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DEPARTMENT OF DEFENSE'S SOLE-SOURCE ANTHRAX VACCINE PROCUREMENT

HEARING

BEFORE THE

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS, AND INTERNATIONAL RELATIONS

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

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DEPARTMENT OF DEFENSE'S SOLE-SOURCE ANTHRAX VACCINE PROCUREMENT

WEDNESDAY, JUNE 30, 1999

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS, AND INTERNATIONAL RELATIONS,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:05 a.m., in room 2154, Rayburn House Office Building, Hon. Christopher Shays (chairman of the subcommittee) presiding.

Present: Representatives Shays, Terry, Tierney, and Schakowsky.

Staff present: Lawrence J. Halloran, staff director and counsel; Robert Newman, professional staff member; Jason Chung, clerk; David Rapallo, minority counsel; and Jean Gosa, minority staff assistant.

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

In the 1998 Defense authorization bill, Congress conditioned funding for the new Joint Strike Fighter aircraft on the availability of two jet engine manufacturers. Why? Because the development of critical weapons systems demands competitive innovation and a robust industrial base. But the Department of Defense [DOD], has been unable to bring the same competition and additional production capacity to the acquisition of what has been called a critical force protection system: the anthrax vaccine.

Why more vigorous procurement standards for jet engines than anthrax injections? To meet the requirements of the mandatory, force-wide Anthrax Vaccine Immunization Program, referred to as AVIP, DOD today finds itself captive to the demands of the sole-source provider. With no emergency production facility for the current vaccine and no alternative vaccine ready for use, the Pentagon is locked in a dependent relationship with BioPort Corp., the newly privatized, apparently under-capitalized anthrax vaccine manufacturer.

To those who see the need for the AVIP, the current procurement strategy should raise grave concerns about the security of the sole production facility and the predictability of vaccine supply. To those who question the safety or efficacy of the mandatory program, BioPort's financial troubles engender fears that cost cutting will affect vaccine quality.

Just 9 months ago, the Department of Defense awarded a $29 million contract to BioPort based on the company's business plan,

optimistic cash-flow projections, and promises to fix longstanding quality problems at the production facility.

Today, the plant remains closed, costs far exceed estimates, and revenues are below expectations. Facing a financial crisis, the company has requested extraordinary relief from DOD in the form of a $10 million advance to pay off creditors, a substantial per-dose price increase, and the right to sell up to 20 percent of vaccine production on the private market. In short, in order to maintain any production capability for its own needs, DOD must pay more money for less vaccine, while BioPort sells more vaccine to get more money.

What happened? How did DOD so misjudge the capacity of the sole vaccine provider to perform essential contractual obligations? How did BioPort so miscalculate the time and cost to bring a State-run facility into the notoriously difficult world of commercial vaccine production?

To help address these questions, the subcommittee asked the General Accounting Office [GAO], to review the anthrax vaccine contracts. The GAO findings, as well as observations by DOD's own internal auditors, raise serious doubts BioPort can meet current contract commitments. They also conclude BioPort inherited an accounting system incapable of allocating costs as required by Government contracts, and has not made promised improvements to account for costs.

That finding raises more troubling questions about the extent to which BioPort knew, or should have known, the proposed contract prices were unrealistic; and about the extent to which DOD knew, or should have known, that BioPort would be unable to perform under the contract.

A mandatory, force-wide immunization program to address the preeminent biological warfare threat ought to be based on more than an optimistic business plan and speculative private vaccine sales. Resting on so weak a foundation, can the anthrax vaccine program be sustained in its current form?

We asked our witnesses to address these important questions this morning and look forward to their participation.

And what we will do is we will jump right into it. I will introduce our first panel. Our first panel is comprised of Louis Rodrigues, who is Director, Defense Acquisition Issues, National Security and International Affairs Division, U.S. General Accounting Office. And he is accompanied by Ralph Dawn, who is the Assistant Director of this division. And it is my understanding, Mr. Rodrigues, you will be making the statement and then both will be responsive to questions. Is there anyone else that you think you may need to have put under oath that might answer questions so we could have them stand?

Mr. RODRIGUES. No, Mr. Chairman.

Mr. SHAYS. OK, it will be the two of you?

Mr. RODRIGUES. Yes.

Mr. SHAYS. And if I could ask you to stand and raise your right hands?

[Witnesses sworn.]

Mr. SHAYS. And note for the record that our witnesses have responded in the affirmative.

Before beginning, let me just say that I have read the testimony of the three witnesses. I think this is a very difficult issue, and I in no way want to conclude that there is an easy answer. And so I am very interested in this hearing and will be interested in the responses to questions.

Thank you.

STATEMENT OF LOUIS J. RODRIGUES, DIRECTOR, DEFENSE ACQUISITIONS ISSUES, NATIONAL SECURITY AND INTERNATIONAL AFFAIRS DIVISION, U.S. GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY RALPH DAWN, ASSISTANT DIRECTOR, DEFENSE ACQUISITIONS ISSUES, NATIONAL SECURITY AND INTERNATIONAL AFFAIRS DIVISION, U.S. GENERAL ACCOUNTING OFFICE

Mr. RODRIGUES. Thank you, Mr. Chairman. If I could, I would like my full statement submitted for the record?

Mr. SHAYS. Sure.

Mr. RODRIGUES. And I will proceed with a shorter oral version.

Mr. Chairman, it is a pleasure to be here this morning to discuss the contractual relationships between the Department of Defense and BioPort Corp. for production of the anthrax vaccine. Until 1998, DOD had been procuring the anthrax vaccine from a biological facility owned by the State of Michigan. The facility is the only biological facility in the country licensed by the Food and Drug Administration to produce the vaccine.

In 1997, the Food and Drug Administration identified numerous manufacturing problems that could have led to the revocation of the facility's license. In response to concerns about the potential loss of anthrax vaccine production, DOD began funding renovation efforts. Production facilities were shut down in early 1998. Later, in the summer of 1998, the State of Michigan sold the facility to BioPort Corp. for $25 million. Also, the contracts DOD had with the State of Michigan facility were transferred to BioPort.

DOD has made a significant investment in renovating BioPort's biological facility to meet the military's requirement for anthrax vaccine. However, BioPort has experienced delays in completing the renovation efforts and, as a result, production of the vaccine is about 5 months behind schedule. Because of the delays, the company has not received the revenues it expected and now faces a serious cash-flow problem. The cash-flow problem we believe is due to the company's inability to achieve its overly optimistic business plan.

In response to its cash-flow problem, BioPort requested, and DOD has authorized, the sale of 70,000 doses to other customers before meeting its contractual requirements to the Department. In addition, the company has proposed several actions to resolve its financial problems, including asking DOD for advance payments and to increase contract prices. DOD officials are considering what actions, if any, should be taken to resolve BioPort's cash-flow problem.

BioPort projects a significant operating loss for the year ending December 1999. In fact, those losses are greater than those during the fiscal years 1993 through 1996 when the State of Michigan owned and operated the biological facility. During those years,

losses increased from about $1 million in 1993 to $6.6 million in 1996.

In June 1999, the Defense Contract Audit Agency [DCAA] completed an audit of BioPort's financial condition. According to this report, there is substantial doubt that BioPort will be able to continue performing its contracts, and the company needs additional cash to meet ongoing expenses and debt commitments.

According to BioPort officials, the company is proposing significant price increases because (1) the production capacity is less than it was planned to be; (2) costs have increased; and (3) sales to other customers have not materialized as planned.

BioPort's proposed prices are several times higher than current contract prices. Moreover, BioPort is proposing to provide DOD about 3 million fewer doses than contractually required to better reflect its production capabilities and its desire to increase its private sales. According to BioPort officials, the reduced doses will be sufficient to support the Department's immunization policy.

According to DCAA, the company's proposed increased price for the 2.5 million doses currently under contract is overstated. In addition, the Agency found that BioPort's accounting system was inadequate and recommended that any company data submitted in support of a price increase be reviewed to ensure the accuracy before any contract price is re-negotiated.

Mr. Chairman, that concludes my remarks, and I will be happy to answer any questions.

[The prepared statement of Mr. Rodrigues follows:]

United States General Accounting Office

GAO

Testimony

Before the Subcommittee on National Security, Veterans Affairs, and International Relations, Committee on Government Reform, House of Representatives

For Release on Delivery
Expected at
10:00 a.m., EDT
Wednesday,
June 30, 1999

CONTRACT MANAGEMENT

Observations on DOD's Financial Relationship With the Anthrax Vaccine Manufacturer

Statement of Louis J. Rodrigues, Director, Defense Acquisitions Issues, National Security and International Affairs Division

GAO/T-NSIAD-99-214

Mr. Chairman and Members of the Subcommittee:

It is a pleasure to be here this morning to discuss the contractual relationship between the Department of Defense (DOD) and BioPort Corporation for production of the anthrax vaccine. I will discuss (1) DOD's investment in BioPort's biologic facility and contracts to produce the vaccine, (2) BioPort's current cash flow situation, and (3) proposals to improve the company's financial health.

We have studied and reported on a number of issues concerning biological terrorism for this Subcommittee and others. A list of related GAO reports and testimonies is at appendix I to this statement.

BACKGROUND

From the 1970s until 1998, DOD has been procuring the anthrax vaccine from a biologic facility owned by the State of Michigan. The facility, first known as the Biologic Products Division of the Michigan Department of Public Health and later as the Michigan Biologic Products Institute, is the only biologic facility in the country licensed by the Food and Drug Administration (FDA) to produce the vaccine. In 1997, FDA identified numerous manufacturing problems that could have led to the revocation of the facility's license. In response to concerns about the potential loss of anthrax production, DOD began funding renovation efforts. Production facilities were shut down in early 1998. Later, in the summer of 1998, the State of Michigan sold the facility to the BioPort Corporation for $25 million. The company paid $3.25 million in cash, securing $12.15 million in notes payable to the State of Michigan, and agreeing to pay $9.6 million based on other obligations,

including a percentage of future sales. The contracts DOD had with the State of Michigan facility were transferred to BioPort.

RESULTS IN BRIEF

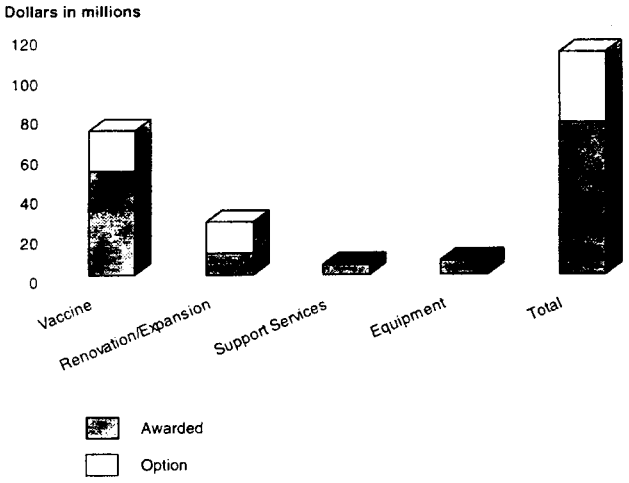
DOD has made a significant investment in renovating BioPort's biologic facility to meet the military's requirements for anthrax vaccine. However, BioPort has experienced delays in completing its renovation efforts, and as a result, production of the vaccine is about 5 months behind schedule.

Because of the delays, the company has not received the revenues it expected and now faces a serious cash flow problem. The cash flow problem, we believe, is due to the company's inability to achieve its overly optimistic business plan. In response to its cash flow problem, BioPort requested—and DOD has authorized—the sale of 70,000 doses to other customers before meeting its contractual requirements with DOD. In addition, the company has proposed several actions to resolve its financial problems, including asking DOD for advance payments and increasing contract prices. DOD officials are considering what actions, if any, should be taken to resolve BioPort's cash flow problem.

DOD INVESTMENT IN BIOPORT'S BIOLOGIC FACILITIES

Since 1988, DOD has provided about $112 million in contracts, including options, to help ensure the viability of the anthrax vaccine biologic facility. As shown in figure 1, DOD's contracts provided monies to (1) produce the vaccine, (2) renovate and expand the production facility, (3) provide various support services, and (4) purchase equipment to enhance production capacity.

Figure 1: Value of Contracts for the Anthrax Vaccine Biologic Facility



Source: GAO analysis of DOD contracts.

DOD has also provided contract terms and conditions to help ensure the success of the anthrax vaccine program. For example, under P.L. 85-804, which allows for government indemnification of contractors for unusually hazardous risks, DOD indemnified BioPort against product liability. In addition, DOD agreed to allow the company to sell up to 200,000 doses of anthrax vaccine to others, using government-furnished equipment rent-free, after DOD's requirements are met.

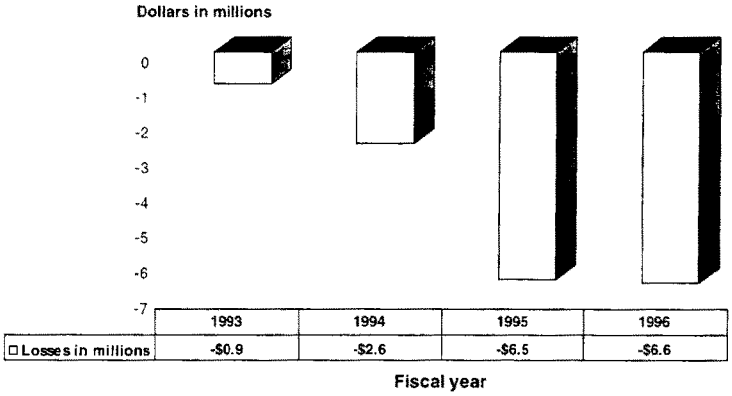
BIOPORT'S CASH FLOW PROBLEMS

BioPort's renovation efforts have taken longer than expected and delayed production about 5 months. As a result, the revenues the company expected to receive have not

materialized. The company has continued to accumulate costs, including significant payroll costs. According to BioPort officials, the company does not have sufficient cash reserves or the ability to obtain commercial financing at reasonable rates to cover its operating expenses.

BioPort projects a significant operating loss for the year ending December 1999.[1] In fact, the losses are greater than those during fiscal years 1993-96 when the State of Michigan owned and operated the biologic facility (see fig. 2).[2]

Figure 2: Biologic Facility Operating Losses in Fiscal Years 1993-96



Source: Independent accountants' reports

In June 1999, the Defense Contract Audit Agency (DCAA) completed an audit of BioPort's financial condition to determine if the contractor has adequate financial resources to

[1]BioPort considers its projected operating loss for the year ending December 31, 1999, proprietary information and, therefore, it is not included in this statement.
[2]Data regarding the State of Michigan's operating losses were available only for fiscal years 1993-96.

perform its DOD contracts. According this report, there is substantial doubt that BioPort will be able to continue performing its contracts. The company needs additional cash to meet ongoing expenses and debt commitments. For example, under the terms of its purchase agreement, BioPort must pay $8.8 million of its debt to the State of Michigan on September 4, 1999.

We believe BioPort's cash flow problem is due to its inability to achieve its overly optimistic business plan. The company's business plan, in addition to meeting DOD's requirements, provided for the sale of anthrax vaccine to other customers. Because renovation efforts are taking longer than expected, vaccine production for DOD as well as other customers has been delayed about 5 months, and expected revenues have not materialized.

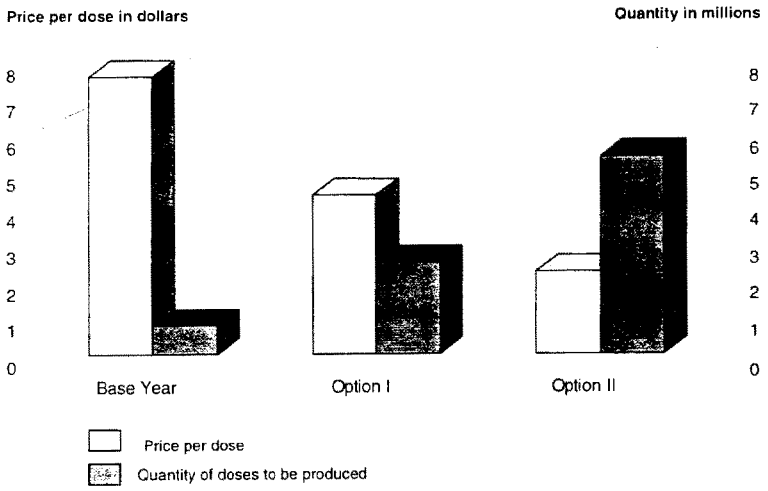
EFFORTS TO IMPROVE BIOPORT'S FINANCIAL HEALTH

BioPort recently requested and received DOD's authorization to sell 70,000 doses of anthrax vaccine to other customers. DOD has approved the sale of 30,000 doses to the Canadian Armed Forces, in part so the company can generate revenues to help cover operating expenses. BioPort intends to sell the remaining 40,000 doses to other potential customers; these sales would also require approval under export control regulations. DOD gave its approval even though BioPort was not fully meeting its contractual delivery requirements. BioPort officials indicated that the sale of the 70,000 doses is expected to generate several million dollars of revenue.

In addition to this short-term action, BioPort has requested that DOD modify its contract to provide for, among other things, advance payments and significantly higher contract prices. DOD and BioPort are now discussing these modifications.

According to BioPort officials, the company is proposing significant price increases because (1) production capacity is less than it was planned to be, (2) costs have increased, and (3) sales to other customers have not materialized as planned. BioPort has informed DOD that it will not to be able to produce all of the 2.5 million doses or all of the 5.4 million doses contractually required to be produced in option years one and two, respectively. As shown in figure 3, the contractual price per dose was expected to decrease as production quantities increased.

Figure 3: Contract Prices and Production Requirements



Source: GAO analysis of DOD contracts.

BioPort's proposed prices are several times higher than current contract prices. Moreover, BioPort is proposing to provide DOD about 3 million fewer doses than contractually required to better reflect its production capabilities and its desire to increase its private sales. According to BioPort officials, the reduced doses will be sufficient to support DOD's immunization policy.

According to DCAA, the company's proposed price for the 2.5 million doses currently under contract is overstated. In addition, the agency found that BioPort's accounting system was inadequate and recommended that any company data submitted in support of the price increase be reviewed to ensure accuracy before any contract price is renegotiated.

- - - -

Mr. Chairman, Members of the Committee and Subcommittee, that concludes my prepared remarks. I would be happy to answer any questions you may have.

Related GAO Products

Combating Terrorism: Observations on Growth in Federal Programs (GAO/T-NSIAD-99-181, June 9, 1999).

Medical Readiness: Safety and Efficacy of the Anthrax Vaccine (GAO/T-NSIAD-99-148, Apr. 29, 1999).

