

CRS Report for Congress

Project BioShield: Appropriations, Acquisitions, and Policy Implementation Issues for Congress

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Summary

The Project BioShield Act of 2004 (P.L. 108-276) established a 10-year program to acquire civilian medical countermeasures to chemical, biological, radiological and nuclear (CBRN) agents for the Strategic National Stockpile. Provisions of this act were designed to encourage private companies to develop these countermeasures by guaranteeing a government market for successfully developed countermeasures. Both the Department of Homeland Security (DHS) and the Department of Health and Human Services (HHS) have responsibilities in this program. Funds for this program are appropriated to DHS, while contracts are executed through HHS. The interagency process responsible for deciding which countermeasures to procure has changed multiple times since this program's inception.

The Homeland Security Appropriations Act, 2004 (P.L. 108-90) provided an advance appropriation of \$5.6 billion to acquire CBRN countermeasures over a 10-year period (FY2004–FY2013). This act also limited the amount that could be obligated during specified time periods. The Project BioShield Act of 2004 (P.L. 108-276) assigned the \$5.6 billion advance appropriation to Project BioShield countermeasure acquisitions. The Consolidated Appropriations Act, 2004 (P.L. 108-199) and the Consolidated Appropriations Act, 2005 (P.L. 108-447) reduced the total amount available for Project BioShield by a total of \$25 million. Congress retains the power to make additional appropriations and rescissions to this account.

HHS has awarded Project BioShield contracts for a countermeasure against botulinum toxin, two types of anthrax vaccine, two types of anthrax treatments, and three kinds of countermeasures against radiological or nuclear agents. HHS reports that it has obligated approximately \$1.831 billion from the Project BioShield account. However, the largest contract, \$878 million for an anthrax vaccine, was cancelled in December 2006, for failure to meet a contract milestone. Taking this into account, approximately \$2.389 billion remains available for obligation in FY2007–FY2008 and \$4.564 billion available for obligation through the end of the program in FY2013.

Some outside observers and interested companies have criticized specific HHS awards decisions and the rate at which they are made. Additionally, contract awards reported by HHS do not directly correspond with budgetary figures provided in the President's annual budget documents, which may suggest problems with interagency coordination and communication.

This report discusses actions taken by Congress and the Administration that have affected this program, describes the decision-making process for choosing countermeasures, describes the countermeasures for which the Department of Health and Human Services (HHS) has contracted, and discusses accounting discrepancies present in budget documents describing Project BioShield. This report may be updated.

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Project BioShield: Appropriations, Acquisitions, and Policy Implementation Issues for Congress

The need to develop and procure medical countermeasures (e.g., diagnostic tests, drugs, vaccines, and other treatments) against weapons of mass destruction is well established. The enactment of the Project BioShield Act of 2004 (P.L. 108-276) was designed to be an important part of federal efforts to obtain new civilian medical countermeasures. It provides countermeasure developers with a guaranteed government market for their products. As Congress continues oversight of federal efforts to protect the United States, the effectiveness and efficiency of the Project BioShield implementation may draw legislative attention.

This report discusses actions taken by Congress and the Administration that have affected this program, describes the decision-making process for choosing countermeasures, describes the countermeasures for which the Department of Health and Human Services (HHS) has contracted, and discusses accounting discrepancies between the President's Budget and HHS reporting of Project BioShield awards.

Overview of Project BioShield

The Project BioShield Act of 2004 (P.L. 108-276) contains three major provisions. One relaxes some procedures for bioterrorism-related procurement, hiring, and research grant awarding. Another permits the emergency use of treatments not approved by the Food and Drug Administration (FDA). The third authorizes a 10-year program to encourage the development and production of new countermeasures for chemical, biological, radiological, and nuclear (CBRN) agents. This last provision is usually referred as Project BioShield and is the focus of this report.¹

In contrast to federal programs that directly fund research and development of biomedical countermeasures, Project BioShield is a procurement program. It acts as a guarantee that the federal government will buy successfully developed countermeasures for the Strategic National Stockpile (SNS).² It allows the government to enter into contracts to procure countermeasures while they still are in development, up to eight years before product delivery is expected. The government guarantees that it will buy a certain quantity at a specified price, once the countermeasure meets specific requirements. The government pays the agreed-upon

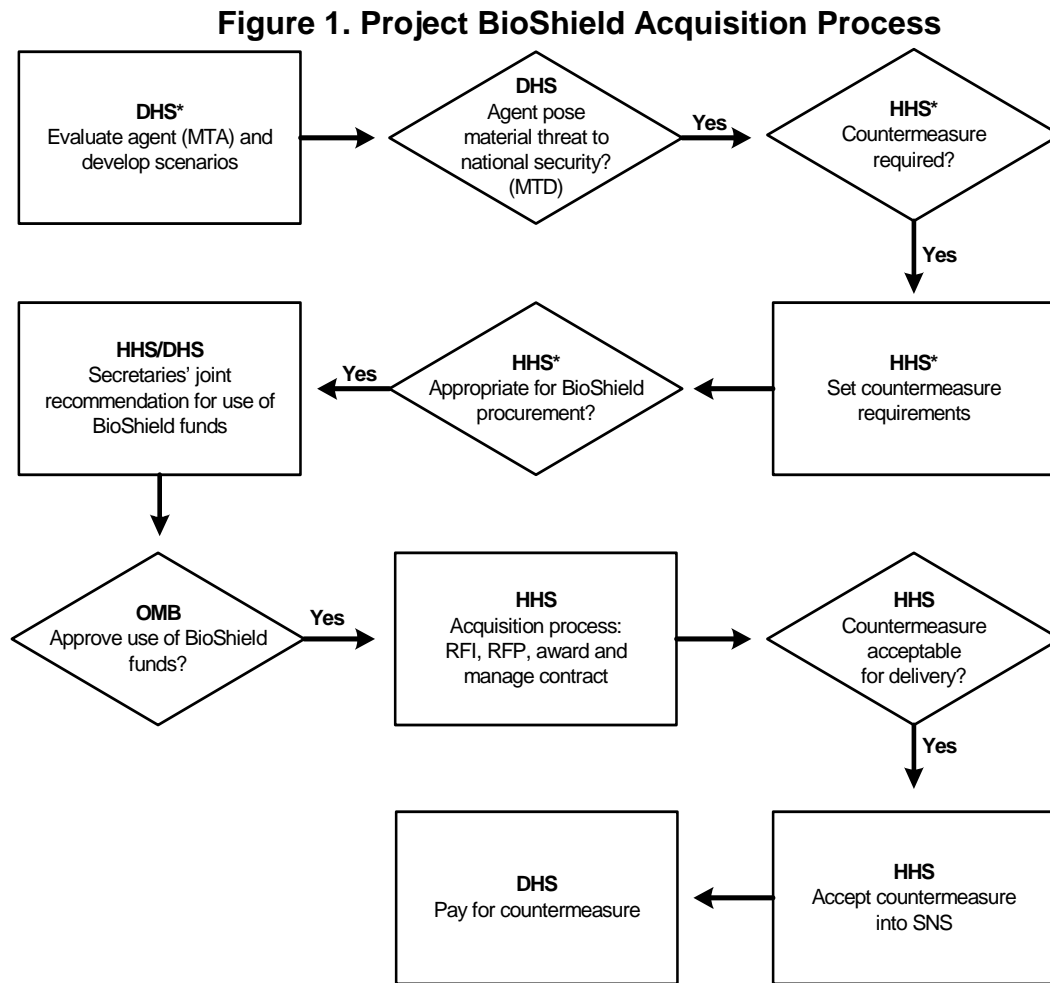
¹ For brief overview of this program and information on other aspects of this act, see CRS Report RS21507, *Project BioShield*, by Frank Gottron.

