

## SPECIAL FEATURE: A DECADE IN BIOSECURITY

# THE EVOLUTION OF LAW IN BIOPREPAREDNESS

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The decade following the terrorist attacks on September 11, 2001, and ensuing anthrax exposures that same fall has seen significant legal reforms designed to improve biopreparedness nationally. Over the past 10 years, a transformative series of legal changes have effectively (1) rebuilt components of federal, state, and local governments to improve response efforts; (2) created an entire new legal classification known as “public health emergencies”; and (3) overhauled existing legal norms defining the roles and responsibilities of public and private actors in emergency response efforts. The back story as to how law plays an essential role in facilitating biopreparedness, however, is pocked with controversies and conflicts between law- and policymakers, public health officials, emergency managers, civil libertarians, scholars, and others. Significant legal challenges for the next decade remain. Issues related to interjurisdictional coordination; duplicative legal declarations of emergency, disaster, and public health emergency; real-time legal decision making; and liability protections for emergency responders and entities remain unresolved. This article explores the evolving tale underlying the rise and prominence of law as a pivotal tool in national biopreparedness and response efforts in the interests of preventing excess morbidity and mortality during public health emergencies.

*Public health legal preparedness is a core foundation of our ability to ensure the nation is prepared to prevent, respond to, and reduce the adverse health effects of public health emergencies and disasters.*<sup>1</sup>

Rear Admiral Craig Vanderwagen and Tanya Popovic

**B**Y MANY ACCOUNTS THE DECADE following the Al Qaida attacks on September 11 and the ensuing anthrax exposures during fall 2001 began with considerable uncertainty about the role of government, law, and policy in national biopreparedness and response. Prior to these terrorist acts, emergency preparedness was largely an abstraction to most lawmakers and policymakers, government officials, healthcare workers, and the American public. Despite prominent advance warnings of potential bio-

threats and early preparedness exercises like Dark Winter,<sup>2</sup> there seemed little need for national alarm over mere possibilities of catastrophic occurrences. Distinct preparedness education efforts and activities concerning biothreats were few. Funding for bioterrorism preparedness was minimal. Most viewed these types of threats as distant and unlikely.

There was even less focus over what, if any, specific role law played in preparing for a bioterrorism or mass casualty event. Only a few law- and policymakers who were attuned

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to bioterrorism and other emergency threats prior to 2001 argued for major legal changes, and virtually none foresaw the need for wholesale restructuring of government to respond.<sup>3</sup> Yet, as described below, these changes were forthcoming. Among the many lessons in the decade following 9/11, captured by Vanderwagen and Popovic above, is the essential role of law in facilitating national, state, and local preparedness. This lesson was learned early and often. During the anthrax attacks, existing laws were suddenly viewed as potential barriers to effective response by federal, state, and local law- and policymakers. Critical reforms at all levels of government were quickly called for.<sup>4</sup> After years of indifference, policymakers were prepared to move rapidly to effectuate change. Law, as a result, became a central tool of enhanced biopreparedness. What developed over the decade ahead was a series of transformative legal reforms that effectively (1) rebuilt components of federal, state, and local governments to improve response; (2) created an entire new legal classification known as “public health emergencies”; and (3) overhauled existing legal norms defining the roles and responsibilities of public and private actors in emergency response efforts.

The modern legal framework for biopreparedness and response was born, but not without rigorous debate. Efforts to develop model proposals to guide state and local legal reforms were met with criticism among some scholars, civil rights advocates, and media and, at times, disbelief among the public. Labeled as “antiquated” and “draconian,”<sup>5</sup> public health emergency laws crafted from traditional and routine governmental public health powers were cast as antithetical to individual freedoms and modern response efforts.<sup>6</sup> Legal efforts to expeditiously test, screen, vaccinate, treat, isolate, and quarantine individuals to protect the public’s health were portrayed by some critics as affronts to personal autonomy and violations of principles of justice. All the while, national, state, and local legislators and regulators systematically used model legal principles and corresponding efforts to reform their emergency laws to include exactly these sorts of public health powers.

Collectively, these reforms stand among some of the most significant (and contentious) legal achievements designed to protect the public’s health in the nation’s history. Legal changes in response to bioterrorism in 2001, and other public health emergency threats following Hurricane Katrina in 2005 and the H1N1 pandemic in 2009, altered how national public health and emergency preparedness systems respond by improving interjurisdictional coordination and reducing known legal and policy barriers.

