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CASE BRIEF:

THE FAILURES OF PROJECT BIOSHIELD & CONGRESSIONAL ATTEMPTS TO REMEDY IT

Megan O'Reilly

I. THE THREAT OF A BIOLOGICAL TERROR ATTACK

In response to the 2001 terrorist attacks, the United States government began a crash program to develop drugs, vaccine and diagnostic tests to protect the nation from biological terrorism.¹ As part of this effort, President Bush signed Project BioShield into law on July 21, 2004. The legislation was intended to facilitate a faster process to research, develop, purchase and make bioterrorism countermeasures available to combat bioterrorist threats.² However, Project BioShield is not drawing the interest it aimed for. The legislation has faced significant criticism because the law has failed to adequately provide consistent and well-coordinated financing, and sufficient, ensured markets, as well as any liability protection for vaccine developers.³ The threat of a biological attack is very real.⁴ To ensure that Project BioShield assists in protecting the nation from future bioterrorist attacks, it is necessary to evaluate the successes and setbacks the initiative has faced. In doing so, this brief will examine: (1) the legislative intent of Project BioShield; (2) the pharmaceutical market, and the impediments within in the industry that cause it to refrain from researching and developing bioterrorism countermeasures; (3) the effect of Project BioShield in the pharmaceutical industry and its production of new drugs; (4) the current legislative proposals attempting to address the law's alleged failures; and (5) what else needs to be done to ensure that adequate

¹ Andrew Pollack, *Untested Companies Enlist in U.S. Biodefense*, N.Y. TIMES, Mar. 23, 2003, at 3.

² Sandra Basu, *BioShield Not Drawing Interest it Aimed For* (Nov. 2004), available at: <http://www.usmedicine.com/article.cfm?articleID=967&issueID=68> (last visited Oct. 12, 2006).

³ Business Wire, *Project BioShield Success Depends on Ability to Guarantee Consistent, Long-Term Financing, Markets and Indemnity for BioDefense Vaccine Developers* (Apr. 4, 2003), available at: <http://www.highbeam.com/DocPrint.aspx?DocId=1G1:99604540> (last visited Oct. 12, 2006).

⁴ *Id.*

countermeasures are developed and America is prepared for a future bioterrorist attack.

II. PROJECT BIOSHIELD

The looming threats of biological terrorism demand that the United States develop clear strategies and dependable resources for defending against and responding to potential public health emergencies.⁵ In 2002, the Centers for Disease Control determined that one of the most serious vulnerabilities America faces is the fact that many potential biological terrorism agents lack available countermeasures.⁶ Pharmaceutical companies were electing not to manufacture countermeasures because the market is relatively small and the profits are limited. As a result, there was minimal economic incentive to invest the resources necessary to bring a new treatment to market.⁷

Hoping to encourage the development of new bioterrorism countermeasures, President George W. Bush proposed Project BioShield in his 2003 State of the Union address.⁸ The legislation was intended to encourage the development of new bioterrorism countermeasures.⁹ On July 21, 2004, President Bush signed the Project BioShield Act of 2004 into law. The law intended to: (1) relax the procedures for bioterrorism-related procurement, hiring, and awarding of research grants; (2) grant the Secretary of Health and Human Services (HHS) to, within his discretion, use an expedited award process for grants, contracts, and cooperative agreements related to biomedical countermeasure research and development activity; (3) guarantee a federal government market for new biomedical countermeasures; (4) permit emergency use of unapproved countermeasures; and (5) require that the HHS Secretary submit annual reports to the Government Accountability Office (GAO) about the exercise of the authorities granted in the legislation.¹⁰ The GAO is charged with producing a report four years after the law's enactment to assess actions taken under authorities granted by the act to determine the act's effectiveness and recommend additional measures to address

⁵ Press Release, Eshoo and Rogers Introduce Biodefense Measure: Strategies, Recourses Defend Against Terror Attacks, Pandemic Outbreaks (June 7, 2006) (on file with author).

⁶ Frank Gottron, *Project BioShield*, CRS REP. RS21507, at 1 (June 5, 2006).

