The Rule of Law and Bioterrorism

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Bioterrorism is defined as the deliberate release of pathogens or their toxins into a civilian population for the purpose of causing illness or death. In a world made uncertain by terrorists, a chemical weapon or bioterrorism threat or even a hoax can shut down a business for days and create an unique new type of environmental liability, as well as lead to workplace safety issues and other liabilities. Physicians and public health officials would bear the brunt of the health nightmare caused by an act of bioterrorism. Mass casualties and the "worried well" would crowd healthcare facilities that barely cope with normal healthcare loads. Often overlooked in thinking about bioterrorism and its effects is the foundation that law provides for effective public health activities. 3

The United States Commission on Civil Rights has been warned by the head of the Public Health Association that this country is unprepared for a bioterrorist attack and would be dramatically affected since a large segment of the population is already medically underserved.⁴

ABBREVIATIONS: BIC = business interruption insurance; BSL = biosafety level; BSC = biosafety cabinets; CDC = Centers for Disease Control and Prevention; COC = chain of custody; FBI = Federal Bureau of Investigation; HSPD-5 = Homeland Security Presidential Directive 5; OSHA = Occupational Safety and Health Act; PPE = personal protective equipment; US = United States.

INDEX TERMS: bioterrorism; civil liberties; rule of law.

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THE RULE OF LAW

The use of a biological weapon in the United States would trigger a public health and political emergency. Governmental response to national emergencies in many countries has historically brought about the rule of law.³ The rule of law is the idea that human affairs are governed by law, not the arbitrary exercise of power, and that under immense pressure, the latter could result in the abandonment of fundamental legal protections for populations. The internment by the United States of Japanese-Americans after Pearl Harbor stands as an example of the fact that governmental action in an emergency can challenge the boundaries of the rule of law and beyond.⁵ Fred Korematsu was a Japanese-American born in Oakland, California in March 1942, when President Franklin D. Roosevelt was empowered through legislation to restrict movement of residents of any designated military area or war zone where he felt such restriction was necessary to national security. He issued Executive Order #9066 that declared, "The successful prosecution of the war requires every possible protection against espionage and against sabotage to national defense material, national defense premises, and national defense utilities." The restrictions ranged from the imposition of curfews to forced removal to "relocation centers" outside Military Area I. Mr. Korematsu had been a loyal, law-abiding American citizen, but rather than submit to confinement, he ran away and posed as Chinese. He was arrested and tried in federal district court for knowingly violating the Civilian Exclusion Order.

More recent examples of the government's acting in response to national security are President George W. Bush's secret

domestic spying and foreign bank money tracking programs, both implemented following the September 11, 2001, terrorist attacks. President Bush vigorously defended his order authorizing eavesdropping on overseas telephone calls and the email of US citizens with suspected terrorists. He contended he was obligated to protect US citizens against attack, which justified a circumvention of the traditional process in a fast-moving, high-tech battle with a shadowy enemy.⁶ The president did not offer details about how many people were under surveillance, what standard must be met to intercept communications, or what terrorist plots had been disrupted as a result of the program. The recent congressional debate over renewal of the US Patriot Act, a measure bolstering the powers of law enforcement agencies passed shortly after the September 11, 2001 attacks, was fueled by this National Security Agency spy program.

The money tracking program allows US counterterrorism analysts using broad government subpoenas to obtain financial information from a vast database maintained by a company based in Belgium.⁷ President Bush defended the program with much the same defense used for the National Security Agency's warrantless wiretap program. Another article published in the wake of the money tracking report said the first newspaper to report this program ran afoul of Section 798 of title 18, the so-called Comint statute. This statute was written in the wake of Japan's attack on Pearl Harbor and gives intelligence agencies a leg up against foreign adversaries by prosecuting anyone who passes on communications intelligence that "could be prejudicial to the safety or interest of the US or for the benefit of any foreign government to the detriment of the US".

The American legal system is not designed to deal with such complex and insidious acts of violence caused by bioweapons. The two areas of American law most immediately affected by bioweapons would be public health law and the law managing disasters or emergencies.⁵ The powers and provisions in these two areas of law relevant to responding to a bioterrorism event were created to deal with other types of emergencies, not something as unique as the intentional use of pathogenic microorganisms to make large numbers of individuals ill or die.

Tabletop exercises and simulated bioterrorism events have demonstrated that neither public health law nor emergency management law could currently support an effective response to a major bioweapons event.8 The government would be under extreme pressure to take actions that might sweep away the rule of law in the midst of panic or uncertainty.