As discussed below, the story of how law became an essential tool of public health preparedness and response over the past decade is convoluted and controversial. It remains an unfinished tale with ongoing challenges, but it deserves to be told in part now on the decadal remembrance of 9/11. The genesis of this tale begins with a national “call to action” to improve laws to protect population health. Meeting this call led to the development of

model legal principles to define and cast a new type of “public health emergency,” with accompanying support and criticisms among various actors and entities. Ultimately, legislative and regulatory reforms designed to address national and regional biopreparedness changed the legal landscape, but significant challenges remain. Multiple emergency declarations in response to specific crises obfuscate roles and responsibilities, lending to confusion among public and private actors. Practicing emergency legal powers requires advance and real-time training and skills that remain underdeveloped nationally. And the extent to which healthcare providers, volunteers, and entities are protected from liability for their negligent acts during declared emergencies continues to be one of the most controversial policy issues to date. These and other core challenges are prime for resolution to advance this nation’s legal biopreparedness.

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## THE GENESIS OF PUBLIC HEALTH EMERGENCY LEGAL REFORMS

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From the time of the terrorist attacks and anthrax exposures in 2001, preparedness and response efforts on the frontlines were typically viewed as matters for state and local governments. These governments have always been primarily responsible for protecting and promoting the public’s health within the federalist system of government that vests states (and municipalities pursuant to delegated state authority) with traditional powers to protect the health, safety, and general welfare of populations.<sup>7</sup> Existing federal agencies like the Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) played important roles in providing guidance, expertise, personnel, and resources. However, these agencies lacked sufficient legal authority or manpower to address specific local public health needs in mass casualty events. Federal assistance through expert epidemiologic investigations or the infusion of limited personnel, resources, or guidance were generally welcomed by states. Conversely, federal attempts to step further into state and local preparedness efforts were often perceived negatively. Even in emergencies that may affect the health and life of millions of Americans, the reach of the federal government to assure the public’s health was never viewed as extending to citizens’ front doors.

Where the federal government does have unquestionable jurisdiction is in its need to protect the nation from national security threats. This includes the 2001 mass distribution of anthrax spores through the U.S. postal system targeting federal legislators and implicating federal postal workers (among others). Characterizing this and other bioterrorism events as threats to national security invites federal intervention under varying legal standards grounded more in criminal law than public health protections.

So arose a central quandary in real time following 9/11: Which level of government, federal or state, is most responsible for addressing and curtailing biothreats that pose risks both to national security and community health? Answering this question proved elusive at best in 2001 as governments competed over primacy and responsibility for differing national, state, and local needs arising from the anthrax exposures. One of the first legal lessons of the national response to this bioterrorism incident, more recently repeated in President Obama's 2011 Presidential Policy Directive on National Preparedness, was the critical need for integrated, interjurisdictional coordination across all levels of government.<sup>8</sup> Absent coordination, emergency response efforts would be more happenstance than targeted toward ameliorating individual and community health. Although this lesson was illustrated in 2001, public and private sectors had not learned how to work effectively across boundaries. Interjurisdictional coordination gaffes prominently on display in the bungled federal and state responses to Hurricane Katrina in 2005<sup>8,9</sup> led to significant federal and state legal reforms (discussed further below).

Yet, there is more to the story stemming from the 2001 anthrax exposures. As Congress and the Federal Bureau of Investigation (FBI) sought elusive answers to who perpetrated this national biothreat, states expressed immediate concern about their roles in responding to what many viewed as a new type of emergency. Unlike tornadoes, floods, fires, or earthquakes, bioterrorism events had the unpredictable potential for systemic, long-term, and widespread disability and death in the population. Field-trained emergency managers were unfamiliar with public health interventions designed to control the spread of communicable or noncommunicable conditions. Even long-standing public health actors were unsure of their essential public health powers or how to use them. A call to action erupted from largely state and local policymakers in fall 2001.<sup>10</sup> They were poised to address biothreats legislatively and via regulation, but they wanted to know how.

