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DECLARING AND TERMINATING PUBLIC HEALTH EMERGENCIES: PERFORMATIVE UTTERANCES THAT CAN CHANGE THE WORLD

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Declarations and terminations of public health emergencies are performative utterances that shift the balance of governmental power and can change our world. They can provide and then extinguish the ability to provide grants and funding, deploy the military, waive and modify regulatory requirements, and curtail civil liberties, many times with limited legislative oversight. But public health emergency laws at every level are inconsistent at best and are being legislated in a reactionary manner that may limit the ability to effectively respond in future public health emergencies. With such high stakes and during a time when executive agency authority is evolving, appropriate guidance on the felicity conditions for these performative utterances is thus urgently needed. Instead of simply accepting lengthy unfettered executive public health emergency powers or enacting strict legislative limitations on executive authority that could hinder an effective public health response in the future, this Article focuses on a singular first step in calling for a diverse, multi-disciplinary team of scholars and stakeholders to examine the existing web of public health emergency legislation and provide input and guidance on felicity conditions for declaring, continuing, and terminating specific public health emergencies that build in mechanisms for accountability and relevant, appropriate checks and balances.

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INTRODUCTION

In his State of the Union Address on February 7, 2023, President Biden explained that "thanks to the resilience of the American people, we have broken COVID's grip on us. . . . And soon we'll end the public health emergency."[1] Two days later, on February 9, 2023, the Secretary of the U.S. Department of Health and Human Services ("HHS"), Xavier Becerra, declared that the public health emergency authorized under Section 319 of

1. President Joseph Biden, State of the Union Address (Feb. 07, 2023), https://www.whitehouse.gov/briefing-room/speeches-remarks/2023/02/07/remarks-of-president-joe-biden-state-of-the-union-address-as-prepared-for-delivery/.

the Public Health Services Act ("PHSA") would expire in ninety days.[2] On May 11, 2023, the Section 319 public health emergency officially ended.[3]

Since the public health emergency was declared in the early days of 2020, more than seven million COVID-19 deaths have been recorded worldwide, with over one million of those in the United States,[4] and life expectancy has dropped by two years.[5] The pandemic disrupted families, schools, the health care system, businesses, and the supply chain,[6] with vulnerable populations being the hardest hit.[7] And while the public health

2. *Letter to U.S. Governors from HHS Secretary Xavier Becerra on Renewing COVID-19 Public Health Emergency (PHE)*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Feb. 9, 2023), https://www.hhs.gov/about/news/2023/02/09/letter-us-governors-hhs-secretary-xavier-becerra-renewing-covid-19-public-health-emergency.html.

3. *Fact Sheet: End of the COVID-19 Public Health Emergency*, U.S. DEP'T OF HEALTH & HUM. SERVS. (May 9, 2023), https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html. The actions taken by Secretary Becerra in ending the PHSA public health emergency were generally consistent in timing with those of the World Health Organization ("WHO"). On May 4, 2023, the WHO's International Health Regulations Emergency Committee ("IHREC") convened and, based on decreasing infection rates, deaths, and hospitalizations and increasing levels of vaccination, recommended ending the public health emergency of international concern ("PHEIC"). *See Statement on the Fifteenth Meeting of the IHR (2005) Emergency Committee on the COVID-19 Pandemic*, WORLD HEALTH ORG. (May 5, 2023), https://www.who.int/news/item/05-05-2023-statement-on-the-fifteenth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic. WHO's Director General, Dr. Tedros Adhanom Ghebreyesus, concurred with the IHREC's findings and announced: "It is with great hope I declare Covid-19 over as a global health emergency." *See* Stephanie Nolan, *W.H.O. Ends Global Health Emergency Designation for Covid*, N.Y. TIMES (May 5, 2023), https://www.nytimes.com/2023/05/05/health/covid-who-emergency-end.html.

4. *See WHO Coronavirus (COVID-19) Dashboard*, WORLD HEALTH ORG., https://covid19.who.int/ (last visited Jan. 31, 2024); *COVID Data Tracker*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://covid.cdc.gov/covid-data-tracker/#maps_percent-covid-deaths (last visited Jan. 31, 2024); William Msemburi et al., *The WHO Estimates of Excess Mortality Associated with the COVID-19 Pandemic*, 613 NATURE 130, 130 (2022) (estimating 14.83 million excess deaths globally, 2.74 times more deaths than the 5.42 million due to COVID-19 for the period); Melody Schreiber, *Who Is Dying from COVID Now and Why*, SCI. AM. (Nov. 16, 2022), https://www.scientificamerican.com/article/who-is-dying-from-covid-now-and-why/.

5. Steven H. Woolf, Ryan K. Masters & Laudan Y. Aron, *Effect of the Covid-19 Pandemic in 2020 on Life Expectancy Across Populations in the USA and Other High-Income Countries: Simulations of Provisional Mortality Data*, 373 BRITISH MED. J. 1 (2021), https://www.bmj.com/content/373/bmj.n1343 (estimating that life expectancy in the U.S. decreased by two years, largely due to the pandemic, with significant declines in minority groups).

6. *See e.g.*, WENDY PARMET, CONSTITUTIONAL CONTAGION: COVID, THE COURTS AND PUBLIC HEALTH 74 (2023) ("Many businesses and families suffered significant economic losses as customers stayed away and businesses shuttered. Children and parents were harmed as schools went online. . . . As long as large numbers of people were dying and the health care system was strained, the economy would suffer.").

7. *See id.* at 73, 140–60 ("Communities of color suffered disproportionately, especially in the pandemic's first year, as did immigrants, people with disabilities, and seniors."). *See generally* Racquaiijah Yearby & Seema Mohapatra, *Systemic Racism, the Government's Pandemic Response, and Racial Inequities in COVID-19*, 70 EMORY L. J. 1419 (2021); Douglas B. White, Lisa Villarroel & John L. Hick, *Inequitable Access to Hospital Care — Protecting Disadvantaged Populations*

emergency is over, the virus remains.[8] COVID-19 has not been eradicated; rather, the pandemic has morphed into an endemic with thousands continuing to become infected with COVID-19 and many continuing to die.[9]

Throughout history, pandemics, along with other public health emergencies ("PHEs"), have occurred with some regularity. Between 2007 and 2020, the World Health Organization ("WHO") declared six different pandemics to be a Public Health Emergency of International Concern ("PHEIC"),[10] each of which was spread from human to human by a virus that originated from an animal host or reservoir.[11] Towards the end of the COVID-19 public health emergency, another virus, Mpox,[12] was declared a public health emergency both globally[13] and in the United States.[14] Even with advances in infectious disease surveillance, detection, and response, the potential for new infectious diseases to emerge and spread exists. A recent

During Public Health Emergencies, 385 NEW ENG. J. MED. 2211, 2211–14 (2021); Cheryl A. Levine & Daire R. Jansson, *Concepts and Terms for Addressing Disparities in Public Health Emergencies: Accounting for the COVID-19 Pandemic and the Social Determinants of Health in the United States*, 16 DISASTER MED. PUB. HEALTH PREP. 1, 1–4 (2021).

8. *See CDC Museum COVID-19 Timeline*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 15, 2023), https://www.cdc.gov/museum/timeline/covid19.html/.

9. *See supra* note 4 and accompanying text.

10. Annelies Wilder-Smith & Sarah Osman, *Public Health Emergencies of International Concern: A Historic Overview*, 27 J. TRAVEL MED. 1, 1, 3–7 (2020).

11. *See generally* Richard L. Schader, *Zoonotic Viruses: The Mysterious Leap from Animals to Man*, 40 CLINICAL THERAPEUTICS 1225 (2018); Interview with Dr. Pat Lord, Ph.D., Wake Forest Univ., Dep't of Biology (July 27, 2023).

12. *See Mpox*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/poxvirus/mpox/index.html (last visited July 27, 2023).

13. *See WHO Director-General's Statement at the Press Conference Following IHR Emergency Committee Regarding the Multi-Country Outbreak of Monkeypox*, WORLD HEALTH ORG. (July 23, 2022), https://www.who.int/director-general/speeches/detail/who-director-general-s-statement-on-the-press-conference-following-IHR-emergency-committee-regarding-the-multi—country-outbreak-of-monkeypox—23-july-2022.

14. *Biden-Harris Administration Bolsters Monkeypox Response; HHS Secretary Becerra Declares Public Health Emergency*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (Aug. 4, 2022), https://www.hhs.gov/about/news/2022/08/04/biden-harris-administration-bolsters-monkeypox-response-hhs-secretary-becerra-declares-public-health-emergency.html. Mpox had not spread from human to human prior to 2022. *See 2022–2023 U.S. Map & Case Count*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 26, 2023), https://www.cdc.gov/poxvirus/monkeypox/response/2022/us-map.html. Another virus, Avian H5N1 influenza virus, is being carefully monitored by scientists and public health officials. It is circulating in wild bird populations but has also infected domestic poultry, leading to culling of millions of domestic poultry in Europe, Africa, Asia, and North and South America. The potential does exist for it to spread from human to human. *See H5N1 Bird Flu: Current Situation Summary*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/flu/avianflu/avian-flu-summary.htm (last visited Dec. 13, 2023).

study, in fact, showed the probability of a three-fold increase in novel disease outbreaks in the coming decades.[15]

Establishing the conditions under which declarations, continuations, and terminations of public health emergencies ought to be made is particularly important given the implications such decisions have and the competing interests that underlie them. Declarations of public health emergencies are what noted philosopher and scholar J.L. Austin called "performative utterances."[16] Performative utterances are statements that have the effect to act, cause an action, or change social reality—in contrast to descriptive phrases, which are simply true-or-false statements like "the sky is blue."[17] In his book *How to Do Things with Words*, Austin provides common examples of performative utterances, such as "I take you to be my lawfully wedded spouse," or "I name this ship the Queen Elizabeth."[18] Within health care, performative utterances are critical, such as the declarations heard far too often during the COVID-19 pandemic: "I pronounce this patient dead," or "time of death is 9:02 AM."

For a performative utterance to effectuate or terminate actions, certain conditions—called felicity conditions—must be in place.[19] These are the criteria that must be met for an utterance or speech act to perform its function, such as the speaker having the authority to make the utterance. Thus, if a random person stands in front of two individuals expecting to marry and pronounces them lawfully wedded, the couple has not become married. If the person then walks up to a super yacht in a harbor with a bottle of champagne and declares a name for the yacht, the ship's name has not been changed. Likewise, if a stranger walks into an intensive care unit and states, "I pronounce the patient dead at 9:02 AM," that declaration is infelicitous and in no way changes the patient's legal status. In these cases, the speaker lacks the requisite authority to render the utterances effective.

15. Marco Marani et al., *Intensity and Frequency of Extreme Novel Epidemics*, 118 PROC. NAT'L ACAD. SCIS., Aug. 23, 2021, at 1–4, https://www.pnas.org/doi/10.1073/pnas.2105482118 (analyzing the rate of occurrence of significant epidemics based on a global data set of epidemics over 400 years and further considering "increasing rates of disease emergence from animal reservoirs associated with environmental change").

16. J.L. AUSTIN, HOW TO DO THINGS WITH WORDS 6 (1962).

17. *Id.*

18. *Id.* at 5.

19. *Id.*

Declarations of public health emergencies are critical performative utterances, as emergency powers[20] provide a wide range of resources,[21] from allocating grants and funding, deploying the military, waiving or modifying regulations and requirements for certain administrative agencies and social welfare programs,[22] to curtailing certain liberties and shuttering businesses if needed to protect life, property, or public health. When invoked, executive emergency powers often negate the need for legislative authorization during the span of the emergency.[23]

However, emergency declarations can also spur legislation, such as the Coronavirus Aid, Relief, and Economic Security ("CARES") Act, which was signed into law on March 27, 2020, and provided for paid sick leave, insurance coverage for COVID-19 testing, loosened telehealth restrictions, nutrition programs, and other national and global programs.[24] Moreover, such declarations can spark agency reform, such as when HHS Secretary Becerra elevated the Office of Assistant Secretary for Preparedness and Response to a standalone agency (like the FDA or CDC)—now the Administration for

20. The scope of executive powers during an emergency has been debated since (and before) our government was structured. Even the founders had different visions of the reach of executive powers during an emergency. *See* Joshua L. Friedman, *Emergency Powers of the Executive: The President's Authority When All Hell Breaks Loose*, 25 J.L. & HEALTH 265, 267, 269 (2012) (discussing John Locke and Alexander Hamilton's views on the breadth and depth of presidential emergency powers).

21. Note that there is some overlap between emergency powers and public health emergency powers, but emergency powers are generally broader than public health emergency declarations. For an excellent overview of emergency powers, see BRENNAN CTR. FOR JUST., A GUIDE TO EMERGENCY POWERS AND THEIR USE (2019), https://www.brennancenter.org/sites/default/files/2023-02/2019_09_EmergencyPowers.pdf.

22. These include but are not limited to the Food and Drug Administration ("FDA"), Centers for Disease Control ("CDC"), Health Insurance Portability and Accountability Act, Medicare, Medicaid, and the Children's Health Insurance Program ("CHIP").

23. *See* BRENNAN CTR. FOR JUST., *supra* note 21, which explains:

> Of the 136 authorities available to the president in a national emergency, 96 require nothing more than her signature on the emergency declaration. Twelve contain a de minimis restriction, such as a requirement that an agency head certify the necessity of the measure (something the president can presumably order the agency head to do). Fifteen contain a more substantive restriction, such as a requirement that the emergency relate to a particular subject matter or that it involve the use of armed forces. Only 13 require a congressional (versus presidential) declaration of emergency.

24. Kellie Moss et al., *The Coronavirus Aid, Relief, and Economic Security Act: Summary of Key Health Provisions*, KAISER FAM. FOUND. (Apr. 9, 2020), https://www.kff.org/coronavirus-covid-19/issue-brief/the-coronavirus-aid-relief-and-economic-security-act-summary-of-key-health-provisions/.

Strategic Preparedness and Response ("ASPR")[25]—to coordinate a more efficient national response with future public health emergencies.[26]

As we saw in March 2020, public health emergency declarations—those described in more detail below—are performative utterances that change our world. Such declarations favor executive branch action because the President (or Governor or Tribal Leader) is seen as the face of the response.[27] To illustrate further, after learning of the terrorist attacks of September 11, 2001, then President George W. Bush addressed both Congress and the nation, stating: "Make no mistake: The United States will hunt down and punish those responsible for these cowardly acts."[28] At the same time, the Federal Aviation Administration, an executive branch agency, took immediate action, shutting down U.S. airspace and grounding all flights.[29]

Terminations of public health emergencies are also critical performative utterances. Presume that, in non-emergency times, ordinary laws, regulations, and procedures appropriately balance government power with individual rights. It is essential, then, to have a clear understanding of when the state of the public health emergency ends so that we can return to non-emergency and (presumably) appropriately balanced laws, regulations, and

25. *HHS Strengthens Country's Preparedness for Health Emergencies, Announces Administration for Strategic Preparedness and Response (ASPR)*, U.S. DEP'T OF HEALTH & HUM. SERVS. (July 22, 2022), https://www.hhs.gov/about/news/2022/07/22/hhs-strengthens-countrys-preparedness-health-emergencies-announces-administration-for-strategic-preparedness-response.html.

26. *Id.*

27. BRENNAN CTR. FOR JUST., *supra* note 21. While it is appropriate to provide the executive branch the authority and ability to react in an emergency, note that the Brennan Center report found that at times presidential emergency powers have been used as a "pretext to deal with other problems":

> Emergency powers are being used as a pretext to deal with other problems. Presidents Obama and Trump invoked nonexistent economic crises to decrease or eliminate statutory pay increases for federal workers. (While there was arguably an economic crisis at the beginning of Obama's administration, he continued to invoke this emergency law throughout his two terms.) President Trump invoked the 9/11 state of emergency in 2017 to fill a chronic shortage in Air Force pilots.

Id. But see Friedman, *supra* note 20, at 267 ("The broad grant of executive authority in exigent circumstances is warranted. 'With no time for ex ante deliberation, and no metric for ex post assessments, the executive's capacities for swift, vigorous, and secretive action are at a premium.'" (quoting Deborah N. Pearlstein, *Form and Function in the National Security Constitution*, 41 CONN. L. REV. 1549, 1565 (2009))).

28. *9/11: The Steel of American Resolve*, NAT'L ARCHIVES, GEORGE W. BUSH PRESIDENTIAL LIB. & MUSEUM, https://www.georgewbushlibrary.gov/explore/exhibits/911-steel-american-resolve (last visited Dec. 13, 2023); *see also* Friedman, *supra* note 20, at 293 (quoting President Bush's comments, "I've ordered that the full resources of the federal government to help the victims and their families and to conduct a full-scale investigation," and noting "[t]he immediate response to the 9/11 attacks on the political, economic, and military might of the United States was necessary, both by law and by symbolic determination").

29. *A Brief History of the FAA*, U.S. DEP'T OF TRANSP., FED. AVIATION ADMIN., https://www.faa.gov/about/history/brief_history (last visited Dec. 13, 2023).

procedures. So, for example, on September 18, 2022, we heard from President Biden: "The pandemic is over."[30] The statement created quite a stir because people questioned why, if the President as the "face" of the emergency declared the pandemic over, the United States would continue with the massive spending associated with public health emergency status.[31]

Because the applicable law, however, did not provide President Biden the authority to eliminate the public health emergency declarations under Section 319 of the Public Health Services Act or Section 564 of the Food, Drug, and Cosmetic Act, the statement was not an effective performative utterance. While President Biden may have the authority to make such a performative utterance under the National Emergencies Act, because he did not follow the proper procedures under that legislation, his statement did not meet the felicity conditions for declaring an end to the public health emergency. Rather than terminating the public health emergency, the federal public health emergency continued; partisan discord continued; and Congress proposed legislation to force the public health emergency's termination.[32]

Currently, U.S. laws fail to provide consistent, clear guidance on procedures, conditions, and mechanisms for ending most public health emergency declarations. Because the stakes are so high[33] and affect the

30. On CBS's *60 Minutes* on September 18, 2022, President Biden stated: "The pandemic is over. We still have a problem with COVID. We're still doing a lotta work on it. . . . [B]ut the pandemic is over." Scott Pelley, *President Joe Biden: The 2022 60 Minutes Interview*, CBS NEWS (Sept. 18, 2022), https://www.cbsnews.com/news/president-joe-biden-60-minutes-interview-transcript-2022-09-18/.

31. *See e.g.*, Letter from Representative Tim Burchett et al., to President Joseph R. Biden (Sept. 19, 2022), https://burchett.house.gov/sites/evo-subsites/burchett.house.gov/files/evo-media-document/2022-09-19%20Letter%20to%20Biden%20to%20Terminate%20the%20COVID-19%20National%20Emergency.pdf ("Under the emergency declaration, the federal government is estimated to have spent upwards of $10 trillion, resulting in an economic crisis, record inflation, and contributing to our nearly $31 trillion national debt."); *see also* Courtney Bublé, *Biden Said the 'Pandemic Is Over.' Now Republicans Want the Administration to Act*, GOV'T EXEC. (Sept. 20, 2022) https://www.govexec.com/management/2022/09/biden-said-pandemic-over-now-republicans-wants-administration-act/377413/.

