# Building a Biodefense Industry—One Step at a Time

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It has been more than 20 years since one of the first cases of bioterrorism was detected. The incident involved a religious cult that contaminated a salad bar with salmonella poison, causing hundreds of residents of Wasco County, Oregon, to be hospitalized.[1] Since then, there have been numerous scattered incidents of actual and attempted anthrax poisoning of U.S. Postal Service and congressional employees; and increasing concern about virulent flu strains—such as avian flu—that could potentially spread to pandemic proportions[2] or be used as a terrorist weapon.[3]

Yet few new biological countermeasures have reached the marketplace and Congress continues to search for ways to encourage a domestic biodefense industry, despite having enacted the Project BioShield Act of 2004 (BioShield). The emerging biodefense industry identified shortcomings in BioShield quickly. Congress recently attempted to address these shortcomings by enacting the Public Readiness and Emergency Preparedness Act in December 2005.[4] Yet it remains to be seen whether that Act will fully achieve its intended purposes any more than BioShield has.

In this article, we briefly discuss the initial efforts undertaken to stimulate a biodefense industry and the various follow-on legislative proposals designed to further induce private sector participation in the development and manufacture of countermeasures. Next, we examine the targeted liability protections of the Public Readiness and Emergency Preparedness Act and discuss some of the Act's potential limitations. Finally, we review the government's approach to the development of the nuclear industry in the 1950s, which utilized a guaranteed market approach to develop a uranium market. That approach could serve as a potential model of an additional step that Congress could take to ensure the appropriate quantity and quality of countermeasures are available to combat bioterrorism and other pandemics and epidemics.

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## Background

The first major policy initiative designed to stimulate the development and manufacture of countermeasures to combat bioterrorism was the Project BioShield Act of 2004, Pub. L. No. 108-276, signed by President George W. Bush on July 21, 2004. The stated intent of the Act is:

> To provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States by giving the National Institutes of Health contracting flexibility, infrastructure improvements, and expediting the scientific peer review process, and streamlining the Food and Drug Administration approval process of countermeasures.[5]

Thus, BioShield established several new countermeasure procurement authorities, expedited approval procedures, and created a $5.6 billion special reserve fund for the procurement of countermeasures for the Strategic National Stockpile. The Department of Health and Human Services (HHS) assigned the Office of Research and Development Coordination as the central point of authority to coordinate the procurement of requested countermeasures.

Despite the new authorities and funds provided in BioShield and the apparent demand for new and sophisticated countermeasures, the private sector has not rushed to enter the biodefense market.[6] In addition to concerns over transparency and overall direction, the biotechnology and pharmaceutical communities have faced two primary challenges to entering the countermeasure market: (1) the lack of a guaranteed market for their products; and (2) the prospect of catastrophic liability if their products result in death or bodily injury.

First, due to the long and expensive development period of any new drug, device, or biological product, manufacturers face a tremendous risk if there is no customer to purchase the product upon completion. BioShield did not establish a guaranteed procurement mechanism, and, therefore, many manufacturers have been reluctant to invest the resources in new drugs or technologies without a clear sense as to who will purchase the new products upon completion. Similarly, companies engaged in developing and manufacturing biological countermeasures face unique risks because of the very nature of the underlying threat and the difficulty of responding to it. The threat ranges from natural pathogens delivered intentionally by surprising means to microorganisms genetically engineered for

nefarious purposes.[7] BioShield also failed to provide HHS with any additional liability protection mechanisms for manufacturers and distributors of these inherently dangerous countermeasures.[8]

Recognizing the need to broaden the federal government's biodefense program, Congress explored several legislative proposals in 2005 designed to induce the private sector into participation in this critical arena. Senator Judd Gregg undertook the initial effort to launch a second round of BioShield on January 24, 2005, with the introduction of S. 3, Protecting America in the War on Terror Act of 2005. Senator Gregg's bill offered several incentives to encourage development of countermeasures including patent extensions, tax credits, and litigation reforms. Soon thereafter, Senators Orrin Hatch and Joseph Lieberman, the authors of BioShield, introduced S. 975, the Project BioShield II Act of 2005. That bill was a more comprehensive piece of legislation and offered a number of incentives to encourage and establish biodefense, infectious disease, vaccine, and research tool industries, including tax credits, patent term restoration and extensions, and liability protections.

