

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 encourage companies to develop new bioterror countermeasures. The main provisions of that proposal include: (1) relaxing procedures for bioterrorism-related procurement and peer review; (2) guaranteeing a market through contract authority granted to the Secretary of Health and Human Services (HHS) to buy countermeasures following Presidential approval, funded by a permanent, indefinite appropriation; and (3) allowing the Secretary of HHS to permit the emergency use of countermeasures that have not been approved. S. 15, introduced by Senator Gregg incorporates these proposals. Some of these provisions are controversial. Some critics suggest that biotechnology and pharmaceutical companies will require even more incentives than contained in Project BioShield. Additional 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 attacks in the fall of 2001 underscored the nation's vulnerability to biological terrorism. Five people were killed by those attacks and thousands required 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 do not exist for many of the biological threats deemed the most dangerous by the Centers for Disease Control and Prevention (CDC). For example, botulinum toxin, plague, tularemia, and many viral hemorrhagic viral fevers (VHFs) lack licensed vaccines. HHS recognizes a need for better vaccines for anthrax and smallpox

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and better treatments for anthrax, plague and botulism.¹ Smallpox and VHFs lack any specific treatments.

Many attribute the paucity of 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.

Project BioShield

To encourage the development of new bioterrorism countermeasures, President Bush proposed Project Bioshield in his 2003 State of the Union address. The Biodefense Improvement and Treatment of America Act (S. 15, Sen. Gregg), as reported by the Senate Committee on Health, Education, Labor and Pensions (HELP) on March 25, contains the administration proposal, with some revisions. It provides expedited procedures for bioterrorism-related procurement and peer review of research and development (R&D) proposals, making it easier for HHS to quickly commit substantial funds to countermeasure projects. The Secretary of HHS would be granted permanent, indefinite contract authority to purchase countermeasures approved by the President. Starting in FY2003, the bill as reported authorizes and appropriates for each fiscal year “such sums as may be necessary” to procure countermeasures. This mandatory funding, not subject to the annual appropriations process, is intended guarantee a market for those companies that develop and produce such countermeasures. Another provision gives the Secretary of Health and Human Services the power to temporarily allow the emergency use of countermeasures that lack Food and Drug Administration (FDA) approval. No corresponding bill has yet been introduced in the House, although hearings have been held, on March 27 jointly by the House Energy and Commerce Subcommittee on Health and the Homeland Security Subcommittee on Emergency Preparedness and Response, and on April 4 by the House Government Reform Committee.

Relaxing Acquisition Procedures. S. 15 would relax procedures under the Federal Acquisition Regulation for procuring property or services used in performing, administering, or supporting biomedical countermeasure R&D. It would increase the threshold, from \$100,000 to \$25 million, for contracts awarded under simplified acquisition procedures. S. 15 would also allow these purchases using other than full and open competition. Another provision would increase the micro-purchase threshold 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 (HSA, P.L. 107-296). The HSA provisions sunset in 2007 (DHS) and 2003 (other federal agencies) but the changes in S. 15 are permanent. They would decrease the amount of paperwork required for these types of purchases, but also the potential for oversight. Critics have suggested that relaxing procedures designed to

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, February, 2002.

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

prevent waste, fraud and abuse will make it difficult to assure that this money is spent wisely.³

Expedited Peer Review. S. 15 would authorize 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 not more than \$1.5 million. Whether these procedures would apply to only a few such awards, or to many, will depend on what needs the Secretary considers pressing. Some have expressed concerns that an expedited peer review process will reduce the quality of the research.⁴ Peer review is designed to maximize the chances that only proposals with the greatest scientific merit get funding. The award process is not described in detail in the bill. NIH uses expedited peer review in some programs, but assessments of the success of those procedures were not available for this report.

Market Guarantees. A major provision of Project BioShield is designed to reassure biotechnology and pharmaceutical companies that if they successfully develop a new biological countermeasure, the government will buy it. S. 15 would allow the HHS Secretary, with concurrence of the DHS Secretary and upon the approval of the President, to contract to purchase a product for inclusion in the Strategic National Stockpile (SNS) up to five years before the product is reasonably expected to be deliverable.⁵ To recommend such a purchase, the HHS Secretary must determine that there is no other significant market for the countermeasure. Congress would not be consulted before the purchase but must be informed by the DHS Secretary after the President approves it.

The Bush Administration has stated that the best method to reassure companies that the money will be available to purchase countermeasures is to exempt those funds from the uncertainties of the annual appropriations process by funding the contract authority with a permanent, unlimited appropriation for that purpose.⁶ The Administration estimates using \$6 billion over 10 years to purchase countermeasures; however, S. 15 permits expenditure of “any moneys in the Treasury not otherwise appropriated.” Funds appropriated under this provision could not be used to purchase vaccines under procurement contracts entered into before January 1, 2003, or for administrative costs.

Although the permanent appropriation is intended to create market guarantees, it is unclear if it is sufficient or necessary. First, any permanent appropriation is subject to the actions of a subsequent Congress and President. Second, contract authority funded by a specific appropriation amount, such as at the level estimated by the Administration, conceivably could provide similar incentives and assurances to individual companies as much as contract authority funded by a permanent, unlimited appropriation.

