

# FROM [A]NTHRAX TO [Z]IKA: KEY LESSONS IN PUBLIC HEALTH LEGAL PREPAREDNESS

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## I. INTRODUCTION

Over fifteen years ago, the 2001 terrorist and anthrax attacks in the United States led to seminal law and policy changes in public health planning, preparedness, and response.<sup>1</sup> Coextensively, a litany of major public health threats and challenges (e.g., West Nile Virus, Hurricane Katrina, H1N1, Ebola, Measles, Zika) have emerged. Each of these events required real-time responses and solutions among federal, tribal, state, and local actors, as well as private sector partners. These responses pursuant to “legal triage”<sup>2</sup> include significant reforms in public health emergency (PHE) laws and policies during and after the exigencies.

Emergency preparedness is a primary focus across all levels of government and throughout health care and other industries. Hundreds of billions of dollars have been spent to prepare for and prevent public health events that are unpredictable in their timing, physical and mental health impacts, and costs. Hundreds of thousands of public health officials, health care workers (HCWs), emergency managers, and others have been educated and trained in preparedness and response efforts. The science of preparedness has revealed innovative approaches to abating negative public health repercussions while minimizing intrusions on individual rights. Americans are more knowledgeable and aware of public health risks, though some public health preparedness messages have had limited utility (e.g., colored terrorism level alerts from the Department of Homeland Security (DHS)).<sup>3</sup>

The field of emergency public health preparedness has been reformed

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1. James G. Hodge, Jr., *The Evolution of Law in Biopreparedness*, 10 BIOSECURITY & BIOTERRORISM 38, 39 (2012).

2. 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, 252 (2008).

3. John Schwartz, *U.S. to Drop Color-Coded Terror Alerts*, N.Y. TIMES, Nov. 25, 2010, at A24.

globally and domestically in less than a decade and a half. And now, with multiple events in hindsight, long-term observations and lessons in emergency legal preparedness are coming into sharper focus. Fundamental issues of national and regional legal preparedness in the United States are explored below in five premier themes.

Part II examines the changing definitions and scope of PHEs at all levels of government. By no means bootstrapped to initial conceptions of PHEs immediately following 9/11, PHEs continue to be declared in response to multifarious events, some of which are warranted, others less so. Part III assesses the pervasive classification of PHEs as national security threats (NSTs) under federal laws and policies. The propensity of the President and other federal actors to tag PHEs as threats to national security brings public health policy into new realms that may strain federal-state relations in future events.

Part IV looks closely at newly implemented federal social distancing powers crafted by the Centers for Disease Control and Prevention (CDC). Moving past decades-old, antiquated notions of federal roles in separating ill and well populations, the CDC revolutionized and expanded its powers, but at what costs? Part V dives into the liability “sinkhole” impacting participatory efforts among HCWs and volunteers. The potential for emergency responders to be liable for unproven, sometimes chaotic efforts to screen, test, and treat patients has always been a major concern. Longstanding debates on how to best address these concerns while assuring injured patients access to justice are finally becoming clearer.

Finally, Part VI describes one of the most important lessons of public health legal preparedness: that its utility is not limited to one-off-ramp emergency events or short-term responses. As illustrated through multiple examples, creating and applying emergency preparedness laws and policies affect routine, day-to-day public health laws and practices. Preparedness is not only good for emergencies, but also for regular public health practices. A brief conclusion follows.

## II. THE SCOPE OF PUBLIC HEALTH EMERGENCIES

For decades, the concept of PHE preparedness in the United States was largely unheralded, misunderstood, or ignored by most lawmakers, government officials, HCWs, and citizens.<sup>4</sup> The role of law in preparing for a bioterrorism or mass casualty event was under-studied, and as a result, underdeveloped. Only select law- and policy-makers argued for legal changes or systemic overhauls to address emerging threats, and virtually none foresaw the need for a complete restructuring of government to respond to public health emergencies.<sup>5</sup>

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4. See James G. Hodge, Jr., *Public Health Emergency Legal and Ethical Preparedness*, in OXFORD HANDBOOK OF AM. HEALTH L. 1008 (Glenn Cohen et al. eds., 2015) (explaining that apathy is hard to understand given multiple and diverse public health threats experienced nationally or regionally leading up to September 11, 2001).

5. Cantigny Conf., *State Emergency Health Powers & the Bioterrorism Threat* (April 26-27, 2001), <http://www.heart-intl.net/HEART/Legal/Comp/StateEmergencyPowers.htm> [<https://perma.cc/UQ4W-QULY>].

The terroristic acts and anthrax attacks in September 2001 changed everything. Combatting terrorism in all its forms became a primary, national objective, which continues to modern day as per the expressed goals of defeating terrorist cells espoused by Donald J. Trump as part of his presidential campaign.<sup>6</sup> Immediately following the terrorist attacks on 9/11, the nation welcomed major changes ushered in through systemic legal reforms to: (1) rebuild legal response capabilities; (2) newly classify PHEs; (3) rebalance individual rights with government's need to protect populations from national or regional public health or security threats; and (4) define emergency roles and responsibilities among public and private actors.

During this time, the Centers for Law and the Public's Health drafted and introduced the Model State Emergency Health Powers Act (MSEHPA) in December 2001.<sup>7</sup> Subject to some criticisms among scholars, civil rights advocates, media, and the public,<sup>8</sup> MSEHPA laid out a structured and cohesive menu of model provisions largely for state and local governments considering how to respond to bioterrorism or other public health crises.<sup>9</sup> A primary goal of MSEHPA was to balance individual and communal interests underlying modern responses to a PHE, defined as:

an occurrence or imminent threat of an illness or health condition that: (1) is believed to be caused by . . . bioterrorism; the appearance of a novel or previously controlled or eradicated infectious agent or biological toxin [or other causes]; . . . and (2) poses a high probability of . . . a large number of deaths in the affected population; a large number of serious or long-term disabilities in the affected population; or widespread exposure to an infectious or toxic agent that poses a significant risk of substantial

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6. Full text: *Donald Trump's speech on fighting terrorism*, POLITICO (Aug. 15, 2016, 3:15 PM), <http://www.politico.com/story/2016/08/donald-trump-terrorism-speech-227025> [https://perma.cc/5CHR-98AQ].

7. James G. Hodge, Jr. & Lawrence O. Gostin, *Protecting the Public's Health in an Era of Bioterrorism: The Model State Emergency Health Powers Act*, 10 ACCOUNTABILITY IN RES. 91 (2003).

8. GEORGE J. ANNAS, *WORST CASE BIOETHICS: DEATH, DISASTER, AND PUBLIC HEALTH* (2010).

9. See U.S. DEP'T OF HEALTH & HUMAN SERVS., *Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) - Legal and Regulatory Issues*, (2006), <http://www.publichealthlaw.net/Research/PDF/ESAR%20VHP%20Report.pdf> [https://perma.cc/4QD9-SPDE] (explaining that despite some concerns, multiple national public health and policy-making entities supported the premises of the Act, including CDC, the American Public Health Association (APHA), Association of State and Territorial Health Officials (ASTHO), National Association of County and City Health Officials (NACCHO), National Conference of State Legislatures (NCSL), National Governors Association (NGA), National Association of Attorneys General (NAAG), and American Medical Association (AMA). Perhaps the most telling support for MSEHPA came from legislatures and regulatory agencies across the United States and internationally).

future harm to a large number of people in the affected population.<sup>10</sup>

A state- or local PHE declaration may be issued by the Governor (with recommended input from state health authorities) only when an act of bioterrorism or other public health threat poses a “high probability” of a large number of deaths, disabilities, or exposures to agents that could cause future harms. These definitional limits were intended to confine PHE declarations to circumstances where rapid factors militated an efficient and effective public health response that may necessitate differing standards relating to respect for individual rights. Soon after national implementation of legal reforms based on MSEHPA,<sup>11</sup> however, the concept and role of PHEs began to change. As per Table 1, below, PHE declarations arose in response to a variety of differing threats with variable impacts.

