

## **PANDEMICS, POPULISM AND THE ROLE OF LAW IN THE H1N1 VACCINE CAMPAIGN**

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In the spring of 2009, a new strain of type A influenza (H1N1) arrived triggering the first influenza pandemic of the 21st century.<sup>1</sup> With the initial discovery of the virus, scientists began working on developing a vaccine, the intervention widely believed to offer the greatest protection against an influenza pandemic.<sup>2</sup> Shortly thereafter, federal health officials utilized a series of legal tools that had been put into place in the years prior to the pandemic to facilitate the rapid development and distribution of a vaccine.<sup>3</sup> By many measures, the use of these tools was a great success. By the end of 2009, approximately 61 million Americans had been vaccinated against H1N1; by January 2010, over 124 million doses of vaccine had been distributed in the U.S.<sup>4</sup> Although vaccination rates varied widely by state, in most states vaccination rates for children, a group at high risk for severe disease from H1N1, were higher than their prior rates for seasonal flu vaccination.<sup>5</sup> Perhaps more importantly, the Vaccine Adverse Event

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1. A dispute exists as to whether the H1N1 outbreak should be described as a pandemic. In May 2009, WHO changed its definition of a pandemic so as to exclude any consideration of the severity of a disease. See Deborah Cohen & Philip Carter, *WHO and the Pandemic Flu "Conspiracies,"* 340 BRIT. MED. J. 1274, 1275 (2010). Despite this debate, the H1N1 outbreak will be termed a pandemic throughout this article.

2. See Press Release Ctr., *CDC Briefing on Public Health Investigation of Human Cases of Swine Influenza*, CTRS. FOR DISEASE CONTROL & PREVENTION (CDC) (Apr. 23, 2009), <http://cdc.gov/media/transcripts/2009/t090423.htm>. See also Ctrs. for Disease Control & Prevention, *Interim Results: Influenza A (H1N1) 2009 Monovalent Vaccination Coverage – United States, October – December 2009*, 59 MORBIDITY & MORTALITY WKLY. REP. 44, 46-47 (2010) (discussing that by the end of 2009, eighty-five million doses of H1N1 vaccine had been produced by U.S. drug manufacturers, and an estimated sixty-one million Americans had received the vaccine).

3. See *infra* text accompanying notes 54-77 and 195-96.

4. Ctrs. for Disease Control & Prevention, *Interim Results: State-Specific Influenza A (H1N1) 2009 Monovalent Vaccination Coverage—United States, October 2009 - January 2010*, 59 MORBIDITY & MORTALITY WKLY. REP. 363, 363 (2010).

5. *Id.* at 364.

Reporting System (VAERS) uncovered no “unusual events or pattern of adverse events,” different from that which is seen for seasonal flu vaccine.<sup>6</sup>

By other measures, however, the campaign appeared less successful. Despite scientists’ best efforts, the vaccine took longer than anticipated to produce and was in woefully short supply during the height of the pandemic.<sup>7</sup> As a result, many children and adults at high risk for severe disease were unable to obtain a vaccine when they most needed it, in the early fall of 2009.<sup>8</sup> Yet, by late fall and early winter, as supplies became more plentiful, the public’s fears of the disease abated and were increasingly replaced by concerns about the vaccine’s safety.<sup>9</sup> Critics also charged that the pandemic had been hyped by health officials to provide profits for vaccine makers.<sup>10</sup> By the winter of 2010, over sixty million doses of vaccine were unused; many were destined to be destroyed.<sup>11</sup>

What role did law play in both the successes and the shortfalls of the H1N1 vaccine campaign? What lessons can be learned to guide future efforts to use law to protect the public from pandemic flu? This article explores those questions, focusing on public health emergency laws’ impact on the H1N1 vaccine program and the interaction of those laws with the current populist stance in American political culture.<sup>12</sup> Populism, a recurring riff in American history, is a political attitude most pointedly characterized by a profound distrust of elites.<sup>13</sup> As such, it represents a significant challenge

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6. Ctrs. for Disease Control & Prevention, *Summary of 2009 Monovalent H1N1 Influenza Vaccine Data – Vaccine Adverse Event Reporting System, Data Through May 29, 2010* (2010), available at [http://vaers.hhs.gov/resources/2010H1N1Summary\\_June03.pdf](http://vaers.hhs.gov/resources/2010H1N1Summary_June03.pdf) (finding that as of May 29, 2010, sixty deaths were reported to the Vaccine Adverse Event Reporting System (VAERS) in conjunction with the H1N1 vaccine. However, the CDC found no evidence to suggest these deaths were caused by the vaccine.).

7. Associated Press, *Poll Indicates Swine Flu Vaccine Scarce*, BOSTON GLOBE, Nov. 7, 2009, at A2.

8. Stephanie Ebbert, *Mom vs. Mom, Anxiety Fuels Competition to Score Swine Flu Shots for their Kids*, BOSTON GLOBE, Nov. 21, 2009, at 26; Gillian K. SteelFisher et al., *The Public’s Response to the 2009 H1N1 Influenza Pandemic*, 362 NEW ENG. J. MED. e65(1), e65(1)-(2), e65(4)-(5) (2010).

9. *Id.* at e65(5).

10. See Barbara Loe Fisher, *Politics, Profits & Pandemic Fear Mongering*, NAT’L VACCINE INFO. CTR. BLOG (May 1, 2009), <http://www.nvic.org/NVIC-Vaccine-News/May-2009/Friday,-May-01,-2009-Politics,-Profits---Pandemic-.aspx>.

11. Stephen Smith, *Swine Flu Vaccine is Widely Unused*, BOSTON GLOBE, May 22, 2010, at B1; Mike Stobbe, Associated Press, *Millions of Vaccine Doses to be Burned*, ABC NEWS, July 1, 2010, available at <http://abcnews.go.com/Health/wireStory?id=11061293>.

12. For a discussion of contemporary populism, see Steve Fraser & Joshua B. Freeman, *The Strange History of Tea Party Populism*, SALON (May 3, 2010), [http://www.salon.com/news/feature/2010/05/03/tea\\_party\\_populism\\_history](http://www.salon.com/news/feature/2010/05/03/tea_party_populism_history).

13. Political scientists and political historians have offered many definitions of populism. Michael Kazin, in his history of American populism, writes that the most “telling definition of

to public health officials and policymakers, who are almost always elites, or are at least widely perceived as such, in their attempt to respond to a pandemic. In particular, populism poses a dilemma for public health professionals who seek to protect public health via vaccination because populism builds upon and exacerbates distrust of health officials' assertions about the need for vaccination and its safety. At the same time, the public's distrust of vaccines may spur officials to act even more forcefully than they otherwise would. In either case, law may bridge or widen the divide between public health officials and the populations they are charged with protecting.

Part One begins by providing a brief review of influenza pandemics and recent efforts to prepare for one. The section then describes the 2009 H1N1 vaccine campaign within the U.S. Part Two examines why vaccines are critical to pandemic preparedness and considers the challenges policymakers face in securing both an adequate supply and a robust demand for pandemic vaccines. Part Three reviews the legal responses that have been put in place over the last thirty years to address supply side problems. Part Four turns to the demand side of the equation, reviewing the legal responses that public health officials have employed to address the public's reluctance to be vaccinated. Both Part Five and the Conclusion assess the relationship between the legal responses to supply and demand problems, and suggest that the laws that have been enacted to facilitate the development and distribution of pandemic vaccines may heighten the public's distrust of public health officials. If so, these laws may fail to achieve their goal of protecting the public from a pandemic.

#### PART ONE: A PANDEMIC PREDICTED

For more than five years, the specter of pandemic influenza has hovered over U.S. and world public health policy.<sup>14</sup> In the past one hundred years, there have been three major influenza pandemics, none more lethal than the misnamed 1918 "Spanish flu" pandemic.<sup>15</sup> That pandemic, which

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populism" is a "language whose speakers conceive of ordinary people as a noble assemblage not bounded narrowly by class, view their elite opponents as self-serving and undemocratic, and seek to mobilize the former against the latter." MICHAEL KAZIN, *THE POPULIST PERSUASION: AN AMERICAN HISTORY* 1 (Cornell University 1998) (1995).

14. See, e.g., Sandra Mounier-Jack & Richard J. Coker, *How Prepared is Europe for Pandemic Influenza: Analysis of National Plans*, 367 *LANCET* 1405, 1405-11 (2006) (analyzing European countries' pandemic preparedness plans). See also Jaro Kotalik, *Preparing for an Influenza Pandemic: Ethical Issues*, 19 *BIOETHICS* 422, 422-31 (2005) (analyzing pandemic preparedness plans of Canada, United Kingdom, and the United States from an ethical perspective).

15. See JOHN M. BARRY, *THE GREAT INFLUENZA: THE EPIC STORY OF THE DEADLIEST PLAGUE IN HISTORY* 4, 113-14, 117 (2004).

broke out in the waning days of World War I, is estimated to have killed between twenty and one hundred million people around the globe, making it the most deadly outbreak in recorded history.<sup>16</sup> In 1957, the less lethal but still quite deadly Asian flu pandemic struck, killing approximately two million people worldwide.<sup>17</sup> In 1967, the Hong Kong flu pandemic killed an estimated one million people.<sup>18</sup>

In the years since 1967, scientists have repeatedly warned that another influenza pandemic, possibly as grave as the 1918 outbreak, was inevitable.<sup>19</sup> That warning struck a chord with the Ford Administration in 1976 when it ordered an unprecedented vaccination program after several soldiers at Fort Dix, New Jersey, contracted, and one died, from a swine flu virus that scientists thought resembled the 1918 strain.<sup>20</sup> After approximately forty million Americans were vaccinated, the dreaded pandemic failed to materialize.<sup>21</sup> The program was shelved as worries grew that the vaccine caused Guillain-Barré syndrome.<sup>22</sup> In subsequent years, the 1976 swine flu vaccine campaign served to illustrate the pitfalls public health officials face when they initiate prevention campaigns based on limited information.<sup>23</sup> The campaign's history also highlights the potential gulf between the perspective of public health officials, who stress the need to

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16. *Id.* at 4. See also GINA KOLOTA, *FLU: THE STORY OF THE GREAT INFLUENZA PANDEMIC OF 1918 AND THE SEARCH FOR THE VIRUS IT CAUSED* 7 (1999).

17. *Global Alert and Response, Ten Concerns if Avian Influenza Becomes a Pandemic*, WORLD HEALTH ORG. (Oct. 14, 2005), <http://www.who.int/csr/disease/influenza/pandemic10things/en> [hereinafter WHO]. See also BARRY, *supra* note 15, at 115.

18. WHO, *supra* note 17.

19. Peter A. Patriarca & Nancy J. Cox, *Influenza Pandemic Preparedness Plans for the United States*, 176 J. INFECTIOUS DISEASES S4, S4 (1997).

20. RICHARD NEUSTADT & HARVEY FINEBERG, *THE SWINE FLU AFFAIR: DECISION-MAKING ON A SLIPPERY DISEASE* 5-6, 24-30 (University Press of the Pacific 2005) (1978). See also KOLOTA, *supra* note 16, at 121-50 (recounting the 1976 death of a soldier at Fort Dix, the effort to identify the virus, and the Ford Administration's response).

21. KOLOTA, *supra* note 16, at 167; J.S. Malik Peiris, Leo L.M. Poon & Yi Guan, *Emergence of a Novel Swine-Origin Influenza A Virus (S-OIV) H1N1 Virus in Humans*, 45 J. CLIN. VIROLOGY 169, 170 (2009).

22. Nina S. Appel, *Liability in Mass Immunization Programs*, 1980 BYU L. REV. 69, 72 (1980); Peiris, Poon & Guan, *supra* note 21, at 170. Whether the vaccine actually caused Guillain-Barré syndrome remains controversial. See, e.g., Andrew Pollack, *Fears of a Swine Flu Epidemic in 1976 Offer Some Lessons, and Concerns, Today*, N.Y. TIMES, May 9, 2009, at A11 (quoting experts who question whether the 1976 vaccine caused Guillain-Barré syndrome); Lawrence B. Schonberger et al., *Guillain-Barre Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976-1977*, 110 AMER. J. EPIDEMIOLOGY 105, 105-22 (1979) (finding an association between the vaccine and the syndrome).

23. NEUSTADT & FINEBERG, *supra* note 20, at 1-2.

“err on the side of overreaction,”<sup>24</sup> and the views of the populations that officials seek to protect.

In the 1990s, in response to a plethora of new infectious diseases, as well as broader social developments,<sup>25</sup> scientists, health officials, and the media increasingly focused their attention on the dangers of so-called emerging diseases.<sup>26</sup> As fear of contagion took hold,<sup>27</sup> scientists were quick to warn that no disease has ever proven more lethal than the 1918 influenza and that there was no reason to assume that such a horrific pandemic could not happen again.<sup>28</sup> That prophecy seemed prescient in 1997, when several young, previously healthy people died in Hong Kong from a new strain of avian influenza, known as H5N1.<sup>29</sup> Fortunately, Hong Kong was able to quash the outbreak by slaughtering its chickens.<sup>30</sup> But the virus did not vanish with the chickens; in the years that followed, H5N1 spread around the globe. By 2005, the virus had infected birds in sixteen countries and over 120 people.<sup>31</sup> Although the virus was not easily transmissible among humans (almost everyone who became ill had been in close contact with infected birds), it had a high (approximately fifty percent)

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24. David J. Sencer & J. Donald Millar, *Reflections on the 1976 Swine Flu Vaccination Program*, 12 EMERGING INFECTIOUS DISEASES 29, 33 (2006), reprinted in THE DOMESTIC AND INTERNATIONAL IMPACTS OF THE 2009-H1N1 INFLUENZA A PANDEMIC 297, 305 (David Relman et al., 2009).

25. Wendy Parmet, *Public Health and Social Control* 14-19 (Int'l Council on Human Rights Pol'y, Working Paper, 2009), available at [http://www.ichrp.org/files/papers/173/public\\_health\\_and\\_social\\_control\\_wendy\\_parmet.pdf](http://www.ichrp.org/files/papers/173/public_health_and_social_control_wendy_parmet.pdf). The claims that scientists and public health officials focused attention on emerging diseases is not meant to imply that they acted in bad faith; rather that they responded to social as well as biological developments.

26. See *id.* for a more complete discussion of the renewed concern that scientists, officials, and the media gave to infectious disease in the 1990s.

27. See PRISCILLA WALD, *CONTAGIOUS: CULTURES, CARRIERS, AND THE OUTBREAK NARRATIVE* 1-28 (Duke University Press, 2008) (discussing fear of contagious disease in the 1990s).

28. E.g., W. Paul Glezen, *Emerging Infections: Pandemic Influenza*, 18 EPIDEMIOLOGIC REVS. 64, 64-65 (1996); Robin Marantz Henig, *The Flu Pandemic*, N.Y. TIMES, Nov. 29, 1992, at 28; Kennedy F. Shortridge, *The Next Pandemic Influenza Virus?*, 346 LANCET 1210, 1210-11 (1995).

