~~FOR OFFICIAL USE ONLY~~

Audit Report

CONTRACTING FOR ANTHRAX VACCINE

Report No. D-2000-105 March 22, 2000

Office of the Inspector General
Department of Defense

~~Special Warning~~

~~This report contains contractor information that may be company confidential or proprietary. Title 10, U.S.C., Section 1905, and title 41, U.S.C., section 423, provide specific penalties for the unauthorized disclosure of company confidential or proprietary information. This report must be safeguarded in accordance with DoD Regulation 5400.7-R.~~

~~This document is exempt from the mandatory disclosure under the Freedom of Information Act exemption number 4.~~

Additional Copies

To obtain additional copies of this audit report, contact (b) (6) at (b) (6) (DSN (b) (6)) or (b) (6) at (b) (6) (DSN (b) (6)).

Suggestions for Audits

To suggest ideas for or to request audits, contact the Audit Followup and Technical Support Directorate at (b) (6) (DSN (b) (6)) or fax (703) 604-8932. Ideas and requests can also be mailed to:

OAIG-AUD (ATTN: AFTS Audit Suggestions)
Inspector General, Department of Defense
400 Army Navy Drive (Room 801)
Arlington, VA 22202-2885

Defense Hotline

To report fraud, waste, or abuse, contact the Defense Hotline by calling (800) 424-9098; by sending an electronic message to Hotline@dodig.osd.mil; or by writing to the Defense Hotline, The Pentagon, Washington, DC 20301-1900. The identity of each writer and caller is fully protected.

Acronyms

AVA	Anthrax Vaccine Adsorbed
DCAA	Defense Contract Audit Agency
FAR	Federal Acquisition Regulation
FDA	Food and Drug Administration

INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
400 ARMY NAVY DRIVE
ARLINGTON, VIRGINIA 22202-2884

March 22, 2000

MEMORANDUM FOR UNDER SECRETARY OF DEFENSE FOR ACQUISITION, TECHNOLOGY, AND LOGISTICS
DIRECTOR, DEFENSE CONTRACT AUDIT AGENCY
DIRECTOR, DEFENSE LOGISTICS AGENCY
AUDITOR GENERAL, DEPARTMENT OF THE ARMY

SUBJECT: Audit Report on Contracting for Anthrax Vaccine
(Report No. D-2000-105)

We are providing this report for your information and use. The audit was requested by Congressman Walter B. Jones. Because this report contains no recommendations, no written comments were required on the draft version, and none were received. Therefore, we are publishing this report in final form.

We appreciate the courtesies extended to the audit staff. For additional information on this report, please contact (b) (6) at (b) (6) (DSN (b) (6)) (b) (6)) or (b) (6) at (b) (6) (DSN (b) (6)) ((b) (6)). See Appendix E for the report distribution. The audit team members are listed inside the back cover.

Robert J. Lieberman
Assistant Inspector General
for Auditing

~~Special Warning~~

~~This report contains contractor information that may be company confidential or proprietary. Title 18, U.S.C., section 1905 and title 41, U.S.C. 423 provide specific penalties for the unauthorized disclosure of company confidential or proprietary information. This report must be safeguarded in accordance with DoD Regulation 5400.7-R.~~

~~This document is exempt from the mandatory disclosure under the Freedom of Information Act exemption number 4.~~

Office of the Inspector General, DoD

Report No. D-2000-105 **March 22, 2000**
(Project No. 9CK-5029)

Contracting of Anthrax Vaccine

Executive Summary

Introduction. This audit was requested by Congressman Walter B. Jones to review the financial and contractual relationship between the DoD and BioPort Corporation, the sole U.S. manufacturer of the anthrax vaccine. Specifically, Congressman Jones requested we review the renegotiation of the sole source Anthrax Vaccine Adsorbed contract that increased financial assistance to BioPort Corporation.

In 1970, the Food and Drug Administration granted the only Anthrax Vaccine Adsorbed license in the United States to the State of Michigan. Prior to September 1998, Michigan Biologic Products Institute, a facility in Lansing, Michigan, owned by the State of Michigan, manufactured the Anthrax Vaccine Adsorbed. In December 1995, the State of Michigan decided to initiate a privatization of Michigan Biologic Products Institute. In November 1996, the Food and Drug Administration inspected the Michigan Biologic Products Institute and in March 1997 issued a notice of intent to revoke their license. On September 4, 1998, BioPort Corporation acquired the Michigan Biologic Products Institute from the State of Michigan for about (b)(4) in a combination of cash, loans, products, and royalties. As part of the sale, Michigan Biologic Products Institute agreed to enter into a novation agreement that transferred three DoD contracts to BioPort Corporation.

On December 15, 1997, the Secretary of Defense ordered all military personnel to be inoculated against the biological weapon anthrax. On September 15, 1998, the U.S. Army Medical Research Acquisition Activity, Fort Detrick, Maryland awarded BioPort Corporation a firm-fixed price contract, DAMD17-98-C-8052, for the production, bottling, and storage of (b)(4) doses of the Anthrax Vaccine Adsorbed for about (b)(4), with options for (b)(4) doses for (b)(4), and (b)(4) doses for about (b)(4). In addition, the contract included about (b)(4) for renovations and to purchase equipment. The total basic contract value was about (b)(4).

Objectives. The overall audit objective was to determine whether the DoD complied with applicable Federal Acquisition Regulations and DoD guidance when procuring the anthrax vaccine. Specifically, we determined whether the contracts and related financial arrangements regarding the procurement of Anthrax Vaccine Adsorbed were proper and prudent. See Appendix A for a discussion of the audit scope and methodology and Appendix B for prior coverage.

~~(FOUO)~~ **Results.** In June 1999, BioPort Corporation requested financial assistance from the DoD to pay the loans owed to the State of Michigan and for other operating expenses. From June through July 1999, the Defense Contract Audit Agency issued three reports identifying deficiencies in BioPort Corporation's accounting system, financial capability, and request for extraordinary contractual relief. Nevertheless, in August 1999, DoD granted extraordinary contractual relief in the net amount of (b)(4) and amended contract DAMD17-98-C-8052. This action complied with Federal Acquisition Regulation requirements. DoD provided BioPort (b)(4) as an interest-free advance payment. In addition, the contract modification included a decrease in the number of doses to be produced from (b)(4) to (b)(4), and changed the price per dose from (b)(4) to (b)(4) per dose for Option Year I and from (b)(4) to (b)(4) for Option Year II. The modification also included a price redetermination clause.