**Table 1. Public Health Emergency Declarations – Select Examples**

Date	Jurisdiction	Declaring Person/Entity	Purpose/Reason	Brief Summary
9/2/05	State of Louisiana	Gov. Kathleen B. Blanco	Hurricane Katrina	Declaration of PHE to Suspend Out-of-State Licensure for Medical Professionals and Personnel. Due to statewide shortage of medical professionals and personnel following Hurricane Katrina. La. Exec. Order No. KBB 2005-26.
5/6/08	Pima County (AZ)	Cnty. Bd. of Supervisors	Measles outbreak	Proclamation of the existence of a PHE. County resolution ratified the local proclamation made on May 1, 2008. Pima Cnty. Bd. of Supervisors Res. No. 2008-107.

10. LAWRENCE O. GOSTIN, PROPOSED DRAFT: THE MODEL STATE EMERGENCY HEALTH POWERS ACT § 104(m), THE CTR. FOR LAW & PUB.’S HEALTH AT GEORGETOWN & JOHNS HOPKINS UNIV., (Dec. 21, 2001) <http://www.publichealthlaw.net/MSEHPA/MSEHPA.pdf> [https://perma.cc/L3HS-NYYK].

11. THE CTR. FOR LAW & PUB.’S HEALTH AT GEORGETOWN & JOHNS HOPKINS UNIV., THE MODEL STATE EMERGENCY HEALTH POWERS ACT (MSEHPA) STATE LEGISLATIVE ACTIVITY 1 (2006) (noting that by 2006, thirty-eight states’ legislatures had passed bills related to the Act), <http://www.publichealthlaw.net/MSEHPA/MSEHPA%20Leg%20Activity.pdf> [https://perma.cc/J95G-8PD3]; see also NETWORK FOR PUBLIC HEALTH, THE MODEL STATE EMERGENCY HEALTH POWERS ACT SUMMARY MATRIX 7 (2011), [https://www.networkforphl.org/\\_asset/80p3y7/Western-Region---MSEHPA-States-Table-8-10-12.pdf](https://www.networkforphl.org/_asset/80p3y7/Western-Region---MSEHPA-States-Table-8-10-12.pdf) [https://perma.cc/NN6T-GJYJ] (noting that in 2011, the Network for Public Health Law reported that 26 states and D.C. had legislatively crafted PHEs, or like terms, as part of their laws. Prior to 2001, virtually no state featured this type of emergency classification).

Date	Jurisdiction	Declaring Person/Entity	Purpose/Reason	Brief Summary
4/26/09	United States (U.S.)	Acting HHS Sec'y. Charles E. Johnson	H1N1 outbreak	PHE Determination. PHE to address Swine Influenza declared via the Public Health Service Act, 42 U.S.C. §247d.
6/17/09	Town of Libby (MT)	EPA Admin. Lisa P. Jackson	Release & threatened release of amphibole asbestos	Determination and Findings of PHE for the Libby Asbestos Site in Lincoln County, Montana. Declaration made under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) §104(a)(4).
10/5/10	City of Oakland (CA)	Oakland City Council	Shortage of affordable & safe medical cannabis	Resolution Renewing the City Council's Declaration of a Local PHE with Respect to Safe, Affordable Access to Medical Cannabis in the City of Oakland. Oakland City Council. Res. No. 82994.
2/4/11	Marquette County (MI)	Cnty. Health Dept.	Use of designer drugs (bath salts)	Emergency Order to Prevent Imminent Danger to Health or Lives. Marquette Cnty. Health Dep't. Order. <sup>12</sup>
3/9/12	Cnty. of Hawai'i (HI)	Council of the Cnty. of Hawai'i	Food insecurity	Emergency Ordinance That Finds and Declares That a PHE Exists and Makes an Emergency Appropriation of \$200,000 to Alleviate Hunger. Cnty. of Haw. Ordinance No. 1235.
8/9/12	Dallas County (TX)	Judge Clay Jenkins	West Nile Virus outbreak	PHE declared to help control mosquito populations and address the crisis. <sup>13</sup>

12. See CDC, *Emergency Department Visits After Use of a Drug Sold as "Bath Salts"* (May 20, 2011) <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6019a6.htm> [https://perma.cc/9SVC-EC28].

13. *West Nile Crisis: Public Health Emergency, A Conversation with Judge Clay Jenkins*, MOSQUITO CONTROL MAG., Summer 2013, at 8, [http://www.town.boxford.ma.us/Pages/BoxfordMA\\_BOH/mosquitos/MosqControlSummer2013.pdf](http://www.town.boxford.ma.us/Pages/BoxfordMA_BOH/mosquitos/MosqControlSummer2013.pdf) [https://perma.cc/X6WS-W942].

Date	Jurisdiction	Declaring Person/Entity	Purpose/Reason	Brief Summary
1/12/13	State of New York	Governor Andrew M. Cuomo	Severe flu season	Executive Order Declaring a Disaster Emergency in the State of New York and Temporarily Authorizing Pharmacists to Immunize Children Against Seasonal Influenza. N.Y. Exec. Order No. 90.
3/27/14	Commonwealth of Massachusetts	Gov. Deval Patrick	Opioid addiction epidemic	PHE Declaration. Declaration made to prevent escalation of the epidemic and aid in addict recovery. <sup>14</sup>
10/7/14	State of Connecticut	Gov. Daniel P. Malloy	Ebola	PHE declared via Conn. G. S. § 19a-131 to provide the Commissioner of Public Health and other officials with all authorities necessary to prevent any potential transmission of the Ebola virus.
3/26/15	Scott County (IN)	Gov. Mike Pence (3/26/15) Health Comm'r. Jerome Adams (5/21/15)	HIV Outbreak	Executive Order Declaring a PHE. The State Health Commissioner then declared and extended the PHE in Scott Cnty. Together, these declarations allowed the Scott Cnty. Health Dept. to administer a needle exchange program to combat HIV. Ind. Exec. Order 15-05.
10/20/15	Calaveras and Lake Counties (CA)	Ca. Dept. of Public Health Sec'y. Karen L. Smith	Aftermath of wildfires	Declaration of Health Emergency. Declaration made pursuant to CA Health and Safety Code § 101080 to address debris and hazardous material in ash resulting from wildfires.
12/15/15	City of Flint (MI)	Mayor Karen Weaver Gov. Rick Snyder (1/5/16)	Lead levels in drinking water	Declaration of State of Emergency. The declaration mobilized the National Guard to distribute water supplies.

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14. Press Release, Deval Patrick, Governor Patrick Declares Public Health Emergency, Announces Actions to Address Opioid Addiction Epidemic (Mar. 27, 2014) <http://archives.lib.state.ma.us/bitstream/handle/2452/207588/ocn795183245-2014-03-27b.pdf?sequence=1&isAllowed=y> [<https://perma.cc/JA47-S5MT>].

