



May 2014

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 or Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

BIOLOGICAL DEFENSE

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

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.

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Abbreviations

CBDP	Chemical and Biological Defense Program
CBRN	chemical, biological, radiological, and nuclear
DHS	Department of Homeland Security
DOD	Department of Defense
FDA	Food and Drug Administration
HHS	Health and Human Services
HSPD	Homeland Security Presidential Directive
IRF	Integrated Research Facility
NICBR	National Interagency Confederation for Biological Research
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
TRA	Terrorism Risk Assessment
USAMRIID	U.S. Army Medical Research Institute for Infectious Diseases

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May 15, 2014

Congressional Committees

The 2001 anthrax attacks on U.S. soil, potential emerging H5N1 (bird flu) and H1N1 (swine flu) influenza pandemics, the spread of the Middle East respiratory syndrome coronavirus since 2012, and the spread of the scientific knowledge and capabilities to produce effective biological weapons out of diseases such as equine encephalitis and Ebola have contributed to concerns about the nation's vulnerability to biological attacks and naturally occurring diseases. Multiple federal agencies are involved in addressing these biological threat agents, including the Department of Defense (DOD), which researches and develops medical countermeasures—vaccines, drugs, and diagnostics—against biological threat agents that could affect military personnel. According to DOD data and our analysis,¹ in fiscal years 2001 through 2013 the department received over \$20 billion in total funding for its Chemical and Biological Defense Program (CBDP) to lead the department's efforts to protect military personnel, particularly the warfighter, against a wide range of threats that include biological agents.

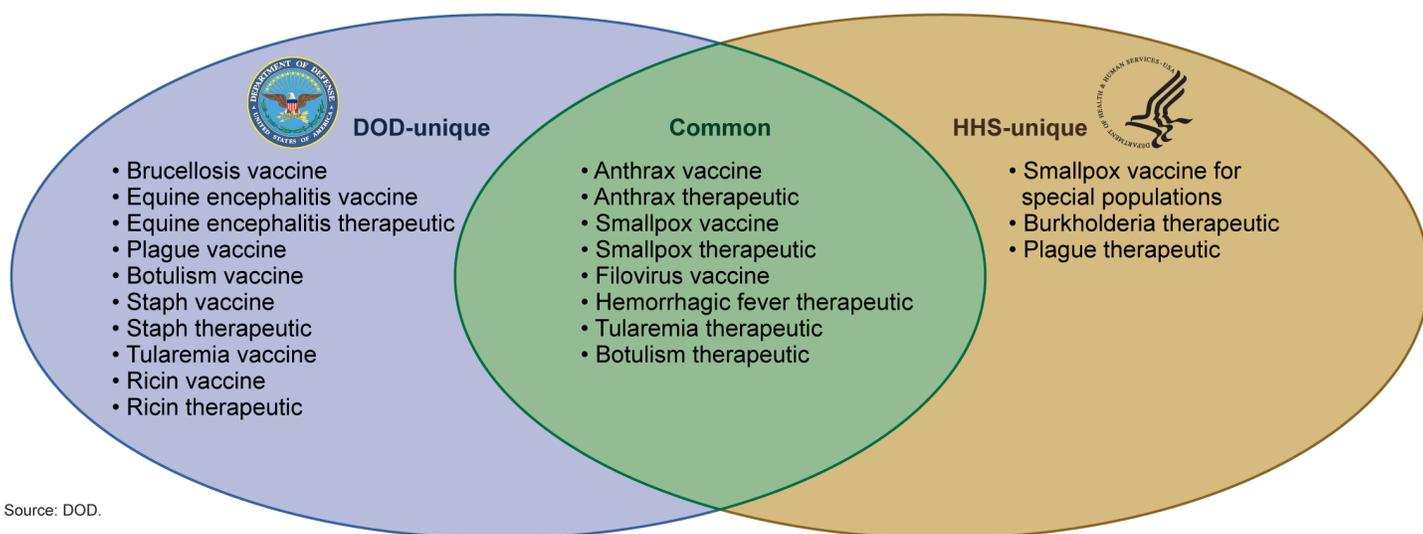
While DOD is involved in researching and developing medical countermeasures against biological threat agents for military personnel, the Department of Health and Human Services (HHS) leads the federal public health and medical response to potential chemical, biological, radiological, and nuclear (CBRN) threats and emerging infectious diseases. Under the Project BioShield Act, HHS is required to assess, on an ongoing basis, the potential public health consequences of any CBRN agents that the Department of Homeland Security (DHS) determines pose a threat sufficient to affect national security.² This law requires HHS to determine the threat agents for which countermeasures are necessary to protect the public health. In 2006, HHS established the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), a federal

¹All budget or funding figures represent data from DOD's Joint Service Chemical and Biological Information System. These figures are adjusted to account for inflation using DOD's Total Obligational Authority index for Research, Development, Test, and Evaluation, and represent constant fiscal year 2013 dollars. See app. II for all original, nonadjusted funding figures.

²42 U.S.C. § 247d-6b(c)(2)(A)(B).

interagency body that includes various HHS agencies and other federal departments, such as DOD and DHS, to advise the Secretary of Health and Human Services on medical countermeasure priorities and approaches to the development, acquisition, stockpiling, and distribution of medical countermeasures.³ Figure 1 illustrates DOD's and HHS's current unique and shared biological medical countermeasure needs.

Figure 1: Department of Defense (DOD) and Department of Health and Human Services (HHS) Current Unique and Shared Biological Medical Countermeasure Needs



Source: DOD.

³The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) is composed primarily of officials from the HHS Office of the Assistant Secretary for Preparedness and Response, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the National Institutes of Health, which have specific responsibilities for countermeasure development and acquisition. PHEMCE also includes officials from other federal departments and offices, such as the Departments of Defense, Homeland Security, Veterans Affairs, and Agriculture, and the Executive Office of the President. Prior to the establishment of PHEMCE—from 2004 to 2006—the Executive Office of the President led interagency coordination efforts to establish chemical, biological, radiological, and nuclear medical countermeasure requirements.

Congress has raised concerns about whether DOD is successfully developing medical countermeasures to respond to biological incidents.⁴ A House Armed Services Committee Report⁵ accompanying the bill for the National Defense Authorization Act for Fiscal Year 2014 mandated that GAO evaluate DOD's efforts to research and develop medical countermeasures against prioritized biological threat agents. Our report:

1. describes DOD funding for CBDP, including overall funding for biological medical countermeasures as well as funding by particular stages of development;
2. evaluates DOD's progress in researching, developing, and making available medical countermeasures for use against biological threat agents, including the process DOD uses to prioritize biological medical countermeasure development;
3. describes the status of DOD's efforts to internally coordinate the allocation of resources to medical countermeasures against biological threat agents; and
4. evaluates the extent to which DOD's efforts to coordinate with HHS and DHS to research and develop medical countermeasures against prioritized biological threat agents align with best practices for collaboration.

For the purposes of our review, we defined "medical countermeasures" as the vaccines, drugs, and diagnostics used to respond to chemical, biological, and radiological threats. We defined "medical countermeasures against biological threat agents" as the pretreatments, prophylaxes, therapeutics, and diagnostics used to respond specifically to

⁴See, for example, Subcommittee on Intelligence, Emerging Threats and Capabilities, Committee on Armed Services, House of Representatives, *Biodefense: Worldwide Threats and Countermeasure Efforts for the Department of Defense*, 113th Cong., 1st sess., October 11, 2013; Subcommittee on Emergency Preparedness, Response, and Communication, Committee on Homeland Security, House of Representatives, *Taking Measure of Countermeasures (Part 1): A Review of Government and Industry Efforts to Protect the Homeland through Accelerated Research, Development, and Acquisition of Chemical, Biological, Radiological and Nuclear Medical Countermeasures*, 112th Cong., 1st sess., 2011; and Committee on Homeland Security and Governmental Affairs, U.S. Senate, *Six Years after Anthrax: Are We Better Prepared to Respond to Bioterrorism?* 110th Cong. 1st sess., October 23, 2007.

⁵H. Rep. No. 113-102, at 220-21 (June 7, 2013).

biological threats.⁶ We included in our definition of “biological threat agents” those that are traditional, emerging, and genetically modified agents.⁷ We included budget data from fiscal year 2001 through fiscal year 2013, since that period would be sufficient to allow us to analyze funding since the 2001 anthrax attacks.

To address our first objective, we analyzed fiscal year 2001 through 2013 data from the CBDP budget office and identified the total funding related specifically to medical countermeasures. We reviewed funding that CBDP tracked in its Joint Service Chemical and Biological Information System.⁸ Unless otherwise noted in the report, all dollar figures in this report are in constant 2013 dollars. We adjusted the funding amounts for inflation using DOD’s Total Obligational Authority index for Research, Development, Test, and Evaluation to present them in constant 2013 dollars.⁹ We did not independently validate the data, but we interviewed CBDP officials about how they use the system and about the steps they take to ensure the accuracy of the tracked data, and we determined that the data were sufficiently reliable to analyze overall funding levels for medical countermeasures and also funding levels for medical countermeasures research and development for fiscal years 2001 through 2013.

To address our second objective, we compared the requirements of DOD’s directive on the prioritization of research and development of biological defense vaccines¹⁰ and a directive on the roles and

⁶Personal protective equipment (e.g., gas masks, gloves, and boots) and bio-surveillance and detection equipment were not in the scope of our review.

⁷For the purposes of our report, “traditional” biological threat agents are naturally occurring microorganisms or toxin products with the potential to be disseminated to cause mass casualties. “Emerging agents” are previously unrecognized pathogens that might be naturally occurring and present a serious risk to human populations, and “genetically modified” agents are organisms that have either been artificially modified or developed to bypass traditional countermeasures or produce a more-severe or enhanced disease.

⁸Except for fiscal year 2013, we define funding as obligations. Funding data for fiscal year 2013 is based on DOD budget allocations.

⁹Department of Defense, *National Defense Budget Estimates for Fiscal Year 2014* (May 2013).

¹⁰Department of Defense Directive 6205.3, *DOD Immunization Program for Biological Warfare Defense* (Nov. 26, 1993).

responsibilities within CBDP¹¹ to the process CBDP uses to prioritize investments in medical countermeasures against biological threat agents. Further, we compared the biological threat agents listed on DOD's most-recent biological threat list with documents on the status of medical countermeasures that are in research, development, or have been made available for use to the warfighter. To confirm our understanding of these documents, we interviewed officials from CBDP and its component offices.

To address our third objective, we reviewed the DOD directive on the roles and responsibilities of CBDP stakeholders and CBDP's 2012 business plan for management and operations of CBDP. We also interviewed Army, Navy, and Air Force officials to obtain military service-level perspectives on practices for coordinating DOD's efforts to allocate resources to medical countermeasures against biological threat agents.

To address our fourth objective, we reviewed interagency agreements, memorandums of understanding, and other requirements for coordination, as well as tools that foster interagency coordination. We interviewed DOD, HHS, and DHS officials about interagency coordination efforts, and compared the coordination efforts with the elements we identified in our best practices for enhancing and sustaining collaboration among federal agencies—specifically, to identify and address needs by leveraging resources and establishing policies and procedures and other means to operate across agency boundaries.¹² A more-detailed explanation of our scope and methodology can be found in appendix I.

