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United States Government Accountability Office  
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July 24, 2009

Congressional Committees

Subject: *Project BioShield Act: HHS Has Supported Development, Procurement, and  
Emergency Use of Medical Countermeasures to Address Health Threats*

This report formally transmits the attached briefing in response to section 247d-6c of title 42 of the United States Code. (See the enclosure.) The statute required the Comptroller General to examine the Department of Health and Human Services' (HHS) support for the development and procurement of and authority for the emergency use of medical countermeasures to address chemical, biological, radiological, and nuclear threats to public health, and provide the results to the congressional committees by July 21, 2009.<sup>1</sup> HHS determines priorities for medical countermeasure procurement based on those chemical, biological, radiological, and nuclear agents that have been identified by the Department of Homeland Security as posing a material threat to the U.S. population that could affect national security. We provided the briefing to staff of your committees to satisfy the mandate reporting requirement on July 20, 2009, and July 21, 2009.

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We are sending copies of this report to the Secretary of HHS, the Secretary of Homeland Security, and other interested parties. In addition, the report will be available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff have any questions regarding this report, please contact me at (202) 512-7114 or [bascettac@gao.gov](mailto:bascettac@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributions to this report were made by Karen Doran, Assistant Director; George Bogart; Natalie Herzog; Amy C. Leone; Roseanne Price; and Rasanjali Wickrema.

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Director, Health Care

Enclosure

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<sup>1</sup>The Project BioShield Act of 2004 also required the Comptroller General to review other issues, such as how HHS has used its Project BioShield Act contracting and purchasing authorities to enhance its ability to procure medical countermeasures, and the extent to which HHS has sufficient internal controls in place to manage and ensure the appropriate use of its Project BioShield Act contracting and purchasing authorities. We address these issues in a separate report, *Project Bioshield: HHS Can Improve Agency Internal Controls for Its New Contracting Authorities*, GAO-09-820 (Washington, D.C.: July 21, 2009).

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## **Project BioShield Act: HHS Has Supported Development, Procurement, and Emergency Use of Medical Countermeasures to Address Health Threats**

### **Briefing for the staffs of the**

Committee on Health, Education, Labor, and Pensions  
Committee on Homeland Security and Governmental Affairs  
Subcommittee on Homeland Security, Committee on Appropriations  
Subcommittee on Labor, Health and Human Services, Education, and Related Agencies,  
Committee on Appropriations  
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Committee on Appropriations  
House of Representatives

**July 20, 2009, and July 21, 2009**



## Overview

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## Introduction

- The terrorist attacks of September 11, 2001, and the subsequent attacks using anthrax-laced letters have raised congressional concerns that the United States is vulnerable to threats from chemical, biological, radiological, and nuclear (CBRN) agents, including agents responsible for naturally emerging infectious diseases that could cause illness on a scale that adversely affects national security.
- Members of the Congress have noted the need for the United States to have medical countermeasures (MCM), such as vaccines, drugs, therapies, and diagnostic tools, to respond to CBRN agents and to adequately protect the public from such threats or provide after-exposure treatment.
- Members of the Congress and others have attributed the limited availability of CBRN countermeasures to a lack of economic incentives to invest the millions of dollars required to bring treatments to market for uncommon diseases and conditions, such as anthrax.



## Introduction (cont.)

- To encourage the development of new CBRN medical countermeasures, the Project BioShield Act of 2004 (Pub.L.No.108-276), was enacted to, among other things,
  - facilitate the creation of a government market by authorizing the appropriation of about \$5.6 billion from fiscal years 2004 through 2013 to purchase MCMs, including those that may require additional development;
  - under specified conditions, allow the Secretary of the Department of Health and Human Services (HHS) to authorize the temporary emergency use (through emergency use authorizations, or EUAs) of (1) certain medical products that have not yet received Food and Drug Administration (FDA) approval or (2) unapproved use of an FDA-approved product; and
  - provide HHS with authorities to facilitate CBRN MCM research- and development-related spending, including a streamlined authority for hiring experts.
- The Project BioShield Act directs the Department of Homeland Security (DHS) to conduct assessments of the threats posed by CBRN agents and to issue material threat determinations for CBRN agents that pose a threat to the U.S. population that could affect national security.



