BIODEFENSE

A Legal Framework Rework

When Peacetime is the Only Time

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32 | The Federal Lawyer | October 2002

BIOTERRORISM IS A THREAT of catastrophic proportions, yet in the wake of the fall 2001 anthrax attacks, it became evident that our nation was sadly unprepared. Our innocence as a nation has been replaced by the sobering reality that we are vulnerable in a way previously contemplated only in the cinematography of Hollywood, as in "Outbreak" (1995), or in fictional reading, as in "The Cobra Event" (Richard Preston, 1999). So, too, the aftermath of 9/11 and the subsequent anthrax attacks raise new policy challenges and legal issues at the heart of our system of laws.

Why? The first revelation is the unique features of bioterrorism make it particularly unmanageable in our current legal framework. Federal authorities and experts have organized these as weapons of mass destruction, earning the collective acronym, WMD; yet radiological, nuclear, and chemical threats differ significantly from biological threats. Radiological, nuclear, and chemical threats are known when they occur, are spent immediately upon their attack, and have a relatively contained geographical region of impact. In marked contrast, biological threats are clandestine in their delivery, with the time of attack being unknown; the impact of a biological threat is not spent upon attack but increases exponentially in its effect on human life. The geographical region affected is limited only by the planet, facilitated by the wide use of air travel by individuals. The expertise to deal with these weapons also differs, and it is the public health community that is most critical in addressing the threat of bioterrorism. Prevention, too, is markedly different: criminal investigation with attendant tracking of chemicals and radiological materials is required through the ports of entry and transportation systems. Biological materials must be tracked through medical data obtained by public health surveillance systems. In contrast, monitoring ports of entry and transportation systems is meaningless where much smaller quantities of biological materials than chemical and radiological materials can be used for a deadly attack. It is critical that our infrastructure evolve to account for these unique features of bioterrorism.

So, too, the legal framework created according to the constitutional concepts of federalism as it now exists is unrealistic in light of the threat to national security. Currently, our national defense against bioterrorism is driven by 54 different state and territorial public health systems, linked only by the web of *volunteer* efforts of national associations of epidemiologists, public health officers, and emergency response officials, with no overarching federal authority or coordination. This is a result of our historical interpretation of the 10th Amendment, which mandates

that "those powers not given to the U.S. Congress, nor prohibited by it to the states, shall be reserved to the states. ..." Public health law has been a power of the state since the time of the colonies, and only through Commerce Clause power has the U.S. Congress taken any of the states' powers, based upon effects on interstate commerce, such as food safety and drug sales.

National efforts to develop exercises to address the policy and public health needs have focused primarily on the medical aspects and have only scratched the surface of issues that must be resolved in law and federalism while we have the opportunity to do so in a nonemergency context. In August 2002, "Pale Horse 2002," at Fort Sam Houston in San Antonio, Texas, was the first such national exercise to recognize the vital need to comprehensively address the legal framework for these responses.

Legal issues and relevant case law, which must be addressed by the legal community in order to provide for an effective national defense, include such issues as separation of powers, federalism, federal and state government roles, private sector effects, and criminal and civil implications, as well as technological and scientific areas. To address these legal challenges, an overview of these areas can assist in developing a dialogue within the nation's legal community.

The Changing Nature of Federalism

Bioterrorism does not fit well within our traditional notions of the point in time when national security emergency power should shift from state power. The threat of bioterrorism requires a federal presence in the public health system long before we have a national security emergency, because biological threats are an emergency before they are known. The shift to national power would come much too late to provide for our national security without catastrophic consequences. Simply put, a legal framework that minimizes jurisdictional boundaries — because biological agents ignore jurisdictional boundaries is essential to national security. An example of such a shift in federalism is evident in the federal response to environmental disasters. Just as public health law is now a state power, so too, was property law in relation to environmental pollution prior to the 1970s. After Congress recognized the failure of having a 50-state system of environmental protection — when pollution recognizes no jurisdictional boundaries — it took action to create a series of federal environmental statutes that pre-empted states' traditional sovereign power in property law.

