

Law, Liability, and Public Health Emergencies

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ABSTRACT

According to many experts, a public health emergency arising from an influenza pandemic, bioterrorism attack, or natural disaster is likely to develop in the next few years. Meeting the public health and medical response needs created by such an emergency will likely involve volunteers, health care professionals, public and private hospitals and clinics, vaccine manufacturers, governmental authorities, and many others. Conducting response activities in emergency circumstances may give rise to numerous issues of liability, and medical professionals and other potential responders have expressed concern about liability exposure. Providers may face inadequate resources, an insufficient number of qualified personnel, overwhelming demand for services, and other barriers to providing optimal treatment, which could lead to injury or even death in some cases. This article describes the different theories of liability that may be used by plaintiffs and the sources of immunity that are available to public health emergency responders in the public sector, private sector, and as volunteers. It synthesizes the existing immunity landscape and analyzes its gaps. Finally, the authors suggest consideration of the option of a comprehensive immunity provision that addresses liability protection for all health care providers during public health emergencies and that, consequently, assists in improving community emergency response efforts. (*Disaster Med Public Health Preparedness*. 2009;3:1–9)

Key Words: liability, immunity, public health emergencies, responders, causes of action

The threat of a severe influenza pandemic affecting the United States has prompted intensive preparedness efforts at all levels of government, as well as among health care providers and organizations, the business community, volunteer organizations, and many other sectors.¹ Pandemic preparedness also builds upon lessons learned from recent disasters and other emergencies, including the 2001 terrorist and anthrax attacks, the 2003 epidemic of severe acute respiratory syndrome, and the 2005 hurricane disasters. Real-time experience with and postevent analyses of public health emergencies have highlighted critical gaps in preparedness and response capacities.

Although the literature is replete with reports documenting public health and other scientific implications of such emergencies,² serious efforts to identify and characterize related legal issues were rare before the terrorist events of September 11, 2001. One such gap is the uncertainty surrounding potential legal liability risks for individuals likely to become involved in responses to an influenza pandemic and other emergencies, including government employees, private-sector health care providers, and volunteers. Liability is defined as “(t)he quality or state of being legally obligated or responsible.”³ As an example of these concerns, response efforts to the 2005 hurricane disasters may have been hindered by confusion about legal liability and licensure requirements for health professionals who wished to provide assistance in states other than their state of residence.^{4,5} Despite the importance of these considerations, the liability and immunity schemes that exist constitute a patchwork that leaves many gaps and unanswered questions.

In this article, we describe and summarize 2 critically important aspects of the legal framework that governs public health emergency response work—liability and immunity. Although much has been written about liability protection for volunteers,⁶ this article addresses liability and immunity that affect all health care providers—paid and unpaid, both in the private and public sectors—and entities, as well as individual responders. Public health professionals, who may be called upon to provide disaster relief services, must be aware of these issues and should find this work to be a useful resource. Even though multiple sectors and many different skilled and unskilled workers may be involved in emergency response efforts, we focus only on health care providers. These professionals have special qualifications and licensure requirements, which intensify their concerns about liability. In addition, we restrict our assessment to liability and immunity associated specifically with declared public health emergencies, and not other types of emergencies.

We first outline the legal context of emergencies, discussing the various categories of emergency responders and the mechanisms by which public health emergencies are declared. We next summarize the concepts of liability and standard of care, and we examine selected legal theories (“causes of action”) that could be used by plaintiffs to bring civil lawsuits alleging injuries associated with response activities or by government prosecutors to pursue criminal prosecutions. Furthermore, we analyze various liability protections and sources of immunity that are potentially available to emergency responders. We synthesize the existing immunity landscape, elucidating which parties are likely to enjoy immunity in the context of a public health emergency and which are not. We also review the purposes of liability and briefly suggest an option for

addressing the confusing patchwork of liability protections that exists. The analysis in this article fills a gap in the public health literature and should serve to enhance legal preparedness and community emergency response efforts.

PUBLIC HEALTH EMERGENCIES

Public health emergencies raise acute concerns for health care providers relating to liability. Some of the key participants likely to be involved in an emergency response, and therefore potentially vulnerable to liability, include hospitals, health care professionals, volunteers,⁷ volunteer coordinators and registry operators, government officials and employees at all levels, and producers of vaccines and other medical supplies (Table 1).

