Vaccine-Related Liability: Past Approaches, Current Challenges, and Proposals for Encouraging Future Innovation and More Widespread Vaccine Use

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ABSTRACT

Scientists, governments, and pharmaceutical companies face significant obstacles to global adoption of COVID-19 vaccines. Chief among these challenges are public fear of vaccine-related injury and manufacturers' fears of liability arising from those injuries. Through the lens of the COVID-19 pandemic, we explore the history and current landscape of liability related to vaccines, and we propose potential solutions to the challenges of ensuring widespread adoption of vaccines.

Part II provides background on vaccine development, discussing the challenges of achieving herd immunity—a situation in which sufficient numbers of a community are vaccinated and thus immune, leading to containment or eradication of an infectious disease—and the history of and obstacles to implementing mandatory vaccination policies in the United States and around the world.

Against this historical backdrop, Part III summarizes and critiques the steps taken in the United States and globally to address liability related to the development and release of vaccines, including for COVID-19. It describes how vaccine-related liability has discouraged pharmaceutical companies from developing vaccines and how various countries have mitigated this risk and spurred innovation by establishing vaccine injury compensation programs. Part III discusses the Vaccine Injury Compensation Program (VICP) in the United States, which compensates people injured by vaccines, and no-fault vaccine compensation regimes that other countries around the world have implemented. And it discusses the invocation of the Public Health Emergency Preparedness Act (PREP Act) and the issuance of Declarations by the Secretary of Health and Human Services in response to the COVID-19 pandemic as a way to provide immunity to vaccine manufacturers. Although PREP provides expansive immunity, it does not prevent litigants from bringing suit, and those invoking PREP will have to litigate their entitlement to its protections. Finally, Part III discusses vaccine liability in the context of three previous pandemics: H1N1, Ebola, and Dengue fever in the Philippines.

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Part IV provides an overview of the skepticism about the effectiveness and safety of vaccines, exploring historical examples of vaccine controversy. In particular, it discusses public perceptions of vaccines and the impact of the decision by the Centers for Disease Control and Prevention (CDC) to withdraw its recommendation for the RotaShield vaccine.

Finally, Part V offers recommendations aimed at establishing a more effective injury compensation regime designed to encourage innovation and swift adoption of vaccines and other pandemic responses. In this section, we discuss the importance of global coordination in limiting liability. We propose three strategies for establishing a global vaccine-injury compensation scheme: a global treaty, a third-party intermediary declaration modeled after the PREP Act, and letters of agreement modeled after the response to H1N1. In addition, in the United States, we recommend reforms to the VICP so that this system can accommodate claims related to COVID-19 vaccines. To ensure the prompt adoption of effective vaccines so as to achieve herd immunity, we recommend developing enforceable and near-mandatory vaccination requirements. And we propose strategies for addressing two related hurdles that have previously stymied vaccine development and pandemic preparedness: global amnesia, which describes the collective forgetting of key details of a public health crisis once a situation has resolved, and hindsight bias, which describes the tendency to misjudge, after-the-fact, the challenges and uncertainties experienced during a crisis.

I. INTRODUCTION

The global COVID-19 pandemic has reaffirmed two truisms: nature remains the most powerful bioterrorist we know, and a virus does not care about or respect local or national borders. The world was largely unprepared for the COVID-19 pandemic, even though for decades epidemiologists have been sounding the alarm that a pandemic caused by a vaccine-preventable infectious disease was imminent. In 2002, infectious diseases accounted for about 26% of the 57 million deaths worldwide that year. Noting as much in a speech in 2005, Dr. Anthony Fauci, Director of the United States' National Institute of Allergy and Infectious Diseases at the National Institutes of Health, posed a rhetorical question that remains as relevant today as it was then: what decision will pharmaceutical companies make when faced with the choice between developing treatments for known chronic ailments and investing hundreds of millions of dollars in an emerging pathogen?[1]

Indeed, the severe acute respiratory syndrome (SARS)[2] epidemic of 2002 and 2003 should have served as a potent warning that global interdependence has made it inevitable that infectious diseases will spread rapidly around the world. SARS is caused by a coronavirus strain that was the most severe coronavirus known to science prior to the discovery of SARS-CoV-2, or as we all now know it, COVID-19.[3] The SARS epidemic lasted from November 2002 to July 2003, infecting more than 8,000

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[1] Bernard Avishai, *The Case for a Coronavirus-Vaccine Bond*, NEW YORKER (Aug. 15, 2020), https://www.newyorker.com/news/daily-comment/the-case-for-a-coronavirus-vaccine-bond [https://perma.cc/T5T2-3U6].

[2] *Frequently Asked Questions About SARS*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/SARS/about/faq.html (last reviewed May 3, 2005) [https://perma.cc/U8S4-DGT2].

[3] Ajai A. Dandekar & Stanley Perlman, *Immunopathogenesis of Coronavirus Infections: Implications for SARS*, 5 NATURE REVS. IMMUNOLOGY 917–27 (2005).

people and killing 774.[4] SARS began in Guangdong province, China, and spread throughout Asia before making its way to Toronto via an airline passenger.[5] The speed and ease with which SARS spread highlighted the need for a global mechanism for responding to infectious disease threats by sharing information, developing vaccines, and initiating other necessary global health interventions.

Vaccination is one of the most effective tools in the world's public health arsenal; vaccines are both cost-effective and medically efficacious. According to World Health Organization (WHO) estimates, vaccines prevent 4 to 5 million deaths per year.[6] The United States' National Vaccine Advisory Committee (NVAC) has reported that for "each [United States] birth cohort vaccinated against 13 diseases in accordance with the routine childhood immunization schedule, $13.6 billion in direct medical costs and 42,000 lives are saved, and 20 million cases of disease are prevented."[7] As these figures demonstrate, vaccines play an important role in improving health outcomes and reducing childhood mortality rates. Despite vaccines' proven effectiveness, the vaccine development systems in the United States and throughout the world are lacking, in part because of the high costs of such systems, including complex legal liability issues that disincentivize vaccine development.

Given their proven effectiveness at preventing infectious diseases, vaccines are being touted as the way to conquer COVID-19 and return the world to "normal."[8] At the time of this writing, in March 2021, the vaccine rollout of several effective COVID-19 vaccines is underway and has shown promising results.[9] In the United States, which, by March 2021, had issued emergency use authorization for three vaccines—Pfizer-BioNTech, Moderna, and Johnson & Johnson[10]—prospects for a

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[4] *Frequently Asked Questions About SARS*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/SARS/about/faq.html (last reviewed May 3, 2005) [https://perma.cc/82K5-B9W8].

[5] Peter A. Singer, Solomon R. Benatar, Mark Bernstein, Abdallah S. Daar, Bernard M. Dickens, William M. Scholl, Susan K. MacRae, Ross E.G. Upshur, Linda Wright & Randi Zlotnik Shaul, *Ethics and SARS: Lessons from Toronto*, 327 BMJ, 1342, 1343 (2003) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC286332/ [https://perma.cc/H7NY-Y25X].

[6] *Immunization Coverage*, WORLD HEALTH ORG. (July 15, 2020), https://www.who.int/en/news-room/fact-sheets/detail/immunization-coverage [https://perma.cc/H9UB-NP79].

[7] Nat'l Vaccine Advisory Comm., *Protecting the Public's Health: Critical Functions of the Section 317 Immunization Program-A report of the National Vaccine Advisory Committee*, 128 PUB. HEALTH REP. 78–95 (2013).

[8] *See, e.g.*, Adam Finn & Richard Malley, *A Vaccine That Stops Covid-19 Won't Be Enough*, N.Y. TIMES (Aug. 24, 2020), https://www.nytimes.com/2020/08/24/opinion/coronavirus-vaccine-prevention.html [https://perma.cc/JAU6-B5QR]; Alvin Powell, *Vaccines Can Get Us to Herd Immunity, Despite the Variants*, HARVARD GAZETTE (Feb. 25, 2021), https://news.harvard.edu/gazette/story/2021/02/vaccines-should-end-the-pandemic-despite-the-variants-say-experts/ [https://perma.cc/AKC4-G7GX].

[9] *See* Josh Holder, *Tracking Coronavirus Vaccinations Around the World*, N.Y. TIMES (updated May 18, 2021), https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html [https://perma.cc/T2C9-5LCV]; Ido Efrati, *Fewer Deaths, Less Infection: Israel Sees Improvement on All COVID Fronts*, HAARETZ (Mar. 10, 2021), https://www.haaretz.com/israel-news/israel-sees-lowest-rates-of-positive-covid-tests-since-december-1.9607180 [https://perma.cc/XSC9-G4G2].

[10] *See, e.g.*, *Pfizer-BioNTech COVID-19 Vaccine*, U.S. FOOD & DRUG ADMIN. (Dec. 18, 2020), https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine [https://perma.cc/K836-4RFG]; Denise Grady, Abby Goodnough & Noah Weiland, *F.D.A. Authorizes Moderna Vaccine, Adding Millions of Doses to U.S. Supply*, N.Y. TIMES (Dec. 18, 2020), https://www.nytimes.com/2020/12/18/health/covid-vaccine-fda-moderna.html [https://perma.cc/T95S-T84S]; Press Release, U.S. Food & Drug Admin., *FDA Issues Emergency Use Authorization for Third*

return to normal began to rise as vaccine distribution and administration accelerated.[11] And there are more vaccine candidates in the pipeline,[12] with at least 115 vaccines[13] under development and, at least as of March 2021, ninety already in clinical trials.[14] In the United States, the politicization of discussions regarding vaccines and other COVID-19 issues has only exacerbated the legal liability issues that discourage vaccine development, and the willingness of individuals to receive COVID-19 vaccines when they become available.

A vaccine's full potential can be realized only when a high percentage of a community's members take the vaccine.[15] A high immunization rate vastly reduces a pathogen's prevalence by reducing its ability to pass from person to person.[16] It is also critical to reaching so-called "herd immunity," the term used to describe when a large proportion of a community is immune to a disease. Herd immunity is key to protecting vulnerable populations—like the immunocompromised, the elderly, and newborn infants—who cannot safely be vaccinated.[17] While it is difficult to quantify the societal benefit of achieving some herd immunity through widespread vaccination, that benefit cannot be overstated.

According to polls from the fall of 2020 and the spring of 2021, Americans' willingness to take an approved COVID-19 vaccine increased steadily over the course of the pandemic. By February 2021, after the rollout of the Pfizer, Moderna, and Johnson & Johnson vaccines, 71% of Americans said they were willing to take an approved COVID-19 vaccine, with the number trending in the right direction and up from 63% in December 2020 and 50% in September.[18] Commentators have suggested that vaccination rates far above 50% are needed to bring this pandemic to an end. In

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COVID-19 Vaccine (Feb. 27, 2021), https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine [https://perma.cc/LV32-KV2V].

[11] Domenico Montanaro & Chloee Weiner, *Biden Sets Goal of July 4th to 'Mark Independence' From Coronavirus*, NPR (Mar. 11, 2021), https://www.npr.org/sections/coronavirus-live-updates/2021/03/11/975420676/biden-to-address-the-nation-marking-1-year-of-coronavirus-pandemic [https://perma.cc/2LDM-MCLG].

[12] Lynne Peeples, *News Feature: Avoiding Pitfalls in the Pursuit of a COVID-19 Vaccine*, 117 PNAS 8218–21 (2020).

[13] Carolyn Y. Johnson, *Inside the Extraordinary Race to Invent a Coronavirus Vaccine*, WASH. POST (May 3, 2020), https://www.washingtonpost.com/science/2020/05/02/coronavirus-vaccine/ [https://perma.cc/3XU3-JXAT].

[14] Carl Zimmer, Jonathan Corum & Sui-Lee Wee, *Coronavirus Vaccine Tracker*, N.Y. TIMES, https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html (last updated July 6, 2021) [https://perma.cc/VLX4-SZJ4].

[15] Jan Hoffman, *How Anti-Vaccine Sentiment Took Hold in the United States*, N.Y. TIMES (Sept. 23, 2019), https://www.nytimes.com/2019/09/23/health/anti-vaccination-movement-us.html [https://perma.cc/G3LC-VFZ9].

[16] University of Oxford, *Herd Immunity (Herd Protection)*, VACCINE KNOWLEDGE PROJECT (Aug. 29, 2019), http://vk.ovg.ox.ac.uk/vk/herd-immunity [https://perma.cc/HLG5-LJ35]; But herd immunity does not protect from all vaccine-preventable diseases. For instance, herd immunity does not protect against diseases caused by bacteria found in the environment like tetanus. *Id.*

[17] *Id.*

[18] *See* Nicholas Nissen, *Americans' Willingness to get COVID-19 Vaccines Reaches Record High: Poll*, ABC NEWS (Feb. 10, 2021), https://abcnews.go.com/Health/americans-willingness-covid-19-vaccines-reaches-record-high/story?id=75807568 [https://perma.cc/7Q7Z-HQD3]; Megan Brenan, *Willingness to Get COVID-19 Vaccine Ticks Up to 63% in U.S.*, GALLUP (Dec. 8, 2020), https://news.gallup.com/poll/327425/willingness-covid-vaccine-ticks.aspx [https://perma.cc/3NU8-ZEU3].

other words, this country has a two-fold problem: developing a vaccine that is safe and effective, and then implementing strategies to ensure sufficient numbers of people get vaccinated quickly.[19]

This paper provides an overview of how vaccine-related liability has inhibited the development and adoption of vaccines and how various stakeholders have addressed these challenges. We also summarize measures taken to address vaccine-related liability during the COVID-19 pandemic and the merits of those approaches. We close by recommending structural solutions for encouraging the development and public acceptance of vaccines.

Part II provides a historical overview of challenges to vaccine development and mandatory vaccination policies. Part III evaluates vaccine-liability programs intended to mitigate vaccine liability risk and spur innovation. Part IV addresses challenges with vaccine adoption, and finally, Part V offers recommendations aimed at improving vaccine development and adoption.

II. BACKGROUND ON VACCINE DEVELOPMENT

Developing and bringing safe and effective vaccines to market is a challenging, complicated endeavor. Beyond the scientific challenges, regulatory hurdles and liability risks also present barriers to vaccine development and deployment. And, even after approval, there are major barriers to successful adoption and use of vaccines.

As just one example of the challenges facing global vaccine manufacturers, unlike most medical interventions, the success of a vaccine in the United States is dependent on the actions of not one, but two federal agencies—Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC). A vaccine, like any other medical intervention, must first be approved by FDA before it can be introduced to the public. But a vaccine's success is heavily dependent on CDC's recommendation about which populations should receive the licensed vaccine.[20] A CDC recommendation can take different forms, ranging from a short statement about use of the vaccine as a part of best practices, to a broad-ranging endorsement recommending that the vaccine be routinely administered to those identified in a target population.[21] A broad-ranging endorsement from the CDC is critical to a vaccine's success, both from a medical and a business perspective.[22]

The challenges of vaccine development are illustrated by the fate of vaccines for rotaviruses and SARS. RotaShield was a vaccine developed to prevent common but severe diarrheal diseases caused by rotaviruses, which are estimated to kill 215,000

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[19] Recent polling suggests that the COVID-19 vaccine has become part of the partisan, political vortex in the United States. *See* Caitlin Owens, *Concern about Republican Vaccine Hesitancy is Growing*, AXIOS (Mar. 15, 2021) (nearly half of Republican men indicated they would decline a vaccine if offered one), https://www.axios.com/concern-republican-coronavirus-vaccine-hesitancy-trump-6220b95e-f334-49c4-ad4f-854d5af6b76b.html [https://perma.cc/6DBJ-D9ZA].

[20] Jason L. Schwartz, *The First Rotavirus Vaccine and the Politics of Acceptable Risk*, 90 MILBANK QUARTERLY 278, 284 (2012), https://doi.org/10.1111/j.1468-0009.2012.00664.x [https://perma.cc/6DKL-5LRV].

[21] *Id.*

[22] *Id.*

children worldwide per year.[23] Wyeth, RotaShield's manufacturer, removed RotaShield from the market in October 1999, a mere fourteen months after it was licensed and seven months after CDC's Advisory Committee on Immunization Practices (ACIP) had recommended its routine administration for all infants. ACIP withdrew its recommendation for the routine administration of RotaShield after studies showed an increased risk of a serious side effect, intussusception,[24] after RotaShield was administered.[25] Although additional studies found that the risk of intussusception was significantly lower than had initially been believed, RotaShield never returned to market. Wyeth executives were reported as saying "you don't do trials with a vaccine that nobody would ever use."[26]

Thus, by both medical and commercial measures, RotaShield was not a success. Wyeth invested significant time and resources to develop and market RotaShield, which it believed would be routinely administered to all infants, only to have it withdrawn from the market about a year after its approval. In the end, the vaccine was on the market for a short period and was administered to a fraction of the infants expected.

With respect to SARS, a vaccine was never fully developed even though scientists and public health experts warned that more research was needed in advance of a future infectious disease outbreak.[27] One of the challenges that stymied vaccine development for a number of other infectious diseases, including SARS, dengue, and respiratory syncytial virus (RSV), is the phenomenon of "immune enhancement," by which some recipients of a vaccine develop a more severe form of the disease when later exposed to the virus than those who had not been vaccinated. In other words, the vaccine causes the immune system to overreact to a natural infection.[28] Scientists have cautioned that when developing and launching any COVID-19 vaccine, the researchers must carefully evaluate the danger of immune enhancement before releasing the vaccine to the public.[29]

The immune enhancement phenomenon was observed during the 1960s in a trial vaccine to treat RSV, a leading cause of respiratory illnesses in infants. A number of trial vaccine recipients became seriously ill when they were later infected naturally, and two toddlers died. The children's deaths ended the study of that vaccine and derailed research into RSV for many years. Indeed, the first RSV vaccine candidate since that 1960s vaccine is currently in clinical trials.[30] The immune enhancement phenomenon was also observed in a vaccine candidate for SARS; while the scientists believed they had identified a solution, the study ran out of funds before they could

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[23] *Rotavirus*, WORLD HEALTH ORG. (Dec. 2018), https://www.who.int/immunization/diseases/rotavirus/en/ [https://perma.cc/DVK7-VEWD].

