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PUBLIC HEALTH PREPAREDNESS

Developing and Acquiring Medical Countermeasures Against Chemical, Biological, Radiological, and Nuclear Agents

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Highlights

Highlights of GAO-11-567T, a testimony before the Subcommittee on Emergency Preparedness, Response, and Communications, Committee on Homeland Security, House of Representatives

Why GAO Did This Study

The anthrax attacks of 2001 and a radiation leak after the recent natural disaster in Japan highlighted concerns that the United States is vulnerable to threats from chemical, biological, radiological, and nuclear (CBRN) agents, which can cause widespread illness and death. Medical countermeasures—such as drugs, vaccines, and diagnostic devices—can prevent or treat the health effects of exposure, but few are currently available for many of these CBRN agents.

GAO was asked to testify on the Department of Health and Human Services' (HHS) CBRN medical countermeasure development and acquisition activities. This statement focuses on (1) how HHS determines needed CBRN medical countermeasures and priorities for development and acquisition and (2) selected challenges to medical countermeasure development and acquisition. This statement of preliminary findings is based on ongoing work. To do this work, GAO examined relevant laws and presidential directives, analyzed federal agency documents and reports from advisory boards and expert groups, and interviewed officials from HHS and the Department of Homeland Security (DHS) about the processes for developing and acquiring CBRN medical countermeasures and the challenges related to those efforts. GAO shared the information in this statement with HHS. HHS provided technical comments, which GAO incorporated as appropriate.

View GAO-11-567T or key components. For more information, contact Cynthia A. Bascetta at (202) 512-7114 or bascettac@gao.gov.

What GAO Found

HHS coordinates and leads federal efforts to determine CBRN medical countermeasure priorities and develop and acquire CBRN medical countermeasures, primarily through an interagency body that includes other federal agencies with related responsibilities, such as DHS and the Department of Defense. HHS's medical countermeasure acquisition strategy is based on a four-step process: (1) identify and assess the threat of CBRN agents, (2) assess medical and public health consequences of attacks with these agents, (3) establish medical countermeasure requirements, and (4) identify and prioritize near-, mid-, and long-term development and acquisition. Through these processes, HHS determines which countermeasures to buy for specific CBRN agents, including the desired characteristics of these countermeasures—such as how many doses a vaccine requires to confer immunity—the needed quantity of certain medical countermeasures, and the acquisition priorities. While a few CBRN countermeasures can be immediately acquired, most have not yet been developed. Therefore, HHS and the interagency body support and oversee several stages of research and development to try to obtain usable countermeasures. These include basic cellular and biological research to understand the effects of these agents on humans; applied research to validate approaches, such as testing the effectiveness of treatment in animals; early development to assess the safety of potential countermeasures; and advanced development, in which the products are more fully evaluated for safety and effectiveness, including their formulation and manufacturing processes.

The federal government faces a variety of challenges in developing and acquiring medical countermeasures, such as the high failure rate in research and development and difficulties meeting regulatory requirements. For example, the failure rate for development and licensure of most drugs, vaccines, and diagnostic devices can be more than 80 percent, depending on the stage of scientific research and development. Given this risk, as well as a lack of a commercial market for most medical countermeasures, attracting large, experienced pharmaceutical firms to research and develop them is challenging. Smaller biotechnology companies are more likely to be developing medical countermeasures, but HHS must provide more guidance to these less experienced small companies than might be typical with larger companies. In addition, several challenges exist related to regulatory processes for evaluating promising medical countermeasures. These challenges include (1) proving a countermeasure's effectiveness using animals as proxies for humans, because humans cannot ethically be used in studies involving CBRN agents; (2) determining appropriate doses of countermeasures for children, who may be more vulnerable to exposure to CBRN agents; and (3) evaluating the safety and effectiveness of medical countermeasures for use in a public health emergency if they have not yet been approved or licensed. Finally, HHS faces the logistical challenge of ongoing replenishment of expiring medical countermeasures in the U.S. Strategic National Stockpile, the national repository of medications, medical supplies, and equipment for public health emergencies.