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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 unapproved countermeasures. S. 15 (Gregg) incorporates these proposals. H. R. 2122 (Tauzin) is similar to S. 15. The largest difference is rather than creating a permanent, indefinite appropriation, H. R. 2122 establishes a special fund and authorizes the subsequent appropriation of up to $5.593 billion for the purchase of countermeasures through FY2013. Some provisions of Project BioShield are controversial. Some critics suggest that biotechnology and pharmaceutical companies will require even more incentives than contained in these proposals. 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 exist for few of the biological threats deemed the most dangerous by the Centers for Disease Control and Prevention (CDC).[1]

[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.

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, contains the administration proposal, with some revisions. The corresponding House bill, The Project BioShield Act of 2003 (H. R. 2122, Tauzin), contains many of the same provisions. The House passed H. R. 2122 on July 16, 2003. S. 15 and H. R. 2122 provide 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 contract authority to purchase countermeasures approved by the President. Another provision would give the Secretary of HHS the power to temporarily allow the emergency use of countermeasures that lack Food and Drug Administration (FDA) approval.

The largest difference between the bills is how each would fund the purchase of countermeasures. S. 15 authorizes and appropriates for each fiscal year in perpetuity "such sums as may be necessary" to procure countermeasures. This mandatory funding is not subject to the annual appropriations process. In contrast, H. R. 2122 does not appropriate any money, but establishes a special fund for the purchase of countermeasures and authorizes the appropriation of up to $5.593 billion total for the fiscal years 2004 to 2013. An additional difference between the bills is the additional reports required by H.R. 2122. The House version requires annual reports from the Secretary of HHS about the exercise of the authorities granted in this bill. Four years after enactment, H. R. 2122 requires a National Academy of Sciences review of how countermeasure development has been helped by this act and to suggest any additional actions that would be helpful.

Relaxing Acquisition Procedures. Both S. 15 and H. R. 2122 would relax procedures under the Federal Acquisition Regulation for procuring property or services used in performing, administering, or supporting biomedical countermeasure R&D. They would increase the threshold, from $100,000 to $25 million, for contracts awarded under simplified acquisition procedures. Each proposal 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 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 proposed in both bills are permanent. They would decrease the amount of paperwork required for these types of purchases, but also the potential for oversight. H. R. 2122 requires the HHS Secretary to report the use of these provisions annually to Congress.

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

Expedited Peer Review. S. 15 and H. R. 2122 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.[3] 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.

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 for inclusion in 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. S. 15 and H. R. 2122 would allow the HHS Secretary, with concurrence of the DHS Secretary and upon the approval of the President, to contract to purchase a product up to five years before the product is reasonably expected to be deliverable. Congress would be notified of a purchase 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.[4] S. 15 incorporates this concept. 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. H. R. 2122 would use such specific appropriations to fund a special fund.

The Administration estimates using $5.6 billion over 10 years to purchase countermeasures, although S. 15 permits expenditure of "any moneys in the Treasury not otherwise appropriated." The Congressional Budget Office projects that S. 15 would cost approximately $8.1 billion over 10 years, 45% more than the Administration estimate. H. R. 2122 authorizes the appropriation of up to $5.593 billion over for fiscal years 2004 through 2013. Under both proposals, these funds could not be used for administrative costs or to purchase vaccines under procurement contracts entered into before January 1, 2003 (under S. 15) or before enactment of Project BioShield (under H. R. 2122).

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

[4] 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 some of the provisions of S. 15.[5] 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 under S. 15. In contrast, H. R. 2122 would return any unobligated funds to the U.S. Treasury after FY2013. Some critics have expressed concern over S. 15 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 H. R. 2122, the fund would be subject to annual review through the appropriations process. Furthermore, H. R. 2122 would require the HHS Secretary to prepare annual reports detailing actions taken under this Act including identification of each person or entity that received, or was considered and rejected for grants, cooperative agreements, or contracts under this Act.

To qualify for purchase, S. 15 would require the HHS Secretary to determine that there is no other significant market for the countermeasure other than as a biological countermeasure. Some have suggested that this will not encourage the development of some of most useful countermeasures such as new wide-spectrum antivirals or antibiotics, since these 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. H. R. 2122 would require the HHS Secretary only to factor whether there is a lack of a significant commercial market into the decision to recommend the purchase of a countermeasure.

Exemptions to FDA Approval Process. S. 15 and H. R. 2122 allow the purchase of unapproved and unlicenced countermeasures. S. 15 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 5 years." H. R. 2122 omits the 5 year constraint. 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.[6] 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 and H. R. 2122 allow contracts to be written so that unapproved products may be purchased at lower cost than approved products.

S. 15 and H. R. 2122 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: 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.

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[5] Lisa Richwine. "Concerns Raised About Funding for U.S. Biodefense Program." *Reuters*. March 27, 2003.

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

Although this provision would permit the Secretary to circumvent the FDA approval process, its use would be limited to dire circumstances.

Policy Options

Alternative Contract Mechanisms. Some have suggested that the new contracting authority granted by S. 15 or H. R. 2122 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.[7] Some manufactures 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 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.[8] 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. Sellers of such technology may feel that they still have an unacceptable risk of litigation stemming from adverse effects of their products.

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.[9] 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

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

[8] See CRS Report RL31649 *Homeland Security Act of 2002: Tort Liability Provisions.*

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

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.[10] 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.[11] 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.[12] 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.[13] Such companies may find that the unrelated-patent extension provision in S. 666 provides enough incentive to justify the opportunity costs to their stockholders. These issues will likely face Congress during any debate on this legislation.

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[10] See CRS Report RS20971 *Orphan Drug Act: Background and Proposed Legislation in the 107th Congress.*

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

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

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