

## SUPPORT FOR THE FIRST LINE OF DEFENSE IN PUBLIC HEALTH EMERGENCIES

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\* J.D., Northwestern University School of Law, 2011; B.S., University of Washington, 2007. I would like to thank Professor Marshall Shapo and Dr. Sachin Patel for their advice and feedback in developing this Comment, as well as the members of the *Northwestern University Law Review* for their editorial work. I would especially like to thank Dr. Bryan Chow for his love and support during this entire process. All errors are my own.

## INTRODUCTION

In the last ten years, the United States has come close to experiencing several national public health emergencies.<sup>1</sup> While the rest of the world remains afflicted with pandemics, the United States effectively manages many infectious diseases.<sup>2</sup> In 2009, fear of H1N1, a novel strain of influenza infecting a significant portion of the population, drove U.S. federal and state governments to implement a massive public immunization campaign.<sup>3</sup> Fortunately, in the United States H1N1 cases peaked in the winter of 2009 and appeared to dissipate afterward.<sup>4</sup>

But what if the United States had not been so lucky? What if the “plausible scenario” laid out in the report on H1N1 to President Obama, which estimated 1.8 million hospital admissions and as many as 90,000 deaths, had actually occurred?<sup>5</sup> Most public health officials agree that it is simply a matter of time before the United States suffers a disastrous in-

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<sup>1</sup> In the last ten years, the United States monitored outbreaks of novel strains of influenza around the world. *See H1N1 (Swine Flu)*, FLU.GOV, <http://www.flu.gov/individualfamily/about/h1n1/index.html> (last visited Oct. 15, 2011). On April 26, 2009, the Department of Health and Human Services issued a national public health emergency declaration in response to a number of confirmed cases of H1N1 (commonly known as “swine flu”) in the United States. *See id.* On June 11, 2009, the World Health Organization declared a global pandemic resulting from the spread of H1N1. *Id.* The World Health Organization also continues to monitor outbreaks of H5N1 (also known as “avian influenza”) around the world. *H5N1 (Bird Flu)*, FLU.GOV, <http://www.flu.gov/individualfamily/about/h5n1/index.html> (last visited Oct. 15, 2011). There have been no reported cases of H5N1 in the United States, but it remains a serious concern because of its potential to cause a deadly pandemic. *See id.* As a countermeasure, the United States currently bans the importation of poultry from countries affected by H5N1. *See* 9 C.F.R. § 94.6(e) (2010). In 2003, an outbreak of Severe Acute Respiratory Syndrome (SARS) in Asia infected 8098 people worldwide, and 774 of those infected died. *Fact Sheet: Basic Information About SARS*, CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP’T HEALTH & HUMAN SERVS. (May 3, 2005), <http://www.cdc.gov/ncidod/sars/factsheet.htm>. In the United States, only eight people were diagnosed with SARS, but the Centers for Disease Control continue to work with other federal agencies and state and local health departments to plan for the rapid recognition of person-to-person transmission of SARS. *See id.* In addition, the terrorist attacks on September 11, 2001, anthrax exposures, and Hurricane Katrina have put possible health emergencies at the forefront of government concerns. *See* Sharona Hoffman, *Responders’ Responsibility: Liability and Immunity in Public Health Emergencies*, 96 GEO. L.J. 1913, 1916 (2008).

<sup>2</sup> Robin B. McFee, *Global Infections—Avian Influenza and Other Significant Emerging Pathogens: An Overview*, 53 DISEASE-A-MONTH 343, 343 (2007).

<sup>3</sup> *Swine Flu (H1N1 Virus)*, N.Y. TIMES (Jan. 4, 2010), <http://www.nytimes.com/info/swine-flu-h1n1-vaccine>.

<sup>4</sup> *Updated CDC Estimates of 2009 H1N1 Influenza Cases, Hospitalizations and Deaths in the United States, April 2009–April 10, 2010*, CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP’T HEALTH & HUMAN SERVS., [http://www.cdc.gov/h1n1flu/pdf/CDC\\_2009\\_H1N1\\_Est\\_PDF\\_May\\_4\\_10\\_fulltext.pdf](http://www.cdc.gov/h1n1flu/pdf/CDC_2009_H1N1_Est_PDF_May_4_10_fulltext.pdf) (last visited Oct. 15, 2011).

<sup>5</sup> EXEC. OFFICE OF THE PRESIDENT, REPORT TO THE PRESIDENT ON U.S. PREPARATIONS FOR 2009-H1N1 INFLUENZA, at viii (2009), available at [http://www.whitehouse.gov/assets/documents/PCAST\\_H1N1\\_Report.pdf](http://www.whitehouse.gov/assets/documents/PCAST_H1N1_Report.pdf).

fluenza epidemic.<sup>6</sup> In such a scenario, the public will depend on physicians to serve the millions of patients needing medical care.<sup>7</sup>

Private physicians, however, may hesitate to provide unconditional service during a public health emergency because of the legal and personal risks this service entails. It is difficult to predict how physicians, the majority of whom lack training for such situations, would respond amidst the chaos of a hospital beyond its “surge capacity.”<sup>8</sup>

During a public health emergency, physicians face ethical situations uncommon in daily practice.<sup>9</sup> If a physician decides to administer a new vaccine and a patient dies from an adverse reaction to that vaccine, should the physician be subject to civil liability? If a physician refuses to treat a quarantined patient because he does not want to expose his children to a pathogen, should that physician be held liable for malpractice? The United States has yet to face a modern pandemic; thus, there is no direct case law to provide answers to these questions. Instead, policymakers must consider society’s expectations of physicians, injured persons’ need for redress, and the government’s need to efficiently respond to public health emergencies.

Surprisingly, despite legislatures’ recent efforts to promote emergency preparedness at the state and federal levels, they have not provided a clear answer regarding a private physician’s duties during a public health emergency. During a crisis, the government can invoke emergency laws that promote efficient responses to public need at both the state and federal levels. These emergency laws significantly alter the legal landscape and provide liability protection for emergency responders by giving them civil immunity for conduct that does not constitute willful misconduct or gross negligence. Recent analyses by Professors Sharona Hoffman and James G.

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<sup>6</sup> Anthony S. Fauci, *Infectious Diseases: Considerations for the 21st Century*, 32 CLINICAL INFECTIOUS DISEASES 675, 677 (2001). The last great influenza pandemic that significantly affected the United States was the 1918 Spanish Influenza. In the United States alone, over 500,000 people died and almost one third of all Americans were infected. B. Kurt Copper, Comment, “High and Dry?” *The Public Readiness and Emergency Preparedness Act and Liability Protection for Pharmaceutical Manufacturers*, J. HEALTH L., Winter 2007, at 65, 83. The medical literature debates whether future pandemics will similarly affect the population, but the 1918 Spanish Influenza illustrates the importance of emergency preparedness. *Id.* at 84.

<sup>7</sup> See James G. Hodge, Jr., Lance A. Gable & Stephanie H. Cálves, *The Legal Framework for Meeting Surge Capacity Through the Use of Volunteer Health Professionals During Public Health Emergencies and Other Disasters*, 22 J. CONTEMP. HEALTH L. & POL’Y 5, 7–8 (2005) (emphasizing the importance of having public health and medical systems that are prepared to increase surge capacity, especially during large-scale emergencies).

<sup>8</sup> “Surge capacity” refers to a “health care system’s ability to expand quickly beyond normal services to meet an increased demand for medical care in the event of bioterrorism or other large-scale public health emergencies.” AGENCY FOR HEALTH CARE RESEARCH AND QUALITY, PUB. NO. 06-0027, BIOTERRORISM AND HEALTH SYSTEM PREPAREDNESS: ADDRESSING SURGE CAPACITY IN A MASS CASUALTY EVENT I (2006), available at <http://archive.ahrq.gov/news/ulp/btbriefs/btbrief9.pdf>.

<sup>9</sup> See Gregory R. Ciottono, *Introduction to Disaster Medicine*, in DISASTER MEDICINE 3, 5–6 (Gregory R. Ciottono et al. eds., 2006).

Hodge show, however, that there are significant gaps in the liability protection provided by health emergency laws, particularly for private physicians.<sup>10</sup> These gray areas of liability coverage make it necessary to analyze how and when traditional tort law applies during a public health emergency in the absence of clear statutory or regulatory suspension.<sup>11</sup>

This Comment contributes to the analysis by offering novel common law-based defense theories to protect private physicians from civil liability during a public health emergency where legislative protection remains inadequate. Part I summarizes existing emergency laws and the extent to which they provide liability protection for emergency responders. Part II argues that private physicians should be given limited immunity during a public health emergency and details Professor Hoffman's proposed legislative reform. In the absence of legislative reform, however, judicial outcomes will play a vital role in shaping physicians' incentives. Part III examines whether traditional tort doctrines, such as Good Samaritan immunity and applicable standards of care, are consistent with the proposal of limited physician liability during public health emergencies. This Part concludes that the foundation for physician immunity during public health emergencies already exists in state common law precedents. Thus, even in the absence of coverage by emergency statutes, private physicians may still be afforded protection from civil liability. Part IV discusses federal preemption and compensation funds to demonstrate the need for coordination between state and federal governments to provide comprehensive liability protection for emergency responders.

## I. THE EXISTING IMMUNITY LANDSCAPE DURING A DECLARED PUBLIC HEALTH EMERGENCY

### A. *What Is a Public Health Emergency?*

From the outset, it is important to distinguish public health emergencies from other types of emergencies or disasters. Many definitions exist in the medical and public health literature, but in general public health emergencies are distinguished by both their potential impact on the mortality of the affected population and their impact on local infrastructure.<sup>12</sup> For example, the Model State Emergency Health Powers Act (MSEHPA), prom-

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<sup>10</sup> E.g., Hodge, Gable & Cálves, *supra* note 7, at 10 (analyzing the uncertain legal environment that volunteer health professionals face during emergencies); Hoffman, *supra* note 1, at 1953–55 (discussing the exclusion of paid responders and nongovernmental entities from immunity coverage).

<sup>11</sup> See James G. Hodge, Jr. & Evan D. Anderson, *Principles and Practice of Legal Triage During Public Health Emergencies*, 64 N.Y.U. ANN. SURV. AM. L. 249, 255 (2008) (“Legal practitioners and others who focus only on emergency-specific laws during actual emergencies may fail to appreciate the ongoing role of non-emergency laws during crises.”).

<sup>12</sup> See, e.g., Hoffman, *supra* note 1, at 1918–19 (defining a public health emergency pursuant to the Model State Emergency Health Powers Act).

ulgated in part by the Centers for Disease Control (CDC), defines a public health emergency as the occurrence or imminent threat of an illness or health condition that:

- (1) is believed to be caused by any of the following:
  - (i) bioterrorism;
  - (ii) the appearance of a novel, or previously controlled or eradicated infectious agent or biological toxin;
  - (iii) [*a natural disaster*;]
  - (iv) [*a chemical attack or accidental release*; or]
  - (v) [*a nuclear attack or accident*]; and
- (2) poses a high probability of any of the following harms:
  - (i) a large number of deaths in the affected population;
  - (ii) a large number of serious or long-term disabilities in the affected population; or
  - (iii) 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>13</sup>

Under this definition, the key factor in defining a public health emergency is its impact on the morbidity and mortality of the affected population.<sup>14</sup> The definition does not turn on how the health condition arises.<sup>15</sup> Thus a hurricane, while not innately health related, may constitute a public health emergency because of its collateral effects.<sup>16</sup> In contrast, events that occur on a localized scale, such as a community shooting, will likely not be a public health emergency, even though they may be considered a terrorist attack against the country.<sup>17</sup>

A public health emergency is also defined by its impact on the infrastructure of the affected area.<sup>18</sup> A public health emergency overwhelms the

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<sup>13</sup> MODEL STATE EMERGENCY HEALTH POWERS ACT 11, § 104(m) (Ctr. for Law & the Pub.'s Health at Georgetown & Johns Hopkins Univs., Draft for Discussion 2001) [hereinafter MSEHPA], available at <http://www.publichealthlaw.net/MSEHPA/MSEHPA.pdf>.

<sup>14</sup> JAMES G. HODGE, JR. & LAWRENCE O. GOSTIN, THE MODEL STATE EMERGENCY HEALTH POWERS ACT—A BRIEF COMMENTARY 18 (2002), available at <http://www.publichealthlaw.net/MSEHPA/Center%20MSEHPA%20Commentary.pdf>.

<sup>15</sup> *Id.*

<sup>16</sup> See, e.g., HHS Secretary Extends Public Health Emergency for States Affected by Hurricane Katrina, U.S. DEP'T HEALTH & HUMAN SERVS. (Dec. 1, 2005), <http://archive.hhs.gov/news/press/2005pres/20051201a.html>.

<sup>17</sup> For example, the Fort Hood shooting in November 2009 “severely taxed local hospitals” and resulted in several deaths. Nadia Taha, *Shooting Victims Flood Local Hospitals*, N.Y. TIMES (Nov. 5, 2009), <http://www.nytimes.com/2009/11/06/us/06victims.html>. Although the shooting was suspected of being a terrorist attack, see Richard Esposito, Matthew Cole & Brian Ross, *Officials: U.S. Army Told of Hasan's Contacts with al Qaeda*, ABC NEWS (Nov. 9, 2009), <http://abcnews.go.com/Blotter/fort-hood-shooter-contact-al-qaeda-terrorists-officials/story?id=9030873>, the Fort Hood event was not declared a public health emergency.

