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The Project BioShield Act: Issues for the 113th Congress

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Summary

In 2004, Congress passed the Project BioShield Act (P.L. 108-276) to provide the federal government with new authorities related to the development, procurement, and use of medical countermeasures against chemical, biological, radiological, and nuclear (CBRN) terrorism agents. However, the government still lacks countermeasures against many of the CBRN terrorism agents determined by the government to pose the greatest threat. Congress is likely to consider whether modifications of these authorities or new authorities would help address remaining gaps.

The authority generally referred to as Project BioShield allows the government to guarantee a market for CBRN medical countermeasures. Under this provision, the Secretary of Health and Human Services (HHS) may obligate funds to purchase countermeasures that still need up to 10 more years of development. Since 2004, HHS has obligated approximately $3.309 billion to guarantee a government market for countermeasures against anthrax, smallpox, botulism, radiation, and nerve agents.

Another provision of the Project BioShield Act established a process through which the HHS Secretary may temporarily allow the emergency use of countermeasures that lack Food and Drug Administration (FDA) approval. The HHS has used this authority to allow the emergency use of unapproved products several times.

The Department of Homeland Security (DHS) Appropriations Act, 2004 (P.L. 108-90) advance appropriated $5.593 billion to acquire CBRN countermeasures through Project BioShield between FY2004 and FY2013. Subsequent Congresses rescinded or transferred $2.291 billion, more than one-third, from this advance appropriation. The transfers from this account supported CBRN medical countermeasure advanced development, pandemic influenza preparedness and response, and basic biomedical research. The Consolidated Appropriations Act, 2014 (P.L. 113-76) provides $255 million for Project BioShield procurements to remain available until expended. For FY2015, the President requests $415 million.

Since passage of the Project BioShield Act, Congress has considered additional measures to further encourage countermeasure development. The Pandemic and All-Hazards Preparedness Act (P.L. 109-417) created the Biomedical Advanced Research and Development Authority (BARDA) in HHS and modified the Project BioShield procurement process. Among other duties, BARDA oversees all of HHS's Project BioShield procurements. The Pandemic and All-Hazards Preparedness Reauthorization Act (P.L. 113-5) authorized Project BioShield appropriations of $2.8 billion for FY2014 through FY2018 and modified some Project BioShield-related authorities.

The 113th Congress may also consider modifying the amount and manner by which it funds Project BioShield procurements. Additionally, Congress may consider whether HHS is optimally using its CBRN-related authorities to close remaining countermeasure gaps and appropriately planning for long-term costs associated with maintaining a countermeasure stockpile.

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Introduction

Following the terrorist attacks of 2001, both the Administration and Congress determined that the federal government needed new medical countermeasures (such as diagnostic tests, drugs, vaccines, and other treatments) to respond to an attack using chemical, biological, radiological, or nuclear (CBRN) agents. Representatives of the pharmaceutical industry attributed the paucity of CBRN agent countermeasures to the lack of a significant commercial market.[1] They argued that, because these diseases and conditions occur infrequently, the private sector perceived little economic incentive to invest the hundreds of millions of dollars required to bring a new treatment to market.

In 2004, Congress passed the Project BioShield Act (P.L. 108-276) to encourage the development of CBRN medical countermeasures. The 108th Congress also appropriated $5.6 billion to acquire countermeasures through Project BioShield for FY2004 to FY2013. Subsequent Congresses have evaluated implementation of Project BioShield. In response to perceived problems with Project BioShield countermeasure procurement, the 109th Congress created the Biomedical Advanced Research and Development Authority (BARDA) and the position of Assistant Secretary for Preparedness and Response in the Department of Health and Human Services (HHS) through the Pandemic and All-Hazards Preparedness Act (PAHPA, P.L. 109-417).

The 113th Congress reauthorized and modified some of the authorities granted by the Project BioShield Act. The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (P.L. 113-5) extended the Project BioShield procurement program through FY2018 and authorized appropriations of up to $2.8 billion for FY2014 through FY2018. This law also modified authorities related to the use of countermeasures during an emergency. The Consolidated Appropriations Act, 2014 (P.L. 113-76) provided $255 million for Project BioShield procurements to remain available until expended.

This report provides a brief overview of the Project BioShield authorities and appropriations, identifies the medical countermeasures obtained through Project BioShield, reviews the relationship between Project BioShield and the Biomedical Advanced Research and Development Authority (BARDA), and discusses policy issues for congressional policy makers and related legislation in the 113th Congress.

The Project BioShield Act

President Bush proposed Project BioShield in his 2003 State of the Union address. The 108th Congress considered this proposal and passed the Project BioShield Act of 2004 (P.L. 108-276, signed into law July 21, 2004).[2] The Pandemic and All-Hazards Preparedness Act (PAHPA, P.L. 109-417) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (P.L. 113-5) modified some Project BioShield Act authorities and reauthorized appropriations through FY2018. The Project BioShield Act provides the federal government with authorities related to

[1] For example, Alan Pemberton, Pharmaceutical Research and Manufacturers of America, Testimony before the U.S. House of Representatives Select Committee on Homeland Security, May 15, 2003.

[2] For legislative history of this law, see CRS Report RL32549, *Project BioShield: Legislative History and Side-by-Side Comparison of H.R. 2122, S. 15, and S. 1504*, by (name redacted) and (name redacted).

the development, acquisition, and use of medical countermeasures against CBRN attacks. Project BioShield creates a government-market guarantee by permitting the HHS Secretary to obligate funds to purchase countermeasures while they still need up to 10 more years of development.[3] Another provision of the act establishes a process through which the HHS Secretary may temporarily allow the emergency use of countermeasures that lack Food and Drug Administration (FDA) approval.[4]

Project BioShield Contracts

Project BioShield contracts can have several elements that may help the development of CBRN medical countermeasures for government use, but these contracts can only be used for certain products. These contracts can assure countermeasure developers that the government will buy their product, once it is sufficiently developed. Additionally, the contracts can specify payments during development for meeting specified milestones. These contracts can only be used for countermeasures against CBRN agents which the government has determined pose a material threat to national security. The HHS may use Project BioShield contracts to stockpile countermeasures that have not been approved by the Food and Drug Administration.

Market Guarantee and Milestone Payments

Project BioShield contracts can have multiple benefits to potential CBRN medical countermeasure developers. The contracts can reduce market risk by defining the minimum economic value of a product. They can also mitigate development risk and provide some revenue during product development through milestone-based payments.

A key factor for companies deciding whether to develop a new product is its potential economic value. The U.S. government may be the most economically significant customer for new CBRN countermeasures. The federal government maintains the Strategic National Stockpile (SNS), a supply of pharmaceuticals, vaccines, medical supplies, and medical equipment to respond to terrorist attacks and other emergencies. Thus, one difficulty facing potential CBRN developers is knowing whether the federal government would buy their product for the SNS and, if so, at what price.

