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NATIONAL PREPAREDNESS

HHS Is Monitoring the
Progress of Its
Medical
Countermeasure
Efforts but Has Not
Provided Previously
Recommended
Spending Estimates

Why GAO Did This Study

Public health emergencies—the 2001 anthrax attacks, the 2009 H1N1 influenza pandemic, and others—have raised concerns about national vulnerability to threats from chemical, biological, radiological, and nuclear agents and new infectious diseases. There are some medical countermeasures—drugs, vaccines, and medical devices such as diagnostics—available to prevent, diagnose, or mitigate the public health impact of these agents and diseases, and development continues. HHS leads federal efforts to develop and procure countermeasures through the interagency PHEMCE. The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 mandated GAO to examine HHS's and PHEMCE's planning documents for medical countermeasure development and procurement needs and priorities.

This report examines the extent to which HHS developed timelines, milestones, and spending estimates for PHEMCE priorities. GAO reviewed relevant laws; analyzed HHS's 2012 PHEMCE Strategy and Implementation Plan, HHS's tools for tracking the implementation of PHEMCE activities, and data on countermeasure spending from fiscal years 2010 through 2013; and interviewed HHS officials.

What GAO Recommends

Although GAO is not making any new recommendations, based on prior work GAO is continuing to emphasize its 2011 recommendation that HHS make more specific anticipated spending information available to countermeasure developers. In its comments, HHS discussed its efforts to develop spending estimates.

View [GAO-14-90](#). For more information, contact Vijay A. D'Souza at (202) 512-7114 or dsouzav@gao.gov.

NATIONAL PREPAREDNESS

HHS Is Monitoring the Progress of Its Medical Countermeasure Efforts but Has Not Provided Previously Recommended Spending Estimates

What GAO Found

The Department of Health and Human Services (HHS) has established timelines and milestones for the 72 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) priorities—33 activities, 25 threat-based approaches, and 14 capabilities—that HHS selected as key to fulfilling PHEMCE strategic goals. However, HHS has not made spending estimates for its medical countermeasure development or procurement priorities (priority countermeasures) publicly available. In the PHEMCE implementation plan, HHS has grouped the 72 PHEMCE priorities into three time frames for completion—near-term (fiscal years 2012 through 2014), midterm (fiscal years 2015 through 2017), and long-term (fiscal year 2018 and beyond). For 21 priority activities, 10 priority threat-based approaches, and 8 priority capabilities, HHS and PHEMCE have identified specific deliverables, each tied to a milestone or set of milestones that delineate the steps necessary to complete deliverables, and established more specific timelines for completion of deliverables and milestones. For example, HHS's Office of the Assistant Secretary for Preparedness and Response (ASPR) is to lead the development of medical countermeasure requirements, which outline countermeasure quantity, type, and desired characteristics. Deliverables are the threat-specific requirements, such as for antidotes for mustard gas and other blister agents. Milestones for mustard gas antidote requirements reflect the PHEMCE activities to develop the requirements and the necessary approvals; the milestones are tied to interim timelines and culminate in approval by the ASPR Assistant Secretary by September 2013. HHS has not established specific deliverables, milestones, or timelines for the remaining 12 priority activities, 15 priority threat-based approaches, and 6 priority capabilities other than their overall completion within the specified near- or midterm time frame. HHS monitors progress in completing deliverables and milestones for the priorities monthly, with PHEMCE partners meeting to discuss potential barriers to completing deliverables or meeting milestones and possible options to mitigate these barriers. As of September 2013 (the most recent information available), HHS reported that PHEMCE partners have completed 10 deliverables for the 72 priorities, resulting in completion of 5 priorities. GAO did not examine the status of the priorities that did not have specific deliverables, timelines, and milestones.

HHS has developed spending estimates for priority countermeasures for internal planning purposes but has not made them publicly available. In 2011, GAO recommended that HHS provide more specific anticipated spending information in an updated plan to assist with long-term planning. HHS's 2012 plan contains information on how countermeasures may be funded, such as through advanced development funds, but does not include estimates of how much PHEMCE may spend to develop specific countermeasures. HHS officials said they are hesitant to provide estimates because they do not want to create the expectation that estimates would reflect final contract amounts. However, consistent with our prior recommendation and Pandemic and All-Hazards Preparedness Reauthorization Act requirements, HHS plans to include spending estimates in the next iteration of the plan, anticipated in September 2014, but has not determined the nature and format of the estimates that would be included. Providing estimates would allow HHS's industry partners to suitably target research and development to fulfill countermeasure priorities, especially in tighter budget climates.

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Abbreviations

ASPR	Office of the Assistant Secretary for Preparedness and Response
BARDA	Biomedical Advanced Research and Development Authority
CBRN	chemical, biological, radiological, and nuclear
CDC	Centers for Disease Control and Prevention
DHS	Department of Homeland Security
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
MTA	material threat assessment
NIH	National Institutes of Health
PAHPRA	Pandemic and All-Hazards Preparedness Reauthorization Act of 2013
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
SNS	Strategic National Stockpile
TRA	terrorism risk assessment

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December 27, 2013

The Honorable Tom Harkin
Chairman
The Honorable Lamar Alexander
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Henry Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

Public health emergencies in the new millennium—the 2001 anthrax attacks, the 2009 H1N1 influenza pandemic, the Middle East respiratory syndrome coronavirus currently circulating in Saudi Arabia and other countries, and others—continue to raise concern about our nation’s vulnerability to threats from chemical, biological, radiological, and nuclear (CBRN) agents and new or reemerging infectious diseases. Rapid diagnosis, treatment, and prevention may minimize the public health effects of a release of a CBRN agent or the spread of a new or reemerging infectious disease. There are some medical countermeasures—drugs, vaccines, and devices to diagnose, treat, prevent, or mitigate potential health effects of exposure—available for these agents and diseases. However, research and development to create usable countermeasures is a lengthy, complex, and expensive process that requires public and private investment. Since 2004, Congress has authorized over \$8 billion for the procurement of medical countermeasures for use against CBRN agents.¹ However, the general lack of a commercial market for medical countermeasures against these agents and diseases may reduce incentives for industry—pharmaceutical and medical device manufacturers—to invest millions of dollars to develop CBRN medical countermeasures instead of other products that may be more lucrative.

¹6 U.S.C. § 321j; 42 U.S.C. § 247d-6b(g)(1).

The Department of Health and Human Services (HHS) is the federal agency primarily responsible for identifying needed medical countermeasures to prevent or mitigate potential health effects from exposure to CBRN agents and new or reemerging infectious diseases and for engaging with industry to develop those countermeasures. In 2006, HHS established the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), a federal interagency body whose partners include certain HHS agencies and offices, the Department of Homeland Security (DHS), the Department of Defense, and other federal agencies. PHEMCE is responsible for providing recommendations to the Secretary of Health and Human Services on medical countermeasure priorities and development and procurement activities. PHEMCE also coordinates the life cycle of medical countermeasure research and development from basic research, through advanced research and development, to procurement for the Strategic National Stockpile (SNS)—the national repository for medications, medical supplies, and equipment for use in a public health emergency—and develops policies, plans, and guidance for the use of countermeasure products.

