



# **The Project BioShield Act: Issues for the 112<sup>th</sup> 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. As the expiration of some of these authorities approaches, Congress is considering whether these authorities have sufficiently contributed to national preparedness to merit extension.

The Project BioShield Act provides three main authorities: (1) guaranteeing a federal market for new CBRN medical countermeasures, (2) permitting emergency use of countermeasures that are either unapproved or have not been approved for the intended emergency use, and (3) relaxing regulatory requirements for some CBRN terrorism-related spending. The Department of Health and Human Services (HHS) has used each of these authorities. The HHS obligated approximately \$2.625 billion to guarantee a government market for countermeasures against anthrax, botulism, radiation exposure, and smallpox. The HHS allowed the emergency use of several unapproved products, including during the 2009 H1N1 influenza pandemic. The HHS used expedited review authorities to approve contracts and grants related to CBRN countermeasure research and development.

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 for FY2004-FY2013. Subsequent Congresses have removed \$2.078 billion from this account through rescissions and transfers, more than one-third of the advance appropriation. The transfers from this account supported CBRN medical countermeasure advanced development, pandemic influenza preparedness and response, and basic biomedical research.

Since passing 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 112<sup>th</sup> Congress is considering several Project BioShield-related policy questions. One question is whether the Project BioShield acquisition mechanism merits extension based on its relative cost and contribution to national preparedness. If so, congressional policymakers may consider whether changes to the funding levels or how Congress provides Project BioShield funds would improve the program's efficiency or performance. Additionally, congressional policymakers are considering whether the federal government sufficiently plans and coordinates its CBRN countermeasure efforts from basic research to distribution. Finally, Congress is considering whether changes to the emergency use authority will improve preparedness and planning.

Four bills in the 112<sup>th</sup> Congress address some of these Project BioShield-related issues, H.R. 2356, H.R. 2405, H.R. 6672, and S. 1855.

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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.<sup>1</sup> They argued that, because these diseases and conditions occur infrequently, the private sector perceived little economic incentive to invest the millions of dollars required to bring treatments to market.

In 2004, Congress passed the Project BioShield Act (P.L. 108-276) to encourage the development of CBRN medical countermeasures. The 108<sup>th</sup> 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 109<sup>th</sup> 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 112<sup>th</sup> Congress is considering several Project BioShield-related policy questions. One question is whether the Project BioShield acquisition mechanism has sufficiently improved national preparedness relative to its costs to merit extension. If so, congressional policymakers may consider whether changes to the funding levels or how Congress provides Project BioShield funds would improve the program's efficiency or performance. Additionally, congressional policymakers are considering whether the federal government sufficiently plans and coordinates its CBRN countermeasure efforts from basic research to distribution. Finally, Congress is considering whether changes to the emergency use authority will improve preparedness and planning.

The Pandemic and All-Hazards Preparedness Reauthorization Act of 2011 (H.R. 2405, passed the House on December 6, 2011), the Pandemic and All-Hazards Preparedness Act Reauthorization of 2011 (S. 1855, passed the Senate on March 7, 2012), the Pandemic and All-Hazards Preparedness Reauthorization Act of 2012 (H.R. 6672, passed the House on December 19, 2012), and the WMD Prevention and Preparedness Act of 2011 (H.R. 2356, reported by the House Committee on Homeland Security on September 12, 2012) address some of these issues.

This report will provide a brief overview of the authorities established by the Project BioShield Act of 2004, discuss the availability of Project BioShield appropriations, identify the medical countermeasures obtained through Project BioShield, review the relationship between Project BioShield and the Biomedical Advanced Research and Development Authority (BARDA), review policy issues and options faced by congressional policymakers, and review current Project BioShield-related legislation.

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<sup>1</sup> 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.

## The Project BioShield Act

President Bush proposed Project BioShield in his 2003 State of the Union address. The 108<sup>th</sup> Congress considered this proposal and passed the Project BioShield Act of 2004 (P.L. 108-276, signed into law July 21, 2004).<sup>2</sup> It has three main provisions. The first provision, the one generally referred to as Project BioShield, creates a government-market guarantee by permitting the HHS Secretary to obligate funds to purchase countermeasures while they still need several more years of development. The second main provision establishes a process through which the HHS Secretary may temporarily allow the emergency use of countermeasures that lack Food and Drug Administration (FDA) approval. The third main provision provides HHS with expedited procedures for CBRN terrorism-related spending, including procuring products, hiring experts, and awarding research grants. This law also requires HHS and the Government Accountability Office (GAO) to produce certain reports.

### Market Guarantee

When companies decide to develop a new product, its potential economic market value is often a key factor. With new CBRN countermeasures, the U.S. government may be the most economically significant customer. Thus, one difficulty facing potential CBRN developers is knowing whether the federal government would buy their product and, if so, at what price. Companies may find it difficult to justify investing millions of dollars developing new countermeasures without knowing the potential economic value of the government market. Congress designed the Project BioShield Act to guarantee companies that the government will buy new, successfully developed CBRN countermeasures for the Strategic National Stockpile (SNS).<sup>3</sup> The act allows the Secretary of HHS, with the concurrence of the Secretary of Homeland Security 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.<sup>4</sup> Such 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.”<sup>5</sup>

These contracts define the minimum economic value of the market for the company developing the product. The Project BioShield Act, as passed, allowed the HHS to pay a company only on the delivery of a substantial portion of the countermeasure. Such contracts reduce the market risk faced by the developers, but do not mitigate the risk that the product might fail during development or testing and be undeliverable. The Pandemic and All-Hazards Preparedness Act (P.L. 109-417) modified the Project BioShield Act to allow for milestone-based payments of up to

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<sup>2</sup> 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 Frank Gottron and Eric A. Fischer.

<sup>3</sup> The SNS contains pharmaceuticals, vaccines, medical supplies, and medical equipment to respond to terrorist attacks and other emergencies.

<sup>4</sup> President Bush delegated the presidential approval step to the Director of the Office of Management and Budget (OMB). The OMB retains 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.

<sup>5</sup> 42 U.S.C. §247d-6b(c)(2).

half of the total award before delivery.<sup>6</sup> The milestone payments can mitigate the cost to the company of the product failing during development. Thus, HHS can now use Project BioShield contracts to reduce the company's exposure to market risk and development risk.