Project BioShield provides a mechanism for the federal government to define the minimum value of the government market for a medical countermeasure under development. The HHS Secretary may contract to purchase a product up to 10 years before it is reasonably expected to be delivered to the SNS. These contracts specify the amount and price of the countermeasure that the government will buy if the developer successfully develops the product. Thus, these contracts define the minimum economic value to the company of a successfully developed product. The developers might be able to market products to other entities to increase the countermeasure's economic value above that of the Project BioShield contract.

[3] Under P.L. 108-276 this limit was 8 years. The Pandemic and All Hazards Preparedness Reauthorization Act of 2013 (P.L. 113-5) increased this to 10 years.

[4] For a discussion of other authorities provided by this law, see CRS Report R42349, *The Project BioShield Act: Issues for the 112th Congress*, by (name redacted), and CRS Report R41033, *Project BioShield: Authorities, Appropriations, Acquisitions, and Issues for Congress*, by (name redacted).

Countermeasure developers also face the significant risk that their product will fail during development. Project BioShield contracts may include provisions for milestone-based payments of up to half of the total contract value before delivery. Such payments are for successfully meeting product development milestones, not for delivery to the SNS. Such milestone payments can mitigate the cost to the company of the product failing during development. The remainder of the contract remains contingent on delivery of the successfully developed countermeasure.

Material Threat Determinations

Project BioShield contracts are only available for products designed for use against CBRN agents that the Department of Homeland Security (DHS) has determined pose "a material threat against the United States population sufficient to affect national security."[5] This determination is distinct from other periodic DHS CBRN-related threat risk assessments, such as the Biological Terrorism Risk Assessment.[6] **Table 1** lists the CBRN agents that DHS has determined to pose a material threat.

Table 1. CBRN Agents Determined to Pose a Material Threat

Agent	Disease
hydrogen cyanide, potassium cyanide, and sodium cyanide	
volatile nerve agents	
Bacillus anthracis and multi-drug resistant Bacillus anthracis	anthrax
Burkholderia mallei	glanders
Burkholderia pseudomallei	melioidosis
Botulinum toxins	botulism
Ebola virus	hemorrhagic fever
Francisella tularensis	tularemia
Junin virus	hemorrhagic fever
Marburg virus	hemorrhagic fever
Rickettsia prowazekii	typhus
Variola virus	smallpox
Yersinia pestis	plague
radiological and nuclear agents	

Source: Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, "HHS Public Health Emergency Medical Countermeasures Enterprise Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats," 72 *Federal Register* 20119, April 23, 2007; U.S. Government Accountability Office, *Chemical, Biological, Radiological, and Nuclear Risk Assessments: DHS Should Establish More Specific Guidance for Their Use*, GAO-12-272, January 2012, p. 10; and personal communication with HHS staff, January 29, 2014.

[5] 42 U.S.C. §247d-6b(c)(2).

[6] For additional information on these assessments, see U.S. Government Accountability Office, *Chemical, Biological, Radiological, and Nuclear Risk Assessments: DHS Should Establish More Specific Guidance for Their Use*, GAO-12-272, January 2012.

Unapproved Products

Under Project BioShield, HHS may purchase unapproved and unlicensed countermeasures. It requires the HHS Secretary to determine that "sufficient and satisfactory clinical experience or research data ... support a reasonable conclusion that the countermeasure will qualify for approval or licensing within 10 years."[7] Project BioShield contracts may specify larger awards for approved products than unapproved products. The HHS used Project BioShield to acquire unapproved countermeasures for anthrax, smallpox, and botulinum toxin (see "Acquisitions" below).

Emergency Use of Unapproved Products

The FDA designed its standard approval and licensing processes to protect people from ineffective or dangerous treatments.[8] The Project BioShield Act allows the HHS Secretary to temporarily allow the use of medical products that FDA has not approved or licensed.[9] This authority is not limited to products acquired through Project BioShield. These allowances are known as emergency use authorizations (EUAs). The HHS Secretary may issue EUAs during a military, domestic, or public health emergency, significant potential emergency, or following the identification of a material threat sufficient to affect national security (see "Material Threat Determinations"). To exercise this authority, the HHS Secretary must conclude that

- the agent for which the countermeasure is designed can cause serious or life-threatening disease;
- the product may reasonably be believed to be effective in detecting, diagnosing, treating, or preventing the disease;
- the known and potential benefits of the product outweigh its known and potential risks;
- no adequate alternative to the product is approved and available; and
- any other criteria prescribed in regulation are met.[10]

The HHS Secretary has issued several EUAs.[11] Two EUAs related to CBRN agents remain active. One permits the distribution of antibiotic kits containing doxycycline hyclate to U.S. Postal

[7] 42 U.S.C. §247d-6b(c)(1)(B)(bb).

[8] For overviews of these processes, see CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, by (name redacted), and CRS Report RL34045, *FDA Regulation of Follow-On Biologics*, by (name redacted).

[9] The HHS Secretary may also permit the emergency use of an FDA-approved product for purposes for which it lacks approval.

[10] 21 U.S.C. §360bbb-3(c). For more information on how the Secretary determines whether a product meets these conditions, see U.S. Department of Health and Human Services, Food and Drug Administration, *Guidance—Emergency Use Authorization of Medical Products*, July 2007, at http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm; and U.S. Department of Health and Human Services, Food and Drug Administration, *Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) Medical Countermeasure (MCM) Authorities: FDA Questions and Answers for Public Health Preparedness and Response Stakeholders*, January 2014, at http://www.fda.gov/downloads/EmergencyPreparedness/MedicalCountermeasures/UCM380269.pdf.

[11] The FDA maintains lists of current and previously issued EUAs. See http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm and http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm264224.htm.

Service employees volunteering in the National Postal Model emergency countermeasure distribution program.[12] The other CBRN-related active EUA permits distributing doxycycline hyclate before an emergency and its mass dispensing without a prescription during an emergency to prevent inhalational anthrax.[13] Active EUAs, unrelated to CBRN threats, allow the use of diagnostic tests for the naturally occurring diseases H7N9 influenza and Middle East Respiratory Syndrome Coronavirus.[14]

Appropriations

Congress funded the first 10 years of Project BioShield acquisitions as an advance appropriation in FY2004. The Department of Homeland Security Appropriations Act, 2004 (P.L. 108-90) appropriated $5.593 billion "to secure medical countermeasures against biological terror attacks" into the DHS "Biodefense Countermeasures" account. Subsequently, the Project BioShield Act specified that the appropriation was to be used only for the procurement of CBRN countermeasures using Project BioShield authorities for FY2004 through FY2013. The Consolidated Appropriations Act, 2010 (P.L. 111-117) transferred the funds remaining in the DHS "Biodefense Countermeasures" account at that time to the HHS Public Health and Social Services Emergency Fund.[15] The Project BioShield portion of the Public Health and Social Services Emergency Fund is sometimes referred to as the "special reserve fund."

Congressional authorization of appropriations has remained effectively constant over the duration of Project BioShield at $560 million annually. The Project BioShield Act, as originally passed, authorized $5.593 billion in appropriations through FY2013. The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (P.L. 113-5) authorized up to $2.8 billion in total appropriations for Project BioShield for FY2014 through FY2018.