29. See PETE DAVIES, *THE DEVIL'S FLU: THE WORLD'S DEADLIEST INFLUENZA EPIDEMIC AND THE SCIENTIFIC HUNT FOR THE VIRUS THAT CAUSED IT* 1-64 (2000). In the wake of the outbreak in Hong Kong, several authors wrote books designed to acquaint a popular audience with the 1918 epidemic and warn about the possibility of a new pandemic. See, e.g., BARRY, *supra* note 15; KOLOTA, *supra* note 16.

30. Nina Y. Kung et al., *Risk for Infection with Highly Pathogenic Influenza A Virus (H5N1) in Chickens, Hong Kong, 2002*, 13 EMERGING INFECTIOUS DISEASES, 412, 412 (2007).

31. HOMELAND SECURITY COUNCIL, NATIONAL STRATEGY FOR PANDEMIC INFLUENZA 1, 1 (2005) [hereinafter NATIONAL STRATEGY].

case mortality rate.<sup>32</sup> Chastened by the world's experience in 2003 with severe acute respiratory syndrome (SARS), health officials around the globe intensified their cry for pandemic preparedness.<sup>33</sup>

The Bush Administration responded in 2005 by releasing the *National Strategy for Pandemic Influenza*<sup>34</sup> (*Strategy*), which was designed to guide federal efforts to plan and prepare for a potential influenza pandemic.<sup>35</sup> Vaccination played a prominent role in the *Strategy*:

In combination with traditional public health measures, vaccines and antiviral drugs form the foundation of our infection control strategy. Vaccination is the most important element of this strategy, but we acknowledge that a two-pronged strategy incorporating both vaccines and antivirals is essential.<sup>36</sup>

More specifically, the *Strategy* called for enhancing domestic production of influenza vaccination so that the entire population could be vaccinated within six months of the start of a pandemic, stockpiling sufficient pre-pandemic avian influenza vaccine to immediately vaccinate "front-line personnel and at risk populations including military personnel," developing distribution plans, and eradicating "regulatory and other legal barriers to the expansion of our domestic vaccine production capacity."<sup>37</sup>

The federal government's approach for meeting those goals was spelled out more explicitly in the Homeland Security Council's 2006 *Implementation Plan*.<sup>38</sup> Underlying the *Implementation Plan* was the assumption that pandemic influenza would initially develop overseas. The plan aimed to improve surveillance and detection of influenza around the world so that the federal government could try to contain, or at least slow down, the spread of a pandemic within the United States until such time as a vaccine would be widely available.<sup>39</sup> Targeted deployment of pre-pandemic vaccine and

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32. *Id.*; DAVIES, *supra* note 29, at 26-27; Arunee Thitithanyanont et al., *High Susceptibility of Human Dendritic Cells to Avian Influenza H5N1 Virus Infection and Protection by IFN- $\alpha$  and TLR Ligands*, 179 J. IMMUNOLOGY 5220, 5220 (2007).

33. See Richard J. Webby & Robert G. Webster, *Are We Ready for Pandemic Influenza?*, 320 SCIENCE 1519, 1519 (2003) (reviewing pandemic preparedness plans after threats of severe acute respiratory syndrome (SARS), bioterrorism, West Nile virus, and other threats).

34. See NATIONAL STRATEGY, *supra* note 31.

35. Around the same time, the CDC published proposed revised quarantine regulations, but the regulations were never promulgated. Control of Communicable Diseases, 70 Fed. Reg. 71892 (Nov. 20, 2005). Additionally, the Public Readiness and Emergency Preparedness Act (PREPA), Pub. L. 109-148, was enacted in 2005. For a more complete discussion of PREPA, see *infra* text accompanying notes 179-99.

36. NATIONAL STRATEGY, *supra* note 31, at 5.

37. *Id.*

38. See HOMELAND SECURITY COUNCIL, NATIONAL STRATEGY FOR PANDEMIC INFLUENZA: IMPLEMENTATION PLAN 104-07 (2006) [hereinafter IMPLEMENTATION PLAN].

39. *Id.* at 1.

antiviral medications, potentially in conjunction with non-pharmaceutical interventions (such as quarantines or border closings), were critical to the plan.<sup>40</sup>

Although a pandemic was widely predicted, the one that arrived in the spring of 2009 did not conform to health officials' prognostications.<sup>41</sup> Pandemic planning reports had repeatedly cited the 1918 outbreak, warning that "a modern pandemic could lead to the deaths of 200,000 to 2 million people in the United States alone."<sup>42</sup> Fortunately, H1N1 proved to be far less deadly. As of March 2010, the Centers for Disease Control and Prevention (CDC) reported that about 12,000 people died from H1N1,<sup>43</sup> meaning that fewer Americans died from the H1N1 pandemic than die from so-called seasonal flu in a typical year.<sup>44</sup> That comparison, however, may understate H1N1's impact. In contrast to seasonal flu, but as in 1918, serious illness and death were disproportionately experienced by persons under age forty-five.<sup>45</sup> Young children and pregnant women faced especially high risks.<sup>46</sup> In the first wave of the pandemic, between April and August 2009, five percent of all deaths from H1N1 were among pregnant women, even though pregnant women represent only one percent of the

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40. *Id.* at 105-08.

41. See Ctrs. for Disease Control & Prevention, *The 2009 H1N1 Pandemic: Summary Highlights, April 2009-April 2010* (June 16, 2010), <http://cdc.gov/h1n1flu/cdcreponse.htm>, for a discussion of evolution of the 2009 pandemic [hereinafter *Summary Highlights*].

42. See IMPLEMENTATION PLAN, *supra* note 38, at 1.

43. Press Release, CDC 2009 H1N1 Flu Media Briefing, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 29, 2010), <http://cdc.gov/media/transcripts/2010/t100329.htm>.

44. There is debate over the death toll of seasonal flu because most deaths attributed to influenza are not confirmed by laboratory analysis, and influenza resembles and may complicate many other illnesses. Estimates vary from approximately 21,000 deaths per year in the U.S. to over 40,000 deaths per year. For a review of the literature and a discussion of one regression model that purports to show an annual average death toll of 41,000, see Jonathan Dushoff et al., *Mortality Due to Influenza in the United States – An Annualized Regression Approach Using Multiple-Cause Mortality Data*, 163 AM. J. EPIDEMIOLOGY 181, 181-87 (2005). Recently, the CDC has lowered its estimate of annual deaths from seasonal flu from 36,000 to 24,000. See *Estimate Lowered of Typical Flu Toll*, N.Y. TIMES, Aug. 27, 2010, at A14.

45. Kristen A. Swedish, Gina Conenello & Stephanie H. Factor, *First Season of 2009 H1N1 Influenza*, 77 MOUNT SINAI J. MED. 103, 105, 108 (2010).

46. *Id.* These groups are also at high risk for seasonal flu. What distinguished H1N1 is that individuals over sixty-five did not face high risks. Other high risk groups for H1N1 included people with chronic diseases or obesity. See *id.* at 108.

U.S. population.<sup>47</sup> Disproportionate rates of morbidity and mortality were also reported among American Indian and Alaskan Natives.<sup>48</sup>

H1N1 also defied predictions by originating in North America.<sup>49</sup> Contrary to expectations,<sup>50</sup> by the time the virus was detected, it had already spread widely in the United States and Mexico.<sup>51</sup> Containment by targeted distribution of antiviral medications, border closings, or quarantine was impossible.<sup>52</sup> As a result, health officials were forced to rely on widely promulgated appeals for hand-washing and respiratory etiquette to slow the virus' spread.<sup>53</sup>

Federal officials also quickly launched the nation's second swine flu vaccine campaign, even as they noted that vaccine would not be available for many months.<sup>54</sup> As early as April 26, 2009, just days after the CDC announced that the first cases of H1N1 had been identified, the Department of Health and Human Services (DHHS) declared a public health emergency, setting the stage for the issuance of "Emergency Use Authorizations" (EUAs)

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47. Alicia M. Siston et al., *Pandemic 2009 Influenza A (H1N1) Virus Illness Among Pregnant Women in the United States*, 303 JAMA 1517, 1522-23 (2010).

48. Ctrs. for Disease Control & Prevention, *Deaths Related to 2009 Pandemic Influenza A (H1N1) Among American Indian/Alaska Natives - 12 States, 2009*, 58 MORBIDITY & MORTALITY WKLY. REP. 1341, 1341 (2009).

49. *Novel H1N1 Flu: Background on the Situation*, CTRS. FOR DISEASE CONTROL & PREVENTION (July 31, 2009), <http://www.cdc.gov/h1n1flu/background.htm>.

50. As historians and sociologists have noted, it is common to assume that fearsome diseases derive from "abroad." See Parmet, *Public Health and Social Control*, *supra* note 25, at 13-14.

51. SARAH A. LISTER & C. STEPHEN REDHEAD, CONG. RESEARCH SERV., R 40554, *THE 2009 INFLUENZA A (H1N1) "SWINE FLU" OUTBREAK: AN OVERVIEW* 1, 1 (2009); *Novel H1N1 Flu: Background on the Situation*, *supra* note 49.

52. LISTER & REDHEAD, *supra* note 51, at 2.

53. See *Questions and Answers: 2009 H1N1 ("Swine Flu") and You*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 10, 2010), <http://www.cdc.gov/h1n1flu/qa.htm> (CDC's recommendations to prevent H1N1 spreading by hand washing and covering coughs). In the early days of the pandemic, some communities closed their schools. LISTER & REDHEAD, *supra* note 51. The CDC stated that "[s]chool dismissal and childcare closures are an important part of a comprehensive, layered mitigation approach" to H1N1. *CDC Health Update: School (K - 12) Dismissal and Childcare Facilities: Interim CDC Guidance in Response to Human Infections with The Influenza A H1N1 Virus*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 1, 2009), <http://www.cdc.gov/h1n1flu/HAN%050109.htm>. A few days later, CDC revised its guidance to recommend that schools only be closed if too many students and teachers were ill to enable the schools to function. *Media Statement, Change in CDC's School and Childcare Guidance*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 5, 2009), <http://www.cdc.gov/media/pressre/2009/S090505.htm>.

54. Andrew Pollack, *Swine Flu Vaccine May Be Months Away*, N.Y. TIMES, Apr. 29, 2009, at A10.



permitting the unlicensed use of laboratory tests and antiviral medications.<sup>55</sup> In May 2009, the federal government set aside \$1 billion for vaccine development.<sup>56</sup> By June, as the virus spread around the world, *The Wall Street Journal* reported that drug companies were “ramping up [vaccine] production.”<sup>57</sup> Around the same time, DHHS Secretary Kathleen Sebelius issued the first of many so-called “PREPA” declarations, finding H1N1 to be a public health emergency and authorizing immunity for those making or administering H1N1 vaccines.<sup>58</sup>

In July 2009, citing the risk that the H1N1 pandemic could reappear in the fall, the federal government decided to push ahead with the H1N1 vaccine campaign.<sup>59</sup> The CDC issued guidance to state and local public health departments about the coming fall vaccination campaign and held a “summit” to discuss plans and priorities.<sup>60</sup> That same month, an advisory committee for the Food and Drug Administration (FDA) recommended that the FDA license the vaccine without waiting for the results of clinical trials.<sup>61</sup> On July 13, the federal government signed a \$1 billion contract with four companies to purchase components for the vaccine.<sup>62</sup>

Throughout the summer of 2009, work continued on manufacturing the vaccine and planning for its eventual distribution.<sup>63</sup> But on October 16, scientists reported that the vaccine was taking longer than anticipated to

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55. Charles E. Johnson, Dep’t of Health & Human Servs., *Determination that a Public Health Emergency Exists*, FLU.GOV (Apr. 26, 2009), <http://www.flu.gov/professional/federal/h1n1emergency042609.html>. The emergency was eventually allowed to expire on June 23, 2010. Press Release, *Influenza Public Health Emergency Determination Expired on June 23: HHS Encourages Americans to Continue to Practice Flu Prevention Techniques*, FLU.GOV, <http://www.flu.gov/news/h1n1pheexpiration.html> (last visited Sept. 26, 2010); *Summary Highlights*, *supra* note 41 (issuing an Emergency Use Authorization allows usage of antiviral drugs in a manner different than what was approved by the FDA).

56. Betsy McKay, *For Flu Vaccine, U.S. Sets Aside \$1 Billion*, WALL ST. J., May 23-24, 2009, at A4.

57. Jeanne Whelan, *Flu Pandemic Spurs Queries About Vaccine*, WALL ST. J., June 15, 2009, at A11.

58. *Pandemic Influenza Antivirals – Amendment*, 74 Fed. Reg. 29213 (June 19, 2009) (amendment pursuant to 42 U.S.C. § 247d-6d, 319F-3(b)).

59. Betsy McKay, *Plans for Vaccination Campaign Begin*, WALL ST. J., July 10, 2009, at A4.

60. *Summary Highlights*, *supra* note 41.

61. Jennifer Corbett Dooren & Nicholas Winning, *Swine Flu Prevention Takes on New Urgency*, WALL ST. J., July 24, 2009, at A3.

62. Jennifer Corbett Dooren, *Health & Wellness: U.S. to Buy H1N1 Vaccine Components from Four Firms*, WALL ST. J., July 14, 2009, at D4.

63. See Rob Stein, *Swine Flu Could Infect Half of U.S.: Presidential Panel’s Estimate is First to Gauge Possible Impact of Epidemic*, WASH. POST, Aug. 25, 2009, at A1.

produce.<sup>64</sup> As the public waited for the vaccine, fear of the pandemic began to diminish and distrust of the vaccine started to take hold.<sup>65</sup> Shortly after the FDA licensed four vaccines to be used against the virus,<sup>66</sup> a poll taken by the Harvard School of Public Health found that only forty percent of adults were sure they would be vaccinated.<sup>67</sup> *The Washington Post* quoted Gregory Poland, an expert on influenza vaccine at the Mayo Clinic, as stating: "There's a lot of misinformation out there. . . .Then you mix into that people's concerns about conspiracy theories and government misbehavior and conflicts of interest and all of that, and the average layperson has a difficult time discerning what to do."<sup>68</sup>

In many ways, the vaccine campaign that was unfurled in the fall of 2009 was marked by a series of contrasting fears: fears about not being able to get the vaccine, fears about being vaccinated, and fears of being forced to be vaccinated. In the summer of 2009, New York's Board of Health, fearing that health workers would reject vaccination, issued an emergency regulation requiring hospital workers with patient contact to be vaccinated for both seasonal and H1N1 influenza.<sup>69</sup> Health care workers responded by filing at least four lawsuits challenging the regulation.<sup>70</sup> Shortly after a state trial judge issued a temporary restraining order barring enforcement of the regulation, the state rescinded it, noting the shortage of pandemic vaccine.<sup>71</sup> This litigation was echoed in cases throughout the country brought by employees, or their unions, protesting hospital policies mandating vaccination.<sup>72</sup> Yet, while many health care workers fought mandatory vaccination, most people who wanted to be vaccinated could not be. By early November 2009, the Associated Press reported that only

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64. Press Release, *Weekly 2009 H1N1 Flu Media Briefing*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 16, 2009), <http://www.cdc.gov/media/transcripts/2009/t091016.htm>.

