basic views of Guard and Reserve pilots and other aircrew members regarding the program; and, three, the extent of adverse reactions experienced by anthrax vaccine recipients.

As you know, these components provide essential support to critical defense operations on a worldwide basis. They provide strategic

and tactical airlift, aerial refueling, troop transport, aero-medical evacuation and augment DOD's overall fighter force.

To conduct our work, we developed, pretested and validated a questionnaire that was sent to over 1,200 randomly selected Guard and Reserve pilots and other aircrew members. These included pilots, flight engineers, load masters, navigators, crew chiefs, and others. Collectively, they represent about 13,000 service members.

We administered the survey on an anonymous basis between May and September 2000. The overall response rate was 66 percent. The information we are presenting today has been weighted to represent the population of those Guard and Reserve pilots and other aircrew members who are currently active and assigned to a unit.

Before I discuss the results of our survey, let me discuss the context of this subject.

In August 1998, DOD began a mandatory anthrax vaccine immunization program for its 2.4 million U.S. military personnel, including Active and Reserve component personnel.

As you know, Mr. Chairman, this program has been the subject of much controversy. Some members of the Armed Forces have expressed concerns regarding the safety and efficacy of the anthrax vaccine. Those refusing the vaccine have been disciplined under service-specific policies for disobeying a lawful order.

While some Reservist and National Guard members have publicly stated they have resigned or transferred to non-flying positions that do not require the anthrax vaccination at this time, DOD officials have denied such losses were due to the anthrax vaccine program.

It is important to note that DOD neither collects uniform records on such changes of status, nor has it done any survey to assess the extent and impact of such losses.

The Reserve components are currently experiencing difficulties in filling their ranks with new recruits at a time when DOD is relying on them more heavily to conduct operations around the world. Specifically, the retention of pilots and other aircrew members have been and continues to be a problem that could impact readiness. Without adequate numbers of pilots and air crew, the Guards and Reservists could experience difficulties supporting the Active force in its worldwide operations.

In addition, it costs the military an average of almost $6 million to train and develop a fully qualified, experienced aviator, which the Air Force suggests takes about 9 years.

Turning to the results of our survey, I have three findings to report: First, the anthrax program is having adverse impacts on the retention of Guard and Reserve pilots and aircrew members.

As you can see on slide one, an estimated 25 percent of the pilots and aircrew members of the Guard and Reserve in this population had either left the military altogether, transferred to a non-flying position in another unit, or moved to inactive status. Below that line, you find, additionally, 18 percent of those still participating in or assigned to a unit reported in our survey their intentions to change their status, including leaving within the next 6 months.

While several reasons influenced their decision, both groups ranked the anthrax immunization as the most important factor for

their decision for the change, followed by other reasons such as employment opportunities, unit workload and family reasons.

Of those who are either separated or no longer in military flying status because of the anthrax vaccine immunization program, 43 percent stated that they would likely return if the anthrax programs were done away with. So 43 percent of the 25 percent in there.

Each of these groups, those who have left and those who are planning to do so, have accumulated an average of more than 3,000 flight hours, which symbolizes a seasoned and experienced work force.

Second, the anthrax vaccine program is very unpopular among Guard and Reserve pilots and crew members. As you can see in slide two, despite DOD's high visibility campaign to educate service members about anthrax immunization programs, two in four, or 39 percent, said they are moderately or very dissatisfied with the timeliness of the information provided to them on the DOD anthrax Web site, over half, or 54 percent, on the completeness of the information, and three in five, or 58 percent, on the accuracy of the information provided. Finally, three in four, or 74 percent, found the information to be moderately or very biased.

With regard to their views on the anthrax program, you can see on slide three, whereby 65 percent indicated that they have no support for the anthrax program. Three out of four, or 76 percent, indicated they probably would not take the shots if the anthrax immunization program were voluntary; and 9 out of 10 indicated that they would probably have safety concerns if additional vaccines for other biological warfare agents were added to the military immunization program.

Mr. Chairman, this last finding has important implications for DOD's future biological warfare vaccine initiatives.

Finally, adverse reactions are seriously underreported to FDA's Vaccine Adverse Events Reporting System [VAERS], which is, as you know, a passive system. Service members apparently do not trust military health care providers or supervisors enough to discuss their reactions with them. It is therefore important for you to know that the statements made by FDA and DOD on the safety of this vaccine are based on limited data from some service members.

Moreover, there has been no systematic followup to obtain data on the clinical conditions. As you can see on slide four, 42 percent of the respondents reporting they had received one or more anthrax shots. Of those taking one or more shots, 86 percent reported experiencing some type of local and/or systemic reactions; 71 percent reported being unaware of VAERS itself. Further, 60 percent of those experiencing the reaction had not discussed them with military health care personnel or their supervisors, half of them citing fear of loss of flight status and possible adverse effects on their military or civilian careers and ridicule as reasons for nondisclosure.

For some local and systemic reactions, the reported duration was more than 7 days. In my written statement we have a table showing the list of some 20 different reactions which the respondent had checked out. Some of these reactions could have implications for work performance. Since many individuals are not reporting their reactions to military medical personnel or to the various systems,

the actual duration, the extent or impact on unit individual and ultimate resolution of these reactions are unknown.

Mr. Chairman, this concludes 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
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ANTHRAX VACCINE

Preliminary Results of GAO's Survey of Guard/ Reserve Pilots and Aircrew Members

Statement of Kwai-Cheung Chan, Director, Applied Research and Methods





GAO-01-92T

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the preliminary results of the ongoing work we are doing at your request on the Department of Defense's (DOD) Anthrax Vaccine Immunization Program. As you know, numerous concerns have been raised about the program since DOD began vaccinating its 2.4 million active duty and reserve members in 1998.[1] Of particular concern was the program's potential impact on the Air National Guard and Air Force Reserve's retention of trained and experienced personnel.

In response to your request, we are examining the impact of the vaccination program on retention, the basic views of Guard and Reserve pilots and other aircrew members regarding the program, and the extent of adverse reactions experienced by anthrax vaccine recipients. These components provide essential support to critical defense operations on a worldwide basis. They provide strategic and tactical airlift, aerial refueling, aeromedical evacuation, and augment DOD's overall fighter force.

To conduct our work, we developed, pre-tested, and validated a questionnaire that was sent to 1,253 randomly selected Guard and Reserve pilots and other aircrew members. These included pilots, flight engineers, loadmasters, navigators, crew chiefs, and others. Collectively, they represent about 13,000

[1] We have previously reported on a number of concerns regarding the safety and efficacy of the anthrax vaccine and other related matters. (See Appendix III).

servicemembers of the total fiscal year 1999 end strength of approximately 176,000, which includes about 29,000 officers and 147,000 enlisted personnel. We shared the draft questionnaire with DOD program officials and their medical experts and incorporated appropriate comments and suggestions. We administered the survey on an anonymous basis between May and September 2000. The overall response rate was 66 percent. Our methodology is described in detail in appendix I. The information we are presenting today has been weighted to represent the population of those Guards and Reserve pilots and other aircrew members who are currently active and assigned to a unit.

SUMMARY

While many factors can influence an individual's decision to leave the military, surveyed Guard and Reserve pilots and aircrew members cited the anthrax immunization as a key reason for leaving or otherwise changing their military status. Since September 1998, an estimated 25 percent of the pilots and aircrew members of the Guard and Reserve in this population transferred to another unit (primarily in a non-flying position), left the military, or moved to inactive status. While several reasons influenced their decision, when asked to rank the one most important factor, the anthrax immunization was the highest, followed by other employment opportunities, and family reasons. Further, about one in five (18 percent) left before qualifying for military retirement benefits. Additionally, 18 percent of those still participating in or assigned to a unit reported their intentions

to leave within the next 6 months. These individuals also ranked the anthrax immunization as the most important factor for their decision to leave, followed by unit workload and family reasons. Each of these groups—those who have left and those who plan to do so--had accumulated an average of more than 3,000 flight hours, which symbolizes a seasoned and experienced workforce.

On our survey, most Guard and Reserve pilots and aircrew members expressed a positive view toward general immunizations. Almost three out of four believe that immunizations are effective (74 percent), and more than half believe immunizations to be safe (60 percent). However, their views on the anthrax immunization program and potential biological warfare immunizations in the future are very different. For example, two out of three reported little or no support for the anthrax program (65 percent). Despite DOD's high-visibility campaign to educate servicemembers about the anthrax immunization program, only about one in four believes that the information provided on DOD's anthrax Web site is timely (25 percent), 19 percent believe it to be complete, and 17 percent believe it to be accurate. Just 1 in 10 (11 percent) believe the information to be unbiased. Further, three out of four indicated they would not or probably would not take the shots if the anthrax immunization program were voluntary (76 percent). Eighty-seven percent, or almost 9 out of 10, indicated they would or probably would have safety concerns if additional vaccines for other biological warfare agents were added to the military immunization program.

Forty-two percent of the respondents reported that they had received one or more anthrax shots. Of those taking the shots, 86 percent reported experiencing some type of local or systemic reactions, for example, a knot in the arm or joint pain. For some reactions, the reported duration was more than 7 days (for example, limited arm/body motion and joint pain). Some of these reactions could have implications for work performance. About one-third (36 percent) reported that they had been provided information concerning what action to take in the event of side effects or reactions. But 71 percent reported being unaware of the Food and Drug Administration's Adverse Events Reporting System which is a passive surveillance system to alert the Food and Drug Administration and the Center for Disease Control and Prevention of adverse events that may be associated with licensed vaccines. Further, about 60 percent of those experiencing reactions had not discussed them with military health care personnel or their supervisors—some citing fear of the loss of flight status, possible adverse effects on their military or civilian careers, and ridicule as reasons for nondisclosure (49 percent).

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. In August 1998, DOD began immunizing its 2.4 million U.S. military personnel—including active and reserve component personnel—with a licensed anthrax vaccine. This program is mandatory. Some members of the armed forces have

expressed concerns regarding the safety and efficacy of the anthrax vaccine. Those refusing the vaccine have been disciplined under service-specific policies for disobeying a lawful order. Anecdotal information suggests that an unknown number of Reservists and National Guard members have resigned or transferred to units or non-flying positions that do not require anthrax vaccinations at this time. DOD does not collect uniform records on such changes in status.

Congress and the Department of Defense have become increasingly concerned about the readiness of U.S. armed forces. Key reasons for this concern are the increasing pace (tempo) of operations due to deployments, parts shortages and maintenance backlogs, and past problems in recruiting and retaining quality people. The reserve components are experiencing difficulties in filling their ranks with new recruits at a time when DOD is relying on them more heavily to support operations around the world. Specifically, the retention of pilots and other aircrew members has been and continues to be a problem that could impact readiness. The impact of an exodus of Guard and Reserve pilots and aircrew members would be significant. Without adequate numbers of pilots and aircrew, the Guard and Reserve could not support the active force in its worldwide operations. In addition, it costs the military an average of almost $6 million to train and develop a fully qualified experienced aviator, which the Air Force suggests takes about 9 years.

ANTHRAX IS A KEY FACTOR AFFECTING INDIVIDUAL DECISIONS TO CHANGE MILITARY STATUS

Twenty-five percent of the pilots and aircrew members of the Guard and Reserve we surveyed have transferred to another unit, left the military, or moved to inactive status. Of these, 25 percent ranked anthrax immunization as the most important factor influencing their decision to leave or transfer followed by other employment opportunities at 16 percent and family reasons at 16 percent. The general military immunization program was cited as the least important reason for a change in their military duty status. Further, about one in five (18 percent) left before they had qualified for a military retirement. Forty-three percent of those who separated or are no longer in military flying status because of the anthrax program indicated that they would or probably would consider returning to a unit or to military flying status if the anthrax vaccination program were not mandatory.

Of those who are still in Guard and Reserve units, 18 percent reported that they planned to leave the military within the next 6 months. Again, when asked to rank the most important factor for their decision to leave, the anthrax immunization was the most frequently reported reason (61 percent), followed by heavy unit workload and family reasons. Each of these groups (that is, those who left and those who intend to leave) had in excess of 3,000 flight hours, which symbolizes a seasoned and experienced workforce.

ANTHRAX VACCINE IMMUNIZATION PROGRAM IS NOT WIDELY SUPPORTED

Most Guard and Reserve pilots and aircrew members support immunization programs in general; however, relatively few appear to support the anthrax program or future immunization programs for other biological warfare agents. Almost three out of four (74 percent) of the pilots and aircrew members of the Guard and Reserve believe that immunizations in general are moderately to very effective, and 60 percent believe that immunizations are moderately to very safe. On the other hand, 65 percent, or two out of three servicemembers, reported little or no support for the anthrax immunization.

DOD has employed a high-visibility campaign to educate servicemembers about the program and has taken steps to address the controversy surrounding the program. In addition, it expanded its communications efforts by updating the program's Internet site, opening a toll-free anthrax information line and forming a speakers' bureau of anthrax experts. DOD also updated briefings for installation leaders and medical personnel to provide more detailed information on the anthrax threat. We had previously reported in October 1999 that servicemembers were not satisfied with the information provided to them.[2] In our current survey, relatively few respondents reported being moderately to very

[2]*Medical Readiness: DOD Faces Challenges in Implementing Its Anthrax Vaccine Immunization Program* (GAO/NSIAD-00-36, October 1999).

satisfied with the information provided at the DOD Web site. For example, only 19 percent were satisfied with the completeness of the information, 17 percent were satisfied with the information's accuracy, and 25 percent were satisfied with its timeliness. Just 11 percent were satisfied that the information was unbiased.

In terms of all information provided by DOD to servicemembers on the anthrax program through the Web site and other sources, 39 percent indicated that they were moderately to very satisfied with the information provided on the military anthrax threat. On the other hand, only 12 percent were moderately to very satisfied with the information received about the vaccine's long-term safety.

Seventy-six percent of survey respondents indicated that they would not or probably would not take the shots if the anthrax immunization program were voluntary. Just 11 percent reported they would or probably would take the shot on a voluntary basis. About 13 percent were uncertain. Further, 87 percent reported that they would or probably would have concerns about safety if additional vaccines for other biological warfare agents were added to military immunization requirements.

MOST ADVERSE EVENTS TO ANTHRAX IMMUNIZATIONS ARE NOT REPORTED

Adverse events are adverse outcomes for which a cause and effect relationship with an exposure (to a vaccine or a medication) has not yet been determined. DOD has used data from the Vaccine Adverse Event Reporting System to monitor adverse events (or reactions) to anthrax vaccinations. It is a "passive" surveillance system, which relies on vaccine recipients or their health care providers to report any adverse events after receiving the vaccine. Studies show that significantly fewer adverse events are reported under a passive system when compared to an active surveillance system in which vaccine recipients are actively monitored to identify and track any adverse reactions to a vaccine.

Forty-two percent of the respondents reported that they had received one or more anthrax shots. Of these, 86 percent reported experiencing side effects or adverse reactions. About 60 percent indicated that they had not discussed any side effect to the anthrax vaccine with military health care personnel or their supervisors—some (49 percent) citing as their reasons fear of losing their flight status, adverse effects on their military or civilian careers, and ridicule. Seventy-one percent reported that they were unaware of the Food and Drug Administration's Vaccine Adverse Events Reporting System. Slightly less than 6 percent of those who had a reaction reported to this system.

Our survey showed that for some local and systemic reactions (for example, a knot or lump in the vaccinated arm and joint pain), the reported duration was more than 7 days. (See table 1 in app. II for a list of reported reactions). The prevalence and duration of the reported symptoms varied widely. A number of reported symptoms are expected reactions to the anthrax vaccine; however, their frequency and duration was more than DOD reported (0.007 percent). For example, two out of three reported burning in the vaccinated arm (79 percent) and a knot or a lump in the vaccinated arm (82 percent). Also, 10 percent reported swelling in the arm lasting for more than 7 days, and 6 percent reported arm pain and limited motion for more than 7 days. Six percent reported extreme fatigue, and 7 percent reported joint pain lasting for more than 7 days.

These reported reactions are significant because they could potentially impact individual ability to carry out military duties. However, 60 percent of those who experiencing reactions had not discussed them with military health care personnel or their supervisors. Forty-nine percent did not report because the reactions were not severe enough; however, another 49 percent did not report because of the fear of losing flight status, possible adverse effects on their military and civilian careers, and a fear of ridicule. Since many individuals are not reporting their reactions to military medical personnel or to the Vaccine Adverse Events Reporting System, the actual duration, the extent or impact on units and individuals, and the ultimate resolution of these reactions are unknown.

Because we had limited time to analyze all of the data we obtained, we will provide additional detailed analyses of the data to the Committee in a later report. Other issues such as impact of anthrax vaccine program on morale and quality of life will also be addressed in that report.

Mr. Chairman, this concludes my prepared statement. I would be happy to answer any questions you have at this time.

Contacts and Acknowledgments

For future questions regarding this testimony, please contact Kwai-cheung Chan at (202) 512-3652. Other individuals making key contributions to this testimony includes Sushil K. Sharma, Ph.D., DrPH, Foy D. Wicker and Stanley J. Kostyla.

Appendix II

The adverse reactions in the table were reported by those who received one or more anthrax immunizations. The reactions are categorized by duration of the event.

Table 1: Prevalence of Local and Systemic Adverse Reactions By Duration

Type of reaction	≤ 1 Day	1-3 Days	4-7 Days	≥ 7 Days	Total
Local	**Percent**	**Percent**	**Percent**	**Percent**	**Percent**
Redness 2.5 inches or less	21	20	7	5	53
Redness >2.5 inches	5	12	10	6	33
Swelling in arm	16	18	11	10	55
Burning in arm	60	14	3	2	79
Arm Pain limited motion	20	22	11	6	59
Itching in arm	18	10	7	5	40
Knot/lump in arm	17	14	21	30	82
Systemic					
Chills	5	4	3	1	13
Fever	7	6	2	1	16
Extreme fatigue	6	7	3	6	22
Dizziness	1	2	1	1	5
Headaches	6	6	2	1	15
Blurred vision	1	1	0	1	3
Numbness in extremities	3	1	1	2	7
Joint pain	6	5	5	7	23
Memory loss	1	1	1	2	5
Blackouts	0	0	0	0	0
Ringing in ears	2	1	1	2	6
Insomnia	1	1	2	1	5
Nausea	3	2	2	0	7
Other	1	1	2	3	7

Source: GAO Survey, 2000.

Appendix I

SCOPE AND METHODOLOGY

The best way to reliably assess the pulse and views of military members is by surveying a representative sample of personnel. This year, we developed and administered such a survey that was designed to obtain the views of selected Air National Guard and Air Force Reserve personnel regarding issues associated with the DOD's Anthrax Vaccine Immunization Program (AVIP). The survey was mailed in May 2000 to a random sample of 1,258 personnel. As of September 7, 2000, 829 individuals had completed and returned the survey. Our work was conducted in accordance with generally accepted government auditing standards.

QUESTIONNAIRE DEVELOPMENT

The survey was developed with the assistance of discussion groups made up of pilots and other aircrew members of the Air National Guard and Air Force Reserve. It was pretested at Andrews Air Force Base, Maryland, and further pretested and refined at Guard and Reserve units located in Hartford, Connecticut; Newburg, New York; Madison, Wisconsin; Battle Creek Michigan; Memphis, Tennessee; Travis Air Force Base, California; March Air Force Reserve Base, California; Fort Wayne, Indiana; and, Dover, Delaware

SAMPLE CONSTRUCTION

The sample consisted of 1,253 Air National Guard and Air Force Reserve aircrew personnel who were in the service at any time between September 1998 and February 2000. Our sample was drawn from pilot and aircrew member populations provided by the Air National Guard and Air Force Reserve in early 2000. In addition the Anthrax Vaccine Immunization Program Office provided information as to vaccination status. For the sample design, personnel in our universe were categorized by two factors: military status (left versus on board) and vaccine status (shot versus no shot). The sample was adjusted for groups with differing expected rates of survey completion and adjusted to provide a level of precision of $\pm$ 7 percentage points.

SURVEY ADMINISTRATION

As of September 7, 2000, we had received 828 responses from eligible respondents, an overall response rate of 66 percent. We used a contractor to create a database based on reported responses. We validated the data provided to us by the contractor to ensure accuracy.

WEIGHTING RESPONSES AND POTENTIAL NONRESPONSE BIAS

The survey responses were weighted to reflect the Air National Guard and Air Force Reserve population for the survey. This weighting procedure adjusts for the different proportions of individuals sampled from each cell and the actual response rate for that cell in the sample design. The survey results assume that nonrespondents would have answered like respondents. This assumption involves some unknown risk of nonresponse bias. Weighting can be used to statistically adjust for differing sampling rates and response rates; however, weighting cannot adjust for possible differences between those who do and those who do not respond to a survey.

Appendix III

RELATED GAO PRODUCTS

Gulf War Illnesses: Questions About the Presence of Squalene Antibodies in Veterans Can Be Resolved (GAO/NSIAD-99-5, Mar. 29, 1999).

Medical Readiness: Safety and Efficacy of the Anthrax Vaccine (GAO/T-NSIAD-99-148, Apr. 29, 1999).

Contract Management: Observations on DOD's Financial Relationship with the Anthrax Vaccine Manufacturer (GAO/T-NSIAD-99-214, June 30, 1999).

Medical Readiness: Issues Concerning the Anthrax Vaccine (GAO/T-NSIAD-99-226, July 21, 1999).

Anthrax Vaccine: Safety and Efficacy Issues (GAO/T-NSIAD-00-48, Oct. 12, 1999).

Medical Readiness: DOD Faces Challenges in Implementing Its Anthrax Vaccine Immunization Program (GAO/-NSIAD-00-36, Oct. 1999).

Medical Readiness: DOD continues to Face Challenges in Implementing Its Anthrax Vaccine Immunization Program (GAO/T-NSIAD-00-157, Apr. 2000).

(713048)

Mr. BURTON. I think, Mr. Shays, you had a chance to review the GAO report last night, did you not? Mr. Chan just completed his statement. I think you had that report last night.

General West.

General WEST. Sir, I will not make any comment on the GAO report because I did not get it last night. I do not have it yet, and I don't know what the results were other than what I just saw before you.

Normally, we would receive the report, we would have an opportunity to respond, that response then would be reviewed by them, and we would have a chance to discuss that, and that has not happened yet.

Mr. BURTON. Were you briefed about it at all, General?

General WEST. I was not, no, sir.

Mr. BURTON. What we would like to do then—Mr. Chan, did you brief DOD about this?

Mr. CHAN. Yes, sir. Last Monday, before the past hearing, we briefed three of his staff, at least two are present here. We gave them, in fact, very in-depth presentations beyond what we sent to you.

Mr. BURTON. Who were those that you briefed? Do you recall their names?

Mr. CHAN. I remember two names, Colonel Gerber and Colonel Randolph, plus another person.

Mr. BURTON. Are those staff members of yours, General West?

General WEST. They don't work directly for me, but they work on the anthrax program, and they are both good and competent people. One of them is here today. So if you have questions for them——

Mr. BURTON. The only thing is, I was wondering why you weren't briefed by them about that. Do they normally brief you when you are going to testify before Congress if they have been briefed by GAO?

General WEST. Well, sir, I knew that they had had a meeting with FDA, but they weren't given a copy of the report, and we have not had any opportunity to respond to it. It would be improper for me to give you an official DOD response to something that has not been delivered to us yet.

Mr. BURTON. Well, we will not quibble about that now. I hope in the future if GAO does give staff members a lead time appraisal or in-depth report on one of their findings that they will be given to the superior officer, like you, General West, so you are prepared to testify before the Congress. In any event, maybe you can, after you review it, along with your staff, you can give us some written response to it.

In any event, if you have an opening statement, why don't you proceed?

General WEST. We will look forward to doing that, sir, and certainly I am very interested in pursuing some of the things that he presented on those charts and some of the things that my staff talked to me about. We will need to see the report before we can do it.

Mr. SHAYS. Could I interrupt to ask a question?

Mr. BURTON. Sure.

Mr. SHAYS. General, were you aware that the GAO was going to be making testimony today? Were you aware that you would be on the dais with them?

General WEST. Yes, sir, I was.

Mr. SHAYS. Did you ask for their statement?

General WEST. I wanted a copy of the report.

Mr. SHAYS. I asked a question. It wasn't that. I asked if you asked for their statement today?

General WEST. I didn't specifically ask for it, no, sir.

Mr. SHAYS. Why not? When you come before this committee, you don't want to know what other people are going to say?

General WEST. Yes, sir, I do. But——

Mr. SHAYS. And is it your practice that when you come before these committees you don't ask to know what other people are going to say that are going to appear on the same panel with you? Is that your practice? You just simply don't ask?

General WEST. No, sir, I do want to know what is going to be presented to you, and I want to be able to respond to it. I would have loved to have had a copy of the report so I could have.

Mr. SHAYS. I am not talking about a report. I am talking about their testimony, and I can't believe that you wouldn't have wanted to know what the testimony of the other people was. They have to submit it before today. You had to, didn't you?

General WEST. Yes, sir.

Mr. SHAYS. Wasn't it logical that GAO would have submitted something?

General WEST. Yes, sir.

Mr. SHAYS. Isn't it logical that you might want to look at it?

General WEST. Yes, sir.

Mr. SHAYS. And isn't it logical that you might then just care to ask to see it? Wouldn't you have just asked the people that work with you to get a copy of the statement?

General WEST. Getting a copy of the statement or knowing what they are going to say is not the same thing as an official response to a report.

Mr. SHAYS. Just start with the statement. It is logical they have a statement to make; and I would think, thinking that the Army likes to be prepared, that you would simply have said I would like a copy of all the people that are going to testify.

General WEST. I was briefed on what they intended to say and what they were going to present as testimony.

Mr. SHAYS. That is important to know. It is important to know you were briefed on what they intended to say. It is a little disingenuous—with all due respect, you say their report. This is testimony that they are giving.

Your report is going to be given when, Mr. Chan?

Mr. CHAN. Hopefully within 2 to 3 months. It is not complete. That is why we call it preliminary results, sir.

Mr. SHAYS. It is not a report yet, is it?

Mr. CHAN. No, sir.

Mr. SHAYS. Let me ask you something else, Mr. Chan. Is there anything in your statement that you have given today that basically is new, that wasn't submitted to us last night?

Mr. CHAN. No. If I can say, we have shared with the three people we mentioned in much greater detail than what I presented today to you.

Mr. SHAYS. I just want to explain something. I feel like when you come before us that we have to know specifically what you are saying, because if we don't ask it the right way, you give us a false impression. The false impression I had was this is all news to you, and in fact you were briefed yesterday about what they were going to say. Isn't that true?

General WEST. Sir, there was nothing disingenuous about the statement. I merely want——

Mr. SHAYS. Just answer my question, and then you can tell me how you want to qualify it. You were briefed yesterday on what they were going to say, is that not correct?

General WEST. I was briefed earlier in the week, not specifically yesterday.

Mr. SHAYS. So you pretty much knew what they were going to say today?

General WEST. Yes, sir.

Mr. SHAYS. OK, thank you.

General WEST. But there was nothing disingenuous about my answer. I only wanted to get on the record that I can't give an official DOD response to a report that we haven't received yet nor haven't been given a copy of, as you have. That is not disingenuous, sir.

Mr. SHAYS. No, but it is disingenuous, because what we have is their testimony, and you were briefed on their testimony, and so you can comment to their testimony, not to their report. You have every reason, an obligation, to testify to what they said today.

General WEST. I can comment on what they say, and I am very willing to do that, and every answer that I give you will be an honest answer. What I can't do is give you an official DOD response to a report we haven't received.

Mr. SHAYS. I don't want an official. I want your response.

Mr. BURTON. Thank you, Mr. Shays.

Before we hear your testimony, your opening statement, General West, before we began this recent round of hearings on the anthrax program, we invited the vice chairman of the Joint Chiefs of Staff to appear, but he requested that others on his staff appear on his behalf. Of course, we are disappointed that General Meyers has not joined us to share with us his opinions as well as those of the chairman, General Shelton.

Our concern is to what degree the chairman and vice chairman are personally aware and engaged on this issue and the problems that have been presented at our hearings. My concern is that they may be letting staff handle the problem and they aren't getting all the facts.

Readiness of our Armed Forces is the direct and personal responsibility of the chairman, vice chairman and the Joint Chiefs of Staff. Retention is a readiness issue of significant proportion.

Has the Joint Staff and the DOD been asleep at the switch in not discovering what the GAO has found out that has an adverse impact on the readiness arising from the AVIP program?

These are things we want to find out. We would like to make absolutely sure that, even though this report is not going to be com-

pleted probably for a month or two, that the graphs, charts and findings that have been reported by Mr. Chan and his associates today are conveyed to the chairman and vice chairman of the Joint Chiefs of Staff as quickly as possible.

As Mr. Shays said, it is troubling that several people, one in particular that is here with you today, was briefed in more depth than we were about the statements and the information we received today, and yet it appears as though you weren't given a full briefing by your subordinates, who are here with you today.

I would hope in the future, if we have future hearings, if GAO or some other entity in the government briefs your staff people that they will make sure you get a full briefing on what was said so you are prepared.

Mr. SHAYS. Mr. Chairman, General, I want to apologize to you in referring to you as the Army, since you obviously are part of the U.S. Marine Corps. I apologize. You also wanted to make a point about it being an official report. I interrupted you. I apologize for that.

My problem, sir, though, is that you gave the implication that you didn't know anything about this report, that it was news to you, when in fact your people were given this report and you were briefed. I don't even concede that you weren't given a thorough briefing.

So whether you have a report that you can give an official comment on, you have a history with us, and the history is you seem to give implications like only one person refused to take anthrax, when in fact we know more did; and that is why I have this sense of concern about how you communicate with us.

So I just would like to know, you were briefed, correct, on this statement that was going to be made by Mr. Chan?

General WEST. Sir, I was briefed. I was given a full briefing by my staff. They are good staff, and they do a good job. I made one point, and that is—and you just said we got the report. We didn't get the report. We still don't have the report. If you have it, you have it, and I don't.

Mr. SHAYS. I don't have a report.

General WEST. But the only thing I said was I can't give an official DOD response to something we haven't received.

Mr. SHAYS. But you can give a response to what you have heard today, is that not correct?

General WEST. I can and I will.

Mr. SHAYS. And all the statistics that were involved, that were presented here?

General WEST. Yes, sir.

Mr. BURTON. General West, we are ready for your opening statement.

General WEST. Thank you, sir. I am just going to make a few comments. I had a prepared oral statement I was going to make, but, as you know, I have appeared here several times and you have heard some of it before, so I am not going to use that part.

I am just going to make a few points in response to what we have already heard today, because I think they are important. I have been here several times. I have never given you one statement that was a false official statement. I have never given you

one lie, never called anyone a malingerer; and I don't intend to do that today.

I have been in this job 14 months. During that time, I have spent every working day of my life working on the anthrax issue in one way or another. When I came to this job, I quickly realized that there was a lot of contention about it and that there were differing opinions about it, and I started my job by going to the opposition side, sitting down with them and listening to their concerns.

I went through them one by one. I have met with people that are sick and believe that they had an adverse reaction. I have met with people that have read things on the Web site that caused them concern. I have tracked those things down as best I could, one by one.

I need to tell you that, after that 14 months of effort, I am honestly and sincerely convinced, more than ever, that the anthrax vaccine immunization program is the right thing for the Department to do. I am going to try to quickly tell you why I believe that.

If I could ask the lieutenant with me to hold up just a simple chart—I don't have anything to put up on the screen. Show the Desert Storm picture, please. That is not just a picture that somebody dreamed up. That is an actual depiction of a combat seen during Desert Storm.

I was on the ground on the south side of that picture. I was looking into the burning oil wells and the smoke over there. Later, I had to lead my men through that. We did that, and when we got to the other side, what we found was that our adversary on the other side of that snug had weaponized anthrax. It was colorless, it was odorless, it was tasteless, it is very difficult to detect, and if you breathe it and you haven't been vaccinated, in 3 to 4 days you are probably going to die.

We had a force on the battlefield that was not protected. We found out that the threat that we had suspected, but we validated it, we found out that it was bigger than we thought it was.

In the process of the investigating and the peacekeeping force going in and meeting with some of the Iraqi people, meeting with some of their counterparts in the Soviet Union that had worked on this program, we found that they had a lot of bad stuff and that that stuff would kill you very, very quickly if you weren't protected. We found out that the enemy had gone so far that they had deployed into the battlefield, that their unit commanders had parameters under which they could use it, and they even had flare pistols loaded with the right color flare to shoot to let their troops know that they were getting ready to deploy a biological weapon and they should don the appropriate equipment to give themselves protection.

We had a responsibility to the mothers and fathers of America to provide the best protection that we could come up with against that kind of threat, that existed not just there in Southwest Asia but in other places in the world as well. The protection that we came up with was the anthrax vaccine. It was approved by the National Institutes of Health. It was approved by the Food and Drug Administration. It had been reviewed by the Centers for Disease Control. It has since been reviewed by a vaccine expert review committee. And all of them, the people that we pay to make these kinds of decisions, these kinds of certifications and give us these

kinds of recommendations, told us that the vaccine was safe and that it was going to be effective, used against a threat that we were planning to use it against.

We wanted that kind of protection for our force. So we did it. We went forward with it.

The Secretary conducted a long review. He got all of the data and all the information that he could, and then he made a decision based on a recommendation of the Joint Chiefs of Staff who have also taken this vaccine, as has the Secretary and the Deputy Secretary and myself and the majority of the senior leadership in the Pentagon.

No matter how good a pilot a person like Lieutenant Colonel Heemstra is—and I assume he is a good one, and I assume that everything he told today was the truth as he believed it—but no matter how good he is, if he goes to the battlefield and he is unprotected and the enemy uses a threat they have already got that will kill him, he is not going to be any good to us in a few days.

As a commander, if I go back there and the enemy uses it and I haven't used protection that all the people we depend upon to tell us if something is safe and effective, I have a lot of letters to write to a lot of mothers and fathers telling them why their sons and daughters died on the battlefield when I could have protected them. I did not want to do that, and the Secretary did not.

I encourage all of the members of the committee to go sit down with the CIA, get a full brief on this threat, find out how bad it is and where it is and how many people we think have it. I don't think there will be many of you that will not want to not provide protection against that threat after you hear the briefs, sir.

Mr. Gilman talked about us not responding to your committee's report. We did respond. It was over 70 pages. It had a lot of medicine and science in it that he talked about wishing that we would look at, but apparently it didn't make a difference or was not reviewed.

I am concerned about some of the data that the pilots gave out here today about the numbers within their units, and I learned some things today that I need to go back and investigate. But I can tell you that I have a chart on each of the six components of our Guard and Reserve forces, all six of them, the Army National Guard, the Army Reserve, the Navy Reserve, the Marine Corps Reserve, the Air Force Reserve and the Air National Guard, and in the year 2000 they all have a lower attrition rate than they did in 1998 when we started this program.

So if somewhere in between their story and our official charts there is a discrepancy and we need to get to the bottom of that, I promise you that I am going to do the best that I can to do that and tell you where those differences are. Because I haven't come over here, nor do I believe the other people that came with me, lied to you about our retention statistics.

Retention is very important to us. To be honest with you, losing, as I told my friend, Congressman Jones, who I have a great deal of respect for, and he mentioned this at the last hearing without saying my name, but I don't mind it being used—losing one serviceman or woman for no other reason than they have been led to believe they should not take a vaccine that is only meant to be good

for them is a concern to me. That is a problem. Losing—I am an aviator myself. Losing one good pilot out of a unit that is trained with that unit, that is current in his airplane and ready to go to war is a retention problem, it is an attrition problem, and I do not want to have that.

I welcome the committee's oversight and the committee's help to make our program better, and you have done some things and led us to some things that have made it better. But we need your help to make it better, not to stop it. Because if we stop it, we are going to send people to work every day in an arena where weaponized, aerialized anthrax that can kill them in 3 to 4 days can be delivered on them at any moment; and I don't want to come before you and tell you that I had protection against that threat and didn't use it.

Things like the witness that would have been to my left told you about earlier, we are very interested in those things. We are pursuing them. Dr. Wenguard is one of the DOD people that came before you as a witness before. She is interested in it. We have helped fund that.

But as he said, it is 4 years away. And once he has that, once it is approved, how do you know that the enemy has used something that is tasteless, odorless and colorless and very difficult to detect? And after you give them antibiotics and you give it to them for 60 days, I may be wrong, but I don't believe it provides you continuous protection. It is just for that interim period of time that you use the antibiotics to kill what has already contaminated your body. We need something better than that, because we can't predict when they are going to use it, and we probably won't know that they have until people start to die.

There is nothing disingenuous about this kind of testimony. It is just the way I see it as a commander.

Mr. BURTON. Thank you, General. Does that conclude your statement?

General WEST. Yes, sir.

[The prepared statement of General West and General Weaver follows:]

ANTHRAX VACCINE IMMUNIZATION PROGRAM
What We Have Learned
And its Effect on Readiness and Retention

STATEMENT BY

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INTRODUCTION

Chairman Burton and Distinguished Committee Members, I appreciate the opportunity to appear before this Committee today to discuss what we have learned since the inception of Anthrax Vaccine Immunization Program (AVIP) and its effect on retention and readiness. I am accompanied today by Major General Paul Weaver, Jr., Director of the Air National Guard.

BACKGROUND

When Secretary Cohen accepted the recommendation of the Joint Chiefs of Staff to vaccinate all U.S. military personnel against the biological agent anthrax, he did so to protect our men and women in uniform from a colorless, odorless and tasteless aerosolized weapon.

Our intelligence indicates that several countries either have or are attempting to acquire anthrax as a biological weapon. The threat exists for countries to produce and deliver anthrax against our troops in the high threat areas of Southwest Asia and Korea. This means that many of our military men and women stationed around the world go to work every day under the threat of a weaponized, anthrax attack.

This difficult–to-detect agent is a highly lethal biological warfare agent that can cause swift and almost certain death when an unprotected person is exposed.

Based on this intelligence, the Department developed a three-phased AVIP implementation plan with the objective of first vaccinating those members at greatest risk of exposure to the biological weapon of anthrax.

We have conducted Phase 1 of the program, vaccinating those military members assigned to or deploying to Southwest Asia and the Korean Peninsula for the past two and one half years.

During Phase 1, we have administered more than 1.9 million doses of safe and effective, FDA-licensed vaccine to over 487,000 individuals. While the Committee has expressed an interest in the 442 individuals who have refused to obey a direct order to take the anthrax vaccine, these individuals represent less than one-tenth of one percent of those who have taken the vaccine.

READINESS

Reserve component readiness, is examined under four major categories of readiness ratings – Personnel, Equipment on Hand, Equipment Readiness and Training.

In regard to AVIP's impact on Reserve component readiness, we have examined those four categories.

The only readiness rating to which AVIP could be directly related is Personnel. Over the past two years, we have actually seen increases in personnel readiness for four of the six DoD Reserve components, with decreases in two components. We have no indications that the decreases are directly related to concerns about the AVIP program. While there have been individual cases of Reserve component members refusing the vaccination, documented losses from such cases are a very small minority.

WHAT WE HAVE LEARNED

We have learned a great deal in the past few years about the program and our management of it. These lessons will result in a better program as we work toward vaccinating the total force in the years to come.

We have also learned a great deal from our service members. For instance, we have become aware of the unique characteristics of our aviation community and the concerns they have for the implications of the military's anthrax vaccination program to their careers. Some members fear the vaccine will adversely impact their health, FAA medical certification, airline employment opportunities and insurance coverage, affecting their ability to support their families and continue in a field that they love.

To address these concerns, the DoD's AVIP web site provides a hot link to the Virtual Flight Surgeons® web site (www.aviationmedicine.com). At this web site, independent aerospace medicine physicians present balanced information regarding

the anthrax vaccine for the aviation community. To do this, they provide links to both advocate and opponent web sites identifying them by one of four primary categories of information: 1) military sources; 2) government (non-military) sources; 3) non-government, academically based sources; and 4) anti-vaccine advocate sources.

The www.aviationmedicine.com web site presents a "Rumor Control" section that provides a forum for discussing the issues of greatest concern to the aviators. Such issues include fears that the FAA will revoke their medical certificate if they receive the anthrax vaccine, that the airline will not hire them or terminate them if they take the anthrax vaccine or that the medical insurance carriers will drop coverage for conditions resulting from the anthrax vaccine. For each concern, the site then provides ample objective, factual information that corrects the misconceptions.

Despite such factual information provided by the FAA and by web sites such as Virtual Flight Surgeons® the rumors and anxieties continue.

When I first came to this position fourteen months ago, I sat with dozens of members who felt this program had injured either their careers or their health. They made us aware that certain improvements in the program were warranted. In response we developed and instituted new administrative and medical exemption policies that better enable members to be exempted from the vaccination under apppropriate circumstances.

All of these lessons have allowed the Department to better educate, protect and retain highly valuable Active Duty and Reserve Component members. Despite our efforts to improve our program however, the Department still needs more FDA licensed vaccine to expand the AVIP to protect the total force.

STEPS WE HAVE TAKEN

Since the inception of the AVIP, we have continuously improved the type, number and quality of educational tools available to our service members, their families and the public.

We are now using the most current technology and applying communication strategies and tools that more effectively relay information and address the concerns and questions of our service men and women.

We are continuing to work hard at making this type of information more available to everyone. To do this, we utilize a variety of methods, focusing on those tools that are most effective. This involves using new education and training techniques.

The best example of this is our Internet web site. This cost-effective communication tool allows us to present accurate, fact-based information 24 hours a day at users' convenience,. We also use more conventional tools like brochures, journal articles, other printed materiel like wallet cards, the 877-GET-VACC telephone information line, training videotapes, other multi-media products and silent training aids as well. Silent training aids include items such as message pens, beverage containers

and clinical penlights. These durable, time tested objects, commonly used by service members, serve as a continuous reminder of key program messages, contact sources for AVIP information and adverse event reporting.

About 30,000 visitors come to our Internet Website each month, with an average of 210,000 to 300,000 page views per month. We provide individualized answers to the e-mailed questions of about 160 people per month (avip@otsg.amedd.army.mil). In addition, we answer about 80 calls per month on our toll-free 877-GET-VACC line.

SAFETY SURVEILLANCE

To date, 13 studies have established the safety of the anthrax vaccine. These 13 studies include the collection of both active (solicited) and passive (spontaneously provided) data from anthrax vaccine recipients. They also include focused and broad-based studies, and short and long-term studies.

Results from our studies have already been publicly presented to numerous civilian scientific assemblies and have started appearing in highly respected medical journals. Many more presentations and publications will follow. We have shared raw data with the nation's senior scientists, with members of respected independent advisory panels and with a new panel of independent civilian scientists selected and established by the Department of Health & Human Services. We have collaborated with public health experts at the Centers for Disease Control and Prevention, the FDA and

leading universities. Pending final publication of the results, we have posted the interim findings from the studies on our web site, www.anthrax.osd.mil for the world to read.

One of the 13 safety studies involves an independent civilian panel review of reports to the Vaccine Adverse Events Reporting System (VAERS). The chief value of VAERS is to look for rare, unexpected events that are temporally associated with the vaccination. At the Department's request, the Department of Health and Human Services convened a civilian panel, the Anthrax Vaccine Expert Committee (AVEC), to review each VAERS report submitted for the anthrax vaccine. After two years in which almost 1,200 reports and medical records have been reviewed by the committee, the AVEC continues to report that they have identified no unexpected events and no disease syndromes associated with the anthrax vaccine.

CONCLUSION

DoD embraces the "Total Quality" concept and seriously considers all recommendations for continuous, incremental improvement. All department and divisions with DoD use Quality Improvement processes. During the past two and half years, since the inception of the AVIP, DoD has made many changes to improve the program and we will continue to implement improvements.

Nearly one-fifth of our servicemen and women are benefiting from anthrax vaccine protection. That means nearly 500,000 more military members have begun receiving protection against anthrax today, than were protected when our nation was last involved in armed conflict in an anthrax-threatened theatre. That is not enough however. All who serve and defend our nation deserve and should be protected from the deadly anthrax infection.

We are eager to resume and expand our vaccination effort to include the total force, as soon as an adequate supply of safe and effective, FDA-licensed vaccine becomes available. We will work diligently with the FDA toward achieving new production as soon as it is safely practical and to ensure that the newly produced vaccine remains safe, pure, sterile and potent throughout its shelf life.

Our highest priority has been, and will always remain, to protect the safety and well being of the men and women who safeguard our country.

Those men and women who choose to serve their country do so in the knowledge that such service is an honor. They realize that it comes with a set of responsibilities and obligations including the responsibility to maintain their personal readiness. Such readiness includes protection against diseases such as anthrax. Failure to provide such protection would be a serious dereliction of duty.

Mr. BURTON. General, how did the Iraqis who had the flare gun that they were going to fire to show their troops that they had dispensed the anthrax, how were they going to protect their troops?

General WEST. I don't know that fully, sir. I assume that they used a vaccine that the Soviets provided them. It is not like our vaccine. It is a different one.

Mr. BURTON. You don't know from our intelligence sources whether or not they were going to wear protective clothing or whether they were vaccinated?

General WEST. I know that they had some protective clothing. It would not have been enough to provide them full protection.

Mr. BURTON. Do you know anything about the vaccination process with the Iraqi army?

General WEST. I know a little bit about it. I know——

Mr. BURTON. Were they vaccinated?

General WEST. Some of them were, yes, sir.

Mr. BURTON. How many?

General WEST. I don't know that.

Mr. BURTON. Were all of them vaccinated?

General WEST. I don't know that either, sir.

Mr. BURTON. Well, it seems to me from our intelligence services after the war, it seems to me the first thing that you ought to know at the Pentagon, if you thought there was a threat from anthrax and you knew the enemy was going to use it, that you would find out what they were doing to protect their troops. It seems to me and I believe that it probably was not a vaccination. It was probably protective clothing and other gear to protect their troops.

But, in any event, that would be the first thing I would think the Pentagon would want to do is find out—if they were going to use some kind of a biological substance, that they would find out how they were going to protect their troops.

General WEST. We did want to know that, and we asked those questions, and we have part of the answer. We know that they had protective gear, we know that some of them were vaccinated, we know that they planned to shoot it forward from their positions with the wind blowing south in the hopes that only our force would be exposed.

Mr. BURTON. Well, General, in World War I they were using mustard gas and they were firing it one way and it was blowing back the other way, so the wind does change. I don't think that is probably a real good answer because it seems to me that the first thing they do is figure out how to protect their troops in the event that they use the biological weapon.

But let me go into some other questions, because we have a vote, and Congressman Shays is going to come back——

General WEST. I think General Weaver had a short statement he wanted to make, sir.

Mr. BURTON. Oh, I am sorry, General Weaver. Did you want to go ahead and make your statement right now?

General WEAVER. It is up to you.

Mr. BURTON. Sure. Go ahead. But I do have some questions.

General WEAVER. Mr. Chairman, distinguished members of the committee, and especially my good friend Congressman Ben Gilman who I have known since 1985 personally and professionally,

I appreciate the opportunity to address the committee today regarding recruiting, retention and readiness in the Air National Guard.

As you know, the Air National Guard is a volunteer force but also an integral part of the total Air Force. Our units deploy to every theater as part of the Air Force's air expeditionary force. Consequently, our recruiting, our retention and our readiness have a direct bearing on the success of the total Air Force.

Mr. Chairman, to give you an example, through AES, Air Expeditionary Forces 1 through 10, approximately 25,000 Air National Guardmen and women deployed alongside their active duty counterparts, and over the next 30 months, over half of the Air National Guard force, 50,000, will deploy in the upcoming AES. In the Air National Guard alone, we provide over 20 percent of the aviation package and about 8 percent of the support package, so we truly are a very integral part of our total Air Force.

I am pleased to also report that we met our recruiting goal for fiscal year 2000, but we fell short of our end-strength by approximately 300 people out of 106,000 strong. It was not easy, but with the help that we received from Congress, we were able to put more recruiters in the community and increase our advertising budget.

On our retention front, we had an equally good year. Our attrition rate for fiscal year 2000 was 10.7 percent. This is in line with and could end up being an improvement, which it is, over the last year's rate of 11.3 percent, the best of all of the military forces in DOD, and I am very proud of that.

I understand the committee has some concerns regarding the impact of the anthrax vaccine on recruiting and retention, and I, too, looked carefully at any and all factors that could impact personal readiness rates. Since December 1999, we have asked commanders to report to us the results of exit surveys of departing members. These surveys track any and all reasons why a person was leaving the Air National Guard. This is from December to October of this last year, sir.

As of August 31st, we have had over 100 enlisted, over 30 pilots and 60 nonflying officers that have self-reported, self-reported that anthrax was one of the reasons that they were leaving the Air National Guard. I emphasize that these are self-reported reasons. There may be more, and I know there are more. The exit surveys are voluntary, and we have to take them at face value, but it is an indicator.

Is it possible that someone is leaving because of the anthrax but not indicating the reason on the survey? Absolutely. Some may indicate employer problems, when it is really pressure from their family. But I must emphasize that the Air National Guard still has the best attrition rate of any Reserve component. Every loss, every loss of our trained personnel is regrettable, but we cannot allow these losses to deter us from protecting our men and women from a real threat; and as the director of the Air National Guard, I owe them no less.

Mr. BURTON. We would like to have your testimony submitted for the record, both of you, if we might.

I don't understand—excuse me just 1 second.

I don't understand why in the surveys that were sent out, and I wrote a letter to the Pentagon about this, that there isn't one question to the spouses or to the servicemen and women about anthrax. You have known about the concern of the Congress, many Members of the Congress, about anthrax for a long time, and I cannot for the life of me figure out why you would send out a questionnaire to all of the members of the Reserve and their wives and not have one single question about Desert Storm and the side effects, or anthrax.

Can you give me—even after we asked about an addendum being attached to it, the Pentagon came back and said no. Why is that?

General WEST. Sir, I wasn't part of designing the survey, but I will tell you what I know about it.

The survey that we put together was designed to go out and ask people what their reasons were for being unhappy with or leaving the service, and we wanted their answer. We didn't want to suggest one to them.

The survey that GAO did, from what I know about it, was almost exclusively an anthrax-related survey to two components of our Reserve forces. They asked them a bunch of yes and no questions about anthrax; they offered them a shopping list of reactions and asked them if they had had any of those. Whereas the survey people tell us that you get a more accurate response if you go out with a survey that asks the people why they are leaving and let them come up with their answer, anonymously, no names on the survey, rather than suggest what the answer would be.

Mr. BURTON. But General, there were all kinds of specific questions on that survey. I will be glad to give you a copy of it. Have you read it? Have you read the survey? The survey goes into all kinds of things. I mean——

Here it is, right here. "What is your spouse's present pay grade? Have you ever served in the U.S. Armed Forces or Active duty or National Guard Reserve? Are you currently in the Armed Forces?" And then it has 57, it has 102, it has 114 questions.

"In your opinion, how do the following groups or individuals view your spouse's participation in the National Guard Reserve?" This is the spouse's questionnaire. "If your spouse is mobilized or deployed more than 30 days, how likely are you or your family to make use of the following military services?"

They go into everything, but the one thing they don't ask is about something that is very relevant to all of the people in the military right now. Because we have a Web site, and they are hitting on that on a regular basis, and when we asked the military, why didn't you ask one single question about the anthrax vaccine, they said, well, you know—they didn't have an answer, except they were not going to put that in there.

If you don't ask the question, you are not going to get the answer. There is no place for them to volunteer that on here, except comments on the back, but a lot of these people are very concerned that their comments, if they pertain to the anthrax, as you have heard from the testimony of these officers who testified, or previous officers that testified today, they are afraid it would reflect bad on them, get them an Article 15, a dishonorable discharge and court-martial or financial penalty or jail sentence.

General WEST. Well, the survey that was sent out was an anonymous one, and they didn't have to put their name on it, and I know that the people that put it together I believe were well motivated to do a good survey. They went out and sought professional expertise to help put it together. When we got the letter suggesting that we had an addendum to that and they went back and talked to the people that helped put them together, their suggestion was that if you put an addendum question like that on the end of the survey that you will bias the results.

Mr. BURTON. When did they start working on this survey, do you know?

General WEST. I don't know.

Mr. BURTON. Was it 6 months ago, a year ago, 2 years ago? When did they start working on this survey?

According to staff, they started working on the survey about a year ago, a year before the survey went out.

The problem with the anthrax vaccine and the concerns about it have been around for 2, 3 or 4 years, so they knew well before this survey was put together that was a major concern of the military and possible retention, and for that not to be included in there just mystifies me.

I have to run and vote. Congressman Shays will come back and reconvene the hearing as soon as he gets back, and then I will take the Chair when I get back, but I should be back here and Congressman Shays should be back in about 5 or 6 minutes. We stand in recess.

[Recess.]

Mr. SHAYS [presiding]. I am going to call the hearing to order, but I am doing it over here, if it is all right. I am going to take a deep breath.

What has been established so far at the hearing I think is that the GAO has documented that we have a lot of people leaving our forces in large measure because of anthrax. What you countered, General, last was that the—I am sorry. General, you countered by basically saying those numbers were not your numbers, and you disagreed with it, and you feel that the attrition is not as bad as it was before. That is your testimony.

My general sense, too, General, is that you then had shown a picture that said that you were in the Gulf war and that your forces came across weaponized anthrax, correct?

General WEST. We came across evidence on the battlefield that there was weaponized anthrax there that had been deployed forward in the theater.

Mr. SHAYS. I am not playing a game with you, I just said that you came across weaponized anthrax. So what are you saying? You seem to be qualifying it, so what am I not hearing here?

General WEST. That the intelligence reports, the small unit commanders' notebooks that we had, the warning devices that were recovered indicated that the enemy had it deployed to the forward battlefield. I did not personally see one of those weapons, if that is what you are asking me.

Mr. SHAYS. So you did not see this. I mean, there was a very dramatic picture, but your troops did?

General WEST. Sir, we would have to go into a classified setting to give you a full answer to what you are getting at, but I can tell you without breaching intelligence rules that documents and signal devices and interrogations that we did from people that surrendered told us that it was deployed to the battlefield and that the peacekeeping force later confirmed that was true.

Mr. SHAYS. So it was not our troops, it was captured intelligence?

General WEST. I can answer concisely and explicitly what you are getting at, but we will have to go to a classified hearing.

Mr. SHAYS. I am just commenting on what you said, and I thought you were saying your troops came across weaponized anthrax.

The reason why that is interesting to me is that we also had hearings on Gulf war illnesses, and just to deal with this word disingenuous, we had witnesses from the DOD who said our troops were not exposed to chemicals. And then they qualified it by defensive use of chemicals—excuse me, defensive—offensive use of chemicals. So that was the word I didn't capture. I didn't think about it.

Then we had a witness who came to us who actually had a video of us blowing up Kamasia, and we had it—we scheduled a hearing on a Tuesday, and the week before, on a Friday before Tuesday, now—we are in a position now where DOD is saying our troops were not exposed to, and now they are saying offensive use of chemicals, and we had a witness who actually had videos of the canisters of chemicals, chemical agents at Kamasia, and blowing them up and the plumes going up and spreading and showering over our troops.

So, at 12 o'clock on a Friday, DOD says, we are going to have a press conference at 4 o'clock in which at 4 o'clock they acknowledged that our troops were exposed to defensive use of chemicals, which meant I guess, in layman's terms, that we had blown up, and it wasn't offensive, it was defensive. I didn't care if it was offensive or defensive. I just wanted to know if our troops were exposed to chemicals. So now we found out they were.

What is interesting to me is now you are describing a circumstance in which I thought you were saying our troops came across weaponized anthrax, and you are not saying that, correct?

General WEST. No, sir. I know of no biological weapon being used. I did not find one, I did not see one, nor none of my troops reported seeing one. We did find——

Mr. SHAYS. I am sorry.

General WEST. We did find documents that said that they had been deployed there.

Mr. SHAYS. Documents, but not the actual chemical, anthrax, correct?

General WEST. Not the antibiotic anthrax, no, sir.

Mr. SHAYS. Right. The implication that I got and maybe no one else got from this was there are troops lined up and when they went through the field and—I think the picture you showed us was the oil wells, correct?

General WEST. Yes, sir.

Mr. SHAYS. So all that smoke is all that oil which we thought would have an adverse affect on our troops, but the implication I

got—incorrect, but happy I asked—was that they went through this and on the other side they came across this weaponized anthrax, not used, but they came across it. And now you are telling me there are documents, and we learned from captured soldiers, enemy soldiers, that we had that.

General WEST. We learned from several areas that I couldn't talk about.

Mr. SHAYS. OK. I understand. I understand.

I would like to have another briefing on this issue with the CIA. I want to make sure I am doing the right one. I would love it if you would go with me when I do that.

General WEST. I would be glad to, sir.

Mr. SHAYS. OK. Now, no one has ever questioned, General, your sincerity about your belief in the program. What I question is your total conviction to this program may distort, frankly, your better judgment, and that you are kind of like building the bridge over the River Quai and you are doing it, and you take such pride in it that we need to go forward when maybe you are not—maybe you need to step back and take another look. And that is the purpose of the hearing, to learn these other facts. You believe they have the weapons; I know they have the weapons. You believe they could use it; I believe they could use it.

Now, let's look at what your policy is doing.

One of the things we know is you are using a 1950's technology vaccine. You are not using a modern vaccine. You are using a vaccine where you try to crunch it all together and you try to get out the vaccine, but it is not pure, and that is one reason why you need to have six shots. So is it inappropriate for someone on this committee to suggest maybe that you not use that vaccine and that we develop a modern vaccine as a way to do it? You would probably say we need to act now. I don't think it is inappropriate.

I think you are putting our troops at risk. Has anyone in the FDA or anyone from HHS said to you that this vaccine can and should be used as a weaponized prophylactic?

General WEST. They have told us that the vaccine is safe, that it could be effective in protecting against aerialized anthrax. They have told us that the vaccine that has been released has been tested and proven to be pure. And it is the only protection we have. I would love to have a vaccine that could only be given in one shot, or something that could be taken as a pill. But those things are 3 or 4 years away. There is only one thing today.

Mr. SHAYS. So this is important, though. You are establishing a fact. You think in the next 3 years we could have this threat. So you have made a decision—maybe you didn't, but you are carrying out the order now so you are speaking for DOD and you are defending it, so maybe in 3 years. Maybe if we have started a few years earlier we would be done by now and we wouldn't be even getting into this argument, but the bottom line is you are saying in maybe 3 years we could have this vaccine. So then the issue that we could logically have is should we wait 3 years?

General WEST. I think the 3 years is probably optimistic, but we have been working on things for a while. We do not have anything that is immediately around the corner in terms of promise that is better.

Mr. SHAYS. General, that is my version of disingenuous, and I should be more respectful. I am having a problem with that answer. The reason I am having a problem is the implication is that we are on a full-steam-ahead exercise to develop a new vaccine, and that is not true, is it?

General WEST. I would say we stop short of being on a full-steam-ahead. We have funded programs that are exploring alternatives.

Mr. SHAYS. Exploring alternatives is not developing a modern vaccine, using modern technology for a modern vaccine to replace this vaccine. You are looking at alternatives, but you are not developing a modern vaccine, a vaccine in which you can isolate the protein and you know it is pure. You are not doing that. We discontinued it. We were doing it. We discontinued it. Have you started it back up? What is that program called?

General WEST. I don't know the program title. There is a funded R&D effort to develop a new vaccine. There is a funded program to reevaluate the six-shot protocols.

Mr. SHAYS. How much spending are we doing on that?

General WEST. I would have to give you that for the record, sir.

Mr. SHAYS. Well, because the fact is, we are really not. The fact is, we don't have an all-out effort to replace this vaccine. We stopped it. We started to—what we are doing is we are developing an old vaccine, and we are using Bioport to do it.

Now, the problem with it is Bioport's vaccines haven't been approved. Why haven't they been approved? The ones they have done, the lots haven't been approved. Why not?

General WEST. The lots that Bioport has made, because their license hasn't been reapproved by FDA since they built their new facility.

Mr. SHAYS. Right. And the reason why they had to build a new facility is the old facility they used made the old lots. But in today's technology, we don't allow that old plant to operate. It wouldn't pass today's standards. So it is true that the lots that we have used on our troops at one time were approved under an old standard, but under the new standard they can't be approved, isn't that correct?

General WEST. They are approved under the current standard that FDA has.

Mr. SHAYS. No, no. See, the new law, the Bioport isn't getting under—they can't reach that new standard. They can't meet it.

General WEST. They haven't yet? I suspect that they will.

Mr. SHAYS. Well, they haven't. Well, you have been saying that for a while.

General WEST. Yes, sir. I wish I could tell you today they have, but they haven't yet.

Mr. SHAYS. No, but there is a reason why. It is a different standard. It is a tougher test. But it is an old technology. It is a 1950's technology. It is a 1950's technology that doesn't use modern means. This is a plant that has to be isolated. You can't do anything else in it, because it is an old technology. If you used a new technology that we use for other vaccines, you wouldn't have to have an isolated plant, isn't that true?

General WEST. I suspect that you would still want to produce something like anthrax in pretty much an isolated facility, but it is definitely true that they are—that they tried to build a new manufacturing facility for two reasons. One was to modernize it as best they could in terms of what was available today for production and also to meet the increased production rate that DOD would require for a program of this size, which is one of the reasons that the State of Michigan didn't want to keep it in the beginning. But FDA tells me that the vaccine that we are using does meet today's standards for purity, sterility and safety.

Mr. SHAYS. It met the standards when it was approved. The new lots are not meeting the standard, and it is even under a new plant, because the standards are higher, and they are higher because we want to protect the people who get these vaccines.

General WEST. We haven't tested the new lots yet, but there is no need to until they have a license to produce it. Because without a license, if it passed the test, we wouldn't be able to use it.

Mr. SHAYS. Now, at one time DOD had made a request to use this drug as an experimental drug and they were turned down. Why is that? Why were they turned down? DOD was turned down.

General WEST. I am personally not aware of DOD asking to use the vaccine as an experimental new drug. I will ask that question of all of the people I work with when I go back; and if I am wrong, I will correct it for the record.

Mr. SHAYS. For the record, I can't verify it either. So on that issue, I can't make that claim. But I would like you to help me in responding, and maybe Mr. Chan or Mr. Sharma, could you help me on this issue?

What did DOD request that they ultimately withdrew? They made a request in terms of the use of anthrax. Were they asking for its use as an experimental drug, or were they asking to have it approved as a weaponized agent?

Mr. SHARMA. Bioport has submitted an IND to FDA which is on the record asking for change in labeling to include that it is approved for—against inhalation anthrax.

Mr. SHAYS. Against weaponized anthrax.

Mr. SHARMA. That is correct.

Mr. SHAYS. Because when FDA approved this drug, they did not approve it as a prophylactic against a weaponized agent, anthrax, isn't that true?

Mr. SHARMA. The labeling does not say specifically against inhalation, but I think to understand this you have to understand the context under which this vaccine was developed and the specific language.

When this vaccine was developed, it was developed to mitigate the disease among the mill workers, and the number of such workers or people at risk were extremely small. And it specifically states that it is approved for the population at risk. As a matter of fact, the 1985 FDA's advisory committee defines who are those people at risk, which does not include the military or the people—the troops who will be exposed in a battlefield scenario.

Mr. SHAYS. The bottom line, the recommended uses for immunization with an antigen is recommended for individuals who may come in contact with important animal hides, furs, bonemeal, wool,

hair, especially goat hair and bristles, and for all personnel in factories handling these materials and for individuals contemplating investigational studies involving anthrax. And it was contact, touch.

Mr. SHARMA. That is right, yes.

Mr. SHAYS. It wasn't by air. It wasn't an aerosol.

Now, isn't it true that Bioport wanted this to be approved to also be a counter as an aerosol?

Mr. SHARMA. That is correct.

Mr. SHAYS. And they withdrew their application, or it is still pending?

Mr. SHARMA. No, it is still pending.

Mr. SHAYS. So FDA has not approved that?

Mr. SHARMA. That is correct.

Mr. SHAYS. When General West talks about FDA has approved this, what did they approve it for? What did they approve this anthrax vaccine for?

Mr. SHARMA. The labeling, as I said, does not specifically state the scenario, other than the fact that it defines population at risk, and those populations at risk do not include the military or battlefield exposure.

Mr. CHAN. Can I answer this question?

Mr. SHAYS. Yes.

Mr. CHAN. As far back as 1996, the Department of Defense reviewed possible use of this against aerosol anthrax, and they themselves state the following, and let me read it from the Defense Department's report: Current anthrax vaccine is not——

Mr. SHAYS. Move the mic a little closer to you and lower it down, if you would.

Mr. CHAN [continuing]. "The current anthrax vaccine is not licensed for aerosol protection. Preliminary information based on animal studies show vaccine confers protection against aerosol exposure. Considerably more data will be needed to support a request to change FDA license to accommodate a dosage regimen appropriate to aerosol protection for humans." And then they stated "The objective would be to achieve a shortened course for vaccination requirements."

So there are basically two fundamental issues here. One is——

Mr. SHAYS. Who are you reading from? Who is the document from?

Mr. CHAN. This is the DOD's reports.

Mr. SHAYS. Do you have a date?

Mr. CHAN. It is called System Threat Assessment Report 1996 on Bioagents, and this is a nonclassified paragraph that I am quoting.

The point I am trying to make is that there were two problems back then. One, they need to make sure that, in fact, they can apply it for—as a preexposure prophylactic. That is the first thing. The second thing is that they would really like to change the regimen of six shots over 18 months, because we are willing to do that logistically. So, essentially, that is what they request from the internal request, looking for this.

As I remember, the FDA's response, which they have gone through with extensive briefings the conclusion was based on a memo by Dr. Freedman which basically says that if you use this

vaccine for this purpose, it is not inconsistent with the labeling of this product. That is basically the wording that has been used. So I don't think—you know, not inconsistent does not necessarily imply, I don't know, that it is consistent with the labeling.

Mr. SHAYS. That is what we have to do. We have to constantly mince words.

Mr. CHAN. Exactly. But that is what is stated. So what you find is often that has been given as an answer to aerosol anthrax.

Mr. SHAYS. They didn't say it is consistent. They said——

Mr. CHAN. They said it is not inconsistent.

Mr. SHAYS. Mr. Sharma.

Mr. SHARMA. I think I would like to add that that was a letter which from a legal perspective, is a personal communication from FDA to DOD. It is by no means an official FDA endorsement that can be incorporated into the labeling, and that is why Bioport has submitted an IND for a label change.

Mr. SHAYS. I want to just be very clear on this. This is basically a letter from FDA that does not have the backing of hearings, does not have the backing of response. It is basically the FDA writing a letter to the DOD which enables them to be able to say somewhat that FDA has signed off, but technically, in a court of law, it won't have much strength. Is that your statement? I don't want to put words in your mouth.

Mr. SHARMA. I think FDA has—when they are changing the labeling, they have procedures; and this does not, you know, fit under their procedures.

Mr. SHAYS. This does not meet the requirement of the regulations if you want to change it.

Mr. SHARMA. Right.

Mr. SHAYS. OK.

Mr. Burton, I haven't done this, and I would be happy to have you go through this question.

Mr. BURTON. If you would like to proceed for a minute or 2, that would be find. Go ahead, because I have some other questions I want to ask.

Mr. SHAYS. General Weaver, I want to run a short video.

General WEAVER. Yes, sir.

Mr. SHAYS. This tape shows you testifying before our subcommittee on September 29 of last year. In this you stated under oath that we have 10,700 people inoculated for anthrax in the Air National Guard with one known refuser documented.

The second half of this segment is a closed circuit briefing to the Air National Guard. In this you responded to a question about the refusers by stating that after the segment shown on the news that you clarified that quote: "we had other people with no commitment to walk." However, staff has reviewed your statement after the segment we just saw, and there is no reference to "other people with no other commitment walking."

Would you tell me again, General, what the punishment—well, just let me go with that. Just show the video.

[Video shown.]

Mr. SHAYS. General Weaver, that just seems so inaccurate.

General WEAVER. May I explain? Our interpretation, we the Air National Guard, when we were going through the—trying to get

the right information on the anthrax, considered a refusal was one who had a commitment to the Air National Guard. That has always been at that time, up until that hearing, our basis for people leaving. I mean, individuals can walk out of the Air National Guard who have no commitment for whatever reason.

If I had the statement to do over again, I would have changed it. Because I certainly was aware that other individuals walked out of Connecticut, but at my level we had no written documentation except for what was being said to the media.

Even today, getting the accurate information of people leaving the Air National Guard, asking them—after Congressman Shays asked me to start questioning why our Guardsmen and women were leaving the Air National Guard, it is very difficult to get an accurate picture, especially when in light that one of the previous witnesses today who requested a transfer but had no reason—had put down no reason to include anthrax, just requesting the Air National Guard—or to leave the Air National Guard to go to the Air Force Reserve. So at the end of that hearing, Congressman Shays, our commanders got all together, and we had a senior leadership conference to address this issue, because it is an extremely big issue for us. I mean, we are Guardsmen. We can walk.

Mr. BURTON. Would the gentleman yield, please?

General WEAVER. Yes, sir.

Mr. BURTON. Mr. Shays.

Mr. SHAYS. Yes.

Mr. BURTON. If people are on duty overseas, they are operational, even though—can they walk?

General WEAVER. Well, no, I wouldn't expect them to walk under an order of being overseas, sir.

Mr. BURTON. So the point is, even though they are volunteers and they are in the service, if they are operational, if they are overseas, they can't walk.

General WEAVER. I wouldn't expect them to, sir.

Mr. BURTON. OK. I got to tell you, General, after watching that and remembering the statements, you know, we in Congress deal with thousands of issues on a regular basis. And when people from an agency, particularly the Defense Department and the Pentagon come over here and testify, and they make a statement like only one person has left because of that, you know, we take that at face value.

Then we see something like this, and then we hear these Reservists come in, and they testify that many, many people have left various Reserve units around the country and one of the main reasons is because of the anthrax vaccine and the fear of it. And then you say only one. It really looks like there is a deliberate attempt on the part of the Pentagon to mislead the Congress.

Then when you say that you are trying to get all of these facts and you are trying to get all of this information so that you can make an informed judgment and really see if there is a problem and you send out questionnaires to the spouses and to the members of the Reserve and you don't even ask a question about a relevant issue, even though it has been in the news for 2 years, 3 years, it looks like you don't want to hear that answer because you

don't want that answer to be something that you have to deal with. And it really is troubling.

General WEAVER. Sir, I disagree with that, respectfully.

Mr. BURTON. You do?

General WEAVER. Yes, sir. And I can only speak for the Air National Guard, sir. I can only speak for the Air National Guard. As the controversy with anthrax heated up over a year ago with our Guard family, and as I said to Congressman Shays previously, got all of our commanders together to discuss how we could get the right information out there and what we needed to do to find out if there truly was a problem and if there is a problem, what we needed to do to fix it.

We had Dr. Craig Polin from the Mayo Clinic come in and talk to all of the senior leadership of the entire Air National Guard. We didn't have the right number—we didn't have the accurate numbers that we needed to say, because we heard the anecdotal evidence by some of the previous witnesses about thousands of pilots leaving the Air National Guard.

Sir, for the record, I have got what we have done in the last 5 years as far as our total pilots in the Air National Guard. I can say it is very consistent. In fact, in 1999—from 1996, 301 pilots short; in 1997, 269 pilots short; in 1998, 246 pilots short.

Mr. BURTON. General, let me interrupt you for a moment. The gentlemen that testified who were on-line pilots for the Air National Guard testified that, yes, there are replacements coming in, but they don't have the combat training, they don't have the training that they did, and what you are losing is you are losing an awful lot of people who are qualified to go into combat immediately with people who are not yet combat-ready, and that you also have to have additional training for those people.

Did you not hear what they said? In one unit there was five vacancies still vacant, and the ones that have been replaced in large part have been replaced by people who are still in the training process that are not yet ready for combat, as were the ones who left. Now, don't you think that is a problem?

General WEAVER. Yes, sir, it is.

Mr. BURTON. Especially in view of the fact that it costs $6 million to train a pilot to have him ready to go into Kosovo or Iraq or someplace else. So you can use numbers, numbers fly and sometimes people stretch the truth about numbers, but when you are talking about a combat-ready military, they have to be ready.

Mr. SHAYS. Would the gentleman yield?

Mr. BURTON. Yes.

Mr. SHAYS. I would just like to—again, I thought you all were saying something different. I thought you were disputing with the first panel that you haven't lost as many people, and it is good to listen, because what you are saying is, you have lost more people, but you are just replacing them, isn't that correct?

General WEAVER. Sir, I can give you the figures of the attrition rates——

Mr. SHAYS. No, no, you are losing more people, you are just replacing them, or are you claiming under oath that you are not losing more people? And please be careful.

General WEAVER. Yes, sir. Can I go through these figures with you, sir, and I would like to submit them for the record as well.

Mr. BURTON. Sure.

Mr. SHAYS. Can we see them?

General WEAVER. I only have the one copy, sir.

Mr. SHAYS. Let me interrupt you, but you will have a chance to go back. You all did know that this is what the hearing was about today.

General WEAVER. Recruiting, retention and combat capability.

Mr. SHAYS. When you say, General West, you will get back to us on this, you should be fully prepared to deal—respond to anything dealing with retention, correct? General West, I mean you are the one who made the comment. I was thinking—like you said, well, we don't have an opportunity to respond to this. You should know exactly what your retention is and everything dealing with the military, right, and you would have it available to us and we don't have to wait for it, correct?

General WEST. I should be as absolutely prepared as I can be, sir, and answer all of your questions honestly, and that is what I am trying to do.

Mr. SHAYS. So you should be prepared to take the different bases that were discussed and be able to tell us if we have lost more or less, correct, in retention, correct?

General WEST. If we have lost more or less than the report says?

Mr. SHAYS. Do you agree or disagree with the numbers you have heard today?

General WEST. I have no reason to disagree with them, but I haven't analyzed them, nor have I tried to explain them, and I will do it as soon as we can.

Mr. SHAYS. Yes. We will do it today.

General WEAVER. Congressman Shays.

Mr. SHAYS. Yes.

General WEAVER. Between the losses and the gains for the last 5 years, I think that will give you a good indication.

Mr. SHAYS. I just want to know losses first.

General WEAVER. Losses are pretty much average from 1996 through 2000. In 1996, we entered 353 losses, 189 for retirement, 164 separated; 1997, 122 retirement, 147 separated, for a total of 269; in 1998, 168 pilots retired, 205 separated, for a total of 373; in 1999, 131 retired, 211 separated, for a total of 342.

Mr. SHAYS. Is the retirement rate going down or up, and are those who are separating going down or up?

General WEAVER. The actual retirement rate is going down, sir.

Mr. SHAYS. So you are having more leave earlier, correct?

General WEAVER. That is correct. We are running from about 164 that separated in 1996 to about 266 in 2000.

Mr. SHAYS. Just hold on a second. I just want to make sure I am understanding. So, overall, you are losing more now, not to retirement, but they are leaving earlier. Isn't that true?

General WEAVER. That is correct.

Mr. SHAYS. Isn't that really our point? Obviously, when people retire, they retire. But you are having more people leave earlier, and that kind of has an implication.

General WEAVER. Yes, sir. But also, since 1996, we have been brought into the forefront of combat capability with the AEF. We are performing almost 500,000, approximately, work days more than at the height of Desert Shield, Desert Storm in work in the Air National Guard. So there are other stressors.

Mr. SHAYS. I would concede to you willingly that there are other reasons today why people may want to leave besides anthrax, but wouldn't it be sad, really sad, if the thing that trips them over is anthrax? Because these are the people who aren't retiring, they are leaving early, and I would think that you would be able to tell us to a person why each one left, to a person.

Which gets me to the issue that when you appeared last year, you said, let me just—well, first off, oh, let me do this. Let me just end my participation in the hearing by saying that, in response to General Weaver—OK, this is where the question begins: I would make a request that any person who leaves the Reserve or National Guard be specifically asked if anthrax vaccine was a factor in their decision and to what extent it was. And I then said, and I will be following it up to see if that is done.

General WEAVER. Yes, sir.

Mr. SHAYS. And you said yes, sir, I will do that. So tell me why all these people left.

General WEAVER. I can't tell you for each specific one, sir.

Mr. SHAYS. Why not? There are not that many, in your own words. I mean, there are a few hundred. I would think you would specifically, particularly after this hearing, after you basically say you will do it, I would think you would specifically want to know why they had left. It would be great, because you could either prove you are right or wrong. You could prove you are right or wrong. You would have the answer, and we wouldn't have to spend millions of dollars to find out.

You would just simply—maybe even you could do it yourself. You might even fly them in. You might say, I need to know why you left. Is our anthrax program the reason why you left? Afterwards, you may find that they did. You may find that your statistics are somewhat similar to what you find from GAO, and you might still decide to do the program, because you believe you need to do it. But you will have better information.

General WEAVER. Sir, we do have, after your advice to me and counsel to me last September 29th, we instituted, only in Air National Guard, a survey that we asked the commanders. I cannot direct them to do it.

Mr. SHAYS. You asked the commanders or you asked the individuals?

General WEAVER. No, sir. We asked the commanders to conduct the exit survey. Because, sir, I am trying to get to the same point that you are.

Mr. SHAYS. OK. I just want to understand.

General WEAVER. So we asked the commanders to counsel each individual leaving concerning—and again, I asked them, I can't direct them to do anything. I am the Director of the Air National Guard, not the Commander. I can only do it by asking through their adjutant general to see if there was that problem with anthrax.

If I can give you some anecdotal——

Mr. SHAYS. Not anecdotal yet, let's talk specific. Because, basically, we made a request that you specifically ask if anthrax vaccine was a factor in their decision, and you said to me you would do that.

General WEAVER. I would do that, yes, sir.

Mr. SHAYS. I don't think you have.

General WEAVER. Sir, there are only certain things that I can do as the director of the Air National Guard. I cannot command the State Adjutant General to do—really, he is the commander in chief of those military forces within that State. I asked every one of them, to include the Adjuvant General, to let us research, do the exit surveys to why our individuals are leaving.

Mr. SHAYS. So you didn't ask if they are leaving specifically because of anthrax?

General WEAVER. Sir, that is in the other category, and the exit survey that we get——

Mr. SHAYS. That is what the issue is, it is anthrax. Now, I need to know if you did what you said you would do. I need to know if you specifically asked, and I want to see the document that will prove to me that you did it, because we are getting to this kind of game where I have to ask the perfect question to get an answer that I just want. And I don't get mad with people when they don't play games. I am not trying to prove a point one way or the other, I just want the truth.

General WEAVER. I want to give you the truth, sir.

Mr. SHAYS. I want to know what document you can show me that specifically asks the generals of our National Guard, the Adjutant Generals of our National Guard, specifically what pilots have left in particular because of anthrax.

General WEAVER. It doesn't say anthrax, sir. It does not say anthrax.

Mr. SHAYS. I understand anthrax.

Mr. BURTON. Would the gentleman yield real briefly?

Mr. SHAYS. If I could just not lose this question——

Mr. BURTON. I don't want to lose that question. This bears—the previous panel, you will recall, indicated, and I don't know if you were here at that particular time, that there is some pressure put upon the members, on the exit questions, about whether or not or what the reasons are they are leaving, and many of them are afraid to use the anthrax as a reason because of possible repercussions from their superiors. I just thought that ought to be thrown in the equation.

Mr. SHAYS. And that is the reason why I responded when we were making reference that the commanders were being asked to kind of do this, because you all have heard your men and women say they have been under pressure to give different answers. And I got to believe you want to know the truth.

General WEAVER. Yes, sir, I do.

Mr. SHAYS. And if you want to know the truth, it would strike me that you might just say here is an envelope, here is the question; please give it to every one of the people that have left, is anthrax a factor in your decision, and, if so, what is it? It is not a lot of people. You would have given it to each one of those individ-

uals, and you could have basically just dumped them on your desk and said I did what you asked, Congressman, and I said I would do it, and I did it, and here is the answer. And I don't think you have done what you said you would do.

It was specifically about anthrax. So the question comes back to did you specifically do what you said you would do about anthrax?

General WEAVER. No, sir, I didn't. I put out a survey and asked the commanders to respond in kind why our people are leaving. It wasn't concentrated on anthrax, sir.

Mr. SHAYS. But that was what the question was all about. Isn't it?

General WEAVER. Yes, sir.

Mr. SHAYS. OK. I am not trying to embarrass. I just want to feel like when we are a committee, we can ask a question and we get an answer, and we deal openly with each other. Not just honestly, but openly, and we don't play games. And I am just, given your last answer, I don't want to embarrass you further, because I think it is an embarrassment, if I show that second shot, where you basically have said that you said something else, that you didn't really say.

Mr. BURTON. I think the whole enchilada should be shown, Mr. Shays, so I will request to put the video up there. Then I would like to ask some questions, General.

The following is a transcript of a video shown of M.G. Weaver, September 29:

Mr. SHAYS. How many are leaving? In some Air Guard units, attrition among pilots and technicians may be as high as 30 percent, but DOD appears unable or unwilling to discern a trend.

ANNOUNCER. General Paul Weaver, Director of the Air National Guard, testified that the number of pilot resignations have been exaggerated.

General WEAVER. So when I hear all of these other figures about these mass resignations and whatnot, they are just not there. There are challenges with explaining, with discussing, as they all are, with the members of their unit on the anthrax issue. But when it really gets down to it, we have had 10,700 people inoculated for anthrax in the Air National Guard, with one known refusal.

M.G. Weaver, October 26, 1999.

General WEAVER. I also just received a fax, and it said, a question for General Weaver. You recently testified to Congress under oath that when it really gets down to it, we had 10,700 people inoculated at that time for anthrax in the Air National Guard with one known refusal. Previous to your testimony, seven pilots from the Madison Air National Guard F–16 unit refused to take the vaccine, as did eight of the Connecticut National Guard A–10 unit. Were you aware of these refusals?

What you needed to also understand, my further comment is that I said we had other people who had no commitment, who walked instead of taking the vaccine. We are a volunteer organization. For the ones who had had a commitment at that time, we had only one refusal. I was very much aware, and, as I said, we had in my sworn testimony as well, is that we had people that had decided to, what I consider make a decision, a non-informed decision, to leave our Air National Guard family.

Mr. BURTON. I will pick up where Mr. Shays left off in the statement. Staff has reviewed your statement, General Weaver, after the segment we just saw, and there is no reference to other people with no commitment walking. Would you tell me again, General, what the punishment for an officer to lie is?

General WEAVER. I am sorry, sir?

Mr. BURTON. Staff reviewed your statement after the segment we just saw and there is no reference to other people with no commit-

ment walking. There is no reference to that. Should there have been a reference to that?

General WEAVER. I believe what I thought I had said during that, that I had made the implication that I was aware of other individuals leaving the Air National Guard.

Mr. BURTON. Well, I guess the bottom line is, General, that the troops, many of troops feel like they were misled in that closed circuit briefing. How do you respond to that, to these people that feel like they weren't told the truth in that briefing?

General WEAVER. Sir, I have briefed the senior leadership of our Air National Guard, the Adjutant Generals, on our challenges within our Air National Guard family, concerning anthrax. They are all working toward the same end in that all the right information, our commanders' tool box, all of the information that we could get out to our troops so they can make an extremely informed decision, be in their hands prior to them making a decision to leaving their career, if that is their so desire.

Mr. BURTON. Well, we had nine people last week, we had four today, I guess we could bring in many more people in the military to state, you know, that this was a major concern of theirs, and that is why they left, or decided to be transferred, but I don't know that we need to do that.

Let me go on to a different subject. Last week we received a report, and I am going to address this to the GAO, from Congressman Metcalf, one of our colleagues that has been doing a lot of work on the anthrax vaccine, and it was about the discovery of squalene in the anthrax vaccine.

Could you explain the significance of squalene being found in the anthrax vaccine?

Mr. CHAN. First of all, let me say that it was a total surprise to us that something like that was found. As you know, we have done a study for Congressman Metcalf. It took us an extraordinary amount of time to get it done, because we thought it was a pretty straightforward question that was asked of us.

But we issued a report on it, and basically we have received from the DOD and FDA, that there was no such thing used in the vaccine, and in fact we were proposing a means to develop an assay to detect possible antibodies to squalene that some of the ill Gulf war era veterans have and of course GAO would not be the right agency—let me say it that way—to develop the assay ourselves, to show the presence of antibodies was there. So we left that for DOD and FDA, and basically they recently initiated research to develop such an assay, but also to show that, in fact, the current vaccine, anthrax vaccine, doesn't contain such an adjuvant, or additive.

Our understanding is that as DOD had requested, Stanford Research Institute to do a number of tests on the lots that are available, and whereupon they found nothing there at the trace level, the test they did. So it was a surprise to me and to my colleagues that when FDA went ahead and did a test, a much more refined test, and found traces of squalene in the anthrax vaccine itself.

Mr. BURTON. Let me get this straight. I want everybody to understand. The Department of Defense said there was no trace of squalene, right?

Mr. CHAN. That is right.

Mr. BURTON. And then FDA came back and they did testing and they did find squalene?

Mr. CHAN. Yes, sir.

Mr. BURTON. Now, tell us about squalene. As I understand it, squalene stimulates the immune system to fight off a specific biological agent, right?

Mr. CHAN. It is an adjutant—my understanding is the only adjuvant that is used in vaccine that is approved by FDA is aluminum hydroxide, alum, and nothing else. But using this particular additive, an oily substance, like liver oil the intent is that it helps to increase the immune response to the antigen, OK, thereby coming out with greater amount of antibody.

Mr. BURTON. I want to put this in layman's language, because we have talked about this and this is very important. It will increase the anthrax vaccine as far as fighting a specific strain of anthrax. But as you told me, it also can and will suppress the person's immune system against other things. Is that correct? It causes an auto-immune response.

Mr. CHAN. The only information we have is based on animal studies. Right now we, as you have requested us to do, is look at this chemical significance of the presence of squalene in the vaccine itself.

Mr. BURTON. And?

Mr. CHAN. And you asked us. I am sorry.

Mr. BURTON. But in the animal studies, did it not suppress the immune system?

Mr. SHARMA. We have just started looking at this issue at your request and we have, at least, found one article, it is a recent article, that was published by a researcher in Canada in which it does show that squalene does have a harmful effect on the immune system. But we have not done very thorough, systematic research of the literature. We have, so far, only found one because it was published around the time, right after we had issued our report. So we happened to have reviewed it. I am sure that, you know, there is more research because in the new vaccines that are in the development stage, a lot of different adjuvants are being used.

Mr. BURTON. I guess the point I am trying to make is it seems to me that the Food and Drug Administration and our health agencies, as well as the military, before they started using on a widespread basis the vaccine for anthrax, would have found out every component part of that vaccine. And you have found squalene in lots of the vaccine that the military said did not contain squalene, and yet the FDA found it. And there is a body of evidence that indicates that squalene depresses the immune system if it is in a vaccine.

Has the military checked that out? Has the FDA checked that out? And, if not, why wasn't that done before you started immunizing all these people with the vaccine? That is the first thing.

The other thing I would like for you to answer is, you know, you said that there had been testing done on the vaccine and that FDA had, in effect, given approval. I don't know of any testing that has been done, maybe you can give me some information on an aerosol anthrax bacteria. Has there been any testing on an aerosol that you know of by the FDA or anybody else?

General WEST. Sir, there are good answers to both of those questions. DOD did not put an adjuvant in the vaccine of squalene.

Mr. BURTON. It is in there. It is in the lots.

General WEST. Yes, sir. And FDA was here last week and they testified before this committee, and it is on the record that they tested the vaccine for squalene and it wasn't there, that they subsequently developed a more sophisticated test for squalene, and they found a trace amount, and they also said that it would have took 2 million times that much to act as an adjuvant in the vaccine. They said that squalene existed in almost everything in the environment, and if you get your test sophisticated enough, you can find it.

They told us you can put a fingerprint on a piece of glass, and when you analyze that, there will be squalene in it that came out of your body because your body makes it. The issue was whether we put it in the vaccine to be used as adjuvant, and I don't believe we did, and we said that. And I stand by that answer. I believe FDA thoroughly supported that in testimony last week.

Mr. BURTON. Just 1 second. We had Baylor University experts that told us that there was enough squalene in there to cause adverse impact on the immune system.

General WEST. FDA disagrees with that. They believe it would take 2 million times the amounts that they found in—they were the one that did the analysis. They are the ones that we paid to do this and to make these kind of decisions, and they said, we do not believe that DOD or anybody else put squalene in the vaccine. It's a very minute trace amount and won't make a difference.

Mr. BURTON. When you are talking about adverse reactions, a lot of the military people leaving the military and being very concerned about it, and the adverse reactions that I am going to put in the record in a few minutes, you would think you would want to have really all the consultation and advice you could possibly get. If Baylor University, one of their scientists down there, said there was enough in there, squalene, according to his research to cause an auto immune response, then that should have been at least factored in. But none of that had even been checked out.

Let me ask you something else: How many strains of anthrax will the vaccine deal with?

General WEST. We believe that the vaccine that we are using, because it is based on a protective antigen approach, will work against any strain of anthrax. Can I say we have tested it against every strain? No. I can't even say I know for sure how many strains there are. But the scientific and medical theory of a protective antigen vaccine, it should work against anything that is anthrax. Will it work against something that isn't? I guess not, sir.

Mr. BURTON. Well, I think you ought to contact Dr. Dorothy Lewis of Baylor University and check on her research too, because I think it is relevant to what we are talking about.

Can you illuminate a little bit about the various strains of anthrax? I think when I talked to you yesterday, you said that there were some things that could be added to the anthrax bacteria that could have made it difficult for the anthrax vaccine to deal with it. Is that not correct?

Mr. CHAN. Let me first answer the question. Instead of my comment about it, let me quote the person who testified before you last week, what he said to you, because it is his publication that I would refer to.

Mr. BURTON. OK.

Mr. CHAN. Because, remember, the question was really the non-human primate would be a better model for humans, because we cannot expose humans to aerosol attack.

Let me quote: In the non-human primate aerosol challenge model, AVA, that is anthrax vaccine, since we had only one, protects against two strains, including the so-called vaccine resistant Ames strain. Experiments are ongoing to test the effectiveness of anthrax vaccine which is the anthrax vaccine, against a geographically diverse collection of strains. In the guinea pig intramuscular challenge model, 8 of 32 strains overcame the immunity induced by anthrax vaccine to the same degree as did in the Ames strength.

So by that statement, we have at least 32 strains——

Mr. BURTON. And according, as I understand what you just read——

Mr. CHAN [continuing]. That we tested. I think it says a total of two or three strains against aerosol challenge.

Mr. BURTON. So they tested 2 or 3, and there are 32 strains.

Mr. CHAN. Yes, sir.

Mr. BURTON. They said in guinea pigs, at least eight of those strains overcame the vaccine and caused infection.

Mr. CHAN. That is right.

Mr. BURTON. So what you are saying is according to the guinea pig test, and it was not on primates, it was not on monkeys or other animals that are more closely related to human beings, they have not had any testing like that. But on the guinea pigs, it still would infect the person who was injected or who got the aerosol in at least 8 of the 32 strains? Did you know that, General?

General WEST. Sir, I know the guinea pig model, when used against most vaccines, does not produce 100 percent results. I know that the test that gives us the most validity for an aerosolized channel is the human primate model, and in every test that we did, it was effective, and against every strain that we tested it against, it was effective. The medical and scientific community that we have gone to tells us that it is reasonable to assume that it will protect against every strain of anthrax.

Mr. BURTON. Mr. Chan, do you have any more information on that?

Mr. CHAN. Well, let me give you my own personal understanding, the way it has been answered, that, in fact, I remember you asked the question about the regimen of six shots and when someone stops, what would happen.

The answer was as long as you have the antibodies, the PA level is high enough, then we can increase it. To me it sort of suggests that we really don't know enough about the science of this vaccine. In a sense that somehow the correlation between the level of antibody to at least the animal models, they are not quite the same. That means the higher level of antibody you have, does not mean you have greater amount of protection.

So as a result, I think it is, as DOD I understand is doing, is to try to figure out what is the right measure in terms of correlates, so one, in the future vaccine we develop, we need not expose humans for testing in terms of efficacy. But right now it is very unclear.

So for one to say most likely it works, we can just keep on giving them shots and start all over again or not start over again and continue, I am not quite sure where the science is, sir.

Mr. BURTON. I have some more questions.

Mr. Cummings, do you have some questions, sir?

Mr. CUMMINGS. Yes, I do, Mr. Chairman.

General Weaver, last week when we had our hearing, we had an opportunity to see some pictures of a young man who, I will tell you, it looks like he had been burnt, almost, I guess, 70 percent of his body, and there was no other explanation for this than this vaccine.

Then we had the sister of a young lady come in who had died, and I think we had a wife of a gentleman who had died. He worked at Bioport.

I guess the thing that is so troubling about all of this, one person said something, I don't know, did you see that hearing?

General WEAVER. No,sir, I was TDY.

Mr. CUMMINGS. I think the thing that touched me, and I am sure it touched other committee members who saw it, there was one gentleman who said I am willing to die for my country. I am willing to die for my country. Even after he had gone through all of the problems with anthrax, a lot of problems with anthrax, the vaccine, but he expressed tremendous disappointment in the way he had been treated by his country. And I think for all of us, it was a very painful experience, because we are guardians. We are supposed to make sure that people are treated right and we have certain expectations ever the military, as I said a little earlier, right after Chairman Burton questioned you earlier had made some statements earlier.

I guess what I am trying to get at is do you think, based upon what you know, that we need to revisit this whole policy, this vaccine policy? I am just curious. I mean, maybe I am putting you on the spot, but I am just asking you a personal opinion, if you have one.

General WEAVER. Sir, when we began the need and the order went out to inoculate our individuals for anthrax, I too personally, as a guardsman, and I have been a guardsman since 1975, had questions about the need and the efficacy of the shot.

I asked my medical people, because it was something that we had heard in Desert Shield-Desert Storm, and I was there in Tehran on the flight of skewed attacks, of why now, and is the shot safe?

I heard a lot of information and realizing that there was so much information out there that we needed, and having an all-volunteer force in our Air National Guard family, that there would be questions in regards to that, and especially with both Agent Orange and the Gulf War Syndrome still there.

We probably did a less than satisfactory job, in fact, we did a less than satisfactory job in the very beginning, in educating our men

and women in our Air National Guard concerning the threat and the efficacy of the shot.

Realizing that there were concerns, big concerns by all of us, we made a concerted effort to start educating our people, to understand the threat, and then to understand the efficacy of the shot. We brought in our experts, who we thought were experts, Dr. Craig Polin from the Mayo Clinic, and I think probably he singly, along with the flight surgeons, virtual flight surgeons on the Web, but I sent Dr. Polin's comments that we are on the right track. Having already understood the threat and got that education, but we still didn't get it down into the units. We didn't do a good job. Admittedly, we did not do a good job.

We have come a long way, thanks to the help of this committee and these hearings as well, to educate our kids on why the shot, why the necessity of it. As I—and I just recently returned from Northern Watch, I leave for Southern Watch tomorrow, in talking to all of our individuals that are out there, I feel that now that we have turned the corner on them understanding, not only the threat, but the need for the shot and the efficacy of the shot. But it wasn't without a lot of heartache and pain, I should say, when we saw fellow guardsmen and women leave the guard for misinformation, what we thought was misinformation.

Mr. CUMMINGS. Well, you know, it is interesting you said that, because I asked the same gentleman that said he was willing to die for his country, I asked him if he had it to do all over again, would he do it. Would he take the shots. And he said he would not take the shots. But he said something else that was so interesting. He said I found out more information on Mr. Burton's Web page than I—I mean, he said it was a phenomenal amount of information, and the military had not done anything near that.

I guess the question becomes, first of all, when you say "the threat," you mean the war threat?

General WEAVER. The real threat. The individuals or countries we feel have anthrax.

Mr. CUMMINGS. I just wanted to make sure it wasn't a threat to harming them.

General WEAVER. I know, sir.

Mr. CUMMINGS. You know, I tell you, this thing really troubles me, because we also had—they showed a picture of a little girl, I think it was a little girl, and her mother had died, which is about 4 or 5 years old or something like that. I thought about it, and I said here we are, this great country, and we are supposed to be looking out for our service people who are willing to die for their country, and here is this little girl that is going to grow up without her mother. I guess what I am trying to get at is at some point, at some point, I think we have to admit that maybe, just maybe, we made a mistake, or maybe we need to do something another way.

I think sometimes I get really frustrated sitting here, because it seems like it is so hard for people to admit, that maybe we did make a mistake. Because, I will tell you, I often say we have one life to live, and this is no dress rehearsal, and this so happens to be that life. And if you have people suffering the way they are, that is a problem.

Let me just hit two other questions——

General WEST. Sir, could I offer one comment on that, because I really think this gets to the heart of the issue of one of the reasons why we are here.

Mr. CUMMINGS. Please do.

General WEST. I was as touched by all those pictures as you were. It tears my heart out the same way it tears yours out. But the fact is that the way that those pictures were used and the way those stories are told is one of the reasons why people would elect not to take the shot and get out. Specialist Edwards is sick. There is no question about that. He deserves great medical care, the best our country can give him.

But the truth is, when we brought him back from his deployment to one of those high threat areas, he went to Brooks Medical Center and was evaluated and they made a diagnosis, and they determined that his condition wasn't related to the shot. We then sent him to a civilian independent review, at Emory University, and they agreed with Brooks' diagnosis. We sent that information to the anthrax expert review committee, and they got more than a 9 billet card with information of yes or no. And they ruled on it. And nobody believes that it was related to the anthrax vaccine.

I talked to his father afterward, because I felt very badly for him and for his father and what they were going through. His father had been led to believe it had been conclusively proved that his son's problem was the anthrax vaccine. When we put things on our Web site, everything we put on there as best we know it, meets every standard of honesty and integrity we can expose it to. Some of the other people putting out information are putting out innuendo and supposition and sometimes misinformation, and it is scaring people, it is causing them to make a bad decision, and it is affecting lives and careers. That is one of the reasons we had to have these many hearings.

Mr. CUMMINGS. Let me ask this, I am almost finished, Mr. Chairman. Are you trying to tell me that you believe, and help me now with this, I don't want to put words in your mouth, that anthrax vaccine has not caused illness or the death of personnel?

General WEST. I believe that there have been some reactions to the anthrax vaccine. I believe that most of them have been very minor. I believe that the ones that are serious are lower in number than most of the other vaccines that we give, and that the benefit far outweighs the image or the negative reactions.

I do not believe specialist Edwards' condition is related to anthrax. I have no knowledge of the young lady whose sister died. That was a surprise to us. We asked about her, we wanted an opportunity to investigate that so we would have good answers, but we weren't allowed to know who that was going—that story was going to be about, so we haven't finished investigating that one yet, but we will. And if we find out it was related to anthrax in any way, we will come back over here and tell you that, honestly, man-to-man, face-to-face. But those people that were here last week, there was only one at this table that there had been a diagnosis that it was related to anthrax, and one that is in dispute. The others, there was no known connection.

Mr. CUMMINGS. Now, Mr. Chan, do you agree with what he just said to my last question based upon your investigation?

Mr. CHAN. Well, I am not a doctor, first of all, so I wouldn't make the statement, whether I know it for sure one way or another.

Mr. CUMMINGS. I know that.

Mr. CHAN. But the survey we did, to me is that we are but the mouthpiece for the soldiers, and if you look at the numbers and if you actually see all the written comments they made, these guys, both men and women, are very knowledgeable, way beyond the Web site information. They check on everything. They know the information well. They challenge even what we wrote down and they check behind them.

So I am not quite sure that, first of all, I would state that they would look at the Web sites and information they receive and accept them in faith. They challenge us when we visit them. But fundamentally what I find is that I would like to have DOD look at the information we received. When we state that for those people receiving one or more shots, 86 percent of them found they have reactions.

Now, I am not sure whether it is death or anything, but the level of illness as I look at it, it is quite comparable with the ones we informed this committee a while back from Korea, where there was an active monitoring. That was based on only two shots. Here the average is close to three-and-a-half to four shots. But the frequency and types are very similar.

My point is, I don't know if there is a pattern, but for someone to say there isn't a pattern, before they gather the information, at least from researchers' points of view, I have a problem with that.

I also have a problem to say that we assume people, as they exit, that they would tell or not tell the truth. We asked the question, and 30 percent of them said they weren't telling the truth in the exit interviews in our survey.

So I think there is a lot of problem in terms of the information that they are receiving, but also there is a problem in terms of trust. I would guarantee you, sir, that if I wrote down that our survey is done by DOD, you would have different sets of answers, regardless of how we protect them. I would guarantee you that. Because when we visit some of those people, they said who is GAO? Why are you guys here asking this? I actually had to write a letter explaining to the people, ahead of time, that GAO is sending you a form, a questionnaire.

By the way, we are doing it at the request of Congress, with this committee and so on, to explain to them. Some people called and said we don't trust you. So we have to go through that hurdle ourselves to increase the response rate.

I am not sure whether this is a cause and effect, but I must say that the information that is being sent, at least the information that we talk about it from a passive system, and is therefore limited. Out of the entire response we had, there was something like a total of 16 or so forms on file, and we saw all these illnesses that they believe is—they actually checked each one, shot after shot. We have all the data. We can analyze them all. We haven't done that yet, but we will.

I think, you know, what I am saying is that the information is out there, and the important thing is to gather them, do not draw a conclusion about them until we analyze them, because the front line, the people have spoken. And I think at least for me, I want to present to you what they are saying before I draw anything.

Mr. SHARMA. I would like to add, as we show in our chart, you know, 70 percent did not report their reactions, and 60 percent did not discuss their condition with the military health care provider or their immediate supervisor.

To me, this is very telling, and the reason why I believe this, I will share with you. Some of the experiences we had when we went to different sites in different parts of the country, these were the Air National Guard and Reserve units. Both Foy and I, and we had some other team members, we went to different places.

We came across, and I will describe to you three frequently reported symptoms that aren't listed in the product insert. Every vaccinee has some knots, and we recognize that. Some have worse than others, like typhoid. They do go away, not a big deal. But here what we are talking about is we had one person who had a big knot 3 months after he received his last shot, his entire unit brought him to us. Look, you want to see what the reactions are? Here is the reaction. It was a knot the size of a tennis ball, hard like a rock.

Despite the fact that he had the reaction, this guy told us he was given another shot. He had this problem after shot two, which is 2 weeks' interval. In that 2 weeks, he got another shot on top of that knot.

We went to another place, here is a pilot, who came to us at midnight. He was afraid because we were running a focus group, people were not trusting the military officials, and we have shared this information, by the way, with DOD officials during our exit interview, exit conference. This guy is a pilot. He is in his 40's, very seasoned. He waited until he made sure everybody else left, because he didn't want to be seen that he was seeing us, at which time Mr. Chan called me in his room.

This guy literally cried, and he said, look, look at my hand. His fingers were bent. And we tried to straighten them out. They were just bent. He said I don't know if it has to do with anthrax. I really don't. But all I know is I didn't have it before, now I have it.

This guy was very angry at himself because he could not maneuver the plane, and he had to use the wrist and what was bothering to him was the fact that he was risking the life of his other crew members. And what was bothering to me and us was that this was the condition that perhaps can be treated, but he is not coming forward. He does not trust the system.

I think there is a very compelling message that 60 percent, are not discussing with their health care professional. Now, with this huge number, there is a very strong message. Something is not right.

Mr. CUMMINGS. Last but not least, General West, when you hear what we just heard, I guess the question becomes what kind of evidence does it take to come to the conclusion that just maybe, just maybe, we are going in the wrong direction, and maybe we need to suspend things until we can figure out what is going on?

I often sit and I wonder when people make decisions, can they put themselves in the place of the people who may suffer? And I wonder if you had the knots, and if you went through the kind of changes and with you were—or your son was going to these gentleman at midnight, at what point do we have to get to? How many people have to die? How many people have to suffer? At what point do we get to when we say wait a minute? I am not talking about just forget about it, but at least say wait a minute, what are we doing here?

The other thing that concerns me too is how that must affect the morale of our military. We up here are very concerned about that morale. We try to do everything that we can to keep it up. I am just wondering how do you think—assume that you don't believe that, that you don't buy it. It is out there. Soldiers are believing it.

So how do you deal with that? I am sure you want a military that has high morale too, right?

General WEST. Absolutely, sir.

Mr. CUMMINGS. How do you deal with that?

General WEST. I want the leadership of our department to have the trust of the people that serves under us. That is very important to me. It is very, very bothersome even to hear a report about it, and we are working hard to make the education system better. We are working hard to make the varies reporting system better. We went to extra lengths to have the review committee made up of all civilian personnel, not DOD personnel.

We are trying to followup on every one of these. If there was a serviceman, and I assume there was, because much his testimony, that had a knot the size of a tennis ball on his arm where he got the shot, he should not have gotten another shot. He should have been given a medical exemption, not asked to take another one, until we found out for sure what caused that knot. As long as there was any doubt, he shouldn't have gotten another shot, and he should not be required to resign because of that.

Mr. CUMMINGS. That leads me to another question, Mr. Chan. Did you find people who had suffered adverse effects, who then said, you know, look, I shouldn't be doing any more of this until I get this thing figured out? Did you all find people like that in your research? Do you follow what I am saying? I am going back to what General West just said.

See, I can't figure out at what point, in other words, these people you are saying are suffering along. Some may suffer adverse affects after the first shot, some maybe the second. And they hear all of these things about the effect of the vaccine. So they have got to be saying gee, it got me too.

Did you find people to say wait a minute, we want to say time out?

Mr. CHAN. Well, one of the things that I found was that, you know, I mentioned the word "trust." Let me give you an example of that, whereas you asked General West, who has said he is working very hard to improve that.

We visited a number of sites, as you know, to try to answer the question, and at the end we realized we had to send a questionnaire, because we found what we were told officially and what the

people were telling as was different. We said how do we get to the truth, except to send it in the mail to the individuals at their home, not even through the base.

The soldiers, the pilots and so on, first of all, they will not talk to us if their wing commander was there. They would not speak. OK. If the person is there, they would wink at me and say that's a lie, like that. So, you know, an organization cannot operate as a unit, a fighting unit, when you have these kinds of dissensions.

My own view is that—but the interesting thing is that the commander himself often has the same problem. They said, you know, I remember talking to one who said you know, I have to do this. This is ordered. I cannot change this. I understand their concern, I want to help them, but I can't. So they worry about is my group any different than other groups? That is the first issue.

The second thing, what we found was surprising enough, in one case we found a commander was the sickest person among the rest of them. But he is not reporting about it. They are being good soldiers. It is a legal, lawful order.

So I think, you know, it is basically, I don't think it is just the soldiers themselves and the pilots and air crews, but I think it may be higher up, they have similar issues. But it is just not being raised at that level.

Mr. CUMMINGS. Thank you.

Mr. BURTON. Thank you very much. Mr. Shays, I think what I will do is I will give you the gavel, you go ahead and ask your questions and you recess when you finish your questions, because I have a series of questions I have to ask you, gentleman, as I haven't gotten to them.

Mr. SHAYS. Why don't we just adjourn and both come back together.

Mr. BURTON. We will recess and be back in just a few minutes then.

[Recess.]

Mr. BURTON. If we could have everyone take their seats, we will try to wrap up our hearing here in the next half-hour or 45 minutes. I have a number of questions, and I am sure Mr. Shays does when he returns. So you will go ahead and start my questioning and then when Mr. Shays gets back, I will defer to him, because he is next.

Mr. Chan, your testimony today focuses on the Reserve and the Guard. Have you conducted focus groups around the country with active duty service members?

Mr. CHAN. Only indirectly, sir, because while we visit those places, sometimes we get a request from the active side saying why, how come you are not talking to us? We have our story too. So we did a couple of those. As you know, the logistics problem really we had trouble applying it.

Mr. BURTON. I understand. It was rather limited. I think you are probably going to get a request from this committee to do a wider one. I know it is going to keep you awake nights thinking about that, but we want you to do a wider one. In any event, based upon the limited experience you had with active duty members, were their concerns pretty consistent with the Reservists?

Mr. CHAN. I would think so. It is a similar issue, but I would not think they have the liberty to change that.

Mr. BURTON. I understand. But with the ones you talked to, was it pretty consistent with what you heard from the National Guard and the Reservists?

Mr. CHAN. Yes. In terms of issues concerning the program itself, my answer would be yes.

Mr. BURTON. Thank you.

Mr. Wicker, we haven't asked you any questions, but what is your assessment of problems with the message that DOD is communicating?

Mr. WICKER. When we visited a number of units in starting this whole program, or starting this effort, we sat down and talked to the pilots and aircrew and the commander at that particular unit would, you know, basically think we didn't have—we had no influence on picking the individuals that showed up.

In going through all of those various units that we talked to, one thing basically came to mind afterwards, that people were complaining and upset about the fact that the communication around the anthrax program seemed to be on pretty much of a one-way street, from the top down. Folks expressed a lot of concern or irritation over the fact that when they raised an issue, they raised a concern. The first reaction seemed to be in most cases to ignore it, pass it off, say don't pay any attention, it is not a problem.

If they brought up a study, an expert or someone else that had a different slant on the anthrax program, again, the typical response was to attack the credibility of the source, either the individual or the study or whatever the particular individual brought up. That, in a nutshell, is basically the kind——

Mr. BURTON. Of problems you ran into?

Mr. WICKER. Yes. People similarly don't trust the information they are being told about this program, it is very clear from the onset. They don't—and it is because of apparently some of these attitudes that they have observed that I guess they have reached that conclusion.

Mr. BURTON. Yes. General, both of you generals, are you familiar with these things?

General WEAVER. Yes, sir.

Mr. BURTON. Is this part of your educational program on anthrax?

General WEST. Yes, sir.

Mr. BURTON. This is the kind of stuff that some of my colleagues give out in the campaign. This says anthrax used as a biological weapon represents a grave and urgent threat to U.S. Armed Forces. Anthrax is 99 percent fatal, as deadly as the Ebola virus. We have a safe and effective FDA approved vaccine to protect you against the deadly effects of weaponized anthrax.

FDA approved. The FDA has approved a vaccination for anthrax used as a weapon as an aerosol?

General WEST. Yes, sir, I believe they have: I can tell you three steps to why I believe that.

Mr. BURTON. Wait just a minute. My staff says they have not approved it. You got a letter—what was it? It is under investigation right now, is it not?

General WEST. No, sir.

Mr. BURTON. It is not under investigation?

General WEST. It is not.

Mr. BURTON. Just 1 second. We have the IND downstairs. Do you want us to go get it?

General WEST. No, sir.

Mr. BURTON. If we have the IND, it hasn't been approved by the FDA, has it?

General WEST. The FDA has sent the department a letter and they have sent you, sir, and your committee a letter, saying that they believe that use of the anthrax vaccine against an aerosolized threat, it will both provide safe and effective protection and it is not an off-label use, and I can produce that letter.

Mr. BURTON. Well, I know of the letter you are talking about, but it is not licensed for that. It has not been——

General WEST. Sir, the only thing the license says is it protects against bacillus anthracis. It doesn't say the skin, it doesn't say swallowing it, and it doesn't say breathing it. It just says it protects against bacillus anthracis. That is the license.

Mr. BURTON. Well, there is a procedure that the FDA goes through to approve a vaccine, and I don't believe this has gone through that approval process. Now, if you know something I don't know, I would like to know about it.

General WEST. Sir, it has. They have testified to that effect before this committee, that they have approved the use of this vaccine. It is not an IND.

Mr. BURTON. Why does Bioport have an IND right now?

General WEST. They submitted an IND because in the beginning, as I understand it, and I wasn't here then, but in the beginning the question was raised by the opposition group as to whether or not the use of the vaccine against bacillus anthracis also included the aerosolized part of the threat. So Bioport wanted to go to FDA and get that clarified. But before that ever had to be acted upon, the FDA communicated with the Department, and subsequently with the Congress, saying that they had reviewed it, and they considered that an appropriate use. That didn't need to be acted on any more.

Mr. BURTON. Mr. Chan, do you have any information on this? Either one of you?

Mr. SHARMA. I think there is truth in everything. It is true that when a drug or a vaccine is licensed by FDA, it can be used for any indication. It is considered as off-label use. It is really up to the practitioners. So when they say it can be used, yes, it can be used, but you are asking a very technical question which is, has it been licensed as opposed to their telling you it is OK to use? For that, the way our Office of General Counsel has explained to us, that Bioport has submitted an IND, which is, that we—it is an investigational new drug, and FDA has not acted upon it. So that means that it is still pending.

Mr. BURTON. It is still in the investigative stages?

Mr. SHARMA. For that particular use.

Mr. BURTON. Against an aerosol?

Mr. SHARMA. That is correct. But it is also FDA saying, which is technically correct, and that is what, you know, General West is

using, that, yes, you can go ahead and use it, because once it is licensed, you can use it for any other indication. But if you want to, make sure that it is covered to protect yourself, then you have to go through the process which is what Bioport is doing.

Mr. BURTON. Mr. Chan, you read something earlier regarding, I think it was what the DOD said.

Mr. CHAN. Yes. I am trying to produce a document, unfortunately I don't have it with me, but I went over a little bit about the fact that DOD earlier stated in 1996, that, in fact, the current anthrax vaccine is not licensed for aerosol protection. OK.

Now, as Dr. Sharma has said, one can use it off-label. That is the difference here. When you apply for a license, it is intended for that use, and you want to license it, it requires you have data in terms of safety and efficacy.

Mr. BURTON. What about the data and the safety and the efficacy? You said guinea pigs had been tested and there were eight strains of anthrax it did not protect against. What about monkeys and other primates?

Mr. SHARMA. I think we cannot comment on this question. We have not looked at it, and I think this is something—we don't specifically know what data has been submitted in support of licensing for inhalation of anthrax.

Mr. BURTON. Submitted to the FDA?

Mr. SHARMA. Right.

Mr. BURTON. Have we requested that, the information that has been submitted to the FDA?

General WEST. It has been partially discussed here in previous testimony, and they talked about the human primate studies and the fact that every Rhesus monkey that had been vaccinated with at least two shots and then exposed to an aerosolized challenge survived, and they also testified that they did not believe it was an off-label use.

I would agree with what Dr. Sharma said, except for that. This is not off label. The people that the country pays and depends upon to make that ruling have written the department and the Congress and said we don't consider it off label. Or IND.

Mr. BURTON. If it is not, why do they have to do an IND then?

General WEST. They don't, sir, because now there is a written opinion on it.

Mr. BURTON. So the Bioport people are just doing this for the heck of it, not because it is necessary?

General WEST. I don't believe they are doing it at all now, nor do I believe FDA is working on it.

Mr. BURTON. We have the IND from Bioport. We have it now.

General WEST. I believe that was submitted before we got the FDA ruling, it wasn't required. But I will go back and check that to make sure I am correct.

Mr. BURTON. We would like to have that checked by both staff. Did you have a comment?

Mr. CHAN. No, I don't.

Mr. BURTON. Let me go on to some other questions.

General West, you have no idea, I guess, how the squalene got into the anthrax vaccine. You say it was a naturally occurring thing?

General WEST. That is what FDA testified last week, sir. We didn't know it was in there at all. Their original analysis indicated there wasn't any in there, and then when they came up with a more sophisticated test, they found a very, very minute portion of it in the vaccine in two of the samples that they conducted, I believe. But their statement to us was that it was nothing to be concerned about, and it would take 2 million times that much to act as an adjuvant.

Mr. BURTON. We have a difference of opinion from another scientist which I mentioned to you a few minutes ago.

Why is it that—you know, would be of the things that really concerns me is there is a lot of tainted vaccine that is not being used, but it is being kept in the case of an emergency. I think there are several million doses of the vaccine being kept, which will be injected into the military personnel in the event that we are having an attack or if there is an emergency.

Why is it they are keeping that vaccine? If it is tainted or if it is contaminated?

General WEST. Well, there is vaccine that has been produced that is in three categories. There is a vaccine that has been produced that is certified and safe for use, which is held by Bioport and shipped to the facilities that we want to use it at about the world.

There is a second group that has been manufactured by Bioport, but has not been released and has not been tested and cannot be until Bioport gets their license and has an approved testing methodology and procedure that FDA will allow to be used to test that vaccine. It may or may not someday become available for use. That will be FDA's decision, not ours.

There is another——

Mr. BURTON. Why does Bioport have to get a license for that again, that category?

General WEST. Part of the certification process they are going through includes how they make the vaccine, how they store the vaccine, how they test the vaccine, how they expose the animals to run the tests to assure that the vaccine has efficacy, how they run the test for potency, and those procedures haven't been finally approved by FDA for the new facility yet.

Mr. BURTON. Oh, for the new facility. So the vaccine that is ready for use right now was produced in the old facility and it did pass muster?

General WEST. The vaccine we are using now was produced in the old facility and has passed muster, in most cases has passed muster more than once.

Mr. BURTON. What about the third category you are talking about?

General WEST. The third category of vaccine is a batch of vaccine that was found in subsequent tests to not have the required amount of femoral preservative in it.

Mr. BURTON. That is mercury?

General WEST. It is the preservative that——

Mr. BURTON. That is not it? Oh, themorol.

General WEST. It causes the vaccine to remain good once the vial is open. In those lots of vaccine, for some reason a very, very minute amount of the femoral has bonded to the glass. The vaccine

is still sterile, it is still good, we are not using it. We have no plans to use it. It is not perfect because a little bit of the femoral has bonded to the glass. Scientists' opinions are that it would still do its job, even though it is not suspended in the solution, but because it is not perfect, we are not going to use it. But we made what we thought was a prudent decision to keep that locked up at Bioport until we had more vaccine, because I would submit that if there was a large scale terrorist attack somewhere in the Nation, and that was the only vaccine we had, we may want to offer that under an IND for emergency use. But we were not saving it to use on our troops. We are just keeping it because we think it would be a prudent thing to have those lots as opposed to nothing.

Mr. BURTON. I see Mr. Shays has come back. Do you have questions, Mr. Shays?

Mr. SHAYS. Mr. Chairman, I have questions, two basic areas of questions. They both involve GAO report. I would like the GAO to look at these—I shouldn't call it a report, because what it is, it is the GAO statement, and it is the chart from their statement. I would like you to walk me through it again, Mr. Chan and Mr. Sharma, and then I would like you, General West, to comment on what they are saying.

Mr. CHAN. OK. This chart applies to only those people who are still in the military, not those who have left. What the chart said, the first bar graph suggests then out of all the people who receive one or more shots, 86 percent of them have one or more adverse event. OK.

Of that same group of people——

Mr. SHAYS. Of the 86 percent——

Mr. CHAN. The total.

Mr. SHARMA. Of those who received one shot.

Mr. CHAN. That is the denominator. That is the population. Of those who received a shot or more, 71 percent did not know about the risk at the time they responded to us.

Mr. SHAYS. So it is not 71 percent of the 86 percent. So they received the shot and had an adverse reaction?

Mr. CHAN. Right.

Mr. SHAYS. So of the 86 percent, 86 percent who took the shot, one or more shots, 86 percent had an adverse reaction.

Mr. CHAN. Right.

Mr. SHAYS. Of that amount, 71 percent of the 86——

Mr. CHAN. No, 71 percent of 100 percent did not know about the risk, and also did not have any discussion with the military.

Mr. SHAYS. Of all the people that took the shot, 71 percent didn't know about VAERS.

Mr. SHARMA. I want to make correct. The 60 percent pertains to——

Mr. SHAYS. Hold on second.

Mr. SHARMA. I am sorry. 60 percent——

Mr. SHAYS. Hold on. I don't want to go where you are going, because I want to make sure we all understand. I want to make sure I understand and I want to make sure the general understands. We are saying 71 percent who took the shots did not know about VAERS?

Mr. CHAN. Yes.

Mr. SHAYS. Now, I want you to explain what VAERS is, for the record.

Mr. CHAN. It is a passive surveillance system on adverse events that the recipient can report under any kind of event they want to report.

Mr. SHAYS. It is 71 percent of the people who took the shot did not even know they had the ability——

Mr. CHAN. To report.

Mr. SHAYS. Did not know they had the ability to go somewhere to say they had a negative reaction.

Mr. CHAN. Exactly, yes.

Mr. SHAYS. What you are saying is almost—it is pretty obvious. Go to 60 percent.

Mr. CHAN. 60 percent did not discuss——

Mr. SHAYS. 60 percent of everyone that took the shot?

Mr. CHAN. Yes. Did not discuss any reactions they have with the military.

Mr. SHAYS. OK. So did all 60 percent—is this 60 percent who had an adverse reaction? Is it 60 percent of 86 percent?

Mr. CHAN. No, it is the whole thing.

Mr. SHAYS. OK.

Mr. CHAN. Then the only one that is misleading in here is that out of all of the people with reactions, 49 percent of them said that it is because of fear of loss of flight safety, adverse——

Mr. SHAYS. OK.

Mr. CHAN. That is where the mislabeling occurs.

Mr. SHAYS. OK. But 49 percent of the 86 percent had reasons——

Mr. CHAN. Yes. For those who could report, they didn't do so for fear of the following reasons, and we picked the ones that, you know, particularly in terms of loss of flight status, adverse affects on career and so on, because that is usually what we were told in our focus group when we asked them: why don't you report?

The other reason they said, well, I don't think it was serious enough, that kind of thing. Or, in fact, I went to see somebody else. I went to civilian providers rather than the military, and those kinds of reasons.

Mr. SHAYS. I am sorry to be redundant, but I want to just make sure. Given your last comment, I want to make sure, is it 49 percent of 60 percent or 49 percent of 86 percent?

Mr. CHAN. Eighty-six percent. Sorry.

Mr. SHAYS. General West, what are the implications of this, if they are true?

General WEST. I am very concerned about that. There are some things we want to look at very hard. I am puzzled by it, because I know that VAERS is covered in our informational video, it has been covered in the informational brochures we hand out, it has been covered in our directive to commanders, it has been covered in our instruction program to doctors. There is no way that GAO should go out to the field and learn that 71 percent of people taking a shot don't know how to submit a VAERS. That is a real problem for me, and we have to fix it.

Mr. SHAYS. Let's go to the first one. Eighty-six percent had one or more reaction. That wouldn't surprise you because almost everyone would have a negative reaction to some degree.

General WEST. If you include the minor reactions, redness and swelling, probably so.

Mr. SHAYS. So that doesn't surprise you, the 86 percent?

General WEST. No, sir, although it is a little higher than the other surveys.

Mr. SHAYS. How about the 60 percent who chose not to discuss their adverse reaction?

General WEST. That is a big concern to me.

Mr. SHAYS. But are you surprised by it?

General WEST. Yes, sir.

Mr. SHAYS. Why would you be surprised since we have had so much testimony, and I am sure even if you are not here, in other hearings you would be briefed on it, that some of our soldiers and sailors and marines and air crew, in this case we are talking air crew, they felt intimidated about reporting the fact that they had adverse reaction. I mean, they felt intimidated because you weren't, you know, taking the party line. The party line is take your shot and get on with life. So why would you be surprised?

General WEST. I am surprised because, initially, as Major General Weaver said earlier, I think our education program and information programs were lacking. We have put a lot of effort and a lot of time into making those better.

We have sent people to some of the sites. One of the things we learned was that, as soon as the opposition group learned that we were going to be starting vaccinations somewhere, that they showed up a week to 10 days prior and started an information campaign, to include putting posters up on light poles aboard base and scheduling town meetings and things like that. They even advertised it on their Web site. They have instructions about how to put up those posters to get people out to hear their side of the story.

Faced with that kind of a challenge, we tried to beef up our information campaign; and one of the things we tried to be sure of is that everybody knew about the VAERS system. So that is an alarming and disappointing number to me, and we owe you an answer on why that is true.

Mr. SHAYS. But General West, we have had continual people come under oath, and they are your military people, they are people that you can trust, who have said they have felt intimidated from coming forward and expressing anything to do with their possibly leaving or not feeling well. They have said that they have not felt comfortable in doing that. So I am surprised you are surprised, because it fits what we have been told. So you shouldn't be the last to know.

I would like to have you comment on what I read earlier, and I don't need to go into it in great detail. Dr. Walker, who is from the Harvard School of Public Health, who was basically a witness, came to talk about the fact that you have certain adverse effects in any vaccine, and you look at the good far outweighs the bad and you make a determination. But in it he said, I can obviously only speak from the point of view of civilian medicine. I don't know the

military. In the general society I think it is a bad practice to compel vaccination. People may make mistakes, but I think it is just a violation of fundamental liberties.

Now, I understand that when you are in the military, you give up liberties, so I am not going down that route as much as I am mentioning the fact that you hold these men in trust. And believe me—you are in the military, I wasn't; you have risked your life in the military, I haven't—so I stand in awe of that, and I know for a fact that you care about your men and women.

But what I don't understand is that it would strike me that if you had a negative reaction, why that wouldn't justify not going to the second, third or fourth or fifth vaccine, inoculation. That is what I don't understand. It would seem to me that if they are under order and you know there are going to be some people that have a negative impact, that you would simply say these people who are responding in a negative way, under no circumstances should they be under an order—should they be under an order to take it, should they be potentially court-martialed if they don't.

Isn't it a fact—and I will let you answer both questions, obviously. Isn't it a fact that you have had some people who have said that they have had an adverse reaction where you have ordered them to take it, and when they haven't, they have potentially been court-martialed? That has been a threat to them.

General WEST. It is a fact that I have had reports of people having adverse reactions and being required to take a shot. I am not specifically aware of that resulting in a court-martial. I am aware of a case where it almost did, and we got involved to stop that when we learned of it.

But it should not happen. If a person has a reaction, they should immediately be given a medical exemption, and they should not be required to take another shot until we can determine what caused the reaction and whether or not it is safe to give them another shot. If they truly had a reaction, we probably never will determine that it is safe to give them another shot. They should not be under court-martial, they should not be charged with anything, they should continue to serve proudly, and it should not be a negative mark in any way.

Any of those cases like that are true—and I heard Dr. Chan talk about one of them a moment ago. I hope he will share that information with me, because I want to go and fix that. Those are wrong. They shouldn't happen.

Mr. SHAYS. General, it is an easy thing to solve. You contact everyone under your command and you tell them that anyone who has had an adverse reaction shouldn't be required to take the second or third shot or fourth shot. It is an easy thing to do. We already have testimony from an expert that nobody challenges that some people will have a negative reaction.

So, again, I used the word court-martial. I am trying to train myself not to be so precise, because you are precise coming back, and I didn't really just mean it to be court-martialed. Isn't it true that there are people who have been disciplined, who have a record that shows that they have not taken—obeyed the command to take the shot, and the reason they did it, bless their hearts, is they believe they are being made sick from this, and they think they shouldn't

have to take the second or third shot. They took the first, so it wasn't like they just said, I am not doing this. They took a shot, they saw they had a bad reaction, they said, don't give me the second or the third or the fourth.

Isn't it true there have been more than one under those circumstances, not court-martialed, who have been disciplined?

General WEST. I hope there are none that we didn't catch before the disciplinary process finished itself. If there are, we need to go back and fix those. If you will make me aware of them, I will try to do that.

Mr. SHAYS. What do you mean "didn't catch"? Are you saying that you do not believe that there is anyone who refused to take the second or third or fourth shot because they—it wasn't because they had an adverse reaction of a previous shot?

General WEST. If they had minor redness or swelling or soreness for a day or two, that should not have been a reason not to take the second shot. But if they had something beyond that, they should not have been required to take the shot, and they should not have been disciplined.

Mr. SHAYS. But I think that we have had testimony, and I can give you the names, General, of people who have come before us, and I think that it can be documented by this report that there are people who had more than just what I might have gotten when I got the polio vaccine and I had a redness when I was much younger. But I think that you know that, too. I do. I really do. I really think that you know that we have had this kind of testimony. Isn't it true that we have had that testimony?

General WEST. I am aware of some cases where a person has been charged, and when we have reviewed the facts on it, we had determined that they deserved and needed to be examined by a doctor and the doctor make the determination whether they should have another shot. If there is someone that fell in that category that was subsequently disciplined, I would like to have that person's name, and I will go back and make that right.

Mr. SHAYS. Would you define what you mean by review, a doctor reviewed it? What? A doctor looked at it and he looked at the report and said, no, you get a second shot? How do you define review?

General WEST. In most cases, I would define review as that person seeing the doctor personally, talking to the doctor, the doctor asking him questions, the doctor reviewing his medical history and making a qualified and competent determination as to whether or not there is a reaction.

Mr. SHAYS. Because I can almost concede to you that we could both disagree on whether we need anthrax and whether we need one that has the recombinant which is a newer anthrax that isolates the protein that does the job the way it should do it and without more than—without up to six shots. We could have all of our disagreements about that.

General WEST. I want that, too, sir.

Mr. SHAYS. No, but you don't want it bad enough to have done it and done it full speed ahead. Because there has been a time when we haven't done it. We just went with the old vaccine. So you don't want it as much as I think you should.

But I think that none of us could disagree with this: If, in fact, you have the right to order someone to take a vaccine and they have an adverse effect, I sincerely believe that you have no viable system to really know who are the bad ones, who are reacting in a way where they shouldn't have the second or third shot. I would like to know if the GAO has come to that same conclusion?

Mr. CHAN. This is from meetings with some of the pilots and their crews in various places, but I can recall one case where, I think General West is correct, when people have said I have reactions to it and they were sent to Walter Reed for examination, and at least from these people they said that Walter Reed granted them waivers for not taking another shot. Whereupon, the command basically said that they were giving too many waivers, so from then on they don't send them there, they send them to Andrews Air Force base where no more waivers would be granted. That is what I heard. I am trying to relate this to you.

Mr. BURTON. Would the gentleman yield?

That is almost criminal. If a person has had a reaction and they send him to Walter Reed and they are getting waivers from getting another shot and in order to minimize the number of people getting waivers they send them out to Andrews because they won't give them waivers out there, man, that is bordering on criminal negligence.

Mr. CHAN. These are testimonial evidence that is given to me and my colleagues here, and we were told that, and we did not go and verify those. I just wanted to let you know that.

Mr. BURTON. We want to have GAO do that.

Go ahead, I am sorry, Mr. Shays. I just think that we will make an additional request of GAO not only for the active military but to check with Andrews Air Force Base and the personnel, and I would like to put those people under oath, if necessary, bring them in to find out if they were instructed by their superior officers not to grant waivers when waivers should have been granted and that they were diverting people from Walter Reed because too many waivers were granted, because that is highly questionable. So we will make that request, and I want to talk to you about that.

General WEST. Sir, I absolutely agree with you that what you said is exactly right, but I don't believe you are going to find that to be true.

Mr. BURTON. Well, we are going to check it out, General.

Mr. SHAYS. General, we may not find that to be true, but we did have a witness last week who testified that he had an adverse reaction, and he was not examined, the doctor just looked at his papers. So it sounds to me like we don't have a very good standard that is universally applied and properly applied.

You would agree with me that if someone has—excuse me, I don't mean with me. You would agree that if someone has an adverse reaction that you should determine whether, in fact, it is related to the vaccine before they are given another one, is that true?

General WEST. Yes, sir.

Mr. SHAYS. But you can't speak with total confidence that that is the case?

General WEST. We published an exemption policy, we sent it to our commanders, and we sent it to our medical people and told

them that is what we wanted. That is the way it should be working.

Mr. SHAYS. But we send mixed messages. That is the problem. The military sends mixed messages. So it is the message and the mixed message.

When I first opened my office, when I first was elected, I heard someone answer the phone, and they said, Congressman Shays isn't here, and I was in the next office, and I thought, this is interesting. I thought—I called the staff person in, and I said, I just heard you tell somebody I wasn't here. She said, yes, but you said you didn't want to be bothered. So I said, I don't want to be bothered now. So what I had to say to my staff person is you heard, that is correct, but I didn't want you to lie; I just simply wanted you to say that he is busy. That is the truth.

But the point I am trying to make to you is, there is—I gave two messages as far as that person was concerned, and I think the military is doing that. You don't want this program to potentially be jeopardized, because you so strongly believe in it that the mixed message that I think you are sending, whether you intend to or not is, tough it out like a soldier and get your shot and obey orders, because you have to, because in the battlefield we need to make sure you have the shot. You, in the end, have the right to do it, but if the message is or if the result is that people are being forced to take the shot, then we got a big problem.

The last slide and then I will yield the floor, if I could just look at the last slide. Walk me through that slide.

General, do you have that copy in front of you?

General WEST. No, sir.

Mr. SHAYS. Would you just hand him a copy of it, please? I am sorry, I would have thought you would have asked for it, but I will make sure you got it.

Would you go through the slide, please?

Mr. CHAN. Basically, you see the slide has two rows. The first row represents the people who have changed their status by leaving, by moving to another unit, by being inactive, OK. That represents 25 percent of the total number of people that we sampled.

Then the second row basically represents those who remained. That means the 75 percent of the people who are still with the active military. So it is—unfortunately, we are rushing through this thing.

Let me walk through the first row there.

Twenty-five percent——

Mr. SHAYS. I am in no rush, so you don't have to be. Let me just say, this is very important.

Mr. CHAN. Twenty-five percent have changed their status, of which the top reason for their change is anthrax, which represents 25 percent of those who—now, when we asked that question, we said, of these eight or nine different reasons, from family reasons to other employment opportunities to OPTEMPO and all of those issues, they checked only one reason as your top reason. That is how we picked that. And 25 percent, or one-quarter of those people picked anthrax program as the reason for their change in status.

Then, we asked the question: If the anthrax program becomes voluntary rather than mandatory, would you return? And 43 percent of those said, yes, they would.

Mr. SHAYS. OK. And you have explained the 61 percent?

Mr. CHAN. The 61 percent—and that is why I am saying it is a little bit difficult in terms of comparing apples and oranges. First of all, the 18 percent is of the 75 percent who are still there. So in fact, if you try to sum the two, there is a tendency for some to do that, it is 25 percent plus 13.5 percent, and 13.5 represents 18 percent of 75 percent. So the total number of people who either left, changed their status or intend to leave in 6 months is a total of 38.5 percent of total force.

Mr. SHAYS. With all due respect, we must have asked you to come to this hearing too quickly, because you probably could have made it simpler. But let me just put it in my words, OK? And if I can understand it, the General clearly can.

My understanding is, of all the people who left, of all the people who left, is the 25 inactive and the 25 anthrax just a coincidence?

Mr. CHAN. Yes, absolutely, yes.

Mr. SHAYS. OK. So basically, you are saying 25 percent of this group left of 100 percent, correct?

Mr. CHAN. Yes.

Mr. SHAYS. And it is just a coincidence that it is 25 percent.

Of the people who left, and they could only give one reason, you only allowed them to give one reason, there could be other reasons, but they could only give one reason, 25 percent said it was anthrax. That was the reason if they could only pick one reason.

Mr. CHAN. Yes.

Mr. SHAYS. Of the people who said anthrax, if only one reason, you are saying that 43 percent of them would have come back.

Mr. CHAN. Yes, sir.

Mr. SHAYS. OK. Now, when you allowed the others the—of the 75 percent who are left, you said what, 18 percent would leave?

Mr. CHAN. Eighteen percent, right.

Mr. SHAYS. Within 6 months.

Mr. CHAN. Yes.

Mr. SHAYS. And you only allowed them to use one reason?

Mr. CHAN. In this case, we allowed them to pick one or more.

Mr. SHAYS. They could pick one or more. So they could pick a lot of reasons. But then you said, of that, which is the most important? You asked it a little differently. Sixty-one percent said anthrax was a key factor.

Mr. CHAN. Yes, sir.

Mr. SHAYS. OK.

Mr. CHAN. And let me give you the next reason. Family reason is 16 percent. That is the next highest.

Mr. SHAYS. What? Say that again.

Mr. CHAN. Family reason, 16 percent; other employment opportunities, 16 percent; OPTEMPO, 10 percent. So just to give you a comparison.

Mr. SHAYS. So for comparison purposes, it is more than three to one.

Mr. CHAN. Yes, that is right, sir.

Mr. SHAYS. Now, in your statement, you said the overall response rate was 66 percent. What is that issue? Sixty-six percent responded?

Mr. CHAN. That is right. As you know, we sampled the 13,000 troops that represent—that are pilots and air crews.

Mr. SHAYS. And you got a 66 percent response?

Mr. CHAN. Wait a minute. To sample that, we have 1,253 questionnaires sent out. We received 66 percent return on the questionnaire.

Mr. SHAYS. So 1,253, and it was sent at random. You didn't pick out——

Mr. CHAN. At random. So what we said is that it could be representative of the entire 13,000.

Mr. SHAYS. No, I mean statistically, getting a sample of 1,253 out of 13,000 is extraordinary. And statistically, to get a 66 percent response is extraordinary.

Mr. CHAN. It is quite good in the sense that we have to send these questionnaires to the individual's home address, and some of them may be deployed, and some of them may not be around, so we account for that. What we were hoping for is above 50 percent to give us a reasonable random sample. So it is pretty good, given the circumstance.

Mr. SHAYS. So how confident are you that this is a good representative model of the entire 13,000?

Mr. CHAN. Very much so. It would give us—most of my answers would give us a cost limit of maybe plus or minus 4 to 7 percent.

Mr. SHARMA. Ninety-five percent confidence. Our confidence interval is 95 percent on these numbers.

Mr. CHAN. Plus or minus 4 to 7 percent.

Mr. SHAYS. So this is Guard and Reserves.

Mr. CHAN. Yes, sir.

Mr. SHAYS. Pilots? Air crew.

Mr. CHAN. Air crew, yes, sir.

Mr. SHAYS. So what can we draw about the entire force structure?

Mr. CHAN. We haven't done that.

Mr. SHAYS. But are there implications here?

Mr. CHAN. The only implication to draw from is, you know, I really don't—I can't answer that question because I think we can try to sample those people and find out. We did have some focus groups where we——

Mr. SHAYS. So your point is that this is air crew, and it may be more or less with different—if I was a pilot, for instance, and I believe that my reactions and my sensitivity, and I am a commercial pilot, I might be a little more concerned about—I mean, I am just trying to think here. What seems to show up on our radar screen are pilots, and part of the reason is that they are one of the most costly to train. Our air crews in general are the most costly to train and the most significant when we receive a loss. So it is an extraordinarily high number, from my standpoint.

I would like to know, General West, how you react.

General WEST. The numbers are high. The numbers are a concern. I have already said one is too many.

I believe that there are a couple of things that impact the results of the survey. One of them is how actively the opposition group has been encouraging people to send them out, to fill them out and send them back. I think the committee even had a Web site that asked similar questions that encouraged people to get their input in.

There were things like Mr. Edwards' situation that was put up on the wall here during a press release. This is a committee of the Congress of the United States. That picture went up there and went to the homes and the bedrooms and the living rooms of America; and, at the time, nobody here knew whether or not there was a connection between the fact that he was sick and he also took an anthrax shot.

All of these kinds of things, and as actively as the opposition group have worked against it, as much publicity as this has gotten, the fact that it was sent to the two components of DOD where we have had the most problem, the Air National Guard and the Air Force Reserve, is going to give you the worst statistics that you can collect and come up with on this issue. But they are still too high. They are still too high.

Mr. SHAYS. General, let me just respond. General, of all the answers you could give me, I think that is one of the worst, because I don't think of you as the opposition.

General WEST. You don't think what, sir?

Mr. SHAYS. I don't think of you as the opposition. Just the term "opposition" is kind of almost alarming to me. These——

General WEST. I wasn't speaking of you then, sir, I was speaking of——

Mr. SHAYS. No, not me, not me, but even the people. I mean——

General WEST. They call themselves that on the Web site. Their name is the No Group.

Mr. SHAYS. Let me just ask you, are these witnesses today, are they part of the opposition? Those three individuals that testified earlier, are they part of the opposition?

General WEST. I can show you dozens of e-mails that they sent back and forth within the No Group.

Mr. SHAYS. No. What they are, are your fellow soldiers and sailors and marines and air crew. That is what they are. These are your family.

General WEST. I think they are, sir, and I am very disappointed that they have chosen to leave.

Mr. SHAYS. That they have chosen to what?

General WEST. That they have chosen to leave the service. I wish they were all still in. I wish they were all still doing what they were trained to do and say they enjoyed doing. I am very disappointed that they have been misled into saying this was a bad decision.

Mr. SHAYS. So you think this is being misled.

General WEST. I do, sir.

Mr. SHAYS. Well, you know, I was going to go out graciously. I don't feel inclined to do that. I mean, just think of what you just said. They have been misled. Think of it. Have they been misled, or has this Congress been misled?

I was content to leave General Weaver out of it. Did he mislead? And mislead doesn't even mean lie. Mislead means kind of distort the truth, give implications that something happened that didn't happen.

Only one person—the implication was only one person decided to leave when, in fact, you know, and we should have known—there was the term "walk." I think we have been dealing with being misled and when the military, the people who are the trustees mislead, how can you blame your rank and file for not having trust in you? I don't have trust in what we have been told by the Pentagon, and I sure wouldn't if I was in the military, because I would see it up close and personal.

We have had too many witnesses, General. We have too many witnesses that have said their companion officers have said, take it. We have had too many witnesses say that: You didn't have an adverse effect; you know, just tough it out. So I mean—and we have had too many witnesses who said when they were sick they didn't get the care they needed and yet they were ordered to do it. So "misled" I think is a wrong term for you to use. And I guess you have used it so it is on the record. I feel you——

General WEST. I am sorry you feel that way, sir. I can tell you that——

Mr. SHAYS. I feel that you have misled us. I feel that General Weaver has misled us. I feel that DOD has misled us. I didn't say lie, I said misled.

General WEST. Every answer I have given has been as honest as I could possibly portray it.

Mr. SHAYS. I think "possibly" gives you too many outs.

Let me just, with the last—Joint Chiefs, I would like to end with this. When was the last briefing that the chairman or vice chairman of the Joint Chiefs personally received from a representative of OSD, which is the Office of the Secretary of Defense, regarding the AVIP?

General WEST. I don't remember the exact date, sir. It would have been approximately, when we had them all together, it would have been approximately 4 months ago when we were making a decision whether to go on with phase one or to scale it back.

Mr. SHAYS. So approximately 4 months ago. How long did the briefing last?

General WEST. Probably 45 minutes. But it was briefed at several levels before—I mean, you normally will brief the staff, and then you will brief the 1-stars, you will brief the vice chiefs, they will have a read-ahead when they come in. The briefing usually goes fairly quickly just because they are so busy.

Mr. SHAYS. I know they are very busy, but you have said this is a very important program. Are they aware of all of the problems that have been talked about in all of these hearings?

General WEST. I certainly believe that they are generally aware. They are probably not aware of 100 percent of the things that are discussed here, but certainly we would have a 90 percent solution or so, in that area.

Mr. SHAYS. Thank you. Thank you, General.

Mr. BURTON. Thank you, Mr. Shays.

Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman.

Have you all taken a vaccine, the full regimen?

General WEST. Yes, sir. I have only had five. When I came to this job, I had not taken it because I had not been to the two theaters that we were vaccinating, nor was I scheduled to go there, but given the job that I had, I felt that I should. And it takes 18 months to get them all. I have only been here 14. But I will take the sixth, as soon as my 6 months is past.

Mr. CUMMINGS. Have you had any side effects?

General WEST. No, sir. I literally got the first shot in the field and then got in my car and drove to the Pentagon the same hour. I haven't had anything beyond a little bit of minor soreness and a little bit of an ache a few seconds after the injection.

Mr. CUMMINGS. What about you, General Weaver?

General WEAVER. Sir, I have had all six. When we first began, I asked all of my leadership to show the example, if they would take the shot, and they all did. No adverse reactions.

Mr. CUMMINGS. General West, you said something that I just want you to clarify for us. You know, sometimes hearings can have the effect of—sometimes they don't end up in law or policy, but they can have an effect. Have these hearings had any effect on what is going on with regard to the vaccine, or any other hearings in the Congress that you know of in the last year or so?

General WEST. Sir, I would say it has had two effects. One of them is very good, and one of them has made the problem harder.

The good effect that it has had is that it has caused us to go back and reexamine everything that we are doing, and that is congressional oversight, and that is good. That is good government. We need it. We thank you for it. The program is better today because of it.

But it has been bad because all of the publicity that it has gotten and all that has been written about it and all that has shown up on TV about it, and some of the things like—and I said this at the last hearing, but when you take a half a million people and give them a shot, some of them are going to get sick, and if you put everybody that gets sick on the stand or if everybody you put on the stand is someone that also got sick without connecting it medically and scientifically to a vaccine reaction, that is publicity that doesn't help.

Mr. CUMMINGS. Now, when I listened to Mr. Chan, he talks about this 86 percent of the people, talking about the side effects. You know, one of the things I guess that—I have listened to all of the witnesses, and I try to give the benefit of the doubt as best I can. And I don't know about being misled, I just haven't gotten to that point. But one thing I have noticed is that it seems as if you are really—you are in this position, and maybe that is how they teach you to be in the military, and it seems like you are rigid, and you are holding that ground.

I think that what bothers me about that, being rigid—and like I said, I won't go as far as to say misled—but being rigid, is that I really—deep in my heart, I believe that while you are standing there and being rigid, I really do believe people are suffering. And that is what bothers me. You know, I don't see——

You say you feel this compassion. I am going to tell you, if I heard the stories that I have heard, first of all, I would want to say, OK, these are human beings, these are my men and women, and I would want to say, well, wait a minute. You know, let me see—you know, let me look here at this 86 percent. Who are these people?

And you were here. You were here. You heard the stories, you know, just like we heard them. And I still feel that you are there and you are at the gate and you are saying, no. But at the same time, people are suffering.

I will tell you, I guess there is a time to be rigid, but there is also a time to have compassion and for all of us, all of us, none of us are perfect, and for us to really take a close look at what we are doing.

Now, one of the things that you said was you talked about the medical exemption, and you said something that was very interesting. You said that if there was a side effect, you believe that person—I talked about the knot, Mr. Shays talked about the side effect, and you said if they had a side effect, which would be almost anything, I guess, that they should not be made to go on, you know, continue the shots. Is that what you said?

General WEST. Anything beyond minor local reaction. And I would define minor local as redness, soreness, minor swelling. If it goes beyond that, if it causes a knot that doesn't go away in a couple of days, if it causes the person to be dizzy or to have nausea or to feel tired or to feel dizzy, those are things that should be investigated, and that person should have an exemption until we get to the bottom of that.

Mr. CUMMINGS. Now, when I get a shot, immunization, whatever, they always give you—first of all, the doctor usually tells you, if you have these problems, this is what you need to do, and a lot of times they give you a written document saying, if you have problems, call us immediately.

Do we have something that says to folks in the military, if you have anything beyond this, what you just described, first of all, you should see the doctor immediately. But, more importantly, and that is what I am most concerned about, does it say, you don't have to continue to take these shots if it has—is there anything written anywhere that says that, says that policy that you told us that you believe in?

General WEST. Yes, sir. It is in two places. It is in our medical exemption communication to the commanders, and it is also in some of the information that AVIP puts out. I am going to ask Colonel Randolph, if you don't mind, if he would expand on this a little bit. He was sworn earlier, and he works with it every day.

Mr. BURTON. Colonel Randolph, if you want to scoot up there.

Mr. CUMMINGS. Why don't you pull your chair up? You would be more comfortable.

Colonel RANDOLPH. Colonel Randy Randolph, I am the Director of the Anthrax Vaccine Immunization Program Agency, which is an office under the Office of the Army Surgeon General.

We are the focal point for information. We run the DOD Web site. We started the toll-free information line. We answer e-mails, questions from soldiers, sailors, airmen, marine, moms, dads,

spouses. We do outreach visits. We visit various posts, installation camps.

We also go to various forums to which we are invited to provide education. The education includes not only educational outreach materials such as the silent training aids that were brought up earlier but video programs and briefings, PowerPoint information, wallet cards with the anthrax vaccine Web site on it, and much, much more.

Mr. CUMMINGS. The things you just stated, are those pre and post shots?

Colonel RANDOLPH. Yes, Congressman, they are both. They are both.

Mr. BURTON. Would the gentleman yield?

Mr. CUMMINGS. Yes.

Mr. BURTON. You know, I listened very carefully to your answer, and I don't think you answered Representative Cummings' questions. Do you give to the person getting the shot a piece of paper that says, when they get the shot, if you have an adverse reaction, do this, and if you have an adverse reaction that is severe enough besides redness or whatever, you don't have to take another shot. Do you give them a document, a piece of paper at the time of the shot that explains this to them?

Colonel RANDOLPH. Congressman, before they start the program, they get education and a piece of paper, it is a quadfold pamphlet that not only gives them information about adverse reactions, side effects to expect, the minor lumps and bumps, what people have self-reported in terms of headaches, it also gives them very clearly how to file a VAERS report. It not only gives them our Web site—and you can go to the front page on our Web site and click and file one of those reports—but it also gives them the toll-free information number to the FDA to file that report.

Mr. BURTON. If the gentleman will yield for one more question.

Colonel RANDOLPH. I didn't finish the answer to your question, though.

Mr. BURTON. I know, but do you give that to them simultaneous with the—getting the shot, or do you give that to them——

Colonel RANDOLPH. And then, yes, sir, they are supposed to get it when they get the shot, and then the information is supposed to continue afterwards. There are written policies in all four services that mandate that.

One of the reasons we started the Web site is, in fact, because the quad-folds and the PowerPoint briefings we found were not, in fact, given in all of the cases. So to improve on that educational process and make it more available, we put it on the Web site.

Mr. BURTON. One more followup question. When did you start this program? When did you start giving them this information?

Colonel RANDOLPH. We started giving them information from the very beginning of the program.

Mr. BURTON. No, I mean the document.

Colonel RANDOLPH. Sir, the pamphlet was given to them in March 1998 during the accelerated program during Desert Thunder. I was the person responsible for FedEx'ing 30,000 of those pamphlets into Desert Shield/Desert Storm. The pamphlets at that time did not include the VAERS reporting. That came as a lesson

learned. People wanted us to put the VAERS report on, and so the subsequent product did have the VAERS report on it.

Mr. BURTON. I see some people in the audience shaking their heads.

Mr. SHAYS. Mr. Cummings, I don't want to defer you from your questions, but if you are going to stay on this issue, I would not interrupt you, but if you are going off to another issue, I would ask——

Mr. CUMMINGS. I am going to stay on this.

Mr. BURTON. Mr. Cummings still has the time.

Mr. SHAYS. When you are ending this part, I would love to just jump in.

Mr. CUMMINGS. Sure.

When was it changed?

First of all, Mr. Chairman, we would like to have—do you have the old document, the old card? I would like to have that as a part of the record, and the new card.

Colonel RANDOLPH. We can provide it for the record, and we can provide all the dates that they have had changes. They have changed about four or five times.

Mr. CUMMINGS. When did the VAERS report information come onto the card?

Colonel RANDOLPH. Congressman, I would have to take that for the record to give you an exact date. I believe it was the fall of 1998, but I would be disingenuous to guarantee that was the date.

Mr. CUMMINGS. And what brought that change about?

Colonel RANDOLPH. Input from customers, input from this committee and Mr. Shays' committee that is what they wanted to see. They wanted us to address—oh, and, also, the GAO study recommended that VAERS information be given to our service members, family members, everyone.

Mr. CUMMINGS. And so can you give us the language? I mean, just—I mean, if you can, the language of that part. Did it say—I mean, I know you can't say exact words. I am not asking that.

