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CHAPTER 10

Legal Aspects of Biosecurity

When bad men combine, the good must associate; else they will fall one by one, an unpitied sacrifice in a contemptible struggle.

Edmund Burke

Objectives

The study of this chapter will enable you to:

1. Discuss the definitions of terrorism and weapons of mass destruction and their relation to the illicit use of biological agents.
2. List all legislative and administrative documents that address the legal aspects of the unlawful use of biological agents.
3. Discuss the prohibited uses of biological agents under US law.
4. Discuss the prohibited uses of biological agents under international law.
5. List and briefly discuss the Homeland Security Presidential Directives that apply to biosecurity and biodefense.

INTRODUCTION

Biodefense programs and initiatives have been with us since World War II. These programs were developed out of a need to counter the threat from our enemies and protect military forces and the homeland from biological attack. On the other hand, biosecurity is a more recent development, made up of policies and measures designed to protect the homeland, food supply, and agricultural resources from natural and accidental outbreaks and bioterrorism attacks. Many of the recent initiatives in biodefense and biosecurity came after the fall of the Soviet Union, as officials from NATO countries worried about the potential for Soviet biological weapons falling into the wrong hands. In the United States, the Clinton administration took a fairly proactive stance toward biological threat reduction. The events of September 11, 2001, and the Amerithrax incident further solidified national resolve against weapons of mass destruction (WMD) and acts of terrorism.

Politicians have felt the pressure from strong public reaction to recent acts of bioterrorism. Many articles and speeches emphasized the potential for devastating outbreaks from emerging and reemerging pathogens. Government officials had to act decisively to quell fears from the public and instill or renew trust in government. We can all appreciate
the need to protect livestock and cash crops, which could prevent huge losses to the economy. Since the 1984 Rajneeshee incident in Oregon, lawmakers moved to enact legislation designed to define the illegality of the ill-intended use, production, dissemination, or storage of biological agents (Miller et al., 2001).

The United States works from a federal system with two levels of government: the federal government, which exercises the powers of the US Constitution, and state governments, which exercise the rights that they withheld from the federal government as sovereign states. State governments retain their basic police power. Our federal system allows for parallel tracks of the legal system on the local, state, and federal levels. The most important specific powers of the federal government are those that regulate interstate and foreign commerce, the power to provide for the national defense, and the right to tax the people and spend revenues collected for the public welfare. States and local government entities use their power to exercise their responsibility to protect the public health and safety.

Federal laws authorized by the US Constitution became the “law of the land” and are binding even in the face of state laws that may be inconsistent with them. In many instances, both state and federal laws address the same issue. Statutes enact the laws that are to be followed by the executive branch and enforced by the courts at the state or federal level. In areas where there has been no legislative enactment, courts in the United States follow the legal precedents established over the years and born out of decisions related to particular controversies. Administrative agencies at both levels of government draft regulations that are legally binding and aim to apply the law to even more specific situations. At the local level, ordinances are promulgated and act as regulations within specific local municipalities. Ordinances are adopted under powers delegated from the state and establish rules applicable within the jurisdiction of the municipality that create them.

Executive orders, from either the president or a governor, are primarily regarded as directions from the head of each level of government to the officers and employees of federal and state government, respectively. As an example, the president’s “declaration of emergency” is a form of executive order. Directives, such as a National Security Presidential Directive (NSPD) or Homeland Security Presidential Directive (HSPD) are executive orders at the federal level. These directives cannot change the “law of the land,” as required by the US Constitution or statutes. Instead, they are intended to direct officers of the federal government to apply and exercise whatever discretion they may have under the rule of law in a particular fashion. These directives are important tools in creating new programs, announcing initiatives, and addressing national concerns during times of need or crisis.

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**The Law**

*Law is a prediction of what a court will do when faced with a particular set of facts.*

*Oliver Wendell Holmes*
This chapter seeks to identify many of the administrative aspects of biodefense and biosecurity. That is, international bodies and government at all levels have had to address the threat of biological agents, whether in a military context or civilian setting. The aim of this chapter is to discuss the most relevant treaties, laws, statutes, regulations, directives, and government directives aimed at reducing the biological threat and deal with those that use biological agents with ill intent. The chapter was not written for legal professionals. Therefore, the material is covered using plain language and in a cursory manner. In many instances, relevant text from the actual documents is used verbatim so that there is no misinterpretation on the part of the author.