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 a reasonable conclusion that the product will qualify for [FDA] approval or licensing … within eight years.”<sup>7</sup> Because most drugs that begin the approval process fail to become approved treatments, critics of this provision suggest that the government will end up purchasing countermeasures that may never be approved. Some of the countermeasures procured through Project BioShield since 2004 lack FDA approval. To reduce the government's financial risk associated with this provision, the act, as amended, allows HHS to write contracts in which unapproved products may be purchased at lower cost than approved products. Additionally, HHS has included provisions for milestone payments and for payments contingent on FDA approval in Project BioShield contracts. For an overview of those countermeasures obtained through these authorities, 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.<sup>8</sup> During a military, domestic, or public health emergency, the Project BioShield Act allows the HHS Secretary to temporarily allow the use of medical products that FDA has not approved or licensed.<sup>9</sup> These allowances are known as emergency use authorizations (EUAs). 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.<sup>10</sup>

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<sup>6</sup> 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.

<sup>7</sup> 42 U.S.C. §247d-6b(c).

<sup>8</sup> For overviews of these processes, see CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, by Susan Thaul, and CRS Report RL34045, *FDA Regulation of Follow-On Biologics*, by Judith A. Johnson.

<sup>9</sup> The HHS Secretary may also permit the emergency use of an FDA-approved product for purposes for which it lacks approval. See footnote 13 for examples.

<sup>10</sup> 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>.

Such EUAs remain in effect for one year unless the Secretary terminates them. The Secretary may renew expiring authorizations.

The HHS Secretary has issued several EUAs. The HHS Secretary issued an EUA allowing the vaccination of Department of Defense (DOD) personnel with a specified type of anthrax vaccine.<sup>11</sup> The HHS Secretary issued EUAs to permit use of certain countermeasures during the 2009 H1N1 “swine” influenza outbreak:<sup>12</sup> the antiviral influenza treatments Tamiflu (oseltamivir), Relenza (zanamivir), and Peramivir;<sup>13</sup> N95 respirators; and several diagnostic kits to help identify cases of this disease.<sup>14</sup> Two EUAs remain active. One permits the distribution of antibiotic kits containing doxycycline hydiate to U.S. Postal Service employees volunteering in the National Postal Model emergency countermeasure distribution program.<sup>15</sup> The other active EUA permits distributing doxycycline hydiate before an emergency and its mass dispensing without a prescription during an emergency to prevent inhalational anthrax.<sup>16</sup>

## Expedited Procedures

The Project BioShield Act relaxed and expedited the Federal Acquisition Regulation procedures HHS must follow when 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 also increases the maximum amount (from \$100,000 to \$25 million) for contracts awarded under simplified acquisition procedures. According to the Government Accountability Office (GAO), HHS used the simplified acquisitions procedure authority for five contracts. These contracts, all executed in 2004 and 2005 using funds from the National Institutes of Health (NIH), totaled approximately \$30 million.<sup>17</sup>

The Project BioShield Act authorizes the HHS Secretary to use an expedited peer review 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. The act limits this authority to awards worth \$1.5 million or less. This expedited award process replaces the normal

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<sup>11</sup> 70 Fed. Reg. 5452, February 2, 2005.

<sup>12</sup> For additional information, see CRS Report R40554, *The 2009 Influenza Pandemic: An Overview*, by Sarah A. Lister and C. Stephen Redhead; U.S. Department of Health and Human Services, *Project BioShield Annual Report to Congress January 2009-December 2009*, 2011, pp. 9-13; and <http://www.cdc.gov/h1n1flu/eua/>.

<sup>13</sup> The FDA previously approved Tamiflu and Relenza for treating influenza. The EUA allowed their use for children younger than had been previously allowed. In contrast, FDA had not approved Peramivir and had restricted its use to experimental trials. The EUA allowed its use outside experimental trials.

<sup>14</sup> 75 Fed. Reg. 20441-20480, April 29, 2010.

<sup>15</sup> 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>.

<sup>16</sup> Unless revoked earlier or renewed, both of these active EUAs will remain in effect until July 2013. See 77 Fed. Reg. 40060, July 6, 2012. For more information, see the FDA’s EUA website, <http://www.fda.gov/emergencypreparedness/counterterrorism/ucm182568.htm>.

<sup>17</sup> The HHS used these contracts to purchase treatments for botulism and internal radioactive particle contamination. These contracts are distinct from the contracts using Project BioShield funds described later in this report (see “Acquisitions”). See U.S. Government Accountability Office, *Project BioShield: HHS Can Improve Agency Internal Controls for Its New Contracting Authorities*, GAO-09-820, July 21, 2009, p. 7.

peer review process. Some scientists have expressed concerns that an expedited review process would reduce research quality.<sup>18</sup> The normal peer review process can provide proposals that have greater scientific merit a higher probability of receiving funding, a factor potentially lost in an expedited process. According to the National Institute of Allergy and Infectious Diseases (NIAID), grants that go through the normal peer review process typically take 9 to 17 months to receive funding.<sup>19</sup> Between 2004 and 2008, NIAID awarded 5 contracts and 55 grants using expedited peer review. NIAID funded these awards between 3 and 9 months after the application deadline.<sup>20</sup> Since 2008, NIAID funded all 7 grants awarded through this review mechanism more than 18 months after the application deadline.<sup>21</sup> In 2011, NIAID did not fund any grants using expedited peer review.<sup>22</sup>

## Reporting Requirements

The Project BioShield Act of 2004 requires the HHS Secretary to report annually to Congress on the use of some of the authorities granted by this law. The annual reports must summarize each instance that HHS used the expedited procurement and grant procedures and allowed the emergency use of unapproved products. The annual reports must explain why HHS needed to use these authorities.<sup>23</sup>

This act also required 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 recommended that HHS improve some internal controls for the expedited contracting procedures (see “Expedited Procedures” above).<sup>24</sup> The second report described the manner in which HHS had used Project BioShield to support development and procurement of CBRN medical countermeasures.<sup>25</sup> This report contained no recommendations for improving Project BioShield.<sup>26</sup>

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<sup>18</sup> John Miller, “Interview with Richard Ebright,” *The Scientist*, vol. 17 (7), April 7, 2003, p. 52.