Gulf War Illnesses: Questions About the Presence of Squalene Antibodies in Veterans Can Be Resolved (GAO/NSIAD-99-5, Mar. 29, 1999).

Combating Terrorism: Observations on Biological Terrorism and Public Health Initiatives (GAO/T-NSIAD-99-112, Mar. 16, 1999).

Combating Terrorism: Observations on Federal Spending to Combat Terrorism (GAO/T-NSIAD/GGD-99-107, Mar. 11, 1999).

Combating Terrorism: Efforts to Protect U.S. Forces in Turkey and the Middle East (GAO/T-NSIAD-98-44, Oct. 28, 1997).

Combating Terrorism: Status of DOD Efforts to Protect Its Forces Overseas (GAO/NSIAD-97-207, July 21, 1997).

(707423)

Mr. SHAYS. Thank you very much. Based on your experience reviewing DOD procurement, are the terms that were originally set out generous, and are the terms now overly generous?

Mr. RODRIGUES. Let me try to answer that more in terms of other kinds of contracts that we have looked at, sole-source contracts.

Mr. SHAYS. And you can define generous if you want.

Mr. RODRIGUES. OK. Let me try to deal with this in terms of comparing this to other types of sole-source contracts that we have looked at. It is rather unusual, this was rather unusual to end up with a situation where you have a company whose cost controls are so unreliable that there is no way at all that we could negotiate based on cost. We end up negotiating based on theoretically a price analysis. Yet, when you look at all the details involving this negotiation, it really looks more like a cost-base activity. The cost system, when DCAA looked at it, had been invalidated as appropriate for use in negotiations. Normally, you may be able to go price-base, but you would also have the option of falling back to cost-base pricing if you needed to.

In a high-risk type of endeavor like this, I say it is high-risk from an investment standpoint on our part simply because you had a company that financially wasn't as stable as you might like to have, didn't have a lot of financial resources to carry itself through in the event of any problems occurring. At the time we signed the contract, the plant was closed down. It was being renovated, and had a projected date for re-opening. Some very optimistic kinds of things that needed to happen in order for their financial plans to come through. The company where they are relying on us basically as their only source of funds for the time being and, yet, didn't have the cash reserves to encounter any kinds of problems that ultimately have occurred and affected the delay. This 5 month delay in re-opening the production facility, created a real problem in terms of their ability to sustain themselves. They only put in $3.25 million in cash in the acquisition, didn't have a great deal of funds available.

So this kind of a situation where you have a company who is relying basically solely on this product for its future viability and, yet, we are sitting there with only projections to deal with in terms of when it would be able to reopen, when you would have sales, when you would be able to generate the cash to cover yourself in terms of any unforeseen problems. All of those things would be rather unusual.

Mr. SHAYS. Let me try to put it in a context that I can understand. The DOD determined that its force protection would be—that we would go the route of vaccines and the first vaccine that we would seek to do, concern about use by another country or by terrorists, would be the anthrax vaccine. We make a determination that we are going to make this a mandatory program for all our military and that this is not just one shot, this is up to six shots or more.

Now we have made that determination, we, DOD, and now we go and see who can provide this program to us. Now during the war in the Gulf, we did not have it mandatory I don't think for all of our military personnel but a good number were required to take

the anthrax vaccine. And so we had negotiated an agreement with this plant that was in Michigan and it was owned by the public sector, the State of Michigan. So we had some relationship there.

But in the end, DOD decided to have this program and it went out in a bid process and only one manufacturer responded is my understanding, and that was the State of Michigan. Is that correct so far?

Mr. RODRIGUES. Yes, sir.

Mr. SHAYS. Now then there was concern that the State might not want to hold on to this plant. So there was interaction with the Governor, Mr. Engler, in Michigan to keep this plant running and ultimately that took place. Then it was sold by the State, I think for about $25 million. And then it was obviously generous terms in terms of financing. But they were going to shut it down, and I don't know what the value of the plant would have been if they had shut it down, and these are questions that I would love to know.

But the bottom line is that the DOD decided this program was so important that they were going to go with this manufacturer. And it was sold. It then became a private investment. And DOD has set certain terms what they would do to the plant and also what they would pay per vaccine. And so there was this agreement established.

Now what I guess I want to know is in a circumstance like that where there is really I think one manufacturer in the country, I don't think there was another manufacturer. What options are really available to the military that they can go with that one provider or they can do what?

Mr. RODRIGUES. In this case, because they had an immediate need, and there is only one licensed provider, you really don't have an option. But it becomes a matter of what is your strategy for the future? Do you lock yourself into a single provider and stay with that or do you look to try to establish a second source for—it could be any number of reasons? The problem here is the volume probably doesn't justify, at this point, a second source from an economic standpoint. But if we are relying upon this vaccine as part of the backbone of our defensive biological program, the question of vulnerability to a single site becomes an issue. If you made a decision with respect to that vulnerability that led you to want to have an alternative site, then we probably should be looking at establishing a second source. But it is not going to be cheaper.

Mr. SHAYS. Now one thing DOD could have done, couldn't they, is just simply delayed the decision until they had better options? In other words, they could have decided to begin—they could have even have gone into a contractual arrangement but just not determined to begin the mandatory program as early as they did, correct?

Mr. RODRIGUES. I am not in a position to address that. That has to do with a policy level decision on deciding to vaccinate——

Mr. SHAYS. No, but that clearly is an option?

Mr. RODRIGUES. Well, sure, it would be an option but it would be a policy decision.

Mr. SHAYS. In the cases that you are aware of where there is only one provider, what is usually the options available again? Mr. Dawn, do you want to——

Mr. RODRIGUES. Usually when you have one provider, that one provider in a sole-source environment isn't so dependent on that single product for its financial viability. They usually have other product lines that are generating income and if they run into a problem on this one line, it won't put them out of business. In this case, problems with this vaccine, with the production and delivery of this vaccine to the Department of Defense puts this corporation in an extremely bad financial position. And that is rather unusual.

Mr. SHAYS. I am going to ask you a few more questions about the contract and also in regards to the 70 doses and then I will yield, or not yield, but recognize Ms. Schakowsky, who I welcome. So let me just ask you, what particularly do you find overly optimistic, those were the terms you used, "overly optimistic" about BioPort's business plan upon which DOD based its contract?

Mr. RODRIGUES. Yes, in terms of the optimism, the fact that they had very little cash on hand to be able to sustain themselves in the event of any of their projections—where their income was going to come from and when their source of income was going to come back on line. So they didn't have a lot of cash available to carry themselves in case of unforeseen delay against their plan.

The other thing was the production activity was scheduled to come up in January 1999. If it didn't come up in January 1999, given their limited cash reserves, what were they going to do about that? They were projecting what was going to occur and if it didn't, we were going to start to have problems.

They were projecting sales to others, both of the vaccine itself and of other products that weren't occurring because the plant was shutdown.

And those kinds of things. They were all projections on hopeful sales, hopeful re-start of the line. There is no income coming in, the plant is closed. And if those things don't occur, how do you get through the period where you are not able to deliver products and therefore receive money?

Mr. SHAYS. One of the challenges was they had a best case scenario and you are not aware that they had fall back plans, and you have already stated they weren't capitalized in a way that would enable them to draw on their own—so this is basically, we were rolling the dice and expecting that it had to come out really great and if it didn't, we had a big problem?

Mr. RODRIGUES. Exactly.

Mr. SHAYS. And that is what has happened.

Mr. RODRIGUES. Exactly, Mr. Chairman. And the other part of it was, of course, that they were locked in an agreement with the State of Michigan to continue to employ that full work force for 1 year after the initiation of the contract. So they couldn't deal with downsizing that work force during the period either.

Mr. SHAYS. But the State of Michigan was going to shut down the plant and put everyone out of work, but they have a contract with us, the U.S. Government, that we have to keep them employed and they sold the plant for $25 million?

Mr. RODRIGUES. No, they don't have a contract with us. The agreement between BioPort and Michigan was that they had to continue to employ those people.

Mr. SHAYS. I would love to know what they would have gotten if they shut the plant down. In place of a firm fixed price contract, what would you have recommended as a more workable and appropriate form of procurement?

Mr. RODRIGUES. Clearly, in this type of a situation, a firm fixed price contract isn't the appropriate contract vehicle, some type of cost contract is. But the problem we had was the cost systems at BioPort wouldn't support a cost-based contract. On the other hand, we did nothing to force BioPort's hand and make them come up with a cost control system, not a cost accounting standard kind of compliance system. But at least a cost control system that would allow us to determine allocability and allowability of cost so that it could properly price the product that we are buying. We just deferred to a firm fixed price contract, based on theoretical price analysis. Although when you really look at the record, it really all ties back to cost analysis. And, yet, we know the cost data are no good.

Mr. SHAYS. Basically, part of your testimony is that we really had no factual information on which to base our reimbursement, isn't that correct?

Mr. RODRIGUES. Correct.

Mr. SHAYS. How much was our investment in the renovation?

Mr. RODRIGUES. To date, we have obligated $11.3 million in renovation expansion and another $7.1 million in Government-furnished equipment and direct buy of some equipment by the corporation.

Mr. SHAYS. It is $11 million plus what? I'm sorry.

Mr. RODRIGUES. $7.1 million—$6.8 million in Government-furnished equipment and another $250,000 that we gave to BioPort or provided to BioPort on the contract to buy some holding tanks.

Mr. SHAYS. And that was in the original contract?

Mr. RODRIGUES. Everything but the holding tanks and I believe there was another $191,000——

Mr. SHAYS. Let me just say this, I would prefer if Mr. Dawn has a closer expertise in this to just respond.

Mr. DAWN. Yes. [Laughter.]

Mr. SHAYS. See, I just wanted a simple answer.

Mr. DAWN. As Lou said, most of the money for renovation and the equipment was in the 1991 contract. There were modifications to the 1991 contract, although there was a small piece that was included in the 1998 contract.

Mr. SHAYS. You mean the 1991 and the 1998 contract are interrelated?

Mr. DAWN. Interrelated, yes. The 1991 contract was transferred from the State of Michigan to BioPort.

Mr. RODRIGUES. If I could, Mr. Chairman?

Mr. SHAYS. Sure.

Mr. RODRIGUES. Virtually all of the money was provided as modifications to the original 1991 contract with the State of Michigan. Since BioPort took over, there were two minor modifications, one to move a generator, another one for some electrical changes. Those two totaled $193,000. And then in addition, we provided for equipment—$250,000 for two holding tanks. That was provided under

the 1998 contract to BioPort. Everything else came over with the renovated contracts from the Michigan facility.

Mr. SHAYS. What was the exact arrangement between DOD and BioPort with regard to the sale of the 70,000 dosages? What was the arrangement that was made?

Mr. RODRIGUES. The arrangement was they approved the sale of the 70,000 doses, or they authorized the sale, and they have since approved the sale of 30,000 of those to Canadian forces. The arrangement is BioPort gets the money.

Mr. SHAYS. But they are able to make the sale before they meet their contractual obligations to DOD?

Mr. RODRIGUES. Yes, Mr. Chairman.

Mr. SHAYS. Before means they would still supply to DOD and at the same time supply—or all 70,000 come first?

Mr. RODRIGUES. The 70,000 actually exist. And we had a difficult time figuring out where that 70,000 comes from. But as best we can tell, at the time that BioPort bought the facility, with the facility came, at least 860,000 doses, 790,000 of those were delivered under the base-year contract of the Department of Defense. And, as we understand it, although we are not clear, there must have been an additional 70,000 doses that were available. BioPort claimed that those were unexpected excess production, but there hasn't been any production going on since BioPort——

Mr. SHAYS. Yes, which is going to be my last question. How can we determine that the 70,000 doses makes sense and that they are in excess of what DOD requires? And I am making an assumption right now, since we don't have production, we need it.

Mr. RODRIGUES. It is my understanding that the Department, with the stocks on hand, has enough to carry them through and that the approval of the 70,000 doses was, in effect, to provide some financial relief of the corporation, allow them to sell it. Does the Department still have a requirement for that dosage? Yes. Do you need it today in order to do the vaccination program? I believe the answer is no.

Mr. SHAYS. So your testimony is that the program is operating without interruption, that we are keeping up to exactly the plan that we intended to?

Mr. RODRIGUES. That is my understanding right now.

Mr. SHAYS. Well, that raises the question to me then that if the production isn't—I thought that one of the problems that BioPort has said is that they don't have production, therefore, they don't have income. But they do have income. They have this backlog of vaccines, dosages, that they are able to sell, correct?

Mr. RODRIGUES. Well, yes, the 70,000.

Mr. SHAYS. They had 800,000-plus?

Mr. RODRIGUES. Right, and they have delivered that and been paid for it and those funds are gone too. And that you could have seen in the projections that are coming as well. Their cash reserves plus assets on hand with the sale prices that they had, if you ran into problems, you still had this potential financial problem that they are having to deal with right now.

Mr. SHAYS. Let me recognize Ms. Schakowsky. But, first, let me ask unanimous consent that all members of the subcommittee be permitted to place an opening statement in the record and that

record remain open for 3 days for that purpose. And without objection, so ordered. And I ask further unanimous consent that all witnesses be permitted to include their written statement in the record. And without objection, so ordered. You are on.

Ms. SCHAKOWSKY. Thank you. I find this whole situation quite disturbing that since 1988, the DOD has provided about $112 million to help ensure the viability of the BioPort facility. I am talking about funds to produce the vaccine, renovate and expand the facility, provide support services, purchase equipment to enhance production capability. And I know we will get into this more later, but DOD has also indemnified BioPort against product liability claims and, yet, they are in a cash-flow crisis right now, in part because are all the lines shut down? Are they producing at all?

Mr. RODRIGUES. They are back up right now. But they were 5 months behind where they should have been.

Ms. SCHAKOWSKY. Right. And even though the procurement contract between DOD and BioPort is only 9 months old, I know that the GAO has reported that BioPort already has requested modifications to the arrangement. First they asked to be permitted to charge DOD more than originally negotiated in the contract and this proposal is designed to address, I am sure at least in part, the cash-flow problems that BioPort has experienced. It justifies this increase on lower than expected production capacity, increased costs, and the failure of sales to other customers to materialize as planned.

I wanted to ask you, you stated that BioPort is also proposing to reduce the number of doses it is required to provide DOD under the contract by $3 million. Will these doses be provided at a later date?

Mr. RODRIGUES. I would assume the Department would want those at a later date. You are going to have to ask the Department's representatives. And, once again, the Department of Defense, to my knowledge, has not agreed to any of these proposals at this point.

Ms. SCHAKOWSKY. You mean any of the modifications of the contract?

Mr. RODRIGUES. These are BioPort proposals.

Ms. SCHAKOWSKY. Right.

Mr. RODRIGUES. And they are, as I understand, in discussion with the Department on these issues now.

Ms. SCHAKOWSKY. So all of the questions I was going to ask regarding price increases because essentially we do see the number of doses as essentially a price increase, are these better directed where?

Mr. RODRIGUES. Certainly, you can ask the Department. Let me talk to that a little bit. One of the problems that you have is the quantities that were in that contract, it was 2.5 million doses for option year one, which is the current year 1999, and 5.4 million doses for option year two, which is year 2000. Those quantities were based on all production being deliverable. And what we find is that usually at the outside, 80 percent of the product produced would actually be deliverable. So the estimates were already high to start with and BioPort saying, "Well, we can't produce at those rates, can't deliver at those rates," whether you can produce is a

different issue. So they are looking for relief from the quantities. And their position is it wouldn't affect the Department's inoculation program plan. So I think the Department would be better able to answer that. It does appear that they could make adjustments if they chose possibly, but you are better off asking them.

But the fact of the matter is it was rather optimistic in terms of getting the quantity specified under the contract actually delivered out of that facility.

Ms. SCHAKOWSKY. But essentially we are talking about a third fewer——

Mr. RODRIGUES. Yes.

Ms. SCHAKOWSKY [continuing]. Being made available. So how can we possibly even think about achieving the same goals with a third fewer doses?

Mr. RODRIGUES. If you are talking goals in terms of price?

Ms. SCHAKOWSKY. In terms of serving DOD's needs?

Mr. RODRIGUES. Right.

Ms. SCHAKOWSKY. And price?

Mr. RODRIGUES. On the price side, you do have fewer doses but what they wanted to do is substantially increase their sales to other customers with a lot of the cost being shifted to the commercial sale side of the house. Clearly, with lower production, you are going to end up with higher unit prices. But they were going to increase their sales to their other customers, which should allow us to keep some kind of control on the price increases.

Ms. SCHAKOWSKY. Has anyone at GAO compared the original contract terms with the terms that BioPort is now proposing? In other words, how much did DOD originally agree to pay for 8.8 million doses, including renovations and equipment and all other DOD funding?

Mr. RODRIGUES. Yes, ma'am. As I said, the prices that are being proposed are substantially higher. The data we have has been marked proprietary by the company, so I can't give you the exact numbers. But they are a great deal higher than the prices that have been negotiated in the contract.

Ms. SCHAKOWSKY. So if DOD accepts all of BioPort's proposals for decreased supply and increased price and advanced payment, how much will we be paying for 5.8 million doses?

Mr. DAWN. Well, we can say that it will be several times more than we are paying now.

Ms. SCHAKOWSKY. Several times more than we are paying, two, three? Three is usually several.

Mr. RODRIGUES. Several. It is more than two.

Ms. SCHAKOWSKY. More than two. Less than four?

Mr. RODRIGUES. The problem is if I give you the exact multiplier, than I am going to be giving you the price and we are getting into this issue of proprietary data at this point.

Ms. SCHAKOWSKY. Thank you.

Mr. SHAYS. Let me just ask one or two other questions. The bottom line is we have a program that our DOD has determined is necessary to protect our soldiers. And we are going to require 2.4 to 2.7 million men and women to take a vaccine some of them don't want to take. In Great Britain, it is voluntary and in France, they are not touching it. They are going more toward protection with

protective gear. The negative of that is that some biological agents you don't detect until they have already killed you or have caused serious injury. The plus is that the protective gear can protect you from more than one form of attack. So we have variations here.

The DOD has determined they want this program and they want it so bad that they have agreed to a sole-source provider who is under-capitalized, using what is old technology, in the sense—excuse me, an old licensed product that could be made better but that takes time. Rather than waiting to have this product improved and to have more options, they decided to jump right in. We have a situation now where BioPort, under-capitalized, is not able to meet the requirements.