In October 2011, we reported on HHS's and PHEMCE's efforts to develop and procure priority medical countermeasures and found that some improvements were needed for HHS to effectively oversee these efforts.² For example, we found that HHS lacked an adequate strategy to monitor the implementation of recommendations from its 2010 PHEMCE review. We also found that HHS had not yet updated the first PHEMCE Implementation Plan for procuring CBRN countermeasure priorities, published in 2007, even though HHS had planned to update it biennially. We recommended that the department update the plan, include more specific information about anticipated spending, and strengthen its oversight of how HHS agencies and offices were implementing certain activities intended to enhance PHEMCE. HHS agreed with our overall recommendations but did not provide any comments specifically about its plans to include anticipated spending estimates in any implementation plan updates. We discuss the current status of this recommendation later

²See 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).

in the report. In June 2012, HHS published the PHEMCE Strategy,³ and in December 2012 it published the PHEMCE Implementation Plan,⁴ which serves to update the 2007 implementation plan.

The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) requires GAO to examine HHS's PHEMCE strategy and implementation plan, which lay out PHEMCE's strategic goals and activities for achieving these goals and developing and procuring priority medical countermeasures.⁵ This report addresses the extent to which HHS has developed timelines, milestones, and anticipated spending estimates to achieve PHEMCE priorities laid out in these documents. We provide information on HHS's spending on medical countermeasure development and procurement from fiscal year 2010 through fiscal year 2013 in appendix I.

To determine the extent to which HHS has developed timelines, milestones, and anticipated spending estimates to achieve the PHEMCE priorities, we reviewed relevant laws to determine requirements for HHS to develop the PHEMCE Strategy and Implementation Plan and any required elements to be included in these documents. We obtained and analyzed HHS's most recent PHEMCE planning documents, including its 2012 PHEMCE Strategy and 2012 PHEMCE Implementation Plan, to identify PHEMCE priorities, and we reviewed the 72 items in the implementation plan that HHS selected as key priorities for fulfilling PHEMCE's strategic goals within the next 5 years. We also analyzed these documents and other documents HHS uses to track the implementation of PHEMCE activities to identify any timelines, milestones, and anticipated spending estimates HHS may have established to achieve these priorities. We compared these documents to the Project Management Institute's *The Standard for Program Management*—which calls for development of timelines, milestones, and cost estimates as program management leading practices—to determine whether HHS had appropriate controls in place to oversee the

³Department of Health and Human Services, *2012 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy* (Washington, D.C.: June 2012).

⁴Department of Health and Human Services, *Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Implementation Plan* (Washington, D.C.: December 2012).

⁵42 U.S.C. § 300hh-10(d)(3).

implementation of PHEMCE activities.⁶ We also examined information on the progress PHEMCE participants had made in meeting timelines and milestones to achieve the priorities, based on HHS reporting from its tracking documents through September 2013, the most recent information available at the time of our review. We did not conduct further analysis of the progress that has been made because of the relatively short period from the publication of the implementation plan in December 2012 to the time we completed our review. We interviewed PHEMCE partners from HHS agencies and offices—including the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Biomedical Advanced Research and Development Authority (BARDA), the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA)—to obtain information on HHS timelines, milestones, and spending estimates for PHEMCE priorities; how HHS tracks the progress of PHEMCE partners in implementing the PHEMCE priorities; and progress made to date.

In addition, to provide information on HHS's spending on medical countermeasure development and procurement in appendix I, we obtained and analyzed HHS data on its spending for medical countermeasure advanced research, development, and procurement from fiscal year 2010 through fiscal year 2013.⁷ We chose this period because we previously reported on HHS's medical countermeasure spending from fiscal year 2007 through fiscal year 2010.⁸ We obtained information from HHS and interviewed officials about how they ensure the accuracy of the funding information provided. We did not independently verify the spending information provided by HHS, but we determined, through interviews and reviews of supporting information, that the data we received from HHS were sufficiently reliable for our purposes.

We conducted this performance audit from May 2013 through December 2013 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to

⁶See Project Management Institute, *The Standard for Program Management*, 3rd ed. (Newton Square, Pa.: 2013).

⁷For the purposes of this report, we use spending to mean obligations. Generally, an obligation is a definite commitment that creates a legal liability of the government for the payment of goods and services ordered and received.

⁸See [GAO-12-121](#).

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.

Background

Since 2004, Congress has authorized over \$8 billion for medical countermeasure procurement. The Project BioShield Act of 2004 authorized the appropriation of \$5.6 billion from fiscal year 2004 through fiscal year 2013 for the Project BioShield Special Reserve Fund,⁹ and funds totaling this amount were appropriated.¹⁰ The act facilitated the creation of a government countermeasure market by authorizing the government to commit to making the Special Reserve Fund available to purchase certain medical countermeasures,¹¹ including those countermeasures that may not be FDA-approved, cleared, or licensed.¹² In 2013, PAHPRA authorized an additional \$2.8 billion to be available from fiscal year 2014 through fiscal year 2018 for these activities,¹³ but funding has not yet been appropriated for these years. In addition to the

⁹6 U.S.C. § 321j.

¹⁰The Department of Homeland Security appropriations act for fiscal year 2004 appropriated this amount. Pub. L. No. 108-90, 117 Stat. 1137, 1148 (2003).

¹¹6 U.S.C. § 321j; 42 U.S.C. §§ 247d-6b(c). The Project BioShield Act also authorizes the federal government to use specific contracting authorities to procure certain medical countermeasures for CBRN agents. 42 U.S.C. § 247d-6b(c)(7). The act allowed for the use of the Special Reserve Fund only for medical countermeasure procurement; however, since 2006, various appropriations acts have transferred \$2.1 billion from the Special Reserve Fund, \$1.9 billion of which was transferred for advanced research and development.

¹²Under federal law and FDA regulations, vaccines and other biologics are “licensed,” drugs are “approved,” and devices may either be “approved” or “cleared.” See 42 U.S.C. § 262, 21 U.S.C. § 355, 21 U.S.C. §§ 360e, 360(k). The Special Reserve Fund may be used to acquire medical countermeasures that are reasonably expected to qualify for FDA approval, clearance, or licensure within a certain number of years. The Project BioShield Act initially stipulated expected FDA approval, clearance, or licensure within 8 years, and PAHPRA subsequently extended this period to 10 years. 42 U.S.C. § 247d-6b(c)(1)(B)(i)(III)(bb). The Secretary of Health and Human Services may also authorize, under specified conditions, the temporary emergency use of products that have not yet received FDA approval, clearance, or licensure. 21 U.S.C. § 360bbb-3.

¹³42 U.S.C. § 247d-6b(g). PAHPRA provides that amounts appropriated pursuant to this section are authorized to remain available until September 30, 2019. PAHPRA also stipulates that HHS may use not more than 50 percent of the amounts authorized for the Special Reserve Fund for medical countermeasure advanced research and development.

Special Reserve Fund, Congress has also made funding available through annual and supplemental appropriations to respond to influenza pandemics, including developing vaccines and other drugs.¹⁴

Federal Roles and Responsibilities Related to Medical Countermeasures

HHS is the primary federal department responsible for public health emergency planning and response, including medical countermeasure development, procurement, and distribution. HHS also coordinates with other federal departments, such as DHS, through PHEMCE.

Within HHS, several offices and agencies have specific responsibilities for public health preparedness and response.

