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BIODEFENSE: WHO'S IN CHARGE?

Victoria Sutton[†]

I. INTRODUCTION

The recent anthrax attacks demonstrated more than what any number of scholarly articles could describe about our lack of organizational and federalism considerations for responding to a domestic biological attack.

In 2000, The National Commission on Terrorism, a Congressional commission, concluded that the Department of Defense should be the lead agency rather than the FBI or FEMA, the current federal agency leaders in a terrorist attack, writing that the Pentagon's "ability to command and control vast resources for dangerous, unstructured situations is unmatched by any other department or agency."¹

Joshua Lederberg, Nobel Prize Recipient for discovering genetic recombinant DNA techniques and the organization of genetic material of bacteria, was asked in Spring 2001, "If you could suggest one thing to the government that it should focus on, or one thing that needs improving, what would that be?" He responded, "Coordination of the different response agencies. At this point, structure is all important. There are lots of resources available or could be made available if [the government] could develop some concerted cooperative effort, but it is still fragmented."²

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¹ *Panel Recommends Pentagon Response to Domestic Terror Threat*, DRUDGE REPORT (June 3, 2000), available at <http://www.drudgereport.com>.

² "Interview with Joshua Lederberg," 6 *The Georgetown Public Policy Review* 135 (Spring 2001).

In 2000 and 2001, law review articles by this author encouraged a national approach to defense against bioterrorism through a coordinated interagency system, and federal legislation to address the shift in federalism from states to the federal government in the area of public health law during peacetime.³

After the fall anthrax attacks, the President established an Office of Homeland Security and appointed Governor Tom Ridge to head the new organization in the Executive Office of the President, in November. In June 2002, the President proposed legislation to create a Department of Homeland Security, which would take parts of departments and combine them into a cabinet-level department with the mission of homeland security.

In response to that legislation, David Walker, Comptroller General of the United States, testified before Congress that “federal initiatives should be conceived as national, not federal in nature.”⁴ Rarely has been made such a statement favoring movement toward a national approach by a federal official in an official capacity. CDC continues to operate in the pre-9-11 world, relying upon the states in their public health role, as do the states which continue to rely upon their traditional police powers in public health in their considerations of preparation and response to a bioterrorism event.⁵

Why does the federal government seem in such a confused state concerning the appropriate preparedness and response responsibilities?

This article seeks to describe the current organizational structure, the role of the federal agencies in the context of biodefense and the federalism relationship with the states. The President’s proposal for a Department of Homeland Security is also examined in the context of

³ See Victoria V. Sutton, A Precarious Legal “Hot Zone” – The President’s Plan to Combat Bioterrorism, 164 MIL. L. REV. 135 (June 2000) (examining the preparedness of government to effectively respond to bioterrorism emergencies). See also Victoria V. Sutton, *Bioterrorism Preparation and Response Legislation – The Struggle to Protect States’ Sovereignty While Preserving National Security*, 6 GEO. PUB. POL’Y REV. 2, (Spring 2001).

⁴ *Testimony before the Subcommittee on Technology, Terrorism and Government Information, Committee on the Judiciary*, Statement of David Walker, Comptroller General of the United States, “Proposal for Cabinet Agency Has Merit, But Implementation Will be Pivotal to Success,” GAO-02-886T (2002), at <http://www.gao.gov/main.html>.

⁵ The local tabletop exercises in bioterrorism, funded and planned pursuant to the Nunn-Lugar-Domenici Act of 1996, include only a local and state response with no role for an assumption of the response activity by the federal government. Exercises can move to completion with no material involvement by the federal government in a biological attack!

the legal implications for biodefense, and the shift in federalism in that proposal. In conclusion, although the Congress passed legislation creating a Department of Homeland Security, the responsibility for a defense against bioterrorism remains undefined, and this article recommends a national approach to biodefense and considerations for the future are discussed.

II. CURRENT ORGANIZATIONAL STRUCTURE FOR BIODEFENSE

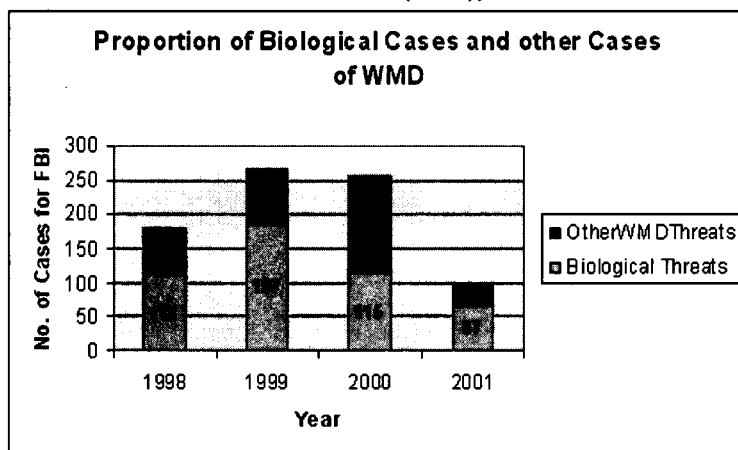
There are three major failures which will continue to create an impasse in identifying appropriate governmental leadership and which threaten our ability to organize our federal interagency and intra-governmental coordination. First, is the failure to separately organize our resources for biodefense from that of other weapons of mass destruction; second, is the failure to recognize that because biological terrorism is very different than any other threat with which we have dealt, the usual lead agencies are not appropriate in terms of training or resources; and third, is the failure to address the relationship between the federal government and the state and local government systems because of state sovereignty issues in public health.

First, the failure to recognize that all weapons of mass destruction are not created equally prevents us from organizing our resources in a manner which addresses the uniqueness of biological warfare. For several obvious reasons, biological weapons are very different from chemical and nuclear weapons. Nuclear and chemical attacks are relatively straightforward – we know immediately when we have been attacked; we know that that attack is not a naturally occurring event; and we know that chemical and nuclear attacks are spent at the moment of the attack, while a biological attack leads to an exponential increase in harm through the procreative nature of biological organisms. To group weapons of mass destruction together and address them simultaneously is either to ignore the threat or to be completely insensitive to the differences. This has pervaded approaches to effective action by our federal government: Congressional legislation, such as the Nunn-Lugar-Domenici Act provided funding on the basis of this group of weapons, for training; and the Executive Branch – the Department of Defense – organized chemical, biological and nuclear threats under one command.

The incidents involving biological threats have increased to a majority of all cases of weapons of mass destruction, further exacerbating the failure to address the unique threat of bioterrorism. In testi-

mony in 2001⁶, the FBI reported the following number of cases since 1998.

Figure 1: Proportion of Biological Cases and other Cases of WMD (Source: Sutton, Law and Bioterrorism (Carolina Academic Press (2002))



Second, the agencies identified to take the lead against bioterrorism are the usual players in domestic crime and natural disasters, but very much the wrong choices for the unique threat of biological warfare. In the Presidential Decision Directives 39, 62 and 63 (PDD 39, 62 and 63), the FBI is designated as the lead agency for “domestic crisis response” and FEMA as the lead agency for “consequence management” for all weapons of mass destruction. The Centers for Disease Control (CDC) its Epidemiology Investigative Service (EIS) and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) are the world's leading centers for forensic epidemiological investigative analyses and have been recommended by leading terrorism experts for leadership roles in bioterrorism, yet our federal organization merely makes them supporting players should the FBI choose to call upon them.

Third, the relationship between the national and state government during peacetime gives power to the states in public health authority, in accordance with the Tenth Amendment.⁷ Not until there exists a

⁶ *Statement for the Record of J.T. Caruso on Bioterrorism Before the S. Judiciary Subcomm. on Technology, Terrorism and Gov't Information, Fed. Bureau of Investigation, at <http://www.fbi.gov/congress/congress01/caruso110601.htm> (Nov. 6, 2001).*

⁷ U.S. CONST. amend. X.

national emergency, or an attack against the United States is made, does the power to take control of a response shift to the federal government. In the case of bioterrorism, an attack may take place in peacetime with no federal system of involvement under our current federalism structure. Without involvement by the federal government in a systematic way during peacetime, there is little chance that an effective response to protect our nation will be made in the context of an emergency shift in power. The federal government has typically taken action in the form of legislation only in the wake of disasters. For example, the Biologics Act of 1906 was in response to the deaths of several children from a vaccine infected with tetanus; Superfund was the result of the Love Canal environmental contamination incident; and the Emergency Planning and Community Right-to-Know Act of 1986 was in response to the accidental release of methyl isocyanate by Union Carbide into the Bhopal, India community.

In the summer of 2002, Congress acted to broaden the planning powers of the CDC to include bioterrorism through the passage of the Public Health Security and Bioterrorism Preparation and Response Act of 2002. The President's proposal for a Department of Homeland Security supporting the Homeland Security Act of 2002, further addressed some of the necessary institutional changes required for a federal system of biodefense. November 25, 2002, the President signed into law, legislation creating the Department of Homeland Security. Several major Presidential initiatives have followed including Project Bioshield announced by President Bush in the State of the Union address in January 2003, and later in March 2003, Secretary Ridge announced Operation Liberty Shield. Both of these initiatives specifically addressed bioterrorism, but failed to define the responsibilities between state and federal governments, leaving implementation in question.

The federal public health agencies continue to coordinate in biodefense; while parts of agencies and departments critical to biodefense in areas of federal control, e.g., environmental and agriculture areas, were brought together under a departmental umbrella. An examination of the original statutory mission of these federal agencies and departments and how the remaining agencies which were excluded from this reorganization contribute to our nation's defense in bioterrorism is critical to our analysis of the function of the Department of Homeland Security.

A. The FBI as the Lead Agency

The Federal Bureau of Investigation (FBI) was formed by President Herbert Hoover to investigate racketeering and terrorism in the

early twentieth century. Investigating terrorism is within the scope of power intended by Congress for the FBI.

Apprehension of the bioterrorist is clearly within the mission of the FBI, which reads as follows: "The mission of the FBI is to uphold the law through the investigation of violations of federal criminal law; to protect the United States from foreign intelligence and terrorist activities; to provide leadership and law enforcement assistance to federal, state, local, and international agencies; and to perform these responsibilities in a manner that is responsive to the Constitution of the United States."⁸ The statutorily defined mission further defines the scope of powers with the FBI.⁹ The FBI should clearly be involved – leading the apprehension role, but equally clearly, should not be directing the effort to either prepare for, or to respond to, bioterrorism. However, there is an effort to redefine the mission of the FBI in the context of bioterrorism: In testimony before the U.S. Congress November 6, 2001, Deputy Assistant Director of the Counterterrorism Division of the FBI stated that, "the primary mission of law enforcement and the public health community is saving lives."¹⁰

The 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, its limited experience in counter-intelligence within governmental agencies; and its lack of skills crucial to the investigation and apprehension of extra-governmental counterintelligence agents involved in bioterrorism events. For example, Senator Feinstein remarked after testimony from FBI Director Mueller, during the first week in November, "I was really taken aback by how little they seem to know."¹¹ In October, the FBI was consulted about the destruction of more than 100 vials of different anthrax strains collected over decades by the Iowa State University in Ames, and even after discovery that the Florida incident of anthrax was a result of terrorism,

⁸ *What is the mission of the FBI?*, General Frequently Asked Questions, at <http://www.fbi.gov/aboutus/faqs/faqone.htm> (last visited April 4, 2002).