<sup>18</sup> See Hoffman, *supra* note 1, at 1917–18.

local health care system and requires the community to seek outside support and resources.<sup>19</sup> This aspect of a public health emergency is consistent with official definitions used by practitioners of disaster medicine. The World Health Organization defines a disaster as “a sudden ecological phenomenon of sufficient magnitude to require external assistance.”<sup>20</sup> Similarly, the United Nations’ International Strategy for Disaster Reduction defines a disaster as “a serious disruption of the functioning of a community or a society causing widespread human, material, economic or environmental losses that exceed the ability of the affected community or society to cope using its own resources.”<sup>21</sup>

Although the medical literature attempts to define a public health emergency, it is generally recognized that health care providers and policymakers “know a disaster when they see one.”<sup>22</sup> In the face of disaster conditions, the President, the Secretary of the U.S. Department of Health and Human Services (HHS), state governors, and sometimes local officials have the authority to declare a state of emergency.<sup>23</sup> As discussed in the next section, an emergency declaration triggers state and federal emergency laws that give particular government actors special powers,<sup>24</sup> suspend burdensome statutory or regulatory requirements,<sup>25</sup> and provide some emergency responders with limited protection from civil liability.<sup>26</sup>

#### *B. Federal Emergency Laws and Federal Protection of Public Entities*

Most federal emergency powers are embodied in the Stafford Act.<sup>27</sup> This Act creates a system to provide federal aid to states affected by major disasters or emergencies.<sup>28</sup> The President invokes its provisions when he declares a state of emergency or a major disaster.<sup>29</sup> The Act defines a state

<sup>19</sup> See *id.* at 1918.

<sup>20</sup> David E. Hogan & Jonathan L. Burstein, *Basic Perspectives on Disaster*, in *DISASTER MEDICINE* 1, 2 (David E. Hogan & Jonathan L. Burstein eds., 2d ed. 2007).

<sup>21</sup> Mark E. Keim, *Environmental Disasters*, in *ENVIRONMENTAL HEALTH: FROM GLOBAL TO LOCAL* 843, 844 (Howard Frumkin ed., 2d ed. 2010).

<sup>22</sup> Hogan & Burstein, *supra* note 20, at 2.

<sup>23</sup> Hoffman, *supra* note 1, at 1921.

<sup>24</sup> *E.g.*, Public Health Service Act, 42 U.S.C. § 247d(a) (2006) (granting the HHS Secretary the power to make grants, enter into contracts, and investigate the cause and prevention of disease); Stafford Act, 42 U.S.C. § 5121.

<sup>25</sup> *E.g.*, Project BioShield Act of 2004, Pub. L. No. 108-276, sec. 4(a), § 564(a)(1)–(2), 118 Stat. 835, 853 (amending the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3 (2006)) (allowing the HHS Secretary to expedite procedures for FDA approval of emergency countermeasures during a public health emergency).

<sup>26</sup> *E.g.*, Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d (providing partial civil immunity to entities in the chain of distribution for approved emergency countermeasures); see also *infra* notes 87–93 (providing a full discussion of the Act).

<sup>27</sup> See Stafford Act, 42 U.S.C. §§ 5121–5202.

<sup>28</sup> *Id.* § 5121(b).

<sup>29</sup> *Id.* § 5122(1)–(2).

of emergency as any situation where “[f]ederal assistance is needed to supplement State and local efforts and capabilities to save lives and to protect property and public health and safety, or to lessen or avert the threat of a catastrophe.”<sup>30</sup> The President can also declare a major disaster when an emergency “causes damage of sufficient severity and magnitude to warrant major disaster assistance” beyond typical emergency services.<sup>31</sup>

On March 31, 1979, President Carter issued Executive Order 12,127, which consolidated federal emergency response authority under the Federal Emergency Management Agency (FEMA).<sup>32</sup> FEMA is responsible for directing and coordinating all disaster-related assistance.<sup>33</sup> FEMA instituted federal emergency plans in the 1980s to create a framework and common language within which disaster agencies at the local, regional, and national level could communicate.<sup>34</sup> FEMA also assisted in the creation of the National Disaster Medical System (NDMS),<sup>35</sup> which is a partnership of “four federal agencies (HHS, FEMA, and the Departments of Defense and Veterans Affairs), state and local governments, and the private sector.”<sup>36</sup> NDMS consists of volunteer health professionals divided into teams, each of which focuses on a particular area of disaster relief.<sup>37</sup> These teams can be rapidly deployed to areas of need during an emergency.<sup>38</sup>

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<sup>30</sup> *Id.* § 5122(1).

<sup>31</sup> *Id.* § 5122(2). “Emergencies” tend to be smaller events where the federal government may only need to play a limited role whereas “disasters” require more direct involvement by the federal government. For example, on August 27, 2010, President Bush declared a state of emergency in Louisiana because of Hurricane Katrina. *Emergency Aid Authorized for Hurricane Katrina Emergency Response in Louisiana*, FED. EMERGENCY MGMT. AGENCY (Aug. 27, 2005), <http://www.fema.gov/news/newsrelease.fema?id=18447>. The emergency declaration required FEMA to supplement state and local emergency measures by providing equipment to meet immediate lifesaving needs and protect property. *Id.* The emergency declaration also provided that state and local officials would be reimbursed for 75% of their costs of emergency measures. *Id.* As the magnitude of the effects of Hurricane Katrina became clearer, however, President Bush declared major disasters in several states including Florida, Mississippi, Alabama, and Louisiana. These declarations allowed FEMA to assist in debris removal, oversee evacuation procedures, and provide temporary housing. For a limited time, the major disaster declaration also supplied federal funding for 100% of emergency-related costs. *President Declares Major Disaster for Mississippi*, FED. EMERGENCY MGMT. AGENCY (Aug. 29, 2005), <http://www.fema.gov/news/newsrelease.fema?id=18474>.

<sup>32</sup> Exec. Order No. 12,127, 3 C.F.R. 376 (1980); David W. Callaway, *Emergency Medical Services in Disasters*, in *DISASTER MEDICINE*, *supra* note 20, at 127, 128.

<sup>33</sup> See 44 C.F.R. § 206.1 (2009).

<sup>34</sup> See Callaway, *supra* note 32, at 128.

<sup>35</sup> *Id.*

<sup>36</sup> KEITH BEA, CONG. RESEARCH SERV., RS22023, ORGANIZATION AND MISSION OF THE EMERGENCY PREPAREDNESS AND RESPONSE DIRECTORATE: ISSUES DURING THE 109TH CONGRESS 3 (2005), available at [www.ndu.edu/library/docs/crs/crs\\_rs22023\\_11jan05.pdf](http://www.ndu.edu/library/docs/crs/crs_rs22023_11jan05.pdf).

<sup>37</sup> *National Disaster Medical System*, U.S. DEP’T OF HEALTH & HUMAN SERVS., <http://www.phe.gov/preparedness/responders/ndms> (last visited Oct. 15, 2011); *National Disaster Medical System (NDMS) Response Teams*, U.S. DEP’T OF HEALTH & HUMAN SERVS., <http://www.phe.gov/Preparedness/responders/ndms/teams> (last visited Oct. 15, 2011) (providing links to the various NDMS

During a public health emergency, the HHS Secretary has broad discretion to make grants, enter into contracts, and conduct investigations into the cause and prevention of disease.<sup>39</sup> Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the HHS Secretary has authority to activate the NDMS.<sup>40</sup> The HHS Secretary can even waive or modify certain legal requirements that apply to health care providers and manufacturers of medical products.<sup>41</sup> This broad authority facilitates expeditious responses to emergencies.

Despite federal statutes purporting to provide for expansive judicial review and government liability, government entities (such as FEMA) and their employees enjoy extensive protection from civil liability that may arise during a public health crisis. Under the Administrative Procedure Act,<sup>42</sup> “a person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action . . . is entitled to judicial review”<sup>43</sup> “except to the extent that . . . statutes preclude judicial review.”<sup>44</sup> Generally, under the Federal Tort Claims Act (FTCA), a federal agency can be held liable in the same circumstances as a private person in accordance with state law.<sup>45</sup> However, agency actions during a state of emergency may fall under the FTCA’s “discretionary function” exception, which immunizes government actors for actions taken under duties for which they possess discretion<sup>46</sup> or analogous exceptions contained in emergency statutes. For example, like the FTCA, the Stafford Act explicitly limits the United States’ liability by providing that “[t]he Federal Government shall not be liable for any claim based upon the exercise or performance of or the failure to exercise or perform a discretionary function or duty.”<sup>47</sup> The analysis of whether an agency’s actions are discretionary and therefore excepted from

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team services, including general medical services, international surgical assistance, veterinarian support, and victim identification expertise).

<sup>38</sup> BEA, *supra* note 36, at 3.

<sup>39</sup> Public Health Service Act, 42 U.S.C. § 247d(a) (2006).

<sup>40</sup> 42 U.S.C. § 300hh-11.

<sup>41</sup> For example, the Emergency Medical Treatment and Labor Act requires a hospital to evaluate all individuals who come to the hospital’s emergency department. *See* 42 U.S.C. § 1395dd(a). The HHS Secretary may also temporarily waive this requirement during a public health emergency. 42 U.S.C. § 1320b-5(b)(3).

<sup>42</sup> 5 U.S.C. §§ 551–559, 701–706 (2006).

<sup>43</sup> *Id.* § 702.

<sup>44</sup> *Id.* § 701(a).

<sup>45</sup> 28 U.S.C. §§ 2671–2672 (2006).

<sup>46</sup> *See id.* § 2680(a) (excusing agencies and their employees from civil liability for “[a]ny claim based upon . . . the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government”); *see also* United States v. Gaubert, 499 U.S. 315, 322–24 (1991) (describing cases in which the FTCA’s “discretionary function” exception operated to excuse government agents’ negligence because the government entrusted them with judgment in specific capacities).

<sup>47</sup> 42 U.S.C. § 5148 (2006).

liability under the Stafford Act is synonymous with that under the FTCA.<sup>48</sup> When confronting the question of whether the agency's actions during an emergency situation were discretionary in nature, courts are typically reluctant to hold U.S. agencies and employees liable.<sup>49</sup> Courts recognize the need to allow the government latitude when implementing measures to relieve human suffering and economic damage in a disaster situation.<sup>50</sup>

At the individual level, government emergency responders are protected by qualified civil immunity. This doctrine protects "government officials performing discretionary functions" when "their conduct does not violate clearly established statutory or constitutional rights of which a reasonable person would have known."<sup>51</sup> Thus, as long as the emergency responder's actions in a public health crisis fall within a reasonable range, liability will not attach. Qualified immunity extends not only to public health officials but also to private individuals deputized by the HHS Secretary to assist in emergency response efforts.<sup>52</sup> For example, people performing medical, surgical, or related functions for the NDMS, even on an intermittent basis, are classified as "federal employees" and are thus entitled to qualified immunity.<sup>53</sup>

### C. Federal Protection for Private Entities Responding to Public Health Disasters

Federal emergency laws provide protection not only for public entities but also for some purely private entities including drug manufacturers.

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<sup>48</sup> See *Sunrise Vill. Mobile Home Park, L.C. v. United States*, 42 Fed. Cl. 392, 397–98 (1998) (describing the FTCA's and the Stafford Act's "discretionary function" exceptions as "analogous and similarly stated"); *Dureiko v. Phillips & Jordon Inc.*, No. 95-1441, 1996 WL 825402, at \*1–2 (S.D. Fla. Apr. 29, 1996) (describing the two exceptions as "virtually identical").

<sup>49</sup> See, e.g., *Sunrise Vill.*, 42 Fed. Cl. at 397–400 (noting that the legislative history of the Stafford Act makes clear the public policy purpose of the "discretionary" exception); see also 96 CONG. REC. 11,912 (1950) (statement of Rep. William M. Whittington) ("[I]f the agencies of the Government make a mistake in the administration of the [Stafford] Act . . . the Government may not be sued.").

<sup>50</sup> See, e.g., *Sunrise Vill.*, 42 Fed. Cl. at 397–98 (noting that Congress designed special measures to assist states affected by emergencies "because disasters often cause loss of life, human suffering, loss of income, and property loss and damage; and . . . because disasters often disrupt the normal functioning of governments and communities, and adversely affect individuals and families with great severity" (omission in original) (quoting 42 U.S.C. § 5121(a))).

<sup>51</sup> *Harlow v. Fitzgerald*, 457 U.S. 800, 818 (1982).

<sup>52</sup> See Abigail Williams, *Liability Issues in Emergency Response*, in *DISASTER MEDICINE*, *supra* note 9, at 71, 76–77; see also *Bartell v. Lohiser*, 215 F.3d 550, 556–59 (6th Cir. 2000) (holding that a private foster care contractor and its private social workers could assert qualified immunity because of their close association with and supervision by governmental agencies). See generally 42 U.S.C. § 300hh-11(c) (giving authority to the HHS secretary to deputize individuals assisting in the development of emergency countermeasures as Federal Public Health Service employees).

<sup>53</sup> See 42 U.S.C. § 300hh-11(c)(2) (stating that, with respect to liability, the individuals appointed pursuant to 42 U.S.C. § 300hh-11(d)(1) as part of the NDMS are employees of the Public Health Service); Williams, *supra* note 52, at 77 (describing the application of qualified immunity statutes to government responders during disasters).

Federal immunity provisions for manufacturers emerged in the beginning of the 1960s as the result of conflicts between state tort law and national public health policies. Since then, Congress has passed numerous federal statutes providing broad liability protection for medical product manufacturers.

1. *The Historical Tension Between Tort Law and Public Health Policies.*—For much of recent history, the goals of tort law and government public health policy have coexisted in an uneasy tension. In particular, the rise of strict liability during the 1960s threatened the government’s ability to respond to public health threats. As a result, in the last fifty years, the federal government has passed several pieces of legislation to respond to state-imposed liability on manufacturers of emergency countermeasures.

During the 1950s and 1960s, the federal government attempted to eradicate polio through mass administration of polio vaccines.<sup>54</sup> One of the types of the polio vaccine contained live polio virus, which made the vaccine more effective but may also have caused several people to contract polio.<sup>55</sup>

Before the 1960s, the “learned intermediary”<sup>56</sup> doctrine provided an almost absolute defense in personal injury suits for vaccine manufacturers.<sup>57</sup> Under this doctrine, a manufacturer does not need to warn the patient of the risks associated with the product so long as they warn the patient’s prescribing physician.<sup>58</sup> The theory behind the learned intermediary doctrine is that the physician is not a “mere conduit of the product” but instead “exercise[s] ‘independent discretion and judgment’ in weighing the benefits of the manufacturer’s product” for the patient.<sup>59</sup> Other justifications for the doctrine include the impracticability of communication between the manufacturer and the patient and the reluctance to interfere with the traditional doctor–patient relationship.<sup>60</sup>

In the groundbreaking 1968 case *Davis v. Wyeth Laboratories, Inc.*, the Ninth Circuit held the learned intermediary doctrine inapplicable when a

<sup>54</sup> See *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1269–70 (5th Cir. 1974) (attributing the precipitous drop in cases of polio to, among other things, a massive federal immunization program).

