Terrorist attacks, novel influenzas, emerging infectious diseases, and natural disasters have prompted a reexamination of the nation’s public health system. The jetliner and anthrax attacks of 2001, the SARS outbreak of 2003, hurricanes Rita and Katrina in 2005, the 2009 H1N1 influenza pandemic, Hurricane Irene in 2011, Hurricane Sandy in 2012, the Texas fertilizer plant explosion in 2013, and the West African Ebola epidemic in 2014–15 have focused attention on public health preparedness. In the years following the 2001 attacks, “the conceptual framework of emergency preparedness and response subsume[d] ever larger segments of the field of public health.”1 The outpouring of resources and attention to biosecurity has supported a public health law renaissance. Perceived government failures in response to public health emergencies continue to stoke public anxiety, adding political pressure for more effective preparedness planning.

All-hazards and resilience have become watchwords in preparedness.2 Vertical strategies targeting specific threats (e.g., development of pathogen- or toxin-specific vaccines and treatments) remain a priority. But horizontal strategies (e.g., investment in public health infrastructure) are
needed to ensure preparedness for a broad range of emergencies while also enhancing capabilities to meet routine needs. At the federal level, the National Response Framework (NRF) integrates existing preparedness, response, and recovery programs to “align key roles and responsibilities, . . . guide how the Nation responds to all types of disasters and emergencies,” and ensure “security and resilience.” At a time when governments are investing significant resources in preparedness for rare events that may never occur, it is politically useful to frame these expenditures and legal reforms as supporting preparedness for more likely events such as natural disasters. And in practice, obvious benefits derive from expanding public health infrastructure’s capacity to handle routine needs.

Modern public health emergency preparedness strategies continue to draw on ancient public health law interventions such as isolation and quarantine while also adopting updated approaches to social distancing, development and rapid deployment of medical countermeasures, and allocation of scarce resources under exigent circumstances. Policies must delicately balance protecting individual rights with meeting collective needs, promoting cooperation and coordination across jurisdictions, and ensuring fairness in meeting the needs of particularly vulnerable populations. We begin by examining the federal-state balance in public health emergency preparedness. We then follow the emergency planning cycle (see figure 11.1 and table 11.1), discussing disaster and emergency declarations; evacuation and sheltering; development and rapid deployment of medical countermeasures; and isolation, quarantine, and social distancing.

THE FEDERAL-STATE BALANCE IN PUBLIC HEALTH PREPAREDNESS

Public health emergency preparedness addresses hazards and vulnerabilities whose scale, rapid onset, or unpredictability threatens to overwhelm routine capabilities. It encompasses chemical, biological, radiological, and nuclear exposures (CBRN) as well as natural, industrial, and technological disasters (e.g., hurricanes, floods, earthquakes, dam failures, and radiation leaks), all of which require advance planning, rapid detection, and effective response. Threats may be naturally occurring (e.g., emerging disease outbreaks), or they may originate from intentional acts (e.g., terrorism) or unintentional releases (e.g., chemical spills). Biosecurity refers to precautions against the spread of harmful microorganisms, but it is sometimes used more broadly to refer to all
**Figure 11.1.** The emergency management cycle.

<table>
<thead>
<tr>
<th>Table 11.1</th>
<th>Key Terms in Emergency Management</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td><strong>Example</strong></td>
</tr>
<tr>
<td>Prevention</td>
<td>Activities that prevent hazards</td>
</tr>
<tr>
<td>Mitigation</td>
<td>Pre-event activities aimed at reducing the impacts of a hazard without preventing it from occurring</td>
</tr>
<tr>
<td>Preparedness</td>
<td>The pre-event process of building capacity to respond to or recover from hazards</td>
</tr>
<tr>
<td>Response</td>
<td>Postevent activities to ameliorate the immediate impacts of hazards to prevent mortality, morbidity, and property damage</td>
</tr>
<tr>
<td>Recovery</td>
<td>Postevent activities that address the long-term impacts of a hazard to restore communities, including rebuilding</td>
</tr>
</tbody>
</table>
public health emergencies. Biosafety (a related concept) refers to the maintenance of safe conditions in biological research to prevent inadvertent escape of hazardous materials. Biological samples can create major hazards when researchers do not use rigorous containment procedures (see box 11.1).

Public health emergencies unite one of the most fundamental functions of the federal government—national security—with one of the most fundamental functions of the state governments—public health. Public health emergencies pose enormous challenges to American federalism, with myriad laws at the local, state, tribal, and federal level—many of which were developed “to address more mundane public health matters, or designed to respond to more traditional emergency situations.” This federalist structure has resulted in conflicting jurisdictional claims as well as confusion about, or even denials of, ultimate responsibility in times of disaster management.

The jetliner and anthrax attacks of 2001 launched more than a decade of capacity building, including reforms of long-standing federal disaster and emergency response laws and state public health laws. Many reforms were dramatic, including the largest restructuring of the federal administrative state since the New Deal with the newly created Department of Homeland Security (DHS) and the establishment of federal direct-response systems for medical resources and personnel. At the state level, the Model State Emergency Health Powers Act was adopted to some extent in thirty-nine states and the District of Columbia. The vast expansion of emergency preparedness laws has raised concerns about coordination among different levels of government, interagency coordination within each level of government, and protections for individual rights.