² The SNS contains pharmaceuticals, vaccines, medical supplies, and medical equipment to respond to terrorist attacks and other emergencies.

amount only after these requirements are met and the product is delivered to the Strategic National Stockpile. If the product does not meet the requirements within the specified time frame, the contract can be cancelled without any payment to the contractor. Thus, Project BioShield reduces the developer’s market risk; that is, the possibility that no customer will buy the successfully developed product. However, it does not reduce the development risk; that is, the possibility that the countermeasure will fail during development.

Project BioShield Procurement Process

The Project BioShield procurement process requires actions by the Department of Homeland Security (DHS), HHS, and the President, and relies on interagency working groups. **Figure 1** illustrates the Project BioShield decision-making and acquisition process.



Note: Bold indicates lead agency, * indicates interagency input. MTA: Material Threat Assessment, MTD: Material Threat Determination, OMB: Office of Management and Budget, RFI: Request for Information, RFP: Request for Proposals, SNS: Strategic National Stockpile.

Source: CRS analysis.

DHS Roles. The first step in the BioShield acquisition process is to determine whether a particular CBRN agent poses a material threat to national security. This analysis, generally referred to as a Material Threat Assessment (MTA), is performed by DHS. Between 30 and 40 subject matter experts are consulted during an MTA.³ On the basis of this assessment, the DHS Secretary determines whether that agent poses a material threat to national security. The Project BioShield Act of 2004 requires such a written Material Threat Determination (MTD) for procurement using BioShield funds and authorities. This declaration neither addresses the relative risk posed by an agent nor determines the priority of its acquisition. Furthermore, the issuance of an MTD does not guarantee that the government will pursue countermeasures against that agent.

The MTA process is distinct from the risk assessments that DHS performs under Homeland Security Presidential Directive (HSPD) 10 and HSPD-18.⁴ HSPD-10 directed DHS to develop, and periodically update, risk assessments that include a ranking of relative risks for biological agents. HSPD-10 states that this overall biological agent risk assessment is to be used to prioritize federal government-wide planning and response to the threat of biological agent attacks. The first iteration of this assessment was delivered in 2006. Now that it is completed, this overall biological agent risk ranking may be used to help determine which agents should have MTAs.⁵ HSPD-18 requires DHS to develop a comprehensive risk assessment that integrates all CBRN agents into a single ranking of relative risk.⁶

In addition to these roles, DHS develops credible attack scenarios for use by interagency groups and HHS to establish countermeasure requirements.

HHS Roles. For agents that have received an MTD, HHS assesses the public health consequences of an attack using that agent. This analysis relies on interagency working groups (see below) and is coordinated by the HHS Office of Public Health Emergency Medical Countermeasures (OPHEMC). OPHEMC is within the Office of the Assistant Secretary for Preparedness and Response (ASPR).⁷ Following this

³ Dr. John Vitko, Director, DHS Chemical and Biological Division, Public comments at the Project BioShield Stakeholders Meeting, Washington DC, September 25, 2006.

⁴ Executive Office of the President, *Homeland Security Directive 10*, April 28, 2004 and Executive Office of the President, *Homeland Security Directive 18*, January 31, 2007.

⁵ Dr. John Vitko, Director, DHS Chemical and Biological Division, Public comments at the Project BioShield Stakeholders Meeting, Washington DC, September 25, 2006.

⁶ The first such assessment is required by June 1, 2008.

⁷ These offices have undergone several name changes. The Office the Assistant Secretary for Preparedness and Response (ASPR) was formerly the Office of Public Health Emergency Preparedness (OPHEP), and was renamed pursuant to P.L. 109-417, The Pandemic and All-Hazards Preparedness Act, in December 2006. The name OPHEP was created administratively in August 2004 (69 *Fed. Reg.* 51679-51680). Prior to that, the office was called the Office of the Assistant Secretary for Public Health Emergency Preparedness (ASPHEP), pursuant to P.L. 107-188, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (67 *Fed. Reg.* 48903-48905). Briefly,

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assessment, HHS determines if this material threat lacks an existing, effective countermeasure and whether a countermeasure should be procured using Project BioShield authorities and funds. If so, the HHS and DHS Secretaries may jointly submit a recommendation for presidential approval to use BioShield funds to acquire such a countermeasure.

The HHS Secretary is also responsible for establishing countermeasure requirements, such as dosage, patient administration method (e.g., injection or pill), minimum effectiveness, and quantity. This process is coordinated by OPHEMC and relies on input from interagency working groups. HHS is responsible for the entire Project BioShield contracting process, including issuing Requests for Information, Requests for Proposals, awarding contracts, managing awarded contracts, and determining whether contractors have met the minimum requirements for payment. OPHEMC maintains a website detailing all Project BioShield solicitations and awards.⁸

Presidential Roles. Presidential approval is required before HHS enters into any Project BioShield countermeasure procurement contract or issues a call for countermeasure development. The President may only make such approval subsequent to a joint recommendation from the Secretaries of HHS and DHS. The President delegated this approval responsibility to the Director of the Office of Management and Budget.⁹

The Executive Office of the President also coordinates the interagency process, largely through the Homeland Security Council (HSC), the National Security Council (NSC), and the National Science and Technology Council (NSTC).

Interagency Roles. Much of the Project BioShield procurement process relies on interagency working groups and cooperation. In addition to the roles detailed above, both DHS and HHS participate fully in the interagency process. The interagency process has been changed multiple times in the past, and will be changed moving forward as the Administration implements HSPD-18 and the Pandemic and

⁷ (...continued)

before that, it was called the Office of Public Health Preparedness, which was created administratively in January 2002 (67 *Fed. Reg.* 1980). In July 2006, Office of Public Health of Emergency Medical Countermeasures, an office within ASPR, was renamed, replacing the name Office of Research and Development Coordination (ORDC, 71 *Fed. Reg.* 38403-38405). ORDC was created administratively within ASPHEP in December 2002 (67 *Fed. Reg.* 71568).

⁸ See online at [<http://www.hhs.gov/ophep/ophemc/bioshield/PBSPrcrtPrjct/>]. OPHEMC is also responsible for procurement of countermeasures (e.g., vaccines, antiviral drugs and tests) for a possible influenza pandemic. Pandemic procurements are not financed through Project BioShield. See CRS Report RS22576, *Pandemic Influenza: Appropriations for Public Health Preparedness and Response* by Sarah A. Lister. See also OPHEMC online at [http://www.hhs.gov/aspr/ophemc/PanFlu/procurement_activities/index.html].