In 1989 the United States was engaged on many fronts to ban the use of chemical weapons. That year the US Congress enacted the Biological Weapons Anti-Terrorism Act. It was modeled after similar legislation found in the United Kingdom, Australia, and New Zealand. Cited as the *Biological Weapons Anti-Terrorism Act of 1989*, the legislation makes it unlawful for “anyone to develop, employ, produce or stockpile any biological material that is intended to cause harm, illness, injury or death.” The purpose of the Biological Weapons Anti-Terrorism Act of 1989 is to implement, within the United States, the Biological Weapons Convention (BWC). You may recall from chapter *Seeds of Destruction* that the BWC is an international agreement, ratified by the US Senate in 1974, and signed by more than 100 other nations, including the Soviet Union. The Biological Weapons Anti-Terrorism Act of 1989 was also detailed to protect the United States against the threat of biological terrorism. Nothing in the Biological Weapons Anti-Terrorism Act of 1989 was intended to restrain or restrict peaceful scientific research or development. Chapter 10 of the act, “Biological Weapons,” is made up of four sections:

- prohibitions with respect to biological weapons,
- seizure, forfeiture, and destruction,
- injunctions, and
- definitions.

For this text, the most relevant section of the Biological Weapons Anti-Terrorism Act of 1989 is Section 175, “Prohibitions with Respect to Biological Weapons,” which specifies that “Whoever knowingly develops, produces, stockpiles, transfers, acquires, retains, or possesses any biological agent, toxin, or delivery system for use as a weapon, or knowingly assists a foreign state or any organization to do so, or attempts, threatens, or conspires to do the same, shall be fined under this title or imprisoned for life or any term of years, or both.”

It goes on to say that

*Whoever knowingly possesses any biological agent, toxin, or delivery system of a type or in a quantity that, under the circumstances, is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose, shall be fined under this title, imprisoned not more than 10 years, or both.*
In this subsection, the terms **biological agent** and **toxin** do not encompass any biological agent or biological toxin that is in its naturally occurring environment. This means that if the biological agent or toxin “has not been cultivated, collected, or otherwise extracted from its natural source,” there may be no violation of law. For the purposes of this section, the term *for use as a weapon* includes the development, production, transfer, acquisition, retention, or possession of any biological agent, toxin, or **delivery system** for other than prophylactic, protective, bona fide research, or other peaceful purposes (US Code, Title 18, Part I: Chapter 10, Section 175).

Terrorism directly threatens the foundations of government order, people, their way of life, and economic prosperity. In the modern world, populations live in densely populated urban areas, making cities conspicuous targets for terrorists and WMD attacks. In accordance with US Code (Title 18; Chapter 113B, Section 2331), **terrorism** is defined as 

> activities that involve an act dangerous to human life, or potential destruction of critical infrastructure or any key resource, intended to intimidate or coerce the civilian population, or influence a government, or affect a government by mass destruction, assassination, or kidnapping.

As such, acts of terrorism are a violation of the criminal laws of the United States, or any state or other subdivision of the United States in which it occurs. It goes without saying that biological agents are dangerous to life. When biological agents are used to harm or threaten another, the act will surely be classified as an act of terrorism, known as **bioterrorism**. We learned in the previous part that agriculture has been designated as critical infrastructure. Therefore, an act where someone uses a biological agent against the agricultural sector will also be considered an act of terrorism, known as **agroterrorism**.

A follow-up on Chapter 2332a, Section 921 of Title 18 of the aforementioned code defines **weapons of mass destruction** as

- “Any explosive, incendiary, or poison gas, bomb, grenade, rocket having a propellant charge of more than four ounces, or missile having an explosive or incendiary charge of more than one-quarter ounce, or mine or similar device.”
- “Any weapon that is designed or intended to cause death or serious bodily injury through the release, dissemination, or impact of toxic or poisonous chemical or their precursors.”
- “Any weapon that is designed to release radiation or radioactivity at a level dangerous to human life.”
- “Any weapon involving a disease organism.”

The last point made in that section is apropos to the threat that is the topic of this book. Indeed, what the previous two administrative documents indicate is that the illicit use of biological agents is not only unlawful, it is an act of terrorism and constitutes the use of a WMD. Each of these has ramifications as to how a person or persons may be investigated, charged, tried, prosecuted, and incarcerated. In addition, these terms have
implications for government agencies involved in investigative and response functions. Therefore even the most seemingly small act that involves the unlawful use of a biological agent can bring the entire weight of the federal government down on the head of the offending party.

**Critical Thinking**

Consider a young gang member mashing up a small quantity of castor beans to impress his delinquent friends. Armed with a dozen castor beans and a terrorist cookbook, he generates a crude extract of ricin. He places the extract in a vial and tells his friends that he intends to use it against a rival gang. Two days later, he uses the crude extract in an attempt to poison several gang members. Is this an act of terrorism? Is this the use of a WMD? In accordance with local and state laws, what other infractions might he be charged with?

