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## Lawrence O. Gostin on Biosecurity Policy: Are We Safer Today?

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***Lawrence O. Gostin on Biosecurity Policy: Are We Safer Today?***

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By Dean Lawrence Gostin

September 16, 2008

**SUMMARY:** World-acclaimed authority Lawrence O. Gostin analyzes biosecurity policy since 9/11. He begins with the question: Are we safer now? Then comes a review of biosecurity legislation, followed by discussion of planning to deal with specific diseases and the problems with such an approach, and then an explanation of what the right approach is. He concludes by covering the Model State Emergency Health Powers Act and related civil liberties questions.

**ARTICLE:** In the wake of the trauma of September 11, 2001, the United States and the rest of the world have feared, and prepared for, the next mass disaster, whether biological, nuclear, chemical, or natural (such as a hurricane, tsunami, or earthquake). n1 Biosecurity policy has lurched from one scare to the next, ranging from anthrax, smallpox, and SARS to avian influenza. Even small clusters of disease caused by a homegrown terrorist can produce enormous anxiety, as the recent debates over the identity of the anthrax suspect Bruce Ivins amply demonstrate. In response, the government has gone to war in Iraq and Afghanistan, poured billions of dollars into biosecurity preparedness, and entirely reorganized public health and emergency services through the Department of Homeland Security (DHS). But, with all the planning and resources, a single question remains--are we safer today than we were before the attacks on the World Trade Center and the subsequent anthrax outbreaks?

**Are We Safer?**

Since 9/11 and the anthrax attacks, a substantial federal investment totaling nearly \$50 billion has been allocated to increase our nations ability to prepare for, and respond to, public health emergencies. Congress and the administration have launched a myriad of biosecurity measures. Despite government claims that we are much safer, it is unclear whether these policies and investments have left the nation better prepared for the next bioterrorist attack, epidemic, or any other large-scale public health emergency. n2 This situation is not due to a shortage of biosecurity measures, but to vague goals, weak accountability, and the wrong priorities. Rather than focus on remote risks that happen to garner public attention, it would be far more cost effective to build health system capacity--for research (vaccines and pharmaceuticals), public health (laboratories, surveillance, and response), and health care (clinics, hospitals, and medical equipment).

This commentary first reviews biosecurity legislation and disease-specific plans that the President has trumpeted as models of success, but that have been mostly ineffective, and in some cases costly failures. It then describes what real reform would entail, with the potential to make the nation far safer.

**Biosecurity Legislation**

Among the myriad of initiatives to improve public health emergency preparedness, perhaps the most highly touted are BioShield and the Pandemic and All-Hazards Preparedness Act. These statutes improve governance in a public

health emergency and incentivize industry to develop medical countermeasures, but have serious deficiencies.

#### *Project BioShield; Vaccine Development*

The biotechnology industry has not systematically developed countermeasures for emerging infectious diseases and bioterror agents because the market is speculative. As a result, industry has focused on products of commercial value. According to the Institute of Medicine, vaccine development has been poorly organized, planned, and funded, putting the nation at risk. n3 To encourage companies to develop new biodefense countermeasures, Congress enacted Project BioShield Act of 2004, n4 which establishes a Special Reserve Fund of \$5.6 billion over ten years to purchase medical countermeasures against a broad array of chemical, biological, radiological, and nuclear agents. BioShield also authorizes the Food and Drug Administration (FDA) to permit rapid distribution of promising yet unapproved and unlicensed new drugs and antidotes in emergencies.

Project BioShield has not encouraged industry to develop vaccines, as shown by the limited number of countermeasures it has procured for the stockpile. The DHS has thus far authorized special reserve funds for only four countermeasures (anthrax, smallpox, botulinum toxin, and radiological/nuclear devices), and has awarded few contracts. Commentators attribute this lack of success to several factors. n5 First, BioShield is a late-stage procurement program, so that industry bears financial risk for early research and development. Small biotech companies, in particular, cannot afford the considerable start-up costs. Second, funding levels were insufficient to entice larger pharmaceutical companies because selling a product for procurement to the U.S. stockpile was not as lucrative as popular commercial products. Third, if countermeasures fail in development, or if the government decides not to procure the product after development, biopharmaceutical companies would sustain significant losses. And in several cases federal agencies have canceled or delayed requests for proposals or industry contracts. Finally, the industry has expressed concerns about liability associated with developing untested countermeasures. Beyond all of this, BioShield is restricted to intentional acts of terror and not naturally occurring infectious diseases, which means it has little utility in the event of a major naturally occurring epidemic.

