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IMMUNITY FOR IMMUNIZATIONS: TORT LIABILITY, BIODEFENSE, AND BIOSHIELD II

Lincoln Mayer

NOTE

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INTRODUCTION: AFTER 9/11

The September 11, 2001 attacks forced the United States to reassess the possibility of a mass-casualty bioterror event. If terrorists could coordinate the destruction of four large commercial aircraft, two of the tallest skyscrapers in the country, and an entire section of the Pentagon in a single day, killing thousands of people, then they might eventually release a catastrophically lethal biological agent. Indeed, shortly after September 11, an unknown assailant sent anthrax spores to congressional offices and other targets, causing several fatalities and sowing widespread fear of being poisoned through the mail. Barely a year later, the outbreak of Severe Acute Respiratory Syndrome (SARS) and, after that, avian influenza, woke the public to a pandemic threat of a scale not seen since the million-death influenza strains that circulated in 1968-1969 and 1957-1958 (and perhaps even the 1918-1919 Spanish flu, which killed 40 million people worldwide).²

The federal government has determined that the country is woefully unprepared for a pandemic or major biological attack, particularly because of the lack of effective medical countermeasures. For example, in 2001, in its Third Annual Report to the President and the Congress, the Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction concluded that “[l]imited research, development, and production capability for certain vaccines is one of the largest hurdles currently facing military and civilian responders as they prepare for biological threats.”³ Indeed, in 2003, the Commissioner of the Food and Drug Administration (FDA), Mark B. McClellan, called counterterrorism that agency’s “biggest new challenge.”⁴

Such concerns prompted Congress to enact Project Bioshield (also known as “Bioshield I”) in 2004. President Bush, inaugurating the multibillion-dollar program to develop and stockpile vaccines and antidotes to the most likely biological weapons, pledged to “rally the great promise of American science and innovation to confront the greatest danger of our time.”⁵ The drug industry’s lackluster response to Bioshield I, however, disappointed the legislation’s supporters.

2. *World Health Agency Tones Down Alarm on Possible Flu Pandemic*, N.Y. TIMES, Oct. 1, 2005, at A5.

3. ADVISORY PANEL TO ASSESS DOMESTIC RESPONSE CAPABILITIES FOR TERRORISM INVOLVING WEAPONS OF MASS DESTRUCTION, THIRD ANNUAL REPORT TO THE PRESIDENT AND THE CONGRESS vi (2001), available at <http://www.rand.org/nsrd/terrpanel/terror3-screen.pdf>.

4. Mark B. McClellan, Comm’r, Food & Drug Admin., Address at the Food and Drug Law Institute’s 46th Annual Educational Conference (Apr. 1, 2003), in 58 FOOD & DRUG L.J. 191, 201 (2003).

5. Eric Lipton, *Setbacks Stymie Bid to Stockpile Bioterror Drugs*, N.Y. TIMES, Sept. 18, 2006, at A1.

The following year, Congress responded with competing versions of legislation that became known as “Bioshield II.”⁶ These proposals offered a sweeping array of reforms to coordinate national biodefense efforts and stimulate private development of medical countermeasures for deadly biowarfare agents. This Note focuses on the development and implications of Bioshield II’s broad tort immunity for entities that develop or deploy covered countermeasures, as well as its no-fault compensation scheme to pay for any injuries that these countermeasures cause.

Congress passed part of the Bioshield II program—the liability protections and no-fault compensation scheme—in the form of the Public Readiness and Emergency Preparedness (PREP) Act, which the President signed on December 30, 2005.⁷ In conferring nearly impregnable immunity from tort suits on designated products, Bioshield II built on a post-September 11 trend toward liability limitations and terrorism-related no-fault schemes. In 2001, Congress created a no-fault administrative scheme for victims of the al Qaeda attacks that offered generous compensation while constraining victims’ recourse to tort.⁸ Shortly thereafter, it passed the Homeland Security Act of 2002, giving limited but uncertain liability protection under section 304 to manufacturers, distributors, and administrators of countermeasures, while offering little compensation to injury victims.⁹ The Smallpox Emergency Personnel Protection Act of 2003 (SEPPA) soon followed, addressing liability and compensation concerns for one of the most lethal potential biowarfare agents.¹⁰ Bioshield I arrived in 2004, allocating billions of dollars to develop and stockpile drugs for diverse biological threats.¹¹ The drug industry, however, viewed these measures as insufficient,¹² and, in 2005, Congress passed the PREP Act to facilitate faster development of biowarfare and pandemic countermeasures.¹³

6. Legislators have proposed several different versions of Bioshield II. This Note will discuss the most salient differences between them, identifying particular bills and sponsors where appropriate. Otherwise, the various bills are collectively termed “Bioshield II.”

7. 42 U.S.C. §§ 247d-6d to -6e (2007).

8. Elizabeth Berkowitz, *The Problematic Role of the Special Master: Undermining the Legitimacy of the September 11th Victim Compensation Fund*, 24 YALE L. & POL’Y REV. 1, 24-37 (2006) (arguing that by constraining the tort option for 9/11 victims, the otherwise generous fund undercut its legitimacy).

9. 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, 17-18 (2005).

10. James T. O’Reilly, *Bombing Bureaucratic Complacency: Effects of Counter-Terrorism Pressures upon Medical Product Approvals*, 60 N.Y.U. ANN. SURV. AM. L. 329, 336-37, 344 (2004) (using smallpox as an example of a logical bioterrorism agent).

11. Project Bioshield Act of 2004, Pub.L. No. 108-276, 118 Stat. 835.

12. Marc Kaufman, *Bioterrorism Response Hampered by Problem of Profit*, WASH. POST, Aug. 7, 2005, at A5.

13. 42 U.S.C. § 247d-6d (2007).

This Note begins at the origin of U.S. biodefense concerns, then explains and assesses Bioshield II as a possible solution. Part I introduces the post-9/11 threats that America faces from bioterrorism and pandemics. After examining the intersection between biodefense and the tort system, this Part concludes that modifying tort was necessary to stimulate more effective private sector involvement in biodefense.

Part II focuses on the text, structure, and purpose of the Bioshield II legislation itself, mapping the PREP Act as well as key parts of Bioshield II bills that Congress passed over but may yet consider again.

Part III analyzes Bioshield II's most significant risks—inadequate compensation for victims, insufficient deterrence of negligent tortfeasors, and concerns that “a slippery slope” will develop that carries the legal innovations of Bioshield II into the broader realm of medical products liability.

Part IV suggests specific reforms to Bioshield II in light of the following three conclusions: First, the government must fully account for the positive externalities associated with developing biodefense and pandemic countermeasures.¹⁴ Second, to internalize these externalities, Congress should create a more robust guaranteed market for biodefense products than that which Bioshield I achieved, as well as circumscribe tort liability for entities that develop, distribute, or administer these products. Third, Bioshield II should retain the core aspirations of the tort system—providing victims with adequate compensation and inducing potential tortfeasors to take socially optimal precautions. To that end, this Note identifies aspects of Bioshield II that are ripe for reconsideration.

14. Externalities are the positive or negative effects that people generate with their actions but do not capture (or suffer) themselves. Biodefense research, for example, generates significant benefits in preparing the country to avert or respond to a biowarfare attack or pandemic, but a company cannot naturally reap those benefits in the form of profits because there is little or no commercial market for these products. The government, therefore, must “internalize” this externality by buying the products and minimizing the legal and financial risks for the company.

A company's inability to obtain insurance for the development and use of a dangerous product might indicate that the product should not reach the market. For biodefense, however, such market signals do not reflect the true net value of these products, which are especially risky because of the unusual limits on clinical testing and uncertainty regarding scope of use. Furthermore, as others have noted, tort cannot deter the most proximate cause of an epidemic—terrorists or nature (though it can deter negligence in the actions of the drug companies, hospitals, and caregivers in preparing for and responding to an attack). There is some debate over whether it is possible to dissuade terrorism by subjecting state sponsors of terrorism to civil liability in U.S. courts. That debate is beyond the scope of this Note, but it is worth noting that the defendants are usually pariah states such as Iran, which stand to lose only assets frozen in the United States to which the terror-supporting regime has no access anyway. The most prominent example of a state sponsor of terrorism paying out significant compensation from its general treasury is Libya's multibillion-dollar payment for the Pan Am Flight 103 bombing, but this settlement came, as one would expect, as part of a diplomatic agreement rather than from victims' suing in tort.

I. THE FAILURE OF “BIOSHIELD I” AND THE NEED FOR TORT IMMUNITY

Few major companies have entered the biodefense market, and even fewer are developing novel biodefense therapies. In 2000, the Defense Department determined that of fifty-seven medicines and medical devices the United States would need to be ready for a biological attack, only one existed.¹⁵ By 2005, only two existed.¹⁶

The drug industry offered an unequivocal explanation: tort liability and limited commercial prospects. In April 2005, the vice president for public policy at pharmaceutical giant Merck stated, “we think the two critical issues are a strong, guaranteed purchase commitment and liability protection.”¹⁷ James Greenwood, who heads Biotechnology Industry Organization (BIO)—the industry’s trade association—similarly asserted that “you aren’t going to have companies risk their entire corporate existence without sufficient liability protection.”¹⁸ Drug companies, however, do risk substantial sums, and sometimes their entire existence, to bring new products to market without any tort immunity or government purchase guarantee, often striking it rich or failing spectacularly.¹⁹ Companies’ reticence to shoulder the risk for biodefense medicines implies that they perceive far greater downside in the political risks and legal liabilities than upside in the field’s potential profit margins.²⁰

Insurers echo the drugmakers’ reading of the inherent risks in the biodefense market.²¹ First, it is difficult to predict the frequency and severity of

15. Kaufman, *supra* note 12.

16. *Id.*

17. Sarah Lueck, ‘Bioshield’ Drug-Patent Plan Draws Fire; Generics Makers Fight Extending Exclusivity Protection to Areas Outside Biodefense, WALL ST. J., Apr. 1, 2005, at A4.

18. Bernard Wysocki, Jr., *Missing Medicine—Emergency Response: Fearing Avian Flu, Bioterror, U.S. Scrambles to Fill Drug Gap*, WALL ST. J., Nov. 9, 2005, at A1.

19. Compare, for example, the success of Pfizer’s drug Lipitor with its withdrawal of Torcetrapib after spending \$800 million on research and development. See Theresa Agovino, *Pfizer’s Shares Sink as It Halts Plans for Cholesterol Drug*, WASH. POST, Dec. 5, 2006, at D2.

20. For example, it is particularly important for biodefense that the government rebuild its credibility with the pharmaceutical industry on respecting intellectual property in a crisis. Companies fear that even if they developed a successful biodefense or pandemic drug, the government would essentially confiscate it in an emergency. The drugmakers remember well that in the wake of the 2001 anthrax attacks, the United States and foreign governments threatened to revoke Bayer’s patent on Cipro if the company refused to drastically cut its price beyond the heavy discount it had already offered. Editorial, *Project Bioshield*, WASH. POST, May 24, 2004, at A22 (“Too many [drug companies] remember the pressure put on Bayer, the producer of the anthrax drug Cipro, to cut prices dramatically following the 2001 anthrax attacks, as well as congressional threats to suspend Bayer’s patent if the company refused.”). Congress and foreign governments should try to regain credibility with large pharmaceutical companies by authorizing a significant one-time payment to Bayer to offset the additional price reductions that the governments forced on the company under threat of expropriation.

