Project BioShield: Purposes and Authorities

Frank Gottron
Specialist in Science and Technology Policy

May 4, 2009

Congressional Research Service
7-5700
www.crs.gov
RS21507

CRS Report for Congress
Prepared for Members and Committees of Congress

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 108th Congress passed the Project BioShield Act of 2004, and President Bush signed it into law on July 21, 2004 (P.L. 108-276).

The main provisions of this law include (1) relaxing procedures for some CBRN terrorism-related spending, including hiring and awarding research grants; (2) guaranteeing a federal government market for new 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. The HHS used the authority to guarantee a government market to obligate approximately $2.3 billion to acquire countermeasures against anthrax, botulism, radiation, and smallpox. In response to the 2009 influenza A (H1N1) "swine flu" outbreak, HHS has used the emergency use authority to ease the distribution of two antiviral medications and to allow their use in children younger than the ages for which the drugs are currently approved. Certain respirators and a diagnostic test were also approved for emergency use against this outbreak.

HHS Project BioShield countermeasure procurement funding comes from the Department of Homeland Security Appropriations Act, 2004 (P.L. 108-90), which appropriated $5.593 billion for FY2004 to FY2013. Congress subsequently removed $25 million from this account through rescissions in FY2004 and FY2005. In the Omnibus Appropriations Act, 2009 (P.L. 111-8), Congress transferred $412 million from this account to other programs to support countermeasure advanced research and development and pandemic influenza preparedness and response.

Since passing the Project BioShield Act, subsequent congresses have considered several additional measures to further encourage countermeasure development. The 109th Congress passed the Pandemic and All-Hazard Preparedness Act (P.L. 109-417) to create the Biomedical Advanced Research and Development Authority (BARDA) in the Department of Health and Human Services. Questions remain regarding the impact BARDA will have on countermeasure development, the continuing implementation of Project BioShield, and whether additional legislation would further encourage countermeasure development.

Contents

Contacts

Introduction

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

Project BioShield

To encourage the development of new CBRN countermeasures, President Bush proposed Project BioShield in his 2003 State of the Union address. The 108th Congress considered this proposal and passed the Project BioShield Act of 2004 (P.L. 108-276, signed into law July 21, 2004).[3] This act has three main provisions. It provides the Department of Health and Human Services (HHS) expedited procedures for CBRN terrorism-related spending including procuring products, hiring experts, and awarding research grants. The act creates a government-market guarantee by allowing the HHS Secretary to obligate funds to purchase countermeasures while they still have several more years of development. However, companies only receive payment when development is complete and the product is delivered. The act also authorizes the HHS Secretary to temporarily allow the emergency use of countermeasures that lack Food and Drug Administration (FDA) approval.

Expedited Procedures

The act relaxes procedures under the Federal Acquisition Regulation for procuring property or services used in performing, administering, or supporting CBRN countermeasure research and development (R&D). This decreases both the amount of paperwork required for these expenditures and the potential for oversight. The act increases the maximum, from $100,000 to $25 million, for contracts awarded under simplified acquisition procedures. It also allows these purchases using other than full and open competition. Another provision increases the micro-purchase maximum from $2,500 to $15,000. These increases are similar to, but greater than, changes granted to the Department of Homeland Security (DHS) and other departments and agencies in the Homeland Security Act (P.L. 107-296) and the National Defense Authorization Act, 2004 (P.L. 108-136). According to its annual reports to Congress required by this act, HHS has not used these authorities.[4]

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

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

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

[4] These reports are available online at http://www.hhs.gov/aspr/barda/bioshield/annualreport/.

The act authorizes the HHS Secretary to use an expedited award process, rather than the normal peer review process, for grants, contracts, and cooperative agreements related to CBRN countermeasure R&D activity, if the Secretary deems there is a pressing need for an expedited award. This power is limited to awards of $1.5 million or less. Some scientists have expressed concerns that an expedited peer review process will reduce the research quality.[5] The normal peer review process is designed to provide proposals with greater scientific merit a higher probability of receiving funding. Congress allowed HHS to establish the details of this new alternative expedited award process.

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

Market Guarantee

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

The Project BioShield Act allows the purchase of unapproved and unlicenced 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] The approval and licensing processes are designed to preclude the marketing of ineffective or dangerous treatments. Because most drugs that begin this process 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 contracts to be written so that unapproved products may be purchased at lower cost than approved products.

---

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

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

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

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

[9] 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.

[10] 118 Stat. 844.

