

RESPONDING TO BIOTERRORISM: AN ANALYSIS OF TITLES I AND II OF THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

I. INTRODUCTION

The anthrax attacks of 2001 showed Americans that our government was ill-prepared to handle the challenges associated with preparing for and responding to a major act of bioterrorism. The locus of some of those attacks—congressional office buildings in Washington, D.C.—also made lawmakers keenly aware of these inadequacies.¹ Thus, introduced in the immediate wake of the attacks and signed into law six short months later, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 promised to be a major tool in the federal government's fight against bioterrorism.² However, like many bills passed in the wake of September 11th, the major provisions of the Bioterrorism Preparedness and Response Act are in need of critical analysis.³ This Note seeks to review Title I and Title II of the Act as they address federal preparedness and response capabilities.

Part II of this Note provides an overview of the problems associated with bioterrorism by first focusing on the past and present threats from a bioterrorism attack and then turning to the state of the federal government response capabilities prior to the anthrax events of 2001. In doing so, it brings to light the structural and bureaucratic obstacles the federal government faced in trying to respond to the anthrax attacks and provides

1. Robert Pear, *House Passes Measure Tightening Toxin Controls*, N.Y. TIMES, Oct. 26, 2001, at B9.

2. See Committee News Release, The Committee on Energy and Commerce, *Tauzin Hails Conference Agreement on Landmark Bioterrorism Bill* (May 21, 2002), available at http://energycommerce.house.gov/107/News/05212002_575print.htm.

3. For examples of post-September 11, 2001 congressional action, see Terrorism Risk Insurance Act of 2002, Pub. L. No. 107-297, 116 Stat. 2322 (2002); Homeland Security Act of 2002, Pub. L. No. 107-296, 116 Stat. 2135 (2002); Maritime Transportation Security Act of 2002, Pub. L. No. 107-295, 116 Stat. 2064 (2002); Terrorist Bombings Convention Implementation Act of 2002, Pub. L. No. 107-197, 116 Stat. 721 (2002); Mychal Judge Police and Fire Chaplains Public Safety Officers' Benefit Act of 2002, Pub. L. No. 107-196, 116 Stat. 719 (2002); Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (2002); Enhanced Border Security and Visa Entry Reform Act of 2002, Pub. L. No. 107-173, 116 Stat. 543 (2002); Victims of Terrorism Tax Relief Act of 2001, Pub. L. No. 107-134, 115 Stat. 2427 (2002); USA PATRIOT ACT of 2001, Pub. L. No. 107-56, 115 Stat. 272 (2001); Air Transportation Safety and System Stabilization Act, Pub. L. No. 107-42, 115 Stat. 230 (2001).

a glimpse of the political climate which resulted in the passage of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Part III analyzes the provisions of the Act aimed at addressing the major problems in coordinating the federal response to bioterrorism, namely, the lack of statutory authority addressing the bioterrorism threat, fragmentation in agency responsibilities, inadequacy in the federal response infrastructure, and the lack of restrictions on the possession and use of dangerous pathogens. Part IV then briefly proposes some additional changes to the federal government's response structure that are aimed at addressing problems not fully considered by the Act. Finally, Part V concludes that the Act is an encouraging first step in the federal government's fight against bioterrorism, but many coordination and structural problems must be addressed in order to fully prepare against future threats.

II. BACKGROUND/OVERVIEW

A. *The Problem: Bioterrorism*

1. *Historical Perspective*

The use of biological agents as a means to invoke fear and inflict destruction dates back to at least 1346 when soldiers loaded victims of bubonic plague into catapults to launch over city walls.⁴ By World War I, after the establishment of the germ theory, the German Army utilized biological agents in an attempt to infect Allied horses and troops.⁵ By the 1940s and the outbreak of World War II, the United States, Japan, and the Soviet Union all counted biological agents as major parts of their arsenal of offensive weapons.⁶

While the U.S. military developed major offensive biological-weapon programs after World War II,⁷ little attention was paid to the threat of bioterrorism at home until the 1980s and then was not taken seriously until

4. Robert E. Armstrong & Jerry B. Warner, *Biology in the Battlefield*, DEFENSE HORIZONS, Apr. 2003, at 1. These actions were taken by Tartar soldiers in the besieged Black Sea Port of Kaffa and some medical historians believe that this act was responsible for the Black Death (bubonic plague) that ravaged Europe in the 14th century. *Id.*

5. *Id.* This German operation may also be one of first uses of biological weapons against domestic U.S. interests as the program was carried out by German agents in the U.S. who tried (unsuccessfully) to infect the horses before they were shipped to Europe. *Id.*

6. *Id.*

7. American Gulf War Veterans Association, *History of Biological Warfare*, at <http://www.gulfwarvets.com/biowar.htm> (last visited Jan. 31, 2005).

the Japanese Aum Shinrikyo cult failed ten times in the early 1990s to release anthrax and botulinum toxin in central Tokyo.⁸ After these events and the tragic circumstances of the Oklahoma City bombing in 1995, federal officials finally began to consider the possibility of a bioterrorism attack on U.S. soil.⁹

2. *The Anthrax Attacks of 2001*

In early September of 2001, the General Accounting Office (“GAO”) stated in a report on federal preparedness for a bioterrorism event that “the probability of a domestic bioterrorist attack has been considered to be low,” and “the possibility that terrorists may use chemical or biological materials may increase over the next decade.”¹⁰ However, just days later three members of press organizations in the New York area, two United States Postal employees in New Jersey, and an employee of American Media Inc. in Florida all reported to hospitals after coming into contact with anthrax spores sent via the mail.¹¹ On October 15, 2001, an employee of former Senator Tom Daschle opened a letter containing anthrax in one of the Senate office buildings; soon after, postal workers in both the District of Columbia and New Jersey reported symptoms of anthrax exposure.¹² From the beginning of October 2001 until the end of

8. Armstrong & Warner, *supra* note 4, at 2. In 1984, Indian guru Bagwan Shree Rajeesh and his followers contaminated salad bars with salmonella in a rural part of Oregon causing 750 cases of food poisoning and sending forty-five people to the hospital. *Id.* In 1995, the Japanese Aum Shinrikyo cult used sarin gas to kill twelve people and injure 5,000 in the Tokyo subway system. *Id.* However, what shocked U.S. authorities was the discovery that the cult had built a biological weapon facility at its Naganohara headquarters. *Global Proliferation of Weapons of Mass Destruction: Hearing Before the Permanent Subcomm. on Investigations of the Sen. Gov't Affairs Comm.*, 104th Cong. 63 (1995) (Staff Statement: Global Proliferation of Weapons of Mass Destruction: A Case Study on the Aum Shrinkyo). Even more surprising to U.S. officials was that the group had designed and tested biological toxins using computer software sold directly to the cult by companies in Oregon and Missouri. *Id.* at 78–79.

9. See generally RICHARD A. FALKENRATH ET AL., *AMERICA'S ACHILLES' HEEL* (1998); see *infra* notes 90–97 (discussing the rise of the Federal Response Plan and Presidential Decision Directive 39, which was adopted after the Oklahoma City Bombing in 1995). For a more complete history of the law and bioterrorism, see VICTORIA SUTTON, *LAW AND BIOTERRORISM* 3–9 (2003) [hereinafter SUTTON, *LAW AND BIOTERRORISM*].

10. GEN. ACCT. OFF., GAO-01-915, *BIOTERRORISM: FEDERAL RESEARCH AND PREPAREDNESS ACTIVITIES* 5 (2001) [hereinafter *FEDERAL RESEARCH AND PREPAREDNESS ACTIVITIES*].

11. GEN. ACCT. OFF., GAO-04-152, *BIOTERRORISM: PUBLIC HEALTH RESPONSE TO ANTHRAX INCIDENTS OF 2001*, at 34 (2003) [hereinafter *RESPONSE TO ANTHRAX INCIDENTS OF 2001*]. The first cases of cutaneous anthrax consisted of two NBC employees, a New York Post employee, the child of an ABC employee, and two postal employees from New Jersey. *Id.* The afflicted Florida employee was the first reported inhalational anthrax case and was also the first casualty on October 5, 2001. *Id.* All of these cases resulted from letters filled with anthrax spores in powder form. *Id.*

12. *Id.*

November, a total of twenty-two people were infected with anthrax in five states and the District of Columbia.¹³ Five of those twenty-two died from the attacks.¹⁴ This major domestic bioterrorism attack tested the public trust in the federal government's response capabilities¹⁵ and highlighted the weaknesses in coordination, planning, and public health readiness for biological attacks.¹⁶

3. Future Threats

The anthrax attacks of 2001 forced the federal government to reevaluate the seriousness and imminence of a biological attack launched by terrorists.¹⁷ The attacks also created a need for greater research and public education on the types of biological agents that might be used in an attack¹⁸ and the countermeasures, such as vaccines, that would be vital in any type of response.¹⁹

13. *Id.* at 34–36.

14. *Id.* at 1. Of the twenty-two people infected, eleven had cutaneous anthrax and eleven came down with the inhalation form. *Id.* All five deaths were caused by inhalational form, *id.*, which has a fatality rate of approximately 75% compared to the 25%–60% fatality rate for cutaneous anthrax. *Id.* at 6.

15. See Charles Ornstein, *A Faltering Confidence in the Call for Calm*, L.A. TIMES, Oct. 31, 2001, at A3 (quoting Helen Schaffler, executive director of the Center for Health and Public Policy Studies at UC Berkeley as saying “[t]he ineptitude of the response of our officials to this is unbelievable, . . . [t]hey keep giving these false reassurances, and all it's doing is undermining their credibility.”).

16. RESPONSE TO ANTHRAX INCIDENTS OF 2001, *supra* note 11, at 2 (“The response to the incidents has been characterized by several public officials, academics, and other commentators as problematic and an indication that the country was unprepared for a bioterrorist event.”); Lawrence K. Altman & Gina Kolata, *Anthrax Missteps Offer Guide To Fight Next Bioterror Battle*, N.Y. TIMES, Jan. 6, 2002, at A1 (chronicling the failures of the government's response to the attacks and quoting experts as stating that the government failed to understand “the difference between the goals of terrorism and the goals of warfare”).

17. The flurry of legislation, agency reports, and the statements of government officials addressing the need for increasing the federal government's preparedness best indicates this point. See *supra* note 3.