[12] U.S. Department of Health and Human Services, "Determination and Declaration Regarding Emergency Use of Doxycycline Hyclate Tablets Accompanied by Emergency Use Information," 73 *Fed. Reg.* 58242, October 1, 2008. President Obama created the National Postal Model emergency countermeasure distribution program by executive order. Executive Order 13527, "Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack," 75 *Fed. Reg.*737, January 6, 2010. For more on this program, see http://www.phe.gov/Preparedness/planning/postal/Pages/default.aspx.

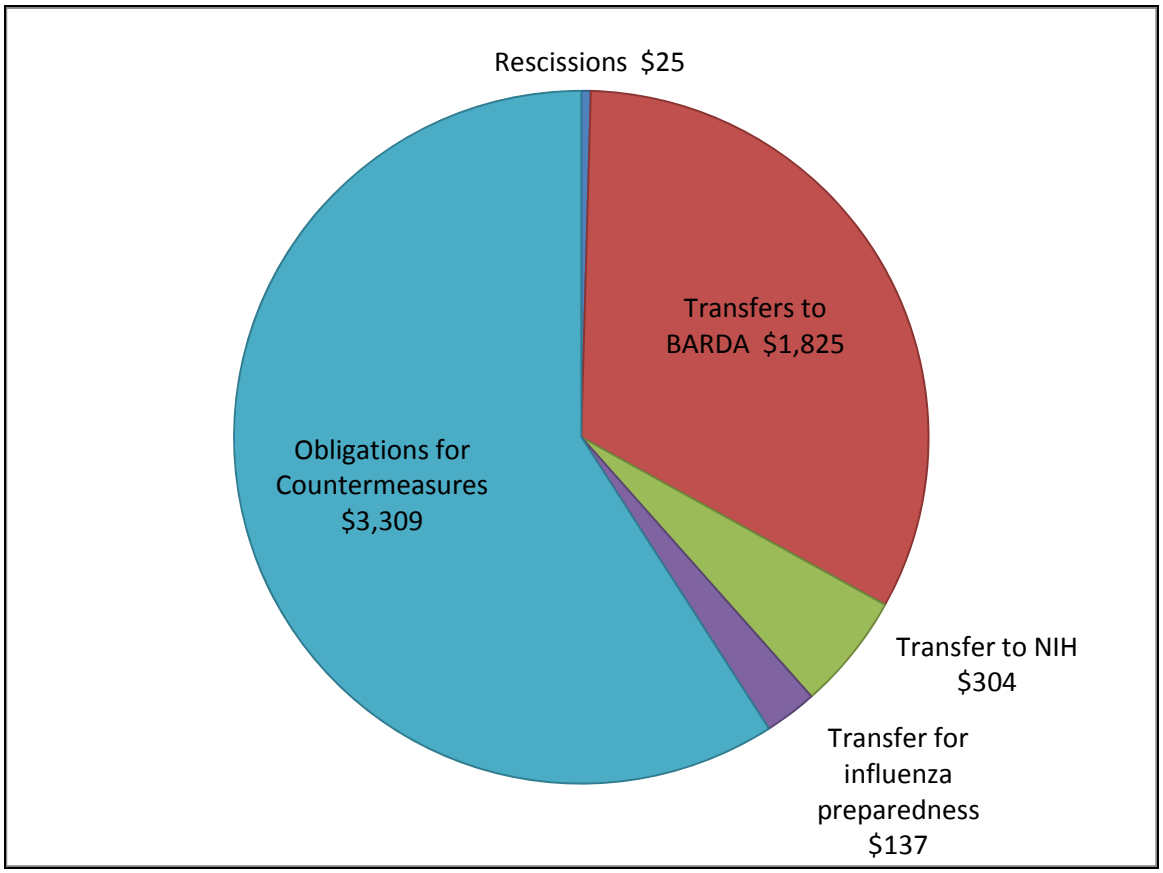
[13] U.S. Department of Health and Human Services, Food and Drug Administration, "Authorization of Emergency Use of Oral Formulations of Doxycycline; Availability," 76 *Fed. Reg.* 47197, August 4, 2011. For more information, see the FDA's EUA website, http://www.fda.gov/emergencypreparedness/counterterrorism/ucm182568.htm.

[14] U.S. Department of Health and Human Services, Food and Drug Administration, "Authorization of Emergency Use of an In Vitro Diagnostic for Detection of the Novel Avian Influenza A(H7N9) Virus; Availability," 78 *Fed. Reg.* 38044, June 25, 2013; and U.S. Department of Health and Human Services, Food and Drug Administration, "Authorization of Emergency Use of an In Vitro Diagnostic for Detection of the Middle East Respiratory Syndrome Coronavirus; Availability," 78 *Fed. Reg.* 42779, July 17, 2013.

[15] P.L. 111-117 stated that the transferred funds remained exclusively available for medical countermeasure procurement using the Project BioShield authorities.

Figure 1. Use of FY2004-FY2013 Advance Appropriations

(Millions)



Source: CRS analysis of FY2004-FY2013 appropriation acts, HHS reports, and HHS budget documents.

Of the $5.6 billion FY2004-FY2013 advance appropriation, Congress rescinded or transferred approximately $2.3 billion and HHS obligated the remaining approximately $3.3 billion for CBRN medical countermeasures. See **Figure 1**. Thus the average obligation rate for this time period was $330 million annually.

Since the expiration of the advance appropriation, requested and appropriated funding has been less than the authorized amount. For FY2014, the President requested $250 million "to remain available until expended" for the Project BioShield special reserve fund.[16] The Consolidated Appropriations Act, 2014 (P.L. 113-76) provided $255 million for Project BioShield acquisitions to remain available until expended. For FY2015, the President requests $415 million for Project BioShield acquisitions.[17]

[16] U.S. Department of Health and Human Services, *Public Health and Social Services Emergency Fund Justification of Estimates for Appropriations Committees FY2014*, pp. 18, 22, and 80-82.

[17] Executive Office of the President, Office of Management and Budget, *Fiscal Year 2015 Appendix Budget of the U.S. Government*, p. 493.

Rescissions and Transfers

While Congress used the advance appropriations mechanism to fund the first 10 years of the program, it retained the power to decrease or increase the amount in the special reserve fund through rescission, transfer, or additional appropriation. Congress rescinded or transferred for other purposes approximately 40% of the FY2004-FY2013 advance appropriation ($2.291 billion of $5.593 billion). See **Table 2**.

Table 2. Project BioShield Rescissions and Transfers

Fiscal Year	Public Law	Purpose	Amount ($ in millions)
2004	P.L. 108-199	Rescission	5
2005	P.L. 108-447	Rescission	20
2009	P.L. 111-8	Transfer for countermeasure advanced development	275
		Transfer for pandemic flu preparedness	137
2010	P.L. 111-117	Transfer for countermeasure advanced development	305
		Transfer for NIAID basic research	304
2011	P.L. 112-10	Transfer for countermeasure advanced development	415
2012	P.L. 112-74	Transfer for countermeasure advanced development	415
2013	P.L. 113-6	Transfer for countermeasure advanced development	415
		Rescissions and Transfers Enacted	2,291

Source: CRS analysis of P.L. 108-199, P.L. 108-447, P.L. 111-8, P.L. 111-117, P.L. 112-10, P.L. 112-74, and P.L. 113-6.