21. See Lavonne Kuykendall, *GAO: Some Terrorist Attack Risks May Be Uninsurable*,

bioterror attacks and pandemics. Second, it will be impossible to gauge the safety and efficacy of key biodefense therapies, because human clinical trials would be unethical for deadly diseases that seldom naturally occur, such as Ebola and anthrax. Third, terrorist attacks are not random occurrences. Over the long term, at least from an insurance perspective, Nature is more predictable than humankind. Fourth, potentially “catastrophic” risks are difficult or impossible to insure.²² The September 11 attacks killed 3000 people and produced tens of billions of dollars in insured losses; in the aftermath, terrorism-related insurance dried up.²³ Yet, September 11 was a conventional attack. Terrorists did not use nuclear, chemical, biological, or radiological weapons. An unconventional attack (let alone pandemic flu) could be much worse. Civil immunity, then, is essential because the tort system presents manufacturers of biodefense products with an unquantifiable, uninsurable, and therefore unmanageable risk.²⁴

A series of unfavorable court decisions that began in 1974 with *Reyes v. Wyeth Laboratories*²⁵ prompted insurers to dramatically reassess vaccine makers’ liability exposure, and provoked an exodus of companies from the vaccine market. The added risks of biodefense did not entice them to return. Major vaccine manufacturer Aventis, in a statement to Congress on Bioshield I, asserted that “[t]he issue of potential liability . . . absolutely must be addressed in order to stimulate private sector interest in entering into agreements for such countermeasures.”²⁶ An Aventis executive further testified, “We would try to obtain commercial insurance, but the practical reality today is that it is unlikely to be available for projects of this nature.”²⁷

Aventis’s reluctance to take on biodefense projects is significant because it is the world’s largest company “devoted entirely to vaccine[s],” producing

DOW JONES NEWSWIRES, Sept. 28, 2006 (discussing the four criteria for a loss to be insurable).

22. *Id.*

23. For a discussion of terrorism-related insurance, see *infra* note 157.

24. One could, however, debate whether *all* biodefense products need Bioshield II protection. Some products, such as aspirin and antidepressants, might be needed in greater quantities during a biological event but would not have been manufactured or modified specifically for biodefense purposes. It seems doubtful that these products require or deserve the same immunity from suit that, say, the manufacturer of an Ebola vaccine should receive. These issues are addressed in the discussion of the slippery slope from biodefense tort reform to general tort reform, *infra* Part III.C.

25. 498 F.2d 1264 (5th Cir. 1974) (affirming pharmaceutical company’s liability on a theory of inadequate warning where company had failed to provide direct Spanish-language warning for possible side effects of a polio vaccine to Spanish-speaking plaintiff).

26. *Regarding Project Bioshield: Hearing Before the S. Comm. on the Judiciary and S. Comm. on Health, Educ., Labor and Pensions*, 108th Cong. 4 (2004) (statement of Christine Grant, Vice President of Public Policy and Government Relations, Aventis Pasteur); see also *id.* at 3 (“Congress can significantly improve [Bioshield I] in the area of liability protection . . . by amending the law as part of Project Bioshield II.”).

27. *Id.*

“approximately 1.4 billion doses of vaccines annually . . . to protect 500 million people across the globe . . . against 20 bacterial and viral diseases.”²⁸ The company epitomizes the commercial experience and expertise that Congress had hoped to enlist with Bioshield I but failed to attract.

To address the market’s understandable perception of a lopsided risk-reward ratio for biodefense medicines, the government needed to both reduce the risk and raise the reward. Granting companies immunity from suit, however, is highly contentious, and Congress sought to sidestep the issue. While Bioshield I passed with great fanfare, 99-to-0 in the Senate²⁹ and 414-to-2 in the House,³⁰ these resounding votes of approval reflect that the bill achieved consensus at the cost of efficacy.

Bioshield I did not allocate enough money to procurement and ignored the problem of tort liability. These inadequacies became apparent as soon as the Department of Health and Human Services (HHS) asked for bids on its first major contract: a nearly \$1 billion award to develop and stockpile a new anthrax vaccine. No bids came in from major pharmaceutical companies because of concerns about profit potential and tort liability.³¹ HHS had little recourse but to award the \$877 million contract to VaxGen, a small, struggling biotech company with no track record of bringing products to market.³²

28. *Id.* at 2.

29. Press Release, Sen. Joe Lieberman, Lieberman Applauds Signing of Bioshield into Law (July 21, 2004), available at <http://lieberman.senate.gov/newsroom/release.cfm?id=224418>.

30. *House Passes Bill to Finance Development of Bioterrorism Antidotes*, N.Y. TIMES, July 15, 2004, at A19.

31. Lipton, *supra* note 5; see also Paul Elias, *Bioshield Dispute Underscores Problems with Defense Program*, AP DATASTREAM, Sept. 28, 2006 (detailing the “laundry list of failures” that VaxGen has experienced with its product and timeline, and corroborating that Bioshield I only “generate[d] indifference among the big pharmaceutical companies the government hoped to woo”). But see *Project Bioshield Act of 2003: Hearing Before the H. Energy and Commerce Subcomm. on Health and the Subcomm. on Emergency Preparedness and Response of the H. Select Comm. on Homeland Security*, 108th Cong. (2003) (statement of J. Leighton Read, on behalf of the Biotechnology Industry Organization), available at <http://www.bio.org/healthcare/biodefense/20030327.asp> (affirming the biotech industry’s firm support for Project BioShield). Since biotech companies stand to benefit more than large pharmaceutical companies from Bioshield I, BIO’s stronger support is understandable. Still, BIO’s statement includes a section titled, “Product-liability concerns could defeat our best efforts to engage the private sector,” which cites the Price-Anderson, Swine Flu, and National Childhood Vaccine Injury Acts as models for “assur[ing] private sector partners that they will not be exposed to a risk of litigation out of proportion to the rewards for success.” *Id.* The following year, BIO gave congressional testimony in support of Bioshield II that focused on liability protections. See *Project Bioshield II: Hearing Before the S. Comm. on Health, Educ., Labor, and Pensions and the S. Comm. on the Judiciary*, 108th Cong. (2004) (statement of the Biotechnology Industry Organization), available at <http://www.bio.org/healthcare/biodefense/20041006.asp>.

32. See, e.g., *Bioshield Dispute Underscores Problems with Defense Program*, *supra* note 31.

Problems plagued the program and,³³ eventually, prompted the government to cancel its order.³⁴ The rewards Bioshield I held out were inadequate because, in a world of multibillion-dollar blockbuster drugs³⁵ and costs of hundreds of millions of dollars to bring a new drug to market,³⁶ Congress's \$5.6 billion over ten years seemed paltry. Furthermore, that modest cash pool came fraught with the political risks of dealing with the government,³⁷ and the market risks of the government being the sole or primary purchaser.³⁸ Major pharmaceutical companies bring a depth of experience and resources that small biotech firms cannot match, which was why the government had hoped to attract "Big Pharma" in the first place. Without added incentives, however, these companies made the obvious financial choice to stay on the sidelines.

Professor Michael Greenberger, who directs the Center for Health and Homeland Security at the University of Maryland, contends that "inept implementation of [Bioshield I] . . . led the best brains and the best scientists to give up, to look elsewhere or devote their resources to medical initiatives . . . not focused on biodefense."³⁹ Bioshield I came to appear ill-fated so soon after its passage that legislators introduced Bioshield II the following year to address companies' concerns with legal liability and bureaucratic confusion.⁴⁰

II. BIOSHIELD II: A THICK, STURDY SHIELD

In late 2004, with Bioshield I already showing signs of failure, the FDA found that a British factory's entire production run of flu vaccine had become

33. *See, e.g., id.*

34. Michael S. Rosenwald, *Emergent Tries Add-On for Its Anthrax Vaccine; Firm Seeks to Accommodate Government*, WASH. POST, Mar. 26, 2007, at D1 (stating that the government canceled the VaxGen contract in late 2006, and that the company is now appealing the decision).

35. For example, Lipitor, one of the most successful drugs in the world, racked up \$12.2 billion in sales in 2005. *See Court Invalidates a Patent that Pfizer Holds for Lipitor*, N.Y. TIMES, Aug. 3, 2006, at C9.

36. Agovino, *supra* note 19 (reporting that Pfizer's stock declined steeply after the company discontinued tests of cholesterol drug torcetrapib, having spent \$800 million on research and development).

37. *See, e.g.,* Editorial, *Project Bioshield*, WASH. POST, May 24, 2004, at A22.

38. O'Reilly, *supra* note 10 at 336.

39. Lipton, *supra* note 5.

40. While Bioshield II proposals on both sides of the aisle would have established a new federal agency to streamline biodefense procurement and oversee research and development, the PREP Act did not include the new agency because Republicans and Democrats could not agree over its functions and authority. Republicans had hoped to launch the Biomedical Advanced Research and Development Authority (BARDA), while Democrats sought to establish the National Biodefense Trust ("the Trust"). *See, e.g.,* H.R. 5533, 109th Cong. (2005) (amending Title III of the Public Health Service Act (42 U.S.C. § 241 et seq.) by adding "SEC. 319L. Biomedical Advanced Research and Development Authority"); S. 1880, 109th Cong. § 101(a)(6) (2005) (establishing, if it had been passed, the National Biodefense Trust). *See generally id.* § 101(a).

irretrievably contaminated.⁴¹ The vaccines had been destined for the U.S. market, and their loss halved the number of doses available to Americans for the 2004-2005 flu season.⁴² Widespread shortages ensued, prompting the federal Centers for Disease Control to establish the first-ever permanent panel to set ethical guidelines for distributing vaccines.⁴³ That crisis, amplified by the presidential election that took place in its midst, drew into sharp relief the decline of the U.S. vaccine industry over the past generation. The industry had become so uncompetitive that no vaccine manufacturer could make up for a serious production shortfall at any other.⁴⁴ Citizens and policymakers quickly extrapolated that the United States was unprepared for a major epidemiological event. According to medical experts, “[t]he manufacturing failure that has thrown the nation’s flu vaccination program into chaos this season . . . is a wake-up call for a health system that is dangerously vulnerable to other epidemics, both natural and man-made”⁴⁵ Among other factors, commentators pointed to tort liability as a major cause of the industry’s decline. Congress answered with Bioshield II.

A. Preparing for the Worst: The Structure and Significance of the PREP Act

The PREP Act dramatically expanded the scope of the Smallpox Emergency Personnel Protection Act of 2003 (SEPPA), which had pertained to smallpox alone but now covers any biodefense or pandemic countermeasure.⁴⁶ Its liability protections form the core of Bioshield II’s broader vision.

1. Operative structure: expansive liability protection at the discretion of HHS

The Secretary of Health and Human Services has broad discretion over whether and when to issue a declaration extending Bioshield II’s generous liability protections to specific products or entities;⁴⁷ to the extent that the

41. Gardiner Harris, *Tainted Vaccine is Unsalvageable*, *F.D.A. Says*, N.Y. TIMES, Oct. 16, 2004, at A1.

42. *Id.*

43. Gardiner Harris, *U.S. Creates Ethics Panel on Priority for Flu Shots*, N.Y. TIMES, Oct. 28, 2004, at A18.

44. Matthew B. Stannard, *U.S. Ill-Prepared to Handle Bioterror Attack, Experts Warn; Flu Vaccine Crisis Called Symptom of Far Wider Problem*, S.F. CHRON., Nov. 1, 2004, at A1; see also U.S. GOV’T ACCOUNTABILITY OFFICE, *INFLUENZA VACCINE: SHORTAGES IN 2004-05 SEASON UNDERSCORE NEED FOR BETTER PREPARATION* (2005).

45. Stannard, *supra* note 44, at A1; see also U.S. GOV’T ACCOUNTABILITY OFFICE, *supra* note 44.

46. 42 U.S.C. § 239 (2007).

47. In February 2007, the Bush Administration invoked the PREP Act to shield the development and use of drugs to combat avian flu. See Jane Zhang, *Vaccine Firms Get Immunity from the U.S.*, WALL ST. J., Feb. 2, 2007, at A12.

legislation constrains the Secretary at all, those constraints favor potential tort defendants. The core statutory language is both broad and vague,⁴⁸ and exempts the Secretary's decisions from judicial review.⁴⁹

The liability coverage of a declaration is furthermore thorough and durable. Indeed, the only constraint on the Secretary's power to amend existing declarations is that he or she "shall not retroactively *limit* the applicability" of those declarations.⁵⁰ The declaration completely preempts state and local law, rendering moot any legislation or case law that conflicts with it.⁵¹ If the Secretary issues a declaration to purchase a countermeasure for the Strategic National Stockpile, the declaration is suspended when the medicine is deposited into the stockpile and automatically reenters into effect if and when the government withdraws and distributes the countermeasure.⁵²

Despite conferring the power to grant such potent liability protection, Bioshield II imposes minimal oversight, accountability, and process on the

48. 42 U.S.C. § 247d-6d(b)(1) (2007) (authorizing the Secretary to issue a declaration "if the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, *or* that there is a *credible risk* that the disease, condition, or threat *may in the future* constitute such an emergency" (emphasis added)).

