Project BioShield: Purposes and Authorities

name redacted
Specialist in Science and Technology Policy

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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 regulatory requirements 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 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" influenza to receive specific antiviral drugs.

The Department of Homeland Security (DHS) Appropriations Act, 2004 (P.L. 108-90) advance-appropriated $5.593 billion for FY2004 to FY2013 for Project BioShield. Subsequent Congresses have removed approximately 8% of the advance appropriation through rescissions and transfers to other accounts. In FY2004 and FY2005, Congress removed a total of approximately $25 million through rescissions. In the Omnibus Appropriations Act, 2009 (P.L. 111-8), Congress transferred $412 million to other programs supporting countermeasure advanced research and development and pandemic influenza preparedness and response. For FY2010, President Obama has proposed transferring an additional $305 million to support countermeasure advanced research and development and transferring the account from DHS to HHS. The Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2010 (H.R. 3293) would make both these requested transfers. This legislation would also make a transfer that was not in the President's request: $500 million out of the Project BioShield account to support basic research in HHS.

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. Amongst other duties, this office oversees all of HHS' Project BioShield activities. 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 issues. Primary among them is assessing whether Project BioShield is successfully encouraging medical countermeasure development. A second issue is whether to allow additional diversions of the Project BioShield advance appropriation, a key element of the government's market guarantee, to support other activities. A third is whether to broaden Project BioShield's mandate beyond CBRN countermeasures in the face of other threats such as pandemic influenza.

Contents

Tables

Contacts

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. 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 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).[2] 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. It creates a government-market guarantee by allowing the HHS Secretary to obligate funds to purchase countermeasures while they still need several more years of development. It 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 thousand to $25 million, for contracts awarded under simplified acquisition procedures. It also allows these purchases using other than full and open competition. According to the Government Accountability Office (GAO), HHS has used the simplified acquisitions procedure authority for only five contracts. These contracts were all executed between 2004 and 2005 totaled approximately $30 million. HHS has stated that it has not used its authority to use other than full and open competition.[3]

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, if the Secretary deems that 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

[1] 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).

[3] U.S. Government Accountability Office, *Project BioShield: HHS Can Improve Agency Internal Controls for Its New Contracting Authorities*, GAO-09-820, July 21, 2009, http://www.gao.gov/new.items/d09820.pdf.

research quality.[4] 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 the most recent data available from HHS, it awarded 14 grants through this expedited peer review process between July 2004 through July 2007.[5] The National Institutes of Allergy and Infectious Diseases (NIAID) awarded these grants within three to five months after the application deadline.[6] All these awards supported research on 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).[7] 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.[8] Originally, a company was to be paid only on the delivery of a substantial portion of the countermeasure. 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.[9] Therefore, this guarantee reduces the market risk for the company and the milestone payments partially reduce its exposure to development risk (i.e., the risk that the countermeasure will fail during testing and be undeliverable).

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."[10] 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 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 structuring each of the Project BioShield contracts discussed below ("Acquisitions").

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

[5] See U.S. Department of Health and Human Services, *Project BioShield: Annual Report to Congress July 2004—July 2006*, p. 2, and U.S. Department of Health and Human Services, *Project BioShield: Annual Report to Congress August 2006—July 2007*, p. 32.

[6] 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.

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

[8] President Bush delegated the presidential approval step to the Director of the Office of Management and Budget (OMB). 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 *Fed. Reg.* 70349, December 3, 2004.

[9] 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 (name redacted) and (name redacted).

[10] 118 Stat. 844.

Emergency Use of Unapproved Products

The FDA and HHS approval and licensing processes are designed to protect people from ineffective or dangerous treatments. The Project BioShield Act 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.[11] Such emergency use authorizations (EUA) remain in effect for one year unless terminated earlier by the Secretary. The Secretary may renew expiring authorizations.

