



Project BioShield: Purposes and Authorities

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Summary

Many potential chemical, biological, radiological, and nuclear (CBRN) terrorism agents lack available countermeasures. In 2003, President Bush proposed Project BioShield to address this need. The Project BioShield Act became law in July 2004 (P.L. 108-276).

This law has three main provisions: (1) relaxing procedures for some CBRN terrorism-related spending, including hiring and awarding research grants; (2) guaranteeing a federal government market for new CBRN medical countermeasures; and (3) permitting emergency use of unapproved countermeasures. The Department of Health and Human Services (HHS) has used each of these authorities. The HHS used expedited review authorities to approve grants relating to developing treatments for radiation exposure and used the authority to guarantee a government market to obligate approximately \$2.3 billion to acquire countermeasures against anthrax, botulism, radiation, and smallpox. The HHS has also employed the emergency use authority several times including allowing young children with H1N1 “swine flu” to receive specific antiviral drugs.

The Department of Homeland Security Appropriations Act, 2004 (P.L. 108-90) advance-appropriated \$5.593 billion for FY2004 to FY2013 for Project BioShield. In addition to the approximately \$2.3 billion used for countermeasure procurement, Congress has decreased the available amount in the BioShield account. In FY2004 and FY2005, Congress removed approximately a total of \$25 million through rescissions. In the Omnibus Appropriations Act, 2009 (P.L. 111-8), Congress transferred \$412 million to other programs to support countermeasure advanced research and development and pandemic influenza preparedness and response. President Obama has proposed transferring an additional \$305 million in FY2010 to support countermeasure advanced research and development. The administration also seeks to transfer management of this account from the Department of Homeland Security to HHS. The President has also requested that the type of countermeasures that could be procured using these funds be expanded from solely CBRN to include countermeasures against pandemic influenza. Such an action would likely decrease the amount of BioShield money that would be available for CBRN countermeasures.

Since passing the Project BioShield Act, subsequent congresses have considered additional measures to further encourage countermeasure development. The 109th Congress passed the Pandemic and All-Hazard Preparedness Act (P.L. 109-417) which created the Biomedical Advanced Research and Development Authority (BARDA) in HHS. This office oversees all of HHS’ Project BioShield activities, amongst other duties. The Pandemic and All-Hazard Preparedness Act also modified the Project BioShield procurement process. Questions remain regarding whether these changes have sufficiently improved countermeasure development and procurement.

The 111th Congress faces several challenging policy decisions. Primary among them is assessing whether Project BioShield is successfully encouraging medical countermeasure development. A second issue is whether to allow additional diversions of Project BioShield appropriations, a key element of the government’s market guarantee, to support other activities. A third is whether to broaden what has been a CBRN countermeasure mandate in the face of other threats such as pandemic influenza.

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Introduction

Following the terrorist attacks of 2001, the federal government determined that it would need new medical countermeasures (e.g., diagnostic tests, drugs, vaccines, and other treatments) to respond to an attack using chemical, biological, radiological, or nuclear (CBRN) agents.¹ The pharmaceutical industry attributes the paucity of CBRN agent countermeasures to the lack of a significant commercial market.² Because these diseases and conditions occur infrequently, the private sector perceives little economic incentive to invest the millions of dollars required to bring treatments to market.

The Project BioShield Act

To encourage the development of new CBRN countermeasures, 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).³ This act has three main provisions. It provides the Department of Health and Human Services (HHS) expedited procedures for CBRN terrorism-related spending including procuring products, hiring experts, and awarding research grants. The act creates a government-market guarantee by allowing the HHS Secretary to obligate funds to purchase countermeasures while they still have several more years of development. The act also authorizes the HHS Secretary to temporarily allow the emergency use of countermeasures that lack Food and Drug Administration (FDA) approval.

Expedited Procedures

The act relaxes procedures under the Federal Acquisition Regulation for procuring property or services used in performing, administering, or supporting CBRN countermeasure research and development (R&D). These expedited procedures decrease both the amount of paperwork required for these expenditures and the potential for oversight. The act increases the maximum amount, from \$100,000 to \$25 million, for contracts awarded under simplified acquisition procedures. It also allows these purchases using other than full and open competition. Congress granted similar, but smaller, contract-level increases to the Department of Homeland Security (DHS) and other departments and agencies in the Homeland Security Act (P.L. 107-296) and the National Defense Authorization Act, 2004 (P.L. 108-136). According to HHS, it has not used these authorities.⁴

¹ For additional information and analysis of the procurement provisions of Project BioShield, see CRS Report RL33907, *Project BioShield: Appropriations, Acquisitions, and Policy Implementation Issues for Congress*, by Frank Gottron.

