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The Project BioShield Act of 2004: An Innovative Failure

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## Abstract

On July 21, 2004, the President signed into law the Project BioShield Act of 2004. This legislation was intended to stimulate research, development, and procurement of countermeasures against biological, chemical, radiological or nuclear agents that may be used in a terrorist attack against the United States, given America's demonstrated and increasing vulnerability to these attacks, as well as the deficit in countermeasures to prevent and ameliorate the effects of such attacks. Despite the innovative provisions of the Act, it has been largely a failure and has not properly incentivized the private pharmaceutical industry to develop these needed products. This paper examines the Act and the criticism surrounding its implementation. The paper then evaluates alternatives to the Project BioShield Act, including BioShield II, now pending in the 109<sup>th</sup> Congress. The paper concludes by finding that the Project BioShield Act is a good first step in addressing biodefense, but Congress needs to go farther to order to respond to America's vulnerabilities to a biological terrorist attack.

## I.

## **Introduction**

September 11<sup>th</sup> and the subsequent anthrax attacks drew attention to the possibility of a biological attack against America. These events also highlighted America's lack of preparation for such an attack. This deficit was in part the result of an inadequate natural market for the types of medical and scientific products that would prevent or ameliorate the effects of such an attack. The President and United States Congress responded with an initiative called the Project BioShield Act of 2004. Part II of this paper provides background information, explaining the real threat of a terrorist attack and this country's specific vulnerabilities. Part II also discusses how some of these vulnerabilities are the result of a stymied market for biodefense countermeasures and how the government is expected to respond to produce such a market. Part III describes the actual enacted legislation—the Project Bioshield Act of 2004. The Act is comprised of four main sections: countermeasures research and development authorities, countermeasure procurement authorities, authorization for medical products for use in emergencies, and reporting requirements. In addition to summarizing these sections, Part III provides a brief history and the legislative intent of the Act. Part IV discusses the actual implementation of the Act and the criticism surrounding that implementation, including a confusing government bureaucracy; unaccounted for public health priorities; funding gaps; and the absence of any liability protection for companies researching, developing and manufacturing countermeasures. Alternatives and improvements upon the Act, including a comprehensive new bill,—BioShield II—are offered at Part V.

### **I.**

## **Background: The Problem**

### **a.**

## Vulnerabilities

The threat of biological agents being used deliberately to harm civilian populations has long been a reality, but after September 11, 2001 and the subsequent anthrax attacks, Americans began to realize that America is vulnerable to these threats.<sup>1</sup> The potential devastation resulting from such an attack is enormous. President Bush declared that, “Armed with a single vial of biological agent, small groups of fanatics, or failing states, could gain the power to threaten great nations, threaten the world peace. America, and the entire civilized world, will face this threat for decades to come. We must confront the danger with open eyes and unbending purpose.” In a Homeland Security Presidential Directive, the White House outlined that attacks with biological weapons could: cause catastrophic numbers of acute casualties, long-term disease and disability, psychological trauma, and mass panic; disrupt critical sectors of the American economy and the day-to-day lives of Americans; and create cascading international effects by disrupting and damaging international trade relationships, potentially globalizing the impacts of an attack on United States soil.<sup>2</sup> Senate Majority Leader Bill Frist, during a session of Congress, asserted, “Agents of bioterror are potentially the most powerful and devastating weapons of mass destruction that are known to man. Bioterror agents are more powerful than traditional weapons of mass destruction, are more powerful than chemical weapons, are more powerful than

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<sup>1</sup>Ryan Kemper, *Responding to Bioterrorism: An Analysis of Titles I and II of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, 83 WASH. U. L. Q. 385, 386 (2005) (noting that the use of biological agents as a means to invoke fear and inflict destruction dates back to at least 1346 when soldiers loaded victims of bubonic plague into catapults to launch over city walls).

<sup>2</sup>Biodefense for the 21<sup>st</sup> Century, Homeland Security Presidential Directive – 10, April 28, 2004, <http://www.fas.org/irp/offdocs/nspd/hspd-10.html>, last accessed April 10, 2006. The President has also often pointed to biological threats emanating from Saddam Hussein, although these threats have failed to materialize. In his State of the Union Address to Congress in 2003, the President explained, “The United Nations concluded in 1999 that Saddam Hussein had biological weapons sufficient to produce over 25,000 liters of anthrax –enough doses to kill several million people. He hasn’t accounted for that material. He’s given no evidence that he has destroyed it. The United Nations concluded that Saddam Hussein had materials sufficient to produce more than 38,000 liters of botulinum toxin—enough to subject millions of people to death by respiratory failure. He hadn’t accounted for that material. He’s given no evidence that he has destroyed it. Our intelligence officials estimate that Saddam Hussein had the materials to produce as much as 500 tons of sarin, mustard and VX nerve agent. In such quantities, these chemical agents could also kill untold thousands. He’s not accounted for these materials. He has given no evidence that he has destroyed them. U.S. intelligence indicates that Saddam Hussein had upwards of 30,000 munitions capable of delivering chemical agents. Inspectors recently turned up 16 of them—despite Iraq’s recent declaration denying their existence. Saddam Hussein has not accounted for the remaining 29,984 of these prohibited munitions. He’s given no evidence that he has destroyed them.” Address Before a J. Session of the Congress on the State of the Union, 107 WEEKLY COMP. PRES. DOC. 114 (Jan. 28, 2003).

nuclear weapons.”<sup>3</sup> His rationale was that bioterror agents can be infectious: “they are agents of virus, of bacteria, of another living organism that cannot be seen, that cannot be touched, that cannot be smelled or heard.” Further, he reasoned, “They know no borders. There are no geographic borders. They attack indiscriminately, and they can travel through a school, they can travel through a community, they can travel through a State, they can travel through a country, and they can travel, indeed, through a continent. They are powerful, powerful agents.”<sup>4</sup> There is no dispute with the President or the Senator’s contentions that the consequences of a biological attack on American soil would be devastating, yet America has shown it is wholly unprepared to deal with these kinds of biological threats.<sup>5</sup>

In the fall of 2001, letters containing anthrax spores were mailed to news media personnel and congressional offices.<sup>6</sup> Outbreaks of the disease were concentrated in six locations: Florida; New York; New Jersey; Capitol Hill in Washington, D.C.; the Washington, D.C. regional area, including Maryland and Virginia; and Connecticut.<sup>7</sup> The anthrax incidents caused illness in 22 people: 11 with cutaneous (skin) form of the disease and 11 with inhalational (respiratory) form.<sup>8</sup> Five people died.<sup>9</sup> Demands on public health resources reached far beyond even the six epicenters of the outbreak.<sup>10</sup> Once officials realized that mail processed at contaminated postal facilities could be cross-contaminated and end up anywhere in the country, residents brought samples of suspicious powders to officials for testing and worried about the safety of their daily

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<sup>3</sup>150 CONG. REC. S5744, 5760 (2004).

<sup>4</sup>*Id.*

<sup>5</sup>*See* 150 CONG. REC. H5721, 5729 (2004) (statement of Rep. Turner) (“[I]n spite of this dire and clear warning, our biodefenses are no better than they were in September of 2001. No new medical treatments, vaccines, or lifesaving drugs have been approved for use. There is no antitoxin for ricin poisoning, no vaccine to protect against the plague, and no treatments of any kind against the deadly ebola virus.”).

<sup>6</sup>U.S. GOV’T ACCOUNTABILITY OFFICE, BIOTERRORISM: PUBLIC HEALTH RESPONSE TO ANTHRAX INCIDENTS OF 2001 1 (2003).

<sup>7</sup>*Id.*

<sup>8</sup>*Id.*

<sup>9</sup>*Id.*

<sup>10</sup>*Id.* at 9.

mail.<sup>11</sup>

In dealing with this crisis, there were deficiencies in both the local public health response and the federal government's ability to manage it. Local and state public health officials explained that problems arose because they had not fully anticipated the extent of coordination needed among responders and they did not have the necessary agreements in place to put the plans into operation rapidly.<sup>12</sup> They reported that communication among response agencies was generally effective, but they ran into trouble reaching clinicians to provide them with guidance, and that they had not anticipated the number of entities with which they would have to communicate.<sup>13</sup> The state and local officials in the epicenters also reported that the capacity of the public health workforce and clinical workforce was strained and they would have been unable respond to a more extensive outbreak.<sup>14</sup>

The federal government was similarly challenged as the Centers for Diseases Control and Prevention (CDC) had to meet demands from local and state officials as well as coordinate the federal response. The CDC reported that it was not fully prepared to manage the federal public health response and had difficulty in handling the voluminous amount of information coming into the agency, and in communicating with public health officials, the media and the public.<sup>15</sup> The anthrax incidents also revealed the shortcomings in clinical tools available to respond to anthrax—such as vaccines and drugs—and the lack training for clinicians in how to recognize and respond to an outbreak of anthrax.<sup>16</sup>

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<sup>11</sup> *Id.* at 1.

<sup>12</sup> *Id.*

<sup>13</sup> Public health departments had to coordinate their responses with those of local and federal enforcement, emergency responders, the postal community, environmental agencies, and clinicians. *Id.* at 11.

<sup>14</sup> *Id.* at 1.

<sup>15</sup> *Id.* CDC Employees slept in their laboratories around the clock to perform tests on tens of thousands of specimens. David Johnston, *Report Calls U.S. Agencies Understaffed for Bioterror*, N.Y. TIMES, July 6, 2003, §1 at 1.

<sup>16</sup> U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 6, at 1. One article detailed the tragic death of a postal worker in the D.C. metro area who had gone to the hospital with "flu-like symptoms," but the hospital did not know initially that he was a postal worker and sent him home with medications for nausea and dehydration. Elizabeth Becker and Robin Toner, *A Nation Challenged: The Victims; Postal Workers' Illness Set Off No Alarms*, N.Y. TIMES, Oct. 24, 2001, at B1.

Another biological attack occurred two years later when the toxin ricin was discovered in Senator Frist's office in the Dirksen Office Building, in February 2004, and in a postal facility in Greenville, South Carolina, in October 2003.<sup>17</sup> Ricin is a potent plant toxin found in the seeds of the castor plants.<sup>18</sup> It works by blocking cell protein synthesis and can lead to organ failure and death of the victim.<sup>19</sup> After the toxin was discovered in a letter-opening machine in the Senator's office, federal investigators examined some 20,000 pieces of mail hoping to find the source of the ricin, but turned up nothing to lead them to a suspect.<sup>20</sup> They were unable to determine whether the ricin had been there for hours, weeks, or even months before it was discovered by an intern in the office.<sup>21</sup> Many experts believe that it would be difficult to use ricin as a weapon of mass destruction because ricin needs to be injected, ingested, or inhaled by the victim to injure.<sup>22</sup> Thus, deploying ricin to cause mass casualties is logistically impractical even for a well-funded terrorist organization.<sup>23</sup> However, most experts agree that ricin is a formidable weapon if used in small-scale attacks.<sup>24</sup> There is currently no vaccine available for use by the general public, nor any specific medicine available to treat ricin exposure.<sup>25</sup> However, there are currently several methods available to detect the release of ricin, but these detectors are not widely implemented in civilian settings.<sup>26</sup>

Despite the ineffectiveness demonstrated by public health officials in the anthrax and ricin attacks, vulnerabilities to bioterrorism remain.<sup>27</sup> In discussing the likelihood of a bioterrorist attack, industry leaders see the

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<sup>17</sup>Allan Lengel, *Probe of Ricin on Hill Still Wide Open, FBI says; Toxin found in February Provides Few Clues*, WASH. POST, April 6, 2004, at B04.

<sup>18</sup>DANA A. SHEA AND FRANK GOTTRON, CONG. RESEARCH SERV, RS21383, RICIN: TECHNICAL BACKGROUND AND POTENTIAL ROLE IN TERRORISM 2 (2004).

<sup>19</sup>*Id.*

<sup>20</sup>Lengel, *supra* note 17.

<sup>21</sup>*Id.*

<sup>22</sup>SHEA AND GOTTRON, *supra* note 18, at 6.

<sup>23</sup>*Id.*

<sup>24</sup>*Id.*

<sup>25</sup>*Id.* at 2-3.

<sup>26</sup>*Id.* at 3.

<sup>27</sup>Sari Horwitz and Christian Davenport, *Terrorism Could Hurl D.C. Area Into Turmoil; Despite Efforts Since 9/11, Response Plans Incomplete*, WASH. POST, September 11, 2005, at A01.



question not as *whether* America will be attacked with an organism for which we have no countermeasure, but *when*.<sup>28</sup> One noted, “Any high school student can create genetically engineered organism.”<sup>29</sup> While many technological hurdles exist for anyone attempting to use biological weapons against a civilian population, some say that it is all but inevitable that al Qaeda or another terrorist group will be able to gain the expertise necessary to inflict mass casualties in this manner.<sup>30</sup> Advances in bioscience and the rapid dissemination of this knowledge worldwide—especially through the internet—make it easier to create dangerous pathogens.<sup>31</sup> Richard Danzig, a former Navy secretary and current biowarfare consultant to the Pentagon conjectures that, “it seems like that, over a period of between a few months and a few years, broadly skilled individuals equipped with modest laboratory equipment can develop biological weapons. Only a thin veil of terrorist ignorance and inexperience now protects us.”<sup>32</sup>

Threats of biological attacks also derive from more concrete sources. During the 1970s and 80s, the Soviet Union was developing biological weapons using specially engineered strains of dangerous pathogens, including anthrax, plague and smallpox.<sup>33</sup> A Government Accountability Office (GAO) report from April 2000 found that biological weapons institutes in the former Soviet Union “continue to maintain vast collections of dangerous pathogens that could be used for...an offensive biological weapons program.” For instance, Vector, one of the institutes, is one of the world’s two authorized smallpox repositories and also contains a culture collection that includes the highly lethal Marburg and Ebola viruses.<sup>34</sup> The GAO report found that

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<sup>28</sup>*Is BioShield Doing the Job?*, 24 BIOTECHNOLOGY L. REP. 56, 56 (2005).

<sup>29</sup>*Id.*; Specifically, some scientists believe that a sophisticated terrorist would not even need to obtain the natural smallpox virus, but could make it from scratch. Andrew Pollack, *With Biotechnology, A Potential to Harm*, N.Y. TIMES, November 27, 2001, at F6. Robert L. Erwin, Chief executive of Large Scale Biology Corporation, a biotech company that does research involving plant viruses, claims that the complete genome sequence of the virus is freely available on the Internet and, in theory, could be used to transform a related virus into smallpox itself. *Id.*

<sup>30</sup>John Mintz, *Technological Hurdles Separate Terrorists from Biowarfare*, WASH. POST, Dec. 20, 2004, at A01.