Structurally, in the United States, political power is divided between state and federal governments. Under the US Constitution, state governments, not the federal government, have the primary legal authority and responsibility for public health.3 A bioweapons event would trigger a public health emergency and state governments and legal systems would be critical in addressing the event and its aftershocks.

The events surrounding Hurricane Katrina in August 2005 illustrate the constitutional framework created by our founders in which each state ceded some of its powers to the federal government to create one united yet limited central government. Accordingly, state and local governments assume the first and foremost line of defense against civil disturbance and threats to public safety. President Harry Truman issued Executive Order 10427 in 1952 which emphasized that federal disaster assistance was intended to supplement, not supplant, the resources of state, local, and private sector organizations.9 State and local governments, who know the unique requirements of their citizens and geography and are best positioned to respond to incidents in their own jurisdictions, play a large role in disaster response. Today, the centerpiece legislation for providing federal aid in disaster relief is the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act) which reinforces the principle that response efforts should first utilize state and local resources.9 This act establishes a process for State governors to request assistance from the federal government when an incident overwhelms state and local resources and is frequently invoked in disaster and emergency response such as Katrina. Governors of affected states request a disaster declaration from the president. 10 The Homeland Security Act was enacted in 2002 and President Bush issued Homeland Security Presidential Directive 5 (HSPD-5) in February 2003.9 This order established national policies, priorities, and guidelines to strengthen US homeland security. The components of the national response plan, when applied together, should provide for a unified command structure to serve as the local, multi-agency coordination center for the effective and efficient coordination of federal, state, local, tribal, nongovernmental, and private-sector organizations with primary responsibility for incident-related prevention, response, and recovery actions.

Soon after Katrina made landfall, state and local authorities understood the devastation was serious, but, due to the destruction of infrastructure and response capabilities, lacked the ability to communicate with each other and coordinate a response. Federal officials struggled to perform responsi-

bilities generally conducted by state and local authorities. Shortfalls in the federal response to Hurricane Katrina highlight that current homeland security architecture, to include policies, authorities, plans, doctrine, operational concepts, and resources at the federal, state, local, private sector, and community levels, must be strengthened and transformed. At the most fundamental level, the current system fails to define federal responsibility for national preparedness in catastrophic events. Instead, the United States currently has guidelines and individual plans, across multiple agencies and levels of government that do not yet constitute an *integrated* national system that ensures unity of effort.

The legal authority and power to respond to traditional threats to US national security rests primarily with the federal government. The structural challenge to the rule of law here is that state governments and public health law are as or more important than the federal government and federal law. The US has no legal framework for dealing with a serious national security threat that depends so heavily on the quality of state public health law and its institutions.

Simulated bioterrorist events have shown how difficult cooperation between state and federal government personnel can be in times of emergency.⁸ Federal-state turf wars and lack of coordination could be deadly in preventing effective public health responses to such an event.

There are several components to a bioweapons challenge to the rule of law. First, such an event would implicate many different areas of the law, including public health, emergency management, civil rights, criminal, and national security law. Second, the law would have to:

- deter the development and use of bioweapons;
- prepare state and federal governments for the possibility of bioterrorism;
- empower state and federal governments to respond effectively during a bioweapons event;
- discipline governmental exercises of power to protect individual rights as much as possible; and
- facilitate identification of and retribution against the bioterrorists.

Third, public health law would be on the forefront during such an event, but US public health law experts argue this body of law is antiquated. A bioweapons event would trigger many legal worries, including the liability of overrun hospitals and healthcare professionals operating in an emergency

environment, the liability of drug and vaccine manufacturers, and the inevitable lawsuits after the crisis is over.

Fourth, there are similar concerns about federal and state emergency management laws. Fifth, the US legal system is highly protective of individual rights. The US concept of government is that of a limited government, one that cannot infringe arbitrarily on the rights and freedoms of citizens. A bioweapons event could exert enormous pressure on the US government to infringe in drastic ways on individual rights without going through the normal procedural and substantive tests for such restrictions. Forced quarantine or isolation, compulsory treatment or vaccination, and seizure and destruction of property might be required.

