

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 main provisions of that proposal include (1) relaxing procedures for bioterrorism-related procurement, hiring, and awarding research grants; (2) guaranteeing a federal government market for new countermeasures through a permanent, indefinite appropriation; and (3) permitting emergency use of unapproved countermeasures. Congress considered these proposals in S. 15 (Gregg), S. 1504 (Gregg), and H.R. 2122 (Tauzin). President Bush signed S. 15 (The Project BioShield Act of 2004, P.L. 108-276) into law on July 21, 2004. The largest difference between the enacted version and the President's initial proposal is that the law authorizes the appropriation of up to \$5.593 billion for the purchase of countermeasures through FY2013, while the President originally requested a permanent, indefinite appropriation. The Department of Homeland Security Appropriations Act, 2004 (P.L. 108-90) appropriated \$5.593 billion for FY2004-FY2013 to secure medical countermeasures against biological terror attacks. Additional industry incentives being considered by the 108th Congress include protection from litigation because of adverse reactions to the countermeasures and tax and intellectual property incentives (S. 666, Lieberman). Other options include directly funding development or increasing the scope of existing federal programs designed to encourage technology commercialization. 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 antibiotic treatment. If there had not been effective medical countermeasures for 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 Many attribute the paucity of

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.

bioterrorism countermeasures to the lack of a significant commercial market.² Because these diseases occur infrequently, there has been little economic incentive for the investment of the millions of dollars required to bring a new treatment to market.

The Administration began the acquisition process for some countermeasures before enactment of the Project BioShield Act of 2004. A next generation anthrax vaccine is acknowledged as the first target for BioShield funds.³ This vaccine is expected to be ready for purchase in the summer of 2005. Other acknowledged targets include new vaccines for smallpox and plague and new treatments for anthrax and botulism.

Project BioShield

To encourage the development of new bioterrorism countermeasures, President Bush proposed Project BioShield in his 2003 State of the Union address. The Project BioShield Act of 2003 (S. 15, Senator Gregg), as reported by the Senate Committee on Health, Education, Labor and Pensions, contained the administration proposal, with some revisions. The corresponding House bill, H.R. 2122 (Tauzin), and a subsequently introduced Senate bill, S. 1504 (Gregg), contain 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. S. 15 as passed by the Senate more closely resembles H.R. 2122 and S. 1504, than the version of S. 15 reported by committee.⁴ S. 15 passed the House on July 14, 2004. President signed S. 15 into law on July 21, 2004 (P.L. 108-276).

The Project BioShield Act of 2004 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 would be granted contract authority to purchase countermeasures approved by the President. The HHS Secretary would have the power to temporarily allow the emergency use of countermeasures that lack Food and Drug Administration (FDA) approval.

The largest difference between the enacted version and the President's initial proposal is how each would fund the purchase of countermeasures. The President's proposal (embodied in the version of S. 15 reported by the Senate Committee on Health, Education, Labor and Pensions) contained a permanent, indefinite appropriation. This mandatory funding is not subject to the annual appropriations process. In contrast, the enacted version of S. 15 does not appropriate any money, it authorizes the appropriation of up to \$5.593 billion total for FY2004 to FY2013. The appropriations for Project BioShield were included in the Department of Homeland Security (DHS) Appropriations

² Ceci Connolly. "U.S. Hopes Incentives Will Push Vaccine Development." *Washington Post*. January 30, 2003. p. A08.

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

⁴ For a detailed comparison of the legislative proposals, see CRS Report RL32416 *Project BioShield: Side by Side Comparison of House- and Senate-Passed Versions* By Frank Gottron.

Act, 2004 (P.L. 108-90), which appropriated \$5.593 billion for FY2004 to FY2013. This is an advance appropriation for the entire 10-year cost of Project BioShield. This act specifies that \$890 million are available to be obligated in FY2004 and \$3.418 billion are available for obligation in FY2004 to FY2008. Obligation is the promising of the money through a contract as opposed to the spending of the money which would occur upon delivery of the countermeasures at some later date.

Relaxing Acquisition Procedures. The Project BioShield Act of 2004 (P.L. 108-276) relaxes procedures under the Federal Acquisition Regulation for procuring property or services used in performing, administering, or supporting biomedical countermeasure 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 (HSA, 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 types of purchases and the potential for oversight. The Project BioShield Act of 2004 requires the HHS Secretary to report any 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 considers pressing. Some scientists have expressed concerns that an expedited peer review process will reduce the quality of the research.⁵ 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 Guarantees. The Project BioShield Act of 2004 is designed to reassure biotechnology and pharmaceutical companies that if they successfully develop a new biological countermeasure, the government will buy it for the Strategic National Stockpile (SNS). The SNS contains pharmaceuticals, vaccines, medical supplies, and medical equipment designed to help respond to terrorist attacks and other emergencies. The act allows the HHS Secretary, with 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 would be notified of a recommendation for a stockpile purchase after Presidential approval.