**LEGISLATION AND PRESIDENTIAL DIRECTIVES**

**Select Agent Rule and Laboratory Biosecurity**

In June 2002 President George W. Bush signed Public Law 107–188, the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (see Fig. 10.1). The act directs the Secretary of Health and Human Services to establish and maintain a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety (“select agents”). Furthermore, the act requires all facilities and individuals in possession of those same “select agents” to register with the Department of Health and Human Services (HHS). The act created a like program at the US Department of Agriculture, which is being implemented through the Animal and Plant Health Inspection Service. (This portion of the chapter was excerpted largely from a statement made by The Honorable John H. Marburger, Director, Office of Science and Technology Policy, before the Committee on Science, U.S. House of Representatives, October 10, 2002.)

HHS has maintained a list of “select agents” since April 1997. The rule has since been refined and amended with the publication date of March 18, 2005 (42 CFR Parts 72 and 73). The rule covers the transfer of select agents, including the registration of facilities engaging in transfers and exemptions from such registration. The intent of Public Law 107–188 was to ensure that the federal government would have visibility for all legitimate uses and inventory of biothreat organisms.

Officials from the Centers for Disease Control (CDC) assembled an interagency working group to review the original list of biological agents and toxins from October 1997. From this collective wisdom, the working group proposed a revised list of agents, identified minimum quantities of toxins that would require registration, and defined genetic elements requiring regulation. Table 10.1 lists all of the select agents.
Figure 10.1 “Biological weapons are potentially the most dangerous weapons in the world,” said President George W. Bush at the signing of H.R. 3448, the Public Health Security and Bioterrorism Response Act of 2002, in The Rose Garden, Wednesday, June 12. “Last fall’s anthrax attacks were an incredible tragedy to a lot of people in America, and it sent a warning that we needed and have heeded. We must be better prepared to prevent, identify, and respond. And this bill I’m signing today will help a lot in this essential effort.” Courtesy of the White House. Photograph by Susan Sterner.

Table 10.1 Department of Health and Human Services “select agents” and toxins

- Abrin
- Botulinum neurotoxins
- Botulinum neurotoxin producing strains of *Clostridium*
- Conotoxins
- *Coxiella burnetii*
- Crimean-Congo hemorrhagic fever virus
- Diacetoxyscirpenol
- Eastern equine encephalitis virus
- Ebola viruses
- Lassa fever virus
- Lujo virus
- Marburg virus
- Monkeypox virus
- Reconstructed 1918 influenza pandemic virus
- Ricin
- *Rickettsia prowazekii*
- Severe acute respiratory syndrome (SARS)-associated coronavirus (SARS-CoV)
- Saxitoxin
- Shiga-like ribosome inactivating proteins
- South American hemorrhagic fever viruses (Chapare, Junin, Machupo, Sabia, Guanarito)
- Staphylococcal enterotoxins A, B, C, D, E subtypes
- T-2 toxin
- Tetrodotoxin
- Tickborne encephalitis complex (flavi) viruses (Far Eastern and Siberian subtypes, Kyasanur Forest and Omsk hemorrhagic fever viruses)
- *Vāriola major* virus (smallpox virus)
- *Vāriola minor* virus (Alastrim)
- *Yersinia pestis*

For purposes of 18 USC 175b, the list of select agents constitutes the list of select agents and toxins set forth at 42 CFR 73.3 and 73.4. Shown here are those agents specified in 73.3.

Source: CDC website available at: [http://www.selectagents.gov/SelectAgentsandToxinsList.html](http://www.selectagents.gov/SelectAgentsandToxinsList.html)
In August 2002 the CDC published a *Federal Register* notice requiring all facilities in possession of select agents to notify it of their holdings. A form was sent to more than 200,000 institutions for this purpose, requesting a response, even if the facilities did not possess such agents. The CDC received more than 100,000 responses to the request. Only a small proportion of those respondents declared possession of select agents.

Public Law 107–188 also requires “establishment of safeguard and security measures to prevent access for such agents and toxins for use in domestic or international terrorism or for any other criminal purpose.” Therefore, the CDC working group addressed laboratory biosecurity measures to maintain secure environments in facilities that hold and work with select agents. The fruits of that effort have been published in Appendix F of the *Biosecurity in Microbiological and Biomedical Laboratories Manual* (U.S. Department of Health and Human Services, 2009), an online publication maintained by the CDC. Provisions necessary to enhance laboratory biosecurity can vary from one facility to another and depend largely on the principal function, the nature of the agents in use, the conditions for their maintenance (eg, plant or animal pathogens often require facilities different from human pathogens), and vulnerabilities or types of threats most likely to be encountered.

Another key element of Public Law 107–188 is a requirement that individuals deemed to have a legitimate need for access to select agents undergo a background check administered by the Department of Justice. This background check consists of a review of criminal, immigration, national security, and other electronic databases available to the federal government. Institutions possessing select agents are also required to have a comprehensive security plan based on threat analyses and risk assessments.