³ Congressman Waxman, Public Comments, U.S. House Committee on Government Reform, April 4, 2003.

⁴ John Miller, “Interview with Richard Ebright,” *The Scientist*, Vol. 17 (7), p. 52, April 7, 2003.

⁵ The SNS contains pharmaceuticals, vaccines, medical supplies, and medical equipment designed to help respond to terrorist attacks and other emergencies.

⁶ Anthony S. Fauci, Testimony before the U.S. House Committee on Energy and Commerce Health Subcommittee and Select Committee on Homeland Security, March 27, 2003.

Several have criticized this provision of S. 15.⁷ Although it is meant to address the perception of an urgent and presumably transient need for upgrading the SNS, there is no sunset clause to this appropriation. Some critics have expressed concern over changing the nature of congressional oversight from the continuous and consultative annual appropriations process to one of simply reviewing executive decisions after the fact.

Exemptions to FDA Approval Process. Section 3 of S. 15 allows the purchase of unapproved and unlicensed countermeasures, provided that the HHS Secretary determines that there is “...sufficient and satisfactory clinical experience or research data (including data, if available, from preclinical and clinical trials) [to] support a reasonable conclusion that the product will qualify for approval or licensing...within five years.” The approval and licensing processes are designed to preclude the marketing of ineffective and dangerous treatments. Only about 1 of 5 drugs that begin the approval process actually become approved treatments.⁸ Because it is not possible to predict the outcome of the approval process, 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, S. 15 allows contracts to be written so that unapproved products may be purchased at lower cost than approved products.

S. 15 would allow 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:

- 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 advantages of the product outweigh its known and potential risks;
- There is no adequate alternative to the product that is approved and available; and
- 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. However, some have suggested that the language should be changed to include provisions to further protect informed consent, patient follow-up and the reporting of adverse effects.⁹

Policy Options

Alternative Funding Mechanisms. As discussed above, some have raised concerns about the unlimited nature of the appropriation and changing the role of

⁷ Lisa Richwine, “Concerns Raised About Funding for U.S. Biodefense Program,” *Reuters*, March 27, 2003.

⁸ Food and Drug Administration, *From Test Tube to Patient: Improving Health Through Human Drugs*, Washington, DC, September 1999, p.21.

⁹ Congressman Waxman, Op. cit.

congressional oversight. One alternative is to cap the contract authority at a specific amount and provide a lump-sum appropriation to fund it for several years. Further contract authority could be made when needed, subject to further appropriations. This would effectively cap the amount that could be spent, but eliminates the need for additional appropriations for several years. However, neither this method nor the Administration's proposal can guarantee the future availability of funds, since a subsequent Congress could change the law.

Alternative Contract Mechanisms. Some have suggested that the new contracting authority granted by S. 15 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 the market, the government could structure the contracts so that this assumption of development risk translates into lower costs of procurement. This may allow companies to more easily justify to their stockholders the opportunity costs associated with developing a new countermeasure. They would be trading uncertain potential earnings for a guaranteed, albeit lower, profit.

Indemnification. Some feel that one of the largest barriers preventing more companies from developing countermeasures is risk of litigation stemming from adverse effects.¹⁰ 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 a complete indemnification such as the one granted for the smallpox vaccine (P. L. 107-296).

Increasing Basic Research. Congress has recently increased National Institute of Allergy and Infectious Diseases bioterrorism research six-fold to approximately \$1.5 billion in FY2003. It is difficult to determine the optimal level of funding for basic research, but at some point the law of diminishing returns will apply. Some have suggested that this has already occurred and will inevitably lead to funding of unworthy projects.¹¹ Other critics suggest that the bottleneck for new countermeasures is in the transfer of promising leads from basic research to the 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 through tax incentives

¹⁰ Dr. Kim Bush, Testimony before the of the U.S. Senate Committee on Health, Education, Labor, and Pensions, Health Subcommittee, January 30, 2003.

¹¹ John Miller, "Bioterrorism research: New Money, New Anxieties," *The Scientist*, Vol. 17(7), p. 52, April 7, 2003.

and market exclusivity agreements.¹² 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.¹³ In contrast to Project BioShield's promise of a market at the end of 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. Some have suggested expanding these programs will 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, Sen. 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 to fund the research 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 Project BioShield would provide 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.¹⁴ 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.¹⁵ Such companies may find that the unrelated-patent extension provision in S. 666 provides enough incentive to justify the opportunity costs to their stockholders. Some critics have stated that Project BioShield will exclude some of the most useful countermeasures, such as new antibiotics and antivirals, since these would likely have a significant market beyond biodefense. These issues will likely face Congress during any debate on this legislation.

¹² See CRS Report RS20971, *Orphan Drug Act: Background and Proposed Legislation in the 107th Congress*.

¹³ See CRS Report 95-50, *The Federal Role in Technology Development*, and CRS Issue Brief IB91132, *Industrial Competitiveness and Technological Advancement*.

¹⁴ U.S. House Committee on Energy and Commerce Health Subcommittee and Select Committee on Homeland Security, March 27, 2003.

¹⁵ Andrew Pollack and Melody Petersen, "Untested Companies Enlist in U.S. Biodefense," *New York Times*, March 23, 2003.