We conducted this performance audit from August 2013 to May 2014 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

¹¹Department of Defense Directive 5160.05E, *Roles and Responsibilities Associated with the Chemical and Biological Defense (CBD) Program (CBDP)* (Oct. 9, 2008).

¹²See GAO, *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, [GAO-12-1022](#) (Washington, D.C.: Sept. 27, 2012) and *Results Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, [GAO-06-15](#) (Washington, D.C.: Oct. 21, 2005).

Background

Federal Roles and Responsibilities Related to Medical Countermeasures

Several federal departments and agencies have responsibilities as part of their mission for assessing the threat of biological agents and determining requirements and priorities for developing and obtaining countermeasures for these agents.

Department of Defense. DOD has exclusive responsibility for research, development, and acquisition of medical countermeasures to prevent or mitigate the health effects of biological agents and naturally occurring diseases on armed forces personnel.¹³ DOD contributes to DHS's terrorism risk assessments, including the identification of biological global threats, and also coordinates with HHS on efforts to identify common medical countermeasure priorities and jointly stockpile countermeasures, as appropriate. The Defense Intelligence Agency also performs its own threat analysis for Chemical, Biological, and Radiological Defense, called a Capstone Threat Assessment, at least every 2 years. CBDP leads DOD's efforts to anticipate, respond to, mitigate, and manage the health effects of biological threat agents that could affect the warfighter. According to DOD Directive 5160.05E, which assigns roles and responsibilities associated with CBDP, the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs, through the Deputy Assistant Secretary of Defense for Chemical and Biological Defense, is responsible for overseeing CBDP activities, policy guidance, and interagency coordination.¹⁴ Within CBDP, the following organizations have key roles in medical countermeasure efforts:

- **Chairman of the Joint Chiefs of Staff**, in consultation with the commanders of the combatant commands; the Secretaries of the military departments; and the Director, Defense Intelligence Agency, validates and prioritizes CBRN threats to DOD personnel, equipment, and weapon systems.
- **Joint Requirements Office**, which is part of the Joint Staff, sets requirements for medical countermeasures—including performance

¹³Executive Office of the President, Homeland Security Presidential Directive 18: *Medical Countermeasures against Weapons of Mass Destruction*, 14(b) (Jan. 21, 2007).

¹⁴DOD Directive 5160.05E.

parameters and quantity—and develops DOD’s biological threat lists¹⁵ and Joint Priorities List¹⁶ to ensure that countermeasures will be feasible for DOD use.

- **Joint Science and Technology Office** performs applied research¹⁷ and engages in early development of medical countermeasures against biological threat agents.
- **Joint Program Executive Office** supports advanced development and life-cycle management¹⁸ of potential medical countermeasures.
- The **Army, as CBDP Executive Agent**, supports the views of the military services and combatant commands during the Program Objective Memorandum¹⁹ process, and is responsible for reviewing CBDP’s funding requirements.

Department of Homeland Security. DHS leads federal interagency coordination and planning for emergency response to CBRN incidents in the United States and is responsible for assessing the risks to the civilian population posed by various CBRN agents, as directed by the Project BioShield Act of 2004,²⁰ Homeland Security Presidential Directive (HSPD) 10 (*Biodefense for the 21st Century*), HSPD 18 (*Medical Countermeasures against Weapons of Mass Destruction*), and HSPD 22 (*National Domestic Chemical Defense*). DHS’s Science and Technology

¹⁵“Biological threat list” is a generic term to describe the list of threats and associated risks that CBDP uses to prioritize investments in medical countermeasures to respond to biological threat agents. The requirement for this list is established in DOD Directive 6205.3, which requires the Chairman of the Joint Chief of Staff to annually prioritize and validate the list of biological warfare threats to DOD personnel and forward that list to the CBDP Executive Agent (the Army).

¹⁶The CBDP Joint Priorities List is a list of the 29 CBRN core capabilities required by the joint force, based on input from the military services and combatant commands.

¹⁷Applied, or translational, research builds on basic research by validating and testing concepts in practical settings to identify potential products. Successful concepts move from the applied research stage into the early development stage to demonstrate basic safety, reproducibility, and ability to be used in humans.

¹⁸“Life-cycle management” includes the maintenance of medical countermeasures that have been acquired and the removal of expired products from stockpiles.

¹⁹A Program Objective Memorandum is the final product of DOD’s programming process. It displays the resource-allocation decisions of a particular military department over the next 6 years in accordance with broader DOD guidance and priorities.

²⁰42 U.S.C. § 247d-6b(c)(2)(A).

Directorate develops CBRN Terrorism Risk Assessments (TRA) and Material Threat Assessments, which include assessments of the relative risks posed by CBRN agents based on variable threats, vulnerabilities, and consequences. Since 2004, DHS has developed TRA reports every other year.

Department of Health and Human Services. HHS leads all federal public health and medical response to public health and medical emergencies covered by the National Response Framework. Additionally, HHS is responsible for the protection of the civilian population against biological threat incidents, as stipulated by the Project BioShield Act. Within HHS, the following organizations play key roles in leading the federal response:

- **Public Health Emergency Medical Countermeasures Enterprise** is an interagency decision-making body that makes recommendations to the Secretary of Health and Human Services regarding CBRN and emerging infectious-disease medical countermeasure development and acquisition. PHEMCE is led by the HHS Office of the Assistant Secretary for Preparedness and Response and includes three primary HHS internal agency partners: the Centers for Disease Control and Prevention, the Food and Drug Administration (FDA), and the National Institutes of Health, as well as several interagency partners: DOD, DHS, the Department of Veterans Affairs, and the Department of Agriculture.
- **Office of the Assistant Secretary for Preparedness and Response** leads PHEMCE and the federal medical and public health response to public health emergencies, including strategic planning, medical countermeasure prioritization, medical requirements development, and support for developing and procuring medical countermeasures.
- **Biomedical Advanced Research and Development Authority**, within the Office of the Assistant Secretary for Preparedness and Response, coordinates and supports advanced research and development,²¹ manufacturing, and initial procurement of medical

²¹In the advanced research and development stage, potential medical countermeasures are further evaluated to demonstrate safety and effectiveness for preventing, diagnosing, or treating disease. Successful products are then available for manufacturing and procurement. In addition, at HHS, the Biomedical Advanced Research and Development Authority determines whether manufacturing, scale-up production, and licensing of countermeasures can be achieved in a timely and reliable manner.

countermeasures for CBRN threats, pandemic influenza, and emerging infectious diseases. The Biomedical Advanced Research and Development Authority also oversees HHS's efforts to develop and utilize flexible manufacturing capabilities²² for medical countermeasure development and medical emergency response.

- **National Institutes of Health** conducts and funds basic and applied research to develop new or enhanced medical countermeasures and related medical tools to protect the nation against threats posed by CBRN agents and emerging infectious diseases.
- **Centers for Disease Control and Prevention** maintains the Strategic National Stockpile—the national repository for medical countermeasures for use in a public health emergency²³—and provides guidance and recommendations for the mass distribution and use of medical countermeasures for public health emergencies.
- **Food and Drug Administration** assesses the safety and efficacy of medical countermeasures and regulates their development, approval, licensure, emergency use, and postmarket surveillance.²⁴ The FDA makes the primary determination of the safety and efficacy of medical countermeasures for DOD, and is involved throughout the research and development process to help facilitate the approval of new medical countermeasures.²⁵

The Medical Countermeasure Development Process and DOD's Funding

DOD's medical countermeasure research and development process for the warfighter is similar to the process used by DHS and HHS for the civilian population. In consultation with DHS, DOD leads the first step in the process to assess, on an ongoing basis, the threat of biological agents and determine which of these agents pose a threat to the warfighter. Step two of the process is applied research and early

²²“Flexible manufacturing” is the use of disposable equipment and alternative technologies for product development and rapid manufacturing.

²³The Strategic National Stockpile contains medications, medical supplies, and equipment for use in a public health emergency.

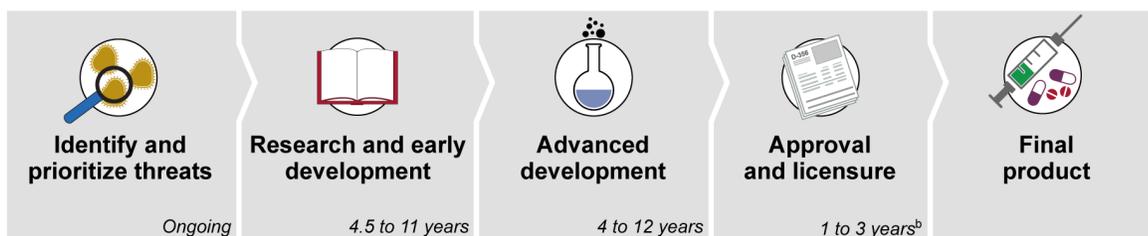
²⁴Generally, under federal law and FDA regulations, drugs and devices are “approved,” and vaccines and other biologics are “licensed.” See 21 U.S.C. § 355; 21 U.S.C. § 360e; and 42 U.S.C. § 262. For this report, we use the term “approve” to refer to both approval and licensing.

²⁵Department of Defense, *Test and Evaluation Policy for Chemical and Biological Defense Program Systems*, 3(e)(3) (July 23, 2007).

development of medical countermeasures, which can take from 4.5 to 11 years. DOD may have multiple candidates at a particular stage of the development process in support of a single medical countermeasure. Successful concepts are moved into the early development stage to be tested for product modes, such as vaccines, therapeutics, or diagnostics. Step three is advanced development, which includes further evaluation of potential medical countermeasures in animal studies to demonstrate safety and effectiveness for use in humans. DOD officials told us that human clinical trials must also be performed at this stage of development to further assess the safety of the product. In addition, in this stage, manufacturing of the vaccine, drug, or diagnostic is increased from the level used for early development to the proposed commercial scale and the product is further evaluated for approval and licensure. This stage could take from 4 to 12 years. The licensing and acquisition of medical countermeasures is the final stage of the development process. In figure 2, we show DOD's, DHS's, and HHS's role in the process to develop medical countermeasures.

Figure 2: Department of Defense's (DOD), Department of Homeland Security's (DHS), and Department of Health and Human Services' (HHS) Role in the Medical Countermeasure Development Process

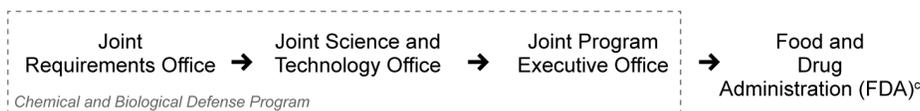
\$1.2 billion^a
average cost per countermeasure



Military programs:



Department of Defense (DOD)



Civilian programs:



Department of Homeland Security (DHS)

Science and Technology Directorate



Department of Health and Human Services (HHS)

Assistant Secretary for Preparedness and Response

National Institutes of Health

Biomedical Advanced Research and Development Authority

Food and Drug Administration (FDA)^c

Source: GAO analysis of DOD, DHS, and HHS information.