Throughout the summer of 2005, Senator Richard Burr, chair of the Subcommittee on Bioterrorism and Public Health Preparedness of the Senate HELP Committee, conducted several roundtable discussions focusing on how to develop and manufacture necessary medical countermeasures for the government's BioShield program. These discussions culminated in the introduction of S. 1873, the Biodefense and Pandemic Vaccine and Drug Development Act of 2005. Similar to the other legislative proposals, S. 1873 provided several incentives to the private sector including extending market exclusivity for the patents on certain countermeasure products, the creation of a new Biodefense Medical Countermeasure Development Fund, and liability protections in the form of immunity from suit, with an exception for willful misconduct determined by the secretary of HHS. Senator Burr's bill also proposed a new agency, the Biomedical Advanced Research and Development Agency, within HHS to coordinate and oversee the activities that support and accelerate the research and development of medical countermeasures and qualified pandemic or epidemic products.[9]

Despite the numerous competing proposals, only one of the bills was even reported out of committee and none received floor consideration. Thus, the 2005 legislative session appeared to be drawing to a close without any congressional action to stimulate the development of biological countermeasures. However, with the threat of pandemic avian flu looming in the press, Congress finally took action, just hours before adjourning for the year-end holidays.

## New Law: "Public Readiness and Emergency Preparedness Act"

In the final hours of last year's congressional session, Senate Republicans added a controversial new liability protection measure for entities that produce and administer biological countermeasures in the Department of Defense Appropriations Act for fiscal year 2006 (H.R. 2863). The Public Readiness and Emergency Preparedness Act (PREPA) contained elements of some of the earlier introduced Bioshield, but also included entirely new components not previously aired. In general, PREPA provides a potentially broad immunity to any entity that qualifies as a "covered person" and administers or uses a "covered countermeasure" within the parameters of a declaration issued by the secretary of HHS.

Senate Majority Leader Bill Frist and other Republican leaders argued that the liability measure was necessary to further induce biotechnology companies to develop drugs and vaccines to counter pandemic flu and other bioterrorism threats.[10] Opponents of the bill, including Senator Edward Kennedy, a Democrat, labeled the liability provision as an early "Christmas present" and a giveaway to the pharmaceutical industry.[11] No matter the political spin, PREPA provides the secretary of HHS a new tool to spur countermeasure development, but only if the secretary chooses to use it.

### General Overview

PREPA amends the Public Health Service Act (42 U.S.C. §§ 243 *et seq.*) by adding two new sections regarding liability protections for "covered countermeasures" and an alternative compensation system for those injured from the administration or use of covered countermeasures. Specifically, the liability protection provides that a "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 if a declaration . . . has been issued with respect to such countermeasure."[12] The only exception to the immunity is for a federal cause of action against a "covered person" for death or serious physical injury that is proximately caused by willful misconduct.

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Thus, the potential scope of the immunity for a covered person is broad. Specifically, the immunity applies "to any claim for loss that has a causal relationship with administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation . . . marketing . . . sale . . . prescribing . . . of such countermeasure."[13] A "covered person"

includes the United States, a manufacturer, distributor, or program planner of a covered countermeasure, or a qualified person who administered the countermeasure. The definition of a covered countermeasure is also potentially broad, as it includes any qualified pandemic or epidemic product ("qualified product"), any security countermeasure (responding to a material threat determined under BioShield), and any drug, biological product, or device authorized for emergency use under section 564 of the Federal Food Drug and Cosmetic Act (FFDCA). A qualified product is further defined as a drug, biological product, or device that is (1) used to prevent or cure a pandemic, epidemic, or life-threatening disease; and (2) approved under the FFDCA, or authorized for emergency use under the FFDCA, or is the object of research for possible use to prevent or cure a pandemic, epidemic, or life-threatening disease and is subject of an exemption under the FFDCA.

