

Testimony

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

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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





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 in appendix I to this statement.

Background

From the 1970s until 1998, DOD had 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 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 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.

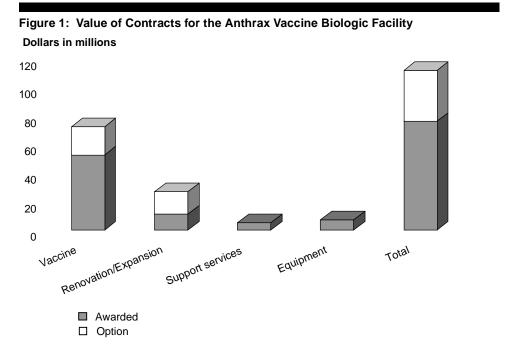
Because of the delays, the company has not received the revenues it expected and now faces a serious cash flow problem. The cash flow problem, we believe, is due to the company's inability to achieve its overly optimistic business plan. In response to its cash flow problem, BioPort requested—and DOD has authorized—the sale of 70,000 doses to other customers before meeting its contractual requirements with DOD. In

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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.



Source: GAO analysis of DOD contracts.

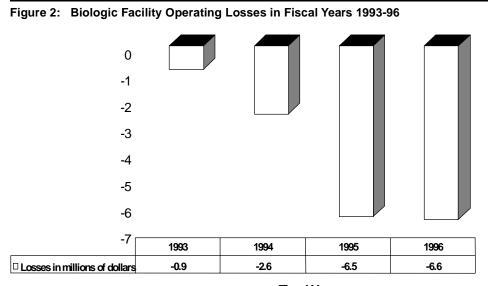
DOD has also provided contract terms and conditions to help ensure the success of the anthrax vaccine program. For example, under Public Law 85-804, which allows for government indemnification of contractors for unusually hazardous risks, DOD indemnified BioPort against product liability. In addition, 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.

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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



Fiscal Year

Source: Independent accountants' reports.

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¹BioPort considers its projected operating loss for the year ending December 31, 1999, proprietary information and, therefore, it is not included in this statement.

²Data regarding the State of Michigan's operating losses were available only for fiscal years 1993-96.

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 perform its DOD contracts. According to 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 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.

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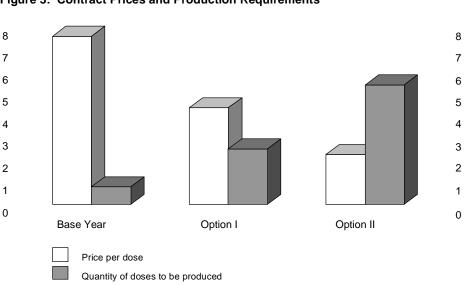


Figure 3: Contract Prices and Production Requirements

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. For the record, major contributors to the testimony were Johana R. Ayers, Ralph C. Dawn, Christopher P. Galvin, and Paul M. Greeley. I would be happy to answer any questions you may have.

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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).

<u>Gulf War Illnesses: Questions About the Presence of Squalene Antibodies in Veterans Can Be Resolved</u> (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).

<u>Combating Terrorism: Observations on Federal Spending to Combat Terrorism</u> (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).

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

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