32. *Id.*; *House Passes Bills to End COVID-19 Public Health Emergency, Vaccine Mandate for Health Care Workers*, AM. HOSP. ASS'N (Feb. 1, 2023), https://www.aha.org/news/headline/2023-02-01-house-passes-bills-end-covid-19-public-health-emergency-vaccine-mandate-health-care-workers. It was not until January 30, 2023, that the White House indicated that it would follow the appropriate procedures to wind down the public health emergencies on May 11, 2023. Off. of Mgmt. & Budget, Exec. Off. of the President, Statement of Administrative Policy (Jan. 30, 2023), https://www.whitehouse.gov/wp-content/uploads/2023/01/SAP-H.R.-382-H.J.-Res.-7.pdf [hereinafter Statement of Administrative Policy]; *see infra* note 125 and accompanying text.

33. For an excellent overview of the high stakes of terminating the COVID-19 public health emergency, see generally Abbe R. Gluck & Lawrence O. Gostin, *Why the End of the Public Health Emergency Really Matters*, HEALTH AFFS. (May 11, 2023), https://www.healthaffairs.org/content/forefront/why-end-public-health-emergency-really-matters.

fundamental structure of our government,[34] we should be quite intentional in developing procedures and establishing criteria for declaring, continuing, and terminating public health emergencies. Existing policies generally favor one of two extremes: either lengthy unfettered executive public health emergency powers or enacting strict legislative limitations on executive authority.[35] Both extremes may hinder an effective public health response or create chaos in our health care systems and government operations.

Because of the stakes involved, as a first step, diverse multi-disciplinary teams of scholars and stakeholders should examine public health emergency legislation to provide input and guidance and identify potential unintended consequences—in other words, to create felicity conditions for declaring, continuing, and terminating specific public health emergencies in a manner that incorporates relevant, appropriate checks and balances.

Part I of this Article examines pertinent public health events that shaped public health emergency response to the COVID-19 pandemic. Part II provides an overview of public health emergency legislation. Part III considers the relationships between laws governing the declaration and termination of public health emergencies and makes recommendations for an initial step in the path forward.

I. SELECTED PUBLIC HEALTH EVENTS THAT SHAPED THE COVID-19 PUBLIC HEALTH EMERGENCY RESPONSE

History provides a useful framework to identify patterns that have their roots in past events.[36] Understanding some of these events and subsequent patterns may shed light on our current public health emergency structure and illuminate the path forward for making and terminating emergency public health declarations.

The idea that the government should be responsible for protecting public health[37] originated in English common law, continued throughout the

34. *See generally* Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579, 635–38 (1952) (Jackson, J., concurring) (establishing a three-pronged test for determining whether the constitutional reach of executive power is constitutionally permissible: (1) whether the President's actions were explicitly or implicitly authorized by Congress; (2) whether the President's actions were taken in a field that has been traditionally reserved for the legislative branch, and (3) whether the President's actions were inconsistent with the powers of the legislative branch). There have been well over 1,000 lawsuits filed challenging COVID-19 orders, with many of them challenging executive branch overreach. Michele Mello & Wendy Parmet, *Public Health Law After Covid-19*, 385 NEW ENG. J. MED. 1153, 1153–55 (2021); *see, e.g.*, Fabick v. Evers, 956 N.W.2d 231 (Wis. 2021) (holding that Wisconsin Governor Tony Evers unlawfully exceeded his powers by declaring multiple states of emergency through certain executive orders).

35. *See supra* Section III.B.

36. *See generally* MARTIN HALLIWELL, AMERICAN HEALTH CRISIS: ONE HUNDRED YEARS OF PANIC, PLANNING, AND POLITICS (2021).

37. James A. Tobey, *Public Health and the Police Power*, 4 N.Y.U. L. REV. 126, 126 (1927).

American colonial period, and is considered to be embodied in the federal Constitution as part of the states' police powers.[38] But public trust and the resulting deference granted to the public health emergency decision-making have waxed and waned in the United States.

This Section starts its examination in the early twentieth century, discussing some early landmark decisions and public health emergencies and noting that this era is generally marked with public support for executive and judicial measures to help combat disease. With the advent of the patient autonomy movement,[39] the discussion next examines the FDA's decision-making during the Thalidomide scare and the AIDS crisis, and how those decisions and other events affected public trust and led to some reforms in the drug approval process. Finally, this Section discusses modern public health emergency preparedness starting with the attacks of September 11, 2001, and discusses how overconfidence and a lack of public health funding and resources affected the U.S.'s ability to plan and prepare for a pandemic on the scale of COVID-19.

A. Early Twentieth-Century Public Health Emergencies (1900s–1950s)

Two cases at the turn of the twentieth century illustrate the judiciary's broad support for public health emergency orders. In *Compagnie Francaise de Navigation a Vapeur v. Louisiana State Board of Health*,[40] the U.S. Supreme Court upheld a Louisiana law that imposed an involuntary quarantine on a French merchant ship and prohibited it from docking in New Orleans. The Court deemed the state quarantine law constitutional because it was designed to prevent the transmission of infectious diseases.[41] In other words, the Court ruled that the state's declaration that changed the status of the ship met legitimate felicity conditions.

Three years later, the Court decided *Jacobson v. Massachusetts*,[42] upholding a public law that allowed boards of health to enforce vaccination requirements.[43] Specifically, in *Jacobson*, the city of Cambridge, Massachusetts, required citizens aged twenty-one and over to be vaccinated

38. *See* Gibbons v. Ogden, 22 U.S. 1, 70–72 (1824) (describing the concurrent powers of the state and federal governments); Hennington v. Georgia, 163 U.S. 299, 308–09 (1896) (describing health and quarantine laws as within the state's "reserved power to provide for the health, comfort, and safety of its people").

39. Erin C. Fuse Brown & Aaron S. Kesselheim, *The History of Health Law in the United States*, 387 NEW ENG. J. MED. 289, 290 (2022).

40. 186 U.S. 380 (1902).

41. *Id.* at 393; *see also* Christine Coughlin, *Public Health Policy: Revisiting the Need for a Compensation System for Quarantine to Maximize Compliance*, 7 WAKE FOREST J.L. & POL'Y 415, 422 (2017) (discussing the history of quarantine laws in the United States).

42. 197 U.S. 11 (1905).

43. *Id*. at 27.

for smallpox.[44] The penalty for failure to vaccinate was a five-dollar fine.[45] Jacobson refused to be vaccinated and was charged and found guilty.[46] In upholding the vaccination requirement, the *Jacobson* Court explained, "[t]here are manifold restraints to which every person is necessarily subject for the common good. . . . Society based on the rule that each one is a law unto himself would soon be confronted with disorder and anarchy."[47] The Court concluded, "[t]he authority to determine for all what ought to be done in such an emergency must have been lodged somewhere or in some body; and surely it was appropriate for the legislature to refer that question, in the first instance, to a board of health."[48] The Court thus determined that the state's declaration, which transformed Jacobson from a law-abiding citizen to a person in violation of the law and subject to a penalty, met legitimate felicity conditions.

As reflected by the *Compagnie Francaise* and *Jacobson* decisions, the early twentieth century was marked with broad support for decisions of local public health boards.[49] These cases would ultimately pave the way for public health emergency legislation at the local, state, and federal levels.[50]

44. *Id.* at 12.

45. *Id.*

46. *Id.* at 13.

47. *Id.* at 26.

48. *Id.* at 27.

49. *See, e.g.*, Blue v. Beach, 56 N.E. 89 (Ind. 1900) (upholding the power of boards of health to create and carry out all reasonable regulations, rules, and bylaws in the interest of public health, as given to them by the legislature); Viemeister v. White, 72 N.E. 97 (N.Y. 1904) (upholding the constitutionality of a law requiring vaccination for public school attendance); Abeel v. Clark, 24 P. 383 (Cal. 1890) (upholding the legislature's power to enact laws that secure and maintain the health of the state, which subject persons and property to reasonable restraints and burdens). *But see* Wong Wai v. Williamson, 103 F. 1 (N.D. Cal. 1900) (ruling health boards had the authority to pass public health measures but that public health requirements that were discriminatory should not be enforced); Jew Ho v. Williamson, 103 F. 10 (N.D. Cal. 1900) (ruling that while police powers are broad, public health laws that were discriminatory should not be enforced). For an excellent overview of the history of public health authority, see NETWORK FOR PUB. HEALTH L., PROPOSED LIMITS ON PUBLIC HEALTH AUTHORITY: DANGEROUS FOR PUBLIC HEALTH 3 (2021), https://www.networkforphl.org/wp-content/uploads/2021/06/Proposed-Limits-on-Public-Health-Authority-Dangerous-for-Public-Health-FINAL.pdf [hereinafter PROPOSED LIMITS ON PUBLIC HEALTH AUTHORITY] ("The boards of health that were established in the nineteenth and twentieth centuries were granted broad general powers, as well as more specific authorities relating to common diseases (such as tuberculosis) or interventions (such as quarantine). The breadth of their authority allowed them to respond quickly to new, potentially unforeseeable situations, while also carrying out the everyday work necessary to protect the public from unsafe conditions and significant health hazards."). *See generally* Wendy E. Parmet, *From Slaughter-House to Lochner: The Rise and Fall of the Constitutionalization of Public Health*, 40 AM. J. LEGAL HIST. 476 (1995).

50. *See* Friedman, *supra* note 20, at 298.

The influenza pandemic of 1918—responsible for approximately 675,000 deaths in the United States[51]—was also generally characterized by compliance with flu-related public health orders that contained "reasonable measures to slow the spread of disease."[52] Unlike the current pandemic, this era was marked by legislative support for public health measures, public compliance, and deference by the courts for public health measures, including the ability to regulate public gatherings.[53]

During the 1918 influenza pandemic, states began to move their public health powers from local boards to state officials, a trend that continued during the Cold War and polio outbreaks of the 1950s.[54] State governors enjoy broad emergency powers that are "sometimes more extensive than what is available under traditional public health laws."[55] Moreover, with public health measures like clean water and milk pasteurization as well as advances in drugs and vaccines,[56] "[b]y the middle of the twentieth century, noncommunicable diseases replaced infectious diseases as the leading source of death in the United States."[57]

B. The Drug Approval Process: Access, Reform, and Public Trust (1960s–1990s)

Concerning the FDA's drug approval process, the pendulum has swung back and forth between favoring public safety and favoring access and

51. *1918 Pandemic (H1N1 Virus)*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 20, 2019), https://archive.cdc.gov/#/details?url=https://www.cdc.gov/flu/pandemic-resources/1918-pandemic-h1n1.html.

52. Lindsay F. Wiley, *Democratizing the Law of Social Distancing*, 19 YALE J. HEALTH POL'Y L. & ETHICS 50, 63 (2021). This is not to say that everyone agreed and complied with public health orders. In fact, some of the same issues of non-compliance and disinformation seen in the COVID-19 pandemic, occurred in the 1918 influenza pandemic. *See* PARMET, *supra* note 6, at 44 ("In both the United States and Europe, opposition to [vaccine mandates] was fierce. . . . They . . . began to seek individual exemptions, envisioning that individuals should be able to opt out of public health laws.").

53. Wiley, *supra* note 52, at 63–64 (first citing Jason Marisam, *Local Governance and Pandemics: Lessons from the 1918 Flu*, 85 U. DET. MERCY L. REV. 347 (2008); and then citing Bradford Luckingham, *To Mask or Not to Mask: A Note on the 1918 Spanish Influenza Epidemic in Tucson*, 25 J. ARIZ. HIST., 191, 194 (1984)); *see also* Nancy Tomes, *"Destroyer and Teacher": Managing the Masses During the 1918–1919 Influenza Pandemic*, 125 PUB. HEALTH REPS. 48 (2010) (describing the social history of state and local decisions about social distancing and community hygiene in the 1918 pandemic).

54. PROPOSED LIMITS ON PUBLIC HEALTH AUTHORITY, *supra* note 49 (explaining that for this reason, "most Governors have relied in large measure on their general emergency powers during the COVID pandemic").

55. *Id.*

56. PARMET, *supra* note 6, at 59.

57. *Id.*

deregulation.[58] In 1962, during a time when health law was shifting from a professional autonomy to a patient autonomy model,[59] a drug approval case reached the public eye after an FDA medical officer refused—despite significant pressure from the manufacturer—to approve Thalidomide, a drug marketed in Europe to alleviate morning sickness in pregnant women.[60] Soon thereafter, researchers in Europe linked the drug to severe birth defects,[61] which motivated Congress to pass the Kefauver-Harris Drug Amendments of 1962 and helped usher in a more paternalistic, cautious approach to new drug approvals.[62]

In 1976, the CDC identified a strain of influenza genetically similar to the influenza strain responsible for the 1918 flu pandemic. President Gerald Ford, who was running for reelection, reportedly pressured the administration to implement a nationwide mass vaccination program.[63] The pandemic never materialized, but news reports that linked the vaccine with deaths and Guillain-Barré syndrome—even without sufficient evidence—garnered significant negative publicity.[64] CDC Director David Sensor later reflected, "[t]his public misperception, warranted or not, ensured that every coincidental health event that occurred in the wake of the swine flu shot would be scrutinized and attributed to the vaccine."[65] And arguably, medical historians can trace some early origins of today's public distrust regarding the COVID-19 vaccines and partisan public health emergency decision-

58. *See* Christine Coughlin, *Challenging the FDA's Authority Isn't New – The Agency's History Shows What's at Stake When Drug Regulation Is in Limbo*, CONVERSATION (Apr. 26, 2023, 8:28 AM), https://theconversation.com/challenging-the-fdas-authority-isnt-new-the-agencys-history-shows-whats-at-stake-when-drug-regulation-is-in-limbo-204263.

59. *See* Fuse Brown & Kesselheim, *supra* note 39.

60. *Frances Oldham Kelsey: Medical Reviewer Famous for Averting a Public Health Tragedy*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/fda-history-exhibits/frances-oldham-kelsey-medical-reviewer-famous-averting-public-health-tragedy (last updated Feb. 1, 2018).

61. Katie Thomas, *The Story of Thalidomide in the U.S., Told Through Documents*, N.Y. TIMES (Mar. 23, 2020), https://www.nytimes.com/2020/03/23/health/thalidomide-fda-documents.html; Katie Thomas, *The Unseen Survivors of Thalidomide Want to Be Heard*, N.Y. TIMES (Mar. 23, 2020), https://www.nytimes.com/2020/03/23/health/thalidomide-survivors-usa.html; Katie Thomas, *Pursuing an Untold Story of Thalidomide*, N.Y. TIMES (Mar. 23, 2020), https://www.nytimes.com/2020/03/23/reader-center/insider-thalidomide-fda.html; Katie Thomas, *Thalidomide Use Did Happen Here, These Americans Say*, N.Y. TIMES (Mar. 23, 2020), https://www.nytimes.com/2020/03/23/health/thalidomide-drug-pharmaceuticals-united-states.html.

62. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962).

63. *See* Christine Coughlin, *FDA's Accelerated Approval, Emergency Use Authorization, and Pre-Approval Access: Considerations for Use in Public Health Emergencies and Beyond*, 23 N.C. J. L. & TECH. 741, 759 (citing David J. Sencer & J. Donald Millar, *Reflections on the 1976 Swine Flu Vaccination Programs*, 12 EMERGING INFECTIOUS DISEASES 29, 30 (2006)).

64. Christopher Klein, *When the US Government Tried to Fast-Track a Flu Vaccine*, HISTORY (Sept. 2, 2020), https://www.history.com/news/swine-flu-rush-vaccine-election-year-1976.

65. Richard Fisher, *The Fiasco of the 1976 'Swine Flu Affair'*, BBC (Sept. 21, 2020), https://www.bbc.com/future/article/20200918-the-fiasco-of-the-us-swine-flu-affair-of-1976.

making to this public health fiasco.[66] The "swine flu snafu" resulted in litigation against both the government and vaccine makers, which then broadened to include other vaccines, including mandatory childhood vaccines, causing many vaccine makers to leave the market.[67] Congress ultimately responded in 1986 by passing the National Childhood Vaccine Injury Vaccine Compensation Act.[68]

The early 1980s were marked by the emergence of a mysterious disease that primarily affected gay men—the human immunodeficiency virus ("HIV") that resulted in acquired immune deficiency syndrome ("AIDS").[69] Tragically, by the end of 1986, nearly 25,000 U.S. citizens died; treatment options were limited or nonexistent.[70] During these years, state and local agencies were the focal point of the response, as federal agencies lacked sufficient resources following the Reagan administration budget cuts.[71]

AIDS patients and their advocates, however, began demanding a federal response, becoming vocal critics of the FDA and other government agencies involved in drug development.[72] The FDA is a powerful agency whose declarations change the status of drugs and devices in the United States, determining whether they are available at all and under which conditions, e.g., over-the-counter, by prescription, or only in a research study. During the AIDS crisis, critics argued that government agencies like the FDA and CDC were too paternalistic, protective, and bureaucratic—and not sufficiently focused on helping patients who were dying.[73] Unapproved drugs that could treat AIDS, like DDI, existed but were inaccessible because of policy concerns about safety and efficacy that had shifted to become too protective

66. *See id.*

67. Jonathan L. Iwry, *FDA Emergency Use Authorization From 9/11 to COVID-19: Historical Lessons and Ethical Challenges*, 76 FOOD & DRUG L.J. 337, 340–41 (2021).

68. National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 to 34; Iwry, *supra* note 67, at 341.

69. *See* Marie-Amélie George, *The Fight Against AIDS Has Shaped How Potential COVID-19 Drugs Will Reach Patients*, WASH. POST (Apr. 29, 2020), https://www.washingtonpost.com/outlook/2020/04/29/fight-against-aids-has-shaped-how-potential-covid-19-drugs-will-reach-patients/.

70. *Snapshots of an Epidemic: An HIV/AIDS Timeline*, AMFAR, https://www.amfar.org/about-hiv-aids/snapshots-of-an-epidemic-hiv-aids/ (last visited Nov. 13, 2023).

71. Steven Colbrook, *Why Pandemics Matter to the History of U.S. State Development*, 4 MOD. AM. HIST. 315, 315–16 (2021), https://www.cambridge.org/core/journals/modern-american-history/article/why-pandemics-matter-to-the-history-of-us-state-development/272739B98B24E3E458DFD744AAC4F23D.

72. EVE NICHOLS, ROUNDTABLE FOR THE DEV. OF DRUGS AND VACCINES AGAINST AIDS, EXPANDING ACCESS TO INVESTIGATIONAL THERAPIES FOR HIV INFECTION AND AIDS (1991).

73. George, *supra* note 69.

following events such as the Thalidomide scare.[74] Dying patients, they argued, should have the right to incur risks.[75]

On October 11, 1988, AIDS activists launched a massive protest at FDA headquarters, calling it, *inter alia*, the "Federal Death Administration."[76] Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, proposed a parallel track program to administer DDI to eligible patients and groups of patients.[77] President George H.W. Bush ultimately encouraged the FDA to adopt the program as part of its expanded access pathway.[78] This, along with other existing FDA mechanisms, such as Investigational New Drugs Applications ("INDs") and Expedited Development protocols,[79] helped normalize the concept of alternative pathways for approval and authorization, such as Emergency Use Authorization ("EUA").[80] In doing so, the federal government changed the felicity conditions for issuing determinations that change the status of drugs.

C. Modern Public Health Emergency Preparedness (2001–January 31, 2020)

The concept of a nationwide public health emergency, along with the recognition of the need for strong and coordinated federal and state collective responses, gained traction following the terrorist attack of September 11, 2001, and the anthrax mail attacks that occurred one week later.[81]

74. Iwry, *supra* note 67, at 343.

75. George, *supra* note 69.

76. *Police Arrest AIDS Protesters Blocking Access to FDA Office*, L.A. TIMES ARCHIVES (Oct. 11, 1988, 12:00 AM), https://www.latimes.com/archives/la-xpm-1988-10-11-mn-3909-story.html; *see* LEWIS A. GROSSMAN, CHOOSE YOUR MEDICINE: FREEDOM OF THERAPEUTIC CHOICE IN AMERICA 163 (2021).

