

## Why GAO Did This Study

The United States remains vulnerable to terrorist and other threats posed by chemical, biological, radiological, and nuclear (CBRN) agents. Medical countermeasures—drugs, vaccines, and diagnostic devices—can prevent or treat the effects of exposure, but few are currently available. The Department of Health and Human Services (HHS) leads federal efforts to develop and acquire countermeasures, primarily through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), an interagency body. This report examines the extent to which HHS (1) based its priorities for developing and acquiring countermeasures on CBRN risk assessments; (2) addressed its own recommendations to improve acquisition and development; and (3) coordinated internally for these efforts. GAO reviewed relevant laws, agency documents, CBRN risk assessments, and reports from outside experts; interviewed HHS and industry officials; and analyzed HHS funding for CBRN countermeasures from fiscal years 2007 through 2010.

## What GAO Recommends

GAO recommends that HHS update its development and acquisition plan; provide budget priorities for acquisitions; and develop a strategy to monitor implementation of its initiatives. HHS agreed with the first two recommendations. For the third one, HHS said that it had a strategy to track implementation, but in GAO's assessment, the strategy does not meet standards and practices to allow for adequate monitoring.

## NATIONAL PREPAREDNESS

### Improvements Needed for Acquiring Medical Countermeasures to Threats from Terrorism and Other Sources

## What GAO Found

Through PHEMCE, HHS laid out its CBRN medical countermeasure development and acquisition priorities in 2007 in a publicly available plan based primarily on two types of CBRN risk assessments—one from the Department of Homeland Security (DHS) and one from HHS—but HHS has not updated the plan as intended. The 2007 plan outlined spending for these priorities through 2013, when special federal funding for countermeasure acquisition will expire. HHS invested about \$1.9 billion in development and \$2.4 billion for acquisition of countermeasures to fulfill these priorities from fiscal year 2007 to fiscal year 2010. Since 2007, DHS and HHS have continued to assess the risks that CBRN agents pose to national security and public health, and HHS has reassessed decisions on the quantities and types of medical countermeasures needed. However, HHS has not updated its plan, as it had intended to do biennially, to indicate whether any priorities have changed. Further, HHS has not provided specific information on anticipated budget priorities for countermeasure acquisition—information desired by companies to help them decide whether to invest in product development.

HHS has begun to address most recommendations from its August 2010 review of PHEMCE and of HHS's countermeasure activities, but HHS has not developed an adequate strategy to monitor implementation. HHS's initiatives to address the recommendations are intended to improve product development and acquisition and PHEMCE's structure and management. These initiatives are led by different agencies and offices—for example, the Food and Drug Administration has begun efforts to improve its regulatory framework, while the National Institutes of Health has begun to implement a program to increase the number of potential products in the pipeline. HHS officials said they have a monitoring strategy that includes quarterly updates of a planning document and quarterly and annual reviews of progress. However, the planning document contains incomplete information and does not allow for measuring progress across all initiatives. Thus, HHS's monitoring strategy is not consistent with federal internal control standards and program management best practices. Given the initiatives' complexity and dispersed HHS leadership responsibilities, an adequate monitoring strategy would help HHS assess overall progress and provide information about whether HHS is meeting its countermeasure development and acquisition objectives.

HHS's establishment of PHEMCE in 2006 and its subsequent written agreements have facilitated intradepartmental coordination on the development and acquisition of CBRN medical countermeasures, but some coordination challenges remain. PHEMCE established an intradepartmental coordination process and documented the roles and responsibilities of its partners through written agreements. However, some industry and outside experts have reported that HHS's agencies and offices do not coordinate well to advance products through development to acquisition, which hampers industry's efforts to supply countermeasures. HHS officials are renewing the PHEMCE intradepartmental memorandum of understanding and charter for the governing body. These written agreements, once finalized, should continue to enhance and sustain intradepartmental coordination on countermeasure development and acquisition activities. In addition, effectively implementing some of the initiatives from HHS's August 2010 review may help mitigate these coordination challenges.