[24] Intussusception is a form of bowel obstruction in which one segment of intestine telescopes inside of another. It is a serious condition that may require surgery. *Intussusception*, MAYO CLINIC (Nov. 6, 2018), https://www.mayoclinic.org/diseases-conditions/intussusception/symptoms-causes/syc-20351452 [https://perma.cc/QV9X-GUTS].

[25] Schwartz, *supra* note 20, at 290.

[26] *Id.* at 293.

[27] Dandekar & Perlman, *supra* note 3.

[28] Peeples, *supra* note 12.

[29] *Id.*

[30] *Id.*

confirm it. That was around the time that SARS stopped spreading and interest in a SARS vaccine waned.[31] The scientists who were working on the SARS vaccine believe that if they had received funding for clinical trials, COVID-19 vaccines could have been developed much more quickly; because SARS and COVID-19 are closely related coronavirus strains, much of the SARS research could have been applied to developing a COVID-19 vaccine.[32]

The fates of the RotaShield and SARS vaccines serve as cautionary tales for vaccine manufacturers. The ultimate failure of these two vaccines highlights the pitfalls of vaccine development, which ultimately create disincentives for manufacturers: vaccines are notoriously difficult to develop, vaccines can have deadly consequences, even an effective vaccine may not be adopted because of fears about side effects that create expensive litigation, and vaccines are not nearly as profitable as treatments for chronic illnesses. For these reasons, from a business standpoint, pharmaceutical companies are generally not inclined to invest in vaccine development.

A. The Challenge of Achieving Herd Immunity

The primary purpose and benefit of vaccines is to create immunity in an individual against a pathogen that may cause serious illness or death.[33] When sufficient numbers of individuals in a community are vaccinated and become immune, a pandemic can be contained, or an infectious disease eradicated. Despite this straightforward benefit, since their discovery, vaccines have always drawn opposition from portions of the population.[34] In their attempts to balance societal needs to contain or eliminate infectious pathogens with individual beliefs that oppose vaccination, governments have implemented an array of vaccination policies, ranging from compulsory to optional.

The United States' approach has primarily been to take a middle ground by adopting "mandatory" vaccination policies, which do not outright require vaccinations, but withhold certain benefits from people who are not vaccinated. As discussed *infra* Section II.D, jurisdictions throughout the United States permit some exemptions to vaccination policies for medical, religious, and philosophical beliefs. Other countries, notably Italy and France, have gone further, implementing compulsory vaccine policies that make it illegal to refuse a vaccine.[35] Indeed, after seeing a decrease in vaccination rates, France and Italy recently increased the number of vaccines on their compulsory vaccination list from three to eleven.[36]

This decrease in vaccination rates is partially attributable to an uptick in people around the world questioning the safety, value, and necessity of vaccines,[37] despite

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[31] The SARS and MERS outbreak waned before it could attract the investment needed to develop a vaccine. Avishai, *supra* note 1.

[32] *Id.*

[33] Samantha Vanderslott, Bernadeta Dadonaite & Max Roser, *Vaccination*, OUR WORLD IN DATA (revised Dec. 2019), https://ourworldindata.org/vaccination [https://perma.cc/FF6D-PDLR].

[34] *Id.*

[35] *Id.*

[36] *Id.*

[37] Barbara Loe Fisher, *Vaccination: What's Trust Got to Do with It?*, NAT'L VACCINE INFORMATION CTR. (Sept. 13, 2020), https://www.nvic.org/NVIC-Vaccine-News/September-2020/vaccination-whats-trust-got-to-do-with-it.aspx [https://perma.cc/6TKF-M2VC].

vaccines' proven effectiveness at preventing the spread of some of the world's most infectious and deadly diseases.

The public's move away from vaccines can be partially attributed to the increased focus in medical ethics on obtaining an individual patient's informed consent prior to a medical intervention.[38] "[I]nformed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention."[39] The requirements for what constitutes informed consent have become more onerous over time, as seen in the detailed consent forms that became common place for a time.

Recognizing that detailed consent forms were contributing to growing opposition to vaccines, the federal government loosened its informed consent requirements pursuant to the National Childhood Vaccine Injury Act of 1986 (NCVIA). The initial NCVIA informed consent protocol required that parents receive ten pieces of information in the Vaccine Information Materials (VIM) before consenting to their child receiving a vaccination. The actual document was twelve pages long and required the parent's signature.[40] The disclosure requirements were loosened, and the VIM was shortened after the American Academy of Pediatrics advised that the VIM was "too long" and that it "scared" parents away from having their children vaccinated.[41] In 1993, Congress passed legislation to enact the changes that pediatricians had recommended. As a result, today the VIM provides only four types of information to parents: the benefits of the vaccine, the risks, references to the VICP, and contact information for the CDC. The signature requirement was also repealed.[42]

This approach is consistent with the position of commentators who have argued that vaccines are public goods for which informed consent requirements are unworkable and not ethically required.[43] The argument follows that vaccines, like other public health measures such as food safety policies, cannot be tailored to individual choice. Thus, informed consent cannot be ethically required for public goods because it would be impossible to provide each person with an individual choice.[44] In practice, this view does not strip individuals of all choice; rather, the democratic process allows individuals with some collective choice as far as selecting policymakers or even by lobbying their representatives to enact certain policies.[45]

While loosening consent requirements for vaccines may seem in tension with modern medical ethics, this approach finds support in the theories of justice that

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[38] Onora O'Neill, *Informed Consent and Public Health*, 359 PHIL. TRANSACTIONS ROYAL SOC. LOND. B 1133 (2004), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1693386/pdf/15306401.pdf [https://perma.cc/SU54-T4ZE].

[39] *Informed Consent*, AM. MED. ASS'N, https://www.ama-assn.org/delivering-care/ethics/informed-consent (last visited Aug. 13, 2021) [https://perma.cc/Y8NL-ZD72].

[40] Mary Holland, *Compulsory Vaccination, the Constitution, and the Hepatitis B Mandate for Infants and Young Children*, 12 YALE J. HEALTH POL'Y L. & ETHICS 41, 79–80 (2012), https://digitalcommons.law.yale.edu/cgi/viewcontent.cgi?article=1194&context=yjhple [https://perma.cc/H73R-YGSQ].

[41] *Id.*

[42] *Id.*

[43] O'Neill, *supra* note 38, at 1135.

[44] *Id.*

[45] *Id.*

provide underpinnings for medical ethics.[46] In particular, John Stuart Mill's theory of justice has been used to support public health initiatives. Mill believed that "self-protection" is the "the sole end" that justifies humankind's interference "with the liberty of any of their number."[47] This rationale supports the view that it may be justified to compel those public health initiatives (e.g., vaccines) that are necessary to protect others.

Mill's theory seems especially relevant to the COVID-19 pandemic: it supports a mandatory vaccination policy for those who can safely receive a vaccine to protect those who cannot be vaccinated. COVID-19 is a deadly disease that will continue to kill many, and make many others very ill, until safe and effective vaccines are globally available and herd immunity is otherwise achieved.[48] Because we now have safe and effective vaccines for COVID-19, under Mill's view, mandating vaccination would be justified by the protection the vaccine offers to the population as a whole. Commentators relied on Mill's theory to justify a mandatory vaccine policy for an approved SARS vaccine.[49] The case for a mandatory COVID-19 vaccine is proving even stronger: COVID-19 is a more infectious disease, and the COVID-19 pandemic, as of July 2021, is responsible for more than 4 million deaths, compared to less than 800 deaths associated with SARS.[50]

B. Mandatory Vaccine Policies

Today in the United States, CDC recommends that eighteen vaccines be administered to all children between birth and the age of eighteen.[51] To ensure that these recommendations are followed, the federal government funds a program to offer vaccines at no cost to those without insurance coverage.[52] Further, each of the fifty states has its own mandatory school vaccination policy,[53] and certain other groups of

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[46] *Id.*

[47] *Id.* (quoting JOHN STUART MILL, ON LIBERTY 13 (1859)).

[48] Spencer Bokat-Lindell, *What if We Have to Wait Years for a Coronavirus Vaccine*, N.Y. TIMES (Sept. 10, 2020), https://www.nytimes.com/2020/09/10/opinion/coronavirus-vaccine-treatments.html [https://perma.cc/TZ3K-W85T].

[49] O'Neill, *supra* note 38, at 1135.

[50] Eskild Petersen, Marion Koopmans, Unyeong Go, Davidson H. Hamer, Nicola Petrosillo, Francesco Castelli, Merete Storgaard, Sulien Al Khalili & Lone Simonsen, *Comparing SARS-CoV-2 with SARS-CoV and Influenza Pandemics*, 20 LANCET 238, 238 (July 2020), https://www.thelancet.com/action/showPdf?pii=S1473-3099%2820%2930484-9 [https://perma.cc/N2ZF-LRNP]; *WHO Coronavirus (COVID-19) Dashboard*, WORLD HEALTH ORG. (July 20, 2021), https://covid19.who.int/ [https://perma.cc/K32T-LY7A].

[51] *Recommended Vaccines by Age*, CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 22, 2016), https://www.cdc.gov/vaccines/vpd/vaccines-age.html [https://perma.cc/FM95-H7F4]; *Recommended Child and Adolescent Immunization Schedule for Ages 18 Years and Younger*, CTRS. FOR DISEASE CONTROL & PREVENTION (2020), https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf [https://perma.cc/M7TY-AXRJ].

[52] *Vaccines for Children Program (VFC)*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 18, 2016), https://www.cdc.gov/vaccines/programs/vfc/index.html [https://perma.cc/4DPY-8DLE].

[53] JARED P. COLE & KATHLEEN S. SWENDIMAN, CONG. RSCH. SERV., RS21414, MANDATORY VACCINATIONS: PRECEDENT AND CURRENT LAWS (May 21, 2014), https://fas.org/sgp/crs/misc/RS21414.pdf [https://perma.cc/QWU4-N33N].

people, like healthcare workers and military personnel, are also subject to vaccine mandates.[54]

In this Section, we discuss the jurisprudence that undergirds the country's mandatory vaccine policies. Next, we discuss the exceptions to mandatory vaccination policies, and finally, we discuss the federal programs designed to support the goal of widespread vaccination.

C. Case Law on Mandatory Vaccine Policies in the United States

One of the earliest decisions on mandatory vaccine policies was *Viemeister v. White*, handed down by New York State's Appellate Division and affirmed by the state's highest court. Relying on decisions from several other jurisdictions, *Viemeister* held that New York's mandate for school vaccination was consistent with the right, in the state's constitution, to a public education. The court reasoned that because the mandatory vaccine policy applied equally to all students, the policy comported with an individual's due process and equal protection rights under the state's constitution. It also suggested that courts owe great deference to the legislature on matters of public health policy.[55]

Approximately two years later, the U.S. Supreme Court upheld an early mandatory vaccine policy in what remains the landmark case on the issue, *Jacobson v. Massachusetts*. In *Jacobson*, the Supreme Court held that it was a proper exercise of states' police power to impose reasonable regulations to protect public health and public safety, even if those policies infringe on some individual liberties. *Jacobson* was a challenge to a Cambridge, Massachusetts regulation that compelled all adults to receive a smallpox vaccine or otherwise pay a five-dollar fine ($110 in today's dollars).[56] Mr. Jacobson brought suit against the state after refusing the smallpox vaccine and refusing to pay the fine. He argued that the regulation violated his rights under the Fifth and Fourteenth Amendments because it threatened his life, liberty, and property and deprived him of his due process rights and equal protection under the law. The crux of Mr. Jacobson's argument was that his personal liberty and right to bodily integrity outweighed the state's right to impose its mandatory vaccine policy for the sake of public health.

In upholding the Cambridge regulation, the Supreme Court reasoned that individual liberties were not unlimited, and states could exercise their police powers to protect public health and safety. The regulation did not violate the Fourteenth Amendment because it was "applicable equally to all in like condition."[57] The Supreme Court further reasoned that states (and their municipalities) had the power to enact reasonable regulations. It found that the Cambridge regulation was not "unreasonable, arbitrary, [or] oppressive" given the circumstances: the mandate required that all adults receive a single vaccine to prevent smallpox, a highly contagious and deadly disease during an epidemic, and the fine for noncompliance was de minimis.[58]

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[54] *Id.*

[55] Viemeister v. White, 88 A.D. 44, 45–46 (N.Y. App. Div. 1903).

[56] Holland, *supra* note 40, at 39, 45.

[57] Jacobson v. Massachusetts, 197 U.S. 11, 30 (1905).

[58] *Id.* at 26.

But the Court did not give state governments carte blanche authority to infringe on individual freedoms for the sake of public health or safety. Instead, the *Jacobson* Court held that it "would be cruel and inhuman in the last degree" to vaccinate a person who was unfit to receive a vaccine.[59] And thus, the medical exception to mandatory vaccination policies was born. The Supreme Court cautioned that it was the duty of the courts to evaluate state laws that are purportedly in furtherance of public health but in fact have "no real or substantial relation to those objects, or [are], beyond all question, a plain, palpable invasion of rights secured by the fundamental law."[60]

Prior to *Jacobson*, some courts had upheld mandatory vaccine policies (which were not pervasive at the time), including those that excluded unvaccinated children from school. The *Jacobson* decision solidified the view that mandatory vaccine policies were constitutional and paved the way for mandatory vaccine policies around the country.

Several years after *Jacobson*, the Supreme Court in *Zucht v. King* held that a mandatory smallpox vaccine requirement for school admission was a proper exercise of the state's police power. Relying on *Jacobson*, the Court denied the petitioner's claim that her Fifth and Fourteenth Amendment rights had been violated.[61] The Court reasoned that the vaccine mandate was not arbitrary; rather, it provided "only that broad discretion required for the protection of the public health."[62]

Zucht differed from *Jacobson* in that it broadened the scope of mandatory vaccination policies: it affirmed a vaccine policy that applied only to a subset of the population (children), and it affirmed the use of a mandate as a preventative measure even in the absence of an emergency situation, like an epidemic. In line with *Zucht*, many of today's mandatory school vaccination laws and policies were enacted in response to the measles outbreaks of the 1960s and 1970s.[63]

D. Exemptions to Mandatory Vaccine Policies

Jacobson paved the way not only for medical exemptions to vaccination requirements, but also for religious, philosophical, and conscientious belief exemptions. Today, all fifty states have medical exemptions to mandatory vaccine policies, while forty-five states and Washington, D.C. also have religious exemptions, and fifteen states have either philosophical or conscientious belief exemptions.[64]

The process for invoking an exemption to a vaccine policy varies from state to state. To invoke a medical exemption for a child, the most common process is for the parent or guardian to provide documentation from a physician establishing that the child is immunocompromised, allergic to the vaccine, ill at the time of vaccination, or otherwise has contraindications to the vaccine.[65] The requirements to invoke a

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[59] *Id.* at 38–39.

[60] *Id.* at 31.

[61] Zucht v. King, 260 U.S. 174, 176 (1922).

[62] *Id.* at 177.

[63] *See* Jared P. Cole & Kathleen S. Swendiman, *Mandatory Vaccinations: Precedent and Current Laws*, 17 NOVA SCI. PUBLISHERS 256, 258 (2014).

[64] NAT'L CONF. OF STATE LEGISLATORS, *States with Religious and Philosophical Exemptions from School Immunization Requirements* (June 26, 2020), https://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx [https://perma.cc/DU56-BJUL]; *see id.*

[65] *See* Cole & Swendiman, *supra* note 63, at 258.

religious exemption also vary across states, ranging from signing a simple statement invoking the religious exemption to signing a more detailed statement explaining that the child is a member of a certain religion that opposes immunization.[66] Members of all faiths, including recognized religions and less well-known religions, may invoke the religious exemption to a mandatory vaccine policy.[67] For certain vaccines, notably the HPV vaccine, some states also offer wide-ranging opt-out rights under the philosophical or conscientious belief rubric.[68]

E. Workplace Mandatory Vaccine Policies and Exemptions

In general, mandatory vaccine policies in the workplace require employees to receive certain vaccines unless they qualify for a medical or religious exemption under the Americans with Disabilities Act (ADA) or Title VII.[69] Workplace mandatory vaccine policies are common for healthcare professionals and members of the military but are less common in other settings.[70]

In October 2009, Equal Employment Opportunity Commission (EEOC) issued guidance on pandemic preparedness, declaring that mandatory flu vaccine policies that include medical and religious exemptions were permitted in the workplace. EEOC updated that guidance in March 2020 to address the COVID-19 pandemic, and in December 2020, it released updated and expanded guidance regarding vaccination and the workplace.[71] In its updated guidance, EEOC backtracked from its 2009 recommendation that employers avoid mandatory vaccination policies but did not outright endorse such a policy for the COVID-19 vaccine.[72] EEOC did, however, offer employers guidance on how an employer may impose a mandatory vaccination program consistent with the ADA and Rehabilitation Act protections for employees who, for medical reasons, cannot take the vaccine.[73] The guidance also states that Title VII's protections for a sincerely held religious belief apply to the COVID-19 vaccine.[74]

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66 *Id.*

67 *See* Sherr v. Northport-East Northport Union Free Sch. Dist., 672 F. Supp. 81 (E.D.N.Y. 1987) (invalidating a limitation on a religious exemption that required those invoking the exemption to be members of a "recognized religious organization" and finding that individuals, including plaintiffs, who sincerely hold religious beliefs that prohibit inoculation are covered by the exemption); Boone v. Boozman, 217 F. Supp. 2d. 938 (E.D. Ark. 2002) (invalidating a religious exemption on establishment and free exercise grounds); Berg v. Glen Cove City Sch. Dist., 853 F. Supp. 651, 654–55 (E.D.N.Y. 1994) (holding that a Jewish parent's "sincere religious belief" may support an exemption to a vaccine, even though the Jewish religion does not explicitly prohibit vaccinations).

68 *See* Va. Code § 32.1–46 (2014); D.C. Code § 7-1651.04(b) (2014).

69 U.S. EQUAL EMP. OPPORTUNITY COMM'N, PANDEMIC PREPAREDNESS IN THE WORKPLACE AND THE AMERICANS WITH DISABILITIES ACT (Mar. 21, 2020), https://www.eeoc.gov/laws/guidance/pandemic-preparedness-workplace-and-americans-disabilities-act [https://perma.cc/V6LP-HNHN].