77. *See* George, *supra* note 69.

78. For an excellent overview of the impact of the AIDS crisis on FDA policy, see Iwry, *supra* note 67, at 342–45.

79. *See* George, *supra* note 69; Coughlin, *supra* note 63, at 755.

80. As the recent debate over Adulhelm for treatment of early Alzheimer's Disease has illustrated, tensions continue to exist in finding the appropriate balance between access and safety:

> FDA works to balance the seemingly competing goals of protecting the public from unsafe treatments with increasing access to investigational treatments to support individual autonomy. Finding the appropriate balance, however, is understandably difficult, particularly given these seemingly conflicting goals. Critics argue that FDA is overly bureaucratic, stifles innovation and development, and delays access to products that may help treat patients who may not have the luxury of time; others believe FDA tries to employ a "thoughtful, savvy, and swift introduction of new medicines through the review process."

Coughlin, *supra* note 63, at 755 (first citing Benjamin N. Rome & Jerry Avorn, *Drug Evaluation During the Covid-19 Pandemic*, 382 NEW ENG. J. MED. 2282, 2283 (2020); and then quoting Peter J. Pitts, *Too Fast or Too Slow: Is the FDA Moving at the Right Speed?*, HEALTH AFFS. (Mar. 19, 2021), https://www.healthaffairs.org/content/forefront/too-fast-too-slow-fda-moving-right-speed).

81. *See infra* notes 154–155 and accompanying text.

Recognizing how antiquated and inconsistent the various state health codes had become, particularly in a time when coordination among the states and federal government was critical, the CDC proposed a model response be created.[82] The Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities, led by public health scholars Lawrence O. Gostin and James G. Hodge, collaborated to draft the Model State Emergency Health Powers Act ("MSEHPA"), which provided for state model response to issue time-limited but renewable public health orders relating to communicable disease control.[83]

Congress also passed the Project BioShield Act of 2004, providing funds to stockpile medical countermeasures and to purchase vaccines in the event of a bioterrorist attack, and granting the FDA authority to issue EUAs, subject to an emergency declaration by the HHS Secretary.[84] Because Project BioShield provided no liability protections, Congress passed the Public Readiness and Emergency Preparedness ("PREP") Act, which provided for a liability shield for medical countermeasures used in public health emergencies.[85] At the time, Congress was focused primarily on the threat of bioterrorism,[86] but the focus expanded to include disaster relief following Hurricane Katrina in August 2005.[87] Then, in 2009, EUAs were used to

82. James G. Hodge Jr. et al., *State Public Health Emergency Powers in Response to COVID-19*, 113 AM. J. PUB. HEALTH 275, 277 (2023).

83. CTR. FOR L. & THE PUB.'S HEALTH AT GEO. & JOHNS HOPKINS UNIVS., THE MODEL STATE EMERGENCY HEALTH POWERS ACT (2001), https://law.asu.edu/sites/default/files/pdf/msehpa_-_final.pdf; Wiley, *supra* note 52, at 66 (citing Laine Rutkow, *An Analysis of State Public Health Emergency Declarations*, 104 AM. J. PUB. HEALTH 1601, 1601 (2014)).

84. FRANK GOTTRON, CONG. RSCH. SERV., R43607, THE PROJECT BIOSHIELD ACT: ISSUES FOR THE 113TH CONGRESS 1 (2014).

85. Public Readiness and Emergency Preparedness Act, Pub. L. No. 109-148, 119 Stat. 2680 (2005) (codified at 42 U.S.C. § 247d-6d).

86. Michelle M. Mello & Lawrence O. Gostin, *Public Health Law Modernization 2.0: Rebalancing Public Health Powers and Individual Liberty in the Age of COVID-19*, 42 HEALTH AFFS. 318, 318 (2023). In addition to preparing for bioterrorist threats, the Bush Administration, however, enacted a National Response Plan, which addressed many different emergency scenarios, including a biological health quarantine. U.S. DEP'T OF HOMELAND SEC., NATIONAL RESPONSE PLAN (2004), https://www.hsdl.org/?view&did=450766. The Federal Emergency Management Agency ("FEMA") currently runs the National Preparedness System to "help people and communities to be more prepared by developing the capabilities needed to prevent, protect against, respond to, recover from, and mitigate against all threats and hazards. Whether we face risks related to earthquakes, cyberattacks or chemical spills, our goal is shared: safety and resilience." *See National Preparedness*, FEMA (Dec. 28, 2022), https://www.fema.gov/emergency-managers/national-preparedness; *see* Hodge et al., *supra* note 82, at 275 (discussing how the "2001 terrorist and bioterrorism attacks led to modernization of a patchwork of inconsistent and incongruous state emergency laws"). For an excellent overview of the public health framework post-9/11, see THE COVID CRISIS GRP., LESSONS FROM THE COVID WAR: AN INVESTIGATIVE REPORT 73–74 (2023).

87. Hurricane Katrina is just one example of many devastating disasters. With over 1,800 lives lost and $125 billion in damages, it led to the Post-Katrina Emergency Reform Act on Oct. 4, 2006.

successfully combat the H1N1 swine flu epidemic, opening the door wider for EUAs to be used as a tool for epidemics and pandemics.[88] Up until that point, the FDA had only authorized already approved drugs for unapproved uses; during that time, the FDA also began authorizing yet-to-be-approved drugs, such as the antiviral, Peramivir.[89]

Public interest and funding in emergency preparedness decreased with the downturn in the economy during and after the Great Recession of 2008.[90] Perhaps this was because the string of epidemics predicted in the mid-1900s never materialized, success with EUAs and other measures resulted in over-confidence, or the horrors of 9/11 simply began to fade. Despite the reason, even when significant public health vulnerabilities were exposed following Hurricane Sandy in 2012, the Ebola virus epidemic in 2014, and the Zika virus epidemic in 2015–16, a new focus on emergency preparedness did not emerge.[91] If anything, the hyper-partisan politics during the last decade made responses less efficient.[92]

As public health scholars Lawrence Gostin and Jennifer Nuzzo note, "[a]djusting for inflation, federal preparedness funding for state and local health departments decreased by nearly half between 2003 and 2021" and "[f]ederal funding for hospital preparedness decreased by nearly two-

This legislation significantly reorganized FEMA and provided it with new authority to remedy gaps in recovery policy and funding for preventative infrastructure to be rebuilt. *See, e.g.*, Kim Tyrrell, Kristen Hildreth & Shelly Oren, *The Storm That Changed Disaster Policy Forever*, NAT'L CONF. OF STATE LEGISLATURES (Apr. 14, 2022), https://www.ncsl.org/research/environment-and-natural-resources/the-storm-that-changed-disaster-policy-forever-magazine2022.aspx.

88. *See* Jonathan Iwry, *FDA Emergency Use Authorization: A Brief History from 9/11 to Covid-19*, FOOD & DRUG L. INST. (2021), https://www.fdli.org/2021/09/fda-emergency-use-authorization-a-brief-history-from-9-11-to-covid-19. In 2003, the severe acute respiratory syndrome ("SARS") outbreak occurred. The outbreak affected 8,098 people worldwide, 774 of whom died. As only eight people in the United States ever contracted the disease, each of whom had traveled to countries with outbreaks, the epidemic never fully materialized in the United States. *SARS Basics Fact Sheet*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 6, 2017), https://www.cdc.gov/sars/about/fs-sars.html. However, public health scholars considered it a wake-up call to modernize quarantine and isolation policy. *See, e.g.*, Mark A. Rothstein et al., *Quarantine and Isolation: Lessons Learned From SARS: A Report to the Centers for Disease Control and Prevention*, UNIV. OF LOUISVILLE SCH. OF MED. (2003). As seen in the pandemic response, the wake-up call did not happen as it should have.

89. Iwry, *supra* note 67, at 351; *see* Debra Birnkrant & Edward Cox, *The Emergency Use Authorization of Peramivir for Treatment of 2009 H1N1 Influenza*, 361 NEW ENG. J. MED. 2204, 2204 (2009).

90. *See* Lauren Weber, et al., *Hollowed Out Public Health System Faces More Cuts Amid Virus*, WASH. POST (Aug. 24, 2020, 3:56 PM), https://www.washingtonpost.com/health/correction-virus-outbreak-public-health-story/2020/08/24/f743fc7a-e643-11ea-bf44-0d31c85838a5_story.html.

91. *Id.*

92. *See* Coughlin, *supra* note 41, at 418–19; Christine N. Coughlin & Adam Messenlehner, *Isolationist Policies Threaten Public Health*, 107 AM. J. PUB. HEALTH, 860–61 (2017).

thirds."[93] A Kaiser Health Network and Associated Press report showed that local health department spending decreased by eighteen percent per capita between 2010 and 2020.[94] Public health agencies lost approximately 55,000 jobs[95] and did not have the resources to equip offices with new technologies to support data management, analysis, and collaboration.[96] Overall, this era is marked by overconfidence that pandemics and epidemics would not affect the United States on a large-scale basis, hyper-partisanship about the appropriate role of the government during public health emergencies, and significantly less attention paid to public health preparedness.

Given the wax and wane of public trust, along with the deference provided and preparedness of the public health system since the 1900s, U.S. public health conditions were far less than optimal to deal with a public health emergency on the scale of COVID-19 when, on January 31, 2020, HHS Secretary Azar uttered the first U.S. public health emergency declaration related to COVID-19.[97] However, for reasons described below, despite our lack of preparedness to optimally execute a large-scale public health response, Secretary Azar's statement met the felicity conditions—the criteria that had to be met for the statement to be effective or legitimate—and, therefore, could trigger public health emergency legislation, an overview of which is discussed in the next Section.

II. PUBLIC HEALTH EMERGENCY LEGISLATION: A BRIEF OVERVIEW

Throughout U.S. history, public health emergency laws have played a critical role in defining the appropriate governmental response to situations ranging from natural disasters and bioterrorist threats to pandemics and epidemics. Through the lens of the COVID-19 pandemic, this Section examines the constitutional and federal public health emergency framework, specifically, the Public Health Services Act; the National Emergencies Act of 1976; the Robert T. Stafford Disaster and Emergency Assistance Act; Emergency Use Authorization under Section 564 of the Federal Food, Drug,

93. Lawrence O. Gostin & Jennifer B. Nuzzo, *Twenty Years After the Anthrax Terrorist Attacks of 2001: Lessons Learned and Unlearned for the COVID-19 Response*, JAMA NETWORK 2009, 2010 (2021), https://jamanetwork.com/journals/jama/fullarticle/2785780.

94. Lauren Sausser, *Public Health Agencies Try to Restore Trust as They Fight Misinformation*, KFF HEALTH NEWS (Jan. 4, 2023), https://kffhealthnews.org/news/article/public-health-agencies-try-to-restore-trust-as-they-fight-misinformation/.

95. *See* Gostin & Nuzzo, *supra* note 93.

96. At the beginning of the pandemic, for example, many health departments were using antiquated fax machines to report COVID-19 case counts. This resulted in incomplete transmission of data and data being sent in unusable format. *See* Sarah Kliff & Margot Sanger-Katz, *Bottleneck for U.S. Coronavirus Response: The Fax Machine*, N.Y. TIMES (July 13, 2020), https://www.nytimes.com/2020/07/13/upshot/coronavirus-response-fax-machines.html.

97. *See infra* note 113 and accompanying text.

and Cosmetic Act; and the Public Readiness and Emergency Preparedness Act. Following an examination of these federal public health emergency laws, this Section then briefly examines the role that state public health declarations play.

Article II of the U.S. Constitution, which provides for the Executive Branch to execute and enforce laws passed by Congress, does not provide the President with general emergency powers.[98] Rather, Congress can—and usually does—provide the President broad powers to act in times of emergency.[99] Article II, Section 2 provides a framework for the President's Cabinet, which includes the Vice President, the Attorney General, and the Secretaries of the fifteen executive branch departments, including Health and Human Services, Defense, and Homeland Security.[100] Through enabling acts, Congress creates administrative agencies that are generally (but not always) housed within one of the executive branch departments. The FDA and CDC, for instance, are administrative agencies housed within HHS.[101] Congress delegated broad authority to the respective agency to enact regulations and other laws that further the administrative mission,[102] which may include the power to act in times of emergency.[103]

98. For insights concerning how some general emergency powers may be reformed, see Elizabeth Goitein, *2022 Update: Reforming Emergency Powers*, BRENNAN CTR. FOR JUST. (Feb. 2, 2022), https://www.brennancenter.org/our-work/analysis-opinion/2022-update-reforming-emergency-powers.

99. BRENNAN CTR. FOR JUST., *supra* note 21; *see also* JENNIFER K. ELSEA ET AL., CONG. RSCH. SERV., R46379, EMERGENCY AUTHORITIES UNDER THE NATIONAL EMERGENCIES ACT, STAFFORD ACT, AND PUBLIC HEALTH SERVICE ACT (2020).

100. Specifically, besides the Vice President and Attorney General, the presidential Cabinet includes Secretaries of Agriculture, Commerce, Defense, Education, Energy, Health and Human Services, Homeland Security, Housing and Urban Development, Interior, Labor, State, Transportation, Treasury, and Veterans Affairs. *The Cabinet*, WHITE HOUSE, https://www.whitehouse.gov/administration/cabinet/ (last visited Jan. 30, 2023).

101. *HHS Organizational Charts Office of Secretary and Divisions*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Aug. 17, 2023), https://www.hhs.gov/about/agencies/orgchart/index.html.

102. For an overview of administrative deference under *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984), and how the evolving Major Questions Doctrine is affecting administrative deference, see BENJAMIN BARCZEWSKI, CONG. RSCH. SERV., R44954, *CHEVRON* DEFERENCE: A PRIMER (2023). This term, however, the Supreme Court has consolidated two cases, *Loper Bright Enterprises v. Raimondo* and *Relentless, Inc. v. Department of Commerce*, and will determine whether the *Chevron* doctrine should be overruled or narrowed. *See* BENJAMIN M. BARCZEWSKI, CONG. RSCH. SERV., LSB11061, *CHEVRON* AT THE BAR: SUPREME COURT TO HEAR CHALLENGES TO *CHEVRON* DEFERENCE (2023); *see also infra* note 284 and accompanying text.

103. Administrative Procedure Act, 50 U.S.C. §§ 500–596 (governing the administrative process); *see, e.g.*, *About OSHA*, U.S. DEP'T OF LABOR, OCCUPATIONAL SAFETY & HEALTH ADMIN., https://www.osha.gov/aboutosha (last visited Nov. 11, 2023).

Concerning public health emergencies, under the Tenth Amendment to the Constitution,[104] the federal government enjoys limited public health powers, whereas state and local governments retain the primary responsibility to regulate public[105] and private health.[106] The various federal, state, and local public health emergency powers, however, work concurrently and can be declared by the federal government, any of the fifty state governments, or any of the approximately 2750 local or tribal governments.[107] To help—or perhaps complicate—matters further, the United States is one of 196 signatories that follow the WHO's recommendations during a Public Health Emergency of International Concern, or PHEIC, which was initially declared on January 30, 2020, for COVID-19.[108]

Given the ebb and flow of judicial and legislative deference to public health emergency orders, and with so many government entities having the power to issue and implement emergency orders within our fragmented

104. U.S. CONST. amend. X ("The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.").

105. And despite a lack of general awareness, public health interventions have been wildly successful for the most part. For example, in the twentieth century, life expectancy increased by sixty-two percent. *See* PROPOSED LIMITS ON PUBLIC HEALTH AUTHORITY, *supra* note 49. Infant mortality, moreover, has decreased by approximately ninety percent. *See generally* PERRI KLASS, THE BEST MEDICINE: HOW SCIENCE AND PUBLIC HEALTH GAVE CHILDREN A FUTURE (2022).

106. *Two Centuries of Law Guide Legal Approach to Modern Pandemic*, AM. BAR ASS'N (Apr. 2020), https://www.americanbar.org/news/abanews/publications/youraba/2020/youraba-april-2020/law-guides-legal-approach-to-pandemic ("In 1824, the Supreme Court drew a clear line in *Gibbons v. Ogden* between the state and federal governments when it came to regulating activities within and between states. In a unanimous ruling, then-Chief Justice John Marshall cited the 10th Amendment in saying that police powers are largely reserved to states for activities within their borders."). For an insightful overview of horizontal and vertical federalism in public health, see Nicole Huberman, *Federalism, Leadership and COVID-19: Evolving Lessons for the Public's Health*, *in* COVID-19 AND THE LAW: DISRUPTION, IMPACT AND LEGACY 153, 153–54 (I. Glenn Cohen et al. eds., 2023):

> Federalism divides power, responsibility, and capacity for health policies across multiple levels of government, most often between federal and state governments. Though federalism is the default choice for structuring health laws, often it is not a constitutionally required one. States are invited through federal laws to participate in national policies with the promise of money and regulatory guardrails but also policy flexibility. Proponents claim the vertical division of authority between governments fosters tailored policies for local populations, experimentation, and innovation. Yet divided authority also requires more coordination between government officials, which increases complexity in a public health emergency, requiring each leader to act in the right way at the right time and leaving more room for error when they do not.

107. *See* Huberman, *supra* note 106, at 154; *Directory of Local Health Departments*, NAT'L ASS'N OF CNTY. & CITY HEALTH OFFS., https://www.naccho.org/membership/lhd-directory (last visited Dec. 13, 2023).

108. *See The U.S. Government and the World Health Organization*, KAISER FAM. FOUND. (May 22, 2023), https://www.kff.org/coronavirus-covid-19/fact-sheet/the-u-s-government-and-the-world-health-organization/.

public health structure,[109] there is confusion and uncertainty about who, how, when, and for what reasons a public health emergency may be declared and may be terminated. Answers to these questions are all critically important. On one hand, premature elimination of public health emergency orders creates a risk of resource shortages, which has a disparate impact on our most vulnerable populations—who also tend to be most negatively affected by the underlying public health problem. On the other hand, extending the emergency status indefinitely can wreak budgetary havoc, lead to unrealized consumer expectations, and create separation of powers issues. Maintaining the delicate balance of when to declare and terminate public health emergencies is therefore extremely complex, and as such, requires intentional action and an understanding of how the emergency powers can and should work together given the realities of the specific public health emergency.

A. Public Health Services Act

In the United States, the first stop with public health emergency declarations on a national scale is typically under Section 319 of the Public Health Services Act ("Section 319" or "PHSA"), which acts as the backbone of the federal government's response to public health emergencies.[110] Specifically, it vests the authority with the HHS Secretary to lead the federal response through the CDC by declaring that:

- a disease or disorder presents a public health emergency; or
- that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.[111]

This declaration authorizes the HHS Secretary to respond in various ways. For example, he or she can allocate emergency authority funds to help support the government response from several sources, including but not limited to the Public Health Emergency Fund, the Infectious Disease Response Reserve Fund, the Public Health and Social Services Emergency Fund, the CDC Foundation Emergency Response Fund, and the Project BioShield Special Reserve Fund. The Secretary can also assist the states in coordinating federal, state, local, public, and private responses; maintain the Strategic National Stockpile; and conduct research and surveillance to help prevent "the introduction, transmission, and spread of communicable diseases from foreign countries into the [United] States," among other actions.[112]

109. Mark A. Rothstein, *Flattening the Curve, Then What?*, HASTINGS CTR. (Mar. 23, 2020), https://www.thehastingscenter.org/flattening-the-curve-then-what/.