## Objectives

GAO is required to report on the implementation of the Project BioShield Act by provisions of the act. This briefing describes the status of

1. Medical countermeasures supported by the Project BioShield Act that are available or being developed to address identified and emerging threats to public health from CBRN agents determined by DHS.
2. HHS's use of its authority to allow the temporary emergency use of medical countermeasures, and whether it developed procedures governing such use.
3. HHS's use of its streamlined personnel authority under the Project BioShield Act.





## Scope and Methodology

- We reviewed HHS and DHS information and documentation, including
  - HHS's annual reports to the Congress on the implementation of the Project BioShield Act
  - HHS's Public Health Emergency Medical Countermeasures Enterprise Strategy (referred to as the HHS Enterprise Strategy)
  - HHS's Public Health Emergency Medical Countermeasures Enterprise Implementation Plan (referred to as the HHS Enterprise Implementation Plan), which guides MCM research, development, and procurement
  - FDA guidance on authorizing the emergency use of MCMs
  - DHS determinations of CBRN agents that pose threats to the U.S. population
- We interviewed officials from
  - HHS's Office of the Assistant Secretary for Preparedness and Response (ASPR) and the Biomedical Advanced Research and Development Authority (BARDA)
  - Centers for Disease Control and Prevention (CDC)
  - National Institutes of Health (NIH)
  - FDA
  - DHS



## Scope and Methodology (cont.)

- We also reviewed
  - legislation,
  - presidential directives,
  - *Federal Register* notices and federal agency letters about EUAs, and
  - documents from the Congressional Research Service.
- We conducted our work from April 2009 through July 2009 in accordance with all sections of GAO's Quality Assurance Framework that are relevant to our objectives. The framework requires that we plan and perform the engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations in our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for any findings and conclusions in this product.



## Background

### Project BioShield Authorities and Funding

- The Project BioShield Act of 2004 provides authorities and authorizes funding to accelerate the research, development, acquisition, and availability of effective MCMs.
- The Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA) (Pub.L.No. 109-417) clarified that the scope of the Project BioShield Act includes MCMs for biological agents that could cause naturally occurring infectious diseases that may cause a public health emergency affecting national security. PAHPA also established BARDA as a focal point within HHS for the advanced development and acquisition of MCMs.
- The Project BioShield Act authorized the appropriation of \$5.593 billion over 10 years (fiscal years 2004 through 2013) for the procurement of MCMs. The Department of Homeland Security Appropriations Act, 2004 (Pub.L.No. 108-90 (2003)) appropriated \$5.593 billion for this purpose.



## Background

### Identified CBRN Agents

- DHS has identified 13 CBRN agents that pose a material threat to national security.
  - HHS has incorporated these identified agents in its Enterprise Implementation Plan. (See table 1.)
  - HHS's Enterprise Implementation Plan also includes volatile nerve agents, which had not received a DHS material threat determination as of July 2009.



## Background Identified CBRN Agents (cont.)

**Table 1: 13 CBRN Agents Identified by DHS as Posing a Material Threat to National Security, as of July 2009**

2004	2006
Anthrax ( <i>Bacillus anthracis</i> )	Glanders ( <i>Burkholderia mallei</i> )
Botulism (botulinum toxins)	Ebola virus (hemorrhagic fever)
Radiological/nuclear agents	Junin virus (hemorrhagic fever)
Smallpox (variola virus)	Marburg virus (hemorrhagic fever)
	Melioidosis ( <i>Burkholderia pseudomallei</i> )
	Multi-drug-resistant anthrax (MDR <i>Bacillus anthracis</i> )
	Plague ( <i>Yersinia pestis</i> )
	Tularemia ( <i>Franciscella tularensis</i> )
	Typhus ( <i>Rickettsia prowazekii</i> )

Sources: DHS, HHS Enterprise Implementation Plan, and the HHS Project BioShield Annual Report to Congress, August 2006-July 2007.



## Background

### HHS's Role in MCMs

- Through the Project BioShield Act, PAHPA, and national planning documents, HHS is charged with providing leadership in research, development, acquisition, deployment, and guidance for use of MCMs through its various components, including
  - BARDA (within ASPR), which is responsible for providing a coordinated, systematic approach to the development and acquisition of MCMs;
  - CDC, which maintains MCMs in the Strategic National Stockpile (SNS; the federal supply of pharmaceuticals, vaccines, and so forth, for critical medical care of high-priority diseases and conditions) and acquires some FDA-approved MCMs for the SNS;
  - FDA, which approves pharmaceuticals, licenses biologicals such as vaccines, and clears or approves medical devices that could be used as MCMs; and
  - NIH, which has been authorized to expedite and simplify the solicitation, review, and award of grants and contracts for the development of MCMs.