49. *Id.* § 247d-6d(b)(7). The "traditional tools of statutory interpretation," however, such as text, legislative history, and political context, as well as agency technical expertise in the medical field, suggest that courts would tend to defer to agency judgments anyway per *Chevron* and *Skidmore*. See *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984) (requiring courts to use the traditional tools of statutory interpretation to determine whether Congress intended to delegate to the agency the authority to decide the matter at issue); *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944) (establishing that agency decisionmaking would receive deference proportional to the degree of technical expertise needed to understand the issue, the depth of the agency's evidence, and its general power to persuade).

50. *Id.* § 247d-6d(b)(4) (emphasis added). The Secretary, then, may only amend a declaration to extend its scope—for instance, to lengthen the time period that it remains in effect, to incorporate new countermeasures, or to enlarge its geographic or demographic coverage. An earlier Bioshield II proposal, by comparison, limited the validity of declarations to six months, unless amended, and allowed the Secretary to amend a declaration expansively or restrictively. S. 1873, 109th Cong. § 6 (2005) (stating that a declaration "shall be not longer than 6 months" and that the "Secretary may subsequently amend . . . [it] to shorten or extend such effective period").

51. 42 U.S.C. § 247d-6d(b)(8) to (b)(8)(B) (2007) ("During the effective period of a Declaration[,] . . . no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that (A) is different from, or is in conflict with, any requirement applicable under this section; and (B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this Act, or under the Federal Food, Drug, and Cosmetic Act.").

52. *Id.* § 247d-6d(b)(3)(C).

Secretary. For example, Congress requires only that the Secretary provide an explanatory report within thirty days of issuing a declaration.⁵³ There also is no opportunity for notice and comment because the Secretary's declarations and amendments take effect immediately upon publication in the *Federal Register*.⁵⁴ The statute declares that "[n]o court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection."⁵⁵ In short, the executive branch has decisive control of the process, which should produce greater efficiency and direction but also calls for some form of independent oversight.

Furthermore, the Secretary can shroud in secrecy the basis for any declaration, pursuant to a Freedom of Information Act (FOIA) exemption.⁵⁶ When sensitive intelligence is involved, a FOIA exemption is necessary to protect national security, but this exemption has no such stipulation. The Secretary can invoke it for any purpose, which risks hampering informed debate as well as making it close to, if not completely, impossible for would-be tort plaintiffs to obtain information that may be crucial to their cases.

2. Mechanisms for shielding tortfeasors

The PREP Act incorporates SEPPA's airtight exclusivity provision,⁵⁷ which precludes a tort remedy for most plaintiffs.

53. *Id.* § 247d-6d(b)(9).

54. *Id.* § 247d-6d(b)(1) (authorizing "the Secretary [to] make a Declaration[] through publication in the Federal Register," and requiring no notice-and-comment or other pre-declaration process). Even so, the PREP Act scaled back from one of the leading Bioshield II proposals. Senator Orrin Hatch's Bioshield II bill, S. 975, would have allowed "[a]ny person [to] recommend to the Secretary at any time" that a declaration be promulgated, "and [to] provide data and information to support such recommendation," effectively granting an opportunity to be heard to any party proposing a declaration even as it withheld that privilege from any party opposing one. S. 975, 109th Cong. § 341(a)(4)(E) (2005). Congress ultimately settled on simply giving no one a formal opportunity to be heard. While this decision removes a check that would have created a more deliberative process, extensive notice-and-comment procedures would have generated self-defeating inefficiencies.

55. 42 U.S.C. § 247d-6d(b)(7) (2007).

56. *Id.* § 247d-6d(b)(5) ("In publishing a Declaration . . . in the Federal Register, the Secretary is not required to disclose any matter described in [FOIA].").

57. *Id.* § 233(a) ("The remedy against the United States provided by sections 1346(b) and 2672 of Title 28, or by alternative benefits provided by the United States where the availability of such benefits precludes a remedy under section 1346(b) of Title 28, for damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions, including the conduct of clinical studies or investigation, by any commissioned officer or employee of the Public Health Service while acting within the scope of his office or employment, shall be exclusive of any other civil action or proceeding by reason of the same subject-matter against the officer or employee (or his estate) whose act or omission gave rise to the claim.").

The first striking aspect of Bioshield II's liability coverage is the breadth of the statutory language itself. The Secretary can designate a "covered countermeasure" for biodefense or a pandemic, and can cover a drug, device, or almost any other product "manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or to limit the harm such pandemic or epidemic might otherwise cause"⁵⁸ The language "modified, licensed, or procured," in particular, empowers the Secretary to confer immunity on products not originally developed for biodefense or pandemic protection, such as painkillers and antidepressants. Because they already exist, however, such medicines are obviously profitable enough not to need this extraordinary immunity. While the Secretary might choose not to cover such products, the slope is slippery.

The definition of a "covered person" is no less broad than the definition of a covered countermeasure. Covered persons include the federal government, manufacturers, distributors, program planners, entities such as hospitals, and people such as doctors qualified to administer the countermeasure.⁵⁹ The terms "distributor," "manufacturer," "person," and "program planner" are also broadly defined so as to include anyone remotely involved in the process, such as warehouses that stored the countermeasure and private scientists who gave technical advice to the government relating to use of the countermeasure.⁶⁰ Extending the liability shield to these secondary and tertiary defendants should prevent the type of endless and costly collateral lawsuits that arose in asbestos litigation after the primary tortfeasors went bankrupt.⁶¹

Once an entity receives protection from a PREP Act declaration, it has virtually no civil liability.⁶² Furthermore, the definition of covered losses is all-encompassing—death,⁶³ physical injury,⁶⁴ emotional distress,⁶⁵ fear of

58. *Id.* § 247d-6d(i)(7)(A)(i).

59. *Id.* § 247d-6d(i)(7)-(7)(A)(ii).

60. *See id.* § 247d-6d(i)(3)-(i)(6).

61. In case a judge has any doubt regarding the statute's scope, the Act further declares that its "immunity . . . applies to any claim for loss that has a causal relationship with . . . a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure." *Id.* § 247d-6d(a)(2)(B). Providing liability protection to these secondary entities is arguably necessary to maximize private sector participation in biodefense programs. For instance, a trucking company might well be unwilling to transport biodefense drugs from the factory to a warehouse or from the warehouse to hospitals if there were any risk of bankrupting lawsuits.

62. *Id.* § 247d-6d(a)(1) ("[The] covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure").

63. *Id.* § 247d-6d(a)(2)(A)(i).

64. *Id.* § 247d-6d(a)(2)(A)(ii).

65. *Id.*

physical injury or emotional distress “including any need for medical monitoring,”⁶⁶ and property damage or business interruption.⁶⁷ In short, the PREP Act blocks every doctrinal avenue for recovery in tort.

3. *Virtually no recourse to tort*

To reach a courtroom, a plaintiff would have to show either (1) that a defendant disobeyed the declaration, or (2) that a defendant engaged in willful misconduct. A defendant disobeys a declaration only when straying beyond its parameters. For example, if a doctor administers the covered countermeasure to someone outside the geographic, demographic, or other descriptive limits of the declaration—say, to someone in Albany when the declaration only covers New York City—then the doctor “loses” immunity.⁶⁸ If a defendant did not follow the declaration’s parameters, however, then it never had immunity to begin with, so this provision concedes little ground to plaintiffs.

Of course, defendants retain immunity for sheer incompetence—for example, if they inject a countermeasure into the wrong muscle and accidentally cause paralysis. The immunity is also severable, so that one defendant’s misconduct does not infect other potential defendants. If a Minnesota hospital administers a countermeasure authorized for use only in Florida, the manufacturers and distributors of that countermeasure would remain immune from suit.⁶⁹

Defendants further benefit from two powerful obstacles that plaintiffs would have to overcome to prove breach of a declaration. First, there is a rebuttable presumption that “any administration or use [of a covered countermeasure] during the effective period of the emergency declaration . . . shall have been” proper.⁷⁰ Second, defendants can invoke a “reasonable belief” defense, absolving them of liability if they “reasonably could have believed” that they were complying with the declaration.⁷¹ This defense powerfully augments the rebuttable presumption requirement.

If a defendant stays within the parameters of the declaration (or is “reasonably” close), then “the sole exception to the[ir] immunity from suit and liability . . . shall be for an exclusive Federal cause of action . . . for death or serious physical injury proximately caused by *willful misconduct*.”⁷²

66. *Id.* § 247d-6d(a)(2)(A)(iii).

67. *Id.* § 247d-6d(a)(2)(A)(iv).

68. *See id.* § 247d-6d(a)(3).

69. *Id.* § 247d-6d(a)(4)(A) (“In the case of a covered person who is a manufacturer or distributor of the covered countermeasure involved, the immunity applies without regard to whether such countermeasure was administered to or used by an individual in accordance with the conditions [of the Declaration].”).

70. *Id.* § 247d-6d(a)(6) (emphasis added).

71. *Id.* § 247d-6d(a)(4)(B).

72. *Id.* § 247d-6d(d)(1) (emphasis added).

The legislation makes the already formidable willful misconduct standard even tougher to meet in five respects:

First, “the term ‘willful misconduct’ shall . . . denote an act or omission that is taken (i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.”⁷³ It is unlikely that any defendant would meet these exacting culpability requirements, which set a much higher bar than negligence or recklessness would have.⁷⁴

Second, the plaintiff would have to prove by “clear and convincing” evidence, a considerably higher threshold than the “preponderance of the evidence” standard that typically governs civil proceedings.⁷⁵ Furthermore, as the immunity is severable, proving willful misconduct by one defendant would not strip other defendants of their liability protection. Finally, even a plaintiff who could prove willful misconduct would only recover for physical injury,⁷⁶ and not for noneconomic harm.

Third, the PREP Act leaps beyond the learned intermediary doctrine to completely remove any meaningful cause of action for inadequate warning. It is a sufficient defense against failure-to-warn variations of willful misconduct claims for a defendant simply to have notified “the Secretary, or a State or local health authority” of any “serious physical injury or death from the administration or use of a covered countermeasure that is material to the plaintiff’s alleged loss within 7 days of the actual discovery of such information”⁷⁷ Some version of this provision is necessary because these drugs cannot be fully tested for safety and efficacy in humans and will therefore have unpredictable and potentially disastrous side effects. Furthermore, in an epidemiological emergency, informed consent could well be an unaffordable luxury.⁷⁸ The question is whether informing the government should be necessary or sufficient. In the chaos of a bioterror attack or pandemic, perhaps notifying health authorities is the most effective way to warn the public, though the seven-day window seems excessively lax. The statute should instead require that the company report this information as soon as practicable, with seven days as the outermost limit.

73. *Id.* § 247d-6d(c)(1)(A)-(A)(iii).

74. *See id.* § 247d-6d(c)(1)(B) (“[K]nowingly . . . shall be construed as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness.”).

75. *Id.* § 247d-6d(c)(3) (“[T]he plaintiff shall have the burden of proving by clear and convincing evidence willful misconduct by each covered person sued and that such willful misconduct caused death or serious *physical* injury.” (emphasis added)).

76. *Id.*

77. *Id.* § 247d-6d(c)(4).

78. For the counterargument that informed consent should not be discarded, see Wendy E. Parmet, *Informed Consent and Public Health: Are They Compatible when It Comes to Vaccines?*, 8 J. HEALTH L. & POL’Y 71, 89-92 (2005).