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.* at 4.

the law's shortfalls.¹¹ The law did not appropriate any money for implementation, however \$5.593 billion was subsequently authorized for FY 2004 to FY 2013.¹² With this money, the administration hoped that companies would be enticed to develop new drugs and vaccines for anthrax, smallpox, botulism, Ebola, as well as other deadly diseases.¹³

Project BioShield, which was intended to be a procurement mechanism, allows the government to finance the stockpiling of countermeasures for biological, chemical, nuclear and radiological weapons.¹⁴ Prior to awarding a contract, the Department of Homeland Security (DHS) must make a "material threat determination."¹⁵ DHS will evaluate the medical and public health consequences to the threat, and then determine what medical countermeasures would be required to mitigate that threat.¹⁶ It is only after interagency consultation and presidential approval that a contract will be awarded. Furthermore, the government requires reasonable assurance that the specific countermeasure will be available in "sufficient quantities" and will be licensable by the Food and Drug Administration (FDA).¹⁷ However, a Project BioShield contract may provide that countermeasures not licensed at the time of delivery can be purchased at a discount with a bonus payable to the manufacturer upon FDA licensure.¹⁸

III. THE PHARMACEUTICAL INDUSTRY'S REJECTION OF PROJECT BIOSHIELD

Critics of Project Bioshield claim that the law has failed to deliver.¹⁹ Despite initially pledging their support, large drug companies have been unwilling to become involved with the law's efforts for a number of reasons. First, federal agencies have historically taken months if not years to decide which treatments they wanted and in what quantities. The time cycles needed to secure BioShield investments are uncertain,

¹¹ *Id.*

¹² *Id.* at 3.

¹³ Eric Lipton, *Bid to Stockpile Bioterror Stymied by Setbacks*, N.Y. TIMES, Sept. 17, 2006, at A6.

¹⁴ Luciana L. Borio and Gigi Kwik Gronvall, *Anthrax Countermeasures: Current Status and Future Needs*, 3 BIOSECURITY AND BIOTERRORISM: BIODEFENSE STRATEGY, PRACTICE, AND SCIENCE 2, at 105 (2005).

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ Lipton, *supra* note 13.

and companies cannot afford to halt product development if a particular funding stream does not materialize.²⁰ Furthermore, the industry is unsure of whether the BioShield initiative represents a long-term government commitment of sufficient size to make the venture worthwhile.²¹

To ignite participation, the market created by BioShield must be viewed as large enough to convince biotechnology companies that they have a partner who understands the high costs, complexity, and significant risk of developing therapeutics and bringing them to market.²² As it now stands, health scholars have stated that one reason pharmaceutical companies are reluctant to get involved in Project BioShield is because of the inept implementation of the program. This has led the most well respected and best scientists to give up, look elsewhere, or devote their resources to medical initiatives other than biodefense.²³

After an adequate and reliable market, the industry's greatest concern is indemnification.²⁴ Larger pharmaceutical companies do not want to assume the risks associated with developing countermeasures because Project BioShield contains no liability protections for manufacturers, even though the risk may be higher than for other products.²⁵ The law allows products to bypass usual clinical trials, required for FDA approval, but provides no protection against litigation that would stem from possible adverse effects related to a bioterrorism countermeasure.²⁶ The CEO of AVANT Immunotherapeutic stated that a biotechnology company like AVANT "cannot afford to risk their stockholders' investments and employees' livelihoods by venturing into the biodefense realm where large portions of the population will be inoculated in a program of administration over which we have little or no control."²⁷ Consequently, unless companies are protected to a fair and reasonable degree from the risk of lawsuits, many in the biotechnology industry have been unwilling to participate and assume the risk. The pharmaceutical companies fear ensuing lawsuits could

²⁰ Borio, *supra* note 14, at 109.

²¹ Business Wire, *supra* note 3.

²² *Id.*

²³ Lipton, *supra* note 13.

²⁴ Business Wire, *supra* note 3, at 2.

²⁵ Borio, *supra* note 14, at 108.

²⁶ Sarah Lister, *An Overview of the U.S. Public Health System in the Context of Emergency Preparedness*, CRS Report RL31719, (March 17, 2005).

²⁷ Business Wire, *supra* note 3, at 2.

put them out of business just by their existence, rather than their merit.²⁸

In addition to the fear of lawsuits, large pharmaceutical companies are restrained by their obligations to their board of directors and shareholders. The Securities and Exchange Commission's current guidelines state that companies cannot count payments for products as revenue unless the countermeasures are used.²⁹ Consequently, not recognizing the revenue from these government contracts could potentially hurt reported profits and earnings per share, and as a result, stock prices as well.³⁰

IV. PROJECT BIOSHIELD & ANTHRAX COUNTERMEASURES

With larger pharmaceutical companies unwilling or unable to participate in Project BioShield, smaller companies have come to dominate the biodefense countermeasure market.³¹

However, attempts to stockpile an anthrax vaccine have magnified the shortfalls of Project BioShield. As one senior health agency official stated, the top three threats to this nation are "anthrax, anthrax, anthrax."³²

The first Project BioShield contract dealt directly with anthrax and was announced November 4, 2004.³³ VaxGen Inc. was granted \$877.5 million to deliver 75 million doses of a new type of anthrax vaccine within three years.³⁴ This award fueled doubts about the law and drew complaints from Emergent BioSolutions, the maker of the previously used anthrax vaccine, because VaxGen is a relatively small

²⁸ *Id.*

²⁹ Borio, *supra* note 14, at 108.

