STATEMENT OF
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DEPARTMENT OF DEFENSE
BEFORE THE
SENATE ARMED SERVICES COMMITTEE
ON
DEFENSE ANTHRAX VACCINE CONTRACTING


Office of the Inspector General
Department of Defense

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Mr. Chairman and Members of the Committee:

I appreciate the opportunity to be here today to discuss contracting issues related to the production of anthrax vaccine.

Congressional Request

On August 13, 1999, the Office of the Inspector General, DoD, received a request from Congressman Walter B. Jones for a review of the financial and contractual relationship between the Department of Defense and BioPort Corporation, the sole U.S. domestic source of Anthrax Vaccine Adsorbed (AVA). In his request letter, Congressman Jones noted that the General Accounting Office and Defense Contract Audit Agency had reported that BioPort was experiencing financial problems and having difficulty performing against Army contracts for AVA production. Congressman Jones expressed concern that "despite these serious questions regarding the overall viability of BioPort, the Federal government has chosen to more than double the value of the existing contract." The Congressman specifically requested that we review the renegotiation of the Army 1998 AVA production contract to provide relief to BioPort.
In response to this request, we conducted an audit between September 1999 and February 2000. We did not duplicate the extensive coverage of the anthrax vaccine program and related contracting issues by the General Accounting Office and Defense Contract Audit Agency. Each of those organizations had issued eight audit reports on these subjects by February 2000, and additional coverage was ongoing or planned. We focused primarily on determining the amount of relief provided to BioPort, the ways in which the relief was provided, whether the Department had legal authority to provide it, and whether it had alleviated the risk in the program.

Report D-2000-105, Contracting for Anthrax Vaccine,
March 22, 2000

To comply with statutory and regulatory requirements for protecting contractor proprietary information, the full text version of our report is For Official Use Only and distribution is limited. Likewise, I am somewhat constrained today in terms of what details about the contractor's financial condition can be discussed in an open hearing.

I will begin with a brief recap of the history of AVA production. In 1970, the Food and Drug Administration granted
a license for producing AVA to the State of Michigan, which
owned a vaccine manufacturing facility in Lansing. At the time,
the primary market for AVA was commercial. The first of what
would eventually be several Army contracts with the Michigan
Biologic Products Institute or Michigan Department of Public
Health was awarded in September 1988. In November 1996, the
Food and Drug Administration inspected the production facility
and in March 1997 issued a notice of intent to revoke its
license. The facility was closed for major renovation from

On September 4, 1998, BioPort Corporation purchased the Michigan
Biologic Product Institute from the State of Michigan. The
Michigan Biologic Products Institute entered into a novation
agreement that transferred 3 open Army contracts to BioPort. A
much larger AVA production contract was awarded by the Army to
BioPort on September 15, 1998 to support the new DoD policy that
all military personnel were to be inoculated against anthrax.
The DoD expected to acquire about 8.7 million AVA doses for
$29.4 million.

In June 1999, BioPort requested financial assistance from the
Army to meet its immediate and short term cash flow deficit.
Lacking Food and Drug Administration approval, BioPort had been
unable to make U.S. commercial sales. The firm also requested a
decrease in the number of doses, an increase in the price per
dose and a one-time advance cash payment.

The Army Contract Adjustment Board granted BioPort extraordinary
contractual relief on the 1998 contract in a Memorandum of
Decision, ACAB No. 1246, dated July 27, 1999. The Army provided
extraordinary contractual relief to BioPort because the
corporation had insufficient money to fund its operating
expenses and satisfy its loan from the State of Michigan.
Without extraordinary contractual relief, according to the
Board, BioPort would not have been able to continue producing
AVA, thus compromising the safety of military personnel and the
national defense.

In accordance with the Board's decision, the Army amended
the September 1998 contract with BioPort and provided a net
$24.1 million in relief, including an $18.7 million interest
free advance payment. The number of doses in the contract
options was reduced from 7.9 million to 4.6 million. The price
was increased from $4.36 to $10.64 per dose for Option Year I
and from $2.26 to $10.64 per dose for Option Year II.
We concluded that the Army had the legal authority to grant BioPort's request for extraordinary contractual relief. 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.

Despite the relief that was provided, during the period of our audit there was ample evidence of continued risk and of need for additional DoD financial assistance.

In December 1999, the Food and Drug Administration provided the results of its initial inspection of the BioPort facility and its review of BioPort's application, which is technically called a biologic establishment license application supplement. The inspection and review identified about 40 deficiencies of varying degrees of significance and today the application supplement remains unapproved, although we understand the DoD believes considerable progress has been made in addressing the deficiencies. We do not have current and first hand information on what impediments to approval remain or when it might be attained. Nor have we audited any contracting actions taken by the Department, subsequent to the measures taken to provide extraordinary relief in 1999. We are aware, however, that the Department is intensively managing the situation at BioPort,
including issues raised by the auditors. We strongly support
the decision to establish a permanent Defense Contract
Management Agency presence at the facility in Lansing. We also
recently received a June 22, 2000 Defense Contract Audit Agency
report indicating that BioPort's accounting system is now
adequate, which resolves one of our concerns.

Conclusion

In summary, we determined that applicable laws and regulations
allowed the Department to provide extraordinary relief to
BioPort Corporation during late FY 1999, but significant risks
continued. Because there appears to be no alternative U.S.
domestic source, at least in the near term, the DoD anthrax
vaccination policy is viable only if BioPort can bring its
production facility up to Food and Drug Administration standards
this year.

Beyond the current issues concerning AVA, however, we believe
the DoD and Congress need to continue working toward a
comprehensive, long term defensive strategy against the spectrum
of potential chemical and biological warfare threats. Our work
in DoD chemical and biological defense programs, as outlined in
the attached list of reports and testimony, has indicated a wide
range of unresolved issues and difficult challenges in this broad area, whose importance to national security will surely continue to grow in the coming years.

This concludes my statement.
Inspector General, DoD, Reports on Chemical and Biological Defense

Report No. 94-154, Reliability of M-17 Series and M-40 Chemical Protective Masks, June 30, 1994 (Secret)

Report No. 95-021, Defense Hotline Allegations Regarding DoD Fielding of Chemical Protective Masks, November 2, 1994 (Secret)

Report No. 95-224, Army Chemical Protective Mask Requirements, June 8, 1995


Report No. 97-102, Inventory Accuracy at the Defense Depot, Columbus, Ohio, February 27, 1997

Report No. 97-217, Chemical and Biological Defense Readiness, September 19, 1997 (Secret)

Report No. 98-174, Unit Chemical and Biological Defense Readiness Training, July 17, 1998

Report No. 99-045, Chemical and Biological Warfare Defense Resources in the U.S. Pacific Command, December 3, 1998 (Secret)


Report No. 99-102, Chemical and Biological Defense Resources in the U.S. European Command, March 4, 1999 (Secret)

IG Semiannual Report to Congress for the Period Ending March 31, 1999, Focus Area on Chemical and Biological Defense


All reports and testimony listed above that are not Classified or For Official Use Only are available on the Internet at www.dodig.mil. Also, a redacted version of some reports is available.