The first Project BioShield contract was announced November 4, 2004.[11] VaxGen Inc. would have received $878 million to deliver 75 million doses of a new type of anthrax vaccine within three years. On December 17, 2006, HHS terminated this contract because VaxGen failed to meet a contract milestone.[12] Other contracts include $1.095 billion for 43 million doses of the currently approved anthrax vaccine (Emergent BioSolutions); $165 million for 20,000 doses of ABthrax, a treatment for anthrax (Human Genome Sciences); $144 million for 10,000 doses of Anthrax Immune Globulin, a treatment for anthrax (Cangene); $363 million for 200,000 doses of botulinum antitoxin, a treatment for botulinum toxin exposure (Cangene); $16 million for 5 million doses of a pediatric form of potassium iodide, a treatment for radioactive iodine exposure (Fleming & Company); $22 million for 395,000 doses of Ca-DTPA and 80,000 doses of Zn-DTPA, two treatments for internal radioactive particle contamination (Akorn); and $500 million for 20 million doses of a new smallpox vaccine (Bavarian Nordic). Thus, excluding the canceled VaxGen contract, HHS has obligated approximately $2.267 billion to date. Future targets for Project BioShield procurement include countermeasures against anthrax, viral hemorrhagic fevers, and radiation.[13]

Emergency Use of Unapproved Products

The act also allows the HHS Secretary to 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: (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.[14] Although this provision would permit the Secretary to circumvent the normal approval process, its use appears to be intended to be limited to dire circumstances.

The HHS Secretary has used this Emergency Use Authority (EUA) several times. The emergency use of four countermeasures has been permitted in response to the 2009 influenza A(H1N1)[15] outbreak: the antiviral influenza treatments Tamiflu (oseltamivir) and Relenza (zananivir),[16] N95 respirators, and a diagnostic kit to help identify cases of this disease.[17] In October 2008, the antibiotic kits containing Doxycycline Hyclate were allowed to be distributed to certain people

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

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

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

[14] 118 Stat. 855.

[15] The new flu strain was initially dubbed "swine flu" because it contained genetic material from flu strains that normally circulate in swine. However, there has been no evidence to date that pigs are involved in the transmission of this virus. There have been concerns that the term "swine flu" has had unwarranted trade implications for swine and pork products, among other concerns. On April 30, 2009, WHO began referring to the new strain as influenza A(H 1N1). For additional information, see CRS Report R40554, *The 2009 H1N1 "Swine Flu" Outbreak: An Overview*, by Sarah A. Lister and C. Stephen Redhead.

[16] 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.

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

participating in the Cities Readiness Initiative.[18] 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.[19] This EUA expired in January 2006.

Reporting Requirements

The Project BioShield Act of 2004 requires annual reports from the HHS Secretary about the exercise of the authorities granted in this bill.[20] This act also requires the Government Accountability Office (GAO) to produce a report to assess actions taken under authorities granted by the act, to determine the effectiveness of the act, and to recommend additional measures to address deficiencies. This report is expected to be issued in July 2009.[21]

Appropriations

This act did not appropriate any money. Instead, it authorized the appropriation of up to a total of $5.593 billion for FY2004 to FY2013 for countermeasures procurement. The Department of Homeland Security Appropriations Act, 2004 (P.L. 108-90) appropriated this amount with explicit windows in which the money could be obligated. The act specified that $3.418 billion was available for obligation for FY2004 to FY2008. The balance of the advance appropriation plus the unobligated funds for FY2004 to FY2008 became available for FY2009 to FY2013. This money is only for the procurement of countermeasures using the Project BioShield authorities, not for grants to support countermeasure development.

Although Congress advance-appropriated the 10-year program, it retains the power to annually increase or decrease the amount available for Project BioShield. Congress removed $25.475 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). The Omnibus Appropriations Act, 2009 (P.L. 111-8), transferred $412 million from this account. Of this amount, $275 million went to fund countermeasure advanced research and development through the Biodefense Advanced Research and Development Authority (BARDA), and $137 million went to help respond to and prepare for pandemic influenza.[22]

Policy Issues

Stockpile Replenishment

Like all medicines, those added to the SNS through Project BioShield have explicit expiration dates, after which they are no longer legally usable. For example, to maintain a stockpile of at

[18] 73 *Fed. Reg.* 62507. For more on this program, see http://www.bt.cdc.gov/cri/.

[19] 70 *Fed. Reg.* 5452.

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

[21] Personal communication with GAO, April 10, 2009.

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

least 10 million doses from 2006 to 2011, HHS had to buy 29 million doses of anthrax vaccine.[23] The GAO suggested an inventory-sharing agreement between HHS and DOD, to allow DOD to use the HHS vaccines in its active troop vaccination program before expiration.[24] These agencies subsequently implemented this type of shared stockpile approach for anthrax vaccines and pandemic influenza countermeasures.[25] However, this solution would not be applicable to the expiration problems of countermeasures lacking other high-volume users. Such countermeasures may require additional periodic 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.