Fourth, there is an implicit and robust regulatory compliance defense. If the action that the plaintiff alleges as willful misconduct is regulated by the Public Health Service Act⁷⁹ (of which the PREP Act is a part) or by the federal Food, Drug, and Cosmetic Act,⁸⁰ then the plaintiff cannot state a claim for willful misconduct unless the Secretary of HHS or the U.S. Attorney General has initiated an “enforcement action”⁸¹ over the alleged misconduct. The enforcement action must further be ongoing or have concluded by sanctioning the defendant with a severe “covered remedy.”⁸²

Finally, the Secretary can—and probably *must*—make it even harder for plaintiffs to file suit by narrowing the definition of acts that would constitute willful misconduct. After consulting with the Attorney General, the Secretary “*shall* promulgate regulations . . . that further restrict the scope of actions or omissions by a covered person that may qualify as ‘willful misconduct.’”⁸³ It seems odd to *require* the Secretary to issue regulations raising the bar for tort any higher, but the drafters used “shall” instead of “may,” mandating new restrictive regulations if a chink should appear in the statutory armor.

4. *Plaintiffs who reach the tort system face additional hurdles and sharply limited recovery*

Plaintiffs who reach the tort system would face a heightened pleading standard⁸⁴ and rigorous requirements for submitting proof of injury with the pleading,⁸⁵ and would be unable to conduct discovery until after the court rules on a defendant’s motion to dismiss (and, if the defendant so moves, until after an interlocutory appeal to the D.C. Circuit).⁸⁶ These cases, then, would be risky

79. 42 U.S.C. § 201 (2007).

80. 21 U.S.C. §§ 301-399 (2007).

81. The definition of an “enforcement action” is found at 42 U.S.C. § 247d-6d(c)(5)(B)(i) (2007) and includes, for example, criminal prosecution, a government request for an injunction against the defendant, a seizure action, a debarment proceeding, and a variety of other actions if grounded in willful misconduct.

82. This general provision of the PREP Act is found at 42 U.S.C. § 247d-6d(c)(5)(A)-(A)(ii) (2007). The specific definition of “covered remedy” is found at section 247d-6d(c)(5)(B)(ii), and includes, among other sanctions, a criminal conviction, a debarment, an injunction, a civil monetary payment, or a product recall. Note that, based on the language in section 247d-6d(c)(5)(B)(i), “product recall” probably means that the defendant refused a government request to recall the product voluntarily and was subsequently forced to recall it *by the Secretary of HHS* (per section 247d-6d(c)(5)(C)(ii)) as opposed to the FDA—a scenario that is unlikely to occur given that the Secretary issued the declaration in the first place and any government decision to withdraw the product would almost certainly meet with voluntary compliance from the drug company. While it is possible that a defendant could be hit with such an action, it is, again, a high threshold to make plaintiffs cross.

83. *Id.* § 247d-6d(c)(2)(A) (emphasis added).

84. *Id.* § 247d-6d(e)(3)-(3)(C).

85. *Id.* § 247d-6d(e)(4)-(4)(C)(ii).

86. *Id.* § 247d-6d(e)(6).

for an attorney using the contingency-fee financing model. Given the expense of a trial that may require extensive expert testimony, and the PREP Act's mandatory and rigorous enforcement of Rule 11 sanctions,⁸⁷ many plaintiffs would experience difficulty obtaining counsel. Indeed, Senator Orrin Hatch's original Bioshield II proposal sought to address this concern, encouraging attorney involvement by providing for awards of attorney fees "calculated on a reasonable amount of work performed on behalf of the plaintiff," and allowing attorneys to recover fees even when their clients lose.⁸⁸ The enacted legislation, however, defaulted to SEPPA's denial of attorney fees and costs.⁸⁹

If a plaintiff obtains counsel, makes it past the procedural barriers, and wins on the merits, the PREP Act would limit her recovery in two ways. First, the collateral source rule would not apply. A "collateral source benefit," further, is broadly defined as any public or private benefit provided "as a result of the injury or wrongful death."⁹⁰ As with the September 11 Victim Compensation Fund (9/11 Fund), the plaintiff would face offsets for such commonplace investments as life insurance and health insurance, dramatically diminishing the attraction of tort for plaintiffs even in the rare case when it is an option. Second, while the Act allows noneconomic damages in tort, any recovery must be "directly proportional to the percentage of responsibility of a defendant for the harm to the plaintiff."⁹¹ For example, if the manufacturer of a covered countermeasure engaged in willful misconduct but a jury attributed ninety percent of the plaintiff's injury to an incompetent doctor, the plaintiff would recover only the ten percent of his noneconomic damages attributable to the drug company (the doctor being immune from suit). This provision is intuitively equitable but further limits the scheme's deterrence and compensatory functions.

5. *Victim compensation scheme*

The PREP Act established the Covered Countermeasure Process Fund ("the Fund"), which also tracks SEPPA,⁹² to compensate victims for the restrained tort option.

87. *Id.* § 247d-6d(e)(9) (commanding that for any violation of Rule 11, "the court *shall* impose upon the attorney, law firm, or parties . . . an appropriate sanction . . . sufficient to deter repetition of such conduct or comparable conduct by others similarly situated, and to compensate the party or parties injured by such conduct" (emphasis added)). In contrast, the current version of Rule 11 states that courts "may" impose sanctions. FED. R. CIV. P. 11(c).

88. S. 975, 109th Cong. § 319F-10(b)(5) (2005).

89. *See* Castillo v. United States, 707 F.2d 422, 424 (9th Cir. 1983) ("42 U.S.C. §§ 233 and 2458a serve to preclude reimbursement for attorney fees and costs . . .").

90. 42 U.S.C. § 247d-6d(e)(7)(A) (2007) ("[A]n award of damages that would otherwise be made to a plaintiff shall be reduced by the amount of collateral source benefits to such plaintiff").

91. *Id.* § 247d-6d(e)(8).

92. *Id.* § 247d-6e(b)(4).

The scheme pays, first, for all “reasonable” and “necessary” medical expenses.⁹³ There is a de facto offset provision, however, for any collateral medical benefits, including first-party health insurance.⁹⁴ The implicit message is that in a massive public health emergency, the government will face heavy burdens and will not be able to allocate scarce resources to people who already have the means to pay for their own care. This provision, like most of the Act, seems to reflect a need-based philosophy that views recovery by victims who have insurance as something of an undeserved windfall.

Second, the scheme covers loss of income, generally based on the victim’s earnings at the time of injury. This provision discounts future earning potential, thereby diminishing recovery for most children and some elderly. While the Secretary of HHS has discretion to account for “wage-earning capacity”⁹⁵—theoretically creating a safety valve for cases in which the gap between present and future earnings appears unjustly large—the default position of devaluing harm to people in these groups is dubious and warrants closer scrutiny.

Like workers compensation, the Fund would replace up to two-thirds of the victim’s income, or three-quarters if the claimant has any dependents.⁹⁶ A broad offset applies, however, making such payments secondary to any other benefits for lost income,⁹⁷ which include sources such as private insurance, state unemployment insurance, and federal Social Security payments. The Secretary, though, may adjust lost income benefits when “reasonable and necessary” to account for overtime pay⁹⁸ and cost of living.⁹⁹ Also, in the case of minors, the scheme prospectively estimates loss of income caused by disabling injuries (as opposed to death).¹⁰⁰

SEPPA and Bioshield II, however, contain low compensation ceilings, consistent with a need-based philosophy. The scheme limits lost income benefits to \$50,000 per year¹⁰¹ and caps total lifetime benefits at the amount

93. *Id.* § 239c(a) (“[T]he Secretary shall make payment or reimbursement for medical items and services as reasonable and necessary to treat a covered injury of an eligible individual . . .”).

94. *Id.* § 239c(b) (“Payment or reimbursement for services or benefits under subsection (a) of this section shall be secondary to any obligation of the United States or any third party (including any State or local governmental entity, private insurance carrier, or employer) under any other provision of law or contractual agreement, to pay for or provide such services or benefits.”).

95. *Id.* § 239d(b)(3)(A) (incorporating 5 U.S.C. § 8115 (1966)).

96. *Id.* § 239d(b).

97. *Id.* § 239d(c)(1)(A) (“Any compensation under . . . this section shall be secondary to the obligation of the United States or any third party (including any State or local governmental entity, private insurance carrier, or employer), under any other law or contractual agreement, to pay compensation for loss of employment income or to provide disability or retirement benefits.”).

98. *Id.* § 239d(b)(3)(A) (incorporating 5 U.S.C. § 8114 (1966)).

99. *Id.* (incorporating 5 U.S.C. § 8146a (1980)).

100. *Id.* § 239d(b)(3)(B) (incorporating 5 U.S.C. § 8113 (1974)).

101. *Id.* § 239d(c)(3)(A)(i).

that would have been payable in case of death,¹⁰² which is only \$250,000 in 2001 dollars adjusted for inflation.¹⁰³ If those caps do not kick in first, then income replacement terminates when the victim reaches the age of sixty-five.¹⁰⁴ The lifetime cap does not apply, however, to individuals who suffer “permanent and total disability,”¹⁰⁵ allowing them to collect up to \$50,000 per year in perpetuity.

The death benefit is calculated according to the Public Safety Officers’ Benefits Program (PSOB), as if the victim were a police officer or firefighter killed in the line of duty.¹⁰⁶ The only difference is that PSOB offsets any death benefit by the payments for lost income that the victim received prior to dying,¹⁰⁷ whereas Bioshield II would still pay the full death benefit.¹⁰⁸ Presumably, Bioshield II’s framers did not feel comfortable imposing financial penalties on the next of kin when the victim did not die instantaneously.

Bioshield II is also more generous than SEPPA to victims with young children. The parent or guardian of a victim’s dependent minor can elect to receive lost income benefits in lieu of the death benefit, with the limitation that such benefits terminate when the youngest dependent reaches eighteen years of age.¹⁰⁹

Fund claimants, however, must forfeit their right to sue in tort for willful misconduct.¹¹⁰ The United States also would assert a right of subrogation against an injury victim who wins a medical malpractice suit.¹¹¹ Finally, while benefits are modest, they might further decline if Congress decides not to adequately endow the Fund.

102. *Id.* § 239d(c)(3)(A)(ii).

103. *Id.* § 3796(a). Note that Congress amended the amount in 2001, from \$100,000 to \$250,000, to be automatically adjusted for inflation in subsequent years, per USA PATRIOT Act of 2001, Pub. L. No. 107-56, § 613(a), 115 Stat. 272.

104. 42 U.S.C. § 239d(c)(5) (2007).

105. *Id.* § 239d(c)(3)(B) (tracking the definition of permanent and total disability under § 416(i)).

106. *Id.* § 239e(a)(1) (“The Secretary shall pay . . . an eligible individual . . . a death benefit in the amount determined . . . in the same manner as death benefits are paid pursuant to the Public Safety Officers’ Benefits Program”); *id.* § 239e(a)(2)(A) (“The amount of the death benefit . . . shall equal the amount of the comparable benefit calculated under the Public Safety Officers’ Benefits Program”). The PSOB legislation is located at section 3796.

107. *Id.* § 239e(a)(2)(B).

108. *Id.* § 247d-6e(b)(2) to (b)(3) (“Neither reasonable and necessary medical benefits nor lifetime total benefits for lost employment income due to permanent and total disability shall be limited by [the death benefit provisions of SEPPA, § 239e].”).

109. *Id.* § 239e(b)(3)(A). As with other payments under the scheme, though, these benefits are secondary to all other forms of compensation for the victim’s death, including life insurance payments and retirement benefits. *Id.* § 239e(b)(3)(B)(i). The scheme would meaningfully help families of low-income victims, but probably not anyone else.

110. *Id.* § 247d-6e(d)(4).

111. *Id.* § 233(g)(2).

6. Eligibility for the fund

The Secretary of HHS has wide discretion to determine eligibility criteria.¹¹² He would first establish a table of injuries with all adverse effects that the vaccine is known to cause. The Secretary must design the injury table based on “compelling, reliable, valid, medical and scientific evidence,”¹¹³ though the design is not subject to judicial review.¹¹⁴ Any person who suffers an injury conforming to the table would have a rebuttable presumption of PREP Act coverage.¹¹⁵ Alternatively, a public or private entity carrying out a declaration and administering covered countermeasures can certify that an individual qualifies for the Fund.¹¹⁶ Finally, if a claimant files on her own and the government disputes her eligibility, the Secretary would determine whether to cover the injury based on “a preponderance of the evidence standard and take into consideration all relevant medical and scientific evidence.”¹¹⁷

While there is no independent tribunal, the claimant at least benefits from the less demanding standard of preponderance of the evidence, and from the possibility of calling expert witnesses to establish the cause of her injuries.¹¹⁸ On the other hand, plaintiffs’ attorneys might be unwilling to shoulder the cost of expert witnesses given the modest sums that most Bioshield II cases would involve. HHS, with the legal and financial resources of the federal government, is therefore better able than claimants to call expert witnesses. Consequently, the process for determining eligibility may follow more of an inquisitorial than adversarial model.

