



Highlights of GAO-06-756T, a testimony before the Chairman, Subcommittee on National Security, Emerging Threats, and International Relations, House Committee on Government Reform, House of Representatives

Why GAO Did This Study

GAO has done many studies over the past 7 years on anthrax vaccine safety and anthrax detection methods. GAO has reported the lack of validated methods for detecting anthrax contamination and has recommended a coordinated approach to improving the overall process for detecting anthrax that included a probability-based sampling strategy.

GAO also reported that the vaccine has not been adequately tested on humans; no studies have been done to determine the optimum number of doses; the long-term safety has not been studied and data on short-term reactions are limited; however, women report higher rates of reactions than do men. Given these problems, GAO recommended the development of a better, alternative vaccine.

What GAO Recommends

The Secretary of Homeland Security needs to develop a formal strategic plan, including a roadmap, outlining how individual agency efforts would lead to the validation of the overall sampling process.

www.gao.gov/cgi-bin/getrpt?GAO-06-756T.

To view the full product, click on the link above. For more information, contact Keith Rhodes at (202) 512-6412 or rhodesk@gao.gov.

ANTHRAX

Federal Agencies have taken Some Steps to Validate Sampling Methods and to Develop a Next Generation Anthrax Vaccine

What GAO Found

The threat of bioterrorism has long been recognized in the United States and abroad. The Department of Defense (DOD) considers inhalation anthrax to be the greatest biological warfare threat to U.S. military forces. The U.S. Army Medical Research Institute of Infectious Diseases has been conducting basic and applied research on biological threats since 1969, in order to develop medical countermeasures—prophylactics, vaccines, medical diagnostics—to protect warfighters.

The anthrax incidents in 2001 highlighted major gaps in civilian preparedness to detect and respond to anthrax attacks, leading the federal government to focus on developing new drugs, vaccines, and therapeutics to protect U.S. citizens. As a result, the Department of Health and Human Services (HHS) now has major responsibility to ensure that appropriate medical countermeasures are available for civilians. And the Department of Homeland Security (DHS) assumes major responsibility for coordinating federal responses to national incidents of chemical, biological, radiological, and nuclear release.

Despite the many recommendations GAO has made over the past few years regarding problems related to the anthrax vaccine's safety and effectiveness and the reliability of anthrax detection, deficiencies remain. While agencies have taken steps in the right direction, the government still lacks a strategic plan outlining how individual agency efforts would lead to the validation of the overall sampling process, including methods, and the development of a probability-based sampling strategy that accounts for the complexity of indoor environments.

In November 2004, HHS awarded a contract for \$877.5 million to procure 75 million doses of a new anthrax vaccine—the first contract awarded under Project Bioshield for medical countermeasures procurement. The terms of the award state that the urgency of the current threat requires an accelerated pace of vaccine development, testing, approval, and procurement. While developing vaccine is known to be difficult and highly likely to encounter testing and production issues in the best of circumstances, the contract's milestones leave little room for slippage from established delivery dates.

The biotechnology sector is watching to see if government and industry can make this partnership work. Understanding the unique issues in this early phase of the biodefense strategy is important. Problems with this initial Project Bioshield contract could affect the biotechnology industry's response to future government overtures to develop and procure medical countermeasures against the many other biothreat agents still to be addressed.