18. The Centers for Disease Control now offers fact sheets and extensive information on at least twenty-seven biological agents that could be used in a bioterrorism event. See Centers for Disease Control and Prevention, *CDC Emergency Preparedness & Response: Bioterrorism Agents/Diseases*, at <http://www.bt.cdc.gov/agent/agentlist.asp> (last modified Nov. 19, 2004). The CDC lists six organisms as “Category A agents,” which are defined as those that “are believed to pose the greatest potential threat for adverse public health impact and have a moderate to high potential for large-scale dissemination.” Centers for Disease Control and Prevention, *Frequently Asked Questions About Smallpox*, at <http://www.bt.cdc.gov/agent/smallpox/disease/faq.asp> (last modified Dec. 29, 2004). The six “Category A agents” are: (1) Smallpox (*Variola major*) is widely thought to be eradicated worldwide, but it is one of the most feared agents that could be used as a weapon because it is virulently contagious and can be fatal in 30% of cases. *Id.* (2) Anthrax (*Bacillus anthracis*) is not contagious, but the spores can survive in soil for years and the inhalation form of the resulting disease is usually fatal. Centers for Disease Control and Prevention, *Questions and Answers About Anthrax*:

B. Federal Government Preparedness and Response

Preparing for and responding to a bioterrorism event necessarily involves a wide array of local, state, and federal government agencies.²⁰ Local governments provide many of the “first responders” in an attack and control much of the health infrastructure that is needed for addressing the release of a biological agent.²¹ States have traditionally regulated all

Frequently Asked Questions, at <http://www.bt.cdc.gov/agent/anthrax/faq/index.asp> (last modified Jan. 28, 2005). (3) Plague (*Yersinia pestis*),

used in an aerosol attack could cause cases of the pneumonic form of plague. . . . Once people have the disease, the bacteria can spread to others who have close contact with them. Because [there is a] delay between being exposed to the bacteria and becoming sick, people could travel over a large area before becoming contagious and possibly infecting others. . . . A bioweapon carrying *Y. pestis* is possible because the bacterium occurs in nature and could be isolated and grown in quantity in a laboratory.

Centers for Disease Control and Prevention, *Frequently Asked Questions (FAQ) About Plague*, at <http://www.bt.cdc.gov/agent/plague/faq.asp> (last reviewed Jul. 27, 2004). (4) Botulism (*Clostridium botulinum*) is a bacterium that produces a fatal nerve toxin and is a major threat to food supplies. Centers for Disease Control and Prevention, *Facts About Botulism*, at <http://www.bt.cdc.gov/agent/botulism/faq/index.asp> (last modified Oct. 14, 2001). (5) Tularemia (*Francisella tularensis*) “is highly infectious . . . [and a] small number of bacteria (10–50 organisms) can cause disease. If *Francisella tularensis* were used as a bioweapon, the bacteria would likely be made airborne so they could be inhaled. People who inhale the bacteria can experience severe respiratory illness, including life-threatening pneumonia and systemic infection.” Centers for Disease Control and Prevention, *Frequently Asked Questions (FAQ) About Tularemia*, at <http://www.bt.cdc.gov/agent/tularemia/faq.asp> (last modified Oct. 8, 2003). (6) Viral Hemorrhagic Fevers, such as Ebola, hantavirus and the Marburg virus, are highly infectious and have no known treatment or established cure. However, they are hard to handle safely, which makes them difficult for terrorist use. Council on Foreign Relations, *Others Biological Agents: Botulism, Plague, Tularemia, HFVs*, at http://cfrterrorism.org/weapons/otheragents_print.html (last visited Mar. 1, 2005).

19. See *Bioterrorism and Proposals to Combat Bioterrorism: Hearing Before the House Comm. on Energy and Commerce*, 107th Cong. 54 (2001) (testimony of Hon. Tommy Thompson, Secretary, Department of Health and Human Services) (“The President and the Department [of Health and Human Services] are . . . committed to the development and the approval of new vaccines and therapies [to combat bioterrorism].”).

20. GEN. ACCT. OFF., GAO-03-654T, *INFECTIOUS DISEASE OUTBREAKS: BIOTERRORISM PREPAREDNESS EFFORTS HAVE IMPROVED PUBLIC HEALTH RESPONSE CAPACITY, BUT GAPS REMAIN* 3–4 (2003) (prepared testimony of Janet Heinrich, GAO Director of Health Care-Public Health Issues, before the House Committee on Government Reform) [hereinafter *INFECTIOUS DISEASE OUTBREAKS*].

21. *Id.* “Local health care organizations, including hospitals, are generally responsible for the initial response to a public health emergency . . . [H]ospitals and their emergency departments would be on the front line, and their personnel would take on the role of first responders.” *Id.* at 3. “The burden of responding to [a bioterrorism] attack would fall initially on personnel in state and local emergency response agencies. These ‘first responders’ include firefighters, emergency medical service personnel, law enforcement officers, public health officials health care workers (including doctors, nurses, and other medical professionals), and public works personnel.” GEN. ACCT. OFF., GAO-02-141T, *BIOTERRORISM: PUBLIC HEALTH AND MEDICAL PREPAREDNESS 2* (2001) [hereinafter *PUBLIC HEALTH AND MEDICAL PREPAREDNESS*] (prepared testimony of Janet Heinrich, GAO Director of Health Care-Public Health Issues, before the Subcommittee on Public Health of the Senate Committee on Health, Education, Labor, and Pensions).

aspects of the public health system pursuant to their police powers,²² and the federal government has the authority to act to protect public health under the auspices of national security.²³ However, this multi-layered structure has the potential to create conflicts that could hamper efforts to address the threats of bioterrorism.²⁴ Thus, some experts have suggested that the federal government should have the chief role in responding to bioterrorism.²⁵

22. *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) (The protection and preservation of the public health is among the most important duties of state government); *Compagnie Francaise de Navigation a Vapeur v. State Board of Health*, 186 U.S. 380, 387 (1902) (holding that a state can promulgate quarantine laws “for the purpose of preventing, eradicating, or controlling the spread of contagious or infectious diseases”); James G. Hodge, Jr., *Bioterrorism Law and Policy: Critical Choices in Public Health*, 30 J.L. MED. & ETHICS 254, 256 (2002) [hereinafter Hodge, *Salient Issues in Public Health Law*] (discussing the broad powers of the state governments to protect the health, safety and general welfare under their traditional police powers); Victoria Sutton, *Bioterrorism Preparation and Response Legislation—The Struggle to Protect States’ Sovereignty While Preserving National Security*, 6 GEO. PUB. POL’Y REV. 93, 94 (2001) [hereinafter Sutton, *Struggle to Protect States’ Sovereignty*] (“The regulation of public health has traditionally been a police power of the states, arising from the regulation of contagion and disease in colonial times.”).

One of the most important developments in state bioterrorism law has been the adoption of parts of the Model State Emergency Health Powers Act (MSEHPA) by 32 states. MODEL STATE EMERGENCY HEALTH POWERS ACT (Dec. 2001), available at <http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf>. MSEHPA clearly defines the powers of state health officials during a bioterrorism attack and provides a comprehensive framework for state quarantines of individuals. *Id.* States have used the MSEHPA to supplement their existing public health laws and clarify state responsibilities in the face of a bioterrorism attack. Lawrence O. Gostin & James G. Hodge, Jr., *Public Health Emergencies & Legal Reform: Implications for Public Health Policy and Practice*, PUB. HEALTH REP., Sept.–Oct. 2003, available at http://www.publichealthreports.org/userfiles/118_5/118477.pdf. However, few states have implemented the entire MSEHPA and have instead adopted their own changes as a gloss to existing state public health law. *Id.* Missouri presents an example of this typical state structure as scattered sections of the Missouri Statutes were recently amended to address bioterrorism. See MO. REV. STAT. § 44.010 (Supp. 2003) (the Civil Defense Chapter was amended to include the word “bioterrorism” in the state’s emergency response framework); *id.* § 21.800 (establishing the Joint Committee on Terrorism, Bioterrorism, and Homeland Security to revise Missouri statutes to address the threat of a bioterrorism attack).

23. Sutton, *Struggle to Protect States’ Sovereignty*, *supra* note 22, at 94 (stating that national security is controlled by the federal government, but noting that this usually has meant dealing in the international arena).

24. *Id.* at 93. “The coordination of traditional emergency response mechanisms . . . are those which are clearly defined and practiced. However, the coordination for peacetime preparations for bioterrorist action is not so clearly defined and remains a vulnerable position for the United States.” *Id.*

25. *Id.* at 102; see also Hodge, *Salient Issues in Public Health Law*, *supra* note 22, at 258 (discussing six reasons why state and local authorities should defer to the federal government; briefly they are: (1) greater financial capability, (2) greater bargaining power to buy vaccines and drugs, (3) the migratory nature of a biological agent across state lines, (4) better ability to develop institutional expertise, (5) national security implications of bioterrorism, and (6) the federal government’s ability to coordinate intelligence and law enforcement).

1. *Agency Roles*

While the federal government may be in the best position to respond to a bioterrorist attack because of its vast resources, this broad range of capabilities also gives rise to fragmentation among federal agencies in response planning.²⁶ This fragmentation necessarily results from the lack of a centralized or coherent statutory or regulatory framework addressing the threat posed by a bioterrorist attack.²⁷ Thus, federal agencies with relevant responsibilities are forced to coordinate with each other formally (formal agreements), informally (working groups and partnerships), or simply develop their own independent plan for responding to an attack.²⁸ As a pre-anthrax-attack GAO report explained, “different agencies are responsible for various coordination functions, which limits accountability and hinders unity of effort.”²⁹ Thus, a review of the roles played by relevant federal agencies before the anthrax attacks of 2001 gives us an idea of the landscape prior to congressional action.³⁰

a. *Department of Health and Human Services*

The Department of Health and Human Services (“DHHS”) is the lead federal agency in managing public health responses to terrorist events and other emergencies.³¹ Under the Public Health Services Act,³² the Secretary of DHHS has broad statutory powers to respond to a public health crisis and is authorized to develop and take such actions as necessary to implement a plan to control infectious diseases.³³ In addition, the Act

26. PUBLIC HEALTH AND MEDICAL PREPAREDNESS, *supra* note 21, at 1 (“more than 20 federal departments and agencies [have] a role in preparing for or responding to the public health and medical consequences of a bioterrorist attack.”).

27. Jason W. Sapsin, *Introduction to Emergency Public Health Law for Bioterrorism Preparedness and Response*, 9 WIDENER L. SYMP. J. 387, 395 n.49 (2003) (describing the federal law related to a public health response as “sprawling”).

28. FEDERAL RESEARCH AND PREPAREDNESS ACTIVITIES, *supra* note 10, at 4.

29. *Id.*

30. By “relevant” agencies I mean those affected by the provisions of the Public Health Security and Bioterrorism Preparedness Act (the topic of this Note). “Congressional Action” refers to the legislative activity undertaken by the 107th Congress in the months subsequent to the anthrax attacks—culminating in the passage of the Public Health Security and Bioterrorism Preparedness Act and the Homeland Security Act in 2002. For an exhaustive review of the federal agencies involved in responding to a bioterrorism event, see Victoria Sutton, *Biodefense: Who’s in Charge?*, 13 HEALTH MATRIX 117, 121–48 (2003).

31. FEDERAL RESEARCH AND PREPAREDNESS ACTIVITIES, *supra* note 10, at 48; FED. EMERGENCY MGMT. AGENCY, NO. 9230.1-PL, INTERIM FEDERAL RESPONSE PLAN 16 (2003) [hereinafter INTERIM FEDERAL RESPONSE PLAN].