III. THE RISKS OF BIOSHIELD II

Bioshield II provides needed liability protections for biodefense but generates concomitant risks:

112. *Id.* § 239a(a).

113. *Id.* § 247d-6e(b)(5)(A).

114. *Id.* § 247d-6e(b)(5)(C).

115. *Id.* § 239a(c)(1).

116. *Id.* § 239a(b).

117. *Id.* § 239a(c)(2). The Secretary further may “obtain and consider the views of qualified medical experts.” *Id.* This provision ensures that victims whose injuries fall beyond the scope of the table could still benefit from expert testimony, though the statutory language suggests that only the Secretary can call for experts. Causation would be an especially complex issue—in the event of a major attack or pandemic, during which large numbers of people contract the disease, it would be difficult to determine who became infected from a covered countermeasure and who did not.

118. The PREP Act does not specifically authorize plaintiffs to call experts, nor does it expressly so forbid.

A. *The Risk of Inadequate Victim Compensation*

The legislation is not generous to victims because its proponents primarily aimed to create a liability shield. However, as Professor Robert L. Rabin writes, “[I]t is critical to recognize that responses to dissatisfaction with tort . . . can take the form of immunities that do not ignore the injury compensation goal.”¹¹⁹

Looking to the legislation’s general structure, Professor George W. Conk raises two troubling aspects of SEPPA—and, by extension, Bioshield II:

First, the absence of judicial review leaves claimants with few process protections. While this provision increases the system’s efficiency, it also removes an important self-correcting mechanism from the system.

Second, the compensation scheme has an inflexible statute of limitations that bars claims filed later than one year after receiving the covered vaccine.¹²⁰ On the one hand, such a provision mitigates causation difficulties that become increasingly nettlesome the further one gets from the date of exposure. On the other hand, long latency is a typical problem with toxic torts. A one-year limitation, therefore, seems to strike the wrong balance between overinclusiveness and underinclusiveness. Furthermore, because Bioshield II gives claimants virtually no access to the tort system, the scheme should err toward overinclusiveness.¹²¹ Finally, Professor Rabin raises three concerns endemic to all such programs: that compensation levels will be allowed to lapse due to the availability of private insurance, that the scheme’s administrators might become miserly if confronted with “a staggering volume of claims for catastrophic loss,” and that recovery caps make the scheme “least generous to the most devastatingly disabled (counting pain and suffering as a real, albeit unrecoverable, element of loss).”¹²²

Legislators should not disregard victim compensation because providing adequate recovery is rational public policy in three respects: preparing emergency services and health personnel for a biological incident, promoting effective postmarket safety monitoring of biodefense drugs, and achieving the most favorable cost-benefit ratio for taxpayers.

119. See generally Robert L. Rabin, *Some Thoughts on the Efficacy of a Mass Toxics Administrative Compensation Scheme*, 52 MD. L. REV. 951 (1993).

120. George W. Conk, *Reactions and Overreactions: Smallpox Vaccination, Complications, and Compensation*, 14 FORDHAM ENVTL. L.J. 439, 497 (2003) (criticizing as one of the “most troubling aspects” of SEPPA that it contains “a statute of limitation incapable of relaxation even where vaccine related problems do not manifest themselves in vaccinees until more than one year after administration”).

121. Rabin, *supra* note 119, at 974 (“[A]ny wage-loss ceilings adopted under a compensation scheme might be set at more modest levels in recognition of the continuing prospect of residual tort liability.”). The corollary to Professor Rabin’s argument, that no-fault schemes which offer claimants a choice to opt for tort can afford to be less generous, is that schemes that deny claimants the tort option should have higher compensation levels.

122. *Id.* at 975-76.

First, inadequate compensation for people injured by covered countermeasures will seriously impede preventive vaccination programs. While few people would refuse a vaccine or treatment *after* an outbreak occurs, the same is not true *prior* to an outbreak. Most people reasonably would estimate the chance of an attack as being very low (since no major biological attack has yet occurred), and accordingly would demand a promise of generous compensation in case of death or serious injury from preventive treatment.

The problem became clear when Washington launched a campaign in January 2003 to inoculate 500,000 civilian first responders—the frontline troops in any epidemiological incident—against smallpox. The federal government asked states how many inoculated first responders they anticipated needing in case of a smallpox attack, then aggregated the states' responses to reach a figure of 500,000.¹²³ Congress next made the smallpox vaccine available to those health workers, along with the miserly SEPPA no-fault scheme for anyone who suffered an adverse reaction.

The events of September 11, 2001, and the subsequent anthrax attacks, were still fresh in people's minds, and fears of a bioterrorist attack remained high; nevertheless, by 2005, fewer than 40,000 personnel—less than ten percent of the *original* target pool—had taken the vaccine.¹²⁴ The federal government had realized early on that the response rate would be dismal and hastily revised the target down from 500,000 to 50,000, ignoring that with so few inoculated workers, their haphazard geographic distribution could leave many states completely unprepared.¹²⁵ Professor Greenberger identified several obstacles to the success of the program, known as “Phase I,” but singled out the greatest of these as “the federal government's inability to provide *both* sufficient liability protection for vaccine administrators *and also* adequate compensation to those injured by the vaccine.”¹²⁶

A promise of adequate victim compensation was absent but essential because these first responders realized that the risk of a serious adverse reaction was small but not negligible, the consequences of such a reaction could be grave, and SEPPA compensation might not provide much to their families if they died or became permanently disabled. Hence, as Professor Greenberger concluded, “A pre-event program that does not include *both* [adequate liability protection and victim compensation] . . . is destined to fail.”¹²⁷ The failure of

123. SUSAN THAUL, SMALLPOX VACCINE INJURY COMPENSATION 13 (2003), available at www.thememoryhole.org/crs/more-reports/RL31960.pdf.

124. *Id.*

125. *Id.* at 13-14.

126. Greenberger, *supra* note 9, at 8.

127. *Id.* at 9-10; see also THAUL, *supra* note 123, at 15-16 (“As health care workers face (or are asked to face) each new product—whether vaccine or antitoxin . . . they will ask about compensation for potential injuries.”); Parmet, *supra* note 78, at 89-92 (arguing that victims of injuries from voluntary vaccination programs should receive adequate compensation).

the Phase I smallpox inoculation program provides powerful evidence for that proposition.

Second, as with medical care in general, prevention is not only safer but also an order of magnitude cheaper than treatment. A more openhanded prevent compensation scheme, which gives civilian first responders enough incentive to inoculate themselves against likely biowarfare agents, would lead to a small number of serious adverse reactions. The public can afford to generously compensate these victims who assumed a material risk for the public's benefit. Following an attack, the advantages of having an inoculated civilian health force would be astronomical in terms of saving both lives and money. As Dr. Martin Blaser, president of the Infectious Diseases Society of America (IDSA) and Chair of the Department of Medicine at New York University, stated in a letter to Senator Ted Kennedy, the cost of a munificent no-fault scheme is "a bargain when measured against the toll of life-threatening pathogens and antimicrobial resistance: the loss of thousands of lives and the avoidable costs of billions of health-care dollars."¹²⁸

Third, because biodefense is a component of national defense, which is a common good, the government is the party best suited to internalize the risks and benefits of biodefense products. Washington might not be able to predict when or where the next terrorist attack or deadly flu virus will strike, but the government does control whether and when it issues a declaration absolving drug manufacturers, hospitals, and other entities of legal liability for their actions. If the government has committed itself to a generous compensation scheme in advance, it is likely to monitor the safety and efficacy of countermeasures more closely, and make more careful decisions about who should use them, when, and where. Ironically, then, in seeking to minimize public financial risks, Congress might inadvertently increase public health risks, which in turn jeopardize the health of the nation's economy.¹²⁹

128. Wysocki, *supra* note 18.

129. This idea was inspired by Rochelle Chodock et al., "Insuring" the Continued Solvency of Pharmaceutical Companies in the Face of Product Liability Class Actions, 40 TORT & INS. L.J. 997, 1015 (2005). The authors argue that having the federal government underwrite liability for pharmaceutical companies would improve "post-market surveillance to ensure that class actions not exceed the caps that it has set for . . . liability, lest the public be responsible for underwriting the catastrophic financial loss." *Id.*

Although Bioshield II garnered some support from moderate Democrats, the proposals generally reflected a conservative approach; liberals, however, offered an alternative vision of SEPPA, Bioshield II's underlying framework, back in 2003. Senator Ted Kennedy, for example, would have covered rehabilitative therapy and special equipment, allowed Medicare recipients to qualify for SEPPA medical benefits, and calculated lost income using projected future earnings, which are usually more generous than actual earnings and are especially so for children. THAUL, *supra* note 123, at 9. Finally, he would have increased the death benefit to \$75,000 per year and allowed it to continue for the life of the spouse or until the youngest dependent minor reached age twenty-two. *Id.* (The report states that the proposed raise from \$50,000 to \$75,000 was an increase in "the lifetime cap," but this must

The compensation provisions of the PREP Act suggest that the framers of Bioshield II believed in minimizing payments to protect both the drug industry and the taxpayer. Someone, however, must bear the losses that would arise from a major bioterror attack. The PREP Act implies that losses should (mostly) lie where they fall, and this inclination from fiscally responsible politicians is understandable given the potentially catastrophic economic repercussions from a mass-casualty biomedical event.

In the context of national defense, however, the federal government is as well positioned to spread the losses after an attack as it is to spread the costs of preparing for one. Widespread approval of congressional generosity to 9/11 victims did not simply reflect that 9/11 was an extraordinary event. It also reflected public support for approaching such events as one nation, treating an attack on any part of America as an attack on all Americans, and sharing the economic losses accordingly even (or perhaps especially) when the loss of life is geographically concentrated.¹³⁰

be an error. The amounts must refer to the *annual* cap because \$50,000 was the successfully proposed annual cap, and no lifetime cap of \$50,000 was ever suggested.)

Congressman Henry Waxman led House Democrats in offering an alternative, H.R. 865, which tracked the National Childhood Vaccine Injury Act's (NCVIA) compensation model. Even more generous than the Kennedy proposal, the Waxman version would have paid 100 percent of actual lost wages with no cap, mimicked the \$250,000 noneconomic damages payment of the 9/11 Fund, included more generous compensation for permanent disability, and upped the death benefit to \$850,000 from \$262,100 (both figures use 2003 dollars unadjusted for inflation). *Id.* at 10.

Senate Democrats additionally offered a competing version of Bioshield II in 2005, which also would have tracked the NCVIA model. S. 1880, 109th Cong. § 701(a)(q)(3) (2005) ("The Secretary shall by regulation establish procedures and standards for the Compensation Program that follow the procedures and standards applicable under the National Vaccine Injury Compensation Program."). The bill set scheduled damages according to an injury table designed by "experts," and would have placed greater emphasis on ensuring that victims receive "adequate and just compensation" *Id.* § 701(a)(q)(4)(B)(iii); *see also id.* § 701(a)(q)(4)(B)(i)-(ii) (providing for an expert-designed injury table).

The compensation provisions of S. 1880 differ most materially from Republican versions in their harsher treatment of tortfeasors, rather than in more lenient treatment of claimants. For example, the Democrats retain the exclusivity and offset provisions of the Republican bill, *id.* § 801(4), but direct the United States to recover money it pays out to claimants from any tortfeasor that failed to perform its contractual obligations or committed "grossly negligent, reckless, . . . or illegal conduct or willful misconduct" 42 U.S.C. § 233(p)(6)(A) (2007).