Colonel RANDOLPH. OK. I will provide the pamphlets for the record so you have the exact language.

But in paraphrasing, it does say, if you suspect any kind of symptom or adverse event subsequent to a dose of vaccine, whether or not it is related to the vaccine or not, we encourage you to file a VAERS report with the FDA. Then we give them our Web site; and, like I said, it is on our Web site; and we give them the FDA toll-free information number.

Mr. CUMMINGS. Is there something that says that you won't be given an Article 15, I guess I am using the right term, or be court-martialed if you refuse to take—and I am not talking about on the card. I mean anywhere, anywhere where they would have access to the information, if you refused to take further shots if you have—when you have side effects?

Colonel RANDOLPH. I can't say honestly whether or not it says in any policy that we have written that if you believe you have a symptom or an adverse event subsequent to taking a dose you won't be called a whistle-blower or anything else if you report it.

Mr. CUMMINGS. Do you think, based upon what General West just said, that would be appropriate?

Colonel RANDOLPH. I think all of us are saying that not only from the preliminary results we have seen today and the numbers that they indicate and what that might implicate about trust that we need to do a better job educating. And, yes, Congressman, I agree that is one of the points that needs to be emphasized.

I spend 12 to 16 hours a day, every day, to include many hours on the weekends, personally talking to service members and family members. I did it again this weekend. I care very greatly about it. And it is gravely disappointing to me that, A, the information is not getting out to where it needs to get out; and even beyond that, that if you believe the preliminary results, it indicates they distrust the information that is there anyway. That is very disappointing.

Mr. CUMMINGS. Why do you think that is? I mean, you know, we have the military on the one hand saying—we have General West saying that these guys should not be punished, and I guess one theory would be that they want to be macho, I guess, I don't know, but the distrust. I mean—and it is almost like a culture of fear that seems to be running rampant.

And you are doing the job you are doing. You seem to be a real sensitive kind of person, and you seem—I assume you are doing a good job. But something is going haywire. Something is wrong. Something is awfully wrong when you have that kind of fear, when people are sneaking in in the middle of the night, people winking and stuff like that. I mean, something is wrong.

I guess what I am concerned about is whether we are all missing the boat. Something is missing, and whatever is missing creates this culture of fear, culture of distrust, culture of illness that we seem to be turning our heads to a certain degree and saying that it doesn't—I mean, if these guys and women really believe that this is happening, believe me, some of them, it is happening to some of them. And I guess I just want us to get to the bottom line.

I have often said that what we do so often is that we meet, meet, meet with no results. That is why I asked the question, whether the hearings were having any effect. I asked that question earlier, because I think that is so important, because, see, we may not see you all for another year.

Mr. BURTON. Oh, yes, we will.

Mr. CUMMINGS. Oh, OK. But in the meantime, whenever we see them, Mr. Chairman, you know, there is going to be more people that are going to go through more changes. I guess that is where I am trying to get to. I am trying to make sure that when the dust settles that we have had an effect.

Colonel RANDOLPH. Congressman, you have had an effect, this committee has had an effect, Congressman Shays' subcommittee has had an effect. Everything we take into consideration. We have changed educational products multiple times. We have added educational—we did not have the DOD Web site at the beginning. We didn't have a toll-free information line. The toll-free information line is just an absolutely wonderful instrument, because people can connect with warm bodies and talk to them, and we can answer their specific questions and their concerns. If they have a medical evaluation problem, we can get them to the right health care provider to be taken care of.

You hit on one other thing, too. Perception is nine-tenths of the law. Education is to try to change those perceptions. If they perceive that there is a problem with the vaccine, then we have got a challenge, a bigger challenge, to give them fact-based evidence that says otherwise.

Mr. BURTON. Will the gentleman yield?

Mr. CUMMINGS. I yield to the gentleman.

Mr. BURTON. I just talked to some Desert Storm soldiers and they have—and I have also talked to some who weren't in Desert Storm, and they said that there are some documents out at Walter Reed that we are going to subpoena that deal with adverse reactions and what constitutes an adverse reaction and how people should go ahead and get the shots, even though some of those adverse reactions go beyond just redness. We are going to get those documents.

I want to ask you one more time, Colonel. On this fold-out that you say they give to the recipients of the shots, does it specifically tell the person who is getting the shot that if they have any adverse reaction, they do not have to take another shot? I don't care about the VAERS. I don't want any of that. Does it say, if you have an adverse reaction, you can report it. And we are saying an adverse reaction beyond redness and minor things, that you do not have to take the other shot. Does it say that anywhere?

Colonel RANDOLPH. Congressman, I will have to take that for the record. I believe it talks about medical exemptions, but I am not sure.

Mr. BURTON. I want to see that document, and I want the committee to have copies of that document. Because you referred to, while the VAERS reporting is mentioned on there, but you did not say that it specifically tells them that if there is an adverse reaction, they don't have to followup with the shots.

Colonel RANDOLPH. No, Congressman, I didn't say that at all. You are right.

Mr. BURTON. OK. Well, I want to see that, and I want to have that for the record.

Colonel RANDOLPH. Someone has passed me a note that perhaps I said I was the one responsible for sending pamphlets to Desert Thunder.

Mr. BURTON. 30,000, you said.

Colonel RANDOLPH. Someone said that I might have said Desert Shield/Desert Storm back in 1989 and 1990.

Mr. BURTON. No, Desert Thunder, you said.

Colonel RANDOLPH. OK, good.

Mr. BURTON. When you finish, I have a number of questions I want to ask.

Mr. CUMMINGS. I am almost finished.

General West, did you have something?

General WEST. I want to respond to something you said earlier. It is very important to me as a leader.

I was very sincere when I said that I was concerned and had compassion for everybody that was here last week. And we have already taken some steps to try to be sure that the people that were here, whether they were anthrax reactions or not, get the very best treatment that we can provide them and that we take care of that

cost concern that was mentioned that was new information to me. But I want you to believe that there is nothing more important to me as a leader than taking care of the men and women that give their life to keep this country the best place to live on the planet.

But the other side of it for me is that I may be leading them across that next line of departure, and it may be against one of those adversaries that have got this very, very bad agent that they can use against us, and part of my compassion is to get them to best protection that I can.

I mean, yes, after spending 14 months following every lead I can followup with and tracking down every complaint that I can and studying everything I can find about it and talking to as many experts as I can get to, I am convinced that it is a safe and effective vaccine and that it is something we have to use against a very, very real and very, very devastating threat until we get that better medicine that Mr. Shays talks about.

Mr. CUMMINGS. Do you see us getting that better medicine anytime soon?

General WEST. No, sir. I see us working harder and harder on it all the time, but with today's approval processes and R&D timeframes and the cost of it and the way it has to be tested and the number of months that takes and the amount of data you have to collect, it is going to be a matter of a few years, not months. I wish that wasn't true.

Mr. CUMMINGS. This is my last question, and I guess it is—again, I am going back to, how do we have an effect? General West, you said that, you talked about this policy, and I still don't think that it is the policy that if you have an adverse effect, what the chairman was talking about, if you have the adverse effect, you don't have to continue to take shots and you won't be—and this is my part, won't be court-martialed or given an Article 15, I don't know the military terms, but you know what I am talking about, go through some trial process. Now, that is not—you are saying that is or is not written somewhere, anywhere? Is it written anywhere?

General WEST. I don't remember it being written down anywhere that if you have a reaction and don't take the shot that you won't be disciplined, but it certainly says in the published exemption policy that you are not required to take a shot if you have a reaction that goes beyond a minor local event level. And nobody is going to be disciplined until they have a chance to see a lawyer, until they talk to their doctor. They are going to get that information, but I promise you that we will go back and review and see if there are better ways that we can communicate that.

Mr. CUMMINGS. Thank you.

Thank you, Mr. Chairman.

Mr. BURTON. Thank you, Mr. Cummings.

We have a number of military personnel here who are in the audience, and we are going to meet with them, General, when we get through and go over the testimony today, and we will be asking you and the Colonel and General Weaver to come back in the not-too-distant future. I still have subpoena authority, and we can have hearings after we adjourn sine die, and I intend to have hearings on this because I think it is of such import.

Let me just also say that I am very concerned about some of the information that we have not received. We talked about the data base that tracked the shots given to our troops during the Gulf war. We have been told that that has been lost. I don't know how in the world you followup with a six-shot regimen of anthrax vaccine when you don't have any record of the first or second shots, and yet the Pentagon tells us they have lost that information. How can that be?

General WEST. Sir, I don't have a good answer for that question. I didn't know we had told you that.

Mr. BURTON. Well, that has been told to us, and we will be subpoenaing from the Pentagon immediately any information whatsoever regarding the shots that were given to our troops during the Gulf war, and if there was—if it was lost, I want to know—in the subpoena we are going to ask how it was lost, and we are also going to ask how in the world they could, in a coherent way, continue to give shots, a regimen that is supposed to be given in a sequential timeframe, without knowing who got the previous shots and when. So, you know, we want to know what happened with that.

Do you think that the Gulf war veterans that are ill have squalene antibodies in their blood?

General WEST. I don't know, sir, but if they do, I don't think it came from anthrax vaccine.

Mr. BURTON. You don't know, though, do you?

General WEST. Well——

Mr. BURTON. Have you tested anybody to find out those who have suffered from the Persian Gulf Syndrome, have you tested any of them to see if they have squalene in their bodies? I want to know that.

General WEST. I would have to get that.

Mr. BURTON. If one of our enemies used one of these other threats tomorrow—I am talking about one of the other 31 strains of anthrax vaccine—or if they use something that was totally different—let's say they used another biological weapon, and there are lots of biological weapons. We have talked to a lot of people who said there are a number of biological weapons that could be used. The most common one would be anthrax, but if they used one of these other biological or chemical weapons, how would we protect our troops?

General WEST. Well, there are intelligence reports of other biological weapons that are being pursued; and at the same time they are pursuing them, we are pursuing the most effective ways to counter them.

But the only way we have now is what I would consider some very primitive detection capability, some protective clothing and equipment that works but has to be maintained and kept clean and kept—filters changed very, very rigorously and very, very devotedly, and there are other medical solutions that are being pursued. But, beyond that, I don't have a better answer. It is a very, very ugly threat and a very, very big problem. We believe in this case we did have protection.

Mr. BURTON. I know one thing, if I were Saddam Hussein and I knew that you did have an effective anthrax vaccine and I was

going into combat with you and I didn't think there was anything that you were going to do with a nuclear retaliatory effort or anything else like we threatened to use in Desert Storm, I would use one of those other agents. I sure as heck wouldn't use one I thought you had protection for.

Anyhow, you had a comment, Mr. Shays.

Mr. SHAYS. General Weaver, I just realized that I need to ask you just this question. It is not a trick question. It is just intended to be prepared for your document.

You have already said that you didn't specifically ask those people who were transferring or separating whether it was related to anthrax, but you did say you did send out a document to your commanders to survey for why they were transferring or separating.

What would be the date of that document? I know you don't have it here, but what would be the date? When did you make that request?

General WEAVER. One moment, sir.

Sir, my staff tells me that we made it right after the senior leadership conference, which would have been in the November 1999, timeframe. We had a hearing——

Mr. SHAYS. It would be a document that would be in November or December of last year?

General WEAVER. Yes, sir.

Mr. SHAYS. That will say that you have requested it. It will be a written document?

General WEAVER. Sir, I asked. I cannot request.

Mr. SHAYS. Let's not get into that. The bottom line is this document you are giving me is going to be dated last year, correct?

General WEAVER. I will check that for sure, sir.

Mr. SHAYS. But you anticipate it is last year's document?

General WEAVER. According to my staff.

Mr. SHAYS. Thank you.

Mr. BURTON. Let me just ask two remaining questions: According to Tulane University, some of the Gulf war veterans that are ill have squalene antibodies in their blood. Did you know that, General?

General WEST. Sir, I was not part of the Gulf war illness study. I have read the Tulane report. I don't know that—I don't know whether it has been confirmed. I just don't know enough about that to give you a good answer.

Mr. BURTON. Well, according to the GAO and some others we have talked to, squalene does have a repressive effect on the immune system; and if squalene was found in the antibodies or in the blood of these Gulf war veterans, I would like to know how it got there, if it wasn't in the vaccine. So that is something else we need to check. I don't know if any of the lots of the vaccine that were used in Desert Storm are still available, but if there is we ought to take a look at that and have it analyzed. I would like to have you take a look that if you could.

The last thing I would like to ask you is, we have a letter from the Association for Civilian Technicians, which I will place in the record, regarding their support of legislation to hold the anthrax program in abeyance until it is proven safe and effective.

As you know, civilian technicians are in the Guard; and their full-time job is working for the Guard. If these individuals become sick from anthrax vaccine and can no longer serve in the Guard, they will lose their full-time job as well. The civilian technicians are a critical component to keeping our planes flying. How many technicians have lost their job as a result of the anthrax vaccine? Do you have any idea?

General WEST. No, sir.

Mr. BURTON. Can you get that information for us?

General WEST. I should be able to, yes, sir.

Mr. BURTON. Would you do that?

We have a lot more questions which we would like to submit to you for the record. If you could answer those and send them back to us, we would really appreciate it, General Weaver, both of you.

I want to thank Mr. Chan and the people at GAO. We appreciate it. You will be getting a further request from us, and I know you are going to love it, because it is going to involve a lot of work.

In any event, we will have further hearings on this, and we will have further questions for you, so we will be back in touch. Thank you very much.

We stand adjourned.

[Whereupon, at 4:40 p.m., the committee was adjourned, subject to the call of the Chair.]

[The prepared statement of Mrs. Chenoweth-Hage and additional information submitted for the hearing record follow:]

Statement of Congressman Chenoweth-Hage
Committee on Government Reform
2157 Rayburn House Office Building
October 3, 2000

Thank you, Mr. Chairman. I appreciate and commend the ongoing attention and the time the Committee has taken to examine the anthrax immunization program. This hearing, "*The Anthrax Vaccine Immunization Program - What Have We Learned? - Part II*," will be important in resolving many outstanding questions from last week's hearing.

At every step, this Committee has provided the oversight necessary to resolve outstanding problems with the anthrax vaccine. Just last week, I was saddened to hear about the possible vaccine-related death of one of one of Bioport's own employees. Of course, as expected, we heard from Bioport that this death couldn't possibly be related to the vaccine.

With this in mind, I would ask the Committee to pay close attention to the witnesses we have before us today. They are the ones who are closest to th realities of military readiness. They are the ones who are directly affected by the vaccine. They are the ones who have put their careers on the line.

We are not.

Today's hearing, while a continuation of last week's hearing, completes a marked departure from the course that Congress has taken in the recent past. The "official line" is no longer taken for granted, nor should it be. Over the past several years, we have heard obfuscations and distortions emanate from this administration. While this has not been true when the military has spoken to issues, the prior restraint of speech exercised by this administration is noticeable. That is why I have a hard time blaming the force for the spin we have constantly heard.

Mr. Chairman, after a certain amount of time, individual servicemen and officers have concluded that their acquiescence would mean betrayal of their brethren. While this is true in their case, it is a decision that each member of the service must come to after thoughtful consideration. We must not become the judges of their conscience.

Today, I look forward to those who, have in conscience, decided that they can no longer acquiesce. In particular, I look forward to hearing from Lieutenant Colonel Tom Heemstra. Just last year, he predicted a decline in readiness of fifty percent in the 163rd Fighter Squadron should nothing be done regarding the anthrax vaccine. Today, we have seen his predictions come to fruition. I would encourage the members of the Committee to listen closely to his compelling testimony.

Mr. Chairman, again, I would like to thank both you and this Committee for holding this hearing. We owe not only our current servicemen an answer to our questions regarding the anthrax vaccine, we owe an answer to those who have come before us. They are the ones who purchased liberty at the cost of their lives. They are represented by the endless rows of Crosses and Stars of David at countless battlefields. They would expect nothing less of us, besides the protection of our current servicemen.

Thank you, Mr. Chairman.

RCS: DD-RA(OT)2087
Exp. 03/31/01

2000 Survey of Reserve Component Personnel

Form M















DMDC Survey No. 00-0002M

DEFENSE MANPOWER DATA CENTER
ATTN: SURVEY PROCESSING ACTIVITY
DATA RECOGNITION CORPORATION
5900 BAKER ROAD
MINNETONKA, MN 55345-5967

- **Use a blue or black pen, or a pencil.**
- **Select answers you believe are most appropriate.**
- **Do not make any marks outside of the response and write-in boxes.**
- **Please PRINT where applicable.**
- **Place an "X" in the appropriate box or boxes.**

RIGHT	WRONG
X	✓ O

- **To change an answer using pen, completely black out the wrong answer and put an "X" in the correct box as shown below.**

CORRECT ANSWER	INCORRECT ANSWER
X	■

- **To change an answer using pencil, completely erase the wrong answer and put an "X" in the correct box.**

ABOUT THIS QUESTIONNAIRE

WHAT IS THE PURPOSE OF THIS SURVEY?

This survey asks about your attitudes and opinions on a wide range of personnel issues in the Reserve components such as morale, well being, and your military plans. This survey will be used to assess programs, policies, and issues affecting Reserve component members and their families. **While no decisions about you alone will be made based on this survey, survey results will influence policy discussions and may result in changes that affect Reserve component members and families.** If you don't respond, your views and the views of other members like you will not be considered in personnel policy reviews and changes.

WHY ME?

You have been selected scientifically to be part of a sample of people who represent members of the Reserve components. Based on your responses and the responses of others, conclusions may be drawn about the views and experiences of Reserve component members overall, and those of demographic subgroups. The validity of these conclusions depends, in part, on receiving enough completed surveys from individuals like you. **The survey results will not be valid if you allow someone else to fill out the survey for you.**

WILL MY SURVEY RESPONSES BE KEPT PRIVATE?

Yes. Under no circumstances will any information about identifiable individuals be released. Your responses will be combined with information from many other members to represent the views and experiences of groups of members. **Do not use any personal, unit, or place names anywhere on this survey.**

PRIVACY NOTICE

In accordance with the Privacy Act of 1974 (Public Law 93-579), this notice informs you of the purpose of the survey and how the findings will be used. Please read it carefully.

AUTHORITY: 10 United States Code, Sections 136, 1782, and 2358.

PRINCIPAL PURPOSE: Information collected in this survey will be used to assess the attitudes and perceptions of Department of Defense and Department of Transportation personnel about programs and policies. This information will help formulate policies that may be needed to improve the working environment.

ROUTINE USES: Reports may be provided to the Secretaries of Defense, Transportation, and the Military Departments, and to the Joint Chiefs of Staff. Findings may be used in reports and testimony provided to Congress. Some findings may be published by the Defense Manpower Data Center (DMDC) or professional journals, or reported in manuscripts presented at conferences, symposia, and scientific meetings. In no case will the data be reported or used for identifiable individuals.

DISCLOSURE: Providing information on this survey is voluntary. There is no penalty if you choose not to respond. However, maximum participation is encouraged so that the data will be complete and representative. Your survey instrument will be treated as confidential. Identifying information will be used only by persons engaged in, and for the purposes of, the survey. Only group statistics will be reported.

I. MILITARY BACKGROUND

1. Of which Reserve component are you a member?

Army National Guard
Naval Reserve
Air National Guard
Coast Guard Reserve
Army Reserve
Marine Corps Reserve
Air Force Reserve
No Reserve component ⇨ **STOP. RETURN SURVEY**

2. How many years have you served in any of the following components? *Mark all that apply. Do not count partial years. Include as Reserve component years:*

- *Time spent mobilized/activated on active duty*
- *Time spent in a full-time active duty program*
- *Time spent in Individual Ready Reserves (IRR)*
- *Time spent as an Individual Mobilization Augmentee (IMA)*

COMPONENT
Active Army (USA)
Army National Guard (ARNG)
Army Reserve (USAR)
Active Navy (USN)
Naval Reserve (USNR)
Active Air Force (USAF)
Air National Guard (ANG)
Air Force Reserve (USAFR)
Active Marine Corps (USMC)
Marine Corps Reserve (USMCR)
Active Coast Guard (USCG)
Coast Guard Reserve (USCGR)

3. What is your current paygrade?

E-1	E-6	W-1	O-1/O1E
E-2	E-7	W-2	O-2/O2E
E-3	E-8	W-3	O-3/O3E
E-4	E-9	W-4	O-4
E-5		W-5	O-5
			O-6 or above

4. If you stay in the National Guard/Reserve, when would you expect to be selected for your next promotion to a higher grade?

Does not apply, I do not expect a promotion ⇨ **GO TO QUESTION 6**
Does not apply, I have no opportunities for promotion ⇨ **GO TO QUESTION 6**
I have been selected, but not yet received it
Less than 3 months
3 months to less than 7 months
7 months to less than 1 year
1 year to less than 2 years
2 years or more

5. When would you expect to actually receive your next promotion to a higher grade?

Less than 7 months
7 months to less than 1 year
1 year to less than 2 years
2 years or more
I don't expect to receive it

6. How long have you been in your present unit? *Do not count partial years.*

Less than 1 year

7. Are you in a different unit now than you were two years ago?

I am no longer in a unit ⇨ **GO TO QUESTION 10**
I was not in a National Guard/Reserve unit two years ago ⇨ **GO TO QUESTION 10**
No, I am in the same unit ⇨ **GO TO QUESTION 10**
Yes, in different unit but in same component
Yes, in different unit in different component

8. Did the following contribute to your changing units? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Was offered a promotion		
b. Promotion was more likely in new unit		
c. Relocated away from previous unit because of civilian job, school, or personal reasons		
d. Previous unit was moved		
e. Went to a unit that was closer		
f. Reorganization within previous unit		
g. Previous unit was closed, deactivated or disestablished		
h. Previous unit moved to another component		
i. Wanted to retrain in a different skill		
j. Thought I would like the job better in new unit		
k. Problems with co-workers or chain of command		
l. Didn't like unit environment		
m. Inadequate administrative support from Reserve or Guard unit/center		
n. Operations Tempo (OPTEMPO) or Personnel Tempo (PERSTEMPO) was too high		
o. Had a new assignment		
p. Was released from active component		
q. Changed Reserve status (e.g., changed from drilling unit to IRR)		
r. Conflict with civilian employment		
s. Mandatory rotation		
t. Family problems		

9. Did you have to retrain in a new skill when you changed units?

No
Yes

10. Have you ever been mobilized or deployed as a member of the National Guard/Reserve?

No ⇨ **IF NO, GO TO QUESTION 16**
Yes

◆ **11. Were you mobilized or deployed as a Reservist for the operations listed below?** ***Mark "No" or "Yes" for each item. If you mark "Yes" in column A, please indicate whether it was voluntary or involuntary, the deployment's location, and its length. If you mark "No" in column A, go to the next item in column A.***

	A. Were you mobilized or deployed as a member of the National Guard/Reserve for the operations (a-k) listed below?		B. Was your mobilization voluntary or involuntary?		C. Where did you deploy? (Mark one)				D. How long were you mobilized or deployed? Write in number of months. If under 1 month, enter "00". If mobilized/deployed now, write number of months so far.
	No	Yes	Voluntary	Involuntary	Does not apply, did not deploy	In own state or equivalent (e.g., DC, GU, PR, VI)	To another state or equivalent (e.g., DC, GU, PR, VI)	Outside US	
a. Operation Desert Shield/Storm									
b. Saudi Arabia (Aug 92-present)									
c. Centam, Hurricane Mitch Recovery/Rehab									
d. Operation Restore/Uphold Democracy (Haiti)									
e. Operation Desert Fox/Iraqi Crisis (SW Asia)									
f. Operation Joint Forge/Guard/ Endeavor (Bosnia)									
g. Operation Restore/Continue Hope (Somalia)									
h. Operation Joint Task Force (Cuba)									
i. Operation Allied Force (Kosovo)									
j. Other mobilization or deployment (1) ***Describe:***									
k. Other mobilization or deployment (2) ***Describe:***									

12. Are you mobilized/deployed now? ***If yes, indicate the operation in Question 11 for which you are mobilized/deployed.***

No Yes →

IF YES, MARK ONE →

a	d	g	j
b	e	h	k
c	f	i	

If you are currently mobilized/deployed, answer Questions 13-15 about your current mobilization/deployment. If you are not currently mobilized/deployed, answer Questions 13-15 about your most recent mobilization/deployment.

13. Please estimate your (and your spouse's) total income change from all sources as a result of your most recent mobilization or deployment. ***If you (and your spouse) have continuing losses from a business or practice, include those in your estimate.***

Increased $5,000 or more	Decreased $2,500-4,999
Increased $2,500-4,999	Decreased $5,000-9,999
Increased $1-2,499	Decreased $10,000-24,999
No change in income	Decreased $25,000-49,999
Decreased $1-2,499	Decreased $50,000 or more

14. Did the following changes in expenses occur as a result of your being mobilized or deployed? ***Mark "No" or "Yes" for each item.***

	No	Yes
a. Medical expenses increased		
b. Medical expenses decreased		
c. Telephone expenses increased		
d. Household maintenance and car repairs increased		
e. Household maintenance and car repairs decreased		
f. Childcare increased		
g. Mortgage payments declined		

15. What health insurance options did you choose the last time you were mobilized or deployed? ***Mark "No" or "Yes" for each option.***

	No	Yes
a. I kept my private/civilian health insurance		
b. I dropped my private/civilian health insurance		
c. I did not have any health insurance before mobilization/deployment		

16. The questions below are about your preparedness. ***Mark one answer for each item.***

	No	Yes	Not applicable
a. If you are a single parent or are married to a military member, do you have a family care plan?			
b. If you have a family care plan, is it up to date?			
c. Do you have a current written will?			
d. Does anyone currently hold your power-of-attorney?			
e. Do you have life insurance other than SGLI/VGLI?			
f. Have you ever filled out a record of emergency data?			
g. Have you verified/updated your record of emergency data in the past 12 months?			
h. Does your spouse or next-of-kin know where to find your important papers (e.g., will, car registration, checkbook, bank statements)?			

17. Do you plan to elect the Reserve components Survivor Benefit Plan (SBP) when eligible? ***Mark only one.***

- Does not apply, I don't plan to remain until eligible for retirement
- I have already elected to participate
- I have already elected not to participate
- Yes, upon receipt of my 20-year letter
- Yes, when I am 60 years old
- No
- Uncertain, I am not aware of the plan at all
- Uncertain, I don't understand the plan clearly
- Uncertain, I have not made up my mind

18. Have you volunteered for any operations (floats, police actions, training exercises, etc.) for which you were not mobilized or deployed?

- No
- Yes

19. How unlikely or likely is it that you would volunteer for a mobilization or deployment occurring in the next 5 years?

- Very unlikely
- Unlikely
- Neither likely nor unlikely
- Likely
- Very likely

20. How unlikely or likely do you think it is that you, as an individual, will be mobilized or deployed in the next 5 years?

- Very unlikely
- Unlikely
- Neither likely nor unlikely
- Likely
- Very likely

21. How unlikely or likely do you think it is that your unit will be mobilized or deployed in the next 5 years?

- Does not apply, I am not in a Guard/Reserve unit
- Very unlikely
- Unlikely
- Neither likely nor unlikely
- Likely
- Very likely

In this survey, the definition of "military duties" includes deployments, TADs/TDYs, training, military education, time at sea, and field exercises/alerts.

22. In the past 12 months, have you been away from your home overnight because of your military duties? ***Do not include nights spent away from home before out-of-town drills.***

- No ⇨ **IF NO, GO TO QUESTION 24**
- Yes

23. During the past 12 months, how long were you away from your home for the following military duties? ***Add up all nights away from home; assign each night to only one type of military duty.***

	10 months to 12 months	7 months to less than 10 months	5 months to less than 7 months	3 months to less than 5 months	1 month to less than 3 months	Less than 1 month	None
a. Peacekeeping or other contingency operation							
b. Foreign humanitarian assistance mission							
c. Unit training at combat training centers							
d. Counter drug operation							
e. Domestic disaster or civil emergency							
f. Time at sea for scheduled deployments (other than for the above)							
g. Other time at sea (other than for the above)							
h. Joint training/field exercises/ alerts (other than for the above)							
i. Drills or Annual Training/Active Duty Training (ACDUTRA) (other than for the above)							
j. Military education (other than for the above)							
k. Other TADs/TDYs							

♦ **24. If you were to be mobilized or deployed for 3 months, how much of a problem would each of the following be for you or your family?**

	Does not apply	Don't know	A very serious problem	A serious problem	Somewhat of a problem	A slight problem	Not a problem
A. Employer problems at the beginning of the mobilization/ deployment							
B. Getting the same job back after returning							
C. Loss of a promotion opportunity							
D. Loss of civilian job							
E. Demotion in civilian job							
F. Hostility from supervisor							
G. Hostility from co-workers							
H. Would get behind in advances in civilian occupation							
I. Loss of civilian health benefits during mobilization							
J. Loss of seniority or job responsibility on civilian job							
K. Loss of income during mobilization							
L. Business or professional practice would be damaged (e.g., medical, dental, legal)							
M. Problems for patients, clients, customers							
N. Other employer problems when you returned to your job							
O. Studies at school or college would be disrupted							
P. Spouse would need a job but would have trouble finding one							
Q. Increased chances for a marital separation or divorce							
R. Burden on spouse							
S. Problems for children							
T. Problems for other dependents							
U. Childcare							
V. Other							

If you marked even a slight problem for "Other," please specify ⇨

25. Have you already experienced any of the problems listed in Question 24 as a consequence of being mobilized or deployed as a member of the National Guard/Reserve?

Does not apply - Have never been mobilized or deployed as a member of the National Guard/ Reserve ⇨ **GO TO QUESTION 28**

No, I have not experienced any problems as a consequence of being mobilized or deployed ⇨ **GO TO QUESTION 28**

Yes

26. Which of the problems listed in Question 24 have you already experienced as a consequence of being mobilized or deployed as a member of the National Guard/Reserve? ***Mark all that apply.***

A	F	K	P	U
B	G	L	Q	V
C	H	M	R	
D	I	N	S	
E	J	O	T	

27. Of the problems you marked having experienced in Question 26, which were the most serious? ***Print the letters of the most serious problems.***

Most serious problem	2nd most serious problem	3rd most serious problem

II. MILITARY PLANS

28. People participate in the National Guard/Reserve for many reasons. How much have each of the following contributed to your decision to stay in the National Guard/Reserve?

	Very great influence	Great influence	Some influence	Little influence	Not at all
a. Serving the country					
b. Using educational benefits					
c. Obtaining training in a skill that would help get a civilian job					
d. Serving with the people in the unit					
e. Getting credit toward National Guard/Reserve retirement					
f. Promotion opportunities					
g. Opportunity to use military equipment					
h. Challenge of military training					
i. Needing the money for basic family expenses					
j. Wanting extra money to use now					
k. Saving income for the future					
l. Travel/"get away" opportunities					
m. Just enjoying the National Guard/Reserve					
n. Pride in my accomplishments in the National Guard/Reserve					
o. Amount of enjoyment from military job					
p. Special and incentive pay					
q. Reenlistment bonus or continuation pay program					
r. Required to fulfill an obligation					

29. Suppose that you have to decide whether to continue to participate in the National Guard/Reserve. Assuming you could stay, how likely is it you would choose to do so?

- Very unlikely
- Unlikely
- Neither likely nor unlikely
- Likely
- Very likely

30. If you could stay in the National Guard/Reserve as long as you want, how likely is it that you would chose to serve in the military until eligible for retirement?

- Does not apply, I am already eligible for retirement
- Very unlikely
- Unlikely
- Neither likely nor unlikely
- Likely
- Very likely

31. When you finally leave the National Guard/Reserve, what paygrade do you think you will have? *Mark one.*

E-1	E-6	W-1	O-1/O1E
E-2	E-7	W-2	O-2/O2E
E-3	E-8	W-3	O-3/O3E
E-4	E-9	W-4	O-4
E-5		W-5	O-5
			O-6 or above

32. When you finally leave the National Guard/Reserve, how many years of service do you expect to have? *Print years of service. If less than 1 year, print "00".*

III. MILITARY TRAINING

33. Are you currently trained/qualified in your duty Military Occupational Specialty/Designator/Rating/Air Force Specialty Code (MOS/D/R/AFSC)?

- No
- Yes

34. Are you currently working in your primary MOS/D/R/AFSC?

- No
- Yes

35. Considering all your National Guard/Reserve time on duty in 1999, what percentage of it was spent performing skills related to your primary MOS/D/R/AFSC?

- None
- 1-24%
- 25-49%
- 50-74%
- 75-99%
- All

36. Is your current primary MOS/D/R/AFSC the same one you had while on active duty?

- Does not apply, I don't have prior active duty service ⇨ **GO TO QUESTION 38**
- Yes ⇨ **GO TO QUESTION 38**
- No

37. When you joined the National Guard/Reserve, did you have to change your primary MOS/D/R/AFSC and did you want to? *Mark "No" or "Yes" for each item.*

	No	Yes
a. I had to change my MOS/D/R/AFSC		
b. I wanted to change my MOS/D/R/AFSC		

38. In 1999, how many calendar days did you spend in a compensated (pay or points) National Guard/Reserve status?

- Does not apply, I am in a full-time active duty National Guard/Reserve program
- None
- 1-24 days
- 25-47 days
- 48 days or more

39. In an average month in 1999, how many unpaid hours, off duty, did you spend on your National Guard/Reserve unit's business?

- Does not apply, I am in a full-time active duty National Guard/Reserve program
- None

40. In an average month in 1999, how many unpaid hours, off duty, did you spend on your professional development in the National Guard/Reserve?

- Does not apply, I am in a full-time active duty National Guard/Reserve program
- None

41. How many nights did you spend away from your home on official military duties in 1999? *Do not include nights spent away from home before out-of-town drills.*

- None

42. How did you attend the 1999 Annual Training/Active Duty Training (ACDUTRA)?

- A few days at a time, several times over the year
- A week or more at a time, more than once
- All at once
- Does not apply, did not attend 1999 Annual Training/Active Duty Training (ACDUTRA)

IV. YOUR MILITARY UNIT

43. Please indicate the category of the Selected Reserve to which you belong. *Mark one.*

Drilling unit Reservist/Traditional Guardsman
In a full-time active duty National Guard/Reserve program ⇨ **GO TO QUESTION 50**
Individual Mobilization Augmentee (IMA) ⇨ **GO TO QUESTION 51**

44. How satisfied are you with . . . ?

	Does not apply	Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
a. Training received during your unit drills						
b. Your unit's activities at 1999 Annual Training/ACDUTRA						
c. Opportunities to use your primary MOS/D/R/AFSC skills during unit drills						
d. Opportunities for promotion in your unit						
e. Opportunities for leadership in your unit						
f. Type of weapons or equipment your unit uses during drills						
g. Mechanical condition of the weapons and equipment your unit uses during training						
h. Supervision and direction given during unit drills						
i. Facilities in which you train						
j. Your job						
k. Job security						
l. Workload						
m. Assignment stability						
n. Unit social activities						
o. Work group/co-workers						
p. Acquaintances/friendships						
q. Time required at National Guard/Reserve activities						
r. Your possibility of being mobilized or deployed in the future						
s. Number of recent mobilizations or deployments you have experienced						
t. Not being included in recent mobilizations or deployments						

45. Are you a military technician? *(A military technician provides full-time support as a civilian government employee for administration, training, and maintenance of the unit.)*

No Yes

46. How much of a problem is each of the following for your unit/organization in achieving training objectives?

	Don't know	A very serious problem	A serious problem	Somewhat of a problem	A slight problem	Not a problem
a. Out-of-date equipment/weapons						
b. Poor mechanical condition of equipment/weapons						
c. Being below strength in grades E-1 to E-4						
d. Being below strength in grades E-5 to E-9						
e. Being below strength in grades WO-1 to WO-5						
f. Being below strength in grades O-1 to O-6						
g. Not enough staff resources or time to plan effective training						
h. Poor administrative support						
i. Low attendance at unit drills						
j. Low attendance of unit personnel at Annual Training/ ACDUTRA						
k. Ineffective training during Annual Training/ACDUTRA						
l. Shortage of MOS/D/R/AFSC qualified personnel						
m. Quality of personnel in lower-grade drill positions						
n. Quality of leaders						
o. Inadequate time to plan training objectives						
p. Lack of access to good training facilities and grounds						
q. Lack of good instruction manuals and materials						
r. Lack of supplies, such as ammunition, gasoline, etc.						
s. Lack of spare/replacement parts						
t. Excessive turnover of personnel						
u. Inadequate access to command's operating schedule to plan unit annual training						
v. Uncertainty about future status of unit/organization						
w. Unit reorganizing/restructuring						
x. Inadequate resources to support mission						
y. Inadequate access to computers						
z. Inadequate access to long-term training schedules						

47. About how far do you live from the place where your unit meets/drills?

Less than 50 miles	250-299 miles
50-99 miles	300-349 miles
100-149 miles	350-399 miles
150-199 miles	400 miles or more
200-249 miles	

48. How do you usually get to the place of regular military duty or drills? ***Mark "No" or "Yes" for each item.***

	No	Yes
a. Drive myself		
b. Driven by spouse		
c. Driven by another family member		
d. Car pool		
e. Civilian air transportation		
f. Military air transportation		
g. Public transportation (e.g., bus, taxi)		
h. Walk/bicycle		

49. How long does it usually take you to get from home to the place where your unit meets/drills?

Less than 1/2 hour
1/2 hour to less than 1 hour
1 hour to less than 1 1/2 hours
1 1/2 hours to less than 2 hours
2 hours to less than 4 hours
4 hours or more

50. In general, how would you describe the morale of military personnel in your unit?

Very low	High
Low	Very high
Neither high nor low	

51. In general, how would you describe your morale?

Very low	High
Low	Very high
Neither high nor low	

V. BENEFITS AND PROGRAMS

52. For each family program or service listed, mark its availability to you and your level of satisfaction with the quality of the service/program. ***For each item, mark one response in column A and one response in column B.***

	A. Availability	B. Satisfaction
	Don't know Not available Off installation only On installation only Both on- and off-installation	Very satisfied Satisfied Neither satisfied nor dissatisfied Dissatisfied Very dissatisfied No basis to judge
a. Individual counseling/therapy		
b. Pre-marital programs		
c. Marriage and family counseling/therapy/enrichment		
d. Family support centers		
e. Programs for families with disabled members		
f. Services for families during separation		
g. New parent classes		
h. Single parent programs		
i. Childcare services		
j. Youth/teen programs		
k. Eldercare		
l. Alcohol/drug abuse programs		
m. Spouse employment services		
n. Spouse/child abuse services		
o. Rape counseling services		
p. Crisis referral services		
q. Chaplain services/religious activities		
r. Legal assistance		
s. Financial counseling/management education		
t. Recreational programs		
u. Educational Services Center		
v. Services for single members		

◆ **53. During the past 12 months, how often did you and/or your family use the following military on-installation programs, facilities, or services and civilian off-installation programs, facilities, or services? *For each item, mark one response in column A and one response in column B.***

	A. Military On-Installation Program, Facility, or Service 12+ times 6-11 times 3-5 times 1-2 times 0 times Not available	B. Civilian Off-Installation Program, Facility, or Service 12+ times 6-11 times 3-5 times 1-2 times 0 times Not available
a. Auto, crafts, hobby shops		
b. Bank or credit union		
c. Bowling center or movie theater		
d. Commissary, supermarket, grocery store		
e. Clubs/dance/night clubs		
f. Fitness center/gym		
g. Golf course		
h. Library services		
i. Main exchange/department store		
j. Outdoor recreation areas (campgrounds, picnic areas, beach, stables, etc.)		
k. Outdoor recreation equipment rental		
l. Post office		
m. Recreation center (recreation room, music/TV, game room/amusement machines, etc.)		
n. Recreation lodging/hotels/resorts		
o. Shoppette/mini-mart		
p. Class VI/package store/liquor store		
q. Social activities for single service members (trips, special events, tournaments, etc.)		

54. During the past 12 months, have you used any of the following programs and services? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Adult continuing education/counseling		
b. Tuition assistance programs for college/higher education		
c. Technical/vocational programs		
d. Basic skills education		

55. How much do the following limit your use of the commissary or exchange? *Mark one answer for each row.*

	Completely Very much Somewhat Very little Not at all
Commissary	
a. Prices	
b. Stock	
c. Hours	
d. Distance	
e. The law does not allow more frequent use	
Exchange	
a. Prices	
b. Stock	
c. Hours	
d. Distance	

56. Overall, to what extent do you think you or your family save by using the commissary instead of civilian grocery stores?

- Does not apply, do not use commissary
- Not at all
- Small extent
- Moderate extent
- Large extent
- Very large extent

57. Do you currently use the *EXCHANGE* closest to you?

- No, I don't use an exchange
- No, I use an exchange, but it's not the closest
- Yes, I use the exchange closest to me

58. How long does/would it normally take to get to the exchange closest to you?

- 10 minutes or less
- 11-20 minutes
- 21-30 minutes
- 31-60 minutes
- More than 1 hour
- Don't know

59. Please rate the selection of merchandise at the exchange closest to you.

- Very poor
- Poor
- Average
- Good
- Excellent
- Don't know

60. Please rate the prices at the exchange closest to you compared with prices at other stores in town.

Very poor	Good
Poor	Excellent
Average	Don't know

61. At which Service's exchange do you shop most often?

Does not apply, I do not shop at an exchange
Army and Air Force Exchange Service (AAFES), Post Exchange (PX) or Base Exchange (BX)
Navy Exchange
Marine Corps Exchange

62. What average savings, not considering sales tax, are available at the exchange?

I believe I pay more at the exchange	6-10% savings
No savings	11-20% savings
5% savings or less	More than 20% savings
	Don't know

63. Are your (and your spouse's) shopping privileges limited at exchanges?

No Yes Don't know

64. Can an exchange's merchandise be ordered on the Internet?

No Yes Don't know

65. Are you now using or eligible for educational benefits as a result of military service?

No ⇨ **IF NO, GO TO QUESTION 68**
Yes

66. For which educational benefits are you eligible as a result of your military service?

	Earning eligibility now	Yes, already eligible	No
a. State benefits for National Guard/ Reserve service			
b. Montgomery GI Bill (MGIB) for Selected Reserve			
c. MGIB-Selected Reserve Kicker (A kicker is assistance given to personnel filling critical shortages in skills.)			
d. Active Force benefits (VEAP, MGIB, or tuition assistance)			
e. MGIB-Active Duty Kicker			
f. Tuition assistance (for members of a full-time active duty program)			

67. Which educational benefits are you now using? ♦
Mark "No" or "Yes" for each item.

	No	Yes
a. State benefits for National Guard		
b. MGIB for Selected Reserve		
c. Active Force benefits (VEAP, MGIB, or tuition assistance)		
d. ROTC/NROTC scholarship		

68. The National Guard/Reserve components are developing new information materials. Below is a list of topics that might be included. How interested would you be in receiving such materials?

	Very interested	Somewhat interested	Neither interested nor uninterested	Uninterested	Very uninterested
a. Retirement benefits					
b. Survivor Benefit Plan					
c. Family benefits in the National Guard/Reserve					
d. Mobilization information for family members					
e. Montgomery GI Bill for the Selected Reserve					
f. Soldiers/Sailors Civil Relief Act					
g. Dental insurance					
h. Medical insurance					
i. Mobilization preparation for business owners, partners and independent practitioners					
j. Employer-employee relations/rights					

69. Do you have any medical/hospitalization coverage(s)?

No ⇨ **IF NO, GO TO QUESTION 72**
Yes

70. Do you have the following medical/hospitalization coverage(s)? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Your civilian employer's healthcare plan		
b. Your school's healthcare plan		
c. Your spouse/family member's civilian employer's health plan		
d. Your active duty military healthcare coverage		
e. Your spouse/family member's active duty/retired military healthcare coverage		
f. Veterans' (VA) coverage		
g. Other private coverage		

71. How satisfied are you with the coverage provided by your medical insurance?

Very dissatisfied
Dissatisfied
Neither satisfied nor dissatisfied
Satisfied
Very satisfied

72. If you could buy medical insurance through National Guard/Reserve participation, what is the maximum premium cost you would be willing to pay per month?

Not applicable, I have medical insurance through National Guard/Reserve participation already
Less than $100 per month
$100-149 per month
$150-199 per month
$200-249 per month
$250-299 per month
$300 or more per month

73. How much did you spend on health care services and products (for you and your family) last year? *Include TRICARE/CHAMPUS deductions, enrollment fees, civilian insurance premiums, drugs, co-pays, deductibles, etc. Do not include dental care.*

Don't know
$0-$100
$101-$500
$501-$1,000
$1,001-$1,500
$1,501-$2,500
More than $2,500

74. Is basic dental insurance available to you as a member of the Selected Reserve?

No
Yes

75. Do you have any dental coverage(s)?

No ⇨ **IF NO, GO TO QUESTION 78**
Yes

76. Which of the following dental coverage(s) do you have? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Your civilian employer's dental plan		
b. Your spouse/family member's civilian employer's dental plan		
c. Your active duty military coverage		
d. Your spouse/family member's active duty military coverage (military dental clinic, TRICARE Family Member Dental Plan)		
e. Veteran (VA) coverage		
f. Other private coverage		

77. How satisfied are you with the coverage provided by the civilian dental insurance that you have?

Does not apply, do not have civilian dental insurance
Very dissatisfied
Dissatisfied
Neither satisfied nor dissatisfied
Satisfied
Very satisfied

78. Are you actively considering changing, expanding or getting dental insurance within the next year?

No ⇨ **IF NO, GO TO QUESTION 81**
Yes

79. What is the maximum premium cost you would be willing to pay to enroll yourself in a comprehensive dental plan?

Less than $10 per month
$10-19 per month
$20-29 per month
$30-39 per month
$40-49 per month
$50 or more per month

80. What is the maximum premium cost you would be willing to pay to enroll yourself and your family members in a comprehensive dental plan?

Not applicable
Less than $10 per month
$10-19 per month
$20-29 per month
$30-39 per month
$40-49 per month
$50-59 per month
$60-69 per month
$70 or more per month

VI. INDIVIDUAL AND FAMILY CHARACTERISTICS

81. Are you . . . ?

Male
Female

82. Are you Spanish/Hispanic/Latino? *Mark "No" if not Spanish/Hispanic/Latino.*

No, not Spanish/Hispanic/Latino
Yes, Mexican, Mexican American, Chicano
Yes, Puerto Rican
Yes, Cuban
Yes, other Spanish/Hispanic/Latino

83. What is your race? *Mark one or more races to indicate what you consider yourself to be.*

White
Black or African American
American Indian or Alaska Native
Asian (e.g., Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese)
Native Hawaiian or other Pacific Islander (e.g., Samoan, Guamanian or Chamorro)
Some other race ⇨ ***Please specify***

84. Are you a citizen of the United States? *Mark one.*

Yes, born in the United States
Yes, born in Puerto Rico, Guam, the U.S.Virgin Islands, or the Northern Marianas
Yes, born abroad of American parent or parents
Yes, a U.S. citizen by naturalization
No, not a citizen of the United States

85. Were either of your parents (or guardians) in the military when you were born?

No
Yes, at least one was on active duty
Yes, at least one was a Reservist
Don't know

86. Did you vote in the last local election? In the last presidential election?

A. Last local election
Yes, in person at the polls
Yes, by absentee ballot
No

B. Last presidential election
Yes, in person at the polls
Yes, by absentee ballot
No

87. Which of the following best describes the type of place where you are living now?

In military housing on a base/installation
In a large city (over 250,000)
In a suburb near a large city
In a medium-sized city (50,000-250,000)
In a suburb near a medium-sized city
In a small city or town (under 50,000)
On a farm or ranch
In a rural area but not on a farm or ranch

88. How long have you lived in your present neighborhood?

Less than 1 year
1 year to less than 3 years
3 years to less than 5 years
5 years or more

89. What is the highest degree or level of school that you have completed? *Mark the one answer that describes the highest grade or degree you have completed.*

11th grade or less
12 years of school, no diploma
High school diploma or the equivalent (e.g., GED), not from home schooling
High school diploma or the equivalent (e.g., GED), from home schooling
Some college credit, but less than 1 year
1 or more years of college, but no degree
Associate's degree (e.g., AA, AS)
Bachelor's degree (e.g., BA, AB, BS)
Master's degree (e.g., MA, MS)
Doctoral or professional degree (e.g., PhD, MD, JD)

90. What is the highest school grade or academic degree that you think you will complete in the future? *Mark the one answer that describes the highest grade or degree you think you will complete.*

Does not apply, I don't plan to attend school in the future
11th grade or less
12 years of school, no diploma
High school diploma or the equivalent (e.g., GED), not from home schooling
High school diploma or the equivalent (e.g., GED), from home schooling
Some college credit, but less than 1 year
1 or more years of college, but no degree
Associate's degree (e.g., AA, AS)
Bachelor's degree (e.g., BA, AB, BS)
Master's degree (e.g., MA, MS)
Doctoral or professional degree (e.g., PhD, MD, JD)

91. What kind of civilian school are you currently enrolled in?

Not currently enrolled in civilian school
High school (home schooling)
High school (public or private)
GED completion
Vocational/trade/business or other career training school
Junior or community college (2-year)
Four-year college or university
Graduate/professional school
Other

92. **Overall, how much did your family members or others in your life encourage you about entering the National Guard/Reserve?** *Mark one for each item.*

	Strongly encouraged	Encouraged	Neither encouraged nor discouraged	Discouraged	Strongly discouraged
a. Father/stepfather/other male guardian					
b. Mother/stepmother/other female guardian					
c. Brothers/stepbrothers					
d. Sisters/stepsisters					
e. Personal friends					
f. Teacher(s)					

93. **Have any of your family members or others in your life served in or retired from the military?** ***(Include National Guard/Reserve.) Please indicate their current military status. Mark all that apply.***

	Retired from the military	Served 8 years or more and separated	Served less than 8 years and separated	Currently serving in the military	Never served in the military
a. Father/stepfather/other male guardian					
b. Mother/stepmother/other female guardian					
c. Brothers/stepbrothers					
d. Sisters/stepsisters					
e. Personal friends					
f. Teacher(s)					

94. **Do you have any children aged 10 and older with whom you talk about post-high school options such as jobs and education?**

No ⇨ **IF NO, GO TO QUESTION 97**
Yes

95. **When you talk with your children about their future do you encourage them to consider the military?**

No
Yes

96. **When you talk with your children about their future choices, how positive or negative are you about the following?**

	Very positive	Positive	Neither positive nor negative	Negative	Very negative
a. The military, in general					
b. Career opportunities in the military					
c. Serving in the military, but not as a career					
d. Part-time (National Guard/ Reserve) opportunities in the military					
e. Career opportunities as a civilian Federal government employee					
f. Career opportunities in the private/civilian sector					
g. Seeking a college education					

97. **In your opinion, how do the following groups or individuals view your participation in the National Guard/Reserve?**

	Does not apply	Very favorably	Somewhat favorably	Neither favorably nor unfavorably	Somewhat unfavorably	Very unfavorably
a. Your spouse						
b. Your children						
c. Your spouse's relatives						
d. Your relatives						
e. Your neighbors						
f. Your civilian supervisor						
g. Your civilian co-workers						
h. Your National Guard/Reserve unit members						

98. **Have you ever used a personal computer (PC)?**

No ⇨ **IF NO, GO TO QUESTION 102** Yes

99. **Where during the last 12 months have you regularly used a PC?** *Mark "No" or "Yes" for each item.*

	No	Yes
a. Home/residence		
b. Civilian work/office		
c. Guard/Reserve duty station or Armory		
d. Installation/ship library		
e. Installation/ship recreation center		
f. Installation/ship education center		
g. Installation/ship family center		
h. Other military location		
i. Other non-military location (for example, public library)		

100. Do you have access to the Internet/World Wide Web?

No ⇨ **IF NO, GO TO QUESTION 102**
Yes

101. From which location do you most frequently access the Internet/World Wide Web? *Mark one.*

Home/residence
Civilian work/office
Guard/Reserve duty station or Armory
Installation/ship library
Installation/ship recreation center
Installation/ship education center
Installation/ship family center
Other military location
Other non-military location (for example, public library)

102. What is your current marital status? *Mark one.*

Married
Separated
Divorced ⇨ **GO TO QUESTION 113**
Widowed ⇨ **GO TO QUESTION 113**
Never married ⇨ **GO TO QUESTION 113**

103. How many years have you been married to your current spouse?

Less than one year

104. Is your spouse . . . ? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Working full-time in a Federal civilian job		
b. Working part-time in a Federal civilian job		
c. Working full-time in a civilian job (not Federal)		
d. Working part-time in a civilian job (not Federal)		
e. Managing or working in family business		
f. Self-employed in own business or profession		
g. An unpaid worker (volunteer)		
h. Unemployed and looking for job		
i. Unemployed, not looking for job, but would like employment		
j. Unemployed, not looking for job, and does not want employment		
k. In school		
l. Retired		
m. A homemaker, housewife, househusband		
n. Working multiple jobs		
o. Working temporary job(s)		

105. Does your spouse speak English as his or her main language at home?

No
Yes

106. To what extent do you and your spouse agree on your civilian career plans?

Does not apply, I do not have a civilian job
Strongly disagree
Disagree
Neither agree nor disagree
Agree
Strongly agree

107. To what extent do you and your spouse agree on your military career plans?

Strongly disagree
Disagree
Neither agree nor disagree
Agree
Strongly agree

108. How has your spouse's support for your decision about staying in the military changed in the past year?

Greatly decreased
Somewhat decreased
Has not changed
Somewhat increased
Greatly increased

109. Has your current spouse ever served (past or present) in the U.S. Armed Forces, either on active duty or in the National Guard/Reserve?

No ⇨ **IF NO, GO TO QUESTION 113**
Yes, currently serving on active duty (not a member of the National Guard/Reserve)
Yes, currently a member of the National Guard/Reserve in a full-time active duty status
Yes, currently a member of a drilling unit in the National Guard/Reserve
Yes, currently an IMA, IRR or ING ⇨ **IF IMA/IRR/ING, GO TO QUESTION 111**
Yes, spouse is separated or retired from service ⇨ **IF SEPARATED/RETIRED, GO TO QUESTION 111**

110. Are you presently assigned to the same installation or geographic location as your spouse?

Yes
No, but I expect my spouse will be assigned to this location soon
No, but I expect to be assigned to my spouse's location soon
No, we were unable to get assigned to the same location
No, for other reasons

111. Has your spouse ever been mobilized or deployed as a member of the National Guard/Reserve?

No ⇨ **IF NO, GO TO QUESTION 113**
Yes

◆ **112. Was your spouse mobilized/deployed as a Reservist for the operations listed below?** ***Mark "No" or "Yes" for each item. If you mark "Yes" in column A, please indicate whether it was voluntary or involuntary, the deployment's location, and its length. If you mark "No" in column A, go to the next item in column A.***

	A. Was your spouse mobilized or deployed as a member of the National Guard/Reserve for the operations (a-k) listed below?		B. Was his/her mobilization voluntary or involuntary?		C. Where did he/she deploy? (Mark one)				D. How long was he/she mobilized or deployed? Write in number of months. If under 1 month, enter "00". If mobilized/deployed now, write number of months so far.
	No	Yes	Voluntary	Involuntary	Does not apply, did not deploy	In own state or equivalent (e.g., DC, GU, PR, VI)	To another state or equivalent (e.g., DC, GU, PR, VI)	Outside US	
a. Operation Desert Shield/Storm									
b. Saudi Arabia (Aug 92-present)									
c. Centam, Hurricane Mitch Recovery/Rehab									
d. Operation Restore/Uphold Democracy (Haiti)									
e. Operation Desert Fox/Iraqi Crisis (SW Asia)									
f. Operation Joint Forge/Guard/ Endeavor (Bosnia)									
g. Operation Restore/Continue Hope (Somalia)									
h. Operation Joint Task Force (Cuba)									
i. Operation Allied Force (Kosovo)									
j. Other mobilization or deployment (1) ***Describe:***									
k. Other mobilization or deployment (2) ***Describe:***									

113. How much of a problem is there for your family when you spend . . . ?

	Does not apply	Very serious problem	Serious problem	Somewhat of a problem	Slight problem	Not a problem
a. Time away for weekend drills						
b. Time away for Annual Training/ACDUTRA						
c. Extra time at National Guard/ Reserve business or activities						
d. Time away for mobilization or deployment						

For Questions 114-119, "dependents" includes children and anyone else in your family, except your spouse, who has or is eligible to have a Uniformed Services identification card (military ID card) or is eligible for military health care benefits and is enrolled in the Defense Enrollment Eligibility Reporting System (DEERS).

114. Based on the definition following Question 113, do you have legal dependents (not including your spouse)?

No ⇨ **IF NO, GO TO QUESTION 120**
Yes

115. Are arrangements for your dependents who live with you realistically workable for each of the following situations?

	Does not apply	Definitely	Probably	Probably not	Definitely not
a. Short-term (less than 30 days) emergency situation such as a mobilization exercise					
b. Long-term situation such as being mobilized or deployed for 30 days or more					

116. Do you have a spouse, child, or other legal dependent enrolled in the Exceptional Family Member Program (EFMP) or the Coast Guard Special Needs Program?

No
Yes

117. Do any of your dependents (not including your spouse) have a physical, mental, or emotional condition requiring specialized treatment or care?

No
Yes, dependent requires temporary treatment or care
Yes, dependent requires permanent treatment or care

118. How many children or other dependents do you have in each age group? *Print the number of dependents you have in each age group.*

Less than 1 year old	1 year - under 2 years old	2-5 years old	6-13 years old	14-22 years old	23-64 years old	65 years old or older

19. How many of your children or other dependents in each age group live with you?

Less than 1 year old	1 year - under 2 years old	2-5 years old	6-13 years old	14-22 years old	23-64 years old	65 years old or older

20. Do you have caregiver responsibilities for an elderly family member (such as shopping, home maintenance, transportation, checking on them by phone, finances, and arrangements for care)? *Include family who live with you or live somewhere else.*

No ⇨ **IF NO, GO TO QUESTION 122**

Yes ⇨ **How many?**

21. During the past 12 months, did you lose any time from your military duties due to eldercare responsibilities?

No
Yes

VII. CIVILIAN WORK

22. Are you currently a member of a full-time active duty Reserve program (i.e., Active Guard and Reserve (AGR), Training and Administration of the Reserve (TAR), or Active Reserve (AR))?

No ⇨ **IF NO, GO TO QUESTION 125**
Yes

23. In 1999, did you have a civilian job?

No ⇨ **IF NO, GO TO QUESTION 148**
Yes

124. How interested are you in working in a National Guard/Reserve job that is similar to your civilian job?

Very uninterested
Uninterested
Neither interested or uninterested
Interested
Very interested

125. In your civilian job, do you work as any of the following? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Physician, registered nurse, dentist, optometrist		
b. Pilot/navigator		
c. Information technology professional (computer programmer, systems manager, etc.)		
d. Clergy		
e. Lawyer		

126. Are you currently . . . ? *Mark "No" or "Yes" for each item.*

	No	Yes
a. A member of a full-time active duty program, working an additional civilian job		
b. Working full-time as an Army or Air Force National Guard/Reserve military technician		
c. Working full-time in a civilian job (not military technician)		
d. Working part-time in a civilian job		
e. Employed in a civilian job but not at work due to temporary illness, vacation, strike, layoff, etc.		
f. Managing or working in family business		
g. Self-employed in own business or profession		
h. Unpaid worker (volunteer)		
i. Unemployed and looking for job		
j. Unemployed, not looking for job, but would like employment		
k. Unemployed, not looking for job, and do not want employment		
l. In school		
m. Retired		
n. Homemaker, housewife, househusband		
o. Working multiple jobs		
p. Working temporary job(s)		

127. In 1999, how many weeks were you without a civilian job and looking for civilian work?

Not applicable, I had a civilian job throughout 1999
The entire year

◆ **128. During 1999, did you do any civilian work for pay?** ***Answer "Yes" even if you worked only an average of an hour a week as a civilian, or helped without pay in a family business or farm for an average of 15 or more hours per week.***

No ⇨ **IF NO, GO TO QUESTION 148**
Yes

Questions 129-147 are about your civilian job in 1999. If you had more than one, answer these questions for the one where you worked the most hours per week for most of the year.

129. What kind of business or industry is/was this? ***Describe the activity at the location where you were employed. For example: hospital, newspaper publishing, mail order house, auto repair shop, bank. Do not write the name of the company.***

130. What kind of work are/were you doing? ***For example: registered nurse, personnel manager, supervisor of order department, auto mechanic, accountant.***

131. What are/were your most important activities or duties at this job? ***For example: patient care, directing hiring policies, supervising order clerks, repairing automobiles, reconciling financial records.***

132. Which of the following best describes your civilian employer in 1999? ***Mark one.***

Federal government
State government
Local government (including public schools)
Working without pay in family business or farm
Self-employed in own business
Private sector firm with 500 or more employees
Private sector firm with 100-499 employees
Private sector firm with less than 100 employees

133. In 1999, what was your employment status in your primary civilian job? ***Mark one.***

Permanent employee
Temporary employee

134. During a typical week, what days do/did you work in your main civilian job? ***Mark all that apply.***

Sun Mon Tues Wed Thur Fri Sat

135. In 1999, how many hours per week did you usually work at your main civilian job?

136. In 1999, how many hours per week did you usually work at all of your civilian jobs?

137. In 1999, did you ever work more than 40 hours per week at your main civilian job?

No ⇨ **IF NO, GO TO QUESTION 140**
Yes

138. In 1999, how many weeks did you work more than 40 hours per week at your main civilian job?

139. In 1999, how were you compensated when you worked overtime (e.g., over 40 hrs. in a week)? ***Mark "False" or "True" for each item.***

	False	True
a. Not paid extra for working overtime		
b. Received compensatory time		
c. Paid at my regular pay rate		
d. Paid time-and-a-half		
e. Paid double-time		
f. Paid more than double-time		
g. Received bonus		
h. Received more fees/commission		

140. In 1999, did you have a second civilian job in addition to your primary civilian job?

No ⇨ **IF NO, GO TO QUESTION 142**
Yes

141. How much did each of the following contribute to your having a second job?

	Completely	Very much	Somewhat	Very little	Not at all
a. Needed additional income to meet basic expenses					
b. Nice to have extra income to use					
c. Saving extra income for future needs					
d. Independence					
e. Self-esteem					
f. Enjoyment of work itself					
g. To gain experience for a non-military second career					

142. In 1999, how often did you lose opportunities for overtime/extra pay because of your National Guard/ Reserve obligations?

Never
Rarely
Occasionally
Frequently
Always

143. Were you self-employed in 1999?

No
Yes ⇨ **IF YES, GO TO QUESTION 146**

144. Which of the following describes how you got time off from your civilian job to meet the following National Guard/Reserve obligations in 1999?

	I used military leave/leave of absence	I used vacation/sick/personal days	Obligation was on day(s) I did not work	Does not apply, I did not attend	Does not apply, no conflict with job
a. Military schooling					
b. Annual Training/ACDUTRA					
c. Required drills					

145. Which of the following best describes how you were paid for the time you took from your civilian job for National Guard/Reserve obligations in 1999?

	Does not apply, I did not attend	Other	Received military pay and full civilian pay	Received military pay and partial civilian pay	Received only military pay	Military obligations were on days I didn't work
a. Military schooling						
b. Annual Training/ACDUTRA						
c. Required drills						

146. How much of a problem is there for your main employer (or for you, if self-employed) when you spend . . . ?

	Does not apply	Don't know	Very serious problem	Serious problem	Somewhat of a problem	Slight problem	Not a problem
a. Time away for required drills							
b. Time away for Annual Training/ACDUTRA							
c. Extra time spent on National Guard/Reserve activities or business							
d. Time away for mobilization or deployment							

147. How similar was your civilian job to your National Guard/Reserve duty?

Does not apply, my civilian job was as a National Guard/Reserve military technician
Very dissimilar
Somewhat dissimilar
Neither similar nor dissimilar
Somewhat similar
Very similar

148. Have you ever been forced to leave college, technical training, apprenticeship training, or any other kind of educational experience because of a mobilization or deployment (voluntary or involuntary)? *Mark all that apply.*

No ⇨ **IF NO, GO TO SECTION VIII on page 20**
Yes, for involuntary duty
Yes, for voluntary duty

149. What type of educational program were you enrolled in? *Mark all that apply.*

College/university (public/state)
College/university (private)
Technical training
Apprenticeship training
Continuing professional education
None of the above

150. Were you able to . . . ? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Obtain a full refund for tuition and/or fees paid for the semester/quarter interrupted by military duty?		
b. Obtain a partial refund for tuition and/or fees paid for the semester/ quarter interrupted by military duty?		
c. Receive credit for course work completed?		
d. Re-enroll, without prejudice, in the same educational institution after performing military duty?		

151. Have you ever participated in computer-based distance learning?

No
Yes

VIII. ECONOMIC ISSUES

The questions in this section address economic issues in the lives of military members and their families. The information will be used to better understand the economic and financial concerns of military members and their families. Although people will have different views on what is or is not personal, most people will consider at least some of the questions to be personal. As with all other questions in this survey, your responses will be held in confidence.

152. Which of the following best describes the financial condition of you (and your spouse)?

- Very comfortable and secure
- Able to make ends meet without much difficulty
- Occasionally have some difficulty making ends meet
- Tough to make ends meet but keeping your head above water
- In over your head

153. Overall, how do you feel about your family income (that is, all the money that comes to you and other members of your family living with you)?

- Very dissatisfied
- Dissatisfied
- Neither satisfied nor dissatisfied
- Satisfied
- Very satisfied

154. During the past 12 months, did you (or your spouse) receive any income or financial support from the following sources? *Mark "No" or "Yes" for each item.*

	No	Yes
a. A second job		
b. Alimony		
c. Child support		
d. Supplemental Security Income (SSI)		
e. Unemployment or Workers' Compensation		
f. State-funded childcare assistance		
g. Women, Infants, and Children (WIC)		
h. Food Stamp Program		
i. Head Start Program		
j. Temporary Assistance for Needy Families (TANF)		
k. Medicaid		
l. Other public welfare or assistance		
m. Interest and dividends on savings		
n. Stocks, bonds, or other investments		
o. Pensions from federal, state, or local government employment		
p. Pensions from private employer or union		
q. Veterans benefits or pensions		
r. GI Bill		
s. Social Security or Railroad Retirement		
t. Other sources not including earnings from wages or salaries		

155. What is your total monthly gross (before tax) household income from all sources? *Please include your military earnings, your civilian earnings, your spouse's earnings, and income or financial support from any other source.*

$1-1,000	$6,001-7,000
$1,001-2,000	$7,001-8,000
$2,001-3,000	$8,001-9,000
$3,001-4,000	$9,001-10,000
$4,001-5,000	$10,001 and above
$5,001-6,000	

156. Which of the following best reflects how you use your National Guard/Reserve income? *Mark one.*

- To pay bills
- On extra things (vacations, niceties, etc.)
- Savings and/or investments

157. Do you (or your spouse) pay child support or alimony? *Mark "No" or "Yes" for each item.*

	No	Yes	Does Not Apply
a. You pay child support			
b. Your spouse pays child support			
c. You pay alimony			
d. Your spouse pays alimony			

158. In the past 12 months, did any of the following happen to you (or your spouse)? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Bounced two or more checks		
b. Received a letter of indebtedness (e.g., a letter from a lender to your commanding officer that payment is late)		
c. Had your wages garnished		
d. Fell behind in paying your rent or mortgage		
e. Fell behind in paying your credit card, AAFES, or NEXCOM account		
f. Was pressured to pay bills by stores, creditors, or bill collectors		
g. Had a bill collector contact your unit leader		
h. Pawned or sold valuables to make ends meet		
i. Borrowed money from friends or relatives to help you with a financial difficulty		
j. Borrowed money through an Emergency Loan Assistance Program or a Service Aid Society		
k. Had your utilities (telephone, cable, water, heat or electricity) shut off		
l. Had a car, household appliances, or furniture repossessed		
m. Went bankrupt (declared personal bankruptcy)		

59. What is the average monthly amount of money that you (and your spouse) pay to meet the following expenses? ***Please round off amount to the nearest dollar. For example, if your rent is $695.40 per month, enter 0695 in the boxes.***

EXPENSE	MONTHLY COST
a. Rent or mortgage	$ .00
b. Utilities (electric, gas, water, etc.)	$ .00
c. Maintenance (home, yard, etc.)	$ .00
d. Loans/leases on cars, trucks, cycles	$ .00
e. Groceries	$ .00
f. Other	$

60. What is the amount of payments that you (and your spouse) made last month to cover personal unsecured debt? ***Include all credit cards, debt consolidation loans, AAFES loans, NEXCOM loans, student loans, and other personal loans. Exclude home mortgage and car loans.***

- $0
- $1-150
- $151-300
- $301-450
- $451-600
- $601-750
- $751-900
- $901-1050
- $1051 and above

61. After the last payment was made on personal unsecured debt, what was the total amount you (and your spouse) still owed? ***Include all credit cards, debt consolidation loans, AAFES loans, NEXCOM loans, student loans, and other personal loans. Exclude home mortgage and car loans.***

- $0
- $1-1,000
- $1,001-2,500
- $2,501-5,000
- $5,001-7,500
- $7,501-10,000
- $10,001-12,500
- $12,501-15,000
- $15,001-17,500
- $17,501-20,000
- $20,001 and above

62. Roughly, what is the total amount of savings you (and your spouse) have? ***Please include funds in bank accounts, individual retirement accounts, money market accounts, certificates of deposit, savings bonds, mutual funds, stocks and/or bonds.***

- $0
- $1-1,000
- $1,001-2,500
- $2,501-5,000
- $5,001-7,500
- $7,501-10,000
- $10,001-12,500
- $12,501-15,000
- $15,001-17,500
- $17,501-20,000
- $20,001-50,000
- $50,001-100,000
- $100,001 and above

163. Do you rent or own your principal residence?

- Rent
- Own
- Neither, live in government-owned or -leased housing ⇨ **GO TO QUESTION 165**
- Neither, live with friends/relatives and pay no costs ⇨ **GO TO QUESTION 165**
- Neither, live in other accommodations ⇨ **GO TO QUESTION 165**

164. How long have you rented or owned your current residence?

- Less than one year

IX. FULL-TIME ACTIVE DUTY NATIONAL GUARD/RESERVE

165. Are you a member of a full-time active duty National Guard/Reserve program (i.e., Active Guard and Reserve (AGR), Training and Administration of the the Reserve (TAR), or Active Reserve (AR)?

- No ⇨ **IF NO, GO TO QUESTION 173**
- Yes

166. In the next year, do you plan to . . . ? ***Mark "No" or "Yes" for each item.***

	No	Yes
a. Retire		
b. Leave the National Guard/Reserve (before retiring)		
c. Transfer to an Active component		
d. Transfer to another National Guard/ Reserve component		
e. Become a drilling unit member		
f. Transfer to IMA program		
g. Transfer to Individual Ready Reserve (IRR)/Inactive National Guard (ING)		
h. Remain as an AGR/TAR/AR		

167. If you were to leave the AGR/TAR/AR program now and try to find a civilian job, how likely would you be to find a good civilian job?

- Very unlikely
- Unlikely
- Neither likely nor unlikely
- Likely
- Very likely

168. As of today, how many months have you been assigned as an AGR/TAR/AR to your present post, base or duty station? ***Please include any extensions you may have had in the total months assigned.***

- Less than one month

169. How much longer do you expect to be at your present location?

Does not apply, I don't have a specified tour length or I expect to be here indefinitely
Less than 1 month

Full months

170. In all the time you have been in the AGR/TAR/AR program, how many times did you move to a new location because of your permanent change of station (PCS)? *Do not count permanent changes of assignment.*

None ⇨ **IF NONE, GO TO QUESTION 173**

171. For your most recent PCS move, were any of the following a problem?

	Does not apply	Don't know	Very serious problem	Serious problem	Somewhat of a problem	Slight problem	Not a problem
a. Adjusting to a higher cost of living							
b. Moving and setting up a new household							
c. Temporary lodging expenses							
d. Cost of setting up a new residence (curtains, carpeting, paint, etc.)							
e. Transportation costs incurred during move							
f. Finding civilian employment for your spouse or dependents							
g. Continuing your education							
h. Continuing spouse/ dependent education							
i. Transferability of college credits							
j. Finding permanent housing							
k. Finding shopping areas, recreational facilities, etc.							
l. Children adjusting to new environment							
m. Spouse adjusting to new environment							
n. Adjusting yourself to new environment							
o. Medical care for Exceptional Family Program member							
p. Educational facilities for Exceptional Family Program member							

172. In all the time you have been in the AGR/TAR/AR program, how many times did your spouse/ dependents move to a new location because of your permanent changes of station (PCS)?

Does not apply, had no spouse/dependents when I PCS'd

X. MILITARY LIFE

173. Do you perform volunteer work for the National Guard/Reserve, another Defense/Service organization, or for a civilian organization?

No ⇨ **IF NO, GO TO QUESTION 175**
Yes

174. How many hours in an average month do you perform volunteer work for a National Guard/ Reserve, other Defense/Service, or civilian organization? *Answer for each, then go to Question 176.*

a. National Guard/Reserve

b. Other Defense or Service group

c. Civilian organization

175. What prevents you from volunteering? *Mark "No" or "Yes" for each item.*

	No	Yes
a. I do not have time		
b. I am not interested		
c. Location		
d. Times in which activities are scheduled		
e. Lack of childcare		
f. I do not have transportation		
g. I have not been asked		
h. I am physically unable		

176. How do you feel about the amount of time you spend on each activity listed below?

	Does not apply	I spend too much time	I spend about the right amount of time	I don't spend enough time
a. Your civilian job				
b. Family activities				
c. Leisure activities				
d. National Guarc/Reserve activities				
e. Community activities				

177. All things considered, how satisfied or dissatisfied are you with each feature of the National Guard/ Reserve listed below?

	Not applicable	Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
a. Basic pay						
b. Special and incentive pay						
c. Availability of recruiting/ retention bonuses						
d. Commissary privileges						
e. Exchange privileges						
f. Morale/welfare/recreation privileges						
g. Retirement pay you would get						
h. Cost of living adjustments (COLA) to retirement pay						
i. Other retirement benefits, such as medical care and use of base services						
j. Educational benefits						
k. Frequency of moves						
l. Amount of discipline						
m. Opportunity to serve your country						
n. Respect from Active component						
o. Your participation in the National Guard/Reserve						

178. How much do you agree or disagree with each of the following statements about military life?

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
a. Life in the military is what I expected it to be					
b. Military personnel in the future will have at least as good retirement benefits as I have					
c. My military pay and benefits will not keep up with inflation					

179. How satisfied are you with the following characteristics of the location where you live now? *If you live on an installation, answer for your installation. If you do not live on an installation, answer for your community.*

	Does not apply	Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
a. Climate						
b. Cost of residence						
c. Distance to workplace						
d. Distance to shopping areas						
e. Distance to recreation areas						
f. Safety of the area where you live						
g. Family's ability to handle cost of living						
h. Availability of military housing						
i. Quality of military housing						
j. Availability of civilian housing						
k. Availability of goods and services at the installation or duty station						
l. Recreational facilities						
m. Attitudes of local residents toward military families						
n. Availability of Federal employment for spouse or dependents						
o. Availability of other civilian employment for spouse or dependents						
p. Quality of school for dependents						
q. Availability of medical care for you						
r. Quality of medical care for you						
s. Availability of medical care for spouse or dependents						
t. Quality of medical care for spouse or dependents						
u. Availability of military family support programs or services						

180. Would you like to know the results of this survey? *If you are interested in being notified when a brief summary of the results is available on the Web, please print your e-mail address below. This e-mail address will be used for no other purpose than this notification.*

181. On what date did you complete this survey?

COMMENTS

182. If you have comments or concerns that you were not able to express in answering this survey, please print them in the space provided.



- PLEASE RETURN YOUR COMPLETED SURVEY IN THE BUSINESS REPLY ENVELOPE. (If you misplaced the envelope, mail the survey to DMDC, c/o Data Recognition Corp., 5900 Baker Road, Minnetonka, MN 55345-5967.)
- IF YOU ARE RETURNING THE SURVEY FROM ANOTHER COUNTRY, BE SURE TO RETURN THE BUSINESS REPLY ENVELOPE ONLY THROUGH A U.S. GOVERNMENT MAIL ROOM OR POST OFFICE.
- FOREIGN POSTAL SYSTEMS WILL NOT DELIVER BUSINESS REPLY MAIL.

THANK YOU FOR YOUR TIME AND ASSISTANCE

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Exp. 03/31/01

2000 Survey of Spouses of Reserve Component Personnel

Form S



- **Use a blue or black pen, or a pencil.**
- **Select answers you believe are most appropriate.**
- **Do not make any marks outside of the response and write-in boxes.**
- **Please PRINT where applicable.**
- **Place an "X" in the appropriate box or boxes.**

RIGHT	WRONG
X	✓ O

- **To change an answer using pen, completely black out the wrong answer and put an "X" in the correct box as shown below.**

CORRECT ANSWER	INCORRECT ANSWER
X	■

- **To change an answer using pencil, completely erase the wrong answer and put an "X" in the correct box.**

ABOUT THIS QUESTIONNAIRE

WHAT IS THE PURPOSE OF THIS SURVEY?

This survey asks about your attitudes and opinions on a wide range of personnel issues in the Reserve components such as family well being and use of family programs and services. This survey will be used to assess programs, policies, and issues affecting Reserve component members and their families. **While no decisions about you alone will be made based on this survey, survey results will influence policy discussions and may result in changes that affect Reserve component members and families.** If you don't respond, your views and the views of other spouses like you will not be considered in personnel policy reviews and changes.

WHY ME?

You have been selected scientifically to be part of a sample of people who represent members of the Reserve components. Based on your responses and the responses of others, conclusions may be drawn about the views and experiences of Reserve component spouses overall, and those of demographic subgroups. The validity of these conclusions depends, in part, on receiving enough completed surveys from individuals like you. **The survey results will not be valid if you allow someone else to fill out the survey for you.**

WILL MY SURVEY RESPONSES BE KEPT PRIVATE?

Yes. Under no circumstances will any information about identifiable individuals be released. Your responses will be combined with information from many other spouses to represent the views and experiences of groups of spouses. **Do not use any personal, unit, or place names anywhere on this survey.**

PRIVACY NOTICE

In accordance with the Privacy Act of 1974 (Public Law 93-579), this notice informs you of the purpose of the survey and how the findings will be used. Please read it carefully.

AUTHORITY: 10 United States Code, Sections 136, 1782, and 2358.

PRINCIPAL PURPOSE: Information collected in this survey will be used to assess the attitudes and perceptions of spouses of Department of Defense and Department of Transportation personnel about programs and policies. This information will help formulate policies that may be needed to improve the working environment for members and programs for families.

ROUTINE USES: Reports may be provided to the Secretaries of Defense, Transportation, and the Military Departments, and to the Joint Chiefs of Staff. Findings may be used in reports and testimony provided to Congress. Some findings may be published by the Defense Manpower Data Center (DMDC) or professional journals, or reported in manuscripts presented at conferences, symposia, and scientific meetings. In no case will the data be reported or used for identifiable individuals.

DISCLOSURE: Providing information on this survey is voluntary. There is no penalty if you choose not to respond. However maximum participation is encouraged so that the data will be complete and representative. Your survey instrument will be treated as confidential. Identifying information will be used only by persons engaged in, and for the purposes of, the survey. Only group statistics will be reported.

I. FAMILY MILITARY EXPERIENCE

1. In which National Guard/Reserve component is your spouse? ***Mark one.***

- Army National Guard
- Army Reserve
- Naval Reserve
- Marine Corps Reserve
- Air National Guard
- Air Force Reserve
- Coast Guard Reserve
- No Reserve component ⇨ **STOP HERE AND RETURN SURVEY**

2. What is your spouse's present paygrade? ***Mark one.***

E-1	E-6	W-1	O-1/O1E
E-2	E-7	W-2	O-2/O2E
E-3	E-8	W-3	O-3/O3E
E-4	E-9	W-4	O-4
E-5		W-5	O-5
			O-6 or above
			Don't know

3. Was your spouse's original decision to join the National Guard/Reserve made before or after you married?

- Before
- After

4. Have you ever (past or present) served in the U.S. Armed Forces, either on active duty or in the National Guard/Reserve?

- No, I have never served ⇨ **GO TO QUESTION 10**
- Yes, I have served/am serving

5. Are you currently in the U.S. Armed Forces?

- No, I am retired
- No, I separated and have no remaining obligation
- Yes, I am on active duty (not a member of the National Guard/Reserve)
- Yes, I am a member of the National Guard/Reserve in a full-time active duty program
- Yes, I am still in the Individual Ready Reserve (IRR) or Inactive National Guard (ING)
- Yes, I am another type of National Guard/Reserve member (e.g., in a drilling unit, Individual Mobilization Augmentee (IMA), military technician)

6. In which component are/were you? ***Mark current component, or last component if separated.*** ◆

Active Army	Army National Guard
Army Reserve	Active Navy
Naval Reserve	Active Air Force
Air National Guard	Air Force Reserve
Active Marine Corps	Marine Corps Reserve
Active Coast Guard	Coast Guard Reserve

7. What is/was your highest paygrade? ***Mark one.***

E-1	E-6	W-1	O-1/O1E
E-2	E-7	W-2	O-2/O2E
E-3	E-8	W-3	O-3/O3E
E-4	E-9	W-4	O-4
E-5		W-5	O-5
			O-6 or above

8. When you finally leave (or left) military service, how many years of service do you expect to have (or did you have)? ***Print years of service. If less than 1 year, print "00".***

9. If you previously served in the military and you are not currently serving, why did you leave the military? ***Mark the one most important reason.***

- Does not apply, still serving in the military
- Forced to separate, did not want to leave
- Did not like the specific military job assignment
- Did not like the military in general
- Better civilian job opportunity
- Left to have or raise child/family
- Health reason
- Spouse wanted me to leave
- Retired
- Family problems
- Drills/duty conflicted with civilian job
- Drills/duty conflicted with family responsibilities
- Drills/duty conflicted with school
- Drills/duty conflicted with spouse's military or civilian job
- Other
- None of the above

II. INDIVIDUAL AND FAMILY CHARACTERISTICS

10. Are you . . . ?

Male
Female

11. What age were you on your last birthday?

12. Have your parents (or guardians) served in or retired from the military (including the National Guard or Reserve)?

No
Yes

13. Are you a citizen of the United States? ***Mark one.***

Yes, born in the United States
Yes, born in Puerto Rico, Guam, the U.S. Virgin Islands, or the Northern Marianas
Yes, born abroad of American parent or parents
Yes, a U.S. citizen by naturalization
No, not a citizen of the United States

14. Are you Spanish/Hispanic/Latino? ***Mark "No" if not Spanish/Hispanic/Latino.***

No, not Spanish/Hispanic/Latino
Yes, Mexican, Mexican American, Chicano
Yes, Puerto Rican
Yes, Cuban
Yes, other Spanish/Hispanic/Latino

15. What is your race? ***Mark one or more races to indicate what you consider yourself to be.***

White
Black or African American
American Indian or Alaska Native
Asian (e.g., Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese)
Native Hawaiian or other Pacific Islander (e.g., Samoan, Guamanian or Chamorro)
Some other race ⇨ ***Please specify***

16. Do you speak English as your main language at home?

Yes
No, some other language ⇨ ***Please specify***

17. What is the highest degree or level of school that you have completed. ***Mark the one answer that describes the highest grade or degree that you have completed.***

11th grade or less
12 years of school, no diploma
High school diploma or the equivalent (e.g., GED), not from home schooling
High school diploma or the equivalent (e.g., GED), from home schooling
Some college credit, but less than 1 year
1 or more years of college, but no degree
Associate's degree (e.g., AA, AS)
Bachelor's degree (e.g., BA, AB, BS)
Master's degree (e.g., MA, MS)
Doctoral or professional degree (e.g., PhD, MD, JD, DVM)

18. What kind of civilian school are you currently enrolled in?

Not currently enrolled in civilian school
High school (home schooling)
High school (public or private)
GED completion
Vocational/trade/business or other career training school
Junior or community college (2-year)
Four-year college or university
Graduate/professional school
Other

19. Have you ever participated in computer-based distance learning?

No
Yes

20. How long does it normally take to get to the closest military installation?

10 minutes or less
11-20 minutes
21-30 minutes
31-60 minutes
More than 1 hour
Don't know

21. What is your marital status?

Married for the first time
Remarried
Separated
Divorced ⇨ **STOP HERE AND RETURN SURVEY**

22. How many years have you been married to your current spouse?

Less than one year

For Questions 23-27 "dependents" includes children and anyone else in your family, except your spouse, who has or is eligible to have a Uniformed Services identification card (military ID card) or is eligible for military health care benefits and is enrolled in the Defense Enrollment Eligibility Reporting System (DEERS).

23. Based on the definition above, do you and your spouse have a child, children, or other legal dependents?

No ⇨ **IF NO, GO TO QUESTION 39**
Yes

24. How many children or other dependents do you and your spouse have in each age group? ***Print the number of dependents you have in each age group.***

Less than 1 year old	1 year-under 2 years old	2-5 years old	6-13 years old	14-22 years old	23-64 years old	65 years old or older

25. Do any of the dependents in Question 24 live with someone other than you?

No ⇨ **IF NO, GO TO QUESTION 27**
Yes

26. With whom do these dependants live? ***Mark "No" or "Yes" for each item.***

	No	Yes
a. Spouse		
b. Ex-spouse		
c. Grandmother and/or grandfather		
d. Other relative		
e. Friend		
f. At school		
g. Other non-relative		

27. Do any of your dependents have a physical, mental, or emotional condition requiring specialized treatment or care?

No
Yes, dependent requires temporary treatment or care
Yes, dependent requires permanent treatment or care

28. Do you have children under the age of 15 who usually live with you?

No ⇨ **IF NO, GO TO QUESTION 39**
Yes

29. During the last year, who usually took care of your youngest (or only) child while you worked, looked for work, or were in school? ***Mark the one arrangement in which the child spent the most hours.***

Does not apply, I was not working, looking for work, or in school ⇨ **IF DOES NOT APPLY, GO TO QUESTION 36**
Spouse cared for child
Child's brother or sister aged 15 or over
Child's brother or sister under 15
Child's grandparent
Other relative of child
Child cares for self
Child was in school or daycare
Other non-relative of child

30. Where was your youngest or only child usually cared for under this arrangement? ***Mark one.***

Military daycare center
Nursery or preschool
Child Development Center/daycare center
Elementary or secondary school
Child's home
Licensed family daycare home
Other private home (not licensed)
None of the above

31. During a typical week in the last year, how many hours was your youngest or only child cared for under this arrangement?

32. During a typical month, how much did you pay for childcare for your youngest or only child? ***Please round off to the nearest dollar. For example, if you pay $395.40 per month, you would enter 0395 in the boxes.***

Does not apply, I spend no money on childcare arrangements for my youngest or only child.

33. How many of your dependent children use childcare?

34. What is the total amount that you spend during a typical month on childcare arrangements for all of your children? *Please round off to the nearest dollar.*

Does not apply, I spend no money on childcare arrangements.

35. Approximately how many hours per week does your spouse care for any of your children on a regular basis while you work, look for work, or are in school?

36. Do you need childcare when your spouse is gone for National Guard/Reserve activities?

No ⇨ **IF NO, GO TO QUESTION 39**
Yes

37. During which of these activities of your spouse do you need childcare? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Weekend drill		
b. Annual training/Active Duty Training		
c. Mobilization (e.g., deployment, state emergency duty, etc.)		

38. What is the total amount that you spent in the last 12 months on childcare arrangements for all of your children when your spouse was gone for National Guard/Reserve activities? *Please round off to the nearest dollar.*

Does not apply, I spent no money on childcare arrangements.

39. Do you have caregiver responsibilities for an elderly family member (such as shopping, home maintenance, transportation, checking on them by phone, finances, and arrangements for care)? *Include family who live with you or live somewhere else.*

No ⇨ **IF NO, GO TO QUESTION 43**
Yes

40. How many elderly family members do you have caregiver responsibilities for?

One
Two
Three or more

41. Do any of these elderly family members live with you?

No
Yes

42. How much care is needed by your elderly family members for whom you have caregiver responsibilities?

No care needed
Small amount of care
Moderate amount of care
Large amount of care
Very large amount of care

III. FAMILY WORK EXPERIENCE

43. Are you currently . . . ? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Working full-time in a civilian job		
b. Working part-time in a civilian job		
c. Managing or working in a family business		
d. Self-employed in your own business or profession		
e. An unpaid worker (volunteer)		
f. Unemployed and looking for job		
g. Unemployed, not looking for job, but would like employment		
h. Unemployed, not looking for job, and do not want employment		
i. In school		
j. Retired		
k. A homemaker, housewife, househusband		
l. Working multiple jobs		
m. Working temporary job(s)		

44. To what degree do you and your spouse agree on your career plans?

Strongly disagree
Disagree
Neither agree nor disagree
Agree
Strongly agree

45. To what extent does your paid job(s) conflict with your spouse's National Guard/Reserve job?

Does not apply, I do not have a paid job
⇨ **IF NO PAID JOB, GO TO QUESTION 47**
Not at all
Small extent
Moderate extent
Large extent
Very large extent

46. To what extent does your spouse's National Guard/Reserve job conflict with your current paid job(s)?

Not at all
Small extent
Moderate extent
Large extent
Very large extent

47. Did you have a paid job at any time during 1999?

No ⇨ **IF NO, GO TO QUESTION 52**
Yes

48. Which of the following best describes your civilian employer in 1999? ***Mark one.***

Federal government
State government
Local government (including public schools)
Working without pay in family business or farm
Self-employed in own business
Private sector firm with 500 or more employees
Private sector firm with 100-499 employees
Private sector firm with less than 100 employees

49. In 1999, how many hours per week did you usually work at your main civilian job?

50. Altogether in 1999, what was the total amount you earned from your civilian job or your business, before taxes and other deductions? Include commissions, tips, or bonuses. ***Please give your best estimate.***

$0	$40,001-50,000
$1-1,000	$50,001-60,000
$1,001-5,000	$60,001-70,000
$5,001-10,000	$70,001-80,000
$10,001-15,000	$80,001-90,000
$15,001-20,000	$90,001-100,000
$20,001-30,000	Over $100,000
$30,001-40,000	

51. How much did each of the following contribute to your decision to work or seek work at a paid job or business?

Very important
Somewhat important
Not important

a. Need money for basic family expenses
b. Desire for a career
c. Want extra money to use now
d. Want to save money for the future
e. Want independence
f. Enjoy working
g. Want to gain experience for future career.

52. How much of a contribution does your spouse's National Guard/Reserve income make toward each of the following items?

Major
Moderate
Minor
None

a. Meeting basic expenses
b. Extra money to use now
c. Savings for the future

53. To what extent do you and your spouse agree on his/her civilian career plans?

Strongly disagree
Disagree
Neither agree nor disagree
Agree
Strongly agree

54. To what extent do you and your spouse agree on his/her military career plans?

Strongly disagree
Disagree
Neither agree nor disagree
Agree
Strongly agree

55. In 1999, did your spouse have a civilian job?

No
Yes

56. Which of the following best describes your spouse's current military status?

A member of the National Guard/Reserve in a full-time active duty program
A member of the IRR or ING
Other type of National Guard/Reserve member (e.g., drilling unit, IMA, military technician)

57. Is your spouse currently . . . ? ***Mark "No" or "Yes" for each item.***

	No	Yes
a. Working full-time in a Federal civilian job		
b. Working part-time in a Federal civilian job		
c. Working full-time in a civilian job (not Federal)		
d. Working part-time in a civilian job (not Federal)		
e. Managing or working in family business		
f. Self-employed in own business or profession		
g. An unpaid worker (volunteer)		
h. Unemployed and looking for job		
i. Unemployed, not looking for job, but would like employment		
j. Unemployed, not looking for job, and do not want employment		
k. In school		
l. Retired		
m. A homemaker, housewife, househusband		
n. Working multiple jobs		
o. Working temporary job(s)		

IV. NATIONAL GUARD/RESERVE PROGRAMS

58. National Guard/Reserve units or centers have programs or activities for family members. For each program/activity listed, mark in column A whether the program/activity was available during the last 12 months. If it was available to you, mark in column B whether you attended or participated in it.

	A. Was it available?			B. Did you attend/participate?			
	Don't know	No	Yes	No	Yes, once	Yes, twice or more	Don't recall
a. Meetings for families of new members							
b. Family oriented social events, dinners, athletic programs, bake sales, etc.							
c. Family oriented information programs about the National Guard/Reserve							
d. Meetings about mobilization							
e. Meetings about National Guard/Reserve medical benefits							
f. Meetings about National Guard/Reserve retirement benefits							
g. Family support group meetings							

59. During the past 12 months, how often did you and/or your family members use the following military on-installation programs, facilities, or services and civilian off-installation programs, facilities, or services? ***For each item, mark one response in column A and one response in column B.***

	A. Military On-Installation Program, Facility, or Service	B. Civilian Off-Installation Program, Facility, or Service
	12+ times	12+ times
	6-11 times	6-11 times
	3-5 times	3-5 times
	1-2 times	1-2 times
	0 times	0 times
	Not available	Not available
a. Auto, crafts, hobby shops		
b. Bank or credit union		
c. Bowling center or movie theater		
d. Commissary, supermarket, grocery store		
e. Clubs/dance/night clubs		
f. Fitness center/gym		
g. Golf course		
h. Library services		
i. Main exchange/department store		
j. Outdoor recreation areas (campgrounds, picnic areas, beach, stables, etc.)		
k. Outdoor recreation equipment rental		
l. Post office		
m. Recreation center (recreation room, music/TV, game room/amusement machines, etc.)		
n. Recreation lodging/hotels/resorts		
o. Shoppette/mini-mart		
p. Class VI/package store/liquor store		

60. During the past 12 months, have you used any of the following programs and services? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Adult continuing education/counseling		
b. Tuition assistance programs for college/higher education		
c. Technical/vocational programs		
d. Basic skills education		

61. Are you ever eligible to use commissaries and exchanges on military installations?

- No ⇨ **IF NO, GO TO QUESTION 71**
- Yes
- Don't know

62. How much do the following limit your use of the commissary or exchange? *Mark one answer for each row.*

	Completely	Very much	Somewhat	Very little	Not at all
Commissary					
a. Prices					
b. Stock					
c. Hours					
d. Distance					
e. The law does not allow more frequent use					
Exchange					
a. Prices					
b. Stock					
c. Hours					
d. Distance					

63. Overall, to what extent do you think you or your family save by using the commissary instead of civilian grocery stores?

- Does not apply, do not use commissary
- Not at all
- Small extent
- Moderate extent
- Large extent
- Very large extent

64. Do you currently use the *EXCHANGE* closest to you?

- No, I don't use an exchange
- No, I use an exchange, but it's not the closest
- Yes, I use the exchange closest to me

65. How long does/would it normally take to get to the exchange closest to you?

- 10 minutes or less
- 11-20 minutes
- 21-30 minutes
- 31-60 minutes
- More than 1 hour
- Don't know

66. Please rate the selection of merchandise at the exchange closest to you.

- Very poor
- Poor
- Average
- Good
- Excellent
- Don't know

67. Please rate the prices at the exchange closest to you compared with prices at other stores in town.

- Very poor
- Poor
- Average
- Good
- Excellent
- Don't know

68. At which Service's exchange do you shop most often?

- Does not apply, I do not shop at an exchange
- Army and Air Force Exchange Service (AAFES), Post Exchange (PX) or Base Exchange (BX)
- Navy Exchange
- Marine Corps Exchange

69. What average savings, not considering sales tax, are available at the exchange?

- I believe I pay more at the exchange
- No savings
- 5% savings or less
- 6-10% savings
- 11-20% savings
- More than 20% savings
- Don't know

70. Are your and your spouse's shopping privileges limited at exchanges?

- No
- Yes
- Don't know

71. Can an exchange's merchandise be ordered on the Internet?

- No
- Yes
- Don't know

72. Have you ever used a personal computer (PC)?

No ⇨ **IF NO, GO TO QUESTION 76**
Yes

73. Where during the last 12 months have you regularly used a PC? ***Mark "No" or "Yes" for each item.***

	No	Yes
a. Home/residence		
b. Civilian work/office		
c. Guard/Reserve duty station or Armory		
d. Installation/ship library		
e. Installation/ship recreation center		
f. Installation/ship education center		
g. Installation/ship family center		
h. Other military location		
i. Other non-military location (for example, public library)		

74. Do you have access to the internet/World Wide Web?

No ⇨ **IF NO, GO TO QUESTION 76**
Yes

75. From which location do you most frequently access the Internet/World Wide Web? ***Mark one.***

Home/residence
Civilian work/office
Guard/Reserve duty station or Armory
Installation/ship library
Installation/ship recreation center
Installation/ship education center
Installation/ship family center
Other military location
Other non-military location (for example, public library)

76. Do you have any medical/hospitalization coverage(s)?

No ⇨ **IF NO, GO TO QUESTION 79**
Yes

77. Do you have the following medical/hospitalization coverage(s)? ***Mark "No" or "Yes" for each item.***

	No	Yes
a. Your civilian employer's healthcare plan		
b. Your school's healthcare plan		
c. Your spouse/family member's civilian employer's health plan		
d. Your active duty/retired military healthcare coverage		
e. Your spouse/family member's active duty military healthcare coverage		
f. Veterans' (VA) coverage		
g. Other private coverage		

78. How satisfied or dissatisfied are you with the coverage provided by your medical insurance?

Very dissatisfied
Dissatisfied
Neither satisfied nor dissatisfied
Satisfied
Very satisfied

79. Do you have any dental coverage(s)?

No ⇨ **IF NO, GO TO QUESTION 82**
Yes

80. Which of the following dental coverage(s) do you have? ***Mark "No" or "Yes" for each item.***

	No	Yes
a. Your civilian employer's dental plan		
b. Your spouse/family member's civilian employer's dental plan		
c. Your active duty military coverage		
d. Your spouse/family member's active duty military coverage (military dental clinic, TRICARE Family Member Dental Plan)		
e. Veteran (VA) coverage		
f. Other private coverage		

81. How satisfied are you with the coverage provided by the dental insurance that you have?

Very dissatisfied
Dissatisfied
Neither satisfied nor dissatisfied
Satisfied
Very satisfied

82. Do you perform volunteer work for the National Guard/Reserve, another Defense/Service organization, or for a civilian organization?

No ⇨ **IF NO, GO TO QUESTION 84**
Yes

83. How many hours in an average month do you perform volunteer work for a National Guard/Reserve, other Defense/Service, or civilian organization? ***Answer for each, then go to Question 85.***

a. National Guard/Reserve

b. Other Defense/Service group

c. Civilian organization

84. What prevents you from volunteering? ***Mark "No" or "Yes" for each item.***

	No	Yes
a. I do not have time		
b. I am not interested		
c. Location		
d. Times in which activities are scheduled		
e. Lack of childcare		
f. I do not have transportation		
g. I have not been asked		
h. I am physically unable		

85. Does your local Armory or Reserve unit/center have a family support group (or something similar to a family support group)?

No
Yes, but not very active
Yes, an active family support group
Not sure

86. The National Guard/Reserve components are developing new information materials. Below is a list of topics that might be included. How interested would you be in receiving such materials?

	Very interested	Somewhat interested	Neither interested nor uninterested	Uninterested	Very uninterested
a. National Guard/Reserve organization					
b. The mission of your spouse's unit					
c. The unit's role in mobilization					
d. Educational benefits for Reservists					
e. Medical benefits for deployed members/dependents					
f. Retirement benefits for Reservists					
g. Survivor benefits for Reservists					
h. Leave and earnings statements					
i. Advance schedules for drills and Annual Training/ACDUTRA					
j. Family's role in the event of mobilization					
k. Family support groups					
l. Family counseling					
m. Family care plans					
n. Defense Enrollment Eligibility Reporting System (DEERS)					
o. Dealing with family separations due to mobilization/deployment					
p. Dealing with family reunions after mobilization/deployment					
q. Soldiers and Sailors Civil Relief Act					
r. Uniform Services & Employment Reemployment Rights Act (USERRA)					
s. National Committee for Employer Support of National Guard & Reserve					

87. How do you feel about the amount of time your spouse spends on each activity listed below?

	Does not apply	Spends too much time	Spends the right amount of time	Doesn't spend enough time
a. Civilian job				
b. Family activities				
c. Leisure activities				
d. Community activities				
e. Duty at Armory/Reserve Center				
f. National Guard/Reserve Annual Training				
g. National Guard/Reserve mobilizations or deployments				
h. National Guard/Reserve domestic emergencies				

88. How much of a problem for your family is each of the following aspects of your spouse's National Guard/Reserve duty?

	Not applicable	A very serious problem	A serious problem	Somewhat of a problem	A slight problem	Not a problem
a. Time away for weekend drills						
b. Time away for Annual Training/ ACDUTRA						
c. Extra time spent at National Guard/Reserve						
d. Time away from spouse's civilian job due to National Guard/Reserve						
e. Effects of National Guard/ Reserve duty on spouse's pay and promotion opportunities in civilian job						
f. Time away from children due to National Guard/Reserve duty						
g. Time away from you due to National Guard/Reserve duty						
h. Drills on special days (e.g., Mothers' Day, Easter)						
i. Unscheduled National Guard/ Reserve activities						
j. Scheduling family vacations						
k. Using vacation time for National Guard/Reserve duty						
l. Absence for domestic emergencies (floods, storms, etc.)						
m. Absence for mobilization/ deployment (Operation Desert Storm, Haiti, Bosnia, etc.)						

89. Has your spouse ever been mobilized or deployed as a member of the National Guard/Reserve?

No ⇨ **IF NO, GO TO QUESTION 104**
Yes

90. Was your spouse mobilized/deployed as a Reservist for the operations listed below? *Mark "No" or "Yes" for each item. If you mark "Yes" in column A, please indicate whether it was voluntary or involuntary, the deployment's location, and its length. If you mark "No" in column A, go to the next item in column A.*

	A. Was your spouse mobilized or deployed as a member of the National Guard/Reserve for the operations (a-k) listed below?		B. Was his/her mobilization voluntary or involuntary?		C. Where did he/she deploy? (Mark one)				D. How long was he/she mobilized or deployed? Write in number of months. If under 1 month, enter "00". If mobilized/deployed now, write number of months so far.
	No	Yes	Voluntary	Involuntary	Does not apply, did not deploy	In own state or equivalent (e.g., DC, GU, PR, VI)	To another state or equivalent (e.g., DC, GU, PR, VI)	Outside US	
a. Operation Desert Shield/Storm									
b. Saudi Arabia (Aug 92-present)									
c. Centam, Hurricane Mitch Recovery/Rehab									
d. Operation Restore/Uphold Democracy (Haiti)									
e. Operation Desert Fox/Iraqi Crisis (SW Asia)									
f. Operation Joint Forge/Guard/ Endeavor (Bosnia)									
g. Operation Restore/Continue Hope (Somalia)									
h. Operation Joint Task Force (Cuba)									
i. Operation Allied Force (Kosovo)									
j. Other mobilization or deployment (1) ***Describe:***									
k. Other mobilization or deployment (2) ***Describe:***									

91. Is your spouse mobilized/deployed now? ***If yes, indicate the operation in Question 90 for which your spouse is deployed.***

No Yes ⇨

IF YES, MARK ONE ⇨

a	d	g	j
b	e	h	k
c	f	i	

If your spouse is currently mobilized/deployed, answer Questions 92 to 102 about his/her current mobilization/deployment.

If your spouse is not currently mobilized/deployed, answer Question 92 to 102 about his/her most recent mobilization/deployment.

92. Did you need family support services during your spouse's most recent mobilization or deployment?

No ⇨ **IF NO, GO TO QUESTION 94**
Yes

93. Were you able to access family support services from/through the military?

No
Yes

94. What health insurance options did you choose the last time your spouse was mobilized or deployed? *Mark "No" or "Yes" for each item.*

	No	Yes
a. I chose TRICARE as my primary health insurance		
b. I kept my private/civilian health insurance		
c. I dropped my private/civilian health insurance		
d. I used TRICARE as a second payer to my primary health insurance		
e. I did not have any health insurance before mobilization/deployment		
f. Other ⇨		

If you marked "Yes" please specify ⇨

95. Did you file a TRICARE/CHAMPUS medical claim during your spouse's most recent mobilization or deployment?

No ⇨ **IF NO, GO TO QUESTION 99**
Yes

96. Did you need assistance to help you file medical claims during your spouse's most recent mobilization or deployment?

No ⇨ **IF NO, GO TO QUESTION 98**
Yes

97. What level of assistance was available to help you file medical claims?

None
Low
Moderate
High
Very high

98. How satisfied were you with the medical claims processing service you received?

Very dissatisfied
Dissatisfied
Neither satisfied nor dissatisfied
Satisfied
Very satisfied

99. How supportive of families were the following at your location during your spouse's most recent mobilization or deployment?

	Not applicable	Very supportive	Supportive	Neutral	Unsupportive	Very unsupportive
a. Officers in high positions at nearby military installation						
b. Personnel at nearby Reserve Center/Armory/Activity						
c. Officers in my spouse's unit						
d. Noncommissioned officers/petty officers in my spouse's unit						
e. Family Service/Support Centers						
f. Command representative (e.g., ombudsman)						
g. Civilian community						
h. Other National Guard/Reserve spouses						
i. Friends						
j. Your spouse's civilian employer						
k. Your civilian employer						

100. Did the following changes in expenses occur as a result of your spouse's most recent mobilization or deployment? ***Mark "No" or Yes" for each item.***

	No	Yes
a. Medical expenses increased		
b. Medical expenses decreased		
c. Telephone expenses increased		
d. Household maintenance and car repairs increased		
e. Household maintenance and car repairs decreased		
f. Childcare increased		
g. Mortgage payments declined		

101. Were there any changes in income for you or your family during your spouse's most recent mobilization or deployment? ***Mark "No" or Yes" for each item.***

	No	Yes
a. Increase in spouse's earnings		
b. Increase in my earnings since I worked more hours or took a second job		
c. Reduction in spouse's earnings		
d. Reduction in my earnings since I was unable to work as much		
e. Delays in getting military pay		
f. Income from business or practice declined		
g. Other increase		
h. Other decrease		

102. Please estimate your and your spouse's <u>total income change</u> from all sources as a result of your spouse's most recent mobilization or deployment. ***If you and your spouse have continuing losses from a business or practice, include those in your estimate.***

Increased $5,000 or more
Increased $2,500-4,999
Increased $1-2,499
No change in income
Decreased $1-2,499
Decreased $2,500-4,999
Decreased $5,000-9,999
Decreased $10,000-24,999
Decreased $25,000-49,999
Decreased $50,000 or more

103. How many times has your spouse been mobilized or deployed since 1992? ***If none, print "00".***

104. How many nights did your spouse spend away from your home on official military duties in 1999? ***Do not include nights spent away from home before out-of-town drills.***

None

V. FAMILY ISSUES

105. Which of these community/civilian social services have you or your family used during the past 12 months? *Mark "Not used" or Used/using" for each item.*

	Not used	Used/ using
a. Individual counseling/therapy		
b. Pre-marital programs		
c. Marriage or family counseling/ therapy/enrichment		
d. Programs for families with disabled members		
e. New parent classes		
f. Childcare services		
g. Youth/teen programs		
h. Eldercare		
i. Alcohol/drug abuse programs		
j. Employment services		
k. Spouse/child abuse services		
l. Rape counseling services		
m. Crisis referral services		
n. Chaplain services/religious programs		
o. Legal assistance		
p. Financial counseling/management education		
q. Recreational programs		

106. How do you feel about the amount of time you spend on each activity listed below?

	Does not apply	I spend too much time	I spend about the right amount of time	I don't spend enough time
a. Your civilian job				
b. Family activities				
c. Leisure activities				
d. Community activities				
e. National Guard/Reserve activities				

107. How unlikely or likely do you think it is that your spouse will be mobilized or deployed in the next 5 years?

- Very unlikely
- Unlikely
- Neither likely nor unlikely
- Likely
- Very likely

108. Which of the following would your spouse have to take care of before being mobilized or deployed? *Mark "No" or "Yes" for each item.*

	No	Yes
a. Dependent care problems		
b. His/her personal health problems		
c. Family health problems		
d. Preparation of emergency data (will, power of attorney, etc.)		
e. Financial arrangements		
f. Transportation arrangements		
g. Civilian job-related arrangements		
h. School-related arrangements		
i. Vehicle or household maintenance		

109. If your spouse were mobilized/deployed for more than 30 days, how likely are you and your family to make use of the following military services?

	Not available	Very likely	Likely	Neither likely nor unlikely	Unlikely	Very unlikely
a. Individual counseling/therapy						
b. Marriage or family counseling/ therapy/enrichment						
c. Family support centers						
d. Programs for families with disabled members						
e. Services for families during separation						
f. New parent classes						
g. Childcare services						
h. Youth/teen programs						
i. Eldercare						
j. Alcohol/drug abuse programs						
k. Spouse employment services						
l. Spouse/child abuse services						
m. Crisis referral services						
n. Chaplain services/religious activities						
o. Legal assistance						
p. Financial counseling/ management education						
q. Recreational programs						
r. Educational Services Center						

110. The questions below are about your family preparedness. *Mark one answer for each item.*

	Don't know	Yes	No
a. Are you currently enrolled or pre-enrolled in the Defense Enrollment Eligibility Reporting System (DEERS)?			
b. Does your spouse have a current written will?			
c. Does anyone currently hold your spouse's power-of-attorney?			
d. Does your spouse have life insurance other than Servicemen's Group Life Insurance (SGLI) or Veterans' Group Life Insurance (VGLI)?			
e. Has your spouse ever filled out a record of emergency data?			
f. Has your spouse verified/updated his/her record of emergency data in the past 12 months?			
g. Do you know where to find important papers (e.g., will, car registration, checkbook, bank statements)?			

111. People participate in the National Guard/Reserve for many reasons. In your opinion, how much have each of the following contributed to your spouse's decision to stay in the National Guard/Reserve?

	Very great influence	Great influence	Some influence	Little influence	Not at all
a. Serving the country					
b. Using educational benefits					
c. Obtaining training in a skill that would help get a civilian job					
d. Serving with the people in the unit					
e. Getting credit toward National Guard/Reserve retirement					
f. Promotion opportunities					
g. Opportunity to use military equipment					
h. Challenge of military training					
i. Needing the money for basic family expenses					
j. Wanting extra money to use now					
k. Saving income for the future					
l. Travel/"get away" opportunities					
m. Just enjoying the National Guard/Reserve					
n. Pride in accomplishments in the National Guard/Reserve					

112. All things considered, how satisfied are you with each feature of the National Guard/Reserve listed below? ◆

	Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
a. Military pay and allowances					
b. Commissary privileges					
c. Exchange privileges					
d. Morale/welfare/recreation privileges					
e. Time required at National Guard/Reserve activities					
f. Military retirement pay and benefits					
g. Unit social activities					
h. Acquaintances/friendships					
i. Member educational benefits					

113. What is your overall attitude toward your spouse's participation in the National Guard/Reserve?

Very unfavorable
Somewhat unfavorable
Neither favorable nor unfavorable
Somewhat favorable
Very favorable

114. In your opinion, how do the following groups/individuals view your spouse's participation in the National Guard/Reserve?

	Does not apply	Very favorably	Somewhat favorably	Neither favorably nor unfavorably	Somewhat unfavorably	Very unfavorably
a. Your personal friends						
b. Your children						
c. Your relatives						
d. Your spouse's relatives						
e. Your neighbors						
f. Your spouse's civilian supervisor						
g. Your spouse's civilian co-workers						
h. Your spouse's National Guard/Reserve unit members						

♦ 115. Would you like to know the results of this survey? *If you are interested in being notified when a brief summary of the results is available on the Web, please print your e-mail address below. This e-mail address will be used for no other purpose than this notification.*

116. On what date did you complete this survey?

COMMENTS

117. If you have comments or concerns that you were not able to express in answering this survey, please print them in the space provided.



- PLEASE RETURN YOUR COMPLETED SURVEY IN THE BUSINESS REPLY ENVELOPE. (If you misplaced the envelope, mail the survey to DMDC, c/o Data Recognition Corp., 5900 Baker Road, Minnetonka, MN 55345-5967.)
- IF YOU ARE RETURNING THE SURVEY FROM ANOTHER COUNTRY, BE SURE TO RETURN THE BUSINESS REPLY ENVELOPE ONLY THROUGH A U.S. GOVERNMENT MAIL ROOM OR POST OFFICE.
- FOREIGN POSTAL SYSTEMS WILL NOT DELIVER BUSINESS REPLY MAIL.

THANK YOU FOR YOUR TIME AND ASSISTANCE

Data Recognition Corp. 3G00585-2703-54321

United States House of Representatives

Committee on Government Reform

Chairman: The Honorable Dan Burton

Statement by Mr. Dennis L. Schornack Accompanying the Submission of Documents Concerning the Sale of the Michigan Biologic Products Institute to BioPort Corporation

November 3, 2000

My name is Dennis L. Schornack. I was the Chair of the Michigan Biologic Products Commission (the "Commission"), duly appointed by the Governor of Michigan and charged by state law with the duty to sell the state asset known as the Michigan Biologic Products Institute ("MBPI"). Today, I am submitting to the Committee on Government Reform a series of official state documents concerning the sale of MBPI to BioPort Corporation, which sale was concluded on September 4, 1998.

The process of selling MBPI commenced in earnest, in mid-February of 1996 with the effective date of Executive Order 95-25. The Commission followed a linear and logical process beginning with an independent determination of MBPI's fair market value using the "income approach" to valuation. Analyses showed that MBPI lost up to $6 million per year for the 4 years prior to the decision to sell the lab (1993-96). Engineering studies and independent analyses of MBPI's aging physical plant indicated the need to invest approximately $40 million in order to continue operations in compliance with good manufacturing practices as required by the U.S. Food and Drug Administration, MBPI's chief regulator.

MBPI was the last remaining state-government owned and operated manufacturing facility for biologic products including vaccines and blood derivatives. The decision to sell MBPI was made for several reasons including its lack of a legitimate state purpose, its drain on the state budget, and its need for large capital investments. Ordinarily, the agency would have been closed and its approximately 200 employees either transferred or severed from state government service. However, because MBPI was the sole manufacturer of anthrax vaccine adsorbed for the United States military, the Administration felt duty bound to provide for the continuation of the agency as a private sector company. Selling the asset allowed for the continued supply of a product viewed as important to defend American soldiers against the increasing risk of bio-warfare.

The legislation authorizing the sale of MBPI was passed with strong bipartisan support. With the exception of a single legislative critic, the Commission enjoyed strong bipartisan support and cooperation throughout the sale process, and the Commission welcomed the oversight of several independent bodies.

The sale of MBPI was the most highly scrutinized transaction in the history of Michigan state government. The transaction was reviewed by the state House and Senate Fiscal Agencies, the Legislative Auditor General, and the Office of the Attorney General. The transaction withstood legal challenges and the scrutiny of an independent fairness opinion. Ultimately, the sale was approved by the State Administrative Board, a body consisting of Michigan's highest elected and appointed officials including the Governor, Lieutenant Governor, Attorney General, Secretary of State, Treasurer, and the Superintendent of Public Instruction.



The highly visible and public nature of the sale process, coupled with the oversight of the Michigan Legislature and independently contracted financial experts assured a clean, if not expeditious, process. I am pleased that the intense scrutiny of so many parties found not a single impropriety throughout the entire transaction.

I am submitting the attached copies of official state documents concerning the sale of MBPI to BioPort Corporation so that the Committee can deal with facts, not falsehoods. I trust the Committee will agree that the sale process is a closed matter. Thank you.

DLS/jlf

Attachments

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Chronology of Significant Events During MBPI Sale

• February, 1996 -- E.O. 95-25 effective; establishes MBPI as two-year temporary agency destined for sale; establishes Commission and directs it to prepare plan and legislation to authorize MBPI sale and to conduct a preliminary valuation.

• July, 1996 -- Connaught's acellular pertussis vaccine licensed; DTaP renders MBPI's whole-cell vaccine obsolete.

• July-October, 1996 -- KPMG Peat Marwick develops financial proforma and preliminary valuation of MBPI for Commission; Commission prepares legislation and plan for Legislature.

• November/December, 1996 -- MBPI sale legislation passed with strong bipartisan majorities; U.S. FDA conducts intense inspection of MBPI.

• March, 1997 -- U.S. FDA issues Notice of Intent to Revoke (NOIR) license letter to MBPI.

• April, 1997 -- MBPI presents Strategic Plan for Compliance to U.S. FDA and commences Institute-wide measures to comply with U.S. FDA regulations; Commission engages W.Y. Campbell & Co. as its selling agent; State Administrative Board engages First of Michigan Corp. for fairness opinion.

• June, 1997 -- E.O. 1997-8 effective; transfers security and warehouse functions from DMB and DCH to MBPI consistent with Strategic Plan for Compliance; MBPI budget passed, provides 6 months of appropriations for FY 98. Governor's retirement plan takes effect.

• July, 1997 -- MBPI declared for sale; Wall Street Journal ad runs, direct marketing begins. MBPI's blood plasma supply contract with American Red Cross regions ends. U.S. DoD approves funds for implementing Strategic Plan for Compliance.

• August-October, 1997 -- Firms interested in acquiring MBPI conduct due diligence including site visits, document reviews, and employee interviews. Direct General Fund subsidies for MBPI end; DMB maintenance of MBPI ends. New plasma supply contract with Southern Biologics, Inc., signed; supplies < 50% of MBPI capacity.

• November, 1997 -- Bidding field narrows to 3 firms; employee bid rejected by Commission. MBPI team loses U.S. DoD JVAP contract to DynPort. International tensions arise over UN inspections of Iraq; weaponized anthrax is focus.

• December, 1997 -- Bidding field narrowed to 1 firm; Secretary of Defense Cohen announces anthrax vaccination policy; Middle East Tensions escalate. State and SmithKline Beecham agree to terminate contracts.

• January, 1998 -- Commission re-opens bidding; General Doesburg and Commission brief Legislature and request continuation of appropriations for MBPI through end of FY 98; anthrax vaccine production facilities closed for renovation.

• February, 1998 -- Governor signs PA 8 of 1998 extending MBPI through end of FY 98; U.S. FDA arrives for post-NOIR inspection of MBPI; Iraq tensions ease. Larry Harris arrested in Las Vegas with what appears to be anthrax.

• February-May, 1998 -- Interested bidders conduct detailed due diligence.

• March, 1998 -- U.S. DoD steps up implementation of anthrax vaccination policy; Commission begins to receive new bids; U.S. DoD congratulates MBPI workers on a job well done in supplying anthrax vaccine.

• April, 1998 -- U.S. FDA issues letter commending MBPI on implementation of Strategic Plan for Compliance, but noting need for more work.

• May, 1998 -- Commission asks bidders to conclude due diligence and submit firm offers in form desired by state (Asset Purchase Agreement); President Clinton announces plans to stockpile vaccines and antibiotics for civilian use.

• June, 1998 -- Commission conducts auction process with bidders; recommends BioPort to State Administrative Board; sends APA to First of Michigan for fairness opinion. Fourteen MBPI employees retire under Governor's plan.

• July, 1998 -- State Administrative Board receives fairness opinion; prepares to approve sale transaction between state and BioPort. Closing to follow.

STATE OF MICHIGAN
OFFICE OF THE GOVERNOR

JOHN ENGLER
GOVERNOR

EXECUTIVE ORDER
1995 - 25

MICHIGAN DEPARTMENT OF PUBLIC HEALTH
BIOLOGIC PRODUCTS DIVISION
MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

EXECUTIVE REORGANIZATION

WHEREAS, Article V, Section 2, of the Constitution of the State of Michigan of 1963 empowers the Governor to make changes in the organization of the Executive Branch or in the assignment of functions among its units which he considers necessary for efficient administration; and

WHEREAS, Article V, Section 4, of the Constitution of the State of Michigan of 1963 authorizes the establishment of temporary commissions or agencies for special purposes with a life of no more than two years and provides that such temporary commissions or agencies need not be allocated within a principal department; and

WHEREAS, Section 9111 of Act No. 368 of the Public Acts of 1978, being Section 333.9111 of the Michigan Compiled Laws, authorized establishment of the Biologic Products Division within the Michigan Department of Public Health; and

WHEREAS, Act No. 204 of the Public Acts of 1986, being Section 333.9112 of the Michigan Compiled Laws created the Pharmaceutical Products Fund in the state treasury and made the Michigan Department of Public Health responsible for administering it; and

WHEREAS, the functions, duties and responsibilities assigned to the Biologic Products Division can be more effectively administered and executed outside the Michigan Department of Public Health, due in part to the need of the Biologic Products Division to meet Federal regulatory and commercial requirements; and

WHEREAS, the long-term capability of the Biologic Products Division to meet Federal regulatory and other commercial requirements can best be achieved by removing the Division from state government as soon as is practicable; and

WHEREAS, the manufacture of products by the Biologic Products Division is not critical to the mission of the Michigan Department of Public Health.

NOW, THEREFORE, I, John Engler, Governor of the State of Michigan, pursuant to the powers vested in me by the Constitution of the State of Michigan of 1963 and the laws of the State of Michigan, do hereby order the following:

I. ESTABLISHMENT OF THE MICHIGAN BIOLOGIC PRODUCTS INSTITUTE AND THE MICHIGAN BIOLOGIC PRODUCTS COMMISSION

A. Definitions:

In this Executive Order the following definitions shall apply.

1. "Commission" means the Michigan Biologic Products Commission established as a temporary commission by this Executive Order.

2. "Director" means the person initially designated by the Governor as the Director of the Michigan Biologic Products Institute established as a temporary agency by this Executive Order.

3. "Institute" means the Michigan Biologic Products Institute established as a temporary agency by this Executive Order.

4. "Member" means a member appointed by the Governor to the Michigan Biologic Products Commission established as a temporary commission by this Executive Order.

B. Establishment of the Michigan Biologic Products Institute

1. The Michigan Biologic Products Institute is established by this Executive Order, pursuant to Article V, Section 4, of the Constitution of the State of Michigan of 1963, as a temporary agency with a life of no more than two years from the effective date of this Executive Order.

2. The Institute shall be an independent and autonomous entity with the intent that its authority, powers, duties and responsibilities and the authority, powers, duties and responsibilities of the Director, including personnel, budgeting, procurement and management-related functions, be exercised free from the direction and supervision of the principal departments in the Executive Branch.

3. The Director shall be the head of the Institute within the meaning of the Constitution of the State of Michigan of 1963, and of the Executive Organization Act of 1965, Act No. 380 of the Public Acts of 1965, being Section 16.101 et seq. of the Michigan Compiled Laws, and shall be the Appointing Authority as that term is used in the Constitution of the State of Michigan of 1963, and in the rules and procedures of the Civil Service Commission.

4. The Biologic Products Division of the Michigan Department of Public Health and the Pharmaceutical Products Fund, established under Sections 9111 and 9112 of Act No. 368 of the Public Acts of 1978, being Section 333.9111 and 333.9112 of the Michigan Compiled Laws are hereby transferred to the Michigan Biologic Products Institute by a Type III transfer, as defined by Section 3 of Public Act No. 380 of the Public Acts of 1965, being Section 16.103 of the Michigan Compiled Laws. The Michigan Biologic Products Institute shall assume all functions, duties, contractual obligations, responsibilities, inventory, tangible and intangible property and employees of the Biologic Products Division of the Michigan Department of Public Health, including administration of the Pharmaceutical Products Fund.

C. Establishment of the Michigan Biologic Products Commission

1. The Michigan Biologic Products Commission is established by this Executive Order, pursuant to Article V, Section 4, of the Constitution of the State of Michigan of 1963, to serve as a temporary entity with a life of no more than two years from the effective date of this Executive Order.

2. The Commission shall have three (3) voting members who shall be appointed by the Governor and such members shall serve as members at the pleasure of the Governor. None of these members shall be employees of the Institute. The Governor shall designate one (1) member of the Commission to serve as its chair and that member shall serve as chair at the pleasure of the Governor.

3. Members of the Commission shall serve without compensation for their membership on the Commission. Members of the Commission may receive reimbursement for necessary travel and expenses according to relevant procedures of the Civil Service Commission and the Department of Management and Budget.

4. The Commission may promulgate bylaws, not inconsistent with law and with this Executive Order, governing its organization and procedure. A majority of the serving voting members constitutes a quorum for the transaction of business at a meeting, notwithstanding the existence of one (1) or more vacancies. Voting upon actions taken by the Commission shall be conducted by a majority vote of the members present in person at a meeting of the Commission or present by use of amplified telephonic equipment.

5. The Commission shall meet at the call of the chair and as may be provided in the bylaws of the Commission. Meetings of the Commission may be held anywhere within the State of Michigan. The Commission shall be subject to the Open Meetings Act, Act No. 267 of the Public Acts of 1976, being Section 15.261 et seq. of the Michigan Compiled Laws. The Commission may, as appropriate, make inquiries, studies and investigations, hold hearings and receive comments from the public.

II. DUTIES AND RESPONSIBILITIES OF THE MICHIGAN BIOLOGIC PRODUCTS COMMISSION

The Commission shall provide supervision, policy control and direction to the Institute, and the Director. The Commission may, consistent with the provisions of this Executive Order, establish general goals and objectives relating to the operation and development of the Michigan Biologic Products Institute for the guidance of the Director.

The Michigan Biologic Products Commission shall:

1. Within eight (8) months of their initial organizational meeting, prepare, or cause to be prepared under contract, a detailed business plan with supporting documentation, including, but not limited to, any necessary legislation, describing the means by which the Michigan Biologic Products Institute will be transferred out of state government and into the private sector within the two year term of its temporary agency status under this Executive Order.

2. As part of the business plan, cause the fair market value of all state property, inventory, equipment and other assets associated with the manufacture of biologic products to be determined.

3. Contract with the initial Director; designate and contract with any future Directors.

4. Perform such other duties and responsibilities as may be assigned or transferred to the Commission by statute or by executive order.

III. OPERATIONS OF THE INSTITUTE

The current Responsible Head of biologic products manufacturing under licenses granted by the Food and Drug Administration is hereby designated to serve as the initial Director of the Institute. The Director shall report to and be directly responsible to the Commission. The Director

shall, in addition to the other duties and responsibilities given to the Director herein or assigned or transferred to the Director as head of the Institute by statute or executive order, be responsible for the oversight and supervision of employees of the Institute, for administration of the Pharmaceutical Products Fund, for management of the Institute's facilities and for the operations of the Institute. The Director shall also perform such other duties and exercise other powers as the Commission may prescribe.

The Director may appoint or contract with such other deputies, assistants and employees as are necessary.

The Director shall receive reasonable compensation. Such compensation shall be established according to relevant procedures of the Civil Service Commission.

The Director shall:

1. Maintain the establishment license of the facilities for biologic product production and maintain existing product licenses, except for obsolete products, and obtain new licenses as appropriate.

2. Maintain existing contractual relationships and expand the value of the work being undertaken while transferring responsibility for such work out of state government.

3. Fulfill the duties of a Responsible Head as delineated in 21 CFR 600.10(a), if applicable.

4. Report to the Commission on actions that affect the business of the Institute.

Notwithstanding Executive Directive 1995-2, the Director may hire or retain such contractors, subcontractors, advisors, consultants, and agents as the Director may deem advisable and necessary, in accordance with relevant statutes, and the rules and regulations of the Civil Service Commission, and may make and enter into contracts necessary or incidental to the exercise of the powers of and the performance of the duties of the Institute and the Director.

It is the intent of the Executive Order that the Director, the employees, and representatives of the Institute shall have the benefit of the provisions of Sections 2228(2) and 2465(2) of Act No. 368 of the Public Acts of 1978, being Sections 333.2228(2) and 333.2465(2) of the Michigan Compiled Laws.

IV. OPERATIONS OF BOTH THE INSTITUTE AND THE COMMISSION

Employees of the Institute are subject to Act No. 317 of the Public Acts of 1968, being Section 15.321 et seq. of the Michigan Compiled Laws, or Act No. 318 of the Public Act of 1968, being Section 15.301 et seq. of the Michigan Compiled Laws, as appropriate. Members of the Commission and employees of the Institute are subject to Act No. 196 of the Public Acts of 1973, being Section 15.341 et seq. of the Michigan Compiled Laws. Employees of the Institute are also subject to applicable Civil Service Commission rules and regulations concerning conflicts of interest.

A member of the Commission, the Director, employees and agents of the Institute shall discharge the duties of their positions in a nonpartisan manner, with good faith and with that degree of diligence, care and skill which an ordinarily prudent person would exercise under similar circumstances in a like position. In discharging their duties, a member of the commission, the Director, employees and agents of the Institute, when acting in good faith, may rely upon the opinion of counsel for the Institute, upon the report of an independent appraiser selected with reasonable care by the Institute and upon financial statements of the Institute represented to a member of the commission, the Director, employees or agents of the Institute to be

correct by the person having charge of the Institute's books or accounts or represented to be correct in a written report by a certified public accountant or firm of certified public accountants.

V. MISCELLANEOUS PROVISIONS

All the licenses and contracts associated with the Biologic Products Division along with all property and equipment needed to support the licenses and to fulfill the contracts are hereby transferred to the Michigan Biologic Products Institute which shall continue to perform pursuant to those licenses and to fulfill those contracts.

The Director of the Michigan Biologic Products Institute shall provide executive direction and supervision for the implementation of the transfers. The Director of the Michigan Biologic Products Institute shall make internal organizational changes as may be administratively necessary to complete the realignment of responsibilities prescribed by this order.

The Director of the Michigan Biologic Products Institute shall immediately enter into negotiations with other state departments or individuals or groups outside of state government to obtain services such as personnel, budgeting, procurement, security, maintenance, and janitorial services.

All records, personnel, property and unexpended balances of appropriations, allocations and other funds used, held, employed, available or to be made available to the Biologic Products Division for the activities transferred are hereby transferred to the Michigan Biologic Products Institute .

The Michigan Department of Public Health shall make internal organizational changes as may be administratively necessary to complete the realignment of responsibilities prescribed by this order.

The Director of the Department of Public Health and Director of the Biologic Products Institute shall immediately initiate coordination to facilitate the transfer and develop a memorandum of record identifying any pending settlements, issues of compliance with applicable federal and state laws and regulations, or obligations to be resolved by the Michigan Biologic Products Institute.

All rules, orders, contracts and agreements relating to the assigned functions lawfully adopted prior to the effective date of this order shall continue to be effective until revised, amended or repealed.

Any suit, action or other proceeding lawfully commenced by, against or before any entity affected by this order shall not abate by reason of the taking effect of this order. Any suit, action or other proceeding may be maintained by, against or before the appropriate successor of any entity affected by this order.

The invalidity of any portion of this Executive Order shall not affect the validity of the remainder thereof.

All departments, boards, commissions or officers of the state or of any political subdivision thereof shall give to the Commission, or to any member or representative thereof, any necessary assistance required by the Commission, or any member or representative thereof, in the performance of the duties of the Commission so far as is compatible with its, his or her duties; free access shall also be given to any books, records or documents in its, his or her custody, relating to matters within the scope of the inquiry, study or investigation of the Commission.

The Institute may accept grants of funds and donations of funds, property, labor or other things of value from any department or agency of the State of Michigan and the United States and from any other public or private agency or person.

In fulfillment of the requirements of Article V, Section 2, of the Constitution of the State of Michigan, the provisions of this Executive Order shall become effective 60 days after filing.

Given under my hand and the Great Seal of the State of Michigan this 5th day of December, in the Year of our Lord, One Thousand Nine Hundred Ninety-Five.

GOVERNOR

BY THE GOVERNOR:

SECRETARY OF STATE

STATE OF MICHIGAN
OFFICE OF THE GOVERNOR
LANSING

JOHN ENGLER
GOVERNOR

December 5, 1995

The Honorable Dick Posthumus
Majority Leader of the Michigan Senate

The Honorable Paul Hillegonds
Speaker of the Michigan House of Representatives

Dear Legislative Leaders:

With this letter, I am transmitting Executive Order 1995-25 regarding the Biologic Products Division of the Michigan Department of Public Health.

This Executive Order removes the Biologic Products Division from the Department of Public Health and establishes it as an autonomous, temporary two-year agency to be known as the Michigan Biologic Products Institute. All of the duties, responsibilities, facilities, licenses, and personnel previously associated with the Division are transferred to the Institute. The current Division Chief and Responsible Head of Manufacturing, under licenses granted by the United States Food and Drug Administration, will become the Director of the Institute.

The Institute will be governed by a three-member Commission which will be responsible for causing the fair-market value of the Institute's assets to be determined, and for developing a plan, including any necessary legislation, to move the Institute out of state government and into the private sector within two years. The Director of the Institute will report to the Commission.

The Biologic Products Division has long played a role in protecting Michigan's children from disease by manufacturing and distributing vaccines to prevent diphtheria, tetanus, and pertussis (DTP), three of the nine pediatric diseases for which immunization is required under Michigan law. The Division has also played an important role in protecting U.S. troops from the threat of biological warfare, and in providing blood fractionation services to the American Red Cross. However, recent changes in the market for pediatric vaccines, and the growth of the Division's relationships with customers other than the State of Michigan have led me to conclude that the Division can no longer fulfill a state government function and can become a self-sustaining private enterprise.

The DTP vaccine made by the Division, while still safe and effective, is no longer a state-of-the-art vaccine. Acellular pertussis and more comprehensive combination vaccines are rapidly replacing the vaccines made by the Division which contains whole-cell pertussis, and which were first licensed over forty years ago. The success of the U.S. FDA-sponsored clinical trials in Sweden and Italy last summer will accelerate the licensure and use of acellular pertussis vaccine in America. Last year, even the Michigan Department of Public Health distributed over 150,000 doses of these privately manufactured vaccines, and next year, the federal Centers for Disease Control plan to stop buying whole-cell pertussis altogether. Many Michigan health-care providers are choosing to buy these advanced combination vaccines over using the "free" vaccine provided by the Division because they provide broader immunity with fewer shots. Finally, the federal government recently imposed an excise tax on the Division's DTP vaccine which increased its cost to Michigan taxpayers by 500%.

Michigan is one of only two states engaged in the manufacture of pediatric vaccines; all other states utilize vaccines made by private pharmaceutical firms. As a strategy to fulfill the public health mission of achieving high infant immunization rates, government vaccine manufacturing has been a dismal failure. Despite providing "free" vaccines made by state government to health-care providers, a recent study ranked Michigan last among states in its rate of infant immunization, and there was no difference between the rate for DTP coverage and rates for the other six required vaccine. In fact, recent studies by the U.S. General Accounting Office have concluded that cost is not a significant barrier to immunization.

This fall, in response to the study concerning Michigan's low rate of infant immunization, I asked Acting Public Health Director, Jim Haveman, to develop a comprehensive strategy to increase infant immunization rates to achieve our goal of 90% coverage by the year 2000. This strategy will rely upon collaboration between public and private health care providers, parents, and other parties across Michigan.

In recent years, more and more of the Division's work has been for public and private customers other than the State of Michigan. Agreements between the Division and private firms like SmithKline Beecham, Athena, North American Biologicals, Inc., and public customers including the American Red Cross and the United States military have enabled the Division to reduce its dependence upon General Fund dollars by earning increased restricted revenues. In fact, the FY 1997 budget request for the Institute will contain no General Fund dollars and the Institute will become entirely self-supporting.

Even as the Division has developed new relationships with other customers, its chief regulator, the U.S. FDA, has cited difficulties in the Division's ability to

meet standards for current good manufacturing practices that are directly related to its position in the Department of Public Health and Civil Service. The authority and latitude required for a Responsible Head of Manufacturing under U.S. FDA licenses is inconsistent with the authority of a division chief within a state department. Moreover, the arcane rules and regulations inherent in the Civil Service system impose significant barriers to efficient operation.

These trends in the market for pediatric vaccines, in the ability of the Division to establish new relationships with private and public customers other than the State of Michigan, and growing difficulties of efficiently managing the Division within the confines of the Michigan Department of Public Health have all led me to conclude that the Division should be established as an autonomous, two-year agency while a plan to move it into the private sector is developed.

I believe that you will agree that the steps I am taking provide the greatest opportunity to retain the skilled jobs associated with the production of vaccines and other biologic products in Michigan.

Sincerely,

John Engler
Governor

JE/jlf

Act No. 521
Public Acts of 1996
Approved by the Governor
January 12, 1997
Filed with the Secretary of State
January 13, 1997

STATE OF MICHIGAN
88TH LEGISLATURE
REGULAR SESSION OF 1996

Introduced by Reps. Gilmer, Johnson and Emerson

ENROLLED HOUSE BILL No. 6191

AN ACT to amend sections 17*l*, 19, 20, and 44 of Act No. 240 of the Public Acts of 1943, entitled as amended "An act to provide for a state employees' retirement system; to create a state employees' retirement board and prescribe its powers and duties; to establish certain funds in connection with the retirement system; to require contributions to the retirement system by and on behalf of members of the retirement system; to create certain accounts and provide for expenditures from those accounts; to prescribe the powers and duties of certain state and local officers and agencies; and to prescribe penalties and provide remedies," section 17*l* as amended by Act No. 176 of the Public Acts of 1995 and sections 19 and 20 as amended and section 44 as added by Act No. 195 of the Public Acts of 1993, being sections 38.17*l*, 38.19, 38.20, and 38.44 of the Michigan Compiled Laws.

The People of the State of Michigan enact:

Section 1. Sections 17*l*, 19, 20, and 44 of Act No. 240 of the Public Acts of 1943, section 17*l* as amended by Act No. 176 of the Public Acts of 1995 and sections 19 and 20 as amended and section 44 as added by Act No. 195 of the Public Acts of 1993, being sections 38.17*l*, 38.19, 38.20, and 38.44 of the Michigan Compiled Laws, are amended to read as follows:

Sec. 17*l*. (1) An employee of the state accident fund who has 5 or more but less than 10 years of credited service as of the effective date of the transfer in order to qualify for a retirement allowance under this act may purchase additional service credit under this subsection. A member who purchases additional service credit shall contribute within 10 years after the effective date of the transfer an amount equal to the product of the following:

(a) Ten less the number of years and fraction of a year of that employee's credited service.

(b) The employee's full-time or equated full-time fiscal year compensation for the last fiscal year before the effective date of the transfer.

(c) The actuarial cost percentage determined under section 1a for the year in which the effective date of the transfer occurred.

(2) In order to qualify for a retirement allowance under this act, an employee of the Michigan biologic products institute who has 5 or more but less than 10 years of credited service as of the effective date of the conveyance of the Michigan biologic products institute under the Michigan biologic products institute transfer act may purchase additional service credit under this subsection. A member who elects within 1 year after the effective date of the conveyance to purchase additional service credit under this subsection shall contribute within 11 years after the effective date of the conveyance an amount equal to the product of the following:

(a) Ten less the number of years and fraction of a year of that employee's credit service.

(b) The employee's full-time or equated full-time fiscal year compensation for the last fiscal year before the effective date of the conveyance.

(c) The actuarial cost percentage determined under section 1a(2) for the year which is 1 year after the year in which the effective date of the conveyance occurred.

(3) Subsection (2) applies only to members who were employees of the Michigan biologic products institute as of the effective date of the conveyance and who maintain employment with the transferee for not less than 1 year unless the employee is laid off by the new employer for reasons other than good cause.

(4) An employee of the liquor control commission created by section 5 of the Michigan liquor control act, Act No. 8 of the Public Acts of the Extra Session of 1933, being section 436.5 of the Michigan Compiled Laws, whose employment is terminated due to the privatization of the distribution of spirits within this state pursuant to the resolution and order adopted by the liquor control commission on February 7, 1996, a plan adopted pursuant to statute or court order, or a plan adopted pursuant to both statute and order of the liquor control commission and who has 5 or more but less than 10 years of credited service on the date the privatization is effectuated in order to qualify for a retirement allowance under this act may purchase additional service credit under this subsection. The cost of benefits paid under this section shall be paid out of the revolving fund created under section 10 of Act No. 8 of the Public Acts of the Extra Session of 1933, being section 436.10 of the Michigan Compiled Laws. A member who elects within 1 year to purchase additional service credit under this subsection shall contribute within 6 years after the privatization date or the date of separation from state employment, whichever occurs first, an amount equal to the product of the following:

(a) Ten less the number of years and fraction of a year of that employee's credited service.

(b) The employee's full-time or equated full-time fiscal year compensation for the last fiscal year before the privatization date.

(c) The actuarial cost for the year in which the privatization date occurred.

(5) Not more than 5 years of additional service credit may be purchased under this section.

Sec. 19. (1) A member who is 60 years of age or older and has 10 or more years of credited service may retire upon written application to the retirement board, stating a date, not less than 30 or more than 90 days after the execution and filing of the application, on which he or she desires to retire. Beginning on the retirement allowance effective date, he or she shall receive a retirement allowance computed according to section 20(1).

(2) A member who is 55 years of age or older, but less than 60 years of age, and has 15 or more years of credited service, may retire upon written application to the retirement board stating a date, not less than 30 or more than 90 days after the execution and filing of the application, on which he or she desires to retire. Upon retirement he or she shall receive a retirement allowance computed according to section 20(1). The retirement allowance of a member who has less than 30 years' credited service shall be reduced by an amount which is 0.5% of the retirement allowance multiplied by the number of months the person's age at retirement is under 60 years. The reduction of 1/2 of 1% for each month and fraction of a month from the member's retirement allowance effective date to the date of the member's sixtieth birthday provided for in this subsection does not apply to a member who retired before July 1, 1974 and before attainment of age 60, with 30 or more years of credited service. The retirement allowance of a retirant or beneficiary of a retirant who retired before that date shall be recalculated disregarding the reduction, and the person receiving the retirement allowance is eligible to receive an adjusted retirement allowance based on the recalculation beginning October 1, 1987, but is not eligible to receive the adjusted amount attributable to any month beginning before October 1, 1987. The recalculated retirement allowance provided by this subsection shall be paid by January 1, 1988. The retirement allowance of a retirant who dies before January 1, 1988, and who has not nominated a retirement allowance beneficiary pursuant to section 31, shall not be recalculated pursuant to this subsection.

(3) Notwithstanding any other provision of this section, effective April 1, 1988, a member may retire with a retirement allowance computed according to section 20(1), without regard to the reduction in subsection (2), if all of the following apply:

(a) The member files a written application with the retirement board stating a date, not less than 30 or more than 90 days after the execution and filing of the application, on which the member desires to retire, and which is within the early retirement effective period.

(b) The member was employed by the state for the 6-month period immediately preceding the member's retirement allowance effective date. This subdivision does not apply to a member who had been restored to active service during that 6-month period pursuant to section 33.

(c) On the last day of the month immediately preceding the retirement allowance effective date stated in the application, the member's combined age and length of credited service is equal to or greater than 80 years and the member is 50 years of age or older.

(d) For purposes of this subsection, "early retirement effective period" means 1 of the following:

(*i*) Except as provided in subparagraph (*ii*), the period beginning on April 1, 1988 and ending on April 1, 1989.

(*ii*) For a member employed by a hospital or facility owned or operated by the department formerly known as the department of mental health that is in the process of being closed by the department formerly known as the department of mental health, the period beginning on April 1, 1988 and ending on October 1, 1989.

(4) As used in subsections (5) to (9):

(a) "Agency of the department" means 1 of the following:

(*i*) Southwest Michigan community living services.

(*ii*) Wayne community living services.

(b) "Department inpatient facility" means 1 of the following:

(*i*) A developmental disability center that is directly operated by the department formerly known as the department of mental health for purposes of providing inpatient care and treatment services to persons with developmental disabilities.

(*ii*) A psychiatric hospital that is directly operated by the department formerly known as the department of mental health for purposes of providing inpatient diagnostic and therapeutic services to persons who are mentally ill.

(5) Notwithstanding any other provision of this section, a member who is an employee of an agency of the department or a department inpatient facility and is on layoff status because the agency or inpatient facility has been designated by the state officer formerly known as the director of mental health for closure on or after October 1, 1989, may retire as provided in subsection (7) or (8), as applicable, with a retirement allowance computed according to section 20(1), without regard to the reduction in subsection (2), upon satisfaction of any 1 of the following conditions:

(a) The member is 51 years of age or older and has 25 or more years of credited service, the last 5 of which are as an employee of an agency of the department designated for closure or a department inpatient facility designated for closure.

(b) The member is at least 56 years of age and has 10 or more years of credited service, the last 5 of which are as an employee of an agency of the department designated for closure or a department inpatient facility designated for closure.

(c) The member has 25 or more years of credited service, regardless of age, as an employee of an agency of the department designated for closure or a department inpatient facility designated for closure.

(6) When a department inpatient facility or agency is designated for closure on or after October 1, 1989, the state officer formerly known as the director of mental health shall certify in writing to the state legislature and the retirement board, not less than 240 days before the designated official date of closure, which facility or agency is to be closed and the designated official date of closure.

(7) Except as provided in subsection (8), a member who is eligible to receive a retirement allowance under subsection (5) may retire effective on the date that an agency of the department or a department inpatient facility designated for closure as provided in subsection (5) actually closes, upon written application to the retirement board not less than 30 or more than 180 days before the designated official date of closure. Beginning on the retirement allowance effective date, he or she shall receive a retirement allowance computed according to section 20(1).

(8) A member who is on layoff status, is not working for the state, and becomes eligible to receive a retirement allowance under subsection (5) and who was an employee of an agency of the department or a department inpatient facility that has been designated for closure as provided in subsection (5) and that actually closes on or after October 1, 1989, may retire upon written application to the retirement board, stating a date, not less than 30 or more than 180 days after the facility actually closes, upon which he or she wishes to retire. Beginning on the retirement allowance effective date, he or she shall receive a retirement allowance computed according to section 20(1).

(9) Any additional accrued actuarial cost and costs for health insurance resulting from the implementation of subsection (5) shall be funded from appropriations to the department formerly known as the department of mental health for this purpose.

(10) A member who is an employee of the state accident fund on the date of transfer to a permitted transferee as that term is defined by section 701a of the worker's disability compensation act of 1969, Act No. 317 of the Public Acts of 1969, being section 418.701a of the Michigan Compiled Laws, may retire if the member's age and his or her length of service is equal to or greater than 70 years on the date of transfer. The member may retire upon written application to the retirement board, stating a date, not less than 30 or more than 90 days after the execution and filing of the application, on which he or she desires to retire. Beginning on the retirement allowance effective date, he or she shall receive a retirement allowance computed according to section 20(1) without regard to the reduction required by subsection (2).

(11) A member who is an employee of the Michigan biologic products institute on the date the institute is conveyed pursuant to the Michigan biologic products institute transfer act may retire if the member's age and his or her length of service is equal to or greater than 70 years on the date of the conveyance. The member may retire upon written application to the retirement board, stating a date, not less than 30 or more than 90 days after the execution and filing of the application, on which he or she desires to retire. Beginning on the retirement allowance effective date, he or she shall receive a retirement allowance computed according to section 20(1) without regard to the reduction required by subsection (2).

(12) A member who is an employee of the liquor control commission created by section 5 of the Michigan liquor control act, Act No. 8 of the Public Acts of the Extra Session of 1933, being section 436.5 of the Michigan Compiled Laws, whose employment is terminated due to the privatization of the distribution of spirits within this state is effectuated pursuant to the resolution and order adopted by the liquor control commission on February 7, 1996, a plan adopted pursuant to statute or court order, or a plan adopted pursuant to both statute and order of the liquor control commission may retire if the member's age and his or her length of service is equal to or greater than 70 years on the

date the privatization is effectuated. The member may retire under this subsection upon written application to the retirement board, stating a date, not less than 30 or more than 90 days after the execution and filing of the application, on which he or she desires to retire. Beginning on the retirement allowance effective date, he or she shall receive a retirement allowance computed according to section 20(1), without regard to the reduction required by subsection (2). The cost of benefits paid under this section shall be paid out of the revolving fund created under section 10 of Act No. 8 of the Public Acts of the Extra Session of 1933, being section 436.10 of the Michigan Compiled Laws.

Sec. 20. (1) Upon his or her retirement, as provided for in section 19, 19a, 19b, 19c, or 19d, a member shall receive a retirement allowance equal to the member's number of years and fraction of a year of credited service multiplied by 1-1/2% of his or her final average compensation. The member's retirement allowance is subject to subsection (3). Upon his or her retirement, the member may elect an option provided for in section 31(1).

(2) Pursuant to rules promulgated by the retirement board, a member who retires before becoming 65 years of age may elect to have his or her regular retirement allowance equated on an actuarial basis to provide an increased retirement allowance payable up to his or her attainment of 65 years of age and a reduced retirement allowance payable after his or her attainment of 65 years of age. His or her increased retirement allowance payable up to age 65 shall approximately equal the sum of his or her reduced retirement allowance payable after age 65 and his or her estimated social security primary insurance amount. In addition, upon retirement the member may elect an option provided for in section 31(1).

(3) If a retirant dies before receiving payment of his or her retirement allowance in an aggregate amount equal to the retirant's accumulated contributions credited to the retirant in the employees' savings fund at the time of his or her retirement, the difference between his or her accumulated contributions and the amount of retirement allowance received by him or her shall be paid to the person or persons that he or she nominated by written designation duly executed and filed with the retirement board. If the person or persons do not survive the retirant, then the difference, if any, shall be paid to the retirant's legal representative or estate. Benefits shall not be paid under this subsection on account of the death of the retirant if he or she elected an option provided for in section 31(1).

(4) If a member has 10 or more years of credited service, or has 5 or more years of credited service as an elected officer or in a position in the executive branch or the legislative branch excepted or exempt from the classified state civil service as provided in section 5 of article XI of the state constitution of 1963, and is separated from the service of the state for a reason other than retirement or death, he or she shall remain a member during the period of absence from the state service for the exclusive purpose of receiving a retirement allowance provided for in this section. If a former employee of the state accident fund who had 5 or more years of service as an employee of the state accident fund returns to employment with the state before receiving a retirement allowance under this act, the employee shall be required to accumulate 10 or more years of credited service before receiving a retirement allowance under this act. If a former employee of the Michigan biologic products institute who is eligible to and has elected to purchase additional credited service pursuant to section 17*l*(2) returns to employment with the state before receiving a retirement allowance under this act, the employee shall be required to accumulate 10 or more years of credited service, without regard to the additional credited service purchased pursuant to section 17*l*(2) but including any credited service authorized under section 16, before receiving a retirement allowance under this act. If the member withdraws all or part of his or her accumulated contributions, he or she ceases to be a member. Upon becoming 60 years of age or older, the member may retire upon his or her written application to the retirement board as provided in section 19(1). If a member elects an option as provided under section 31(4), but dies before the effective date of his or her retirement, the option elected by the member shall be carried out, and the beneficiary of the member is entitled to all advantages due under that option.