<sup>31</sup>*Id.*

<sup>32</sup>*Id.*

<sup>33</sup>Philip Taubman, *An Arsenal of Germs*, N.Y. TIMES, June 20, 1999, §7 (Book Review Desk) at 15. The program was one of the best-kept secrets of the cold war, consuming close to \$1 billion per year and employing more than 60,000 people at dozens of sites while Mikhail Gorbachev was the Soviet leader. *Id.*

<sup>34</sup>U.S. GOV’T. ACCOUNTABILITY OFFICE, BIOLOGICAL WEAPONS: EFFORT TO REDUCE SOVIET THREAT OFFERS BENEFITS,

these institutes—consisting of as many as 15,000 underpaid scientists and researchers, specialized facilities and equipment and large collections of dangerous pathogens—continue to threaten U.S. national security.<sup>35</sup> They could pose a potential danger if hostile countries or groups were to hire them or the biological weapons scientists to conduct research, or were to obtain dangerous pathogens originating from the institutes.<sup>36</sup> GAO noted that deteriorated physical safety and security conditions could leave dangerous pathogens vulnerable to theft or distribution into the local environment.<sup>37</sup> Finally, given the existing infrastructure, there is potential for renewed production of biological agents in the institutes.<sup>38</sup>

b.

#### **Deficiencies in the Market for Countermeasures**

i.

##### **Vaccines not profitable**

Despite massive potential threats posed by deleterious biological agents, the harm from such agents can be alleviated by effective countermeasures. The anthrax attacks were mitigated by the fact that there were prophylactic antibiotics available for that strain of anthrax.<sup>39</sup> Had the government not had accessible large quantities of Cipro, a known countermeasure, the casualties would have been much greater.<sup>40</sup> However, the

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POSES NEW RISKS 13 (2000).

<sup>35</sup>*Id.* at 5.

<sup>36</sup>*Id.*

<sup>37</sup>*Id.*

<sup>38</sup>*Id.* at 9.

<sup>39</sup>FRANK GOTTRON AND ERIC FISCHER, CONG. RESEARCH SERV., RL32549, PROJECT BIOSHIELD: LEGISLATIVE HISTORY AND SIDE-BY-SIDE COMPARISON OF H.R. 2122, S.15, AND S. 1504 1 (2005).

<sup>40</sup>H.R. REP. NO.108-147, pt. 2, at 15-16.

government's response to make this product available highlights some of the trepidations that pharmaceutical companies have about entering into the biodefense vaccine market. At the time that Cipro was desperately needed by the government, Bayer, a large pharmaceutical company held the patent. Bayer was making the drug available to the government at below wholesale cost.<sup>41</sup> But in a panic that not enough of the product would be available, members of Congress and Secretary of Health and Human Services, Tommy Thompson, threatened to force compulsory licensing of the patent on Cipro in order to enable generic companies to enter the market, thereby forcing Bayer to lower its already discounted price for the drug.<sup>42</sup> While Cipro's patent has since ended, this incident draws attention to a fear of the drug industry: the government will eviscerate its profits in a time of crisis.<sup>43</sup> Pharmaceutical companies need clear assurance that their patent and intellectual property rights will not be compromised in similar circumstances.<sup>44</sup>

The vaccine industry has been going through a slump in the last few decades because most private sector research and development dollars go to drugs or devices that will have continuous commercial application.<sup>45</sup> For instance, last year, sales of Liptor were more profitable than sales for the entire vaccine industry

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<sup>41</sup>Cynthia M. Ho, *Inoculation Inventions: The Interplay of Infringement and Immunity in the Development of Biodefense Vaccines*, 8 J. HEALTH CARE L. & POL'Y 111, 113 (2005).

<sup>42</sup>*Id.*

<sup>43</sup>See Gregory M. Lamb, *New Buffer for Bioterror's Tempest*, CHRISTIAN SCIENCE MONITOR, July 1, 2004, at 14 ("After the anthrax letters scare, Tommy Thompson, the HHS secretary, demanded that Bayer lower its prices on Cipro, an anthrax drug, or risk losing its patent—sending a chilling signal to drugmakers."); *Roundtable Discussion: When Terror Strikes—Preparing an Effective and Immediate Public Health Response: Hearing of the Comm. on Health, Education, Labor, and Pensions*, 109<sup>th</sup> Cong. 45-46 (2005) (response to questions of the committee by Chuck Ludlam, Esq., former legal counsel to Senator Joseph Lieberman) ("They say, 'Look what happened to Bayer,' which was subject to virtual expropriation of its antibiotic, Cipro, by HHS following the 2001 anthrax attack. In fact, the outrageous actions of HHS in that case have plagued our ability to engage this industry in this research. We must have credible Administration officials state categorically that these Mafioso tactics will never ever be seen again against a company that develops countermeasures for infectious pathogens. The companies must be rewarded, not vilified.").

<sup>44</sup>See *Project BioShield: Contracting for the Health and Security of the American Public: Hearings Before the Comm. on Gov't Reform*, 108<sup>th</sup> Cong. 16 (2003) (statement of Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases) ("However, when you're dealing with a product for which there is no guarantee of a return, or for which the market is tenuous, these companies clearly need some assurances that there will ultimately be a return for their investment. Without such assurances, they will simply pursue the development of other products.") [hereinafter *Project BioShield: Contracting for the Health and Security of the American Public Hearing*].

<sup>45</sup>Scott Hensley and Bernard Wysocki Jr., *Missing Medicine—Shots in the Dark: As Industry Profits Elsewhere, U.S. Lacks Vaccines, Antibiotics; Incentives are Low to Develop Some Public-Health Drugs; New Moves in Washington; A \$200 Million Legal Fight*, WALL ST. J., November 8, 2005, at A.1.

combined.<sup>46</sup> There is little incentive for publicly-traded drug companies to make products with low profit margins, infrequent use and a high likelihood of liability lawsuits, such as vaccines.<sup>47</sup> Moreover, drugs that treat a disease are more lucrative than vaccines to prevent it partly because people are more inclined to pay for a medicine that treats a condition they already have.<sup>48</sup> For example, in one economic model, an expert determined that revenue from drugs to treat AIDS would be twice as high as from a vaccine to prevent it.<sup>49</sup> A successful vaccine may also devour its own market by eradicating the disease it protects against.<sup>50</sup> And, even though some current generation drugs or devices may have special uses as countermeasures to biological agents like Ebola, there is little motivation to perform the research, development or production activities that might tailor the drug or drug approvals for such a purpose.<sup>51</sup> It is not enough that there may be a possible one-time purchase by the federal government.<sup>52</sup>

ii.

### Liability

Pharmaceutical companies are reluctant to enter the vaccine industry because they are subject to potentially huge liability. One industry tale is enough to make anyone uneasy about the future market for vaccine. Wyeth started making smallpox vaccine in 1885 and was a principle supplier of childhood vaccines in the United States for most of the 20<sup>th</sup> Century.<sup>53</sup> But beginning in the 1980s, it became the target of lawsuits linking vaccines to a wide range of illnesses without obvious causes, such as epilepsy and attention deficit disorder.<sup>54</sup> Wyeth estimates the industry has spent more than \$200 million defending itself against hundreds of lawsuits

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<sup>46</sup> *Id.*

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> H.R. REP. NO.108-147, pt. 3 at 17.

<sup>52</sup> *Id.*

<sup>53</sup> Hensley and Wysocki, *supra* note 45.

<sup>54</sup> *Id.*

alleging that a preservative in some vaccines called thimerosal causes autism and other diseases.<sup>55</sup> Yet, since the lawsuits against thimerosal were filed, four large studies performed in Denmark, the United States, and the United Kingdom showed that children who received vaccines containing thimerosal were not more likely to have neurological problems such as speech and language delays, tics, learning disabilities, or autism than those who did not receive these vaccines.<sup>56</sup> In 2004, a group of scientists from the Institute of Medicine, an independent research organization within the National Academy of Sciences, reviewed studies that examined the relationship between thimerosal and neurological damage; all studies found the same thing: Thimerosal, at the level contained in vaccines, did not cause harm.<sup>57</sup> The lawsuits have not gone to trial.<sup>58</sup>

Product liability is an especially risky prospect in the biodefense industry where products cannot be ethically tested on humans. Drugs to treat diseases like anthrax and smallpox cannot be fully tested in humans because it would be unethical to poison someone to test the drug's efficacy.<sup>59</sup> Researchers must use relevant animal models to determine the appropriate human dose of new drugs and gather efficacy data.<sup>60</sup> The Food and Drug Administration (FDA) acknowledged the inherent limitations of testing by waiving human clinical trials, instead allowing appropriate studies in animals, "to provide substantial evidence of new drug and biological products used to reduce or prevent the toxicity of chemical, biological, radiological or nuclear substances."<sup>61</sup> Another risk-producing fact is that biodefense-related vaccines and drugs may also be quickly

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<sup>55</sup>*Id.* Autism has no known cause and no cure. Sandy Kleffman, *Is There a Link Between Vaccines; Is There a Link Between Vaccines, Autism?; Some Experts Say Hearing Should Wait for More Evidence*, MILWAUKEE J. SENTINEL, Feb. 9, 2004, at 01G.

<sup>56</sup>Paul A. Offit, *Saving Vaccines*, 24 PROD. LIABILITY L. & STRAT., 3, 3 March 2006

<sup>57</sup>*Id.*

<sup>58</sup>Hensley and Wysocki, *supra* note 45.

<sup>59</sup>James T. O'Reilly, *Bombing Bureaucratic Complacency: Effects of Counter-Terrorism Pressure Upon Medical Product Approvals*, 60 N.Y.U. ANN. SURV. AM. L. 329, 336, n.33 (2004) ("This uncertainty is inherent in the antidote research effort, but it makes the investor less willing to support the development costs and it expands the company's liability concerns.").

<sup>60</sup>*Biodefense: Next Steps: Hearings Before the Subcomm. on Bioterrorism and Public Health Preparedness of the Comm. on Health, Education, Labor, and Pensions*, 108<sup>th</sup> Cong. 47 (Statement of George Painter, CEO, ChimereX).

<sup>61</sup>*New Drug and Biological Drug Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible*, 68 Fed. Reg. 37988, 37988-37989 (May 31, 2002).

distributed in an emergency situation and given to millions of people.<sup>62</sup> Given the financial consequences stemming from even potential liability lawsuits, coupled with the increased risks intrinsic to the biodefense industry, companies have shied away from the manufacture of these products.

iii.

### Lengthy FDA Approval Process

Even if a product has been developed to treat diseases or conditions, if the product has not yet been approved by the FDA, access to the therapy is greatly limited. The FDA approval process is lengthy and complicated. The conservative and cautious approval process reflects the accepted role of the FDA as a gatekeeper.<sup>63</sup> Drug approval by the FDA is intentionally arduous and meticulously detailed in its evidentiary requirements in order to screen out products that may pose health risks.<sup>64</sup> One estimate is that the investigational new drug (IND) process takes seven to thirteen years and costs between \$30 million and \$50 million.<sup>65</sup> Another more recent article finds that “costs of new drug developments range from \$400 million to over \$800 million” and the costs accumulate over an estimated ten to fifteen years required to gain FDA approval.<sup>66</sup>

Nothing in the Food Drug and Cosmetic Act allows for the suspension of approval requirements to ensure

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<sup>62</sup>Bernard Wysocki Jr., *Missing Medicine—Emergency Response: Fearing Avian Flu, Bioterror, U.S. Scrambles to Fill Drug Gap; Congress Debates Incentives and Liability Protection for Vaccines, Antibiotics; Trial Lawyers: ‘That’s Unfair,’* WALL ST. J., November 9, 2005, at A.1.

<sup>63</sup>O’Reilly, *supra* note 59, at 333.

<sup>64</sup>*Id.* at 334.

<sup>65</sup>PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW, CASES AND MATERIALS* 514 (2<sup>nd</sup> Ed. 1991).

<sup>66</sup>Janene Boyce, *Disclosure of Clinical Trial Data: Why Exemption 4 of the Freedom of Information Act Should be Restored*, 2005 DUKE L. & TECH. REV. 3, 8 (2005); *see also*, James Thuo Gathii, *Rights, Patents, Markets and the Global AIDS Pandemic*, 14 FLA. J. INT’L L. 261, 340 (2002) (“The forgoing process of drug approval takes at least seven years.”); *Crossing the Valley of Death: Bringing Promising Medical Countermeasures to BioShield: Hearing before the Comm. on Health, Education, Labor and Pensions, Bioterrorism and Public Health Preparedness Subcomm.*, 109<sup>th</sup> Cong. 17 (2005) (Statement of Joe Palma, Medical Director, Chemical/Biological Defense Programs, Office of the Deputy Assistant to the Secretary, U.S. Department of Defense) (“Fewer than 100 candidates will receive approval by the FDA, and once a product receives FDA approval it can take, in our estimation, between eight and 10 years and \$500 million to \$800 million to bring it to market.”) [hereinafter *Hearing on Crossing the Valley of Death*].

access to unapproved drugs and devices on a large-scale basis in times of emergency.<sup>67</sup> Under present law, if a product is not approved by the FDA, then it is unlawful to provide that product to an individual, unless the product has been authorized for distribution under an IND application (for a drug or biologic) or an investigational device exemption (IDE). When a drug or device is available under such procedures, a number of conditions apply that make the use of an IND or IDE infeasible in times of national emergency, where drugs and devices may need to be deployed at rapid rates. Even if a drug, biologic, or device is highly promising in treating a disease or condition associated with biological, chemical, radiological or nuclear agents, and even if it is the only therapy available, current FDA law does not allow for rapid deployment of the product.<sup>68</sup>

c.

### Government Intervention

Given these failings in the market for available countermeasures, members of Congress have accepted that it is their job to do something to affect the stymied market for biodefense countermeasures in order to provide for the possible occurrence of a biological attack against Americans. The new cognizance of America's vulnerability to potentially devastating bioterrorist attacks has produced sea change in the way that the federal government approaches biodefense. As one expert testified after the attacks, "We must understand that public health is now an essential aspect of national security."<sup>69</sup> Members of Congress from both sides of the aisle support this premise. One representative discussed how the sheer fact that the American government is doing anything to deal with the potential of a terrorist attack deters the very possibility of

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<sup>67</sup>H.R. REP. NO.108-147, pt. 3 at 17.

<sup>68</sup>*Id.*

<sup>69</sup>Frank Rapoport, Christopher C. Bouquet, and Scott Flukinger, *Project BioShield Act of 2004: Dawn of a New Industry?*, 40 SPG PROCUREMENT LAW 3, 3 (2005)., quoting *Terrorism Through the Mail: Protecting Postal Workers and the Public*, J. Hearing Before the Comm. on Governmental Affairs and the Subcomm. on Int'l Security, Proliferation & Fed. Servs., 107<sup>th</sup> Cong. (2001) (testimony of Tara O'Toole, M.D.).

such an attack: “The reality is if al Qaeda knows that we are unprepared for a chemical, a biological or a radiological attack, then they are incentivized to make that kind of attack. On the other hand if they know that we have invested the money and done the research and we have developed countermeasures so that a biological attack or an anthrax attack, an attack of ebola or of the plague is something we are prepared for, then they are discouraged to even make that kind of attack.”<sup>70</sup> He also made the case that this is a job for the government given that “The American people expect us to do everything humanly possible to prepare for the event of an attack; but even more importantly they want us to deter any attacks. They want us to protect the American people from an attack.”<sup>71</sup> Representative Waxman made a claim against adopting a laissez faire attitude toward the market, stating, “I also agree with [the] premise that when the market cannot foster the development of critical products by itself, the government must rise to the challenge.”<sup>72</sup> In his Senate confirmation hearing, Mike Leavitt—now Secretary of Health and Human Services—when questioned about BioShield and how to revitalize the vaccine industry, similarly voiced a role for the federal government: “One, we can’t expect that we will have people stepping up to manufacture unless there’s a market. And there needs to be a market. Sometimes it may need to be the federal government to make certain that there’s a market.”<sup>73</sup> The Legislative and the Executive Branches have both evinced a strong desire to confront the problem of lack of countermeasures, but it was unclear how that would be done.