Leading public health authorities like the American Public Health Association (APHA), the Association of State and Territorial Health Officials (ASTHO), and the National Association of County and City Health Officials (NACCHO) heard their call. So did the newly founded Public Health Law Program at CDC. Its representatives, joined by CDC's general counsel's office, sought immediate assistance and found it through the fledgling Centers for Law and the Public's Health at Georgetown and Johns Hopkins Universities. Founded just months prior to 9/11 with support from CDC, a drafting team of Center faculty and staff responded within weeks with an initial version of the Model State Emergency Health Powers Act (MSEHPA) on October 23, 2001.<sup>10</sup> While a full account of the preparation of MSEHPA is chronicled elsewhere,<sup>11,12</sup> it is worth noting that the draft was based in large part on (1) initial best practices from a group of experts who had assembled previously in the summer of 2001 outside of

Chicago (at what is known as the Cantigny Conference<sup>3</sup>); (2) early conceptual efforts for a broader model law project, which later produced the comprehensive Turning Point Model State Public Health Act; and (3) existing state laws researched by the Center drafting team on key issues.<sup>12</sup> After a national observation period over several weeks, during which hundreds of comments were received and considered by the Center drafting team, MSEHPA was completed and circulated widely on December 21, 2001.<sup>13</sup> The anthrax exposures were already in the past, but ensuing legal reforms had just begun.

## REFORMING LAWS TO PROTECT THE PUBLIC'S HEALTH IN EMERGENCIES

MSEHPA introduced a structured and cohesive series of model provisions for state and local governments considering how to respond to bioterrorism or other public health threats.<sup>10</sup> Though sometimes mischaracterized as a mandate to state and local governments (largely related to misconceptions about CDC's role and support), the Act presented a menu of potential powers for consideration and adoption by policymakers. MSEHPA drafters sought to balance individual and communal interests underlying modern responses to a new type of "public health emergency," defined as:

... an occurrence or imminent threat of an illness or health condition that: (1) is believed to be caused by... bioterrorism; the appearance of a novel or previously controlled or eradicated infectious agent or biological toxin [*or other causes*];...and (2) 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.<sup>14</sup>

This definition was criticized initially by some as overly broad in concept and subject to misuse by state governors authorized to issue states of public health emergency with guidance from the state public health authority. In reality, the definition of public health emergency is considerably more limited than existing state-based definitions of "emergency" or "disaster." Unlike these existing classifications, a public health emergency declaration may be issued only when it can be shown that an act of bioterrorism or other public health threat poses a "high probability" of a large number of deaths, disabilities, or exposures to agents that could cause future harms.<sup>10</sup> These definitional limits confine a declaration of public health emergency to those rare cases where quickly developing factors militate a rapid and effective public health response. We can think of pandemic diseases like H1N1 or bioterrorism threats like

anthrax or smallpox as potential public health emergencies, but not the global spread of obesity or HIV/AIDS.

Upon a declaration of a public health emergency, MSEHPA authorizes a series of optional, expedited public health powers for government public health authorities (in concert with public safety and emergency management actors) to respond. Among its central purposes, the Act authorizes public health officials to:

- Collect data and records to facilitate the early detection of a health emergency;
- Abate public health nuisances and destroy dangerous or contaminated materials;
- Take private property with just compensation as needed to care for patients or protect the public's health;
- Close roads, implement curfews, and evacuate populations where justified;
- Collect specimens and implement safe handling procedures for the disposal of human remains or infectious wastes;
- Test, screen, vaccinate, and treat exposed or infected persons;
- Separate exposed or infected individuals from the population at large to prevent further transmission of communicable conditions;
- Seek the assistance of out-of-state healthcare volunteers through licensure reciprocity; and
- Inform the population of public health threats through media and language that are accessible and understandable across cultures.<sup>14</sup>

It also authorizes the governor to waive specific laws that may impede response efforts for the duration of an emergency, coordinate services among public health and emergency actors, allocate state resources, and expend finances as needed to effectuate emergency response efforts.<sup>10</sup> Limited immunities for some state and private actors (including volunteers) from legal causes of action grounded in mere negligence<sup>14</sup> proved to be highly contentious as a national policy objective, as discussed below.