70 *See* Cole & Swendiman, *supra* note 63, at 5, 10.

71 *See* Press Release, U.S. Equal Emp. Opportunity Comm'n, EEOC Issues Updated Covid-19 Technical Assistance Publication (Dec. 16, 2020), https://www.eeoc.gov/newsroom/eeoc-issues-updated-covid-19-technical-assistance-publication-3 [https://perma.cc/LA7K-NBJY].

72 *See What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws*, U.S. EQUAL EMP. OPPORTUNITY COMM'N (Dec. 16, 2020), https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws [https://perma.cc/743X-N5YE].

73 *Id.*

74 *Id.*

Outside of the COVID-19 context, at least one court has held that granting a nurse a religious exemption to a mandatory flu vaccination policy, while allowing her to keep her patient-centric job responsibilities, would have imposed an undue hardship on her employer.[75] Thus, plaintiff's request for the religious exemption accommodation was denied.[76]

Further, as discussed *supra* Section II.D, some states also permit philosophical and conscientious exemptions to mandatory vaccine policies. Thus, employers in those states may be required to allow employees to opt out of a mandatory vaccine policy based on philosophical or conscientious beliefs.

In light of the December 2020 EEOC guidance permitting employer-mandated vaccinations, several states have begun considering legislation that would shield employees from a vaccine requirement.[77] The measures range from prohibiting employer-mandated vaccinations to permitting them only in certain occupations or recognizing more exemptions.[78]

F. Federal Vaccination Programs

Two major programs are central to the federal government's immunization program: Vaccine for Children (VFC) and section 317 of Public Health Service Act (PHS Act). Both programs provide vaccines at no costs to those who qualify.[79] These programs ensure that routinely recommended vaccines are widely available to the public, especially children and adolescents.

VFC provides routinely recommended vaccines at no costs to children and adolescents who are Medicaid-eligible, American Indian or Alaska Native, and underinsured or uninsured.[80] PHS § 317, on the other hand, authorizes the federal government to purchase vaccines for the public. Historically, vaccines purchased pursuant to PHS § 317 were directed towards priority populations, especially those who were underinsured or uninsured. But PHS § 317's policy changed in response to the Affordable Care Act, which increased private and public insurance coverage for immunizations.[81] Now, PHS § 317-purchased vaccines will not be used for routine vaccinations for children and adults with insurance. Instead, PHS § 317 will be used

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[75] *See* Robinson v. Children's Hospital Boston, No. 14-10263, 2016 WL 1337255, at *5–10 (D. Mass. Apr. 5, 2016) (applying Title VII's undue burden standard and religious belief accommodation requests).

[76] *Id.* ("Had the Hospital permitted her to forgo the vaccine but keep her patient-care job, the Hospital could have put the health of vulnerable patients at risk. To allow Robinson to avoid relatively more vulnerable patients and not others would have been unworkable as well. It would have forced the Hospital to arrange its work flow around uncertain factors. On this record, accommodating Robinson's desire to be vaccine-free in her role would have been an undue hardship because it would have imposed more than a *de minimis* cost.") (citations omitted).

[77] Jenna Brofky, Natalie Holden, Reagan Kays, Zaina Niles & Lowell Pearson, *50 State Update on Pending Legislation Pertaining to Employer-Mandated Vaccinations*, JDSUPRA (Mar. 5, 2021), https://www.jdsupra.com/legalnews/50-state-update-on-pending-legislation-3726932/?origin=CEG&utm_source=CEG&utm_medium=email&utm_campaign=CustomEmailDigest&utm_term=jds-article&utm_content=article-link [https://perma.cc/K497-Y3TC].

[78] *Id.*

[79] *Questions Answered on Vaccines Purchased with 317 Funds*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 17, 2016), https://www.cdc.gov/vaccines/imz-managers/guides-pubs/qa-317-funds.html [https://perma.cc/NN6Q-4U3U].

[80] *Id.*

[81] *Id.*

to provide vaccines for those who do not have insurance coverage for vaccines, incarcerated individuals, certain newborns at risk of contracting hepatitis B, those affected by public health crises (such as an outbreak, disaster relief, post-exposure prophylaxis), and for mass vaccination campaigns.

Both programs are critical tools in the nation's immunization toolkit and will likely be tapped to support the mass-vaccination effort for COVID-19. Both programs act as stopgaps to ensure that vaccine costs are not impediments to the widespread vaccination that is needed to achieve and maintain herd immunity against the most infectious and dangerous diseases.

G. Vaccination Policies Around the World

Vaccination policies vary widely around the world. Globally, regimes range from comprehensive (covering a wide range of vaccines) to targeted (covering only a few vaccines) and have a range of enforcement mechanisms, including legal mandates and financial incentives.[82] As in the United States, some countries offer exemptions to their vaccine policies—the most common exemptions being for medical reasons—and a few countries also offer religious or conscientious beliefs exemptions.[83] In Finland, for example, while immunization is not mandatory, the country's voluntary program has proven effective. The Finnish vaccine program offers free vaccines, regular opportunities to receive vaccinations, a population monitoring system, and regulations requiring that healthcare providers offer counseling on vaccines.[84]

Slovenia, by contrast, has a mandatory vaccination program that has been described as "aggressive and comprehensive."[85] There, vaccines for nine diseases are compulsory: infants, within the first three months of life, are required to receive vaccinations for tuberculosis, tetanus, polio, pertussis, and Hemophilus influenza type B, and within eighteen months, infants must receive vaccinations for measles, mumps, and rubella.[86] Then, before starting school, children must receive the hepatitis B vaccine. The Slovenian vaccine program provides for medical exemptions, if approved by a committee, but no religious or conscientious exemptions are allowed. Parents are subject to a fine for noncompliance.[87]

Other European countries take a different approach. Belgium, for example, requires only the polio vaccine.[88] And in yet another approach, Australia does not make vaccination mandatory, but the government offers financial incentives to increase

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[82] *See, e.g.*, Katie Attwell, Shevaun Drislane & Julie Leask, *Mandatory Vaccination and No Fault Vaccine Injury Compensation Programs: An Identification of Country-Level Policies*, 37 VACCINE 2843–48 (2019); Erin Walkinshaw, *Mandatory Vaccinations: The International Landscape*, 183 CMAJ E1167–68 (2011); Katie Gravagna, Andy Becker, Robert, Valeris-Chancin, Inari Mohammed, Sailee Tambe, Fareed A. Swan, Traci L. Toomey & Nicole E. Basta, *Global Assessment of National Mandatory Vaccination Policies and Consequences of Non-Compliance*, 38 VACCINE 7865–73 (Oct. 2020).

[83] *See* Attwell et al., *supra* note 82.

[84] SABIN VACCINE INST., *Legal Provisions to Increase Vaccine Uptake: Case Studies Prepared for the Sabin European Workshop on Immunization Legislation* (Mar. 2017), https://www.sabin.org/sites/sabin.org/files/case_study-provisions_to_increase_uptake_0.pdf [https://perma.cc/96P6-VY9N].

[85] *See* Walkinshaw, *supra* note 82, at 1168.

[86] *Id.*

[87] *Id.*

[88] *Id.*

compliance, and unvaccinated children are barred from attending class during disease outbreaks.[89]

III. VACCINE MANUFACTURER LIABILITY PROTECTION PROGRAMS

Vaccine manufacturer liability protection programs also vary from country to country. In the United States, the two programs that provide liability protection to vaccine manufacturers are the Vaccine Injury Compensation Program (VICP) and the U.S. Public Readiness and Emergency Preparedness Act (PREP Act). In addition to the federally mandated VICP and the PREP Act, some states also have their own liability programs. Internationally, vaccine manufacturer liability programs vary widely from being non-existent in many countries to more robust, no-fault compensation programs in others. We discuss the importance of vaccine liability protection and vaccine manufacturer liability programs for each region mentioned in turn below.

A. The Case for Liability Protection

Liability protection for vaccine manufacturers serves an important public health purpose and is an essential component of ensuring development and widespread availability of vaccines. The threat of liability, if circumscribed, is a disincentive for pharmaceutical companies to invest in the development and production of vaccines. The unpredictability of the law, the potential for big damages payouts, and the negative press attention associated with product liability litigation all pose problems for potential vaccine manufacturers. The risk is greater, too, with vaccines, as opposed to medicines developed for specific conditions or diseases, because vaccines are intended to be widely distributed to the general public. Without protections, manufacturers are less inclined to think that the societal benefits of developing vaccines outweigh the potentially substantial costs. This may be especially true in developing countries, where the prices of vaccines are usually deeply discounted. Thus, revenue from sales of these vaccines contribute less to offsetting research and development costs.[90] In addition, the manufacturer is at risk for bearing litigation and compensation costs, which likely results in the manufacturer having less funds available to invest in necessary research.

B. The Vaccine Injury Compensation Program (VICP)

The VICP in the United States is a longstanding vaccine compensation fund that compensates people injured by vaccines. For a vaccine to be added to the Vaccine Injury Table (the list of covered vaccines under the VICP), CDC and the Secretary of the U.S. Department of Health and Human Services (HHS) must recommend it for the "routine administration to children," or the Secretary of HHS must go through an administrative process.[91] Either option can take months.

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[89] *Id.*

[90] *See, e.g.*, R. Gordon Douglas & Vjay B. Samant, *The Vaccine Industry*, PLOTKIN'S VACCINES, 2018, at 41–50, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7151793/ [https://perma.cc/5TVJ-VAWU]; Michael Kremer, *Pharmaceuticals and the Developing World*, 16 J. ECON. PERSPS. 67, 73 (2002).

[91] *See* 42 U.S.C. § 300aa-10 (1989); 42 U.S.C. § 300aa-14 (Dec. 13, 2016). The VICP was established in 1986 after vaccine manufacturers expressed strong concerns about the risk of tort lawsuits, a decline in

Once a vaccine is added to the table, individuals claiming an injury from that vaccine may file a petition for compensation with the Vaccine Court. A petitioner may file a claim in civil court against the vaccine company and/or the vaccine administrator, but only after first filing a claim under the VICP and then rejecting the decision of the Vaccine Court.

C. The U.S. Public Readiness and Emergency Preparedness Act (PREP ACT)

To address pandemics like COVID-19, the federal government invokes the PREP Act, which provides broad immunity to manufacturers of covered countermeasures. The PREP Act was enacted on December 30, 2005 as an amendment to the Public Health Service Act, PL 109-148, Div. C, §2.[92] Pursuant to the statute, the Secretary of HHS is authorized to issue a declaration in the Federal Register providing immunity from tort liability for claims of loss or injury caused by countermeasures against diseases or other threats to public health emergencies. The Secretary has broad discretion to decide what qualifies as a covered countermeasure. The PREP Act requires only that the Secretary consider the "desirability of encouraging the design, . . . packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of such countermeasure."[93]

If the Secretary determines that a disease, health condition, or other threat to health constitutes—or may in the future constitute—a public health emergency, the Secretary may then make a declaration recommending the administration or use of a covered countermeasure.[94] Although the Secretary's decision with respect to the scope or duration of a declaration is not subject to judicial review, the Secretary must notify the appropriate congressional committees within forty-eight hours of making a declaration and publish the declaration in the Federal Register.

A PREP Act declaration differs significantly from the determination of a public health emergency: a PREP Act declaration may be made in advance of a public health emergency and may provide liability immunity for activities both before and after a declared public health emergency.

1. Liability Immunity for Manufacturers

Immunity from liability under the PREP Act covers persons and entities involved in the manufacture, testing, distribution, administration, and use of covered

vaccination rates, and a resurgence of preventable diseases. *See Vaccine Injury Compensation Programs*, HIST. OF VACCINES (Jan. 17, 2018), https://ftp.historyofvaccines.org/index.php/content/articles/vaccine-injury-compensation-programs [https://perma.cc/6VWK-4C5B]; *see* James Hamblin, *Why the Government Pays Billions to People who Claim Injury by Vaccines*, THE ATLANTIC (May 14, 2019), https://www.theatlantic.com/health/archive/2019/05/vaccine-safety-program/589354/ [https://perma.cc/LX2V-PT45]. With the development of products liability law in the United States in the 1960s and 1970s vaccine, manufacturers became frequent targets for lawsuits related to both real and purported safety issues. *Id.* Congress established the VICP prompted by a crisis in the development specifically of pertussis vaccines. *Id.* Manufacturers faced a wave of lawsuits after reports that the vaccine caused encephalopathy. *Id.* This litigation resulted in a decline in the number of vaccine manufacturers in the United States—which prompted Congress to step in. *Id.*

92 Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d (2005).

93 42 U.S.C. § 247d-6d(b)(6).

94 42 U.S.C. § 247d(a).

countermeasures.[95] A "covered countermeasure" under the PREP Act must be a "qualified pandemic or epidemic product," or a "security countermeasure," or a drug, biological product, or device authorized for emergency use in accordance with the Federal Food, Drug, and Cosmetic Act (FDCA). A qualified pandemic product includes a drug, device, or biological product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause.[96] Any covered countermeasure, qualified pandemic or epidemic product, or security countermeasure must also be approved or cleared under the FDCA, licensed under the PHS Act, or authorized for emergency use under Sections 564, 564A, or 564B of the FDCA.

PREP Act immunity applies to claims arising from either 1) any arrangement with the federal government; or 2) any activity that is part of an authorized emergency response at the federal, regional, state, or local level.[97] Immunity under the PREP Act means that courts must dismiss claims brought against any entity or individual covered by the PREP Act. The immunity applies to losses sounding in tort or contract, as well as claims for loss relating to compliance with local, state, or federal laws, regulations, or other legal requirements. The immunity covers, but is not limited to, claims for death; physical, mental, or emotional injury, illness, disability, or condition or fear of any such injury, illness, disability or condition; and any need for medical monitoring; and property damage or loss, including business interruption loss.[98] While PREP Act immunity does not expressly extend to local laws, the PREP Act expressly preempts any state and local law that "is different from, or is in conflict with, any requirement applicable under [the PREP Act]."[99]

The PREP Act created a few exceptions to immunity, allowing liability in the following narrow circumstances: any action brought by the federal government—whether civil, criminal, or administrative; any action brought pursuant to federal law seeking equitable relief; or any claim arising out of willful misconduct. Willful misconduct is defined in the PREP Act as an act or failure to act that is taken: 1) intentionally to achieve a wrongful purpose; 2) knowingly without legal or factual justification; and 3) in disregard of a known or obvious risk that is so great as to make

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[95] The Coronavirus Aid, Relief and Economic Security Act, § 3103 (CARES Act), enacted on March 27, 2020, amended the PREP Act to authorize non-medical respiratory protective devices as covered countermeasures if they are approved by the National Institute for Occupational Safety and Health (NIOSH). If NIOSH approves a respiratory protective device, that device must still be subject to an emergency use authorization (EUA) issued by FDA. The CARES Act also revised the covered person definition to limit liability for volunteer healthcare professionals—whether or not they have administered a covered countermeasure. Under the CARES Act amendments to the PREP Act, qualified healthcare volunteers are not liable for the provision of healthcare services during the present public health emergency with respect to COVID-19. *Id.* at § 3215.

[96] 42 U.S.C. § 247d-6d(i)(7).

[97] Dep't of Health and Human Services, Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 58 Fed. Reg. 15198 (Mar. 17, 2020), https://www.govinfo.gov/content/pkg/FR-2020-03-17/pdf/2020-05484.pdf [https://perma.cc/Y75Z-D8WK]; *see also* 42 U.S.C. § 247d-6d(i)(2).

[98] 42 U.S.C. § 247(a)(2)(A)(i)–(iv).

[99] 42 U.S.C. § 247d-6d(b)(8)(A); *see also* 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 (May 19, 2020), https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-april-14-2020.pdf [hereinafter ADVISORY OPINION] [https://perma.cc/956Z-PFJ6].

it highly probable that the harm will outweigh the benefit. A plaintiff must prove all three of these conditions with clear and convincing evidence.[100]

The statute also carves out immunity from liability for foreign claims over which the United States has no jurisdiction. But immunity may be available for administration or use of a countermeasure outside the United States if the claim is based on events that take place in a United States territory, or the plaintiff can establish a link that makes it reasonable to apply United States' law to the claim.

2. Countermeasure Injury Compensation Program and Previous Uses

The PREP Act authorizes an emergency fund administered by the Health Resources and Services Administration (HRSA) via the Countermeasures Injury Compensation Program (CICP), which must be funded by a congressional appropriation. Congress does not have to make the appropriation for the Secretary to issue a declaration. The fund provides compensation to residents and healthcare workers for injuries directly caused by administration or use of a countermeasure covered by the Secretary's declaration. And, protection is granted irrespective of the method by which the vaccine is sold and distributed (i.e., through government contracts, hospitals, or pharmacies).

But compensation for injuries is more limited than the liability immunity afforded under the PREP Act. While the PREP Act provides immunity for claims sounding in tort or contract, the CICP provides compensation only for eligible claims of serious physical injury or death. The CICP does not compensate claims related to emotional injury, fear of injury, business losses, or other types of claims for which immunity is provided.

The HHS Secretary has previously utilized PREP Act declarations to provide immunity to manufacturers that developed vaccines to combat influenza. The original pandemic influenza vaccine declaration was published on January 26, 2007 and was amended and extended multiple times through 2012.[101] The HHS Secretary also issued a PREP Act declaration in response to the 2014 Ebola outbreak. That declaration has been amended several times, most recently in January 2019, and is effective through December 31, 2023.[102]

3. PREP Act Declaration in Response to the COVID-19 Pandemic

On March 17, 2020, the Secretary of HHS, invoking the PREP Act, issued a notice of Declaration providing "liability immunity for activities related to medical countermeasures against COVID-19."[103] The Declaration is in effect through the end of the emergency or October 1, 2024, whichever comes first.[104] Subsequently, over the

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[100] ADVISORY OPINION, *supra* note 99, at 2; *PREP Act Q&As*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Sept. 5, 2019), https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx [https://perma.cc/KU8W-ZBNN].