Since the mid-twentieth century, the federal government has assumed responsibility for financing disaster recovery efforts that overwhelm local resources, thus spreading the economic burden of disasters. Through health, safety, and environmental regulation and the administration’s national security and international development agendas, the federal government also plays a leadership role in prevention and mitigation. This is particularly true with regard to terror attacks and global pandemics, though climate-change mitigation efforts have been stymied by political gridlock. The federal government regulates biologic agents of public health concern (see box 11.2), conducts surveillance for emerging infectious diseases (see chapter 9), and provides financial support and guidance for state and local government preparedness efforts. In recent years, the federal government’s increasing role as a direct pro-
Biosafety

These events revealed totally unacceptable behavior. They should never have happened. I’m upset, I’m angry, I’ve lost sleep over this, and I’m working on it until the issue is resolved.

—Thomas Frieden, CDC Director, 2014

Biosafety refers to the maintenance of safe conditions in biological research to prevent the escape of hazardous materials that could harm workers, persons outside the laboratory, or the environment. Multiple incidents uncovered in 2014 publicly embarrassed prominent government agencies and raised grave concerns about laboratory containment procedures for dangerous pathogens.

In June 2014, more than seventy-five scientists and staff at the Centers for Disease Control and Prevention (CDC) were exposed to live anthrax spores as a result of a lapse in safety procedures at two of the agency’s labs. Later investigation found that CDC laboratories did not follow proper procedures for destroying the spores: scientists mistakenly used the protocol for destroying a less robust bacterium, brucella. The CDC vaccinated exposed workers and gave them a preventative course of antibiotics; none developed symptoms.¹

The investigation also uncovered an even more dangerous lapse that had occurred earlier in the year. The U.S. Department of Agriculture (USDA) had asked the CDC to send them samples of H9N2 bird flu, a strain thus far not particularly transmissible to or virulent among humans. However, the CDC mistakenly shipped a sample contaminated with H5N1, a highly virulent strain of flu that kills around 60 percent of those infected. Worse still, after the USDA informed the CDC lab of the mistake, six weeks passed before CDC leadership was informed. The CDC then temporarily closed its flu and anthrax laboratories and placed a moratorium on shipment of biological materials from its high-security labs.²

Other serious incidents in 2014 also illustrate significant biosecurity lapses. In April 2014, the Institut Pasteur, a French research foundation, discovered that 2,300 vials of the virulent coronavirus that causes severe acute respiratory syndrome (SARS) had gone missing from its labs. In July, samples of smallpox (an eradicated pathogen thought to be confined to just two high-security repositories in the world) were discovered in an unused storage room at the National


². Centers for Disease Control and Prevention, Report on the Inadvertent Cross-Contamination and Shipment of a Laboratory Specimen with Influenza Virus H5N1 (Atlanta, GA: Centers for Disease Control and Prevention, 2014).
Institutes of Health (NIH). And in December, CDC researchers mistakenly allowed Ebola virus samples to be handled in a less secure laboratory than required by protocols. Fortunately, the mistake was discovered within twenty-four hours and immediately reported to agency leaders.

These breaches are particularly unsettling because the CDC, the NIH, and the Institut Pasteur host some of the world’s preeminent research laboratories. Laboratories are indispensable for providing vital information about disease threats and developing effective countermeasures. However, these incidents show that without proper biosafety measures, labs themselves can threaten biosecurity.

vider of services—not merely a financer and adviser to state and local governments—represents a major expansion of its preparedness and response efforts.

The Legal Basis for Federal Preparedness, Response, and Recovery Efforts

The Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act) governs federal involvement in disaster relief and emergency preparedness and response, while Section 319 of the Public Health Service Act (PHSA) governs federal public health emergency declarations. The terrorist attacks of 2001, the SARS outbreak, and concerns about pandemic influenza prompted a series of reforms to expand federal capacity and support for state, local, and tribal efforts, including the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act); the Project BioShield Act of 2004; the Public Readiness and Emergency Preparedness Act of 2005 (PREP); and the Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA, reauthorized in 2013). The Bush and Obama administrations also developed the National Response Framework and the National Strategy for Pandemic Influenza to coordinate federal efforts.

Emergency Declarations

Federal response and recovery assistance are often contingent on specific legal declarations. Emergency declarations at the federal and state level also trigger important changes to the legal frameworks in place to deal with routine needs. In some cases, these changes expand govern-
“Dual Use” Research of Concern

Multiple federal agencies (DHHS, the CDC, and the Department of Agriculture’s Animal and Plant Inspection Service) regulate the possession, use, and transfer of biological select agents and toxins (BSATs). These agencies are working together to address dual-use research of concern (DURC): life sciences research intended for benefit, but which could be misapplied to do harm, such as through bioterrorism. For example, researchers may alter viruses to render them more virulent or transmissible from person to person. This research (called “gain of function”) can improve scientific understanding of pathogens, potentially facilitating surveillance and development of countermeasures. But dangerous pathogens also pose a risk of inadvertent or deliberate release from laboratories, posing risks to workers and the public at large.