³⁰ *Id.*

³¹ *Id.*

³² Lipton, *supra* note 13. There have been problems with the current anthrax vaccine. After the 2001 anthrax attacks, the health agency bought enough antibiotics for 41 million Americans, but recommended treatment supplements those drugs with a vaccine. The vaccine the government already had for military personnel was seen as ineffective based on the lengthy eighteen month treatment and the potentially fatal side effects. Reports stated that at least six military personnel died and others suffered serious complications, including lymphoma and multiple sclerosis. The military finally stopped mandatory vaccinations in 2004 after soldiers complained and filed lawsuits. *Id.*

³³ Gottron, *supra* note 6, at 2.

³⁴ Lipton, *supra* note 13.

firm that had never taken a drug to the market.³⁵ The company's history included a failed AIDS drug in 2003, and financial troubles which caused it to be barred from Nasdaq in 2004 for accounting errors.³⁶ The only other companies that bid on the new anthrax vaccine were also relatively small with limited experience.³⁷ Larger companies declined to bid on the anthrax vaccine due to the market limitations and the fear of liability if someone became ill or died after being inoculated. As a result of the potentially small market and limited profits, the larger pharmaceutical companies saw the effort as unappealing and found little or no incentive to participate in the project.³⁸

Rather than trying to develop a new anthrax vaccine, Emergent had been trying to persuade the government to buy hundreds of millions of dollars worth of the already existing vaccine. Emergent began an intense lobbying effort against the VaxGen vaccine to try and persuade lawmakers to purchase Emergent's anthrax vaccine instead. Emergent claimed that the VaxGen's new vaccine was based on a modified version of the old one and also pointed to tests on the drug in 2005 which showed that an ingredient in the drug caused it to decompose, making it impossible to survive in the emergency stockpile.³⁹

This exhaustive and expensive lobbying campaign has placed other BioShield endeavors in jeopardy, as one critic noted: "the maneuvering has been so intense, with lobbyists and media consultants helping the companies undermine the competition, even some of the people who have profited now express disgust."⁴⁰ The Emergent/VaxGen conflict is an additional reason larger pharmaceutical companies would rather not get involved in Project Bioshield. Consequently, Agency officials are scheduled to meet with industry representatives to discuss a new strategy for Project Bioshield.⁴¹ In the meantime, after spending millions of dollars, the country still does not have the countermeasure needed to defend itself against a large scale anthrax attack.⁴²

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

³⁹ Lipton, *supra* note 13.

⁴⁰ *Id.* at 5.

⁴¹ *Id.*

⁴² *Id.*

V. POLICY PROPOSALS TO ADDRESS THE SHORTFALLS OF PROJECT BIOSHIELD

In an effort to entice more companies to develop countermeasures and expand the scope of Project BioShield, Congress has introduced and passed additional legislation to address the concerns raised by some of the larger pharmaceutical companies. For companies developing countermeasures, Congress included a limited liability provision in the 2006 Defense Appropriations Act. The indemnification provision seeks to address the concerns surrounding the risk of litigation stemming from adverse effects.⁴³

Advocates of Project Bioshield claim changes also need to be made within the contracting authority of Project BioShield. They claim that the process would be more effective if modeled after that used by the Defense Advanced Research Projects Agency (DARPA), which also fund high risk projects.⁴⁴ DARPA contracts usually only last a few years and can be renewed only when specific milestones are met.⁴⁵ While the fear may be that the government would be funding countless risky development projects that will never make it to market, the contracts could be structured so that this assumption of development risk translates into lower procurement costs.⁴⁶

VI. LEGISLATIVE PROPOSALS OF THE 109TH CONGRESS⁴⁷

As the 109th Congress comes to an end in December 2006, many of the bills introduced to expand Project BioShield and encourage the development of additional countermeasures are in jeopardy of dying in Committee. Legislation introduced during the 109th Congress included: (1) the Protecting America in the War on Terror Act of 2005; (2) the Project BioShield II Act of 2005; (3) the Biodefense and Pandemic Vaccine and Drug Development Act of 2005; (4) the Biodefense and Pandemic Preparedness Act of 2005; and (5) the Biodefense and Pandemic Vaccine Drug Development Act of 2006.⁴⁸

⁴³ Gottron, *supra* note 6, at 4.