~~(FOUO)~~ Public Law 85-804 has been interpreted to give the Government broad powers to grant the contractor whatever relief is necessary even when it may be caused by losses on non-Government work. DoD officials provided financial relief to make BioPort financially viable. DoD officials provided BioPort Corporation an advance payment that was (b)(4) more than BioPort requested and about (b)(4) more than the Defense Contract Audit Agency recommended. In addition, DoD officials included a (b)(4) in the revised price. At the revised price of (b)(4), (b)(4) In addition, (b)(4)

~~(FOUO)~~ In November 1999, the Food and Drug Administration performed an on-site inspection at the BioPort facilities in Lansing, Michigan. In addition, the Food and Drug Administration reviewed the establishment license application supplement submitted by BioPort. As a result of the on-site inspection and review of the establishment license application supplement, the Food and Drug Administration did not approve BioPort's application supplement, and found over 40 major and minor deficiencies. A significant finding concerned the anthrax vaccine process validation, which needed to be revalidated under current standards and not the standards of the 1970s that were previously used. BioPort's production of the Anthrax Vaccine Adsorbed without Food and Drug Administration approval of the renovated BioPort facilities and processes is considered "at risk" production, and consequently, the product may not be approved. If the product does not obtain Food and Drug Administration approval, it cannot be sold or distributed. As of March 16, 2000, the Food and Drug Administration had not approved the establishment license application supplement and BioPort's goal for obtaining approval is (b)(4).

~~(FOUO)~~ BioPort expended the total (b)(4) advance payment from DoD to repay the loans from the State of Michigan ((b)(4)), to make a settlement payment to their plasma supplier ((b)(4)), and to pay for nonspecific expenses ((b)(4)). BioPort has liquidated about (b)(4) of the advance payment against performance payments as of January 26, 2000. In December 1999, BioPort officials verbally informed DoD officials that they needed about (b)(4) in additional funds to pay for consultants to assist in complying with Food and Drug Administration requirements and other operating expenses. In BioPort's Management Plan 2000 dated January 24, 2000, BioPort identified (b)(4). In January 2000, (b)(4). The Defense Contract Audit Agency confirmed through

~~(FOUO)~~ an audit that (b)(4) and that there was substantial doubt that BioPort will be financially able to continue performing on Government contracts without further relief.

~~(FOUO)~~ (b)(4) Ultimate disposition of the Anthrax Vaccine Adsorbed doses produced to date without Food and Drug Administration approval of BioPort's revised processes and renovated facilities also is unresolved. (b)(4) Any amount of additional assistance may include additional extraordinary contractual relief pursuant to Public Law 85-804 and require congressional notification. See Appendix C for information on the ownership of BioPort Corporation. See Appendix D for a chronology of significant events.

Management Comments. We provided a draft of this report on February 22, 2000. Because the draft report contained no recommendations, written comments were not required, and none were received. Therefore, we are publishing this report in final form.

~~Special Warning~~

~~This report contains contractor information that may be company confidential or proprietary. Title 18, U.S.C., section 1905 and title 41, U.S.C. 423 provide specific penalties for the unauthorized disclosure of company confidential or proprietary information. This report must be safeguarded in accordance with DoD Regulation 5400.7-R.~~

~~This document is exempt from the mandatory disclosure under the Freedom of Information Act exemption number 4.~~

Table of Contents

Introduction

The audit was requested by Congressman Walter B. Jones to review the financial and contractual relationship between the DoD and BioPort Corporation (BioPort), the sole U.S. manufacturer of the anthrax vaccine. Specifically, Congressman Jones requested we review the renegotiation of the sole source contract, DAMD17-98-C-8052, to increase financial assistance to BioPort. BioPort submitted a request for extraordinary contractual relief which DoD granted and amended the contract pursuant to the authority of Public Law 85-804 and Federal Acquisition Regulation (FAR) part 50, "Extraordinary Contractual Actions."

Background

Anthrax Vaccine Adsorbed. On December 15, 1997, the Secretary of Defense, William Cohen, issued an order for all military personnel to be inoculated against the biological weapon Anthrax. The inoculation process entails a series of six vaccinations given over an 18-month period plus annual boosters.

State of Michigan Facility. Prior to September 1998, Michigan Biologic Products Institute, a facility in Lansing, Michigan owned by the State of Michigan, manufactured the Anthrax Vaccine Adsorbed (AVA). The Food and Drug Administration (FDA) had approved the only AVA license in 1970 to the State of Michigan. In addition to AVA, Michigan Biologic Products Institute had an establishment biologic license and had FDA licenses for at least four other vaccines including rabies and tetanus and at least three blood derivative products. In the mid-1990s, the State of Michigan decided to initiate a privatization and to sell Michigan Biologic Products Institute through a competitive solicitation. In November 1996, the FDA inspected the Michigan Biologic Products Institute and in March 1997 issued a notice of intent to revoke its license.

~~(FOUO)~~ On September 4, 1998, BioPort acquired Michigan Biologic Products Institute for approximately (b)(4) in a combination of cash, loans, products, and royalties. BioPort paid (b)(4) in cash to the State of Michigan. (b)(4)

The State of Michigan was the first lien holder. BioPort secured the promissory notes with a mortgage and security agreement which granted the State of Michigan security interest in all real property and buildings in Lansing, Michigan, and all fixtures, appliances, machinery, equipment, and other tangible personal property excluding inventory. A novation agreement was executed that transferred three DoD contracts to BioPort. Michigan Biologic Products Institute had performed the majority of the work on the three contracts prior to the time of the transfer to BioPort.

The three contracts transferred, with a total value of about (b)(4), were for:

- remodeling existing facilities, manufacturing, testing, bottling, and storing AVA, and providing insurance;
- testing of AVA and pentavalent botulinum toxoid adsorbed for potency, stability, and sterility; and
- maintenance, accountability, and storage of Government property.

~~(FOUO)~~ **Ownership of BioPort.** The largest stockholder of BioPort is Intervac, L.L.C., which is owned by I & F Holdings, Fuad and Nancy El-Hibri, and retired Navy Admiral William J. Crowe, Jr. I & F Holdings is owned by Ibrahim El-Hibri who is Fuad El-Hibri's father. In July 1999, BioPort's board of directors instituted an employee stock option plan for nonvoting shares. (b)(4) BioPort's Board of Directors includes Fuad El-Hibri, Robert Myers and Admiral William J. Crowe, Jr. See Appendix C for further information on the ownership of BioPort.

