

CRS Report for Congress

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Project BioShield

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Summary

Many potential biological terrorism agents lack available countermeasures. President Bush proposed Project BioShield to address this need. The 108th Congress considered this proposal in S. 15, S. 1504, and H.R. 2122. President Bush signed S. 15 into law on July 21, 2004 (The Project BioShield Act of 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-FY2013. Additional measures to encourage countermeasure development are being considered by the 109th Congress in S. 3 (Gregg), S. 975 (Lieberman), S. 1873 (Burr), S. 1880 (Kennedy), S. 2564 (Burr), and H.R. 5533 (Rogers). This report will be updated in response to legislative developments.

Introduction

The anthrax mailings of 2001 killed five people and required thousands to take prophylactic treatment. If there had not been effective medical countermeasures against this strain of anthrax, the death toll would have been higher. Effective countermeasures exist for few of the biological threats deemed the most dangerous by the Centers for Disease Control and Prevention (CDC).¹ The paucity of bioterrorism countermeasures is attributed to the lack of a significant commercial market.² Because these diseases occur infrequently, there has been little economic incentive to invest the millions of dollars required to bring a new treatment to market.

¹ National Institute of Allergy and Infectious Disease. *NIAID Biodefense Research Agenda for CDC Category A Agents*. Department of Health and Human Services. Washington, DC. 2002.

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.

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Project BioShield

To encourage the development of new bioterrorism countermeasures, President Bush proposed Project BioShield in his 2003 State of the Union address. S. 15 (Gregg) contained the administration proposal, with some revisions. The corresponding House bill, H.R. 2122 (Tauzin), and a subsequently introduced Senate bill, S. 1504 (Gregg), contained many of the same provisions as S. 15. The House passed H.R. 2122 on July 16, 2003. On May 19, 2004, the Senate passed an amended S. 15 which contained several important differences from the version which had been reported from committee.³ S. 15 passed the House on July 14, 2004. The President signed the Project BioShield Act of 2004 into law on July 21, 2004.

The Project BioShield Act of 2004 (P.L. 108-276) provides expedited procedures for bioterrorism-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 HHS Secretary can contract 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 HHS Secretary also gained the ability to temporarily allow the emergency use of countermeasures that lack Food and Drug Administration (FDA) approval.

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. 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-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-FY2008 remaining unobligated will be available for FY2009-FY2013.

The first Project BioShield contract was announced November 4, 2004. VaxGen Inc. will receive \$877.5 million to deliver 75 million doses of a new type of anthrax vaccine within three years.⁴ Other acknowledged potential targets for Project BioShield procurement include more advanced anthrax vaccines and treatments, next generation smallpox vaccines, botulinum anti-toxin and vaccine, a next generation plague vaccine, and anti-radiation treatments.⁵

Relaxing Acquisition Procedures. The Project BioShield Act of 2004 relaxes procedures under the Federal Acquisition Regulation for procuring property or services

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.

⁴ Other awards have followed. See the HHS Project BioShield procurement page for status of current requests and contracts at [<http://www.hhs.gov/ophep/bioshield/PBPrctPrjct.htm>].

⁵ Phillip Russell. "Research and Development Update." HHS Secretary's Council for Public Health Preparedness. May 3, 2004.

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 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 the amount of paperwork required for these purchases and the potential for oversight. The Project BioShield Act of 2004 requires the HHS Secretary to report use of these provisions annually to Congress.

Expedited Peer Review. The Project BioShield Act of 2004 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. Whether these procedures would apply to only a few such awards, or to many, will depend on what needs the Secretary deems pressing. 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 Project BioShield Act of 2004 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 contract to purchase a product up to eight years before the product is reasonably expected to be deliverable. Congress will be notified of a recommendation for a stockpile purchase after Presidential approval. A company will 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).

Some experts criticized early versions of Project BioShield for attempting to change the nature of congressional oversight from the continuous and consultative annual appropriations process to one of reviewing executive decisions after the fact. Under the enacted version of Project BioShield, use of the advanced appropriation is subject to annual review through the appropriations process. Future Congresses could rescind funds already appropriated but not yet obligated. As part of a general rescission in the Consolidated Appropriations Act, 2004 (P.L. 108-199), Congress reduced the 10-year appropriation to \$5.588 billion and the amount available for obligation in FY2004 to \$885 million.

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.

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 would 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.

The Project BioShield Act of 2004 allows the purchase of unapproved and unlicensed 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." 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 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 Project BioShield Act of 2004 allows the HHS Secretary to authorize the emergency use of medical products that have not yet been 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) there is no adequate alternative to the product that 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, presumably, would be limited to dire circumstances.

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. The Government Accountability Office (GAO) will 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.