^aAccording to DOD officials, this figure is widely reported as the cost to research and develop a single medical countermeasure in the private sector and incorporates the cost associated with failed attempts to develop a medical countermeasure. DOD officials told us they face similar costs.

^bHHS officials told us this step takes 1.5 to 3 years, while DOD officials told us that a time frame of 1 to 2 years is realistic. We are reporting the range as 1 to 3 years to encompass the low and high end of these estimates.

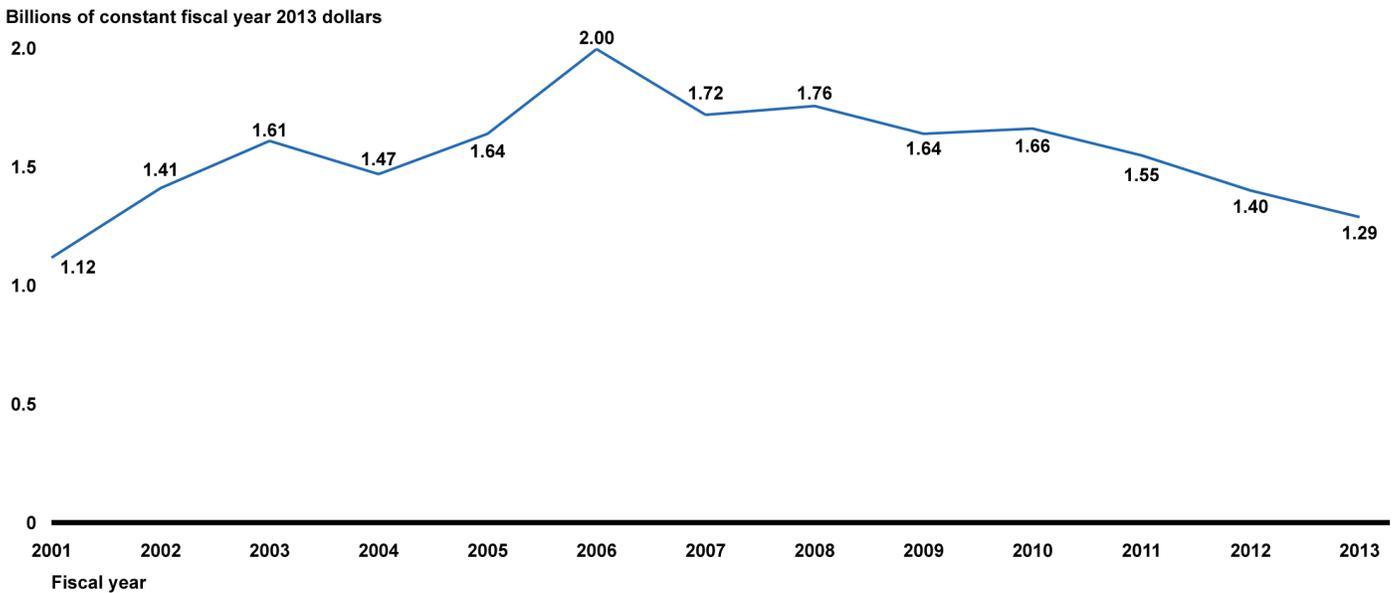
^cThe FDA is involved throughout the research and development process to help facilitate the approval of new medical countermeasures.

The federal government faces a variety of challenges in its medical countermeasure efforts, including lengthy, complex, and expensive research and development processes and the risk of technical failure. It can take about 12 years for a medical countermeasure to progress from research and early development to the point at which the vaccine, drug, or diagnostic has been approved by the FDA and is available for use. DOD officials told us the costs to research and develop a new medical countermeasure average \$1.2 billion. Additionally, DOD officials told us the lack of a commercial market for most medical countermeasures for biological threat agents hindered large pharmaceutical companies from entering the market, although HHS officials told us this has changed over the last 2 years.²⁶

As noted above, from fiscal year 2001 through fiscal year 2013, DOD received about \$20 billion in funding for CBDP to protect the warfighter against a wide range of threats using approaches such as medical countermeasures, personal protective equipment, and threat-detection sensors. Figure 3 shows the amount of this funding CBDP received by fiscal year in constant fiscal year 2013 dollars. Appendix II presents the original, noninflation adjusted figures (in nominal dollars).

²⁶See GAO, *National Preparedness: Improvements Needed for Acquiring Medical Countermeasures to Threats from Terrorism and Other Sources*, [GAO-12-121](#) (Washington, D.C.: Oct. 26, 2011); *National Preparedness: DHS and HHS Can Further Strengthen Coordination for Chemical, Biological, Radiological, and Nuclear Risk Assessments*, [GAO-11-606](#) (Washington, D.C.: June 21, 2011); and *Public Health Preparedness: Developing and Acquiring Medical Countermeasures Against Chemical, Biological, Radiological, and Nuclear Agents*, [GAO-11-567T](#) (Washington, D.C.: Apr. 13, 2011).

Figure 3: Funding Received for the Department of Defense (DOD) Chemical and Biological Defense Program by Fiscal Year



Source: GAO analysis of DOD data.

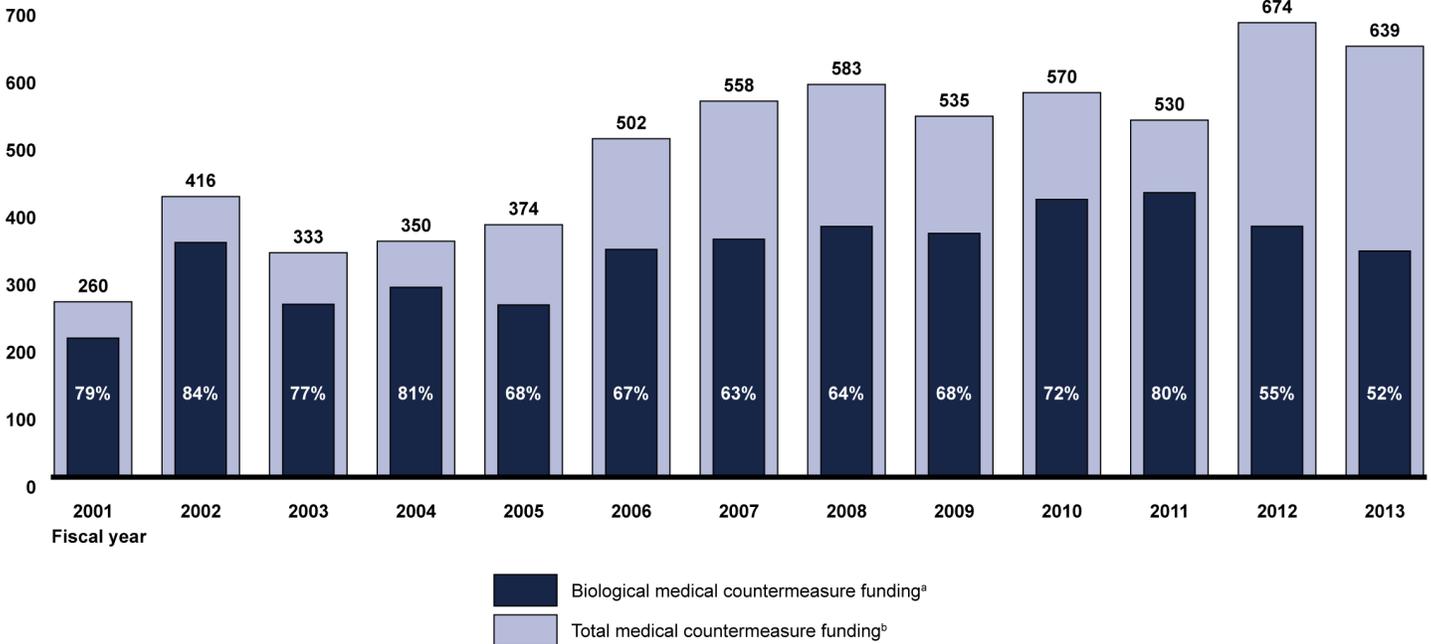
DOD Received about \$6 Billion since 2001 in Total Funding for Medical Countermeasures, of Which \$4.3 Billion Was Targeted Against Biological Threat Agents

Of the \$20 billion in total funding that DOD received for CBDP in fiscal year 2001 through fiscal year 2013 to protect military personnel against a wide range of threats, DOD budgeted about one-third, or about \$6 billion over that same period for medical countermeasures against chemical, biological, and radiological threats. According to our analysis of data in the Joint Service Chemical and Biological Information System, of the \$6 billion in funding for these medical countermeasures, nearly 70 percent, or about \$4.3 billion, was for medical countermeasures against biological threat agents. CBDP officials told us they are concentrating research and development on biological medical countermeasures because they have already fielded a number of effective medical countermeasures against chemical threats.²⁷ While total medical countermeasure funding generally increased between fiscal years 2001 and 2013, the percentage budgeted for medical countermeasures against biological threat agents remained above 50 percent, but has fluctuated from year to year, as shown in figure 4.

²⁷All funding totals for medical countermeasures against biological threats include pretreatments, prophylaxes, and therapeutics, but do not include diagnostics.

Figure 4: Department of Defense (DOD) Funding for All Forms of Medical Countermeasures by Fiscal Year and the Associated Percentages of Funding for Medical Countermeasures against Biological Threat Agents

Millions of constant fiscal year 2013 dollars



Source: GAO analysis of DOD data.

^a“Biological medical countermeasure funding” is for medical countermeasures against biological threat agents, but does not include diagnostics.

^b“Total medical countermeasure funding” is for all forms of medical countermeasures, such as chemical countermeasures and diagnostics.

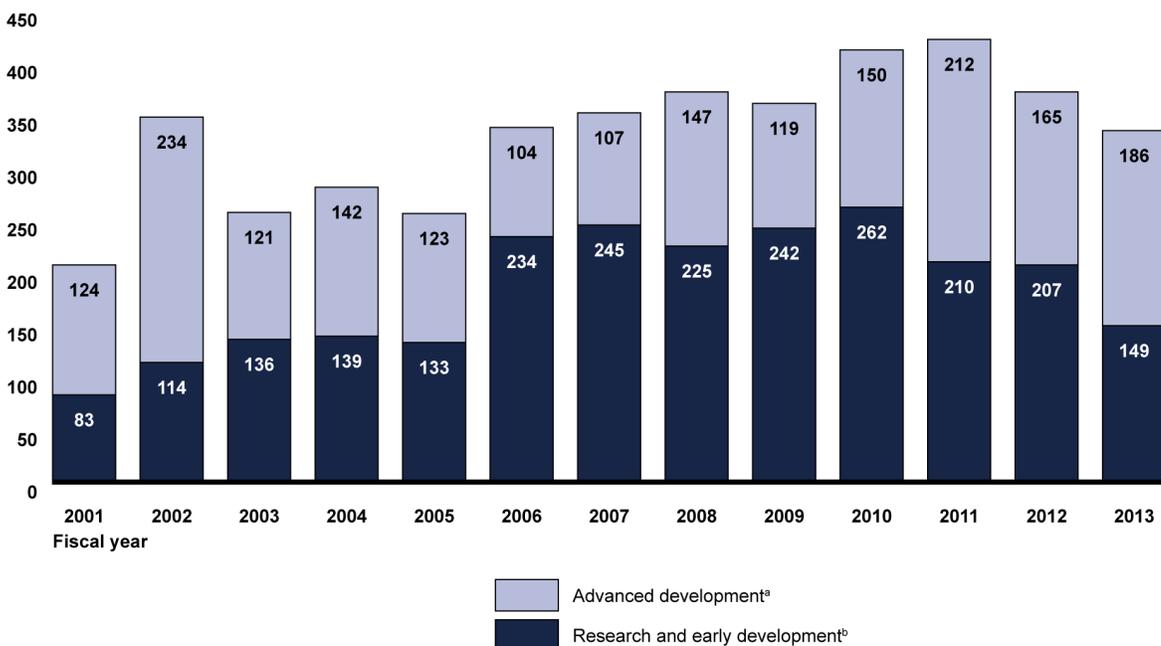
According to CBDP officials, these fluctuations are due to varying needs each year, such as funding for specific initiatives or the need to support specific countermeasures as they move into more-expensive stages of development. During the fiscal year 2001 through 2013 period, the percentage of funding for research and early development averaged about 55 percent of the \$4.3 billion in funding for medical countermeasures against biological threat agents, while the funding for advanced development—including procurement—averaged about 45 percent. Figure 5 shows how the funding for research and early development and the funding for advanced development varied by fiscal year.