This manner of evolving federalism is not, therefore, foreign to our legal system or to the U.S. Constitution. James Madison wrote in *The Federalist Paper No. 46*, "If, therefore ... the people should in future become more partial to the federal than to the State government, the people ought not to be precluded from giving most of their confidence where they may discover it to be most due. ..."

Our system of federalism divides specific powers between state and federal governments. Congressional powers are those enumerated in the U.S. Constitution; and state powers are all those other powers that include police powers and criminal and public health laws. The 10th Amendment specifically provides that "powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively. ..."1 Even in Colonial times, states had quarantine powers to police the public health of the colonists. Only in times of emergency and war do powers shift to the federal government; while in peacetime, power remains with the states. The problem with this relationship is that in a biological attack - unlike a chemical, radiological, or nuclear one - days or weeks will pass before we know we have been attacked. Peacetime is the critical time for the federal government to have a national surveillance system and the authority to address a biological attack in its earliest stages before it becomes a national emergency. Otherwise, days or weeks will have passed before states call on the Centers for Disease Control and Prevention (CDC) under the current legal framework.

The bill proposing a Department of Homeland Security, which passed the House 295 to 132 on July 26 and is currently being considered by the U.S. Senate, would begin a shift in the current federalism balance in the area of public health to respond to our need for national security.²

Federal Government Organization

The federal government's current coordination mechanism does not address the unique demands of a biological attack. Under the Clinton administration, Presidential Decision Directives 39, 62, and 63 (PDD 39, 62, and 63) determined that, in a terrorist attack, the FBI would be the lead agency, the Federal Emergency Management Agency (FEMA) would be the lead for consequence management, and the National Security Council would be the interagency coordinator of terrorism policy. This system works for nuclear, chemical, or bombing incidents, but is ineffective with a biological attack. The glaring omission of

In 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. However, the expertise and institutional culture required for epidemiological investigations and biological warfare are more strongly centered in the mission of the Public Health Service. The CDC and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) are more adequately staffed to investigate biological contamination and to provide rapid epidemiological identification of the process and agent being used in any particular bioterrorism event. Both CDC and USAMRIID are considered the world's leading centers for forensic analysis and have been recommended by leading terrorism experts for leadership roles in bioterrorism, yet our existing current federal organization merely gives lip service to these agencies, and the proposed department does not reflect their unique resources, which are so essential to leadership roles in biodefense.

Apprehension of bioterrorists is definitely within the mission of the FBI, which reads: "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." The FBI should clearly be involved but equally clearly should not be directing the effort to either prepare for or respond to bioterrorism.

Utilizing the FBI in a role so counter to a mission that it does not have the tools or the culture to address is an experiment that we cannot now afford. So, too, FEMA, as the lead agency for responding to a bioterrorism event, has skill primarily in planning for and responding to natural disasters, which typically require immediate infrastructure compensation to communities for such natural disasters as earthquakes, flooding, and volcanic eruptions and do not address the kinds of responses necessary for the leadership role in bioterrorism response and preparedness.

The President's June 2002 proposal for a Department of Homeland Security contained three significant signals for a shift from state to federal power in the war against bioterrorism for national security purposes. First, the proposal plans that "the Department would set national policy and establish guidelines for state and local governments," which takes that role from the states' public health agencies. Second, the proposal makes the Department of Homeland Security "the lead agency preparing for and responding to ... biological ... terrorism," which assumes part of the states' public health agencies' responsibility. Third, the proposal directs that "the new Department would ensure that local law enforcement entities and the public — receive clear and concise information from their national government," which again assumes part of the states' public health agencies' responsibility for originating their own public health information. These federalism shifts for purposes of national security are consistent with constitutional constraints, and legislation should reflect this distribution of powers.

State Powers

State powers in biodefense are no less important. They involve existing state public health laws, states' police powers to quarantine and require vaccinations, the proposal of new bioterrorism legislation, utilization of the state national guard, and state common law applicable to bioterrorism. Until a federal system of biodefense is created, our national defense powers lie with the states with assistance from the CDC upon request by the states, mandated by the CDC's enabling statutory language.