- HHS's ASPR leads PHEMCE and the federal medical and public health response to public health emergencies, including strategic planning, medical countermeasure prioritization, and support for developing, procuring, and planning for the effective use of medical countermeasures.
- Within ASPR, BARDA—established by the Pandemic and All-Hazards Preparedness Act of 2006¹⁵—oversees and supports advanced development and procurement of some medical countermeasures into the SNS.¹⁶
- NIH conducts and funds basic and applied research and early development needed to develop new or enhanced medical countermeasures and related medical tools for CBRN and infectious disease threats.¹⁷

¹⁴See, for example, Pub. L. No. 111-32, 123 Stat. 1859, 1884-86 (2009).

¹⁵42 U.S.C. § 247d-7e(c). The act also gave BARDA the authority to make advance and milestone-based payments to vendors prior to product delivery to the SNS. 42 U.S.C. § 247d-7e(c)(5)(C), (D).

¹⁶In 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 development and procurement. BARDA also determines whether manufacturing, scale-up production, and licensing of countermeasures can be achieved in a timely and reliable manner.

¹⁷Basic, or early, research seeks to better understand CBRN agents and the response of the host organism to the agents through the study of the cellular and molecular biology of agents and hosts, their physiologic processes, and their genome sequences and structures. Applied, or translational, research builds on basic research by validating and testing concepts in practical settings to identify potential products.

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- CDC maintains the SNS, including purchasing commercially available products as necessary, and supports state and local public health departments' efforts to detect and respond to public health emergencies, including providing guidance and recommendations for the mass dispensing and use of medical countermeasures from the SNS.
 - FDA assesses the safety and effectiveness of medical countermeasures; regulates their development; approves, clears, or licenses them; and conducts postmarket surveillance as part of its overall role to assess the safety and effectiveness of medical products. FDA also provides technical assistance to help ensure that product development meets FDA's regulatory requirements and provides technical support for the development of regulatory science tools. FDA may authorize the emergency use of medical products that have not yet been approved, cleared, or licensed or were approved, cleared, or licensed only for other uses.

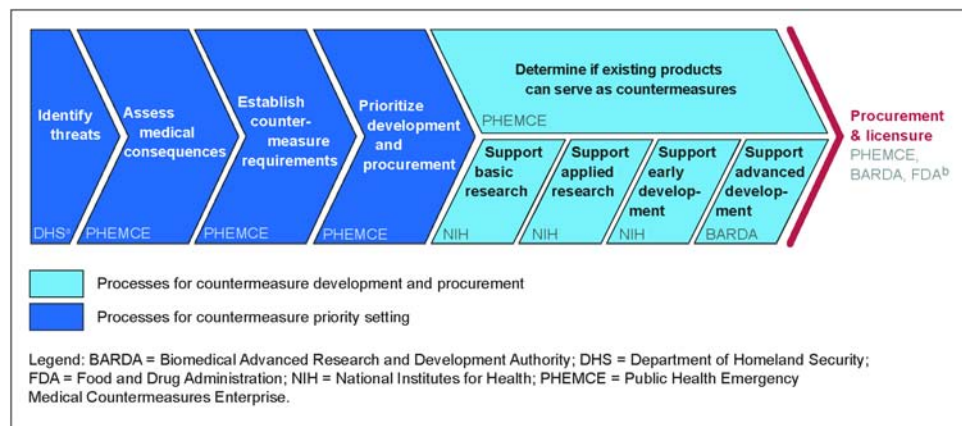
DHS develops material threat assessments (MTA), in coordination with HHS, to assess the threat posed by given CBRN agents or classes of agents and the potential number of human exposures in plausible, high-consequence scenarios. DHS uses the MTAs to determine which CBRN agents pose a material threat sufficient to affect national security and to provide HHS with a basis for determining needed countermeasures for those agents. DHS also develops terrorism risk assessments (TRA) to assess the relative risks posed by CBRN agents based on variable threats, vulnerabilities, and consequences.¹⁸

HHS's PHEMCE is responsible for establishing civilian medical countermeasure priorities for CBRN and emerging infectious disease threats, including influenza; coordinating federal efforts to research, develop, and procure medical countermeasures to enhance preparedness and response for public health threats; and developing policies, plans, and guidance for the use of countermeasure products in a public health emergency. PHEMCE is composed of officials from ASPR,

¹⁸For more information on DHS's MTAs and TRAs, see GAO, *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 *Chemical, Biological, Radiological, and Nuclear Risk Assessments: DHS Should Establish More Specific Guidance for Their Use*, [GAO-12-272](#) (Washington, D.C.: Jan. 25, 2012).

including BARDA; CDC; FDA; NIH; and other federal departments, including the Departments of Agriculture, Defense, Homeland Security, and Veterans Affairs. HHS and PHEMCE establish federal medical countermeasure development and procurement priorities through a multistep process. This process includes assessing the threat posed by CBRN agents and the potential consequences they pose to public health, determining medical countermeasure requirements—the type of countermeasure (vaccines, drugs, or medical devices such as diagnostics), the amount needed, and characteristics of the countermeasures (such as formulations, dosing, and packaging)—for these agents, evaluating public health response capability, and developing and procuring countermeasures against these CBRN agents. (See fig. 1.)

Figure 1: Processes for Medical Countermeasure Development and Procurement



Source: GAO analysis of Department of Health and Human Services (HHS) information.

^aDHS collaborates with the Department of Health and Human Services (HHS) and other federal partners to identify threats.

^bIn addition to approving, clearing, or licensing medical countermeasures, FDA works with researchers throughout the development stages to review safety and effectiveness test results and provide technical assistance to help ensure that product development meets FDA’s regulatory requirements.

PHEMCE Strategy, Implementation Plan, and Priorities

The 2012 PHEMCE Strategy lays out the four PHEMCE strategic goals and their underlying objectives for building HHS’s countermeasure capabilities to respond to a public health emergency. The 2012 PHEMCE Implementation Plan updates the 2007 implementation plan and describes the activities that HHS and its interagency partners plan to conduct to achieve the four strategic goals and their associated objectives, the medical countermeasures HHS wants to develop and

procure, and the capabilities HHS wants to build to support countermeasure development and procurement. The plan also includes 72 items that HHS selected as key priorities for fulfilling PHEMCE's strategic goals within the next 5 years, which the agency placed into three categories. For the purposes of this report we refer to the items in these categories as "priority activities," "priority threat-based approaches," and "priority capabilities."

- The 33 priority activities reflect activities that support PHEMCE's overall mission and include pursuits such as developing systems to track countermeasure activities across all PHEMCE partners, enhancing national laboratory capabilities, and developing guidance documents and information for the public on using medical countermeasures in an emergency. (See table 1 for examples of PHEMCE priority activities by strategic goal.)

