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## BIOLOGICAL DEFENSE

### DOD Has Strengthened Coordination on Medical Countermeasures but Can Improve Its Process for Threat Prioritization

#### Why GAO Did This Study

The spread of the scientific capabilities to produce effective biological weapons has contributed to concerns about the threat posed to the warfighter from biological attacks.

GAO was mandated to review DOD's efforts to research and develop medical countermeasures against prioritized biological threat agents. This report (1) describes DOD's funding of medical countermeasures against biological threat agents from fiscal years 2001 through 2013; (2) evaluates DOD's progress in researching, developing, and making available medical countermeasures against biological threat agents, including DOD's prioritization process; (3) describes DOD's internal coordination to allocate resources to medical countermeasures against biological threat agents; and (4) evaluates DOD's coordination with HHS and DHS to research and develop medical countermeasures against biological threat agents.

GAO analyzed DOD budget information from fiscal years 2001 through 2013, policies, and strategies relating to biological medical countermeasures and analyzed information and interviewed officials from DOD, HHS, and DHS on collaborative efforts to research and develop biological medical countermeasures.

#### What GAO Recommends

GAO recommends that DOD implement a process to update its list of biological threats according to its current policies. DOD concurred and identified steps to address the recommendation.

View GAO-14-442. For more information, contact Joseph Kirschbaum at (202) 512-9971 or [kirschbaumj@gao.gov](mailto:kirschbaumj@gao.gov) or Marcia Crosse at (202) 512-7114 or [crossem@gao.gov](mailto:crossem@gao.gov).

#### What GAO Found

From fiscal years 2001 through 2013, the Department of Defense (DOD) received over \$4.3 billion in total funding (in constant fiscal year 2013 dollars) to research, develop, and make available medical countermeasures that respond to biological threat agents. Of that \$4.3 billion, approximately \$3.75 billion was for the research and development of new medical countermeasures.

DOD has made progress in researching, developing, and making available medical countermeasures against biological threat agents, but does not use its established process for annually updating its list of threat priorities. DOD's Chemical and Biological Defense Program (CBDP) is researching, is developing, or has obtained Food and Drug Administration approval for countermeasures that address 10 of the 19 biological threat agents DOD has identified as threats to the warfighter. Of DOD's 43 candidates for medical countermeasures, 13 use technologies that may allow them to respond to various emerging or genetically modified biological threat agents. However, DOD does not use its established process to annually update its list of biological threat priorities. DOD Directive 6205.3, *DOD Immunization Program for Biological Warfare Defense*, establishes roles and responsibilities and an annual process for updating DOD's biological threat list. GAO found that the list has not been updated annually and, when it was updated in 2001 and 2012, DOD did not receive input from key stakeholders. By not following its established process for annually updating its biological threat list, DOD cannot ensure that its investments—and those of its partners—are applied toward responding to the most-serious and likely biological threats.

CBDP has taken steps to increase transparency and improve coordination practices within DOD to allocate resources to address biological threats. In response to concerns raised by military service officials that CBDP was not completely transparent in how it prioritized requirements and made resourcing decisions, CBDP issued a business plan in 2012 to update its coordination methods. While military service officials were supportive of CBDP's actions, they stressed the need for continuing dialogue and collaboration in the future.

DOD's efforts to coordinate with the Department of Health and Human Services (HHS) and the Department of Homeland Security (DHS) align with best practices GAO has identified for collaborating across agency boundaries—specifically, to leverage available resources; establish mutually reinforcing joint strategies; and develop compatible policies, procedures, and other tools to operate across agency boundaries. DOD, HHS, and DHS share a joint research campus—the National Interagency Biodefense Campus at Fort Detrick, Maryland—to study biological threat agents. The campus has its own governance structure, which allows the agencies to leverage available resources and facilitate scientific exchange. Senior leaders at DOD and HHS also have developed interagency agreements and other tools that facilitate communication on the various stages of medical countermeasure development. Finally, DOD and DHS have established processes for identifying biological agents that pose domestic threats and risks.