<sup>19</sup> See <http://www.niaid.nih.gov/researchfunding/grant/strategy/pages/7time.aspx>.

<sup>20</sup> See U.S. Department of Health and Human Services, *Project BioShield Annual Report to Congress July 2004-July 2006*, 2007, p. 2; *Project BioShield Annual Report to Congress August 2006-July 2007*, 2008, p. 32; *Project BioShield Annual Report to Congress August 2007 through December 2008*, 2009, p. 9; *Project BioShield Annual Report to Congress January 2009-December 2009*, 2011, p. 6; and *Project BioShield Annual Report to Congress January 2010-December 2010*, 2011, p. 4.

<sup>21</sup> U.S. Department of Health and Human Services, *Project BioShield Annual Report to Congress January 2009-December 2009*, 2011, p. 6; U.S. Department of Health and Human Services, *Project BioShield Annual Report to Congress January 2010-December 2010*, 2011, p. 4.

<sup>22</sup> U.S. Department of Health and Human Services, *Project BioShield Annual Report to Congress January 2011-December 2011*, 2012, p. 3.

<sup>23</sup> Available online at <https://www.medicalcountermeasures.gov/barda/cbrn/project-bioshield-overview/project-bioshield-annual-report.aspx>.

<sup>24</sup> U.S. Government Accountability Office, *Project BioShield: HHS Can Improve Agency Internal Controls for Its New Contracting Authorities*, GAO-09-820, July 21, 2009.

<sup>25</sup> 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.

<sup>26</sup> Other Project BioShield-related GAO reports include *National Preparedness: Improvements Needed for Acquiring Medical Countermeasures to Threats from Terrorism and Other Source*, GAO-12-121, October 26, 2011; and *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.

## Appropriations, Rescissions, and Transfers

The Project BioShield Act did not appropriate any funds. Instead, it authorized the appropriation of up to \$5.593 billion for procuring countermeasures from FY2004 through FY2013. The Department of Homeland Security Appropriations Act, 2004 (P.L. 108-90) had previously appropriated this amount into a special reserve fund and provided explicit time windows during which the money could be obligated. The Project BioShield Act specified that the funds in this DHS “Biodefense Countermeasures” account are only for the procurement of CBRN countermeasures using the Project BioShield authorities and may not be used for other purposes, such as countermeasure development grants or program administration. The Consolidated Appropriations Act, 2010 (P.L. 111-117) transferred the Project BioShield account from DHS to HHS.<sup>27</sup>

While Congress used the advanced appropriations mechanism to fund the 10-year program, it retains the power to decrease or increase the amount in the special reserve fund through rescission, transfer, or additional appropriation. 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). See **Table 1**.

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 “BioShield and BARDA” below) and \$137 million to help respond to and prepare for pandemic influenza.<sup>28</sup> 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 NIAID. 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.<sup>29</sup> See **Table 1**.

The Consolidated Appropriations Act, FY2012 (P.L. 112-74) transferred \$415 million to BARDA for countermeasure advanced development and administrative costs.<sup>30</sup> President Obama had requested transferring up to \$665 million to BARDA for that purpose and an additional \$100 million to establish an independent medical countermeasure strategic investment corporation.<sup>31</sup> Congress did not approve the transfer for the strategic investment corporation.<sup>32</sup>

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<sup>27</sup> The Project BioShield countermeasure appropriations account is sometimes referred to as the “special reserve fund” and is a portion of the Public Health and Social Services Emergency Fund.

<sup>28</sup> P.L. 111-8 explanatory statement, *Congressional Record*, February 23, 2009, p. H2240.

<sup>29</sup> This amount includes funds transferred to BARDA through the earlier FY2011 continuing appropriations acts (P.L. 111-242, P.L. 111-290, P.L. 111-317, P.L. 111-322, P.L. 112-4, P.L. 112-6, and P.L. 112-8).

<sup>30</sup> U.S. Congress, House Committee on Appropriations, *Military Construction and Veterans Affairs and Related Agencies Appropriations Act, 2012*, Conference Report to Accompany H.R. 2055, 112<sup>th</sup> Cong., 1<sup>st</sup> sess., December 15, 2011, H.Rept. 112-331 (Washington: GPO, 2011), p. 298.

<sup>31</sup> U.S. Department of Health and Human Services, *Public Health and Social Services Emergency Fund Justification of Estimates for Appropriations Committees FY2012*, pp. 49 and 56.

<sup>32</sup> The 112<sup>th</sup> Congress similarly rejected a FY2011 request to transfer \$200 million from Project BioShield funds to establish an independent medical countermeasure strategic investment corporation.

**Table I. Project BioShield Rescissions and Transfers**

<b>Fiscal Year</b>	<b>Public Law</b>	<b>Purpose</b>	<b>Amount (\$ in millions)</b>
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 <sup>a</sup>
2013	P.L. 112-175	Transfer for countermeasure advanced development	202 <sup>b</sup>
		Rescissions and Transfers Enacted	2,078

**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, H.Rept. 112-331, and P.L. 112-175.

**Note:** Amounts rounded to nearest million.

- a. The conference report, H.Rept. 112-331, states “up to \$415 million.”
- b. CRS partial year estimate based on Section 101(a) of P.L. 112-175, “Such amounts as may be necessary, at a rate for operations as provided in the applicable appropriations Acts for fiscal year 2012 and under the authority and conditions provided in such Acts.”

For FY2013, President Obama requested transferring up to \$415 million of Project BioShield appropriated funds to BARDA for countermeasure advanced development and administrative costs.<sup>33</sup> The Administration calculates that the combination of this transfer and its planned FY2013 countermeasure acquisitions will exhaust the remaining funds.<sup>34</sup> The Continuing Appropriations Resolution, 2013 (P.L. 112-175) provides for a transfer of up to \$202 million to BARDA. This amount represents BARDA funding through March 27, 2013, at its “rate of operations” for FY2012.<sup>35</sup>

## Acquisitions

The HHS awarded Project BioShield contracts for 10 different medical countermeasures. The HHS has used Project BioShield to acquire countermeasures against only a few CBRN threats: anthrax, smallpox, botulinum toxin, and radiological and nuclear threat agents. These countermeasures include vaccines, antibodies, antivirals, and chemical compounds. **Table 2** groups the Project BioShield countermeasures by threat and describes some of the details of the contracts.