Other controversies followed the Act from its initial issuance. Numerous expert and lay comments received by the Center reflected deep concern for perceived infringements of individual rights flowing from its provisions. Many of these comments seemed driven by emotion, not facts.<sup>12</sup> One lay commenter remarked: "Any doctor who intends to strip me naked, forcibly 'examine' me, and inject me with medications had better be willing to fight to the death, because you can bet that I will."<sup>15</sup> MSEHPA's draft provisions did not allow forcible strippings, examinations, or injections. The Tucson-based Association of American Physicians and Surgeons, Inc., incorrectly blogged on its website, "This Act, in effect, empowers the Governor to create a police state by fiat. . . ."<sup>16</sup> It did not. Web-based and print media questioned the intended goals of the Act. A particularly sensational headline of the *Sierra Times* read:

"BioTerrorism: CDC's Model State Emergency Health Powers Act May Terrorize Americans."<sup>17</sup> Another lay commenter summed up a minority position: "I understand what you are trying to do is safeguard the general public, . . . [b]ut this proposed act is so repugnant that I . . . will actively work to see it crushed and trashed."<sup>15</sup>

Some scholars and ethicists expressed negative opinions as well, criticizing MSEHPA as misguided and unbalanced in several prominent journals. George J. Annas, writing in the *New England Journal of Medicine* in early 2002, stated: "The model act seems to have been drafted for a different age; it is more appropriate for the U.S. of the 19th century than for the U.S. of the 21st century."<sup>18</sup>(p1340) Annas perpetuated these criticisms in a chapter in his 2010 text, *Worst Case Bioethics: Death, Disaster, and Public Health*.<sup>5</sup> In their commentary in *Science* in 2002, Ronald Bayer and James Colgrove characterized the Act as a "... stark expression of the view that a public health emergency might necessitate the abrogation of privacy rights, the imposition of medical interventions, and the deprivation of freedom of itself."<sup>19</sup>(p1811) By 2003, scholars John Colmers and Daniel M. Fox noted in the *American Journal of Public Health* that "[t]he Model Act has become a contentious document in a process of policymaking that is likely to continue as long as the threat of bioterrorism persists."<sup>20</sup>(p397)

Members of the Center's MSEHPA drafting team thoroughly reviewed and responded to these and other comments in amending the original draft of the Act.<sup>12</sup> Key reforms between initial and final drafts included revamped efforts to assure individual liberties were respected amidst the potential for government abuses during emergencies. Extensive due process protections related to quarantine or isolation powers were strengthened. Stop-gap protections to limit the duration of a state of public health emergency (to no more than 30 days), absent a redeclaration, were added. Additional modifications clarified the larger goals of the Act itself—notably to protect individual and communal health via public and private sectors during potentially catastrophic circumstances.<sup>21</sup>

The Center countered allegations that MSEHPA's provisions unconstitutionally violated individual freedoms by illustrating that none of the powers featured in the Act were new to public health. In fact, powers to test, screen, vaccinate, and isolate individuals were used, and continue to be used constitutionally, in routine public health practice. Similar suggestions that these public health powers exemplified antiquated techniques of a bygone era were addressed by the Center through explanations, grounded in public health sciences, empirical studies, and best practices, that these interventions actually work to curtail morbidity and mortality in emergencies.<sup>7</sup>

While negative comments garnered headlines surrounding MSEHPA, they actually comprised a minority of assessments. Considerable additional input reflected very different perspectives.<sup>12</sup> Multiple national public health and policymaking entities openly recognized and supported

the premises of the Act. These included CDC, ASTHO, NACCHO, APHA, the National Conference of State Legislatures (NCSL), the National Governors Association (NGA), the National Association of Attorneys General (NAAG), and the American Medical Association (AMA). Countless public health leaders and practitioners at the state and local levels championed the Act individually.

Perhaps the most telling support for MSEHPA came through legislatures and regulatory agencies across the United States and internationally. On July 23, 2002, several months after the completion of MSEHPA, *USA Today* ran a brief front-page story about the Act under the following headline: “Many States Reject Bioterrorism Law.”<sup>22</sup> In reality, a markedly different trend was emerging. Like the contagions and bioterrorism threats it was meant to address, the Act essentially went viral. Within months of its completion, state legislatures or agencies in more than half of the states and the District of Columbia had introduced legislative bills or regulatory changes based in whole or in part on MSEHPA.<sup>23</sup> According to the Center’s legislative tracking, 39 state legislatures had passed bills related to MSEHPA by 2006.<sup>24</sup> More recently, in 2011, the Network for Public Health Law determined that 26 states and DC had legislatively crafted “public health emergencies,” or like terms, as part of their laws.<sup>25</sup> Prior to 2001, virtually no state (except Colorado) featured this type of emergency classification. Colorado’s existing statutory definitions of “bioterrorism”<sup>26</sup> and “emergency epidemic”<sup>27</sup> (to include “cases of an illness or condition, communicable or non-communicable, caused by bioterrorism, pandemic influenza, or novel and highly fatal infectious agents or biological toxins”) were both considered in drafting similar terms in MSEHPA.