#### *PAHPA: Pandemic Preparedness*

The Pandemic and All-Hazards Preparedness Act (PAHPA) was enacted in 2006 to improve the organization, direction, and utility of preparedness efforts. n6 PAHPA centralizes federal responsibilities, requires state-based accountability, proposes new national surveillance methods, addresses surge capacity, and improves BioShield. PAHPA aspires to answer the pivotal question of who is in charge by placing the Department of Health and Human Services (DHHS) as the lead agency for federal public health and medical response[s] to public health emergencies covered by the National Response Plan, which otherwise vested most emergency management functions in the DHS. n7 The problem is that states have the historic and primary constitutional police powers to safeguard the public's health. n8 PAHPA acknowledges the importance of interjurisdictional coordination, but does not specify how federal entities should align with tribal, state, and local governments. The Act does little to instill confidence that the leadership and coordination so painfully absent during Hurricane Katrina will change in the face of a new disaster.

Meeting surge capacity during catastrophic events is also a key priority. Rather than ensuring an adequate number of well trained health professionals and critical medical equipment, PAHPA focuses on federal oversight of volunteers through the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) and Medical Reserve Corps (MRC). PAHPA coordinates qualified volunteers, but does not motivate them or the entities that send or host them by reducing the fear of civil recourse. PAHPA represents a missed opportunity to appoint emergency volunteers as federal employees so that they could be protected from liability like members of the U.S. Public Health Service Commissioned Corps.

Finally, and importantly, PAHPA promises rapid development of biological interventions, attempting to rectify the entrenched problems in BioShield. The Act establishes a new Biomedical Advanced Research and Development Authority (BARDA) within the DHHS charged with fostering collaboration, supporting research, encouraging

innovation, and offering technical guidance. PAPHHA authorizes \$1 billion through the Biodefense Medical Countermeasure Development Fund, and grants the DHHS authority to support advanced-stage research and development. Yet, PAPHHA still does not recognize practical market-based realities or overcome political apathy. It fails to authorize sufficient funding to create strong incentives, and Congress has allocated only a small percentage of the funds that were authorized.

### **Disease-Specific Plans: The Wrong Approach and Flawed Implementation**

The government has devoted enormous energy to and resources on a few diseases that have captured public and political attention, but pose relatively remote risks. In this sense, policy has been highly reactive, lurching from one disease to the next, rather than taking an all-hazards approach. In response to a handful of anthrax cases in 2001, the government compelled vaccination in the military. The President wrongly perceived that Saddam Hussein had biological weapons, so he launched a mass smallpox vaccination campaign the following year. More recently, the federal government has expended vast resources on pandemic influenza, which is a serious threat, but has thus far been confined almost exclusively to avian populations. The problem in each case was not simply that the government had the wrong priorities, but that it mismanaged the response.

#### *Anthrax: Ineffective Vaccine and Flawed Criminal Investigation*

Until the FDA approved the anthrax vaccine absorbed (AVA) in December 2003, there was no approved anthrax vaccine. Nonetheless, in 1998 the Department of Defense (DoD) established the Anthrax Vaccine Immunization Program (AVIP), designed to achieve total force protection against anthrax by 2004. The military is concerned about battlefield safety, but the AVIP remains highly controversial. The evidence for the safety and effectiveness of the anthrax vaccine is equivocal. Members of the armed forces are concerned about possible adverse effects in the short and long term, and they question the DoD's decision to compel soldiers to be vaccinated against their will. In 2003, members of the armed forces successfully challenged the AVIP in *Doe v. Rumsfeld*.<sup>9</sup> Days after the court halted the program, the FDA published a final rule categorizing the vaccine as safe and effective for use against inhalation anthrax.<sup>10</sup> In doing so, however, the FDA violated its own rules requiring time for meaningful public comment, so the judiciary halted the program again in October 2004.<sup>11</sup> For the next two years, the program proceeded under a voluntary protocol and participation rates did not exceed 50%. After the FDA issued a proper formal rule finding the vaccine safe and effective, the DoD announced on October 15, 2006, that it would resume mandatory anthrax vaccinations.