What options, as you look on the outside are available to DOD because from my standpoint it seems to me BioPort basically can say, "You don't like it, then that's the breaks." And DOD is faced with well, we think it is an important program. We better meet their demand or we are going to have to go somewhere else and they have nowhere else to go. So tell me under those circumstances what options are available?

Mr. RODRIGUES. First of all, I wouldn't want to leave you with the impression that only BioPort has all the cards to play. The fact of the matter is if we don't buy that vaccine from them, they don't have a customer to keep them in business.

Mr. SHAYS. Right.

Mr. RODRIGUES. It is a mutual dependency at this point. So the Department has quite a bit of leverage, I think. Now how they use it, that's a different issue and you can certainly address that with the people who will follow us here at the platform. But it isn't BioPort that has us over a barrel and we have no leverage with it to use. We do. The company, if it wants to continue, needs the Department at this point for sales.

The other thing is this is a licensed item which requires approval by the Department of Defense. They are also manufacturing it off of equipment rent-free so they have to have approval from the Department of Defense. So we do have quite a bit of leverage on the Department side too in dealing with this issue.

Mr. SHAYS. So if you were advising the military, they should—I am being somewhat facetious, but, frankly, the more important they say this program is, the more they are basically saying we are going to make a deal? I mean the bottom line is we are saying it is an essential program. It is so essential, we are willing to have good men and women resign from the force because they refuse to take it. And we feel so strongly evidently that it is worse losing good men and women, who out of conscience don't want to take this, and that says, if I am BioPort, that I have a very willing buyer. But your point is if they back off, BioPort goes out of business and they lose their relatively small investment given the amount of production costs and so on. It is a very small investment for them.

Mr. RODRIGUES. Yes, it is.

Mr. SHAYS. The other thing that BioPort got though was they got indemnification, correct?

Mr. RODRIGUES. Yes.

Mr. SHAYS. Have you been able to ascertain what the value of that was?

Mr. DAWN. There wasn't a cost assigned to the indemnification clause, no.

Mr. SHAYS. So we don't know technically what our liability is?

Mr. DAWN. No, not technically.

Mr. SHAYS. It could potentially be billions or millions or hundreds of thousands, depending on what effects happen in the years to come. So the only risk that BioPort has basically now is their initial investment?

Mr. RODRIGUES. Yes.

Mr. SHAYS. OK. Do we know how much more money they have put into the program?

Mr. DAWN. They have put in a little over $1 million in owner's financing.

Mr. SHAYS. In addition to the $3.5 million?

Mr. DAWN. In addition to the $3.25 million.

Mr. SHAYS. And we still do not have clear accounting records to justify——

Mr. DAWN. Any cost increase or price increase.

Mr. SHAYS. Correct?

Mr. DAWN. That is correct, yes.

Mr. SHAYS. Is it GAO's recommendation that we absolutely get that first before we make any agreement?

Mr. RODRIGUES. I think, in whatever negotiations go on, that we need to hold the line on the company establishing the cost controls that we will need to properly price this in the future. I am not sure if you can say—it depends on the Department's needs and that is rather unclear to me. But if you have an absolute need—or the other part is the financial viability of the company, they have a need to sell this product in order to remain financially available. It is in the Department's interest to keep them going in order to support their program, then you would have to continue on in some kind of contractual relationship. But we should be using whatever opportunities we have to get the company to establish the proper cost controls so that we would then be on a basis to better deal with the pricing of this product.

Mr. SHAYS. I would be happy to recognize Ms. Schakowsky?

Ms. SCHAKOWSKY. Thank you. I wanted to followup a bit on this liability question. First of all, I wanted to ask you if it is a typical arrangement for the Department to indemnify a contractor, a vendor against liability claims?

Mr. RODRIGUES. It isn't unusual on this type of a product.

Ms. SCHAKOWSKY. It is not unusual?

Mr. RODRIGUES. Not unusual.

Ms. SCHAKOWSKY. Well, then so what measures accountability for quality control, particularly given the history, very recent history of this company on vaccine stockpiles and newly produced anthrax vaccine exists, what kind of accountability would exist? It would seem to me that given the relatively small investment on their part, a large investment on our part and their history, that we are at risk here?

Mr. RODRIGUES. The controls are mostly in the form of the FDA approval process, the process itself to make sure that the outputs

are appropriate, that the vaccine is a good vaccine, and then the testing of the deliverable items to make sure that it meets the standard. The indemnification isn't really directly related to that. You would still want to make sure that even if they were getting insurance to indemnify themselves that the product was a good product.

Ms. SCHAKOWSKY. There was a story today in the Hartford Courant, concern over anthrax where it says, it quotes Army Secretary Louis Caldera to the Michigan-based manufacturer of anthrax vaccines, that says as a result of "the unusually hazardous risks associated with the potential for adverse reactions in some recipients, that DOD would take responsibility for indemnifying the product." Can you give us any other examples of situations where the Department in situations like this has indemnified against liability, another company?

Mr. RODRIGUES. I am sure I could provide some for the record. I don't have them off-hand. But I think if you would look at this type of activity in general, commercial vaccines, there is a cost built into the item, into the charge for the item itself, that goes into an indemnification fund. The problem with the indemnification issue, as we are looking at, it is one where you do not want to have yourself subject to a lot of lawsuits, not whether you lose them or whether you would actually be found guilty, but whether you would find yourself in court all the time because people have adverse reactions to vaccines. And so there is this whole thing with vaccination programs and indemnification that is an issue for any kind of vaccination program.

In this case, the Department, virtually the only buyer, would have a choice, it would seem to me, of either paying 100 percent of the cost of the indemnification or self-indemnifying. And you certainly can ask them about their decision but indemnification has to occur somehow, either in the form of having some kind of insurance or paying an additional cost to cover that.

Ms. SCHAKOWSKY. But the question is who takes the risk? And in this case, it seems that at every stage along the route in terms of money that had to be laid out, risks that had to be taken, that it was the taxpayers that are paying out?

Mr. RODRIGUES. And I think any time you find yourself as virtually the sole buyer of an item, you are going to incur the costs. It isn't as though at this point in time, or the point in time the Department entered these contractual relationships, that there are a whole bunch of people lined up with contracts to buy this so that they are selling large volumes to other people. We were virtually the market. And when you are the market, you incur the costs. There is no sharing, there is no pooling. It is not like a warranty on your car where you are buying one of several million cars and the warranty costs are pooled.

Ms. SCHAKOWSKY. Did the GAO look at or were there ever any situations where since we take all the risks, put in much of the investment, that the DOD would just own and run the company so that we could impose our own controls and do it our own way? Was that ever considered?

Mr. RODRIGUES. Yes, there are Government-owned contractor-operated facilities. Could you do that? Yes. I don't know what the De-

partment's position is on that. I think Mr. Oliver would be in a much better position to address that.

Ms. SCHAKOWSKY. Thank you.

Mr. SHAYS. Let me just end by talking about that memorandum of decision that was signed by the Secretary, Louis Caldera, on September 3, 1998. And he talks about the obligation assumed by MBPI, which is the Michigan Biologic Products Institute, which was the predecessor to BioTech—BioPort rather. And it says, "The obligation assumed by MBPI under this contract involves unusual hazardous risks associated with the potential for adverse reactions in some recipients and the possibility that the desired immunological effect will not be obtained by all recipients." So basically you can sue if you have bad effects and you can sue if it doesn't protect you.

And then I am looking at a document from the Department of Army dated earlier, April 7th, and it talks about the cost of insurance. This is a memorandum that was, its subject is addendum to the contract officer's request for authorization for indemnification under the authority of public law, so on. But it was dated April 7th. And it says, "Cost of insurance: The maximum amount of insurance MBPI has been able to identify to date is $35 million with premiums at $446,820 a year." Now $35 million is just a drop in the bucket and yet it would have cost them close to a half a million dollars a year. But then I make the same assumption that we have put ourselves at risk and multiply the number by 10 just to even have a protection of $350 million, which in this kind of area—that would probably be a small amount. And even there it would cost us like $4.4 million.

So it is fair to say that DOD wants this and they could withdraw it and BioPort is left out in the cold. But in this case, the argument before is that BioPort has made an investment. The investment has not turned out right and they are asking the Federal Government to bail them out. And you are telling me that we have the ability to—that we have options. It doesn't strike me that we have much option unless we decide to postpone this program until we get it right, until we know we have a product that we are more comfortable with and until we know it is the right policy. And even if we think it is the right policy, it may be the right policy but maybe now isn't the time because we don't have a producer who can provide the product we want at a price we think is right. And I guess these are the questions that we will need to address to our next two witnesses. And you have obviously provided us a wonderful introduction to this issue.

Mr. RODRIGUES. Thank you, Mr. Chairman.

Mr. SHAYS. Is there anything, Mr. Dawn, anything you would like to say? I felt like some of these questions, you wanted to jump in?

Mr. DAWN. No, sir.

Mr. SHAYS. You are all set? OK, I don't want to hear later that we should have asked you a question. Is there any question that we should have asked you, Mr. Rodrigues, that you feel needs to be on the record? You can ask the question and answer it. What question would you ask yourself?

Mr. RODRIGUES. I was just thinking through on your last statement. In dealing in the issue of not going forward with anything with BioPort, once again, the problem the Department would face then is that this company is dependent upon the Department for its future. It will not exist, financially, it doesn't look as though it could exist, if the Department chose to no longer buy any anthrax vaccine, if that is what they choose to do. If that is true, while you search for other options, and if the other options take an extreme amount of time, you now have lost your only source. And I think that's the dilemma the Department is faced with and you may want to address that with the witnesses that follow.

Mr. SHAYS. Thank you very much. We will go to our next panel and invite David Oliver, Jr., Principal Deputy Under Secretary of Defense for Acquisition Technology, U.S. Department of Defense, accompanied by General Ronald Blanck, Surgeon General, U.S. Army. And testimony by Fuad El-Hibri, chief executive officer, BioPort Corp. And that is in Lansing, MI, accompanied by Robert Myers, chief operating officer, BioPort Corp.

We will have testimony from both the DOD and BioPort and invite the others to participate as well.

I will ask you to remain standing and I will swear you all in.

If you would raise your right hands, please?

[Witnesses sworn.]

STATEMENTS OF DAVID R. OLIVER, JR., PRINCIPAL DEPUTY UNDER SECRETARY OF DEFENSE FOR ACQUISITION TECHNOLOGY, U.S. DEPARTMENT OF DEFENSE; GENERAL RONALD B. BLANCK, SURGEON GENERAL, U.S. ARMY; FUAD EL-HIBRI, CHIEF EXECUTIVE OFFICER, BIOPORT CORP., LANSING, MI; AND ROBERT C. MYERS, CHIEF OPERATING OFFICER, BIOPORT CORP., LANSING, MI

Mr. SHAYS. Mr. Oliver, it is my understanding you will give the testimony and General Blanck will participate in responding to questions?

Mr. OLIVER. Yes, sir.

Mr. SHAYS. And, Mr. El-Hibri, my understanding is you will have testimony and that Dr. Myers will respond to questions, as well.

One of the things I would just suggest is that I think you have a sense of the questions we have, and happy to have you give your testimony, but if you can also respond to some of those questions, that will also probably be helpful.

Mr. El-Hibri, I think your written testimony was quite good, but it was somewhat lengthy because you responded and made some general comments and then you responded to each question. And we would want to keep you within 10 minutes. We will take 5 and then we will rollover. So I will let you figure out how you want to divide up your testimony, but it was very helpful and it is all on the record.

Mr. Oliver, we will start with you.

Mr. OLIVER. Yes, sir. I have submitted my written testimony, Mr. Chairman. The substance of the issue from the Department of Defense's point of view is there is a threat, which the Joint Chiefs of Staff have identified to the Secretary and asked the Secretary to

address. We have a safe vaccine to solve that threat. And that vaccine is also effective.

I am comfortable with the facility that produces that vaccine. I think the program is on solid ground, and I am anxious to address many of the questions you asked the previous witness because I am the source to whom those should be addressed.

And I am ready to answer any of your questions, sir.

Mr. SHAYS. Is that the extent of your testimony?

Mr. OLIVER. Sir, you have my testimony.

Mr. SHAYS. Right, but do you want to orally——

Mr. OLIVER. My testimony essentially answers your questions. It says that I saw no problem in the buying. Essentially, what we had was the State of Michigan for 70 years has owned a facility that produced the vaccine and for good reasons because they started it when they found out that their children were not being vaccinated. And they kept it, and this is an important issue because it goes to indemnification, is that particularly during the late 1970's, early 1980's when the drug companies in this country plummeted because of suits against the drug companies and then the Congress stepped in and passed indemnification for all the commercial drug companies, which was a wise thing to do because otherwise they wouldn't exist. And at that time, during that time, the State of Michigan, as you may recall, saw even more reason to have this because they had found out they could not buy any protection for the children. And so they kept that on-line.

Subsequently, when they looked at it, and I think the Governor was very wise because he looked at this as Government-operated and Government-owned issue, and he decided he was losing money, let us say on the order of $5 million a year. And he is absolutely right because every time you have a Government-owned, Government-operated facility, there are all sorts of indirect and backdoor methods by which money goes into it, so you have no idea what the bottom line is. The good thing about industry, a couple of good things, is, one, there is a bottom line; and, two, they know what their costs are and they end up finding out what their costs are and that is important, which you frequently do not in Government-owned operations.

If you look at the history, in fact, the State of Michigan has been funding the U.S. Defense Department for several years and that is not right. The State of Michigan has been providing funds for the U.S. military indirectly through the fact that BioPort was running a loss. I do not think anyone knew how much. And then we were buying equipment at below market rates. So the Governor decided to get rid of that, and I think that was a wise thing. He established a commission. I talked to the head of the commission. I reviewed all the records of all of their findings. I think they conducted a good sale. They ended up with two people who bid approximately the same amount within a couple of hundred thousand dollars. And they decided to sell to one.

Now I have determined from looking at the records and talking to people, and the General Accounting Office says the same, that there is no indication that the Defense Department was involved in that sale inappropriately, other than the fact on a couple of

things, which are included in my testimony, we provided encouragement to the Governor, et cetera and said we are interested.

There is no indication that the State intended to close that down. The State intended to sell it because they decided they no longer had a need. The State was last in the country in a number of immunizations for children. It was costing them more to have it done by BioPort than it could be done by the rest of industry. And, in fact, Michigan was the only State that had its only facility producing immunizations. So they made a very wise decision. But they intended to sell it. They had two willing bidders. Both of them offered the same amount approximately. The State decided to sell it. We stayed hands off of that because that was the decision between the State and a private investor.

And then after that, we needed to resolve whether or not the price is right. I went out there, I was sworn in on June 1 of last year. I was in BioPort within a month because I wanted to look at it. I was comfortable with the situation. I was impressed with the gentleman who was running it, Mr. Bob Myers. I thought the security was—which had just been checked on several world-class inspections. I thought the way the anthrax serum or vaccine was stored was safe. I looked at the facility. There were some things I wanted to change because I believe if you are not improving, you are not staying the same. And we proceeded on and we are paying attention to that.

I went back about 6 months later, and I forget why, but for some reason I was there, and at the time, I became concerned that I was not sure—they had done some good things. They hired some good people. I am really impressed. The situation is better now with a private company running it than it was with the State of Michigan. And that's obvious. And that is because the State of Michigan was not interested in investing more money in an area in which they decided was not in their best interest. The company has invested more money. And, more importantly, they have hired some good people. They have hired good people. They now have good people, in my opinion, better people doing quality control, better people doing their processes. I talked to those people. I am comfortable with those people. I think they are on their way to significant improvement. I looked at the new facility. I like the new facility. I like the fact that the gauges are calibrated properly. I like the type of equipment they put in. That is working.

But at the same time, I was concerned that I did not think we had written a good contract with them with respect to price and you spent a great deal upon that in the earlier conversation. I am convinced—I went back and talked to various people, I am convinced that neither BioPort, now this is a company that operated for 7 years with the State government and, if my hypothesis is correct, what I am telling you is they don't tend to know what the stuff costs. And you only know that when you sever it and cut everything off and make it a private company. BioPort did not know what their product cost and the people who negotiated the contract did not know what the contract cost. The contract is in the order of over the life of the contract, something like roughly $3.50 a dose.

I have two references. One was a study done a year and a half ago for me or my office about a year ago that said that they

thought the price of that would be $12, in excess of $12 with 1 percent profit for the company. And at the time this was done, the contract was written, there was independent Government cost estimates that each dose should cost $7.50 a piece. If it is costing you $7.50 and you are getting paid $3.50, it is tough to make up that difference on volume.

Now the problem is I don't think BioPort knew what it was costing and I don't think the Government—the person who did the contract knew what he was doing. He was just trying to do the best thing for the Government without paying attention to the fact that if he drove this company out of business or caused them to fire some of those good people that we have met, that I have met up there, then the product quality would decrease.

So I am not uncomfortable with—I don't know what is going to happen with the change of price. I know that BioPort has come in with a request. I personally did not read that, but passed it to my staff who are looking at it because I have two hats, one of which is I am going to provide what the Secretary of Defense and the chairman of the Joint Chiefs of Staff think is necessary for the troops on one hand. On the second hand, I have the responsibility to make sure that the taxpayers are not charged extra and the Government has the right deal. Have a group of people working, as I told you, staff. They are working on it. They are going to come up with options. I do not know what those options are. They will come forward to me. And what I can assure you, Mr. Chairman, is that whatever decision we make will be made in the best interest of the U.S. taxpayers and the U.S. Government, including the Department of Defense but I have no idea what those are.

[The prepared statement of Mr. Oliver follows:]

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ON NATIONAL SECURITY, VETERANS AFFAIRS,
AND INTERNATIONAL RELATIONS

STATEMENT OF

THE HONORABLE DAVID R. OLIVER, JR

PRINCIPAL DEPUTY UNDERSECRETARY OF DEFENSE
(ACQUISITION AND TECHNOLOGY)

ON ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP)

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INTERNATIONAL RELATIONS.

Introduction

Chairman Shays, Representative Blagojevich and Distinguished Committee Members, I am honored to appear before your Committee today to address your questions regarding the Anthrax Vaccine Immunization Program (AVIP).

I am Mr. Dave Oliver, Principal Deputy Undersecretary of Defense (Acquisition & Technology), Office of the Secretary of Defense. I have been in my present position since June 1, 1998.

My office is responsible for the development and acquisition of all materiel, of which the anthrax vaccine is one component, for the Department of Defense (DoD). With me today LTG Ron Blanck, the Army Surgeon General, who is responsible for execution of the Departments Anthrax Vaccine Immunization Program.