65. SteelFisher et al., *supra* note 8, at e65(5).

66. Press Release, *FDA Approves Vaccines for 2009 H1N1 Influenza Virus: Approval Provides Important Tool to Fight Pandemic*, U.S. FOOD & DRUG ADMIN. (Sept. 15, 2009), <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm182399.htm>.

67. Press Release, *Survey Finds Just 40% of Adults "Absolutely Certain" They Will Get H1N1 Vaccine*, HARVARD SCH. PUB. HEALTH (Oct. 2, 2009), <http://www.hsph.harvard.edu/news/press-releases/2009-releases/survey-40-adults-absolutely-certain-h1n1-vaccine.html>.

68. Robert Stein, *Vaccine Is On Its Way, But Public Still Wary, Swine Flu Campaign Faces Key Barriers: Unease, Ambivalence*, WASH. POST, October 4, 2009, at A18.

69. 10 N.Y. ADC 66-3.2.

70. Wendy E. Parmet, *Pandemic Vaccines—The Legal Landscape*, 362 NEW ENG. J. MED. 1949, 1951 (2010).

71. *New York Court Stops State From Requiring Flu Vaccinations for Health Care Workers*, 18 HEALTH L. REP. (BNA) 1414 (Oct. 22, 2009). See also Order to Show Cause at 2-3, *Brynien v. Daines*, No. 8853-09 (N.Y. Sup. Ct. Oct. 15, 2009); Order to Show Cause at 1, *Patterson v. Daines*, No. 8830-09 (N.Y. Sup. Ct. Oct. 16, 2009), 2009 WL 3444742.

72. Parmet, *Pandemic Vaccines—The Legal Landscape*, *supra* note 70, at 1951-52.

one third of adults who tried to be vaccinated, including those who were considered at high risk for significant complications, could find vaccine.<sup>73</sup> Parents were reported to be anxious and frustrated, as were doctors and health officials, who had to deal with short and seemingly random supplies.<sup>74</sup> Then in December 2009, as supplies picked up, the CDC announced two voluntary “non-safety” recalls of H1N1 vaccine.<sup>75</sup> Meanwhile, worries about the pandemic abated, as the dreaded second wave appeared no more virulent than the first. By March 2010, newspapers reported that the flu season had “fizzled;” cases of flu had dwindled to fewer than those in a typical year.<sup>76</sup> With 155 million doses of H1N1 vaccine distributed in the U.S., only 86 million individuals had been vaccinated, a number lower than the typical number of people who are vaccinated annually for seasonal flu.<sup>77</sup>

Fortunately complications from the vaccine appeared to be relatively infrequent and usually mild. As of April 30, 2010, the VAERS had received reports of 11,029 adverse events following the administration of the H1N1 vaccine, the vast majority of which were deemed non-serious.<sup>78</sup> Only 7.5% of reported adverse events were serious; a percentage similar to that expected for seasonal flu vaccine.<sup>79</sup> Fifty-six deaths were reported and were being investigated, but preliminary findings did not “suggest” any association with the vaccine.<sup>80</sup>

Was the campaign necessary? Was it a resounding success or a dispiriting failure? Scientists will undoubtedly debate those questions in the years to come. The sections below focus on a different, but no less important set of questions: what role did law play in promoting the

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73. Associated Press, *Poll Indicates Swine Flu Vaccine Scarce*, *supra* note 7.

74. Stephen Smith, *A Day in the Life of a Pandemic*, BOSTON GLOBE, Nov. 8, 2009, at A11.

75. *Non-Safety-Related Voluntary Recall of Certain Lots of Sanofi Pasteur H1N1 Pediatric (0.25 mL, for 6-35 month olds) Vaccine in Pre-Filled Syringes: Questions & Answers*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 15, 2009), [http://www.cdc.gov/h1n1flu/vaccination/syringes\\_qa.htm](http://www.cdc.gov/h1n1flu/vaccination/syringes_qa.htm); *Voluntary Non-Safety-Related Recall of Specific Lots of Nasal Spray Vaccine for 2009 H1N1 Influenza*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 22, 2009), [http://www.cdc.gov/h1n1flu/vaccination/sprayrecall\\_qa.htm](http://www.cdc.gov/h1n1flu/vaccination/sprayrecall_qa.htm).

76. Betsy McKay, *The Flu Season That Fizzled: Cases of H1N1 Have Dwindled, Seasonal Flu has Been a No-Show and Doctors Wonder Why*, WALL ST. J., March 2, 2010, at D1.

77. *Id.* at D2.

78. CTRS. FOR DISEASE CONTROL & PREVENTION, SUMMARY OF 2009 MONOVALENT H1N1 INFLUENZA VACCINE DATA—VACCINE ADVERSE EVENT REPORTING SYSTEM DATA THROUGH APRIL 30, 2010, at 1 (2010), available at [http://vaers.hhs.gov/resources/2010H1N1Summary\\_May07.pdf](http://vaers.hhs.gov/resources/2010H1N1Summary_May07.pdf)

79. *Id.*

80. *Id.* at 1-2.

successes and fostering the limitations of the 2009 H1N1 vaccine campaign?

#### PART TWO: INFLUENZA VACCINES – THE PROMISES AND CHALLENGES

The central role accorded to vaccines in U.S. pandemic preparedness plans is not surprising. Vaccines are widely recognized as among the most effective public health interventions.<sup>81</sup> In the event of a deadly influenza pandemic, vaccines are especially important because of the lack of adequate alternatives. Although antiviral medications may lessen influenza's impact, and when used in conjunction with isolation, reduce the number of cases of influenza in a pandemic,<sup>82</sup> many strains of influenza are resistant to one or more antiviral medicines.<sup>83</sup> The widespread prophylactic use of antivirals may also lead to the transmission of resistant strains reducing the drugs' efficacy for clinical cases.<sup>84</sup> Likewise, non-pharmaceutical interventions, such as quarantines, border closings, curfews, and school closings are of limited (and contested) utility against influenza.<sup>85</sup> They also impose enormous social costs.<sup>86</sup> Vaccines, in contrast, can reduce flu's transmission without exacting widespread social disruption.<sup>87</sup>

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81. See DEP'T OF IMMUNIZATION, VACCINES & BIOLOGICALS, WORLD HEALTH ORG. & UNICEF, GIVS: GLOBAL IMMUNIZATION VISION AND STRATEGY: 2006-2015 3 (2005), available at [http://www.who.int/vaccines-documents/DocsPDF05/GIVS\\_Final\\_EN.pdf](http://www.who.int/vaccines-documents/DocsPDF05/GIVS_Final_EN.pdf).

82. Some researchers suggest that the rapid use of antiviral medications could help contain or at least slow the spread of a novel influenza virus. E.g., Marc Lipsitch et al., *Antiviral Resistance and the Control of Pandemic Influenza*, 4 PUB. LIBR. SCI. MED., 111, 112 (2007); Ira M. Longini, Jr., *Containing Influenza With Antiviral Agents*, 169 AM. J. EPIDEMIOLOGY 623, 630 (2004).

83. Ctrs. for Disease Control & Prevention, *Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2008*, 57 MORBIDITY & MORTALITY WKLY. REP. 1, 39-40 (2008); U.S. Food & Drug Admin., *Influenza (Flu) Antiviral Drugs and Related Information*, <http://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm100228.htm#AntiviralMedications> (last visited Sept. 15, 2010).

84. See Ctrs. for Disease Control & Prevention, *Oseltamivir-Resistant 2009 Pandemic Influenza A(H1N1) Virus Infection in Two Summer Campers Receiving Prophylaxis-North Carolina, 2009*, 58 MORBIDITY & MORTALITY WKLY. REP. 969, 969 (2009).

85. See Julia E. Aledort et al., *Non-Pharmaceutical Public Health Interventions for Pandemic Influenza: An Evaluation of the Evidence Base*, 7 BMC PUB. HEALTH 208, 213-14 (2007).

86. See Sencer & Millar, *supra* note 24, at 68-69.

87. Indeed, vaccines can provide what is known as herd immunity. If a sufficiently large percentage of a population is vaccinated, the transmission of a disease may be disrupted. As a result, even individuals who are not vaccinated may be protected. N.T. Begg & N.J. Gay, *Theory of Infectious Disease Transmission and Herd Immunity*, in 3 TOPLEY AND WILSON'S MICROBIOLOGY AND MICROBIAL INFECTIONS: BACTERIAL INFECTIONS 148, 151 (William J. Hausler, Jr. & Max Sussman eds., 9th ed. 1997).

Although vaccines theoretically offer our best defense to pandemic influenza, developing and administering pandemic vaccines is not easy. Both technical and social (including legal and economic) challenges complicate efforts to rely upon vaccines in the face of a pandemic.

The technical problems relate both to the nature of the influenza virus and the way vaccines used to prevent it are developed. The influenza virus changes rapidly and thus far, new strains require new vaccines.<sup>88</sup> In the case of seasonal flu, vaccine is prepared based upon health officials' prediction of the strains that will be prevalent during the next flu season.<sup>89</sup> That prediction is generally made in February, leaving a limited amount of time to produce vaccine for the next season.<sup>90</sup> Production of pandemic vaccine is even more challenging because a pandemic strain is inevitably a new strain, and as H1N1 illustrated, cannot be easily predicted.<sup>91</sup> As a result, an effective pandemic vaccine cannot be developed until the pandemic virus has been detected.<sup>92</sup> By that time, however, as was true with H1N1, the virus may already be widely dispersed around the world.

Complicating the problem is the fact that influenza vaccine is grown in eggs, a time-consuming and delicate process.<sup>93</sup> For years, scientists have eagerly anticipated the development of cell-based technologies that could eliminate the need for eggs.<sup>94</sup> This would be especially important in the event of an avian influenza pandemic since that virus kills eggs.<sup>95</sup> Although progress has been made in developing this technology, it was not available

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88. For a more detailed discussion, see Lauren M. Smith & Gigi Kwik Gronvall, *Influenza Vaccine Production for the U.S. Market*, 7 *BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC. & SCI.* 259, 259-60 (2009). Scientists hope to develop a vaccine that will work for all strains of influenza. See *id.* at 261-62. Until that happens, new vaccines will need to be developed continuously to track the virus' evolution.

89. *Id.* at 260.

90. TIM BROOKES, *A WARNING SHOT: INFLUENZA AND THE 2004 FLU VACCINE SHORTAGE* 15-16 (2005).

91. *Pandemic Influenza Vaccine Manufacturing Process and Timeline*, WORLD HEALTH ORG. (August 6, 2009), [http://www.who.int/csr/disease/swineflu/notes/h1n1\\_vaccine\\_2009\\_0806/en/index.html](http://www.who.int/csr/disease/swineflu/notes/h1n1_vaccine_2009_0806/en/index.html).

92. *Id.*

93. Smith & Gronvall, *supra* note 88, at 260-61. For a further discussion of the process of developing vaccine in eggs, see BROOKES, *supra* note 90, at 15-22.

94. Smith & Gronvall, *supra* note 88, at 261. See BROOKES, *supra* note 90, at 18.

95. See Richard Harris, *Pandemic Flu Spurs Race for New Vaccine Methods*, NPR.ORG (Dec. 6, 2005), <http://www.npr.org/templates/story/story.php?storyId=5039634>.

in time for the H1N1 pandemic.<sup>96</sup> Indeed, in 2009, problems growing the vaccine in eggs were blamed for delays in the vaccine's production.<sup>97</sup>

The social barriers to the rapid development, distribution, and administration of a pandemic vaccine may be even more formidable than the technical challenges. For a variety of reasons, including extensive regulatory requirements, the labor-intensive nature of vaccine production, and the fact that vaccines are not given to individuals daily (as are many of the most profitable medications), vaccines are costly to develop and provide relatively low profits to their manufacturers.<sup>98</sup> As discussed below, manufacturers also claim that the risk of legal liability undermines vaccines' profitability.<sup>99</sup> Regardless of whether these risks are as great as manufacturers contend, there is little doubt that in the late twentieth century manufacturing capacity in the U.S. declined precipitously. In 1967, twenty-six companies produced vaccines in the U.S.; by 2005, only five companies did so.<sup>100</sup> In 2008, there was only one domestic manufacturer of influenza vaccine.<sup>101</sup> The dangers of this meager supply became evident in 2004, when one of two manufacturers licensed to produce influenza vaccine for the U.S. market had to limit production due to contamination in a plant in Great Britain.<sup>102</sup> The result was a significant shortage of flu vaccine during the fall flu season.<sup>103</sup> As will be discussed below, many of the legal changes initiated as part of pandemic planning focused on solving these "supply side" problems.

Public health policymakers, however, have also had to consider the demand side of the equation—the willingness of individuals to be

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96. See Scott Gottlieb, Am. Enter. Inst. Pub. Pol'y Res., *Responding to the H1N1 Pandemic with Vaccines: Vulnerabilities and Lessons Learned*, HEALTH POL'Y OUTLOOK, no. 15, 2009, at 1, 4-5.

97. *Id.*; Stephen Smith, *Swine Flu Shots Delayed for Most*, BOSTON GLOBE, Oct. 1, 2009, at A15.

98. COMM. ON THE EVALUATION OF VACCINE PURCHASE FINANCING IN THE U.S., INST. OF MED., *FINANCING VACCINES IN THE 21<sup>ST</sup> CENTURY: ASSURING ACCESS AND AVAILABILITY* 111-16 (2004) [hereinafter FINANCING VACCINES].

99. For a more detailed discussion of the perceived economic disincentives to vaccine production, see BROOKES, *supra* note 90, at 34-35; Michelle M. Mello & Troyen A. Brennan, *Legal Concerns and the Influenza Vaccine Shortage*, 294 JAMA 1817, 1819-20 (2005).

100. Mello & Brennan, *supra* note 99, at 1820.

101. U.S. CONG. BUDGET OFFICE, U.S. POLICY REGARDING PANDEMIC INFLUENZA VACCINES 4 (2008), available at <http://www.cbo.gov/ftpdocs/95xx/doc9573/09-15-PandemicFlu.pdf> [hereinafter U.S. POLICY].

102. U.S. GOV'T ACCOUNTABILITY OFFICE, *INFLUENZA VACCINE: SHORTAGES IN 2004-2005 SEASON UNDERSCORE NEED FOR BETTER PREPARATION*, GAO-05-984, at 1 (2005) [hereinafter GAO]. See Cormac Sheridan, *Next Generation Flu Vaccine Boosted by Chiron Debacle*, 22 NATURE BIOTECHNOLOGY 1487, 1487 (2004).