Government officials never intended that Public Law 107–188 limit the availability of biological agents and toxins for research, education, and other legitimate purposes. However, as one might surmise, the select agent rule introduced bureaucratic procedures and “red tape” into the world of scientific research. The select agent rule was not embraced by all scientists and became the incentive for some to abandon projects or destroy stocks (Cimons, 2005).

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**The Threat of Bioterrorism**

Bioterrorism is a real threat to our country. It’s a threat to every nation that loves freedom. Terrorist groups seek biological weapons; we know some rogue states already have them… It’s important that we confront these real threats to our country and prepare for future emergencies.

*President George W. Bush, June 12, 2002*

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**Presidential Directives**

In the George W. Bush administration, the directives that are used to promulgate presidential decisions on national security matters are designated NSPDs. As discussed in
NSPD 1, this new category of directives replaces both the presidential decision directives and the presidential review directives of the previous administration. Unless otherwise indicated, past directives remain in effect until they are superseded. The first directive, dated February 13, 2001, was formally approved for release by the National Security Council staff on March 13, 2001. On October 29, 2001, President Bush issued the first of a new series of HSPDs. The following is a short summary of the HSPDs that address concerns for biological agents and state initiatives in biodefense and biosecurity.

**HSPD 4. National Strategy to Combat Weapons of Mass Destruction**

In this directive, published in December 2002, President Bush outlined the US strategy to combat WMDs. The strategy contains three principal pillars: (1) counterproliferation to combat WMD use, (2) strengthened nonproliferation to combat WMDs, and (3) proliferation consequence management to respond to WMD use. This general document did not have much specifically to say about biological threats. In fact, it stated that

> Our approach to defend against biological threats has long been based on our approach to chemical threats, despite the fundamental differences between these weapons. The United States is developing a new approach to provide us and our friends and allies with an effective defense against biological weapons.

It did promise to advance new programs to promote constructive and realistic measures to strengthen the BWC. It also promised to strengthen the Australia Group.

**HSPD 9. Defense of United States Agriculture and Food**

As discussed in chapter *Biological Threat to Agriculture*, a nation’s agriculture and food systems are vulnerable to disease, regardless of whether these outbreaks are natural, accidental, or intentionally introduced. President Bush published HSPD 9 to establish a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies. The directive’s intent is to protect against a successful attack on the US agriculture and food system, which could have catastrophic health and economic effects. It aims to do so by

> identifying and prioritizing sector-critical infrastructure and key resources for establishing protection requirements; developing awareness and early warning capabilities to recognize threats; mitigating vulnerabilities at critical production and processing nodes; enhancing screening procedures for domestic and imported products; and enhancing response and recovery procedures.

**HSPD 10. Biodefense for the 21st Century**

This directive is the cornerstone of modern-day biodefense and biosecurity initiatives. The components of this comprehensive national biodefense program are threat awareness, prevention and protection, surveillance and detection, and response and recovery. National biodefense preparedness and response requires the involvement of a wide range of federal departments and agencies. Accordingly, the directive delineates responsibility
and requires specific officials to optimize critical functions, such as information management and communications; research development and acquisition; creation and maintenance of needed biodefense infrastructure, including the human capital to support it; public preparedness; and strengthened bilateral, multilateral, and international cooperation. The Secretary of the Department of Homeland Security was designated as the principal federal official for domestic incident management and was made responsible for coordinating domestic federal operations to prepare for, respond to, and recover from biological weapons attacks. This HSPD detailed the following:

- A comprehensive framework for biodefense,
- The creation of the National Biodefense Analysis and Countermeasure Center, and
- Increased funding for
  - New vaccines (e.g., Ebola virus),
  - Intelligence initiatives,
  - Biosurveillance, and
  - Mass casualty care, to include decontamination.

More on the Threat of Bioterrorism

* Armed with a single vial of a biological agent, small groups of fanatics, or failing states, could gain the power to threaten great nations, threaten the world peace. America, and the entire civilized world, will face this threat for decades to come. We must confront the danger with open eyes, and unbending purpose.*

*President George W. Bush, February 11, 2004, included in HSPD 10*

**HSPD 18. Medical Countermeasures Against Weapons of Mass Destruction**

This directive builds on the vision and objectives articulated in the National Strategy to Combat Weapons of Mass Destruction (HSPD 4) and Biodefense for the 21st Century (HSPD 10). In those two directives, response and recovery were identified as key components of managing the consequences of a WMD attack. Mitigating illness and preventing death are the principal goals of medical countermeasure efforts. Biological agents offer the greatest opportunity for medical mitigation, and this directive accordingly assigns priorities to countermeasure efforts. The directive recognizes that development and acquisition of effective medical countermeasures to mitigate illness, suffering, and death resulting from chemical, biological, radiological/nuclear, and explosive agents is central to consequence management efforts. Although it is not feasible to develop and stockpile medical countermeasures against every possible biological threat, the directive aimed at tackling some of the more important ones. The directive promotes the development of vaccines and drugs to prevent or mitigate adverse health effects caused by exposure to biological agents. This directive also provides for tailoring ongoing research and acquisition efforts to continue to yield new countermeasures against chemical,
biological, radiological, and nuclear agents and for incorporating such new discoveries into domestic and international response and recovery planning efforts.