The HHS Secretary has issued several EUAs. Currently, five countermeasures to the 2009 H1N1 "swine" influenza[12] outbreak are permitted to be used under EUA: the antiviral influenza treatments Tamiflu (oseltamivir) and Relenza (zananivir),[13] N95 respirators, and two diagnostic kits to help identify cases of this disease.[14] The other active EUA allows the distribution of antibiotic kits containing doxycycline hyclate to certain people participating in the Cities Readiness Initiative.[15] 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.[16] This EUA expired in January 2006.

Reporting Requirements

The Project BioShield Act of 2004 requires the HHS Secretary to report annually to Congress the use of some of the authorities granted by this law. The reports must summarize each instance that the Department used the expedited procurement and grant procedures and allowed the emergency use of unapproved products. The reports must explain why HHS needed to use these authorities. The HHS has produced two such reports to date: one covering activities from July 2004 through July 2006 and another covering August 2006 to July 2007.[17]

This act also requires the Government Accountability Office (GAO) to assess actions taken under authorities granted by the act, determine the effectiveness of the act, and recommend additional measures to address deficiencies. In July 2009, GAO published two reports in response to this requirement. The first report recommends that HHS improve some of its internal controls implemented for the expedited contracting procedures (see "Expedited Procedures" above).[18] The

[11] For more information on the EUA process and considerations, see Food and Drug Administration, *Guidance - Emergency Use Authorization of Medical Products*, July 2007, available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm.

[12] For additional information, see CRS Report R40554, *The 2009 Influenza Pandemic: An Overview*, by (name redacted) and (name redacted).

[13] 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.

[14] For more information on these EUAs, see http://www.cdc.gov/h1n1flu/eua/.

[15] For more on this program, see http://www.bt.cdc.gov/cri/.

[16] 70 *Fed. Reg.* 5452.

[17] Available online at http://www.hhs.gov/aspr/barda/bioshield/annualreport/.

[18] U.S. Government Accountability Office, *Project BioShield: HHS Can Improve Agency Internal Controls for Its New* (continued...)

second report determined that HHS has used Project BioShield to support development and procurement of CBRN medical countermeasures.[19] This report contained no recommendations for improving Project BioShield.[20]

Appropriations

The Project BioShield Act did not appropriate any funds. Instead, it authorized the appropriation of up to a total of $5.593 billion for countermeasures procurement from FY2004 through FY2013. 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. P.L. 108-90 specified that $3.418 billion was available for obligation for FY2004 to FY2008. The balance of the advance appropriation plus unobligated funds remaining from FY2004 to FY2008 became available in FY2009 for obligation from FY2009 to FY2013. The Project BioShield Act specified that these funds are 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 retained 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.[21]

(...continued)

Contracting Authorities, GAO-09-820, July 21, 2009, http://www.gao.gov/new.items/d09820.pdf.

[19] U.S. Government Accountability Office, Project BioShield Act: HHS Has Supported Development, Procurement, and Emergency Use of Medical Countermeasures to Address Health Threats, GAO-09-878R, July 24, 2009, http://www.gao.gov/new.items/d09693r.pdf.

[20] Other BioShield-related GAO reports include: U.S. Government Accountability Office, *Anthrax: Federal Agencies Have Taken Some Steps to Validate Sampling Methods and to Develop a Next-Generation Anthrax Vaccine*, GAO-06-756T, May 9, 2006 and U.S. 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 23, 2007.

[21] 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.

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**

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

Note: Amounts rounded to nearest million.

For FY2010, the Obama Administration has requested a transfer of $305 million from the BioShield special reserve fund to fund countermeasure advanced development through BARDA.[22] See **Table 2**. The Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2010 (H.R. 3293), which passed the House on July 24, 2009, would transfer $305 million to BARDA for advanced development activities. This act would also transfer $500 million from the BioShield special reserve fund to the National Institute of Allergy and Infectious Disease for basic research activities.

Table 2. Project BioShield Proposed Transfers

($ in millions)

Proposal	Purpose	Amount
President's FY2010 Budget Request	Transfer for Advanced Development	305
H.R. 3293	Transfer for Advanced Development	305
H.R. 3293	Transfer for Basic Research	500

Source: CRS analysis of FY2010 Presidential Budget Request and H.R. 3293.