32. Public Health Services Act, 42 U.S.C. § 201 (2000).

33. 42 U.S.C. § 243 (2000).

authorizes DHHS to provide assistance to a state or local governments, upon request, to respond to a health emergency that is “of such a nature as to warrant Federal assistance.”³⁴ However, the most sweeping powers given to DHHS are those that allow the Secretary to promulgate rules to establish federal quarantines in an effort to prevent the spread of cholera, diphtheria, tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers, and SARS.³⁵ Federal law also allows the Secretary broad authority in times of war to apprehend and detain persons who are infected with a biological agent, are contagious, and pose a threat of infecting any member of the armed forces.³⁶

The Secretary is authorized to develop (and may take such action as may be necessary to implement) a plan under which personnel, equipment, medical supplies, and other resources of the [Public Health] Service and other agencies under the jurisdiction of the Secretary may be effectively used to control epidemics of any disease or condition and to meet other health emergencies or problems.

Id. § 243(c)(1).

34. *Id.* § 243(c)(2). “The Secretary may, at the request of the appropriate State or local authority, extend temporary (not in excess of six months) assistance to States or localities in meeting health emergencies of such a nature as to warrant Federal assistance.” *Id.* The statute is unclear as to exactly what emergency would “warrant Federal assistance,” but DHHS regulations provide some guidance at 42 C.F.R. § 70.2.

35. 42 U.S.C. § 264(a):

The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.

Id. Exec. Order No. 13,295, 68 Fed. Reg. 17,255 (Apr. 9, 2003) (adding Severe Acute Respiratory Syndrome (SARS) to the list of communicable diseases for which the Secretary can order a quarantine); 42 C.F.R. §§ 70.5, 70.6 (2002) (DHHS regulations authorizing the Secretary to implement and enforce a quarantine). 42 U.S.C. § 264(d) provides for the actual detention of infected individuals:

[R]egulations prescribed under this section may provide for the apprehension and examination of any individual reasonably believed to be infected with a communicable disease in a communicable stage and (1) to be moving or about to move from a State to another State; or (2) to be a probable source of infection to individuals who, while infected with such disease in a communicable stage, will be moving from a State to another State. Such regulations may provide that if upon examination any such individual is found to be infected, he may be detained for such time and in such manner as may be reasonably necessary.

Id. Note that this is the pre-2002 version of § 264(d). The subsection was significantly amended by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. For a thorough discussion of quarantine powers and the many legal issues raised by their implementation, see Michael Greenberger, *The Law of Counterterrorism Wants You!*, 35 MD. B.J. 10, 12–13 (Dec. 2002); Lorena Matei, Note, *Quarantine Revision and the Model State Emergency Health Powers Act: “Laws for the Common Good,”* 18 SANTA CLARA COMPUTER & HIGH TECH L.J. 433 (2002); and for a discussion on what role the military might play in quarantine enforcement, see Richard H. Kohn, *Using the Military at Home: Yesterday, Today, and Tomorrow*, 4 CHI. J. INT’L L. 165 (2003).

36. 42 U.S.C. § 266 (2000).

This broad statutory grant of powers made DHHS the logical choice for centralizing bioterrorism preparedness and response capabilities, but the agency itself is not structured to perform this function.³⁷ Instead, DHHS contains five federal agencies that work on differing bioterrorism issues.³⁸ Of these five, the Centers for Disease Control and Prevention (“CDC”) and the Office of Emergency Preparedness (“OEP”) play the greatest role in preparation for, and response to, a bioterrorism attack, while the Food and Drug Administration (“FDA”) and others focus mainly on research.³⁹

b. Centers for Disease Control and Prevention

In 1998, the CDC began specifically addressing the public health threats of a bioterrorism event by creating the “Bioterrorism Preparedness and Response Program” under the direction of DHHS.⁴⁰ The purposes of this program were to enhance public health capacity at all levels of government, develop a national pharmaceutical stockpile, and study aspects of a bioterrorism event.⁴¹ The National Center for Infectious Diseases administers the program and oversees research efforts on biological agents, health surveillance activities, and epidemiological response actions.⁴²

37. See *infra* notes 38–39 and accompanying text.

38. FEDERAL RESEARCH AND PREPAREDNESS ACTIVITIES, *supra* note 10, at 48. The five agencies are: (1) the Agency for Healthcare Research and Quality (AHRQ), (2) the Food and Drug Administration (FDA), (3) The National Institutes of Health (NIH), (4) the Centers for Disease Control and Prevention (CDC), and (5) the Office of Emergency Preparedness (OEP). *Id.* This diffuse arrangement of bioterrorism activities within a single agency fosters the same fragmentation that has the potential to hinder the collective response of all federal agencies to a bioterrorism event. See RESPONSE TO ANTHRAX INCIDENTS OF 2001, *supra* note 11, at 40 (DHHS comments on GAO report indicating that DHHS’s role in responding to anthrax attacks should not be downplayed in light of the CDC’s efforts; “The [GAO] could enhance the utility of the report by making explicit that the CDC role, invaluable as it was, is only part of the story.” (emphasis added)).

39. FEDERAL RESEARCH AND PREPAREDNESS ACTIVITIES, *supra* note 10, at 54–59. THE AHRQ, the FDA, and the NIH are mostly involved in the research end of bioterrorism, while the CDC and the OEP focus on preparedness and response capabilities. *Id.* However, with the passage of the Bioterrorism Response Act the FDA assumed new duties in protecting the nation’s food supply. See Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, §§ 301–36, 116 Stat. 594 (2002).

40. Centers for Disease Control and Prevention, *Programs in Brief: Bioterrorism and Public Health Preparedness*, at <http://www.cdc.gov/programs/bt.htm> (last reviewed June 23, 2004). Although created in 1998, the first time this program was put into effect was the onset of the anthrax attacks of 2001. *Id.*

41. FEDERAL RESEARCH AND PREPAREDNESS ACTIVITIES, *supra* note 10, at 49 (noting that as of fiscal year 2001 the program had focused on assisting states with emergency planning, enhancing laboratory capacity and disease surveillance at all levels of government, and improving communications and training for responders).

42. Centers for Disease Control and Prevention, *National Center For Infectious Diseases: About*

In 1999, the CDC was charged with creating the National Pharmaceutical Stockpile (“NPS”)⁴³ “to provide a re-supply of large quantities of essential medical material to states and communities during an emergency within twelve hours of the federal decision to deploy.”⁴⁴ These “12-hour push packs” contain antidotes, antibiotics, and other life-saving materials, and are stored in secure warehouses in non-disclosed strategic locations.⁴⁵ The decision to deploy the assets of the NPS starts with a state governor’s office directly seeking the release of the push packs from the CDC.⁴⁶ The CDC then decides the appropriate course of action after consulting with other federal officials.⁴⁷ Finally, the NPS is bolstered by the Vendor Managed Inventory System (“VMI”), which provides additional medical supplies, pharmaceuticals, and medical equipment within twenty-four to thirty-six hours after the vendors are notified of a need.⁴⁸

Also in the summer of 1999, the CDC launched the Laboratory Response Network (“LRN”) in response to Presidential Decision Directive 39.⁴⁹ The LRN is a multi-level system designed to link first-responder labs

the Center, at <http://www.cdc.gov/ncidod/about.htm> (last reviewed Nov. 10, 2003).

43. The National Pharmaceutical Stockpile Program became the Strategic National Stockpile (SNS) with the passage of the Bioterrorism Response Act of 2002, Pub. L. No. 107-188, § 121, 116 Stat. 594, 611-613 (2002). In addition, the Homeland Security Act of 2002 transferred the power to set goals for the stockpile and manage actual distribution from the CDC to the Department of Homeland Security, Pub. L. No. 107-296, § 503(b), 116 Stat. 2135, 2213 (2002).

44. Centers for Disease Control and Prevention, *The Strategic National Stockpile*, at <http://www.bt.cdc.gov/stockpile/index.asp> (last modified Feb. 10, 2005) [hereinafter *The Strategic National Stockpile*] (discussing the “mission” of the SNS as mandated by Congress and DHHS).

45. *Id.* The “12-hour push packs” are designed to be deployed to any location in the continental United States within twelve hours of the decision to activate the NPS. *Id.* The CDC also deploys a team of experts with the push packs called the Technical Advisory Response Unit (TARU) that escorts the packs to the site and provides aid to state and local officials in distributing and maximizing the supplies. *Id.* The first time the CDC deployed push packs was on September 11, 2001. Association of State & Territorial Health officials (Kristine Maxymiv), *National Pharmaceutical Stockpile Program Responds to Terrorist Attacks and Florida Anthrax Cases*, at http://www.astho.org/templates/display_pub.php?pub_id=655 (last visited Mar. 1, 2005). The agency delivered fifty tons of medical supplies to New York City just seven hours after the World Trade Center Towers collapsed. *Id.*

46. *The Strategic National Stockpile*, *supra* note 44.

47. Before passage of the Homeland Security Act, the Director of the CDC was in charge of this decision; however, after the establishment of the Department of Homeland Security (DHS), the CDC must now share this decision-making authority with the DHS. *Id.*

48. *Preventing and Responding to Bioterrorism Threats: Hearing Before the Subcomm. on Health of the House Comm. on Veterans Affairs*, 107th Cong. (2002), available at <http://www.cdc.gov/washington/testimony/bt041002.htm> (testimony of Dr. Kevin Yeskey, M.D., Director of CDC’s Bioterrorism Preparedness and Response Program) (noting that the VMI is a part of “NPS[’s] . . . two-tier response.”). However, if the biological agent is well-defined, CDC may use VMI as its first choice because it would be able to request specific pharmaceuticals instead of sending the pre-made push-packs. *The Strategic National Stockpile*, *supra* note 44.

49. Centers for Disease Control and Prevention, *Summary on the Laboratory Response Network*,

in hospitals and other local institutions with state public health and crime labs and major federal laboratories, including the CDC, Department of Defense, and Department of Agriculture.⁵⁰ One central and continuing problem in addressing a bioterrorism event is providing local responders with enough information about the agent so they can choose the appropriate response plan.⁵¹ The LRN is an attempt to solve this problem by providing local “sentinel” labs with a direct link to core federal “reference” laboratories so specimens can be accurately and quickly identified by the foremost public health experts.⁵² Like many other CDC response systems, the LRN’s first real test came during the anthrax attacks of 2001 when the network tested between 125,000 and 150,000 clinical specimens and environmental samples for *Bacillus anthracis*.⁵³

Due to the need for a multi-government and multi-agency response to a bioterrorism event, communication capacity is one of the most important aspects of the CDC’s response role.⁵⁴ To meet the challenge of disseminating and receiving information from a vast number of local and state agencies, the CDC developed the Health Alert Network (“HAN”).⁵⁵ The network consists of high-speed internet connections for state and local officials that are dedicated to the transfer of health alerts, disease data,

(Apr. 17, 2002), at <http://www.cdc.gov/cic/functions-specs/function4Docs/nLRNvision-summary.doc> [hereinafter *Summary on the LRN*]; see Presidential Decision Directive 39, *infra* note 91.