The policy impacts of MSEHPA were not limited to state governments. Larger cities and counties with home rule authority explored and used its provisions as well.<sup>28</sup> Members of Congress vested HHS with a similar “public health emergency” declaration authority through the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.<sup>29</sup> Several foreign countries, including Canada, the U.K., China, India, Australia, and New Zealand, introduced similar national or regional legislation.<sup>30</sup> Provisions of MSEHPA providing licensure reciprocity for healthcare practitioners across states, liability protections for volunteers, and expedited modern powers to test, screen, vaccinate, isolate, and quarantine individuals and populations were reflected in sections and themes in other model public health acts, including the aforementioned Turning Point Act of 2003<sup>31</sup> and the Uniform Emergency Volunteer Health Practitioners Act of 2007.<sup>32</sup> In 2007, the World Health Organization’s overhaul of its International Health Regulations (IHRs) took effect, including specific themes from MSEHPA embedded in IHRs’ new definition of “public health emergency of international concern.”<sup>33</sup> Collectively, the infusion of MSEHPA principles directly or indirectly into interna-

tional, federal, state, tribal, and local emergency laws and policies over the past decade represents among the most significant public health law reforms in history.

## PUBLIC HEALTH LEGAL PREPAREDNESS IN THE MODERN ERA

MSEHPA and its progeny may have changed the game related to legal biopreparedness, but they certainly do not resolve all related conflicts of law and policy. In some cases, legislative or regulatory reforms designed to correct identified issues of law and policy create additional problems. Remaining challenges in emergency legal preparedness are manifold, thorny, and varied across jurisdictions. As discussed below, 3 key challenges include (1) legal quandaries stemming from multiple emergency declarations and response efforts, (2) unresolved and understudied needs to engage in “legal triage,” and (3) ongoing disputes related to liability protections for practitioners and entities implementing crisis standards of care in response to declared emergencies.

### *A Multitude of Emergency Declarations and Response Efforts*

While emergency responders continue to advocate for an “all-hazards” approach to consolidate dwindling resources and enhance preparedness capabilities,<sup>34</sup> federal, state, and local emergency laws are built on a different platform that does not necessarily reflect this view. One of the unintended consequences of national uptake of MSEHPA is the possibility for multiple and differing states of emergency in response to the same event. At the federal level alone, multiple laws address specific issues arising in a national or regional public health emergency. The Federal Public Health Security and Bioterrorism Preparedness and Response Act of 2002<sup>35</sup> authorizes the implementation of the National Disaster Medical System (NDMS) to coordinate rapid deployment of specialized response teams.<sup>36</sup> The Project BioShield Act of 2004<sup>37</sup> (1) established the Strategic National Stockpile (SNS)<sup>38</sup> to expedite distribution of essential medicines and supplies nationally, and (2) amended the Food, Drug, and Cosmetic Act<sup>39</sup> to enable emergency use authorizations of yet-to-be-approved drugs or devices during declared emergencies.<sup>40</sup> The Homeland Security Act of 2002<sup>41</sup> and the Public Health Threats and Emergencies Act of 2000<sup>42</sup> create and set the responsibilities of the Department of Homeland Security (DHS). The Social Security Act was amended to authorize emergency waivers of (1) certain requirements of the Emergency Medical Treatment and Labor Act (EMTALA),<sup>43</sup> which typically requires all persons seeking emergency care to be treated by hospitals receiving federal funds; and (2) eligibility requirements for Medicaid and Medicare programs.<sup>44</sup>

Most federal emergency powers are concentrated in the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act),<sup>45</sup> the National Emergencies Act,<sup>46</sup> the Public Health Service Act (PHSA),<sup>47</sup> and the Pandemic and All-Hazards Preparedness Act (PAHPA).<sup>48</sup> Pursuant to these acts, the federal government is authorized to declare states of (1) general emergency, (2) disaster, and (3) public health emergency. The first 2 declarations may be made by the President via the Stafford Act<sup>49</sup> or the National Emergencies Act. In general, a Stafford Act emergency can be declared only after a state governor requests federal assistance “to save lives and to protect property and public health and safety, or to lessen or avert the threat of a catastrophe.”<sup>50</sup> A state of disaster may be declared at the governor’s request typically in response to natural calamities (eg, tornadoes, earthquakes, snowstorms, or droughts).<sup>51</sup> While these declarations and corresponding federal powers are exceedingly broad, they are not tailored to public health emergencies involving mass communication of infectious diseases.<sup>52</sup>