Policy Options

Indemnification. One of the most often cited barriers preventing more companies from developing countermeasures is the risk of litigation stemming from adverse effects. Congress has attempted to address these concerns by passing liability limitations as part of the 2006 Defense Appropriations Act (P.L. 109-148).⁸ It is too early to determine

⁸ See CRS Report RS22327, *Pandemic Flu and Medical Biodefense Countermeasure Liability* (continued...)

whether this provision will increase the number of companies participating in Project Bioshield.

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 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 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, albeit lower, profit.

Increasing Basic Research. Following the anthrax attacks, Congress increased National Institutes of Health bioterrorism research funding budget. It is now 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.⁹ Additionally, some scientists argue that the increases in bioterrorism research has come at the expense of other important infectious disease research.¹⁰ Other critics suggest that the bottleneck for new countermeasures is not in basic research, but in the transfer of promising leads to the product development stage.

Alternative Policies to Encourage Technology Commercialization. Other federal programs are designed to encourage research, development, and commercialization of new treatments. For example, the Orphan Drug Act (P.L. 97-414) encourages development of new treatments for very rare diseases through tax incentives and market exclusivity agreements. Other federal programs include cooperative research and development agreements (CRADAs) between government laboratories and universities or industry; the Advanced Technology Program, which provides seed money to develop generic technologies that have broad application across industries; 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, providing incentives for commercialization of the results. Expanding these programs may make the market guarantees in Project BioShield more effective in encouraging countermeasure development.

⁸ (...continued)

Legislation: P.L. 109-148, Division C (2005), by Henry Cohen.

⁹ John Miller. "Bioterrorism research: New Money, New Anxieties." *The Scientist*. Vol. 17(7), April 7, 2003. p. 52.

¹⁰ Sidney Altman, et al. "An Open Letter to Elias Zerhouni." *Science*. March 4, 2005. p. 1409.

Legislative Proposals in the 109th Congress

S. 3 (Gregg), S. 975 (Lieberman), S. 1873 (Burr), S. 1880 (Kennedy), S. 2564 (Burr), and H.R. 5533 (Rogers) include additional measures to encourage the development of countermeasures. The Senate Committee on Health, Education, Labor, and Pensions ordered reported favorably S. 1873 on October 24, 2005. The House passed H.R. 5533 on September 26, 2006.

Similarities. These bills share many provisions, although the specific language may be different. While most of the bills address countermeasure tort liability concerns, Congress appears to have already considered this issue by enacting liability provisions in the 2006 Defense Appropriations Act (P.L. 109-148). Each bill contains additional financial incentives to encourage countermeasure development, although the nature of the incentives vary. For example, each bill contains market-based incentives through agreements to be the government's exclusive source of a particular countermeasure, lengthening periods of entire market exclusivity, or patent extensions.¹¹ S. 3, S. 975, S. 1873, and S. 1880 would offer tax-related incentives for infrastructure investments. All these bills, except S. 1880, would expand the categories of products that could be purchased with BioShield funds to include detection technologies. All of the bills, except H.R. 5533, would grant antitrust exemptions for certain countermeasure-related communication between the government and industry. All of the bills, except S. 3, would allow HHS to use "other transactions" as alternative contracting mechanisms. Finally, all of these bills would require the Food and Drug Administration to provide help to developers and manufacturers during the licensing process.

Differences. Although these bills share the same goal and some similar provisions, many of the provisions and most of the language is different. A few of the greatest differences are discussed here. S. 975 would create a new HHS Assistant Secretary for Public Health Countermeasure Development, a new DHS Assistant Secretary for Medical Readiness and Response, and a new DHS Terrorism and Infectious Disease Countermeasure Fund similar to the Project BioShield special reserve fund. S. 1873, S. 2564, and H.R. 5533 would create the Biomedical Advanced Research and Development Authority (BARDA), a new office in HHS to support, coordinate, and provide oversight of advanced development of vaccines and biodefense countermeasures (S. 1873 substitutes "Agency" for "Authority"). S. 1873 and S. 2564 would fund BARDA by transferring money from the BioShield special reserve fund (\$1 billion in S. 1873 and \$340 million in S. 2564). In contrast, H.R. 5533 authorizes, but does not appropriate, \$160 million for BARDA in FY2007. S. 1874 would exempt BARDA from the Federal Advisory Committee Act (FACA) and the Freedom of Information Act (FOIA). S. 2564 and H.R. 5533 also exempt BARDA from FACA, but limit the FOIA exemption to certain types of information. S. 1880 would create the National BioVenture Trust to administer Project BioShield and to identify and support the development of technologies that could lead to new countermeasures. The Trust would be in HHS, but could also issue common stock to raise capital to fund countermeasure technology development. HHS would be required to hold no less than 51% of this stock. S. 1880 would also allow, under certain circumstances, HHS to develop countermeasures itself or through contracts.

¹¹ For more information, see CRS Report RL32917, *Bioterrorism Countermeasure Development: Issues in Patents and Homeland Security*, by Wendy Schacht and John Thomas.