50. *Summary on the LRN*, *supra* note 49. Hospitals typically have clinical microbiology labs that do not have the capacity or the ability to handle dangerous pathogens, thus, the LRN gives them secure access to larger state and metropolitan labs that have the ability to identify specific agents used in a bioterrorism event. *Id.* These labs are then supported by the major federal agencies with laboratory capability, including the Department of Energy’s Lawrence Livermore National Laboratory, the National Institutes for Health’s Office of Research Services, the Department of Justice’s FBI crime labs, and the EPA’s Office of Research and Development. *Id.*

51. RESPONSE TO ANTHRAX INCIDENTS OF 2001, *supra* note 11, at 15–16 (describing how hospitals in the epicenters of the anthrax attacks needed immediate information on how to identify inhalational anthrax so doctors could initiate the proper treatment).

52. Centers for Disease Control and Prevention, *Facts About the Laboratory Response Network*, at <http://www.bt.cdc.gov/lrn/factsheet.asp> (last modified Aug. 11, 2004). There are about 25,000 “sentinel” laboratories in the LRN that monitor the local population, initially handle a biological agent and ensure that it is sent to the proper “reference” laboratory. *Id.* There are 120 “reference” labs in the LRN that house the most advanced technology in handling deadly pathogens and perform the “rule-out, rule-in” analysis needed in agent identification; this includes the CDC’s own Rapid Response and Advanced Technology Laboratory. *Id.*

53. *Summary on the LRN*, *supra* note 49; see *supra* note 18 for a brief discussion of agents that could be used in a bioterrorist attack.

54. RESPONSE TO ANTHRAX INCIDENTS OF 2001, *supra* note 11, at 24–25 (discussing the CDC’s concurrent roles of leading the public health response and collecting and analyzing data to communicate specific guidance information to local responders, the media, and the public).

55. Centers for Disease Control and Prevention, *Public Health Practice Program Office: Health Alert Network Fact Sheet*, at <http://www.phppo.cdc.gov/han/FactSheet.asp> (last reviewed Jan. 23, 2002).

treatment guidelines, and the secure transmittal of disease surveillance and other sensitive data.⁵⁶ The CDC relied on the HAN during the anthrax attacks to distribute guidance to local officials assessing the threat of inhalation anthrax via the mail.⁵⁷ However, the system was only marginally effective as many local jurisdictions received incomplete data.⁵⁸

*c. Office of Emergency Preparedness*⁵⁹

The OEP is primarily responsible for two major programmatic initiatives for preparedness, the National Disaster Medical System (“NDMS”) and the Metropolitan Medical Response System (“MMRS”).⁶⁰ The NDMS is a public-private partnership of medical providers that strives to ensure the availability of adequate medical personnel and resources during any event that overwhelms local health care systems.⁶¹ The NDMS primarily accomplishes this goal via the organization and deployment of Disaster Medical Assistance Teams (“DMATs”).⁶² DMATs are made up of groups of thirty-five health professionals who are able to deploy to the scene of a disaster with enough supplies to sustain

56. *Id.*

57. RESPONSE TO ANTHRAX INCIDENTS OF 2001, *supra* note 11, at 25. The HAN played a vital role in disseminating new information during the attacks. *Id.* After the first cases were discovered, the CDC did not believe there was a risk of contracting inhalational anthrax from a sealed letter, therefore the CDC did not recommend antibiotic treatment for those individuals exposed only to sealed letters. *Id.* However, after a postal worker in Washington, D.C. contracted inhalational anthrax after exposure to a sealed envelope containing anthrax spores, the CDC was able to immediately amend its guidance using HAN. *Id.*

58. *Id.* All of the state health departments were connected to HAN during the attacks, but only thirteen of those states had similar connections to their local health departments. *Id.* Thus, CDC’s guidance did not reach many local areas, and many of the areas that did receive the messages only received some of the necessary information. *Id.* at 25–26.

59. The OEP has since been renamed the “Office of Emergency Response,” within the Office of the Assistant Secretary for Public Health Emergency Preparedness (OASPHEP) (created under DHHS by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002). 67 Fed. Reg. 48,903 (July 26, 2002). However, the Homeland Security Act of 2002 moved the OASPHEP under the Department of Homeland Security. *See* Homeland Security Act of 2002, Pub. L. No. 107-296, §§ 501, 503(5), 116 Stat. 2135 (2002).

60. FEDERAL RESEARCH AND PREPAREDNESS ACTIVITIES, *supra* note 10, at 63–66. The Homeland Security Act moved both the NDMS and the MMRS under the Department of Homeland Security. *See* § 502, 116 Stat. at 2135.

61. FEDERAL RESEARCH AND PREPAREDNESS ACTIVITIES, *supra* note 10, at 63–65. The other federal agencies involved in this partnership are: DHHS, Department of Defense, Department of Veterans Affairs, and the Federal Emergency Management Agency. *Id.* at 63. “The overall purpose of the system is to establish a single, integrated national medical response capability to (1) assist state and local authorities . . . with the . . . health effects of major peacetime disasters and (2) . . . support . . . the military and VA medical systems in caring for casualties.” *Id.*

62. *Id.* at 64–65.

themselves for seventy-two hours of providing medical care in temporary facilities.⁶³ In addition, the NDMS contains four National Medical Response Teams (“NMRTs”) that specialize in caring for victims of a weapon of mass destruction.⁶⁴ Three of these teams are deployable anywhere in the United States with enough medical supplies and pharmaceuticals to treat 5,000 people.⁶⁵ However, the GAO indicated in a 2001 report that most of their supplies focused on preparedness for a chemical attack.⁶⁶ In the wake of the September 11th attacks, several DMATs were deployed to the World Trade Center site and to the Pentagon to provide immediate assistance.⁶⁷

The MMRS began in 1996 and is basically a contractual arrangement between the OEP and local governments to develop and coordinate local medical response in disaster situations.⁶⁸ This system functions to help first responders coordinate their activities in the period before federal resources can be mobilized.⁶⁹ Unlike the NDMS, the focus of the MMRS is specifically tailored to help local communities cope with the use of a weapon of mass destruction.⁷⁰

2. *Prior Congressional Action*

In the years before the threat of a bioterrorism attack morphed into reality in the fall of 2001, Congress acted on several pieces of legislation to address terrorism preparedness.⁷¹ While Congress did not pass a bill

63. PHS-1 Disaster Medical Assistance Team, *Public Health Service Disaster Medical Assistance Team (PHS-1 DMAT) website: NDMS and DMAT*, at <http://teams.fema.gov/dmat/about/ndms.html> (last visited Feb. 27, 2005). DMATs can also specialize in a particular service like burn care, mental health, or Disaster Mortuary Operational Response Teams (DMORTs) that provide victim identification and mortuary services. FEDERAL RESEARCH AND PREPAREDNESS ACTIVITIES, *supra* note 10, at 64.

64. FEDERAL RESEARCH AND PREPAREDNESS ACTIVITIES, *supra* note 10, at 64.

65. *Id.*

66. “[T]hese stockpiles are primarily for treating victims of a chemical weapon.” *Id.*

67. *Id.* at 64 n.5 (noting that the initial DMAT units included more than 300 medical and mortuary personnel). For a detailed chronology of one DMAT deployment to the World Trade Center site following the September 11th attacks, see PHS-1 Disaster Medical Assistance Team, *History of NY WTC Deployment*, at <http://teams.fema.gov/dmat/news/events/WTC/history.htm> (last visited Feb. 27, 2005).

68. FEDERAL RESEARCH AND PREPAREDNESS ACTIVITIES, *supra* note 10, at 65 (noting that, as of 2001, OEP had contracted with ninety-seven local areas to develop response capabilities).

69. The Metropolitan Medical Response System, *About MMRS*, at <http://mmrs.fema.gov/Main/About.aspx> (last visited Feb. 27, 2005) (noting that the system is designed to coordinate “first response” personnel planning in the first forty-eight hours of a public health crisis).

70. *See id.*

71. *See* Counter-Terrorism Training and Resources for Law Enforcement, *Legislation*, at <http://www.counterterrorismtraining.gov/leg/index.html> (last visited Nov. 14, 2003) (providing a

specifically dealing with bioterrorism, several bills dealt with the issue under provisions for domestic preparedness.⁷² Congress included one of the most important bioterrorism preparedness provisions in the Antiterrorism and Effective Death Penalty Act of 1996 (“AEDPA”).⁷³ Section 511 of the AEDPA achieved two very important things: (1) it made it a crime to attempt to obtain biological agents that could be used as weapons⁷⁴ and (2) it authorized the regulation of biological agents that “pose a severe threat to public health and safety.”⁷⁵ One of the motivating forces behind passage of the AEDPA was an incident where an individual surreptitiously attempted to mail-order strains of plague from a biological agent supply company.⁷⁶ Federal officials apprehended the individual, but had no legal means to charge him with a crime other than mail fraud.⁷⁷ Thus, the AEDPA amended the U.S. Criminal Code to make any attempt, threat, or conspiracy to attempt or threaten to obtain any biological agent for “use as a weapon” a crime punishable by up to life in prison.⁷⁸

To further address this glaring loophole in federal law, the AEDPA ordered the Secretary of DHHS to compile a list of all biological agents that have “the potential to pose a severe threat to public health and safety”;

comprehensive list of current and past legislation affecting counter-terrorism strategies and efforts); Library of Congress THOMAS Legislative Information Network, *Legislation Related to the Attack of September 11, 2001*, at <http://thomas.loc.gov/home/terrorleg.htm> (last visited Nov. 14, 2003) (providing a list of all terrorism-related legislation introduced in the wake of September 11th through the conclusion of the 107th Congress).

72. For example, Congress included the Defense Against Weapons of Mass Destruction Act (also referred to as the Nunn-Lugar-Domenici Amendments) in the National Defense Authorization Act for fiscal year 1997. *See* National Defense Authorization Act for FY 1997, Pub. L. No. 104-201, 110 Stat. 2422 (1996). Title XIV, Subtitle A “Domestic Preparedness” of the Defense Authorization Act authorized the Department of Defense to undertake measures to coordinate and assist civilian response to a biological or chemical attack. *Id.* These provisions eventually led to the formation of the MMRS under the OEP and greatly enhanced the capabilities and cooperation of first responders after an attack. *See supra* notes 68–69.

73. Antiterrorism and Effective Death Penalty Act of 1996, Pub. L. No. 104-132, 110 Stat. 1214 (1996).

74. § 511(b), 110 Stat. at 1284 (codified at 42 U.S.C. § 262).

75. § 511(d)-(f), 110 Stat. at 1284-85 (codified at 42 U.S.C. § 262).

76. Centers for Disease Control and Prevention, *Backgrounder, The Select Agent Rule* (Dec. 9, 2002), at <http://www.cdc.gov/od/oc/media/pressrel/b021210.htm> [hereinafter *The Select Agent Rule*].