Because state and federal governments must have effective and efficient procedures through which to exercise the public health and emergency powers they possess, there is also an implementation challenge.³ The state of Colorado had the legal authority to quarantine populations in Denver during the 2000 exercise there, but was unable to implement the quarantine effectively which undermined the substantive power to implement quarantine as a public health measure.⁸ Implementation not only touches on formal legal rules, but also on larger social values and norms such as fairness and equity. This will influence how public officials ration scarce resources such as antibiotics.

Considerable legal analysis needs to be done in connection with preparation for bioterrorist attacks. Diligent and creative work in this area will help ensure the rule of law does not become one of the casualties of the use of bioweapons.³

HISTORICAL PERSPECTIVE

Sanitation laws are the oldest public health measures.¹³ The English statutory and common law recognized the right of the state to quarantine and limit the movement of plague carriers. The American colonies adopted the English laws on the control of diseases. The Constitution, when written, left public health power to the states because it was considered fundamental to the state's police power.

Acknowledging the public's justified fear of infectious disease, courts have given broad powers to public health officers. ¹³ Questioning of the value of public health restrictions by a substantial segment of the population has only recently become more common. This diminishing support for public health restrictions is rooted more in a loss of fear of communicable diseases than an increased sensitivity to individual

liberties. The only successful attacks on the exercise of state police power to protect citizens from communicable disease have been based on federal preemption of state laws that restricted interstate commerce. If a state law or regulation is substantially related to health and safety, the Supreme Court will uphold it.¹³ Laws enacted to protect society, including vaccinations and quarantines, have been upheld even when individuals have been forced to sacrifice individual liberty and privacy. Public health jurisprudence is deeply rooted in the fear of pestilential diseases.

SOCIAL AND WORKPLACE ISSUES

Uninsured Americans are the most vulnerable in the event of a bioterrorist attack. 4 Many Americans lack access to healthcare in this country. Individuals who live in inner cities often lack access to healthcare, even when they have full insurance coverage. A bioterrorist attack will further exacerbate the difficulties of the uninsured in obtaining any type of healthcare services. The level of casualties among the members of this group and the public at large could be considerable. For example, many substance abusers, minorities, and residents of rural communities have local public health systems lacking mechanisms to serve them in such an emergency.⁴

Claims of death and illness caused by the 2001 anthrax-laced letters received or opened in the workplace were covered by workers' compensation policies.2 War exclusion that applies to many policies do not apply to workers' compensation policies. The September 11, 2001 attacks as well as the anthrax letters have had an economic impact on Americans. According to an assistant vice president of workers' compensation at the National Association of Independent Insurers, workers' compensation rates, set by each state, were predicted to rise as a result of the attacks. Losses from bioterrorism have not previously been contemplated by insurers and the projected costs associated with such losses likely will be factored into future insurance rates.2

Employers are now trying to plan responses to bioterrorist and terrorist attacks such as car bombs, anthrax-tainted mail, and planes crashing into buildings. The general duty clause of the Occupations Safety and Health Act (OSHA) requires employers to provide a workplace free from recognized hazards that cause or are likely to cause death or injury. The definition of a recognized hazard is now in question. Employers are well advised to put sensible mail handling procedures in place to let employees know prudent steps are being taken to protect them from tainted mail.

Employers must now also be concerned with forced business shutdowns as a result of bioterrorism or chemical attacks, the threat of such an attack, or even hoaxes. Business interruption insurance (BIC) would possibly cover some such shutdowns. BIC covers lost business income, net profit or loss before income taxes, and, if incurred, continuing normal operating expenses including payroll. If a hospital is closed due to physical damage of the building caused by fire, its loss of income is covered.

A number of insurance companies denied BIC coverage for the events of September 11 on the grounds that the policyholders did not suffer a total "suspension" of all of their operations and thus BIC was not triggered.¹⁴ Usually BIC language in most policy forms is so vague that it ensures if a claim is large enough, there will be a dispute. Some property insurance companies argued that business interruption recovery was diminished by the wider economic effects of the September 11 attacks. The insurance industry in the wake of September 11 successfully contested BIC claims where the policyholder sought to increase the amount of lost income by including consideration of the widespread effect of the physical loss or damage. This type of coverage, however, can be voided if the policyholder does not give timely notice of its losses. An immediate review of coverages and time limits will be critical to any facility or organization seeking BIC damages in the wake of future bioterrorist attacks

If a trace of anthrax or another potential bioweapon is found in a healthcare facility and the facility has to shut down its operations at the affected site and move patients to other locations, its loss of income and extra expenses will probably be covered.² Biological agents would cause physical damage to a facility because they must be cleaned and removed from the site and would trigger the physical damage obligation.