Note: Amounts rounded to nearest million.

Congress removed $25 million from this account through rescissions enacted in the Consolidated Appropriations Act, 2004 (P.L. 108-199) and the Consolidated Appropriations Act, 2005 (P.L. 108-447). Congress has also transferred funds from this account for various purposes. The Omnibus Appropriations Act, 2009 (P.L. 111-8) transferred $275 million to fund countermeasure advanced development through the Biomedical Advanced Research and Development Authority (BARDA; see "PHEMCE, BARDA, and BioShield " below) and $137 million to help respond to and prepare for pandemic influenza.[18] The Consolidated Appropriations Act, 2010 (P.L. 111-117) transferred $305 million to BARDA for countermeasure advanced development and $304 million to fund basic research on biodefense and emerging infectious diseases at the National Institute of Allergy and Infectious Diseases (NIAID, part of the National Institutes of Health). In FY2011, the Department of Defense and Full-Year Continuing Appropriations Act (P.L. 112-10) transferred $415 million to BARDA for countermeasure advanced development. The Consolidated Appropriations Act, FY2012 (P.L. 112-74) transferred $415 million to BARDA for countermeasure advanced development and administrative costs. In FY2013, the Consolidated and Further Continuing Appropriations Act, 2013 (P.L. 113-6) transferred $415 million to BARDA for countermeasure advanced development and administrative costs.

[18] U.S. Congress, House Committee on Appropriations, *Omnibus Appropriations Act, 2009, Legislative Text and Explanatory Statement Book 2 of 2*, committee print, 111th Cong., 1st sess., March 2009, J.Prt. 47-494 (Washington: GPO, 2009), p. 1301.

Acquisitions

The HHS obligated $3.3 billion of the $5.6 billion Project BioShield advance appropriation to acquire medical countermeasures against CBRN agents.[19] The HHS awarded Project BioShield contracts for 12 medical countermeasures against the CBRN threats anthrax, smallpox, botulinum toxin, radiological and nuclear threat agents, and nerve agents. These countermeasures include vaccines, antibodies, antivirals, and chemical compounds.[20] **Table 3** groups the Project BioShield countermeasures by threat and describes some of the details of the contracts.

Anthrax

The first Project BioShield contract was announced on November 4, 2004. The HHS contracted with VaxGen, Inc., for delivery of 75 million doses of a new type of anthrax vaccine (recombinant protective antigen or rPA) within three years. This contract had a value of $879 million. The HHS terminated this contract in 2006 because VaxGen, Inc., failed to meet a contract milestone.[21]

The HHS successfully used $1.454 billion of Project BioShield funds to acquire anthrax countermeasures. The HHS obligated roughly half of this total, $700 million, for 29 million doses of the currently approved anthrax vaccine, Anthrax Vaccine Adsorbed (AVA), from Emergent BioSolutions, Inc. The HHS obligated the other half on treatments for anthrax: $530 million for 125,000 doses of Raxibacumab from Human Genome Sciences, Inc., and GlaxoSmithKline, plc., and $224 million for 20 million doses of anthrax immune globulin from Cangene Corp.[22]

Smallpox

The HHS used $1.1 billion of Project BioShield funds to acquire smallpox countermeasures. The HHS obligated $652 million for 24 million doses of the Modified Vaccinia Ankara (MVA) smallpox vaccine from Bavarian Nordic, Inc. This vaccine is intended for use in people who have medical conditions that would prevent the use of the other smallpox vaccine in the stockpile. The HHS obligated $433 million for 1.7 million doses of the antiviral Arestvyr from SIGA Technologies, Inc.

Botulinum Toxin

The HHS used $476 million of Project BioShield funds to acquire botulinum toxin countermeasures. The HHS obligated that amount for 200,000 doses of botulinum antitoxin from Cangene Corp.

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[19] U.S. Department of Health and Human Services, *Project BioShield Annual Report to Congress January 2012-December 2012*, p. 4.

[20] U.S. Department of Health and Human Services, *Project BioShield Annual Report to Congress January 2012-December 2012*; and personal communications with HHS staff, August 11, 2013, November 4, 2013, and April 14, 2014.

[21] U.S. Department of Health and Human Services, "Termination Letter—Contract No. HHSO100200500001C," Letter to VaxGen, Inc., December 19, 2006.

[22] The Cangene contracts for anthrax immune globulin specify 10,000 doses of finished product and sufficient precursor material to produce 10,000 additional doses.

Radiological and Nuclear

The HHS used $235 million of Project BioShield funds to acquire radiological or nuclear countermeasures. The HHS obligated roughly 80% of this total, $195 million, for blood cell growth factors to be used to treat acute radiation syndrome. Amgen USA, Inc., will receive $157 million for 541,000 doses of Neupogen and Sanofi US, LLC, will receive $37 million for 66,000 doses of Leukine.[23] The HHS obligated $22 million to Akorn, Inc., for 474,000 doses of calcium/zinc diethylene triamine pentaacetic acid (DTPA), a treatment for internal radioactive particle contamination. The HHS obligated $18 million to Fleming Pharmaceuticals for 5 million doses of a pediatric form of potassium iodide, a preventative measure for radioactive iodine exposure.

Nerve Agent

The HHS used $58 million of Project BioShield funds to acquire nerve agent countermeasures. The HHS obligated this amount for 776,000 autoinjectors and 675,000 muti-dose vials of the anticonvulsant Midazolam from Pfizer, Inc.[24] This anticonvulsant would be used to treat seizures caused by exposure to nerve agents.

Unapproved Countermeasures

As discussed above, HHS may use Project BioShield to acquire products lacking FDA approval to the SNS. Some of the products that HHS acquired through Project BioShield, such as the AVA anthrax vaccine, had FDA approval at the time of their acquisition. Other Project BioShield countermeasures, such as Leukine, Neupogen, and Midazolam, have FDA approval for specific uses, but not for their intended stockpile use. The Project BioShield countermeasures Anthrax Immune Globulin, Raxibacumab, MVA smallpox vaccine, Arestvyr, and the botulinum antitoxin lacked any FDA approval at the time of their acquisition.

Project BioShield contracts have required that countermeasure developers seek FDA approval for their products' intended stockpile use. The countermeasures Raxibacumab and the botulinum antitoxin received FDA approval after their addition to the SNS.[25] During an emergency, countermeasures lacking FDA approval would likely be dispensed under an EUA.

[23] The Sanofi contract includes approximately $22 million for late stage development activities.

[24] This contract includes $30.2 million for late stage development activities.

[25] Letter from Edward Cox, Director, Office of Antimicrobial Product, Center for Drug Evaluation and Research, Food and Drug Administration, to Sally Bolmer, Senior Vice President, Development and Regulatory Affairs, Human Genome Sciences, Inc., December 14, 2012, http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/125349Orig1s000ltr.pdf; and Letter from Jay S. Epstein, Director, Office of Blood Research and Review, Center for Biologics Evaluation and Research, Food and Drug Administration, to Terry Kraynyk, Cangene Corporation, March 22, 2013, http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/ucm345137.htm.