⁹ See 18 U.S.C. § 3052 (2002). "The Director, Associate Director, Assistant to the Director, Assistant Directors, inspectors and agents of the Federal Bureau of Investigation of the Department of Justice may carry firearms, serve warrants and subpoenas issued under the authority of the United States and make arrests without warrant for any offense against the United States committed in their presence, or for any felony cognizable under the laws of the United States if they have reasonable grounds to believe that the person to be arrested has committed or is committing such felony."

¹⁰ CARUSO, *supra* note 7.

¹¹ Dan Eggen & Jim McGee, *FBI Rushes to Remake Its Mission*, WASH. POST, Nov. 12, 2001, at A1.

the FBI approved the destruction of this vital collection.¹² This more than illustrates the absolute lack of understanding and training on the part of the FBI in comprehending that the anthrax collection could have provided invaluable evidence in identifying the source of the anthrax, by comparing the DNA of the anthrax found in Florida with that of strains in the collection. In another example, the FBI sought advice concerning its investigation of a physician's report concerning a black lesion on the calf of one of the 9-11 hijackers, Al Haznawi. He was also identified as the suspect who inquired about the use of cropdusters – a potential dissemination method for biological weapons. In their investigation, the FBI contacted not the appropriate government agency, but Johns Hopkins University, which was reported to have concluded that the lesion was likely to be the result of anthrax. However, the Chair of the American Academy of Dermatology's Bioterrorism Task Force, remarked that it was "highly unlikely" to contract cutaneous anthrax on one's lower leg.¹³ The FBI's informal search for expertise in medical and scientific forensic issues, such as this one, highlight the insufficiencies of the agency.

But training alone is not sufficient for an agency which lacks the ability to make a culture shift. Just in November, after at least six weeks with which the FBI had the opportunity to become familiar with anthrax investigations, the FBI still was not trained for basic investigations of anthrax threats. One former FBI agent was quoted as saying, "It's just unrealistic to ask 7,000 agents to overnight become sufficiently knowledgeable about bioterrorist agents and possible means of theft of those items and how they might be disseminated lethally to an American populace."¹⁴ Experts have further commented that the FBI "traditionally has had trouble understanding the language, and the demands of science."¹⁵ Another expert concluded that the FBI "are not geared up for prevention of anything."¹⁶

However, within the appropriate scope of powers delegated by Congress to the FBI, its efforts to coordinate the criminal investigation effort with the U.S. Postal Service are appropriate. The FBI

¹² William J. Broad et al., *Experts See FBI Missteps Hampering Anthrax Inquiry*, N.Y. TIMES, Nov. 9, 2001, at A1 (explaining how the FBI does not completely understand how science can increase the agency's effectiveness).

¹³ Steve Fainaru & Ceci Connolly, *Memo on Florida Case Roils Anthrax Probe, Experts Debate Theory Hijacker Was Exposed*, WASH. POST, Mar. 29, 2002, at A3.

¹⁴ Broad et al., *supra* note 13 (quoting former FBI forensic metallurgist, Bill Tobin).

¹⁵ *Id.*

¹⁶ Eggen & McGee, *supra* note 12.

maintains a website with information about the anthrax investigation¹⁷ and contact information, describing a cooperative effort with the U.S. Postal Service in developing protocols, and offering a reward for information leading to the arrest and conviction of the mailers of the four envelopes containing anthrax. The role in developing protocols for mail-handling, however, is not within the scope of powers delegated to the FBI, and should be the role of a public health agency, such as the Public Health Service, or the Centers for Disease Control and Prevention.

1. The Process of Response to a Potential Bioterrorism Event

In Congressional testimony, in October 2001, the FBI confirmed their leadership role in crisis management with FEMA's leadership role in consequence management and together, the responsibility for coordination of the overall federal government response.¹⁸ The response, the FBI, testifies,

begins with a threat assessment coordinated by the Weapons of Mass Destruction Operations Unit (WMDOU). This is initiated when the FBI receives notification of an incident or threat. WMDOU immediately notifies subject matter experts and federal agencies with relevant authorities to conduct a real-time assessment and determine the credibility of the threat. Based on the credibility and scope of the threat, WMDOU will coordinate an appropriate and tailored response by federal assets and the owners and operators of the facility to meet the requirements of the on-scene responders, and will oversee the investigation to its successful conclusion.

About one month later, in November 2001, in Congressional testimony, the FBI presented its approach to the bioterrorism threat in terms of a coordinated approach. The FBI official presented the bioterrorism threat as one of either an overt attack or a covert attack – the overt attack being “an announced release of an agent, often with some type of articulated threat,” such as an envelope containing anthrax with an announcement that the recipient has been exposed to

¹⁷ *Amerithrax – Seeking Information, at* <http://www.fbi.gov/anthrax/amerithraxlinks.htm> (last visited April 25, 2002).

¹⁸ *Terrorism: Are Americana's Water Resources and Environment at Risk? Hearing Before the Subcomm. on Water Resources and Env't of the House Comm. on Transportation and Infrastructure*, (2001) (statement of Ronald L. Dick, Deputy Ass. Director, Counterterrorism Division and Director, National Infrastructure Protection Center, FBI).

anthrax; the covert threat being one that is a release "not accompanied by any articulated or known threat."¹⁹ The difference, the FBI testifies, is that the FBI takes the lead in both types of attacks, but in the covert attack the public health community is the first to detect the attack, and once it is known as an attack, the FBI assumes the lead.

In addressing biological threats, the FBI divides the response into two areas: the local and the federal. The division is made between coordination at the local level and a separate coordination approach at the federal level: state or local public health officials work with the local FBI WMD Coordinator, of which there is one in every FBI office; but at the federal level, the FBI and CDC work together.

The FBI also testified to the coordination with other federal agencies. After the threat assessment is made, the FBI alone determines the credibility of the threat, the immediate concerns involving health and safety of the responding personnel, and the requisite level of response warranted by the federal government. Then input from:

[T]he necessary federal agencies with an interest in the particular incident. In a biological event, representatives from Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS), United States Department of Agriculture (USDA) and Food and Drug Administration (FDA) are the key agencies called upon to assist FBI personnel in assessing the particular threat. Based upon the assessment, a determination is made as to the level of response necessary to adequately address the particular threat, which could range from a full federal response if the threat is deemed credible to collection of the material in an effort to rule out the presence of any biological material if the threat is deemed not credible.

After the threat assessment is made, the FBI alone determines the level of response, which may include the determination of biological factors. Throughout this process, the FBI is potentially acting without the input from other agencies.

The collection of any biological material is also within the jurisdiction of the FBI under PDD 39 and 62, and the FBI follows their Hazardous Material Response Unit (HMRU) protocols which are the same as those used by local HAZMAT teams. In August 2002, the FBI, in association with the Epidemiology Investigation Service (EIS)

¹⁹ CARUSO, *supra* note 7.

produced a draft protocol for guidance in the collection of biological materials in a potential bioterrorist event.

A common protocol, recognized and followed by all federal agencies, state and local HAZMAT teams, is necessary to ensure that sufficient evidentiary samples are collected, screened and overpacked according to scientific safety guidelines for transportation to the appropriate testing facility, as well as in recognition of the need to document the chain of custody and the observance of protocols for criminal prosecution evidentiary matters. The FBI initiates and leads the collection procedure, but depends upon the more than 85 state health laboratories to perform analyses on behalf of CDC in the coordinated collection of facilities known as the Laboratory Response Network (LRN). Once the testing is completed, results are provided to the FBI for dissemination in the appropriate manner. The results of the analysis are then disseminated to first the exposed person or persons, then local first responders and the local public health department. Additionally, results will be forwarded to the Centers for Disease Control and Prevention (CDC) in Atlanta, GA. In this protocol, the CDC joins the investigation late in the process, and is effectively isolated from early decision-making processes.

2. The FBI Re-Organization

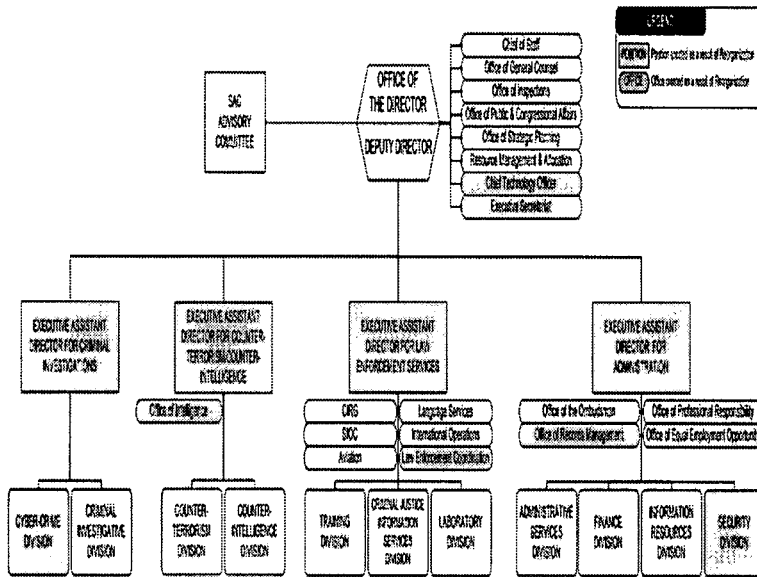
The Federal Bureau of Investigation is part of the Department of Justice, which has been undergoing reorganization. On November 8, 2001, the Federal Bureau of Investigation announced a "wartime reorganization"²⁰ suggesting that Attorney General John Ashcroft intends to maintain the FBI in its current role in the plan to respond to bioterrorism under the current PDD 39. While the role of apprehension of a bioterrorist within the domestic territory of the United States is clearly within the scope of the mission of the FBI, the complexity of the threat belies what seems to be a simple decision for leadership.

The organizational changes published on November 8, 2001 do not account for the range of expertise required for biological threats, again, focusing on intelligence and investigation which have roles in the process, but certainly not the elements necessary to take the lead for the national security plan to combat bioterrorism. The following organizational chart was presented to the public by the Director of the FBI on November 8, 2001 with the new offices highlighted in their reorganization. It is immediately evident that weapons of mass de-

²⁰ David Johnston, *Ashcroft Plan Would Recast Justice Dept. in a War Mode*, N.Y. TIMES, Nov. 9, 2001, at B1.

struction are not separately identified, nor are any of those treated separately (nuclear, radiological, chemical and biological).

Figure 2: Federal Bureau of Investigation, REORGANIZATION CHART OF THE FBI (2001)²¹



B. The Role of the CDC

The role of the Centers for Disease Control and Prevention is limited in scope and recognizes the sovereignty of states in the regulation of public health, with some emergency powers. However, the Public Health Act and Bioterrorism Preparedness and Response Act of 2002, provides for an expanded role for the CDC in peacetime involvement with the management of states' surveillance activities.