BIC usually has a clause that covers losses caused by action of civil authority that prohibits access to the business or as a result of civil authority orders from other locations. If, however, a business shuts down as a precaution and not under civil authority orders, it is probably not covered. Facilities (including healthcare facilities) need to look at BIC policies and be aware of the coverage limitations.

PUBLIC HEALTH LAW

What is the government's duty to protect the public health in response to a bioterrorism event? State governments traditionally have police powers to protect the health, safety, and general welfare of the public and such duty may be viewed as

comprehensive and extensive. 15 State public health authorities could take almost any action to protect the population from a threat. Authorities may have to temporarily constrain certain civil liberties, require private sector participation in public health objectives, shut down potentially harmful industries, destroy contaminated property, deport or prevent the entry of individuals who may infect others, ration supplies, and control the flow of information. 15

Can authorities temporarily ignore constitutional principles that respect individual liberties, such as the right to due process, travel, or assembly? Can federal health officials who lack broad police powers command state public health officials to participate in a federal, national response to a bioterrorist event if limited to one state?

Proposed Model State Emergency Health Powers Act

This act was written as a response to concerns about bioterrorism raised by the events of September 11, 2001. It is based on the assumption that existing state laws are wholly inadequate to confront a bioterrorism event and should be superseded by a comprehensive act that will override existing laws from different states.¹⁵ Even before September 11, the federal government wanted states to update public health laws, some of which date to the 19th century.¹⁶

The proposed Model State Emergency Health Powers Act would give public health authorities the ability to exercise enhanced powers to protect individuals and manage property upon the declaration of a public health emergency by the state governor. 16,17 A large-scale bioterrorism event will accentuate existing uncertainties in the distribution of public health powers. The critical choice for public health authorities is not to decide where the power to protect public health lies or which level of government has the primary power to act, but rather from where the leadership to respond to a bioterrorism event will be derived. Public health authorities must also choose how to coordinate with law enforcement and national security authorities. Every bioterrorist attack involves a criminal investigation that is outside the purview of public health authorities.

The act and the December 2001 revision would give state authorities the right to mandate medical testing of its citizens, to isolate people deemed a threat to the public health, and to order private physicians and other healthcare professionals to assist public health officials.¹⁶ In a bioterrorism emergency, states could "require a healthcare facility to provide services or use of its facility if such services or use are reasonable and

necessary to respond to the public health emergency with the right to take immediate possession thereof". 18 Officials could also take over other property and "communication devices" believed necessary to stop a biological attack from killing huge numbers of people. The law would be triggered by the governor during a bioweapons event or an epidemic that posed substantial risk of significant casualties. It would provide authorities broad powers to close buildings, take over hospitals, and order quarantines during an attack. The act would also shield health officers from legal liability, along with anyone working under their direction.¹⁹

In almost any widespread and rapidly developing bioterrorist event, available public health resources will be quickly taxed. Scarce resources could include healthcare personnel such as laboratory professionals.¹⁵ The Model Act would allow state executive authorities to confiscate hoarded supplies, take possession of facilities or other property for public health purposes, and to seek the assistance of medical (including laboratory professionals) personnel during a public health emergency.

The September 11 attacks have seemed to create a new world order that appears out of order. Congress has grappled with bioterrorism. The Air Transportation Safety and System Stabilization Act limited the liability of airlines involved in the September 11 attacks and created a special fund for victims. The Bioterrorism Preparedness Act of 2001 strengthened the development of new countermeasures against bioterrorism and protection of existing ones. One of its primary goals was to facilitate the production of vaccines. The bill offered some legal protection to manufacturers of vaccines specifically developed as a priority countermeasure to treat or prevent infections by a biological pathogen and administered for such use by order or recommendation of the Secretary of Health and Human Services to respond to the use or threatened use of a biological agent.19

THE LABORATORY

Bioterrorist events may first be identified by local medical institutions. The local laboratory will play an important part in providing rapid identification of the agent used influencing the administration of antidote or vaccine to affected victims. 20 Lack of familiarization with the four levels of biosafety of the Centers for Disease Control and Prevention (CDC) criteria (see Table 1) represent potent barriers to the laboratory in responding to a bioterrorist attack. It will be important for laboratories to coordinate all activities with the local and state health departments and the FBI. A chain-of-custody (COC) document should accompany a specimen from collection during these events.