Two important police powers of the state in the area of public health law are in requiring quarantines and vaccinations. The state power has been recognized since Justice Marshall established the states' quarantine authority in *Gibbons v. Ogden*³ — the landmark Commerce Clause case. In *Jacobson v. Massachusetts*,⁴ the U.S. Supreme Court recognized the power of states to penalize those who refused mandatory smallpox vaccinations. *Prince v. Massachusetts*⁵ precluded a religious objection to vaccination when the protection of the public health would be in danger. Constitutional due process, right of privacy, and the public health interests of the state are issues that balance this power. The current CDC Smallpox Plan relies upon state public health authorities to take the lead in an emergency.

In the area of state legislation, the National Association of Governors, with the CDC and others, commissioned the development of the Model Public Health Act for states, and, after the anthrax attacks, accelerated it to completion in the winter of 2001. Approximately 33 states have introduced some form of the Model Act, and 11 states have passed some form of new public health law legislation.

The use of the National Guard also has raised new issues about state powers. A state's National Guard responds to requests of the governor or requests of the President. The U.S. Constitution, Art. I, § 8, cl. 15 and 16, provides for a militia to execute the laws of the union. This provides for the states' authority to appoint officers and to control their militia when not in the service of the national government. National Guard members serve as members of both their state National Guard as well as the National Guard of the United States.⁶ The role of the National Guard and the states' public health authorities must be a focus in state and federal plans and legislation.

State common law was utilized unsuccessfully in the recent anthrax attacks by the postal workers seeking to obtain an injunction against the U.S. Postal Service, in an effort to close the Morgan postal facility in New York. The plaintiffs alleged that the U.S. Postal Service had "actions and omissions ... with respect to the handling of anthrax [which] have created a public nuisance because of the po-

tential exposure of the general public to a deadly bacteria." Because of the Federal Tort Claims Act limitation on money damages and because Congress did not waive sovereign immunity for injunctive relief, the injunction was denied.⁷

Other conceivable tort issues for the state in the event of bioterrorism could include negligence in failing to prepare for an emergency, failure to respond with appropriate medical treatment, and failure to warn. These must be examined on a state-by-state basis.

The U.S. Constitution, New Federal Statutes and Tools

The Biological Weapons and Anti-Terrorism Act of 1989 was passed as part of our responsibility under the international Biological Weapons Convention of 1972 to enact domestic laws to combat bioterrorism. The September 1984 Bhagwan Shree Rajneesh attack on salad bars in Oregon - using salmonella contamination in an attempt to skew an election - was also part of the impetus behind the statute's passage. This statute applies to anyone who "knowingly develops, produces, stockpiles, transfers, acquires, retains or possesses any biological agent, toxin or delivery system for use as a weapon."8 This section also applies extraterritorially to a U.S. national.⁹ It was the arrest of Larry Wayne Harris in 1995 that prompted the U.S. Congress to pass the Anti-Terrorism and Death Penalty Act of 1996. Harris' peaceful plans to use plague bacteria to develop a vaccine intended to protect the public from Iraqi attacks made it difficult to find culpability under the Biological Weapons and Anti-Terrorism Act of 1989. Ultimately, he was given probation for a mail fraud conviction that would not have been possible had he not misrepresented himself in a letter to the laboratory where he otherwise legally obtained the plague bacteria. In response to this, a new statute criminalized the unauthorized possession of biological agents used for weapons. Congress passed the Anti-Terrorism and Effective Death Penalty Act of 1996, which expands the federal government's power to prosecute individuals and groups who attempt or even threaten to develop or use a biological weapon and broadens the definition of bioweapons to include engineered organisms. Again, escaping serious culpability, Larry Wayne Harris, a member of a domestic hate group known as "Identity," obtained the bacteria through an authorized laboratory and claimed that he was working on a vaccine to protect citizens from a biological attack. This 1996 statute was used in United States v. Wise¹⁰ against domestic bioterrorists attempting to use botulinum toxin, and the 1989 act was employed in United States v. *Baker*,¹¹ a case involving the use of ricin, a deadly derivative of the castor bean, as a bioweapon. Two defendants after United States v. Lopez attempted to invalidate the 1989 act, charging that it exceeded Congress' power under the Commerce Clause. In United States v. Slaughter¹² the district court held that "there is insufficient evidence that the threatened use of anthrax would have affected interstate commerce to support a conviction ..."; whereas in United States v. Wise, the circuit court held that the act did not violate the Commerce Clause, opining, "[t]he threat itself crossed state boundaries; therefore, it cannot be argued that an effect on interstate commerce is lacking in this case."¹³ The recent trend in Commerce Clause cases reviewed by the U.S. Supreme Court would suggest that public health law would be infringed by the reach of the Commerce Clause under this statute, particularly since it does not involve economics as in *Solid Waste Agency of Cook County* and *United States v. Morrison*, which limited Commerce Clause power to those areas that truly have economic effects.