² Alan Pemberton, Pharmaceutical Research and Manufacturers of America, Testimony before the U.S. House of Representatives Select Committee on Homeland Security, May 15, 2003.

³ For a detailed comparison of the legislative proposals, see CRS Report RL32549, *Project BioShield: Legislative History and Side-by-Side Comparison of H.R. 2122, S. 15, and S. 1504*, by Frank Gottron and Eric A. Fischer.

⁴ See HHS, *Project BioShield: Annual Report to Congress July 2004—July 2006*, and HHS, *Project BioShield: Annual Report to Congress August 2006—July 2007*. These reports are available at <http://www.hhs.gov/aspr/barda/bioshield/annualreport/>.

The Project BioShield Act authorizes the HHS Secretary to use an expedited award process for grants, contracts, and cooperative agreements related to CBRN countermeasure R&D activity, if the Secretary deems a pressing need for an expedited award exists. This authority is limited to awards of \$1.5 million or less. This expedited award process replaces the normal peer review process. Some scientists have expressed concerns that an expedited review process will reduce research quality.⁵ The normal peer review process is designed to provide proposals with greater scientific merit a higher probability of receiving funding, a factor potentially lost in an expedited process.

According to HHS, it has awarded 14 grants through this expedited peer review process.⁶ The National Institutes of Allergy and Infectious Diseases (NIAID) awarded these grants between three and five months of the application deadline.⁷ All awards were related to medical countermeasures to be used following radiation exposure.

Market Guarantee

The Project BioShield act is designed to guarantee companies that the government will buy new, successfully developed CBRN countermeasures for the Strategic National Stockpile (SNS).⁸ The act allows the HHS Secretary, with the concurrence of the DHS Secretary and upon the approval of the President, to promise to buy a product up to eight years before it is reasonably expected to be delivered.⁹ A company was to be paid only on the delivery of a substantial portion of the countermeasure. Therefore, this guarantee reduces the market risk for the company but does not affect its exposure to development risk (i.e., the risk that the countermeasure will fail during testing and be undeliverable). The Pandemic and All-Hazard Preparedness Act (P.L. 109-417) modified the Project BioShield Act to allow for milestone-based payments of up to half of the total award before delivery.¹⁰

The Project BioShield Act allows HHS to purchase unapproved and unlicensed countermeasures. It requires the HHS Secretary to determine that "... sufficient and satisfactory clinical experience or research data ... support[s] a reasonable conclusion that the product will qualify for approval or licensing ... within eight years."¹¹ The approval and licensing processes are designed to protect people from ineffective or dangerous treatments. Because most drugs that begin these processes fail to become approved treatments, critics of this provision suggest that the government will end up purchasing countermeasures that may never be approved. To reduce the government's

⁵ John Miller, "Interview with Richard Ebright," *The Scientist*, vol. 17 (7), April 7, 2003, p. 52.

⁶ See HHS, *Project BioShield: Annual Report to Congress July 2004—July 2006*, p. 2, and HHS, *Project BioShield: Annual Report to Congress August 2006—July 2007*, p. 32.

⁷ Grants that go through the normal peer review process typically take nine to 18 months to receive funding. See http://www.niaid.nih.gov/ncn/grants/charts/timeline_resub.htm.

⁸ The SNS contains pharmaceuticals, vaccines, medical supplies, and medical equipment to respond to terrorist attacks and other emergencies.

⁹ President Bush delegated the presidential approval step to the Director of the Office of Management and Budget. OMB maintains this authority in the Obama administration. See, Executive Office of the President, "Designation and Authorization to Perform Functions Under Section 319F-2 of the Public Health Service Act," 69 *Federal Register* 70349, December 3, 2004.

¹⁰ For more on this law, 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.