Table 3. Project BioShield Acquisition Activity

Threat	Product	Doses (thousands)	Cost ($ millions)	Company	Award Date
Anthrax	rPA vaccine	0	2[a]	VaxGen, Inc.	11/2004
	AVA vaccine	28,750	700	Emergent BioSolutions, Inc. (formerly BioPort Corp.)	5/2005; 5/2006; 9/2007; 4/2012
	Raxibacumab	125	530	GlaxoSmithKline, plc (formerly Human Genome Sciences, Inc.)	6/2006; 7/2009; 9/2013
	Anthrax Immune Globulin	20[b]	224	Cangene Corp.	7/2006; 4/2012; 9/2013
Smallpox	MVA vaccine	24,000	652	Bavarian Nordic, Inc.	6/2007, 4/2012, 9/2012, 4/2013
	Arestvyr	1,700	433	SIGA Technologies, Inc.	5/2011
Botulinum Toxin	Botulinum antitoxin	200	476[c]	Cangene Corp.	6/2006; 6/2011
Radiological/ Nuclear	Potassium Iodide	4,800	18	Fleming Pharmaceuticals	3/2005; 2/2006
	Calcium/Zinc DTPA	474	22	Akorn, Inc.	2/2006
	Neupogen	541	157	Amgen USA, Inc.	9/2013
	Leukine	67	37[d]	Sanofi US, LLC	9/2013
Nerve Agent	Midazolam	776	58[e]	Pfizer, Inc.	9/2013
	Total:		**3,309**		

Source: CRS analysis of HHS's Project BioShield annual reports to Congress 2006-2012 and personal communications with HHS, August 11, 2013, November 4, 2013, and April 14, 2014.

Note: These figures may include multiple awards and/or subsequent award modification.

a. The HHS awarded VaxGen, Inc., $879 million for 75 million doses of rPA anthrax vaccine. When HHS terminated this contract in December 2006, VaxGen, Inc., kept approximately $2 million it had spent for HHS-mandated facility security upgrades. Personal communication with HHS, June 8, 2009.

b. This figure includes 10,000 doses of finished product and sufficient precursor material to produce 10,000 additional doses of finished product. HHS obligated $63 million for the precursor in September 2013.

c. This figure includes $50 million HHS obligated from the Project BioShield special reserve fund to this company in FY2004 after the DHS Appropriations Act, 2004, funded this account but before passage of the Project BioShield Act. See HHS, *Project BioShield Annual Report to Congress July 2004-July 2006*, p. 31.

d. This amount includes $14 million for the Leukine and $22 million for late stage development activities.

e. This amount includes $23 million for 776,000 autoinjectors, $5 million for 675,000 multidose vials, and $30 million for late stage development activities.

PHEMCE, BARDA, and BioShield

Project BioShield is only one piece of the federal efforts to develop and acquire medical countermeasures to protect against CBRN attacks. Homeland Security Presidential Directive 18 (HSPD-18), *Medical Countermeasures Against Weapons of Mass Destruction*, and Homeland Security Presidential Directive 21 (HSPD-21), *Public Health and Medical Preparedness*, provide the overall policy framework and strategy for federal efforts to develop and acquire CBRN countermeasures.

Implementation of the federal countermeasure strategy requires coordinated activities by several separate agencies. The interagency working group, the Public Health and Emergency Medical Countermeasure Enterprise (PHEMCE), is responsible for coordinating these activities to ensure federal countermeasure needs are addressed efficiently. The PHEMCE is headed by the HHS Assistant Secretary for Preparedness and Response and includes representatives from the FDA, Centers for Disease Control and Prevention, National Institutes of Health, Department of Defense, Department of Homeland Security, Department of Agriculture, and Department of Veterans Affairs.[26]

As part of the Office of the Assistant Secretary for Preparedness and Response, the Biomedical Advanced Research and Development Authority (BARDA) manages and executes Project BioShield contracts. The Pandemic and All-Hazards Preparedness Act (P.L. 109-417) established BARDA to develop and procure medical countermeasures against CBRN agents, pandemic influenza, and emerging infectious diseases. In addition to supporting countermeasure development through Project BioShield, BARDA can contract with companies to develop and commercialize potential countermeasures. These contracts specify development activities for the company to perform and may extend multiple years. The BARDA typically uses such contracts to support advanced development of CBRN countermeasures that it has determined are not yet mature enough for a Project BioShield acquisition contract. Thus, BARDA has two separate mechanisms to support CBRN countermeasure advanced development and commercialization: countermeasure advanced development contracts and Project BioShield acquisition contracts with developmental milestone payments.

In theory, HHS can contribute to all phases of a countermeasure's development: basic research supported by the National Institutes of Health and advanced development and commercialization supported by BARDA. HHS can purchase countermeasures using Project BioShield funds (through BARDA) or the Strategic National Stockpile funds (through the Centers for Disease Control and Prevention).

Legislation in the 113th Congress

The 113th Congress has enacted two laws with important ramifications for the use and effectiveness of Project BioShield: the Pandemic and All-Hazards Preparedness Reauthorization

[26] For additional information on PHEMCE, see U.S. Department of Health and Human Services, *2012 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy*; and U.S. Department of Health and Human Services, *2012 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Implementation Plan*, http://www.phe.gov/Preparedness/mcm/phemce/Pages/strategy.aspx.

Act of 2013 (PAHPRA, P.L. 113-5) and the Consolidated Appropriations Act, 2014 (P.L. 113-76). Additionally, Congress continues deliberation on a third piece of legislation with some Project BioShield-related provisions, the WMD Prevention and Preparedness Act of 2014 (H.R. 4034, introduced February 11, 2014).

PAHPRA

The 113th Congress reauthorized and modified key Project BioShield–related authorities through the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA, P.L. 113-5). The House passed its version of this bill (H.R. 307) on January 22, 2013. The Senate considered a related bill (S. 242), before passing an amended version of H.R. 307 on February 27, 2013. The House passed the Senate-amended version on March 4, 2013. The President signed PAHPRA into law on March 13, 2013.

This law extended the Project BioShield procurement program, changed some aspects of the countermeasure development and acquisition process, and modified some authorities relating to the use of unapproved countermeasures.

Project BioShield Appropriation Reauthorization and Modification

The PAHPRA extended the Project BioShield procurement program to FY2018. It authorized appropriations of $2.8 billion for five fiscal years (FY2014-FY2018), the same average annual appropriations as the $5.6 billion appropriated for FY2004-FY2013. It also authorized $415 million annually for BARDA advanced countermeasure development for the same period.

The PAHPRA provides the HHS Secretary with the authority to redirect Project BioShield appropriations to BARDA countermeasure advanced development activities. The Secretary may redirect up to a total of $1.4 billion of Project BioShield appropriations from FY2014 through FY2018. Such amounts would be in addition to any amounts Congress appropriated directly to BARDA for that purpose. This new authority allows future transfers, up to the statutory limit, at the discretion of the HHS Secretary rather than through the congressional appropriations process.