The most recent statute, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,¹⁴ engrossed June 12, moves toward closing loopholes in the previous statutes. The new statute eliminates the need to prove intent to use the biological agent as a weapon, and it creates a "reckless disregard" of the public health and safety standard for the handling of biological agents.

The Fourth Amendment's search and seizure provision was at issue in United States v. Larry Wayne Harris,¹⁵ where vials of plague bacteria were found in the glove compartment of the defendant's car, which was parked in his driveway. The court found the evidence admissible because the warrant for the address permits a search of a car in the driveway, such as in this case; and also where there is consent - which there was in this case; and the officers had probable cause to believe the vials were in the glove compartment of the car. Searches will be more difficult because of the inherently small quantities of biological agents, such as vials, as in this case. Plain view will be unlikely to reveal the usually small sample quantities of biological weapons, and a very specific idea of the location of the agents will be necessary to successfully recover evidence of biological weapons.

An exception from departure from the Federal Sentencing Guidelines was not upheld by the circuit court in United States v. Leaby,¹⁶ where Leaby was convicted under the 1989 act involving ricin. The circuit court found that departure upwards where "the court finds that there exists an aggravating or mitigating circumstance of a kind, or to a degree, not adequately taken into consideration by the Sentencing Commission in formulating the guidelines that should result in a sentence different from that described,"17 is acceptable but not in this case. The court held that the district court erred in its selection of the analogous sentencing guideline "because there was no evidence showing that Leahy engaged in an actual act or attempted act of terrorism. ..."18 Given the new criminal statute, the Bioterrorism Prevention Act of 2001, and the seriousness of mere possession of bioweapons, the Sentencing Commission should re-examine the sentencing guidelines after this decision to fashion appropriate guidelines or identify an analogous sentence.

Civil Issues Arising from Bioterrorism

In the recent *Smith v. Potter* case,¹⁹ the postal workers at New York's Morgan facility, which had been contaminated with anthrax spores, utilized a theory under the federal environmental statute, Resources Conservation and Recovery Act (RCRA), requiring emergency cleanup of hazardous materials where there is an "imminent and substantial endangerment." Unfortunately, the court did not reach that issue, which would have determined how the court might have interpreted "hazardous material" and the application of RCRA to biological attacks.

Tort claims for the use of a vaccine that has unintended harmful effects resulted in landmark litigation with the polio vaccine²⁰ and the swine flu vaccine.²¹ As a result of the liability created for pharmaceutical companies that produced a vaccine that had a narrow profit-margin, the federal government feared that the vaccine would become unavailable. The National Vaccine Injury Compensation Program (NVICP) was developed, enabled by the National Childhood Vaccine Injury Act of 1986,22 which provides no-fault compensation for injury or death from the vaccines for polio, diphtheria, pertussis, tetanus, measles, mumps, rubella, hepatitis B, heamophilius influenza type B, varicella (chicken pox), rotavirus, and pneumoccocal 7-valent conjugate.²³ The development of new vaccines as well as the anticipated use of smallpox vaccine for the broad vaccination program for adults as well as children - as contemplated by the CDC - will make new legislation necessary.