<sup>55</sup> *Id.* at 1273–74.

<sup>56</sup> The term “learned intermediary” was first used in *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966). James Ottavio Castagnera & Richard Ryan Gerner, *The Gradual Enfeeblement of the Learned Intermediary Rule and the Argument in Favor of Abandoning It Entirely*, 36 TORT & INS. L.J. 119, 120 n.4 (2000).

<sup>57</sup> Castagnera & Gerner, *supra* note 56, at 122.

<sup>58</sup> Kathy A. King-Cameron, Comment, *Carving Another Exception to the Learned Intermediary Doctrine: Application of the Learned Intermediary Doctrine in Silicone Breast Implant Litigation*, 68 TUL. L. REV. 937, 942–43 (1994).

<sup>59</sup> *Id.* at 943 (quoting Paul D. Rheingold, *Products Liability—The Ethical Drug Manufacturer’s Liability*, 18 RUTGERS L. REV. 947, 986 (1964)).

<sup>60</sup> See *id.* at 944–45.

vaccine was distributed freely through clinics and not through prescription.<sup>61</sup> The court looked to section 402A of the *Second Restatement of Torts*<sup>62</sup> and the accompanying comment k.<sup>63</sup> Comment k encompasses unavoidably unsafe products, providing that strict liability shall not be applied to such products so long as they were properly prepared and marketed.<sup>64</sup> The *Davis* court found that the manufacturer's failure to warn consumers of the risks of the polio vaccine made the vaccine "unreasonably dangerous."<sup>65</sup> Thus, the court held the manufacturer strictly liable for injuries resulting from the vaccine.<sup>66</sup> Six years later, the Fifth Circuit reaffirmed the Ninth Circuit's *Davis* ruling in *Reyes v. Wyeth Laboratories*.<sup>67</sup>

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<sup>61</sup> 399 F.2d 121, 130–31 (9th Cir. 1968).

<sup>62</sup> The *Restatement* provides:

Special Liability of Seller of Product for Physical Harm to User or Consumer:

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
  - (a) the seller is engaged in the business of selling such a product, and
  - (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
- (2) The rule stated in Subsection (1) applies although
  - (a) the seller has exercised all possible care in the preparation and sale of his product, and
  - (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

RESTATEMENT (SECOND) OF TORTS § 402A (1965).

<sup>63</sup> Comment k to § 402A provides:

*Unavoidably Unsafe Products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

*Id.* at cmt. k.

<sup>64</sup> *Id.*

<sup>65</sup> *Davis*, 399 F.2d at 128–30.

<sup>66</sup> *Id.* at 130.

<sup>67</sup> 498 F.2d 1264, 1272–76 (5th Cir. 1974) (stating that although the vaccine—the same one at issue in *Davis*—was not “unreasonably dangerous per se” because the benefits of the vaccine outweighed the potential harm, the vaccine was unreasonably dangerous as marketed because it failed to adequately warn vaccine patients of the possibility of contracting polio).

*Reyes* and *Davis* opened the floodgates for suits against vaccine manufacturers. Numerous plaintiffs successfully litigated against pharmaceutical companies for vaccine-related injuries.<sup>68</sup> Between 1980 and 1984, plaintiffs sought \$3.5 billion in damages from vaccine manufacturers.<sup>69</sup> Many manufacturers fled the market, and those who continued manufacturing vaccines significantly increased prices and thus passed on the costs of litigation to consumers.<sup>70</sup> The resulting “public health disaster” spurred Congress to pass legislation addressing the liability crisis in the vaccine industry.<sup>71</sup>

2. *Federal Statutory Protections for Manufacturers of Covered Countermeasures.*—Beginning in the 1970s, Congress enacted several statutes to protect manufacturers from the imposition of liability by state courts. In 1976, New Jersey experienced an outbreak of a novel strain of influenza at Fort Dix.<sup>72</sup> The government feared a large-scale pandemic and began working on a mass immunization program against the Fort Dix flu (later dubbed the “swine flu”).<sup>73</sup> The program stalled, however, when pharmaceutical manufacturers and their insurers became reluctant to participate in the program due to the burden of liability for vaccine-related injuries.<sup>74</sup>

In response to growing public panic over a possible influenza pandemic, Congress passed the National Swine Flu Immunization Program of 1976,<sup>75</sup> which provided an exclusive remedy against the government for injuries resulting from the vaccine.<sup>76</sup> In 1977, Professor Marshall Shapo ana-

<sup>68</sup> See Robert M. McKenna, Comment, *The Impact of Product Liability Law on the Development of a Vaccine Against the AIDS Virus*, 55 U. CHI. L. REV. 943, 954–55 (1988).

<sup>69</sup> Erik Volker Ernst Eisele, Comment, *A Dose of Reality: Revisiting Pharmaceutical Manufacturer Liability for an HIV Vaccine*, 30 HOUS. J. INT’L L. 703, 712–13 (2008).

<sup>70</sup> *Id.* at 713.

<sup>71</sup> *Id.* (describing the enactment of the National Childhood Vaccine Injury Act of 1986, “a national no-fault compensation scheme for victims of certain vaccine-related injuries”).

<sup>72</sup> Marshall S. Shapo, *Swine Flu and Legal Policy*, A.B.A. J., Jan. 1977, at 51, 51.

<sup>73</sup> *Id.* The nickname “swine flu” arose from scientific evidence that the Fort Dix flu was similar to strains of influenza that circulate in pigs. Taia T. Wang & Peter Palese, *Unraveling the Mystery of Swine Influenza Virus*, 137 CELL 983, 983 (2009).

<sup>74</sup> Shapo, *supra* note 72, at 51–52 (“[T]here arose some political issues that threatened the program. These stemmed from the fears of vaccine manufacturers concerning their potential exposure to liability for personal injuries that might occur to those who subjected themselves to immunization.”); see also Marc A. Franklin & Joseph E. Mais, Jr., *Tort Law and Mass Immunization Programs: Lessons from the Polio and Flu Episodes*, 65 CALIF. L. REV. 754, 769 (1977) (“The imposition of liability in *Reyes* and in other polio cases and the uncertainty surrounding the basis for liability in these cases made insurance companies reluctant to underwrite a national flu immunization program.” (footnote omitted)).

<sup>75</sup> Pub. L. No. 94-380, § 2, 90 Stat. 1113 (amending Public Health Service Act, 42 U.S.C. § 247b) (codified at 42 U.S.C. § 201 (2006)).

<sup>76</sup> See *id.* at 1115 (“The United States shall be liable with respect to claims submitted after September 30, 1976 for personal injury or death arising out of the administration of swine flu vaccine under the swine flu program and based upon the act or omission of a program participant . . .”); *In re Swine Flu Immunization Prods. Liab. Litig.*, 89 F.R.D. 695, 699 (D.D.C. 1981) (“Under the Act, the United States

lyzed the government's novel approach to the Fort Dix flu, including its decision to compensate patients for physical harms resulting from the vaccine program and its assumption of a general duty to protect the public from a pandemic.<sup>77</sup> Although these decisions were controversial in the 1970s, the federal government continues to adhere to the policy underlying these decisions in promulgating other public health emergency statutes and programs. The National Swine Flu Immunization Program became the foundation for future government compensation funds covering injuries resulting from national public health measures.

In 1986, Congress passed the National Childhood Vaccine Injury Act (NCVIA).<sup>78</sup> The liability protection for manufacturers under NCVIA is not as comprehensive as that under the National Swine Flu Immunization Program. Nonetheless, NCVIA requires that individuals adjudicate claims over \$1000 through the Vaccine Injury Compensation Program before filing a civil claim.<sup>79</sup> The NCVIA creates a federal no-fault system for compensating vaccine-related injuries and deaths through a procedure involving the U.S. Court of Federal Claims and its special masters.<sup>80</sup> After NCVIA's passage, the national vaccine stockpile stabilized; nonetheless, manufacturers continue to avoid the market because of the low profit margin in vaccines.<sup>81</sup>

After the events of September 11, 2001, public health became an issue of national security. Congress thus passed the Project BioShield Act of 2004 to facilitate the development of countermeasures against possible terrorist attacks.<sup>82</sup> The Act streamlined the research and FDA approval of drugs, devices, and other products deemed to be priorities during public health emergencies.<sup>83</sup> For example, the HHS Secretary may expedite the peer review process for scientific research.<sup>84</sup> She also has the authority to

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accepted primary responsibility for injuries caused by the manufacture, distribution, or administration of this swine flu vaccine.”).

<sup>77</sup> See Shapo, *supra* note 72, at 53–54.

<sup>78</sup> Pub. L. No. 99-660, § 311(a), 100 Stat. 3755, 3756 (codified at 42 U.S.C. §§ 300aa-1 to 300aa-34).

<sup>79</sup> 42 U.S.C. § 300aa-11(a)(2)(A)–(3).

<sup>80</sup> See *id.* § 300aa-12; see also *McDonald v. Lederle Labs.*, 775 A.2d 528, 529 (N.J. Super. Ct. App. Div. 2001) (“[T]he Act bars an individual, who files an untimely petition, from later seeking recovery for injuries resulting from an adverse reaction to vaccination in a subsequently filed State civil action.”).

<sup>81</sup> Copper, *supra* note 6, at 74–75.

<sup>82</sup> See Pub. L. No. 108-276, 118 Stat. 835 (codified in scattered sections of 42 U.S.C.) (amending the Public Health Service Act to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States).

<sup>83</sup> 42 U.S.C. § 247d-6a(a)–(c).

<sup>84</sup> *Id.* § 247d-6a(c)(1) (“The Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, employ such expedited peer review procedures (including consultation with appropriate scientific experts) as the Secretary, in consultation with the Director of [the National Institutes of Health], deems appropriate to obtain assessment of scientific and technical merit and likely contribution to the field of qualified countermea-

approve a product for emergency use even if it has not been previously approved for commercial distribution or for the particular use that she is promoting.<sup>85</sup> In addition, individuals developing countermeasures under a government contract are considered federal employees of the HHS and are therefore entitled to qualified immunity from tort suits stemming from their work.<sup>86</sup>

The Public Readiness and Emergency Preparedness Act (PREPA)<sup>87</sup> is the most sweeping emergency law passed after September 11, 2001. It encourages the development of vaccines and other countermeasures to address potential public health emergencies.<sup>88</sup> PREPA gives almost unlimited authority to the HHS Secretary to declare a medical product a “covered countermeasure.”<sup>89</sup> Once a product is declared a “covered countermeasure,” “covered person[s]” along the chain of distribution have limited immunity under federal and state law “with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.”<sup>90</sup> A “covered person” under the statute may be a person or an entity that manufactures or distributes the countermeasure.<sup>91</sup> Someone qualified to administer or prescribe the countermeasure may also be covered.<sup>92</sup> The statute, however, does not grant immunity from liability for an injury caused by the willful misconduct of covered persons.<sup>93</sup>

Individuals injured by a product approved for emergency use under PREPA can recover from the Covered Countermeasure Process Fund.<sup>94</sup>

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sure research, in place of the peer review and advisory council review procedures that would [otherwise] be required . . .”).

<sup>85</sup> 21 U.S.C. § 360bbb-3(a)(1)–(2) (2006).

<sup>86</sup> 42 U.S.C. § 247d-6a(d)(2)(A) (“A person carrying out a contract under paragraph (1), and an officer, employee, or governing board member of such person, shall, subject to a determination by the Secretary, be deemed to be an employee of the Department of Health and Human Services for purposes of claims under sections 1346(b) and 2672 of title 28 for money damages for personal injury, including death, resulting from performance of functions under such contract.”).

<sup>87</sup> Pub. L. No. 109-148, 119 Stat. 2818 (2005) (codified as amended at 42 U.S.C. §§ 247d-6d to -6e).

<sup>88</sup> See 42 U.S.C. §§ 247d-6d to -6e; Copper, *supra* note 6, at 66–67 (“PREPA represents another attempt by Congress to respond to the widespread concerns of disease outbreak in this era of bioterrorism by shielding pharmaceutical manufacturers from liability for injuries caused by countermeasures employed to combat a public health emergency.”).

<sup>89</sup> See 42 U.S.C. § 247d-6d(b)(1). A covered countermeasure is defined as one of the following: a “qualified pandemic or epidemic product”; a “security countermeasure”; or “a drug . . . , biological product . . . , or device . . . that is authorized for emergency use in accordance with . . . the Federal Food, Drug and Cosmetic Act. *Id.* § 247d-6d(i)(1)(C).

<sup>90</sup> *Id.* § 247d-6d(a)(1).

<sup>91</sup> *Id.* § 247d-6d(i)(2)(B)(i)–(ii).

<sup>92</sup> *Id.* § 247d-6d(i)(2)(B)(iv). The statute also provides liability protection for agents and employees of covered persons. *Id.* § 247d-6d(i)(2)(B)(v).

<sup>93</sup> *Id.* § 247d-6d(d)(1).

<sup>94</sup> *Id.* § 247d-6e.