Table 1: Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategic Goals and Examples of Priority Activities

Strategic goal	Example of priority activity
1. Identify, create, develop, manufacture, and procure critical medical countermeasures	<p>Implement tools that track progress of medical countermeasure development and procurement contracts across all PHEMCE partners to further enable coordinated planning and management</p> <p>Formalize roles, responsibilities, policies, and procedures for conducting the next generation of material threat assessments and terrorism risk assessments</p> <p>Establish a network of clinical research organizations to assist the Biomedical Advanced Research and Development Authority in conducting phase I through IV clinical trials of investigational medical countermeasures^a</p>
2. Establish and communicate clear regulatory pathways to facilitate medical countermeasure development and use	<p>Establish a multidisciplinary action team to provide regulatory support for the development of multiplex diagnostic devices^b</p> <p>Establish a multidisciplinary action team to facilitate the development and regulatory review of radiation biodosimetry devices and provide regulatory support for the performance of these devices^c</p> <p>Establish a program to link FDA scientists with external partners to pursue cutting-edge regulatory science projects</p>
3. Develop logistics and operational plans for optimized use of medical countermeasures at all levels of response	<p>Establish a process to validate laboratory methods and enhance national capacity to rapidly test clinical specimens and determine who has been exposed to biological agents</p> <p>Develop decision-making and planning guidance for medical countermeasure dispensing models to meet the diverse needs of communities</p> <p>Develop a comprehensive action plan for monitoring the safety and clinical benefit of medical countermeasures during public health emergencies</p>
4. Address medical countermeasure gaps for all sectors of the U.S. civilian population	<p>Provide clinicians with dosing and use guidance for administering stockpiled medical countermeasures to pediatric populations in public health emergencies</p> <p>Ensure that public health and medical information distributed during public health emergencies is delivered in a manner that takes into account the range of communication and other needs of the intended audience, including at-risk individuals^d</p> <p>Integrate operational requirements, considerations, resource, and action items for pediatric and other at-risk populations into HHS emergency response playbooks^e</p>

Source: GAO analysis of Department of Health and Human Services (HHS) information.

^aManufacturers conduct clinical trials in human volunteers in five phases (0 through IV) to determine whether candidate countermeasures are effective and safe.

^bMultiplex diagnostic devices are those that allow for the testing of multiple agents using the same technology.

^cBiodosimetry devices and bioassays are tools that determine the level of radiation in the body and the type of radiological isotope to which an individual has been exposed.

^dHHS recognizes at-risk individuals to include children, senior citizens, and pregnant women, in addition to those individuals who have additional communication, medical care, and other needs or who may need additional assistance in a public health emergency as a result of disability, transportation needs, limited or no English proficiency, or other reasons.

^eHHS Office of the Assistant Secretary for Preparedness and Response playbooks are intended to provide strategic guidance for HHS's medical and public health response under the National Response Framework. The playbooks outline key options and recommended actions to support the HHS Secretary in directing and coordinating HHS's response to disasters and public health emergencies.

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- In addition to the 33 priority activities, the 25 items identified as priorities for threat-based approaches are intended to directly address threats such as anthrax or smallpox. These priorities include pursuits such as publishing updated clinical guidance for anthrax countermeasures; developing and qualifying with FDA animal models to test the safety and efficacy of medical countermeasures for certain biological, radiological, and nuclear threats;¹⁹ and developing new plans for the distribution and dispensing of pandemic influenza antivirals.
 - The remaining 14 items identified as priority capabilities reflect what HHS refers to as crosscutting capabilities. The priority capabilities are a mix of programs or technological applications that may, for example, support the development of countermeasures for a range of existing CBRN threats or for any new threats that may emerge in the future, or build infrastructure to provide countermeasure developers assistance with advanced development and manufacturing services. The priority capabilities include such pursuits as initiating a research program to fill gaps in knowledge in the area of patient decontamination in a chemical incident and establishing a network of facilities to support the filling and finishing of vaccines and other countermeasures.²⁰

In addition to the 72 items HHS selected as key priorities for fulfilling PHEMCE's strategic goals, the implementation plan also identifies the medical countermeasures that constitute HHS's priorities for development and procurement to fulfill strategic goal 1, which we refer to as "priority countermeasures" for the purposes of this report. (See table 2.) Many of

¹⁹Under the Animal Rule, in selected circumstances, FDA may grant marketing approval of CBRN countermeasures based on adequate and well-controlled animal studies, using animal models, when it is neither ethical nor feasible to conduct human efficacy studies, provided that the results of those studies establish that the drug or biological product is reasonably likely to produce clinical benefit in humans. 21 C.F.R. §§ 314.600-.650, 601.90-.95. FDA developed a process to qualify animal models and encourages countermeasure developers to qualify these models when the model has the potential to be used for licensure or approval of multiple medical countermeasures. FDA's animal model qualification process uses analytically valid measurements of the model, which can be relied upon to have a specific use in drug development. FDA makes information on qualified animal models public; countermeasure developers may then use the qualified animal model within its defined purpose without requiring FDA to reconfirm the model's utility, which may help expedite the approval of new drug applications.

²⁰The filling and finishing of countermeasures refers to the process by which individual drugs are packaged for use, such as in vials and syringes, and includes labeling, patient instructions, outside packaging, transport, and promotional materials.

the threat-specific countermeasures for which PHEMCE set procurement priorities in 2007 continue to be priorities for development and procurement in the 2012 plan, such as anthrax vaccine, smallpox antivirals, chemical agent antidotes, and diagnostic devices for radiological and nuclear agents.²¹ The 2012 plan also includes pandemic influenza countermeasures and nonpharmaceutical countermeasures, such as ventilators, as priorities, whereas the 2007 plan focused on CBRN medical countermeasures only.

²¹In addition to the priority countermeasures, the 2012 plan also identifies other medical countermeasure development activities, including improving the delivery systems of countermeasures already in the SNS, evaluating existing commercial drugs for use in public health emergencies, and seeking FDA approval or clearance for certain countermeasures in the SNS.

Table 2: Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Medical Countermeasure Advanced Development and Procurement Priorities (Priority Countermeasures)

Medical countermeasure	Advanced development priority ^a	Procurement priority ^b
Anthrax antitoxin	X	X
Anthrax vaccine	X	X
Botulism antitoxin	X	
Broad spectrum antimicrobials ^c	X	X
Chemical decontamination products	X	
Cyanide antidote	X	X
Diagnostics for biological agents	X	
Nerve agent antidote	X	X
Nuclear agents, gastrointestinal, skin, and lung therapeutics	X	X
Nuclear agents, hematopoietic therapeutics	X	X
Nuclear agents, thermal burn therapeutics	X	X
Pandemic influenza antivirals	X	X
Pandemic influenza diagnostics	X	
Pandemic and prepandemic influenza vaccine	X	
Radiological agents, decorporation and blocking agents	X	X
Radiological and nuclear bioassay/biodosimetry ^d (diagnostics)	X	X
Respiratory protective devices ^e	X	X
Smallpox antivirals	X	X
Smallpox vaccine	X	X
Ventilators	X	X
Viral hemorrhagic fever antivirals	X	
Volatile nerve agent diagnostics	X	

Source: Department of Health and Human Services (HHS).

^aHHS's and PHEMCE's medical countermeasure advanced development priorities include new products currently in development and enhancements to current products in the Strategic National Stockpile.

^bFor the purposes of this report, we consider HHS's and PHEMCE's medical countermeasure procurement priorities to include those countermeasures that HHS plans to purchase for the SNS through fiscal year 2017, dependent upon the availability of funds.

^cBroad spectrum antimicrobials include those for anthrax, plague, tularemia, typhus, and secondary infections from pandemic influenza and exposure to radiological and nuclear agents.