⁴⁴ *Id.* at 5.

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ The 109th Congress convened from January 2005- December 2006, *available at*: <http://www.house.gov/Welcome.shtml>, (last visited Oct. 23, 2006).

⁴⁸ *Id.*

While the language contained in these bills may differ, they share many similar provisions and share the goal of generating the tools and resources necessary to develop effective biological weapon countermeasures. These legislative initiatives proposed to: (1) include detection technologies and expand the categories of products eligible to be purchased with BioShield funds; (2) offer additional financial incentives to encourage countermeasure development, including market based such as exclusivity agreements, and lengthening exclusivity terms and patent extensions; (3) grant antitrust exemptions for communications between the government and industry; and (4) require that the Food and Drug Administration assist developers and manufacturers during the licensing process.⁴⁹

On September 27, 2006, the House of Representatives unanimously passed the Biodefense and Pandemic Vaccine and Drug Development Act of 2006 (H.R. 5533).⁵⁰ The legislation, sponsored by Congresswoman Anna G. Eshoo (D-CA) and Congressman Mike Rogers (R-MI), seeks to ensure that more bioterrorism countermeasures are made available in the market. The concern this legislation addresses is the fact that many promising countermeasures are not making it through the advanced research and development necessary to bring projects to the point of eligibility for Project BioShield. They are dying in the "Valley of Death," which refers to the period between early-stage research and commercialization.⁵¹ Specifically, the legislation would: (1) reorganize and enhance activities in HHS into the Biomedical Advanced Research and Development Authority (BARDA); (2) expand countermeasures covered by Project BioShield to include infectious diseases; (3) create an FDA rapid-action team to assist manufacturers to avert shortages of a vaccine or countermeasure; (4) allow HHS to enter into exclusive sales contracts for a particular product; (5) permit BioShield contracts to receive advance payments for meeting specified milestones; and (6) allow other executive agencies to order countermeasures through HHS.⁵²

⁴⁹ Gottron, *supra* note 6, at 6.

⁵⁰ Press Release, U.S. House Passes Eshoo Biodefense Bill (Sept. 27, 2006) (on file with author).

⁵¹ HOUSE ON ENERGY AND COMMERCE COMMITTEE, 109TH CONG., H.R. 5533, Rogers/Eshoo BARDA Bill Needed to Foster Stronger Biodefense (Sept. 2006).

⁵² Biodefense and Pandemic Vaccine and Drug Development Act of 2006: Hearing on H.R. 5533 Before the House Comm. On Energy and Commerce, 109th Cong., Talking points of Congresswoman Anna G. Eshoo, Member, House Comm. On Energy and Commerce (2006) (on file with author).

It is unclear what the future of this legislation will be. The Senate companion bill, S. 3678 is awaiting consideration by the full Senate.⁵³ The Bill's Senate sponsor, Senator Richard Burr of North Carolina, believes that the Senate will vote on the legislation before the 109th Congress adjourns.⁵⁴

VII. CONCLUSION

The threat of a biological attack is very real and the consequences of such an attack could undoubtedly be catastrophic. While it is incredibly difficult to estimate what a future attack will entail, the implementation of Project BioShield has created unnecessary obstacles to adequate preparation for such an attack. Stalled legislation and feuding pharmaceutical companies stand in the way of developing the measures needed to combat a biological attack. However, larger pharmaceutical companies may be motivated by the market to engage in Project BioShield should Congress address their indemnification concerns. The future development of bioterrorism countermeasures is likely to focus on the production of new vaccines, which are generally more profitable than old ones. Furthermore, biologicals have a limited shelf life and will need to be replaced in stockpile after several years, which could create additional incentives for manufacturers to compete for contracts that will last for several cycles.⁵⁵ With over \$5.6 billion over the next 10 years allocated to the procurement of bioterrorism countermeasures, Congress will likely continue to introduce new legislation to address the concerns expressed by the industry in an effort to ensure that this country is equipped with the most effective countermeasures possible in the wake of a bioterrorist attack.

⁵³ U.S. House Passes Eshoo Biodefense Bill, *supra* note 51.

⁵⁴ E-mail from Jennifer Nieto, Legislative Assistant, Congresswoman Anna G. Eshoo (Sept. 22, 2006, 10:45:59 CST) (on file with author).

⁵⁵ Borio, *supra* note 14, at 108.