As this poorly planned military vaccination program unfolded, there has been continuing concern about the effectiveness of the anthrax vaccine. The AVA does not protect individuals from spore germination, infection, and/or bacteremia. Moreover, protective immunity must be generated via a lengthy injection schedule and maintained by a yearly booster.<sup>12</sup> Yet, despite intense efforts, little progress has been made in finding a more effective vaccine.<sup>13</sup>

In addition to anthrax vaccine improvement, the other major government priority was to identify and successfully prosecute the individual(s) who sent highly refined anthrax spores through the mail in 2001. Some seven years later, after appearing to implicate the wrong person, the Federal Bureau of Investigation (FBI) laid out its case against Bruce Ivins, a microbiologist at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) in Fort Detrick, Maryland. Mr. Ivins committed suicide prior to formal charges being filed, amidst lingering doubts. I don't think we're ever going to put the suspicions to bed, said an FBI spokesman. There's always going to be a spore on a grassy knoll.<sup>14</sup>

The fact that a U.S. Army laboratory specialist possibly perpetrated the most serious bioterrorist attack on American soil has worried commentators.<sup>15</sup> The number of laboratories working with highly dangerous, top security pathogens is exponentially greater today than it was in 2001. That leaves the potential for laboratory employees to exploit their positions, either by engaging in acts of terror themselves or helping others secure highly pathogenic strains.

#### *The Smallpox Vaccine Campaign: Mass Immunization for an Eradicated Disease*

If anything the smallpox vaccination campaign launched by President Bush on December 13, 2002, was even more speculative and flawed than the response to anthrax. More than twenty years earlier the World Health Organization certified the global eradication of smallpox, and the last vaccinations in the United States were given in the 1970s.

The national smallpox vaccination plan represented an extraordinary policy decision--mass vaccination against a disease that did not exist with a vaccine that had well documented risks. The plan had several phases: immediate and mandatory vaccination of half a million military personnel who are or may be deployed in high threat areas; voluntary vaccination of up to 500,000 health care workers and smallpox response teams within thirty days; vaccination of up to ten million health care personnel and other first responders, such as firefighters and police; and vaccination with a new, not-yet-approved vaccine to members of the public who insist on access.

The military smallpox vaccination program went essentially as planned; in less than six months the DoD administered 450,293 smallpox vaccinations. The plan to vaccinate up to 500,000 civilian health care workers who would be responsible to vaccinate the public in the event of a smallpox attack, however, faltered badly, and was officially paused in June 2003, with a response rate of less than 10% of eligible physicians and nurses. The campaign, if successfully implemented, would have subjected healthy volunteers to the risk of adverse effects, ranging from mild and self-limited to severe and life-threatening. Vaccinated individuals also could transmit vaccinia to close contacts. The programs justification was the risk of intentional release of smallpox virus, but the White House did not disclose evidence that the virus existed outside the two known repositories. The CDCs vaccine advisory committee said the risk was low and indeterminate. n16 Never before had a vaccination program been undertaken where there was no natural hazard but only the hypothetical threat posed by the possibility of a terrorist attack.

The national smallpox vaccination campaign was the subject of intense criticism. The Institute of Medicines principal findings were that White House had failed to communicate the policys rationale and curtailed the CDC from communicating with key constituencies. n17 The American Public Health Association stated that the CDCs implementation plan did not provide adequate resources, including costs derived from monitoring adverse events, treating complications, and training personnel. n18 The vaccine industry and hospitals that administered vaccinations 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 unifying theme was a lack of planning and collaboration with major stakeholders that resulted in a loss in trust in government, which ultimately led to the plans failure.

The national smallpox vaccination program offers a poignant case study at the intersection of public health and national security. The order for vaccinations came from the highest level--the President of the United States. It began with intense media coverage of smallpox in the aftermath of the trauma of September 11, and continued with the build-up to the war in Iraq. Public health and health care professionals remained deeply skeptical and dodged in the face of a Presidents call to action. In many ways, the breakdown in trust between national security and public health was sad and remarkable--a lesson that, if not learned well, could harm national interests in a time of crisis.

#### *Highly Pathogenic Influenza: A Future Pandemic?*

Highly pathogenic Influenza A (H5N1) has captured the close attention of policy makers who regard pandemic influenza as a national security threat. The virus is endemic in avian populations in Southeast Asia, with serious outbreaks now in Africa, Europe, and the Middle East. International trade, travel, and migratory birds will likely bring the infection to other continents. The economic consequences are severe, with millions of birds culled or dead from infection, and bans placed on poultry imports.