## II.

### **The Enacted Legislation: The Project BioShield Act of 2004**

In his State of the Union Address in early 2003, President Bush called upon Congress “to add to our future

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<sup>70</sup>150 CONG. REC. H5721, 5733 (2004) (Statement of Rep. Shadegg).

<sup>71</sup>*Id.*

<sup>72</sup>149 CONG. REC. H6908, 6930 (2003).

<sup>73</sup>*Nomination of Michael O. Leavitt, Hearing of the Comm. on Health, Education, Labor and Pensions*, 109<sup>th</sup> Cong. 49 (2005).



security with a major research and production effort to guard our people against bioterrorism, called Project BioShield.”<sup>74</sup> He explained that the budget he planned to send to Congress would propose almost \$6 billion “to quickly make available effective vaccines and treatments against agents like anthrax, botulinum toxin, Ebola, and plague.”<sup>75</sup> In this same speech, the President emphasized the potential threat of bioterrorism, explaining that the “gravest danger in the war on terror, the gravest danger facing American and the world” arises from what he called, “outlaw regimes,” that come to possess nuclear, chemical and biological weapons that they will use for “blackmail, terror, and mass murder.”<sup>76</sup> These regimes could, in turn, sell those weapons to “terrorist allies, who would use them without the least hesitation.”<sup>77</sup>

Congress complied by passing the Project BioShield Act of 2004. The Act does much to accomplish the goals the President outlined. It provides needed incentives to the private pharmaceutical industry to produce the very vaccines for diseases the President mentioned, such as anthrax. However, the Act does not go far enough to make comprehensive biodefense a reality. This section will summarize the Project BioShield Act, explaining the key provisions. Then it will turn to a discussion of the rationales and legislative intent behind the Act. The following section will discuss the implementation of this Act—both the successes and obvious deficits.

**a.**

### **Overview of the Project BioShield Act of 2004**

The Project BioShield Act of 2004 was designed to address the Nation’s inadequate means to deal with the threat from bioterrorism by creating a market for countermeasures. The Act’s stated purpose is “to provide

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<sup>74</sup>Address Before a Joint Session of the Congress on the State of the Union, WEEKLY COMP. PRES. DOC. 107, 109 (Jan. 28, 2003).

<sup>75</sup>*Id.*

<sup>76</sup>*Id.* at 113.

<sup>77</sup>*Id.*

protections and countermeasures against chemical, radiological or nuclear agents that may be used in a terrorist attack against the United States by giving the National Institutes of Health contracting flexibility, infrastructure improvements, and expediting the scientific peer review process and streamlining the Food and Drug Administration approval process of countermeasures.”<sup>78</sup> The Project BioShield Act does not actually appropriate any money, but instead authorizes the appropriation of up to a total of \$5.593 billion for fiscal year 2004 to fiscal year 2013, for the procurement of security countermeasures.<sup>79</sup> During fiscal year 2004, \$890 million is authorized to be obligated and for fiscal years 2004 through 2008, up to \$3.418 million may be obligated.<sup>80</sup>

## **Section 2: Countermeasures Research and Development Authorities**

The Act gives the Secretary of HHS authority to use expedited procedures related to the research and development of “qualified countermeasures,” which are defined as a drug, biological product or device that used to “(A) treat, identify, or prevent harm from any biological, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security or (B) treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device that is used as described in subparagraph (A).”<sup>81</sup> The Act relaxes acquisition procedures under the Federal Acquisition Regulation for the Secretary’s procurement of property or services for use in qualified countermeasure research or development activities.<sup>82</sup> It does this first by increasing the maximum to \$25 million for contracts awarded under simplified acquisition procedures.<sup>83</sup>

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<sup>78</sup>Project BioShield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835 (2004).

<sup>79</sup>§319-F(2)(b)(1)(a). The Department of Homeland Security Appropriations Act appropriated this amount. P.L. No. 108-90, 117 Stat. 1137 (2004).

<sup>80</sup>Project BioShield Act of 2004, §319-F(2)(b)(1)(a).

<sup>81</sup>*Id.* §§319F-1(a)(2)(A) – (B).

<sup>82</sup>*Id.* §319F-1(b)(1)(A); FRANK GOTTRON, CONG. RESEARCH SERV., RS21507, PROJECT BIOSHIELD 3 (2005).

<sup>83</sup>Project BioShield Act of 2004 §319F-1(b)(1)(A).

Without this authority, the simplified acquisition threshold would be limited to a range of \$100,000 to \$1,000,000, depending on the classification of the procurement under Federal Acquisition Regulation.<sup>84</sup> The Act allows these purchases to be made on a basis “other than full and open competition.”<sup>85</sup> Otherwise known as “sole-sourcing,” the Secretary may operate pursuant to this provision even if there is more than one responsible company that can perform the contract—a departure from the standard under the Federal Property and Administrative Services Act of 1949,<sup>86</sup> which only allows for sole-source procurements where there is a finding that the needed item is available from only one responsible source and no other type of product meets the agency’s needs.<sup>87</sup> Other provisions decrease the amount of paperwork required and the potential for oversight.<sup>88</sup> Further, a procurement-related decision may only be subject to review by filing a protest with either the contracting agency or the Comptroller General; not the Court of Federal Claims or U.S. District Court.<sup>89</sup> Moreover, the act specifically commits to agency discretion authorizations to award and perform procurement contracts despite bid protests lodged pursuant to the traditional procurement protest system.<sup>90</sup>

The Project BioShield Act allows the Secretary of HHS to use an expedited award process, rather than the normal peer review process, for grants, contracts, and cooperative agreements related to biomedical countermeasure research and development activity, if the Secretary deems there is a pressing need for an expedited award.<sup>91</sup> The frequency with which the secretary will subvert the traditional peer review process will depend on the interpretation the Secretary accords “pressing need.”<sup>92</sup>

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<sup>84</sup>Rapoport, et al., *supra* note 69, at 4.

<sup>85</sup>Project BioShield Act of 2004 §319F-1(b)(1)(D).

<sup>86</sup>41 U.S.C. §253(c)(1).

<sup>87</sup>Rapoport, et al., *supra* note 69, 4.

<sup>88</sup>GOTTRON, *supra* note 82, at 3.

<sup>89</sup>Project BioShield Act of 2004 §319F-1(b)(4)(A).

<sup>90</sup>*Id.* §§319F-1(b)(4)(B)(i)-(ii); 31 U.S.C. §§3553(c)(2), (d)(3)(C).

<sup>91</sup>Project BioShield Act of 2004 §319F-1(c)(1). The Secretary may not use expedited peer review for qualified countermeasure research and development activities that are greater than \$1,500,000. *Id.* §(c)(1)(B).

<sup>92</sup>Congressional Research Service reports that some scientists have expressed concerns that an expedited peer review process

### Section 3: Countermeasure Procurement Authorities

The Project BioShield Act provides for a Strategic National Stockpile (SNS), to be maintained by the Secretary of HHS, in coordination with the Secretary of the Department of Homeland Security (DHS).<sup>93</sup> The SNS is a stockpile of “drugs, vaccines and other biological products, medical devices, and other supplies. . . to provide for the security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.”<sup>94</sup> One provision specifically calls for smallpox vaccines to be added to the stockpile, “sufficient to meet the health security needs of the United States.”<sup>95</sup> The animating principle behind this section of the Act is for the Secretary to create a market for countermeasures by contracting to buy new and successfully developed countermeasures for the Strategic National Stockpile, financed from a newly-created special reserve fund.<sup>96</sup> This authority to purchase countermeasures includes products that the Secretary deems will qualify for FDA approval and licensing in up to eight years.<sup>97</sup>

To initiate a process for the procurement of products for the National Strategic Stockpile, the Secretary for DHS first completes a material threat assessment.<sup>98</sup> These assessments are made on a continuous basis to evaluate current and ongoing threats of chemical, biological, radiological, and nuclear agents and to “determine which of such agents present a material threat against the U.S. sufficient to affect national security.”<sup>99</sup>

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will reduce the quality of the research as that process is designed to maximize the chances that only proposals with the greatest scientific merit will get funding. GOTTRON, *supra* note 82, at 3.

<sup>93</sup>Project BioShield Act of 2004 §319F-2(a)(1). Several provisions of new section 319F-2 simply transfer provisions of law from the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, as amended by the Homeland Security Act of 2002, including language establishing the Strategic National Stockpile. H.R. REP. NO. 108-147, pt. 1, at 15 (2003).

<sup>94</sup>Project BioShield Act of 2004 §319F-2(a)(1).

<sup>95</sup>*Id.* §319F-2(b)(1).

<sup>96</sup>*Id.* §319F-2 (c)(4)(ii); GOTTRON, *supra* note 82, at 3.

<sup>97</sup>Project BioShield Act of 2004 §319F-2(c)(1)(B)(III)(aa).

<sup>98</sup>*Id.* §319F-2(c)(2).

<sup>99</sup>*Id.* §§319F-2(c)(2)(A)(i) – (ii).

The Secretary of HHS will then evaluate the potential health consequences stemming from exposure to agents DHS identifies as material threats, and the necessary countermeasures to combat those consequences.<sup>100</sup> The Secretaries of HHS and DHS are obligated to notify designated congressional committees of material threat assessments.<sup>101</sup>

Once the Secretaries for HHS and DHS establish a material threat, they will then make a determination as to the availability and appropriateness of specific countermeasures to address that identified threat.<sup>102</sup> If they identify an appropriate countermeasure that is either currently unavailable for procurement, or is approved, licensed, or cleared only for alternative uses, they will then submit a proposal to the President to issue a call for the development of such countermeasure.<sup>103</sup> This call will include, at a minimum, a commitment that, if the development of the countermeasure meets the conditions, the Secretaries will make a *recommendation* that the special reserve fund be made available for the procurement that countermeasure.<sup>104</sup> The procurement proposal will include 1) the estimated quantity of purchase; 2) the necessary measures of minimum safety and effectiveness; 3) the estimated price for each dose or effective course of treatment regardless of dosage forms; and 4) other information necessary to facilitate research, development and manufacture of the countermeasure or its specifications.<sup>105</sup> In other words, the federal government will issue a request to the industry that includes a commitment to create the market for that countermeasure, if the appropriate specifications are achieved.

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<sup>100</sup> *Id.* §§319F-2(c)(2)(B)(i) – (ii).

<sup>101</sup> *Id.* §319F-2(c)(2).

<sup>102</sup> *Id.* §319F-2(c)(3).

<sup>103</sup> *Id.*

<sup>104</sup> *Id.* §319F-2(c)(4), *see* Rapoport, et al., *supra* note 69, at 5.

<sup>105</sup> *Id.* §319F-2(c)(4)(B).

The Secretary of HHS then has the responsibility for determining which countermeasures are appropriate for inclusion in the stockpile and as a result, funding from the special reserve fund.<sup>106</sup> In making this judgment, the Secretary must consider 1) the quantities of the product that will be needed; 2) the feasibility of production and delivery of sufficient quantities of the product within eight years; and 3) whether there is a lack of an alternative commercial market for the product at the time of procurement, other than as countermeasure qualifying for special reserve fund monies.<sup>107</sup> The Secretary of HHS, jointly with the Secretary for DHS, must submit to the President a recommendation that the special reserve fund be made available for the procurement of such countermeasure.<sup>108</sup> The special reserve fund is only available only if the President approves the Secretaries' recommendation.<sup>109</sup> Once the President issues an approval, the Secretaries have the added responsibility of notifying designated congressional committees of that decision.<sup>110</sup>

The actual procurement contracting is left to the Secretary of HHS.<sup>111</sup> The Secretary is responsible for negotiating terms—including quantity, production schedule, and price—and entering into contracts and cooperative agreements.<sup>112</sup> The Secretary is further authorized to issue regulations necessary to implement this procurement authority.<sup>113</sup>

Money from the Project BioShield reserve fund is not available to companies until delivery of the total number of units, unless the Secretary provides that an advance payment is necessary to ensure success of the project.<sup>114</sup> The advance payment may not exceed ten percent of the contract amount and must be

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<sup>106</sup>*Id.* §319F-2(c)(5)(A).

<sup>107</sup>*Id.*

<sup>108</sup>*Id.* §319F-2(c)(6)(A).

<sup>109</sup>*Id.* §319F-2(c)(6)(B).

<sup>110</sup>*Id.* §319F-2(c)(6)(C).

<sup>111</sup>*Id.* §319F-2(c)(7)(C)(i).

<sup>112</sup>*Id.* §319F-2(c)(7)(C)(i)(I).

<sup>113</sup>*Id.* §319F-2(c)(7)(C)(i)(II).

<sup>114</sup>*Id.* §319F-2(c)(7)(C)(ii)(I).

repaid if the vendor does not ultimately deliver the product.<sup>115</sup> Thus, the government guarantee reduces the market risk for the company, but does not affect its exposure to development risk—in other words that the countermeasure will fail during testing and be thus undeliverable.<sup>116</sup>

The Secretary also has the authority to avoid many of the complexities of government contracts laws if the Secretary determines “there is a pressing need for a procurement of a specific countermeasure.”<sup>117</sup> These simplified procurement authorities grant an exemption from, for example, the rigid strictures of the Truth in Negotiations Act, which permits the government to obtain from the offeror on certain sole-source procurements cost or pricing data revealing nearly all of the offeror’s confidential business information concerning the offer, including profit margins.<sup>118</sup> The Secretary also has authority similar to that of Section 2 to use other than full and open competition if the countermeasure is available from only responsible source or only from a limited number of responsible sources.<sup>119</sup>

#### **Section 4: Authorization for Medical Products for Use in Emergencies**

The Project BioShield Act allows for the Secretary of HHS to authorize emergency use of products not approved by the Food and Drug Administration or Health and Human Services.<sup>120</sup> The Secretary may approve an emergency use of a product that is either 1) an unapproved product<sup>121</sup> or 2) an unapproved use of an approved product.<sup>122</sup> To exercise this authority the Secretary must first determine the existence of a justifying emergency 1) pursuant to the Public Health Service Act that a public health emergency exists and that it affects, or has potential to affect national security and involves a specific biological, chemical, radiological or nuclear agent; 2) pursuant to a determination by the Secretary of Homeland Security there

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<sup>115</sup> *Id.*

<sup>116</sup> GOTTRON, *supra* note 82, at 3.