⁹ President Bush, "Designation and Authorization to Perform Functions Under Section 319F-2 of the Public Health Service Act," 69 *Fed. Reg.* 70349, December 3, 2004.

All-Hazards Preparedness Act (P.L. 109-417, as discussed in more detail in a subsequent section of this report).

Weapons of Mass Destruction Medical Countermeasures Subcommittee. As stated above, much of the priority-setting and requirement-determining activities have input from multiple agencies, such as HHS (including FDA and Centers for Disease Control and Prevention (CDC)), DHS, Department of Defense, and some of the intelligence agencies. The mechanism by which these inputs are considered has changed over time. In the past, this activity relied on expertise resident in the Weapons of Mass Destruction Medical Countermeasures (WMD MCM) Subcommittee. This interagency group predates Project BioShield. It is part of the National Science and Technology Council (NSTC). This Cabinet-level Council acts to coordinate science and technology policy across the federal research and development enterprise.¹⁰ The WMD MCM Subcommittee is a part of the NSTC Committee on Homeland and National Security. According to HHS, the charter of the WMD MCM Subcommittee was changed in 2005, and it began reporting to the joint HSC/NSC Biodefense Policy Coordinating Committee in 2005.¹¹ According to NSTC, the Subcommittee also remains within NSTC.¹² The WMD MCM Subcommittee contains representatives from CDC, FDA, National Institutes of Health, DHS, Department of Defense, Department of Agriculture, Nuclear Regulatory Commission, Department of Energy, Department of Veterans Affairs, Environmental Protection Agency, Homeland Security Council, National Security Council, Office of the Vice President, Office of Science and Technology Policy, Office of Management and Budget, and various intelligence agencies.¹³

Public Health Medical Countermeasures Enterprise. The Public Health and Emergency Medical Countermeasures Enterprise (PHEMCE) is an interagency working group that was established in July 2006 during the HHS Office of Public Health Emergency Preparedness reorganization. It is to:

- (1) define and prioritize requirements for public health medical emergency countermeasures, (2) coordinate research, early and late stage product development and procurement activities addressing the requirements [including BioShield procurement], and (3) set deployment and use strategies for medical countermeasures held in the Strategic National Stockpile.¹⁴

¹⁰ See online at [<http://www.ostp.gov/nstc/index.html>].

¹¹ HHS, *Project BioShield Annual Report to Congress: July 2004 – July 2006*, January 26, 2007, p. 17.

¹² See online at [http://www.ostp.gov/nstc/html/_committees.html].

¹³ HHS, *Project BioShield Annual Report to Congress: July 2004 – July 2006*, January 26, 2007, p. 17.

¹⁴ HHS, “Office of Public Health Emergency Preparedness; Statement of Organization, Functions, and Delegations of Authority,” 71 *Fed. Reg.* 38404, July 6, 2006. This regulation establishes the name of this group as the Public Health Medical Countermeasures Enterprise (PHMCE). This name was apparently changed to include “Emergency” in the title, making it the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). See 71 *Fed. Reg.* 53097, September 8, 2006.

PHEMCE is distinct from the HHS Office of Public Health Emergency Medical Countermeasures (OPHEMC). PHEMCE is an interagency working group while OPHEMC resides solely within HHS. However, the Director of OPHEMC is also responsible for coordinating PHEMCE. Neither its establishing regulation nor the draft PHEMCE strategy¹⁵ state to whom this interagency group reports nor detail its membership.

According to HHS, the WMD MCM Subcommittee's duties were transferred to the PHEMCE Governance Board.¹⁶ However, the apparent continuance of the WMD MCM Subcommittee in the NSTC suggests that not all of its duties have transferred to PHEMCE.¹⁷ It is unclear what effect this transfer of duties from a subcommittee of a Cabinet-level Council to an interagency working group associated with an office under the Assistant Secretary for Preparedness and Response will have on the interagency process and the efficiency of the Project BioShield acquisition process.

HSPD-18. Homeland Security Presidential Directive 18 (HSPD-18), issued January 31, 2007, when fully implemented, may change the interagency process described above. HSPD-18 establishes a government-wide strategy for developing and acquiring civilian WMD countermeasures. One of its provision requires the HHS Secretary to

establish an interagency committee to provide advice in setting medical countermeasure requirements and coordinate HHS research, development, and procurement activities.¹⁸

HSPD-18 also requires the HHS Secretary to establish a

dedicated strategic planning activity to integrate risk-based requirements across the threat spectrum and of the full range of research, early-, mid- and late-stage development acquisition and life-cycle management of medical countermeasures.¹⁹

The Secretary is to align all relevant HHS programs to support this plan.

These roles are similar to those of the PHEMCE and its draft strategy.²⁰ However, it is unclear if PHEMCE will be interpreted as the interagency group that HSPD-18 requires. HSPD-18 gave the Secretary 60 days to establish an interagency

¹⁵ HHS, "Office of Public Health Emergency Preparedness; Draft HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy for Chemical, Biological, Radiological and Nuclear Threats," 71 *Fed. Reg.* 53097, September 8, 2006.

¹⁶ HHS, *Project BioShield Annual Report to Congress: July 2004 – July 2006*, January 26, 2007, p. 18.

¹⁷ See online at [<http://www.ostp.gov/nstc/index.html>].

¹⁸ Executive Office of the President, *Homeland Security Directive-18*, January 31, 2007.

¹⁹ Executive Office of the President, *Homeland Security Directive-18*, January 31, 2007.

²⁰ 71 *Fed. Reg.* 53097, September 8, 2006.

working group. This directive, issued more than six months after the establishment of PHEMCE, may indicate that PHEMCE has been deemed insufficient to meet the needs of the federal government. On the other hand, the issuance of this directive could simply be a restatement of the need for PHEMCE and a way to formalize the composition and reporting requirements of this interagency group. HSPD-18 requires this working group to “apprise” the joint HSC/NSC Biodefense Policy Coordination Committee of countermeasure development and acquisition progress.

The Pandemic and All-Hazards Preparedness Act. The Pandemic and All-Hazards Preparedness Act (P.L. 109-417), enacted December 19, 2006, may also affect the Project BioShield interagency decision-making process.²¹ It gives the HHS Secretary until June 19, 2007 to

develop and make public a strategic plan to integrate biodefense and emerging infectious disease requirements with the advanced research and development, strategic initiatives for innovation, and the procurement of... countermeasures²²

This role is similar to that directed by HSPD-18. If finalized, the *Draft PHEMCE Strategy* may fulfill this requirement.