Countermeasure Development and Acquisition Process Modification

The PAHPRA provides HHS with additional flexibility in structuring Project BioShield procurement contracts. It explicitly allows Project BioShield countermeasure procurement contracts to include development costs. Additionally, it allows Project BioShield contracts to be signed up to 10 years before the expected delivery date of the countermeasure to the stockpile, rather than 8 years under previous law.

This law requires new formal planning activities and reporting. It requires the HHS Assistant Secretary for Preparedness and Response to develop an annual "coordinated 5-year budget plan" for countermeasure basic and advanced research, development, and procurement activities. This law also requires the HHS Assistant Secretary for Preparedness and Response to prepare and annually update the PHEMCE Strategy and Implementation Plan and provide it to Congress.[27]

[27] The HHS updated its 2007 Public Health and Emergency Medical Countermeasure Enterprise strategy and implementation plans in 2012. See https://www.medicalcountermeasures.gov/.

This law requires these plans to include specific information and analysis. The plans must describe the CBRN threats; describe the efforts to develop countermeasures for each threat; evaluate the progress of all activities to develop, procure, stockpile, deploy, and use countermeasures; identify and prioritize near-term, mid-term, and long-term needs; summarize all advanced development and procurement awards; provide timelines, metrics, and intended uses for each countermeasure under development; evaluate progress on all such awards; report the amount available in the BioShield fund; incorporate stakeholder input; and address the need for pediatric countermeasures. The PAHPRA also requires the annual plans to report each use of the authorities granted by the Project BioShield Act.

Use of Unapproved Countermeasures

Congress modified some aspects of the HHS emergency use authority for medical countermeasures through PAHPRA. The HHS Secretary may now issue an EUA following the determination that a significant potential for a public health emergency exists. This authority now parallels other previously granted authorities to issue an EUA on the basis of potential military or domestic emergencies. Under PAHPRA, all EUAs expire when the HHS Secretary determines the underlying emergency circumstances no longer exist rather than automatically after one year as under previous law. It also permits the Secretary to modify active EUAs.

The Secretary may now issue an EUA for countermeasures against any agents that DHS has determined pose a material threat to national security. As discussed above, a material threat determination is required for all Project BioShield countermeasure acquisitions. Thus, the HHS Secretary can issue an EUA for all countermeasures acquired through Project BioShield, regardless of whether a separately declared emergency or potential emergency exists.[28]

This law also permits the mass dispensing of approved medical countermeasures during an emergency without an individual prescription. Previously such distribution would require an EUA. This law also permits federal, state, or local governments to pre-position or stockpile unapproved medical countermeasures in anticipation of emergencies.

Consolidated Appropriations Act, 2014

The 10-year, $5.6 billion advance appropriation for Project BioShield expired at the end of FY2013. The Consolidated Appropriations Act, 2014 (P.L. 113-76) appropriated $255 million for Project BioShield acquisitions to remain available until expended. This was the first new appropriation into the Project BioShield fund since its inception in FY2004. In addition, Congress appropriated $415 million for BARDA for FY2014.

This appropriation act marks the transition from using a multiyear advance appropriation mechanism to annual appropriations. The FY2014 appropriation act is also the first year that Congress funded BARDA CBRN countermeasure development activities directly. As noted

[28] For additional information on EUA changes, see U.S. Department of Health and Human Services, Food and Drug Administration, *Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) Medical Countermeasure (MCM) Authorities: FDA Questions and Answers for Public Health Preparedness and Response Stakeholders*, January 2014, at http://www.fda.gov/downloads/EmergencyPreparedness/MedicalCountermeasures/UCM380269.pdf.

above, prior BARDA funding came from Congress transferring funds from the Project BioShield advance appropriations.

WMD Prevention and Preparedness Act of 2014

The WMD Prevention and Preparedness Act of 2014 (H.R. 4034, introduced February 11, 2014) contains Project BioShield and BARDA-related provisions. This bill was referred to the House Committees on Homeland Security, Energy and Commerce, Transportation and Infrastructure, Foreign Affairs, and Intelligence. The 112th Congress considered, but did not enact, similar legislation, the WMD Prevention and Preparedness Act of 2011 (H.R. 2356).[29]

H.R. 4034 would create new formal planning and reporting activities, and a new White House Special Assistant to the President for Biodefense to coordinate federal biodefense policy. This person would be the principal advisor to the President on coordination of federal biodefense policy, be responsible for developing several federal biodefense-related plans, and conduct oversight and evaluation of federal biodefense activities.

The Special Assistant to the President for Biodefense would lead the development of a National Biodefense Plan that would include prevention, protection, response, and recovery activities. This plan would identify which biological risks facing the nation should be addressed; delineate the activities to be performed to address these risks; identify biodefense assets and capability gaps; define organizational roles and responsibilities; and incorporate input from stakeholders. This report would be delivered to the President and Congress 18 months after enactment and updated as necessary.

The Special Assistant to the President for Biodefense would also lead the development of an annual cross-cutting biodefense budget analysis. This submission would include detailed, account-level amounts for biodefense activities and how these activities support the National Biodefense Plan. This analysis would include the biodefense budgets of the Departments of Agriculture, Commerce, Defense, Energy, Health and Human Services, Homeland Security, State, Veterans Affairs, Justice, and the Environmental Protection Agency, National Science Foundation, and United States Postal Service.

H.R. 4034 would require DHS to review whether those CBRN agents that it previously determined pose a material threat to national security continue to do so. DHS reassessment of an agent as no longer a material threat would result in some countermeasures becoming excluded from Project BioShield.

Policy Issues and Options for Congress

Although the 113th Congress addressed several Project BioShield-related policy issues through PAHPRA (P.L. 113-5) and the Consolidated Appropriations Act, 2014 (P.L. 113-76), several issues remain. The 113th Congress will make several policy choices through the appropriations process, including how much to fund Project BioShield, whether to continue using annual appropriations, and whether to place limits on the uses of funds appropriated for Project

[29] H.Rept. 112-665.

BioShield. Other issues that the 113th Congress may consider include how to fund the replacement of expiring countermeasures and whether the planning process has appropriately prioritized which countermeasures to acquire.

Appropriations

The 113th Congress will consider whether to continue to provide funds for Project BioShield acquisitions. Congressional policy makers could decide not to fund Project BioShield for several reasons. One reason could stem from the difficulty in determining how much safer Project BioShield has made the nation. Given the continued absence of any CBRN terrorist attacks in the United States since 2001, congressional policy makers could deem that the perceived risk of an attack no longer justifies continued investment in Project BioShield. Alternatively, policy makers could deem other, more conventional, countermeasure procurement methods sufficient or more efficient than Project BioShield and redirect funding to those programs. Finally, policy makers could decide that those funds could be better used for other federal uses or not spent.

If Congress decides to appropriate funds for Project BioShield, then it will face additional policy choices regarding how much to provide and whether to use an advance appropriation.