<sup>33</sup> U.S. Department of Health and Human Services, *Public Health and Social Services Emergency Fund Justification of Estimates for Appropriations Committees FY2013*, pp. 10 and 52-61.

<sup>34</sup> U.S. Department of Health and Human Services, *Public Health and Social Services Emergency Fund Justification of Estimates for Appropriations Committees FY2013*, pp. 52-53 and 58.

<sup>35</sup> Section 101(a), P.L. 112-175.

The first Project BioShield contract was announced on November 4, 2004.<sup>36</sup> 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. See **Table 2**. On December 17, 2006, HHS terminated this contract because VaxGen, Inc., failed to meet a contract milestone.<sup>37</sup> Subsequent contracts, grouped by threat agent, include

- \$691 million for 29 million doses of anthrax vaccine adsorbed (AVA), the currently approved anthrax vaccine from Emergent BioSolutions, Inc.;
- \$334 million for 65,000 doses of Raxibacumab (ABthrax), a treatment for anthrax from Human Genome Sciences, Inc. (since acquired by GlaxoSmithKline plc);<sup>38</sup>
- \$144 million for 10,000 doses of Anthrax Immune Globulin, a treatment for anthrax from Cangene Corporation;
- \$505 million for 20 million doses of Modified Vaccinia Ankara (MVA), a new smallpox vaccine from Bavarian Nordic, Inc.;
- \$433 million for 1.7 million doses of ST-246, an antiviral treatment for smallpox from SIGA Technologies, Inc.;
- \$476 million for 200,000 doses of botulinum antitoxin, a treatment for botulinum toxin exposure from Cangene Corporation;
- \$18 million for 5 million doses of a pediatric form of potassium iodide, a treatment for radioactive iodine exposure from Fleming Pharmaceuticals; and
- \$22 million for 395,000 doses of pentetate calcium trisodium (Ca-DTPA) and 80,000 doses of pentetate zinc trisodium (Zn-DTPA), two treatments for internal radioactive particle contamination from Akorn, Inc.

Thus, excluding the canceled VaxGen contract, HHS has obligated approximately \$2.63 billion to date. In FY2013, HHS plans to use remaining Project BioShield funds to replace expiring anthrax treatments and smallpox vaccine currently in the SNS and to acquire countermeasures against radiological, nuclear, and chemical threat agents.<sup>39</sup>

As discussed above, HHS may add products lacking FDA approval to the SNS through Project BioShield. Anthrax Immune Globulin, MVA smallpox vaccine, ST-246, and the botulinum antitoxin acquired through Project BioShield lack FDA approval. At the time of its acquisition, Raxibacumab (ABthrax) lacked approval; however, FDA subsequently approved its use.<sup>40</sup>

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<sup>36</sup> For the status of current requests and contracts, see the U.S. Department of Health and Human Services Project BioShield procurement page at <https://www.medicalcountermeasures.gov/BARDA/procurement/CBRN.aspx>. For issues regarding these awards, see CRS Report RL33907, *Project BioShield: Appropriations, Acquisitions, and Policy Implementation Issues for Congress*, by Frank Gottron.

<sup>37</sup> U.S. Department of Health and Human Services, “Termination Letter - Contract No. HHSO100200500001C,” Letter to VaxGen, Inc., December 19, 2006.

<sup>38</sup> This figure represents \$326 million for the countermeasure and \$8 million in additional payments for studies to support FDA approval. See HHS, *Project BioShield Annual Report to Congress January 2011-December 2011*, p. 4.

<sup>39</sup> U.S. Department of Health and Human Services, *Public Health and Social Services Emergency Fund Justification of Estimates for Appropriations Committees FY2013*, p. 52.

<sup>40</sup> U.S. Food and Drug Administration, “FDA Approves Raxibacumab,” press release, December 14, 2012.

**Table 2. Project BioShield Acquisition Activity**

Threat	Product	Doses (thousands)	Cost (\$ millions)	Company	Award Date
<b>Anthrax</b>	rPA vaccine	75,000	879 <sup>a</sup>	VaxGen, Inc.	11/2004
	AVA vaccine	28,750	691 <sup>b</sup>	Emergent BioSolutions, Inc. (formerly BioPort Corp.)	5/2005; 5/2006; 9/2007
	Raxibacumab	65	334 <sup>c</sup>	Human Genome Sciences, Inc. (now part of GlaxoSmithKline, plc)	6/2006; 7/2009
	Anthrax Immune Globulin	10	144	Cangene Corp.	7/2006
<b>Smallpox</b>	MVA vaccine	20,000	505	Bavarian Nordic, Inc.	6/2007
	ST-246	1,700	433	SIGA Technologies, Inc.	5/2011
<b>Botulinum Toxin</b>	Botulinum antitoxin	200	476 <sup>d</sup>	Cangene Corp.	6/2006; 6/2011
<b>Radiological/ Nuclear</b>	Potassium Iodide	4,800	18	Fleming Pharmaceuticals	3/2005; 2/2006
	Ca-DTPA	395	22	Akorn, Inc.	2/2006
	Zn-DTPA	80			
<b>Total Announced Obligations:</b>			<b>3,502</b>		
<b>Total Current Obligations:</b>			<b>2,625<sup>e</sup></b>		

**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, Project BioShield Annual Report to Congress August 2007 through December 2008; HHS, Project BioShield Annual Report to Congress January 2009-December 2009; DHS, Office of Health Affairs, Biodefense Countermeasures Congressional Justification FY2010; HHS, Project BioShield Annual Report to Congress January 2011-December 2011; and personal communication with HHS, June 8, 2009.

**Note:** Some products received multiple awards.

- a. This figure includes approximately \$1.5 million that HHS paid to VaxGen, Inc. for mandatory security upgrades. When HHS terminated this contract in December 2006, VaxGen, Inc. kept this amount, while approximately \$877 million obligated for the vaccine became available for other Project BioShield procurements. Personal communication with HHS, 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 figure includes \$8 million in additional payments for studies to support FDA approval. See HHS, *Project BioShield Annual Report to Congress January 2011-December 2011*, p. 4.
- d. 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.
- e. Announced awards minus \$877 million for the cancelled rPA contract (see note a).