¹¹ 118 Stat. 844.

financial risk associated with this provision, the act allows HHS to write contracts so that unapproved products may be purchased at lower cost than approved products. HHS used some of these authorities when designing each of the Project BioShield contracts discussed below (“Acquisitions”).

Emergency Use of Unapproved Products

The Project BioShield Act also allows the HHS Secretary to temporarily authorize the emergency use of medical products that are not approved by the FDA or HHS. To exercise this authority, the HHS Secretary must conclude that: (1) the agent for which the countermeasure is designed can cause serious or life-threatening disease; (2) the product may reasonably be believed to be effective in detecting, diagnosing, treating, or preventing the disease; (3) the known and potential benefits of the product outweigh its known and potential risks; (4) no adequate alternative to the product is approved and available; and (5) any other criteria prescribed in regulation are met.¹²

The HHS Secretary has used this emergency use authority (EUA) several times. Currently, four countermeasures to the 2009 influenza A (H1N1)¹³ outbreak are permitted to be used under EUA: the antiviral influenza treatments Tamiflu (oseltamivir) and Relenza (zanamivir),¹⁴ N95 respirators, and diagnostic kits to help identify cases of this disease.¹⁵ As of October 2008, antibiotic kits containing Doxycycline Hyclate are allowed to be distributed to certain people participating in the Cities Readiness Initiative.¹⁶ That EUA remains in effect. In January 2005, the HHS Secretary used this authority to allow the vaccination of Department of Defense (DOD) personnel with a specified type of anthrax vaccine.¹⁷ This vaccine EUA expired in January 2006.

Reporting Requirements

The Project BioShield Act of 2004 requires annual reports from the HHS Secretary about the exercise of the authorities granted in this bill.¹⁸ This act also requires the Government Accountability Office (GAO) to produce a single report assessing actions taken under authorities granted by the act, determining the effectiveness of the act, and recommending additional measures to address deficiencies. GAO expects to issue this report in July 2009.¹⁹

¹² 118 Stat. 855.

¹³ For additional information, see CRS Report R40554, *The 2009 Influenza Pandemic: An Overview*, by Sarah A. Lister and C. Stephen Redhead.

¹⁴ Although the antiviral treatments had been previously approved for treating influenza, the EUA makes it easier to distribute these treatments and allows their use for infants and children younger than had been previously allowed.

¹⁵ For more information on these EUAs, see <http://www.cdc.gov/swineflu/eua/>.

¹⁶ 73 *Fed. Reg.* 62507. For more on this program, see <http://www.bt.cdc.gov/cri/>.

¹⁷ 70 *Fed. Reg.* 5452.

¹⁸ Available online at <http://www.hhs.gov/aspr/barda/bioshield/annualreport/>.

¹⁹ Personal communication with GAO, April 10, 2009.

Appropriations

The Project BioShield Act did not appropriate any money. Instead, it authorized the appropriation of up to a total of \$5.593 billion for FY2004 through FY2013 for countermeasures procurement. The Department of Homeland Security Appropriations Act, 2004 (P.L. 108-90) appropriated this amount into a special reserve fund with explicit time windows in which the money could be obligated. The act specified that \$3.418 billion was available for obligation for FY2004 to FY2008. The balance of the advance appropriation plus any unobligated funds remaining from FY2004 to FY2008 became available for FY2009 to FY2013. The act specified that this money is only for the procurement of CBRN countermeasures using the Project BioShield authorities and may not be used for other purposes such as for grants to support countermeasure development or program administration.

Congress advance-appropriated the 10-year program, but retains the power to annually increase or decrease the amount in the special reserve fund. Congress removed \$25 million from this account through rescissions in the Consolidated Appropriations Act, 2004 (P.L. 108-199), and the Consolidated Appropriations Act, 2005 (P.L. 108-447). See **Table 1**. The Omnibus Appropriations Act, 2009 (P.L. 111-8), transferred \$412 million from the special reserve fund to HHS. Of this amount, \$275 million went to fund countermeasure advanced research and development through the Biodefense Advanced Research and Development Authority (BARDA, see below), and \$137 million went to help respond to and prepare for pandemic influenza.²⁰

Table 1. Project BioShield Rescissions, and Transfers

(\$ in Millions)

Public Law	Action	Amount
P.L. 108-199	0.59% Rescission	5
P.L. 108-447	0.8% Rescission	20
P.L. 111-8	Transfer for Advanced Development	275
P.L. 111-8	Transfer for Pandemic Flu	137
Total of Transfers and Rescissions to Date		437
President's FY2010 Budget Request	Transfer for Advanced Development	305

Source: CRS analysis of P.L. 108-199, P.L. 108-447, P.L. 111-8, and FY2010 Presidential Budget Request.