The President has also requested that the remaining balances in the special reserve fund be transferred from the DHS "Biodefense Countermeasure" account into the HHS "Public Health and Social Services Emergency Fund" account. These funds would remain available for obligation through FY2013 for Project BioShield-related countermeasure purchases. The Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2010 (H.R. 3293) would make this transfer. The House Committee on Appropriations estimates that, after accounting for the Administration's estimated obligations from this fund in FY2009 and the transfers out of the Special Reserve Fund for other purposes, the remaining balance will be $764 million.[23]

[22] U.S. Department of Health and Human Services, *FY2010 Budget in Brief*, p. 108.

[23] H.Rept. 111-220, p. 194.

Acquisitions

The first Project BioShield contract was announced on November 4, 2004.[24] The HHS contracted with VaxGen for delivery of 75 million doses of a new type of anthrax vaccine (rPA) within three years. This contract was worth $879 million. See **Table 3**. On December 17, 2006, HHS terminated this contract because VaxGen failed to meet a contract milestone.[25] Subsequent contracts include

- $690 million for 29 million doses of the currently approved AVA anthrax vaccine (Emergent BioSolutions);
- $165 million for 20 thousand doses of Raxibacumab, 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 (MVA) 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.[26]

[24] See the U.S. Department of Health and Human Services 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 (name redacted).

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

[26] U.S. Department of Health and Human Services, Public Health Emergency Medical Countermeasure Enterprise, "Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats," 72 *Fed. Reg.* 20122, April 23, 2007.

Table 3. 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	28,750	690[b]	Emergent BioSolutions (formerly BioPort Corp.)	5/6/05; 5/5/06; 9/25/07
	Raxibacumab	20	165	Human Genome Sciences Inc.	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[c]	Cangene Corp.	6/1/06
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:			**1,961**[d]		

Source: CRS analysis of HHS, *Project BioShield: Annual Report to Congress July 2004—July 2006*; 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 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 a $405 million contract for 14.5 million doses of AVA anthrax vaccine that HHS announced on September 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 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*, January 2007, p. 31.

d. Announced obligations minus the cancelled rPA contract.

BioShield and BARDA

Congress has scrutinized the implementation and effectiveness of the Project BioShield Act since its enactment. In response to perceived problems with Project BioShield countermeasure 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. Congress created the Biodefense Medical Countermeasure Development Fund to pay for such advanced development contracts. Although this account is separate from the Project BioShield account in DHS, Congress has funded the advanced development account through transfers from the Project BioShield account (see **Table 1** and **Table 2**).

Critics of government programs funding advanced development 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, directly funding advanced development inserts government decision makers into the countermeasure development process, a role critics argue is better suited to industry experts and entrepreneurs.[27] Some critics would prefer to have the government set product requirements and have industry determine how best to meet them. As originally enacted, Project BioShield took this latter approach, an approach that Congress found insufficient in this particular case. Because advanced development activities generally take several years, it may take several more years to determine if this change has yielded better results than the original Project BioShield.

In addition to funding the advanced development of countermeasures, BARDA manages HHS' role in Project BioShield. BARDA leads the efforts to determine countermeasure requirements and executes all Project BioShield contracts.

Policy Issues

The 111th Congress faces several BioShield-related policy issues. These include: whether to grant the President's request to transfer the account from DHS to HHS; the diversion of BioShield funds for other purposes; how to replace stockpiled countermeasures as they expire; and whether this program has sufficiently encouraged the development of broad spectrum countermeasures.