^dBiodosimetry devices and bioassays are tools that determine the level of radiation in the body and the type of radiological isotope to which an individual has been exposed.

^eRespiratory protective devices include items such as N95 respirators, which are designed to prevent the wearer from breathing in at least 95 percent of airborne particles, and surgical masks.

HHS Has Established Timelines and Milestones for Key PHEMCE Priorities but Has Not Yet Provided Previously Recommended Anticipated Spending Estimates for Priority Countermeasures

HHS has established timelines and milestones for the 72 priority activities, threat-based approaches, and capabilities identified in the 2012 PHEMCE Implementation Plan as key to fulfilling PHEMCE's strategic goals. However, while HHS has developed spending estimates for its priority medical countermeasures for internal planning purposes, it has not made these estimates publicly available, as we previously recommended in 2011.

HHS Has Established Timelines and Milestones for Key PHEMCE Priorities

HHS has established timelines and milestones for the 72 items it selected as key priorities for fulfilling PHEMCE's strategic goals. Leading practices for program management call for establishing time frames and milestones as part of a plan to ensure that organizations achieve intended results.²² In the implementation plan, HHS has assigned each of the 33 priority activities, the 25 priority threat-based approaches, and the 14 priority capabilities to one of three time frames for completion—near-term (fiscal years 2012 through 2014), midterm (fiscal years 2015 through 2017), and long-term (fiscal year 2018 and beyond). In addition, HHS has placed PHEMCE's priority countermeasures into these time frames. All but 2 of the 33 priority activities, and all of the priority threat-based approaches and capabilities, are slated for completion in either the near term or the midterm.

HHS has also identified deliverables and milestones for some of the priority activities, threat-based approaches, and capabilities, and assigned them more specific timelines. For 21 of the 33 priority activities, 10 of the 25 priority threat-based approaches, and 8 of the 14 priority capabilities, HHS and the PHEMCE agency or office responsible for carrying out the activity have identified specific deliverables intended to complete them. PHEMCE partners have tied each deliverable to a specific milestone or set of milestones, which delineate the steps

²²The Project Management Institute, *The Standard for Program Management*, 3rd ed.

necessary to complete the deliverable. In addition, the deliverables and milestones may have more specific timelines, such as an actual month or year of expected completion within the broader multiyear near- or midterm time frame. Examples of deliverables, milestones, and more specific timelines for PHEMCE priorities include the following:

- For the priority activity that states that ASPR is to lead PHEMCE in developing or updating medical countermeasure requirements for certain CBRN threats by the end of fiscal year 2014, ASPR has identified the requirements for each specific threat—such as requirements for countermeasures for mustard gas and other blister agents—as the individual deliverables for this activity. The blister agents requirement deliverable has four associated milestones that reflect the various activities of a PHEMCE working group to develop the requirements and the levels of PHEMCE and HHS approval needed, culminating in the approval by the ASPR Assistant Secretary by September 2013.
- For the priority threat-based approach of qualifying animal models for biological threats, the deliverable is FDA qualification of the animal model, and the three milestones are the development of animal models for anthrax, plague, and tularemia in fiscal year 2015.²³
- For the priority capability of initiating funding for the development of diagnostic systems for biological and chemical threat agents, and systems to identify and characterize unknown threats, the deliverable is NIH's awarding of funds to eligible applicants; the set of milestones for this deliverable are obtaining NIH approval to publish a solicitation for proposals for development of the diagnostics, publishing the solicitation in July 2013, and making awards in fiscal year 2014. NIH also plans to award additional funds in fiscal year 2015 for the development of multiplex diagnostic platforms for multiple threats.²⁴

²³In commenting on a copy of our report, FDA officials stated that in contrast to the targeted fiscal year 2015 completion date for these milestones, as indicated in HHS tracking information, they expect the completion date for the milestones for this priority to occur sometime in the midterm (fiscal year 2015 through fiscal year 2017). In addition, although the PHEMCE Implementation Plan and HHS's tracking information for these priorities states that the animal models will be for anthrax, plague, and tularemia, FDA officials stated that, while these were the most likely threats for the models, they were not definite.

²⁴Multiplex diagnostic platforms are those that allow for the testing of multiple agents using the same technology.

-
- For the priority countermeasures, HHS officials told us that the department includes specific milestones in the contracts it awards to developers; these milestones reflect the expected course for research and development, such as holding and completing clinical trials to test the efficacy of a countermeasure or submitting inventory and storage plans, and have associated completion dates.

For the remaining 12 priority activities, 15 priority threat-based approaches, and 6 priority capabilities, HHS has not established specific deliverables with milestones and timelines other than the overall completion of the priority within the specified near- or midterm time frame. HHS officials told us that some activities do not have specific timelines because HHS considers them to be ongoing activities that PHEMCE conducts regularly. For example, at least every 18 months, ASPR conducts formal reviews across participating PHEMCE agencies of medical countermeasure portfolios for specific threats in order to monitor progress in developing and procuring medical countermeasures for those threats, identify remaining gaps and challenges to developing and procuring countermeasures, and develop potential solutions. For activities in the implementation plan that are slated for completion in the long term, HHS officials said that they intend to develop more specific timelines as the near- and midterm activities are completed.

ASPR tracks the progress of participating PHEMCE partners in implementing the priority activities, threat-based approaches, and capabilities by holding monthly meetings²⁵ to collect information on progress.²⁶ According to HHS officials, during these monthly meetings, PHEMCE participants discuss their progress in completing deliverables, potential barriers to completion, and any options to help mitigate these barriers.²⁷ ASPR officials told us they rely on the PHEMCE partner

²⁵ASPR holds separate monthly meetings for the CBRN-related initiatives and the pandemic-influenza-related initiatives.

²⁶ASPR also tracks the progress of PHEMCE partners in carrying out other initiatives identified in the 2012 PHEMCE implementation plan; we did not examine those initiatives for this report because HHS did not identify them in the implementation plan as key to fulfilling PHEMCE's strategic goals in the near and midterm.

²⁷HHS officials told us that for some priorities that are ongoing, such as development or procurement of specific priority countermeasures, ASPR may collect updates less frequently. For example, for priority countermeasures, ASPR does not track operational activities such as the manufacturing of a specific countermeasure on a monthly basis but does ask for periodic updates.

responsible for the activity to have adequate project management controls in place to determine the amount of progress that the partner agency has made. If an agency anticipates delays in or barriers to completing and meeting certain milestones, ASPR officials may assist in identifying additional support within PHEMCE partner agencies or within other federal agencies. For example, HHS officials told us that for one priority activity's deliverable—developing requirements for anthrax antitoxins—CDC and FDA officials differed in their professional opinions on guidance for clinicians to administer the drug. PHEMCE senior management worked with the agencies to develop consensus wording for the guidance document to complete that deliverable. ASPR officials told us that they enter information collected in the meetings into a spreadsheet that contains descriptions of the PHEMCE priority activities, threat-based approaches, and capabilities; their associated deliverables, milestones, and timelines; and information on current progress, barriers to completion, and mitigation options.²⁸ ASPR follows up with PHEMCE partners after the meetings to obtain any additional information, if necessary. ASPR distributes the finalized spreadsheet to PHEMCE partners about 1 week in advance of the next monthly meeting for them to use as reference for that meeting. ASPR officials told us they developed the tracking spreadsheet in response to the recommendation in our 2011 report that HHS develop a written strategy to monitor the implementation of recommendations from HHS's 2010 PHEMCE review and incorporated the PHEMCE priorities into the spreadsheet when HHS updated the implementation plan.²⁹

²⁸We identified the deliverables, timelines, and milestones for the 21 priority activities, 10 priority threat-based approaches, and 8 priority capabilities from the tracking tool HHS uses to assess the implementation of PHEMCE initiatives. For the remaining 12 priority activities, 15 threat-based approaches, and 8 capabilities, HHS is indirectly tracking the progress of some of them by linking them to other activities, threat-based approaches, and capabilities it is tracking so that their progress may be reflected in another priority. We did not examine the status of the priorities that HHS is not actively tracking.