103. GAO, *supra* note 102; BROOKES, *supra* note 90, at 43-46.

vaccinated. Despite their proven efficacy – indeed, perhaps in part because of their effectiveness<sup>104</sup> – vaccines have always been the subject of heated controversy.<sup>105</sup> Ever since Edward Jenner demonstrated the efficacy of the smallpox vaccine in 1798, vaccination has ignited virulent opposition.<sup>106</sup> Many so-called anti-vaccinationists have religious objections to vaccination; others simply believe that vaccines are unnatural and/or dangerous, especially to children.<sup>107</sup> This distrust of vaccines and, indirectly, the health officials who recommend them, is widely evident on the many Internet websites that stress both the hazards of vaccines (including their alleged link to autism) and the supposedly impure financial incentives of vaccine manufacturers.<sup>108</sup> Although overall vaccination rates for American children remain high,<sup>109</sup> researchers have noted the growth in ardency, if not in numbers, of this anti-vaccinationist movement.<sup>110</sup> Not surprisingly, the public's unease, or just disinterest, in vaccines affects the supply. With the

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104. This is especially the case with childhood vaccines. As vaccines have helped make once-feared childhood diseases less common, many parents have come to believe that vaccines pose a greater risk to their child than the diseases the vaccines prevent. See Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37 UNIV. MICH. J.L. REFORM 353, 404 (2004).

105. ARTHUR ALLEN, *VACCINE: THE CONTROVERSIAL STORY OF MEDICINE'S GREATEST LIFESAVER* *passim* (2007).

106. *Id.* at 56-111. Indeed, vaccination's predecessor, the practice of inoculating individuals with the pus of people who were sick with smallpox to prevent a severe case of the disease, was also highly controversial. See *id.* at 28-45.

107. See Calandrillo, *supra* note 104, at 414, 416.

108. Andrea Rock, *The Lethal Dangers of the Billion-Dollar Vaccine Business*, MONEY, Dec. 1, 1996, at 148. For an analysis of these sites, see P. Davies, S. Chapman & J. Leask, *Antivaccination Activists on the World Wide Web*, 87 ARCHIVES OF DISEASE IN CHILDHOOD 22, 22-24 (2002); Anna Kata, *A Postmodern Pandora's Box: Anti-Vaccination Misinformation on the Internet*, 28 VACCINE 1709, 1709-15 (2010); Robert M. Wolfe, Lisa K. Sharp & Martin S. Lipsky, *Content and Design Attributes of Antivaccination Web Sites*, 287 JAMA 3245, 3245-47 (2010). For an overview of the movement alleging that vaccines cause autism, see SETH MNOOKIN, *PANIC VIRUS: A TRUE STORY OF MEDICINE, SCIENCE AND FEAR* 99-273 (2011). The claim that vaccines, or more specifically thimerosal, a preservative that was once widely used in childhood vaccines, causes autism is laid out in DAVID KIRBY, *EVIDENCE OF HARM: MERCURY IN VACCINES AND THE AUTISM EPIDEMIC: A MEDICAL CONTROVERSY* *passim* (2006). Most scientists reject this claim, as have courts in vaccine cases. See, e.g., *Cedillo v. Sec'y Dep't Health & Human Servs.*, 617 F.3d 1328, 1334 (Fed. Cir. 2010); *Hazlehurst v. Sec'y Dep't Health & Human Servs.*, 604 F.3d 1343, 1345 (Fed. Cir. 2010); Christofer S. Price et al., *Prenatal and Infant Exposure to Thimerosal From Vaccines and Immunoglobulins and Risk of Autism*, 126 PEDIATRICS 656, 660-63 (2010).

109. CDC Survey Finds Childhood Immunization Rates Remain High, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/media/pressrel/2010/r100916.htm> (Sept. 16, 2010) (reporting that the "coverage for most of the routine vaccines remain[s] at or over 90 percent").

110. ALLEN, *supra* note 105, at 327-70.

demand for vaccine uncertain, manufacturers are even more reluctant than they might otherwise be to invest in increased production capacity.<sup>111</sup> In other words, lack of demand reduces supply.

It is not surprising that this skepticism or distrust of vaccines was prevalent during the H1N1 epidemic which struck during a period in which Americans questioned not only the competency but also the intentions of many institutions, including large corporations and the federal government.<sup>112</sup> According to a review of several polls taken during the fall H1N1 pandemic, only about half of all Americans stated that they expected to be vaccinated.<sup>113</sup> Concern about the safety of the vaccine was the most common reason cited by those who expected to decline vaccination for either themselves or their children.<sup>114</sup> Critics went further and questioned whether public health organizations, including CDC and the World Health Organization (WHO), pushed vaccination in order to secure revenue for vaccine makers.<sup>115</sup> In response, WHO announced an investigation into its handling of the pandemic.<sup>116</sup>

The coupling of supply side shortages with the public's disquiet, and even among some, zealous opposition, to vaccination presents policymakers with a difficult dilemma: how can they speed up and increase the supply of vaccine during a pandemic while ensuring that the public will accept the vaccine when it is offered? In other words, can public health officials err on the side of precaution when it comes to pandemic vaccines without undermining the public's support for vaccination? Section Three looks at the legal strategies that have been employed to address these issues on the supply side. Section Four looks at the tools that have been used or contemplated to resolve the problem on the demand side. As the discussion below suggests, both sets of legal strategies risk exacerbating the chasm between public health officials and the public.

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111. BROOKES, *supra* note 90, at 32-33.

112. PEW RESEARCH CENTER FOR PEOPLE & THE PRESS, *DISTRUST, DISCONTENT, ANGER AND PARTISAN RANCOR: THE PEOPLE AND THEIR GOVERNMENT 1* (2010), available at <http://people-press.org/reports/pdf/606.pdf> [hereinafter *THE PEOPLE AND THEIR GOVERNMENT*] (reporting on polls showing that "[b]y almost every conceivable measure Americans are less positive and more critical of government these days" and that only twenty-two percent of the public has favorable views of banks and financial institutions, and only twenty-five percent has a favorable view of large corporations).

113. SteelFisher et al., *supra* note 8, at e65(2).

114. *Id.* at e65(3).

115. *E.g.*, Cohen & Carter, *supra* note 1, at 1274; Jeff Levy, *Did the World Health Organization Exaggerate the H1N1 Flu Threat?*, NEW JERSEY NEWSROOM (June 10, 2010), <http://www.newjerseynewsroom.com/pdf/healthquest/did-the-world-health-organization-exaggerate-the-h1n1-flu-threat.pdf>.

116. See Cohen & Carter, *supra* note 1, at 1279.



## PART THREE: SUPPLY SIDE LEGAL STRATEGIES

A. *Federal Investment and Regulatory “Reform”*

Believing that quick and widespread availability of vaccines is critical to combating a pandemic, the federal government has pursued a number of legal strategies to increase the supply of vaccine.<sup>117</sup> Perhaps the least controversial policy has been the injection of federal money directly into vaccine development and sales.<sup>118</sup> As noted above, vaccines are not an especially profitable enterprise for pharmaceutical companies; they are expensive to produce and are used with less regularity than most “blockbuster” drugs.<sup>119</sup> These problems are exacerbated in the case of vaccines for diseases that primarily affect the developing world,<sup>120</sup> as well as in the case of pandemics that may or may not occur. As a result, private companies, operating without government support, are apt to invest less than optimal amounts (from a public health perspective) in vaccine research and development.

Assuming that the private market does not support what health officials believe to be an adequate investment in vaccines,<sup>121</sup> the federal government invests heavily in vaccine development.<sup>122</sup> It also acts as a large purchaser of vaccines, helping to ensure a steady demand. For example, the 1993 Vaccines for Children Program provides federally purchased vaccines to

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117. Efforts to increase the supply of vaccine have primarily come from the federal government; hence this section focuses on federal laws and policies. In contrast, efforts to compel vaccination have originated in both the federal and state arenas. Thus Section Four, which looks at demand side laws, considers both federal and state legal issues.

118. As Lawrence Gostin has noted, ethical questions should be raised about the amount of money the government has allocated to the development of pandemic flu vaccine in comparison to spending on “chronically underfund[ed] more cost-effective public health services.” Lawrence O. Gostin, *Swine Flu Vaccine: What Is Fair?*, HASTINGS CTR. REP., Sept/Oct 2009, at 9, 9.

119. For a more detailed discussion of why vaccines provide relatively low levels of profits to pharmaceutical companies, see BROOKES, *supra* note 90, at 34-35.

120. See, e.g., OWEN BARDER, RUGH LEVINE, MICHAEL KREMER, CTR. FOR GLOBAL DEV., MAKING MARKETS FOR VACCINES: IDEAS TO ACTION 3 (2005), available at <http://www.cgdev.org/doc/books/vaccine/MakingMarkets-complete.pdf>.

121. Most vaccines are partial public goods; they benefit not only those who are vaccinated but others. For this reason alone, it is unlikely that private investment alone can achieve an efficient and adequate allocation of vaccines. See FINANCING VACCINES, *supra* note 98, at 41, 43.

122. After 2001 and prior to 2005’s focus on pandemic planning, the federal government enhanced its investment in vaccines and other bioterrorist “countermeasures.” See, e.g., Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (2002); Project Bioshield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835 (2004) [hereinafter Project Bioshield].

millions of children.<sup>123</sup> As a result, as of 2004, the federal government purchased between fifty-two percent and fifty-five percent of all childhood vaccines, helping to make vaccines widely available to children while also ensuring a market for producers.<sup>124</sup>

The federal government has employed a similar mix of investment and purchasing programs to secure pandemic vaccine. In 2005, Congress allocated \$3.3 billion to DHHS for pandemic planning, including vaccine development and stockpiling.<sup>125</sup> By December 2006, DHHS had obligated \$1.3 billion on vaccine-related activities.<sup>126</sup> This money was spent primarily on supporting vaccine development and procuring pre-pandemic vaccines for the national stockpile.<sup>127</sup> In 2009, in response to the H1N1 pandemic, the federal government purchased the H1N1 vaccine, helping to ensure that manufacturers would produce it.<sup>128</sup>

Congress has also sought to address supply problems by easing what producers cite as regulatory burdens on the manufacture of pandemic vaccines. In 2004, Project BioShield Act amended the Food, Drug, and Cosmetic Act<sup>129</sup> to permit the Secretary of DHHS, after declaring a public health emergency, to authorize the emergency use of drugs, medical devices, and biological products (including vaccines) that have not yet been licensed or approved for use, or have not been licensed or approved for a

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123. 42 U.S.C. § 1396s (2006). In fact, public support for vaccination, and its forerunner, inoculation, dates back to colonial times. See Wendy E. Parmet, *Health Care and the Constitution: Public Health and the Role of the State in the Framing Era*, 20 HASTINGS CONST. L.Q. 267, 286-99.

124. See FINANCING VACCINES, *supra* note 98, at 47. The government's large presence in the vaccine market, however, can also deter production since the government is able, as a large purchaser, to extract lower prices than would private payers. Hence government purchasing may have both positive and negative impacts on supply. See *id.* at 5-6.

125. U.S. DEP'T OF HEALTH & HUMAN SERVS., REPORT TO CONGRESS: PANDEMIC INFLUENZA PREPAREDNESS SPENDING, CONFERENCE REPORT 109-359, at 1 (2006), available at <https://www.medicalcountermeasures.gov/BARDA/documents/hhsplanfluspending-0612.pdf> [hereinafter CONFERENCE REPORT].

126. In December 2005, Congress allocated \$3.3 billion to HHS for pandemic planning. HHS reported that, as of December 2006, it had obligated \$1.3 billion on vaccine-related activities. *Id.* at 3. See Michael O. Leavitt, Sec'y, U.S. Dep't of Health & Human Servs., The HHS Pandemic Influenza Plan before the Committee on Energy and Commerce, U.S. House of Representatives (Nov. 8, 2005).

127. U.S. POLICY, *supra* note 101, at 2.

128. See Dooren, *supra* note 62, at D4. However, as interest in the vaccine waned, the federal government exercised provisions in some of its contracts to reduce its orders. Simeon Bennett & Tom Randall, *U.S. Trims Vaccine Order from CSL as Interest Wanes (Update 2)*, BLOOMBERG NEWS (Jan. 11, 2010), <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aNI27tKpye4g>.

129. 21 U.S.C. § 301 (2006).

particular use (so-called "off-label" use).<sup>130</sup> By allowing the Secretary of HHS to waive ordinary licensing requirements, the emergency use authorization (EUA) procedure allows manufacturers to bring vaccines and other so-called countermeasures to market before they are fully tested.<sup>131</sup> Without this procedure, such vaccines could only be used as investigational drugs, necessitating informed consent and all of the protections typically provided subjects of human research.<sup>132</sup> By allowing potentially wide use of unlicensed vaccines without requiring those legal protections, the EUA procedure speeds the process and lowers the cost of production and distribution, theoretically enabling the rapid deployment of pharmaceutical interventions necessary to respond to a public health emergency.

During the H1N1 pandemic, the EUA procedure was utilized, although not for vaccines. On April 26, 2009, Secretary Sebelius issued an EUA for certain antiviral medications, personal respiratory devices, and diagnostic tests.<sup>133</sup> This declaration was updated numerous times.<sup>134</sup> Commentators also speculated that an EUA would be issued for the vaccine, especially if it contained an adjuvant, an ingredient that can be added to a vaccine to boost its effectiveness, thereby stretching supplies.<sup>135</sup> Ultimately the FDA licensed the H1N1 vaccine without any adjuvant, and without waiting for full clinical trials, reasoning that the vaccine was not fundamentally different than the seasonal flu vaccine.<sup>136</sup> Nevertheless, the discussion of a possible EUA, and the decision to license the vaccine without full testing, may have

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130. 21 U.S.C. § 360bbb-3 (2006).

131. The Act also allows the Secretary to impose conditions on the use of such products. For a more detailed discussion, see Susan E. Sherman, Joseph Foster & Sonal Vaid, *Emergency Use Authority and 2009 H1N1 Influenza*, 7 *BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC. & SCI.* 245, 245 (2009).

132. Sandra Crouse Quinn et al., *Public Willingness to Take A Vaccine or Drug Under Emergency Use Authorization During the 2009 H1N1 Pandemic*, 7 *BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC. & SCI.* 275, 276, 277 (2009).

133. See Sherman, Foster & Vaid, *supra* note 131, at 249.

134. KATHLEEN SEBELIUS, SEC'Y, U.S. DEP'T OF HEALTH & HUMAN SERVS., *DECLARATION OF AN EMERGENCY PURSUANT TO SECTION 564 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT*, 21 U.S.C. § 360BBB-3(B) (2010), available at <http://www.fda.gov/downloads/EmergencyPreparedness/Counterterrorism/UCM206802.pdf>. For a more detailed discussion, see Sherman, Foster & Vaid, *supra* note 131, at 249-50.