Department of Defense Relationship with the Michigan Department of Public Health and Its Successors / Sole-Source Contract Awards

The Department of Defense has had a contractual relationship with the Michigan Department of Public Health (MDPH) and its successors, the Michigan Biologic Products Institute (MBPI) and the BioPort Corporation. This contractual relationship was established for the procurement of the only Food and Drug Administration (FDA) licensed anthrax vaccine and the renovation of facilities to ensure continued availability of the vaccine product.

A competitive solicitation was issued in May 1988 for anthrax vaccine production with only one responder, the Michigan Department of Public Health. An award was made in September 1988 to the Michigan Department of Public Health for 300,000 doses of anthrax vaccine (Contract No. DAMD17-88-C-8242 for $2.1M). The Food and

Drug Administration confirmed that the Michigan Department of Public Health was the only establishment holding a FDA license to manufacture the anthrax vaccine.

Contract No. DAMD17-90-C-0159 for $4.7M (10 lots @70,000 doses per lot) was a sole-source award to the Michigan Department of Public Health in September 1990, to allow for the immediate scale-up of FDA licensed anthrax vaccine production in support of urgent DoD requirements resulting from Operation Desert Shield. The Justification and Approval (J&A) cited as the reason for the award, both the urgent need requirement and the fact that the Michigan Department of Public Health was the sole FDA licensed producer of anthrax vaccine.

In May 1991, a competitive solicitation was again issued in an effort to generate alternate sources for the production of 6.3 million doses of anthrax vaccine. Two responses were received, one from the Michigan Department of Public Health (MDPH) and one from Program Resources, Inc. (PRI) which would have used existing facilities at the National Cancer Institute (NCI), Ft. Detrick, Maryland in cooperation with MDPH under their existing license. PRI was to have produced bulk product, which would then be shipped to Michigan for filling and testing. Both bidders were awarded contracts. With the end of the Gulf War, the urgent need requirement for anthrax vaccine was no longer valid. Subsequently it was determined that the necessary FDA-recommended improvements to the PRI-NCI facilities were not cost-effective and PRI's contract was terminated, with continued production falling to the Michigan Department of Public Health under their $33.5M contract (DAMD17-91-C-1139)

Contract DAMD17-98-C-8052 was a sole-source award to BioPort in September 1998. This Firm-Fixed Price contract was for 790,000 doses of anthrax vaccine for $6.004M, with options for an additional 2.5 million doses for $10.9M and an additional 5.4 million doses for $12.204M. The J&A for other than full and open competition cited MBPI as the sole FDA licensed producer of anthrax vaccine as the reason for the award. Preparing a J&A is the standard method used within the Federal government to document the need for a sole source contract award. Notice of the intent to award a

sole source contract is then published in the Commerce Business Daily so that any party that might be interested in performing the contract has an opportunity to respond. No responses were received.

Two other contracts were awarded since 1991 as follows:

- Contract DAMD17-97-D-0003 ($8.5M) – Sole-source award to the Michigan Biologic Products Institute for the storage, testing, and preparation for shipment of anthrax vaccine being produced
- Contract DAMD17-97-E-0004 ($25K) – Sole-source award to the Michigan Biologic Products Institute for the maintenance of Government Furnished Equipment (GFE) and property

Department of Defense is again examining the feasibility of developing an alternate anthrax vaccine production source. Two options are currently being explored: 1) BioPort would develop a second site under its current license; and 2) a contractor other than BioPort would develop, license, and produce a new anthrax vaccine. The studies are in progress and the results are not yet available.

Licensing a second facility to produce anthrax vaccine is a very complex and time consuming endeavor. It requires new construction or renovation of an existing facility, training of qualified staff, production of consistency lots to qualify the equipment and production process, and completion of clinical studies on the safety, formulation of the doses' strength, number of shots required for protection, and the equivalent immunogenicity of the new vaccine. These steps are required to meet the stringent Food and Drug Administration requirements for the licensing of any vaccine. Another factor is that the current vaccine (AVA) requires a dedicated production facility since it is a spore-forming organism. Under current FDA regulations, the AVA manufacturing suite and related equipment cannot be used to manufacture any other biologic product.

The relatively limited quantities of anthrax vaccine required by the Department of Defense, the high investment cost to license a dedicated production facility, and the time required to meet current FDA licensing requirements do not provide sufficient incentives for other manufacturers to produce the anthrax vaccine.

Department of Defense Role in the Sale of BioPort

The Department of Defense was not a party in the sale of the Michigan Biologic Products Institute to BioPort. The Michigan Biologic Products Commission was responsible for executing the sale to BioPort. The Department's only role was to emphasize the importance of the vaccine in support of national security. To this end the following correspondence occurred between the Department and the State of Michigan

- On 13 January 1998, the Joint Program Manager for Biological Defense, Brigadier General John Doesburg, wrote Governor John Engler to reinforce the importance of maintaining Michigan Biologic Products Institute's production and storage capability.
- On 15 January 1998, Governor Engler wrote Secretary Cohen to assure him of his personal commitment to support the Department of Defense immunization policy ensuring the continued viability of the production and storage capabilities of the Michigan Biologic Products Institute. He stated, howeverm that he counld not guarantee that the transition to private industry would occur before the 18 February 1998 deadline, (the two year point for mandatory date for dis-establishment of MBPI, in the absence of action by the Michigan legislature) and solicited Secretary Cohen's support for the prompt passage of State legislation for an extension.
- On 21 January 1998, Brigadier General Doesburg briefed the Michigan Legislature on the importance of the Michigan Biologic Products Institute to the national defense and stressed the importance of extending the deadline to keep the Michigan Biologic Products Institute a viable entity.

- On 10 February 1998, Secretary Cohen sent Governor Engler a letter stating his support for the Governor's efforts to extend the deadline and avoid disruption of work under the Army contract.

Formal transfer from State control to private ownership by BioPort was completed on 5 September 1998. Prior to finalizing the sale, BioPort submitted an Exon-Florio package to the Committee on Foreign Investment in the United States (CFIUS), Department of the Treasury, informing them of the proposed acquisition of Michigan Biologic Products Institute by BioPort, which is 64% owned by Intervac, L.L.C., a Maryland company, much of which is owned by a Netherlands Antilles company. The CFIUS review, which was coordinated with the Department of Defense (Office of the Deputy Under Secretary of Defense (Industrial Affairs and Installations)), determined there were no issues of national security sufficient to warrant an investigation under Section 721 of the Defense Production Act. The Department of Defense advised the CFIUS that, in their opinion, the anthrax vaccine was International Traffic in Arms Regulation (ITAR) controlled. BioPort was notified of the results in an official letter from CFIUS on 20 August 1998. The fax cover that accompanied the letter noted the Department of Defense comments and reminded BioPort of its responsibility to comply with U.S. export control laws and regulations with regard to the vaccine.

Government Furnished Equipment and Facilities Renovations

The total value of all renovations and Government Furnished Equipment funded by the Government since 1991 is $11.3M. Of this amount, $3.7M funded anthrax vaccine Production Suite Renovations, and $7.6M funded other facility renovations that support the production, testing, and stockpiling of the anthrax vaccine. Total value of industrial plant equipment and real property owned by the Department of Defense and reflected on DoD Form 1662 (DoD Property in the Custody of Contractors), dated October 30, 1998, is $6.9M.

Included in the renovations were the procurement of equipment, establishing a Biolevel Safety - 3 animal facility, renovating the anthrax production suite, upgrading the cold room storage facility, renovating the filling and packaging suite, installing a backup generator, and upgrading the security capabilities of the BioPort facility.

These renovations and upgrades are necessary to maintain a strong infrastructure that will meet all FDA regulatory requirements for the continued production of a licensed vaccine. All of these projects were initiated when the contractor was a state agency, either the Michigan Department of Public Health or the Michigan Biologic Products Institute. No Department of Defense funded renovation projects or equipment acquisitions have been initiated with the BioPort Corporation, although a small amount of funds (approximately $191,000 of the total $11.3M) was placed on contract after BioPort acquired MBPI.

The rationale for financing facility improvements and other improvements as part of these contracts is that the renovation projects are considered a necessary part of the anthrax vaccine procurement. The principal purpose of the contract actions was for the procurement of anthrax vaccine, and the greater proportion of the funding is for the purchase of the vaccine. DoD provided government furnished equipment to contractors for a variety of reasons, including supporting industrial preparedness programs or when it is in the public interest to do so. At this time, we have about $9B of government owned industrial plant equipment and real property in the possession of DoD contractors.

Conclusion

Anthrax Vaccine Adsorbed (AVA) is a vital product for protecting our Service members against the lethal threat of anthrax. The Department of Defense is working with BioPort, currently the only Food and Drug Administration licensed manufacturer of the anthrax vaccine, to ensure the viability of the facility with the production capability to provide a sufficient supply of the vaccine to meet Department of Defense requirements.

Mr. SHAYS. Thank you, Mr. Oliver. Just to comment before I recognize Mr. El-Hibri, You have outlined clearly you think there is a threat and you think it is a safe vaccine. And then you said the program is on solid ground. The one thing we all know is the program isn't on solid ground. We have big problems. And if you even look strangely at my making that statement raises big concerns. If you had said to me, "I think there is a threat. I think the vaccine is safe, but we have got problems with the program,"

I would say, well, that is a fair analysis. So I take strong issue with your saying the program is on solid ground. The program isn't on solid ground. We don't have the production at the level it is supposed to. We agreed on a price. They have come in for more.

And then when you say the private sector knows the bottom line and knows it costs, that's true. And if they don't recognize their bottom line, they are out of business. In this case, they didn't know what their bottom line was and they didn't know what the cost was. And the Government is trying to sort this all out.

So, no, this isn't a program on solid ground. There are big problems with the program. And the one thing I have to be careful of is, in the process of not liking and having questions about this program, that I don't advocate that my colleagues go in a direction that might not be wise. And so it is an open question on whether we should have this program, whether it should be mandatory or voluntary or whether if it is mandatory, it should be only for those who are really in the theater.

Mr. OLIVER. Mr. Chairman, may I respond? By solid ground, what I mean is this, there is enough vaccine in existence that if the company does not get up and produce before about August of next year, there is still enough vaccine to provide the doses to the soldiers, sailors, and airmen to protect them through that period without interruption if the company doesn't produce anything. That's one.

Second, the company is producing the product right now. Now when we get through, and essentially I have got people there checking, looking at the thing for quality, and shortly, I am going to put somebody there from the Defense Contract Audit Agency to try to work on their recordkeeping and also somebody from the Joint Program Office who is going to supervise and be concerned about the quality control because I do not want to tell you that this is operating as effectively as General Electric right now because of the money.

Mr. SHAYS. No, but that is an understatement. It is not operating well.

Mr. OLIVER. I am just trying to give you why I said that I was comfortable with it.

Mr. SHAYS. OK, we just have a different terminology on solid ground. It is not on solid ground. You want it to get on solid ground. But we will talk about that.

Mr. OLIVER. OK.

Mr. SHAYS. Let me just have Mr. El-Hibri. Am I pronouncing your name correctly?

Mr. EL-HIBRI. Yes, you are.

Mr. SHAYS. It is nice to have you here and thank you for coming.

Mr. EL-HIBRI. Mr. Chairman——

Mr. SHAYS. I need you to put the microphone a little closer. Thank you.

Mr. EL-HIBRI. OK. Mr. Chairman and distinguished members of the subcommittee——

Mr. SHAYS. Just turn the microphone a little toward you. Yes, thank you, sir. Can you still see your statement?

Mr. EL-HIBRI. Yes, I can, thank you.

My name is Fuad El-Hibri and I am the chief executive officer of BioPort Corp., a bio-pharmaceutical company headquartered in Lansing, MI.

I have been asked to discuss, from BioPort's point of view, the procurement activities related to the purchase of anthrax vaccine by DOD. Joining me is Dr. Bob Myers, our chief operating officer.

BioPort purchased the lab from the State of Michigan on September 5, 1998. For 30 years, the State of Michigan had been the sole provider of anthrax vaccine to DOD. Several years ago, the State expressed its intentions to sell the lab, and planned to close the facility if it did not find a suitable buyer.

BioPort bought the facility with the firm conviction that we would operate it as a viable commercial entity. We knew that privatization of a State-owned facility would involve certain vagaries and risks. However, over the last 9 months, we have encountered more difficulties than we initially anticipated. Despite our efforts and prior due diligence, certain problems have arisen that would make it difficult for us, and we believe for any company, to operate with the existing DOD contracts. We are in the process of discussing changes to these contracts that will enable us to operate on a viable basis in the future and continue to produce a safe, pure, and effective vaccine.

By way of corporate background, BioPort's primary mission is to meet the needs of the Anthrax Vaccine Immunization Program. BioPort has only one key customer, DOD, and one key product, anthrax vaccine. We manufacturer two other biologic products, rabies vaccine and plasma derivatives, but sales of these products are limited and insignificant.

We employ more than 200 people who are committed to providing the highest quality product to protect against bio-warfare and bio-terrorism. BioPort makes the only FDA-licensed bio-defense vaccine in the country today.

By way of personal background, I have been involved for the past 10 years in the business aspects of the bio-tech industry, in particular, the field of bio-defense. Previously, I was a director with Porton Products, a bio-tech company based in England. During my association with Porton, I participated in the marketing and distribution of substantial quantities of Porton's UK-licensed anthrax vaccine.

When I learned that the sale of the Michigan lab was going forward, I joined forces with Dr. Myers and his team. I invited Admiral William Crowe to join the group, since he has been a friend of my family for many years and has a deep concern for the protection of the men and women who serve our Nation.

In May of last year, we formed BioPort, which is largely an employee-owned company with a stock option program that allows every employee to participate in the ownership of the company. The

sales process, which took almost 2 years, was public, open, and competitive.

At the time of the acquisition, we were aware that we were taking over an unprofitable venture with an aging physical plant that had never before been operated in a commercial environment. As it turns out, we have encountered problems that are substantially beyond what we had anticipated.

The major problems encountered can be summarized in five areas.

First, identifying and tracking costs. Under the State, there was no effective system for tracking costs. There appears to have been no clear relationship between the lab's cost of producing anthrax vaccine and the prices paid by DOD.

Second, overcoming delays in renovation. At the time of acquisition, the anthrax facility was under renovation with an aggressive schedule. Unforeseen delays of almost 5 months in completing the renovation have deferred revenues and increased costs.

Third, improving regulatory compliance and relationships with FDA. The labs regulatory problems with the FDA required more time and money than anticipated. We have expended considerable resources in developing an enhanced relationship with the FDA.

Fourth, dealing with uncertain commercial sales of anthrax vaccine. Traditionally, and this is very important, vaccine manufacturers have been able to offer lower prices to the Government by covering a substantial portion of their costs through commercial sales. Without a commercial market, the Government cannot expect the rock bottom pricing that would otherwise be available.

Fifth, changing the organizational culture. The culture was that of a State bureaucracy where no effective performance standards existed to ensure accountability throughout the organization. Changing that culture has been a difficult and costly endeavor.

Indeed, the problems we have experienced are not unique to us. It appears that every major pharmaceutical company in this country has avoided getting into the defense vaccine business. A vaccine manufacturer must face an environment involving high capital costs, limited market potential, significant regulatory hurdles, costly liability issues, and other technical complexities. These factors may explain why most U.S. pharmaceutical companies abandoned the vaccine business during the 1970's. It is no accident that today the U.S. vaccine industry is dominated by only four large companies.

Notwithstanding these continuing challenges, BioPort has taken important steps toward improving the viability of the company. These steps can be summarized in five areas.

First, introducing critically needed business systems. We are now implementing business systems, such as cost accounting, inventory control, management information, and material requirements planning to better manage and control the organization.

Second, we are re-starting the manufacturing of the anthrax vaccine in the renovated facility. In May of this year, BioPort resumed production of the anthrax vaccine. The delivery of the product remains subject to approval of the renovated facility and final release by FDA.

Third, improving regulatory compliance. Since privatization, BioPort has neared completion of the implementation of its strategic plan for compliance. A mutually agreed upon plan by which the FDA can monitor our compliance progress.

Fourth, changing the culture of the organization. We have developed a corporate mission, corporate values, and are finalizing major responsibilities and performance standards for each one of our employees. We have augmented the staff with 56 people who have experience in the commercial industry.

Fifth, implementing measures to minimize losses. We have maintained salaries that are on average, below the industry norm, especially at management level. We have temporarily suspended performance-based bonuses and have implemented policies for expense control and accountability.

Notwithstanding these measures, however, the current pricing structure is unrealistic and unsustainable given the total costs of manufacturing the anthrax vaccine. BioPort is currently in the process of restructuring our production contract with DOD. The two main terms under review are: (1) the price per dose; and, (2) the production level. The proposed average price per dose will compare favorably with prices many other vaccines—sorry, favorably with prices of many other vaccines purchased by the Government.

The proposed production levels can comfortably meet the anticipated requirements of the Anthrax Vaccine Immunization Program. BioPort believes that a fair and equitable adjustment to the contract can be achieved within the timeframe needed.

In conclusion, let me simply state that all of us at BioPort remain committed to providing a safe, pure, and effective vaccine that meets the requirements of DOD, our key customer.

Thank you.

[The prepared statement of Mr. El-Hibri follows:]

CORPORATION 3500 N. MARTIN LUTHER KING JR. BLVD. • LANSING, MI 48906

Testimony of Mr. Fuad El-Hibri
President and Chief Executive Officer, BioPort Corporation

Presented to
The Subcommittee on National Security, Veterans Affairs, and International Relations of the House Committee on Government Reform

June 30, 1999

Mr. Chairman and distinguished members of the Subcommittee, my name is Fuad El-Hibri and I am the President and Chief Executive Officer of BioPort Corporation, a bio-pharmaceutical company headquartered in Lansing, Michigan.

I have been asked to discuss, from BioPort's point of view, the acquisition strategy and procurement activities related to the Department of Defense's (DoD's) purchase of anthrax vaccine. Joining me is Dr. Bob Myers, our Chief Operating Officer, who has previously testified before this Subcommittee and who can provide added detail regarding the historical and technical aspects of the relationship.

As the Subcommittee is aware, BioPort has been operational for about nine months. BioPort was formed to purchase the Michigan Biologic Products Institute (MBPI) from the State of Michigan and to operate the facility as a private sector facility. For thirty years, MBPI had been the sole provider of Anthrax Vaccine Adsorbed (AVA) to the DoD. For a number of years prior to our purchase of MBPI, the State of Michigan had expressed its intention to sell the facility and get out of the AVA business, but had been unable to find a buyer. It is our understanding that the State of Michigan planned to close the facility if it did not find a suitable buyer.