## **BioShield and BARDA**

Congressional policymakers have scrutinized the implementation and effectiveness of the Project BioShield Act since its enactment. In response to perceived problems with medical countermeasure development and acquisition, Congress created the Biomedical Advanced Research and Development Authority (BARDA) through the Pandemic and All-Hazards Preparedness Act (P.L. 109-417) in 2006.

Congress created in BARDA a dedicated infrastructure to manage and fund advanced development and commercialization of CBRN countermeasures. As part of the Office of the HHS Assistant Secretary for Preparedness and Response (ASPR), BARDA contracts with companies to develop and commercialize countermeasures. These contracts specify development activities for the company to perform and may extend multiple years. Congress funds this BARDA activity through annual appropriations into the Biodefense Medical Countermeasure Development Fund. The BARDA typically uses these funds to develop countermeasures that it has determined are not yet mature enough for a Project BioShield acquisition contract.

The BARDA also manages and executes all Project BioShield acquisition contracts.<sup>41</sup> Thus, BARDA has two separate mechanisms to support countermeasure advanced development and commercialization: countermeasure development contracts and Project BioShield acquisition contracts with developmental milestone payments. In theory, HHS can now contribute to all phases of a countermeasure's development: basic research supported by NIAID, advanced development and commercialization supported by BARDA, and acquisition supported by BARDA and the Strategic National Stockpile (SNS). The Public Health and Emergency Medical Countermeasure Enterprise, an interagency group headed by ASPR, is responsible for coordinating these activities to ensure needs are addressed efficiently. The PHEMCE includes members from FDA, CDC, NIH, DOD, DHS, the Department of Agriculture, and the Department of Veterans Affairs.<sup>42</sup>

Several groups, including the Institute of Medicine, the National Biodefense Science Board, and GAO, have evaluated how these changes have affected federal efforts to develop and acquire medical countermeasures. These studies determined that the creation of BARDA and PHEMCE have helped, but that additional changes would further improve federal medical countermeasure development and acquisition. These recommendations are discussed below in "Countermeasure Development and Acquisition Process."

## **Policy Issues and Options for Congress**

As discussed above, the federal government has successfully used the Project BioShield Act authorities to contribute to national preparedness for a CBRN attack and pandemic influenza.

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<sup>41</sup> Another part of ASPR, the Office of Policy and Planning, provides BARDA with specific countermeasure requirements. U.S. Department of Health and Human Services, *Public Health and Social Services Emergency Fund Justification of Estimates for Appropriations Committees FY2012*, p. 68.

<sup>42</sup> For additional information on PHEMCE, see U.S. Department of Health and Human Services, *2012 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy*, <http://www.phe.gov/Preparedness/mcm/phemce/Pages/strategy.aspx>.

However, questions remain on whether additional modifications to Project BioShield authorities would improve their efficiency or performance and whether expiring authorities merit extension. The 112<sup>th</sup> Congress is considering whether to reauthorize and modify the Project BioShield acquisition mechanism, whether to change the countermeasure development and acquisition process, and whether to modify the authority to allow the emergency use of unapproved medical countermeasures.

## **Project BioShield Acquisition Authority and Appropriations**

The 10-year time period for which Congress funded Project BioShield acquisitions extends through FY2013. As this date approaches, Congress may consider whether this procurement mechanism merits reauthorization and additional appropriations. Congressional policymakers may determine that the program does not merit additional resources. Alternatively, congressional policymakers may decide to extend the program as is or with modifications. If congressional policymakers decide to extend the program, Congress may also change the amount appropriated for these acquisitions.

### **End Project BioShield**

Congressional policymakers could choose to let Project BioShield lapse for several reasons. One reason could stem from the difficulty in determining how much safer Project BioShield has made the nation. Most experts deem CBRN terrorist attacks as events with high consequences but low probabilities of occurring. Thus, the federal government is unlikely to use medical countermeasures acquired by Project BioShield. The medical countermeasures acquired through Project BioShield to date provide protection against a limited number of all potential CBRN threats. The number of doses acquired limits this potential protection to only a part of the population. Additionally, all of these products expire. Maintaining each product's potential benefit requires regular replacement, which may add significant costs to the SNS budget.

Congressional policymakers could deem that the potential benefits provided by Project BioShield do not justify continuing the program. Alternatively, policymakers could deem other, more conventional, countermeasure procurement methods sufficient or more efficient than Project BioShield and let it lapse. Finally, policymakers could decide that those funds could be better used for other federal programs or not spent.

### **Extend Project BioShield**

Three bills in the 112<sup>th</sup> Congress, H.R. 2405, H.R. 6672, and S. 1855, would extend the Project BioShield acquisition authority. Policymakers considering extending the Project BioShield acquisition program will likely consider how much to fund this program and for how long.

#### ***Funding Amount***

By using the advanced appropriations mechanism to provide \$5.6 billion to Project BioShield for 10 years, Congress anticipated an average annual obligation rate of \$560 million. However, through FY2012, HHS obligated these funds at a slower pace, an average of \$290 million annually. Additionally, HHS could have purchased some of these products through other funding

sources, such as SNS appropriations. These factors might lead policymakers to decrease the average annual appropriation for Project BioShield acquisitions.

Alternatively, congressional policymakers 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.<sup>43</sup> Congressional policymakers could determine that this investment will soon begin producing more countermeasures eligible for Project BioShield contracts in the near future. A potential increase in eligible countermeasures might lead Congress to maintain or increase the average annual appropriation for Project BioShield acquisitions.

### ***Duration***

In addition to determining the overall level of Project BioShield appropriations, congressional policymakers may consider changing the method of providing appropriations. Previously, Congress chose to advance appropriate funds for 10 years. Potential countermeasure developers considered the establishment of a multiyear, advance-funded account dedicated solely to countermeasure procurement as integral to their ability to develop countermeasures through this program. The advance funding was to help assure developers that payment for successfully developed countermeasures would not depend on future, potentially uncertain appropriations processes. Although providing advance funding to the Project BioShield account may have assured stable funding to developers, these funds have been subject to the annual appropriations process. Subsequent Congresses have rescinded or transferred more than one-third of the advance appropriation for other purposes. See **Table 1**.