Although the H5N1 virus is highly contagious among birds, it is rare in humans due to a significant species barrier. A few cases of human-to-human transmission have occurred, principally involving intimate contact, but transmission has not continued beyond one person. The virus appears highly pathogenic with a reported death rate exceeding 50%.

Although the prevalence is currently very low (and pales in comparison to pandemics of HIV, malaria, and tuberculosis), health officials express concern about the potential for pandemic spread. Historically, the world has experienced three or four influenza pandemics per century. The 20th century witnessed the Spanish flu (1918, H1N1, 20-50 million deaths), Asian flu (1957, H2N2, 1-2 million deaths), Hong Kong flu (1968, H3N2, 700,000 deaths), and Swine flu (1976, H1N1, no pandemic). Through adaptive mutation or viral reassortment, the virus could become highly transmissible among humans. Recent evidence that the 1918 pandemic was caused by an avian influenza virus lends credence to the theory that current outbreaks have pandemic potential. Extrapolating from the 1918 pandemic, modeling studies indicate that, in the absence of intervention, half a million to a million Americans could die, with tens of millions of deaths globally.

The United States<sup>n19</sup> and the WHO<sup>n20</sup> issued strategic plans to prevent and control influenza in 2005/06. Therapeutic countermeasures (e.g., vaccines and antiviral medications) and public health interventions (e.g., infection control, social separation, and quarantine) form the two principal strategies for prevention and response. Vaccination and, to a lesser extent, antiviral medication (oseltamivir [Tamiflu] or zanamivir [Relenza]) are the most important interventions for reducing morbidity and mortality associated with influenza.

Despite the promise of medical countermeasures, there is a chronic mismatch of public health needs and private control of production. Vaccine production has been unreliable even for seasonal influenza, which is the leading cause of vaccine-preventable mortality; only a fraction of the recommended population is vaccinated each year. For example, the United States lost half its supply in 2004/05 when the United Kingdom withdrew Chiron Corporations license due to bacterial contamination. The best way to ensure pandemic preparedness is to increase the baseline for seasonal countermeasures.

Public/private strategies, rather than private markets, are most likely to ensure stable, economically viable vaccines to meet potentially massive public needs. As alluded to above, market forces create disincentives that inhibit vaccine development: high investment costs, limited or variable markets, and regulatory compliance. Vaccine manufacturers are leaving the industry, creating the risk of severe shortages. In 1967, twenty-six companies were licensed for vaccines in the U.S. market, but less than half as many today; only four companies supply influenza vaccine, with only two manufacturing domestically--MedImmune (FluMist only) and Sanofi Pasteur.<sup>n21</sup>

The White House strategic plan devotes a great deal of resources to pandemic influenza. Although the threat is real, it is not certain whether the money is well spent. First, the expenditure is for a single disease threat that may or may not materialize. The vast majority of proposed expenditures in the \$6.7 billion federal influenza plan is devoted to medical countermeasures: \$4.7 billion for cell-based vaccine technology and stockpiling experimental vaccine, and \$1.4 billion for antiviral medicines. Yet, medical countermeasures are unlikely to impede pandemic spread: Experimental H5N1 vaccines may not be effective against a novel human subtype, neuraminidase inhibitors may become resistant, and medical countermeasures will be extremely scarce. Even if all of these problems could be solved, how would it be possible to get the vaccine and antiviral medications to people? The vaccine might have to be administered in two separate doses, and the antivirals need to be administered within days of the onset of symptoms. It would not be prudent to have people leave their homes, as they might infect one another, and there are no viable plans to get the countermeasures to people in their homes in a timely manner.

This leaves conventional public health measures such as surveillance, personal hygiene, hospital infection control, decreased social mixing/increased social distance (e.g., school and workplace closures), and isolation and quarantine.<sup>n22</sup> Thus, the key question is: Which measure, or combination of measures, works best at each stage of the pandemic? Multiple, targeted approaches are likely to be most effective, but can have deep adverse consequences for the economy and civil liberties.