Date	Jurisdiction	Declaring Person/Entity	Purpose/Reason	Brief Summary
2/12/16	State of Hawai'i	Gov. David Y. Ige	Dengue fever	Emergency Proclamation to fight dengue fever authorized under HAWAII REV. STAT. § 127.
8/12/16	Puerto Rico	HHS Sec'y. Sylvia M. Burwell	Zika virus	Determination that a PHE Exists in Puerto Rico as a Consequence of the Zika Virus Outbreak. At the request of P.R. Gov. Padilla, HHS Secretary declared a PHE of national significance.

Government declarations supported emergency response efforts in natural disasters like Hurricanes Katrina and Rita (2005) and later Isaac and Sandy (2012). The spread of novel, infectious diseases (an original target of MSEHPA) also garnered declarations, notably including the 2009/2010 H1N1 pandemic. Localized outbreaks of infectious conditions, such as a 2012 uptick in human cases of West Nile Virus in Dallas County, Texas, also led to declared states of PHE. These sorts of declarations fell within the scope of pre-conceived notions reflected in MSEHPA as to what constitutes a PHE sufficient to enhance local, state, or federal public health powers.

However, lawmakers and executive officials also viewed an array of additional conditions or circumstances as PHEs that were arguably far outside the scope of the originally-crafted definition in MSEHPA. These include PHE declarations in cases of contamination of public water supplies, release of amphibole asbestos, domestic violence, shortages of affordable and safe medical cannabis, severe storms and tornadoes, food insecurity, opiate addiction, and wildfires. Though existing routine public health powers may sufficiently authorize response efforts to these public health threats, they were nevertheless classified as PHEs, potentially implicating civil rights infringements for little to no public health gain. To the extent PHE powers should be used only when justified and for limited duration, the invocation of declarations across a swath of conditions or threats reflects a shift in policy over time that may ultimately dilute emergency response efforts.

### III. PUBLIC HEALTH EMERGENCIES AS NATIONAL SECURITY THREATS

On April 1, 2016, former President Barack Obama proclaimed that public health is the key to national security and well-being at home and abroad.<sup>15</sup> His views were not merely aspirational. They are consistent with an emerging trend among federal leaders and agencies to classify PHEs as threats to national

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15. Press Release, Office of the White House Press Sec'y, Presidential Proclamation: Nat'l Pub. Health Week, 2016 (Apr. 1, 2016), <https://www.whitehouse.gov/the-press-office/2016/04/01/presidential-proclamation-national-public-health-week-2016> [https://perma.cc/9KEP-MLC9].

security. Federal authorities to address national security are grounded in multiple Constitutional provisions,<sup>16</sup> clarified in statutory enactments,<sup>17</sup> and extended well beyond the President.<sup>18</sup>

In the late 1980s NSTs began to increasingly include infectious diseases, bioterrorism, and environmental degradation.<sup>19</sup> In January 2000, the Central Intelligence Agency (CIA) detailed several impacts on national security of infectious diseases, including the potential for a high number of deaths, economic setbacks, delays in political developments, travel restrictions, and heightened probability of domestic attacks.<sup>20</sup> Since this report, multiple public health threats have garnered some level of national security designation<sup>21</sup> under three common

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16. See U.S. CONST. art. 1, § 8 (establishing the national defense as an exclusive federal role and authorizing Congress to declare war and provide for the common defense); See also U.S. CONST. art. 2 § 2 (establishing the President as Commander in Chief); See also U.S. CONST. art. 4 § 4 (guaranteeing a republican form of government and State protection from invasion).

17. See, e.g., THE NAT'L SEC. STRATEGY ARCHIVE (last visited Aug. 27, 2017), <http://nssarchive.us> [<https://perma.cc/4KSK-B4SL>]. The National Security Act of 1947, 50 U.S.C. § 401 (2012), established the National Security Council (NSC) and Central Intelligence Agency (CIA), and restructured military forces to gather data and contribute to executive responses. NSC is tasked with advising the President on foreign and domestic matters of national security to appropriately coordinate effective plans and responses. The Defense Production Act of 1950, 50 U.S.C. §§ 4501-4568 (2015), empowers the President to protect national security interests by allocating materials, services, and facilities to promote national defense, and controlling market forces in crises. The Goldwater-Nichols Defense Department Reorganization Act of 1986, 50 U.S.C. § 404(A) (2012), requires the President to submit to Congress an annual national security strategy report and budget proposal that frames security threat responses, interests, and goals each year.

18. See *Project Bioshield: Progress in the War on Terror*, THE WHITE HOUSE: PRESIDENT GEORGE W. BUSH (2004), <http://georgewbush-whitehouse.archives.gov/infocus/bioshield> [<https://perma.cc/679L-GQTN>]. The Foreign Assistance Act (FAA) of 1961, 22 U.S.C.A. § 2151 (1974), authorizes coordinated efforts of NSC and Department of Defense (DoD) to provide humanitarian aid abroad. The Project BioShield Act in 2004, 42 U.S.C. § 247d-6b (2004), seeks to improve public health infrastructure and medical countermeasures related to chemical, biological, radiological, or nuclear (CBRN) threats and increase bio-surveillance of harmful pathogens. It authorizes DHS' Secretary to issue material threat determinations regarding a CBRN event to fund essential countermeasures. 42 U.S.C. § 247d-6b(c)(2) (2012). In 2004, DHS received \$5.6 billion to use over ten years to purchase next-generation countermeasures against anthrax, smallpox, and other biothreats classified as MTDs.

19. David P. Fidler, *Public Health and National Security in the Global Age: Infectious Diseases, Bioterrorism, and Realpolitik*, 35 GEO. WASH. INT'L L. REV. 787, 791-92 (2003).

20. *The Global Infectious Disease Threat and Its Implications for the United States*, NAT'L INTELLIGENCE COUNCIL, NIE 99-17D, 10 (Jan. 2000) [hereinafter *The Global Infectious Disease Threat*], <http://www.fas.org/irp/threat/nie99-17d.htm> [<https://perma.cc/8ED9-DKDC>].

21. JENNIFER BROWER & PETER CHALK, THE GLOBAL THREAT OF NEW AND REEMERGING INFECTIOUS DISEASES: RECONCILING U.S. NATIONAL SECURITY AND PUBLIC HEALTH POLICY, (RAND 2003) [https://www.rand.org/content/dam/rand/pubs/monograph\\_reports/](https://www.rand.org/content/dam/rand/pubs/monograph_reports/)



classifications (see Table 2).

**Table 2. National Security Classifications**

National Security Threat	National Security Priority	Material Threat Determination
Systemic threat to domestic, regional, or global health or safety, or political, civil, or economic security, requiring significant additional resources, planning, and action by the U.S. (and other nations). <sup>22</sup>	Determination that potential humanitarian, economic, or political losses support a heightened level of national attention by the President, HHS, DHS, NSC, DoD, or other federal entity. <sup>23</sup>	DHS determination that CBRN agent poses a plausible threat to a significant number of American lives, permitting HHS to utilize BioShield reserve funds for necessary countermeasures. <sup>24</sup>

In 2002, the National Intelligence Council (NIC) projected that HIV/AIDS would seriously implicate national security interests as the disease spread to more populous countries.<sup>25</sup> President Bill Clinton initiated federal efforts to significantly increase the HIV/AIDS global prevention budget, accelerate vaccination research, mobilize new resources, and encourage international humanitarian efforts.<sup>26</sup> Later, in 2003, President George W. Bush created the President's Emergency Plan for AIDS Relief (PEPFAR), to fund treatment and

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MR1602/MR1602.pref.pdf [https://perma.cc/ENA8-NS77].