## Background

### HHS's Role in EUAs

- The Project BioShield Act also authorizes the HHS Secretary to allow the temporary use of certain medical products, such as drugs, vaccines, or medical devices, as MCMs.
- These products include
  - unapproved products (i.e., products not yet approved or cleared by FDA) and
  - unapproved uses of approved products (i.e., unapproved uses of approved drugs and cleared or approved devices).
- These products could be used in a declared emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN agents when there are no adequate, approved, and available alternatives.



## Background

### HHS's Role in EUAs (cont.)

- In using this authority, the HHS Secretary would first declare an emergency justifying the temporary use of a product based on a determination of an actual or significant potential for one of three types of emergency involving specific CBRNs:
  - a domestic emergency determined by the DHS Secretary involving a heightened risk of attack,
  - a military emergency determined by the Secretary of Defense involving a heightened risk of attack to U.S. military forces, or
  - a public health emergency determined by the HHS Secretary that affects or could affect national security.
- The Secretary has delegated to the FDA Commissioner the responsibility for issuing EUAs after the declaration of an emergency.
- The FDA Commissioner may issue an EUA when certain criteria are met. For example,
  - the agent specified in the emergency declaration can cause a serious or life-threatening disease and
  - the known and potential benefits outweigh the known and potential risks of the product to diagnose, prevent, or treat the condition.





## Background

### Streamlined Personnel Authority

- The Project BioShield Act provides streamlined personnel authority for the hiring of professional and technical employees at NIH to perform, administer, or support research and development for MCMs.
- This authority allows for
  - streamlined hiring of up to 30 individuals at NIH at any one time,
  - a flexible pay scale for those employees, and
  - preference for specific individuals when hiring those employees.



## Results

1. Under the Project BioShield Act, HHS has supported development and procurement of seven MCMs to address four CBRN agents that are identified as threats to public health and has plans for additional MCMs that address both identified and emerging threats.
2. Using its delegated authority from the Secretary of HHS, FDA has issued seven EUAs for medical products to address existing threats of exposure to the novel influenza A (H1N1) virus and potential threats from the intentional use of anthrax. Additionally, FDA has developed guidance for issuance of the EUAs.
3. HHS has used its streamlined personnel authority to hire seven staff at NIH as of July 2009.



## **1: HHS Has Supported Development of MCMs for Some Threats and Has Plans to Address Others**

### **Seven MCMs for Four CBRN Agents Identified as Threats**

- Seven MCMs are available or being developed under existing procurement contracts to address four CBRN agents that are identified as threats to public health. (See table 2.)
- The seven MCMs address the first four public health threats identified by DHS in 2004 (anthrax, botulism, radiological/nuclear, and smallpox).
- Two of the four threats have more than one MCM because the MCMs are for different uses or have unique characteristics.
- In addition, HHS has announced two requests for proposals to develop additional MCMs for
  - a “next generation” anthrax vaccine using the latest technology and
  - a smallpox antiviral drug for individuals who may be symptomatic with smallpox disease and for whom the current vaccine would be ineffective.



## 1: HHS Has Supported Development of MCMs (cont.)

### Status of MCMs for CBRN Agents Identified as Threats

**Table 2: Status of MCMs Supported by the Project BioShield Act for Identified Threats from CBRN Agents**

CBRN agent	MCM	MCM use	MCM unique characteristic	Status of MCM
Anthrax	AVA anthrax vaccine	FDA licensed for prevention before exposure. Prevention after exposure in combination with antibiotics.	This is the only currently licensed anthrax vaccine.	Available, FDA licensed for prevention before exposure
	Raxibacumab	Treatment of anthrax disease.	An antibody therapy directed against the anthrax toxin to treat symptomatic individuals.	Under development
	Anthrax immune globulin	Treatment of anthrax disease.	A plasma-derived therapy against the anthrax toxin to treat symptomatic individuals.	Under development



## 1: HHS Has Supported Development of MCMs (cont.)

### Status of MCMs for CBRN Agents Identified as Threats (cont.)

CBRN agent	MCM	MCM use	MCM unique characteristic	Status of MCM
Botulism	Heptavalent botulism antitoxin	Treatment of botulinum poisoning.	Antitoxin is the only available treatment for any of the seven botulinum toxins.	Under development
Radiological/ nuclear	Potassium iodide	Treatment after exposure to radioactive iodine.	This product would be used for children to protect the thyroid gland from damage due to radioactive iodine.	Available
	Intravenous pentetate calcium trisodium and pentetate zinc trisodium	Treatment after exposure to certain forms of radioactive matter (transuranic elements).	This product would be used to bind specific ingested or inhaled forms of radioactive matter and remove them from the body.	Available
Smallpox	Modified vaccinia ankara smallpox vaccine	Prevention before exposure to smallpox.	This vaccine is being developed as a potentially safer vaccine for certain populations (i.e., immune-compromised persons).	Under development

Source: HHS.