[101] *See, e.g.*, Pandemic Countermeasures, 72 Fed. Reg. 4710 (Feb. 1, 2007); Amendment to Public and Readiness and Emergency Act, 72 Fed. Reg. 67731 (Nov. 30, 2007); Pandemic Influenzas Vaccine—amendment, 73 Fed. Reg. 61871 (Oct. 17, 2008).

[102] *See* Ebola Vaccine Disease Vaccine—Amendment, 84 Fed. Reg. 764 (Jan. 31, 2019).

[103] *See* Declaration, 85 Fed. Reg, 15198 (Mar. 17, 2020).

[104] *Id.*

course of the pandemic, HHS issued several amendments to the Declaration, expanding and clarifying the scope of immunity under the PREP Act.

By invoking the PREP Act in March 2020, the Secretary of HHS afforded liability immunity to "Covered Persons," which initially included manufacturers and their officials, agents, and employees, among others, of "Covered Countermeasures," defined as "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product."[105] Covered countermeasures must also be a "qualified pandemic or epidemic product" drug, device, or biological product (including a vaccine) that is authorized for investigation or emergency use as defined in the PREP Act, the FDCA, and the PHS Act. Liability immunity was afforded to Covered Persons for "Recommended Activities" defined as the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures that arise out of federal agreements or activities arising from the public health and medical response following the emergency declaration that prescribes, administers, delivers, distributes, or dispenses the Covered Countermeasure.

PREP Act immunity applies a "reasonably could have believed" standard when determining whether a product is a Covered Countermeasure.[106] Thus, a "person or entity that otherwise meets the requirements for PREP Act immunity will not lose that immunity—even if the product is not a covered countermeasure—if that person or entity reasonably could have believed that the product was a covered countermeasure."[107] Therefore, the use of a prelicensed vaccine arising from an agreement with the federal government and/or by a public health or medical official would likely fall within the protections of the PREP Act.

The Secretary of HHS also authorized CICP to provide benefits to eligible individuals who sustain a serious physical injury or die as a direct result of the administration or use of a Covered Countermeasure, like a COVID-19 vaccine. When countermeasures are administered or used outside the United States, CICP applies only to otherwise eligible individuals at U.S. embassies, military installations abroad, and North Atlantic Treaty Organization (NATO) installations.

Through March 2021, the Secretary issued six separate amendments to the initial Declaration, expanding liability protections and clarifying their scope. For example, in August 2020, the Declaration was amended to provide liability protections to certain licensed pharmacists who order and administer, and pharmacy interns (who are acting under the supervision of a licensed pharmacist) who administer, any vaccine that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through eighteen.[108]

The December 3, 2020 amendment made a few notable changes. Prior to this amendment, to qualify as a pandemic or epidemic product, the product had to be 1)

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[105] *Id.*

[106] U.S. DEP'T. OF HEALTH & HUM. SERVS., ADVISORY OPINION ON THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT AND THE MARCH 10, 2020 DECLARATION ACT OF APRIL 17, 2020 1, 4 (2020) [hereinafter U.S. DEP'T. OF HEALTH & HUM. SERVS., ADVISORY OPINION].

[107] *Id.*

[108] 85 Fed. Reg. 52,136 (Aug. 24, 2020).

used for COVID-19; and 2) approved, licensed, or cleared by FDA; authorized under an Emergency Use Authorization (EUA); described in an Emergency Use Instruction (EUI); or used under either an Investigational New Drug (IND) application or an Investigational Device Exemption (IDE).[109] Therefore, a prelicensed vaccine could be considered a "qualified pandemic product" if it was being used pursuant to an IND or if the vaccine qualified for an IDE. Further, a vaccine manufacturer could specifically petition FDA for an emergency use authorization for a prelicensed vaccine[110] as another means of bringing a COVID-19 vaccine within the scope of the PREP Act. The December 3 amendment, however, expanded "Covered Countermeasures" to include "all qualified pandemic and epidemic products" and not merely those approved or authorized by FDA for combating COVID-19.[111] As to the distribution of a Covered Countermeasure specifically, the December 3 amendment expanded the protections, extending immunity to the distribution of otherwise-covered products and services even if there is no federal contract giving rise to that activity, provided certain conditions are met.[112] In addition, the amendment expressly adopted HHS Office of General Counsel's (OGC) Advisory Opinions regarding the scope of the PREP Act.[113]

Finally, two amendments in February 2021 further increased the category of individuals who receive liability protection under the PREP Act. These amendments broadened the liability protection provisions to cover additional categories of individuals involved in the rollout and administration of COVID-19 vaccines, including healthcare professionals whose licenses expired in the previous five years but have been granted special dispensation to administer the COVID-19 vaccines and other volunteers who are involved in the vaccination drive.[114]

4. Pre-PREP Act Mass Vaccination Cases

Prior to the creation of the VICP and the passage of the PREP Act, the issue of manufacturer liability for vaccine injuries was primarily in the purview of the courts. In 2011, the Supreme Court in *Bruesewitz v. Wyeth LLC* held that "the National Childhood Vaccine Injury Act preempts all design-defect claims against vaccine manufacturers arising from injury or death caused by vaccine side effects."[115] This suggests that other claims, including those arising from a COVID-19 vaccine against manufacturers, would be preempted and the immunity provisions would kick in to block state tort claims.[116] Thus, although most vaccine injuries are or will be adjudicated within the scope of the VICP or the PREP Act, we believe that the earlier

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[109] U.S. DEP'T. OF HEALTH & HUM. SERVS., ADVISORY OPINION, *supra* note 106, at 4.

[110] For details about the how to secure an Emergency Use Authorization, see U.S. FOOD & DRUG ADMIN., EMERGENCY USE AUTHORIZATION OF MEDICAL PRODUCTS AND RELATED AUTHORITIES (Jan. 2017), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities [https://perma.cc/K6FQ-MS4V].

[111] Amendment, 85 Fed. Reg. 79,190 (Dec. 9, 2020).

[112] *Id.*

[113] *Id.*

[114] Fifth Amendment to Act, 86 Fed. Reg. 7,873 (Feb. 2, 2021); Sixth Amendment to Act, 86 Fed. Reg. 9,516 (Feb. 16, 2021).

[115] Bruesewitz v. Wyeth, 562 U.S. 223, 250 (2011).

[116] *See, e.g.*, Garcia v. Welltower OpCo Group, No. SACV 20-02250JVS, 2021 WL 492581 at *9 (C.D. Cal. Feb. 10, 2021) (holding that the PREP Act preempts state law and that operators of a senior living facility were immune from suit).

cases remain persuasive, and could be controlling, if for some reason the PREP Act and eventually the VICP did not bar civil litigation stemming from a COVID-19 vaccine.

This earlier case law, which imposes a duty to warn on manufacturers, even as part of a mass vaccination campaign, underscores the importance of PREP Act immunity.

The most significant case is *Reyes v. Wyeth Laboratories*, which dealt with the oral polio vaccine.[117] In May 1970, after eight-month-old Anita Reyes received a dose of a Wyeth vaccine, she was diagnosed with paralytic poliomyelitis. Her father sued, alleging that the vaccine had caused his daughter's polio and that Wyeth was liable on account of its failure to warn. Wyeth appealed after a jury awarded $200,000 in damages. The Fifth Circuit held that although the vaccine was an "unavoidably unsafe" product—meaning that it could not be made "safe" no matter how carefully it was manufactured—Wyeth was liable for a failure to warn. Normally, as to prescription medicines, the duty to warn would be limited "to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use."[118] In this case, however, the vaccine was given by a nurse in a medical clinic, with no "individualized medical judgment interven[ing] between the manufacturer . . . and the ultimate consumer."[119] Because Wyeth either knew or had a reason to know that the vaccine would be administered in this manner, where there was no physician that could perform an "individualized balancing" of the vaccine's risks for a particular patient, Wyeth had a duty to warn the ultimate consumer.[120] The court held that this exception would apply notwithstanding the fact that the inoculation occurred during a "mass" vaccination or part of an "ongoing program."[121] This is the so-called "mass immunization" exception whereby the manufacturer has a duty to warn of the risks of the vaccine when it knows or has reason to know that health care providers would not be in an intermediary position to evaluate the risks on an individual basis, which includes a mass vaccination campaign.[122]

A more recent (but still pre-PREP Act) decision from the Third Circuit is *Mazur v. Merck & Co., Inc.*, which involved a mandatory school-based vaccination campaign, where school nurses performed the inoculations with no physicians present.[123] There, the court first reaffirmed that vaccines are "unavoidably unsafe" products and then concluded that the nurses administering the vaccine were not "learned intermediaries"

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[117] *See* Reyes v. Wyeth Lab'ys, 498 F.2d 1264, 1269 (5th Cir. 1974).

[118] *Id.* at 1275.

[119] *Id.* at 1276.

[120] *Id.*

[121] *Id.* at 1277.

[122] While the mass immunization exception does not have a robust common law following, courts have expanded it beyond the situation in Reyes. *Compare* Stanback v. Parke, Davis & Co., 657 F.2d 642, 646 (4th Cir. 1981) (explaining that mass immunization limitation is limited to a "small number of cases concerning injuries resulting from live virus polio vaccines" and a "special, nationwide immunization program"), *and* Walker v. Merck & Co., Inc., 648 F. Supp. 931, 934 (M.D. Ga. 1986) ("This court will not extend the [*Reyes*] . . . decision beyond [its] facts, as the exception to the learned intermediary rule established for polio cases is 'quite narrow and highly fact specific.'") (quoting *Stanback*, 657 F.2d at 647)), *with* Petty v. United States, 740 F.2d 1428, 1440 (8th Cir. 1984) (affirming that duty to warn extends to ultimate consumer in a mass-immunization case stemming from the swine flu vaccine), *and* Allison v. Merck & Co., Inc., 110 Nev. 762 (Sup. Ct. Nev. 1994) (holding same as to MMR vaccine).

[123] *See* Mazur v. Merck & Co., Inc., 964 F.2d 1348, 1361 (3d Cir. 1992).

that would shield Merck from having to provide specific warnings to the vaccine recipients. The court then took up the question whether Merck could satisfy its duty to warn in the context of a mass immunization program by contracting with CDC (which it had done) to inform uses of the risks of the vaccine directly. Ultimately, the court concluded that Merck could indeed so satisfy its duty and that it had acted reasonably by contracting with CDC, informing CDC of the risks of the vaccine and relying on CDC's guarantee that the vaccine would only be administered "after a meaningful warning had been provided" to recipients.[124]

These two cases and other pre-PREP Act case law have established, in general, that vaccines are "unavoidably unsafe" products that give rise to a manufacturer's duty to warn; that manufacturers have a duty to warn the recipient of the vaccine when there is no individualized "learned" intermediary independently evaluating the risks, even as part of a mass vaccination campaign; and that the manufacturer will be liable for a failure to warn notwithstanding any precautions it took, but that a manufacturer can avoid liability by properly contracting with the federal government to provide such information.

5. PREP Act Immunity Cases and COVID-19

It remains an open question how courts will assess the extent of the PREP Act immunity protections as they pertain to COVID-19, but a few early cases suggest a narrow reading of the statute. To date, there have only been a handful of cases that touch on the scope of PREP Act immunity as it relates to COVID-19.[125] Thus far, litigation has centered on subject matter jurisdiction in light of the PREP Act. For its part, HHS has taken an increasingly expansive view of federal jurisdiction under the PREP Act, asserting through an Advisory Opinion from HHS OGC and, most recently, through updated amendments to the Secretary's PREP Act Declaration, that the PREP Act is a complete preemption statute.[126] At least one court has deferred specifically to HHS's view, finding complete preemption (and ultimately immunity); other courts have taken a narrower view, however, finding no preemption.[127]

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[124] *Id.* at 1364.

[125] *See, e.g.*, Sherod v. Comprehensive Health Care Mgmt. Servs., No. 20CV1198, 2020 WL 6140474 at *5 (W.D. Pa. Oct. 16, 2020); Jackson v. Big Blue Healthcare, Inc., No. 2:20-cv-2259-HLT-JPO, 2020 WL 4815099 at *4 (D. Kan. Aug. 19, 2020); Maglioli v. Andover Subacute Rehab. Ctr. I, No. 20-6605(KM)(ESK), 2020 WL 4671091 at *528 (D.N.J. Aug. 12, 2020).

[126] For example, the fifth amendment to the PREP Act Declaration, issued January 28, 2021, explained HHS's view that "[t]he plain language of the PREP Act makes clear that there is complete preemption of state law as described . . . . Furthermore, preemption of State law is justified to respond to the nation-wide public health emergency caused by COVID-19 . . . ." *See* 86 Fed. Reg. 7,972–76 (2021); *see* U.S. DEP'T OF HEALTH & HUMAN SERVS., ADVISORY OPINION 21-01 ON THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT SCOPE OF PREEMPTION PROVISION (Jan. 18, 2021), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101081078-jo-advisory-opinion-prep-act-complete-preemption-01-08-2021-final-hhs-web.pdf [https://perma.cc/T2UN-WDPP].

[127] *Compare* Garcia v. Welltower OpCo Grp., No. SAVC 20-02250JVS (KESx), 2021 WL 492581, at *7 (C.D. Cal. Feb. 10, 2021) ("Given th[e] recent [HHS] guidance, the Court finds that the PREP Act provides for complete preemption."), *with* McCalebb (*In re* Estate of McCalebb) v. AG Lynwood, No. 2:20-cv-09746-SB-PVC, 2021 WL 911951, at *3 (C.D. Cal. Mar. 1, 2021) ("Deference to the Secretary's jurisdictional assertion is not due, and adherence to his conclusory assertion is not warranted . . . ."), *and* Dupervil v. All. Health Operations, No. 20-CV-4042 (PKC) (PK), 2021 WL 355137, at *10 (E.D.N.Y. Feb. 2, 2021) (rejecting complete preemption and "find[ing] that the [HHS] interpretation lacks the 'power to persuade'").

D. State Law Vaccine Liability Programs

As COVID-19 spread across the country in the spring and summer of 2020, many states enacted measures that limited liability for legal claims related to the pandemic. These laws and executive orders offer various and often sweeping protections to businesses, healthcare workers, and others involved in responding to the COVID-19 pandemic. Broadly speaking, they narrow the types of state law claims that plaintiffs can bring and under what circumstances, and make it more difficult for plaintiffs to prevail. In general, these liability protections are typically tied to a state's emergency declaration, applying retroactively and lasting until the declaration expires or is repealed (or a set period of time thereafter).[128] A few of these protections have been limited but, as of March 2021, most of them remained fully in place.[129] And into the fall and winter of 2020, states continued to add protections.[130]

One major area that states have provided liability protection is for claims sounding in premises liability. In Iowa, for example, a premises owner "shall not be liable" for "any injuries sustained from an individual's exposure to COVID-19" unless that owner "recklessly disregards a substantial and unnecessary risk" or "acts intentionally or with actual malice."[131] Likewise, in Utah, "a person is immune from civil liability for damages or an injury resulting from exposure of an individual to COVID-19 on the premises owned or operated by the person" unless there is "willful misconduct," "reckless infliction of harm," or "intentional infliction of harm."[132] Many other states have adopted similar language.[133]

Georgia's regime operates differently: the law creates a "rebuttable presumption of assumption of the risk" by a claimant when the owner of a premises issues a standard warning about the risk of COVID-19 and a waiver of liability for claims related to the "transmission, infection, exposure or potential exposure of COVID-19," excepting claims based on more serious conduct.[134]

States have also explicitly protected healthcare and medical workers from claims, limiting when and how plaintiffs can sue for COVID-19-related issues. For example, under New Jersey law, healthcare professionals "shall not be liable . . . for injury or death alleged to have been sustained as a result of an act or omission . . . in the course of providing medical services in support of the State's response to the outbreak . . . ."[135] This law extends to acts "undertaken in good faith . . . to support efforts to treat COVID-19 patients and to prevent the spread of COVID-19 . . . ."[136]

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[128] *E.g.*, Act of Jun. 24, 2020, S.L. 2020-89, 2020 N.C. Sess. Laws; S.B. S7506B, 2019–2020 Leg. (N.Y. 2020). *But see* S.B. 359, 2019–2020 Reg. Sess. § 4 (Ga. 2020) (sunsetting July 14, 2021).

[129] *See, e.g.*, *COVID-19 Survey of State Liability Reform*, KING & SPALDING, https://www.kslaw.com/pages/covid-19-survey-of-state-liability-reform [https://perma.cc/DFM9-EUQC].

[130] *See, e.g.*, *id.*

[131] S. File 2338, 83rd Gen. Assemb. § 6 (Iowa 2020).

[132] S.B. 3007, 2020 Third Special Sess. § 1 (Utah 2020).

[133] *E.g.*, S.B. 359, 2019–2020 Reg. Sess. § 3 (Ga. 2020) (limiting premises liability claims to "gross negligence, willful and wanton misconduct, reckless infliction of harm, or intentional infliction of harm" may proceed); Ala. Governor's Proclamation at 4 (May 8, 2020) (limiting claims to those stemming from "wanton, reckless, willful, or intentional misconduct").

[134] S.B. 359, 2019–2020 Reg. Sess. § 3 (Ga. 2020).

[135] S.B. 2333, 219th Legis. § 1c (N.J. 2020).