(5) A person who is a member after January 1, 1981, who has at least 5 years of credited service, and whose employment with the department formerly known as the department of mental health is terminated by reason of reduction in force related to deinstitutionalization that may or may not result in facility closure, shall remain a member during the period of absence from the state service for the exclusive purpose of receiving a service retirement allowance as provided in this subsection. As used in this subsection, "deinstitutionalization" means planned reduction of state center or hospital beds through placement of individuals from the hospital or facility, or through limiting admissions to centers and hospitals, or both. If a member withdraws all or part of the member's accumulated contributions, the member ceases to be a member. Upon becoming 60 years of age or older, the member may retire upon written application to the retirement board. The application shall specify a date, not less than 30 days or more than 90 days after the execution and filing of the application, on which the member desires to retire. Upon retirement, the member shall receive a retirement allowance equal to the number of years and fraction of a year of credited state service multiplied by 1-1/2% of the member's final average compensation. Upon retirement, the member may elect an option provided in section 31(1). If the member elects an option provided for in section 31(4), but dies before the effective date of retirement, the option elected by the member shall be carried out, and a beneficiary of the member is entitled to all advantages due under the option.

(6) A retirant or the beneficiary of a retirant who retired before July 1, 1974 shall have his or her retirement allowance recalculated based on the retirant's number of years and fraction of a year of credited service multiplied by 1.5% of his or her final average compensation. The retirant or beneficiary is eligible to receive the recalculated retirement allowance beginning October 1, 1987, but is not eligible to receive the adjusted amount attributable to any

month beginning before October 1, 1987. The recalculated retirement allowance provided by this subsection shall be paid by January 1, 1988 and shall be the basis on which future adjustments to the allowance, including the supplement provided by section 20h, are calculated. The retirement allowance of a retirant who dies before January 1, 1988, and who did not nominate a retirement allowance beneficiary pursuant to section 31, shall not be recalculated pursuant to this subsection.

(7) Each retirement allowance payable under this act shall date from the first of the month following the month in which the applicant satisfies the age and service or other requirements for receiving the retirement allowance and terminates state service. A full month's retirement allowance is payable for the month in which a retirement allowance ceases.

(8) An employee of the state accident fund who has 5 or more but less than 10 years of credited service as of the effective date of the transfer authorized by section 701a of the worker's disability compensation act of 1969, Act No. 317 of the Public Acts of 1969, being section 418.701a of the Michigan Compiled Laws, and who is permitted to receive a retirement allowance under subsection (4) is eligible for health care benefits under section 20d on the date of his or her retirement to the same extent as a member with 10 years of credited service who vested on the same date.

(9) An employee of the Michigan biologic products institute who has 5 or more but less than 10 years of credited service as of the effective date of the conveyance authorized by the Michigan biologic products institute transfer act and who is permitted to receive a retirement allowance under subsection (4) is eligible for health care benefits under section 20d on the date of his or her retirement to the same extent as a member with 10 years of credited service who vested on the same date.

Sec. 44. (1) An employee of the state accident fund who was vested in the state retirement system on or before the effective date of the transfer authorized by section 701a of the worker's disability compensation act of 1969, Act No. 317 of the Public Acts of 1969, being section 418.701a of the Michigan Compiled Laws, is entitled to all of the rights, privileges, and benefits provided by this act accrued as of the effective date of the transfer.

(2) An employee of the Michigan biologic products institute who was vested in the state retirement system on or before the effective date of the conveyance authorized by the Michigan biologic products institute transfer act is entitled to all of the rights, privileges, and benefits provided by this act accrued as of the effective date of the conveyance.

(3) An employee of the liquor control commission created by section 5 of the Michigan liquor control act, Act No. 8 of the Public Acts of the Extra Session of 1933, being section 436.5 of the Michigan Compiled Laws, who was vested in the state retirement system on or before the date the privatization of the distribution of spirits within this state is effectuated pursuant to the resolution and order adopted by the liquor control commission on February 7, 1996, a plan adopted pursuant to statute or court order, or a plan adopted pursuant to both statute and order of the liquor control commission is entitled to all of the rights, privileges, and benefits provided by this act accrued as of the date the privatization is effectuated.

Section 2. This amendatory act shall not take effect unless House Bill No. 6192 of the 88th Legislature is enacted into law.

This act is ordered to take immediate effect.

Clerk of the House of Representatives.

Carol Morey Viventi

Secretary of the Senate.

Approved _____

Governor.

Act No. 522
Public Acts of 1996
Approved by the Governor
January 12, 1997
Filed with the Secretary of State
January 13, 1997

STATE OF MICHIGAN
88TH LEGISLATURE
REGULAR SESSION OF 1996

Introduced by Reps. Gilmer, Johnson and Emerson

ENROLLED HOUSE BILL No. 6192

AN ACT to authorize the conveyance of the assets and liabilities of the state related to the operation of the Michigan biologic products institute; to authorize the state administrative board to approve the conveyance and to make determinations that certain conditions upon the conveyance have been met; to permit the acceptance of consideration in exchange for the conveyance; to make certain findings and determinations of the interest of the state relative to the conveyance; to authorize the state administrative board to approve certain agreements for continued services and products by certain state agencies to transferred facilities or to the state from the transferred facilities; to authorize the Michigan biologic products commission to negotiate and, upon concurrence of the state administrative board, approve certain agreements related to the conveyance of the assets and liabilities of the state associated with the Michigan biologic products institute, certain agreements for the marketing of the assets and liabilities, certain agreements for continued services and products, and certain agreements for the retention of rights, interests, and easements in certain conveyed assets; to authorize employees and employee based entities to bid for or make proposals to acquire the assets and liabilities of the state associated with the Michigan biologic products institute; to prescribe the powers and duties of certain public officers and certain state agencies and departments; to grant exclusive jurisdiction over claims related to the conveyance to the court of claims and to limit the time in which claims related to the conveyance or to the products produced by the Michigan biologic products institute may be brought; to provide for the disposition of the revenue derived from the conveyance; and to make an appropriation.

The People of the State of Michigan enact:

Sec. 1. This act shall be known and may be cited as "the Michigan biologic products institute transfer act".

Sec. 2. The legislature finds and declares all of the following:

(a) That increasing regulatory costs, the need to replace manufacturing facilities, the need to develop and the cost of developing new biologic products, the changing pediatric vaccine market, and the need to serve other markets outside the borders of this state have adversely affected the ability of the state to sustain a viable, self-supporting operation for the manufacture and distribution of vaccines and blood derivative products.

(b) That allowing the Michigan biologic products institute to be conveyed to a private enterprise would assist the institute to become self-sustaining, avoid the need for future state general fund subsidies, retain the employment of many employees of the institute, and assure the state's access to biologic products to protect Michigan's citizens from infectious disease.

(c) That the conveyance of the assets associated with the institute will not impair the public health mission of the department of community health and, if the institute is not conveyed to a private enterprise, the operations of the institute could be discontinued. If the operations of the institute are discontinued, the legislature recognizes the need for the disposal of the facilities and the expense to the state of costs related to employee separation from the institute

and of costs related to disposal of the assets associated with the institute, both of which the legislature desires to offset by authorizing the conveyance of the assets associated with the institute to a private enterprise.

Sec. 3. As used in this act:

(a) "Assets" means all or part of the following that are associated with the institute and are subject to conveyance under this act:

(*i*) Real property, including all rights to coal, oil, gas, and other materials, and all rights to sand, gravel, clay, and other nonmetallic minerals, found on, within, or under real property conveyed under this act, except that the agreement for the conveyance of the assets and liabilities of the institute entered into under this act shall specify that the state shall receive not less than 1/2 of the net royalties from the development, if any, of coal, oil, gas, or other minerals on or under the real estate.

(*ii*) Personal property.

(*iii*) Intangible property.

(*iv*) Product inventory, including, but not limited to, manufactured products that have been released by the federal food and drug administration for public sale and use, manufactured products that have not been released by the federal food and drug administration for public sale and use, and products that are in the process of being manufactured and components of those products.

(b) "Chair" means the chair of the commission.

(c) "Commission" means the Michigan biologic products commission established by Executive Order 1995-25 pursuant to section 4 of article V of the state constitution of 1963.

(d) "Conveyance" means sale, transfer, assignment, or other disposition.

(e) "Institute" means the Michigan biologic products institute established by Executive Order 1995-25 pursuant to section 4 of article V of the state constitution of 1963.

(f) "Local health department" means that term as defined in section 1105 of the public health code, being section 333.1105 of the Michigan Compiled Laws.

(g) "Pharmaceutical products fund" means the pharmaceutical products fund established under section 9112 of the public health code, being section 333.9112 of the Michigan Compiled Laws.

(h) "Public health code" means Act No. 368 of the Public Acts of 1978, being sections 333.1101 to 333.25211 of the Michigan Compiled Laws.

(i) "Real property" means all or a portion of the real property associated with the institute, more particularly described as follows:

(*i*) A parcel of land in the NE 1/4 of section 5, T4N, R2W, Ingham County, Michigan and more particularly described as commencing at the northeast corner of said section 5; thence N89°59'49"W 124.94 feet, on the north line of said section 5; thence S00°00'11"W 33.00 feet, to the point of beginning of this description; thence S33°12'59"W 315.33 feet; thence N53°08'14"W 101.37 feet; thence S89°11'38"W 47.55 feet; thence S00°42'03"W 63.21 feet; thence S89°45'02"W 73.97 feet; thence S00°59'58"W 106.92 feet; thence 132.16 feet, on the arc of a curve to the right with a central angle of 33°53'18", a radius of 223.46 feet, and a long chord bearing and distance of S22°22'16"W 130.25 feet; thence S59°26'51"W 14.65 feet; thence S77°08'54"W 92.93 feet; thence S88°34'58"W 131.49 feet; thence S01°57'43"E 41.46 feet; thence S88°02'17"W 153.47 feet; thence S01°57'43"E 132.00 feet; thence S88°02'17"W 351.61 feet; to the easterly right of way line of Logan Street; thence N00°28'13"E 716.63 feet, to the southerly right of way line of Sheridan Road; thence S89°59'49"E 1155.21 feet, on said right of way to the point of beginning, containing 12.56 acres, more or less.

(*ii*) A parcel of land in the SE 1/4 of Section 32, T5N, R2W, Clinton County, Michigan and more particularly described as beginning at the S 1/4 corner of said section 32; thence N00°12'30"W 2152.16 feet on the N-S 1/4 line of said section 32; thence S89°57'16"E 683.94 feet to the westerly Right-of-Way of DeWitt Road at a point 500.00 feet southerly of the E-W 1/4 line of said section 32; thence on the westerly Right-of-Way of DeWitt Road for the next five calls; thence S04°03'50"E 112.68 feet; thence 299.44 feet on the arc of a curve to the left with a central angle of 23°26'19", a radius of 731.99 feet and long chord bearing and distance of S15°47'00"E 297.36 feet; thence S27°30'10"E 927.69 feet; thence 356.62 feet on the arc of a curve to the right with a central angle of 27°41'37", a radius of 737.82 feet and a long chord bearing and distance of S13°39'21"E 353.16 feet; thence S00°11'27"W 30.40 feet; thence S88°07'13"W 171.96 feet; thence S17°13'15"W 128.78 feet; thence S02°36'04"W 161.34 feet; thence N89°52'39"W 420.93 feet; thence S00°06'07"E 267.69 feet to the south line of said section 32, thence N89°59'49"W 632.45 feet on the south line of said section 32 to the N 1/4 corner of section 5, T4N, R2W; thence S89°27'29"W 6.45 feet on the south line of said section 32 to the point of beginning, containing 46.94 acres, more or less.

(j) "State administrative board" means the state administrative board created under Act No. 2 of the Public Acts of 1921, being sections 17.1 to 17.11 of the Michigan Compiled Laws.

Sec. 4. (1) Subject to the requirements of this act, including the approval of the state administrative board, the commission may perform 1 or more of the following acts relative to the conveyance of assets under this act:

(a) Determine the assets that are subject to the proposed conveyance.

(b) Determine the liabilities of the institute, if any, that a proposed transferee would be required to assume.

(c) Negotiate and approve agreements on behalf of the state for the conveyance of all or a portion of the assets to 1 or more transferees and for the assumption of all, a portion of, or none of the liabilities of the institute by 1 or more transferees. An agreement negotiated and approved under this subdivision may include any term determined by the commission to be necessary or convenient for the conveyance of the assets, including, but not limited to, 1 or more of the following:

(*i*) The retention of rights, interests, and easements in or in the favor of the state to certain assets.

(*ii*) An agreement on behalf of the state to grant rights for the future purchase of assets retained by the state.

(*iii*) An agreement on behalf of the state to buy or sell steam and other utility services from assets retained by the state or conveyed by the state to a transferee.

(*iv*) A joint production agreement on behalf of the state related to steam and other utility services from assets conveyed by the state to a transferee.

(*v*) Agreements on behalf of the state for the provision of service or products by 1 or more state agencies to a transferee and agreements for the provision of service or products by a transferee to 1 or more state agencies.

(*vi*) Option or similar agreements on behalf of and in favor of the state related to the repurchase of all or a portion of the conveyed assets upon the occurrence of events specified in the option or similar agreement.

(*vii*) Deeds and other instruments of conveyance associated with real property.

(d) Retain a selling agent to assist the commission in marketing the assets and the liabilities of the institute.

(e) Solicit prospective purchasers or other transferees for the assets using the method or methods considered most appropriate by the commission.

(f) Recommend to the state administrative board the terms of 1 or more proposed agreements with 1 or more proposed transferees for the conveyance of all or a portion of the assets to 1 or more transferees and for the assumption of all, a portion of, or none of the liabilities of the institute.

(g) Upon approval of the state administrative board, authorize the chair or his or her designee to execute agreements, deeds and other instruments of conveyance, bills of sale, and closing documents necessary to complete the conveyance of all or a portion of the assets.

(h) Exercise any other power necessary or convenient to effect or complete the transactions permitted under this act, including, but not limited to, all actions necessary to transfer permits and licenses related to the operation of the institute.

(2) The commission, for and on behalf of the state, without giving any reasons and without any liability therefor, at any time and in any respect, may amend or terminate any activities with respect to the conveyance of the assets, commence and terminate discussion with any or all persons seeking to acquire the assets, reject any or all proposals to acquire the assets, and negotiate and consummate the conveyance of the assets with any person. This subsection does not restrict the right of the commission to enter into a binding purchase agreement upon approval of the state administrative board pursuant to section 5.

(3) The commission shall identify in an agreement for the conveyance of the assets the consideration to be received in exchange for the conveyance of the assets. In addition to the consideration recognized by the legislature in section 2, the commission may accept as part of the conveyance any other valuable consideration.

Sec. 5. (1) Upon recommendation of the commission, the state administrative board may approve and authorize the chair or his or her designee to execute 1 or more agreements, instruments of conveyance, and bills of sale in the name of the state for the conveyance of all or a portion of the assets to 1 or more transferees, and for the assumption of all, a portion of, or none of the liabilities of the institute by 1 or more transferees, subject to all of the following conditions:

(a) Before the effective date of the conveyance, the state administrative board shall determine that the consideration to be received under the conveyance is fair and adequate so that the credit of the state does not need to be granted to a public or private person, association, or corporation.

(b) The terms of the conveyance must require the transferee to provide the state for use in Michigan with preferential access to biologic products, including, but not limited to, the first option to access vaccines and biologic products, from among those products and product components made by the institute on the effective date of the agreement and licensed by the federal food and drug administration or subsequently made by the transferee, as determined by the state, and for the period and subject to conditions and prices contained in the agreement.

(c) Before the effective date of the conveyance, the state administrative board shall determine that the conveyance includes a commitment by the proposed transferee to continue the employment of institute employees who elect to

continue employment with the transferee, for not less than 1 year after the effective date of the agreement. This subdivision does not affect the transferee's ability to terminate an employee's employment for cause.

(2) If more than 1 transferee is recommended by the commission to the state administrative board under subsection (1), the determinations and requirements prescribed by subsection (1)(b) and (c) apply to that transferee to which those assets directly involved in the manufacture of vaccines and blood derivative products are proposed to be transferred.

(3) The state administrative board may, in its sole discretion, evaluate the terms of any recommendation made by the commission under subsection (1) and approve or reject any recommendations of the commission made under this act without assigning reasons for the evaluation, approval, or rejection.

(4) In addition to the conditions upon the execution of a conveyance specified in subsection (1), the state administrative board shall receive, before the effective date of the conveyance, an independent opinion that the consideration for the assets or liabilities, or both, of the institute is fair and adequate.

(5) The state administrative board may rely upon the opinions or reports of legal counsel, independent appraisers, accountants, financial advisors, and other experts when performing its duties and exercising its powers under this act.

(6) The auditor general shall review the entire process used by the commission under this act to convey the assets and liabilities of the institute and shall report the results of its review to the legislature before the state administrative board approves the recommendations made by the commission under subsection (1).

Sec. 6. (1) The monetary consideration received under this act for the conveyance of the assets shall be deposited in the pharmaceutical products fund and, except as otherwise provided in this section, shall be used solely for the purchase of vaccines and other biologic products necessary to promote and protect the public health.

(2) The money in the pharmaceutical products fund not needed to fund the appropriations made by Act No. 364 of the Public Acts of 1996 for the 1996-97 state fiscal year is appropriated for the following purposes and in the following order of priority:

(a) Payment of fees associated with the services provided by a selling agent in marketing the assets, if such services are retained and used by the commission.

(b) For payment of accrued sick and annual leave time to employees of the institute upon separation of employment from the state if current fiscal year appropriations available for that purpose are insufficient.

(c) For reimbursement of the state for payouts for accrued sick and annual leave time from current fiscal year appropriations available for that purpose to employees of the institute upon separation of employment from the state.

(d) To reimburse the state employees' retirement system for the actuarial cost of providing an optional early-out program for employees of the institute whose combined age and service credit equal 70 or greater, regardless of age, on the date of separation of employment from the state.

(e) Separation costs including, but not limited to, expenses incurred in moving non-institute employee work stations and other equipment in to other state office locations and converting the facilities of the institute to private operations.

(f) To pay other costs related to the negotiation and closing of the agreement for the conveyance of the assets, including title insurance and any opinions or reports required by the state administrative board, and the fees of attorneys and consultants used to develop and complete the conveyance.

(3) There is appropriated an additional $2,000,000.00 for the institute for the fiscal year ending September 30, 1997 for the construction of phase 1-B of the renovations to building 16 for regulatory compliance purposes. Of the $2,000,000.00, $630,000.00 is appropriated from other federal revenues and $1,370,000.00 is appropriated from biologic product sales and other revenue.

(4) The amounts that can be expended for the purposes prescribed in subsection (2)(a), (e), and (f) shall not exceed $2,500,000.00. The amounts that can be expended for the purposes prescribed in subsection (2)(b), (c), and (d) shall not exceed $2,500,000.00.

(5) All unexpended money of the pharmaceutical products fund shall be retained in the pharmaceutical products fund at the end of the fiscal year in which the conveyance of the assets is completed. After the conveyance is completed, the community public health agency within the department of community health shall administer the pharmaceutical products fund.

Sec. 7. (1) An employee of the institute or a group composed in whole or in part of employees of the institute may bid on or make a proposal to acquire the assets and enter into 1 or more agreements related to the conveyance of all or a portion of the assets to the employee or group.

(2) When acting with the knowledge or upon the direction of the commission or in entering into an agreement to accept employment with a potential acquirer of the assets, an employee of the institute shall not be considered to have violated Act No. 196 of the Public Acts of 1973, being sections 15.341 to 15.348 of the Michigan Compiled Laws, if the employee provided written notice to the commission of the proposed employment agreement and the terms of that agreement before its execution.

Sec. 8. Except for taxes otherwise imposed by the state or a political subdivision of the state, the conveyance of assets permitted under this act is free and clear of any liens, claims, or interests of the state or of a person claiming through or under the state.

Sec. 9. (1) Except for the pharmaceutical products fund, any assets that have not been conveyed on or before the expiration of the life of the commission shall be transferred to the department of management and budget or any other state executive department, as the state administrative board may direct.

(2) Not less than 90 days after the conveyance of assets and liabilities is completed under this act, the state administrative board shall make a report in writing to the legislature of the terms of the conveyance.

Sec. 10. (1) The court of claims has exclusive jurisdiction over a claim asserted against the state and arising out of or related to this act.

(2) The validity of the proceedings of, or the determinations made by, the state administrative board or the commission under this act are conclusive if not challenged by filing suit with the court of claims within 60 days after the action that is the subject of the suit is taken.

(3) A person shall not bring or maintain an action related to a product manufactured by the institute or to recover damages for injuries to persons unless the action is commenced within 6 months after the claim first accrued to the plaintiff or to someone through whom the plaintiff claims. A claim subject to this subsection accrues at the time the plaintiff or someone through whom the plaintiff claims discovered or should have discovered through reasonable diligence the existence of the claim or the injury that is the basis for the claim.

This act is ordered to take immediate effect.

Clerk of the House of Representatives.

Carol Morey Viventi

Secretary of the Senate.

Approved _____

Governor.

STATE OF MICHIGAN
DEPARTMENT OF ATTORNEY GENERAL

STANLEY D. STEINBORN
Deputy Attorney General

P.O. Box 30212
LANSING, MICHIGAN 48909

FRANK J. KELLEY
ATTORNEY GENERAL

November 20, 1996

Members of the 1996 Legislature:

Over the past eight months, several assistant attorneys general have worked cooperatively with the Michigan Biologic Products Commission (the "Commission") and special assistant attorneys general appointed at the request of the Commission, to develop the process for transferring the assets of the Michigan Biologic Products Institute (the "Institute") to the private sector. Although there are still a few minor issues to resolve, House Bill 6192 has incorporated much of this cooperative effort into a statute authorizing the transfer of the assets and establishing an orderly and open process for conducting the transaction. The companion bill, House Bill 6191, addresses retirement issues of the Institute's employees.

HB 6192 assures that the state will receive fair and adequate consideration for the assets of the Institute, and that the credit of the state will not be granted to any prospective purchaser. The bill defines the metes and bounds of the real property proposed for transfer, and empowers the Commission to define additional assets and liabilities to be included in the transaction. Ultimately, the State Administrative Board is responsible for approving the transaction with one or more transferees recommended by the Commission. While some minor changes to the language of this Bill remain to be made, these are of such a nature that I am confident that they can be resolved shortly.

Sincerely yours,

FRANK J. KELLEY
Attorney General

OFFICE OF THE MAYOR
9th Floor, City Hall
124 West Michigan Avenue
Lansing, Michigan 48933-1694
(517) 483-4141 (Voice)
(517) 483-4479 (TDD)
(517) 483-6066 (FAX)

David C. Hollister, Mayor

November 19, 1996

Dear Legislators:

I am writing to support the passage of House Bills 6191 and 6192 authorizing the transfer of the Michigan Biologic Products Institute to the private sector and providing favorable retirement options for its employees.

The Institute is located in the City of Lansing and employs approximately 150 skilled workers in the manufacture of vaccines and blood derivatives. It is a significant contributor to the economy of Lansing and the State of Michigan. If the Institute is transferred to the private sector, it will help to support our schools and other essential community services.

The Institute has a long and distinguished history of public service to the people of Michigan by providing vaccines to protect our children from infectious disease. Today, however, the pediatric vaccine made by the Institute is being rendered obsolete by newer products, its aging facilities are in need of replacement, and most of its revenues are already derived from private and public customers other than the State of Michigan. These factors combine to create peril as well as opportunity for the Institute.

The Institute needs an infusion of capital, new facilities, and a new product pipeline that can and should come from the private sector. The alternative is closure, layoffs, building demolition. Clean-up is undesirable from both a human and economic perspective. I am hopeful that by selling the Institute, along with vacant land upon which replacement facilities could be built, that a new enterprise may be brought to Lansing to grow, prosper, and contribute to the well-being of our community well into the future.

Sincerely,

David C. Hollister
Mayor

"Equal Opportunity Employer"

MICHIGAN BIOLOGIC PRODUCTS COMMISSION

BYLAWS

ARTICLE 1 -- THE COMMISSION

Section 1 -- Name. The name of this body shall be the Michigan Biologic Products Commission, hereinafter referred to as the "Commission."

Section 2 -- Authority. As provided in Executive Order 1995-25, the Commission shall provide supervision, policy control, and direction to the Michigan Biologic Products Institute, hereinafter referred to as the "Institute," and the Director of the Institute.

Section 3 -- Office Location. The principal office of the Commission shall be at the Olds Plaza, 111 S. Capitol, 4th Floor, Lansing, Michigan, or via phone at 517/335-6847, with other offices at such places as the Commission may from time to time designate.

Section 4 -- Membership. The members of the Commission shall be appointed by the Governor. The Governor shall also designate one member to be the Chair.

Section 5 -- Officers and Employees. The Chair shall preside at all meetings of the Commission. An Executive Secretary shall be appointed, who need not be a member of the Commission, who shall be responsible for keeping the minutes of Commission meetings, all official correspondence and papers of the Commission, and such other duties as may be assigned by the Commission.

ARTICLE 2 -- MEETINGS

Section 1 -- Quorum. A majority of the serving voting members constitutes a quorum for the transaction of business at a meeting, notwithstanding the existence of one (1) or more vacancies. A member may be present in person at a meeting of the Commission. One member may be present by use of amplified telephonic equipment.

Section 2 -- Order of Business. By vote of a majority of the members participating at any regular or special meeting of the Commission, any matter may be placed on the agenda at such meeting. The Chair may place on the agenda any matter which he/she determines to be important for consideration by the Commission.

Section 3 -- Voting. Voting upon actions taken by the Commission shall be conducted by a majority vote of the members present in person at a meeting of the Commission. One member may present by use of amplified telephonic equipment.

Section 4 -- Regular Meetings. Regular meetings of the Commission shall be held on the first Friday of every month at 8:30 a.m., at the principal office, or at locations otherwise determined by the Commission. All meetings of the Commission shall comply with the provisions of the Open Meetings Act, Act 267 of the Public Acts of 1976, as amended.

Section 5 -- Special Meetings. The Chair of the Commission may call special meetings of the Commission that warrant the consideration and prompt attention of the Commission. A quorum of the membership shall be required for any action to be taken at special meetings. Meetings of the Commission may be held anywhere in the State of Michigan.

Section 6 -- Minutes. Minutes of the all Commission meetings, including all votes, shall be kept and shall be corrected and approved at a succeeding meeting. The minutes of each meeting of the Commission shall be open and available to the public in compliance with the Open Meetings Act , Act No. 267 of the Public Acts of 1976, as amended; and the Freedom of Information Act, Act No. 442 of the Public Acts of 1976, as amended.

Section 7 -- Procedures. The rules contained in the current edition of Robert's Rules of Order shall be followed in all applicable cases not inconsistent with these Bylaws and/or any special rules which may, from time to time, be adopted by the Commission.

Section 8 -- Open Meetings Act. Any member of the public wishing to speak on a specific agenda item or on any other Commission-related subject at a Regular Meeting of the Commission shall give 48 hours notice of this intent to the Executive Secretary. Any member of the public wishing to speak on a specific agenda item at a Special Meeting of the Commission for which an agenda has been prepared and distributed at least ten (10) days in advance of the meeting shall give 48 hours notice of this intent to the Executive Secretary. Any member of the public wishing to speak on a specific agenda item at a Special Meeting of the Commission for which an agenda has not been prepared and distributed at least ten (10) days in advance of the meeting shall notify the Executive Secretary of the Commission prior to the start of the meeting of his/her intent. In all cases, a person wishing to speak shall provide at the time of notification his/her name and the topic to be addressed. Any group larger than twenty (20) persons planning to attend a meeting of the Commission shall, when possible, notify the Executive Secretary of the Commission at least 48 hours prior to the time for commencement of the meeting.

Section 9 -- Limitations as to Length and Number of Presentations. The Chair of the Commission may limit in a reasonable fashion the length of a presentation or the number of speakers on any issue in order to facilitate the orderly conduct of the Meeting.

Section 10 -- Waiver of Notification. The Chair may, in the interest of encouraging public participation, waive any of the above notification requirements.

ARTICLE 3 -- AMENDMENT AND SUSPENSION OF BYLAWS

Section 1 -- Amendment. These bylaws may be amended by Resolution adopted by the affirmative vote of a majority of the members of the Commission at any meeting, provided that notice of intention to present such Resolution shall be given at least five (5) days in advance of the meeting at which the motion to adopt such Resolution is made. Such notice shall be given in writing to the Executive Secretary and mailed or delivered to the business or home address of each member or, in the alternative, such notice may be given orally at any meeting, in which event such notice shall be noted in the minutes of the meeting at which it is given. Advance notice of motions to amend the proposed amendments to the Bylaws need not be given.

Section 2 -- Suspension. Any and all of the provisions of the Bylaws, except those required by state law, may be suspended by unanimous consent of the members constituting a quorum present at any meeting of the Commission.

ARTICLE 4 -- LIABILITY of MEMBERS, OFFICERS, EMPLOYEES AND AGENTS

Liability. No member of the Commission or any officer, employee, or agent for the Commission, including any person executing any documents or certificates on behalf of the Commission shall be liable personally for any action taken by the Commission or any document or certificate executed on behalf of the Commission.

RESOLUTION NO. 1

A RESOLUTION APPOINTING THE EXECUTIVE SECRETARY FOR THE MICHIGAN BIOLOGIC PRODUCTS COMMISSION

WHEREAS, the Michigan Biologic Products Commission, hereinafter the "Commission," was created by Executive Order 1995-25 to provide supervision, policy control, and direction to the Institute and its Director; and

WHEREAS, the Commission has adopted bylaws providing for the location and conduct of meetings, and the appointment of an Executive Secretary; and

WHEREAS, the Commission is a public body as defined in the Open Meetings Act, Act No. 267 of the Public Acts of 1976, as amended; and

WHEREAS, the writings of the Commission are subject to the Freedom of Information Act, Act No. 442 of the Public Acts of 1976, as amended; and

NOW, THEREFORE, BE IT RESOLVED, that the Commission hereby appoints J. Louise Findley to be Executive Secretary to the Commission, and to be responsible for the following:

1. Keeping minutes of all Commission meetings, and maintaining the file of all official Commission correspondence and papers.

2. Posting notice of all Commission meetings and agendas in compliance with the Open Meetings Act and the Bylaws of the Commission, assuring that members of the Commission receive such notices and agendas in a timely manner, and otherwise assuring that the Commission complies with the provisions of the Open Meetings Act.

3. Being the initial point of public contact for the Commission, including phone, written, or other contacts.

4. Serving as the Freedom of Information officer for the Commission, and assuring that the Commission complies with the Freedom of Information Act.

5. Receive, date and time stamp, and distribute all written communications to the Commission.

6. Certify true copies of all official Commission records and keep these records on file.

RESOLUTION NO. 2

A RESOLUTION DEFINING THE RELATIONSHIP BETWEEN THE COMMISSION AND THE INSTITUTE

WHEREAS, the Michigan Biologic Products Commission, hereinafter referred to as the "Commission," and the Michigan Biologic Products Institute, hereinafter referred to as the "Institute," were both established by Executive Order 1995-25, to serve as temporary entities with lives of no more than two (2) years from the effective date of the Executive Order; and

WHEREAS, the Commission is charged with providing supervision, policy control and direction to the Institute, and to its Director, and may establish general goals and objectives relating to the operation and development of the Institute for the guidance of the Director; and

WHEREAS, the Commission is also charged with preparing or causing to be prepared a detailed business plan including any necessary legislation, causing the property of the Institute to be valued, and with contracting with the Institute's Director; and

WHEREAS, the Director of the Institute reports to and is directly responsible to the Commission; and

WHEREAS, the Director is also responsible for the oversight and supervision of Institute employees, for administration of the Pharmaceutical Products Fund, for management of the Institute's facilities and for the Institute operations, and is specifically authorized to hire employees and contractors, to enter into contracts, and to contract with other state departments for services; and

WHEREAS, as Responsible Head of Manufacturing for U.S. Federal Drug Administration purposes, the Director must "exercise control of the establishment in all matters relating to compliance ... and with authority to enforce or to direct the enforcement of discipline and the performance of assigned functions by employees engaged in the manufacture of products." (21 CFR 600.10); and

WHEREAS, it is important both for the orderly operation of the Commission and of the Institute, and for the Director to appropriately discharge his duties, that a clear delineation of the duties and responsibilities between the Commission and the Director be established.

NOW THEREFORE, BE IT RESOLVED, that the Commission establishes the following duties, responsibilities, and goals for the Commission and the Institute:

A. The Commission

1. The Commission defines its primary role as preparing and executing a business plan for privatizing the Institute, through sale or other means.

2. The Commission intends to maintain and enhance the value of the Institute as a successful enterprise.

3. The Commission will work with the Legislature on legislation concerning the Institute, other than the budget.

4. The Commission will review and approve the submission of the annual budget of the Institute to the Michigan Department of Management and Budget, including any major modifications during the fiscal year. Because the FY 1997 budget has already been submitted, the Commission will accept a briefing in lieu of approval for FY 1997.

5. The Commission will review and approve the organizational structure of the Institute, including organizational changes that affect reporting to the Director or which have substantial cost implications.

6. The Commission will approve review and capital expenditures over $250,000.

7. The Commission will formally accept gifts and donations from any source for deposit into the Pharmaceutical Products Fund.

8. The Commission will contract with the Director, and such contract will also provide for performance evaluation of the Director.

9. The Commission will enter into contracts for the development of a formal business plan for the Institute, and, to the extent necessary, for valuing the property of the Institute.

10. The Commission will review and approve new contracts with customers of the Institute, and any substantive changes to existing contracts with customers of the Institute.

B. The Institute

1. The Director shall at all times be responsible for the efficient operation of the Institute, including but not limited to the hiring and management of all employees, meeting the contractual obligations of the Institute, and managing the finances of the Institute within appropriated limits.

2. The Director will work with the Legislature on the budget of the Institute.

3. The Director may appoint, contract with, hire or retain deputies, assistants, employees, contractors, subcontractors, advisors, consultants, and agents as the Director may deem advisable and necessary, and to make and enter into contracts necessary or incidental to the exercise of the powers of and the performance of the duties of the Institute and the Director, in accordance with state administrative procedures.

4. The Director will negotiate with other state departments, or individuals or groups outside of state government to obtain services, and shall be responsible for signing and implementing these contracts, and assuring compliance with the provisions of these contracts, including performance objectives, in accordance with state administrative procedures.

5. The Director will report to the Chair of the Commission on a regular basis and to the Commission at every Commission meeting. At least quarterly, the Director shall report on the finances of the Institute.

6. The Director shall provide information, resources, and staff support to the Commission for business plan preparation, asset valuation, or other services as the Commission deems necessary and appropriate.

C. Goals of the Institute and the Commission

1. To maintain the U.S. Food and Drug Administration establishment license for the facilities for biologic products production and maintain existing product licenses, and obtain new licenses as appropriate.

2. To maintain existing contractual relationships and expand the value of the work being undertaken during the Institute's transition to the private sector.

3. To become a successful, self-supporting private enterprise within two years, consistent with the Commission's business plan.

4. To recruit and/or retain a high-quality workforce.

5. To enact legislation supporting the privatization of the Institute as necessary.

MBPI FY 1997 Capital Outlay Request
Building 16 Renovation and Expansion

Resolution #3

WHEREAS, the Institute has a placeholder request for $8.65 million in capital outlay authority in the Revised Executive Recommendations for FY 1997 Capital Outlay; and

WHEREAS, this broad proposal goes beyond regulatory concerns and accommodates potential customer interest in expanding production capacity; and

WHEREAS, commitments of substantial financing from Institute customers is needed to justify expansion of production capacity which are not yet in place; and

WHEREAS, much of the $8.65 million project would not be constructed until the Institute is separated from state government; and

WHEREAS, expansion of capacity is a proper subject of the business plan; and

WHEREAS, addressing regulatory concerns of the U.S. Food and Drug Administration remains a high priority of the Commission; and

WHEREAS, it is most efficient to address regulatory concerns during a larger renovation project to minimize downtime.

NOW THEREFORE, BE IT RESOLVED:

That the Michigan Biologic Products Commission hereby authorizes the Director to request $2 million in capital outlay authority in the Revised Executive Recommendations for FY 1997 Capital Outlay, to be used for renovating Building 16 to address regulatory concerns over the configuration of the existing facility. This will be in place of the $8.65 million in authority currently being requested of DMB.

RESOLUTION NO. 4

A RESOLUTION TO SPECIFY GOALS AND TO MAKE CERTAIN DETERMINATIONS WITH RESPECT TO THE PRIVATIZATION OF THE MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

WHEREAS, the Michigan Biologic Products Commission (the "Commission") recognizes the value of the skills, know-how, and experience of the employees of the Michigan Biologic Products Institute (the "Institute") and their contribution to the economy of the State of Michigan (the "State"); and

WHEREAS, the ownership and operation of the means of production for biologic products by state government is not needed to achieve the public health goal of age-appropriate immunization for all Michigan children and can be transferred to the private sector; and

WHEREAS, Executive Order 1995-25 requires the Commission to prepare a business plan, including any necessary legislation, to transfer the Institute out of state government and into the private sector, and to determine the fair market value of all State assets associated with the manufacture of biologic products; and

WHEREAS, the Commission has engaged special counsel to structure the transaction and develop legislation to effect the transfer of the Institute out of state government and into the private sector; and

WHEREAS, the structure of the transaction and legislation to transfer the Institute out of state government and into the private sector is partly dependent upon the goals of the Commission; and

WHEREAS, the Commission also desires to make certain determinations to further guide the structuring of the transaction and development of legislation to move the Institute out of state government and into the private sector.

NOW THEREFORE, BE IT RESOLVED, that the Commission establishes the following goals with respect to the transaction to transfer the Institute out of state government and into the private sector:

1. The transaction should be structured as a single transaction to sell all of the State assets associated with the manufacture of biologic products, including but not limited to all personal and real property, licenses, contracts, and inventory.

2. The transaction should be structured to provide the highest probability for the successor entity to become a profitable, viable enterprise

contributing to the economy of the State that is able to retain and increase the number of jobs it provides, accumulate the capital necessary to replace its biologic production facilities, and to keep the know-how associated with the manufacture of biologic products in Michigan.

3. The transaction should be structured to assure, to the greatest extent practicable, preferential State access to biologic products for use by Michigan public health agencies to prevent disease.

4. The transaction should be structured so that the State receives fair consideration for the assets being sold.

AND, BE IT FURTHER RESOLVED, that the Commission makes the following determinations in the interest of achieving the aforementioned goals:

1. The physical campus of the Institute will be surveyed to establish metes and bounds, and the fair market value of the assets of the Institute will be determined.

2. The Institute and its various lines of business, (e.g., vaccines, blood products, etc.) will be sold as a single unit and not on a piecemeal basis.

3. The successor entity will be independent of any future organizational control by state government, however, the State will retain certain property easements, including a right of entry to the power plant.

4. The consideration that the State receives from the sale of the Institute may be in the form of cash and/or future benefits such as biologic products, utilities, and other services or benefits to the people of the State.

5. The Commission recognizes the likelihood that a transaction which includes employee participation will be more conducive to achieving the State's goals.

6. The currently preferred procedure for identifying potential purchasers of the Institute is the request for qualification ("RFQ") procedure.

AND BE IT FINALLY RESOLVED, that copies of this resolution be distributed to the employees of the Institute and placed in the permanent files of the Commission.

This is a true copy as passed by the Michigan Biologic Products Commission on July 12, 1996

J. Louise Findley

J. Louise Findley
Executive Secretary, MBPC

RESOLUTION NO. 5

A RESOLUTION AFFIRMING THE SURVEY OF THE EAST CAMPUS OF THE MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

WHEREAS, Executive Order No. 1995-25 established the Michigan Biologic Products Institute (the "Institute") and directed it to assume, among other things, all of the tangible property of the Biologic Products Division of the Michigan Department of Public Health associated with the manufacture of biologic products; and

WHEREAS, Executive Order 1995-25 charged the Michigan Biologic Products Commission (the "Commission") with causing the fair market value of all state property, among other things, associated with the manufacture of biologic products to be determined and to prepare any necessary legislation to effect the sale or transfer of the Institute; and

WHEREAS, in order to define the boundaries of the land occupied by the campus of the Institute on the east side of Martin Luther King, Jr., Boulevard, the Commission directed that the perimeter of the campus be surveyed by the Michigan Department of Management and Budget, Office of Facilities; and

WHEREAS, the survey known as Drawing No. 96016, Map of Boundary Survey for the Michigan Department of Public Health North Logan Complex -- Proposed Transfer, (the "Survey") was completed on August 1, 1996.

NOW, THEREFORE, BE IT RESOLVED, that the Commission hereby affirms the boundaries defined in the Survey as establishing the perimeter of the east campus of the Institute located on the east side of Martin Luther King, Jr., Boulevard, Lansing, Michigan; and

BE IT FURTHER RESOLVED, that the Commission directs that the legal description of the property contained in the Survey be incorporated into any legislation necessary to effect the sale or transfer of the Institute.

RESOLUTION NO. 6

A RESOLUTION AFFIRMING THE SURVEY OF THE WEST CAMPUS OF THE MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

WHEREAS, Executive Order 1995-25 established the Michigan Biologic Products Institute (the "Institute") and directed it to assume, among other things, all of the tangible property of the Michigan Biologic Products Division of the Michigan Department of Public Health associated with the manufacture of biologic products; and

WHEREAS, the property on the west side of Martin Luther King, Jr., Boulevard otherwise known as "the sheep farm" has long supported the manufacture of biologic products by providing animals and animal products necessary for such production; and

WHEREAS, Executive Order 1995-25 charged the Michigan Biologic Products Commission (the "Commission") with causing the fair market value of all state property, among other things, associated with the manufacture of biologic products to be determined and to prepare any necessary legislation to effect the sale or transfer of the Institute; and

WHEREAS, the Michigan Department of Management and Budget, Office of Facilities completed the survey of the land otherwise known as "the sheep farm" located on the west side of Martin Luther King, Jr., Boulevard, being Drawing No. 95022, Map of Boundary Survey for Michigan Department of Public Health, North Logan Complex -- Surplus Property (the "Survey") on August 28, 1996. The property contains 46.94 acres, more or less; and

WHEREAS, the surveyed property was appraised by the Dean Appraisal Company on June 22, 1995, and found to have a fair market value at that time of $7,500.00 per acre; and

WHEREAS, the surveyed property was declared surplus by the Michigan Department of Public Health on November 22, 1995; and

WHEREAS, the Commission agrees that the value and marketability of the Institute will be enhanced by incorporating the surveyed land into the overall campus of the Institute, by providing space for replacement facilities and future growth.

NOW, THEREFORE, BE IT RESOLVED, that the Commission hereby affirms the boundaries defined in the Survey, subject to final certification by the Department of Management and Budget, as establishing the perimeter of the west campus of the Institute; and

BE IT FURTHER RESOLVED, that the Commission directs that the legal description of the property contained in the Survey be incorporated into any legislation necessary to effect the sale or transfer of the Institute.

RESOLUTION NO. 7

A RESOLUTION TO APPROVE THE MICHIGAN BIOLOGIC PRODUCTS INSTITUTE'S STRATEGIC PLAN FOR COMPLIANCE WITH U.S. FOOD AND DRUG ADMINISTRATION STANDARDS AND REGULATIONS

WHEREAS, on March 11, 1997, the U.S. Food and Drug Administration (hereinafter "the FDA") notified the Michigan Biologic Products Institute (hereinafter "the Institute") that the FDA intended to commence proceedings to revoke the Institute's establishment license unless the Institute took immediate action to comply with all applicable FDA standards and regulations; and

WHEREAS, the Institute promptly notified the FDA of its firm commitment to comply with FDA standards and regulations and immediately began preparing a plan to correct deviations from FDA standards and requirements; and

WHEREAS, based on a comprehensive assessment of all operational aspects of the Institute and with the assistance and support of key customers and industry knowledgeable consultants, the Institute has completed it Strategic Plan for Compliance (hereinafter "the Plan") and will be submitting the Plan to the FDA within the thirty-day preparation period granted by the FDA; and

WHEREAS, the Michigan Biologic Products Commission (hereinafter "the Commission") recognizes that the Plan requires certain actions by the State of Michigan and the Commission.

NOW, THEREFORE, BE IT RESOLVED that the Commission supports the following elements of the Plan:

1. The immediate transfer to the Institute, by executive action, of the units, funding, and staff associated with warehousing and security functions;

2. The reorganization of the Institute as provided for in the Plan and as outlined in the organizational charts contained in Appendix A of the Plan;

3. The establishment of a transition team as provided for in the Plan to replace support services currently provided to the Institute by other agencies of state government at least until the Institute's transition from the public to the private sector is complete;

4. The orderly internalization by the Institute of all maintenance functions including, but not limited to, janitorial, pest control, and groundskeeping;

5. The orderly internalization by the Institute of administrative functions including, but not limited to, human resources, finance, procurement, facilities management, and all other functions needed to effect complete termination of reliance on other state agencies for these services; and

BE IT FURTHER RESOLVED, that the Commission continues to support funding for fiscal year 1997 as authorized in Acts No. 364 and 522 of the Public Acts of 1996 being $16,258,700 for the operations of the Institute, $2,000,000 for capital outlay projects, and $5,000,000 for employee and other costs related to the separation of the Institute from state government, subject to the availability of appropriated resources; and

BE IT FURTHER RESOLVED, that the Commission and the state agencies and offices represented on the Commission are firmly committed to the timely resolution of any and all remaining issues related to the separation of the Institute from the rest of state government consistent with the Plan; and

BE IT FINALLY RESOLVED, that the Commission hereby grants its support and approval for the Plan and urges the Institute to immediately submit the Plan to the FDA.

This is a true copy as passed by the Michigan Biologic Products Commission on April 8, 1997.

J. Louise Findley
Executive Secretary, MBPC

RESOLUTION NO. 8

A RESOLUTION TO DECLARE THAT THE MICHIGAN BIOLOGIC PRODUCTS INSTITUTE IS FOR SALE

WHEREAS, Public Act No. 522 of 1996, known as "The Michigan Biologic Products Institute Transfer Act (hereinafter "the Transfer Act"), authorized the conveyance of the assets and liabilities of the state related to the operation of the Michigan Biologic Products Institute (hereinafter "the Institute") and charged the Michigan Biologic Products Commission (hereinafter "the Commission") with the responsibility for managing the transfer of the Institute to the private sector, and

WHEREAS, in accord with the Transfer Act, the Commission has engaged the services of a selling agent to assist the Commission in marketing the assets and liabilities of the Institute to potential purchasers. The selling agent has completed the preparation of the necessary selling documents and has identified a substantial list of potential purchasers, including the employees of the Institute, and

WHEREAS, the State Administrative Board has engaged the services of an independent fairness opinion provider to evaluate the terms and conditions of any sales agreement which may be negotiated by the Commission with a potential purchaser of the Institute to assure that the consideration received by the state is fair and adequate, and

WHEREAS, after extensive preparation, the Commission is now ready to commence a comprehensive search for prospective purchasers of the Institute.

NOW, THEREFORE, BE IT RESOLVED that the Commission hereby officially declares that the assets and liabilities of the Institute are: FOR SALE, and

BE IT FURTHER RESOLVED, that the Commission hereby directs its selling agent, W.Y. Campbell & Company, to immediately commence the marketing of the assets and liabilities of the Institute to prospective purchasers, and

BE IT FINALLY RESOLVED, that notice of this resolution be posted in the Michigan Register.

This is a true copy as passed by the Michigan Biologic Products Commission on July 1, 1997.

J. Louise Findley

J. Louise Findley
Executive Secretary, MBPC

RESOLUTION NO. 8

A RESOLUTION TO DECLARE THAT THE MICHIGAN BIOLOGIC PRODUCTS INSTITUTE IS FOR SALE

WHEREAS, Public Act No. 522 of 1996, known as "The Michigan Biologic Products Institute Transfer Act (hereinafter "the Transfer Act"), authorized the conveyance of the assets and liabilities of the state related to the operation of the Michigan Biologic Products Institute (hereinafter "the Institute") and charged the Michigan Biologic Products Commission (hereinafter "the Commission") with the responsibility for managing the transfer of the Institute to the private sector, and

WHEREAS, in accord with the Transfer Act, the Commission has engaged the services of a selling agent to assist the Commission in marketing the assets and liabilities of the Institute to potential purchasers. The selling agent has completed the preparation of the necessary selling documents and has identified a substantial list of potential purchasers, including the employees of the Institute, and

WHEREAS, the State Administrative Board has engaged the services of an independent fairness opinion provider to evaluate the terms and conditions of any sales agreement which may be negotiated by the Commission with a potential purchaser of the Institute to assure that the consideration received by the state is fair and adequate, and

WHEREAS, after extensive preparation, the Commission is now ready to commence a comprehensive search for prospective purchasers of the Institute.

NOW, THEREFORE, BE IT RESOLVED that the Commission hereby officially declares that the assets and liabilities of the Institute are: FOR SALE, and

BE IT FURTHER RESOLVED, that the Commission hereby directs its selling agent, W.Y. Campbell & Company, to immediately commence the marketing of the assets and liabilities of the Institute to prospective purchasers, and

BE IT FINALLY RESOLVED, that notice of this resolution be posted in the Michigan Register.

This is a true copy as passed by the Michigan Biologic Products Commission on July 1, 1997.

J. Louise Findley

J. Louise Findley
Executive Secretary, MBPC

RESOLUTION NO. 9

A RESOLUTION ESTABLISHING GUIDELINES FOR THE EVALUATION OF BIDS FOR THE MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

WHEREAS, on July 12, 1996, the Michigan Biologic Products Commission (the "Commission") adopted Resolution No. 4 establishing its goals with respect to the sale of the Michigan Biologic Products Institute (the "Institute") and making certain determinations in the furtherance of these goals; and

WHEREAS, on July 1, 1997, the Commission adopted Resolution No. 8 officially declaring the Institute for sale; and

WHEREAS, the Commission has concluded its initial marketing of the Institute and parties interested in purchasing the assets of the Institute have completed their initial due diligence investigations; asset purchase agreements are being developed.

NOW THEREFORE, BE IT RESOLVED, that the Commission reaffirms the goals and determinations of Resolution No. 4 and provides the following guidelines for the evaluation of bids to acquire the Institute:

- The amount and form of the consideration the state will receive for the assets of the Institute.
- The terms and conditions of employment for employees of the Institute, including plans to meet the requirements of P.A. No. 522 of 1996.
- The terms and conditions under which the liabilities of the Institute will be assumed.
- The term and conditions for providing the State of Michigan with preferential access to vaccines and other biologic products, consistent with P. A. No. 522 of 1996.
- The ability of the purchaser to continue operating the Institute in accord with U.S. FDA licensing standards.

AND BE IT FURTHER RESOLVED, that the Commission's selling agent, W.Y. Campbell & Company, and legal counsel to the Commission are hereby instructed to evaluate all bids for the Institute in consideration of the aforementioned guidelines and report their recommendations to the Commission no later than November 3, 1997.

This is a true copy as passed by the Michigan Biologic Products Commission on October 23, 1997.

J. Louise Findley

J. Louise Findley
Executive Secretary, MBPC

STATE OF MICHIGAN

JOHN ENGLER, Governor

DEPARTMENT OF COMMUNITY HEALTH

LEWIS CASS BUILDING
LANSING, MICHIGAN 48913
JAMES K. HAVEMAN, JR., Director

FOR IMMEDIATE RELEASE
January 2, 1998

PRESS CONTACT: Geralyn Lasher
(517) 241-2112

Bidding on Michigan Biologic Products Institute Re-Opened

Commission to Seek Temporary Extension to Protect Employee Jobs

The Michigan Biologic Products Commission today re-opened the bidding process on the sale of the Michigan Biologic Products Institute (MBPI). The Commission believes that the decision of the United States Department of Defense to vaccinate all troops against anthrax and the agreement to terminate with SmithKline Beecham may have a positive impact on the marketability of the Institute. MBPI is the only remaining state owned laboratory in the country.

The Commission believes these actions enhance the marketability of the Biologic Products Institute and will now re-open discussions with companies which have previously expressed an interest in acquiring the Institute. They noted that a continued relationship with the military had been expected and that the KPMG Peat Marwick valuation of the lab remains on target.

In order to protect the jobs of the employees of the MBPI and to continue to protect the men and women in the military from the threat of biological warfare and terrorism, the Commission announced it will seek a temporary extension of the Institute until it is sold. The extension will likely require an action of the state legislature.

"The employees of the Institute are an enormous asset. Their knowledge and ability cannot easily be reproduced. As a Commission, our priority is to sell the Institute as a whole in order to protect the jobs of these critical employees. Extending the Institute until it is sold will protect these employees and enable the nation to benefit from their expertise," said Commissioner James K. Haveman, Jr.

"The Department of Defense is the Institute's largest and most valued customer," said Haveman. "Providing the anthrax vaccine to the United States Military is critical to national defense and we will do all we can to ensure they receive an uninterrupted supply of licensed biologic products."

MBPI is a temporary two-year agency established under Article V, Section 4 of the Constitution of Michigan of 1963, which term shall end on February 18, 1998. Contracts for nearly half of the employees at MBPI expire on the sooner of the date of the sale or February 17, 1998, and the FY 1998 spending authorization for MBPI was appropriated at a level to provide for only six months of operations.

(More)

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MBPI currently has several biologic products in various stages of manufacture and is undertaking numerous activities in order to maintain compliance with U.S. Food and Drug Administration regulations. A disruption of MBPI operations such as that which would occur if MBPI is temporarily closed due to the expiration of its status as a temporary agency would threaten the loss of these products and MBPI's U.S. FDA licensed status.

MBPI has had a supply and distributions agreement with SmithKline Beecham since 1992. The State of Michigan and SmithKline Beecham have mutually agreed to end this agreement in the best interest of both parities.

Michigan Biologic Products Commissioners include Governor Engler's Special Advisor for Strategic Initiatives Dennis Schornack, State Budget Director Mary Lannoye and Department of Community Health Director James K. Haveman, Jr.

- 30 -

RESOLUTION NO. 10

A RESOLUTION TO RE-OPEN THE BIDDING PROCESS AND TO SEEK A TEMPORARY EXTENSION OF THE MICHIGAN BIOLOGIC PRODUCTS INSTITUTE UNTIL SOLD

WHEREAS, recently there have been three significant events which the Commission and its advisors believe have had a significant impact of the process of divesting the assets of the Michigan Biologic Products Institute (MBPI) and which warrant a return to the market:

> First, the United States Department of Defense (U.S. DoD) announced a new policy on December 15, 1997, to immunize all active duty and reserve military personnel against the deadly biological warfare agent anthrax. The U.S. DoD policy affirms the Commission's expectations and analyses dating back to October 1996. The U.S. DoD is MBPI's largest and most valued customer; the provision of anthrax vaccine to the U.S. DoD is considered critical to the national defense.
>
> Second, the State of Michigan and SmithKline Beecham have agreed in principle to terminate their contractual relationship.
>
> Third, the Commission's preferred bidder, after extensive due diligence investigations of MBPI, has expressed limited interest in acquiring MBPI assets and continued concerns that prevent it from making a firm acquisition offer, and

WHEREAS, the Commission believes that the aforementioned events may enhance the marketability of MBPI to parties that have previously expressed an interest in MBPI sufficient to conduct initial due diligence, and to other parties who have expressed an acquisition interest but are not presently able to access the divesture process, and

WHEREAS, MBPI is a temporary two-year agency established under Article V, Section 4 of the Constitution of Michigan of 1963, which term shall end on February 18, 1998. Contracts for nearly half of the employees at MBPI expire on the sooner of the date of the sale or February 17, 1998, and the FY 1998 spending authorization for MBPI was appropriated at a level to provide for only six months of operations, and

WHEREAS, MBPI currently has several biologic products in various stages of manufacture and is undertaking numerous activities in order to maintain compliance with U.S. Food and Drug Administration regulations. A disruption of MBPI operations such as that which would occur if MBPI is temporarily closed due to the expiration of its status as a temporary agency would threaten the loss of these products and MBPI's U.S. FDA licensed status, and

WHEREAS, the Commission is committed to ensuring the ongoing operational viability of MBPI until its transfer to the private sector is complete. In so doing, the State of Michigan will receive maximum consideration for MBPI assets, customers including the U.S. DoD will continue to receive an uninterrupted supply of licensed biologic products, regulators will be assured of continuity and a commitment to compliance, and MBPI employees will continue to work at their jobs without interruption.

NOW, THEREFORE, BE IT RESOLVED, that the Commission hereby re-opens the bidding process for MBPI to parties that have previously expressed an interest in acquiring MBPI sufficient to conduct initial due diligence, and to other parties who have expressed an acquisition interest in MBPI but are not presently engaged in the divestiture process. The Commission hereby directs its selling agent, W.Y. Campbell & Company, to contact such parties to advise them of the aforementioned events and to ascertain their interest in acquiring MBPI in light of these events and to report back to the Commission by January 9, 1998, on the outcome of these contacts, and

BE IT FURTHER RESOLVED, that the Commission will, through any and all means including the enactment of appropriate state legislation, seek a temporary extension of the MBPI until it is sold.

This is a true copy as passed by the Michigan Biologic Products Commission on January 2, 1998.

J. Louise Findley

J. Louise Findley
Executive Secretary, MBPC

RESOLUTION NO. 11

A RESOLUTION TO RECOMMEND A PROPOSED TRANSFEREE AND THE TERMS OF A PROPOSED TRANSACTION

WHEREAS, Public Act No. 522 of 1996, as amended by Public Act No. 8 of 1998, the "Michigan Biologic Products Institute Transfer Act" (the "Transfer Act") authorizes the transfer of the assets and liabilities of the Michigan Biologic Products Institute (the "Institute") and authorizes the Michigan Biologic Products Commission (the "Commission") to retain a selling agent, solicit prospective transferees, and negotiate the terms of one or more proposed agreements for the conveyance with one or more proposed transferees; and

WHEREAS, the Commission established its goals with respect to the transfer transaction through the adoption of Resolution No. 4 on July 12, 1996; and

WHEREAS, the Commission, through its selling agent W.Y. Campbell & Company, has actively and exhaustively solicited prospective transferees since July 1, 1997; and

WHEREAS, the Transfer Act established certain conditions for the conveyance including commitments by the purchaser to provide the state with preferential access to vaccines and other biologic products and to continue the employment of Institute employees for not less than one year after the transfer; and

WHEREAS, the Commission has negotiated the terms of a proposed Asset Purchase Agreement with a proposed transferee which comply with the conditions established by the Transfer Act.

NOW, THEREFORE, BE IT RESOLVED, that the Commission recommends the firm of BioPort Corporation as its proposed transferee, and

BE IT FURTHER RESOLVED, that the Commission hereby recommends the terms of the proposed transaction to the State Administrative Board (the "Board") and requests the Board's approval to execute the proposed agreement in the name of the state. Pending Board approval, the Commission deems the Asset Purchase Agreement to be advisory and preliminary to a final determination, and

BE IT FINALLY RESOLVED, that copies of this resolution and the terms of the proposed transaction be simultaneously distributed to the State Administrative Board and its fairness opinion provider, and be placed in the permanent files of the Commission.

This is a true copy as passed by the Michigan Biologic Products Commission on June 2, 1998.

J. Louise Findley

J. Louise Findley
Executive Secretary, MBPC

Approved
Signed

DRAFT

RESOLUTION NO. 12

A RESOLUTION TO DISSOLVE THE COMMISSION AND TRANSFER ADMINISTRATION OF THE ASSET PURCHASE AGREEMENT TO THE MICHIGAN DEPARTMENT OF MANAGEMENT AND BUDGET

WHEREAS, the Michigan Biologic Products Commission (the "Commission") was initially established by Executive Order 1995-25, given certain statutory responsibilities pursuant to Public Act No. 522 of 1996, and re-established by Public Act No. 8 of 1998; and

WHEREAS, the Commission's essential purpose was to transfer by sale, or otherwise, the assets and liabilities of the Michigan Biologic Products Institute (the "Institute") out of state government and into the private sector; and

WHEREAS, the Commission, with the assistance of its selling agent, W.Y. Campbell and Company, conducted an extensive, open, and competitive sales process which lasted nearly two years and engaged the interest of nearly two dozen firms; and

WHEREAS, the Commission concluded its modified auction of the assets and liabilities of the Institute on June 2, 1998, and recommended BioPort Corporation as its proposed transferee; and

WHEREAS, pursuant to Public Act No. 522 of 1996, as amended by Public Act No. 8 of 1998, the State Administrative Board approved the sale of the Institute and authorized the Commission to execute an Asset Purchase Agreement between the State of Michigan and BioPort Corporation on July 7, 1998; and

WHEREAS, the Commission closed the sale of the Institute by executing an Asset Purchase Agreement between the State of Michigan and BioPort Corporation on September 4, 1998; and

WHEREAS, the statutory duties and responsibilities of the Commission have been completed; and

WHEREAS, the Commission was not charged with responsibility to administer the contractual terms and conditions of the Asset Purchase Agreement between the State of Michigan and BioPort Corporation; and

WHEREAS, pursuant to the Asset Purchase Agreement, from time to time, monetary payments or other obligations of BioPort Corporation may become due to the State of Michigan; and

No. 1 of 1

DRAFT

WHEREAS, pursuant to Public Act 431, 1984 as amended, the Michigan Department of Management and Budget is responsible for establishing and administering state procurement practices, contract monitoring, facility management, and establishing a system of internal financial controls.

NOW, THEREFORE, BE IT RESOLVED, that the Commission hereby transfers all of its administrative authority, including signatory authority, duties, and documents to the Michigan Department of Management and Budget; and

BE IT FURTHER RESOLVED, that the Commission assigns to the Director of the Michigan Department of Management and Budget complete authority to perform any and all tasks and duties assigned to the Chair of the Commission under the Asset Purchase Agreement and related agreements, and to sign any documents required by such agreements; and

BE IT FINALLY RESOLVED, that the Commission is hereby dissolved. "Venimus, vendidimus, execessimus."

This is a true copy as passed by the Michigan Biologic Products Commission on July 26, 1999.

J. Louise Findley

J. Louise Findley

From Institute to Incorporation: A Plan to Convert the Michigan Biologic Products Institute into a Private Business

A Report to the Governor
from the Michigan Biologic Products Commission

November, 1996

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE
ROBERT C. MYERS, D.V.M., DIRECTOR
3500 N. MARTIN LUTHER KING, JR., BLVD.
P.O. BOX 30035
LANSING, MICHIGAN 48909
TELEPHONE: (517) 335-8120
FAX: (517) 335-9486

MICHIGAN BIOLOGIC PRODUCTS COMMISSION
DENNIS L. SCHORNACK, CHAIR
JAMES K. HAVEMAN, JR.
MARY A. LANNOYE

November 7, 1996

The Honorable John Engler
Governor of Michigan
Olds Plaza Building
111 S. Capitol
Lansing, Michigan 48933

Dear Governor Engler:

I commend to you the enclosed plan of the Michigan Biologic Products Commission required under Executive Order 1995-25. The plan details the reasons, goals, and process for transferring the Michigan Biologic Products Institute (MBPI) out of state government and into the private sector. It includes a pro forma balance sheet for the MBPI as of September 30, 1995, and pro forma statements of operations for the fiscal years ended September 30, 1993-96, compiled by independent accountants as well as a preliminary valuation of the MBPI assets. An outline of the necessary implementing legislation is also included.

The Commission is confident that the decision to transfer the MBPI out of state government and into the private sector is the correct one. The state will save money while at the same time providing the best opportunity to retain the jobs and other economic benefits associated with the manufacture of biologic products in Michigan. We look forward to immediate implementation of the plan.

Sincerely,

Dennis L. Schornack
Chair
Michigan Biologic Products Commission

DLS/jlf

Enclosure

for public or private use outside of Michigan (see MCL 333.9112 and related analysis in Appendix A). This allowed the Division to retain the revenues generated from the manufacture and sale of biologic products in a segregated fund for investment in improving the facilities and the biologic products program.

By 1990, the Division began to position itself to become financially self-sufficient and partnered with several private sector firms and other non-state organizations. The MBPI currently has contracts to supply products to private firms such as SmithKline Beecham, Athena Neurosciences, North American Biologicals, Inc., and public organizations including two Michigan Red Cross regions and the United States Department of Defense. Revenues earned under these contracts have enabled the MBPI to reduce its dependence upon State funds and achieve its goal to become self-supporting. In fact, the Fiscal Year 1997 budget for the MBPI contains no general fund dollars.

Products. The MBPI is engaged in the production, sale, and associated research and development of vaccines for the prevention of infectious diseases in children and adults; it also provides blood fractionation services to two regions of the Michigan Red Cross. The MBPI's physical plant is licensed by the U.S. FDA. All of the MBPI's product licenses are current and subject to ongoing U.S. FDA regulation.

Exhibit 1.1 shows the MBPI's U.S. FDA and USDA product licenses, and all MBPI products currently made under Investigational New Drug (IND) Applications. Exhibit 1.2 shows the dates Michigan received licenses for its currently made vaccine and blood products.

Exhibit 1.1 U.S. FDA and USDA Product Licenses and IND Applications

U.S. FDA Product Licenses
Anthrax Vaccine Adsorbed
Rabies Vaccine Adsorbed
Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed
Diphtheria and Tetanus Toxoids Adsorbed
Tetanus Toxoid Adsorbed
Pertussis Vaccine Adsorbed
Albumin (Human)
Antihemophilic Factor (Human) 500 IU/vial
Immune Globulin (Human) 16.5%
U.S. FDA Investigational New Drug (IND) Applications
Botulinum Toxin Type B
Pentavalent Botulinum Toxoid
Hepatitis B Immune Globulin, Virus Inactivated
Anthrax Vaccine Adsorbed
DTPw plus Hib
DTPw plus Hepatitis B plus Hib
DTPa plus Hepatitis B plus Hib
DTPa
DTPa plus Hepatitis B
USDA Biologic Licenses
Botulinum Toxoid Type B, for equine use

Exhibit 1.2 Currently Made Licenses for Vaccines and Blood Products by MBPI

Vaccines	
Tetanus	October, 1930 (antitoxin); September, 1955 (adsorbed)
Rabies	First licensed in 1932; improvements in 1973 and 1989
Pertussis (whole-cell)	November, 1935
DTP	September, 1955
DT (pediatric)	August, 1955
Anthrax	November, 1970
Blood Derivatives	
Albumin	December, 1948
Immune Serum Globulin	December, 1948
Anti-Hemophilic Factor	May, 1964

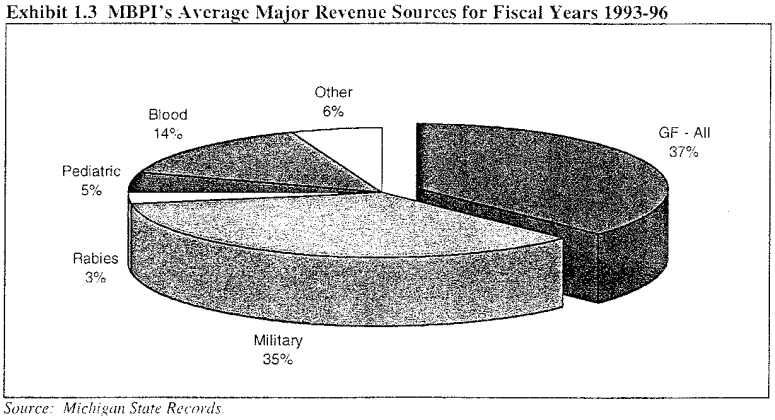
It should be noted that the MBPI has manufactured and distributed three of the nine pediatric vaccines required for children to enter daycare and school under State immunization laws. One of these vaccines, whole-cell pertussis, is no longer being manufactured by the MBPI because its has recently been rendered obsolete by the licensure of the improved acellular pertussis vaccine. Since pertussis vaccine is administered in combination with diphtheria and tetanus, Michigan's basic DTP

vaccine is no longer in demand. The MBPI is also the *only* licensed manufacturer of the intramuscular (IM) rabies and anthrax vaccines in North America (another IM rabies vaccine is made in Europe and imported to the U.S.).

Finally, the MBPI is registered by the U.S. Department of Agriculture under the Animal Welfare Act to produce and maintain animals for testing, and houses the only SIV-free, reproducing rhesus monkey colony in North America (approximately 80 animals).

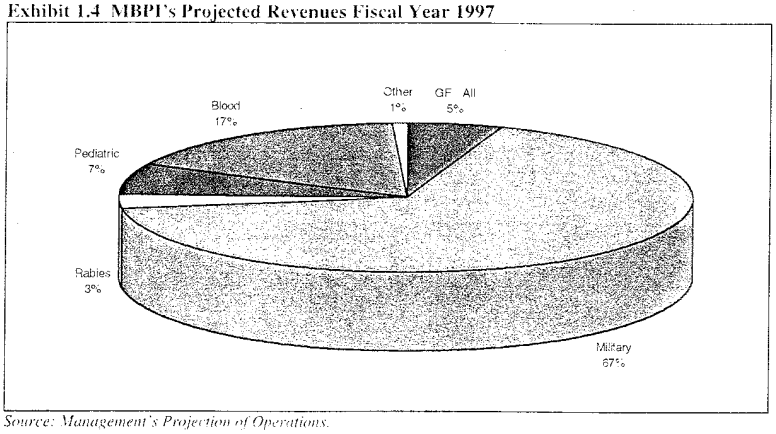
Market. From 1993 to 1996, 37% of MBPI's revenue came from the general fund, as shown in Exhibit 1.3. It should be noted that the general funds have been eliminated for FY 1997 and will no longer be provided when the MBPI becomes a private business. The largest source of revenue from product sales are military vaccines, which comprised 35% of the MBPI's total revenues. Revenues from the sale of blood products generated 14%, while revenues from the manufacture and sale of pediatric and rabies vaccines generated 5% and 3%, respectively.

Exhibit 1.3 MBPI's Average Major Revenue Sources for Fiscal Years 1993-96



Source: Michigan State Records

Exhibit 1.4 MBPI's Projected Revenues Fiscal Year 1997



Source: Management's Projection of Operations.

Total revenues from product sales are forecasted by management to increase from their current levels over the next five years. Revenues generated from blood products and from the distribution and sale of vaccine products, primarily to the U.S. Department of Defense, are forecasted to gradually increase over the next three years. The MBPI appears to have a steady and significant customer in the U.S. military for sales of the anthrax vaccine and various botulinum toxoids well into the future. On October 2, 1996, it was reported that U.S. military officials have endorsed a plan to vaccinate all U.S. troops against anthrax—a vaccine for which the MBPI is the only licensed manufacturer. The MBPI has long played an important role in protecting U.S. troops from the threat of biological warfare, and, in 1991 it received the Commanders Award for Public Service for its role in Desert Storm.

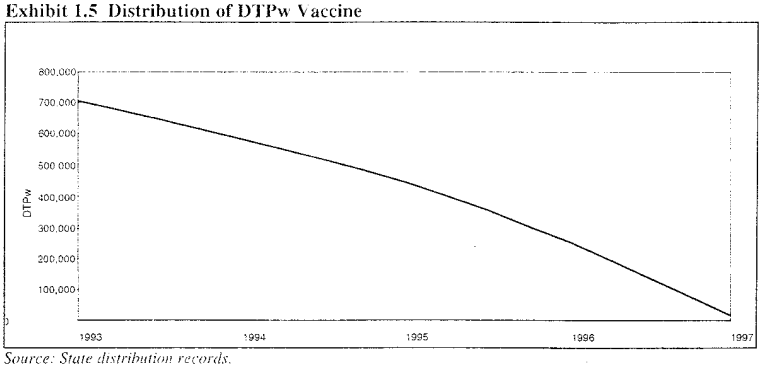
Pediatric Vaccine Market. The pediatric DTPw vaccine containing whole-cell pertussis has long been the raison d'etre of the Biologic Products Division as a state agency. The state makes and combines the component antigens for the DTPw vaccine and distributes it at no cost to local public health clinics throughout Michigan. However, the advent of new and improved pediatric vaccines has led to its obsolescence. Acellular pertussis (Pa) and more comprehensive combination vaccines (e.g., DTPa Hib) are rapidly displacing the DTPw vaccine. The results of major clinical trials in Sweden and Italy announced during the summer of 1995 showed that DTPa is not only safer (i.e., produced fewer adverse reactions), but more effective than DTPw vaccines such as that made by the MBPI.

Based on these clinical findings, the licensure of DTPa vaccine was accelerated, and in August 1996, the first acellular vaccine for infants was licensed. The market for this product is quickly developing; several manufacturers are expected to receive licenses in the immediate future. Many Michigan health-care providers, including the State public health agency, are choosing to buy these

state-of-the-art combination vaccines over using the "free" vaccine available from the MBPI. In 1995, the Michigan Department of Public Health distributed over 150,000 doses of the DTPa vaccine and next year the Federal Centers for Disease Control (CDC) plans to stop buying the whole-cell pertussis containing (DTPw) vaccine altogether.

In a three-year period, distribution of the Division's DTPw vaccine fell from 703,625 doses in 1993 to 584,000 doses in 1994 to 447,200 doses in 1995. In 1996, distribution through September was 184,460 doses, and the annual total will likely be less than 250,000 doses. Distribution in 1997 is expected to fall as low as 20,000 doses.

Exhibit 1.5 Distribution of DTPw Vaccine



Source: State distribution records.

In the late 1980's, the Division ceased development of its own DTPa vaccine for two basic reasons: Further clinical trials represented an unacceptable cost; and a licensed DTPa vaccine would have required new production facilities.

Exhibit 1.6 illustrates significant milestones in MBPI's history.

Exhibit 1.6 Milestones in MBPI's History

1921	Governor Groesbeck signed law allowing manufacture, purchase, and distribution of products for control of diphtheria.
1926	Establishment license No. 99 granted to laboratories for the manufacture of biologic products. Diphtheria vaccine made.
1927	Manufacture or purchase of any biologic product for the control of communicable disease is authorized; law permitting manufacture only if cheaper than purchase is repealed
1935-42	Most of MBPI's buildings constructed under Work Projects Administration of Franklin D. Roosevelt.
1940	Pertussis vaccine made and distributed; certification by War Department of laboratories as primary defense industry.
1941	Statewide blood plasma collection and processing program begun.
1953	Synnematin B, an antibiotic for typhoid, is the first patented state product; a lack of commercial activity leads to its discontinuation.
1957	Blood fractionation laboratory enlarged and automated.
1965	Development of rabies vaccine begun.
1967-68	Original anthrax contract.
1970	Anthrax vaccine licensed.
1972	Power plant completed; cooperative program with Red Cross Regional Blood Centers established for plasma fractionation.
1973	Improved rabies vaccine developed with federal funding support.
1984-85	Liability crisis results in shortage of DTP and MMR vaccines
1986	Federal Vaccine Injury Compensation Fund established to compensate victims of adverse reactions (Sec. 4131 of 1986 IRS Code).
1989	Improved intramuscular rabies vaccine approved.
1991	Commanders Award for Public Service given for providing vaccines to protect troops in Desert Shield and Desert Storm conflict.
1992	Contracts with SmithKline Beecham for out-of-state distribution of pediatric and rabies vaccines; first DTPa booster licensed.
1993	State agreed to pay vaccine excise tax like all manufacturers.
1996	First DTPa vaccine licensed for infants; DTPw obsolete.

II. Executive Order 1995-25

As a state agency, the Division is subject to all of the operating constraints of a public sector entity. These constraints are not conducive to operating a biotechnology organization that is financially viable and able to compete in a dynamic marketplace. Even as the Division has developed new products and customer relationships, the U.S. FDA continues to monitor the Division's ability to comply with standards for current Good Manufacturing Practices (cGMP). For example, U.S. FDA regulations require the Responsible Head of Manufacturing to exercise complete managerial control over the entire enterprise [21 CFR 600.10 (a)], a degree of authority and latitude that is inconsistent with the authority of a division chief within a state department.

Government constraints slow the development of new products, complicate customer relationships, and make it difficult to acquire and accumulate the capital needed to replace existing production facilities. Civil Service regulations, the annual legislative appropriations process, and the extensive controls over public procurement inhibit the Division's ability to respond with a business sense of urgency to market conditions.

Consider the nature of developing new products and taking them through clinical trials to licensure: Today, it takes five to seven years and approximately $100 million to move a new product through clinical trials to licensure, and only a handful of new products ever actually become licensed to enter the marketplace. Competing in the biotechnology industry on these terms is an inappropriate risk and a significant financial venture for Michigan's taxpayers.

Owning the means of production and taking risks with public funds in the pursuit of potential future profits is inconsistent with the general philosophy and function of state government in a capitalist democracy. Michigan Governor John Engler concluded that competing with today's biotechnology industry is not essential to fulfilling the State's public health mission of assuring age-appropriate immunization of children. Even without the Division's pediatric vaccines, Michigan's public health community will continue to have access to state-of-the-art vaccines at no cost through the federal Vaccines for Children and Sec. 317 grant programs that other states utilize to meet their public health needs.

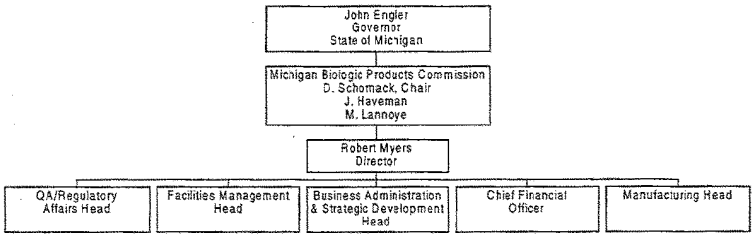
In recognition that the best interest of the public and the Division would be served by moving the Division out of state government and into the private sector, Governor Engler signed Executive Order 1995-25 on December 15, 1995. The Executive Order established the Michigan Biologic Products Institute (MBPI), transferred all assets and personnel from the Division to it, and created the Michigan Biologic Products Commission (the "Commission") to provide policy control and to develop and implement a plan to move it into the private sector (See Appendix C).

The MBPI was created as a temporary agency with a life of no more than two years. The Division and the administration of the Pharmaceutical Products Fund (PPF), established under Sections 9111 and 9112 of Act No. 368 of the Public Acts of 1978 (see Appendix A), were transferred to the MBPI by a Type III transfer, as defined by Section 3 of Public Act No. 380 of the Public Acts of 1965. The MBPI assumed all functions, duties, contractual obligations, responsibilities, inventory, tangible and intangible property and employees of the Division,

including administration of the PPF. Furthermore, the existing Chief of the Division, Robert C. Myers, DVM, became the Responsible Head of Manufacturing and the initial Director of the MBPI; he reports to the Commission.

The Commission, which was also created as a temporary agency with a life of no more than two years, is composed of a three-member committee whose purpose is to prepare a plan, including any necessary legislation, to transfer the MBPI out of state government and into the private sector, and to determine the fair-market value of all the State's assets associated with the manufacture of biologic products. Exhibit 2.1 depicts the reporting structure of the MBPI.

Exhibit 2.1 Reporting Structure of the Michigan Biologic Institute



III. Goals of the Michigan Biologic Products Commission

Resolution No. 4, included in Appendix D, specifies the goals of the Commission and makes certain determinations with respect to the transaction to sell the MBPI. In brief, Resolution No. 4 states that the transaction to sell all of the State's assets associated with the manufacture of biologic products should be structured so that:

- it is a single transaction and assets or lines of businesses are not sold piecemeal;
- the purchasing entity is able to effectively contribute to Michigan's economy by increasing jobs, retaining the know-how associated with the manufacture of biologic products, and maintaining production capacity by replacing the existing facilities;
- the State retains preferential access to biologic products for use by Michigan public health agencies; and,
- the State receives fair consideration for the assets being sold.

Resolution No. 4 also encourages employee participation in the process.

IV. MBPI Assets and Financial Condition

MBPI Facilities. Pursuant to Resolution No. 4, the Commission required the campus grounds to be surveyed to accurately define the perimeters of the MBPI. Included in Appendix D are Commission Resolutions No. 5 and No. 6 which detail the east and west campus surveys, and provide the actual legal descriptions for the lands on which the MBPI campus is located.

A Master Plan Study and Facilities Inventory for the North Logan/Martin Luther King, Jr. Boulevard Government Complex was substantially completed June 28, 1996, by the independent engineering firm Smith, Hinchman & Grylls Associates, Inc. (SH&G). The detailed study encompassed the existing facilities of the Departments of Public Health, Natural Resources, Management and Budget, and their common site, and identified deficiencies in order to provide a data base for the State's future planning for State laboratories. The MBPI's facilities are a subset of those examined in the SH&G report.[3]

The MBPI consists of 28 buildings containing 245,606 gross square feet of laboratory, pharmaceutical manufacturing, office, and warehouse space. The MBPI also houses its own power plant which provides pharmaceutical grade steam, water for human injection, and vacuum and compressed air to its facilities. The site is located on the northwest side of the City of Lansing. The North Logan/Martin Luther King, Jr. Boulevard divides the site into two parcels, commonly referred to as the east and west campuses. (Appendix E depicts an aerial photograph of both campuses, a map of the regional context of the facilities, and a map of the site context of the facilities.) Two of the MBPI's buildings, numbers 45 and 46, are owned by the U.S. Department of Defense, and some of the MBPI's other major customers have made significant investments in the MBPI's laboratories. SH&G's evaluation of the MBPI buildings is summarized in Exhibit 4.1.

There has been a long-standing recognition that facilities at both the east and west campuses are antiquated and in need of substantial renovation or replacement. It is widely agreed that the surplus vacant land comprising the west campus will be attractive to potential buyers when considering a location for replacement facilities and future growth. Furthermore, the Code of Federal Regulations states that locating a new production facility within the "general physical location of the existing facility" will require only a supplement to the current establishment license rather than an application for a new license. The User Fee Act (P.L. 102-571) further defines "general physical location" to include all buildings within five miles of each other [2.1 USC Sec 379(g)].

[3] The SH&G report is available for review upon request.

Exhibit 4.1 Michigan Biologic Products Institute Campus Buildings

Bldg. No.	Building Name	Function	Year Built/ Improved	Gross Sq. Ft.	Overall Recommendation	
					Renovate	Remove
1	C.C. Young	Office, Lab, Security	1937	29,714	✔	
2	MBPI Administration & Research	Office, Lab	1976	29,338	✔	
3	Blood Fractionation Laboratory	Lab, Production	1935	18,716	✔	
4	Blood Fractionation	Storage	1936-43	6,032		✔
5	Tetanus Scale-Up	Lab	1939	5,097		✔
6	Stock Room	Storage	1926	7,504	✔	
7	Maintenance Shop	Maintenance	1939	9,807	✔	
8	Electric Substation	Services	1937	1,712	✔	
9	Vaccine Laboratory	Lab	1935	4,141		✔
10	Barn (includes NIH Rhesus Colony)	Animal Housing	1926	12,098		✔
11	Cell Culture Lab	Lab	1932	2,046		✔
12	Vaccine Production, Animal Testing	Production, Animal Housing	1943	12,944	✔	
13	Rabies Vaccine Production	Lab, Production	1939	3,052	✔	
14	Botulinum Laboratory	Lab, Production	1941	1,930	✔	
16	Vaccine Production, Filling, Packaging	Manufacturing	1942	24,254	✔	
17*	Water Resource Laboratory	Lab	1936-79	2,885	✔	
20	Chemical Storage Vault	Storage	1935	630		✔
22	Farm Building (W of MLK Blvd.)	Storage	1942	3,625		✔
23	Farm Building (W of MLK Blvd.)	Storage	1943	3,922		✔
24	Barn (W of MLK Blvd.)	Animal Housing	1938	19,652		✔
25	Small Heating Plant	Services	—	509		✔
29*	Neo-Natal Lab	Lab	1948	13,946	✔	
30	Quality Control	Lab	1966	13,144	✔	
31	Animal Production	Lab	1970	13,996	✔	
32	Heating & Distribution Plant	Services	1971	8,937	✔	
45	BL-3 Animal Facility	Animal Housing	1995	1,461	None	None
46	Biologic Warehouse	Storage	1994	3,881	None	None

** Indicates buildings occupied by non-Institute personnel.*

Source: Master Plan Study and Facilities Inventory for the North Logan/Martin Luther King, Jr. Boulevard Government Complex, Smith, Hinchman & Grylls Associates, Inc. Report, Executive Summary, Vol. 1, Evaluation Summary Matrix.

Financial Condition. The MBPI has operated as a state agency since its inception. As such, it has had general fund appropriations and generally funded services such as maintenance and administrative overhead to subsidize its operations. The pro forma balance sheet and pro forma statements of operation presented in Appendix F represent the MBPI "as if" it were in operation as a separate business during each of the three years ended September 30, 1995, 1994 and 1993, respectively.[4]

Under generally accepted accounting principals, general fund monies and generally funded services are not considered revenue to the MBPI and therefore are not included as revenue in the pro forma financial statements. In a business context, these funds would be considered "tax subsidies." This fact largely accounts for the net operating losses for the years presented.

The MBPI's historical financial position (as represented by the pro forma balance sheet) consists of accounts receivable, inventory (stated at the lower of estimated average cost or market), and property, plant and equipment less accumulated depreciation. Correspondingly, MBPI's total assets at September 30, 1995, were approximately $14.6 million, over half of which is receivables.

Valuation of MBPI. KPMG Peat Marwick LLP (KPMG) conducted a preliminary determination of the fair market value of the Institute as of October 18, 1996 (the valuation date). For purposes of the study, fair market value was defined as follows:

> "The price at which the property would change hands between a willing buyer and a willing seller when the former is not under any compulsion to buy and the latter is not under any compulsion to sell, both parties having reasonable knowledge of relevant facts."

Since there were no plans at the valuation date to liquidate the Institute in whole or in part, fair market value was determined on a going-concern basis. While it was originally anticipated that KPMG's valuation would consist of a comparative company approach to value, which would include analysis of historical financial and operating results as well as study of comparative acquisitions of comparable businesses, the absence of positive earnings over the 1994-1995 period together with the expected occurrence of a number of material events concerning the Institute in 1997 resulted in KPMG's reliance upon a discounted cash flow (DCF) approach to value. The DCF approach is based upon estimated future income streams (in this case over the 1997-2002 period), the average annual rate of return anticipated, and market rates of return. To develop an opinion of the present value of the future benefits of ownership of the Institute, the income streams are capitalized by means of a discount rate reflecting both general risks and those specific to the asset in question.

KPMG provided an estimated range of values contingent upon certain variable assumptions set forth in its valuation conclusion letter, included within this report as Appendix E. As stated in the conclusion letter,

[4] Fiscal Year 1996 pro forma figures will be available in a separate report.

"Taking into account all that was developed through our study, it is our preliminary opinion that the fair market value of the equity of the Michigan Biologic Products Institute on a going-concern basis at the valuation date ranged from nominal, assuming projected anthrax vaccine sales of 1.5 million to 2.5 million doses annually, to $10.5 million, assuming anthrax vaccine sales of 3.0 million to 5.0 million doses annually at a price of $3.25 per dose."

V. Process to Move MBPI Out of State Government

The process of moving the MBPI out of State government, to be accomplished by the sale or transfer of the MBPI business to a private sector buyer, has two discrete steps: 1) the adoption of legislation authorizing the transfer, and 2) the actual sale or transfer process itself. By authorizing the sale or transfer of the MBPI business, the Legislature will allow the Commission to move forward with the actual transfer. That transfer, to be accomplished in accordance with Executive Order 1995-25 and the goals established by the Commission in Resolution No. 4, may best be accomplished with the help of a professional experienced in structuring, pricing and implementing sales of ongoing business entities.

Legislative Step of the Move of MBPI out of State Government. The legislative proposal for the implementation of the MBPI transaction is outlined in Appendix H. This proposal would authorize the State Administrative Board to approve the transfer of all or a portion of the assets and liabilities of the MBPI to one or more transferees recommended by the Commission.

The legislation proposes certain conditions upon the State Administrative Board's approval of the transfer of MBPI, including the following:

1. A determination that consideration to be received is sufficient to prevent the lending of the credit of the State.
2. A determination that the process employed by the Commission to select the recommended transferee has given due consideration to a transferee which includes employee participation.
3. Subject to satisfactory performance, that the recommended transferee will agree to continued employment for at least one year of current MBPI employees electing employment with the transferee.
4. The transferee will agree to provide the State with preferential access to the biologic products it makes.

Upon approval of the State Administrative Board, the Chair of the Commission, or his or her designee, would be authorized to execute an agreement effectuating the transfer.

The proposed legislation would also appropriate the monies in the Products Fund and the net proceeds from the sale of the MBPI. This appropriation could be expended to fund, in order of priority, the payment of accrued sick and annual leave time of MBPI employees who separate from state employment, the reimbursement of the State for any other payments of accrued sick and annual

leave time paid from other appropriated funds, the reimbursement of the state employee retirement system for the cost of the proposed early retirement option elected by eligible MBPI employees and expenses of the State related to the transaction. Any unexpended amount would be retained in the Pharmaceutical Products Fund to improve the state's immunization program.

Eligible employees of the MBPI who stay with the transferee for one year after the sale would be granted the right to purchase years of credited service at the state's actuarial cost, excluding the cost of health and medical benefits. In addition, eligible employees of the MBPI may elect early retirement similar to the rights granted to State Accident Fund employees upon separation from the State. In particular, non-vested employees with five or more years of credited service would be allowed to purchase credited service sufficient to vest them for pension and retirement health/medical benefits. Employees with MBPI with combined 70 years of age and service could elect early retirement at unreduced benefit levels.

Actual Transfer of MBPI out of Government. Once the Legislature has authorized the transfer of the MBPI, the actual sale or transfer may be undertaken. Several different procedures could be used to identify potential purchasers of the MBPI and to accomplish the transaction. The actual sale procedure selected will be dependent on the determination as to the preferred structure of the transaction and the likelihood of receiving multiple offers which meet the Commission's goals.

Sale procedures include a "bid" procedure, a request for qualification ("RFQ") procedure and a "negotiated" procedure. The bid procedure might be most appropriate in a circumstance in which the Commission is able to determine with some specificity the structure of the transaction in a manner which will assure the accomplishment of the Commission's goals, and that multiple parties will be willing to bid on the transaction as so structured. The RFQ process will be more appropriate in circumstances where the Commission is uncertain as to the market acceptability of any particular structure but believes that multiple parties may be interested in structuring a transaction which would meet the its goals. Finally, the negotiated process might be appropriate in a circumstance where the Commission determines that the greatest likelihood of achieving the maximum percentage of its goals lies with structuring the transaction with a unique entity or combination of entities.

The most appropriate procedure and the one preliminarily selected, given the terms of Executive Order 1995-25 and the goals of the Commission (see Commission Resolution No. 4 in Appendix D), is the RFQ procedure. Suggested steps for the RFQ procedure are generally as follows:

1. Completion of financial information and valuation.
2. Completion of internal procedures for sale including due diligence reviews, environmental investigations and clean-up of matters as necessary.
3. Preparation of disclosure documents describing the MBPI and the Commission's goals.
4. Circulation of RFQ document requesting (a) statement of qualifications, (b) expression of interest, and (c) proposed structure of the transaction.
5. Analysis of responses and selection of party with whom to negotiate.
6. Negotiation of transaction.
7. Completion of due diligence.
8. Finalization of transaction.

9. Confirmation of adequacy of consideration through receipt of fairness opinion or valuation confirmation.
10. Closing.

Role of the Selling Agent. The Commission recognizes there may be the need to consider the retention of a selling agent to assist it in the sale process. The agent may help develop the sale process by identifying potential bidders or buyers, managing the RFQ process, developing appropriate disclosure documents, and otherwise aid the Commission in comparing qualifications and quotes. The Commission also notes that the State Administrative Board may, at its sole discretion, require an opinion as to the fairness of the financial transaction prior to approval of the sale.

VI. Conclusion

Michigan is the *last* state in the nation that still produces vaccines; all other states rely on the federal Vaccines for Children and Section 317 grant programs to meet their public health needs for vaccines. Even without the vaccines made by the MBPI, Michigan children will continue to receive needed pediatric vaccines at no cost through the same local health departments and physicians' offices that they do today. The State's mission to protect the public health through age-appropriate immunization of children will not be impaired by the sale of the MBPI.

While making its own DTPw vaccine helped Michigan through the shortage of the 1980's, the advent of the national Vaccine Injury Compensation Fund for victims of vaccine injuries has led to a resurgence of private manufacturers. Today, there are eight manufacturers making pediatric vaccines. More importantly, the MBPI no longer makes pediatric vaccines that are used and sold separately; its DTPw vaccine is obsolete, and its diphtheria and tetanus vaccines are essentially useful only as building block components of the new multivalent vaccines now beginning to dominate the market. Since the MBPI makes only 2 of the 9 vaccines required for school entry in Michigan, it has never been able to cover the contingency of shortages of vaccines it does not make. The argument that state government should continue to make its own vaccines to protect against potential future shortages is no longer valid.

From a practical and public policy point of view, the State should not own the means of production for biologic products. The operating constraints of the public sector make it ill-suited for the efficient management of a technically complex enterprise in a highly competitive market environment. More importantly, it is inappropriate to risk public funds on the costly research and development of new products that may or may not become licensed. By transferring operations to the private sector, the state can fulfill its responsibility to protect its citizens in a far more efficient manner.

It has long been recognized that the MBPI facilities are in need of replacement. Indeed, the vast majority of the renovations that have been done on these facilities over the past decade have been funded not by the State, but rather by the MBPI's customers. The State has been appropriately reluctant to invest public funds in new biologic production facilities given competing needs for

other public works such as schools and prisons. The Commission believes that the need for replacement facilities will more likely be met from private sources with a stake in the enterprise.

Transferring the MBPI to the private sector also presents challenges. While the market is an efficient engine of production—it is unpredictable. Becoming a private business will mean that the MBPI will be run for profit, and unprofitable activities will be curtailed. Decisions regarding what will be manufactured, and where, will be made on an economic basis rather than a political basis. The transfer of operations from the public to the private sector will also impact MBPI's employees, all of whom have a stake in the manner and outcome of this change.

The Commission recognizes the historical contribution to the State made by the employees of the MBPI, and the continuing value of the production know-how they possess. For these reasons, the Commission is recommending very fair retirement considerations, assured employment with the transferee for one year following the sale, and the opportunity for employees to participate in the purchase of the MBPI. The Commission firmly believes that the prospect for future employment for existing MBPI employees is far brighter if the MBPI is moved into the private sector as opposed to remaining a state agency.

The purpose of this plan is to describe the reasons, goals, and process for transferring the MBPI out of state government. Implementing this plan will require the passage of legislation consistent with the outline contained in Appendix H and an orderly and open process for concluding the sale.

333.9111 Pharmaceutical, biologic, and diagnostic products and by-products for human, veterinary, or agriculture use; developing, producing, purchasing, and receiving by gift; research; distribution; costs.

Sec. 9111. (1) The department may develop produce purchase and receive by gift pharmaceutical, biologic, and diagnostic products and by-products for human, veterinary, or agricultural use. The department, when necessary, may engage in research to improve these products to develop new products. The department may distribute the products and by-products within this state and recover the actual costs associated with the products and by-products. The department shall provide and distribute these products and by-products at no cost upon request of local health departments, hospitals, or physicians for use within this state if considered necessary by the department to protect the public health.

(2) The department may develop and produce pharmaceutical, biologic, and diagnostic products and by-products for human, veterinary, or agricultural use for distribution or sale outside this state for both public and private use, if the distribution or sale will not impair any program in this state. Compensation for these products and by-products distributed or sold under this subsection shall cover the actual costs associated with the products and by-products. Distribution outside this state may be made without cost if approved by the governor in emergency situations and if the products and by-products are available and are not required for immediate needs in this state.

History: 1978, Act 368, Eff. Sept. 30, 1978;--Am. 1986, Act 204, Imd. Eff. July 25, 1986.

333.9112 Pharmaceutical products fund.

Sec. 9112. (1) The pharmaceutical products fund is created in the state treasury and shall be administered by the department. The fund shall only be expended as provided in this section.

(2) The state treasurer shall credit to the pharmaceutical products fund all revenues received by the department pursuant to section 9111.

(3) The department shall utilize the pharmaceutical products fund to update and improve the facilities used to develop and produce pharmaceutical, biologic, and diagnostic products pursuant to section 9111, or to otherwise improve the biologics products program, pursuant to appropriations.

History: Add. 1986, Act 204, Imd. Eff. July 25, 1986.

S.B. 579: SECOND ANALYSIS DPH PHARMACEUTICALS/IMMUNITY

SAS SENATE ANALYSIS SECTION

Lansing, Michigan 48909

Senate Bill 579 (as enrolled)
Sponsor: Senator William Sederburg
Senate Committee: Public and Mental Health
House Committee: Public Health

RATIONALE

The Public Health Code authorizes the Department of Public Health (DPH) to manufacture or purchase pharmaceuticals, including biological products and antimicrobial agents for use in the prevention and control of disease and disability. The department's biological products lab currently produces six vaccines, various products for the fractionation of human plasma, and one product for veterinary use, which it provides and distributes throughout the state. Some of the products produced by the lab are made nowhere else, and others have few producers. The lab is the sole source of Anthrax vaccine in the free world and single antigen pertussis vaccine in the United States. If the department receives FDA approval for the rabies vaccine it has developed, it would be the only producer of it other than France. Michigan and Massachusetts are the only states that produce DPT (diptheria, pertussis, tetanus) vaccine, and there are currently only two commercial producers.

There is a growing concern in the medical community that if current trends continue, there may be shortages of vaccines in the future. In 1968 there were 37 licensed vaccine manufacturers, but by 1983 there were 14. For part of 1984 and 1985 there was only one commercial producer of DPT and a shortage of the vaccine occurred, causing the Center for Disease Control to recommend less frequent DPT innoculations until the supply could be built up. (Michigan and Massachusetts were not affected because they had their own supply.) It has generally been argued that vaccine producers are disappearing because, though vaccines are essential, they offer companies relatively low profits and, because vaccines cause adverse reactions in a small percentage of the population, they invite liability suits.

The code authorizes the department to distribute its pharmaceuticals outside the state under the conditions that compensation for the products is adequate to cover the costs and that the distribution does not impair any state program. An attorney general opinion (No. 6254 of 1984), however, found that the power to engage in selling these products outside the state had not been expressly conferred upon the department, and that the department could only distribute the products to other governmental agencies, not private concerns. Some people feel that prohibiting the department from dealing with other state's doctors, hospitals, or private concerns limits the distribution of important medical products, and that the code should be amended specifically to allow such distribution.

CONTENT

The bill would amend the Public Health Code to revise the code's provisions that regulate the production and distribution of pharmaceuticals by the Department of Public Health, and to permit the department to distribute and sell products outside the state for both public and private use.

The bill specifies that the DPH could develop and produce pharmaceutical, biologic, and diagnostic products and by-products for human, veterinary, or agricultural use, for the distribution or sale of the products outside the state for public or private use, if the distribution or sale did not impair any program within the state. Compensation would have to be adequate to cover the actual costs associated with the products.

Revenue received by the department from the sale of these products would be placed in the pharmaceutical products fund created by the bill and administered by the Department of Treasury. The fund could be used only to update and improve facilities used to develop and produce the products, or otherwise to improve the biologic products program pursuant to appropriation.

The bill would allow the department to develop and produce pharmaceutical, biologic, and diagnostic products and by-products for human, veterinary, or agricultural use, and to distribute the products within the state and recover the actual costs associated with the products. The department would be required to provide the products at no cost if requested by local health departments, hospitals, or physicians for in-state use, if considered necessary by DPH to protect the public health.

MCL Reference 333.9111 et al.

FISCAL INFORMATION

The Senate Fiscal Agency reports that Senate Bill 579 would have an indeterminate fiscal impact on the state. The agency reports that the maximum amount that could be expected to be credited to the pharmaceutical products fund would be $3.2 million, but that the actual figure would depend on demand for the products, the charge for each, the amount available for distribution outside the state, and liability insurance for the program. (2-13-86)

OVER

ARGUMENTS

Supporting Argument

The DPH biological products lab remains an important producer of vaccines and blood serums that have a wide range of medical uses at a time when the number of manufacturers in the vaccine production business has been severely reduced. This reduction is because vaccines generally offer a company a low profit margin and have provoked some expensive liability lawsuits since a certain percentage of people have serious side-effects from innoculation. If the reduction in production of certain vaccines continues, or a few large producers are forced to discontinue their vaccine business, the nation could be faced with a shortage of necessary preventive medicines. Studies have shown that, particularly for some highly contagious diseases, as the incidence of innoculation falls the incidence of infection rises.

As companies leave the market the importance of the DPH lab is multiplied; under Senate Bill 579, though there could be nationwide shortages of vaccines, the supply in Michigan would remain stable. The state is one of only two that produces its own vaccines, and the DPH lab, once gone, could not be replaced easily. In addition, since we depend on other states for some products that we are unable to manufacture at this time, we should be able to supply other states with those products that are only made here. Yet, because of an attorney general opinion, the state has been restricted in distributing important medical products to other states. The bill, by specifically allowing the department to sell its products to other states' public and private concerns, would ensure that available supplies could be distributed without undue restrictions and that revenues for such sales were properly directed to the department.

Opposing Argument

Some people have questioned the need for the state to be in the business of producing vaccines and other biological products, specifically, whether the program should continue or be left to the private sector. If the state is to continue to fund the program, the question arises of whether the funding should be done through fees or by use of general fund dollars. Perhaps these issues should be resolved before any new activities are authorized.

Senate group endorses immunity for state lab vaccine

STATE JOURNAL 2-12-86

By JOHN B. ALBRIGHT
Lansing State Journal

Legislation to immunize Michigan from lawsuits stemming from the development, manufacture and distribution of vaccines coming out of a state laboratory on North Logan Street was endorsed Tuesday by the Senate Committee on Public and Mental Health.

The panel approved two measures needed because state lawyers fear increased interstate distribution of state-made bio-products might open the door to damage suits, said Sen. William A. Sederburg, R-East Lansing and the bills' sponsor.

"We don't mind exporting vaccines, we just don't want to import lawsuits," Assistant Attorney General Vincent J. Leone testified to the health panel.

A survey last year showed nine Michigan residents were suing the state for a total of $56 million in claims for injury from state-made vaccines.

According to Sederburg, a representative of the Michigan Trial Lawyers Association has objected to his bills.

Lawyer Leonard Esquina Jr. told the committee the state's liability for vaccine-related injuries should be resolved in the broader legislative framework of an ongoing governmental immunity issue, Sederburg said.

The state lab, which has made vaccines since the 1920s, is under an advisory by state Budget Director Robert Neftaly to become self-supporting or close out.

Under that spur, lab officials want to expand at-cost sales of the vaccines to users in other states to recover some of the lab's outlays, according to Dr. Kenneth Wilcox, head of the state lab's epidemiological services.

About 2 percent of the lab's products go to out-of-state users, Wilcox said.

If out-of-state distribution climbed to about 10 percent, Wilcox said, lawyers for any vaccine-injured persons could argue Michigan is distributing the vaccines for profit and therefore would lose the shield of governmental immunity from injury lawsuits.

One of the bills headed for the Senate floor next week would write the vaccine-making operation into an immunity law as a state function, and would set up a health department fund for the sales receipts. Now that money goes to the state's general fund.

The other would assert the state's immunity to civil action in producing vaccine and other biologic products.

In December 1984, Neftaly told health officials to prepare to phase out the vaccine operation.

Health officials said the production of vaccines was necessary for the public good, since many private manufacturers were stopping production because of a swelling volume of legal awards to vaccine-injured persons.

Michigan and Massachusetts are the only states which make vaccines.

In the wake of Neftaly's advisory, health officials began talking about selling the vaccine operation to a private firm.

See VACCINE, Page 3B

Vaccine From 1B

But that's been set aside, Wilcox said, in view of the lack of profits for vaccine manufacturing and sales.

The state vaccine operation with 80 employees and an annual budget of $4.7 million may be continued under some new arrangements, Wilcox said.

This, he said, might be "some form of an institute or some mechanism with other (than state) participation."

The state lab is scheduled to turn out 1.5 million doses of vaccine this fiscal year, with 650,000 of those to be a three-way item known as DTP — a vaccine against diphtheria, tetanus and whooping cough.

This fiscal year, the lab's financial mainstay is $2,916,400 from the state general fund. But no general funds are recommended for the lab in Gov. James Blanchard's 1986-87 budget, according to the lab office.

The $4,726,200 lab budget for the coming fiscal year relies on $209,900 in federal contracts and $4,516,300 lumped together for sales of vaccines and other products, contributions from the American Red Cross, payments from state police for breathalyzer test kits and from the Department of Corrections for hepatitis test materials.

This year, receipts for sale of vaccines and other products in Michigan and elsewhere is put at $1,084,700.

Wilcox said the lab has no cost-accounting to show the manufacturer's price of a dose of DTP vaccine, which runs $4.28 on the private market. The lab has a $100,000 state allocation for such a cost study, and it will be started soon, Wilcox said.

On the private market, most of the costs of the vaccine are attributed to liability for vaccine-injury suits, Wilcox said.



Sen. William Sederburg: Legislation addressess fear of lawsuits.

Lansing State Journal
Feb 12 1986

State may increase vaccine production

By JERRY MOSKAL
Gannett News Service

Stepped-up vaccine production is being considered by the Michigan Department of Public Health (DPH) to ease shortages around the nation.

However, DPH officials are leery of making their diphtheria-tetanus-pertussis (DTP) vaccine available to other states because of possible damage suits.

MICHIGAN AND Massachusetts are the only two states that produce vaccines in their own laboratories. Dr. John Mitchell, DPH biological products director, said Michigan has a 10-month supply available for in-state use.

"We have the same problem with product liability as commercial labs have," Mitchell said. "If we send the product outside of the state, we have the same liability. We want to help, but how much risk can we afford to take?"

Michigan already faces a liability problem. About a dozen claims have been filed by state residents over DTP, Mitchell said. He said state health officials are concerned Michigan's immunity statute may be ruled invalid, subjecting the department to money damages.

Mitchell indicated the go-ahead to ship vaccine to other states may not be issued unless the federal government steps in to protect Michigan from liability.

HE BLAMED the shortages on the federal government's failure to establish a liability protection program for commercial vaccine producers. Bills are pending in Congress to establish such a fund through a surcharge on manufacturers.

The U.S. Public Health Service said the shortage cropped up after two of the three commercial makers of DTP dropped production and the remaining one, Lederle Laboratories of Pearl River, N.Y., held up release of recent lots for further testing.

But, on the same day that federal health officials last week announced the shortage, Wyeth Laboratories, which had said in June that it had "ceased production" of its DTP vaccine, disclosed to Gannett News Service that it never had stopped making the vaccine.

Dr. Daniel L. Shaw, vice president of medical affairs for Wyeth, said his company has been supplying the vaccine to Lederle, which markets it under the Lederle label and has accepted all liability risks.

SHAW SAID Wyeth has supplied almost 3 million doses to Lederle since Wyeth stopped selling the vaccine in June, and expects to supply Lederle with more than 8.2 million doses of DTP in 1985 — roughly half the volume needed nationally.

Federal officials said Lederle stopped distribution because tests showed recent batches failed to meet its requirements. They said testing could take several months, meaning new Lederle lots may not be available until next February.

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November 18, 1985

SECTION: TECHNOLOGY; Pg. 256

LENGTH: 966 words

HEADLINE: Scared shotless

BYLINE: By Francesca Lunzer; Edited by Stephen Kindel

How profitable is saving lives when you're being sued for 40 times revenues? That's a question Lederle Laboratories and other vaccinemakers are asking.

PAST PRESIDENTS of Lederle Laboratories hardly ever met with their lawyers. Why should they? Few of the company's 675 products ever attracted lawsuits. But since Robert Johnson took the company helm in 1984, his life has been nothing but court papers and lawyers' offices. That's because the pertussis, or whooping cough, component of the company's D-T-P vaccine -- that's short for diphtheria, tetanus, pertussis -- has attracted more than 100 lawsuits amounting to almost $2 billion in claims in just the past three years. What changed in the vaccine to attract such problems since Lederle started marketing it in 1943?

Absolutely nothing.

For more than 40 years children have been effectively vaccinated against whooping cough. Before the vaccination practically eliminated the disease in this country, thousands of children, usually under the age of seven, died of the disease each year, and hundreds of thousands more were afflicted with coughing spasms so violent they often suffered brain and lung damage.

In all that time, Lederle, which currently holds two-thirds of the $80 million pertussis vaccine market, was sued only twice for damage caused by the vaccine.

All that has changed since 1982, after highly negative television coverage of the vaccine and its side effects. Reports aired on such widely watched programs as NBC's Today show and ABC's Nightline charged that parents had not been told that the pertussis vaccine can cause death and permanent brain damage. Since then, the company has had an avalanche of suits, including 76 so far this year.

The vaccine can indeed cause both death and permanent brain damage. Toxins in the vaccine, which is made from whole cells, probably cause side effects such as fever and prolonged crying in 1% of children who are inoculated. Says one doctor, "It's one of the cruddiest vaccines we have." Scientists have not been able to isolate exactly which part of the killed pertussis bacteria confers immunity and which causes the side effects -- they could be the same parts -- so the whole cell is injected.

But even with its impurities, permanent brain damage comes to only one child in 310,000, and death is even rarer. "The reaction isn't peculiar to the vaccine, it's peculiar to the bacteria," says Dr. Jean Lockhart of the American Academy of Pediatrics. Yet in many countries where "exposes" on whooping cough vaccine have been published, its use dropped dramatically. After two children in Japan died from side effects, the vaccine was withdrawn from the Japanese market for two months in 1975. Even when it was returned, many parents refused to have their children inoculated. The result: Between 1979 and 1982, 35,000 children contracted pertussis and 118 died.

The same thing happened in Britain. Between 1977 and 1980, following a media scare, Britain reported 100,000 cases of pertussis and 36 deaths.

With reactions like that, and the lawsuits that are more typical in the U.S., it's a wonder that anyone stays in the vaccine business. The pharmaceutical industry had revenues of over $17 billion last year, of which all vaccines accounted for only $250 million. Moreover, the U.S. market for the seven childhood vaccines is fairly fixed; it can grow only as fast as the population of young children. U.S. vaccinemakers can't expand their markets overseas, largely because vaccinations in many foreign countries are government-subsidized and therefore U.S. manufacturers can't compete on price.

Caught between a rock and a hard place, American pharmaceutical houses have been steadily leaving the vaccine business, and new vaccines are finding the path to the market difficult. There were once eight companies that made pertussis vaccine, but following difficulties in getting full insurance coverage once the public began bringing large suits against Lederle, only Lederle and Connaught Laboratories, a Canadian firm, market the vaccine.

All of this has had a dramatic effect on the price of pertussis vaccine. Since 1982 it has shot up from under $7 for a 15-dose vial to $64. Lederle's Johnson expects that price to go still higher because the company needs to set up reserve funds for pending suits. But if the suits continue, it is not clear how long Lederle will stay in the pertussis vaccine market. After all, vaccines make up only 2% of parent company American Cyanamid's $3.9 billion in revenues (see story, p. 230). "You're not going to take an entire corporation's business and jeopardize it," says Johnson.

But what happens if lawsuits do force pharmaceutical companies out of vaccine production? The National Institutes of Health has so far put only small amounts of money into developing a new pertussis vaccine, and better vaccines from other sources are only at the testing stage.

The solution in the U.S., if any, is likely to be legislative. Congress is now considering a number of compensation bills that would allow parents whose children have been harmed by any vaccine to claim damages from a compensation board so long as they don't also sue the company. In one bill, those compensation fees would be funded by a pool into which vaccine manufacturers would pay. Of course, this means even higher fees for vaccinations.

While parents and the press have been quick to point out the damage the pertussis vaccine can cause, they seldom mention that the vaccine has practically eradicated the disease. "It's easy to bring a picture into your living room of a tremendously damaged child," says Dr. Alan Hinman, director of the immunization division of the Centers for Disease Control in Atlanta. "A picture of millions of children who don't have the disease because they were vaccinated has no dramatic impact whatever."

GRAPHIC: Picture, Robert Johnson of Lederle Laboratories, "We're not going to risk the company." Darryl Pitt

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August 15, 1984, Wednesday, PM cycle

SECTION: Washington News

LENGTH: 487 words

HEADLINE: Doctors worried by shortage of whooping cough vaccine

BYLINE: By THOMAS FERRARO

DATELINE: WASHINGTON

The American Academy of Pediatrics is concerned by spot shortages of the vaccine against whooping cough that one of three manufacturers recently stopped producing.

The academy said the two other makers have promised to increase production to meet the demand, but noted they may also drop out because of litigation and increased liability premiums related to rare adverse reactions.

"We don't know what may happen," Susan Casey, an academy spokesman, said Tuesday. "We may need federal intervention" to obtain and maintain an adequate supply.

The vaccine has been used in the United States to immunize children for more than a half century, nearly eliminating the disease that had been blamed for more than 7,500 deaths a year in the 1930s.

But for every 310,000 doses of the vaccine, there is normally one case of permanent brain damage -- often resulting it million dollar lawsuits.

Paul Wehrle, president of the 27,000-member academy, said, "Pertussis (whooping cough) would potentially produce 10 times the rate of brain damage as the pertussis vaccine."

Wehrle said, "The problems confronting us are not novel in the history of vaccines. When disease is rampant, we accept the more serious effects of vaccines. But when the vaccine works -- as pertussis has -- and the disease is gone and forgotten, the risks and rare adverse effects become intolerable."

U.S. supply of vaccine began to fall in June when Wyeth Laboratories, which had produced 25 percent to 40 percent of the nation's supply, discontinued its pertussis operation.

Connaught Laboratories and Lederle Laboratories said they are committed to keeping the vaccine on the market, but warned they may be forced to follow Wyeth's lead because of litigation.

Ms. Casey said the organization has received reports of spot shortages of the vaccines in a number of areas across the country, including Detroit, Baltimore and Philadelphia.

United Press International August 15, 1984, Wednesday, PM cycle

"The Centers for Disease Control say we don't have a shortage, but a 'maldistribution,'" she said. "We are concerned."

Last week, the academy formed a task force to "develop a rational plan" for immunizing children against whooping cough in response to recent shortages of the vaccine.

Task force members include representatives from pediatrics, public health, the Food and Drug Administration, the National Institute of Allergy and Infectious Disease and pharmaceutical companies, as well as lawyers and parents.

The academy, as part of a longterm solution, is backing legislation in Congress that would create a national compensation system.

It would provide assistance to families with legitimate vaccine-related claims and help protect manufacturers from frivolous suits.

The academy said pertussis immunizations have fallen off in the United Kingdom and Japan as the result of exaggerated reports of risks. In both countries, it said, epidemics of whooping cough have followed.

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September 15, 1984

SECTION: Vol. 18 ; Pg. 173; ISSN: 0031-305X

LENGTH: 981 words

HEADLINE: Pertussis vaccines: assets and liabilities.

BYLINE: Bruni, Patricia J.

Pertussis vaccine: Assets and liabilities

If we were suddenly to stop immunizing infants and children against pertussis, about 2 million American children would develop whooping cough within a decade. Without immunization, about 800 children would die of the disease each year, and about 80,000 would require hospitalization, according to James D. Cherry, MD, professor of pediatrics, chief of the division of pediatric infectious diseases, University of California, Los Angeles, UCLA School of Medicine.*

* Cherry JD: The epidemiology of pertussis and pertussis immunization in the United Kingdom and the United States: A comparative study. Curr Probl Pediatr 1984, 14 (February), 69.

The Centers for Disease Control (CDC) in Atlanta reports that with the immunization program in place, between 1,500 and 2,000 cases of whooping cough were reported annually from 1973 through 1983, according to a CDC spokesman. In that period, 5-10 deaths each year were attributed to pertussis. "Most people, including many physicians, haven't seen enough whooping cough to be worried about it these days. With rare exceptions, physicians should immunize everybody,' says Thomas F. Dolan, MD, director of pediatrics at Yale-New Haven Primary Care Center, and professor of pediatrics, Yale University School of Medicine, New Haven, Conn.

Despite the virtual certainty of an epidemic without widespread pertussis immunization, momentum has been building against the immunization program since 1982. Opposition has been fueled by what many health care professionals consider exaggerated reports in the media of the vaccine's potential for injury or death.

The program has also been jeopardized by the proliferation of expensive liability suits alleging pertussis vaccine injury. While aimed mostly at vaccine manufacturers, they have put both physicians and producers on the defensive. Bad publicity and legal entanglements led to reductions in the pertussis vaccination programs in Japan and the United Kingdom beginning in the mid-1970s: In both countries the disease reemerged in epidemic proportions.

"Many things attributed to the vaccine as complications really aren't. The vast majority of what seem to be severe reactions are not due to the vaccine but to other sources, such as infantile spasm and hereditary neurologic diseases that, many times, occur at the same time as vaccination,' says Dr. Cherry. Both Drs. Cherry and Dolan say familiarity with contraindications to pertussis vaccine can help avert problems. The contraindications are:

- The presence of acute febrile illness
- Hypersensitivity to vaccine components
- The presence of an evolving neurologic disorder

- A history of severe reaction following a previous dose (usually within 48 hours)

Severe reactions include collapse or shock, a persistent screaming episode lasting three or more hours, unexplained temperature of 40.5(C (105(F) or greater within 24 hours following immunization, convulsion with or without accompanying fever, severe alterations of consciousness, generalized or local neurologic signs, and systemic allergic reactions. Defer immunization in children with personal histories of convulsion. The risk of convulsion associated with the vaccine may be greater if a family member has a history of nonfebrile convulsions.*

* For a discussion of contraindications see Committee on Infectious Diseases: Pertussis vaccine. Pediatrics 1984; 74:303-5.

Concerns about vaccine shortages arose in mid-June, when Wyeth Laboratories, a major manufacturer of the vaccine, pulled out of the market because of what it deemed intolerable legal fees and insurance costs. Coincidentally, its announcement came soon after the CDC released findings of a cost-benefit study that showed continued use of the killed-bacteria vaccine to be justifiable.** Although vaccine producers have not disclosed the financial extent of vaccine-related litigation, in 1983 Lederle Laboratories faced law suits whose dollar demands were 200 times as great as the total gross sales of its DPT (diptheria-pertussis-tetanus) vaccine, says Martha Homma, a Lederle spokeswoman. "In all those cases the vaccine fully met all Food and Drug Administration requirements for safety and effectiveness,' she adds. Lederle plans to step up vaccine production in an effort to cover the Wyeth short-fall. The production scale-up, however, is expected to take 6-8 months. At press time, Pennsylvania, Michigan, and Maryland had already been cited by the American Academy of Pediatrics (AAP) as having shortages of the vaccine.

** Hinman AR, Koplan JP: Pertussis and pertussis vaccine: Reanalysis of benefits, risk, and costs. JAMA 1984; 251:3109-13.

Connaught Laboratories, Inc., of Swiftwater, Pa., has no immediate plans to withdraw from the market. "On the other hand, we are having some of the same difficulties as Wyeth in terms of litigation and its impact on insurance coverage and costs,' says Douglas Reynolds, a Squibb/Connaught, Inc. spokesman. For now, Squibb, the distributor of Connaught's DPT vaccine, has limited vaccine shipments to contract obligations. Connaught boosted its vaccine price ninefold approximately a year and a half ago to keep up with increasing legal costs. Lederle has also recently increased prices to comparable levels.

As researchers work toward producing a safer vaccine, Congress is considering legislation that would provide compensation to the victims and families of vaccine-injured children. In recent meetings called by the pertussis strategy task force of the AAP, federal health officials and representatives of the vaccine producers have focused on easing the shortages of vaccine caused by Wyeth's absence from the marketplace and on finding ways to reduce the product liability burden of drug manufacturers by modifying the proposed legislation.

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June 19, 1984, Tuesday, Final Edition

SECTION: First Section; A1

LENGTH: 832 words

HEADLINE: Pertussis Liability Cited;
Firm Ceases Making Vaccine

BYLINE: By Cristine Russell, Washington Post Staff Writer

Wyeth Laboratories, one of the two leading American manufacturers of a vaccine used to immunize almost every child in the United States against whooping cough, has stopped production of the product, citing rising liability problems from rare complications linked to the shots.

Wyeth's withdrawal from the whooping cough--or pertussis--vaccine market, the latest in a series by pharmaceutical firms in recent years, puts new pressure on Congress to resolve the controversial issue of how best to compensate victims of vaccine complications.

At the same time, the federal Centers for Disease Control released a new national study stressing that the overall benefits of universal vaccination against whooping cough far outweigh the costs.

"We found that every dollar invested in vaccination reaps $11 in potential savings" by preventing the disease and saving the costs of treatment, said CDC's Dr. Jeffrey Koplan. "There continue to be major public health benefits to have this vaccine . . . . Serious side effects are a rare event, but are more common than with other widely used vaccines. That's part of the problem."

The side effects range from minor discomfort near the site of the shot to serious brain damage. The chances of serious long-term harm, however, appear to be only 1 in 310,000. Side effects are believed to show up soon after administration of the shot.

Vaccine compensation legislation, stimulated largely by public concern about pertussis complications and by lawsuits, has been introduced by Sen. Paula Hawkins (R-Fla.) and Rep. Henry A. Waxman (D-Calif.).

"Until we have a compensation plan for permanently damaged children," Hawkins said yesterday, "there is the danger that all manufacturers will drop out."

"It is distressing to find pertussis vaccine manufacturers with no competition because you run the risk of letting liability concerns drive up the price and having no redress. The other company may drop out too, in which case you're in big trouble," said a Waxman aide.

"We have been concerned that liability burden, among other issues, might force producers out of the business," said a spokesman for the American Academy of Pediatrics, which represents doctors who treat children. "We hope other producers will continue to meet the needs of the American public and we will not have a national emergence of pertussis disease . . . . Until we have a better vaccine, this is the best we've got."

The Hawkins bill was drafted with the help of the academy, along with Dissatified Parents Together, a group of parents whose children have suffered side effects from the vaccine. The bill gives parents the options of suing through existing legal channels or seeking redress through a new administrative

compensation system, with funds collected through a surcharge on the vaccine, a Hawkins aide said.

The aide, said, however, that the approach was opposed by the Reagan administration and many drug manufacturers, who want to set up a compensation system that would exclude regular lawsuits.

Dr. Kenneth Bart of the CDC said that short-term vaccine supplies appearedadequate, "but it will be several months before we appreciate the total effect" of Wyeth's pullout. He said that more than 18 million doses of pertussis vaccine are delivered each year in this country as part of a combination diphtheria, pertussis and tetanus (DPT) shot.

A Wyeth spokesman estimated that the company held at least 25 percent of the United States market. Wyeth notified its customers that as of June 13 it had "ceased production" of the pertussis portion of the vaccine after 30 years because of "dramatic increases in the cost of participating in this market," but that "existing supplies . . . will be available until exhausted." The spokesman cited increased insurance costs, the risk of liability from pertussis vaccine suits and the costs of defending the company.

The other major American producer is Lederle Laboratories, which said yesterday that it has "no plans for pulling out" and will attempt to pick up Wyeth's share of the market. In addition, Food and Drug Administration experts said that a Canadian company, Connaught Laboratories, distributes a more expensive vaccine through E.R. Squibb & Co., and two state health departments, those of Michigan and Massachusetts, make their own.

The CDC study, using the latest available data, estimated that more than 350,000 cases of pertussis would occur annually without the vaccination program, compared with 34,000 under universal vaccination. CDC believes that 457 persons would die of whooping cough without the vaccine, compared with 44 under the program.

The study shows that the rare long-term complications may occur more often among those vaccinated than among those who do not get the shots. It suggested that there may be 54 such cases annually with a vaccination program, compared with 29 without a program. However, both the disease and complications are thought to be underreported.

STATE OF MICHIGAN
OFFICE OF THE GOVERNOR
LANSING

JOHN ENGLER
GOVERNOR

December 5, 1995

The Honorable Dick Posthumus
Majority Leader of the Michigan Senate

The Honorable Paul Hillegonds
Speaker of the Michigan House of Representatives

Dear Legislative Leaders:

With this letter, I am transmitting Executive Order 1995-25 regarding the Biologic Products Division of the Michigan Department of Public Health.

This Executive Order removes the Biologic Products Division from the Department of Public Health and establishes it as an autonomous, temporary two-year agency to be known as the Michigan Biologic Products Institute. All of the duties, responsibilities, facilities, licenses, and personnel previously associated with the Division are transferred to the Institute. The current Division Chief and Responsible Head of Manufacturing, under licenses granted by the United States Food and Drug Administration, will become the Director of the Institute.

The Institute will be governed by a three-member Commission which will be responsible for causing the fair-market value of the Institute's assets to be determined, and for developing a plan, including any necessary legislation, to move the Institute out of state government and into the private sector within two years. The Director of the Institute will report to the Commission.

The Biologic Products Division has long played a role in protecting Michigan's children from disease by manufacturing and distributing vaccines to prevent diphtheria, tetanus, and pertussis (DTP), three of the nine pediatric diseases for which immunization is required under Michigan law. The Division has also played an important role in protecting U.S. troops from the threat of biological warfare, and in providing blood fractionation services to the American Red Cross. However, recent changes in the market for pediatric vaccines, and the growth of the Division's relationships with customers other than the State of Michigan have led me to conclude that the Division can no longer fulfill a state government function and can become a self-sustaining private enterprise.

The DTP vaccine made by the Division, while still safe and effective, is no longer a state-of-the-art vaccine. Acellular pertussis and more comprehensive combination vaccines are rapidly replacing the vaccines made by the Division which contains whole-cell pertussis, and which were first licensed over forty years ago. The success of the U.S. FDA-sponsored clinical trials in Sweden and Italy last summer will accelerate the licensure and use of acellular pertussis vaccine in America. Last year, even the Michigan Department of Public Health distributed over 150,000 doses of these privately manufactured vaccines, and next year, the federal Centers for Disease Control plan to stop buying whole-cell pertussis altogether. Many Michigan health-care providers are choosing to buy these advanced combination vaccines over using the "free" vaccine provided by the Division because they provide broader immunity with fewer shots. Finally, the federal government recently imposed an excise tax on the Division's DTP vaccine which increased its cost to Michigan taxpayers by 500%.

Michigan is one of only two states engaged in the manufacture of pediatric vaccines; all other states utilize vaccines made by private pharmaceutical firms. As a strategy to fulfill the public health mission of achieving high infant immunization rates, government vaccine manufacturing has been a dismal failure. Despite providing "free" vaccines made by state government to health-care providers, a recent study ranked Michigan last among states in its rate of infant immunization, and there was no difference between the rate for DTP coverage and rates for the other six required vaccine. In fact, recent studies by the U.S. General Accounting Office have concluded that cost is not a significant barrier to immunization.

This fall, in response to the study concerning Michigan's low rate of infant immunization, I asked Acting Public Health Director, Jim Haveman, to develop a comprehensive strategy to increase infant immunization rates to achieve our goal of 90% coverage by the year 2000. This strategy will rely upon collaboration between public and private health care providers, parents, and other parties across Michigan.

In recent years, more and more of the Division's work has been for public and private customers other than the State of Michigan. Agreements between the Division and private firms like SmithKline Beecham, Athena, North American Biologicals, Inc., and public customers including the American Red Cross and the United States military have enabled the Division to reduce its dependence upon General Fund dollars by earning increased restricted revenues. In fact, the FY 1997 budget request for the Institute will contain no General Fund dollars and the Institute will become entirely self-supporting.

Even as the Division has developed new relationships with other customers, its chief regulator, the U.S. FDA, has cited difficulties in the Division's ability to

meet standards for current good manufacturing practices that are directly related to its position in the Department of Public Health and Civil Service. The authority and latitude required for a Responsible Head of Manufacturing under U.S. FDA licenses is inconsistent with the authority of a division chief within a state department. Moreover, the arcane rules and regulations inherent in the Civil Service system impose significant barriers to efficient operation.

These trends in the market for pediatric vaccines, in the ability of the Division to establish new relationships with private and public customers other than the State of Michigan, and growing difficulties of efficiently managing the Division within the confines of the Michigan Department of Public Health have all led me to conclude that the Division should be established as an autonomous, two-year agency while a plan to move it into the private sector is developed.

I believe that you will agree that the steps I am taking provide the greatest opportunity to retain the skilled jobs associated with the production of vaccines and other biologic products in Michigan.

Sincerely,

John Engler
Governor

JE/jlf

STATE OF MICHIGAN
OFFICE OF THE GOVERNOR

JOHN ENGLER
GOVERNOR

EXECUTIVE ORDER
1995 - 25

MICHIGAN DEPARTMENT OF PUBLIC HEALTH
BIOLOGIC PRODUCTS DIVISION
MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

EXECUTIVE REORGANIZATION

WHEREAS, Article V, Section 2, of the Constitution of the State of Michigan of 1963 empowers the Governor to make changes in the organization of the Executive Branch or in the assignment of functions among its units which he considers necessary for efficient administration; and

WHEREAS, Article V, Section 4, of the Constitution of the State of Michigan of 1963 authorizes the establishment of temporary commissions or agencies for special purposes with a life of no more than two years and provides that such temporary commissions or agencies need not be allocated within a principal department; and

WHEREAS, Section 9111 of Act No. 368 of the Public Acts of 1978, being Section 333.9111 of the Michigan Compiled Laws, authorized establishment of the Biologic Products Division within the Michigan Department of Public Health; and

WHEREAS, Act No. 204 of the Public Acts of 1986, being Section 333.9112 of the Michigan Compiled Laws created the Pharmaceutical Products Fund in the state treasury and made the Michigan Department of Public Health responsible for administering it; and

WHEREAS, the functions, duties and responsibilities assigned to the Biologic Products Division can be more effectively administered and executed outside the Michigan Department of Public Health, due in part to the need of the Biologic Products Division to meet Federal regulatory and commercial requirements; and

WHEREAS, the long-term capability of the Biologic Products Division to meet Federal regulatory and other commercial requirements can best be achieved by removing the Division from state government as soon as is practicable; and

WHEREAS, the manufacture of products by the Biologic Products Division is not critical to the mission of the Michigan Department of Public Health.

NOW, THEREFORE, I, John Engler, Governor of the State of Michigan, pursuant to the powers vested in me by the Constitution of the State of Michigan of 1963 and the laws of the State of Michigan, do hereby order the following:

I. ESTABLISHMENT OF THE MICHIGAN BIOLOGIC PRODUCTS INSTITUTE AND THE MICHIGAN BIOLOGIC PRODUCTS COMMISSION

A. Definitions:

In this Executive Order the following definitions shall apply.

1. "Commission" means the Michigan Biologic Products Commission established as a temporary commission by this Executive Order.

2. "Director" means the person initially designated by the Governor as the Director of the Michigan Biologic Products Institute established as a temporary agency by this Executive Order.

3. "Institute" means the Michigan Biologic Products Institute established as a temporary agency by this Executive Order.

4. "Member" means a member appointed by the Governor to the Michigan Biologic Products Commission established as a temporary commission by this Executive Order.

B. Establishment of the Michigan Biologic Products Institute

1. The Michigan Biologic Products Institute is established by this Executive Order, pursuant to Article V, Section 4, of the Constitution of the State of Michigan of 1963, as a temporary agency with a life of no more than two years from the effective date of this Executive Order.

2. The Institute shall be an independent and autonomous entity with the intent that its authority, powers, duties and responsibilities and the authority, powers, duties and responsibilities of the Director, including personnel, budgeting, procurement and management-related functions, be exercised free from the direction and supervision of the principal departments in the Executive Branch.

3. The Director shall be the head of the Institute within the meaning of the Constitution of the State of Michigan of 1963, and of the Executive Organization Act of 1965, Act No. 380 of the Public Acts of 1965, being Section 16.101 et seq. of the Michigan Compiled Laws, and shall be the Appointing Authority as that term is used in the Constitution of the State of Michigan of 1963, and in the rules and procedures of the Civil Service Commission.

4. The Biologic Products Division of the Michigan Department of Public Health and the Pharmaceutical Products Fund, established under Sections 9111 and 9112 of Act No. 368 of the Public Acts of 1978, being Section 333.9111 and 333.9112 of the Michigan Compiled Laws are hereby transferred to the Michigan Biologic Products Institute by a Type III transfer, as defined by Section 3 of Public Act No. 380 of the Public Acts of 1965, being Section 16.103 of the Michigan Compiled Laws. The Michigan Biologic Products Institute shall assume all functions, duties, contractual obligations, responsibilities, inventory, tangible and intangible property and employees of the Biologic Products Division of the Michigan Department of Public Health, including administration of the Pharmaceutical Products Fund.

C. Establishment of the Michigan Biologic Products Commission

1. The Michigan Biologic Products Commission is established by this Executive Order, pursuant to Article V, Section 4, of the Constitution of the State of Michigan of 1963, to serve as a temporary entity with a life of no more than two years from the effective date of this Executive Order.

2. The Commission shall have three (3) voting members who shall be appointed by the Governor and such members shall serve as members at the pleasure of the Governor. None of these members shall be employees of the Institute. The Governor shall designate one (1) member of the Commission to serve as its chair and that member shall serve as chair at the pleasure of the Governor.

3. Members of the Commission shall serve without compensation for their membership on the Commission. Members of the Commission may receive reimbursement for necessary travel and expenses according to relevant procedures of the Civil Service Commission and the Department of Management and Budget.

4. The Commission may promulgate bylaws, not inconsistent with law and with this Executive Order, governing its organization and procedure. A majority of the serving voting members constitutes a quorum for the transaction of business at a meeting, notwithstanding the existence of one (1) or more vacancies. Voting upon actions taken by the Commission shall be conducted by a majority vote of the members present in person at a meeting of the Commission or present by use of amplified telephonic equipment.

5. The Commission shall meet at the call of the chair and as may be provided in the bylaws of the Commission. Meetings of the Commission may be held anywhere within the State of Michigan. The Commission shall be subject to the Open Meetings Act, Act No. 267 of the Public Acts of 1976, being Section 15.261 et seq. of the Michigan Compiled Laws. The Commission may, as appropriate, make inquiries, studies and investigations, hold hearings and receive comments from the public.

II. DUTIES AND RESPONSIBILITIES OF THE MICHIGAN BIOLOGIC PRODUCTS COMMISSION

The Commission shall provide supervision, policy control and direction to the Institute, and the Director. The Commission may, consistent with the provisions of this Executive Order, establish general goals and objectives relating to the operation and development of the Michigan Biologic Products Institute for the guidance of the Director.

The Michigan Biologic Products Commission shall:

1. Within eight (8) months of their initial organizational meeting, prepare, or cause to be prepared under contract, a detailed business plan with supporting documentation, including, but not limited to, any necessary legislation, describing the means by which the Michigan Biologic Products Institute will be transferred out of state government and into the private sector within the two year term of its temporary agency status under this Executive Order.

2. As part of the business plan, cause the fair market value of all state property, inventory, equipment and other assets associated with the manufacture of biologic products to be determined.

3. Contract with the initial Director; designate and contract with any future Directors.

4. Perform such other duties and responsibilities as may be assigned or transferred to the Commission by statute or by executive order.

III. OPERATIONS OF THE INSTITUTE

The current Responsible Head of biologic products manufacturing under licenses granted by the Food and Drug Administration is hereby designated to serve as the initial Director of the Institute. The Director shall report to and be directly responsible to the Commission. The Director

shall, in addition to the other duties and responsibilities given to the Director herein or assigned or transferred to the Director as head of the Institute by statute or executive order, be responsible for the oversight and supervision of employees of the Institute, for administration of the Pharmaceutical Products Fund, for management of the Institute's facilities and for the operations of the Institute. The Director shall also perform such other duties and exercise other powers as the Commission may prescribe.

The Director may appoint or contract with such other deputies, assistants and employees as are necessary.

The Director shall receive reasonable compensation. Such compensation shall be established according to relevant procedures of the Civil Service Commission.

The Director shall:

1. Maintain the establishment license of the facilities for biologic product production and maintain existing product licenses, except for obsolete products, and obtain new licenses as appropriate.

2. Maintain existing contractual relationships and expand the value of the work being undertaken while transferring responsibility for such work out of state government.

3. Fulfill the duties of a Responsible Head as delineated in 21 CFR 600.10(a), if applicable.

4. Report to the Commission on actions that affect the business of the Institute.

Notwithstanding Executive Directive 1995-2, the Director may hire or retain such contractors, subcontractors, advisors, consultants, and agents as the Director may deem advisable and necessary, in accordance with relevant statutes, and the rules and regulations of the Civil Service Commission, and may make and enter into contracts necessary or incidental to the exercise of the powers of and the performance of the duties of the Institute and the Director.

It is the intent of the Executive Order that the Director, the employees, and representatives of the Institute shall have the benefit of the provisions of Sections 2228(2) and 2465(2) of Act No. 368 of the Public Acts of 1978, being Sections 333.2228(2) and 333.2465(2) of the Michigan Compiled Laws.

IV. OPERATIONS OF BOTH THE INSTITUTE AND THE COMMISSION

Employees of the Institute are subject to Act No. 317 of the Public Acts of 1968, being Section 15.321 et seq. of the Michigan Compiled Laws, or Act No. 318 of the Public Act of 1968, being Section 15.301 et seq. of the Michigan Compiled Laws, as appropriate. Members of the Commission and employees of the Institute are subject to Act No. 196 of the Public Acts of 1973, being Section 15.341 et seq. of the Michigan Compiled Laws. Employees of the Institute are also subject to applicable Civil Service Commission rules and regulations concerning conflicts of interest.

A member of the Commission, the Director, employees and agents of the Institute shall discharge the duties of their positions in a nonpartisan manner, with good faith and with that degree of diligence, care and skill which an ordinarily prudent person would exercise under similar circumstances in a like position. In discharging their duties, a member of the commission, the Director, employees and agents of the Institute, when acting in good faith, may rely upon the opinion of counsel for the Institute, upon the report of an independent appraiser selected with reasonable care by the Institute and upon financial statements of the Institute represented to a member of the commission, the Director, employees or agents of the Institute to be

correct by the person having charge of the Institute's books or accounts or represented to be correct in a written report by a certified public accountant or firm of certified public accountants.

V. MISCELLANEOUS PROVISIONS

All the licenses and contracts associated with the Biologic Products Division along with all property and equipment needed to support the licenses and to fulfill the contracts are hereby transferred to the Michigan Biologic Products Institute which shall continue to perform pursuant to those licenses and to fulfill those contracts.

The Director of the Michigan Biologic Products Institute shall provide executive direction and supervision for the implementation of the transfers. The Director of the Michigan Biologic Products Institute shall make internal organizational changes as may be administratively necessary to complete the realignment of responsibilities prescribed by this order.

The Director of the Michigan Biologic Products Institute shall immediately enter into negotiations with other state departments or individuals or groups outside of state government to obtain services such as personnel, budgeting, procurement, security, maintenance, and janitorial services.

All records, personnel, property and unexpended balances of appropriations, allocations and other funds used, held, employed, available or to be made available to the Biologic Products Division for the activities transferred are hereby transferred to the Michigan Biologic Products Institute .

The Michigan Department of Public Health shall make internal organizational changes as may be administratively necessary to complete the realignment of responsibilities prescribed by this order.

The Director of the Department of Public Health and Director of the Biologic Products Institute shall immediately initiate coordination to facilitate the transfer and develop a memorandum of record identifying any pending settlements, issues of compliance with applicable federal and state laws and regulations, or obligations to be resolved by the Michigan Biologic Products Institute.

All rules, orders, contracts and agreements relating to the assigned functions lawfully adopted prior to the effective date of this order shall continue to be effective until revised, amended or repealed.

Any suit, action or other proceeding lawfully commenced by, against or before any entity affected by this order shall not abate by reason of the taking effect of this order. Any suit, action or other proceeding may be maintained by, against or before the appropriate successor of any entity affected by this order.

The invalidity of any portion of this Executive Order shall not affect the validity of the remainder thereof.

All departments, boards, commissions or officers of the state or of any political subdivision thereof shall give to the Commission, or to any member or representative thereof, any necessary assistance required by the Commission, or any member or representative thereof, in the performance of the duties of the Commission so far as is compatible with its, his or her duties; free access shall also be given to any books, records or documents in its, his or her custody, relating to matters within the scope of the inquiry, study or investigation of the Commission.

The Institute may accept grants of funds and donations of funds, property, labor or other things of value from any department or agency of the State of Michigan and the United States and from any other public or private agency or person.

In fulfillment of the requirements of Article V, Section 2, of the Constitution of the State of Michigan, the provisions of this Executive Order shall become effective 60 days after filing.

Given under my hand and the Great Seal of the State of Michigan this 5th day of December, in the Year of our Lord, One Thousand Nine Hundred Ninety-Five.

GOVERNOR

BY THE GOVERNOR:

SECRETARY OF STATE

This is a true copy as passed by the Michigan Biologic Products Commission on July 12, 1996.

J. Louise Findley
Executive Secretary, MBPC

RESOLUTION NO. 4

A RESOLUTION TO SPECIFY GOALS AND TO MAKE CERTAIN DETERMINATIONS WITH RESPECT TO THE PRIVATIZATION OF THE MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

WHEREAS, the Michigan Biologic Products Commission (the "Commission") recognizes the value of the skills, know-how, and experience of the employees of the Michigan Biologic Products Institute (the "Institute") and their contribution to the economy of the State of Michigan (the "State"); and

WHEREAS, the ownership and operation of the means of production for biologic products by state government is not needed to achieve the public health goal of age-appropriate immunization for all Michigan children and can be transferred to the private sector; and

WHEREAS, Executive Order 1995-25 requires the Commission to prepare a business plan, including any necessary legislation, to transfer the Institute out of state government and into the private sector, and to determine the fair market value of all State assets associated with the manufacture of biologic products; and

WHEREAS, the Commission has engaged special counsel to structure the transaction and develop legislation to effect the transfer of the Institute out of state government and into the private sector; and

WHEREAS, the structure of the transaction and legislation to transfer the Institute out of state government and into the private sector is partly dependent upon the goals of the Commission; and

WHEREAS, the Commission also desires to make certain determinations to further guide the structuring of the transaction and development of legislation to move the Institute out of state government and into the private sector.

NOW THEREFORE, BE IT RESOLVED, that the Commission establishes the following goals with respect to the transaction to transfer the Institute out of state government and into the private sector:

1. The transaction should be structured as a single transaction to sell all of the State assets associated with the manufacture of biologic products, including but not limited to all personal and real property, licenses, contracts, and inventory.

2. The transaction should be structured to provide the highest probability for the successor entity to become a profitable, viable enterprise

contributing to the economy of the State that is able to retain and increase the number of jobs it provides, accumulate the capital necessary to replace its biologic production facilities, and to keep the know-how associated with the manufacture of biologic products in Michigan.

3. The transaction should be structured to assure, to the greatest extent practicable, preferential State access to biologic products for use by Michigan public health agencies to prevent disease.

4. The transaction should be structured so that the State receives fair consideration for the assets being sold.

AND, BE IT FURTHER RESOLVED, that the Commission makes the following determinations in the interest of achieving the aforementioned goals:

1. The physical campus of the Institute will be surveyed to establish metes and bounds, and the fair market value of the assets of the Institute will be determined.

2. The Institute and its various lines of business, (e.g., vaccines, blood products, etc.) will be sold as a single unit and not on a piecemeal basis.

3. The successor entity will be independent of any future organizational control by state government, however, the State will retain certain property easements, including a right of entry to the power plant.

4. The consideration that the State receives from the sale of the Institute may be in the form of cash and/or future benefits such as biologic products, utilities, and other services or benefits to the people of the State.

5. The Commission recognizes the likelihood that a transaction which includes employee participation will be more conducive to achieving the State's goals.

6. The currently preferred procedure for identifying potential purchasers of the Institute is the request for qualification ("RFQ") procedure.

AND BE IT FINALLY RESOLVED, that copies of this resolution be distributed to the employees of the Institute and placed in the permanent files of the Commission.

This is a true copy as passed by the Michigan Biologic Products Commission on September 13, 1996.

J. Louise Findley
J. Louise Findley
Executive Secretary, MBPC

RESOLUTION NO. 5

A RESOLUTION AFFIRMING THE SURVEY OF THE EAST CAMPUS OF THE MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

WHEREAS, Executive Order No. 1995-25 established the Michigan Biologic Products Institute (the "Institute") and directed it to assume, among other things, all of the tangible property of the Biologic Products Division of the Michigan Department of Public Health associated with the manufacture of biologic products; and

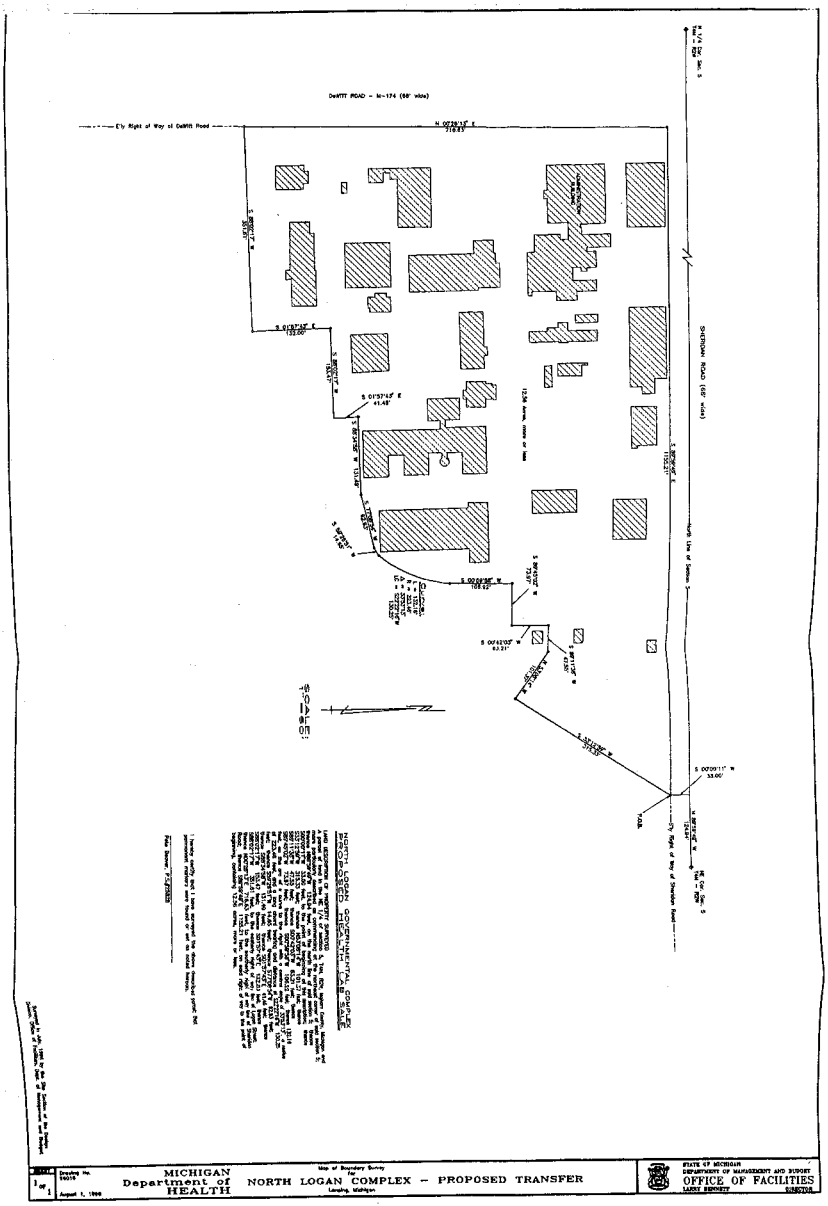
WHEREAS, Executive Order 1995-25 charged the Michigan Biologic Products Commission (the "Commission") with causing the fair market value of all state property, among other things, associated with the manufacture of biologic products to be determined and to prepare any necessary legislation to effect the sale or transfer of the Institute; and

WHEREAS, in order to define the boundaries of the land occupied by the campus of the Institute on the east side of Martin Luther King, Jr., Boulevard, the Commission directed that the perimeter of the campus be surveyed by the Michigan Department of Management and Budget, Office of Facilities; and

WHEREAS, the survey known as Drawing No. 96016, Map of Boundary Survey for the Michigan Department of Public Health North Logan Complex -- Proposed Transfer, (the "Survey") was completed on August 1, 1996.

NOW, THEREFORE, BE IT RESOLVED, that the Commission hereby affirms the boundaries defined in the Survey as establishing the perimeter of the east campus of the Institute located on the east side of Martin Luther King, Jr., Boulevard, Lansing, Michigan; and

BE IT FURTHER RESOLVED, that the Commission directs that the legal description of the property contained in the Survey be incorporated into any legislation necessary to effect the sale or transfer of the Institute.


DeWITT ROAD - M-174 (66' wide)
SHERIDAN ROAD (66' wide)
NORTH LOGAN GOVERNMENTAL COMPLEX
PROPOSED HEALTH LAB SALE
MICHIGAN
Department of
HEALTH
Map of Boundary Survey
NORTH LOGAN COMPLEX - PROPOSED TRANSFER
Lansing, Michigan
STATE OF MICHIGAN
DEPARTMENT OF MANAGEMENT AND BUDGET
OFFICE OF FACILITIES
LANSY BENNETT
SUBSTITUTE

This is a true copy as passed by the Michigan Biologic Products Commission on September 13, 1996.