In 2012, researchers modified strains of the H5N1 influenza virus to facilitate airborne transmission in mammals. Following a prepublication review process, the National Science Advisory Board for Biosecurity (NSABB)—which provides advice, guidance, leadership, and oversight on the biosecurity aspects of DURC—recommended that details of the experimental methods and results be redacted from publications of the research in open forums because of the potential for this information to be used by terrorists.

The NSABB’s advice provoked heated international debate in the academic and health communities. Some viewed the recommendations as an “assault on the openness and accessibility upon which the modern scientific endeavor relies.” Others argued that the even a small risk of pandemic caused by a highly transmissible, highly pathogenic influenza virus outweighed the benefits of disclosing the full details of the research.

The NSABB ultimately revised its earlier decision, recommending full publication of one paper and partial publication of another.

In 2013, DHHS released a framework to guide its funding of proposals for research anticipated to generate H5N1 viruses that are transmissible by respiratory droplets among mammals. In 2014, the White House Office of Science and Technology Policy released a DURC policy developed collaboratively by several federal agencies, setting forth review and oversight requirements for DURC conducted at universities and other institutes that receive federal funding.

ment authority; in others they are deregulatory. In some instances, restraints on government power derived from individual rights are relaxed or overridden because of extenuating circumstances.

Disaster and Emergency Declarations under the Stafford Act

The Stafford Act authorizes two types of presidential declarations that trigger federal relief: major disaster and emergency. The act defines major disaster as a “natural catastrophe (including any hurricane, tornado, storm, high water, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm, or drought).” This definition excludes pressing biosecurity threats such as bioterrorism and naturally occurring pandemics, which are thus ineligible for important forms of financial assistance. The act defines emergency more broadly, as “any occasion or instance for which, in the determination of the President, Federal assistance is needed to supplement State and local efforts and capabilities to save lives and to protect property and public health and safety, or to lessen or avert the threat of a catastrophe in any part of the United States.” An emergency declaration authorizes the president to direct any federal agency to use its existing authorities and resources to coordinate disaster relief and to assist state and local governments with health and safety measures, issue risk and hazard warnings and health information, control public health threats, and distribute medicines and food.

Generally, the president’s declaration must be preceded by a state governor’s request. This traditional “pull” approach works most of the time, but it contributed to devastating failures in the aftermath of Hurricane Katrina. In the case of “catastrophic incidents,” the homeland security secretary (or his or her designee) can trigger expedited (and unrequested) federal assistance (a “push” approach), but this authority has not been exercised to date. Many were critical of the secretary’s failure to declare a catastrophic incident following Hurricane Katrina. Instead, federal and state authorities engaged in days of negotiations while thousands of residents were struggling to survive in deplorable conditions.

Public Health Emergency Declarations under the Public Health Services Act

The PHSA authorizes a third type of federal declaration. The secretary of the Department of Health and Human Services (DHHS) is author-
ized to declare a public health emergency on finding that “(1) a disease or disorder presents a public health emergency; or (2) a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists.” The president and HHS secretary may declare emergencies simultaneously. A public health emergency declaration is not contingent on a state request. It triggers the HHS secretary’s authority to make grants, finance expenses, enter into contracts, and conduct investigations, and to provide federal financial assistance from the Public Health Emergency Fund.

The declaration of a public health emergency also allows the HHS secretary to waive certain provisions of federal law that could impede emergency response. As the federal government has become increasingly involved in more mundane aspects of health care delivery (e.g., ensuring access to emergency medical treatment, health information privacy, and drug safety), the growing framework of federal health laws has become a potential impediment to preparedness, response, and recovery efforts. The HHS secretary may suspend provisions relating to health care providers’ conditions of participation in Medicare or Medicaid, provisions of the Food, Drug and Cosmetic Act, and agency enforcement actions under the Emergency Medical Treatment and Active Labor Act (EMTALA) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

State Emergency Declarations

The first responders and the infrastructure for immediate response to a public health emergency are largely governed at the level of the city, municipality, or county. Thus a broad array of state and local laws—governing such matters as emergency declarations, school closure, quarantine and isolation, and professional licensing—comes into play. These provisions vary from state to state and even from locality to locality. State and local laws govern a vast range of minutiae, from licensing of emergency medical technicians to disposal of corpses.

In the aftermath of the 2001 attacks, policy makers and academics urged states to modernize their public health statutes to ensure legal preparedness for public health emergencies. As part of this effort, the CDC commissioned the Model State Emergency Health Powers Act (MSEHPA—see box 11.3), which defined a public health emergency as an imminent threat that “poses a high probability of . . . a large number of deaths in the affected population; a large number of serious or long
term disabilities in the affected population; or widespread exposure to an infectious or toxic agent that poses a significant risk of substantial future harm to a large number of people in the affected population.”

In the decade that followed the 2001 attacks, the majority of states incorporated public health emergency declarations into their public health or disaster preparedness laws, with declarations typically triggering special authorities, regulatory flexibilities, and financial assistance.