**HSPD 21. Public Health and Medical Preparedness**

This directive establishes for the United States a strategy for public health and medical preparedness. In addition, it seeks to transform the national approach to protecting the health of Americans against all disasters. This strategy draws key principles from the National Strategy for Homeland Security (October 2007), HSPD 4 (December 2002), and HSPD 10 (April 2004) that can be generally applied to public health and medical preparedness. The directive outlines a strategy to accomplish the following:

- Preparedness for all potential catastrophic health events;
- Coordination across levels of government, jurisdictions, and disciplines;
- Regional approach to health preparedness;
- Engagement of the private sector, academia, and other nongovernment entities in preparedness and response efforts; and
- Delineate the important roles of individuals, families, and communities.

The directive ambitiously aims to transform the nation’s approach to health care in the context of a catastrophic health event to enable public health and medical systems to respond effectively to a broad range of incidents. Components of the directive include biosurveillance, countermeasure stockpiling and distribution, mass casualty care, community resilience, risk awareness, and education and training. Moreover, the directive outlined a framework for a functional Disaster Health System and national health security strategy. The directive specifies the creation of a task force to develop the two Disaster Health System and national health security strategy and established a deadline for an implementation plan.

**PUBLIC HEALTH AND THE APPLICATION OF LAW**

In this book, a great deal of emphasis has been placed on the *R* in RAIN: recognition. After all, to do something about a problem, one has to know that it exists. Along those lines, the federal government created systems and stipulated rules and guidelines for mandatory surveillance and reporting. Specific reporting requirements vary from state to state. Depending on the state, there may be penalties for noncompliance. An example of mandatory reporting requirements is the *Model State Emergency Health Powers Act*, Article III, §301. This act stipulates that

1. “healthcare providers ‘shall’ report illnesses/diseases that may be potential cause of public health emergency, including diseases listed by CDC or by Public Health Authority;”
2. “pharmacists ‘shall’ report unusual pharmacy visits, prescriptions;” “within 24 h, with detailed info about the patient and illness; and”
3. “veterinarians, livestock owner, vet diagnostic lab director ‘shall’ report animal diseases that may be potential causes of public health emergency.”
From this and other long-standing orders, the United States has a sophisticated reporting system for nationally notifiable infectious diseases (NNIDs). The listing covers most of the diseases caused by HHS Categories A, B, and C and many others that have significance for public health agencies. A quick review of the list, which is too long to post here, shows the comprehensive nature of the NNID surveillance system. The [Websites](#) section at the end of this chapter includes a link to the NNID listing.

In most instances patients have a right to privacy of their medical condition and medical records. Furthermore, individuals have a right to refuse medical care, which includes treatment and prophylaxis. One of the most recent but also far-reaching legal rules governing privacy of medical records are the provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Congress enacted HIPAA to ensure continuity of health insurance coverage when people changed employers. It required Congress to address how confidential medical information from one medical plan would move to another and to provide standards designed to protect the confidentiality of medical information contained in health-care electronic transactions. Under HIPAA, the Secretary of HHS was required to create regulations to ensure confidentiality of individually identifiable health information. The rules HHS created regulate the disclosure by any public entity of any “protected health information,” which is defined as information that identifies or can be used to identify an individual and relates to the physical or mental health condition of, or treatment, or payment for treatment of, an individual. So what does this have to do with an act of bioterrorism?

Clearly, an outbreak of infectious disease caused by a select agent or one in Category A, B, or C may have implications for government and public health officials. In fact, some, such as smallpox, have major implications for national security and global health. That said, why should HIPAA preclude us from sharing information and stifling containment efforts when there may be time-sensitive pieces of information that should not be suppressed. For that reason, provisions of HIPAA are excluded and the information may flow when a public health emergency is declared.