Note: Amounts rounded to nearest million.

The Obama administration has proposed transferring the remaining Project BioShield advance-appropriated funds from DHS to HHS in FY2010. After accounting for expected obligations in FY2009, the Administration estimates the remaining balance will be \$1.569 billion. Because of a “lower than expected obligation rate,”²¹ \$305 million of the transferred amount would fund countermeasure advanced development through BARDA.²² According to this proposal, any

²⁰ U.S. Congress, House Committee on Appropriations, *Omnibus Appropriations Act, 2009 (H.R. 1105; P.L. 111-8)*, committee print, 111th Cong., 1st sess., March 2009, p. 1301.

²¹ DHS, Office of Health Affairs, *Biodefense Countermeasures Congressional Justification FY2010*, p. BIO-2.

²² HHS, *FY2010 Budget in Brief*, p. 108.

remaining transferred funds would go into the HHS Public Health and Social Services Emergency Fund and be available for obligation through FY2013 for Project BioShield-related purchases.

Acquisitions

The first Project BioShield contract was announced on November 4, 2004.²³ The HHS contracted with VaxGen Inc. for delivery of 75 million doses of a new type of anthrax vaccine within three years. This contract was worth \$879 million. See **Table 2**. On December 17, 2006, HHS terminated this contract because VaxGen failed to meet a contract milestone.²⁴ Subsequent contracts include \$690 million for 29 million doses of the currently approved anthrax vaccine (Emergent BioSolutions); \$165 million for 20 thousand doses of ABthrax, a treatment for anthrax (Human Genome Sciences); \$144 million for 10 thousand doses of Anthrax Immune Globulin, a treatment for anthrax (Cangene); \$505 million for 20 million doses of a new smallpox vaccine (Bavarian Nordic); \$416 million for 200 thousand doses of botulinum antitoxin, a treatment for botulinum toxin exposure (Cangene); \$18 million for 5 million doses of a pediatric form of potassium iodide, a treatment for radioactive iodine exposure (Fleming & Company); and \$22 million for 395 thousand doses of Ca-DTPA and 80 thousand doses of Zn-DTPA, two treatments for internal radioactive particle contamination (Akorn). Thus, excluding the canceled VaxGen contract, HHS has obligated approximately \$1.96 billion to date. Future targets for Project BioShield procurement include countermeasures against anthrax, viral hemorrhagic fevers, and radiation.²⁵

²³ See the HHS Project BioShield procurement page for status of current requests and contracts at <http://www.hhs.gov/aspr/barda/procurement/cbrnactivities.html>. For issues regarding these awards, see CRS Report RL33907, *Project BioShield: Appropriations, Acquisitions, and Policy Implementation Issues for Congress*, by Frank Gottron.

²⁴ HHS, "Termination Letter - Contract No. HHSO100200500001C," Letter to VaxGen, Inc., December 19, 2006.

²⁵ HHS Public Health Emergency Medical Countermeasure Enterprise, "Implementation Plan For Chemical, Biological, Radiological and Nuclear Threats," *72 Fed. Reg.* 20122, April 23, 2007.

Table 2. Project BioShield Acquisition Activity

Threat	Product	Doses (thousands)	Cost (\$ millions)	Company	Award Date
Anthrax	rPA vaccine	75,000	879 ^a	VaxGen, Inc.	11/4/04; Cancelled 12/19/06
	AVA vaccine ^b	28,750	690	Emergent BioSolutions (formerly BioPort Corp.)	5/6/05; 5/5/06; 9/25/07
	ABthrax	20	165	Human Genome Sciences	6/19/06
	Anthrax Immune Globulin	10	144	Cangene Corp.	7/28/06
Smallpox	MVA vaccine	20,000	505	Bavarian Nordic A/S	6/4/07
Botulinum Toxin	Botulinum Antitoxin	200	416	Cangene Corp.	6/1/06 ^c
Radiological/ Nuclear	Potassium Iodide	4,800	18	Fleming & Company	3/18/05 and 2/8/06
	Ca-DTPA	395	22	Akorn, Inc.	2/13/06
	Zn-DTPA	80			
Total Announced Obligations:			2,839		
Total Active Announced Obligations^d:			1,961		