State public health emergency declarations have been used for a variety of purposes. During the 2009 H1N1 influenza pandemic, some governors declared public health emergencies, while others did not, feeling that existing authorities were sufficient to handle the situation. In 2014, the governor of Connecticut declared a public health emergency to enable rapid response to potential Ebola cases, and the governor of Massachusetts, Deval Patrick, declared a public health emergency on opioid abuse. The declaration enabled him to immediately remove regulatory barriers to naloxone access, which prevents overdose deaths (see chapter 6), ban high-risk, hydrocodone-only painkillers, and mandate that prescribers consult the state’s Prescription Drug Monitoring Program (PDMP) prior to every prescription for Schedule II and III substances. These emergency measures were temporary, with the state health department working to make them permanent through a lengthier administrative process.

**Evacuation and Emergency Sheltering: The Needs of Vulnerable Populations**

In addition to lives lost to injury during a disaster, mortality and morbidity can be attributed to unsanitary conditions in the aftermath. Concerns include increased exposure to infectious disease through contaminated floodwaters or unsanitary shelter conditions; increased exposure to hazardous chemicals or radiological materials through unintentional releases; carbon monoxide poisoning due to the use of emergency generators; disruption in medical care for those suffering from chronic conditions; and the mental health impact of devastating losses of life and property. These indirect effects are difficult to predict and quantify, but considering their magnitude is essential to effective preparedness and response. Climate change offers a pertinent illustration of ongoing efforts to adapt to anticipated impacts and save lives (see box 11.4).
A week after the terrorist attacks of September 11, 2001, letters containing anthrax bacteria were mailed from Trenton, New Jersey, to the three major network news stations in New York City, and to two tabloid newspapers, sickening twenty-two people and killing five. In the midst of these events, the CDC asked the Centers for Law and the Public’s Health at Georgetown and Johns Hopkins Universities to draft what became known as the Model State Emergency Health Powers Act (MSEHPA). The model statute was designed to provide state legislatures with a roadmap for updating their public health emergency laws. The MSEHPA addresses five key public health functions: preparedness and planning, surveillance, management of property, protection of persons, and communication and public information.\textsuperscript{1}

The model statute also provides clearer standards and stronger guarantees of due process than public health statutes that predate modern judicial conceptions of individual rights.\textsuperscript{2}

Under the model statute, coercive public health powers can be exercised in response to a disease outbreak only after the governor has declared a state of emergency.\textsuperscript{3} A declaration gives public health officials the power to carry out examinations necessary for diagnosis and treatment. Authorities have the power to isolate and quarantine individuals when warranted to prevent a substantial risk of transmission of infection, but they must adhere to human rights principles: choosing the least restrictive alternative, providing safe and habitable environments, and fulfilling individual needs for medical treatment and necessities of life. Although the model statute was created with recognition that exigencies may preclude a predetention hearing, the government is required to petition for a court order within ten days of issuing a quarantine or isolation directive, and detainees have the right to counsel.

Nonetheless, some scholars criticized the MSEHPA for insufficient protection of civil liberties, particularly concerning quarantine.\textsuperscript{4} Other

\begin{itemize}
  \item Model State Emergency Health Powers Act §§ 401–405 (“During a state of public health emergency, the public health authority shall use every available means to prevent the transmission of infectious disease”).
\end{itemize}
Learning from Past Failures

Natural disasters like hurricanes Katrina and Sandy have overwhelmed emergency response systems. The slow, uncoordinated response from all levels of government left residents living on overpasses waiting to be rescued, trapped in their homes, or residing in shelters with insufficient food, water and medical supplies, where evacuees faced threats of violence. News reports exposed the horrific conditions endured by survivors, particularly the poor, older people, and persons with physical or mental disabilities. These events seared into the American consciousness the inequities that can ensue in a public health emergency and highlighted the imperative of special attention to the needs of the disadvantaged.

Emergency management plans are often inadequate to meet the needs of vulnerable people. The failure to provide accessible emergency information may mean that people with hearing disabilities remain unaware of imminent emergencies, while those with intellectual disabilities may have difficulty comprehending evacuation messages. Individuals with mobility impairments have been left behind in evacuation efforts because vehicles were not equipped with lifts or ramps—sometimes with fatal results. Over 40 percent of Katrina survivors not evacuated in a timely manner were either themselves physically unable to leave or were caring for others unable to leave. Hospitals and nursing homes were ill equipped and failed to evacuate in time. States failed to provide an adequate

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number of special-needs shelters, and persons with disabilities were turned away. Those who were admitted struggled to access basic services such as medical care, restrooms, food, water, and shuttle services.33

These failures served as a catalyst for efforts to better integrate the needs of people with disabilities into emergency management planning.34 Congress amended the Stafford Act to incorporate disability and special needs. The new law, called the Post-Katrina Emergency Management Reform Act of 2007 (the Post-Katrina Act),35 required the inclusion of people with disabilities in every phase of planning and set out detailed guidance on the steps needed to protect persons with disabilities in case of disaster. PAHPA incorporated similar provisions for “at-risk” individuals into the PHS and established the public health and medical needs of at-risk individuals as a national preparedness objective.36

Taken together, federal and state laws still fall short of ensuring comprehensive protection for individuals with special functional and access needs in emergencies. These limitations have come to the fore in a series
of lawsuits brought by disability advocacy groups against state and city governments. In 2013, for example, a federal district court found that New York City’s emergency response plans had failed to accommodate the needs of people with disabilities. The class action suit, originally filed in response to Hurricane Irene, went to trial shortly after Hurricane Sandy. Witnesses with disabilities testified that they were trapped inside apartment buildings waiting for help. Many residents in city housing projects were reduced to “an almost primal state of living” — trapped in upper-floor apartments without water, heat, or power.