22. Exec. Order No. 13,691, 80 Fed. Reg. 9,349 (Feb. 20, 2015). *See also* Press Release, The White House Office of the Press Sec'y, Remarks by the President After Meeting on Ebola (Oct. 6, 2014), <https://www.whitehouse.gov/the-press-office/2014/10/06/remarks-president-after-meeting-ebola> [https://perma.cc/QC74-2C42].

23. James G. Hodge, Jr. & Kim Weidenaar, *Public Health Emergencies as Threats to National Security*, 9 J. NAT'L SECURITY L. & POL'Y 81, 86 (2017) [http://jnsllp.com/wp-content/uploads/2017/04/Public\\_Health\\_Emergencies\\_as\\_Threats\\_to\\_National\\_Security\\_FINAL.pdf](http://jnsllp.com/wp-content/uploads/2017/04/Public_Health_Emergencies_as_Threats_to_National_Security_FINAL.pdf) [https://perma.cc/PL3V-K87R]. *See also* Tom Friedman, *Executive Order Issued on One of the Most Urgent Health Concerns Facing Us Today*, DEP'T OF HEALTH & HUM. SERV. (Sept. 19, 2014), <http://www.hhs.gov/blog/2014/09/executive-order-issued-combating-antibiotic-resistant-bacteria.html>; Sylvia Mathews Burwell, *Our Response to the Ebola Crisis*, DEP'T OF HEALTH & HUM. SERV. (Sept. 17, 2014), <http://www.hhs.gov/blog/2014/09/our-response-ebola-crisis.html>.

24. STAFF OF H. COMM. ON HOMELAND SECURITY, SUBCOMM. ON EMERGENCY PREPAREDNESS, RESPONSE, & COMMUNICATIONS, 112TH CONG. (2011) (testimony of Segaran Pillai, Ph.D., Chief Med. and Sci. Advisor, Directorate Chem. and Biological Def. Div., Dep't of Homeland Sec.), [https://homeland.house.gov/files/Testimony%20Pillai\\_0.pdf](https://homeland.house.gov/files/Testimony%20Pillai_0.pdf) [https://perma.cc/8Q8X-87VS].

25. *The Next Wave of HIV/AIDS: Nigeria, Ethiopia, Russia, India, and China*, NAT'L INTELLIGENCE COUNCIL, ICA 2002-04D (Sept. 2002), <https://fas.org/irp/nic/hiv-aids.html> [https://perma.cc/Q97S-AWAC].

26. THE WHITE HOUSE, A NATIONAL SECURITY STRATEGY FOR A GLOBAL AGE (Dec. 2000), <http://nssarchive.us/NSSR/2001.pdf> [https://perma.cc/J23K-FLH4].

prevention measures for millions of persons largely in African countries.<sup>27</sup>

Diseases like Severe Acute Respiratory Syndrome (SARS), Middle East Respiratory Syndrome (MERS), multi-drug-resistant tuberculosis (MDR-TB), and pandemic influenzas have equally been classified as national security priorities. President Obama identified antibiotic-resistant bacteria as a national security and public health priority in 2014 via an Executive Order that outlined cross-sector efforts and investments to prevent and control outbreaks.<sup>28</sup> On September 22, 2006, DHS issued a material threat determination for Ebola viral disease (EVD) on grounds of national security.<sup>29</sup> Almost a decade later, President Obama described EVD as a NST in October 2014<sup>30</sup> to support federal aid through military health-related operations and funding for research, supplies, and biosurveillance.<sup>31</sup> On February 26, 2016, former Secretary of the Department of Health and Human Services (HHS), Sylvia Burwell, stated that Zika virus has “. . . significant potential to affect *national security* or the health and security of United States citizens living abroad . . . ,”<sup>32</sup> justifying action by HHS consistent with national security implications.<sup>33</sup>

Despite these and other examples of public health threats labeled under national security nomenclatures, predicting what qualifies as a NST remains difficult given their classified nature. Multiple criteria supporting these determinations include the: (1) existence of a potential or current threat to political, economic, and social stability; (2) limitations of civic and social participation stemming from the threat; (3) potential diminutions in military power; (4) capacity of the threat to exceed transnational borders; (5) systemic human rights abuses; and (6) insufficiencies of global public health responses.<sup>34</sup>

Regardless of the justification, classification of PHEs as NSTs has the capacity to change the nature of response efforts by increasingly “federalizing” these events. Characterizing PHEs as NSTs constitutionally stops state and local

27. THE HENRY J. KAISER FAMILY FOUNDATION, THE U.S. PRESIDENT’S EMERGENCY PLAN FOR AIDS RELIEF (PEPFAR) (June 2014), <https://kaiserfamilyfoundation.files.wordpress.com/2014/06/8002-05-the-u-s-presidents-emergency-plan-for-aids-relief-pepfar1.pdf> [<https://perma.cc/5EGC-CJJ5>], (noting that Congressional budget appropriations under PEPFAR peaked at \$6.9 billion under President Obama in 2010).

28. Exec. Order No. 13,676, 79 Fed. Reg. 56,931 (Sept. 18, 2014).

29. Declaration Regarding Emergency Use of in Vitro Diagnostics for Detection of Ebola Virus, 79 Fed. Reg. 47,141 (Aug. 12, 2014).

30. Press Release, Remarks by the President After Meeting on Ebola, *supra* note 22.

31. Jane Evans, *Pandemics and National Security*, 1 GLOBAL SEC. STUD. 100 (2010), <http://globalsecuritystudies.com/Evans%20PANDEMICS.pdf> [<http://perma.cc/392B-TJEC>].

32. 81 Fed. Reg. 10,878, 10,879 (Mar. 2, 2016) (emphasis added).

33. Sylvia M. Burwell, *Determination that a Public Health Emergency Exists in Puerto Rico as a Consequence of the Zika Virus Outbreak*, DEP’T OF HEALTH & HUMAN SERS. (Aug. 12, 2016), <http://www.phe.gov/emergency/news/healthactions/phe/Pages/zika-pr.aspx> [<http://perma.cc/P4EV-T3QT>] (noting that five months later, on August 12, 2016, HHS’ Secretary Burwell declared a PHE related to the spread of Zika virus in Puerto Rico).

34. See e.g., Hodge & Weidenaar, *supra* note 23, at 94.

governments from implementing public health efforts that they traditionally might have undertaken, or at least shared with federal authorities previously. In the years ahead, this jurisdictional shift of power promises to change the game regarding national PHE management, preparedness, and response.

#### IV. EXPANSION OF FEDERAL SOCIAL DISTANCING POWERS

Creating social distances between infectious individuals and at-risk communities is a long-standing and essential measure to counter public health repercussions of emerging infectious diseases such as SARS (2003),<sup>35</sup> H1N1 (2009),<sup>36</sup> EVD (2014),<sup>37</sup> and MERS (2014).<sup>38</sup> Like the ongoing shift to respond to these types of threats as NSTs, federal powers to apprehend, quarantine, and isolate individuals have undergone major revisions following decades of almost archaic notions of their exercise nationally.<sup>39</sup>

For decades under the Public Health Service Act (PHSA), HHS Secretary can take measures to prevent infectious agents from entering and spreading across the country.<sup>40</sup> Corollary federal regulations authorize CDC to detain, medically examine, and release persons travelling into the U.S., or between states, that are reasonably suspected of carrying specific communicable diseases<sup>41</sup> listed via federal Executive Order.<sup>42</sup> Though issuance of federal social distancing orders has been historically rare,<sup>43</sup> prior examples reveal embedded deficiencies.