Broad Spectrum Countermeasures

Many experts believe that broad spectrum countermeasures, those that address multiple CBRN agents, would be the most valuable additions to the SNS. Such nonspecific countermeasures might be the best defense against currently unknown threats, such as emerging diseases or genetically engineered pathogens. Furthermore, such countermeasures are more likely to have other nonbiodefense-related applications. P.L. 108-276 does not exclude procuring such countermeasures; however it does require that the presence of another commercial market be factored into the HHS Secretary's decision to purchase the countermeasure. HHS has stated its interest in using Project BioShield to acquire new broad spectrum countermeasures.[26] However, all the Project BioShield contracts to date have been specifically targeted at 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.

Increasing Basic Research

Following the anthrax attacks, Congress increased the National Institutes of Health budget for CBRN countermeasure research to approximately $1.5 billion per year. It is difficult to determine the optimal funding level for basic research, but eventually the law of diminishing returns will apply. Some scientists have suggested that this has already occurred and inevitably leads to funding unworthy projects.[27] Additionally, some scientists argue that the increases in bioterrorism research have come at the expense of other important infectious disease research,[28] although others dispute this assertion.[29]

---

[23] HHS News Release, "HHS Purchases Additional Anthrax Vaccine For Stockpile," September 26, 2007.

[24] 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.

[25] 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.

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

[27] John Miller, "Bioterrorism Research: New Money, New Anxieties," *The Scientist*, vol. 17(7), April 7, 2003, p. 52.

[28] Sidney Altman, et al., "An Open Letter to Elias Zerhouni," *Science*, March 4, 2005, p. 1409.

[29] Gerald Epstein, "Security Is More Than Public Health: Commentary on Casting a Wider Net For Countermeasure R&D Funding Decisions," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, vol. 5(4), 2007, pp. 353-357.

The Biomedical Advanced Research and Development Authority

Since the passage of the Project BioShield Act, Congress has scrutinized its implementation and effectiveness. Such evaluation is likely to continue through the 111th Congress and beyond. As part of the Pandemic and All-Hazards Preparedness Act (P.L. 109-417), Congress created the Biodefense Advanced Research and Development Authority (BARDA) in HHS to increase the effectiveness of the government's ability to acquire CBRN countermeasures.

Some experts suggested that Project BioShield would more effectively encourage countermeasure development if modeled after the Defense Advanced Research Projects Agency (DARPA). DARPA funds many projects with a potential high risk of failure. These contracts often last a few years and can be renewed if specified milestones are met. Companies are allowed to make a defined profit during the development phase. Although the direct funding of risky development projects implies that the government will fund many products that never make it to market, the government might also structure the contracts so that this assumption of development risk translates into lower procurement costs. The Pandemic and All-Hazards Preparedness Act (P.L. 109-417) allows HHS to use similar contracting mechanisms through BARDA. These transactions are not funded through Project BioShield appropriations, but rather through a separate account, the Biodefense Medical Countermeasure Development Fund.

Another area that some experts thought required improvement was how the government helped transition promising leads from basic research to 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. Several federal programs exist to encourage research, development, and commercialization of new products. Such programs include cooperative research and development agreements (CRADAs) between government laboratories and universities or industry; the Central Intelligence Agency-funded, nonprofit, venture capital corporation In-Q-Tel; the Small Business Technology Transfer Program; and the Small Business Innovation Research Program. In contrast to Project BioShield's market guarantee at the end of a potentially long and risky development process, each of these programs offers direct help during the development process and provides incentives for commercialization of the results. In BARDA, Congress created a dedicated infrastructure to manage and fund advanced development and commercialization of CBRN countermeasures. In theory, BARDA funding will take those promising drugs from the basic research through the advanced development stage, which may include clinical trials. Critics of such programs suggest that because of the high product failure rate in advanced development, the government will inevitably fund unusable products. In addition to removing the development risks traditionally borne by industry, it inserts government decision makers into the countermeasure development process, a role critics argue is better suited to industry experts and entrepreneurs.[30] Some critics would prefer to have the government set product requirements and have industry determine how best to meet them. Because advanced research and development activities generally take several years, it will likely take more time to determine the full effect BARDA has on U.S. civilian biodefense preparedness.

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

Author Contact Information

Frank Gottron
Specialist in Science and Technology Policy
fgottron@crs.loc.gov, 7-5854