



Highlights of [GAO-08-208T](#), a testimony before the Committee on Homeland Security and Governmental Affairs, U.S. Senate

Why GAO Did This Study

The anthrax attacks in September and October 2001 highlighted the need to develop medical countermeasures. The Project BioShield Act of 2004 authorized the Department of Health and Human Services (HHS) to procure countermeasures for a Strategic National Stockpile. However, in December 2006, HHS terminated the contract for a recombinant protective antigen (rPA) anthrax vaccine because VaxGen failed to meet a critical contractual milestone. Also, supplies of the licensed BioThrax anthrax vaccine already in the stockpile will start expiring in 2008.

GAO was asked to testify on its report on Project BioShield, which is being released today. This testimony summarizes (1) factors contributing to the failure of the rPA vaccine contract and (2) issues associated with using the BioThrax in the stockpile. GAO interviewed agency and industry officials, reviewed documents, and consulted with biodefense experts.

What GAO Recommends

GAO recommended that the HHS Secretary ensure that (1) for future procurements the concept of use and all critical requirements for medical countermeasures are clearly articulated at the outset, (2) expired stockpile vaccines are destroyed, and (3) the HHS and the Department of Defense (DOD) Secretaries develop an integrated stockpile for BioThrax with rotation based on a first-in, first-out principle. HHS and DOD generally concurred with GAO's recommendations.

To view the full product, including the scope and methodology, click on [GAO-08-208T](#). For more information, contact Keith Rhodes, (202) 512-6412 or rhodesk@gao.gov.

PROJECT BIOSHIELD

Actions Needed to Avoid Repeating Past Mistakes

What GAO Found

Three major factors contributed to the failure of the first Project BioShield procurement effort for an rPA anthrax vaccine. First, HHS's Office of the Assistant Secretary for Preparedness and Response (ASPR) awarded the procurement contract to VaxGen, a small biotechnology firm, while VaxGen was still in the early stages of developing a vaccine and had not addressed many critical manufacturing issues. This award preempted critical development work on the vaccine. Also, the contract required VaxGen to deliver 25 million doses of the vaccine in 2 years, which would have been unrealistic even for a larger manufacturer. Second, VaxGen took unrealistic risks in accepting the contract terms. VaxGen officials told GAO that they accepted the contract despite significant risks due to (1) the aggressive delivery time line for the vaccine, (2) VaxGen's lack of in-house technical expertise—a condition exacerbated by the attrition of key company staff as the contract progressed—and (3) VaxGen's limited options for securing any additional funding needed.

Third, important Food and Drug Administration (FDA) requirements regarding the type of data and testing required for the rPA anthrax vaccine to be eligible for use in an emergency were not known at the outset of the procurement contract. In addition, ASPR's anticipated use of the rPA anthrax vaccine was not articulated to all parties clearly enough and evolved over time. Finally, according to VaxGen, the purchase of BioThrax for the stockpile as a stopgap measure raised the bar for the VaxGen vaccine. All these factors created confusion over the acceptance criteria for VaxGen's product and significantly diminished VaxGen's ability to meet contract time lines. ASPR has announced its intention to issue another request for proposal for an rPA anthrax vaccine procurement but, along with other HHS components, has not analyzed lessons learned from the first contract's failure and may repeat earlier mistakes. According to industry experts, the lack of specific requirements is a cause of concern to the biotechnology companies that have invested significant resources in trying to meet government needs and now question whether the government can clearly define future procurement contract requirements.

GAO identified two issues related with the use of the BioThrax in the Strategic National Stockpile. First, ASPR lacks an effective strategy to minimize the waste of BioThrax. Starting in 2008, several lots of BioThrax in the Strategic National Stockpile will begin to expire. As a result, over \$100 million per year could be lost for the life of the vaccine currently in the stockpile. ASPR could minimize such potential waste by developing a single inventory system with DOD—a high-volume user of BioThrax—with rotation based on a first-in, first-out principle. DOD and ASPR officials identified a number of obstacles to this type of rotation that may require legislative action. Second, ASPR planned to use three lots of expired BioThrax vaccine in the stockpile in the event of an emergency. This would violate FDA rules, which prohibit using an expired vaccine, and could also undermine public confidence because the vaccine's potency could not be guaranteed.