BioPort's Initial AVA Contract. On September 15, 1998, a contracting officer at the U.S. Army Medical Research Acquisition Activity, Fort Detrick, Maryland, awarded BioPort a combination firm-fixed price and fixed-price incentive contract, DAMD17-98-C-8052, for the production, bottling, and storage of (b)(4) doses of AVA for about (b)(4) or (b)(4) per dose, with options for (b)(4) doses for (b)(4) or (b)(4) per dose and (b)(4) doses for about (b)(4) or (b)(4) per dose. In addition, the contract included about (b)(4) for renovations and to purchase equipment for the Lansing facility. The total basic contract value was about (b)(4).

Performance-Based Payments. Contract DAMD17-98-C-8052 contains FAR clause 52.232-32, "Performance-Based Payments," which entitles BioPort to a performance-based payment upon " . . . successful accomplishment of the event or performance criterion for which payment is requested." BioPort receives payments based on milestone completion, not on costs. There are four phases of the AVA process on which performance-based payments can be made.

- (b)(4) payment: manufacturing stage;
- (b)(4) payment: formulation stage;
- (b)(4) payment: filling stage; and,
- (b)(4) payment: release stage. Payment is predicated on FDA release of lot.

BioPort can be paid up to (b)(4) of the AVA per dose price before FDA approval.

Renovated Facilities. When BioPort bought the facility from the State of Michigan, renovations were in progress. The facilities were shut down for renovations from the beginning of 1998 to about mid-May 1999, which resulted in reduced revenues because of lack of production of AVA and other products. A BioPort official stated the renovation took 4 months longer than planned. Although BioPort renovated the AVA facilities, they cannot release for use any AVA products produced from mid-May 1999 under revised production processes and in those renovated facilities until the FDA approves the processes and facilities.

Extraordinary Contractual Relief

BioPort requested additional funds from DoD in the form of extraordinary contractual relief to relieve their cash shortfall, repay their loans to the State of Michigan and to fund their operating expenses. BioPort requested a decrease in the number of doses, an increase in the AVA price per dose, and a one-time advance payment. The Army Contract Adjustment Board granted a net amount of (b)(4) in extraordinary contractual relief and the contract was modified to reflect the changes.

BioPort's Request for Additional Funds

~~(FOUO)~~ **Submission for Extraordinary Contractual Relief.** BioPort's official request for extraordinary contractual relief pursuant to Public Law 85-804, and FAR part 50 for contract DAMD17-98-C-8052 was submitted on June 24, 1999, to the contracting officer. BioPort requested extraordinary contractual relief to solve their cash deficit and to fund their operating expenses. If BioPort were not provided with extraordinary contractual relief, it would have been detrimental to the Anthrax vaccination program, which is essential to the safety of our military personnel and our national defense. (b)(4)

BioPort's decision to apply for extraordinary contractual relief was based on the factors as outlined below.

- ~~(FOUO)~~ (b)(4)
- ~~(FOUO)~~ (b)(4)
- ~~(FOUO)~~ The renovations of the BioPort facility exceeded the original timeline by about 4 months (b)(4) BioPort requested that DoD provide BioPort a one-time advance payment for operating expenses.

~~(FOUO)~~ **Number of Doses Produced.** BioPort requested that the number of doses be reduced from (b)(4) to (b)(4) in Option Year I and from (b)(4) to (b)(4) in Option Year II. The request constitutes an overall reduction of (b)(4) doses for Option Year I and Option Year II. (b)(4) In addition (b)(4), BioPort requested that DoD allow an 80 percent/20 percent split for all new AVA production during Option Year I and Option Year II, which would allow the Government to retain 80 percent and BioPort to retain 20 percent of all new AVA doses.

~~(FOUO)~~ **AVA Price Per Dose.** In order for BioPort to achieve financial stability, BioPort requested that DoD increase the AVA price per dose. BioPort contended the DAMD17-98-C-8052 contract price per dose (b)(4) BioPort requested the price per dose to be increased from (b)(4) to (b)(4) for Option Year I and from (b)(4) to (b)(4) for Option Year II. As a result of the increase to the price per dose, the overall contract value would have been increased by about (b)(4).

~~(FOUO)~~ **Advance Payment.** In addition to the price per dose increase, BioPort requested a one-time advance payment in the amount of (b)(4) to fund current operating expenses. BioPort has planned to repay the advance payment by (b)(4). As of January 26, 2000, BioPort has liquidated (b)(4) of the advance payment through performance-based payments.

~~(FOUO)~~ **Commercial Financing.** According to FAR part 50.304(b)(8), "Facts and evidence," before extraordinary contractual relief can be granted, the Government contractor must attempt to obtain commercial financing. (b)(4)

~~(FOUO)~~ **Submission for Contract Modification.** On June 28, 1999, BioPort, subsequent to their request for extraordinary contractual relief, requested contract DAMD17-98-C-8052 be modified to account for conditions since the contract was executed. In consideration for modifying the contract, (b)(4). BioPort requested the following changes to contract DAMD17-98-C-8052.

- ~~(FOUO)~~ (b)(4)
- ~~(FOUO)~~ (b)(4)
- ~~(FOUO)~~ (b)(4)

~~(FOUO)~~ (b)(4)

- ~~(FOUO)~~ (b)(4)

~~(FOUO)~~ **Value of FDA Licenses.** (b)(4) On July 15, 1999, BioPort officials provided the value of the FDA AVA biologics license to the contracting officer. In addition, BioPort pledged the FDA licenses as collateral to the DoD for the advance payment.

~~(FOUO)~~ **Deferred Revenue.** When BioPort receives funds from DoD under "performance-based payments," for doses of AVA produced prior to FDA approval, (b)(4) since the newly produced doses of AVA have not received final FDA approval. When BioPort receives final facility approval and lot approval for the newly produced AVA doses, BioPort will (b)(4) If final FDA approval is not granted for those doses or the facility, (b)(4) . BioPort may have to replace the rejected doses and seek additional relief from DoD. As of December 31, 1999, (b)(4)

DCAA Reviews

At the request of Defense Contract Management Command, DCAA performed three audits of BioPort within a short timeframe. DCAA performed an "Accounting System Audit," a "Financial Capability Audit," and an "Audit of Request for Extraordinary Contractual Relief Under P.L. 85-804."

~~(FOUO)~~ **DCAA Report No. 2261-99G11070001, "Accounting System Audit," June 11, 1999,** concludes that BioPort's accounting system was inadequate for accumulating and reporting costs on Government contracts. According to DCAA, BioPort's accounting system does not segregate direct and indirect costs, does not compute indirect expense rates, and does not ensure the exclusion of the FAR unallowable costs. The inadequacies adversely affect BioPort's ability to determine the costs incurred to produce each of their products including AVA. DCAA was unable to determine the cost to produce AVA.