## **1: HHS Has Supported Development of MCMs (cont.)**

### Plans for MCMs for Identified Threats

- The HHS Enterprise Implementation Plan covers proposed development and procurement through 2013 for MCMs for identified threats. (See table 3.)
  - Through future Project BioShield Act contracts, HHS proposes to help develop and procure additional MCMs to address all of the 13 identified threats.
  - An additional class of agents identified in the HHS Enterprise Implementation Plan, volatile nerve agents, is not addressed through Project BioShield Act contracts; instead, HHS is pursuing development and acquisition of these MCMs for volatile nerve agents using other funding.



# 1: HHS Has Supported Development of MCMs (cont.)

## Planned MCMs for CBRN Agents Identified as Threats

**Table 3: Planned MCM Development and Procurement through Fiscal Year 2013 for Identified Threats**

<b>CBRN agents</b>	<b>Planned MCMs</b>
Anthrax ( <i>Bacillus anthracis</i> )	Broad spectrum antibiotics (effective against a wide range of bacteria), diagnostic tools, antitoxin
Botulism (botulinum toxins)	Diagnostic tools
Glanders ( <i>Burkholderia mallei</i> )	Broad spectrum antibiotics, diagnostic tools
Ebola virus (hemorrhagic fever)	Antiviral and/or a vaccine, diagnostic tools
Junin virus (hemorrhagic fever)	Diagnostic tools
Marburg virus (hemorrhagic fever)	Antiviral and/or a vaccine, diagnostic tools
Melioidosis ( <i>Burkholderia pseudomallei</i> )	Broad spectrum antibiotics, diagnostic tools
Multi-drug-resistant anthrax (MDR <i>Bacillus anthracis</i> )	Broad spectrum antibiotics, diagnostic tools, antitoxin
Plague ( <i>Yersinia pestis</i> )	Broad spectrum antibiotics, diagnostic tools
Radiological/nuclear agents	Bioassay to determine the strength of these agents, biodosimetry to assess the likelihood of developing acute radiation syndrome, and others
Smallpox (variola virus)	Diagnostic tools, antivirals
Tularemia ( <i>Franciscella tularensis</i> )	Broad spectrum antibiotics, diagnostic tools
Typhus ( <i>Rickettsia prowazekii</i> )	Broad spectrum antibiotics, diagnostic tools
Volatile nerve agents	Not addressed by Project BioShield Act funding

Source: HHS Enterprise Implementation Plan.



## **1: HHS Has Supported Development of MCMs (cont.)**

### Plans for MCMs for Emerging Threats

- The HHS Enterprise Strategy and the HHS Enterprise Implementation Plan include guidelines and principles for addressing emerging threats, which are defined as naturally occurring organisms that are newly recognized or anticipated to present a public health threat, such as severe acute respiratory syndrome (SARS).
- In addition to plans for developing MCMs specific to individual agents, the HHS Enterprise Strategy and the HHS Enterprise Implementation Plan contain plans for countermeasures with broader applications to address emerging threats, including the following:
  - Developing flexible MCMs to address more than one threat, such as broad-spectrum antibiotics to address multiple bacterial agents.
  - Developing “platform technologies” that provide the capability to rapidly develop and produce MCMs to address emerging threats.





## **2: FDA Has Issued Seven EUAs as of July 2009 and Established Procedures for Their Use**

- Using its delegated authority from the HHS Secretary, FDA has issued seven EUAs for medical products to address existing threats of exposure to the novel influenza A (H1N1) virus and potential threats from the intentional use of anthrax:
  - five EUAs for a public health emergency,
  - one EUA for a military emergency, and
  - one EUA for a domestic emergency.