²⁹[GAO-12-121](#).

At the completion of our review, PHEMCE was halfway through its near-term period of fiscal year 2012 through fiscal year 2014. As of September 2013 (the most recent information available):³⁰

- PHEMCE partners reported completing five deliverables for the 21 priority activities. For example, for the priority activity that specifies that HHS, DHS, and other federal partners are to formalize roles, responsibilities, policies, and procedures for conducting the next generation of MTAs and TRAs, HHS and DHS completed one of two deliverables by developing and cosigning a strategic implementation plan to conduct MTAs.³¹
- PHEMCE partners reported completing three deliverables for the 10 priority threat-based approaches. For example, for one of the threat-based approaches, PHEMCE partners report completing the sole deliverable of developing guidance that establishes the order in which different groups of affected individuals would receive anthrax vaccination in a public health emergency. The completion of the three deliverables resulted in the completion of three priority threat-based approaches.³²
- PHEMCE partners reported completing two deliverables for the eight priority capabilities. For example, for one of the priority capabilities, PHEMCE partners have reported completing the sole deliverable that specifies that BARDA will initiate a research program to address knowledge gaps in chemical decontamination of exposed individuals by awarding a contract to a university to gather data and develop decontamination procedures. The completion of the two deliverables resulted in the completion of two priority capabilities.³³

³⁰In addition to completing deliverables for certain PHEMCE priorities, PHEMCE partners also report partial progress for other deliverables for the priority activities, approaches, and capabilities. For example, 3 of the 10 priority threat-based approaches with a sole deliverable were 50 percent or more complete.

³¹Of the 21 priority activities with deliverables and milestones, 13 had a single deliverable and the remaining 8 had multiple deliverables.

³²All 10 priority threat-based approaches had a single deliverable.

³³Seven of the priority capabilities had a single deliverable, and one had multiple deliverables.

HHS Has Not Provided Previously Recommended Spending Estimates for Priority Countermeasures

HHS has not provided publicly available spending estimates for research, development, or procurement for the countermeasures it identified as priorities in the 2012 implementation plan. We previously recommended that HHS provide more specific information on anticipated countermeasure spending when it updated its 2007 plan. Additionally, PAHPRA directs HHS to include anticipated funding allocations for each countermeasure priority in the PHEMCE strategy and implementation plan.³⁴ The implementation plan contains information on the source of the funds for research, development, and procurement, such as the Special Reserve Fund. However, the plan does not include any estimates of how much of these funds HHS may spend to develop or procure specific priority countermeasures. HHS officials told us that while PHEMCE has developed spending estimates for internal planning, they are hesitant to provide these estimates to manufacturers because they do not want to create the expectation that the estimates would reflect any final contract amounts. In addition, anticipated spending estimates for future years may be unreliable because, according to HHS officials, the Special Reserve Fund will be appropriated annually after fiscal year 2014, as opposed to the fiscal year 2004 appropriation, which appropriated funds for a 10-year period.³⁵ Additionally, officials stated that because HHS published the PHEMCE Implementation Plan prior to the passage of PAHPRA, the department did not include any spending estimates in the plan because it was unaware that PAHPRA would include that requirement. HHS officials said that they plan to include estimates in the next iteration of the plan, which they anticipate publishing in September 2014, based on the time frames laid out in PAHPRA. However, the nature and format of the spending estimates that would be included in the plan had not been determined. As we stated in our previous recommendation, information on anticipated spending would allow HHS's industry partners to suitably target research and development to fulfill PHEMCE's countermeasure priorities, especially in tighter budget climates.³⁶ While HHS officials expressed concerns regarding sharing internal spending estimates and the short-term nature of annual appropriations, these concerns could be addressed by agency communications with manufacturers when providing the spending estimates to make clear that spending estimates

³⁴42 U.S.C. § 300hh-10(d)(2)(D)(ii).

³⁵Pub. L. No. 108-90, 117 Stat. 1137, 1148 (2003).

³⁶[GAO-12-121](#).

may not reflect final contract amounts, which depend on enacted appropriations levels, among other factors.

Concluding Observations

Developing and procuring medical countermeasures is a complex process that requires engagement across the federal government and with countermeasure developers in private industry. HHS has strengthened PHEMCE planning and oversight and has made progress in developing and procuring some medical countermeasures. However, given its almost 10-year efforts and the continuing lack of available countermeasures to fulfill PHEMCE's many priorities, HHS would benefit from sharing information on its anticipated spending estimates with industry, to assist countermeasure developers with long-term business planning. PAHPRA's requirement for HHS to include spending estimates for each medical countermeasure priority in future PHEMCE implementation plans is consistent with our 2011 recommendation. HHS's plans to include more specific spending estimates in future plan updates could help implement both this requirement and our 2011 recommendation, provided the department makes meaningful estimates of spending for countermeasure research, development, and procurement available to industry. These estimates—or ranges of estimates—will provide HHS's industry partners with more transparency on anticipated returns on investment in the face of competing priorities for developing other drugs with a commercial market. We believe the value of making this information available outweighs HHS's concerns, especially those related to uncertainty over future appropriations; anticipated countermeasure spending would provide industry with the information it needs to determine whether and how to suitably target their research and development programs in tight budget climates.

Agency Comments

We provided a draft of this report to HHS, and its comments are reprinted in appendix II. In its comments, HHS acknowledged the effort we have taken to document HHS's tracking processes for the activities in the 2012 PHEMCE Implementation Plan. HHS commented that the 72 activities we focused on in this review—which were described in the implementation plan as key to HHS's efforts in the near and midterm—were a subset of 255 near- and midterm activities delineated in the implementation plan and that these 72 items were meant to be an illustrative but not comprehensive list of priorities. Further, HHS stated that it considered all 255 near- and midterm activities as priorities. HHS provided information on its efforts to track its progress on the remainder of these items that we did not discuss in the report and to establish deliverables and interim

milestones for the activities slated for the midterm (fiscal years 2015 through 2017) as that period approaches. Finally, HHS provided information on its efforts to quantify its resource needs and provide more transparent anticipated spending information for its medical countermeasure development efforts while maintaining the integrity of the federal contracting process. HHS stated that it is working to find a compromise solution that will provide this transparency in light of statutory requirements and GAO's 2011 recommendation. HHS also provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the Secretary of Health and Human Services. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or dsouzav@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 III.