The statutory authority granted to CDC describes the sharing of powers between the federal government and the states. This power authorizes the Secretary of Health and Human Services to accept aid from the states for federally imposed quarantines, and to "assist States and their political subdivisions in the prevention and suppression of communicable diseases."²² The power also includes the resources to provide planning and training to the states and to provide assistance "at the request of the state" for any public health emergency for a pe-

²¹ Federal Bureau of Investigation, REORGANIZATION CHART OF THE FBI (2001), at <http://www.fas.org/irp/news/2001/12/chart.htm> (last visited Oct. 9, 2002).

²² 42 U.S.C. § 243(a) (2000) (emphasizing a cooperative federal and state program).

riod of time.²³ The CDC protocol for reporting bioterrorism events optimistically directs the public health community as follows: *The public health sector has important responsibilities related to BT detection, response, and control of health consequences, but the public health response will be most effective if the overall response by all sectors – pre-hospital and hospital care, law enforcement, public safety, etc. – is coordinated by the FBI.*²⁴ However, the CDC suggests that the state health departments should voluntarily contact the CDC in the event of a potential attack – but this is only on a voluntary basis.²⁵ Cooperative agreements between the CDC and volunteer asso-

²³ 42 U.S.C. § 243 (2000). § 243. *General grant of authority for cooperation.* (a) *Enforcement of quarantine regulations; prevention of communicable diseases.* The Secretary is authorized to accept from State and local authorities any assistance in the enforcement of quarantine regulations made pursuant to this Act which such authorities may be able and willing to provide. The Secretary shall also assist States and their political subdivisions in the prevention and suppression of communicable diseases and with respect to other public health matters, shall cooperate with and aid State and local authorities in the enforcement of their quarantine and other health regulations, and shall advise the several States on matters relating to the preservation and improvement of the public health. (b) *Comprehensive and continuing planning; training of personnel for State and local health work; fees.* The Secretary shall encourage cooperative activities between the States with respect to comprehensive and continuing planning as to their current and future health needs, the establishment and maintenance of adequate public health services, and otherwise carrying out public health activities. The Secretary is also authorized to train personnel for State and local health work. The Secretary may charge only private entities reasonable fees for the training of their personnel under the preceding sentence. (c) *Development of plan to control epidemics and meet emergencies or problems resulting from disasters; cooperative planning; temporary assistance; reimbursement of United States.* (1) 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 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. The Secretary may enter into agreements providing for the cooperative planning between the Service and public and private community health programs and agencies to cope with health problems (including epidemics and health emergencies). (2) The Secretary may, at the request of the appropriate State or local authority, extend temporary (not in excess of six months) assistance to State or localities in meeting health emergencies of such a nature as to warrant Federal assistance. The Secretary may require such reimbursement of the United States for assistance provided under this paragraph as he may determine to be reasonable under the circumstances. Any reimbursement so paid shall be credited to the applicable appropriation for the Service for the year in which such reimbursement is received.

²⁴ Interim Recommended Notification Procedures for Local and State Public Health Department Leaders in the Event of a Bioterrorist Incident, at <http://www.bt.cdc.gov/EmContact/Determine.htm> (last visited Nov. 4, 2001).

²⁵ *Interim Recommended Notification Procedures for Local and State Public Health Department Leaders in the Even of a Bioterrorist Incident*, at

ciations such as the Association of State and Territorial Epidemiologists (ASTE) and others provide, for example, uniform case reporting criteria for communicable diseases.²⁶

However, the U.S. Congress recognized that the CDC mission and powers do not fit the new demands of bioterrorism, and amended the scope of the powers of CDC in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. In their findings, the Congress "finds that the Centers for Disease Control and Prevention has an essential role in defending against and combating public health threats"²⁷ The Public Health Security Act expanded and enhanced existing powers and responsibilities in capabilities in preparedness and response to public health emergencies, training, communications and improving surveillance and laboratory facilities for emergencies,²⁸ but stopped short of any substantive expansion of the role of CDC.

1. Federal Quarantine Power

The CDC has Congressionally mandated authority to impose quarantines where there is a threat of interstate transmission of a communicable disease²⁹ based upon Constitutionally delegated power to Congress to regulate interstate commerce.³⁰ The CDC shall only

<http://www.bt.cdc.gov/EmContact/Notify1.htm> (Nov. 4, 2001).

²⁶ See, e.g., Ctrs. for Disease Control and Prevention, *Case Definitions for Infectious Conditions Under Public Health Surveillance*, MORBIDITY AND MORTALITY WEEKLY REPORT, May 2, 1997, at 57 (collaborating on definitions of infectious conditions with the ASTE).

²⁷ 42 U.S.C. § 247d-4 (2002). *Revitalizing the Centers for Disease Control and Prevention (a) Facilities; capacities. (1) Findings. Congress finds that the Centers for Disease Control and Prevention has an essential role in defending against and combating public health threats and requires secure and modern facilities, and expanded and improved capabilities related to bioterrorism and other public health emergencies, sufficient to enable such Centers to conduct this important mission.*

²⁸ *Id.* *Revitalizing the Ctrs. for Disease Control and Prevention (3) Improving the capacities of the Centers for Disease Control and Prevention. The Secretary . . . shall expand, enhance, and improve the capabilities of the Centers for Disease Control and Prevention relating to preparedness for and responding effectively to bioterrorism and other public health emergencies. Activities that may be carried out under the preceding sentence include – (A) expanding or enhancing the training of personnel; (B) improving communications facilities and networks, including delivery of necessary information to rural areas; (C) improving capabilities for public health surveillance and reporting activities, taking into account the integrated system or systems of public health alert communications and surveillance networks under subsection (b); and (D) improving laboratory facilities related to bioterrorism and other public health emergencies, including increasing the security of such facilities.*

²⁹ 42 U.S.C. § 264 (2002).

³⁰ U.S. CONST., art. I, § 8, cl. 3, provides [Congress shall have power] "To

implement these measures where the state's measures are "insufficient to prevent the spread of any of the communicable diseases from such State . . . to any other."³¹ However, if this quarantine requires the detention of individuals rather than commodities, the quarantine is limited to individuals who have a list of specific communicable diseases.³²

The CDC published the first comprehensive document to address a strategic plan for anti-bioterrorism. In 1998, CDC completed a plan to address emerging diseases and a plan for prevention with *Preventing Emerging Infectious Disease: A Strategy for the 21st Century* which focused on four areas: surveillance and outbreak response; applied research in diagnostic tests, drugs, and vaccines; infrastructure and training; and disease prevention and control. In 1999, a CDC representative testified before Congress that in their bioterrorism coordination, they work closely with the Department of Justice, including the FBI and the National Domestic Preparedness Office, with the Food and Drug Administration, the National Institutes of Health, the Department of Defense and the Federal Emergency Management Agency.³³

On September 11, 2001, the CDC sent an alert to state and local governments entitled, "Terrorist Activity Response Health Advisory," alerting the health departments that "CDC is on heightened alert status

regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes."

³¹ 42 C.F.R. § 70.2 (2001) (emphasis omitted). *Measures in the event of inadequate local control. Whenever the Director of the Centers for Disease Control and Prevention determines that the measures taken by health authorities of any State or possession (including political subdivisions thereof) are insufficient to prevent the spread of any of the communicable diseases from such State or possession to any other State or possession, he/she may take such measures to prevent such spread of the diseases as he/she deems reasonably necessary, including inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or articles believed to be sources of infection.*

³² Interstate Quarantine, 42 C.F.R. § 70.6 (2001). *Apprehension and detention of persons with specific diseases. Regulations prescribed in this part are not applicable to the apprehension, detention, or conditional release of individuals except for the purpose of preventing the introduction, transmission, or spread of the following diseases: Anthrax, chancroid, cholera, dengue, diphtheria, granuloma inguinale, infectious encephalitis, favus, gonorrhoea, leprosy, lymphogranuloma venereum, meningococcus meningitis, plague, poliomyelitis, psittacosis, relapsing fever, ringworm of the scalp, scarlet fever, streptococcal sore throat, smallpox, syphilis, trachoma, tuberculosis, typhoid fever, typhus, and yellow fever.*

³³ *Enhancing National Public Health Capacity to Respond to Bioterrorism: Hearing Before the Subcomm. on National Security, Veterans Affairs and International Relations of the House Comm. on Government Reform, 105th Cong. (1999)* (testimony of Dr. Scott R. Lillibridge).

to monitor for any possible unusual disease patterns associated with today's events, including chemical and biological agents."³⁴ There was an immediate effort to respond to the possibility of a biological attack as well as the immediate concern of the use of the airlines for attacks.

2. Existing Programs in CDC for Biodefense³⁵

The federalism relationship between the CDC and state and local governments, has resulted in a series of programs to fill public health needs which include associations and non-governmental entities.

i. Programs with local and state governments

Emerging Infections Program (EIP). The CDC has established EIP sites by entering into agreements with selected state health departments in collaboration with local academic, government, and private sector organizations, to establish sites that conduct active, population-based surveillance for selected diseases, as well as for unexplained deaths and severe illnesses in previously healthy people.

National Electronic Disease Surveillance System (NEDSS). This is a system for public health surveillance which will support automated collection, transmission and monitoring of disease data from multiple sources (clinicians' offices, laboratories, etc.) from local to state health departments to the CDC. NEDSS will replace multiple and independently designed systems.

ii. Training

Epidemiologic and Laboratory Capacity (E.C.) Program. The CDC has implemented this system with more than 75 public health professionals (including 24 Epidemiologists and 25 laboratorians) as part of the training effort to assist state and large local health departments to acquire the skills and resources to address infectious diseases.

³⁴ City of Lubbock, *Health Department Receives Alert from the CDC in Response to Terrorist Activities* (Sept. 11, 2001), available at <http://www.ci.lubbock.tx.us/article.asp?ID=373> (last modified Mar. 18, 2002).

³⁵ See Ctrs. for Disease Control and Prevention, *Public Health Emergency Response: The CDC Role*, at <http://www.bt.cdc.gov/DocumentsApp/ImprovingBioDefense/ImprovingBioDefense.asp> (last reviewed Oct. 14, 2001) (including early detection and rapid communications programs).

iii. Programs with Associations and other Non-Governmental Entities

National Pharmaceutical Stockpile (NPSP) and the Metropolitan Medical Response Systems. CDC has developed a stockpile of vaccines, drugs and anti-toxins which can reach the victims anywhere in the continental U.S. within 12 hours. The Metropolitan Medical Response Systems (MMRS) contracts with local entities for distribution of the pharmaceuticals, when the demand is made. In October 2001, a representative of the Department of Health and Human Services testified that the MMRS is a system of contracts with existing emergency response systems, medical and health providers, mental health providers, public health departments, law enforcement and fire departments, emergency medical services and the National Guard “to provide an integrated, unified response to a mass casualty event.”