## Secretary's Declaration

As mentioned above, the only key limitation on the liability protection is that it is available for the administration or use of a covered countermeasure during the period and in accordance with a declaration issued by the secretary of HHS. Specifically, if the secretary determines that a disease, 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, the secretary may make a declaration recommending under various conditions the administration or use of a covered countermeasure.

The declaration is required to identify for each covered countermeasure the disease or health condition against which the countermeasure should be used, the effective immunity period, the population of individuals for which immunity would apply, and geographic area(s) for which the immunity applies with respect to the administration or use of the covered countermeasure. The secretary's decision with respect to the scope or duration of a declaration is not subject to judicial review, and the only additional notification required is that the secretary must notify the appropriate congressional committees within 30 days of making a declaration. Furthermore, the declaration must be published in the *Federal Register*.

However, there may be little transparency to the decision-making process as the secretary is explicitly *not* required to provide to the public "any statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal and informal procedures available."[14] The only additional guidance or "factors to be considered" provided in PREPA is that when deciding whether and under what circumstances to issue a declaration, the secretary must consider the "desirability of encouraging" the development or manufacture of a specific countermeasure.[15] No guidance is included on what type of disease, health condition, or threat now or in the future may constitute a public health emergency. Furthermore, PREPA does not establish any procedures or offer the public any mechanism for requesting that the secretary issue a declaration. Because PREPA itself provides no guidance on how and when declarations of public health emergencies will be made, companies currently developing countermeasures cannot be certain that the products they are developing will be eligible for the liability protections.

## Willful Misconduct Exception to Immunity

In the event the secretary issues a declaration for a specific covered countermeasure, the only exception to the covered person's immunity is when a plaintiff can provide clear and convincing evidence of "willful misconduct" on the part of the covered person that resulted in death or serious physical injury to the plaintiff. PREPA sets a high standard for what qualifies as willful misconduct as only those acts or omissions that are undertaken "intentionally to achieve a wrongful purpose," "knowingly without legal or factual justification," and "in disregard of a known or obvious risk so great as to make it highly probable that the harm will outweigh the benefit."[16] In addition, the secretary, in consultation with the attorney general, is directed to develop regulations that "further restrict" the definition, describing the scope of acts or omissions that "may qualify as willful misconduct" for purposes of the authorized civil suit.[17]

PREPA also sets forth two types of activities that do not qualify as willful misconduct as a matter of law. First, "willful misconduct" is ruled out if the "program planner"[18] or "qualified person"[19] who administered the covered countermeasure followed the directions or recommendations contained in the secretary's declaration and notified health authorities of the relevant injury within seven days. Second, if the conduct in question is regulated by the FFDCA or the Public Health Service Act, a lawsuit for willful misconduct can only be brought if the federal government has taken an enforcement action against the manufacturer's or distributor's conduct.

With respect to the exclusive federal cause of action for "willful misconduct," PREPA makes several changes to the normal rules of civil procedure. For instance, the action must be filed in the U.S. District Court for the District of Columbia, and will be governed by the law of the state in which the alleged willful misconduct occurred, unless such law is inconsistent with or preempted by federal law. The lawsuit will be initially assigned to a three-judge panel to hear all pretrial motions to dismiss and for summary judgment. If the defendants fail to get the case dismissed, the case will then be assigned to a single judge in that same district for trial.

In addition, PREPA imposes heightened pleading requirements on the plaintiff, including a requirement that each element of the claim be pled with particularity, including the specific acts or omissions constituting willful misconduct by each defendant and facts supporting proximate causation and serious physical injury or death. The

plaintiff must also file an affidavit attesting to the truth of the facts alleged, as well as an affidavit from a medical expert on proximate causation and certified medical records evidencing serious physical injury or death.