77. *Id.*

78. § 511(b), 110 Stat. at 1284 (amending 18 U.S.C. § 175(a)) (codified at 42 U.S.C. § 262). The current version of 18 U.S.C. § 175(a) states:

Whoever knowingly develops, produces, stockpiles, transfers, acquires, retains, or possesses any biological agent, toxin, or delivery system for use as a weapon, or knowingly assists a foreign state or any organization to do so, or attempts, threatens, or conspires to do the same, shall be fined under this title or imprisoned for life or any term of years, or both.

18 U.S.C. § 175(a) (2000).

promulgate regulations to ensure the safe transfer of harmful agents; and establish guidelines for laboratory facilities so as to prohibit unauthorized access by terrorists and criminals.⁷⁹ In response, the Secretary of DHHS turned to the CDC for the promulgation of a final rule.⁸⁰ The CDC developed a list of thirty-eight “select agents”⁸¹ that posed a significant risk to the public and concurrently established a registration program for laboratories that wished to transfer them.⁸² The final rule provided that commercial suppliers, government agencies, universities, and private companies had to register with the CDC before they could transfer any of the select agents and certify that their lab had sufficient safety measures in place to handle the pathogen.⁸³ The rule also required that a “responsible facility official” must verify the contents of each shipment so the CDC could more effectively track each pathogen and notify federal law enforcement if discrepancies occurred.⁸⁴ The rule enforced these provisions by providing for federal criminal and civil penalties for individuals that refused to comply.⁸⁵ However, while this rule allowed the CDC to track agents that were sent between registered facilities, it provided no means of accounting for possible bioterrorism agents that were stored in labs across the country.⁸⁶ In addition, the CDC’s reluctance to force regulation on their peers in the scientific community—combined with the agency’s concerns about the rule’s possible impact on research capabilities—left enforcement in question.⁸⁷

79. § 511(d)-(f), 110 Stat. at 1284 (codified at 42 U.S.C. § 262).

80. *The Select Agent Rule*, *supra* note 76; *see also* 61 Fed. Reg. 29,327 (June 10, 1996) (notice of proposed rule entitled “Additional Requirements for Facilities Transferring or Receiving Select Infectious Agents”).

81. Select Agent “means a microorganism (virus, bacterium, fungus, rickettsia) or toxin . . . includ[ing]: Genetically modified microorganisms or genetic elements from organisms” and organisms containing genetic material from a select agent. 42 C.F.R. § 72.6(j) (2004).

82. 42 C.F.R. § 72.6. “This final rule and associated criminal penalties apply only to interstate and intrastate transfer of these agents. *Possession* of these agents is outside the scope of this final rule.” 61 Fed. Reg. 55,194 (Oct. 24, 1996) (emphasis supplied); Centers for Disease Control and Prevention, *Select Agent Program*, available at <http://www.cdc.gov/od/sap> (last reviewed Mar. 1, 2005).

83. 42 C.F.R. § 72.6(a)-(c).

84. *Id.* § 72.6(e)(1) (“Prior to transferring any agent covered by this part, the transferor’s responsible facility official must verify with the requestor’s responsible facility official, and as appropriate, with the registering entity: (i) That the requesting facility retains a valid, current registration; [and] (ii) That the requestor is an employee of the requesting facility.”).

85. *Id.* § 72.7 (stating that an individual that makes a “false, fictitious, or fraudulent statement or representation on . . . forms required in the part for registration of facilities or for transfers of select agents” is subject to a fine and five years in jail).

86. *See* 42 C.F.R. § 72.6(a)-(c) (note the absence of requirements for possession of select agents).

87. *The Threat of Bioterrorism in America: Assessing the Adequacy of Federal Law Relating to Dangerous Biological Agents: Hearing Before the Subcomm. On Oversight and Investigations of the*

3. *Response Planning*

The Federal Response Plan is the key document for the implementation of federal government resources in the event of a terrorist attack.⁸⁸ Originally drafted by the Federal Emergency Management Agency in 1992 under the Stafford Act,⁸⁹ it defines the responsibilities of the twenty-seven federal agencies involved in responding to a major disaster.⁹⁰ In 1995, President Clinton further refined the plan's focus on terrorism response by issuing Presidential Decision Directive 39 ("PDD-39").⁹¹ The most significant aspect of this Directive was the clear designation of Federal Lead Agency ("FLA") responsibilities to the Department of Justice ("DOJ") in responding to an attack involving weapons of mass destruction.⁹² As outlined in PDD-39, the DOJ's responsibility, as delegated to the FBI, is to act as the FLA for "Crisis Management" under the Federal Response Plan and it can choose to involve only those federal agencies it deems necessary to provide assistance or guidance in responding.⁹³ PDD-39 places the Federal Emergency Management

House Comm. On Commerce, 106th Cong. 25-27 (1999) (prepared statement of Stephen M. Ostroff, M.D., Associate Dir. Of Epidemiologic Science, Nat'l Center for Infectious Diseases, Centers for Disease Control).

CDC has worked extensively with our partners in the scientific community to develop and implement the regulation, even though we believe the regulatory framework has adversely impacted the longstanding working relationships with some of these partners.

....

... We believe it is critical for safeguards to be carefully balanced against other important societal concerns, notably the need to support and encourage legitimate and important research involving these substances.

Id.

88. See *Department of Health and Human Services' Role at the NDPO*, THE BEACON-NAT'L DOMESTIC PREPAREDNESS NEWSLETTER (National Domestic Preparedness Office, Washington, D.C.) June 15, 1999, at 7.

89. Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. § 5121, et seq. (2000).

90. *Foreword to INTERIM FEDERAL RESPONSE PLAN*, *supra* note 31 ("The Federal Response Plan (FRP) . . . implements the Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended, to assist state and local governments when a major disaster or emergency overwhelms their ability to respond effectively to save lives."). In 1999, FEMA completed a revised version of the FRP that substantially updated the original 1992 version. See *id.* By contrast, the Interim 2003 FRP reflects mostly terminology changes due to the passage of the Homeland Security Act of 2002 that moved FEMA under the DHS. *Id.* FEMA considers the January 2003 FRP "interim" until DHS can complete a thorough review. *Id.*

91. Presidential Decision Directive 39, signed June 21, 1995, available at <http://www.ojp.usdoj.gov/odp/docs/pdd39.htm> (last visited Feb. 27, 2005) (abstract of classified document). PDD-39 is a classified document because it assigns specific missions to federal agencies responding to a terrorism threat or attack. *Id.*

92. *Id.*

93. *Id.* Crisis Management is defined as "measures to identify, acquire, and plan the use of

Agency⁹⁴ in charge of “Consequence Management,” defined broadly as protecting health and safety and restoring essential government services after an attack.⁹⁵ The other four agencies listed as signatories to the “Terrorism Incident Annex” portion of the Federal Response Plan are charged with providing technical support to the overall channeling of resources by the DOJ.⁹⁶ Thus, in the case of a bioterrorism attack, DHHS and the CDC—the agencies with the greatest expertise and resources in managing a public health emergency—may be reduced to a supporting role.⁹⁷ Some experts have criticized this arrangement and questions remain about the FBI’s ability to effectively respond to a bioterrorism event.⁹⁸

C. Recognizing Problems in Federal Preparedness and Response

The anthrax attacks of 2001 strained the federal framework designed to prepare and respond to bioterrorism attacks and exposed several underlying weaknesses that spurred congressional action.⁹⁹

First, the lack of a singular piece of legislation or federal statute addressing federal bioterrorism preparedness and response activities created a funding vacuum for vital programs. Thus, simply not having a bioterrorism-focused law on the books resulted in inadequate or unfocused

resources needed to anticipate, prevent, and/or resolve a threat or act of terrorism.” FED. EMERGENCY MGMT. AGENCY, TERRORISM INCIDENT ANNEX TI-15 (2003) [hereinafter TERRORISM INCIDENT ANNEX].

94. The Interim FRP now names the DHS as the lead federal agency for consequence management, although FEMA still fulfills this role. TERRORISM INCIDENT ANNEX, *supra* note 93, at TI-3; Presidential Decision Directive 39, *supra* note 91.

95. Consequence management is defined as “measures to protect public health and safety, restore essential government services, and provide emergency relief to governments, businesses, and individuals affected by the consequences of terrorism.” TERRORISM INCIDENT ANNEX, *supra* note 93, at TI-15.

96. *Id.* at TI-1. The other signatories to the Terrorism Incident Index (in addition to DOJ/FBI and Department of Homeland Security) are: the Department of Defense, Department of Health and Human Services, Department of Energy, and the Environmental Protection Agency. *Id.*

97. According to the Terrorism Incident Annex, “[D]HHS will activate technical operations capabilities to support the Federal response to threats or acts of WMD terrorism.” *Id.* at TI-13. The Terrorism Incident Annex suggests that DHHS could activate its own Medical Services Support Plan in response to a biological attack, but still must coordinate everything through DOJ or DHS. *Id.* at TI-13. The CDC is not mentioned in the Terrorism Incident Annex.

98. *See* Sutton, *supra* note 30, at 122 (stating that “[t]he shortcomings of the FBI within the context of its current leadership in biodefense, preparedness and response have been identified to include its lack of expertise with respect to all weapons of mass destruction”).

99. *See* 147 CONG. REC. S13,902-03 (daily ed. Dec. 20, 2001) (statement of Sen. Kennedy) (“In recent weeks, a handful of anthrax cases stretched our health care system to the breaking point. A larger attack could be a disaster, and the attack of the past weeks has clearly sounded the alarm . . . and we’re not ready yet.”).

spending on a multitude of diverse civilian and military functions addressing the bioterrorism threat.¹⁰⁰

Second, as a result of a fragmented approach in developing preparedness and response activities, those agencies with the most public health expertise were not assigned leading roles relative to other agencies involved in preparing for a bioterrorist attack.¹⁰¹

Third, vital components of the federal response lacked adequate capabilities to respond to the anthrax attacks.¹⁰² For example, a GAO report analyzing the CDC's performance during the attacks found that: (1) the CDC was not ready to assume the lead in responding to a bioterrorism attack, but rather was more prepared to provide a supporting role to state and local responders; (2) the CDC had significant difficulty in communicating with other agencies and the public during the attacks; and (3) the CDC lacked specific expertise to manage the health consequences of anthrax.¹⁰³ In addition, other significant components of the federal response such as the NPS and the NDMS did not have a bioterrorism focus.¹⁰⁴ The NPS had limited capabilities with respect to deploying specific vaccinations against specific biological agents and had no program to amass the quantity of vaccine needed to respond to events such as a smallpox attack.¹⁰⁵ Similarly, the NDMS needed upgrades in training and resources to enable its personnel to provide appropriate treatment during a biological attack.¹⁰⁶

Finally, and maybe most importantly, section 511 of the AEDPA and the rule promulgated by the CDC to regulate the transfer of dangerous biological agents fell short of establishing a true tracking system of

100. See Joshua Green, *Weapons of Mass Confusion*, WASH. MONTHLY, May 2001, at 1 (discussing how Congress's rush to respond to the threat of bioterrorism after the release of sarin gas in Tokyo led to massive and uncoordinated federal spending on questionably effective military and civilian response programs).