Appropriations, Rescissions, and Future Funding Options

Appropriations

The Department of Homeland Security Appropriations Act, 2004 (P.L. 108-90) provided an advance appropriation of \$5.593 billion to procure civilian medical countermeasures for a 10-year period (FY2004–FY2013). This appropriation was enacted October 1, 2003, almost a year before the July 21, 2004 enactment of the Project BioShield Act of 2004 (P.L. 108-276). The appropriations act established the “Biodefense Countermeasures” account for “necessary expenses for securing medical countermeasures against biological terror attacks.”²³

Although all the funds for this account were provided in the 2004 appropriations act, only a portion became available for obligation upon enactment. The Department of Homeland Security Appropriations Act, 2004 specified that no more than \$890 million could be obligated in FY2004, and no more than \$3.418 billion could be obligated from FY2004 through FY2008 (**Table 1**). Any money not obligated within these defined periods would remain available through FY2013. Thus, before rescissions were enacted, DHS had \$890 million available as budget authority for this

²¹ For more on this legislation, see CRS Report RL33589, *The Pandemic and All-Hazards Preparedness Act (P.L. 109-417): Provisions and Changes to Preexisting Law* by Sarah A. Lister and Frank Gottron.

²² The Pandemic and All-Hazards Preparedness Act (P.L.109-417), §401.

²³ The Department of Homeland Security Appropriations Act, 2004 (P.L. 108-90), 117 STAT. 1148 (6 USC 320(a)).

account in FY2004. In FY2005, an additional \$2.528 billion would have become available. The remaining \$2.175 billion would become available in FY2009 (**Table 2**).

The Project BioShield Act of 2004 (P.L. 108-276) designated the “Biodefense Countermeasures” account established by the Department of Homeland Security Appropriations Act, 2004 (P.L. 108-90) as the special reserve fund for Project BioShield acquisitions.²⁴ P.L. 108-276 placed additional restrictions on the use of these funds, including requiring a determination that an agent constitutes a material threat to national security, requiring Presidential approval before a countermeasure can be purchased, and restricting these funds to procurements only (i.e., not for administrative costs). It also broadened the types of countermeasures that may be acquired from this account to include those against biological, chemical, radiological, and nuclear agents.

Rescissions

Although Congress provided the entire appropriation for the 10-year program, Congress retains the power to increase or decrease the amount available for Project BioShield. Two separate rescissions have removed \$25 million from the Project BioShield special reserve fund.

The Consolidated Appropriations Act, 2004 (P.L. 108-199) contained an across-the-board rescission of 0.59%. This rescission applied to the amount of the Project BioShield advance appropriation that became available for obligation in FY2004 (**Table 2**). This rescission removed \$5 million from the amounts available for obligation in FY2004, as well as reducing the total special reserve fund by an equal amount. Thus, the amount available for obligation in FY2004 was reduced from \$890 million to \$885 million, and the total amount available for FY2004-2013 was reduced from \$5.593 billion to \$5.588 billion (**Table 1** and **Table 2**).

The Consolidated Appropriations Act, 2005 (P.L. 108-447) contained an across-the-board rescission of 0.8%. This rescission applied to the \$2.528 billion that became available for obligation in FY2005 (**Table 2**). This removed \$20 million from the amount available for obligation for FY2005–FY2008 as well as reducing the total special reserve fund by an equal amount. Thus, the amount that became available for obligation in FY2005 was reduced from \$2.528 billion to \$2.508 billion, and the total amount available until FY2013 was reduced from \$5.588 billion to \$5.568 billion (**Table 1** and **Table 2**).

Future Funding Options

Across-the-board rescissions generally only affect those amounts that become available in that fiscal year. Therefore, the special reserve fund is unlikely to be affected by future across-the-board rescissions, except in FY2009, when the remaining \$2.175 billion becomes available (**Table 2**). However, Congress retains the power to make both specific appropriations and rescissions to this account and

²⁴ The Project BioShield Act of 2004 (P.L. 108-276), 118 STAT. 852, (6 USC 320 (b)).

could thus directly increase or decrease the amount available for Project BioShield obligations.

Table 1. Project BioShield Appropriation and Rescissions by Years Funding Is Available

		Years Money Is Available (\$ in millions)		
Public Law	Action	FY2004	FY2004– FY2008	FY2004– FY2013
P.L. 108-90	Appropriation	890	3,418	5,593
P.L. 108-199	0.59% Rescission	(-5)	(-5)	(-5)
P.L. 108-447	0.8% Rescission	n.a.	(-20)	(-20)
Total		885	3,393	5,568

Source: CRS analysis of P.L. 108-90, P.L. 108-199, and P.L. 108-447.

Note: Amounts rounded to nearest million.

Table 2. Project BioShield Appropriation and Rescissions by Year Money First Becomes Available

		Year Money First Becomes Available (\$ in millions)		
Public Law	Action	FY2004	FY2005	FY2009
P.L. 108-90	Appropriation	890	2,528	2,175
P.L. 108-199	0.59% Rescission	(-5)	n.a.	n.a.
P.L. 108-447	0.8% Rescission	n.a.	(-20)	n.a.
Total		885	2,508	2,175

Source: CRS analysis of P.L. 108-90, P.L. 108-199, and P.L. 108-447.

Note: Amounts rounded to nearest million.

Acquisitions

The HHS has reported awarding \$1,831.2 million worth of Project BioShield contracts (Table 3).²⁵ These contracts address three material threats: *Bacillus*

²⁵ HHS, *Project BioShield: Annual Report to Congress July 2004– July 2006*, January 26, 2007. HHS also maintains an updated list of awards on their *Project BioShield: Procurement Activities* website available online at

(continued...)

anthracis (the bacteria which cause anthrax), botulinum toxin, and radiological and nuclear agents. The distribution of contract awards has been uneven between these threats, with \$1,429.2 million against *Bacillus anthracis* (78%), \$363.6 million against botulinum toxin (20%) and \$37.8 million against radiological and nuclear weapons (2%). While HHS has made additional requests for information from all companies developing CBRN countermeasures, none have resulted in contract offers.²⁶

On December 17, 2006, HHS terminated an anthrax countermeasure contract for failure to meet a contract milestone.²⁷ This contract was the first, and largest to date, awarded using Project BioShield funds. Its \$877.5 million value represented nearly half of the total funds obligated to date. This cancellation took place after the preparation of both the HHS' *Project BioShield Annual Report to Congress* and the President's FY2008 Budget. Thus, neither of these documents reflect the recovery of these funds. Taking this cancellation into account, the HHS has obligated \$953.7 million to date (**Table 3**).

Anthrax

The Project BioShield countermeasures against anthrax fall into two categories, vaccines and treatments.²⁸ The vaccines would likely be used after an attack to prevent those people who were exposed to *Bacillus anthracis* from developing the disease anthrax, a procedure called postexposure prophylaxis.²⁹ This contrasts with the manner in which most vaccines (e.g. childhood vaccines) are administered before exposure.

²⁵ (...continued)

[<http://www.hhs.gov/ophep/ophemc/bioshield/PBSPrcrtPrjct/>]. HHS asserts that all of the obligations from this account are detailed on that website. Personal communication with HHS staff, November 20, 2006.

²⁶ These requests addressed smallpox, acute radiation syndrome, chemical agents, and a general request for information from all companies developing CBRN countermeasures. For details, see [<http://www.hhs.gov/ophep/ophemc/bioshield/PBSPrcrtPrjct/>].

²⁷ HHS, "Termination Letter - Contract No. HHSO100200500001C," Letter to VaxGen, Inc., December 19, 2006.