The fund provides compensation for individuals whose injuries are “caused by the administration or use of a covered countermeasure pursuant to [a] declaration” by the HHS Secretary.<sup>95</sup> The HHS Secretary has broad discretion to determine who can receive compensation and the time period during which the injury must manifest.<sup>96</sup> The fund provides compensation for medical benefits, lost employment income, and death benefits,<sup>97</sup> but it does not provide damages for pain and suffering.<sup>98</sup>

3. *Summary of Federal Liability Protection During Public Health Emergencies.*—Federal law provides liability protection for three groups: (1) government entities and employees; (2) private individuals deputized by the HHS Secretary, pursuant to statutory authority, as federal employees; and (3) private manufacturers and distributors of emergency countermeasures.<sup>99</sup> These groups are generally protected from liability for acts that do not amount to willful misconduct, gross negligence, or criminal conduct.<sup>100</sup>

In contrast, private sector physicians, regardless of their vital role in public health and safety, are often ineligible for liability protection under federal emergency laws.<sup>101</sup> The closest federal emergency laws come to providing protection for private health care workers is the immunity provision of PREPA.<sup>102</sup> However, immunity under PREPA requires that the injury result from the use of medical products specifically approved as covered countermeasures.<sup>103</sup> Thus, when private health care workers use something other than a covered countermeasure, they receive no explicit protection from civil liability under federal law.

#### D. State Emergency Laws

Historically, most state statutes did not mandate emergency preparedness specifically for public health emergencies.<sup>104</sup> Public health policies evolved independently within states, which made it difficult to coordinate responses to multijurisdictional public health issues.<sup>105</sup> In the wake of September 11, 2001, and the subsequent anthrax attacks, the CDC pushed for the development of a comprehensive plan for responding to a public health emergency.<sup>106</sup> The Center for Law and the Public’s Health at Georgetown

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<sup>95</sup> *Id.* § 247d-6e(b)(1).

<sup>96</sup> *See id.* § 247d-6e(b)(4)–(5).

<sup>97</sup> *Id.* §§ 239c–239e, 247d-6e(b)(2).

<sup>98</sup> *See id.* §§ 239c–239e, 247d-6e(b)(2).

<sup>99</sup> *See Hoffman, supra* note 1, at 1950–54.

<sup>100</sup> *See id.*

<sup>101</sup> *Id.* at 1953–54.

<sup>102</sup> *See supra* notes 87–98 and accompanying text.

<sup>103</sup> *See supra* notes 90–92 and accompanying text.

<sup>104</sup> *See HODGE & GOSTIN, supra* note 14, at 10–11.

<sup>105</sup> *Id.*

<sup>106</sup> MSEHPA, *supra* note 13, at 6.

and Johns Hopkins Universities, in coordination with the CDC, drafted MSEHPA to help state legislatures develop public health emergency laws.<sup>107</sup> By 2010, thirty-eight states and the District of Columbia had created statutes modeled after provisions in MSEHPA.<sup>108</sup>

The immunity provisions in MSEHPA reflect the extent of liability protection provided in federal emergency laws. The MSEHPA liability section provides immunity for the good faith acts of state officials as long as the acts do not constitute gross negligence or willful misconduct.<sup>109</sup> MSEHPA also provides liability protection for entities contracting with the state under provisions of MSEHPA and for those who render assistance at the request of the state.<sup>110</sup> These provisions, however, are worded more broadly than federal laws granting the HHS Secretary authority to designate individuals as federal employees. For example, to be deputized as a federal employee under the NDMS system an individual must be officially appointed by the HHS Secretary.<sup>111</sup> In contrast, liability protection under MSEHPA requires only a showing that the individual was either directed by the state or that the state requested the individual's advice or assistance.<sup>112</sup> No official appointment is necessary.

A limited number of states provide broader liability protection than MSEHPA. In Maine, for example, private institutions and individuals receive the same immunity protection that state agencies and employees receive during "extreme public health emergenc[ies]."<sup>113</sup> In Louisiana during a public health emergency, any health care provider is immune from liability for causing injury as long as his actions do not constitute willful misconduct or gross negligence.<sup>114</sup>

Some states maintain laws that only address general emergencies.<sup>115</sup> These general emergency laws also provide certain liability protections, which range from broad immunity shielding public and private actors alike to limited immunity protecting only public health providers.<sup>116</sup>

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<sup>107</sup> *Id.* at 1 n.1, 6.

<sup>108</sup> *The Model State Emergency Health Powers Act (MSEHPA)*, CTRS. FOR LAW & PUB.'S HEALTH, <http://www.publichealthlaw.net/ModelLaws/MSEHPA.php> (last modified Jan. 27, 2010); *see, e.g.*, Louisiana Health Emergency Powers Act, LA. REV. STAT. §§ 29:760–772 (2007).

<sup>109</sup> MSEHPA, *supra* note 13, at 37, § 804(a).

<sup>110</sup> *Id.* at 37–38, § 804(b).

<sup>111</sup> 42 U.S.C. § 300hh-11(c) (2006).

<sup>112</sup> *See* MSEHPA, *supra* note 13, at 37–38, § 804(b).

<sup>113</sup> ME. REV. STAT. ANN. tit. 22, § 816(1) (2010).

<sup>114</sup> Louisiana Health Emergency Powers Act, LA. REV. STAT. § 29:771(B)(2)(c) (2007).

<sup>115</sup> Hoffman, *supra* note 1, at 1949–50 (listing California, Michigan, and Minnesota as states with general emergency statutes).

<sup>116</sup> *See, e.g.*, California Emergency Services Act, CAL. GOV'T CODE §§ 8655, 8657, 8659 (West 2005 & Supp. 2011) (providing liability protection for state employees, volunteers, and private health care workers who render services during an emergency); Emergency Management Act, MICH. COMP.

Existing state and federal emergency laws create a nebulous scheme of liability protection for private emergency responders. For example, a physician treating a patient during a Severe Acute Respiratory Syndrome (SARS) outbreak could be sued for malpractice under state common law. But if the virus spreads to other states, the HHS Secretary could respond by declaring a federal public health emergency and thus triggering liability protection for certain emergency responders. The physician could then attempt to argue that he is covered by federal immunity provisions. Courts, however, have not yet addressed whether immunity provisions in federal emergency laws would preempt or otherwise affect state common law claims.<sup>117</sup> Thus, due to the confusing layers of state and federal emergency laws, private emergency responders have no certainty about their legal liabilities during public health emergencies.<sup>118</sup>

## II. EXPANDING LIABILITY PROTECTION FOR PRIVATE PHYSICIANS DURING PUBLIC HEALTH EMERGENCIES

The structure of the U.S. health care system makes private physicians the first group to respond to a public health emergency.<sup>119</sup> Physicians who are not deputized by the government but nonetheless respond to public health emergencies serve the public's interests often at great risk to themselves. Thus, private physicians should be afforded the same liability protection as public health care workers during public health emergencies.

### A. Facilitating Physician Response: Encouragement over Coercion

A public health emergency strains already limited health care resources.<sup>120</sup> In the event of an influenza pandemic, the HHS estimates that hospitalization would increase three to seven times and that there would be a fourfold increase in outpatient visits compared to a normal flu year.<sup>121</sup> In addition, hospitals and physicians may need to establish quarantines to isolate infected individuals from the rest of the patient population.<sup>122</sup> In sum, a public health emergency places extreme pressure on both financial and human resources. To meet the surge in demand for medical services during a

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LAWS ANN. § 30.411 (West Supp. 2011) (providing disaster responders other than state employees with the same immunity as state employees).

<sup>117</sup> See discussion *infra* Part IV.A.

<sup>118</sup> See HODGE & GOSTIN, *supra* note 14, at 10–11.

<sup>119</sup> See Hogan & Burstein, *supra* note 20.

<sup>120</sup> Carl H. Coleman, *Beyond the Call of Duty: Compelling Health Care Professionals to Work During an Influenza Pandemic*, 94 IOWA L. REV. 1, 8 (2008).

<sup>121</sup> Vickie J. Williams, *Fluonomics: Preserving Our Hospital Infrastructure During and After a Pandemic*, 7 YALE J. HEALTH POL'Y L. & ETHICS 99, 109 (2007).

<sup>122</sup> See Coleman, *supra* note 120, at 8 (“Hospitals will also need to find space to treat infected patients and, possibly, to quarantine individuals who are not sick but who may have been exposed to the virus.”).

public health emergency, it is imperative to mobilize as many health care workers and facilities as possible.

Recent examples of health care provider behavior during health emergencies, however, have led experts to question whether private physicians will adequately respond to public need in an emergency.<sup>123</sup> The outbreak of SARS in 2002 had a disproportionate impact on health care workers and infrastructure.<sup>124</sup> In Hong Kong, physicians and nurses accounted for 22% of the SARS deaths.<sup>125</sup> In Taiwan, more than 90% of SARS infections occurred in hospitals, and 160 health care workers chose to resign rather than work with SARS patients.<sup>126</sup> Private health care employees were reluctant to treat SARS patients due to the risk of exposure to the virus, the disruption to their lives resulting from such an exposure, and the accompanying social ostracism.<sup>127</sup>

Physicians and nurses in the United States are unlikely to respond differently than their foreign counterparts.<sup>128</sup> One of the most telling examples of physician reluctance occurred when the AIDS pandemic came to the forefront of national concern in the 1980s. Some doctors turned away AIDS patients after studies revealed that the virus could be transferred through bodily fluids.<sup>129</sup> In its first statement on the AIDS issue, the American Medical Association (AMA) condoned the right to refuse treatment, advising physicians to care for HIV-positive patients only if they were “emotionally able” to do so.<sup>130</sup> Although the AMA reversed its policy on AIDS after substantial criticism,<sup>131</sup> its original statement demonstrates that the medical pro-

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<sup>123</sup> See, e.g., Williams, *supra* note 121, at 101 (“The broad impact that such a pandemic would have raises a litany of questions: How will the nation’s hospitals [fare] when faced with the financial demands imposed during and after a pandemic? Even if they can withstand the immediate fiscal impact of the pandemic, will they ultimately survive the ordeal? Will they act in the best interests of the public’s health, even if it causes them potentially fatal economic injury?”).

<sup>124</sup> See Mark A. Rothstein, *Are Traditional Public Health Strategies Consistent with Contemporary American Values?*, 77 TEMP. L. REV. 175, 185–86 (2004).

<sup>125</sup> *Id.*

<sup>126</sup> *Id.*

<sup>127</sup> *Id.* at 186.

<sup>128</sup> *Id.* (“The refusal to care for infected patients might be even more widespread in the United States than in Asia and Canada. . . . The issue of health care providers refusing to treat infected patients, however, is more complicated than merely the fears and prejudices of some health care providers. There has been a major loss of community in healthcare. Through managed care and other measures, the physician-patient relationship has eroded.”).

<sup>129</sup> Williams, *supra* note 121, at 16.

<sup>130</sup> See Coleman, *supra* note 120, at 11.

<sup>131</sup> *Id.* at 11–12 (“Following extensive criticism, the AMA quickly reversed course and declared that ‘[a] physician may not ethically refuse to treat a patient whose condition is within the physician’s current realm of competence solely because the patient is seropositive for HIV.’” (footnote omitted) (quoting COUNCIL ON ETHICAL & JUDICIAL AFFAIRS, AM. MED. ASS’N, CODE OF MEDICAL ETHICS: CURRENT OPINIONS WITH ANNOTATIONS § 9.131 (2008))).

fession is as susceptible as the rest of the public is to the fears and anxieties that accompany a health crisis.<sup>132</sup>

The AMA's initial response to HIV follows a historical change in professional expectations for physicians. The AMA's first Code of Ethics (promulgated in 1847) stated that "[w]hen pestilence prevails, it is [physicians'] duty to face the danger, and to continue their labors for the alleviation of suffering, even at the jeopardy of their own lives."<sup>133</sup> Over time, however, the AMA tempered the language of this provision, and in 1977 it removed the provision altogether.<sup>134</sup>

U.S. history and recent events abroad demonstrate that society cannot depend solely on physician altruism to provide adequate medical resources in a public health emergency. Policymakers should therefore concentrate on removing disincentives to physician participation in emergency response plans and ensuring that physicians who do participate are not punished for their altruism.

By excluding private physicians from liability protection, current emergency laws take for granted physicians' humanitarian values and assume that all physicians are accustomed to facing emergency situations or high risks of infection. An oncologist, rheumatologist, or family practitioner, however, likely does not face such risks in her normal practice. Thus, the burdens placed on physicians during a public health emergency can, as one commentator put it, "exceed the ethical commitments individuals make when they accept a professional license."<sup>135</sup> It would therefore be a mistake to penalize physicians by making them civilly liable for the difficult moral and professional choices they must make during public health emergencies.<sup>136</sup>

Policymakers should concentrate on removing disincentives like civil liability to encourage private physician participation in public health emergencies. A substantial literature documents the effects of liability on the market for medical care. Malpractice premium costs are a significant factor

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<sup>132</sup> See, e.g., Leslie A. Nickell et al., *Psychosocial Effects of SARS on Hospital Staff: Survey of a Large Tertiary Care Institution*, 170 CAN. MED. ASS'N J. 793, 796–97 (2004) (finding that SARS had significant psychosocial effects on hospital staff and their families and negatively impacted their lifestyles).

<sup>133</sup> Coleman, *supra* note 120, at 10 (second alteration in original) (quoting Samuel J. Huber & Matthew K. Wynia, *When Pestilence Prevails . . . Physician Responsibilities in Epidemics*, AM. J. BIOETHICS, Winter 2004, at W5, W6) (internal quotation marks omitted).

<sup>134</sup> *Id.* at 10–11.

<sup>135</sup> *Id.* at 3.

<sup>136</sup> See Kenneth Kipnis, *Overwhelming Casualties: Medical Ethics in a Time of Terror*, 10 ACCOUNTABILITY RES. 57, 61 (2003) ("Mass casualties and professionalism force a transformation of everyday moral intuitions. Two errors are common in implementing disaster triage, both traceable to understandable and ordinarily praiseworthy character traits: the virtue of compassion, and perseverance.").

in medical students' choice of specialty.<sup>137</sup> Insurance premiums and caps on damage awards also affect where recently graduated physicians choose to locate their practices.<sup>138</sup> Even after establishing their practices, physicians may decide to discontinue high-risk procedures, turn away high-risk patients, close practices, or move out of state to avoid potential litigation costs.<sup>139</sup> Thus, from the day they graduate from medical school, physicians are highly aware of their liability exposure when making practice-related decisions.