### **Real Reform: What Would Make the Public Healthier and Safer?**

The considerable influx of funding and attention to public health emergency preparedness has undoubtedly

improved safety, especially if one of the specific threats that the government has placed its bet on materializes, such as anthrax, smallpox, or Influenza A (H5N1). The time and resources, however, could be spent far more cost-effectively by focusing on building capacity for a broad range of health threats, whether naturally occurring or deliberately inflicted. n23

Real reform would have the following elements: (1) build capacity in the health system (public health and health care) to meet everyday health needs of the population; (2) ensure surge capacity in the event of a health emergency; (3) plan for just allocation of services under conditions of shortage; (4) develop a broad capability for a wide range of medical countermeasures (vaccines and pharmaceuticals); and (5) plan for the use of traditional public health strategies to reduce risk to the population. These measures may lack the glamour or political allure of planning to rescue the country from a few frightening diseases, but what they lack in glamour they gain in effectiveness because they deal with the most common and likely causes of illness and death in the population.

#### *Build Public Health Capacity*

Even with all the biosecurity funding, a miniscule proportion of health spending (1-2%) is devoted to prevention and population-based services, even though spending on upstream causes of disease are much more cost-effective. Researchers find that a small strategic investment in disease prevention could result in significant savings in U.S. health care costs. An investment of \$10 per person per year in proven community-based programs could save the country more than \$16 billion annually within five years, with a return of \$5.60 for every \$1 spent. n24

The resources spent on disease-specific threats, moreover, tend to create silos within public health agencies. These programs are not very effective for two reasons. They are directed primarily toward a single health threat, draining the agency's ability to deal with current or emergent health hazards. Thus, while they may prove beneficial against that particular hazard in the unlikely event that it does occur, they sap attention and resources from work on current needs (e.g., HIV, TB, tobacco, obesity) and future threats (e.g., emerging and resurgent infectious diseases and bioterrorism) that may save many more lives. They also tend to be time-limited, so that once the government moves onto the next health threat that garners attention in the media, whatever it might be, the funding for current programs dries up. This is a cause of great frustration to public health professionals seeking sustainable and scalable programs for disease prevention and health promotion.

Leading administration officials argue that specific programs, such as those devoted to anthrax, smallpox, and pandemic influenza, do create overall capacity. Although this is true to a certain extent, the value added to health system capacity is much lower than if the money were devoted specifically to that purpose. Moreover, when state health departments started using the idea of dual capacity to signify their intent to use bioterrorism grants for broader capacity building, the DHHS disapproved, requiring the funds to be spent strictly for the activities specified in the grant.

Building public health capacity includes the following core services: (1) public health *research* to gain knowledge of the most cost-effective measures to prevent and contain health threats; (2) *surveillance* for a broad range of pathogens and other health threats to ensure early detection; (3) *laboratories* to test pathogens and other causes of illness and death, including drug-resistant strains; (4) a well trained and financed public health *workforce*; (5) trained teams to assess, investigate, and respond to disease *outbreaks*; and (6) plans and facilities for a rapid and effective public health *response* to disease threats, including conventional strategies, such as separation of the sick from the healthy. Devoting significant resources to build a public health infrastructure would have the dual benefits of strengthening programs for current health threats and also detecting and responding to a broad array of health emergencies should they arise. n25

#### *Build Health Care System Capacity*

Health spending in the United States rose to above \$2 trillion in 2006 and has nearly doubled in the past decade, amounting to an average of \$7,000 per person. This represents 16% of the total national output of good and services,



nearly twice the amount spent in comparable developing countries. n26 This level of spending should produce the kind of capacity necessary to deal adequately with current needs, as well as provide a margin of safety in a public health emergency. However, the reverse is probably true because an inordinate amount of the resources is devoted to high technology solutions for relatively few individuals or spent during the last six to twelve months of life. Nearly forty-six million Americans, or 15.3% of the population, are without health insurance, n27 and a further twenty-five million are underinsured. n28 This is not simply a problem of equity, but more fundamentally one of security for the nation in the event of an epidemic or bioterror attack with a transmissible agent.