101. See *supra* note 97 and accompanying text.

102. See 147 CONG. REC. S13,902-04 (daily ed. Dec. 20, 2001) (statement of Sen. Kennedy):

Usually, a few dozen CDC experts respond to a disease outbreak. But CDC assigned nearly 500 specialists to the anthrax attacks. One out of eight employees at CDC headquarters in Atlanta is working on the current outbreak. Staffers worked round the clock and slept in hallways and only 18 cases of actual illness was [sic] known.

Id.

103. RESPONSE TO ANTHRAX INCIDENTS OF 2001, *supra* note 11, at 5.

104. See *infra* notes 105-106.

105. See GEN. ACCT. OFF., GAO-01-666T, COMBATING TERRORISM: ACCOUNTABILITY OVER MEDICAL SUPPLIES NEEDS FURTHER IMPROVEMENT 11-12 (2001).

106. See GEN. ACCT. OFF., GAO-01-14, COMBATING TERRORISM: FEDERAL RESPONSE TEAMS PROVIDE VARIED CAPABILITIES; OPPORTUNITIES REMAIN TO IMPROVE COORDINATION 22 (2000).

dangerous pathogens.¹⁰⁷ By stopping short of requiring all those in possession of dangerous agents to register with the federal government, Congress and the CDC missed an opportunity to trace the origin of the anthrax that terrified much of the United States in 2001.¹⁰⁸

Thus, in light of these shortcomings and under public pressure to address bioterrorism legislatively, Congress proposed and enacted the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (“Bioterrorism Response Act”).¹⁰⁹

D. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Heralded as the “Nation’s first line of defense against bioterrorism,”¹¹⁰ the Bioterrorism Response Act sets forth provisions for national preparedness, enhancing controls on dangerous biological agents, protecting the safety and security of the food and drug supply, and protecting drinking water supplies from acts of terrorism.¹¹¹ Representative Billy Tauzin and Senator Ted Kennedy introduced similar versions of the Bioterrorism Response Act in their respective chambers in December of 2001¹¹² while the country was still coping with the anthrax

107. See § 511(b)-(f), 100 Stat. at 1243 (codified at 42 U.S.C. § 262 note); 42 C.F.R. § 72.6(a)-(c). Note that these provisions only covered the transfer of select agents before the passage of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

108. See David Malakoff & Martin Enserink, *New Law May Force Labs to Screen Workers*, 294 SCIENCE 971 (2001) (noting that the lack of a registration requirement for those possessing deadly biological agents caused the CDC much embarrassment in 2001 because it could not “specify how many U.S. labs might have produced the anthrax that . . . contaminated U.S. mailrooms”).

109. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (2002).

110. 148 CONG. REC. H2,838-41 (daily ed. May 22, 2002) (statement of Rep. Tauzin).

111. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (2002). Note that this Note deals with Title I and Title II of the Act concerning national preparedness and enhancing controls on dangerous biological agents, respectively. *Id.* Title III addresses protecting the safety and security of the food and drug supply, and Title IV covers protecting drinking water supplies. *Id.* Titles III and IV present topics that are beyond the scope of this Note; however, new regulations concerning food protection adopted pursuant to the Act have generated academic interest. See 21 C.F.R. § 1 (requiring all domestic and foreign food facilities that hold food for U.S. consumption to register with the FDA); 21 C.F.R. § 21 (requiring foreign food producers to give the FDA notice before importation of food into the U.S.); Nicholas Freitag, *Federal Food and Drug Act Violations*, 41 AM. CRIM. L. REV. 647, 666 (2004). For a review of the Act’s provisions affecting drinking water safety, see Varu Chilakamarri, *A New Instrument in National Security: The Legislative Attempt to Combat Terrorism Via the Safe Drinking Water Act*, 91 GEO. L.J. 927, 930–32 (2003).

112. The House version was H.R. 3448, and the Senate version S. 1765 (107th Congress). Public Health Security and Bioterrorism Preparedness and Response Act of 2002, CONGRESSIONAL INFORMATION SERVICE, LEGISLATIVE HISTORIES OF U.S. PUBLIC LAWS 2002, 113 (2002).

attacks.¹¹³ However, Congress did not adopt a final measure until June of 2002.¹¹⁴

The anthrax attacks highlighted the inherent weaknesses in the federal government's preparedness and response capabilities and provided the context for the Bioterrorism Response Act's passage.¹¹⁵ But, does the Act really address these problems? Do the provisions go far enough in reducing fragmentation and enhancing cooperation? Does it really help the federal government make us safer? These questions provide the underpinnings for the following analysis of Title I and Title II (the preparedness and response titles, respectively) of the Bioterrorism Response Act.

III. ANALYSIS

A. *Title I—National Preparedness for Bioterrorism and Other Public Health Emergencies*

1. *Addressing Bioterror at a National Level*

Section 101 of the Bioterrorism Response Act amends the Public Health Service Act to authorize the Secretary of DHHS to establish a National Preparedness Plan “building upon the core public health capabilities” already present in the statute.¹¹⁶ The section states that the plan is to have a “[n]ational approach” that coordinates all bioterrorism activities with state and local governments.¹¹⁷ Further, the Act sets out five “[p]reparedness goals” for addressing the bioterrorism threat that focus on providing “effective assistance to State and local governments.”¹¹⁸ Finally, the Act makes it clear that this section in no way expands the regulatory power of the Secretary beyond what is already authorized in the statute.¹¹⁹

113. See RESPONSE TO ANTHRAX INCIDENTS OF 2001, *supra* note 11, at 36.

114. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594, 697 (2002).

115. See *supra* notes 99–107 and sources cited therein.

116. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 101(a)(1), 116 Stat. 594, 596 (2002).

117. § 101(a)(2), 116 Stat. at 596.

118. § 101(b), 116 Stat. at 597. The five “preparedness goals” of the Act are: (1) effective assistance to state and local governments; (2) ensuring state and local governments have adequate surveillance, laboratory, medical personnel, and communications capacity; (3) development of drugs and vaccines (countermeasures) against biological agents; (4) ensuring cooperation and preventing overlap in federal, state and local activities; and (5) enhancing health facility readiness. § 101(b)(1)–(5), 116 Stat. at 597.

119. § 101(d), 116 Stat. at 598.

Section 101 provides a good illustration of the strengths and weaknesses of the Act as a whole. The section succeeds in placing the federal government at the forefront of *planning* for a bioterrorism attack via the National Preparedness Plan, but it fails in that it immediately embraces the present federalism model of the public health system and explicitly does not expand federal powers.¹²⁰ Thus, one of the lingering questions after the anthrax attacks—who will have the primary leadership role in responding to a bioterrorism attack—remains unanswered.¹²¹ This has two main consequences. First, the benefit of latching on to the existing structure is that it may avoid some of the problems associated with assigning the federal government the primary role in responding to a bioterrorism attack.¹²² This approach helps eschew the quagmire of federal bureaucratic red tape and makes the lack of federal “first responders” a non-issue.¹²³ Second, however, this maintenance of the status quo in statutory authority may make it more difficult for the federal government to fully utilize its resources.¹²⁴ Maintaining this uneasy balance among the federal, state, and local governments has the effect of slowing the flow of federal dollars to the urgent needs of the public health system¹²⁵ and

This section may not be construed as expanding or limiting any of the authorities of the Secretary that, on the day before the date of the enactment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, were in effect with respect to preparing for and responding effectively to bioterrorism and other public health emergencies.

Id.

120. James Hodge best describes the present federalism model of the public health system:

There is no central public health system in the United States. Instead, a collaborative workforce of federal, state, and local authorities work in conjunction with other inter-level agencies . . . to accomplish public health outcomes. In this system, public health roles and responsibilities of the federal, state, and local levels of government are complex and unclear.

Hodge, *Salient Issues in Public Health Law*, *supra* note 22, at 257.

121. See Sutton, *supra* note 30, at 118 (posing the question, “[w]hy does the federal government seem in such a confused state concerning the appropriate preparedness and response responsibilities?”).

122. See Hodge, *Salient Issues in Public Health Law*, *supra* note 22, at 258 (stating that “[c]hoosing to assign a primary leadership role to the federal government for responding to bioterrorism threats does have its drawbacks.”).

123. *Id.*

124. See Sutton, *Struggle to Protect States’ Sovereignty*, *supra* note 22, at 102 (stating “[w]ith the threat of bioterrorism, people are likely to expect federal preparedness for a national security threat. . . . [T]hey may be unaware that the long-held powers of the states’ governments, which have so ably protected the public since colonial times, may well prove to be an impediment to the effective role of the federal government.”).

125. In a December 2003 report, the Trust for America’s Health, a non-profit health promotion organization, found that only half the states had full access to the federal money made available by the Bioterrorism Preparedness Act of 2002 because much of the aid was “wrapped up in red tape.” SHELLEY A. HEARNE ET AL., *READY OR NOT? PROTECTING THE PUBLIC’S HEALTH IN THE AGE OF BIOTERRORISM 2* (2003).

hinders a true response plan for pathogens that cover multiple jurisdictions.¹²⁶

2. *Addressing Fragmentation*

Section 102(a) establishes the Assistant Secretary for Public Health and Emergency Preparedness (“ASPHEP”) under DHHS.¹²⁷ The section consolidates all coordination activities under the ASPHEP and brings all of DHHS’s emergency response activities that relate to bioterrorism under the ASPHEP’s control.¹²⁸ Thus, it is the assistant secretary’s job to communicate with other parts of the federal government and state and local officials.¹²⁹ Section 108 addresses coordination problems among agencies with public health responsibilities by establishing a single federal working group on bioterrorism.¹³⁰ This working group is headed by the Secretary of DHHS and its primary purpose is to coordinate twelve enumerated aspects of bioterrorism preparedness, including “clarifying the responsibilities among Federal officials . . . for related revisions of . . . the Federal response plan.”¹³¹

Obvious fragmentation and confusion within the federal government in responding to the anthrax attacks of 2001 was the major impetus for the Act’s coordination provisions.¹³² However, the Act falls short of adequately addressing these problems. First, consolidation of DHHS’ response capabilities under the ASPHEP is a logical and much needed step in an agency with the significant potential for taking a commanding role in dealing with a bioterrorism event; however, no role is outlined for the ASPHEP in dealing with the CDC—the most important arm of DHHS’ response capabilities.¹³³ This hinders communication between the CDC

126. See Sutton, *Struggle to Protect States’ Sovereignty*, *supra* note 22, at 101 (noting that it is necessary for the federal government to establish a “coordinated national response” to bioterrorism because it is impossible for the states, acting as fifty independent sovereigns, to do so).

127. § 102(a)(1), 116 Stat. at 599.

128. § 102(a)(2)(B), 116 Stat. at 599.

129. § 102(a)(2)(A)-(D), 116 Stat. at 599–600. Also, note that the ASPHEP is responsible for overseeing DHHS programs like the National Disaster Medical System and the bioterrorism activities of the CDC. *Id.*

130. § 108(a), 116 Stat. at 609; see also H.R. CONF. REP. NO. 107-481, at 110 (2002).