<sup>117</sup> Project BioShield Act of 2004 §319F-2(c)(7)(C)(ii).

<sup>118</sup> Rapoport, et al., *supra* note 69, at 5.

<sup>119</sup> Project BioShield Act of 2004 §319F-2(c)(7)(C)(iv).

<sup>120</sup> See Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360bbb-3 (2006).

<sup>121</sup> A product that not approved, licensed or cleared for commercial distribution. *Id.* §360bbb-3(a)(2).

<sup>122</sup> A produce that is approved, licensed or cleared for commercial distribution, but which use is not an approved use. *See id.* §360bbb-3(a)(2).

is a domestic, or is potential for, a domestic emergency, involving heightened risk of attack with a specified biological, chemical, radiological or nuclear agent; or 3) pursuant to a determination by the Secretary of Defense that there is or is potential for a military emergency involving a heightened risk to the United States military forces of attack with a specified biological, chemical, radiological or nuclear agent.<sup>123</sup>

Once the emergency is declared, the Secretary, upon consultation with the Director of the National Institutes of Health and the Director of the Centers for Disease Control and Prevention, may issue an authorization for the emergency use of a product if the Secretary makes certain conclusions. These include: 1) that the agent causing the emergency can cause serious or life-threatening disease or condition; *and* 2) that based on all of the scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating, or prevent such disease or condition or another serious or life-threatening disease that is caused by a product aimed at the first disease or condition; *and* 3) the known and potential benefits of the product outweigh the known and potential risks of the product; *and* 4) there is no adequate, approved, and available alternative to the product; *and* 5) other criteria that the Secretary may prescribe by regulation.<sup>124</sup> Additionally, when authorizing the emergency use of the product, the Secretary, to the extent practicable given the emergency, must establish conditions to protect health care professionals who administer the product; to ensure that individuals to whom the product is administered are informed of the known risks and benefits of the products use, including the option to refuse the product; to monitor and report adverse events associated with the emergency use of the product; and to direct the manufacturers of the product in recordkeeping and reporting with respect to emergency use of the product.<sup>125</sup> Thus, Project BioShield, within certain parameters, makes available drugs, devices, or biological products that would otherwise be inaccessible due to their unapproved status.

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<sup>123</sup>*Id.* §360bbb-3(b)(A) – (C).

<sup>124</sup>*Id.* §360bbb-3(c).

<sup>125</sup>*Id.* §360bbb-3(e)(1)(A).



## Section 5: Reporting Requirements

Project BioShield requires annual reports to designated congressional committees as well as to the Government Accountability Office (GAO).<sup>126</sup> GAO will produce a report four years after the enactment to review actions taken pursuant to the Act, make recommendations to improve the authorities granted under the Act, determine the effectiveness of the Act, and recommend additional measures to address deficiencies.<sup>127</sup>

b.

### Rationales

The Project BioShield Act of 2004 was lauded as “truly bipartisan work of both bodies [of Congress] across multiple committees of jurisdiction to protect our country and to promote public health security from the many new dangers that we face today.”<sup>128</sup> In general, members of Congress saw Project BioShield as an initiative to “spur the research and development of new vaccines, new drugs and other countermeasures to deal with those biological, chemical, nuclear, or radiological agents that pose a material threat to our national security.”<sup>129</sup> Senate Majority Leader Bill Frist described the bill as, “improve[ing] our ability to investigate to develop, and to produce these new such countermeasures.”<sup>130</sup> He specifically noted, “For the first time, we have well defined this new paradigm of a public and private partnership working together to develop these countermeasures in our Nation’s interests.”<sup>131</sup>

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<sup>126</sup>42 U.S.C. 247d-6c.

<sup>127</sup>*Id.* §247d-6c(b).

<sup>128</sup>150 CONG. REC. H5721, 5729 (2004) (statement of Rep. Barton).

<sup>129</sup>*Id.*

<sup>130</sup>150 CONG. REC. S5744, 5760-5761 (2004).

<sup>131</sup>150 CONG. REC. S5744, 5761 (2004).

Other members also referenced the public-private partnership the Project BioShield Act created to develop these needed products. The sponsor of the House version of Project BioShield, Representative Tauzin, stated, “This bill seeks to make sure that the private sector does the work along with government to find the antidotes, the treatment for these kinds of agents that might be used in such an attack which might not otherwise be developed in the private sector.”<sup>132</sup> During debate, another member stated, “We have some incredibly talented people in this country in the public and in the private sector, and this joint partnership will ensure that we are moving ahead to effectively protect the American people from the potential of a bioterrorism attack.”<sup>133</sup>

Constituents from the private sector also praised the government’s involvement in this endeavor. A representative from the Advanced Medical Technology Association (“AdvaMed”), before a joint session of the House Energy and Commerce Health Subcommittee and Select Committee on Homeland Security Emergency Preparedness and Response Subcommittee stated, “We believe that harnessing the creative abilities of both the public and private sectors will be necessary to effectively address the bioterrorist threats that we may face. We believe Project BioShield will allow the public to benefit from the many prevention, detection, and treatment capabilities our industry can provide. AdvaMed stands ready to work with your committee to assure the enactment of BioShield legislation consistent with our testimony.”<sup>134</sup>

Calls for the government to create this new market came from representatives of several Executive agencies. Secretary of Health and Human Services, Tommy Thompson, noted the uniqueness of the situation: “Private investment should drive the development of most medical products. Bioterrorism, however, is different. None

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<sup>132</sup>150 CONG. REC. H5721, 5730 (2004).

<sup>133</sup>149 CONG. REC. H6908, 6933 (2003) (statement of Rep. Langevin).

<sup>134</sup>*Furthering Public Health Security: Project BioShield: Hearings Before the Subcomm. on Health, H. Energy and Commerce Comm. and the Subcomm. on Emergency Preparedness and Response, H. Select Homeland Security Comm.*, 108<sup>th</sup> Cong. 66 (2003) (statement of Gary Noble, Vice President for Medical and Public Health Affairs, Johnson & Johnson) [hereinafter *Furthering Public Health Security: Project BioShield Hearing*].

of us ever expected that 16th century illnesses and diseases could be used and be weaponized and could be used as bioterrorist threats in the year 2003 and that's what we're facing and there's no market out there to develop the vaccines, the anti-viruses, the antidotes and the antibiotics.”<sup>135</sup> Similar comments were expressed by FDA Commissioner, Dr. Mark McClellan: “In some cases, we have done the work to demonstrate safety and effectiveness of certain products for counterterrorism use, but we don't yet have companies willing to produce these products. To bring badly needed safer and more effective countermeasures to our nation's defense, we're going to need to do more to encourage all parties—basic science researchers in government labs, as well as the major medical companies—to take up the cause of developing countermeasures.”<sup>136</sup> The Director of the National Institutes of Health, Elias Zerhouni, echoed these sentiments, stating in a separate hearing before the Senate Committee of Health, Education, Labor, and Pensions, “I will not repeat the comments that Dr. McClellan made about the importance of BioShield and the need for us to expand the current statutory limits on our authority to develop new and innovative approaches for public and private partnerships that will entice industry to enter the field once research has been done to the point where advanced development of these products is needed.”<sup>137</sup>

Despite this insistence that the private sector was a necessary partner in the development and production of biodefense products, some representatives initially questioned the need to create a market for private pharmaceutical companies rather than directly funding government researchers. For instance, the ranking member of the Select Committee on Homeland Security, Representative Turner, queried Secretary Thompson as to whether an alternative structure that would provide “government funded research dollars either to the private sector to do the research internally, and then once the successful vaccine is discovered to then procure that through government purchases from the private sector or, in fact, to do it through government labs

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<sup>135</sup>*Id.* at 15.

<sup>136</sup>*Project BioShield: Contracting for the Health and Security of the American Public: Hearings Before the Comm. on Government Reform*, 108<sup>th</sup> Cong. 18 (2003).

<sup>137</sup>*Fed. Biodefense Readiness: Hearings before the Comm. on Health, Education, Labor, and Pensions*, 108<sup>th</sup> Cong. 13 (2003).

with private contractors in those labs as we do in some instances now in the military.”<sup>138</sup> He specifically questioned the assumption that “privately funded research and production is superior to government funded research and production.”<sup>139</sup> Congresswoman Lowey also suggested looking internal to the government: “I find this really upsetting and especially that the large pharmaceutical companies won’t have any interest because there won’t be enough profit and it seems to me that we may want to look into other ways to manufacture the product similar to the way the Department of Defense does.”<sup>140</sup> She further went on to say that “it seems unacceptable that the large companies that really can handle this won’t be interested in it and we have to dig around for some smaller companies who may not have the experience and, as you said, don’t have the experience to produce this kind of product in the large quantities we need.”<sup>141</sup> It was not a given that Congress was going to look to the private industry to prompt the research and production necessary to successfully provide comprehensive biodefense. In fact, the House version of the Project BioShield Act contained a provision that would have allowed the government to directly develop countermeasures.<sup>142</sup> This could be done through several mechanisms including government owned-government operated facilities or government-owned-contractor operated facilities.<sup>143</sup> However, this provision was not included in the Senate

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<sup>138</sup> *Furthering Public Health Security: Project BioShield Hearing*, *supra* note 134, at 30.

<sup>139</sup> *Id.* Representative Turner went on to suggest, “if we’re truly concerned about getting this job done quickly, it seems to me that a Manhattan project type approach to it that would utilize government funded research and government funded production would be perhaps the superior alternative because if you advance contract to a given private company to develop and then produce by guaranteeing them a market, you may in fact stifle the innovation, that as some member, I believe it was Mr. Thompson suggested, that if you grant a contract to one company and perhaps another comes up with a better vaccine then you’ve already committed to spend the money on the inferior vaccine and we’ve wasted a lot of money.” *Id.*

<sup>140</sup> *Furthering Public Health Security: Project BioShield Hearing*, *supra* note 134, at 42.

<sup>141</sup> *Id.* Director Fauci responded directly to Representative Lowey: “Ms. Lowey, not to comment in any way negative or whatever on the DOD process which in many respects has worked for them, the companies, the Big Pharm as well as the biotech companies are so good. They are so unparalleled in their capability that I personally feel as a scientist that we must embrace them in the process. They will do it quicker and better than anyone in the world.” *Id.* at 44. .

<sup>142</sup> Project BioShield Act of 2003, H.R. 2122, 108<sup>th</sup> Cong. §2(c). Representative Brown looked specifically to the military as an avenue of research and development. *See Furthering Public Health Security: Project BioShield Hearing*, *supra* note 134, at 22. He asked Secretary Thompson to comment on the accomplishments at Walter Reed and the fact that “they have done the anti-malarial both vaccines and drugs better than any public or private organization in the world over the last 100 years, well almost certainly. Their budget, however, is only about \$20 million. The drug industry says a new drug costs them to develop about, counting factoring failures into that, about \$800 million. Many of us question that number but it’s certainly multiples of the budget of Walter Reed.” *Id.*

<sup>143</sup> GOTTRON AND FISCHER, *supra* note 39.

version of the Act, which was eventually adopted.<sup>144</sup>

Ultimately, Congress recognized its essential role in providing needed incentives to the private sector for it to accomplish governmental priorities that would otherwise be neglected. The special reserve fund was created to be a pool of money only available for the procurement of these specific products that had been pre-identified as necessary to meet material threats that the Secretary of Homeland Security, in conjunction with the Secretary of Health and Human Services, had identified.<sup>145</sup> Because the money was obligated in advance, once the President approved the call for a security countermeasure, private pharmaceutical companies could be sure of a market for the fruits of their labor. As one Representative saw it, the special reserve fund was the most important feature of the Act because, “without this clear commitment of funding in future years, private sector companies that are capable of such development will not undertake the heavy investment and risk associated with developing products that deal with agents that do not affect significant populations today and hopefully never will.”<sup>146</sup> As Dr. Fauci—when describing the types of pharmaceutical companies the bill was intended to attract—so succinctly put it, “Many of these firms are willing to help in the development of biodefense countermeasures, but the fact remains that they are businesses and are not non-profit organizations. And they need a tangible incentive to get involved.”<sup>147</sup>

Proponents of the legislation intended to create a market where none existed. However, Congress refused to give a black check to the Executive branch for the procurement of countermeasures. The original bill as

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<sup>144</sup>See Project BioShield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835 (2004).

<sup>145</sup>H.R. REP. NO.108-147, pt 1, at 16. (“However, the Committee emphasizes that the monies obligated from the special reserve fund created under section 3 of this Act may not be use[d] to pay for research and development activities, but only for procurement of countermeasures paid upon substantial delivery of the product. . .”).

<sup>146</sup>150 CONG. REC. H5721, 5729 (2004) (statement of Rep. Barton).

<sup>147</sup>*Project BioShield: Contracting for the Health and Security of the American Public Hearing*, *supra* note 44, at 16 (statement of Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases).

reported in the Senate contained a provision that would grant indefinite appropriation for the purchasing of countermeasures to be spent at the President's discretion.<sup>148</sup> During the first committee hearing on the bill, Representative Dingell, the Ranking Member of the Energy and Commerce Committee, asked about what he called "unlimited, unfettered future appropriations without limits and without constraints."<sup>149</sup> He went on to call the provision "a blank check of the most extraordinary character that I have ever seen."<sup>150</sup> Secretary Thompson defended the President's original proposal maintaining that the mandatory funding was necessary to create the market.<sup>151</sup> "You got to be able to manufacture it and unless there's mandatory funding," he went on, "there's less likelihood that the company will want to go through that unless they know they're assured of the money, they're assured of the possibility of having that valid contract. That's why the mandatory versus the discretion."<sup>152</sup> The Secretary then gave of an example of an incident of discretionary funding allocated for developing a new anthrax drug that was then taken away in the budget appropriation.<sup>153</sup> However, after the House version of the bill passed, but before floor debate in the Senate could begin, Senator Byrd put a hold on the bill, objecting to the way it would take control over spending out of the hands of appropriators.<sup>154</sup> He, along with other legislators, persuaded the Senate to adopt an amendment that stripped the guaranteed funding from the program.<sup>155</sup> The final bill—S.15—as enacted did not give the President a "blank check," but rather authorized to be appropriated \$5.6 billion—the amount the administration predicted that would be spent through fiscal year 2013 on countermeasure procurement.<sup>156</sup> Whether or not the incentives would be sufficient—mandatory or not—to entice the private sector was left

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<sup>148</sup>GOTTRON AND FISCHER, *supra* note 39, at 5.

<sup>149</sup>*Furthering Public Health Security: Project BioShield Hearing*, *supra* note 134, at 9.

<sup>150</sup>*Id.*

<sup>151</sup>*Id.* at 22.

<sup>152</sup>*Id.*

<sup>153</sup>*Id.*

<sup>154</sup>Kate Schuler, *BioShield Bill Breaks Free in Senate, Expected to Reach President's Desk Soon After Memorial Day Recess*, CONG. Q. WKLY., May 22, 2004, at 1215.