DEVELOPMENT AND DISTRIBUTION OF MEDICAL COUNTERMEASURES

All stages of planning and implementation of disaster response should be guided by the universal ethical values of fairness, transparency, consistency, proportionality, and accountability. Incorporating these principles ensures that in stewardship of available scarce resources, the best possible care is given to individuals and the population as a whole. Delivery of health care under crisis standards is ultimately about maximizing the care delivered to the population as a whole under austere circumstances that may limit treatment choices for both providers and patients.

— Institute of Medicine, Crisis Standard of Care, 2012

Federal programs accelerate the development of medical countermeasures and stockpile them for rapid deployment; enhance health care facilities’ surge capacity in response to mass casualty events; increase health care workers’ ability to identify and treat diseases resulting from bioterrorism; and facilitate work across jurisdictions and sectors. The federal government has made new forays into direct involvement via the Strategic National Stockpile (SNS) of essential pharmaceutical resources, the CDC’s National Electronic Disease Surveillance System (NEDSS), the National Disaster Medical Service (NDMS), and the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP).

Development and Government Procurement of Medical Countermeasures

Therapeutic countermeasures are medical interventions to prevent and treat disease and other health hazards attributable to public health emergencies. Vaccines can prevent disease, with herd immunity afford-
Climatic changes have affected and will continue to affect human health, water supply, agriculture, transportation, energy, coastal areas, and many other sectors of society, with increasingly adverse impacts on the American economy and quality of life. Certain groups of people are more vulnerable to the range of climate change related health impacts, including the elderly, children, the poor, and the sick. Others are vulnerable because of where they live, including those in floodplains, coastal zones, and some urban areas. Improving and properly supporting the public health infrastructure will be critical to managing the potential health impacts of climate change.


Efforts to limit the severity of global climate change by reducing the concentration of greenhouse gases in the atmosphere (referred to as “mitigation”) have been largely unsuccessful. The findings presented in the report quoted above—that the health effects of climate change are already evident, and that those effects will intensify, significantly increasing mortality and morbidity—serve as a wake-up call. In addition to undertaking mitigation efforts, governments worldwide are engaged in scientific research and policy change aimed at reducing the impact of climate change on human health and well-being (called “adaptation”). Demands on the public health system as society adapts to the health consequences of climate change will be significant.

In the United States, climatic and environmental changes are altering public health needs both through the introduction of new threats and through the intensification and geographical shifting of current threats. One of the most evident and tangible threats of climate change is more extreme weather-related disasters. Although media coverage tends to focus on natural disasters like floods and hurricanes that provide captivating visual images, the leading cause of weather-related deaths in the United States is heat waves, which are becoming more frequent and more extreme. Climate change is having more gradual effects on health as well. Rising temperatures and more frequent wildfires exacerbate poor air quality, contributing to respiratory and cardiovascular disease. Changing weather patterns may result in an increased incidence of zoonotic, vector-, food-, and waterborne diseases.  

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The health effects of climatic and environmental changes will challenge our nation’s already overburdened public health infrastructure in new ways. Every public health function will be called on, but disaster preparedness and response, disease surveillance, infectious disease control, and vector control will be particularly salient. Whether or not they actually offer evidence of anthropogenic climate change, natural disasters like hurricanes Katrina, Irene, and Sandy, and the emergence of vector-borne diseases like West Nile virus and zoonotic diseases like hantavirus, provide a glimpse of the health hazards that global climate change will bring. The lessons learned are crucial to ongoing adaptation.

Therapeutic countermeasures are crucial to an effective public health response to CBRN attacks and naturally occurring disease outbreaks.

Yet effective countermeasures are not available for many of the biological terrorism agents deemed most dangerous by the CDC, such as botulinum toxin, plague, tularemia, and viral hemorrhagic fevers. For others, like smallpox and anthrax, countermeasures exist, but stockpiles are insufficient to respond to major outbreaks. The pharmaceutical industry, moreover, has few incentives to develop countermeasures for rare, unpredictable events, such as novel influenzas, biowarfare, or a terrorist attack. The infrequent natural occurrence of these events, the substantial expense of developing new products, the unpredictability of market demand, and an uncertain regulatory environment result in a dearth of effective countermeasures.