²⁸ For a discussion of possible anthrax countermeasures, see Luciana Borio and Gigi Grönvall, "Anthrax Countermeasures: Current Status and Future Needs," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, Vol. 3, No. 2, 2005, pp. 102-112.

²⁹ Some scientific studies support the use of vaccines in conjunction with antibiotics following exposure to *Bacillus anthracis*. For examples, see Z. Altboum *et al.*, "Postexposure Prophylaxis Against Anthrax: Evaluation of Various Treatment Regimens in Intranasally Infected Guinea Pigs," *Infection and Immunity*, Vol. 70, No. 11, November 2002, pp. 6231-6241; and N. Vietri *et al.*, "Short-course Postexposure Antibiotic Prophylaxis Combined with Vaccination Protects Against Experimental Inhalational Anthrax," *Proceedings of the National Academy of Sciences*, Vol. 103, No. 20, May 3, 2006, pp. 7813-7816.

Table 3. HHS Reported Project BioShield Contract Awards

Material Threat	Product	Doses (thousands)	Cost (\$ millions)	Company	Award Date
Anthrax	rPA vaccine	75,000	877.5	VaxGen, Inc.	11/4/04 <i>Cancelled</i> 12/19/06
	AVA vaccine	10,000	242.7	Emergent BioSolutions (formerly BioPort Corp.)	5/6/05 and 5/5/06
	ABthrax	20	165.2	Human Genome Sciences	6/19/06
	Anthrax Immune Globulin	10	143.8	Cangene Corp.	7/28/06
Botulinum Toxin	Botulinum Antitoxin (Heptavalent)	200	362.6	Cangene Corp.	6/1/06
Radiological/ Nuclear	Potassium Iodide (Liquid)	4,800	17.5	Fleming & Company	3/18/05 and 2/8/06
	Ca-DTPA	395	21.9	Akorn, Inc.	2/13/06
	Zn-DTPA	80			
Total Announced Obligations to Date:			\$1,831.2	million	
Total Current Obligations:^a			\$953.7	million	

^a Accounts for cancellation of the rPA vaccine.

Source: HHS, *Project BioShield: Procurement Activities* website [<http://www.hhs.gov/ophep/ophemc/bioshield/PBSPrctPrjct>]; *Project BioShield: Annual Report to Congress July 2004- July 2006*, January 26, 2007; and CRS calculations.

rPA Vaccine. The vaccine based on recombinant Protective Antigen (rPA) is often referred to as the “second generation anthrax vaccine,” to differentiate it from the anthrax vaccine adsorbed (AVA) vaccine, which is currently used by the Department of Defense (DOD).³⁰ In 2002, the Institute of Medicine (IOM) stated, “Although AVA appears to be sufficiently safe and effective for use, it is far from optimal.”³¹ The IOM supported the development of a new anthrax vaccine. Officials at HHS believe that, when fully developed, the rPA vaccine will address many of the shortcomings of the AVA vaccine as identified in the IOM report.³²

In November 2004, HHS awarded VaxGen, Inc. an \$877.5 million contract for the delivery of 75 million doses of rPA vaccine to the Strategic National Stockpile (\$11.70 per dose). On December 17, 2006, HHS terminated this contract for VaxGen’s failure to meet a contract milestone.³³

HHS had planned that each person would require a three dose regimen of this vaccine for protection.³⁴ Thus, 75 million doses would be sufficient for 25 million people. The Food and Drug Administration (FDA) has not licensed this vaccine. Although FDA licensing is not required for delivery to the stockpile, this vaccine required additional clinical testing before it could be accepted by the government. Under the contract with VaxGen, delivery was to begin by the end of 2006 and be completed by the end of 2007. Technical difficulties repeatedly delayed delivery.³⁵

This first, largest Project BioShield contract has drawn intense scrutiny. Critics of this contract award point to VaxGen’s previous unsuccessful attempts to develop products, financial difficulties, and problems meeting the contract deadlines as indicative of problems in HHS’ implementation of Project BioShield authorities.³⁶ HHS responded to such criticisms by stating VaxGen won the contract through open competition after all the proposals were subjected to “a robust technical and business

³⁰ Stewart Simonson, Assistant Secretary, Department of Health and Human Services, Office of Public Health and Emergency Preparedness, Testimony before the Senate Committee on Appropriations, Subcommittee on Homeland Security, April 28, 2005.

³¹ *The Anthrax Vaccine: Is It Safe? Does It Work?* Institute of Medicine, National Academy Press: Washington, DC, 2002, p. 20.

³² Stewart Simonson, Assistant Secretary, Department of Health and Human Services, Office of Public Health and Emergency Preparedness, Testimony before the Senate Committee on Appropriations, Subcommittee on Homeland Security, April 28, 2005.

³³ HHS, “Termination Letter - Contract No. HHSO100200500001C,” Letter to VaxGen, Inc., December 19, 2006.

³⁴ HHS, “HHS Buys New Anthrax Vaccine for Stockpile,” *News Release*, November 4, 2004.

³⁵ Renae Merle, “Anthrax Vaccine Testing Called Off: VaxGen Contract in Doubt as FDA Raises Concerns,” *Washington Post*, November 4, 2006.

³⁶ Elizabeth MacDonald and Robert Langworth, “Spore Wars,” *Forbes*, Vol. 175, No. 12, p. 162, June 6, 2005; and Eric Lipton, “Bid to Stockpile Bioterror Drugs Stymied by Setbacks,” *New York Times*, September 18, 2006.

evaluation process.”³⁷ HHS portrayed the delays as part of the normal drug development process.³⁸ VaxGen reportedly denied responsibility for the delays, stating that they arose from the government changing its requirements.³⁹

Following the cancellation of the contract, it remains unclear whether HHS still plans to acquire an rPA anthrax vaccine for the SNS.

AVA Vaccine. The AVA anthrax vaccine was originally licensed in 1970. It is currently approved by the FDA for use in 18- to 65-year olds prior to exposure to *Bacillus anthracis* (pre-exposure prophylaxis). Neither this vaccine, nor the rPA vaccine, is approved by the FDA for post-exposure prophylaxis. The FDA-approved regimen for pre-exposure prophylaxis requires a series of six doses administered over the course of 18 months.

The DOD currently uses this vaccine for troops and other personnel deployed in certain areas, including South Korea, Afghanistan, and Iraq. Its use has been controversial, due to complaints of adverse reactions and questions about the vaccine’s efficacy. In October 2004, a federal judge ordered the DOD to stop mandatory vaccinations pending FDA review.⁴⁰ After this order, DOD continued to use this vaccine on a voluntary, rather than mandatory, basis. The FDA completed its review in December 2005.⁴¹ In October 2006, DOD announced plans to resume mandatory vaccinations. Reportedly, several DOD employees plan to sue to block implementation of mandatory vaccinations.⁴²

In May 2005 and May 2006, HHS awarded contracts to Emergent BioSolutions (formerly BioPort Corp.) for the delivery of AVA vaccine to the Strategic National Stockpile. Combined, the contracts are for 10 million doses of AVA vaccine for \$242.7 million (\$24.27 per dose). According to the company, 9 million doses have been delivered to the government, and the remainder is to be delivered in 2007.⁴³

This contract award has also drawn criticism on the basis of cost and questions of policy. Despite the manufacturer carrying no developmental risk, the AVA

³⁷ Stewart Simonson, Assistant Secretary, Department of Health and Human Services, Office of Public Health and Emergency Preparedness, Testimony before the Senate Committee on Appropriations, Subcommittee on Homeland Security, April 28, 2005.