Some commentators argue that physicians do not need liability protection to incentivize emergency care response.<sup>140</sup> Yet federal and state governments support liability protection for other groups of emergency responders like public employees and volunteers, including those participating in the NDMS system.<sup>141</sup> Courts have also recognized the need to provide Good Samaritan immunity to physicians assisting at the scene of an accident.<sup>142</sup> Moreover, to construe the argument for physician immunity as implying that physicians are reluctant to cooperate with public officials is an oversimplification. Physician response to a public health emergency is not simply a question of whether a physician will show up for work but of how aggressively the physician will treat his patients and how engaged he will be in emergency response plans. For example, physicians may be more willing to put in longer hours, despite exhaustion, if they do not have to be concerned about malpractice liability stemming from their treatments. Similarly, physicians may be more willing to administer risky but effective emergency countermeasures if they know that they will not be held liable for resulting injuries. By providing liability protection, policymakers help alleviate concerns that physicians may have when participating in emergency response plans and thus encourage a more aggressive approach to the public health emergency.

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<sup>137</sup> See B.F. Kiker & Michael Zeh, *Relative Income Expectations, Expected Malpractice Premium Costs, and Other Determinants of Physician Specialty Choice*, 39 J. HEALTH & SOC. BEHAV. 152, 163 (1998).

<sup>138</sup> Chiu-Fang Chou & Anthony T. Lo Sasso, *Practice Location Choice by New Physicians: The Importance of Malpractice Premiums, Damage Caps, and Health Professional Shortage Area Designation*, 44 HEALTH SERVICES RES. 1271, 1272 (2009).

<sup>139</sup> See GOVERNOR'S SELECT TASK FORCE ON HEALTHCARE PROF'L LIAB. INS., at iii (2003), [www.doh.state.fl.us/myflorida/DOH-Large-Final\\_Book.pdf](http://www.doh.state.fl.us/myflorida/DOH-Large-Final_Book.pdf) (describing malpractice premium effects in Florida); Michelle M. Mello, David M. Studdert & Troyen A. Brennan, *The New Medical Malpractice Crisis*, 348 NEW ENG. J. MED. 2281, 2281 (2003) (describing the recent malpractice crisis in which physicians were unable to obtain malpractice coverage, causing hospitals to temporarily close or threaten to close emergency rooms, obstetric, and other high-risk services).

<sup>140</sup> See, e.g., George J. Annas, *Standard of Care—In Sickness and in Health and in Emergencies*, 362 NEW ENG. J. MED. 2126, 2126 (2010) (pointing out that physicians did not need liability protection as an inducement to respond to the September 11, 2001 attacks).

<sup>141</sup> For a discussion of protections for these types of responders, see *supra* notes 52–53 and accompanying text.

<sup>142</sup> See *infra* Part III.B.

*B. Distinguishing Public Health Emergencies from Typical Emergency Medicine*

Even emergency-trained physicians should be afforded liability protection because public health crises present unique situations. Public health emergencies involve different considerations and often require actions that fall outside the normal duties of the physician.<sup>143</sup> One might argue that emergency room physicians should not receive liability protection because they regularly face emergency situations where they must make difficult decisions: local hospitals are often inundated with patients as a result of car crashes and other crises. In particular, emergency medicine physicians are uniquely equipped with the foundational knowledge and skill set required to cope with a public health emergency.<sup>144</sup> They regularly risk exposure and are accustomed to a broad and unpredictable practice environment.<sup>145</sup>

By definition, however, the scale of the emergency distinguishes a public health emergency.<sup>146</sup> At any time, an emergency room may experience a surge as a result of local disasters and may handle the situation without any decline in care, a demonstration of its surge capacity.<sup>147</sup> However, there comes a point at which the surge stresses the health care system and makes it impossible to adequately maintain the normal standard of care.<sup>148</sup> Then the emergency is no longer a part of the routine flux but becomes a public health emergency.

During a public health emergency, physicians must look beyond specific patients' needs and consider how decisions will affect the safety of the public at large.<sup>149</sup> As a result, physicians may need to adjust their standards of care for the greater good. The surge in demand for medical care and limited resources during a public health emergency dramatically change triage procedures.<sup>150</sup> For instance, disaster triage requires physicians to

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<sup>143</sup> Ciottono, *supra* note 9, at 5 (“There are no practitioners who leave home in the morning intent on seeing disaster patients. . . . [T]he disaster falls on an unsuspecting emergency responder who is forced to abandon his or her normal duties and adopt a role in the overall disaster response.”).

<sup>144</sup> Hogan & Burstein, *supra* note 20, at 3.

<sup>145</sup> *See id.* at 2–3.

<sup>146</sup> *See* discussion *supra* Part I.A.

<sup>147</sup> *See* Transcript of Web Conference, Agency for Healthcare Research & Quality, Surge Capacity and Health System Preparedness: Addressing Surge Capacity in a Mass Casualty Event (Oct. 26, 2004), <http://archive.ahrq.gov/news/ulp/btsurgemass/masscastr.htm> [hereinafter Surge Capacity Conference]; *see also supra* note 8.

<sup>148</sup> David E. Hogan & Julio Rafael Lairer, *Triage*, in *DISASTER MEDICINE*, *supra* note 20, at 12, 13 (distinguishing “mass casualty incident” triage, during which “the local emergency care system becomes more stressed but is not overwhelmed,” from “disaster triage,” during which “the local resources are unable to provide immediate care on a timely basis” to all patients); Surge Capacity Conference, *supra* note 147.

<sup>149</sup> Hogan & Lairer, *supra* note 148, at 13; *see also infra* Part III.A.

<sup>150</sup> The process of determining a patient’s priority for treatment is known as “triage.” Physicians serving in World War I introduced the triage system to the United States. *See* Matthew D. Sztajnkrzyer, Bo E. Madsen & Amado Alejandro Báez, *Unstable Ethical Plateaus and Disaster Triage*,

prioritize patients based on predicted survivability.<sup>151</sup> This triage may require diverting resources from critically ill or injured patients, whose treatment would be resource intensive, to patients for whom limited resources can do the greatest amount of good.<sup>152</sup> In contrast, ordinary triage procedure in an emergency room prioritizes care to severely injured individuals and seeks to provide optimal care to all patients.<sup>153</sup> Thus, during a public health emergency, physicians encounter unique ethical and medical situations not seen in typical emergency situations or in the regular practice of other areas of medicine.<sup>154</sup>

Ultimately, whether an event constitutes a public health emergency may be a policy determination made by elected or appointed government officials. The executive branch of either the state or federal government must decide if large-scale coordination is necessary to address the emergency and, if so, declare a public health emergency. Unlike a car crash or other common emergency, a public health emergency requires public and private health care workers to coordinate to provide medical care and institute prevention plans. It is therefore the role of policymakers, typically through the executive branch, to decide if a disaster rises to the level of a public health emergency and necessitates coordinated, immediate action that may not be appropriate in an everyday emergency. When officials determine that the emergency rises to this level, physician immunity should play an essential role in ensuring full participation and assistance from the medical community.

### C. Professor Hoffman's Proposal for Legislative Reform

Professor Hoffman proposes that federal and state legislatures create a comprehensive immunity provision addressing liability for all health care workers, public and private.<sup>155</sup> The comprehensive provision would be incorporated in the Public Health Service Act and state public health emergency laws.<sup>156</sup> Mirroring the current extent of federal liability protection,

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24 EMERGENCY MED. CLINICS N. AM. 749, 752 (2006). Triage is based on the utilitarian theory that, in order for medical care to be truly lifesaving when resources are limited, it must be provided to those most in need. *Id.* Thus, a physician can withhold care when either it is futile or it is possible to delay care until a later time. *Id.*

<sup>151</sup> See Ciottone, *supra* note 9, at 5.

<sup>152</sup> *Id.* at 5–6.

<sup>153</sup> Hogan & Lairet, *supra* note 148, at 13. Triage is performed daily and routinely in an emergency room. The overall goal of daily triage is “to identify the sickest patients to supply early evaluation and treatment. . . . [T]he highest intensity of care is provided to the most seriously ill patients, even if those patients have a low probability of survival. In this [normal emergency room] setting, optimal care is provided to all presenting patients.” *Id.* In disaster triage, physicians’ priorities shift from providing optimal care to the sickest patients to “doing the greatest good for the greatest number.” *Id.*

<sup>154</sup> See Ciottone, *supra* note 9, at 5.

<sup>155</sup> Hoffman, *supra* note 1, at 1959.

<sup>156</sup> *Id.*

the legislation would immunize health care providers responding to declared public health emergencies as long as the physicians did not engage in willful misconduct, gross negligence, or criminal activity.<sup>157</sup> As with other emergency provisions, a declaration of a public health emergency would trigger the immunity provision.<sup>158</sup> When the state or federal executive branch decided that the extraordinary mobilization of resources to respond to the effects of a public health emergency was no longer required, liability protection would no longer be needed and would be terminated.<sup>159</sup> Professor Hoffman argues that comprehensive limited immunity would encourage physicians to lend their services during public health emergencies while still holding them accountable for serious medical mistakes.<sup>160</sup>

In the absence of an applicable immunity provision, however, it falls to the judicial system to determine whether a physician should be subject to civil liability for injuries sustained during a public health emergency. In such a situation, courts and lawyers must recognize the tension between common law precedent and the need to provide a just and fair decision given the unique situation of a public health emergency. The next Part argues that defendant physicians need not be constrained by traditional tort doctrines. Within the common law there is precedent allowing judges acting as gatekeepers to take into account the circumstances surrounding a public health emergency.

### III. TORT LAW AND PRIVATE PHYSICIAN LIABILITY DURING PUBLIC HEALTH EMERGENCIES

Courts often provide liability protection for actors serving the public interest. In *Harlow v. Fitzgerald*, the Supreme Court explicitly recognized the need to balance the public interest advanced by public officials against individual plaintiffs' need for compensation.<sup>161</sup> The Court expressed concern that subjecting government officials to litigation would distract them from their duties and inhibit their discretionary actions, ultimately deterring qualified people from public service.<sup>162</sup>

Courts have also recognized that exposure to civil liability and punitive damages may discourage participation in government disaster relief. In *Doe v. American National Red Cross*, a federal district court held that punitive damages were not available to a plaintiff who brought an action against the Red Cross after contracting HIV through a blood transfusion.<sup>163</sup> The court accorded great weight to the "governmental" services provided by the

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<sup>157</sup> *Id.* at 1959–61.

<sup>158</sup> *Id.* at 1963.

<sup>159</sup> *See id.*

<sup>160</sup> *Id.* at 1967.

<sup>161</sup> 457 U.S. 800, 814–16 (1982).

<sup>162</sup> *Id.* at 816.

<sup>163</sup> 847 F. Supp. 643, 645 (W.D. Wis. 1994).

Red Cross, such as “furnishing volunteer aid to the armed forces in wartime, acting as a medium of communication between the people of the United States and the armed forces, and carrying on a system of national and international relief.”<sup>164</sup> Although the Red Cross presented no substantial evidence that the threat of punitive damages would affect its services, the court did not want to risk deterring the Red Cross from providing public services in the future.<sup>165</sup>

These cases address the liability of parties acting as arms of the government. A physician responding to a public health emergency, however, works in a private capacity unless officially deputized by the state or federal government. The following sections examine traditional tort doctrines that frequently arise in medical malpractice cases. I argue that judges and lawyers should adapt these doctrines to the unique circumstances of public health emergencies to provide physicians with greater protection from civil liability.

### A. *Applicable Standards of Care*

To establish a prima facie case for medical malpractice, a plaintiff must show (1) a duty stemming from a doctor–patient relationship, (2) a standard of care to which the defendant is required to conform, (3) a breach of that standard by the defendant, and (4) a causal connection between the defendant’s conduct and the plaintiff’s injury.<sup>166</sup> The applicable standard of care is perhaps the most debated issue in medical malpractice cases. The formulation of the standard of care is a question of law for the court.<sup>167</sup> Once the court has formulated the standard, the application of the standard to the facts of the case is for the jury, absent summary judgment.<sup>168</sup>

Until the 1970s, most jurisdictions applied the “locality rule,” which holds physicians to the standard of care of their local community.<sup>169</sup> The lo-

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<sup>164</sup> *Id.* at 648–49.

<sup>165</sup> *Id.* at 649 (“There is a significant risk that subjecting defendant to damages large enough to punish or deter it would interfere gravely with defendant’s performance of the governmental functions for which it was chartered. . . . [T]he impact of [a punitive damage award] is likely to be both unpredictable and at times, substantial, and we are sensitive to the possible strain on local treasuries and therefore on services available to the public at large.” Punitive damages awards have the possibility of placing a similar strain on defendant’s financial resources and on its ability to carry out the services it performs on behalf of the government in wartime and in disaster relief.” (citation omitted) (quoting *Newport v. Fact Concerts, Inc.*, 453 U.S. 247, 271–72 (1981)).

<sup>166</sup> Theresa K. Porter, *Cause of Action Against Physician or Surgeon for Breach of the Duty of Attention and Care*, in 21 CAUSES OF ACTION 1 (1990).

<sup>167</sup> RESTATEMENT (SECOND) OF TORTS § 328B(c) (1965).

<sup>168</sup> *Id.* cmt. d (explaining that questions of fact are “within the recognized province of the jury as triers of fact” but that “over such questions of fact the courts always have reserved a preliminary power of decision, as to whether there is sufficient doubt about the issue to justify its submission to the jury”).