Policymakers may choose to change how Project BioShield funds are appropriated, for example to annual appropriations. However, developers continue to contend that a multiyear advance-funded account devoted to Project BioShield acquisitions remains integral to their ability to develop countermeasures.<sup>44</sup> Additionally, annual appropriations may complicate HHS's long-term countermeasure development and acquisition planning. The inherent uncertainty in the countermeasure development process produces 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 for countermeasures. However, in years in which no countermeasures reach that point in development, HHS might not obligate any money for Project BioShield contracts. Policymakers may partially address some of these concerns by coupling annual appropriations with allowing funds to remain available until expended.

Alternatively, Congress could use the advanced 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 a 10-year advance appropriation for this program during the current fiscal environment may prove

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<sup>43</sup> 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.

<sup>44</sup> 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, 111<sup>th</sup> Cong., 2<sup>nd</sup> sess., May 12, 2010 (Washington: GPO, 2010), pp. 197-204.

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. Congressional policymakers may decide to balance these competing pressures by advance-appropriating funds for longer than 2 years but less than 10 years.

## Countermeasure Development and Acquisition Process

Project BioShield is a piece of the federal effort to research, develop, and acquire countermeasures for civilian use. Other aspects of this effort include risk assessment, strategic planning, countermeasure prioritization, basic research, countermeasure approval, and countermeasure distribution. Various federal agencies and departments have roles in different parts of this effort.<sup>45</sup> The Institute of Medicine and the National Biodefense Science Board examined the federal government's biodefense efforts and concluded that better coordination and stronger management of the overall process would increase the pace of countermeasure development and acquisition.<sup>46</sup> Their report provided additional recommendations including empowering a single office to have the authority and responsibility to align component agencies' efforts; developing a coordinated budget request for HHS and DOD countermeasure development, approval, and acquisition; developing a common set of prioritized product needs and research goals to support them; and increasing the funding available for countermeasure acquisition and advanced development.

In 2009, HHS Secretary Sebelius ordered a comprehensive review of how HHS develops and acquires countermeasures to all public health threats, including CBRN agents.<sup>47</sup> In August 2010, HHS published the results of its review and recommendations.<sup>48</sup> The review recommended creating a private strategic investment corporation to inject capital into small companies developing novel technologies that could support public health needs and medical countermeasure development.<sup>49</sup> The HHS review modeled this corporation after In-Q-Tel, a private corporation founded by the government to serve the needs of the intelligence community.<sup>50</sup> In FY2011 and FY2012, Congress rejected President Obama's requests to use Project BioShield funds to establish such a corporation.<sup>51</sup> For FY2013, President Obama has

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<sup>45</sup> For additional information, see CRS Report R41123, *Federal Efforts to Address the Threat of Bioterrorism: Selected Issues and Options for Congress*, by Frank Gottron and Dana A. Shea.

<sup>46</sup> Institute of Medicine, Board on Health Sciences Policy, *The Public Health Emergency Medical Countermeasures Enterprise Innovative Strategies to Enhance Products from Discovery Through Approval: Workshop Summary*, National Academies Press, 2010; and National Biodefense Science Board, *Where Are the Countermeasures? Protecting America's Health from CBRN Threats*, March 2010.

<sup>47</sup> Secretary of Health and Human Services Kathleen Sebelius, remarks to The American Medical Association Third National Congress on Health System Readiness, Washington, DC, December 1, 2009.

<sup>48</sup> U.S. Department of Health and Human Services, Assistant Secretary for Preparedness and Response, *The Public Health Emergency Medical Countermeasures Enterprise Review: Transforming the Enterprise to Meet Long-Range National Needs*, August 2010.

<sup>49</sup> For a description of HHS plans for this corporation, see U.S. Department of Health and Human Services, *Public Health and Social Services Emergency Fund Justification of Estimates for Appropriations Committees FY2012*, p. 56.

<sup>50</sup> Although analysts generally consider In-Q-Tel a success, similar corporations established for other agencies have been less successful. See Thomas J. Benjamin, Mary T. Tyszkiewicz, and Deborah Prigal, et al., *Venture Capital Concept Analysis Final Report*, Homeland Security Institute, December 2005; and John M. Nolan, Emad U. Samad, and Lawrence F. Jindra, et al., "Seeking Innovation: Incentive Funding for Biodefense Biotechs," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, vol. 8, no. 4 (2010), pp. 365-372.

<sup>51</sup> President Obama requested a \$200 million transfer in FY2011 and \$100 million transfer in FY2012.

again requested establishing such a corporation. However, in contrast to previous requests, the corporation would be funded by \$50 million in new budget authority, not through using Project BioShield appropriations.<sup>52</sup>

The HHS review also recommended changing the medical countermeasure enterprise management. The review determined that the HHS's medical countermeasure decision-making process would be improved by creating a centralized decision-making body and by creating and implementing a "disciplined, metric-driven, systematic" decision-making process.<sup>53</sup> Additionally, the review recommended the creation of a new position, the Medical Countermeasure (MCM) Development Leader, to coordinate and integrate medical countermeasure development efforts throughout the department. The review also determined that HHS should institute a five-year budget-planning system for medical countermeasure development activities. According to GAO, HHS has made some progress implementing the review's recommendations, but challenges remain.<sup>54</sup> In 2012, HHS released an updated five-year strategic plan for its medical countermeasure enterprise that incorporates many of the review's recommendations.<sup>55</sup>

The 112<sup>th</sup> Congress is considering these and other related policy options in H.R. 2405, H.R. 2356, H.R. 6672, and S. 1855.

## Emergency Use Authority

The Project BioShield Act provided the HHS Secretary with a mechanism to allow the emergency use of unapproved countermeasures in certain circumstances. As noted above, HHS used this authority several times. However, current legal restrictions on this authority may hinder emergency planning and response.<sup>56</sup> For example, current law states that HHS may issue an EUA on the basis of an actual ongoing public health, military, or domestic emergency, as determined by HHS, DOD, and DHS respectively. However, HHS may also issue EUAs on the basis of potential military or domestic emergencies, but not potential public health emergencies.<sup>57</sup> This creates some uncertainty for stakeholders developing response plans about whether HHS will authorize the use of a particular countermeasure during a particular emergency. The requirement for a declared public health emergency also complicates countermeasure pre-positioning programs. Although HHS has used EUAs to allow two countermeasure prepositioning programs on the basis of a DHS declared potential emergency, the FDA deems the EUA process too unwieldy to apply more broadly.<sup>58</sup> Additionally, many proposed methods of dispensing even FDA approved countermeasures during an emergency would require an EUA. Modifying the EUA authority or specifically allowing emergency dispensing of FDA approved countermeasures

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<sup>52</sup> U.S. Department of Health and Human Services, *Public Health and Social Services Emergency Fund Justification of Estimates for Appropriations Committees FY2013*, pp. 8 and 60-61.