~~(FOUO)~~ **DCAA Report No. 2261-99G17600008, "Financial Capability Audit," June 11, 1999,** concludes that there is substantial doubt BioPort will be able to continue performing Government contracts. (b)(4)

~~(FOUO)~~ **DCAA Report No. 2261-99G17200004, "Audit of Request for Extraordinary Contractual Relief Under P.L. 85-804," July 21, 1999,** concludes that BioPort's request for extraordinary contractual relief did not fully comply with the requirements of FAR parts 32.4 and 50. (b)(4)

DCAA recommended an advance payment of (b)(4)

Army Contract Adjustment Board

The Army Contract Adjustment Board granted BioPort extraordinary contractual relief in a Memorandum of Decision, ACAB No. 1246, dated July 27, 1999. According to the FAR part 50, contract adjustment boards have the power, in cases where it is essential to the national defense, to provide extraordinary contractual relief to Government contractors. The Army provided extraordinary contractual relief to BioPort because it had insufficient money to fund its operating expenses and satisfy its loan to the State of Michigan. Without extraordinary contractual relief, BioPort would not have been able to continue producing AVA, thus compromising the safety of our military personnel and our national defense. The FAR part 50.202, "Contract adjustment boards," states that a contract adjustment board may be established " . . . with authority to approve, authorize, and direct appropriate action under this Part 50 and to make all appropriate determinations and findings. The decisions of the board shall not be subject to appeal; however, the board may reconsider and modify, correct, or reverse its previous decisions."

Public Law 85-804 has been interpreted to give the Government broad powers to grant the contractor necessary relief. In certain cases, a contract adjustment board may grant an amount that may be larger than losses as long as the amount was necessary to complete contract performance. Relief has also been granted when the impairment was caused by losses on non-Government work.

Specific Conditions in Granting the Relief. The Army Contract Adjustment Board decided to grant BioPort's request for extraordinary contractual relief to modify contract DAMD17-98-C-8052 as discussed in the following paragraphs.

- Exercise Option Year II, for the production of (b)(4) doses of AVA.

- Change the quantity of doses to be produced from (b)(4) doses to (b)(4) doses for Option Year I and Option Year II. The price per dose increased from (b)(4) to (b)(4) per dose for Option Year I and from (b)(4) to (b)(4) for Option Year II. As a result of the changes to the quantity and price per dose, the overall value of Option Year I and Option Year II increased by (b)(4).

- Include a price redetermination clause.

- ~~(FOUO)~~ Pay (b)(4) in the form of an advance payment. The (b)(4) advance payment is interest free. The advance payment is (b)(4) more than BioPort requested and (b)(4) more than DCAA recommended in its Audit Report No. 2261-99G17200004, "Audit of Request for Extraordinary Contractual Relief Under P.L. 85-804." The first portion of the advance payment, (b)(4), will be used only for operating expenses. The second portion of the advance payment, (b)(4), will be used to repay the State of Michigan. Once the State of Michigan is paid off, the DoD will be the first lien holder on the BioPort facility.

The Board also stipulated the following additional terms and conditions for granting the extraordinary contractual relief.

- BioPort was to establish a separate bank account to deposit the advance payment.

- BioPort was to have a contract-based cost accounting system in place no later than January 1, 2000.

- DCAA was to conduct a follow-up audit in 6 months to determine whether the accounting system is adequate. Defense Contract Management Command was to place an individual full-time in the BioPort facility.

- BioPort was to attempt to renegotiate with the State of Michigan a restructuring of the loan to a reduced payment or an extended payment period.

- BioPort was to liquidate the advance payment by crediting the Government (b)(4) of the (b)(4) per dose price for each dose produced.

- All FAR regulatory requirements were to be met.

- The Government was to have paramount liens to all of BioPort's assets.

- The advance payment was strictly for operating expenses and not to be used for dividends, or to repay additional paid-in-capital, to any officer, director, shareholder, owner, employee, or any other party other than the State of Michigan.

~~(FOUO)~~ The price per dose of (b)(4) represents a "financially viable" price per dose. DoD calculated the (b)(4) revised AVA price to include (b)(4) . The extraordinary contractual relief included a (b)(4) . In DCAA, Report No. 2261-99G17200004, "Audit of Request for Extraordinary Contractual Relief Under P.L. 85-804," DCAA determined that (b)(4) for Option Year I and Option Year II was adequate. DCAA estimated that BioPort's proposed prices of (b)(4) for Option Year I and (b)(4) for Option Year II included (b)(4) .

~~(FOUO)~~ **BioPort's Renegotiated AVA Contract.** Based on the Army Contracting Adjustment Board's "Memorandum of Decision," July 27, 1999, the contracting officer at U.S. Army Medical Research and Material Command - Acquisition Activity issued modification P00005 to contract DAMD17-98-C-8052 providing extraordinary contractual relief. Modification P00005 was signed by all parties on August 4, 1999, and effective the same date. In accordance with the "Memorandum of Decision," the modification decreased the number of doses, increased the price per dose, included a price redetermination clause, provided an advance payment, (b)(4) , allowed the contractor to credit AVA doses against the advance payment, required BioPort to implement a contract-based cost accounting system, and provided the Government a usage fee for Government furnished equipment used on commercial production.

~~(FOUO)~~ The result of the increase in price per dose and decrease in the number of doses was an increase of about (b)(4) to the total basic contract value of (b)(4) . Also, a contract line item for renovations in the amount of about (b)(4) was deleted revising the overall contract value to about (b)(4) .

~~(FOUO)~~ A reduction of (b)(4) from the (b)(4) for a usage fee for Government furnished equipment resulted in a net amount of (b)(4) for extraordinary contractual relief. (b)(4) . As of March 20, 2000, (b)(4)

Number of Doses. The number of doses to be produced decreased from (b)(4) to (b)(4) doses in Option Year I and from (b)(4) to (b)(4) doses in Option Year II. This constitutes a net decrease of (b)(4) doses for Option Year I and Option Year II.

Price Per Dose. The price per dose for AVA increased from (b)(4) (average of original Option Year I and Option Year II prices) to (b)(4) for Option Year I and Option Year II, a net increase of (b)(4) per dose. The change in the quantity and price per dose price increased the overall value of Option Year I and Option Year II by (b)(4). The (b)(4) base year AVA doses price remained at (b)(4) per dose.