<sup>155</sup>*Id.*

<sup>156</sup>GOTTRON AND FISCHER, *supra* note 39, at 5. Representative Dingell remained committed to the a bill that followed the normal appropriations process and in debate on the bill in the House stated, "Finally, I commend Chairman Tauzin of the Committee on Energy and Commerce and my other colleagues for deciding to proceed with an authorization for funding, rather than with the mandatory appropriation sought by the Administration." 149 CONG. REC. H6908, 6940 (2003).

an open question.

Those members deliberating the Act knew that manufacturer liability was an issue. In discussing Section 319F-2(c)(4)(B), which provides that the Secretaries of HHS and DHS should include in any call for proposals for countermeasure production information that may be necessary to encourage or facilitate research and development into such countermeasures, the Committee on Energy and Commerce “recognize[d] that an important factor companies will consider in determining whether to invest scarce research and development dollars into security countermeasures is whether and to what extent they may face liability relating to the development or production of such countermeasures.”<sup>157</sup> While liability guidelines were not part of the bill, “the Committee...encourage[d] the Secretaries to indicate in any call for proposals the potential availability of indemnification or liability protections under other laws.”<sup>158</sup>

The need for liability protections was pointed out during committee hearings and Congressional debates. One representative from the private pharmaceutical industry noted that the bill overall did not adequately take into account the high-risk and costly process of bringing new medicines to the market, specifically, “the time consuming and resource intensive middle part of the process.”<sup>159</sup> He pointed to challenges inherent in biodefense-related research and development, noting that some products will be distributed without the typical battery of clinical trials that are required for medical approval, and, given that all medicines present an inherent and unavoidable risk of adverse events, “manufacturers may be exposed to devastating product liability suits and...not only the companies but also those patients who receive it and those people who administer these treatments also may be affected by those suits. Private insurance may simply be

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<sup>157</sup>H.R. REP. NO 108-147, pt. 1 at 15.

<sup>158</sup>*Id.*

<sup>159</sup>*Furthering Public Health Security: Project BioShield Hearing, supra* note 134, at 58 (2003) (statement of Dr. Michael Friedman, Pharmaceutical Research and Manufacturers Association of America).

unavailable.”<sup>160</sup> Another witness explained “that from the point of view of a small company, it isn’t even a meritorious legal case that is a threat. Even just the threat itself of liability is enough to prevent investment and put small companies out of business. So this is a risk that small companies simply can’t take.”<sup>161</sup> Congress members listened and acknowledged these repeated appeals from the private industry to strengthen liability protections, but did not put any in the bill.

Continued concerns about the absence of liability protections both for the private pharmaceutical companies developing and procuring countermeasures, as well as for the public health administrators who would ultimately deliver the vaccines, were voiced. In debate, one member noted, “I am very concerned that the liability provisions in this bill are not sufficiently protective of the companies that would step forward to address the need to create these BioShield defenses. I am not at all convinced that the immunity is broad enough or dependable enough.”<sup>162</sup> But even that member left it for another day, ominously forecasting, “Time will tell.”<sup>163</sup> Representative Davis, Chairman of the House Government Reform Committee, explained that liability protection would be an incentive for companies that “are going to be engaging in research and development and manufacture things that they didn’t do otherwise” Thus, because he saw it as Congress’ mission to get companies to engage in that research and development, it was important to be aware that if those companies were exposed to massive lawsuits, “it could bankrupt the entire company and expose the rest of its business.”<sup>164</sup>

Congressman Waxman framed the issue a little differently by bringing up the issue of compensation for

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<sup>160</sup>*Id.*

<sup>161</sup>*Project BioShield: Contracting for the Health and Security of the American Public Hearing*, *supra* note 44, at 92 (testimony of Dr. Una S. Ryan, President, Avant Immunotherapeutics).

<sup>162</sup>150 CONG. REC. H5721, 5733 (2004) (statement of Rep. Andrews).

<sup>163</sup>*Id.*

<sup>164</sup>*Project BioShield: Contracting for the Health and Security of the American Public Hearing*, *supra* note 44, at 58 (statement of Dr. Una S. Ryan, President, Avant Immunotherapeutics).



those who would be harmed by products made by indemnified companies. He somewhat rhetorically asked Commissioner McClellan of the FDA, if Congress is “going to indemnify the companies that manufacture countermeasures by providing the liability protection, some of those products still may harm consumers. If the administration can guarantee liability protection to manufacturers, shouldn’t it also compensate those who are injured by the products?”<sup>165</sup> He brought up the issue again with Dr. Friedman of the Pharmaceutical Research and Manufacturers Association, who added that indemnity should be available for “the people who are delivering the product—that is the health care providers—physicians and so forth.”<sup>166</sup> Then Congressman Waxman summed up: “So you think the manufacturers should be protected from liability to give the incentive to develop these products, but the public that’s exposed to them that may have some adverse effects should also be compensated?”<sup>167</sup> Thus, despite the obvious need for some kind of liability and compensation provisions that not only witnesses representing the pharmaceutical industry noted, but also many members of Congress, there were no such provisions enacted as part of the Project BioShield Act of 2004.

Many members of Congress also recognized that some of the provisions of BioShield—particularly those allowing the Secretary to authorize the use of unapproved products and to make procurement contracts with less than open competition—were extreme. Both Congresswoman Maloney and Congressman Waxman observed that “provisions of BioShield authorizing the emergency distribution of unapproved drugs and devices, whose risks and benefits are not fully tested, impose an unprecedented responsibility on the government.”<sup>168</sup> They directed that the “FDA must be vigilant in protecting the public against unnecessary risks from these products. In part because of these concerns, the bill requires that health care providers and

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<sup>165</sup>*Id.* at 61.

<sup>166</sup>*Id.* at 114.

<sup>167</sup>*Id.*

<sup>168</sup>150 CONG. REC. H5721, 5731, 5740 (2004) (statement of Rep. Maloney and Rep. Waxman). The statements of both members were identical.

patients be informed that the products have not been approved and be informed of their risks.”<sup>169</sup> During debate, Congressman Langevin, declared:

“[u]nder this program, the Federal government will be able to enhance the Strategic National Stockpile, promote research and development of countermeasures, and, in an emergency, move forward with public distribution of certain drugs and treatments that may not yet have FDA approval. It is never pleasant to imagine a scenario where this kind of preparation and flexibility will be necessary, but the threat is indeed there. Project BioShield will help lay the groundwork to respond to that threat quickly and effectively.”<sup>170</sup> In the Senate, Senator Gregg described the procedure for circumventing the FDA review process as only available in “certain very limited situations where there is a clear and obvious emergency... where specifically we have been attacked.”<sup>171</sup>

There is no indication that any members of Congress were contemplating less than a real emergency situation for the FDA to allow for the administration of a product for an unapproved use or use of an unapproved product.<sup>172</sup>

Similarly, legislators did not believe that the government’s ability to use accelerated procedures, such as less than full and open competition, were to be used on any kind of regular basis. Representative Maloney acknowledged the ability to use these procedures, but only if there exists a “pressing need to do so.”<sup>173</sup>

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<sup>169</sup> *Id.*

<sup>172</sup> Secretary Thompson himself acknowledged that he would only be allowed “to suspend the full lengthy FDA approval process if a product in the approval pipeline is absolutely urgently needed and has great potential to protect, diagnose, treat, or prevent a serious disease caused by a bioterror agent.” *Furthering Public Health Security: Project BioShield Hearing*, *supra* note 134, at 16.

<sup>173</sup> 150 CONG. REC. H5721, 5731 (2004).

Senator Levin likewise saw the norm as a procurement process subject to full and open competition “unless the Secretary determines that the mission of the BioShield program would be seriously impaired by this requirement. This provision ensures that the BioShield program, like other Federal programs, will be subject to government wide competition requirements.”<sup>174</sup> It therefore appears that members of Congress envisioned these provisions to be used only in specially-warranting situations.

Project BioShield was not intended to come at the expense of other public health initiatives. Congressman Brown exclaimed that “Project BioShield is not a blank check. Congress has a responsibility to weigh competing priorities and set funding levels appropriately.” He asserted that while “Bioterrorism funding is certainly important... it must not come at the expense of research on cancer and research on Alzheimer’s and muscular dystrophy and AIDS and other significant health threats.”<sup>175</sup> He specifically rejected the idea of putting money into BioShield if it were to mean “diverting [it] from other promising medical research, TB, multiple sclerosis, all other kinds of medical research.” The Congressman was resolute that trade-offs were unacceptable: “trade-offs that set back the clock on cures for deadly and disabling diseases; trade-offs the public did not bargain for and should not abide. . . The last thing Congress or the President should do is assure the public that we are doing everything we can more than ever to find cures for major illnesses like cancer and Parkinson’s when actually we are choking off funding for medical research.”<sup>176</sup> Representative Jackson-Lee pointed out that the deliberate spread of HIV/AIDS could also be seen as an act of bioterrorism.<sup>177</sup> She directed her colleagues not to forget “the other preventable diseases or other contagious diseases and the other work of NIH so that we are assured that we are protecting the homeland in many ways. We must seek to balance the fear of the American people with the health needs of the American people.”<sup>178</sup>

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<sup>174</sup>150 CONG. REC. S5744, 5767 (2004).

<sup>175</sup>150 CONG. REC. H5721, 5730 (2004).

<sup>176</sup>*Id.*

<sup>177</sup>*Id.* at 57234.

<sup>178</sup>*Id.*

Even as the Project BioShield Act reflected an innovative attempt to foster a practically nonexistent industry and provide for greater authority and flexibility to provide countermeasures against a biological or other attack, it was subject to a variety of limitations. Some of the limitations of the legislation—such as the omission of liability and compensation provisions—come from the inherent inadequacy of the bill itself, while others were deliberately imposed by Congress so as not to harm other interests—such as established appropriations and drug approval procedures as well as public health research and development initiatives. The law was thus a inventive balance between many competing priorities and it should come as little surprise that its implementation has been subject to a great deal of criticism.

### III.

#### Implementation and Implementation Problems

Legislators had high hopes for accomplishments stimulated by Project Bioshield. President Bush, in a Rose Garden ceremony, when signing the bill into law, proclaimed, “By acting today we are making sure we have the best medicine possible to help the victims of a biological attack. Project Bioshield is part of a boarder strategy to defend America against the threats of weapons of mass destrutions.<sup>179</sup> He highlighted that with the \$5.6 billion authorized by Project Bioshield, the government, acting as a willing buyer for the best new medical technologies, would be ensuring that America’s drug stockpile remains safe, effective, and advanced.<sup>180</sup> Yet critics have voiced concerns about many of the provisions of Project Bioshield. Despite a few procurement accomplishments under the Act, it has not brought about the lofty ambitions of the legislators who passed it. First, the government simply has failed to dedicate funds and award contracts. And the one company that has been awarded a contract has failed to perform. The failure to award contracts

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<sup>179</sup>Statement By President George W. Bush Upon Signing S. 15, 40 WEEKLY COMP. PRES. DOC. 1346-1347 (July 21, 2004).

<sup>180</sup>*Id.*

stems, in part, from bureaucratic red-tape and the government's inability to make clear its expectations under the Act. Next, the Act has outraged the very scientists who were intended to accomplish the essential research and development to create new countermeasures. These scientists, along with others, feel that Congress has misplaced priorities, concentrating too much on low risk events rather than other meta-problems in the public health structure and naturally occurring epidemics. Private drug companies have largely found the deal not to be sweet enough to participate, complaining of the insufficiency of funding and the lack of indemnification provisions.

a.

### **The VaxGen Failure**

The largest contract awarded pursuant to the Project Bioshield Act has been to VaxGen, Inc., for 75 million doses of a next-generation anthrax vaccine. This was the first countermeasure contract from BioShield's special reserve fund.<sup>181</sup> The VaxGen contract is valued at \$877.5 million, the equivalent of about fifteen percent of the amount appropriated for BioShield over the next ten years.<sup>182</sup> The contract provides for the payment of \$754 million in advance of specific milestones; when and if the milestones are accomplished, VaxGen will receive specified per dose price supplements.<sup>183</sup> The Secretary of HHS elected not to use simplified acquisition procedures with respect to this contract.<sup>184</sup>

NIH spelled out a demanding schedule for the anthrax-vaccine bidders, such as delivering early trial results

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<sup>181</sup>Frank Rappaport, et al., *supra* note 69, at 5

<sup>182</sup>*Id.* at 6.

<sup>183</sup>*Id.*

<sup>184</sup>*Id.*

by the end of 2003.<sup>185</sup> A predecessor of the drug giant Sanofi-Aventis, SA declared this timetable impossible to meet and was disqualified from early funding.<sup>186</sup> VaxGen reported a failure in a major human test and is at least a year behind schedule, with some estimating delivery will not be accomplished until 2008 or 2009, long after the anthrax attacks of 2001 prompted the government to desire a better defense.<sup>187</sup> Given the VaxGen delay, the government recently purchased five million doses of an older, controversial anthrax vaccine—enough to treat fewer than two million people.<sup>188</sup> And now, VaxGen is being investigated by the FDA for making “false and misleading statements” about the vaccine that were not warranted on the basis of early research.<sup>189</sup> The FDA has threatened court action unless VaxGen devises a plan to disseminate truthful, non-misleading, and complete information about the vaccine to anyone who might have received the original problematic claims—including thousands of individual stockholders.<sup>190</sup> Representative Cannon prompted the Director of National Institute of Allergy and Infectious Diseases (NIAID), Anthony Fauci, to admit that in regards to the next-generation anthrax contract, “the other companies refused to bid because it was not feasible to do it in the timeframes. . . suggested, and so now we have a small company failing to perform in an area where we. . . have an experimental technology to deal with a disease that we have already been attacked with, it has already been a bioterrorist tool, attacked several times with, and yet we don’t have a stockpile, even though my understanding is that we have a company that has an FDA-approved vaccine for anthrax.”<sup>191</sup>

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<sup>185</sup>Bernard Wysocki Jr., *Missing Medicine—Radical Therapy: Agency Chief Spurs Bioterror Research—And Controversy; As Dr. Fauci Pours NIH Funds into Makers of Vaccines, Some Say he Oversteps; A Lawsuit over Virus Strains*, WALL ST. J., December 6, 2006, at A.1.

<sup>186</sup>*Id.*.

<sup>187</sup>Justin Gillis, *No Hope for Stockpile of New Anthrax Vaccine by November; Developer Seeks Extension After Setback on Crucial Test*, WASHINGTON POST, March 17, 2006 at A01.

<sup>188</sup>*Id.*

<sup>189</sup>Justin Gillis, *FDA Warns Maker of Anthrax Vaccine*, WASHINGTON POST, April 5, 2006, at D01.

<sup>190</sup>*Id.*

<sup>191</sup>*The National Pandemic Influenza Preparedness and Response Plan: Is the United States Ready for Avian Flu?: Hearing*, 109<sup>th</sup> Cong. 89 (2005).

b.