We bought MBPI with the firm conviction that we could operate the facility as a viable commercial entity. We knew that privatization of a facility that had been state-owned and operated involved certain vagaries and risks. We were convinced that we could get through the privatization process and establish BioPort as a viable entity and a reliable supplier to DoD within the first year of operation.

However, over the last nine months, we have encountered more difficulties in privatizing the facility than initially anticipated. Despite our best efforts (and the due diligence that we conducted before the purchase), certain unanticipated problems have arisen that would make it difficult for any company to operate on a viable commercial basis with the existing DoD contracts. We are in the process of discussing with DoD changes in our contracts that will enable us to operate the company on a viable basis in the future and continue to produce a safe, pure and effective vaccine.

ADMIN 517-327-7230 FAX 517-327-7235 FACILITIES MGMT 517-327-1525 FAX 517-327-1524
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Testimony of Mr. Fuad El-Hibri
President and Chief Executive Officer, BioPort Corporation
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The purpose of my testimony (in addition to answering the questions posed by the Subcommittee in its letter of June 15, 1999) is to discuss the business considerations that have led us to where we are today, and to assure the Subcommittee that, with the changes under discussion, BioPort will be in a position to serve DoD as a reliable supplier of AVA long into the future.

Background

BioPort's primary mission is to meet the needs of DoD's Anthrax Vaccine Immunization Program (AVIP). BioPort has only one key customer -- DoD -- and one key product -- AVA. We manufacture two other biologic products, rabies vaccine and plasma derivatives, but sales of these products are limited and these products currently have only minimal significance to the viability of the company.

BioPort's core purpose is to protect life by fighting disease. We know that anthrax is a deadly weapon in the arsenal of bio-warfare and bio-terrorism -- that some hostile nations and terrorist groups have access to weaponized anthrax, and that the DoD considers, as we do, BioPort's vaccine, which is licensed by the Food and Drug Administration (FDA), to be pure and safe and an effective protection against an anthrax attack. We employ more than 200 people who are fully committed to providing the highest quality product as the best possible protection against these dangers. Parenthetically, I would like to point out that more than 100 of our employees have received anthrax vaccine shots -- some for more than 20 years -- and that I am one of those 100 employees. BioPort makes the only FDA-licensed bio-defense vaccine in the country, and we are committed to continue producing the vaccine and doing so with the highest quality.

By way of personal background, I would like to explain the basis for my interest in leading the acquisition of MBPI last fall. For the past ten years, I have been involved in the business aspects of the biotechnology industry -- in particular, the field of bio-defense. Previously, I was a director with Porton Products Ltd., a biotech company based in the United Kingdom. At Porton, I was involved in the oversight of operations that encompassed drugs and biologic products. During my association with Porton, which had a marketing agreement with the Centre for Applied Microbiology and Research (CAMR), a United Kingdom government-owned lab, I participated in the marketing and distribution of substantial quantities of two bio-defense vaccines -- botulinum Type A and anthrax.

In 1996, I learned that the long-anticipated sale of the Michigan lab, MBPI, was going to move forward. Because of the unique similarities between Porton and the Michigan lab, specifically with respect to bio-defense vaccines, I later joined forces with the managers of the lab, including Dr. Myers, who had formed Michigan Biologic Products, Inc., a management-owned company, in an effort to acquire the assets of the lab. I invited Admiral William J. Crowe, Jr. to join the group to bid for the acquisition of MBPI.

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Admiral Crowe has been a friend of my family for many years. When BioPort was originally conceived, we believed that Admiral Crowe's background would be important in ensuring that we did everything correctly in establishing a company that would best serve DoD's needs. We are honored to have him as a director of BioPort. We received financial backing from I and F Holdings N.V., a Netherlands Antilles investment company which is owned by my father, Ibrahim El-Hibri. I and F Holdings had participated previously in Porton Products Ltd. as a passive investor.

The Privatization Effort

Together, Dr. Myers and I took the lead in developing a comprehensive plan to privatize MBPI and to perform MBPI's contracts with the DoD. In May of 1998, we formed BioPort Corporation, which is largely an employee-owned company, registered in Michigan. On September 5, 1998, BioPort purchased certain of the assets and assumed certain of the obligations of MBPI from the State of Michigan. The sales process, which took almost two years, was public, open and competitive.

At the time of the transaction, we were well aware that we were taking over an unprofitable venture with an aging physical plant that had never before been operated in a commercial environment. We knew there would be difficulties in establishing a viable commercial operation after years of management by the State. As it turns out, we have encountered problems -- and costs -- in privatizing the entity that are substantially beyond what we had anticipated:

- **Identifying and tracking costs.** Under the State, the financial accounting system was organized to support the State's appropriations process and there was no effective system in place for tracking costs. To meet regulatory standards, a company in this business must have substantial quality assurance and quality control systems. State-of-the-art renovations are continually needed which require lengthy FDA review prior to being put into service, and evolving product standards require ever-improving analytical methods. Unfortunately, the State's management practices did not include calculation of these costs. The cost information available was minimal in content and difficult to analyze. It turns out that there was no direct relationship between MBPI's costs of producing AVA and prices paid by DoD for AVA. It has become clear to us that the prices paid by DoD for AVA are significantly below BioPort's costs for producing AVA and what is necessary to enable BioPort to operate as a viable entity.

- **Overcoming delays in renovations.** At the time of the acquisition, MBPI was in the midst of renovating the anthrax production facility with, in retrospect, an unrealistic timetable. Unforeseen delays in completion of the anthrax production facility have delayed production and increased costs. In May of this year, after completion of the anthrax facility renovation, BioPort re-

sumed production of the anthrax vaccine (although the delivery of the product is subject to FDA release), but with a delay in excess of four months.

- **Improving regulatory compliance and relationships with FDA and DoD.** MBPI's regulatory problems with the FDA required more resources than previously anticipated. Since privatization, BioPort has neared completion of the implementation of its Strategic Plan for Compliance, an accepted plan by which the FDA monitors our compliance progress. We have expended considerable resources in developing new and improved relationships with the FDA as well as with our key customer, DoD.

- **Dealing with the uncertain availability of AVA for commercial sales.** Traditionally, vaccine manufacturers have been able to offer lower prices to the Government by recovering a substantial portion of their costs through commercial sales. Under this approach, prices for commercial sales of vaccines are established at levels that are much higher than the prices paid by the Government. Because of the current unavailability of product, the commercial sales market has not materialized as anticipated. Without a second market, the Government cannot expect the rock-bottom pricing it enjoys with some of the other vaccines it purchases.

- **Difficulties associated with production of other products.** BioPort's business plan anticipated additional revenues from the sale of other products: *i.e.*, plasma derivatives and rabies vaccine. BioPort encountered unanticipated start-up problems related to the manufacture of plasma derivatives and rabies vaccine. This has contributed to the negative effects on BioPort's financial condition.

- **Changing the culture and organization.** The culture was that of a state bureaucracy -- where no effective performance standards assured accountability throughout the organization. Changing that culture has been a difficult and costly endeavor. We have augmented the staff with 56 people who have experience in the commercial industry. We are developing business systems, such as cost accounting, inventory control, management information, and material requirements planning to better manage and control the organization.

We have come to understand that the State of Michigan routinely funded the operations of MBPI beyond what we initially understood (in effect, subsidizing DoD's acquisition of AVA). At the same time, the State failed to address urgent needs for facility improvements, which jeopardized the FDA license. As a commercial entity, BioPort cannot continue to subsidize the DoD. However, we are committed to improving the facilities and working closely with the FDA to ensure compliance with all quality measures. All of this has caused us to incur costs beyond what was originally anticipated with respect to producing AVA.

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Indeed, our experience confirms why every major pharmaceutical company in this country has avoided getting into the defense vaccine business, why limited interest was found in bidding for the Michigan lab, and why the government has had problems retaining suppliers of certain specialized vaccines. It has long been recognized that a vaccine R&D and manufacturing business must operate in an environment involving high capital costs, limited product market potential, significant regulatory hurdles, liability issues, and other technical complexities. I have been advised that this has been independently documented in reports of the Congressional Office of Technology Assessment in 1979, reaffirmed by the Institute of Medicine, National Academy of Sciences in 1985, and most recently in the 1995 Mercer Report commissioned by the U.S. Department of Health and Human Services.

These factors may explain why most U.S. pharmaceutical manufacturers abandoned the vaccine business during the 1970s. It is no accident that today the U.S. vaccine industry is dominated by only four large companies. The CEOs of smaller biotech companies experience major challenges in securing the necessary financing to sustain the tremendous costs of their clinical development, regulatory and manufacturing operations in making these life-saving vaccines available to the public.

Plan For Future Operations

In the last nine months, BioPort has incurred losses at a rate that cannot be sustained in the future. We have taken key measures to minimize such losses. Our employees receive, on average, salaries below the industry norm; performance based bonuses have been temporarily suspended; expenses are being controlled by the CFO directly; and any expenditures not immediately critical to the continued operation have been put on hold. Notwithstanding these measures, however, the current pricing structure is unrealistic given the total costs of manufacturing AVA.

BioPort is currently in the process of restructuring the production and delivery contract with the DoD. The two main terms we are addressing jointly are the price per dose and the quantity of doses committed. The price per dose needs to be adjusted to a level where BioPort can operate on a viable basis. The production levels that are being discussed allow for a growth in the Government inventory for unexpected surges in demand, while still providing BioPort with enough vaccine to meet any reasonable demand from the civilian private sector.

With the changes that are being discussed, BioPort will be in a position to meet all requirements of the AVIP and to serve DoD as a reliable supplier long into the future. The proposed average price per dose will still compare favorably with prices of many other vaccines purchased by the Government. BioPort believes that a fair and equitable adjustment to the contract can be achieved within the time frame needed.

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Conclusion

In conclusion, let me simply state that all of us at BioPort are deeply committed to providing a safe, pure and effective vaccine that meets DoD's force protection needs.

We are working diligently to transform ourselves from a somewhat neglected state agency to a competitive and respected biologics company. This transition will require time and will not be accomplished without the support of our most important customer.

We welcome the scrutiny of this Subcommittee and assure you that as long as we manufacture anthrax vaccines, they will be safe, pure and effective.

Responses To Subcommittee Questions

Now, I would like to turn to the specific questions raised in your letter of June 15, 1999.

Testimony of Mr. Fuad El-Hibri
President and Chief Executive Officer, BioPort Corporation
June 30, 1999

Question #1: Discuss in detail the legal and financial relationship between DoD and the BioPort Corporation, including the status of BioPort's performance under current DoD contracts, and the financial, organizational and operational capacity of BioPort to meet all contract obligations.

When BioPort acquired the assets and liabilities of MBPI, we assumed three existing contracts with the DoD and entered into a fourth contract that had originally been offered to the State of Michigan. All of these contracts relate to aspects of the production of anthrax vaccine -- future production, stockpile maintenance, equipment and storage. Three of these contracts were novated, which means they were transferred from the State directly to BioPort Corporation without amendment. The fourth contract was negotiated with DoD concurrently with the final negotiations with the State on the acquisition of MBPI's assets. Meanwhile, the State's budget was exhausted, people were beginning to leave the lab, and the State had threatened to shut down the lab, potentially leaving the country without any source of FDA-licensed anthrax vaccine.

After the acquisition, we discovered that the costs of production had been seriously underestimated by the State for years. Under State ownership, a cost accounting system was non-existent. Therefore, the methods used to allocate costs were not very useful in assisting management in running an efficient and financially sound private enterprise. In the case of AVA, as one State official has told us, the State of Michigan essentially subsidized the DoD procurement of anthrax vaccine for nearly 30 years. The State assured solvency, paid unemployment insurance, workers' compensation and liability insurance, assured payroll, covered emergencies, and maintained the physical plant while the DoD paid artificially low prices.

As an illustration of the kind of problems inherited by BioPort in the pre-existing arrangement between the DoD and the State of Michigan, BioPort is responsible for paying all costs associated with the renovation of the anthrax facility, which is only reimbursed by the DoD sometime later, without consideration for the cost of money. BioPort may not charge handling or administrative fees, and must assume the responsibility of supervising and partly executing timely completion without compensation. This is an artifact of the DoD's arrangements with the State, but does not work well in a commercial setting.

The newly renovated anthrax production facility is now up and running and currently performing at a higher level than before, although delivery of AVA is subject to FDA release. However, the renovation and startup of the upgraded anthrax production area took more than four months longer than planned at the time of contract negotiation.

BioPort has recently submitted a request for restructuring the contract with the DoD. The price per dose and the quantity of doses committed are inversely correlated when using a cost plus approach to pricing; therefore, in light of a lower projected production level, if

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all other things were equal, the price per dose would adjust upward. DoD and BioPort are currently reviewing BioPort's financial figures of the last nine months, including an audited financial statement of 1998, and BioPort's projections for years 1999 and 2000. We are jointly determining a fair price and quantity requirement within the guidelines established by the Federal Acquisition Regulations and taking into account that BioPort is primarily a one client, one product manufacturer, with limited private sales.

BioPort will be able to meet the anticipated requirements of the AVIP in the years to come. This production level not only meets the anticipated requirements of the AVIP, but allows for a growth in the Government inventory for unexpected surges in demand, while still providing BioPort with enough vaccine to meet the projected demand of the civilian private sector.

BioPort has spent the last several months strengthening the company's organizational capacity to meet our contractual obligations. We have added several highly qualified individuals with extensive industry experience -- particularly in the regulatory, compliance, financial controls and product development areas. We have established a regulatory affairs division, a financial division, a legal affairs division, a human resources and a corporate services division. We conducted national searches before hiring a Chief Financial Officer, an Executive Vice President for Operations, a Vice President for Regulatory Affairs and a Vice President for Marketing. We have designated an Executive Vice President for Business Development. These steps have greatly strengthened our organizational capacity and financial control.

BioPort has the operational capacity to continue producing a safe and effective anthrax vaccine at the revised production level (subject to FDA release) meeting the AVIP requirements. Our ability to operate on a viable commercial basis, however, depends upon arriving at a fair and equitable contract price with the DoD.

Testimony of Mr. Fuad El-Hibri
President and Chief Executive Officer, BioPort Corporation
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Question #2: Describe the corporate structure of BioPort, including the identity of all incorporators, directors, principals and all those with any equity, debt or ownership interest of any kind.

BioPort was incorporated in Michigan on May 12, 1998, pursuant to an agreement between Intervac LLC and Michigan Biologic Products, Inc., for the sole purpose of acquiring the assets of MBPI. As mentioned earlier, the core purpose of the corporation is to protect life by fighting disease. A five-member Board of Directors, which I chair, governs us. BioPort's other board members are Admiral William J. Crowe, Jr.; Myron W. Solter; Dr. Robert C. Myers; and Robert C. van Ravenswaay.

BioPort's stock is split into two classes: 80% of the shares are voting; 20% are non-voting. The non-voting shares are being awarded to each and every BioPort employee, so every one at BioPort has a stake in the company. Managers and employees today own more than 50 percent of the company, assuming a full vesting of all stock options.

Three companies currently hold voting equity in BioPort: Intervac LLC and Intervac Management LLC, which are both Maryland limited liability companies, and Michigan Biologic Products, Inc., a Michigan corporation. Intervac LLC is the controlling shareholder. Intervac LLC is owned by Admiral Crowe, my wife Nancy and me, and I and F Holdings N.V., a Netherlands Antilles investment company owned by my father Ibrahim El-Hibri. As mentioned earlier, I and F Holdings is an investment company in biotech operations, which previously had invested in the management buy-out of Porton Products Ltd. Admiral Crowe and I are the controlling members of Intervac LLC.

I am the general manager of Intervac LLC, which is a private investment group, and of Intervac Management LLC, which includes a group of four dedicated professionals who work with me and assisted in the acquisition. Dr. Myers is President of Michigan Biologic Products, Inc., shares of which are predominantly held by seven former managers of MBPI who have been active in the daily management of BioPort. A minority of Michigan Biologic Products, Inc. shares are held by four local lawyers, who helped the company with legal matters during the sale process.

Our major creditor is the State of Michigan, who agreed, as part of the sale, to hold promissory notes secured by essentially all of BioPort's property. We also have product and royalty obligations to the State of Michigan in addition to the notes. I and F Holdings has advanced additional funds to BioPort to help meet unanticipated but continuing short-term cash deficits. In addition, BioPort has incurred indebtedness in the form of a capital lease from Bank One for the purchase of a blood plasma fractionation centrifuge.

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Question #3: Discuss any efforts or plans to identify or construct additional anthrax vaccine production source(s).

Although BioPort currently produces anthrax vaccine at a single site, we are looking at developing additional anthrax vaccine production facilities to assure continued product availability in the event of a natural disaster or terrorist attack. When BioPort entered into the current production contract with the DoD, we agreed to evaluate converting an existing idle production area to the production of anthrax vaccine. Although the preliminary engineering design indicates such a conversion can in fact be done, it would be at substantial cost and would still not provide a geographically separate production site to protect against disaster.

BioPort has had preliminary discussions with the DoD to identify other facilities for possible conversion in the U.S. We have also talked to the Canadian government and with the Centre for Applied Microbiology and Research in the United Kingdom about the possibility of establishing a second production site that could serve both the redundancy needs of the DoD and the anticipated market demand.

It is important to emphasize that a second facility will require a significant commitment of time and money. *Bacillus anthracis* is a spore-forming organism and, under current practice, the vaccine must be manufactured in a dedicated facility. To build a new anthrax vaccine production facility using BioPort's technology at a new site, approved by the FDA, would take approximately five to seven years and cost between $70 - $100 million based on BioPort's analysis. Converting an existing biologics facility, which has basic infrastructure, would save time, but would still take 4-5 years, and cost substantially less, depending on the quality of the existing facility. Therefore, BioPort is in the process of identifying existing U.S. facilities suitable and available for conversion.

We should also recognize that many vaccines -- including, but not limited to, anthrax -- have only one manufacturing source. In addition to anthrax, there are at least 14 significant adult vaccines, which are produced by single source manufacturers. These include cholera, Lyme disease, all the MMR series, yellow fever, Japanese equine encephalitis, and meningitis vaccines. Anthrax vaccine, with a single manufacturer, is not unusual.

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Question #4: Describe the nature and value of Government Furnished Equipment used in the manufacture of anthrax vaccine and the nature and value of other facility improvements provided or financed by DoD since 1991, including the current renovation and expansion.