Vijay A. D'Souza
Acting Director, Health Care

Appendix I: HHS Spending on Advanced Research, Development, and Procurement of Medical Countermeasures

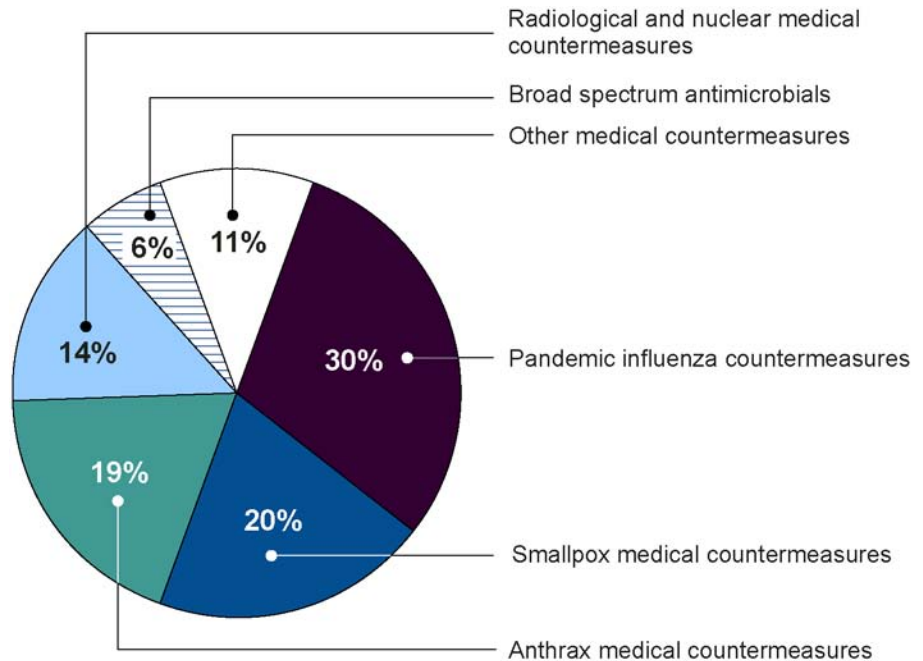
The Department of Health and Human Services (HHS) spent approximately \$3.6 billion¹ in advanced research, development, and procurement of chemical, biological, radiological, and nuclear (CBRN) and pandemic influenza medical countermeasures from fiscal year 2010 through fiscal year 2013.² Of this amount, HHS spent 30 percent for countermeasures against influenza, 20 percent for smallpox countermeasures, and 19 percent for anthrax countermeasures. (See fig. 2.) The spending on influenza countermeasures reflects, in part, HHS's response to the 2009 H1N1 influenza pandemic using annual and supplemental funds appropriated for that response.³

¹For purposes of this report, we use spent to mean obligated. Generally, an obligation is a definite commitment that creates a legal liability of the government for the payment of goods and services ordered and received.

²In 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 development and procurement.

³The Supplemental Appropriations Act, 2009, provided nearly \$1.9 billion in supplemental appropriations to respond to the H1N1 pandemic and an additional \$5.8 billion that were available for obligation only in the amounts designated by the President in a notice to Congress as emergency funds to address critical needs related to emerging influenza viruses. Pub. L. No. 111-32, 123 Stat. 1859, 1884-85.

Figure 2: Percentage of Advanced Research, Development, and Procurement Spending by Medical Countermeasure Type, Fiscal Year 2010 through Fiscal Year 2013



Source: GAO analysis of the Biomedical Advanced Research and Development Authority (BARDA) data.

Note: HHS spent a total of \$3.6 billion in medical countermeasure research, development, and procurement. For the purposes of this report, we use spent to mean obligated.

Of HHS’s total medical countermeasure spending of \$3.6 billion, from fiscal year 2010 through fiscal year 2013, HHS spent almost \$2.1 billion on contracts dedicated to advanced research and development, of which HHS’s Biomedical Advanced Research and Development Authority (BARDA) spent nearly \$700 million (almost 34 percent) for influenza antivirals, diagnostics, and vaccines. (See table 3.) Of the remaining \$1.5 billion, HHS spent nearly \$403 million on contracts dedicated to the procurement of pandemic influenza antivirals and vaccines. (See table 4.) BARDA also spent almost \$1.2 billion on contracts dedicated to both advanced research and development and procurement of CBRN medical countermeasures. (See table 5.) In addition to the contracts that have already been awarded, HHS issues annual announcements for additional funding opportunities in the areas of advanced research and development of CBRN medical countermeasures; advanced development of medical countermeasures for pandemic influenza; and innovative science and technology platforms for medical countermeasure development. The

Appendix I: HHS Spending on Advanced Research, Development, and Procurement of Medical Countermeasures

announcements state anticipated funding for the overall program. For example, the announcement for CBRN countermeasure advanced research and development states that anticipated funding for the overall effort—not per award—ranges from an estimated \$2 million to an estimated \$415 million, subject to congressional appropriations, and does not reflect a contractual obligation for funding.

Table 3: Biomedical Advanced Research and Development Authority Spending on Contracts Dedicated to Chemical, Biological, Radiological, and Nuclear and Pandemic Influenza Medical Countermeasure Advanced Research and Development, Fiscal Year 2010 through Fiscal Year 2013

Medical countermeasure	Fiscal year 2010 spending	Fiscal year 2011 spending	Fiscal year 2012 spending	Fiscal year 2013 spending	Total
Animal model development	\$0	\$4,553,869	\$36,976,777	\$25,110,914	\$66,641,560
Anthrax therapeutics	43,378,000	27,395,213	65,010,124	25,930,925	\$161,714,262
Anthrax Vaccines	115,752,134	17,792,675	72,653,968	24,646,955	\$230,845,732
Biodosimetry and biodiagnostics medical countermeasures	1,934,605	43,311,987	59,995,715	30,179,501	\$135,421,808
Botulism	0	61,455,464	0	0	\$61,455,464
Broad spectrum antimicrobials	27,559,110	39,478,000	(7,898,701) ^a	152,131,767	\$ 211,270,175
Chemical medical countermeasures	2,100,000	15,603,816	5,975,494	5,678,348	\$29,357,658
Influenza antivirals	0	295,109,349	28,379,502	44,092,454	\$367,581,305
Influenza diagnostics	3,452,940	15,070,000	3,061,000	6,174,090	\$27,758,030
Influenza vaccines	1,015	269,833,512	3,045	31,959,217	\$301,796,789
Innovation	40,921,483	12,099,068	2,503,538	6,820,532	\$62,344,621
Radiological and nuclear medical countermeasures	42,617,799	89,044,223	81,053,199	95,731,031	\$308,446,252
Smallpox medical countermeasures	11,297,562	75,622,527	10,008,737	7,285,322	\$104,214,148
Ventilators	2,600,000	0	0	0	\$2,600,000
Total	\$291,614,648	\$966,369,703	\$357,722,398	\$455,741,055	\$2,071,447,804

Source: GAO analysis of Department of Health and Human Services (HHS) data.

Note: Totals may not add due to rounding.

^aIn fiscal year 2012, HHS terminated a contract, which resulted in the deobligation of funds that had been obligated in the prior fiscal year.