Some experts criticized early versions of Project BioShield for changing the nature of congressional oversight from the continuous and consultative annual appropriations process to one of simply 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, since future Congresses could rescind funds

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

already appropriated but not yet obligated. Furthermore, the HHS Secretary must prepare annual reports detailing actions taken under this act, including identifying entities that received or were rejected for an award.

Early versions of Project BioShield would have required the HHS Secretary to determine that there is no other significant market for the countermeasure. Critics suggested that this would not encourage the development of some of most useful countermeasures, such as new wide-spectrum antivirals or 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. The enacted version 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 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 any deficiencies.

Policy Options

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 end up funding many products that never make it to market, the government could structure the contracts so that this assumption of development risk translates into lower costs of procurement. Companies could rationalize to their stockholders that they would be trading uncertain potential earnings for a guaranteed, albeit lower, profit.

Indemnification. Some analysts feel that one of the largest barriers preventing more companies from developing countermeasures is the risk of litigation stemming from adverse effects.⁶ Some manufacturers would like to see a program developed similar to the National Vaccine Injury Compensation Program (P.L. 99-660), which provides an alternative to the traditional tort system for resolving claims of adverse reactions. Another alternative is complete indemnification such as the one granted for the smallpox vaccine by the HSA (P.L. 107-296). Another provision of the HSA, the SAFETY Act, limits the tort liability of sellers of anti-terrorism technologies.⁷ Since these limits do not apply to harm caused when no act of terrorism has occurred, this provision might not cover products, such as vaccines or detectors, that might be deployed when an attack is only suspected or threatened. Some manufacturers may feel that this represents an unacceptable litigation risk.

Increasing Basic Research. Congress increased National Institutes of Health bioterrorism research funding to approximately \$1.6 billion in FY2004. It is difficult to determine the optimal funding level for basic research, but at some point the law of diminishing returns will apply. Some scientists have suggested that this has already occurred and inevitably leads to funding unworthy projects.⁸ 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. There are other federal programs 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 that companies would not otherwise find profitable to develop 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; as well as 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

⁶ Dr. Kim Bush, President Vaccines Division, Baxter Healthcare Corp. Testimony before the U.S. Senate Committee on Health, Education, Labor, and Pensions, Health Subcommittee. January 30, 2003.

⁷ See CRS Report RL31649, *Homeland Security Act of 2002: Tort Liability Provisions* by Henry Cohen.

⁸ John Miller. "Bioterrorism research: New Money, New Anxieties." *The Scientist*. Vol. 17(7), April 7, 2003. p. 52.

Program.⁹ In contrast to Project BioShield's guarantee of a market at the end of what can be viewed as a long and risky development process, each of these programs offers direct help during the development process and provides incentives for commercialization of the results. Expanding these programs may make the market guarantees in Project BioShield more effective in encouraging countermeasure development.

Other Legislative Proposals

The Biological, Chemical, and Radiological Weapons Countermeasures Research Act (S. 666, Lieberman) includes additional economic incentives to encourage development of bioterrorism countermeasures. In addition to offering market guarantees, S. 666 includes tax and intellectual property rights incentives. Among the tax incentives available are the ability to issue a special class of stock that would not subject investors to any capital gains tax and special tax credits to help fund the research. Intellectual property incentives include the lengthening of patent term for countermeasures or a two-year extension of any unrelated patent held by the corporation. S. 666 also includes indemnification provisions, limited antitrust exemptions, and incentives to increase research and manufacturing capacity.

Conclusions

It is difficult to forecast if the Project BioShield Act of 2004 provides enough incentives for the development of new bioterrorism countermeasures. In congressional testimony, several industry witnesses have been supportive of the proposal but have also called for more incentives.¹⁰ Some have noted that Project BioShield may entice smaller companies to develop countermeasures while larger pharmaceutical companies may still find the guaranteed market too small to justify the opportunity costs associated with redirecting development efforts from potentially much larger markets.¹¹ Larger companies may find that the unrelated-patent extension provision in S. 666 provides enough incentive to justify the opportunity costs to their stockholders.

Many of the policy options discussed above will continue to face Congress, despite the passage of the Project BioShield Act of 2004. Senators Hatch and Lieberman expect to introduce legislation dubbed BioShield II to address some of the remaining barriers to countermeasure development.¹² Other members of Congress have stated a need for liability reform especially in the context of countermeasure development.¹³

⁹ See CRS Report 95-50, *The Federal Role in Technology Development* and CRS Issue Brief IB91132, *Industrial Competitiveness and Technological Advancement* both by Wendy Schacht.

¹⁰ U.S. House Committee on Energy and Commerce Health Subcommittee and Select Committee on Homeland Security. March 27, 2003.

¹¹ Andrew Pollack and Melody Petersen. "Untested Companies Enlist in U.S. Biodefense." *New York Times*. March 23, 2003.

¹² Sen. Lieberman. "Lieberman Applauds Signing Of Project BioShield into Law." *Press Release*. July 21, 2004.

¹³ For example, see Sen. Frist. *Congressional Record*. May 19, 2004. p. S5761.