In 2007, local public health authorities in Georgia asked Atlanta-based attorney Andrew Speaker to forgo his planned travels after determining he may be infected with extreme drug resistant tuberculosis (XDR-TB).<sup>44</sup> CDC officials

35. *Timeline: SARS Outbreak*, CNN (Apr. 24, 2003, 8:29 AM), <http://www.cnn.com/2003/HEALTH/04/24/timeline.sars/> [<http://perma.cc/K9FS-Y6US>].

36. *The 2009 H1N1 Pandemic: Summary Highlights, April 2009-April 2010*, CTRS. FOR DISEASE CONTROL & PREVENTION (last updated June 16, 2010), <https://www.cdc.gov/h1n1flu/cdcresponse.htm> [<http://perma.cc/QB4T-4MDV>].

37. *Ebola: Mapping the Outbreak*, BBC NEWS (Jan. 14, 2016), <http://www.bbc.com/news/world-africa-28755033> [<http://perma.cc/E7CJ-VP86>].

38. Press Release, CDC Announces First Case of Middle East Respiratory Syndrome Coronavirus Infection (MERS) in the United States, CTRS. FOR DISEASE CONTROL & PREVENTION (May 2, 2014) [hereinafter CDC Announcement], <https://www.cdc.gov/media/releases/2014/p0502-us-mers.html> [<http://perma.cc/7RSR-J873>].

39. *History of Quarantine*, CTRS. FOR DISEASE CONTROL & PREVENTION (last updated July 31, 2014), <https://www.cdc.gov/quarantine/historyquarantine.html> [<http://perma.cc/3V3G-X95S>].

40. Pub. Health Serv. Act, 42 U.S.C. § 6A (2016).

41. *Legal Authorities for Isolation and Quarantine*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 2015), <http://www.cdc.gov/quarantine/aboutlawsregulations/quarantineisolation.html> [<https://perma.cc/F29D-KW8C>].

42. Exec. Order No. 13,295, 68 Fed. Reg. 68 (Apr. 4, 2003).

43. *Quarantine Stations*, CTRS. FOR DISEASE CONTROL & PREVENTION (last updated Jan. 15, 2014), <https://www.cdc.gov/quarantine/quarantinestations.html> [<https://perma.cc/S3HE-PZJ6>].

44. Vikki Valentine, *A Timeline of Andrew Speaker's Infection*, NPR (June 6, 2007), <http://www.npr.org/news/specials/tb/> [<https://perma.cc/M6RK-LM3Z>].

stepped in when Speaker rebuffed local requests and travelled to several European countries for his honeymoon over a lengthy period of days. Amidst a barrage of international publicity, Speaker eventually flew to Canada, was apprehended by CDC agents after crossing the U.S. border into New York, and was flown and isolated at a Denver hospital for several weeks where he was treated for what was ultimately determined to be less serious form of drug-resistant TB. Speaker's case illustrated the limits of federal authorities, working in concert with local health officials, in CDC's own backyard.

Federal social distancing powers have been more prominently exercised in widespread outbreaks constituting PHEs. In 2014, an international outbreak of MERS reached the U.S. when two infected individuals returned from abroad.<sup>45</sup> Their conditions went undetected for several days, ultimately entailing case investigations of over 700 close contacts and costing over \$250,000.<sup>46</sup> Later that year, EVD reached the U.S. after spreading rapidly from West Africa through major international transportation hubs. An infected Liberian, Thomas Eric Duncan, went undetected through international travels to visit family in Dallas, Texas.<sup>47</sup> He later died at a Texas hospital where two of his treating nurses also became infected with EVD. Subsequently, over 35,000 travelers underwent health screenings at U.S. airports between October 2014 and the end of the outbreak. Despite enormous costs of such long-term screenings, no incoming EVD cases were actually detected through these routes.<sup>48</sup>

Increased societal mobilization meshed with complex infectious diseases with little to no effective treatments (at least initially) necessitated modernization of CDC's social distancing powers. The agency attempted for years to reform its provisions. In 2005, it proposed the detainment of individuals up to three business days pending issuance of a federal social distancing order.<sup>49</sup> Extensive public concerns grounded in enforcement and monitoring responsibilities for airlines and civil liberties infringements led to the abandonment of this proposal. In 2012, CDC broadened several of its existing regulations' definitions without substantively upgrading its authority.<sup>50</sup>

Following months of regulatory process beginning in 2015, including a major overhaul of an initial draft circulated in August 2016<sup>51</sup> (see Table 3), HHS/CDC

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45. CDC Announcement, *supra* note 38.

46. Control of Communicable Diseases, 81 Fed. Reg. 54,229 (proposed Aug. 15, 2016).

47. Greg Botelho & Jacque Wilson, *Thomas Eric Duncan: First Ebola Death in U.S.*, CNN (Oct. 8, 2014), <http://www.cnn.com/2014/10/08/health/thomas-eric-duncan-ebola/> [https://perma.cc/9WZF-UZV3].

48. James G. Hodge, Jr. et al., *Federal Powers to Control Communicable Conditions: Call for Reforms to Assure National Preparedness and Promote Global Security*, 15 HEALTH SECURITY 123 (2017).

49. Control of Communicable Diseases, 70 Fed. Reg. 71,892, 71,895 (proposed Nov. 30, 2005).

50. Control of Communicable Diseases: Interstate; Scope and Definitions, 77 Fed. Reg. 75,936, 75,937 (proposed Dec. 26, 2012).

51. See CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 43.

issued its Final Rule<sup>52</sup> to modernize regulations on January 19, 2017, just one day prior to the inauguration of President Trump. The Final Rule authorizes federal public health prevention measures at transportation hubs (e.g., airports, seaports, railway stations, and bus terminals).<sup>53</sup> Travelers may be subject to prevention measures, and asked to provide contact, travel, and health information.<sup>54</sup> In general, infected individuals may not engage in interstate or international travel without a federal travel permit.<sup>55</sup>

“Ill person” is defined broadly in the Rule to include virtually anyone with signs or symptoms of a communicable disease.<sup>56</sup> CDC officials can apprehend, isolate, quarantine, or conditionally release any individual upon “reasonable beliefs” that the person is infected with a quarantinable communicable condition listed via the aforementioned Executive Order.<sup>57</sup> They may be subject to a medical examination by a licensed HCW and tested as reasonably necessary to confirm or rule out an infectious condition.<sup>58</sup>

**Table 3. CDC’s 2017 Final Rule**

Change	2017 Final Rule
Removed	Requirement that individuals unilaterally agree to submit to measures including hospitalization, vaccination, and medical treatment
Added	Requirement that CDC agents reassess a social distancing order within 72 hours of issuance to determine whether less restrictive measures would fulfill the public health objective
Added	Requirement that medical examinations be conducted by a licensed health worker only upon informed consent
Modified	Definition of “non-invasive” to replace “physical inspection” with “visual inspection”
Added	Requirement that CDC provide certain accommodations, medical treatment, and means of communications for affected individuals
Added	A right to legal counsel by revising the term “Representatives,” and ensuring the appointment of counsel to indigent individuals
Added	A right to appeal where affected individuals can present witnesses and introduce expert testimony
Modified	The threshold for who may be considered indigent from 150% of the federal poverty level to 200%
Added	Requirement that CDC must respond to requests for travel permits within 5 business days, and to repeals of denials within 3 business days

52. Control of Communicable Diseases, 82 Fed. Reg. 6890 (Jan. 19, 2017).

53. *Id.* at 6891.

54. *Id.* at 6892.

55. *Id.* at 6891.

56. *Id.* at 6892, 6893.