Appendix I: HHS Spending on Advanced Research, Development, and Procurement of Medical Countermeasures

Table 4: Biomedical Advanced Research and Development Authority Spending on Contracts Dedicated to Pandemic Influenza Medical Countermeasure Procurement, Fiscal Year 2010 through Fiscal Year 2013

Medical countermeasure	Fiscal year 2010 spending	Fiscal year 2011 spending	Fiscal year 2012 spending	Fiscal year 2013 spending	Total
Influenza antivirals	\$27,591,014	\$0	\$0	\$0	\$27,591,014
Influenza vaccines	134,249,059	18,875,394	55,389,975	166,445,837	\$374,960,263
Total	\$161,840,073	\$18,875,394	\$55,389,975	\$166,445,837	\$402,551,277

Source: GAO analysis of Department of Health and Human Services (HHS) data.

Note: Totals may not add due to rounding.

Table 5: Biomedical Advanced Research and Development Authority Spending on Contracts Dedicated to Chemical, Biological, Radiological, and Nuclear Medical Countermeasure That Include Both Advanced Research and Development and Procurement, Fiscal Year 2010 through Fiscal Year 2013

Medical countermeasure	Fiscal year 2010 spending	Fiscal year 2011 spending	Fiscal year 2012 spending	Fiscal year 2013 spending	Total
Anthrax Therapeutics	\$0	\$8,000,000	\$16,591,540	\$261,869,865	\$286,461,405
Chemical medical countermeasures	0	0	0	60,790,629	\$60,790,629
Radiological and nuclear medical countermeasures	0	0-	0	194,655,775	\$194,655,775
Smallpox medical countermeasures	0	440,687,626	36,587,261	137,926,401	\$615,201,288
Total	\$0	\$448,687,626	\$53,178,801	\$655,242,671	\$1,157,109,098

Source: GAO analysis of Department of Health and Human Services (HHS) data.

Note: Totals may not add due to rounding.

Appendix II: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

DEC 16 2013

Vijay D'Souza
Acting Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. D'Souza:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "National Preparedness: HHS Updated Its Medical Countermeasure Plans but Has Not Provided Previously Recommended Spending Estimates" (GAO-14-90).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

A handwritten signature in black ink that reads "Jim R. Esquea".

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES' (HHS) GENERAL COMMENTS TO GAO'S DRAFT REPORT, "HHS UPDATED ITS MEDICAL COUNTERMEASURE PLANS BUT HAS NOT PROVIDED PREVIOUSLY RECOMMENDED SPENDING ESTIMATES" (GAO-14-90)

The Department appreciates the opportunity to review and comment on this draft report.

HHS established the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) as the coordinating body for the federal agencies in charge of protecting the civilian population from potential adverse health impacts of chemical, biological, radiological, and nuclear agents and emerging infectious diseases through the use of medical countermeasures that can lessen the harmful effects of these threats.

HHS recognizes that a periodic assessment of strategy and capabilities to advance national preparedness in light of changing scientific and fiscal circumstances is appropriate and necessary. To this end, HHS released the updated *PHEMCE Strategy and Implementation Plans* in 2012. Together the two documents provide the blueprints PHEMCE will follow in the near-, mid-, and long-terms to make the best use of available resources to enhance national health security.

HHS would like to take this opportunity to clarify and expand on some of the ongoing initiatives that are documented in this report.

HHS acknowledges the time and effort GAO has taken to document the extensive tracking processes we have put into place to monitor progress against the 255 near and mid-term activities called out in the *2012 PHEMCE Implementation Plan*. While the 72 of these activities that GAO specifically looked at were identified in the *Implementation Plan* as key milestones during these timeframes, it should be noted that this list was meant to be illustrative and not comprehensive. Indeed, all of the 255 activities detailed in the *Implementation Plan* are priorities for HHS and our interagency partners as we seek to accomplish the Goals and Objectives laid out in the 2012 *PHEMCE Strategy*.

HHS has worked with our interagency partners to define concrete deliverables and interim milestones, and to track monthly, those items with near and mid-term timeframes, including multiple activities not captured in the 72 items that were the focus of the GAO inquiry. We are also regularly tracking progress on all 255 of the activities called out in the *Implementation Plan*, and will be establishing concrete deliverables and interim milestones for those items slated for accomplishment in the fiscal year (FY) 2015-2017 timeframe as we move closer to that period. We anticipate providing a progress report against all 255 activities in the *Implementation Plan* to senior PHEMCE leadership in early 2014.

We recognize that GAO undertook this review in the context of previous studies that have examined HHS' medical countermeasures initiatives over the last several years. In particular, this report evaluates the *PHEMCE Strategy and Implementation Plan* in light of previous recommendations from GAO-12-121. We appreciate GAO's continued interest in ways in which we can improve our communications with our industry stakeholders and would like to take this opportunity to provide some additional context to address GAO's recommendation that we

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**THE DEPARTMENT OF HEALTH AND HUMAN SERVICES' (HHS) GENERAL
COMMENTS TO GAO'S DRAFT REPORT, "HHS UPDATED ITS MEDICAL
COUNTERMEASURE PLANS BUT HAS NOT PROVIDED PREVIOUSLY
RECOMMENDED SPENDING ESTIMATES" (GAO-14-90)**

include spending estimates for specific medical countermeasures in the *Strategy and Implementation Plan*.

As noted above, in the time since the previous report was published, HHS undertook a rigorous reevaluation of the PHEMCE goals and priorities, culminating in the 2012 release of the updated *Strategy and Implementation Plan*. While neither document was intended as a budget or spending plan we have been mindful of ways in which we can be more transparent with our partners, while maintaining the integrity of the federal contracting process. Our experience over ten years of Project Bioshield Special Reserve Fund procurements has shown that we will only be successful if we balance the needs of the federal government with requests for information from our industry partners. Fortunately, we have been able to work in concert with our private sector partners to identify priorities and target resources on a negotiated basis throughout the contracting process. Finally, it is important to note that many of the tasks outlined are part of a multi-year, all-hazards approach to achieving our medical countermeasures priorities. Consequently, they are not tied to one particular countermeasure—or even one particular threat—making it extremely difficult to quantify the associated resource needs.

Given GAO's continued interest in this topic, and the fact that Congress has requested, more concrete spending information in further PHEMCE documents, HHS is working to find a compromise solution that provides more transparency while allowing for flexibility in the contracting process. We anticipate including more specific information in our 2014 documents.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Vijay A. D'Souza, (202) 512-7114 or dsouzav@gao.gov

Staff Acknowledgments

In addition to the contact named above, Karen Doran, Assistant Director; Shana R. Deitch; Carolyn Feis Korman; Tracey King; and Roseanne Price made significant contributions to this report.

Related GAO Products

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.

National Preparedness: Improvements Needed for Measuring Awardee Performance in Meeting Medical and Public Health Preparedness Goals. [GAO-13-278](#). Washington, D.C.: March 22, 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.

Chemical, Biological, Radiological, and Nuclear Risk Assessments: DHS Should Establish More Specific Guidance for Their Use. [GAO-12-272](#). Washington, D.C.: January 25, 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.

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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.

Combating Nuclear Terrorism: Actions Needed to Better Prepare to Recover from Possible Attacks Using Radiological or Nuclear Materials. [GAO-10-204](#). Washington, D.C.: January 29, 2010.

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