J. Louise Findley
Executive Secretary, MBPC

RESOLUTION NO. 6

A RESOLUTION AFFIRMING THE SURVEY OF THE WEST CAMPUS OF THE MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

WHEREAS, Executive Order 1995-25 established the Michigan Biologic Products Institute (the "Institute") and directed it to assume, among other things, all of the tangible property of the Michigan Biologic Products Division of the Michigan Department of Public Health associated with the manufacture of biologic products; and

WHEREAS, the property on the west side of Martin Luther King, Jr., Boulevard otherwise known as "the sheep farm" has long supported the manufacture of biologic products by providing animals and animal products necessary for such production; and

WHEREAS, Executive Order 1995-25 charged the Michigan Biologic Products Commission (the "Commission") with causing the fair market value of all state property, among other things, associated with the manufacture of biologic products to be determined and to prepare any necessary legislation to effect the sale or transfer of the Institute; and

WHEREAS, the Michigan Department of Management and Budget, Office of Facilities completed the survey of the land otherwise known as "the sheep farm" located on the west side of Martin Luther King, Jr., Boulevard, being Drawing No. 95022, Map of Boundary Survey for Michigan Department of Public Health, North Logan Complex -- Surplus Property (the "Survey") on August 28, 1996. The property contains 46.94 acres, more or less; and

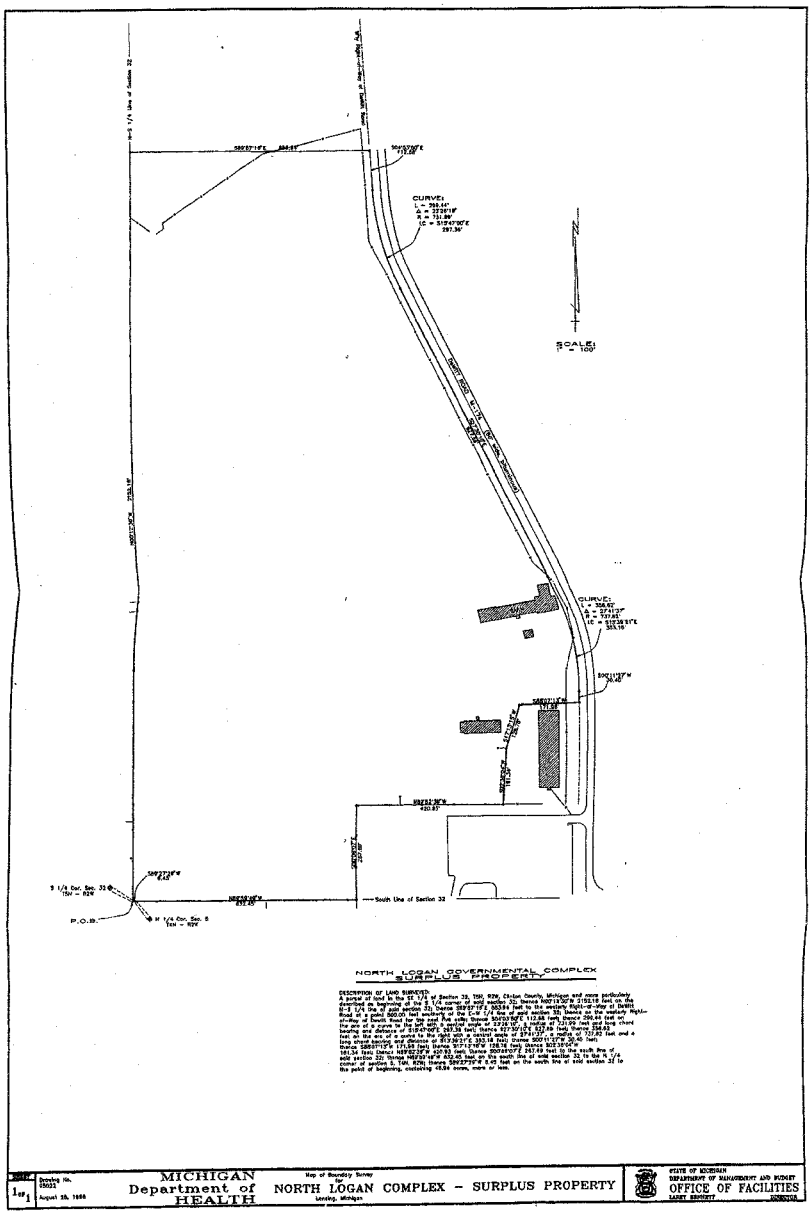
WHEREAS, the surveyed property was appraised by the Dean Appraisal Company on June 22, 1995, and found to have a fair market value at that time of $7,500.00 per acre; and

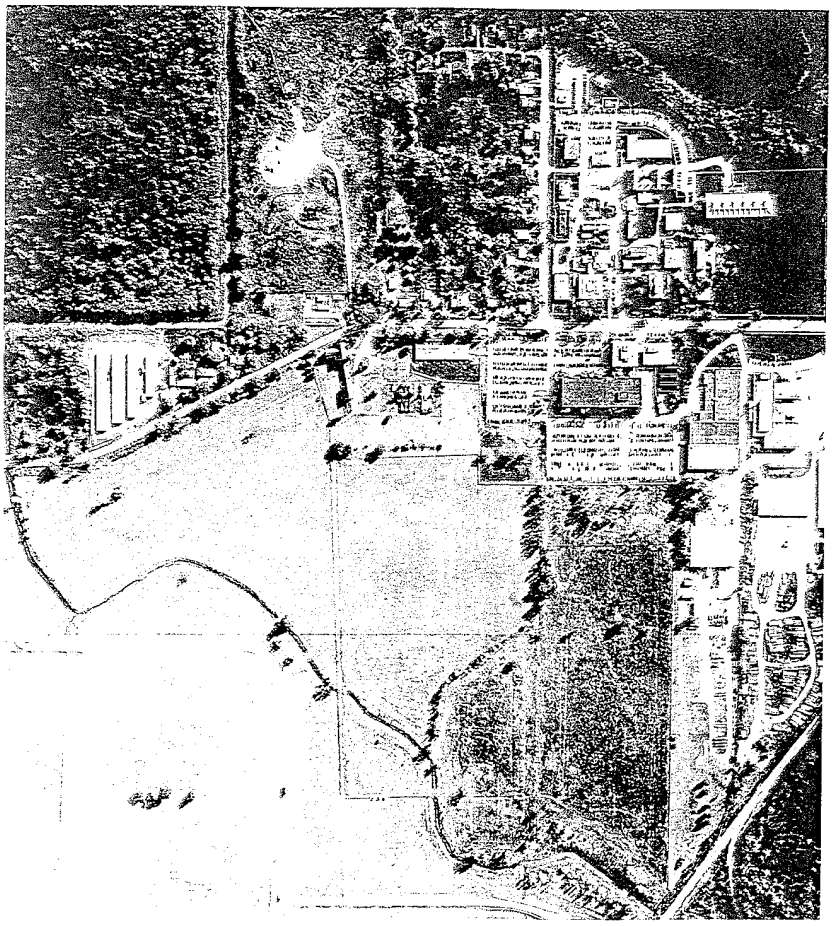
WHEREAS, the surveyed property was declared surplus by the Michigan Department of Public Health on November 22, 1995; and

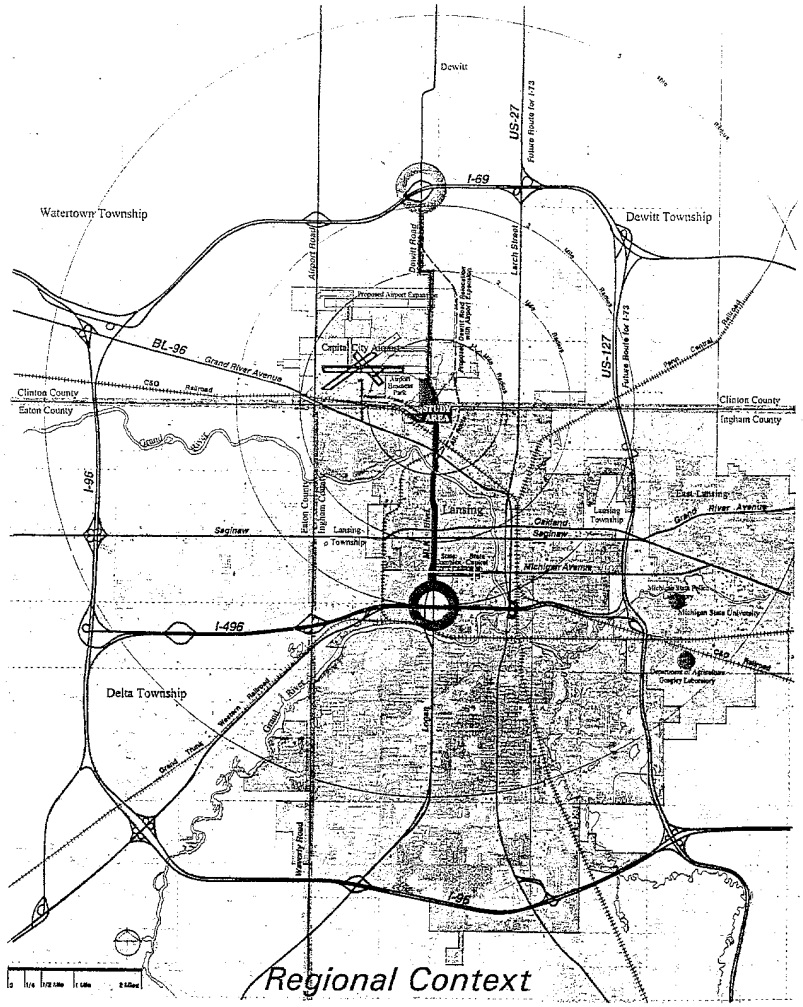
WHEREAS, the Commission agrees that the value and marketability of the Institute will be enhanced by incorporating the surveyed land into the overall campus of the Institute, by providing space for replacement facilities and future growth.

NOW, THEREFORE, BE IT RESOLVED, that the Commission hereby affirms the boundaries defined in the Survey, subject to final certification by the Department of Management and Budget, as establishing the perimeter of the west campus of the Institute; and

BE IT FURTHER RESOLVED, that the Commission directs that the legal description of the property contained in the Survey be incorporated into any legislation necessary to effect the sale or transfer of the Institute.


CURVE:
L = 396.44'
Δ = 22°26'18"
R = 751.89'
LC = 519°47'00"E
297.36'
SCALE:
1" = 100'
CURVE:
L = 356.67'
Δ = 27°41'37"
R = 737.83'
LC = 512°39'51"E
353.16'
South Line of Section 32
P.O.B.
NORTH LOGAN GOVERNMENTAL COMPLEX
SURPLUS PROPERTY
DESCRIPTION OF LAND SURVEYED:
A parcel of land in the SE 1/4 of Section 32, T5N, R2W, Clinton County, Michigan and more particularly described as beginning at the S 1/4 corner of said section 32; thence N00°13'30"W 2152.18 feet on the N-S 1/4 line of said section 32; thence S89°57'19"E 50.94 feet to the westerly right-of-way of Dwight Road at a point 560.00 feet southerly of the E-W 1/4 line of said section 32; thence on the westerly right-of-way of Dwight Road for the next five (5) thence S00°03'50"E 112.88 feet; thence 296.44 feet on the arc of a curve to the left with a radius of 2292.10', a radius of 751.89 feet and long chord bearing and distance of S19°47'00"E 297.36 feet; thence 227°30'10"E 637.88 feet; thence 356.67 feet on the arc of a curve to the right with a central angle of 27°41'37", a radius of 737.83 feet and a long chord bearing and distance of S12°39'51"E 353.16 feet; thence S00°11'37"W 30.40 feet; thence S89°57'19"E 171.88 feet; thence S00°13'30"E 1262.18 feet; thence S00°03'50"E 191.34 feet; thence N89°52'30"W 420.93 feet; thence S00°49'00"E 267.49 feet to the south line of said section 32; thence N89°57'19"W 632.45 feet on the south line of said section 32 to the N 1/4 corner of section 5, T4N, R2W; thence S00°27'30"W 5.00 feet on the south line of said section 32 to the point of beginning, containing 48.84 acres, more or less.
Drawing No. 05032
August 28, 1986
MICHIGAN
Department of
HEALTH
Map of Boundary Survey
NORTH LOGAN COMPLEX - SURPLUS PROPERTY
Lansing, Michigan
STATE OF MICHIGAN
DEPARTMENT OF MANAGEMENT AND BUDGET
OFFICE OF FACILITIES
LAREY BRIDGETT
DIRECTOR

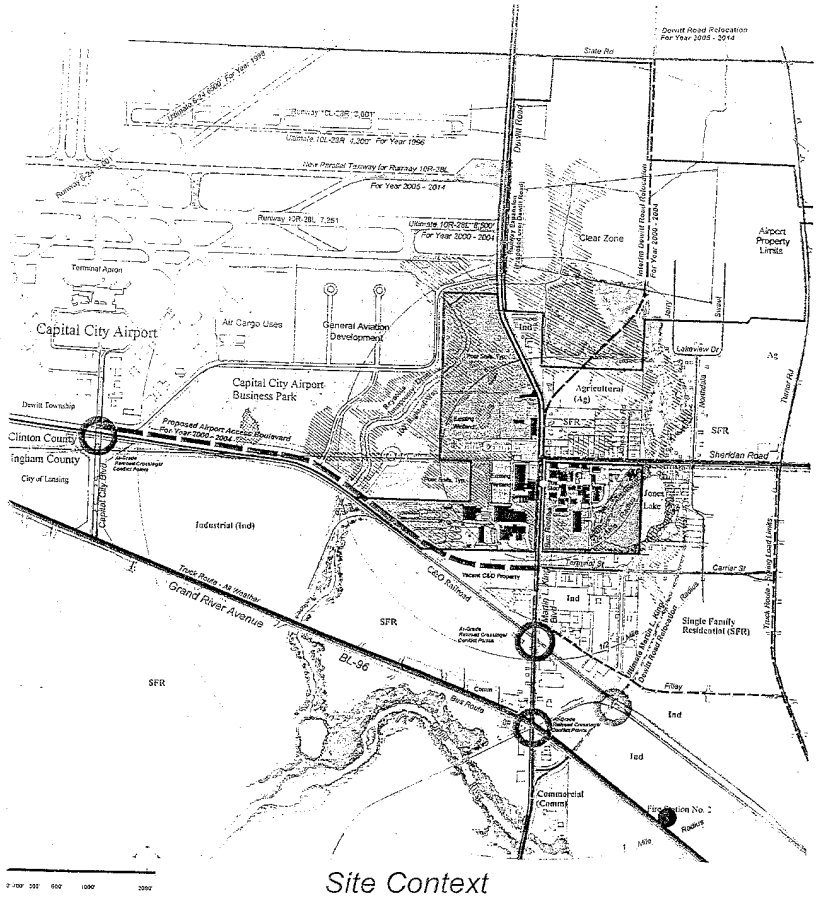




State of Michigan -
North Logan/ M. L. King Jr.
Government Complex
Lansing, Michigan

SH&G
Smith, Hinchman & Grylls Associates, Inc.
Architects/ Engineers/ Planners
100 West Jefferson Avenue
Suite 300
Detroit, Michigan 48226

JJR
Johnson, Johnson & Roy, Inc.
Planners / Landscape Architecture / Urban Design / Engineering / Environmental Services
110 West
Ann Arbor, Michigan 48104



State of Michigan -
North Logan/ M. L. King Jr.
Government Complex
Lansing, Michigan

SH&G JJR

KPMG

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Proforma Financial Statements

September 30, 1996

(With Independent Accountants'
Compilation Report Thereon)

KPMG Peat Marwick LLP

1400 Abbott Road, Suite 220
East Lansing, MI 48823

Telephone 517 336 3300

Telefax 517 336 3333

Independent Accountants' Compilation Report

Members of the
Michigan Biologic Products Commission:

We have compiled the accompanying pro forma balance sheet of the Michigan Biologic Products Institute as of September 30, 1996, and the pro forma statement of operations for the year ended September 30, 1996, in accordance with Statements on Standards for Accounting and Review Services issued by the American Institute of Certified Public Accountants.

A compilation is limited to presenting in the form of financial statements information that is the representation of management. We have not audited or reviewed the accompanying pro forma financial statements and, accordingly, do not express an opinion or any other form of assurance on them.

KPMG Peat Marwick LLP

November 15, 1996

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Pro Forma

Balance Sheet

September 30, 1996

Assets	
Current assets:	
Cash	$ -
Receivables	5,125,088
Inventories	2,149,618
Total current assets	7,274,706
Property, plant and equipment:	
Land	23,963
Buildings and building improvements	9,196,730
Machinery and equipment	6,251,958
	15,472,651
Less accumulated depreciation	(10,561,524)
Net property, plant and equipment	4,911,127
Total assets	$ 12,185,833
Liabilities and Equity	
Current liabilities:	
Accounts payable	$ 518,198
Accrued expenses	861,283
Total current liabilities	1,379,481
Other liabilities (see note 7)	-
Total liabilities	1,379,481
Contingencies (see note 7)	
Equity	10,806,352
Total liabilities and equity	$ 12,185,833

See accompanying Independent Accountants' Compilation Report and notes to proforma financial statements.

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Pro Forma

Statement of Operations

Year ended September 30, 1996

Revenues:	
Army product sales	$ 3,546,533
Other product sales	3,085,785
Red Cross	725,000
Other	153,369
Total revenue	7,510,687
Expenses:	
Salaries and wages	5,833,071
Fringe benefits	2,241,651
Contractual services, supplies and materials	3,682,746
General services	1,183,990
Depreciation	985,569
State/Department overhead	647,411
Inventory adjustment	(817,264)
Other	304,628
Total expenses	14,061,802
Net (loss)	$ (6,551,115)

See accompanying Independent Accountants' Compilation Report and notes to proforma financial statements.

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Notes to Pro Forma Financial Statements

September 30, 1996

(1) Description of Entity

The objective of the accompanying pro forma financial statements is to present the Michigan Biologic Products Institute (the "Institute") "as if" it was in operation as a separate business during the year ended September 30, 1996. However, these pro forma financial statements are not necessarily indicative of the financial position or results of operations that would have been attained had the Institute actually existed during the period. Historical financial statements of the Institute are not available.

The Institute was created on December 5, 1995, by Executive Order 1995-25 pursuant to Article V, Section 4, of the Constitution of the State of Michigan of 1963. The Institute is a temporary State agency with a life of no more than two years.

The Biologic Products Division (the "BPD") of the Michigan Department of Public Health (the "MDPH") and the Pharmaceutical Products Fund (the "PPF"), established under Sections 9111 and 9112 of Act No. 368 of the Public Acts of 1978, were transferred to the Institute by a Type III transfer, as defined by Section 3 of Public Act No. 380 of the Public Acts of 1965. The Institute assumed all functions, duties, contractual obligations, responsibilities, inventory, tangible and intangible property and employees of the BPD, including administration of the PPF.

The Institute is an independent and autonomous State entity. The Director is the head of the Institute within the meaning of the Constitution of the State of Michigan of 1963 and of the Executive Organization Act of 1965, Act No. 380 of the Public Acts of 1965, and is the Appointing Authority as that term is used in the Constitution of the State of Michigan of 1963, and in the rules and procedures of the Civil Service Commission. The Director:

- Maintains the establishment license of the facilities for biologic product production and maintains existing product licenses, except for obsolete products, and obtains new licenses as appropriate.
- Maintains existing contractual relationships and expand the value of the work being undertaken while preparing to transfer responsibility for such work out of State government.
- Fulfills the duties of a Responsible Head as delineated in 21 CFR 600.10(a).
- Reports to the Commission on actions that affect the business of the Institute.

The Michigan Biologic Products Commission (the "Commission") was also established by Executive Order 1995-25, pursuant to Article V, Section 4, of the Constitution of the State of Michigan of 1963, and also has a life of no more than two years. The Commission provides supervision, policy control and direction to the Institute and the Director. In addition, the Commission must:

- Within eight (8) months of its initial organizational meeting, prepare a plan describing the means by which the Institute will be transferred out of State government and into the private sector within the two year term of its temporary agency status.

(Continued)

- As part of the plan, cause the fair market value of all state property, inventory, equipment and other assets associated with the manufacture of biologic products to be determined.
- Contract with the initial Director; designate and contract with any future Directors.
- Perform such other duties and responsibilities as may be assigned or transferred to the Commission by statute or by executive order.

(2) Summary of Significant Accounting Policies

(a) Description of Business

The Institute is engaged in the production and sale, and associated research and development of vaccines for the prevention of infectious diseases in children and adults. The Institute is also engaged in the production of blood derivatives.

The Institute is licensed by the United States Food and Drug Administration (FDA) to produce and market its products (see note 6). These products are subject to rigorous tests by the FDA of each lot produced. FDA approval must be obtained to release a lot for distribution (sale). There is no assurance that the Institute's products will continue to obtain the required regulatory approvals.

(b) Principles of Accounting

The accompanying pro forma financial statements of the Institute have been prepared in conformity with generally accepted accounting principles utilizing the accrual basis approach. Statements of cash flows and changes in equity are not presented.

(c) Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and disclosure of contingencies. Actual results could differ from those estimates.

(d) State Funding

As a division of the MDPH, the BPD had revenues to offset its appropriations with the difference being funded by the State's general fund. These general fund monies are not considered revenues of the Institute and therefore are not included in the accompanying financial statements. The general fund appropriation for the year ended September 30, 1996 was $2,851,500.

The State has also funded the acquisition of capital assets, however, complete historical accounting records supporting the cumulative amount of such funding are not available. The assets that have been acquired are included in the accompanying financial statements as property, plant and equipment and the State funding is included in equity, net of cumulative results of operations since inception.

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Notes to Pro Forma Financial Statements, Continued

(e) Receivables

Receivables are recorded when they are measurable and earned as defined in the contract with each of MBPI's customers. A related allowance for uncollectible receivables is not considered necessary due to the Institute's past collection experience. At September 30, 1996, receivables were comprised of the following:

	1996
Army	$ 3,726,294
Red Cross	325,525
Other	1,073,269
Total	$ 5,125,088

(f) Inventories (Inventory adjustment)

Inventories are carried at the lower of estimated average cost or market and are comprised of raw materials, work in process and finished product (released for distribution by the FDA), as follows:

	1996
Raw materials	$ 339,149
Work in process	1,038,720
Finished product	771,749
Total	$2,149,618

The inventory adjustment is reported because the detailed accounting records necessary to accurately report cost of sales are not available. The adjustment represents the net change in the carrying value of inventories from the beginning to the end of the year.

(g) Property, Plant and Equipment

Property, plant and equipment are stated at original historical cost.

Depreciation on plant and equipment is calculated on the straight-line method over the estimated useful lives of the assets. Estimated useful lives are 40 years for buildings, 10 years for building improvements and 3-10 years for computers and equipment.

(h) Taxes

The Institute operates as a State agency, accordingly, there is no provision for income taxes, property taxes or the single business tax.

(i) Revenue Recognition

The Institute recognizes revenue when it is measurable and earned, encompassing the net change in accounts receivable for the period, and adjusted for reimbursement of items capitalized.

(j) Salaries and Wages

Salaries and wages represent the amounts reported in the Statewide accounting system for BPD, including the PPF, for the period presented. These represent actual costs for the period, adjusted for changes in accrued vacation and sick leave (accrued expenses).

(Continued)

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Notes to Pro Forma Financial Statements, Continued

(k) Fringe Benefits
Fringe benefits represent the amounts reported in the Statewide accounting system for the BPD, including the PPF, for the period presented. Fringe benefits include payroll taxes, retirement and health and other insurance. These represent actual costs for the period.

(l) Contractual Services, Supplies & Materials
Contractual services, supplies and materials represent the amounts reported in the Statewide accounting system for the BPD, including the PPF, for the period presented. These represent actual costs for the period, adjusted for items capitalized.

(m) General Services
General services represent the cost of utilities, security and maintenance for the Institute's properties. The amounts reported are based on an estimate of the portion of the MDPH costs which are attributable to the Institute's properties.

(n) State and Department Overhead
State and department overhead represents the estimated share of Statewide and MDPH general and administrative costs that are attributable to the Institute, based on MDPH's indirect cost rate study.

(3) Product Distributed in Michigan
As provided in section 333.9112 of the Public Health Code of the State of Michigan, the Institute distributes vaccines, some of which are produced by the Institute and others are provided by the federal government, to local public health departments and certain private physician clinics throughout the State at no cost. The vaccines and number of doses produced by the Institute and distributed in the year ended September 30, 1996 are provided below:

Vaccine	*1996*
Diphtheria- Tetanus Toxoid	27,570
Diphtheria- Tetanus- Pertussis	255,790
Immune Globulin	28,524
Pertussis	1,410
Rabies	4,834
Tetanus- Diphtheria Toxoids	343,220
Totals	661,348

In addition, at September 30, 1996 the Institute had the following vaccines and dosages on hand for future distribution:

Vaccine	*1996*
Diphtheria- Tetanus Toxoid	74,180
Diphtheria- Tetanus- Pertussis	338,550
Totals	412,730

(Continued)

(4) Contracts

In addition to several contracts with the Army (see note 5), the Institute has contracts with three Michigan Red Cross regions, North American Biologics, Inc. (NABI), SmithKline Beecham (SB) and Athena Neurosciences, Inc. (Athena).

The contracts with three Michigan Red Cross regions were renewed in 1995 and expire in June 1997. Under these contracts the Institute receives a fee to fractionate up to 50,000 liters of blood and deliver albumen to the Red Cross. Other fractions are distributed by the Institute and revenues are shared with the Red Cross (80% Institute and 20% Red Cross).

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The Institute has a collaboration with Athena aimed at developing uses for the botulinum toxin. Athena is conducting trials of using botulinum to treat cervical dystonia with product manufactured by the Institute. The Institute is reimbursed for the greater of its costs or $40,000 per quarter for this activity during the clinical trials period. If the trials are successful and the product is licensed, the Institute will produce botulinum toxin for the product. Athena will reimburse the cost of manufacture and pay an additional 5% of net sales to the Institute.

(5) Business Concentration - Major Customer

The Institute has several contracts with its primary customer, the United States Army (Army), and is continually negotiating additional agreements.

The Army has funded the acquisition of significant pieces of equipment and separate buildings and retains ownership of these properties (which are not included in the accompanying financial statements). These properties are necessary for the Institute to continue providing the products and services purchased by the Army.

(6) Licensing Status

The Institute has product licenses from the FDA as indicated below and establishment license number 99. These licenses are current and subject to ongoing FDA monitoring.

(a) FDA Product Licenses

Anthrax Vaccine
Rabies Vaccine
Diphtheria and Tetanus Toxoids and Pertussis Vaccine
Diphtheria and Tetanus Toxoids
Tetanus Toxoid
Pertussis Vaccine
Albumin (Human)
Antihemophilic Factor (Human) 500 IU/ vial
Immune Globulin (Human)- 16.5%

(Continued)

(b) FDA Investigational New Drug (IND) Application
Botulinum Toxin Type B
Pentavalent Botulinum Toxoids adsorbed for protection of laboratory personnel
Pentavalent Botulinum Toxoids adsorbed for protection of healthy volunteers
DTPw plus Hib
DTPw plus Hepatitis B plus Hib
DTPa plus Hepatitis B plus Hib
DTPa
DTPa plus Hepatitis B
Anthrax Vaccine Absorbed
DTPa plus Hepatitis B reduced antigen content
Virus Inactivated Hepatitis B Immune Globulin
Virus Inactivated Hepatitis B Globulin for intravenous administration

(c) USDA Animal Drug Licenses
Botulinum Toxoid Type B, for equine use

In addition, the Institute has a license from the United States Department of Agriculture (USDA) to produce and maintain animals for testing, including a certified virus free monkey colony.

(7) Contingencies
Liabilities are reported for loss contingencies, including environmental remediation costs, arising from claims, assessments, litigation, fines and penalties, and other sources when the amount of the assessment and/or remediation costs are probable and can be reasonably estimated. Management believes there are no significant loss contingencies to be reported.

No liabilities for employees post-retirement benefits are reported because such amounts are dependent on future events.

The Institute's ability to market its products is subject to ongoing FDA approval. FDA conducted a thorough review of the Institute in the Spring of 1995 which resulted in the issuance of a "warning" letter. Failure to promptly correct the deviations cited in the warning letter may result in regulatory action without further notice (license suspension and/ or revocation, seizure, and/ or injunction). Management has responded vigorously to the deficiencies cited in the letter, taken corrective actions, and communicated such to the FDA. Management believes the FDA will respond favorably to the Institute's actions.

KPMG Peat Marwick LLP

74 North Pearl Street
Albany, NY 12207

Telephone 518 462 9651

Telefax 518 455 8809

Independent Accountants' Compilation Report

Members of the
Michigan Biologic Products Commission:

We have compiled the accompanying pro forma balance sheet of the Michigan Biologic Products Institute as of September 30, 1995, and the pro forma statements of operations for the years ended September 30, 1995, 1994, and 1993, in accordance with Statements on Standards for Accounting and Review Services issued by the American Institute of Certified Public Accountants.

A compilation is limited to presenting in the form of financial statements information that is the representation of management. We have not audited or reviewed the accompanying pro forma financial statements and, accordingly, do not express an opinion or any other form of assurance on them.

KPMG Peat Marwick LLP

September 20, 1996

Member Firm of
Klynveld Peat Marwick Goerdeler

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Pro Forma

Balance Sheet

September 30, 1995

Assets	
Current assets:	
Cash	$ –
Receivables	7,942,976
Inventories	1,332,354
Total current assets	9,275,330
Property, plant and equipment:	
Land	23,963
Buildings and building improvements	9,196,730
Machinery and equipment	5,757,827
	14,978,520
Less accumulated depreciation	(9,575,800)
Net property, plant and equipment	5,402,720
Total assets	$ 14,678,050
Liabilities and Equity	
Current liabilities:	
Accounts payable	393,826
Accrued expenses	792,304
Total current liabilities	1,186,130
Other liabilities (see note 7)	–
Total liabilities	1,186,130
Contingencies (see note 7)	
Equity	13,491,920
Total liabilities and equity	$ 14,678,050

See accompanying Independent Accountants' Compilation Report and notes to proforma financial statements.

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Pro Forma

Statement of Operations

Years ended September 30, 1995, 1994 and 1993

	1995	1994	1993
Revenues:			
Army product sales	$ 4,276,037	3,642,490	4,573,295
Other product sales	3,489,810	3,491,915	4,742,482
Red Cross	720,257	725,364	674,480
Other	109,277	211,965	161,292
Total revenue	8,595,381	8,071,734	10,151,549
Expenses:			
Salaries and wages	5,018,584	4,528,154	3,990,291
Fringe benefits	2,139,070	1,890,356	1,632,264
Contractual services, supplies and materials	4,602,132	2,244,749	2,801,545
General services	1,141,839	1,238,801	1,100,461
Depreciation	921,880	751,222	624,784
State/Department overhead	622,999	646,915	731,906
Inventory adjustment	327,247	(909,379)	(108,441)
Other	296,084	287,629	301,225
Total expenses	15,069,835	10,678,447	11,074,134
Net (loss)	$ (6,474,453)	(2,606,713)	(922,585)

See accompanying Independent Accountants' Compilation Report and notes to proforma financial statements.

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Notes to Pro Forma Financial Statements

September 30, 1995, 1994 and 1993

(1) Description of Entity

The objective of the accompanying pro forma financial statements is to present the Michigan Biologic Products Institute (the "Institute") "as if" it was in operation as a separate business during each of the three years ended September 30, 1995. However, these pro forma financial statements are not necessarily indicative of the financial position or results of operations that would have been attained had the Institute actually existed during the three year period. Comparable historical financial statements of the Institute are not available.

The Institute was created on December 5, 1995, by Executive Order 1995-25 pursuant to Article V, Section 4, of the Constitution of the State of Michigan of 1963. The Institute is a temporary State agency with a life of no more than two years.

The Biologic Products Division (the "BPD") of the Michigan Department of Public Health (the "MDPH") and the Pharmaceutical Products Fund (the "PPF"), established under Sections 9111 and 9112 of Act No. 368 of the Public Acts of 1978, were transferred to the Institute by a Type III transfer, as defined by Section 3 of Public Act No. 380 of the Public Acts of 1965. The Institute assumed all functions, duties, contractual obligations, responsibilities, inventory, tangible and intangible property and employees of the BPD, including administration of the PPF.

The Institute is an independent and autonomous State entity. The Director is the head of the Institute within the meaning of the Constitution of the State of Michigan of 1963 and of the Executive Organization Act of 1965, Act No. 380 of the Public Acts of 1965, and is the Appointing Authority as that term is used in the Constitution of the State of Michigan of 1963, and in the rules and procedures of the Civil Service Commission. The Director:

- Maintains the establishment license of the facilities for biologic product production and maintains existing product licenses, except for obsolete products, and obtains new licenses as appropriate.
- Maintains existing contractual relationships and expand the value of the work being undertaken while preparing to transfer responsibility for such work out of State government.
- Fulfills the duties of a Responsible Head as delineated in 21 CFR 600.10(a).
- Reports to the Commission on actions that affect the business of the Institute.

The Michigan Biologic Products Commission (the "Commission") was also established by Executive Order 1995-25, pursuant to Article V, Section 4, of the Constitution of the State of Michigan of 1963, and also has a life of no more than two years. The Commission provides supervision, policy control and direction to the Institute and the Director. In addition, the Commission must:

- Within eight (8) months of its initial organizational meeting, prepare a plan describing the means by which the Institute will be transferred out of State government and into the private sector within the two year term of its temporary agency status.

(Continued)

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Notes to Pro Forma Financial Statements, Continued

- As part of the plan, cause the fair market value of all state property, inventory, equipment and other assets associated with the manufacture of biologic products to be determined.
- Contract with the initial Director; designate and contract with any future Directors.
- Perform such other duties and responsibilities as may be assigned or transferred to the Commission by statute or by executive order.

(2) Summary of Significant Accounting Policies

(a) Description of Business

The Institute is engaged in the production and sale, and associated research and development of vaccines for the prevention of infectious diseases in children and adults. The Institute is also engaged in the production of blood derivatives.

The Institute is licensed by the United States Food and Drug Administration (FDA) to produce and market its products (see note 6). These products are subject to rigorous tests by the FDA of each lot produced. FDA approval must be obtained to release a lot for distribution (sale). There is no assurance that the Institute's products will continue to obtain the required regulatory approvals.

(b) Principles of Accounting

The accompanying pro forma financial statements of the Institute have been prepared in conformity with generally accepted accounting principles utilizing the accrual basis approach. Statements of cash flows and changes in equity are not presented.

(c) Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and disclosure of contingencies. Actual results could differ from those estimates.

(d) State Funding

As a division of the MDPH, the BPD had revenues to offset its appropriations with the difference being funded by the State's general fund. These general fund monies are not considered revenues of the Institute and therefore are not included in the accompanying financial statements. General fund appropriations were as follows:

1995- $3,347,900
1994- $3,260,700
1993- $3,360,700

The State has also funded the acquisition of capital assets, however, complete historical accounting records supporting the cumulative amount of such funding are not available. The assets that have been acquired are included in the accompanying financial statements as property, plant and equipment and the State funding is included in equity, net of cumulative results of operations since inception.

(Continued)

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Notes to Pro Forma Financial Statements, Continued

(e) Receivables

Receivables are recorded when they are measurable and earned as defined in the contract with each of MBPI's customers. A related allowance for uncollectible receivables is not considered necessary due to the Institute's past collection experience. At September 30, 1995, receivables were comprised of the following:

	1995
Army	$ 7,198,099
Red Cross	176,175
Other	568,702
Total	$ 7,942,976

(f) Inventories (Inventory adjustment)

Inventories are carried at the lower of estimated average cost or market and are comprised of raw materials, work in process and finished product (released for distribution by the FDA), as follows:

	1995
Raw materials	$ 191,677
Work in process	657,101
Finished product	483,557
Total	$1,332,354

The inventory adjustment is reported because the detailed accounting records necessary to accurately report cost of sales are not available. The adjustment represents the net change in the carrying value of inventories from the beginning to the end of the year.

(g) Property, Plant and Equipment

Property, plant and equipment are stated at original historical cost.

Depreciation on plant and equipment is calculated on the straight-line method over the estimated useful lives of the assets. Estimated useful lives are 40 years for buildings, 10 years for building improvements and 3-10 years for computers and equipment.

(h) Taxes

The Institute operates as a State agency, accordingly, there is no provision for income taxes, property taxes or the single business tax.

(i) Revenue Recognition

The Institute recognizes revenue when it is measurable and earned, encompassing the net change in accounts receivable for the period, and adjusted for reimbursement of items capitalized.

(j) Salaries and Wages

Salaries and wages represent the amounts reported in the Statewide accounting system for BPD, including the PPF, for the periods presented. These represent actual costs for the applicable periods, adjusted for changes in accrued vacation and sick leave (accrued expenses).

(Continued)

(k) Fringe Benefits
Fringe benefits represent the amounts reported in the Statewide accounting system for the BPD, including the PPF, for the periods presented. Fringe benefits include payroll taxes, retirement and health and other insurance. These represent actual costs for the applicable periods.

(l) Contractual Services, Supplies & Materials
Contractual services, supplies and materials represent the amounts reported in the Statewide accounting system for the BPD, including the PPF, for the periods presented. These represent actual costs for the applicable periods, adjusted for items capitalized.

(m) General Services
General services represent the cost of utilities, security and maintenance for the Institute's properties. The amounts reported are based on an estimate of the portion of the MDPH costs which are attributable to the Institute's properties.

(n) State and Department Overhead
State and department overhead represents the estimated share of Statewide and MDPH general and administrative costs that are attributable to the Institute, based on MDPH's annual indirect cost rate study.

(3) Product Distributed in Michigan
As provided in section 333.9112 of the Public Health Code of the State of Michigan, the Institute distributes vaccines, some of which are produced by the Institute and others are provided by the federal government, to local public health departments and certain private physician clinics throughout the State at no cost. The vaccines and number of doses produced by the Institute and distributed in each of the years ended September 30, 1995, 1994 and 1993 are provided below:

Vaccine	*1995*	*1994*	*1993*
Diphtheria- Tetanus Toxoid	25,578	38,523	23,070
Diphtheria- Tetanus- Pertussis	451,288	603,978	701,010
Immune Globulin	35,050	55,740	75,009
Pertussis	6,915	8,143	4,203
Rabies	1,742	1,636	2,826
Tetanus Toxoid	930	8,385	18,660
Tetanus- Diphtheria Toxoids	324,805	324,850	315,895
Totals	846,308	1,041,255	1,140,673

In addition, at September 30, 1995 the Institute had the following vaccines and dosages on hand for future distribution:

Vaccine	*1995*
Diphtheria- Tetanus Toxoid	108,310
Diphtheria- Tetanus- Pertussis	394,910
Tetanus- Diphtheria Toxoids	324,410
Totals	827,630

(Continued)

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Notes to Pro Forma Financial Statements, Continued

(4) Contracts

In addition to several contracts with the Army (see note 5), the Institute has contracts with three Michigan Red Cross regions, North American Biologics, Inc. (NABI), SmithKline Beecham (SB) and Athena Neurosciences, Inc. (Athena).

The contracts with three Michigan Red Cross regions were renewed in 1995 and expire in June 1997. Under these contracts the Institute receives a fee to fractionate up to 50,000 liters of blood and deliver albumen to the Red Cross. Other fractions are distributed by the Institute and revenues are shared with the Red Cross (80% Institute and 20% Red Cross).

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Tetanus Toxoid
Pertussis Vaccine
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Antihemophilic Factor (Human) 500 IU/ vial
Immune Globulin (Human)- 16.5%

(Continued)

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DTPw plus Hib
DTPw plus Hepatitis B plus Hib
DTPa plus Hepatitis B plus Hib
DTPa
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Botulinum Toxoid Type B, for equine use

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KPMG Peat Marwick LLP

1400 Abbott Road, Suite 220
East Lansing, MI 48823

Telephone 517 336 3300

Telefax 517 336 3333

November 12, 1996

Private and Confidential

State of Michigan
Department of Management and Budget
Office of Purchasing
530 West Allegan Street
Mason Building, 2nd Floor
Lansing, Michigan 48933

Re: Preliminary Determination of the Fair Market Value of The Michigan Biologic Products Institute

Dear Sirs/Madam:

The Valuation and Appraisal Group of KPMG Peat Marwick LLP ("KPMG") was retained to make a preliminary determination of the fair market value of the equity of the Michigan Biologic Products Institute ("MBPI" or "the Institute") in connection with the separation of MBPI from the Michigan Department of Health and the eventual privatization of the Institute. Our determination is as of October 18, 1996 ("the valuation date").

This letter sets forth our conclusion, as well as the methodology and procedures we used and the factors we considered in formulating our opinion. In addition, we have commented on the adequacy of access to necessary materials and personnel in the course of our investigation and noted any limitations on our opinion.

A. Valuation Definitions and Considerations

At the valuation date, MBPI was an autonomous State entity reporting to the Michigan Biological Products Commission. As a result, there was no established market for interests in MBPI or its assets. For the purposes of our opinion, therefore, fair market value was defined in accordance with Revenue Ruling 59-60, as follows:

> The price at which the property would change hands between a willing buyer and a willing seller when the former is not under any compulsion to buy and the latter is not under any compulsion to sell, both parties having reasonable knowledge of relevant facts.

We considered the following factors in determining the preliminary fair market value of MBPI at the valuation date:

1. The history and operations of the Institute including published market data and other available public information relating to the Institute and the biological products industry;

2. The financial information describing the financial condition and operating results of the Institute used by KPMG to develop compiled financial statements for the Institute for the fiscal years ended September 30, 1993-1995, including:

a. Analysis of assets, liabilities, and book value; and

b. Historical operating results including profits generated and factors affecting profits;

3. A general description of the overall business outlook for the Institute, and of the assumptions on which the description was based at the valuation date, as embodied in a spreadsheet prepared by KPMG, and upon which we furnished comments, entitled "Management's projection of MBPI's operations" as of October 18, 1996, showing anticipated financial results from operations of the Institute for the 1997-2002 period;

4. Information regarding material contracts in effect, those currently being negotiated at the valuation date, and those expected to be negotiated or renegotiated within six months of the valuation date;

5. Information regarding the FDA Warning Letter issued to MBPI on August 31, 1995;

6. Appraisal reports and other analytical documents regarding the land and fixed assets of the Institute as prepared by Manufacturers Equipment Appraisal, Inc. of Dearborn, Michigan; Dean Appraisal Company of Birmingham, Michigan; and Smith, Hinchman & Grylls Associates, Inc. of Detroit, Michigan;

7. Published market data and other available public information relating to the Institute and the biological products industry, including:

a. Relevant historical trends, current performance indicators, and outlook at the valuation date for the economy and the biological products industry;

b. Bases of investors' appraisal, at the valuation date, of publicly traded shares of companies that could be used for comparative purposes; and

8. Other relevant factors.

As the Institute was expected to operate in the future as a going concern, we determined value under a going concern premise. This premise of fair market value is not intended to represent the amount that might be realized from the liquidation and piecemeal disposition of the Institute or its property in the marketplace or from some other use of the property.

B. Valuation Approach

In our study, we considered the three traditional approaches to value. Following is a summary of these approaches:

- The *Income Approach* to value is based upon the estimated future income streams associated with a specific asset, considering the estimated remaining life of the asset, the average annual rate of return anticipated, and market rates of return. To develop an opinion of the present value of the future benefits of the asset's ownership, the income streams are capitalized by means of a discount rate reflecting both general risks and those specific to the asset in question.

- The *Cost Approach* is based upon the current cost to recreate or duplicate the asset less an appropriate allowance for a decrease in value due to the passage of time or obsolescence.

- The *Market Approach* is an indication of value based on comparing the property to be appraised either to similar comparable property recently sold or to the asking prices of similar items offered for sale. Using similar units of comparison, adjustments are made based on the characteristics and relative performance of these assets being compared, to the sales price. A basic assumption to this approach is that market transactions are conducted between willing buyers and willing sellers at arm's length.

In determining the preliminary value of the equity in the Institute, the approach which was used was the Income Approach. This approach was most significant because of a number of factors including:

- The absence of positive earnings for the Institute over the 1993-1995 period, which would provide a basis with which to apply a Market Approach to value; and

- The expected occurrence of a number of material events during the 1997 fiscal year, including the possible award of material new contracts and the possible completion or termination of certain current contracts from which the Institute has derived a material portion of its revenues in the past.

As a result of the above, a market approach to value was not employed. While we considered the fair market value of the fixed assets of the Institute, a cost approach was not used in the valuation of the Institute because of the assumption that the Institute would continue to operate as a going concern.

C. Access to Information and Personnel

During the course of our investigation, we believe that we had access to all available materials and personnel. No limitations were imposed by the Institute on the scope of our investigation. However, certain historical financial and business information was limited due to the lack of certain historical records.

We interviewed the following individuals who provided significant assistance in the course of our study:

The Michigan Biologic Products Institute
Robert C. Myers, D.V.M., Director
Rob van Ravenswaay, Deputy Director

The Michigan Biological Products Commission
Dennis L. Schornack, Chairman

We visited MBPI's facilities in Lansing, Michigan and reviewed the Institute's compiled historical financial statements for fiscal years ended September 30, 1993 through 1995.

We reviewed Management's projection of MBPI's operations, which was prepared as of October 18, 1996 and which presents expected financial results from operations for the 1997-2002 period. This projection varies according to certain important assumptions, including:

1. The assumed processing capacity of MBPI for blood plasma fractionation ranged from 60,000 to 80,000 liters.

2. The award of future contracts from the Department of Defense for the production of Anthrax vaccine would occur in amounts projected to immunize significant segments of the United States Armed Forces. Assumed vaccine production ranged from 1.5 million doses per year in 1998 and 1999, and 2.5 million doses annually in 2000 and beyond ("low end"), to 3.0 million doses per year in 1998 and 1999, and 5.0 million doses annually in 2000 and beyond ("high end"). Assumed pricing ranged from $2.50 per dose to $3.25 per dose.

3. The continuation of the workforce of the size currently employed at approximately its current compensation.

4. The assumption that the FDA Warning Letter issued to MBPI on August 31, 1995 will not result in a material impact on the financial outlook for the Institute.

5. The assumption that all accounts receivable on the books of the Institute immediately prior to the valuation date, and any proceeds from the Pharmaceutical Products Fund, would not be available to the Institute, or any potential purchaser of the Institute.

6. Included in the valuation of the Institute is the fair market value of an unused real estate parcel held for future expansion located north of the Michigan Department of Health's North Logan Complex, West Campus. The value of this parcel was determined by Dean Appraisal Company to be $390,000 as of May 18, 1995.

7. The assumed contract award for the Joint Vaccine Acquisition Program of the Department of Defense to Battelle, on whose development and production team MBPI would be included.

D. Conclusions

Taking into account all that was developed through our study, it is our preliminary opinion that the fair market value of the equity of the Michigan Biologic Products Institute on a going-concern basis at the valuation date ranged from nominal, assuming projected anthrax vaccine sales of 1.5 million to 2.5 million doses annually, to $10.5 million, assuming anthrax vaccine sales of 3.0 million to 5.0 million doses annually at a price of $3.25 per dose.

E. Limiting Conditions and Assumptions

1. This letter is intended for the specific purpose stated on page one and may not be used for any other purpose. Except as described in our engagement letter, no third party may be shown or given the letter, or a copy thereof, without the express written consent of KPMG Peat Marwick LLP, which will not be unreasonably withheld.

2. The appraisal of any financial instrument or business is a matter of informed judgment. The accompanying preliminary appraisal has been prepared on the basis of information and assumptions set forth in the attached letter. As part of this engagement, we have relied upon publicly available data which have not been, in all cases, independently verified.

3. We have relied on information supplied by the Institute without audit or verification. We have assumed that all information furnished is complete, accurate and reflects management's good faith efforts to

describe the status and prospects of the Institute at the valuation date from an operating and a financial point of view.

4. We have assumed that the Institute had no undisclosed real or contingent assets or liabilities, no unusual obligations or substantial commitments, other than in the ordinary course of business, nor had any litigation pending or threatened that would have a material effect on our analyses.

5. Any use of management's projections or forecasts in our analysis does not constitute an examination or compilation of prospective financial statements in accordance with standards established by the American Institute of Certified Public Accountants (AICPA). We do not express an opinion or any other form of assurance on the reasonableness of the underlying assumptions or whether the prospective financial statements used, if any, are presented in conformity with AICPA presentation guidelines. Further, there will usually be differences between prospective and actual results because events and circumstances frequently do not occur as expected, and those differences may be material.

6. The terms of our engagement are such that we have no obligation to update this letter or to revise the valuation because of events and transactions occurring subsequent to the valuation date.

7. Neither KPMG Peat Marwick LLP nor any individual signing or associated with this letter shall be required to give testimony or appear in court or other legal proceedings, unless specific arrangements therefore have been made in advance.

8. No responsibility is assumed for legal matters including interpretations of either the law or contracts. No investigation of legal title has been made and owner's claims to property have been assumed valid. No consideration has been given to liens or encumbrances except as specifically stated. Our valuation assumed that all required licenses, permits etc. are in full force and effect. We assume no responsibility that the valuation approaches used in our letter are acceptable as legal evidence in any particular court or jurisdiction. The suitability of our letter for any legal forum is a matter for the client and the client's legal advisor.

9. Neither our preliminary opinion nor our letter is a fairness opinion as to the fairness of an actual or proposed transaction, or a solvency opinion, or an investment recommendation, but, instead, is an expression of our preliminary determination of the fair market value of the equity of MBPI between a hypothetical willing buyer and a hypothetical willing seller in an assumed transaction on an assumed valuation date. For various

reasons, the price at which the equity of MBPI might be sold in a specific transaction between specific parties on a specific date might be significantly different from its fair market value as expressed in our letter.

10. Our fees for this engagement are in no way contingent upon our reported conclusion.

KPMG Peat Marwick LLP

F. Statement of Qualifications and Disinterest

This letter was prepared under the direction of Mr. M. Mark Lee, a principal at KPMG. Our Certification of Value is attached. KPMG has no present or contemplated future interest in MBPI, or any other interest which might prevent us from performing an unbiased valuation.

Very truly yours,

KPMG Peat Marwick LLP

Certification of Value

I certify that, to the best of my knowledge and belief:

- The statements of fact contained in this letter are true and correct;
- The reported analyses, preliminary opinions, and preliminary conclusions are limited only by the reported assumptions and limiting conditions, and are my personal, unbiased professional analyses, preliminary opinions, and preliminary conclusions;
- Neither KPMG Peat Marwick LLP nor I have any present or prospective interest in the property that is the subject of this letter, and have no personal interest or bias with respect to the parties involved;
- My compensation is not contingent on an action or event resulting from the analyses, preliminary opinions, or preliminary conclusions, in, or the use of, this letter;
- The following professionals provided significant professional assistance to the person signing this letter:

  William F. Pittock, CFA
  Curtis Johnson

M. Mark Lee

M. Mark Lee, Principal

MILLER, CANFIELD, PADDOCK AND STONE, P.L.C.

OUTLINE OF
LEGISLATIVE IMPLEMENTATION OF MBPI PRIVATIZATION

I. Empowerment of State Administrative Board.

A. Authorize the State Administrative Board to approve the transfer of all or a portion of the assets and liabilities of the MBPI to 1 or more transferees recommended by the Commission and to authorize the Chair of the Commission, or his or her designee, to enter into agreements on behalf of the State related to the transfer.

1. Permit acceptance of consideration.

2. Make a legislative determination that the State has an interest in continuing operations at the existing site as a viable enterprise contributing to the economy of the State.

B. Conditions upon SAB approval of transfer of MBPI.

1. Determination by the SAB that the consideration to be received is fair and appropriate so that the credit of the state shall not have been granted to, nor in aid of, any person, association, or corporation, public or private.

2. The agreement to be entered into by the Commission and the proposed transferee requires the transferee to provide the State, for use in Michigan as determined by the State and for the period and subject to the conditions and prices agreed upon, with preferential access to biologic products it makes.

3. Subject to the ability to terminate employment for cause, the agreement to be entered into by the Commission and the proposed transferee includes a plan of operation which assures the continuation of employment for 1 year of current MBPI employees electing employment with the transferee.

C. Options for SAB.

1. To rely upon the opinions or reports of counsel, independent appraisers, accountants, financial advisors and other experts.

2. To require the receipt before the effective date of the transfer of an independent opinion that the consideration for the assets to be transferred is fair and adequate.

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3. Approve or reject recommendation of the Commission. Rejection shall not be required to assign reasons.

D. Authorize SAB to approve any contracts for continued service by state agencies to the transferred facilities and any contracts for continued service from the transferred facilities to state agencies.

II. Authority of Commission.

A. Define assets subject to transfer and include or exclude any portion of the operation of the MBPI.

1. Inventory (including products released, unreleased and being manufactured).

2. Accounts Receivable.

3. Real, personal and intangible property, including licenses, contractual rights and royalties.

B. Determine liabilities of MBPI subject to transfer or to be retained by the State.

C. Authorize agreements relating to:

1. The sale, conveyance, assignment, and disposition of assets and liabilities of the MBPI, wherever situated.

2. The granting of rights for the future purchase of assets of MBPI retained by the State.

3. The retention of options, rights, interests and easements in the State to specified properties and assets.

4. The production of steam and other specialized utilities.

5. The retention of a selling agent to market the MBPI.

D. Solicit bids and/or proposals to purchase the assets of the MBPI and negotiate an agreement with 1 or more prospective transferees for the transfer of all or a portion of the assets and liabilities of the MBPI.

E. Any other powers necessary or convenient to effect or complete the transactions permitted, including all actions necessary to transfer permits and licenses to the transferee.

III. Disposition of the Products Fund/ Net Sale Proceeds

A. Sale Proceeds shall be deposited in the Product Fund. The Legislature appropriates the moneys in the Product Fund, as of the end of the fiscal year in which the transfer of the assets of the MBPI occurs, for use for 1 or more of the following purposes in the following order of priority:

1. For payment of fees of a selling agent.

2. For payment of accrued sick and annual leave time to MBPI employees upon separation from the State if current fiscal year appropriations available for that purpose are insufficient.

3. In relation to payouts for accrued sick and annual leave time from current fiscal year appropriations available for that purpose, for reimbursement of the State for such payments to MBPI employees upon separation from the State.

4. To reimburse State Employee Retirement System for actuarial cost of providing optional early out program for employees of MBPI whose combined age and service credit equal 70 or greater (regardless of age) on the date of transfer.

5. Costs related to separation, negotiation and closing of transaction, including title insurance and any opinions or reports required by the SAB.

B. All unexpended assets of the Product Fund shall be retained by the state and, after the transfer of the assets of the MBPI, the Product Fund shall be administered by the Community Public Health Agency in the Department of Community Health.

IV. Employee/Pension Matters

A. Authorize employees or an employee based entities to bid or make proposals to acquire the assets of the MBPI notwithstanding conflict provisions of state laws.

B. Allow nonvested employees who have 5 or more years of credited service as of the effective date of the transfer and who leave state employment by reason of electing employment with the transferee(s) to purchase at actuarial cost that amount of credited service necessary to attain vesting (10 years) and entitlement to a retirement allowance and health benefits under section 20d of the State Employees Retirement Act, so long as

MILLER, CANFIELD, PADDOCK AND STONE P.L.C

they work for the transferee for 1 year following separation from the state.

C. Provide employees of MBPI on the date of transfer who have combined age and service equal to 70 or greater (regardless of age) early retirement with unreduced benefits.

V. Miscellaneous Matters.

A. Provide that sale of assets are free and clear of any liens, claims, or interests of the State or any person claiming through or under the State, except for state or local taxes.

B. Grant Court of Claims exclusive jurisdiction over any claim asserted against the State arising out of or related this transfer.

C. Limit the period in which a claim against the State related to the products produced by MBPI may be brought to 6 months after plaintiff discovers or should have reasonably discovered the existence of the claim.

D. Provide that the validity of the proceedings of or the determinations made by the State Administrative Board or the Commission shall be considered conclusive if not challenged in the court of claims within 60 days after such action is taken. Limit the period in which a cause of action against the State seeking to enjoin or otherwise restrain the transfer of assets and liabilities of MBPI may be brought to 1 year after the effective date of the legislation.

E. Require a report to the Legislature on the terms of the transfer after the transfer of the assets and liabilities has been completed.

MILLER, CANFIELD, PADDOCK AND STONE, P.L.C.

F

W.Y. Campbell & Company
Investment Banking
200 Renaissance Center, 26th Floor
Detroit, MI 48243

Contact: Mr. Dennis L. Schornack
Chair, Michigan Biologic
Products Commission
(517) 335 - 6847

Or

Alex Markus, Vice President
Or Cliff Roesler, Vice President
W. Y. Campbell & Company
(313) 259 - 3040

W.Y. Campbell & Company has been exclusively retained to assist the State of Michigan (the "State") with the divestiture of its Michigan Biologic Products Institute (the "Institute"). The Institute is the last state-owned biologics manufacturing complex in the United States. Established in 1926, the Institute manufactures both bacterial and viral vaccines and fractionates blood plasma for several public and private customers. The vaccines and plasma derivatives currently licensed by the U.S. FDA for manufacture by the Institute include: Tetanus, Rabies, Pertussis (Whole Cell), DTP, DT (pediatric), Anthrax, Albumin and Immune Serum Globulin. In addition to these product licenses, the Institute holds, along with the Institute's sponsors, a number of U.S. FDA Investigational New Drug Applications ("I.N.D."). These I.N.D.'s include: Botulinum Toxin Type B, Pentavalent Botulinum Toxoid, Hepatitis B Immune Globulin (Virus Inactivated), Anthrax Vaccine Adsorbed, DTPw plus Hib, DTPw plus Hepatitis B plus Hib, DTPa plus Hepatitis B plus Hib, DTPa and DTPa plus Hepatitis B. The Institute also has a USDA Biologic License for Botulinum Toxoid Type B for equine use.

The Institute's revenues are derived from two primary sources: 1) the manufacture and sale of anthrax vaccine to the U.S. military, and 2) plasma fractionation services.

1) One of the Institute's major customers is the U.S. military. On October 2, 1996, it was reported that U.S. military officials endorsed a plan to vaccinate all U.S. troops against anthrax - a vaccine for which the Institute is the only licensed manufacturer in North America. The Institute has a long and valued relationship with the U.S. military and in 1991 it received the Commanders Award for Public Service for its role in Desert Storm.

2) The Institute's second major source of revenues is from its plasma fractionation services for the American Red Cross and NABI. The shortage of this service in the market makes the Institute's ability to fractionate plasma a valued capability. The Institute has the ability to fractionate 60,000 liters of plasma per year.

The remainder of the Institute's revenues are derived from the sale of pediatric and rabies vaccines. The rabies vaccine produced by the Institute, like the Anthrax vaccine, is a vaccine for which the Institute is the only licensed manufacturer in North America.

The Institute consists of 27 buildings containing approximately 247,000 gross square feet of laboratory, pharmaceutical manufacturing, office and warehouse space. The Institute also houses its own power plant which provides steam, and vacuum and compressed air to its facilities. Water for human injection is produced by separate utilities on the Institute's campus. The site is located on the northwest side of the City of Lansing, Michigan. The North Logan/Martin Luther King, Jr. Boulevard divides the site into two parcels, commonly referred to as the East and West Campuses. The West Campus has 47 acres of vacant, unimproved land contiguous to the taxiway for Capitol City Airport suitable for future expansion of the Institute's facilities.

One of the Institute's unique assets is its rhesus monkey colony. The Institute is registered by the U.S. Department of Agriculture under the Animal Welfare Act to produce and maintain animals for testing and houses the only SIV-free, reproducing rhesus monkey colony in North America. Approximately, 80 animals reside in this colony.

As of May, 1997, the Division employed a total of 153 salaried and hourly workers. Of the 153 employees, 81 are unionized and are represented by one of three unions. The Institute's management believes that the substantial experience and knowledge of these employees is a meaningful intangible asset of the Institute.

The State of Michigan has concluded that owning the means of biologics production and taking risks with public funds in the pursuit of future profits is inconsistent with the general philosophy and function of state government. Manufacturing pediatric vaccines has also been determined to be non-essential to the fulfillment of the State's public health mission of assuring age-appropriate immunization of children. Even without the Institute's pediatric vaccines, Michigan's public health community will continue to have access to state-of-the art vaccines at no cost through the Federal Vaccines for Children and Section 317 Grant Programs that all other states utilize to meet their public health needs.

In December of 1995, Governor Engler issued Executive Order 1995-25 which separated the Institute and its assets from the Michigan Department of Public Health and established it as a two-year temporary agency under the oversight of the Michigan Biologic Products Commission (the "Commission"). The Commission was charged with providing policy control and with developing and implementing a plan to move the Institute out of state government and into the private sector. Integral to the Commission's plan to transfer the Institute to the private sector was the passage of Public Act No. 522 of 1996 (See attached).

Public Act No. 522 authorizes the Commission to proceed with the transfer of the Institute to the private sector and establishes the conditions under which that transfer is to occur. The Act provides that employees may bid on the assets of the Institute and requires that any purchaser agree to retain the Institute employees for one year following the sale. The sales agreement will be subject to an independent fairness opinion and final approval by the State administrative board.

Given the FDA requirements the Institute must meet to stay in compliance with federal regulations, qualified bidders at a minimum must have experience in operating a cGMP compliant biologics manufacturing facility.

CAPITAL JOURNAL
By Gerald F. Seib

American Divide: Globalist Coasts, Populist Prairie

THE POMP AND CIRCUMSTANCE unfold this week in glorious Madrid, where President Clinton and fellow chieftains of the North Atlantic Treaty Organization are agreeing to add three new countries.

Soon, the bumping and grinding will begin here at home, when the president goes to Congress and the country to convince Americans that NATO expansion is a good idea. All things considered, expansion probably is the best option available, particularly considering that the idea has moved so far down the track that retrieving it would produce a real mess.



When the president's sales staff goes to the country to sell the idea, though, they will find that support for NATO expansion, and for internationalism generally, is breaking along some intriguing and potentially dangerous lines in America. Support for engagement in the world is highest along the East and West coasts and in urban areas generally. It is lowest in the Midwest and South and in rural areas generally.

In other words, when it comes to international involvement today, the heavily populated coasts resemble two bookends, where support for globalization is high, holding up a middle of the country where a whiff of old-fashioned prairie populism—maybe even isolationism—is in the air.

To Mr. Clinton and fellow interna-

Airlines Taxi Into Position Around Capitol Hill As Lawmakers Make Decisions on Ticket Taxes

By Greg Hitt
Staff Reporter of The Wall Street Journal

WASHINGTON — More than 1,000 pilots, mechanics and others who work for the nation's seven largest airlines will rally at the Capitol today as the lobbying battle over the tax bill heats up. AMR Corp.'s American Airlines is even offering employee "volunteers" two free plane tickets for participating in the event.

The airlines are lining up behind the House-passed tax bill that would require discount carriers, such as **Southwest Airlines**, to shoulder more of the tax burden on airline tickets. Southwest, which says the House bill would result in higher fares, is backing the Senate-passed bill—which effectively continues the current system — with newspaper ads and an employee letter-writing campaign.

Fees on International Travel

Meantime, some airlines are seeking to enlist their passengers to help fight lawmakers' plans for more taxes on frequent fliers and international flights. "If they are successful, your family's long-awaited vacation and your international business travel could cost you several hundred dollars more in taxes," **Delta Air Lines** warns in a letter to customers.

Air travelers have a huge stake as lawmakers enter final negotiations this week on a final tax package that will determine the ebb and flow of billions of dollars within the U.S. airline industry. A lot of the debate is between the big airlines and their discount competitors, but there are other fights that cut across the industry's top tier, such as those over fees on international travel.

The House and Senate tax bills approved last month fly in opposite directions when it comes to airline taxes. Both would raise about $34 billion over five years to help pay for tax cuts, but they would have sharply different outcomes for the industry and consumers.

The House bill, at its core, is designed to address concerns raised by the major airlines that the current system gives an unfair advantage to discount competitors. Beginning Oct. 1, the bill would lower

Coffee, Tea or Taxes?

Here's how tax bills passed by the House and Senate would affect airline passengers:

HOUSE

- ***Reduces the current 10% ticket tax*** *to 7.5%*, beginning Oct. 1, but imposes a new $2 fee on "flight segments" flown by passengers. The fee would be increased to $3 by 2002.
- ***Applies the 7.5%*** ticket tax to bank and credit-card payments to airlines under frequent-flier programs.
- ***Levies a $15.50 fee*** on international departures and arrivals, replacing the current $6 departure fee.

SENATE

- ***Renews the 10% ticket tax***, which expires Oct. 1, but taxes flight segments to and from rural airports at 7.5%.
- ***Applies the 10% tax*** to the domestic legs of international flights and to cash payments made to carriers under frequent flier programs.
- ***Raises the international departure fee to $8 from $6*** and applies the fee to arrivals as well.

didn't take off until this year, when Republicans and the White House forged a bipartisan budget agreement.

A simple renewal of existing airline taxes would have raised about $30 billion over five years, $4 billion less than now envisioned by the House and Senate. Ironically, some critics suggest the Big Seven's lobbying campaign enticed lawmakers to consider higher taxes on the industry.

"Clearly, the industry knocked on doors that it wasn't prepared to walk through," says Tim Hannegan, assistant director of aviation issues at the General Accounting Office, the watchdog arm of Congress.

With their separate bills in hand, GOP leaders, now negotiating among themselves as well as with the White House, are looking for compromise. A final deal isn't expected until late this month. But Senate Majority Leader Trent Lott of Mississippi is already staking out his ground. Mr. Lott says he doesn't support the House's proposed changes, suggesting he doesn't want to redistribute the burden of airline taxes.

Yet he voices hope for a middle ground between the House and Senate approaches: "What we need is a blend of the two." Sen. Lott, for example, favors dropping a Senate proposal to levy the 10% tax on the domestic legs of international flights. The House bill has no such provision in it.

For his part, Mr. Archer is promising to work to reduce international taxes in the House plan. But otherwise, Mr. Archer is standing by his bill. "It has the appropriate mix of fees that should apply to the airline industry, and that's the position he hopes would prevail," says Ari Fleischer, an Archer spokesman.

BUSINESS FOR SALE

Pursuant to the State of Michigan's Public Act 522, the State of Michigan hereby invites interest and offers with respect to its decision to sell its 100% interest in the:

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Qualified parties with experience in operating a cGMP compliant biologics manufacturing facility are encouraged to contact the State of Michigan's selling agent:

W. Y. CAMPBELL & COMPANY
200 Renaissance Center
26th Floor
Detroit, Michigan 48243
(313) 259 - 3040 Telephone
(313) 259 - 2414 Facsimile

Attn: Alex G. Markus, Vice President
or Clifton H. Roesler, Vice President

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MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

JOHN ENGLER, GOVERNOR

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3500 N. MARTIN LUTHER KING, JR., BLVD.
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LANSING, MICHIGAN 48909
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MICHIGAN BIOLOGIC
PRODUCTS COMMISSION
DENNIS L. SCHORNACK, CHAIR
JAMES K. HAVEMAN, JR.
MARY A. LANNOYE

FOR IMMEDIATE RELEASE
July 8, 1997

CONTACT: Dennis Schornack
(517) 335-6847

Michigan Biologic Products Institute: FOR SALE

The last state-owned vaccine lab in the country, the Michigan Biologic Products Institute, is officially for sale and a national search for a buyer is underway.

"An advertisement promoting the Institute is scheduled to run in the Wall Street Journal on Wednesday, and solicitations have been sent to 35 potential purchasers that include customers, employees and other vaccine makers to facilitate a sale," said Dennis Schornack, chair of the Michigan Biologic Products Commission, which oversees the Institute.

"Government ownership of the means of production for vaccines and other biologic products is incompatible with the goal of maintaining a successful enterprise," Schornack said. "The best opportunity for future survival in the competitive world of biologics production is for the Institute to become a private firm."

State legislators and Governor John Engler agreed last year to privatize the Institute and set the process in motion with Public Act 522 of 1996. Schornack said he hopes the sale will be closed by the end of September.

W.Y. Campbell & Company, of Detroit, is the broker selling the facility.

# # #

State ready to sell vaccine lab

By A.J. Evenson
Lansing State Journal 7.8.97

Michigan's vaccine lab will finally go up for sale this week, state officials will announce today.

The Michigan Biologic Products Institute will solicit prospective buyers through advertisements in the Wall Street Journal that begin running Wednesday, said Dennis Schornack, chairman of the lab's governing commission.

"It's the best opportunity for this enterprise to continue — to find someone willing to invest money in this facility," Schornack said.

The Legislature voted last year to move the aging bio-lab, the last state-owned operation of its kind in the country, into private hands.

Lawmakers cited the lab's inability to pay for itself and the incompatibility of state government and the fast-paced pharmaceutical industry.

> "It's the best opportunity for this enterprise to continue."
>
> **Dennis Schornack**
> lab's board chairman

The lab produces several vaccines, including those for diphtheria, pertussis, tetanus and rabies. It is the exclusive producer and supplier of anthrax vaccines to the U.S. military.

State officials began a search last spring for a broker to sell the Lansing-based property, which includes about 60 acres and 27 buildings off Martin Luther King Boulevard.

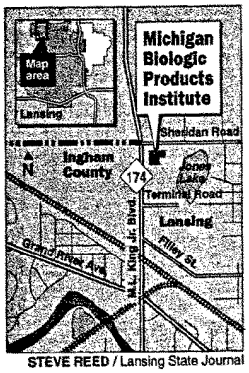
They selected W.Y. Campbell & Co. of Detroit.

Officials hope to find a buyer, negotiate a deal and close the sale by Sept. 30, the end of the 1997 fiscal year, Schornack said.

It's not clear what, if anything, will happen if a buyer is not found by then.

In addition to national advertising, invitations to take a closer look at the institute have been sent to what officials say are their best prospects.

Those prospects include the lab's current customers and employees, who have expressed an interest in taking over.



STEVE REED / Lansing State Journal

Among the customers are SmithKline Beecham, which announced earlier this year that it would invest $3 million in the operation, and NABI.

Just what the operation will bring in terms of a purchase price is not known.

The labs need a number of renovations and improvements if the facility is to compete in the pharmaceutical industry or even continue operations, say those who oversee the labs.

Several were identified during a Food and Drug Administration investigation that cited various problems at the lab and threatened closure.

FDA officials have accepted the lab's plan.

That plan will need to be part of the sale, Schornack said.

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MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

W. Y. CAMPBELL & COMPANY

INVESTMENT BANKING

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MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

W.Y. CAMPBELL & COMPANY

INVESTMENT BANKING

Michigan Biologic Products Institute

This Offering Memorandum (the "Memorandum") has been prepared by W.Y. Campbell & Company ("WYC&C") solely for informational purposes from information supplied to WYC&C by the State of Michigan (the "State") and is being furnished through WYC&C, as the State's exclusive authorized agent solely for use by prospective purchasers in considering their interest in acquiring the Michigan Biologic Products Institute (the "Institute").

The information contained herein has been prepared to assist interested parties in making their own evaluation of the Institute and does not purport to contain all of the information that a prospective purchaser may need or desire. In all cases, interested parties should conduct their own investigation and analysis of the Institute and the data set forth in this Memorandum. Neither WYC&C nor the State have independently verified any of the information contained herein; neither WYC&C nor the State make any representation or warranty as to the accuracy or completeness of this Memorandum and shall have no liability for any representations (expressed or implied) contained in, or for any omissions from, this Memorandum or any other written or oral communications transmitted to this recipient in the course of its evaluation of the Institute.

This Memorandum includes certain statements, estimates, and projections provided by the State with respect to the Institute's anticipated future performance. Such statements, estimates, and projections reflect various assumptions by the State concerning anticipated results, which assumptions may or may not prove to be correct. No representations are made as to the accuracy of such statements, estimates, or projections.

By accepting this Memorandum, the recipient acknowledges and agrees that: (1) the information contained herein is of a highly confidential nature and the recipient will maintain and control all of such information -- and all other information made available to the recipient in connection with any further investigation -- in accordance with the Confidentiality Agreement ("Agreement") previously executed with the State and WYC&C governing such confidential material ("Material"); (2) none of such information will be used by the recipient or any of its employees or representatives in any manner whatsoever, in whole or in part, other than in connection with its evaluation of the Institute for the purpose of considering its acquisition by the recipient on the specific basis proposed herein; (3) the recipient will not reproduce this Memorandum, in whole or in part, and will not distribute all or any portion of this Memorandum to any person other than a limited number of the recipient's employees or representatives (which does not include lenders or other financing sources) who have a clear need to know such information for the purpose of evaluating the Institute and who are informed by the recipient of the confidential nature of such information and are bound by the Confidentiality Agreement; (4) if the recipient does not wish to pursue this matter, it will return this Memorandum to WYC&C as soon as practicable, together with any other Material relating to the Institute which the recipient may have received from

WYC&C or the State; and (5) any proposed actions by the recipient which are inconsistent in any manner with the foregoing agreements will require the prior written consent of the State or WYC&C.

The State reserves the right to negotiate with one or more prospective buyers and at any time to enter into a definitive agreement for the sale of the Institute without prior notice to you or other prospective purchasers. Also, the State reserves the right to terminate, at any time, further participation in the investigation and proposal process by any party and to modify data and other procedures without assigning any reason therefore. The State intends to conduct business of the Institute in the ordinary manner during the evaluation and offer period; however, the State reserves the right to take any action, whether in or out of the ordinary course of business, which it deems necessary or prudent in the conduct of such business.

W. Y. CAMPBELL & COMPANY

200 Renaissance Center
26th Floor
Detroit, Michigan 48243
Telephone: 313/259-3040
Facsimile: 313/259-2414

July 1997

Inquiries and requests for information should be directed to one of the following at W.Y. Campbell & Company:

Alex G. Markus
Vice President

Clifton H. Roesler
Vice President

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EXECUTIVE SUMMARY

INTRODUCTION

The Michigan Biologic Products Institute is the last state-owned biologics manufacturing complex in the United States. Established in 1926, the Institute manufactures both bacterial and viral vaccines and fractionates blood plasma for several public and private customers. The vaccines and plasma derivatives currently licensed by the U.S. FDA for manufacture by the Institute include: Tetanus, Rabies, Pertussis (Whole Cell), DTP, DT (pediatric), Anthrax, Albumin and Immune Serum Globulin. In addition to these product licenses, the Institute holds, along with the Institute's sponsors, a number of U.S. FDA Investigational New Drug Applications ("I.N.D."). These I.N.D.'s include: Botulinum Toxin Type B, Pentavalent Botulinum Toxoid, Hepatitis B Immune Globulin (Virus Inactivated), Anthrax Vaccine Adsorbed, DTPw plus Hib, DTPw plus Hepatitis B plus Hib, DTPa plus Hepatitis B plus Hib, DTPa and DTPa plus Hepatitis B. The Institute also has an USDA Biologic License for Botulinum Toxoid Type B for equine use.

For the twelve month period ending September 30, 1997, the Institute has projected that its product sales will climb to approximately $17 - $18 million versus $7.5 million for 1996. This substantial increase in revenues is principally the result of increased anthrax purchases by the U.S. military (the U.S. military provides the Institute with over 50% of its revenues). On October 2, 1996, it was reported that U.S. military officials endorsed a plan to vaccinate all U.S. troops against anthrax - a vaccine for which the Institute is the only licensed manufacturer in North America. The Institute has a long and valued relationship with the U.S. military and in 1991 it received the Commanders Award for Public Service for its role in Desert Storm. In addition to the Institute's current relationship with the U.S. military, the Institute has recently agreed to be part of a consortium to bid on a contract to provide a number of vaccines to the U.S. military - J.V.A.P. (Joint Vaccine Acquisition Program). The Institute's consortium is led by Battelle Memorial Institute. If awarded to the consortium, this contract would provide the Institute with upwards of $100 million in revenues over the term of the contract. The Institute's second major source of revenues is from its plasma fractionation services for the American Red Cross and NABI. The shortage of this service in the market makes the Institute's ability to fractionate plasma a valued capability. The Institute has the ability to fractionate 60,000 litres of plasma per year. The remainder of the Institute's revenues are derived from the sale of pediatric and rabies vaccines. The rabies vaccine produced by the Institute, like the Anthrax vaccine, is a vaccine for which the Institute is the only licensed manufacturer in North America.

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As of May, 1997, the Division employed a total of 153 salaried and hourly workers. Of the 153 employees, 81 are unionized and are represented by one of three unions. The Institute's management believes that the substantial experience and knowledge of these employees is a meaningful intangible asset of the Institute.

As a state agency, the Institute is subject to all of the operating constraints of a public sector entity. These constraints are not conducive to operating a biotechnology organization that is financially viable and able to compete in a dynamic marketplace. Even as the Institute has developed new products and customer relationships, the U.S. FDA continues to monitor the Institute's ability to comply with standards for current Good Manufacturing to exercise complete managerial control over the entire enterprise, a degree of authority and latitude that is inconsistent with the authority of a director within a state department.

Government constraints slow the development of new products, complicate customer relationships, and make it difficult to acquire and accumulate the capital needed to replace existing production facilities. Civil Service regulations, the annual legislative appropriations process, and the extensive controls over public procurement inhibit the Institute's ability to respond with a business sense of urgency to market conditions. A current example of the impact of government constraints is the warning letter received by the Institute from the FDA citing the Institute with deviations from applicable process standards and facility requirements. Although the Institute, with the assistance of its clients, is currently addressing the FDA's warning letter. The Institute might not of experienced this situation if it were owned by a private entity whose foremost concern was the long-term viability of the Institute rather than a state government with a multitude of competing interests for funding.

The State of Michigan has concluded that owning the means of biologics production and taking risks with public funds in the pursuit of future profits is inconsistent with the general philosophy and function of state government. Manufacturing pediatric vaccines has also been determined to be non-essential to the fulfillment of the State's public health mission of assuring age-appropriate immunization of children. Even without the Institute's pediatric vaccines, Michigan's public health community will continue to have access to state-of-the art vaccines at no cost through the Federal Vaccines for Children and Section 317 Grant Programs that all other states utilize to meet their public health needs.

In December of 1995, Governor Engler issued Executive Order 1995-25 which separated the Institute and its assets from the Michigan Department of Public Health and established it as a two-

year temporary agency under the oversight of the Michigan Biologic Products Commission (the "Commission"). The Commission was charged with providing policy control and with developing and implementing a plan to move the Institute out of state government and into the private sector. Integral to the Commission's plan to transfer the Institute to the private sector was the passage of Public Act No. 522 of 1996.

Public Act No. 522 authorizes the Commission to proceed with the transfer of the Institute to the private sector and establishes the conditions under which that transfer is to occur. The Act provides that employees may bid on the assets of the Institute and requires that any purchaser agree to retain the Institute employees for one year following the sale. The sales agreement for the Institute will be subject to an independent fairness opinion and final approval by the State administrative board.

The reader is urged to examine Executive Order 1995-25, Public Act No. 522 of 1996 and Resolution Four of the Michigan Biologic Products Commission ("A Resolution To Specify Goals And To Make Certain Determinations With Respect To The Privatization Of The Michigan Biologic Products Institute") in Appendix VI of this memorandum.

SELECTED FINANCIAL DATA

The table below depicts the summary pro forma financial results of the Institute "as if" it was in operation as a separate/private business (i.e. without State funding) for the years ended September 30 1994, through 1996. In addition, the table below incorporates relevant balance sheet information for the Institute as of September 30, 1995 and 1996. These financial results have been compiled by the accounting firm of KPMG Peat Marwick.

Table I

Summary of Operations Data
For the Year Ended
September 30,
($000)

	1993	1994	1995	1996
Net Sales	$10,151	$8,072	$8,595	$7,510
Expenses:				
Salaries and Wages	3,990	4,528	5,019	5,833
Fringe Benefits	1,632	1,890	2,139	2,241
Contractual Services	2,802	2,245	4,602	3,683
General Services	1,100	1,239	1,142	1,184
Depreciation	625	751	922	986
State Overhead	732	647	623	647
Inventory Adjustment	(108)	(909)	327	(817)
Other	301	288	296	305
Net (Loss)	(923)	(2,607)	(6,474)	(6,551)

Summary Balance Sheet Data
As of September 30,
($000)

	1995	1996
Current Assets	$9,275	$7,275
Current Liabilities	1,186	1,379
Total Assets	14,678	12,186
L.T. Liabilities	0	0
Shareholder's Equity	13,492	10,806

The historical financials of the Institute portray the financial performance of an entity structured and operated to attain social goals rather than business goals. Consequently, as would be expected, profit has not been a primary objective of the Institute. Consequently, a new, private-

sector acquiror will have to restructure the capabilities of the Institute to refocus this entity on a new set of objectives. In envisioning the financial performance of a privatized-Institute, KPMG, with the assistance of the management of the Institute, assembled a set of projected financials for the 1997-2002 period. These projected financials are in Appendix V of this Offering Memorandum.

INVESTMENT CONSIDERATIONS

The following is a summary of the key attributes of the Michigan Biologic Products Institute which should be considered in the evaluation of the Institute:

* **Proprietary Product in High Demand by U.S. Military:** The Institute is the only licensed manufacturer of anthrax vaccine in North America. The military has recently deepened its commitment to protecting troops from biological warfare -- a recommendation is pending on Secretary of Defense Cohen's desk to vaccinate all troops against anthrax.

* **FDA Licensed Facility:** The Institute is a U.S. FDA licensed establishment for the development and manufacture of biologic products, chiefly vaccines (both bacterial and viral) and plasma products (albumin, immune globulin, etc.). The license is transferable to a new owner that demonstrates to the U.S. FDA that they can comply with FDA regulations. For any foreign company wishing to establish a biologics manufacturing presence in America or any company needing new or additional licensed manufacturing space and facilities, the Institute poses an expedient solution. It would take many years and millions of dollars to build, validate, and license new facilities from scratch.

* **Expansion Capabilities:** Located contiguous to the main production campus (East Campus), is the West Campus consisting of over 47 acres of vacant farmland that may be used to build new replacement production and/or distribution facilities. The land is contiguous to a regional airport's industrial park and accesses a taxiway for ready air transport of products. Utilities are readily available, including power, steam, etc. from the Institute's own power plant that has three 20,000 psi gas-fired boilers. The whole complex is located within a hub of air, land and rail transportation.

* **Experienced and Capable Management and Employees:** The State of Michigan has expended considerable effort in staffing the Institute with a management team and workforce possessing considerable experience in the development and manufacture of human vaccine and plasma products under cGMP conditions -- an important feature given that manufacture of biologic products is rigorously controlled by the FDA.

* **Long-Term Client Contracts:** The Institute has long and established relationships with companies such as SmithKline Beecham, Athena Neurosciences, NABI and the Department of Defense. The value of the services provided and products manufactured by the Institute are demonstrated by the long-term contracts these companies have entered into with the Institute.

* **Joint Vaccine Acquisition Program ("JVAP"):** The Institute is currently a member of a consortium bidding on a major military contract to provide U.S. troops with vaccines well into the 21st century. If the contract is awarded to the Institute's consortium, the Institute's share of the JVAP's revenues (in aggregate) would be between $80 and $100 million - the JVAP's total revenues are estimated at upwards of $600 million.

* **Partnerships and Collaborations:** The Lansing area offers excellent opportunities for research partnerships with universities and collaborations with other biotech firms. There are two medical schools at Michigan State University (located in Lansing, MI.), a large veterinary school, and extensive biotech laboratories including a BL-4 containment facility. Private biotech firms in the Lansing, Michigan area include Neogen, and others. Ann Arbor, Michigan is only an hour away from the Institute and adds the presence of the University of Michigan with its medical school, dental school, and public health school, as well as many private biotech firms.

* **Assistance from State Government for the Institute's Buyer:** The State of Michigan has expressed its preference for the Institute post-privatization to continue to contribute to Michigan's economy by sustaining/increasing jobs and retaining the know-how associated with the manufacture of biologic products. Toward this end, the State is willing to hold discussions with serious potential purchasers to evaluate how the State might be able to assist in the long-term viability and prosperity of the Institute.

REASON FOR SALE

While several state governments have at one time or another in the past engaged in the manufacture of vaccines and other biologic products, Michigan is the last state that still makes vaccines and plasma derivatives; all other states now obtain these products through the federal government from private pharmaceutical firms. The State of Michigan realizes that the Institute, as a state agency, is subject to all the operating constraints of a public sector entity and that these constraints are not conducive to operating a biotechnology organization that is able to effectively compete in a dynamic marketplace. Consequently, the State has decided that the long-term viability of the Michigan Biologic Products Institute can best be achieved by moving it out of state government and allowing it to become a self-sustaining private enterprise.

BUSINESS DESCRIPTION

HISTORY

Beginning with the appointment of a state bacteriologist in 1907, the Biologic Products Division (the "Division") of the Michigan Department of Public Health (the "MDPH") has worked to protect Michigan's citizens from infectious disease through the research, development, manufacture, and distribution of vaccines and plasma derivatives. For the first 20 years of the twentieth century, Michigan had the highest reported rate of diphtheria infection and fatalities in the entire world. The situation grew so grave that in 1921, Governor Groesbeck requested legislation providing for the state manufacture, purchase, and distribution of products for the control of diphtheria. The new law permitted state manufacture only if the cost of buying these products exceeded the costs of making them.

Initially, products to combat diphtheria were purchased, but in 1925 when prices jumped 300%, the Division was authorized to manufacture by the State Administrative Board. The first laboratory, stockroom, and animal facilities were built, and in 1926 establishment license No. 99 was granted by the U.S. Public Health Service. The following year, a law was passed to further authorize the Division to manufacture or purchase and distribute any biologic product for the control of communicable disease. This 1927 law also repealed the 1921 law that permitted state manufacturing only if it was cheaper than buying the products.

Over the years, the Division developed various vaccines, toxoids, and other biologic products for the treatment and prevention of infectious disease, including:

- 1926 Diphtheria and typhoid vaccines were produced and distributed.
- 1927 Scarlet Fever toxoid was licensed for interstate commerce.
- 1930 Smallpox vaccine was licensed; large quantities were distributed to combat an epidemic in 1938.
- 1933-1940 Whooping Cough (pertussis) vaccine was developed, culminating in general distribution to physicians and health officers in 1940. Whooping cough was a leading killer of children under 5 years of age.
- 1941 Using funds provided by the Emergency War Board, the Division supplied diphtheria, tetanus, and whooping cough vaccines and toxoids to the military.

Between 1930 and 1942, the vast majority of the buildings on the east campus, of what is now known as the Michigan Biologic Products Institute were built by the State with federal funding under the Works Projects Administration of Franklin D. Roosevelt. In addition, land comprising the west campus of the Michigan Biologic Products Institute was transferred to the MDPH from the Department of Corrections in 1935 for use as a pasture for horses and other animals that supported the manufacture of vaccines and antitoxins. In 1940, the Division, along with other MDPH laboratories, was certified

as a primary defense industry, thus initiating a relationship with the U.S. military that remains strong today.

Using federal funds provided by the Emergency War Board, the Division initially established its plasma processing program in 1941; product distribution began in 1943. In 1944, at the request of Governor Kelly, State funds were appropriated to purchase all of the equipment necessary to support the Plasma Program. The plasma processing plant was enlarged and automated with the appropriation of additional State funds in 1957.

During the mid-1940's, the Division also investigated the development of antibiotics and the use of fermentation as a production technique. Antibiotic research initially focused on tuberculosis, whooping cough, and salmonella, and later upon penicillin-resistant staphylococci. This research led to a patent for Synnematin B, an antibiotic for the treatment of typhoid, issued in 1953. High production costs and the lack of commercial viability for this antibiotic led to the discontinuation of production.

In 1967-68, the MDPH labs established its now long-standing contractual relationship with the U.S. military for the provision of the anthrax vaccine. Using federal funds for development, the anthrax vaccine was initially approved for licensure by the U.S. Public Health Service in 1970. In recent years, anthrax has become the most important product for the Michigan Biologic Products Institute, accounting for over half of its annual revenues.

The Division began developing improved rabies vaccines in the mid-1960's, along with combination vaccines against diphtheria, tetanus, pertussis, and polio. The "quadruple antigen" vaccine program was eventually dropped due to the instability of the pertussis component. At the same time, the MDPH labs ventured into experiments in the development of anticancer agents. While the anticancer program failed to produce much in the way of effective products, an improved rabies vaccine was developed in 1970 using funds provided by the federal government, and was eventually approved for human use in 1973. A further improved intramuscular version of the rabies vaccine was licensed in 1989.

In 1972, the Michigan Legislature supported the Red Cross Regional Blood Centers in supplying the Division with fresh frozen plasma for the production of antihemophilic fractions.

Traditionally, the Division's primary focus was on the research and development of biologic products, many of which were successfully licensed and distributed. Until 1944, when the U.S. Public Health Service was granted regulatory authority over biologic products, the Division was nominally regulated by the federal government. As part of a major reorganization in 1968, the U.S. Food and Drug Administration was placed within the Public Health Service, and in 1972, the regulation of biologic products was transferred to the U.S. FDA.

While the Division continued to grow after World War II, its broad-based research and development of products to protect the public from infectious disease eventually attenuated and narrowed. By the mid-1980's, funding constraints, growing regulatory requirements, and dramatic increases in the cost of developing and licensing new products forced the Division to shift its focus to the manufacture and distribution of licensed biologic products and to de-emphasize research and development.

In the early 1980's, a worldwide shortage of the diphtheria-tetanus-pertussis (DTP) vaccine developed due to low profitability and concerns over the liability arising from adverse reactions to the pertussis component of the vaccine. One in every 310,000 children vaccinated had a severe reaction to the whole-cell pertussis component of the DTP vaccine. The small, birth-rate-limited market for vaccines combined with huge potential product liability losses led to a decline in the number of manufacturers and the resulting vaccine shortage. By 1984, only one private manufacturer of DTP remained in production. Because they manufactured their own DTP vaccine, the states of Massachusetts and Michigan did not have to endure this shortage. Currently, the Institute does not manufacture whole-cell pertussis vaccine because it has been rendered obsolete by the licensure of an improved acellular pertussis vaccine (Note: the Institute is still licensed to manufacture the whole-cell pertussis vaccine and currently holds a large inventory of this product). As a result of the introduction of the improved pertussis vaccine, the Institute's DTPw vaccine is no longer in demand.

In 1985, Congress responded to the vaccine product liability crisis by enacting the National Vaccine Injury Compensation Act which established a national, no-fault insurance pool to compensate victims of adverse reactions. All manufacturers, including Michigan, were required to pay an excise tax on each dose of vaccine they produced for deposit into the insurance fund. The amount of the excise tax for whole-cell pertussis vaccine, presently $4.56 per dose, was approximately five times the cost of production. Under the Omnibus Reconciliation Act of 1993 and the Vaccines for Children Act incorporated therein, the federal government now pays Michigan for its costs of production and the cost of the excise tax in lieu of providing funding for vaccines, as it does for other states that do not make their own vaccine.

In 1985-86, the Legislature recognized the need for additional capital investment and passed a bill establishing the Pharmaceutical Products Fund and allowing the Division to sell its products for public or private use outside of Michigan. This allowed the Division to retain the revenues generated from the manufacture and sale of biologic products in a segregated fund for investment in improving the facilities and the biologic products program.

By 1990, the Division began to position itself to become financially self-sufficient and partnered with several private sector firms and other non-state organizations. The Michigan Biologic Products Institute currently has contracts to supply products to private firms such as SmithKline Beecham, Athena Neurosciences, NABI, and public organizations including two Michigan Red Cross regions and the United States Department of Defense.

In 1995, the State concluded that competing with today's biotechnology industry was not essential to fulfilling Michigan's public health mission of assuring age-appropriate immunization of children and that owning the means of production and taking risks with public funds in the pursuit of potential future profits was inconsistent with the general philosophy and function of state government in a capitalist democracy. Even without the Institute's pediatric vaccines, Michigan's public health community will continue to have access to state-of-the-art vaccines at no cost through the federal Vaccines for Children and Sec. 317 grant programs that other states utilize to meet their public health needs.

In recognition that the best interest of the public and the Institute would be served by moving the Institute out of state government and into the private sector, Governor Engler signed Executive Order 1995-25 on December 15, 1995. The Executive Order established the Michigan Biologic Products Institute, transferred all assets and personnel from the Division to it, and created the Michigan Biologic Products Commission to provide policy control and to develop and implement a plan to move it into the private sector.

As part of its charge under Executive Order No. 1995-25, the Commission prepared legislation necessary to facilitate the sale of the Institute. That legislation, now known as Public Act No. 522 of 1996, was written, introduced, and enacted into law between November 8, 1996 and December 10, 1996. Appendix VI of this memorandum contains copies of the above mentioned Executive Order and Public Act. In addition to these documents, Appendix VI contains a copy of Resolution Four of the Michigan Biologic Products Commission which clearly outlines the State's goals and expectations from this privatization.

PRODUCTS

The Institute is engaged in the production, sale and associated research and development of vaccines for the prevention of infectious diseases in children and adults; it also provides plasma fractionation services to two regions of the Michigan Red Cross. The Institute's physical plant is licensed by the U.S. FDA. All the Michigan Biologic Products Institute's product licenses are current and subject to ongoing U.S. FDA regulation.

Table II shows the Institute's U.S. FDA and USDA product licenses, and all products currently made under Investigational New Drug (IND) Applications. Table III provides the dates that the Institute received licenses for its vaccine and plasma products.

Table II

U.S. FDA and USDA Product Licenses

U.S. FDA Product Licenses

- Anthrax Vaccine Adsorbed
- Rabies Vaccine Adsorbed
- Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed
- Diphtheria and Tetanus Toxoids Adsorbed
- Tetanus Toxoids Adsorbed
- Pertussis Vaccine Adsorbed
- Albumin (Human)
- Antihemophilic Factor (Human) 500 IU/vial
- Immune Globulin (Human) 16.5%

U.S. FDA Investigational New Drug (IND) Applications

- Botulinum Toxin Type B
- Pentavalent Botulinum Toxoid
- Hepatitis B Immune Globulin, Virus Inactivated
- Anthrax Vaccine Adsorbed
- DTPw plus Hib
- DTPw plus Hepatitis B plus Hib
- DTPa plus Hepatitis B plu Hib
- DTPa
- DTPa plus Hepatitis B

USDA Biologic Licenses

- Botulinum Toxoid Type B, for equine use

Table III

Dates of Product Licensure

Vaccines	
Tetanus	October, 1930 (antitoxin); September, 1955 (adsorbed)
Rabies	First Licensed in 1932; improvements in 1973 and 1989
Pertussis (whole-cell)	November, 1935
DTP	September, 1955
DT (pediatric)	August, 1955
Anthrax	November, 1970
Plasma Derivatives	
Albumin	December, 1948
Immune Serum Globulin	December, 1948
Anti-Hemophilic Factor	May, 1964

It should be noted that the Institute has manufactured and distributed three of the nine pediatric vaccines required for children to enter day care and school under State immunization laws and that the Institute is the only licensed manufacturer of the intramuscular rabies and anthrax vaccines in North America. One of these vaccines, whole-cell pertussis, is no longer being manufactured by the Institute because it has recently been rendered obsolete by the licensure of the improved acellular pertussis vaccine (Note: the Institute is still licensed to manufacture whole cell pertussis vaccine and currently holds a large inventory of this product). Since pertussis vaccine is administered in combination with diphtheria and tetanus, Michigan's basic DTP vaccine is no longer in demand. In response to the obsolescence of the whole cell pertussis, the Institute has recently renovated the facilities associated with the production of this vaccine to manufacture other products.

The following paragraphs provide a brief description of the products manufactured by the Institute:

Tetanus and Diphtheria Toxoids Adsorbed (Td) Pediatric consists of a combination of purified and aluminum phosphate absorbed diphtheria and tetanus toxoids. The potency of each component of this product meets or exceeds the requirements of the Bureau of Biologics, and the Food and Drug Administration. Each single dose (0.5 cc) contains not more than .5 mg of glycine and not more than 2.5 mg of aluminum phosphate. The preservative is 0.01% thimerosal. This product contains no serum and cannot induce sensitization to serum.

Rabies Vaccine Adsorbed is a sterile, cell-culture derived rabies vaccine for pre-and post exposure prophylaxis in humans. It is prepared with the CVS Kissling/MDPH strain of rabies virus. The virus is propagated in a diploid cell line derived from fetal rhesus lung cells (FrhL- 2 cell line) in a serum-free, chemically defined, antibiotic-free medium. The virus harvest, which is clarified by centrifugation and filtration, is inactivated with betapropiolactone. After inactivation, the virus is adsorbed to aluminum phosphate.

The final vaccine is a suspension containing 2.5 international units or more of rabies antigen per 1.0 mL dose. It contains no more than 2.0 mg aluminum phosphate per mL and also contains 0.01% sodium ethylmercurithisalicylate (thimerosal) as a preservative. The solution is a light pink color due to the presence of phenol red.

Anthrax Vaccine Adsorbed in a sterile product made from filtrates of microaerophilic cultures of an avirulent, nonencapsulated strain of Bacillus anthracis which elaborates the protective antigen during the growth period. The cultures are grown in a synthetic liquid medium and the final product is prepared from the sterile filtered culture fluid. The potency of this product is confirmed according to the U.S. Food and Drug regulations (21 CFR 620.23): Additional Standards for Anthrax Vaccine Adsorbed. The final product contains no more than 2.4 mg aluminum hydroxide (equivalent to 0.83 mg aluminum) per 0.5 cc dose. Formaldehyde, in a final concentration not to exceed 0.02%, and benzethonium chloride, 0.0025%, are added as preservatives.

Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed (DTP) consists of a combination of purified tetanus and diphtheria toxoids, aluminum phosphate adsorbed, combined with a suspension of *Bordetella pertussis* organisms. Diphtheria toxin is produced by growing *Corynebacterium diphtheria* in a medium composed chiefly of a porcine tryptic digest of casein. Tetanus toxin is produce by growing *Clostridium tetanic* in a medium composed of a porcine tryptic digest of casein. Both toxins are inactivated with formaldehyde, purified by fractionation with ammonium sulfate, adsorbed onto aluminum phosphate, and diluted with 0.85% saline containing thimerosal (mercury derivative) as a preservative.

Pertussis vaccine is prepared by growing Phase 1 B. *Pertussis* organisms on Bordet Gang agar, which contains potato infusion, proteosepeptone, agar, washed sheep red blood cells, glycerol and sodium chloride. The pertussis organisms are washed from the agar with 0.85% saline. Three strains of pertussis organisms are combined, inactivated at room temperature in the presence of thimerosal (mercury derivative), and diluted with 0.85% saline containing thimerosal as preservative.

Pertussis vaccine, diphtheria and tetanus toxoids are combined in physiological saline diluent containing thimerosal a preservative.

Each single dose (0.5 mL) contains 0.2 to 0.6 mg of aluminum by assay as an adjuvant and less than 0.001% residual formaldehyde. It does not contain animal serum and is free of detectable sheep antigens. This product also contains 0.01% sodium ethyulmercurithiosalicylate (thimerosal, a mercury derivative) as a preservative.

Each 0.5 mL dose of vaccine is formulated to contain 6.5 Lf of diphtheria toxoid and 5.5 Lf of tetanus toxoid. The pertussis component is formulated to contain not more than 16 opacity units per single human dose.

When appropriately tested in guinea pigs, the tetanus and diphtheria components stimulate *at least* 2 neutralizing units/mL of serum. The total human immunizing dose is 12 units of pertussis vaccine with an estimate of 4 protective units per single human dose.

The vaccine is supplied as a sterile suspension for intramuscular administration that is ready to use without reconstitution. It contains 0.2 to 0.6 mg of aluminum as an adjuvant, 0.01% thimerosal as a preservative, less than 0.001% residual formaldehyde, sodium chloride, sodium phosphate and water. With thorough agitation, DTP is an opaque white suspension. The licensed name of the product is Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed.

Albumin (Human), 25% This product is prepared from pooled human venous plasma by a modified Cohn fractionation procedure. Each 50 mL bottle contains 12.5 grams of albumin concentrated from pooled human plasma and stabilized with 0.02 M sodium

acetyl-DL-tryptophanate and 0.02 M sodium caprylate. Sodium bicarbonate is used to adjust the pH to 6.9 ± 0.5. This product contains 130-160 milliequivalents of sodium per liter. Albumin (Human), 25% is sterilized by filtration and is treated at 60 degrees Celsius for 10 hours to inactivate hepatitis viruses (2.3). Albumin (Human), 25% is given by the intravenous route.

Pertussis Vaccine Adsorbed Pertussis vaccine is prepared by growing Phase 1 B. *Pertussis* organisms on Bordet Gang agar, which contains potato infusion, proteosepeptone, agar, washed sheep red blood cells, glycerol and sodium chloride. The pertussis organisms are washed from the agar with 0.85% saline. Three strains of pertussis organisms are combined, inactivated at room temperature in the presence of thimerosal (mercury derivative), and diluted with 0.85% saline containing thimerosal as preservative.

Immune Globulin (Human) (IG) is a sterile solution of immunoglobulin intended for intramuscular administration only. It is prepared by cold alcohol fractionation of pooled plasma and consists primarily of immunoglobulin G (IgG), containing 16.5 ± 1.5% protein. IG contains sodium ethylmercurithiosalicylate (thimerosal), a mercurial preservative, at a concentration of 100 mg per liter (0.01%) and glycine at a concentration of 2.25%. The pH of the solution has been adjusted to 6.8 ± 0.4 with sodium bicarbonate and/or sodium acetate-cetic acid buffer.

CUSTOMERS/CONTRACTS

The following summaries have been prepared to briefly describe the significant customer agreements/contracts/collaborations of the Institute. As you read the following summaries, one thing you will notice is that the Michigan Department of Public Health is mentioned quite frequently and what we have defined as the "Institute" is not. For all practical purposes when reading these summarizes, all mention of the Michigan Department of Public Health really refers to the Institute. Up until recently, as you might recall from the brief history section of this memorandum, the Institute and its assets were part of the Michigan Department of Public Health.

SmithKline Beecham

A. Letter of Intent and Update Regarding Agreements with SmithKline Beecham:

The State, the Michigan Department of Public Health ("MDPH") and SmithKline Beecham Pharmaceuticals, a division of SmithKline Beecham Corporation ("SB Corp.") originally entered into a Letter of Intent to Cooperate in the Supply, Distribution and Development of Selected Vaccines which covers various intended transactions (the "Letter"). The Letter addresses the parties' intent to enter into one or more distribution and supply agreements and a collaborative research and development agreement, including a Research and Development Plan and cross-supply arrangements, and the various terms relating thereto. The MDPH entered into two agreements relating to the supply, distribution and development of selected vaccines - the Supply Agreement (summarized below) (the "SADA") and a Collaborative Research and Development Agreement between the State, MDPH and SmithKline Beecham plc (the "CRADA"). The SADA was entered into as of September 16, 1992 and provided for the supply and distribution of certain vaccines. The CRADA was similarly entered into as of September 16, 1992 and provided for a collaborative research and development program to develop certain vaccines. However, effective December 22, 1996, a Heads of Agreement (summarized below) was entered into and among other things, terminated the CRADA and all rights and obligations of the parties thereunder, amended the SADA and provided for the SADA II (as defined and summarized below). Summaries of the SADA, as amended, and the Heads of Agreement which also incorporates the terms of SADA II is provided below. However, because the CRADA has been terminated, there is no summary provided for the CRADA.

B. Supply and Distribution Agreement between the State, MDPH and SB Corp. dated as of September 16, 1992 (the "SADA").

Pursuant to the SADA, MDPH exclusively supplies certain vaccine products manufactured by MDPH to SB Corp. for distribution in the United States (except Michigan). Additionally, SB Corp. and its affiliates, have the exclusive right to market, sell and distribute the following products in the United States (except Michigan): Diphtheria and Tetanus Toxoids and Pertussis Vaccine Absorbed; Diphtheria and Tetanus Toxoids Absorbed; and Rabies Vaccine Absorbed (the

"Products"). MDPH exclusively supplies SB Corp. with all of its forecasted requirements of each Product. The SADA is set for a term of 15 years with various rights of termination under certain circumstances (including certain remedies of continued supply and rights of first refusal to SB Corp.). While termination of the CRADA can trigger termination of the SADA, the parties have agreed to continue the SADA with certain amendments.

MDPH has responsibility for legal and regulatory requirements as well as testing of the Products. MDPH has further obligations to provide various documentation to SB Corp. prior to delivery. SB Corp. has the right to inspect such documentation and each lot of Product to be delivered. SB Corp. may under certain circumstances reject the delivery of Products. Costs associated with any Product recall are apportioned between the parties depending upon the circumstances and cause of the recall.

SB Corp. is required to submit a quarterly report of sales of each Product. The price payable by SB Corp. for Products supplied by MDPH is generally the MDPH Cost of the Product plus the applicable excise tax. Originally, SB Corp. was further required to remit an annual donation to MDPH of the greater of 5% of Net Sales during the previous year or $100,000. However, the Heads of Agreement deleted the minimum $100,000 donation contained in the SADA. Thus, the required annual donation is 5% of Net Sales.

SB Corp. must indemnify, defend and hold MDPH harmless from and against damages, losses or liabilities arising from claims for any injury or death arising from or relating to the administration of Products which are distributed or sold by or for SB Corp. during the term of the SADA. However, under the Heads of Agreement, if the State transfers the Michigan Biologic Products Institute vaccine laboratory assets or business, the indemnification obligation will exclude claims resulting from the gross negligence or willful misfeasance of the transferee. Both parties have confidentiality obligations.

As referenced above, the SADA was amended by the Heads of Agreement among The Institute, the State of Michigan (the "State"), SB Corp., SmithKline Beecham plc ("SB plc"), and SmithKline Beecham Biologicals SA ("SBB") effective as of December 22, 1996 (the "Heads of Agreement"). In addition to the amendments referenced above, the Heads of Agreement contains additional agreements between the parties with respect to the SADA.

SB Corp. has waived its rights of first refusal under the SADA and has consented to the assignment of the SADA and SADA II (discussed below) to a new owner. However, such waiver and consent is conditioned upon rights of SB Corp. to buy at fair market value the technology and facilities used in the production of the SADA Products and Bulk DT Products (defined below) under the SADA II and/or to terminate the SADA and SADA II under various circumstances, including a determination that the proposed transferee is incapable of assuming the obligations, the proposed transferee is a competitor, upon material breach by, or insolvency of, the transferee, the State is unable to sell the vaccine laboratory assets and desires to demolish or dispose of such, or the

transferee desires to sell. Should the SADA and SADA II be terminated under certain of the above referenced circumstances, The Institute may have additional supply obligations.

A transferee must either purchase or lease certain investments made or to be made by SB Corp. in the Institute vaccine facilities, or SB Corp. may remove them. Additionally, upon the transfer of the Institute vaccine laboratory assets or business, the transferee and SB Corp. must negotiate certain terms regarding termination. During the terms of the SADA and SADA II, a transferee must first offer for sale the technology and facilities used in the production of the SADA Products and Bulk DT Products before selling or transferring The Institute assets or business.

C. The Heads of Agreement among The Institute, the State, SB Corp., SB plc, and SBB effective as of December 22, 1996.

Pursuant to the Heads of Agreement, SB Corp. consents to the assignment of the SADA and the CRADA by MDPH to The Institute. However, the CRADA is terminated as of December 22, 1996. With respect to the SADA, the Heads of Agreement provides for the terms and conditions of various amendments to SADA as discussed above.

In addition to the SADA II discussed below, the Heads of Agreement further provides for investments by SB Corp. to upgrade The Institute facilities (in addition to the upgrade to the Institute diphtheria facility being completed). These upgrades include those to the tetanus production facilities, as provided in the Gift and Acceptance Agreement to be entered into by and between SB Corp. and the State, and the ancillary support facilities, provided that such funding by SB Corp. will not exceed $1.75 million. The State is to use its best efforts to undertake and fund various ancillary support facility upgrades. SB Corp. and The Institute were to determine in which investments SB Corp. retained ownership.

D. Bulk DT Supply Agreement between SmithKline Beecham Biologicals SA ("SBB") and The Institute (the "SADA II")

The Heads of Agreement further provides for the terms of the SADA II (and if no formal agreement is entered into serves as the SADA II) pursuant to which The Institute agrees to sell to SBB and SBB agrees to purchase in bulk, and in accordance with certain specifications, the D and/or T vaccine components produced by The Institute (the "Bulk DT Products"). The SADA II authorizes SBB to use, sell and distribute the Institute D and T on a worldwide basis in any vaccine product, formulation and/or combination vaccine. The SADA II is for a term of 12 years with SBB's right to extend for two additional five year terms. SBB consents to an assignment by The Institute of the SADA II on the same terms as provided for the SADA I (see summary of the SADA I).

SBB's requirements are supplied, in accordance with the applicable specifications, at Cost plus a mark-up of 15% of Cost ("CGS Plus"). The CGS Plus shall not exceed $0.01 per Lf provided that SBB orders at least 65 Mio Lf of T and 26 Mio Lf of D annually. The $0.01 limit on the CGS

Plus mark-up will be adjusted annually. Upon execution of the SADA II and The Institute's acquisition of necessary export licenses and permits, SBB is to purchase 20 Mio Lf of D (phenoxyethanol preserved) and 25 Mio Lf of T (phenoxyethanol preserved) for $787,500. SBB must provide The Institute for the first three years of the SADA II reasonable support services for Quality Control/Regulatory provided that the value of such services does not exceed $100,000 per year.

SBB has certain minimum purchase obligations, and The Institute must guarantee certain supply. The Institute must supply SBB's requirements of the Bulk DT Products for purposes of clinical testing of new products at no charge. The Institute has certain rights to sell to third parties if such would not jeopardize its ability to fulfill its obligations under the SADA II.

The Institute must use its best efforts to develop and/or optimize a commercially reasonable (a) production process on the basis of a synthetic medium and (b) large scale tetanus fermentation process, pursuant to which SBB must pay $600,000 on or before September 30, 1997 to defray costs. Upon completion or request of SBB, the processes are to be transferred to SBB with a royalty-free license back to The Institute. SBB has certain obligations to make donations of vaccines upon request and in times of shortages to allow The Institute first call to purchase D and T containing SB pediatric vaccines at private market prices.

E. Gift and Acceptance Agreement between SB Corp. and the State for the MDPH dated October 25, 1995

Pursuant to the Gift Agreement, SB Corp. agreed to construct and donate a renovation and expansion of a certain existing facility structure in Lansing owned by the State (the "Existing Facility Structure") to be used by MDPH as a diptheria vaccine production facility. The expansion was intended to be used for vaccine production so long as it was leased by SB Corp. for such purpose or until the State was no longer required to produce pediatric vaccine under the terms of the SADA. SB Corp. has no lien on, nor any reverter interest in, the expansion. However, any equipment or other personal property installed by SB Corp. remains the property of SB Corp.

MDPH retained various rights under the Gift Agreement, including under the Construction Contract between SB Corp. and the Contractor, as well as various approval rights relating to the expansion. MDPH must provide certain information to the Contractor, regularly observe in-progress and completed work and periodically inspect completed portions of the expansion. MDPH must also provide notification of defects or non-compliance with specifications and drawings, contractual provisions or legal or regulatory requirements. Upon substantial completion, MDPH and SB Corp. must inspect the expansion for approval and ultimately for acceptance. Acceptance of the gift of the expansion becomes effective at the time of Substantial Completion of the Expansion (as determined under the Construction Contract and as agreed by the State under the Gift Agreement including issuance of the Certificate of Substantial Completion).

MDPH granted SB Corp. a license to enter the existing facility to perform the work. SB Corp. has certain indemnification obligations and agreed to perform a certain environmental assessment. If contamination is found, the State must use its best efforts to assist in obtaining the issuance of an administrative order on consent or other appropriate order or decree containing a covenant by the State and its agencies not to sue or take judicial or administrative action against SB Corp. for an environmental claim related to the existing contamination and constituting a settlement within the meaning of CERCLA and the Michigan Environmental Response Act.

F. Gift and Acceptance Agreement between SB Corp. and the Institute dated November 1, 1996

SB Corp. agreed to construct and donate a renovation and expansion of a certain existing facility structure in Lansing owned by the State (the "Existing Facility Structure") to be used by the Institute as a tetanus vaccine production facility. The expansion was intended to be used for vaccine production so long as it was leased by SB Corp. for such purpose or until the State was no longer required to produce vaccine under the terms of the SADA. SB Corp. has no lien on, nor any reverter interest in, the expansion. However, any equipment or other personal property installed by SB Corp. remains the property of SB Corp. Other relevant terms of this agreement mirror those of the October 25, 1995 Gift and Acceptance Agreement described directly above.

Athena Neurosciences, Inc.

A. Collaboration Agreement between MDPH and Athena Neurosciences, Inc. ("Athena") dated as of July 25, 1991.

This Agreement provides for a collaboration between MDPH and Athena to establish manufacturing processes for the preparation of Botulinum Toxin ("BT"). In particular, MDPH agrees to support Athena in Investigational New Drug applications or foreign equivalents for Compounds (composition containing BT as an active ingredient intended for therapeutic and diagnostic use in humans) submitted to the FDA or foreign equivalent ("IND Filings"), to maintain materials and information to support IND Filings and make them available to Athena, and to exclusively collaborate with Athena to establish manufacturing processes for Compounds derived from BT, including assisting with research and establishment of manufacturing processes, providing certain necessary supplies for preclinical testing of Compound, establishing and validating methods and analyses pertinent to the manufacture of Compound at MDPH, and performing certain preclinical activities required for further clinical manufacture of Compound.

Athena must compensate MDPH for its costs in conducting the collaboration work, indemnify MDPH for Athena's activities under this Agreement, limit the use of any BT identified by work within the Project Plan (the research and development work to be carried out by the parties) to in vitro and non-human in vivo research, refrain from using any BT identified within the Project Plan in human subjects, and support the collaboration with the skills and facilities of its own research operation. Athena must fund a minimum level of reimbursable activity expenses during

each year of the collaboration (adjusted each year). MDPH may not look to Athena for reimbursement of worker's compensation claims filed by an MDPH employee.

Project Technology (certain tangible items and proprietary information) possessed by MDPH when entering into the Agreement or subsequently developed by the parties belongs to MDPH with respect to all worldwide human and veterinary vaccine products and to Athena with respect to all worldwide commercial rights, including exclusive marketing and distribution rights, for Compounds. Each must provide a license to the other to enable the other to effectively practice its rights. (The definition of Project Technology provides that ownership and title of Project Technology shall reside in the party who has discovered or developed such Project Technology provided that mutual discoveries or developments of Project Technology shall be owned jointly by MDPH and Athena.)

The term of the Agreement is ten years following the first commercial sale by Athena of a Compound. Confidentiality obligations are set forth in a separate Disclosure Agreement effective June 26, 1991 between the parties.

North American Biologicals, Inc. ("NABI").

A. Supply and Distribution Agreement between MDPH and NABI dated August 9, 1995.

Under the Agreement, MDPH appoints NABI the sole, worldwide distributor of Products and By-Products and agrees to exclusively supply Products and By-Products to NABI. "Product" refers to virally inactivated (v.i.) hepatitis B immune globulin (Human) or other specific hyper-immune globulin that may be developed by NABI and is manufactured by MDPH according to certain specifications. "By-Product" refers to cryoprecipitate in bulk form, and albumin and virally inactivated normal immune globulin products in finished vial form, recoverable solely from fractionation contracted by NABI, suitable for commercial sale and manufactured by MDPH according to certain specifications. NABI supplies the plasma needed to make the Products and By-Products at its cost.

Each year following the first shipment from MDPH to NABI of Product approved by the FDA for commercial sale by NABI ("Contract Year"), NABI must pay to MDPH $41 per liter for the first 20,000 liters and $32 per liter for each liter over 20,000 liters, of plasma fractionated and finished into Product and By-Product (Fractionation Fee). NABI must additionally pay $2 per vial for each vial of Product delivered to NABI (Finishing Fee). NABI is also required to pay 20% of the Net Proceeds received within a Calendar Quarter for the sale of By-Product to a third party. For each Contract Year following the Calendar Quarter in which the FDA provides ELA/PLA approval for commercial distribution of the Product ("Quarter of Approval"), NABI must pay for the equivalent payment due for a minimum of 60,000 5 ml Vial Equivalents and 20,000 Liters of fractionation as described above ($940,000) and is thus invoiced for this amount less payments already invoiced for orders placed for delivery in that Contract Year.

At the end of the Agreement's term, at any point during the term at NABI's discretion, or if NABI terminates the Agreement upon 12 months' notice, title to selected equipment and facility upgrades, purchased by NABI for producing Product and By-Product, transfers to MDPH without any representations or warranties. Certain other selected equipment and facility upgrades, purchased by NABI for MDPH's use associated with implementation of Product manufacturing and other MDPH processing, are to be retained as MDPH property, with reimbursement of the cost of the purchases to NABI.

MDPH is responsible for testing of each batch of each Product and By-Product shipped provided that NABI at its option may conduct additional testing. However, NABI is responsible for administering testing, and clinical and non-clinical studies, required solely for Product License Application/Establishment License Application. Products and By-Products supplied to NABI must be accompanied by full batch documentation. NABI has certain rights of inspection and to reject delivery under certain circumstances. Recall costs are apportioned depending on the circumstances and cause of recall. There are certain indemnification obligations of NABI to MDPH. Both parties have confidentiality obligations.

The term of this Agreement is for five years from the beginning of the Quarter of Approval. Unless either party terminates the Agreement by written notice at least six months before the end of the original or any extended terms, the Agreement is renewed for additional five year periods. Certain termination by MDPH provides NABI with rights of continued supply and rights of first refusal.

The Agreement contains a non-compete clause which applies during the term of the Agreement and for a period of five years thereafter and which restricts MDPH, with certain exception to meet a public health need in Michigan not being satisfied by NABI, from using its PLA or ELA for hepatitis B immune globulin or other Product to produce certain products.

American Red Cross

There are the following three agreements with the Red Cross:

A. Agreement between American Red Cross Blood Services, Mid-Michigan Region, and the MDPH, Bureau of Infectious Disease Control, for the period July 1, 1995 through June 30, 1997.

B. Agreement between American Red Cross Blood Services, S.E. Michigan Region, and the MDPH, Bureau of Infectious Disease Control, for the period July 1, 1995 through June 30, 1997

C. Agreement between American Red Cross Blood Services, Wolverine Region, and the MDPH, Bureau of Infectious Disease Control, for the period July 1, 1995 through June 30, 1997

The Agreements provide for the fractionation of human plasma provided to MDPH by the American Red Cross and for the preparation of blood derivatives from that plasma. However, the

Agreements are to expire June 30, 1997. The Red Cross has elected to let the agreements expire June 30, 1997. In March, the Red Cross indicated it would cease delivering plasma immediately. However, there are still several outstanding issues between the parties.

Serum Institute of India, Ltd.

A. Technology Transfer and Licensing Agreement between the Serum Institute of India, Ltd. ("SIIL") and the Michigan Biologic Products Institute ("The Institute"), dated effective May 3, 1996.

Under this Agreement, The Institute agrees to transfer the technology for, and to grant SIIL the right to use, the manufacturing process for Rabies Vaccine Adsorbed ("RVA") for production, sale and distribution by SIIL in India and elsewhere as may be later agreed upon. This Agreement is in effect for fifteen (15) years from the date SIIL is licensed to produce and distribute RVA in India. It was intended as the beginning of a collaborative relationship between the parties.

The Agreement contemplates the transfer of Licensed Technology (generally intellectual property and know-how owned by The Institute in the general area of manufacture and preparation of RVA) to SIIL (the "Technology Transfer"). The Technology Transfer is divided into two phases. Supervision of the initial phase, on which The Institute had commenced work prior to the execution of this Agreement including the provision of information and biological products, was the responsibility of The Institute. Its purpose was to familiarize SIIL personnel with the Licensed Technology. SIIL personnel were to visit the Institute to become versed in all aspects of production and testing of the Licensed Technology. It was contemplated that The Institute would provide further information and biological products for testing and manufacture of RVA. The second phase is primarily the responsibility of SIIL. This work was to commence upon execution of the Agreement. SIIL was to select a site for the manufacturing facility, construct it and operate it. The Licensed Technology would be available to SIIL for the second phase. During the second phase, The Institute employees are to be available for consultations with SIIL, and The Institute has the opportunity to make periodic inspections. SIIL is to advise The Institute of improvements it develops in the manufacturing process.

Any intellectual property first arising during the initial phase of the Technology Transfer is the property of The Institute. Any intellectual property first arising during the second phase of the Technology Transfer is the property of SIIL. The Agreement provides for the licensing of each to the other party.

As consideration, SIIL was to make a Technology Transfer payment upon execution of the Agreement of $100,000. For the exclusive license for SIIL to use the Licensed Technology to make, use and sell RVA in India, SIIL must pay to The Institute a royalty of 8% of net sales of all materials manufactured using the Licensed Technology. However, no royalties are due more than seven years after licensure. For a non-exclusive license to use the Licensed Technology to sell

RVA outside of India, but excluding the United States, a royalty of 8% of net sales is additionally due. This obligation continues for as long as such sales continue. SIIL is further obligated to pay certain costs and taxes and has certain indemnification obligations. Both parties have confidentiality obligations.

The Agreement further provides that if SIIL receives approval from the FDA to supply bulk quantities of RVA to The Institute for finishing, packaging and distribution in the United States, the parties would negotiate a price based generally on a multiple of the Indian maximum retail price per milliliter of bulk. The parties contemplated that SIIL would sell bulk RVA to The Institute in five to ten liter quantities for repackaging into one milliliter vials.

Battelle Memorial Institute, etc.

A. Teaming Agreement between the National Security Division of Battelle Memorial Institute ("Battelle"), The Institute, the Massachusetts Public Health Biologics Laboratory, the Microbiological Research Authority acting through its Centre for Applied Microbiology and Research and The Salk Institute for Biological Studies dated March 27, 1996.

The Teaming Agreement provides for a team arrangement among the parties for the preparation and submittal of a proposal seeking a Prime Systems Contract (the "Contract") from the U.S. Army Medical Research Acquisition Activity (the "Government") for the Medical Biological Defense Products ("MBDP") solicitation (the "Program"). The Agreement contemplates that all parties would contribute their respective expertise, capabilities and interests to prepare and submit the proposal and work together on the Program should the Contract be awarded to Batelle.

Under the Teaming Agreement, Batelle is to prepare and submit a proposal which addresses the requirements detailed by the Government in the Program solicitation with any amendments (the "Proposal") as Prime Systems Contractor for the Program. The other parties to the Teaming Agreement (the "Production Team") are to assist Batelle and have an opportunity to approve the final contents of the technical, management and cost submissions. Batelle must identify the contribution of each Production Team member in the Proposal and propose each as a subcontractor.

If Batelle is awarded the Contract, each Production Team member is to negotiate individual subcontracts with certain required provisions. The terms and conditions of each subcontract (excluding labeled proprietary information) are to be furnished to the other Production Team members.

The Teaming Agreement further provides for a Steering Committee consisting of Batelle and members of the Production Team. The Steering Committee has various responsibilities including those relating to the production, testing, shipping and storage of MBDPs, applications and reports (including Product License Applications and Establishment License Applications), the proposed

electronic database, and during the proposal preparation phase, determination of the products and services to be supplied by each member and the member's respective responsibilities.

Each party bears their own costs, expenses, risks and liabilities, and there is no sharing of profits or losses arising out of the efforts of the parties in connection with the Teaming Agreement. However, the parties have confidentiality obligations with respect to proprietary information. Furthermore, publicity, advertising, or other form of public announcement relating to the Teaming Agreement may not be released without prior written approval by the other parties.

Each party retains ownership of all of its proprietary intellectual property, know-how, materials, etc., existing at the date of the execution of its subcontract. Such property arising out of the Proposal effort or the subsequent Prime Systems Contract that are conceived or reduced to practice by one of the parties remains the property of the originating party. Such information and materials that are jointly conceived or reduced to practice shall be subject to further negotiations between those parties. If Batelle is awarded the Contract, each party must grant royalty-free licenses to the Government necessary for the Government's purposes.

The Teaming Agreement remains in effect until the execution of all subcontracts entered into under the provisions of the Prime Systems Contract unless earlier terminated. For example, the Teaming Agreement automatically terminates upon the expiration of 24 months unless extended by written agreement of the parties or upon the occurrence of other events.

FFF Enterprises, Inc. ("FFF")

A. Letter from Patrick Schmidt, President of FFF, to Ms. Hargrove and Dr. Myers of the Biologic Products Division ("BPD") dated October 10, 1995.

This letter provides specific responses to a request for information from BPD dated October 2, 1995. The objective of FFF is to distribute MDPH Intermuscular Immune Globulin ("IMG") to end-users or pharmacies and physicians with individual patient needs. FFF explains its services and standard operating procedures. FFF notes that its customers are healthcare provides; not wholesalers or other medical suppliers. FFF agrees to a percentage mark-up of between 10 - 25% of MDPH reimbursement cost of $21.00 per three vial package. MDPH would need to provide FFF with certain information (i.e., customer and delivery information) to deal with existing backorders. It was then contemplated that new orders would be handled by FFF for immediate input into its system. FFF would name MDPH-State of Michigan as an additional insured.

United States Department of Defense

The Institute has worked with the United States Military for close to sixty years. After certifying the Biologics program as a primary defense industry in 1940, the Army actually completed the main laboratory for Biologics in 1943. During this period, the Army purchased vaccines and

helped establish the first plasma collection programs. In the late 1960s, the Army played a limited role in Michigan starting to produce anthrax vaccine, and its initial involvement with production of botulinum toxoids.

The relationship with the military blossomed again in the late 1980s, as concern over biological weapons grew. Anthrax vaccine production contracts started in 1986, and have grown steadily since then. Pentavalent botulinum production started a couple of years later, and still continues. Stockpile maintenance and testing contracts have followed on behind the production contracts.

The following are brief descriptions of current and pending Department of Defense contracts.

Current Department of Defense Contracts

Contract DAMD-17-91-C-1139 - Antrhax Vaccine Adsorbed Production
This is a Firm Fixed Price contract; with some reimbursable elements.
Contracting Agency: United States Army Medical Research Acquisition Activity
Period of Performance: 11 September 1991- February 28, 1998
Dollar Value - $28,905,040.58
Brief Description of Program: Remodel facilities for Anthrax Vaccine production; produce Anthrax Vaccine Adsorbed in large quantities.

Contract DAMD-17-94-C-4076 B - Pentavalent Botulinum Toxoid Production
This is a Firm Fixed Price contract with some reimbursable elements.
Contracting Agency: United States Army Medical Research Acquisition Activity
Period of Performance: September 28, 1994 - February 28, 1997
Completion Date - mid -1997
Dollar Value - $1,212,850.81
Brief Description of Program: Contract to make 110,050 doses (net) of pentavalent botulinum toxoids. Army supplies Types C and E; MI supplies Types A, B, and D and combines all five. Some potency testing is also covered, along with some travel.

Contract DAMD 17-97-D-0003 This is a Delivery Order Contract - Firm Fixed Price with reimbursable elements, the prices will be renegotiated in September 1997, to be effective in October 1997.
Program Title: Anthrax and Botulinum Vaccine Stability Testing, Storage and Packaging
Contracting Agency: United States Army Medical Research Acquisition Activity
Period of Performance: May 1997 - April 2002
Dollar Value - Original: $11,068,550
Brief Description of Program: Provides for long term storage and regular stability and potency testing of anthrax and botulinum (both monovalent and pentavalent) vaccines with a view toward extending the labeling period.

Army Facilities contract DAMD-17-92-E-2001
Contracting Agency: United States Army Medical Research Acquisition Activity
Contract Type: Reimbursable
Period of Performance: June 29, 1992 to (open)
Dollar Value - Not meaningful
Brief Description of Program: Acquisition and maintenance of Government Furnished Equipment; transfer of equipment from two earlier contracts. This was intended to be a vehicle contract that could be used if no other contract vehicles are available, but will likely be folded into the next anthrax production contract.

Pending Department of Defense Contracts

Request for Proposal DAMD 17-97-R-0014 - Anthrax Vaccine Production. The contract type is to be determined, but probably will be a firm fixed price with reimbursable elements
Contracting Agency: Unites State Army Medical Research Acquisition Activity
Dollar Value - Unknown; will be defined by the request for proposals final scope of work and Institute's response to it.
Brief Description of Program: This will provide for continued production of anthrax vaccine. Notice was published CBD on March 6, 1997 that the United States Army Medical Research & Material Command will enter a sole source agreement with Michigan with one base year and four option years .

Request for Proposal Number: DAMD 17-95-R-5020 - Joint Vaccine Acquisition Program (JVAP)
Contract Type: Firm Fixed Price with reimbursable elements
Agency: United States Army Medical Research Acquisition Activity
Projected Period of Performance: Late 1997 - late 2007
Dollar Value - could be in excess of $500 million for the entire contract. MBPI should receive between $80 and $100 million, primarily in 2001 and beyond.
Brief Description of Program: Aimed at hiring a systems integrator to oversee the development, testing and FDA licensure of 18 biological defense vaccines, including 8 botulinum vaccines and possibly an improved anthrax vaccine. MBPI is teamed with Battelle (systems integrator), other bio-defense manufacturers (Salk Institute, Centre for Applied Microbiology and Research), the Massachusetts labs and Harris (for clinical tests) for RFP. Our team has passed the preliminary screens and is submitting its Best and Final Offer on May 27. Award is targeted for June 30.

FDA REGULATORY STATUS

The Institute is a licensed establishment (Establishment License No. 0099) under the regulations set forth in 21 CFR Subchapter F for biologic products. The Institute holds product licenses for several vaccines and plasma derivatives and also conducts work on several biological products under approved Investigational New Drug Applications.

Presently these licenses are without regulatory restriction and FDA considers the Institute free to manufacture and market its products in the United States.

There is, however, scrutiny of the Institute by FDA in the area of compliance. The Institute and the FDA share a concern regarding the Institute's ability to manufacture its products in full compliance with the Good Manufacturing Practice (GMP) regulations. Inspections and related interactions with the FDA in recent years have documented compliance problems at the Institute. The following is a brief history of the Institute's interaction with the FDA.

i. **A comprehensive spring, 1995 inspection of the Institute resulting in 50 inspectional findings.** The Institute promptly responded, outlining how it would resolve each issue.

ii. **An August, 1995 warning letter from the FDA as a follow-up to the spring, 1995 inspection.** Cited in this letter were failures of compliance with GMPs and, in general, the failure of the Responsible Head of the Institute to exercise control of the establishment in all matters relating to compliance with all pertinent regulations. The Institute responded to the warning letter to the FDA's satisfaction, pending further review in the form of an inspection to be held later at an unspecified time.

iii. **The inspection by the FDA of November, 1996, during which the inspectors documented 70 observations of non-compliance.** The Institute promptly responded, again outlining plans to resolve each issue of non-compliance.

iv. **A March 11, 1997 letter from the FDA following up the November, 1996 inspection and warning the Institute that the FDA would initiate steps to revoke the Institute's establishment and product licenses unless immediate action is taken to correct deficiencies.** In its letter, the FDA reiterated many of the documented violations found on inspection, determining that continuing problems represent a failure to comply with the regulations that safeguard the drug and pharmaceutical industry. Again the FDA expresses that in its judgement management of the Institute had not fulfilled its responsibilities to exercise control in all matters relating to compliance with federal regulations and applicable standards of its establishment and product licenses.

As of today, the Institute has responded to the March 11, 1997 letter with the document entitled: *Thirty-Day Response to FDA Letter of March 11, 1997* (please refer to Appendix III to view the

March letter and the Thirty-Day Response), in which a Strategic Plan for Compliance is outlined. The Strategic Plan for Compliance was presented to the FDA at an April 22, 1997 meeting. On June 2, 1997, the Institute received a letter from the FDA accepting the Institute's Strategic Plan for Compliance and stating the FDA's intention to verify compliance upon reinspection. (This letter is also included in Appendix III.)

SUPPLIERS

The table below depicts the Institute's largest suppliers.

Table IV

Ten Largest Suppliers
($000)

Supplier	Product	Amount of Purchases During 8 Months End. 5/27/97
Electronic Data Systems	Computer/Peripherals	$474,610.53
VWR Scientific Products	Bio/Pharm. Products	$356,045.31
B. Braun Biotech Inc.	Bio/Pharm. Products	$263,055.72
Axiom Systems	LIMMs Software	$210,374.73
Contamination Control Devices	Bio./Pharm Products	$181,790.62
VECTECH Inc.	Consulting/Validation	$173,387.53
Millipore Corporation	Bio/Pharm. Products	$167,685.34
Paul Meuller Company	Facility Equipment	$148,772.50
Charles River	Animals	$132,824.35
Benchmark Products Inc.	Bio/Pharm. Products	$110,556.05

MACHINERY AND EQUIPMENT

Table V lists the Institute's principal manufacturing equipment.

Table V
Major Manufacturing Equipment List

Manufacture	Brand Name	Description
Chase-Logeman		Vial filling machinery
Chase-Logeman		Tray loads vials
New Jersey Machine		Vial labeler
B.Braun		Used for Diphtheria fermentation-30L fermenter
Varian DMS		Spectronic 20
ICN Micromedic Sys.	Apex	Gamma counter radio immunology and assay
Cozzoli		
APV Crepaco		Albumin pasteurizer
Environmental Tectonics		Autoclave
Reitz		Blood production plasma crusher
B. Braun Melsun Genag		Tetanus production
B. Braun		10L fermenter
B. Braun		10L fermenter
Filtrane		Process chiller
Cherry Burrell AMCA	International	150L holding tank
B. Braun Biostat U		
Scientific Industries		Sterilizer for bulk manufacturing
Hewlett-Packard		Quality control testing
Pharmacia	BioProcess	Column chromatography Unit
New Jersey Machine		Vial labeler
B. Braun		100L fermenter
Scientek		Animal cage washer
Getinge	BioFoe GMP	Autoclave - Tetanus manufacturing
Beta Star Corp		Autoclave used in filling
Bosch		Cartoner
The West Company		Not ni use - vial capper
Virtis		R&D freeze dryer
Getinge International		Autoclave
Amer. Sterilizer Co.		Autoclave
Paul Mueller Co.		Clean Steam Gen.
Paul Mueller Co.		Clean Steam Gen.
AAF-McQuay Inc		140 Ton Chiller
Steris Corp		Glassware
Temtral		Air Handling Unit
Dober Chem Corp		Clean in Place Sep.
Quality Air Service		Laminar Flow Sys
Varian		Chem Analysis Sys
LECO		Nitrogen Determinater

PRODUCTION CAPACITY

The following table provides an estimate of the maximum amounts of product which the Institute can currently manufacture on an annual basis.

Table VI
Production Capacity

Product	Staffing/Equipment	Annual Capacity
Diptheria**	Staff at 4 utilizing 1 fermenter	30,000,000 Lf
	Staff at 7 utilizing maximum equipment capacity (2 fermenters)	120,000,000 Lf
Tetanus**	Staff a 4 utilizing 8 fermenters	30,000,000 Lf
	Staff at 8 utilizing maximum equipment capacity (16 fermenters)	120,000,000 Lf
Anthrax *	Confidential Information	Confidential Information
	Confidential Information	Confidential Information
Rabies	Staff at 7 at current capacity (= maximum)	40,000 - 50,000 Doses
Filling and Packaging	Current Capacity, 2-2.5 lots per week*** (=maximum)	100 Lots per year
Albumin	Capacity based on centrifugation capacity at a throughput of 60,000 liters per year	114,000 Vials
Immune Globulin		492,000 Vials
Botulinum Toxoids	No Facilities	0
* Production capacity for Anthrax is confidential information which will be shared with qualified purchasers later in the divestiture process.	** Capacities for D and T facilities when completed; they are currently under construction, renovation and/or validation.	***Lot sizes vary by product; there is a standard "set-up" time, but fill times vary depending on vial volume.

FACILITIES

The Institute consists of 27 buildings containing approximately 247,000 gross square feet of laboratory, pharmaceutical manufacturing, office and warehouse space. The Institute also houses its own power plant which provides pharmaceutical grade steam, water for human injection, and vacuum and compressed air to its facilities. The site is located on the northwest side of the City of Lansing, Michigan. The North Logan/Martin Luther King, Jr. Boulevard divides the site into two parcels, commonly referred to as the east and west campuses (Appendix II depicts an aerial photograph of both campuses, a map of the regional context of the facilities, and a map of the site context of the facilities). Table VII provides a brief description of each building at the Institute.

Two of the Institute's buildings and some of the Institute's production equipment are owned by the U.S. Department of Defense. The equipment supplied by the Department of Defense has been provided to the Institute at no charge to the Institute. Technically, this equipment has not been sold, but rather "provided for use" by the military to the Institute. The military retains title, but does permit alternative uses other than for producing military products, so long as these other uses do not interfere with the timely delivery of products to the military. The Institute's other major customers have also made significant investments in the Institute's laboratories.

Located contiguous to the main production campus (East Campus), is the West Campus consisting of over 47 acres of vacant farmland that may be used to build new replacement production and/or distribution facilities. The land is contiguous to a regional airport's industrial park and accesses a taxiway for ready air transport of products. Utilities are readily available, including power, steam, etc. from the Institute's own power plant that has three 20,000 psi gas-fired boilers. The whole complex is located within a hub of air, land and rail transportation.

One of the unique facilities at the Institute is its rhesus monkey colony. The Institute is registered by the U.S. Department of Agriculture under the Animal Welfare Act to produce and maintain animals for testing, and houses the only SIV-free, reproducing rhesus monkey colony in North America (approximately 80 animals).

Table VII
Institute Buildings

Bldg. No.	Building Name	Function	Year Built/ Improved	Gross Sq. Ft.
1	C.C. Young	Office, Lab, Security	1937	29,500
2	Admin & Research	Office, Lab	1976	25,500
3	Plasma Fractionation Lab	Lab, Production	1935	15,100
4	Plasma Fractionation	Storage	1936-43	5,700
5	Tetanus Scale-Up	Lab	1939	4,800
6	Stock Room	Storage	1926	7,600
7	Maintenance Shop	Maintenance	1939	5,800
8	Electric Substation	Services	1937	7,000
9	Vaccine Laboratory	Lab	1935	4,300
10	Barn (includes NIH Rhesus Colony)	Animal Housing	1926	24,000
11	Cell Culture Lab	Lab	1932	3,800
12	Vaccine Production, Animal Testing	Production, Animal Housing	1943	6,200
13	Rabies Vaccine Production	Lab, Production	1939	3,000
14	Botulinum Laboratory	Lab, Production	1941	1,350
16	Vaccine Production, Filling, Packaging	Manufacturing	1942	24,000
17	Water Resource Laboratory	Lab	1936-79	2,950
20	Chemical Storage Vault	Storage	1935	600
22	Farm Building (W Of Mlk Blvd.)	Storage	1942	3,950
23	Farm Building (W of MLK Blvd.)	Storage	1943	3,950
24	Barn (W of MLK Blvd.)	Animal Housing	1938	15,500
25	Small Heating Plant	Services	-------	508
29	Neo-Natal Lab	Lab	1948	13,800
30	Quality Control	Lab	1966	12,700
31	Animal Production	Lab	1970	13,633
32	Heating & Distrib. Plant	Services	1971	6,100
45	BI-3 Animal Facility	Animal Housing	1995	1,375
46	Biologic Warehouse	Storage	1994	3,840

MANAGEMENT INFORMATION SYSTEM

The Institute has about 130 personal computers and 18 servers, generally configured into a Windows NT (version 4.0) network on a 100 MBPS FDDI ring. The network is becoming functional this month. Computers are purchased monthly, with an aim of replacing each computer every 3 to 4 years. The standard software load is Microsoft Office 97 and MacAfee Anti-Virus; with a number of users also using Microsoft Project. Axiom provides the Laboratory Information Management System. Document handling is using PC DOCS; Datastreams is used for preventative maintenance scheduling. All are installed on SQL Server 6.5 for the enterprise's data depository. MRP and MES systems are currently being evaluated. For security and compliance reasons, the Institute network is a closed network, with no direct connections to the Internet; the machines further have their "A" drives removed and software loads are strictly controlled. Electronic documents as checked in and out of the system through a single point of contact.

INVENTORY

The following table provides a breakdown of inventory as of May 29, 1997.

Table VIII
Inventory on Hand
May 29, 1997

	Inventory Cost/Unit	Quantity	Inventory Value
DTPw market value est - net of excise tax	0.5	282,360	$141,180
DT-market value estimate	0.3	63,970	$19,191
Pertussis Vaccine	0.18	9,280	$1,670
TD-Market value estimate	0.3	19,090	$5,727
Dip unadsorbed w/2-PE (Lf)	0.012	28,329,102	$339,949
Tetanus unadsorbed w/2-PE (Lf)	0.009	15,200,170	$136,802
		Finished Goods:	**$644,519**
Dip adsorbed w/Thimerosol (Lf)	0.012	5,827,650	$69,932
Tetanus adsorbed w/Thimerosol (Lf)	0.009	8,942,750	$80,485
Pertussis three strain concentrate (ds equiv)	0.12	253,740	$30,449
Individual strains	0.09	4,149,604	$373,464
Albumin fractions	45	4,000	$180,000
		Work in Process:	**$734,330**

MANAGEMENT AND EMPLOYEES

MANAGEMENT

The Institute's management team is composed of individuals who have accumulated many years of experience in the development, production and testing of biologic products. The following is a list of the Institute's key management, their titles, and ages.

Table IX

Key Employees

Name	Position
Robert C. Myers	Director
Robert C. van Ravenswaay	Strat. Plan. & Bus. Dev. - Deputy Director
Dianne M. Dreyer	Manufacturing - Deputy Director
Nancy A. Summerton	Facilities Management - Deputy Director
Anthony M. Luttrell	Quality Assurance - Deputy Director

Dr. Robert C. Myers, Director - Michigan Biologic Products Institute, has been employed by the Institute since 1990. Dr. Myers has over 18 years' experience in the development, production, and testing of vaccines, including vaccines for rabies, anthrax, botulism, whooping cough, tetanus and diphtheria. His 6 years of effective leadership as Responsible Head of the Institute has proven his unique and broad qualifications. He has served as Principal Investigator to the Army for several defense vaccine contracts in total amounting to over $50 million. Dr. Myers participates on multi agency teams pursuing FDA approval of animal models of efficacy for defense vaccines, licensure of Pentavalent botulinum toxoid and changes in the dose, route, and schedule for Anthrax Vaccine. Dr. Myers received both his B.S. (Biologic Sciences) and Doctorate in Veterinary Medicine from Michigan State University.

Mr. Robert C. van Ravenswaay, Strategic Planning and Business Development - Deputy Director, has been employed by the Institute since 1993. In addition to his duties as Deputy Director of Strategic Planning and Business Development, Mr. Van Ravenswaay is also responsible for general administration, information technology (Chief Information Officer) and in addressing legal issues experienced by the Institute. Mr. Van Ravenswaay received his B.S. in communications from Michigan State University and his J. D. from the Franklin Pierce Law Center.

Ms. Dianne M. Dreyer - Manufacturing - Deputy Director. Ms. Dreyer has extensive experience and knowledge gained working for several companies in the areas of manufacturing, production, quality control, and quality assurance. She applies these unique multi disciplinary qualifications to direction and planning of the Institute's manufacturing operations. She directs the planning of the manufacture of final bulk lots of biologic products made by the Institute. Ms. Dreyer directs the development of plans to effectively utilize the facilities and resources used for filling and packaging of vaccines and plasma derivatives while also planning and overseeing the work on the development of new vaccines and plasma derivatives. Ms. Dreyer started her employment with the Institute in May, 1997. Ms. Dreyer received her B.S. in Biology and Chemistry from Ashland College.

Ms. Nancy A. Summerton - Facilities Management - Deputy Director, has served in this position since 1990. Ms. Summerton is highly experienced in the design, construction, and validation of pharmaceutical facilities for vaccine manufacture. She has led the oversight of design, installation, and qualification of two large-scale water for injection distillation and distribution systems, several thousand square feet of clean room manufacturing areas, a diphtheria fermentation and downstream processing area, three pharmaceutical-grade steam generation systems, an anthrax vaccine manufacturing area, a tetanus manufacturing area, a pilot-scale botulinum toxin manufacturing facility, a BL-3 animal test facility, and numerous support areas and pieces of equipment. Her positive track record of several FDA facilities/utilities ELA supplement approvals makes her a valued member of the Institute's management team. Ms. Summerton received her B.S. in Chemical Engineering from Michigan Technological University.

Mr. Anthony M. Luttrell - Quality Assurance - Deputy Director. Mr. Luttrell has experience in planning, purchasing, materials management, manufacturing, quality assurance, and quality control for pharmaceutical and biological products in domestic and international markets. As a Quality Assurance Director he has been responsible for insuring compliance to cGMPs for the manufacture of biological and pharmaceutical products, including final responsibility for corporate quality management programs, policies and batch releases. He has developed complete quality assurance programs for regulatory compliance with domestic and international agencies and administration of all quality systems and programs. He has been responsible for the complete validation program in a start-up sterile products pharmaceutical facility that included the development and control of all plant metrology and calibration. He has been responsible for quality control laboratories, had direct first-line supervision of hourly and salaried employees in a complex clean room and laboratory. Mr. Luttrell started his employment with the Institute in February, 1997. Mr. Luttrell received his B.A. (Biology) from Spring Arbor College and his MBA from Oakland University.

Employees

As of May, 1997, the Institute employed a total of 153 salaried and hourly workers. Of the 153 employees, 81 are unionized employees. These unionized employees are represented either by the Michigan State Employees Association (2 employees), the Michigan Professional Employees Society (26 employees) or the United Technical Employees Association (53 employees). The Institute's management feels that employee relations are excellent and that the employees fully support the privatization of the Institute.

Employment Contracts

The Institute has not entered into any employment contracts with members of its management teams.

Employee Benefits

The employees of the Institute are covered by a number of benefit plans. Appendix IV provides a summary of all the benefits provided to both hourly and salaried employees.

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Proforma Financial Statements

September 30, 1996

(With Independent Accountants'
Compilation Report Thereon)

KPMG Peat Marwick LLP

1400 Abbott Road, Suite 220
East Lansing, MI 48823

Telephone 517 336 3300

Telefax 517 336 3333

Independent Accountants' Compilation Report

Members of the
Michigan Biologic Products Commission:

We have compiled the accompanying pro forma balance sheet of the Michigan Biologic Products Institute as of September 30, 1996, and the pro forma statement of operations for the year ended September 30, 1996, in accordance with Statements on Standards for Accounting and Review Services issued by the American Institute of Certified Public Accountants.

A compilation is limited to presenting in the form of financial statements information that is the representation of management. We have not audited or reviewed the accompanying pro forma financial statements and, accordingly, do not express an opinion or any other form of assurance on them.

KPMG Peat Marwick LLP

November 15, 1996

Pro Forma

Balance Sheet

September 30, 1996

Assets	
Current assets:	
Cash	$ -
Receivables	5,125,088
Inventories	2,149,618
Total current assets	7,274,706
Property, plant and equipment:	
Land	23,963
Buildings and building improvements	9,196,730
Machinery and equipment	6,251,958
	15,472,651
Less accumulated depreciation	(10,561,524)
Net property, plant and equipment	4,911,127
Total assets	$ 12,185,833
Liabilities and Equity	
Current liabilities:	
Accounts payable	$ 518,198
Accrued expenses	861,283
Total current liabilities	1,379,481
Other liabilities (see note 7)	-
Total liabilities	1,379,481
Contingencies (see note 7)	
Equity	10,806,352
Total liabilities and equity	$ 12,185,833

See accompanying Independent Accountants' Compilation Report and notes to proforma financial statements.

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Pro Forma

Statement of Operations

Year ended September 30, 1996

Revenues:	
Army product sales	$ 3,546,533
Other product sales	3,085,785
Red Cross	725,000
Other	153,369
Total revenue	7,510,687
Expenses:	
Salaries and wages	5,833,071
Fringe benefits	2,241,651
Contractual services, supplies and materials	3,682,746
General services	1,183,990
Depreciation	985,569
State/Department overhead	647,411
Inventory adjustment	(817,264)
Other	304,628
Total expenses	14,061,802
Net (loss)	$ (6,551,115)

See accompanying Independent Accountants' Compilation Report and notes to proforma financial statements.

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Notes to Pro Forma Financial Statements

September 30, 1996

(1) Description of Entity

The objective of the accompanying pro forma financial statements is to present the Michigan Biologic Products Institute (the "Institute") "as if" it was in operation as a separate business during the year ended September 30, 1996. However, these pro forma financial statements are not necessarily indicative of the financial position or results of operations that would have been attained had the Institute actually existed during the period. Historical financial statements of the Institute are not available.

The Institute was created on December 5, 1995, by Executive Order 1995-25 pursuant to Article V, Section 4, of the Constitution of the State of Michigan of 1963. The Institute is a temporary State agency with a life of no more than two years.

The Biologic Products Division (the "BPD") of the Michigan Department of Public Health (the "MDPH") and the Pharmaceutical Products Fund (the "PPF"), established under Sections 9111 and 9112 of Act No. 368 of the Public Acts of 1978, were transferred to the Institute by a Type III transfer, as defined by Section 3 of Public Act No. 380 of the Public Acts of 1965. The Institute assumed all functions, duties, contractual obligations, responsibilities, inventory, tangible and intangible property and employees of the BPD, including administration of the PPF.

The Institute is an independent and autonomous State entity. The Director is the head of the Institute within the meaning of the Constitution of the State of Michigan of 1963 and of the Executive Organization Act of 1965, Act No. 380 of the Public Acts of 1965, and is the Appointing Authority as that term is used in the Constitution of the State of Michigan of 1963, and in the rules and procedures of the Civil Service Commission. The Director:

- Maintains the establishment license of the facilities for biologic product production and maintains existing product licenses, except for obsolete products, and obtains new licenses as appropriate.
- Maintains existing contractual relationships and expand the value of the work being undertaken while preparing to transfer responsibility for such work out of State government.
- Fulfills the duties of a Responsible Head as delineated in 21 CFR 600.10(a).
- Reports to the Commission on actions that affect the business of the Institute.

The Michigan Biologic Products Commission (the "Commission") was also established by Executive Order 1995-25, pursuant to Article V, Section 4, of the Constitution of the State of Michigan of 1963, and also has a life of no more than two years. The Commission provides supervision, policy control and direction to the Institute and the Director. In addition, the Commission must:

- Within eight (8) months of its initial organizational meeting, prepare a plan describing the means by which the Institute will be transferred out of State government and into the private sector within the two year term of its temporary agency status.

(Continued)

- As part of the plan, cause the fair market value of all state property, inventory, equipment and other assets associated with the manufacture of biologic products to be determined.
- Contract with the initial Director; designate and contract with any future Directors.
- Perform such other duties and responsibilities as may be assigned or transferred to the Commission by statute or by executive order.

(2) Summary of Significant Accounting Policies

(a) Description of Business

The Institute is engaged in the production and sale, and associated research and development of vaccines for the prevention of infectious diseases in children and adults. The Institute is also engaged in the production of blood derivatives.

The Institute is licensed by the United States Food and Drug Administration (FDA) to produce and market its products (see note 6). These products are subject to rigorous tests by the FDA of each lot produced. FDA approval must be obtained to release a lot for distribution (sale). There is no assurance that the Institute's products will continue to obtain the required regulatory approvals.

(b) Principles of Accounting

The accompanying pro forma financial statements of the Institute have been prepared in conformity with generally accepted accounting principles utilizing the accrual basis approach. Statements of cash flows and changes in equity are not presented.

(c) Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and disclosure of contingencies. Actual results could differ from those estimates.

(d) State Funding

As a division of the MDPH, the BPD had revenues to offset its appropriations with the difference being funded by the State's general fund. These general fund monies are not considered revenues of the Institute and therefore are not included in the accompanying financial statements. The general fund appropriation for the year ended September 30, 1996 was $2,851,500.

The State has also funded the acquisition of capital assets, however, complete historical accounting records supporting the cumulative amount of such funding are not available. The assets that have been acquired are included in the accompanying financial statements as property, plant and equipment and the State funding is included in equity, net of cumulative results of operations since inception.

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Notes to Pro Forma Financial Statements, Continued

(e) Receivables

Receivables are recorded when they are measurable and earned as defined in the contract with each of MBPI's customers. A related allowance for uncollectible receivables is not considered necessary due to the Institute's past collection experience. At September 30, 1996, receivables were comprised of the following:

	1996
Army	$ 3,726,294
Red Cross	325,525
Other	1,073,269
Total	$ 5,125,088

(f) Inventories (Inventory adjustment)

Inventories are carried at the lower of estimated average cost or market and are comprised of raw materials, work in process and finished product (released for distribution by the FDA), as follows:

	1996
Raw materials	$ 339,149
Work in process	1,038,720
Finished product	771,749
Total	$2,149,618

The inventory adjustment is reported because the detailed accounting records necessary to accurately report cost of sales are not available. The adjustment represents the net change in the carrying value of inventories from the beginning to the end of the year.

(g) Property, Plant and Equipment

Property, plant and equipment are stated at original historical cost.

Depreciation on plant and equipment is calculated on the straight-line method over the estimated useful lives of the assets. Estimated useful lives are 40 years for buildings, 10 years for building improvements and 3-10 years for computers and equipment.

(h) Taxes

The Institute operates as a State agency, accordingly, there is no provision for income taxes, property taxes or the single business tax.