Source: CRS analysis of HHS, Project BioShield: Annual Report to Congress July 2004—July 2006, January 2007; HHS, Project BioShield: Annual Report to Congress August 2006—July 2007; HHS, “CBRN Acquisition Activities” <http://www.hhs.gov/aspr/barda/procurement/cbrnactivities.html>; DHS, Office of Health Affairs, Biodefense Countermeasures Congressional Justification FY2010; and personal communication with HHS, June 8, 2009.

- a. This figure includes an additional approximately \$1.5 million that HHS paid to VaxGen for mandatory security upgrades. When HHS terminated the vaccine contract, VaxGen kept this amount, while the approximately \$878 million for the vaccine became available for other BioShield procurements. Personal communication with BARDA, June 8, 2009.
- b. This total does not include the \$405 million contract for 14.5 million doses of AVA anthrax vaccine HHS announced on 9/30/2008. According to HHS, this contract used Centers for Disease Control and Prevention funds rather than the Project BioShield special reserve fund. Personal communication with HHS, June 8, 2009.
- c. This number includes \$50 million that was obligated from this account to this company in FY2004 before passage of the Project BioShield Act. See HHS, *Project BioShield: Annual Report to Congress July 2004—July 2006*, January 2007, p. 31.
- d. Announced obligations minus the cancelled rPA contract.

Policy Issues

The 111th Congress faces several BioShield-related policy decisions. These include: whether to allow Project BioShield funds to be diverted for other purposes; whether to grant the President's request to transfer the account to HHS; whether to rely on Project BioShield funds to replenish the Strategic National Stockpile; whether to pursue broad spectrum countermeasures; and whether Project BioShield and BARDA are encouraging medical countermeasure development sufficiently.

Diversion of Appropriations for Other Purposes

One of the distinguishing features of Project BioShield is the ten-year \$5.6 billion advanced appropriation. Potential countermeasure developers considered the establishment of an advanced funded separate account dedicated solely to countermeasure procurement as integral to their participation in this program. The advanced funding helped assure developers that payment for countermeasures they successfully developed would not depend on future potentially uncertain appropriations processes. Although advanced funding the Project BioShield account may have provided some assurance of stability to developers, in practice, subsequent Congresses have removed approximately 8% of the advanced appropriation through rescission and transfer to other accounts. See **Table 1**. These transfers fall into two categories: those devoted to CBRN countermeasures advanced development and those related to influenza pandemic preparedness.

In FY2009, Congress transferred \$275 million from the special reserve fund to BARDA to support CBRN countermeasure advanced research and development. President Obama has proposed a similar transfer for FY2010 of \$305 million. The administration justifies the proposed transfer by asserting that these funds will support “future successful acquisitions of medical countermeasures under Project BioShield.”²⁶ Thus, such transfers could be viewed as an attempt to improve the “lower than expected” rate of Project BioShield acquisitions.²⁷

If Congress agrees to this proposed transfer, the precedent set in FY2009 may be reinforced that advanced research and development funding should be viewed as linked to procurement (and that such activities should be funded by transfers from the Project BioShield special reserve fund). Annual transfers from this account to fund such activity will continue to lower the amounts available for procuring CBRN countermeasures, their originally intended purpose. However, if funding becomes a limitation to acquiring countermeasures, Congress can appropriate additional money for this purpose. However, such a course of events may cause the potential developers to feel dependent on the actions of future appropriators, precisely the situation that establishment of the special reserve fund was designed to ameliorate.

Such fund transfers may modify the respective roles of the federal government and the private sector in Project BioShield. Congress designed Project BioShield to minimize the risk that the government would pay for countermeasures which fail during development (see “Market Guarantee” above). Developers were expected to manage this risk, using the government-market guarantee to entice investors to fund countermeasure development. Congress attempted to assure

²⁶ HHS, *FY2010 Congressional Justification for the Public Health and Social Services Emergency Fund*, p. 46.