During an epidemic, whether naturally occurring or deliberate, the health care system performs at least three critical public health tasks: detection, containment, and treatment. Early detection is essential so that effective countermeasures can be initiated before the epidemic escalates. However, the early warning system will fail if patients stay away from physicians and hospitals because they are uninsured. Even if all Americans cannot obtain full health insurance, significant barriers to seeking evaluation for suspected infectious illnesses should be reduced. Any threats of deportation or financial loss due to testing for and reporting infectious illnesses should be removed, and the cost for these evaluations should be borne by the government as a necessary national security expense. n29

The task of containment is important because physicians may have to take rapid action to report a person with an infectious agent to public health authorities and initiate isolation or quarantine. Containment might fail if physicians view themselves only as advocates for individual patients, ignoring their social obligations as health professionals.

The task of administering effective treatment is the most traditional and well accepted function of the health care system. Treatment benefits not only the individual but also the community because a person under treatment for most infectious diseases is likely to be less infectious to others. However, treatment might fail if physicians do not accept their professional duty to treat patients during epidemics. During the SARS outbreaks, for example, many physicians refused to work with SARS patients, fearing for their own health and the health of their families. Thus, an ethical, and perhaps legal, obligation should be placed on health care professionals to treat exposed or infected patients during a public health emergency.

#### *Ensure Surge Capacity in a Public Health Emergency*

Even if the health system has adequate capacity to meet ongoing demands for prevention, care, and treatment, there will undoubtedly be a need for a surge of capacity during a public health emergency. Whether caused by a natural disaster, terrorism, or an infectious agent, a catastrophic event will result in mass casualties, far beyond those that hospitals can deal with unless they have an influx of resources. Everything from bandages, antibiotics, and blood for transfusions to ventilators and hospital beds will be needed to cope with a major event. Thus, government, together with its partners in the health system, should consider ways to get critical supplies to physicians and patients in the time of dire need.

This entails having stockpiles of critical equipment and supplies, together with plans to get them to areas in need rapidly. There also should be plans for ensuring that human resource needs are met by facilitating the movement of physicians, nurses, lab technicians, and other professionals to the scene of a disaster.

#### *Fair Allocation Under Conditions of Scarcity*

Government can do a great deal to help ensure surge capacity, but what is certain is that there will be extreme scarcity of countermeasures in the short term. One of the most challenging questions facing society is how to ration scarce, life-saving resources: Who shall live when not all can live? n30 Blind justice might dictate a random allocation of scarce interventions (e.g., a lottery or first-come-first served). Yet, this seems unsatisfying when lifesaving countermeasures can be targeted more cost-effectively. American society has often accepted need as the singular principle for ethical allocation--e.g., the sick or elderly. Given the devastating social, economic, and political ramifications of a serious pandemic, the following rationing criteria are worth consideration.

1. *Prevention/Public Health.* The historic mission of public health is prevention, so countermeasures to impede transmission should be a high priority. Thus, where feasible, rapid deployment of vaccines or prophylaxis to groups at risk of acquiring infection should be used to contain localized outbreaks. For example, ring vaccination of direct contacts in a family, congregate setting, or local community could be an effective intervention that would maximize lives saved.

2. *Scientific/Medical Functioning.* If the first political priority is public health, then it is essential to protect individuals who innovate and produce vaccines or antivirals, provide treatment, and protect the public's health. These are critical social missions necessary to save lives and provide care for the sick. Consequently, priority should be given to key personnel in developing countermeasures (scientists, laboratory workers), delivering health care (nurses, physicians, hospital staff), and devising public health strategies (epidemiologists, health officials).

3. *Social Functioning/Critical Infrastructure.* A pandemic could result in key sectors of society not being able to function. Many public and private actors are necessary for the public's health and safety: first responders (ambulance, fire, humanitarian assistance), security (police, national guard, military), essential products/services (water, food, pharmacies), critical infrastructure (transportation, utilities, telecommunications), and sanitation (undertakers, garbage processors, infectious waste handlers). Continued functioning of governance structures such as the executive, legislative, and judicial systems similarly would be important.

4. *Medical Need/Vulnerability.* As mentioned, medical need is a widely accepted rationing principle. This criterion focuses on reducing serious illness and death among individuals and, therefore, targets those most vulnerable. It requires a scientific or epidemiologic judgment about at-risk groups that may vary.

5. *Intergenerational Equity.* The medical need criterion often favors the elderly because they are most vulnerable to disease complications. However, there may be reasons not to routinely favor this age group. Interventions may be less beneficial to the elderly than to younger, healthier populations. Vaccines, for example, may be less effective in older people due to poor immune system function. All human lives have equal worth, but interventions targeted toward the young may save more years of life. Would a fair innings principle militate in favor of children, young adults, and pregnant women?