135. Quinn et al., *supra* note 132, at 277. Because there is no influenza vaccine with an adjuvant currently licensed in the U.S., an EUA would have been required if the federal government had decided to go ahead and order vaccine using an adjuvant. *Id.*

136. See *General Questions and Answers on 2009 H1N1 Influenza Vaccine Safety*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 15, 2009), [http://www.cdc.gov/h1n1flu/vaccination/vaccine\\_safety\\_qa.htm#e](http://www.cdc.gov/h1n1flu/vaccination/vaccine_safety_qa.htm#e). Earlier an FDA advisory committee had concluded that the H1N1 vaccine would be sufficiently similar to the seasonal flu vaccine that it could be used without waiting for the results of full-scale clinical trials. See Dooren & Winning, *supra* note 61.

helped to fuel a public perception that the vaccine was rushed and untested.<sup>137</sup>

### B. Liability Protections

Vaccine manufacturers and federal health policymakers have long argued that tort liability creates a barrier to an adequate supply of vaccine. The argument and the debate surrounding vaccine liability dates back to the 1950s' campaign to vaccinate children against polio when a contaminated lot of the Salk vaccine killed at least ten people and paralyzed 164.<sup>138</sup> In the litigation that ensued, courts began to impose strict liability on the vaccine's manufacturers.<sup>139</sup> Then in the 1960s and 1970s, appellate courts held that vaccine makers had a duty to warn patients of a vaccine's potential dangers.<sup>140</sup>

Not surprisingly, manufacturers and the companies that insured them were not pleased. Hence, when the Ford Administration decided to vaccinate the entire population against swine flu, insurance companies refused to provide liability coverage to manufacturers.<sup>141</sup> Manufacturers, in turn, refused to produce or distribute vaccine unless the government removed their risk of liability.<sup>142</sup> When an outbreak of Legionnaire's disease was initially (incorrectly) feared to be the swine flu that was detected at Fort Dix, Congress capitulated to manufacturers' demands, relieving them of liability by creating an exclusive remedy against the United States for personal injuries and death caused by the vaccine.<sup>143</sup> As a result, when cases of Guillain-Barré syndrome arose among those who were vaccinated, federal taxpayers, not manufacturers or insurers, were left to bear the cost.<sup>144</sup>

The 1976 program set a precedent and taught a lesson. The precedent was that vaccine manufacturers would demand and receive liability protection in order to maintain an adequate supply of vaccine.<sup>145</sup> The

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137. See text accompanying notes 237-39 *infra*.

138. See PAUL A. OFFIT, *THE CUTTER INCIDENT: HOW AMERICA'S FIRST POLIO VACCINE LED TO THE GROWING VACCINE CRISIS* 89 (2005).

139. *Id.* at 133-54.

140. *E.g.*, *Reyes v. Wyeth Labs.*, 498 F.2d 1264 (5th Cir. 1974); *Davis v. Wyeth Labs.*, 399 F.2d 121 (9th Cir. 1968).

141. NEUSTADT & FINEBERG, *supra* note 20, at 48-56.

142. *Id.* Indeed, manufacturers demanded that liability protection be afforded by act of Congress. Contractual assurances of indemnification were insufficient to assure their cooperation in the program. *Id.* at 59-62.

143. 42 U.S.C. § 247b(j)-(l) (1976).

144. See Joanna B. Apolinsky & Jeffrey A. Van Detta, *Rethinking Liability for Vaccine Injury*, 19 CORNELL J.L. & PUB. POL'Y 537, 548-49 (2010).

145. See *id.* at 548.

lesson was that the government's assumption of liability created significant costs for the federal treasury. In response, since 1976, Congress has consistently coupled liability protection for vaccine makers with limitations on compensation for injured parties.<sup>146</sup> For the most part, this coupling has occurred in the context of limited no-fault compensation schemes that, at least theoretically, provide faster and more efficient (if less generous) relief to injured parties. In other words, the schemes provide some benefits to both injured individuals and the federal government.<sup>147</sup> For example, the 1986 National Childhood Vaccine Injury Act (NCVIA)<sup>148</sup> requires plaintiffs seeking more than \$1,000 in damages for injuries related to covered vaccines to file their claim initially before the National Vaccine Injury Compensation Program (VICP).<sup>149</sup> Under this program, claimants who suffer from so-called "table injuries,"<sup>150</sup> injuries that are widely recognized as clearly associated with vaccines and are listed on an approved table, can receive compensation relatively quickly, without needing to prove causation.<sup>151</sup> Recovery, however, is limited to economic damages plus \$250,000 for pain and suffering or death.<sup>152</sup> For so-called "non-table" injuries, claimants can file a claim before a special master of the Federal Court of Claims (the so-called Vaccine Court) and try to prove that the vaccine caused the injury.<sup>153</sup> In contrast to the 1976 swine flu program, compensation for claims paid under NCVIA is financed by a special excise tax on vaccines.<sup>154</sup> Importantly, while NCVIA creates significant barriers and disincentives to bringing a civil lawsuit, it does not preclude aggrieved individuals from having their day in court. Parties who receive no award, or are dissatisfied with their award from the Vaccine Court, can seek review from the Federal Court of Claims and then the Federal Circuit.<sup>155</sup> Claimants can also eventually bring a civil case in state or federal court, but actions are barred for injuries that were "unavoidable" or for a vaccine

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146. *Id.* at 554, 555, 557.

147. *Id.* at 557-58.

148. 42 U.S.C. §§ 300aa-10-300aa-34 (2006). For a critique of NCVIA, see Mary Holland, *Reconsidering Compulsory Childhood Vaccination*, 24-26, 31-32 (N.Y.U. Sch. Law, Working Paper No. 10-64, 2010), available at <http://ssrn.com/abstracts=1677565>.

149. 42 U.S.C. § 300aa-11(a)(2)(A).

150. 42 U.S.C. § 300aa-14.

151. 42 U.S.C. §§ 300aa-33(6)(B), 300aa-13(a), 300aa-15. For an explanation and listing of table injuries, see *National Vaccine Injury Compensation Program, Vaccine Injury Table*, HEALTH RESOURCES & SERVS. ADMIN., <http://www.hrsa.gov/vaccinecompensation/table.htm>.

152. 42 U.S.C. § 300aa-15.

153. *Id.* at § 300aa-11.

154. *Id.* at § 300aa-14.

155. *Id.* at §§ 300aa-12; 300aa-21.

maker's failure to provide direct warnings to a customer.<sup>156</sup> Thus, strict liability claims are greatly diminished, if not barred. In 2009, in *Bruesewitz v. Wyeth*, the United States Court of Appeals for the Third Circuit held that NCVIA also preempts all state law design defect claims.<sup>157</sup> The Supreme Court recently affirmed that ruling.<sup>158</sup>

Although vaccine critics initially lauded NCVIA for providing a quick and efficient remedy to individuals injured by vaccines,<sup>159</sup> they have more recently assailed the program.<sup>160</sup> In part, their criticism stems from the fact that the Act places the United States in the position of defending vaccines, and in recent years, the government has done so zealously.<sup>161</sup> Moreover, the United States Court of Appeals for the Federal Circuit, which reviews decisions of the Federal Court of Claims, has imposed relatively stringent causation requirements upon claimants trying to prove non-table injuries.<sup>162</sup> In addition, changes made by DHHS to the vaccine injury table in the 1990s led to an increasing number of non-table claims.<sup>163</sup> The fact that thousands of cases alleging that vaccines caused autism languished for years before the Vaccine Court concluded that vaccines do not cause autism<sup>164</sup> also

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156. *Id.* at § 300aa-22.

157. *Bruesewitz v. Wyeth*, 561 F.3d 233 (3d Cir. 2009), *aff'd* 2011 WL 588789 (Feb. 22, 2011).

158. As this paper was in press, the Supreme Court decided *Bruesewitz v. Wyeth*, 2011 WL 588789 (Feb. 22, 2011) (holding that NCVIA preempts state design defect claims).

159. At the time, most of the controversy related to whole-cell pertussis vaccine, which continued to be used in the United States even though a safer, acellular form of the vaccine was feasible. For a more detailed discussion, see ALLEN, *supra* note 105, at 251-93.

160. Of course, whether claimants' injuries are related to vaccines is precisely the question on which vaccine critics and public health policymakers remain deeply divided.

161. In 1999, leading vaccine critic Barbara Loe Fisher criticized HHS' role, arguing that the agency had used its discretionary authority to undermine the intent of NCVIA and had created an "uneven playing field." *Compensating Vaccine Injuries: Are Reforms Needed?: Hearing Before the H. Subcomm. on Criminal Justice, Drug Policy and Human Resources, 106th Cong. (1999)* (statement of Barbara Loe Fisher, Co-Founder and President, National Vaccine Information Center), available at <http://www.whale.to/m/fisher88.html>.

162. *De Bazan v. Sec'y Health & Human Servs.*, 539 F.3d 1347, 1351-52 (Fed. Cir. 2008).

163. James B. Currier, *Too Sick, Too Soon?: The Causation Burden Under the National Vaccine Injury Compensation Program Following De Bezan v. Secretary of Health & Human Services*, 19 FED. CIR. B.J. 229, 247 (2009).

164. Due to the number and complexity of autism-related cases, the Vaccine Court established several test cases that would serve to decide key questions, such as whether particular vaccines cause autism. For a more detailed discussion, see *Hazelhurst v. Sec'y Health & Human Servs.*, 604 F.3d 1343, 1345-54 (Fed. Cir. 2010). In the last two years, the Vaccine Court has handed down a series of decisions in test cases, all of which have held that claimants failed to prove that vaccines caused their neurological deficits. See, e.g., *id.*; *Cedillo v. Sec'y Health & Human Servs.*, 89 Fed. Cl. 158, 182-83 (Fed. Cl. 2009), *aff'd* 617 F.3d 1328 (Fed. Cir. 2010); *Synder v. Sec'y Health & Human Servs.*, 88 Fed. Cl. 706, 745-

soured the faith of parents who fervently believed that vaccines are linked to autism.

Despite its limitations, NCVIA is more generous to claimants than subsequent statutes limiting the liability of vaccine producers.<sup>165</sup> For example, Section 302 of the Homeland Security Act,<sup>166</sup> enacted in 2002, created an exclusive remedy against the United States for injuries caused by the smallpox vaccine following a declaration by the Secretary of Homeland Security.<sup>167</sup> However, the scope of Section 302's liability protection and compensation provisions were unclear.<sup>168</sup> In contrast to NCVIA, Section 302 did not provide no-fault compensation for those who were injured; rather claimants had to demonstrate that the manufacturer or other covered entity had been negligent.<sup>169</sup> Given the relatively high rate of adverse events associated with the smallpox vaccine, and the fact that there were no naturally-occurring cases of smallpox, Section 302's failure to provide clear and adequate compensation is thought to have deterred many health care workers and others from participating in the Bush Administration's 2002-2003 smallpox vaccine campaign.<sup>170</sup>

In the spring of 2003, Congress responded to Section 302's limitations by enacting the Smallpox Emergency Personnel Protection Act of 2003

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46 (Fed. Cl. 2009). In at least one case, however, the federal government entered into a settlement with parents of child who had a rare mitochondrial defect and claimed that a vaccine, in conjunction with her defect, led to autism-like injuries. See Gardiner Harris, *Deal in an Autism Case Fuels Debate on Vaccines*, N.Y. TIMES, Mar. 8, 2008, at A9.

165. A full discussion of the liability-limiting statutes and regulations that may be applied to vaccines is beyond the scope of this article. Other provisions that might have been used for pandemic vaccines, in the absence of the laws discussed *infra*, include Pub. L. 85-804, which authorized Executive Order 10789, allowing for indemnification of federal contractors for losses "arising out of or resulting from risks that the contract defines as unusually hazardous or nuclear in nature." Exec. Order No. 13232, 66 C.F.R. 206 (2001) (expanding indemnification under Exec. Order 10789 to contractors with the Department of Health and Human Services); Support Anti-Terrorism by Fostering Effective Technologies Act of 2002, 6 U.S.C. § 441(b) (2006), which provides broad liability protections for anti-terrorism technologies. See Kevin P. Mullen, *Extraordinary Contractual Relief: Public Law 85-804 in the Homeland Security Era*, 37 PROCUREMENT LAW., Summer 2001, at 1, 9.

166. Science and Technology in Support of Homeland Security, 6 U.S.C. § 182(2) (2006).

167. Homeland Security Act, 42 U.S.C. § 233(p) (2006).

168. See Michael Greenberger, *The 800 Pound Gorilla Sleeps: The Federal Government's Lackadaisical Liability and Compensation Policies in the Context of Pre-Event Vaccine Immunization Programs*, 8 J. HEALTH CARE L. & POL'Y 7, 17-19 (2005).

169. *Id.* at 18.

170. COMM. ON SMALLPOX VACCINATION PROGRAM IMPLEMENTATION, INST. OF MED., THE SMALLPOX VACCINATION PROGRAM: PUBLIC HEALTH IN AN AGE OF TERRORISM 51-52 (2005). If the threat of smallpox had been more apparent, more people may have been willing to risk the vaccine, despite the uncertainty of compensation.

(SEPPA),<sup>171</sup> which established a no-fault remedy for injuries listed on a smallpox vaccine injury table.<sup>172</sup> However, SEPPA's compensation program, which was administered by the Health Resources and Services Administration (HRSA), was substantially less generous than NCVIA's.<sup>173</sup> In particular, SEPPA limited compensation for lost income to two-thirds of the claimant's income plus a modest addition if a claimant had a dependent.<sup>174</sup> Moreover, SEPPA capped lost income awards at \$50,000 per year, and \$262,100 (as of 2003) for a lifetime if the claimant did not have a permanent disability.<sup>175</sup> As of 2003, death benefits were also limited to \$262,100, or an annual payment of \$50,000, until the youngest dependent turned eighteen.<sup>176</sup> In addition, in contrast to NCVIA, SEPPA's remedy was exclusive and unreviewable.<sup>177</sup> Claimants who were unhappy with their award could not bring a civil action; nor could they obtain review in any court.<sup>178</sup>

Undoubtedly SEPPA was the model Congress used in 2005 when it enacted the Public Readiness and Emergency Preparedness Act (PREPA).<sup>179</sup> Testifying before the House Committee on Energy and Commerce about pandemic preparedness in November 2005, DHHS Secretary Michael O. Leavitt explained the rationale for the act, which was passed as part of a Department of Defense Appropriations bill:<sup>180</sup>

[A]s we seek to build domestic [vaccine] manufacturing capacity, we also know that the threat of liability exposure is too often a barrier to willingness to participate in the vaccine business. . . . It is crucial that those engaged in this work be shielded from unwarranted tort suits. Accordingly, the Administration is proposing limited liability protections for vaccine manufacturers and providers, with an exception to allow suits to proceed against companies who act with willful misconduct.<sup>181</sup>

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171. 42 U.S.C. § 239 (2006).

172. 42 U.S.C. § 233(p)(2)(B) (2006).

173. See Greenberger, *supra* note 168, at 20.

174. *Id.*

175. *Id.*

176. *Id.*

177. See 42 U.S.C. § 239a(f)(2) (2006).

178. *Id.*

179. 42 U.S.C. § 247d (2006).

180. See Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act of 2006, Pub. L. No. 109-148, 119 Stat. 2818 (2005). For further discussion about the Act's legislative history, see Apolinsky and Van Detta, *supra* note 144, at 559-62.

181. *Assessing the National Pandemic Flu Preparedness Plan: Hearing Before the Comm. on Energy and Commerce, 109th Cong. 20 (2005)* (statement of Michael O. Leavitt, Secretary, U.S. Department of Health and Human Services).