Declaring a disaster or emergency is a public announcement, a statement or declaration that the government recognizes that an emergency situation exists and, presumably, intends to do something about it. As such, a **declaration** is a legal determination made by an authorized official, in accordance with criteria specified by law, which has the particular effect specified in the governing law. A declaration may trigger special emergency powers, allow expenditure of emergency funds, and waive or modify normal legal requirements. In the realm of public health, a declaration is frequently optional, officials have strong powers to act without declaring a “public health emergency,” and “public health emergency” declarations do not normally trigger availability of significant funds. On the contrary, emergency management agency directors view declarations as critical to taking action, necessary to access emergency authorities, and required to make costs eligible for reimbursement.
Critical Thinking
At early stages of an event, consider whether a declaration is truly needed and whether it may have an adverse impact. For example, during the Amerithrax incident in Washington, DC, the district did not declare a public health emergency. The federal government did not declare a public health emergency. The federal government did not declare a Stafford Act emergency. However, emergency resources were made available quickly from the CDC and Public Health Service. In addition, the strategic national stockpile was deployed within a few hours.

Under 45 CFR §164.510(b), disclosures and uses for public health activities, a covered entity may “disclose protected health information for the public health activities and purposes” to

1. “A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions;”

2. “A public health authority or other appropriate authority authorized by law to receive reports of child abuse or neglect;”

3. “A person or entity other than a governmental authority that can demonstrate that it is acting to comply with requirements or direction of a public health authority; or”

4. “A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition and is authorized by law to be notified as necessary in the conduct of a public health intervention or investigation.”

In addition, state and federal public health officials may exercise principal health authorities to control communicable disease without “declaring” a public health emergency, including quarantine or isolation, travel restrictions, contact tracing, and inoculations or medical examinations.

319 Emergency
A “319 Emergency” is a reference to the section of the Public Health Act authorizing a public health emergency declaration. Section 319 of the Public Health Service Act is codified at 42 USC 247d. Here, the Secretary of HHS may declare a public health emergency after one of the following conditions is met:

- The disease or disorder presents a public health emergency; or
- A public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks otherwise, exists.
The declaration enables the secretary to “take such action as may be appropriate to respond to the public health emergency,” including

- Making grants.
- Providing awards for expenses.
- Entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease and disorder.
- Mobilizing Public Health Service corps.
- Emergency approvals of medical products.
- Allow requirement waivers for Medicare, Medicaid, or other HHS programs.
- Allow waiver of any deadlines for submission of any data or reports required under any law administered by the secretary.

State public health officials have the authority to require persons to undergo medical treatment, which is normally in the form of immunization and testing for communicable diseases, but it also includes requiring persons to get definitive medical treatment. However, this authority is subject to constitutional and statutory procedural protections.

States generally have authority to declare and enforce quarantine within their borders. This authority varies widely from state to state depending on state laws. As discussed later, there is also federal isolation and quarantine authority. The CDC, through its Division of Global Migration and Quarantine, also is empowered to detain, medically examine, or conditionally release persons suspected of carrying certain communicable diseases. This authority derives from Section 361 of the Public Health Service Act (42 USC 264).

**Isolation: For People Who Are Ill**

*Isolation* refers to the separation of persons who have a specific infectious illness from those who are healthy and the restriction of their movement to stop the spread of that illness. Isolation allows for the focused delivery of specialized health care to people who are ill, and it protects healthy people from getting sick. People in isolation may be cared for in their homes, in hospitals, or in designated health-care facilities. Isolation is a standard procedure used in hospitals today for patients with tuberculosis and certain other infectious diseases. In most cases, isolation is voluntary; however, many levels of government (federal, state, and local) have basic authority to compel isolation of sick people to protect the public. Isolation is authorized until the person is no longer contagious.

To contain the spread of a contagious illness, public health authorities rely on many strategies. Two of these strategies are isolation and quarantine. Both are common practices in public health, and both aim to control exposure to infected or potentially infected persons. Both may be undertaken voluntarily or compelled by public health authorities. The two strategies differ in that *isolation* applies to persons who are known to have an illness (see Fig. 10.2) and *quarantine* applies to those who have been exposed to an illness but may or may not become ill (see Fig. 10.3). As to who can invoke quarantine and
isolation, that varies by state. In general, a governor, state public health officer, city or county council, mayor, or local public health office may do so. In most states, a public health emergency declaration is not legally required, but the declaration could be useful if invoking powers for a large population. The bottom line is that one should check with a qualified attorney before powers need to be invoked.

Figure 10.2 The image above is from an Ebola isolation ward that had been equipped with upgraded facilities, and made ready for Ebola patients. The image was captured early in the 2014/15 Ebola outbreak in West Africa. Image courtesy of Centers for Disease Control and Prevention.

Figure 10.3 A sign informing the public that the house and its residents are under an order for quarantine. Courtesy of Centers for Disease Control and Prevention.
Quarantine: For People Who Have Been Exposed But Are Not Ill

Quarantine refers to the separation and restriction of movement of persons who, although not yet ill, have been exposed to an infectious agent and therefore may become infectious. Quarantine of exposed persons is a public health strategy, similar to isolation, that is intended to stop the spread of infectious disease. Quarantine is medically very effective in protecting the public from disease.