110. 42 U.S.C. §§ 201–91(n).

111. *Id.* § 247d(a).

112. *Id.* § 264.

On January 31, 2020, then HHS Secretary Alex Azar declared COVID-19 to be a public health emergency under Section 319 of the PHSA.[113] That declaration provided authority for the United States to issue federal quarantines for citizens evacuated from Wuhan, China, and other high-risk areas.[114] On March 6, 2020, Congress then passed the Coronavirus Preparedness and Response Supplemental Appropriations Act, which provided Secretary Azar further authority to authorize broad telehealth services waivers following the Section 319 PHSA declaration,[115] enabling approximately 28 million Medicare beneficiaries[116] the ability to use telehealth services during the first year of the pandemic.[117]

On March 18, 2020, Congress passed the Families First Coronavirus Response Act,[118] allocating approximately $104 billion in funding, requiring private insurance and Medicare to cover testing, expanding unemployment insurance, and providing for paid sick leave. To complete the trifecta, on March 27, Congress passed the CARES Act,[119] one of the most expensive funding bills in history, which provided compensation checks for most Americans and established the Paycheck Protection Program ("PPP").[120]

113. *See Determination that a Public Health Emergency Exists*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Jan. 31, 2020), https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx ("As a result of confirmed cases of 2019 Novel Coronavirus (2019-nCoV), on this date and after consultation with public health officials as necessary, I, Alex M. Azar II, Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby determine that a public health emergency exists and has existed since January 27, 2020, nationwide.").

114. 42 U.S.C. § 247d-6d.

115. *See* H.R. 6074, 116th Cong. (2020). In addition to providing $8.3 billion in funding for combatting the pandemic, the legislation was unique in that it simplified the process of providing the HHS Secretary with waiver authority under Section 1135 of the Social Security Administration Act. Previously, the Section 319 public health emergency declaration needed to be made in conjunction with a declaration under either the National Emergencies Act of 1976 or the Robert T. Stafford Disaster and Emergency Assistance Act. This legislation provided Section 1135 waiver authority without a corresponding declaration. *See id.*

116. OFF. OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUM. SERVS., TELEHEALTH WAS CRITICAL FOR PROVIDING SERVICES TO MEDICARE BENEFICIARIES DURING THE FIRST YEAR OF THE COVID-19 PANDEMIC (2022), https://oig.hhs.gov/oei/reports/OEI-02-20-00520.pdf.

117. Juliette Cubanski et al., *What Happens When COVID-19 Emergency Declarations End? Implications for Coverage, Costs, and Access*, KAISER FAM. FOUND. (Jan. 31, 2023), https://www.kff.org/coronavirus-covid-19/issue-brief/what-happens-when-covid-19-emergency-declarations-end-implications-for-coverage-costs-and-access/.

118. Pub. L. No. 116-127, 134 Stat. 178 (2020).

119. Pub. L. No. 116-136, 134 Stat. 281 (2020).

120. The PPP was supposed to provide small businesses with government loans during the shutdown to keep their employees employed and paid. Many stories and investigations, however, uncovered issues with the implementation of the legislation, such as loans going to large, lucrative corporations or employers pocketing the funds. *See generally Twenty-Two Charged in Connection with a More Than $11-Million Paycheck Protection Program Fraud Scheme*, U.S. DEP'T OF JUST. OFF. OF PUB. AFFS., (July 22, 2021), https://www.justice.gov/opa/pr/twenty-two-charged-connection-more-11-million-paycheck-protection-program-fraud-scheme; Paycheck Protection

A Section 319 public health emergency[121] declaration is limited in time and must be renewed every ninety days,[122] which happened for thirteen cycles.[123] Amid political pressure from Republicans in Congress who proposed H.R. 382[124] to immediately terminate the Section 319 public health emergency, on January 30, 2023, President Biden announced his plans for a "wind-down" of the public health emergency to officially end on May 11, 2023.[125] In doing so, the Biden administration set out its concerns about abruptly ending the public health emergency as contemplated by H.R. 382, stating that such an action "would create wide-ranging chaos and uncertainty throughout the health care system—for states, for hospitals and doctors' offices, and, most importantly, for tens of millions of Americans."[126]

Program Flexibility Act, Pub. L. No. 116-142, 134 Stat. 641 (2020) (amending the CARES Act to modify some provisions regarding loan forgiveness and enable recipients to defer payroll taxes).

121. In 2021, the National Academies of Science assessed the CDC's response under Section 319 in the following categories: (1) testing, detaining, and releasing individuals who were suspected communicable disease carriers; (2) issuing federal isolation and quarantine orders; and (3) restricting animals and other items from importation that may pose public health risks. It found that the CDC's actions were many times challenged or even blocked by courts that determined that the CDC's actions should be limited to the activities listed in Section 319. The National Academies' report also noted a lack of sufficient large-scale funding methods. As a result, the National Academies recommended that Congress modernize and improve Section 319. NAT'L ACADS. OF SCIS., ENG'G, & MED., IMPROVING THE CDC QUARANTINE STATION NETWORK'S RESPONSE TO EMERGING THREATS 171–206 (2022); *see* Mello & Gostin, *supra* note 86, at 318, 320, 322–26 (setting out proposals to modernize emergency powers and noting that the "National Academies committee made sensible, balanced recommendations for modernizing this act, which Congress should consider adopting").

122. 42 U.S.C. § 247d(a).

123. *Renewal of a Determination that a Public Health Emergency Exists*, U.S. DEP'T OF HEALTH & HUM. SERVS., ADMIN. FOR STRATEGIC PREPAREDNESS & RESPONSE (Oct. 13, 2022), https://aspr.hhs.gov/legal/PHE/Pages/covid19-13Oct2022.aspx.

124. The Pandemic Is Over Act, H.R. 382, 118th Cong. (2023).

125. Statement of Administration Policy, *supra* note 32.

126. *Id.* The Statement of Administration Policy goes on to state:

> During the PHE, the Medicaid program has operated under special rules to provide extra funding to states to ensure that tens of millions of vulnerable Americans kept their Medicaid coverage during a global pandemic. In December, Congress enacted an orderly wind-down of these rules to ensure that patients did not lose access to care unpredictably and that state budgets don't face a radical cliff. If the PHE were suddenly terminated, it would sow confusion and chaos into this critical wind-down. Due to this uncertainty, tens of millions of Americans could be at risk of abruptly losing their health insurance, and states could be at risk of losing billions of dollars in funding. Additionally, hospitals and nursing homes that have relied on flexibilities enabled by the emergency declarations will be plunged into chaos without adequate time to retrain staff and establish new billing processes, likely leading to disruptions in care and payment delays, and many facilities around the country will experience revenue losses. Finally, millions of patients, including many of our nation's veterans, who rely on telehealth would suddenly be unable to access critical clinical services and medications. The most acutely impacted would be individuals with behavioral health needs and rural patients.

B. National Emergencies Act of 1976

Congressional investigations in the 1970s concerning the use of emergency war powers, particularly as they related to the Vietnam conflict, led to a concern about unfettered executive emergency power generally.[127] On September 14, 1976, then President Gerald R. Ford signed the National Emergencies Act of 1976 to "reform the maze of statutes which [had] resulted from the states of emergency under which the country [had] been operating for over 40 years and to provide appropriate procedures related to future declarations of national emergencies."[128] This act applied to all national states of emergency (not limited to public health emergencies) and provides a framework for the President to invoke one or more of approximately 123 legislatively created emergency authorizations,[129] along with mechanisms for some Congressional oversight, including enabling a joint resolution to terminate the emergency, along with reporting requirements.[130]

On March 13, 2020, then President Trump issued Proclamation 9994[131]—an emergency declaration under the National Emergencies Act.[132] Because Proclamation 9994 was made in conjunction with a Section 319 public health emergency declaration, Secretary Azar was granted additional authority under Section 1135 of the Social Security Administration Act[133] to waive or modify requirements within Medicare, Medicaid, CHIP, and HIPAA during the public health emergency,[134] and for the waivers to be retroactively applied to March 1, 2020.

Since that time, additional emergency orders, such as placing the military on ready reserve, have been issued under the National Emergencies

127. ELISABETH M. WEBSTER, CONG. RSCH. SERV. 98-505, NATIONAL EMERGENCY POWERS 7 (2021).

128. *Statement on Signing the National Emergencies Act*, NAT'L PRESIDENCY PROJECT, (Sept. 14, 1976), https://www.presidency.ucsb.edu/documents/statement-signing-the-national-emergencies-act (statement of President Gerald R. Ford).

129. ERICA A. LEE ET AL., CONG. RSCH. SERV., R46809, FEDERAL EMERGENCY AND MAJOR DISASTER DECLARATIONS FOR THE COVID-19 PANDEMIC 11 (2021).

130. MICHAEL GREEN, CONG. RSCH. SERV., R46567, NATIONAL EMERGENCIES ACT: EXPEDITED PROCEDURES IN THE HOUSE AND SENATE (2023).

131. Proclamation No. 9994, 85 Fed. Reg. 15337 (Mar. 13, 2020).

132. *See* 50 U.S.C. §§ 1601 *et seq*.

133. 42 U.S.C. § 1320b-5.

134. *See HHS Legal Authorities Related to Disasters and Emergencies*, U.S. DEP'T OF HEALTH & HUM. SERVS., ADMIN. FOR STRATEGIC PREPAREDNESS & RESPONSE (June 16, 2021), https://www.phe.gov/Preparedness/planning/authority/Pages/default.aspx (explaining that when the President declares an emergency under the National Emergencies Act or the Stafford Act, the HHS Secretary may waive or modify requirements under Medicare, Medicaid, CHIP or HIPAA to help meet the needs of those enrolled in Social Security Act ("SSA") programs under Section 1135 of the SSA).

Act declaration by both the Trump and Biden administrations via Executive Order or Memorandum.[135] In addition, under legislation connected to the National Emergencies Act declaration, Congress enacted legislation with provisions "related to banking and finance, the federal budget, criminal justice, defense, defense procurement, income security, intellectual property, small businesses, transportation, and veterans affairs."[136]

A National Emergencies Act declaration remains effective until terminated by the President or by a joint resolution of Congress if the President issues a continuation notice of the national emergency each year.[137] On April 10, 2023, President Biden signed H.J. Res. 7, which terminated the declaration.[138]

C. Robert T. Stafford Disaster and Emergency Assistance Act

The President may also issue[139] either a major disaster or emergency[140] declaration under the Robert T. Stafford Disaster and Emergency Assistance Act ("Stafford Act")[141] to supplement state emergency or disaster efforts by enabling federal assistance to be directed toward the state.[142] A Stafford Act declaration allows federal agencies to provide funds through the Disaster Relief Fund, as well as other support, directly to the states.[143] While historically used for major disasters, such as Hurricane Katrina,[144] a Stafford Act declaration was previously used for public health emergencies in

135. *See, e.g.*, Exec. Order No. 13,912, 85 Fed. Reg. 18407 (Mar. 27, 2020) (ordering military Ready Reserve through Department of Defense and Coast Guard).

136. *See* ELIZABETH M. WEBSTER ET AL., CONG. RSCH. SERV., IN12088, EFFECTS OF TERMINATING THE CORONAVIRUS DISEASE 2019 (COVID-19) PHE AND NEA DECLARATIONS 1, 3 (2023).

137. 50 U.S.C. § 1622(a), (d).

138. *Bill Signed: H.J. Res. 7*, WHITE HOUSE (Apr. 10, 2023), https://www.whitehouse.gov/briefing-room/legislation/2023/04/10/bill-signed-h-j-res-7/.

139. 44 C.F.R. § 206(B).

140. The Stafford Act defines "emergency" as "any occasion or instance for which, in the determination of the President, Federal assistance is needed to supplement State and local efforts and capabilities to save lives and to protect property and public health and safety, or to lessen or avert the threat of a catastrophe in any part of the United States." *See* 42 U.S.C. § 5122(1).

141. 42 U.S.C. § 5121 *et seq.*

142. The assistance can be either public assistance, through the Federal Emergency Management Association to do things such as repair and replace facilities, or individual assistance to individuals and households. *See How a Disaster Gets Declared*, FEMA (Apr. 25, 2023), https://www.fema.gov/disaster/how-declared.

143. KEITH BEA, CONG. RSCH. SERV., RL33053, FEDERAL STAFFORD ACT DISASTER ASSISTANCE: PRESIDENTIAL DECLARATIONS, ELIGIBLE ACTIVITIES, AND FUNDING (2006).

144. *See generally id.*

situations such as the outbreak of the mosquito-borne West Nile virus[145] and the water contamination in Flint, Michigan.[146]

While, generally, governors must make a request to the President for a Stafford Act declaration, the President can unilaterally act where the emergency involves the primary responsibility of the federal government.[147] To that end, on March 13, 2020, President Trump issued the first nationwide Stafford Act emergency declaration.[148] He subsequently issued additional major disaster declarations for all fifty states, plus the District of Columbia, to enable support with vaccination, emergency medical care, shelter, food distribution, and mobilization of the National Guard.[149]

Instead of a termination or expiration date, Stafford Act declarations, and the response and recovery systems the declaration provides, last for the duration of an incident period.[150] On February 9, 2023, the Federal Emergency Management Association ("FEMA") Administrator announced that the incident periods for all emergency and major disasters declared under the Stafford Act would close on May 11, 2023.[151] The COVID-19 pandemic incident period of 3.5 years marks the longest in the agency's history.[152]

D. Emergency Use Authorization under Section 564 of the Federal Food, Drug, and Cosmetic Act

For investigational drugs, under Section 564 of the Federal Food, Drug, and Cosmetic Act,[153] the FDA can authorize the distribution or sale of yet

145. *See* ERICA A. LEE & BRUCE R. LINDSAY, CONG. RSCH. SERV., IN11229, STAFFORD ACT ASSISTANCE FOR PUBLIC HEALTH INCIDENTS 3 (2021) (describing that on October 11, 2000, and November 12, 2000, President Bill Clinton issued Stafford Act declarations in New Jersey and New York, respectively, to supplement state efforts to reduce the threat of West Nile virus, including mosquito abatement efforts).

146. *Id.* (discussing that on January 16, 2016, President Barack Obama issued an emergency declaration under the Stafford Act for the state of Michigan due to the Flint water crisis which aided with water supplies, water filtration systems, testing kits, etc.).

147. *See How a Disaster Gets Declared*, *supra* note 142.

148. *COVID-19 Emergency Declaration*, FEMA (Mar. 14, 2020), https://www.fema.gov/press-release/20210318/covid-19-emergency-declaration.

149. *See* LEE & LINDSAY, *supra* note 145.

150. The incident period is the "time interval during which the disaster-causing incident occurs." 44 C.F.R. § 206.32(f); *see also* ERICA A. LEE, ELIZABETH M. WEBSTER & DIANE P. HORN, CONG. RSCH. SERV., IN12106, CLOSING THE INCIDENT PERIOD FOR THE STAFFORD ACT DECLARATION FOR THE COVID-19 PANDEMIC 1 (2023).

151. Since March 2020, there were Stafford Act declarations for every state, every territory, and many tribes, with financial assistance estimated at over $100 billion. LEE ET AL., *supra* note 150, at 1.

152. ELIZABETH M. WEBSTER, ERICA A. LEE & WILLIAM L. PAINTER, CONG. RSCH. SERV., R46326, STAFFORD ACT DECLARATIONS FOR COVID-19 FAQ (2020); *see also* 44 C.F.R. § 206.32.

153. 21 U.S.C. § 360bbb-3. Commonly referred to as Section 564, this legislation was first amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 ("PAHPA"). That amendment eliminated the need for a concurrent emergency declaration under Section 319,

unapproved medical treatments and products responsive to public health emergency conditions under an EUA. As discussed earlier, after September 11, 2001, and the anthrax attacks that followed, Congress enacted Project BioShield of 2004,[154] which provided for emergency use authority to encourage rapid "development of new technologies directed to the crisis at hand."[155] This reasoning is consistent with the FDA philosophy post-AIDS crisis, which dictates that certain investigational treatments should be provided to sick and dying patients based on the best evidence available at that time, particularly during an epidemic or pandemic. The FDA made a similar policy choice to craft alternative pathways when it enacted accelerated approval and pre-approval access to investigational drugs following patient protests during the AIDS epidemic.[156]

To trigger the use of EUAs, one of the following conditions must be present:

- The Secretary of Defense determines that a military emergency or significant potential for a military emergency exists;
- the Secretary of Homeland Security determines that a domestic emergency or significant potential for domestic emergency or material threat determination exists; or
- the HHS Secretary determines that a public health emergency or significant potential for a public health emergency exists.[157]

The HHS Secretary next determines that circumstances exist justifying the EUA.[158] Then, the HHS Secretary specifies that unapproved medical

which was previously required to make a public health emergency declaration under Section 564, and it replaced the declaration's one-year limitation for a EUA with a set of conditions. Pub. L. No. 113-5, 127 Stat. 161 (2013); *see Public Health Emergency Determinations to Support an Emergency Use Authorization*, U.S. DEP'T OF HEALTH & HUM. SERVS., ADMIN. FOR STRATEGIC PREPAREDNESS & RESPONSE, https://aspr.hhs.gov/legal/Section564/Pages/default.aspx (last visited Nov. 12, 2023). PAHPA was later amended by the Pandemic and All-Hazards Preparedness and Advancing Innovation Act ("PAHPAI"), which is up for reauthorization in 2023. Pub. L. No. 116-22, 133 Stat. 905 (2019); *see Pandemic and All-Hazards Preparedness and Advancing Innovation Act ("PAHPAIA")*, U.S. DEP'T OF HEALTH & HUM. SERVS., ADMIN. FOR STRATEGIC PREPAREDNESS & RESPONSE, https://aspr.hhs.gov/legal/pahpa/Pages/pahpaia.aspx (last visited Nov. 12, 2023); *see also* Adrianna Evans, *State, Territorial Health Policies Strengthening Emergency Preparedness Efforts*, ASSOC. OF STATE & TERRITORIAL HEALTH OFFS. (Sept. 22, 2022), https://www.astho.org/communications/blog/state-territorial-health-policies-strengthening-emergency-preparedness-efforts/.

154. *See supra* 84 and accompanying text. PAHPAI, passed on June 24, 2019, amended the Public Health Service Act, enhanced HHS authority, authorized the use of the Public Health Emergency Fund, and advance funding for buying medical countermeasures under the Project BioShield Act. It also amended the Food, Drug, and Cosmetic Act to provide better support for the FDA's rapid response to health emergencies. Pub. L. 116-22, 133 Stat. 905.

155. Jacob S. Sherkow, *Regulatory Sandboxes and the Public Health*, 2022 U. ILL. L. REV. 357, 361 (2022).

156. *See* George, *supra* note 69.

157. 21 U.S.C. § 360bbb-3(b)(1)(A) to (C).