There are currently about 100 systems throughout the United States and they each have the responsibility for the first 24 hours following an identified disease outbreak. They are expected to have the capability to provide immunization and prophylaxis as well as the capability to distribute material deployed to the local site from the National Pharmaceutical Stockpile.³⁶

The Epi-X Project. This system is a secure, moderated, web-based exchange for public health officials to rapidly report and discuss disease outbreaks and other health events which may indicate a bioterrorism event. The system is staffed with real-time expertise to assure rapid contact with state and local officials and to provide accurate information.³⁷ As part of this project, CDC has initiated programs in cooperation with professional organizations:

(1) The National Health Alert Network (HAN)

The CDC is implementing this national system in partnership with the National Association of County and City Health Officials (NACCHO), the Association of State and Territorial Health Officials (ASTHO), and other health organizations. The HAN will assist in communications, information, distance-learning, and organizational infrastructure to address the threat of bioterrorism, and will link all public health agencies at the local, state, and federal levels by con-

³⁶ *Bioterrorism Preparedness: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce, 106th Cong. (2001)* (statement of Dr. Scott R. Lillibridge).

³⁷ Ctrs. for Disease Control and Prevention, *National Bioterrorism Preparedness and Response Initiative*, at <http://www.bt.cdc.gov/Documents/RegMeetingSlides/overview.PDF> (last modified May 8, 2000).

tinuous high-speed connection to the Internet, broadcast communications, and satellite and web-based distance-learning.

(2) The Laboratory Response Network (LRN)

The fundamental goal of the Laboratory Response Network for Bioterrorism (LRN) is to enhance laboratory capacity for preparedness and response to an act of bioterrorism by providing a collaborative network to facilitate rapid detection and analysis of chemical and biological agents. The LRN is a joint project supported by CDC and the Association of Public Health Laboratories (APHL).³⁸

The Epidemic Intelligence Service. The Epidemic Intelligence Service (EIS) was created in 1951, in response to concerns about biological warfare during the Cold War. The EIS has been called upon to investigate the first cases of hantavirus, Legionnaire's Disease, West Nile virus outbreak, and Ebola outbreaks in Uganda and Zaire. According to one report, the CIA asked the CDC to investigate the outbreak of West Nile Fever in New York City, as early as 1999, in reaction to information from an Iraqi defector which raised concerns that Saddam Hussein may have developed a West Nile-like encephalitis and launched a bioterrorism attack.³⁹

The EIS program is relatively small. It is a two-year, post-graduate program of service for health professionals who gain experience and on-the-job training in epidemiology. Qualifications for the appointment require that physicians have at least one year of clinical training; persons with a Ph.D. Dr.P.H. or M.D. in epidemiology, biostatistics, the social or behavioral sciences, and the nutrition sciences; dentists, physician assistants, and nurses have an M.P.H. or equivalent degree; and that veterinarians have an M.P.H. or equivalent degree or relevant public health experience.⁴⁰

In January 2002, the EIS was comprised of 130 total EIS officers,⁴¹ but by April 2002, the EIS reported that their numbers had increased to 146.⁴² Each year, the CDC admits 60-80 new agents for a term in the EIS. In previous years, the EIS has addressed approximately 100 investigations requested by states and other countries, and 500 studies or consultations each year, but this is expected to increase

³⁸ *Id.*

³⁹ Elizabeth Kaledin, *Virus: Bio-Terrorism Unlikely*, at <http://www.cbsnews.com/stories/1999/10/11/national/main65855.shtml> (last visited Oct. 13, 2002).

⁴⁰ Ctr. For Disease Control, *Epidemic Intelligence Service Fact Sheet*, at <http://www.cdc.gov/eis/about/factsheet/htm> (last reviewed Feb. 22, 2002).

⁴¹ *Id.*

⁴² M.A.J. McKenna, *War on Terrorism: CDC Enlists 146 Disease Detectives; Unit Works in Epidemic Intelligence*, ATLANTA J. CONST., Mar. 7, 2002, at 12A.

given the new cooperative guidance for investigations between the FBI and the EIS.

The EIS was called to respond to the 9-11 attacks and the anthrax attacks which followed. The EIS sent 35 members to New York City, to assist the New York City Health Department in the ongoing monitoring of public health issues, immediately after the attacks on the World Trade Center. Secretary Thompson explained the relationship between the CDC and local government: "The CDC workers will supplement local efforts in this regard and provide expertise in matters relating to public health. We're responding as rapidly as possible to any needs for resources the city and state need."⁴³ By April 2002, the EIS had mobilized 136 officers from Atlanta for assignments related to terrorism. Before this event, the largest single deployment in EIS history was 46 officers, responding to the fear that Korean soldiers had returned to the United States, possibly infected with biological agents.⁴⁴

3. Problems with the Current Role of the CDC

The CDC was the last federal agency among about a dozen to receive the report of a series of experiments performed in the spring of 2001 involving simulated anthrax-containing letters.⁴⁵ These experiments were performed in Ottawa and Alberta and showed that the possibility of exposure was much greater than previously expected. The Alberta research had been presented on May 31 through October 17. The October 17th meeting was at the Canadian Embassy in Washington, DC, approximately three blocks from the U.S. Capitol, two days after the Sen. Daschle letter was opened. The Ottawa research was presented in mid-May in Canberra, Australia, at a meeting of civil defense experts, where U.S. experts attended. FEMA contacted Public Health Service and the U.S. Environmental Protection Agency. The State Department passed the research on to the FBI, Secret Service and the U.S. Capitol Police. But the CDC did not hear about it until a professor in epidemiology sent the research to a contact in the CDC in November, about the time the anthrax threat was ending. Bradley A. Perkins, the CDC's lead anthrax investigator, remarked: "It would have been good to have that information.

⁴³ U.S. Dept. of Health and Human Services, *HHS Sends 35 Members of Centers for Disease Control and Prevention EIS Team to NYC*, (Sept. 14, 2001), available at <http://www.hhs.gov/news>.

⁴⁴ McKenna, *supra* note 41.

⁴⁵ David Brown, *Agency with Most Need Didn't Get Anthrax Data, CDC Unaware of Canadian Study Before Attacks*, THE WASH. POST, Feb. 11, 2002, at A3.

Regarding the destruction of the anthrax cultures collection at the University of Iowa, under regulations promulgated for the Antiterrorism and Effective Death Penalty Act of 1996, the CDC was directed to develop regulations for the destruction of biological agents. In Congressional testimony in 1999, a CDC representative testified that in accordance with these regulations "CDC must be notified of the disposal or complete consumption of a select agent." Anthrax is one of the select agents. In the months following the anthrax attacks, the CDC was clearly the agency possessing the expertise necessary to respond to the attacks. However, the federal organization under PDD 39 gives CDC only a supporting role to the FBI and FEMA. While this works well for chemical, nuclear or bombs, this organizational relationship fails to match the challenges of a biological event.

C. The Role of FEMA

The United States has utilized a policy of federal disaster assistance since the Congressional Act of 1803, which responded with federal disaster assistance to New Hampshire. The federal approach relied upon special legislation to respond to each disaster, and responsibilities of different federal agencies and departments were unclear. In the first half of the twentieth century, Congress acted to develop the Federal Disaster Assistance Administration, housed within the Department of Housing and Urban Development (HUD). It was not until 1979 that the different disaster relief activities were brought together into a new agency – the Federal Emergency Management Agency, through an Executive Order signed by President Carter.

The Federal Emergency Management Agency (FEMA) is the agency charged with responding to natural and manmade disasters, and is identified in the Presidential Decision Directives as the lead agency for domestic emergency response, in distinction to the FBI which is designated the lead in investigative response. FEMA's experience in disaster training and response with its national network of regional offices provides a nationwide framework for a federal response.

With the creation of the Office of Homeland Security, FEMA coordinated its activities through this office. This is not inconsistent with the FEMA mission – "to lead America to prepare for, prevent, respond to and recover from disasters with a vision of 'A Nation Prepared.'"⁴⁶

⁴⁶ FEDERAL EMERGENCY MANAGEMENT AGENCY, ABOUT FEMA, at <http://www.fema.gov/about/history.shtm> (last updated Sept. 26, 2002).

1. Problems with FEMA's Role

The U.S. Congress addressed the lack of communication and coordination between the FAA and FEMA during the 9-11 attacks, in the context of preparation for a biological attack in H.R. 3255, The Bioterrorism Protection Act (BioPAct) of 2001 introduced in October 2001. The language of the legislation provides for the continuation of air travel for FEMA personnel and supplies to travel to disaster areas, even where air travel has been suspended, otherwise.⁴⁷ The legislation, however, has not been passed.

D. The Role of the Department of Agriculture and the Food and Drug Administration

The Animal and Plant Health Inspection Service (APHIS), Agricultural Research Service (ARS), and the Forest Service are within the Department of Agriculture and have roles in biodefense. Inspections of imported foods is a critical role for the Department of Agriculture, and enhanced monitoring of food safety throughout the cycle of food production in the United States would be required to protect the public from agricultural terrorism (agro-terrorism).

The Food and Drug Administration, an agency, cooperates with the Department of Agriculture on food safety issues, during the food processing phase. Inspections provide an institutional framework for addressing the threat of bioterrorism. After September 11th the Food and Drug Administration proposed new guidelines urging tamper-resistant packaging and other security measures, while the Department of Agriculture continued to contemplate regulations. The FDA's proposal to require tamper-resistant packaging on fruits and vegetables met with industry resistance, and the costs associated with the increased rot and temperature is projected by the industry to cost millions.⁴⁸

The Public Health Security Act, passed June 12, 2002 addressed some of these concerns. The new law provides for an expanded role

⁴⁷ Bioterrorism Protection Act (BioPAct) of 2001, H.R. 3255, 107th Cong. § 126 (2001). *Communication between FAA and FEMA. With respect to airspace that is restricted or closed in response to a bioterrorist attack, the Administrator of the Federal Aviation Administration and the Director of the Federal Emergency Management Agency shall collaborate to develop a plan that provides immediate authority for personnel of such Agency to travel by aircraft to the geographic areas affected by the attack, notwithstanding such restriction or closure of air space.*

⁴⁸ Melinda Fulmer, *Produce Industry Balks at Food Security Guidelines; Regulation: Firms say FDA Proposals to Protect Against Bioterrorism are Ineffective and Costly*, L.A. TIMES, Mar. 28, 2002, § 3, at 1.

for the Food and Drug Administration in the regulation of food safety to protect against acts of bioterrorism. Subtitle A of the Act provides for registration of food distribution facilities, inspections, more systematic refusals of imported food shipments, and surveillance powers for animal diseases. Subtitle B further provides for protection of the drug supply through registrations of foreign manufacturers and more detailed disclosures of components of drugs.

E. The Role of the Department of Defense

The Department of Defense was originally created by the collection of federal parts of agencies under one Department, at the request of President Harry Truman. In December 1945, the President asked Congress to combine the War and Navy Departments into a single department. Then in 1947, The National Security Act consolidated the separate military departments into the Department of Defense. The Department of Defense was conceived in order to defend against a new national security threat – the Cold War.

The threat of terrorism in recent years inspired the Defense Threat Reduction Agency, created in 1998 by President Clinton. The President was inspired to create the agency, in part, as a result of his reading *The Cobra Event*, a fictional biological attack scenario, by Richard Preston. The first director, Dr. Jay Davis, was asked by the President to read the bioterroristic novel.⁴⁹ The Agency combined various parts of the Department of Defense to make grants and implement training programs for preparation and protection against weapons of mass destruction.