~~(FOUO)~~ **Price Redetermination Clause.** The contract includes a price redetermination clause with a redetermination occurring in April 2000. All doses manufactured from the date of modification P00005, August 4, 1999, for 9 months remain fixed at (b)(4). The price redetermination clause provides that there will be a renegotiation to determine a fair and reasonable price if the estimated costs vary plus or minus 15 percent from the contract price. The clause further states that the "price redetermination will employ the same methodology utilized to arrive at prices for the contract modification awarded under the authority of P.L. 85-804." The (b)(4) price per dose in modification P00005 was (b)(4) . If the same methodology were used to arrive at a revised price, the Government would (b)(4)

Advance Payment. The DoD provided BioPort a one-time interest-free advance payment of (b)(4), which was split into two payments. The first payment of (b)(4) was to be used only for operating expenses. The second payment of (b)(4) was to be used to repay the State of Michigan. Under the terms of the contract, BioPort was required to attempt to renegotiate the loan with the State of Michigan to change the payment terms. BioPort renegotiated and reduced the loan with the State of Michigan. Under the terms of the contract, BioPort was allowed to retain the difference between the renegotiated amount and the (b)(4) for operating expenses. After BioPort made payment to the State of Michigan, the DoD would become the first lien holder on the BioPort facility. The terms of the lien were to be the same as they were with the State of Michigan.

Liquidation of Advance Payment. In order to liquidate the advance payment, BioPort will credit the Government for each newly produced dose of AVA using the prescribed performance-based payment method. The credit would be (b)(4) per FDA approved dose of AVA. The credit is (b)(4) per dose prior to FDA lot approval. This would leave BioPort with revenue of (b)(4) per FDA approved dose of AVA or (b)(4) per dose prior to FDA approval.

Conditions of the Advance Payment. As a condition of the advance payment, if the contractor defaults it will agree to request the FDA to transfer the facility license to the Government or use its best effort to obtain approval.

In addition, while the advance payment remains outstanding, the contractor may not:

- make dividend payments to shareholders;

- use the advance payment to repay any loans and any additional paid-in capital to any shareholder, whether a private party, owner, director, officer or employee; and

- put a lien on any assets purchased with the advance payment other than the lien established for the Government.

While the advance payment remains outstanding, the contractor may not without prior approval of the contracting officer:

- make any increases in the base salaries of senior managers and officers or pay any cash bonuses to employees or officers such that the combined total exceeds 20 percent of their annual base salaries,

- (b)(4) , and

- enter into a lease agreement over $1 million or sell or purchase any assets over $500,000.

~~(FOUO)~~ (b)(4)

Commercial Sales of AVA. BioPort cannot sell AVA internationally without prior approval from the DoD. To obtain approval, BioPort must submit a written request, which DoD has 45 days to deny or grant. BioPort may sell domestically to any purchaser provided the purchaser certifies that it will not export the doses outside the United States. BioPort can only sell commercially after the Government's cumulative monthly requirements for production of AVA have been met. If during the contract, BioPort sells more than (b)(4) doses of AVA commercially they will credit the Government 20 percent of the excess sales price over (b)(4) per dose excluding transportation costs, commissions, returns and third-party expenses. The amount credited will be applied to liquidate the advance payment.

BioPort's Accounting System. Under the terms of the contract, the DoD required BioPort to implement a contract-based cost accounting system by January 1, 2000. DCAA will conduct an audit of the accounting system to determine whether it is adequate.

~~(FOUO)~~ **Government Furnished Equipment Usage Fee.** BioPort will issue the Government a credit of (b)(4) per dose for each dose that BioPort produces for commercial purposes. DoD calculated the amount of the extraordinary contractual relief by deducting the Government furnished equipment usage fee of about (b)(4) from the increased amount of the contract. (b)(4) Any doses produced over the Government's requirements will be allocated 50 percent to BioPort and 50 percent to the Government. The doses allocated to the Government will be available for purchase to the Government at (b)(4) per dose.

Events Subsequent to the Extraordinary Contractual Relief

~~(FOUO)~~ BioPort spent all of the (b)(4) advance payment. It has liquidated about (b)(4) of the advance payment through credits for AVA it has produced. BioPort has informed DoD they now need at least (b)(4) in additional funds. The FDA has not approved BioPort's establishment license application supplement for the renovated facilities and processes because of a significant number of deficiencies. DCAA performed three more audits related to BioPort's current financial situation.

Performance Payments and Liquidation of Advance Payment. BioPort is required to liquidate the (b)(4) advance payment through credits to DoD on their performance-based payment invoices. Performance-based payments are made based on milestone completion not on costs. The following amounts are credited for each AVA dose based on the four phases of the AVA process on which performance-based payments can be made:

- manufacturing stage, (b)(4);
- formulation stage, (b)(4);
- filling stage, (b)(4); and,
- release stage, (b)(4).

~~(FOUO)~~ As of January 26, 2000, BioPort had liquidated about (b)(4) of the advance payment against performance payments. BioPort was ahead of their projected payback schedule because they dedicated 100 percent of their production to DoD and because of the changes made in modification P00011.

Modification P00011. Modification P00011 to contract DAMD17-98-C-8052 with an effective date of October 14, 1999 moved up the production of (b)(4) doses from Option Year II to Option Year I. The modification did not change the overall quantity. By increasing the number of doses in Option Year I, the modification accelerated the amount of money that BioPort could receive as performance payments. In addition, by moving the (b)(4) doses from Option Year II to Option Year I, the price will remain fixed at (b)(4) under the price redetermination clause. Likewise, the modification facilitated the repayment of the advance payment back to the Government through credits to performance payments.

~~(FOUO)~~ **BioPort's Accounting System.** As one of the requirements of Modification P00005, BioPort had to fully implement contract-based cost accounting procedures by January 1, 2000. In October 1999, we were told by BioPort officials that the new accounting system (b)(4). BioPort officials stated that the new accounting system would (b)(4). DCAA plans to review BioPort's new accounting system in March 2000.

~~(FOUO)~~ **Monthly Program Reviews.** Since the extraordinary contractual relief was provided on August 4, 1999, DoD and BioPort officials have held monthly program reviews. The reviews include charts and discussions on BioPort's financial status, production updates, facility approval updates, contractual matters, and other areas of interest. In the August 1999 program review, BioPort briefed (b)(4) [redacted].

FDA Inspection and Review. In November 1999, FDA performed an on-site inspection at the BioPort facilities in Lansing, Michigan, and issued Form FDA 483, "Inspectional Observations." In addition, FDA was reviewing the establishment license application supplement submitted by BioPort. FDA issued a letter to BioPort in December 1999 on the additional deficiencies found related to the supplement. As a result of the on-site inspection and review of the establishment license application supplement, FDA had over 40 findings with subparts. A significant finding was the Anthrax process validation, which needed to be validated under the current standards and not the standards of the 1970s that were previously used. As of March 16, 2000, the Food and Drug Administration had not approved the establishment license application supplement.