The statute that Congress then quickly passed provides remarkably broad immunity to the manufacturers and distributors of vaccines and other so-called countermeasures whenever the Secretary of HHS “makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency.”<sup>182</sup> Importantly, the statute does not define the terms “public health emergency” or “credible risk.”<sup>183</sup> As a result, almost any potential threat could provide the basis for a PREPA declaration.<sup>184</sup> Moreover, the Secretary’s decision to issue a declaration under PREPA is totally unreviewable<sup>185</sup> and the declaration can last for as long as the Secretary specifies.<sup>186</sup> Hence, the Secretary theoretically can issue a declaration stating that cancer constitutes a public health emergency warranting the Act’s protection for the manufacturers of all cancer medications for an indefinite period of time.

Once a PREPA declaration is issued, all civil litigation against manufacturers and administrators of a covered vaccine, or other covered countermeasure, is barred, except in cases of “willful misconduct.”<sup>187</sup> In addition, PREPA includes several broad defenses available if a willful misconduct claim is brought.<sup>188</sup> For example, the Act states that an act or omission by a manufacturer that is subject to regulation by FDA shall not constitute willful misconduct if neither the Secretary of DHHS, nor the Attorney General, has initiated an enforcement action with respect to such act or omission.<sup>189</sup>

Following the pattern of previous vaccine-liability acts, PREPA also established, but did not fund, a no-fault compensation scheme to be administered by HRSA.<sup>190</sup> The Act incorporates SEPPA’s compensation

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182. 42 U.S.C. § 247d-6d(b) (2006).

183. *See id.* at § 247d-6d.

184. The statute does provide factors to be considered in issuing a declaration. These include “the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of such countermeasure.” *Id.* at § 247d-6d(b)(6). In other words, the Secretary is told to consider facts relevant to the supply of a countermeasure. The statute does not help define what constitutes a public health threat or a credible risk of such threat.

185. *Id.* at § 247d-6d(b)(7).

186. *Id.* at § 247d-6d(b)(2)(B). It can also be renewed or amended as the Secretary sees fit, although it cannot be amended to retroactively rescind liability protection. *Id.* at § 247d-6d(b)(4).

187. 42 U.S.C. §§ 247d-6d(a)(1), 247d-6d(d)(1) (2006).

188. *Id.* at § 247d-6d(c)(4).

189. *Id.* at § 247d-6d(c)(5).

190. *Id.* at § 247d-6e(a) (incorporating SEPPA’s compensation provisions).

provisions, except that in contrast to SEPPA, dependents of the deceased can obtain lost income benefits in lieu of death benefits.<sup>191</sup> Moreover, as with SEPPA, HRSA's decision with respect to a claim, as well as the Secretary's decision to invoke PREPA's immunity, appear to be unreviewable.<sup>192</sup> If an individual, after having exhausted his or her remedies with HRSA is dissatisfied, he or she is limited to bringing a claim for willful misconduct.<sup>193</sup>

In 2007, the Secretary of DHHS invoked PREPA's protections for countermeasures developed or used in connection with H5N1 avian influenza virus.<sup>194</sup> This was done even though, at the time, no money had been appropriated to the HRSA compensation fund and no regulations existed to handle any claims that might have been submitted. At the start of the H1N1 outbreak, on June 15, 2009, the Secretary of DHHS invoked PREPA to extend the protections previously provided to the producers and administrators of the H5N1 vaccine to those who made or administered the H1N1 vaccine.<sup>195</sup> Shortly thereafter, on June 24, President Obama signed a supplemental appropriations act that allocated \$7.65 billion to DHHS for the H1N1 pandemic and authorized the transfer of funds to PREPA's compensation program.<sup>196</sup> However, as of May 2010, HRSA had yet to finalize regulations governing the claims process.<sup>197</sup> Thus, more than one year after the onset of the pandemic, and more than ten months after the vaccines were licensed, claimants with significant injuries could file a notice

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191. *Id.* at § 247d-6e(b)(3).

192. 42 U.S.C. § 247b-6b(6)(7) (2006). The statute requires exhaustion of its administrative remedy and makes that remedy exclusive, except for the limited remedy for willful misconduct claims. A court, however, might read the denial of review narrowly so as to not preclude review under the Administrative Procedures Act or 28 U.S.C. § 1331. *Cf. Webster v. Doe*, 486 U.S. 591, 603-04 (1988) (reading a statute denying review of an employee's termination claims narrowly so as not to preclude review of employee's constitutional claims).

193. 42 U.S.C. § 247d-6e(d).

194. Pandemic Countermeasures; Declaration Under the Public Readiness and Emergency Preparedness Act, 72 FED. REG. 4710 (Feb. 1, 2007).

195. Pandemic Influenza Vaccines Amendment, 74 FED. REG. 30,294 (June 25, 2009). The declaration also extended protection to so-called "program planners." *Id.* This declaration was extended on Sept. 28, 2009, and again on February 26, 2010. Dep't Health & Human Servs., Pandemic Influenza Vaccines Amendment, 75 FED. REG. 10,268 (Mar. 5, 2010).

196. See Pub. L. No. 111-32, 123 Stat. 1859 (2009).

197. Public Readiness and Emergency Preparedness Act Countermeasures Injury Compensation Program, Procedures for Submitting a Letter of Intent to File Requests for Benefits, 75 FED. REG. 26,773-74 (May 12, 2010).

to file a claim;<sup>198</sup> however, they could not actually have their claims processed, never mind be heard in court, unless they could establish willful misconduct.<sup>199</sup>

#### PART FOUR: USING LAW TO INCREASE DEMAND

An ample supply of vaccine is insufficient to mitigate a pandemic.<sup>200</sup> The population that is at risk must also be willing (even grudgingly) to be vaccinated. If a pandemic is severe enough, or if populations perceive it as very dangerous, acceptance of a vaccine is not apt to be a problem. People will line up willingly, if not desperately, for a vaccine if they are sufficiently frightened of the disease it prevents. Moreover, because a pandemic vaccine will almost invariably be in short supply at the beginning of a pandemic, the most significant problem policymakers usually face at the start of a pandemic is not a shortage of demand, but of supply.<sup>201</sup> For this reason, public health policymakers and scholars have focused much of their preparedness efforts on developing plans for rationing pandemic vaccine.<sup>202</sup>

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198. However, an injured individual can bring a claim in federal court, subject to PREPA's many defenses and limitations, if he or she can show "willful misconduct." See text accompanying notes 187-89, *supra*.

199. 42 U.S.C. § 247d-6d(d) (2006). See also note 197, *supra*.

200. Of course, as noted above, the supply of vaccine will almost always be insufficient during the early months of a pandemic. See text accompanying notes 88-100, *supra*. Because of the shortage in the early fall of 2009, CDC released vaccine to state health authorities, recommending that priority be given to certain high risk groups, including health care workers, pregnant women, and children with chronic diseases. See Press Release, CDC Advisors Make Recommendations for Use of Vaccine Against Novel H1N1, CTRS. FOR DISEASE CONTROL & PREVENTION (July 29, 2009), <http://www.cdc.gov/media/pressrel/2009/r090729b.htm>.

201. See text accompanying notes 88-100, *supra*.

202. For example, in 2005, the Advisory Committee on Immunization Practices (ACIP) and the National Vaccine Advisory Committee provided recommendations to HHS on how to prioritize vaccine distribution during an influenza pandemic. Those recommendations listed vaccine and antiviral manufacturers, as well as health care workers, within the highest tier (i.e. the group to first receive vaccine). Government leaders also appeared high on the list, while healthy individuals between the ages of two and sixty-four, who were not in another category by virtue of their occupation, were at the bottom of the list. See U.S. DEP'T OF HEALTH & HUMAN SERVS., *HHS Pandemic Influenza Plan D-10 tbl.1* (2005) [hereinafter *Pandemic Influenza Plan*], available at <http://www.hhs.gov/pandemicflu/plan/pdf/AppD.pdf>. Nevertheless, during the H1N1 outbreak, that plan turned out to be of limited utility, since the groups most affected by the virus (especially children) were not those who had been expected to be at greatest risk. Hence in July 2009, the ACIP recommended that the H1N1 vaccine be initially given to pregnant women, caregivers of young children, people between six months and twenty-four years of age, and adults younger than twenty-four with chronic health problems, who were not prioritized in earlier pandemic plans. Press Release, CDC Advisors

Although shortages of vaccine are likely at the start of a pandemic, public health emergency plans have also focused on using law to mandate vaccination of individuals who choose not to be vaccinated.<sup>203</sup> The use of law to compel vaccination is not new. Since the 19<sup>th</sup> century, public health officials have employed both law and sometimes brute force to impose vaccination on the unwilling.<sup>204</sup> The use of law to penalize an individual who refuses vaccination during a public health emergency, subject to some exceptions, was famously upheld by the Supreme Court in 1905 in *Jacobson v. Massachusetts*.<sup>205</sup> In 1922, in *Zucht v. King*, the Supreme Court cited *Jacobson* in upholding a state law that required children to be vaccinated in order to attend school.<sup>206</sup> Despite this precedent, school vaccination laws were not widespread until the 1970s when the federal government urged states to enact them.<sup>207</sup>

In the fall of 2001, in the aftermath of the 9/11 and anthrax attacks, the CDC asked the Centers for the Law and the Public's Health at Georgetown and Johns Hopkins Universities to draft a Model State Emergency Health Powers Act (MSEHPA).<sup>208</sup> The draft that emerged proposed granting state public health officials the authority to isolate individuals who refused vaccination during a public health emergency.<sup>209</sup> Many states have since adopted this proposal.<sup>210</sup>

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*Make Recommendations for Use of Vaccine Against Novel H1N1*, *supra* note 200. This recommendation was largely (but not totally) followed by states in the fall of 2009. Considerable consternation arose when the press reported that certain Wall Street firms and other businesses were able to procure vaccine supplies for their employees, even while supplies remained short for many high risk individuals. See, e.g., Bill Berkrot, *Flu Shots for Wall Street Stir Ire In New York*, REUTERS, Nov. 6, 2009, <http://www.reuters.com/article/idUSN0512995020091105>; Esmé E. Deprez, *New York Businesses Get H1N1 Vaccine*, BLOOMBERG BUSINESSWEEK, Nov. 2, 2009, [http://www.businessweek.com/bwdaily/dnflash/content/nov2009/db2009112\\_606442.htm](http://www.businessweek.com/bwdaily/dnflash/content/nov2009/db2009112_606442.htm).

203. See text accompanying notes 211-22, *infra*.

204. James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 845-53 (2001-2002); Wendy K. Mariner, George J. Annas & Wendy E. Parmet, *Pandemic Preparedness: A Return to the Rule of Law*, 1 DREXEL L. REV. 341, 351-54 (2009).

205. *Jacobson v. Massachusetts*, 197 U.S. 11, 39 (1905).

206. *Zucht v. King*, 260 U.S. 174, 175 (1922).

207. ALLEN, *supra* note 105, at 245-47.

208. CTR. FOR LAW & PUBLIC'S HEALTH AT GEORGETOWN & JOHNS HOPKINS UNIVERSITIES, MODEL STATE EMERGENCY HEALTH POWERS ACT 1 (2001), available at <http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf>.

209. *Id.* at 27.

210. See CTR. FOR LAW & PUBLIC'S HEALTH AT GEORGETOWN & JOHNS HOPKINS UNIVERSITIES, MODEL STATE EMERGENCY HEALTH POWERS ACT LEGISLATIVE SURVEILLANCE TABLE (2006), available at <http://www.publichealthlaw.net/MSEHPA/MSEHPA%22Surveillance.pdf>.

The federal pandemic planning documents developed in 2005 and 2006 did not emphasize compulsory vaccination, but they did hint at its possibility. For example, under the heading of “legal preparedness,” DHHS’s November 2005 *Implementation Plan* advised state and local public health agencies to “[d]etermine whether state and local laws allow mandatory vaccination to [sic] protect public health, if needed.”<sup>211</sup>

During the actual 2009 H1N1 outbreak, no jurisdictions appear to have used their public health emergency laws to compel population-wide vaccination.<sup>212</sup> In Massachusetts, however, controversy ensued when the state legislature debated a modified version of the MSEHPA, stoking fears that the state was seeking the authority to compel vaccination.<sup>213</sup> In New York, Health Commissioner Richard F. Daines promulgated an emergency regulation requiring hospital workers who had contact with patients to be vaccinated against both seasonal flu and H1N1.<sup>214</sup> In contrast to standing regulations in other states, such as those in Massachusetts, this regulation did not permit workers to decline vaccination unless it was medically contraindicated.<sup>215</sup> New York’s regulation, which was issued before the H1N1 vaccine was available, was met with fear and anger by health care workers, many of whom resented the state’s imposition on their liberty and

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211. *Pandemic Influenza Plan*, *supra* note 202, at S6-S9 (2005).

212. This statement is based on a widespread review of media reports of the outbreak in the “major papers” library of LexisNexis plus a review in January 2010 of state regulatory documents in LexisNexis’ “state administrative codes and registers” library. See *2009 H1N1 (Swine Flu) Legal Preparedness and Response*, CTRS. FOR LAW & PUBLIC’S HEALTH (Jan. 27, 2010), <http://www.publichealthlaw.net/Projects/swinefluphl.php>.

213. Steven Smith, *In Public Health Bill, a Contagion of Fear, State Rebuts Talk of Forced Injections*, BOSTON GLOBE, Sept. 17, 2009, at A1. Since the fall of 2009, the bill has languished in a deadlocked conference committee. Kyle Cheney, *Prospects for Pandemic Preparedness Bill Grim as Session Winds Down*, BOSTON.COM (July 26, 2010), [http://www.boston.com/news/health/articles/2009/09/17/in\\_public\\_health\\_bill\\_a\\_contagion\\_of\\_fear/](http://www.boston.com/news/health/articles/2009/09/17/in_public_health_bill_a_contagion_of_fear/).

214. N.Y. Comp. Codes R. & Regs. tit. 10, § 66-3 (July 2009). Without doubt, there is a strong public health rationale for vaccinating health care workers. See Paris Nourmohammadi & Brigid Ryan, *Shooting the Moon: Should States Require the H1N1 Vaccine for Healthcare Workers?*, 7 J. EMERGENCY MGMT. 11, 11 (2009); Alexandra M. Stewart, *Mandatory Vaccination of Health Care Workers*, 361 NEW ENG. J. MED. 2015, 2015-17 (2009).