57. Exec. Order No. 13,295, 68 Fed. Reg. 17,255 (Apr. 4, 2003).

58. Control of Communicable Diseases, 82 Fed. Reg. 6891 (Jan. 19, 2017).

How the Final Rule may be implemented by CDC agents in collaboration with state and local public health authorities is unclear. It now has the ability to deploy its social distancing measures without advance notice or approval of regional public health entities, although CDC may still seek such input as a matter of practice.<sup>59</sup> The Rule may be vulnerable to legal challenges depending how CDC actually exercises its authority. CDC's broad definition of "ill person" may unnecessarily capture persons who present little to no risk to societal public health. CDC's insistence on basing its social distancing powers on a "reasonable belief" standard is an affront to evidentiary standards in violation of substantive due process principles.<sup>60</sup> Additionally, the Rule fails to guarantee review of medical decisions outside CDC by a neutral decision-maker—a general staple of due process.<sup>61</sup> Affected individuals can, however, seek independent medical review on their own accord. Ultimately, CDC's updated regulations may only protect the public's health provided that exercises comport with respect for individual and community rights.

#### V. THE LIABILITY "SINKHOLE"

Among the most contentious issues in emergency preparedness is liability.<sup>62</sup> Health care and public health practitioners, volunteers, and others are concerned about their personal liability for patients' or others' injuries or deaths in emergencies.<sup>63</sup> Hospitals, clinics, public health agencies, and nonprofits worry about potential exposure to liability for their acts or omissions.<sup>64</sup> Some suggest these fears are unwarranted given that unscrupulous liability claims during and after PHEs are scarce.<sup>65</sup> Conversely, HCWs point to significant liability claims in national cases<sup>66</sup> involving workers trying to serve or treat patients with limited resources in dire circumstances.

Actual costs of liability exposure during and after emergencies are difficult to measure and assess, but collateral damages correlated to perceptions of risks are demonstrable. Numerous studies illustrate that health practitioners are unwilling to serve during emergencies because of potential liability.<sup>67</sup> Countless

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59. Control of Communicable Diseases, 82 Fed. Reg. 6890 (Jan. 19, 2017).

60. Lawrence Gostin & James G. Hodge, Jr., *Reforming Federal Public Health Powers: Responding to National and Global Threats*, 317:12 JAMA 1211, 1212 (Mar. 28, 2017).

61. *Id.*

62. George J. Annas, *Standard of Care—In Sickness and in Health and in Emergencies*, 352 NEW ENG. J. MED. 2126 (2010).

63. *Id.*

64. *Id.*

65. *Id.*

66. Christopher Drew & Shaila Dewan, *Louisiana Doctor Said to Have Faced Chaos*, N.Y. TIMES (July 20, 2006), <http://www.nytimes.com/2006/07/20/us/20doctor.html> [https://perma.cc/RZ44-2LS].

67. Michealle Carpenter et. al., *Deploying and Using Volunteer Health Practitioners in Response to Emergencies: Proposed Uniform State Legislation Provides Liability Protections and Workers' Compensation Coverage*, 3 AM. J. DISASTER MED. 17 (2008).

anecdotal data suggest that the mere threat of liability drives many HCWs or entities away from participating in PHE response efforts.<sup>68</sup> The Institute of Medicine (IOM) suggested in its 2009 report that “. . . state and local governments should explicitly tie existing liability protections (e.g., through immunity or indemnification) for healthcare practitioners and entities to crisis standards of care.”<sup>69</sup>

To date, however, there are no comprehensive national liability protections for HCWs, volunteers, or entities in all emergency settings. Instead, a patchwork of liability protections exists across all levels of government covering practitioners and entities—particularly volunteers and government entities and officials—who act in good faith and without willful misconduct, gross negligence, or recklessness.<sup>70</sup> These emergency liability protections may immunize or indemnify individuals or entities from specific claims or monetary damages. For example, in the last decade, all states executed the Emergency Management Assistance Compact (EMAC), which provides strong liability protections for state or local agents during declared emergencies.<sup>71</sup> Limited waivers of sanctions or fines for failing to comply with federal or state laws during emergencies offer additional protections.<sup>72</sup>

In 2005, Congress enacted the Public Readiness and Emergency Preparedness (PREP) Act<sup>73</sup> to protect specific entities and individuals implementing certain covered medical countermeasures.<sup>74</sup> Upon a PREP Act declaration by HHS’ Secretary, immunity from tort liability is extended to “covered persons” (e.g., federal officials, manufacturers, drug distributors, pharmacies, and state and local program planners) involved in the development, distribution, and administration

68. James G. Hodge, Jr. et. al., *Practical, Ethical, and Legal Challenges Underlying Crisis Standards of Care*, 41(S1) J.L. MED. & ETHICS 50, 52, 54 (2013).

69. INSTITUTE OF MEDICINE COMMITTEE ON GUIDANCE FOR ESTABLISHING STANDARDS OF CARE FOR USE IN DISASTER SITUATIONS, GUIDANCE FOR ESTABLISHING CRISIS STANDARDS OF CARE FOR USE IN DISASTER SITUATIONS: A LETTER REPORT, at 49 (2009); James G. Hodge, Jr., Dan Hanfling & Tia P. Powell, *Practical, Ethical, and Legal Challenges Underlying Crisis Standards of Care*, 41(S1) J. OF L. MED. & ETHICS 50 (2013).

70. Sharona Hoffman, *Responders’ Responsibility: Liability and Immunity in Public Health Emergencies*, 96 GEO. L.J. 1913 (2008); Sara Rosenbaum et. al, *State Laws Extending Comprehensive Legal Liability Protections for Professional Health-care Volunteers During Public Health Emergencies*, 123 PUB. HEALTH REP. 238, 239 (2008); *TFAH Liability Protections Relevant Statutes*, TRUST FOR AMERICAN HEALTH (2008), <http://healthyamericans.org/reports/bioterror08/pdf/legal-preparedness-law-review-of-state-statutes-and-codes.pdf> [<https://perma.cc/5S7M-54JD>].

71. Emergency Management Assistance Compact, Pub. L. No. 104-321, 110 Stat. 3877 (1996).

72. 42 U.S.C. § 1320b-5 (2008).

73. Public Readiness and Emergency Preparedness Act, Pub. L. 109-148, 119 Stat. 2680 (2005); *see also* 42 U.S.C. § 247d-6d.

74. Peggy Binzer, *The PREP Act: Liability Protection for Medical Countermeasure Development, Distribution, and Administration*, 6 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC. AND SCI. 293 (2008).

of medical countermeasures.<sup>75</sup> The PREP Act also establishes a compensation fund for individuals injured from the administration or use of covered countermeasures.<sup>76</sup> Though strong, these liability protections only apply to persons and covered countermeasures specified by HHS, for a specific period of time, and for acts of negligence, not intentional or criminal acts.

Despite some gaps, existing federal, state, and local laws collectively provide an umbrella of liability protections, sheltering hundreds of thousands of HCWs, volunteers, and entities that play by the rules.<sup>77</sup> Still, these protections have neither placated HCWs (seeking complete immunity) nor dissuaded patient-rights advocates (seeking equal access to courts to adjudicate potential negligence claims).<sup>78</sup> Many law- and policy-makers believe that subjecting practitioners and entities to unforeseen claims for negligent acts or omissions for their emergency responses in the chaos of emergencies runs counter to government protections of the public's health. Absent strong liability protections, HCWs simply will not show up and participate in emergency efforts. While patients' access to judicial relief may be negatively impacted (absent victims' relief funds), providing stronger liability protections to incentivize responders has emerged as a dominant policy objective of federal, tribal, state, and local governments.<sup>79</sup>

#### VI. PUBLIC HEALTH LEGAL PREPAREDNESS AND ROUTINE PUBLIC HEALTH PRACTICES

One of the upsides of PHE legal preparedness is the potential for lessons learned in emergencies to translate to routine public health practices. Public and private sectors often incorporate efficacious policies in emergency responses into day-to-day public health laws and practices.