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

[27] See CRS Report RL33528, *Industrial Competitiveness and Technological Advancement: Debate Over Government Policy*, by (name redacted).

reserve fund, while HHS designs and executes the Project BioShield contracts. As described above, DHS and Office of Management and Budget 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 House and Senate committees on appropriations have recommended transferring the account to HHS and otherwise maintaining the current agency roles.[28]

Diversion of BioShield Funds for Other Purposes

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

Transfers for CBRN Countermeasure Research and Development

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."[29] Thus, such transfers could be viewed as an attempt to improve the "lower than expected" rate of Project BioShield acquisitions.[30] The House Committee on Appropriations reached a similar conclusion: H.R. 3293 would transfer the requested $305 million to BARDA and $500 million to NIAID to support basic research.[31]

If Congress agrees to this proposed transfer, the precedent set in FY2009 that 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) may be reinforced. Annual transfers from this account to fund such activity would continue to lower the amounts available for procuring CBRN countermeasures, their originally intended purpose. However, if funding becomes a limitation to acquiring countermeasures, Congress could appropriate

[28] See H.R. 3293 and S.Rept. 111-31.

[29] U.S. Department of Health and Human Services, *FY2010 Congressional Justification for the Public Health and Social Services Emergency Fund*, p. 46.

[30] U.S. Department of Homeland Security, Office of Health Affairs, *Biodefense Countermeasures Congressional Justification FY2010*, p. BIO-2.

[31] H.Rept. 111-220, p. 194. H.R. 3293 passed the House of Representatives on July 24, 2009.

additional money for this purpose.[32] However, such a course of events might cause potential countermeasure 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 funding transfers may modify the respective roles of the federal government and the private sector in Project BioShield. Congress originally 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 such potential investors that the funding of this program was not subject to the annual appropriations process by providing ten year advance funding. Industry spokespeople reportedly have asserted that transferring money from this account weakens the ability of private firms to raise capital necessary to sustain long-term research and development for countermeasures and hinders potential participation in Project BioShield.[33] However, transferring the funds to support advanced development may reduce the amount that developers need to raise, since the government can directly fund the development. 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).

Transfer for Pandemic Influenza Preparedness

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 that the conference committee on the Supplemental Appropriations Act, 2009 (P.L. 111-32) allow the purchase of influenza countermeasures using the Project BioShield special reserve fund.[34] 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."[35] The conferees declined to provide this authority.[36] Similarly, in the Senate report to accompany the Department of Homeland Security Appropriations Act, 2010 (S. 1298), the committee "strongly urges" not using the special reserve fund to purchase influenza countermeasures.[37]

[32] The House Committee on Appropriations has suggested that they would consider adding additional funds to the special reserve fund in the future. See H.Rept. 111-220, p. 194.

[33] Spencer Hsu, "Bipartisan WMD Panel Criticizes Obama Plan To Fund Flu Vaccine," *Washington Post*, June 8, 2009.

[34] 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.

[35] 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," *CQ Homeland Security News*, June 9, 2009.

[36] P.L. 111-32 and H.Rept. 111-151.

[37] S.Rept. 111-31, p. 96. 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.[38] In 2007, the GAO suggested that 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.[39] These agencies subsequently implemented a shared stockpile approach for anthrax vaccines and pandemic influenza countermeasures.[40] However, this shared stockpile solution is not applicable for countermeasures lacking other high-volume users. The 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. Between 2005 and 2007, BARDA purchased the AVA anthrax vaccine using Project BioShield funds (**Table 3**). However, the purchase of 14.5 million doses of AVA vaccine in 2008 used SNS funds rather than BioShield funds.[41] BARDA adoption of this approach for all expiring stockpiled countermeasures may require increased annual appropriations for SNS procurements.

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.[42] 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. The Project BioShield 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.[43] 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.

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[38] U.S. Department of Health and Human Services, News Release, "HHS Purchases Additional Anthrax Vaccine For Stockpile," September 26, 2007.

[39] 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.

[40] 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.

[41] Personal communication with U.S. Department of Health and Human Services staff, June 8, 2009.

[42] 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.

[43] U.S. Department of Health and Human Services Public Health Emergency Medical Countermeasure Enterprise, "Implementation Plan For Chemical, Biological, Radiological and Nuclear Threats," *72 Fed. Reg. 20122*, April 23, 2007.

Author Contact Information

(name redacted)
Specialist in Science and Technology Policy
[redacted]@crs.loc.gov, 7-....