Funding Amount

Congressional policy makers determining funding for Project BioShield may consider several, sometimes conflicting, factors. The 108th Congress used the advance appropriations mechanism to provide $5.6 billion to Project BioShield for 10 years, thus anticipating an average annual obligation rate of $560 million. However, through FY2013, HHS obligated these funds at a slower pace, an average of $330 million annually. Additionally, HHS could have purchased some of these products through other funding sources, such as SNS appropriations. This historic obligation rate could be used to support funding below the authorized levels.

Alternatively, congressional policy makers might decide to maintain the current level of funding or increase it. Since 2001, HHS has spent more than $15 billion on biodefense-related research and countermeasure development.[30] Congressional policy makers could determine that this investment will soon begin producing more countermeasures eligible for Project BioShield contracts in the near future. The HHS estimates that up to 12 new medical countermeasures will be ready for Project BioShield contracts by 2018.[31] A potential increase in eligible countermeasures might lead Congress to maintain or increase the average annual appropriation for Project BioShield acquisitions.

In FY2014, the first year after the exhaustion of the advance appropriation, Congress appropriated $255 million for Project BioShield acquisitions. This was $5 million over the President's budget request, but lower than the 10-year average obligation rate for this program of $330 million. For FY2015, the President has requested $415 million, approximately 25% more than the historic obligation rate.

[30] For one estimate, see Crystal Franco and Tara Kirk Sell, "Federal Agency Biodefense Funding, FY2012-FY2013," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, vol. 10, no. 2 (2012), pp. 162-181.

[31] U.S. Department of Health and Human Services, *Public Health and Social Services Emergency Fund Justification of Estimates for Appropriations Committees FY2015*, p. 54.

Annual or Advance Funding

The 113th Congress and the Administration have chosen to use the annual appropriations process to fund Project BioShield. This contrasts with the previous method of providing a single appropriation for the duration of the appropriations authority. This change affects both the private countermeasure developers and the federal countermeasure planners.

Developers contend that a multiyear advance-funded account devoted to Project BioShield acquisitions remains integral to their ability to develop countermeasures. Some developers contend that an advance appropriation helps company management more favorably consider a potential countermeasure when weighing internal investment opportunity costs. Additionally, some developers assert that an advance appropriation makes it easier to obtain capital from external investors.[32]

The switch to annual appropriations may complicate HHS's long-term countermeasure development and acquisition planning. However, other agencies, such as the Department of Defense and NASA, successfully use the annual appropriations process for complex, multiyear acquisitions. The federal countermeasure development process will likely continue to produce uneven acquisition opportunities and activity. In some years, one or multiple countermeasures may reach a point in development that HHS deems appropriate for a Project BioShield contract. In those years, HHS might obligate hundreds of millions of dollars to acquire countermeasures. However, in years in which no countermeasures reach that point in development, HHS might not obligate any money for Project BioShield contracts. This issue may be partially addressed by Congress allowing the funds to remain available until expended or until the appropriation authority expires. Congress did so for the FY2014 appropriation and the President has requested this for FY2015 as well.

Alternatively, Congress could use the advance appropriations mechanism to provide funding for multiple years as it did for FY2004-FY2013. This may address the developers' desire for a multiyear appropriation and may help HHS's ability to plan acquisition programs. Developers might prefer advance appropriations for as long a period as possible. However, providing an advance appropriation during the current fiscal environment may prove more difficult than in 2003. Additionally, increasing the duration of the advance appropriation may make it more likely that future Congresses transfer money out of the account for other purposes. Advance appropriating funds for more than one year but less than the four remaining years might balance these competing pressures.

Prior Project BioShield performance might influence congressional policy makers as well. Those who assess the program's production with an advance appropriation favorably might be more likely to support a return to an advance appropriation. Those assessing its performance negatively might be more likely to support an annual appropriation process.

[32] U.S. Congress, House Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, *Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations for 2011*, Part 6, Statements of Members of Congress and Other Interested Individuals and Organizations, 111th Cong., 2nd sess., May 12, 2010 (Washington: GPO, 2010), pp. 197-204.

Use of Project BioShield Appropriations for Other Purposes

Congress has used funds appropriated for Project BioShield acquisitions for other purposes (see **Figure 1**). Congress transferred approximately one-third of the Project BioShield advance appropriation to fund BARDA activities. The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA, P.L. 113-5) allows the HHS Secretary to transfer up to $1.4 billion of FY2014 through FY2018 Project BioShield appropriations to BARDA for countermeasure advanced development. Thus, the HHS Secretary could transfer the entire $255 million FY2014 Project BioShield appropriation to BARDA for advanced development. The Secretary must notify Congress of such transfers and annually report the amount of funding remaining available for Project BioShield procurements. Congressional oversight of such transfers could help ensure that HHS uses Project BioShield appropriations in a manner consistent with congressional intent. Congress could restrict or expand such transfers through future appropriation law provisions.

Countermeasure Replacement Costs

All biomedical countermeasures have a finite shelf-life after which their safety and efficacy may decrease. Thus, the government will need to replace the countermeasures in the SNS in order to maintain the same degree of preparedness. If the federal government increases the number of countermeasures, then such costs would likely increase. The HHS has used funding from the SNS annual appropriations and the Project BioShield advance appropriations to purchase replacements for expiring countermeasures.[33] The National Biodefense Science Board (NBSB) projected that countermeasure replacement costs will pose an increasing strain on SNS funding.[34] Several strategies may mitigate countermeasure replacement costs, including better development and acquisition planning, contracting with vendors to manage and store countermeasures, developing countermeasures with longer shelf lives, extending the shelf life of currently stored countermeasures, and developing broad spectrum countermeasures.

The federal government might mitigate some replacement costs through better planning. According to the NBSB and a 2010 internal HHS review, PHEMCE had insufficiently considered lifecycle costs during countermeasure acquisition planning.[35] Subsequently, HHS has begun a five-year countermeasure budget plan process that includes consideration of replacement costs.[36] The Pandemic and All-Hazards Preparedness Reauthorization Act (P.L. 113-5) codified this

[33] Project BioShield contracts have been used to replace expiring anthrax and smallpox vaccines and the anthrax treatments Raxibacumab and Anthrax Immune Globulin.

[34] National Biodefense Science Board and Office of Public Health Preparedness and Health Response Board of Scientific Counselors, *Anticipated Responsibilities of the Strategic National Stockpile (SNS) in the Year 2020: An Examination with Recommendations*, Washington, DC, April 3, 2013, p. 4.

[35] National Biodefense Science Board and Office of Public Health Preparedness and Health Response Board of Scientific Counselors, *Anticipated Responsibilities of the Strategic National Stockpile (SNS) in the Year 2020: An Examination with Recommendations*, Washington, DC, April 3, 2013, p. 4; and Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services, *The Public Health Emergency Medical Countermeasure Enterprise Review*, August 2010, p. 18.

[36] George Korch, Senior Science Advisor to the Assistant Secretary for Preparedness and Response, in testimony before the House Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, *Oversight Hearing—Public Health Emergency Medical Countermeasure Enterprise*, 113th Cong., 2nd sess., February 27, 2014.

planning requirement, explicitly requiring consideration of replenishment costs in the five-year countermeasure budget plan.