By our accounts, the U.S. Government has furnished, and still owns, equipment and materials used to manufacture anthrax vaccine that originally cost a total of $6.9 million. This equipment, which has been acquired on behalf of the Government since 1991, includes the fermenter trains and formulation tanks used in the manufacture of anthrax vaccine, some filling and packaging equipment, cold room modifications, a formulation room, an animal test facility and a building that warehouses production materials. This listing, which is prepared at the end of each fiscal year, already includes most of the items acquired in the recently completed renovation of the anthrax vaccine production facility. The Government will shortly reimburse any outstanding costs with respect to the recent renovation, which are not substantial at this point. The current value of the Government Furnished Equipment, however, is substantially less, an estimated $3.4 million, based on a depreciated value. In addition, the Government has furnished a total of $4.4 million in renovation costs other than for equipment.

When it came to facility renovations, Michigan's budgeting and procurement practices routinely added months, if not years, to construction schedules. To meet DoD's scheduling requirements, Michigan accepted Government Furnished Equipment on a piece-meal basis, solving short-term problems at the expense of long-term benefits.

Although DoD provided equipment for vaccine production, it contributed very little to the soft costs in installing such equipment in a current Good Manufacturing Practices (GMP) production setting -- validation, periodic re-qualification, and regulatory filings. Under Generally Accepted Accounting Principles, all these costs are included in capital expense. The State previously covered and BioPort now covers all such soft costs not reimbursed by DoD.

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Question 85: Discuss the status of BioPort's investigational New Drug Application (IND 6847) pending before the Food and Drug Administration (FDA), anticipated approval schedule and the impact of approval on current and future procurements.

We continue to hold an Investigational New Drug application -- IND 6847 -- to improve administration of the anthrax vaccine. Further work is currently on hold while the parties consider the costs and benefits of proceeding in the context of overall program priorities (such as getting the upgraded facility in operation).

This IND was started by MBPI in tandem with the DoD in 1996. It has two major objectives: to reduce the number of doses in the current anthrax vaccination schedule and to further evaluate an immunological correlate of protection.

The initial work on the IND indicates the second shot of the series -- given at two weeks -- may be eliminated, but the FDA has specified substantial additional tests that must be conducted before they will consider such a shot elimination. This would reduce the total inoculation series from six shots to five shots.

Further reductions may be possible, but require additional clinical trials and time. There will be no immediate impact on the requirements of the Anthrax Vaccine Immunization Program. The future impact in an estimated two years may be a reduction of the number of shots by one-sixth for initial immunization. However, there are no immediate plans to reevaluate the requirement for annual boosters.

Thank you.

Mr. SHAYS. Thank you very much. I appreciate all of you being here and we will try to nail down where we have our differences and where we have our agreements and where we just simply don't understand and are happy to be enlightened.

Ms. Schakowsky, do you want to start?

Ms. SCHAKOWSKY. Secretary Oliver, despite your rather ringing endorsement of the value of this private sector venture, the good thing about industry, they know what their costs are, in fact, it sounds like the new contract talks about costs that are about three times as high. It sounds to me like the investment that the taxpayers have made in this plant since its purchase, and I am looking at renovation and Government equipment, is maybe six times more than this private company has invested, about $18 million, $11.8 for renovation?

Mr. OLIVER. The renovation was planned before they were bought, ma'am. And essentially I think the GAO testified, the GAO and I talked Monday because my staff tells me we have added something like $130,000, $30 odd thousand to the contract since they were bought. And GAO thinks it is somewhere in the order of $250,000. And I didn't bother to track down the difference in numbers.

Ms. SCHAKOWSKY. The cost estimates for product, we are talking about——

Mr. OLIVER. That's an important issue.

Ms. SCHAKOWSKY [continuing]. Three times as much.

Mr. SHAYS. Would the gentle lady yield to me?

Ms. SCHAKOWSKY. Sure.

Mr. SHAYS. I just want to be clear on this, just so we are not talking two different directions here. How much has the Government put into this plant? And I am happy to have you say what was before BioPort and what was after?

Mr. OLIVER. Let me give you an answer and also take it for the record, somewhere between, the Government has put into this plant somewhere between $11 and $19 million, I mean Government furnished equipment. It falls in that range, and I don't remember where.

Mr. SHAYS. So her question was not an unreasonable question.

Mr. OLIVER. No, when the State of Michigan had it is my point.

Mr. SHAYS. OK.

Mr. OLIVER. My point was, I don't want——

Mr. SHAYS. Now this renovation that is going on now is being paid for by BioPort?

Mr. OLIVER. No—yes, it is but what the point of it—we will eventually pay for it in price because we are their customer. What I am saying is that renovation was planned before the plant was sold. All I am trying to do is to say this is not a sweetheart deal.

Mr. SHAYS. No, I know, all I am trying to do—well, we didn't say it was a sweetheart deal. I haven't said it. Did you say it was a sweetheart deal? We are just trying to understand the specifics.

Mr. OLIVER. Right.

Mr. SHAYS. I am not trying to be cute with you.

Mr. OLIVER. No, I understand, sir.

Mr. SHAYS. You have a concern that you want us to know that we got a value and so on, but let's be more specific. Let's not say between $11 and $19, let's nail this down.

Mr. OLIVER. No, I said I would take it for the record, sir.

Mr. SHAYS. Pardon me?

Mr. OLIVER. I will take it for the record. I don't recall the number at the moment. I will ask my staff to produce it. They will undoubtedly hand me a paper in 2 seconds.

Mr. SHAYS. Are you saying to us that the investment that has taken place, the shutdown of the plant and all the renovation is being paid for out of BioPort's investment or is the Government paying for this investment?

Mr. OLIVER. The agreement was that BioPort would pay for the renovation.

Mr. SHAYS. OK.

Mr. OLIVER. Can I talk about something else——

Mr. SHAYS. Sure.

Mr. OLIVER [continuing]. On the——

Mr. SHAYS. No, no, finish your sentence.

Mr. OLIVER. Period. [Laughter.]

Mr. SHAYS. So this investment that is taking place now is not Federal dollars? Now they may recapture it obviously in the sale of a product, but you are saying that all this investment now is not the Government investment?

Mr. OLIVER. Yes, there is an exception—what I am saying there is an exception for something like, somewhere between $193,000 and $250,000.

Mr. SHAYS. So all the investment that has taken place, this $11 to $19, and you are going to nail down the number, that was DOD funding from the old contract with the State of Michigan?

Mr. OLIVER. Yes, sir.

Mr. SHAYS. Do you mind just 1 second?

Ms. SCHAKOWSKY. No, sure, not at all.

Mr. SHAYS. No, just before we leave this, but in the process of acquisition, then what did we get when this—how much of the sale did the United States get for a product? Do we own the production facility that is in this plant? It is our dollars?

Mr. OLIVER. No, sir, we have a certain amount of Government-furnished equipment, which I am told is $7 million of Government-furnished equipment. And, as the Congresswoman said, we have put in $111 million in renovation since 1991, or excuse me, $11 million, close.

Mr. SHAYS. OK, now so we have put in $11 million, who owns that $11 million?

Mr. OLIVER. We own the Government-furnished equipment.

Mr. SHAYS. No, I didn't ask the $7 million, I didn't ask about the $7 million. Does BioPort own it or does the U.S. Government own it?

Mr. OLIVER. BioPort owns it. We own the Government-furnished equipment.

Mr. SHAYS. And we are going to just stick with this a little longer? Do you mind?

Ms. SCHAKOWSKY. Not at all.

Mr. SHAYS. We put in $11 million before this plant was owned by BioPort, and I am going to come to BioPort and ask you your understanding of this. And this was investment in a plant owned by the State of Michigan?

Mr. OLIVER. Yes, sir.

Mr. SHAYS. OK. Did we give it to the State of Michigan, was it an outright gift? Did we ask that we be reimbursed when this plant was sold for the money we put in? They got $25 million. If you don't know, just say you don't know.

Mr. OLIVER. No, I will find out. I will find out, Congressman. Let me take it for the record, please. I will find out.

Mr. SHAYS. But I want you to tell me you either know or you don't know?

Mr. OLIVER. Oh, I do not know, sir.

Mr. SHAYS. OK, fair enough. So one question on the table is what happened to this original investment of the Federal Government. And what you are saying—and I thank you for yielding—what you are saying is that presently in the plan is about $7 million of Government-owned equipment?

Mr. OLIVER. Government-furnished equipment, yes, sir.

Mr. SHAYS. Is it Government-owned?

Mr. OLIVER. It is Government-owned.

Mr. SHAYS. It was furnished by the Government, we still own it?

Mr. OLIVER. Yes, sir.

Mr. SHAYS. OK. And it has some depreciation to it, but obviously it is our equipment. Yes, fair enough. Thank you.

Ms. SCHAKOWSKY. This is a very unusual private sector venture that has $11 million of previous taxpayer investment, that has $7 million of equipment and is now going to re-negotiate a previously agreed to contract for three times or whatever, we don't know, the amount of the original contract. And what I wanted to ask Mr. El-Hibri, am I doing that right? OK. Was this issue of unforeseen problems.

Mr. OLIVER. Ma'am, before you do, can I address the part, there are lots of companies that we have Government-furnished equipment to, private companies in excess of that amount of money in which we have contracts and re-negotiate, so that is actually pretty normal. OK, we frequently are furnishing Government-furnished equipment to private companies.

Ms. SCHAKOWSKY. And is it also pretty normal, because I also wanted to remind myself, as well as the GAO, to grant immunity from liability to companies?

Mr. OLIVER. This is precisely what you do in this area of the drug world and it is where I talked to you about the late 1970's, early 1980's where we were in this company, the lawsuits almost drove the cost of child DPT-type immunizations through the roof, the reason this body passed a law providing indemnification for those drug companies was because of the same reason the Department of Defense indemnified BioPort.

Ms. SCHAKOWSKY. Let me ask you this before I get your response then, what is the total U.S. investment in BioPort exactly?

Mr. OLIVER. If my note is correct, then it is the $7 million of GFE and $11 million for previous renovation, for a total of about $18 million.

Ms. SCHAKOWSKY. OK, thank you. The issue now of these unforeseen problems that you saw, if, as you have stated, that a tracking system is an essential component of this type of company, you must have known that whatever they call it, the Michigan owned company, did not have that. Did you examine the question before you purchased the company?

Mr. EL-HIBRI. Oh, absolutely. We were fully aware that no cost accounting system was available, nor that there was a general accounting system, financial accounting system in place that would be compliant with normal GAAP principles. So what we did was make our own projections at the time we took over the facility, based on estimates in the future, and used those projections in arriving at a price, together with the DOD.

Ms. SCHAKOWSKY. Well, another unforeseen problem that you mentioned in your testimony is the delay in renovations. You stated that MBPI was in the midst of renovating the facility with, in retrospect, an unrealistic timetable. And, again, I would think that most purchasers would carefully examine that. Did you do that kind of analysis and how come you weren't able to determine that the timetable was not realistic?

Mr. EL-HIBRI. We understood very well that with renovations, especially in a highly regulated environment such as biologics, delays might occur because we are concerned about safety and compliance. And, certainly, certain expectations were there. But it wasn't really only up to us to decide. We were in negotiations with the contracting office. The contracting office explained to us: "this is our Government equipment and by building in unreasonable delays, we don't want to pay for it. We believe that the State had submitted a plan where the facility could be up and running by January of this year." And we need 2.5 million doses by September of this year. Our proposal, incidentally at the time, was significantly less, actually more in line with what we are proposing now. At the time when we negotiated with the contracting office, we had limited information and both sides in good faith tried——

Ms. SCHAKOWSKY. Excuse me, let me jump in here, then it wasn't unforeseen. You originally stated that you could not produce at the levels that ended up in the contract?

Mr. EL-HIBRI. The delay was unforeseen. However, you build into pricing allowances for delays, which were not accepted. Normally, I would say, look, if the price of this product is, let's say $10 per dose, I would allow for another $2 or $3 per dose for potential delays.

Ms. SCHAKOWSKY. But at the time that what you had recommended was not accepted——

Mr. EL-HIBRI. That's right.

Ms. SCHAKOWSKY [continuing]. But now you are renegotiating about three times the cost. You said that the Department said we don't want to pay for it. In fact, don't we, and "we" is really the taxpayers——

Mr. EL-HIBRI. Right.

Ms. SCHAKOWSKY [continuing]. Will pay for it then in a——

Mr. EL-HIBRI. If you will allow me, please, to clarify the situation. If you look at most of the vaccines that are purchased today by the Government, the average price, at least based on the infor-

mation that is available to us, is about $10 to $12 per dose. The reason why you have been receiving doses substantially below that price in the past is because the State of Michigan was unable to track their costs. So when we have an average price of $3 built into the contract today and want to increase that to about $10 per dose on average, although it is three times as much, the end price is still within the norm. And we are competing against other manufacturers who have a private sales market where they can distribute their costs, not solely to the Government, but across several clients.

Ms. SCHAKOWSKY. It seems to me that given the fact that your company now does employ—Mr. Oliver, you said there were a number of new people and you are trying to change the culture, but, in fact, you do employ many of the same people that were there. I am still trying to pin down this notion of unforeseen when it seems to me that you had the actual individuals who had been there, you supposedly had expertise, and it sounds as if some of these things were not, in fact, unforeseen, that you actually mentioned them in trying to negotiate an original contract. So I am confused about how we ended up at three times as much now?

Mr. EL-HIBRI. OK, I will try to shed some more light on that. The reason why we ended up with three times—we didn't end up yet, this is simply a proposal and it is subject to DOD's approval.

Ms. SCHAKOWSKY. Your proposal is three times as high——

Mr. EL-HIBRI. Yes, our proposal is three times——

Ms. SCHAKOWSKY [continuing]. Let me clarify that.

Mr. EL-HIBRI [continuing]. As much simply to bring our price per dose, which is still at low volumes compared to other manufacturers, in line with what other manufacturers would charge the Government. And, incidentally, with $10 per dose, we can barely cover our costs. It is not that we are trying to generate extraordinary profits or somehow use those funds in any other way. It is to cover expenses, and expenses that we are controlling. And, incidentally, I take issue with that matter. We do have a financial system in place that tracks total expenses very accurately. We have audited financial reports. The thing we don't have yet is a cost accounting system in place. That will come in the next few months. We are working on it. It takes time. We only 2 to 3 months ago found a CFO who was interested in joining us.

Ms. SCHAKOWSKY. OK, Dr. Myers you introduced is next to you. Is one of those individuals who was director of MBPI before you purchased, I mean it would seem to me then that in terms of the information that you needed to avoid unforeseen situations in the person of Dr. Myers is right here. He is now, what is his role now in the company?

Mr. EL-HIBRI. Chief operating officer.

Ms. SCHAKOWSKY. Chief operating officer of the company was director of the company that you say was essentially without controls?

Mr. EL-HIBRI. That is correct.

Ms. SCHAKOWSKY. Could you explain that to me?

Mr. EL-HIBRI. It simply was without controls. Dr. Myers, as I understand it, used to report to the State. The financial decisions were not in his hands. And maybe he can comment more appro-

priately to this, but when we, BioPort, took over the lab, there were no financial systems in place.

Ms. SCHAKOWSKY. And the director of—I would like to ask Dr. Myers, if you don't mind?

Dr. Myers, we are faced with what in part were unforeseen, although I know that the chairman, we want to talk a little bit more about what was actually foreseen and not unforeseen situations that have resulted in a re-negotiation of the contract. You were there at MBPI. Could you not as director, and now as chief operating officer, couldn't you have been more helpful in pointing out what the situations might have been so that we could have a reasonable contract originally?

Mr. MYERS. Yes, let me respond to that and thank you for asking me to respond. I have to tell you first that the Michigan Department of Public Health was an organization of about 1,500 employees, of which there were 75 to 125, through most of the last 15 years, who worked in an in-line division within a bureau within that major department within the State of Michigan. And I know you grapple with these issues everyday at the Federal level, but you can imagine how the support services for 75 people were not in the 75 peoples' hands. That includes personnel, that includes financial administration, that includes budgeting, that includes procurement, sales, and other administrative issues. And it is notable that the FDA, quite wisely, recognized that several years ago and observed in a written observation that the control of the facility was not in the hands of the head of the facility, me.

So the fact that there were no cost accounting systems or tracking systems in place, the fact that the janitorial services were hired by an agency downtown, now we are into the 60,000 people who are State employees in Government. It was not uncommon at all, I don't believe in any State's government. It was not uncommon for us. We simply didn't have a hold of it. We submitted a management plan every year. That management plan was filtered at the bureau level. It was filtered at the Department level. It made its way down to the State capitol in the appropriations process. We were given an appropriation that had from 2 to 10 lines. And we spent in accordance with the appropriation.

Ms. SCHAKOWSKY. Right, but you did make requests that you thought were in line with what your needs were?

Mr. MYERS. We certainly did.

Ms. SCHAKOWSKY. OK, so you knew what those costs were, is that true? If you, to the best of your ability, estimated those costs that were then by the bureaucrats whittled down, then you should have known?

Mr. MYERS. Well, certainly we were asked and we complied with the same sorts of budgeting processes that I expect people need to comply with at the Federal level. That is, give us 100 percent of last year, give us 95 percent of last year, give us 90 percent of last year, and give us 105 percent of last year. That is what I inherited, and that is how we were asked to manage our program budget, and that is how we managed it.

Ms. SCHAKOWSKY. Well, let me ask you this, are we in a similar situation? Mr. El-Hibri, I'm sorry, you said that you had made estimates that in fact were more accurate to begin with?

Mr. EL-HIBRI. Estimates on the number of doses that we submitted in the middle of last year, just before the privatization.

Ms. SCHAKOWSKY. So how did you end up signing on to an original contract that was out of whack to begin with and you knew that?

Mr. EL-HIBRI. Well, I didn't know that it would be out of whack. All I knew, was that it did not have any room for contingencies.

Ms. SCHAKOWSKY. By a lot, by a third.

Mr. EL-HIBRI. By a lot, absolutely. And this is what I explained to the contracting office, that we are dealing with a company that produces biologic products and there needs to be contingencies built in. But the approach was a cost-plus-type approach where they looked at our costs, allocated certain costs to the production of anthrax vaccine and did not allow for any contingencies. We were under a time constraint. We wanted to meet the DOD requirements, that the program was to continue and in good faith, we tried to meet those demands. And at that time, I would have felt a little uncomfortable adding significant contingencies to the price, which I couldn't defend other than to say that this is standard in the biologics industry.

Ms. SCHAKOWSKY. Thank you.

