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CRS Report for Congress

Project BioShield: Purposes and Authorities

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Summary

Many potential chemical, biological, radiological, and, nuclear terrorism agents lack available countermeasures. President Bush proposed Project BioShield to address this need. The 108th Congress passed the Project BioShield Act of 2004 (S. 15) 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 bioterrorism-related procurement, hiring, and awarding of research grants; (2) guaranteeing a federal government market for new biomedical countermeasures; and (3) permitting emergency use of unapproved countermeasures. Project BioShield countermeasure procurement is funded by the Department of Homeland Security Appropriations Act, 2004 (P.L. 108-90), which advance-appropriated $5.593 billion for FY2004 to FY2013. The 109th Congress considered several measures to further encourage countermeasure development and passed the Pandemic and All-Hazard Preparedness Act (S. 3678). The President signed it into law on December 19, 2006 (P.L. 109-417). This law created 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 implementation of Project BioShield, and whether additional legislation would further encourage countermeasure development. This report will be updated periodically.[1]

Introduction

The anthrax mailings of 2001 killed five people and required thousands to take prophylactic treatment. If effective medical countermeasures against this strain of anthrax did not exist, the death toll would have been higher. Effective countermeasures exist for few of the threats deemed most dangerous by the Centers for Disease Control and

[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.

Prevention (CDC).[2] The paucity of countermeasures to chemical, biological, radiological, and nuclear (CBRN) agents is attributed to the lack of a significant commercial market.[3] 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 countermeasures to CBRN agents, President Bush proposed Project BioShield in his 2003 State of the Union address. The 108th Congress considered this proposal in S. 15 (Gregg), H.R. 2122 (Tauzin), and S. 1504 (Gregg). On May 19, 2004, the Senate passed S. 15. The House passed S. 15 on July 14, 2004. The President signed the Project BioShield Act of 2004 into law on July 21, 2004 (P.L. 108-276).[4] This act has three main provisions. It provides expedited procedures for CBRN terrorism-related procurement, hiring, and awarding of research grants, making it easier for the Department of Health and Human Services (HHS) to quickly commit substantial funds to countermeasure projects. 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 biomedical countermeasure research and development (R&D). 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 Defense Department Authorization Act, 2004 (P.L. 108-136). These provisions decrease both the amount of paperwork required for these purchases and the potential for oversight.

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 biomedical 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.

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[2] National Institute of Allergy and Infectious Diseases, *NIAID Biodefense Research Agenda for CDC Category A Agents*, Department of Health and Human Services, Washington, DC, 2002.

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

[4] 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.

HHS has used this authority to award more than $35 million in grants and contracts.[5] Some scientists have expressed concerns that an expedited peer review process will reduce the quality of the research.[6] Peer review is designed to maximize the chances that only proposals with the greatest scientific merit get funding. The alternative award process is not described in detail in the law.

Market Guarantee. The act is designed to guarantee biotechnology and pharmaceutical companies that the government will buy new, successfully developed biological countermeasures for the Strategic National Stockpile (SNS).[7] The act allows the HHS Secretary, with the concurrence of the DHS Secretary and upon the approval of the President, to promise to buy a product up to eight years before the product is reasonably expected to be delivered. Congress is to be notified of a recommendation for a stockpile purchase after Presidential approval. A company would be paid only on the delivery of a substantial portion of the countermeasure. Therefore, this guarantee reduces the market risk for the company, but does not affect its exposure to development risk (i.e., the risk that the countermeasure will fail during testing and be undeliverable). The Pandemic and All-Hazard Preparedness Act (P.L. 109-417) modified the Project BioShield Act to allow for milestone-based payments for up to half of the total award before delivery.

The act allows the purchase of unapproved and unlicenced countermeasures. It requires that the HHS Secretary determine that there is "... sufficient and satisfactory clinical experience or research data... [to] support a reasonable conclusion that the product will qualify for approval or licensing... within eight years."[8] The approval and licensing processes are designed to preclude the marketing of ineffective or dangerous treatments. 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 will eventually fail to be approved. To reduce the 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.

Emergency Use of Unapproved Products. The act 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. Although this provision would permit the Secretary to circumvent the FDA approval process, its use, appears to be intended to be limited to dire circumstances.

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[5] Alex Azar II, HHS Deputy Secretary, testimony before the House Committee on Energy and Commerce Subcommittee on Health, April 6, 2006.

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

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

[8] 118 Stat. 844.

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.[9] This act also requires the Government Accountability Office (GAO) to produce a report four years after enactment 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 due in 2008.

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 (DHS) Appropriations Act, 2004 (P.L. 108-90) advance-appropriated this amount with explicit windows in which the money could be obligated. The act specified that $3.418 billion is available for obligation for FY2004 to FY2008. Of that amount, no more than $890 million was available for obligation in FY2004. The balance of the advance appropriation plus any of the available funds for FY2004 to FY2008 remaining unobligated will be 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 ten-year program, Congress retains the power to increase or decrease the amount available for Project BioShield. Two separate rescissions have removed $25.475 million from the Project BioShield special reserve fund (the Consolidated Appropriations Act, 2004 P.L. 108-199 and the Consolidated Appropriations Act, 2005 P.L. 108-447).