<sup>169</sup> See Michelle Huckaby Lewis, John K. Gohagan & Daniel J. Merenstein, Commentary, *The Locality Rule and the Physician’s Dilemma: Local Medical Practices vs the National Standard of Care*, 297 JAMA 2633, 2634 (2007). Twenty-nine states and the District of Columbia have adopted a national

cality rule is both a rule of substantive law and a rule of evidence.<sup>170</sup> As a rule of substantive law, it requires physicians to possess and exercise the degree of skill and care ordinarily employed in similar circumstances by physicians in good standing in their respective communities.<sup>171</sup> The rule historically operated “to protect rural and small town physicians,”<sup>172</sup> who were assumed to have restricted access to information and resources because of limited communication, distance, and financial constraints.<sup>173</sup>

When operating as a rule of evidence, the locality rule limits which physicians can be certified to testify as expert witnesses during a jury trial. Due to the esoteric nature of medical practice, testimony by an expert witness is crucial to determining whether a defendant met the applicable standard of care.<sup>174</sup> Under the strictest early form of the locality rule, only a physician who practiced in the same community could serve as an expert witness to establish the standard of care of that community.<sup>175</sup> Courts later expanded the rule to hold physicians to the same standard as those in the “same or similar locality.”<sup>176</sup> Moreover, some judges admitted expert testimony by physicians who demonstrated familiarity with local standards even if they did not practice locally.<sup>177</sup>

The locality rule fell into disfavor among the majority of jurisdictions in the 1970s.<sup>178</sup> The nationalization of medical education and the ability to communicate cheaply and efficiently supported a move towards standardizing the medical profession.<sup>179</sup> Most courts currently use a national standard whereby a physician is under a duty to use that degree of care and skill that is expected of a reasonably competent practitioner in the same specialty act-

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standard, while twenty-one states maintain some version of the locality rule. Eleanor D. Kinney et al., *Altered Standards of Care for Health Care Providers in the Pandemic Influenza*, 6 IND. HEALTH L. REV. 1, 5 (2009).

<sup>170</sup> See 33 AM. JUR. 2D *Proof of Facts* § 6 (1983 & Supp. 2010).

<sup>171</sup> See Kinney et al., *supra* note 169, at 4; Lewis, Gohagan & Merenstein, *supra* note 169, at 2634.

<sup>172</sup> See Kinney et al., *supra* note 169, at 4.

<sup>173</sup> John C. Drapp III, *The National Standard of Care in Medical Malpractice Actions: Does Small Area Analysis Make It Another Legal Fiction?*, 6 QUINNIPIAC HEALTH L.J. 95, 101 (2003); Kinney et al., *supra* note 169, at 4.

<sup>174</sup> *Mather v. Griffin Hosp.*, 540 A.2d 666, 670 (Conn. 1988) (“In a medical malpractice action, expert testimony is required to establish the standard of professional care to which the defendant is held . . . .”); Drapp, *supra* note 173, at 98–99; Lewis, Gohagan & Merenstein, *supra* note 169, at 2633 (“97% of medical malpractice cases involve expert medical testimony, with an average of 5 witnesses per trial.”).

<sup>175</sup> Lewis, Gohagan & Merenstein, *supra* note 169, at 2634.

<sup>176</sup> *Id.*

<sup>177</sup> See, e.g., *Katsetos v. Nolan*, 368 A.2d 172, 178 (Conn. 1976) (“[T]he ‘crucial question’ is not whether the witness has practiced in the neighborhood but ‘whether he knows what those standards are.’” (quoting *Ardoline v. Keegan*, 102 A.2d 352, 355 (Conn. 1954))).

<sup>178</sup> Lewis, Gohagan & Merenstein, *supra* note 169, at 2634.

<sup>179</sup> *Hall v. Hilbun*, 466 So. 2d 856, 870–71 (Miss. 1985) (asserting the reasons for moving to a national standard of care); Drapp, *supra* note 173, at 101.

ing in the same or similar circumstances.<sup>180</sup> Thus, the local practice of the physician's community is no longer a crucial factor in determining the applicable standard of care.<sup>181</sup>

In a public health emergency, however, there are strong justifications for retaining the locality rule or, at the very least, using the locality rule to provide a foundation for courts to take into account the unique circumstances of an area affected by a public health emergency. I propose that, during a public health emergency, a physician should not be held to the national standard of care that governs in ordinary malpractice cases. Instead, the standard should be determined by the practices of physicians and public health care workers from the same or a similar community affected by the public health emergency.

A national standard of care should not be applied during a public health emergency because physicians in the affected community face significantly different opportunities, experiences, and conditions of practice depending on how the community responds to the public health emergency.<sup>182</sup> Although the nationalized standard of care purports to be flexible by taking into account the circumstances under which a physician practices,<sup>183</sup> public health emergencies are so rare that few physicians have the experience to testify about what should be done in those exceptional circumstances.<sup>184</sup> The medical literature demonstrates a dearth of guidance about the appropriate public health emergency standard of care, resulting in great uncertainty among physicians.<sup>185</sup> During Hurricane Katrina, for example, physicians struggled to identify the appropriate standard of care.<sup>186</sup> As a re-

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<sup>180</sup> Lewis, Gohagan & Merenstein, *supra* note 169, at 2633–34.

<sup>181</sup> *Id.* at 2634.

<sup>182</sup> See James G. Hodge, Jr. et al., *Risk Management in the Wake of Hurricanes and Other Disasters: Hospital Civil Liability Arising from the Use of Volunteer Health Professionals During Emergencies*, 10 MICH. ST. U. J. MED. & L. 57, 62 (2006); Surge Capacity Conference, *supra* note 147.

<sup>183</sup> See, e.g., George J. Annas, Author's Response to Letter to the Editor, 363 NEW ENG. J. MED. 1380, 1380 (2010) (arguing that "the current standard of care already covers disasters by explicitly recognizing that circumstances and resources constrain what physicians can do").

<sup>184</sup> Lawrence O. Gostin et al., Letter to the Editor, 363 NEW ENG. J. MED. 1378, 1378–79 (2010) (critiquing the lack of guidance for physicians on crisis standards of care).

<sup>185</sup> See *id.* at 1379 ("A usable framework regarding crisis standards of care that are based on expert consensus building helps ensure the equitable and fair distribution of limited health care resources, thereby reducing morbidity and mortality in emergencies."); see also HEALTH SYS. RESEARCH, INC., ALTERED STANDARDS OF CARE IN MASS CASUALTY EVENTS I (2005) (explaining that one purpose of the report is to identify the tools and guidance necessary to ensure "effective health and medical care response[s]" to mass casualty events, which can compromise the ability of local and regional health systems to deliver services consistent with established standards of care).

<sup>186</sup> Gostin et al., *supra* note 184, at 1378–79; see also Ofer Merin et al., Perspective, *The Israeli Field Hospital in Haiti—Ethical Dilemmas in Early Disaster Response*, 362 NEW ENG. J. MED. E38(1), E38(1) (Mar. 18, 2010), <http://www.nejm.org/doi/pdf/10.1056/NEJMp1001693> (describing the extreme circumstances under which physicians practiced in the aftermath of the earthquake in Haiti and the triage decisions they were forced to make).

sult, establishing a nationally recognized standard of care in a public health emergency becomes extremely difficult if a testifying physician has no experience or training under the applicable circumstances, and the medical literature itself does not provide any clear standards.

As such, a standard of care based on the locality rule provides a more just way of determining whether a physician acted negligently under the circumstances. For example, during a public health emergency, a physician may need to defer taking care of patients with urgent medical needs.<sup>187</sup> The increased wait time may have a significant negative effect on a patient's condition resulting in injury.<sup>188</sup> In a jurisdiction applying a national standard of care, a plaintiff can present expert testimony from a physician who practices in an area remote from the disaster and who purports to account for all the circumstances under which the defendant physician was practicing. This testimony, however, does not provide the trier of fact with relevant information. Without having been involved in a similar emergency situation herself or having demonstrated knowledge of local emergency response plans, the expert cannot provide insight into the reasonableness of the defendant's actions.<sup>189</sup> Thus, experts should be required to testify about the local emergency response policies and the practices of local physicians responding to the crisis to provide evidence of the applicable standard of care. Courts must consider that the decision to defer patient care may not be negligence but a local decision of how to allocate strained community resources during a public emergency.<sup>190</sup>

Taking into account local characteristics in determining the applicable standard of care is consistent with recent trends in the provision of public health services. Public health experts promote increased "regionalization" of public health services to better meet the needs of local communities during health crises.<sup>191</sup> A region is comprised of communities likely to be simi-

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<sup>187</sup> See Ciottone, *supra* note 9, at 5; see also Kipnis, *supra* note 136, at 61 ("It is easy to accede to the everyday moral imperative to accord the greatest attention to the worst-off victims, but this compassionate response cascades into major problems later on. On any ordinary day, clinicians would do whatever it took to save this patient's life. Today she must be black-tagged as 'expectant' and left to die, even as those with lesser wounds are treated.").

<sup>188</sup> See George P. Smith, II, *Re-shaping the Common Good in Times of Public Health Emergencies: Validating Medical Triage*, 18 ANNALS HEALTH L. 1, 9–13 (2009) (criticizing the modern triage system and how individuals who are "in the best shape" are forced to wait for treatment).

<sup>189</sup> See James G. Hodge Jr. & Brooke Courtney, Commentary, *Assessing the Legal Standard of Care in Public Health Emergencies*, 303 JAMA 361, 362 (2010) (highlighting the difficulty in defining what a reasonable practitioner would do in an emergency, even within the same locality, given that the scarcity of resources may make optimal care impossible).

<sup>190</sup> See *id.* (arguing that malpractice claims should be examined based on how consistent a practitioner acts with the need to maximize a community's health outcome).

<sup>191</sup> See Howard K. Koh et al., *Regionalization of Local Public Health Systems in the Era of Preparedness*, 29 ANN. REV. PUB. HEALTH 205, 206 (2008) (referring to "regionalization" as "the addition of a regional structure to supplement local government agencies, which in some instances might lead to consolidation of services or agencies").

larly affected by a public health crisis. Emergency response plans are then tailored to fit the specific needs of a region. When designing a regional plan for the provision of public health services, authorities consider factors such as local geography, demographics, citizen mobility, and the local media market.<sup>192</sup> Because characteristics of a local community play an important part in government emergency response plans, these factors should also be taken into account on the private side of emergency response through the applicable standard of care.

A defendant physician may need to overcome court precedents that do not recognize an altered standard of care in other unique practice environments. In particular, some courts have refused to apply an altered standard of care for medical treatment administered in prisons. In *Moss v. Miller*, an inmate filed a medical malpractice action against an optometrist for failing to refer him to an ophthalmologist, which allegedly resulted in a serious eye injury.<sup>193</sup> At trial, the defense attacked the credibility of the plaintiff's expert witness, who testified about the national standard of care, by pointing out that the expert had never practiced in a prison and thus could not know the applicable standard of care.<sup>194</sup> The appeals court held that the jury could not "draw a distinction between medical decisions made in a prison setting and those made in the community just outside its walls."<sup>195</sup>

The appeals court, however, did not foreclose the possibility of an altered standard of care in limited situations. Although it rejected the application of the locality rule to medical treatment in prisons, it went on to state that physicians should not be held liable for injuries resulting from institutional constraints that cause delay or limit resources.<sup>196</sup> Following this reasoning, courts determining the applicable standard of care should consider a physician's limited resources and the constraints of the practice environment. A physician working during a public health emergency faces challenges similar to those that justify the use of the locality rule in remote communities, namely a lack of both expertise and health care resources.<sup>197</sup> Applying localized considerations in determining the standard of care acknowledges that a physician must adapt her practice to the idiosyncratic needs of and resources available in the affected community. In addition, it

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<sup>192</sup> See, e.g., Michael A. Stoto & Lindsey Morse, *Regionalization in Local Public Health Systems: Public Health Preparedness in the Washington Metropolitan Area*, 123 PUB. HEALTH REP. 461, 462 (2008) (detailing factors considered in developing a regional public health plan for the Washington, D.C. area).

<sup>193</sup> 625 N.E.2d 1044, 1047 (Ill. App. Ct. 1993).

<sup>194</sup> *Id.* at 1051–52. The defense argued that jurors should consider the locality rule in assessing the applicable standard of care, in this case by distinguishing between medical treatment in prison and medical treatment outside prison. *Id.* at 1051.

<sup>195</sup> *Id.* at 1051.

<sup>196</sup> *Id.* For example, the court explained that if a doctor makes a referral but there is a delay due to prison regulations, the doctor should not be held liable for injuries resulting from those constraints. *Id.*

<sup>197</sup> See *supra* notes 169–77 and accompanying text.

recognizes that only physicians who have experience working within that affected community or a similarly affected community can offer evidence to properly define the appropriate standard of care in that emergency situation.

Moreover, public health emergencies can be distinguished from prison situations because the access to resources in the former is not artificially limited. A prison doctor may have opportunities outside of the institutional constraints of a prison to ensure adequate care. For example, the optometrist in *Moss* could have gone to the department responsible for referral requests to expedite the referral.<sup>198</sup> In contrast, during a public health emergency, a physician faces the very real constraints of locally available resources and personal stamina.

In summary, courts should alter the applicable standard of care during public health emergencies. The standard should be defined by the practices of the local community or a similar community when affected by a public health emergency. Utilizing this rule would allow courts to account for the unique circumstances of medical practice during a public health emergency and to recognize the lack of a comprehensive national standard. Adopting the locality rule in these situations also would facilitate the principle that physicians should not be liable for injuries that result from constraints on human and medical resources. Judges formulating the standard of care should consider that a shortage of trained personnel, limited hospital resources, and pressures from local health authorities in the midst of a patient surge may require physicians to make extraordinarily difficult but necessary medical decisions for the good of the community—decisions that ordinarily might be the basis for a malpractice claim.<sup>199</sup>

### B. Good Samaritan Laws

An affirmative defense to liability that physicians can invoke is Good Samaritan immunity. In 1959, California enacted the first state statute providing physicians with Good Samaritan immunity from civil liability resulting from emergency care.<sup>200</sup> This statute provided that “[n]o person licensed under this chapter, who in good faith renders emergency care at the scene of an emergency, shall be liable for any civil damages as a result of any acts or omissions by such person in rendering the emergency care.”<sup>201</sup>

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<sup>198</sup> See *Moss*, 625 N.E.2d at 1048–49.

<sup>199</sup> See Hodge & Courtney, *supra* note 189, at 362 (“Decisions to restrict, limit, or deny care to specific patients may be warranted by communal needs arising from [an] emergency . . .”).