(i) Revenue Recognition

The Institute recognizes revenue when it is measurable and earned, encompassing the net change in accounts receivable for the period, and adjusted for reimbursement of items capitalized.

(j) Salaries and Wages

Salaries and wages represent the amounts reported in the Statewide accounting system for BPD, including the PPF, for the period presented. These represent actual costs for the period, adjusted for changes in accrued vacation and sick leave (accrued expenses).

(Continued)

(k) Fringe Benefits
Fringe benefits represent the amounts reported in the Statewide accounting system for the BPD, including the PPF, for the period presented. Fringe benefits include payroll taxes, retirement and health and other insurance. These represent actual costs for the period.

(l) Contractual Services, Supplies & Materials
Contractual services, supplies and materials represent the amounts reported in the Statewide accounting system for the BPD, including the PPF, for the period presented. These represent actual costs for the period, adjusted for items capitalized.

(m) General Services
General services represent the cost of utilities, security and maintenance for the Institute's properties. The amounts reported are based on an estimate of the portion of the MDPH costs which are attributable to the Institute's properties.

(n) State and Department Overhead
State and department overhead represents the estimated share of Statewide and MDPH general and administrative costs that are attributable to the Institute, based on MDPH's indirect cost rate study.

(3) Product Distributed in Michigan
As provided in section 333.9112 of the Public Health Code of the State of Michigan, the Institute distributes vaccines, some of which are produced by the Institute and others are provided by the federal government, to local public health departments and certain private physician clinics throughout the State at no cost. The vaccines and number of doses produced by the Institute and distributed in the year ended September 30, 1996 are provided below:

Vaccine	*1996*
Diphtheria- Tetanus Toxoid	27,570
Diphtheria- Tetanus- Pertussis	255,790
Immune Globulin	28,524
Pertussis	1,410
Rabies	4,834
Tetanus- Diphtheria Toxoids	343,220
Totals	661,348

In addition, at September 30, 1996 the Institute had the following vaccines and dosages on hand for future distribution:

Vaccine	*1996*
Diphtheria- Tetanus Toxoid	74,180
Diphtheria- Tetanus- Pertussis	338,550
Totals	412,730

(Continued)

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Notes to Pro Forma Financial Statements, Continued

(4) Contracts

In addition to several contracts with the Army (see note 5), the Institute has contracts with three Michigan Red Cross regions, North American Biologics, Inc. (NABI), SmithKline Beecham (SB) and Athena Neurosciences, Inc. (Athena).

The contracts with three Michigan Red Cross regions were renewed in 1995 and expire in June 1997. Under these contracts the Institute receives a fee to fractionate up to 50,000 liters of blood and deliver albumen to the Red Cross. Other fractions are distributed by the Institute and revenues are shared with the Red Cross (80% Institute and 20% Red Cross).

A five year contract with NABI was entered into on August 9, 1995 under which NABI accesses the remaining fractionation capacity (approximately 30,000 liters). The Institute is guaranteed payment for fractionating 20,000 liters of blood per year. Other fractions are distributed by NABI with 20% of the revenues being paid to the Institute.

A fifteen year supply and distribution contract was entered into on September 16, 1992 under which the Institute appointed SB as its exclusive distributor in the United States, outside of Michigan, for certain vaccines. SB reimburses the Institute for the cost of manufacture and pays 5% of net sales to the Institute (no less than $100,000 annually). The Institute also has a collaborative research and development agreement with SB.

The Institute has a collaboration with Athena aimed at developing uses for the botulinum toxin. Athena is conducting trials of using botulinum to treat cervical dystonia with product manufactured by the Institute. The Institute is reimbursed for the greater of its costs or $40,000 per quarter for this activity during the clinical trials period. If the trials are successful and the product is licensed, the Institute will produce botulinum toxin for the product. Athena will reimburse the cost of manufacture and pay an additional 5% of net sales to the Institute.

(5) Business Concentration - Major Customer

The Institute has several contracts with its primary customer, the United States Army (Army), and is continually negotiating additional agreements.

The Army has funded the acquisition of significant pieces of equipment and separate buildings and retains ownership of these properties (which are not included in the accompanying financial statements). These properties are necessary for the Institute to continue providing the products and services purchased by the Army.

(6) Licensing Status

The Institute has product licenses from the FDA as indicated below and establishment license number 99. These licenses are current and subject to ongoing FDA monitoring.

(a) FDA Product Licenses

Anthrax Vaccine
Rabies Vaccine
Diphtheria and Tetanus Toxoids and Pertussis Vaccine
Diphtheria and Tetanus Toxoids
Tetanus Toxoid
Pertussis Vaccine
Albumin (Human)
Antihemophilic Factor (Human) 500 IU/ vial
Immune Globulin (Human)- 16.5%

(Continued)

(b) FDA Investigational New Drug (IND) Application
Botulinum Toxin Type B
Pentavalent Botulinum Toxoids adsorbed for protection of laboratory personnel
Pentavalent Botulinum Toxoids adsorbed for protection of healthy volunteers
DTPw plus Hib
DTPw plus Hepatitis B plus Hib
DTPa plus Hepatitis B plus Hib
DTPa
DTPa plus Hepatitis B
Anthrax Vaccine Absorbed
DTPa plus Hepatitis B reduced antigen content
Virus Inactivated Hepatitis B Immune Globulin
Virus Inactivated Hepatitis B Globulin for intravenous administration

(c) USDA Animal Drug Licenses
Botulinum Toxoid Type B, for equine use

In addition, the Institute has a license from the United States Department of Agriculture (USDA) to produce and maintain animals for testing, including a certified virus free monkey colony.

(7) Contingencies
Liabilities are reported for loss contingencies, including environmental remediation costs, arising from claims, assessments, litigation, fines and penalties, and other sources when the amount of the assessment and/or remediation costs are probable and can be reasonably estimated. Management believes there are no significant loss contingencies to be reported.

No liabilities for employees post-retirement benefits are reported because such amounts are dependent on future events.

The Institute's ability to market its products is subject to ongoing FDA approval. FDA conducted a thorough review of the Institute in the Spring of 1995 which resulted in the issuance of a "warning" letter. Failure to promptly correct the deviations cited in the warning letter may result in regulatory action without further notice (license suspension and/ or revocation, seizure, and/ or injunction). Management has responded vigorously to the deficiencies cited in the letter, taken corrective actions, and communicated such to the FDA. Management believes the FDA will respond favorably to the Institute's actions.

KPMG Peat Marwick LLP

74 North Pearl Street
Albany, NY 12207

Telephone 518 462 9651

Telefax 518 455 3809

Independent Accountants' Compilation Report

Members of the
Michigan Biologic Products Commission:

We have compiled the accompanying pro forma balance sheet of the Michigan Biologic Products Institute as of September 30, 1995, and the pro forma statements of operations for the years ended September 30, 1995, 1994, and 1993, in accordance with Statements on Standards for Accounting and Review Services issued by the American Institute of Certified Public Accountants.

A compilation is limited to presenting in the form of financial statements information that is the representation of management. We have not audited or reviewed the accompanying pro forma financial statements and, accordingly, do not express an opinion or any other form of assurance on them.

KPMG Peat Marwick LLP

September 20, 1996

Member Firm of
KPMG Peat Marwick Cooperative

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Pro Forma

Balance Sheet

September 30, 1995

Assets	
Current assets:	
Cash	$ –
Receivables	7,942,976
Inventories	1,332,354
Total current assets	9,275,330
Property, plant and equipment:	
Land	23,963
Buildings and building improvements	9,196,730
Machinery and equipment	5,757,827
	14,978,520
Less accumulated depreciation	(9,575,800)
Net property, plant and equipment	5,402,720
Total assets	$ 14,678,050
Liabilities and Equity	
Current liabilities:	
Accounts payable	393,826
Accrued expenses	792,304
Total current liabilities	1,186,130
Other liabilities (see note 7)	–
Total liabilities	1,186,130
Contingencies (see note 7)	
Equity	13,491,920
Total liabilities and equity	$ 14,678,050

See accompanying Independent Accountants' Compilation Report and notes to proforma financial statements.

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Pro Forma

Statement of Operations

Years ended September 30, 1995, 1994 and 1993

	1995	1994	1993
Revenues:			
Army product sales	$ 4,276,037	3,642,490	4,573,295
Other product sales	3,489,810	3,491,915	4,742,482
Red Cross	720,257	725,364	674,480
Other	109,277	211,965	161,292
Total revenue	8,595,381	8,071,734	10,151,549
Expenses:			
Salaries and wages	5,018,584	4,528,154	3,990,291
Fringe benefits	2,139,070	1,890,356	1,632,264
Contractual services, supplies and materials	4,602,132	2,244,749	2,801,545
General services	1,141,839	1,238,801	1,100,461
Depreciation	921,880	751,222	624,784
State/Department overhead	622,999	646,915	731,906
Inventory adjustment	327,247	(909,379)	(108,441)
Other	296,084	287,629	301,225
Total expenses	15,069,835	10,678,447	11,074,134
Net (loss)	$ (6,474,453)	(2,606,713)	(922,585)

See accompanying Independent Accountants' Compilation Report and notes to proforma financial statements.

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Notes to Pro Forma Financial Statements

September 30, 1995, 1994 and 1993

(1) Description of Entity

The objective of the accompanying pro forma financial statements is to present the Michigan Biologic Products Institute (the "Institute") "as if" it was in operation as a separate business during each of the three years ended September 30, 1995. However, these pro forma financial statements are not necessarily indicative of the financial position or results of operations that would have been attained had the Institute actually existed during the three year period. Comparable historical financial statements of the Institute are not available.

The Institute was created on December 5, 1995, by Executive Order 1995-25 pursuant to Article V, Section 4, of the Constitution of the State of Michigan of 1963. The Institute is a temporary State agency with a life of no more than two years.

The Biologic Products Division (the "BPD") of the Michigan Department of Public Health (the "MDPH") and the Pharmaceutical Products Fund (the "PPF"), established under Sections 9111 and 9112 of Act No. 368 of the Public Acts of 1978, were transferred to the Institute by a Type III transfer, as defined by Section 3 of Public Act No. 380 of the Public Acts of 1965. The Institute assumed all functions, duties, contractual obligations, responsibilities, inventory, tangible and intangible property and employees of the BPD, including administration of the PPF.

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- Maintains the establishment license of the facilities for biologic product production and maintains existing product licenses, except for obsolete products, and obtains new licenses as appropriate.
- Maintains existing contractual relationships and expand the value of the work being undertaken while preparing to transfer responsibility for such work out of State government.
- Fulfills the duties of a Responsible Head as delineated in 21 CFR 600.10(a).
- Reports to the Commission on actions that affect the business of the Institute.

The Michigan Biologic Products Commission (the "Commission") was also established by Executive Order 1995-25, pursuant to Article V, Section 4, of the Constitution of the State of Michigan of 1963, and also has a life of no more than two years. The Commission provides supervision, policy control and direction to the Institute and the Director. In addition, the Commission must:

- Within eight (8) months of its initial organizational meeting, prepare a plan describing the means by which the Institute will be transferred out of State government and into the private sector within the two year term of its temporary agency status.

(Continued)

- As part of the plan, cause the fair market value of all state property, inventory, equipment and other assets associated with the manufacture of biologic products to be determined.
- Contract with the initial Director; designate and contract with any future Directors.
- Perform such other duties and responsibilities as may be assigned or transferred to the Commission by statute or by executive order.

(2) Summary of Significant Accounting Policies

(a) Description of Business

The Institute is engaged in the production and sale, and associated research and development of vaccines for the prevention of infectious diseases in children and adults. The Institute is also engaged in the production of blood derivatives.

The Institute is licensed by the United States Food and Drug Administration (FDA) to produce and market its products (see note 6). These products are subject to rigorous tests by the FDA of each lot produced. FDA approval must be obtained to release a lot for distribution (sale). There is no assurance that the Institute's products will continue to obtain the required regulatory approvals.

(b) Principles of Accounting

The accompanying pro forma financial statements of the Institute have been prepared in conformity with generally accepted accounting principles utilizing the accrual basis approach. Statements of cash flows and changes in equity are not presented.

(c) Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and disclosure of contingencies. Actual results could differ from those estimates.

(d) State Funding

As a division of the MDPH, the BPD had revenues to offset its appropriations with the difference being funded by the State's general fund. These general fund monies are not considered revenues of the Institute and therefore are not included in the accompanying financial statements. General fund appropriations were as follows:

1995- $3,347,900
1994- $3,260,700
1993- $3,360,700

The State has also funded the acquisition of capital assets, however, complete historical accounting records supporting the cumulative amount of such funding are not available. The assets that have been acquired are included in the accompanying financial statements as property, plant and equipment and the State funding is included in equity, net of cumulative results of operations since inception.

(Continued)

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Notes to Pro Forma Financial Statements, Continued

(e) Receivables

Receivables are recorded when they are measurable and earned as defined in the contract with each of MBPI's customers. A related allowance for uncollectible receivables is not considered necessary due to the Institute's past collection experience. At September 30, 1995, receivables were comprised of the following:

	1995
Army	$ 7,198,099
Red Cross	176,175
Other	568,702
Total	$ 7,942,976

(f) Inventories (Inventory adjustment)

Inventories are carried at the lower of estimated average cost or market and are comprised of raw materials, work in process and finished product (released for distribution by the FDA), as follows:

	1995
Raw materials	$ 191,677
Work in process	657,101
Finished product	483,557
Total	$1,332,354

The inventory adjustment is reported because the detailed accounting records necessary to accurately report cost of sales are not available. The adjustment represents the net change in the carrying value of inventories from the beginning to the end of the year.

(g) Property, Plant and Equipment

Property, plant and equipment are stated at original historical cost.

Depreciation on plant and equipment is calculated on the straight-line method over the estimated useful lives of the assets. Estimated useful lives are 40 years for buildings, 10 years for building improvements and 3-10 years for computers and equipment.

(h) Taxes

The Institute operates as a State agency, accordingly, there is no provision for income taxes, property taxes or the single business tax.

(i) Revenue Recognition

The Institute recognizes revenue when it is measurable and earned, encompassing the net change in accounts receivable for the period, and adjusted for reimbursement of items capitalized.

(j) Salaries and Wages

Salaries and wages represent the amounts reported in the Statewide accounting system for BPD, including the PPF, for the periods presented. These represent actual costs for the applicable periods, adjusted for changes in accrued vacation and sick leave (accrued expenses).

(Continued)

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Notes to Pro Forma Financial Statements, Continued

(k) Fringe Benefits
Fringe benefits represent the amounts reported in the Statewide accounting system for the BPD, including the PPF, for the periods presented. Fringe benefits include payroll taxes, retirement and health and other insurance. These represent actual costs for the applicable periods.

(l) Contractual Services, Supplies & Materials
Contractual services, supplies and materials represent the amounts reported in the Statewide accounting system for the BPD, including the PPF, for the periods presented. These represent actual costs for the applicable periods, adjusted for items capitalized.

(m) General Services
General services represent the cost of utilities, security and maintenance for the Institute's properties. The amounts reported are based on an estimate of the portion of the MDPH costs which are attributable to the Institute's properties.

(n) State and Department Overhead
State and department overhead represents the estimated share of Statewide and MDPH general and administrative costs that are attributable to the Institute, based on MDPH's annual indirect cost rate study.

(3) Product Distributed in Michigan
As provided in section 333.9112 of the Public Health Code of the State of Michigan, the Institute distributes vaccines, some of which are produced by the Institute and others are provided by the federal government, to local public health departments and certain private physician clinics throughout the State at no cost. The vaccines and number of doses produced by the Institute and distributed in each of the years ended September 30, 1995, 1994 and 1993 are provided below:

Vaccine	*1995*	*1994*	*1993*
Diphtheria- Tetanus Toxoid	25,578	38,523	23,070
Diphtheria- Tetanus- Pertussis	451,288	603,978	701,010
Immune Globulin	35,050	55,740	75,009
Pertussis	6,915	8,143	4,203
Rabies	1,742	1,636	2,826
Tetanus Toxoid	930	8,385	18,660
Tetanus- Diphtheria Toxoids	324,805	324,850	315,895
Totals	846,308	1,041,255	1,140,673

In addition, at September 30, 1995 the Institute had the following vaccines and dosages on hand for future distribution:

Vaccine	*1995*
Diphtheria- Tetanus Toxoid	108,310
Diphtheria- Tetanus- Pertussis	394,910
Tetanus- Diphtheria Toxoids	324,410
Totals	827,630

(Continued)

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Notes to Pro Forma Financial Statements, Continued

(4) Contracts

In addition to several contracts with the Army (see note 5), the Institute has contracts with three Michigan Red Cross regions, North American Biologics, Inc. (NABI), SmithKline Beecham (SB) and Athena Neurosciences, Inc. (Athena).

The contracts with three Michigan Red Cross regions were renewed in 1995 and expire in June 1997. Under these contracts the Institute receives a fee to fractionate up to 50,000 liters of blood and deliver albumen to the Red Cross. Other fractions are distributed by the Institute and revenues are shared with the Red Cross (80% Institute and 20% Red Cross).

A five year contract with NABI was entered into on August 9, 1995 under which NABI accesses the remaining fractionation capacity (approximately 30,000 liters). The Institute is guaranteed payment for fractionating 20,000 liters of blood per year. Other fractions are distributed by NABI with 20% of the revenues being paid to the Institute.

A fifteen year supply and distribution contract was entered into on September 16, 1992 under which the Institute appointed SB as its exclusive distributor in the United States, outside of Michigan, for certain vaccines. SB reimburses the Institute for the cost of manufacture and pays 5% of net sales to the Institute (no less than $100,000 annually). The Institute also has a collaborative research and development agreement with SB.

The Institute has a collaboration with Athena aimed at developing uses for the botulinum toxin. Athena is conducting trials of using botulinum to treat cervical dystonia with product manufactured by the Institute. The Institute is reimbursed for the greater of its costs or $40,000 per quarter for this activity during the clinical trials period. If the trials are successful and the product is licensed, the Institute will produce botulinum toxin for the product. Athena will reimburse the cost of manufacture and pay an additional 5% of net sales to the Institute.

(5) Business Concentration - Major Customer

The Institute has several contracts with its primary customer, the United States Army (Army), and is continually negotiating additional agreements.

The Army has funded the acquisition of significant pieces of equipment and separate buildings and retains ownership of these properties (which are not included in the accompanying financial statements). These properties are necessary for the Institute to continue providing the products and services purchased by the Army.

(6) Licensing Status

The Institute has product licenses from the FDA as indicated below and establishment license number 99. These licenses are current and subject to ongoing FDA monitoring.

(a) FDA Product Licenses

Anthrax Vaccine
Rabies Vaccine
Diphtheria and Tetanus Toxoids and Pertussis Vaccine
Diphtheria and Tetanus Toxoids
Tetanus Toxoid
Pertussis Vaccine
Albumin (Human)
Antihemophilic Factor (Human) 500 IU/ vial
Immune Globulin (Human)- 16.5%

(Continued)

(b) FDA Investigational New Drug (IND) Application
Botulinum Toxin Type B
Pentavalent Botulinum Toxoids adsorbed for protection of laboratory personnel
Pentavalent Botulinum Toxoids adsorbed for protection of healthy volunteers
DTPw plus Hib
DTPw plus Hepatitis B plus Hib
DTPa plus Hepatitis B plus Hib
DTPa
DTPa plus Hepatitis B

(c) USDA Animal Drug Licenses
Botulinum Toxoid Type B, for equine use

In addition, the Institute has a license from the United States Department of Agriculture (USDA) to produce and maintain animals for testing, including a certified virus free monkey colony.

(7) Contingencies

Liabilities are reported for loss contingencies, including environmental remediation costs, arising from claims, assessments, litigation, fines and penalties, and other sources when the amount of the assessment and/or remediation costs are probable and can be reasonably estimated. Management believes there are no significant loss contingencies to be reported.

No liabilities for employees post-retirement benefits are reported because such amounts are dependent on future events.

The Institute's ability to market its products is subject to ongoing FDA approval. FDA conducted a thorough review of the Institute in the Spring of 1995 which resulted in the issuance of a "warning" letter. Failure to promptly correct the deviations cited in the warning letter may result in regulatory action without further notice (license suspension and/ or revocation, seizure, and/ or injunction). Management has responded vigorously to the deficiencies cited in the letter, taken corrective actions, and communicated such to the FDA. Management believes the FDA will respond favorably to the Institute's actions.

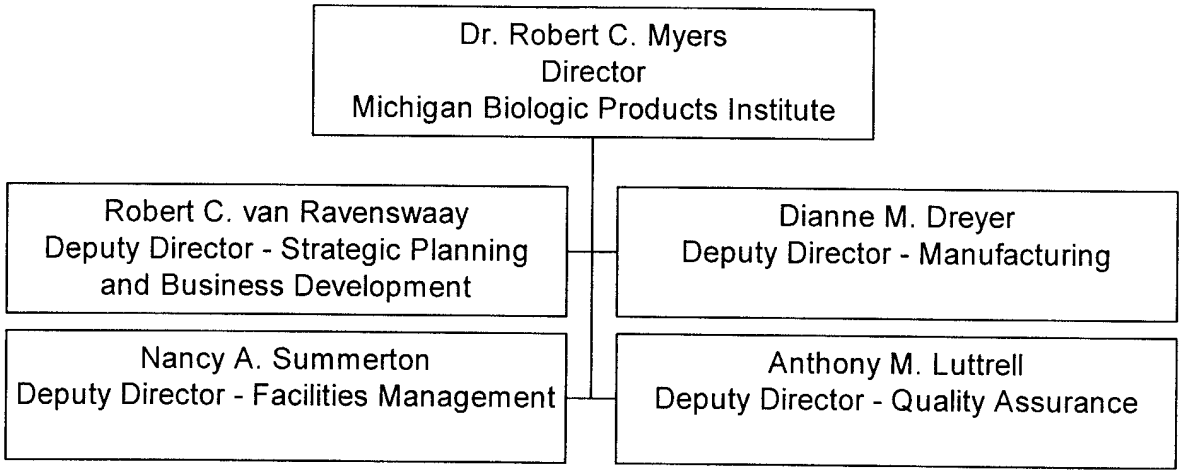
OFFERING PROCEDURES

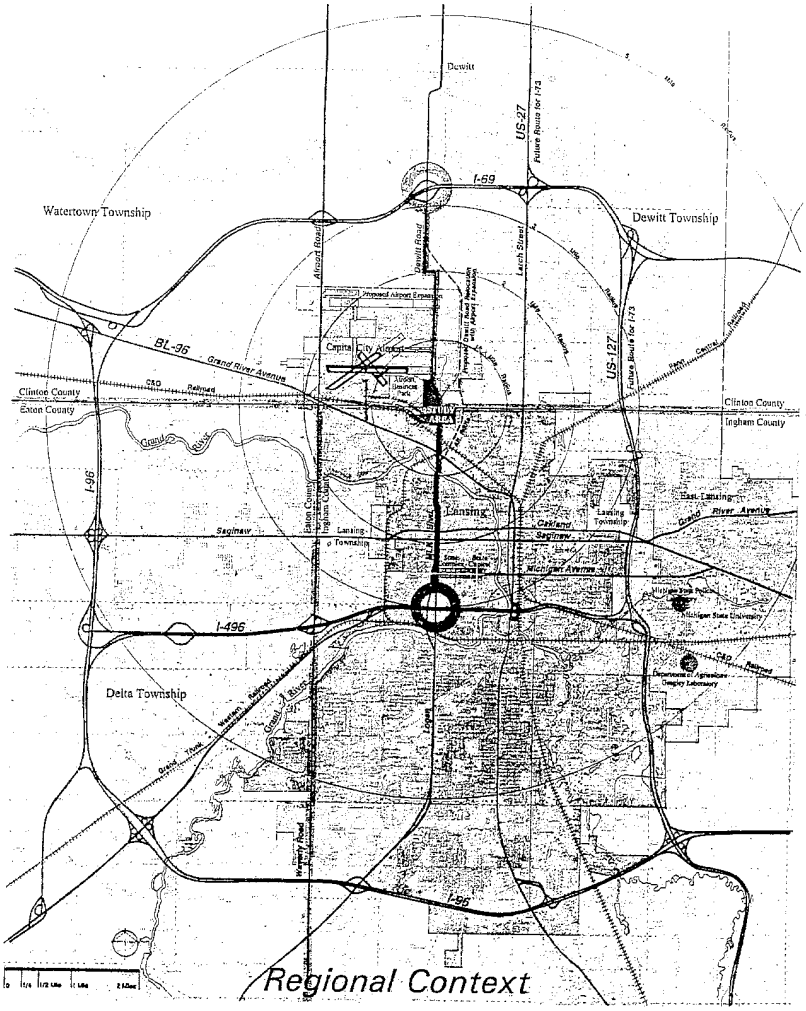
This Offering Memorandum is being furnished to financially qualified parties who are believed to have an interest in acquiring the Institute and who have agreed to abide by the Confidentiality Agreement. If, after review of the Offering Memorandum, a prospective purchaser wishes to proceed with an in-depth review of the Institute such prospective purchaser should contact the designated representatives at W. Y. Campbell & Company.

Once conversations between W. Y. Campbell & Company and a prospective purchaser lead to a mutual determination of a high level of interest at an appropriate range of value, such prospective purchaser may be given access to (i) additional confidential supporting information, as requested, (ii) senior management of the Institute and (iii) relevant facilities. However, the State undertakes no obligation to provide such access to this additional information. Upon request, the recipient of this Offering Memorandum will promptly return all material received from the State, the Institute or W. Y. Campbell & Company during the selling process. The State expressly reserves the right, without giving reasons therefore, at any time and in any respect, to amend or terminate these procedures, to terminate discussions with any or all prospective purchasers, to reject any or all proposals, or to negotiate with any party with respect to a transaction.

Organizational Chart

Michigan Biologic Products Institute

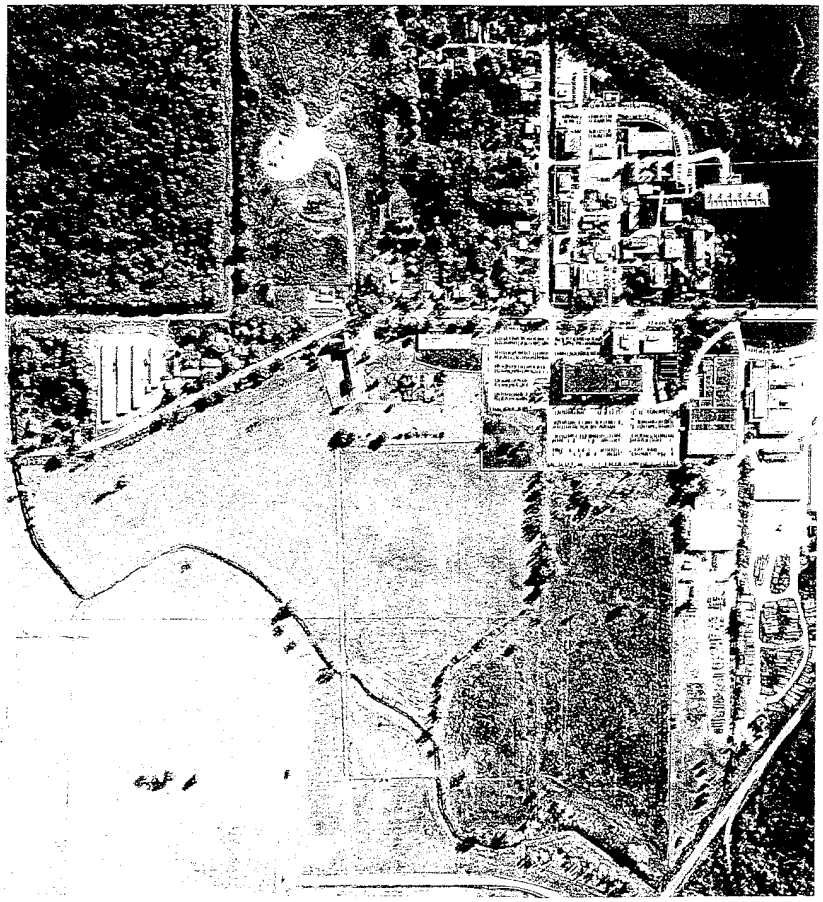




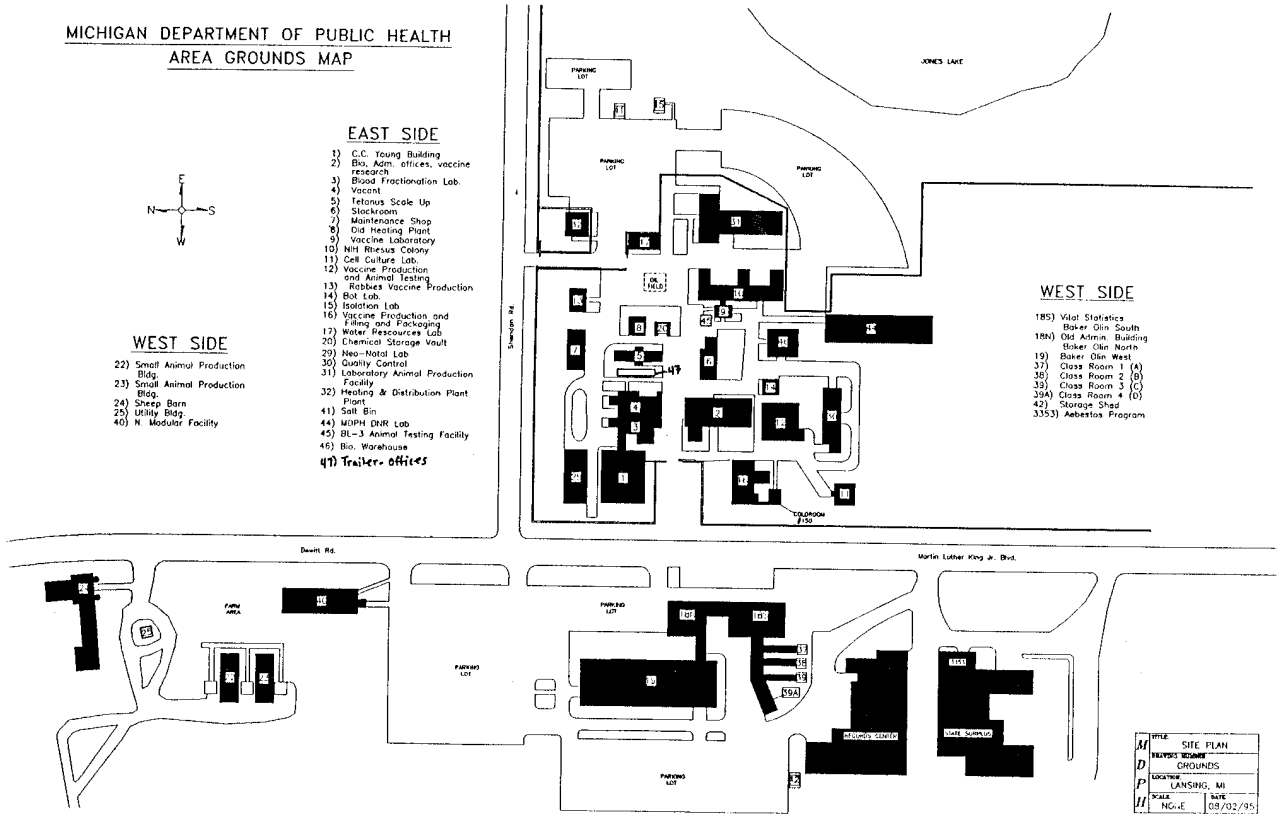
State of Michigan -
North Logan/ M. L. King Jr.
Government Complex
Lansing, Michigan

SH&G

JJR



MICHIGAN DEPARTMENT OF PUBLIC HEALTH
AREA GROUNDS MAP



EAST SIDE

1) C.C. Young Building
2) Bio. Adm. offices, vaccine research
3) Blood Fractionation Lab.
4) Vacant
5) Tetanus Scale Up
6) Stockroom
7) Maintenance Shop
8) Old Heating Plant
9) Vaccine Laboratory
10) NIH Rhesus Colony
11) Cell Culture Lab.
12) Vaccine Production and Animal Testing
13) Rabbies Vaccine Production
14) Bot Lab.
15) Isolation Lab
16) Vaccine Production and Filling and Packaging
17) Water Resources Lab
20) Chemical Storage Vault
29) Neo-Natal Lab
30) Quality Control
31) Laboratory Animal Production Facility
32) Heating & Distribution Plant Plant
41) Salt Bin
44) MDPH DNR Lab
45) BL-3 Animal Testing Facility
46) Bio. Warehouse
47) Trailer- offices

WEST SIDE

22) Small Animal Production Bldg.
23) Small Animal Production Bldg.
24) Sheep Barn
25) Utility Bldg.
40) N. Modular Facility

WEST SIDE

18S) Vital Statistics Baker Olin South
18N) Old Admin. Building Baker Olin North
19) Baker Olin West
37) Class Room 1 (A)
38) Class Room 2 (B)
39) Class Room 3 (C)
39A) Class Room 4 (D)
42) Storage Shed
3353) Asbestos Program

M	TITLE: SITE PLAN	
D	DRAWING NUMBER: GROUNDS	
P	LOCATION: LANSING, MI	
H	SCALE: NONE	DATE: 08/02/95

MAR 1 4 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

RECEIVED

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Food and Drug Administration
Center for Biologics Evaluation and Researc
1401 Rockville Pike
Rockville MD 20852-1448

CERTIFIED - RETURN RECEIPT REQUESTED MBPC

Robert Myers, D.V.M.
Responsible Head
Michigan Biologic Products Institute
3500 North Martin Luther King, Jr., Blvd.
P.O. Box 30035
Lansing, Michigan 48909

Dear Dr. Myers:

The Food and Drug Administration (hereinafter "FDA" or "the agency") conducted an inspection of Michigan Biologic Products Institute, Lansing, Michigan, between November 18 and 27, 1996. During the inspection, FDA investigators documented numerous significant deviations from the applicable standards and requirements of Subchapter C, Parts 210 and 211, and Subchapter F, Parts 600-680, Title 21, Code of Federal Regulations, and the applicable standards in your license. The deviations noted on the Form FDA 483, Inspectional Observations, issued at the conclusion of the inspection include, but are not limited to the following:

1. Failure of the quality control unit to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products [21 CFR 211.22(a)] in that the Zeta Plus (Cuno) filters and plastic bags used during production and storage of blood derivatives and the pre-sterilized foil/plastic bags used as buffer bags in production did not undergo release by the quality control unit.

2. Failure of the quality control unit to approve or reject all procedures or specifications impacting on the identity, strength, quality, and purity of drug products [21 CFR 211.22(c)]. For example:

   a. Validation of loading patterns for the AMSCO autoclave #13289 performed in June 1995, was not reviewed/approved by Quality Assurance ("QA").
   b. Temperature mapping of the Incubator Room #6 performed on April 19, 1996 was not reviewed by QA.
   c. Analytical method validation for Total Organic Carbon was not reviewed/approved by QA.
   d. Eight deviations of the air handling system in the aseptic fill area identified during the May 1, 1996, requalification of the building 16 were not reviewed/approved by QA.

3. Failure to establish and/or follow written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess and to assure that such procedures, including any changes, are drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by quality control [21 CFR 211.100]. For example:

   a. The standard operating procedure ("SOP") 5407 entitled "Operation of The Manifold Dryer for Drying Albumin and Fraction II Protein Solutions" was not followed in that there was no qualification for operation of the manifold dryer indicating it can operate as designed and intended.
   b. The SOP 6776 entitled "Division Wide Environmental Monitoring Program" was not followed in that investigations had not been initiated of continuously exceeded environmental action limits for nonviable particulates in the Class 1000 area filling suite.
   c. SOP 7866 entitled "Departure Identification, Investigation, Product Disposition, and Related Corrective and Preventive Measures" was not followed in that temperature deviations noted on temperature recording charts for walk-in cold rooms and freezers in building 3 had not been investigated and notification of departure was not issued. Additionally, there is no written procedure for the review of temperature recorder charts.
   d. SOP 5503 entitled "Critical Temperature Ranges of Refrigeration Equipment" does not specify the operating temperature ranges for each refrigerator and freezer in the Blood Derivatives section.
   e. SOP 5209 entitled "Preparation of 1.0M Sodium Caprylate Stock Solution" does not describe the preparation of the sterile 20 liter storage bottle.
   f. SOPs for operation of the AMSCO autoclave, used for sterilization of receiving tanks and sterile filter assemblies for Albumin (Human), Immune Globulin (Human), and other equipment, do not include load pattern diagrams or descriptions.
   g. SOP 1335 entitled "Washing 2ml Bottles" did not have the correct dry heat oven load patterns for trays filled with 2ml vials.

4. Failure to establish and follow appropriate written procedures designed to prevent microbiological contamination of drug products purporting to be sterile and to assure that such procedures include validation of any sterilization processes [21 CFR 211.113(b)] in that:

   a. Validation studies to demonstrate microbial retention and compatibility have not been conducted for sterilizing filters used for Albumin (Human) and Immune Globulin (Human).
   b. The Water For Injection ("WFI") tubing in building 3 used for final rinse of reaction tank valves, contained pooled water after use. The tubing was not stored so that the WFI would drain.

c. There is no written procedure to prevent the flow of personnel between room 107 (rabies viral lab) and the cell culture laboratory.

5. Failure to establish and follow control procedures to monitor the output and to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product [21 CFR 211.110(a)] in that:

a. There was no qualification for operation of the manifold dryer used to produce the Albumin and Immune Globulin powders as described in SOP 5407.
b. All load patterns have not been validated for the AMSCO autoclave in room 218 used for sterilization.

6. Failure to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity [21 CFR 211.160(b)] in that specifications have not been established for pressure differential readings taken from magnehelic gauges in the capper, filling, and gowning rooms.

7. Failure to establish and/or follow written testing programs designed to assess the stability characteristics of drug products [21 CFR 211.166(a)] in that there is no documentation available to support acceptable storage temperature excursion time frames for samples of Immune Globulin (Human) and Rabies Vaccine.

8. Failure to follow the stability program for the rabies vaccine [21 CFR 211.166(a)(2)] to assure valid estimate of stability in that there is limited control over storage conditions of samples prior to time zero which can be as long as three months.

9. Failure to establish separate or defined areas or other control systems for manufacturing and processing operations to prevent contamination or mixups [21 CFR 211.42(c) and 600.11(a)] in that:

a. The door to the powder harvest room 115, which is a controlled Class 100,000 area, was propped open to room 116, which is an uncontrolled area, during powder harvest.
b. There is no separate airlock for degowning after working with live rabies virus.
c. There is no segregation of quality control raw material testing for fetal bovine serum and research activities in room 201.
d. The gowning room was open to the general hallway and open to the core production area simultaneously.

10. Failure to clean, maintain, and sanitize equipment and utensils at appropriate intervals to prevent malfunction or contamination that would alter the safety, identity, strength, quality, or purity of the drug product [21 CFR 211.67(a)] in that:

    a. Cleaning validation studies have not been completed for routine cleaning procedures on multi-use equipment.
    b. Rust was observed on the Whirlpool freezer used to store intermediate products.

11. Failure to maintain or follow written procedures for cleaning and maintenance of equipment including utensils, used in the manufacture, processing , packing, or holding of a drug product [21 CFR 211.67(b)] in that the SOP 5102 entitled "Use of Centrifuge Parts and Stainless Steel Piping Between Albumin Production Steps" does not list the parts to be washed and does not describe the procedure used to clean the parts.

12. Failure to routinely calibrate, inspect, or check automatic, mechanical, or electronic equipment used in the manufacture, processing, packaging, and holding of a drug product according to a written program designed to assure performance [21 CFR 211.68(a)] in that the temperature control system of the manifold loading area of the manifold dryer has not been calibrated. The manifold dryer is used to produce the Albumin and Immune Globulin powders.

13. Failure to store and handle components and drug product containers and closures in a manner to prevent contamination [21 CFR 211.80(b)] in that chemicals tested and released as in compliance with good manufacturing practices were not segregated from chemicals not tested and released.

14. Failure to identify and control rejected components, drug product containers, and closures under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable [21 CFR 211.89] in that materials rejected by quality control are not clearly labeled "rejected."

15. Failure to calibrate instruments, apparatus, gauges, and recording devices at suitable intervals [21 CFR 211.160(b)(4)] in accordance with an established written program, in that:

    a. The conductivity meter for distillate in the WFI system in building 16 was past due for calibration and had not been calibrated.
    b. The chart recorder on the BioFreezer, used to store cryoprecipitate at -70°C or colder, was past due for calibration on November 14, 1996, and was reading -68°C. Review of the chart recorder records indicated that the temperature of the freezer was out of specification (-66°C to -68°C) since April 1996.
    c. All chart recorders and temperature probes which monitor the product temperature in the reaction tanks and the jacket temperatures were past due for calibration.

16. Failure to maintain buildings used in the manufacture, processing, packing, or holding of a drug product in a clean and sanitary condition [21 CFR 211.56(a) and 600.11(a)] in that:

    a. There is no spill clean-up or periodic floor cleaning when plasma spills onto the floor during the several hour plasma pool/thaw process.
    b. Dead insects were present in room 216.
    c. A live insect was observed in capping room 307.

17. Failure to establish written procedures describing the cleaning schedules, methods, equipment, and materials to be used in cleaning the buildings and facilities [21 CFR 211.56(b)] in that:

    a. There is no SOP for the clean-up of live rabies virus spills in room 101.
    b. The floors, walls, and ceilings of the production area were not cleaned at the prescribed frequency as required by SOP 1167.20 entitled "Cleaning Procedures for Blood Derivatives Section, Building 3."

18. Failure to maintain buildings used in the manufacture, processing, packing, or holding of a drug product in a good state of repair [21 CFR 211.58] in that:

    a. Condensate was observed dripping from tank piping onto open pfaudler tanks filled with Fraction IV-4F supernatant in room 106.
    b. Standing water was observed underneath the pasteurizer in room 121 and underneath the Prosperity Washer in room 310.
    c. Rust and chipped paint were observed on the banister and around the centrifuges in room 106, and on the transfer cage in the capping room.
    d. Chipped paint was observed on the walls of room 115.
    e. A leak was observed in the ceiling of room 212.
    f. In cold room 103, the lights were inoperable, stains and flaking paint were observed on the walls, and the thermostat was iced over.

19. Failure to provide adequate space for the orderly placement of equipment and materials to prevent mixups between different components, drug product containers, closures, labeling, in-process materials, or drug products, and to prevent contamination [21 CFR 211.42(b)] in that:

    a. Plastic bags, used to cover the filled drying manifold cylinders after product freezing, were stored without protection on top of the freezer in the wash room.
    b. Boxes of packaged gowning supplies were on the floor in the hallway outside of the second floor gowning room for the post virus inactivation area.
    c. A tipped box containing an opened plastic bag with pre-sterilized foil/plastic bags was on the floor in the hallway outside of Cold Room 211.
    d. In Rooms 101 and 103, there was no segregation and labeling of clean and dirty glassware.

20. Failure to assure that the equipment used in the manufacture, processing, packing, or holding of a drug product is of appropriate design and of adequate size for its intended use and for its cleaning and maintenance [21 CFR 211.63] in that an indoor/outdoor thermometer, which can not be calibrated, monitors the temperature in freezer #12764, used to store retention samples of pastes and powders.

21. Failure to concurrently record the performance of each step in the manufacture and distribution of products [21 CFR 600.12(a)] in that the temperature recorder chart times did not agree with manually recorded log book times for sterilization.

22. Failure to assure that equipment with surfaces that contact components, in-process materials, or drug products is not reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of a drug product [21 CFR 211.65 and 600.11(b)] in that a cutting board constructed of plywood, which is not a sanitary or easily cleaned surface, is used in room 216 for cutting teflon liners for centrifuge bowls.

23. Failure to properly identify storage containers and their contents as well as major equipment used during the production of a batch of a drug product [21 CFR 211.105(a)]. For example, the label on the cartridge filter housing stored inside cold room 211 indicating the status and contents was not readable.

While these deviations were documented in the most recent inspection, we note that significant deviations have been documented during previous FDA inspections of May 4 through May 7, 1993; May 31 through June 3, 1994; and April 24 through May 5, 1995. The seriousness of these deficiencies was emphasized to you in a letter dated December 22, 1993, and a Warning Letter dated August 31, 1995.

Based on the nature and number of the deficiencies identified during the recent inspection, it is the agency's judgment that management of the Michigan Biologic Products Institute has not fulfilled its responsibilities to exercise control in all matters relating to compliance with federal regulations and the applicable standards of your establishment and product licenses, or to assure that personnel are adequately trained and supervised and have a thorough understanding of the procedures that they perform, as required by 21 CFR 600.10(a) and (b), and 21 CFR 211.25(a) and (b).

The above identified deviations are not intended to be an all-inclusive list of deficiencies at your establishment. It is your responsibility as Responsible Head to assure compliance with all requirements of the federal regulations and the standards in your license.

We have reviewed your letter dated January 16, 1997, regarding the corrective actions which you proposed to the observations of the most recent inspection. We note that your firm has

repeatedly promised corrective actions in the past, but follow-up inspections continue to show that adequate, effective, and long term corrective action has not been taken. Accordingly, we have no assurance that the corrective actions will be properly implemented to correct the deficiencies noted during the most recent inspection.

Pursuant to 21 CFR 601.5(b), this letter is to provide you with notice that, unless you demonstrate or achieve compliance with the applicable standards and regulations, it is the intent of the FDA to institute proceedings to revoke U.S. license 0099-001, issued to Michigan Biologic Products Institute, 3500 North Martin Luther King, Jr., Blvd., Lansing, Michigan, for the manufacture of Diphtheria Toxoid Adsorbed, Tetanus Toxoid Adsorbed, Rabies Vaccine Adsorbed, Antihemophilic Factor (Human), Immune Globulin (Human), Albumin (Human), Anthrax Vaccine Adsorbed, Pertussis Vaccine Adsorbed, Diphtheria & Tetanus Toxoids Adsorbed, and Diphtheria & Tetanus Toxoids & Pertussis Vaccine Adsorbed, and to issue a notice of opportunity for hearing on the proposed revocation pursuant to 21 CFR 12.21(b). The agency will proceed with the revocation of U.S. license 0099-001 unless you do the following:

1. Within ten (10) days of receipt of this letter, advise FDA in writing of your commitment to correct the noted deficiencies, explaining the approach by which compliance will be achieved in an expeditious manner.

2. Within thirty (30) days of receipt of this letter, submit a comprehensive report and detailed approach supplementing your January 16, 1997, response addressing the methods which will be used to bring your facility into compliance, including a proposed completion date for correction of the noted deficiencies. Your plan should include corrective actions regarding all noted deficiencies, and should specifically emphasize your firm's plan for:

    a. ensuring that the QA Section functions in an adequate, effective, and timely manner, including addressing all QA oversight deficiencies;

    b. conducting a thorough review of all standard operating procedures to achieve compliance with good manufacturing practices as specified in 21 CFR 210 and 211;

    c. establishing a system of training and evaluation to ensure that personnel have capabilities commensurate with their assigned functions and a thorough understanding of the manufacturing operations which they perform;

    d. conducting a review of all observations listed on the Form FDA 483 issued November 27, 1996, to determine whether or not product quality has been affected, including addressing the need for possible recall of product if deemed necessary.

These submissions should be sent to Mr. James C. Simmons, Director, Office of Compliance, HFM-600, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Suite 200N, Rockville, Maryland, 20852-1448. Mr. Simmons may be reached at (301) 594-2066. Additionally, a copy of all submissions should be sent to the FDA's Detroit district office, 1560 E. Jefferson Avenue, Detroit, Michigan, 48207-3179, to the attention of Ms. Brenda Holman. In addition, we request a meeting with you at your earliest convenience to discuss the compliance status of your firm. We suggest that you also invite representatives from the State of Michigan and the Department of Defense to attend the meeting. Please telephone Mr. Simmons to discuss an appropriate date and time for the meeting.

If we do not receive an adequate response within the prescribed time, or if subsequent inspection of your firm finds your corrective actions to be inadequate, we shall proceed pursuant to the regulations governing formal evidentiary public hearings, as found in 21 CFR 12.21(b), and publish in the Federal Register a notice of opportunity for hearing on a proposal to revoke U.S. license 0099-001 and your product licenses for the manufacture and sale of Diphtheria Toxoid Adsorbed, Tetanus Toxoid Adsorbed, Rabies Vaccine Adsorbed, Antihemophilic Factor (Human), Immune Globulin (Human), Albumin (Human), Anthrax Vaccine Adsorbed, Pertussis Vaccine Adsorbed, Diphtheria & Tetanus Toxoids Adsorbed, and Diphtheria & Tetanus Toxoids & Pertussis Vaccine Adsorbed.

If you choose not to bring your establishment into compliance and wish to waive the opportunity for a hearing, you must contact Mr. Simmons within ten (10) days of receipt of this letter. The waiver must be confirmed in writing and may be accomplished by your voluntary request that U.S. license 0099-001 be revoked.

Copies of this letter have been sent to members of the Michigan Biologic Products Commission. In addition, the appropriate state officials will be notified of this administrative action.

Sincerely yours,

Mark A. Elgin

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

cc: The Honorable John R. Engler
Governor, State of Michigan
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Thirty-Day Response to FDA Letter of March 11, 1997

Submitted by
Michigan Biologic Products Institute

April 9, 1997

JOHN ENGLER, GOVERNOR

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MICHIGAN BIOLOGIC PRODUCTS COMMISSION
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April 9, 1997

Mr. James C. Simmons
Director
Office of Compliance
HFM-600
Center for Biologics Evaluation and Research
1401 Rockville Pike
Suite 200 N
Rockville, Maryland 20852-1448

Dear Mr. Simmons:

We acknowledge receipt of the Agency's March 11, 1997 letter, which stated the intent of FDA to institute proceedings pursuant to 21 CFR 601.5(b) to revoke U.S. license 0099-001, issued to Michigan Biologic Products Institute (MBPI), unless MBPI demonstrates or achieves compliance with applicable standards and regulations.

A previous letter, as requested in the Agency's letter of March 11, was forwarded on March 20, 1997, which notified FDA of our firm commitment to correct noted deficiencies and explained our intention to remain a viable supplier of licensed biological products. In this letter and the accompanying report, we are once again notifying you of our firm commitment in this regard. The enclosed report, hereto referred to as the Strategic Plan for Compliance, explains in detail the approach by which MBPI will achieve compliance with applicable standards and regulations. This plan is being submitted within the requested timeframe, 30 days from receipt, as specified in the Agency's letter of March 11, 1997.

MBPI has received guidance and support from the Michigan Biologic Products Commission in the development of this report. MBPI has held numerous meetings over the past few weeks with its key customers and several knowledgeable consultants. Our customers have continually expressed complete support and have offered significant expert assistance in order to accelerate our planned improvements for upgrading MBPI quality systems, facilities and personnel. We have and will continue to receive significant resources from the State of Michigan and from our key customers as we upgrade and modernize our facilities and operating systems. The recruitment of individuals with applicable industry experience for critical management and staff positions at MBPI is an ongoing effort as MBPI proceeds on the path to the private sector. It is important to emphasize that MBPI, as the U.S. license holder, takes full and ultimate responsibility for compliance with cGMPs and the terms of our licenses. We reiterate our firm commitment that MBPI will be a fully functional and cGMP compliant organization.

The enclosed Strategic Plan for Compliance addresses critical areas identified by both FDA and MBPI as essential for operating an organization in full compliance with standards, regulations and applicable licenses. The approach taken to the development and execution of this plan is outlined below. It is important to highlight that this plan not only provides for significant organizational changes and clear definition of roles within MBPI, but also includes specific details of how MBPI will improve the functionality, effectiveness and timeliness of Quality oversight by the Quality Assurance unit and the full implementation of modern Quality systems.

In concert with this broad-based approach to enhancing Quality systems, the plan calls for a concerted effort to evaluate and revise Standard Operating Procedures (SOPs) and the supporting

document control systems. The plan provides for implementation of enhancements to our training program to ensure comprehensive and technically sound administration and built in mechanisms for evaluation of training effectiveness. It requires the review of all observations noted on the Form FDA 483, issued November 27, 1996, in order to draw conclusions regarding the potential impact on product quality. Finally, the strategic plan includes a mechanism to provide the Agency with progress reports and supporting documentation. At present, we intend to report once per quarter unless directed otherwise.

The actions leading to development of the Strategic Plan for Compliance, the elements of the plan and the execution activities for the plan, both short and long term, are briefly outlined as follows.

PLAN DEVELOPMENT ACTIVITIES

MBPI and its key customers have and will continue to perform a comprehensive assessment of the existing organization, resources, policies, procedures and systems. Particular attention has been paid to Quality systems and organization; however, a comprehensive assessment of all MBPI operational elements was also undertaken to ensure a broad-based approach to correcting deficiencies and enhancing all operations at MBPI. For the purposes of assessment, individual work groups were formed and have produced work plans that include identification of areas in need of improvement or development. These work plans also include plans for corrective action, summaries of which form the basis of this strategic plan.

PLAN PURPOSE

The Strategic Plan for Compliance both informs FDA/CBER of the actions MBPI is taking to address the issues raised in the FDA letter of March 11, 1997 and serves as a template by which MBPI will manage the improvement and maintenance of its Quality and Operating systems in order to achieve and maintain compliance with cGMPs and applicable regulations and standards (21 CFR Part 211; 21 CFR Part 600, etc.). This plan and the subsequent quarterly progress reports will also allow both MBPI and FDA to evaluate and monitor the progress of execution of the plan.

PLAN ELEMENTS

While MBPI remains a public entity at this time, efforts continue to successfully transition the Institute to the private sector. The Strategic Plan for Compliance is designed to be executed, operational and effective, irrespective of MBPI's position as a public or private company. The plan also provides the necessary flexibility as the transition from State government to private sector progresses.

To this end, MBPI is taking immediate steps to change the existing culture, to continually stress the essential nature of cGMP compliance and to clearly define roles, responsibilities and authorities for each organizational unit, and for the company as a whole. This approach includes immediate actions, as well as long-term activities that will be evidenced over time as the transition occurs. A full discussion of the immediate, transitional and long term actions are presented in the accompanying plan. As the acquisition and leveraging of resources are essential to successful execution, the plan provides for a transitional period during which external resources will be secured to assist MBPI in the improvement and implementation of plan elements and to assist in the training of MBPI staff for the long-term maintenance of systems and programs.

The plan, formatted into distinct, yet related sections that present details of the approach to ensuring compliance, addresses the following areas:

- The formation and implementation of a Transition Team to transition MBPI to an independent, self-sufficient cGMP compliant manufacturing facility
- Organizational changes, and role and responsibility definitions
- Budget/Resources Status
- Facility upgrade projects - completed, ongoing and planned
- Status of transition to the private sector
- Specific responses to the items and issues outlined in the FDA letter of March 11, 1997 (paragraph 2, items 2a-d and the 23 deficiencies noted from the November 27, 1996 FDA Form 483)
- A systemic approach to the development, improvement and implementation of Quality systems and related operational systems - including work plan summaries and accompanying timelines for completion
- Summary of the status of all Form 483 inspectional observations included in the November 27, 1996 Form FDA 483 (details of the responses will continue to be addressed under separate cover)
- Summary of the plan, including reiteration of commitments and elements of the progress reports to be submitted to the FDA on a quarterly basis

MBPI clearly recognizes that this project is resource-intensive and requires the application of project management tools for its successful execution. The commitments and timeframes of the approach presented in the plan have been designed to be realistic, as well as timely. While some actions and activities will be completed promptly, others will necessitate longer completion times. In the development of the timelines and commitments, the activities were prioritized according to the criticality to cGMP compliance.

MBPI understands the serious nature of the challenges ahead and is fully committed to the successful implementation of the Quality and Operational systems outlined in the plan. Furthermore, MBPI recognizes that activities such as internal assessments/audits, technological improvements, and facility, equipment and system upgrades are essential for the continued maintenance of a cGMP compliant organization. The Strategic Plan for Compliance also calls for the continuation of these activities, as appropriate, for the long term to provide ongoing assurance that products made are of continued high quality and remain safe, pure and effective.

MBPI acknowledges confirmation of an April 22, 10 A.M. - 12 P.M. meeting in WOC Conference Room 1A to discuss the enclosed Strategic Plan for Compliance. Attendees will also include representatives from our key customers as participants at this meeting. Our goal is to have a productive discussion of the plan and the overall approach to execution and to receive the Agency's input and recommendations.

Sincerely,

Robert C. Myers, DVM

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I. STRATEGIC PLAN

Overview

MBPI is moving to become an independent entity that will have full control of its operations as a biologics manufacturing facility. A transition team will be used to effect this change from dependency on the State of Michigan as well as functioning under State administration rules. MBPI will be reorganized into a structure that more closely resembles a private sector company. Additional resources to assist in this change are being obtained from key customers to fund new positions, and to undertake facility upgrades in addition to those recently completed or in progress. Finally, the status of the transfer of MBPI to the private sector is presented in Section IE.

A. Transition Team

Currently, MBPI derives a number of infrastructure support services through an interagency agreement with other agencies of the State of Michigan. MBPI seeks separation from the State dependency and in effecting this change will employ the expertise of a team of consultants, referred to as a "transition team," to transition to an independent, self-sufficient cGMP compliant manufacturing facility. The scope of work for the transition team will be developed during the period 4/11/97 - 5/8/97, followed by a period of assessment by team leaders during the ensuing months. Implementation of the transition team recommendations and comprehensive plan will occur thereafter. It will be organized along the lines of functional activities within the Institute and will operate on-site for defined periods. While some components of the transition team will complete assigned responsibilities on an immediate (4/97-6/97) basis (e.g., assessment of security systems), other components will be required for most of the transition period (6/97-9/97) (e.g., human resources). It is likely that the transition team will include use of consultant expertise on both an immediate and long-term (9/97 or later) basis, the hiring of temporary employees with subsequent replacement by permanent staff, and in some cases the hiring of temporary employees who could subsequently be hired directly by MBPI. We intend to implement a section of the transition team immediately. Others will wait until completion of the initial assessment and we will additionally consider input from the Agency.

The requirements for transition team composition are defined in a table at Appendix A along with functional requirements and estimates of when the respective activities will occur. [For further detail regarding the implementation of the functional responsibilities, see the individual work plans (Section V)].

B. Projected Organizational Structure

Introduction

The organization and the function of the MBPI have changed rapidly in its first year of existence and will undergo further, dramatic change in the coming months as part of the Strategic Plan for Compliance. The changes to be made in the near term will create the structure and function necessary for MBPI to exercise control in all matters relating to compliance with federal regulations and applicable standards of our establishment and product licenses. The key elements include:

- The retirement of 24 of the most senior staff under a State-wide government employee retirement incentive program. These retirements will result in the departure of several dedicated and knowledgeable employees.
- The subsequent hiring of industry experienced individuals for key managerial and nonmanagerial positions, bringing the leadership, knowledge and attitude to foster positive, compliance-minded cultural change in the workforce.

- The transfer to MBPI, by executive action, of the units, funding and staff of the warehousing and security functions, bringing these functions under our full control.
- The direct MBPI contracting for janitorial, pest control, groundskeeping and other purchased services, enabling MBPI to hold the providers of these services directly accountable for satisfactory performance.
- The contracting of the transition team that will assess, transitionally staff and assist in the recruitment of personnel in areas such as human resources, finance, procurement, facilities management and all other functions needed to effect a complete termination of the reliance on other State agencies.
- The development, as part of the Transition Team's charge, of a complete system of job descriptions, training requirements, performance evaluations, compensation package recommendations and work rules. Once implemented, this system will provide all tools necessary to hire, train and retain a qualified workforce, directly accountable to the management of MBPI for satisfactory job performance with fair and appropriate incentives and disciplinary measures.

The Projected Overall Organizational Structure

The overall projected organizational structure is presented in Figure B-1 of Appendix B. Effective concurrently with the Agency's acceptance of the Strategic Plan for Compliance, the present overall organizational structure will be changed in several key ways:

- While Robert Myers will continue to serve as Director of the Institute, an industry experienced individual will be retained to more completely address Regulatory Affairs topics including the several ELA supplements for facilities upgrades now underway or soon to be initiated as described in Appendix C.
- Presently, Dr. Myers continues to serve as Responsible Head but will rely heavily on the new incumbents in both Quality Assurance and Regulatory Affairs to meet the attendant responsibilities of the Responsible Head as specified in 21 CFR 600.10. In 6 months, Dr. Myers and key managers will reassess his role as Responsible Head.
- A knowledgeable and experienced scientist will be appointed to the position of Senior Scientific Advisor to provide top level input to the Director, securing the necessary and unique knowledge to meet the challenge presented by the retirement of several key scientists and managers.
- MBPI will be organized into four operating divisions as follows:

  - Mr. Anthony Luttrell, newly appointed Director of the Quality Assurance/Quality Control Division will be responsible for all of the functions assigned to the quality control unit as defined by 21 CFR 210.3 (b) (15). Mr. Luttrell will also serve as alternate Responsible Head. Mr. Luttrell has also been given the lead responsibility for the development of and upgrade to the Quality Systems described in Section IVA.
  - All product manufacturing activities will be incorporated into the Manufacturing Division. Recruitment is in progress to fill the Manufacturing Division Director's position.
  - The Strategic Planning and Business Development Division will continue to be directed by Mr. Robert vanRavenswaay. He will oversee the growth of the business service activities, as determined in conjunction with the Transition Team's recommendations. He will also serve as the Director's overall deputy for administrative and business matters.
  - The Technical Operations/Facilities Maintenance Division will be directed by Ms. Nancy Summerton. The new units of Engineering/Construction Project Services and Facility Maintenance Services will be constituted based on the recommendations of the Transition Team and key Institute personnel.

The Michigan Biologic Products Commission, our key customers and our own managers are assessing the structure and function of MBPI and all changes will be finalized in 90 days. Recruitment to fill existing vacant positions is in progress. Contingent upon identification of required resources, recruitment for new positions will begin immediately. Descriptions of the operating divisions and, as appropriate, subunits of these divisions follow.

Projected Quality Assurance/Quality Control Division

The organizational structure of the Quality Assurance/Quality Control Division is provided in Figure B-2 of Appendix B. The immediate Quality Assurance goals are to put more QA presence in the day-to-day operations and to put into place effective, meaningful and modern quality systems at MBPI (see response to item 2a of the March 11, 1997 letter Section IIA). Several changes to the present QA organization are taking place.

- Mr. Anthony Luttrell was appointed to the position of Director of the QA/QC Division, effective February 17, 1997. Mr. Luttrell's knowledge and experience as well as his managerial skills and motivation are already demonstrating a QA function that is more effective and efficient in exercising its authority and responsibilities.
- Dr. Leigh Charamella retired effective April 1, 1997 as director of QA.
- To provide the staff to achieve the QA goals and objectives, a Quality Systems Manager will be hired. This individual will be recruited from industry and the successful candidate will possess the requisite knowledge and experience to function effectively as a key manager for Mr. Luttrell.
- A full-time staff of seven individuals will further develop and upgrade quality systems, and will perform the quality control unit functions as specified in 21 CFR 211.22. Three of these seven will be existing staff, transferred to the unit, while four additional staff positions will be recruited.
- Mr. James Wangelin, a recent addition to our staff will be transferred to QA as Validation Manager, to ensure that all validations receive adequate QA review on a timely basis, both during the planning stages and after execution.
- Because of their importance to full development of quality operations, the Stability Program Coordinator and the Document Control Coordinator will report directly to Mr. Luttrell. This reporting structure will be reevaluated in 6 months and changes made if appropriate.
- The analytical laboratory (see Figure B-3, Appendix B) will report to the Director of QA/QC and will serve to test and report test results to QA. The lead position of the Analytical Lab is now vacant. The position will be filled by the recruitment of an industry experienced individual. Additions to the analytical laboratory will consist of an environmental monitoring unit and the Anthrax Vaccine animal potency testing unit.
- Because the primary mission of the Animal Production and Care Section is to provide and care for animals used in product testing, it will be placed in the QA/QC Division. For animal welfare issues, the section head, Barbara Kintner, D.V.M. will participate in and provide knowledgeable leadership for the Institutional Animal Care and Use Committee and she will report directly to the MBPI Director on behalf of this committee.

Projected Manufacturing Division

The organizational structures for the Manufacturing Division are presented as Figures B-4 through B-6 of Appendix B. The Manufacturing Division has been reorganized to include all of the product manufacturing activities. This includes the functional consolidation of the manufacture of vaccines and plasma derivatives into a single division. This change provides top level direction to all manufacturing areas, assuring consistency and continuity in the development and application of the quality systems. It will also result in uniform application of site-wide administrative, managerial

and operational directives, actions and activities. The key elements of change to the Manufacturing Division include:

- The appointment of a new Division Director. The successful candidate for this position will possess at least 10 years of manufacturing experience in the manufacture of FDA-regulated drugs and/or biologics. Recruitment for this position is in progress and an offer has been made to the preferred candidate.
- The retirements of both the Section Head and the Production Manager of the Vaccine Production Section, Dr. George Burgoyne and Mr. Richard Hoort, respectively, effective April 18,1997.
- The appointment of Dr. William White as Acting Section Head of the Vaccine Production Section. Dr. White is providing overall direction and managerial leadership for the Vaccine Production Section and Dr. Burgoyne and Mr. Hoort have been placed on special assignment to complete tasks largely concerning the upgrades to the tetanus and diphtheria facilities.
- The placement, on an interim basis, of the Filling and Packaging Unit within the Vaccine Production Section to provide coordination and focus on compliance and manufacturing issues through the direction of Dr. White. This placement will be reevaluated within 6 months and appropriate changes made if indicated.
- The addition of several employees each to Vaccine Production and to Plasma Derivatives sections. The addition of these employees will provide the required staff needed for more timely response to the compliance upgrade initiatives being undertaken across MBPI and within each operating area.
- The retirement of the production manager and production supervisor in the Plasma Derivatives Section, effective this spring. Recruitment of replacements for these positions seeks to obtain individuals with appropriate experience in the large-scale manufacture of products from plasma by the cold ethanol fractionation method.

Projected Technical Operations/Facilities Maintenance Division

One of the most profound changes in the MBPI organization will occur in the Technical Operations/Facilities Maintenance Division. The organizational structure of this division is shown in Figure B-7 of Appendix B. While final decisions on the responsibilities and staffing levels of this division rest with the recommendations of the Transition Team, it is expected that up to 23 additional staff will be hired to meet the added responsibilities of the division. The decision to charge this division with the responsibility for facilities maintenance and the planning and oversigh of facilities upgrades is final and is consistent with the essential need to completely separate these activities from other agencies within State government, thereby acquiring the institutional control required by 21 CFR 600.10. Specific changes include:

- The expansion of the responsibilities of Ms. Nancy Summerton to include the overall direction for facilities maintenance. This change will bring these activities directly under MBPI control pursuant to 21 CFR 600.10.
- The creation of a Facilities Maintenance Section, with new staff of up to 16 employees to meet the specific needs of MBPI.
- The creation of a Engineering/Construction Project Services to oversee and manage the design and construction of facility upgrade projects now underway or to be initiated soon.
- The hiring of three additional employees to Qualification/Validation Services to better meet the need for maintaining the existing facilities and equipment in a state of adequate qualification ar to address qualification needs for the upgraded facilities, including the writing and execution c protocols in a more timely and cGMP compliant manner.

- The organizational separation of instrument calibration/metrological services from the Qualification/Validation Services group to provide specific focus and management of these two activities, while at the same time fostering integration of these services for facilities upgrade and validation projects.

Projected Strategic Planning/Business Development (SP/BD) Division

The staffing and responsibilities of the SP/BD Division have begun to expand and will continue to undergo expansion in the immediate future. Additions to the scope of authority and responsibility include human resources management, purchasing, contract administration, warehousing, health and safety and security. The addition of these responsibilities is important to the separation of MBPI from reliance on other State agencies and is crucial to the ability of the management of MBPI to exercise control in all matters impacting manufacturing at the establishment. As with the Technical Operations/Facilities Management Division, final decisions on staffing levels and skill sets of the SP/BD Division will be made after receipt of recommendations from the Transition Team. While there are 11 employees now, additions, largely to the administrative services, will increase the staffing of this area to a total of 30 or more employees. The organizational structure of the section to be most greatly changed, the Administrative Services Section, is provided as Figure B-8 of Appendix B. Key changes in this area include:

- The transfer, by executive action, of both the Security Services function and staff and the warehousing function and staff to serve the specific needs of MBPI. This transfer will provide for direct oversight, with a focus on compliance, of these two activities.
- The development, within MBPI, of staffed units for human resource management, purchasing, and contract administration .
- The hiring of a health and safety officer to develop and administer a program of health and safety tailored specifically for MBPI. While housed within the Administrative Services Section, the health and safety officer will directly report all health and safety issues to the Director of MBPI.

In addition, the Information Resource Center is now developing a forward-looking set of systems to ultimately achieve a PC-based, paperless operation of MBPI. Leadership is proceeding cautiously and is focusing on commercial, off-the-shelf, software with proven successful application in the pharmaceutical sector. First to be incorporated will be electronic document management, computerized facilities maintenance management and laboratory information management systems. Later activities include integrated approaches to paperless manufacturing and materials resource planning.

Organization Structure and Function Conclusion

MBPI is reorganizing its structure to address its current compliance status, to secure control in all matters relating to compliance with federal regulations and applicable standards of our establishment and product licenses, and to generally improve its overall operation. The developed organizational structure emphasizes changes that ensure the adequate, effective and timely function of the quality control unit and the efficient development of systemic approaches to enhancement of quality.

The methods used to determine this organizational structure included the judgment of managerial staff of MBPI and the key customers of MBPI and their contractors. In total, MBPI staff will need to increase by 40-60 employees. Required will be several key individuals with industry experience in the FDA-regulated environment and in critical organizational support areas. Central to the final determination of the required skill sets and staffing levels will be the recommendations of the Transition Team.

Contingencies

The organizational changes described above are contingent upon:

- The changes being consistent with the applicable laws and regulations of the State of Michigan.
- The expenditures of MBPI associated with the development and staffing of this organizational structure being within the amounts appropriated in the FY97 budget and/or to be additionally appropriated in FY98 budget.
- The financial contributions of MBPI's customers being at a level needed to offset expenditures not in the currently appropriated budget.
- The ability of the State to efficiently effect the transfers of staff and function, and the authorities and responsibilities described in the discussion of the proposed organizational structure.
- The acceptance of this plan by FDA.

MBPI will update the Agency on the status of the resolution of these contingencies as details become available.

C. Budget/Resources

The commitments made in the Strategic Plan for Compliance will be met by combining existing resources and the resources of key customers of MBPI.

As long as the Institute remains part of the State government, its spending is controlled by State budget practices. Presently, the Institute must have spending authorization approved by the legislature each year. Certain expenditures made on behalf of the Institute by customers do not need to be appropriated.

The Institute has spending authority for Fiscal Year 1997 (ends Sept. 30, 1997) of $18,258,700, which includes $2,000,000 for capital outlay projects.

Specific additional resources needed to completely execute the Strategic Plan for Compliance are now being determined. The resources needed and the source of these resources will be determined during the second, third and fourth quarters of this year as assessments and plans of action are determined by the transition team.

D. Facilities Upgrades

MBPI recognizes that facility infrastructure is commensurate with the improvement and operation of quality systems. In recent years MBPI has upgraded and added to existing facilities in a staged fashion to develop facilities that comply with cGMPs and industry standards.

Examples of projects already completed by the Institute and approved by the Agency include:

- Reference No. 84-0198 - A new WFI system for plasma derivatives building, approved 12-21-94;
- Reference No. 89-0369 - New WFI and clean steam systems for building 16, servicing bacterial vaccine bulk and final formulation areas and the third floor filling and packaging area, approved 4-13-92;
- Reference No. 90-1694 - Upgrades to building 12 Anthrax Vaccine, Adsorbed manufacturing area, approved 7-27-93; and
- Reference No. 94-0808 - A new warehouse for quarantined and released storage of incoming materials and supplies, approved 8-17-94.

Other finished projects incorporated in larger ELA supplements now being completed include:

- Upgrades to floors, walls and other improvements to the plasma derivatives facilities in building 3, and
- A new facility for the animal potency testing of Anthrax Vaccine, Adsorbed.

Additional facility upgrades are currently ongoing to further ensure the manufacture of quality products for our customers. These projects include new construction as well as renovation of existing facilities that provide significant enhancements and additions that bring the facilities into full compliance for the manufacture of biological products.

Examples include:

- Upgrade and expansion of the bulk tetanus toxoid component manufacturing facility in building 12 currently under construction.
- Improvements to the aseptic processing area of the first floor of building 16, where bacterial vaccine components are adsorbed and where final bulk lots of bacterial vaccines are prepared, are under construction.
- Ancillary areas supporting the operations on the first floor of building 16 are under construction.

The specific projects in building 12 and building 16 were presented to the Agency during pre-ELA meetings held in June 1995 and August 1996. The quality systems supporting these operations were also discussed with the Agency at those meetings. ELA supplements for these projects are intended for submission in the third and fourth quarter of 1997. MBPI intends to have quality systems in place for compliance at the time of submission. These supplements will demonstrate validation and operation of these facilities in compliance with cGMP.

To support MBPI's strategic vision, MBPI will promptly hire a consulting firm to work with MBPI management to develop a facility Master Plan that will outline requirements for continued compliance in concert with user requirements. The Master Plan will be flexible and at the same time establish priorities for the facilities management workload and potential impacts on manufacturing.

Several examples of future facility renovations to be identified in the Master Plan include:

- Filling and packaging area upgrades in building 16 to improve flow of materials and personnel and architectural upgrades to provide smooth and easily cleaned surfaces;
- Upgrades to the building 13 Rabies Vaccine Adsorbed manufacturing facility; and
- Additional upgrades to the building 3 plasma derivatives manufacturing facility.

Global considerations for facilities, now and in the future, are provided at Appendix C. Also provided is a comprehensive list of facility upgrade projects and an ELA supplement submission timeline.

Timelines for all projects currently underway and new projects scheduled and funded are included in Appendix D.

E. Status of Transition to the Private Sector

As the Agency is aware, Michigan's Biologics program is being transitioned to the private sector. The first step was the creation of the Michigan Biologic Products Institute (MBPI) in early 1996 by Executive Order 1995-25. The creation of MBPI and its subsequent sale are essential to securing the authority, responsiveness and independence necessary to exercise full control over the establishment as required by 21 CFR 600.10. Taking steps toward the private sector is resulting in significant change in the way the organization operates. Moving along this course is facilitating both a needed cultural change in MBPI's work force and the rapid and complete maturation and enhancement of quality systems to demonstrate, achieve and maintain compliance with the cGMPs and applicable regulations and standards. Separation of the program from the Michigan Department of Public Health gave MBPI some changes that were needed, including increased flexibility in hiring, and management of budget and daily operations. It also allowed better identification of the assets that relate to MBPI and its licenses.

The December 1996 passage of Public Act 522 of 1996 established the procedure for the State of Michigan to sell the assets of MBPI. The Michigan Biologic Products Commission will arrange the sale, subject to the approval of the State Administrative Board (which will obtain an independent fairness opinion). Presently, a selling agent has been selected by the Commission and a fairness opinion provider has been selected by the State Administration Board. Contracts will be finalized on April 14, and work will commence immediately.

At the time the selling agents were solicited, the Commission tentatively targeted July 31, 1997 to complete MBPI's transfer out of government; however, it appears late August to late September 1997 is a more realistic completion date. MBPI is funded through the end of September 1997. The pending FY98 budget will provide a continuation of spending authority until February 1998. The transfer of MBPI into the private sector will facilitate the timely execution of this plan and achievement of full regulatory compliance because it will no longer be subject to the procedural delays, policy uncertainty, and operating constraints inherent in being a public agency. As a private corporation, MBPI will be more flexible and responsive to changes in its operating environment. Finally, "privatization" will facilitate the adoption of a much needed cultural change whereby workers will directly connect their income to their performance of work activities consistent with cGMP standards and the manufacture of safe and efficacious products of the highest quality.

The inspection observations of November 27, 1996 and the subsequent letter of March 11, 1997 make clear that the pace of the growth of quality systems, operational practices and cultural attitudes should be hastened and take precedence over the transition to the private sector. The Strategic Plan for Compliance presented here describes several immediate actions being taken. In addition, mid-term and long-term actions are addressed that allow MBPI to assume control of all matters relating to compliance with federal regulations and applicable standards now and in the very near future. Taking these immediate actions is consistent with and well ahead of the original plan to transition the biologics manufacturing program to the private sector.

II. Responses to Items 2a through 2d of the FDA March 11, 1997 Letter

A. Adequacy, Effectiveness and Timeliness of Quality Systems

This section addresses the Agency's request expressed in paragraph 2a of the letter of March 11, 1997 to: *[ensure] that the QA Section functions in an adequate, effective and timely manner, including addressing all QA oversight deficiencies.*

Several major initiatives are planned at MBPI to address the noted deficiencies in the Quality Assurance functions.

1. As stated earlier, we have recruited and hired a Quality Assurance Director, Mr. Anthony Mark Luttrell. His appointment was effective February 17, 1997. Mr. Luttrell is leading the effort to modernize quality systems.

2. A full assessment of the organization and staffing of the Quality Assurance function at MBPI is currently being conducted by our key customers as well as outside consultants and will be finalized within 30 days. The goal is to provide more Quality Assurance presence in the day-to-day operations and to put in place effective, meaningful and modern quality assurance systems at MBPI. Our initial assessment indicates the need for expanded Quality Assurance auditor positions, improved service in our document control function, and the positioning of Validation management in the Quality Assurance organization. These actions will provide for more timely review of documents and greater control of key quality systems such as investigation, documentation and correction of deviations and change control. An organization chart showing key positions is provided in Appendix B, Figure B-2.

3. Key quality policies for MBPI, in which all employees will be trained and held accountable are being funded, developed and codified. Quality policies will be developed and approved by senior MBPI management. Policies will cover relevant topics such as the role and authority of Quality Assurance, validation, document control, etc. Policies to be further developed and codified are:

   - Inspection Policy (Regulatory Agencies)
   - Validation Policy
   - Technology Transfer and Process Scale-up
   - Training Policy
   - Quality Systems Policy (Quality Management)
   - Quality Assurance Audit Policy
   - Document Control Policy
   - Calibration/Metrology Policy
   - Housekeeping/Facility Maintenance
   - Environmental Monitoring Policy
   - Quality Control Test Policy
   - Process Control/Statistical Methods Policy
   - Handling of Animals Policy
   - Stability Testing Policy
   - Materials Control Policy
   - Computer Controls Policy
   - Release/Reject Policy (Non-Conformance Lots)
   - Batch and Master Record Policy
   - Supplier/Vendor Audit Policy

4. As part of the quality system, and other operating system improvements, we plan the upgrading of key plant-wide standard operating procedures (SOPs) such as those for change control, deviations/departures, validation, out of specification results, procedures, etc. New SOPs will be developed for the areas where there are none currently. Key quality system procedures will be reviewed and upgraded/rewritten according to a timeline.

The upgrade and assessment of essential quality systems will result in more efficient and timely review of key documents and will ensure a consistent quality assurance presence. Quality assurance personnel will be responsible for the following areas (refer to the attached organization chart with function overlay, Appendix B).

QA responsibilities (cGMP defined Quality Control Unit)

- Audits: internal and external (vendors)
- Training
- Document Control/Batch Record Review
- Raw Materials/Components/Product Release
- SOP Review/Approval
- Validation Review/Approval
- Change Control Systems
- Investigation of Deviations & Failures
- Environmental Control, Water Controls, QC Oversight
- Trend Analysis (with QC)
- Stability Program Oversight
- Labeling and Packaging Control
- Warehouse Oversight
- Customer Complaints (CMC)
- Collaboration with Regulatory Affairs

B. Review of All Standard Operating Procedures to Achieve Compliance with Good Manufacturing Practices as Specified in 21 CFR 210 and 211

This section addresses the Agency's request expressed in paragraph 2b of the letter of March 11, 1997 to: *[conduct] a thorough review of all standard operating procedures to achieve compliance with good manufacturing practices as specified in 21 CFR 210 and 211.*

Authorization, release and control of documents are Quality Assurance functions under the direct control of the Document Control Coordinator who reports to the Director of QA/QC. There has been a comprehensive assessment of the existing document control system that currently includes approximately 1,200 SOPs, protocols, policies and batch production records. It has been concluded that policies and SOPs will be controlled under a separate system from production records. Additionally, validation protocols and final reports will be separated from the SOP system. Administration of all systems will fall under the ultimate responsibility of the Document Control Coordinator.

Policies

- Policies are being written by the Responsible Head and will serve as guidance for operations to be carried out by each department at MBPI.
- Adherence to policies is mandatory for all MBPI staff.
- Policies will be numbered and tracked independently from other document systems and will be maintained by the Document Control Coordinator.

SOPs

It has been concluded that a number of enhancements are necessary to ensure that the SOP system operates in an efficient manner so that documents are readily available and revisions are properly controlled and tracked, implemented and provided to those affected. The planned enhancements will ensure that the following elements are properly addressed:

- The SOP system will be reconfigured into three levels that relate to each other:

  Policies - Top level Institute-wide guidance documents
  Master Procedures - Institute-wide program level documents (i.e., validation program; environmental monitoring)
  Specific Operating Procedures - To support master procedures/programs

- All documents will be stored in a centralized area.
- QA management in conjunction with manufacturing support units will evaluate relevant SOPs to ensure comprehensive coverage of all manufacturing and quality operations. Areas where additional SOPs are needed will be identified and relevant SOPs will be written.
- Existing SOPs will be evaluated to identify areas of redundancy and overlap in an effort to reduce the number of unnecessary documents and to consolidate efforts to ensure consistency and accuracy.
- The approval and signature requirements for SOPs will be evaluated and will be streamlined in an effort to reduce cycle time to implementation. This process will include the author (written by:); author's supervisor or area manager (reviewed by:); and quality assurance (approved by:). For SOPs that serve multiple interests, other functional units will be involved in the writing, as necessary, or will be fully informed and receive copies of all relevant documentation.
- Personnel affected by new or revised SOPs will be alerted and trained prior to assignment of the SOPs effective date.
- The numbering system for SOPs and protocols will be revised to assign a unique numbering series to groups of SOPs that is related to their application in functional areas, e.g., QA prefix for Quality, M prefix for Manufacturing. Manufacturing SOPs will be further identified as appropriate by numbering to assign them to product-specific manufacturing lines, i.e., MB (blood products), MD (diphtheria).
- A change control system will ensure changes to SOPs are properly documented and approved by appropriate individuals and/or departments. A chronological history of the changes to each SOP will be maintained and available for assessment. Such tracking and documentation will ensure that the correct version of every SOP is in use by all functional units at the site. The historical database resulting from this type of documentation will also allow a quality assessment of SOP review documents to determine the nature and appropriateness of changes over time.
- A system will be established to ensure the proper issuance and tracking of all forms that are related to the use of an SOP. Forms may not be included in the SOP, but will be appended to the master copy. A bi-directional link to an SOP will be established to ensure that revisions to either or both, are made as necessary and appropriate. This will allow flexibility in the use of similar forms for multiple SOPs. Issuance of forms will be controlled by the assignment of unique, sequential tracking numbers.
- The master SOP on generation of SOPs will be assessed and revised to reflect all areas described. The master SOP will also provide for regular review of SOPs, e.g. annually or biennially by the quality unit.

Batch Production Record Control

- Approved master production records will be centrally maintained by the Document Control Coordinator in QA.
- Issuance and control of individual batch records will be the responsibility of the QA supervisors assigned to the specific production facilities.
- Review and approval of batch records will also be the responsibility of each individual QA supervisor with final batch release under the authority of the Director, QA/QC.

Validation Protocols and Reports

- Validation protocols will be separated from the SOP system and assigned unique numbers.
- Protocols and final reports will be filed centrally in the document control system.
- Review and approval of validation protocols and reports will remain as a Quality Assurance responsibility.

C. Establishment of a System of Training and Evaluation

This section addresses the Agency's request expressed in 2c on page 7 of the letter of March 11, 1997 to: *[establish] a system of training and evaluation to ensure that personnel have capabilities commensurate with their assigned functions and a thorough understanding of the manufacturing operations which they perform.*

Assessment of the Existing Training and Training Evaluation Program

MBPI's existing training program has been assessed by MBPI's first line and senior management along with key customers and consultants. This evaluation identified areas in need of improvement including the development of a human resources mechanism that provides a system of rewards and disciplinary actions based on performance and correlated to job-oriented tasks. The assessment also identified a need for an enhanced documentation and tracking system to allow for efficient scheduling and administration of appropriate training/re-training and the regular evaluation of training efforts by the training coordinator and senior management. Finally, the assessment also highlighted the need to elevate training activities to a higher priority in the MBPI organization. Other areas to be targeted by the enhanced training program are addressed in detail below.

Elements of Enhanced Training Program

The training program will be enhanced to ensure compliance with 21 CFR 211.25 and will provide for the following elements:

- A revised Training Program SOP will be developed by Quality Assurance and implemented with support from management.
- Training Program Coordinator. A position description will be developed and a qualified individual will be hired as an MBPI employee (see Program Development and Implementation Activities-Short and Long-Term later in this section).
- Defined position descriptions for all MBPI employees. Existing position descriptions will be evaluated and revised. New position descriptions will be created. All descriptions will establish a set of skills and knowledge required to perform the intended function. Skills and knowledge requirements will be used to develop training curricula and syllabi (see Training Program Curricula below).

- A centralized employee performance management system. A system will be developed that utilizes the defined position descriptions (and other skills information) to set performance criteria by which effectiveness of training can be measured.

Training Program Curricula

- Curricula for general site-wide cGMP training to cover the general concepts presented in 21 CFR Section 211 and other pertinent regulations, guidelines and regulatory policies. All MBPI employees and contractors (as appropriate) will attend mandatory refresher training annually.
- Curricula for job-specific training for all MBPI functional areas. Individual area syllabi will be compiled based on a needs assessment that correlates the defined job functions in the area and the skills requirements of the employees in the area. Training and refresher training will occur at regular intervals, schedules to be determined by the area supervisors, based on resource needs.
- Job-specific training will augment regular SOP training and refresher training that is described in Section IIB.
- Refresher cGMP training. All current MBPI employees will attend refresher training within 90 working days of submission of this Strategic Plan for Compliance.
- A centralized documentation system. This system will be developed and employed to track all training completed by employees. The Training Program SOP will be revised to reflect this and appropriate forms will be created to record details of training and evaluation of training effectiveness. It will be the responsibility of the functional unit supervisors to ensure that their employees receive necessary training and refresher training at all levels (job-specific and cGMP) and that this training is properly documented. Training to be documented includes the following:

  - Mandatory cGMP training
  - SOP training
  - Job-specific and skills training (format to be developed by area supervisor)
  - Ancillary support training (university courses, professional organization conferences, workshops and seminars, etc.)

Each employee will have a comprehensive training file that incorporates documentation and, as appropriate, evaluation of training effectiveness for all programs completed. Computerization of the documentation system is being explored at this time.

- Quality assurance oversight - proper documentation of training, as per the Training Program SOP, will be an oversight function of the Quality Assurance unit and regular (annual) audits of the training files (maintained in central repository and/or unit supervisor files) will be conducted.
- A system for "training the trainers." This will include mandatory training of supervisors and managers in the principles of management and leadership, as well as the basic tools for effective training. Individuals within the MBPI organization will be identified, based on skills and competencies, as potential trainers. These individuals will be afforded the opportunity to enhance their proficiencies in teaching and training through a variety of educational channels (see Program Development and Implementation Activities-Short and Long-Term below).
- A system for safety training. The requirements set forth by the Occupational Safety and Health Administration (OSHA) and the corollary agencies in the State of Michigan will be considered in the re-engineering of the overall training program. Necessary elements to fulfill these requirements will be incorporated into the overall Institute training program as appropriate. A safety officer will be hired to track pertinent issues and requirements and will coordinate with the Training Program Coordinator for SOP review and revision, and administration of training.

- A system to ensure appropriate training and refresher training (including cGMP training) for all employees involved in any functions related (directly or indirectly) to the manufacture of biological products and the maintenance of systems, equipment and facilities. This training applies to all MBPI employees, contractors, consultants, vendors, etc.
- Appropriate intervals for refresher training of individuals in job-specific areas (determined by supervisor) and cGMPs (annually). This will be fully integrated with the plan for SOP development, revision and execution as described in the response to 2d on page 7 of the March 11, 1997 FDA letter.

Program Development & Implementation Activities - Short and Long Term

MBPI recognizes the importance of training as a critical tool in the operation of a fully compliant organization. Therefore, the development of an enhanced training program has been elevated to a higher priority and is an essential element of this overall Strategic Plan for Compliance. To develop and implement the elements of the enhanced training program promptly, MBPI feels that it is necessary to solicit the short-term assistance of external resources.

This approach for program development and implementation is three-fold. First, to ensure support for necessary activities and resources, the effective and comprehensive training of individual employees will be a performance goal for all supervisors and managers.

Second, MBPI intends to secure the services of a consultant or firm with expertise in training program development. Representatives of this firm will be retained and charged with the development of the comprehensive training program, based on the assessments performed and resources available. The consultants will also assist MBPI in administering "hands-on" training, training the trainers and facilitating the transition to an internal program that is administered and maintained by MBPI employees.

Third, MBPI is researching the availability of commercial resources in the form of audio and video tapes and interactive computer software to allow for "self-training" that will augment the mandatory training. Review of these relevant materials, per specified schedules, will also become mandatory for MBPI employees.

Integration with Other Quality Systems

Because training is integral to the development and implementation of all quality systems at MBPI, much consideration will be given to the integration of the Training Program with other systems. Specifically, the SOP and document control systems will be developed in concert with the elements of the training program; the Human Resources system will be developed to ensure that training is provided and adequately measured for effectiveness; and the scheduling of production and quality activities will be completed with full consideration of the status of relevant training activities.

D. Relationship of Form FDA 483 Observations to Product Quality

This section addresses the Agency's request expressed in paragraph 2d of the letter of March 11, 1997 to: *[conduct] a review of all observations listed on the Form FDA 483 issued November 27, 1996, to determine whether or not product quality has been affected, including addressing the need for possible recall of product if deemed necessary.*

We have completed a review of the observations from the Form FDA 483 of November 27, 1996 with respect to potential effect on product quality and the necessity of initiating a recall. Our review efforts to date have led to the conclusion that there is no concrete evidence that the Form FDA 483 observations have adversely affected product quality.

We have performed a preliminary assessment of products that were within expiration date as of March 27, 1997. The table below lists the number of lots and doses of each MBPI licensed product that was in date as of March 27, 1997. The table also lists the number of adverse event reports (AERs) and product complaints received by MBPI for each product, with specific annotations of the nature of the events. It is important to note that only one of the adverse events reported to MBPI resulted in a 15-day alert report to the Agency. A second table that describes the nature of the three product complaints received by MBPI for the lots in question is also included. The relatively low number and minor nature of both AERs and complaints listed in the table support our conclusion that safety, sterility, efficacy, and purity of MBPI products have not been compromised.

The Form FDA 483 observations, evaluated as a whole, do serve to identify critical areas and Institute-wide programs in need of significant improvement, most notably, Manufacturing and QA. Continued emphasis in both of these areas will be on the effectiveness of training and document review and management. Our plans for upgrading and enhancing both the training and document management programs at MBPI were presented in Sections IIB and IIC.

As stated we do not believe there is a reason to initiate a recall of any MBPI manufactured products. However, in addition to this initial assessment and to be fully responsive to the Agency's concerns MBPI will, within 90 days of your receipt of this response, complete a thorough review of the documentation for all products that were within expiration dating on March 27, 1997 to ensure purity, potency, efficacy, and safety of the products. Our review will include:

- Manufacturing batch record review for each significant step in the production of each lot of every product in date on March 27, 1997
- Review of all laboratory tests; chemical, *in vivo, in vitro* and microbiological, to ensure conformance to in-process and release product specifications
- Review and analysis of AERs to assess product safety
- Review and analysis of all customer complaints
- Review of sterility test results to reassess sterility assurance of the product
- Review and reevaluation of the cause of any batch failures and rejections with relevant trend analysis to ensure that any deviation was lot-specific and unrelated to preceding or subsequent batches
- Evaluation of compliance of operations and documentation practices with MBPI standards and procedures

This product purity, safety and potency review will be integrated with the ongoing initiatives to improve the effectiveness of cGMP compliance and document control, and QA systems.

History of AERs and Product Complaints for MBPI Products in Date as of March 27, 1997

Product	Lots in Date	Distributed Doses	AERs	Nature of AERs	Complaints
ALBUMIN (HUMAN) 25%	32	157,238	0		0
DT TOXOID, ADSORBED	1	60,100	3	Hives, fever, loose stools, "fussy"	0
DTP, ADSORBED	1	67,340	0*		0
IMMUNE GLOBULIN (HUMAN) 16.5%	27	1,765,032	1	Hives, shortness of breath, throat closing off	3 (See attached)

PERTUSSIS VACCINE, ADSORBED	1	6,000	0		0
RABIES VACCINE, ADSORBED	22	33,391	10	Tachycardia, injection site reaction, shortness of breath, cold, fever, headache, weak legs, nausea, itching and redness on trunk and limbs, vomiting, diarrhea, fatigue	0
TETANUS AND DIPHTHERIA TOXOIDS, ADSORBED	1	323,750	16**	Injection site reaction, swelling, chills, flu-like symptoms, shortness of breath, cold feet, fever, fainting, swollen throat, dyspnea, nausea, syncope, hypoxia	0
ANTHRAX VACCINE, ADSORBED	32	6,622,518***	0		0

* One AER received could not be related to an MBPI produced product
** One 15-day alert report sent for 76-year old female with prior history of heart disease
*** Doses stockpiled for Department of Defense

Immune Globulin Product Complaints

Lot Number	Received	Bio #	Exp. Date	Nature of Complaint	Nature of Investigation	File Closed
IG110	5/26	95PC1G1	2/3/98	Vials in a box of three appeared to contain different fill volumes	Examined returned vials; evidence of multiple stopper punctures and different volumes in two opened vials, third vial had normal fill volume; concluded that liquid inadvertently transferred	6/19/95
IG114	3/14/96	96PC1G1	4/14/98	Wrong number of vials in boxes, seals intact, one vial had metal button missing and	Vials returned and inspected; most likely conclusion was that the packages were opened at	10/18/96
IG116	5/14/96	96PC1G2	9/19/98	One package of immune globulin was damaged; of the three vials in the package, one was destroyed	Examined returned package; QA investigated individuals at MBPI and PROVO pharmacy; conclusion that damage could have occurred at MBPI after packaging or in the field after pick-up from MBPI	9/23/96

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Biologics Evaluation and Resear
1401 Rockville Pike
Rockville MD 20852-1448

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MBPC

CERTIFIED - RETURN RECEIPT REQUESTED

Robert Myers, D.V.M.
Responsible Head
Michigan Biologic Products Institute
3500 North Martin Luther King, Jr., Blvd.
P.O. Box 30035
Lansing, Michigan 48909

Dear Dr. Myers:

This letter acknowledges receipt of your letters dated January 16, 1997, March 20, 1997, and April 9, 1997. These letters served as your response to both the 13-page, 70-item Form FDA 483 issued at the conclusion of the inspection of your facility conducted by the Food and Drug Administration (FDA) between November 18 and 27, 1996, and FDA's March 11, 1997, notice that unless your firm demonstrated or achieved compliance with the applicable regulations and standards, the FDA would institute proceedings to revoke U.S. license 0099, issued to Michigan Biologic Products Institute (MBPI), Lansing, Michigan.

The Center for Biologics Evaluation and Research, Office of Compliance, and the Detroit district office have reviewed your responses and your corrective action plan as well as additional information provided during a meeting with you on April 22, 1997. While our review has found your responses and corrective action plan to be generally acceptable, and will be verified upon inspection, we have the following comments:

1. As part of your corrective action plan you made reference to the changes that will be made to the organizational structure of MBPI, including the retirements from and subsequent hiring of individuals for key managerial and non-managerial positions. It appears that a void will be present during the personnel turn-over. We are concerned that any delays in filling the vacancies at key positions could hinder your progress to achieve compliance.

2. The timelines outlined in Appendix G submitted as part of your corrective action plan for completion of your work plans appear to be very long, specifically in the area of Process Validation. Your response indicates that the process validation protocols will be executed March 20, 1998, which appears to be an excessive period of time to determine whether products are being manufactured consistently. We believe that some level of review (e.g., defining critical process parameters and then retrospectively reviewing available data) may be appropriate to provide an initial assessment on the process until prospective or concurrent validation is completed.

3. As part of your corrective action plan you made reference to the changes that will be made to the Standard Operating Procedure (SOP) System. We would like to stress that the SOPs should be easily accessible and written so they are useful to employees for training and or reference as needed.

As previously stated, your responses and assessment of your firm's overall compliance status will be evaluated on the next inspection. Should you have any questions concerning this letter, you may reach me by telephone at (301) 594-2066.

Sincerely yours,

for James C. Simmons
Director, Office of Compliance
Center for Biologics Evaluation and Research

cc: The Honorable John R. Engler
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MBPI FRINGE BENEFITS PACKAGE

The following is a brief description of the benefits package applicable to state employees:

DIRECT PAY ITEMS:

Overtime Premiums: The Federal Fair Labor Standards Act (FLSA) applies to state workers, the basic import of which is that non-exempt employees are entitled to premium pay rates at not less than 1 1/2 their regular rate of pay for all hours worked in excess of 40/week; compensatory time off (at the rate of 1 1/2 time the overtime hours worked) is allowed upon mutual agreement between the employee and the supervisor. Some (generally highly paid) employees have been treated as exempt executive, administrative or professional employees. By State policy and labor contracts, employees covered by FLSA are also eligible for minimum on-call pay and call-back pay.

Shift Differential: Generally, shift differential pay of 5% of the employee's base salary is paid for all hours worked on a shift where 50% of more of the scheduled hours fall between 4:00PM and 5:00AM.

Longevity Pay: Employees holding permanent (indefinite, as opposed to temporary, duration) appointments earn an annual longevity payment after six (6) years of service. The amount of the longevity pay increases in 4-year increments, ranging from $240 for 6 through 9 years of service up to $1,040 for 30 or more years of service.

PAID LEAVE TIME:

Holidays: All permanent employees are granted 12 paid holidays per year.

Personal Leave: All employees receive 16 hours of paid personal leave per year. Personal leave not used in the year in which it is granted may convert it to annual leave if the total of annual leave and personal leave does not exceed the maximum annual leave balance permitted.

Annual Leave (Vacation): Employees earn vacation time which increases in increments of 5 years of service, ranging from 4.0 hours for each 80-hour pay period completed for less than 1 year of service, to 10.2 hours per 80-hour pay period. The maximum vacation time that can be accumulated ranges from 240 hours for employees with less than 5 years of service to 300 hours with 25 or more years of service; accumulated vacation time is paid off upon separation.

School Leave: Each employee is granted 8 hours of school leave which may be used for active participation in school sponsored secular educational (non-recreational) activities; unused balances are not carried forward from year to year.

Sick Leave: Sick leave is earned at the rate of 4.0 hours per 80-hour pay period completed and may be used for personal or family illness or injuries; medical appointments; attending family funerals; and to supplement workers compensation payments up to the employee's regular salary. There is no limit on the number of sick leave hours an employee may accumulate. Sick leave balances of employees hired by the State prior to October 1, 1980 are paid off at varying percentages of the balance (not more than 50%) upon the employee's separation, depending upon the reason for separation (death, retirement, other) and depending upon the number of hours accumulated at the time of separation. Under the State's Long Term Disability group insurance program, the employee's sick leave balance is used in determining duration of benefits and portion of premium for which the employee is liable.

GROUP INSURANCE BENEFITS:

Flexible Benefits Platform: Employees enroll in group insurances under the State's Flexible Benefits Program, with an IRS-approved plan document under Section 125 of the IRS Code. Employee-share of premiums (where applicable) are pre-tax, and employees earn cash refunds for 'opting down or out' for some insurance plans.

Health Insurance: The State Health Plan is a very comprehensive Basic-Major Medical health plan. Hospital-based and professional services are paid at 100% and Major Medical services at 90%, with a $100/$200 individual/family deductible and $750 stop-loss limit. Mental Health/Substance Abuse services are separately administered by a PPO with separate copayments and deductibles. Prescription coverage is offered through a participating pharmacy (ID Card) PPO plan and a mail-order program; copays on the ID Card Plan are $7/Rx for brand name drugs, $2/Rx for generic; there is no copay for mail order prescriptions. The State pays 95% of the premium and the enrolled member pay 5% of the premium for all tiers of coverage (e.g., employee only; employee/spouse; full family).

Employees may also enroll in one of about 19 HMOs with nearly identical health benefits design as the State Health Plan (typically there is no copay for major medical services, and only a $2/Rx copay). The State pays the full HMO premium, up to the same dollar contribution as paid toward the State Health Plan, for both employee and employee/dependent coverage.

Employees may also enroll in a 'catastrophic health plan' intended for those with insurance coverage through some other source (e.g., a spouse). This plan offers basic (hospitalization) benefits only, with a deductible of 1 to 1 1/2 month's salary. Employees receive a cash incentive of $1,300/year under the flexible benefits plan enrolling in this plan (and for declining all health plan enrollment!).

Dental Insurance: Employees may enroll in one of three dental plans. The 'standard' dental plan is provided at 95% of premium paid by the State for all coverage categories, and provides 100% coverage for preventive services; 90% for x-rays, oral surgery, restoratives, endodontics and periodontics; 60% for orthodontics ($1,500 lifetime maximum per member).

A dental maintenance organization dental program is also provided at 100% state-paid premiums, with no benefit maximums except for adult orthodontics.

A preventive dental plan is also offered at 100% state paid premiums. Employees receive a $100/year cash incentive for enrolling in this plan under the flexible benefits program (or for not enrolling in any dental plan).

Vision Plan: Employees may enroll in this 100% State paid program for all coverage categories. When participating providers are used, the plan provides annual examinations with a $5 copay, one pair of glasses/contacts every 2 years with a $7.50 copay, non-medically necessary contact lenses ($90 maximum benefit).

Life Insurance: Employees are provided 100% State paid life insurance with a face value of 2 times annual salary up to $200,000. Employees may also 'opt down' to a face value equal to salary or $50,000, and receive a cash incentive under the flexible benefits program. Dependent life insurance at group rates is available at 100% employee cost.

Long Term Disability Insurance: Employees may enroll in an income protection plan which provides monthly benefits equal to 2/3 of the employee's salary in case of total disability. Payment begins after sick leave is exhausted. The State pay 50% of the program costs, with the employee's share varying in relation to their accumulated sick leave balance. The plan includes a 100% State-paid rider which pay 100% of the health insurance premium while wage loss benefits are paid, for up to six months.

DEFERRED COMPENSATION

401(k) and 457: The State offers two tax sheltered plans that allow employees to systematically set aside a portion of their income before income taxes into a saving program. The plans are currently being transitioned to State Street Global Advisors (State StreetBank, Boston) for administration and record

keeping.

Medical Spending & Family Care Accounts: Employees may set aside a portion of their income before taxes (in addition to the 401(k) & 457 programs) to pay eligible expenses for medical, child and other dependent care. The plan is administered by the State, with all contributions made by the employee. Deferred amounts not used are forfeited by the employee.

Rev. 6/6/97, OSE

RETIREMENT PROGRAMS:

Normal (Defined Benefits) Service-based Retirement: The State provides employees hired before April 1, 1997, with a fully State-funded retirement plan with a formula of 1.5% of 3-year Final Average Compensation time years of credited service. Normal retirement age for unreduced benefits is Age 55 and 30 years of service, or age 60 and 10 years of service; employees age 55 with at least 15 but less than 30 years of service may retire with an allowance reduced by .5% for each month his or her age at retirement is under 60 years. Employees vest after 10 years of service; an employee may take a deferred retirement and begin collecting retirement benefits at age 60. Duty and non-duty disability and survivor benefits are available. Retirants (including deferred retirants at age 60) are eligible for State-paid health, dental, vision and reduced life insurances.

"70-and-Out" and "Buy-Up" Plan: Under Public Act 521 of 1996, employees of MBPI are granted options for early retirement and a special purchase-of-service in the event the Institute is sold. In addition, Act 521 specifies that employees of the MBPI who are vested in the retirement system on or before the sale of the Institute are entitled to all of the rights, privileges, and benefits provided by the Act that were accrued as of the date of the sale.

The Act provides an early retirement option for MBPI employees whose age and length of service equal 70 or more on the date of the Institute=s sale. An employee retiring under this provision will receive a full retirement allowance (1.5% X service years X F.A.C., including full insurance benefits), with no minimum age requirement.

An MBPI employee whose age and service time totals to less than 70, but who has at least five but less than 10 years of service on the date of sale, will be allowed to purchase up to 5 additional years of service to reach a total of 70 points, or to obtain 10 years of service credit (the amount needed to become Avested≅ in the system, as well as to take conventional full retirement at age 60). An employee who purchases service credit will be eligible for health care benefits upon becoming eligible for a retirement allowance, the same as a person with 10 >actual= years of service credit who vested on the same date. The employee must elect to purchase the service credit within one year after the date of the sale, and will have 11 years after the date of sale to pay for the credit, at actuarial cost. To be eligible to purchase service credit, the employee must not only be an employee

of the Institute on the date of the sale, but must also maintain employment with the new owner for at least one year, unless the employee is laid off by the new employer for reasons other than good cause. If the employee purchases service and then returns to state employment before reaching retirement age, he or she must accumulate at least 10 years of service (not counting the years of purchased service credit) before becoming vested in the State=s system.

Defined Contributions (DC) Plan: Employees hired on and after April 1, 1997 are eligible for the newly enacted DC Plan, an extension of the existing 401(k) deferred compensation program; such employees are not eligible for the defined benefits plan. Other employees currently eligible for the defined benefits plan may voluntarily switch to the new DC plan at various times over the next 12 months. The State will have mandatory contributions of 4% of the employees earning, and an employer match of up to another 3% of earning; the employee=s voluntary contribution ranges up to 17% of earnings (subject to IRS regulations). The employee=s interest in the State=s contributions vests at 50% after 2 years of service, 75% after 3 years of service, and 100% at 4 years of service.

Michigan Biologic Products Institute - Management's Projection of Operations

Inflation - 3.0%
Val Date October 18, 1996

Fiscal Years Ended September 30,

	1995		1996		1997		1998		1999		2000		2001		Terminal Year (2002)	
	$	%	$	%	$	%	$	%	$	%	$	%	$	%	$	%
Blood Fractions																
Red Cross Agreements																
Contract Fractionation	500	5.7%	500	6.3%	375	2.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Administration Cost Reimb.	0	0.0%	170	2.1%	128	0.7%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
CSSM Cost Reimb	0	0.0%	55	0.7%	41	0.2%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Immune Globulins	1,423	16.3%	1,220	15.3%	1,000	5.3%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Other By-Products	203	2.3%	685	8.6%	300	1.6%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Total Red Cross Revenues	2,126	24.3%	2,630	33.0%	1,844	9.7%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
NABI																
Contract Fractionation																
Litres Processed (#)					40,000		80,000		80,000		80,000		80,000		80,000	
First 20,000 litres - Fee					41.00		41.00		41.00		41.00		41.00		41.00	
Proceeds					820	4.3%	820	4.5%	820	4.4%	820	3.1%	820	2.7%	820	2.7%
Remaining litres - Fee					32.00		32.00		32.00		32.00		32.00		32.00	
Proceeds					640	3.4%	1,920	10.5%	1,920	10.3%	1,920	7.1%	1,920	6.4%	1,920	6.4%
Total Proceeds					1,460	7.7%	2,740	15.0%	2,740	14.7%	2,740	10.2%	2,740	9.2%	2,740	9.2%
By-Product Sales																
Albumin																
Litres Processed (#)					40,000		80,000		80,000		80,000		80,000		80,000	
Rate of Albumin Prod. (vials/l)					0.0		0.0		0.0		0.0		0.0		0.0	
Yield Red. - Source Plasma (%)					0%		0%		0%		0%		0%		0%	
Sale Price of Albumin ($/vial)					0.00		0.00		0.00		0.00		0.00		0.00	
Proceeds-20% ($000)					0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
HBIG (Fraction II)																
Litres Proc into HBIG (#)					14,000		15,000		16,000		17,000		18,000		19,000	
Rate of HBIG Prod. (vials/l)					0.0		0.0		0.0		0.0		0.0		0.0	
Yield Red. - Source Plasma (%)					0%		0%		0%		0%		0%		0%	
HBIG Finishing Fee ($/vial)					0.00		0.00		0.00		0.00		0.00		0.00	
Proceeds ($000)					0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Cryo Precipitates (Fraction I)																
Litres Proc into Cryo (#)					40,000		80,000		80,000		80,000		80,000		80,000	
Rate of Cryo Prod. (g/l)					8.0		8.0		8.0		8.0		8.0		8.0	
Sale Price of Cryo ($/kg)					500.00		500.00		500.00		500.00		500.00		500.00	
Proceeds-20% ($000)					32	0.2%	64	0.4%	64	0.3%	64	0.2%	64	0.2%	64	0.2%
ISG (Fraction III)																
Litres Proc into ISG (#)					26,000		65,000		64,000		63,000		62,000		61,000	
Rate of ISG Prod. (vials/l)					8.2		8.2		8.2		8.2		8.2		8.2	
Yield Red. - Source Plasma (%)					10%		10%		10%		10%		10%		10%	
Sale Price of ISG ($/vial)					4.00		4.00		4.00		4.00		4.00		4.00	
Proceeds-20% ($000)					154	0.8%	384	2.1%	378	2.0%	372	1.4%	366	1.2%	360	1.2%
Total NABI Revenues					1,646	8.7%	3,188	17.5%	3,182	17.1%	3,176	11.8%	3,170	10.6%	3,164	10.6%
Total Blood Fractions Revenues	2,126	24.3%	2,630	33.0%	3,489	18.4%	3,188	17.5%	3,182	17.1%	3,176	11.8%	3,170	10.6%	3,164	10.6%

Michigan Biologic Products Institute - Management's Projection of Operations

Inflation - 3.0% Val Date October 18, 1996	Fiscal Years Ended September 30,															
	1995		1996		1997		1998		1999		2000		2001		Terminal Year (2002)	
	$	%	$	%	$	%	$	%	$	%	$	%	$	%	$	%
Vaccine Products																
Department of Defense																
Anthrax contract No. 1139	3,020	34.5%	2,765	34.7%	6,439	34.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Anthrax contract No. 5014	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Reimbursements	330	3.8%	211	2.6%	356	1.9%	377	2.1%	400	2.2%	424	1.6%	449	1.5%	450	1.5%
Insurance on Vaccine Sent	11	0.1%	20	0.3%	750	4.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Filling and Packaging	0	0.0%	0	0.0%	552	2.9%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Botulinum contract No. 3109	136	1.6%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Botulinum contract No. 3112	1,263	14.4%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Botulinum contract No. 4076	0	0.0%	987	12.4%	210	1.1%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Future DOD Contracts																
Number of Doses					0		3,000		3,000		5,000		5,000		5,000	
Anthrax Dose Price to DoD							3.25		3.35		3.45		3.55		3.66	
Anthrax/Botulinum Production					0	0.0%	9,750	53.4%	10,043	54.0%	17,240	64.2%	17,757	59.5%	18,290	61.3%
Prime Systems Integrator (Battelle)					0	0.0%	500	2.7%	500	2.7%	500	1.9%	500	1.7%	500	1.7%
Annual Potency Testing																
Contract No. 5014 (Anthrax)	0	0.0%	0	0.0%	3,339	17.8%	761	4.2%	484	2.6%	513	1.9%	1,632	5.5%	528	1.8%
Contract No. 5014 (Botulinum)	0	0.0%	0	0.0%	648	3.4%	430	2.4%	395	2.1%	418	1.6%	443	1.5%	431	1.4%
Total DOD Revenues	4,760	54.4%	3,983	50.0%	12,293	64.9%	11,818	64.8%	11,821	63.6%	19,095	71.1%	20,781	69.6%	20,199	67.7%
Other																
Anthrax Vaccine (non-military)	39	0.4%	15	0.2%	15	0.1%	15	0.1%	15	0.1%	15	0.1%	15	0.1%	15	0.1%
Botulinum Toxoid (Neogen)	137	1.6%	312	3.9%	375	2.0%	386	2.1%	398	2.1%	410	1.5%	422	1.4%	435	1.5%
Diptheria Toxin	2	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Tetanus Toxoid (Immuno, NABI)	0	0.0%	0	0.0%	0	0.0%	0	0.0%	300	1.6%	300	1.1%	300	1.0%	300	1.0%
Pertussus Cell Concentrate	8	0.1%	3	0.0%	3	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
DTPw (non-US)	34	0.4%	20	0.3%	500	2.6%	500	2.7%	500	2.7%	500	1.9%	500	1.7%	150	0.5%
Total Other Vaccine Revenues	219	2.5%	350	4.4%	893	4.7%	901	4.9%	1,213	6.5%	1,225	4.6%	1,237	4.1%	900	3.0%
Total Vaccine Product Revenues	4,978	56.8%	4,333	54.3%	13,187	69.7%	12,719	69.7%	13,034	70.1%	20,320	75.7%	22,018	73.7%	21,099	70.7%
SmithKline Beecham Contracts																
DTP Vaccine	1,036	11.8%	158	2.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
D&T Components	0	0.0%	0	0.0%	1,380	7.3%	1,000	5.5%	1,000	5.4%	1,400	5.2%	1,400	4.7%	2,100	7.0%
Rabies Vaccine	210	2.4%	430	5.4%												
SKB Doses Sold					12,000		20,000		20,000		20,000		20,000		20,000	
SKB Price per Dose					130.00		133.90		137.92		142.05		146.32		150.71	
SKB Gross Sales ($000)					1,560		2,678		2,758		2,841		2,926		3,014	
MBPI Dosage Cost - Fully Loaded					50.00		51.50		53.05		54.64		56.28		57.96	
MBPI Cost Reimbursement ($000)					600		1,030		1,061		1,093		1,126		1,159	
Rabies Donation ($000)					46		78		81		83		86		88	
Total Rabies Payments ($000)					646		1,108		1,142		1,176		1,211		1,247	
Seriological Doses					750		750		750		750		750		750	
MBPI Dosage Cost - Fully Loaded					50.00		51.50		53.05		54.64		56.28		57.96	
Total Seriological Revenue ($000)					38		39		40		41		42		43	
Total Rabies Revenue ($000)					683		1,147		1,181		1,217		1,253		1,291	
Rebate (5% of Sales or $100,000)	99	1.1%	100	1.3%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Total SKB Products	1,345	15.4%	688	8.6%	2,083	10.8%	2,147	11.8%	2,181	11.7%	2,617	9.7%	2,653	8.9%	3,391	11.4%

Michigan Biologic Products Institute - Management's Projection of Operations

nflation - 3.0% /.il Date October 18, 1996	Fiscal Years Ended September 30,															
	1995		1996		1997		1998		1999		2000		2001		Terminal Year (2002)	
	$	%	$	%	$	%	$	%	$	%	$	%	$	%	$	%
Athena Neurosciences Contract																
Dystonia Patient Population (US) (000)	150		150		150		150		150		150		160		170	
Doses per Patient per Year	3		3		3		3		3		3		3		3	
Annual Doses (000)	450		450		450		450		450		450		480		510	
Athena Share	0%		0%		0%		0%		0%		1%		3%		3%	
Athena Doses Produced (000)	0		0		0		0		0		5		14		15	
Cost per Dose	83.33		83.33		83.33		83.33		83.33		83.33		85.83		88.40	
Cost Reimbursement ($000)	0		0		0		0		0		375		1,236		1,353	
Price per Dose	833.33		833.33		833.33		833.33		833.33		833.33		858.33		884.08	
Athena Gross Sales ($000)	0		0		0		0		0		3,750		12,360		13,526	
Gross to Net	95%		95%		95%		95%		95%		95%		95%		95%	
Athena Net Sales ($000)	0		0		0		0		0		3,562		11,742		12,850	
Donation Percentage	5%		5%		5%		5%		5%		5%		5%		5%	
Donation	0		0		0		0		0		178		587		643	
CANADA Athena Revenues ($000)	18		160		160		160		160		160		160		160	
Total Athena Revenues ($000)	*18*	*2.5%*	*160*	*2.0%*	*160*	*0.8%*	*160*	*0.8%*	*160*	*0.9%*	*713*	*2.7%*	*1,983*	*6.6%*	*2,155*	*7.2%*
Major Revenue Sources																
Blood Fractions																
Red Cross	2,126	24.3%	2,630	33.0%	1,844	9.7%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
NABI	0	0.0%	0	0.0%	1,646	8.7%	3,188	17.5%	3,182	17.1%	3,176	11.8%	3,170	10.6%	3,164	10.6%
Total	*2,126*	*24.3%*	*2,630*	*33.0%*	*3,489*	*18.4%*	*3,188*	*17.5%*	*3,182*	*17.1%*	*3,176*	*11.8%*	*3,170*	*10.6%*	*3,164*	*10.6%*
Vaccine Products																
Department of Defense	4,760	54.4%	3,983	50.0%	12,293	64.9%	11,818	64.8%	11,821	63.6%	19,095	71.1%	20,781	69.6%	20,199	67.7%
Other	219	2.5%	350	4.4%	893	4.7%	901	4.8%	1,213	6.5%	1,225	4.6%	1,237	4.1%	900	3.0%
Total	*4,978*	*56.9%*	*4,333*	*54.3%*	*13,187*	*69.7%*	*12,719*	*69.7%*	*13,034*	*70.1%*	*20,320*	*75.7%*	*22,018*	*73.7%*	*21,099*	*70.7%*
SmithKline Beecham	1,345	15.4%	688	8.6%	2,063	10.9%	2,147	11.8%	2,181	11.7%	2,617	9.7%	2,653	8.9%	3,391	11.4%
Athena Neurosciences	218	2.5%	160	2.0%	160	0.8%	160	0.9%	160	0.9%	713	2.7%	1,983	6.6%	2,155	7.2%
Total Major Source Revenues	*8,667*	*99.1%*	*7,811*	*98.0%*	*18,899*	*99.8%*	*18,214*	*99.8%*	*18,557*	*99.8%*	*26,825*	*99.9%*	*29,824*	*99.9%*	*29,809*	*99.9%*
Other Revenue Sources																
Animals	31	0.4%	39	0.5%	30	0.2%	30	0.2%	30	0.2%	30	0.1%	30	0.1%	30	0.1%
Aluminum Testing	2	0.0%	4	0.1%	3	0.0%	3	0.0%	3	0.0%	3	0.0%	3	0.0%	3	0.0%
Rabies Reagents	30	0.3%	25	0.3%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Legionella	2	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Insurance Rebate	16	0.2%	94	1.2%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Other	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	81	0.9%	162	2.0%	33	0.2%	33	0.2%	33	0.2%	33	0.1%	33	0.1%	33	0.1%
Total Revenues	8,748	100.0%	7,973	100.0%	18,932	100.0%	18,247	100.0%	18,590	100.0%	26,858	100.0%	29,857	100.0%	29,842	100.0%

Michigan Biologic Products Institute - Management's Projection of Operations

Inflation - 3.0%
Val Date October 18, 1996

Fiscal Years Ended September 30,

	1995		1996		1997		1998		1999		2000		2001		Terminal Year (2002)	
	$	%	$	%	$	%	$	%	$	%	$	%	$	%	$	%
Costs of Goods Sold																
Projected Production Cost Analysis																
Units of Blood Plasma Processed																
Direct Cost					3,000		3,090		3,183		3,278		3,377		3,478	
Total Blood Direct Cost					3,000	15.8%	3,090	16.9%	3,183	17.1%	3,278	12.2%	3,377	11.3%	3,478	11.7%
Dosages of Anthrax Produced					0		3,000		3,000		5,000		5,000		5,000	
Direct Cost per Dose					1.50		1.55		1.59		1.64		1.69		1.74	
Direct Cost of Anthrax Produced					0		4,635		4,774		8,195		8,441		8,695	
Cost to Complete Contract 1139					2,993											
Contract 5014 Cost Reimbursements					356		377		400		424		449		450	
Contract 5014 - Insurance on Vaccine Sent					750											
Contract Transitioning Costs					750		250									
Total Anthrax Direct Cost					4,848	25.6%	5,262	28.8%	5,174	27.8%	8,619	32.1%	8,890	29.8%	9,145	30.8%
Battelle Integrator Contract Dosages					0		0		0		0		0		0	
Direct Cost (NET RESULT IN REVENUES)					0		0		0		0		0		0	
Total Batelle Direct Cost					0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Potency Testing																
Number of Anthrax Tests					93		30		12		12		38		0	
Direct Cost per Test					35,000		36,050		37,132		38,245		39,393		40,575	
Number of Botulinum Penta Tests					9		5		4		4		4		4	
Direct Cost per Test					55,000		56,650		58,350		60,100		61,903		63,760	
Number of Botulinum Mono Tests					12		6		6		6		6		6	
Direct Cost per Test					19,000		19,570		20,157		20,762		21,385		22,026	
Total Potency Testing Direct Cost					3,978	21.0%	1,482	8.1%	800	4.3%	824	3.1%	1,873	6.3%	387	1.3%
SmithKline Contract Dosages																
D&T Components - million LF produced							91		120		150		180		210	
Direct Cost per LF ($)							0.016		0.015		0.010		0.010		0.011	
Indirect Facility Validation Cost					600		400		0		0		0		0	
Total D&T Comp. Direct Cost					600		1,856		1,800		1,500		1,854		2,228	
Rabies Vaccine - Dosages					12,000		20,000		20,000		20,000		20,000		20,000	
Direct Cost per Dose					43.80		45.11		46.47		47.86		49.30		50.78	
MBPI Cost Reimbursement					600		1,030		1,061		1,093		1,126		1,159	
Total Rabies Direct Cost					1,126		1,932		1,990		2,050		2,111		2,175	
Total SKB Direct Cost					1,726	9.1%	3,788	20.8%	3,790	20.4%	3,550	13.2%	3,965	13.3%	4,403	14.8%
Athena and Other Product Lines																
Direct Cost					0		0		0		375		1,236		1,353	
Total Athena & Other Direct Cost					0	0.0%	0	0.0%	0	0.0%	375	1.4%	1,236	4.1%	1,353	4.5%
Overhead, Indirect and Other Costs																
Executive and General Mgmt.					1,200		1,236		1,273		1,311		1,351		1,391	
Depreciation					1,367		1,788		1,853		1,911		1,964		1,976	
Other					2,000		2,060		2,122		2,185		2,251		2,319	
Total Overhead, Indirect, & Other Costs					4,567	24.1%	5,084	27.9%	5,248	28.2%	5,408	20.1%	5,566	18.6%	5,686	19.1%
Total Projected Costs					18,119	95.7%	18,707	102.5%	18,195	97.9%	22,054	82.1%	24,907	83.4%	24,451	81.9%
Income Before Income Taxes	(6,321)	(72.3%)	(7,425)	(93.1%)	813	4.3%	(460)	(2.5%)	395	2.1%	4,804	17.9%	4,950	16.6%	5,391	18.1%

Michigan Biologic Products Institute - Management's Projection of Operations

Inflation 3.0%	Fiscal Years Ended September 30,															
Val Date October 18, 1996	1995		1996		1997		1998		1999		2000		2001		Terminal Year (2002)	
	$	%	$	%	$	%	$	%	$	%	$	%	$	%	$	%
Capital Expenditures																
Planned Projects	Estimated Total Cost															
Building 12																
Special Utilities Supply to Anthrax Vaccine Manufacturing Area	700															
Mod. to Animal Test Facilities	300															
Second Floor Anthrax Vaccine Mfg. Area																
Project Planning	250															
Project Completion	1,500															
Tetanus Vaccine Upgrade	2,639															
General Renovation Cost	834															
Separate Anthrax Vaccine Building	7,000															
Building 16																
Third Floor Filling & Packaging Area	275															
Cold Room Storage Capacity & Quality	200															
Ren. of 1st Floor Aseptic Mfg. Space	2,700															
Diptheria Vaccine Expansion	0															
General Renovation Cost	0															
Building 1 - General Renovation Cost	1,081															
Building 2 - General Renovation Cost	1,228															
Building 3 - General Renovation Cost	764															
Building 4 - Demolition Cost	67															
Building 5 - Demolition Cost	46															
Building 6 - General Renovation Cost	315															
Building 7 - Gene al Renovation Cost	296															
Building 8 - General Renovation Cost	93															
Building 9 - Demolition Cost	41															
Building 10 - Demolition Cost	132															
Building 11 - Demolition Cost	23															
Building 13 - General Renovation Cost	165															
Building 14 - General Renovation Cost																
Building 15 - Demolition Cost	7															
Building 17 - General Renovation Cost	164															
Building 20 - Demolition Cost	16															
Building 22 - Demolition Cost	34															
Building 23 - Demolition Cost	37															
Building 24 - Demolition Cost	168															
Building 25 - Demolition Cost	7															
Building 29 - General Renovation Cost	551															
Building 30 - General Renovation Cost	565															
Building 31 - General Renovation Cost	398															
Building 32 - General Renovation Cost	189															
Building 45 - General Renovation Cost																
Building 46 - General Renovation Cost																
Gross Capital Expenditures	21,781															
Gross Capital Exp. excl. Demolition	21,204															

Michigan Biologic Products Institute - Management's Projection of Operations

Inflation - 3.0%
Val Date October 18, 1996

Fiscal Years Ended September 30,

	1995		1996		1997		1998		1999		2000		2001		Terminal Year (2002)	
	$	%	$	%	$	%	$	%	$	%	$	%	$	%	$	%
Capital Expenditures (continued)																
Gross Capital Expenditures	22,781															
Gross Capital Exp. excl. Demolition	22,204															
Less: Capex Reimbursements																
Building 12																
Special Utilities Supply to Anthrax	700															
Tetanus Vaccine Upgrade	1,450															
Separate Anthrax Vaccine Building	7,000															
Building 16																
Third Floor Filling & Packaging Area	100															
Cold Room Storage Capacity & Quality	195															
Ren. of 1st Floor Aseptic Mfg. Space	2,630															
Diptheria Vaccine Expansion	0															
	12,075															
Building 12, 16 Capital Exp. less Reimb	3,489				1,744		1,744									
Gen. Renovation Cost (incl. Bldg 12,16)	6,641				1,328		1,328		1,328		1,328		1,328		1,109	
Demolition Expense	577				577											
Span of Capex Implementation (years)	5															
Total Planned Projects					3,649		3,072		1,328		1,328		1,328		1,109	
General Equipment Purchases					800		824		849		874		900		927	
Total Capital Expenditures					4,449		3,896		2,177		2,202		2,229		2,036	
Income Before Income Taxes (above)			(7,425)	(93.1%)	813	4.3%	(460)	(2.5%)	395	2.1%	4,804	17.9%	4,950	16.6%	5,391	18.1%
Provision for Income Taxes																
Current			0	0.0%	406	2.1%	208	1.1%	215	1.2%	1,610	6.0%	1,830	6.1%	1,984	6.6%
Deferred			0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Total			0	0.0%	406	2.1%	208	1.1%	215	1.2%	1,610	6.0%	1,830	6.1%	1,984	6.6%
Income After Income Taxes			(7,425)	(93.1%)	407	2.1%	(668)	(3.7%)	181	1.0%	3,194	11.9%	3,121	10.5%	3,407	11.4%
Capital Expenditure Requirements			0		4,449		3,896		2,177		2,202		2,229		2,036	
Working Capital Requirements			(155)		2,192		(137)		69		1,654		600		(3)	
Depreciation and other Non-Cash Exp.			1,155		1,367		1,788		1,853		1,911		1,964		1,976	
Debt-Free Cash Flow			(6,115)		(4,867)		(2,639)		(212)		1,250		2,257		3,350	

Michigan Biologic Products Commission
Policy Statement

Standards of Employee Conduct
Relative to Sale of the
Michigan Biologic Products Institute

PREMISES

The Legislature has passed and the Governor has signed legislation (1996 PA 522) which authorizes the sale of all or a portion of the assets and liabilities of the Michigan Biologic Products Institute.

Under 1996 PA 522, the Michigan Biologic Products Commission is charged with soliciting prospective purchasers or other transferees for the assets of the Institute using the method or methods considered most appropriate by the Commission.

Prospective purchasers specifically contemplated by 1996 PA 522 include employees of the Institute or a group composed in whole or in part of employees of the Institute. To facilitate employee participation in the process, 1996 PA 522 authorized Institute employees to make a proposal to acquire the assets of the Institute and, if they are the successful bidder, to enter into agreements related to the conveyance of assets of the Institute to them.

Moreover, 1996 PA 522 provided that employee actions would not violate other statutory codes of ethics if (i) the employee's actions are with the knowledge of the Commission or (ii) the employee acted under the direction of the Commission, and (iii) prior to execution of an employment agreement with a potential acquirer of the Institute's assets, the employee provided the Commission with written notice of the proposed employment agreement and its terms.

The goals of the Commission in structuring and facilitating a sale of the Institute's assets are to allow all prospective purchasers a fair opportunity to acquire the Institute assets and to insure that the State receives fair and adequate consideration from this sale.

The Commission believes that the articulation of basic standards of conduct for Institute employees will help all Institute employees understand the most important principles and requirements that must govern the processes relative to the sale of the Institute's assets to assure attainment of these goals. It is, of course, expected that all employees will continue to comply with all legal requirements related to their jobs and the performance thereof. These standards of conduct are designed to provide Institute employees basic directions to govern their daily

activities, and are to be considered in conjunction with State laws and rules of the Civil Service Commission.

Each Institute employee is expected to comply with these directions, as well as all requirements of laws, rules, and regulations otherwise applicable, and avoid activities which present a conflict of interest. These standards should not be construed so as to prevent employees from preparing a proposal.

EMPLOYEE STANDARDS OF CONDUCT

1. Institute employees shall perform their jobs in a manner which advances the interests of their employer, the State of Michigan. Such performance is expected to maintain and enhance the value of the Institute. To this end, Institute employees shall avoid financial and other outside relationships which would interfere with job performance.

2. Institute employees shall immediately and fully report to the selling agent, the due diligence coordinator or any Commission member any information of which they become aware during the performance of their job which they believe would have a material impact on the value of the Institute.

3. Institute employees shall give notice to the Commission of any information requested by an identified bidder, including an employee or group of employees, and may release such information only upon approval of the Chair of the Commission. Employees shall not withhold, however, information from any other employee which is necessary or appropriate for the other employee to perform his or her job.

4. While it is recognized that certain employees may acquire confidential, non-public information in the course of their employment that may be useful in preparing a proposal to purchase assets of the Institute, employees should not use their positions to acquire confidential, non-public information not related to the performance of their jobs, for use in preparing or presenting a proposal. In addition, employees should not disclose confidential, non-public information about the Institute to anyone for the purpose of assisting in preparing a proposal to acquire assets of the Institute.

5. Institute employees shall use Institute property or facilities only for the benefit of the Institute.

6. Institute employees shall not engage in an activity related to the possible acquisition of the assets of the Institute during the particular employee's working hours, including paid or non-paid overtime required to carry out their duties, or during working hours while traveling on trips paid for by the State.

7. Institute employees shall not use confidential, non-public information obtained in the course of performing their duties for the Institute in preparing a proposal to acquire the assets of the institute.

8. Institute employees shall notify the Commission if they intend to bid on or make a proposal to acquire all or part of the assets of the Institute. If part of a group, a single notification listing participating employees may be made on behalf of the entire group.

This is a true copy as passed by the Michigan Biologic Products Commission on May 6, 1997.

J. Louise Findley

J. Louise Findley
Executive Secretary, MBPC

attorney/97rjs/Biologics/standards

HOUSE FISCAL AGENCY

MICHIGAN HOUSE OF REPRESENTATIVES
309 N. WASHINGTON SQUARE, SUITE 012
LANSING, MI 48933
517.373.8080
FAX: 517.373.5874
www.house.state.mi.us/hfa

	NET PRESENT VALUE OF SALE	PAYMENT SCHEDULE							TOTAL PAYMENTS
		AT CLOSING	YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5	YEAR 6	
NOTE #1	$3,363,176.3	$0.0	$1,127,054.1	$1,127,054.1	$1,127,054.1	$1,127,054.1	$1,127,054.1	$0.0	$6,635,270.3
NOTE #2	$2,832,630.5	$0.0	$3,402,000.0	$0.0	$0.0	$0.0	$0.0	$0.0	$3,402,000.0
NOTE #3	$3,748,877.6	$0.0	$4,500,000.0	$0.0	$0.0	$0.0	$0.0	$0.0	$4,500,000.0
SUBTOTAL	$9,942,685.4	$0.0	$9,029,054.1	$1,127,054.1	$1,127,054.1	$1,127,054.1	$1,127,054.1	$0.0	$13,537,270.3
ROYALTIES	$2,764,393.2	$0.0	$833,333.3	$833,333.3	$833,333.3	$833,333.3	$833,333.3	$833,333.3	$5,000,000.0
PRODUCT	$2,245,641.9	$0.0	$752,550.0	$752,550.0	$752,550.0	$752,550.0	$752,550.0	$0.0	$3,762,750.0
LEASE	$360,029.4	$0.0	$144,773.2	$144,773.2	$144,773.2	$0.0	$0.0	$0.0	$434,319.5
CASH	$3,250,000.0	$3,260,000.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$3,260,000.0
SUBTOTAL	$18,562,769.9	$3,260,000.0	$10,759,710.5	$2,857,710.5	$2,857,710.5	$2,712,937.4	$2,712,937.4	$833,333.3	$25,994,339.7
RETAINED WORKING CAPITAL	($1,217,113.0)	($1,217,113.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	($1,217,113.0)
TOTAL	$17,345,656.9	$2,032,887.0	$10,759,710.5	$2,857,710.5	$2,857,710.5	$2,712,937.4	$2,712,937.4	$833,333.3	$24,767,226.7

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE
Robert C. Myers, D.V.M., Director
[illegible]
P.O. Box [illegible]
[illegible]
[illegible]
[illegible]
John Engler, Governor

MEMORANDUM

TO: Members of the State Administrative Board

FROM: Members of the Michigan Biologic Products Commission

RE: Executive Summary, Michigan Biologic Products Institute: Sales Process, Recommended Transferee, and Recommended Transaction

DATE: July 1, 1998

The following summarizes the lengthy process employed by the Michigan Biologic Products Commission (the "Commission") to identify and recommend a proposed transferee and the terms of a proposed transaction to the State Administrative Board (the "Board") for the sale of the Michigan Biologic Products Institute (the "Institute") in accord with P.A. No. 522 of 1996, as amended (the "Transfer Act").

Summary information is provided about the recommended transferee and the key terms and conditions of the recommended transaction. Certain terms and conditions are derived directly from the Transfer Act, including those regarding employees and the retention of preferential access to biologic products for the state. But the most important condition for the conveyance of the Institute is the Board's approval of the recommended transferee and transaction upon the receipt of an independent fairness opinion.

The Asset Purchase Agreement was sent to the fairness opinion provider retained by the Board, First of Michigan Corporation, shortly after the adoption of Resolution No. 11 (see attached). We are advised that an opinion will be rendered and transmitted to the Board on or about June 30, 1998. We consider our recommendations to be advisory and preliminary to final Board action.

As you read the attached Asset Purchase Agreement (the "APA"), Schedules are lists of things like equipment and inventory that have been kept up to date and will be easy to finalize at closing. Exhibits are agreements secondary to the APA such as the Preferential Access Agreement and the Building 29 lease. All Exhibits are substantially complete including all economic terms, however, some will require subsequent Board approval as they are finalized (e.g., the Building 29 lease).

We respectfully request that your review of the APA be scheduled at the Board's earliest convenience; we have targeted July 7, 1998, as the date for Board action. Commission Executive Secretary, Ms. Louise Findley, will call to set briefing times for you and/or your designees in advance of the July 7 meeting.

The Sale Process

The lengthy process of transferring the assets and liabilities associated with the Institute began on the February 1996 effective date of Executive Order 1995-25 which reorganized the Michigan Department of Public Health and established the Institute as a temporary state agency under Article V, Section 4 of the Michigan Constitution. The order also established the Commission and gave it 8 months to prepare a business plan, implementing legislation, and a preliminary valuation of the Institute by a nationally recognized accounting firm.

In July 1996, the Commission established its goals regarding the sale of the Institute by adopting Resolution No. 4. The Commission's business plan, implementing legislation, and preliminary valuation were presented to the Legislature in late October 1996. The Legislature passed the Transfer Act (see attached) and an associated early retirement bill with broad bipartisan support in December 1996, and P.A. No. 522 of 1996 was signed into law in January 1997. The Transfer Act affirmed E.O. 95-25 and authorized the Commission to engage a selling agent, solicit potential purchasers, and negotiate the terms and conditions of agreements to convey the Institute out of the public, and into the private sector.

In April 1997, the Commission engaged the firm of W.Y. Campbell & Company to be its selling agent; the Institute was officially put up for sale on July 1, 1997, with the adoption of Resolution No. 8. Simultaneously, on July 9, 1997, a sales ad for the Institute ran in the international edition of the *Wall Street Journal* (circulation > 1.4 million readers) and the direct solicitation of more than 30 strategic buyers began. Over 80 firms from 5 countries responded to this initial marketing.

By November 3, 1997, 3 candidate purchasers had submitted proposals to purchase the Institute based on the completion of initial due diligence. However, by early December, 1 firm withdrew its offer, and another was rejected by the Commission. The rejected offer was submitted by Michigan Biologic Products, Inc., a firm formed by employees of the Institute as permitted by P.A. No. 522. After extensive of negotiations with the remaining bidder, it became clear that closing a transaction was not likely; this bidder eventually became non-responsive and withdrew from the sales process.

In January 1998, the Commission reopened bidding and renewed its marketing of the Institute (see Resolution No. 10), encouraged by Secretary of Defense William Cohen's announced plans to inoculate troops against the deadly bioweapon, anthrax. Presently, the Institute is the sole-source provider of a U.S. FDA licensed vaccine against anthrax to the U.S. Department of Defense (DoD). The DoD is by far the Institute's largest customer, accounting for two-thirds of its annual product sales revenues. A mutual agreement in principle with pharmaceutical giant SmithKline Beecham to terminate its contracts with the Institute also greatly simplified the transaction and improved its prospects for success.

Thanks to the support of the U.S. military and the Michigan Legislature, legislation was enacted in February 1998 to extend appropriations for the Institute

until the end of FY 98 and give the Commission additional time to complete its work. The correctness of these actions was confirmed by the quantity and quality of new bidders attracted, and the steady improvement in the amount of consideration offered to the state for the Institute.

Over the course of the sale process, nearly twenty firms from nine different countries ultimately conducted detailed investigations of the Institute and the transaction. Detailed due diligence included site visits, document reviews, and interviews with key Institute employees. As intentions to acquire firmed up, some firms engaged consultants to conduct Phase I environmental investigations at their own expense. Several firms requested and were granted permission to engage in preliminary discussions with the DoD, and by early May, five bidders submitted firm offers for the Institute ranging in nominal value from approximately $7 to $25 million.

On May 1, bidders were asked to complete their due diligence and submit bids in the form of the Asset Purchase Agreement (APA) prepared by the state. The two firms with the highest pending bids submitted APAs to the Commission on May 18, and a third strong bidder withdrew its offer. The two other firms that had reasonable offers pending before the Commission did not submit APAs and subsequently did not receive further consideration.

Following two weeks of an often intensely competitive auction process conducted by the Commission's selling agent, the Commission reached its decision with respect to recommending a transferee and transaction to the Board. On June 2, 1998, the Commission adopted Resolution No. 11 (see attached) to recommend the firm of BioPort and the attached transaction to the Board.

We believe that the proposed transaction is consistent with the Transfer Act and our goals as expressed long ago in Resolution No. 4. We are confident that the transaction is in the best interest of the State of Michigan, and we respectfully request your approval and authorization to execute closing documents.

Recommended Transferee: BioPort Corporation

BioPort is a new Michigan company formed for the purpose of acquiring the Institute. The lead investor in BioPort is Intervac, L.L.C., a Maryland-based pharmaceutical investment firm of which retired Admiral William Crowe is the Managing Director and lead party for the BioPort bid. Admiral Crowe and other Intervac managers have served on the boards of large pharmaceutical firms including Pfizer and Speywood Holdings. Another investor in BioPort is Michigan Biologic Products, Inc., a Michigan firm formed largely by seven top Institute managers and Intervac.

Twenty percent of BioPort's stock will be reserved for employees who elect to stay and work for BioPort and will be distributed based on BioPort's performance and the performance of employees against stipulated goals. The 20% of Bioport stock reserved for employees will be Class B non-voting stock.

BioPort has also established a strategic partnership with Neogen Corporation, a Lansing-based biotechnology firm led by Mr. James Herbert. This partnership is based on common interests and an agreement to cooperate in the equine botulinum vaccine business which will be acquired by Neogen. Neogen reportedly has plans to lease space at the Institute to accommodate the expansion of its Lansing base, and to cooperate in research and development with BioPort.

Porton International, Inc., and FFF Enterprises both submitted letters supporting the BioPort bid, indicating BioPort's access to bioproduction services, marketing, and product distribution. Porton is a large international pharmaceutical company based in Great Britain with experience in the commercialization of biopharmaceutical products. Porton owns 49% of DynPort, the winner of the U.S. DoD's $325 million Joint Vaccine Procurement contract. FFF Enterprises is a national distributor of specialty bioproducts, and is presently the distributor for the Institute's immune serum globulin blood plasma product.

BioPort discussed it business plan with the DoD which, in turn, separately confirmed its willingness to novate its contracts with the Institute to allow BioPort to become its successor. BioPort also includes the employees responsible for developing, implementing, and adhering to the Strategic Plan for Compliance submitted to the U.S. FDA in April 1997, so it is expected that the transfer of the Institute's licenses will proceed smoothly and with continuity. The ability to work with the U.S. DoD and comply with U.S. FDA regulations were deemed important qualities for all serious bidders.

Recommended Transaction -- Key Terms and Conditions

Assets Sold: All real, personal, tangible and intangible property associated with the Institute, including land, buildings, equipment, licenses, inventory, books, records, etc., will be sold to BioPort. Real property includes the East Campus where all current Institute operations are located, and the West Campus which comprises some 47 acres of undeveloped farm land contiguous to the airport.

Consideration: BioPort proposed to pay total nominal consideration to the State of Michigan of approximately **$25 million**, the highest offer received by the Commission on both a nominal and a net present value basis. Consideration includes cash, notes secured by the assets, donated products, and royalties from products sales as detailed in the attached spreadsheet prepared by W.Y. Campbell & Company. Payments with donated products were valued at average wholesale prices taken from the "Redbook," and, along with royalties and the notes, were heavily discounted for evaluation purposes at the rate of 20.1% based upon a recommendation from the Michigan Department of Treasury. Higher discount rates generate lower net present value, thus the net present value of the BioPort bid is quite conservative. The lease rate reduction for Building 29 was discounted at a 10% rate given its lower risk. Finally, the unlimited 5% royalty from domestic civilian anthrax vaccine sales was not formally assigned a value because no such sales or program presently exist; it, thus, represents a purely upside potential for additional consideration to the State of Michigan.

Employees: BioPort has committed to comply with the requirements of P.A. No. 522 of 1996 to offer employment to all Institute employees, including contract employees, on the date of closing. All employees who elect to accept BioPort's offer of employment are guaranteed a job for at least one year from the date of closing, unless cause exists for dismissal. BioPort stated their intention to pay total compensation comparable to that presently paid by the state for salaries, wages, and benefits. In addition, BioPort will reserve 20% of its non-voting stock for employees to earn based on the performance of the company and each employee. The stock plan is structured so that Intervac will remain in control of BioPort's board.

Preferential Access to Products: BioPort will donate rabies and pediatric DT vaccines and immune serum globulin to the state in annual quantities approximately equal to the average annual state usage for the next five years, to be used over the next seven years. In addition, the state will be granted preferential access to these and other BioPort products at market prices for the next five years in accord with P.A. No. 522 of 1996. Preferential access gives state purchase orders priority over those of other customers, and is important to protect state interests in times of shortages.

Environmental Liability: Liability for historical contamination of the real property, if any, is retained by the state which has occupied the site for over 70 years. BioPort has conducted a Phase I environmental assessment at its own expense; a mutually agreed to third-party environmental consultant will conduct a Phase II assessment which will determine the extent and cost of any required remediation. The cost of any required environmental remediation will reduce consideration paid to the state by the amount of the remediation expenses incurred, subject to an overall cap of $1 million.

The remediation costs identified in the Phase II assessment which may offset consideration to be received from BioPort must relate to environmental remediation and asbestos abatement that a prudent owner or operator would consider reasonably necessary under law either given the current condition of the property transferred or for certain identified structural demolitions or renovations performed within the next two years. BioPort has agreed to pay the excess of actual costs of these activities over the costs identified by the Phase II consultant for these activities.

Phase I investigations have identified several "recognized environmental concerns" that need further characterization, however, based on the nature of the concerns and previous Phase II work, the Commission does not expect to find extensive contamination, or incur expensive remediation costs.

Building 29 Lease: Building 29 is a 13,800 sq. ft. building that currently houses the DCH's neonatal testing lab; it is the only building on the Institute campus that is occupied by another state agency. BioPort will lease this building to the state for the next two years with a one-year renewal option at a 50% discount off the rate calculated by the state for such a lease, including a 50% discount on utilities.

Right of First Refusal and Option Agreement: For a period of five years, the state will retain an option to re-purchase the West Campus (a.k.a., the "North 40") at the lesser of its present appraised value ($390,000) inflated @ 8% per annum, or its appraised price if BioPort does not develop the property for biopharmaceutical purposes, or if BioPort proposes to sell the property to a third party.

Summary

In summary, the Commission is pleased to present its recommended transferee and transaction to the Board. We respectfully request your approval of our recommendations and your authorization to execute closing documents.

DCH/MAL/JKH/jlf

Attachments

STATE OF MICHIGAN
STATE ADMINISTRATIVE BOARD

Resolutions of the State Administrative Board Regarding
the Conveyance of Assets and Liabilities of the
Michigan Biologic Products Institute

WHEREAS, Public Act No. 522 of 1996, as amended by Public Act No. 8 of 1998, (the "Act") authorizes the Michigan Biologic Products Commission (the "Commission") to negotiate the sale of all or a portion of the assets, and the assumption of all or a portion of the liabilities, associated with the Michigan Biologic Products Institute (the "Institute"); and

WHEREAS, upon recommendation of the Commission and the satisfaction of certain conditions, the Act also authorizes the State Administrative Board to approve and to authorize the execution of agreements and instruments of conveyance for the conveyance of all or a portion of the assets, and the assumption of all or a portion of the liabilities, associated with the Michigan Biologic Products Institute (the "Transaction"); and

WHEREAS, the Commission has conducted an open and competitive sale process in which a number of bids where evaluated, culminating in best and final offers being submitted by 2 bidders; and

WHEREAS, the Commission has recommended, through the adoption of its Resolution No. 11, that the State Administrative Board approve the conveyance of assets and certain liabilities of the Institute to BioPort Corporation and approve an Asset Purchase Agreement substantially in the form presented to the State Administrative Board; and

WHEREAS, pursuant to Section 5 of the Act, First of Michigan Corporation has presented an independent opinion that the consideration to be received for the assets and liabilities of the Institute proposed to be transferred under the terms of the proposed Asset Purchase Agreement is fair and adequate; and

WHEREAS, the report of the Auditor General required by Section 5 of the Act has been made to the Legislature; and

WHEREAS, this Board has examined the proposed Asset Purchase Agreement, a copy of which is attached hereto, by which the State of Michigan would be prepared to consummate the Transaction with BioPort Corporation.

THEREFORE, BE IT RESOLVED by the State Administrative Board of the State of Michigan, pursuant to the authority granted in the Act, as follows:

1. In reliance upon all facts, circumstances, certifications and opinions known to or received by the Board, the consideration to be received under the terms of the Asset Purchase Agreement is

determined to be fair and adequate and is sufficient such that the credit of the State of Michigan does not need to be granted to a person, association or corporation, public or private.

2. The terms of the proposed Preferential Access Agreement between the State of Michigan and BioPort Corporation to provide the State of Michigan with preferential access to certain biologic products are determined to meet the requirements of the Act.

3. The terms of the conveyance are determined to include a commitment by BioPort Corporation to continue the employment of Institute employees who elect to continue employment with BioPort Corporation for not less than 1 year after the closing date of the Transaction, as required by the Act and subject to the qualifications set forth in the Act.

4. This Board acknowledges the receipt of and accepts and approves the opinion of First of Michigan Corporation, concluding that the consideration for the assets and liabilities of the Institute is fair and adequate.

5. This Board has reviewed the goals of the Commission regarding the sale and the process used by the Commission to identify potential purchasers, receive bids and negotiate the Asset Purchase Agreement, and has determined that these goals and the process used to implement these goals has resulted in an open and competitive sale process.

6. The Asset Purchase Agreement between the State of Michigan and BioPort Corporation recommended by the Commission is approved in substantially the form presented. The Chairperson of the Commission is authorized to execute and deliver the Asset Purchase Agreement in the name of the State of Michigan, with those changes the Chairperson of the Commission may approve which do not materially and substantially modify its terms as presented, such approval to be conclusively evidenced by the execution of the Asset Purchase Agreement.

7. The Chairperson of the Commission is also authorized and empowered, in the name of the State of Michigan, to do or cause to be done any and all such acts or things as he may deem necessary, appropriate or desirable and to execute, verify, acknowledge, file and deliver deeds, bills of sale, other instruments of conveyance, and other agreements and certificates necessary to effectuate the terms of the conveyance agreed to under the Asset Purchase Agreement, including but not limited to the following agreements in substantially the form presented with those changes the Chairperson of the Commission may approve which do not materially and substantially modify their terms as presented, such approval to be conclusively evidenced by their execution:

a. The Preferential Access Agreement.

b. The Escrow Agreement.

c. The Right of First Refusal and Conditional Option Agreement.

d. The Mortgage and Security Agreement.

8. The State Treasurer is hereby directed to receive all monies directly paid to the State of Michigan and to deposit such monies in the Pharmaceutical Products Fund to be used in the manner authorized by the Act.

9. All Resolutions and parts of Resolutions, only insofar as the same may be in conflict herewith, are hereby superseded.

10. This Resolution shall take effect immediately upon its adoption by the State Administrative Board.

Arlene Oisten
Secretary

ASSET PURCHASE AGREEMENT

between

STATE OF MICHIGAN,

Seller

and

BIOPORT CORPORATION,
a Michigan corporation,

Purchaser

Dated: July 8, 1998

ASSET PURCHASE AGREEMENT

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ASSET PURCHASE AGREEMENT

This ASSET PURCHASE AGREEMENT ("Agreement"), dated as of July ___, 1998, is made and entered into by and among the STATE OF MICHIGAN ("Seller") and BIOPORT CORPORATION, a Michigan corporation ("Purchaser"). Capitalized terms not otherwise defined herein shall have the meanings set forth in Article 14.