The DARPA and SBCCOM were created to explore creative and new technologies which could be used for the national defense. DARPA has played a major role in the exploration of surveillance technologies and biosensing technology in their focus on biological terrorism. Within DARPA exists the Biosurveillance Program, created after 9-11. Admiral John Poindexter was appointed to be its Director. This office is expected to develop capabilities for the collection of public health information and other sources of data to create an early detection system for any biological attack. This group is the first of the scientific and technological agencies to consider the legal framework and how their research and development can best be utilized.⁵⁰

⁴⁹ Private Conversation with Dr. Jay Davis, Pentagon, Room 3B 253, (Thursday, July 30, 1998).

⁵⁰ Victoria Sutton, *Privacy Issues and Legal Surveillance*, Invited Presentation at DARPA and The Potomac Institute, Arlington, VA, (Tuesday, June 4, 2002).

F. The Expanding Role of the Environmental Protection Agency

The statutory basis for involvement of the U.S. EPA in the national biodefense activities is found in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), the Comprehensive Emergency Response, Compensation and Liability Act (CERCLA), the Emergency Planning and Community Right-to-Know Act (EPCRA), the Resources Conservation and Recovery Act (RCRA), providing for potential response authority where there is an imminent and substantial threat to human health or the environment. The Safe Drinking Water Act (SDWA), the Clean Water Act (CWA) are also important statutes for addressing threats to water systems, and represent the preventive component of EPA's responsibility. The U.S. EPA is also a participant in the Domestic Preparedness Program, part of the Nunn-Lugar-Domenici Act.⁵¹

As early as February 1998, the EPA issued a Fact Sheet⁵² outlining its role in bioterrorism. The EPA with the Department of Defense (DOD), the Department of Energy (DOE), the Federal Bureau of Investigation (FBI), the Federal Emergency Management Agency (FEMA) and the Public Health Service (PHS) are cooperatively responsible for response and training in defense against all weapons of mass destruction.

In July 1998, the EPA issued another Fact Sheet which described the role of the U.S. EPA in relation to its responsibilities required by Presidential Decision Directives 39, 62 and 63. The EPA provides (1) help to state and local responders to plan for emergencies; (2) coordination with key Federal Partners; (3) training for first responders; and (4) provision of resources in the event of a bioterrorism attack. Within the U.S. EPA, the Office of Emergency and Remedial Response (OERR), the Chemical Emergency Preparedness and Prevention Office (CEppo), the Office of Radiation and Indoor Air (ORIA) and the National Enforcement Investigations Center (NEIC) are the critical components involved in the planning and response activities.

President Clinton gave the U.S. EPA authority for two distinct parts of counter-terrorism activity:

⁵¹ United States Environmental Protection Agency et al., *Counter Terrorism – EPA's Role and Authority*, available at <http://www.epa.gov/ceppo/ct-epro.htm> (last modified May 22, 2001).

⁵² United States Environmental Protection Agency, Fact Sheet EPA 55-F-98-014 (Feb. 1998).

- (1) *Assisting the FBI in determining what sort of hazardous substance may be or has been, released in a terrorist incident; and*
- (2) *Following an incident, assisting with environmental monitoring, decontamination efforts, and long-term site cleanup operations.*⁵³

After the anthrax attacks, the U.S. Congress responded with a number of proposals which would include additional support from the U.S. EPA. Recognizing the resources within the EPA, on October 17, 2001, the U.S. Senate introduced S. 1560, The Biological Agent B Environmental Detection Act of 2001⁵⁴ which provided for strengthening the United States capabilities in environmental detection and the monitoring of biological agents. The proposal included the enhancement of early detection environmental monitoring technologies in food, water, air and other vectors, as well as a genomic library for identification.⁵⁵

This bill encouraged cooperative agreements between the government and the private sector in detecting common pathogens; new technologies and approaches to identify clandestine laboratories; investigation and development of technologies to identify possible bio-

⁵³ EPA's Role in Counter-Terrorism Activities (Feb. 1998), *available at* <http://www.epa.gov/swercepp/factsheets/ct-ctsh.pdf>.

⁵⁴ S. 1560, 107th Cong. (2001).

⁵⁵ *See id.* at §§ 2-3. § Sec. 2. *Findings. Congress makes the following findings:*

- (1) The threat of bioterrorism depends on the ability to produce and distribute biological agents that cause illness or death. A bioterrorism attack, once executed, requires containment and treatment that relies on primary-care provider capabilities as well as information and communication infrastructure.
- (2) Early detection of a biological threat will minimize the number of people exposed to the agent and the extent that the agent or disease will spread.
- (3) Preventative measures that consider production, processing and distribution of biological or chemical agents could significantly reduce the threat of bioterrorism.
- (4) New tools capable of detecting small quantities of infectious agents in food, water, air, and other vectors are needed, as well as a library of the genomic signatures of unique agents.

Sec. 3. Novel Detection and Surveillance Tools

(a) IN GENERAL. - The Secretary of Health and Human Services, in conjunction with the Secretary of Defense, the Secretary of Energy, the Director of the National Science Foundation, the Administrator of the Environmental Protection Agency, and representatives from industry, shall form an inter-agency research task force to encourage non-duplicative, public-private research relating to environmental monitoring and detection tools with respect to biological agents."

logical or chemical attacks using atmospheric remote detection technologies; and establishing a means of testing and calibration of new detection and surveillance tools.⁵⁶ Although, this proposal never passed, the Department of Homeland Security announced the implementation of biological agent air monitoring devices through the U.S. Environmental Protection Agency network of existing air monitoring devices, January 22, 2003.

1. Decontamination

The U.S. EPA participated in a visible role throughout the anthrax attacks in decontamination of buildings during the response phase. This role was part of the national plan outlined above, utilizing the expertise of EPA in cleaning hazardous waste sites. EPA conducted the decontamination of the Hart Senate Building and other federal buildings contaminated during the anthrax attacks of fall 2001.

Reflecting this role, the President's Budget for FY 2003 requested \$124 million in new funding for a total EPA investment of \$133.4 million in homeland security, with more than half dedicated to decontamination activities.⁵⁷

2. Protection of the Nation's Water Supply

In June 1990, four unrelated people living in the same block of apartment buildings in Edinburgh, Scotland, became infected with giardiasis, a diarrheal illness caused by a microorganism found in water. It was discovered that all of the apartment buildings were sup-

⁵⁶ *Id.* at § 3(b).

⁵⁷ *Budget of the United States – Fiscal Year 2003*, Office of Management and Budget – The Executive Office of the President (last visited February 7, 2003) at <http://www.whitehouse.gov/omb/budget/fy2003>.

\$75 million	For conducting research on better technologies and assessments to clean up buildings contaminated with biological and chemical agents
\$19 million	For maintaining security contracts and continue upgrades at EPA facilities
\$16.9 million	For conducting drinking water system vulnerability assessments on small to mid-sized systems
\$13.2 million	For continued operation of the West Coast Environmental Response Team
\$5 million	For grants to the states to enhance homeland security coordination
\$3.8 million	For special agents who will provide environmental crimes expertise
\$0.5 million	For enhanced outreach on the Agency's Homeland Security efforts to the public

plied water from tanks on the roof, accessible through inspection hatches. An investigation revealed that fecal material containing the *Giardia* cysts was intentionally placed in the tanks.⁵⁸

Other more dangerous organisms could also be a threat to drinking water supplies, if intentionally used by terrorists.

In June 12, 2002, the U.S. Congress amended the Safe Drinking Water Act with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, addressing the need to require local governments to research methods to prevent and respond to intentional contamination of drinking water supplies.⁵⁹ Specifically, the mandate requires real time monitoring systems for the detection of contaminants,⁶⁰ methods to notify operators and individuals of any contamination,⁶¹ development of education and awareness,⁶² procedures and equipment to prevent the flow of contaminated drinking water,⁶³ and provision of equipment to mitigate contamination of drinking water.⁶⁴ Regarding supply disruption, the U.S. EPA is to

⁵⁸ See Robert S. Root-Bernstein, *Infectious Terrorism*, THE ATLANTIC, May 1991, at 44, 48, available at <http://www.theatlantic.com/issues/91may/rootbernstein.htm> (explaining how water supplies are susceptible to premeditated contamination).

⁵⁹ Pub. L. No. 107-188, sec. 401, § 1434-35, (“*In General – The Administrator, in consultation with the Centers for Disease Control and, after consultation with appropriate departments and agencies of the Federal Government and with State and local governments, shall review (or enter into contracts or cooperative agreements to provide for a review of) current and future methods to prevent, detect and respond to the intentional introduction of chemical, biological or radiological contaminants into community water systems and source water for community water systems . . .*”).

⁶⁰ *Id.* at § 1434(a)(1) (“*Methods, means and equipment, including real time monitoring systems, designed to monitor and detect various levels of chemical, biological, and radiological contaminants or indicators of contaminants and reduce the likelihood that such contaminants can be successfully introduced into public water systems and source water intended to be used for drinking water*”).

⁶¹ *Id.* at § 1434(a)(2) (“*Methods and means to provide sufficient notice to operators of public water systems, and individuals served by such systems, of the introduction of chemical, biological or radiological contaminants and the possible effect of such introduction on public health and the safety and supply of drinking water*”).

⁶² *Id.* at § 1434(a)(3) (“*Methods and means for developing educational and awareness programs for community water systems*”).

⁶³ *Id.* at § 1434 (a)(4) (“*Procedures and equipment necessary to prevent the flow of contaminated drinking water to individuals served by public water systems*”).

⁶⁴ *Id.* at § 1434(a)(5) (“*Methods, means, and equipment which could negate or mitigate deleterious effects on public health and the safety and supply caused by the introduction of contaminants into water intended to be used for drinking water, including an examination of the effectiveness of various drinking water technologies in removing, inactivating, or neutralizing biological, chemical, and radiological contaminants*”).

review methods by which terrorists might disrupt safe water supplies,⁶⁵ by destroying pipes or conveyances,⁶⁶ destroying distribution facilities,⁶⁷ effecting cross-contamination of water supplies,⁶⁸ disrupting computer controlled systems,⁶⁹ ways of preventing these results,⁷⁰ and in the event of such an attack, the provision of alternative water supplies.⁷¹

G. The Role of the Military

The role of the military in civilian biodefense is primarily that of providing resources and personnel to utilize equipment and resources. However, other organizations within the Department of Defense, U.S. Army, – the Material Command and the Medical Command – undertake weapons of mass destruction research and response activities.

⁶⁵ *Id.* at § 1435(a) (“Disruption of Supply or Safety – The Administrator, in coordination with the appropriate departments and agencies of the Federal Government, shall review (or enter into contracts or cooperative agreements to provide for a review of) methods and means by which terrorists or other individuals or groups could disrupt the supply of safe drinking water or take other actions against water collection, pretreatment, treatment, storage and distribution facilities which could render such water significantly less safe for human consumption . . .”).

⁶⁶ *Id.* at § 1435(a)(1) (“Methods and means by which pipes and other constructed conveyances utilized in public water systems could be destroyed or otherwise prevented from providing adequate supplies of drinking water meeting applicable public health standards”).

⁶⁷ *Id.* at § 1435(a)(2) (“Methods and means by which collection, pretreatment, treatment, storage and distribution facilities utilized or used in connection with public water systems and collection and pretreatment storage facilities used in connection with public water systems could be destroyed or otherwise prevented from providing adequate supplies of drinking water meeting applicable public health standards”).