158. 21 U.S.C. § 360bbb-3(b)(1)(C).

products that may be effective in diagnosing or treating the threat should be made available to patients.[159] Consistent with prior practice, at this point, the HHS Secretary delegates EUA authority to the FDA Commissioner to analyze the "totality of scientific evidence"[160] submitted by a manufacturer or sponsor for new medical countermeasures to determine whether:

- it is reasonable to believe that the product "may be effective";
- the known and potential benefits of authorization outweigh the known and potential risks; and
- there are no formally approved alternatives available.[161]

Where all three conditions are satisfied, the FDA can authorize the product to be used and sold in the marketplace. In addition, the FDA may issue EUAs for unapproved uses of already-approved products.[162] This authorization remains in place until the emergency status is ended, at which point the FDA has the discretion to immediately end the EUAs for specific medical products and require any product stock to be discarded or subjected to a grace period.[163]

After an EUA is issued, product sponsors must report data generated from its use in the real world.[164] Sometimes this data provides support for sponsors to move forward and obtain full FDA approval, as occurred with Remdesivir, along with the Pfizer and Moderna-Bio N Tech vaccines.[165] Other times, the new data show the product is either unsafe or ineffective, as with the use of hydroxychloroquine phosphate and chloroquine phosphate early on in the COVID-19 pandemic.[166] That authorization was rescinded seventy-eight days after issuance when data showed the drugs could cause cardiac issues,[167] and it was neither an effective treatment nor post-exposure

159. *See Emergency Use Authorization*, U.S. FOOD & DRUG ADMIN. (June 15, 2023), https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

160. Sherkow, *supra* note 155, at 375 (quoting 21 U.S.C. § 360bbb-3(c)(2)).

161. *Id.* at 374 (quoting 21 U.S.C. § 360bbb-3(c)(2)(A)).

162. 21 U.S.C. § 360bbb-3.

163. U.S. FOOD & DRUG ADMIN, TRANSITION PLAN FOR MEDICAL DEVICES ISSUED EMERGENCY USE AUTHORIZATIONS (EUAS) RELATED TO CORONAVIRUS DISEASE 2019 (COVID-19): GUIDANCE FOR INDUSTRY, OTHER STAKEHOLDERS, AND FOOD AND DRUG ADMINISTRATION STAFF (2023), https://www.fda.gov/media/155039/download.

164. 21 U.S.C. § 360bbb-3(e)(1)(A)(iii) to (iv).

165. *Id.* § 360bbb-3(c)(2); *see, e.g.*, Carrie MacMillan, *Emergency Use Authorization Vs. Full FDA Approval: What's the Difference?* YALE MED. (Mar. 7, 2022), https://www.yalemedicine.org/news/what-does-eua-mean.

166. *See, e.g.*, Matthew Herper, *FDA Warns Against Widespread Use of Hydroxychloroquine, Drug Touted by Trump*, STAT (Apr. 24, 2020), https://www.statnews.com/2020/04/24/fda-warns-against-widespread-use-of-hydroxychloroquine-drug-touted-by-trump/.

167. *Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine*, U.S. FOOD & DRUG ADMIN. (June 15, 2020),

prophylactic.[168] To date, at least seventeen product EUAs for COVID-19 have been revoked, primarily due to problems with safety or effectiveness.[169]

Before the pandemic, the FDA implemented a modest number of EUAs for the following emergencies: Anthrax (two categories issued); H1N1 Pandemic Influenza (four categories issued); Zika (six categories issued); Ebola (four categories issued); MERS (two categories issued); Enterovirus (one category issued); and Avian Influenza H7N9 (three categories issued).[170] Other than the 2008 EUA issued to authorize the use of antibiotic emergency kits containing doxycycline hyclate tables for anthrax exposure, which was reauthorized in 2016 and remains in effect today,[171] pre-pandemic EUAs were usually terminated by the HHS Secretary promptly, typically because the feared pandemic or epidemic failed to materialize.[172]

For the COVID-19 pandemic, HHS Secretary Azar declared a public health emergency on January 31, 2020, and subsequently declared that the COVID-19 pandemic justified the authorization of EUAs on February 4, 2020.[173] Since those declarations, the FDA has issued well over 600 EUAs—significantly more than in all the prior public health emergencies combined.[174] There were perceived partisan pressures[175] surrounding the

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and.

168. David R. Boulware et al., *A Randomized Trial of Hydroxychloroquine as Postexposure Prophylaxis for Covid-19*, 383 NEW ENG. J. MED. 517, 522 (2020).

169. Itay Moshkovits & Daniel Shepshelovich, *Emergency Use Authorizations of COVID-19-Related Medical Products*, 182 JAMA INTERNAL MED. 228, 229 (2021), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2787205.

170. *FAQs: What Happens to EUAs When a Public Health Emergency Ends?*, U.S. FOOD & DRUG ADMIN (May 12, 2023), https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/faqs-what-happens-euas-when-public-health-emergency-ends/ [hereinafter *FDA FAQ*].

171. Authorization of Emergency Use of Doxycycline Hyclate Tablet Emergency Kits for Eligible United States Postal Service Participants in the Cities Readiness Initiative and Their Household Members; Availability, 73 Fed. Reg. 62507 (Oct. 21, 2008). The FDA further issued subsequent orders replacing this, such as the Doxycycline Emergency Dispensing Order in April 2016 to permit emergency dispensing of FDA-approved oral dosage forms of doxycycline products for the post-exposure prophylaxis of inhalational anthrax during an emergency.

172. *See generally Emergency Use Authorization – Archived Information*, U.S. FOOD & DRUG ADMIN. (June 14, 2023), https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information. *See also* David S. Jones, *History in a Crisis — Lessons for Covid-19*, 382 NEW ENG. J. MED. 1681–83 (Apr. 30, 2020), https://www.nejm.org/doi/full/10.1056/NEJMp2004361.

173. Determination of a Public Health Emergency, 85 Fed. Reg. 7316 (Feb. 7, 2020).

174. *Emergency Use Authorization*, U.S. FOOD & DRUG ADMIN. (June 15, 2023), https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#prepact.

175. *See* Aris Angelis & Jonathan Darrow, *Safeguarding Evidence-Based Decision Making in the FDA for COVID-19*, 39 VACCINE 2328, 2328 (2021) (discussing the "understanding and fear that FDA decision-making was yielding to political pressure," and subsequent steps to combat this

EUA process which, at least in the context of the Pfizer and Moderna vaccines, resulted in dire public health consequences[176] and public distrust of the EUA process.

Although the Section 319 PHSA, the National Emergencies Act, and the Stafford Act declarations have all been terminated, the public health emergency or public health threat declaration under Section 564 of the Food, Drug, and Cosmetic Act remains ongoing.[177] Effective March 15, 2023, HHS Secretary Becerra amended the initial determination of February 4, 2020, and stated that "COVID-19, a disease attributable to SARS-CoV-2, continues to present a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad."[178]

E. Public Readiness and Emergency Preparedness Act

Relatedly, the PREP Act[179] provides immunity from liability to the government, manufacturers or sponsors, program planners,[180] and other qualified persons[181] if subject to a liability claim for a loss[182] due to the administration or use of a covered medical countermeasure, such as one

including that "the biopharmaceutical industry took an unprecedented pledge to 'stand with science' and senior FDA officials committed to protect the agency's science-based decisions from political interference").

176. *The Changing Political Geography of COVID-19 Over the Last Two Years*, PEW RSCH. CTR. (Mar. 3, 2022), https://www.pewresearch.org/politics/2022/03/03/the-changing-political-geography-of-covid-19-over-the-last-two-years/.

177. COVID-19 Emergency Use Authorization Declaration, 88 Fed. Reg. 16644, 16644–45 (Mar. 20, 2023); *see also FDA FAQ*, *supra* note 170.

178. *See* COVID-19 Emergency Use Authorization Declaration, 88 Fed. Reg. at 16644–45.

179. 42 U.S.C.§ 247d-6d.

180. KEVIN J. HICKEY, CONG. RSCH. SERV., LSB10443, THE PREP ACT AND COVID-19, PART 1: STATUTORY AUTHORITY TO LIMIT LIABILITY FOR MEDICAL COUNTERMEASURES 1–2 (2022) [hereinafter PREP ACT AND COVID-19, PART 1] ("*Program planners* include Indian Tribes, state governments, and local governments who supervise programs that dispense, distribute, or administer covered countermeasures, or provide policy guidance, facilities, and scientific advice on the administration or use of such countermeasures.").

181. "*Qualified persons* include licensed health professionals and other individuals authorized to prescribe, administer, or dispense covered countermeasures under state law, as well as other categories of persons identified by the Secretary in a PREP ACT declaration. Employees and agents of all these persons and entities are also covered persons." *See id.* at 2.

182. All claims for loss include claims both under federal and state law. A "claim for loss" is defined as an event that has "a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use" of "a covered countermeasure." 42 U.S.C. § 247d-6d(a). Loss is defined as "any type of loss" including "(i) death, (ii) physical, mental, or emotional injury, illness, disability, or condition," (iii) fear of any such injury, including medical monitoring costs, and "(iv) loss of or damage to property, including business interruption loss." *Id.* § 247d-6d(a)(2)(A)(i) to (iv).

authorized through an EUA. The PREP Act specifies the following four types of covered countermeasures:

- a qualified "pandemic or epidemic product";[183]
- a "security countermeasure";[184]
- a "drug . . . , biological product . . . , or device" authorized by the FDA under an EUA;[185] and
- a "respiratory protective device."[186]

When enacting the PREP Act, Congress determined that providing immunity from liability for medical countermeasures during a public health emergency "was necessary to ensure that potentially life-saving countermeasures will be efficiently developed, deployed, and administered."[187] To help individuals injured by the administration or use of medical countermeasures, however, the PREP Act provides an opportunity to seek compensation through the Countermeasures Injury Compensation Program ("CICP"), which provides reimbursement for reasonable medical and other types of expenses.[188] For these reasons, there is a two-fold process to invoke the PREP Act:

183. 42 U.S.C. § 247d-6d(h)(i)(1)(A). A pandemic or epidemic product includes any medical countermeasure approved or authorized by the FDA used to "'diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic'" or used to "'limit the harm such pandemic or epidemic might otherwise cause.'" *See* PREP ACT AND COVID-19, PART 1, *supra* note 180 (quoting 42 U.S.C. § 247d-6d(h)(i)(7)(1)(A)(i)(I) to (II)).

184. 42 U.S.C. § 247d-6d(i)(1)(B); *see* KEVIN J. HICKEY, CONG. RSCH. SERV., LSB10730, THE PREP ACT AND COVID-19, PART 2: THE PREP ACT DECLARATION FOR COVID-19 COUNTERMEASURES 2 (2023) [hereinafter PREP ACT AND COVID-19, PART 2]. A security countermeasure includes any medical countermeasure used to "diagnose, mitigate, prevent, or treat harm from any biological agent (including organisms that cause an infectious disease) or toxin, chemical, radiological or nuclear agent" identified by the Secretary of Homeland Security as a material threat to national security. 42 U.S.C. § 247d-6a(a)(2)(A)(i); *see also* PREP ACT AND COVID-19, PART 1, *supra* note 180.

185. 42 U.S.C. § 247d-6d(i)(1)(C).

186. *Id.* § 247d-6d(i)(1)(D); *see* Families First Coronavirus Response Act, Pub. L. No. 116-127, 134 Stat. 178 (2020); Coronavirus Response Act, Pub. L. No. 116-127, § 6005 (2020); CARES Act, Pub. L. No. 116-136, 134 Stat. 281 (2020); *see also* PREP ACT AND COVID-19, PART 1, *supra* note 180.

187. *See* PREP ACT AND COVID-19, PART 1, *supra* note 180, at 1. The PREP Act does have a singular exception for willful misconduct where the covered person acted "(i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; *and* (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit." *Id.* at 3. Public health law scholars James G. Hodge and Jennifer Piatt in their article *COVID's Counterpunch: State Legislative Assaults on Public Health Emergency Powers* hold out the PREP Act as a "preeminent example of federal preemptive prowess." 36 BYU J. PUB. L. 31, 43 (2022). The scholars note that a PREP Act declaration "preempt[s] contravening state-level actions related to health care licensures, medical countermeasures, and liability protections" for the length of the federal public health emergency declaration. *Id.* at 43–44.

188. *See* 42 U.S.C.§ 247d-6e. Funding for the CICP comes through the CARES Act and the Coronavirus Preparedness and Response Supplemental Appropriations Act. *See also National Vaccine Injury Compensation Program*, HEALTH RES. & SERVS. ADMIN. (Nov. 2023),

- The HHS Secretary must first find that a public health emergency or credible threat of a public health emergency exists; and
- the HHS Secretary must analyze "the desirability of encouraging the design, development, testing, manufacture, and use of countermeasures in determining whether to issue a PREP Act declaration."[189]

On March 10, 2020, HHS Secretary Azar made a PREP Act declaration.[190] PREP Act emergency declarations include a set end date, which in this case was estimated to be October 1, 2024.[191] However, on May 11, 2023, Secretary Xavier Becerra amended that date[192] and the current periods for liability immunity under the PREP Act depend on the type of countermeasure, along with its mode of distribution and administration.[193] Thus, while some liability protections ended with the Section 319 public health emergency termination, others continue to apply to the emergency declarations to which they are attached (such as an EUA) or the December 31, 2024 date, whichever comes first.[194]

F. State Emergency Declarations

The states (including tribal governments and territorial entities), and localities within the state, enjoy police powers that enable certain public officials to declare an "emergency."[195] Authorization for these declarations occurs via legislation, regulation, state executive orders, and emergency

https://www.hrsa.gov/vaccine-compensation (providing compensation for injuries caused by most vaccines routinely administered in the US, such as the MMR, polio, and hepatitis A vaccines); PREP ACT AND COVID-19, PART 1, *supra* note 180, at 1.

189. PREP ACT AND COVID-19, Part 1, supra note 180, at 2; *see* 42 U.S.C.§ 247d-6d.

190. Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19, 85 Fed. Reg. 15198, 15202 (Mar. 17, 2020); *see also* U.S. DEP'T OF HEALTH & HUM. SERVS., ADVISORY OPINION ON THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT AND THE MARCH 10, 2020 DECLARATION UNDER THE ACT APRIL 17, 2020, AS MODIFIED ON MAY 19, 2020 (2020), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc_0.pdf.

191. Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19, 85 Fed. Reg. at 15202.

192. Eleventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 88 Fed. Reg. 30769 (May 11, 2023).

193. *Id.*

194. *See* PREP ACT AND COVID-19, PART 2, *supra* note 184; *see also* James G. Hodge, *"*Out Like a Lion:" Terminating the COVID-19 National Public Health Emergency (Mar. 16, 2023) (unpublished manuscript), https://ssrn.com/abstract=4383405.

195. *See* Rebecca Haffajee, Wendy E. Parmet & Michelle M. Mello, *What Is a Public Health "Emergency"?*, 371 NEW ENG. J. MED. 986, 986 (2014).

proclamations.[196] The standards for determining and defining emergency vary between the states and localities regarding how the jurisdiction determines or defines "emergency," and what powers and limitations the laws provide to the designated officials.[197]

Generally, state public health laws have been upheld where there is a "public necessity"[198] and the laws are not applied in an "oppressive, arbitrary or unreasonable"[199] manner. And since *Jacobson v. Massachusetts*, courts have generally deferred to public health decisions made by state and local governments.[200] During the COVID-19 pandemic, however, while many courts continued to defer to public health decisions made by state and local governments,[201] some courts appeared to scrutinize the separation of powers

196. *COVID-19: State Emergency Declarations & Mitigation Policies*, LAWATLAS: POL'Y SURVEILLANCE PROGRAM (July 1, 2020), https://lawatlas.org/datasets/covid-19-emergency-declarations. In addition, unlike the federal government, many states cannot engage in deficit spending. States generally have either statutory or constitutional balanced budget requirements for their operating funds, which require that anticipated revenues be balanced with expenditures and prohibit states from carrying forward deficits. State budget reserves are many times limited by set criteria for their use. Within the COVID-19 pandemic and resulting economic downturn, many states saw rising costs and decreasing revenue, which may have led states to terminate the emergencies expeditiously. Louise Sheiner & Sophia Campbell, *How Much Is COVID-19 Hurting State and Local Revenues?*, BROOKINGS (Sept. 24, 2020), https://www.brookings.edu/blog/up-front/2020/09/24/how-much-is-covid-19-hurting-state-and-local-revenues/; *see also State Fiscal Briefs*, URB. INST. (July 2023), https://www.urban.org/policy-centers/cross-center-initiatives/state-and-local-finance-initiative/projects/state-fiscal-briefs; Huberman, *supra* note 106, at 153, 159–64 (explaining that through the concept of vertical federalism "states are invited through federal laws to participate in national policies with the promise of money," "regulatory guardrails," and "policy flexibility," but some states chose not to participate).

197. *See supra* note 196.

198. Wiley, *supra* note 52, at 62 (quoting Kirk v. Wyman, 65 S.E. 387, 388 (S.C. 1909)).

199. *Id*. (quoting Huffman v. District of Columbia, 39 A.2d 558, 560 (D.C. 1945)).

200. *See* Friedman, *supra* note 20, at 273. Discussing *Marbury v. Madison* and judicial deference of health emergency orders, Friedman states the following:

> Justice [John] Marshall found that "the president is invested with certain important political powers, in the exercise of which he is to use his own discretion, and is accountable only to his country in his political character, and to his own conscience. [B]eing entrusted to the executive, the decision of the executive is conclusive." According to Justice Marshall, the Court does not have the jurisdiction to address political questions, including, for example, issues of emergency health situations.

Id. (quoting Marbury v. Madison, 5 U.S. 137, 166, 170 (1803)). *But see* Richard A. Epstein, *Let the Shoemaker Stick to His Last: A Defense of the "Old" Public Health*, 46 PERSP. BIOLOGY & MED. S138, S148–58 (2003). For a thoughtful discussion on the continuing vitality of *Jacobson* post-COVID-19, see Lindsay F. Wiley, *The Jacobson Question: Individual Rights, Expertise, and Public Health Necessity*, *in* COVID-19 AND THE LAW, DISRUPTION, IMPACT AND LEGACY, *supra* note 106, at 206, 207 (arguing "the foundational principles enshrined in *Jacobson* endure, but public health advocates will need to craft new arguments that incorporate these principles within modern (and sometimes less deferential) standards of judicial review").

201. *See, e.g.*, Binford v. Sununu, No. 217-2020-CV-00152, at *29–30 (N.H. Sup. Ct. Mar. 25, 2020) (rejecting claim that New Hampshire governor exceeded authority by limiting gatherings and closing businesses); Mello & Gostin, *supra* note 86, at 320 (noting that over 1,000 lawsuits have

issues more heavily.[202] Many states have proposed legislation to limit public health emergency authority,[203] and the Supreme Court has clarified that emergency public health orders cannot discriminate based on religion.[204]

Because of the vast number of state and local governments and their varied public health emergency powers, a significant variation among emergency responses can and does exist. This variation, inherent within our federalist system, ideally enables state and local governments to be responsive to the unique needs, demographics, and geography of the affected populations.[205]

The Model State Emergency Health Powers Act ("MSEHPA"), a proposed uniform act crafted after 9/11, was an attempt to standardize state and local variations by balancing best individualized public health practices

been filed, and "[a]lthough most—but far from all—courts have upheld state and local public health orders, the litigation has been disruptive").

202. *See, e.g.*, T & V Assocs. v. Dir. of Health & Hum. Res., No. 361727, 2023 WL 4277882, at *8 (Mich. Ct. App. June 29, 2023) (ruling that Michigan's health director's authority to close restaurants to control communicable disease spread was unconstitutional as it upset the balance among the three branches of government by shifting too much control to the executive branch).

203. *See* Elizabeth Platt et al., *Trends in U.S. State Public Health Emergency Laws, 2021–2022*, 113 AM. J. PUB. HEALTH 288, 290 (2023) (finding that in 2021–2022, twenty-five states passed legislation that limited public health authority); Anna Maria Barry-Jester et al., *Pandemic Backlash Jeopardizes Public Health Powers, Leaders*, AP NEWS (Dec. 11, 2020), https://apnews.com/article/pandemics-public-health-michael-brown-kansas-coronavirus-pandemic-5aa548a2e5b46f38fb1b884554acf590 ("In the courts, public health powers are being undermined. Lawmakers in at least 24 states have crafted legislation to weaken public health powers, which could make it more difficult for communities to respond to other health emergencies in the future.").