Although no single definition of “public health emergency” has been universally adopted by all public health authorities, one useful definition is the occurrence of a health condition or imminent threat of illness that is believed to be caused by bioterrorism, a novel or previously controlled or eliminated infectious or biological agent, a natural disaster, a chemical attack or an inadvertent chemical release, or a nuclear incident or attack that poses a high likelihood of a large number of deaths, serious or long-term disabilities, or other harm to a substantial number of people.⁸ This definition excludes localized events (eg, a tornado that injures or kills only people within a confined area); however, a more widespread disaster such as a hurricane, which causes large numbers of injuries and massive population displacement, may produce a public health emergency.

At the federal level, a public health emergency can be declared by the Department of Health and Human Services (DHHS) secretary under the authority of the Public Health Service Act,⁹ as was done in the wake of Hurricane Katrina in August 2005. Governors in all states have authority to declare emergencies,

and in some states governors may specifically declare public health emergencies.¹⁰

Declarations of emergency allow governmental authorities to exercise special powers and to suspend certain legal requirements that could be excessively burdensome. Consequently, such declarations are often essential to achieving effective emergency responses. For example, Section 1135 of the Social Security Act (Sec. 1135[42 USC 1320b-5]) empowers the DHHS secretary to issue particular waivers during declared public health emergencies.¹¹ In response to Hurricane Katrina, the secretary issued a Section 1135 waiver that suspended the following obligations: certain conditions of participation in Medicare, Medicaid, and the State Children’s Health Insurance Program; state licensure requirements; sanctions under the Emergency Medical Treatment and Active Labor Act; Medicare Advantage patients’ restrictions on using out-of-network providers; and sanctions under the Health Insurance Portability and Accountability Act of 1996 privacy regulations.¹² Similarly, at the state level, some statutes confer various powers upon the governor or state public health officials following the declaration of an emergency. These powers include, for example, authority to use state and local resources in support of emergency response efforts, to alter the functions of some state agencies, to mobilize and deploy the state’s National Guard, to act under interstate mutual aid agreements to share resources with or request aid from other states, and to request assistance from the federal government.¹³

LEGAL CONTEXT: LIABILITY AND STANDARD OF CARE

The press of medical needs generated by a public health emergency will require that communities’ public health and health care systems possess surge capacities involving numerous public and private sector health care providers. In an emergency, these professionals may be confronted with issues of liability associated with such problems as insufficient num-

TABLE 1
Key Providers and Their Functions During a Public Health Emergency

Emergency Response Participants	Selected Functions
Hospitals, physicians, nurses, pharmacists, and other health care providers	Evaluate and treat large volumes of patients Establish operations in offsite locations
Volunteers (unpaid health care providers, retirees, students, others with some medical training)	Assist paid health care providers and government authorities in response efforts
Volunteer coordinators and registry operators	Supply necessary volunteers Coordinate transportation and other volunteer logistics Verify credentials
Government officials and employees	Supervise volunteer response activities Coordinate among different government authorities and sectors Collaborate with nongovernmental entities and people Disseminate timely and accurate information to the public Prepare for expeditious decision making within a “chain of command” structure
Producers of vaccines and other medical supplies and equipment	Address increased demand for products and supplies Accelerate production Consider implications for quality control

bers of qualified personnel and inadequate resources. Moreover, during an emergency, health care providers may be forced to depart from medical practice standards that prevail in less exigent circumstances, and consequently may provide patients with services that are associated with greater risks for morbidity or mortality. Law enforcement authorities and people who are injured or their survivors may seek to hold responders legally liable for their actions and to obtain redress.

A well-known illustration is the case of Dr Anna Maria Pou, a cancer surgeon who treated patients at New Orleans' Memorial Medical Center during Hurricane Katrina and its aftermath. Pou and 2 nurses were arrested in July 2006 and accused of administering lethal amounts of morphine and midazolam to 4 older adult patients on September 1, 2005, thereby intentionally killing them. Pou has asserted that the medications were given only to relieve pain and distress. Louisiana's attorney general decided not to pursue charges against the 2 nurses in exchange for their cooperation, and the grand jury ultimately declined to indict Pou. However, at the time of this writing, 3 civil suits, brought by relatives of the 4 deceased patients, are pending against Pou.¹⁴