Further regulatory changes may be needed to address the process for testing and approving such vaccines that are investigational new drugs (IND), such as the current smallpox vaccine. For example, the CDC smallpox plan requiring vaccination must include a process of informed consent and each recipient of the vaccine because it is in the IND status, which cannot be waived for civilians.²⁴

Federal labor law was utilized in the recent anthrax contamination of a postal facility in Florida in Miami Area Local v. United States Postal Service,²⁵ where the labor union sought negotiations to provide for worker safety. Wrongful death actions have been initiated with the death of two postal workers exposed to anthrax while working in the Brentwood postal facility in Washington, D.C. One family has settled with the hospital, and the second family has proceeded through the pretrial litigation stage. In Morris v. Kaiser,²⁶ the theory of recovery is based in negligence on the part of the hospital and medical care providers, while a third-party complaint for indemnification and contribution has been filed against the United States by the defendant for the government's role in failing to take action with the contaminated postal facility and its workers.

In the private sector of risk management, a serious crisis has been created by insurance companies that have dropped their coverage for risks and losses associated with terrorism. Airline companies, hotels, and transportation systems are most seriously affected by this loss in coverage. In June 2002, the Senate rejected a bill that would exclude punitive damages against businesses for losses due to terrorist attacks without a finding of criminal negligence. Insurance companies would be co-insured by the federal government for 80 to 90 percent of the amounts claimed. As this article goes to press, the conferees are continuing to consider the terms, particularly the award of punitive damages. Currently, the language pro-

hibits awarding punitive damages in excess of the defendant's direct proportion of responsibility for the plaintiff's physical harm.²⁷

Civil Rights Issues in Public Health Law Concerning Bioterrorism

Civil rights issues will be a concern within the context of the threat of bioterrorism. Surveillance, characterization of the threat, response, and quarantine issues at each phase of an attack will raise fundamental rights questions.

In surveillance, Fourth Amendment search and seizure protections will be a consideration in the collection of samples from individuals, the requirement to provide samples, and the need to enter homes. The right of privacy will be raised in the context of medical information and the need to share this information with public health authorities or law enforcement authorities.

In the response phase of a bioterrorism attack, the use of the military will be governed by the Posse Comitatus Act in order to protect against the use of military force against civilians. This statute was passed in response to the experience of martial law in the South after Reconstruction and precludes the military from having enforcement interface with civilians. The statute is limited to providing resources and personnel but stops short of strategy and military command as part of a civilian operation. The first major infraction under this act was found during the Wounded Knee incident in South Dakota, where the military was utilized without a mandatory order from the President.²⁸

The Fifth and 14th Amendments' protections against taking without just compensation provisions will be invoked where the requirement to take residences, businesses, or vehicles arises in the context of a biological event. Some states are considering legislation to provide for the need to take property in the event of a biological attack.

Human remains are required to be returned to families under the constitutional right of privacy, but this must be done without a risk to public safety. Jurisdiction for human remains is within state law and considers the right of the family to have the remains and the obligation of the family to take possession of the remains. Jurisdiction for human remains in a government building or a military installation is federal, and military guidelines for human remains apply. For example, in the aftermath of the 9/11 attacks, the jurisdiction for human remains in the World Trade Center was within that of the state of New York; while the jurisdiction for human remains in the Pentagon was that of the U.S. military.

For quarantine issues, Fifth and 14th Amendment due process requirements must be met in detaining individuals, and Fourth, Fifth, and Sixth Amendment protections must be raised against noncriminal detentions. The lessons learned from the recent anthrax attacks, which involved a number of local quarantines demonstrated in one case, conflict with interpretations of due process, which will result in political chaos. For example, it was reported that in Jefferson County, Mo., private security officers had to be hired to replace the county deputies when the sheriff refused to have his deputies evacuate and enforce a quarantine of the building, properly ordered by the county commissioner when an anthrax scare occurred.²⁹ Although the commissioner had authority to issue this order, the refusal to enforce the quarantine based upon the judgment of the county law enforcement officials raises serious concerns and suggests a need for a national approach to defining due process in the context of quarantine to lessen the chaos in the event of any need to quarantine in a biological attack.