Our analysis of DOD data showed that most of the funding for medical countermeasures against biological threat agents in fiscal years 2001

through 2013 was targeted to research and development efforts, with research and development funding totaling approximately \$3.75 billion, or nearly 90 percent of the \$4.3 billion in funding; the remaining amount was for procurement. According to CBDP officials, this emphasis is due in part to the lengthy time frames for researching and developing new medical countermeasures.

Figure 5: Department of Defense (DOD) Funding for Medical Countermeasures Against Biological Threat Agents by Stages of Development by Fiscal Year

Millions of constant fiscal year 2013 dollars



Source: GAO analysis of DOD data.

^a "Advanced development" includes advanced component development and prototypes, system development and demonstration, and procurement.

^b "Research and early development" includes basic research, applied research, and advanced technology development.

According to DOD's directive for chemical and biological defense roles and responsibilities, CBDP oversees the allocation of funds for medical countermeasures.²⁸ The various organizations within CBDP oversee

²⁸DOD Directive 5160.05E (Oct. 9, 2008).

funds within the stage of research and development for which they are responsible. For example, the Joint Science and Technology Office manages funding for research and early development, while the Joint Program Executive Office manages funding for advanced development. CBDP officials told us that they track budget and obligation data using the Joint Service Chemical and Biological Information System. According to CBDP officials, they began using this tool in 1996, and all organizations within CBDP can access the funding data using the tool. CBDP officials indicated that the tool is intended to track funding by different categories, such as stage of development or specific countermeasure program, and could also be used to help track specific countermeasure costs at the per-dose level.

DOD Has Made Progress in Researching, Developing, and Making Available Medical Countermeasures Against Biological Threat Agents, but Has Not Updated Its List of Threat Priorities as Required

DOD is researching and developing over 40 candidates for medical countermeasures for use against traditional, emerging, and genetically modified biological threat agents, and is researching, developing, or has obtained FDA approval for countermeasures that address 10 of the 19 biological threat agents it has identified as threats to the warfighter. Over the past 15 years, the biological threat list that DOD's CBDP uses to prioritize its investments in medical countermeasures has been updated, in various ways, to respond to policy changes, but DOD does not follow its established process for annually updating the biological threat list.

DOD Researched, Developed, and Made Available Medical Countermeasures against Traditional, Emerging, and Genetically Modified Biological Threat Agents

Medical Countermeasures
Against Biological Threat
Agents

DOD's CBDP is researching, developing, or has obtained FDA approval for medical countermeasures that address 10 of the 19 biological threat agents it has identified as threats to the warfighter. CBDP is researching, developing, or has available 47 medical countermeasures or candidates for medical countermeasures for use by the warfighter to respond to biological agents on its threat list; 4 of these medical countermeasures are FDA-approved and they respond to 2 of DOD's 19 identified threats. Nine candidates for medical countermeasures are in advanced development, and 34 are in research or early development. Of the medical countermeasure candidates, 13 are being developed using broad-spectrum technologies that show promise for use against a variety of threats, including emerging or genetically modified threats. According to DOD officials, medical countermeasures are used as part of a layered defense strategy meant to protect the warfighter from the effects of CBRN threats. Figure 6 shows the status of DOD's medical countermeasures against biological threat agents.

Figure 6: Status of Department of Defense (DOD) Medical Countermeasures Against Biological Threat Agents

 Identify and prioritize threats		 Research and early development^a	 Advanced development^a	Available for use^b
Threat 1	Vaccine candidate	2		
	Vaccine			2001
	Therapeutic			2013
Threat 2	Vaccine candidate	1		
	Vaccine candidate		1	
	Therapeutic candidate	3		
Threat 3	Vaccine candidate		1	
Threat 4	Vaccine candidate	1		
	Vaccine candidate		1	
Threat 5	Vaccine candidate	3		
	Vaccine candidate		1	
	Therapeutic candidate	5		
Threat 6	Vaccine candidate	3		
Threat 7	Vaccine			2007
	Pretreatment			2005
Threat 8	Vaccine candidate		2	
	Therapeutic candidate ^c	9		
	Therapeutic candidate ^c		2	
Threat 9	Vaccine candidate	6		
Influenza ^d	Therapeutic candidate ^c		1	
Broad-spectrum antibacterial ^e	Therapeutic candidate ^c	1		
Threat 10	No research or development programs related to these threats are currently being conducted by Chemical and Biological Defense Program (CBDP), however, there are commercially available therapeutics that can be used to treat them.			
Threat 11				
Threat 12				
Threat 13				
Threat 14				
Threat 15	No research or development programs related to these threats are currently being conducted by CBDP.			
Threat 16				
Threat 17				
Threat 18				
Number of medical countermeasures at this stage		34	9	4

Product has reached research and early development
 Product has reached advanced development
 Product is available for use

Source: GAO analysis of DOD data.

Emerging and Genetically Modified Biological Threat Agents

Notes: Threats are given a numerical designation, since their identity and linking them to a specific countermeasure is classified information. Blanks for the threats labeled 10 through 18 indicate that there are no countermeasures available or in research and development against those threats.

^aNumbers in the research and early development and advanced development columns represent the number of medical countermeasure candidates at those particular stages of development.

^bNumbers in the available for use column represent the year the medical countermeasure was made available for use by the warfighter.

^cDOD intends for these therapeutic candidates to have broad-spectrum capabilities.

^dDOD officials told us the medical countermeasure candidate shown for influenza is a broad spectrum antiviral that DOD intends to use to treat other viruses that may affect the warfighter.

^eDOD officials told us these antibacterial therapeutic candidates are being developed to address several threats from this list, including: threats 1, 3, 6, and 11.

DOD is using a number of strategies to research, develop, and make available medical countermeasures for use against emerging and genetically modified (i.e., “novel”) threats. CBDP’s 2012 Strategic Plan indicates that to protect the warfighter against novel threats, CBDP will leverage cutting-edge and broad-spectrum capabilities that address current threat agents as a model for rapid response to novel threats that may arise in the future.²⁹ DOD is investing in threat-specific medical countermeasures for certain threats, but is also researching and developing broad-spectrum medical countermeasures, which have the possibility of addressing more than one threat on its biological threat list as well as providing capability against emerging and genetically modified threats. For example, of the 47 medical countermeasures or candidates for medical countermeasures that CBDP is researching, developing, or has made available, 13 are designed to be used against multiple threats. Furthermore, DOD has also developed and continues to invest in diagnostic capabilities that allow for the identification and characterization of biological threat agents. Specifically, CBDP is researching additional capabilities to add to the Joint Biological Agent Identification and Diagnostic System, which currently can diagnose five biological threat agents. DOD officials believe that CBDP’s efforts to develop medical countermeasures more quickly are aided by DOD’s investment in enabling technologies and platform technologies. Officials told us that one key enabling technology is represented by the Defense Advanced Research Projects Agency’s research to produce a pandemic flu vaccine using tobacco plant-based manufacturing, as opposed to the traditional egg-based production techniques that require much more lead time and

²⁹Department of Defense, *CBDP Strategic Plan* (June 2012).

more-controlled environments. Furthermore, CBDP officials told us that DOD is investing in platform-based vaccines for filoviruses and various strains of encephalitis in order to reduce the time and costs associated with developing medical countermeasures. Officials told us that platform technologies might be adapted to other various emerging or genetically modified threats (similar to the process used to develop the annual influenza vaccine, which is altered to be effective against different strains of that virus every year).

Another component of DOD's strategy to address emerging and genetically modified biological threats is a new facility for advanced development and manufacturing of medical countermeasures to be located near Gainesville, Florida. CBDP officials said that this facility, which is currently under construction and is projected to be operational in April 2015, will be designed with a focus on disposable or rapidly adaptable equipment so that it can produce small batches of numerous medical countermeasures with a relatively short lead time, while also providing the capability to increase production, when needed. DOD officials believe that this facility represents an opportunity for DOD to efficiently maintain fresh stockpiles of countermeasures that are rarely used, quickly produce new medical countermeasures in small amounts as may be needed for DOD's purposes, and to provide a capability to scale up production in the event of a national emergency.

DOD Has Not Used Its Established Process to Annually Update Its Validated List of Biological Threat Priorities

According to DOD Directive 6205.3, *DOD Immunization Program for Biological Warfare Defense*, the Chairman of the Joint Chiefs of Staff shall, annually and as required, validate and prioritize the biological warfare threats to DOD personnel in consultation with the combatant commands, military service chiefs, and the Director of the Defense Intelligence Agency, and forward that list to the CBDP Executive Agent (the Army) through the Assistant Secretary of Defense for Health Affairs.³⁰

Since April 2000, the list that DOD uses to prioritize the validated biological threat agents that pose a risk to the warfighter has only been updated occasionally, usually in response to broader policy or strategy

³⁰DOD Directive 6205.3 (Nov. 26, 1993). The requirement that the Chairman validate and prioritize CBRN threats also is stated in DOD Directive 5160.05E.

changes made within the department. For example, officials told us the 2012 update assessed CBRN threats; however, it did not include input from key stakeholders and it was not updated as part of an annual process as required by DOD Directive 6205.3. Examples of DOD's biological threat lists include:

- **Chairman of the Joint Chiefs of Staff Threat List (April 2000)** serves as the basis for each of the ensuing lists. DOD officials told us this list was developed in response to DOD Directive 6205.3, issued in November 1993, which establishes policy for DOD's immunization program for biological warfare defense and requires that the Chairman of the Joint Chiefs of Staff annually validate and prioritize biological warfare threats to DOD personnel.
- **Medical Risk Management Matrix (May 2001)**. DOD officials told us this list was developed in response to the *2001 Quadrennial Defense Review*, which was under development at the same time, and advocated for a capabilities-based approach to defense, focusing more on how an adversary might fight than who an adversary might be.³¹ Officials said this analysis was carried out by a contracting service that applied a risk analysis to the *2000 Chairman of the Joint Chiefs of Staff Threat List* to develop the new list, which maintained many similar threats, but categorized them into risk categories based on the likelihood and effect of such an attack.
- **Medical Operational Consequence Assessment (September 2012)** is an assessment of all CBRN threats. The assessment used a similar methodology to the Medical Risk Management Matrix, but also included chemical and radiological inputs. A CBDP official told us the Medical Operational Consequence Assessment was used indirectly to inform DOD's budget for fiscal year 2015, since the fiscal year 2015 budget was based on previous budgets, which directly relied on the same assessment to help prioritize investments for specific medical countermeasures.