In those cases in which a plaintiff prevails in a suit for willful misconduct, PREPA directs that any award of damages be reduced by the amount of any collateral source benefits to be paid or received by the plaintiff. Furthermore, with respect to any noneconomic damages, including pain and suffering and other nonpecuniary damages, a defendant may only be held liable for an amount directly proportional to the percentage of responsibility for the harm to the plaintiff.

## Alternative Compensation System

Prior to bringing a lawsuit directly against a covered person for willful misconduct, an individual harmed by a covered countermeasure must exhaust the remedies provided under section 319F-4, the covered countermeasure process (CCP). This new section requires that upon the issuance of a declaration, an emergency fund, entitled the Covered Countermeasure Process Fund, be established to provide compensation to individuals who suffer injuries as the result of the administration or use of a covered countermeasure. Although PREPA provides for the creation of the fund, it does not appropriate any money for the fund.

The CCP is generally modeled after the smallpox compensation program created by the Smallpox Emergency Personnel Protection Act of 2003 (SEPPA).[20] SEPPA authorized the secretary of HHS to establish the Smallpox Vaccine Injury Compensation Program, which was initially appropriated $42 million to provide medical, lost employment income, and death benefits to those individuals injured by smallpox vaccinations. In 2003, the secretary published an interim final rule that set forth a smallpox (vaccinia) vaccine injury table.[21] The table identifies adverse effects (including injuries, disabilities, conditions, and deaths) within specific time periods that are presumed to result from the receipt of, or exposure to, the smallpox vaccine. The secretary will use this table, as well as the procedures set out in the interim final rule, in deciding whether persons are eligible to receive benefits under CCP. PREPA also specifically directs that the CCP be administered in accordance with the SEPPA regulations. Given the short history of SEPPA's compensation program, it is not clear how effective the CCP will be in providing compensation to persons injured by biological countermeasures.[22]

As mentioned above, plaintiffs must exhaust their administrative remedies through the compensation program before suing under the willful misconduct exception. This requirement, however, is waived if Congress fails to fund the compensation program or if the secretary fails to make a final determination on a claim for compensation within 240 days after such request is filed. Nonetheless, if a plaintiff receives and accepts an award under the compensation program, he or she may not file suit against a covered person under the willful misconduct exception.

## Potential Limitations on Act's Effectiveness

PREPA is targeted to liability issues, but does not address other important industry concerns. As indicated, PREPA provides no visibility into how HHS will determine which covered countermeasures may qualify for a declaration and the immunity protection, thus leaving manufacturers uncertain as to their potential liability exposure. Further, PREPA does not contain any mechanism to guarantee a market for biodefense products nor to ensure the federal government's long-term commitment to sustain private sector efforts to develop and manufacture critical countermeasures.[23]

Opponents of the new immunity protection have threatened to reopen the controversial liability provision and derail any future efforts at a second round of biodefense legislation.[24] In fact, on February 15, 2006, Senator Kennedy and 19 colleagues from the House and Senate sent Senator Bill Frist a letter voicing their opposition to PREPA, and introduced what they described as a "reasonable alternative" to the Act, the Responsible Public Readiness and Emergency Preparedness Act of 2006 (S. 2291).[25] Senate bill 2291 would repeal the Public Readiness and Emergency Preparedness Act of 2006, and replace it with liability protection under the Federal Tort Claims Act for a limited set of countermeasures, and a fully funded compensation program modeled on the successful Vaccine Injury Compensation Program.

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To the extent the liability provision is reexamined, Congress may wish to consider directing the secretary to publish regulations that describe in greater detail the process by which a declaration for a covered countermeasure will be issued. Additionally, as with SEPPA, Congress should appropriate some level of funding so that the alternative compensation system can offer a viable path for injured persons to be fairly compensated. The lack of funding may discourage the very investments in research and development that the liability protections are designed to induce.