204. *See, e.g.*, Roman Cath. Diocese of Brooklyn v. Cuomo, 141 S. Ct. 63, 69 (2020) (issuing a preliminary injunction against New York Governor's executive order limiting the number of people who could gather in a place of worship); S. Bay United Pentecostal Church v. Newsom, 140 S. Ct. 1613 (2020) (per curiam) (declining to enjoin enforcement of California Governor's order limiting attendance at churches and places of worship to twenty-five percent or 100 attendees); Calvary Chapel Dayton Valley v. Sisolak, 140 S. Ct. 2603, 2609 (2020) (rejecting petition to enjoin Nevada order limiting fifty percent capacity on religious worship); Tandon v. Newsom, 141 S. Ct. 1294, 1296 (2021) (granting injunctive relief from a neutral California regulation that limited gatherings to no more than three households, which resulted in limited in-home Bible studies); S. Bay United Pentecostal Church v. Newsom, 141 S. Ct. 716 (2021) (blocking California's ban on indoor worship, but leaving some restrictions in place); Gateway City Church v. Newsom, 141 S. Ct. 1460 (2021) (blocking California ban on indoor religious services). For a comprehensive overview of judicial decisions related to public health powers, see Wendy E. Parmet & Faith Khalik, *Judicial Review of Public Health Powers Since the Start of the COVID-19 Pandemic: Trends and Implications*, 113 AM. J. PUB. HEALTH 280 (2023); Wiley, *supra* note 52, at 65–66.

205. *See, e.g.*, New State Ice Co. v. Liebmann, 285 U.S. 262, 375–387 (1932) (Brandeis, J., dissenting); Paul C. Erwin, Kenneth W. Mucheck & Ross C. Brownson, *Different Responses to COVID-19 in Four U.S. States: Washington, New York, Missouri, and Alabama*, 111 AM. J. PUB. HEALTH 647–51 (2021). *See generally* Nancy J. Knauer, *The COVID-19 Pandemic and Federalism: Who Decides?*, 23 LEGIS. & PUB. POL'Y 1, 5 (2020); Charles W. Tyler & Heather K. Gerken, *The Myth of the Laboratories of Democracy*, 122 COLUM. L. REV. 2187 (2022).

and due process considerations.[206] MSEHPA drafters defined public health emergency as "'an occurrence or imminent threat of an illness or health condition' . . . posing a substantial risk of significant deaths, disabilities, or future health harms."[207] Approximately forty states and the District of Columbia have passed legislation that includes MSEHPA, in part or whole.[208]

With respect to COVID-19, state public health legislation based on MSEHPA did not lead to a uniform public health response.[209] MSEHPA provisions tend to focus more on individual containment than on community mitigation practices.[210] In addition, due to the unprecedented scope of challenges associated with COVID-19, including enormous logistical issues, many states needed broader emergency powers than those available through public health laws.[211]

During the pandemic, political leaders[212] in all fifty states made a broad variety of emergency declarations in response to COVID-19,[213] which, like the federal emergency orders, triggered access to resources unavailable during non-emergency times.[214] States and local entities were responsible for

206. Wiley, *supra* note 52, at 65–66.

207. *See* Hodge et al., *supra* note 82, at 275 (quoting JAMES G. HODGE JR., PUBLIC HEALTH LAW IN A NUTSHELL (4th ed. 2022)).

208. James G. Hodge, Jr., *Protecting the Public's Health in An Era of Bioterrorism: The Model State Emergency Health Powers Act*, 10 ETHICS, INTEGRITY & POL'Y 91, 91 (2010); Joseph Mishel, The Model State Emergency Health Powers Act: Balancing Public Safety and Civil Liberties 6 (Dec. 14, 2018) (unpublished manuscript), https://scholarship.shu.edu/cgi/viewcontent.cgi?article=2019&context=student_scholarship.

209. Wiley, *supra* note 52, at 58, 65–66.

210. *Id*. at 65–66. According to the CDC, community mitigation strategies are non-pharmaceutical actions that people and communities can take to slow down the spread of a new virus, such as masking, hand washing, social distancing, isolation, quarantine, and restricting gatherings. *See* CTRS. FOR DISEASE CONTROL & PREVENTION, QUICK LINKS TO COVID-19 COMMUNITY MITIGATION STRATEGIES AND TOOLS: RESOURCES FOR STATES, TRIBES, TERRITORIES, AND LOCALITIES (2020), https://www.cdc.gov/coronavirus/2019-ncov/downloads/php/open-america/community-mitigation-quicklinks.pdf#:~:text=Community.

211. Hodge et al., *supra* note 82, at 277.

212. This includes leaders of tribal government and territorial entities, most of which also declared emergencies. With respect to those initial emergency orders, by the end of March 2020, despite the fact that the majority of states had adopted MSEHPA, only thirteen states had formally declared public health emergencies; four states declared public health emergencies along with general emergencies, and the other thirty-three used general emergency or disaster declarations to initiate their responses, as the broader emergency powers provided a wider array of authority. *See id.* at 275–77. For an insightful overview of pandemic response, see generally THE COVID CRISIS GRP., *supra* note 86.

213. *State Emergency Health Orders During the Coronavirus (COVID-19) Pandemic, 2021–2023*, BALLOTPEDIA, https://ballotpedia.org/State_emergency_health_orders_during_the_coronavirus_(COVID-19)_pandemic,_2021-2023 (last updated Aug. 14, 2023).

214. *See States' COVID-19 Public Health Emergency Declarations*, NAT'L ACAD. FOR STATE HEALTH POL'Y, https://www.nashp.org/governors-prioritize-health-for-all/ (last updated June 13, 2023).

enacting restrictions on businesses and people. The policies state and local governments enacted directly affected the day-to-day lives of citizens—for example, shutting down businesses, issuing stay-at-home orders or curfews, and enforcing mask mandates, to name a few.[215] And, in the earliest days of the pandemic, both Republican and Democratic leaders issued similar state and local public health emergency orders to contain and mitigate the pandemic.[216]

As the pandemic continued, however, state responses began to vary. With some exceptions, states with Democratic governors generally issued stricter COVID-19 interventions, including, but not limited to school closings, the shuttering of businesses, and mask mandates, which focused on public health and limiting risk, particularly for vulnerable populations.[217]

215. For an excellent overview of the state legislative response to COVID-19, see various reports by Temple University Beasley School of Law, Center for Public Health Law Research, including Elizabeth Platt & Kathleen Moran-McCabe, *State Legislation Addressing Public Health Emergency Authority*, TEMP. UNIV. BEASLEY SCH. OF L., CTR. FOR PUB. HEALTH L. RSCH. (Jan. 24, 2023), https://phlr.org/product/state-legislation-addressing-public-health-emergency-authority; Elizabeth Platt, *COVID-19 State Medicaid Waivers for Substance Use Disorder Treatment*, TEMP. UNIV. BEASLEY SCH. OF L., CTR. FOR PUB. HEALTH L. RSCH. (Feb. 15, 2022), https://phlr.org/product/covid-19-state-medicaid-waivers-substance-use-disorder-treatment; Kathleen Moran-McCabe et al., *Sentinel Surveillance of Emerging Laws Limiting Public Health Emergency Orders*, TEMP. UNIV. BEASLEY SCH. OF L., CTR. FOR PUB. HEALTH L. RSCH. (July 28, 2022), https://phlr.org/product/sentinel-surveillance-emerging-laws-limiting-public-health-emergency-orders; Scott Burris et al., *COVID-19 Policy Playbook: Legal Recommendations for a Safer, More Equitable Future*, TEMP. UNIV. BEASLEY SCH. OF L., CTR. FOR PUB. HEALTH L. RSCH. (Mar. 23, 2021), https://phlr.org/product/covid-19-policy-playbook-legal-recommendations-safer-more-equitable-future. *See also* Wiley, *supra* note 52, at 69 (citing Jennifer Kates, Josh Michaud & Jennifer Tolbert, *Stay-At-Home Orders to Fight COVID-19 in the United States: The Risks of a Scattershot Approach*, KAISER FAM. FOUND. (Apr. 5, 2020), https://www.kff.org/coronavirus-policy-watch/stay-at-home-orders-to-fight-covid19).

216. The earliest restrictions appear to be successful. For example, according to one study, Governors' recommendations to limit nonessential travel led to a decrease in mobility regardless of political affiliation. Guy Grossman et al., *Political Partisanship Influences Behavioral Responses to Governors' Recommendations for COVID-19 Prevention in the United States*, 117 PROC. NAT'L ACAD. SCIS. 24145 (2020), https://www.pnas.org/doi/abs/10.1073/pnas.2007835117.

217. Cary Funk et al., *Americans Reflect on Nation's COVID-19 Response*, PEW RSCH. CTR. (July 7, 2022), https://www.pewresearch.org/science/2022/07/07/americans-reflect-on-nations-covid-19-response ("The overall findings reflect two competing critiques of the nation's response. One, widely expressed among Republicans, is that the country has not focused enough on business concerns and respecting individual choices. The other, more widely held by Democrats, centers concern around efforts to protect public health and limit health risks for vulnerable populations."). Ultimately, states that adopted more protective policies generally had fewer cases and fewer deaths per 100,000 residents than those states with less protective policies. *See* Julie Van Dusky-Allen & Olga Shvetsova, *How America's Partisan Divide Over Pandemic Responses Played Out in the States*, CONVERSATION (May 12, 2021, 8:46 AM), https://theconversation.com/how-americas-partisan-divide-over-pandemic-responses-played-out-in-the-states-157565; *see also* Brian Neelon et al., *Associations Between Governor Political Affiliation and COVID-19 Cases, Deaths, and Testing in the United States*, 61 AM. J. PREV. MED. 115, 115–16 (2021) (finding that between June 3, 2020, and December 6, 2020, cases and deaths were 1.8 times higher per 100,000 residents in states with Republican governors than in states with Democratic governors).

States with Republican governors tended to issue less stringent COVID-19 interventions, focusing on individual choice and economic growth.[218] Interestingly, however, according to one study, Republican governors in Ohio, Massachusetts, and Maryland who "sounded the alarm on COVID-19" tended to be most successful in encouraging individual compliance with public health restrictions, even among Democrat-leaning voters.[219]

Generally, public health authorities saw significant state legislative action during the pandemic.[220] Between January 2021 and May 2022, state legislators introduced 1531 bills, 191 of which were enacted into law in forty-three states and the District of Columbia.[221] Although twelve states expanded emergency authority,[222] twenty-five states limited the authority of governors and other state and local officials to respond in a public health emergency[223] by restricting the scope issuance or durations of orders, or how the orders can be terminated or overridden.[224] Another six states reallocated authority by removing public health emergency power from the executive branch and

218. *See* Wolfgang Stroebe et al., *Politicization of COVID-19 Health-Protective Behaviors in the United States: Longitudinal and Cross-National Evidence*, 16 PLOS One 1, 1–3 (2021); Michele Gelfand et al., *Persuading Republicans and Democrats to Comply with Mask Wearing: An Intervention Tournament*, 101 J. EXPERIMENTAL SOC. PSYCH. 1, 1–3 (2022).

219. Grossman et al., *supra* note 216; *see* C. Funk, et al., *supra* note 217.

220. *See* PROPOSED LIMITS ON PUBLIC HEALTH AUTHORITY, *supra* note 49; DONNA E. LEVIN ET AL., SUMMARY OF ENACTED LAWS AND PENDING BILLS LIMITING PUBLIC HEALTH AUTHORITY: THE SECOND WAVE (2022), https://www.networkforphl.org/wp-content/uploads/2022/06/Summary-of-Enacted-Laws-and-Pending-Bills-Limiting-Public-Health-Authority-2.pdf.

221. Platt et al., *supra* note 203, at 290; *State Legislation Addressing Public Health Emergency Authority*, LAWATLAS: POL'Y SURVEILLANCE PROGRAM, https://lawatlas.org/page/state-legislation-addressing-public-health-emergency-authority (last visited July 27, 2023).

222. According to Platt et al., these states include Colorado, COLO. REV. STAT. § 24-33.5-1621(3)(b) (2023) (enhancing organizational independence of health agencies); Georgia, GA. CODE ANN. §§ 31-12-3.1, 43-34-26.1 (2023) (authorizing local health authorities to disseminate vaccine information but barring state and local governments from requiring proof of vaccination), Indiana, IND. CODE ANN. § 12-8-1.5-7.5 (2023) (enhancing state health authority during COVID-19 pandemic); Louisiana, LA. STAT. ANN. § 49:962 (2023) (new emergency rule making procedures); Maryland; New Jersey (vaccine pandemic task force on health disparities but terminating governor's public health emergency and related executive orders); Oregon; Pennsylvania (enhancing authority during Covid-19 pandemic); South Carolina; Virginia; Vermont; and West Virginia. Platt et al., *supra* note 203, at 290.

223. Twenty-one states enacted laws that limited the scope of public health emergency orders, sixteen states limited how emergency orders could be issued, fifteen states limited the duration of emergencies, and eleven states addressed public health emergency termination. *See* Platt et al., *supra* note 203, at 290–91.

224. *Id*.; *see* LEVIN ET AL., *supra* note 220. For an updated listing of legislation restricting executive action in emergencies, see *Legislative Oversight of Emergency Executive Powers*, NAT'L CONF. OF STATE LEGISLATURES (Sept. 22 2023), https://www.ncsl.org/about-state-legislatures/legislative-oversight-of-emergency-executive-powers ("Legislative chambers in at least 29 states introduced or considered over 100 bills or resolutions in 2023 that provide expressly for direct legislative involvement in or oversight of certain gubernatorial or executive actions during pandemic or other emergencies (some of these measures are carryover bills from 2022).").

giving it to the legislative branch (or other official or agency).[225] Since that time, at least Idaho,[226] Utah,[227] North Dakota,[228] Louisiana,[229] West Virginia,[230] Virginia,[231] and New Hampshire[232] have enacted laws that limit the scope of public health emergency orders or executive branch authority regarding public health emergencies.

Public health emergency legislation continues to evolve in response to COVID-19. Thus, the Uniform Law Commission recently approved model legislation drafted under the guidance of Prof. Robert Gatter, a public health law scholar, titled The Model Public-Health Emergency Authority Act ("MPHEA").[233] According to MPHEA's prefatory note, the catalyst for the project was uncertainties in the public health emergency framework:

> This project emerged from the uncertainties in state law that the COVID-19 pandemic made acutely apparent. These legal uncertainties contributed to the decision of many individuals, businesses, and some legislatures to file lawsuits challenging the statutory and constitutional authority of Governors and other executive officials to respond to the risks posed by the pandemic. Moreover, these same uncertainties have resulted in state legislation clawing back core public health emergency powers from Governors and executive-branch officials. Consequently,

225. *See* Platt et al., *supra* note 203, at 290–91 (discussing Kansas Senate Bill 40 which allows local government to enact rules that are less strict than those enacted by the governor and requires county commissioners approve a local public health officials order regarding masking, restricting gatherings or business activities).

226. IDAHO CODE § 73-503 (2023) (disallowing COVID-19 vaccine requirements).

227. UTAH CODE ANN. § 26-68-103(2)(a) (2023) (prohibiting governmental entities and employers from discriminating against or imposing requirements for vaccination).

228. N.D. CENT. CODE § 23-12-20 (2023) (prohibiting government entities or private businesses from requiring, publishing, or sharing documentation of vaccination status or other information about an employee's COVID-19 status).

229. LA. STAT. ANN. §§ 29:727(D)(1), 29:737(C) (2023) (limiting public health emergencies to thirty days absent extension by mayor, chief executive officer, or parish president, and limiting extensions to ninety days absent approval from municipal or parish governing authority).

230. W. VA. CODE §15-5-6 (2023) (providing for a gubernatorial proclamation of state of emergency which would generally last for sixty days but which can be extended by the legislature to ninety days, and prohibiting gubernatorial authority to close churches or other houses of worship or suspend or limit sale, transfer or transportation of firearms and ammunition).

231. VA. CODE ANN. § 44-146.17 (2023).

232. N.H. REV. STAT. ANN. § 9-G:1 (2023) (prohibiting vaccination or vaccination documentation by government or business entities); *Id.* § 275-I:1 (2023) (prohibiting enforcement or collaboration of any federal law that requires proof of COVID-19 vaccination status or to submit a negative test for COVID-19 more than once a month).

233. *See* MODEL PUBLIC HEALTH EMERGENCY AUTHORITY ACT 1 (UNIF. L. COMM'N 2023) ("The [MPHEA] is designed to improve the preparedness of states for public health emergencies. Specifically, this Act clarifies the powers of a governor to declare a public health emergency and to issue orders in response to that emergency. Simultaneously, this Act establishes measures to promote a Governor's accountability to the Legislature and to the public at large.").

> Governors and health officials in many states may no longer have the legal authority to protect public health adequately during the next emergency, and the legal precedents and legislative examples from those states undermine the legal and political reliability of public health emergency powers in all states.[234]

Although it is too early for state adoption at the time of this writing, the MPHEA should be a powerful tool for future state emergency power legislation, particularly as it relates to the scope of gubernatorial authority to declare a public health emergency and issue responsive emergency orders, as well as measures to ensure accountability. This distinguishes it from the earlier act, MSHEPA, which focused primarily on issues of isolation and quarantine, rather than "the power of Governors to issue orders designed to mitigate the effects of a novel contagious disease that has taken root in a population."[235]

In reviewing public health emergency legislation, it is helpful to remember that when establishing or changing the conditions under which governments may make performative utterances that change the status of individuals, groups, drugs, or other entities under their authority, they are establishing or changing the felicity conditions for those statements. When restrictions governments impose to promote public health are challenged in courts of law, we may understand courts as assessing whether those restrictions are legitimate, i.e., whether the felicity conditions previously established are legitimate and whether the utterances met those felicity conditions. In addition to positive developments, such as the Model Public-Health Emergency Authority Act,[236] the considerations discussed in this Section should lead us to analyze our current public health framework in its entirety and identify the growth areas that exist within the structure.

III. UNTANGLING THE WEB OF PUBLIC HEALTH EMERGENCY LEGISLATION

We will certainly face future epidemics, pandemics, and other public health emergencies.[237] It is therefore imperative to strengthen our public

234. *Id.*

235. *Id.* at 2.

236. *Id.*

237. *See supra* note 15 and accompanying text; *see also* Jennifer B. Nuzzo & Lawrence O. Gostin, *The First 2 Years of COVID-19: Lessons to Improve Preparedness for the Next Pandemic*, 327 JAMA 217, 217 (2022), https://jamanetwork.com/journals/jama/fullarticle/2787943. The authors discuss that global pandemics are probably the new normal:

> Although the global tolls of COVID-19 are unprecedented in the modern era, novel diseases are likely to accelerate. Just in the last few decades, the world experienced multiple disease emergencies: West Nile virus (1999), SARS (2003), H5N1 avian influenza (2004), pandemic H1N1 influenza (2009), Middle East respiratory syndrome (2012), Ebola in West Africa (2014), and Zika (2015), and more disease outbreaks should be expected. Even accounting for improved surveillance, novel emerging diseases have

health system through measures including, but not limited to, providing sufficient resources for surveillance, prevention, and containment. But we also need to focus on two less-discussed problems that exist within the public health emergency framework: (1) the lack of consistency and clarity in the frameworks for public health emergencies regarding the felicity conditions surrounding their declaration and termination; and (2) the discrepancy between the term "emergency," which usually involves immediate and intense short-term actions, and the realities of public health emergencies, which usually involve complex, long-term problems. This Part analyzes both of those issues and provides potential criteria, guidelines, and models to consider that may provide for some surrogate checks and balances. While we acknowledge that much needs to be done to prepare for the future with public health emergencies and their frameworks, this Part then emphasizes the need for, as a first step, a multi-disciplinary team of scholars and practitioners to review the various mechanisms for declaring, continuing, and terminating public health emergencies and provide input—in other words, felicity conditions—for every stage.