We found that DOD's May 2001 and September 2012 biological threat list updates were not performed in accordance with DOD Directives 6205.3 and 5160.05E. For example, key stakeholders, such as officials from the CBDP Executive Agent and military service officials from the chemical and biological countermeasure community, were unaware of an updated

³¹Department of Defense, *Quadrennial Defense Review Report* (Sept. 30, 2001).

biological threat list because the list was not sent to them for review or input, as required by the directives. Officials from the Joint Requirements Office—which is part of the Joint Staff—expressed uncertainty about the applicability of DOD Directive 6205.3, which they believe was made obsolete when the *2001 Quadrennial Defense Review* established DOD’s emphasis on capability-based planning over threat-specific planning, an emphasis that was continued through the more recent *2010 Quadrennial Defense Review*. However, DOD Directive 6205.3 remains in effect and has not been formally superseded or cancelled. In commenting on a draft of this report, officials from DOD said the 2001 and 2012 analyses were assessments based on the 2000 list rather than updates to the official threat list. However, we continue to believe that the process described in DOD Directive 6205.3 should have been applied to these assessments because the biological threats listed changed as a result of these analyses, reflecting changes in CBDP priorities.

The requirement that the Chairman of the Joint Chiefs of Staff validate and prioritize CBRN threats also is contained in a more-recent directive, which addresses roles and responsibilities within CBDP.³² While DOD has moved toward capability-based planning and risk-informed analysis, DOD officials told us that they continue to seek information about current threats to assist their planning efforts. In addition, as shown in figure 7, the changes to the methodology—which did not always include input from key stakeholders—resulted in changes to the threats included in the lists. Specifically, some threats included in the 2000 list were removed in the 2001 list, and then reinstated as part of the 2012 list.

Figure 7: The Department of Defense’s (DOD) Evolving Biological Threat List

Threat	2000 Threat List	2001 Threat List	2012 Threat List
Threat 1	✓		
Threat 2	✓	✓	✓
Threat 3	✓		
Threat 4	✓	✓	✓
Threat 5	✓	✓	✓
Threat 6	✓	✓	✓
Threat 7			✓

³²DOD Directive 5160.05E (Oct. 9, 2008).

Threat	2000 Threat List	2001 Threat List	2012 Threat List
Threat 8	✓	✓	✓
Threat 9	✓	✓	✓
Threat 10	✓		✓
Threat 11			✓
Threat 12	✓	✓	✓
Threat 13	✓		✓
Threat 14	✓	✓	✓
Threat 15	✓	✓	✓
Threat 16	✓	✓	✓
Threat 17	✓	✓	✓
Threat 18	✓	✓	✓
Threat 19	✓	✓	✓
Threat 20	✓	✓	✓
Threat 21	✓	✓	✓
Threat 22	✓	✓	

Legend

✓ = threat was included on the respective list

Source: GAO analysis of DOD data.

Note: Threats are given a numerical designation, since their identity is classified.

By not following its directives and regularly updating its biological threat list and priorities, DOD cannot be fully assured that its investments and allocation of resources—and those of its partners—are being applied toward developing medical countermeasures to respond to the most-serious and likely biological threat agents.

DOD Has Taken Steps to Enhance Internal Coordination on Resource Allocation for Medical Countermeasures Against Biological Threat Agents

CBDP has taken steps to increase transparency and improve coordination practices within DOD as it allocates resources to address biological threat agents. Military service officials with whom we met indicated that prior to the most-recent budget development cycle, there was a lack of transparency in how CBDP prioritized requirements and made resourcing decisions for medical countermeasures. To address these concerns and better incorporate service priorities and perspectives, CBDP issued a business plan in 2012, which updated its coordination methods. Military service officials agreed with CBDP's actions and stressed the need for continuing dialogue and collaboration. In addition, CBDP also has established processes for internal DOD coordination throughout the stages of research and development of specific medical countermeasures against biological threat agents.

CBDP Has Taken Steps to Enhance Coordination and Address Military Service Concerns

CBDP is responsible for establishing both medical and nonmedical defense capabilities, and is also responsible for overseeing its budget processes and allocating funds.³³ However, military service officials indicated that, in the past, CBDP did not have transparent processes for prioritizing requirements and allocating funding among these capabilities during the preparation of the budget. Specifically, officials expressed concern that while the Army, as CBDP Executive Agent, works to build consensus among the military services as it coordinates and integrates requirements, CBDP has made key prioritization decisions without communicating its justification to key stakeholders, including the Army. For instance, CBDP and military service officials told us that CBDP officials decided to prioritize medical countermeasure research and development, while transferring funds from military service requirements, such as personal protective equipment and threat-detection sensors. Specifically:

- According to Army officials, during preparation of future budget plans in 2010, CBDP leadership transferred funding from programs that would have provided personal protective equipment in order to increase funding for a medical countermeasures initiative. According to Army officials, this occurred after the Army had integrated and coordinated priorities with the other military services and combatant commands, and CBDP leadership did not coordinate this change with key stakeholders. CBDP's actions affected 24 different programs and

³³DOD Directive 5160.05E (Oct. 9, 2008).

totaled about \$1.2 billion over the course of the 4-year budget, according to Army officials. Though the Army, in its role as Executive Agent, ultimately concurred with the final CBDP budget plan, it expressed its concern about CBDP's decisions when doing so.

- During the same time frame, CBDP transferred funding from an Air Force threat-detection sensor program, according to Air Force officials. The officials indicated that the program was a high priority for their service and had, until that point, received sufficient funding. However, according to the officials, CBDP removed nearly all of the funding, approximately \$50 million, in order to support other priorities, including medical countermeasures.
- Navy officials indicated that in fiscal year 2013, CBDP removed \$90 million in funding for upgrades to a ship-based threat-detection sensor program. This program would have addressed issues with the current version of the system, such as false alarms and high rates of repair. According to Navy officials, though they met frequently with the Joint Requirements Office to advocate for the program, CBDP leadership removed the funding during its review of the proposed budget.

CBDP officials acknowledged that they did not effectively communicate with the military services regarding some of these actions, but stated that their decisions were driven by the need to balance resources among all priorities, including medical countermeasures. Also, CBDP officials noted that the services had equipment available to respond to short-term requirements. Additionally, CBDP officials told us that some of the increased investments in medical countermeasures would not continue, but were necessary to initiate specific programs, such as the creation of a DOD facility for advanced development and manufacturing of medical countermeasures. According to CBDP officials, they are now strategically planning how they fund medical countermeasures for the future, so that they do not have to transfer funding from other programs, though they recognize that they will not always be able to meet all military service resource-allocation requests. In addition, Army and Navy officials stated that the Office of Cost Assessment and Program Evaluation within the Office of the Secretary of Defense is conducting a study of DOD's biological defense capabilities and, among other things, the most-effective balance between capabilities, such as medical countermeasures and personal protective equipment and threat-detection sensors. Army officials told us that this study, which is slated for completion in mid-2014, will help inform CBDP prioritization and resourcing decisions in the future.

Since CBDP made some of these funding decisions, it has updated its practices for collaboration by issuing a business plan that details how it will coordinate with stakeholders in the future, and military service officials have agreed that these changes have resulted in improvements in coordination among CBDP components. CBDP intends for its business plan, issued in October 2012, to help it manage the program and develop capabilities in a focused and collaborative manner by laying out a framework through which CBDP stakeholders can align strategies. CBDP established a yearly cycle to develop strategic guidance and establish priorities, which ultimately inform CBDP's budget planning and resource decisions. In order to implement this cycle, CBDP created multiple teams, at varying levels of authority, to provide input and recommendations. For example, the Integrated Product Team includes representatives from all of the military services and other members of CBDP. Members of this team assess the composition of the CBDP portfolio, coordinate and align CBDP efforts across the program, provide input on portfolio priorities, and support budget development. Similar teams and boards at higher organizational levels then review this input and make decisions. Additionally, CBDP can charter teams to address specific issues as needed. For example, CBDP officials said that a Medical Working Integrated Product Team began holding meetings in January 2014 to examine specific threats and determine which medical countermeasures against biological threat agents DOD needs, and how to prioritize among them.

According to the business plan, these processes support decision making and incorporate perspectives from key stakeholders, including the military services. According to CBDP officials, these efforts have resulted in increased predictability, transparency, and representation of stakeholder perspectives, including agreement on budget plans. Military service officials complimented CBDP's work to improve coordination, especially the ability to provide early input into the strategic priorities, and said that this change has resulted in a more-transparent budget process. These officials told us that it will be important for CBDP to continue to improve coordination and collaboration in the future. In particular, Army officials expressed concern that potential revisions to the DOD directive on CBDP roles and responsibilities could weaken their role and authorities as Executive Agent.³⁴ Under the current directive, the Army reviews the

³⁴DOD Directive 5160.05E (Oct. 9, 2008).

CBDP funding plan, and provides senior-level input to CBDP leadership. Army officials indicated that the Army nonconcurred on a draft revision to this directive in October 2012, and CBDP officials told us that they informally provided the Army an updated draft in March 2014.

CBDP Coordinates the Activities of DOD Components Involved in the Research and Development of Medical Countermeasures against Biological Threat Agents

In addition to the internal DOD coordination processes that CBDP has established for resource-allocation priorities and plans, CBDP has also created groups to coordinate the stages of development of medical countermeasures against biological threat agents. As previously discussed, multiple DOD components are involved in researching and developing medical countermeasures against biological threat agents, and some countermeasure programs can shift back and forth between components. According to CBDP officials, consistent coordination among the components is needed to ensure that DOD provides mature capabilities to the warfighter. To help improve coordination, CBDP established the following teams.

- **Translational Teams.** Members from multiple components within CBDP participate in these teams to help transition medical countermeasures against biological threat agents among the various stages of development, such as moving from a research prototype into advanced development. The teams provide visibility into the status of each program, enabling each organization to better prepare to support the programs, and also assist with CBDP resource allocation, as they enable the shifting of funds among the organizations depending upon the pace of development. Additionally, the teams can serve as technical support, and help identify solutions for DOD requirements.
- **Integrated Product Teams.** These multidisciplinary teams integrate all activities that DOD would need to perform to plan for and ultimately acquire a medical countermeasure against biological threat agents. According to officials, one team exists for each specific program, such as filoviruses, and assesses the cost, schedule, and performance of each program.

DOD's Efforts to Coordinate across Agency Boundaries Align with Best Practices

DOD's efforts to coordinate with HHS and DHS align with best practices we have 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.³⁵ 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 have also 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.