## Remaining Challenge: Guaranteeing Demand for Biodefense Products

In February 2003, the Bush administration likened the new biodefense initiative to the early days of the space program.[26] However, companies participating in the space program had a dedicated government customer—the National Aeronautics and Space Administration—that paid not only for their research efforts but also purchased the resulting products. In contrast, the demand for biodefense products is diffuse and tenuous, unless and until a catastrophic event occurs. Moreover, while the National Institutes of Health is a key underwriter of biotechnology research and development, there is no equivalent to NASA for biodefense products as the government is not expected to be the primary direct purchaser of most biological countermeasures. Therefore, it is not clear that the biotechnology industry will invest the considerable resources required to develop them, in the absence of an assured market for these products[27] or a decision by the federal government to purchase and stockpile large quantities of countermeasures.

Critics of the existing BioShield program claim that the Bush administration has not done enough to signal the government's commitment to make biological countermeasures commercially available in the event of a catastrophic event. House Government Reform Committee Chairman Tom Davis has cited the unavailability of a countermeasure to treat acute radiation syndrome as an example of the administration's inadequate response efforts.[28] It thus seems clear that further action will be necessary to help stimulate the necessary market demand.

In considering how best to build a market for biodefense products, it may be instructive to examine some of the incentives used to stimulate the domestic nuclear industry in the 1950s and 1960s in response to President Eisenhower's announced "Atoms for Peace" program.[29] At the time, there were many obstacles to building a nuclear industry not dissimilar to those faced by the biodefense industry today. These included the very significant costs and regulatory hurdles required to build and operate nuclear power plants, the potential for extraordinary liability associated with a catastrophic nuclear incident, and the lack of domestically available raw materials for the production of nuclear power. Moreover, the government would not be the sole or even the major purchaser of electricity generated by nuclear reactors, so it was imperative to create a commercial demand for this novel source of power and for the nuclear source materials required to produce it.

Congress addressed these issues in a series of bold legislative actions in the 1950s. Among other important initiatives, the liability issues were specifically addressed in the Price Anderson Act, which established a liability limitation and indemnification program for nuclear power plant operators and companies under contract with the then-Atomic Energy Commission (AEC).[30] Congress also took steps to establish a mechanism for ensuring that there would be sufficient uranium available domestically to induce commercial power producers to consider the use of nuclear power. The chosen mechanism was to guarantee a minimum purchase price for uranium ores that met specifications set by the AEC.[31]

The guaranteed purchase program may be instructive in considering approaches for the biodefense industry. Under that program, the AEC published a standard form contract that had the legal effect of being a binding offer to purchase as much uranium as miners could produce for a guaranteed purchase price.[32] A similar program was undertaken by the General Services Administration in the 1960s to encourage the domestic production of manganese under the Defense Production Act for the national stockpile.[33]

The notion of a guaranteed purchase price or advanced purchase commitment is currently being explored as a means of stimulating the development of vaccines against HIV and malaria for use in developing countries where there would otherwise not be sufficient market pull for manufacturers to justify the necessary development costs.[34] Under various approaches being considered, international aid organizations would not necessarily purchase the products, but would commit to make up any difference between the guaranteed purchase price and the market price for the product when eventually sold.

These and other market-making mechanisms may be worth exploring for possible application to the biodefense industry in the United States.