In contrast, PHSA<sup>53</sup> authorizes the HHS Secretary to declare a federal public health emergency.<sup>54</sup> Unlike MSEHPA, federal law does not define “public health emergency.” Instead, the secretary has discretion to declare such whenever “a disease or disorder presents a public health emergency...” or in response to “significant outbreaks of infectious diseases or bioterrorist attacks...”<sup>55</sup> Upon such declaration, HHS can enter into grants or contracts; provide awards for expenses; conduct and support investigations into the cause, treatment, or prevention of a disease or disorder; access the Public Health Emergency Fund;<sup>56</sup> and waive certain Medicare and Medicaid requirements,<sup>57</sup> among other powers. Additional federal legislative efforts to further expand HHS’s powers in a declared public health emergency are under consideration.<sup>58</sup>

Amidst this soup of federal acts, the potential for overlapping federal emergency declarations and authorities is rampant. In response to Hurricane Katrina, for example, states of emergency and major disaster were declared pursuant to the Stafford Act on August 27, 2005, and August 29, 2005, respectively.<sup>59</sup> Additionally, HHS’s Secretary declared a public health emergency for Louisiana on August 29.<sup>52</sup> Responding to multiple declarations, federal agency officials were unsure how to best deploy their resources, resulting in major gaps in services. Lacking strong interagency collaboration,<sup>9</sup> these disorganized efforts led to the federal enactment of PAHPA on December 19, 2006,<sup>60</sup> to help improve federal coordination.<sup>61</sup> Currently up for Congressional review and renewal,<sup>62</sup> PAHPA centralized federal responsibilities and encouraged state-based preparedness capacities for public health emergencies. It firmly identifies HHS (and not DHS) as the lead agency for federal public health and medical responses to public health emergencies.<sup>61</sup> Despite PAHPA’s legal clarifications, Congress left in place the

need for dual declarations of public health emergency (via HHS) and emergency or disaster (via the President) to fully empower HHS to respond to future events like the 2009-10 H1N1 pandemic.<sup>63</sup>

The emergency legal environment among many state and local governments is equally overlapping. As state and local policymakers passed legislative or regulatory reforms based on public health emergencies, they layered these on top an already crowded emergency legal framework. Every state, for example, had preexisting classifications of “emergency” or “disaster” prior to their passage of MSEHPA-like provisions. As a result, all of the 26 states that now define “public health emergency” also define “emergency” or “disaster.” The capacity for dual declarations led governors in Louisiana (following Hurricane Katrina<sup>64</sup>) and Maryland (during the 2009-10 H1N1 pandemic<sup>65</sup>) to issue competing declarations, largely because the statutory constructs of emergencies, disasters, and public health emergencies are not mutually exclusive. In fact, they often share common components.

Duplicate emergency declarations not only add redundancy, complexity, and confusion to already strained response efforts; they can lead to significant legal dilemmas. Different state or local agencies are responsible for coordinating responses depending on the type of emergency declared. Typically, emergency management officials coordinate emergency or disaster responses. Public health officials, however, tend to be authorized to lead public health emergency responses. Simultaneous declarations may vest similar authorities in divergent government agents, fail to set lines of demarcation for action among competing government entities, or grant powers to act in one instance while restricting them in another. Politically accountable officials, seeking to respond to internal and external pressures to respond to a crisis that has an impact on the public’s health, may feel the need to employ their emergency powers, notwithstanding the potential for duplication, conflict, and controversy.

One legal fix, of course, might be to limit the ability to declare more than one state of emergency at any one point in time at each level of government. This is politically difficult, however. State governors may resist shedding their existing emergency options. Local officials may claim their own emergency powers, because they are always on the frontlines of response. Emergency managers, who are powerful voices in many jurisdictions, may disdain any curtailment of their abilities to respond. And public health authorities may be reluctant to see legislative or regulatory changes that essentially proscribe declarations of public health emergency, since it is generally easier statutorily to declare states of emergency or disaster for the same event under lesser defined standards for these types of declarations. If only one type of emergency can be issued, general declarations of emergency or disaster may always “win,” because they are easier to justify under existing, broader definitions.