131. § 108(a)(1), 116 Stat. at 609-10.

132. See Stephen Labaton & Robert Pear, *Anthrax Menace Exposes Badly Coordinated Defense*, N.Y. TIMES, Oct. 18, 2001, at B7 (noting the congressional concern over lack of coordination in handling the anthrax attacks and quoting Senator Fred Thompson (R-TN) as saying, “The good news is that there are many agencies working on all of these [anthrax] issues. The bad news is that there are many federal agencies working on all of these issues.”).

133. See GEN. ACCT. OFF., GAO-04-219, CENTERS FOR DISEASE CONTROL AND PREVENTION: AGENCY LEADERSHIP TAKING STEPS TO IMPROVE MANAGEMENT AND PLANNING, BUT CHALLENGES

and the managing arm of DHHS and increases the chances that the CDC will again be on its own in coordinating a response.¹³⁴ Second, the Act fails to meaningfully address the problematic FBI-CDC relationship that crippled federal response to the anthrax attacks.¹³⁵ This omission leaves the FBI free to spearhead the response to a bioterrorism attack and effectively “freeze-out” the CDC much in the same way as it did in 2001.¹³⁶ Consequently, Congress may have spent a billion dollars to revitalize the CDC and the public health communication system,¹³⁷ but left its usefulness contingent on the willingness of the FBI to share information during an attack. This situation is one that puts too much faith in an agency that has struggled to understand bioterrorism and has been heavily criticized for hoarding critical information in the past.¹³⁸ Finally, establishing a unified working group for all federal agencies generates the correct approach to the problem, and making review of the FRP a priority poses the opportunity for DHHS via the CDC to play a larger role.¹³⁹

REMAIN 5 (2004). *But cf.* Katherine Eban, *Waiting for Bioterror: is our public health system ready?*, THE NATION, Dec. 9, 2002, at 11 [hereinafter Eban, *Waiting for Bioterror*] (noting that the current ASPHEP, Jerome Hauer, does keep in contact with the director of the CDC).

134. The CDC was heavily criticized for poor performance during the anthrax attacks of 2001 and was not prepared to handle the laboratory and diagnostic work associated with a limited number of anthrax exposures. *See* Eban, *Waiting for Bioterror*, *supra* note 133, at 13 (stating that “[f]or three weeks . . . Americans seeking clear information from the CDC were out of luck”).

135. Marc Siegel, *The Anthrax Fumble: Bureaucratic Timidity and Turf Battles Needlessly Put Many Americans at Risk*, THE NATION, Mar. 18, 2002, at 14.

136.

In October, when the first anthrax-laden envelopes were received, the FBI froze the Centers for Disease Control and Prevention out of the high-profile investigation, according to CDC officials. That meant half the country’s experts on bio-attacks and the only scientists with a special interest in public health were kept out of the loop.

Id.

137. *See* § 103(c)(1)(A), 116 Stat. at 603. “In FY 2003, the CDC is providing \$1.03 billion to continue upgrading state and local capacity to prepare for bioterrorism and other public health emergencies.” *Federal Biodefense Readiness: Hearing Before the Senate Comm. on Health, Education, Labor and Pensions*, 108th Cong. 34 (2003) (statement of Julie L. Gerberding, M.D., M.P.H., Director of the CDC).

138. *See* Sutton, *supra* note 30, at 122–23 (noting that—even after it was discovered that the Florida anthrax cases were terrorist related—the FBI allowed the destruction of over 100 vials of different anthrax strains collected at Iowa State University that could have been used to identify the source of the anthrax via DNA testing); William J. Broad et al., *Experts See F.B.I. Missteps Hampering Anthrax Inquiry*, N.Y. TIMES, Nov. 9, 2001, at A1; Marilyn Werber Serafini, *Who Goes, Who Stays?*, NAT’L JOURNAL, Sept. 21, 2002, at 2706, 2707 (quoting a congressional aide regarding the FBI-CDC relationship, “you just don’t have the kind of coordination that’s necessary to fight bioterrorism . . . [h]ow can the public health community work with the FBI? It’s critical that we do, but otherwise it’s a joke. The FBI isn’t that capable on its own.”).

139. *See supra* notes 90–97. The CDC is not currently a part of the Federal Response Plan, even though it would play a central role in any type of bioterrorism event.

However, with no reporting provisions, there is little incentive to generate hard and fast solutions to fragmentation problems.¹⁴⁰

3. *Upgrading the Centers for Disease Control and Prevention*

Section 103 states that “Congress finds that the Centers for Disease Control . . . has an essential role in . . . combating public health threats and requires secure and modern facilities, and . . . improved capabilities related to bioterrorism.”¹⁴¹ To upgrade the CDC labs, the section authorizes \$300 million in appropriations for building new facilities and renovating old ones.¹⁴² To improve capacity, the section gives the Secretary of DHHS power to “officially” establish the HAN as the main system for surveillance and communication between federal, state, and local public health officials, private laboratories, hospitals, and personnel of other health care facilities.¹⁴³

In enacting section 103, Congress did two very important things. First, it gave the CDC the contracting power and the funding to procure a much-needed facelift and to provide security for labs that hold the most dangerous pathogens in the world.¹⁴⁴ Second, Congress recognized the “essential role” that the CDC must play in preparedness and response by both literally stating it and providing authorizing language for CDC capacity.¹⁴⁵ This language is seemingly insignificant, but it gives the CDC a very important seat at the table when essential funds are appropriated for bioterrorism.¹⁴⁶ However, while the Act provides funding for *facilities* and *communication networks*, it ignores the need for expanding the *biodefense workforce* at the CDC.¹⁴⁷ One recent report noted that 44.6% of the CDC

140. See § 108(a), 116 Stat. at 610 (note the absence of reporting requirements).

141. § 103(a)(1), 116 Stat. at 603.

142. § 103(a)(2)(A), 116 Stat. at 603; § 103(c)(1)(A), 116 Stat. at 603.

143. § 103(b)(1), 116 Stat. at 603. Subsection 103(b)(2) also requires that this system be secure, and provide for the timely transmission of essential information concerning a bioterrorism attack. *Id.* § 103(b)(2).

144. See 148 CONG. REC. H2,839 (daily ed. May 22, 2002) (statement of Rep. Linder) (“[T]he CDC is a group of world class intellects in a Third World facility. It has no security.”); Judith Miller, *New Biolabs Stir a Debate Over Secrecy and Safety*, N.Y. TIMES, Feb. 10, 2004, at F1 (noting that security at the CDC has been tightened over concerns about the deadly biological agents housed there).

145. § 103(a)(1), 116 Stat. at 603.

146. See *supra* note 100.

147. The only provision that somewhat addresses potential shortfalls in trained health-care professionals for biodefense is section 106(a), “The Secretary may make awards of grants and cooperative agreements to appropriate public and nonprofit private health or educational entities . . . for the purpose of providing low-interest loans, partial scholarships, partial fellowships, revolving loan funds, or other cost-sharing forms of assistance for the education and training of individuals in any category of health professions for which there is a shortage.” § 106(a), 116 Stat. at 607-08.

employees with medical backgrounds and 47% with biological knowledge would be eligible to retire by fiscal year 2008.¹⁴⁸ The Act overlooks these troubling statistics and the impacts are likely to be severe. First, the CDC was stretched thin during the anthrax attacks because it lacked expertise in dealing with agents of bioterrorism and—regardless of facilities—a sharp decline in biodefense talent will only make the problem worse by understaffing key positions.¹⁴⁹ Second, once employees are lost to retirement or the private sector, the government is at a disadvantage in hiring new workers in the field because of the lack of competitive compensation and promotion opportunities.¹⁵⁰ Finally, the Act's failure to focus on human-capital needs makes it less likely that the CDC will be able to adequately fund human resources.¹⁵¹ This makes it difficult to assess the weaknesses in biodefense staffing within the Agency and to locate qualified persons for those positions.¹⁵² Thus, by failing to address this imminent loss of human infrastructure, the Act nearly undermines the goal of truly “revitalizing” the CDC.

4. *Establishing the NDMS and the SNS*

Section 102(b) maintains the NDMS's collaborative approach among federal, state, and private entities, and gives the Secretary wide latitude to activate the NDMS when “the Secretary has determined that a location is

148. THE P'SHIP FOR PUB. SERV., *HOMELAND INSECURITY: BUILDING THE EXPERTISE TO DEFEND AMERICA FROM BIOTERRORISM* 18 (2003). This report estimated that the CDC could lose as many as 1,500 personnel with medical experience by 2008. *Id.*

149. See RESPONSE TO ANTHRAX INCIDENTS OF 2001, *supra* note 11, at 5; THE P'SHIP FOR PUB. SERV., *supra* note 148, at 12 (“The anthrax attack, a small scale attack according to most biodefense experts, stretched our resources to capacity because the limited supply of biodefense talent available to CDC has diminished in recent years . . . [T]he CDC may employ only one to three experts in any given disease specialty.”).

150. This is a problem plaguing almost all federal agencies and specifically those like the CDC where the personnel they need to employ in biodefense (doctors, disease experts, etc.) can command much larger compensation in academia or in the private sector. GEN. ACCT. OFF., GAO-03-120, *HIGH RISK SERIES: STRATEGIC HUMAN CAPITAL MANAGEMENT* 3, 14 (2003).

151. See THE P'SHIP FOR PUB. SERV., *supra* note 148, at 20 (“Since 1992, human resource support to agencies government-wide has declined by approximately 27 percent, and by as much as nearly 50 percent in some biodefense agencies.”).

152. One DHHS employee recently remarked,

There are simply not enough human resources professionals to perform the personnel work of the agency. We not only hire a lot of employees, but we must successfully screen a large number of applications to select the best. Unfortunately, we do not have enough human resources professionals with the scientific or technical understanding needed to provide managers with strategic advice or assistance.

Id.

at risk of a public health emergency.”¹⁵³ In addition, the section gives intermittent employees of the NDMS qualified immunity under the Federal Tort Claims Act while they are performing health-related functions, and gives them some of the same employment rights as military personnel while deployed by the Secretary.¹⁵⁴

Section 121 formally establishes the Strategic National Stockpile (“SNS”) and authorizes the Secretary of DHHS to maintain the SNS “to provide for the emergency health security of the United States . . . in the event of a bioterrorist attack or other public health emergency.”¹⁵⁵ But, most importantly, section 121(b)(1) requires that the SNS contain enough smallpox vaccine, as determined by the Secretary of DHHS, “to be sufficient to meet the health security needs of the United States.”¹⁵⁶

The NDMS and the SNS represent two of the most important programs included in federal preparedness and response that previously did not focus on bioterrorism or biological weapons readiness.¹⁵⁷ Thus, the codification of these programs under the auspices of the Bioterrorism Response Act is significant because it makes bioterrorism response a central concern. For the NDMS this means that—in setting criteria for the system under section 102(c)—the Secretary can include bioterrorism-related training for all personnel and improve expertise with respect to handling certain pathogens. For the SNS, this means the inclusion of biological agent-specific countermeasures in the actual stockpiles and considerable funding to facilitate the development of a smallpox vaccine stockpile. But, weaknesses remain that were not addressed by the Act. In April of 2003, GAO found that the planning necessary to implement the distribution of the SNS in a time of crisis was incomplete.¹⁵⁸ This situation could have been prevented by mandating “test distributions” of the system in a similar fashion as those required under section 102(b)(2)(C) of the Act for the NDMS.¹⁵⁹ However, the SNS distribution planning under section 121 is largely discretionary and without mandates that the system actually be tested.¹⁶⁰ Likewise, under the smallpox provisions of the SNS, the Act

153. § 102(b)(3)(A)(ii), 116 Stat. at 600.