The Strategic National Stockpile

The HHS secretary, in conjunction with the CDC and DHS, maintains a strategic national stockpile of “drugs, vaccines and other biological products, medical devices and other supplies . . . to provide for the emergency health security of the United States . . . in the event of a bioterrorist attack or other public health emergency.” The Project Bioshield Act of 2004 funded the procurement of medical countermeasures against a broad array of CBRN agents, with funding reauthorized
in 2013. However, delays, bureaucracy, and lack of coordination with the private sector have plagued Bioshield. The development of a safer, more effective anthrax vaccine—the government’s highest priority prior to the 2014–15 West African Ebola epidemic—has been mired in disputes. The cancellation of a large contract with VaxGen for the anthrax rPA vaccine sparked concerns about bureaucratic delays. Congress has repeatedly reformed the program, most notably through PAHPA in 2006, which organized Bioshield activities under the Biodefense Advanced Research and Development Authority (BARDA). PAHPA provided crucial funding to bridge the “valley of death” between National Institutes of Health funding for early-stage basic research and SNS procurement for products in the late stages of development. Despite these reforms, concerns remain regarding transparency and the slow pace of development.

After a rocky start, Bioshield has added about a dozen new products to the SNS, with about eighty more in various stages of development. In the aftermath of Katrina, many criticized the investment of resources in CBRN countermeasures when the intensification of more routine medical needs during a disaster was a more pressing concern (see box 11.5). In 2013, controversy over federal spending on two million doses of the smallpox medicine Arestvyr, at a cost of two hundred dollars per dose, indicated that political support might be waning for investments in CBRN countermeasures for agents that do not pose a routine threat. In 2014, media reports gave Bioshield credit for ensuring that Ebola vaccines and treatments were already in development when the West African epidemic struck, but no proven medical countermeasures were in place during the crisis.

Safety Concerns about SNS Deployment
Critics have also expressed safety concerns about the SNS, noting that although procurement contracts specify that manufacturers must seek FDA approval for intended stockpile uses, crucial SNS products remain unapproved. It is difficult to ensure that newly developed and rapidly deployed medical countermeasures are safe and effective. Many diseases that spread during a public health emergency may not occur naturally or may occur only in such small numbers that it is not feasible to run clinical trials. It would be unethical to deliberately infect human participants with potentially lethal agents to test the effectiveness of new
The Hurricane Katrina “Push Pack” Story

Following the government’s failed response to Hurricane Katrina, one of the many factors that emerged as having contributed to the devastating impact of the disaster was the failure of the Strategic National Stockpile (SNS) to meet the needs of Hurricane Katrina survivors.1 SNS supplies are stored in fifty-ton push packs designed to be delivered anywhere in the United States within twelve hours. The SNS is touted as being capable of responding to any public health emergency, regardless of its cause. As with many aspects of the National Response Framework, however, the emphasis on preparedness for terrorism in SNS development has detracted from its ability to meet the needs of the population following other types of disasters.

Many survivors of the initial impact of Hurricane Katrina lost their medications and had difficulty accessing and refilling prescriptions, sometimes with fatal consequences.2 Individuals with diabetes, hypertension, HIV/AIDS, and other chronic conditions risk serious health complications or even death if their access to medications is disrupted. Even many months after the hurricane’s initial impact, vulnerable individuals were still unable to obtain the medicines they needed. Health care personnel working in New Orleans reported a rise in patients with untreated chronic illness. “These people come in with extremely severe problems. . . . Diabetics have been off their insulin for six months. They come to us in diabetic ketoacidosis.”3

After Hurricane Katrina, twelve-hour push packs were deployed from the SNS but did not arrive until three days after the storm hit.4 Local governments were responsible for managing the evacuation of individuals with special needs but failed to ensure adequate care for the chronically ill. Shelters could not provide insulin, dialysis, or food

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2. Ibid.
countermeasures. The Presidential Commission for the Study of Bioethical Issues expressed particular concern about the use of medical countermeasures in pediatric populations, given that pre-event testing on children is even less feasible than testing on adults.

Seeking to balance the potential risks of clinical trials against the need for rigorous testing of novel vaccines and treatments, the FDA has adopted an unorthodox approach. The “Animal Rule” allows regulatory approval for new medical countermeasures on the basis of animal studies so long as (1) the mechanisms of toxicity of the product are well understood; (2) the effect is established in more than one species of animal expected to be predictive for humans; (3) the study’s endpoint is clearly related to enhancing human survival or preventing major morbidity (or other benefits to humans); and (4) the workings of the drug are sufficiently well understood to allow for the selection of an effective dose in humans. The fact that manufacturers have not yet taken advantage of this regulatory pathway suggests that either the requirements are too difficult to meet or the incentives to seek approval are too low.

Other, simpler mechanisms are also available. The FDA can grant emergency use authorization, approve investigational new drug applications, or exercise discretion in declining to pursue enforcement action on an emergency basis. Public health emergencies sometimes do warrant the deployment of unapproved drugs through expedited means, but balancing the risks and benefits under conditions of scientific uncertainty is challenging. Infamous government missteps in the past caution against mass deployment of insufficiently tested countermeasures, which can cause serious harm and erode the public’s trust (see box 11.6).
Mass Emergency Vaccination Programs: From the 1976 Swine Flu to Smallpox

Just about everybody in public health knows something about 1976. . . . The swine flu program has become part of public health lore, with the moral of the tale depending on who is telling it and why it is being told. But the swine flu program is not the stuff of folklore. It is far too complex. There are no villains. It does not lend itself to easy analysis.