Findings of liability are associated with a departure from the expected standard of care. In law, the standard of care can be defined in terms of what a reasonable practitioner would do under similar circumstances.¹⁵ The legal standard of care, therefore, takes into account the conditions under which providers operate. During the exigent circumstances of an emergency, the conduct of health care professionals who are evaluating and treating patients is not likely to be judged as harshly by courts as it would be under ordinary circumstances. Some experts have used the terminology "altered standards of care" when proposing medical practice guidelines for public health emergencies.² Because the legal standard of care is by definition fact specific and flexible, however, there is no single standard of care that is expected at all times, and thus there is no "altered" standard of care during an emergency. The standard of care is naturally different when providers must operate with scarce resources and overburdened staffs. In fact, in its recently published *Adapting Standards of Care Under Extreme Conditions*, the American Nurses Association recognizes that "[n]o emergency changes the basic standards of practice, code of ethics, competence, or values of the professional." Rather, "the specific application of standards will be based on the reality of the specific situation, such as presence or absence of usual equipment, medications, or colleagues."¹⁶ Thus, we believe that the term "altered standard of care" is somewhat confusing and misguided. Instead, it would be more accurate to speak in terms of modified care or modified standard procedures.

POTENTIAL CAUSES OF ACTION

Some individuals may bring lawsuits for monetary damages or other redress for injuries that they believe they suffered as the result of inadequate care received during emergency response

efforts. Several of the key legal theories, or causes of action, underlying these lawsuits are listed in Table 2. Three of the most likely legal theories—negligence, constitutional claims, and criminal prosecution—are briefly summarized below.

Lawsuits alleging responder negligence, especially malpractice, are among the most likely legal actions to be filed by people (ie, plaintiffs) who assert that they suffered harm as the result of responders' (ie, defendants') provision of inadequate treatment or other actions or omissions. To prevail in such a lawsuit, a plaintiff will need to establish 4 basic elements: the defendant's duty of care owed to the plaintiff, the defendant's breach of that duty, the occurrence of injury to or damages suffered by the plaintiff, and causation—a causal link between the plaintiff's injuries and the defendant's actions (or omissions) that represent a failure to meet the appropriate standard of care.¹⁷ As indicated in Table 2, 3 relevant subcategories of negligence suits are negligence by health care providers, corporate negligence, and vicarious liability.

Constitutional claims can be brought against government entities and officials, but not against private parties. Plaintiffs may assert that the government violated their Fifth or Fourteenth Amendment guarantees against deprivation of life, liberty, and property without due process of law or their right to equal protection. For example, people who are quarantined may assert that they were unlawfully deprived of liberty without due process of law. Likewise, if individuals of a specific race and/or ethnicity believe that they received inferior services during an emergency because of their race or ethnicity, they may bring an equal protection claim.

Finally, criminal liability may be incurred by health care professionals who provide suboptimal medical care or withhold or withdraw treatment from individuals, thereby causing injury or death, or, in some jurisdictions, by clinicians who provide services for which they are not licensed. A case that received significant media attention is that of Dr Pou, who was accused of euthanizing 4 patients, as discussed above. A much-discussed hypothetical that could well become a reality in a future public health emergency is a respirator shortage. If all of a hospital's respirators are being used to treat older adult patients for whom the therapy is not futile, and physicians decide to remove these respirators to use them to provide treatment for newly admitted, younger patients, then the doctors may be vulnerable to criminal prosecution for their actions. It should be noted that immunity from prosecution is not available with regard to criminal behavior and, unlike civil cases, criminal cases are brought against defendants by government prosecutors rather than by private citizens.

SOURCES OF IMMUNITY

Emergency responders have many potential sources of immunity that can prevent or limit liability arising from the potential causes of action described above. Immunity can be

TABLE 2

Select Causes of Action That May Be Brought by Individuals or the State to Address Injuries Allegedly Resulting From Acts or Omissions on the Part of Health Care Providers Responding to a Public Health Emergency