Quarantine and isolation restrict the personal liberty of individuals. Many state health laws do not spell out the procedural requirements for quarantine and isolation, whereas others have fairly detailed provisions. Most of these protections are derived from the fact that the Constitution requires due process when depriving an individual of “liberty.” The individual in question has a right to counsel. These protections may require notice and hearing requirements, showing that detention is necessary to protect public health, and a reviewable final decision. If other measures are workable and protect public health, then they may be constitutionally required. A court might find it unreasonable to arrest and forcibly quarantine people if a lesser restraint would be effective. It may also be important for health officials to estimate how important 100% compliance is with a quarantine order to protecting the public health. Alternatively, would a stay-at-home quarantine be effective if 80% of the population comply?

Federal Powers: Quarantine of Travel

“A person who has a communicable disease in the communicable period

• Shall not travel from one state or possession to another…
• Without a permit from the health officer of the state, possession, or locality of destination, if such permit is required under the law applicable to the place of destination.”

To prevent the interstate spread of disease, the federal government may restrict the movement of persons suspected of being infected with certain communicable diseases. This very old law may be a powerful tool in the hands of a qualified public health official to ensure the health and safety of the public. Only the director of the CDC can issue a permit for people within the contagious phase of certain communicable diseases (cholera, plague, smallpox, typhus, or yellow fever) to travel on board an interstate conveyance (eg, plane, train, bus). In addition, an individual in the communicable stage of a disease may not travel from one state to another without obtaining a permit from the health officer of the destination state, assuming that such a permit is required under the law of the destination state (42 CFR §70.3). The diseases for which quarantine is authorized are listed in an executive order of the president, the most recent of which is Executive Order 13,295, issued on April 1, 2005. This list now includes severe acute respiratory syndrome and H5N1 influenza A virus.
TRANSPORTING BIOHAZARDOUS MATERIALS

The shipment of hazardous materials is regulated by the US Department of Transportation (DOT) and the International Air Transport Association (IATA, 2007). The purpose of hazardous materials regulations is to protect the shippers, the carriers, the environment, and the recipients of each package from exposure to the contents. Failure to comply with the regulations can result in substantial fines or jail terms. The DOT defines hazardous material as substances that are capable of posing an unreasonable risk to health, safety, and property when transported in commerce (U.S. Department of Transportation, 49 CFR). This includes diagnostic specimens, infectious agents, biological products, and dry ice. Such shipments must arrive at their destination in good condition and present no hazard during shipment (U.S. Public Health Service, 42 CFR, Part 72).

Individuals who ship hazardous materials are required to comply with these regulatory requirements:

• Hazardous material shipments must be properly packaged, marked, documented, and labeled.
• Individuals who offer hazardous materials for shipment must receive training.
• There are specific requirements for the packaging and labeling of biological materials. Biological materials include infectious substances (etiologic agents), diagnostic (clinical) specimens, and biological products. Proper shipping papers, Shipper’s Declaration for Dangerous Goods, must be completed for shipment of infectious substances but not for biological products or diagnostic specimens. However, all three groups of materials require proper packaging. Human blood always requires “universal precautions” and may be considered a diagnostic specimen and shipped without the dangerous goods paperwork. A biohazard sticker must be present when shipping human blood, according to the OSHA Blood-Borne Pathogens standard. However, if the human blood is known to be infected with an infectious substance, it must be packaged and shipped as such and requires the dangerous goods paperwork (29 CFR, 1910.1030).

CONCLUSION

The administrative and legal aspects of biosecurity include international treaties (eg, the BWC), laws, statutes, regulations, and government directives aimed at reducing the threat due to the biological agents and enabling enforcers to deal with those that use them with ill intentions. These administrative measures have helped define programs and strengthen bio-defense and biosecurity all over the globe. The aim of this chapter is to discuss the most relevant documents in hopes that the reader can now appreciate the authority and framework given to officials by these measures. As mentioned in the introduction, the chapter is not written for legal professionals. Rather, it is written for professionals that may have to apply the rules of law in everyday situations, especially in the public health arena. Care should be taken to consult a legal professional before utilizing any of the concepts related to public health law.
ESSENTIAL TERMINOLOGY

Note: The terms here are defined with the original language found in the legislative document in which they are used. The legal definitions of terms that have been used throughout this book should be applied when determining the illegality or administrative nature of whatever activity is being analyzed.