~~(FOUO)~~ BioPort established, in December 1999, an AVA Strategic Initiative to address the over 40 FDA findings and meet compliance requirements in order to obtain FDA approval. On January 11, 2000, BioPort responded to FDA on the findings from the inspection but still had to respond to the additional deficiencies from the review of the establishment license application supplement. According to BioPort's latest estimate they are trying to obtain final FDA approval by (b)(4) [redacted]. However, according to the FDA, any AVA produced prior to FDA approval of the newly renovated facilities and processes is considered to be "at risk." Although it is a common industry practice to continue to produce a product prior to FDA approval, it is still considered to be "at risk" production because the product may not receive approval. As of December 31, 1999, BioPort has produced (b)(4) [redacted] AVA doses that are considered "at risk" doses and may not be able to be used. DoD has paid about (b)(4) [redacted] in performance payments, not including the credits to the advance payment BioPort has made, related to the (b)(4) [redacted] AVA doses.

~~(FOUO)~~ **Capital Expenditures.** Although capital improvement expenditures are allowable, BioPort spent over (b)(4) [redacted] on items that in light of their financial condition may not have been appropriate. BioPort spent about (b)(4) [redacted] These expenditures also included approximately (b)(4) [redacted]. In addition, BioPort spent (b)(4) [redacted].

Need for Additional Funds

~~(FOUO)~~ In addition to the net amount of (b)(4) in extraordinary contractual relief already received, BioPort officials verbally informed DoD officials in December 1999 that they needed an additional (b)(4) to pay for consultants to assist in complying with FDA requirements and other operating expenses. BioPort will not be able to receive extraordinary contractual relief over (b)(4) without congressional notification. In BioPort's Management Plan 2000 dated January 24, 2000, BioPort identified (b)(4) . In January 2000, (b)(4) BioPort states that it will require further actions by DoD to meet its financial obligations. At the request of the contracting officer, DCAA performed three audits of BioPort relating to their financial condition.

Congressional Notification. FAR part 50.203(b)(4), "Limitations on exercise of authority," states that "[n]o contract, amendment, or modification shall be made under the Act's authority – [t]hat will obligate the Government for any amount over $25 million, unless the Senate and House Committees on Armed Services are notified in writing of the proposed obligation and 60 days of continuous session of Congress have passed since the transmittal of such notification." As a result of Modification P00005, BioPort has been granted (b)(4) in extraordinary contractual relief. DoD must notify Congress of any extraordinary contractual relief DoD intends to provide BioPort above (b)(4) .

~~(FOUO)~~ **DCAA Audits.** On January 21, 2000, the AVA procurement contracting officer requested that DCAA perform three audits of BioPort's current financial capability, an analysis of data related to the extraordinary contractual relief, and BioPort's financial forecasts for their Plasma and Rabies products for calendar year 2000. As previously noted in DCAA Audit Report No. 2261-99G11070001, "Accounting System Audit," June 11, 1999, BioPort's accounting system was not adequate for accumulating and reporting costs under Government contracts. (b)(4)

~~(FOUO)~~ **DCAA Audit Report No. 2261-2000G17600002, "Financial Capability Audit," February 4, 2000.** BioPort's calendar year 2000 Cash Flow Projections contained (b)(4) In the opinion of DCAA, there is substantial doubt that BioPort will be financially able to continue performing its Government contracts. (b)(4) Based on DCAA's audit of BioPort's calendar year 2000 Cash Flow Projections, (b)(4) BioPort's calendar year 2000 budget includes (b)(4) DCAA states that (b)(4)

~~(FOUO)~~ (b)(4) [redacted]

~~(FOUO)~~ **DCAA Audit Report No. 2261-2000G17900005, "Audit of BioPort's Analysis of Actual Data for CY 1999 Compared to Data Submitted in Relation to Request for Extraordinary Contractual Relief Under P.L. 85-804," February 4, 2000.** DCAA determined that BioPort expended all of the (b)(4) advance payment provided by DoD. The advance payment was used to repay the loans from the State of Michigan ((b)(4)), settlement payment to their plasma supplier ((b)(4)), and the balance was used for nonspecific expenses ((b)(4)). The items comprising nonspecific expenses (b)(4) [redacted] As of January 26, 2000, BioPort has liquidated about (b)(4) of the advance payment through performance payments.

~~(FOUO)~~ DCAA noted excessive costs, which may not have been prudent in light of BioPort's financial situation and are unallowable in accordance with the FAR. DCAA noted (b)(4) [redacted]

~~(FOUO)~~ **DCAA Audit Report No. 2261-2000G17900006, "Audit of BioPort's Financial Forecasts for Plasma and Rabies Products for CY 2000," February 3, 2000.** In the opinion of DCAA, BioPort's sales projections for Plasma and Rabies products are not reasonable. Based on BioPort's January 24, 2000, financial forecast, DCAA determined BioPort (b)(4) [redacted]. On January 27, 2000, BioPort informed DCAA that they have decided to liquidate all Plasma inventory and close the Plasma business by the end of March 2000. In addition, BioPort stated it plans to suspend production of Rabies products until after BioPort receives FDA approval of the AVA facilities and processes. The DCAA audit was not based on the January 27, 2000, information from BioPort.

Potential Solutions. BioPort developed several actions in their Management Plan 2000 dated January 24, 2000, to be considered by DoD to relieve their financial situation.

- ~~(FOUO)~~ (b)(4) [redacted]
- ~~(FOUO)~~ (b)(4) [redacted]
- ~~(FOUO)~~ (b)(4) [redacted]

- ~~(FOUO)~~ (b)(4) [redacted]
- ~~(FOUO)~~ (b)(4) [redacted]
- ~~(FOUO)~~ (b)(4) [redacted]
- ~~(FOUO)~~ (b)(4) [redacted]

Conclusion

~~(FOUO)~~ DoD provided extraordinary contractual relief in accordance with the FAR procedures. Relief was necessary to ensure BioPort's financial capability to produce AVA. Some of BioPort's subsequent expenditures were not appropriate in light of their financial condition. (b)(4) [redacted] Ultimate disposition of the AVA doses produced to date without FDA approval of BioPort's revised processes and renovated facilities also is unresolved. (b)(4) [redacted] Any amount of additional assistance may include additional extraordinary contractual relief pursuant to Public Law 85-804 and require Congressional notification.