DOD, HHS, and DHS Share a Joint Biological Research Campus

DOD, HHS, and DHS share a joint biological research campus, known as the National Interagency Biodefense Campus, at Fort Detrick, Maryland, which has its own governance structure. The campus is intended to maximize resource sharing and facilitate scientific exchange on the study of dangerous biological pathogens.³⁶ The creation of the research campus and governance structure, which leverages available resources and establishes joint strategies, aligns with our best practices for collaborating across agency boundaries to help ensure that the departments reach desired outcomes. DOD's, HHS's, and DHS's respective biological facilities at the shared campus include the following:

- DOD's U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID) engages in scientific research of dangerous biological threat agents. Its work after the terrorist attacks of September 11, 2001, expanded to include biological threat characterization, enhanced studies of disease, and the development of medical countermeasures.

³⁵See [GAO-12-1022](#) and [GAO-06-15](#). Key practices include establishing mutually reinforcing or joint strategies to achieve the outcome; identifying and addressing needs by leveraging resources; and reinforcing agency accountability for collaborative efforts through agency plans and reports.

³⁶The Department of Agriculture's Agricultural Research Service is also a member of National Interagency Biodefense Campus at Fort Detrick, Maryland, and participates in the federal interagency governance structure.

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- HHS's National Institute of Allergy and Infectious Diseases, of the National Institutes of Health, built the Integrated Research Facility (IRF) that includes biocontainment laboratories, which are shared with other federal departments at the joint campus. The IRF allows HHS to support its mission to study disease and develop improved methods of treatment.
 - DHS's National Biodefense Analysis and Countermeasures Center, also located at the shared campus, allows DHS to share its repository of pathogens and specimens to identify biological threat agents, and characterize the potential threats to the civilian population through studies to determine the cause of diseases.

In 2003, officials developed a governance structure for the Fort Detrick research campus—the National Interagency Confederation for Biological Research (NICBR)—that includes DOD, HHS, and DHS scientists who engage in interagency scientific research of dangerous biological pathogens.³⁷ The primary goal of the NICBR is to respond to the need for a “whole of government” effort by the federal government to address bioterrorism. Most, if not all, aspects of medical countermeasure research and development activities and associated finances fall under the auspices of many federal departments that have different requirements, funding sources, metrics, and areas of expertise and responsibility. No one agency within the departments is involved in the end-to-end development of medical countermeasures, nor does any one agency have a complete overview of the medical countermeasure landscape across the federal government. In an effort to link agency activities, NICBR partners engage in shared efforts related to biological threat characterization, studies to determine the cause of disease, and the development of medical countermeasures to treat diseases resulting from exposure to the pathogens. DOD, HHS, and DHS have ratified a strategic plan to enhance coordination among the members of the NICBR. These efforts align with our best practices for collaborating across agency boundaries to help ensure that the departments reach desired outcomes,

³⁷The Army, National Institute of Allergy and Infectious Diseases, and the National Cancer Institute originally signed the constitution for the NICBR on April 22, 2003, and DHS and the Department of Agriculture joined the NICBR near the end of 2003. The Centers for Disease Control and Prevention became a NICBR partner in 2005.

specifically by leveraging available resources and establishing joint strategies.³⁸

The NICBR governance structure includes the Fort Detrick Interagency Coordinating Committee, made up of all NICBR partner representatives, leading multiple subcommittees and working groups.³⁹ According to NICBR officials, the various members that make up NICBR meet weekly, at a minimum, and subcommittee and working group members meet routinely to share scientific expertise, information, and technical services, in accordance with their interagency agreements. NICBR partners share responsibility for the governance structure and ongoing collaborative research efforts. Along with regular meetings, DOD officials said that NICBR partners also meet on an ad hoc basis due to the professional relationships that have formed since the establishment of the governance structure. In an example of this interagency collaboration and coordination, according to DOD officials, the NICBR members facilitated joint research efforts on the emerging infectious disease known as the Middle East respiratory syndrome coronavirus. To advance the study of the disease, Navy scientists collected specimens of the pathogen from a foreign site and shared it with other DOD, DHS, and HHS scientists at Fort Detrick, who conducted studies to understand the cause of the disease. DOD scientists also collaborated with DHS and HHS scientists at the campus to conduct other research towards a potential medical countermeasure for the disease. DOD and IRF officials described the interagency coordination to research the Middle East respiratory syndrome coronavirus as mutually reinforcing research by leveraging available expertise and facilitating scientific exchange. These efforts correspond with best practices for enhancing collaborative efforts by facilitating information sharing and communication and leveraging available resources.⁴⁰

In addition, DOD officials from USAMRIID told us that the communication and collaboration that occurs informally at Fort Detrick has significantly

³⁸[GAO-12-1022](#).

³⁹The Fort Detrick Interagency Coordinating Committee reports to an Executive Steering Committee comprising of equivalent leadership officials from all partner agencies. The Executive Steering Committee reports to a Board of Directors consisting of senior leaders from all the partner agencies.

⁴⁰[GAO-12-1022](#).

improved their understanding of emerging diseases. DOD officials said that shared biocontainment laboratories also facilitate scientific exchange, data sharing, and collaboration on research. For example, IRF officials told us that working with DOD scientists on biological defense helps HHS understand how medical requirements to treat diseases can be defined to support both the military and civilian population. DOD officials added that because the field of senior-level scientists and officials involved in research on biological threat agents at the shared campus is relatively small, and scientists often move from one department to another within the NICBR organization, valuable insights have been shared and collaborative relationships have improved significantly.

DOD and HHS Have Established Interagency Agreements and Collaboration Tools to Promote Coordination

Interagency Agreements

DOD and HHS have signed various interagency agreements to support joint activities for the various stages of the medical countermeasure process. For example, the departments share interagency agreements and memorandums of understanding that support interagency coordination for medical countermeasure activities, such as coordinating on early research and development, sharing certain resources at advanced development facilities, and stockpiling medical countermeasures, such as anthrax and smallpox vaccines. Together, the agreements, which stipulate the roles and responsibilities for coordination, are consistent with best practices for collaboration and generally serve to promote agency collaboration by defining common outcomes and providing interagency agreement on roles and responsibilities, as called for in our previous work.⁴¹

To support early research and development, DOD and HHS developed various interagency agreements intended to promote coordination. The

⁴¹[GAO-06-15](#).

agreements generally describe the basis for joint activities to mitigate the threat of CBRN agents and global public health challenges, including emerging infectious diseases. For example, one memorandum of understanding supports the transfer of information and shared intellectual property between DOD and HHS.⁴² DOD officials told us that sharing medical countermeasure research has facilitated the ability to understand the causes of disease. Another memorandum of understanding supports information sharing between DOD and HHS regarding cutting-edge, broad-spectrum capabilities that address current threat agents for both military and civilian use.⁴³ DOD officials said that collaborating on broad-spectrum countermeasures is important to support efforts to address novel threats that may arise in the future. HHS officials said that these broad-spectrum countermeasures, which provide the capability of addressing more than one threat, also offer opportunities for financial savings, commercial investment, and scientific efficiencies.

To support advanced development and manufacturing of biological countermeasures, DOD and HHS have established a memorandum of understanding to facilitate collaboration at their facilities for advanced development and manufacturing. Both departments have set up individual centers that support each other. For example, in 2012, for the purposes of national defense, DOD began plans for a dedicated facility for advanced development and manufacturing of medical countermeasures with the ability to use flexible technologies to manufacture biological countermeasures rapidly and in large quantities. Similarly, in June 2012, to assist CBRN medical countermeasure developers and augment domestic manufacturing surge capacity against emerging infectious diseases or unknown biological threat agents,⁴⁴ HHS awarded three contracts to establish Centers for Innovation in Advanced Development and Manufacturing utilizing flexible manufacturing technologies—the use

⁴²Memorandum of understanding between U.S. Department of Defense Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs and U.S. Department of Health and Human Services Centers for Disease Control and Prevention (July 2011).

⁴³Memorandum of understanding between the U.S. Department of Health and Human Services Assistant Secretary for Preparedness and Response and U.S. Department of Defense Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs, annex II (2011).

⁴⁴HHS officials said that the centers' efforts also are intended to augment domestic manufacturing surge capacity against pandemic influenza.

of disposable equipment and alternative technologies for product development and rapid manufacturing—to aid in the development and production of medical countermeasures.⁴⁵ DOD and HHS plan to collaborate at their respective centers by sharing access to a network of biodefense medical countermeasure innovators (including those from the private sector) that can use emerging platform technologies to enhance the production of biological medical countermeasures. The two departments also plan to use their separate centers to reduce scientific research and development expenses, risks of scientific failure, and to provide more-reliable and sustainable medical countermeasure manufacturing during times of need. According to DOD and HHS officials, the centers are expected to advance scientific discovery through the use of flexible technologies that support large-scale surge capacity for biological medical countermeasures in quantities that will be sufficient during emergencies and available for shared purposes.

To make medical countermeasures available for the warfighter, DOD and HHS also have developed interagency agreements that allow DOD to purchase, and HHS to rotate, certain products from HHS's Strategic National Stockpile for use by DOD's military personnel. For example, DOD and HHS have agreements that establish a framework allowing DOD to purchase smallpox and anthrax vaccines from the Strategic National Stockpile.⁴⁶ According to DOD officials, DOD's ability to purchase the vaccines from the Strategic National Stockpile benefits both departments financially and minimizes duplicative efforts. A similar agreement facilitates coordination in the event of a shortfall in critical medical countermeasures needed by either department in the event of a public health incident related to a domestic catastrophic incident.⁴⁷ Under

⁴⁵In addition, the facilities will provide packaging support for medical countermeasure distribution, known as the Fill Finish Manufacturing Network. See related report, GAO, *National Preparedness: HHS Has Funded Flexible Manufacturing Activities for Medical Countermeasures, but It Is Too Soon to Assess Their Effect*, [GAO-14-329](#) (Washington, D.C.: Mar. 31, 2014).

⁴⁶Interagency Support Agreement between the Department of Defense Chemical Biological Medical Systems Joint Vaccine Acquisition Program (supplier) and Department of Homeland Security US Coast Guard (receiver) for Anthrax and Smallpox Vaccines (Feb. 2012).

⁴⁷Interagency Agreement between the Department of Health and Human Services and the Department of Defense for Support of Contingency Medical Materiel Requirements (May 2005).

this agreement, HHS and DOD agree to share medical countermeasures, including pharmaceuticals, biologics, medical and surgical supplies and equipment that are needed by HHS or DOD to prepare for, respond to, or recover from a public health incident of national significance. The agreement is intended to create a standardized approach to coordinate mutual support in the event of a medical countermeasures shortfall during an emergency. DOD officials said that the agreement includes materials and products from the Strategic National Stockpile as well as DOD contingency materiel stockpiles. DOD officials said that the shared stockpile benefits DOD both financially and in terms of logistics. For example, DOD is able to access products it needs through the Strategic National Stockpile, which provides efficiencies for the federal government because the Centers for Disease Control and Prevention is able to rotate medical countermeasures out of its stockpile. HHS officials agreed that the ability to share stockpiles of medical countermeasures contributes significantly during federal emergencies.