<sup>53</sup> U.S. Department of Health and Human Services, Assistant Secretary for Preparedness and Response, *The Public Health Emergency Medical Countermeasures Enterprise Review: Transforming the Enterprise to Meet Long-Range National Needs*, August 2010, p. 17.

<sup>54</sup> U.S. Government Accountability Office, *National Preparedness: Improvements Needed for Acquiring Medical Countermeasures to Threats from Terrorism and Other Sources*, GAO-12-121, October 26, 2011.

<sup>55</sup> U.S. Department of Health and Human Services, *2012 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy*, 2012, <http://www.phe.gov/Preparedness/mcm/phemce/Pages/strategy.aspx>.

<sup>56</sup> H.Rept. 112-286, p. 25, and FDA personal communication with CRS, August 10, 2011.

<sup>57</sup> 21 U.S.C. §360bbb-3(b)(1).

<sup>58</sup> FDA, personal communication with CRS, August 10, 2011.

without a prescription might ease federal, state, tribal, and local government planning activities and improve response during an emergency.

The 112<sup>th</sup> Congress is considering several modifications to the emergency use authority in H.R. 2405, H.R. 6672, and S. 1855.

## **Current Legislation**

The 112<sup>th</sup> Congress is considering legislation that would address some of these policy issues. Three bills, the Pandemic and All-Hazards Preparedness Reauthorization Act of 2011 (H.R. 2405, passed by the House on December 6, 2011), the Pandemic and All-Hazards Preparedness Act Reauthorization of 2011 (S. 1855, passed by the Senate on March 7, 2012), and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2012 (H.R. 6672, passed by the House on December 19, 2012) would extend the Project BioShield procurement program, change the countermeasure development and acquisition process, and modify the emergency use authority. A fourth bill, the WMD Prevention and Preparedness Act of 2011 (H.R. 2356, reported by the House Committee on Homeland Security on September 12, 2012), would change some aspects of the countermeasure development and acquisition process.

### **H.R. 2405**

The House passed the Pandemic and All-Hazards Preparedness Reauthorization Act of 2011 (H.R. 2405) on December 6, 2011. Some provisions of this bill would affect Project BioShield implementation, address the use of the special reserve fund for purposes other than acquisition, change the countermeasures development and acquisition process, and modify the emergency use authority.

This bill would extend the Project BioShield procurement program to FY2018. It would authorize appropriations of \$2.8 billion for five fiscal years (FY2014-FY2018), the same average annual appropriations as current law. It would also grant the HHS Secretary the authority to use up to \$840 million of Project BioShield appropriations for BARDA countermeasure advanced development activities. The HHS Secretary would have to report to Congress when the special reserve fund available balance dropped below \$1.5 billion.

H.R. 2405 would reauthorize BARDA and require formal planning activities and reporting. The bill would authorize \$415 million in annual appropriations for BARDA countermeasure development activities through FY2016, in addition to any funds transferred from the BioShield special reserve fund. Additionally, it would require the HHS Assistant Secretary for Preparedness and Response (ASPR) to develop a “comprehensive cross-cutting 5-year budget analysis” for its countermeasure advanced research, development, and procurement activities. H.R. 2405 would require the ASPR to develop an annual Countermeasure Implementation Plan that would be provided to Congress. The plan 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. H.R. 2405 would also repeal the reporting requirements section of the Project BioShield Act discussed above (“Reporting Requirements”).

H.R. 2405 would modify some aspects of the HHS emergency use authority for medical countermeasures. H.R. 2405 would allow the Secretary to issue an EUA following the determination that a significant potential for a public health emergency exists, making it parallel with the ability to issue an EUA on the basis of potential military or domestic emergencies. Under this bill, all EUAs would expire when the HHS Secretary determines the underlying emergency circumstances no longer exist rather than automatically after one year. H.R. 2405 would also allow the Secretary to modify active EUAs and waive certain manufacturing process requirements for approved products during an emergency. It would allow mass dispensing of approved medical countermeasures during an emergency without an individual prescription (independent of an EUA) and pre-positioning of unapproved medical countermeasures by federal, state, or local governments in anticipation of emergencies.

## **S. 1855**

The Senate passed the Pandemic and All-Hazards Preparedness Act Reauthorization of 2011 (S. 1855) on March 7, 2012. Some of the provisions of this bill would affect Project BioShield implementation, address the use of the special reserve fund for purposes other than acquisition, change the countermeasures development and acquisition process, and modify the emergency use authority.

This bill would extend the Project BioShield procurement program to FY2018. It would authorize appropriations of \$2.8 billion for five fiscal years (FY2014-FY2018), the same average annual appropriations as current law. The HHS Secretary would have to report to Congress when the special reserve fund available balance dropped below \$1.5 billion. In contrast to H.R. 2405, it would not authorize the Secretary to use the Project BioShield special reserve fund to support BARDA countermeasure development activities. It would explicitly allow Project BioShield countermeasure procurement contracts to include development costs. Additionally, it would allow Project BioShield contracts to be signed up to 10 years before the expected delivery date of the countermeasure to the stockpile, rather than eight years under current law.

S. 1855 would also reauthorize BARDA and require formal planning activities and reporting. The bill would authorize \$415 million in annual appropriations to BARDA for countermeasure development activities through FY2016. The bill would require the ASPR to develop a biennial “Public Health and Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan.” This plan must consider and reflect all CBRN-countermeasure-related activities, including basic research, development, procurement, stockpiling, deployment, and distribution; identify and prioritize near-term, mid-term, and long-term needs; identify projected timelines, funding, benchmarks, and milestones for each countermeasure; be informed by National Biodefense Science Board recommendations; report on advanced research and development awards; report on BioShield contracts; identify progress in meeting goals, benchmarks, and milestones; and be publicly available. Additionally, the HHS Secretary would be required to develop and annually update a coordinated five-year budget plan for all activities related to the Public Health and Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan. This plan must identify countermeasure life-cycle costs and include measurable outputs and outcomes to track progress towards meeting needs. This plan would be made available to the appropriate congressional committees.