⁶⁸ *Id.* at § 1435(a)(3) (“Methods and means by which pipes, constructed conveyances, collection, pretreatment, treatment, storage and distribution systems that are utilized in connection with public water systems could be altered or affected so as to be subject to cross-contamination of drinking water supplies”).

⁶⁹ *Id.* at § 1435(a)(5) (“Methods and means by which information systems, including process controls and supervisory control and data acquisition and cyber systems at community water systems could be disrupted by terrorists or other groups”).

⁷⁰ *Id.* at § 1435(a)(4) (“Methods and means by which pipes, constructed conveyances, collection, pretreatment, treatment, storage and distribution systems that are utilized in connection with public water systems could be reasonably protected from terrorist attacks or other acts intended to disrupt the supply or affect the safety of drinking water”).

⁷¹ *Id.* at § 1435(b) (“Alternative Sources – The review under this section shall also include a review of the methods and means by which alternative supplies of drinking water could be provided in the event of the destruction, impairment or contamination of public water systems”).

Within the Medical Command is the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), which houses the medical defense program of the United States.

1. *Posse Comitatus*

The role of the military is limited by federal legislation and the interpretation of the *Posse Comitatus* Act. In 1867, the U.S. Congress passed The Reconstruction Act which established martial law in the southern states at the end of the U.S. Civil War, 1860-1864. The *Posse Comitatus* Act was signed into law June 18, 1878 in response to abuses of military control over the south after the U.S. Civil War, during Reconstruction. Thereafter, the United States declared that the military should never have enforcement powers against civilians, except in a declared state of emergency.

The *Posse Comitatus* Act has been amended to address changing needs for resources and assistance. In 1968, a separate statutory exception was created to provide assistance to the Secret Service in carrying out its protective duties.⁷² During the civil disturbances of the 1960s and 1970s, the military was utilized in the development of an interdepartmental plan for civil disturbances in order to address overlapping jurisdictions.⁷³ The Department of Defense articulated a policy directive to address terrorist incidents as either a civil disturbance or a criminal act, and how the incident was defined would give rise to the legal framework within which it was analyzed.⁷⁴

In 1981, an amendment to the Act codified the existing relationship between the military and civilian law enforcement agencies. This provided for increased cooperation through specific provision of intelligence,⁷⁵ facilities, including materials not reasonably available from another source which is "any material or expertise of the Department of Defense appropriate for use in preparing for or responding to an emergency involving chemical or biological agents," such as biosensors, protective clothing and antidotes,⁷⁶ training and advice,⁷⁷ and assistance in the operating and maintaining military equipment to

⁷² Pub. L. No. 90-331, 82 Stat. 170 (1968).

⁷³ *Interdepartmental Action Plan for Civil Disturbances* (Apr. 1, 1969).

⁷⁴ See Department of Defense Directive No. 3025.12, *Military Assistance for Civil Disturbances*, at <http://www.dtic.mil/whs/directives/corres/html/302512.htm> (Feb. 4, 1994). The Department of Defense initially issued Directive No. 3025.12 on August 19, 1971. This issuance was cancelled by the updated version in 1994.

⁷⁵ 10 U.S.C. § 371 (2002).

⁷⁶ 10 U.S.C. § 372 (2002).

⁷⁷ 10 U.S.C. § 373 (2002).

monitor air and sea traffic.⁷⁸ The Act further provides that the military may “monitor, contain, disable, or dispose of the weapon involved or elements of the weapon.”⁷⁹ In the case of biological weapons, the military may not directly participate in arrest, search or seizure of evidence or intelligence gathering for law enforcement purposes, unless it is necessary to save human life and civilian authorities are unable to do so.⁸⁰ Such involvement by the military is also limited in time and scope to addressing only the specific biological incident.⁸¹

But the 1981 Amendment added additional prohibitions for the use of the military, including any use which would adversely affect military preparedness for national defense,⁸² as well as the proviso that the use of military resources may be contingent upon reimbursement by the local or state governments or other federal agency.⁸³

Following the 1981 Amendment, the interdepartmental plan was formalized with a Memorandum of Understanding between the Department of Justice, the Federal Bureau of Investigation, and the Department of Defense in 1983 which provided for responsibilities in the event of a domestic terrorist attack.⁸⁴ In 1988, another amendment was made to codifying further clarifications, but added the use of the military for its new role in drug interdictions, and formally gave the Department of Defense lead authority for advising civilian law enforcement agencies concerning the types of equipment and assistance available.⁸⁵

The military cannot be used to enforce laws against civilians in the United States. There are constitutional exceptions to this act, as well as statutorily provided exceptions. The constitutional exceptions

⁷⁸ 10 U.S.C. § 374(b)(2)(a) (2002).

⁷⁹ 10 U.S.C. § 382(c) (2002).

⁸⁰ 10 U.S.C. § 382(d) (2002).

⁸¹ *Id.*

⁸² 10 U.S.C. § 376 (2002).

⁸³ 10 U.S.C. § 377 (2002).

⁸⁴ *Memorandum of Understanding*, (Aug. 5, 1983). Although the *Posse Comitatus* Act does not permit military personnel to actively engage in the law enforcement mission unless expressly authorized, the Act does not prohibit military observers from reporting to the Department of Defense; nor does it generally prohibit the preparation of contingency plans for lawful military intervention; advice to civilian officials, sharing intelligence information collected during the normal course of military operations, including operations relating to the incident; the loan of specialized equipment or weaponry; the use of military personnel to deliver and maintain equipment for civilian use, provided those personnel do not operate that equipment; or the use of military personnel to train civilian law enforcement officials in the operation and maintenance of military equipment. See 10 U.S.C. §§ 371-378 (2002) (Military support for civilian law enforcement).

⁸⁵ 10 U.S.C. § 380 (2002).

are Presidential powers in emergency authority and the protection of federal property and operations. The act provides for exceptions where it is "impracticable to enforce the laws of the United States . . . by the ordinary course of judicial proceedings,"⁸⁶ or the use of the military by the President to control an insurrection.⁸⁷ Otherwise, the use of the military required that a state's governor make such a request, and the President must issue an order to activate the military for that purpose. The failure to have the President formally issue an order can raise questions with use of the military under the *Posse Comitatus* Act.⁸⁸ However, specific passive activities have been held to be compliant with the Act, which include for example, reconnaissance missions.⁸⁹

In summary, the *Posse Comitatus* Act prohibiting military involvement with civilians can be excepted in two constitutional exceptions and four statutory and regulatory exceptions. The constitutional exceptions are the President's emergency powers to respond to insurrection and the protection of federal property and governmental functions. The statutory powers to the President include a national emergency involving civil disturbances,⁹⁰ rebellions which make it impracticable to enforce federal laws,⁹¹ any insurrection or violence which impedes the state's ability to protect citizens and/or the state is unable or unwilling to protect those rights.⁹²

2. USAMRIID

The United States Army Medical Research Institute of Infectious Diseases (USAMRIID) is the biological defense laboratory housed within the U.S. Army division of the Department of Defense. The

⁸⁶ 10 U.S.C. § 332 (2002).

⁸⁷ 10 U.S.C. §§ 331-333 (2002).

⁸⁸ *Cf.* United States v. Jaramillo, 380 F. Supp. 1375, 1379 (1974) (noting that "the use of troops to execute the laws [i]s forbidden, unless expressly authorized by the Constitution or an Act of Congress").

⁸⁹ *See* United States v. Red Feather, 392 F. Supp. 916, 924-25 (D. S.D. 1975) ("Congress did not intend to make unlawful the involvement of federal troops in a passive role in civilian law enforcement activities").

⁹⁰ 10 U.S.C. §§ 331-334 (2002). *See also* Department of Defense Directive No. 3025.12, § 4.1.1, *Military Assistance for Civil Disturbances*, at <http://www.dtic.mil/whs/directives/corres/html/302512.htm> (Feb. 4, 1994) (detailing the President's authority in time of uprisings).

⁹¹ 10 U.S.C. § 332 (2002). *See also* Department of Defense Directive No. 3025.12, § 4.1.1, *Military Assistance for Civil Disturbances*, at (Feb. 4, 1994) (regarding the President's authority).

⁹² 10 U.S.C. § 333 (2002). *See* Department of Defense, Directive No. 5525.5 (1986).

stated mission of the USAMRIID is to conduct research to develop products, procedures and training programs “for medical defense against biological warfare threats and naturally occurring infectious diseases that require special containment.”⁹³

The USAMRIID focuses on the development of countermeasures to sustain the fighting ability of the military, and is also engaged in response to worldwide emerging diseases in investigation and response activities with the CDC. The military and civilian staff includes physicians, veterinarians, microbiologists, pathologists, chemists, molecular biologists, physiologists and pharmacologists. The staff of the USAMRIID includes 70 Medical Research Volunteer Subjects (MRVS) who are highly trained laboratory technicians who have requested to participate in clinical trials of vaccines and drugs developed at USAMRIID, which comprise the first phase of human testing in the vaccine and drug development protocol. The staff also includes teams which are trained to deploy to combat zones to establish diagnostic laboratories, or to respond to a disease outbreak, anywhere in the world, and to evaluate patients under the most stringent containment conditions.

USAMRIID works to improve vaccines for anthrax, Venezuelan equine encephalitis, plague, and botulism, and to develop new vaccines for toxins such as staphylococcal enterotoxins and ricin. Work is also being conducted for medical countermeasures to viral hemorrhagic fevers and arboviral illnesses, and for the development of diagnostic tools for identifying the presence of biological agents or endemic disease threats.

3. National Guard Bureau

The National Guard Bureau is a division of the Department of Defense, Reserve Affairs and includes the 54 National Guard units in the states and territories. The responsibilities of the National Guard include the “contracting for supplies and services, managing supply operations and movements, preparing and distributing meals, purifying, storing, and removing waste, repairing vehicles and equipment,

⁹³ USAMRIID, GENERAL INFORMATION, at <http://www.usamriid.army.mil/general/index.html> (last modified July 25, 2002). *The U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) conducts research to develop strategies, products, information, procedures, and training programs for medical defense against biological warfare threats and naturally occurring infectious diseases that require special containment. USAMRIID, an organization of the U.S. Army Medical Research and Materiel Command (USAMRMC), is the lead medical research laboratory for the U.S. Biological Defense Research Program.*

constructing life support centers and removing debris.”⁹⁴ The National Guard may be utilized by the Governor,⁹⁵ or by the President,⁹⁶ in a state or national emergency, respectively.

H. The Role of the Public Health Service and the Indian Health Service (IHS) and the Department of Veterans Affairs

These three agencies, the Public Health Service, the Indian Health Service and the Department of Veterans Affairs have national health-care responsibilities. The U.S. Public Health Service is provided with quarantine and inspection powers where communicable diseases may spread into the United States or from one state to another.⁹⁷ The Public Health Service has no specific role in the federal bioterrorism response responsibilities. However, after the anthrax attacks, one bill was introduced to mandate that the U.S. Public Health Service have membership in the National Security Council, although that measure has thus far failed.⁹⁸

The Indian Health Service (IHS) is a component of the U.S. Public Health Service and its mission to deliver healthcare to Native Americans.⁹⁹ The Indian Health Service was the lead agency in the

⁹⁴ Barry Kellman, *Managing Terrorism's Consequences: Legal Issues*, THE MEMORIAL INSTITUTE FOR THE PREVENTION OF TERRORISM, Chs. 2, 26 (forthcoming March 2002).