130. The same rationale does not apply to losses arising from a naturally occurring pandemic. The existence, however, of institutions such as the Federal Emergency Management Agency (FEMA) reflects Americans' support for spreading the economic losses from natural disasters. A pandemic, furthermore, does not carry the same moral hazard and cross-subsidization problems as do programs such as national flood insurance. Flood insurance often reduces the price of living in a particularly flood-prone area to an amount that is less than socially optimal. A pandemic flu, in contrast, would threaten the population and economy of the country as a whole.

B. *The Risk of Inadequate Tortfeasor Deterrence and Monitoring*

Compensation and deterrence are inextricably linked in traditional tort but are decoupled in a no-fault scheme in which the government pays all claims. Such schemes thus call for extra attention to deterrence mechanisms. Bioshield II is particularly at risk because the scheme so thoroughly insulates tortfeasors from civil liability. The government must make up the consequent loss of deterrent effect with increased monitoring of product safety. A sufficiently generous no-fault scheme will encourage the government to monitor experimental, liability-shielded drugs more carefully than what it has thus far committed to do. The FOIA exemptions for the Secretary's deliberations and (if one is created) for any biodefense agency dissipate political accountability while preventing plaintiffs from accessing crucial information, thereby removing an important incentive to safety for potential defendants. A good first step would be to restrict these exemptions to situations where national security certifiably calls for them.

While the risks of inadequate deterrence are explored throughout this Note, one point that merits special consideration is whether caregivers—the doctors, hospitals, and other entities that would administer any countermeasures—should be covered by Bioshield II at all. Drug companies, of course, can choose to allocate their resources to areas other than biodefense depending on the incentive structure, but hospitals and doctors exist to treat sick people and vaccinate healthy people—a fact that does not change with biodefense pathogens versus comparably serious natural ailments. Indeed, one commentator on vaccine injury compensation, Professor Arnold Reitze, Jr., contends that “[t]here seems to be no reason to shelter health care providers from malpractice claims in the vaccine area. One cannot read the case law concerning vaccination injuries without being aware of the number of cases of obvious failure to provide acceptable medical care.”¹³¹ He further argues that “vaccine-related injuries are an insignificant part” of medical malpractice insurance costs.¹³² Tort liability for vaccines always fell more heavily on manufacturers than on health care providers, hence the structure of the National Childhood Vaccine Injury Act of 1986.

Bioshield II, however, appropriately covers caregivers for three reasons: First, if doctors and hospitals would see their insurance premiums rise dramatically without this protection, then shielding them is part of ensuring that these caregivers do not disproportionately bear the costs of biodefense. Second, insurance premiums might currently take little account of the risks from bioterror- and pandemic-related lawsuits, much as the insurance industry heavily discounted the economic threat from terrorism prior to 9/11. After a

131. Arnold W. Reitze, Jr., *Federal Compensation for Vaccination Induced Injuries*, 13 B.C. ENVTL. AFF. L. REV. 169, 206 n.226 (1985).

132. *Id.*

mass-casualty attack or pandemic, however, caregivers could well face prohibitively expensive insurance if insurers offered any at all. The government would then probably intervene (as it did after 9/11), so covering caregivers in advance avoids massive disruptions while reaching the same result. Third, caregivers are as much a part of biodefense as drug manufacturers and entities at other points in the supply chain, so any program addressing national readiness as a whole should not signal that caregivers are less important or merit any less protection.

Opposition to the breadth of Bioshield II primarily stems from the program's draconian compensation provisions, but, instead of trying to narrow the legislation's scope, opponents should aim to create a more munificent administrative scheme.

C. The Risk of a Slippery Slope

The principal rationale behind Bioshield II—protecting drug manufacturers from tort liability in order to stimulate production of new medicines—applies well beyond the counterterrorism context. Indeed, the war on terror is, definitionally, not a unique limiting factor because Bioshield II includes natural pandemics. Some commentators advocate extending this model still further, such as to facilitate general vaccine production¹³³ or the development of new antibiotics.¹³⁴ An analogous no-fault scheme could even transform the medical malpractice arena, and might find particular traction in parts of the country experiencing an “emergency” shortage of doctors. It is unsurprising that many proponents of Bioshield II, such as the Pharmaceutical Research and Manufacturers of America (PhRMA), also support tort reform more generally. Those who favor general tort reform will see Bioshield II as a starting point rather than a stopping point.

Indeed, advocates of many stripes, including the bill's sponsors, hope to expand Bioshield II (or adopt a similar measure) to stimulate research on a range of medical problems. Senator Hatch, unveiling the Project Bioshield II Act of 2005, declared that while Bioshield II was an important beginning that demonstrated America's commitment to biodefense, “[w]e [also] need to do more to combat natural threats such as AIDS, SARS, Avian Flu, malaria, antibiotic resistant organisms, and other agents, including genetically

133. Kapil Kumar Bhanot, *What Defines a Public Health Emergency? An Analysis of the Strategic National Stockpile and the National Childhood Vaccine Injury Act: The Need for Prevention of Nonterror National Medical Emergencies*, 21 J. CONTEMP. HEALTH L. & POL'Y 137, 138-39 (2004).

134. *Concerning Project Bioshield Reauthorization Issues: Hearing Before the Subcomm. on Health of the H. Energy and Commerce Comm.*, 109th Cong. 4 (2006) [hereinafter IDSA Congressional Testimony] (statement of the Infectious Diseases Society of America (IDSA), presented by Dr. Martin J. Blaser, President of IDSA), available at <http://www.idsociety.org/Template.cfm?Section=Home&CONTENTID=15861&TEMPLATE=/ContentManagement/ContentDisplay.cfm>.

manipulated materials Comprehensive legislation is needed today to thwart tomorrow's biological threats"¹³⁵ Doctor Blaser offers one illustrative example in his April 2006 testimony to the House Subcommittee on Health. Asserting that IDSA was testifying on behalf of patients and not industry, Blaser stated, "IDSA urges you to extend [Bioshield's] scope beyond products intended to address bioterrorism-related pathogens and apply current incentives to . . . antimicrobial resistant infections."¹³⁶ Another example is a recent article arguing that the Strategic National Stockpile is an ideal model for avoiding shortages of regular childhood vaccines, and that liability protections for the makers of childhood vaccines need to be as comprehensive as those for biodefense.¹³⁷

The logic of extending tort immunity for biodefense-related products goes beyond vaccines and anti-infectives. If federal quasi-no-fault liability coverage is good policy for biodefense drugs, then why not for cancer or heart disease, which arguably pose graver threats to the American people?¹³⁸ Cancer and heart disease have claimed millions of American lives since 9/11, while biological attacks have claimed five,¹³⁹ and potentially pandemic viruses such as SARS and avian flu have caused few deaths in the United States. And infectious diseases, while receiving much less press attention than America's leading killers, present another grave threat. As Dr. Blaser argued, "Not one American has died from bioterrorism since President Bush first announced Project Bioshield in February of 2003, but drug-resistant bacterial and other infections have killed hundreds of thousands of Americans . . . and millions of people across the world during that same short period of time."¹⁴⁰ Nature, simply put, has been far more deadly than biowarfare, so public threat perceptions are unlikely to shift absent a major bioterrorist attack.

Even some proponents of Bioshield II worry about its expansive language. Kathleen Jaeger, head of the Generic Pharmaceutical Association (GPhA), which supports Bioshield II,¹⁴¹ argued at a June 2005 news conference that

135. Press Release, Sen. Orrin Hatch, Hatch, Lieberman, Brownback Call for Next Step in Bioterrorism Preparedness: Senators Unveil Bipartisan BioShield II Legislation (Apr. 28, 2005) [hereinafter Hatch Press Release], available at http://hatch.senate.gov/index.cfm?FuseAction=PressReleases.View&PressRelease_id=1339.

136. IDSA Congressional Testimony, *supra* note 134, at 1.

137. Bhanot, *supra* note 133.

138. The inverse argument, however, does not work—namely, that if we retain the tort option for companies researching lifesaving drugs for cancer and heart disease, then we should keep unadulterated tort for biodefense. Chronic diseases are immensely profitable to treat, so much so that companies are willing and able to bear litigation risks with the help of private insurance. Biodefense drugs, by comparison, have virtually no market except for the government and are uninsurable, entailing more risk for less profit.

139. Scott Shane, *After a Shower of Anthrax, an Illness and a Mystery*, N.Y. TIMES, June 7, 2005, at F1 (reporting that the federal Centers for Disease Control and Prevention confirmed five fatal cases of inhalation anthrax).

140. IDSA Congressional Testimony, *supra* note 134, at 2.

141. Consistent with the economic interests of its members, GPhA supports Bioshield

“[t]he term countermeasure is overly broad. Almost any product in your medicine cabinet would be deemed a countermeasure.”¹⁴² According to Jaeger, such products would include Paxil (to treat depression following a bioterrorist attack) and Botox (to treat migraines).¹⁴³ Other groups less supportive of Bioshield II share her worry. Barbara Loe Fisher, who leads the National Vaccine Information Center (NVIC)—an organization founded by parents of children who suffered vaccine-related injuries—similarly contends that Bioshield II coverage will reach drugs unrelated to homeland security, and worries that drug companies will abuse this immunity.¹⁴⁴

Finally, by displacing state tort law and proposing a new federal agency that could become a source of preemption in its own right, Bioshield II opens another front in the debate at the intersection of preemption and tort reform. Three factors that weigh in favor of preemption here are uniformity, expertise, and safety.

First, creating a uniform standard makes corporate compliance cheaper and easier, prevents the balkanization of the national economy, and ensures that reasonable consumer expectations in one part of the country transfer to any other part. Preemption also prevents some of the larger states from using their sizeable populations and economic weight to dictate policy to the rest of the country. For example, whenever certain regulations, such as vehicle emissions, are left to the states, California, New York, and Texas can sometimes set or significantly influence national policy by controlling access to their markets.

Second, government agencies such as the FDA have substantial scientific and technical expertise. These agencies arguably know better than lay judges and juries what risks are reasonable and when a product is, on balance, safe and effective. Of course, scientists can make honest mistakes, and perhaps even be subtly influenced by the revolving door between government agencies and the private firms they regulate.

Third, the federal government is better positioned and incentivized to optimize risk management for the nation as a whole. Some states would regulate too little, allowing unsafe products into the stream of commerce, while others would regulate too much, depriving consumers of products that have significant net benefits. Because the federal government must balance the views of the states, it is less likely to take an extreme position in an area of regulation where optimal safety is a question of balance.

Preemption’s skeptics, such as Professors Clayton P. Gillette and James E. Krier, respond that transferring responsibility for risk management from courts

II’s product liability protections, research and development incentives, and FDA fast track review for countermeasures. *GPhA Reasserts Position Against BioShield II Legislation*, DRUG INDUSTRY DAILY, June 14, 2005, at 4.

142. *Id.*

143. *Id.*

144. Marta Lawrence, *Drug Companies Gain from BioShield II*, SECURITY MGMT., June 1, 2006, at 38(2).

to agencies is fraught with problems.¹⁴⁵ They argue that technical experts overstate lay judges' and juries' "obsession" with public risk (such as fear of nuclear plants or food additives) and tolerance of private risk, or their suspicion of new technology and acceptance of old technology.¹⁴⁶ Gillette and Krier also contend that agencies, in addition to having their own flaws, might not have the advantages that their proponents claim.

First, agency expertise regarding risk assessment is sometimes irrelevant, such as in examining "abundant quantities of unexotic data" on a mundane issue such as the speed limit.¹⁴⁷ Other data interpretations and risk predictions, however, are less straightforward, as with clinical studies of a new drug's safety. Of course, courts can incorporate expert testimony, so while they might not benefit from the same depth of institutional knowledge on complex technical questions, the gap between judicial and agency expertise might not be the chasm that some commentators portray.