Cause of action	Comment
Negligence	
Negligence by health care providers	Elements of a negligence claim Duty of care Breach of duty Injury Causal link between injury and breach of duty
Corporate negligence	Corporate health care provider duty likely includes Maintenance of safe and adequate facilities and equipment Selection and retention of competent staff Oversight of patient care Development and implementation of good-quality patient care policies
Vicarious liability	Vicarious liability claim would be Based on the legal doctrine of “respondeat superior” (“let the superior answer”) Intended to hold health care organization responsible for actions of employees or independent contractors as “ostensible agents” of the organization
Constitutional claims	Likely supporting theories would include Deprivation of life, liberty, or property rights without due process of law Denial of equal protection
Criminal liability	Criminal intent may be found with regard to Failure to treat Inadequate treatment Medical treatment outside scope of usual practice Medical treatment by unlicensed persons
Invasion of privacy/breach of confidentiality	Claims for improper disclosure of protected health information could arise due to Imperfect record-keeping practices Media pressure to disclose information
Violation of the Americans with Disabilities Act (ADA) [42 USC §§ 12101-12213]	Prohibits disability-based discrimination by “public services” and “public accommodations” “Public accommodations” include a private “pharmacy, insurance office, professional office of a health care provider, hospital, or other service establishment” Plaintiffs must prove actual discrimination associated with their disabilities rather than inadequate treatment because of emergency circumstances or must establish that their needs could be accommodated without undue hardship
Violation of the Rehabilitation Act [29 USC §794]	Narrower scope than ADA Covered entities include health care organizations receiving federal financial assistance Qualified disabled individuals would be required to demonstrate that exclusion or denial of benefits was due to discrimination based on disability
State constitutions and civil rights statutes	The US system of justice creates the potential for lawsuits based not only on federal law but also on applicable state laws
State licensure requirements for health care professionals	Violations may occur with regard to provision of services By unlicensed personnel In a jurisdiction other than where provider is licensed Outside scope of usual practice
Emergency Medical Treatment and Labor Act [42 USC §1395dd]	Generally requires screening and stabilization of emergency room patients regardless of the patients’ ability to pay for these services

defined as an exemption from a duty or liability.³ Several representative immunity defenses are outlined in this section.

Government Immunity for Tort Claims

Protection against judicial findings of wrongdoing on the part of government agencies and employees who respond to public health emergencies within the scope of their official duties exists through the doctrine of governmental sovereign immunity, which is reflected in state and federal immunity statutes. Although most states have enacted tort claims acts that limit state sovereign immunity, they generally have

retained immunity for discretionary decisions—that is, actions undertaken by officials in their official capacity that fall within a range of permissible actions. Under the Federal Tort Claims Act, the federal government similarly has waived its sovereign immunity, although immunity is preserved for federal officials who are challenged for discretionary actions undertaken in good faith in their official capacity.¹⁸

Immunity for Constitutional Claims

Constitutional claims for money damages brought against state and federal government entities, such as the US Department of

Veterans Affairs hospitals and their employees, may be dismissed based on the defense of governmental immunity. State sovereign immunity is rooted in the Eleventh Amendment to the US Constitution, although this amendment does not extend protection to local governmental entities.¹⁹ Similarly, a doctrine of federal sovereign immunity has been developed to protect the United States from being sued without its consent.²⁰ In addition, state and federal officials are shielded from liability for discretionary functions performed in their official capacity by the defense of qualified immunity unless they had knowledge that their actions or omissions violated clearly established statutory or constitutional rights.²¹

Emergency Management Assistance Compact

The Emergency Management Assistance Compact (EMAC)²² is a mutual aid agreement enacted in statute by all of the states and ratified by the Congress. It is triggered by a state governor's declaration of emergency, including a public health emergency, and a subsequent request for assistance from another state. The Emergency Management Assistance Compact establishes licensure reciprocity and provides immunity to any "party state or its officers or employees" offering assistance in another state and acting in good faith (ie, without willful misconduct, gross negligence, or recklessness).²³ One limitation of EMAC is that it does not specify exactly who can be considered officers or employees of a party state. Some states have addressed this gap through statutes that, for liability purposes, classify as state employees all people who act under EMAC.²⁴ Through the use of appropriate legal authority and intrastate mutual aid agreements, states can access local assets, including private sector assets, and have those assets benefit from EMAC's licensure reciprocity and immunity provisions.²⁵

Good Samaritan Laws

State "Good Samaritan" statutes shield health care professionals or other people who provide care at the scene of an accident or during an emergency from civil liability.¹⁰ Subject to the specific requirements of these laws, volunteers are protected from civil liability for ordinary negligence, but not for gross negligence or wanton misconduct. These statutes generally apply only to individual rescuers and not to entities such as hospitals or businesses. However, the entity liability issue was recently addressed in Iowa by enactment of Iowa Code Ann. §135.147, extending Good Samaritan liability protection to good-faith assistance provided by corporations and nonprofit entities during public health emergencies.