6. *Social Justice/Equitable Access.* The allocation of benefits should not favor the rich, powerful, or politically connected. The Gulf Coast hurricanes seared into the American consciousness the inequities that could ensue in a public health emergency--evacuation and relief services disfavored the poor and minorities. Special efforts, therefore, should be made to ensure fair distribution of lifesaving countermeasures to traditionally underserved populations.

### **The Model State Emergency Health Powers Act: Public Health and Civil Liberties in Conflict**

In the midst of the anthrax attacks in 2001, the CDC asked the Centers for Law and the Public Health at Georgetown and Johns Hopkins Universities to draft what became known as the Model State Emergency Health Powers Act (MSEHPA). It addresses five key public health functions discussed in this Commentary: preparedness and planning, surveillance, management of property, protection of persons, and communication and public information. The MSEHPA is designed to standardize and clearly delineate the powers states have when responding to public health emergencies. It was also drafted in recognition of the fact that most public health statutes pre-dated modern judicial conceptions of individual rights, so it provides clearer standards and stronger guarantees of due process. n31

Under the MSEHPA, coercive public health powers can be exercised in response to an outbreak only after the governor has declared a state of emergency. A declaration gives public health officials the power to carry out examinations necessary for diagnosis and treatment. Authorities have the power to conduct isolation and quarantine when warranted to prevent a substantial risk of transmission of infection, but must adhere to human rights principles: the least restrictive alternative, safe and habitable environments, and fulfillment of individual needs for medical treatment and necessities of life. Although the MSEHPA was created with recognition that exigencies may prevent a

pre-detention 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.

The MSEHPA had considerable political success, as thirty-seven states adopted it in whole or in part. Nonetheless, it provoked a storm of controversy, raising age-old concerns about public health versus civil liberties. Some scholars criticized the MSEHPA for insufficient protection of individual rights, particularly those concerning quarantine; other scholars argued that coercive powers are often ineffective and may cause health workers to under-rely on medical countermeasures; while still others expressed concern that extraordinary powers might be used in response to routine public health events. The MSEHPA, in an era of deep concern about terrorism and civil liberties, became a lightning rod for debates about public health preparedness and conformance with the rule of law. n32

In thinking about public health preparedness for the future, we should learn from the lessons of history since the attacks on the World Trade Center and anthrax outbreaks. History teaches us that it is unwise to focus on what is politically salient at the moment, lurching from one disease to the next, because that particular health hazard may never transpire. Rather, the goal should be to build a strong public health and health care infrastructure to defend against a broad range of health hazards. This will entail strong incentives for biotechnology to ensure a steady pipeline of innovative vaccines and pharmaceuticals; investing in the core functions of state and local public health departments for early detection and rapid response to all hazards; ensuring that everyone has access to high quality health care; preparing for surge capacity in the event of a mass disaster; and responding to a public health emergency on the basis of social justice, with fair allocation of scarce resources and particular attention to the needs of the least advantaged.

In exercising public health powers, it will sometimes be necessary to use compulsion, but only as a last resort. And when compulsory powers are exercised, due regard should be given for the rights and liberties of individuals. Above all, public health powers, even when society is most at risk, should be exercised under the rule of law and in accordance with the principles of social justice.

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n32 Compare Lawrence O. Gostin, *The Model State Emergency Health Powers Act: Public Health and Civil Liberties in a Time of Terrorism*, 13 *Health Matrix* 3-32 (2003), with Wendy E. Parmet, *Quarantine*

*Redux: Bioterrorism, AIDS, and the Curtailment of Individual Liberty in the Name of Public Health*, 13 Health Matrix 85-116 (2003).

**RELATED LINKS:** For more information see

- 42 U.S.C. §§ 247d-3a;
- 264.

On Smallpox Emergency Personnel Protection, see

- 42 U.S.C. §§ 239-239h.

On the Smallpox Compensation Program, see

- 42 C.F.R. §§ 102.1-102.92.

And for the National All-Hazards Preparedness Public Health Emergencies statutes, see

- 42 U.S.C. §§ 300hh to 300hh-16.

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More information is at <http://www.law.georgetown.edu/faculty/gostin/index.html> (Dean Gostin) and <http://www.publichealthlaw.net/index.php> (the Centers for Law & the Publics Health).