⁹⁵ See generally 10 U.S.C. §§ 1 et seq. (2000) (detailing the Governor's power over the National Guard).

⁹⁶ See 32 U.S.C. §§ 104(d)-(c), 111 (2000) (detailing the President's power over the National Guard).

⁹⁷ 42 U.S.C. § 264 (2002). See also 42 C.F.R. §§ 70.1-73.0 (2002). *Communicable disease means illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment.* (42 C.F.R. § 70.1(a)(2002).

⁹⁸ Bioterrorism Protection Act (BioPAct) of 2001, H.R. 3255, 107th Cong. § 127 (2001). *Public Health Representation on the NSC. It is the sense of the congress that the Surgeon General of the Public Health Service should serve as a member of the National Security Council.*

⁹⁹ U.S. Dept. of Health and Human Services, *Indian Health Service Introduction*, at <http://www.ihs.gov/AboutIHS/IHSintro.asp> (last modified June 18, 2002). The Indian Health Service states “*Our Mission . . . to raise the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level. Our Goal . . . to assure that comprehensive, culturally acceptable personal and public health services are available and accessible to American Indian and Alaska Native people. Our Foundation [is] . . . to uphold the Federal Government's obligation to promote healthy American Indian and Alaska Native people, communities, and cultures and to honor and protect the inherent sovereign rights of Tribes.*” *Id.*

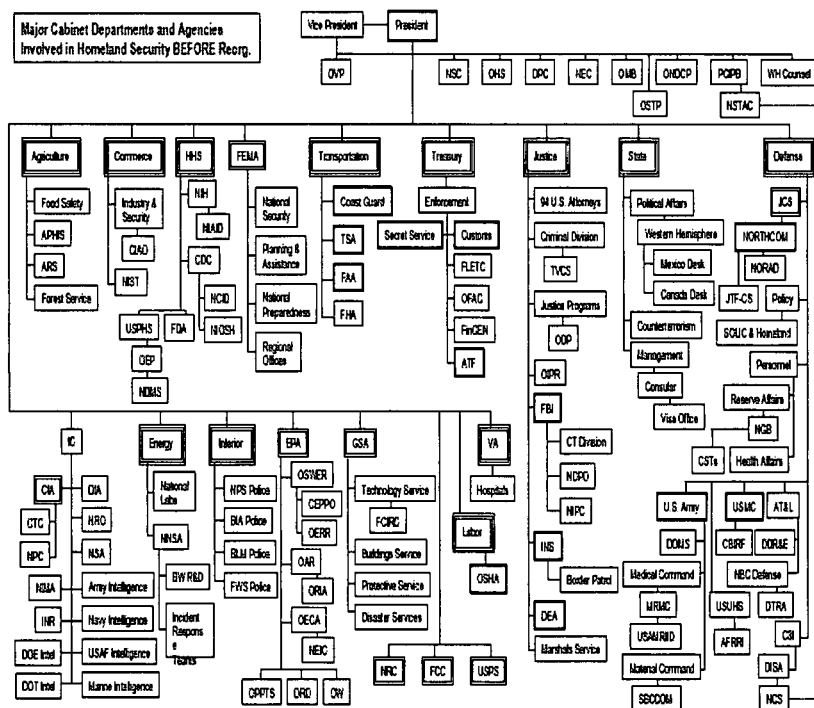
investigation of the Haunta virus outbreak in the Navajo Nation, and has had the experience of addressing a highly lethal biological agent in an epidemiological investigation. Interestingly, IHS was not included in the agencies involved in homeland security issues in the President's proposal (See Figure 3).

The Department of Veterans Affairs manages a system of hospitals throughout the United States which serve qualified military veterans throughout their lives. The system of hospitals provides an opportunity for a federal presence in communities in creating a national biodefense system, ensuring trained military medical personnel are within communities throughout the U.S.

I. Other Departments and Agencies

There are components of every cabinet-level department and many agencies which have a role in homeland security, and are an important part of an integrated plan to address bioterrorism. In the President's Proposal for a Department of Homeland Security, a diagram identifies the organizations within the federal government with a role in homeland security. About 60% of those agencies have an important role specifically in bioterrorism.

Figure 3: President George W. Bush, The Department of Homeland Security (June 2002).¹⁰⁰



III. FEDERALISM, NATIONAL SECURITY, STATES AND THE DEPARTMENT OF HOMELAND SECURITY PROPOSAL

Biodefense is currently supported through the distribution of powers between the national government, state government and private groups; the other weapons of mass destruction are preempted by federal legislation and are in the exclusive jurisdiction of the federal government (See Fig. 4). The unique features of bioterrorism coupled with a legal framework, unlike that of any of the other weapons of mass destruction, require analysis of not only the resources of the na-

¹⁰⁰ President George W. Bush, The Department of Homeland Security (June 2002), at <http://www.whitehouse.gov/deptofhomeland/book.pdf>.

tional government and those of the state governments, but also the constitutional framework in which any changes must be balanced.

A. The President's Proposal for a Department of Homeland Security

A legislative solution in order to provide for a federal role is required to address the need for federal involvement in peace time with public health powers. The most important movement in that direction has been the President's proposal for a Department of Homeland Security, June 6, 2002.¹⁰¹

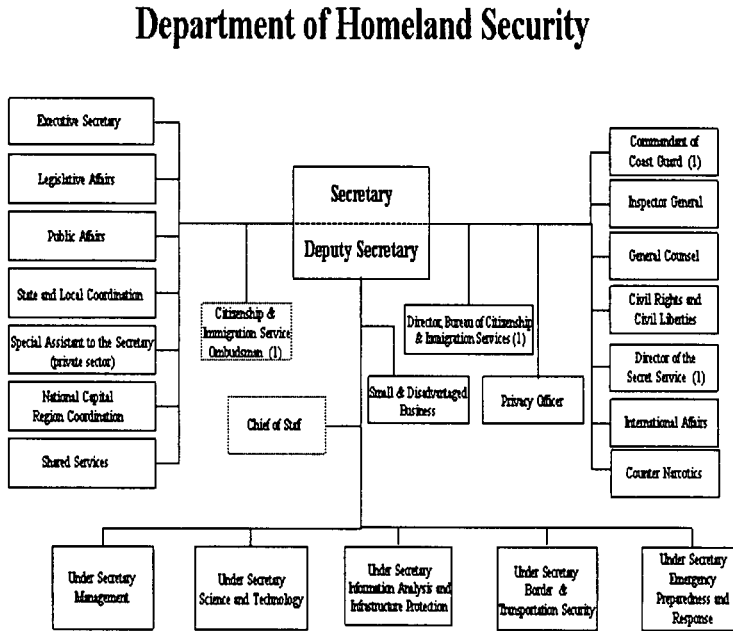
On June 6, 2002, President George W. Bush proposed a new Department of Homeland Security,¹⁰² which would become the third largest department in the President's cabinet (See Figure 4). This proposal comes just nine months after the formation of the Office of Homeland Security, which the President found insufficient to address the needs of governmental organization. This legislation also closely follows the passage of the Public Health Security Act and Bioterrorism Preparedness and Response Act of 2002¹⁰³ assigning most of the bioterrorism responsibilities in the federal government to the Department of Health and Human Services, passed June 12, 2002, although making no significant commitments toward assuming more national responsibility, except in existing areas of federal authority through federal environmental and agricultural statutes.

¹⁰¹ See *Analysis for the Homeland Security Act of 2002*, at <http://www.whitehouse.gov/deptofhomeland/analysis/hsl-bill-analysis.pdf> (last visited Oct. 7, 2002) (analyzing and explaining the sections of the Homeland Security Act).

¹⁰² President George W. Bush, *The Department of Homeland Security* (June 2002), at <http://www.whitehouse.gov/deptofhomeland/book.pdf>.

¹⁰³ Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (June 12, 2002) (updating government powers in response to terrorist attacks).

Figure 4: From Pres. George W. Bush, The Department of Homeland Security (June 2002)



Note (1): Effective March 27, 2003

Legislation for a Department of Homeland Security was introduced in the U.S. House of Representatives in June, and was assigned to Committee in the House,¹⁰⁴ and then passed the House of Representatives in a vote of 295 to 132, July 26, 2002. In August and September, the U.S. Senate offered amendments, in part amending the status of federal government employees to enjoy all civil service employment protections, in distinction to the House bill which provided for more flexibility in hiring and firing of employees in a Department of Homeland Security.¹⁰⁵

¹⁰⁴ Homeland Security Act of 2002, P.L. 107-296 [H.R. 5005], Nov. 25, 2002, 107th Cong. (2d Sess. 2002), available at <http://www.whitehouse.gov/deptofhomeland/bill/hsl-bill.pdf>.

¹⁰⁵ S. 2452, 107th Cong. (2002).

The legislation languished until after the midterm elections and a new Republican Senate majority was elected. On November 19, 2002 the Senate passed a Department of Homeland Security bill, 90-9; and on November 22, 2002, the House agreed to the Senate amendments. The bill became law on November 25, 2002 with the President's signature.

The approach to weapons of mass destruction has been to address them in the same manner with the same organizations within the federal government; however, the President proposed separate offices for chemical, nuclear and biological, acknowledging the need for different approaches. But more importantly, the inclusion of biological threats includes a federal field not heretofore occupied by the federal government, as are nuclear and chemical activities of all kinds. Even on the basis of public safety, a federal court has held that the federal government has preempted the field in nuclear activities; and although public safety may be a sovereign power of the states, it cannot legislate in a field which has been preempted constitutionally by the federal government.

The President's proposal for a Department of Homeland security begins with a statement signaling that the federal government was taking responsibility for public health in a bioterrorism context: "The President's most important job is to protect and defend the American people." His discussion criticized the lack of one agency with a primary mission of homeland security. The dispersed functions among the "more than 100 different government organizations" was cited as evidence of this lack of centralization. In this reorganization, the President makes three very strong indications that the shift in federalism from the states to the federal government should occur in the field of bioterrorism.

Among the reasons cited that "The Department of Homeland Security would make Americans safer" was "because our nation would have: . . . One department to coordinate our efforts to protect the American people against bioterrorism and other weapons of mass destruction." Critical is the use of the word "protect" because it shifts the responsibility to the federal government from the state government in matters of public health law protection of public health. The constitutional balance of federalism reserves those powers not enumerated to Congress nor prohibited by it to the states [Tenth Amendment]. Among those powers reserved to the states is the power to protect its citizens in matters of public health. Only during a national emergency or threat of national security does the power shift to the federal government. In the President's proposal, the power shifts to the federal government during the time to "protect" the American people which would be the period before a bioterrorism event begins

to become evident, because after that point the opportunity to truly protect the American people is diminished.