S. 1855 would authorize BARDA to partner with a private non-profit corporation to foster and accelerate the development and innovation of medical countermeasures. This “strategic investor” would use venture capital practices to promote new technologies related to CBRN countermeasures and other public health needs identified by the HHS Secretary. The funding to establish and maintain this partnership would be part of the \$415 million authorized for all BARDA countermeasure activities.

S. 1855 would modify some aspects of the HHS emergency use authority for medical countermeasures. Similar to H.R. 2405, S. 1855 would allow the Secretary to issue an EUA following the determination that a significant potential for a public health emergency exists. EUAs would expire when the HHS Secretary determines the underlying emergency circumstances no longer exist rather than automatically after one year as under current law. Also like H.R. 2405, S. 1855 would allow the Secretary to modify active EUAs; waive certain manufacturing process requirements for approved products during an emergency; and allow pre-positioning of unapproved medical countermeasures by federal, state, or local governments in anticipation of emergencies. However, unlike H.R. 2405, S. 1855 would also allow the Secretary to 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, under S. 1855, the HHS Secretary would be allowed to issue an EUA for all countermeasures acquired through Project BioShield, regardless of whether an emergency or potential emergency exists.

## **H.R. 6672**

Following Senate passage of S. 1855, the House considered and passed the Pandemic and All-Hazards Preparedness Reauthorization Act of 2012 (H.R. 6672) on December 19, 2012. This bill contains provisions similar to those in H.R. 2405 and S. 1855 that would affect Project BioShield implementation, address the use of the special reserve fund for purposes other than acquisition, change the countermeasures development and acquisition process, and modify the emergency use authority.

Similar to both H.R. 2405 and S. 1855, H.R. 6672 would extend the Project BioShield procurement program to FY2018. It would authorize appropriations of \$2.8 billion for five fiscal years (FY2014-FY2018), the same average annual appropriations as current law. This bill would grant the HHS Secretary the authority to use up to \$1.4 billion of Project BioShield appropriations for BARDA countermeasure advanced development activities. This is greater than the \$840 million that H.R. 2405 would allow for such use. Similar to S. 1855, H.R. 6672 would explicitly allow Project BioShield countermeasure procurement contracts to include development costs and allow those contracts to be signed up to 10 years before the expected delivery date of the countermeasure to the stockpile. Similar to both H.R. 2405 and S. 1855, this bill would require the HHS Secretary to report to Congress when the special reserve fund available balance dropped below \$1.5 billion.

H.R. 6672 would reauthorize BARDA and require formal planning activities and reporting. The bill would authorize \$415 million in annual appropriations for BARDA countermeasure development activities through FY2017, in addition to any funds transferred from the BioShield special reserve fund. Additionally, it would require the HHS Assistant Secretary for Preparedness and Response (ASPR) to develop and annually update a coordinated five-year budget plan for its countermeasure advanced research, development, and procurement activities. H.R. 6672 would require the ASPR to develop and provide to Congress an annual Public Health and Emergency

Medical Countermeasure Enterprise Strategy and Implementation Plan. The plan must describe the CBRN threats; describe the efforts to develop countermeasures for each threat; evaluate the progress of all activities to research, develop, procure, stockpile, deploy, and use countermeasures; identify and prioritize near-term, mid-term, and long-term countermeasure 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 identify the progress in meeting countermeasure needs for at-risk individuals, including children. H.R. 6672 would require this annual plan to include reporting the use of the authorities granted by the Project BioShield Act while eliminating the requirement for a separate annual Project BioShield report as discussed above (“Reporting Requirements”).<sup>59</sup>

H.R. 6672 would modify some aspects of the HHS emergency use authority for medical countermeasures. Similar to H.R. 2405 and S. 1855, H.R. 6672 would allow the Secretary to issue an EUA following the determination that a significant potential for a public health emergency exists. EUAs would expire when the HHS Secretary determines the underlying emergency circumstances no longer exist rather than automatically after one year as under current law. Also like H.R. 2405 and S. 1855, H.R. 6672 would allow the Secretary to modify active EUAs; waive certain manufacturing process requirements for approved products during an emergency; and allow pre-positioning of unapproved medical countermeasures by federal, state, or local governments in anticipation of emergencies. H.R. 6672, similar to S. 1855, would also allow the Secretary to 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, under either S. 1855 or H.R. 6672, the HHS Secretary would be allowed to issue an EUA for all countermeasures acquired through Project BioShield, regardless of whether an emergency or potential emergency exists. Similar to H.R. 2405, H.R. 6672 would allow mass dispensing of approved medical countermeasures during an emergency without an individual prescription (independent of an EUA) and pre-positioning of unapproved medical countermeasures by federal, state, or local governments in anticipation of emergencies.

## **H.R. 2356**

The WMD Prevention and Preparedness Act of 2011 (H.R. 2356) was introduced June 24, 2011. This bill would change the countermeasure development and acquisition process. This bill was referred to the House Committees on Homeland Security, Energy and Commerce, Transportation and Infrastructure, Foreign Affairs, and Intelligence. The House Committee on Homeland Security reported this bill on September 12, 2012.<sup>60</sup>

H.R. 2356 would create a new White House position to coordinate federal biodefense policy and require new formal planning activities and reporting. This bill would require the President to appoint a Special Assistant to the President for Biodefense. This person would be the principal advisor to the President on coordination of federal biodefense policy, be responsible for

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<sup>59</sup> The HHS updated its 2007 Public Health and Emergency Medical Countermeasure Enterprise strategy and implementation plans in 2012. See <https://www.medicalcountermeasures.gov/>.

<sup>60</sup> H.Rept. 112-665.

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, responsibilities, and coordination of federal, state, local, and tribal authorities; 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 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 the United States Postal Service.

H.R. 2356 would require DHS to review the CBRN agents that it previously determined pose a material threat to national security to assess whether they continue to do so. Only countermeasures against CBRN agents DHS determines to pose a material threat are eligible for acquisition using Project BioShield. Thus, DHS reassessment of these agents could result in some countermeasures becoming excluded from Project BioShield.

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