International Law and Bioterrorism

The revelations in 1993 that not only did the Soviet Union have a biological weapons production network, Biopreparat, with huge quantities of smallpox, but that Iraq, too, had a not-unrelated biological weapons production facility, which had been discovered at the end of Desert Storm, alerted Congress to the increasing risk of a biological attack.

The first international instrument to address the threat of bioterrorism - at least in a broad sense - was the Geneva Convention of 1925, which simply required civil behavior between countries. Between 1925 and 1969, bioweapons programs proliferated. In 1969, President Nixon ended the nation's biological weapons program that had begun in the mid-1940s and converted all operations to a defensive program, when he said to the world, "I have decided that the United States of America will renounce the use of any form of deadly biological weapons that either kill or incapacitate." The Biological Weapons Convention of 1972 was the first instrument to address the worldwide elimination of biological weapons, which followed President Nixon's announcement. Currently, 172 countries are signatories to the convention, including the former Soviet Union and Iraq. The lack of a monitoring mechanism in the convention has made it convenient for the proliferation of facilities that produce biological weapons in the former Soviet Union and Iraq.

The Anti-Terrorism and Death Penalty Act permits the United States to prevent the entry of members of groups known to be engaged in terrorism, such as the Aum Shinrikyo group of Japan, responsible for the sarin gas attacks in the Tokyo subway in 1995.

Other countries are struggling with the need to develop domestic protection against biological threats, while balancing that need against civil liberties. Comparing other countries' laws, the United States still measures up favorably in protection of civil liberties, even after the passage of the USA PATRIOT Act of 2001.

In Japan, the Anti-Subversive Activities Law of 1952 is intended to provide a legal process by which groups identified as threats can be disbanded. The standard for disbandment is a clear danger of engaging as an organization in violent subversive activities for political purposes repeatedly and continuously in the future. Even after the Aum Shinrikyo sarin attack in the Tokyo subway, the Japanese commission failed to find that the acts rose to the level of disbandment. In November 1999, the Japanese Parliament passed new legislation to provide for the tracking of organizations that in the last five years had committed indiscriminate mass murders. Authorities are allowed to keep such groups under surveillance for up to three years and the police can conduct searches without probable cause at any time. These groups also have a requirement to report their activities on a quarterly basis. Violations can result in temporary or permanent disbandment.

On July 22, 2001, the French Parliament passed new legislation that would allow the French government to disband organizations whose leaders commit crimes. This law allows groups that employ techniques to alter thinking to be identified as cults. A commission appointed by the French government has identified 172 such cults, which are candidates for disbandment should their leaders commit a crime. This law was widely criticized by France's citizens as a serious threat to civil liberties, yet it remains law.

A recent Gallup Organization poll in the United States reported in June 2002 that 30 percent of Americans favor easier access to mail, e-mail, and telephone conversations for legal authorities,³⁰ which suggests a move toward more tolerance of government intrusions into traditional areas of privacy, if it provides homeland security.

Science Issues, Law, and Bioterrorism

Last month, the National Academy of Sciences released a study on the use of science and technology in the war against terrorism.³¹ New technologies are on the horizon to create biological weapons that offer combined characteristics of several biological agents that have no known vaccine or cure, making vaccines ineffective in producing the necessary antibodies needed to create immunity. New regulations to monitor the laboratories engaged in these studies — or to limit the publication of new discoveries in biotechnology that could aid terrorists in the development of such weapons — must ultimately be considered as a measure for national security.

Recent measures to monitor foreign students enrolled in research facilities in the U.S. are of limited utility in identifying bioweapons threats but instead create a broad "watch list," which could merely divert federal personnel from more critical homeland security tasks. Focusing our resources in the most efficacious manner on science and technology is critical for our nation in our war on terrorism.

Conclusion

The legal community now has a window in which to examine impediments to optimal national security, based upon a successful rule of law system, the Constitution, and a system of federalism. Challenges to our civil rights require vigilance and protection as we seek to preserve our freedoms in the context of homeland security, but a broader dialogue should begin among federal lawyers to address the challenges to shaping our legal framework in all of these critical areas. A new Department of Homeland Security will be successful only if these legal challenges are addressed. **TFL**

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Endnotes

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