In the example of “[c]ommunicating to the American people,”¹⁰⁶ the report reads: “The new Department would ensure that local law enforcement entities – and the public – receive clear and concise information from their national government.”¹⁰⁷ This is a second critical signal in the report that authority of the states in public health will be shifted to the “national government” in the context of “a chemical or biological attack.”¹⁰⁸ This is counter to current response protocols which specify that state governments will take the lead in a bioterrorism attack [e.g., CDC Smallpox Response Plan, Nov. 19, 2001], and in conflict with the current Model Public Health Law, posed by the National Governors Association and the Centers for Disease Control and Prevention. The federal approach is more consistent with the role of national security in our balance of federalism, and should shift the power from the states to the federal government, even in peace time.

The third example reads that the “scientific assets” are described which would make possible the detection of bioterrorist attacks:

*The anthrax attacks of October 2001 proved that quick recognition of biological terrorism is crucial to saving lives. The Department of Homeland Security would lead efforts to develop, deploy, manage and maintain a national system for detecting the use of biological agents within the United States. This system would consist of a national public health data surveillance system to monitor public and private databases for indications that a bioterrorist attack has occurred, as well as a sensor network to detect and report the release of bioterrorist pathogens in densely populated areas.*¹⁰⁹

This is the third critical mention of a shift of power from state public health authority to federal authority. The “maintain”, “manage”, and “monitor”¹¹⁰ verbs indicate a federal government involvement before a national security attack occurs – before the time when power shifts from the states to the federal government in our constitutional framework. The nature of biological attack, however, makes essential that a federal system of monitoring be in place to carry out the national security role of the federal government.

¹⁰⁶ Bush, *supra* note 100, at 5.

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ Bush, *supra* note 100, at 13.

¹¹⁰ *Id.*

The legislation does not mandate more responsibility for the national government, but attempts to maintain the cooperative federalism approach to national security in biodefense – unlike areas of chemical, nuclear and radiological threats. Through the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, existing federal powers in the area of federal environmental statutes were expanded in scope to include protection of the nation's drinking water from bioterrorists' attacks under the relevant federal statute,¹¹¹ and for the protection of the nation's food supply under another relevant federal statute.¹¹² Functions of the Department of Health and Human Services under the Public Health Security Act are transferred to the new Department of Homeland Security for the Strategic National Stockpile and for Smallpox vaccine development.¹¹³

While the federal government begins to examine its national approach, states are moving ahead with what has been their traditional authority and power – to protect the public health of its citizens. On September 19, 2002, the National Governors Association (NGA), announced their plan to develop a national network for homeland security information, beginning with a pilot plan which involves five to eight states.¹¹⁴ Governor Barnes, Georgia, was quoted as saying, "To date, the main costs of homeland security have been born almost entirely by the state and local government . . . We can't really wait until next year to get this money [money currently appropriated by Congress]." ¹¹⁵ This effort may not be consistent with a national approach, which will exacerbate the existing lack of coordination between the national and state governments. For example, each state will have its own version of any statutory mandate for homeland security, much like the states who have proceeded with genetic legislation in the almost complete absence of action on the part of Congress. Now half of the states have some kind of law regulating the use of genetic information, using many different approaches.¹¹⁶ Further, the use of compacts between states is specifically forbidden by the Constitution.¹¹⁷

¹¹¹ 42 U.S.C. §§ 300g-3 to i-4 (2002).

¹¹² Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 21 U.S.C. §§ 331-99 (2002).

¹¹³ P.L. 107-188 [H.R. 2448], June 12, 2002, Public Health Security Act and Bioterrorism and Preparedness Act of 2002, § 905(a).

¹¹⁴ Press Release, Governors Announce New Homeland Security Initiatives, Propose Driver's License Project, at http://www.nga.org/nga/newsRoom/1,1169,C_PRESS_RELEASE^D_4360,00.htm.

¹¹⁵ *Id.*

¹¹⁶ VICTORIA SUTTON, LAW AND BIOTECHNOLOGY, § 2.0 (forthcoming 2003).

¹¹⁷ U.S. CONST. art. I, § 10 ("No State shall enter into any Treaty, Alliance, or Confederation").

James Madison, one of the authors of *The Federalist Papers* explained, that “for reasons which need no explanation” the prohibition against states entering into treaties “is copied into the new Constitution” from the Articles of Confederation.¹¹⁸ Compacts among states, therefore may be unconstitutional without explicit approval from Congress.¹¹⁹

A national approach to biodefense will ultimately require a shift in federalism, and if the Department of Homeland Security legislation is passed, it is predictable that amendments will follow which will move toward a more national approach to homeland security and to move away from the present, fifty different systems. James Madison, with particular foresight in the context of biodefense, wrote, “[i]f, therefore, . . . the people should in future become more partial to the federal than to the State governments, . . . the people ought not surely to be precluded from giving most of their confidence where they may discover it to be most due.”¹²⁰ Alexander Hamilton, further warned against becoming a nation that does not allow for preparation of a national defense before attack: “[Warning that we should not be] a nation incapacitated by its Constitution to prepare for defense before it was actually invaded.”¹²¹

Finally, the U.S. Supreme Court has observed that the protection and preservation of the public health is among the most important duties of state government,¹²² however, James Madison wrote that “[s]tate legislatures will be unlikely to attach themselves sufficiently to national objects.”¹²³

IV. RECOMMENDATIONS

The responsibilities of the federal government for homeland security require an executive branch infrastructure which is capable of meeting the challenge of biodefense. The most important change in federalism that can be made in biodefense is to create a national sys-

¹¹⁸ THE FEDERALIST NO. 44, at 280-81 (James Madison) (Clinton Rossiter ed., 1961).

¹¹⁹ See, e.g., Low-Level Radioactive Waste Policy Act, 42 U.S.C. § 2021(d) (2002) (authorizing states to enter into compacts to provide for the operation of regional disposal facilities for low-level radioactive waste).

¹²⁰ THE FEDERALIST NO. 46 (James Madison) (Clinton Rossiter ed., 1961).

¹²¹ THE FEDERALIST NO. 25 (Alexander Hamilton) (Clinton Rossiter ed., 1961) (discussing the importance of raising armies in peacetime).

¹²² See, e.g., *Jacobson v. Massachusetts*, 197 U.S. 11, 30 (1905) (holding that Massachusetts could constitutionally require vaccination of its citizens to preserve public health).

¹²³ THE FEDERALIST NO. 46 (James Madison) (Clinton Rossiter ed., 1961).

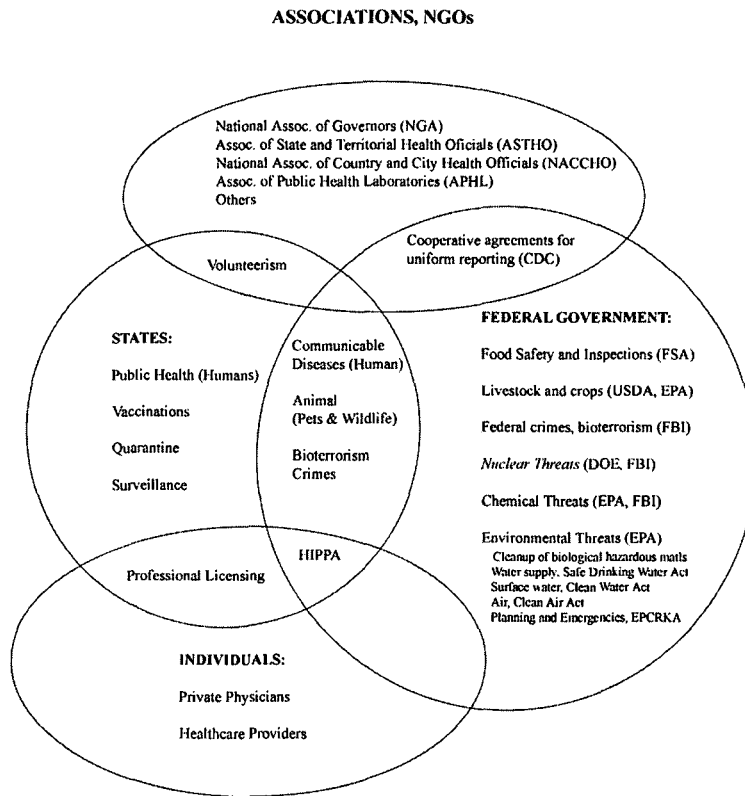
tem of public health surveillance, with a uniform system of reporting. It is not enough that PHSA 126(a) provides for the federal government to *evaluate* public health surveillance technology for states' use. There must be a national surveillance system, with meaningful data which can predict the earliest stages of an attack, not fifty different systems with jurisdictional lines which become not only meaningless, but serve as impediments to responding to a public health emergency.

The proposed Department of Homeland Security has been organized without including the federal law enforcement organization which has been designated as the lead agency for responding to biological attacks – the FBI. While other agencies and departments have divisions excised for transfer to the new Department, the FBI has no such transfer of any functions. If the lead for a bioterrorism attack is to remain with the FBI, then the new Department of Homeland Security makes little progress in the organization of the federal government. At least the relevant investigative units should be transferred from the FBI to the new Department of Homeland Security.

The new division of Biological and Agricultural Terrorism must address the very different legal jurisdictions, as illustrated in Figure 5. While conceptually, these threats may seem appropriate to group together, the legal framework is so different between human public health and agricultural terrorism, that legislation will be needed to have any national jurisdiction over public health. The new legislation creating the Department of Homeland Security has a mere coordination role with states and local governments.

Finally, it is not evident that human public health is included in this organization, other than through a staff line to the Secretary labeled, “state, local and private sector coordination.” (see Figure 4). Allowing our homeland defense against bioterrorism to be left in the hands of each individual state is a recipe for disaster. In James Madison’s persuasive discussion for federalism, he wrote, “[s]tate legislatures will be unlikely to attach themselves sufficiently to national objects.” The need for a national system of biodefense is essential to utilize the fifty state systems and resources. Without sacrificing the experience and expertise of each state, a movement toward a national linking of every state – more than a coordination mechanism – is imperative, before time and divergent legislatures make it more difficult to address. But most importantly, the future of our defense is a stake, and it is that aspect of federalism described by The Federalists, which enables our nation to respond to a homeland security threat, and concurrently recognize the Constitutional assignment of powers.

Figure 5: Distribution of Powers in Biodefense compared to Other Weapons of Mass Destruction



V. CONCLUSION

The organization of the federal government is essential to biodefense. National security is the highest of compelling interests that might be held by a government. The federalism aspects of the movement from a state-based system of national security, to a national system of biodefense requires more than the piecemeal approach offered by the Public Health Security Act of 2002, but also more than the reorganization of agencies and departments into a Department of Homeland Security without consideration of the federalism balance that must be struck. Although these are both important pieces of legislation which move toward a national system of biodefense, both fall short of addressing the shift in federalism necessary to effect the intent of Congress, which is to "(A) prevent terrorist attacks within the

United States; (B) reduce the vulnerability of the United States to terrorism; [and] (C) minimize the damage, and assist in the recovery, from terrorist attacks that do occur within the United States.”¹²⁴ Congress should consider the federalism relationship in the context of biodefense to affect a true national defense.

¹²⁴ Homeland Security Act of 2002, H.R. 5005, 107th Cong. §§ 101(b)(1)(a)-(c) (2002).