Collaboration Tools

DOD and HHS, through the PHEMCE's Integrated Portfolio, collaborate on the status of medical countermeasure activities using tools intended to promote communication on product development timelines and milestones, clinical progress achieved, and other metrics for tracking and monitoring. DOD and HHS have initiated actions consistent with practices identified in our past work as well as federal internal control standards to enhance information sharing and coordination.⁴⁸ Specifically, DOD and HHS have established the Integrated Portfolio Charter and other tools to channel information across and within the departments to help ensure that agency officials at all levels are informed of each department's medical countermeasures efforts. Both DOD and HHS officials said that they often talk and meet more often than the monthly meetings that the Integrated Portfolio Charter specifies. The Integrated Portfolio, made up of senior-level HHS and DOD officials with responsibility for portfolio analysis of CBRN medical countermeasures, has developed tools such as a portfolio tracking system and knowledge-based standard terms to help agencies communicate about the stages of research and development. According to DOD and HHS officials, the tools have enabled DOD and HHS to leverage investments and resources by sharing information and metrics to understand each department's

⁴⁸GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: Nov. 1999) and [GAO-06-15](#).

requirements, scope, schedule, and budget for developing countermeasures. For example, the medical countermeasure Portfolio Tracking Tool currently is being updated to support real-time viewing of the status of all medical countermeasure products, allowing users to analyze the status of countermeasures; develop estimates of key planning parameters, including investments needed to meet requirements; and minimize duplication of effort by anticipating transition points. According to DOD officials, the ability to have an overview of all existing medical countermeasure activities in one location has helped to inform recommendations related to portfolio planning, including for funding transitions and to improve gaps in each agency's medical countermeasure stockpiles. The Integrated Portfolio also aligned Technology Readiness Levels, which is a shared language for medical countermeasure research and development terms that are intended to provide a common method to understand, at a general level, the maturity of medical countermeasure development products over the development life cycles. According to HHS officials, the aligned definitions facilitate interagency communication during all stages of the medical countermeasure process.

DOD and DHS Have a Shared Process for Identifying Domestic Biological Threat Agents and Risks

DOD and DHS officials coordinate on the identification of biological threat agents that pose risk to the nation through DOD's participation in DHS's senior-level, quarterly terrorism risk-assessment working group meetings. These efforts align with practices we have identified for collaborating across agency boundaries—specifically, implementing practices that enhance and sustain collaboration, including frequent communication among and within the agencies.⁴⁹ DOD provides input at the meetings where information is gathered that is used to produce DHS's biennial Biological Terrorism Risk Assessments, which are distributed to national organizations for the prioritization of medical countermeasures. While DHS is responsible for assessing and prioritizing biological threat agents that pose a risk to the civilian population, as directed by the Project BioShield Act of 2004⁵⁰ and various HSPDs,⁵¹ DHS officials told us they

⁴⁹GAO-06-15 and GAO/AIMD-00-21.3.1.

⁵⁰42 U.S.C. & 247d-6b(c)(2)(A).

⁵¹Executive Office of the President, Homeland Security Presidential Directive 10, *Biodefense for the 21st Century* (June 12, 2002); Homeland Security Presidential Directive 18, *Medical Countermeasures against Weapons of Mass Destruction* (Jan. 31, 2007).

provide informal feedback to DOD on DOD's prioritized biological threat lists or risk assessments. DOD officials told us that DOD makes limited use of information from DHS to prioritize its own threat list because DHS focuses on domestic threats to civilians, while DOD focuses its threat and risk assessments on global scenarios that pose a risk to the warfighter.⁵² DOD and DHS also have agreements to operate across agency boundaries, which aligns with our best practices.⁵³ For example, DOD and DHS have developed a memorandum of understanding to foster information sharing and collaboration in areas of chemical and biological defense, including science and technology research. Areas of cooperation that are considered include use of facilities, exchange of information and personnel, jointly produced documentation, and joint project ventures. DHS officials told us the interagency cooperation would generally occur at the Fort Detrick campus where the National Biodefense Analysis and Countermeasures Center performs biological research using its biocontainment laboratories with forensic capabilities. Although DHS has agreements to share its facilities and resources with DOD, DHS officials told us that to-date they have not performed extensive work for DOD at the biological research facilities, though the departments have had initial conversations for such efforts.

Conclusions

DOD's efforts within the department and with interagency partners have resulted in progress in DOD's ability to plan for and develop medical countermeasures to respond to biological threat agents. However, some elements need attention to capitalize on this progress. To ensure that DOD officials are able to better prepare for and respond to potentially catastrophic attacks with a biological threat agent, DOD guidance requires annual updates and revalidation of its biological threat list. Yet, DOD does not follow its established process for updating its biological threat priorities, which has, in the past, led to conditions in which the list has been updated without including input and review from key stakeholders and in which the list has not been updated for long periods of time—years in some cases. By following DOD guidance for updating its biological threat list or by revising the list development process to reflect its emphasis on capabilities- and risk-based planning, DOD could help

⁵²DOD is not required to collaborate with other federal agencies in developing its prioritized threat list.

⁵³See [GAO-06-15](#).

ensure that the list remains current and is validated regularly using input from all key stakeholders. This, in turn, would help DOD sustain the progress it has made in planning for medical countermeasures against biological threat agents.

Recommendation for Executive Action

To help ensure that DOD's investments are being applied toward developing medical countermeasures to respond to the most serious and likely biological threat agents, we recommend that the Secretary of Defense direct the appropriate DOD officials to develop and implement a process to update and validate DOD's list of biological threats, as required by DOD Directives 5160.05E and 6205.3, or implement a process that aligns with the department's current policies, practices, and priorities as reflected in the 2001 and 2010 *Quadrennial Defense Reviews*.

Agency Comments and Our Evaluation

In written comments on a draft of this report, DOD concurred with our recommendation to develop and implement a process for updating and validating the department's list of biological threats to ensure that they align with current policies, practices, and priorities. DOD officials indicated that they will review the relevant directives addressing biological warfare threats to ensure that they align with DOD's capabilities-based planning processes and reflect a threat-informed, risk-based assessment. We believe this effort, and any related specific actions, will address the intent of our recommendation. The full text of DOD's comments is reprinted in appendix III. DOD also provided us with technical comments, which we incorporated, as appropriate.

HHS did not provide formal agency comments on a draft of this report, but provided technical comments, which we incorporated, as appropriate. DHS also did not provide formal agency comments and had no technical comments.

We are sending copies of this report to interested congressional committees; the Secretaries of Defense, Health and Human Services, and Homeland Security; the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs; the Acting Deputy Assistant Secretary of Defense for Chemical and Biological Defense; the Chairman of the Joint Chiefs of Staff; the Secretaries of the Army, the Navy, and the Air Force; the Commandant of the Marine Corps; the Director, Centers for Disease Control and Prevention; the Commissioner, Food and Drug Administration; the Director, National Institutes of Health; and the

Director, Office of Management and Budget. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions concerning this report, please contact Joseph Kirschbaum at (202) 512-9971 or KirschbaumJ@gao.gov or Marcia Crosse at (202) 512-7114 or CrosseM@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.

Joseph W. Kirschbaum

Handwritten signature of Joseph W. Kirschbaum in black ink, featuring a large, stylized 'J' and 'K'.

Acting Director
Defense Capabilities and Management

Marcia Crosse

Handwritten signature of Marcia Crosse in black ink, written in a cursive style.

Director
Health Care

List of Committees

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Chairman
The Honorable James Inhofe
Ranking Member
Committee on Armed Services
United States Senate

The Honorable Richard Durbin
Chairman
The Honorable Thad Cochran
Ranking Member
Subcommittee on Defense
Committee on Appropriations
United States Senate

The Honorable Howard P. McKeon
Chairman
The Honorable Adam Smith
Ranking Member
Committee on Armed Services
House of Representatives

The Honorable Rodney Frelinghuysen
Chairman
The Honorable Pete Visclosky
Ranking Member
Subcommittee on Defense
Committee on Appropriations
House of Representatives

Appendix I: Scope and Methodology

For the purposes of our review, we defined “medical countermeasures” as the vaccines, drugs, and diagnostics that respond to chemical, biological, and radiological threats. We defined “medical countermeasures against biological threat agents” as the pretreatments, prophylaxes, therapeutics, and diagnostics that respond specifically to biological threats. We did not include personal protective equipment, such as gas masks, gloves, and boots, or biosurveillance and detection equipment in our analysis. We included in our definition of “biological threat agents” traditional, emerging, and genetically modified agents. We defined “traditional” biological agents as those naturally occurring microorganisms or toxin products with the potential to be disseminated to cause mass casualties. We defined “emerging” biological agents as previously unrecognized pathogens that might be naturally occurring and present a serious risk to human populations, and “genetically modified” agents as organisms that have either been modified or developed to bypass traditional countermeasures or produce a more-severe or enhanced disease. We included budget data from fiscal year 2001 through fiscal year 2013, since that period would be sufficient to allow us to analyze funding since the 2001 anthrax attacks.

To describe the Department of Defense’s (DOD) funding for medical countermeasures from fiscal year 2001 through fiscal year 2013, we obtained and analyzed data from the Chemical and Biological Defense Program (CBDP) budget office and identified the total funding related specifically to medical countermeasures against biological threat agents. For the purposes of this objective, we defined medical countermeasures against biological threat agents in alignment with the data DOD provided, which did not include diagnostics. Specifically, we reviewed results from CBDP’s Joint Service Chemical and Biological Information System, which is used by CBDP for tracking this information. CBDP officials confirmed that the data reflected obligations for fiscal year 2001 through 2012, and budget allocations for fiscal year 2013. Using DOD’s *National Defense Budget Estimates for Fiscal Year 2014*, we adjusted all figures for inflation. Specifically, we used the research, development, test, and evaluation deflation index for fiscal year 2013 from the Total Obligational Authority by Appropriation Title table. After adjusting figures to fiscal year constant 2013 dollars, we converted figures from thousands to millions when appropriate for presentation purposes, and conducted analysis to determine totals and percentages. Further, we interviewed agency officials about how they use the Joint Service Chemical and Biological Information System and how they ensured the accuracy of the data provided, but we did not independently verify or validate the data provided by DOD. Through these steps, we determined that the funding data

provided by DOD were sufficiently reliable to provide an overview of total funding levels for medical countermeasures against biological threat agents.

To evaluate DOD's progress in researching, developing, and making available medical countermeasures for use against prioritized biological threat agents, including DOD's process to prioritize biological medical countermeasure development, we compared the requirements of DOD Directive 6205.3, *DOD Immunization Program for Biological Warfare Defense* and DOD Directive 5160.05E, *Roles and Responsibilities Associated with the Chemical and Biological Defense Program*, to the practices CBDP uses to prioritize investments in medical countermeasures against biological threat agents. Further, we compared the threats listed on DOD's Chairman of the Joint Chiefs of Staff Threat List, the Medical Risk Management Matrix, and the Medical Operational Consequence Assessment, which were all developed by CBDP's Joint Requirements Office to identify significant biological threats to the warfighter, and compared them to the medical countermeasures DOD is researching, developing, and has made available for use. Finally, we examined DOD's efforts to research and develop medical countermeasures against emerging and genetically modified biological threat agents by reviewing DOD's efforts to facilitate development of broad-spectrum medical countermeasures and other unique production and diagnosis capabilities that would be effective against a wide variety of pathogens, including genetically modified threat agents. To corroborate our understanding of the documents we reviewed, we interviewed officials from CBDP and its component offices, and obtained these officials' perspectives on their methodology and practices for updating lists of prioritized threat agents.