## Conclusion

The enactment of the Project BioShield Act of 2004 and the Public Readiness Emergency Preparedness Act are important first steps toward stimulating private sector investment in the development and production of biological countermeasures. However, additional government action will likely be required to ensure that effective biological countermeasures reach the public. Additional steps that the administration could take include providing greater transparency into the government's decision-making process for purchasing biological countermeasures and for determining public health emergencies; providing full funding of a compensation system for persons injured by countermeasures; and creating a guaranteed or advance purchase program to help stimulate a market demand for products that are otherwise not marketable. PL

## Endnotes

1. J. Miller, S. Engelberg, and W. Broad, Germs—Biological Weapons and America's Secret War (2001).

2. As of January 30, 2006, the World Health Organization reported 85 deaths due to avian flu and 160 confirmed human cases in six countries. *See Cumulative Number of Confirmed Cases of Avian Influenza A/(H5N1) Reported to WHO*, January 30, 2006, *available at* http://www.who.int/csr/disease/avian_influenza/country/cases_table_2006_01_30/en/index.html

3. *See* Testimony of Stewart Simonson, assistant secretary for Public Health Emergency Preparedness, Department of Health and Human Services, before the House Committee on Government Re-

form (July 14, 2005).

4. In a December 22, 2005, press release, Jim Greenwood, the president and CEO of the Biotechnology Industry Organization noted that "[i]t has become clear during the last few years that our nation's vaccine infrastructure needs to be augmented—both research and development as well as manufacturing—and we believe [the Public Readiness and Emergency Preparedness Act] will provide that impetus . . . [and] will lead to opportunities for more companies to enter the vaccine business, increasing the capacity and diversity of our nation's vaccine industry."

5. Pub. L. No. 108-276, 118 Stat. 835.

6. *See* Rebecca Adams, *Project BioShield: A Second Look*, CQ WEEKLY (January 20, 2006); Darren Fonda, *Inside the Spore Wars: Controversial contracts, bureaucratic bungling—the Fed's biodefense program is a mess. How did it go so wrong?*, TIME (January 9, 2006).

7. Testimony of J. Leighton Read, M.D., general partner, Alloy Ventures, before the House Energy and Commerce Committee, Subcommittee on Health, and the House Select Homeland Security Committee, Subcommittee on Emergency Preparedness and Response, (March 27, 2003).

8. In limited situations, HHS has used its indemnification authority under Pub. L. No. 85-804 to indemnify contractors against certain risks associated with contracts for the production of anthrax and smallpox vaccines. *See* AP, *Government Shields Makers of Vaccine for Smallpox, Anthrax From Lawsuits, Senate Debates Protection for Childhood Vaccines,*" ST. LOUIS POST-DISPATCH, Nov. 17, 2002, A7; Bernadett Tansey, *Vaxgen Gets $878 Million U.S. Contract; Brisbane Biotech Company to Supply Stockpile of 75 Million Doses of Anthrax Vaccine*, SAN FRANCISCO CHRON., Nov. 5, 2004, C1.

9. Senator Burr's bill also included several new procurement mechanisms for HHS designed to provide assurances to manufacturers that their research and development expenses will eventually be recovered. For instance, the bill would permit advance payments or payments to increase manufacturing capacity to ensure success of the project, of up to 10 percent of the contract amount. *See* S. 1873, § 13. The contract could also provide for up to three additional advance payments of 5 percent each for meeting the milestones specified in the contract, for a total of 25 percent of the contract price paid in advance of final delivery. The bill also proposes a sales exclusivity provision that would permit the vendor to be the sole and exclusive supplier of the product to the federal government for a specified period of time, not to exceed 15 years, on the condition that the vendor is able to satisfy the needs of the government.

10. Press release of Senator Frist, "Frist Hails Passage of FY06 Defense Appropriations Conference Report: Highlights Vaccine Liability Provisions, Support Our Scouts Act," December 21, 2005.

11. Press release of Senator Kennedy, "Kennedy, Harkin and Dodd Protest Frist Liability Giveaway: Plan Would Threaten America's Safety and Let Companies Under Investigation Off the Hook", December 21, 2005. Senator Kennedy suggested that "the Bush administration could identify Vioxx as a needed countermeasure to treat the arthritis epidemic or to treat pain associated with flu, and completely immunize Merck from lawsuits currently pending against it." *Id.*

12. Section 319F-3(a)(1) of Part B of title III of the Public Health Service Act, codified at 42 U.S.C. § 247d-6d.

13. Section 319F-3(a)(1)(B) of Part B of title III of the Public Health Service Act, codified at 42 U.S.C. § 247d-6d.

14. 5 U.S.C. § 552(b).