215. Compare 105 MASS. CODE REGS. 130.325 (2010) (regulation requiring hospital workers to be vaccinated against influenza but providing medical and religious exemptions, as well as the right of workers to decline vaccinations) with N.Y. Comp. Codes R. & Regs. tit 10 § 66-6 (2009) (providing an exemption from the mandatory vaccination requirement for health care workers for whom the vaccine is medically contraindicated).

feared the not-yet-licensed vaccine.<sup>216</sup> At least four lawsuits were filed, charging the state with violating state administrative law principles as well as the plaintiffs' constitutional rights.<sup>217</sup> On October 16, 2009, a trial judge issued a temporary restraining order in two of the cases.<sup>218</sup> Shortly thereafter, the state revoked the emergency regulation, citing the shortage of the H1N1 vaccine.<sup>219</sup> After that, no other state mandated the H1N1 vaccine, although many hospitals and other health care settings required their workers to be vaccinated.<sup>220</sup> Some of these private sector mandates also provoked legal challenges, generally alleging violations of collective bargaining agreements and federal labor laws.<sup>221</sup> Not surprisingly, these challenges also garnered a fair amount of media attention, casting further doubt on the safety and efficacy of the vaccine.<sup>222</sup>

#### PART FIVE: VACCINE LAW, PUBLIC HEALTH POWERS AND PUBLIC TRUST

In recent years, public health officials and public health scholars have appreciated the important role that law can play in safeguarding public health.<sup>223</sup> This has led many to emphasize what has become known as "public health legal preparedness," which stresses law's vital role in responding to a public health emergency, such as a pandemic.<sup>224</sup> In the case of pandemic vaccines, the focus on public health legal preparedness has spurred the enactment of several federal laws granting public health

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216. Donald G. McNeil, Jr. & Karen Zraick, *New York Health Care Workers Resist Flu Vaccine Rule*, N.Y. TIMES, Sept. 21, 2009, at A18. See Parmet, *Pandemic Vaccines—The Legal Landscape*, *supra* note 70, at 1951.

217. For a list of cases, see Parmet, *Pandemic Vaccines—The Legal Landscape*, *supra* note 70, at 1950.

218. *Id.* at 1951.

219. *Id.* As Nourmohammadi & Ryan explain, health care workers may also have been concerned because of a shortage of thimerosal-free H1N1 vaccine. Some states have laws prohibiting the administration of vaccines with thimerosal to pregnant women and young children except during emergencies. Nourmohammadi & Ryan, *supra* note 214, at 13. Nevertheless, these provisions may reinforce the belief among health care workers, and others, that vaccines with thimerosal are not safe, making individuals even more reluctant to receive the H1N1 vaccine. See Parmet, *Pandemic Vaccines—The Legal Landscape*, *supra* note 70, at 1950-51.

220. Parmet, *Pandemic Vaccines—The Legal Landscape*, *supra* note 70, at 1951.

221. *Id.* at 1951-52.

222. *Id.* at 1952.

223. WENDY E. PARMET, *POPULATIONS, PUBLIC HEALTH & THE LAW* 267 (2009); Anthony D. Moulton, Richard A. Goodman & Wendy E. Parmet, *Perspective: Law and Great Public Health Achievements*, in *LAW IN PUBLIC HEALTH PRACTICE* 3, 3 (Richard A. Goodman et al. eds., 2d ed. 2007).

224. Anthony D. Moulton et al., *What is Public Health Legal Preparedness?*, 31 J.L. MED. & ETHICS 672, 672 (2003).

officials significant authority to dispense with the normal rules regarding the licensing and liability of pandemic vaccines. In many states, public health legal preparedness has prompted the adoption of public health emergency laws, often modeled on the MSEHPA, authorizing health officials, upon the declaration of a public health emergency, to detain individuals who refuse to be vaccinated. Supporters justify these laws as both practical responses to the supply and demand problems afflicting pandemic vaccines and as necessary corollaries to the widely stated belief that public health protection, especially during an emergency, requires the sacrifice of individual liberty.<sup>225</sup> In either case, these laws rely, to a significant degree, on a relatively simple vision of the relationship between law and public health, one that assumes that laws can protect a population's health simply by granting officials power to undertake measures that are designed to prevent the spread of disease.

In reality, law's relationship to public health is far more complex. Without doubt, the informed exercise of public health authorities can often improve public health.<sup>226</sup> But in order to do so, public health laws must do more than simply empower public officials; they need to foster a social environment that is supportive of health. To do that, public health laws need to take account of and seek to improve the public's perception of public health officials and other parties vital to the public health system, including pharmaceutical companies. In other words, in order to protect public health, laws must promote, rather than erode, the public's trust in the public health system. This can be challenging in an era, such as the current one, in which there is widespread cynicism and distrust of both governments and large corporations.<sup>227</sup>

It is especially important that pandemic preparedness laws inspire the public's trust.<sup>228</sup> As a practical matter, no matter how much authority officials are granted, laws cannot ensure that individuals wash their hands, cover their mouths when they cough, or stay at home if they have flu-like symptoms. Nor can laws effectively compel masses to submit to a vaccination campaign or wait patiently while others at greater risk are vaccinated. All of these health-promoting behaviors, which may be essential in the face of pandemic influenza, require the population's trust in the public health system. If public health emergency laws foster that trust,

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225. For a more detailed discussion, see Mariner, Annas & Parmet, *supra* note 204, at 354-55.

226. See Moulton, Goodman & Parmet, *supra* note 223, at 18.

227. See THE PEOPLE AND THEIR GOVERNMENT, *supra* note 112, at 1-6.

228. Heidi J. Larson & David L. Heymann, *Public Health Response to Influenza A (H1N1) as an Opportunity to Build Public Trust*, 303 JAMA 271, 271 (2010); Quinn et al., *supra* note 132, at 287.

they may be able to achieve their goals. But if public health laws erode the public's trust, they risk being ineffective in the short-term and dangerous in the long-term as they instigate a vicious cycle in which health officials seek greater and greater authority to impose policies on an ever-more unwilling public.

Whether the vaccine laws employed during the H1N1 outbreak enhanced the public's trust in health officials or widened the circle of distrust is an empirical question whose answer remains unknown. Without doubt, H1N1 vaccine was produced and disseminated to large numbers of people relatively rapidly.<sup>229</sup> Moreover, the vaccine appears to have been relatively safe.<sup>230</sup> This "success" may have boosted the public's confidence in the public health system.

Nevertheless, there are reasons to worry that the extant pandemic vaccine legal regime, which effectively reduced the risk faced by vaccine makers while simultaneously diminishing the rights of individuals,<sup>231</sup> might have broadened the gulf between public health officials and a wary public,<sup>232</sup> a risk that might have been even greater if the H1N1 vaccine, like the 1976 swine flu vaccine, had been associated with a large number of significant adverse effects. Rather than assuring individuals that their safety is the law's first priority, and that they will be cared for if a vaccine causes them injury, the pandemic vaccine laws that were utilized during the 2009 outbreak may have reaffirmed populist suspicions about the intentions of government, public health officials, and vaccine makers. At the least, the laws fit comfortably within the populist, antigovernment narrative, thereby providing, however unintentionally, support for suspicions about the actions of health officials and the safety of vaccines.

Consider first the least controversial set of pandemic laws, those providing for government's purchase of pandemic vaccines. Given that pandemic vaccines are partial public goods, government investment in them is probably necessary to assure an adequate supply. Without government support, manufacturers would probably continue to under-invest in vaccines. But by agreeing to purchase vaccines before the need for them was certain,

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229. See *supra* text accompanying note 4.

230. See *supra* text accompanying notes 6, 78-80.

231. The question of whether PREPA unconstitutionally limits the rights of individuals by limiting review of the Secretary's actions, including, potentially, decisions as to individual claims, is beyond the scope of this paper. Nevertheless, the act's jurisdiction-stripping provisions clearly raise serious constitutional questions. For a relatively recent discussion of the perplexing and oft-discussed question about Congress' power to strip the courts of jurisdiction, see Douglas E. Edlin, *A Constitutional Right to Judicial Review: Access to Courts and Ouster Clauses in England and the United States*, 57 AM. J. COMP. L. 67, 70-71 (2009).

232. See RICHARD HOFSTADTER, *THE PARANOID STYLE IN AMERICAN POLITICS AND OTHER ESSAYS* 77-86 (1964).



the government effectively shifted the risk of over-production from manufacturers to the taxpayers. Indeed by investing so heavily in vaccines and antiviral medications, the government ensured what leading anti-vaccinationist Barbara Loe Fisher called a “pharmaceutical company stockholder dream scenario”<sup>233</sup> and what leading public health law scholar Lawrence O. Gostin more dispassionately described as a “windfall for the pharmaceutical industry.”<sup>234</sup>

This possible windfall inevitably provided fodder for vaccine critics who claimed that health authorities hyped the pandemic to support the interests of the pharmaceutical companies. The belief that the pandemic was exaggerated to benefit vaccine makers was widespread in Europe, where the European Parliament and the Council of Europe, among other entities, have investigated the close ties between members of WHO’s advisory boards and pharmaceutical makers, questioning whether the interests of the latter influenced WHO’s decision to declare a pandemic.<sup>235</sup> Of course, as Deborah Cohen and Phillip Carter noted in the *British Medical Journal*, “[p]lanning for the worst while hoping for the best remains a sensible approach.”<sup>236</sup> If WHO and governments had not declared a pandemic and governments had failed to invest in vaccines, and the virus had proven more lethal, many more lives would have been lost. Nevertheless, by guaranteeing that vaccine makers would earn substantial sums even if the outbreak proved to be mild, the federal government, like the WHO, became vulnerable to the perception that it acted in the interests of pharmaceutical makers, rather than the public.

Other supply side laws utilized by the federal government during the pandemic may have reinforced this perception. As was noted above, the EUA procedure permits unlicensed medications and vaccines to be administered when the Secretary of DHHS declares a public health emergency.<sup>237</sup> According to Quinn and colleagues, many members of the public had misgivings about receiving an unlicensed vaccine and the EUA procedure may diminish the public’s trust in health authorities.<sup>238</sup> This

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233. Barbara Loe Fisher, *supra* note 10.

234. Gostin, *supra* note 118, at 9. Focusing on childhood vaccines, Mary Holland argues that the “vaccine industry has largely ‘captured’ its regulators” and that there is a “culture of conflicts” between the industry and regulators. Holland, *supra* note 148, at 3, 36.

235. Cohen & Carter, *supra* note 1, at 1274. In April 2010, WHO responded to critics’ charge that the pandemic had been hyped by convening a review committee to evaluate WHO’s response to the pandemic. See *WHO Director-General’s Letter to BMJ Editors*, WORLD HEALTH ORG. (June 8, 2010), [http://www.who.int/mediacentre/news/statements/2010/letter\\_bmj\\_20100608/en/index.html](http://www.who.int/mediacentre/news/statements/2010/letter_bmj_20100608/en/index.html).

236. Cohen & Carter, *supra* note 1, at 1279.

237. See *supra* text accompanying notes 129-32.

238. Quinn et al., *supra* note 132, at 284-85.

problem is especially grave among populations, including African Americans, who already have high levels of distrust of public health authorities.<sup>239</sup> Although the research by Quinn and colleagues did not consider whether the EUA process may also provoke distrust among people who believe there are conflicts of interest between the government and pharmaceutical companies, it seems plausible that such individuals would be even more troubled than others about the EUA process. In other words, individuals who believe that the risk from the pandemic was over-stated to profit vaccine makers may be especially apt to believe that the EUA process permits the use of dangerous, untested vaccines.

PREPA provides even greater fuel for populist conspiracy theorists. By shielding manufacturers from virtually any liability, on the basis of an unfettered and unreviewable declaration of a public health emergency,<sup>240</sup> and by limiting review of HRSA's compensation decisions,<sup>241</sup> the Act creates the perfect target for anti-vaccinationists and others who believe that unsafe pandemic vaccines were foisted upon a vulnerable public. Thus during the H1N1 outbreak, the National Vaccine Information Center, one of the best known and most active anti-vaccinationist groups, posted articles on its website emphasizing PREPA's broad liability provisions.<sup>242</sup> For example, a September 2009 article by Barbara Loe Fisher stated:

If you or your child are injured from getting a flu [sic] swine flu shot, you are on your own. Because Congress shielded the vaccine manufacturers and any person giving swine flu shots from lawsuits if people get hurt. There is no funded government vaccine injury compensation program for swine flu vaccine.<sup>243</sup>

Although this statement was misleading because the HRSA-run compensation program was funded by September 2009, Fisher's point was essentially correct: Congress had shielded vaccine makers from almost all liability. Moreover, the quite limited compensation program established by PREPA was not yet up and running.<sup>244</sup>

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239. See *id.*

240. See *supra* text accompanying notes 185-86.

241. See *supra* text accompanying notes 192-93.

242. See Barbara Loe Fisher, *Mild Swine Flu and Over-Hyped Vaccine*, NAT'L VACCINE INFO. CTR. (Sept. 29, 2009), <http://www.nvic.org/NNVI-Vaccine-News/September-2009/Mild-Swine-Flu-Over-Hyped-Vaccine.aspx>; Barbara Loe Fisher, *H1N1: Fact or Fiction?*, NAT'L VACCINE INFO. CTR. (Nov. 11, 2009), <http://www.nvic.org/NVIC-Vaccine-News/November-2009/H1N1--Fact-or-Fiction--by-Barbara-Loe-Fisher.aspx>.

243. Barbara Loe Fisher, *Mild Swine Flu and Over-Hyped Vaccine*, *supra* note 242 (citation omitted).

244. See *supra* text accompanying notes 196-99.

Ironically, as the public's trust in vaccine diminishes, public health officials seem even more anxious to compel vaccination.<sup>245</sup> As discussed above, compulsory vaccination laws are likely to be of little merit during a pandemic in which the most pressing problem is a shortage of vaccine, rather than the public's unwillingness to be vaccinated.<sup>246</sup> Nevertheless, as the anti-vaccination movement has gained strength, public health scholars have increasingly focused their attention on compelling vaccination.<sup>247</sup> Of course, correlation is not causation, but it seems plausible to think that the renewed interest in mandatory vaccination responds in part to officials' concern that the public is growing increasingly wary of vaccines and is ever-more-likely to reject them.<sup>248</sup>

What is often overlooked when public health officials attempt to mandate vaccination is that compulsory immunization laws can themselves heighten the public's distrust in vaccines, thereby exacerbating the very problem the laws are designed to counter. This may especially be true when mandates are imposed rapidly, with relatively little public debate, regarding new vaccines, to which the public has not had time to become comfortable.<sup>249</sup> For example, an executive order issued by Texas Governor Rick Perry in 2007 adding Gardasil, a recently-licensed human papilloma virus vaccine, to the state's list of vaccines required for entering school,

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245. Likewise, the fear of frivolous litigation and the cries for immunity may well rise as the public's faith in vaccines diminish.

246. See *supra* text accompanying notes 200-02.

247. There have been many articles in recent years reviewing and/or advocating for the use of compulsory vaccination. See, e.g., Lawrence O. Gostin, *When Terrorism Threatens Health: How Far Are Limitations on Personal and Economic Liberties Justified?*, 55 FLA. L. REV. 1105, 1151 (2003); Elizabeth Weeks Leonard, *The Public's Right to Health: When Patient Rights Threaten the Commons*, 86 WASH. U.L. REV. 1335, 1390 (2009); Stewart, *supra* note 214.