154. § 102(d)(2), 116 Stat. at 601; § 102(e)(3)(A), 116 Stat. at 601.

155. § 121(a)(1), 116 Stat. at 612. Note that the “National Pharmaceutical Stockpile” was renamed the “Strategic National Stockpile.”

156. § 121(b)(1), 116 Stat. at 612.

157. See *supra* notes 105–06.

158. See INFECTIOUS DISEASE OUTBREAKS, *supra* note 20, at 25.

159. See § 102(b)(2)(C), 116 Stat. at 600.

160. The only subsection that deals with planning states, “The Secretary, in managing the stockpile . . . shall . . . (E) devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private

fails to state how the SNS will be used in conjunction with an actual vaccination program.¹⁶¹ This has had a negative effect on the most recent vaccination efforts because some states—in order to cut costs—decided to forgo vaccinating health-care workers now in reliance on the SNS for coverage if they needed it in the future.¹⁶² This sets up a dangerous situation where possibly hundreds of thousands of health-care workers would depend on the SNS for smallpox vaccinations in a very short period of time, thus making distribution to the general public more difficult.¹⁶³

B. Title II—Enhancing Controls on Dangerous Biological Agents and Toxins

Section 201 amends 42 U.S.C. § 262 to significantly tighten the regulations concerning the transfer, possession, and availability of dangerous biological agents.¹⁶⁴ Subsection (d) requires that anyone using, possessing, or transferring a select agent must register with the Secretary and that the regulations must ensure they *possess* the substance for a lawful purpose.¹⁶⁵ To restrict access to these substances, the regulation must include provisions requiring registered entities to prohibit access to anyone that does not have a need to handle the agents and to submit to the Attorney General the names and identifying information of anyone who is allowed access.¹⁶⁶ The Attorney General then screens these names to

health care infrastructure.” § 121(a)(2)(E), 116 Stat. at 612.

161. See § 121(b), 116 Stat. at 612. Note the omission of any implementation mechanisms or references to other vaccination programs.

162. See Holly Myers et al., *The Threat of Smallpox: Eradicated But Not Erased: A Review of the Fiscal Logistical and Legal Obstacles Impacting the Phase I Vaccination Program*, J. HOMELAND SEC., Feb. 2004, at 6 (noting that when states were asked to estimate how much smallpox vaccine they would need to immunize their designated health-care workers some states, “decided . . . that they would rely upon the Strategic National Stockpile should the need for more vaccine arise.”). This vaccination program was a part of President Bush’s plan to vaccinate about 450,000 “first responders” from all states. *Id.* Congress did, however, pass legislation authorizing benefits and other compensation for “first responders” who are injured by the administration of the smallpox vaccine. See Smallpox Emergency Personnel Protection Act of 2003, Pub. L. No. 108-20, 117 Stat. 638 (to be codified at 42 U.S.C. § 239).

163. See White House Press Release, *Protecting Americans: Smallpox Vaccination Program* (Dec. 13, 2002), available at <http://www.whitehouse.gov/news/releases/2002/12/20021213-1.html>.

164. See H.R. CONF. REP. NO. 107-481, at 119 (2002). The principal way in which this is accomplished is the promulgation of regulations governing the possession of any “select agents” that “pose a severe threat to public health and safety.” § 201(a)(1)(A), 116 Stat. at 637.

165. § 201(d)(1), 116 Stat. at 638. Note, however, that section 201 continues the current flexibility of the Secretary to exempt things like Botox from regulation, and exempts certain clinical and diagnostic labs from registration when they are in possession of a “select agent” contained in a laboratory specimen. See H.R. CONF. REP. NO. 107-481, at 121–22 (2002).

166. § 201(e)(2), 116 Stat. at 639.

“weed-out” anyone who is reasonably suspected of being a terrorist, is affiliated with a terrorist or criminal organization, or is a spy for a foreign government.¹⁶⁷

Section 201 is a significant step in closing the loopholes left wide open by the AEDPA.¹⁶⁸ First, it regulates the possession and use of select agents—not just the transfer of those materials.¹⁶⁹ With this regulation in place, the CDC can finally specify who has control of agents of bioterrorism, where those agents are located, and why that entity or individual possesses that type of agent.¹⁷⁰ This provides a complete tracking system that will aid the CDC in identifying particular strains or forms of an agent by making available millions of samples for comparative DNA analysis.¹⁷¹ In addition, health officials may be better able to determine whether a breach of laboratory security may endanger the surrounding community because information on the types of pathogens stored in particular labs will be readily available.¹⁷²

Second, the Act addresses the CDC’s reluctance to regulate the scientific community by delegating screening duties to the Attorney General.¹⁷³ This situation has two main benefits. One, it keeps the CDC clear of battles over access that have the potential to hurt its credibility with the largely self-governed scientific community.¹⁷⁴ Two, it makes for much more stringent enforcement as the FBI will be in charge of doing background checks and enforcing the denial of access.¹⁷⁵ This is a common sense arrangement as the CDC, like many other public health

167. § 201(e)(3)(A)-(B), 116 Stat. at 639-40. The section also provides for administrative and judicial review of persons denied access and requires information that could jeopardize national security to be reviewed *ex parte*. § 201(e)(7), 116 Stat. at 641.

168. See *supra* note 86, discussing loopholes in the AEDPA of 1996.

169. § 201(c)(1), 116 Stat. at 638.

170. Up until this point, the CDC had no way of knowing what specific pathogens a laboratory might possess unless those pathogens were transferred after the enactment of section 511 of the AEDPA and the promulgation of 42 C.F.R. § 72.6 in 1996. See 61 Fed. Reg. 29,328 (June 10, 1996) (stating that the pre-1996 regulation “does not . . . contain provisions restricting parties who may transfer these agents.”); see *supra* note 108.

171. See Sutton, *supra* note 30, at 123.

172. See *supra* notes 55, 57 and accompanying text.

173. § 201(e)(2), 116 Stat. at 639.

174. See Neil Munro, *The Bioterror Threat Is Putting Pressure on Scientists to Govern Themselves Better. Will They, or Will the Public and Politics Intervene*, NAT’L JOURNAL, Sept. 6, 2003, at 2698, 2700–02.

175. See Hodge, *Salient Issues in Public Health Law*, *supra* note 22, at 258 (stating, “Bioterrorism, by definition, is the product of criminal activity . . . Every bioterrorism event thus involves a criminal investigation that is outside the purview of public health authorities.”).

organizations, has eschewed involvement in criminal matters and this type of intelligence gathering.¹⁷⁶

Finally, the section mandates a reporting requirement—absent from CDC’s current regulations—that requires anyone in possession of a select agent to notify federal, state, and local law enforcement agencies immediately if an agent is lost or stolen.¹⁷⁷ This is a vital update to the select agent regulations because it sets in motion an immediate response by law enforcement and gives public health authorities notice of what type of pathogen terrorists might use in an attack. Specifically, it could lead to a reduction in casualties because responders could prepare countermeasures for the missing or stolen biological agent.¹⁷⁸ In addition, these types of reports have already led to more effective enforcement of the select agent rule as the federal government has vigorously pursued investigations of missing or lost pathogens.¹⁷⁹

IV. PROPOSALS

Congress’ passage of the Bioterrorism Response Act addressed several major problem areas of federal preparedness and response identified after the anthrax attacks of 2001. However, significant areas for improvement remain and caution must be encouraged.

First, Congress must further consider options for clarifying the role of DHHS and the CDC in initial terrorism response. The Terrorism Incident Annex to the Federal Response Plan must be revised with a bioterrorism attack in mind and the CDC must be specifically included in all of the health-related provisions. This will enable the agency with the most bioterrorism expertise to take the lead in responding to an attack as a public health crisis, instead of a criminal investigation.¹⁸⁰

176. *See id.* “Public health authorities resist participating in criminal investigations primarily because there is the potential that public health authorities could be seen by community members as health police.” *Id.*

177. § 201(e)(8), 116 Stat. at 642.

178. *Cf. Green, Weapons of Mass Confusion, supra* note 100, at 4 (noting that the New York City response plan for a bioterrorism attack calls for “scrupulously monitor[ing] sales of diarrhea medication as an indicator that a biological attack may have occurred.”).

179. *See* David Malakoff, *Plague of Lies Lands Texas Scientist in Jail*, 299 *SCIENCE* 489 (2003) (relating how the FBI vigorously investigated and arrested a Texas Tech University researcher who reported thirty vials of plague missing from his laboratory to cover up the fact that he failed to document destroying them).

180. *See supra* notes 134–39 and accompanying text.

Second, Congress should act to ensure that statutory requirements of the SNS will be met. Congress has made progress toward this goal by passing proposals such as the Project BioShield Act of 2004,¹⁸¹ which authorizes the purchase of millions of doses of vaccines and drugs to respond to anthrax and smallpox attacks and makes the government a guaranteed purchaser of new counter-terrorism drugs produced by private industry. Yet, more must be done to ensure that these newly acquired doses can actually be administered in the event of a bioterrorism attack. Congress should mandate the testing of the SNS distribution systems and specifically allocate appropriations to coordinate the distribution of vaccines and treatments through first responders. However, Congress must also be mindful of its oversight functions. Bigger and more expensive response mechanisms are not always better and can lead to the kind of fragmentation and unfocused spending that left the CDC unable to respond to an attack that only sickened twenty-two people.

Third, Congress must confront the impending shortage of skilled biodefense workers. This means investing significant resources in keeping medical and biological professionals employed in agencies like the CDC by offering competitive compensation and opportunities for advancement that more closely mirror the private sector. It also entails focusing resources on skilled human resources personnel to identify staffing weaknesses in agencies engaged in biodefense.

Finally, the federal government must continue to revamp, revise, and fully fund federal bioterrorism programs. The lessons of the anthrax attacks of 2001 are already beginning to fade, and public fears of smallpox outbreaks and biological terrorism are generally subsiding. However, as other issues arise and take center stage, policy makers and elected officials cannot allow the federal government's preparedness and response capabilities to fall back to pre-2001 levels.

V. CONCLUSION

Federal response capabilities are vital in responding to a bioterrorism attack that will not be confined within traditional state boundaries. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 helped strengthen and remedy problems borne out by the anthrax attacks of 2001. However, the Act did not initiate a new consolidated

181. Project BioShield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835 (2004).

federal approach, and improvements in coordination and planning are needed to respond to future threats.

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