Social distancing measures, including isolation and quarantine, are a primary example. Isolation and quarantine measures generated from emergencies or crises responses to infectious conditions are often applied in routine practice. Due process measures explicitly built into MSEP for purposes of assuring constitutionally sound quarantine and isolation efforts were also embedded two years later into the Turning Point Model State Public Health Act of 2003, which

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75. *Id.* at 293.

76. COUNTERMEASURES INJURY COMPENSATION PROGRAM, U.S. DEP'T OF HEALTH & HUMAN SERVS. (last updated Feb. 2017), <https://www.hrsa.gov/cicp/cicpfactsheet.pdf> [<https://perma.cc/42KC-X2CA>].

77. TABLE – LEGAL LIABILITY PROTECTIONS FOR EMERGENCY MEDICAL/PUBLIC HEALTH RESPONSES, NETWORK FOR PUB. HEALTH LAW (as of Feb. 20, 2017), [https://www.networkforphl.org/\\_asset/xbt7sg/Liability-Protections-for-Emergency-Response.pdf](https://www.networkforphl.org/_asset/xbt7sg/Liability-Protections-for-Emergency-Response.pdf) [<https://perma.cc/W5S7-JRX3>].

78. On August 9th, 2011, the American Bar Association (ABA) House of Delegates approved Resolution 125 to oppose adoption of laws, particularly immunity provisions, which “would alter the legal duty of reasonable care in the circumstances owed to victims of a natural or manmade disaster by relief organizations or health care practitioners.” AMERICAN BAR ASSOCIATION, REPORT TO THE HOUSE OF DELEGATES ON RESOLUTION 125 (2011).

79. INSTITUTE OF MEDICINE, *supra* note 69, at 48-50.



in turn was adopted for routine practices among multiple states.<sup>80</sup> Modern state requirements for HCWs to receive flu or other vaccinations also derive from emergency policies. After the 2009 H1N1 influenza outbreak in New York, the State health department required HCWs at hospitals, home health care agencies, and hospice care centers to be vaccinated for seasonal flu and H1N1.<sup>81</sup> Other states soon followed. As of 2015, 18 states had similar requirements.<sup>82</sup>

Expanded scopes of practice allowing pharmacists to administer vaccines also has its roots in contagious disease responses. MSEHPA, for example, would allow for sufficient expansion of scope of practice limitations among pharmacists in declared PHEs to allow them to directly administer vaccines.<sup>83</sup> In 1996 the Mississippi Department of Public Health asked the Mississippi Pharmacists Association to help combat seasonal adult influenza by training pharmacists to administer vaccines.<sup>84</sup> Over the next decade many other states began passing practice laws allowing pharmacists to administer flu vaccines, as well as common childhood vaccines like pertussis and MMR.<sup>85</sup> Pharmacists can administer multiple types of vaccines in 46 states; the remaining four (NH, NY, WV, WY) limit vaccines to influenza.<sup>86</sup>

New and investigational drugs used during pandemic responses are often later incorporated into general public health practice. The Food and Drug Administration (FDA) is authorized to issue Emergency Use Authorizations (EUAs) during emergency circumstances that involve chemical, biological,

80. James G. Hodge, Jr. et al., *Transforming Public Health Law: The Turning Point Model State Public Health Act*, 34 J. L., MED., & ETHICS 77 (Spring 2006).

81. Anemona Hartocollis, *State Requires Flu Vaccination for Caregivers*, N.Y. TIMES (Aug. 18, 2009), <http://www.nytimes.com/2009/08/19/health/policy/19swine.html?scp=6&sq=flu&st=cseNew%20rule%20adopted> [https://perma.cc/96QF-NE7L].

82. Chyongchiu Jeng Lin et al. *Association of State Laws and Healthcare Workers' Influenza Vaccination Rates*. 108 J. NAT'L MED. ASS'N. 99 (2016); CTRS. FOR DISEASE CONTROL & PREVENTION, *Menu of State Hospital Influenza Vaccination Laws* (2015), <https://www.cdc.gov/phlp/docs/menu-shfluvacclaws.pdf> [https://perma.cc/HVU8-WXPZ].

83. MODEL STATE EMERGENCY HEALTH POWERS ACT § 603(a)(1) (2001).

84. Michael D. Hogue et al., *Pharmacist Involvement with Immunizations: A Decade of Professional Advancement*, 46 J. AM. PHARM. ASS'N 168,169-70 (2006).

85. Cason Schmit & Allison Reddick, *Pharmacist Vaccination Laws Map*, LAW ATLAS, <http://legacy.lawatlas.org/query?dataset=pharmacist-vaccination> [https://perma.cc/R9MD-R2JQ] (last visited on Sept. 8, 2017); Amanda Schaffer, *Should You Go to the Drugstore for Your Flu Shots?* SLATE, (Oct. 17, 2012), [http://www.slate.com/articles/double\\_x/doublex/2012/10/vaccines\\_at\\_the\\_pharmacy\\_states\\_should\\_let\\_drugstores\\_give\\_shots.html](http://www.slate.com/articles/double_x/doublex/2012/10/vaccines_at_the_pharmacy_states_should_let_drugstores_give_shots.html) [https://perma.cc/TB4E-3D2A]; Sewell Chan, *Should Pharmacists Give Flu Shots?*, N.Y. TIMES (Mar. 5, 2008, 12:15 PM), <https://cityroom.blogs.nytimes.com/2008/03/05/should-pharmacists-give-flu-shots/> [https://perma.cc/WH8R-S4BY].

86. Krystalyn Weaver, *Pharmacist-administered immunizations: What does your state allow?*, PHARMACY TODAY (Oct. 2015), [https://www.pharmacist.com/sites/default/files/files/1015\\_PT\\_63A.pdf](https://www.pharmacist.com/sites/default/files/files/1015_PT_63A.pdf) [https://perma.cc/EH2Z-XPEF].

radiological, or nuclear agents.<sup>87</sup> EUAs allow responders to use otherwise-unapproved lifesaving preventatives, treatments, and tests in response to emergency situations.<sup>88</sup> In the midst of the H1N1 pandemic in 2009, FDA issued an EUA for the antiviral peramivir to treat H1N1 intravenously.<sup>89</sup> The agency eventually approved the drug fully in 2014.<sup>90</sup>

PHEs involving non-communicable diseases may also catalyze changes in routine public health practice. As noted in Table 1, in March 2014, Massachusetts Governor Deval Patrick declared a PHE in response to an increase in heroin and opioid overdoses.<sup>91</sup> Emergency responders were authorized to carry naloxone, an overdose reversal medication.<sup>92</sup> Pharmacies were allowed to dispense the drug without a prescription.<sup>93</sup> With opiate overdose numbers skyrocketing nationally,<sup>94</sup> many states have similarly changed their policies to make naloxone more easily available. As of 2016, 45 states allow third party individuals to receive a prescription for naloxone;<sup>95</sup> 33 states and the District of Columbia allow pharmacies to dispense naloxone without a prescription.<sup>96</sup>

Syringe exchange programs (SEPs) represent another cross-over from emergencies to routine practice. In 1993, the City of San Francisco declared a local emergency and exempted the City and County from state laws regarding

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87. *Emergency Use Authorization of Medical Products and Related Authorities*, FOOD & DRUG ADMIN. (January 2017), <https://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm> [<http://perma.cc/G4PB-R5DU>].