For countermeasures with viable commercial markets, such as antibiotics, the government can reduce replacement costs by contracting with the vendor to store the countermeasure. The vendor rotates its normal commercial stock through this storage. Thus, rather than the government acquiring specific vials of countermeasure that will expire, the government has acquired the right to immediately access a specific amount of countermeasure that the vendor is constantly refreshing. According to BARDA, this vendor-managed-inventory approach "ensures [countermeasures] will not expire due to stockpiling and significantly reduces the overall life-cycle management cost for these products."[37] The Project BioShield contracts for the anti-radiation countermeasures Leukine and Neupogen use this vendor-managed-inventory model.[38]

Countermeasures requiring less frequent replacement could reduce cost. The PHEMCE is actively pursuing countermeasures that have a longer shelf-life than current versions. For example, BARDA is supporting the advanced development of a more stable smallpox vaccine.

The FDA Shelf Life Extension Program can extend the useful life for stored countermeasures beyond their original expiration date. Through this program, the FDA tests the stability and quality of drugs stored in the SNS and other federal partners. The FDA may approve a new expiration date for those drug lots meeting the appropriate criteria.[39] This program is only available for countermeasures regulated as drugs, not those regulated as biologics. Many of the most expensive countermeasures acquired through Project BioShield, including vaccines and the anthrax and botulinum antitoxins, are biologics and not eligible for this FDA program.

Reducing the number of products in the SNS may lower replacement costs. Such a reduction may occur by HHS shifting towards acquiring countermeasures that address multiple material threats. Additionally, countermeasures designed against multiple threats may be more likely to have a commercial market. For example, BARDA is supporting the advanced development of a new antibiotic to treat plague and tularemia that may have a commercial market for treating certain pneumonias and urinary tract infections.[40]

Countermeasure Prioritization

The Project BioShield contracts have not been used to acquire countermeasures against all of the material threats determined by DHS. Of the $3.3 billion of Project BioShield appropriations used to acquire countermeasures, HHS devoted approximately 90% to just three threats: anthrax, smallpox, and botulinum. See **Figure 2**. Project BioShield did not acquire any countermeasures against the other eight material threats.

[37] U.S. Department of Health and Human Services, *Public Health and Social Services Emergency Fund Justification of Estimates for Appropriations Committees FY2015*, p. 55.

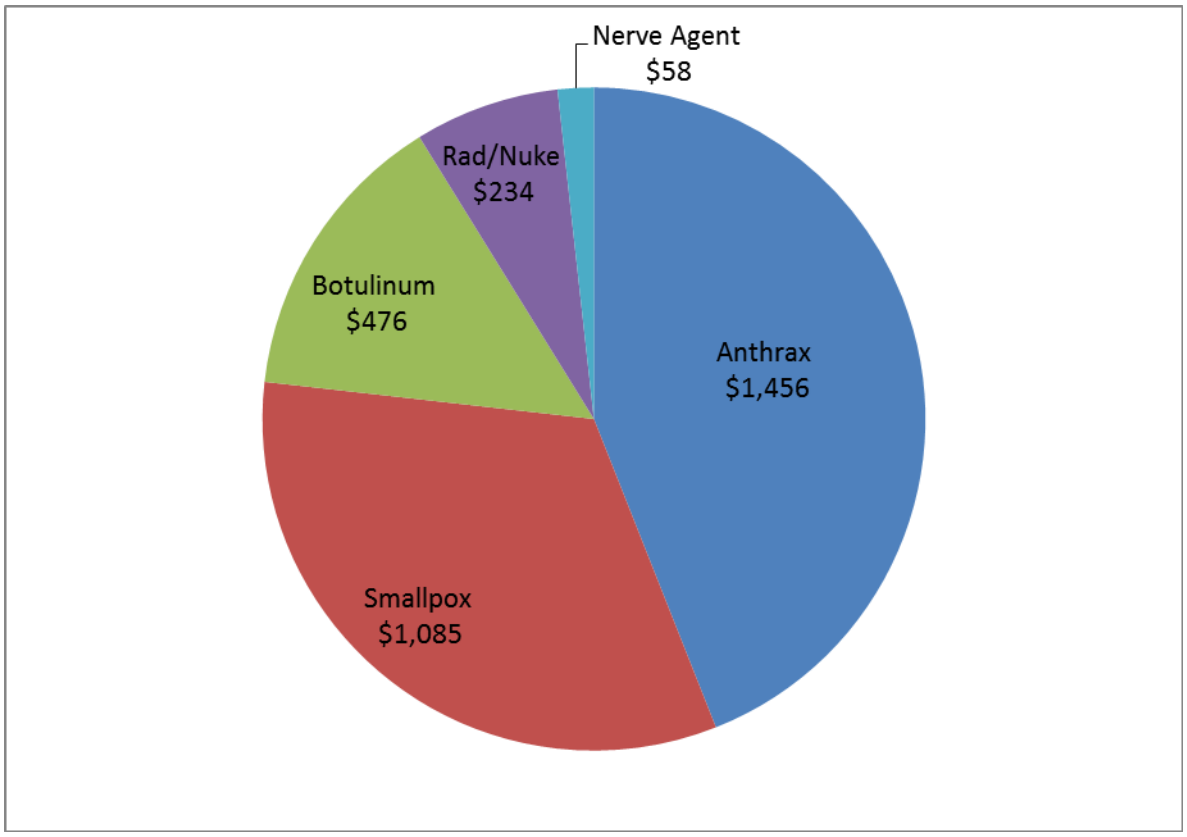
[38] U.S. Department of Health and Human Services, *Public Health and Social Services Emergency Fund Justification of Estimates for Appropriations Committees FY2015*, p. 55.

[39] U.S. Department of Health and Human Services Food and Drug Administration, *Medical Countermeasures Initiative FY2013 Program Update*, 2013, p. 7.

[40] U.S. Department of Health and Human Services, *Public Health and Social Services Emergency Fund Justification of Estimates for Appropriations Committees FY2015*, p. 58.

Figure 2. Project BioShield Countermeasure Acquisition by Threat FY2004-FY2014

($ in millions)



Source: CRS analysis of HHS budget documents.

Notes: The total only includes amounts used for countermeasure acquisition. It excludes amounts transferred for other purposes or rescinded.

Medical countermeasure procurement planning is complex. The disparity between material threats and acquired countermeasures might be attributable to any of the following factors. A DHS material threat determination is required for Project BioShield countermeasure procurement, but it does not address how appropriate it is that HHS pursue a countermeasure through Project BioShield. Planners must consider many other factors in pursuing a balanced countermeasure portfolio, including whether existing commercially available countermeasures might address the threat; the likely impact of a successful attack; how effectively a countermeasure could be deployed and used during an emergency; how much time and money the countermeasure would need before it could be added to the stockpile; and the cost and benefit gained from a countermeasure compared to other potential countermeasures.

Despite the complicated decision processes associated with countermeasure development and acquisition planning, active congressional oversight may help ensure the most effective use of Project BioShield funds. Such oversight may be helped through more detailed HHS reporting requirements mandated in the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (P.L. 113-5).

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