248. There have been outbreaks of vaccine-preventable diseases that have been attributed, at least in part, to parents' refusal to have their children fully vaccinated. Ctrs. for Disease Control & Prevention, *Measles – United States, January 1 – April 25, 2008*, 57 *Morbidity & Mortality Wkly. Rep.* 1-4 (2008) (early release), available at <http://www.cdc.gov/mmwr/preview/mmwrhtmlmm57e501a1.htm>; Daniel R. Feikin et al., *Individual and Community Risks of Measles and Pertussis Associated with Personal Exemptions to Immunization*, 284 *JAMA* 3145 (2000). Childhood vaccination rates for children in the United States nevertheless remain high. See ALLEN, *supra* note 110.

249. School vaccine laws, which generally compel children to have well-established vaccines, and in most states include significant exemptions, may thus be different. Although these laws have aroused controversy, they may not engender quite the same apprehension as emergency laws requiring vaccines that are perceived as new. For the argument that school vaccine laws should not be viewed as highly coercive, see Parmet, *Public Health and Social Control*, *supra* note 25, at 45. See also Gail Javitt, Deena Berkowitz & Lawrence O. Gostin, *Assessing Mandatory HPV Vaccination: Who Should Call the Shots?*, 36 *J.L. Med. & Ethics* 384, 385 (2008). For a critique of these laws, see Holland, *supra* note 148, at 41-44.

created a furor among both social conservatives and libertarians.<sup>250</sup> The controversy became even hotter when word came out that Gardasil's manufacturer, Merck & Company had contributed to Perry's political action committee.<sup>251</sup> Responding to public outrage, the Texas legislature overrode Perry's executive order.<sup>252</sup>

Likewise, New York's attempt to compel health care workers to be vaccinated against both seasonal and pandemic influenza ignited heated opposition.<sup>253</sup> Without doubt, there are strong public health reasons to support the vaccination of health care workers. As New York State Health Commissioner Richard Daines stated in an open letter to health care workers, "Medical literature convincingly demonstrates that high levels of staff immunity confer protection on those patients who cannot be or have not been effectively vaccinated, while also allowing the institution to remain more fully staffed."<sup>254</sup> However, while laws may be able to increase the vaccination rate of health care workers, Daines' emergency regulation, which required workers to accept what they viewed as a new vaccine (for which they might not be able to receive compensation if they were injured)<sup>255</sup> was almost destined to provoke a protest. The ensuing litigation by angry nurses and their unions was predictable. Although commentators might have been accurate in arguing that the Constitution permits a state to penalize individuals who reject vaccination during a health emergency,<sup>256</sup> their assessment overlooked both the strength of the protesters' non-constitutional claims,<sup>257</sup> and the social impact of unpopular mandates. In

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250. Micah Globerson, *Protecting Women: A Feminist Legal Analysis of the HPV Vaccine, Gardasil*, 17 TEX. J. WOMEN & L. 67, 75-77 (2007).

251. *Id.* at 78 n.68; Sylvia Law, *Human Papillomavirus Vaccination, Private Choice, and Public Health*, 41 U.C. DAVIS L. REV. 1731, 1759 n.146 (2008); Pauline Self, *The HPV Vaccination: Necessary or Evil?*, 19 HASTINGS WOMEN'S L.J. 149, 155-56 (2008).

252. H.B. 1098, 80th Leg., Reg. Sess. (Tex. 2007), and identical S.B. 438, 80th Leg., Reg. Sess. (Tex. 2007).

253. See McNeil & Zraick, *supra* note 216, at A18.

254. Letter from Richard F. Daines, New York State Health Commissioner, to the health care workers of New York State (Sept. 24, 2009), *quoted in* Stewart, *supra* note 214, at 2015.

255. As noted above, HRSA's compensation system was not yet in effect. See *supra* text accompanying notes 197-99.

256. See Stewart, *supra* note 214, at 2017.

257. Public health lawyers often focus on whether a public health law is constitutional. But litigators protesting such laws are perhaps more apt to succeed by emphasizing administrative law and statutory grounds for relief. In the New York litigation, the plaintiffs argued that the emergency regulation exceeded the scope of the Commissioner's authority and violated New York's Administrative Procedure Act. *E.g.*, Petition at 14-19, *Patterson v. Daines*, No. 8830-09 (N.Y. Sup. Ct. Oct. 15, 2009); Petition at 14-19, *Brynien v. Daines*, No. 8853-09 (N.Y. Sup. Ct. Oct. 16, 2009). See also *New York Court Stops State From Requiring Flu Vaccinations for Health Care Workers*, *supra* note 71, at 1414.

New York, protests by nurses contesting the emergency regulation as well as the litigation about the mandate, received significant media attention.<sup>258</sup> The impact of these stories, emphasizing *health care workers'* resistance to vaccination, is uncertain, but surely they did not enhance the general public's faith in the H1N1 vaccine. Indeed, it is hard to think of an image more corrosive of the public's trust in the vaccine than that of a nurse protesting a law requiring vaccination.

Ironically, the battle over New York's H1N1 vaccine regulation was for naught. Commissioner Daines eventually concluded that there was little merit in continuing to litigate a regulation requiring health care workers to accept a vaccine that was in short supply.<sup>259</sup> The emergency regulation was rescinded before the vaccine became readily available;<sup>260</sup> but not before the damage to the vaccine's image, and to the public's trust in public health officials, may have been done.

By failing to anticipate the potential social responses to his regulation, Commissioner Daines may have misplayed his hand. Like many public health officials, he may have viewed public health law as a potent tool for promoting vaccination, a worthy goal from a public health perspective. But what Daines and other public health officials and policymakers frequently fail to recognize is that law, without the public's support, may be of limited utility. Suspicion and mistrust, so widely evident today, can cast doubt upon public health laws that may seem both cost-effective and even beneficent to public health officials. Suspicion and doubt can grow when vaccination laws put all of the risk on ordinary individuals and remove all of the risk from health officials and pharmaceutical makers. Under these circumstances, it is not surprising that nurses took to the courts; nor is it surprising that millions of doses of vaccine had to be destroyed for lack of use.<sup>261</sup>

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258. See, e.g., Anemona Hartocollis, *Mandatory Flu Vaccination for N.Y. Health Workers is Criticized*, N.Y. TIMES, Oct. 13, 2009, <http://www.nytimes.com/2009/10/14/health/policy/14vaccine.html>; McNeil & Zraick, *supra* note 216, at A18; Delthia Ricks, *Workers Rap Vaccine Order*, NEWSDAY, Oct. 11, 2009, at A02; Rob Stein, *Mandatory Flu Shots Hit Resistance: Many Health Care Workers Required to Get Vaccines*, WASH. POST, Sept. 26, 2009, at A01.

259. See *supra* text accompanying notes 217-19.

260. See *id.*

261. See *supra* notes 11, 216-21.

## CONCLUSION

Many public health scholars and officials recognize the importance of trust in determining the efficacy of a public health campaign.<sup>262</sup> Writing in the January 20, 2010 issue of the *Journal of the American Medical Association*, Heidi J. Larson and David L. Heymann observed that:

Lack of trust can cause health programs to fail with harmful consequences. Measles out-breaks in the United Kingdom and the United States and the spread of polio across Africa from Northern Nigeria underscore the importance of building—and maintaining—public trust in health interventions and in the authorities who provide them. Trust relationships must be built over time so that they become the social framework in which health interventions—and positive health outcomes—can thrive.<sup>263</sup>

The authors go on to explain that transparency is “an essential criteria of trust”<sup>264</sup> and that:

rather than becoming defensive in the face of an increasingly questioning public, the medical and public health communities must recognize the importance of changing the conversation with individual patients and the public and the importance of being open to hearing real concerns that will affect the acceptance or rejection of health services.<sup>265</sup>

In making these important points, Larson and Heymann echo others in viewing the public’s lack of trust in public health policies as a result of poor health communication.<sup>266</sup> But while transparency, listening, and honest communication—all elements that Larson and Heymann associate with good public health communication—are each important to the development and maintenance of trust, they may be insufficient if the underlying architecture of public health campaigns, created by public health laws, is distrustful of the public.

By placing all of the risk of vaccine campaigns on ordinary individuals and none on either public health officials or pharmaceutical makers, the laws that governed the H1N1 vaccine campaign reflected a profound

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262. See, e.g., Danielle Ofri, *The Emotional Epidemiology of H1N1 Influenza Vaccination*, 361 NEW ENG. J. MED. 2594, 2594-95 (2009); David A. Shore, *Communicating in Times of Uncertainty: The Need for Trust*, 8 J. HEALTH COMM. 13, 13-14 (2003).

263. Larson & Heymann, *supra* note 228, at 272.

264. *Id.*

265. *Id.*

266. E.g., Ofri, *supra* note 262, at 2595 (“Our science has not been dithering at all, but our articulation of that science has often seemed that way...”); Kumanan Wilson et al., *Parental Views on Pediatric Vaccination: The Impact of Competing Advocacy Coalitions*, 17 PUB. UNDERSTANDING SCI. 231, 241 (2008) (finding that parental acceptance of vaccination rates had to do with trust, and that public health “will likely have to consider alternative strategies centered on communication targeted to the belief system of the recipients”).

disrespect for the people they were supposed to serve. Indeed, when supply and demand side pandemic vaccine laws are viewed together, they appear to have presupposed that the public was both foolish and litigious. Why else did these laws protect pharmaceutical companies and health officials from the anticipated poor decisions – either to abstain from the vaccine or to sue –of ordinary individuals?

By assuming that the public is the problem, rather than the client, of public health services, pandemic vaccine laws risk exacerbating the growing distrust between public health officials and the public. To put it another way, by giving the public a legitimate reason to fear that public health laws fail to allocate the risks associated with pandemic vaccines in an equitable manner, pandemic vaccine laws risk reinforcing the suspicions and distrust to which they respond. At the very least, these laws provide public health critics with grist to grind in their mill.

If this hypothesis is correct, (and without a doubt more empirical support is required to affirm it), the “solution” cannot rely simply on better communication skills. Honest and transparent communication cannot “sell” a product that disserves the public’s interest. In the case of the H1N1 vaccine, a candid and transparent disclosure of the risk allocation scheme established by the pandemic vaccine laws would have required explaining to individuals that although there was no reason to believe that the risks of the vaccine were greater than those associated with the typical seasonal flu vaccine, individuals who did experience an adverse outcome would have been entitled to very limited, or no compensation at all, via a system that was not fully established, and which was not likely subject to any external review or oversight. They also would have been told that vaccine makers that profited from the vaccine were absolved of almost all liability, even if the vaccine was produced negligently. They would have been told that the laws of many states permitted health officials (if a public health emergency was declared) to detain them if they refused this vaccine. This transparent and candid disclosure seems unlikely to entice many people to seek vaccination, unless the pandemic itself were sufficiently frightening, in which case, of course, there may have been little need to worry about insufficient demand for the vaccine.

What, then, is the solution to the dilemma of pandemic vaccines? Unfortunately, there are no simple answers. Public health policymakers face real and complex problems in trying to ensure a rapid and adequate supply of vaccines in the face of uncertain risks. These problems may make the reallocation of some economic risk to the taxpayers sensible. Still, it is critical that policymakers appreciate what law can and cannot do.

Public health law is an essential and powerful tool for protecting the public health, albeit one subject to constitutional and other legal limitations.<sup>267</sup> In the case of pandemic vaccines, public health law has been used, successfully and not so successfully, to expedite the production, licensing, and distribution of vaccines. Public health law may also provide officials with significant authority to determine the allocation of vaccine, or even, to impose penalties on individuals who refuse vaccines.

But legal authority cannot protect public health without the acceptance, and perhaps active support, of affected populations. To garner that acceptance, support, and indeed trust, public health laws must do more than provide officials with authority or corporations with financial incentives. They must also provide a firm basis for public trust, so that when public health officials communicate with candor and transparency the story they tell is one that does not incite suspicion.

To ensure that the story does not erode trust, public health policymakers may need to reconsider how pandemic vaccine laws allocate risk, both financial and legal. Almost certainly government investment in vaccine research and production, and the potential conflicts of interest that may engender,<sup>268</sup> are unavoidable. But PREPA's liability provisions seem far more protective of industry, and far less protective of the public, than is necessary or useful. Vaccine manufacturers receive significant liability protections under NCVIA; but that Act is far more generous to individuals who believe they have been harmed than is PREPA. Perhaps most importantly, NCVIA provides some basis for accountability and oversight, since claimants maintain the right to an independent decision-maker to hear their claims. That most fundamental right, often associated with due process,<sup>269</sup> as well as our system of checks and balances, is insufficiently recognized by PREPA.

In addition, there is little justification for giving individuals who are injured by pandemic vaccine less compensation than they would receive if they were injured by another vaccine. Indeed, since it is more important, from a public health perspective, for an individual to accept a pandemic vaccine, than many other vaccines covered by NCVIA,<sup>270</sup> the compensation

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267. See LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* 4 (2d ed. 2008).

268. See *supra* text accompanying notes 118-21.

269. See, e.g., *Concrete Pipes & Prods. Cal. v. Constr. Laborers Pension Trust*, 508 U.S. 602, 617-18 (1993) (emphasizing the importance of a detached and neutral decision maker).

270. *National Vaccine Injury Compensation Program: Covered Vaccines*, HEALTH RESOURCES & SERVS. ADMIN., [http://www.hrsa.gov/vaccinecompensation/covered\\_vaccines.htm](http://www.hrsa.gov/vaccinecompensation/covered_vaccines.htm) (last visited Jan. 9, 2011). Yet the tetanus vaccine only protects the individual who is vaccinated and does not protect others since tetanus is not a causally-transmitted disease. See M. PATRICIA JOYCE, *TRAVELERS' HEALTH—YELLOW BOOK*, Chapter 2: Tetanus (2010),



for injuries due to pandemic vaccines should be at least as great as those under NCVIA. This should especially be the case for any vaccines that are distributed pursuant to the EUA process. Individuals who willingly take an unlicensed vaccine should not forfeit their right to compensation for any injuries they may suffer. Rather, just like vaccine makers, individuals should have their risks protected.

Public health officials may also want to reconsider their fondness for vaccine mandates, at least during pandemics. As the H1N1 pandemic illustrated, mandates are relatively useless in the early weeks and months of a pandemic when vaccine is in short supply. But talk of mandates can create needless anxiety and garner negative publicity, as anti-vaccinationists, civil libertarians, and individuals who fear they will be subject to the mandate organize in opposition.

Most importantly, public health lawyers and policymakers should rethink their conception of public health legal preparedness. In order to prepare for a pandemic, or any other public health emergency, public health officials must know the laws under which they operate. But legal “powers” and extraordinary “authorities” alone cannot assure the public’s health. Trust and the willingness to comply with the advice of public health officials are also essential. For that, public health lawyers need to think both more broadly and more subtly. They need to consider how law can be used to build a robust and resilient community that can withstand the ravages of a public health emergency.<sup>271</sup> Additionally, they need to consider how to use law with a gentle hand that respects the rights and interests of not only the powerful, but also the public that public health laws are meant to serve.

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available at <http://wwwnc.cdc.gov/travel/yellowbook/2010/chapter-2/tetanus.aspx> (“Tetanus has no direct person-to-person transmission.”).

271. Mariner, Annas & Parmet, *supra* note 204, at 343.