A. Lack of Consistency and Clarity

As discussed earlier, each emergency and public health declaration is distinct, but they can and usually do exist in tandem with other declarations.[238] To illustrate, the table below compares several different federal public health emergency declarations, their purposes, and the relevant conditions for their declaration and termination:

> steadily increased since 1940. There are strong biological and environmental reasons to expect epidemics as, or more, serious than COVID-19.

Nuzzo & Lawrence, *supra*, at 218 (internal citations omitted). For an excellent overview of the goals and challenges of public health law, see generally Lawrence O. Gostin, *A Theory and Definition of Public Health Law*, 10 J. HEALTH CARE L. & POL'Y 1 (2007).

238. *See supra* Part II.

Authority for Declaration	Type/Purpose	Definition of Emergency	Conditions for Declaration	Terminating the Declaration
World Health Organization, through its International Health Regulations (IHR).	Provides the legal framework that defines signatories' rights and obligations for global public health emergencies.	A public health emergency of international concerns (PHEIC) is "an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response."	After a report from signatory nation that an outbreak is "serious, sudden, unusual or unexpected; carries implications for public health beyond the affected State's national border; and may require immediate international action," the WHO Director General may make a PHEIC declaration after considering factors (including the risk to human health and international spread) and receiving advice from IHREC, which includes a member from the affected nation.	Every three months, the IHREC meets to determine whether the PHEIC still exists, and if so, renews the declaration and suggests any additional actions signatory nations should consider taking.
Public Health Services Act, Section 319, 42 U.S.C. § 247d.	Allows the HHS Secretary to take actions to respond to the public health emergency, usually with the ASPR and CDC leading response.	Where the HHS Secretary determines that a disease or disorder presents a public health emergency.	The HHS Secretary determines or declares, after consultation with other public health officials as necessary, that a public health emergency exists and notifies Congress.	Ninety days or until the HHS Secretary determines the emergency no longer exists, whichever is first, but can be renewed.
National Emergencies Act, 50 U.S.C. § 1621.	Provides the framework for the President to use statutory powers and authorities in a national emergency. The different types of emergency authority activated by the President determine which federal agencies lead the response.	The Act does not define an emergency.	(1) The President must identify which statutory authority is being invoked by declaring the national emergency; (2) the national emergency proclamation must be published in the Federal Register; (3) all rules and regulations created to mitigate emergency, along with records, must be provided to Congress; and (4) an accounting of expenses related to the emergency must be provided every six months following the national emergency declaration.	(1) automatically after one year unless the President renews it; (2) a declaration by the President ending the emergency; or (3) a joint resolution of Congress terminating the emergency.

Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§ 5121–5207.	Provides federal assistance where needed to supplement state and local efforts to protect public health and safety in either emergencies or major disasters and allows FEMA to lead the federal response.	Emergency is defined as "any occasion or instance for which, in the determination of the President, Federal assistance is needed to supplement State and local efforts and capabilities to save lives and to protect property and public health and safety, or to lessen or avert the threat of a catastrophe in any part of the United States."	The President may declare an emergency where (1) the state's governor, territorial leader or tribe executive asks the President to declare an emergency; or (2) unilaterally by the President where the federal government has primary responsibility for responding to the emergency (this unilateral action option does not apply to major disaster declarations).	FEMA sets an end date by determining the "incident period" for the emergency.
Emergency Use Authorization under the Food, Drug, and Cosmetic Act, Section 564, 21 U.S.C. § 360bbb-3.	FDA can authorize for distribution or sale yet unapproved medical treatments and products responsive to the public health emergency conditions.	The Act does not define emergency.	One of the following determinations must be in place: (1) The DoD Secretary issues a determination of military emergency or significant potential for military emergency; (2) The DHS Secretary issues a determination of domestic emergency or significant potential for domestic emergency; (3) The HHS Secretary issues a determination of public health emergency or significant potential for public health emergency or material threat determination. After one of the above determinations occur, the HHS Secretary can issue a declaration that circumstances exist to justify issuing the EUA. The FDA publishes public notice of each EUA that is issued in the Federal Register.	An EUA declaration continues until HHS Secretary terminates it. Individual EUAs may be revoked if: (1) the circumstances justifying the EUA no longer exist; (2) the criterion for the EUA is no longer met, or (3) other circumstances make revocation appropriate to protect public health or safety.

Public Readiness and Emergency Preparedness Act, 42 U.S.C.§ 247d-6d.	Provides immunity from a liability claim for a loss due to the administration or use of a covered medical countermeasure, such as through an EUA. Establishes the Countermeasures Injury Compensation Program ("CICP") to provide reimbursement for reasonable medical and other expenses for individuals injured by medical countermeasures.	The Act does not define an emergency.	HHS Secretary must first find that public health emergency or a credible threat of a public health emergency exists. The HHS Secretary must analyze "the desirability of encouraging the design, development, testing, manufacture, and use of countermeasures" in determining whether to issue a PREP Act declaration.	A PREP Act emergency declaration includes an estimated set end date.

As the table reflects, each of the listed major public health emergency declarations differs in effect, scope, imitation, and processes for declaring emergencies. To that end, the definition of "public health emergency" justifying a declaration from the HHS Secretary to enable the FDA to issue EUAs, which has no time limit, is not dependent on the declaration of a "public health emergency" under the PHSA, which provides a broad standard and a ninety-day limit for reauthorization. As discussed earlier, this very scenario has played out with the COVID-19 pandemic.[239] But the definition of an emergency for an EUA also differs from a declaration of a public health emergency under the PREP Act, even though these two measures were meant to work in tandem. And, concerning the PREP Act, some liability protections have expired and only some remain ongoing.[240] Furthermore, the processes for terminating different public health emergencies in the United States vary and differ significantly from the WHO's termination of a PHEIC.[241] Adding to this complexity are the public health emergency declarations that may be applicable in each of the fifty states, territories, tribes, or local governments.[242]

239. *See supra* notes 177–178 and accompanying text.

240. *See supra* notes 191–194 and accompanying text.

241. *See* WORLD HEALTH ORG., https://www.who.int/ (last visited Jan. 10, 2023). With respect to the COVID-19 pandemic, the WHO Director declared the outbreak a public health emergency of international concern on January 30, 2020. *See also* Annelies Wilder-Smith & Sarah Osman, *Public Health Emergencies of International Concern: A Historic Overview*, 27 J. TRAVEL MED. 1, 8 (2020), https://pubmed.ncbi.nlm.nih.gov/33284964/.

242. *See* James G. Hodge, *Nationalizing Public Health Emergency Legal Responses*, 49 J.L., MED. & ETHICS 315, 317–18 (2021).

Public health scholars have tried to make sense of it all by developing numerous frameworks for determining when a public health emergency should be declared. For instance, following the 2014 Ebola outbreak, Professors Rebecca Haffajee, Wendy Parmet, and Michelle Mello identified three criteria that should be present for a public health emergency to be declared:

- the situation is exigent;
- the anticipated or public harm could be calamitous; and
- the harm cannot be avoided through ordinary procedures.[243]

In 2021, Professor James Hodge pinpointed seven different principles for coordinating an effective national response to public health emergencies.[244] These principles are as follows: (1) focus on national security interest; (2) use federal interstate commerce authorities assertively for consistency; (3) provide federal control over acquisition, production, and distribution of essential goods; (4) promote uniformity in spending; (5) provide for centralized oversight of testing, screening, surveillance, and health services; (6) broaden PREP Act and other federal laws to preempt conflicting state actions or inactions; and (7) recognize states' essential role as the front-line response but provide federal guidance to assure greater uniformity across states and maximize every American's chance to survive the next calamity.[245]

More recently, Professor Lindsay Wiley set forth six guidelines that legislatures should consider when thinking about drafting future public health emergency laws and preparing for the next public health emergency[246]: (1) transparency; (2) renewable time limits; (3) a scaled response; (4) neutral orders that do not discriminate based on religion; (5) support, legal protections, and accommodations of safer alternatives; and (6) criminal enforcement imposed only when it is the least restrictive alternative.[247]

During a public health emergency, it is imperative to provide clarity and consistency for the public—as shown by Haffajee, Parmet & Mello's proposed criteria, Hodge's principles, and Wiley's proposed guidelines—to foster trust and perceived legitimacy with the public health measures, thereby

243. *See* Haffajee et al., *supra* note 195, at 986. They expressed concern over use of public health emergency declaration with the opioid epidemic because it did not fit the typical mold of infectious disease outbreaks, natural disasters, or terrorism. Thus, "health threats related to noncommunicable diseases or commonplace injuries seldom" would "justify relaxing . . . legal protections" because of the potential restrictions on ordinary citizens and business. *Id.* at 988.

244. Hodge, *supra* note 242.

245. *Id.* at 317–18.

246. Lindsay F. Wiley, *Public Health Emergency Reform Is Coming—These Six Principles Should Guide It*, HEALTH AFFS. (Jan. 12, 2021), https://www.healthaffairs.org/do/10.1377/forefront.20210105.516753.

247. *Id.*

improving compliance.[248] During the COVID-19 pandemic, the public was keenly aware of the differing standards regarding masking, social distancing, and school closures that were being applied nationwide. The public had unprecedented access to sensational media, and with newer platforms, mis- and disinformation spread like wildfire with tragic results.[249] The lack of consistency—coupled with mis- and disinformation campaigns—limited understanding and decreased public trust, as shown by a 2021 poll reflecting that many Americans lost trust in federal, state, and local public health recommendations and orders during the pandemic.[250] When juxtaposed with the rugged individualism on which we pride ourselves in the United States, this loss of trust correlated with a loss of the "perceived legitimacy of the public health initiatives,"[251] which in turn affected compliance with even the simplest public health measures, such as wearing a mask.[252] Establishing therefore, to the extent possible, consistent felicity conditions for such declarations in terms of the criteria that should be met and procedures that should be followed—and communicating the underlying reasoning clearly and widely—is critical.[253] Guidance regarding not only who is in authority,

248. *See* Mesay Sata Shanka & Mesay Moges Menebo, *When and How Trust in Government Leads to Compliance with COVID-19 Precautionary Measures*, 139 J. BUS. RSCH. 1275, 1281 (2022) ("Government health communication messages should focus on developing and maintaining trust among the public by providing transparent, coherent, clear, timely, and accurate information that reduces people's uncertainty and enhances compliance.").

249. After vaccines became widely available, individuals in Republican-leaning counties experienced a significantly higher mortality rate than those in Democrat-leaning counties due in part to misinformation about the safety and efficacy of vaccines. Jacob Wallace et al., *Excess Death Rates for Republicans and Democrats During the COVID-19 Pandemic* (Nat'l Bureau of Econ. Rsch., Working Paper No. 30512, 2022); *see also* Nancy Krieger et al., *Relationship of Political Ideology of U.S. Federal and State Elected Officials and Key COVID Pandemic Outcomes Following Vaccine Rollout to Adults: April 2021–March 2022*, 16 LANCET REG'L HEALTH 1, 1 (2022) (finding that, in the context of adult vaccine availability, the higher the exposure to conservatism across several political metrics, the higher the COVID-19 age-standardized mortality rates, even after considering social characteristics); *see* THE COVID CRISIS GRP., *supra* note 86, at 209–11.

250. Mello & Gostin, *supra* note 86, at 320 (citing HARV. T.H. CHAN SCH. OF PUB. HEALTH & ROBERT WOOD JOHNSON FOUND, THE PUBLIC'S PERSPECTIVE ON THE UNITED STATES PUBLIC HEALTH SYSTEM, (2021), https://www.hsph.harvard.edu/wp-content/uploads/sites/94/2021/05/RWJF-Harvard-Report_FINAL-051321.pdf); *see also Harvard // Robert Wood Johnson Foundation Polls*, HARV. T.H. CHAN SCH. OF PUB. HEALTH (May 13, 2021), https://www.hsph.harvard.edu/horp/horp-robert-wood-johnson-foundation-polls/.

251. Mello & Gostin, *supra* note 86, at 320 (citing Stephanie Morain & Michele Mello, *Legal Interventions Directed at Health Behavior to Fight Noncommunicable Disease*, 32 HEALTH AFFS. 486–96 (2013)).

252. *Id.*; *see supra* THE COVID CRISIS GRP., *supra* note 86, at 209–14.

253. The new Model Public Health Emergency Authority Act is a step in the right direction. *See supra* notes 233–236 and accompanying text.

but how and under what circumstances they may exercise that authority, is urgently needed.[254]

B. Length of Public Health Emergencies

At the beginning of the pandemic, the resounding message was that closing schools, shuttering businesses, and canceling events for a short time would "flatten the curve" and stop COVID-19's spread.[255] And, as previously discussed, in the earliest days of the pandemic, both Republican and Democratic leaders issued similar state and local public health emergency orders to contain and mitigate the spread of disease, compliance with which was successful regardless of political affiliation.[256] As the pandemic continued, the "flatten the curve" mantra lost effectiveness,[257] and public health emergency responses—particularly at the state level—began to shift.[258] The varied emergency responses led to confusion and a general shift from public health—protecting your community—to individual health—protecting yourself.[259]

Pandemic fatigue,[260] as the weeks of the public health emergency turned into months and ultimately years, has many causes. One reason is the discrepancy between the term "emergency," which usually involves immediate and intense short-term actions, and the realities of public health

254. *See supra* note 121 and accompanying text (discussing the National Academies' recommendation that Section 319 of the PHSA be modernized and reformed).

255. The term is attributed to medical historian Dr. Howard Markel. John Kruzel, *Doctor Behind 'Flatten the Curve' Urges Bipartisan Response to Outbreak*, HILL (March 20, 2020, 6:00 AM), thehill.com/policy/healthcare/488559-doctor-behind-flatten-the-curve-urges-bipartisan-response-to-outbreak/; *see* Helen Branswell, *Why 'Flattening the Curve' May Be the World's Best Bet to Slow the Coronavirus*, STAT (March 11, 2020), https://www.statnews.com/2020/03/11/flattening-curve-coronavirus/.

256. *See* Guy Grossman, et al., *Political Partisanship Influences Behavioral Responses to Governors' Recommendations for COVID-19 Prevention in the United States*, 117 PNAS 24144, 24151 (Sept. 15, 2020).

257. *See* Dylan Scott, *Flattening the Curve Worked—Until It Didn't*, VOX (Dec. 31, 2020, 9:30AM), https://www.vox.com/22180261/covid-19-coronavirus-social-distancing-lockdowns-flatten-the-curve.

258. While there were exceptions to state public health emergency orders and responses at the state and local levels, as the pandemic continued, Democratic leaders generally maintained more stringent COVID-19 interventions, while Republican leaders tended to focus on individual choice and economics. *See* Sean McMinn et al., *Covid's Deadly Trade-offs, by the Numbers: How Each State Has Fared in the Pandemic*, POLITICO (Dec. 15, 2021, 5:00 AM) https://www.politico.com/interactives/2021/covid-by-the-numbers-how-each-state-fared-on-our-pandemic-scorecard/; Wolfgang Stroebe et al., *supra* note 218, at 3–4.

259. *See* Scott, *supra* note 257.

260. The World Health Organization defines pandemic fatigue at "distress which can result in demotivation to follow the recommended protective behaviours, emerging gradually over time and being affected by a number of emotions, experiences, and perceptions." WORLD HEALTH ORG., PANDEMIC FATIGUE: REINVIGORATING THE PUBLIC TO PREVENT COVID-19, at 4 (2020), https://www.who.int/europe/publications/i/item/WHO-EURO-2020-1573-41324-56242.

emergencies, which usually involve complex, long-term problems requiring multi-faceted solutions.

Specifically, an emergency is generally defined as an "unforeseen combination of circumstances or the resulting state that calls for immediate action; an urgent need for assistance or relief."[261] An "emergency" triggers extreme anxiety and an adrenaline rush associated with the immediacy of the situation and the need to take action,[262] which can be difficult to sustain over time. Applying the common definition of "emergency" leads to the misconception that public health emergencies and their corresponding states of emergency are limited to the initial actions that occur in an emergency and can be effectively dealt with by legislation that imposes a short-term time limit.[263]

The Brennan Center's report on emergency powers points out the reality regarding the length of public health emergencies:

> [S]tates of emergency last a long time, and they're getting longer. . . . The average duration of declared emergencies is 9.6 years. Twenty-five emergencies have lasted 10 years or longer; 13 of these were declared between 2001 and 2008."[264]

To illustrate, the ongoing Opioid crisis was first declared a public health emergency in 2017 by then Acting HHS Secretary Eric D. Hargan.[265] This state of emergency has been repeatedly renewed.[266] At this point, due to the complex medical, psychological, social, economic, and policy factors that surround the Opioid crisis, there does not appear to be a plan to terminate its emergency status.[267]

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261. *Emergency*, MERRIAM WEBSTER, https://www.merriam-webster.com/dictionary/emergency (last visited Jan. 27, 2023).

262. *See generally* CTRS. FOR DISEASE CONTROL & PREVENTION, CRISIS + EMERGENCY RISK COMMUNICATION: PSYCHOLOGY OF A CRISIS 7 (2019), https://emergency.cdc.gov/cerc/ppt/CERC_Psychology_of_a_Crisis.pdf.

263. Adding to the complexity is that different public health emergency frameworks have different definitions of "emergency." *See supra* notes 226–232. States that adopt the new Model Public Health Emergency Authority Act may help remedy this part of the problem, at least at the state level. *See supra* notes 233–236 and accompanying text.

264. BRENNAN CTR. FOR JUST., *supra* note 21.

265. *Determination that a Public Health Emergency Exists*, U.S. DEP'T OF HEALTH & HUM. SERVS., ADMIN. FOR STRATEGIC PREPAREDNESS & RESPONSE (Oct. 26, 2017), https://aspr.hhs.gov/legal/PHE/Pages/opioids.aspx ("As a result of the consequences of the opioid crisis affecting our Nation, on this date and after consultation with public health officials as necessary, I, Eric. D. Hargan, Acting Secretary of Health & Human Services, pursuant to the authority vested in me under section 391 of the Public Health Services Act, do hereby determine that a public health emergency exists nationwide.").

266. *Declarations of a Public Health Emergency*, U.S. DEP'T OF HEALTH & HUM. SERVS., ADMIN. FOR STRATEGIC PREPAREDNESS & RESPONSE, https://aspr.hhs.gov/legal/PHE/Pages/default.aspx (last visited Nov. 22, 2023).

267. *Opioid Facts and Statistics*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.hhs.gov/opioids/statistics/index.html (last visited Feb. 4, 2023).

In the context of public health emergencies, although the PHSA has a ninety-day time limit that can be renewed, many of the pre-COVID-19 public health emergency laws were enacted after 9/11 for short-lived emergencies.[268] Consequently, despite the harsh realities of many public health emergencies, particularly the ongoing Opioid Crisis and the COVID-19 pandemic, some states have decided to limit—or at least place a time-limiting framework—on their public health emergency status. According to a study published in the *American Journal of Public Health*,[269] from January 2021 to May 2022, fifteen states enacted eighteen laws limiting public health emergency duration, ranging from ten days in Wyoming[270] to ninety days in Ohio.[271] The average length of these laws limiting public health emergencies is thirty-three days.[272] Since the study concluded, at least Louisiana,[273] West Virginia,[274] and Virginia[275] have also enacted conditional time restrictions on public health emergencies.