Mr. SHAYS. One of the advantages of just listening to my colleague ask questions is I am also hearing the questions that she is formulated her next question, and I am left with a very uneasy feeling because I am either to believe, Mr. El-Hibri, that you are a very capable and knowledgeable person who knows your business. And, Dr. Myers, you have already appeared before us. I know you are very knowledgeable. And I can believe that. And if I believe that, then there is no way I can understand how you could have agreed to a contract that didn't look at the best and worse case scenarios and sought to have something at least in the middle. You are either very knowledgeable and capable or we are just not getting the story as it truly is. And the response that Ms. Schakowsky asked you, you did know what you thought the costs were and you did request it and you didn't get the agreement from DOD.

And, Mr. Oliver, as I am hearing you, you have come in after the fact, correct? And you have looked at this agreement and you think that DOD pressed too hard and didn't have an agreement that would be fair to both sides?

Mr. OLIVER. That's correct, sir.

Mr. SHAYS. Well, that is the way you view it. And, Mr. El-Hibri, I think the answer to the question would be more accurate that you had a sense of what this would take and you all agreed to something less and is that a fact?

Mr. EL-HIBRI. That's a fact.

Mr. SHAYS. OK. So the words of unanticipated and so on, I think are a little disingenuous.

Mr. EL-HIBRI. Specific things that happened were unanticipated. Generally speaking, you allow for contingencies and imponderables that may be of any nature.

Mr. SHAYS. You have got a little wiggle room, but not much.

Mr. EL-HIBRI. Sorry?

Mr. SHAYS. You have got a little wiggle room but not much. The bottom line is you had a sense of what this operation would cost. You knew what you wanted to be——

Mr. EL-HIBRI. No, I did not have a sense, I am sorry, because I did not know this facility.

Mr. SHAYS. Let me ask you something.

Mr. EL-HIBRI. OK.

Mr. SHAYS. I want you to be—because this will be the first of many hearings if we don't satisfy some basic information. And I am pretty fair to witnesses that come before us. And whatever I feel about the mandatory nature of this program is not going to color what I think about this. These are two somewhat related but not—if this program makes sense, we should do it. If it doesn't make sense, we shouldn't. I am talking about the viability of the protection and so on. What I want to do is hopefully not have two or three hearings. I have really tried to be a good listener here.

What I am hearing is that you all wanted a contract. You had a sense of what the cost would be and you had the sense that you needed this to cover costs. And that any businessman who makes an investment is not going to—well, some do, but they sometimes regret it, they bet the shop on it and then everything has to turn out just perfectly. But most people who get into this kind of arrangement have to establish contingency plans. So you anticipated the best case scenario. And so if you can say, "Well, we didn't anticipate the best case scenario," that is where I am thinking you are being a little disingenuous.

The bottom line is, you knew, you had a sense, isn't it correct, you had a sense of what it would take to run this plant. And you signed a best case scenario with the DOD, that if everything turned out perfectly, you would do all right. And if it didn't, you would have some problems. Isn't that a more accurate description?

Mr. EL-HIBRI. May I use my own words, Mr. Chairman?

Mr. SHAYS. Sure, I would prefer that.

Mr. EL-HIBRI. At the time we took over the facility, we had very limited data and information. We tried to the best of our ability to project forward what would be reasonable costs. The contract we ended up signing was below what we thought would be reasonable costs, OK. The reason we did that, and maybe it was poor judgment, but we needed to continue keeping our people employed, meeting the DOD requirements, and moving forward. If we would have taken 3, 4, 5, 6 months to negotiate the contract, we might have ended up in a disastrous situation. At the end of the day, I felt I was compelled to act quickly because I was dealing with Government-furnished equipment that doesn't belong to us and that we needed to meet a very important program, as we understand it, by the Government.

Mr. SHAYS. OK, I appreciate your candor. But when you purchased this plant, you purchased this plant with the understanding that you would have a buyer of your product?

Mr. EL-HIBRI. Yes.

Mr. SHAYS. So what kind of dialog took place between you and the Government. In other words, I can say $3.5 million is not a big investment, for me it is big, but for an investor——

Mr. EL-HIBRI. For us it is big too.

Mr. SHAYS [continuing]. Well, but that is unsettling. But I will accept the fact that for you it is.

Mr. EL-HIBRI. And when I say we, "we" include managers who have put up personal funds as part of our equity and that is what I meant by saying to us too.

Mr. SHAYS. OK, but how did you determine the price of $25 million? On what basis would you determine a price like that?

Mr. EL-HIBRI. Well, really the price of $25 million has been—I'm not saying is an incorrect price, but let us take a moment to really understand what it represents. It represents a $3.25 million down payment that was made at the time of closing. It represents $4.5 million of a deferred purchase note, which is payable over 5 years, one-half a million the first year and then $1 million the subsequent 4 years. The rest was just an ability for us to receive working capital. For example, we took another note from the State of $3.15 million for inventory. And we sold that inventory and we received that money. So that was to be used for working capital. There were receivables of $4.5 million. We also collected those receivables. But we agreed after a year to pay that back to the State, again, having not only the $3.1 million, but also the $4.5 million as working capital.

So going into this deal, we had brought forward $3.25 million in cash and would have roughly $8 million of working capital, which we believed was enough to keep this——

Mr. SHAYS. It was about $8 what, I'm sorry?

Mr. EL-HIBRI. $8 million, if you add the——

Mr. SHAYS. I understand.

Mr. EL-HIBRI [continuing]. $4.5 million plus $3.1——

Mr. SHAYS. The inventory and accounts receivable?

Mr. EL-HIBRI. Sorry?

Mr. SHAYS. The inventory plus accounts receivable?

Mr. EL-HIBRI. Yes, that is correct.

Mr. SHAYS. Now you are not going to get all your accounts receivable, but——

Mr. EL-HIBRI. But we did get them all. They were DOD receivables.

Mr. SHAYS. OK, you are going to get them?

Mr. EL-HIBRI. Yes, and we got them all.

Mr. SHAYS. OK.

Mr. EL-HIBRI. So the inventory was to be under contract with the Government, so really we thought there was little risk and the receivables were from the Government.

Mr. SHAYS. But what is your total obligation to the State of Michigan?

Mr. EL-HIBRI. The total obligation remains to be these two notes, which add up to $7.65 million and royalties. We pay them between 3 to 5 percent of our sales in royalties over the next 5 years. And product donations. They were interested in receiving some of our products for free. But they are really insignificant in the larger picture.

Mr. SHAYS. OK. And that is capped over a certain period of time?

Mr. EL-HIBRI. Over 5 years. Everything is over 5 years except for the inventory and receivable notes that are due within a year, from when we took over.

Mr. SHAYS. The bottom line, you have your purchase note and your inventory and your receivables that you have obligations to make payment on?

Mr. EL-HIBRI. That is correct.

Mr. SHAYS. What was the obligation about the 200 employees?

Mr. EL-HIBRI. I believe it was written in the legislation that the buyer was to take over all employees or provide an opportunity for each employee to remain employed for 1 year, and we complied with that.

Mr. SHAYS. So now your only obligation is to keep those employees who truly you need?

Mr. EL-HIBRI. We still are obligated until September.

Mr. SHAYS. Oh, September, I'm sorry.

Mr. EL-HIBRI. Yes, because we only took over September 5th, so the full year would be over this coming September.

Mr. SHAYS. Mr. Oliver, I am going under an assumption that if you hear any information that is inaccurate or anyone else who is with you today, that you would correct the record. Otherwise, I am going to assume that DOD concurs with what is being said. If you don't have knowledge, then I want to know that. But do these numbers strike you as what you understand them to be?

Mr. OLIVER. Yes, sir, and besides that I am working up the courage to correct the record, and I am just sort of waiting for a lull when you appear to be——

Mr. SHAYS. OK, I am in a very kind mood.

Mr. OLIVER. Are you? [Laughter.]

Mr. SHAYS. Yes.

Mr. OLIVER. This is the right time then?

Mr. SHAYS. Right time.

Mr. OLIVER. What I want to point out is I mis-spoke earlier when I talked about who was going to fund the restoration. We funded that at $4.7 million. It was planned and programmed before the sale, but DOD funded it.

Mr. SHAYS. OK, so some of the renovation now is being funded by DOD?

Mr. OLIVER. Yes, sir.

Mr. SHAYS. Right, agreed to under the previous owners?

Mr. OLIVER. Yes, sir, $4.7 million.

Mr. SHAYS. Thank you. I am very happy you corrected the record. It was my understanding that the DOD did have some problem, so it would have been something we clearly would have checked. Thank you for correcting the record now and not later. Thank you.

So the way I see things as they stand now, the bottom line, Mr. El-Hibri, is that you agreed to a contract which you prayed would work out in the end with the best case scenario happening. It didn't happen that way and you are back attempting to get a contract you think is workable with DOD.

And, Mr. Oliver, what I am hear you say is that you looked at the contract, and coming after it had been negotiated, you don't feel the contract was a plausible one?

Mr. OLIVER. Mr. Chairman, people are human and everybody has their own responsibility in my organization. I am not sure the contracting officer recognized that we were not buying toy wagons from BioPort. I mean if you are buying toy wagons, you can just

negotiate whatever cut-throat price you want. And, as the General Accounting Office talked about earlier, the Government really has a great deal of power in this situation because they are buying a product, because we have some equipment, and we are the only buyer, and you have contracting officers who are very good and do an excellent job of getting the taxpayers money. But I am not sure they recognized that what we were providing, in my view, is an entitlement.

And when the Secretary of Defense decided, bravely in my view, that we were going to address the issues of the new world and not worry about the old world and barbed wire so much as the new problems in bio-medicine and made that decision, we essentially said to the mothers and fathers across the country, we are going to protect your sons and daughters that we send into combat and into dangerous areas from anthrax. And so, therefore, we made it an entitlement. And, in my view, that shifts the importance of this contract significantly, and I'm not sure my people all recognized it.

Now it is my job to make sure they do and to recognize those things from a bigger perspective. It is the reason I have gone there twice. It is the reason I personally have started taking the anthrax vaccine and have taken the shots. And it is not because I expect that we are going to get attacked over at the Pentagon, although we might, but it is because I wanted to demonstrate that I am comfortable with the quality control. I am with comfortable with what BioPort is doing. And so I am willing to put it in my body, which is final. But the crux of this is I am not sure people recognize that work for me that things were shifting, that we had shifted from a toy wagon program to an entitlement program in which we were going to have to respond to all the mothers and fathers across the country as to how we were protecting their sons and daughters.

Mr. SHAYS. I appreciate that response but it really does beg another response from one aspect. You are calling it an entitlement but there are some people who don't want to be entitled?

Mr. OLIVER. There are some people who don't want to be entitled to Social Security. There are some people who don't want to be entitled to everything.

Mr. SHAYS. And they have the ability to turn it back. You made that point that you are thinking about them, so I am just going to give you a different view for the record.

Mr. OLIVER. Yes, sir.

Mr. SHAYS. The different view is that while you are willing to put this in your body, some don't. And yet some still want to serve the country and they have served it gallantly in the past and want to continue to. And you have—your Department has made a determination that whether or not they want it, they take it. And they even take it if they are not in a zone that may demand that they be protected from it. And that is the craziness of this.

And one of the things, and it does raise a point, my understanding is one of the issues is that DOD is determined to buy 3 million less doses, is that correct?

Mr. OLIVER. Sir?

Mr. SHAYS. Purchase 3 million less dosages of the anthrax, that is not correct?

Mr. OLIVER. No, let me be completely careful. As I said to you, my staff is evaluating BioPort's proposal. I have not looked at it. I would have, in fact, I would have liked to before the hearing——

Mr. SHAYS. Let me clarify this, BioPort is suggesting that you all buy 3 million less?

Mr. EL-HIBRI. May I clarify?

Mr. SHAYS. Yes, I just want to understand the facts.

Mr. EL-HIBRI. Yes, it is important that we understand the facts. For the contract year one or option year one and two, there were 2.5 million doses negotiated back in September. Those numbers were derived from, as I understand it, the theoretical capacity of what we believed the new renovated facility that hadn't been completed by then would deliver.

Now, in our proposal, we had significantly lower doses, in line with about 1.5 million, I believe, and 3.4 million for the next year.

Mr. SHAYS. This is production capacity?

Mr. EL-HIBRI. Right. Because in our proposal, we allowed a little bit for private sales and we allowed a little bit for contingencies because you never really can operate at full capacity.

Mr. SHAYS. Right.

Mr. EL-HIBRI. But since it wasn't our equipment and since we were told we have to deliver everything to the Government, we were possibly not as insistent about our potential inability to deliver those quantities. Now it turns out that these numbers were derived more from capacity and not really from the actual requirements of the AVA program. When we then studied the AVA program, as we understand it, we realized that the AVA program does not require 2.5 million doses this year and 5.4 million does next year. Actually, to our understanding, we don't know what they would do with those doses. So we revised our proposal based on the more realistic production levels, while allowing us also to allocate a few doses for private sales.

Mr. SHAYS. OK, let me, but you are also doing it based on what you think the DOD needs?

Mr. OLIVER. Yes, sir.

Mr. SHAYS. And, General Blanck, maybe you could respond to this. What are the DOD requirements for vaccine doses this year?

General BLANCK. This year just under 1 million doses.

Mr. SHAYS. And next year?

General BLANCK. Next year it depends if we go from phase one, which we are currently in and which the vaccine is required for those who are in or would deploy to high-threat areas. And so the requirement would be approximately the same, even slightly less if we remain at phase one next year. If we go to phase two, which——

Mr. SHAYS. I'm sorry, if you stay in phase one, it is about a million more next year?

General BLANCK. Perhaps a little less.

Mr. SHAYS. And if you go to phase two?

General BLANCK. If we go to phase two, then that is the follow-on forces, so it would be approximately three times that. And I don't have the exact figure. I can get that for the record.

[The information referred to follows:]

Mr. Shays, during our June 30th testimony, you asked for the DOD requirements for vaccine doses to proceed into Phase 2. We completed this analysis and anticipate the following requirements through 2002:

Phase 2:

2000 2.924 Million Doses
2001 3.655 Million Doses
2002 4.225 Million Doses

Mr. SHAYS. 2001?

General BLANCK. 2001 remains the same. It doesn't increase substantially until about——

Mr. SHAYS. Be the same as whatever next year is?

General BLANCK. Yes, sir.

Mr. SHAYS. OK. I guess one of the things that I want to be certain of is DOD has a concern that their sole provider is able to meet its needs. BioPort would obviously have a concern that you could be asking for more or less and they have got to be able to operate and make their capital costs and also their employee costs have some stability. And what I want to be certain is that you don't decide to base, go into phase two based on the needs of BioPort?

Mr. OLIVER. Absolutely, we are not going to. In fact, I really wanted to point out whatever he may think is DOD's needs, it is not his responsibility. That is our responsibility to determine.

Mr. SHAYS. Right.

Mr. OLIVER. And it has nothing to do with what he thinks is best for him and is not going to have anything to do with it. That is what I started to say when you called on the General. We are going to determine—first of all, we are not going to go to phase two until this production line that he has in has been approved by the FDA and by the people who work for me and who work for the General, the Secretary is not going to consider going to phase two until we have assured production line. That is to start with.

Second, I like some of the people up in Lansing, MI, but we are not going to run the Defense Department based on what is best for their business. That is one reason we wanted to cut it off because it is a lot easier to deal with a private company, which is harder for them, but a lot easier for us. It is not going to be policy.

Can I talk about two other things, Mr. Chairman?

Mr. SHAYS. Sure.

Mr. SHAYS. I wanted to talk about when we go from phase one to phase two——

Mr. SHAYS. Right.

Mr. OLIVER. I mean that is going to be dependent upon an assured production line that is in existence. As I told you, we have enough right now, we can make it through August. In the event we have problems, which I think allows us significant months to fix any problems that come up. And, second, it is not BioPort's—I am not terribly interested in what is in BioPort's best interest in this area. This is what the Secretary of Defense and the Joint Chiefs of Staff said.

I would just like to return, because I don't want it on the record, the discussion you had with the General Accounting Office on this 70,000 doses, 30,000 doses. The question is what did we sell to Canada. Right? What did I approve to sell to Canada? First of all, let's talk about the process. The process is the people who did the contract originally, although I don't think either side understood

the costs for the reasons I've talked about. They don't understand the costs until they got actually divorced from the State of Michigan and subsequently got rid of all those little arteries that were pumping in money that were not known. So I don't think the people on either side understood the costs.

But they did what I think is a good contract in that they specified that BioPort was permitted to use the Government-furnished equipment to produce 200,000 doses a year in excess of what the Government needed for private sales. And that is a good idea because it induces BioPort to use more effective processes, to make sure they don't have wastage through poor quality control. And it introduces some capitalistic drivers in it. And so I think it was a really good idea.

What we added to that, and it is not in the contract, what we added to it is though that they can't sell that to anybody. There are various end-users that the Department of Defense is not interested in them selling to. So what we did is we put it under what is called the International Trade and Arms Regulation restrictions. BioPort is not interested in us doing this, but that is the breaks. And what happens with ITAR, as you know, it is the same thing you use whether you are going to sell a tank or anything else, it needs the Department of Defense to review this process and needs the State Department to review the process. In other words, is this in our best interest? Does it cause problems in the world, et cetera? So they cannot just go out on the street and sell this stuff. They have to go through a lengthy process.

My staff proposed to me that we permit BioPort to sell a number of dosages from what BioPort owned, not from what the Government had bought, but from what BioPort had separately. OK, so it wasn't Government property.

Mr. SHAYS. And this is previous?

Mr. OLIVER. Yes, sir, previously manufactured——

Mr. SHAYS. OK.

Mr. OLIVER [continuing]. Lot—in 44. And so Canada had come in with a request and Canada came in with a request and said we would like to have some anthrax vaccine for those soldiers that we have with you that are poised, that are monitoring Israel and monitoring the Middle East, that are up in Saudi Arabia ready to go in the Gulf and that are operating with your Naval forces in the Gulf. And we would like to have some vaccine to do that. And here is Canada, one of our very best allies, and no one that I ever think is going to turn against us, and they would like to be protected the same way our soldiers and sailors are protected, and I think that is a tough thing to turn down.

Mr. SHAYS. I am just going to qualify. They want the soldiers who are in deployed areas to have the vaccine?

Mr. OLIVER. Same as ours, same as our 10 areas, our phase one.

Mr. SHAYS. Right, yes.

Mr. OLIVER. And so they asked to do that and that ends up being 5,000 or 6,000 doses a year over 5 years. And so we approved that through the process in the Department of Defense. And, in fact, and then it went over to the State Department, and I think a couple of weeks ago, the State Department finally issued a license to BioPort to issue 3,000 doses or some number. And that went

through and that was sold directly—BioPort sold that directly to the Canadian Government instead of washing it through us, which is the way we are doing lots and lots of contracts right now.