<sup>200</sup> Stewart R. Reuter, *Physicians as Good Samaritans: Should They Receive Immunity for Their Negligence When Responding to Hospital Emergencies?*, 20 J. LEGAL MED. 157, 157 (1999); see also CAL. BUS. & PROF. CODE § 2395 (West 2003) (providing the current language of the statute).

<sup>201</sup> *Colby v. Schwartz*, 144 Cal. Rptr. 624, 627 (Cal. Ct. App. 1978) (quoting CAL. BUS. & PROF. CODE § 2144 (1976)).

Since 1959, all states have adopted varying degrees of immunity for physicians who act in a Good Samaritan capacity in providing emergency care.<sup>202</sup>

Good Samaritan immunity allows physicians to provide prompt care in the case of an accident without fear of malpractice suits.<sup>203</sup> These statutes typically relieve a person from liability if she renders emergency care in good faith.<sup>204</sup> A judge can decide that Good Samaritan immunity applies as a matter of law upon summary judgment unless the plaintiff establishes that there is room for reasonable disagreement about the facts or about whether the defendant met the standard of conduct required by the law.<sup>205</sup> A judge applying and interpreting Good Samaritan immunity thus acts as a gatekeeper by determining which malpractice cases proceed to the jury.

Good Samaritan immunity typically applies only when a physician renders aid without a preexisting duty to do so—for example, if a physician comes upon a patient by chance or on an irregular basis.<sup>206</sup> In contrast, a physician who visits a patient in a hospital already owes a duty to the patient and therefore needs no additional inducement to offer aid.<sup>207</sup> Thus, physicians rendering emergency care in hospitals are usually barred from invoking this immunity.

To determine whether there is a preexisting duty, a judge will often look for an employment contract or an established physician–patient relationship.<sup>208</sup> However, even contractual employment with a hospital or physician group may not be determinative of whether the physician has a preexisting duty of care. A physician working in a hospital who does not ordinarily respond to emergency situations, such as a family practitioner, may be able to assert the defense. For example, in *McKenna v. Cedars of Lebanon Hospital*, the defendant physician showed that he was not on call for emergencies, did not typically respond to emergencies, and did not have a preexisting relationship with the plaintiff.<sup>209</sup> The judge held that under the circumstances the doctor was a volunteer even though he was employed by the hospital and that he therefore qualified for the Good Samaritan de-

<sup>202</sup> Reuter, *supra* note 200, at 157.

<sup>203</sup> See 61 AM. JUR. 2D *Physicians, Surgeons, and Other Healers* § 282 (2002).

<sup>204</sup> See, e.g., *Clayton v. Kelly*, 357 S.E.2d 865, 867–68 (Ga. Ct. App. 1987); *Gomes v. Hameed*, 184 P.3d 479, 484 (Okla. 2008); *McIntyre v. Ramirez*, 109 S.W.3d 741, 744 (Tex. 2003).

<sup>205</sup> See RESTATEMENT (SECOND) OF TORTS §§ 328B–328C (1965) (discussing the functions of the judge and jury in a negligence action).

<sup>206</sup> See Reuter, *supra* note 200, at 167.

<sup>207</sup> See *Colby v. Schwartz*, 144 Cal. Rptr. 624, 628 (Cal. Ct. App. 1978).

<sup>208</sup> See, e.g., *Gomes*, 184 P.3d at 484 (indicating that the Oklahoma court would evaluate prior contractual relationships between the injured person and his rescuer); *McIntyre*, 109 S.W.3d at 744 (naming whether the rescuer regularly administers care in a hospital emergency room setting as a factor for determining whether the Good Samaritan statute applies). See generally RESTATEMENT (SECOND) OF TORTS § 328B(b) (stating that whether the defendant owes a legal duty is a question of law for the court).

<sup>209</sup> 155 Cal. Rptr. 631, 635 (Cal. Ct. App. 1979).

fense.<sup>210</sup> Following *McKenna*'s reasoning, a physician employed by a hospital does not have a preexisting duty to *all* patients in the hospital and may be covered by Good Samaritan immunity when providing aid during a hospital emergency.

In circumstances more akin to a public health crisis, some courts are willing to extend Good Samaritan immunity to physicians responding to community emergencies.<sup>211</sup> *Willingham v. Hudson* considered a situation in which a tornado struck a Georgia town and inundated local hospitals with severely injured victims.<sup>212</sup> Local physicians were requested to assist in treating the influx of patients.<sup>213</sup> The defendant was a local family practitioner who responded to the request.<sup>214</sup> He treated and sutured a tornado victim's lacerated leg.<sup>215</sup> Several days later, the patient's leg became infected, and it ultimately had to be amputated.<sup>216</sup>

The Georgia appellate court upheld summary judgment for the defendant, finding that Good Samaritan immunity applied.<sup>217</sup> The statutory requirement that care be administered at the "scene of an emergency" was satisfied because the hospital faced a surge of patients resulting from a natural disaster.<sup>218</sup> Although the patient's leg laceration was not critical, the court found that the defendant's treatment constituted emergency care because it was administered during "an unforeseen circumstance that called for immediate action."<sup>219</sup> Most significant, the court determined that the defendant did not have a preexisting duty to the plaintiff even though he had an employment contract with the hospital because he had not been required to report for duty on the night of the tornado.<sup>220</sup>

Whether a physician has a preexisting duty to treat a patient can turn on what the court considers to be the "normal course of practice" for a particular physician defendant. This standard was first implemented in *Colby v. Schwartz*, a case that provided significant insight into the policy considerations behind Good Samaritan immunity.<sup>221</sup> Walter Colby sustained serious injuries from a car accident.<sup>222</sup> He was rushed to the local emergency room where a physician began treating him and then transferred him to an

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<sup>210</sup> *Id.*

<sup>211</sup> *Willingham v. Hudson*, 617 S.E.2d 192, 197–98 (Ga. Ct. App. 2005).

<sup>212</sup> *Id.* at 193.

<sup>213</sup> *Id.*

<sup>214</sup> *Id.* Defendant Mark Hudson was neither an on-call physician nor an emergency room backup physician on the date of the incident. *Id.*

<sup>215</sup> *Id.* at 193–94.

<sup>216</sup> *Id.* at 194.

<sup>217</sup> *Id.* at 195.

<sup>218</sup> *Id.*

<sup>219</sup> *Id.* at 195–97.

<sup>220</sup> *Id.* at 197.

<sup>221</sup> See *Colby v. Schwartz*, 144 Cal. Rptr. 624, 627–29 (Cal. Ct. App. 1978).

<sup>222</sup> *Id.* at 625–26.

intensive care unit.<sup>223</sup> In the intensive care unit, another physician examined the patient and ordered an exploratory surgical procedure.<sup>224</sup> While in surgery, Colby died from lacerations to multiple organs caused by the blunt force of the car accident.<sup>225</sup>

Colby's widow and children sued the physicians and surgeons who attended to him on the day of his accident, challenging the timeliness of the diagnosis and the remedial steps taken.<sup>226</sup> The defendants moved for summary judgment under California's Good Samaritan statute, claiming they had provided "emergency medical care" and that "their care conformed to the standard exercised by prudent physicians acting under the same or similar circumstances."<sup>227</sup> The court rejected the defendants' request and reasoned that the Good Samaritan statute only covered physician aid when the "the expertise of the physician and facilities could be severely limited" and acknowledged that "the general practitioner might well find himself treating an individual for needs outside his training."<sup>228</sup>

The circumstances under which Good Samaritan statutes protect physician aid might well apply to a public health emergency. During such an emergency, the shortage of trained personnel will likely prompt hospitals to request assistance from physicians with all types of specialty training, many of whom are not trained in emergency medicine.<sup>229</sup> Thus, physicians working outside the ordinary scope of their duties in the face of a public health crisis will likely be eligible for this immunity.

The language in *Colby* also provides insight into how Good Samaritan immunity can extend to a physician trained in emergency medicine. The court indicated that the scope of Good Samaritan protection depends on a defendant's skills and training *and* whether the circumstances placed unusual demands on those skills.<sup>230</sup> During a public health emergency, the surge of patients may alter the availability of medical resources and personnel so drastically that the hospital environment differs significantly from the

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<sup>223</sup> *Id.* at 626.

<sup>224</sup> *Id.*

<sup>225</sup> *Id.*

<sup>226</sup> *Id.* at 625.

<sup>227</sup> *Id.* at 625–26 (quoting defendants' declarations) (internal quotation marks omitted).

<sup>228</sup> *Id.* at 628.

<sup>229</sup> Hodge et al., *supra* note 182, at 63 ("To meet surge capacity, hospitals may draw upon their existing workforce, temporarily hired personnel, or [volunteer health professionals.]); *see also* Sayeedha Ghorri Uddin et al., *Emergency Preparedness: Addressing a Residency Training Gap*, 83 ACAD. MED. 298, 298–99 (2008) (noting that after Hurricane Katrina, physicians of all specialties, including internal medicine, neurosurgery, and ophthalmology, faced the reality of providing care after the disaster).

<sup>230</sup> *See Colby*, 144 Cal. Rptr. at 628 ("[D]efendants in performing the exploratory surgical procedure were practicing within their area of expertise and with all of the benefits of full hospital facilities. It is therefore not unreasonable to hold them to the level of skill and training required under such circumstances. Further, there is no indication in the record that the exigencies of decedent's condition placed any unusual or unforeseen demands on defendants' skills.").

situation to which emergency physicians are accustomed.<sup>231</sup> For instance, rapidly transforming an emergency room into a clinic or mass immunization center falls outside the normal scope of emergency physicians' duties.<sup>232</sup>

In addition, an emergency physician likely must shift focus from a patient-oriented perspective to a public-needs perspective.<sup>233</sup> Recent studies on the education of medical residents have found, however, that emergency physicians are not specially trained to address mass public health needs.<sup>234</sup> Moreover, the medical field recognizes disaster medicine as a distinct specialty requiring multidisciplinary study.<sup>235</sup> Thus, a physician's limited training in disaster medicine and the broader public health arena could be used to argue that she should be eligible for Good Samaritan immunity in a public health crisis.

In sum, although Good Samaritan immunity does not typically cover physicians confronting emergencies in hospitals, some courts have opened the door for the expansion of immunity protection to physicians responding to public health emergencies.

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<sup>231</sup> See, e.g., Hodge et al., *supra* note 182, at 62 ("The incorporation of new professionals into the operational structure of a hospital requires careful planning, adept management, and rigorous oversight, particularly during an emergency when circumstances may be stressful, novel, and chaotic."); Williams, *supra* note 121, at 105–12 (explaining how hospital revenues and reserves could be quickly depleted during emergency responses).

<sup>232</sup> The medical literature recognizes that there is no standardized approach to managing a mass clinic; rather, doing so relies on the intuitions of health workers and the practical realities of available resources. See Paul Campbell Erwin, Lorinda Sheeler & John M. Lott, *A Shot in the Rear, Not a Shot in the Dark: Application of a Mass Clinic Framework in a Public Health Emergency*, 124 PUB. HEALTH REP. 212, 213 (2009).

<sup>233</sup> See *supra* notes 149–54 and accompanying text. In normal emergency triage, the physician already considers more than the needs of the individual patient, but in a public health emergency, she additionally must consider not only those in her emergency room but also the public at large and the needs of the government emergency response plans. See Ciottone, *supra* note 9, at 5; Hodge & Courtney, *supra* note 189, at 362 (noting that communal needs may take precedence over individual patients' needs during a public health emergency); see also Hogan & Burstein, *supra* note 20, at 3 ("The provision of health care after a disaster is dependent on multiple areas of medical expertise, such as public health, primary care, surgery, infectious diseases, toxicology, and many others.").

<sup>234</sup> Uddin et al., *supra* note 229, at 299. Although there is widespread recognition in the medical field that physician involvement and leadership are important in emergency preparedness, the literature also suggests that residencies of various specialties, including surgery and emergency medicine, are not addressing the training needs adequately. For example, only 49% of resident physicians have trained for terrorism-related conditions; thus, residents are not receiving enough training for decisionmaking in resource-poor settings. *Id.*; see also Steve Kefalas & Anna S. Shalkham, *Resident Education and Training in Disaster Medicine*, DISASTER MED. SEC. (Am. Coll. Emergency Physicians) (Jan. 2006), <http://www.acep.org/ACEPmembership.aspx?id=40128> (explaining that the Residency Review Committee does not require disaster response training as part of the emergency medicine residency curriculum).

<sup>235</sup> See Ciottone, *supra* note 9, at 5 ("The field of disaster medicine involves the study of subject matter from multiple medical disciplines.").

IV. FEDERAL AND STATE COORDINATION OF EMERGENCY PUBLIC HEALTH  
POLICY TO FACILITATE LIABILITY PROTECTION FOR EMERGENCY  
RESPONDERS

Part III has presented state tort doctrines that can be applied to protect physicians from civil liability during public health emergencies. Applying these common law protections during public health emergencies is especially important in the absence of comprehensive immunity statutes, such as the one proposed by Professor Hoffman.<sup>236</sup> Even if federal laws protect private physicians from liability, state court decisions will continue to affect physician liability unless federal law expressly preempts state common law or state legislatures pass corresponding immunity provisions. In addition, states may depend on federal laws that create alternative forms of plaintiff compensation so that they can pass state legislation providing for physician immunity during public health emergencies. Thus, in order to provide liability protection for private physicians and other emergency responders, state and federal governments must coordinate their emergency health care policies. This Part briefly explores issues of preemption and victim compensation that often arise in discussions of liability protection at the state and federal levels.

*A. Federal Preemption*

Private physicians responding to public health emergencies should be concerned about preemption. Federal protection of potential codefendants (such as drug manufacturers) may force plaintiffs to seek redress primarily from physicians.<sup>237</sup> Moreover, even if federal laws offer some liability protection for private physicians, courts may not always interpret the federal law as preempting state common law. Although preemption deserves a separate study unto itself, this Part briefly explores preemption issues that may arise in the context of a public health emergency and their impact on the liability of public health emergency responders.