To describe the status of DOD's efforts to internally coordinate the allocation of resources to medical countermeasures against biological threat agents, we compared the coordination requirements established in DOD's policies, priorities, and strategies for its medical countermeasure efforts to the way DOD agencies actually coordinate with each other to prioritize, research, develop, and budget for medical countermeasures. Specifically, we reviewed DOD Directive 5160.05E, *Roles and Responsibilities Associated with the Chemical and Biological Defense Program*, and CBDP's 2012 business plan. To corroborate our understanding of these policies and processes, and to understand how DOD has applied its practices, we interviewed officials from within DOD organizations responsible for researching and developing medical countermeasures regarding each office's responsibilities to coordinate

medical countermeasure efforts, including CBDP, Joint Requirements Office, Joint Science and Technology Office, Joint Program Executive Office, and Office of the Assistant Secretary of Defense for Health Affairs. To understand service perspectives on DOD's current practices, we interviewed officials from the Army, the Navy, and the Air Force, and reviewed documentation for the examples they cited. We also reviewed guidelines established by DOD that are relevant to the organization and structure of DOD's medical countermeasure coordination efforts, including the *CBDP Strategic Plan* and the Chairman of the Joint Chiefs of Staff's *National Military Strategy to Counter Weapons of Mass Destruction*.

To evaluate the extent to which DOD's efforts to coordinate with the Department of Health and Human Services (HHS) and the Department of Homeland Security (DHS) to research and develop medical countermeasures against prioritized biological threat agents align with best practices for collaboration, we reviewed DOD, HHS, and DHS policies and procedures, strategies, memorandums of understanding, and other documents on medical countermeasure efforts to understand how the departments coordinate and communicate. We interviewed DOD, HHS, and DHS officials responsible for medical countermeasure efforts against prioritized biological threat agents. Specifically, we compared the coordination efforts of DOD, HHS, and DHS with the 2008 *National Defense Strategy*, which advocates for a "whole of government" approach to national security issues that requires that federal partners improve efficiencies by working together on roles and missions,¹ as well as prior GAO reports on federal practices to enhance and sustain agency collaboration that require, in particular, that agencies leverage available resources, establish mutually reinforcing joint strategies, and develop compatible policies, procedures, and other tools to operate across agency boundaries.² We also compared the efforts against the *Standards for Internal Control in the Federal Government*, which call for (1) management to ensure that there are adequate means of communicating with, and obtaining information from, external stakeholders, and (2)

¹Department of Defense, *National Defense Strategy* (June 2008).

²See GAO, *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, [GAO-12-1022](#) (Washington, D.C.: Sept. 27, 2012) and *Results Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, [GAO-06-15](#) (Washington, D.C.: Oct. 21, 2005).

effective communication flowing down, across, and up the organization to enable managers to carry out their internal control responsibilities.³

Finally, we interviewed selected subject-matter experts from academia to obtain their perspectives on DOD's interagency coordination efforts with HHS and DHS for the research and development of medical countermeasures against biological threat agents.

We obtained relevant data and documentation and interviewed officials from the following organizations:

Department of Defense

- Office of the Under Secretary of Defense for Acquisition, Technology and Logistics
 - Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs
 - Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense
- Office of the Assistant Secretary of Defense for Health Affairs
- Joint Chiefs of Staff
 - Joint Staff Directorate for Force Structure, Resources and Assessment (J-8)
 - Joint Requirements Office
- Defense Threat Reduction Agency
 - Joint Science and Technology Office
- Defense Advanced Research Projects Agency
- Defense Intelligence Agency
- Military services
 - Army
 - Office of the Assistant Secretary of the Army for Acquisitions, Logistics, and Technology

³GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: Nov. 1999).

- Joint Program Executive Office for Chemical and Biological Defense
- Office of the Deputy Chief of Staff for Programming (G-8)
- Office of The Surgeon General and U.S. Army Medical Command
- U.S. Army Medical Research and Materiel Command
 - U.S. Army Medical Materiel Development Activity
 - U.S. Army Medical Research Institute of Infectious Diseases
- Navy
 - Chief of Naval Operations, Surface Warfare (N96), Chemical, Biological, Radiological, and Nuclear Defense Branch
- Air Force
 - Air Staff
 - Operations, Plans and Requirements
 - Logistics, Installations and Mission Support
 - Medical Support Agency

Department of Health and Human Services

- Assistant Secretary for Preparedness and Response
 - Biomedical Advanced Research and Development Authority
- Public Health Emergency Medical Countermeasures Enterprise
 - Integrated Portfolio Team
- National Institutes of Health
 - National Institute of Allergy and Infectious Diseases
 - Integrated Research Facility
- Centers for Disease Control and Prevention
- Food and Drug Administration

Department of Homeland Security

- Science and Technology Directorate
- Office of Health Affairs

- National Biodefense Analysis and Countermeasures Center

Other

- University of Pittsburgh Medical Center for Health Security
- National Interagency Confederation for Biological Research

We conducted this performance audit from August 2013 to May 2014 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Department of Defense (DOD) Funding for Chemical and Biological Defense Program and Medical Countermeasures, in Nominal Dollars

Dollars in thousands

Fiscal year	CBDP funding	Total medical countermeasure funding ^a	Biological medical countermeasure funding	Biological medical countermeasure research and early development funding ^b	Biological medical countermeasure advanced development funding ^c
2001	\$876,151	\$203,938	\$161,646	\$64,780	\$96,866
2002	1,123,209	331,412	277,080	90,895	186,185
2003	1,306,638	270,123	208,097	110,158	97,939
2004	1,223,967	291,384	234,569	116,203	118,366
2005	1,406,094	321,123	218,947	113,866	105,081
2006	1,758,413	442,166	297,617	206,332	91,285
2007	1,548,862	502,460	317,914	221,159	96,755
2008	1,615,510	535,735	341,820	206,651	135,169
2009	1,528,812	499,231	337,225	225,824	111,401
2010	1,573,359	540,183	390,216	247,823	142,393
2011	1,494,492	511,158	407,310	202,622	204,688
2012	1,376,580	662,474	365,533	203,186	162,347
2013	1,288,292	639,128	335,476	149,469	186,007
Total	\$18,120,379	\$5,750,515	\$3,893,450	\$2,158,968	\$1,734,482

Source: GAO analysis of DOD data.

^aTotal medical countermeasure funding includes funding for all forms of medical countermeasure, such as chemical countermeasures, and diagnostics.

^bResearch and early development includes basic research, applied research, and advanced technology development.

^cAdvanced development includes advanced component development and prototypes, system development and demonstration, and procurement.

Appendix III: Comments from the Department of Defense



NUCLEAR, CHEMICAL, AND
BIOLOGICAL DEFENSE PROGRAMS

ASSISTANT SECRETARY OF DEFENSE
3050 DEFENSE PENTAGON
WASHINGTON, DC 20301-3050

MAY -5 2014

Mr. Joseph Kirschbaum
Director, Defense Capabilities and Management
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

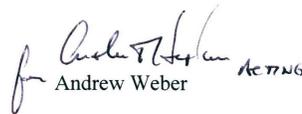
Dear Mr. Kirschbaum:

This is the Department of Defense (DoD) response to the GAO Draft Report, GAO-14-442SU, 'BIOLOGICAL DEFENSE: DoD Has Strengthened Coordination on Medical Countermeasures, but Can Improve Its Process for Threat Prioritization,' dated April 3, 2014 (GAO Code 351859).

The Department appreciates the opportunity to review the draft report and concurs with the recommendation of the GAO. The Department will review the directives addressing biological warfare threats to ensure they align with current capabilities-based planning processes to reflect a holistic threat-informed, risk-based assessment.

If you need additional information, please do not hesitate to call me at 703-697-1771. My point of contact for this effort is Ms. Sharon Doby, Office of the Assistant Secretary of Defense (NCB), 703-695-5486, sharon.doby.civ@mail.mil.

Sincerely,


for Andrew Weber ACTING

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contacts

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Marcia Crosse, (202) 512-7114 or CrosseM@gao.gov

Staff Acknowledgments

In addition to the contact named above, GAO staff who made key contributions to this report include Mark A. Pross, Assistant Director; Karen Doran, Assistant Director; Natalya Barden; Richard Burkard; Mae Jones; Amie Lesser; Carolina Morgan; Randy Neice; Carol Petersen; Terry Richardson; Jennifer Spence; and Elaine Vaurio.

Related GAO Products

National Preparedness: HHS Has Funded Flexible Manufacturing Activities for Medical Countermeasures, but It Is Too Soon to Assess Their Effect. [GAO-14-329](#). Washington, D.C.: March 31, 2014.

National Preparedness: HHS Is Monitoring the Progress of Its Medical Countermeasure Efforts but Has Not Provided Previously Recommended Spending Estimates. [GAO-14-90](#). Washington, D.C.: December 27, 2013.

National Preparedness: Efforts to Address the Medical Needs of Children in a Chemical, Biological, Radiological, or Nuclear Incident. [GAO-13-438](#). Washington, D.C.: April 30, 2013.

High-Containment Laboratories: Assessment of the Nation's Need Is Missing. [GAO-13-466R](#). Washington, D.C.: February 25, 2013.

National Preparedness: Countermeasures for Thermal Burns. [GAO-12-304R](#). Washington, D.C.: February 22, 2012.

National Preparedness: Improvements Needed for Acquiring Medical Countermeasures to Threats from Terrorism and Other Sources. [GAO-12-121](#). Washington, D.C.: October 26, 2011.

Influenza Pandemic: Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning. [GAO-11-632](#). Washington, D.C.: June 27, 2011.

Influenza Vaccine: Federal Investments in Alternative Technologies and Challenges to Development and Licensure. [GAO-11-435](#). Washington, D.C.: June 27, 2011.

National Preparedness: DHS and HHS Can Further Strengthen Coordination for Chemical, Biological, Radiological, and Nuclear Risk Assessments. [GAO-11-606](#). Washington, D.C.: June 21, 2011.

Public Health Preparedness: Developing and Acquiring Medical Countermeasures Against Chemical, Biological, Radiological, and Nuclear Agents. [GAO-11-567T](#). Washington, D.C.: April 13, 2011.

High-Containment Laboratories: National Strategy for Oversight Is Needed. [GAO-09-1045T](#). Washington, D.C.: September 22, 2009.

High-Containment Laboratories: National Strategy for Oversight Is Needed. [GAO-09-1036T](#). Washington, D.C.: September 22, 2009.

High-Containment Laboratories: National Strategy for Oversight Is Needed. [GAO-09-574](#). Washington, D.C.: September 21, 2009.

High-Containment Biosafety Laboratories: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States. [GAO-08-108T](#). Washington, D.C.: October 4, 2007.

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