### Complex Government Bureaucracy

The issues with VaxGen are emblematic of the larger problems in the BioShield process. Like many other federal government undertakings, the execution of the Project BioShield Act has been hampered by difficult and confusing bureaucracy. In Congressional hearings, executives from biotech companies have criticized the BioShield process as “anything but the red-tape-free haven” that was originally envisioned.<sup>192</sup> The executives say that government officials keep changing the requirements and delaying contracts.<sup>193</sup> During his opening statement, when calling to order a hearing of the Education, Labor and Pensions Committee, Senator Burr remarked, “It is also not clear if the implementation of the BioShield Act has resulted in a predictable procurement process that ensures the companies and others know what kind of countermeasures the government and nation needs and how much.” He then quoted the CEO of a biotech firm who termed the process of bringing new countermeasures to the stockpile, “potholes in the road to BioShield.”<sup>194</sup> Critics say that the government has been “coy—even evasive—about what products it wants to purchase and at what price.”<sup>195</sup>

An executive from one company noted the many challenges faced by his organization post-enactment, noting specifically, “What we haven’t been able to meet and what we can’t figure out are the bureaucratic confusion—or...the gaps that exist between BioShield and the real world.”<sup>196</sup> He told the Subcommittee on Bioterrorism and Public Health Preparedness:

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<sup>192</sup>Wysocki, *supra* note 62.

<sup>193</sup>*Id.*

<sup>194</sup>*Hearing on Crossing the Valley of Death*, *supra* note 66, at 2.

<sup>195</sup>Rebecca Adams, *Project BioShield: A Second Look*, CONG. Q. WKLY., Jan. 23, 2006, at 234.

<sup>196</sup>*Hearing on Crossing the Valley of Death*, *supra* note 66, at 32 (statement of Alan Timmins, President/CEO, AVI Bio-Pharma).

The perception of the process of BioShield, of BioShield acquisition, is a complete black box: It's not understood by industry, it's not understood by the street, companies shy away from participating in BioShield because it's considered to be too difficult or perhaps too mystery-endowed to be worthwhile for a company to risk its assets moving forward with a BioShield product.<sup>197</sup>

Officials from the private companies the bill was intended to attract repeated these themes to legislators. One pharmaceutical executive said, "I'd characterize HHS as unengaged, almost apologetics, hostile... every question we asked, we were told, 'We can't talk about it.'"<sup>198</sup> The CEO of another company that possesses a drug "with potential to treat acute radiation syndrome" said that, despite the phenomenal progress with his drug and "the suitability for a BioShield contract, we have heard very little from the federal government in regards to procurement of this drug."<sup>199</sup> This has had concrete consequences for his company, noting, "we don't know how to scale our batch sizes, what drug delivery configuration is preferred or how many manufacturers we should validate," he went on to explain, "these activities cost tens of millions of dollars and have reached the point where decisions have to be made or the project risks meaningful delays."<sup>200</sup> And, even more problematic, he reported "delays by HHS have caused Hollis-Eden to lose approximately \$600 million in market capitalization."<sup>201</sup> He suggested that "the individuals who are implementing [Project BioShield] have made up the rules as we go along,"<sup>202</sup> and recommended "more open dialogue, clear transparency and guidelines, so that the people implementing the bill are directly interfacing with industry representatives, so the process is transparent and everyone knows what's expected of one another."<sup>203</sup>

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<sup>198</sup>Adams, *supra* note 195, at 234.

<sup>199</sup>*One Year Later: Evaluating the Effectiveness of Project Bioshield: Hearing before the H. Govt Reform Comm.*, 109<sup>th</sup> Cong. 82 (2005) (statement of Richard Hollis, CEO, Hollis-Eden Pharmaceuticals).

<sup>200</sup>*Id.* at 82-83.

<sup>201</sup>*Id.* at 83.

<sup>202</sup>*Id.* at 110.

<sup>203</sup>*Id.* at 111.



c.

## Priorities

i.

### Public health system

The Project Bioshield Act is aimed particularly at the creation of countermeasures and not the general public health infrastructure. Several members of Congress have pointed out that, without an effective delivery system, it will not actually matter how much of any particular vaccine the government has stockpiled. As one Representative astutely pointed out, “not only is it possible that hundreds of millions of dollars could be spent to develop a medicine or vaccine and it be totally useless, but the very best of medicines, vaccines or other agents will be worthless to you, me and the people we serve without an intact public health system.”<sup>204</sup> Even Senator Frist pointed out, that there “are other initiatives such as strengthening our public health system,” which he noted, “has been neglected over the last 25 or 30 years. That public health system, that public health infrastructure, is the frontline in response to these agents.”<sup>205</sup> And Senator Kennedy, who noted before the passage of the Act that “The Institute of Medicine in 2003 found that America’s health agencies have ‘vulnerable and outdated health information systems and technologies, an insufficient and inadequately trained public health workforce, antiquated laboratory capacity, a lack of realtime surveillance in epidemiological systems, an ineffective and fragmented communications network, incomplete domestic preparedness and emergency response capabilities, and communities without access to

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<sup>204</sup>150 CONG. REC. H5721, 5738 (2004) (statement of Rep. Christensen). This Representative went on to detail how the administration’s decision to not fund health care resulted in “health care disparities in minorities and in our rural areas.” *Id.* She appealed to the Speaker, “We cannot just throw money at the problem of terrorism, as this administration has the tendency to do, without adequate planning. In this case, we must first and foremost insist that our public health system is intact and that it can ensure that people are healthy and our bodies are in a better condition to fight off infections and the other biological assaults that may come from a bioterrorism attack.” *Id.* at H5739.

<sup>205</sup>150 CONG. REC. S5744, 5761 (2004).

essential public health services.”<sup>206</sup> Eight months after the Act was signed into law, he continued with the same message, directing his colleagues to “recognize that even the best new treatments will do little good if our emergency rooms are so overburdened that doctors and nurses cannot deliver the effective care. The most modern disease-monitoring system will be of little use if public health agencies are so starved [for] funds they cannot keep their communities safe.”<sup>207</sup>

Bioshield, by exclusively focusing on incentives needed to encourage private pharmaceutical companies to develop bioterror countermeasures, does not focus on this public health infrastructure. However, stockpiles alone cannot equip communities for the full array of functions needed to detect and respond to a bioterrorist attack.<sup>208</sup> Some experts have predicted that “[n]ew equipment, communications systems, laboratories, hospital surge capacity, and training and public administration skills will be needed for local law enforcement, first responders, public officials, and hospitals to be able to accurately detect a bioattack, properly handle the victims, efficiently move large quantities of drugs to attack zones, diagnose and treat exotic diseases, and maintain order and execute quarantine or evacuation plans. To operationalize this new arsenal of drugs, America will require a variety of ancillary products, services, and expertise. . . .”<sup>209</sup>

ii.

### **Naturally-Occurring Diseases and Pathogens**

One criticism leveled at the entire BioShield program is that it prioritizes possible bioterrorism low-risk threats over more likely naturally occurring dangers. In the process, the administration is transforming NIH

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<sup>206</sup> *Id.* at 5766.

<sup>207</sup> *Examining the Biodefense Research Program of the National Institutes of Health, Focusing on the Development of Medical Countermeasures Against a Bioterrorist Attack: Hearing before the Subcomm. on Bioterrorism and Public Health Preparedness of the Comm. on Health, Education, Labor and Pensions*, 109<sup>th</sup> Cong. 3 (2005).

<sup>208</sup> Rapoport, et al., *supra* note 69, at 8.

<sup>209</sup> *Id.*

from a civilian research institution into part of the machinery of the nation's homeland defense system.<sup>210</sup> In other words, in the place of NIH's long-time focus mainly on curing naturally occurring diseases, NIH is increasingly geared to defending against manmade biological threats.<sup>211</sup> A group of 758 scientists wrote an open letter to Elias Zerhoni, Director of NIH, describing their dissatisfaction with the shift in priorities. They wrote: "the decision by the [NIAID] to prioritize the research of high biodefense, but low public health significance" threatens the NIH peer review process and the research sector.<sup>212</sup> The result of the shift in priorities, they said, "has been a massive influx of funding, institutions, and investigators into work on prioritized bioweapons agents... The number of grants awarded by NIAID that reference these agents has increased by 1500%."<sup>213</sup> This increase is in contrast to "the massive efflux of funding, institutions, and investigators from work on non-biodefense-related [work]... This diversion of research funds from projects of high health importance to projects of high biodefense but low public-health importance represents a misdirection of NIH priorities and a crisis for NIH-supported microbiological research."<sup>214</sup> Dr. Ebright, a molecular biologist at Rutgers University, who was the primary organizer of the petition, explained in a interview, "A majority of the nation's top microbiologists—the very group that the Bush administration is counting on to carry out its biodefense research agenda—dispute the premises and implementation of the biodefense spending."<sup>215</sup> In another interview he bluntly stated that "there's a lot of money we scientists see being spent in a manner that serves no scientific or public health purpose."<sup>216</sup>

A growing number of scientists such as these worry that biodefense work is siphoning resources from research on AIDS, bacterial pneumonia, malaria and other diseases that affect millions of people every year.<sup>217</sup> As

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<sup>210</sup>Adriel Betelheim, *Public Health, Political Priorities of Bioterrorism Research*, CONG. Q. WKLY., Jan. 23, 2006, at 230.

<sup>211</sup>*Id.*

<sup>212</sup>Sidney Altman, et al., *An Open Letter to Elias Zerhouni*, 307 SCIENCE 1409 (2005)

<sup>213</sup>*Id.*

<sup>214</sup>*Id.*

<sup>215</sup>Scott Shane, *U.S. Germ-Research Policy is Protested by 758 Scientists*, N.Y. TIMES, March 1, 2005, at A14.

<sup>216</sup>Betelheim, *supra* note 210.

<sup>217</sup>*Id.*

one researcher put it, “The question is, do you really want to remove resources from areas like that to put them into a threat that may never materialize.”<sup>218</sup> Critics note that the pie is shrinking, even as NIH defense spending continues to rise.<sup>219</sup> The institutes’ total 2006 budget actually declined a tenth of a percent from 2005 levels, marking the first such cut since 1970.<sup>220</sup> In fact, this will be the third year that NIH will lose ground due to inflation; the Bush administration requested \$28.6 billion for NIH, the same funding it received for fiscal year 2006.<sup>221</sup> The ranking member of the House Appropriations Committee, David Obey, pointed out that that figure results in a \$1 billion of lost purchasing power resulting in 655 fewer research grants than fiscal year 2006 and 1,570 fewer than in 2004.<sup>222</sup> The budget for NIH’s largest institute, the National Cancer Institute, rose about two percent in 2005, but was held flat for 2006.<sup>223</sup> Other divisions, such as the National Heart, Lung and Institute and the National Institute of Mental Health, are in similar situations.<sup>224</sup> Thus, it is no wonder that conflicts are arising between new biodefense priorities and long-standing efforts, such as developing drugs to combat Alzheimer’s, diabetes, stroke, Parkinson’s and arthritis.

However, Eliah Zerhouni and Anthony Fauci, the directors of the NIH and NIAID respectively, refute these claims. In a response to the open letter, the directors asserted that “funding for biodefense research has been additive to nonbiodefense research efforts supported by NIAID.”<sup>225</sup> Further, they maintained in the response, “with the establishment of the designation of biodefense money, studies of many pathogens previously funded from the general pool of microbiology money were funded by biodefense money, allow additional grants for nonbiodefense pathogens.”<sup>226</sup> They also attacked the accounting methodology of the authors of the letter

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<sup>218</sup> *Id.*

<sup>219</sup> *Id.*

<sup>220</sup> *Id.*

<sup>221</sup> Neil Munro and Marilyn Werber Serafini, *Doubling Down at NIH*, NAT’L J., April 15, 2006.

<sup>222</sup> Neil Munro and Marilyn Werber Serafini, *National Institutes of Health Feels Budget Squeeze*, NAT’L J., April 14, 2006.

<sup>223</sup> Betelheim, *supra* note 210.

<sup>224</sup> *Id.*

<sup>225</sup> Elias Zerhouni & Anthony Fauci, *NIH Response to Open Letter*, 308 SCIENCE 49.

<sup>226</sup> *Id.*

because it only took into account a fraction of the overall biodefense and nonbiodefense programs at NIH.<sup>227</sup> And, they specifically took issue with the scientists' designation of biodefense concerns being of "low public health significance."<sup>228</sup>

Dr. Fauci perceives naturally occurring diseases and bioterror threats as pieces of the same pie: "the way NIAID look[s] at the scientific component of it is that we have a big program what we call emerging and reemerging diseases and from the scientific standpoint a deliberately released microbe is just another form of an emerging and reemerging disease."<sup>229</sup> He also sees crossovers between the "expertise...for biodefense" and "something like SARS...pandemic flu or a variety of other issues."<sup>230</sup> Thus a reallocation of funding is likely less problematic to him than the scientists who work on niche topics because there are overall benefits derived from biodefense research.

d.

### **Incentives Not Adequate**

i.

### **Funding**

Unfortunately, regardless of any debates about the relative funding of biodefense prerogatives versus other public health research, the incentives provided by the Project Bioshield Act have largely not been enough to attract the private pharmaceutical industry. While \$5.6 billion sounds like a lot of money it is spread out

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<sup>227</sup> *Id.*

<sup>228</sup> *Id.*

<sup>229</sup> *Furthering Public Health Security: Project BioShield Hearing*, *supra* note 134, at 32.

<sup>230</sup> *Id.*

over ten years and is not much in the context of the vast expenditures on pharmaceuticals in the U.S.<sup>231</sup> In fact, the appropriated amount comes out to only \$20 per person.<sup>232</sup> In a hearing last month, Richard Falkenrath of the Brookings Institution reported to the Senate Health, Education, Labor and Pensions Committee that “the pharmaceutical industry has not yet been effectively mobilized to this task. Everyone understands that.”<sup>233</sup> Most of the nation’s biggest drug companies have avoided the program, seeing little profit but big risk to their reputations if they cannot carry out a high-profile government contract.<sup>234</sup> A representative from one pharmaceutical company stated succinctly, big companies “cannot make the type of profits” necessary to invest in the research the government hoped they would.<sup>235</sup> The government instead has had to depend on small, financially shaky biotechnology companies.<sup>236</sup>

The Secretary of HHS lacks the ability to use public funds extensively to shore up companies. The Secretary can pay them up to ten percent of the value of a contract in advance, and companies can get research subsidies early in a project, but the rest has to wait until they deliver the product.<sup>237</sup> Thus companies themselves must finance the expensive middle stages—between the time of proof of scientific principle and the time when a product is ready to be considered for BioShield—largely on their own.<sup>238</sup> Biotech companies have dubbed that financing gap the “Valley of Death.”<sup>239</sup> A lack of funding for advanced development at this critical stage stalls many promising drugs and vaccines in the lab.<sup>240</sup> The President and Chief Operating Officer

<sup>231</sup>Justin Gillis, *White House Admits Lag in Bioterror Effort; House Hearing Decries Lack of a Strategic Plan*, WASHINGTON POST, April 7, 2006, at A11.