[136] *Id.*

But the law allows claims resulting from gross negligence.[137] Similarly, Oklahoma offers immunity protections to healthcare workers for acts "in the course of arranging for or providing COVID-19 healthcare services for the treatment of the person who was impacted by the decision," with similar exceptions for serious conduct.[138] New York passed a similar statute in April 2020, S. 7506, that extended immunity to activities relating to "arranging for" care or services to "prevent" COVID-19.[139]

State measures also extend, in some cases, to the manufacture and distribution of COVID-19-related medical supplies. Louisiana, for example, passed H.B. No. 826, which states that no one that "designs, manufacturers, labels, or distributes personal protective equipment in response to the COVID-19 public health emergency shall be liable for civil damages for injury or death caused by such personal protective equipment, unless such damages were caused by the gross negligence or willful or wanton misconduct."[140] This immunity broadly bars claims by any individual who "uses, employs, dispenses, or administers" such equipment for any resulting injury.[141]

Some states have also included so-called "safe harbor" provisions that protect businesses and other entities from claims where they have taken steps to follow governmental regulation and guidance when developing COVID-19-related operating procedures. For example, in Iowa, a person "shall not be held liable for civil damages for any injuries . . . if the act . . . was in substantial compliance or was consistent with any federal or state statute, regulation, order, or public health guidance related to COVID-19 that was applicable to the person or activity at issue at the time of the alleged exposure."[142] Mississippi's law goes further, extending immunity as long as a person "attempts in good faith to follow applicable public health guidance."[143]

State regimes vary in their degree of comprehensiveness and specificity. Utah, for example, has enacted a measure that concerns only premises liability and limits claims to those stemming from willful, reckless, or intentional actions.[144] North Carolina offers blanket immunity from COVID-19-related claims for individuals, businesses, and other entities for all claims other than those arising from "gross negligence, willful or wanton conduct, or intentional wrongdoing."[145] Similarly, Mississippi's liability-immunity bill provides wide-ranging liability protections—from premises liability to manufacturing and construction COVID-19-related liabilities.[146]

Some states have tried but failed to pass liability-shield legislation or have already begun to rescind or limit those protections. In Arizona, legislators had proposed a measure that would have allowed COVID-19-related lawsuits against businesses only with a showing of "gross negligence," but the legislative session ended in May 2020

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[137] *Id.*

[138] S.B. 300, 2020 Reg. Sess. § 1C (Okla. 2020).

[139] S.B. S7506B, 2019–2020 Leg. § 3082 (N.Y. 2020).

[140] H.B. 826, 2020 Reg. Sess. § 2 (La. 2020).

[141] *Id.*

[142] S. File 2338, 83rd Gen. Assemb. § 7 (Iowa 2020).

[143] S.B. 3049, 2020 Reg. Sess. § 3 (Miss. 2020).

[144] *See* S.B. 3007, 2020 3d Spec. Sess. (Utah 2020).

[145] *See* Act of June. 24, 2020, S.L. 2020-89, 2020 N.C. Sess. Laws § 1.

[146] *See* S.B. 3049, 2020 Reg. Sess. § 3 (Miss. 2020).

without enacting the measure.[147] In New York, Governor Andrew Cuomo signed S.8835, which retrenches prior liability protections by limiting their availability only to claims involving treatment and by narrowing the definition of "healthcare services" to refer only to the direct treatment of COVID-19.[148] Likewise, in Michigan, Governor Gretchen Whitmer rescinded her March 29, 2020 Executive Order (2020-30), which provided blanket immunity for healthcare professionals and facilities responding to COVID-19 and vetoed a bill that would have extended and expanded the immunity through the end of 2020.[149]

E. Approaches to Limiting Vaccine Liability Outside the United States

Currently, there is no international mechanism for limiting manufacturer or healthcare professional liability associated with the administration of vaccines. As of 2018, no-fault vaccine compensation programs are available in 25 of the 194 WHO member states (12.9%).[150] The specifics of claims processing and receiving compensation vary from country to country.

This section discusses the liability protections available in Canada, Europe, Africa, and Asia-Pacific. Each of these geographic areas presents challenges and varying legal structures to provide compensation for injuries resulting from prelicensed or licensed vaccines. For instance, countries' vaccine injury compensation programs vary widely: some programs cover only mandatory or recommended vaccines, while others cover all licensed vaccines, and still others cover only vaccines believed to have an associated risk.[151]

As discussed *infra* section V.A, the designation that a COVID-19 vaccine receives in the United States (e.g., recommended for the entire population or a subset of the population or suggested as a best practice[152]) is likely to influence the treatment such

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[147] *See* Howard Fischer, *Arizona Senate Ends Session, Doesn't Vote on COVID-19 Business-Liability Protection*, TUCSON.COM (May 27, 2020), https://tucson.com/news/state-and-regional/arizona-senate-ends-session-doesnt-vote-on-Covid-19-business-liability-protection/article_d54f4259-4f16-5d25-a98a-fd34e3e5f629.html [https://perma.cc/6DPM-YJYS].

[148] *See* S.B. S8835, 2019–2020 Leg. Sess. (N.Y. 2020); Emily Crowley, *New York Narrows COVID-19 Liability Protections in Healthcare*, JDSUPRA (Aug. 7, 2020), https://www.jdsupra.com/legalnews/new-york-narrows-Covid-19-liability-63790/ [https://perma.cc/LUC8-7VXF].

[149] *See* Craig Mauger, *Michigan Gov. Whitmer Vetoes Bill to Expand Legal Protections for Healthcare Industry*, DETROIT NEWS (Aug. 10, 2020), https://www.detroitnews.com/story/news/politics/2020/08/10/whitmer-vetoes-bill-expand-legal-protections-health-care-industry/3338802001/ [https://perma.cc/8XQV-K8JD].

[150] Randy G. Mungwira, Christine Guillard, Adiela Saldaña, Nobuhiko Okabe, Helen Petousis-Harris, Edinam Agbenu, Lance Rodewald & Patrick L.F. Zuber, *Global Landscape Analysis of No-Fault Compensation Programmes for Vaccine Injuries: A Review and Survey of Implementing Countries*, PLOS ONE (May 2020), https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0233334&type=printable [https://perma.cc/ZN3P-36SJ].

[151] *See* Clare Looker & Heath Kelly, *No-Fault Compensation Following Adverse Events Attributed to Vaccination: A Review of International Programmes*, WORLD HEALTH ORG. 3 (Mar. 21, 2011), https://www.who.int/bulletin/volumes/89/5/10-081901/en/ [https://perma.cc/CT83-AYSU].

[152] As to the three vaccines that first received emergency use authorization from FDA: Pfizer was cleared for individuals sixteen and up whereas Moderna and Johnson & Johnson were cleared for individuals eighteen and up. Helen Branswell & Rachel Cohrs, *FDA Authorizes Johnson & Johnson's Single-Dose Covid-19 Vaccine*, STAT (Feb. 28, 2021), https://www.statnews.com/2021/02/27/fda-authorizes-jnj-covid19-vaccine/ [https://perma.cc/P27A-VBXY].

a vaccine receives around the world, which would in turn affect the vaccine's inclusion in the vaccine injury compensation programs discussed below.

1. Canada

Québec is the only Canadian province that has a vaccine injury compensation program. In 1985, Québec introduced a no-fault Compensation for Victims of Vaccination Program.[153] For individuals who qualify, compensation is provided for "any victim of bodily injury caused by a voluntary vaccination against disease." The Program defines a "victim" as "the vaccinated person, a person having contracted the disease from a vaccinated person, [or] the fetus of either such persons" and defines "bodily injury" as a "serious permanent physical or mental injury, or death."[154]

2. Europe

No-fault vaccine compensation funds exist in fifteen European countries: Austria, Denmark, Finland, France, Germany, Hungary, Iceland, Italy, Latvia, Luxembourg, Norway, Russia, Slovenia, Sweden, Switzerland, and the United Kingdom.[155] Most of the European compensation funds were enacted legislatively and are operated by government departments. The specifics of claims processing and receiving compensation vary from country to country. But the European Court of Justice (ECJ) has the authority to review how EU law is applied in member states. In a recent French-based vaccine injury case, *W. v. Sanofi Pasteur MSD SNC*, the ECJ appears to have modified the burden of proof in vaccine-injury cases by holding that courts may consider "serious, specific and consistent evidence" regarding a vaccine injury, even if medical research has not yet established a connection.

Most European countries permit those who have suffered vaccine injuries to receive compensation either from a compensation fund or through the courts. For instance, France permits those injured by state-mandated vaccinations to receive compensation either from its vaccine injury fund or through the courts.[156] Denmark and the United Kingdom permit injured parties to seek compensation from both their vaccine-injury compensation programs and the courts.[157] Damage awards in the compensation programs are adjusted according to the amounts recovered in the court system.[158] Litigation risk arising from vaccine-related injuries in these jurisdictions remains high, which appears to have been a stumbling block in the European Union's efforts to secure supplies of the various COVID-19 vaccines.[159] The risk of litigation may be

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[153] *See* Quebec Public Health Act, Chapter VII, Division III, Compensation for Victims of Vaccination (June 14, 2020), http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=2&file=/S_2_2/S2_2_A.html [https://perma.cc/WU5E-MTV5].

[154] *Id.*

[155] Mungwira et al., *supra* note 150.

[156] *See* Looker & Kelly, *supra* note 151.

[157] *See* Vaccine Damage Payments Act 1979, c. 17 (UK), http://www.legislation.gov.uk/ukpga/1979/17/section/1 [https://perma.cc/E9DK-YL3Q]; *see also Vaccine Damage Payment: Overview*, GOV.UK, https://www.gov.uk/vaccine-damage-payment/overview. In the UK, victims may also go through the court system to receive compensation.

[158] Looker & Kelly, *supra* note 151, at 3.

[159] *See* Francesco Guarascio, *Limited Legal Protection for COVID Vaccine Makers Hampers EU Deals*, REUTERS (Aug. 26, 2020), https://www.reuters.com/article/us-health-coronavirus-eu-vaccines/limited-legal-protection-for-covid-vaccine-makers-hampers-eu-deals-idUSKBN25M0RQ [https://perma.cc/D4F7-C89S]; Francesco Guarascio, *COVID-19 Vaccine Makers See EU Shield Against Side-Effect*

related, at least in part, to vaccine skepticism being more pervasive in certain European countries, which may foster wider public distrust when it comes to vaccines and vaccine manufacturers.[160]

These issues may be playing out in real time with the AstraZeneca COVID-19 vaccine. After several reports of blood clots and abnormal bleeding in recipients of the AstraZeneca vaccine, a group of European countries briefly suspended their use in March 2021.[161] Vaccinations resumed, however, after European regulators declared the vaccine safe and effective, finding that the benefits of the AstraZeneca vaccine outweighed the risks.[162] Amidst the controversy, however, local prosecutors in Italy seized a batch of nearly 400,000 doses of the AstraZeneca shot following the death of a man hours after receiving the vaccine.[163] Beyond the perils of civil litigation, it goes without saying that the prospect of a criminal investigation and potential criminal penalties related to the adverse effects of a vaccine serve as a serious disincentive to future vaccine development.[164]

3. Africa[165]

In African countries, weaknesses in the legal systems present significant challenges to manufacturer immunity. For example, in Liberia, Sierra Leone, and Guinea, the legal systems in place are simply not equipped to handle large numbers of products liability lawsuits. In addition, the governments of several African countries have undergone dramatic shifts in recent years, which calls into question their abilities to consistently regulate and administer any kind of vaccine compensation funds. Given these considerations, it is difficult to assess the size and scope of the COVID-19

Claims, REUTERS (Sept. 22, 2020), https://www.reuters.com/article/us-health-coronavirus-eu-vaccine/covid-19-vaccine-makers-see-eu-shield-against-side-effect-claims-idUSKCN26D0TY [https://perma.cc/ZJP2-SS55].

[160] *See, e.g.*, Jillian Deutsch & Sarah Welton, *How Europe Fell Behind on Vaccines*, POLITICO (Jan. 27, 2021), https://www.politico.eu/article/europe-coronavirus-vaccine-struggle-pfizer-biontech-astrazeneca/ [https://perma.cc/V5EG-8NF3]; *see also* Katherine Ellen Foley, *Europe Has Never Been Confident in Covid-19 Vaccines*, QUARTZ (Mar. 17, 2021), https://qz.com/1984817/europe-lacked-confidence-in-covid-19-vaccines-even-before-astrazeneca/ [https://perma.cc/V4K3-59M2] ("Despite being one of the wealthiest countries to have access to Covid-19 vaccines, people living in some European countries have been among the least willing to take them, according to a[n] [October 2020] study . . . .").

[161] Loveday Morris, William Booth & Luisa Beck, *European Regulator Says AstraZeneca's Coronavirus Vaccine is 'Safe and Effective' but Link to Rare Blood Clots Cannot be Ruled Out*, WASH. POST (Mar. 18, 2021), https://www.washingtonpost.com/world/europe/astrazeneca-ema-blood-clots/2021/03/18/26e9ff4a-85ab-11eb-be4a-24b89f616f2c_story.html [https://perma.cc/8MMF-UJLR].

[162] Marc Santora, *Europe Lifts Vaccine Suspension as Virus Surge Brings New Lockdowns*, N.Y. TIMES (Mar. 19, 2021), https://www.nytimes.com/2021/03/19/world/europe/coronavirus-vaccine-europe-astrazeneca.html?action=click&module=Spotlight&pgtype=Homepage [https://perma.cc/manage/create?folder=7007-124397]; Silvia Amaro, *European Nations Resume Use of AstraZeneca Covid Vaccine After Regulator Signs Off*, CNBC (Mar. 18, 2021), https://www.cnbc.com/2021/03/18/ema-approves-astrazeneca-covid-vaccine-after-blood-clot-reports.html [https://perma.cc/Z55S-CW7Z].

[163] *Italy Prosecutors Seize Batch of AstraZeneca Vaccine After Death of Man*, REUTERS (Mar. 15, 2021), https://www.reuters.com/article/us-health-coronavirus-italy-astrazeneca/italy-prosecutors-seize-batch-of-astrazeneca-vaccine-after-death-of-man-idUSKBN2B71QQ [https://perma.cc/TNK5-WZPW].

[164] *See* discussion *infra* Section III.F.3 (discussing Dengvaxia-related liability in the Philippines).

[165] For purposes of clarity and succinctness, this Article addresses the geographic area of Africa as opposed to the individual countries within those areas.

vaccine product liability risk in Africa and how this risk could be managed, other than through the measures proposed below.

4. Asia-Pacific

The Asia-Pacific countries that have adopted no-fault vaccine compensation funds include Japan, New Zealand, Nepal, Republic of Korea, Taiwan (China), Thailand, and Vietnam.[166] In Japan, the fund covers all recommended vaccines, and in Taiwan all "routine and compulsory vaccines" are covered.[167] New Zealand offers broad coverage through an Accident Compensation Corporation (ACC), a statutory corporation that provides no-fault compensation for any personal injury or death caused by "accident," including vaccine-related injuries.[168]

F. Vaccine Liability: The H1N1 and Ebola Outbreaks, and Dengue Fever in the Philippines

Given what we know about no-fault compensation funds and their unavailability in many countries, manufacturers developing vaccines to address pandemics have used a variety of strategies to deal with the global litigation risk. To illustrate the complexities of trying to manage international vaccine-injury risks, we discuss the approaches undertaken during the H1N1 pandemic and Ebola outbreaks as well as Sanofi Pasteur's experience with liability arising from injuries associated with its Dengvaxia vaccine in the Philippines.

1. H1N1 Pandemic

During the H1N1 pandemic, WHO adopted a global framework called the Vaccine Deployment Initiative to deploy the H1N1 vaccine in coordination with governments, foundations, manufacturers, and distributors. In addition to its coordination function, the Deployment Initiative crafted legal agreements to immunize vaccine manufacturers and distributors from vaccine-injury liability and provided compensation for vaccine injuries.[169] Provisions limiting liability for manufacturers were included in Letters of Agreement between WHO and manufacturers. These Letters of Agreement established that in the event of any injuries resulting from the use of the vaccine, manufacturers were discharged from liability unless the injury was caused by a failure of the company to comply with current Good Manufacturing Practice (cGMP) standards. As a condition of receiving vaccines, each recipient-country's government signed these Letters of Agreement.

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166 Randy G. Mungwira, Christine Guillard, Adiela Saldaña, Nobuhiko Okabe, Helen Petousis-Harris, Edinam Agbenu, Lance Rodewald & Patrick L.F. Zuber, *Global Landscape Analysis of No-Fault Compensation Programmes for Vaccine Injuries: A Review and Survey of Implementing Countries*, PLOS ONE (May 2020), https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0233334&type=printable [https://perma.cc/Y7US-HULC].

167 *Id.*; *See* Ping-Cheng Wang, *Updates on Vaccine Injury Compensation Program in Taiwan and Program Evaluation*, 31 TAIWAN EPIDEMIOLOGY BULLETIN 149, 151 (2015), https://www.cdc.gov.tw/En/File/Get/nDYkbF-ODBJh7hLtNk5TUQ [https://perma.cc/7ETS-RG5C].

168 Mungwira et al., *supra* note 166.

169 *See* WORLD HEALTH ORG., REPORT OF THE WHO PANDEMIC INFLUENZA A (H1N1) VACCINE DEPLOYMENT INITIATIVE 9 (2012), http://www.who.int/influenza_vaccines_plan/resources/h1n1_deployment_report.pdf. [https://perma.cc/SW96-DFLA].

2. Ebola Outbreaks

The Democratic Republic of Congo and some countries in West Africa dealt with several Ebola outbreaks during 2014 and 2018. Public health officials were better prepared to handle the 2018 Ebola outbreaks than the 2014 outbreaks, in part because a vaccine had been developed to prevent infection in people who had likely been exposed to the disease.[170] Working with Merck and GAVI,[171] WHO distributed thousands of vaccines to front-line health workers and others who had contact with those infected.[172] The vaccines were purchased and distributed pursuant to an Advance Purchase Agreement between Merck and GAVI. The Asset Purchase Agreement included a number of provisions that were crucial to what has been described as a successful public health effort to distribute the 2018 Ebola vaccine. The most important of those provisions required GAVI's precommitment to purchasing a large number of vaccines once certain conditions were met; this provision limited Merck's financial risk and acted to incentivize Merck to develop and manufacture an emergency stockpile of its Ebola vaccine.[173]

3. Dengvaxia-Related Liability in the Philippines

Sanofi recently faced significant liabilities relating to injuries associated with Dengvaxia, its dengue fever vaccine. Public outrage arose, and the vaccine was pulled from the market after nineteen children, of the 830,000 who had received Dengvaxia, died of dengue. Sanofi eventually admitted that the vaccine could exacerbate cases of dengue in children never previously infected, which may have led to the children's deaths.[174]

Sanofi has made several financial concessions to resolve the situation, including reimbursing the Philippines $23 million for unused Dengvaxia doses and agreeing to cover costs for adverse events scientifically attributed to the vaccine. But Sanofi has refused to refund the $30 million the Philippines spent on administered Dengvaxia doses, because refunding the entire $30 million would imply that the vaccine was ineffective, and Sanofi maintains Dengvaxia's effectiveness.[175] Further, the Philippine

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[170] *See* Helen Branswell, *A Spot of Good News in an Ebola Crisis: Vaccine Supplies are Expected to Las*t, STAT (Jan. 22, 2019), https://www.statnews.com/2019/01/22/some-needed-good-news-on-ebola-vaccine-supplies-are-expected-to-last/ [https://perma.cc/BF26-ETUR].