Volunteer Protection Acts

Congress and all states have enacted additional laws that provide varying levels of liability protection for volunteers responding to a public health emergency. Specifically, the federal Volunteer Protection Act of 1997²⁶ extends limited immunity to volunteers who serve nonprofit organizations and governmental entities. The law specifies the conditions under which immunity is available, imposing requirements such as appropriate licensure and an absence of willful and reckless misconduct on the part of the volunteer. Further-

more, it does not provide enterprise liability protection to the entities for which volunteers work. Among state statutes, the scope of liability protection for volunteers varies considerably. An effort to eliminate the variability among state laws with regard to certain volunteers has been undertaken by the National Conference of Commissioners of Uniform State Laws in the form of a model act called the Uniform Emergency Volunteer Health Practitioners Act.^{10,27} The act has been enacted in 6 states, and was introduced in 9 other states in 2008.²⁷

Immunity for Manufacture, Distribution, Administration, and Use of Selected Therapies and Countermeasures

The Public Readiness and Emergency Preparedness Act²⁸ provides for tort liability immunity (except for willful misconduct) for manufacturers, distributors, and specified individuals involved in administration and use of "covered countermeasures" (drugs, devices, and biological products) when the secretary of DHHS declares that a disease, health condition, or threat to health constitutes or will constitute a public health emergency and recommends use of the countermeasure.²⁹ In addition, under the Federal Food, Drug, and Cosmetics Act, as amended by the Project BioShield Act of 2004,³⁰ during a declared emergency, the DHHS secretary may authorize emergency use of products not yet licensed or approved for commercial distribution. Providers acting pursuant to such an authorization could not be found liable for dispensing unapproved products.

Immunity Based on State Emergency Response Statutes

State laws that specifically address public health emergencies furnish different degrees and types of liability protection. Selected examples of these state statutes and summaries of the scope of immunity they provide are presented in Table 3.

DISCUSSION

We have conducted a detailed review of the broad spectrum of liability exposures and liability protections that affect public and private people and entities participating in public health emergency response activities. The findings of our review reveal that US immunity law constitutes a patchwork with many gaps and inconsistencies. No source of law comprehensively addresses liability and immunity issues. We now offer a brief synthesis of our findings regarding sources of immunity, and we review the theoretical bases for liability. We conclude by briefly describing 1 option for addressing the confusing and incomplete immunity scheme to optimize public health emergency response efforts.

Synthesis of Liability Protections for Emergency Response Participants

As this article suggests, with relatively narrow exceptions federal, state, and local government agencies and their employees or agents who are performing their official duties

TABLE 3

Selected State Law Immunity Provisions for Public Health Emergency Response Participants

State	Selected Immunity Provisions
Arizona [Ariz. Rev. Stat. Ann. §36-790]	Immunity from liability for those engaged in activities required by law, such as disease reporting or quarantine implementation
Delaware [Del. Code Ann. Tit. 20 §3144]	Actions required by law are presumed to be taken in good faith. Immunity extends to People who own or control real estate and allow its use, without remuneration, to shelter people during a public health emergency A private person, firm, or corporation and its employees or agents who provide assistance or advice at the government's request during a public health emergency
Maine [Me. Rev. Stat. Ann. Tit. 22, §816.1, et seq.]	Private institutions and their employees and agents enjoy immunity to the extent that immunity is available to state agencies and employees for certain acts. Included is immunity relating to Credentialing of licensed health care workers consistent with statutory requirements governing the hiring process
New Jersey [N.J. Stat. Ann. §26:13-19]	Participation in good faith investigation or reporting of communicable diseases Immunity is granted during a public health emergency to private entities or people Owning or controlling property used in response efforts Performing a contract with a public entity Providing assistance or advice to a public entity
Wyoming [Wyo. Stat. Ann. §35-4-114]	With respect to acts or omissions authorized by law, unless such acts or omissions constitute a crime, fraud, actual malice, gross negligence, or willful misconduct Immunity is available to health care providers and others who act in good faith to comply with state health officer instructions unless involved in "gross negligence or willful or wanton misconduct."

during a public health emergency will be shielded from liability. Included among the liability protections are the Federal Tort Claims Act or comparable state tort claims acts, sovereign immunity, qualified immunity, EMAC, and state emergency response statute provisions.