WITNESSETH:

WHEREAS, pursuant to Executive Order 1995-25 issued by the Governor of the State of Michigan, the Biologic Products Division of the Michigan Department of Public Health (now known as the Department of Community Health) (the "Division") was established as an autonomous, temporary, two-year agency known as the Michigan Biologic Products Institute (the "Institute") and all duties, responsibilities, facilities, licenses and personnel previously associated with the Division were transferred to the Institute; and

WHEREAS, Act 522 of Public Acts of 1996, as amended by Act 8 of Public Acts of 1998 ("Act 522"), effective on or about January 13, 1997, authorizes the conveyance of the assets and liabilities related to the operation of the Institute; and

WHEREAS, Purchaser desires to purchase and assume from Seller, and Seller desires to sell to Purchaser, the Purchased Assets and the Assumed Liabilities, subject to the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

ARTICLE 1.

SALE OF PURCHASED ASSETS; PURCHASE PRICE; CLOSING

1.1. Purchase and Sale of Assets. At the Closing, Seller shall sell, transfer, convey, assign and deliver to the Purchaser and the Purchaser shall purchase, accept, assume and receive the Purchased Assets defined in Section 1.2 hereof, on and subject to the terms and conditions set forth in this Agreement.

1.2. Sale of Purchased Assets.

1.2.1. Purchased Assets. On the terms and subject to the conditions set forth in this Agreement and except for the Excluded Assets as defined in Section 1.2.2 hereof, Seller shall sell, transfer, convey, assign and deliver to Purchaser, and Purchaser shall purchase and pay for, at the Closing, all of the right, title and interest that Seller possesses as of the Closing Date, and has the right to sell, transfer, convey, assign and

deliver, in and to the following assets of Seller which are used or held for use in connection with the Operations of the Institute as the same shall exist on the Closing Date (the "Purchased Assets"):

1.2.1.1. Real Property Owned. The Real Property Owned as described on Schedule 1.2.1.1 annexed hereto; provided that, pursuant to applicable law, Seller shall specifically retain and reserve to the Seller, one-half (1/2) of the net royalties, if any, received from the development of coal, oil, gas, or other minerals on or under the Real Property Owned.

1.2.1.2. Tangible Personal Property. The Product Inventory, furniture, fixtures, machinery and equipment and other tangible personal property used or held for use in connection with the Operations of the Institute and located on the Real Property Owned ("Tangible Personal Property");

1.2.1.3. Personal Property Leases. Subject to Section 1.11 of this Agreement, the leases of tangible personal property as to which the Institute is the lessee, identified on Schedule 1.2.1.3 annexed hereto together with any options to purchase the underlying property relating to such leases or subleases (the leases described of this Section 1.2.1.3 being referred to herein as the "Personal Property Leases");

1.2.1.4. Contracts. Subject to Section 1.11 of this Agreement, those contracts ("Contracts") related to the Operations of the Institute (other than the Personal Property Leases) identified on Schedule 1.2.1.4 annexed hereto; provided that excluded specifically from the Contracts are all rights of the Institute to receive any services from the State of Michigan or any of its governmental subdivisions and all Contracts relating thereto, and all computer programs and computer databases used in providing such services, except to the extent otherwise agreed by the Seller and Purchaser in accordance with any Transition Services Agreement.

1.2.1.5. Accounts Receivable. Those Accounts Receivable of the Institute mutually agreed upon by Purchaser and Seller, pursuant to Section 8.2 of this Agreement, having an aggregate value of $4,500,000 as of the Closing Date ("Assigned Accounts Receivable");

1.2.1.6. Intangible Personal Property. Excluding any intangible personal property, including names, logos, designs, or other marks directly associated with the State of Michigan or any of its governmental subdivisions and any other name, logo, design or mark that has such a near resemblance thereto as may be likely to cause confusion or mistake to the public, or to otherwise deceive the public, all trade secrets and processes and other intellectual property, including copyrights and patents which are used or held for use by the Institute in the Operations of the Institute, and all rights, privileges, claims, and causes of action relating or pertaining directly to the Purchased Assets, including but not limited

to, the right to use the name "Michigan Biologic Products" ("Intangible Personal Property");

1.2.1.7. Licenses. To the extent their transfer is permitted under applicable Laws and subject to Section 1.11, the Licenses utilized in the conduct of the Operations of the Institute as listed on Schedule 1.2.1.7 annexed hereto; and

1.2.1.8. Books and Records. The Books and Records used or held for use by the Institute in the conduct of the Operations of the Institute ("Institute Books and Records"), it being understood that (i) subject to the provisions of Section 1.10.3 (regarding access to records after Closing) and any applicable law, Seller may, at Seller's sole option elect to retain copies of the Institute Books and Records subsequent to the Closing and (ii) the Books and Records of the Division and all Books and Records of the Institute relating to employee personnel records required by applicable law to remain confidential, employee taxes and benefit matters, and any Books and Records relating primarily to the Excluded Assets or the Retained Liabilities are excluded from the Institute Books and Records but Purchaser shall have a right to make copies thereof at its own expense.

1.2.2. Excluded Assets. Notwithstanding anything contained in this Agreement to the contrary, the following assets and properties of Seller used in connection with or relating to the Operations of the Institute shall be excluded from and shall not constitute any part of the Purchased Assets ("Excluded Assets"):

1.2.2.1. Cash. Cash (including but not limited to (A) checks received by Seller on or prior to the Closing Date, (B) cash in bank accounts and (C) any balances in the Pharmaceutical Products Fund), commercial paper, certificates of deposit and other bank deposits, treasury bills, other cash equivalents and bank accounts;

1.2.2.2. Insurance. Life insurance policies of officers, employees and other representatives of Seller, and all other liability, property, casualty and other insurance policies relating to the Purchased Assets or the Operations of the Institute or otherwise;

1.2.2.3. Employee Benefit Plans. All assets owned or rights held under any Benefit Plan.

1.2.2.4. Tax Refunds. All refunds or credits, if any, of Taxes of Seller;

1.2.2.5. Customer Interests in Certain Assets Excluded. The Purchaser acknowledges and agrees that certain customers of the Institute, including but not limited to, the United States Department of Defense ("Institute Customers"), have furnished to or provided funding for certain assets used by Seller in the Operations of the Institute as described on Schedule 1.2.2.5 attached hereto and

may claim certain interests therein ("Customer Interests") and therefore, except as otherwise specifically provided herein or as otherwise may be agreed by the Institute Customers, the Customer Interests of the Institute Customers in such assets are excluded from the Purchased Assets; and

1.2.2.6. Accounts Receivable. All Accounts Receivable of the Institute other than the Assigned Accounts Receivable.

1.2.2.7. Personal Property. The personal property listed on Schedule 1.2.2.7 annexed hereto (the "Excluded Personal Property");

1.3. Liabilities of Seller.

1.3.1. Assumed Liabilities. In connection with the sale, transfer, conveyance, assignment and delivery of the Purchased Assets pursuant to this Agreement, on the terms and subject to the conditions set forth in this Agreement including the special provisions relating to Environmental and Product Liabilities contained in Section 1.5 of this Agreement and the Stockpile Agreement referenced in Section 1.3.3, at the Closing, Purchaser shall assume and agree to pay, perform and discharge when due all Liabilities relating to or associated with the Purchased Assets (the "Assumed Liabilities") that are payable or performable on or after the Closing Date or result from Purchaser's act or omission following the Closing Date. Purchaser shall discharge in a timely manner all Assumed Liabilities, provided that Purchaser shall have the ability to contest, in good faith, any claim of liability asserted in respect thereof by any Person so long as Seller shall not be required to pay or discharge any such Assumed Liability and subject to Purchaser's other obligations with respect thereto under this Agreement.

1.3.2. Retained Liabilities. Purchaser shall not assume by virtue of this Agreement or the transactions contemplated hereby, and shall have no liability for, any other Liabilities incurred in, or which arise in connection with, the Operations of the Institute or the conditions of the Real Property Owned prior to the Closing Date (the "Retained Liabilities"). Seller shall discharge all of the Retained Liabilities in a manner that will prevent any Lien from attaching to the Purchased Assets or any liability resulting to Purchaser therefrom, provided that Seller shall have the ability to contest, in good faith, any claim of Liability asserted in respect thereof by any Person. Subject to the provisions of Article 10, notwithstanding anything contained herein to the contrary, nothing in this Agreement constitutes an agreement by Seller to indemnify Purchaser or any other person from the Retained Liabilities and that the performance by Seller is subject to and conditioned upon the appropriation, by the Legislature of the State of Michigan, of funds needed for such performance.

1.3.3. Department of Defense Stockpile Agreement. The parties acknowledge and agree that one of the Contracts which comprise the Purchased Assets is a Stockpile Agreement between Seller and the United States Department of Defense ("Stockpile Agreement"). It is the mutual understanding of Purchaser and Seller that the Stockpile Agreement provides that the United States Department of Defense bears the risk of loss

relative to the products stockpiled under the Stockpile Agreement, absent negligence acts or omissions of the other party. Therefore the parties agree that all Liabilities which may arise under the Stockpile Agreement due to (i) a negligent act or omission by Seller prior to the Closing Date and (ii) the failure of product to meet required specifications for any reason (other than the negligent acts or omissions of Purchaser on or subsequent to the Closing Date) shall be part of the Retained Liabilities of Seller. Any Liabilities which arise under the Stockpile Agreement due to the negligent acts or omissions of Purchaser on or subsequent to the Closing Date shall be part of the Assumed Liabilities under this Agreement.

1.4. Environmental Assessments. Prior to the Closing Date, Purchaser shall cause to be completed certain phase II environmental assessments, by an environmental consultant mutually agreed upon by Purchaser and Seller ("Environmental Consultant"), the scope of which shall be reasonably determined by Purchaser (the "Environmental Assessments"). Seller agrees to reimburse the Purchaser in the form of a credit against the Purchase Price for one-half (1/2) of the total costs of the phase II Environmental Assessments ("Environmental Assessment Cost Credit"), provided that the Environmental Assessment Cost Credit shall not, under any circumstances, exceed One Hundred Thousand ($100,000) Dollars. For the purposes hereof, "Environmental Law(s)" means and includes all federal and State of Michigan laws and regulations relating to the protection of the environment, including laws and regulations relating to the treatment of asbestos. If based on the Environmental Assessments, the Environmental Consultant shall determine the existence of potential costs or Liabilities under any Environmental Law ("Environmental Liability"), Purchaser may elect to terminate this Agreement or provide Seller with written notice of the existence of an Environmental Liability, requesting Seller to proceed pursuant to Section 1.5 in determining the Required Environmental Remediation. If Purchaser elects to terminate this Agreement under this Section, the Deposit shall be returned to the Purchaser and the Agreement shall terminate in accordance with Article 13.

1.5. Special Provisions Relating to Environmental and Product Liabilities.

1.5.1. Environmental Liabilities. Without limiting the generality of Section 1.3.2, the Purchaser and Seller specifically agree that any Environmental Liabilities based on, or arising from, the Operations of the Institute or the conditions of the Real Property Owned before the Closing Date and, whether or not specifically identified in the Environmental Assessments to be conducted by Purchaser pursuant to this Agreement, shall be a Retained Liability of Seller, provided that, subject to the provisions of Article 10, notwithstanding anything contained herein to the contrary, nothing in this Agreement constitutes an agreement by Seller to indemnify Purchaser or any other person from the Retained Liabilities and that the performance by Seller is subject to and conditioned upon the appropriation, by the Legislature of the State of Michigan, of funds needed for such performance. Purchaser agrees that Purchaser shall perform, in good faith prior to the Closing Date, a baseline environmental assessment ("BEA") and disclose the results of the BEA to the appropriate Governmental or Regulatory Authority, pursuant to Section 20126(1)(c) of the Natural Resources and Environmental Protection Act (MCLA 324.20126(1)(c)), for purposes of attempting to obtain an exemption from liabilities relative to any pre-existing environmental

contamination. The parties acknowledge that the Environmental Assessments may be utilized by Purchaser in performing and developing the BEA.

1.5.2. Environmental Remediation. The parties acknowledge and agree that the Environmental Assessments may reveal the existence of conditions which a prudent owner and/or operator would consider reasonably necessary to remediate or abate under applicable law ("Required Environmental Remediation"). It is further agreed that, for purposes of this Agreement, the dimension, type, scope and costs of the Required Environmental Remediation shall be determined solely by the Environmental Consultant, whose determination shall be binding upon the parties ("Remediation Plan"). Notwithstanding the foregoing, the Remediation Plan shall only include environmental remediation and asbestos abatement that (i) a prudent owner and/or operator would consider reasonably necessary under applicable law given the current condition of the Real Property Owned and (ii) a prudent owner/operator would consider reasonably necessary under applicable law assuming that the structural demolitions and/or renovations described on Schedule 1.5.2 were performed within two (2) years of the Closing Date. The estimated costs of implementing the Remediation Plan as determined by the Environmental Consultant shall be the "Environmental Plan Costs". It is agreed that the Environmental Plan Costs shall include only those amounts which represent the estimated incremental costs related to the environmental remediation and/or asbestos abatement. If Purchaser elects not to terminate this Agreement pursuant to Section 1.4, then Purchaser shall release Seller from any responsibility relating to the Required Environmental Remediation which is specifically identified by the Environmental Consultant from the Environmental Assessments, in consideration of receiving a credit against the Purchase Price equal to the Environmental Plan Costs, provided that such credit shall be applied first to the cash portion of the Purchase Price due at Closing of up to Five Hundred Thousand ($500,000) Dollars and the remainder of the Environmental Plan Costs, if any, being credited, up to an maximum of an additional Five Hundred Thousand ($500,000) Dollars, against the amount due by Purchaser to Seller under Promissory Note # 3 ("Note #3") referred to in Section 1.6.2.3.3 of this Agreement ("Environmental Remediation Credit"); provided, however, that Purchaser shall retain its right to make a claim against the Escrow Fund for any Environmental Liability not specifically identified in the Environmental Assessments. Notwithstanding anything contained herein to the contrary, Purchaser shall account to Seller for all actual third party costs and expenses incurred relative to implementing the Remediation Plan ("Actual Remediation Costs"), which Actual Remediation Costs shall be charged against the Environmental Remediation Credit. To the extent that the projects described on Schedule 1.5.2 are funded in whole or in part by the Department of Defense or any United States governmental entity, the Purchaser shall use its best efforts to include the "Environmental Plan Costs" associated with such project(s) in that funding. If upon completion of all phases of the Remediation Plan or a date which is two (2) years from the Closing Date, whichever occurs first ("Remediation Completion Date"), the total Actual Remediation Costs are less than the Environmental Remediation Credit, then the parties agree that Purchaser shall pay, within ten (10) days from the Remediation Completion Date, to Seller the amount that the Environmental Remediation Credit exceeds the Actual Remediation Costs. Seller shall not be responsible for any Actual

Remediation Costs in excess of the Environmental Remediation Credit.

1.5.3. Product Liability. The Purchaser and Seller specifically agree that all Liabilities under any product liability or other theory whatsoever (including breach of warranty, negligence, strict liability, violation of Law or otherwise) ("Product Liability") relating to raw materials, work in process or products that are part of the Purchased Assets (including the Product Inventory), whether manufactured or in the process of manufacture on or prior to the Closing Date by the Institute or the Division shall be included in the Assumed Liabilities; provided, however, that Seller's Retained Liabilities shall include Product Liability for products to which ownership has been transferred or delivered to third party customers prior to the Closing Date, including, but not limited to, any products currently held for the United States Department of Defense on the Institute premises under the Stockpile Agreement. Product Liability for products to which ownership is transferred or delivered to third party customers on or after the Closing Date shall be included in Purchaser's Assumed Liabilities.

1.6. Purchase Price, Allocation.

1.6.1. Purchase Price. The aggregate purchase price (the "Purchase Price") for the Purchased Assets shall, in addition to the Assumed Liabilities, be as follows:

1.6.1.1. Fifteen Million Four Hundred Thousand ($15,400,000) Dollars plus;

1.6.1.2. Purchaser shall donate to Seller the donated products (the "Donated Products") pursuant to a Preferential Access Agreement in the form attached hereto as Exhibit E (the "Preferential Access Agreement") to be executed and delivered by or on behalf of Purchaser and Seller at the Closing; plus

1.6.1.3. Purchaser shall pay to Seller, on an annual basis, (i) a five (5%) percent royalty on all Net Domestic Sales, excluding Domestic Civil Anthrax Sales of Purchaser, plus a three (3%) percent royalty on all Pre-Commission International Sales of Purchaser, up to a maximum of One Million ($1,000,000) Dollars per year (limited to an aggregate of Five Million ($5,000,000) Dollars over the term of this Agreement), for each of five (5) years following the Closing Date (the "Base Royalty Payments"); (ii) a five (5%) percent royalty, without limit, on all the Net Domestic Sales of Purchaser from Domestic Civil Anthrax Sales for each of the six (6) years following the Closing Date and (iii) the Base Royalty Payments shall include a payment for the sixth (6th) year following the Closing Date for sales of anthrax vaccines, other than the Domestic Civil Anthrax Sales only, subject to the overall Five Million ($5,000,000) Dollar limitation. For purposes hereof (w) "Net Domestic Sales" shall mean net sales minus direct marketing expenses or commissions of Purchaser on transactions with customers within the United States; (x) "Pre-Commission International Sales" shall mean net sales of Purchaser on transactions with customers located outside the United States determined without regard to any commissions or direct marketing

expenses; (y) "Domestic Civil Anthrax Sales" shall mean purchases of anthrax vaccines pursuant to any United State governmental programs for civil (non-military) domestic use; and (z) "net sales" shall mean the gross amount of sales revenue in U.S. dollars, (at the commercial rate of exchange in effect on the date of receipt) received by the Purchaser, exclusive of freight, insurance and like charges, and net of any taxes, duties, discounts, returns, refunds and collection costs with respect to products sold.

1.6.1.4. Purchaser shall lease to Seller, or its designated governmental subdivision, that portion of the Real Property Owned which is commonly known as Building 29 (i) for a term of three (3) years (with a two (1) year extension options), (ii) at an initial annual rent ("Annual Rent") of One Hundred Twenty Thousand Seven Hundred Seventy-Three and 16/100 Dollars ($120,773.16) with an agreed upon annual escalation formula and an agreed upon formula for pro-rata pass-throughs of common area maintenance expenses and real property taxes, and (iii) with Purchaser providing to Seller an annual credit against utility and pass-through costs associated with Building 29 of Twenty-Four Thousand Dollars ($24,000.00) ("Annual Utility Credits") (the "Building 29 Lease"). [The Building 29 Lease represents additional consideration being transferred from Purchaser to Seller because (y) of the amount of the Annual Rent, which by agreement of the parties, was calculated to be an amount equivalent to one-half (1/2) of the reasonable market rent for Building 29 and (z) the Annual Utility Credits] The definitive terms and conditions of the Building 29 Lease shall be mutually agreed upon by Purchaser and Seller prior to the Closing Date and upon completion shall be annexed to this Agreement as Exhibit F.

1.6.2. Payment of Purchase Price. The Purchase Price, subject to the Environmental Assessment Credit and the Environmental Remediation Credit pursuant to Sections 1.4 and 1.5 respectively and/or other adjustments pursuant to Section 1.7 of this Agreement, shall be payable at the Closing as follows:

1.6.2.1. Purchaser shall deposit One Million ($1,000,000) Dollars of the Purchase Price, in immediately available funds, in escrow with the Escrow Agent identified in the escrow agreement (the "Escrow Agreement") in substantially the form attached hereto as Exhibit A (such amount together with the additional One Million ($1,000,000) Dollars referred to in Section 1.6.2.3.4 of this Agreement and any earnings thereon is referred to herein as the "Escrow Fund").

1.6.2.2. Purchaser shall pay to Seller the sum of Two Million Two Hundred Fifty Thousand ($2,250,000) Dollars, of the Purchase Price, by wire transfer of immediately available funds to an account designated by Seller prior to the Closing. At Closing the Deposit shall be disbursed to the Seller and applied toward the payment of the amount required by this Section 1.6.2.1.

1.6.2.3. Purchaser shall execute in favor of Seller the following non-negotiable promissory notes in the aggregate amount of Twelve Million One

Hundred Fifty Thousand ($12,150,000) Dollars:

1.6.2.3.1. Promissory Note #1, in substantially the form attached hereto as Exhibit M, in the initial principal amount of Four Million Five Hundred Thousand ($4,500,000) Dollars and bearing interest at a rate of eight (8%) percent and having a five (5) year amortization commencing with the Closing Date with Five Hundred Thousand ($500,000) Dollars of principal due on the first anniversary of the Closing Date and One Million ($1,000,000) Dollars of principal due on each of the four subsequent anniversary dates of the Closing Date.

1.6.2.3.2. Promissory Note #2, in substantially the form attached hereto as Exhibit N, in the initial principal amount of Three Million One Hundred Fifty Thousand ($3,150,000) Dollars and bearing interest at a rate of eight (8%) percent and being payable in full one (1) year from the Closing Date.

1.6.2.3.3. Promissory Note #3, in substantially the form attached hereto as Exhibit O, in the initial principal amount of Four Million Five Hundred Thousand ($4,500,000) Dollars and bearing no interest and being payable in full one (1) year from the Closing Date.

1.6.2.3.4. Notwithstanding anything in the foregoing promissory notes to the contrary, the Purchaser and Seller agree that the first One Million ($1,000,000) Dollars of installments due under such notes shall be deposited by Purchaser into the Escrow Fund.

1.6.2.4. Purchaser's payment obligations to Seller evidenced by Promissory Notes #1, #2 and #3 shall be secured by a mortgage and security agreement (the "Mortgage and Security Agreement") which grants to Seller certain security interests in and to the Collateral, as defined therein, substantially in the form attached hereto as Exhibit H. The Seller agrees to execute a subordination agreement in form and substance reasonably satisfactory to a lender to Purchaser, agreeing to subordinate the Security Agreement, as provided in the Mortgage and Security Agreement. Seller further acknowledges that the Mortgage and Security Agreement provides for (i) the release of the Equine Botulism Assets, as defined in the Mortgage and Security Agreement, in conjunction with a transfer thereof to Neogen Corporation and (ii) certain limitations relative to any Restricted Assets, as defined in the Mortgage and Security Agreement.

1.6.2.5. Purchaser shall provide the Donated Products to Seller as provided in the Preferential Access Agreement.

1.6.2.6. Purchaser shall pay to the Seller Royalty Payments commencing on the first anniversary of the Closing Date, with respect to the prior

year, and semi-annually thereafter, with respect to the prior six-month period, by wire transfer of immediately available funds to an account designated by Seller from time to time in writing.

1.6.3. Allocation of Purchase Price. Subject to applicable law, it is agreed that Purchaser shall, prior to the Closing, propose in writing an allocation of the Purchase Price for Seller's approval, which shall not be unreasonably withheld. Each party hereto agrees (i) that any such allocation shall be consistent with the requirements of Section 1060 of the Code and the regulations promulgated thereunder, (ii) to complete jointly a Form 8594, and (iii) that no party hereto shall take a position that is in any manner inconsistent with the terms of any such allocation without the consent of the other party, which consent shall not be unreasonably withheld or delayed.

1.6.4. Deposit. Simultaneously with the execution of this Agreement, Purchaser agrees to deposit the sum of Two Hundred Fifty Thousand ($250,000) Dollars ("Deposit") with Miller, Canfield, Paddock and Stone, P.L.C., ("Deposit Escrow Agent") to be held and distributed in accordance with the terms and conditions of this Agreement, which Deposit shall be credited toward the Purchase Price in accordance with Section 1.6.2.2 of this Agreement. Deposit Escrow Agent shall execute this Agreement for the sole purpose of agreeing to and acknowledging the terms and conditions contained herein relative to the Deposit.

1.7. Adjustments to Purchase Price.

1.7.1. Adjustment Time. The "Adjustment Time" as used herein shall be 12:01 A.M. current local time on the Closing Date.

1.7.2. Adjustment Items. The following items (the "Adjustment Items") shall be prorated as of the Adjustment Time, assuming a 365-day year or a 30-day or 31-day month, as appropriate, and monies shall be paid at Closing in accordance herewith.

1.7.2.1. Rentals or other charges, payable or paid in respect of leasehold interests or tenancies and any and all equipment leases which comprise a part of the Purchased Assets.

1.7.2.2. Any real and personal property taxes or assessments or fees in lieu of taxes (including sewage assessments and fees), if any, levied or assessed against or otherwise paid or payable with respect to any of the Purchased Assets.

1.7.2.3. Transferrable license, permit, and registration fees, and like items.

1.7.2.4. Charges for utilities (including but not limited to electricity, fuel, water, basic monthly telephone charges, long distance telephone calls, and sanitation and garbage disposal) furnished to or in connection with the Purchased Assets.

1.7.2.5. Unpaid obligations of Seller with respect to any lease, contract, or agreement which Purchaser assumes. Purchaser shall be entitled to a credit against the Purchase Price for any such unpaid obligations relating to a period prior to the Closing Date.

1.7.2.6. Other similar items applicable to the Purchased Assets , it being the intention of the parties that all operations prior to the Adjustment Time shall be for the account of Seller, and all operations after the Adjustment Time shall be for the account of Purchaser.

1.7.3. Adjustments After Closing Date. If the amount of any items to be adjusted cannot be readily ascertained or agreed upon on the Closing Date, proration of such items shall be determined within sixty (60) days after the Closing Date and payment therefor shall be made to the party entitled thereto within five (5) days after notice of such determination thereof has been given to Purchaser or Seller, as the case may be.

1.8. Closing. The Closing shall take place at the offices of Miller, Canfield, Paddock and Stone, P.L.C., Lansing Michigan, or at such other place as Purchaser and Seller mutually agree, at 10:00 a.m. local time, on the Closing Date.

1.9. Closing Costs. Each of the parties shall bear their respective costs related to the Closing, provided that (i) Purchaser shall pay all costs associated with the issuance of the Title Policy and the Survey, fees associated with the recordation of the Security Agreement, all transfer taxes and/or documentary stamps, if any, related to the transfer of the Real Property Owned and one-half of any escrow fees associated with the Escrow Agreement; and (ii) Seller shall pay all fees associated with the recordation of the Quit Claim Deed and one-half of any escrow fees associated with the Escrow Agreement.

1.10. Further Assurances, Post-Closing Cooperation.

1.10.1. Seller Documents. Subject to the terms and conditions of this Agreement, at any time and from time to time after the Closing, at Purchaser's reasonable request, Seller shall execute and deliver to Purchaser such other instruments of sale, transfer, conveyance, assignment as Purchaser may reasonably deem necessary or desirable in order to more effectively transfer, convey and assign to Purchaser, the Purchased Assets upon terms consistent with the provisions of this Agreement.

1.10.2. Purchaser Documents. Subject to the terms and conditions of this Agreement, at any time and from time to time after the Closing, at Seller's reasonable request, Purchaser shall execute and deliver to Seller such other instruments of assumption as Seller may reasonably deem necessary or desirable in order to more effectively give effect to Purchaser's obligations under Section 1.3.1 of this Agreement.

1.10.3. Access to Records. Following the Closing, each of Purchaser and Seller shall afford the other party, its counsel and its accountants, during normal business hours, reasonable access to the books, records and other data relating to the Operations

of the Institute in its possession with respect to periods through the Closing and the right to make copies and extracts therefrom to the extent that such access may be reasonably required by the requesting party in connection with (i) the preparation of Tax Returns, (ii) any tax audit, tax protest or other proceeding relating to Taxes, (iii) the determination or enforcement of rights and obligations under this Agreement or the transactions contemplated hereby, (iv) compliance with the requirements of any Governmental or Regulatory Authority, (v) the determination or enforcement of the rights and obligations of any Person entitled to indemnification hereunder, (vi) the determination or verification of the amount of Royalty Payments payable by Purchaser to Seller; or (viii) in connection with any actual or threatened Actions or Proceedings. Further, the Purchaser and Seller each agrees, for a period of ten (10) years after the Closing Date, not to destroy or otherwise dispose of any such books, records and other data unless such party shall first offer in writing to surrender such books, records and other data to the other party and such other party shall not agree in writing to take possession thereof during the thirty (30) day period after such offer is made. Purchaser hereby agrees that in the case of the Institute Books and Records to in no event destroy or dispose of them at any time without having made such offer to Seller (whether during or after such 10 year period). If so requested and at the cost and expense of the requesting party, Purchaser and Seller further agree to cooperate with the other in the conduct of any audit or other proceeding related to Taxes involving the Operations of the Institute. Notwithstanding anything contained herein to the contrary, this Section shall not be construed to extend to records of the Department of Treasury governed by MCL 205.28(1)(f) and access to or disclosure of such records shall be governed thereby. With respect to other records of the State of Michigan, confidentiality, privacy or nondisclosure provisions of law shall likewise take precedence over any commitment to provide records provided in this Section.

1.10.4. Additional Information. If, in order to properly prepare its Tax Returns or other documents or reports required to be filed with any Governmental or Regulatory Authority, it is necessary that either Purchaser or Seller be furnished with additional information, documents or records relating to the Operations of the Institute not referred to in Section 1.10.3, and such information, documents or records are in the possession or control of the other party, such other party shall use its reasonable efforts to furnish or make available such information, documents or records (or copies thereof) at the recipient's request, cost and expense.

1.10.5. Confidentiality. Except as provided by applicable law, any information obtained by Purchaser in connection with this Agreement and the transactions contemplated hereunder shall be held confidential by Purchaser in accordance with the terms of the Confidentiality Agreement, which shall terminate as of the Closing Date. Following the Closing Date and subject to applicable law, including the Michigan Freedom of Information Act ("FOIA") and the exceptions thereto, the Seller shall have the same obligations of confidentiality with respect to Purchaser's confidential information as the Purchaser's had with respect to Seller's confidential information under the Confidentiality Agreement. Seller agrees to provide Purchaser with written notice of any FOIA requests which seek disclosure of Purchaser's proprietary materials.

1.10.6. Adversarial Relationship. Notwithstanding anything to the contrary contained in this Section 1.10, if Seller and Purchaser are in an adversarial relationship in litigation or arbitration, the furnishing of information, documents or records in accordance with this Section 1.10. that are related to such adversarial relationship shall be subject to applicable rules relating to discovery in such proceeding.

1.11. Third-Party Consents. To the extent that any Purchased Asset is not assignable or transferable without the consent of another Person, this Agreement shall not constitute an assignment or transfer thereof, an attempted assignment or transfer thereof or an agreement to effect such an assignment or transfer, if such assignment or transfer or attempted assignment or transfer would constitute a breach thereof. Seller and Purchaser shall use their respective commercially reasonable efforts to obtain the consent of such other party to the assignment or transfer of any such Purchased Asset to Purchaser in all cases in which such consent is or may be required for such assignment or transfer. If any such consent shall not be obtained, the parties expressly intend and agree that the beneficial interest in and to such Purchased Asset shall, to the extent permitted by the relevant agreements and applicable Law, pass to Purchaser. Seller and Purchaser each agree (i) that Seller shall hold all such items for the benefit of Purchaser from and after the Closing Date, (ii) to make or complete the assignment or assignments as soon as reasonably possible, and (iii) to cooperate with each other, at Purchaser's expense, in any other reasonable arrangement designed to enable Seller or Purchaser (on behalf of Seller) to fulfill any such agreements until an effective assignment thereof to Purchaser shall have been obtained. The parties further expressly intend and agree that all liabilities and obligations (and including any liabilities arising from any termination of any such agreement or claim of breach or damage by the other party or parties as a result of the transactions contemplated hereby) under or in respect of any such Purchased Asset shall be assumed by Purchaser as of the Closing Date, whether or not the assignment thereof can be made, and all such liabilities and obligations shall constitute Assumed Liabilities under this Agreement. The provisions of this Section shall not affect the right of Purchaser not to consummate the transactions contemplated by this Agreement if the condition to its obligations hereunder contained elsewhere in this Agreement have not been fulfilled.

1.12. Title and Other Matters; Real Property Owned.

1.12.1. Title Commitment. Purchaser may obtain from a reputable title company of its sole selection (the "Title Company") at Purchaser's expense, an ALTA title insurance commitment, without exceptions and with endorsements for access and zoning (the "Title Commitment") covering the Real Property Owned, showing all matters affecting title to the Real Property Owned and binding the Title Company to issue at Closing an Owner's Policy of Title Insurance in the full amount of the Purchase Price. Seller shall instruct the Title Company to deliver, to Purchaser, Seller and the surveyor described in Section 1.12.2 below copies of the Title Commitment and copies of all instruments referenced in Schedule B and Schedule C thereof.

1.12.2. Survey. Purchaser acknowledges that the Seller has previously commissioned the preparation of a survey of the Real Property Owned and that such survey was a part of the due diligence materials heretofore made available to Purchaser.

In addition, Purchaser may, at Purchaser's expense, employ a surveyor or surveying firm, licensed in the State of Michigan to survey the Real Property Owned and prepare and deliver, to Purchaser, the Title Company and Seller an ALTA survey thereof (the "Survey") reflecting the total area of the land comprising the Real Property Owned, the location of all improvements, recorded easements and encroachments, if any, located thereon and all building and set back lines and other matters of record with respect thereto; and, if applicable, showing any flood plain areas.

1.12.3. Title or Survey Objections: Cure of Objections. Purchaser shall, at least twenty (20) days prior to Closing, notify Seller, in writing, of such objections as Purchaser may have to anything contained in the Title Commitment or the Survey. Any item contained in the Title Commitment or any matter shown on the Survey to which Purchaser does not object shall be deemed a Permitted Exception. In the event Purchaser shall notify Seller of objections to title or to matters shown on the Survey at least twenty (20) days prior to Closing, Seller shall have the right to attempt to cure such objections. Within twenty (20) days after receipt of Purchaser's notice of objections, Seller shall notify Purchaser in writing whether Seller will attempt to cure such objections. If Seller elects to attempt to cure, Seller shall have until the Closing Date to attempt to remove, satisfy or cure the same and the Closing Date will be postponed pending completion of the same. If Seller elects not to cure any objections specified in Purchaser's notice under this section or if Seller is unable to effect a cure prior to the Closing, Purchaser shall have the following options: (i) to accept a conveyance of the Real Property Owned subject to the Permitted Exceptions, specifically including any matter objected to by Purchaser which Seller is unwilling or unable to cure, and without a reduction of the Purchase Price; or (ii) to terminate this Agreement by sending written notice thereof to Seller, and upon delivery of such notice of termination, this Agreement shall terminate, the Deposit shall be returned to the Purchaser.

1.12.4. Conveyance of Title. In accordance with the terms of this Agreement, at Closing, Seller shall, by quitclaim deed, convey and transfer to Purchaser such title to the Real Property Owned as will enable the Title Company to issue to Purchaser, at Purchaser's expense, an ALTA Owner's Policy of Title Insurance (the "Title Policy") covering the Real Property Owned, in the full amount of the Purchase Price. Notwithstanding anything contained herein to the contrary, the Real Property Owned may be conveyed subject to the following matters, which shall be deemed to be Permitted Exceptions:

1.12.4.1. the lien of all ad valorem real estate taxes and assessments not yet due and payable as of the date of Closing, subject to adjustment as herein provided;

1.12.4.2. local, state and federal laws, ordinances or governmental regulations, including but not limited to, building and zoning laws, ordinances and regulations, now or hereafter in effect relating to the Real Property Owned that do not materially impair the present or anticipated use of the Real Property Owned; and

1.12.4.3. those items appearing of record or shown on the Survey and, in either case, not objected to by Purchaser at least twenty (20) days prior to the Closing, and any items waived in writing by Purchaser in accordance herewith.

ARTICLE 2.

REPRESENTATIONS OF SELLER

Seller hereby represents to Purchaser as follows:

2.1. Authority. Pursuant to Act 522, Seller has full power and authority to execute and deliver this Agreement and the Related Agreements to which it is a party, to perform its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and has received State Administrative Board authorization, and all other required State of Michigan authorizations, for the execution of this Agreement and the consummation of the transactions contemplated hereby pursuant to Section 5 of Act 522. All conditions of Act 522 have been satisfied. All acts or proceedings required to be taken by Seller to authorize the execution, delivery and performance of this Agreement and all transactions contemplated hereby have been duly and properly taken.

2.2. No Conflicts. To the Knowledge of Seller, the execution and delivery by Seller of this Agreement and the Related Agreements to which it is a party, the performance by Seller of its obligations under this Agreement and such Related Agreements, and the consummation by Seller of the transactions contemplated hereby and thereby will not:

2.2.1. subject to obtaining the consents, approvals and actions, making the filings and giving the notices disclosed on Schedule 2.3 annexed hereto, conflict with or result in a violation or breach of any material term or provision of any Law or Order applicable to the Operations of the Institute.

2.2.2. (i) conflict with or result in a violation or breach of, (ii) constitute (with or without notice or lapse of time or both) a default under, (iii) require Seller to obtain any consent, approval or action of, make any filing with or give any notice to any Person as a result or under the terms of, or (iv) result in the creation or imposition of any Lien upon the Purchased Assets under or pursuant to any Material Contract or License to which Seller is a party or by which the Institute is bound.

2.3. Governmental Approvals and Filings. To the Knowledge of Seller, except as set forth on Schedule 2.3 annexed hereto, no consent, approval or action of, filing with or notice to any Governmental or Regulatory Authority on the part of Seller is required in connection with the execution, delivery and performance of this Agreement or any Related Agreements to which Seller is a party or the consummation of the transactions contemplated hereby or thereby, except where the failure to obtain any such consent, approval or action, to make any such filing or to give any such notice would not reasonably be expected to be material in nature.

2.4. Legal Proceedings. To the Knowledge of Seller and except as disclosed on Schedule 2.4 annexed hereto:

2.4.1. There are no material Actions or Proceedings pending or, to the Knowledge of Seller, threatened against Seller relating to the Operations of the Institute.

2.4.2. There are no material Orders outstanding against Seller relating to the Operations of the Institute.

2.4.3. There are no Actions or Proceedings pending or threatened against Seller which could reasonably be expected to result in the issuance of an Order restraining, enjoining or otherwise prohibiting or making illegal the consummation of any of the transactions contemplated by this Agreement or any Related Agreements.

2.5. Compliance With Laws and Orders. To the Knowledge of Seller, except for enumerated compliance issues identified by the Federal Food and Drug Administration, which Purchaser acknowledges having been informed about during its due diligence efforts, and except as disclosed on Schedule 2.5 annexed hereto, Seller is not in material violation of or in default under any Laws or Order applicable to the Operations of the Institute.

2.6. Material Contracts. To the Knowledge of Seller, each Contract disclosed on Schedule 1.2.1.4 annexed hereto (a "Material Contract") is in force and effect in all material respects and constitutes a legal, valid and binding agreement of Seller, enforceable against Seller in accordance with its terms, except to the extent that enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws relating to or affecting creditors' rights generally, by laws affecting claims against Seller, and by general principles of equity) (regardless of whether such enforceability is considered in a proceeding at law or in equity, and (ii) except as disclosed on Schedule 2.6 annexed hereto, Seller is not in material violation or breach of or default under any such Material Contract.

2.7. Licenses. To the Knowledge of Seller, Schedule 1.2.1.7 contains a list of all Licenses that are material to the Operations of the Institute. All such Licenses are in full force and effect as of the date hereof and except for enumerated compliance issues identified by the Federal Food and Drug Administration, no material Action or Proceeding is pending or threatened seeking the revocation or limitation of any such License.

2.8. Brokers. Except for W.Y. Campbell & Company, whose fees, commissions and expenses are the sole responsibility of Seller, all negotiations relative to this Agreement, the Related Agreements and the Confidentiality Agreement and the transactions contemplated hereby and thereby have been carried out by Seller directly with Purchaser without the intervention of any Person on behalf of Seller in such manner as to give rise to any valid claim by any Person against Purchaser for a finder's fee, brokerage commission or similar payment.

2.9. Binding Effect. This Agreement and the Related Agreements to which Seller is a party, upon execution and delivery by Seller, will be duly executed and delivered by Seller and (assuming due execution and delivery hereof and thereof by Purchaser) will be legal, valid and

binding obligations of Seller enforceable against Seller in accordance with their respective terms except to the extent that enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws relating to or affecting creditors' rights generally, by laws affecting claims against Seller, and by general principles of equity (regardless of whether such enforceability is considered in a proceeding at law or in equity).

2.10. Certain Taxes.

2.10.1. Seller has filed all federal, state and local tax returns required to be filed on account of the Operations of the Institute relating to withholding, social security and unemployment taxes for employees of the Institute, and has paid all taxes shown on those returns and all assessments received by Seller to the extent that they have become due. To the Knowledge of Seller, there are no claims asserted against Seller with regard to employees of the Institute for federal, state or local withholding, social security or unemployment taxes for any period or periods prior to and including the date hereof.

2.10.2. Seller has taken the position that the Institute is an agency or instrumentality of the State of Michigan, and pursuant to Section 35 of Act No. 228 of the Public Acts of 1975 of the State of Michigan, as amended, being Section 208.35 of the Michigan Compiled Laws, is not subject to the Michigan single business tax. Seller has taken the position that the Institute makes no sales of tangible personal property in the ordinary course of its business or for any purpose other than for resale or to and for the use of the federal government or instrumentalities thereof, or other exempt entities, and as such is not subject to the Michigan sales tax or the Michigan use tax. To the Knowledge of Seller, there are no claims asserted against Seller for Michigan single business taxes, or Michigan sales or use taxes relating to the Operations of the Institute for any period or periods prior to and including the date hereof.

2.10.3. Seller has made or accrued all payments of fees in lieu of taxes required under Section 713 of the Worker's Disability Compensation Act, being Section 418.713 of the Michigan Compiled Laws, except those shown on Schedule 2.10.3 annexed hereto. To the Knowledge of Seller, there are not claims asserted against Seller with regard to payments required by said Section 418.713 for any period or periods prior to and including the date hereof.

2.11. Employees. Schedule 2.11 contains a complete and accurate list of name and job title for each employee of the Institute, which includes all contract and Nonactive Employees as defined in Section 9.2.1 hereof.

2.12. Title to Purchased Assets. The Seller owns the Purchased Assets free and clear of all Liens and are not in the case of the Real Property Owned subject to any rights of way, building use restrictions, exceptions, variances, reservations (except for the reservation for the benefit of Seller contained in Section 1.2.1.1 of this Agreement), or limitations of any nature (other than the Permitted Exceptions).

2.13. Year 2000 Compliance Disclaimer. Seller specifically makes no representations

to Purchaser and disclaims any compliance regarding whether any of the equipment and systems which are a part of the Purchased Assets are or will be as of the Closing compliant with any standards or criteria related to year 2000 issues.

ARTICLE 3.

REPRESENTATIONS OF PURCHASER

Purchaser hereby represents to Seller as follows:

3.1. Corporate Existence of Purchaser. Purchaser is a corporation duly organized, validly existing and in good standing under the laws the laws of the State of Michigan. Purchaser has full power and authority to enter into this Agreement and the Related Agreements to which it is a party, to perform its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby.

3.2. Authority. The execution and delivery by Purchaser of this Agreement and the Related Agreements to which it is a party, and the performance by Purchaser of its obligations hereunder and thereunder, have been duly and validly authorized by all necessary action on the part of the Purchaser, no other action on the part of Purchaser or its owners or constituent entities being necessary therefor. All acts or proceedings required to be taken by the Purchaser to authorize the execution, delivery and performance of this Agreement, the Related Agreements, and all transactions contemplated hereby and thereby have been duly and properly taken.

3.3. No Conflicts. To the Knowledge of Purchaser, the execution and delivery by Purchaser of this Agreement do not, and the execution and delivery by Purchaser of the Related Agreements to which it is a party, the performance by Purchaser of its obligations under this Agreement and such Related Agreements and the consummation of the transactions contemplated hereby and thereby will not:

3.3.1. conflict with or result in a violation or breach of any of the terms, conditions or provisions of the certificate (or articles) of incorporation or by-laws (or other comparable constituent documents) of Purchaser;

3.3.2. subject to obtaining the consents, approvals and actions, making the filings and giving the notices disclosed on Schedule 3.3 annexed hereto, conflict with or result in a violation or breach of any term or provision of any Law or Order applicable to Purchaser or any of its assets and properties, other than such conflicts, violations or breaches which would not in the aggregate reasonably be expected to have a Material Adverse Effect on Purchaser; or

3.3.3. except as disclosed on Schedule 3.3 annexed hereto, or as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect on Purchaser, (i) conflict with or result in a violation or breach of, (ii) constitute (with or without notice or lapse of time or both) a default under, (iii) require Purchaser to obtain any consent, approval or action of, make any filing with or give any notice to

any Person as a result or under the terms of, or (iv) result in the creation or imposition of any Lien upon Purchaser or any of its assets and properties under, any material Contract or License to which Purchaser is a party or by which any of its assets and properties are bound.

3.4. Governmental Approvals and Filings. Except as disclosed on Schedule 3.4 annexed hereto, no consent, approval or action of, filing with or notice to any Governmental or Regulatory Authority on the part of Purchaser is required in connection with the execution, delivery and performance of this Agreement or the Related Agreements to which it is a party or the consummation of the transactions contemplated hereby or thereby, except where the failure to obtain any such consent, approval or action, to make any such filing or to give any such notice would not reasonably be expected to have a Material Adverse Effect on Purchaser.

3.5. Legal Proceeding. There are no Actions or Proceedings pending or, to the Knowledge of Purchaser, threatened against, relating to or affecting Purchaser or any of its respective assets and properties which could reasonably be expected to result in the issuance of an Order restraining, enjoining or otherwise prohibiting or making illegal the consummation of any of the transactions contemplated by this Agreement or any Related Agreements.

3.6. Brokers. All negotiations relative to this Agreement, the Related Agreements, the Confidentiality Agreement and the transactions contemplated hereby and thereby have been carried out by Purchaser directly with Seller without the intervention of any Person on behalf of Purchaser in such manner as to give rise to any valid claim by any Person against Seller for a finder's fee, brokerage commission or similar payment.

ARTICLE 4.

COVENANTS OF SELLER

4.1. Regulatory and Other Approvals. After the date hereof and until the earlier of the Closing or the termination of this Agreement, Seller shall (a) take all commercially reasonable steps necessary or desirable, and proceed diligently and in good faith and use all commercially reasonable efforts to obtain all consents, approvals or actions of, to make all filings with and to give all notices to Governmental or Regulatory Authorities or any other Person required of Seller to consummate the transactions contemplated hereby, (b) provide such other information and communications to such Governmental or Regulatory Authorities or other Persons as such Governmental or Regulatory Authorities or other Persons may reasonably request in connection therewith, and (c) provide reasonable cooperation to Purchaser in obtaining all consents, approvals or actions of, making all filings with and giving all notices to Governmental or Regulatory Authorities or other Persons required of Purchaser to consummate the transactions contemplated hereby and by the Related Agreements.

4.2. Investigation of Operations of the Institute; Access to Properties and Records. Subject to Purchaser's compliance with its obligations set forth in Section 1.10.5, after the date hereof until the Closing or earlier termination of this Agreement, Seller shall (a) afford to Purchaser and its officers, employees, counsel, accountants and other representatives

(collectively, the "Purchaser Representatives") reasonable access to the offices, properties, books and records of Seller during normal business hours, in order that Purchaser may have full opportunity to make such investigations of the Operations of the Institute, the Purchased Assets and the Assumed Liabilities as Purchaser shall reasonably request (provided, however, that such investigation shall be upon reasonable notice and shall not unreasonably disrupt the personnel and operations of Seller), and (b) furnish Purchaser and the Purchaser Representatives with all such information and data (including without limitation copies of Contracts, Licenses, benefit plans and other Institute Books and Records) concerning the Operations of the Institute, the Purchased Assets and the Assumed Liabilities as Purchaser or a Purchaser Representative may reasonably request in connection with such investigation, except to the extent that furnishing any such information or data would violate any Law, Order, Contract or License applicable to Seller or by which any of its assets and properties are bound.

4.3. Conduct of Operations of the Institute. From the date hereof to the earlier of the Closing or the termination of this Agreement, except as disclosed in Schedule 4.3 annexed hereto or as otherwise provided for or contemplated herein or approved by Purchaser, Seller shall, subject to Act 522 and other applicable Laws, use commercially reasonable efforts, to the extent consistent with the best interests of the Institute as determined by Seller in good faith, to (a) conduct the Operations of the Institute in the ordinary course, (b) preserve the present business organization of the Institute in all material respects, (c) keep available (subject to dismissals and retirements in the ordinary course of business) the services of employees, agents and consultants of Seller having material business dealings with the Institute, (d) maintain the condition of the Purchased Assets in accordance with past practices, (e) maintain the goodwill of customers, suppliers and other Persons with whom Seller otherwise has significant business relationships in the conduct of the Operations of the Institute; (f) maintain the level of Product Inventory and Accounts Receivable at or about the level which existed as of the date hereof, and (g) maintain in full force and effect its existing policies of insurance which materially affect the Operations of the Institute.

4.4. Fulfillment of Conditions. From the date hereof to the earlier of the Closing or the termination of this Agreement, Seller shall take all commercially reasonable steps necessary or desirable and proceed diligently and in good faith to satisfy (but not waive) each condition within its reasonable control to the obligations of the parties hereto contained herein.

4.5. Exclusive Dealing. The Seller shall not, after the execution of this Agreement and prior to the Closing, directly or indirectly (a) solicit, initiate, enter into or negotiate, any contract with or make or accept any offer from, any Person (other than Purchaser and any Person designated by Purchaser) regarding the sale, transfer or other disposition, directly or indirectly, of any equity or other interest in the Institute or any part of any of its businesses, assets or properties, or encourage the initiation of any inquiries of offers or participate in any discussion with respect to any such sale, transfer or other disposition, or (b) subject to applicable law, including the Michigan Freedom of Information Act, disclose any non-public information relating to the Institute or its businesses, assets or properties or afford access to its assets, properties, books or records to any other Person that the Person making such disclosure believes may be considering acquiring an equity or other interest in the Institute or any of its respective businesses, assets or properties.

ARTICLE 5.

COVENANTS OF PURCHASER

5.1. Regulatory and Other Approvals. After the date hereof and until the earlier of the Closing or the termination of this Agreement, Purchaser shall (a) take all commercially reasonable steps necessary or desirable, and proceed diligently and in good faith and use all commercially reasonable efforts to obtain all consents, approvals or actions of, to make all filings with and to give all notices to any Governmental or Regulatory Authority or any other Person required of Purchaser to consummate the transactions contemplated hereby, (b) provide such other information and communications to such Governmental or Regulatory Authority or other Persons as such Governmental or Regulatory Authority or other Persons may reasonably request in connection therewith, and (c) provide reasonable cooperation to Seller in obtaining all consents, approvals or actions of, making all filings with and giving all notices to any Governmental or Regulatory Authority or other Persons required of Seller to consummate the transactions contemplated hereby and by the Related Agreements.

5.2. Fulfillment of Conditions. From the date hereof and until the earlier of the Closing or the termination of this Agreement, Purchaser shall take all commercially reasonable steps necessary or desirable and proceed diligently and in good faith to satisfy (but not waive) each condition within its reasonable control to the obligations of the parties hereto contained herein.

ARTICLE 6.

CONDITIONS TO OBLIGATIONS OF PURCHASER

The obligations of Purchaser hereunder to purchase the Purchased Assets and to assume the Assumed Liabilities, are subject to the fulfillment, at or before the Closing, of each of the following conditions (all or any of which may be waived in whole or in part by Purchaser in its sole discretion to the extent permitted under applicable Law):

6.1. Representations. The representations made by Seller in this Agreement shall be true and correct in all material respects on and as of the Closing Date as though made on and as of the Closing Date.

6.2. Performance. Seller shall have performed and complied with, in all material respects, the agreements, covenants and obligations required by this Agreement to be so performed or complied with by Seller at or before the Closing.

6.3. Seller Closing Certificate. Seller shall have delivered to Purchaser a certificate, dated the Closing Date and executed on its behalf by its authorized officer or agent, substantially in the form and to the effect of Exhibit I hereto.

6.4. Orders. There shall not be in effect on the Closing Date any Order restraining, enjoining or otherwise prohibiting or making illegal the consummation of any of the transactions contemplated by this Agreement or any of the Related Agreements.

6.5. Regulatory Consents and Approvals. All consents, approvals and actions of, filings with and notices to any Governmental or Regulatory Authority listed on Schedule 2.3 and Schedule 3.4, which are necessary to permit Purchaser and Seller to perform their respective obligations under this Agreement and the Related Agreements and to consummate the transactions contemplated hereby and thereby, and all material Licenses necessary to permit Purchaser to own and operate the Purchased Assets after the Closing Date, shall have been duly obtained, made or given and shall be in full force and effect, and all terminations or expirations of waiting periods imposed by any Governmental or Regulatory Authority necessary for the consummation of the transactions contemplated by this Agreement and the Related Agreements shall have occurred.

6.6. Third Party Consents. The consents (or waivers in lieu thereof) listed on Schedule 6.6 annexed hereto shall have been obtained and shall be in full force and effect.

6.7. Transfer Instruments. Seller shall have delivered to Purchaser a quit claim deed for to the Real Property Owned, in the form of Exhibit B ("Quit Claim Deed") ; a bill of sale and general assignment for the Tangible Personal Property, Intangible Personal Property and Books and Records, in the form of Exhibit C ("Bill of Sale and General Assignment"); and an Assignment and Assumption Agreement of the Contracts, Licenses, Personal Property Leases, Assigned Accounts Receivables and Assumed Liabilities, in the form of Exhibit D (the "Assignment and Assumption Agreement").

6.8. Legislation. Purchaser shall have received a copy of the legislation authorizing the transactions contemplated under this Agreement, certified by the Secretary of State of Michigan.

6.9. State Administrative Board Resolutions. Purchaser shall have received a copy of the resolutions adopted by the State Administrative Board authorizing the execution of this Agreement and the consummation of the transactions contemplated hereby pursuant to Section 5 of Act 522.

6.10. Opinion of Counsel. Purchaser shall have received an opinion of counsel for Seller in substantially the form attached hereto as Exhibit J.

6.11. Environmental Assessments. Subject to the provisions of Sections 1.4 and 1.5, the Environmental Assessments shall have been completed and the results shall be satisfactory to Purchaser in its sole and absolute discretion.

ARTICLE 7.

CONDITIONS TO OBLIGATIONS OF SELLER

The obligations of Seller hereunder to sell the Purchased Assets are subject to the fulfillment, at or before the Closing, of each of the following conditions (all or any of which may be waived in whole or in part by Seller in its sole discretion to the extent permitted under applicable Law):

7.1. Representations. The representations made by Purchaser in this Agreement shall be true and correct in all material respects on and as of the Closing Date as though made on and as of the Closing Date.

7.2. Performance. Purchaser shall have performed and complied with, in all material respects, the agreements, covenants and obligations required by this Agreement to be so performed or complied with by Purchaser at or before the Closing.

7.3. Purchaser's Closing Certificate. Purchaser shall have delivered to Seller a certificate, dated the Closing Date and executed on its behalf by the Chairman of the Board, the President or any Vice President, substantially in the form and to the effect of Exhibit K hereto.

7.4. Orders. There shall not be in effect on the Closing Date any Order restraining, enjoining or otherwise prohibiting or making illegal the consummation of any of the transactions contemplated by this Agreement or any of the Related Agreements.

7.5. Regulatory Consents and Approvals. All consents, approvals and actions of, filings with and notices to any Governmental or Regulatory Authority listed on Schedule 2.3 or Schedule 3.4 annexed hereto, which are necessary to permit Seller and Purchaser to perform their respective obligations under this Agreement and the Related Agreements and to consummate the transactions contemplated hereby and thereby shall have been duly obtained, made or given and shall be in full force and effect, and all terminations or expirations of waiting periods imposed by any Governmental or Regulatory Authority necessary for the consummation of the transactions contemplated by this Agreement and the Related Agreements shall have occurred.

7.6. Third Party Consents. The consents (or waivers in lieu thereof) listed on Schedule 6.6 annexed hereto shall have been obtained and shall be in full force and effect.

7.7. Authorization Documents. Seller shall have received the following:

7.7.1. a certified copy of the articles of incorporation and bylaws (or comparable governing documents) of Purchaser.

7.7.2. a certified copy of the resolutions duly adopted by the Board of Directors (or comparable governing body) of Purchaser authorizing the execution and delivery of this Agreement and the Related Agreements and the consummation of the transactions contemplated hereby and thereby.

7.7.3. an incumbency certificate with respect to each Person executing this Agreement or any of the Related Agreements on behalf of Purchaser.

7.8. Opinion of Counsel. Seller shall have received an opinion of counsel for Purchaser in substantially the form attached as Exhibit L hereto.

ARTICLE 8.

MUTUAL CONDITIONS TO OBLIGATIONS OF PARTIES

The obligations of Purchaser and Seller hereunder to consummate the purchase and sale transaction contemplated by this Agreement are subject to the fulfillment, at or before the Closing, of each of the following conditions (all or any of which may be waived in whole or in part by the appropriate party in its sole discretion to the extent permitted under applicable Law):

8.1. FDA and USDA Approval. Seller and Purchaser shall have received all required approvals, if any, to the transfer and/or renewal of all United States Food and Drug Administration and United States Department of Agriculture licenses and permits currently held by the Institute to, or in the name of, Purchaser.

8.2. U.S. Department of Defense Contracts. Purchaser and Seller shall have cooperated with each other in negotiations with the United States Department of Defense ("DOD") regarding existing contractual issues and relationships, including the timing of invoicing for products, the payment of accounts receivable due the Seller and the assignment (including novation) of Seller's interests in existing DOD contracts to Purchaser ("DOD Negotiations"). The DOD Negotiations shall have resulted in (i) novation agreements with the DOD in form and substance satisfactory to the Purchaser and Seller consenting to the assignment to Purchaser of Seller's interest in and to all then in effect Contracts ("Existing DOD Contracts") between Seller and DOD ("Novation Agreement"); (ii) an agreement with DOD as to the total amount currently due to Seller under the Existing DOD Contracts ("DOD Accounts Receivable"); (iii) an agreement with DOD as to the timing and amounts of additional invoices to be issued to DOD pursuant to the Existing DOD Contracts ("DOD Invoices"); and (iv) an agreement with DOD as to the timing and payment of the DOD Accounts Receivable and DOD Invoices ("DOD Payments"). In this regard:

8.2.1. Notwithstanding anything contained herein to the contrary, if Purchaser and Seller are unable, on or before August 31, 1998, to obtain the Novation Agreement; establish the DOD Accounts Receivable; establish the timing for issuance of the DOD Invoices; or establish the timing for the DOD Payments, this Agreement shall automatically terminate and the Deposit shall be returned to the Purchaser.

8.2.2. Purchaser and Seller shall have identified the Assigned Accounts Receivable from the Existing DOD Accounts Receivable, which Assigned Accounts Receivable shall have a face amount of $4,500,000 and DOD shall have agree to make DOD Payments in satisfaction of the Assigned Accounts Receivable at or immediately following the Closing. It is anticipated that the Assigned Accounts Receivable will be identified from the Existing DOD Accounts Receivable from DOD Contracts DAMD-17-91-C1139 and DAMD-17-97-D-0003. *

8.2.3. Seller shall have reasonably assisted Purchaser in negotiations with DOD regarding the currently proposed DOD Contract DAMD-17-97-R-0014.

8.3. Termination of SKB and NABI Agreements. Seller shall have terminated the

existing agreements between the Institute and SmithKline Beecham and NABI ("Releasing Parties") and the Releasing Parties shall have given Seller and Purchaser a general release relative to any and all of the Releasing Parties' interests in any of the Purchased Assets and all Contracts between the Releasing Parties and the Seller, such termination and releases to be in form and substance satisfactory to Seller and Purchaser.

8.4. Assignment and Assumption Agreement. Seller and Purchaser shall have executed and delivered to the other party the Assignment and Assumption Agreement, in the form of Exhibit D.

8.5. Preferential Access Agreement. Seller and Purchaser shall have executed and delivered to the other party the Preferential Access Agreement in the form of Exhibit E.

8.6. Building 29 Lease. Seller and Purchaser shall have executed and delivered to the other party the Building 29 Lease, which is a leaseback to Seller, or its designated governmental subdivision, of that portion of the Real Property Owned commonly known as Building 29, in the form to be annexed hereto as Exhibit F upon completion by the parties.

8.7. Right of First Refusal and Conditional Option Agreement. Seller and Purchaser shall have executed and delivered to the other party the Right of First Refusal and Conditional Option Agreement in the form of Exhibit G.

8.8. Transition Services Agreement. Seller and Purchaser shall have executed and delivered to the other party the Transition Services Agreement, if one is mutually agreed upon by Seller and Purchaser; provided, however, that the failure of the Seller and Purchaser to agree on a Transition Services Agreement shall not give either party a right to terminate this Agreement.

8.9. Escrow Agreement. Seller, Purchaser and the Escrow Agent shall have executed and delivered to each other the Escrow Agreement in the form of Exhibit A.

8.10. Schedules. Seller and Purchaser shall have mutually agreed upon all of the Schedules referenced herein, which were not annexed to this Agreement as of the date of execution by the parties hereto ("Incomplete Schedules"), and the Incomplete Schedules shall have been annexed to this Agreement and initialled by the parties.

ARTICLE 9.

EMPLOYEE MATTERS

9.1. Collective Bargaining Agreements. Seller has negotiated collective bargaining agreements with the Michigan State Employees Association; the United Technical Employees Association; and the Michigan Professional Employees Society covering certain employees of the Institute (the "Union Agreements"). Purchaser shall comply with all applicable federal and state law with respect to the employees of the bargaining units under the Union Agreements; provided, however, it is agreed and acknowledged that (i) Purchaser shall not be responsible for,

and shall not assume, any of Seller's obligations under the Union Agreements, all of which shall constitute Retained Liabilities of Seller and (ii) Seller shall not be responsible for any employment matters accruing on or subsequent to the Closing Date relative to Employees hired by Purchaser pursuant to this Article of this Agreement.

9.2. Employees.

9.2.1. All employees of the Institute (including contract employees and Nonactive Employees, as defined herein) listed on Schedule 2.11 shall cease employment with the Institute as of the Closing Date and simultaneously shall be offered employment by Purchaser for a period of at least one (1) year from the Closing Date ("Minimum Employment Period"). Seller represents to Purchaser that Schedule 2.11 lists all Employees of the Institute, including Employees who on the Closing Date had rights to return to employment under Seller's policies and procedures ("Seller Procedures") (such as employees on an approved medical or disability leave of absence, approved personal leave of absence or former employees of the Institute having recall rights pursuant to a written layoff policy) ("Nonactive Employees"). Purchaser agrees to offer employment to any Nonactive Employee, for the remainder of the Minumum Employment Period, at such time as an Nonactive Employee becomes eligible, under the Seller Procedures, to return to work .

9.2.2. Seller shall remain responsible under Civil Service requirements and the applicable Union Agreements to give any and all notices that are required upon layoff, termination of employment or sale of the business. Seller shall comply with all applicable federal and state laws and any obligations under the Union Agreements with respect to the termination of the employees of the Institute, all of which shall constitute Retained Liabilities of the Seller.

9.2.3. All employees of the Institute who elect to be employed by Purchaser as a result of the transaction contemplated herein shall be offered employment with Purchaser pursuant to the requirements of M.C.L.A. §333.26335(c) for a period of not less than one year from the Closing Date (or such shorter period as Purchaser may remain in business), provided that this commitment shall not affect Purchaser's ability to terminate an employee for "cause," and provided further that Purchaser shall have the sole and absolute discretion to determine the compensation and benefits for all such employees. For these purposes, for "cause" shall mean the employee's failure to comply with the rules, policies and procedures for employees as adopted by Purchaser in its sole and absolute discretion.

9.3. Employee Benefits.

9.3.1. It is agreed and acknowledged that Seller shall be fully responsible for, and shall have all obligations and liabilities with respect to, the plans, contracts, programs and arrangements, including, but not limited to, pensions, bonuses, deferred compensation, retirement, severance, hospitalization, dental, prescription drug, life, accidental death and dismemberment, sickness and accident, salary continuation, and

other employee benefit plans, programs or arrangements ("Employee Benefits") maintained by Seller with respect to the Employees of the Institute, accruing during their respective periods of employment with the Institute, all of which shall constitute Retained Liabilities of the Seller.

9.3.2. It is agreed and acknowledged that Purchaser shall be fully responsible for, and shall have all obligations and liabilities with respect to any Employee Benefits which may be provided by Purchaser with respect to the former Employees of the Institute who become employed by Purchaser as of or subsequent to the Closing Date.

ARTICLE 10.

REIMBURSEMENT OF PURCHASER FROM ESCROW FUND

10.1. Reimbursement of Purchaser Escrow Fund.

10.1.1. Escrow Claims. For a period of two (2) year from the Closing Date, Purchaser shall, subject to applicable legal and equitable defenses, have the right to make claims for reimbursement from the Escrow Fund ("Escrow Claim(s)") for any Damages incurred or suffered by Purchaser that directly result from, relate to or arise out of:

10.1.1.1. a material misrepresentation or nonfulfillment of any provision, agreement or covenant on the part of Seller under this Agreement; or

10.1.1.2. a Retained Liability.

10.1.2. Contents of Escrow Claims. Any Escrow Claim of Purchaser shall contain a detailed statement of nature of the claim or demand and the amount or estimated amount of the Damages attendant thereto and be sent by Purchaser in writing to the Seller with a copy to the Escrow Agent.

10.1.3. Conditions of Escrow Claims. Notwithstanding anything to the contrary contained in this Agreement or in any Exhibit or Schedule hereto, no Escrow Claim shall be reimbursed from the Escrow Fund, and no Liability shall otherwise accrue pursuant to this Section 10.1 or otherwise if either:

10.1.3.1. the amount of the Escrow Claim, either as demanded or as settled or adjudicated, is less than Ten Thousand and no/100 Dollars ($10,000); provided that any Escrow Claim which equals or exceeds Ten Thousand ($10,000) Dollars may be subjected to the provisions of this Article 10 in the full amount of the Escrow Claim; or

10.1.3.2. if the cumulative total of Confirmed Escrow Claims, counting only those Confirmed Escrow Claims settled or adjudicated for amounts in excess of Ten Thousand and no/100 Dollars ($10,000), exceeds the balance of the Escrow Fund, in which circumstance only the difference between such cumulative

total and the balance of the Escrow Fund shall be subject to potential reimbursement hereunder, assuming that all of the other necessary conditions for such reimbursement, as provided in this Agreement, are satisfied.

10.2. Purchaser's Method of Asserting Escrow Claims.

10.2.1. Direct Escrow Claims. In the event Purchaser should have an Escrow Claim that does not involve a claim or demand being asserted against or sought to be collected from Purchaser by a third party, Purchaser shall promptly send a written notice with respect to such claim to Seller and the Escrow Agent. If Seller does not give written notice to Purchaser within twenty (20) Business Days from the personal delivery or mailing of such notice from Purchaser, that Seller acknowledges and agrees with such Escrow Claim, then such Escrow Claim shall be deemed to be in dispute and shall be resolved in accordance with Section 10.2.3. If Seller acknowledges and agrees with the Escrow Claim as to subject matter and amount, in writing, then such Escrow Claim shall become a Confirmed Escrow Claim and shall be paid in accordance with the provisions of the Escrow Agreement.

10.2.2. Third Party Claims. In the event that an Escrow Claim is asserted due to a claim against Purchaser by a third party, the following procedures shall apply, and Purchaser shall comply with such procedure and be bound by such procedure and the consequences thereof:

10.2.2.1. Purchaser shall promptly notify Seller and the Escrow Agent of the Escrow Claim, identifying it as having arisen due to a claim of a third party and specifying the nature of the claim and the amount or the estimated amount to the extent then feasible (the "Purchaser's Notice"); provided, however, that the failure to give prompt notice shall not adversely affect an Escrow Claim except to the extent that the Seller is prejudiced thereby.

10.2.2.2. Seller shall have twenty (20) Business Days from the personal delivery or mailing of the Purchaser's Notice (the "Purchaser's Claim Notice Period") to notify Purchaser in writing, (i) whether or not Seller disputes its liability to Purchaser hereunder with respect to such Escrow Claim and (ii) whether or not Seller desires, at Seller's sole cost and expense, to defend Purchaser against such third party claim or demand. Failure to provide written notice to Purchaser within the Purchaser's Claim Notice Period shall result in the Escrow Claim being deemed disputed and that the Seller shall be deemed to have elected not to defend Purchaser against such third party claim or demand.

10.2.2.3. In the event that Seller notifies Purchaser within the Purchaser's Claim Notice Period that Seller both acknowledges and agrees to the Escrow Claim identified in Purchaser's Notice and desires to defend Purchaser against such third party claim or demand, then Seller shall have the right to defend Purchaser by appropriate proceedings, subject to the following conditions:

10.2.2.3.1. The proceedings shall be settled or prosecuted by Seller, in good faith, to a final conclusion;

10.2.2.3.2. Without the prior written consent of Purchaser, which consent shall not be unreasonably withheld or delayed, Seller shall not consent to the entry of any judgment against Purchaser or enter into any settlement or compromise which does not include, as an unconditional term thereof, the giving by the claimant or plaintiff to Purchaser of a release, in form and substance reasonably satisfactory to Purchaser, from all liability in respect of such claim or litigation;

10.2.2.3.3. If Purchaser desires to participate in, but not control, any such defense or settlement, it may do so at its sole cost and expense.

10.2.3. Disputed Escrow Claims. If an Escrow Claim is disputed or deemed to have been disputed by Seller ("Disputed Escrow Claim"), then such Disputed Escrow Claim shall be resolved (A) by written agreement between Seller and Purchaser, (B) by written arbitration award rendered pursuant to Section 15.17 hereof. A Disputed Escrow Claim which is resolved as being an Escrow Claim for which Seller is responsible, shall become a Confirmed Escrow Claim hereunder.

10.2.4. Confirmed Escrow Claim. A "Confirmed Escrow Claim" shall be an Escrow Claim, the amount of which is (A) set forth in the written agreement between Seller and Purchaser, (B) set forth in an arbitration award rendered pursuant to Section 15.17 hereof. All Confirmed Escrow Claims shall be paid to Purchaser out of the Escrow Fund.

ARTICLE 11.

DISCLAIMERS; LIMITATIONS ON REPRESENTATIONS

11.1. Disclaimer of Projections and Memorandum; No Other Representations.

11.1.1. Seller makes no representation to Purchaser except as specifically made in Article 3 of this Agreement and Purchaser acknowledges and agrees that it is not relying on any representation other than those set forth in Article 3 . In particular, Seller makes no representation to Purchaser with respect to, and Purchaser acknowledges and agrees that it is not relying on, and that Seller shall have no liability with respect to:

11.1.1.1. the information set forth in the Confidential Memorandum distributed by W.Y. Campbell & Company in connection with the offering of the Institute, or

11.1.1.2. any financial or other projection or forecast relating to the Operations of the Institute. With respect to any such projection or forecast delivered by or on behalf of Seller to Purchaser, Purchaser acknowledges that (1)

there are uncertainties inherent in attempting to make such projections and forecasts, (2) it is familiar with such uncertainties, (3) it is taking full responsibility for making its own evaluation of the adequacy and accuracy of all such projections and forecasts so furnished to it and (4) it shall have no claim against Seller or any subdivision, department, agency, attorney, agent, officer, employee or independent contractor thereof (or against W.Y. Campbell & Company) with respect thereto.

11.1.2. Notwithstanding anything to the contrary contained in this Agreement, Purchaser acknowledges and agrees that except for the representations made by the Seller in Article 3 hereof, (a) the Purchased Assets are being conveyed to Purchaser on an "AS IS and WHERE IS" basis and (b) SELLER IS NOT MAKING ANY OTHER REPRESENTATION OR WARRANTY WHATSOEVER, WHETHER EXPRESS OR IMPLIED, WITH RESPECT TO THE TITLE, RIGHT TO TRANSFER, ENCUMBRANCES, DESIGN, CAPACITY, CONDITION, SAFETY, PERFORMANCE, VALUE, UTILITY, COMPLIANCE WITH LAWS OR REGULATIONS (INCLUDING ENVIRONMENTAL LAWS AND REGULATIONS) OR OTHERWISE IN CONNECTION WITH THE SALE, ASSIGNMENT OR TRANSFER OF THE PURCHASED ASSETS, THE TRANSACTIONS CONTEMPLATED HEREBY OR ANY MATTER RELATED HERETO, NOR IS IT MAKING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE, ALL OF WHICH ARE HEREBY EXPRESSLY DISCLAIMED.

11.2. Purchaser's Knowledge of Institute. Purchaser hereby acknowledges that its has been provided reasonable opportunity to review the (i) Operations of the Institute and (ii) Books and Records of the Institute ("Due Diligence") and agrees that such Due Diligence has provided Purchaser with a reasonable working knowledge and information regarding the Institute and the Operations of the Institute, independent of the representations of Seller. Notwithstanding the foregoing, however, the Purchaser shall have the right to rely on the representations, covenants and agreements of the Seller contained in this Agreement.

ARTICLE 12.

INDEMNIFICATION BY PURCHASER

12.1. General Indemnification Obligation of Purchaser.

12.1.1. For a period of two (2) years from and after the Closing, Purchaser shall, subject to applicable legal and equitable defenses, reimburse, defend, indemnify and hold harmless Seller and all subdivisions, departments, agencies, attorneys, agents, officers, employees (for purposes of this Article 12, such persons shall be deemed to be included with the term "Seller") thereof against and in respect of any and all Damages incurred or suffered by Seller that result from, relate to or arise out of an act or omission of Purchaser relative to either of the following:

12.1.1.1. the Assumed Liabilities; or

12.1.1.2. any material misrepresentation or nonfulfillment of any provision, agreement or covenant on the part of Purchaser under this Agreement.

12.1.2. Contents of Indemnity Claims. Any Indemnity Claim of Seller shall contain a detailed statement of the nature of the claim or demand and the amount or estimated amount of the Damages attendant thereto, and be sent by Seller in writing to the Purchaser.

12.1.3. Conditions of Indemnity Claims. Notwithstanding anything to the contrary contained in this Agreement or in any Exhibit or Schedule hereto, no Indemnity Claim shall be paid by the Purchaser if the amount of Indemnity Claim, either as demanded or as settled or adjudicated, is less than Ten Thousand Dollars ($10,000); provided that if an Indemnity Claim equals or exceeds Ten Thousand ($10,000) Dollars, then such Indemnity Claim may be subject to the proceedures of this Article 12 in the full amount of the Escrow Claim.

12.2. Seller's Method of Asserting Indemnity Claims, Etc.

12.2.1. Direct Indemnity Claims. In the event Seller should have an Indemnity Claim that does not involve a claim or demand being asserted against or sought to be collected from Seller by a third party, Seller shall promptly send a written notice with respect to such claim to Purchaser. If Purchaser does not give written notice to Seller within ten (10) Business Days from the personal delivery or mailing of such notice from Seller, that Purchaser acknowledges and agrees with such Indemnity Claim, then such Indemnity Claim shall be deemed to be in dispute and shall be resolved in accordance with Section 12.2.3. If Purchaser acknowledges and agrees with the Indemnity Claim as to subject matter and amount, then such Indemnity Claim shall become a Confirmed Indemnity Claim and shall be paid by Purchaser to Seller promptly thereafter.

12.2.2. Third Party Claims. In the event that an Indemnity Claim is asserted due to a claim against Seller by a third party, the following procedures shall apply, and Seller shall comply with such procedure and be bound by such procedure and the consequences thereof:

12.2.2.1. Seller shall promptly notify Purchaser of the Indemnity Claim, identifying it as having arisen due to a claim of a third party and specifying the nature of the claim and the amount or the estimated amount to the extent then feasible (the "Seller's Notice"); provided, however, that the failure to give prompt notice shall not adversely affect an Indemnity Claim except to the extent that the Purchaser is prejudiced thereby.

12.2.2.2. Purchaser shall have ten (10) Business Days from the personal delivery or mailing of the Seller's Notice (the "Seller's Claim Notice Period") to notify Seller in writing, (i) whether or not Purchaser disputes its liability to Seller

hereunder with respect to such Indemnity Claim and (ii) whether or not Purchaser desires, at Purchaser's sole cost and expense, to defend Seller against such third party claim or demand. Failure to provide written notice to Seller within the Seller's Claim Notice Period shall result in the Indemnity Claim being deemed disputed and that the Purchaser shall be deemed to have elected to not defend Seller against such third party claim or demand.

12.2.2.3. In the event that Purchaser notifies Seller within the Seller's Claim Notice Period that Purchaser both acknowledges and agrees to the Indemnity Claim identified in Seller's Notice and desires to defend Seller against such third party claim or demand, then Purchaser shall have the right to defend Seller by appropriate proceedings, subject to the following conditions:

12.2.2.3.1. The proceedings shall be settled or prosecuted by Purchaser, in good faith, to a final conclusion ;

12.2.2.3.2. Without the prior written consent of Seller, which consent shall not be unreasonably withheld or delayed, Purchaser shall not consent to the entry of any judgment against Seller or enter into any settlement or compromise which does not include, as an unconditional term thereof, the giving by the claimant or plaintiff to Seller of a release, in form and substance reasonably satisfactory to Seller, from all liability in respect of such claim or litigation;

12.2.2.3.3. If Seller desires to participate in, but not control, any such defense or settlement, it may do so at its sole cost and expense.

12.2.3. Disputed Indemnity Claims. If an Indemnity Claim is disputed or deemed to have been disputed by Purchaser ("Disputed Indemnity Claim"), then such Disputed Indemnity Claim shall be resolved (A) by written agreement between Purchaser and Seller, (B) by written arbitration award rendered pursuant to Section 15.17 hereof. A Disputed Indemnity Claim which is resolved as being an Indemnity Claim for which Purchaser is responsible, shall become a Confirmed Indemnity Claim hereunder.

12.2.4. Confirmed Indemnity Claim. A "Confirmed Indemnity Claim" shall be an Indemnity Claim, the amount of which is (A) set forth in the written agreement between Purchaser and Seller, (B) set forth in an arbitration award rendered pursuant to Section 15.17 hereof. Purchaser shall promptly pay Seller for all Confirmed Indemnity Claims.

ARTICLE 13.

TERMINATION

13.1. Termination. This Agreement may be terminated, and the transactions contemplated hereby may be abandoned prior to the Closing:

13.1.1. By mutual written agreement of Seller and Purchaser, at any time before the Closing, in which case the Deposit shall be returned to the Purchaser.

13.1.2. By Seller or Purchaser if the Closing Date does not occur on or before August 31, 1998, or such other date as may be mutually agreed by Seller and Purchaser, in which case the Deposit shall be returned to the Purchaser unless the failure to close is determined to have resulted solely from a material breach of this Agreement by the Purchaser.

13.1.3. By Seller or Purchaser, as specifically authorized pursuant to elections established in other Sections of this Agreement.

13.1.4. By Seller or Purchaser as a result of a material breach of this Agreement, prior to Closing, by the other party which is not cured within ten (10) days of written notice of such breach. If this Agreement is terminated under this Section 13.1.4 by Seller because of a material breach by Purchaser, then Seller shall be entitled to retain the Deposit as liquidated damages and its sole remedy against Purchaser shall be retention of the Deposit. If Seller has materially breached this Agreement, Purchaser shall, at its option, have (i) the remedy of specific performance or (ii) the right to terminate this Agreement and to receive the return of the Deposit.

13.1.5. By Seller or Purchaser, at any time before the Closing, in the event that any Order becomes effective (and final and non-appealable) restraining, enjoining, or otherwise prohibiting or making illegal the consummation of any of the transactions contemplated by this Agreement or any Related Agreement which involves Seller, upon notification of the non-terminating party by the terminating party.

13.2. Effect of Termination. If this Agreement is terminated pursuant to Section 13.1, all further obligations of the parties under this Agreement shall terminate, except for the obligations set forth in Sections 1.10.5, 15.5 and 15.6 which shall survive the termination.

ARTICLE 14.

DEFINITIONS

14.1. Definitions.

14.1.1. Defined Terms. In addition to the terms defined elsewhere in this Agreement, as used in this Agreement, the following defined terms have the meanings indicated below:

14.1.1.1. "Accounts Receivable" means all accounts and other receivables of the Institute and all amounts due the Institute whether or not invoiced by the Institute.

14.1.1.2. "Act 522" has the meaning ascribed to it in the recitals.

14.1.1.3. "Actions or Proceedings" means any action, suit, proceeding, arbitration or Governmental or Regulatory Authority investigation.

14.1.1.4. "Affiliate," of a given Person, means any Person that directly, or indirectly through one of more intermediaries, controls or is controlled by or is under common control with such given Person. For purposes of this definition, "control" of a Person means the power, direct or indirect, to direct or cause the direction of the management and policies of such Person, whether by Contract or otherwise.

14.1.1.5. "Agreement" means this Asset Purchase Agreement, the Schedules and Exhibits hereto, and the certificates to be delivered in accordance herewith.

14.1.1.6. "Books and Records," of a given Person, means all files, documents, instruments, papers, books and records relating to the business, operations, condition of (financial or other), results of operations and assets and properties of such Person, including without limitation financial statements and related work papers and letters from accountants, budgets, pricing guidelines, ledgers, journals, deeds, title policies, Contracts, Licenses, customer lists, computer files and programs, retrieval program, operating data and plans and environmental studies and plans.

14.1.1.7. "Business Day" means a day other than Saturday, Sunday or any day on which banks located in the State of Michigan are authorized or obligated to close.

14.1.1.8. "Closing" means the closing of the transactions contemplated by this Agreement.

14.1.1.9. "Closing Date" means (a) the fifth (5th) Business Day after the day on which the last of the consents, approvals, actions, filings, notices or waiting periods described in or related to the filings described herein have been obtained, made or given or has expired, as applicable, or (b) such other date as Purchaser and Seller mutually agree upon in writing.

14.1.1.10. "Code" means the Internal Revenue Code of 1986, as amended, and the rules and regulations promulgated thereunder.

14.1.1.11. "Condition of the Operations of the Institute" means the overall business and the financial condition and results of operations of the Institute taken as a whole.

14.1.1.12. "Confidentiality Agreement" means the letter agreement, dated May 8, 1998, by and between W. Y. Campbell & Company, acting as agent for the Seller, and the Purchaser.

14.1.1.13. "Contract" means any oral or written agreement, lease, license, evidence of Indebtedness, mortgage, indenture, security agreement, purchase order, commitment for the purchase of goods, or other contract, instrument or arrangement to which Seller is a party and which is used or held for use in the conduct of the Operations of the Institute.

14.1.1.14. "Damages" means all liabilities, damages, losses, penalties, fines, assessments, claims, costs and expenses including interest, amounts paid in settlement, court costs, reasonable attorneys' fees, and consultants' and experts' fees. For purposes of clarification, the term Damages is not limited to third party claims but includes Damages in the absence of a third party claim.

14.1.1.15. "Governmental or Regulatory Authority" means any court, tribunal, arbitrator, authority, agency, commission, or other instrumentality of any country or multinational organization (including without limitation the European Community), or any state, county, city, municipality or other political subdivision.

14.1.1.16. "Indebtedness" means all obligations of a given Person (a) for borrowed money or (b) in the nature of the guarantees of the obligations described in clause (a) of any other Person.

14.1.1.17. "Knowledge of Purchaser" means the actual knowledge of the Persons listed on Schedule 14.1.1.18 annexed hereto.

14.1.1.18. "Knowledge of Seller" means the actual knowledge of the Persons listed on Schedule 14.1.1.19 annexed hereto.

14.1.1.19. "Laws" means the constitution of the State of Michigan and all material foreign, federal, state, county, city or municipality laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law.

14.1.1.20. "Liability" or "Liabilities" means any or all Indebtedness, obligations and other liabilities of a Person (whether known or unknown, asserted or not asserted, absolute or conditional, accrued or unaccrued, liquidated or unliquidated, contingent, fixed or otherwise, and whether due or to become due).

14.1.1.21. "Licenses" means all licenses, permits, certificates of authority, authorizations, approvals, registrations, franchises and similar consents granted or issued by any Governmental or Regulatory Authority.

14.1.1.22. "Lien" means any pledge, mortgage, security interest or other encumbrance.

14.1.1.23. "Material Adverse Effect" means, with respect to a Person, an adverse effect on the validity or enforceability of this Agreement or any of the

Related Agreements as against such Person, a material adverse effect on the ability of such Person to consummate the transactions contemplated in this Agreement or the Related Agreements, or any material adverse effect on the condition of the business affairs of such Person.

14.1.1.24. "Operations of the Institute" means the operations of the Institute and, prior to the establishment of the Institute, the operations of the Division.

14.1.1.25. "Order" means any writ, judgment, decree, injunction or similar order of any Governmental or Regulatory Authority (in each such case whether preliminary or final).

14.1.1.26. "Person" means any natural person, corporation, general partnership, limited partnership, proprietorship, other business organization, trust, union, association or Governmental or Regulatory Authority.

14.1.1.27. "Pre-Closing Tax Period" means any Tax period ending on or before the close of business on the Closing Date and, with respect to any Tax period that commences before but ends after the Closing Date, the portion of such period up to the close of business on the Closing Date.

14.1.1.28. "Product Inventory" means the inventories of finished products and components, raw materials, supplies and accessories used in manufacturing finished products and work in process of the Institute, including, but not limited to, "product inventory" as defined in Act 522.

14.1.1.29. "Real Property Owned" means all real property listed on Schedule 1.2.1.1 annexed hereto owned in fee simple by Seller and all plants, offices, manufacturing or remanufacturing facilities, warehouses, buildings, structures and improvements located thereon, and all mineral rights, oil wells, leases and rentals with respect thereto.

14.1.1.30. "Related Agreement" means all agreements, contracts, certificates, instruments or other documents required to executed and/or delivered pursuant to or in connection with this Agreement by any Person.

14.1.1.31. "State Administrative Board" means the state administrative board created under Act 5 of Michigan Public Acts of 1921.

14.1.1.32. "Tax Returns" means a report, return or other information (including any amendments) required to be supplied to any Governmental Authority with respect to Taxes including, where permitted or required, combined or consolidated returns for any group of entities.

14.1.1.33. "Taxes" means any federal, state, county, local or foreign

income, gross receipts, franchise, sales, use, excise, gains, value added, withholding, employment, payroll, social security, property and all other taxes of any nature, fees, levies, duties, assessments, deficiencies or charges imposed by any governmental entity, and includes any interest and penalties (civil or criminal) on or additions to any such taxes and any expenses incurred in connection with the determination, settlement or litigation of any Taxes.

14.1.2. Construction of Certain Terms and Phrases. Unless the context of this Agreement otherwise requires, (i) words of any gender include each other gender; (ii) words using the singular or plural number also include the plural or singular number, respectively; (iii) the terms "hereof," "herein," "hereby" and derivative or similar words refer to this entire Agreement; (iv) the terms "Article," "Section," "clause" or "subclause" refer to the specified Article, Section, clause or subclause of this Agreement; and (v) the phrase "ordinary course of business" of a Person refers to the business of such Person. Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days are specified. The parties have participated jointly in the negotiation and drafting of this Agreement and the Related Agreements. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any of the provisions of this Agreement or any Related Agreement.

ARTICLE 15.

MISCELLANEOUS

15.1. Survival of Covenants and Representations. The covenants and representations of the parties contained in this Agreement and in any Related Agreement shall survive the Closing without limitation unless otherwise provided for in specific covenants or representations, except that the sole remedy of Purchaser shall be provided by Article 10 hereof.

15.2. Notices. All notices, requests and other communications hereunder must be in writing and shall be deemed to have been duly given only if delivered personally or by facsimile transmission or mailed (first class postage prepaid) to the parties at the following addresses or facsimile numbers:

If to Purchaser, to:

BioPort Corporation
c/o Intervac, LLC
12717 Three Sisters Road
Potomac, Maryland 20854
Facsimile No.: 301-983-2299
Attn: Mr. Fuad El-Hibri
General Manager

with a copy to:

Arent Fox Kintner Plotkin & Kahn
1050 Connecticut Avenue, N.W.
Washington, DC 20037-5339
Facsimile No.: 202-857-6395
Attn: Carl A. Valenstein, Esq.

If to Seller, to:

Michigan Biologic Products Commission
Olds Plaza
111 S. Capitol, Second Floor
Lansing, Michigan 48933
Facsimile No.: 517-335-6949
Attn: Dennis L. Schornack, Chair

with a copy to:

Office of the Attorney General of the State of Michigan
One Michigan Ave., Fourth Floor
Lansing, Michigan 48933
Facsimile No.: 517-373-0241
Attn: Ronald J. Styka, Esq.
Assistant Attorney General
Public Health

All such notices, requests and other communications shall (a) if delivered personally to the address as provided in this Section 15.2, be deemed given upon delivery, (b) if delivered by facsimile transmission to the facsimile number as provided in this Section 15.2, be deemed given upon receipt, and (c) if delivered by mail in the manner described above to the address as provided in this Section 15.2, be deemed given upon receipt (in each case regardless of whether such notice, request or other communication is received by any other Person to whom a copy of such notice, request or other communication is to be delivered pursuant to this Section 15.2). Any party hereto from time to time may change its address, facsimile number or other information for the purpose of notices to that party by giving notice specifying such change to the other party hereto.

15.3. Bulk Sales Act. It is the mutual belief and understanding of the parties that the bulk sales act does not apply to the transactions contemplated by this Agreement and that Seller agrees to bear full responsibility for noncompliance therewith.

15.4. Entire Agreement. This Agreement, the Confidentiality Agreement and the Related Agreements supersede all prior discussions and agreements between or among the parties hereto with respect to the subject matter hereof and thereof and contain the sole and entire

agreement between the parties hereto with respect to the subject matter hereof and thereof.

15.5. Expenses. Except as otherwise expressly provided in this Agreement, whether or not the transactions contemplated hereby are consummated, each party hereto shall pay its own costs and expenses incurred in connection with the negotiation, execution and closing of this Agreement and the Related Agreements and the transactions contemplated hereby and thereby.

15.6. Public Announcements. Subject to applicable freedom of information laws, at all times at or before the Closing, Seller, on the one hand, and Purchaser, on the other hand, shall not issue or make any reports, statements or releases to the public or generally to the customers, suppliers or other Persons to whom Seller sells goods or provides services or with whom Seller otherwise has significant business relationships with respect to this Agreement or the transactions contemplated hereby without the consent of the other party, which consent shall not be unreasonably withheld. If either party is unable to obtain the approval of its public report, statement or release from the other party and such report, statement or release is, in the opinion of legal counsel to such party, required by Law in order to discharge such party's disclosure obligations, then such party may make or issue the legally required report, statement or release and promptly furnish the other party with a copy thereof. Each party shall also obtain the other party's prior approval of any press release to be issued immediately following the Closing announcing the consummation of the transactions contemplated by this Agreement.

15.7. Waiver. Any term or condition of this Agreement may be waived at any time by the party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the party waiving such term or condition. No waiver by any party hereto of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion. Except as otherwise expressly provided herein with respect to Seller's right to retain the Deposit as its sole remedy, all remedies, either under this Agreement or by Law or otherwise afforded, shall be cumulative and not alternative.

15.8. Amendment. This Agreement may be amended, supplemented or modified only by a written instrument duly executed by or on behalf of each party hereto.

15.9. No Third Party Beneficiary. The terms and provisions of this Agreement are intended solely for the benefit of the parties hereto and their respective successors or permitted assigns, and it is not the intention of the parties hereto to confer third party beneficiary rights upon any other Person.

15.10. No Assignment; Binding Effect. Neither this Agreement nor any right, interest or obligation hereunder may be assigned by any party hereto without the prior written consent of the other parties hereto, and any attempt to do so shall be void, except for assignments and transfers by operation of Law. Subject to the preceding sentence, this Agreement is binding upon, inures to the benefit of and is enforceable by the parties hereto and their respective successors and assigns.

15.11. Headings. The headings used in this Agreement have been inserted for convenience of reference only and do not define or limit the provisions hereof.

15.12. Invalid Provisions. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future Law, and if the rights or obligations of any party hereto under this Agreement shall not be materially and adversely affected thereby, (A) such provision shall be fully severable, (B) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (C) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (D) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible.

15.13. Governing Law. This Agreement shall be governed by and construed in accordance with the Laws of the State of Michigan, applicable to a contract executed and performed in such State, without giving effect to the conflicts of laws principles thereof.

15.14. Schedules and Exhibits. Disclosure of any fact or item in any Schedule or Exhibit hereto referenced by a particular Section shall, should the existence of the fact or item or its contents be relevant to any other Section, be deemed to be disclosed with respect to such other Section whether or not an explicit cross-reference appears.

15.15. Construction of Certain Provisions. It is understood and agreed that neither the specification of any dollar amount in the representations contained herein nor the inclusion of any specific item in any Schedule or Exhibit hereto, is intended to imply that such amounts or higher or lower amounts, or the items so included or other items, are or are not material, and neither party shall use the fact of the setting of such amounts or the fact of the inclusion of any such item in any Schedule or Exhibit hereto, in any dispute or controversy between the parties hereto as to whether any obligation, item or matter is or is not material for purposes hereof.

15.16. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

ARTICLE 16.

DISPUTE RESOLUTION

16.1. Arbitration. All disputes and controversies of every kind and nature between the parties hereto arising out of or in connection with this Agreement or any of the Related Agreements shall be submitted to arbitration pursuant to the following procedures:

16.1.1. Except as modified hereby, the arbitration shall be governed by the Commercial Arbitration Rules of the American Arbitration Association ("AAA") including the Supplementary Procedures for Large Complex Disputes. After a dispute

or controversy arises, either party may, in a written notice delivered to the other party, demand such arbitration. Such notice shall designate the name of the arbitrator (who shall be an impartial person) appointed by such party demanding arbitration, together with a statement of the matter in controversy in reasonable detail.

16.1.2. Within thirty (30) days after receipt of such demand, the other party shall, in a written notice delivered to the party demanding arbitration, name such party's arbitrator (who shall be an impartial person). If the other party fails to name an arbitrator, then the second arbitrator shall be named by the AAA. The two arbitrators so selected shall name a third arbitrator (who shall be an impartial person) within thirty (30) days, or in lieu of such agreement on a third arbitrator by the two arbitrators so appointed, the third arbitrator shall be appointed by the AAA. If any arbitrator appointed hereunder shall die, resign, refuse, or become unable to act before an arbitration decision is rendered, then the vacancy shall be filled by the methods set forth in this Section for the original appointment of such arbitrator.

16.1.3. The arbitration hearing shall be held in Lansing, Michigan at a location designated by a majority of the arbitrators. The substantive laws of the State of Michigan (excluding conflict of laws provisions) and the Federal Arbitration Act shall apply. The arbitrators shall be authorized and directed to award costs and expenses of the arbitration (including reasonable attorneys' fees) to the prevailing party.

16.1.4. An award rendered by a majority of the arbitrators appointed pursuant hereto shall be final and binding on all parties to the proceeding, shall resolve the question of costs of the arbitrators, legal fees and expenses and all related matters, and judgment on such award may be entered and enforced, subject to applicable law, by either party in any court of competent jurisdiction in Ingham County, Michigan.

16.1.5. The arbitrators may by an interim or final award grant injunctive relief.

16.1.6. The parties stipulate that the provisions of this Section shall be exclusive and constitute a complete defense to any proceeding instituted in any federal, state or local court or before any administrative tribunal with respect to any controversy or dispute arising out of this Agreement. The arbitration provisions hereof shall, with respect to such controversy or dispute, survive the termination or expiration of this Agreement.

16.2. Confidentiality. Subject to applicable law, including the Michigan Freedom of Information Act, the parties hereto and the arbitrators may not disclose the existence or results of any arbitration hereunder without the prior written consent of the other party; nor will any party hereto disclose to any third party any confidential information disclosed by any other party hereto in the course of an arbitration hereunder without the prior written consent of such other party. Notwithstanding the foregoing, a party may disclose the existence or results of an arbitration hereunder, as well as information otherwise required to be disclosed by deposition, subpoena or other court or governmental action.

IN WITNESS WHEREOF, this Agreement has been duly executed and delivered by the duly authorized officer of each party as of the date first above written.

STATE OF MICHIGAN

By: _____
Name: Dennis C. Schornack
Title: Chair, MBPC

BIOPORT CORPORATION

By: _____
Name: FUAD EL-MASRI
Title: PRESIDENT

The undersigned accepts and executes this Agreement in accordance with and for the purposes of Section 1.6.4..

DEPOSIT ESCROW AGENT

By: _____

Miller, Canfield, Paddock
and Stone, P.L.C.

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MBPC

Lansing, Michigan July 7, 1998

A regular meeting of the State Administrative Board was held in the State Capitol, Senate Appropriations Committee Room, 3rd Floor, on Tuesday, July 7, 1998, at 11:00 a.m.

Present: John Engler, Governor, Chairperson
Richard Wheat, Administrative Assistant, representing Connie Binsfeld, Lt. Governor
Candice Miller, Secretary of State
Dr. Douglas B. Roberts, State Treasurer
Theodore Hughes, Assistant Attorney General for Law, representing Frank J. Kelley, Attorney General
Arthur Ellis, Superintendent of Public Instruction
Arlene Oisten, Secretary

Absent: None

Others Present:
Manny Lentine, Louise Findley, Dennis Schornack, Governor's Office; A. Edwin Dore, Secretary of State's Office; Roberta McKennon Department of Treasury; Todd Cohan, Deborah Devine, Ron Styka, Attorney General; James Haveman, Geralyn Lasher, Mary Ann Prince, Department of Community Health; Marsha Foresman, Department of Corrections; Myron Freeman, James Haag, Susan Higinbotham, House Fiscal Agency; Tracy Armstrong, James Burris, Kelly Chesney, David Claus, Jan Claus, Arlene Oisten, Tom Saxton, Bruce Walker, Department of Management and Budget; Wes Van Malsen, Michigan Jobs Commission; Ric Hartig, Department of Transportation; Robert C. Myers, Rob van Ravenswaay, Michael A. Tanner, A. M. Luttrell, Heidi Heuser, Nancy Summerton, Dianne Dreyer, James R. Wangelin, Tim Wilbert, Colleen M. Smith, Michigan Biologic Products Institute; Deborah Ball Cornell, Senate Democratic Office; Admiral William Crowe, BioPort; Gregory Bakeman, Michael Benson, First of Michigan; Shaela Biala, Fuad El-Hibri, Maruro Gibellini, Jim Herbert, Neogen Corporation; Mike Atkins, Jay Rising of Miller, Canfield, Paddock and Stone, PLC.; Paul Roney, Suzznne R. Thelen, Lansing Regional Chamber of Commerce; David Hollister, Mayor of Lansing; Adrian Smilt, Crump Group; Dave Drayton, Lyman and Sheets; Jan Myers

1. CALL TO ORDER:

The meeting was called to order by the Governor Engler. The Reverend Paul Frederick of Mt. Hope United Methodist Church in Lansing gave the invocation. Mr. Ellis led the Pledge of Allegiance to the Flag.

2. READING OF MINUTES OF PRECEDING MEETING AND APPROVAL THEREOF:

Mr. Hughes moved that the minutes of the State Administrative Board for the regular meeting of June 16, 1998, be considered read and approved. Secretary Miller supported the motion, and it was unanimously adopted.

3. HEARING OF CITIZENS ON MATTERS FALLING UNDER JURISDICTION OF THE BOARD:

Representative Lingg Brewer, of the 68th District, spoke with concern about the sale of the Michigan Biologic Products Institute (MBPI). He felt the MBPI should be sold, but had concerns about some contradictions prior to the sale. He noted the value had changed; that the sale was said to be eminent, then not; that there was no significant military interest, then there was a $100,000,000 military contract. He was in contact with a losing bidder and requested a one month delay in the sale until he received a communication from this bidder for clarification.

There were no questions of Representative Brewer by the Committee.

4. COMMUNICATIONS:

Correspondence from Alan H. VanNoord, Department of Treasury, with attached summary and detail investment holding reports for the Veterans Benefit Trust Fund as of March 31, 1998, and a summary of investment transactions for the quarter ended March 31, 1998, in accordance with a resolution adopted by the State Administrative Board.

The Governor accepted the correspondence from the Department of Treasury.

5. UNFINISHED BUSINESS:
None

A G E N D A

FINANCE AND CLAIMS COMMITTEE - STATE ADMINISTRATIVE BOARD

June 30, 1998 Meeting, 11:00 a.m.- Treasurer'. Conference Room

SECTION I. AGENCY CONTRACTS

NEW CONTRACTS

1. DEPARTMENT OF COMMUNITY HEALTH

1)	Healthshare Group Petosky, MI	$ 1,525,500.00 Total Medicaid services for elderly and disabled under Federal Waiver Program Region 9
2)	Senior Services, Inc. Kalamazoo, MI	$ 1,491,600.00 Total Medicaid services for elderly and disabled under Federal Waiver Program Region 3
3)	Various HMO's (List on file with Secretary)	$ 0.00 - Amendment $ 15,640,000.00 - Total Adding additional HMO Providers under previous dollar amount approved
4)	Regents of the University of Michigan Ann Arbor, MI	$ 31,000.00 - Amendment $ 251,950.00 - New total Medical Management for children

2. DEPARTMENT OF CORRECTIONS

1)	Charlevoix County Charlevoix, Michigan	$ 336,000.00 Total Local Facility Expansion Program funds to increase capacities of local facilities. Primary objectives are to decrease prison admissions and prison commitment rates through increase use of jail beds and other community based programming for felons.
2)	Cheboygan County Cheboygan, Michigan	$ 376,000.00 Total Local Facility Expansion Program funds to increase capacities of local facilities. Primary objectives are to decrease

2. DEPARTMENT OF CORRECTIONS Continued

	prison admissions and prison commitment rates through increase use of jail beds and other community based programming for felons.
3) Grand Traverse County Traverse City, Michigan	$ 300,000.00 Total Local Facility Expansion Program funds to increase capacities of local facilities. Primary objectives are to decrease prison admissions and prison commitment rates through increase use of jail beds and other community based programming for felons.
4) Kent County Grand Rapids, Michigan	$ 319,880.00 Total Local Facility Expansion Program funds to increase capacities of local facilities. Primary objectives are to decrease prison admissions and prison commitment rates through increase use of jail beds and other community based programming for felons.
5) Mason County Ludington, Michigan	$ 416,000.00 Total Local Facility Expansion Program funds to increase capacities of local facilities. Primary objectives are to decrease prison admissions and prison commitment rates through increase use of jail beds and other community based programming for felons.
6) Oakland County Pontiac, Michigan	$ 600,000.00 Total local Facility Expansion Program funds to increase capacities of local facilities. Primary objectives are to decrease prison admissions and prison commitment rates through

6. NEW BUSINESS:

Retention and Disposal Schedules:

Department of Agriculture, Office of State Exposition and Fairgrounds, 6/1/98
Northern Michigan University, Administrative and Academic Officers, 5/21/98
Northern Michigan University, Premedical Advisory Board, 5/21/98
Northern Michigan University, Office of the V. P. for University Relations Development Fund, 5/21/98

Superintendent Ellis moved that the Retention and Disposal Schedules be approved. The motion was supported by Mr. Hughes and unanimously adopted.

7. REPORTS AND RECOMMENDATIONS OF COMMITTEES:

(Please see the following page)

COMMITTEE REPORT TO THE STATE ADMINISTRATIVE BOARD

The Honorable John Engler, Governor
and
Members of the State Administrative Board

A meeting of the **Finance and Claims** Committee was held at **11 a.m.** on **June 30, 1998**, those present being:

Chairperson:	Roberta McKennon, representing State Treasurer Roberts	Approved _____
Member	Manny Lentine, representing Governor John Engler	Approved _____
Member:	Socorro Guerrero, representing Attorney General Kelley	Approved _____
Others:	Karen Kalis, Department of Community Health; Stuart Hallgren, Griffin Rivers, Department of Corrections; Alex Douloutes, Michigan School for the Deaf and Blind; Claudia Allen, Tracy Armstrong, Arlene Oisten, Department of Management and Budget; Wes Van Malsen, Michigan Jobs Commission	

The Finance and Claims Committee regular agenda and supplemental agenda were presented.

Following discussion, Mr. Lentine moved that the regular agenda and supplemental agenda be recommended to the State Administrative Board for approval with the withdrawal of items 17 (1), 17 (6), 17 (7), 17 (10), 17 (11), and amending item 17 (4) to a $15.00 recommendation for payment. The motion was supported by Ms. Guerrero and unanimously adopted.

Ms. McKennon adjourned the meeting.

2. DEPARTMENT OF CORRECTIONS Continued

	increase use of jail beds and other community based programming for felons
7) Saginaw County Saginaw, Michigan	$ 504,000.00 Total Local Facility Expansion Program funds to increase capacities of local facilities. Primary objectives are to decrease prison admissions and prison commitment rates through increase use of jail beds and other community based programming for felons

3. DEPARTMENT OF EDUCATION

1) Kimberly Home Health Care Inc. Flint, MI	$ 415,200.00 Total Substitute nurses for the Michgan School for the Deaf and Blind

4. FAMILY INDEPENDENCE AGENCY

1) Wolverine Human Services Grosse Pointe Park, MI	$ 19,265,904.00 Amendment $ 62,042,[illegible]50.08 New Total To provide treatment beds for delinquest youth under the Agency's supervision
2) Wolverine Human Services Grosse Pointe Park, MI	$ 7,725,875.20 Amendment $ 41,994,995.20 New Total To provide high security residential care programs for adjudicated delinquent youth

5. MICHIGAN JOBS COMMISSION

1) Statewide Work Force Development Boards	$ 8,099,339.00 Amendment $ 93,099,339.00 New Total $3,295,075 for Work First Incentive Awards for program performance in 1997; $4,804,264 formula distribution to expand the Work First Program for custodial and non-custodial parents

5. MICHIGAN JOBS COMMISSION Continued

2) Michigan State AFL-CIO Human Resources Development Lansing, MI	$ 1,182,971.00 Total To provide services to dislocated workers residing or terminated from employment by employers located in 11 of Michigan's 25 service delivery areas

SECTION II. DMB CONTRACTS

Requests approval of the following:

NEW CONTRACTS

6. DEPARTMENT OF CORRECTIONS

1) Metropolitan Uniform Company Detroit, MI	$ 409,180.00 - 3 Years 071I8000598 Belts, Caps and Gloves

7. DEPARTMENT OF ENVIRONMENTAL QUALITY

1) McConnell & Scully, Inc. Homer, MI	$ 1,503,500.50 - 1Yr,9Mos 071I8000622 Plugging and Restoration of Various Oil and Gas Wells in Michigan

8. DEPARTMENT OF MANAGEMENT AND BUDGET

1) Auditforce Southfield, MI	$ 740,350.00 - 6 Years 071I8000645 Internal Auditing, DMB, Office of Financial Management

9. DEPARTMENT OF TRANSPORTATION

1) Hydra Platforms Mfg. Inc. Lake Wylie, SC	$ 260,217.18-One-Time Buy 071I8000667 Under Bridge Inspection Platforms, Trailer Mounted

CONTRACT CHANGES/EXTENSIONS

10. DEPARTMENT OF COMMUNITY HEALTH

1) Binson's Hospital Supplies Center Line, MI	$ 5,111,810.00 - Amendment $ 13,797,973.64 - New Total 071B7000563 Diapers and Incontinent Supplies

11. DEPARTMENT OF EDUCATION

1)	Northern Warehousing, Inc. Elmira, MI	$ 469,185.99 - Amendment $ 938,371.98 - New Total 071B7000037 USDA Food Distribution, DOE, Region 3

12. DEPARTMENT OF MANAGEMENT AND BUDGET

1)	Bergen Brunswig Drug Co. Williamston, MI	$ 15,000.000.00 - Amendment $ 64,374,139.24 - New Total 071B3000035 Pharmaceuticals, Statewide

13. MICHIGAN STATE POLICE

1)	Blauer Manufacturing Co. Boston, MA	$ 615,000.00 - Amendment $ 1,201,836.75 - New Total 071B6000200 Correction Officers Jackets and Trousers, All Weather

SECTION III. RELEASE OF FUNDS TO WORK ORDER

14. GRAND VALLEY STATE UNIVERSITY.

Requests release of $2,650,000 and revision to Appropriation 66009 - for the School of Business and Graduate Library. Work to be done by fixed sum contract. Funds are available from 1996 PA 480. The total authorized cost is $52,650,000 (State Building Authority, $37,524,900; General Funds, $100; and College Funds. $15,125,000).

15. UNIVERSITY OF MICHIGAN, FLINT

Requests release of $2,200,000 and revision to Appropriation 66019 - for the Professional Studies and Classroom Building. Work to be done by fixed sum contract. Funds are available from 1996 PA 480. The total authorized cost is $33,123,000 (State Building Authority; $25,942,100; General Funds, $100; College Funds, $7,180,800).

SECTION IV. REVISION TO WORK ORDERS

SECTION V. CLAIMS - PERSONAL PROPERTY LOSS

16. DEPARTMENT OF CONSUMER AND INDUSTRY SERVICES/UNEMPLOYMENT AGENCY

1) Dicie M. Williams $422.94

The claimant (98-SAB-097) requested $422.94 reimbursement for the loss of her leather coat. The coat was stolen from a secured area for employees only. The Department recommended reimbursement of $423.99 with a six month depreciation, estimated by DMB at $317.99.

17. DEPARTMENT OF CORRECTIONS

1) Melvin Carmouche #150412 $ 95.00

The claimant (98-SAB/DOC-083) requested $95.00 reimbursement for damages to his TV. There was a power supply problem on the unit the claimant lived. When the power supply was returned, the claimant's TV no longer worked. Staff confirmed the TV worked prior to the power surge and not after the power surge. The Department recommends denial because it was not under staff control when damaged. However, if the Board decides to reimburse, the Department would recommend the amount of $57.00 for this claim.

2) John Docherty #205587 $133.94

The claimant (98-SAB/DOC-087) requested $133.94 reimbursement for the loss of his clothing. The claimant received clothing through the mail. A sweatshirt was not delivered due to color. The Administrative Hearing allowed the claimant to mail home the sweatshirt. The claimant packed additional items in the box with the sweatshirt. The facility mailed the box and can prove it was received at the stated address. The Department recommends denial of this claim.

3) James Hall #187205 $ 32.50

The claimant (98-SAB/DOC-092) requested $32.50 reimbursement for clothing items damaged in the laundry. There was no grievance filed and no notation by staff that the claimant's laundry had been returned without the seal remaining secured. The Department recommends denial of this claim.

4) Tyrone Jackson #226967 $ 87.70

The claimant (98-SAB/DOC-043) requested $87.70 reimbursement for damages to his TV. The TV was dropped

17. DEPARTMENT OF CORRECTIONS Continued

by staff when it was being returned to the claimant. The TV was purchased 7/15/94 and broken on 9/18/97. The Department recommends denial of any reimbursement due to the age of the TV.

5) Raphael Xaka Johnson #233075 $ 21.50

The claimant (98-SAB/DOC-084) requested $21.50 reimbursement for the loss of four magazines. The magazines were ordered and paid for by the claimant. The magazines were inadvertently given to another prisoner and lost while under staff control. The Department recommends reimbursement of this claim.

6) Andrew Lamont Jones #195237 $ 29.75

The claimant (98-SAB/DOC-089) requested $29.75 reimbursement for the loss of his headphones. The headphones were destroyed by staff prior to an Administrative Hearing. The Department recommends the depreciated value of $23.80 for the year old headphones.

7) Vincent Knight #199549 $240.40

The claimant (98-SAB/DOC-086) requested $240.40 reimbursement for the loss of a 4 month old typewriter. The typewriter and supplies were damaged while under the Department's control. The Department recommends the depreciated value of $192.04 for this claim.

8) Jerry L. Lewis #220218 $283.08

The claimant (98-SAB/DOC-098) requested $283.08 reimbursement for his footlocker and all its contents. The footlocker was lost by staff during a transfer. All receipts were in the footlocker so cost and date of purchase could not be established. The value of photographs was not estimated in the Department's recommendation. The Department recommends the residual value of $27.22 for this claim.

9) Rick Murphy #184674 $ 47.12

The claimant (98-SAB/DOC-065) requested $47.12 reimbursement for the mailing costs of sending his footlocker and clothing home. The footlocker was found to be contraband, but was returned to the claimant after a hearing. The claimant then had his footlocker

17. DEPARTMENT OF CORRECTIONS Continued

and clothing items he had choosen mailed out at his expense. The Department did not order the items mailed out of the institution. They were mailed at the request of the claimant. The Department recommends denial of this claim.

10) Anthony Nelson #210771 $ 38.70

The claimant (98-SAB/DOC-081) requested $38.70 reimbursement for damages to his footlocker. The footlocker was damaged when it was received at a new facility. There is no indication of the footlocker's condition prior to entering the facility. It was considered contraband due to the broken clasp. The administrative hearing gave the claimant 60 days to send it home. The Department recommends denial of this claim.

11) Umar Siddiq #106503 $ 65.00

The claimant (98-SAB/DOC-035) requested $65.00 reimbursement for damages to his TV. The TV was checked prior to leaving the institution and was verified to be in working order. When it was received at the new facility, a notice of intent was written for the broken TV. The Department states there is no proven staff neglect. The Department recommends denial of this claim.

12) Michael Stevenson #221798 $ 13.23

The claimant (98-SAB/DOC-097) requested $13.23 reimbursement for the loss of a cable box. The cable box was apparently stolen by another prisoner prior to the claimant's property being packed up. A search of the area did not locate the cable box. This is a prisoner upon prisoner theft. The Department recommends denial of this claim.

13) John Voskuhl #162501 $ 84.95

The claimant (98-SAB/DOC-088) requested $84.95 reimbursement for the loss of his TV. The TV was damaged during transit, prior to the claimant ever receiving the TV. The Department recommends reimbursement of $84.95 for this claim.

18. DEPARTMENT OF CORRECTIONS

1) Michael J. Kirkwood $101.00

The claimant (98-SAB-151) requested $101.00 reimbursement for damages to his clothing. A container of corrosive chemicals was accidentally dropped and spilled by an employee during an inspection of a facility. The Department recommends the depreciated value of 95.38 for this claim.

2) William John Reese $424.53

The claimant (98-SAB-150) requested $424.53 reimbursement for damages to his vehicle. The vehicle was damaged when children accompanying their mother to a hearing, tried to attack another visitor with a tire iron and hit the claimant's vehicle. The vehicle was parked in a state parking lot for employees. The Department cannot control the actions of the general public and recommends denial of this claim.

19. DEPARTMENT OF MILITARY AND VETERANS AFFAIRS

1) Marilyn S. Sanders $999.99

The claimant (98-SAB-146) requested $999.99 reimbursement for damages to her vehicle. The vehicle was damaged when a tree fell on her vehicle in the parking lot at the Grand Rapids Veteran's Facility. The Department recommends reimbursement of this claim in the amount of $999.00.

20. DEPARTMENT OF STATE

1) Rebecca Robin Gies $ 90.00

The claimant (98-SAB-139) requested $90.00 reimbursement for impound charges for her vehicle. The claimant's license suspension was terminated last September, but her records were not updated. She incurred a $95.00 impound and storage charge due to this error. The Department recommends reimbursement of the entire impound charge in the amount of $95.00.

21. DEPARTMENT OF TRANSPORTATION

1) Mahavir Oza $710.00

The claimant (98-SAB-056) requested $710.00 reimbursement for damages to his vehicle when he hit a

21. DEPARTMENT OF TRANSPORTATION Continued

pothole. The investigation showed that the Department did not have sufficient notice to repair the highway condition which caused the damage. Reasonable maintenance had been done prior to the incident and after the incident. The Department recommends denial of this claim.

2) Judith Shepard $999.00

The claimant (97-SAB-299) requested $999.00 reimbursement for damages to her home due to MDOT construction. MDOT placed curbs in front of the Shepard property. Water drained from the road down the driveway, possibly damaging the home. MDOT installed two catch basins which ended the problem. The Department recommends reimbursement of this claim.

3) Susanna Koenig $234.63

the claimant (98-SAB-152) requested $234.63 reimbursement for damages to her vehicle caused by concrete pieces of a bridge falling off the bridge. The claimant's vehicle struck the concrete and was damaged. The Department recommends reimbursement of this claim.

SECTION VI. CLAIMS - PERSONAL INJURY

22. DEPARTMENT OF NATURAL RESOURCES

1) Carl D. Pulford $999.00

The claimant (98-SAB-117) requested $999.99 reimbursement for a broken leg he incurred while walking on an unmarked wood walk. The investigation showed that the property Mr. Pulford was on is an isolated piece of land, separated from any administered property. The property is land banked for future needs and not listed in any directory, nor is the public invited or encouraged to use it. The structure was clearly substandard and obviously not built nor maintained by the Department. The Department has removed the structure. The claimant did not use reasonable care in using a structure in such poor condition. The claimant's bills were paid for by insurance coverage with the possible exception of $116.98. The Department recommends denial of this claim.

SECTION VII. APPROVAL OF SPECIAL ITEMS

23. DEPARTMENT OF CORRECTIONS

1) Department monthly report submitted pursuant to the Administrative procedures of 06202. Copy of the report is on file with the Administrative Board Secretary.

Department of Corrections - May, 1998 2 Claims Approved

24. FAMILY INDEPENDENCE AGENCY

1) The FIA appropriations bill requires that liens be placed on real property when State Emergency Relief (SER) is issued for mortgage payments, land contract payments, property taxes and home repairs. The lien is required when payments exceed $250 for one or a combination of these services. Such payments were made for delinquent taxes, and the recipients have repaid the Department in full. The Department is requesting permission from the Board to release the following liens:

$ 840.01 at 6249 Wright, Kalamazoo, Michigan
$ 462.33 at 1807 Terrace Ct., Luzerne, Michigan
$ 355.26 at 1152 Cedardale 28th Road, Cornell, Michigan
$ 351.00 at 216 W. Filmore Road, Hart, Michigan
$ 283.96 at 26304 Culver, St. Clair Shores, Michigan
$ 445.24 at 3326 Nimrod Trail, White Cloud, Michigan
$1,037.00 at 6777 M - 65, Hale, Michigan
$1,186.00 at 8107 Rivard, Warren, Michigan
$ 345.36 at 206 East Fifth Street, Scottville, Michigan

The Director of the Department of Management and Budget recommends approval by the State Administrative Board of the items contained in this agenda. Approval by the State Administrative Board of these award recommendations does not require or constitute the award of same. Award of contracts shall be made at the discretion of the DMB Director or designee.

SUPPLEMENTAL AGENDA

FINANCE AND CLAIMS COMMITTEE - STATE ADMINISTRATIVE BOARD

June 30, 1998 Meeting, 11:00 a.m. - Treasurer's Conference Room

SECTION I. AGENCY CONTRACTS

SECTION II. DMB CONTRACTS

Requests approval of the following:

CONTRACT CHANGES/EXTENSIONS

S2. DEPARTMENT OF STATE POLICE

1)	Asplundh Tree Expert Co. Mt. Pleasant, MI	($3,333,334.00) Amendment $6,666,666.00 New Total Emergency Storm Clean-Up for designated Disaster Areas
2)	Davey Commercial Services Kent, OH	$3,333,334.00 Total Emergency Storm Clean-Up for designated Disaster Areas

SECTION III. RELEASE OF FUNDS TO WORK ORDER

SECTION IV. REVISION TO WORK ORDER

SECTION V. CLAIMS - PERSONAL PROPERTY LOSS

SECTION VI. CLAIMS - PERSONAL INJURY

SECTION VII. APPROVAL OF SPECIAL ITEMS

The Director of the Department of Management and Budget recommends approval by the State Administrative Board of the items contained in this agenda. Approval by the State Administrative Board of these award recommendations does not require or constitute the award of same. Award of contracts shall be made at the discretion of the DMB Director or designee.

COMMITTEE REPORT TO THE STATE ADMINISTRATIVE BOARD

The Honorable John Engler, Governor
and
Members of the State Administrative Board

A special meeting of the **Finance and Claims** Committee was held at **10:30 a.m.** on **July 7, 1998**, those present being:

Chairperson: Douglas B. Roberts, State Treasurer — Approved _____

Member: Deborah Devine, representing Attorney General Kelley — Approved _____

Member: Manny Lentine, representing Governor John Engler — Approved _____

Others: Todd Cohan, Ron Styka, Attorney General; Geralyn Lasher, Department of Community Health; Marsh Foresman, Department of Corrections; James Haag, Susan Higinbotham, House Fiscal Agency; Tracy Armstrong, James Burris, David Claus, Jan Claus, Arlene Oisten, Tom Saxton, Bruce Walker, Department of Management and Budget; Robert C. Myers, Rob Van Ravensway, Michael A. Tanner, A. M. Luttrele, Jim Herbert, Nancy Summerton, Dianne Dreyer, Tim Wilbert, Colleen M. Smith, Michigan Biologic Products Institute; Gregory Bakeman, Michael Benson, First of Michigan; Shaela Biala, Neogen Corporation; Mike Atkins, Jay Rising of Miller, Canfield, Paddock and Stone, PLC.

The Finance and Claims Committee considered the Department of Corrections contract with the State of Virginia. Following discussion, Mr. Lentine moved that the Department of Corrections contract be recommended to the State Administrative Board for approval. Ms. Devine supported the motion and it was unanimously adopted.

Mr. Dennis Schornack of the Michigan Biologic Institute, gave the overview of the proposed contract with Bioport for the sale of the Institute. The proposed sale is in accordance with P.A. 522 of 1996. Mr. Schornack stated four ways that the people of the State

are winners with this sale. First the taxpayers will no longer be supporting the cost of maintaining the Institute. Second, the workers at the Institute will keep their jobs up to one year and receive a percentage of the Corporation stock over a period of 5 years. Third, the City of Lansing will increase it's tax base. Fourth, the U.S. armed services will be able to maintain the protection against biological weapons it needs.

The Treasurer asked if the Institute had made a profit and for Mr. Schornack to explain how the price was determined.

The Institute had maintained records for the last six years creating a balance sheet showing that there was no profit for the six years these records were maintained. Historically, it is doubtful that it made any profit since 1979.

The price was based on the Institute being determined as a "going concern." The Auditor General's Report examined the process showing that the Michigan Biologic Products Institute Commission had followed the law and used a fair competitive bid process. The Senate and House had appointed Mr. Gary Olson and Mr. James Haag to review the process on their behalf.

Mr. Roberts asked if there was any public comment. No one responded.

Ms. Devine stated that the Attorney General's Office had reviewed the independent fairness opinion and the asset purchase agreement. They found no lending or credit obligations to the State. She then moved that the resolution for the sale of the Michigan Biologic Institute be recommended for approval by the State Administrative Board. Mr. Lentine supported the motion and it was unanimously adopted.

July 7, 1998 No. 19

A G E N D A

FINANCE AND CLAIMS COMMITTEE - STATE ADMINISTRATIVE BOARD

July 7, 1998 Special Meeting, 10:30 a.m.
Senate Appropriations Room
3rd Floor, Capitol Building

SECTION I. AGENCY CONTRACTS

NEW CONTRACTS

1. DEPARTMENT OF CORRECTIONS

1)	The Virginia Department of Corrections Richmond, Virginia	$ 27,375,000.00 Total To provide housing to state prisoners in other state prisons

SECTION II. DMB CONTRACTS

NEW CONTRACTS

SECTION III. RELEASE OF FUNDS TO WORK ORDER

SECTION IV. REVISION TO WORK ORDER

SECTION V. CLAIMS - PERSONAL PROPERTY LOSS

SECTION VI. CLAIMS - PERSONAL INJURY

SECTION VII. APPROVAL OF SPECIAL ITEMS

2. MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Resolution of the State Administrative Board regarding the conveyance of assets and liabilities of the Michigan Biologic Products Institute.

The Director of the Department of Management and Budget recommends approval by the State Administrative Board of the items contained in this agenda. Approval by the State Administrative Board of these award recommendations does not require or constitute the award of same. Award of contracts shall be made at the discretion of the DMB Director or designee.

July 7, 1998 No. 20

STATE OF MICHIGAN
STATE ADMINISTRATIVE BOARD

Resolutions of the State Administrative Board Regarding the Conveyance of Assets and Liabilities of the Michigan Biologic Products Institute

WHEREAS, Public Act No. 522 of 1996, as amended by Public Act No. 8 of 1998, (the "Act") authorizes the Michigan Biologic Products Commission (the "Commission") to negotiate the sale of all or a portion of the assets, and the assumption of all or a portion of the liabilities, associated with the Michigan Biologic Products Institute (the "Institute"); and

WHEREAS, upon recommendation of the Commission and the satisfaction of certain conditions, the Act also authorizes the State Administrative Board to approve and to authorize the execution of agreements and instruments of conveyance for the conveyance of all or a portion of the assets, and the assumption of all or a portion of the liabilities, associated with the Michigan Biologic Products Institute (the "Transaction"); and

WHEREAS, the Commission has conducted an open and competitive sale process in which a number of bids where evaluated, culminating in best and final offers being submitted by 2 bidders; and

WHEREAS, the Commission has recommended, through the adoption of its Resolution No. 11, that the State Administrative Board approve the conveyance of assets and certain liabilities of the Institute to BioPort Corporation and approve an Asset Purchase Agreement substantially in the form presented to the State Administrative Board; and

WHEREAS, pursuant to Section 5 of the Act, First of Michigan Corporation has presented an independent opinion that the consideration to be received for the assets and liabilities of the Institute proposed to be transferred under the terms of the proposed Asset Purchase Agreement is fair and adequate; and

WHEREAS, the report of the Auditor General required by Section 5 of the Act has been made to the Legislature; and

WHEREAS, this Board has examined the proposed Asset Purchase Agreement, a copy of which is attached hereto, by which the State of Michigan would be prepared to consummate the Transaction with BioPort Corporation.

THEREFORE, BE IT RESOLVED by the State Administrative Board of the State of Michigan, pursuant to the authority granted in the Act, as follows:

1. In reliance upon all facts, circumstances, certifications and opinions known to or received by the Board, the consideration to be received under the terms of the Asset Purchase Agreement is

determined to be fair and adequate and is sufficient such that the credit of the State of Michigan does not need to be granted to a person, association or corporation, public or private.

2. The terms of the proposed Preferential Access Agreement between the State of Michigan and BioPort Corporation to provide the State of Michigan with preferential access to certain biologic products are determined to meet the requirements of the Act.

3. The terms of the conveyance are determined to include a commitment by BioPort Corporation to continue the employment of Institute employees who elect to continue employment with BioPort Corporation for not less than 1 year after the closing date of the Transaction, as required by the Act and subject to the qualifications set forth in the Act.

4. This Board acknowledges the receipt of and accepts and approves the opinion of First of Michigan Corporation, concluding that the consideration for the assets and liabilities of the Institute is fair and adequate.

5. This Board has reviewed the goals of the Commission regarding the sale and the process used by the Commission to identify potential purchasers, receive bids and negotiate the Asset Purchase Agreement, and has determined that these goals and the process used to implement these goals has resulted in an open and competitive sale process.

6. The Asset Purchase Agreement between the State of Michigan and BioPort Corporation recommended by the Commission is approved in substantially the form presented. The Chairperson of the Commission is authorized to execute and deliver the Asset Purchase Agreement in the name of the State of Michigan, with those changes the Chairperson of the Commission may approve which do not materially and substantially modify its terms as presented, such approval to be conclusively evidenced by the execution of the Asset Purchase Agreement.

7. The Chairperson of the Commission is also authorized and empowered, in the name of the State of Michigan, to do or cause to be done any and all such acts or things as he may deem necessary, appropriate or desirable and to execute, verify, acknowledge, file and deliver deeds, bills of sale, other instruments of conveyance, and other agreements and certificates necessary to effectuate the terms of the conveyance agreed to under the Asset Purchase Agreement, including but not limited to the following agreements in substantially the form presented with those changes the Chairperson of the Commission may approve which do not materially and substantially modify their terms as presented, such approval to be conclusively evidenced by their execution:

a. The Preferential Access Agreement.

b. The Escrow Agreement.

c. The Right of First Refusal and Conditional Option Agreement.

d. The Mortgage and Security Agreement.

8. The State Treasurer is hereby directed to receive all monies directly paid to the State of Michigan and to deposit such monies in the Pharmaceutical Products Fund to be used in the manner authorized by the Act.

9. All Resolutions and parts of Resolutions, only insofar as the same may be in conflict herewith, are hereby superseded.

10. This Resolution shall take effect immediately upon its adoption by the State Administrative Board.

Arlene Oisten
Secretary

Treasurer Roberts presented the Finance and Claims Committee Report covering the regular meeting held June 30, 1998, and the Special Meeting held July 7, 1998. Treasurer Roberts pointed out that the Special meeting contained the contract with the State of Virginia for transferring prisoners from Michigan institutions and the resolution for the sale of the Michigan Biologic Products Institute. Treasurer Roberts moved that the regular Finance and Claims Committee Report of June 30, 1998, and the Special Finance and Claims Committee Report of July 17, 1998, be approved. The motion was supported by Superintendent Ellis and was unanimously adopted.

July 7, 1998 No. 24

COMMITTEE REPORT TO THE STATE ADMINISTRATIVE BOARD

The Honorable John Engler, Governor
and
Members of the State Administrative Board

A regular meeting of the **Building** Committee was held at **11:00 a.m.** on **July 1, 1998** those present being:

Chairperson: Roberta McKennon, representing State Treasurer Roberts — Approved _____

Member: Mike Gadola, representing Governor Engler — Approved _____

Member: _____, representing Lt. Governor Binsfeld — Approved _____

Others: Deborah Devine, Attorney General; Tracy Armstrong, James Burris, David Claus, Robert Mosher, Arlene Oisten, Mary Ellen Perkowski, Roxanne Pittman, Department of Management and Budget

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The Building Committee regular agenda and supplemental agenda were presented.

Following discussion, Mr. Gadola moved that the regular agenda and the supplemental agenda be recommended to the State Administrative Board for approval. Supported by Ms. McKennon, the motion was unanimously adopted.

Ms. McKennon adjourned the meeting.

July 7, 1998 No. 25

AGENDA

BUILDING COMMITTEE STATE ADMINISTRATIVE BOARD

July 1, 1998, Meeting, 11:00 a.m., State Treasurer's Conference Room

. . . . . .

The following items are recommended by the Department of Management and Budget:

REVISIONS TO CONSTRUCTION CONTRACTS

1. DEPARTMENT OF MANAGEMENT AND BUDGET, DIMONDALE - Secondary Governmental Complex - Secretary of State Building - New Loading Dock
File No. 071/96180.RLF - Index Nos. 85801, 85850, & 10761
Haussman Construction Company, Lansing; CCO #5, Incr. $7,399.68

2. DEPARTMENT OF MANAGEMENT AND BUDGET, LANSING - State Capitol Complex - Parking Lot Repairs
File No. 071/97227.JDM - Index No. 97227
Spartan Asphalt/Thompson McCully Company, Lansing; CCO #2, Incr. $114,131.45

3. DEPARTMENT OF MANAGEMENT AND BUDGET, DIMONDALE - Secondary Governmental Complex - Parking Lot Repairs
File No. 071/97227.JDM - Index No. 97227
Advanced Paving Company, Lansing; CCO #2, Incr. $93,902.60

4. CENTRAL MICHIGAN UNIVERSITY, MT. PLEASANT - New Music Building - General Conditions
File No. 332/80001.TDK - Index Nos. 50111 & 50112
Three Rivers Construction, Midland; CCO #13, Incr. $171,670.00

5. DEPARTMENT OF COMMUNITY HEALTH, LANSING - Michigan Biologic Products Institute - Building No. 16 - Clean Room Area Renovations
File No. 351/96120.JFT - Index No. 10796
Clark Construction Company, Lansing; CCO #3, Incr. $10,358.00

6. DEPARTMENT OF CORRECTIONS, VARIOUS LOCATIONS - Install Perimeter Intrusion Detection Systems
File No. 472/95191.RTM - Index No. 10592
Easter Owens Integrated Systems, Inc., Romeo; CCO #5, Incr. $10,303.82

7. DEPARTMENT OF ENVIRONMENTAL QUALITY, WAYNE COUNTY - Former Revere Copper & Brass, Lear-Siegler, and Anaconda Brass Sites
File Nos. 46917 & 47368
Homrich, Inc., Carleton; CCO #2, Incr. $828,434.00

RECOMMENDATION FOR CONVEYANCE OF STATE-OWNED PROPERTY

8. DEPARTMENT OF COMMUNITY HEALTH, CLINTON TWP. - That the following property be conveyed, under authority of Act No. 89 of the Public Acts of 1987, to Crescendo Communities of Michigan, Inc., whose address is 31150 Northwestern Highway, Suite 200, Farmington Hills, Michigan 48334, in consideration of payment of $1,020,000.00/without consideration for vacant property on Canal Road located south of the former Macomb Oakland Regional Center.

Commencing at the W 1/4 corner of Section 30, T 38 N, R 1 W; thence N along Section line 2080.07 feet for the point and place of beginning; th. continuing N along the Sec. line 601.63 ft. to the NW corner of Sec. 30, T 38 N, R 1 W and the shore of Lake Huron; th. S 79 deg. 32' E along the shore of Lake Huron 442 ft.; thence S 69 deg. 29' E along the shore of Lake Huron 856.46 ft.; thence S along the shore of Lake Huron 47 deg. 20' 20" E 178.37 ft.; th. S 23 deg. 15' 20" W along the shore of Lake Huron 174.25 ft.; th. S 12 deg 12' W along the shore of Lake Huron 330.37 ft.; th. S 44 deg. 58' W 235.13 ft.; th. N 36 deg. 31' W 678.11 ft.; th. W 640.19 ft. to the point of beginning, being a portion of Gov't. Lot 4, Sec. 30 T 38 N, R 1 W, Michigan.

Further, the conveyance shall be by quitclaim approved by the Attorney General and shall reserve to the State all rights to coal, oil, gas, and other mineral rights, excluding sand, gravel, clay, or other nonmetallic minerals found on, within, or under the conveyed land.

Further, the conveyance shall provide for an access easement on the property to maintain, replace, or repair a sanitary sewer and its appurtenances, which runs north to south, to a trash screen and meter pit at Canal Road, along with the right to drainage for storm water run off separate from the State owned property to the north.

Further, the revenue received under this act shall be deposited in the State Treasury and in a restricted account and shall be appropriated only to the Department of Community Health for use in the development and delivery of mental health program services to the mentally handicapped.

LEASES FOR PRIVATE PROPERTY

Leases with services provided or paid by the State as noted.

9. FAMILY INDEPENDENCE AGENCY, LANSING - Renewal of lease (#7137) from July 1, 1998, through June 30, 2003, with Art Baryames, A Married Man, c/o L.G.T. Central, 1111 Michigan Avenue, Suite 201, Lansing, Michigan 48823-4092, for 1,550 square feet of office space and 4 common parking spaces located at 405 South Grand Avenue, Lansing. The annual per square foot rental rate for this space is $10.03 ($1,295.53 per month). This rate does not include heat, electricity, water/sewer, janitorial services and supplies, replacement of tubes and bulbs. Effective June 15, 1998, and every subsequent June 15, any increase or decrease in real property taxes per annum will be adjusted and paid on an annual basis. This lease contains one five-year renewal option at the same rental rate with the continuation of the above-stated adjustment provisions. This space provides work stations for 2 employees. This lease has been approved by the Attorney General as to legal form. Source of Funds: 45% Federal Funds; 55% General Fund.

10. DEPARTMENT OF STATE POLICE, LANSING - New lease (#10559) from July 1, 1998, through June 30, 2003, with John R. Trevas, A Single Man, c/o DeWitt Fence Company, 3234 West St. Joseph, Lansing, Michigan 48917, for 3,600 square feet of warehouse space and three parking spaces located at 3234 West St. Joseph, Lansing. The annual per square foot rental rate for this space is $4.25 ($1,275.00 per month). This rate does not include heat, electricity, water/sewer, janitorial services and supplies, replacement of fluorescent tubes and bulbs, and rubbish removal. Effective June 15, 2001, and every subsequent June 15, any increase or decrease in real estate property taxes per annum will be adjusted and paid on an annual basis. This Lease has been approved by the Attorney General as to legal form. Source of Funds: 100% Restricted Funds.

LEASE FOR STATE-OWNED PROPERTY

11. DEPARTMENT OF COMMUNITY HEALTH, LANSING - New lease (#10590) from August 1, 1998, through July 31, 2018, between the Michigan Department of Community Health, as Lessor, and Michigan Department of Transportation, as Lessee, for 400 square feet of land located at North Logan Complex, Lansing. The one time rental for this space is $1.00. The State provides no services. This lease contains two ten-year renewal options at the same rate. This lease has been approved by the Attorney General as to legal form. Source of Funds: Aeronautics Fund.

ADDENDA TO LEASES FOR PRIVATE PROPERTY

12. DEPARTMENT OF CONSUMER AND INDUSTRY SERVICES, GRAND RAPIDS - Addendum #2 to lease (#7132) approved by the State Administrative Board on June 7, 1988, Item #35, between H & H Management Company, A Partnership, and subsequently assigned to Henry Pestka, Trustee of the Henry Pestka Restated Trust, DBA H & H Management Company, Trustee, as Lessor, and the State of Michigan, Department of Consumer and Industry Services, as Lessee, for space located at 2922 Fuller Avenue, Suites 114 and 201-B, Grand Rapids, This addendum provides for an additional 1,380 square feet (total square feet 4,681), for the additional annual rental of $17,250.00 ($0.15 per square foot). The new total annual rental for the combined space will be $56,862.00 ($12.15 per square foot). This additional space will provide work stations for five additional employees (total of 18 employees). This addendum will also provide for extending the existing lease for four years, four months through August 31, 2007, with an increase in the annual rental of $7,033.68 per year ($1.50 per square foot). The new total annual rental will be $63,895.68 ($13.65 per square foot) with the continuation of the adjustment schedule. This addendum becomes effective upon the last State Governmental approval and continues to the termination date of the lease, August 31, 2007. This addendum has been approved by the Attorney General as to legal form. Source of Funds: 100% General Fund.

13. FAMILY INDEPENDENCE AGENCY, CHEBOYGAN - Addendum #1 to lease (#10456) approved by the State Administrative Board on February 18, 1997, Item #18, between County of Cheboygan, A Governmental Unit, as Lessor, and the State of Michigan, Family Independence Agency, as Lessee, for space located at 827 South Huron Street, Cheboygan. This addendum provides for correcting the rental rate to amortize the debt over a ten year period instead of for a 15 year period (total square feet 10,950) with an increase in the annual rental of $13,570.32 per year ($1.24 per square foot). The new total annual rental will be $204,867.00 ($18.71 per square foot) with continuation of the adjustment schedule. This addendum has been approved by the Attorney General as to legal form. Source of Funds: 45% Federal Funds; 55% General Fund.

14. DEPARTMENT OF STATE, WYOMING - Addendum #2 to lease (#6838) approved by the State Administrative Board on October 21, 1986, Item #25, between Wyoming Mall, Ltd., A Michigan Limited Partnership, as Lessor, and the State of Michigan, Department of State, as Lessee, for space located at 1288 28th Street, S.W., Wyoming. This addendum provides for adding one five-year renewal option with an increase in the annual rental of $2,196.48 per year ($.88 per square foot). The new total annual rental will be $24,161.28 ($9.68 per square foot) with continuation of the adjustment schedule. In addition this addendum provides for the replacement of carpet and window blinds and to furnish and install electrical to relocate the front counter, with get ready costs in the amount not-to-exceed ($5,753.60) (total square feet 2,496). This addendum becomes effective upon the last State Governmental approval and continues to the termination date of the lease March 31, 2003, or any extension. This addendum has been approved by the Attorney General as to legal form. Source of Funds: 91% Restricted General Funds; 9% General Fund.

RECOMMENDATION FOR CONSTRUCTION CHANGE ORDERS

15. FAMILY INDEPENDENCE AGENCY, DETROIT - Construction Change Order #2 to lease #2205 approved by the State Administrative Board on September 7, 1976, Item #29, between Jacob and Rachel Kellman, and subsequently assigned to 4733 Conner Company L.L.C., as Lessor, and the State of Michigan, Family Independence Agency, as Lessee. This construction change order provides for program items requested by the Family Independence Agency at a cost not-to-exceed $28,629.25 for space located at 4733 Conner, Detroit, Wayne County. Source of Funding: 55% General Fund; 45% Federal Funds.

16. FAMILY INDEPENDENCE AGENCY, DETROIT - Construction Change Order #3 to lease #2506 approved by the State Administrative Board on July 15, 1977, Item #16, between Woodridge Investment Company, and subsequently assigned to Delco Boulevard Associates, L.L.C., as Lessor, and the State of Michigan, Family Independence Agency, as Lessee. This construction change order provides for program items requested by the Family Independence Agency at a cost not-to-exceed $238.05 for space located at 1145 West Grand Boulevard, Detroit, Wayne County. Source of Funding: 55% General Fund; 45% Federal Funds.

17. FAMILY INDEPENDENCE AGENCY, DETROIT - Construction Change Order #2 to lease #3064 approved by the State Administrative Board on April 17, 1979, Item #16, between Terry and Sandra Grosslight, and subsequently assigned to Forest-Ellery L.L.C., as Lessor, and the State of Michigan, Family Independence Agency, as Lessee. This construction change order provides for program items requested by the Family Independence Agency at a cost not-to-exceed $786.60 for space located at 3606 East Forest, Detroit, Wayne County. Source of Funding: 55% General Fund; 45% Federal Funds.

18. FAMILY INDEPENDENCE AGENCY, DETROIT - Construction Change Order #1 to lease #4563 approved by the State Administrative Board on December 16, 1980, Item #16, between Kenyon Investment Company, and subsequently assigned to Maddelein Associates, L.L.C., as Lessor, and the State of Michigan, Family Independence Agency, as Lessee. This construction change order provides for program items requested by the Family Independence Agency at a cost not-to-exceed $34,965.75 for space located at 14050 Maddelein West, Detroit, Wayne County. Source of Funding: 55% General Fund; 45% Federal Funds.

19. FAMILY INDEPENDENCE AGENCY, DETROIT - Construction Change Order #1 to lease #7067 approved by the State Administrative Board on January 1, 1988, Item #1, between Comprehensive Developers Incorporated, and subsequently assigned to DSS #1 Limited Partnership, as Lessor, and the State of Michigan, Family Independence Agency, as Lessee. This construction change order provides for program items requested by the Family Independence Agency at a cost not-to-exceed $58,377.38 for space located at 6534 West Jefferson, Detroit, Wayne County. Source of Funding: 55% General Fund; 45% Federal Funds.

20. FAMILY INDEPENDENCE AGENCY, LINCOLN PARK - Construction Change Order #5 to lease #2703 approved by the State Administrative Board on April 4, 1978, Item #19, between Jerry R. and Sandra L. Brady, and subsequently assigned to Kenyon Investment Co., L.L.C., as Lessor, and the State of Michigan, Family Independence Agency, as Lessee. This construction change order provides for program items requested by the Family Independence Agency at a cost not-to-exceed $644.00 for space located at 999 West Fort Street, Lincoln Park, Wayne County. Source of Funding: 55% General Fund; 45% Federal Funds.

21. FAMILY INDEPENDENCE AGENCY, LINCOLN PARK - Construction Change Order #6 to lease #2703 approved by the State Administrative Board on April 4, 1978, Item #19, between Jerry R. and Sandra L. Brady, and subsequently assigned to Kenyon Investment Co., L.L.C., as Lessor, and the State of Michigan, Family Independence Agency, as Lessee. This construction change order provides for program items requested by the Family Independence Agency at a cost not-to-exceed $1,035.00 for space located at 999 West Fort Street, Lincoln Park, Wayne County. Source of Funding: 55% General Fund; 45% Federal Funds.

22. FAMILY INDEPENDENCE AGENCY, TAYLOR - Construction Change Order #1 to lease #2628 approved by the State Administrative Board on December 6, 1977, Item #20, between Woodridge Investment Company, and subsequently assigned to Kenyon Investment Company, L.L.C., as Lessor, and the State of Michigan, Family Independence Agency, as Lessee. This construction change order provides for program items requested by the Family Independence Agency at a cost-not-to-exceed $53,909.70 for space located at 22050 Pennsylvania, Taylor, Wayne County. Source of Funding: 55% General Fund; 45% Federal Funds.

July 7, 1998 No. 31

SUPPLEMENTAL AGENDA

Building Committee - State Administrative Board

July 1, 1998, Meeting, 11:00 a.m. - State Treasurer's Conference Room

The following item is recommended by the Department of Management and Budget:

RECOMMENDATION FOR GRANT OF ACCESS AND UTILITY EASEMENT

S1. DEPARTMENT OF MANAGEMENT AND BUDGET, LANSING TOWNSHIP - That for and in consideration of payment of a fee in the amount of $ 1.00 for the value of the easement that the State Administrative Board, under authority of Act 431 of the Public Acts of 1984, as amended, grant to the United States of America through the Federal Aviation Administration, 2300 E. Devon Avenue, Des Plaines, Illinois 60018, an easement on the following described property:

An easement from Martin Luther King Boulevard across existing roads, driveways and parking to land at the Capital City Airport lying to the north of the State owned property under the Jurisdiction of the Department of Management and Budget, to provide access and electrical service. The legal description for the easement shall be provided by the Federal Aviation Administration for review and approval by the Department of Management and Budget.

Further, that all legal documents relative to the Grant of Easement be prepared by the Department of Attorney General.

Further, that all monies received be deposited in the General Fund of the State.

Treasurer Roberts presented the Building Committee Report of July 1, 1998. After presentation and review of the forgoing Building Committee Report, Mr. Roberts moved the Building Committee Report covering the regular meeting held July 1, 1998, be approved and adopted. The motion was supported by Secretary Miller and unanimously approved.

COMMITTEE REPORT TO THE STATE ADMINISTRATIVE BOARD

The Honorable John Engler, Governor
and
Members of the State Administrative Board

A regular meeting of the **Transportation and Natural Resources** Committee was held at **3:30 p.m. on July 1, 1998** those present being:

Chairperson:	A. Edwin Dore, Representing Secretary of State Miller	Approved _____
Member:	Richard Wheat, representing Lt. Governor Binsfeld	Approved _____
Member:	Patrick Isom, representing Attorney General Kelley	Approved _____

Others: Tracy Armstrong, Arlene Oisten, Department of Management and Budget; Tasa Businshi, Cheryl Cerqueira, Rod Collins, Kevin Fox, Julie Gee, Connie Hanrahan, Oliver House, Tom Killingsworth, Randy Knapp, Michael Smith, Department of Transportation

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There was no Department of Natural Resources agenda.

The Department of Transportation regular agenda, supplemental agenda, and second supplemental agenda were presented. Following discussion, Mr. Isom moved that the Transportation regular agenda, supplemental agenda, and second supplemental be recommended to the State Administrative Board for approval, with the withdrawal of items 69, 70, 71, 91, and 94. Supported by Mr. Wheat, the motion was unanimously adopted.

The Department's communication of June 18, 1998 explained the emergency contract with Dan's Excavating of Shelby Township, Michigan, in the negotiated amount of $705,294.00. This contract was in response to an emergency in the construction area of M-59 and Elizabeth Lake Road. The communication is on file with the Secretary.

The meeting was adjourned by Mr. Dore.

July 7, 1998 No. 34

AGENDA

DEPARTMENT OF TRANSPORTATION

TRANSPORTATION and NATURAL RESOURCES COMMITTEE
STATE ADMINISTRATIVE BOARD

T&NR Meeting: July 1, 1998 - Secretary of State's Office, 3:30 PM
State Administrative Board Meeting: July 7, 1998 - Capital, 11:00 AM

* *

MDOT PURCHASING / INVITATION TO BID

1. 591I8000665(CS-138- 591S8000261)
Bridge cleaning, high pressure water blast cleaning for bridge decks, drains and other areas as required. State wide; MDOT Zilwaukee Bridge, Rouge River Bridge and fourteen Bascule Bridges located through the State if/as requested. For the period July 8, 1998 to July 7, 2001. 100 % State restricted funds. Awarded to the lowest bidder.

Northern A-1 Services, Inc. **Kalkaska, Mi.**	**$299,400.00**	**4 Requests for Bid** **1 Vendor Response**

AUTHORIZATION TO SUBCONTRACT

2. **Thompson-McCully Co.**
1600 N. Elm, P.O. Box 1134
Jackson, MI

Bituminous Resurfacing

$63,308.22

Approval is requested authorizing the Hillsdale County Road Commission to award a subcontract for cold-milling and bituminous resurfacing. The project is located on M-99, from Lake Avenue easterly past the M-99 and M-34 intersection for a distance of 0.64 miles. The project was advertised and two (2) bids were received. The low bid was selected. One hundred percent State Restricted Funds.

FIXED COST CONTRACTS

3. The 90-Day provision under Section 11C of Act 51 of the Public Act of 1951, as amended in 1982 has been adhered to in that the State Transportation Commission (STC) and the Senate and House Appropriation Committees have been properly notified of the following negotiated contracts:

The Department finds that it is in the public interest that the Local units of government receive a fixed cost contract for these projects because:

1) If Local government units are allowed to use their own forces to do this work, it will enable them to retain most employees year-round to properly maintain the roads on the Local systems.

2) They have the necessary equipment and personnel to do the work and their unit prices are at or below contract prices for the area.

3) Payment for these contracts is from Federal and Local funds. To qualify for Federal funds, the Local units must contribute to the cost of the project. Local units make that contribution by supplying their labor force. If required to contract out for the work, the Local units would have to pay the Local contribution in cash, and as a result, the work would not be done and the area would lose the Federal aid.

Therefore, because it is in the best interest of the public, we request contracts with the following units of government:

Fixed Cost Contract and Municipal Cost Participation for Construction Contract.

Project Numbers: STH 30609, 46256A, STP9830(001), RR1539

Contract: 98-5305 between MDOT and the Hillsdale County Road Commission.

0.90 km of intersection improvement with bituminous surfacing, bituminous crushing and shaping, grading, aggregate base and drainage for West Bacon Road at Sand Lake Road in Hillsdale County.

Total Project Length: 0.90 km

The contract is for $ 172,448.25. Federal funds will be $100,000. The Hillsdale County Road Commission's share will be $72,448.25 which will be provided in the form of work. No State trunkline funds are involved.

4. The 90-Day provision under Section 11C of Act 51 of the Public Act of 1951, as amended in 1982 has been adhered to in that the State Transportation Commission (STC) and the Senate and House Appropriation Committees have been properly notified of the following negotiated contracts:

The Department finds that it is in the public interest that the local units of government receive a fixed cost contract for these projects because:

1) If local government units are allowed to use their own forces to do this work, it will enable them to retain most employees year-round to properly maintain the roads on the local systems.

2) They have the necessary equipment and personnel to do the work and their unit prices are at or below contract prices for the area.

3) Payment for these contracts is from federal and local funds. To qualify for federal funds, the local units must contribute to the cost of the project. Local units make that contribution by supplying their labor force. If required to contract out for the work, the local units would have to pay the local contribution in cash, and as a result, the work would not be done and the area would lose the federal aid.