[171] GAVI, the vaccine alliance, is an NGO whose mission is to improve access to new and under-used vaccines for some of the most vulnerable children around the globe. *See About our Alliance*, GAVI, https://www.gavi.org/our-alliance/about [https://perma.cc/3L6H-XQVB] (last updated Feb. 18. 2021).

[172] *Id.*; *Ebola Virus Disease–Democratic Republic of the Congo*, WORLD HEALTH ORG. (Sept. 7, 2018), http://www.who.int/csr/don/7-september-2018-ebola-drc/en/ [https://perma.cc/Z7F5-H85Q].

[173] *See Ebola Vaccine to Help Tackle DRC Outbreak*, GAVI (May 21, 2018), https://www.gavi.org/ebola-vaccine-to-help-tackle-drc-outbreak [https://perma.cc/G9DZ-SBAS].

[174] *See* Fatima Arkin, *Dengue Vaccine Fiasco Leads to Criminal Charges for Researcher in the Philippines*, SCIENCE (Apr. 24, 2019), https://www.sciencemag.org/news/2019/04/dengue-vaccine-fiasco-leads-criminal-charges-researcher-philippines# [https://perma.cc/SD84-EEKV]; *see also Antibody-Dependent Enhancement (ADE) and Vaccines*, CHILD.'S HOSP. OF PHILA., https://www.chop.edu/centers-programs/vaccine-education-center/vaccine-safety/antibody-dependent-enhancement-and-vaccines (last visited Dec. 28, 2020) [https://perma.cc/9STN-52Y8].

[175] *See* Angus Liu, *Sanofi Refuses to Refund Philippines for Used Dengvaxia, Saying to Do So Would Imply the Shot is Ineffective*, FIERCEPHARMA (Feb. 5, 2018), https://www.fiercepharma.com/vaccines/citing-bad-implication-sanofi-refuses-to-refund-philippines-for-used-dengvaxia [https://perma.cc/UU5Z-PQHV].

government has lodged criminal indictments for "reckless imprudence resulting in homicide" against several regulators, public health officials, and researchers involved with Dengvaxia, including current and former Sanofi officials.[176] The Dengvaxia-Philippines saga is a cautionary tale of the liability risks associated with vaccine-related injuries.

IV. CHALLENGES TO VACCINE ADOPTION

A. Skepticism about Effectiveness and Safety of Vaccines

Skepticism about the safety and efficacy of vaccines is not a new phenomenon. As early as the 1800s, when the smallpox vaccine was widely administered, a segment of the population opposed vaccines for hygienic, religious, and political reasons.[177] In the 1970s, another wave of vaccine opposition arose in response to neurological side effects associated with the Diphtheria-Tetanus-Pertussis (DTP) vaccine.[178]

The current resurgent vaccine-opposition movement, frequently called the "anti-vaxxer" movement, can be traced back to a paper published in 1998 by a British physician, Andrew Wakefield, that claimed a correlation between the measles-mumps-rubella (MMR) vaccine and autism.[179] Although that paper has since been retracted and its findings discredited, it remains influential in the anti-vaxxer movement.[180] Indeed, the view that vaccines caused autism reached the highest level of the U.S. government when a congressional leader expressed his belief that vaccines caused his grandchild's autism.[181] Starting in 1999, seven congressional hearings on vaccine safety were held, during which federal public health officials and other vaccine advocates were extensively questioned about vaccine safety.[182] In addition to government officials, celebrities also latched onto the findings from the Wakefield paper and used their platforms to spread the falsehood that vaccines cause autism or were otherwise unsafe.[183] This celebrity amplification fueled the politicization of

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[176] Karen Lema, *Philippines to Charge Officials of Sanofi, Government Over Dengue Vaccine*, REUTERS (Mar. 1, 2019), https://www.reuters.com/article/us-sanofi-fr-philippines/philippines-to-charge-officials-of-sanofi-government-over-dengue-vaccine-idUSKCN1QI41L [https://perma.cc/Y8U2-SVDP].

[177] Alexandra Minna Stern & Howard Markel, *The History of Vaccines and Immunization: Familiar Patterns, New Challenges*, 24 J. HEALTH AFFS. 611, 617 (2005), https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.24.3.611 [https://perma.cc/M42X-QRGH].

[178] Mussaret Bano Zaidi & Leopoldo Flores-Romo, *The Growing Threat of Vaccine Resistance: A Global Crisis*, 12 CURRENT TREATMENT OPTIONS INFECTIOUS DISEASES 122, 126 (2020).

[179] Jason L. Schwartz, *The First Rotavirus Vaccine and the Politics of Acceptable Risk*, 90 MILBANK QUARTERLY 278, 286 (2012), https://doi.org/10.1111/j.1468-0009.2012.00664.x [https://perma.cc/YT52-JJW5].

[180] *Id.*

[181] James Colgrove & Ronald Bayer, *Could It Happen Here? Vaccine Risk Controversies and the Specter of Derailment*, 24 J. HEALTH AFFS. 729, 734 (2005).

[182] *Id.*

[183] Karin Roberts, *When it Comes to Vaccines, Celebrities Often Call the Shots*, NBC NEWS (Oct. 28, 2018), https://www.nbcnews.com/health/health-care/when-it-comes-vaccines-celebrities-often-call-shots-n925156 [https://perma.cc/V76A-59EB].

vaccine administration and widespread anti-vaccine sentiments, bringing the anti-vaxxer movement to the mainstream.[184]

The current skepticism about the safety of vaccines cannot be ignored, and it is crucial that government leaders and public health officials carefully plan their messaging around COVID-19 vaccines. Even some vaccine researchers have voiced skepticism about COVID-19 vaccines, in part, because of the "warp speed" at which COVID-19 vaccines are being developed. Many in the public have called for transparency from the researchers and the government involved in the vaccine development and approval process.[185]

Public perception about the safety and effectiveness of a vaccine can determine whether the vaccine is ultimately successful. Public perception played a critical role in CDC's decision to withdraw its recommendation for the RotaShield, and in the decision of other international health authorities to reject it.[186] When the RotaShield decision was under consideration, CDC was accused of focusing on vaccine administration instead of vaccine safety.[187] CDC officials eventually acknowledged that the optics relating to infants dying because of RotaShield and public perception regarding CDC's handling of the issue drove their decision to withdraw RotaShield's recommendation as much as reservations about RotaShield's potential benefits.[188]

CDC's decision had international implications: once CDC withdrew its recommendation for RotaShield, the vaccine became politically nonviable in other countries, even though there was limited safety and efficacy data available internationally and rotavirus was a much more serious problem in many countries around the world than it was in the United States.[189] Further, after the WHO convened a meeting on the issue with rotavirus experts, that group determined that it was ethical to conduct further studies on RotaShield in foreign countries as long as special attention was paid to research subjects diagnosed with intussusception. Yet, those findings did nothing to quell the damage that was already done to RotaShield. One foreign health minister was quoted as saying that "if [RotaShield] was not good enough for U.S. kids, it was not good enough for our infants either."[190]

The importance of messaging in the adoption of public health measures is already playing out in the COVID-19 pandemic. For example, in the debate about whether to re-open schools for in-person learning, public health officials struggled to convince

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184 Jan Hoffman, *How Anti-Vaccine Sentiment Took Hold in the United States*, N.Y. TIMES (Sept. 23, 2019), https://www.nytimes.com/2019/09/23/health/anti-vaccination-movement-us.html [https://perma.cc/66Z3-CKT2].

185 Natalie Dean, *I'd Need Evidence Before I Got a Covid-19 Vaccine. It Doesn't Exist Yet*, N.Y. TIMES (Aug. 3, 2020), https://www.nytimes.com/2020/08/03/opinion/sunday/coronavirus-vaccine-efficacy-trials.html [https://perma.cc/32RQ-H2G3].

186 Schwartz, *supra* note 179, at 278.

187 *Id.*

188 *Id.*

189 *Id.* Some scientists concluded that the prevalence of RotaShield's most serious side effects had been overblown after further studies were conducted. They believed that RotaShield was a safe and effective vaccine in the fight against rotavirus. *Id.*

190 *Id.*

parents and teachers that it was safe to do so.[191] After months of strong messaging around taking proper precautions, like social distancing and wearing masks, many parents believed that the public schools were not able to comply with those recommendations to ensure their children's safety. An epidemiologist reviewing the issue found that the problem arose because the public health messaging never evolved from its focus on proper precautions to how those precautions would be implemented in schools to ensure the children and teachers' safety.[192]

The importance of messaging is also apparent in the recommendations around the use of masks. Mask usage is materially higher in states and municipalities where the messaging around their use is thorough, explanatory, consistent, and coupled with some penalty for non-use. Mask usage tends to be lower in municipalities where the practice is not mandatory and the messaging about the effectiveness of masks in the fight against COVID-19 is inconsistent and incomplete.[193] It bears mentioning that a century ago, use of masks and social distancing were credited with helping bring the 1918 Spanish Flu pandemic under control.[194]

It seems clear that if a significant number of Americans do not believe that any approved COVID-19 vaccine is safe and effective, then they are unlikely to accept such a vaccine, thereby undermining our ability to attain herd immunity and contain this pandemic.

V. IMPROVING VACCINE DEVELOPMENT AND ADOPTION

A. Coordinating Vaccine Policies Internationally

The ease with which SARS, Zika, and COVID-19 spread internationally demonstrates that consistent vaccination policies around the globe are critical to eradicating vaccine-preventable diseases. However, there is currently no international mechanism for limiting manufacturer or healthcare professional liability associated with the administration of vaccines. Limiting this liability is essential to incentivizing vaccine development. As noted earlier, no-fault vaccine compensation programs are available in only 25 of the 194 WHO member states, and the limited protections provided by these systems vary widely. As the leaders of some of the world's largest pharmaceutical companies working on developing a COVID-19 vaccine have acknowledged, stopping COVID-19 will take a global effort from multiple stakeholders including "governments, regulatory authorities, academia, NGOs and industry."[195]

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[191] Alec MacGillis, *The Students Left Behind by Remote Learning*, NEW YORKER (Oct. 5, 2020), https://www.newyorker.com/magazine/2020/10/05/the-students-left-behind-by-remote-learning [https://perma.cc/TK7E-7ZND].

[192] *Id.*

[193] *See* Josh Katz, Margot Sanger-Katz & Kevin Quealy, *A Detailed Map of Who is Wearing Masks in the U.S.*, N.Y. TIMES (July 17, 2020), https://www.nytimes.com/interactive/2020/07/17/upshot/coronavirus-face-mask-map.html [https://perma.cc/4RFK-GRPD].

[194] SANDRA OPDYCKE, THE FLU EPIDEMIC OF 1918: AMERICA'S EXPERIENCE IN THE GLOBAL HEALTH CRISIS 27, 29, 107–08 (2014).

[195] *NIH to Launch Public-Private Partnership to Speed COVID-19 Vaccine and Treatment Options*, NAT'L INSTS. OF HEALTH (Apr. 17, 2020), https://www.nih.gov/news-events/news-releases/nih-launch-public-private-partnership-speed-Covid-19-vaccine-treatment-options [https://perma.cc/FFQ6-BRT9].

The increased mobility of the world's population underscores the need for global coordination of vaccine policy. Prior to the COVID-19 pandemic, international travel had grown to unprecedented levels: between 1998 and 2018, international tourism expenditures grew by more than 300%,[196] while international tourism departures increased by more than 240%.[197] Although international travel was decimated by the COVID-19 pandemic, experts believe international travel will eventually rebound.[198] In fact, international travel began a resurgence[199] since the initial height of the pandemic, even as many travel restrictions remained in place.[200]

Governments and other stakeholders should recognize that, as seen with the SARS and COVID-19 pandemics, infectious diseases are a global problem that require global solutions. One means of tackling this problem is coordinating vaccination requirements to ensure that herd immunity is achieved on a global scale. Given recent travel trends, international borders are no longer an effective barrier to keeping diseases at bay, and countries around the world will remain at risk unless vaccine policies, including vaccine liability protections, are coordinated.

B. Limiting International Liability for a COVID-19 Vaccine

COVID-19 vaccines are being used globally, and as discussed above, liability protections vary greatly from country to country. Without a formal international or national compensation fund, the only source of compensation for a person who experiences a vaccine-related injury is a court system, which can be inequitable for the injured and unpredictable in terms of litigation costs. In this section, we discuss different approaches that could be undertaken to secure global protections for authorized (and future) COVID-19 vaccines.[201]

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[196] *International Tourism, Expenditures*, WORLD BANK, https://data.worldbank.org/indicator/ST.INT.XPND.CD [https://perma.cc/HJT5-UMCK] (last visited June 14, 2021).

[197] *International Tourism, Number of Departures*, WORLD BANK, https://data.worldbank.org/indicator/ST.INT.DPRT [https://perma.cc/M33L-J5NQ] (last visited June 14, 2021).

[198] *See, e.g.*, Andrew Jeong & Philip Wen, *Travel is Bouncing Back from Coronavirus, but Tourists Stick Close to Home*, WALL ST. J. (July 18, 2020), https://www.wsj.com/articles/travel-is-bouncing-back-from-coronavirus-but-tourists-stick-close-to-home-11595064589 [https://perma.cc/WK44-JMG6].

[199] According to the United Nations World Tourism Industry, the pandemic caused a 65% decrease in international travel during the first half of 2020. *See UN: Pandemic Causes 65% Drop in International Travel*, VOA NEWS (Sept. 15, 2020), https://learningenglish.voanews.com/a/un-coronavirus-pandemic-causes-65-drop-in-international-travel/5585972.html [https://perma.cc/TN45-WCE9]. *But see* Will Horton, *Corporate Travel Has Surprisingly Fast Rebound For One Airline In Early Indication Of Post-Covid Flying*, FORBES (Aug. 28, 2020), https://www.forbes.com/sites/willhorton1/2020/08/28/corporate-travel-has-surprisingly-fast-rebound-for-one-airline-in-early-indication-of-post-covid-flying/#1c48fec97a16 [https://perma.cc/D4XR-3CMF]; Tatiana Rokou, *Global 'State of the Market' Study Reveals Slow but Steady Rebound of Corporate Travel*, TRAVEL DAILY NEWS (Sept. 22, 2020), https://www.traveldailynews.com/post/global-state-of-the-market-study-reveals-slow-but-steady-rebound-of-corporate-travel [https://perma.cc/5A9K-T3JJ].

[200] *See, e.g.*, Niharika Mandhana & Rachel Pannett, *Covid-19 Travel Bubblers Were Set to Restore Flying but Haven't Taken Off*, WALL ST. J. (Oct. 14, 2020), https://www.wsj.com/articles/Covid-19-travel-bubbles-were-set-to-restore-flying-but-havent-taken-off-11602676868 [https://perma.cc/2U3A-JPN7].

[201] *See* John D. Winter, Cassye Cole & Jonah Wacholder, *Toward a Global Solution on Vaccine Liability and Compensation*, 74 FOOD & DRUG L.J. 1, 13 (2019). The aforementioned article first proposed some of the recommendations discussed herein. *See id.*

1. Global Treaty/Legislated Immunity

For vaccine manufacturers, the best solution is a regime of globally coordinated, treaty-based immunity for injuries sustained from any COVID-19 vaccine. Immunity would not be available, however, if the injury was caused by a company's failure to comply with current cGMP standards.

Precedents for a comprehensive international vaccine development treaty exist. For example, in 1996, a treaty established the International Vaccine Institute. This Institute was the result of an agreement by the Children's Vaccine Initiative (CVI), which is a coalition of governments, multilateral and bilateral agencies, NGOs, and industry dedicated to ensuring the availability of safe, effective, and affordable vaccines; encouraging the development and introduction of improved and new vaccines; and strengthening the capacity of developing countries in vaccine development, production and use of immunization programs. In addition, the treaty provides for privileges and immunities for members of the Institute when exercising official duties.

A global vaccine development and immunity treaty could take the form of a treaty among Member States of the United Nations that would provide manufacturers with liability protection across Member States, thereby encouraging vaccine development.[202] The treaty would provide for a waiver of liability for manufacturers that distribute vaccines within each UN Member State, in consideration of the company's vaccine development and deployment for the benefit of the global community. The treaty could spell out the overarching issues with vaccine testing, approval, and deployment during times of emergency, as well as the risks associated with not having access to licensed vaccines during an outbreak. In addition, the treaty should provide that any injuries sustained by vaccine recipients could be brought before a global compensation fund (see discussion below).

Manufacturers can also work with the EU to craft a Directive on this issue. For example, in 2001, the EU issued a Directive authorizing the distribution of an "unauthorized medicinal product" or prelicensed product in response to the suspected or confirmed spread of disease.[203] The Directive also required Member States to set aside funds to cover manufacturers' potential liability. But any Directive on this issue must comply with other EU Directives in place, such as the Product Liability Directive (PLD), which is the European products liability framework. To increase the likelihood that such a proposal would be adopted, any proposed Liability Directive will likely need to provide benefits and/or compensation comparable to those currently available under the PLD.[204]

A global treaty would have several advantages. First, it would establish uniformity and increase predictability for vaccine manufacturers, making it easier to distribute the vaccine equitably to developed and developing countries alike without the risk of litigation, especially in countries where, due to price discounts, revenues may fall short of development and manufacturing costs. Additionally, an international treaty could

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[202] *See id.*

[203] *See* Directive 2001/83/EC of the European Parliament and of the Council of 6 Nov. 2001.