15. Section 319F-3(b)(6) of Part B of title III of the Public Health Service Act, codified at 42 U.S.C. § 247d-6d.

16. Section 319F-3(c)(1) of Part B of title III of the Public Health Service Act, codified at 42 U.S.C. § 247d-6d.

17. 42 U.S.C. § 319F-3(c)(2).

18. A program planner is defined as "a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration." Section 319F-3(i)(6) of Part B of title III of the Public Health Service Act.

19. A qualified person is "(A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or (B) a person within a category of persons so identified in a declaration." Section 319F-3(i)(8) of Part B of title III of the Public Health Service Act.

20. *See generally* 42 U.S.C. §§ 239 *et seq*.

21. *See* 68 Fed. Reg. 241 (Dec. 16, 2003).

22. *See* H. Myers et al., *The Threat of Smallpox: Eradicated But Not Erased*, J. HOMELAND SECURITY (February 2004) for a critical analysis of the SEPPA program.

23. James C. Greenwood, *Pandemic flu: Prepare now*, WASH. TIMES (January 24, 2006).

24. *Passage of Biodefense Bill Priority for Leadership in 2006*, FDA WEEK (Jan. 27, 2006).

25. Press release of Senator Kennedy, *Kennedy, Colleagues Call on Frist and Hastert to Repeal 'Dead of Night' Vaccine Liability Provision and Enact Real Protections*, Feb. 15, 2006.

26. *See* Remarks on Project BioShield, WEEKLY COMP. PRES. DOC. (Feb. 10, 2003) (stating "[t]he spirit of modern science embodied in our space program can be found here at NIH.").

27. *See* Testimony of J. Leighton Read, M.D., General Partner, Alloy Ventures, Before the Senate Committee on Appropriations, Subcommittee on Homeland Security, (April 28, 2005).

28. *See* transcript of *CBS: 60 Minutes* (Jan. 29, 2006), WLNR 1630093; *see also* Zack Phillips, CQ HOMELAND SECURITY, *House Committee Zeroes in on HHS Purchase of Radiation Sickness Therapies* (Dec. 6, 2005) (quoting committee staff as saying that HHS lacks a "consistent game plan" for implementing Project BioShield).

29. Address before the General Assembly of the United Nations, December 8, 1953, *available at* http://www.eisenhower.archives.gov/atoms.htm.

30. 42 U.S.C. § 2210.

31. 42 U.S.C. § 1805(b)(5) (1946 Ed.). As indicated by the then-Court of Claims in a dispute about a guaranteed purchase contract, the Atomic Energy Act of 1947 was specifically designed "to assure the development of a domestic uranium industry which had been theretofore nonexistent." Jack D. Gay v. United States, 356 F.2d 516 (Ct. Cl. 1966).

32. *See* Industrial Uranium Company v. United States, 376 F.2d 888 (Ct. Cl. 1967) (summarizing the domestic uranium program's history); *see also* J. Collins, *Reclamation and Groundwater Restoration in the Uranium Milling Industry: An Assessment of UMTRCA, Title II*, 11 NAT'L RESOURCES & ENVTL. L. REV. 32 (1995-96).

33. *See* Himfar v. United States, 355 F.2d 606 (Ct. Cl. 1966).

34. *See* UK Government Policy Paper, *Increasing people's access to essential medicines in developing countries: a framework for good practice in the pharmaceutical industry*, Dep't Health (March 2005); *see also* O. Barder, *Making Markets for Vaccines: Ideas to Action*, Center for Global Development (April 7, 2005) *available at* http://www.cgdev.org/content/publications/detail/2792.