Second, agencies are arguably at greater risk of political capture than are courts.¹⁴⁸ Risk producers tend to be concentrated while risk consumers are often dispersed and, to be politically effective, have to overcome the barrier of organizing.¹⁴⁹ Thus, "a deferential attitude toward agency decisions could lead to too much public risk."¹⁵⁰

Third, experts and the voting public may differ in their perceptions of risk, and the public's views are as legitimate as those of the experts. Whereas experts tend to "insist that a death is a death is a death—1,000 lives lost in a single anticipated annual catastrophe, or through many accidents expected every year, or lost ten-fold but only once every decade on average, or lost in a single community or across the country, are all the same,"¹⁵¹ the public disagrees with that conclusion. The loss of an entire community, for example, would be especially devastating because there are different psychological, economic, and other implications. Indeed, the public differs from the experts on

145. See generally Clayton P. Gillette & James E. Krier, *Risk, Courts, and Agencies*, 138 U. PA. L. REV. 1027 (1990).

146. See, e.g., *id.* at 1030; *id.* at 1043 ("Those who now oppose judicial control of public risk contend that the courts deter public risk too much . . ." (footnote omitted)); *id.* at 1058 (citing Peter Huber as arguing that the courts are "institutionally predisposed to favor regressive public risk choices" (footnote omitted)).

147. *Id.* at 1062 ("[T]he risks of driving at various speeds . . . [are] already compiled into transparent statistical statements.").

148. See, e.g., Lipton, *supra* note 5.

149. Gillette & Krier, *supra* note 145, at 1065 ("If . . . risk producers have a comparative advantage over risk consumers in getting the administrative ear, then agency decision making might be marred by access bias just as judicial decision making is [alleged to be].").

150. *Id.* at 1070; see also *id.* at 1086 ("In the judicial setting, access and process bias almost surely cut in opposite directions. In the case of agencies, however, they probably tend in the same direction, and toward undue public risk (judged from the public's point of view).").

151. *Id.* at 1072 (footnote omitted).

risk tolerance precisely because the public has a greater aversion to risks with the “characteristics of catastrophe, involuntariness, unfamiliarity, and severity.”¹⁵²

Finally, even if an agency could achieve the greatest risk efficiency, courts might distribute risk more equitably, such as by enjoining toxic waste dumps from being built in poor communities.¹⁵³

The slippery slope is steep for Bioshield II because combining biodefense and pandemics implies that Congress views public health under the general rubric of safety and security. It is not difficult, then, to envision expanded liability protections and broader preemption within that framework. It is appropriate to be wary of transferring authority from courts to agencies, but biodefense concerns the nation as a whole. The federal government must be able to set and enforce uniform policies. It is furthermore undemocratic to allow one or two states to effectively set national policy through market restrictions, and doing so collides with the principle of sovereign equality between the states.

The 9/11 Fund raises a related question that Bioshield II further complicates: are victims of terrorism “special?”¹⁵⁴ On the one hand, the legislation answers in the affirmative by creating an immunity and no-fault scheme to stimulate research on neutralizing potential biowarfare pathogens.¹⁵⁵ On the other hand, Bioshield II answers in the negative by treating bioterrorism and natural pandemics identically. If Bioshield II incorporates—and implicitly equates—human-created and natural biological threats, then one could logically extend coverage to victims of injuries related to the preparation for or response to any natural disaster. As Professor Rabin observes, it is difficult to demarcate injury victims based on the type of calamity they suffered because “there are serious fairness concerns, both in arriving at a satisfying definition of terrorist-based harm and in justifying a limitation that would exclude other victims of random accidents.”¹⁵⁶ If the victims of terrorism are unique, then Bioshield II should not cover pandemic-related injuries. But since Congress has suggested through this legislation that terrorism and natural disasters are equivalent calamities, Bioshield II could easily and dramatically expand.

152. Gillette & Krier, *supra* note 145, at 1074 (footnote omitted).

153. *Id.* at 1078.

154. Robert L. Rabin, *The September 11th Victim Compensation Fund: A Circumscribed Response or an Auspicious Model?*, 53 DEPAUL L. REV. 769, 792-93 (2003).

155. Many writings on Bioshield II treat the threat from natural pandemics as equivalent to the threat from any one major disease or biowarfare agent. See, for example, Senator Hatch’s references to the dangers of “AIDS, SARS, Avian Flu, malaria, antibiotic resistant organisms, and other agents, including genetically manipulated materials.” Hatch Press Release, *supra* note 135.

156. Robert L. Rabin, *September 11 Through the Prism of Victim Compensation*, 106 COLUM. L. REV. 464, 479 (2006) (citation omitted).

Preparing for bioterror attacks and pandemics under the same legislative framework achieves obvious efficiencies, but voters should insist on severing the biodefense debate from general tort reform. Certain broader reforms, beyond the scope of this Note, could benefit the tort system but should not be framed in terms of national defense.

IV. SMELTING A NEW BIOSHIELD

Some Bioshield II opponents would completely discard the legislation, but would thereby ignore the stifling effect of tort liability on national readiness for biological threats. Targeted reforms could address many concerns without undermining the program's primary objectives.

A. *The Mismatch Between Tort and Biodefense*

Unmodified tort raises three problems in the context of biodefense:

First, the financial risk of lawsuits for many potential defendants is too high, failing to reflect the significant positive externalities that would flow from developing a biodefense countermeasure. Furthermore, the traditional products liability rationale of risk spreading does not apply to drugs developed for uninsurably catastrophic scenarios.¹⁵⁷ In this light, "the question whether tort creates *optimal* incentives to safety . . . [is] a highly debatable proposition."¹⁵⁸

157. Prior to 9/11, "the risk [of a catastrophic terrorist attack] was perceived to be so de minimis that it was covered for 'free.'" Robert J. Rhee, *Terrorism Risk in a Post-9/11 Economy: The Convergence of Capital Markets, Insurance, and Government Action*, 37 ARIZ. ST. L.J. 435, 444 (2005). After 9/11 and the staggering losses—into the tens of billions of dollars—that insurance companies faced, Congress passed the Terrorism Risk Insurance Act (TRIA) of November 2002. TRIA requires "all commercial insurers doing business within the U.S. . . . to participate," which entails providing coverage for terrorist attacks in all "commercial property and casualty policies." Robert L. Rabin & Suzanne A. Bratis, *United States*, in 14 FINANCIAL COMPENSATION FOR VICTIMS OF CATASTROPHES: A COMPARATIVE LEGAL APPROACH 326 (Michael Faure & Ton Hartlief eds., 2006). In exchange, the United States shares in the liability. Insurers must pay a deductible, after which the federal government pays ninety percent of insured losses up to \$100 billion per year industry-wide. *Id.* at 326-27.

There is also a preemption component: "Once an act of terrorism is certified [by the Treasury Secretary, Secretary of State, and the Attorney General], the Act creates an exclusive federal cause of action and remedy . . . [that] preempts certain state law claims and provides for the consolidation of all civil claims." *Id.* at 327. The Act does not, however, make the federal government liable for punitive damage awards, and it confers a right of subrogation on the United States for any federal payments. *Id.*

TRIA was set to expire in December 2005, but Congress extended the measure for two years. Office of Domestic Fin., U.S. Dep't of the Treasury, *Terrorism Risk Insurance Program: Overview* (Mar. 23, 2006), <http://www.ustreas.gov/offices/domestic-finance/financial-institution/terrorism-insurance>. The availability of insurance for terrorist attacks, however, may continue to be a problem. A Government Accountability Office (GAO) study found "little development or movement among insurers or reinsurers toward developing a private-sector mechanism that could provide capacity, without government involvement, to

Second, tort alone might not provide adequate victim compensation because, following a pandemic or bioterror attack, there would be several obstacles to recovery. As with 9/11, “insolvency emerges as the threshold issue”¹⁵⁹ In the September 11 attacks, key defendants such as the airlines would have gone bankrupt well before paying out on all potential claims.¹⁶⁰ Should the insolvency dilemma disappear, doctrinal barriers to liability would remain—foreseeability, negligence, proximate cause—that could preclude many victims from recovering for their losses. Even premises liability is unlikely to be a winning theory for plaintiffs.¹⁶¹ In addition, because terrorists are drawn to major infrastructure targets such as subways, tunnels, and bridges, which are publicly owned and operated, the defendants are likely to be government agencies. Sovereign immunity thus becomes another major impediment to victim compensation through tort.¹⁶²

Third, liberal access to the courts after a catastrophic epidemiological event would overwhelm an already deluged tort system. Following a mass-casualty event, “[i]f tort continues to be available, judicial dockets are likely to remain overburdened by large numbers of claims, massive numbers of tort litigants are likely to incur huge administrative costs, and many will experience interminable conflict over the range of legal issues that has come to characterize these cases.”¹⁶³ Unfortunately, transferring jurisdiction to one federal court to consolidate pretrial discovery, disaggregating test cases when appropriate, and other such measures are inadequate remedies. The problems that plague large-scale toxic tort cases “have occurred just as inexorably in innovatively handled mass tort conflicts as in traditional serial litigation.”¹⁶⁴

absorb losses from terrorist events.” Rhee, *supra*, at 459 (citing the U.S. GEN. ACCOUNTING OFFICE, TERRORISM INSURANCE: IMPLEMENTATION OF THE TERRORISM RISK INSURANCE ACT OF 2002, at 4 (2004)). Indeed, a September 2006 GAO report “concluded that, for the most part, the private sector insurance market is unable to insure against terrorist attacks that involve unconventional weapons. . . . [T]he study did not draw conclusions about conventional attacks, which also are covered by TRIA.” Kuykendall, *supra* note 21.

158. Rabin, *supra* note 156, at 481 n.66 (citation omitted).

159. Rabin, *supra* note 154, at 771.

160. Indeed, several of the biggest carriers, including United, one of the two airlines that lost planes on 9/11, filed for bankruptcy anyway.

161. Rabin, *supra* note 154, at 781 (“Essentially, the courts take three distinct positions in these cases, none of which suggests that tort, as a general proposition, would offer a promising pathway to compensation for victims of random localized terrorist attacks.”). Under the “prior similar incidents” test, the “totality of circumstances” test, or a “balancing” test, defendants are unlikely to be held liable for failing to prepare for a terrorist attack. *Id.* As Professor Rabin observes, the United States has yet to become like Israel, so accustomed to terror attacks that café owners and bus drivers are expected to be perennially vigilant. *Id.*

162. *Id.* at 777-78 & n.25 (citing *Cuffy v. City of New York*, 505 N.E.2d 937 (N.Y. 1987)) (suggesting that *Cuffy* “reiterate[d] from prior case law the need for a ‘special relationship’ to establish a duty of police protection and articulating limiting factors for the test of whether such a relationship exists”).

163. Rabin, *supra* note 119, at 975 (footnote omitted).

164. *Id.* at 979.

The tort system was not designed with such cases in mind, and it is important that the system continue to function for more ordinary life events at reasonable speed and cost. While Bioshield II should leave more room for tort in cases of gross negligence, the bar to tort ought to remain high, because “a major purpose of adopting an administrative compensation approach—reducing the high litigation costs associated with a mass toxics incident—is likely to be defeated by a supplementary tort remedy.”¹⁶⁵

On the other hand, tort offers significant benefits. Americans generally like the values it embodies through its individualized assessment of fault and compensation, even while many people object to the system’s expense. American culture is individual-centric, as opposed to the more collectivist cultures and socialist politics of European states and Israel.¹⁶⁶ Tort also increases the flexibility of the regulatory approval process by providing ongoing deterrence and compensatory mechanisms, removing that burden from regulators.¹⁶⁷

B. Tailoring Tort and Nontort Responses to the Challenges of Biodefense

Bioshield II could balance the advantages and disadvantages of tort, and learn from other experiences with administrative compensation schemes, through several reforms.

First, the system should become more generous to victims, adjusting compensation parameters to at least track NCVIA rather than SEPPA. (Of course, the government would still need to fund the scheme directly from general revenue, rather than an excise tax, because there might be no commercial market for these products.)¹⁶⁸ Even some of Bioshield II’s most vocal critics imply that they would accept the scheme if it followed NCVIA.¹⁶⁹

165. *Id.* at 975.