Appendix A. Audit Process

Scope and Methodology

Work Performed. We reviewed the AVA contract and modifications, DAMD17-98-C-8052, estimated at about (b)(4) and the Government administration of that contract. We reviewed overall policies, procedures, and documentation related to the AVA contract.

We met with personnel from DCAA and the General Accounting Office to discuss their work regarding the AVA contract and BioPort Corporation. We also met with DoD and Army officials to discuss their involvement with the AVA contract.

We reviewed files regarding AVA contracts for production, renovation, and storage. We reviewed contract and project files from the U.S. Army Medical Research Acquisition Activity and Joint Program Office for Biological Defense related to the Anthrax Vaccine Inoculation Program to determine what information the personnel making the decisions knew regarding the extraordinary contractual relief. We met with FDA personnel to discuss the process for approval of BioPort's facility and AVA production lots.

We interviewed personnel from the DoD, Office of Industrial Affairs to obtain information on the ownership of BioPort Corporation. We interviewed personnel from the Defense Contract Management Command to obtain information they had on BioPort Corporation and to understand its role in the administration of the AVA contract.

We visited BioPort Corporation, Lansing, Michigan, to discuss their current DoD contracts and modifications, the extraordinary contractual relief, AVA production, FDA approval status, and the financial aspects including stock option plans, accounting system, financial statements, and ownership structure. We also met with State of Michigan personnel to discuss the sale of Michigan Biologic Products Institute to BioPort and the restructuring of BioPort's loan payment.

Limitations to Scope. We did not evaluate the management control program nor review computer-processed data because of the specific nature of the audit request.

Audit Type, Dates, and Standards. We performed this economy and efficiency audit from September 1999 through February 2000 in accordance with auditing standards issued by the Comptroller General of the United States, as implemented by the Inspector General, DoD.

Contacts During the Audit. We visited or contacted individuals and organizations within the DoD; the Food and Drug Administration, Rockville, Maryland; the General Accounting Office, Washington, D.C.; BioPort Corporation, Lansing, Michigan; and the State of Michigan, Lansing, Michigan. Further details are available on request.

Appendix B. Prior Coverage

The General Accounting Office and DCAA had the following prior coverage related to AVA, Michigan Biologic Products Institute, and BioPort Corporation in the past 5 years.

General Accounting Office

General Accounting Office, Report No. NSIAD-00-54R, "Summary of GAO's Findings on the Safety and Efficacy of the Anthrax Vaccine," November 4, 1999.

General Accounting Office, Report No. NSIAD-00-36, "Medical Readiness: DoD Faces Challenges in Implementing Its Anthrax Vaccine Immunization Program," October 1999.

General Accounting Office, Report No. T-NSIAD-00-48, "Anthrax Vaccine: Safety and Efficacy Issues," October 12, 1999.

General Accounting Office, Report No. T-NSIAD-99-226, "Medical Readiness: Issues Concerning the Anthrax Vaccine," July 21, 1999.

General Accounting Office, Report No. T-NSIAD-99-214, "Contract Management: Observations on DOD's Financial Relationship With the Anthrax Vaccine Manufacturer," June 30, 1999.

General Accounting Office, Report No. T-NSIAD-99-148, "Medical Readiness: Safety and Efficacy of the Anthrax Vaccine," April 29, 1999.

General Accounting Office, Report No. NSIAD-99-5, "Gulf War Illnesses: Questions About the Presence of Squalene Antibodies in Veterans Can Be Resolved," March 1999.

General Accounting Office, Report No. T-NSIAD-98-83, "Chemical and Biological Defense: Observations on DOD's Plans To Protect U.S. Forces," March 17, 1998.

Defense Contract Audit Agency

Defense Contract Audit Agency, Report No. 2261-2000G17600002, "Financial Capability Audit," February 4, 2000.

Defense Contract Audit Agency, Report No. 2261-2000G17900005, "Audit of BioPort's Analysis of Actual Data for CY 1999 Compared to Data Submitted in Relation to Request for Extraordinary Contractual Relief Under P.L. 85-804," February 4, 2000.

Defense Contract Audit Agency (cont'd)

Defense Contract Audit Agency, Report No. 2261-2000G17900006, "Audit of BioPort's Financial Forecasts for Plasma and Rabies Products for CY 2000," February 3, 2000.

Defense Contract Audit Agency, Report No. 2261-99G17200004, "Audit of Request for Extraordinary Contractual Relief Under P.L. 85-804," July 21, 1999.

Defense Contract Audit Agency, Report No. 2261-99G11070001, "Accounting System Audit," June 11, 1999.

Defense Contract Audit Agency, Report No. 2261-99G17600008, "Financial Capability Audit," June 11, 1999.

Defense Contract Audit Agency, Report No. 2261-97G21000018, "Audit of Proposal for Anthrax Vaccine Adsorbed and Expanded Anthrax Production Facility," September 24, 1997.

Defense Contract Audit Agency, Report No. 2261-97G21000002, "Audit of Proposal for Continued Storage and Supplemental Testing of Anthrax Vaccine Adsorbed," November 6, 1996.

Appendix C. BioPort's Ownership Structure and Financial Relationships

~~(FOUO)~~ Table C-1 shows BioPort's Ownership Structure. (b)(4)

[redacted]

~~(FOUO)~~

Table C-1. BioPort's Ownership Structure

(b)(4)

[redacted]

~~(FOUO)~~

~~(FOUO)~~ (b)(4) [redacted]

- ~~(FOUO)~~ (b)(4) [redacted]
- ~~(FOUO)~~ (b)(4) [redacted]

~~(FOUO)~~ (b)(4) [redacted]

~~(FOUO)~~ (b)(4) [redacted]

~~(FOUO)~~ Table C-2 shows the percent ownership of BioPort's (b)(4) shares. (b)(4) [redacted]

~~(FOUO)~~

Table C-2. Ownership of BioPort Corporation (b)(4) shares

Name	Percent ownership of BioPort	(b)(4) shares owned
(b)(4) [redacted]		
Total outstanding (b)(4) shares	(b)(4)	(b)(4)

~~(FOUO)~~

~~(FOUO)~~ Table C-3 shows the authorization of BioPort's (b)(4) shares.
(b)(4)

~~(FOUO)~~

Table C-3. Authorization of BioPort (b)(4) shares

Name	Percent of (b)(4) shares authorized	(b)(4) shares authorized
(b)(4)		

~~(FOUO)~~

Appendix D. Chronology of Significant Events

The following is a chronological listing of significant events related to AVA.