Therefore, because it is in the best interest of the public, we request contracts with the following units of government:

Fixed Cost Contract and Municipal Cost Participation for Construction Contract.

Project Numbers: EDA 22522, 44566A

Agreement: 97-5405 between MDOT and the Dickinson County Road Commission

2.09 kilometers of grading, drainage improvements, peat excavation, subbase, aggregate base, bituminous surfacing and restoration on County Road 426 from 7.10 kilometers east of County Road 581 at Ralph to 9.19 kilometers east of County Road 581 in Dickinson County.

Total Project Length: 2.09 kilometers

The contract is for $283,000.00. State funds will be $215,080.00 or 76%. The county share will be $67,920.00 or 24%, which will be provided in the form of work. No state trunkline funds are involved. Bituminous resurfacing will be subcontracted by the county.

Project Numbers: EDDF 27555, 44469A; DSTP 9827(008), RR 1633

Agreement: 98-5313 between MDOT and the Gogebic County Road Commission

2.74 kilometers of bituminous resurfacing with aggregate shoulders on East Shore Lake Road from the Ontonagon-Gogebic county line then south 2.74 kilometers in Gogebic County.

Total Project Length: 2.74 kilometers

The contract is for $85,690.00. Federal funds will be $68,552.00 or 80%. The county share will be $17,138.00 or 20% which will be in the form of work. No state trunkline funds are involved. The county will furnish and apply bituminous material.

Project Numbers: EDDF 27555, 39306A; STP 9827(007), RR 1629

Agreement: 98-5312 between MDOT and the Gogebic County Road Commission

5.31 kilometers of bituminous resurfacing with aggregate shoulders on Lake Road from 0.95 kilometers northwest of Brace Road then west 3.28 kilometers and from 1.16 kilometers south of Brace Road then north 2.09 kilometers in Gogebic County.

Total Project Length: 5.31 kilometers

The contract is for $171,769.50. Federal funds will be $137,415.60 or 80%. The county share will be $34,353.90 or 20% which will be in the form of work. No state trunkline funds are involved. The county will furnish and apply bituminous material.

Project Numbers: EDD 55555, 39361A

Agreement: 98-5311 between MDOT and the Menominee County Road Commission

2.72 kilometers (1.69 miles) of bituminous surfacing with aggregate shoulders on County Road 571 from M-35 to County Road 320 in Menominee County.

Total Project Length: 2.72 kilometers

The contract is for $100,752.45. State funds will be $80,601.96 or 80%. The county share will be $20,150.49 or 20% and will be in the form of work. No state trunkline funds are involved. The county will purchase and apply the bituminous material.

CONTRACTS

5. MUNICIPAL - Cost Participation for Preliminary Engineering
Contract (98-5005) between MDOT and the City of Farmington Hills providing for participation in the performance of early preliminary engineering services for alternative improvements on Northwestern Highway, 14 Mile Road, Maple Road and Orchard Lake Road from the intersection of Northwestern Highway (M-10) with 14 Mile Road to where Highway M-5 (Haggerty Connector Project) terminates west of the Haggerty Road intersections on 14 Mile Road and Maple Road; environmental clearance evaluation and documentation; preparation of an Environmental Assessment/Environmental Impact Statement; the final determination of the preferred improvement alternative; preparation of plans and specifications and necessary related work.

Estimated Funds:

Federal	$1,200,000
State Restricted	300,000
Total	$1,500,000

6. MUNICIPAL - Cost Participation for Local Agency Construction Contract
Contract (98-5149) between MDOT and the City of Alpena amending contract (96-5230) dated August 19, 1996, providing for participation by the Federal Highway Administration (FHWA) in the construction under contract by the City of the following Transportation Enhancement improvements: The construction of a concrete bikepath, 8 feet in width, and/or the widening of existing portions of the sidewalk to a width of 8 feet, along the westerly side of Ripley Boulevard from Mason to Cambell Streets.

This amendment is to include the relocation of the fire hydrants and pedestrian signals as part of the work to be contracted by the City of Alpena and delete all force account work. The total cost of the project remains the same.

7. MUNICIPAL - Cost Participation for Construction Contract
Contract (98-5158) between MDOT and the City of Portage amending Contract (96-5167) dated September 17, 1997, providing for participation in the following improvements:

Part A - Federal, State and City Participation
Deck replacement, reconstruction and widening of structure S01 of 39013 which carries Centre Avenue over Highway US-131 and which includes the addition of acceleration/deceleration lanes, ramp reconstruction and approach work; together with necessary related work; located within the corporate limits of the City.

Part B - 100% City
The construction of 2.4 m sidewalk along the south side of Centre Street from Angling Road to 12th Street, including across structure R01 of 39013, and which includes parapet railing and 2 m high pedestrian fencing across said structure; together with necessary related work located within the corporate limits of the City.

Estimated Funds:

	Original
Federal	$1,837,600
State Restricted	407,700
City of Portage	51,700
Total	$2,297,000

	Revised Part A	Part B	Total
Federal	$1,837,600	$ -0-	$1,837,600
State Restricted	407,700	-0-	407,700
City of Portage	51,700	150,126	201,826
Total	$2,297,000	$150,126	$2,447,126

The purpose of this amendment is to include the construction of additional new sidewalk and increase the cost to reflect this additional work.

8. MUNICIPAL - Cost Participation for Construction Contract
Contract (98-5160) between MDOT and the City of Kalamazoo providing for participation in the milling and resurfacing the northbound lanes of Douglas Avenue between Kalamazoo Avenue and Ravine Road which will be used as a detour for the Department's Highway M-43 (W. Main) work from Prairie Street to Michigan Avenue; together with necessary related work; located within the corporate limits of the City.

Estimated Funds:

State Restricted	$90,000

9. MUNICIPAL - Cost Participation for Construction Contract
Contract (98-5161) between MDOT and the Genesee County Road Commission providing for participation in the construction improvements for the following roadways used as a detour route by MDOT for its Highway M-15 project: Dodge Road, Irish Road and Highway M-57; together with necessary related work; located within Genesee County, Michigan.

Estimated Funds:

Federal	$65,480
State restricted	14,520
Total	$80,000

10. MUNICIPAL - Cost Participation for Construction Contract
Contract (98-5164) between MDOT and the County of Wayne providing for participation in the construction of the following improvements utilizing Transportation Economic Development (TED) Category C Funds: Furnish and install traffic signals at the north I-94 Service Road and Tyler Road intersections with Belleville Road as may be required.

Estimated Funds:

State Restricted	$51,120
Wayne County	12,780
Total	$63,900

11. MUNICIPAL - Cost Participation for Construction Contract
Contract (98-5173) between MDOT and the Bay County Road Commission providing for participation in the construction of new watermain along Linwood Road to the Highway I-75 interchange and then proceeding along the Highway I-75 right-of-way northerly to the Linwood Rest Area; together with necessary related work; located in Bay County, Michigan.

Estimated Funds:

State Restricted	$330,000

12. MUNICIPAL - Cost Participation for Local Agency Construction Contract
Contract (98-5189) between MDOT and the City of Royal Oak providing for participation by the Federal Highway Administration (FHWA) in the construction under contract by the city of the following Transportation Enhancement improvements: Streetscaping along Main Street for approximately 0.193 km from Kenilworth Street to Rhode Island Street.

Estimated Funds:

Federal	$ 91,800
City of Royal Oak	105,291
Total	$197,091

13. MUNICIPAL - Cost Participation for Local Agency Construction Contract
Contract (98-5230) between MDOT and the City of Wixom providing for participation by the Federal Highway Administration (FHWA) in the construction under contract by the City of the following Transportation Enhancement improvements: The construction of a 2.45 m (8 ft) wide concrete bikepath along Wixom Road from Pontiac Trail to Maple Road.

Estimated Funds:

Federal	$59,324
City of Wixom	62,506
Total	$121,830

14. MUNICIPAL - Cost Participation for Local Agency Construction Contract
Contract (98-5235) between MDOT and the Grand Traverse County Road Commission amending contract (96-5487) dated November 6, 1996 providing for participation by the Federal Highway Administration (FHWA) in the construction under contract by the County of the following Transportation Enhancement improvements: The performance of preliminary and construction engineering activities associated with the landscaping work along Highway US-31 from Beitner Road to Airport Road; together with necessary related work; located within Grand Traverse County, Michigan.

Estimated Funds:

	Original	Revised
Federal	$16,116	$19,390
Grand Traverse County Road Comm.	3,574	4,300
Total	$19,690	$23,690

The purpose of this amendment is to increase preliminary engineering charges to cover the time for the property owners meetings and changes to drawings.

15. MUNICIPAL - Cost Participation for Local Agency Construction Contract
Contract (98-5250) between MDOT and the City of Ann Arbor providing for participation by the Federal Highway Administration (FHWA) in the construction under contract by the City of the following Transportation Enhancement improvements:

The planting of 51 large shade trees along both sides of Packard Road from South Main Street to Highway US-23 overpass.

Estimated Funds:

Federal	$7,000
City of Ann Arbor	$7,000
Total	$14,000

16. MUNICIPAL - Cost Participation for Local Agency Construction Contract
Contract (98-5254) between MDOT and the Montcalm County Road Commission providing for participation by the Federal Highway Administration (FHWA) in the construction under contract by the County of the following Transportation Enhancement improvements: The construction of a 3 meter wide paved bicycle path with paved spur to area school along Route 510 for approximately 8.2 km in Sidney to the north limits of the City of Stanton; the restoration of historic bridge as may be required.

Estimated Funds:	
Federal	$247,793
Montcalm County Road Commission	106,197
Total	$353,990

17. MUNICIPAL - Cost Participation for Local Agency Construction Contract
Contract (98-5266) between MDOT and the City of Lansing providing for participation by the Federal Highway Administration (FHWA) in the construction under contract by the city of the following Transportation Enhancement improvements: Replacement of the existing with new curb and gutter and decorative sidewalk with tree grates along East Michigan Avenue from Hosmer to Holmes Roads.

Estimated Funds:	
Federal	$221,925
City of Lansing	73,975
Total	$295,900

18. AERONAUTICS - Performance Evaluation
Contract (98-0520) between MDOT and Soil and Engineers Material, Inc., provides a performance evaluation of P401 mixtures using modified asphalt binders on airports in Michigan. The term of this contract is from execution to 6/1/99. Funding: Federal $72,000; State $8,000; Total $80,000.

19. AERONAUTICS - Airport Awareness Project
Contract (98-0641) between MDOT and the Alpena County Board of Commissioners, Alpena County Airport to provide for a grant in implementing the Airport Awareness Project under the Michigan Air Service Grant Program. The term of this contract begins upon execution and is effective for 12 months. The cost of the project is estimated to be $16,667; $15,000 from State Aeronautics funds, and $1,667 from the Alpena County Board of Commissioners.

20. AERONAUTICS - Terminal Building
Contract (98-0642) between MDOT and the Marquette County Board of Commissioners, provides construction of terminal building and parking lot with lighting at Sawyer Airport in Gwinn, Michigan. The Contract will be in effect for a period of 36 months. Federal Funds $500,000; State Aeronautics Funds $160,000; Board of County Commissioners of Marquette County $2,740,000; Total $3,400,000.

21. AERONAUTICS - Runway Rehabilitation
Contract (98-0656) between MDOT and Oakland County Board of Commissioners to rehabilitate and widen NE taxiway at Oakland County International Airport in Pontiac, Michigan. The Contract will be in effect for a period of 36 months. Funding: Federal Funds (Via Block Grant) $90,000; State Aeronautics Funds $0; Oakland County Board of Commissioners $10,000; Total $100,000.

22. AERONAUTICS - Runway Construction
Contract (98-0658) between MDOT and the Saginaw County Board of Commissioners to provide Federal and State Grant funds to construct west parallel Taxiway 9/27 and rehabilitate Taxiway D, south of Taxiway C at Harry W. Browne International Airport in Saginaw, Michigan. The Contract will be in effect for a period of 36 months. Funding: Federal Funds (Via Block Grant) $559,800; State Aeronautics Funds $31,100; Saginaw Co. Board of Commissioners $31,100; Total $622,000.

23. AERONAUTICS - Runway Rehabilitation
Contract (98-0659) between MDOT and the Jackson County Board of Commissioners is a sub-grant to provide Federal and State Grant funds to rehabilitate Taxiway F and partial rehabilitation of Taxiways A and B at the Jackson County Airport-Reynolds Field in Jackson, Michigan. The Contract will be in effect for a period of 36 months. Funding: Federal Funds (Via Block Grant) $98,100; State Aeronautics Funds; $5,450; Jackson Co. Board of Commissioners $5,450; Total $109,000.

24. AERONAUTICS - SW Michigan Regional
Contract (98-0665) between MDOT and the Southwest Michigan Regional Airport Board to provide State grant funds for airport pavement crack sealing at the Southwest Michigan Regional Airport in Benton Harbor, Michigan. The Contract will be in effect for a period of 18 months. Funding: State Aeronautics Funds $7,500; Southwest Michigan Regional Airport Board $7,500; Total $15,000.

25. AERONAUTICS - Roben Hood Pavement Sealing
Contract (98-0666) between MDOT and the City of Big Rapids to provide State grant funds for airport pavement crack sealing at the Roben-Hood Airport in Big Rapids, Michigan. The Contract will be in effect for a period of 18 months. Funding: State Aeronautics Funds $5,000; City of Big Rapids $5,000; Total $10,000.

26. AERONAUTICS - Dowagiac Municipal
Contract (98-0668) between MDOT and the City of Dowagiac to provide State grant funds for airport pavement crack sealing at the Dowagiac Municipal Airport in Dowagiac, Michigan. The Contract will be in effect for a period of 18 months. Funding: State Aeronautics Funds $5,000; City of Dowagiac $5,000; Total $10,000.

27. AERONAUTICS - Bishop Airport Pavement Sealing
Contract (98-0669) between MDOT and the Bishop International Airport Authority to provide State grant funds for airport pavement crack sealing at the Bishop International Airport in Flint, Michigan. The contract will be in effect for a period of 18 months. Funding: State Aeronautics Funds $5,000; Bishop International Airport Authority $5,000; Total $10,000.

28. AERONAUTICS - Grosse Ile Pavement Sealing
Contract (98-0670) between MDOT and the Grosse Ile Board of Trustees to provide State grant funds for airport pavement crack sealing at the Grosse Ile Municipal Airport in Grosse Ile, Michigan. The Contract will be in effect for a period of 18 months. Funding: State Aeronautics Funds $10,000; Grosse Ile Board of Trustees $10,000; Total $20,000.

29. AERONAUTICS - Tulip City Pavement Sealing
Contract (98-0671) between MDOT and the City of Holland to provide State grant funds for airport pavement crack sealing at the Tulip City Airport in Holland, Michigan. The Contract will be in effect for a period of 18 months. Funding: State Aeronautics Funds $7,500; City of Holland $7,500; Total $15,000.

30. AERONAUTICS - Ionia County Pavement Sealing
Contract (98-0673) between MDOT and the Ionia County Board of Commissioners to provide State grant funds for airport pavement crack sealing at the Ionia County Airport in Ionia, Michigan. The Contract will be in effect for a period of 18 months. Funding: State Aeronautics Funds $1,500; Ionia County Board of Commissioners $1,500; Total $3,000.

31. AERONAUTICS - Ford Pavement Sealing
Contract (98-0674) between MDOT and the Dickinson County Board of Commissioners to provide State grant funds for airport pavement crack sealing at the Ford Airport in Iron Mountain, Michigan. The Contract will be in effect for a period of 18 months. Funding: State Aeronautics Funds $5,000; Dickinson County Board of Commissioners $5,000; Total $10,000.

32. AERONAUTICS - Gogebic/Iron Pavement Sealing
Contract (98-0675) between MDOT and the Gogebic County Board of Commissioners to provide State grant funds for airport pavement crack sealing at the Gogebic-Iron County Airport in Ironwood, Michigan. The Contract will be in effect for a period of 18 months. Funding: State Aeronautics Funds $10,000; Gogebic County Board of Commissioners $10,000; Total $20,000.

33. AERONAUTICS - DuPont/Lapeer Pavement Sealing
Contract (98-0676) between MDOT and Mayfield Township to provide State grant funds for airport pavement crack sealing at the DuPont-Lapeer Airport in Lapeer, Michigan. The Contract will be in effect for a period of 18 months. Funding: State Aeronautics Funds $15,000; Mayfield Township $15,000; Total $30,000.

34. AERONAUTICS - Garland Pavement Sealing
Contract (98-0677) between MDOT and Garland, Inc. to provide State grant funds for airport pavement crack sealing at the Garland Airport in Lewiston, Michigan. The Contract will be in effect for a period of 18 months. Funding: State Aeronautics Funds $4,500; Garland, Inc. $4,500; Total $9,000.

35. AERONAUTICS - Menominee/Marinette Pavement Sealing
Contract (98-0678) between MDOT and Menominee/Marinette County Board of Commissioners to provide State grant funds for airport pavement crack sealing at the Menominee/Marinette Twin County Airport in Menominee, Michigan. The Contract will be in effect for a period of 18 months. Funding: State Aeronautics Funds $15,000; Menominee/Marinette Co. BOARD. of Commissioners $15,000; Total $30,000.

36. AERONAUTICS - Muskegon Pavement Sealing
Contract (98-0679) between MDOT and the Muskegon County Board of Commissioners to provide State grant funds for airport pavement crack sealing at the Muskegon County Airport in Muskegon, Michigan. The Contract will be in effect for a period of 18 months. Funding: State Aeronautics Funds $15,000; Muskegon County Board of Commissioners $15,000; Total $30,000.

37. AERONAUTICS - Presque Isle/Rogers City Pavement Sealing
Contract (98-0680) between MDOT and the County of Presque Isle/City of Rogers City to provide State grant funds for airport pavement crack sealing at the Presque Isle County/Rogers City Airport in Rogers City, Michigan. The Contract will be in effect for a period of 18 months. Funding: State Aeronautics Funds $6,000; County of Presque Isle/City of Rogers City $6,000; Total $12,000.

38. AERONAUTICS - Browne International Pavement Sealing
Contract (98-0681) between MDOT and the Saginaw County Board of Commissioners to provide State grant funds for airport pavement crack sealing at the Harry W. Browne International Airport in Saginaw, Michigan. The Contract will be in effect for a period of 18 months. Funding: State Aeronautics Funds $5,000; Saginaw County Board of Commissioners $5,000; Total $10,000.

39. AERONAUTICS - MBS International Pavement Sealing
Contract (98-0682) between MDOT and the MBS International Airport Commission to provide State grant funds for airport pavement crack sealing at the MBS International Airport in Saginaw, Michigan. The Contract will be in effect for a period of 18 months. Funding: State Aeronautics Funds $5,000; MBS International Airport Commission $5,000; Total $10,000.

40. AERONAUTICS - Kirsch Municipal Pavement Sealing
Contract (98-0683) between MDOT and the City of Sturgis to provide State grant funds for airport pavement crack sealing at the Kirsch Municipal Airport in Sturgis, Michigan. The Contract will be in effect for a period of 18 months. Funding: State Aeronautics Funds $13,000; City of Sturgis $13,000; Total $26,000.

41. AERONAUTICS - Northwest Regional Pavement Sealing
Contract (98-0684) between MDOT and the Northwestern Regional Airport Commission to provide State grant funds for airport pavement crack sealing at the Cherry Capital Airport in Traverse City, Michigan. The Contract will be in effect for a period of 18 months. Funding: State Aeronautics Funds $15,000; Northwestern Regional Airport Commission $15,000; Total $30,000.

42. AERONAUTICS - Southwest Michigan Regional Pavement Sealing
Contract (98-0685) between MDOT and the Southwest Michigan Regional Airport Board is a sub-grant to provide Federal and State Grant funds to rehabilitate terminal apron at the Southwest Michigan Regional Airport in Benton Harbor, Michigan. The Contract will be in effect for a period of 36 months. Funding: Federal Funds (Via Block Grant) $305,100; State Aeronautics Funds $16,950; Southwest Michigan Regional Airport Board $16,950; Total $339,000.

43. AERONAUTICS - Runway Design/Construction
Contract (98-0686) between MDOT and the City of Evart to provide State grant funds for preliminary design for and construction of Runway 6/24 extension including lighting and existing runway rehabilitation including lights; airport master plan and environmental assessment at the Evart Municipal Airport in Evart, Michigan. The Contract will be in effect for a period of 18 months. Funding: State Aeronautics funds $939,225; City of Evart $147,775; Total $1,087,000.

44. AERONAUTICS - Construction Design Engineering
Contract (98-0687) between MDOT and the Village of Thompsonville to provide State grant funds for design engineering for construction of Runway 9/27, terminal apron and connecting taxiway at the Thompsonville Airport in Thompsonville, Michigan. The Contract will be in effect for a period of 18 months. Funding: State Aeronautics funds $27,000; Village of Thompsonville $3,000; Total $30,000.

45. CONSTRUCTION & TECHNOLOGY - Construction Engineering
Amendatory contract (98-0295/A1) between Hayward Baker and MDOT to provide construction engineering service on the US-131 bridge over the Grand River in Grand Rapids. The amendment will increase the contract from $5,000,000 to $5,550,000 and is for additional bridge repair work. The amendment will take effect on the date of execution and will expire October 31, 1999. Note: The Ad Board was originally notified that this work was of an emergency nature.

46. CONSTRUCTION & TECHNOLOGY - IDS Jack and Bore Inspections
Contract (98-0614) between MDOT and Fleis and Vandenbrink Engineering, Inc. and MDOT to perform jack and bore inspections on an as needed basis. The contract will start on the date of execution and expire on June 30,2001. Authorizations will be issued under this contract on an as needed basis. The amount of the contract is $500,000. The maximum amount of any authorization is $50,000. All work will be quality based selected. Source of funds is 80% FHWA, 20% State.

47. CONSTRUCTION & TECHNOLOGY - IDS Jack and Bore Inspections
Contract (98-0619) between MDOT and North Country Engineering and MDOT to perform jack and bore inspections on an as needed basis. The contract will start on the date of execution and expire on June 30, 2001. Authorizations will be issued on an as needed basis. The amount of the contract is $500,000. The maximum authorization is $50,000. All work will be quality based selected. Source of funds is 80% FHWA, 20% State.

48. CONSTRUCTION & TECHNOLOGY - IDS Pick-Up and Disposal
Contract (98-0633) between MDOT and K&W Landfill to pick up and dispose of contaminated soil on an as needed basis. The contract will start on the date of execution and expire on August 1, 1998. The amount of the contract is $500,000. The maximum authorization is $90,000. The contract will start on the date of execution and expire on August 1, 1998. All work will be competitively bid.

49. CONSTRUCTION & TECHNOLOGY - Claim Analysis & Review Writing
Contract (98-0689) between MDOT and URS Greiner to perform highway construction claim analysis and claim review writing Indefinite Delivery Service. The maximum amount of the contract will be $500,000 and the maximum amount of each authorization will be $90,000. All work will be quality base selected. The contract will start on the date of execution and expire 36 months later. Source of funds is 80% FHWA, 20% State.

50. CONSTRUCTION & TECHNOLOGY - Claim Analysis & Review Writing
Contract (97-0879) between MDOT and Transportation Group, Inc. to perform highway construction claim analysis and claim review writing Indefinite Delivery Service. The maximum amount of the contract will be $500,000 and the maximum amount of each authorization will be $90,000. All work will be quality base selected. The contract will start on the date of execution and expire 36 months later. Source of funds is 80% FHWA, 20% State.

51. CONSTRUCTION & TECHNOLOGY - Claim Analysis & Review
Contract (97-0880) between MDOT and O'Brian Kreitzberg to perform highway construction claim analysis and claim review Indefinite Delivery Service . The maximum amount of the contract will be $500,000 and the maximum amount of each authorization will be $90,000. All work will be quality base selected. The contract will start on the date of execution and expire 36 months later. Source of funds is 80% FHWA, 20% State.

52. CONSTRUCTION & TECHNOLOGY - Claim Review
Contract (97-0881) between MDOT and OMM Engineering to perform claim review Indefinite Delivery Service . The maximum amount of the contract will be $500,000 and the maximum amount of each authorization will be $90,000. All work will be quality base selected. The contract will start on the date of execution and expire 36 months later. Source of funds is 80% FHWA, 20% State.

53. CONSTRUCTION & TECHNOLOGY - Construction Project Closeout
Contract (97-0883) between MDOT and Robert Hawrylak to perform highway construction project closeout Indefinite Delivery Service . The maximum amount of the contract will be $500,000 and the maximum amount of each authorization will be $90,000. All work will be quality base selected. The contract will start on the date of executing and expire 36 months later. Source of funds is 80% FHWA, 20% State.

54. CONSTRUCTION & TECHNOLOGY - Time Extension
Amendatory contract (95-0242/A1) between MDOT and the University of Michigan to allow for continue Pavement Center of Excellence. The amendment will increase the contract time from September 30, 1999 to September 30, 2002. The amount of the contract will increase from $1,250,000 to $2,000,000. The amendment will become effective on August 1, 1998. Source of funds is 100% State Planning and Research (SPR).

55. CONSTRUCTION & TECHNOLOGY - IDS Construction Engineering Services
Authorization to contract (97-0377/Z8) between MDOT and Earth Tech. and MDOT is to perform construction engineering services on an as needed basis for a two year period. Authorization #8 is to perform construction engineering services on US-31 from M-46 easterly to the C & O Railroad. The amount of the authorization is $90,925.63. The contractor was quality based selected. Source of funds is 80% FHWA, 20% State.

56. CONSTRUCTION &TECHNOLOGY - IDS Project Closeout Services
Contract (97-0752) between MDOT and Consor Townsend Envirodyne Engineers to perform highway construction claim analysis, claim review writing and project closeout. The maximum amount of the contract will be $500,000 and the maximum amount of each authorization will be $90,000. All work will be quality base selected. The contract will start on the date of execution and expire 36 months later. Source of funds is 80% FHWA, 20% State.

57. CONSTRUCTION & TECHNOLOGY - IDS Project Closeout Services
Contract (97-0754) between MDOT and North Country Engineering to provide claim review writer, claim evaluation service and project closeout services on an as needed basis. The contract will be an Indefinite Delivery Service Contract. The maximum amount of each authorization will be $90,000. The maximum amount of each contract will be $500,000. All work will be quality base selected. Source of funds is 80% FHWA, 20% State.

58. CONSTRUCTION & TECHNOLOGY - IDS Project Closeout Services
Contract (97-0765) between MDOT and Mannik & Smith Inc., to provide for project claim review, project closeout and claim evaluation service. The maximum amount of each contract is $500,000 and the maximum amount of each authorization is $90,000. The contract is for a three year period. All work will be quality base selected. Source of funds is 80% FHWA, 20% State.

59. CONSTRUCTION & TECHNOLOGY - Project Closeout Services
Contract (97-0766) between MDOT and Hubbell, Roth and Clark Inc., to provide for claim review writer, project closeout and claim evaluation service. The maximum amount of the contract is $500,000. The maximum amount of each authorization is $90,000. The contract is for three years and all work will be quality base selected. Source of funds is 80% FHWA, 20% State.

60. CONSTRUCTION & TECHNOLOGY - Highway Construction Claim Evaluation
Contract (97-0871) between MDOT and Trauner Consulting Services, Inc., to perform highway construction claim evaluation. The maximum amount of the contract will be $500,000 and the maximum amount of each authorization will be $90,000. All work will be quality base selected. The contract will start on the date of execution and expire 36 months later. Source of funds is 80% FHWA, 20% State.

61. CONSTRUCTION & TECHNOLOGY - Highway Construction Claim Evaluation
Contract (97-0872) between MDOT and PMA Consultants LLC to perform highway construction claim evaluation and claim review writing. The maximum amount of the contract will be $500,000 and the maximum amount of each authorization will be $90,000. All work will be quality base selected. The contract will start on the date of execution and expire 36 months later. Source of funds is 80% FHWA, 20% State.

62. CONSTRUCTION & TECHNOLOGY - Highway Construction Claim Evaluation
Contract (97-0874) between MDOT and Sundberg, Carlson and Associates, Inc. to perform highway construction claim evaluation and claim review. The maximum amount of the contract will be $500,000 and the maximum amount of each authorization will be $90,000. All work will be quality base selected. The contract will start on the date of execution and expire 36 months later. Source of funds is 80% FHWA, 20% State.

63. CONSTRUCTION & TECHNOLOGY - Highway Construction Claim Evaluation
Contract (97-0875) between MDOT and Engineering and Environmental Services to perform highway construction claim analysis and claim review writing. The maximum amount of the contract will be $500,000 and the maximum amount of each authorization will be $90,000. All work will be quality base selected. The contract will start on the date of execution and expire 36 months later. Source of funds is 80% FHWA, 20% State.

64. CONSTRUCTION & TECHNOLOGY - Highway Construction Claim Analysis
Contract (97-0876) between MDOT and Coleman Engineering Company to perform highway construction claim analysis and claim review writing. The maximum amount of the contract will be $500,000 and the maximum amount of each authorization will be $90,000. All work will be quality base selected. The contract will start on the date of execution and expire 36 months later. Source of funds is 80% FHWA, 20% State.

65. CONSTRUCTION & TECHNOLOGY - Highway Construction Claim Analysis
Contract (97-0877) between MDOT and Wade-Trim to perform highway construction claim analysis. The maximum amount of the contract will be $500,000 and the maximum amount of each authorization will be $90,000. All work will be quality base selected. The contract will start on the date of execution and expire 36 months later. Source of funds is 80% FHWA, 20% State.

66. CONSTRUCTION & TECHNOLOGY - Project Closeout
Contract (97-0878) between MDOT and Michael Balent to perform highway construction claim review writing and project closeout. The maximum amount of the contract will be $500,000 and the maximum amount of each authorization will be $90,000. All work will be quality base selected. The contract will start on the date of execution and expire 36 months later. Source of funds is 80% FHWA, 20% State.

67. CONSTRUCTION & TECHNOLOGY - Claim Analysis & Review
Contract (97-0882) between MDOT and Earl Knott to perform highway construction claim analysis, claim review writing and project closeout. The maximum amount of the contract will be $500,000 and the maximum amount of each authorization will be $90,000. All work will be quality base selected. The contract will start on the date of execution and expire 36 months later. Source of funds is 80% FHWA, 20% State.

68. CONSTRUCTION & TECHNOLOGY - Jack and Bore Inspections
Contract (98-0613) between MDOT and Earth Tech., Inc. to perform jack and bore inspection services on an as needed basis. Contract will start on the date of execution and expire June 30, 2001. Authorizations will be issued under this contract on an as needed basis. The amount of the contract is $500,000 and the maximum authorization amount is $50,000. All work will be quality base selected. Source of funds is 80% FHWA, 20% State.

69. DESIGN - Design Services
Amendatory contract (97-0609/A2) between MDOT and Alfred Benesch & Company, amending contract 97-0609 providing for the design of I-75 Reconstruction, I-75/I-75 Connector from NYC RR Bridge to Gratiot Avenue in the County of Wayne.

70. DESIGN - Design Services
Contract 98-0654 between MDOT and DeLeuw, Cather & Company of Michigan, provides for the restart to complete design of M-6 Grand Rapids Southbelt (I-96 to W. of Eastern Ave.) in the County of Kent. Design services will include an airport study, M-37 design, golf course crossing, breaking project into multiple construction contracts, writing legal descriptions for ROW parcels, demolition of I-96 rest area and a value engineering study. The term of this contract is from execution and continues until July 31, 2001 The maximum dollar amount of this contract is $5,931,862.00, 80%FHWA and 20% State Trunkline.

71. DESIGN - Design Consultant Services
Contract (97-0785) between MDOT and Consoer Townsend Envirodyne Engineers, Inc. provides for design consultant services on an as needed when needed basis. This contract, which was executed on December 29, 1997, enables MDOT to initiate design activities with authorizations. The limit on these authorizations is $1,000,000. Authorizations in excess of $100,000 require the approval of the State Administrative Board. The term of this contract is from December 29, 1997 to December 29, 2000.

This request is for $125,784.15 which provides for the design of M-52 over Shiawassee River (B02)/CS 70612 - JN 46230D in the County of Shiawassee. The work for structure B02 will consist of superstructure replacement and widening, pier replacement, approach work, and guardrail upgrade for the existing three span bridge. The total length of the bridge is approximately 83.2 m (273 feet), and the existing beams are steel multi-girder composite. The existing deck cross-section consists of 30 foot clear roadway (two lanes). The proposed deck cross-section, for the bridge, will match the existing approach section. Traffic will be maintained by detour. The source of these funds is 80% FHWA and 20% State Trunkline funds

72. DESIGN - Design Services
Amendatory contract (97-0609/A2) between MDOT and Alfred Benesch & Company, provides design of I-75 Reconstruction, I-75/I-75 Connector from NYC RR Bridge to Gratiot Avenue in the county of Wayne.

The purpose of this amendment is to expand the scope of design services to include a Motorist Information Program to assist motorists in traveling through the construction zones by minimizing delays and inconveniences as much as possible. Also to assist businesses with minimizing the effect of the construction on their economic well-being and ability to conduct business. The maximum dollar amount of this contract is increased by $278,758.71 to $2,479,097.14, 90% FHWA and 10% State Trunkline.

73. DESIGN - Design Consultant Services
Authorization to contract (97-0785/Z10) between MDOT and Consoer Townsend Envirodyne Engineers, Inc. provides for design consultant services on an as needed when needed basis. This contract, which was executed on December 29, 1997, enables MDOT to initiate design activities with authorizations. The limit on these authorizations is $1,000,000. Authorizations in excess of $100,000 require the approval of the State Administrative Board. The term of this contract is from December 29, 1997 to December 29, 2000.

This request is for $125,784.15 which provides for the design of M-52 over Shiawassee River (B02)/CS 70612 - JN 46230D in the County of Shiawassee. The work for structure B02 will consist of superstructure replacement and widening, pier replacement, approach work, and guardrail upgrade for the existing three span bridge. The total length of the bridge is approximately 83.2 m (273 feet), and the existing beams are steel multi-girder composite. The existing deck cross-section consists of 30 foot clear roadway (two lanes). The proposed deck cross-section, for the bridge, will match the existing approach

section. Traffic will be maintained by detour. The source of these funds is 80% FHWA and 20% State Trunkline funds.

74. DESIGN - Design Services
Authorization to contract (97-0786/Z1) between MDOT and HNTB Michigan, Inc., provides design consultant services on an as needed when needed basis. This contract, which was executed on June 18, 1996, enables MDOT to initiate design activities with authorizations. The limit on these authorizations is $1,000,000. Authorizations in excess of $100,000 require the approval of the State Administrative Board.

The original request was for $200,000. and provided the design of I-94 over US-127 & M-50 (S06) in the County of Jackson, CS S06 of 38101 - JN 45172D. The work items were superstructure replacement and widening, pier and abutment repair and approach work.

This project has been revised to include complete bridge replacement as US-127 has to be lowered to meet vertical underclearance. This will include widening and approach work and a complete design for all associated road work that is involved in lowering US-127. This request is for an additional $141,403.00 for an authorization total of $341,403.00. The source of these funds is 80% FHWA and 20% State Trunkline funds. The term of this contract is from December 29, 1997 through December 29, 2000.

75. DESIGN - Design Services
Authorization to contract (97-0810/Z1) between MDOT and Hardesty & Hanover provides for design consultant services on an as needed when needed basis. This contract, which was executed on December 29, 1997, enables MDOT to initiate design activities with authorizations. The limit on these authorizations is $1,000,000. Authorizations in excess of $100,000 require the approval of the State Administrative Board.

This request is for $.173,344.00 which provides for the design of US-41/M-26 Vertical Lift Bridge over Portage Lake/CS 31012 - JN 43947D in the county of Houghton. The work will include preparation of plans and specifications for the rehabilitation of the structure work for this bridge according to 1996 MDOTs Standard Specifications for Construction. Maintaining traffic will be designed by MDOT . The Houghton-Hancock bridge is a tower drive vertical lift bridge. The source of these funds is 80% FHWA and 20% State Trunkline funds.

76. DESIGN - Design Consultant Services
Authorization to contract (97-0785/Z11) between MDOT and Consoer Townsend Envirodyne Engineers, Inc. provides for design consultant services on an as needed when needed basis. This contract, which was executed on December 29, 1997, enables MDOT to initiate design activities with authorizations. The limit on these authorizations is 1,000,000. Authorizations in excess of $100,000 require the approval of the State Administrative Board.

This request is for $121,076.08 which provides for the design of M-99 over Spring Brook (B01)/CS 38011 - 46226D in the County of Jackson. This project will consist of all work related to designing this bridge reconstruction project, including but not limited to the following: Replacement and minor widening of the bridge, adding scour protection as required and approach roadway work. The existing 7 meter, one span, multiple concrete T-beam bridge has a clear roadway width of 10.7 meters. The proposed deck cross-section will consist of two 3.6 m lanes and 3 m shoulders. Traffic will be maintained by part-width construction maintaining two-way traffic utilizing a temporary signal. The source of these funds is 100% State Truckling funds.

77. DESIGN - Design Services
Authorization to contract (97-0792/Z4) between MDOT and T.Y. Lin International BASCOR, Inc. provides for design consultant services on an as needed when needed basis. This contract, which was executed on January 7, 1998, enables MDOT to initiate design activities with authorizations. The limit on these authorizations is $400,000. Authorizations in excess of $100,000 require the approval of the State Administrative Board.

This request is for $330,000.00 which provides for the Final Scoping for Projects on NHS Routes in Wayne County which are generally outside the City of Detroit. This project involves the preparation of preliminary and final scoping for 8 selected FY 2001 and 2002 projects. CS 82900 - JN 47313. The source of these funds is 80% FHWA and 20% State Trunkline funds. The term of this contract is from December 29, 1997 through December 29, 2000.

78. DESIGN - Design Services
Authorization to contract (97-0792/Z5) between MDOT and T.Y. Lin International BASCOR, Inc. provides for design consultant services on an as needed when needed basis. This contract, which was executed on January 7, 1998, enables MDOT to initiate design activities with authorizations. The limit on these authorizations is $400,000. Authorizations in excess of $100,000 require the approval of the State Administrative Board.

This request is for $210,000.00 which provides for the Final Scoping for Projects on Interstate routes in Wayne County which are generally with half or more of the projects within the City of Detroit. This project involves the preparation of preliminary and final scoping for 3 selected FY 2001 and 2002 projects. CS 82400 - JN 47314. The source of these funds is 80% FHWA and 20% State Trunkline funds. The term of this contract is from December 29, 1997 through December 29, 2000.

79. DESIGN - Design Services
Authorization to contract (97-0792/Z6) between MDOT and T.Y. Lin International BASCOR, Inc. provides for design consultant services on an as needed when needed basis. This contract, which was executed on January 7, 1998, enables MDOT to initiate design activities with authorizations. The limit on these authorizations is $400,000. Authorizations in excess of $100,000 require the approval of the State Administrative Board.

This request is for $230,000.00 which provides for the Final Scoping for Projects on Non-Interstate routes in Wayne County which are generally with half or more of the projects within the City of Detroit. This project involves the preparation of preliminary and final scoping for 4 selected FY 2001 and 2002 projects. CS 82400 - JN 47450. The source of these funds is 80% FHWA and 20% State Trunkline funds. The term of this contract is from December 29, 1997 through December 29, 2000.

80. DESIGN - Design Services
Authorization to contract (97-0792/Z7) between MDOT and T.Y. Lin International BASCOR, Inc. provides for design consultant services on an as needed when needed basis. This contract, which was executed on January 7, 1998, enables MDOT to initiate design activities with authorizations. The limit on these authorizations is $400,000. Authorizations in excess of $100,000 require the approval of the State Administrative Board.

This request is for $340,000.00 which provides for the Final Scoping for Projects on Non-NHS routes in St. Clair, Macomb and Wayne Counties. This project involves the preparation of preliminary and final scoping for 5 selected FY 2001 and 2002 projects. CS 77900 - JN 47448. The source of these funds is 80% FHWA and 20% State Trunkline funds. The term of this contract is from December 29, 1997 through December 29, 2000.

81. DESIGN - Design Services
Authorization to contract (97-0792/Z8) between MDOT and T.Y. Lin International BASCOR, Inc. provides for design consultant services on an as needed when needed basis. This contract, which was executed on January 7, 1998, enables MDOT to initiate design activities with authorizations. The limit on these authorizations is $400,000. Authorizations in excess of $100,000 require the approval of the State Administrative Board.

This request is for $260,000.00 which provides for the Final Scoping for Projects on Non-NHS routes in St. Clair, Macomb and Oakland Counties. This project involves the preparation of preliminary and final scoping for 7 selected FY 2001 and 2002 projects. CS 50900 - JN 47379. The source of these funds is 80% FHWA and 20% State Trunkline funds. The term of this contract is from December 29, 1997 through December 29, 2000.

82. DESIGN - Design Consultant Services
Authorization to contract (97-0794/Z12) between MDOT and McNamee, Porter & Seeley, Inc. provides for design consultant services on an as needed when needed basis. This contract, which was executed on December 17, 1997, enables MDOT to initiate design activities with authorizations. The limit on these authorizations is $400,000. Authorizations in excess of $100,000 require the approval of the State Administrative Board.

This request is for $106,716.79 which provides for the design of I-94; Georgina Walkover over I-94 in Ypsilanti (P01)/CS 81063 - JN 46853D in the County of Washtenaw. The work will consist of replacing the existing bridge with a new pedestrian bridge. The source of these funds is 100% State Trunkline funds. The term of this contract is from December 17, 1997 through December 17, 2000.

83. DESIGN - Design Consultant Services
Authorization to contract (97-0803/Z11) between MDOT and Ulrich-Ch'ang & Associates, Inc. provides for design consultant services on an as needed when needed basis. This contract, which was executed on January 7, 1998, enables MDOT to initiate design activities with authorizations. The limit on these authorizations is $400,000. Authorizations in excess of $100,000 require the approval of the State Administrative Board.

This request is for $190,976.00 which provides for the design of US-24, South of Dunbar to 7th in the County of Monroe, CS 58052 - JN 36493C. The length of this project is 2 kilometers (1.24 miles). Work items include: perform design and hydraulic surveys; prepare plans, typical cross-sections, details and specifications required for design and construction; prepare pavement marking, traffic signal, permanent signing and bridge plans and special provisions and prepare ROW plans as required. The source of these funds is .8185% FHWA and .1815% State Trunkline funds. The term of this contract is from January 7, 1998 through January 7, 2001.

84. DESIGN - Design Services
Contract (98-0654) between MDOT and DeLeuw, Cather & Company of Michigan, provides for the restart to complete design of M-6 Grand Rapids Southbelt (I-96 to W. of Eastern Ave.) in the County of Kent. Design services will include an airport study, M-37 design, golf course crossing, breaking project into multiple construction contracts, writing legal descriptions for ROW parcels, demolition of I-96 rest area and a value engineering study. The term of this contract is from execution and continues until July 31, 2001 The maximum dollar amount of this contract is 5,931,862.00, 80%FHWA and 20% State Trunkline.

85. DESIGN - Consultant IDS Services
Contract (98-0657) between MDOT and Bergmann Associates will enable MDOT to request specific design services to be performed on an as needed, when needed basis with a written authorization. This consultant has been pre-qualified as a provider of specific design services. The maximum obligation of payment of funds for any individual authorization is $200,000.00. The total obligation of funds under this contract will not exceed $400,000.00 from restricted state, federal or local funds, depending on the source of funds for the particular project authorized. Any individual authorization of $100,000 or more will be submitted to the State Administrative Board for approval. The terms of this contract will commence upon execution and will expire 36 months thereafter. However, authorizations will not be issued after 24 months have elapsed.

This contract was previously issued under agreement 98-0460 for the same total obligation of funds but the consultant was named in error as West Carroll Bergmann.

86. DESIGN - IDS Consultant Services (CS Preauthorized)
The contracts between MDOT and the consultants listed below will enable the MDOT to request specific design services to be performed on an as needed, when needed basis with a written authorization. These consultants have been pre-qualified as providers of specific design services. The maximum obligation for payment of funds for any individual authorization is $400,000.00. The total obligation of funds under these contracts will not exceed $2,000,000.00 from restricted State, Federal or Local funds, depending on the source of funds for the particular project authorized. Any individual authorization of $100,000.00 or more will be submitted to the State Administrative Board for approval. The terms of these contracts will begin upon execution and will expire 36 months thereafter. However, authorizations will not be issued after 24 months have elapsed.

Contract #	Consultant
98-0660	NTH Consultants, Inc.
98-0661	Softdig of North Carolina.

87. MAINTENANCE DIVISION - Bridge Inspection IDS
Contract (98-0711) between MDOT and Sundberg, Carlson and Associates, Inc. to provide for bridge inspection services to be performed on an as needed basis designated by a written work authorization. The contractors have been prequalified for bridge inspection. The maximum amount per contract will be $200,000, with no work authorization exceeding the maximum of $90,000. The term of the contract will be upon execution through three years.

88. MAINTENANCE DIVISION - Bridge Inspection
Contract (98-0712) between MDOT and Wightman and Associates, Inc. to provide for bridge inspection services to be performed on an as needed basis designated by a written work authorization. The contractors have been prequalified for bridge inspection. The maximum amount per contract will be $200,000, with no work authorization exceeding the maximum of $90,000. The term of the contract will be upon execution through three years.

89. MAINTENANCE DIVISION - Bridge Inspection IDS
Contract (98-0713) between MDOT and McNamee, Porter and Seeley, Inc. to provide for bridge inspection services to be performed on an as needed basis designated by a written work authorization. The contractors have been prequalified for bridge inspection. The maximum amount per contract will be $200,000, with no work authorization exceeding the maximum of $90,000. The term of the contract will be upon execution through three years.

90. TRAFFIC & SAFETY - Engineering Services
Authorization to contract (98-0029/Z1) between MDOT and Transcore to provide engineering services on an as needed when needed basis. This contract, which was executed on March 27, 1998, enables MDOT to initiate engineering activities with authorizations. The limit on these authorizations is $250,000. Authorizations in excess of $100,000 require the approval of the State Administrative Board.

This request is for $217,209 which provides for the upgrading and rehabilitation of freeway signing on I-94 from Wyoming to M-102 (8 Mile Road) in the Cities of Detroit and Harper Woods, Wayne County. These are 100% Federal funds. The term of this contract is from March 27, 1998 through March 27, 2001.

91. TRANSPORTATION PLANNING - Property Exchange (Carpool Parking Lot)
Amendatory Contract (97-0610/A1) between MDOT and Silverman Development Company which provides for the exchange of carpool property for the purpose of developing a new carpool parking lot. The Contract specifies that the closing date of the property exchange will not occur sooner than five (5) business days, nor more than thirty (30) business days after the execution date of the Contract. The Contract was executed on November 13, 1997, however, MDOT has not yet closed on the property exchange, due to the fact that the Contractor was not able to start construction on the lot until the Spring of 1998. As a result, MDOT and the Contractor desire to revise the closing date so that the closing will not occur until MDOT has approved the lot construction, and until the lot is open to the public. The Contract expiration date is June 30, 1998. The parties desire to extend the expiration date to June 30, 2008, in order to allow for the Contractor to maintain the parking lot in perpetuity. It is MDOT's intention to amend the contract, as required, to allow such perpetual maintenance of the parking lot. Contract costs will remain unchanged.

92. UPTRAN - Bus Rehabilitation
Amendatory contract (92-0530/A6) between MDOT and the Saginaw Transit System Authority (STSA) which provides Federal Section 5309 funds and State match for the purchase and rehabilitation of a total of 13 buses. STSA was only able to purchase three medium buses rather than four large buses with the funds available in the contract. In addition, STSA was able to rehabilitate a total of seven large buses instead of five. This amendment revises two line item descriptions to reflect actual number of buses purchased and rehabilitated.

The total project amount remains at $1,450,000. Federal share is $1,160,000. State share is $290,000 from FY 1992 Bond Funds.

93. UPTRAN - Bus Purchases

Amendatory contract (94-0913/A2) between MDOT and Saginaw Transit System Authority (STSA) which provides Federal Section 5309 funds and State match for the purchase of five medium buses with lifts. STSA was only able to purchase four medium buses with lifts rather than five with the funds available in the contract. This amendment is to reduce the number of buses purchased to four.

The total project amount remains at $915,000. Federal share is $732,000. State share is $183,000 from FY 1992 Bond Funds.

94. UPTRAN - Rail Infrastructure Loan

The Michigan Rail Loan Assistance Program (MiRLAP) is a rail freight infrastructure loan program which was initiated to help finance capital improvements on Michigan's rail infrastructure. The program was designed to help preserve and improve rail freight service, and by doing so, contribute to the stability and growth of Michigan's businesses and industries. Local governments, railroads and current or potential users of freight railroad services may apply for noninterest bearing loans for eligible projects, e.g., track rehabilitation, bridge and culvert repair, new construction, transload facilities and rail consolidation. The loans provided by the program will fund up to 90% of the rail portion of project costs. The loan recipient will provide a funding match of at least 10 % of the rail portion of project costs, and expenditure of the funding match is required before State funds may be drawn down. Public Act No. 117 of 1997 appropriated $3.3 million for the FY1998 program. Approval is requested for the contracts listed below.

LUCE COUNTY ECONOMIC DEVELOPMENT CORPORATION
Project: Rehabilitate the Luce County portion of the Trout Lake - Munising Branch of Wisconsin Central Railroad. (WC) (MP 41.36 - MP 75.74).
Location: Luce County
Total Cost: $1,111,192
State Share: $1,000,000 -- 90%
Local Share: $111,192 -- 10%
(State funds are limited to $1,000,000 per applicant.)

EXCESS PROPERTY

95. RESOLUTION "A" - Negotiated Sale — Sale: 2-190-N
CS 21025, Parcel 196 Pt. A
The property is located in Brampton Township, Delta County, Michigan, and contains 1.00 acres, more or less. The subject tract was appraised by Donald Sandstrom, Property Analyst, on April 28, 1998, and reviewed and approved at the current market value of $450.00 by Marie Lewis, Manager, Project Development, on May 12, 1998. Marie Patricia Mrosewske and Rosemary Snep, the only abutting owners, have offered to purchase the subject tract at the appraised value.

$450

96. RESOLUTION "B" - Negotiated Sale — Sale 2-191-N
CS 21025, Parcel 196 Pt. B, 197
The property is located in Brampton Township, Delta County, Michigan, and contains 1.00 acres, more or less. The subject tract was appraised by Donald Sandstorm, Property Analyst, on April 28, 1998, and reviewed and approved at the current market value of $450.00 by Marie Lewis, Manager, Project Development, on May 12, 1998. Roger H. and Mary E. Brannstrom, the only abutting owners, offered to purchase the subject tract at the appraised value.

$450

97. RESOLUTION "C" - Negotiated Sale — Sale 3-344-N
CS 67014, Parcel 96 Pt. A
The property is located in Lincoln Township, Osceola County, Michigan, and contains 0.96 acre, more or less. The subject tract was appraised by Richard P. Binder, Jr., SRA, Independent Fee Appraiser, on January 28, 1998, and reviewed at the current market value of $1,300.00 by Janet Hartford, Property Analyst, on March 24, 1998. Gary W. and Beth E. Cehovic (husband and wife), the only abutting owners, offered to purchase the subject tract at the appraised value.

$1,300

98. RESOLUTION "D" - Relinquishment — Sale 7-613-R
CS 12021, Parcel 23A
The area proposed for relinquishment contains 2.64 acres, more or less, and is located in Bronson Township, Branch County, Michigan. Fred and Hope Schlautmann (husband and wife), the underlying fee holders, have requested release of the easement area to clear title of ownership in fee simple. The consideration for this easement is the processing fee of $500. A check for that amount has been deposited with the Financial Operations Division.

$500

In accordance with MDOT's policies and procedures and subject to concurrence by the Federal Highway Administration, the preparation and execution of the appropriate documents approved by the Attorney General, and compliance with all legal and fiscal requirements, the Director recommends for approval by the State Administrative Board the items on this agenda.

The approval by the State Administrative Board of these contracts does not constitute the award of same. The award of contracts will be made at the discretion of the Director-Department of Transportation when the aforementioned requirements have been met. Subject to exercise of that discretion, I approve the contracts described in this agenda and authorize their execution by the responsible Deputy Director of MDOT to the extent authorized by, and in accordance with, the December 14, 1983 resolution of the State Transportation Commissionand the Director's memorandum of February 26, 1991.

Respectfully submitted,

James R. DeSana,
Director

July 7, 1998 No. 61

SUPPLEMENTAL AGENDA

DEPARTMENT OF TRANSPORTATION

TRANSPORTATION and NATURAL RESOURCES COMMITTEE
STATE ADMINISTRATIVE BOARD

T&NR Meeting: July 1, 1998 - Secretary of State's Office, 3:30 PROJECT MANAGER
State Administrative Board Meeting: July 7, 1998 - State Capital, 11:00 AM

* *

BID LETTINGS

1. LETTING OF JUNE 5, 1998 — ENG. EST. $143,765.60 — LOW BID $161,742.78
PROPOSAL 9806006
PROJECT STUL 11413 - 47116A
LOCAL AGRMT. 98-5182 — % OVER/UNDER EST. 12.50%
COMPLETION DATE - 20 work days

1.48 km of bituminous base crushing and shaping and bituminous resurfacing on John Beers Road from Stevensville Village Limits easterly to Cleveland Avenue in Berrien County.

BIDDER	AS-READ	AS-CHECKED	
Klett Construction Co - Hartford, MI	$175,737.33	Same	2
Thompson-McCully Co - Belleville, MI			
Consumers Asphalt Co-Benton Harbor,*	**$161,742.78**	**Same**	**1**

2 BIDDERS

By association with the above construction contract we are also asking for approval of the above-referenced cost participation agreement.

Source of Funds: 18.15 % Berrien County 81.85% Federal

2. LETTING OF JUNE 19, 1998 — ENG. EST. $2,171,478.09 — LOW BID $2,898,992.81
PROPOSAL 9806020
PROJECT NH 33061 - 38015A, etc.
LOCAL AGRMT.
COMPLETION DATE - October 1, 1998
% OVER/UNDER EST. 33.50%

7.08km of bituminous coldmilling, resurfacing, concrete pavement repair and sanitary sewer relocation on M-43 westbound from Rosemary Street easterly to Coolidge Avenue, and deck overlays on M-43 westbound and eastbound over US-127, in the City of Lansing and Lansing Township, Ingham County.

15% DBE Participation Required

BIDDER	AS-READ	AS-CHECKED	
Kamminga & Roodvoets-Grand Rapids,MI*	**$2,898,992.81**	**Same**	1
Thompson-McCully Co - Belleville, MI	2,989,750.75	Same	2
C & D Hughes, Inc. - Charlotte, MI			
Advanced Paving Company - Lansing, MI			

2 BIDDERS

Source of Funds: 80% Federal 2.36% Lansing 17.64% State

3. LETTING OF JUNE 5, 1998 — ENG. EST. $4,025,722.00 — LOW BID $4,571,810.92
PROPOSAL 9806026
PROJECT STU 50458 - 43648A
LOCAL AGRMT.
COMPLETION DATE - May 15, 1999
% OVER/UNDER EST. 13.56%

1.67 km of two to five lane concrete widening and reconstruction, earthwork, temporary road, culvert and storm sewer, bituminous resurfacing, curb and gutter, pavement marking and other related work on Hayes Road from Utica Road to North of 17 Mile Road, Sterling Heights, Macomb County.

8% DBE Participation Required

BIDDER	AS-READ	AS-CHECKED	
Lanzo Construction Co - Roseville, *	**$4,571,810.92**	**Same**	1
Tony Angelo Cement Constr - Novi, MI	$5,135,029.85	Same	4
Ajax Paving Indus. - Madison Hts., MI			
John Carlo, Inc. - Clinton Twp., MI	$4,789,201.54	$4,789,231.54	2
Florence Cement Company - Troy, MI			
Angelo Iafrate Constr - Warren, MI			
Dan's Excavating Inc - Shelby Twp.,	$4,880,395.52	Same	3
Eastern Concrete Paving - Shelby Twp.MI			
Pamar Enterprises - St. Clair, MI	$5,869,630.90	$5,869,634.90	7
Boddy Construction - Marysville, MI	$5,474,102.79	$5,476,102.79	6
L. D'Agostini & Sons - Macomb Twp.,	$5,442,664.35	$5,442,264.35	5
Six-S Inc - Waterford, MI			

7 BIDDERS

Source of Funds: 21.26% Macomb County 78.74% Federal

4. LETTING OF JUNE 5, 1998 — ENG. EST. $1,717,817.18 — LOW BID $2,010,810.00
PROPOSAL 9806030
PROJECT BHT 34081 - 43747A
LOCAL AGRMT. — % OVER/UNDER EST. 17.06%
COMPLETION DATE - August 6, 1999

Deck replacement, pier repair, scour protection and cleaning and coating existing structural steel on M-44 over Chesapeake and Ohio Railroad and Flat River, in the City of Belding, Ionia County.

10% DBE Participation Required

BIDDER	AS-READ	AS-CHECKED	
C.A. Hull Co., Inc. - Walled Lake, M	$2,144,304.36	Same	2
L.W. Lamb, Inc. - Saugatuck, MI			
Milbocker and Sons Inc - Allegan, MI			
Midwest Bridge Co - Williamston, MI			
Abhe & Svoboda, Inc. - Prior Lake, *	**$2,010,810.00**	**Same**	**1**
Hardman Construction - Ludington, MI			
Walter Toebe Constr Co - Wixom, MI			
Diversco Constr Co - Grandville, MI			
Davis Construction, Inc. - Lansing, MI			
Anlaan Corporation - Grand Haven, MI			
Prince Bridge & Marine-Grand Haven,MI			
WWA, Inc. - Ypsilanti, MI			

2 BIDDERS

Source of Funds: 80% Federal 20% State

5. LETTING OF JUNE 5, 1998
PROPOSAL 9806033
PROJECT EDC 82544 - 37450A
LOCAL AGRMT.
COMPLETION DATE - 80 work days

ENG. EST. $2,675,546.80

LOW BID $2,977,443.40

% OVER/UNDER EST. 11.28%

1.3 km (0.81 miles) of reconstruction of concrete pavement, bituminous resurfacing, drainage sewer and structure improvements and related work on Belleville Road from I-94 North Service Road to Tyler Road in Wayne County.

BIDDER	AS-READ	AS-CHECKED	
C.A. Hull Co Inc - Walled Lake, MI			
Deangelis Landscape - Woodhaven, MI			
L. Loyer Constr Co - Wyandotte, MI			
Lanzo Construction Co - Roseville, M	$3,142,703.15	Same	5
Tony Angelo Cement Constr - Novi, MI	$3,026,910.12	Same	3
Peter A. Basile Sons - Livonia, MI	$3,333,333.33	Same	7
Ajax Paving Indus. - Madison Hts., M	$3,387,086.08	Same	8
John Carlo, Inc. - Clinton Twp., MI*	**$2,977,443.40**	**Same**	**1**
Florence Cement Company - Troy, MI			
Angelo Iafrate Const - Warren, MI	$3,197,532.19	Same	6
Dan's Excavating, Inc - Shelby Twp., MI			
Eastern Concrete Paving - Shelby Twp	$3,072,687.71	Same	4
Sunset Excavating Inc - Livonia, MI	$2,984,702.80	Same	2
ABC Paving Company - Trenton, MI			
Zito Construction - Grand Blanc, MI	$3,561,663.42	Same	9
L. D'Agostini & Sons - Macomb Twp., MI			
Six-S Inc - Waterford, MI			

9 BIDDERS

Source of Funds: 30.45% Wayne County 69.55% State

6. LETTING OF JUNE 5, 1998 — ENG. EST. $597,259.29 — LOW BID $721,985.00
PROPOSAL 9806035
PROJECT STE 24011 - 44102A
LOCAL AGRMT. — % OVER/UNDER EST. 20.88%
COMPLETION DATE - June 26, 1999

Substructure and superstructure repair, joint replacement and scour protection measures on US-31 over Bear Creek, in the City of Petoskey, Emmet County.

5% DBE Participation Required

BIDDER	AS-READ	AS-CHECKED	
C.A. Hull Co Inc - Walled Lake, MI			
L.W. Lamb Inc - Saugatuck, MI	$985,415.00	Same	3
Milbocker and Sons Inc - Allegan, MI			
Midwest Bridge Co - Williamston, MI	$833,796.40	Same	2
Abhe & Svoboda, Inc. - Prior Lake, MN			
Hardman Construction - Ludington, MI			
Davis Construction, Inc. - Lansing, MI			
Cordes Excavating - Hillman, MI			
Anlaan Corporation - Grand Haven, M*	**$721,985.00**	**Same**	**1**
Prince Bridge & Marine-Grand Haven,MI			

3 BIDDERS

Source of Funds: 81.85 % Federal 18.15% State

7. LETTING OF JUNE 5, 1998
PROPOSAL 9806056
PROJECT STUL 77412 - 47075A
LOCAL AGRMT.
COMPLETION DATE - 60 work days

ENG. EST. $503,251.70
LOW BID $600,272.19
% OVER/UNDER EST. 19.28%

0.78 km of bituminous reconstruction and widening, with earthwork, storm sewer, curb and gutter, sidewalk, driveway and other related work on Delaware Avenue from Stadium Avenue to Gratiot Avenue (I-94 BL) in the City of Marysville, St. Clair County.

12% DBE Participation Required

BIDDER	AS-READ	AS-CHECKED	
Valley Asphalt Company - Saginaw, MI			
Raymond Excavating Co - Marysville,	$556,378.40	$556,378.50	REJ
John Carlo, Inc. - Clinton Twp., MI			
Angelo Iafrate Constr - Warren, MI	$704,531.43	Same	3
Barrett Paving Mat. - Ypsilanti, MI	$692,999.75	Same	2
ABC Paving Company - Trenton, MI			
Pamar Enterprises - St. Clair, MI	$706,618.59	Same	4
Zito Construction - Grand Blanc, MI			
Boddy Construction Co - Marysville,*	**$600,272.19**	**Same**	**1**
Weston Transport Inc - Kimball, MI			

5 BIDDERS
CHANGE IN LOW BIDDER

Source of Funds: 77.86% Federal 22.14% Marysville

8. LETTING OF JUNE 5, 1998 — ENG. EST. $1,148,751.00 — LOW BID $1,322,176.05
PROPOSAL 9806059
PROJECT STU 50458 - 40206A
LOCAL AGRMT. — % OVER/UNDER EST. 15.09%
COMPLETION DATE - November 30, 1998

1.60 km of composite pavement four to five lane resurfacing and reconstruction, earthwork, storm sewer, joint repair, curb and gutter, sidewalk, pavement marking and other related work on Thirteen Mile Road from Ryan Road to Mound Road in the City of Warren, Macomb County.

12% DBE Participation Required

BIDDER	AS-READ	AS-CHECKED	
Tony Angelo Cement Constr - Novi, MI			
Ajax Paving Indus. - Madison Hts., MI			
Snowden, Inc. - Escanaba, MI			
John Carlo, Inc. - Clinton Twp., MI	$1,586,265.80	Same	3
Florence Cement Company - Troy, MI *	**$1,322,176.05**	**Same**	**1**
Angelo Iafrate Constr. - Warren, MI	$1,409,632.30	Same	2
Borbolla Constr - Clinton Twp., MI			
Six-S Inc - Waterford, MI			

3 BIDDERS

Source of Funds: 81.85% Federal 18.15% Warren County

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9. LETTING OF JUNE 5, 1998
PROPOSAL 9806063
PROJECT BRO 67003 - 40027A, etc.
LOCAL AGRMT.
COMPLETION DATE - June 1, 1999

ENG. EST.	LOW BID
$3,243,924.55	$3,210,003.16
	% OVER/UNDER EST.
	-1.05%

5.39 km of road reconstruction and new construction including clearing, earth and peat excavation, embankment, wetland creation, subbase, culverts, bituminous surfacing, erosion control measures, slope restoration, pavement markings and traffic control on 135th Avenue from 0.44 km south of One Mile Road north to US-10 in Hersey Township, also remove existing three span steel truss bridge, construction of a three span prestressed concrete I-beam bridge and related work, Evart Township and on 135th Avenue bridge over the Muskegon River in Osceola County.

5% DBE Participation Required

BIDDER	AS-READ	AS-CHECKED	
L.W. Lamb, Inc. - Saugatuck, MI Rieth-Riley Const Co - Goshen, IN Milbocker and Sons, Inc - Allegan, M Midwest Bridge Co - Williamston, MI Payne & Dolan, Inc. - Gladstone, MI Hardman Construction - Ludington, MI Geocon, Inc. - Jenison, MI Diversco Construction - Grandville, MI Anlaan Corporation - Grand Haven, MI Prince Bridge & Marine-Grand Haven, MI	$3,463,212.68 $3,264,688.93	Same Same	3 2
D.J. McQuestion/Rieth Riley - Leroy*	**$3,216,003.16**	**$3,210,003.16**	**1**

3 BIDDERS

Source of Funds: 40.64% Osceola County 59.36% State

10. LETTING OF JUNE 5, 1998 — ENG. EST. $3,650,332.23 — LOW BID $4,044,532.00
PROPOSAL 9806067
PROJECT NHG 25032 - 45627A, etc.
LOCAL AGRMT. — % OVER/UNDER EST. 10.80%
COMPLETION DATE - October 1, 1998

17.867 km of guardrail and concrete filler wall construction; and 35.929 km of overband crackfill and microsurfacing on I-75 from Pierson Road northerly to M-46, in Mt. Morris, Montrose, Vienna, Birch Run, Taymouth, Bridgeport and Buena Vista Townships, Genesee and Saginaw Counties.

15% DBE Participation Required

BIDDER	AS-READ	AS-CHECKED	
J. Slagter & Son Constr - Wayland, MI			
Snowden, Inc. - Escanaba, MI			
Nationwide Fence&Supp-Chesterfield, MI			
Strawser, Inc. - Columbus, OH	$4,460,356.38	$4,514,356.38	N/C
Tri-Valley Landscaping - Saginaw, MI			
Terry Construction - Hamilton, OH	*** $4,044,532.00**	**Same**	**1**

2 BIDDERS

Source of Funds: 90% Federal 10% State

11. LETTING OF JUNE 5, 1998 — ENG. EST. $4,173,359.82 — LOW BID $5,461,570.98
PROPOSAL 9806068
PROJECT CIM 63022 - 38090A
LOCAL AGRMT. — % OVER/UNDER EST. 30.87%
COMPLETION DATE - June 30, 1999

1.738 km of bituminous surfacing, grading and drainage to reconstruct interchange, add loop ramp and reconstruct existing roadways, traffic signal installation and watermain alterations on M-5 at the Grand River Avenue/10 Mile Road interchange, in the Cities of Farmington and Farmington Hills, Oakland County.

20% DBE Participation Required

BIDDER	AS-READ	AS-CHECKED	
Cadillac Asphalt Paving - Novi, MI	$7,100,248.73	Same	2
Detroit Concrete Prod. - Milford, MI			
E.C. Korneffel Co - Trenton, MI			
Midwest Bridge Co - Williamston, MI			
Thompson-McCully Co - Belleville, M*	**$5,477,117.20**	**$5,461,570.98**	**1**
Ajax Paving Indus. - Madison Hts., MI			
John Carlo, Inc. - Clinton Twp., MI			
Angelo Iafrate Constr - Warren, MI			
Zito Construction - Grand Blanc, MI			

2 BIDDERS

Source of Funds: 1.55 % Farmington Hills 81.85% Federal 16.60% State

12. LETTING OF JUNE 5, 1998 — ENG. EST. $3,493,148.43 — LOW BID $3,739,960.58
PROPOSAL 9806069
PROJECT BHN 70014 - 40427A, etc.
LOCAL AGRMT. — % OVER/UNDER EST. 7.07%
COMPLETION DATE - November 1, 1999

Concrete deck overlay, railing replacement and partial cleaning and coating on US-31 over Grand River; concrete deck overlay on US-31 over Third Street; concrete deck overlay and partial cleaning and coating on US-31 over Grand Trunk Western Railroad and M-104; and guardrail upgrading on US-31 from South Channel structure northerly to VanWagoner Road, in the Cities of Grand Haven and Ferrysburg, Ottawa County.

12% DBE Participation Required

BIDDER	AS-READ	AS-CHECKED	
C.A. Hull Co., Inc. - Walled Lake, *	**$3,739,960.58**	**Same**	**1**
L.W. Lamb Inc - Saugatuck, MI			
J. Slagter & Son Constr - Wayland, MI			
Midwest Bridge Co - Williamston, MI			
Abhe & Svoboda, Inc. - Prior Lake, M	$4,897,410.00	Same	2
Walter Toebe Constr Co - Wixom, MI			
Anlaan Corporation - Grand Haven, MI			
Prince Bridge & Marine-Grand Haven, MI			

2 Bidders

Source of Funds: 40427A: 80% Federal 20% STF
43736A: 80.7% Federal 19.3% STF
43738A: 80% Federal 20% STF
47165A: 100% Federal

13. LETTING OF JUNE 5, 1998 — ENG. EST. $861,294.56 — LOW BID $804,796.38
PROPOSAL 9806070
PROJECT NH 70081 - 43739A
LOCAL AGRMT. — % OVER/UNDER EST. -6.56%
COMPLETION DATE - June 11, 1999

Concrete deck overlay, railing retrofit, pin and hanger replacement and partial cleaning and coating existing structural steel, on M-104 over Spring Lake Channel, in Spring Lake Township, Ottawa County.

10% DBE Participation Required

BIDDER	AS-READ	AS-CHECKED	
C.A. Hull Co., Inc. - Walled Lake, *	**$754,796.38**	**$804,796.38**	**1**
L.W. Lamb, Inc. - Saugatuck, MI			
J. Slagter & Son Constr - Wayland, MI			
Midwest Bridge Co. - Williamston, MI			
Abhe & Svoboda, Inc. - Prior Lake, M	$1,064,310.00	Same	2
Walter Toebe Constr Co - Wixom, MI			
Anlaan Corporation - Grand Haven, MI			
Prince Bridge & Marine-Grand Haven, MI			

2 Bidders

Source of Funds: 81.85% Federal 18.15% STF

14. LETTING OF JUNE 5, 1998 — ENG. EST. $500,926.78 — LOW BID $503,513.10
PROPOSAL 9806076
PROJECT STT 30031 - 46656A
LOCAL AGRMT.
COMPLETION DATE - 8 work days
% OVER/UNDER EST. 0.52%

20.321 km of double chip seal on M-99 from Michigan/Ohio State Line northerly to M-34, in Amboy, Ransom and Jefferson Townships, Hillsdale County.

BIDDER	AS-READ	AS-CHECKED	
Bituminous Pavers, Inc. - Burton, MI			
D & D Contracting Inc - Grawn, MI			
Pavement Maint Syst - Imlay City, MI			
Fahrner Asphalt Sealers - Plover, W*	**$503,513.10**	**Same**	**1**

1 BIDDER

By association with the above construction contract we are also asking for approval of the above-referenced cost participation agreement.

Source of Funds: 18.15 % State 81.85% Federal

15. LETTING OF JUNE 5, 1998 — ENG. EST. $884,918.75 — LOW BID $995,635.25
PROPOSAL 9806081
PROJECT IM 84900 - 46281A
LOCAL AGRMT.
COMPLETION DATE - November 1, 1999
% OVER/UNDER EST. 12.51%

Bridge joint replacement on I-696 on 19 structures at various locations in Macomb County.

BIDDER	AS-READ	AS-CHECKED	
C.A. Hull Co., Inc. - Walled Lake, M	$1,084,493.00	Same	3
L. W. Lamb, Inc. - Saugatuck, MI			
E.C. Korneffel Co - Trenton, MI	$1,398,554.50	Same	6
Midwest Bridge Co - Williamston, MI	$1,070,658.25	Same	2
Posen Construction, Inc. - Utica, M*	**$995,635.25**	**Same**	**1**
Walter Toebe Constr Co - Wixom, MI	$1,279,812.46	Same	5
WWA, Inc. - Ypsilanti, MI	$1,212,730.00	Same	4

6 BIDDERS

Source of Funds: 90% Federal 10% State

16. LETTING OF JUNE 5, 1998
PROPOSAL 9806097
PROJECT IM 84908 - 45989A
LOCAL AGRMT.
COMPLETION DATE - 23 work days

ENG. EST. $576,037.30

LOW BID $565,881.83

% OVER/UNDER EST. -1.76%

18.540 km of overband crack fill and microsurfacing on US-23 southbound from M-14 northerly to Silver Lake Road, on I-94 westbound from East of Zeeb Road easterly to M-14 and on I-94 from State Road easterly to Ann Arbor Railroad, in Ann Arbor, Northfield, Green Oak, Scio and Pittsfield Townships, Washtenaw and Livingston Counties.

BIDDER	AS-READ	AS-CHECKED	
Strawser Incorporated - Columbus, OH	$606,667.95	$616,668.45	2
Terry Construction Inc - Hamilton, *	**$565,881.83**	**Same**	**1**

2 BIDDERS

6/26/98

Source of Funds: 10 % State 90% Federal

17. LETTING OF JUNE 19, 1998 — ENG. EST. $8,559,691.84 — LOW BID $9,299,598.48
PROPOSAL 9806601
PROJECT NH 38061 - 34106A, etc.
LOCAL AGRMT. — % OVER/UNDER EST. 8.64%
COMPLETION DATE - October 30, 1998

5.60 km of rubblizing concrete pavement, bituminous resurfacing, ramp reconstruction, guardrail upgrading and traffic signal installation on M-60, from Spring Arbor Road northerly to I-94 in Spring Arbor, Summit and Blackman Townships, Jackson County.

15% DBE Participation Required

BIDDER	AS-READ	AS-CHECKED	
Kamminga & Roodvoets - Grand Rapids,	$9,360,277.82	Same	2
Thompson-McCully Co - Belleville, M*	**$9,298,748.47**	**$9,299,598.48**	**1**

2 Bidders

Source of Funds: 34106A: 81.85% Federal 18.15% STF 46418A: 100% Federal

18. LETTING OF JUNE 19, 1998 — ENG. EST. $199,839.75 — LOW BID $209,599.50
PROPOSAL 9806602
PROJECT STG 59051 - 44942A
LOCAL AGRMT.
COMPLETION DATE - 30 work days — % OVER/UNDER EST. 4.88%

44.684 miles of non-freeway sign upgrading on M-66 from Barry North County Line northerly to Mecosta South County Line, in Ionia and Montcalm Counties.

100% DBE Participation Required

BIDDER	AS-READ	AS-CHECKED	
Highway Service Company - Woodhaven*	**$209,599.50**	**Same**	1
Action Traffic Maint. - Utica, MI	$245,150.17	Same	2

2 Bidders

Source of Funds: 97.6% Federal 2.4% STF

19. LETTING OF JUNE 19, 1998 — ENG. EST. $650,216.87 — LOW BID $673,168.64
PROPOSAL 9806603
PROJECT NH 21022 - 46216A
LOCAL AGRMT.
COMPLETION DATE - 30 work days — % OVER/UNDER EST. 3.53%

1.760 km of bituminous surfacing to construct directional crossovers on US-2, from North of Danforth Road northerly to County Road 426, in the City of Escanaba and Wells Township, Delta County.

BIDDER	AS-READ	AS-CHECKED	
Bacco Construction Co. - Iron Ct., *	**$673,168.64**	**Same**	1
A. Lindberg & Sons Inc - Ispheming, MI			
Payne & Dolan, Inc. - Gladstone, MI	$750,570.71	Same	2

2 Bidders

Source of Funds: 81.85% Federal 18.15% STF

20. LETTING OF JUNE 19, 1998 — ENG. EST. $653,618.46 — LOW BID $644,751.70
PROPOSAL 9806604
PROJECT BHI 76023 - 43780A, etc.
LOCAL AGRMT. — % OVER/UNDER EST. -1.36%
COMPLETION DATE - October 1, 1998

Substructure repair, concrete deck overlay, joint replacement and partial cleaning and coating existing structural steel, on I-69 over Central Michigan Railroad in Venice Township, Shiawassee County.

10% DBE Participation Required

BIDDER	AS-READ	AS-CHECKED	
C.A. Hull Co. Inc., Walled Lake, MI*	**$644,751.70**	**Same**	**1**
E.C Korneffel Co - Trenton, MI			
J. Slagter & Son Constr - Wayland, M	$825,484.00	Same	3
Midwest Bridge Co - Williamston, MI			
Abhe & Svoboda, Inc. - Prior Lake, MN			
Hardman Construction - Ludington, MI			
Walter Toebe Constr - Wixom, MI	$659,374.50	Same	2
Prince Bridge & Marine-Grand Haven, MI			

3 Bidders

Source of Funds: 43780A: 80% Federal 20% STF 43781A: 80% Federal 20% STF

21. LETTING OF JUNE 19, 1998 — ENG. EST. $451,818.57 — LOW BID $479,540.00
PROPOSAL 9806605
PROJECT BHN 54014 - 33028A
LOCAL AGRMT. — % OVER/UNDER EST. 6.14%
COMPLETION DATE - October 30, 1998

Scour protection and slope stability measures on US-131 over Muskegon River, in Mecosta Township, Mecosta County.

BIDDER	AS-READ	AS-CHECKED	
L.W. Lamb Inc - Saugatuck, MI			
Maclean Construction Co - Ludington, MI			
Rieth-Riley Constr Co - Goshen, IN			
Milbocker and Sons Inc - Allegan, MI	$706,614.00	Same	4
Nagel Construction Inc - Moline, MI			
Wadel Stabilization Inc- Hart, MI	$594,529.35	Same	2
Hardman Construction - Ludington, M*	$763,569.00	Same	5
Nashville Constr Co - Nashville, MI	**$479,540.00**	**Same**	**1**
Geocon, Inc. - Jenison, MI			
Diversco Constr Co - Grandville, MI			
Manigg Enterprises Inc - Alpena, MI			
Prince Bridge & Marine-Grand Haven, MI			
Heystek Contracting Inc - Montrose, MI			
Kal Excavating Co - Omena, MI	$597,525.60	$597,513.96	1

5 Bidders

Source of Funds: 80% Federal 20% STF

22. LETTING OF JUNE 19, 1998 — ENG. EST. $1,022,047.90 — LOW BID $1,096,818.00
PROPOSAL 9806606
PROJECT IM 84900 - 46280A
LOCAL AGRMT. — % OVER/UNDER EST. 7.32%
COMPLETION DATE - October 15, 1999

Bridge joint replacement on I-696 on 34 structures at various locations in Oakland and Macomb Counties.

BIDDER	AS-READ	AS-CHECKED	
C.A. Hull Co., Inc. - Walled Lake, *	**$1,096,818.00**	**Same**	**1**
L.W. Lamb, Inc. - Saugatuck, MI			
E.C. Korneffel Co.-Trenton, MI	$2,165,464.61	Same	6
J. Slagter & Son Constr - Wayland, MI			
Midwest Bridge Co. - Williamston, MI	$1,322,178.00	Same	4
Abhe & Svoboda, Inc.- Prior Lake, MN	$1,322,178.00	Same	3
Dan's Excavating Inc - Shelby Twp, MI			
Posen Construction, Inc. - Utica, MI	$1,667,784.50	Same	5
Walter Toebe Constr Co - Wixom, MI	$1,099,123.97	Same	2

6 Bidders

Source of Funds: 90% Federal 10% STF

23. LETTING OF JUNE 19, 1998 — ENG. EST. $245,109.90 — LOW BID $242,692.00
PROPOSAL 9806607
PROJECT STT 07041 - 46966A
LOCAL AGRMT. — % OVER/UNDER EST. -0.99%
COMPLETION DATE - 8 work days

11.43 km of double chip seal on M-38, from Houghton East County Line easterly to West of Plains Road, in Baraga Township, Baraga County.

BIDDER	AS-READ	AS-CHECKED	
Bacco Construction Co - Iron Mt., MI			
Payne & Dolan, Inc. - Gladstone, MI*	**$242,692.00**	**Same**	**1**
Fahrner Asphalt Sealers - Plover, MI	$267,780.00	Same	2
Terry Construction Inc - Hamilton, OH			
Scoot Constr Inc - Lake Delton, WI	$333,442.00	Same	3

3 Bidders

Source of Funds: 81.85% Federal 18.15% STF

24. LETTING OF JUNE 19, 1998 — ENG. EST. $647,122.53 — LOW BID $696,887.26
PROPOSAL 9806608
PROJECT ST 62041 - 46436A
LOCAL AGRMT.
COMPLETION DATE - August 21, 1998 — % OVER/UNDER EST. 7.69%

23.973 km of double chip seal, bituminous coldmilling and resurfacing and shoulder chip seal, on M-82 from M-37 easterly to East of US-131, in Brooks, Croton and Reynolds Townships, Newaygo and Montcalm Counties.

5% DBE Participation Required

BIDDER	AS-READ	AS-CHECKED	
Rieth-Riley Constr Co - Goshen, IN			
Thompson-McCully Co - Belleville, MI			
Fahrner Asphalt Sealers - Plover, W*	**$696,887.26**	**Same**	**1**
Terry Construction Inc - Hamilton, OH			

1 BIDDER

Source of Funds: 81.85 % Federal 18.15% State

25. LETTING OF JUNE 19, 1998 — ENG. EST. $260,054.82 — LOW BID $196,233.00
PROPOSAL 9806609
PROJECT M 89801 - 23152
LOCAL AGRMT.
COMPLETION DATE - September 15, 1998 — % OVER/UNDER EST. -24.54%

8.700 km of concrete pavement repair on WB I-96 from St. Joseph Hwy. to Lansing Road in Delta and Windsor Townships, Eaton County, and on Lansing Road from South of Royston Road to Pinch Road in Windsor Township, Eaton County.

BIDDER	AS-READ	AS-CHECKED	
Kelcris Corporation - Williamston, *	**$196,233.00**	**Same**	**1**
Snowden, Inc. - Escanaba, MI	$298,959.00	Same	3
Niles Concrete Sawing - Niles, MI	$280,784.40	Same	2

3 Bidders

Source of Funds: 100% STF

26. LETTING OF JUNE 19, 1998 — ENG. EST. $176,992.50 — LOW BID $163,409.85
PROPOSAL 9806610
PROJECT ASTL 01020 - 46283A
LOCAL AGRMT. 98-5249 — % OVER/UNDER EST. -7.67%
COMPLETION DATE - October 2, 1998

2.09 kilometers of grading, drainage structures, bituminous base crushing and shaping, aggregate base, bituminous surfacing with aggregate shoulders and slope restoration on County Road F-30 (Mikado-Glennie Road) from the Pine River Bridge to County Road F-41 in Alcona County.

BIDDER	AS-READ	AS-CHECKED	
Bolen Asphalt Paving, East Tawa, MI*	**$163,409.45**	**163,409.85**	1
Payne & Dolan, Inc. - Gladstone, MI	$195,334.50	Same	4
Manigg Enterprise Inc. - Alpena, MI	$187,673.50	Same	3
Bernie Johnson Trucking - Leroy, MI	$183,577.85	$183,578.00	2

4 Bidders

Source of Funds: 80% Federal 20% Alcona Co.

By association with the above construction contract we are also asking for approval of the above-referenced cost participation agreement.

27. LETTING OF JUNE 19, 1998 — ENG. EST. $1,710,515.00 — LOW BID $1,683,091.15
PROPOSAL 9806611
PROJECT EDA 82522 - 40938A
LOCAL AGRMT. 98-5131 — % OVER/UNDER EST. -1.60%
COMPLETION DATE - November 15, 1998

1.190 km (0.740 miles) of reconstruction with concrete pavement, drainage & pavement marking, St. Aubin from Clay to Denton & Clay from Northbound I-75 Services Drive to St. Aubin, Wayne County.

BIDDER	AS-READ	AS-CHECKED	
Peter A. Basile Sons - Livonia, MI	$1,779,352.85	Same	3
Ajax Paving Indust. - Madison Hts, MI			
John Carlo, Inc. - Clinton Twp, MI*	**$1,683,071.50**	**$1,683,091.15**	1
Florence Cement Company - Troy, MI			
Angelo Iafrate Constr - Warren, MI	$1,872,902.65	Same	4
Dan's Excavating Inc - Shelby Twp, M	$1,761,759.87	$1,762,779.87	2
Eastern Concrete Paving-Shelby Twp,	$2,157,912.95	Same	5
ABC Paving Company - Trenton MI			

5 Bidders

By association with the above construction contract we are also asking for approval of the above-referenced cost participation agreement.

Source of Funds: 80% STF 20% City of Detroit

28. LETTING OF JUNE 19, 1998 — ENG. EST. $392,800.00 — LOW BID $329,197.04
PROPOSAL 9806612
PROJECT BRO 43011 - 43533A
LOCAL AGRMT. 98-5253 — % OVER UNDER EST. -16.19%
COMPLETION DATE - November 6, 1998

Removal of a single span steel I-beam bridge, construction of a three span timber bridge and related approach work on 76th Street over South Branch Pere Marquette River, Pleasant Plains Township, Lake County.

BIDDER	AS-READ	AS-CHECKED	
Rieth-Riley Constr Co - Goshen, IN	$403,633.87	Same	7
S-L and H Contractors - Corunna, MI			
Milbocker and Sons - Allegan, MI			
Fisher Contracting Co - Midland, MI	$469,979.83	Same	9
Wadel Stabilization Inc - Hart, MI	$376,747.18	Same	5
Hardman Construction - Ludington, MI	$414,449.60	Same	8
Geocon, Inc. - Jenison, MI *	**$329,197.04**	**Same**	**1**
Miller Development Inc - Weidman, MI			
Davis Construction Inc - Lansing, MI	$381,132.72	Same	6
Anlaan Corporation - Grand Haven, MI	$363,520.00	$363,519.99	3
Kal Excavating Co - Omena, MI	$357,686.40	$357,786.99	2
RCL Construction Co, Inc. - Sanford,	$364,316.79	Same	4

9 BIDDERS

By association with the above construction contract we are also asking for approval of the above-referenced cost participation agreement.

Source of Funds: 80% Federal 14.9% STF 5.1% Lake County

29. LETTING OF JUNE 19, 1998 — ENG. EST. $604,726.39 — LOW BID $477,080.16
PROPOSAL 9806613
PROJECT BRO 41004 - 44886A
LOCAL AGRMT. 98-5252 — % OVER/UNDER EST. -21.11%
COMPLETION DATE - May 21, 1999

Removal of a single span steel truss bridge, construction of a single span prestressed concrete I-beam bridge, 0.59 km of approach and related work on Coldwater Road over the Coldwater River in Bowne Township, Kent County.

12% DBE Participation Required

BIDDER	AS-READ	AS-CHECKED	
Kamminga & Roodvoets - Grand Rapids,	$631,689.28	Same	4
L.W. Lamb, Inc. - Saugatuck, MI			
Milbocker and Sons - Allegan, MI *	**$477,080.16**	**Same**	**1**
Hardman Constr Inc - Ludington, MI			
Geocon, Inc. - Jenison, MI	$507,758.71	Same	3
Diversco Constr Co - Grandville, MI			
Davis Construction Inc - Lansing, MI	$485,893.67	Same	2
Anlaan Corporation - Grand Haven, MI			
Prince Bridge & Marine-Grand Haven, MI			

4 BIDDERS

By association with the above construction contract we are also asking for approval of the above-referenced cost participation agreement.

Source of Funds: 80% Federal 15% STF 5% Kent Co.

30. LETTING OF JUNE 19, 1998 — ENG. EST. $752,461.00 — LOW BID $565,895.43
PROPOSAL 9806615
PROJECT NH 59012 - 46447A
LOCAL AGRMT. — % OVER/UNDER EST. -24.79%
COMPLETION DATE - 15 work days

5.522 km of bituminous coldmilling and resurfacing on US-131 from South of Edgar Road northerly to Mecosta South County Line, in Reynolds Township, Montcalm County.

BIDDER	AS-READ	AS-CHECKED	
Rieth-Riley Constr Co - Goshen, IN *	**$565,895.43**	**Same**	**1**
Thompson-McCully Co - Belleville, MI	$623,783.52	Same	2
Central Asphalt Inc - Mt. Pleasant,M	$824,672.88	Same	3

3 BIDDERS

Source of Funds: 81.85% Federal 18.15% STF

31. LETTING OF JUNE 19, 1998 — ENG. EST. $483,979.60 — LOW BID $474,065.00
PROPOSAL 9806616
PROJECT STT 34021 - 46654A
LOCAL AGRMT. — % OVER/UNDER EST. -2.05%
COMPLETION DATE - 30 work days

28.238 km of chip seal on M-50 from South of I-96 southerly and easterly to West of Washington Street, in the Village of Lake Odessa, and Odessa, Campbell, Bowne and Lowell Townships, Ionia and Kent Counties.

BIDDER	AS-READ	AS-CHECKED	
Highway Maintenance - Romulus, MI			
Fahrner Asphalt Sealers - Plover, W*	**$474,065.00**	**Same**	1
Terry Construction Inc - Hamilton, OH			

1 BIDDER

Source of Funds: 81.85% Federal 18.15% STF

32. LETTING OF JUNE 19, 1998 — ENG. EST. $260,244.62 — LOW BID $290,110.16
PROPOSAL 9806617
PROJECT NH 59043 - 46439A
LOCAL AGRMT. — % OVER/UNDER EST. +11.48%
COMPLETION DATE - 30 work days

9.295 km of overband crackfill and microsurfacing on M-46 from East of M-91 easterly to West of M-66, in Cato and Belvidere Townships and the Village of Six Lakes, Montcalm County.

BIDDER	AS-READ	AS-CHECKED	
Strawser Incorporated - Columbus, OH	$348,039.50	Same	2
Terry Construction Inc - Hamilton, *	**$290,110.16**	**Same**	**1**

2 BIDDERS

Source of Funds: 81.85% Federal 18.15% STF

33. LETTING OF JUNE 19, 1998
PROPOSAL 9806618
PROJECT STT 78042 - 46635A
LOCAL AGRMT.
COMPLETION DATE - October 2, 1998

ENG. EST. $396,341.44
LOW BID $424,790.88
% OVER/UNDER EST. 7.18%

15.916 km of overband crack fill and microsurfacing on M-60 from Three Rivers East City Limits easterly to Mendon West Village Limits, in Lockport, Park and Mendon Townships, St. Joseph County.

BIDDER	AS-READ	AS-CHECKED	
Strawser Incorporated - Columbus, O*	**$424,790.88**	**Same**	1
Terry Construction Inc - Hamilton, O	$454,620.42	Same	2

2 BIDDERS

Source of Funds: 81.85% Federal 18.15% STF

34. LETTING OF JUNE 5, 1998
PROPOSAL 9806619
PROJECT IM 39022 - 43732A, etc.
LOCAL AGRMT.
COMPLETION DATE - October 2, 1998

ENG. EST. $4,596,393.38
LOW BID $4,980,969.83
% OVER/UNDER EST. 8.37%

9.596 km of bituminous coldmilling, resurfacing, guardrail upgrading, ramp extensions, bridge repair, and 5.182 km of overband crackfill on I-94 from 9th Street easterly to Miller Road in the Cities of Kalamazoo and Portage, Texas and Comstock Townships, Kalamazoo County.

15% DBE Participation Required

BIDDER	AS-READ	AS-CHECKED	
Klett Construction Co - Hartford, MI	$7,438,560.10	Same	2
Thompson-McCully Co - Belleville, M*	**$5,023,804.83**	**$4,980,969.83**	1

1 BIDDER

Source of Funds: 90% Federal 10% State

In accordance with MDOT's policies and procedures and subject to concurrence by the Federal Highway Administration, the preparation and execution of the appropriate documents approved by the Attorney General, and compliance with all legal and fiscal requirements, the Director recommends for approval by the State Administrative Board the items on this agenda.

The approval by the State Administrative Board of these contracts does not constitute the award of same. The award of contracts shall be made at the discretion of the Director-Department of Transportation when the aforementioned requirements have been met. Subject to exercise of that discretion, I approve the contracts described in this agenda and authorize their execution by the responsible Deputy Director of MDOT to the extent authorized by, and in accordance with, the December 14, 1983 resolution of the State Transportation Commission and the Director's memorandum of February 26, 1991.

Respectfully submitted,

James R. DeSana,
Director

July 7, 1998 No. 84

SECOND SUPPLEMENTAL AGENDA

DEPARTMENT OF TRANSPORTATION

TRANSPORTATION and NATURAL RESOURCES COMMITTEE
STATE ADMINISTRATIVE BOARD

T&NR Meeting: DATE - Secretary of State's Office, 3:30 PROJECT MANAGER
State Administrative Board Meeting: DATE - State Capital, 11:00 AM

* *

CONTRACTS

1. LETTING OF JUNE 5, 1998 — ENG. EST. $160,940.50 — LOW BID $197,352.08
PROPOSAL 9806037
PROJECT STU 25402 - 46493A
LOCAL AGRMT. 98-5204 — % OVER/UNDER EST. 22.62%
COMPLETION DATE - October 2, 1998

1.61 kilometers of grading and bituminous surfacing with aggregate shoulders on Grand Blanc Road from Wise Road to US-23 in Genesee County.

BIDDER	AS-READ	AS-CHECKED	
Saginaw Asphalt Paving - Carrollton,	$201,252.30	Same	2
Valley Asphalt Company - Saginaw, M*	**$197,352.08**	**Same**	**1**
Thompson-McCully Co - Belleville, MI	$272,254.94	Same	5
Ace Asphalt & Paving - Flint, MI			
Lois Kay Contracting Co - Saginaw, M	$214,733.73	Same	3
Bituminous Pavers, Inc. - Burton, MI	$237,434.33	Same	4

5 BIDDERS

By association with the above construction contract we are also asking for approval of the above-referenced cost participation agreement.

Source of Funds: 81.85% Federal 18.15% Genesee

2. LETTING OF JUNE 5, 1998 — ENG. EST. $459,193.83 — LOW BID $262,096.21
PROPOSAL 9806039
PROJECT STL 55900 - 46404A
LOCAL AGRMT. 98-5214
COMPLETION DATE - September 25, 1998 — % OVER/UNDER EST. -42.92%

770 kilometers of pavement marking, countywide in Menominee County.

BIDDER	AS-READ	AS-CHECKED	
Clark Highway Services - Lake City,*	**$262,096.21**	**Same**	**1**

1 BIDDER

By association with the above construction contract we are also asking for approval of the above-referenced cost participation agreement.

Source of Funds: 77.58% Menominee Co. 22.42% Federal

3. LETTING OF JUNE 5, 1998 — ENG. EST. $383,319.48 — LOW BID $382,145.40
PROPOSAL 9806073
PROJECT STT 14051 - 46638A
LOCAL AGRMT.
COMPLETION DATE - September 9, 1998 — % OVER/UNDER EST. -0.31%

13.577 km of double chip seal on M-40, from North of M-60 northerly to South of South Street, in Newburg and Marcellus Townships, Cass County.

BIDDER	AS-READ	AS-CHECKED	
Bituminous Pavers, Inc. - Burton, MI			
D & D Contracting Inc - Grawn, MI			
Pavement Maint Syst - Imlay City, MI			
Fahrner Asphalt Sealers - Plover, W*	**$382,145.40**	**Same**	**1**
Terry Construction - Hamilton, OH			

1 BIDDER

Source of Funds: 81.85% Federal 18.15% STF

4. LETTING OF JUNE 5, 1998
PROPOSAL 9806091
PROJECT STT 14101 - 46631A
LOCAL AGRMT.
COMPLETION DATE - September 9, 1998

ENG. EST. $442,278.99
LOW BID $481,564.84
% OVER/UNDER EST. 8.88%

12.290 km of overband crack fill, double chip seal and bituminous skip patching, on M-152 from Berrien East County Line easterly to M-51, in Silver Creek and Keeler Townships, VanBuren and Cass Counties.

BIDDER	AS-READ	AS-CHECKED	
Klett Construction Co - Hartford, MI			
Thompson-McCully Co - Belleville, MI			
Consumers Asph Co - Benton Harbor, MI			
Bituminous Pavers, Inc. - Burton, MI			
D & D Contracting Inc - Grawn, MI			
Pavement Maint Syst - Imlay City, MI			
Fahrner Asphalt Sealers - Plover, W*	**$481,564.84**	**Same**	**1**
Terry Construction Inc - Hamilton, MI			

1 BIDDER

Source of Funds: 81.85% Federal 18.15% STF

In accordance with MDOT's policies and procedures and subject to concurrence by the Federal Highway Administration, the preparation and execution of the appropriate documents approved by the Attorney General, and compliance with all legal and fiscal requirements, the Director recommends for approval by the State Administrative Board the items on this agenda.

The approval by the State Administrative Board of these contracts does not constitute the award of same. The award of contracts shall be made at the discretion of the Director-Department of Transportation when the aforementioned requirements have been met. Subject to exercise of that discretion, I approve the contracts described in this agenda and authorize their execution by the responsible Deputy Director of MDOT to the extent authorized by, and in accordance with, the December 14, 1983 resolution of the State Transportation Commission and the Director's memorandum of February 26, 1991.

Respectfully submitted,

James R. DeSana,
Director

Secretary Miller gave the presentation of the forgoing Transportation and Natural Resources Committee Report of July 1, 1998. Secretary Miller moved the Transportation and Natural Resources Committee Report covering the regular meeting held July 1, 1998, be approved and adopted. The motion was supported by Mr. Hughes and unanimously approved.

8. MOTIONS AND RESOLUTIONS:

None

The Governor noted the action by the Board would enable the execution of the contract with the State of Virginia to lease prison bed space.

The Governor requested Mr. Schornack to summarize the MBPI sale. Mr. Schornack stated that the sale process commenced on July 9, 1997. The process was open. The process was reviewed by the Michigan Auditor General, the Michigan Attorney General and a private corporation, First of Michigan Corporation, to provide a "Fairness Opinion" on the sale of MBPI.

Mr. Schornack described the transaction as "a four way win" for the people of Michigan. First the taxpayers win by receiving a fair price for the MBPI. The workers at MBPI win because they can keep their jobs. The City of Lansing wins a corporate taxpayer and new jobs. The men and women of the armed forces win with the continued supply of protective products to combat biological weapons.

The Governor thanked Mr. Schornack, Ms. Lannoye, Budget Director of the Department of Management and Budget and Mr. Haveman, Director of Community Health for their extensive efforts to accomplish this sale.

The Governor noted that this was a historic event. The MBPI was the last state owned laboratory for the production of biologic vaccines. He asked Mr. Schornack to address those concerns regarding vaccine availability.

Mr. Schornack confirmed that this was the end of an era of state owned means of production for vaccines. The State of Massachusetts transferred their laboratory to the University of Massachusetts in 1996.

Vaccine, and other biologic products availability is provided for in the "Asset Purchase Agreement." This Agreement provides preferential treatment for the State of Michigan for five years. In addition, BioPort will donate the average annual usage of various vaccinations to the State of Michigan, such as one for rabies, for five years.

The sale of the Institute was advertised world wide. There were approximately 80 initial inquiries, 20 very interested parties, seven serious bids and the highest offer was accepted.

The Governor inquired if there were others, beside Representative Brewer who thought the Institute was undervalued at $25 million. Mr. Schornack was not aware of anyone else who thought it was undervalued and noted the "Fairness Opinion" supported the decision.

The Governor asked Mr. Benson of the First of Michigan Corporation to explain the sale as a "going concern" and, if the State was making a profit while operating the MBPI.

Mr. Benson explained the different types of sales, such as mergers, discounted cash flow and going concerns. The going method of valuation used for MBPI valued it as an operating business generating cash flow. The Corporation's review of MBPI records showed it was not making any profit. BioPort Corporation will have a challenge in taking over the Institute.

Admiral William Crowe addressed the Board, at the Governor's invitation. The Admiral explained that the company will take over the labs and intended to be a good corporate citizen of the City of Lansing. The Corporation intends to stay in Lansing. Twenty percent of the corporate stock will be distributed to employees over the next five years. It will continue to work with the State of Michigan, the City of Lansing, and keep up with the needs of the U.S. Department of Defense. The Corporation will keep all commitments to the military and to the U.S. FDA.

Long term plans include updating facilities and equipment and upgrade production. The Corporation will implement a business system for the laboratories.

The Governor congratulated the Admiral and BioPort on the sale.

Mayor Hollister, of Lansing, was pleased to welcome BioPort Corporation to Lansing and support it as effectively as possible. It is one step in making Lansing a better place.

The Governor asked for other comments. There were none.

9. ADJOURNMENT:

Mr. Hughes moved the meeting be adjourned. The motion was supported by Secretary Miller and unanimously approved.

SECRETARY CHAIRPERSON

A G E N D A

FINANCE AND CLAIMS COMMITTEE - STATE ADMINISTRATIVE BOARD

July 7, 1998 Special Meeting, 10:30 a.m.
Senate Appropriations Room
3rd Floor, Capitol Building

SECTION I. AGENCY CONTRACTS

NEW CONTRACTS

1. DEPARTMENT OF CORRECTIONS

1)	The Virginia Department of Corrections Richmond, Virginia	$ 27,375,000.00 Total To provide housing to state prisoners in other state prisons

SECTION II. DMB CONTRACTS

NEW CONTRACTS

SECTION III. RELEASE OF FUNDS TO WORK ORDER

SECTION IV. REVISION TO WORK ORDER

SECTION V. CLAIMS - PERSONAL PROPERTY LOSS

SECTION VI. CLAIMS - PERSONAL INJURY

SECTION VII. APPROVAL OF SPECIAL ITEMS

2. MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

Resolution of the State Adminsitrative Board regarding the conveyance of assets and liabilities of the Michigan Biologic Products Institute.

The Director of the Department of Management and Budget recommends approval by the State Administrative Board of the items contained in this agenda. Approval by the State Administrative Board of these award recommendations does not require or constitute the award of same. Award of contracts shall be made at the discretion of the DMB Director or designee.

MI DMB PURCHASING Fax:517-335-0046 Jul 2 '98 16:37 P.02

AGENDA

STATE ADMINISTRATIVE BOARD MEETING
Senate Appropriations Committee Room
Third Floor, Capitol Building
11:00 a.m., Tuesday - July 7, 1998

1. **CALL TO ORDER:**

   INVOCATION: Reverend Paul Frederick of Mt. Hope United Methodist Church in Lansing

   PLEDGE OF ALLEGIANCE TO THE FLAG

2. **READING OF MINUTES OF PRECEDING MEETINGS AND APPROVAL THEREOF:**

   Regular meeting of Ju[illegible] 16, 1998

3. **HEARING OF CITIZENS ON MATTERS FALLING UNDER JURISDICTION OF THE BOARD:**

4. **COMMUNICATIONS:**

   Correspondence from Alan H. VanNoord, Department of Treasury, with attached summary and detail investment holding reports for the Veterans Benefit Trust Fund as of March 31, 1998, and a summary of investment transactions for the quarter ended March 31, 1998, in accordance with a resolution adopted by the State Administrative Board.

5. **UNFINISHED BUSINESS:**

6. **NEW BUSINESS:**

   Retention and Disposal Schedules:

   Department of Agriculture, Office of State Exposition and Fairgrounds, 6/1/98
   Northern Michigan University, Administrative and Academic Officers, 5/21/98
   Northern Michigan University, Premedical Advisory Board, 5/21/98
   Northern Michigan University, Office of the V. P. for University Relations Development Fund, 5/21/98

7. **REPORTS AND RECOMMENDATIONS OF COMMITTEES:**

   Finance and Claims Committee -
   regular meeting of June 30, 1998
   special meeting of July 7, 1998
   Building Committee -
   regular meeting of July 1, 1998
   Transportation and Natural Resources Committee -
   regular meeting of July 1, 1998

MI DMB PURCHASING Fax:517-335-0046 Jul 2 '98 16:37 P.03

State Administrative Board Agenda
July 7, 1998
Page 2.

8. **MOTIONS AND RESOLUTIONS:**

9. **ADJOURNMENT:**

I

STATE OF MICHIGAN



RECEIVED
98 JUL -2 AM 8:47
MBPC

JOHN ENGLER, Governor

DEPARTMENT OF MANAGEMENT & BUDGET

P.O. BOX 30026, LANSING, MICHIGAN 48909
JANET E. PHIPPS, Director

July 1, 1998

MEMORANDUM

TO: Arlene Oisten

FROM: Tom Saxton Tom

SUBJECT: MBPI Fairness Opinion

Attached for consideration by the State Administrative Board at its scheduled July 7 meeting is the fairness opinion letter prepared by First of Michigan in connection with the proposed sale of the Michigan Biologic Products Institute. As indicated by their letter, First of Michigan has made a determination "that this transaction from a financial point of view is fair to the State of Michigan."

The report containing the supporting detail for First of Michigan's fairness conclusion is also enclosed. Copies of the report for each Board member, as well as a copy for yourself are included with this transmittal. It is my understanding you will handle distribution to the Board members prior to their meeting.

Attachment

bcc: Dennis Schornack
Mary Lannoye
Janet Phipps
Kathe Rushford Carter
Deborah Devine

First of Michigan
INVESTMENT BANKING Since 1933
300 River Place • Suite 4000 • Detroit, Michigan 48207

June 30, 1998

State Administrative Board
c/o Arlene Oisten, Secretary
530 W. Allegan, Second Floor
Lansing, Michigan 48933

PERSONAL AND CONFIDENTIAL

Dear Members of the State Administrative Board:

The State of Michigan (the "State") has retained First of Michigan Corporation ("FoM") to render an opinion, from a financial point of view, as to the fairness of a transaction whereby the State may sell the assets of the Michigan Biologic Products Institute (the "Institute") to Bioport Corporation.

The results of the study are based on information provided by the State as well as certain independently obtained information. In conducting our investigation and in arriving at the opinion set forth below, we have relied on the accuracy and completeness of all information supplied or otherwise made available to us by the State, and we have not independently verified such information or undertaken an independent appraisal of the assets of the Institute. With respect to the financial forecasts furnished by the Institute, we have assumed that they have been reasonably prepared and reflect the best currently available estimates and judgment of the State of Michigan as to the Institute's expected future financial performance.

As a basis for our fairness opinion study, we utilized the following generally accepted valuation approaches with regard to the financial value of the Institute including:

1. Net Book Value
2. Discounted Cash Flow (DCF) Analysis
3. Comparison of Comparable Publicly-Traded Companies
4. Comparison of Similar Merger & Acquisition Transactions

It should be stressed that none of these valuation tools is inherently better than the others, and each method is used in different circumstances.

In addition to the above generally accepted valuation approaches, First of Michigan reviewed and considered the overall effectiveness and results of the managed sale process as conducted by W.Y. Campbell & Company and all competing offers received for the Institute.

Conclusion:
Based on our review we have determined that this transaction, from a financial point of view, is fair to the State of Michigan.

Respectfully submitted,

FIRST OF MICHIGAN CORPORATION

J. Michael Davis
Managing Director

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

STRICTLY CONFIDENTIAL

Fairness Opinion
as of June 30, 1998

FIRST OF MICHIGAN CORPORATION
INVESTMENT BANKING

JULY, 1998

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Executive Summary

First of Michigan
INVESTMENT BANKING Since 1933
300 River Place • Suite 4000 • Detroit, Michigan 48207

June 30, 1998

State Administrative Board
c/o Arlene Oisten, Secretary
530 W. Allegan, Second Floor
Lansing, Michigan 48933

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As a basis for our fairness opinion study, we utilized the following generally accepted valuation approaches with regard to the financial value of the Institute including:

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Conclusion:
Based on our review we have determined that this transaction, from a financial point of view, is fair to the State of Michigan.

Respectfully submitted,

FIRST OF MICHIGAN CORPORATION



J. Michael Davis
Managing Director

Purpose and Scope of the Valuation

PURPOSE AND SCOPE OF THE VALUATION

First of Michigan has been engaged at the request of the State of Michigan (the "State") to render an opinion, from a financial point of view, as to the fairness of a transaction whereby the State may sell the assets of the Michigan Biologic Products Institute (the "Institute") to Bioport Corporation.

The results of this study are based upon information provided by the State of Michigan as well as certain independently obtained industry information. In addition, we have met with key State officials, the Institute's management, and have visited the Institute's facilities. Finally, a limited review was conducted for the industry in which the Institute operates. We were supplied with pro forma balance sheets and pro forma statements of operations of the Institute for the fiscal years ended September 30, 1995, and 1996 as provided by KPMG Peat Marwick LLP, as well as internally compiled balance sheets and internally compiled statements of operations for the fiscal year ended September 30, 1997 and for the period ended June 17, 1998, as provided by the State. Furthermore, projected statements of operations for the Institute were provided by the State. We did not make an independent examination of these statements or other information, which appears elsewhere in this report.

In conducting our analysis and in arriving at the conclusion expressed herein, we have principally taken into account an analysis of accounting and financial information. The nature of the industry and unique characteristics of the Institute were also considered. The available information was assimilated into the various analytical techniques and methodologies which have been generally accepted and documented by judicial precedent.

Qualifications

QUALIFICATIONS

First of Michigan ("FoM") was founded in 1933 and today has over 1,400 employees located in 70 offices. FoM is a member of the New York Stock Exchange, the American Stock Exchange, the Midwest Stock Exchange, and other principal exchanges. First of Michigan operates as a full service investment bank and provides the following services:

- Underwriting of Initial Public Offerings and Secondary Stock Offerings
- Underwriting of Bonds, Notes, and Convertible Debentures
- Private Placement of Debt and Equity
- Merger, Acquisition & Divestiture Services
- Valuations
- Fairness Opinions
- Financial Advisory and Consulting Services

FoM has conducted numerous valuations for tender offers, mergers and acquisitions, initial public equity offerings, minority shareholders, employee stock ownership plans, as well as for federal and state gift tax and estate tax purposes.

Background of the Investigation

BACKGROUND OF INVESTIGATION

In conducting our analysis, we have reviewed the following materials and procedures:

1. Asset Purchase Agreement for the State of Michigan & Bioport Corporation
2. Change Notice of Contract dated September 30, 1998
3. Collaborative Research & Development Agreement Syllabus
4. Compliance Bi-Weekly Update dated May 25, 1997
5. Confidentiality Agreement as proposed by Memo W.Y. Campbell & Company
6. Contact List, Supporting Letters, Documents, and Additional Memos
7. Copy of bids to purchase Michigan Biologic Products Institute
8. Cost Pricing Data Summary
9. Department of Health & Human Services Notice of Inspection
10. Department of the Army Re: Contract; Contract Modification List, Letters & Supporting Documents dated September 22, 1997
11. Detailed Response by Item to FDA Findings for Inspection of February 4-20, 1998 dated March 20, 1998
12. Draft Letter From: R. Meyers dated December 18, 1997
13. Due diligence request list dated August 20, 1997
14. Evaluation Sheets for Bidders for Fairness Opinion and Selling Agent
15. Executive Reorganization
16. Expressions of Interest
17. Fax dated June 3, 1998 To: J. Michael Davis From: T. Saxton Re: Newspaper Clippings
18. Final Draft Environmental Reports SAIC (Science Applications International Corp)
19. Financial Statements and Projections by management dated October 18, 1996
20. Financial Statements and Projections by management dated April 1, 1998
21. Fiscal Year 1997 and 1998 Total Vaccines & Blood Products Invoiced as of April 29, 1998
22. Fiscal Year Forecast Testing Revenues by Month, Forecast beginning in October 1997
23. Form Letter regarding initial due diligence request dated August 20, 1997
24. Gift and Acceptance Agreement

25. Heads of Agreement dated February 18, 1997
26. Index to Bidders Library dated April 13, 1998
27. Initial Site Tour with Building Specs & Map
28. Letter dated December 29, 1997 State of Michigan Re: Default deadline To: W. Latour From: D. Schornack
29. Letter from Michigan Biologic to J. Simmons Re: FDA483 Findings for February 26, 1998.
30. Letter of Intent to Cooperate in the Supply, Distribution & Development of Selected Vaccines
31. Letter on March 29, 1997 From: Michigan Biologic To: Simmons
32. Letter to J. Michael Davis from T. Saxton Re: Meeting for July 31, 1997 dated July 28, 1997
33. Letter to Lt. Gov. Binsfield from M. Hood Re: James Haag Appointment dated March 2, 1998
34. Letter to Simmons from Quality Assurance dated March 30, 1998 Re: Response to FDA 483 Findings
35. Manufacturers Equipment Appraisal
36. March 30, 1996 Pro forma Financial Statements Years Ended September 30, 1996 and September 30, 1995
37. Memorandum of Understanding
38. Michigan Biologic Meeting Minutes: Regular, Special, & Closed
39. Michigan Biologic Policy Statement: Employee Conduct Relative to the Sale of Michigan Biologic Products Institute
40. Miscellaneous correspondence
41. Offering Memorandum by W.Y. Campbell & Company
42. Order of Supplies of Service dated June 30, 1997
43. Plan to Convert Michigan Biologic into a Private Business
44. Site Summary by Smith Hinchman & Grylls Associates Inc.
45. Statement by Department of Health & Human Services RE: Process Manufacturing of Vaccine
46. Strategic Plan for Compliance FDA/CBER MBPI Meeting April 22, 1997, Supplemental Information
47. Supply and Distribution Agreement Syllabus

48. Thirty Day Response to FDA as of March 11, 1997, from Michigan Biologic Products Institute dated April 9, 1997
49. W.Y. Campbell Confidential Divestiture Profile
50. Other Institute and industry data deemed relevant

Application of Valuation Methodologies

APPLICATION OF VALUATION METHODOLOGIES

Valuation Considerations

A number of appraisal methods and variations have been developed by valuation experts over the years. These approaches consider quantitative (financial and accounting statistics), and qualitative (ability of management, etc.), factors to arrive at an overall valuation.

Four considerations must be taken into account in a valuation regardless of which individual or combination of methodologies are eventually used. They are:

1. Restrictive agreements, if any, which may inhibit the free transfer of a company's common stock or ownership. Because the Michigan Biologic Products Institute is a government owned entity significant restrictions exist with regard to the sale of the assets of the Institute.

2. Analysis of an established market price or other sales of the stock being valued. Prices determined in a free and open market are sometimes the best indications of value. The assets of the Institute are not independently freely traded on any open market.

3. Review of generally accepted approaches to valuations including Net Book Value; Discounted Cash Flow Analysis, Comparison of Comparable Publicly-Traded Companies, and Comparison of Similar Merger & Acquisition Transactions. It should be stressed that none of these valuation tools is inherently better than the others, and each method is used in different circumstances.

4. Review of the overall effectiveness and results of the managed sale process and all competing offers received for the Institute.

Adjustment to Determine Shareholder Value

The Total Enterprise Value (TEV) of a company is defined as shareholder value + total funded debt - excess cash. From the definition of TEV, the following definition of shareholder value can be derived: shareholder value = TEV - total funded debt + excess cash. Therefore, it is necessary to make certain adjustments to the Total Enterprise Value (TEV) of the business to derive shareholder value. Because the Institute has no debt outstanding or excess cash there are no necessary adjustments to determine shareholder value.

Other Adjustments

Michigan Biologic Products Institute is a government entity, which requires other adjustments to reflect various factors affecting value. The most common adjustment is a discount for a lack of marketability of an investment in the Institute. This discount reflects the cost and difficulty of acquiring and/or selling government owned entities and the increased return that investors require for holding a less liquid investment. Factors affecting the amount of this discount include the size of the potential buyer/investor market for the business, transaction costs, appeal of the business as a public offering or as part of a public company, recent business changes, dependence on key people and accounts, and other business risks generally associated with closely-held businesses. Other favorable factors could include proprietary products, technologies, or resources, R&D efforts in place that have not yet been commercialized, reputation, customer base, or excess capacity. Negative factors could include environmental concerns, growth constraints that cannot be easily overcome, excessive leverage that could affect operations or other operating concerns that cannot likely be corrected. In a DCF analysis, this discount is reflected as a higher cost of equity for the increased investor return requirements on these types of businesses.

Net Book Value

NET BOOK VALUE

The net book value or net equity method implies that a business is worth its accumulated retained earnings, or deficit, plus its original capitalization. Net book value is primarily an amount arrived at over a company's existence which reflects accounting history expressed in unadjusted dollars and not the company's potential.

In most going concerns with a viable future it can be demonstrated that these companies would change hands for more than net book value. Book Value is only of importance to the extent it provides an adequate base for the continuance of operations. In most instances where a company earns a significant return on its assets (both tangible and intangible), the net book value approach is not representative of the company's intrinsic business value.

Book Value is an accounting concept, augmented by appropriate Fair Market Value asset adjustments, recording the accumulated financing input from contributed capital and retained earnings. Intrinsic business value is an economic concept estimating future cash output discounted to present value. In essence, book value tells you what you have put in; intrinsic business value estimates what can be taken out.

Because the Michigan Biologic Products Institute is a governmental entity, traditional financial statements are not available. The financial statements provided as of September 31, 1997 and June 17, 1998 are internal compilations which do not calculate book value per Generally Accepted Accounting Principles (GAAP) or in accordance with Statements on Standards for Accounting and Review Services issued by the American Institute of Certified Public Accountants. As a result of the lack of availability of traditional financial statements the calculation of a Net Book Value of the Biologic Products Institute is not applicable.

Discounted Cash Flow Approach

DISCOUNTED CASH FLOW APPROACH

This approach argues that a potential investor will pay a price for a security which yields a targeted minimum rate of return on invested capital (both to suppliers of debt and equity). Using this targeted rate of return as a discount factor, the present value of a stream of estimated future earnings for a given number of years can be computed by discounting each year's estimated earnings to the present time. Other factors considered include the expected cyclical or unpredictable nature (if any) of a company's earnings and cash flow and the investors' willingness to wait out a given length of ownership.

To state the premise another way, DCF valuation posits that the buyer purchases a time series of free cash flows that are generated by the assets purchased. DCF does not value the total cash flow of the business. Rather, it values only the free cash flow. In doing so, this analysis separates and ascribes value only to the cash flows that can be taken out of the business. Cash that is generated but used to sustain the business (such as increases in working capital and capital expenditures) is not included in the DCF value. Cash flow that must be retained in the business creates no incremental value to the buyer.

Another methodological nuance should be noted before defining free cash flow. As noted, DCF valuation uses a discount rate that reflects the firm's weighted cost of capital or the price it must pay to suppliers of both debt and equity. Accordingly, free cash flow to be discounted should be developed independent of financing cost. For the Institute, we have used projections as provided by the State. For the case, free cash flow is defined as net operating income after tax, plus depreciation and amortization, less capital expenditures, less any other net working capital investments.

Terminal Value

DCF valuation is really composed of two values: a forecast of free cash flows for some term of years and a terminal value that is a surrogate for the present value of the DCF's that are expected to occur in the years after the end of the forecast period.

Terminal value at the end of the period of cash flow forecasts may be arrived at in different ways, such as estimating book value, applying a price/earnings multiple to forecasted earnings or employing a cash flow multiple. We feel using a perpetuity based on free cash flow in Year 5 and the long-term cost of capital is most consistent with the DCF methodology. The perpetuity method calculates the terminal value as net operating income after tax in Year 5 divided by the cost of capital. Like the free cash flows, this terminal value is then discounted back to the present at the discount rate for Year 5.

Cost of Capital

Once the free cash flows and terminal values are estimated, the present value of these components must be calculated. The acquirer is paying today for access to the cash flows generated by the assets in their future; therefore, these cash flows must be discounted to the present. The proper discounted rate can be estimated by calculating the marginal weighted average cost of capital. In essence, the discount rate attempts to approximate the rate of return the suppliers of capital will expect to earn. The cost of capital was calculated using a blend of 0% debt and 100% equity. The cost of equity was 25%, yielding a blended cost of capital of approximately 25%. A cost of capital analysis is included in Exhibit C.

Analysis

We have made a five year projection of income statements and balance sheets and cash flows based on the Institute's historical financial performance and State forecasts. We have utilized these projections and reformatted the financial information contained within the statements to arrive an approximation of the Institute's net after tax cash flow from operations. We prepared one scenario from which to evaluate the Institute from a discounted cash flow perspective. Additionally, the case is presented in Exhibit B.

Conclusion

Based on these assumptions, we have forecasted a Discounted Cash Flow Value as follows ($000s):

DISCOUNTED CASH FLOW CALCULATION
($000's)

	State Case
Present Value of Future Cash Flows	$ (6,493)
Present Value of Terminal Value	$ 5,155
Total Future Cash Flows and Terminal Value	$ (1,338)
Less: Adjustment to Shareholder Value	$ -
Total Shareholder Value	**$ (1,338)**

Therefore, the financial value ($000's) of the Institute is $0.00 utilizing the discounted cash flow method.

Comparable Publicly-Traded Companies

COMPARABLE PUBLICLY-TRADED COMPANIES

This approach assumes that a degree of comparability exists between the Institute and other similar firms for which a value has been established over a five year time horizon in an active and free trading market. Once similarity is established, the relationship to market value is expressed as various valuation ratios, such as the price/earnings ratio. These ratios may then be modified to reflect special conditions, risks, or opportunities, which are unique to the Institute.

There are obvious problems in identifying publicly traded firms whose total business parallels the Institute's. Because the Institute is a government owned entity it has certain constraints unlike that of private sector companies including Civil Service regulations, the annual legislative appropriations process, and the extensive controls over public procurement. As a result, the Institute is unable to respond to the dynamic biotechnology market with the necessary urgency and is therefore at a significant competitive disadvantage. Furthermore, historical financial statements that conform to GAAP or are in accordance with Statements on Standards for Accounting and Review Services are unavailable for the Institute. A comparable publicly-traded companies analysis is presented in Exhibit D.

Market Comparisons

A number of factors were considered when determining which companies have similar characteristics to the Institute including:

A. Industry Niche
B. Earnings Growth
C. Revenue Size and Growth
D. Market Diversity
E. Balance Sheet Strength
F. Return on Equity
G. Trading Volume (potential market capitalization)

We have reviewed a broad range of companies, which have similar operating characteristics to the Institute. The following companies have some degree of comparability or at least have significant assets utilized in a similar industry segment.

1. Anergen, Inc.
2. Genelabs Tech., Inc.
3. Gilead Sciences, Inc.
4. Medimmune, Inc.
5. MGI Pharma., Inc.
6. NABI
7. Protein Design Labs, Inc.
8. Serologicals Corp.
9. Titan Pharma., Inc.

Market Comparison Analysis

Overall, we believe this group of companies is most representative of publicly traded securities and their Total Enterprise Value ("TEV")/EBIT (Earnings Before Interest & Taxes) most accurately reflect the market valuation for a quality (as measured primarily by return on equity and other ratios) participant in the biotechnology industry.

The valuation of a publicly traded company is normally expressed as a function of its P/E ratio. We feel that the public market provides the objective evidence as to value. Due to the extenuating circumstances as mentioned above we feel the proper way to view the Institute's valuation is as a function of Price to Earnings.

COMPARISON OF PUBLICLY-TRADED COMPANIES
($000's)

	Comp. Factor	40% Discount	MBPI Base (9/30/97)	MBPI TEV
LTM P/E	20.63	12.38	$ (3,544)	$ (43,875)
Less: Adjustment to Shareholder Value				$ -
Total Shareholder Value				**$ (43,875)**

Comparable Merger and Acquisition Transactions

COMPARABLE MERGER & ACQUISITION TRANSACTIONS

The acquisition value of a company seeks to estimate the price at which the Institute would "trade in the market for corporate control." Acquisition value is the price an acquirer would pay to control the target's assets and the free cash flows (FCF) they generate. Transactions occur in the public market almost daily at prices significantly above current secondary trading levels. The premium paid over the market trading level of the stock of a company is, in fact, a derived figure rather than an analytical tool. When the various valuation methods outlined previously justify a price over current trading prices, then a premium price is paid. The price paid rests on the conclusion of the analysis. To some degree, the prices paid are a result of the intense amount of competition among buyers for quality businesses and to a greater degree they reflect the economic benefits of all the synergies that a buyer may bring to a seller in a corporate combination.

Thus, the value of a company (its intrinsic value) as an independent entity often will be different than the value of the company when it is combined with another firm. The acquisition value will reflect incremental cash flow generated by consolidated tax savings, cost savings due to the elimination of redundant operations, distribution economies, or other business benefits.

Generally, the first step in this approach is to determine a sample of comparable companies that have been involved in a merger or acquisition. From a comparability standpoint, we look at the following aspects of a company: industry, products, processes, customers, distribution channels, and suppliers among others. We reviewed a number of transactions for the Michigan Biologic Products Institute.

There are obvious problems in identifying publicly traded firms whose total business parallels the Institute's. Because the Institute is a government owned entity it has certain constraints unlike that of private sector companies including Civil Service regulations, the annual legislative appropriations process, and the extensive controls over public procurement. As a result, the Institute is unable to respond to the dynamic biotechnology market with the necessary urgency and is therefore at a significant competitive disadvantage. Furthermore, historical financial statements that conform to GAAP or are in accordance with Statements on Standards for Accounting and Review Services are unavailable for the Institute. A comparable merger and acquisition transactions analysis is presented in Exhibit E.

Of these transactions, none of the companies involved are government owned entities. Furthermore, most of the companies involved in the transactions are larger than the Institute and typically are more financially viable.

COMPARISON OF MERGER & ACQUISITION TRANSACTIONS

($000's)

	Comp. Factor	40% Discount	MBPI Base (9/30/97	MBPI. TEV
TEV/Net Income	36.3	21.78	$ (3,544)	$ (77,188)
Less: Adjustment to Shareholder Value				$ -
Total Shareholder Value				**$ (77,188)**

VALUATION SUMMARY

Summary

The results of applying the various valuation techniques are as follows:

SUMMARY OF SHAREHOLDER VALUE CALCULATION
($000's)

Methodology	Method Value	Weighting	Shareholder Value Calculation
Discounted Cash Flow	$ (1,338)	50.00%	$ 0.00
Comparable Publicly-Traded Companies	$ (43,875)	25.00%	$ 0.00
Comparable Merger & Acquisition Transactions	$ (77,188)	25.00%	$ 0.00
Conclusion			**$ 0.00**

Based on the foregoing analysis and our review of the Asset Purchase Agreement between the State of Michigan and Bioport Corporation, we have determined this transaction is fair, from a financial point of view, to the State of Michigan.

EXHIBITS

Historical Financial Statements

Michigan Biologic Products Institute
Historical Income Statements

	For the year ended September 30,										For the period ended June 17,	
	1993	(%)	1994	(%)	1995	(%)	1996	(%)	1997	(%)	1998	(%)
Revenues:												
Army product sales	4,573,295	45.1%	3,642,490	45.1%	4,276,037	49.7%	3,546,533	47.2%	-	0.0%	-	0.0%
Other product sales	4,742,482	46.7%	3,491,915	43.3%	3,489,810	40.6%	3,085,785	41.1%	-	0.0%	-	0.0%
Red Cross	674,480	6.6%	725,364	9.0%	720,257	8.4%	725,000	9.7%	-	0.0%	-	0.0%
Other	161,292	1.6%	211,965	2.6%	109,277	1.3%	153,369	2.0%	12,245,658	100.0%	3,027,794	100.0%
Total revenue	**$ 10,151,549**	**100.0%**	**$ 8,071,734**	**100.0%**	**$ 8,595,381**	**100.0%**	**$ 7,510,687**	**100.0%**	**$ 12,245,658**	**100.0%**	**$ 3,027,794**	**100.0%**
Expenses:												
Salaries and wages	3,990,291	39.3%	4,528,154	56.1%	5,018,584	58.4%	5,833,071	77.7%	-	0.0%	-	0.0%
Fringe benefits	1,632,264	16.1%	1,890,356	23.4%	2,139,070	24.9%	2,241,651	29.8%	-	0.0%	-	0.0%
Contractual services, supplies and materials	2,801,545	27.6%	2,244,749	27.8%	4,602,132	53.5%	3,682,746	49.0%	-	0.0%	-	0.0%
General services	1,100,461	10.8%	1,238,801	15.3%	1,141,839	13.3%	1,183,990	15.8%	-	0.0%	-	0.0%
Depreciation	624,784	6.2%	751,222	9.3%	921,880	10.7%	985,569	13.1%	-	0.0%	-	0.0%
State/Department overhead	731,906	7.2%	646,915	8.0%	622,999	7.2%	647,411	8.6%	-	0.0%	-	0.0%
Inventory adjustment	(108,441)	-1.1%	(909,379)	-11.3%	327,247	3.8%	(817,264)	-10.9%	-	0.0%	-	0.0%
Other	301,225	3.0%	287,629	3.6%	296,084	3.4%	304,628	4.1%	15,789,565	128.9%	11,558,576	381.7%
Total expenses	11,074,035	109.1%	10,678,447	132.3%	15,069,835	175.3%	14,061,802	187.2%	15,789,565	128.9%	11,558,576	381.7%
Net (loss)	**$ (922,486)**	**-9.1%**	**$ (2,606,713)**	**-32.3%**	**$ (6,474,454)**	**-75.3%**	**$ (6,551,115)**	**-87.2%**	**$ (3,543,907)**	**-28.9%**	**$ (8,530,782)**	**-281.7%**

Michigan Biologic Products Institute
Historical Balance Sheets

	As of September 30,			As of June 13,
ASSETS	1995	1996	1997	1998*
Current assets:				
Cash	-	-	-	-
Receivables	7,942,976	5,125,088	15,127,069	4,482,694
Inventories	1,332,354	2,149,618	489,528	752,704
Total current assets	9,275,330	7,274,706	15,616,597	5,235,398
Property, plant and equipment:				
Land	23,963	23,963		
Buildings and building improvements	9,196,730	9,196,730		
Machinery and equipment	5,757,827	6,251,958		
	14,978,520	15,472,651	-	-
Less accumulated depreciation	(9,575,800)	(10,561,524)		
Net property, plant and equipment	5,402,720	4,911,127	-	-
Total assets	**$ 14,678,050**	**$ 12,185,833**	**$ 15,616,597**	**$ 5,235,398**
LIABILITIES AND EQUITY				
Current liabilities				
Account payable	393,826	518,198	472,757	2,347,580
Accrued expenses	792,304	861,283	-	
Other	-	-	4,215	
Total current liabilities	1,186,130	1,379,481	476,972	2,347,580
Other liabilities	-	-	-	-
Total liabilities	**$ 1,186,130**	**$ 1,379,481**	**$ 476,972**	**$ 2,347,580**
Contingencies	-	-	-	-
Equity	**13,491,920**	**10,806,352**	**15,139,625**	**2,887,818**
Total liabilities and equity	**$ 14,678,050**	**$ 12,185,833**	**$ 15,616,597**	**$ 5,235,398**

**Note: A/P as of 6/13/98, A/R as of 6/17/98, Inventory as of 6/30/97*

Discounted Cash Flow Analysis

Michigan Biologic Products Institute
Projected Income Statements
State Case
($000's)

	1995	1996	1997	1998	1999	2000	2001	2002	2003
Sales	**8,595**	**7,511**	**12,246**	**7,709**	**17,796**	**16,893**	**16,764**	**20,322**	**24,030**
Cost of Goods Sold	14,148	13,076	15,790	29,427	12,393	10,470	10,860	12,799	15,134
Gross Profit	**(5,553)**	**(5,566)**	**(3,544)**	**(21,718)**	**5,403**	**6,423**	**5,904**	**7,523**	**8,896**
SG & A Expense	0	0	0	0	3,250	2,199	2,022	2,526	2,987
Earnings Before Int., Tax, Depr., Amort.	(5,553)	(5,566)	(3,544)	(21,718)	2,153	4,223	3,883	4,997	5,909
Depreciation Expense	922	986	0	0	1,853	1,911	1,964	1,976	1,976
Operating Profit	(6,474)	(6,551)	(3,544)	(21,718)	300	2,312	1,919	3,021	3,933
Interest on Long-Term Debt: Excess	0	0	0	0	0	984	815	739	831
Income After Taxes	(6,474)	(6,551)	(3,544)	(21,718)	300	1,329	1,103	2,282	3,101
Net Income	(6,474)	(6,551)	(3,544)	(21,718)	300	1,329	1,103	2,282	3,101

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Michigan Biologic Products Institute
Projected Balance Sheets
State Case
($000's)

	1995	1996	1997	1998	1999	2000	2001	2002	2003
ASSETS:									
Accounts Receivable	7,943	5,125	15,127	4,483	16,134	15,273	15,198	18,424	21,785
Inventory	1,332	2,150	490	753	808	683	708	835	987
Total Current Assets	9,275	7,275	15,617	5,235	16,942	15,956	15,906	19,258	22,772
Gross Fixed Assets	14,955	15,449	19,898	23,794	25,971	28,173	30,402	32,438	34,474
Accumulated Depreciation	9,576	10,562	11,929	13,296	15,149	17,060	19,024	21,000	22,976
Net Fixed Assets	5,379	4,887	7,969	10,498	10,822	11,113	11,378	11,438	11,498
Land	24	24	24	24	24	24	24	24	24
Total Non-Current Assets	5,403	4,911	7,993	10,522	10,846	11,137	11,402	11,462	11,522
Total Assets	14,678	12,186	23,610	15,757	27,788	27,093	27,308	30,720	34,294
LIABILITIES:									
Accounts Payable	394	518	473	96	254	214	222	262	310
Other Current Liabilities - Operating	0	0	4	4	4	4	4	4	4
Long-Term Debt: Excess	0	0	0	0	11,572	9,589	8,692	9,782	10,207
Total Long-Term Debt	0	0	0	0	11,572	9,589	8,692	9,782	10,207
Other Deferrals	792	861	0	0	0	0	0	0	0
Total Liabilities	1,186	1,379	477	100	11,830	9,807	8,918	10,048	10,521
EQUITY:									
Retained Earnings	13,492	10,806	23,133	15,657	15,958	17,286	18,390	20,672	23,774
Common Equity	13,492	10,806	23,133	15,657	15,958	17,286	18,390	20,672	23,774
Total Equity	13,492	10,806	23,133	15,657	15,958	17,286	18,390	20,672	23,774
Total Liabilities & Equity	14,678	12,186	23,610	15,757	27,788	27,093	27,308	30,720	34,294

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Michigan Biologic Products Institute
Funds Flow Statements
State Case
($000's)

	1996	1997	1998	1999	2000	2001	2002	2003
Net Income	**(6,551)**	**(3,544)**	**(21,718)**	**300**	**1,329**	**1,103**	**2,282**	**3,101**
ADJUSTMENTS TO NET INCOME:								
Proceeds from Sale of Assets	(494)	(4,449)	(421)	0	0	0	0	0
Depreciation Expense (Funds)	986	1,367	1,788	1,853	1,911	1,964	1,976	1,976
CHANGES IN LIABILITIES:								
Increase in Accounts Payable	124	(45)	(377)	158	(40)	9	40	48
Increase in Other Current Liabilities	0	4	(0)	0	0	0	0	0
Increase in Total Current Liabilities	124	(41)	(377)	158	(40)	9	40	48
Increase in Long-Term Debt: Excess	0	0	0	11,572	(1,984)	(897)	1,090	425
Increase in Other Deferrals	69	(861)	0	0	0	0	0	0
Increase in Total Non-Current Liabilities	69	(861)	0	11,572	(1,984)	(897)	1,090	425
Increase in Total Liabilities	**193**	**(903)**	**(377)**	**11,730**	**(2,023)**	**(888)**	**1,130**	**472**
CHANGES IN EQUITY:								
Total Sources of Funds	**(5,866)**	**(7,528)**	**(20,729)**	**13,884**	**1,216**	**2,179**	**5,388**	**5,550**
CHANGES IN ASSETS:								
Increase in Net Accounts Receivable	(2,818)	10,002	(10,644)	11,651	(860)	(75)	3,226	3,362
Increase in Inventory	817	(1,660)	263	56	(125)	25	126	152
Increase in Total Current Assets	**(2,001)**	**8,342**	**(10,381)**	**11,707**	**(986)**	**(50)**	**3,352**	**3,514**
Fixed Capital Investment	0	0	3,896	2,177	2,202	2,229	2,036	2,036
Additions to Land	0	0	(0)	0	0	0	0	0
DIVIDENDS:								
Total Uses of Funds	**(2,001)**	**8,342**	**(6,485)**	**13,884**	**1,216**	**2,179**	**5,388**	**5,550**
Net Funds Flow Source (Use)	(3,866)	(15,870)	(14,243)	0	(0)	0	0	0

Michigan Biologic Products Institute
Projected Cash Flow Statements
State Case
($000's)

	1996	1997	1998	1999	2000	2001	2002	2003
Sales	7,511	12,246	7,709	17,796	16,893	16,764	20,322	24,030
Cost of Goods Sold	13,076	15,790	29,427	12,393	10,470	10,860	12,799	15,134
Gross Profit	(5,566)	(3,544)	(21,718)	5,403	6,423	5,904	7,523	8,896
SG & A Expense	0	0	0	3,250	2,199	2,022	2,526	2,987
Depreciation Expense	986	0	0	1,853	1,911	1,964	1,976	1,976
Operating Profit	(6,551)	(3,544)	(21,718)	300	2,312	1,919	3,021	3,933
Depreciation Expense (Funds)	986	1,367	1,788	1,853	1,911	1,964	1,976	1,976
Increase in Other Deferrals	69	(861)	0	0	0	0	0	0
Funds from Operations Before Tax	(5,496)	(3,038)	(19,930)	2,153	4,223	3,883	4,997	5,909
Funds from Operations After Tax	(5,496)	(3,038)	(19,930)	2,153	4,223	3,883	4,997	5,909
Incremental Working Capital Investment	(2,125)	8,383	(10,004)	11,549	(946)	(58)	3,312	3,466
Fixed Capital Investment	0	0	3,896	2,177	2,202	2,229	2,036	2,036
Additions to Land	0	0	(0)	0	0	0	0	0
Proceeds from Sale of Assets	(494)	(4,449)	(421)	0	0	0	0	0
Cash Flow from Operations	***(3,866)***	***(15,870)***	***(14,243)***	***(11,572)***	***2,967***	***1,712***	***(351)***	407
Cash Flow from Operations	(3,866)	(15,870)	(14,243)	(11,572)	2,967	1,712	(351)	407
Interest Expense	0	0	0	0	984	815	739	831
Non-Operating Income	0	0	0	0	0	0	0	0
Net Cash Provided	(3,866)	(15,870)	(14,243)	(11,572)	1,984	897	(1,090)	(425)
Funding Surplus / (Deficit)	(3,866)	(15,870)	(14,243)	(11,572)	1,984	897	(1,090)	(425)
Increase in Long-Term Debt: Excess	0	0	0	11,572	(1,984)	(897)	1,090	425

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Michigan Biologic Products Institute
Projected Indirect Cash Flow Statements
State Case
($000's)

	1996	1997	1998	1999	2000	2001	2002	2003
Net Income	**(6,551)**	**(3,544)**	**(21,718)**	**300**	**1,329**	**1,103**	**2,282**	**3,101**
Plus:								
Depreciation Expense (Funds)	986	1,367	1,788	1,853	1,911	1,964	1,976	1,976
Increase in Other Deferrals	69	(861)	0	0	0	0	0	0
Total Interest Expense	0	0	0	0	984	815	739	831
Less:								
Non-Operating Profit	0	0	0	0	0	0	0	0
Funds from Operations After Tax	(5,496)	(3,038)	(19,930)	2,153	4,223	3,883	4,997	5,909
Plus:								
Increase in Accounts Payable	124	(45)	(377)	158	(40)	9	40	48
Increase in Other Current Liabilities	0	4	(0)	0	0	0	0	0
Less:								
Increase in Net Accounts Receivable	(2,818)	10,002	(10,644)	11,651	(860)	(75)	3,226	3,362
Increase in Inventory	817	(1,660)	263	56	(125)	25	126	152
Cash from Operating Cycle	(3,371)	(11,421)	(9,926)	(9,395)	5,169	3,941	1,685	2,443
Less:								
Fixed Capital Investment	0	0	3,896	2,177	2,202	2,229	2,036	2,036
Additions to Land	0	0	(0)	0	0	0	0	0
Plus:								
Proceeds from Sale of Assets	(494)	(4,449)	(421)	0	0	0	0	0
Cash Flow from Operations	(3,866)	(15,870)	(14,243)	(11,572)	2,967	1,712	(351)	407
Non-Operating Income	0	0	0	0	0	0	0	0
Cash bef. Fin. Cost & Ext. Fin.	(3,866)	(15,870)	(14,243)	(11,572)	2,967	1,712	(351)	407
Interest Expense	0	0	0	0	984	815	739	831
Cash bef. External Financing	(3,866)	(15,870)	(14,243)	(11,572)	1,984	897	(1,090)	(425)
Increase in Long-Term Debt: Excess	0	0	0	11,572	(1,984)	(897)	1,090	425
Increase in Total Long-Term Debt	0	0	0	11,572	(1,984)	(897)	1,090	425

Michigan Biologic Products Institute
Summary of Financial Ratios
State Case
($000's)

	1995	1996	1997	1998	1999	2000	2001	2002	2003
PROFIT PERFORMANCE RATIOS:									
Gross Profit Margin	-64.60%	-74.10%	-28.94%	-281.75%	30.36%	38.02%	35.22%	37.02%	37.02%
Change in Net Income	N/A	1.18%	-45.90%	512.84%	-101.38%	342.40%	-16.94%	106.83%	35.89%
Return on Sales	-75.33%	-87.22%	-28.94%	-281.75%	1.69%	7.86%	6.58%	11.23%	12.91%
Return on Equity	-47.99%	-60.62%	-15.32%	-138.71%	1.88%	7.69%	6.00%	11.04%	13.05%
Return on Assets or Investment	-44.11%	-53.76%	-15.01%	-137.83%	1.08%	8.53%	7.03%	9.83%	11.47%
Return on Net Assets	-45.33%	-56.15%	-15.32%	-138.71%	1.09%	8.60%	7.08%	9.92%	11.57%
LEVERAGE RATIOS:									
Debt/Equity Ratio (%)	0.00%	0.00%	0.00%	0.00%	72.52%	55.47%	47.27%	47.32%	42.93%
Debt/Total Capital (%)	0.00%	0.00%	0.00%	0.00%	42.04%	35.68%	32.10%	32.12%	30.04%
Equity Ratio	91.92%	88.68%	97.98%	99.37%	57.43%	63.80%	67.34%	67.29%	69.32%
Times Interest Earned	N/A	N/A	N/A	N/A	N/A	2.351	2.354	4.089	4.730
ACTIVITY RATIOS:									
Days in Receivables	337.296	249.748	450.885	212.251	330.904	330.904	330.904	330.904	330.904
Days in Receivables (Avg.)	N/A	318.407	301.823	464.259	211.422	340.226	331.722	301.936	305.374
Days in Payables	10.160	14.504	10.928	1.187	7.467	7.467	7.467	7.467	7.467
Days in Payables (Avg.)	N/A	12.764	11.454	3.525	5.143	8.165	7.323	6.901	6.891
Inventory Turnover	10.619	6.083	32.255	39.095	15.334	15.334	15.334	15.334	15.334
Inventory Turnover (Avg.)	N/A	7.511	11.966	47.378	15.879	14.044	15.614	16.591	16.616
Fixed Asset Turnover	1.598	1.537	1.537	0.734	1.644	1.520	1.473	1.777	2.090
Total Asset Turnover	0.586	0.616	0.519	0.489	0.640	0.624	0.614	0.662	0.701
LIQUIDITY RATIOS:									
Quick Ratio	20.169	9.890	31.715	44.864	62.595	70.116	67.136	69.250	69.419
Current Ratio	23.552	14.038	32.741	52.398	65.730	73.251	70.264	72.387	72.564
Working Capital	8,881.50	6,756.51	15,139.63	5,135.39	16,684.07	15,738.11	15,679.85	18,992.27	22,458.41
Operating Working Capital	8,881.50	6,756.51	15,139.63	5,135.39	16,684.07	15,738.11	15,679.85	18,992.27	22,458.41
PER-SHARE DATA:									
VALUE DRIVERS:									
Sales Growth Rate (G)	N/A	-12.62%	63.04%	-37.05%	130.86%	-5.07%	-0.76%	21.22%	18.25%
Operating Profit Margin (P)	-75.33%	-87.22%	-28.94%	-281.75%	1.69%	13.69%	11.44%	14.87%	16.37%
Incremental Fixed Capital Investment (F)	N/A	90.90%	-28.87%	-46.46%	3.21%	-32.23%	-205.43%	1.69%	1.62%
Incremental Working Capital Investment (W)	N/A	195.91%	177.05%	220.50%	114.49%	104.76%	45.16%	93.10%	93.48%
Cost of Capital (K) (%)	25.00%	25.00%	25.00%	25.00%	25.00%	25.00%	25.00%	25.00%	25.00%
Cum. PV of Cash Flows	N/A	N/A	N/A	N/A	(9,257.90)	(7,358.88)	(6,482.44)	(6,626.31)	(6,492.99)
PV of Residual Value	N/A	N/A	N/A	N/A	961.01	5,919.36	3,929.17	4,949.90	5,155.03
Cum. PV of Cash Flows and Residual Value	N/A	N/A	N/A	N/A	(8,296.89)	(1,439.52)	(2,553.26)	(1,676.40)	(1,337.96)
Incr. in Shareholder Value	0.00	0.00	0.00	0.00	(8,296.89)	6,857.37	(1,113.74)	876.86	338.44
Incr. in Shareholder Value (%)	N/A	N/A	N/A	N/A	N/A	-82.65%	77.37%	-34.34%	-20.19%
Present Value of Equity Residual Value	N/A	N/A	N/A	N/A	(11,572.37)	(9,588.81)	(8,692.05)	(9,782.12)	(10,206.77)
Cum. PV of Div and Equity Res. Value	N/A	N/A	N/A	N/A	(11,572.37)	(9,588.81)	(8,692.05)	(9,782.12)	(10,206.77)
Incr. in DDM Value	0.00	0.00	0.00	0.00	(11,572.37)	1,983.57	896.75	(1,090.07)	(424.65)
Incr. in DDM Value (%)	N/A	N/A	N/A	N/A	N/A	-17.14%	-9.35%	12.54%	4.34%
ECONOMIC PROFIT RATIOS									
Return on Invested Capital (%)	N/A	-48.56%	-32.79%	-93.89%	1.92%	8.40%	7.14%	11.16%	12.91%
E.P. Spread (ROIC - RROC) (%)	0.00%	-48.56%	-32.79%	-93.89%	1.92%	8.40%	7.14%	11.16%	12.91%
Adjusted Book Value	13,491.92	10,806.35	23,132.59	15,657.35	27,530.04	26,875.07	27,081.81	30,454.23	33,980.37
Economic Profit	0.00	(6,551.15)	(3,543.91)	(21,718.46)	300.32	2,312.25	1,918.54	3,021.18	3,932.98

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Michigan Biologic Products Institute
Summary of Shareholder Value Calculation
State Case
($000's)

	Cash Flow	Pres Value Cash Flow	Cumul PV Cash Flow
1999	(11,572)	(9,258)	(9,258)
2000	2,967	1,899	(7,359)
2001	1,712	876	(6,482)
2002	(351)	(144)	(6,626)
2003	407	133	(6,493)
PV of Residual Value			5,155
Cum. PV of Cash Flows and Residual Value			(1,338)
Shareholder Value			(1,338)

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COST OF CAPITAL ANALYSIS

Michigan Biologic Products Institute

Cost of Capital

Equity Component					Debt Component					Total Cost of Capital[1]
Cost of Equity		Equity % of Total Capital		**Equity Component**	Cost of Debt[2]		Debt % of Total Capital		**Debt Component**	
25.0%	X	100.0%	=	**25.0%**	5.9%	X	0.0%	=	**0.0%**	**25.0%**

Notes

[1] Equity component plus debt component

[2] 9.0% X (1-34% tax rate); tax rate consistent with incremental rate

COMPARABLE PUBLICLY-TRADED COMPANIES ANALYSIS

Michigan Biologic Products Institute

Comparable Publicly Traded Companies Analysis

($000's) except per share data

	Industry Average	Industry Median	Michigan Biologic Products	Anergen, Inc.	Genelabs Tech., Inc.	Gilead Sciences, Inc.	Medimmune Inc.	MGI Pharma., Inc.	NABI	Protein Design Labs, Inc.	Serologicals Corp.	Titan Pharma. Inc.
Fiscal Year End	*MBP excluded from Average & Median*		30-Sep	31-Dec	31-Dec	31-Dec	31-Dec	31-Dec	31-Dec	31-Dec	31-Dec	31-Dec
Last Financial Period			30-Sep	31-Mar-98	31-Mar	31-Mar	31-Mar	31-Mar	31-Mar	31-Mar	29-Mar	31-Mar
Current Market Data:												
Stock Price (6/24/98)				$1.750	$3.063	$34.500	$64.125	$7.000	$2.781	$24.875	$30.000	$4.750
Shares Outstanding				18,851,000	39,582,511	30,204,790	26,509,269	14,296,101	34,893,917	18,511,656	15,864,254	13,100,883
Market Capitalization	$454,660	$121,221		$32,989	$121,221	$1,042,065	$1,699,907	$100,073	$97,049	$460,477	$475,928	$62,229
Total Enterprise Value (TEV)[A]	$480,011	$216,133	$15,617	$34,300	$131,375	$1,044,589	$1,784,554	$100,073	$216,133	$460,477	$481,371	$67,229
Symbol				ANRG	GNLB	GILD	MEDI	MOGN	NABI	PDLI	SERO	TTNP
Exchange				NASDAQ	NASDAQ	NASDAQ	NASDAQ	NASDAQ	NASDAQ	NASDAQ	NASDAQ	NASDAQ
LTM Price Range - High				$4.313	$5.313	$47.250	$64.250	$24.000	$8.375	$51.500	$31.250	$6.688
LTM Price Range - Low				$0.875	$2.250	$24.000	$16.500	$3.188	$2.625	$20.125	$18.000	$2.375
Book Value	$94,253	$73,812	$15,144	$5,712	$21,386	$311,415	$127,517	$15,039	$73,812	$167,023	$108,950	$17,424
Book Value/Share	$4.04	$2.12		$0.30	$0.54	$10.31	$4.81	$1.05	$2.12	$9.02	$6.87	$1.33
LTM Operating Data												
Total Assets	$134,273	$126,643	$15,617	$8,409	$28,819	$349,421	$258,402	$17,618	$224,428	$174,667	$126,643	$20,046
Net Operating Assets	$130,817	$124,233	$15,144	$7,648	$24,314	$345,874	$252,901	$16,978	$212,048	$174,168	$124,233	$19,187
Total Funded Debt	$30,497	$3,983	$0	$1,311	$472	$2,523	$84,647	$0	$119,084	$0	$5,443	$0
Revenues	$65,237	$19,035	$12,246	$5,122	$13,406	$48,131	$130,164	$14,194	$230,981	$20,605	$107,065	$17,464
EBITDA[B]	$6,959	$2,750	NA	($8,080)	($12,220)	($43,193)	($6,980)	($1,133)	($5,829)	($20,511)	$26,207	$2,750
EBIT	$4,851	$2,436	($3,544)	($8,982)	($12,814)	($46,112)	($9,868)	($1,346)	($16,226)	($23,799)	$21,099	$2,436
Net Income	($8,057)	($9,368)	($3,544)	($8,684)	($12,129)	($27,429)	($9,368)	($1,346)	($14,421)	($23,799)	$13,305	$11,355
EPS	($0.24)	($0.35)		($0.46)	($0.31)	($0.91)	($0.35)	($0.09)	($0.41)	($1.29)	$0.84	$0.87
Proj. 1998 EPS	($0.33)	($0.44)		($0.44)	NA	($1.76)	$0.54	NA	$0.12	($0.86)	$0.95	($0.89)
Proj. 1999 EPS	$0.06	($0.55)		($0.55)	NA	($0.86)	$1.76	NA	$0.20	($0.59)	$1.18	($0.67)
LTM Margins & Ratios												
Gross Margin	7.3%	33.8%	-28.9%	-117.8%	60.0%	-41.6%	35.1%	58.4%	12.5%	-23.8%	33.8%	49.5%
EBITDA Margin	-46.0%	-8.0%	NM	-157.8%	-91.2%	-89.7%	-5.4%	-8.0%	-2.5%	-99.5%	24.5%	15.7%
EBIT Margin	-52.5%	-9.5%	-28.9%	-175.4%	-95.6%	-95.8%	-7.6%	-9.5%	-7.0%	-115.5%	19.7%	13.9%
Net Income Margin	-42.0%	-9.5%	-28.9%	-169.5%	-90.5%	-57.0%	-7.2%	-9.5%	-6.2%	-115.5%	12.4%	65.0%
Capital Turnover	-20.8%	-7.9%	-23.4%	-117.4%	-52.7%	-13.3%	-3.9%	-7.9%	-7.7%	-13.7%	17.0%	12.7%
R&D / LTM Revenues	77.6%	50.5%	NM	217.8%	94.9%	139.7%	25.3%	36.4%	8.7%	123.8%	1.7%	50.5%
Valuation Indicators												
LTM P/E Ratio	20.6	20.6		NM	NM	NM	NM	NM	NM	NM	35.8	5.5
Proj. 1998 P/E Ratio	58.2	31.6		NM	NM	NM	119.9	NM	23.2	NM	31.6	NM
Proj. 1999 P/E Ratio	25.3	25.4		NM	NM	NM	36.5	NM	13.9	NM	25.4	NM
TEV / LTM Revenues	10.1	7.1		6.7	9.8	21.7	13.7	7.1	0.9	22.3	4.5	3.8
TEV / LTM EBITDA	21.4	21.4		NM	NM	NM	NM	NM	NM	NM	18.4	24.4
TEV / LTM EBIT	25.2	25.2		NM	NM	NM	NM	NM	NM	NM	22.8	27.6
Price / Book Value	5.20	4.37		5.78	5.67	3.35	13.33	6.65	1.31	2.76	4.37	3.57

NOTES

(A) Defined as Market Capitalization plus Total Funded Debt plus Preferred Stock less Cash

(B) Earnings Before Interest, Taxes, Depreciation, and Amortization

Michigan Biologic Products Institute

Description of Selected Publicly-Traded Companies

	Description
Anergen, Inc.	Anergen, Inc. is focused on the treatment of autoimmune diseases through the discovery and development of proprietary therapeutics that selectively interrupt the disease process. Anergen's current research and development efforts are focused on two distinct core technologies, AnergiX(TM) and AnervaX(TM), that the Company believes may be used to treat a broad range of autoimmune diseases without generally suppressing the immune system. The Company was founded in 1988 to discover and develop biopharmaceutical compounds for the treatment of autoimmune diseases. To achieve profitable operations, the Company, alone or with others, must successfully develop, obtain regulatory approval for, manufacture, and market products. The Company does not have any products available for sale nor does it expect to have any products commercially available for at least several years, if at all. The Company's potential products are at the early stages of research and development, with only limited human testing of certain of the Company's products undertaken to date. The products currently under development by the Company will require significant research, laboratory testing and clinical trials and investment of capital prior to their commercialization. There can be no assurance that any potential products will be successfully developed, prove to be safe and efficacious in clinical trials, meet applicable regulatory standards, be capable of being produced in commercial quantities at acceptable costs or be successfully marketed.
Genelabs Technologies, Inc.	Genelabs Technologies, Inc. is a biopharmaceutical company with research focused on the discovery of small molecule drugs that function by binding to DNA to regulate gene expression or inactivate pathogens. The lead research program is based on a proprietary enabling technology, MERLIN, for creating gene-specific, small organic, DNA-binding molecules. A recently developed technology, VIRIA, is being applied to the discovery of novel anti-viral RNA-binding compounds. The Company's development efforts are focused on its lead compound, GL701, which is in Phase III clinical trials as a new therapy for systemic lupus erythematosus ("SLE"). The Company conducts its diagnostic business through its wholly-owned subsidiary Genelabs Diagnostics (Pte.) Ltd. ("GLD"), located in Singapore, which sells diagnostic tests for infectious diseases primarily in Europe and Asia. Genelabs has an equity interest in a Taiwan-based company, Genelabs Biotechnology Co., Ltd. ("GBL"), which is focused on late-stage development, manufacture, and commercialization of newly developed or formulated pharmaceuticals for the Asian market. The Company's business is comprised of its discovery technologies, drug development programs, diagnostic business and its Asian biopharmaceutical investment.