²⁷ DHS, Office of Health Affairs, *Biodefense Countermeasures Congressional Justification FY2010*, p. BIO-2.

such potential investors that funding of this program was not subject to the annual appropriations process by providing ten year advanced funding. Industry spokespeople reportedly have asserted that transferring money out of this account weakens the ability of private firms to raise capital necessary to sustain long-term research and development for countermeasures and hinder potential participation in Project BioShield.²⁸ Additionally, by shifting money from procurement to research and development, the government assumes more of the development risk (i.e., the government becomes more likely to spend money on developing countermeasures that will fail during development and never become available).

In FY2009, Congress transferred \$137 million from the Project BioShield special reserve fund to HHS for pandemic influenza preparedness and response. President Obama did not request a similar transfer for FY2010. President Obama did request the supplemental appropriations conference committee to allow the purchase of influenza countermeasures using the Project BioShield special reserve fund.²⁹ Critics of such a move charged that it would damage the biodefense countermeasure industry and “severely diminish the nation’s efforts to prepare for WMD events and will leave the nation less, not more, prepared.”³⁰ The conferees on the supplemental appropriations bill declined to provide this authority.³¹ Similarly, in the Senate report to accompany the Department of Homeland Security appropriations bill (S.Rept. 111-31 and S. 1298), the committee “strongly urges” not using the special reserve fund to purchase influenza countermeasures.³²

Transfer of Account to HHS

In the FY2010 budget request, President Obama has proposed transferring the entirety of the Project BioShield special reserve fund from DHS to HHS. Currently DHS manages the special reserve fund, while HHS designs and executes the Project BioShield contracts. As described above, DHS and OMB must approve each contract. If Congress decides to transfer the account to HHS, depending on how it is transferred, these roles may or may not be preserved. A simple transfer of the account in the absence of additional amendments of the Project BioShield Act provisions would likely maintain the current agency roles. Alternatively, Congress could amend the Project BioShield act to change the agencies’ roles in contract approval. The Senate Committee on Appropriations has recommended transferring the account to HHS and otherwise maintaining the current agency roles.³³

²⁸ Spencer Hsu, “Bipartisan WMD Panel Criticizes Obama Plan To Fund Flu Vaccine,” *Washington Post*, June 8, 2009.

²⁹ Letter from President Barack Obama to Speaker of the House Nancy Pelosi, June 2, 2009, http://www.whitehouse.gov/omb/assets/budget_amendments/supplemental_06_02_09.pdf.

³⁰ Letter from Senator Bob Graham, Chairman of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, and Senator Jim Talent, Vice Chairman of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, to President Obama, June 8, 2009, http://www.preventwmd.gov/6_8_2009/; Spencer Hsu, “Bipartisan WMD Panel Criticizes Obama Plan To Fund Flu Vaccine,” *Washington Post*, June 8, 2009; and Matt Korade, “Lawmakers, Industry Jeer Plan to Fund Flu Preparedness With Bioshield Money,” June 9, 2009.

³¹ P.L. 111-32 and H.Rept. 111-151.

³² S.Rept. 111-31, p. 96. The House Committee on Appropriations report (H.Rept. 111-157) lacks similar language.

³³ S.Rept. 111-31. The Senate Appropriations Committee states in this report that such a transfer, if approved, would be included in the FY2010 Departments of Labor, Health and Human Services, and Education, and Related Agencies appropriation bill. The House Committee on Appropriations report (H.Rept. 111-157) lacks similar language.

Stockpile Replenishment

All medicines, including those added to the Strategic National Stockpile through Project BioShield, have explicit expiration dates. They are not approved for use after this expiration date. As a consequence, HHS must procure a number of doses greater than that stored in the SNS at any given time. For example, HHS had to buy 29 million doses of anthrax vaccine to maintain a stockpile of at least 10 million doses from 2006 to 2011.³⁴ In 2007, the GAO suggested HHS and DOD establish an inventory-sharing agreement that would allow DOD to use the HHS vaccines in its active troop vaccination program before expiration.³⁵ These agencies subsequently implemented a shared stockpile approach for anthrax vaccines and pandemic influenza countermeasures.³⁶ However, this shared stockpile solution is not applicable for countermeasures lacking other high-volume users. HHS may require additional periodic countermeasure purchases to replenish the stockpile to maintain a consistent readiness level. Congress may consider whether such purchases should be funded through the advance-appropriated Project BioShield account or through annual SNS budget authorities. The BARDA used SNS funding to procure 14.5 million additional doses of AVA vaccine for the stockpile for \$405 million.³⁷