After outbreaks of influenza among army recruits in 1976, the CDC identified the causative strain as swine flu, a virus transmitted easily through human-to-human contact.1 Amid speculation that this epidemic would become as catastrophic as the 1918 swine flu pandemic (which killed more than 50 million people worldwide), President Gerald Ford announced an ambitious program to immunize the American population.2 Massive logistical problems ensued. The insurance industry informed pharmaceutical companies that it would not provide liability insurance for the swine flu vaccine, posing a serious threat to supply. Congress acted quickly to underwrite liability costs. Despite waning support among top health officials, the program lurched forward. In October, ten days after the first vaccinations were given, three elderly people in Pittsburgh died shortly after receiving the vaccine. Despite health officials’ claims that the deaths were not related to the vaccine, the media adopted a body-count mentality. In November, a physician in Minnesota reported a case of ascending paralysis, called Guillain-Barré syndrome (GBS), that may have been related to the vaccine. After surveillance activities revealed an increased incidence of GBS, the swine flu immunization program was brought to an end in December.

The federal government launched another mass vaccination program in the wake of the 2001 terrorist attacks. Although the World Health Assembly announced the eradication of smallpox in 1980, CDC and Russian laboratories maintained repositories of the virus, and there was no assurance that it had not fallen into the hands of rogue nations or terrorist organizations.3 Heightened concern led to

3. In May 2014, the World Health Assembly considered (not for the first time) whether the remaining stocks of smallpox should be destroyed but again failed to reach a consensus.
the extraordinary policy decision to undertake mass vaccination against an eradicated disease with a vaccine that had well-documented risks. Based on the assumption that the risk of serious adverse events in a general-population campaign outweighed the risk of a smallpox outbreak, the administration opted to begin with vaccination of selected groups. The plan had several phases: immediate and mandatory vaccination of half a million military personnel deployed in high-threat areas; voluntary vaccination of up to half a million health care workers and response teams within thirty days; vaccination of up to ten million additional health care personnel and other first responders, such as firefighters and police; followed by vaccination with a new, not yet approved vaccine for members of the public who insisted on access.

The military program went essentially as planned; in less than six months the Department of Defense administered nearly 450,293 smallpox vaccinations. However, the plan to vaccinate civilian health care workers who would be responsible for vaccinating the public in the event of a smallpox attack faltered badly. The vaccine industry and hospitals that administered vaccinations had sought, and received, tort immunity in 2002. Health care workers requested compensation for injuries resulting from smallpox vaccination, but Congress did not enact a plan until April 2003, after highly publicized cases of serious adverse events. In the end, the government could not secure the needed buy-in and participation of public health and health care professionals. The program was officially “paused” in June 2003.

8. Homeland Security Act of 2002, Pub. L. No. 107–296, 116 Stat. 2135, § 304 (stating that if the secretary of HHS declares smallpox vaccination to be a “countermeasure . . . to the chemical, biological, radiological, nuclear, and other emerging terrorist threats,” there shall be immunity from tort liability for “any person who is . . . a manufacturer, or distributor,” or is a “health care entity under whose auspices any qualified person administers the smallpox vaccine”).
with a response rate of less than 10 percent of eligible physicians and nurses.\footnote{10}

The swine flu and smallpox vaccination campaigns provide intriguing accounts of policy making under circumstances of uncertainty. Commentators held government scientists responsible for the swine flu program’s failure.\footnote{11} A controversial report pointed to overconfidence among scientific experts spun from meager evidence, conviction fueled by personal agendas, and zeal by scientists to make their lay superiors do right.\footnote{12} The smallpox campaign was also intensely criticized.\footnote{13} Institute of Medicine findings pointed to the White House’s role in failing to communicate the policy’s rationale and preventing the CDC from communicating with key constituencies.\footnote{14} Lack of planning and collaboration with major stakeholders resulted in a loss of trust in government and ultimately in the plan’s failure.

Although instructive, these cautionary tales still fail to answer the critical question of whether, in the face of scientific uncertainty, it is better to err on the side of excess caution or of aggressive intervention. Consider the appropriate response to suspected bioterrorism with a microbial agent such as anthrax or smallpox. In an emergency, to whom should vaccines be made available, and under what circumstances would the government be justified in mandating vaccination? The costs of inaction, if the risk materializes, are lost lives; but the costs of overreaction, if the risk is exaggerated, are wasted public funds and unnecessary burdens of vaccine-induced injury and diminished autonomy.


\footnote{13}Thomas May, Mark P. Aulisio, and Ross D. Silverman, “The Smallpox Vaccination of Health Care Workers: Professional Obligations and Defense against Bioterrorism,” Hastings Center Report, 33, no. 5 (2003): 26–33, arguing that there is no professional moral obligation to receive smallpox vaccination as a matter of either public health or national security.