To illustrate, federal and state health agencies, officials, and employees making policy decisions concerning how to triage patients or ration scarce resources are likely to be immune from liability for tort actions and constitutional claims so long as they act in good faith. A public worker will not be protected against tort or constitutional claims, however, if she hoards scarce vaccines and immunizes all of her friends and family members without a public health rationale for doing so. It should also be noted that immunity protections for public entities and employees most likely do not extend to violations of the Americans with Disabilities Act and Rehabilitation Act, because these do not fall within any liability exemption.

Individual unpaid volunteers who respond to an emergency will also benefit from several sources of immunity. One important source of this protection is the states' Good Samaritan statutes. Second, the federal Volunteer Protection Act of 1997 (Pub L No. 105-19) provides immunity from most lawsuits to properly licensed volunteers for nonprofit organizations and governmental entities. Finally, volunteers are protected by some state laws that specifically address general and public health emergencies.

Although it appears that volunteer health care providers typically should not be concerned about liability, at least 2 important issues remain. First, because volunteers are generally covered only if they are not compensated for their work, an individual whose regular employer continues to pay his or her salary while he or she participates in relief efforts in another state may not be shielded from liability as a "volunteer." Second, liability protection generally extends only to individual volunteers. Thus, corporate or other entities—such as hospitals or clinics that donate their time, space, supplies, and resources to emergency response efforts—will not enjoy the benefit of laws that establish immunity for volunteers.³¹

Consequently, the parties that appear to be most often excluded from the benefits of immunity are private sector entities and paid individual responders. Some may enjoy immunity in specific circumstances under state and federal laws, such as the Public Readiness and Emergency Preparedness Act (Pub L No. 109-148), Section 1135 of the Social Security Act, or particular state emergency response statutes. However, these provisions are limited in scope and offer private sector actors significantly less protection than that available to volunteers and the public sector. The general absence of protection is of concern because these parties are likely to bear the brunt of the burden as hundreds or thousands of patients rush to emergency rooms, clinics, and physicians' offices to receive care. Private entities and paid health care providers may be sued and found liable for a variety of decisions and actions that are likely to be required

during a public health emergency. These include triaging decisions, choices concerning how to ration scarce resources, breaches of confidentiality, provision of medical services without appropriate licensure, and negligent care.

Liability is a significant concern for private sector health care providers even though many of them have medical malpractice insurance coverage. Such coverage does not prevent the initiation of litigation itself, which may expose providers to significant costs associated with hiring attorneys and constructing their defense, generate adverse media coverage, and threaten the viability of their practices. Increased expenses associated with litigation also can lead insurers to raise insurance premiums, a phenomenon that would create further economic difficulties for health care providers.³²

Purpose of Liability

The public policy purposes of liability are first to deter misconduct and second to provide compensation for injured parties.^{17,33} In the context of a public health emergency, however, the goals of liability may be qualified or recalibrated. Although egregious behavior should be deterred, it is less clear that liability should attach to simple negligence that occurs under exigent circumstances. Certainly, one would not want the threat of liability to deter individuals or entities from participating in emergency response activities. The compensatory function of liability also is complicated by the likelihood that some of those who suffer harm because of suboptimal care may have been even worse off absent the negligent services because they would have received no care at all. Some may therefore argue that such individuals should not be compensated.

It should be noted that nonjudicial sources of compensation may be available to public health emergency victims. The Federal Emergency Management Agency provides compensation for property loss and injuries in many circumstances.³⁴ In addition, Congress established a victim relief fund after the events of September 11, 2001³⁵ and could take similar action in response to future catastrophes.

Policymaking Consideration

Public policy decisions concerning the creation of immunity provisions would be facilitated by further empirical evidence regarding what impact potential liability has on the behavior of various actors, particularly in emergency situations. Absent hard data, legislators rely at least partially on intuition and assumptions about behavioral outcomes.

In crafting appropriate liability and immunity provisions for public health emergencies, policymakers face the challenges of promoting and simultaneously balancing individual justice and general public welfare in light of extraordinary and chaotic conditions. Extending liability protection to those emergency responders not shielded from liability under existing laws should serve to induce participation in response activities. Immunity could also serve important economic and efficiency functions by reducing the volume of litigation that stems from public health

emergencies, thereby potentially slowing the rate of increase in malpractice insurance costs for health care providers.