Contract Awards

The first Project BioShield contract was announced November 4, 2004.[10] VaxGen Inc. would have received $877.5 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.[11] Other contracts include $242.7 million for 10 million doses of the currently approved anthrax vaccine (Emergent BioSolutions); $165.2 million for 20,000 doses of ABthrax, a treatment for anthrax (Human Genome Sciences); $143.8 million for 10,000 doses of Anthrax Immune Globulin, a treatment for anthrax (Cangene); $362.6 million for 200,000 doses of botulinum antitoxin, a treatment for botulinum toxin exposure (Cangene); $15.9 million for 4.8 million doses of a pediatric form of potassium iodide, a treatment for radioactive iodine exposure (Fleming & Company); $21.9 million for 395 thousand doses of Ca-DTPA and 80 thousand doses of Zn-DTPA, two treatments for internal radioactive

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[9] HHS has completed one such report. See, HHS, *Project BioShield: Annual Report to Congress July 2004 — July 2006*, January 2007. Available online at [http://www.hhs.gov/ophep/ophemc/bioshield/annualreport/]

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

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

particle contamination (Akorn); and $500 million for 20 million doses of a new smallpox vaccine (Bavarian Nordic). Future targets for Project BioShield procurement include countermeasures against anthrax, viral hemorrhagic fevers, and radiation.[12]

Policy Issues

Indemnification. One of the most often-cited barriers preventing more companies from developing countermeasures is the risk of litigation stemming from adverse effects of their products. The Project BioShield Act did not include any such indemnification provisions. Congress has attempted to address these concerns by passing liability limitations as part of the 2006 Defense Appropriations Act (P.L. 109-148).[13] This provision may increase the number of companies making countermeasures, but as of this date not enough time has passed to determine this.

Broad Spectrum Countermeasures. Early versions of Project BioShield would have required the HHS Secretary to determine that no other significant market for the countermeasure exists. Critics suggested that this might not encourage the development of the most useful countermeasures, such as new wide-spectrum antibiotics, which might be used against common, naturally occurring diseases. Such nonspecific countermeasures might be the best defense against currently unknown threats, such as emerging diseases or genetically engineered pathogens. P.L. 108-276 does not exclude 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 using Project BioShield to acquire new broad spectrum countermeasures.[14] However, none of the Project BioShield contracts to date have been for such broad spectrum countermeasures. They have all been specifically targeted at a single threat agent, a strategy often described as "one bug, one drug." Congress may decide that this outcome is optimal or that HHS needs further guidance to encourage the development and acquisition of new broad spectrum countermeasures.

Alternative Contract Mechanisms. Some advocates have suggested that the new contracting authority granted by Project BioShield would more effectively encourage countermeasure development if modeled after that used by 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 could also structure the contracts so that this assumption of development risk translates into lower procurement costs. Companies could rationalize to their stockholders that they would be trading uncertain potential earnings for a guaranteed,

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

[13] See CRS Report RS22327, *Pandemic Flu and Medical Biodefense Countermeasure Liability Legislation: P.L. 109-148, Division C (2005)*, by Henry Cohen and Vanessa K. Burrows.

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

albeit lower, profit. The Pandemic and All-Hazards Preparedness Act (P.L. 109-417) creates in HHS a Biodefense Advanced Research and Development Authority (BARDA) that will allow such contracting mechanisms. These types of transactions are not to be funded through the Project BioShield advanced appropriation, but rather through a separate account, the Biodefense Medical Countermeasure Development Fund.

Increasing Basic Research. Following the anthrax attacks, Congress increased the National Institutes of Health bioterrorism research funding budget to greater than $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.[15] Additionally, some scientists argue that the increases in bioterrorism research have come at the expense of other important infectious disease research.[16]

Alternative Policies to Encourage Technology Commercialization. Some experts suggest that the bottleneck for new countermeasures is not in basic research, but in the transfer of promising leads 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 do not develop past this point due to lack of funding. Several federal programs exist to encourage research, development, and commercialization of new treatments. Such programs include cooperative research and development agreements (CRADAs) between government laboratories and universities or industry; the Central Intelligence Agency-funded, non-profit 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 provide incentives for commercialization of the results.

The 109th Congress considered these issues and found a need for a new authority in HHS, BARDA, to fund advanced development and commercialization of CBRN countermeasures. In theory, BARDA funding would take those promising drugs from the basic research stage through advanced development, which may include clinical trials. Even fully implemented, it would likely take several years to determine any effect BARDA has had on U.S. civilian biodefense preparedness. Critics of such programs suggest that because of the high product failure rate in advanced development, the government will inevitably fund products that will never be usable. In addition to removing the development risks that industry has traditionally borne, it also inserts government decision makers into the countermeasure development process, a role they argue is better suited to experts and entrepreneurs in industry.[17] Some critics would prefer to have the government set the requirements and have industry figure out how best to meet them. The debate between these solutions will likely continue through the 110th Congress.

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

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

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