## *Practicing Public Health Law in Emergencies*

Multiple declarations raise another series of issues, compounded by the need for rapid decisions in altered legal landscapes.<sup>64</sup> Though a critical component of preparedness and response, the rigors of real-time legal decision making in declared emergencies are substantial. Yet, these skills are nonstandardized,<sup>66</sup> understudied,<sup>67</sup> and, at times, poorly practiced. Ideally, emergency laws should help direct emergency responses in key areas. In reality, these laws do not provide exact legal guidance. Framed often in sweeping language and subject to alternative interpretations, emergency laws offer broad powers and options but not definitive guidance on how or when to use them. Jim Chen analytically describes “disaster law” broadly in terms of “... assembling the best portfolio of legal rules to deal with catastrophic risks....”<sup>68</sup> Though emergency powers are expansive, there are limits to what public and private actors can do.<sup>69</sup> Many laws (eg, constitutional provisions, statutes, regulations, cases, and contracts) may constrain government and private actors even during declared emergencies. Critical decisions must be made sometimes under amorphous legal standards that are subject to change in declared emergencies.<sup>70</sup> Through “legal triage,”<sup>64</sup> public and private health practitioners, emergency responders, and their legal counsel must prioritize legal issues and solutions in real time to facilitate legitimate public health responses during declared states of emergencies by:

- identifying legal issues that may facilitate or impede public health efforts in real time;
- assessing and monitoring changing legal norms during emergencies;
- crafting innovative, legally sound solutions to reported barriers to public health response efforts;
- explaining legal conclusions through tailored communications to responders and the public; and
- revisiting the utility and efficacy of their legal guidance to improve public health outcomes.<sup>71</sup>

Practicing legal triage is not easy, but like most preparedness components it can be perfected through advance training, exercises, and education. One assessment of legal decision making in a simulated emergency event conducted by researchers at Arizona State University in 2010 illustrated the varying criteria and substantive skills used by practitioners to make difficult choices of law and policy.<sup>67</sup> Initial findings, subject to replication through additional research, demonstrate how “multifarious legal, political, and epidemiological bases for key decisions” support legal and ethical training to enhance knowledge and skills in simulated or real-world environments. Decision-making simulations may help practitioners enhance their abilities to use law in real-time emergencies when legal support and guidance are needed most to prevent excess morbidity and mortality.

## *Liability Protections for Practitioners and Entities*

Liability issues underlying legal biopreparedness are contentious and sometimes divisive. Healthcare and public health practitioners, volunteers, and others worry about their personal liability for medical malpractice or other claims in emergencies. Hospitals, clinics, public health agencies, and nonprofits are concerned about their potential exposure to liability related to their acts or omissions. Some say these fears are completely unwarranted: (1) courts are not deluged with unscrupulous liability claims during and after public health crises; (2) liability claims stemming from declared emergencies are rare; and, correspondingly, (3) individuals and entities are not at any real risk of additional liability exposure.<sup>72</sup>

Many practitioners and entity representatives, however, do not agree. They point to the significant opportunities for liability claims in the midst of attempting to serve or treat patients with limited resources in dire emergency conditions. Just as doctors and hospitals practice defensive medicine to avert liability claims in routine medical and public health service delivery, many emergency responders and entities seek risk-avoidance strategies to counter the specter of liability. Highly aware of national cases following major public health emergencies in which practitioners and entities are hit with catastrophic claims, their perceived threat of liability is real. High-profile criminal and civil cases against healthcare practitioners like Dr. Anna M. Pou in New Orleans following Hurricane Katrina heighten concerns.<sup>73</sup> Recently, Tenet Health Systems, which operated Memorial Medical Center in New Orleans, settled claims brought by Katrina victims for \$25 million.<sup>74</sup> The victims’ claims were grounded not only in negligence for Tenet’s failure to respond, but also for its failure to properly plan and prepare for the hurricane and resulting city-wide flooding.<sup>75</sup>

While the actual costs of liability exposure following emergencies may be difficult to measure and assess, collateral damages related to liability fears are demonstrable. Numerous studies attest to the fact that many health practitioners will not be willing to serve during emergencies when faced with potential liability.<sup>76-78</sup> Countless anecdotal data suggest that if exposure to liability is part of the mix for many healthcare or public health workers or healthcare entities during emergencies, they simply will not participate. In its 2009 Letter Report, *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations*, the Institute of Medicine suggested that “... state and local governments should explicitly tie existing liability protections (e.g., through immunity or indemnification) for healthcare practitioners and entities to crisis standards of care.”<sup>79(p49)</sup>