[204] Duncan Fairgrieve, Peter Feldschreiber, Geraint Howells & Marcus Pilgerstorfer, *Products in a Pandemic: Liability for Medical Products and the Fight against COVID-19*, 11 EUROPEAN J. RISK REGUL. 565, 599–600 (2020), https://doi.org/10.1017/err.2020.54 [https://perma.cc/5KBV-XGY6]. The PLD is the European product liability framework requiring producers to compensate parties injured by their defective products, including vaccines. *Id.* at 15.

establish a baseline framework for approval based on safety and efficacy, as well as creating a no-fault compensation system for individuals harmed by vaccines. To qualify for the no-fault compensation scheme under a treaty, a vaccine would have to meet some agreed-upon standard for safety and efficacy—the trade-off for a limitation of liability.

While a treaty of this nature will likely take time to implement, we believe that this type of treaty would provide vaccine manufacturers with the best protection from liability, thereby removing a major impediment to vaccine development. The compensation system should improve perceptions of vaccines and individual willingness to be vaccinated.

2. Third-Party Intermediary Declaration Modeled After a PREP Act Declaration

While a global treaty is the best long-term solution, a second option to mitigate liability arising from a COVID-19 vaccine is to have a third-party intermediary create a PREP-like liability program. Vaccine manufacturers could partner with a third-party intermediary that works with the United Nations or other supranational bodies to create a framework for immunity protection as well as a global compensation fund for COVID-19 vaccine-related injuries. Such a mechanism would provide immunity from suit in all member states. A third-party intermediary declaration could model its approach on the U.S. PREP Act—that is, it would provide broad liability immunity to manufacturers of COVID-19 vaccines and compensation to those injured by a COVID-19 vaccine.

The overarching issue with the creation of a global compensation program, either through a third-party intermediary or a global treaty, is how to fund such a program. Researchers have suggested it would be fairer if donors capitalized the fund directly because this approach is consistent with a global collective interest in security from future epidemic outbreaks. Further, it is important that such a compensation fund provide fair and just compensation—countries are unlikely to accept a PREP-like model if it results in injured parties receiving lower compensation amounts than they already have access to. In particular, European countries are unlikely to accept a PREP-like model if it offers less compensation than they would be entitled to under the PLD.[205]

3. Letters of Agreement Modeled After H1N1 Letters

Until a comprehensive global legislative solution is achieved, a framework of Letters of Agreement administered by a third-party intermediary is the fastest way to mitigate the liability risks associated with global use of COVID-19 vaccines and vaccines for future pandemics. We have a useful model in the Letters of Agreement used as a part of the WHO's Vaccine Deployment Initiative during the H1N1 pandemic. These Letters of Agreement granted complete immunity to manufacturers of vaccines used unless the injury was caused by a failure of the company to comply with current cGMP standards. The Letters of Agreement would be between and among the third-party intermediary and every country where COVID-19 vaccines are administered. Before any vaccines could be deployed, these Letters of Agreement

[205] *Id.* at 599.

would require any country receiving COVID-19 vaccines to accept liability on behalf of its citizens.

This approach is consistent with a UNICEF recommendation for prelicensed vaccines deployed in times of emergency. UNICEF has recommended that the country or government receiving a prelicensed vaccine during an outbreak be required to accept complete liability for any injuries its citizens sustained as a result of the use of that vaccine. UNICEF has also explained that the waiver of liability in favor of the manufacturer would be included as a part of the terms and conditions on the vaccine request form before the vaccine was shipped.[206]

While Letters of Agreement will need to be entered into on a case-by-case basis, it is an alternative that has proven useful in the past and could be utilized until a comprehensive global solution is achieved. A drawback to this mechanism, however, is that many developing nations may not have the resources needed to assume the vaccine-related liability.

A model similar to the Letters of Agreement model proposed here has already been utilized by a vaccine manufacturer during the COVID-19 pandemic. AstraZeneca, manufacturer of one of the COVID-19 vaccines, has secured liability protections from most of the countries with which it has entered into supply agreements. Senior executives were reported to have requested indemnity in those supply agreements because the company would not accept unknown risks that may come to light in the future. Although the list of countries that have agreed to indemnify AstraZeneca remains unknown, AstraZeneca reportedly pledged to supply more than 2 billion doses of their vaccine for no profit in agreements with the United States, Britain, and European countries, as well as other nations and organizations.[207]

4. The World Bank: Pandemic Emergency Financing Facility

To address the resource issues for developing countries associated with the Letters of Agreement model, the World Bank in 2016 created the Pandemic Emergency Financing Facility (PEF). The PEF was designed in collaboration with WHO and a team of experts in epidemiology, public health, and finance. The PEF financing "consists of funding provided by Australia, Germany, IDA, and Japan (Donor Nations) as well as insurance coverage provided in 2017 through catastrophe bonds issued by the World Bank and sold to capital market investors as well as insurance-linked swaps executed by the World Bank with insurance companies."[208]

The PEF has two components: a "cash window" designed to quickly release funding to countries in need, and an "insurance window" to help increase the scale of the response in the event of a worst-case scenario.[209] Funds from the cash window may be

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[206] *See* UNICEF, OPERATIONAL FRAMEWORK FOR MONOVALENT ORAL POLIOVIRUS TYPE 2 (MOPV2) DEPLOYMENT AND REPLENISHMENT 15–16 (Oct. 9, 2014), http://www.who.int/immunization/sage/meetings/2014/october/4_Polio_mOPV2_stockpile_v4_09_10_2014.pdf [https://perma.cc/9GZB-DWQR].

[207] Ludwig Burger & Pushkala Aripaka, *AstraZeneca to Be Exempt from Coronavirus Vaccine Liability Claims in Most Countries*, REUTERS (July 30, 2020), https://www.reuters.com/article/us-astrazeneca-results-vaccine-liability/astrazeneca-to-be-exempt-from-coronavirus-vaccine-liability-claims-in-most-countries-idUSKCN24V2EN [https://perma.cc/4U9F-6S8E].

[208] *Fact Sheet: Pandemic Emergency Financing Facility*, WORLD BANK (Apr. 27, 2020), https://www.worldbank.org/en/topic/pandemics/brief/fact-sheet-pandemic-emergency-financing-facility [https://perma.cc/DN5H-HWMZ].

[209] *Id.*

transferred within days after approval by the steering body. The insurance window operates like a typical insurance policy: a country acquires disease outbreak protection and can draw on the policy when a triggering event occurs. The insureds are the poorest countries, and the premiums are paid by the Donor Nations. Once an outbreak that meets the predetermined criteria occurs, payouts from the insurance window may be activated. To qualify for PEF financing, countries must be members of the IDA. The PEF program can be revised to add new diseases, and it has been revised to include COVID-19.[210]

As of March 2020, all activation criteria including outbreak size, spread, and growth were met for the COVID-19 pandemic. Thus, insured countries were able to access the PEF facilities to cover risks associated with any COVID-19 vaccine. On April 27, 2020, the PEF allocated more than $195 million to sixty-four poorest countries to deal with the COVID-19 pandemic, and as of September 30, 2020, those funds were all distributed.[211]

C. Limiting COVID-19 Liability Claims in the United States

Although the 1918 Spanish flu pandemic took many lives in the United States, its effect on American jurisprudence was minimal. Only a handful of decisions reference the Spanish flu pandemic, and none of those rulings are relevant to the issues related to the COVID-19 pandemic or vaccine liability.[212] By contrast, even before the first COVID-19 vaccine became available, thousands of COVID-19-related personal injury and commercial lawsuits, bankruptcies, business interruption and insurance disputes, commercial and residential litigation, and workplace claims had been filed in federal and state courts.[213]

Although the VICP, PREP Act, and the Countermeasure Injury Program limit vaccine litigation liability risks, they do not act as a complete bar to claims arising out of alleged vaccine-related injuries. Despite the VICP, vaccine injury claims are still filed in courts.[214] The possibility of expansive and time-consuming litigation needs to be better circumscribed and, if a COVID-19 vaccine becomes mandatory nationwide

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[210] *Id.*

[211] *Id.*

[212] *See* Galloway v. U.S., 319 U.S. 372 (1943); Pence v. U.S., 316 U.S. 332 (1942); Carmichael v. S. Coke & Coal, 301 U.S. 495 (1937*)*; Wickwire v. Reinecke, 275 U.S. 101 (1927); Ziang Sung Wan v. United States, 266 U.S. 1 (1924).

[213] *See, e.g.*, Alaska Urological Inst., P.C. v. U.S. Small Bus. Admin., 619 B.R. 6894910291 (D. Alaska 2020) (challenge to Small Business Administration's rules of excluding bankruptcy debtors from loan eligibility under federal COVID-19 relief legislation); Est. of Maglioi v. Andover Subacute Rehab. Ctr., 478 F. Supp. 3d 518 (D.N.J. 2020) (wrongful death and other state law claims stemming from COVID-19 outbreak at nursing facility); Studio 417, Inc. v. Cincinnati Ins. Co., 478 F. Supp. 3d 794 (W.D. Mo. 2020) (action against insurer arising from denial of coverage for loses stemming from COVID-19 pandemic); Gomes v. U.S. Dep't of Homeland Sec., Acting Sec'y, 2020 WL 3577302 (D.N.H. July 1, 2020) (challenge to conditions of confinement in light of COVID-19 brought by detainees being held by Immigration and Customs Enforcement); Lucero-Gonzalez v. Kline, 464 F. Supp. 3d 1078 (D. Ariz. 2020) (constitutional challenge to prison's COVID-19 policies).

[214] *See, e.g.*, Cole v. Sec'y of Health & Hum. Servs., 2015 WL 3745616 (Ct. Fed. Cl. May 13, 2015) (denying claim for compensation for alleged flu vaccine-related injury after petitioner failed to establish that he received the flu vaccine); Porter v. Sec'y of Health & Hum. Servs., 663 F.3d 1242 (Fed. Cir. 2011) (overturning Court of Claims ruling and reinstating special master's determination that petitioners were not entitled to compensation because petitioners had failed to prove that a Hepatitis B vaccine caused them to suffer from autoimmune hepatitis).

for the entire population, the certainty of quick and just compensation outside of the state or federal court system must be enhanced. There are several steps that can be taken to achieve this goal, while encouraging mass vaccination and reducing litigation risk for manufacturers, which has been a barrier to vaccine development for the last fifty years.

First, COVID-19 vaccines should be added to the Vaccine Injury Table, and therefore, be made part of the VICP. The earliest injuries arising from a COVID-19 vaccine, however, will likely be covered by the CICP.[215] The CICP has already processed twenty-nine claims for vaccine-related injury, with the average payment being $207,000.[216] These amounts have been called inadequate and are reportedly much lower than the VICP average of $585,000 per claimant.[217] The difference in payment amounts is attributable to several factors: the CICP has a higher burden of proof and a shorter statute of limitations than the VICP, and unlike the VICP, the CICP does not pay damages for pain and suffering or offer an avenue for appeals.

Second, it already has been suggested that the "inadequacy" of CICP payments might act as a deterrent to people getting a COVID-19 vaccine. Although the VICP, on average, provides higher damage awards, it also has been suggested that VICP damage awards are themselves insufficient.[218] The VICP caps damage awards at $250,000 for vaccine-related deaths and $250,000 for pain and suffering, and these limits have not changed since 1986. But there are no limits on the other types of expenses that the VICP covers, such as non-reimbursable medical expenses, lost earnings, and attorneys' fees.[219]

Increasing the VICP damage awards is important to improving the public's perception of their ability to obtain fair compensation for vaccine-related injuries, which in turn should encourage acceptance of an approved COVID-19 vaccine. Increasing the seventy-five-cent-per-vaccine-administered excise tax is one way to fund this proposed increase to the VICP's damage awards. Alternatively, until HHS

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[215] *See* Peter Loftus & Susan Pulliam, *People Harmed by Coronavirus Vaccines Will Have Little Recourse*, WALL ST. J. (Oct. 11, 2020), https://www.wsj.com/articles/people-harmed-by-coronavirus-vaccines-will-have-little-recourse-11602432000 [https://perma.cc/TB4M-4UMY]. For the most part, side effects of the Pfizer and Moderna COVID-19 vaccines have been relatively mild and in line with other common vaccines such as shingles, but there have been reports of more serious symptoms in the form of severe allergic reactions. *See* Richard Harris, *COVID-19 Vaccine's Side Effects Could Complicate Efforts to Vaccinate Health Workers*, NPR (Dec. 11, 2020), https://www.npr.org/2020/12/11/945578665/covid-19-vaccines-side-effects-could-complicate-efforts-to-vaccinate-health-work [https://perma.cc/DM3F-G4FS]; Associated Press, *Alaska Woman has Allergic Reaction to COVID Vaccine; Health Officials Track Safety*, MPRNEWS (Dec. 16, 2020), https://www.mprnews.org/story/2020/12/16/alaska-woman-has-allergic-reaction-to-covid-vaccine-health-officials-track-safety [https://perma.cc/649S-QQUT]; Katherine J. Wu, *Boston Doctor Reports Serious Allergic Reaction After Getting Moderna's Covid Vaccine*, N.Y. TIMES (Dec. 25, 2020), https://www.nytimes.com/2020/12/25/health/Covid-moderna-vaccine-allergies.html [https://perma.cc/GM3X-VWKR].

[216] Loftus & Pulliam, *supra* note 215.

[217] *Id.*

[218] The average award payment for vaccine-related injuries under the VICP was $824,463 and today the average award is $585,000. *Compare* U.S. DEP'T HEALTH & HUM. SERVS., NATIONAL VACCINE INJURY COMPENSATION PROGRAM, https://www.in.gov/isdh/files/VICP.pdf [https://perma.cc/R5SF-MHYT] (last visited June 14, 2021), *with* Loftus & Pulliam, *supra* note 215.

[219] HEALTH RES. & SERVS. ADMIN., WHAT YOU NEED TO KNOW ABOUT THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM (VICP) 13 (Sept. 2016), https://www.hrsa.gov/sites/default/files/vaccinecompensation/resources/84521booklet.pdf [https://perma.cc/9EKW-FQRZ].

formally declares the COVID-19 pandemic over, the federal government could provide supplemental funds to the VICP on a lump sum or per vaccine basis.

Third, to improve VICP funding and coverage for COVID-related litigation claims, an insurance mechanism similar to those used in the state-run workers' compensation programs could be created. Vaccine manufacturers and employers generally could be mandated to purchase this insurance or to self-insure for damages associated with vaccines as well as workplace-related claims (i.e., a person contracts COVID-19 that is traced to a workplace exposure). The federal government could offer the insurance in a manner similar to some state insurance funds. This would allow the federal government to adjust premiums based on the amount of damages being paid, with the goal of adequately funding the VICP, not profiting from the premiums it collects.

This insurance coverage would have to be broad and include more than traditional vaccine-related injury claims to give vaccine manufacturers and employers certainty that personal injury, workplace, and/or employment-related COVID-19 liability exposure would be adequately covered. The amount of compensation will also have to be sufficiently generous to give employees the sense that if they return to work and if they get sick from workplace exposure, they will be fairly compensated.

Fourth, increasing the amount of VICP awards is necessary for another reform: making VICP the sole and exclusive remedy for claims against vaccine manufacturers for personal injuries and employers for workplace exposure claims. In other words, like state workers' compensation systems, individuals will be required to litigate their claims within the VICP. Currently, individuals can bring suit in civil court if a petition is adjudged non-compensable or dismissed under the VICP, if the petitioner otherwise rejects an award granted by the VICP, or if the vaccine is not covered under the VICP.[220] This is a burden on manufacturers that should be minimized, and workplace exposure claims will be a burden on employers that should be minimized as well. To ensure individuals who are dissatisfied with a COVID-19 damage award have some recourse, a new appeals division within VICP could be created to hear claimants' appeals, instead of permitting the claimants to file suit in civil court.[221] The benefit of this approach is that the process would likely be more efficient, and claimants would receive just compensation in less time than if they had to bring suit in civil court after an initial denial in Vaccine Court. Manufacturers would avoid having to defend suits in court, which is burdensome and discourages vaccine-development.

Fifth, in addition to making VICP the exclusive forum for vaccine-related injury claims, injured parties and/or their representatives, estate, or next of kin would be limited to claims for personal injury based on traditional tort and breach of warranty theories of liability to recover damages for pain and suffering, lost past and future wages, and medical expenses. Including pain and suffering as part of a claimant's damages addresses a criticism of CICP awards. Novel and creative theories of liability

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[220] U.S. DEP'T HEALTH & HUM. SERVS., NATIONAL VACCINE INJURY COMPENSATION PROGRAM, https://www.in.gov/isdh/files/VICP.pdf [https://perma.cc/R5SF-MHYT] (last visited June 14, 2021).

[221] Of course, the specific standards of review for these appeals would have to be determined. In theory, the appeals process would have to balance competing interests: permitting additional recourse for a dissatisfied claimant and keeping the burden on manufacturers low. For example, claimants might prefer de novo review of the substantive claims, which could then lead to near-automatic appeals and an increase to the burden on manufacturers. Short of de novo review, the standards for legal and factual review will need to be addressed as part of the legislative process.

outside of traditional tort claims and breach of warranty, as well as subrogation-based suits, should be barred or considered preempted.

Finally, at minimum, additional resources should be allocated to the administration of the CICP and the VICP. Complaints have already been lodged about the CICP and the VICP's Vaccine Court being understaffed.[222] The number of Special Masters on the VICP has been limited to eight.[223] And a 2014 study from the Government Accountability Office found that most of the nearly 10,000 claims filed with the VICP since 1999 took multiple years to adjudicate and more than 1,000 claims were pending, some for more than a decade.[224] Adequate staffing will ensure that claims are promptly and justly adjudicated. Such a reform would likely assuage some of the public's concern regarding being fairly compensated for any vaccine injury.

The intent of these reforms, including making the VICP the exclusive forum for litigating vaccine-related injuries, is to provide injured parties with greater and more certain compensation than is currently available, and to reduce litigation risks for vaccine manufacturers and employers, as well as to provide better certainty about litigation risks and costs through the excise tax and the insurance mechanisms. Providing greater detail about the proposed insurance model is beyond the scope of this paper but should be considered by policy makers who administer such programs.