In determining the extent to which immunity should be available to health care providers, policymakers face at least 2 noteworthy questions. The first is whether immunity coverage should be provided only to those who are serving under the direction of a government or nonprofit entity, or whether it should also be extended to those spontaneous volunteers who independently appear on the scene and begin dispensing medication or providing treatment. A second matter of concern is whether caregivers should enjoy immunity if they provide services for which they are not licensed. In extreme emergencies, it may be argued that it is better to have unlicensed individuals performing tasks for which they are not credentialed than to withhold care from disaster victims altogether. At the same time, laxity about licensing standards also can lead to irresponsible and unnecessarily deficient medical care.

Option: Comprehensive Immunity Provisions

Existing gaps in the public health emergency immunity scheme may be most effectively filled through enactment of a comprehensive immunity provision that addresses liability for all health care providers, including individuals, entities, paid and unpaid parties, and participants associated with both the private and the public sectors. A possible model for a provision is one establishing that no health care providers will be liable for injuries or harm caused by good faith actions undertaken to respond to a public health emergency so long as the following conditions are met: They are acting in their capacity as public or private entities or their agents or employees in the affected area or are volunteering under the direction of governmental authorities or nonprofit organizations, and they are not engaged in willful misconduct, gross negligence, or criminal activity.

The provision's goal would be to create a comfort level that would encourage entities and individuals to participate in response operations and make unavoidable, difficult decisions, such as those concerning triaging and allocation of scarce resources, without excessive concern about litigation. Incorporation of a "good faith" provision would be essential because it would retain disincentives for willful misconduct, gross negligence, and criminal activity. Thus, for example, if in the midst of chaotic conditions a doctor did not detect a hairline fracture on an x-ray, then he or she would enjoy immunity. However, a doctor who amputated a leg on the wrong patient would most likely be found guilty of gross negligence no matter what conditions existed and would not be entitled to immunity.

It is suggested that the immunity provision be triggered only by a declaration of a public health emergency and that it apply only to activities taking place in response to the emergency and during the emergency's duration. In determining the scope of an immunity statute, other issues to be considered include licensure oversight, the duration of immunity, the definition of "health care provider," and whether emergency responders other than health care providers ought to enjoy immunity.

As discussed in this article, and consistent with principles of federalism on which our system of government is based, effective response to public health emergencies is a shared responsibility of the federal and state governments. If it is determined by policymakers that comprehensive immunity of the sort suggested in the preceding paragraphs would be a valuable legal tool to enhance response efforts, then both federal and state statutory immunity provisions would need to be enacted, because in some cases emergencies will be declared by states but not by the federal government.

CONCLUSIONS

Health care providers who may respond to a public health emergency lack clear guidance regarding the scope of liability that they may face and often express concern about liability exposure. This concern may well prevent them from participating in essential response activities. One option that could resolve existing uncertainties and ambiguities in the law is a comprehensive immunity provision for health care providers that is incorporated into federal and state laws. Such a provision would balance the needs of disaster victims with the needs of those providing aid and the best interests of society at large. It also could encourage involvement in response activities without excusing egregious misconduct and be sufficiently detailed to answer the many questions concerning emergency response initiatives that have been highlighted in this article. An elucidation of liability and immunity standards for health care providers could greatly contribute to the effectiveness of public health emergency response.

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For a more complete discussion of the legal issues raised in this article, see Hoffman S. *Georgetown Law J.* 2008;96:1913–1969.