Michigan Biologic Products Institute

Description of Selected Publicly-Traded Companies

	Description
Gilead Sciences, Inc.	Gilead Sciences, Inc. is an independent biopharmaceutical company that seeks to provide accelerated solutions for patients and the people who care for them. The Company discovers, develops, and commercializes proprietary therapeutics for important viral diseases, including the currently marketed product, VISTIDE (cidofovirinjection), for the treatment of cytomegalovirus ("CMV") retinitis, a sight-threatening viral infection in patients with acquired immune deficiency syndrome ("AIDS"). In addition, the Company is developing products to treat diseases caused by human immunodeficiency virus ("HIV"), hepatitis B virus("HBV") and influenza virus. The successful development and commercialization of the Company's products will require substantial and ongoing efforts at the forefront of the life sciences industry. The Company is pursuing preclinical or clinical development of a number of product candidates. Even if these product candidates appear promising during various stages of development, they may not reach the market for a number of reasons. Such reasons include the possibilities that the potential products will be found ineffective or cause harmful side effects during preclinical or clinical trials, fail to receive necessary regulatory approvals, be difficult or uneconomical to manufacture on a commercial scale, fail to achieve market acceptance or be precluded from commercialization by proprietary rights of third parties. The Company faces significant challenges and risks in an industry undergoing rapid change, including the risks inherent in its research and development programs, uncertainties in obtaining and enforcing patents, the lengthy and expensive regulatory approval process, reliance on third party manufacturers intense competition from pharmaceutical and biotechnology companies, dependence on collaborative relationships, increasing pressure on pharmaceutical pricing from payors, patients, and government agencies, and uncertainties associated with the market acceptance of any of the Company's products in development. The Company was incorporated in Delaware in 1987.
MedImmune, Inc.	MedImmune is a biotechnology company focused on developing and marketing products for the prevention and treatment of infectious disease and for use in transplantation medicine. Since commencing operations in 1988, the Company has pursued a strategy of establishing an initial commercial base using proven technologies and targeting well-understood diseases to support longer-term product development. The Company is currently marketing two products, CytoGam (CytomegalovirusImmune Globulin Intravenous (Human), CMV-IGIV) and RespiGam (RespiratorySyncytial Virus Immune Globulin Intravenous (Human), RSV-IGIV). The Company has filed a Biologic License Application ("BLA") requesting marketing clearance in the United States for a third product, Synagis (palivizumab,formerly known as MEDI-493). Additionally, the Company has five products undergoing clinical trials and a number of product candidates and technologies in the pipeline.
MGI PHARMA, Inc.	MGI PHARMA, INC. is a human pharmaceutical company that acquires, develops and markets differentiated, specialty pharmaceutical, and medical products for therapeutic markets of unmet need. To date, MGI has focused on the oncology (cancer) and rheumatology markets, but it intends to expand into other medical niches. MGI focuses on medical niche markets because it believes such markets can be reached effectively by a relatively small sales force. In the United States, the number of physicians in a particular subspecialty is usually relatively small and these physicians tend to be concentrated in major metropolitan areas. Current trends in pharmaceutical detailing are expected to reduce the number of pharmaceutical sales targets as decisions relating to use of prescription drugs consolidate and become more centralized. MGI currently markets its products through its own commercial organization in the United States. The Company sells to pharmaceutical wholesalers in the United States who distribute MGI's drugs to retail and hospital pharmacies. To commercialize its products in foreign markets, MGI uses international partnerships. The Company was incorporated in Minnesota in November 1979.

Michigan Biologic Products Institute

Description of Selected Publicly-Traded Companies

	Description
NABI	Nabi is a research and development driven biopharmaceutical company making and marketing unique products for people with life threatening conditions. Nabi possesses a broad portfolio of therapeutic products and vaccines to treat and prevent infectious diseases and immune disorders. Nabi's product portfolio includes three products approved by the United States Food and Drug Administration (the "FDA") and nine main products across four classes in development, including four products in clinical trials. Nabi has completed construction and is in the process of validating a new biopharmaceutical manufacturing facility designed to process plasma into therapeutic products. In addition, Nabi is one of the world's largest suppliers of source plasma and specialty plasmas, which are sold to pharmaceutical and diagnostic companies. Some of the plasma that Nabi collects also is used to manufacture Nabi's proprietary products. Nabi collects plasma from an extensive donor base through 71 collection centers in the United States and four collection centers in Germany. During 1996 and 1997 Nabi collected and processed approximately2,322,000 and 2,274,000 liters of plasma, respectively. In addition, Nabi manufactures and markets human-blood and plasma-based diagnostic products and provides testing services on plasma and blood samples for third parties.
Protein Design Labs, Inc.	Protein Design Labs, Inc. ("PDL") is a leader in the development of humanized and human monoclonal antibodies for the prevention and treatment of a variety of disease conditions, including auto immune diseases, inflammatory conditions, cancers and viral infections. The Company uses proprietary computer software and other technologies to develop its SMART[TM] humanized antibodies for potential use as effective pharmaceuticals without the limitations of traditional mouse-derived (murine) antibodies. PDL believes that its technologies are broadly applicable to a variety of diseases, as demonstrated by the Company's diverse product development pipeline and its collaborative arrangements with numerous pharmaceutical companies. The Company and its collaborative partners currently have multiple product candidates in clinical development and numerous additional product candidates in preclinical studies. The Company's most advanced product, Zenapax[R], has been approved for marketing in the United States ("U.S.") and Switzerland for the prophylaxis of acute organ rejection in patients receiving renal transplantations. This product is exclusively licensed to Hoffmann-La Roche Inc. and its affiliates ("Roche"). PDL has received U.S. and European patents that the Company believes cover most humanized antibodies and that may lead to additional corporate partnering, patent licensing and other revenue opportunities.
Serologicals Corporation	Serologicals Corporation is a leading worldwide provider of specialty human antibodiezs and related services to major healthcare companies. The Company's services, including donor recruitment, donor management, and clinical testing services, enable the Company to provide value-added specialty products that are used as the active ingredients in therapeutic products for the treatment and management of such medical indications as Rh incompatibility in newborns, rabies and hepatitis and in diagnostic products such as blood typing reagents and diagnostic test kits. In addition, the Company collects and supplies antibodies for the manufacture of intravenous immune globulin (IVIG), a product containing a broad spectrum of antibodies used in the treatment of a wide variety of medical indications. As of March 20, 1998, the Company conducted its operations through a national network of 59 donor centers and through laboratories located in the United States and the United Kingdom. The Company also operates two monoclonal manufacturing facilities in Scotland. The majority of the Company's16 specialty donor centers are strategically located on or near medical campuses, enhancing the Company's ability to source specialty antibodies from medical community referrals.

Michigan Biologic Products Institute

Description of Selected Publicly-Traded Companies

	Description
Titan Pharmaceuticals, Inc.	Titan Pharmaceuticals, Inc. is engaged in the development of therapeutic products for the treatment of cancer, disorders of the central nervous system ("CNS") and other serious and life-threatening diseases. Titan's lead product, Iloperidone, partnered with Novartis Pharma AG, is targeted to enter phase III testing this year. Iloperidone is being developed for the treatment of schizophrenia and related psychotic disorders--a market expected to exceed $4 billion within two years. Also in the CNS arena, Titan is developing a unique cell based therapeutic, Spheramine-TM- for the treatment of Parkinson's disease, and an implantable drug delivery system with applications in the treatment of CNS disorders. Titan's cancer therapeutics in clinical testing include three immunotherapeutics--CeaVac-TM-, TriAb-TM-, and TriGem-TM---that are designed to stimulate a patient's immune system against cancer cells. Another Titan product in development, Pivanex-TM-, is a small molecule drug that acts as a differentiating agent and is targeted to start phase II testing this year for non-small cell lung cancer. Collectively, this cancer product pipeline has the potential to address more than half of all solid tumor cancers. Additionally, Titan is developing gene therapy products for treatment of prostate cancer, head and neck cancer, and other cancers. The Company was incorporated in Delaware in February 1992 and has been funded through various sources, including private placements of its securities, as well as an initial public offering of its securities in January 1996.

COMPARABLE MERGER AND ACQUISITION TRANSACTION ANALYSIS

Michigan Biologic Products Institute

Comparable Transactions Analysis

($000's except shares outstanding and per share data)

Acquiror			Rhone-Poulenc Rorer Inc	Cambrex Corp	Cytogen Corp	Johnson & Johnson	Investor Group
Target Company & Information	Average	Median	Applied Immune Sciences Inc	BioWhittaker Inc	Cellcor (Hillman Medical Ventu)	Cordis Corp	Fisher Scientific Int'l Inc
Total Revenues			$1,300	$53,900	$1,300	$468,500	$2,165,500
Net Income			($28,800)	$4,400	($8,800)	$53,700	$44,500
Operating Income			($30,300)	$13,100	($4,400)	$90,800	$99,400
Cash Flow			($26,800)	$16,800	($4,000)	$106,800	$144,400
Book Value/Share			$4.20	$4.60	($0.30)	$18.30	$20.00
Book Value			$55,986	$49,496	($1,638)	$299,937	$406,200
Transaction Statistics							
Transaction Form			Merger	Merger	Merger	Merger	Acq. Maj. Int.
Date Effective			11/28/95	10/3/97	10/23/95	2/23/96	1/21/98
Offer Price/Share			$11.75	$11.63	$2.70	$109.00	$48.25
TEV[1]			$114,239	$130,017	$20,843	$1,806,748	$1,349,787
TEV to Net Income	36.3	32.0	NM	29.5	NM	33.6	30.3
TEV to Revenues	6.8	3.8	87.9	2.4	16.0	3.9	0.6
TEV to Cash Flow[2]	14.4	15.9	NM	7.7	NM	16.9	9.3
TEV to Book Value	6.0	3.7	2.0	2.6	NM	6.0	3.3

*(1) TEV = Total Enterprise Value = (offer price * actual common shares) plus cost to retire in-the-money options plus straight debt plus convertible debt plus short term debt plus preferred equity less (cash and marketable securities)*

(2) Applied Immune Sciences, Inc., Gynecare Inc., Neurex Corp., PerSeptive Biosystems Inc., SyStemix Inc., and Univax Biologics Inc. are excluded from TEV/ Revenue Average and Median calculations.

Michigan Biologic Products Institute

Comparable Transactions Analysis

($000's except shares outstanding and per share data)

Acquiror			Rhone-Poulenc Rorer Inc	Cambrex Corp	Cytogen Corp	Johnson & Johnson	Investor Group
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TEV to Cash Flow[2]	14.4	15.9	NM	7.7	NM	16.9	9.3
TEV to Book Value	6.0	3.7	2.0	2.6	NM	6.0	3.3

Michigan Biologic Products Institute

Comparable Transactions Analysis

($000's except shares outstanding and per share data)

Acquiror			Sandoz AG	Johnson & Johnson	American Standard Inc	CR Bard Inc	Elan Corp PLC
Target Company & Information	Average	Median	Genetic Therapy Inc	Gynecare Inc	INCSTAR Corp	MedChem Products Inc	Neurex Corp
Total Revenues			$12,700	$1,100	$45,400	$28,900	$2,000
Net Income			($12,000)	($11,500)	$4,800	$1,700	($28,600)
Operating Income			NA	($12,100)	NA	$3,400	($28,600)
Cash Flow			NA	($11,400)	NA	$6,700	($28,000)
Book Value/Share			$4.70	$1.30	$1.90	$5.30	$2.60
Book Value			$61,382	$10,790	$31,730	$54,272	$58,110
Transaction Statistics							
Transaction Form			Merger	Merger	Merger	Merger	Merger
Date Effective			8/11/95	11/19/97	7/2/97	9/28/95	Pending
Offer Price/Share			$21.00	$8.26	$6.32	$9.25	$32.70
TEV[1]			$623,989	$65,680	$102,865	$102,774	$800,833
TEV to Net Income	36.3	32.0	NM	NM	21.4	60.5	NM
TEV to Revenues	6.8	3.8	NM	59.7	NM	3.6	400.4
TEV to Cash Flow[2]	14.4	15.9	NM	NM	NM	15.3	NM
TEV to Book Value	6.0	3.7	10.2	6.1	3.2	1.9	13.8

Michigan Biologic Products Institute

Comparable Transactions Analysis

($000's except shares outstanding and per share data)

Acquiror			Perkin-Elmer Corp	Genetics Institute Inc	Zynaxis	Arris Pharmaceutical Corp	Baxter International Inc
Target Company & Information	Average	Median	PerSeptive Biosystems Inc	SciGenics Inc	Secretech Inc	Sequana Therapeutics	Somatogen Inc
Total Revenues			$89,500	$800	$200	$15,500	NA
Net Income			($2,100)	($2,200)	($800)	($21,000)	($10,100)
Operating Income			($25,900)	NA	($700)	($23,200)	($18,500)
Cash Flow			$16,700	NA	($700)	($19,500)	($16,900)
Book Value/Share			$2.20	$4.40	($0.60)	$4.80	$2.20
Book Value			$47,322	$9,196	($834)	$49,152	$46,024
Transaction Statistics							
Transaction Form			Merger	Merger	Merger	Merger	Merger
Date Effective			1/23/98	12/6/95	Pending	1/9/98	5/4/98
Offer Price/Share			$12.41	$14.00	$0.85	$16.20	$9.00
TEV[1]			$339,306	$23,947	$1,877	$169,973	$175,471
TEV to Net Income	36.3	32.0	NM	NM	NM	NM	NM
TEV to Revenues	6.8	3.8	3.8	NM	9.4	11.0	NM
TEV to Cash Flow[2]	14.4	15.9	20.3	NM	NM	NM	NM
TEV to Book Value	6.0	3.7	7.2	2.6	NM	3.5	3.8

Michigan Biologic Products Institute

Comparable Transactions Analysis

($000's except shares outstanding and per share data)

Acquiror			Cell Genesys Inc	Mallinckrodt Veterinary Inc	Novartis AG	Procter & Gamble Co	North American Biologicals Inc
Target Company & Information	Average	Median	Somatix Therapy Corp	Syntro Corp	SyStemix Inc (Novartis AG)	Tambrands Inc	Univax Biologics Inc
Total Revenues			NA	$7,000	$4,700	$661,300	$3,800
Net Income			($21,900)	($700)	($45,900)	$46,400	($22,100)
Operating Income			($22,800)	($800)	($49,000)	$93,000	($22,800)
Cash Flow			($20,800)	($400)	($39,200)	$120,200	($20,800)
Book Value/Share			$0.30	$1.00	$6.10	$2.60	$1.70
Book Value			$7,317	$11,400	$109,190	$96,070	$29,223
Transaction Statistics							
Transaction Form			Merger	Merger	Acq. Rem. Int.	Merger	Merger
Date Effective			6/2/97	11/6/95	2/16/97	7/21/97	11/30/95
Offer Price/Share			$3.51	$3.55	$19.50	$50.00	$8.84
TEV[1]			$83,219	$40,057	$401,596	$1,978,686	$158,528
TEV to Net Income	36.3	32.0	NM	NM	NM	42.6	NM
TEV to Revenues	6.8	3.8	NM	5.7	85.4	3.0	41.7
TEV to Cash Flow[2]	14.4	15.9	NM	NM	NM	16.5	NM
TEV to Book Value	6.0	3.7	11.4	3.5	3.7	20.6	5.4

Michigan Biologic Products Institute

Comparable Transactions Analysis

($000's except shares outstanding and per share data)

Acquiror			T Cell Sciences Inc
Target Company & Information	Average	Median	Virus Research Institute Inc
Total Revenues			$3,800
Net Income			($6,600)
Operating Income			($6,500)
Cash Flow			($6,100)
Book Value/Share			$2.20
Book Value			$19,646
Transaction Statistics			
Transaction Form			Merger
Date Effective			Pending
Offer Price/Share			$6.59
TEV[1]			$60,225
TEV to Net Income	36.3	32.0	NM
TEV to Revenues	6.8	3.8	15.8
TEV to Cash Flow[2]	14.4	15.9	NM
TEV to Book Value	6.0	3.7	3.1

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Michigan Biologic Products Institute

Description of Selected Comparable Merger and Acquisition Transactions

Acquiror	Rhone-Poulenc Rorer Inc	Cambrex Corp	Cytogen Corp	Johnson & Johnson
Target	Applied Immune Sciences Inc	BioWhittaker Inc	Cellcor (Hillman Medical Ventu)	Cordis Corp
Description	Rhone-Poulenc Rorer (RP), a unit of French state-owned Rhone-Poulenc, completed its tender offer to acquire the remaining 54% interest which it did not already own in Applied Immune Sciences (AI) for $11.75 in cash per share, or a total value of $84.6 million, by accepting 7,060,315 common shares, or 53% of AI's common stock outstanding, not already owned by RP.	Cambrex acquired BioWhittaker (BW) by completing its tender offer to acquire all the outstanding stock of BW for $11.63 in cash per share, or a total value of $130.539 million, by accepting 10.13 million shares, or 92.54% of BioWhittaker's shares. The offer had been conditioned on a majority of the shares being tendered and was subject to regulatory approval. Previously, in May 1997, BW disclosed it was seeking a buyer for the company.	Cytogen (CYT) acquired all the outstanding shares of Cellcor (CEL), a majority-held unit of Hillman Medical Ventures, in a stock swap transaction valued at $20.414 million. CEL shareholders received .6 and 218.94 CYT common shares for each of their common and convertible preferred shares held respectively. Based on CYT's closing stock price of $4.50 on June 15, the last full trading day prior to the announcement, each CEL common and convertible preferred share was valued at $2.70 and $985.23.	Johnson & Johnson (JJ) acquired Cordis (CD) in a sweetened stock swap transaction valued at $1.878 billion. Each CD shareholder received an amended $109 in JJ common stock for each CD share held. Originally, JJ launched a hostile tender offer to acquire CD for $100 in cash per share, or a total value of $1.76 billion. The transaction had been subject to regulatory approval and in order to gain approval, JJ agreed to divest the neurological products business of CD.

Michigan Biologic Products Institute

Description of Selected Comparable Merger and Acquisition Transactions

Acquiror	Investor Group	Sandoz AG	Johnson & Johnson	American Standard Inc
Target	Fisher Scientific Int'l Inc	Genetic Therapy Inc	Gynecare Inc	INCSTAR Corp
Description	An investor group, including Thomas H. Lee, Chase Capital Partners, Merrill Lynch and DLJ Merchant Banking Partners, a unit of Donaldson Lufkin & Jenrette, acting as a white knight, acquired a 97% interest, or 23,222,330 common shares, in Fisher Scientific International (FS) for an amended $48.25 in cash per share, or a total value of $1.120 billion, in a recapitalization transaction. Originally, the investor group offered $51 per share. Concurrently, Trinity I Fund withdrew intentions to acquire the remaining 91% interest, that it did not already own, in FS.	Sandoz acquired the remaining 96.4% interest in Genetic Therapy (GT) it did not already own in a transaction valued at $283.408 million. Earlier, Sandoz had completed its $21 cash per share tender offer by accepting 12.3 million shares, or 93.91%, of GT's common shares outstanding. The offer had been conditioned upon a majority of GT's shares being tendered and had also been subject to regulatory approval.	Johnson & Johnson (JNJ) acquired Gynecare in a stock swap merger transaction valued at $70.533 million. JNJ offered $8.46 in common shares per Gynecare share. The transaction had been subject to regulatory approval.	American Standard Inc., a unit of American Standard Cos Inc. (ASC), acquired all the outstanding common stock of INCSTAR, a 52%-owned unit of Sorin Biomedica (SB), for $6.32 in cash per share, or a total value of $106.25 million. ASC was a unit of Kelso's ASI Holding subsidiary. The transaction had been contingent upon ASC's acquisition of the European medical diagnostics products business of SB and subject to regulatory approval under the Hart-Scott-Rodino Antitrust Act.

Michigan Biologic Products Institute

Description of Selected Comparable Merger and Acquisition Transactions

Acquiror	CR Bard Inc	Elan Corp PLC	Perkin-Elmer Corp	Genetics Institute Inc
Target	MedChem Products Inc	Neurex Corp	PerSeptive Biosystems Inc	SciGenics Inc
Description	CR Bard (CRB) acquired MedChem Products (MP) in a stock swap transaction valued at $100.83 million. Each MP shareholder received $9.25 in CRB common shares per MP share held. The transaction was accounted for as a pooling of interests. Also, CRB had been granted the option to acquire Gesco, a subsidiary of MP, if the acquisition of MP by CRB did not occur.	Elan Corp. PLC (EC) agreed to acquire Neurex Corp. (NC) in a stock swap transaction valued at $824.501 million. EC offered .51 new ordinary shares per NC share. Based on EC's closing stock price of $64.114 on April 28, each NC share was valued at $32.698. The transaction was to be accounted for as pooling of interests.	Perkin-Elmer (PE) acquired PerSeptive Biosystems (PB) in a stock swap transaction valued at $288.131 million. PE offered .1926 common shares per PB share, subject to a collar agreement. The shares were valued based on PE's closing stock price of $64.4375 on January 21, the last full trading day prior to the announcement. The transaction was accounted as a pooling of interests and was subject to regulatory approval and a lockup agreement.	Genetics Institute (GI), a unit of American Home Products, completed its merger with SciGenics (SG) in a transaction valued at $29.27 million. Earlier, GI had completed a tender offer to acquire all the outstanding stock of SG for an amended $14 in cash per share, or a total value of $29.27 million, by accepting 1,393,641 SG common shares, or 66.7% of SG's outstanding shares. Originally, GI had offered $12 in cash per SG share, or a total value of $25.091 million.

Michigan Biologic Products Institute

Description of Selected Comparable Merger and Acquisition Transactions

Acquiror	Zynaxis	Arris Pharmaceutical Corp	Baxter International Inc	Cell Genesys Inc
Target	Secretech Inc	Sequana Therapeutics	Somatogen Inc	Somatix Therapy Corp
Description	Zynaxis definitively agreed to acquire all the outstanding capital stock of Secretech in a stock swap transaction valued at $1.178 million. Secretech stock holders were to receive .422515 Zynaxis common shares for each of their shares held. Based on Zynaxis' closing stock price of $2 on Jan. 12, the last full trading day prior to the announcement, each Secretech share was valued at $.845.	Arris Pharmaceuticals (AP) merged with Sequana Therapeutics (ST) in a stock swap transaction valued at $169.411 million. AP offered 1.35 common shares per ST share. Based on AP's closing stock price of $12 on October 31, the last full trading day prior to the announcement, each ST share was valued at $16.20. The transaction was subject to regulatory approval. Upon completion the new company was renamed AxyS Pharmaceuticals.	Baxter International Inc (BI) acquired Somatogen Inc (SI) in a stock swap transaction valued $232.875 million. BI offered $9 in common stock and up to $2 in profit-related payments per SI share.	Cell Genesys (CG) acquired Somatix Therapy (ST) in a stock swap transaction valued at $85.718 million. ST shareholders received .385 CG common shares for each ST share held. Based on CG's closing stock price of $9.125 on Jan. 10, the last full trading day prior to the announcement, each ST share was valued at $3.513.

Michigan Biologic Products Institute

Description of Selected Comparable Merger and Acquisition Transactions

Acquiror	Mallinckrodt Veterinary Inc	Novartis AG	Procter & Gamble Co	North American Biologicals Inc
Target	Syntro Corp	SyStemix Inc (Novartis AG)	Tambrands Inc	Univax Biologics Inc
Description	Mallinckrodt Veterinary (MV), a unit of Mallinckrodt Group, acquired all the outstanding common stock of Syntro for $3.55 in cash per share, or a total value of $41.465 million. Earlier, MV completed its tender offer for Syntro by accepting 10,325,610 shares, or 85.44% of Syntro's shares. The offer had been contingent upon at least a majority of MB's shares being tendered.	Novartis completed its tender offer for the remaining 6,233,311 common shares, or 26.8% of SyStemix shares outstanding, that it did not already own, for an amended $19.5 in cash per shares, or a total value of $107.56 million, by accepting 6,233,311 common shares, or 26.3% of SyStemix.	Procter & Gamble acquired all the outstanding common stock of Tambrands for $50 in cash per share, or a total value of approximately $2.004 billion, including the assumption of $150 million in liabilities. The transaction had been subject to regulatory approval.	North American Biologicals (NAB) acquired Univax Biologics (UB) in a stock swap valued at $163.248 million. UB shareholders received .79 NAB common shares for each UB share held. Based on NAB's closing stock price of $11.1875 on August 25, the last full trading day prior to the announcement, each UB share was valued at $8.838. The transaction had been subject to regulatory approval and was accounted for as a pooling of interests. Upon completion, UB was renamed NAB.

Michigan Biologic Products Institute

Description of Selected Comparable Merger and Acquisition Transactions

Acquiror	T Cell Sciences Inc
Target	Virus Research Institute Inc
Description	T Cell Sciences (TCS) agreed to merge with Virus Research Institute (VRI) to form Avant Immunotherapeutics Inc. (AVI) in a stock swap transaction valued at $62.642 million. TCS offered 1.55 common shares per VRI share. Based on TCS' closing stock price of $4.25 on May 11, the last full trading day prior to the announcement, each VRI share was valued at $6.5875. Upon completion, TCS was to own 66% of AVI.



MICHIGAN

OFFICE OF THE AUDITOR GENERAL

SPECIAL REPORT

REVIEW
OF THE

PROCESS USED BY THE MICHIGAN BIOLOGIC PRODUCTS COMMISSION TO CONVEY THE ASSETS AND LIABILITIES OF THE MICHIGAN BIOLOGIC PRODUCTS INSTITUTE



THOMAS H. MCTAVISH, C.P.A.
AUDITOR GENERAL

07-642-97

"...The auditor general shall conduct post audits of financial transactions and accounts of the state and of all branches, departments, offices, boards, commissions, agencies, authorities and institutions of the state established by this constitution or by law, and performance post audits thereof."

– Article 4, Section 53 of the Michigan Constitution

Audit report information may be accessed at:
http://www.state.mi.us/audgen/

STATE OF MICHIGAN
OFFICE OF THE AUDITOR GENERAL
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LANSING, MICHIGAN 48913
(517) 334-8050
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THOMAS H. MCTAVISH, C.P.A.
AUDITOR GENERAL

July 6, 1998

The Honorable Dick Posthumus
Senate Majority Leader
State Capitol
and
The Honorable John D. Cherry, Jr.
Senate Minority Leader
State Capitol
Lansing, Michigan

The Honorable Curtis Hertel
Speaker of the House
State Capitol
and
The Honorable Ken Sikkema
House Minority Leader
Romney Building
Lansing, Michigan

Dear Legislators:

This special report is issued in accordance with Act 522, P.A. 1996, as amended, which mandates that the Auditor General review the entire process used by the Michigan Biologic Products Commission, under this Act, to convey the assets and liabilities of the Michigan Biologic Products Institute (MBPI) to a private entity. This report contains an introduction; purpose of report; scope and methodology; description of the process used by the Commission to convey the assets and liabilities of MBPI; objectives and conclusions; and a glossary of acronyms and terms.

We established two objectives to evaluate the process used by the Commission. Our procedures were of limited scope; therefore, they should not be considered an audit in accordance with *Government Auditing Standards* issued by the Comptroller General of the United States.

If you have any questions or concerns regarding this review, please contact me or Michael J. Mayhew, C.P.A., Director of Audit Operations.

Sincerely,

Thomas H. McTavish, C.P.A.
Auditor General

07-642-97

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REVIEW OF THE PROCESS USED BY THE MICHIGAN BIOLOGIC PRODUCTS COMMISSION TO CONVEY THE ASSETS AND LIABILITIES OF THE MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

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REVIEW OF THE PROCESS USED BY THE MICHIGAN BIOLOGIC PRODUCTS COMMISSION TO CONVEY THE ASSETS AND LIABILITIES OF THE MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

INTRODUCTION

Since 1926, the Biologic Products Division of the Department of Public Health (now the Department of Community Health) has manufactured vaccines and blood derivatives at its facilities in Lansing with the goal of protecting Michigan citizens from infectious diseases. The vaccines produced included tetanus, rabies, pertussis, diphtheria-tetanus-pertussis (DTP), pediatric diphtheria-tetanus (DT), and anthrax, as well as the blood derivatives albumin, immune serum globulin, and anti-hemophilic factor.

Executive Order 1995-25, issued December 5, 1995, removed the Biologic Products Division from the Department of Public Health and established it as an autonomous agency known as the Michigan Biologic Products Institute (MBPI). The Michigan Biologic Products Commission governs MBPI. This Executive Order also provided for the Commission to determine the fair market value of the assets of MBPI and to develop a plan for the transfer of MBPI to a private enterprise.

The Governor signed Act 522, P.A. 1996, on January 12, 1997. This Act authorizes the conveyance of MBPI and establishes the conditions under which the Commission may convey the property. The Act, as amended, provides for the Commission to identify in an agreement the consideration to be received in exchange for the conveyance of MBPI's assets and liabilities; to structure an agreement so that the credit of the State does not need to be granted, the State has preferential access to biologic products, and the purchaser agrees to continue the employment of MBPI employees for at least one year; to allow MBPI employees the opportunity to bid or acquire MBPI assets; to comply with the provisions of the Open Meetings Act (Sections 15.261 - 15.275 of the *Michigan Compiled Laws*); and to operate in accordance with Executive Order 1995-25. The Act also provides for the Auditor General to review and report on the entire process used by the Commission, under this Act, to convey the assets and liabilities of MBPI.

On June 2, 1998, the Commission recommended the terms of the proposed transaction and the Commission's proposed transferee to the State Administrative Board.

PURPOSE OF REPORT

Act 522, P.A. 1996, as amended, mandates that the Auditor General review the entire process used by the Michigan Biologic Products Commission, under this Act, to convey the assets and liabilities of MBPI. The purpose of this report is to convey the results of our review.

SCOPE AND METHODOLOGY

Our procedures were of limited scope; therefore, they should not be considered an audit in accordance with *Government Auditing Standards* issued by the Comptroller General of the United States.

We developed two objectives to evaluate the process used by the Commission. The first objective was to determine the Commission's compliance with the provisions of Act 522, P.A. 1996, as amended. To accomplish our first objective, we reviewed the requirements of this Act. We made inquiries of Commission members, the selling agent, and the Commission's legal counsel. We attended Commission meetings and reviewed the Commission's meeting minutes and bylaws. We examined the offers submitted to the Commission by potential purchasers. We reviewed the asset purchase agreements* negotiated by the Commission with its preferred bidder as of June 30, 1998.

The second objective was to determine the reasonableness of the Commission's process to convey the assets and liabilities of MBPI to a private enterprise. To accomplish our second objective, we reviewed the Commission's and selling agent's methods used to provide information related to the sale to all qualified bidders and the fairness opinion provider*. We also reviewed the information in the bidders library*. We

* *See glossary on page 10 for definition.*

discussed the methods and reviewed documentation related to the selling agent's activities to attract potential bidders interested in purchasing MBPI. We reviewed the Commission's methods and documentation to support the evaluation of the bids and the selection of the preferred asset purchase agreement. We attended Commission meetings and reviewed the Commission's meeting minutes.

Our evaluation covered the period December 5, 1995 (the date of Executive Order 1995-25) through July 1, 1998 (the end of our fieldwork).

DESCRIPTION OF THE PROCESS USED BY THE COMMISSION TO CONVEY THE ASSETS AND LIABILITIES OF MBPI

In accordance with Act 522, P.A. 1996, as amended (Sections 333.26331 - 333.26340 of the *Michigan Compiled Laws*), the Commission conducted the following activities to transfer MBPI to a private entity.

In April 1997, the Commission engaged a selling agent. The selling agent prepared a marketing strategy and an offering memorandum and assisted the Commission in developing the bidders library. The offering memorandum described MBPI, its products, and its customers. The bidders library contained proprietary and other pertinent MBPI information available for review by potential purchasers who signed a confidentiality agreement.

The Commission passed Resolution No. 8 on July 1, 1997, which officially put the assets and liabilities of MBPI up for sale. On July 9, 1997, the selling agent advertised the sale of MBPI in the *Wall Street Journal* in addition to directly soliciting potential purchasers. The selling agent responded to inquiries from or directly contacted over 50 interested parties. On August 5, 1997, the Commission voted to close the official offering period by August 15. Potential purchasers had until August 22 to sign a confidentiality agreement allowing them to obtain an offering memorandum. By that date, 22 potential purchasers had signed confidentiality agreements and were sent an offering memorandum.

The Commission gave the potential purchasers until September 5 to submit a non-binding letter of intent to purchase MBPI. The Commission allowed the 5 potential purchasers who had submitted a letter of intent by the due date to continue on in the sale process. A pharmaceutical firm (a customer) was also allowed to continue because it had a contractual right of first refusal in the event that MBPI was put up for sale. The Commission gave these 6 potential purchasers from August 25 through September 26, 1997 to conduct on-site visits, interview MBPI management, and review documents in the bidders library and at MBPI. One potential purchaser dropped out of the sale process at this point.

On October 10, 1997, the Commission provided the 5 remaining potential purchasers a copy of its preferred asset purchase agreement that outlined the conditions of the transfer. The Commission instructed the 5 potential purchasers to submit a proposed acquisition price, terms of a preferential access agreement for biologic products, and comments on the proposed asset purchase agreement by October 29, 1997. Only 3 potential purchasers responded by the due date.

Of the 3 potential purchasers, one was formed by a group of employees of MBPI. On November 5, 1997, the Commission gave this group five days to demonstrate its financial viability. On November 10, 1997, the Commission disqualified the group from the bidding process because it was unable to provide proof of sufficient working capital. At the same time, another of the potential purchasers withdrew from the process, leaving only 1 potential purchaser.

Two significant events occurred before completing negotiations with the remaining potential purchaser that affected the marketability of MBPI. The first event was the termination of the contractual agreement with the pharmaceutical firm that had the right of first refusal in the event that MBPI was put up for sale. The second event was an announcement by the federal government of its intention to immunize 2.4 million military personnel against the anthrax bacteria. MBPI is the only producer of the anthrax vaccine licensed by the U.S. Food and Drug Administration. As a result of these events, the Commission passed Resolution No. 10 on January 2, 1998 to reopen the bidding process.

In January 1998, the selling agent contacted the potential purchasers previously identified to inform them of Resolution No. 10. In addition, the selling agent and the

Commission provided sale related information and access to MBPI to 14 new potential purchasers over the next several months. This included an offering memorandum and an opportunity to conduct on-site visits, interview MBPI management and other employees, and review documents in the bidders library and at MBPI. On May 1, 1998, the Commission gave notice that a completed asset purchase agreement (bid) was due by May 18, 1998. As of that date, two completed asset purchase agreements were submitted and the Commission began formal negotiations.

On June 2, 1998, the Commission announced its selection of BioPort Corporation as the recommended bidder. The Commission submitted its recommended asset purchase agreement with BioPort Corporation to the State Administrative Board's fairness opinion provider on June 12, 1998 and to the Board's Finance and Claims Committee on June 30, 1998 for consideration by the full Board at its July 7, 1998 scheduled meeting. The Board's approval will depend, in part, on the fairness opinion provider's evaluation of the "fairness" of the consideration. Board approval of the recommendation authorizes the Commission to execute the transfer of the assets and liabilities of MBPI to BioPort Corporation. The Commission will continue to allow any other potential purchaser the opportunity to enter the process and submit a bid for consideration until State Administrative Board approval.

OBJECTIVES AND CONCLUSIONS

We established the following objectives to evaluate the process used by the Commission to convey the assets and liabilities of MBPI. Our conclusion follows each objective.

Objective: To determine the Commission's compliance with the provisions of Act 522, P.A. 1996, as amended.

Conclusion: We determined that the Commission complied with the provisions of Act 522, P.A. 1996, as amended.

Objective: To determine the reasonableness of the Commission's process to convey the assets and liabilities of MBPI to a private enterprise.

Conclusion: We determined that the Commission's process was reasonable. The Commission's efforts were sufficient to attract potential bidders interested in purchasing MBPI. The Commission made relevant information available to all qualified bidders and the fairness opinion provider. The Commission used an appropriate process for evaluating bids and selecting a preferred asset purchase agreement (bid).

Glossary of Acronyms and Terms

asset purchase agreement	Contractual agreement defining the terms and conditions for the conveyance of assets and liabilities.
bidders library	A room maintained by the Commission that contains proprietary and other pertinent MBPI information that is available to potential purchasers to help them understand MBPI and its customers.
fairness opinion provider	A firm contracted by the State Administrative Board to render an independent opinion on whether the consideration recommended by the Commission for the assets and liabilities of MBPI is fair and adequate. This independent opinion is required by Act 522, P.A. 1996, as amended.
MBPI	Michigan Biologic Products Institute.

07-642-97

STATE OF MICHIGAN
DEPARTMENT OF ATTORNEY GENERAL

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P.O. BOX 30217
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JENNIFER MULHERN GRANHOLM
ATTORNEY GENERAL

February 24, 1999

Dennis Schornack
Senior Policy Advisory to the Governor
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Lansing, MI 48933

James K. Haveman, Jr., Director
Department of Community Health
Lewis Cass Building
320 South Walnut St.
Lansing, MI 48913

Mary Lannoye, Director
Budget and Financial Management
Department of Management and Budget
Lewis Cass Building,
320 S. Walnut
Lansing, MI 48909

Dear Mr. Schornack, Mr. Haveman and Ms. Lannoye:

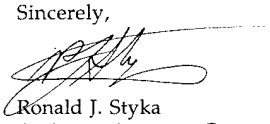
Re: *Lingg Brewer et al v BioPort, Inc. et al*
Court of Claims Case No. 98-17098-CM

Enclosed please find a copy of the Order Granting Defendants' Motions for Summary Disposition, which was signed by Judge Stell and entered with the clerk on February 18, 1999.

Under MCR 7.204(A), the Plaintiffs have 21 days, or until March 11, 1999, to

file a motion for rehearing or a claim of appeal in the Court of Appeals. If Plaintiffs do neither, the order will become final.

Sincerely,



Ronald J. Styka
Assistant Attorney General
Public Health Division
(517) 373-3488

RJS/dac
Enclosure
phdac/attys/rjs99/ltrSchornackHavemanLannoye

STATE OF MICHIGAN
COURT OF CLAIMS

LINGG BREWER, STATE REPRESENTATIVE, JAMES BALE, EDWARD SIMMER, ROY KLAVITER, THOMAS C. WALSH, LINDA FAUSEY and PHILIP BALLBACH,

Plaintiffs,

v

BIOPORT, INC. [sic, CORPORATION], a Michigan corporation, MICHIGAN BIOLOGIC PRODUCTS, INC., a Michigan corporation, MICHIGAN BIOLOGIC PRODUCTS COMMISSION of the MICHIGAN DEPARTMENT OF COMMUNITY HEALTH, a Michigan public body, ROBERT MYERS and ROBERT VAN RAVENSWAAY, jointly and severally,

Defendants.

HON. CAROLYN STELL

Case No. 17098-CM

FILED
1999 FEB 19 P 2:28
MIKE BRYANTON
COUNTY CLERK
INGHAM COUNTY
30TH CIRCUIT

ORDER GRANTING DEFENDANTS' MOTIONS FOR SUMMARY DISPOSITION

At a session of said Court held in the Court of Claims, City of Lansing, County of Ingham, State of Michigan, on the 18th day of February, 1999.

PRESENT: THE HONORABLE CAROLYN STELL, Court of Claims Judge

Defendants BioPort Corporation, Michigan Biologic Products, Inc., Robert Myers and Robert van Ravenswaay filed a motion for summary disposition. Defendant Michigan Biologic Products Commission of the Michigan Department of Community Health also filed a motion for

summary disposition. Plaintiffs filed a brief opposing the motions. Oral arguments were presented to the Court on February 12, 1999.

NOW, THEREFORE, for the reasons stated by the Court on the record at the February 12, 1999 hearing;

IT IS HEREBY ORDERED that Defendants' motions for summary disposition are GRANTED.

Carolyn Stell
HONORABLE CAROLYN STELL
Court of Claims Judge

APPROVED AS TO FORM:

(See attached Page 3)

Edwin M. Bladen (P10857)
Attorney for Plaintiffs

A TRUE COPY
CLERK OF THE COURT
30th JUDICIAL CIRCUIT COURT

Ronald G. Styka by WA Smith w/permission
Ronald J. Styka (P21117)
Todd H. Cohan (P26711)
Attorneys for Michigan Biologic Products Commission

Webb A. Smith
Webb A. Smith (P20718)
Jean G. Schtokal (P40531)
Stephen J. Rhodes (P40112)
Attorneys for Defendants BioPort Corporation, Michigan Biologic Products, Inc., Robert Myers and Robert van Ravenswaay

This Order prepared by:

Webb A. Smith
Foster, Swift, Collins & Smith, P.C.
313 S. Washington Square
Lansing, Michigan 48933
Telephone: (517) 371-8100

S:\158\PLEADING\SUM-MTN.ORD

summary disposition. Plaintiffs filed a brief opposing the motions. Oral arguments were presented to the Court on February 12, 1999.

NOW, THEREFORE, for the reasons stated by the Court on the record at the February 12, 1999 hearing;

IT IS HEREBY ORDERED that Defendants' motions for summary disposition are GRANTED.

HONORABLE CAROLYN STELL
Court of Claims Judge

APPROVED AS TO FORM:

Edwin M. Bladen 2/15/99
Edwin M. Bladen (P10857)
Attorney for Plaintiffs

Ronald J. Styka (P21117)
Todd H. Cohan (P26711)
Attorneys for Michigan Biologic Products Commission

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Jean G. Schtokal (P40531)
Stephen J. Rhodes (P40112)
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STATE OF MICHIGAN

30TH JUDICIAL CIRCUIT COURT (INGHAM COUNTY)

LINGG BREWER, State Representative,
JAMES BALE, EDWARD SIMMER, ROY KLAVITER,
THOMAS C. WALSH, LINDA FAUSEY and
PHILIP BALLACH,

Plaintiffs,

v. Docket No. 98-17098-CM

BIOPORT, INC. (sic, Corporation), a
Michigan corporation, MICHIGAN BIOLOGIC
PRODUCTS, INC., a Michigan corporation,
MICHIGAN BIOLOGIC PRODUCTS COMMISSION
OF THE MICHIGAN DEPARTMENT OF COMMUNITY
HEALTH, a Michigan public body,

Defendants.
_____/

VIDEO MOTIONS FOR SUMMARY DISPOSITION

BEFORE THE HONORABLE CAROLYN STELL, CIRCUIT COURT JUDGE

Lansing, Michigan - Friday, February 12, 1999

FILED
1999 APR -3 A 9:31
FILE COPY
CIRCUIT COURT
INGHAM COUNTY
30TH CIRCUIT COURT

APPEARANCES:

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For the Private Defendants:	MR. WEBB A. SMITH (P20718) 313 S. Washington Square Lansing, Michigan 48933-2193 (517) 371-8100
For Defendant Michigan Biologic Products Commission:	MR. RONALD J. STYKA (P21117) Assistant Attorney General P O Box 30217 Lansing, Michigan 48909 (517) 373-3488
Transcribed by:	Dolman Technologies Group, Inc. P.O. Box 26125 Lansing, Michigan 48909 (517) 393-1668

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WITNESSES:

None.

EXHIBITS:	IDENTIFIED	RECEIVED
None.		

Lansing, Michigan

Friday, February 12, 1999- 3:55 p.m.

THE COURT: This is the matter of Brewer versus Bioport, Docket No. 98-17098-CM. This is the time set for a hearing on Private Defendants' motion for summary disposition.

The Michigan Biologic Products Commission of the Michigan Department of Community Health has also filed a motion for summary disposition, which will be heard at this time.

Would counsel please identify themselves for the record?

MR. SMITH: Your Honor, Webb Smith, on behalf of the Private Defendants.

MR. STYKA: And Ronald Styka, Assistant Attorney General, here representing the Michigan Biological Products Commission.

MR. BLADEN: Edwin Bladen, on behalf of Plaintiffs, your Honor.

THE COURT: All right. Mr. Smith, are you going to begin or Mr. Styka?

MR. SMITH: I would be happy to, your Honor.

THE COURT: All right.

MR. SMITH: Your Honor, as we, we counsel, were sitting here a few minutes ago, a question came up of whether we needed to have oral argument in view of the extensive briefs that have been submitted to you. And in the spirit of our conversation, I will attempt to avoid simply reiterating

everything that we've already said to you.

Early in my venture into the legal system, I was impressed with the statement that there's something wonderful about our law in that there's a common logic thread that goes through everything. I must say, however, your Honor, that in viewing the Plaintiffs' case at this point, I have great difficulty in finding that common logical thread or the law to support their position.

It seems to me that the Plaintiffs here on the one hand are saying we're bringing this suit on behalf of the State, so we're suing the State because the State's elected officials, namely the Legislature and the executive branches of government, didn't do what we happen to want them to do.

Now, they're not seeking relief for themselves; they're not claiming injury or damage for themselves. They're just saying that in our judgment we don't like what you did, so we want to take something from the right hand and put it in the left hand or from the right pocket and put it into the left pocket, but it's still all the State. And that's where my logic breaks down.

And I asked myself what happened if another group of citizens happened to view this transaction that we're talking about and said that in their judgment this contract is the best thing since sliced bread. Would it be right then for that group to bring an action and the next group and the next

group? And I submit, your Honor, that that is the reason why we have a requirement of proper standing in order to bring an action in the first place.

The Attorney General has the right and the duty to represent the People of the State of Michigan. And here the Attorney General approved the sale, the transaction, as a member of the State Administrative Board, and the Attorney General did not sue on any basis against anyone under the Transfer Act, and the Attorney General now is here defending the Commission in this action. And the Commission, with State approval by the Administrative Board, is the one that made the sale.

So I suggest, your Honor, that what we really have is a situation where the Plaintiffs have lost a political battle, and they're now trying to inject the Court to solve the problem that they were unable in their judgment to solve on the political basis.

Let me say one thing, if I may, about Plaintiffs' characterization of the Commission as a nominal defendant at Page 1 of their brief. I suggest, your Honor, that this could be viewed and should be viewed as an admission that they really have no cause of action against the State.

While Michigan authority, in our research anyway, didn't reveal any clear definition of nominal defendant, federal law provides that there is no cause of action or claim against a

nominal defendant. A nominal defendant is a trustee, an agent, or a depository, who must be joined to facilitate collecting the funds. And there, the Court would order a nominal defendant to pay the funds over to one party or the other party, but the nominal defendant doesn't care who wins or who loses.

So when the Plaintiffs describe themselves in their brief or describe the Commission in their brief as a nominal defendant, I suggest that that's an admission that they have no cause of action against that Defendant.

We have argued quite extensively regarding the standing issue. Initially, we made allegations that the Plaintiffs lack standing to sue as taxpayers, as citizens, or as, in Mr. Brewer's case, as a representative.

The only issue that was responded to by the Plaintiffs was that--their right to sue as taxpayers. And I believe that the law is clear that they must allege a specific injury to themselves different than that of other taxpayers or other citizens. Excuse me.

I think it's also important to note, your Honor, that the Plaintiffs lack standing as taxpayers because they have not alleged in their complaint that there's any illegal expenditure of state funds, and that's an absolute necessity for them to do that.

Now, we raised this issue in our filings that were filed

a couple of months ago, and there's been no attempt to amend nor to add anything nor do I believe that in fact the Plaintiffs could amend or add anything in that regard. Because here, under these facts and these circumstances, there is no illegal expenditure of state funds.

So it's understandable why it wasn't alleged, but I think the Court really needs not to determine was there an expenditure, the base question is there's no allegation that there was an expenditure.

Furthermore, the Plaintiffs in their response claim that there is a violation of the Michigan Constitution of 1963, which prohibits the State from using its credit or to offer to guarantee debts or obligations of others. I suggest, your Honor, that the case of Allen v Wayne County, at 388 Michigan 210 makes it clear that the State may transfer something of value like the Michigan Biological Institute under these conditions, and may do that without violating the constitutional provision.

Furthermore, the allegation that the constitutional provision was violated has never been made by the Plaintiffs in this case. That's not a part of their original complaint.

And lastly on that issue, I submit that the finding of the State Administrative Board on July 7th of 1988 (sic) that indeed the statutory requirements were met and that the State Administrative Board determined that there was no impairment

of the State's credit, that that is conclusive, and that the Plaintiffs are barred at this point by the statute from pursuing any claim to the contrary.

The Plaintiffs in their papers also have indicated that they claim to have standing under Section 10 of the Transfer Act. And I suggest, your Honor, that that provision simply provides jurisdiction for the Court of Claims and a statute of limitations and has nothing to do with standing.

Your Honor, I believe that an analysis of the claims, the other claims, that the Plaintiffs are making in this case clearly indicate that we are entitled to the relief that we have requested. We have claimed that the Plaintiffs have no right to pursue or privately enforce a criminal statute. They've not responded to the contrary.

We further have claimed that they have no right to sue under the State Ethics Act. They've not responded to the contrary. I think those are clear.

The only one where they have responded has to do with the claimed violations under the Michigan Antitrust Reform Act. And I submit, your Honor, that the Plaintiffs cannot state an antitrust claim because the sale of the institute was specifically authorized by the state law, and we provided the law in our briefs for your Honor.

The Plaintiffs have suggested in their papers that there was no specific authority for the Defendants to combine or

conspire to rig bids. Well, first of all, there was no rigging of bids, but notwithstanding that, assuming that there were, that doesn't give the Plaintiffs a basis to challenge the State action in selling the institute to the highest bidder on terms and through methods that were authorized by the Transfer Act.

The Plaintiffs further have failed to allege any injury to their own business or property, and that is a fatal defect in their claim under the Michigan Antitrust Reform Act. And further, they have and cannot allege that they suffered any kind of antitrust injury itself.

Your Honor, for the numerous reasons, I would ask that the Court grant our motion for summary disposition.

THE COURT: Thank you very much.

MR. SMITH: Thank you.

THE COURT: Mr. Styka.

MR. STYKA: Good afternoon, your Honor. First, I have to say that I agree with every point made by Mr. Smith in his argument, and I will try not to repeat those and burden the Court with unnecessary statements and arguments.

But we need to look very carefully at this situation. There's a lot of allegations of conclusions in the pleadings, but very few allegations of fact. And as I understand motions of this type, they are decided based on the Court taking as fact well pled facts in the pleadings, but the Court is not

obligated to take into account mere conclusory statements that are made in the pleadings, such as there was bid rigging, without any factual statements to back it up.

We have a situation here where the State operated for many, many decades a laboratory that made pediatric vaccines primarily. In more recent times it started making an anthrax vaccine that's used exclusively by the Department of Defense at this time and in buildings that were built by the Works Progress Administration during the Great Depression.

These are buildings that the State has failed to maintain over the years. The vaccines were provided for the most part at cost or even below cost, for free in many cases. So the Legislature had to appropriate every year to keep these laboratories going, including last year. They didn't make money for the State.

And also, as other manufacturers came into existence making pediatric vaccines, improving on those vaccines from the kinds or types that were made by the State, started manufacturing rabies vaccine, everything but the anthrax, there became less and less reason for the State to make its own vaccines. There were competitors out there competing with each other, keeping the prices down according to the laws of supply and demand.

And except for the anthrax, which again is used currently and has been in the past exclusively by the Department of

Defense, which more or less sets the price, there was no real reason for the State to be in this business anymore. It was becoming more and more difficult for the State to be in this business, as these buildings became less and less operational. Roughly a year and a half, almost two years ago, the licensing authority, the FDA, came in and almost took away the licenses of these facilities because of their condition.

So the Governor issued in February 1996 an executive order creating the Michigan Biologic Products Commission, my client in this case, to oversee the operations of these labs, which he then turned into a two-year temporary agency called the Michigan Biologic Products Institute, and also to go ahead with the processes that would move the laboratories from the State to private enterprise in the hopes that the jobs, et cetera, would stay here in Michigan and these vaccines would continue to be produced as a benefit to our economy.

That became law by virtue of the Transfer Act that's been referenced on January of 1997, which reiterated and adopted the terms the Governor had put in his executive order.

As you have heard, through a long process that is related somewhat in the pleadings but definitely in our responsive brief, there was in fact a recommendation by the Michigan Biologic Products Commission pursuant to the Act, pursuant to the law, on June 2nd, 1998, a recommendation to the State Administrative Board to have Bioport purchase or rather have

the State sell to Bioport these vaccine laboratories.

And in fact, as has been alleged, some State employees, namely some of the higher echelon State workers who helped run these laboratories, who are experts in producing these vaccines, were minor shareholders in this enterprise. But this was again authorized by the Legislature in the Transfer Act. They contemplated that it would be nice if these workers could keep their jobs even after the project went out of state government and that they could continue contributing to the economy of this state.

The State Administrative Board on July 7 of '98 took action, which is attached to my brief, and adopted that recommendation and, in fact, at that time took the legal action that was needed to transfer these laboratories to Bioport.

Now, the paperwork didn't get done till September, but the reality is that the agencies that had to act, the Commission acted on June 2nd and the Ad Board acted on July 7th. And in the Transfer Act, because the Legislature, we think, from the terms of this statute, realized that if you're going to transfer an enterprise out of state government, it can't be bouncing back and forth in and out of state government. When you're in state government, you need appropriations, you need civil servants to work there, et cetera, gave a 60-day period of limitation for the filing of

lawsuits vis-a-vis this transaction.

And in that Section 10(2), it didn't reference closing dates or contract dates; it referenced the dates that the official actions were taken by either or both the Michigan Biologic Products Commission or the State Administrative Board. And those dates I've just mentioned to your Honor.

This lawsuit was filed almost two months after the last of those two dates, and I would submit the first of those dates is probably the pertinent one, the recommendation of the Commission.

When we look at the allegations that are in the complaint, vis-a-vis my client, the Commission, the only real allegations there that pertain to the Commission are that they breached their duty when they chose Bioport, to recommend Bioport to the State Administrative Board. That occurred in June of '98.

And therefore, our first argument here, which was not raised by Mr. Smith, is that in fact there's a specific statute of limitations that is grounded in a specific event, which is sometimes done by the Legislature, that has been violated here in terms of this action. This action was barred and therefore should be dismissed.

Our second argument, as your Honor knows, is the standing arguments that Mr. Webb Smith has made. It is very clear that there is no standing here for these Plaintiffs to come forward

on the taxpayer issues, which Mr. Smith had mentioned. And there is really no other allegations in the complaint for which they have standing.

With regard to this alleged breached duty in Count I of my client, they only make conclusions; they make no factual allegations. There were two bidders; that's a fact. The higher bidder was chosen; that's a fact. I don't think they deny either of those. And in light of that, how could there be a breached duty?

The statutory requirements were such that this whole process was overlooked from so many points of view that it's probably the most watched over transaction in the history of this state. We not only have this independent commission which was working with a selling agent, which was a investment banking firm that was hired through the bidding process that the Department of Management and Budget requires, but there also was another independent banking institution, which had the job--and it was hired through a bidding process through Department of Management and Budget--which worked for a different agency, namely the State Administrative Board, which overlooked the transaction.

The Auditor General was required to overlook the whole process that was involved, which is I think what's really being alleged in the Count I, is that the process was somehow wrong. And the Auditor General had people at the meetings

looking at all the documents, and all of these various organizations--oh, and also, the State House and Senate fiscal agencies were overlooking the shoulders of the independent opinion provider who was overlooking the shoulders of the Commission. I mean, this was the most watched over transaction I have ever heard of. And they all found that, first, the compensation here for the complex was adequate and that the process was proper. They found no violations.

The Attorney General was involved as legal counsel in these matters from the beginning. We had a committee of five Assistant Attorneys General who were involved in this transaction from five different disciplines within the office, which I chaired, and we were all involved in this process.

And we have here some allegations from some taxpayers and one state representative, who I assume is also a taxpayer, I hope so, who claim that something bad happened that none of us saw, none of these agencies saw.

Your Honor, certainly this matter is--there is no standing for these people to come forward. Mr. Smith related to you some of the statutory and case law bases for that. The Menendez case is probably the bulwark from which all the other cases come.

And that case, which is Menendez v City of Detroit, 337 Michigan 400--let's see, 476, just like here, some taxpayers tried to block through the court system a situation where some

bonds were going to be issued, but they were going to be paid for out of another fund, mainly parking meter money, and the taxpayer wasn't going to be directly affected, just like here, and the court said, quote:

> "In each of these cases"--and that's after citing a whole series of cases dealing with taxpayer suits--"it is clearly recognized that prerequisite to a taxpayer's right to maintain a suit of this character against a unit of government, is the threat that he will sustain substantial injury or suffer loss or damage as a taxpayer through increased taxation and the consequences thereof. This is uniformly true of all the Michigan cases considering this subject."

And, your Honor, I don't see how these Plaintiffs have any standing to attack this particular transaction. At best, what they're saying is that some more money should have gotten--should have been obtained in the selling price, at best.

Well, does that increase their taxes? No. It may somehow indirectly perhaps, speculatively, decrease their taxes, but the case law has said that's not enough; that is not a tax--sufficient for a taxpayer case.

And we would say, your Honor, that, first, this matter is barred by the statute of limitations; and, secondly, it should be dismissed for lack of standing.

Finally, your Honor, they didn't state a claim, and I think Mr. Smith alluded to this as well. They failed to state a claim with regard to the so-called breached duty when we have two bidders bidding right to the eleventh hour and the highest bidder getting the award. They failed to state a claim with regard to antitrust for two reasons, especially with regard to my client.

First, under Section 4(3) of the Michigan Antitrust Regulatory Act, the Act shall not invalidate actions of the unit of government when it is authorized by law to so act. And that's what we have here, your Honor, a situation where under the Transfer Act, the Commission and the Ad Board were authorized to act and they then acted in accordance with those statutes. And so under that, there is no statement of a claim here with regard to antitrust.

Secondly, under Section 4(4) of the Michigan Antitrust Regulatory Act, it states that the Act does not apply to transactions which are authorized by law. And, again, this is a basis for finding no statement of a claim.

So on these three bases, we would ask your Honor to dismiss this case for being barred, for lack of standing, and for failing to state a claim.

THE COURT: Thank you very much. Mr. Bladen.

MR. BLADEN: Your Honor, I think I agree; a lot of oral argument, I think, is unnecessary, but I need to make six

points very quickly.

As you well know, this is not a 2.116(C)(10) motion. This is a (C)(7) and (C)(8) motion. And, therefore, the allegations alleged by us are to be taken as true for purposes of this motion.

In that respect, both the Defendant Counsel suggest there is an absence of facts that support the allegations in this case or that they disagree with the facts or that somehow the facts don't measure up to the kind of claim that ought to be heard by the Court.

I submit that we have to take those facts, and let me very briefly with respect to two points in the case point to the facts, because I've done this in the brief as well, but I wish to remind the Court of them.

Let's talk about illegal expenditure of funds. We specifically alleged there's a four and a half million dollar advance of state funds to Bioport at no interest. We contend that's improper, and we go through and describe later what the allegations are.

Now, that happens to have been buttressed by a constitutional provision, which we cite in our brief, saying that they can't advance the credit of the state to private parties. And it's a two-way street under that constitutional provision.

They also say that we have not alleged any injury to the

consumers, if you will, who are the Plaintiffs in this case, in the Michigan Antitrust Reform Act claim. I submit if you look at Paragraph 48 of the--along with the previous first 28 paragraphs of the fact recitations--you'll find that very injury allegation.

What the result is, the facts are well pled and the like. The question isn't one of presumably of law. If it's (C)(8), is do they as a matter of law fail to allege something that we, given an appropriate effort, could prove to be the case. And the answer is, they do. And not only that, the recitation of the law by the Defendants is simply wrong. They leave out crucial statutory provisions in an effort to extricate themselves from this case.

Give you a couple--and I've led them in the brief, but give you a couple examples. First of all, Michigan is one of the few states that adopted a law, not all the states have, that reversed a US Supreme Court decision called Illinois Brick. It's State of Illinois against Illinois Brick Company.

The decision is famous for its provision that says that a consumer does not have standing under Section 4 of the United States Clayton Act to sue under federal antitrust laws if they are an indirect purchaser; they did not buy or deal directly with the wrongdoer.

In that case, the State of Illinois bought a building from a general contractor, and the bricks that went in to make

up the building, the prices were fixed. They were an indirect purchaser.

We've alleged that the Michigan consumers here are indirect purchasers because they buy these biologic products, the prices of which have been affected by the wrongdoing of the parties here, and that they will likely be overcharged, even though they don't deal directly with the institute. They don't have to deal directly with the institute. The consumer deals with their druggist or they deal with their physician. The fact that they pay for something that got to them from the Biologic Products Institute is enough.

With respect to the same notions about immunity, yes, the Biologic Product Commission is essentially a nominal defendant. They are immunized under the Michigan Antitrust Reform Act, particularly Section 4(3). Mr. Styka cited the statute correctly. But that's only as to the governmental entity, not as to the private parties, which if they enjoy any immunity at all, it's under Section 4(4).

And I laid out here the origin of Section 4(4) and what its intention was and the fact that the Michigan Supreme Court has already construed identical language in the Michigan Consumer Protection Act from where we drew in the Michigan Antitrust Reform Act Section 4(4) and held that in Diamond Mortgage case that just because you're licensed as a real estate broker in that case, doesn't authorize you specifically

to engage in deceptive trade practices.

And that's the same thing here. Just because you have a right to buy or engage in a bidding practice or that the institute commission had a right to sell, the institute didn't authorize you to engage in an antitrust violation.

Now, in order to effectuate the remedy under the Antitrust Reform Act, which involves divestiture and equitable remedy, the Commission has to be a party. Not only that, we assert that they're a co-conspirator anyway.

They facilitated the wrongdoing, the consequence of which is that when the institute was actually sold on September 4 of 1998 by the State Ad Board, that is the commencement of the time period which runs for the statute of limitation purposes. Because the statute itself is plain. We cite on Page 8 of our brief the statute, which says: "We filed within the Court of Claims within 60 days after the action that is the subject of the suit is taken." The subject of the suit is the sale of the institute.

THE COURT: Well, you kind of left out the first part of that paren 2.

MR. BLADEN: I'm sorry.

THE COURT: It says: "The validity of the proceedings of or the determinations made by the State Administrative Board or the Commission under this act." And then it says "within 60 days after the action."

MR. BLADEN: Right. And the subject of the suit is the sale by the Board. That's a determination or proceeding by the Board, which was on September 4, 1998, is when the sale took place. The fact that they may have approved it earlier or entered into negotiations earlier is not the ultimate transaction which is the actual sale and the signing of the contracts and so forth. That was done on September 4, 1998, and we filed well within the 60-day time period after September 1998. Indeed, I believe the filing date--

THE COURT: Was October 27th.

MR. BLADEN: Is October 27, 1998.

Now, if you have any questions, I'll be glad to answer them. Otherwise, I'm--I appreciate the opportunity.

THE COURT: Thank you very much.

Did you wish to respond, Mr. Smith?

MR. SMITH: Just a couple of things, your Honor. I don't believe that each point needs to be responded to because I think we've covered most of it in our brief.

But I would simply indicate to the Court on the jurisdiction question in terms of the nominal Defendant, I think that the statute, Section 10 of the Transfer Act, is pretty clear, where the Legislature said that the Court of Claims has exclusive jurisdiction over a claim asserted against the State.

Now, if the position is that we really are just making

them a defendant because we need them as a nominal defendant, then that's not making a claim against the State. And I suggest that that is not an answer to the issue that has been raised and does not defeat or should not defeat our request for summary disposition.

THE COURT: Mr. Styka, anything further?

MR. STYKA: Two points, I think, just require quick mention, your Honor. First, the lending of credit is a red herring; it was never pled anywhere in the pleadings. First time it ever came up was in the brief. And, secondly, it's-- still on the first point, though. And, secondly, it just isn't the case, but that would be a factual argument. The fact is, he never pled it.

Secondly, I think your Honor was correct in pointing out we have to read the entire Section 10(2) with regard to the issue of whether or not there's a bar by limitations. The statute, I think, speaks for itself when you read the entire section and not isolate one sentence. Thank you.

THE COURT: Thank you. I'll have a decision for you in just a few minutes.

First, I would thank counsel for your briefs as well as for your oral argument. I do appreciate the fact that you did not reiterate each and every argument in your brief, however.

The first issue the Court will address is whether or not these Plaintiffs have standing to bring the suit. The Private

Defendants argue that the Plaintiffs lack standing as citizens because they have no substantial interest that will be affected in a manner different from the public at large.

In House Speaker v State Administrative Board, 441 Michigan 547 at 554 (1993), the Supreme Court stated, quote:

> "Standing is a legal term used to denote the existence of a party's interest in the outcome of litigation that will insure sincere and vigorous advocacy. However, evidence that a party will engage in full and vigorous advocacy by itself is insufficient to establish standing. Standing requires a demonstration that the plaintiff's substantial interest will be detrimentally affected in a manner different from the citizenry at large." End of quote.

In Colleen (phonetically) v Wayne County Civil Service Commission, 108 Mich App 14 (1981), which is referred to as Colleen 1, the court further noted, quote:

> "The plaintiff has failed to set forth in the complaint any allegations whereby his rights as a private person have been interfered with in a manner distinct from the public at large. Absent such allegations, a private person has no standing to institute proceedings to redress grievances on behalf of the public at large. Public grievances must be brought into court by public agents and not by private intervention." End of quote.

Similarly, in Saginaw Firefighters Association v Civil Service Commission, 71 Mich App 240 at 244 (1976), the court said, quote:

"Only in cases where individual grievances are distinct from other members of the public may a private citizen proceed to judicial relief. Otherwise, the task falls to those who have been specifically charged with the duty of interference." End of quote.

The Attorney General is the person who is designated to bring suit on behalf of the citizens of the State of Michigan. In this case, the Attorney General reviewed the sale of the institute as a member of the State Administrative Board, approved the sale, and has declined to bring suit on behalf of the citizens of the State of Michigan.

The Plaintiffs have failed to demonstrate or allege that they have any interest which is different from all the citizens of Michigan. In fact, they repeatedly allege that the interest of all of the citizens of Michigan are involved in the sale of the institute. See specifically Paragraph 7, 8, 44, 48, and 50 of the complaint.

Therefore, to the extent that Plaintiffs are relying as-- for standing simply on their standing as citizens, the Court grants summary disposition pursuant to MCR 2.116(C)(5).

The Plaintiffs have cited MCR 2.201(B)(4)(b), which

provides in part an action to prevent illegal expenditure of state funds or to test the constitutionality of a statute relating to such an expenditure may be brought in the names of at least five residents of Michigan who own property assessed for direct taxation by the county where they reside.

MCL 600.2041(3) also provides, quote:

"An action to prevent the illegal expenditure of state funds may be brought in the names of at least five residents of this state who own property assessed for direct taxation by the county wherein they reside."

Colleen 1, however, at Page 18 also says that the taxpayer must allege with particularity how the alleged illegal act will result in injury through "increased taxation," end of quote.

The Plaintiffs' argument that they have standing as taxpayers is flawed by the fact that these expenditures were authorized by the Transfer Act. This complaint does not allege any illegal expenditure of state funds as required by the statute.

The complaint also does not allege any injury resulting in increased taxation from the sale of the institute. What they allege are possible increased costs which may be borne by the citizens of Michigan. That is insufficient.

To the extent Plaintiffs rely on their status as taxpayers, the Court grants summary disposition pursuant to

MCR 2.116(C)(5).

Finally, if Representative Brewer is claiming standing as a state representative, the court in House Speaker v State Administrative Board, which I cited previously at Page 555 indicated that a legislator must overcome a heavy burden to establish standing. Specifically the court said, quote:

> "It would be imprudent and violative of the doctrine of separation of powers to confer standing upon a legislator simply for failing in the political process. For these reasons, plaintiffs who sue as legislators must assert more than a generalized grievance that the law is not being followed. Instead, they must establish that they have been deprived of a personally and legally cognizable interest peculiar to them." End of quote. And I omitted the interior citations.

A legislator may not sue merely to reverse the outcome of a political battle that he has lost.

In the case at bar, Representative Brewer fully and actively participated in the legislative process involving the sale of the institute. Unfortunately, he was not able to persuade a majority of his colleagues to his point of view. To the extent that Plaintiffs rely upon Lingg Brewer's standing as a state representative, the Court grants summary disposition pursuant to MCR 2.116(C)(5).

The motion pursuant to MCR 2.116(C)(8) with its reference

to the Michigan Antitrust Reform Act relies on the argument that the Antitrust Reform Act does not apply because this sale was specifically authorized by law.

Defendants cite MCL 445.774(4) which provides, quote:

> "This act shall not apply to a transaction or conduct specifically authorized under the laws of this state or the United States or specifically authorized under laws, rules, regulations or orders administered, promulgated or issued by a regulatory agency, board or officer acting under statutory authority of this state or the United States." End of quote.

The Transfer Act specifically authorized the sale to a private defendant. The Transfer Act gave the Commission broad power over the sale process.

The Plaintiffs have not suffered an injury to their business or property. The only allegations of injury contained in the complaint are conclusory and rely on their standing as citizen taxpayers. Plaintiffs did not own the institute nor the property upon which the institute sits.

Finally, the Plaintiffs have failed to allege an antitrust injury. In other words, an antitrust injury generally consists of injury caused by higher prices, reduced output or damage to a competitor's business. The injured party must be a participant in the same market as the alleged malefactors.

The Court grants summary disposition with respect to the MARA claim under MCR 2.116(C)(8). And I realize some of these are duplicative. I'm more or less ruling in the alternative.

With respect to the statute of limitations argument, I believe that I've already cited, as has Mr. Bladen, Section 10 of the Transfer Act. And the issue is really an interpretation of law. There's no dispute as to the dates, that it was July 2nd, 1998 when the Commission at a duly noticed special meeting determined to recommend to the State Administrative Board the sale of MBPI to Bioport.

On Sept--I'm sorry, yes, September 4th, 1998, the actual closing occurred. So if the triggering event was the July 2nd date, the statute of limitations provides that this suit is untimely. If the triggering event was the actual closing, then the suit was timely filed.

It is standard interpretation that the Legislature must be presumed to have intended the plain meaning of the words used in the statute and that when meaning of words is clear and unambiguous, judicial construction or interpretation which changes that meaning is not permitted. Arregos Fleet Service, Inc. v State of Michigan Department of State, Bureau of Automotive Regulation, 125 Mich App 790 (1983).

And in Section 10, after providing for jurisdiction in the Court of Claims, the statute says, quote:

"The validity of the proceedings of or the

determinations made by the State Administrative Board or the Commission under this act are conclusive if not challenged by filing suit with the Court of Claims within 60 days after the action that is the subject of the suit is taken."

I think the plain language clearly means that the action that is going to be the subject of the suit must be the action of a decision or determination made by the State Administrative Board or the Commission.

Therefore, in the alterative, the Court grants summary disposition pursuant to MCR 2.116(C)(7).

I realize that I did not address each and every argument made, but I think I've addressed a sufficient number.

Your order to prepare, which one of you? Or do you want to each prepare your own order?

MR. SMITH: Your Honor, I'll do it, whatever the Court's pleasure. We'll be happy to prepare one that would dismiss or grant both motions?

THE COURT: That would be fine. Just remember how peculiar I am. I want you just to say for the reasons stated on the record. Cite the subsection, but don't summarize my argument.

MR. BLADEN: And if I might add, your Honor, you're well aware that I may not be around to look at it.

THE COURT: Have you explained that to counsel?

MR. BLADEN: I don't know how soon you can do this.

MR. SMITH: Your Honor, I can have it done tomorrow.

MR. BLADEN: That's fine with me.

THE COURT: Okay. Thank you.

MR. SMITH: You are going to be around that long, aren't you?

MR. BLADEN: Oh, I'll be around that long. I just don't, you know...

THE COURT: Okay. You explained to your fellow counsel the--

MR. SMITH: Yes.

MR. BLADEN: They're aware--

MR. STYKA: He has; he has, your Honor.

MR. BLADEN: --of the situation.

THE COURT: Thank you very much. And, again, if you need an order, let me know.

MR. SMITH: Okay.

MR. STYKA: And just to polish it off, I agree Mr. Smith can prepare the order. I'll take a look at his language.

THE COURT: Thank you very much.

MR. SMITH: Thank you, your Honor.

THE COURT: You're welcome.

MR. STYKA: Thank you.

(At 4:49 p.m., proceedings concluded)

Tape 1, 2-12-99 16:49:36

CERTIFICATE OF REPORTER

(STATE OF MICHIGAN)
(SS)
(COUNTY OF INGHAM)

I hereby certify that this transcript represents the complete, true and correct rendition of the videotape of the proceedings as recorded.

I further state that I assume no responsibility for any events that occurred during the above proceedings or any inaudible responses by any party or parties that are not discernible on the video of the proceedings.

Dated: April 1, 1999

Charna L. Welch

Charna L. Welch, CER-5973

STATE OF MICHIGAN

BOARD OF ETHICS

98-ED-2

In re: Lingg Brewer,
Complainant

v

Robert Myers and
Robert vanRavenswaay,
Respondents

ORDER

Representative Lingg Brewer filed a complaint alleging that events and circumstances occurred during the sale of the Michigan Biological Products Institute to the Michigan Biological Products, Inc. (MBP, Inc.), which violated section 2(5) and section 2(7) of the State Ethics Act, 1973 PA 196, MCL 15.341 et seq.; MSA 4.1700(71) et seq. Representative Brewer contended that the Respondents, Mr. Robert Myers and Dr. Robert vanRavenswaay, engaged in a business transaction for personal or financial gain and participated in the execution or negotiation of contracts related to a business entity in which they had a personal or financial interest.

The Board met on August 14, 1998, and reconvened on November 12, 1998, in the Capitol Commons Center, Lansing, Michigan, to consider the allegations contained in the complaint.

Findings of Fact

The Michigan Biological Products (Institute) was part of the Department of Community Health. The Institute manufactures vaccine and blood products. The Michigan

Legislature passed the Michigan Biological Products Institute Transfer Act (Act), PA 522 of 1996, which authorized the sale of the Institute. Section 7(1) of the Act provides that an employee group may bid on the facility. Section 7(2) of the Act exempts Institute employees from certain conduct if specific criteria are met:

> (1) An employee of the institute or a group composed in whole or in part of employees of the institute may bid on or make a proposal to acquire the assets and enter into 1 or more agreements related to the conveyance of all or a portion of the assets to the employee or group.
>
> (2) When acting with the knowledge or upon the direction of the commission or in entering into an agreement to accept employment with a potential acquirer of the assets, *an employee of the institute shall not be considered to have violated* Act No. 196 of the Public Acts of 1973, being sections 15.341 to 15.348 of the Michigan compiled Laws [state ethics act], *if the employee provided written notice to the commission of the proposed employment agreement and the terms of that agreement before its execution*. (emphasis added).

Respondents and a group of employees formed MBP, Inc. to purchase and operate the facility. Their bid was not successful. MBP, Inc. later entered into a partnership with BioPort. MBP, Inc. became a 32 percent owner of BioPort. Their bid of $25,000,000 was successful.

The Michigan Biologic Products Commission, chaired by Dennis Schornack, was established by Executive Order 1995-25 to sell or privatize the Institute. Mr. Schornack described the selling process and the large number of safeguards enacted to guard against any improbity. The sale took nearly two years to close. Every step of the sale was examined and reviewed by independent entities, both private and public, such as Peat Marwick, First of Michigan, the Attorney General's office, Miller Canfield, the Michigan Biologic Products Commission and the State Administrative Board. Mr. Schornack testified that Respondents had made their disclosure as required by statute.

The Institute had at least two valuations performed. First of Michigan Corporation indicated the Institute had no value, and possibly a negative value, due to needed

improvements. Peat Marwick later valued the Institute in a range from a nominal value to $10,500,000.

Representative Brewer complained that he filed a lawsuit against the state for failure to disclose documents under the Freedom of Information Act (FOIA). The FOIA request at issue was made to the State, not to Respondents. After the Institute sale was complete, all documents related to the sale were available in unredacted form.

Representative Brewer questioned the selling price of the Institute at $25,000,000 when there was a $130 million Department of Defense contract awarded to the Institute prior to the sale, according to a press release. Respondents explained the $130 million was the amount appropriated from the Department of Defense's budget. It included production, labeling, packaging and shipping of the vaccine. There was no contract for $130 million with the Institute.

Conclusion

Representative Brewer had the burden of proving, by a preponderance of the evidence, that the alleged unethical conduct has occurred, or is occurring, R 15.7(3). The Board of Ethics considered all the documents submitted, the testimony of the parties and/or their representatives, and the testimony of any witnesses presented by the parties. (See, R 15.7; In re: Havis v Fishman, 84-ED-3, at 2, 1984). In light of the evidence presented, which revealed no use of confidential information by Respondents prior to or during the sale of the Institute's assets, no violation of section 2(5) or section 2(7) exists. In addition, it is apparent that Respondents complied with section 7(2) of the Act by serving written notice to the Commission of their interest in MBP, Inc. and BioPort. Accordingly,

IT IS ORDERED that the complaint is dismissed as probable cause does not exist due to an absence of any evidentiary facts to support the allegations contained in the

complaint that a violation of the State Ethics Act, 1973 PA 196, MCL 15.341 et seq;, MSA 4.1700(71) et seq, has occurred, or is occurring.

Members of the Board Participating:

Christopher M. Murray, Chairperson
Robert A. Jamera
Thomas Kern
Reverend Bernard O'Connor
Lita Masini Popke

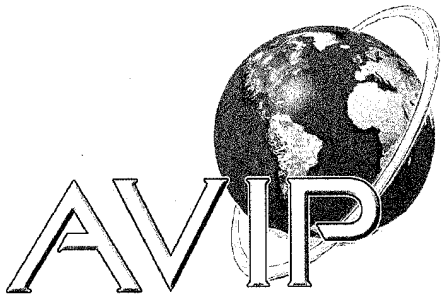
Absent:

Julie Creal Goodridge
John D. Pirich

By Order of the Board

Theodore J. Bened, Executive Secretary

Dated: Feb 26, 1999



Department of Defense
Anthrax Vaccine
Immunization Program

"Questions for the Record"

"The Anthrax Vaccine Immunization Program - What Have We Learned? Part II"

11 October 2000

Committee on Government Reform

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Q: Is this an experimental vaccine?

A: No. Anthrax vaccine has been FDA approved since 1970 (MBPI Establishment License No. 99).

Q: Is this vaccine safe?

A: Yes, this vaccine has been safely and routinely administered in the U. S. to veterinarians, laboratory workers, and livestock handlers since 1970. No reports of serious adverse effects have been received by the manufaccurer, Michigan Biologic Products Institute.

Q: What if I am pregnant?

A: Pregnant women should not receive this vaccine. If you are or believe that you may be pregnant, you should inform your health care provider. The vaccination program will be deferred until the pregnancy is complete.

Q: What other medical conditions should I inform the medical staff about?

A: If you have an active infection or are taking a prescription medicine, inform your health care provider before taking this shot.

Q: The anthrax vaccine was administered to personnel deployed in the Gulf War. Has the anthrax vaccine been linked to illnesses among Gulf War veterans?

A: No. Several national scientific groups, including the National Academy of Sciences, have addressed this issue and found no evidence to link anthrax vaccine with illnesses among Gulf War veterans.

Q: How many shots will I have to take?

A: Six shots, three given two weeks apart followed by three additional injections given at 6, 12 and 18 months. An annual booster shot is required to maintain ongoing immunity.

Q: What are the side effects?

A: As with other vaccinations, pain may occur at the site of injection. Temporary side effects (sore arm, redness, and slight swelling) may occur. The vaccine has been in use since 1970 with no known long term side effects.

Q: Am I required to take the vaccine?

A: Yes. This program will be treated like any other vaccine that is required to prepare you for deployment. You will be required to take it unless medically deferred.

Q: How can I get more information about anthrax vaccine?

A: Your commander or supporting medical facility. In addition, more information on the anthrax vaccine can be accessed at the website:

http://www.defenselink.mil/other_info/protection.html#Anthrax

WHAT EVERY SERVICE MEMBER NEEDS TO KNOW ABOUT THE ANTHRAX VACCINE



Anthrax is a highly lethal biological weapon.

"Vaccination against anthrax is a safe, prudent force protection measure."

William S. Cohen
Secretary of Defense

1071

WHAT IS THE THREAT?

Biological weapons are maintained by several countries around the world. Use of these weapons could cause widespread illness among unprotected military forces.

Anthrax is the biological weapon most likely to be encountered because it is:

- Highly lethal
- Easy to produce in large quantities
- Relatively easy to develop as a weapon
- Easily spread over a large area
- Easily stored and dangerous for a long time

WHAT IS ANTHRAX?

Anthrax is a disease normally associated with plant-eating animals (sheep, goats, cattle, and to a lesser degree swine). It is caused by the bacteria *Bacillus anthracis*. Once common where livestock were raised, it is now controlled through animal vaccination programs. Anthrax still occurs in countries where animals are not vaccinated, mainly in Africa and Asia. It does occur infrequently in many countries, including the United States.

Human infection with anthrax usually results from direct contact with infected animals, or animal products such as wool, meat or hides. However, when anthrax is used as a biological weapon, people become infected by breathing anthrax that is released into the air.

Inhalation anthrax is the disease that results from breathing anthrax.

Symptoms of inhalation anthrax can begin as early as 24 hours after breathing the spores. Initial symptoms include: fever, cough, and weakness and usually progress to breathing problems, shock, and death.

WHY VACCINATE?

Vaccines prevent illness by stimulating the body's natural disease-fighting abilities. They are among the most powerful tools developed by modern medicine for keeping people healthy. Vaccines are routinely used in the United States to protect against diseases such as mumps, measles, whooping cough, and polio. As part of force protection, military personnel are given additional vaccines to protect against naturally occurring diseases encountered when deploying overseas, such as typhoid, hepatitis, and yellow fever. Vaccines also help protect against biological weapons.

The Department of Defense has established a vaccination program to protect military personnel against anthrax.

WHAT IS THE ANTHRAX VACCINE?

Anthrax vaccine is a sterile product made from filtrates of cultures of a strain of the anthrax organism that does not cause disease. The vaccine contains no living or dead anthrax organisms. The anthrax vaccine is not new. Human anthrax vaccines were developed in England and the U.S. in the 1950s and early 1960s. The anthrax vaccine you will receive was licensed by the FDA in 1970 and has been manufactured by the Michigan Biologic Products Institute (MBPI) under Establishment License No. 99.

It has been safely and routinely administered in the United States to veterinarians, laboratory workers, and livestock handlers for more than twenty-five years.

FACTS ABOUT THE ANTHRAX VACCINE

- Vaccination is a critical part of protection against infection
- Manufactured in the United States
- Safely used for more than 25 years
- As with other vaccinations, pain may occur at the site of injection
- Temporary side effects (sore arm, redness, and slight swelling) may occur
- No known long term side effects
- Six shots are required over 18 months, followed by an annual booster

COMMONLY ASKED QUESTIONS & ANSWERS

Q: Why are we getting this vaccine?

A: Anthrax is a lethal weapon we may encounter. Vaccination before exposure is a critical part of our protection against this weapon.

Q: Is the vaccine all I need to protect against inhalation anthrax?

A: Being fully vaccinated greatly increases your chances of surviving an exposure to anthrax. Your chances are further improved by other measures, especially proper use of the protective mask.

Q: Is this vaccine safe?
A: Yes, this vaccine has been safely and routinely administered in the U. S. to veterinarians, laboratory workers, and livestock handlers since 1970. No reports of serious adverse effects have been received by the manufacturer, the Michigan Biologic Products Institute.

Q: Is there anyone who should not receive the vaccine?
A: Anthrax vaccine should be administered only to healthy men and women from 18-65 years of age because investigations to date have been conducted exclusively in that population.

Q: What about pregnancy?
A: Pregnant service members will not receive the vaccine. The vaccination series will be deferred until the pregnancy is complete. There also is no scientific evidence to suggest that future pregnancies by service members or their spouses will be affected by the use of this vaccine.

Q: What other medical conditions could affect the use of this vaccine?
A: If a person has an active infection or is taking some prescription medications, a decision to give the vaccine will be made on a case by case basis.

Q: The anthrax vaccine was administered to personnel deployed in the Gulf War. Has the anthrax vaccine been linked to illnesses among Gulf War veterans?
A: No. Several national scientific groups, including the National Academy of Sciences, have addressed this issue and have found no evidence to link anthrax vaccine with illnesses among Gulf War veterans.

Q: How many shots will be given?
A: Six shots, three given two weeks apart followed by three additional injections given at 6, 12 and 18 months. An annual booster shot is required to maintain ongoing immunity.

Q: What are the side effects?
A: As with other vaccinations, pain may occur at the site of injection. Temporary side effects (sore arm, redness, and slight swelling) may occur. The vaccine has been in use since 1970 with no known long term side effects.

Q: How can I get more information about anthrax vaccine?
A: Information can be obtained from your local command or supporting medical facility. In addition, more information on the anthrax vaccine can be accessed at the website:

http://www.defenselink.mil/other_info/protection.html#Anthrax

- **Anthrax is a threat!**
- **A safe vaccine is available!**
- **U.S. Forces can be protected!**

WHAT EVERY FAMILY MEMBER NEEDS TO KNOW ABOUT THE ANTHRAX VACCINE



Anthrax is a highly lethal biological weapon.

"Vaccination against anthrax is a safe, prudent force protection measure."

William S. Cohen
Secretary of Defense

WHAT IS THE THREAT?

Biological weapons are maintained by several countries around the world. Use of these weapons could cause widespread illness among unprotected personnel.

Anthrax is the biological weapon most likely to be encountered because it is:

- Highly lethal.
- Easy to produce in large quantities
- Relatively easy to develop as a weapon
- Easily spread over a large area
- Easily stored and dangerous for a long time

WHAT IS ANTHRAX?

Anthrax is a disease normally associated with plant-eating animals (sheep, goats, cattle, and to a lesser degree swine). It is caused by the bacteria *Bacillus anthracis*. Once common where livestock were raised, it is now controlled through animal vaccination programs. Anthrax still occurs in countries where animals are not vaccinated, mainly in Africa and Asia. It does occur infrequently in many countries, including the United States.

Human infection with anthrax usually results from direct contact with infected animals, or animal products such as wool, meat or hides. However, when anthrax is used as a biological weapon, people become infected by breathing anthrax that is released into the air. Inhalation anthrax is the disease that results from breathing anthrax.

Symptoms of inhalation anthrax can begin as early as 24 hours after breathing the spores. Initial symptoms include: fever, cough, and weakness and usually progress to breathing problems, shock, and death.

WHY VACCINATE?

Vaccines prevent illness by stimulating the body's natural disease-fighting abilities. They are among the most powerful tools developed by modern medicine for keeping people healthy. Vaccines are routinely used in the United States to protect against diseases such as mumps, measles, whooping cough, and polio. As part of medical protection, personnel are given additional vaccines to protect against naturally occurring diseases encountered when overseas, such as typhoid, hepatitis, and yellow fever. Vaccines also help protect against biological weapons. The Department of Defense has established a vaccination program to protect personnel against anthrax.

WHAT IS THE ANTHRAX VACCINE?

Anthrax vaccine is a sterile product made from filtrates of cultures of a strain of the anthrax organism that does not cause disease. The vaccine contains no living or dead anthrax organisms. The anthrax vaccine is not new. Human anthrax vaccines were developed in England and the U.S. in the 1950s and early 1960s. The anthrax vaccine that Department of Defense personnel will receive was licensed by the FDA in 1970 and has been manufactured by the Michigan Biologic Products Institute (MBPI) under Establishment License No. 99.

It has been safely and routinely administered in the United States to veterinarians, laboratory workers, and livestock handlers for more than twenty-five years.

COMMONLY ASKED QUESTIONS & ANSWERS

Q: Why are Service members getting this vaccine?
A: Anthrax is a lethal weapon that could be used against deployed personnel. Vaccination before exposure is a critical part of the protection against this weapon.

Q: Is the vaccine all this is needed to protect against inhalation anthrax?
A: Being fully vaccinated greatly increases the chances of surviving an exposure to anthrax. Chances are further improved by other measures, especially the proper use of the protective mask.

Q: Is this an experimental vaccine?
A: No, Anthrax vaccine has been FDA approved since 1970 (MBPI Establishment License No. 99).

Q: Is the vaccine all I need to protect against inhalation anthrax?
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Q: Is there anyone who should not receive the vaccine?
A: Anthrax vaccine should be administered only to healthy men and women from 18-65 years of age because investigations to date have been conducted exclusively in that population.

Q: What if I am pregnant?
A: Pregnant women should not receive this vaccine. If you are or believe that you may be pregnant, you should inform your health care provider. The vaccination program will be deferred until the pregnancy is complete.

Q: What other medical conditions should I inform the medical staff about?
A: If you have an active infection or are taking a prescription medicine, inform your health care provider before taking this shot.

Q: The anthrax vaccine was administered to personnel deployed in the Gulf War. Has the anthrax vaccine been linked to illnesses among Gulf War veterans?
A: No. Several national scientific groups, including the National Academy of Sciences, have addressed this issue and have found no evidence to link anthrax vaccine with illnesses among Gulf War veterans.

Q: How many shots will I have to take?
A: Six shots, three given two weeks apart followed by three additional injections given at 6, 12 and 18 months. An annual booster shot is required to maintain ongoing immunity.

Q: What are the side effects?
A: As with other vaccinations, pain may occur at the site of injection. Temporary side effects (sore arm, redness, and slight swelling) may occur. The vaccine has been in use since 1970 with no known long term side effects.

Q: How can I get more information about anthrax vaccine?
A: Your supervisor will have more information. In addition, more information on the anthrax vaccine can be accessed at the website:

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WHAT EVERY PERSON NEEDS TO KNOW ABOUT THE ANTHRAX VACCINE



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Secretary of Defense

1075

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WHY VACCINATE?

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The Department of Defense has established a vaccination program to protect personnel against anthrax.

WHAT IS THE ANTHRAX VACCINE?

Anthrax vaccine is a sterile product made from filtrates of cultures of a strain of the anthrax organism that does not cause disease. The vaccine contains no living or dead anthrax organisms. The anthrax vaccine is not new. Human anthrax vaccines were developed in England and the U.S. in the 1950s and early 1960s. The anthrax vaccine you will receive was licensed by the FDA in 1970 and has been manufactured by the Michigan Biologic Products Institute (MBPI) under Establishment License No. 99.

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FACTS ABOUT THE ANTHRAX VACCINE

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- Manufactured in the United States
- Safely used for more than 25 years
- As with other vaccinations, pain may occur at the site of injection
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- No known long term side effects
- Six shots are required over 18 months, followed by an annual booster

COMMONLY ASKED QUESTIONS & ANSWERS

Q: Why are we getting this vaccine?
A: Anthrax is a lethal weapon we may encounter. Vaccination before exposure is a critical part of our protection against this weapon.

Q: Is this vaccine safe?

A: Yes, this vaccine has been safely and routinely administered in the U.S. to veterinarians, laboratory workers, and livestock handlers since 1970. However, as with other vaccines, minor reactions and, to a lesser extent, more serious adverse reactions may occur in a small number of people.

Q: What if I am pregnant, planning on becoming pregnant, or breast feeding?

A: Anthrax vaccine, like other inactivated vaccines, is not expected to cause fetal harm. No evidence exists that indicates any other adverse reproductive effects including fertility. Prudent medical practice is to defer all immunizations during pregnancy unless clearly needed. Therefore, pregnant women should not receive the anthrax vaccine unless anthrax exposure occurs or is imminent. Service members who believe that they may be pregnant are instructed to inform their health care provider. Anthrax imunizations will be deferred until the pregnancy is complete. A woman does not need to delay becoming pregnant or stop breastfeeding after receiving a dose of anthrax vaccine.

Q: What other medical conditions should I inform the medical staff about?

A: If you have an active infection or are taking a prescription medicine, inform your health care provider before taking this shot.

Q: The anthrax vaccine was administered to personnel deployed in the Gulf War. Has the anthrax vaccine been linked to illnesses among Gulf War veterans?

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Q: How many shots will I have to take?

A: Six shots, three given two weeks apart followed by three additional injections given at 6, 12 and 18 months. An annual booster shot is required to maintain ongoing immunity.

Q: What are the side effects?

A: The vaccine has been in use since 1970, and since that time there have been no long-term side effects identified or reported. However, as with other vaccinations or medications, pain may occur at the site of injection. Temporary side effects (sore arm, redness, and slight swelling) may occur. Small, non-tender nodules or knots under the skin at the site of injection occur in about 30% of vaccine recipients. These nodules usually disappear within a few weeks, but in some cases the process takes several months.

Q: Am I required to take the vaccine?

A: Yes. This program will be treated like any other vaccine that is required to prepare you for deployment. You will be required to take it unless medically deferred.

Q: How can I get more information about anthrax vaccine?

A: Your commanding officer or supporting medical facility. In addition, more information on the anthrax vaccine can be accessed at the website:

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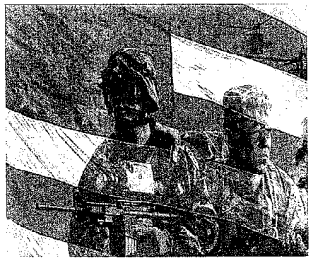
WHAT EVERY SERVICE MEMBER NEEDS TO KNOW ABOUT THE ANTHRAX VACCINE



Anthrax is a highly lethal biological weapon

"Vaccination against anthrax is a safe, prudent force protection measure."

William S. Cohen
Secretary of Defense

UPDATED 02 DECEMBER 1998

WHAT IS THE THREAT?

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WHY VACCINATE?

Vaccines prevent illness by stimulating the body's natural disease-fighting abilities. They are among the most powerful tools developed by modern medicine for keeping people healthy. Vaccines are routinely used in the United States to protect against diseases such as mumps, measles, whooping cough, and polio. As part of force protection, military personnel are given additional vaccines to protect against naturally occurring diseases encountered when deploying overseas, such as typhoid, hepatitis, and yellow fever. Vaccines also help protect against biological weapons.

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WHAT IS THE ANTHRAX VACCINE?

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It has been safely and routinely administered in the United States to veterinarians, laboratory workers, and livestock handlers for more than twenty-five years.

FACTS ABOUT THE ANTHRAX VACCINE

- Vaccination is a critical part of protection against infection
- Manufactured in the United States
- Safely used for more than 25 years
- As with other vaccinations, pain may occur at the site of injection
- Temporary side effects (sore arm, redness, slight swelling, and a small nodule or knot under the skin) may occur.
- No known long term side effects
- Six shots are required over 18 months, followed by an annual booster

COMMONLY ASKED QUESTIONS & ANSWERS

Q: Why are we getting this vaccine?

A: Anthrax is a lethal weapon we may encounter. Vaccination before exposure is a critical part of our protection against this weapon.

Q: Is the vaccine all I need to protect against inhalation anthrax?

A: Vaccination is a vital component of Force Health Protection. Being fully vaccinated greatly increases the chances of surviving an exposure to anthrax. Force Health Protection is further enhanced through sophisticated early warning and detection systems, health surveillance measures, and the proper wear of the protective mask and overgarments.

Q: Is this an experimental vaccine?

A: No, Anthrax vaccine has been FDA approved since 1970.

Q: Is this vaccine safe?

A: Yes, this vaccine has been safely and routinely administered in the U.S. to veterinarians, laboratory workers, and livestock handlers since 1970. However, as with other vaccines, minor reactions and, to a lesser extent, more serious adverse reactions may occur in a small number of people.

Q: Is there anyone who should not receive the vaccine?

A: Anthrax vaccine should be administered only to healthy men and women from 18-65 years of age because investigations to date have been conducted exclusively in that population.

Q: What if I am pregnant, planning on becoming pregnant, or breast feeding?

A: Anthrax vaccine, like other inactivated vaccines, is not expected to cause fetal harm. No evidence exists that indicates any other adverse reproductive effects including fertility. Prudent medical practice is to defer all immunizations during pregnancy unless clearly needed. Therefore, pregnant women should not receive the anthrax vaccine unless anthrax exposure occurs or is imminent. Service members who believe that they may be pregnant are instructed to inform their health care provider. Anthrax imunizations will be deferred until the pregnancy is complete. A woman does not need to delay becoming pregnant or stop breastfeeding after receiving a dose of anthrax vaccine.

Q: What other medical conditions could affect the use of this vaccine?

A: If a person has an active infection or is taking some prescription medications, a decision to give the vaccine will be made on a case by case basis.

Q: The anthrax vaccine was administered to personnel deployed in the Gulf War. Has the anthrax vaccine been linked to illnesses among Gulf War veterans?

A: No. Several national scientific groups, including the National Academy of Sciences, have addressed this issue and have found no evidence to link anthrax vaccine with illnesses among Gulf War veterans.

Q: How many shots will be given?

A: Six shots, three given two weeks apart followed by three additional injections given at 6, 12 and 18 months. An annual booster shot is required to maintain ongoing immunity.

Q: What are the side effects?

A: The vaccine has been in use since 1970, and since that time there have been no long-term side effects identified or reported. However, as with other vaccinations or medications, pain may occur at the site of injection. Temporary side effects (sore arm, redness, and slight swelling) may occur. Small, non-tender nodules or knots under the skin at the site of injection occur in about 30% of vaccine recipients. These nodules usually disappear within a few weeks, but in some cases the process takes several months.

Q: How can I get more information about anthrax vaccine?

A: Information can be obtained from your local command or supporting medical facility. In addition, more information on the anthrax vaccine can be accessed at the website:

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WHAT EVERY FAMILY MEMBER NEEDS TO KNOW ABOUT THE ANTHRAX VACCINE



Anthrax is a highly lethal biological weapon

"Vaccination against anthrax is a safe, prudent force protection measure."

William S. Cohen
Secretary of Defense

UPDATED 02 DECEMBER 1998

WHAT IS THE THREAT?

Biological weapons are maintained by several countries around the world. Use of these weapons could cause widespread illness among unprotected personnel. Anthrax is the biological weapon most likely to be encountered because it is:

- Highly lethal
- Easy to produce in large quantities
- Relatively easy to develop as a weapon
- Easily spread over a large area
- Easily stored and dangerous for a long time

WHAT IS ANTHRAX?

Anthrax is a disease normally associated with plant-eating animals (sheep, goats, cattle, and to a lesser degree swine). It is caused by the bacteria *Bacillus anthracis*. Once common where livestock were raised, it is now controlled through animal vaccination programs. Anthrax still occurs in countries where animals are not vaccinated, mainly in Africa and Asia. It does occur infrequently in many countries, including the United States. Human infection with anthrax usually results from direct contact with infected animals, or animal products such as wool, meat or hides. However, when anthrax is used as a biological weapon, people become infected by breathing anthrax that is released into the air. Inhalation anthrax is the disease that results from breathing anthrax. Under expected battlefield conditions, experts believe you can inhale enough anthrax spores to kill you in one deep breath. Symptoms of inhalation anthrax can begin as early as 24 hours after breathing the spores. Initial symptoms include: fever, cough, and weakness and usually progress to breathing problems, shock, and death.

WHY VACCINATE?

Vaccines prevent illness by stimulating the body's natural disease-fighting abilities. They are among the most powerful tools developed by modern medicine for keeping people healthy. Vaccines are routinely used in the United States to protect against diseases such as mumps, measles, whooping cough, and polio. As part of medical protection, personnel are given additional vaccines to protect against naturally occurring diseases encountered when overseas, such as typhoid, hepatitis, and yellow fever. Vaccines also help protect against biological weapons. The Department of Defense has established a vaccination program to protect personnel against anthrax.

WHAT IS THE ANTHRAX VACCINE?

Anthrax vaccine is a sterile product made from filtrates of cultures of a strain of the anthrax organism that does not cause disease. The vaccine contains no living or dead anthrax organisms. The anthrax vaccine is not new. Human anthrax vaccines were developed in England and the U.S. in the 1950s and early 1960s. The anthrax vaccine that Department of Defense personnel will receive was licensed by the FDA in 1970 and has been manufactured by the Michigan Biologic Products Institute (MBPI) under Establishment License No. 99. BioPort purchased MBPI in September of 1998 and will continue to manufacture the anthrax vaccine.

It has been safely and routinely administered in the United States to veterinarians, laboratory workers, and livestock handlers for more than twenty-five years.

FACTS ABOUT THE ANTHRAX VACCINE

- Vaccination is a critical part of protection against infection
- Manufactured in the United States
- Safely used for more than 25 years
- As with other vaccinations, pain may occur at the site of injection
- Temporary side effects (sore arm, redness, slight swelling, and a small nodule or knot under the skin) may occur.
- No known long term side effects
- Six shots are required over 18 months, followed by an annual booster

COMMONLY ASKED QUESTIONS & ANSWERS

Q: Why are Service members getting this vaccine?

A: Anthrax is a lethal weapon that could be used against deployed personnel. Vaccination before exposure is a critical part of the protection against this weapon.

Q: Is the vaccine all that is needed to protect against inhalation anthrax?

A: Vaccination is a vital component of Force Health Protection. Being fully vaccinated greatly increases the chances of surviving an exposure to anthrax. Force Health Protection is further enhanced through sophisticated early warning and detection systems, health surveillance measures, and the proper wear of the protective mask and overgarments.

Q: Is this an experimental vaccine?

A: No, Anthrax vaccine has been FDA approved since 1970.

Q: Is this vaccine safe?

A: Yes, this vaccine has been safely and routinely administered in the U.S. to veterinarians, laboratory workers, and livestock handlers since 1970. However, as with other vaccines, minor reactions and, to a lesser extent, more serious adverse reactions may occur in a small number of people.

Q: Is there anyone who should not receive the vaccine?

A: Anthrax vaccine should be administered only to healthy men and women from 18-65 years of age because investigations to date have been conducted exclusively in that population.

Q: What if I am pregnant, planning on becoming pregnant, or breast feeding?

A: Anthrax vaccine, like other inactivated vaccines, is not expected to cause fetal harm. No evidence exists that indicates any other adverse reproductive effects including fertility. Prudent medical practice is to defer all immunizations during pregnancy unless clearly needed. Therefore, pregnant women should not receive the anthrax vaccine unless anthrax exposure occurs or is imminent. Service members who believe that they may be pregnant are instructed to inform their health care provider. Anthrax imunizations will be deferred until the pregnancy is complete. A woman does not need to delay becoming pregnant or stop breastfeeding after receiving a dose of anthrax vaccine.

Q: What other medical conditions should I inform the medical staff about?

A: If you have an active infection or are taking a prescription medicine, inform your health care provider before taking this shot.

Q: The anthrax vaccine was administered to personnel deployed in the Gulf War. Has the anthrax vaccine been linked to illnesses among Gulf War veterans?

A: No. Several national scientific groups, including the National Academy of Sciences, have addressed this issue and have found no evidence to link anthrax vaccine with illnesses among Gulf War veterans.

Q: How many shots will I have to take?

A: Six shots, three given two weeks apart followed by three additional injections given at 6, 12 and 18 months. An annual booster shot is required to maintain ongoing immunity.

Q: What are the side effects?

A: The vaccine has been in use since 1970, and since that time there have been no long-term side effects identified or reported. However, as with other vaccinations or medications, pain may occur at the site of injection. Temporary side effects (sore arm, redness, and slight swelling) may occur. Small, non-tender nodules or knots under the skin at the site of injection occur in about 30% of vaccine recipients. These nodules usually disappear within a few weeks, but in some cases the process takes several months.

Q: How can I get more information about anthrax vaccine?

A: Your supervisor will have more information. In addition, more information on the anthrax vaccine can be accessed at the website:

http://www.defenselink.mil/specials/Anthrax

WHAT EVERY PERSON NEEDS TO KNOW ABOUT THE ANTHRAX VACCINE



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UPDATED 02 DECEMBER 1998

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WHY VACCINATE?

Vaccines prevent illness by stimulating the body's natural disease-fighting abilities. They are among the most powerful tools developed by modern medicine for keeping people healthy. Vaccines are routinely used in the United States to protect against diseases such as mumps, measles, whooping cough, and polio. As part of medical protection, personnel are given additional vaccines to protect against naturally occurring diseases encountered when serving overseas, such as typhoid, hepatitis, and yellow fever. Vaccines also help protect against biological weapons.

The Department of Defense has established a vaccination program to protect personnel against anthrax.

WHAT IS THE ANTHRAX VACCINE?

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- No known long term side effects
- Six shots are required over 18 months, followed by an annual booster

COMMONLY ASKED QUESTIONS & ANSWERS

Q: Why are we getting this vaccine?

A: Anthrax is a lethal weapon we may encounter. Vaccination before exposure is a critical part of our protection against this weapon.

Q: Is the vaccine all I need to protect against inhalation anthrax?

A: Vaccination is a vital component of Force Health Protection. Being fully vaccinated greatly increases the chances of surviving an exposure to anthrax. Force Health Protection is further enhanced through sophisticated early warning and detection systems, health surveillance measures, and the proper wear of the protective mask and overgarments.

Q: Is this an experimental vaccine?

A: No, Anthrax vaccine has been FDA approved since 1970.

Q: How many shots will I have to take?

A: Six shots, three given two weeks apart, plus three additional injections given 6, 12 and 18 months later. An annual booster dose is required to maintain ongoing immunity.

Q: Am I required to take the vaccine?

A: Yes. This vaccine, like every other required vaccination, is necessary to prepare you for deployment. Medical exemptions can be granted, if medically appropriate.

Call toll free 1-877-GET-VACC
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- **Anthrax is a highly lethal biological warfare agent.**
- **The anthrax vaccine is an effective and safe vaccine.**
- **The anthrax vaccine does not contain squalene and has never contained squalene.**
- **The threat of anthrax is a clear and present danger.**

Dr. Sue Bailey
Assistant Secretary of Defense
for Health Affairs
and
The Service Surgeons General

WHAT EVERYONE NEEDS TO KNOW ABOUT THE ANTHRAX VACCINE



Anthrax is a highly lethal biological weapon.

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1 November 1999

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WHAT IS THE ANTHRAX VACCINE?

Anthrax vaccine is a sterile product made from a strain (type) of the anthrax organism that does not cause disease. The vaccine contains no living or dead anthrax organisms. Vaccination produces antibodies that neutralize the disease-causing protein common to every strain of anthrax. The anthrax vaccine is not new. Human anthrax vaccines were developed in England and the U.S. in the 1950s and early 1960s. The anthrax vaccine you will receive was licensed in 1970 by the Food and Drug Administration and is manufactured by BioPort Corporation (Lansing, Michigan) under License No. 1290, formerly the Michigan Biologic Products Institute under License No. 99.

It has been safely and routinely administered in the United States to at-risk veterinarians, laboratory workers, and livestock handlers since 1970.

COMMONLY ASKED QUESTIONS & ANSWERS

Q: Why are we getting this vaccine?

A: Anthrax is a lethal biological weapon we may encounter. Vaccination before exposure is a critical part of our protection against this weapon.

Q: Is the vaccine all I need to protect against inhalational anthrax?

A: Vaccination is a vital component of Force Health Protection. Being fully vaccinated greatly increases your chances of surviving an exposure to anthrax. Force Health Protection is further enhanced through sophisticated early warning and detection systems, health surveillance measures, and the proper wear of the protective mask and over-garments. Antibiotics play a limited role, but vaccination is essential.

Q: Is this an experimental vaccine?

A: No. The anthrax vaccine has been FDA licensed since 1970.

Q: Is this vaccine safe?

A: Yes. This vaccine has been safely administered in the U.S. since 1970. However, as with other vaccines, minor reactions are common. Serious adverse events occur rarely after any vaccination.

Q: What are the side effects?

A: Like all vaccines, anthrax vaccine may cause soreness, redness, itching, and swelling at the injection site. Up to 30% of men and 60% of women report mild local reactions, but these reactions usually last only a few days. For both genders, between 1% and 5% report reactions of 1 to 5 inches in diameter. Larger reactions occur about once per hundred vaccinees or less. A lump at the site occurs commonly, usually lasting for a few weeks, before going away on its own, if left alone.

Beyond the injection site, from 5% to 35% will notice muscle aches, joint aches, headaches, malaise, rashes, chills, low-grade fever, nausea, or related symptoms. These symptoms usually go away in less than a week.

Serious events, such as those requiring hospitalization, are rare for any vaccine. For anthrax vaccine, they happen about once per 50,000 doses. Severe allergic reactions occur less than once per 100,000 doses.

Discuss with your health-care provider whether over-the-counter antihistamines or pain relievers before or after vaccination can help reduce bothersome symptoms. Report adverse events after vaccination to your health-care provider promptly, before receiving additional vaccinations.

Q: What about long-term side effects?

A: At Fort Detrick, 1,500 laboratory workers have been followed up to 10 to 20 years or more after anthrax vaccination. These employees have been followed annually. None developed unexplained symptoms due to repeated doses of this or other vaccines they received. From this and other monitoring, no patterns of delayed side effects to anthrax vaccine have been found. Monitoring continues.

Q: What if I am pregnant or breast-feeding?

A: Anthrax vaccine, like other non-living vaccines, is not expected to cause fetal harm. No evidence exists to indicate adverse reproductive effects occur after vaccination, including infertility. Prudent medical practice is to defer vaccination during pregnancy unless clearly needed. Therefore, pregnant women should not receive the anthrax vaccine, unless anthrax exposure occurs or is imminent. Women who believe that they may be pregnant should inform their health-care provider before vaccination. Once pregnancy is confirmed, anthrax vaccinations will be deferred until the woman is no longer pregnant. The Centers of Disease Control and Prevention reports that vaccines are safe for breast-feeding women, causing no harm to children who are breast-fed.

Q: What if I'm planning on having children?

A: The vaccine contains no infectious substance. Therefore, there is no reason to delay child-bearing. This applies to both men and women who are vaccinated.

Q: Anthrax vaccine was administered to personnel deployed in the Gulf War. Has the anthrax vaccine been linked to illnesses among Gulf War veterans?

A: No. Several renowned scientific groups, including the National Academy of Sciences, have addressed this issue and found no evidence to link the FDA-licensed anthrax vaccine with illnesses among Gulf War veterans.

Q: What other medical conditions should I inform the medical staff about?

A: If you have an active illness, a chronic illness under medical treatment, or are taking a prescription medication, inform the medical staff before taking any vaccine.

Q: If I feel I'm having a health problem related to vaccination, what should I do?

A: If an adverse event occurs, seek medical car as appropriate. At a minimum, any adverse event that results in 24 hours or more time lost from duty, or hospitalization, must be reported by your health-care provider using the Health and Human Services Vaccine Adverse Events Reporting System (VAERS). Anyone may repor a vaccine-associated adverse event of any severity or any length of time through VAERS t the FDA. To obtain blank forms, go to www.anthrax.osd.mil/vaers/vaers.htm or contac the FDA by calling 1-800-822-7967. Please see health-care provider for help with filling out the form.

Q: I'm a Reservist/Guard member. If I hav a reaction to the vaccine, can I go to a military (DoD or Coast Guard) hospital or clinic?

A: Adverse events after DoD or USCG directed vaccinations are line of duty illnesses. Therefore, a member of the Reserve Component may present themselves for initial treatment and evaluation at any military treatment facility, after vaccination during a period of duty. The member will be examined and provided necessary medical care. Once treatment is rendered or the individual's emergent condition is stabilized, a Line of Duty and/or Notice of Eligibility status will be determined by the member's unit, as required. No treatment beyond that justified to stabilize the condition o emergency is authorized until Service connectio is validated. Evaluation does not require being in a duty status, nor DEERS enrollment. For more information, contact your unit representative.

Q: What happens if I am late for a shot?

A: All reasonable steps should be taken to receive each vaccination on or as close as possible to the approved schedule. Do not get vaccinated early. If you are late for a vaccination, get it as soon as possible. There is no increase in side effects from late vaccinations. Getting vaccinated late does not reduce the protection you ultimately develop. But you may not be optimally protected during the interval when your shot is overdue.

Q: Am I required to take the vaccine?

A: Yes. This vaccine, like every other required vaccination, is necessary to prepare you for deployment. Medical exemptions can be granted, if medically appropriate.

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Dr. Sue Bailey
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WHAT EVERYONE NEEDS TO KNOW ABOUT THE ANTHRAX VACCINE

1 May 2000



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It has been safely and routinely administered in the United States to at-risk veterinarians, laboratory workers, and livestock handlers since 1970.

COMMONLY ASKED QUESTIONS & ANSWERS

Q: Why are we getting this vaccine?

A: Anthrax is a lethal biological weapon we may encounter. Vaccination before exposure is critical to protect us against this weapon.

Q: Is the vaccine all I need to protect against inhalational anthrax?

A: Vaccination is a vital component of Force Health Protection. Being fully vaccinated greatly increases your chances of surviving an exposure to anthrax. Force Health Protection is further enhanced through early warning and detection systems, health surveillance, and the proper wear of the protective mask and over-garments. Antibiotics play a limited role, but vaccination is essential.

Q: Is this an experimental vaccine?

A: No. The anthrax vaccine has been FDA-licensed since 1970.

Q: Is this vaccine safe?

A: Yes. This vaccine has been safely administered in the U.S. since 1970. However, as with other vaccines, minor reactions are common. Serious adverse events occur rarely after any vaccination.

Q: What are the side effects?

A: Like all vaccines, anthrax vaccine may cause soreness, redness, itching, and swelling at the injection site. Up to 30% of men and 60% of women report mild local reactions, but these reactions usually last only a few days. For both genders, between 1% and 5% report reactions of 1 to 5 inches in diameter. Larger reactions occur about once per hundred vaccinees or less. A lump at the site occurs commonly, usually lasting for a few weeks, before going away on its own, if left alone.

Beyond the injection site, from 5% to 35% will notice muscle aches, joint aches, headaches, malaise, rashes, chills, low-grade fever, nausea, or related symptoms. These symptoms usually go away in less than a week.

Any vaccine can cause serious reactions, such as those requiring hospitalization. For anthrax vaccine, they happen less than once per 200,000 doses. Severe allergic reactions occur less than once per 100,000 doses.

Discuss with a health-care provider whether antihistamines or pain relievers before or after vaccination can help reduce bothersome symptoms. Report adverse events after vaccination to a health-care provider promptly, before receiving additional vaccinations.

Q: What about long-term side effects?

A: At Fort Detrick, MD, 1,500 laboratory workers have been followed up to 10 to 20 years or more after anthrax vaccination. None developed unexplained symptoms due to repeated doses of this or other vaccines they received. From this and other monitoring, no patterns of delayed side effects to anthrax vaccine have been found. Monitoring continues.

Q: What if I am pregnant or breast-feeding?

A: Anthrax vaccine, like other non-living vaccines, is not expected to cause fetal harm. No evidence exists to indicate adverse reproductive effects occur after vaccination, including infertility. Prudent medical practice is to defer vaccination during pregnancy unless clearly needed. Therefore, pregnant women should not receive the anthrax vaccine, unless anthrax exposure occurs or is imminent. Women who believe that they may be pregnant should inform their health-care provider before vaccination. Once pregnancy is confirmed, anthrax vaccinations will be deferred until the woman is no longer pregnant.

The Centers for Disease Control and Prevention (CDC) reports that vaccines are safe for breast-feeding women, causing no harm to children who breast-feed.

Q: What if I'm planning on having children?

A: The vaccine contains no infectious substance. Therefore, there is no reason to delay child bearing. This applies to both men and women who are vaccinated.

Q: Anthrax vaccine was administered to personnel deployed in the Persian Gulf War. Has the anthrax vaccine been linked to illnesses among Gulf War veterans?

A: No. Several renowned scientific groups, including the National Academy of Sciences, have addressed this issue and found no evidence to link the FDA-licensed anthrax vaccine with illnesses among Gulf War veterans.

Q: What other medical conditions should I inform the medical staff about?

A: If you have an active illness, a chronic illness under medical treatment, or take medication that suppresses the immune system, inform the medical staff before taking any vaccine.

Q: If I feel I'm having a health problem related to vaccination, what should I do?

A: If an adverse event occurs, seek medical care as appropriate. At a minimum, any adverse event that results in 24 hours or more time lost from duty, or hospitalization, must be reported by your health-care provider using the Vaccine Adverse Events Reporting System (VAERS). Anyone may report a vaccine-associated adverse event of any severity through VAERS. For blank forms, go to:

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or contact VAERS by calling 1-800-822-7967. Please see a health-care provider for help with filling out the form.

Q: I'm a Reservist/Guard member. If I have an adverse reaction, can I go to a military (DoD or Coast Guard) hospital or clinic?

A: Adverse events after DoD- or USCG-directed vaccinations are line-of-duty illnesses. Therefore, a member of the Reserve Component may seek initial treatment and evaluation at any military treatment facility after vaccination during a period of duty. The member will be examined and provided necessary medical care. Once treatment is rendered or the individual's emergent condition is stabilized, a Line of Duty and/or Notice of Eligibility status will be determined by the member's unit, as required. No treatment beyond that justified to stabilize the condition or emergency is authorized until Service connection is validated. Evaluation does not require being in a duty status, nor DEERS enrollment. For more information, contact your unit representative.

Q: How many shots will I have to take?

A: Six shots, with the first three given 2 weeks apart. The next three are given at intervals of 5 months, 6 months, and 6 months after the date of the previous dose. After the sixth dose, booster doses are given every 12 months to maintain immunity. This is the anthrax vaccine schedule licensed by the FDA and used by the DoD.

Each dose of anthrax vaccine adds to the anthrax-fighting antibodies in your blood stream. This is like climbing steps on a ladder towards full protection. Data from studies show that delays of 18 to 24 months did not reduce the body's ability to respond to the next dose of anthrax vaccine.

When anthrax vaccine supply is restored, those who deferred any doses will resume vaccinations where they left off. Service Members are not expected to restart the shot series. This is consistent with guidance from the Centers for Disease Control & Prevention's Advisory Committee on Immunization Practices.

- **Anthrax used as a biological weapon represents a grave and urgent threat to U.S. Armed Forces**
- **Anthrax is 99% fatal for those unprotected and untreated, as deadly as the Ebola virus**
- **We have a safe and effective FDA-licensed vaccine to protect you from the deadly effects of weaponized anthrax**

For more information on the Anthrax Vaccine Immunization Program
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WHAT EVERYONE NEEDS TO KNOW ABOUT THE ANTHRAX VACCINE

30 September 2000



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- Odorless, colorless, tasteless and difficult to detect

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Inhalational anthrax is the disease that results from breathing in anthrax spores. Under expected battlefield conditions, experts believe you can inhale in one deep breath enough anthrax spores to kill you. Symptoms of inhalational anthrax can begin as early as 24 hours after breathing the spores. Initial symptoms include fever, cough, and weakness. These ultimately progress to breathing problems, shock, and death.

WHY VACCINATE?

Vaccines prevent illness by stimulating the body's natural disease-fighting abilities. They are among the most powerful tools developed by modern medicine to keep people healthy. Vaccines are used routinely in the U.S. to protect against such diseases as tetanus, mumps, measles, whooping cough, and polio. Vaccines also help protect against such biological weapons as anthrax.

As part of Force Health Protection, personnel are given additional vaccines to provide maximum protection against naturally occurring diseases encountered when deploying overseas, such as typhoid, hepatitis A, and yellow fever.

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The vaccine protocol consists of: Six doses, with the first three given two weeks apart. The next three doses are given at intervals of five months, six months, and six months after the date of the previous dose. After the sixth dose, booster doses are given every 12 months to maintain immunity.

Anthrax Vaccine has been safely and routinely administered in the U.S. to at-risk veterinarians, laboratory workers, and livestock handlers since 1970.

Anthrax is a highly lethal biological weapon.

COMMONLY ASKED QUESTIONS & ANSWERS

Q: Why are we getting this vaccine?

A: Anthrax is a lethal biological weapon. Vaccination before exposure is critical to protect us against this weapon.

Q: Is the vaccine all I need to protect against inhalational anthrax?

A: Vaccination is a vital component of Force Health Protection. Being fully vaccinated greatly increases your chances of surviving an exposure to anthrax. Force Health Protection is enhanced through early warning and detection systems, and proper wear of protective gear. Antibiotics play a limited role, but vaccination is essential.

Q: Is this vaccine safe?

A: Yes. As with other vaccines, minor reactions are common. Serious adverse events may occur after any vaccination, but they are rare.

Q: What are the side effects?

A: Like all vaccines, anthrax vaccine may cause soreness, redness, itching, and swelling at the injection site. Up to 30% of men and 60% of women report mild local reactions, but these reactions usually last only a few days. For both genders, between 1% and 5% report reactions of 1 to 5 inches in diameter. Larger reactions occur about once per hundred vaccinees or less. A lump at the site occurs commonly, usually lasting for a few weeks, before going away on its own, if left alone. Beyond the injection site, from 5% to 35% will notice muscle aches, joint aches, headaches, malaise, rashes, chills, low-grade fever, nausea, or related symptoms. These symptoms usually go away in less than a week.

Any vaccine can cause serious reactions, such as those requiring hospitalization. For anthrax vaccine, they happen less than once per 200,000 doses. Severe allergic reactions occur less than once per 100,000 doses.

Discuss with a health-care provider whether antihistamines or pain relievers before or after vaccination can help reduce bothersome symptoms. Report adverse events to a health-care provider promptly, before receiving additional vaccinations.

Q: What about long-term side effects?

A: At Fort Detrick, MD, 1,500 laboratory workers have been followed for 10 years or more after anthrax vaccination. None developed unexplained symptoms due to repeated doses of this or other vaccines they received. From this and other monitoring, no patterns of delayed side effects to anthrax vaccine have been found. Monitoring continues.

Q: What if I am pregnant or breast-feeding?

A: Anthrax vaccine, like other non-living vaccines, is not expected to cause fetal harm. No evidence exists to indicate adverse reproductive effects occur after vaccination, including infertility. Prudent medical practice is to defer vaccination during pregnancy unless clearly needed. Therefore, pregnant women should not receive the anthrax vaccine, unless anthrax exposure occurs or is imminent. Women who believe that they may be pregnant should inform their health-care provider before vaccination. Once pregnancy is confirmed, anthrax vaccinations will be deferred until the woman is no longer pregnant.

The Centers for Disease Control and Prevention (CDC) reports that vaccines are safe for breast-feeding women, causing no harm to children who breast-feed.

Q: What if I'm planning on having children?

A: The vaccine contains no infectious substance. Therefore, there is no reason to delay child bearing. This applies to both men and women who are vaccinated.

Q: Anthrax vaccine was administered to personnel deployed in the Persian Gulf War. Has the anthrax vaccine been linked to illnesses among Gulf War veterans?

A: No. Several renowned scientific groups, including the National Academy of Sciences, have addressed this issue and found no evidence to link the FDA-licensed anthrax vaccine with illnesses among Gulf War veterans.

Q: What other medical conditions should I inform the medical staff about?

A: If you have an active illness, a chronic illness under medical treatment, or take medication that suppresses the immune system, inform the medical staff before taking any vaccine.

Q: If I feel I'm having a health problem related to vaccination, what should I do?

A: If an adverse event occurs, seek medical care as appropriate. At a minimum, any adverse event that results in 24 hours or more time lost from duty, or hospitalization, must be reported by your health-care provider using the Vaccine Adverse Events Reporting System (VAERS). Anyone may report a vaccine-associated adverse event of any severity through VAERS. For blank forms, go to http://www.vaers.org or contact VAERS at 1-800-822-7967.

Q: I'm a Reservist/Guard member. If I have an adverse reaction, can I go to a military (DoD or Coast Guard) hospital or clinic?

A: Yes. Adverse events after DoD- or USCG-directed vaccinations are line-of-duty illnesses. Therefore, a member of the Reserve Component may seek initial treatment and evaluation at any military treatment facility after a vaccination given during a period of duty. The member will be examined and provided necessary medical care. Once the condition is stabilized, a Line of Duty and/or Notice of Eligibility status will be determined by the member's unit. No treatment beyond that justified to stabilize the condition or emergency is authorized until Service connection is validated. Evaluation does not require being in a duty status, nor DEERS enrollment. For more information, contact your unit representative.

Q: What happens if I am late for a dose?

A: All reasonable steps should be taken to receive each vaccination on or as close as possible to the approved schedule. Do not get vaccinated early. If you are late for a vaccination, get it as soon as possible. There is no increase in side effects from late vaccinations. Getting vaccinated late does not reduce the protection you ultimately develop. But you may not be optimally protected during the interval when your dose is overdue.

Q: Am I required to take the vaccine?

A: Yes. This vaccine, like every other required vaccination, is necessary to prepare you for deployment. Medical exemptions can be granted, if medically appropriate.

Q: How does the anthrax vaccine "slowdown" affect me?

A: The slowdown of the program results from a temporary shortage of FDA-released vaccine. During the slowdown, some people who began the vaccination series (but are not currently in high-threat areas) will have scheduled doses temporarily deferred, to preserve the limited supply for those at highest risk—those currently in high-threat areas. When the supply of FDA-released vaccine is restored, the full scope of the program will resume.

Q. Does delaying scheduled shots affect the safety or effectiveness of the vaccine?

A: There is no information to suggest a detrimental effect on health of people who defer doses of any vaccine. Deferred doses have not been found to increase side effects from any vaccine and there is no known reduction in the level of protection achieved once all doses in the series are completed.

GAO
Accountability * Integrity * Reliability

Status Since Sept. 1998

Status		Top Reason		If No Anthrax Will Likely Return
Left/Moved/Inactive	25% →	Anthrax	25% →	43%
Will Leave In Next 6 Months	18% →	Anthrax	61%	

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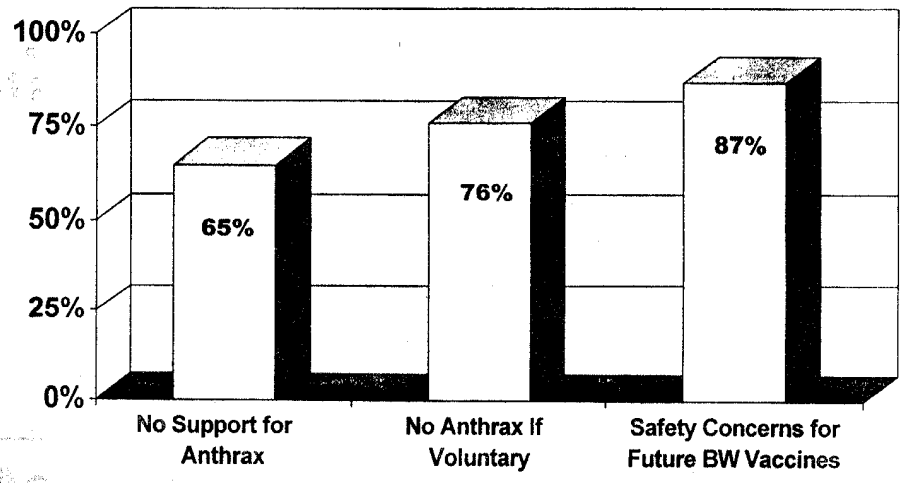
Support for BW Vaccines



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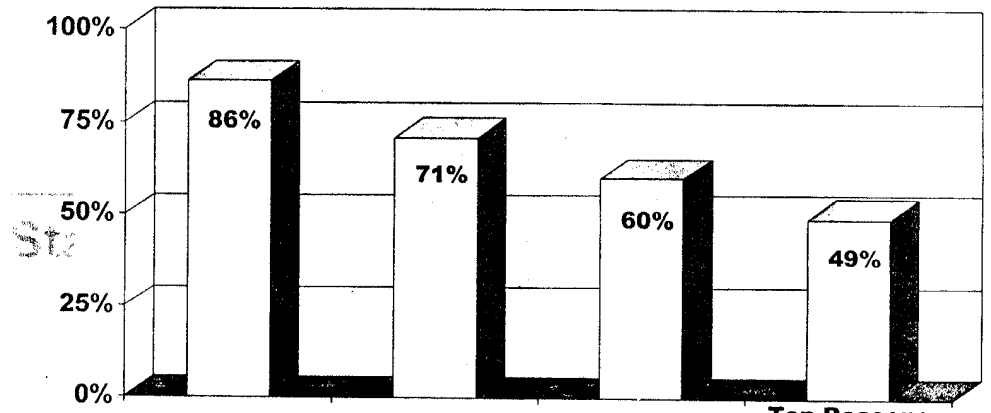
Adverse Reactions



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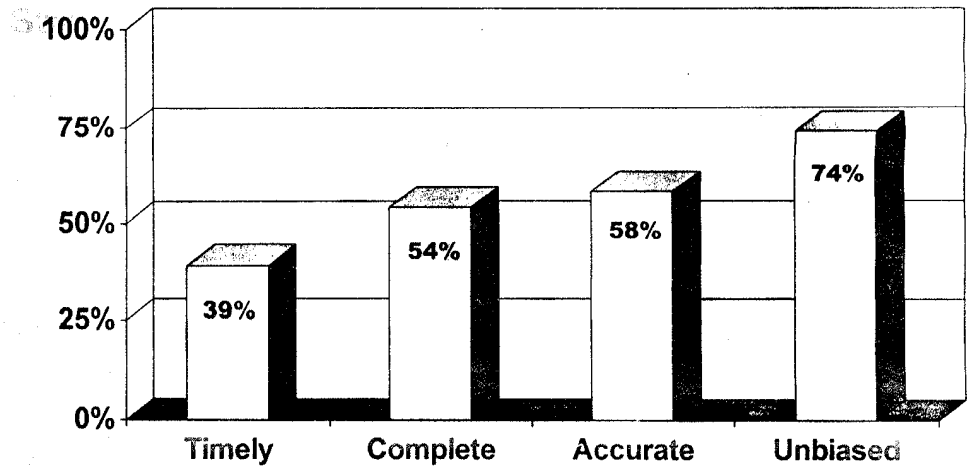
Dissatisfaction with DOD Information on Website



The Nuremberg Code

1. The voluntary consent of the human subject is absolutely essential.

This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. The latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rest upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

A letter written by the administrator of the Armed Forces Epidemiological Board documents Mr. Jackson's role and motivation:

> It was on Mr. Jackson's insistence that the 'Nuremberg Principles' were used in toto in the document, since he stated, these already had international judicial sanction, and to modify them would open us to severe criticism along the line--"see they use only that which suits them."[76]

Thus, the DOD's counsel cited the 1947 Nuremberg military tribunal ruling as establishing an international legal precedent to which American researchers should be held.

It appears that in succeeding months the AFMPC proposal was received unenthusiastically by other DOD committees that reviewed it. In a November 12, 1952, memorandum, the executive director of the Committee on Medical Sciences pointed out that "human experimentation has been carried on for many years." He contended that

> to issue a policy statement on human experimentation at this time would probably do the cause more harm than good; for such a statement would have to be "watered down" to suit the capabilities of the average investigator.[77]

"Human experimentation," the CMS executive director asserted, "has, in years past, and is at present governed by an unwritten code of ethics," which is "administered informally by fellow workers in the field [and] is considered to be satisfactory. . . . To commit to writing a policy on human experimentation would focus unnecessary attention on the legal aspects of the subject."[78]

Notwithstanding the reservations of the CMS and others,[79] the Nuremberg Code proposal had the support of President Truman's secretary of defense, Robert A. Lovett.[80] However, the secretary's aide,

Constance A. Morella

The Anthrax Vaccine Immunization Program - What Have We Learned? Part II"
Statement of Congresswoman Constance A. Morella
Government Reform Committee Hearing
Wednesday, October 11, 2000
10:00 2154 RHOB

Mr. Chairman, thank you for holding this hearing today to examine the impact the Anthrax Vaccine Immunization Program (AVIP), is having on our military's readiness, and retention of its servicemen and women. We are here today to learn more about the concerns with the mandatory anthrax vaccination program.

I want to take a few moments to share some of my thoughts on the anthrax issue as a whole.

I do believe this is an issue that could jeopardize the readiness of our military. Since the announcement of the mandatory vaccination program in 1997, growing numbers of military personnel--particularly Guard and Reservists--are choosing to resign rather than take the anthrax vaccine. Now, military personnel across the country are struggling with their options: take the vaccine or leave the service.

Unfortunately, too many are choosing the latter.

They cite unresolved questions about the safety, efficacy and necessity of the anthrax vaccine program.

I hope we can identify these questions and work together to find the answers.

There is a real need to protect our United States military from potential chemical and biological warfare. If the anthrax vaccine is safe and can effectively combat the threat of anthrax for our military, the Pentagon has failed to convince the very people it is trying to protect.

The questions being raised are serious, legitimate questions that must be addressed in order to ensure our military receives the answers it needs.

This committee has held several hearings on the Anthrax Vaccines Immunization Program, so has the ~~Arms~~ Armed Services Committee. Through these hearings, and the numerous GAO

studies, several issues have been raised regarding the safety and efficacy of anthrax vaccine. Since the Department of Defense requires some of our servicemen and women to take the anthrax vaccines, I believe we must ensure that scientific research is ~~through~~ thorough and complete. Today, anthrax vaccines are the only option we have that the FDA has approved as a medical prevention against anthrax.

Mr. Chairman, I look forward to hearing the testimony of the witnesses today, I believe that it is imperative that we get to the bottom of this; we cannot afford to lose time; we cannot afford to compromise our nation's security; and we owe our servicemen and women the best in modern science and medicine.

STATEMENT FOR THE RECORD
THE HONORABLE BENJAMIN A. GILMAN

MR CHAIRMAN, I ~~WOULD LIKE TO~~ THANK YOU FOR CONVENING THIS MORNING'S IMPORTANT HEARING TO REVIEW THE DEPARTMENT OF DEFENSE'S MANDATORY ANTHRAX VACCINATION PROGRAM EFFECT ON READINESS.

I REGRET THAT I WAS DELAYED DUE TO MY CHAIRING THE OPENING OF OUR PARLIAMENTARIAN MISSION REVIEW IN OUR INTN'L RELATIONS COMM.

THIS MORNING WE WILL HEAR FROM THE GENERAL ACCOUNTING OFFICE, WHICH IS READY TO REPORT ~~SOME~~ PRELIMINARY RESULTS FROM A STUDY THAT I JOINED WITH YOU IN REQUESTING. THIS GAO STUDY EXAMINED THE VACCINE PROGRAM'S EFFECT ON MORALE AND RETENTION IN OUR RESERVES AND NATIONAL GUARD UNITS. WHEN THIS ISSUE WAS FIRST BROUGHT TO MY ATTENTION LAST YEAR, BY SERVICEMEN PERSONNEL I FEARED THAT AIR GUARD AND RESERVE PILOTS WOULD LEAVE THE SERVICE IN DROVES RATHER THAN RECEIVE THE SHOTS. AS WE WILL SEE THIS MORNING, THIS IS WHAT HAS HAPPENED.

IN ADDITION TO THE RESERVE PILOTS

THEIR

I FULLY EXPECT THAT THE DEPARTMENT OF DEFENSE WILL CONTINUE TO MAINTAIN ITS OFFICIAL POSITION THAT THE PROGRAM HAS NOT HAD A DETRIMENTAL EFFECT ON READINESS. THROUGHOUT THE LIFE OF THE PROGRAM, THE PENTAGON HAS MAINTAINED A "SEE NO EVIL" APPROACH TO PERSONNEL SEPARATIONS.

THE REALITY IS THAT WE HAVE A VOLUNTEER MILITARY THAT IS HEAVILY DEPENDENT ON GUARD AND RESERVE PERSONNEL FOR RAPID DEPLOYMENT OF FORCES OVERSEAS, AS WELL AS FOR SUSTAINED THEATER AIR OPERATIONS. WITHOUT RESERVE AND GUARD PILOTS, FUTURE DEPLOYMENTS CAN LITERALLY NOT GET OFF THE GROUND.

MANY OF THE PILOTS WHO HAVE LEFT COME FROM VITAL C-5 TRANSPORT UNITS. HAD THE VACCINE BEEN IMPLEMENTED AT STEWART AFB, NEAR MY CONGRESSIONAL DISTRICT, MORE THAN HALF THE PILOTS WERE PREPARED TO RESIGN. WHEN COMBINED WITH THE SITUATION AT TRAVIS AND DOVER AFBs, THE AIR FORCE'S AIRLIFT CAPABILITIES WOULD HAVE BEEN SEVERELY IMPACTED.

THE PUBLIC RELATIONS CAMPAIGN BEING WAGED BY THE PENTAGON REFUTES THIS OF COURSE. THE OFFICIAL MESSAGE IS THE MAJORITY OF TROOPS ARE TAKING THE VACCINE WITH ONLY A SMALL MINORITY OF DISGRUNTLED INDIVIDUALS REFUSING. IT BEARS NOTING, HOWEVER , THAT THE PENTAGON ONLY LISTS ACTIVE DUTY SHOT-REFUSERS IN THEIR PUBLIC ESTIMATES, NATIONAL GUARD AND RESERVE MEMBERS ARE IGNORED.

FROM THE EVIDENCE THAT I HAVE REVIEWED, EACH NATIONAL GUARD BASE THAT BEGINS TO IMPLEMENT THE VACCINATION PROGRAM SUFFERS ATTRITION AMONG ITS PILOTS THAT CONSISTENTLY AVERAGES BETWEEN 20-40%. THIS IS NOT RUMOR, IT IS REALITY. YET IT IS A REALITY THAT THE PENTAGON REFUSES TO ACCEPT.

IRRESPECTIVE OF THIS, HOWEVER, IS THE FACT THAT OUR MILITARY, WITH ITS CURRENT QUALITY OF LIFE PROBLEMS, COUPLED WITH AN UNPARALLELED RATE OF DEPLOYMENT UNDER THIS ADMINISTRATION, CANNOT AFFORD TO CONTINUE LOSING HIGHLY QUALIFIED PERSONNEL FROM ITS RESERVE AND NATIONAL GUARD UNITS.

REGRETTABLY, THIS FACT DOES NOT APPEAR TO BE A CONSIDERATION OF THE CURRENT ADMINISTRATION, WHICH STILL MAINTAINS THAT ANY POTENTIAL BENEFIT OF THE PROGRAM FAR OUTWEIGHS THE POSSIBLE COSTS INVOLVED IN ITS IMPLEMENTATION.

IT IS MY OPINION THAT WHILE THIS PROGRAM BEGAN WITH GOOD INTENTIONS IT WAS INITIATED IN A HASTY MANNER BEFORE A PROPER AMOUNT OF RESEARCH ON THE EFFICACY AND SAFETY OF THE VACCINE WAS COMPLETED. MOREOVER, THE PENTAGON HAS GONE TO GREAT LENGTHS TO AVOID GETTING A TRUE PICTURE OF THE NUMBER OF ADVERSE REACTIONS AND THE IMPACT ON READINESS.

IT WOULD NOT BE UNFAIR TO SAY THAT DOD OFFICIALS HAVE ALSO ENGAGED IN A SUSTAINED PATTERN OF DECEPTION REGARDING THEIR TESTIMONY BEFORE CONGRESS ON THIS ISSUE. HAVING SERVED AS A MEMBER OF REPRESENTATIVE SHAYS' SUBCOMMITTEE IN THE 105TH CONGRESS, DURING HIS INVESTIGATION OF THE GULF WAR ILLNESS ISSUE, I HAD LEARNED TO VIEW TESTIMONY FROM THE PENTAGON WITH A HEALTHY DOSE OF CYNICISM.

I WAS PLEASED TO SEE THAT THE SUBCOMMITTEE REPORT REACHED MANY OF THE SAME CONCLUSIONS WHICH LED ME TO INTRODUCE LEGISLATION TO HALT THE PROGRAM UNTIL FURTHER STUDY ON THE SAFETY AND EFFECTIVENESS OF THE VACCINE HAD BEEN COMPLETED.

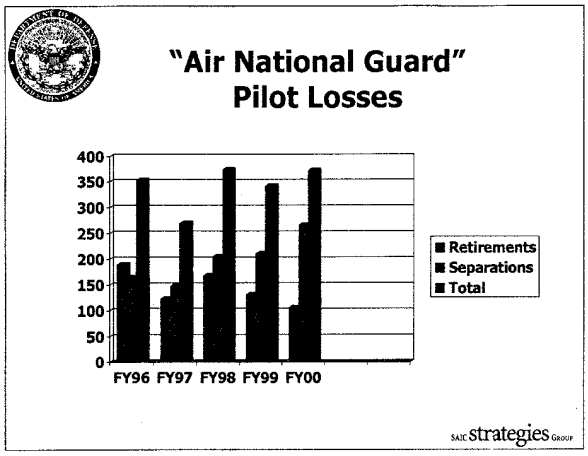
MOREOVER, WHILE THE ARMED SERVICES COMMITTEE CHOSE NOT TO ACT UPON MY LEGISLATION, THE LANGUAGE CALLING FOR INDEPENDENT STUDIES WAS INCLUDED IN THE FY 2000 DEFENSE APPROPRIATIONS CONFERENCE REPORT.

I WAS ALSO PLEASED TO SEE THAT THE GENERAL ACCOUNTING OFFICE AND THE FOOD AND DRUG ADMINISTRATION HAVE CHOSEN SO FAR TO TAKE AN INDEPENDENT AND CRITICAL LOOK AT BOTH THE PROGRAM, ITS EFFECT ON READINESS, AND THE MANUFACTURING PROCESS BEHIND THE VACCINE.

IT ALSO BEARS MENTIONING THAT THROUGHOUT THIS PROCESS DOD OFFICIALS HAVE TAKEN PAINS TO AVOID RESPONDING TO THE CHARGES LEVELED IN THE REPORT APPROVED BY THIS COMMITTEE WITH ANYTHING BEYOND THE OFFICIAL BOILERPLATE RESPONSE. NOT ONCE TO MY KNOWLEDGE HAS ANYONE FROM DOD QUESTIONED THE SCIENCE BEHIND THE CRITICISMS OF THE PROGRAM.

FURTHERMORE, DOD CLAIMS, ESPECIALLY THOSE RELATING TO THE NUMBER AND PERCENTAGE OF SYSTEMIC ADVERSE REACTIONS, INCREASED AFTER INTENSE SCRUTINY WAS PLACED ON THE PROGRAM. THESE ISSUES HAVE MADE AN REACHING AN EFFECTIVE SOLUTION TO THIS PROBLEM DIFFICULT.

ONCE AGAIN, MR. CHAIRMAN, THANK YOU FOR CONVENING THIS MORNING'S HEARING.



Indicates an average of 3.7 losses per Wing per yr

	Fy96	97	98	99	00
Retirement	189	122	168	131	106
Separated	164	147	205	211	266
Tot Losses	353	269	373	342	372
Gains	163	222	336	374	295
Delta	-190	-47	-37	+32	-77

Req	3959	3963	3908	3920	4007
Inv	3658	3694	3662	3735	3674
	301	269	246	185	333

87

246

CREW RATIO INCREASES IN 00

Approx 87

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ONE HUNDRED SIXTH CONGRESS

Congress of the United States

House of Representatives

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INDEPENDENT

Book

August 15, 2000

The Honorable William Cohen
Secretary of Defense
The Pentagon
Washington, DC 20301

Dear Mr. Secretary Cohen:

Pursuant to Rules X and XI of the Rules of the House of Representatives, the Committee on Government Reform has oversight jurisdiction of the Department of Defense (DOD).

It has recently been brought to my attention that the DOD is going to conduct a comprehensive satisfaction survey of military Reserve force personnel and their spouses The surveys will gather information on a wide range of programs, policies and issues affecting Reserve forces personnel and their families. I have reviewed the survey forms and am disappointed that there are no questions surveying the attitudes, opinions or impressions of the Reserve military members or their spouses regarding DOD's Anthrax Vaccine Immunization Program (AVIP). In light of the significant on-going Congressional interest and inquiry regarding the Anthrax vaccine's safety and efficacy, and the growing adverse concerns within the military ranks, dependant community and the public at large, I request that you expand the scope of your survey to include an assessment of the AVIP and the Gulf War Syndrome's impact upon Reserve Component personnel. This survey provides an excellent venue to determine the true impact of both of these programs upon our Reserve forces and their families.

In DOD's August 9, 2000, news release announcing the survey, Mr. Charles Cragin, Principal Deputy Assistant Secretary (Reserve Affairs), stated "...As a department, we must continually strive to do a better job of recognizing and dealing with issues that can adversely affect Reserve component members and their families..." In your statement on December 7, 1997, you said "....to be effective, medical force protection must be comprehensive, well documented and consistent." Surveying DOD's

reserve component personnel and their spouses regarding AVIP program will demonstrate insightful leadership consistent with the above guidance.

I would like to ask that you postpone implementation of this initiative so you may include questions surveying the AVIP program and impacts of the Gulf War Syndrome concerns. Knowing that the surveys have been printed, I would propose that a survey "insert" be developed to be included in the existing survey packets before they are mailed

Please provide your response by this afternoon, Tuesday, August 15 to my Professional Staff Member, S. Elizabeth Clay. I would like to also request the results of the surveys at their time of completion. If you have any questions, please free to contact Ms. Clay at 202-225-5074.

Thank you for your immediate attention to this matter.

Sincerely,

Dan Burton
Chairman

Cc: The Honorable Henry Waxman
Chairman, Joint Chiefs of Staff
The Honorable Bernard Rostker
The Honorable Charles Cragin

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

AUG 25 2000

Honorable Dan Burton
Chairman, Committee on
Government Reform
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Thank you for your letter of August 15, 2000, requesting that we postpone dissemination of our Reserve component member and spouse surveys for the purpose of including questions on the Anthrax Vaccine Immunization Program (AVIP) and the Gulf War Syndrome. We regret that we cannot comply with your request to delay the survey for the purpose of adding special questions. In view of the extensive preparations for this survey over the past two years, our existing contractual obligations and the considerable delay in receiving important force-related information, we believe it is in the best interests of the Total Force to proceed with the survey as planned.

We have taken great care to assure that the survey design and methodology adhere to scientific standards that will produce statistically valid results. Developing additional, reliable survey questions would require testing and evaluation, which takes considerable time, expense and experience. These surveys were carefully designed to follow similar surveys in 1986 and 1992, with many identical questions. Our goal is to develop a longitudinal measure on continuing and evolving issues over time.

While survey questions are designed to elicit responses that may influence policy decisions, it is important to recognize that many of our policy decisions cannot be based on survey results. On matters as important as force health protection and readiness, the requirements of our military and our country are paramount. DoD implemented the AVIP as a Total Force protection measure against an imminent threat.

You also requested the survey results when complete. We plan to share the results of these surveys with members of the Congress and many other interested individuals and organizations.

Sincerely,

Bernard Rostker