<sup>232</sup>Philip Russell, Special Advisor on Vaccine Development and Production, Office of Public Health Preparedness, U.S. Department of Health and Human Services, Remarks at the University of Maryland Symposium: Eliminating Legal, Regulatory, and Economic Barriers to Biodefense Vaccine Development (June 9, 2004).

<sup>233</sup>*A Hearing on the Reauthorization of the Public Health Security and Bioterrorism Preparedness and Response Act before the Senate Comm. on Health, Education, Labor and Pensions*, 109<sup>th</sup> Cong. \*3 (2005).

<sup>234</sup>Justin Gillis, *No Hope for Stockpile of New Anthrax Vaccine by November; Developer Seeks Extension After Setback on Crucial Test*, WASHINGTON POST, March 17, 2006, at A01.

<sup>235</sup>*Hearing on Crossing the Valley of Death*, *supra* note 66, at 32 (statement of David Wright, President/CEO Pharmathene).

<sup>236</sup>*Id.*

<sup>237</sup>*Id.*

<sup>238</sup>*Id.* at 20.

<sup>239</sup>*See generally id.*

<sup>240</sup>Sen. Richard Burr, *How Can Congress Secure a Readily Available Supply of Emergency Vaccines?; ‘Band-Aids’ Won’t*

of one small pharmaceutical company illustrated this point, explaining that, “we, as a small company, look to the capital markets for our funding. Specifically we raise money through sales of stock. We don’t have any sales so we can’t contribute revenues to government research. The money we get in the capital markets is operating capital; it’s not for government seed funding. Therefore, the possibility exists that promising products—for example, our Ebola product—could die on the vine simply because, while it’s been proven scientifically, it’s not far enough along for BioShield.”<sup>241</sup>

This so-called “Valley of Death” is exactly what NIAID Director Fauci has been trying to combat. He has been investing money in start-up drug companies “betting” that they will come up with needed vaccines and other countermeasures.<sup>242</sup> Using NIAID biodefense funding, he “seeks to place bets on multiple companies in the hopes of hitting the jackpot and to dole out the NIH’s money in multiple rounds, using milestones to gauge progress.”<sup>243</sup> He funds rivals, hoping to get them ready to bid against each other for BioShield contracts.<sup>244</sup> Yet his detractors have called him a “venture capitalist,” a role inappropriate for the director of a government agency.<sup>245</sup> And, companies that have not been awarded funds feel that there is a “Fauci Club” of favorites.<sup>246</sup> They worry that without this NIH funding, they will not have the inside track for BioShield.<sup>247</sup> Potential preferences aside, it is not clear how fledging biotech companies would be able to raise the needed capital to overcome the “Valley of Death” without this influx of capital. Whereas some could argue that it is for Congress to explicitly authorize a mechanism to deal with the “Valley of Death” syndrome, Dr. Fauci is unquestionably attempting to further the underlying goals of the Act—generating countermeasures—by getting companies to where they need to be in order to make this a reality.

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*Fix Health Issues*, ROLL CALL, March 13, 2006.

<sup>241</sup> *Id.*

<sup>242</sup> Wysocki, *supra* note 185.

<sup>243</sup> *Id.*

<sup>244</sup> *Id.*

<sup>245</sup> *Id.*

<sup>246</sup> *Id.*

<sup>247</sup> *Id.*

ii.

### Liability

The fact that the Project Bioshield Act omits any type of liability protection for manufacturers or administrators of countermeasures has completely repelled the private pharmaceutical industry. The viability of any of the hoped for research and development programs is in doubt if there is not adequate financial support to protect vaccine manufacturers, sellers, and distributors from liability, and to compensate those injured by the vaccines.<sup>248</sup> Officials from the pharmaceutical industry have repeatedly and vigorously stressed that liability is of paramount importance.<sup>249</sup> “More important though,” said the CEO of AVI Biopharma, “than [other] incentives [is] the liability protection.”<sup>250</sup> Director Fauci summed up at a hearing last year: “I think there’s universal agreement that we need to address the liability issue better than it’s being addressed currently.”<sup>251</sup>

e.

### FDA Emergency Use Authorization

In February 2005, the FDA issued the First Emergency Use Authorization (EUA) under the Project BioShield Act.<sup>252</sup> The EUA was issued after a federal court enjoined the Department of Defense’s (DOD) involuntary anthrax vaccination program on the grounds that the FDA approval of the drug had violated the Admin-

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<sup>248</sup>Melanie Santiago, *Eliminating Legal, Regulatory, and Economic Barriers to Biodefense Vaccine Development*: Introduction, 8 J. HEALTH CARE L. & POL’Y 1, 2 (2005).

<sup>249</sup>Michael Barbaro, *BioShield Too Little for Drug Industry; Companies Want More Protection from Financial Loss*, WASH. POST, July 26, 2004, at E01. (“Executives say, Bioshield doesn’t remove all the uncertainties of developing the drugs. They complain that it does not offer complete liability protection should a drug have adverse effects on patients or fail to protect them against a pathogen, which could lead to lawsuits.”).

<sup>250</sup>*Bioshield II: Responding to an Ever-Changing Threat: Joint Hearing Before the Comm. on the Judiciary and Comm. on Health, Education, Labor and Pensions*, 108<sup>th</sup> Cong. 11 (2004) (testimony of Alan Timmins, CEO, AVI BioPharma) [hereinafter *Bioshield II: Responding to an Ever-Changing Threat Hearing*].

<sup>251</sup>Subcommittee on Prevention of Nuclear and Biological Attack Hearing: “Implementing the National Biodefense Strategy,” 109<sup>th</sup> Cong. 21 (2005).

<sup>252</sup>Authorization of Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax by Individuals at Heightened Risk of Exposure Due to Attack with Anthrax; Availability, 70 Fed. Reg. 5452 (Feb. 2, 2005).



istrative Procedure Act.<sup>253</sup> The court held that “unless and until FDA follows the correct procedures to certify [the vaccine] as a safe and effective drug for its intended use, defendant DOD may no longer subject military personnel to involuntary anthrax vaccinations absent informed consent or a Presidential waiver.”<sup>254</sup> DOD then returned to federal court seeking to modify the injunction to clarify that “defendant can administer [the vaccine] even in the absence of FDA approval of the drug: that is, pursuant to an [EUA] under the Project Bioshield Act of 2004.”<sup>255</sup> The court subsequently modified its injunction to allow DOD to administer the vaccine, on a voluntary basis, pursuant to a lawful EUA.<sup>256</sup> The court expressly reserved judgment on the lawfulness of any EUA.<sup>257</sup> Pending the opinion, the FDA did issue a EUA, pursuant to the request of DOD, for individuals DOD deemed to be at a “heightened risk of exposure due to attack with inhalation anthrax.”<sup>258</sup> As a condition of the EUA, the FDA required that DOD provide service members with both an option to refuse the vaccine and a specially-designed information sheet about the risks and benefits of vaccine.<sup>259</sup> The FDA also required DOD to report any adverse events associated with the vaccine to the FDA.<sup>260</sup>

The basis for DOD’s decision to administer the anthrax vaccine to military forces is largely classified, thus it is difficult to judge the Secretary of Defense’s determination that such vaccination was necessary. However, based on the legislative history of the Project BioShield Act, it does not appear that the EUA provisions were intended to be used as an ex post justification to vaccinate the armed forces without individualized consent. The Project BioShield Act in fact requires that regulations be established to ensure that individuals to whom an unapproved product is administered are informed of the known risks and benefits of the product’s use,

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<sup>253</sup>Doe v. Rumsfeld, 341 F. Supp. 2d 1 (2004).

<sup>254</sup>*Id.* at 43.

<sup>255</sup>Doe v. Rumsfeld, 2005 U.S. Dist. LEXIS 5573, \*1 (2005).

<sup>256</sup>*Id.*

<sup>257</sup>*Id.*

<sup>258</sup>70 Fed. Reg. 5452, *supra* note 252, at 5452.

<sup>259</sup>Gerald F. Masoudi, *Developments in Food and Drug Law*, 60 FOOD DRUG L.J. 107, 107 (2005).

<sup>260</sup>*Id.*

including the option to refuse the product. Hence, the court made the correct ruling when it held that a properly issued EUA would be lawful if the administration of the vaccine were subject to informed consent by members of the armed services. No other EUAs have been issued pursuant to the Project Bioshield Act of 2004.

#### **IV.**

### **Alternatives and Improvements**

Given these implementation problems with the Project Bioshield Act of 2004, critics have suggested alternatives to and improvements upon the Act's provisions. Congress has held an extensive set of hearings to determine what kinds of developments in the law are needed to foster the type of market originally envisioned. As discussed in the previous section, there are four primary—though related—areas that any further Congressional action on BioShield should take into account: 1) confusing government bureaucracy, 2) other public health priorities, 3) overall incentives for private sector participation, and 4) liability for manufacturers and administrators of countermeasures. This section will first discuss existing statutory models for a scheme of government indemnification and then turn to the BioShield II bill, which has been introduced in the 109<sup>th</sup> Congress as a means to advance the original goals of the Project BioShield Act of 2004.

#### **a.**

### **Liability and Compensation Models**

There already exist statutory models for government indemnification of activities related to vaccine manufacture and administration. The first such a program was the National Swine Flu Immunization Program

of 1976.<sup>261</sup> Concerns over manufacturer liability arose when insurers said they would end coverage for vaccine manufactures because of lawsuits.<sup>262</sup> Congress eventually responded by passing the Swine Flu Act to provide liability protection for the vaccine manufacturers, distributors and administrators, as well as compensation for those harmed by the vaccine.<sup>263</sup> The Act established a no fault compensation system for any plaintiff who could demonstrate that their injuries were causally linked to the vaccine.<sup>264</sup> The Swine Flu Act substituted the United States as the defendant via the Federal Tort Claims Act (FTCA), rather than the alleged wrongdoer.<sup>265</sup> However, the government could then seek compensation from manufacturer from negligent organizations or individuals.<sup>266</sup> The federal government ultimately paid out more than \$90 million to ailments related to the Swine Flu vaccine, thus becoming reluctant to assume this large financial risk in the future.<sup>267</sup>

Another statutory model that has been lauded as an example to be followed with respect to BioShield indemnification is the National Childhood Vaccine Act of 1986 (NCVIA).<sup>268</sup> The provisions of this Act are different from the Swine Flu Act. The NCVIA set up a two-staged, no fault compensation system for specific childhood vaccines.<sup>269</sup> The first stage is an administrative remedy where the plaintiff went before a special master of the United States district court to recover based on injuries resulting from childhood vaccination.<sup>270</sup> These injuries however, are capped and thus, the second stage allows for plaintiffs to bring

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<sup>261</sup>National Swine Flu Immunization Program of 1976, 94 P.L. 380, 90 Stat. 1113 (1976).

<sup>262</sup>Michael Greenberger, *The 800 Pound Gorilla Sleeps: The Federal Government's Lackadaisical Liability and Compensation Policies in the Context of Pre-Event Vaccine Immunization Programs*, 8 J. HEALTH CARE L. & POL'Y 7, 11-12 (2005).

<sup>263</sup>*Id.* at 12.

<sup>264</sup>*Id.* at 13.

<sup>265</sup>*Id.*

<sup>266</sup>*Id.*

<sup>267</sup>*Id.*

<sup>268</sup>42 U.S.C. §§ 300aa-1-300aa-34 (2006).

<sup>269</sup>Greenberger, *supra* note 2622, at 14.

<sup>270</sup>*Id.* at 14-15.

a traditional tort suit against the manufacturer, subject to certain limitations.<sup>271</sup>

Experts testifying before Congress have looked to the NCVIA as a model for liability protections for companies that produce countermeasures pursuant to Project BioShield. Senator Burr specifically inquired of one such expert who was before the Subcommittee on Bioterrorism and Public Health Preparedness, “You also mentioned indemnification, and I guess I’d ask you, what type of liability provisions do you believe we should have?”<sup>272</sup> The expert responded, saying “I would mention that the children’s vaccine fund, the process that indemnifies [a] company for children’s vaccines, I think is a model that should be looked at seriously in this regard.”<sup>273</sup> Another expert recommended that the program be “modernized and strengthened,” but that any program to address immunizations in the face of a widespread outbreak should . . . separate . . . and encompass all circumstances where mass emergency immunization would be necessary.”<sup>274</sup>

Another liability program was established incident to the Phase I Smallpox Vaccination Program. Announced by President Bush in December 2002, this program was intended to vaccinate 500,000 first responders against smallpox.<sup>275</sup> The program utilized Section 304 of the Homeland Security Act of 2002<sup>276</sup> to provide protection; however, “the liability protection afforded was ambiguous and the compensation available to those injured was inadequate.”<sup>277</sup> Congress attempted to reinvigorate this liability and compensation scheme and thereby increase the number of vaccinees by passing the Smallpox Emergency Personnel Protection Act of 2003 (SEPPA).<sup>278</sup> SEPPA created a no-fault compensation system that broadened liability coverage, specifically

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<sup>271</sup>*Id.* at 15.

<sup>272</sup>*Hearing on Crossing the Valley of Death, supra* note 66, at 32 (testimony of Phillip Russell, Retired Major General, U.S. Army).

<sup>273</sup>*Id.*

<sup>274</sup>*Biodefense: Next Steps: Hearing Before the Comm. on Health, Education, Labor and Pensions, 109<sup>th</sup> Cong.* 53 (2005) [hereinafter *Biodefense: Next Steps Hearing*].

<sup>275</sup>Greenberger, *supra* note 262, at 17.

<sup>276</sup>Pub. L. No. 107-296, 116 Stat. 2165 (2002).

<sup>277</sup>Greenberger, *supra* note 262, at 18.

<sup>278</sup>Pub. L. No. 108-20, 117 Stat. 628 (2003).

healthcare entities, but was subject to certain limitations like caps on awards.<sup>279</sup> However, the remedies as a whole were not sufficient to make the smallpox initiative successful.<sup>280</sup>

The final statutory example is the recently enacted Support Anti-Terrorism by Fostering Effective Technologies Act (SAFETY Act).<sup>281</sup> The SAFETY Act is, however, inappropriate for indemnification of countermeasures because that was not the intent of the Act, the Act is overly burdensome, and the liability protection is too broad at the expense of those to be compensated by the Act.<sup>282</sup> Even if the SAFETY Act were applicable to biodefense vaccines, the procedural and insurance requirements are too burdensome so that it would be “virtually impossible to obtain vaccine liability protection under the Act.”<sup>283</sup> Michael Greenberger, of the University of Maryland Center for Health and Homeland Security, offered an extensive analysis of the hoops through which a company would have to go through in order to meet the criteria for liability coverage eligibility. First, the seller of the countermeasure must receive designation for its product as a “Qualified Anti-Terrorism Technology,” including a risk exposure assessment.<sup>284</sup> Next, the seller’s product must be certified for placement on the Approved Product List for Homeland Security, after review by the Secretary.<sup>285</sup> The seller must then conform to several insurance requirements, regardless of designation or certification.<sup>286</sup> The Act requires that the seller obtain liability insurance to cover their contractors, subcontractors, supplies and vendors.<sup>287</sup> Then the seller must purchase a specific amount of insurance from

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<sup>279</sup>Greenberger, *supra* note 262, at 20.