88. *Id.*

89. *Authorization of Emergency Use of the Antiviral Product Peramivir Accompanied by Emergency Use Information; Availability*, 74 Fed. Reg. 56644 (Nov. 2, 2009).

90. *FDA approves Rapivab to treat flu infection*, FOOD & DRUG ADMIN (Dec. 22, 2014), <http://web.archive.org/web/20170217030115/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm427755.htm> [<https://perma.cc/4CN5-9ZZJ>].

91. Brian MacQuarrie, *Governor declares an emergency on opiate abuse*, BOSTON GLOBE (Mar. 27, 2014), <https://www.bostonglobe.com/metro/2014/03/27/with-heroin-overdoses-rise-gov-patrick-declares-public-health-emergency-mass/hOajTIJKNshKAnWjZ6wYL/story.html> [<https://perma.cc/TH93-7EV3>].

92. *Id.*

93. Richard Valdmanis, *Massachusetts declares heroin emergency, looks to anti-overdose drug*, REUTERS (Mar. 27, 2014, 5:00 PM), <http://www.reuters.com/article/us-usa-heroin-massachusetts-idUSBREA2Q25D20140327> [<https://perma.cc/QQQ3-9ZLR>].

94. *Opioids: The Prescription Drug & Heroin Overdose Epidemic*, DEP'T OF HEALTH & HUMAN SERVS., <https://www.hhs.gov/opioids/> [<https://perma.cc/27CD-GZLG>] (last visited Sept. 4, 2017).

95. *Naloxone Overdose Prevention Laws*, PRESCRIPTION DRUG ABUSE POLICY SYS., <http://pdaps.org/datasets/laws-regulating-administration-of-naloxone-1501695139> [<https://perma.cc/STR7-CQGX>] (last visited July 1, 2017).

96. *Walgreens expands availability of naloxone without a prescription*, AM. PHARMACISTS ASS'N (Dec. 22, 2016), <https://www.pharmacist.com/article/walgreens-expands-availability-naloxone-without-prescription> [<https://perma.cc/ZN2V-MEXY>].

syringe distribution.<sup>97</sup> SEPs have since proven extremely effective at combatting the spread of HIV/AIDS.<sup>98</sup> Sixteen states now explicitly authorize needle exchanges. Indiana allows SEPs in a declared state of emergency,<sup>99</sup> which former Governor Mike Pence used to abate an epidemic of HIV in a small rural area of the state in 2015 following mass exposures via injecting drug users.<sup>100</sup> In 2016, the federal Consolidated Appropriations Act<sup>101</sup> opened the door for state and local jurisdictions to use federal funds to implement SEPs if they can prove their jurisdiction is experiencing, or at risk for, hepatitis or HIV outbreaks resulting from injected drug use.<sup>102</sup> The Trump administration has not made official statements about SEPs or their continued federal funding.<sup>103</sup>

Efforts to contain Zika virus have also led to public health innovations that may set new standards for public health practices. As Zika-carrying mosquitos (*Aedes aegypti*) are more active during the day, traditional mosquito vector control methods, like insecticide-treated bed nets used to combat malaria, are ineffective.<sup>104</sup> Other mosquito abatement efforts (e.g., eliminating standing water, ground-level insecticide and larvicide spraying, and aerial spraying)<sup>105</sup> have

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97. Carmen L. Masson et al., *Organizational Issues in the Implementation of a Hospital-Based Syringe Exchange Program*, 45 SUBSTANCE USE MISUSE 901 (2010).

98. David Vlahov & Benjamin Junge, *The Role of Needle Exchange Programs in HIV Prevention*, 113 PUB. HEALTH REP. 75, 76 (1998).

99. Austin Coleman, *Needle Exchange Programs*, THE COUNCIL OF STATE GOV'T (June 25, 2015), <http://knowledgecenter.csg.org/kc/content/needle-exchange-programs> [https://perma.cc/6NXS-GL7V].

100. JAMES G. HODGE JR., PUBLIC HEALTH LAW IN A NUTSHELL 260 (West Academic, 2nd ed. 2016).

101. H.R. 2029, 114th Cong. § 520 (2015).

102. DEP'T OF HEALTH & HOSPITAL SERV. IMPLEMENTATION, IMPLEMENTATION GUIDANCE TO SUPPORT CERTAIN COMPONENTS OF SYRINGE SERVICES PROGRAMS (2016).

103. Olivia Becker, *Bad policy: Trump has no plans for tackling HIV/AIDS – and his team has an abysmal track record*, VICE NEWS, (Dec. 1, 2016), <https://news.vice.com/story/trump-has-no-policy-plans-for-hiv-aids-and-his-team-has-an-abysmal-track-record> [https://perma.cc/7ZL8-3WZ4]. However, in 2015 then-Indiana Governor Mike Pence was asked by local, state, and federal health officials to allow SEPs (illegal under state law) in response to an HIV epidemic. Megan Twohey, *Mike Pence's Response to H.I.V. Outbreak: Prayer, Then a Change of Heart*, N.Y. TIMES (Aug. 7, 2016), <https://www.nytimes.com/2016/08/08/us/politics/mike-pence-needle-exchanges-indiana.html> [https://perma.cc/B9QT-SAKT]. It took two months for Governor Pence to declare a PHE and allow a temporary SEP, by which point there were nearly ninety emergent cases. *Governor Pence Declares Public Health Emergency in Response to HIV Epidemic in Scott County*, IN.GOV (Mar. 26, 2015), [http://www.in.gov/activecalendar/EventList.aspx?view=EventDetails&eventidn=214652&information\\_id=212487&type=&syndicate=syndicate](http://www.in.gov/activecalendar/EventList.aspx?view=EventDetails&eventidn=214652&information_id=212487&type=&syndicate=syndicate) [https://perma.cc/JR8S-GBZC].

104. Lorenz von Seidlein, Alexander S. Kekule, & Daniel Stickman, *Novel Vector Control Approaches: The Future for Prevention of Zika Virus Transmission?*, 14(1) PLOS MED (2017).

105. Anna Likos et al., *Local Mosquito-Borne Transmission of Zika Virus – Miami-Dade and Broward Counties, Florida, June-August 2016*, CDC MORBIDITY & MORTALITY WEEKLY REPORT

proven more effective, but public health officials and scientists have sought additional technological methods as well. In August 2016, FDA approved a plan to release a limited number of sterile, genetically-modified mosquitos in the Florida Keys to combat Zika through active breeding.<sup>106</sup> Although still under study, these tactics have demonstrated early success in reducing the presence of *Aedes aegypti* and emerging cases of Zika. Public health officials are considering use of this and other advanced technologies more generally to control mosquitos that transmit other diseases like dengue fever and chikungunya.<sup>107</sup>

## VII. CONCLUSION

Public health legal preparedness laws and policies have undergone massive transformations since September 11, 2001. With these changes have come beneficial improvements in preparedness nationally and regionally, clarifications of policies related to liability protections, and improvements in the delivery of routine public health and health care services. On the horizon, however, are looming uncertainties over the criteria that constitute a PHE as well as the level of government primarily responsible for emergency responses on a large or small scale. Federal incursions over the past decade especially into traditional state-based public health powers are understandable against a political and practical backdrop focused on a need to control emerging public health threats in a mobilized society. Whether the U.S. public health system as currently constructed features sufficient flexibility constitutionally and politically to adapt to continued shifts in the locus of emergency powers is yet to be seen.

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