- **Biological agent.** Any microorganism (including but not limited to bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing
  - Death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism.
  - Deterioration of food, water, equipment, supplies, or material of any kind.
  - Deleterious alteration of the environment.
- **Biological product.** A product prepared in accordance with regulations that govern vaccines, licensed biological products, and the like.
- **Biological toxin.** The toxic material or product of plants, animals, microorganisms (including but not limited to bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes
  - Any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism
  - Any poisonous isomer or biological product, homolog, or derivative of such a substance.
- **Delivery system.** Any apparatus, equipment, device, or means of delivery specifically designed to deliver or disseminate a biological agent, toxin, or vector.
- **Diagnostic specimen.** Any human or animal material including excreta, secretions, blood, blood components, tissue, and tissue fluids being shipped for the purposes of diagnosis. Specimens that are “known or reasonably expected” to contain pathogens must be handled as infectious substances.
- **Declaration.** A legal determination made by an authorized official, in accordance with criteria specified by law, which has the particular effect specified in the governing law.
- **Etiologic agent.** A viable microorganism or its toxin that causes or may cause disease in humans or animals (Department of Transportation).
- **Infectious substances.** Substances known to contain, or reasonably expected to contain, pathogens. Pathogens are microorganisms (including bacteria, viruses, rickettsiae, parasites, fungi) or recombinant microorganisms (hybrid or mutant) that are known or reasonably expected to cause disease in humans or animals (International Air Transport Association).
• **Isolation.** The separation of persons who have a specific infectious illness from those who are healthy and the restriction of their movement to stop the spread of that illness.

• **Quarantine.** The separation and restriction of movement of persons who, although not yet ill, have been exposed to an infectious agent and therefore may become infectious.

• **Terrorism.** Activities that involve an act dangerous to human life or potential destruction of critical infrastructure or any key resource intended to intimidate or coerce the civilian population, or influence a government, or affect a government by mass destruction, assassination, or kidnapping.

• **Weapon of mass destruction (WMD).** A four-part definition that includes any explosive, incendiary, or poison gas, bomb, grenade, rocket having a propellant charge of more than four ounces, or missile having an explosive or incendiary charge of more than one-quarter ounce, or mine or similar device; any weapon that is designed or intended to cause death or serious bodily injury through the release, dissemination, or impact of toxic or poisonous chemical or their precursors; any weapon that is designed to release radiation or radioactivity at a level dangerous to human life; and, *any weapon involving a disease organism.*

**DISCUSSION QUESTIONS**

• How may state authorities require persons to undergo medical treatment?

• With respect to quarantine and isolation, when are they authorized? Who can authorize them? What procedures need to be followed?

• What has become of the initiatives specified in HSPD 10 since it was published?

• What is the difference between isolation and quarantine?

• Can one make an argument for large-scale quarantine? When might this be applicable?

**WEBSITES**

List of select agents and toxins. [http://www.selectagents.gov/SelectAgentsandToxinsList.html](http://www.selectagents.gov/SelectAgentsandToxinsList.html)

List of Nationally Notifiable Infectious Diseases current and historical conditions. Available at: [http://wwwn.cdc.gov/nndss/conditions/](http://wwwn.cdc.gov/nndss/conditions/)

**REFERENCES ON HIPAA**

Centers for Disease Control/Department of Health and Human Services Guidance on Health Insurance Portability and Accountability Act Privacy Rule and Public Health. Available at: [http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm).
Summary of the Health Insurance Portability and Accountability Act Privacy Rule. Available at: [http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf](http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf).

Preamble of Health Insurance Portability and Accountability Act Privacy Rule: 64 Fed. Reg. 59,918 (November 3, 1999), Department of Health and Human Services Website Q&A on HIPAA Privacy Rule. Available at: [http://www.hhs.gov/ocr/privacy/](http://www.hhs.gov/ocr/privacy/).

Center for Disease Control’s Division of Global Migration and Quarantine (DGMQ) Website. Available at: [http://www.cdc.gov/ncezid/dgmq/](http://www.cdc.gov/ncezid/dgmq/).

REFERENCES

Cimons, M., 2005. Rules, regs, and red tape. Howard Hughes Medical Institute Bulletin (Winter) 21–24.

International Air Transport Association, 2007. Dangerous Goods Regulations Manual, forty-eighth ed. IATA, Montreal.

Miller, J., Engelberg, S., Broad, W., 2001. Germs: Biological Weapons and America’s Secret War. Simon and Schuster, New York.

U.S. Department of Health and Human Services, 2009. Biosafety in Microbiological and Biomedical Laboratories, fifth ed. Centers for Disease Control and Prevention, Office for Health and Safety. Available at: [http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf](http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf).

U.S. Department of Labor. Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne Pathogens.

U.S. Department of Transportation. 49 CFR Parts 171-180 and Amendments.

U.S. Public Health Service. 42 CFR Part 72, Interstate Shipment of Etiologic Agents.