Broad Spectrum Countermeasures

Many experts contend that broad spectrum countermeasures, those that address multiple CBRN agents, would be the most valuable additions to the SNS.³⁸ Such nonspecific countermeasures might be a defense against currently unknown threats, such as emerging diseases or genetically engineered pathogens. Furthermore, such countermeasures are more likely to have other nonbiodefense-related applications. P.L. 108-276 does not exclude procuring such countermeasures; however, it does require that the presence of another commercial market be factored into the HHS Secretary's decision to purchase the countermeasure. HHS has stated its interest in using Project BioShield to acquire new broad spectrum countermeasures.³⁹ However, Project BioShield contracts to date have specifically targeted individual threat agents, a strategy commonly described as "one bug, one drug." Congress may decide that HHS needs further guidance or authorities to encourage the development and acquisition of new broad spectrum countermeasures.

The Biomedical Advanced Research and Development Authority

Congress has scrutinized the implementation and effectiveness of the Project BioShield act since its enactment. In response to perceived problems with Project BioShield countermeasure

³⁴ HHS News Release, "HHS Purchases Additional Anthrax Vaccine For Stockpile," September 26, 2007.

³⁵ Government Accountability Office, *Project BioShield: Actions Needed to Avoid Repeating Past Problems with Procuring New Anthrax Vaccine and Managing the Stockpile of Licensed Vaccine*, GAO-08-88, October 2007.

³⁶ Robin Robinson, Deputy Assistant Secretary, Office of the Assistant Secretary for Preparedness and Response, HHS, testimony before the House Committee on Appropriations, Subcommittee on Defense, April 24, 2008.

³⁷ Personal communication with HHS staff, June 8, 2009.

³⁸ For example, see Gigi Gronvall, Jason Matheny, and Bradley Smith, et al., "Flexible Defenses Roundtable Meeting: Promoting the Strategic Innovation of Medical Countermeasures," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, vol. 5, no. 3 (2007), pp. 271-277.

³⁹ HHS Public Health Emergency Medical Countermeasure Enterprise, "Implementation Plan For Chemical, Biological, Radiological and Nuclear Threats," *72 Fed. Reg. 20122*, April 23, 2007.

procurement, the 109th Congress created the Biodefense Advanced Research and Development Authority (BARDA) in HHS through the Pandemic and All-Hazards Preparedness Act (P.L. 109-417).

Congress determined that Project BioShield insufficiently encouraged the transition of promising basic research results into the product development stage. This period in development is often referred to as the “valley of death” for pharmaceuticals since some seemingly promising drugs are not developed past this point due to lack of funding. As discussed above, the Pandemic and All-Hazards Preparedness Act amended the Project BioShield Act to allow BioShield contracts to pay up to half the contract value as milestone payments. Thus companies could receive payments while continuing to develop their promising products. Additionally, Congress created in BARDA a dedicated infrastructure to manage and fund advanced development and commercialization of CBRN countermeasures. In theory, BARDA funding can take those promising drugs from the basic research through the advanced development stage, which may include clinical trials. The Pandemic and All-Hazards Preparedness Act (P.L. 109-417) grants BARDA these funding authorities. Congress created the Biodefense Medical Countermeasure Development Fund to pay for such advanced development contracts.

Critics of such programs suggest that because of the high product failure rate in advanced development, the government will inevitably fund unusable products. In addition to removing the development risks traditionally borne by industry, it inserts government decision makers into the countermeasure development process, a role critics argue is better suited to industry experts and entrepreneurs.⁴⁰ Some critics would prefer to have the government set product requirements and have industry determine how best to meet them. Because advanced research and development activities generally take several years, it may still be too early to assess the full effect BARDA has had on U.S. civilian biodefense preparedness.

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⁴⁰ See CRS Report RL33528, *Industrial Competitiveness and Technological Advancement: Debate Over Government Policy*, by Wendy H. Schacht.