³⁸ Darren Fonda, “Inside the Spore Wars,” *Time*, January 3, 2006.

³⁹ Eric Lipton, “Bid to Stockpile Bioterror Drugs Stymied by Setbacks,” *New York Times*, September 18, 2006.

⁴⁰ Marc Kaufman, “Court Orders Pentagon to Stop Anthrax Vaccinations,” *Washington Post*, October 28, 2004.

⁴¹ 70 *Fed. Reg.* 75180-75198, December 19, 2005.

⁴² Josh White, “Defense Employees Set For Another Suit to Halt Mandatory Anthrax Shots,” *Washington Post*, December 13, 2006.

⁴³ Emergent BioSolutions, “Emergent BioSolutions Delivers Over 3 Million Doses of BioThrax(R) to U.S. Department of Health and Human Services for Strategic National Stockpile,” *Press Release*, December 14, 2006.

vaccine cost per dose is twice the cost per dose of rPA. Additionally, critics observe that DOD studies indicate that up to 35% of people have adverse reactions to this vaccine and that 6% of vaccine recipients have reported serious complications to the FDA's Vaccine Adverse Event Reporting System.⁴⁴ Critics point to this and observations in the IOM report to support their conclusion that AVA is an inferior product. Lastly, since AVA is the only currently licensed vaccine, critics question whether its acquisition has resulted from its unique status rather than filling a Project BioShield need.⁴⁵ Emergent BioSolutions defends its product stating that both the IOM report and the FDA found its product safe and that, as the only FDA-approved anthrax vaccine available, it is filling an urgent need.⁴⁶

ABthrax. ABthrax is an antibody-based treatment that works in a manner similar to anti-venom treatments for snake bites. It is currently under development and it is not yet licensed by the FDA. In June 2006, HHS awarded a \$165.2 million contract to Human Genome Sciences for the delivery of 20 thousand doses of ABthrax (\$8,260 per dose). Human Genome Sciences expects to complete the delivery of ABthrax to the government in 2008.⁴⁷ This high cost per dose, the mechanisms of action, and method of patient administration suggest that ABthrax would be used as a treatment for people who have already developed the symptoms of anthrax, rather than as a post-exposure prophylactic.

Anthrax Immune Globulin. Anthrax Immune Globulin is also an antibody-based therapeutic. It is derived from the blood of people who have received the anthrax vaccine. It is currently under development and is not yet licensed by the FDA. In July 2006, HHS awarded a \$143.8 million contract to Cangene Corp. for the delivery of 10 thousand doses of Anthrax Immune Globulin (\$14,380 per dose). This high cost per dose, the mechanism of action, and likely method of patient administration suggest that Anthrax Immune Globulin would be used as a treatment for people who have already developed the symptoms of anthrax, rather than as a post-exposure prophylactic.

Botulinum Toxin

Botulinum antitoxin is an antibody-based treatment for botulism, a life threatening illness caused by a toxin produced by *Clostridium botulinum* bacteria. In June 2006, HHS awarded a \$362.6 million contract to Cangene Corp. for 200 thousand doses of a botulinum antitoxin (\$1,813 per dose). The company expects to

⁴⁴ Anthrax Vaccine Adsorbed (BioThrax™) FDA-approved package insert, January 31, 2002.

⁴⁵ Elizabeth MacDonald and Robert Langworth, "Spore Wars," *Forbes*, Vol. 175, No. 12, p. 162, June 6, 2005; and Eric Lipton, "Bid to Stockpile Bioterror Drugs Stymied by Setbacks," *New York Times*, September 18, 2006.

⁴⁶ Thomas Williams, "At Odds Over Anthrax," *The Hartford Courant*, April 10, 2006.

⁴⁷ Human Genome Sciences, "U.S. Government Agrees to Purchase ABthrax™ From Human Genome Sciences for the Strategic National Stockpile," *Press Release*, June 20, 2006.

begin delivery by the end of 2007.⁴⁸ Botulinum toxin has several different types; an antitoxin against one type will not be effective against other types. This contract calls for a combination of antitoxins that will work against seven types of botulinum toxins. This combination is known as heptavalent antitoxin. Following an intentional release of botulinum toxin, this antitoxin would probably be administered to people who have developed symptoms of toxin exposure, consistent with the way that similar trivalent products are currently used to treat naturally occurring exposures.

Botulinum antitoxin is produced in a manner similar to anthrax immune globulin, except in this case, it is extracted from horse blood instead of human blood. In 2004, after the Department of Homeland Security Appropriations Act, 2004 provided the advance appropriation, but before the Project BioShield Act was enacted, HHS obligated \$50 million to support the botulinum antitoxin program. These funds were used to process existing horse blood that had been collected by the DOD and to establish horse farms needed to provide new horse blood.⁴⁹ This expenditure would probably not have been eligible for funding from this account after enactment of the Project BioShield Act, as it limited the use of these funds to procuring products. Because these funds were not obligated as part of Project BioShield, they are not included in **Table 3**, but they are included in **Table 4** (see below).

Radiological and Nuclear Agents

In addition to direct blast effects, attacks using radiological or nuclear agents can produce injuries resulting from ionizing radiation, which can damage or kill living cells. HHS determined that the threat posed by both acute radiation sickness and internal contamination with radioactive particles required countermeasures. HHS has contracted for two types of countermeasures designed to reduce internal contamination. Requests for proposals for countermeasures to address acute radiation sickness did not lead to contract offers.⁵⁰

Potassium Iodide. The HHS awarded contracts in March 2005 and February 2006 to Fleming & Company Pharmaceuticals for the delivery of a total of 4.8 million doses of liquid potassium iodide (KI)⁵¹ for a total cost of \$15.9 million (\$3.31 per dose). This product is FDA-approved and available without a prescription to treat people exposed to radioactive iodine.

⁴⁸ Cangene Corp., *Press Release*, May 31, 2006.

⁴⁹ HHS, Personal communication, November 11, 2006.

⁵⁰ HHS, Project BioShield Procurement Activities website, last accessed March 5, 2007 [<http://www.hhs.gov/ophep/ophemc/bioshield/PBSPrctPrjct/>].

⁵¹ Potassium iodide is often abbreviated KI, its chemical formula.

Potassium iodide might be distributed following a release of radioactive iodine into the air, possibly following an attack on a nuclear power plant.⁵² Because the thyroid gland extracts and stores iodine present in the blood, it is vulnerable to injury from radioactive iodine. If administered in time, potassium iodide would block extraction and storage of radioactive iodine by the thyroid. Potassium iodide does not protect against the effects of any other type of radioactive material. Even before these acquisitions, potassium iodide tablets were included in the Strategic National Stockpile, but the tablet formulation was considered poorly suited for children. This liquid preparation, in contrast, is designed for pediatric use.