Despite liability concerns, collateral consequences, and national recommendations, there are no comprehensive national liability protections for healthcare practitioners,

volunteers, or entities in all emergency settings<sup>64</sup> or even during training exercises.<sup>66</sup> Instead, an array of liability protections across government cover practitioners and entities—particularly volunteers and government entities and officials—who act in good faith and without willful misconduct, gross negligence, or recklessness.<sup>80-83</sup> Similar to protections enjoyed by emergency managers and other responders, emergency liability protections (comparable to MSEHPA provisions discussed above) may immunize or indemnify public health and healthcare actors or entities from specific claims or monetary damages. In the past decade, all states have now executed the Emergency Management Assistance Compact (EMAC), which provides strong liability protections for state or local agents during declared emergencies.<sup>84</sup> Limited waivers of sanctions or fines for failing to comply with certain federal or state statutes during emergencies offer additional protections.<sup>85</sup>

Concerns over liability risks inherent in distributing or implementing medical countermeasures in emergencies led Congress to enact the Public Readiness and Emergency Preparedness (PREP) Act<sup>86</sup> in 2005. It provides strong liability protections for manufacturers, distributors, and other entities and individuals implementing certain covered medical countermeasures.<sup>87</sup> Upon a PREP Act declaration by the HHS Secretary, limited immunity from tort liability is extended to “covered persons” (eg, federal officials, manufacturers, drug distributors, pharmacies, and state and local program planners) involved in the development, distribution, and administration of medical countermeasures. The Act expressly establishes a compensation fund for individuals injured from the administration or use of covered countermeasures.<sup>88</sup> PREP Act liability protections only apply (1) to persons and covered countermeasures specified by HHS, (2) for a specific period of time, and (3) concerning negligent acts, not intentional or criminal acts. One recent lower court decision in New York, currently on appeal, suggests that PREP Act liability protections do not immunize a school system or health practitioner involved in the alleged “bad faith” administration of the H1N1 vaccine to a minor student whose parents did not provide their consent.<sup>89</sup>

Though inconsistent, the current patchwork of federal, state, and local laws collectively provides an umbrella of liability protections covering hundreds of thousands of practitioners, volunteers, and entities, so long as they fall under the umbrella and play by the rules. Some liability protections, for example, cover individuals or entities only for their acts during declared emergencies as registered, organized volunteers (as contrasted with spontaneous volunteers who arrive unannounced on the scene of a disaster).<sup>90</sup> Virtually no liability protections immunize or indemnify practitioners or entities for acts that constitute gross negligence, willful or wanton misconduct, or crimes. More limited liability protections cover hospitals, clinics, pharmacies, and other health entities.<sup>91</sup>

Existing liability protections have neither pacified health practitioners (seeking complete immunity) nor dissuaded patient rights advocates seeking equal access to courts to adjudicate potential negligence claims. The battle over emergency liability protections rages on. On August 6, 2011, the American Bar Association (ABA) House of Delegates approved Resolution 125 to express opposition to the adoption of laws, particularly immunity provisions, that “would alter the legal duty of reasonable care in the circumstances owed to victims of a natural or manmade disaster by relief organizations or health care practitioners.”<sup>92</sup> While the resolution does not directly change public or private sector policies, it reflects an influential position among at least some members of the ABA. Authors of the resolution suggest that the flexible nature of the legal standard of care provides adequate assurance to practitioners of protection from unwarranted liability claims. Denying patients their right to sue post-emergency, they opine, is poor policy. Others suggest that subjecting practitioners and entities to unforeseen claims for negligent acts or omissions against a backdrop of chaos and uncertainty in emergencies is antithetical to protecting the public’s health.

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## CONCLUSION

In the decade following the terrorist acts on September 11, 2001, legal biopreparedness reforms have transformed how all levels of government and private sector actors prepare for and respond to biothreats. Federal, state, and local governments have been reorganized. New classifications of public health emergency have emerged. Emergency public health powers have been clarified. These and other changes have not come without controversy. Public health officials, emergency managers, patient rights advocates, and civil libertarians continue to debate the premises of existing and potential legal reforms. Significant legal and policy challenges remain. The next decade will bring new (and likely contested) answers. Yet, the laudable objective of public and private actors largely remains the same: to use law affirmatively and effectively to improve biopreparedness, eliminate actual and perceived barriers to response efforts, and build a legal infrastructure that supports the prevention of morbidity and mortality during major catastrophes that affect the public’s health.

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