Authors' Disclosures

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REFERENCES

1. PandemicFlu.gov/AvianFlu.gov Web site. <http://www.PandemicFlu.gov>. Accessed August 29, 2007.
2. Health Systems Research, Inc. Altered Standards of Care in Mass Casualty Events. <http://www.ahrq.gov/research/altstand/altstand.pdf>. Accessed November 17, 2008.
3. Garner B, ed. *Black's Law Dictionary*. St Paul, MN: Thomson West; 2004.
4. Weiss RI, McKie KL, Goodman RA. The law and emergencies: surveillance for public health-related legal issues during hurricanes Katrina and Rita. *Am J Public Health*. 2007;97:S73–S81.
5. *The Federal Response to Hurricane Katrina: Lessons Learned*. February 2006, page 116. <http://www.whitehouse.gov/reports/katrina-lessons-learned.pdf>. Accessed November 17, 2008.
6. Hodge JG, Pepe RP, Henning WH. Voluntarism in the wake of Hurricane Katrina: the Uniform Emergency Volunteer Health Practitioners Act. *Disaster Med Public Health Prep*. 2007;1:44–50.
7. National Conference of Commissioners on Uniform State Laws, July 7–14, 2006. Uniform Emergency Volunteer Health Practitioners Act Web site. <http://www.uevhp.org/DesktopDefault.aspx?tabindex=1&tabid=55>. Accessed November 17, 2008.
8. Model State Emergency Health Powers Act §104(m). Center for Law & the Public's Health, Discussion Draft 2001. <http://www.publikealthlaw.net/MSEHPA/MSEHPA2.pdf>. Accessed November 17, 2008.
9. 42 USC § 247d (a) (2000).
10. Emergency System for Advance Registration of Volunteer Health Professionals—Legal and Regulatory Issues, Draft Report May 2006. Department of Health & Human Services Web site. ftp://ftp.hrsa.gov/bioterror/May_06_Legal_Report.pdf. Accessed November 17, 2008.
11. 42 USC § 1320b-5 (2000). http://www.ssa.gov/OP_Home/ssact/title11/1135.htm.
12. Waiver Under Section 1135 of the Social Security Act. Health and Human Services Web site. <http://www.hhs.gov/katrina/ssawaiver.html>. Accessed November 17, 2008.
13. La. Rev. Stat. Ann. §29:766 (2007); N.J. Stat. Ann. § 26:4–2 (2007).
14. Okie S. Dr. Pou and the hurricane—implications for patient care during disasters. *N Engl J Med*. 2008;358:1–5.
15. Vaughn V. Menlove, 132 Eng. Rep. 490, 492 (C.P. 1837).
16. Adapting Standards of Care Under Extreme Conditions: Guidance for Professionals During Disasters, Pandemics, and Other Extreme Emergencies. American Nurses Association Web site. <http://www.nursingworld.org/MainMenuCategories/HealthcareandPolicyIssues/DPR/TheLawEthicsofDisasterResponse/AdaptingStandardsOfCare.aspx>. Accessed November 17, 2008.
17. Prosser WL, Keeton WP, Dobbs DB et al, eds. *Prosser and Keeton on the Law of Torts*. 5th ed. St. Paul, MN: West Publishing; 1984.
18. 28 USC §§ 2671–2680 (2000).
19. *Monell v. New York Dept. of Soc. Servs.*, 436 U.S. 658, 690 (1978).
20. Fallon RH, Hart HM, Wechsler H et al. *Hart and Wechsler's The Federal Courts and the Federal System*. 5th ed. Mineola, NY: Foundation Press; 2003, p 1001.
21. *Harlow v. Fitzgerald*, 457 U.S. 800, 818 (1982); *Davis v. Scherer*, 468 U.S. 183, 191 (1984).
22. Pub. L. No. 104-321, 110 Stat. 3877 (1996).
23. Emergency Management Assistance Compact, Art. VI.
24. Ind. Code § 10-14-3-19(d) (2006); Iowa Code Ann. § 135.143.2 (2007); Me. Rev. Stat. Ann. tit 37-B, § 784-A (2006).
25. *A Report on the Emergency Management Assistance Compact to the Committee on Homeland Security and Governmental Affairs*. GAO-07-854. Government Accountability Office Web site. www.gao.gov/cgi-bin/getrpt?GAO-07-854. Accessed November 17, 2008.
26. 42 USC § 14503(a) (2000).
27. The Uniform Emergency Volunteer Health Practitioners Act. <http://www.uevhp.org>. Accessed July 24, 2008.
28. 42 USC § 247d-6d–247d-6e (Supp. 2007).

29. Gostin LO. Medical countermeasures for pandemic influenza: ethics and the law. *JAMA*. 2006;295:554–556.
30. Pub. L. No. 108-276, 118 Stat. 859 (2004), codified at 42 USC § 247d-6a (Supp. 2007).
31. Public/Private Legal Preparedness Initiative. UNC School of Public Health Web site. <http://nciph.sph.unc.edu/law>. Accessed November 17, 2008.
32. Kessler DP, McClellan MB. How liability law affects medical productivity. *J Health Econ*. 2002;21:931–955.
33. Shavell S. *Foundations of Economic Analysis of Law*. Cambridge, MA: Harvard University Press; 2004, p 268.
34. What Is Disaster Assistance? Federal Emergency Management Agency Web site. http://www.fema.gov/assistance/process/individual_assistance.shtm. Accessed November 17, 2008.
35. Wolfe MA. Homeland Security: 9/11 Victims Relief Funds. Congressional Research Service, 2003. <http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL31716.pdf>. Accessed November 17, 2008.