Reasonable and flexible time limitations may make some sense, particularly for a long-term pandemic such as COVID-19. In addition to the devastating loss of life, the COVID-19 pandemic brought novel logistical, economic, social, psychological, and educational challenges, to name a few. In determining when to terminate a public health emergency, public health officials focus on the critical but relatively narrow issue of population health. As Mello and Gostin explain: "Although governors, legislators, and local executives are experienced in balancing many values in making policy decisions, health officials have a narrower mission. A laser focus on public health protection is sensible during short-term public health emergencies, but long-term pandemics require a widening of the lens. . . ."[276]

Time limitations (such as the PHSA's renewable ninety-day timeframe) may seemingly provide for a wider focus on the interrelated harms caused by the pandemic. However, strict legislative limitations on executive emergency power without recourse, or the ability to terminate one type of emergency protocol while keeping others, could cause harm by affecting the ability of state and local public health leaders to take action, ranging from issuing

268. *See* Mello & Gostin, *supra* note 86, at 321.
269. *See* Platt et al., *supra* note 203.
270. WYO. STAT. ANN. § 35-1-310 (2021).
271. OHIO REV. CODE ANN. § 107.42 (2021).
272. Platt et al., *supra* note 203, at 290.
273. LA. STAT. ANN. §§ 29:727(D), 737(C) (2023).
274. W. VA. CODE § 15-5-6 (2023).
275. VA. CODE ANN. § 44-146.17 (2023).
276. Mello & Gostin, *supra* note 86, at 321.

orders and leading the emergency response to providing the resources and financial support reserved for emergencies.[277]

An example of a more nuanced response, rather than the all-or-nothing approach that some advocate, is illustrated by HHS Secretary Beccera's decision to continue EUAs along with certain liability protections under the PREP Act following the termination of other federal public health emergencies. During the pandemic, medications available under EUAs saved countless lives and led to the generation of data about investigational drugs.[278] In a sense, EUAs expanded the freedom of various actors by lifting rules and limits that protect against the use of products that had not demonstrated substantial evidence of safety and efficacy and allow people to buy them. This, in turn, expanded choice, liberty, and freedom.

Terminating EUAs prematurely can harm public health by making some potential products and treatments unavailable in the short term. On the other hand, because the products are authorized for the market more quickly under the lower "may be effective" standard, the products come with heightened safety risks. The public may come to expect continuous use of EUAs for non-emergency situations, or in situations involving rare diseases or medical conditions for which there are few or no pharmaceutical options.[279]

Public health emergencies are complex and require multi-faceted solutions. Different types of public health emergencies will require governments to impose different restrictions for different amounts of time. A one-size-fits-all approach in terms of the length of time that emergency powers are imposed simply does not work. Consider the vast implications and consequences that terminating public health emergencies, and thereby ending support and resources, has on people—particularly the most vulnerable. We should therefore be quite intentional in constructing and receiving input from the multidisciplinary perspective of scholars and stakeholders to develop appropriate felicity conditions that provide for accountability, along with specific procedures and criteria for different types

277. As Mello and Gostin insightfully note: "In many states, legislatures do have the ability to terminate (or not renew) emergency declarations. However, that constitutes a nuclear option with consequences so serious that it might not be a credible check on executive power." Mello & Gostin, *supra* note 86, at 321.

278. *See The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD & DRUG ADMIN. (Nov. 24, 2017), https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm; *see also* Christine Coughlin, Nancy M.P. King & Melissa McKinney, *Regenerative Medicine and the Right to Try*, 18 WAKE FOREST J. BUS. & INTELL. PROP. L. 590, 598–601 (2018).

279. Holly Fernandez Lynch et al., *Helpful Lessons and Cautionary Tales: How Should COVID-19 Drug Development and Access Inform Approaches to Non-Pandemic Diseases?*, 21 AM. J. BIOETHICS 1, 4–19 (2021).

of public health emergencies, particularly when and under which conditions they should be terminated.[280]

C. Moving Forward

As discussed, public health emergencies are performative utterances that shift the balance of governmental power.[281] Along with COVID-19, the traditional role that executive agencies play, and the deference that the courts provide agency decision-making, is being questioned by the Supreme Court.[282] The Court's answer will likely have significant ramifications on clinical and public health.[283]

Another development that may affect—or complicate—matters moving forward is the major questions doctrine's effect on executive regulatory authority.[284] For example, in *Alabama Association of Realtors v. Department of Health and Human Services*,[285] the Supreme Court held that the CDC lacked the legal authority to extend a nationwide eviction moratorium. Likewise, in *National Federation of Independent Business v. Department of Labor, Occupational Safety and Health Administration*,[286] the Court rejected

280. The Haffajee, Parmet & Mello and Hodge criteria do not include a time limitation. Like the PHSA, Wiley's proposed guidelines provide for renewable but non-specific time limits. *See* Haffajee et al., *supra* note 195; Hodge, *supra* note 242.

281. *See supra* text accompanying notes 20–27.

282. *See* Platt et al., *supra* note 203. Currently, the Supreme Court is questioning the long-standing deference afforded by the courts to administrative agencies under its 1984 decision in *Chevron v. National Resources Defense Council*, 467 U.S. 837 (1984). *See* Relentless, Inc. v. Dep't of Com., 144 S. Ct. 325 (2023) (granting certiorari); Loper Bright Ent. v. Raimondo, 143 S. Ct. 2429 (2023) (granting certiorari); *see also* Amy Howe, *Supreme Court Likely to Discard Chevron*, SCOTUSBLOG (Jan. 17, 2024, 6:58 PM), https://www.scotusblog.com/2024/01/supreme-court-likely-to-discard-chevron/.

283. *See supra* note 101 and accompanying text. *See generally* Daniel T. Deacon & Leah M. Litman, *The New Major Questions Doctrine*, 109 VA. L. REV. 1009 (2023); Elissa P. Gentry & W. Kip Viscusi, *The Misapplication of the Major Questions Doctrine to Emerging Risks*, 61 HOUS. L. REV. (forthcoming 2024), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4403411; Erica N. White, *Overcoming the Major Questions Doctrine with Federal Public Health Authorities*, 18 HARV. L. & POL. REV. (forthcoming), https://ssrn.com/abstract=4410940. *But see* Brianne J. Gorod, Brian R. Frazelle & J. Alex Rowell, *Major Questions Doctrine: An Extraordinary Doctrine for 'Extraordinary' Cases*, 58 WAKE FOREST L. REV. 600 (2023) (arguing that a limited application of the major questions doctrine best maintains the constitutional balance of powers).

284. Under the major questions doctrine, if an administrative agency "seeks to decide an issue of major national significance, its action must be supported by *clear* congressional authorization." KATE R. BOWERS, CONG. RSCH. SERV., IF12077, THE MAJOR QUESTIONS DOCTRINE 1 (2022) ("In cases where there is something extraordinary about the 'history and breadth of the authority' an agency asserts or the 'economic and political significance' of that assertion, however, the Court indicated courts should 'hesitate before concluding that Congress meant to confer such authority. . . .'" (quoting West Virginia v. EPA, 142 S. Ct. 2587, 2607–08 (2022))); *see supra* note 282 and accompanying text.

285. 142 S. Ct. 2485 (2021) (per curiam).

286. 142 S. Ct. 661 (2022).

the Occupational Safety and Health Administration's ("OSHA") emergency temporary standard imposing COVID-19 vaccination requirements on employers with over 100 employees. Moreover, in *West Virginia v. Environmental Protection Agency*,[287] the Court held that the Clean Air Act did not grant authority to the Environmental Protection Agency to devise emission caps premised on "generation shifting."[288] And, most recently, in *Biden v. Nebraska*,[289] the Court struck down a Biden administration initiative through the Department of Education to cancel student debt.

While time will tell, the Supreme Court's reliance on the major questions doctrine could result in further legislative intentionality and government accountability for public health emergency declarations, continuations, and terminations. However, it is more likely to limit executive agency authority during public health emergencies by opening further avenues to challenge actions that arguably infringe on individual rights, like mandatory vaccines, mask mandates, quarantine and isolation orders, or continuing public health emergency status. To this point, at least concerning state law, states should consider adopting the new MPHEA in whole or to clarify gubernatorial authority to issue orders, particularly with new or novel contagious diseases.[290] The current scheme, if left unchecked, could have a devastating effect on the public health response for future pandemics and other types of public health emergencies.

One model that can help provide a way forward is the WHO's mechanism, which relies on IHREC for guidance during the entire public health emergency process.[291] The WHO defines a public health emergency of international concern as "an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response."[292] The International Health Regulations shed further light on that definition by

287. 142 S. Ct. 2587 (2022).

288. *Id.* at 2610 (relying on the major questions doctrine to hold that in an "extraordinary case" of "economic and political significance," the agency needs a "clear statement" of authorization from Congress).

289. 143 S. Ct. 2355 (2023).

290. *See* MODEL PUBLIC HEALTH EMERGENCY AUTHORITY ACT 2 (UNIF. L. COMM'N 2023)

291. This is not to say the WHO's response has been perfect. *See, e.g.*, Larry Gostin, *The Great Coronavirus Pandemic: An Unparalleled Collapse in Global Solidarity*, *in* PANDEMIC ETHICS: FROM COVID-19 TO DISEASE X 15 (Julian Savulescu & Dominic Wilkinson eds., 2023) (discussing the failure of global cooperation during COVID-19; the negative effects of the same on the response to the pandemic; failure of nations to adhere to International Health Regulations; the history of international/WHO initial response; and proposed fixes to global cooperation failure).

292. *Emergencies: International Health Regulations and Emergency Committees*, WORLD HEALTH ORG. (Dec. 19, 2019), https://www.who.int/news-room/questions-and-answers/item/emergencies-international-health-regulations-and-emergency-committees.

providing the following criteria for a public health emergency of international concern:

- serious, sudden, unusual, or unexpected;
- carries implications for public health beyond the affected State's national border; and
- may require immediate international action.[293]

IHREC, which always includes an individual from the affected country on the Committee to provide a local perspective, further guides the WHO's Director-General concerning what, if any, recommendations should be implemented by the country experiencing the public health emergency or other countries working to avoid or mitigate the spread of disease, and when and under which conditions to terminate the PHEIC.[294] Following a declaration of a public health emergency of international concern, IHREC reconvenes every three months to examine epidemiological concerns, consider metrics such as vaccinations and case numbers, and provide guidance on whether the emergency should be terminated.[295] For example, in the case of an influenza pandemic, IHREC and WHO have stipulated that the post-pandemic phase begins when "[l]evels of influenza activity have returned to the levels seen for seasonal influenza in most countries with adequate surveillance."[296]

With respect to recommending termination of the COVID-19 PHEIC, on May 4, 2023, IHREC met for five hours to consider evidence and deliberate.[297] The Committee acknowledged that the virus was still circulating, but found support for termination of the PHEIC in the decreasing trend in deaths, hospitalizations, and intensive care admissions and the increasing level of population immunity from past infections and vaccinations.[298] In addition, the Committee reviewed evidence regarding how countries had enhanced their functional capacities, particularly related to emergency coordination, collaborative surveillance, clinical care, and risk communications and communication engagement.[299]

293. *Id.*; *see* Meredith Wadman, *When Is a Pandemic 'Over'?*, 375 SCIENCE 1077, 1077–78 (2022).

294. *Emergencies: International Health Regulations and Emergency Committees*, *supra* note 292.

295. *Id.*

296. WORLD HEALTH ORG., PANDEMIC INFLUENZA PREPAREDNESS AND RESPONSE 11 (2009), https://iris.who.int/bitstream/handle/10665/44123/9789241547680_eng.pdf.

297. *See supra* note 3 and accompanying text.

298. *See supra* note 3 and accompanying text.

299. *See supra* note 3 and accompanying text.

While reasonable minds may critique the WHO and its processes,[300] the United States and its states, territories, and tribes lack a consistent across-the-board procedure for providing diverse perspectives or "widening the lens"[301] when considering the implications surrounding a public health emergency declaration.

In his essay *FDA Emergency Use Authorization: A Brief History from 9/11 to COVID-19*, FDA expert Jonathan Iwry explains that the EUA process (as well as all public health emergency processes) would benefit from further consultation and input: "These issues cannot be resolved by looking to the statutory text; they will inevitably require hard judgments about how to balance deference to scientific expertise with public accountability, how to integrate empirical analysis and value judgments, and how to allocate risk in times of crisis."[302] There is, therefore, a need as a first step to create a mechanism to receive input from a multidisciplinary perspective of scholars and stakeholders who could establish appropriate metrics and criteria that must be met to terminate public health emergencies and provide clarity regarding intended and potential unintended consequences.[303] Since there is no "one size fits all" public health emergency, this approach is more effective

300. A critique of the WHO is outside the scope of this article. WHO resources and communications, however, reflect an ongoing attempt to strengthen the global coalition for future pandemics. For example, the WHO's 194 member states have agreed to draft a new pandemic accord on preparedness and response, which works to improve aspects of global response and collaboration, including the application of International Health Regulations. *See Pandemic Prevention, Preparedness, and Response Accord*, WORLD HEALTH ORG. (June 28, 2023), https://www.who.int/news-room/questions-and-answers/item/pandemic-prevention--preparedness-and-response-accord.

301. *See* Mello & Gostin, *supra* note 86, at 321.

302. Iwry, *supra* note 88. Iwry suggestions a checklist of general questions relevant to the process:

- Should the product in question be made available on a conditional basis to a specific population or sub-population?
- Would making the product widely available interfere with FDA's ability to complete its ordinary investigative protocol—for example, by eliminating an incentive to volunteer for clinical trials?
- What, given the circumstances, is the risk of political interference with the EUA process, both in deciding whether to grant an EUA and in determining how it would be applied?
- What precedent would a given EUA set for future FDA decision making?
- What effect would the circumstances surrounding a given EUA have on public trust in FDA and willingness to comply with public health guidance, regarding both the emergency at issue and future emergencies?

Id.

303. *See* Jeffry V. Lazarus et al., *A Multinational Delphi Consensus to End the COVID-19 Public Health Threat*, 611 NATURE 332 (2022).

than simply enacting a variety of reactive and restrictive legislation that could work to undermine public health responses.[304]

Public health emergencies are necessarily complex problems—understanding the nature of public health emergencies, their vast implications on the different aspects of day-to-day life, as well as their effect on different populations requires multiple perspectives. For instance, while someone with expertise in infectious diseases can provide critical insight concerning disease transmission and progression, they may have, as Mello and Gostin note, a "narrower mission"[305] and may not be able to appropriately assess how a public health measure may affect hourly wage earners' employment and ability to put food on the table, or the effects of any given measure on how children learn or how the supply chain runs. As we saw during the COVID-19 pandemic, some public health challenges, even when successfully navigated, exacted a tremendous psychological toll on society, including stress, anxiety, anger, fear, grief, social isolation, and post-traumatic stress.[306]

Having a range of diverse perspectives can provide recommendations that will more effectively balance competing interests and help decision-makers pinpoint appropriate timing for declaring and ending the public health emergency, which will minimize the unintended consequences of premature terminations of emergencies by allowing necessary support structures that exist outside of emergency powers to be sufficiently ramped up. Existing policies generally favor one of two extremes: lengthy unfettered executive public health emergency powers or enacting strict legislative limitations on executive authority. It may prevent public health emergencies from becoming "overripe" or too lengthy, or being subject to strident partisan stances. In addition, diverse perspectives necessarily foster creativity and innovation.[307] For example, experts in technology innovation may help effectively harness technology to contain and mitigate the public health emergency, while also supporting privacy interests.

304. *See* PROPOSED LIMITS ON PUBLIC HEALTH AUTHORITY, *supra* note 49; LEVIN ET AL., *supra* note 220; THE COVID CRISIS GRP., *supra* note 86, at 295 ("Our emphasis on the federal executive role is not a call for a federal monopoly on the national health security enterprise. It is a call to rebalance its management to make it more national, more operational, and less fragmented.").

305. Mello & Gostin, *supra* note 86, at 321.

306. *See, e.g.*, Arthur C. Evans & Lynn F. Bufka, *The Critical Need for a Population Health Approach: Addressing the Nation's Behavioral Health During the COVID-19 Pandemic and Beyond*, 17 PREVENTING CHRONIC DISEASE 1, 1–5 (2020).

307. *See generally*, Kara L. Hall et al., *Moving the Science of Team Science Forward: Collaboration and Creativity*, 35 AM. J. PREVENTIVE MED. S243 (2008).

Embedding ethicists,[308] community members with relevant lived experiences, and a diverse group of other relevant stakeholders on public health planning teams may prevent those in authority from relying on tactics that erode trust, undermine efforts to curb the spread of disease, and perpetuate injustice. In other words, creating felicity conditions in the planning process for public health emergencies could help promote trust and "perceived legitimacy"[309] that the measure is necessary and uses the least restrictive means given the circumstances.

CONCLUSION

Declarations and terminations of public health emergencies are performative utterances that shift the balance of governmental power and can change our world. They can provide and then extinguish the ability to provide grants and funding, deploy the military, waive and modify regulatory requirements, and curtail civil liberties, many times with limited legislative oversight.[310]

However, public health emergency laws at every level are inconsistent at best and are being legislated in a reactionary manner that may limit the ability to effectively respond in future public health emergencies.[311] While the new MPHEA is a step in the right direction, at least concerning the states, with such high stakes and during a time when long-standing executive agency authority is evolving, appropriate guidance on the felicity conditions for performative utterances is urgently needed.[312] Instead of simply accepting lengthy unfettered executive public health emergency powers or enacting strict legislative limitations on executive authority that could hinder an effective public health response, a diverse, multi-disciplinary team of scholars and stakeholders should examine the existing web of public health emergency legislation and provide input and guidance on felicity conditions for declaring, continuing, and terminating specific public health emergencies that build in mechanisms for accountability and relevant, appropriate checks and balances.[313]

308. Ezekiel J. Emanuel et al., *What Covid Has Taught the World About Ethics*, 387 NEW ENG. J. MED. 1542, 1542 (2022) ("Ethical guidance can make policymakers aware of this knowledge and help them to navigate trade-offs among ethical values and implement ethical principles in future health emergencies.").

309. Mello & Gostin, *supra* note 86, at 320.

310. *See supra* notes 21, 23 (discussing a Brennan Center report on presidential emergency powers).

311. *See supra* Part II.

312. *See supra* Sections III.A–B.

313. *See supra* Section III.C.

Appendix: Commonly Used Acronyms

Coronavirus Aid, Relief, and Economic Security Act	CARES
Centers for Disease Control	CDC
Children's Health Insurance Program	CHIP
Countermeasures Injury Compensation Program	CICP
Department of Defense	DoD
Food and Drug Administration	FDA
Health & Human Services	HHS
International Health Regulations	IHR
International Health Regulation Emergency Committee	IHREC
Office of the Assistant Secretary for Preparedness & Response	ASPR
Office of Public Health Emergency Preparedness	PHEP
The Model Public Health Emergency Authority Act	MPHEA
The Model State Emergency Health Powers Act	MSEHPA
Paycheck Protection Program	PPP
Public Health Emergency	PHE
Public Health Emergency of International Concern	PHEIC
Public Health Services Act	PHSA
Public Readiness and Emergency Preparedness Act	PREP
Respiratory Syncytial Virus	RSV
World Health Organization	WHO