166. See, e.g., Betsy Gray, *Homeland Security and Federal Relief: A Proposal for a Permanent Compensation System for Domestic Terrorist Victims*, 9 N.Y.U. J. LEGIS. & PUB. POL’Y 663, 711 (2006) (“Unlike the United States, [Great Britain and Israel] have socialist governments and are accustomed to delivering welfare on a mass scale through a no fault system such as nationalized health coverage.”); Rabin, *supra* note 119, at 975 (“The strongest argument for retaining tort as an alternative pathway for mass toxics victims is an abiding popular suspicion of ‘welfare’ programs.”).

167. Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2076 (2000) (“With a compensation void created by a regulatory compliance defense, the political pressure to minimize injuries from products passing through the regulatory screen might be substantially enhanced.”).

168. Even if a commercial market does exist, the government might not permit commercial sales.

169. Barbara Loe Fisher, President of NVIC, contends that “[t]he drug companies and doctors got all the liability protection they needed in 1986 but they are greedy and want more.” Press Release, Nat’l Vaccine Info. Ctr., Congress Set to Pass Law Eliminating Liability for Vaccine Injuries (Oct. 19, 2005), available at <http://www.909shot.com/PressReleases/101905Burrbill.htm>. The press release further states that “[e]ven though [the

The counterargument that more generous compensation would be prohibitively expensive does not account for the structure of the PREP Act. The September 11 Victim Compensation Fund may have spent over \$7 billion on the immediate victims of an attack that caused only a small fraction of the potential harm from a bioterror attack or pandemic.¹⁷⁰ Congress, however, committed that money *ex post*, and similarly has not promised *ex ante* to provide *any* money for the PREP Act compensation fund. The government could still treat an attack or pandemic that kills hundreds of thousands of people differently from one that is on the scale of 9/11 or smaller. Moreover, only people who could demonstrate that their injuries stemmed from the covered countermeasure, as opposed to the underlying biological agent, would be eligible to recover from the fund.

Second, because fiscal prudence is essential to the scheme's viability, Bioshield II could either continue offering zero noneconomic compensation and make the economic loss component more robust, or the scheme could institute a modest fixed or flat award for noneconomic damages. Individualized determinations of noneconomic harm quickly would become expensive and contentious, and a scheduled benefit is vastly more efficient from an administrative standpoint. The price of greater efficiency, however, is less personalized treatment.¹⁷¹ Professor Rabin contends that "intangible loss would best be denied, although a modest, lump-sum schedule of awards for designated 'serious' disabling conditions would be a viable option" for this type of scheme.¹⁷²

While claimants would argue that noneconomic harm is as "real" as economic harm and therefore deserves compensation, the principle of triage applies: scarce resources must flow to where they can achieve the greatest good. Tort, of course, generally accounts for noneconomic losses. Yet damages for pain and suffering, no matter how real, are inherently difficult to quantify and especially so without the individualized process that tort provides. In a situation where resources could be extremely scarce, remedying economic harm should take priority because economic losses create more immediate material needs than do noneconomic losses.

Third, even if Bioshield II post-event victim compensation does not change, the program must become more generous to pre-event victims of covered injuries. Without adequate compensation, particularly vulnerable or

NCVIA compensation scheme] has awarded nearly \$2 billion to victims of mandated vaccines, two out of three plaintiffs are turned away." *Id.* Implicitly, NVIC seems to accept the *amount* of compensation offered through NCVIA, challenging only the difficulty that claimants have getting *access* to the scheme.

170. Kenneth R. Feinberg, Op-Ed., *A Fair Deal for 9/11's Injured*, N.Y. TIMES, Dec. 14, 2006, at A41.

171. Gray, *supra* note 166, at 722 ("Increasing efficiency in a compensation system usually has the cost of decreasing individual justice.").

172. Rabin, *supra* note 119, at 971.

important groups might refuse vaccination, as most of the civilian first responders did who were eligible for Phase I smallpox inoculations.¹⁷³ Few people would turn down a vaccine or treatment for a rampaging disease, but comparably few people will volunteer to take a potentially dangerous drug prior to an outbreak, unless they know that compensation for injury or death will be at least generous enough to take care of their families in the manner in which they are accustomed to living.

Severing pre-event and post-event compensation is politically unpalatable, but essential if Congress does not want to raise benefits across the board. Such a bifurcation would signal to post-event victims that the government does not value their suffering as highly. Political leaders undoubtedly would prefer not to telegraph that message, but the government must allocate scarce resources for maximum effect. Biodefense offers a compelling rationale that should overcome problems that this reform would create for the politics and image of the Bioshield program.

Fourth, while Bioshield II should make tort a more viable option, the system ought to force claimants to choose or reject tort at the outset, in contrast to NCVIA's permitting claimants to opt for tort *after* learning the amount of their administrative award, and in sharp contrast to Israel's practice of permitting claimants to make their decision after learning the amount of their *tort* award. As Professor Rabin observes, "Unless recourse to tort constitutes an irrevocable waiver of no-fault compensation, the asbestos experience will be replayed," in which injured workers recover from statutory workers' compensation *and* sue in tort.¹⁷⁴

The counterargument that victims of covered countermeasures should be able to seek the maximum award for the harm they suffered, without being forced to play strategic games with their legal and financial recovery, fails to account for the unique generosity and expense of the American tort system. On the one hand, perhaps the maximum possible award represents what the American people, as jurors and taxpayers, believe the victim deserves. On the other hand, the Israeli framework is workable because tort awards are generally far lower in Israel than in the United States.¹⁷⁵ The munificence of American tort, in contrast, would marginalize the administrative compensation scheme if plaintiffs sacrificed nothing by filing a tort suit. Moreover, allowing people to

173. See Greenberger, *supra* note 9, at 7-12.

174. Rabin, *supra* note 119, at 976.

175. See, e.g., Lucien J. Dhooze, *The Loewen Group v. United States: Punitive Damages and the Foreign Investment Provisions of the North American Free Trade Agreement*, 19 CONN. J. INT'L L. 495, 566 (2004) ("Punitive damages have not gained widespread acceptance in other parts of the world. The mixture of civil law, common law and religious principles common to countries in the Middle East typically limit recovery to compensatory damages in private actions and reserve punitive damages for criminal actions. Israel, perhaps in deference to its British colonial past, permits punitive damages awards under extremely limited circumstances." (footnotes omitted)).

pursue parallel administrative and tort claims before deciding which to accept would generate enormous process costs. The primary advantages to an administrative compensation scheme are outcomes for plaintiffs that are definitive and relatively fast, considerably lower overhead costs, and economic relief for potential defendants that should stimulate greater productivity.

Fifth, the tort option should be attractive enough that legitimate claimants will file suit when the administrative scheme makes eligibility and adequate recovery too difficult, but unattractive enough that claimants will only choose tort when the administrative scheme fails to fulfill its basic compensatory and deterrence purposes. For instance, if tort were “sharply constrained by placing a relatively low ceiling on recovery of non-economic loss and revoking the collateral-source rule for other nontort benefits,”¹⁷⁶ then “[t]hese measures, along with the intrinsic uncertainties of tort law, should suffice to ensure that claimants would opt out of the compensation scheme only in circumstances where it was failing to fulfill its basic purposes.”¹⁷⁷ The alternative is the PREP Act as it now stands—to make tort so unattractive or inaccessible that even a tightfisted administrative scheme can effectively compete. The primary advantage to this setup is in keeping payouts very low. The PREP Act, however, can be a successful liability shield without so dramatically limiting victim compensation. Since the legislation absolves potential defendants of economic consequences for their negligence and recklessness, the question is how much taxpayers want to spend.

If Congress prefers to minimize compensation, the public should recognize that the price is having no incentive structure in place to ensure that the administrative scheme provides even minimally adequate recovery to those who are eligible. Letting losses lie where they fall is often a sensible default position that tends to maximize economic efficiency, but biodefense is a common good. It is reasonable to mitigate the effects of war and natural disaster through loss-spreading when those effects are outside the control of the people who suffer them.¹⁷⁸

Sixth, the government needs to enhance the deterrence component of Bioshield II. The Department of Health and Human Services should seek (and make known that it will seek) reimbursement in cases where the tortfeasor committed gross negligence or, at the very least, in cases of apparent recklessness. Alternatively, Congress could lower the bar to tort in analogous fashion if it prefers to use private rather than public enforcement, or does not trust the executive branch to act aggressively enough. Either way, the current “willful misconduct” standard generates minimal if any deterrent effect. Few companies, in the usual course of business, commit misconduct that meets this

176. Rabin, *supra* note 119, at 976.

177. *Id.*

178. Unlike, for example, people who choose to live in flood-prone areas because the government subsidizes flood insurance.

standard, and even fewer would do so at the price of losing critical PREP Act protection.

Congress should further encourage covered entities to take optimal precautions by instituting market-style performance incentives tied to the safety and efficacy of their products and services. For example, the scheme could award substantial bonus payments on a sliding scale based on the frequency and severity of adverse effects.¹⁷⁹ Congress could also harness the incentive structure of insurance—charging tortfeasors a very small percentage of the government payouts for injuries that their products cause, up to a per incident or per annum deductible.

The principal criticism of a more potent deterrence mechanism is that it would dissuade companies from engaging in biodefense research and thereby defeat the purpose of Bioshield II, but “deterrence” can take the form of opportunity costs rather than absolute costs. Setting up the incentive structure as a bonus system, for example, or as an especially generous bonus system combined with some form of insurance premium, deflates this criticism. A secondary criticism would be the expense of such a bonus system, which could run into the high hundreds of millions or even low billions of dollars for a single drug. The answer, however, is that in a biomedical emergency calling for the product’s use, the product would save far more in life and wealth than the bonus would cost.

Seventh, as a matter of general policy, and because some of the above changes would reduce the attraction of biodefense research to pharmaceutical companies, Congress must create a robust market and large prizes for successful biodefense products—a more generous version of Bioshield I. Indeed, “[a] popular idea among some foundations and economists in recent years is to create a guaranteed bounty for new drugs that market forces wouldn’t normally supply,”¹⁸⁰ which would be “similar to the ‘guaranteed’ contracts promised under the BioShield law.”¹⁸¹ Presently, however, biotech executives say that “the BioShield process [is] anything but the red-tape-free haven envisioned in proposals for a drug bounty,”¹⁸² compounding the problems created by the program’s modest funding.

In short, if Congress wants biodefense to be a national priority, it must be willing to pay. The cost is well worth it, however, because prevention is far

179. Suppose that for any product covered by a PREP Act declaration, the government awarded a bonus of \$25 million for each percentage point of efficacy but subtracted \$100 million from that bonus for each percentage point of severe side effects (this data probably would become available only after an event required widespread use of the drug). The exact amount is a public policy question, but the ratio in this example presumes that a drugmaker deserves a bonus if at least four people would be cured or protected for every one person who falls seriously ill because of the product. The drug companies then have a powerful economic incentive to make the safest product possible even without the threat of tort.

180. Wysocki, *supra* note 18.

181. *Id.*

182. *Id.*

cheaper than treatment. As Professor Greenberger stated regarding the failure of the smallpox inoculation program, the cost of generosity upfront “pales in comparison to what the cost would be should an outbreak occur without the benefit of vaccinated first responders.”¹⁸³ There is proof enough in the 9/11 Fund, which approximated the compensation of tort at a price of \$7 billion for only several thousand claimants, and the fund represented but a modest fraction of the economic losses that the United States suffered from the attack.

CONCLUSION

The reforms outlined above would significantly strengthen Bioshield II’s ability to deter grossly negligent and careless conduct while adequately compensating covered victims. Tort alone is not the best form of risk management for biodefense but should not be abandoned lightly. It is less illuminating to evaluate a system in a vacuum as opposed to comparing it with viable alternatives. As Prime Minister Winston Churchill once commented, “Democracy is the worst form of Government except all those other forms that have been tried”¹⁸⁴ Tort has an important role to play in biodefense—both as a remedy for the most grievous cases of misconduct, and in supplying the philosophical objectives for any administrative scheme that would replace it: optimal deterrence of negligence and adequate compensation of victims.

183. Greenberger, *supra* note 9, at 10.

184. Anthony Z. Roisman et al., *Preserving Justice: Defending Toxic Tort Litigation*, 15 *FORDHAM ENVTL. L. REV.* 191, 193 (2004) (footnote omitted).