Table 1. Biosafety levels for infectious agents²¹

Biosafety level (BSL) 1

Agents: Not known to consistently cause disease in healthy adults

Practices: Standard microbiological practices

Safety equipment (primary barriers): None required

Facilities (secondary barriers): Open bench top, sink required

BSL₂

Agents: Associated with human disease; ingestion, percutaneous injury, mucous membrane exposure hazard

Practices: BSL 1 practice PLUS limited access; biohazard warning signs; "Sharps" precautions; biosafety manual defining any needed waste decontamination or medical surveillance policies

Safety equipment (primary barriers): Primary barriers = Class I or II Biosafety cabinets (BSC) or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infections materials; personal protective equipment (PPE): laboratory coats, gloves, face protection if needed

Facilities (secondary barriers): BSL 1 PLUS autoclave available

BSL₃

Agents: Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences

Practices: BSL 2 practice PLUS controlled access; decontamination of all waste; decontamination of laboratory clothing before laundering; baseline serum

Safety equipment (primary barriers): Primary barriers = Class I or II BSCs or other physical containment devices used for all open manipulations of agents; PPE: protective laboratory clothing, gloves, respiratory protection as needed

Facilities (secondary barriers): BSL 2 PLUS physical separation from access corridors; self-closing, double door access; exhausted air not re-circulated; negative airflow into laboratory

BSL 4

Agents: Dangerous/exotic agents which pose high risk of life-threatening disease, aerosol-transmitted laboratory infections, or related agents with unknown risk of transmission

Practices: BSL 3 practices PLUS clothing change before entering; shower on exit; all material decontaminated on exit from facility

Safety equipment (primary barriers): Primary barriers = all procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied personnel suit

Facilities (secondary barriers): BSL 3 PLUS separate building or isolated zone; dedicated supply and exhaust, vacuum, and decon systems; other requirements as indicated

Laboratory personnel, as first responders, should be familiar with the steps to take to assist in the diagnosis of each disease. The CDC Laboratory Response Network provides an organized system for the detection and diagnosis of biological agents based on laboratory capacity and the degree of risk. Knowledge of the current biosafety levels within the laboratory; development and availability of protocols related to COC; collection, preservation, and shipment of specimens and cultures and detection and identification of targeted agents; location of the nearest higher-level reference laboratory; knowledge of current guidelines to ensure safe handling and shipment of biological agents; and knowledge of basic characteristics of current targeted agents will be important.

Authorities could require the assistance of laboratory personnel during a medical emergency as well as the sequestering of any laboratory supplies needed to address the situation. Personnel could be quarantined, if appropriate, or required to assist with testing or other tasks as mandated by authorities. In addition, the Healthcare Personnel Delivery System, a standby plan developed for the Selective Service System at the request of Congress, could be used to draft healthcare personnel if it is implemented in connection with a national mobilization in an emergency, if Congress and the president approve the plan and pass and sign legislation to enact it.²²

Threat and uncertainty

How will the ongoing threat of terrorism affect living in the US? Long-term consequences of trauma on people have been witnessed and studied.²³ Kosovar families have been interviewed against the background of past and present terror to find out about coping, historically and in the present. The

process of family recovery has been witnessed for two years. Women stepped into leadership roles for murdered husbands and families reorganized roles to care for fatherless children. Family members were asked about lessons learned over the generations of living with uncertainty and the ongoing threat of violence. Professional individuals in Kosova have found that Kosovars have survived not by attempting a national defense, but by banding together as clans of extended family. In Kosova, a person is not an individual, but a family member. Each decision is made to support the survival of the family. What message does the Kosova experience have for Americans? America has been spared the worst of the world's violent conflicts; when Americans fought wars, the fighting took place on foreign soil. The post-September 11 attacks and the threat of future attacks extend to an indefinite future. The lessons to be gleaned from the Kosova experience are:

- children are the American hope;
- energy and attention must be focused on the work before us and on the future; and
- pain must be felt for each other.

Threat and uncertainty will remain a part of the US future and future generations will live differently because of it.

SUMMARY

Bioterrorism is multi-faceted. Its impact will extend beyond the victims, the agent used, and the perpetrator(s). The rule of law must be considered in the wake of September 11 and the fall 2001 anthrax attacks. Bioterrorism preparedness should address rule of law and social issues. Laboratory professionals must be prepared for professional, civil justice, and social impact in the event of a future major bioweapons event.

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