There is little case law addressing the extent to which federal emergency statutes preempt state common law. Under courts' interpretations of the Supremacy Clause,<sup>238</sup> federal law preempts state law in three situations: (1) when Congress has clearly expressed its intent to preempt state law (express preemption), (2) when Congress has shown its intent to occupy an entire field of regulation by legislating comprehensively (field preemption),<sup>239</sup>

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<sup>236</sup> See *supra* Part II.C.

<sup>237</sup> See Gregory D. Curfman, Stephen Morrissey & Jeffrey M. Drazen, Perspective, *Why Doctors Should Worry About Preemption*, 359 NEW ENG. J. MED. 1, 2-3 (2008).

<sup>238</sup> U.S. CONST. art. VI, cl. 2 (making laws enacted by Congress "the supreme Law of the Land"); *Coll. Loan Corp. v. SLM Corp.*, 396 F.3d 588, 595 (4th Cir. 2005).

<sup>239</sup> The intent to occupy a regulatory field

may be inferred from a "scheme of federal regulation . . . so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it," or where an Act of Congress

and (3) when state law conflicts with federal law (conflict preemption).<sup>240</sup> Based on the language of federal emergency statutes and recent Supreme Court cases addressing preemption in the context of medical products, we can speculate as to whether federal emergency laws will preempt causes of action under state law. Two possibilities emerge. First, courts may limit federal preemption of state emergency laws to the medical product context. Second, courts may interpret the broad language used in new federal emergency statutes and the underlying concerns of national security as attempts by Congress to occupy the field of public health emergency response.

Federal public health emergency provisions expressly preempting state law usually concern medical product use. The development of vaccine compensation funds over the last forty years demonstrates the federal government's trend toward absorbing the costs of liability for injuries arising from emergency response measures.<sup>241</sup> After the September 11, 2001 attacks, the federal government expanded immunity provisions, preempting much of state tort law pertaining to civil immunity.<sup>242</sup>

The most sweeping of these recent acts is PREPA.<sup>243</sup> During the effective period, PREPA expressly preempts the enforcement of state laws or legal requirements that relate to the provision of emergency countermeasures (design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use) and differ from PREPA obligations.<sup>244</sup> The statute empowers the HHS Secretary to provide civil immunity to manufacturers of countermeasures and any entity along the chain of distribution.<sup>245</sup> It covers not only stockpiled countermeasures, such as vaccines, but also any product that might be used to respond to a public health emergency.<sup>246</sup> Thus, any tort claim involving a medical product used as a countermeasure should be expressly preempted by federal statute.

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“touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.”

English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990) (alteration in original) (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).

<sup>240</sup> *English*, 496 U.S. at 78–79; *Coll. Loan*, 396 F.3d at 595–96.

<sup>241</sup> See *supra* Part I.C.2.

<sup>242</sup> See George W. Conk, *Will the Post 9/11 World Be a Post-tort World?*, 112 PENN ST. L. REV. 175, 177–80 (2007). For example, under the Smallpox Emergency Personnel Protection Act of 2003, the federal government absorbs liability for claims arising out of the production and distribution of smallpox vaccines during a smallpox emergency. *Id.* at 217–21.

<sup>243</sup> 42 U.S.C. §§ 247d-6d to -6e (2006).

<sup>244</sup> 42 U.S.C. § 247d-6d(a)(1)–(2).

<sup>245</sup> *Id.* § 247d-6d(a)–(b).

<sup>246</sup> See *id.* § 247d-6d(a)(5).

Recent Supreme Court cases involving medical products under the Federal Food, Drug, and Cosmetic Act (FDCA),<sup>247</sup> however, create uncertainty about whether federal statutes like PREPA preempt state common law. In *Riegel v. Medtronic, Inc.*, the Court addressed the issue of whether certain New York tort laws constituted “requirements” that were specifically preempted by the Medical Device Amendments of 1976 (MDA).<sup>248</sup> The Court concluded that both FDA premarket approvals of medical devices and state common law actions for negligence and strict liability imposed requirements under the statute.<sup>249</sup> It therefore held that states could not enforce disparate common law requirements against medical device manufacturers after they received FDA premarket approval.<sup>250</sup>

In *Wyeth v. Levine*,<sup>251</sup> however, the Supreme Court came to a different conclusion about preemption regarding prescription drugs. The Supreme Court held that FDA approval of a label did not preempt state law failure-to-warn claims.<sup>252</sup> The Court distinguished *Wyeth* from *Riegel* because Congress had declined to extend the MDA express preemption provision to prescription drugs.<sup>253</sup>

The application of these precedents to emergency laws is uncertain because emergency countermeasures employ both medical devices and prescription drugs. The Project BioShield Act, for instance, amended the FDCA to authorize the HHS Secretary to approve both medical devices and prescription drugs for emergency use.<sup>254</sup> It is unclear how *Wyeth* and *Riegel* would apply to these emergency authorizations.

Federal emergency laws such as PREPA and the Project BioShield Act, however, differ from other public health laws because they emphasize national security.<sup>255</sup> The federal government traditionally governs in the

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<sup>247</sup> 21 U.S.C. §§ 301–399a (2006).

<sup>248</sup> 552 U.S. 312, 321–22 (2008). The MDA organizes federal safety oversight for medical devices, and the preemption provision of the statute provides that a state shall not

establish or continue in effect with respect to a device intended for human use any requirement— (1) which is different from, or in addition to, any requirement applicable under [federal law] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [relevant federal law].

21 U.S.C. § 360k(a).

<sup>249</sup> *Riegel*, 552 U.S. at 322–24.

<sup>250</sup> *Id.* at 325, 330.

<sup>251</sup> 129 S. Ct. 1187 (2009).

<sup>252</sup> *Id.* at 1203–04.

<sup>253</sup> *See id.* at 1196.

<sup>254</sup> *See* Project BioShield Act of 2004, Pub. L. No. 108-276, sec. 4, § 564(a)(1), 118 Stat. 835, 853 (amending the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3 (2006)).

<sup>255</sup> *See id.* (describing the Project BioShield Act as an Act “[t]o amend the Public Health Service Act to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States”); Copper, *supra* note 6, at 66 (providing that PREPA passed under the Department of Defense, Emergency Supplemental Appropriations to Address

areas of foreign policy and national security.<sup>256</sup> Although public health administration is traditionally viewed as a state or local issue,<sup>257</sup> the September 11, 2001 attacks and subsequent anthrax incidents made clear that bioterrorism poses a legitimate threat to national security.<sup>258</sup> In conjunction with preventing bioterrorist attacks, Congress expressly recognized national epidemics as a possible threat to national security.<sup>259</sup> Hence, federal laws addressing public health emergencies do not distinguish between natural emergencies and terrorist attacks.<sup>260</sup> Viewing emergency laws as part of the federal prerogative of national security creates a stronger possibility that federal laws protecting emergency responders (such as private physicians and drug manufacturers) will preempt state tort laws and provide comprehensive protection from civil liability.

### B. Victim Compensation

Preemption issues often arise when Congress creates federal compensation funds for the collateral effects of emergency response policies.<sup>261</sup> These victim compensation funds are often meant to supplant traditional avenues of recovery and protect emergency responders from civil liability.<sup>262</sup> Federal compensation may also be necessary to garner political support for federal and state statutes providing civil immunity to certain parties. Some debate continues over whether these federal funds provide an adequate alternative to compensation through litigation.

Nevertheless, in a public health emergency, especially in the face of an unforeseen biological agent like a pandemic flu, the federal government may be justified in compensating individuals injured by emergency re-

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Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act of 2006, Pub. L. No. 109-148, 119 Stat. 2680 (2005), a national military appropriations bill).

<sup>256</sup> This is crucial because when addressing preemption courts look to the historical division of power between states and the federal government. See, e.g., *Wyeth*, 129 S. Ct. at 1194–95.

<sup>257</sup> See, e.g., HODGE & GOSTIN, *supra* note 14, at 11.

<sup>258</sup> See Wendy K. Mariner, George J. Annas & Wendy E. Parmet, *Pandemic Preparedness: A Return to the Rule of Law*, 1 DREXEL L. REV. 341, 352–54 (2009) (explaining that the attacks led government officials to find bioterrorism threats very real and very threatening and describing officials' proposed, and often misguided, courses of action for preparing for future bioterrorist attacks).

<sup>259</sup> *Id.*

<sup>260</sup> *Id.* at 353 (“Converting the well-known risk of epidemics into the equivalent of war on the American people enabled the federal government to exert a degree of control over individual patients that was unprecedented in the modern era, and to spend federal dollars to encourage states to do the same.”).

<sup>261</sup> For example President Bush's declaration of a public health emergency required FEMA to compensate state and local officials for the liability costs resulting from emergency measures. See *supra* note 31.

<sup>262</sup> See *supra* notes 68–81 and accompanying text (discussing congressional responses to vaccine manufacturer liability).

sponse measures.<sup>263</sup> There are several advantages to relying on a public fund for this purpose. Establishing a public fund in the wake of a public health emergency creates a sense of solidarity against an unpredictable force and evinces a sense of “collective compassion” for those affected.<sup>264</sup> Moreover, injured individuals can avoid the costs and time of litigation. Claimants are assured compensation under a fund whereas litigants must gamble in court.<sup>265</sup> The no-fault system also allows victims to recover without tarnishing the records or reputations of physicians and hospitals.<sup>266</sup> This is especially desirable because it recognizes the extraordinary circumstances under which health care workers must perform during public health emergencies.<sup>267</sup>

Individuals, however, may be reluctant to seek compensation from a fund due to restrictions on the awards. Funds are often administered on a set schedule and may cap some damages.<sup>268</sup> Some survivors of the September 11, 2001 attacks objected to regulations in the September 11th Victim Compensation Fund of 2001 that cap the decedent’s noneconomic damages at \$250,000 plus \$100,000 for his spouse and each of his dependents.<sup>269</sup> Some existing government compensation programs for public health policies allow claimants to recover actual and projected expenses, including lost wages, medical expenses, and reasonable attorneys’ fees, even where recovery for pain and suffering is capped.<sup>270</sup> Thus, an individual may pursue tort litigation instead of fund compensation if she believes a jury would award substantial noneconomic damages.<sup>271</sup>

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<sup>263</sup> See, e.g., Shapo, *supra* note 72, at 54 (discussing the government’s rationale for creating the 1976 Swine Flu program and justifying the government’s action).

<sup>264</sup> Marshall S. Shapo, *Compensation for Victims of Terror: A Specialized Jurisprudence of Injury*, 30 HOFSTRA L. REV. 1245, 1259 (2002) (noting that the September 11th Victim Compensation Fund of 2001 “provides a certain balm for us all, in our continuing horror at the events, our collective compassion for the victims, and our increased sense of vulnerability”).

<sup>265</sup> See *id.* at 1254.

<sup>266</sup> See *id.* at 1253–54.

<sup>267</sup> Cf. *id.* at 1252–53 (pointing out that the potential defendants in post-September 11, 2001 litigation included airlines and private security providers who received immunity under the September 11th Victim Compensation Fund and explaining that “[s]uits against the carriers, in the view of some, would provide some corrective justice in favor of the victims and survivors” but that “the enactment of the compensation legislation obviously is aimed at fairness in the round—at a kind of distributive justice in a situation where the concept of justice is multifaceted”).

<sup>268</sup> See, e.g., *id.* at 1250–51; see also *id.* at 1256 (arguing that, under the September 11th Victim Compensation Fund, “need is defined, in true capitalist style, as related closely to income levels”).

<sup>269</sup> 28 C.F.R. § 104.44 (2010); Milo Geyelin, *Criticism of Sept. 11 Victims’ Fund Sparks Backlash*, WALL ST. J., Jan. 23, 2002, at B1 (relating that a widowed New York City police officer complained, “I feel your offer spits on my wife, my mother-in-law and my father in law”). See generally 49 U.S.C. § 40101 (2006) (providing the full fund legislation).

<sup>270</sup> See, e.g., Copper, *supra* note 6, at 73 (describing legislative limits on compensation under the National Childhood Vaccine Injury Act of 1986).

<sup>271</sup> See, e.g., Gillian K. Hadfield, *Framing the Choice Between Cash and the Courthouse: Experiences with the 9/11 Victim Compensation Fund*, 42 LAW & SOC’Y REV. 645, 646 (2008) (theorizing

Funds may represent more of a political statement than a well-thought-out alternative to the tort system. Professor Shapo notes in his discussion of the September 11th Victim Compensation Fund that “the statutory references to those eligible for compensation do not appear to be rigorously logical.”<sup>272</sup> Other emergency funds have similar unexplained gaps in coverage. PREPA, for example, has been criticized for its failure to allocate money to the Covered Countermeasure Process Fund;<sup>273</sup> doing so requires additional congressional action.<sup>274</sup> Some Republicans claim that PREPA would not have passed if funds had been allocated directly because it would have been too expensive,<sup>275</sup> but the allocation scheme under PREPA leaves the fund vulnerable in the event of a budget crisis.<sup>276</sup> Without proper funding there is nothing to offset the waiver of liability for manufacturers and public health officials under PREPA, thereby leaving injured individuals without recourse for compensation. So although a federal compensation fund can effectively balance individual compensation with physician immunity during a public health emergency, the design and funding of a compensation fund demands careful deliberation if it is to have any real meaning.

#### CONCLUSION

Giving private physicians immunity from tort suits during public health emergencies does not violate traditional expectations of physicians either legally or socially. Existing tort law already provides a foundation for physician immunity in public health emergencies, and courts could extend these principles easily. Moreover, legislatures have already provided liability protection to other emergency responders, such as manufacturers, public health officials, and government contractors.

In the case of a public health emergency, the first-line responders are those working in the private sector. Thus, to deny liability protection for private physicians who put themselves at risk for the public’s benefit takes for granted an essential part of our health care system.

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that parties may stall a decision to receive fund compensation before waiving the right to litigation in the hope of receiving a higher payout).

<sup>272</sup> Shapo, *supra* note 264, at 1257.

<sup>273</sup> *See, e.g.*, Copper, *supra* note 6, at 91.

<sup>274</sup> *See id.*

<sup>275</sup> *Id.* at 92.

<sup>276</sup> *Id.*