Mr. SHAYS. OK, let me ask you. At a higher price or cheaper price?

Mr. OLIVER. At a higher price, I understand.

Mr. SHAYS. No, Mr. El-Hibri?

Mr. EL-HIBRI. At $40 a dose.

Mr. SHAYS. As opposed to?

Mr. EL-HIBRI. Sorry?

Mr. SHAYS. $40 a dose as opposed to what?

Mr. EL-HIBRI. As opposed to $3 per dose that DOD pays.

Mr. SHAYS. You are saying $40 per dose?

Mr. EL-HIBRI. That's right.

Mr. SHAYS. I think you made the contract with the wrong country. [Laughter.]

Mr. EL-HIBRI. Yes, sir.

Mr. OLIVER. There are some interesting issues in that which is with respect to whether or not we want to have our stuff subsidized, shifted from the State of Maryland—or State of Michigan to the Canadian Government, but, as you may understand. But nevertheless, it was a sum of money that we approved the sale. It was not Government product. Mr. Chairman, at no time at which I was there would we sell what the Government owns, would permit them to sell to somebody else.

Mr. SHAYS. This isn't a trick question though but did you indemnify them for the sale in Canada?

Mr. EL-HIBRI. No.

Mr. SHAYS. There is no indemnification?

Mr. EL-HIBRI. No, we had to sign a waiver.

Mr. OLIVER. There is no indemnification. And the other part you have to understand is no indemnification for negligence either.

Mr. SHAYS. Right.

Mr. OLIVER. That is a key part.

Mr. SHAYS. But if you had a contract for $40 a dose, you would probably be willing to indemnify yourself?

Mr. EL-HIBRI. Sorry?

Mr. SHAYS. If you had a contract with the U.S. Government for $40 a dose, you would probably be willing to take the risk?

Mr. EL-HIBRI. That's correct.

Mr. OLIVER. I am not willing to approve—I do not know what we are going to do, but I want to assure you, Mr. Chairman, $40 is not within the bargaining range that I am looking at. [Laughter.]

Mr. EL-HIBRI. Mr. Chairman, what we are talking about is to bringing it up to a level of approximately $10 per does, consistent with what the Government pays other pharmaceutical companies on average for other vaccines that they purchase out on the market.

Mr. SHAYS. Are you all set?

Mr. OLIVER. No, that was it. I just wanted to talk about the sale and make sure we had on the record what truly happened and also make sure you understood that there were safeguards in place as to end users and also safeguards in place so that we had a Government position on each sale.

Mr. SHAYS. OK. Well, let me just tell you what I think is on the table right now and if you want to correct the record, I want the record corrected. What I think is on the table right now is that we have a program that is still mandatory, that you haven't decided when you are going to go from phase one to phase two. Is it a question of whether you ever will or is it a question you intend to, you just don't know when? I saw a nodding head but that doesn't get recorded.

General BLANCK. Yes, the intention is to go to phase two at a time that we have assured production of the new vaccine, the vaccine that will come off the new production line.

Mr. SHAYS. It is your testimony that a decision to go to phase two will not be based on your keeping up some production level?

General BLANCK. That's correct.

Mr. SHAYS. OK. So there is still an opportunity for others to convince you that maybe that is the wrong way to go?

General BLANCK. Convince the Secretary of Defense.

Mr. SHAYS. Right. But we have a mandatory program in which you intend to go ultimately and cover all military personnel with the anthrax vaccine?

General BLANCK. Yes, the decision is to cover the entire force, total force, active and reserves.

Mr. SHAYS. Whether or not they are in a theater of danger?

General BLANCK. Yes, sir.

Mr. OLIVER. Well, did you say whether or not they are in a threat?

Mr. SHAYS. In a theater of danger?

Mr. OLIVER. Yes, sir, but I——

Mr. SHAYS. So ultimately someone who is based in—a person based in St. Louis will have this anthrax vaccine?

Mr. OLIVER. Yes, sir.

Mr. SHAYS. Whether or not they want it?

Mr. OLIVER. But, Mr. Chairman, I lived in Connecticut for 5 years, the longest place I ever lived in my life and a gorgeous area, I would like to point out. And one might not think that you are not threatened there and how do you know, how does the Secretary know that we are not going to be threatened by a terrorist or that he is not going to ask someone who is currently stationed someplace, whose talents are needed in a threat area, not to go? And not to be part of the military.

Mr. SHAYS. In this day and age, I think we are going to have to figure those things out, honestly. And I think that a one-size-fits-all, of all the things that I come down to in all these hearings is that there has got to be not one-size-fits-all mentality here. And I have been persuaded by some military people that my view that it should be voluntary presents some real morale problems, et cetera. So I am less inclined to advocate that, but I am certainly inclined to say that where they are not under real threat, that there has got to be some evaluation of that. And I think most members in the military would concur with that.

Mr. OLIVER. Mr. Chairman, let me record my personal disagreement with that, but return to my professional thing and talk about how comfortable I am with the current condition of BioPort.

Mr. SHAYS. Well, the only thing I have really agreed with you so far today is that Connecticut is a great place to live. [Laughter.]

Mr. OLIVER. I knew that would come.

Mr. SHAYS. No, I have agreed with other points. But, I'm sorry, let me get to this point. What did you want to say and then we will——

Mr. OLIVER. No, sir.

Mr. SHAYS. The bottom line to my finishing though, this is a mandatory program. It is still going from phase one to phase two, as you all see it. And that you have an agreement with BioPort that it is your sense, Mr. Oliver, it is not a realistic agreement and you are re-appraising this agreement.

From BioPort's point of view, you all made a purchase, somewhat rolling the dice, frankly, that the contract, that there wouldn't be a Congress that would all of a sudden pull this program out from under, that you would have a good case scenario and be able to meet your needs feeling somewhat under pressure from the Government to agree to their—what they were willing to pay since they are the only buyer you got. And things didn't work out as you hoped, but you are not surprised that you are in this circumstance. And you are asking the Government to re-appraise this agreement and that you can't meet the agreement as you originally signed on without literally going belly up?

Mr. EL-HIBRI. It would be difficult to sustain ourselves much longer. Currently, we are not in default but if you were to ask me how much longer we can sustain ourselves given the current contract value, it would be difficult to give assurances that we could meet our obligations throughout the rest of the contract.

Mr. SHAYS. OK, well, then let me just finish up with this line of questioning. What alternatives does DOD have in the short-run and the long-run as it relates to the buying of anthrax vaccine?

Mr. OLIVER. There are no alternatives in the short-run. In the long-run, as you know, Mr. Chairman, we are in the process of evaluating the budget for next year, the one after you are working on right now. In that process, in which I am personally involved, we are evaluating a couple of different options. And one option would be whether or not we had BioPort establish a separate facility physically remote, physically distant. Whether or not we paid to startup a new company because we find no commercial interest and locate it at either in the same State or distance. And the problem with that is, the first one we think takes 3 to 5 years. The second one my staff tells me takes 4 to 7 years. Actually, they tell me 8, but leadership will make that improve a year. And the other option is a new type of technology and to get another drug company to try a new type of technology. We think that also is about 5 to 8 years away.

The problem, of course, and let me discuss this is you have a vaccine for anthrax—you know anthrax is a threat because you know that Iraq has weaponized it, you know that Russia worked on it, you know several other people. So you have a threat. You have something that is safe and effective for the existing problem. And that takes care of anthrax. Let us assume that you have several other things, which your intelligence people tell you that somebody

in the world is working on and trying to weaponize and they may spring on your troops, and you don't have anything against those.

So the question we are going to wrestle with this summer while we are looking at the budget is do I take a chunk of money, several tens of millions of dollars, and I put it against developing a second source to BioPort or developing a different type of approach to solve the anthrax problem and don't take that money and put it against solving another bio-threat or do I accept where BioPort—and instead manage it as effectively as I can to make sure (1) they are not going to rip off the Government; and (2) the quality control stays good, and I am comfortable with their product and the people they have in charge.

All those are issues that we are going to review in the summer and I think that that shows the range of it. And we are not there yet. We do not have consensus, but those are the issues we are looking at, Mr. Chairman.

Mr. SHAYS. Thank you. I think that is a helpful response and not easy answers to those questions. Well, maybe they are easy in one sense. But is there anything else any of you want to say? Dr. Myers, you have been uncharacteristically silent. Do you have any comment you want to make? [Laughter.]

Mr. MYERS. No, other than to say I gained further insight into the issues as you see them today, as I mostly listened to today's proceedings and they were very helpful as an individual to me. And I would hope that I could speak with staff in the future and gain even further insight into your concerns.

Mr. SHAYS. OK. Mr. El-Hibri, any comment?

Mr. EL-HIBRI. Yes, if you allow me, I would like, Mr. Chairman, just to clarify the issue a little bit. I might still be—or at least—I was confused about the amount the Government has invested over the last several years in the Michigan facility. Our records show it is $6.9 million in Government-furnished equipment and about $5 million in renovations. If I am not mistaken, it is a total of $11 million, it is not $11 million plus $7 million, but it is a total of $11.

Again, we inherited State records so I can't tell you with any precision whether that is correct or not. But even if whether it is $11 million or $18 million, if you look back 10 years and ask what it would have taken to establish a new vaccine, new facility, you would see that it would have costed hundreds of millions of dollars to do so. And, incidentally, in the chart of the GAO's statement, I saw that approximately $100 million was spent on product. Well, but that is not an investment. You received product in exchange for it. And what you received was a very cheap product at an average price of about $6 to $7. So that you can't really call that an investment. Sure, it came out of DOD's pocket, but you received product in exchange, just like you buy any vaccine from another manufacturer. And it was the State government that really subsidized that price.

So really what is the DOD's or the Government's exposure? Be it $11 or $18 million for receiving millions of doses of vaccine per year. I think if you put it in that context, those numbers aren't that large.

Mr. SHAYS. Originally, this plant was set up to provide vaccines for veterinarians and so on, people who worked around animals, correct? What was the original purpose? It wasn't to protect our troops against terrorists?

Mr. MYERS. Well, let me——

Mr. SHAYS. I want the short answer. You have done so well.

Mr. MYERS. Very short. It is always called a plant. I just want to make sure everybody understands. It is one floor of a two floor building of 20 buildings.

Mr. SHAYS. But you heard my—my question is, let me just tell you why I am asking. What I am wondering is if anthrax was needed and necessary and it was developed, and I realize there is only one producer, and that was the State of Michigan, there must have been veterinarians and others around the country who wanted this vaccine. But it was what? Like only about 3,000 people a year who were drawing on this?

Mr. MYERS. I think you have the facts pretty well. Let's remember the driving force was laboratory workers.

Mr. SHAYS. Right.

Mr. MYERS. Quite honestly, at the time, that included laboratory workers who were involved in an offensive bio-warfare program, including in this country down the road at Fort Detrick.

Mr. SHAYS. OK.

Mr. MYERS. As well, though, the textile workers——

Mr. SHAYS. Got you.

Mr. MYERS [continuing]. Who were at serious risk of dying.

Mr. SHAYS. But now textile workers—and I guess this is an aside; it is kind of off here, but I have just been curious during this whole hearing—is there not a need today, lab people, people who work with wools, veterinarians, they don't need this vaccine anymore?

Mr. MYERS. The same people who have been served through this vaccine through the last 30 years continue to receive vaccines today. And that is still in the amount of——

Mr. SHAYS. Of the small doses?

Mr. MYERS. Yes, sir.

Mr. SHAYS. OK, and they are still buying from your plant?

Mr. MYERS. They are still obtaining the vaccine from us. That is correct.

Mr. SHAYS. And one last question for you, General Blanck, was also on my list. When this continues, the program continues, after you have gone, if you to phase two with everyone, then what will be the maintenance each year? Will it still continue to be about a million people then because how many people new people do we have, how many leave?

General BLANCK. Well, it will actually be substantially more than that because the current dose schedule requires yearly boosters plus those who will begin their series. And that is the zero to 4 week, 6 month, and so forth. So the need at that point, when we are in phase three, which is scheduled now to be in 2003, will be well in excess of a million.

Mr. SHAYS. I hope whatever contract is ultimately agreed to, if it is re-negotiated and there is a new agreement, that it will not be, that production levels will not be a requirement for BioPort to

continue to function unless you just literally throw away the production because I have this concern that you will end up, whether you stay in this or not, that there will be this great temptation to make sure that you have a certain production level to justify——

Mr. OLIVER. Mr. Chairman, let me assure you, that happens to be my problem is I don't think people—I was concerned that some of my people did not recognize that what I was interested in—I am interested in making sure the Government gets the best interest. I am also interested in ensuring they keep the overhead people that do quality control and process control, no matter what their level of production is. I don't want them to be encouraged to let go of the very people that I am relying upon to keep the dosages safe that I am putting in my body. So I will assure you that I will do that.

Can I correct the record for something?

Mr. SHAYS. Yes, but before you do, just let me ask this other question. Realistically, Mr. El-Hibri, when do you anticipate being back in production? I am also tempted to have you write this down on a paper silently and have you put this down in paper silently, Mr. Oliver, and have you both respond. Mr. Oliver——

Mr. OLIVER. I won't listen.

Mr. SHAYS. No, I just want you to write down a number on a page. Write down when you think it is going to be? Thank you, Mr. El-Hibri.

Mr. EL-HIBRI. We have been back in production since May. [Laughter.]

Mr. SHAYS. No, no, no, you are not playing fair here. This plant is not fully operating. It is not——

Mr. OLIVER. It is not approved, the product is not approved.

Mr. EL-HIBRI. Can I just, I was about to continue.

Mr. SHAYS. OK.

Mr. EL-HIBRI. We are talking about anthrax vaccine production, I believe?

Mr. SHAYS. Right.

Mr. EL-HIBRI. The facility that has been renovated, started producing lots—doses of vaccine in May. We are in the process of completing all the documentation necessary to submit to the FDA in order to approve the renovation. That takes about 6 months or so on average. It is very difficult to—there could be some time slippage there. But only after the FDA has approved our facility, can those doses be made available to the Government.

Mr. SHAYS. Are you at 60 percent of production level or at 10 percent?

Mr. EL-HIBRI. We are right now operating at six sub-lots a week, which translates roughly to a level of about 3 to 3.5 million doses a year.

Mr. SHAYS. So is that the production level you anticipate being at?

Mr. EL-HIBRI. We believe that we can crank the production level up to about 4 to 4.5 million a year.

Mr. SHAYS. OK. By when?

Mr. EL-HIBRI. By next year.

Mr. SHAYS. OK.

Mr. EL-HIBRI. So there will be a slow ramp up. Again, since we are producing three times as much as we have ever done in the past, there is a great burden on our——

Mr. SHAYS. I understand.

Mr. EL-HIBRI [continuing]. Laboratory technicians. We just want to make sure that we continue producing at the rate that is comfortable for our people and that the addition of additional staff is done in a realistic manner.

Mr. SHAYS. OK. We just keep thinking, and my staff keeps thinking of questions that, and I do want to draw this to a conclusion, but technically you are at risk in your production now until they approve? In other words, they could decide that what you have produced for 5 months is not going to be approved?

Mr. EL-HIBRI. That is correct. Is at risk, but we do receive some progress payments from the Government. So we share risks.

Mr. SHAYS. Fair enough. Mr. Oliver, what did you write down?

Mr. OLIVER. February 2000 because although he is correct as to the normal time, 6 months, which would be late December, early January, my experience is that we always experience some delays in there.

Mr. EL-HIBRI. That's correct.

Mr. OLIVER. So I am going to lean on my people to maintain the right schedule, et cetera, which is January. But I always like to be right rather than——

Mr. SHAYS. Good, OK.

Mr. OLIVER. And so I think it is February, that is what I think. Can I correct one thing that he said, sir?

Mr. SHAYS. Yes, you can correct.

Mr. OLIVER. I am not sure, you were interested in Government-furnished equipment and renovations and I am not sure they are counting all the money since 1991. I am not even sure you would know what it is. And if you count all the money since 1991, our records show that the renovations have been $11.3 million and the Government-furnished equipment is $6.9 million.

Mr. SHAYS. That is what we are going with.

Mr. OLIVER. Sir?

Mr. SHAYS. That is what we are going with.

Mr. OLIVER. I just wanted to correct that.

Mr. SHAYS. That's fine.

Mr. EL-HIBRI. And as to production, I didn't mean to answer your question incorrectly. We are actually producing, but it doesn't mean that we have a product that we can sell.

Mr. SHAYS. I understand that and I think your answer was valid based on your response. You are producing now, it just hasn't been FDA approved. But those lots that you are producing now, more than likely will be approved. You can't be certain of it. And you and the Government are sharing the risks.

Mr. EL-HIBRI. That's right, and for the record, we believe it is probably going to be February. [Laughter.]

Mr. SHAYS. OK. I will say this though, the unhealthy part of this is that you are a private sector operation which is forcing the Government to share in your risks. And that is evident from this. The bottom line is this is so important to us that we are going to want this plant to operate. And that is why it is important, Mr. Oliver,

that your people do tremendous oversight. It is a monopoly that we need to operate if you continue with the program as you intend.

Mr. OLIVER. Yes, sir, I appreciate that. As I told you, I have had people out there——

Mr. SHAYS. I hear you.

Mr. OLIVER. I have had lots of people out there.

Mr. SHAYS. I just want you to know that I feel that way on the record.

General Blanck, any closing comments?

General BLANCK. Nothing to add, thank you.

Mr. SHAYS. OK. Anybody else want to make some—yes, sir?

Mr. EL-HIBRI. Yes, please. I would just like to address the issue of sharing risks.

Mr. SHAYS. Are you sure you want to?

Mr. EL-HIBRI. I do.

Mr. SHAYS. OK, well, it is going to open up—fair enough, OK.

Mr. EL-HIBRI. OK, we risked moneys when we took this thing over. We did an evaluation of the risk and return potential.

Mr. SHAYS. Can I say something to you, I don't know if you want to go down this door.

Mr. EL-HIBRI. OK.

Mr. SHAYS. I am going to tell you what your options are first.

Mr. EL-HIBRI. All right. Fine, I take your advice, Mr. Chairman.

Mr. SHAYS. We are going to get into a whole big discussion about really what kind of risks. And we will be here for a lot longer. I will accept the fact that you think you have taken a risk, and we will leave that on the record. And you can accept my feeling that it is a risk with many qualifications. And so it is quite a different risk. It is a shared risk.

All right, folks, thank you very much. I am going to close.

Mr. EL-HIBRI. Thank you.

Mr. OLIVER. Thanks, Mr. Chairman.

[Whereupon, at 12:35 p.m., the subcommittee was adjourned.]

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