Event	Date
State of Michigan – Department of Health receives FDA license for the AVA.	1970
Contract DAMD17-91-C-1139 awarded to the State of Michigan's Department of Public Health for the manufacturing, testing, bottling and storage of AVA, insurance, and the remodeling of existing facilities. The total contract value was about (b)(4) (the contract was modified to over (b)(4) since the effective date).	September 1991
State of Michigan decides to sell Michigan Biologic Products Institute.	December 1995
FDA inspects Michigan Biologic Products Institute and cites the facility for multiple deficiencies and violations.	November 1996
FDA issues a notice of intent to revoke their license.	March 11, 1997
Contract DAMD17-97-D-0003 awarded to the State of Michigan's Department of Public Health for testing the potency, stability, and sterility of AVA and Pentavalent Botulinum Toxoid Adsorbed. The total value of the contract was (b)(4).	May 1, 1997
Michigan Biologic Products Institute is officially offered for sale.	July 1997
Contract DAMD17-97-E-0004 awarded to Michigan Biologic Products Institute for the maintenance, accountability and storage of Government Property. The total value of the contract was (b)(4).	August 29, 1997

Event	Date
~~(FOUO)~~ Michigan Biologic Products, Inc. enters into a (b)(4) agreement with (b)(4) (Agreements were transferred to BioPort.)	November 28, 1997
Defense Secretary William Cohen orders all Military personnel to be inoculated against the biological weapon anthrax.	December 15, 1997
BioPort acquires Michigan Biologic Product Institute and a novation agreement is executed transferring Michigan Biologic Products Institute three contracts with DoD to BioPort.	September 4, 1998
Contract DAMD17-98-C-8052 awarded to BioPort for the manufacturing, bottling and storage of the AVA, and renovation of the BioPort facility. The total contract is valued at about (b)(4).	September 15, 1998
AVA production resumes under the newly renovated facility. All doses produced under the renovated facility cannot be released until FDA approves the processes and facility.	May 1999
BioPort requests extraordinary contractual relief under Public Law 85-804 because it had insufficient cash to continue operations after August 1, 1999, and was unable to borrow additional funds.	June 1999
~~(FOUO)~~ DCAA, Report No. 2261-99G11070001, "Accounting System Audit," concludes that BioPort's accounting system was inadequate for accumulating and reporting costs under Government contracts.	June 11, 1999
~~(FOUO)~~ DCAA, Report No. 2261-99G17600008, "Financial Capability Audit," concludes that there was substantial doubt BioPort would be financially capable to continue performing on Government contracts.	June 11, 1999

Event	Date
~~(FOUO)~~ DCAA, Report No. 2261-99G17200004, "Audit of Request for Extraordinary Contractual Relief Under P.L. 85-804," concludes that BioPort's request for extraordinary contractual relief was not fully compliant with the requirements of FAR.	July 21, 1999
Army Contract Adjustment Board issues Memorandum of Decision, ACAB No. 1246, authorizing extraordinary contractual relief to BioPort.	July 27, 1999
Contract DAMD17-98-C-8052 is modified by Modification P00005 and provides an advance payment of (b)(4) as part of extraordinary contractual relief under P.L. 85-804.	August 4, 1999
BioPort makes a (b)(4) payment to the State of Michigan under the terms of an alternative payment schedule agreed to by the State of Michigan.	September 7, 1999
Modification P00011 adjusted the deliverable quantities for Option Year I and Option Year II. The modification moved (b)(4) doses from Option Year II to Option Year I.	October 14, 1999
FDA performs an on-site inspection at the BioPort facilities in Lansing, Michigan. As a result of the inspection and review of BioPort's submitted license application supplement, FDA cites more than 40 findings with subparts.	November 1999
~~(FOUO)~~ BioPort makes a payment of (b)(4) to the State of Michigan under the terms of an alternative payment schedule agreed to by the State of Michigan.	December 1999
~~(FOUO)~~ BioPort officials verbally inform DoD officials that (b)(4) BioPort stated that they will need approximately (b)(4) in additional funds for operating expenses.	December 1999

Event	Date
~~(FOUO)~~ BioPort has produced about (b)(4) doses from mid-May 1999 through December 31, 1999 that are considered by FDA to be "at risk" because the facility and processes are not approved.	December 31, 1999
~~(FOUO)~~ DCAA, Report No. 2261-2000G17900006, "Audit of BioPort's Financial Forecasts for Plasma and Rabies Products CY 2000," concludes that the (b)(4)	February 3, 2000
~~(FOUO)~~ DCAA, Report No. 2261-2000G17600002, "Financial Capability Audit," concludes that there is substantial doubt that BioPort would be financially able to continue performing on Government contracts.	February 4, 2000
~~(FOUO)~~ DCAA, Report No. 2261-2000G17900005, "Audit of BioPort's Analysis of Actual Data for CY 1999 Compared to Data Submitted in Relation to Request for Extraordinary Contractual Relief Under P.L. 85-804," concludes that (b)(4)	February 4, 2000

Appendix E. Report Distribution

Office of the Secretary of Defense

Under Secretary of Defense for Acquisition, Technology, and Logistics
  Principal Deputy Under Secretary for Acquisition, Technology, and Logistics
  Director, Defense Procurement
  Deputy Under Secretary of Defense (Industrial Affairs)
Under Secretary of Defense (Comptroller)
  Deputy Chief Financial Officer
Assistant Secretary of Defense (Health Affairs)

Department of the Army

Deputy Assistant Secretary of the Army for Procurement
Auditor General, Department of the Army
Commander, Joint Program Office for Biological Defense
Director, Army Medical Research Acquisition Activity

Other Defense Organizations

Director, Defense Contract Audit Agency
Director, Defense Logistics Agency
  Director, Defense Contract Management Command

Non-Defense Federal Organizations

Office of Management and Budget
General Accounting Office
  National Security and International Affairs Division
    Technical Information Center

Congressional Committees and Subcommittees, Chairman and Ranking Minority Member

Senate Committee on Appropriations
Senate Subcommittee on Defense, Committee on Appropriations
Senate Committee on Armed Services
Senate Committee on Governmental Affairs
House Committee on Appropriations
House Subcommittee on Defense, Committee on Appropriations

Congressional Committees and Subcommittees, Chairman and Ranking Minority Member (cont'd)

House Committee on Armed Services
House Committee on Government Reform
House Subcommittee on Government Management, Information, and Technology, Committee on Government Reform
House Subcommittee on National Security, Veterans Affairs, and International Relations, Committee on Government Reform

Audit Team Members

The Contract Management Directorate, Office of the Assistant Inspector General for Auditing, DoD, prepared this report.