Chelators. In February and April 2006, HHS awarded a \$21.9 million contract to Akorn, Inc. for 395 thousand doses of calcium diethylenetriaminepentaacetate (Ca-DTPA) and 80 thousand doses of zinc diethylenetriaminepentaacetate (Zn-DTPA). (a nominal average of \$46 per dose). These chelators might be used to treat those exposed to radioactive material through the detonation of a radiological dispersal device (“dirty bomb”), improvised nuclear device, or terrorist attack against stored radioactive material.⁵³ These products are FDA-approved for this type of internal decontamination.

Radioactive materials that may be inhaled or ingested following a dirty bomb or nuclear attack are treated as minerals in the body. Thus, they enter into biological processes like other minerals and become incorporated into internal organs. Once incorporated, they are very difficult to remove and continue to emit radiation, potentially sickening those exposed. Chelators help remove these radioactive particles from the body by binding to them and facilitating their excretion through normal physiological processes.

Differences in HHS Contract Awards and Annual Budget Document Accounting

The Project BioShield special reserve fund, established by the Department of Homeland Security Appropriations Act, 2004, is managed by DHS. In FY2006, the DHS management of this appropriations account passed internally from the Federal Emergency Management Agency to the Preparedness Directorate. However, the contracts obligating the appropriated funds are executed through the HHS OPHEMC.

Table 4 shows the accounting from the President’s annual budget documents. In FY2004, \$885 million from the advance appropriation became available for obligation.⁵⁴ According to the DHS section of the budget, all available budget authority was obligated in FY2004; no budget authority was carried into the

⁵² HHS, “HHS Awards BioShield Contract for Liquid Potassium Iodide,” *News Release*, May 18, 2005.

⁵³ HHS, “HHS Awards BioShield Contract for Two Additional Medical Countermeasures for Radiological or Nuclear Incidents,” *News Release*, February 13, 2006.

⁵⁴ These figures account for the across-the-board rescissions in P.L. 108-199 and P.L. 108-447.

following fiscal year.⁵⁵ In FY2005, another \$2.508 billion became available for obligation. The budget documents state that \$189 million of this was obligated in FY2005, leaving \$2.324 billion to be carried over into FY2006.⁵⁶ For FY2006, the budget states that \$856 million was obligated, leaving \$1.468 billion to be carried over into FY2007.⁵⁷ DHS anticipates obligations of \$1.045 billion in FY2007, leaving only \$423 million available for obligation in FY2008. The next part of the advance appropriation does not become available for obligation until FY2009 (see **Table 2**).

**Table 4. Disposition of Project BioShield Special Reserve Fund
According to the President's Budget**
(\$ in Millions)

	FY2004 Actual	FY2005 Actual	FY2006 Actual	FY2007 Estimate	FY2008 Estimate
Unobligated Balance from Previous Years	0	0	2,324	1,468	423 ^b
Recovered Obligations from Previous Year	0	5	0	0 ^b	0
New Budget Authority	885 ^a	2,508 ^a	0	0	0
Total Amount Available for Obligation	885	2,513	2,324	1,468 ^b	423 ^b
New Obligations by Fiscal Year	885	189	856	1,045	423
Unobligated Balance Carried Forward	0	2,324	1,468	423 ^b	0 ^b
Cumulative Total of Obligations at End of Fiscal Year	885	1,074	1,930	2,975 ^b	3,398 ^b

^a Includes rescissions made by P.L. 108-199 and P.L. 108-447. See **Table 2**.

^b This figure was estimated by the Administration before the cancellation of the \$878 million rPA anthrax vaccine contract.

Source: *Budget of the United States Government, Fiscal Year 2006—Appendix*, pp. 513-514; *Budget of the United States Government, Fiscal Year 2007—Appendix*, p. 512; *Budget of the United States Government, Fiscal Year 2008—Appendix*, p. 479; and CRS calculations.

⁵⁵ *Budget of the United States Government, Fiscal Year 2006—Appendix*, p. 513-514.

⁵⁶ *Budget of the United States Government, Fiscal Year 2007—Appendix*, p. 512.

⁵⁷ *Budget of the United States Government, Fiscal Year 2008—Appendix*, p. 479.

These figures conflict with totals calculated from the countermeasure awards reported by HHS (**Table 3**). **Table 5** lists all of the contracts that HHS has announced for this account along with their dates of award and fiscal year subtotals.⁵⁸

Table 5. Comparison of HHS Award Reporting and DHS Budget Accounting

	HHS announcements \$ (millions)	DHS' Obligations in President's Budget \$ (millions)	Difference \$ (millions)
FY04	Botulinum Antitoxin Program ^a 50		
	FY04 Total 50	885	-835
FY05	rPA, 11/04 878		
	KI, 3/05 7		
	AVA, 5/05 123		
	FY05 Total 1,008	189	819
FY06	KI, 2/06 10		
	Chelators, 2/06 22		
	AVA, 5/06 120		
	Botulinum Antitoxin, 6/06 363		
	ABthrax, 6/06 165		
	AIG, 7/06 144		
	FY06 Total 824	856	-32
Grand Total	1,882	1,930	-48

^a HHS states that this obligation occurred in FY2004 and does not provide a precise date.

Note: Amounts rounded to nearest million.

Source: HHS, *Project BioShield: Procurement Activities* website [<http://www.hhs.gov/ophep/ophemc/bioshield/PBSPrcrtPrjct>] and *Project BioShield: Annual Report to Congress July 2004– July 2006*, January 26, 2007; *Budget of the United States Government, Fiscal Year 2006—Appendix*, pp. 513-514; *Budget of the United States Government, Fiscal Year 2007 — Appendix*, p. 512; *Budget of the United States Government, Fiscal Year 2008 — Appendix*, p. 479; and CRS calculations. See **Table 3** and **Table 4**.

⁵⁸ HHS, *Project BioShield: Annual Report to Congress July 2004 – July 2006*, January 26, 2007. HHS also maintains an updated list of awards on their *Project BioShield: Procurement Activities* website available online at [<http://www.hhs.gov/ophep/ophemc/bioshield/PBSPrcrtPrjct/>]. HHS asserts that all of the obligations from this account are detailed on that website. Personal communication with HHS staff, November 20, 2006.

According to HHS, the only obligation from this account in FY2004 was \$50 million to support the botulinum antitoxin program. In contrast, the President's FY2006 Budget documents state that \$885 million was obligated in FY2004. Additionally, it describes this obligation as falling under two object classifications; with \$190 million for "other services" (object classification 25.2) and \$695 million for "other purchases of goods and services from Government accounts" (object classification 25.3).⁵⁹ It is not clear what these amounts represent. The \$50 million HHS obligated for the botulinum antitoxin program support could fall under the "other services" category, since it was not an acquisition *per se*, but the amount of this contract does not correlate to the amount categorized as "other services."