<sup>280</sup>*Id.* The author of this article found specifically “that the most significant reason” for the collapse of the federal Phase I Smallpox Vaccination Program, was “the ineffective liability and compensation scheme created by Congress.” *Id.* at 30.

<sup>281</sup>6 USC §§441-444 (2006).

<sup>282</sup>Greenberger, *supra* note 262, at 22-23.

<sup>283</sup>*Id.* at 24.

<sup>284</sup>*Id.* at 25.

<sup>285</sup>*Id.* at 26.

<sup>286</sup>*Id.*

<sup>287</sup>*Id.*

available private sources.<sup>288</sup> He then went on to point out, that once obtained, the protection is “so complete and absolute that those injured by the technology have little ability to be compensated.”<sup>289</sup> The SAFETY Act does not provide compensation comparable to the Swine Flu Act, NCVIA or SEPPA.<sup>290</sup> If the seller has had its product designated, plaintiffs are prohibited from receiving punitive damages or proceeding on a theory of joint and several liability, and there is a cap on liability.<sup>291</sup> The SAFETY Act does not immunize the seller from liability by substituting the federal government as the respondent; sellers will have to pay awards via their private insurance, which will ultimately be passed on to sellers via increased premia and hence, consumers.<sup>292</sup> A second level of protection is afforded to sellers that achieve both certification and designation under the SAFETY Act.<sup>293</sup> In that set of circumstances, the seller may rely on the government contractor defense, which is only rebuttable if the seller acted fraudulently or with willful misconduct, thus leaving injured parties wholly uncompensated except for the rare case.<sup>294</sup>

**b.**

### **Pending Legislation in the 109<sup>th</sup> Congress**

BioShield II,<sup>295</sup> a bill introduced by Senators Lieberman, Hatch and Brownbeck, is the most comprehensive attempt to deal with the issues presented by the implementation of the Project BioShield Act.<sup>296</sup> To contend with the confusing governmental bureaucracy, the bill calls for the establishments new federal offices—one in

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<sup>288</sup>*Id.* at 27.

<sup>289</sup>*Id.* at 28.

<sup>290</sup>*Id.*

<sup>291</sup>*Id.*

<sup>292</sup>*Id.*

<sup>293</sup>*Id.*

<sup>294</sup>*Id.* at 29.

<sup>295</sup>S. 975, 109<sup>th</sup> Cong. (2006).

<sup>296</sup>Other actions in the 109<sup>th</sup> Congress include: Public Readiness and Emergency Preparedness Act, 109 P.L. 148, Div. C; Project BioShield Material Threats Act, H.R. 5028, 109<sup>th</sup> Cong. (2006); Protecting America in the War on Terror Act of 2005, S. 3, 109<sup>th</sup> Cong. (2005); National Biodefense Pandemic Preparedness Act of 2005, S. 1880, 109<sup>th</sup> Cong. (2005); and Responsible Public Readiness and Emergency Preparedness Indemnification, S. 2291 (2006).

HHS and one in DHS—to be responsible for the systematic implementation of Project BioShield’s goals.<sup>297</sup> The legislation establishes the Office of Public Health Countermeasure Development in HHS to be responsible for developing a national preparedness plan with regard to countermeasure development.<sup>298</sup> The plan is to be developed cooperatively with DHS and DOD and, expressly, the private sector.<sup>299</sup> The Act then establishes within DHS an Office of the Medical Readiness and Response to coordinate medical and public health issues around the federal medical response and the federal support to state and local agencies for mass casualty care.<sup>300</sup> Senator Lieberman explained that “ultimately the Secretary of HHS has to be in charge” of “incentivizing the biopharma industry to produce the countermeasures we need to protect the lives of the American people from a bioterrorist attack and infectious diseases.”<sup>301</sup> Hopefully, the designation of new offices to manage these issues specifically will ameliorate the problems identified by the private industry, such as confusing and ambiguous government expectations.

In introducing the bill, Senator Lieberman referenced, in addition to terrorist threats, the SARS virus, the 1918 Spanish flu pandemic, and avian influenza, as motivations for the legislation.<sup>302</sup> S. 975 addresses issues related these and other public health priorities by broadening the covered countermeasures. Pursuant to section 201, expedited procurement authorities and the Special Reserve Fund are available for countermeasures

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<sup>297</sup>The legislation actually establishes ten new related entities: 1) the Terrorism and Infectious Disease Countermeasure Purchase Fund; 2) procurement pools for qualified countermeasures and security countermeasures; 3) the International Public Health Advisory Committee to develop strategies for establishing such pools; 4) the Office of Public Health Countermeasure Development within HHS; 5) the Office of Medical Readiness within DHS to assume functions of the National Disaster Medical System and the Metropolitan Medical Response System; 6) the National Emergency Medical Readiness and Response Board within DHS to oversee emergency medical response plans; 7) the National Center for Healthcare Technology Development to manage NIH intellectual property; 8) the Millennium Medicine Discovery Award; 9) the Office of the Deputy Commissioner for Biological, Chemical, Nuclear, Radiological and Infectious Disease Products; and 10) the Global Disease Detection Trust Fund. CONG. RESEARCH SERV., S.975 SUMMARY AS OF 4/28/2005—INTRODUCED (2005). The two discussed seem to have the most direct bearing on the implementation problems previously addressed.

<sup>298</sup>S. 975, 109<sup>th</sup> Cong. §801.

<sup>299</sup>*Id.* §802.

<sup>300</sup>*Id.* §901.

<sup>301</sup>*Roundtable Discussion: Preparing a National Biodefense: S. 975: Hearing before the Subcomm. on Bioterrorism and Public Health Preparedness*, 109<sup>th</sup> Cong. 16 (2005) [hereinafter *Roundtable Discussion: Preparing a National Biodefense*].

<sup>302</sup>*Statements on Introduced Bills and Joint Resolutions – (S. April 28, 2005)*, 109 CONG. REC. S4549, S4590 (2005).

to “detect, diagnose, treat, or prevent an infectious disease adversely affecting public health.”<sup>303</sup> The legislation would also set up “procurement pools” for infectious disease countermeasures.<sup>304</sup> These pools would allow the Secretary to aggregate funds from entities other than the federal government, such as NGOs, international health agencies, the United Nations and private non-profit organizations.<sup>305</sup> According to Senator Lieberman’s office, these pools “may be the best way to proceed in utilizing BioShield for the development of countermeasures where the United States is not the principal market (e.g. countermeasures for diseases endemic in the developing world).”<sup>306</sup> Further, a prospective seller “can determine the full extent of the market for the countermeasure and then United States can add [incentives]” to contribute to the initiative.<sup>307</sup> Thus, the legislation has a more expansive vision of biological threats by including infectious diseases in the statutory language and acknowledging potential partnerships based on other probable markets for successful countermeasures.

Whereas the Project BioShield Act incentivized the *results* of countermeasure research and development—the seller would fund the research at its own risk and expense—the orientation of BioShield II is additionally to incentivize the research and development *process*.<sup>308</sup> The legislation establishes a purchase fund and authorizes advance, partial, or progress payments to BioShield contractors.<sup>309</sup> Aimed specifically at the “Valley of Death for Small Companies,” section 401 of the measure is to provide funding to firms to ensure that they are able to bid on BioShield contracts.<sup>310</sup> The following section authorizes reimbursement to these small firms for various expenses.<sup>311</sup> The proposed legislation thus directly addresses the issue of funding

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<sup>303</sup>S. 975, 109<sup>th</sup> Cong. §201(a).

<sup>304</sup>*Id.* §202(b)(1).

<sup>305</sup>*Id.* §202(b)(2).

<sup>306</sup>Sen. Joseph Lieberman, *BioShield II, S. 975: Section by Section*, at 4, available at <http://lieberman.senate.gov/issues/security.cfm#homeland> (last accessed April 30, 2006).

<sup>307</sup>*Id.*

<sup>308</sup>*Id.*

<sup>309</sup>S. 975, 109<sup>th</sup> Cong. §101.

<sup>310</sup>*Id.* §401.

<sup>311</sup>*Id.* §402.



streams available for companies to engage in this research and development.

The bill also grants an extensive array of incentives to encourage the participation of the pharmaceutical industry. The bill offers patent extension, federal tax incentives, federal tax credits, and patent protections. A six-month to two-year patent extension is available if the seller has developed a new countermeasure that is “superior to a previously available drug, antibiotic drug, biological product, device, detection technology or research tool.”<sup>312</sup> Firms that enter into BioShield contracts are eligible for their choice of five tax incentives.<sup>313</sup> Next, the bill amends the Internal Revenue code to make companies that engage in countermeasure research eligible for three types of tax credits.<sup>314</sup> Two forms of patent protections are available to companies that successfully complete their BioShield contract: patent restoration and patent extension.<sup>315</sup> Patent term restoration allows a company to restore a patent for a “period equal to the number of days in the regulatory review period,”<sup>316</sup> thus all erosion of the patent from the date of issuance to the date of FDA approval is restored.<sup>317</sup> Patent term extension allows company to secure up to two years extension on an “eligible patent,” which is one that the time the company “entered into the contract to develop [the] countermeasure, was owned by or licensed to” that company.<sup>318</sup> This incentive is only available if the Secretary of HHS deems it is needed according to specified criteria.<sup>319</sup> Otherwise known as a “wild-card patent extension” this incentive in particular, has been the lightning rod for criticism.<sup>320</sup> Critics say that the patent extension is a “giveaway to the drug industry that would keep the costs of widely used drugs unnecessarily high.”<sup>321</sup>

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<sup>312</sup>*Id.* §301(b)(4)(A)(iii)(II).

<sup>313</sup>*Id.* §311(a).

<sup>314</sup>*Id.* §312.

<sup>315</sup>*Id.* §331.

<sup>316</sup>*Id.* §331(b).

<sup>317</sup>Lieberman, *supra* note 306, at 6.

<sup>318</sup>S. 975, 109<sup>th</sup> Cong. §331(c).

<sup>319</sup>*Id.*

<sup>320</sup>Marc Kaufman, *Bioterrorism Response Hampered by Problem of Profit*, WASH. POST, August 7, 2005, at A05.

<sup>321</sup>*Id.*

The generic drug industry is particularly alarmed, as one representative stated, the bill “includes provisions that reach into every medicine cabinet in America by effectively eliminating consumers’ access to affordable generic products of everyday medicine. . . [the provisions] would unnecessarily and excessively penalize consumers to the tune of tens of billions of dollars in lost pharmaceutical savings. They would institute new loopholes that would extend additional and expensive market access savings provisions for brand products already on the market.”<sup>322</sup> Senator Lieberman has defended the provision, appealing to the broader desire “urgently to draw the enormous capabilities of our biotech and pharmaceutical industry into providing countermeasures.”<sup>323</sup> He called the “patent bonus that a company could apply to a patent in its portfolio” an “exchange for achieving the goal we have set which is to protect us from these terrible threats.”<sup>324</sup>

BioShield II addresses liability and compensation principally by extending the provisions of the SAFETY to cover the types of addressed countermeasures. Liability protections are only available for companies that successfully complete BioShield contracts, or during human clinical trials of a countermeasure.<sup>325</sup> The SAFETY Act is expressly amended to include covered countermeasures, including vaccines.<sup>326</sup> The legislation also provides liability protection for administrators of covered countermeasures, like healthcare personnel, volunteers and others, during a declared state or national emergency.<sup>327</sup> The legislation does not provide much in the way of compensation for victims—there are no punitive damages and no noneconomic damages available, and the only grounds for compensation are willful and wanton misconduct.<sup>328</sup> These liability and compensation provisions are not ideal. One expert, testifying in the Senate specifically about this issue, explained:

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<sup>322</sup>*Bioshield II: Responding to an Ever-Changing Threat Hearing*, *supra* note 250, at 13 (statement of Kathleen Jaeger, President/CEO, Generic Pharmaceutical Association).

<sup>323</sup>*Roundtable Discussion: Preparing a National Biodefense*, *supra* note 301, at 3.

<sup>324</sup>*Id.*

<sup>325</sup>S. 975, 109<sup>th</sup> Cong. §341.

<sup>326</sup>*Id.* §341(a).

<sup>327</sup>*Id.* §1204.

<sup>328</sup>*Id.*

A program needs to have the following components: One, protection of the vaccine manufacturer against lawsuits should be absolute, except in the case of gross negligence. What do I mean by that? For instance, a failure to follow good manufacturing procedures during the production and distribution of the vaccine. Two, health care workers and medical facilities participating in the immunization program need complete protection against lawsuits unless they violate standard medical procedures when administering the vaccine. For instance, failure to change needles in withdrawing a vaccine from a multi-dose file. Three, those who develop a complication due to the vaccine should be reimbursed for their medical costs and lost earnings but should not receive punitive damages.<sup>329</sup>

He further explained that, in order to achieve the “overall goal,” of “mak[ing] the necessary vaccines, administer[ing] them to a large number of people and hav[ing] a public willing to be immunized,” the federal government is the “logical entity to provide the compensation.”<sup>330</sup> As such, an extension of the NCVIA is the sensible choice, rather than the extension of the complicated provision of the SAFETY Act and virtual immunity for healthcare workers at the expense of the inevitable victims of countermeasure administration. Overall, BioShield II contains a robust set of provisions aimed at addressing the implementation problems of BioShield. The funding provisions, for instance, directly speak to the challenging experiences of drug companies. The reorganization of HHS and DHS to include offices that focus on these issues will also hopefully clarify the government’s expectations. However, the legislation does not represent a consistent federal government commitment to the animating goals of BioShield. For example, the incentives granted do not come from additional appropriated funds, but higher costs for drugs, fewer generic drugs, and tax expenditures. Additionally, the liability provisions do not contain corresponding compensation provisions coming from the federal government treasury. If the federal government is serious about addressing the threat posed by

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<sup>330</sup> *Id.* §54.

pandemic disease outbreak—emanating from a terrorist source or otherwise—new measures should address these concerns.

V.

### **Conclusion**

Ultimately, it is the federal government's job to make sure that America is doing all that it can to prepare for a possible bioterrorist attack. The Project BioShield Act of 2004 is an innovative measure designed to address real deficits in the market for countermeasures. However, BioShield is only a first step. The Act reflects a balance between the urgent need to stimulate a market for countermeasures, and Congress' need to impose limits on the Executive and make deliberate choices about how to best accomplish the tasks at hand. Since the enactment of Project BioShield, Congress has held numerous hearings and is considering a variety of legislative proposals in order to remedy the defects in the original Act that many industry executives have pointed out. If Congress truly wants to prepare for a possible catastrophic biological attack and accomplish the goals originally intended by Project BioShield, its next actions should account for the legitimate criticisms of the Act and should provide a consistent and strong federal response.