Ensuring Adequate Medical Personnel and Facilities

Medical supplies are essential, but without adequate personnel and facilities, they are useless. In an emergency, local personnel can be rapidly overwhelmed because staffing levels are dictated by routine needs rather than surge capacity. Additionally, health care workers may be burdened by the event’s impact on their own lives, preventing them from reporting for duty. Government programs seek to ensure adequate facilities and the deployment of personnel to areas of need while facilitating the cross-jurisdictional work of volunteers. A coordinated response, facilitated by integrated planning and preparedness, is essential to ensure that government, emergency medical services, and health care providers work together to protect the population’s health.

The National Disaster Medical Service

The National Disaster Medical Service (NDMS) provides an “integrated national medical response capability” to assist state and local governments with “health services, health-related social services . . . and appropriate auxiliary services to respond to the needs of victims of a public health emergency.” The HHS secretary may activate the NDMS even if a public health emergency has not been declared under the PHSA. Hospitals agreeing to join NDMS commit to providing a proportion of their acute-care beds for NDMS patients. More than one-third of all acute-care hospitals in the country are NDMS participants, and collectively they have committed more than one hundred thousand acute-care beds. Yet as one researcher notes, “Although at first glance, this sounds promising, even in a normal year flu patients occupy over 114,000 hospital beds. . . . Hospitals are not eagerly lining up to contribute beds to the NDMS in sufficient numbers to make a dent in the bed capacity that will be needed in the event of even a moderate influenza pandemic.”

Registration and Licensing of Volunteer Health Professionals

Health workers are licensed at the state level, but in an emergency they may volunteer in affected areas outside their jurisdictions without a license to do so. The Uniform Emergency Volunteer Health Practitioners Act, adopted in fourteen states and the District of Columbia, licenses of out-of-state practitioners seeking to provide care during a declared
emergency, provided the practitioners have registered in advance. At
the federal level, ESAR-VHP establishes a national registration system
to provide verifiable, up-to-date information regarding volunteers'
identity and credentials.65

Allocation of Scarce Resources

Even with modern efforts to ensure surge capacity for health workers,
hospitals, and medical countermeasures, scarcity remains likely for
many future emergencies. A crucial bioethical question is how to ration
scarce, life-saving resources: who shall live when not all can live?
Rationing medical countermeasures such as vaccines and antimicrobi-
als, as well as medical equipment such as respirators, requires rational
ethical guidelines. Policy makers may adopt varied priorities but gener-
ally take the following considerations into account.66

Prevention and Public Health

The historic mission of public health is prevention, so deployment of
countermeasures in ways that impede transmission is a high priority.
Rapid deployment of vaccines or prophylaxis to groups at risk could
contain localized outbreaks. For example, vaccination of the direct con-
tacts of an infected person in a family, congregate setting, or local com-
munity could maximize the number of lives saved.

Scientific and Medical Functioning

If the first priority is public health, then it is vital to protect scientists
and manufacturers engaged in vaccine or treatment discovery and pro-
duction, as well as health workers. These are critical social missions
necessary to save lives and provide care. Priority, for example, could be
given to key personnel in developing countermeasures, delivering health
care, and devising public health strategies.

Social Functioning and Critical Infrastructure

A large-scale pandemic could result in key sectors of society not being
able to function. Many public and private actors are necessary to ensure
the public’s health and safety: first responders (ambulance and fire person-
nel and providers of humanitarian assistance), security (police, national
guard, and military personnel), providers of essential products and services (water, food, and medicines), critical infrastructure (transportation, utilities, and telecommunications), and sanitation (undertakers, garbage collectors, and infectious waste collectors). Continued functioning of governance structures, such as the executive, legislative, and judicial systems, would also be important.

Medical Need and Vulnerability

Medical need—a widely accepted rationing criterion—gives priority to those who most require medical services. It requires a careful epidemiological evaluation of differential risks. Seasonal influenza disproportionately burdens infants and the elderly, but highly pathogenic strains may disproportionately affect young adults. Priority could be given to those who are socially marginalized, whose living conditions may create heightened vulnerability due to overcrowding, homelessness, poor nutrition, or other chronic conditions.67

Intergenerational Equity

The medical-need criterion often favors the elderly because they are typically most vulnerable. However, there may be reasons not to routinely favor this age group.68 Interventions may be less beneficial to the elderly than to younger, healthier populations, because vaccines produce fewer antibodies in older people. Furthermore, while all human lives have equal worth, interventions targeted toward the young may save more years of life. Ethicists debate the so-called “fair innings” principle that each person should be given an equal chance of a reasonably long life, which would militate in favor of children, young adults, and pregnant women.69

Social Justice and Nondiscrimination

The allocation of benefits according to the above criteria should not disproportionately favor the rich or politically connected. However, guidelines that are neutral on their face could produce unfair outcomes. For example, favoring scientists, health professionals, and employees of pharmaceutical companies could disproportionately benefit the well-off. Principles of social justice and nondiscrimination suggest that individuals whose needs have not been met by society may have the greatest claim on health resources.70