Another possibility is that the rPA vaccine contract (awarded in November 2004) was accounted for in FY2004 rather than FY2005. This interpretation is supported by the FY2007 Budget reporting that only \$189 million was obligated in FY2005.⁶⁰ However, the total of the \$878 million rPA obligation and the \$50 million botulinum antitoxin program obligation is greater than the budget authority made available in FY2004 (\$885 million). This interpretation also would not account for the division of the funds into the two object classifications. Furthermore, the FY2007 DHS Preparedness Directorate BioDefense Countermeasures Congressional Justification materials list acquiring the rPA vaccine as one of its FY2005 accomplishments. The source of the FY2004 account discrepancy of \$835 million is not apparent.

In FY2005, HHS reported awarding three contracts for a total of \$1.008 billion. The FY2007 Budget states that the actual amount obligated in FY2005 was \$189 million. The DHS FY2007 Congressional Justification documents state that its FY2005 accomplishments include the rPA, KI, and AVA contracts. These would equal the \$1.008 billion calculated from the HHS figures. It is not apparent to what the \$189 million stated in the Budget correlates.

Like the preceding two years, the stated obligations for FY2006 are different according to HHS and the President's Budget. For FY2006, HHS reported awarding six contracts, with obligations totaling \$824 million. This is \$32 million less than the \$856 million stated as "actual obligations" in FY2006 in the President's FY2008 Budget.⁶¹

Combining all of the differences in reporting through FY2006, the President's Budgets state that \$48 million more have been obligated than the HHS documents report.

⁵⁹ *Budget of the United States Government, Fiscal Year 2006 — Appendix*, p. 514.

⁶⁰ *Budget of the United States Government, Fiscal Year 2007 — Appendix*, p. 512.

⁶¹ *Budget of the United States Government, Fiscal Year 2008 — Appendix*, p. 479.

Remaining Available Funds

Knowing the amount of funds available for the Project BioShield is important for both effective management of the program and for external oversight. For the Administration to most effectively plan and prioritize future acquisitions, it must know the amount of funds remaining available. For Congress, knowing the amount of funds remaining can be important in assessing program management, the implementation pace, and general program effectiveness. Due to conflicting statements from executive branch agencies, the amount of funds remaining available for obligation for this program is not clear.

According to HHS, as of March 2007, it has obligated \$1.882 billion from this account. This figure does not include the \$878 million that should be recovered in FY2007 from the cancellation of the rPA anthrax vaccine contract. Taking this recovery into account, \$2.389 billion will be available for obligation in FY2007–FY2008 and \$4.564 billion will be available until the end of the program in FY2013. As stated above, using the President’s Budget figures to calculate obligations would reduce these numbers by \$48 million.

Concluding Observations

Project BioShield plays a key role in the federal government’s response to the threat of chemical, biological, radiological, and nuclear terrorism. It created a process for the government to agree to purchase countermeasures while they still are in development. In addition to increasing the holdings of the Strategic National Stockpile, it was hoped that this government market guarantee would encourage companies to continue to develop promising countermeasures that they might have otherwise abandoned, and induce other companies to begin countermeasure development. It remains unclear how well Project BioShield is meeting these goals.

The rate by which DHS completes Material Threat Determinations has received criticism by stakeholders, industry, and policymakers.⁶² To address these concerns, legislation has been introduced in the previous and current Congress. In the 110th Congress, the Project BioShield Material Threats Act of 2007 (H.R. 1089, Langevin) would require an assessment, and an MTD if appropriate, for all currently known CBRN agents likely to pose a significant national security threat. These assessments would be required to be completed by December 31, 2007. By assessing all known threats and issuing those MTDs necessary, the full spectrum of material threats may be considered when developing a countermeasure acquisition strategy. Such a comprehensive acquisition strategy may allow for more efficient prioritization and balance of countermeasures, providing optimized protection from CBRN attacks using finite funds in the shortest time. Since HHS has not issued contracts for the all

⁶² For example, see U.S. House of Representatives Committee on Homeland Security, Emergency Preparedness, Science, and Technology Subcommittee, *Hearing on Project BioShield*, 109th Cong., 1st Sess., July 12, 2005.

of the agents that already have MTDs, an increase in this number may not increase the rate of countermeasure awards.

Appropriators set limits on how much could be obligated during specified periods of time. The pace by which HHS awards countermeasure contracts roughly corresponds to these limits. By this criterion, this program is on track to fulfill its goals; HHS cannot obligate the money faster than it becomes available.

HHS has been criticized for some of the countermeasures it has chosen. In decisions as complicated and weighty as these, any choice is likely to be criticized. Given the failure of the largest contract to date, some critics may conclude that Project BioShield has fallen short of its goals, since the majority of the money that has been obligated, though not the majority of contracts, has not yet resulted in products in the stockpile. However, one of the unique features of Project BioShield contracts is that the government may contract for products that require up to eight years more of development. It was designed to allow the government to promise to buy something, but only pay for it on delivery. Thus the company, rather than the government, bears the majority of the development risk, i.e. that the product will never be deliverable. One industry group estimates that more than half of all pharmaceuticals will fail during the last eight years of development.⁶³ Thus, it may be expected that at least some Project BioShield contracts will be cancelled.

Since the money available for obligation is finite, the government bears some development risk in the form of opportunity costs, i.e., money obligated to a countermeasure that will ultimately fail in development cannot be simultaneously obligated to another needed countermeasure.

It is possible that the establishment of the Biodefense Advance Research and Development Authority (BARDA) in HHS will reduce the likelihood that future Project BioShield contracts will fail during the advanced development phase. Established by the Pandemic and All-Hazards Preparedness Act (P.L. 109-417), one of BARDA's roles is to support the advanced research and development of promising countermeasures. In theory, funding this part of the development process through such a dedicated mechanism could allow countermeasures to further mature through the development process longer before competing for a Project BioShield contract. This could reduce the risk that a countermeasure will fail while under a Project BioShield contract. P.L. 109-417 included authorization for approximately \$1 billion to support this type of activity for FY2007 through FY2008. However, no money was appropriated for BARDA in FY2007. Even if BARDA becomes operational in FY2007, it will take some time to determine what projects to fund, provide funding, and receive returns on this investment.

Additional criticism of the Project BioShield procurement process may stem from the perceived opacity of its decision-making process. HHS is moving to address some of these issues by publishing its *Draft PHEMCE Strategy for*

⁶³ Pharmaceutical Research and Manufacturers of America, *Industry Profile 2006*, p. 4.

Chemical, Biological, Radiological and Nuclear Threats,⁶⁴ inviting public comment, and reaching out to the public and companies that might develop needed countermeasures through stakeholder meetings.

Some critics also suggest that the Project BioShield process has been poorly managed overall. Such suggestions are reinforced by the annual accounting discrepancies between HHS and DHS. It remains to be seen whether these concerns will be allayed through the management changes being implemented subsequent to: the reorganization of the Office of Public Health Emergency Medical Countermeasures; the establishment of PHEMCE and publication of its draft strategy; the enactment of the Pandemic and All-Hazards Preparedness Act (P.L. 109-417); and the issuance of HSPD-18.

⁶⁴ 71 *Fed. Reg.* 53097, September 8, 2006.