## **2: EUAs as of July 2009 (cont.)**

### **Five EUAs for a Public Health Emergency**

- As of July 2009, FDA has issued five EUAs for MCMs used to identify, prevent, and treat novel influenza A (H1N1) virus:
  - MCMs: Drugs - Relenza and Tamiflu (two EUAs), diagnostic kits (two EUAs), and respirators (one EUA) to identify, prevent, and treat novel influenza A (H1N1) virus.
  - Population affected: General public.
  - Authorized use: The EUA allows the MCMs to be administered for unapproved uses; for example, Tamiflu is allowed to be given to infants under 1 year old, which is younger than previously approved.
  - Effective dates: The EUAs are effective for 1 year with the issuance dates ranging from April 27, 2009, through May 2, 2009, unless terminated or revoked.



## **2: EUAs as of July 2009 (cont.)**

### **One EUA for a Military Emergency**

- As of July 2009, FDA has issued one EUA for an MCM used for prevention of inhalation anthrax for a military emergency:
  - MCM: Anthrax vaccine adsorbed (AVA) for prevention of inhalation anthrax.
  - Population affected: Military individuals deemed by the Department of Defense to be at a heightened risk of exposure from an anthrax attack.
  - Authorized use: The EUA allowed use of the MCM to prevent inhalation anthrax until the resolution of legal actions that deemed it an unapproved use.
  - Effective dates: This EUA was initially effective for 6 months, beginning January 27, 2005. The EUA was extended for an additional 6 months, effective July 22, 2005.



## **2: EUAs as of July 2009 (cont.)**

### **One EUA for a Domestic Emergency**

- As of July 2009, FDA has issued one EUA for an MCM for prevention of inhalation anthrax in response to a determination of a significant potential for a domestic emergency:
  - MCM: Doxycycline hyclate tablets in emergency kits for prevention of inhalation anthrax.
  - Population affected: U.S. Postal Service mail carriers eligible to deliver antibiotics to homes in selected cities during an emergency, as part of the Cities Readiness Initiative Program, and their families.
  - Authorized use: The EUA allows the unapproved use of the MCM because the kits include information that was not part of the approved drug application.
  - Effective dates: The EUA is effective for 1 year from October 1, 2008, unless terminated or revoked.



## 2: EUAs as of July 2009 (cont.)

### FDA Has Established Procedures for EUAs

- FDA established procedures for EUAs in its *Guidance: Emergency Use Authorization of Medical Products*, which was published in July 2007.\*
- The guidance discusses issues such as:
  - Declaration of emergency
  - Eligibility for an EUA
  - Request for consideration for an EUA
  - Processing of an EUA
  - Conditions of authorization for an EUA
  - Revocation or termination of an EUA
  - Preemption issues when states have existing requirements governing dispensing, administration, or labeling of unapproved medical products or approved medical products for unapproved uses
  - Liability protection and compensation under other statutes

\*The guidance was first published in draft form in 2005.



### **3: HHS Has Used the Streamlined Personnel Authority to Hire Seven Staff at NIH**

- HHS has used its streamlined personnel authority to hire seven staff at NIH as of July 2009.
  - HHS officials said NIH has used this authority to fill key positions related to product development, including
    - Associate Director for Biodefense Product Development and
    - Associate Director for Radiation Countermeasures Research and Emergency Preparedness.
  - HHS officials said this authority was helpful because it allowed, among other things, the hiring of staff at NIH at competitive salaries.
  - HHS officials noted that the ability to use this streamlined personnel authority could be critical if a future large-scale emergent threat or terrorist action were to occur. This authority would allow NIH to rapidly identify and appoint experts to assist in responding to the event.



## Agency Comments

To obtain agency comments, we provided a draft of these briefing slides to HHS and DHS and discussed the draft with officials from the two agencies. The agencies provided e-mail and oral comments.

The agencies generally agreed with the information presented in the draft and also provided technical comments, which we incorporated as appropriate.

In commenting on the draft, HHS noted that Project BioShield is an “unprecedented national effort” to procure MCMs against the most pressing CBRN threats to public health and said that the effort has experienced significant success during its first 5 years of implementation. HHS also noted that the Project BioShield Act allows HHS not only to procure available MCMs but also to support development of MCMs through the agency’s ability to award contracts to acquire MCMs as much as 8 years before the MCMs receive FDA approval. HHS also noted that it does not expect to be able to support the development and procurement of MCMs for all 13 of the CBRN agents that have received material threat determinations before 2013, the final year for which appropriations are authorized under the Project BioShield Act, because of both scientific and financial reasons.

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