D. Addressing Costs Associated with Vaccine Development

One of the biggest impediments to a more robust vaccine development environment is the costs associated with it. A company can conduct years of research without developing a safe and effective vaccine. At least 19% of vaccines in development fail to be approved.[225] And as seen with the DTP, RotaShield, and Dengvaxia vaccines, even after a vaccine is approved and brought to market, it is possible that adverse events come to light that can increase liability costs, cause manufacturers to exit the vaccine market, and even cause public health officials to withdraw their recommendations. Thus, making vaccine development more economically feasible is essential to ensuring that the vaccine-development space has adequate resources to conduct the work that is needed to address some of the deadliest and most infectious diseases, including COVID-19.

Early in the pandemic, experts were advising that, given the global spread and infectiousness of COVID-19, more than one vaccine would be needed to tackle the pandemic.[226] In addition to the costs associated with developing multiple vaccines, there are other costs associated with delivering a safe and effective vaccine to the

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[222] *See* Eli Wolfe, *Federal Vaccine Court Quietly Pays Out Billions*, SALON.COM (Dec. 23, 2018), https://www.salon.com/2018/12/23/federal-vaccine-court-quietyly-pays-out-billins_partner/ [https://perma.cc/49R5-CLSV]; Tom Hals, *COVID-19 Era Highlights U.S. 'Black Hole' Compensation Fund for Pandemic Vaccine Injuries*, REUTERS (Aug. 21, 2020), https://www.reuters.com/article/us-health-coronavirus-vaccines-liability/covid-19-era-highlights-u-s-black-hole-compensation-fund-for-pandemic-vaccine-injuries-idUSKBN25H1E8 [https://perma.cc/J5SP-95XG].

[223] Wolfe, *supra* note 222.

[224] U.S. GOV'T ACCOUNTABILITY OFF., GAO-15-142, VACCINE INJURY COMPENSATION (Nov. 2014), https://www.gao.gov/assets/670/667136.pdf [https://perma.cc/S44P-YJ32].

[225] Bernard Avishai, *The Case for a Coronavirus-Vaccine Bond*, NEW YORKER, Aug. 15, 2020, at 2.

[226] Lawrence Corey, John R. Mascola, Anthony S. Fauci & Francis S. Collins, *A Strategic Approach to COVID-19 Vaccine R&D*, 368 SCIENCE MAG. 948 (May 29, 2020).

public, including manufacturing, storing, and administering hundreds of millions to billions of doses of a COVID-19 vaccine.

The question remains how to pay for these costs. Funding vaccine development is challenging under the best of circumstances—much less in the middle of a global pandemic. The most expensive of these costs are likely the development costs.

The federal government has provided funding to some of the leading vaccine development efforts through the Biomedical Advanced Research and Development Authority (BARDA). BARDA has provided millions of dollars in funding to Moderna and pledged up to $1.2 billion dollars to AstraZeneca to develop their vaccine candidates.[227] Moderna also relied on federally funded basic science research in developing its vaccine, while AstraZeneca relied on research conducted at the University of Oxford.[228] Similarly, Pfizer was awarded a government contract for almost $2 billion dollars for 100 million doses and to help it build out its manufacturing capacity for up to 600 million doses.[229] Johnson & Johnson and Sanofi with GlaxoSmithKline also contracted with the federal government to develop and deliver millions of doses of their vaccine. The Johnson & Johnson contract was reportedly worth more than $1 billion, while the Sanofi/GlaxoSmithKline agreement was worth up to $2.1 billon.[230]

Significant government aid after a pandemic started, however, is not the same as providing sufficient resources to ensure that funds are readily available to prospectively develop vaccines for known and currently unknown infectious diseases. Venture capitalists often fund early stage research, but attracting the hundreds of millions of dollars needed to bring a vaccine from the preclinical stage to Phase III, when large-scale human trials are conducted, is often challenging. The difficulty in attracting funding lies in the fact that about 11% of new vaccines make it from Phase I trials to market, while the profit margin for vaccines is about 5%, or roughly three times lower compared to the profit margins for other pharmaceuticals.[231]

Some experts have argued that reducing the risks and possibly increasing the rewards associated with developing vaccines could attract investment from the normal bond markets, providing the capital needed to ensure that the vaccine development environment remains widespread and robust.[232] The solution to the vaccine development funding problem may lie with financial engineering, in what has been dubbed a "vaccine bond." To create the vaccine bond, a portfolio fund would be raised using debt. The fund would then purchase equity in biotech firms, using their research as collateral. The biotech firms would receive additional funding if their research yielded promising results. A bond would issue to investors as a ten-year zero-coupon

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[227] Elisabeth Rosenthal, *How a Covid-19 Vaccine Could Cost Americans Dearly*, N.Y. TIMES, July 6, 2020, at 2.

[228] *Id.*

[229] Avishai, *supra* note 225, at 2.

[230] Noah Higgins-Dunn, *Johnson & Johnson Reaches Deal with U.S. for 100 Million Doses of Coronavirus Vaccine at More Than $1 Billion*, CNBC (Aug. 5, 2020), https://www.cnbc.com/2020/08/05/jj-reaches-deal-with-us-for-100-million-doses-of-coronavirus-vaccine-at-more-than-1-billion.html [https://perma.cc/UH29-LK24].

[231] *See* Avishai, *supra* note 225. Before the coronavirus pandemic, vaccines accounted for about 3.5% of the pharmaceutical market. *Id.*

[232] *See id.*

bond, meaning the investors receive no interest until the bond matures ten years after issue.[233]

The benefit of the portfolio fund is that it diversifies the risk across biotech companies and across investors: the portfolio fund invests in multiple companies, constantly vetting the science, thereby increasing the odds that it will identify a successful product. Issuing bonds allows the portfolio fund to access capital from a broader portion of the bond market, while investors gain access to a diversified biotech portfolio with limited capital investment and with the benefit of diversified risk. The government could make this security even more attractive by acting as a seed investor to further its own vaccine development goals by structuring its involvement to further reduce the portfolio fund's risk profile. The Israeli government has already invested in such a portfolio, which has positive returns after a single investment by Merck into one of its portfolio companies.[234] If such a portfolio fund already existed, it could have readily funded the late stage COVID-19 vaccines, thereby ensuring that the vaccine candidates furthest along in the approval process were adequately funded.

Other costs relevant to bringing a vaccine to the public include the cost of manufacturing large quantities of the vaccine and storing vaccines at proper temperatures prior to administration. For instance, some COVID-19 vaccines need to be transported and stored at temperatures as low as minus eighty degrees Celsius.[235] The average physician's office and even hospital may not have the facilities needed to safely store these COVID-19 vaccines. The federal government announced that doses of a COVID-19 vaccine administered during its COVID-19 vaccination campaign will be provided to Americans at no cost.[236] It also advised that it will provide some of the supplies necessary for the proper administration of each dose, such as needles, syringes, alcohol prep pads, a vaccine record card, and some personal protective equipment.[237] But state and local governments will need to fund other logistical costs such as cold storage, building mass vaccination pod sites, training healthcare providers, staffing vaccination sites, and developing necessary IT systems for patient scheduling, inventory, and supply chain management.[238] These logistical costs are expected to be substantial.[239] State and local governments, whose budgets are already facing immense stress due to the loss of revenues caused by the pandemic, will need

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[233] *See id.*

[234] *See id.*

[235] David Gelles, *How to Ship a Vaccine at -80°C, and Other Obstacles in the Covid Fight*, N.Y. TIMES (Sept. 19, 2020), https://www.nytimes.com/2020/09/18/business/coronavirus-covid-vaccine-cold-frozen-logistics.html [https://perma.cc/3GTJ-29AY]; *see also* Elaine Chen, *From 'Freezer Farms' to Jets, Logistics Operators Prepare for a Covid-19 Vaccine*, WALL ST. J. (Aug. 28, 2020), https://www.wsj.com/articles/from-freezer-farms-to-jets-logistics-operators-prepare-for-a-covid-19-vaccine-11598639012 [https://perma.cc/X399-MSEZ].

[236] Higgins-Dunn, *supra* note 230.

[237] N.Y. STATE DEP'T OF HEALTH, NEW YORK STATE'S COVID-19 VACCINATION PROGRAM 68 (Oct. 2020), https://www.governor.ny.gov/sites/governor.ny.gov/files/atoms/files/NYS_COVID_Vaccination_Program_Book_10.16.20_FINAL.pdf [https://perma.cc/6DXF-TZXN].

[238] *Id.*

[239] *See* Josh Michaud & Jennifer Kates, *Distributing a COVID-19 Vaccine Across the U.S.–A Look at Key Issues*, KAISER FAMILY FOUND. (Oct. 20, 2020), https://www.kff.org/coronavirus-Covid-19/issue-brief/distributing-a-Covid-19-vaccine-across-the-u-s-a-look-at-key-issues/ [https://perma.cc/ZJ7A-WUR8].

to figure out how to fund the logistical costs associated with widespread vaccination.[240] Indeed, the vaccine rollout in the United States began sluggishly, in part because of these many logistical challenges.[241] Congress did, however, step in with funding to address these issues. For example, the COVID-19 relief bill signed into law by President Biden in March 2021 included $14 billion for vaccine distribution and administration.[242]

1. Policy Changes Geared Towards Increasing Vaccination Rates

Epidemiologists and other public health experts agree that increased vaccination rates lead to better health outcomes. Vaccination rates in the United States and some European countries have decreased in recent years due to a rise in anti-vaccination movements that question vaccine safety and efficacy.[243] Vaccine opponents have been able to take advantage of certain vulnerabilities in vaccine exemption policies to avoid taking vaccines. Policy makers should consider implementing the following changes to address some of these weaknesses to increase vaccination rates.

First, the federal government, through its taxing and spending power, can incentivize policy changes geared towards increasing vaccination rates by tying a portion of school funding to vaccination rates and/or adoption of vaccination policies recommended by ACIP. Such changes would likely incentivize states to effectuate policies that increase vaccination rates.

At the state level, exemptions to mandatory vaccine policies should be strictly limited to medical and religious reasons. Even though religious and medical exemptions are legitimate, certain policy changes should be implemented to ensure that they are not abused.

At least one study has shown that exemptions to mandatory vaccine policies are likely abused.[244] The study, conducted in 2001, showed that the number of parents who sought exemptions from mandatory vaccine policies was a direct function of the complexity of the exemption process. The exemption processes reviewed ranged from the least complex, which required a simple form with a parent's signature, to the most complex, which required that the signature on the form or letter be notarized or requiring both a form, obtained from the health department, and a letter. Some states require an additional letter from a religious official or the signature of a state official.[245]

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[240] N.Y. STATE DEP'T OF HEALTH, NEW YORK STATE'S COVID-19 VACCINATION PROGRAM 69 (Oct. 2020), https://www.governor.ny.gov/sites/governor.ny.gov/files/atoms/files/NYS_COVID_Vaccination_Program_Book_10.16.20_FINAL.pdf [https://perma.cc/6DXF-TZXN].

[241] *See, e.g.*, Lauren Leatherby & Amy Schoenfeld Walker, *After Sluggish Start, Vaccine Rollout Is Improving in Every State*, N.Y. TIMES (Feb. 12, 2021), https://www.nytimes.com/interactive/2021/02/12/us/vaccine-doses-distribution.html [https://perma.cc/9UZK-NUCN].

[242] *See, e.g.*, Giovanni Russonello, *What Does $1.9 Trillion Buy?*, N.Y. TIMES (Mar. 10, 2021), https://www.nytimes.com/2021/03/10/us/politics/whats-in-covid-bill.html [https://perma.cc/Q6EL-Z8WP].

[243] Peter Hotez, *America and Europe's New Normal: The Return of Vaccine-Preventable Diseases*, 85 J. PEDIATRIC RSCH. 912, 912 (2019).

[244] *See* J.S. Rota, D.A. Salmon, L.E. Rodewald, R.T. Chen, B.F. Hibbs & E.J. Gangarosa, *Processes for Obtaining Nonmedical Exemptions to State Immunization Laws*, 91 AM. J. PUB. HEALTH 645, 646 (2001) (detailing a study linking more complex exemption requirements to lower exemption rates).

[245] Washington State, for instance, was one of the least immunized states with only 69.2% of toddlers receiving all of the ACIP recommended vaccines. To get an exemption at that time, parents only had to

In states with the most complex exemption process, one percent or fewer of its population used the exemption, while states with the least complex exemption process had exemption rates higher than one percent.[246]

Thus, relatively simple policy changes, such as requiring the exemption form to be notarized or requiring a state official to certify the medical reason for the exemption, could lead to increases in vaccination rates. Further, consideration should be given to repealing philosophical and conscientious belief exemptions in their entirety. Unlike the medical exemptions that are grounded in a 115-year-old Supreme Court precedent,[247] exemptions for philosophical and conscientious belief are matters of legislative grace.[248] In the context of the COVID-19 pandemic, these exemptions may do more harm than good, and repealing them will likely lead to an increase in vaccination rates.

Once a COVID-19 vaccine is widely available around the world, the United States should require proof that a visitor has received a COVID-19 vaccine or otherwise has a medical exemption for entry into the country.[249] Such a requirement is not novel; indeed, it is already in place for certain vaccines. Currently, visitors seeking visas and immigrants seeking permanent residency are required to receive a number of vaccinations, including those specified by statute and some of the vaccines that ACIP recommends for the population at large.[250]

E. Addressing the Intangibles

The importance of messaging to the public in the United States and abroad about the need to be vaccinated cannot be overstated. Thus, to ensure prompt and continued public acceptance of the approved COVID-19 vaccines, the messaging about the vaccine must be transparent, meaning that the public should be advised of both the benefits and the risks associated with the vaccine, especially as it pertains to health risks, efficacy, costs, and any restrictions on personal liberties.[251] The public should also be informed about the rigorous testing and vetting that every approved vaccine undergoes. Government and public health officials also must ensure that any mandatory vaccination policy is proportional to the risk faced by the public, meaning

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check a box. *See* James Lobo, *Vindicating the Vaccine: Injecting Strength into Mandatory School Vaccination Requirements to Safeguard the Public Health*, 57 B.C. L. REV. 261, 277 n.109 (2016).

[246] *See* Rota et al., *supra* note 244, at 647.

[247] *See* Jacobson v. Massachusetts, 197 U.S. 11, 29 (1905).

[248] *See* Lobo, *supra* note 245, at 278.

[249] Some countries have gone further. Israel, for example, which is a global leader in rolling out a COVID-19 vaccine, instituted a "green pass" system granting vaccinated individuals access to previously off-limits activities. *See, e.g.*, Hadas Gold, *Israel Vaccination 'Green Pass' May Offer a Glimpse of a Post-Covid Future*, CNN (Mar. 11, 2021), https://www.cnn.com/travel/article/israel-vaccine-green-pass-wellness/index.html [https://perma.cc/8L65-WHKV].

[250] Immigration and Nationality Act, 8 U.S.C. § 212(a)(1)(A)(ii) (1965); *see also Immigrant, Refugee, and Migrant Health*, CDC DIV. OF GLOBAL MIGRATION AND QUARANTINE, http://www.cdc.gov/immigrantrefugeehealth/exams/medical-examination.html [https://perma.cc/4VYU-N4LR] (last visited June 14, 2021); RUTH ELLEN WASEM, CONG. RSCH. SERV., R40570, IMMIGRATION POLICIES AND ISSUES ON HEALTH-RELATED GROUNDS FOR EXCLUSION 7 (2014), https://fas.org/sgp/crs/homesec/R40570.pdf [https://perma.cc/KB6D-8DGY].

[251] Peter A. Singer, Solomon R. Benatar, Mark Bernstein, Abdallah S. Daar, Bernard M. Dickens, Susan K MacRae, Ross E. G. Upshur, Linda Wright & Randi Zlotnik Shaul, *Ethics and SARS: Lessons from Toronto*, 327 BMJ 1342 (2003).

that the policy being implemented uses the least restrictive methods "reasonably available to limit individual liberties and should apply restrictions without discrimination."[252] Given the mortality and morbidity associated with COVID-19, it should not be difficult to convey the message about the societal and individual benefits of large numbers of people getting vaccinated.

We cannot readily change how we all think, but as policy makers, government officials, scientists, and industry representatives tackle the problems of distributing and having people vaccinated for COVID-19, three aspects of human nature must be remembered: 1) amnesia, 2) hindsight bias, and 3) the law of small numbers. Each of these errors in human reasoning, alone or in combination, may become serious roadblocks to developing and public acceptance of vaccines for future pandemics or for one or more of the 100 vaccines now being developed for COVID-19.

1. Amnesia

One of the biggest challenges to creating a comprehensive vaccine development and deployment program is human nature. We all tend to misremember events or even to forget them entirely. Policy makers and government officials in particular are known for shifting their attention from a planning and/or preparing posture to address the crisis or hot button issue of the day. For instance, the SARS epidemic ended after a few months because it was not as infectious as some other diseases, and as the SARS pandemic waned, so did policy makers' attention and the funding needed to develop treatments to prevent another SARS outbreak. As discussed, *supra* Part II, the failure to continue funding SARS research left the world unprepared for the COVID-19 pandemic.

The human tendency to forget the challenges faced in a global health crisis has been described as "global amnesia." Dr. Howard Markel, the lead author of a 2007 study on pandemic preparedness at the University of Michigan's Center for the History of Medicine, cogently described the problems for vaccine development and acceptance associated with "global amnesia":

> The worst thing about the last act of every epidemic or pandemic I've ever studied is something I call global amnesia. We tend to forget about it, and the political actors go on to the next issue and don't do the funding that needs to be done for steady preparedness. I'm sure you have a fire department in your city, and I bet your house never burnt down. But I also bet you're glad you have a fire department and you pay taxes for that because, in the event that your house does burn down, they'll help you. I use that metaphor for our public health enterprise, from the local to the international level. When it works at its best, we don't know about infectious diseases because they don't break out. But we need to prepare all the time. If COVID-19 teaches us nothing but that, then I think we'll have a healthier world.[253]

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[252] *Id.*

[253] Angel Desai, *Twentieth-Century Lessons for a Modern Coronavirus Pandemic*, 323 JAMA 2118, 2118–19 (2020).

2. Hindsight Bias

"Once harm has been done, even a fool understands it."

- Homer, The Iliad, Book XVII, 1.32

Although there are exceptions, in the context of pharmaceutical products liability lawsuits, most courts in the United States recognize that information learned after labeling has been approved is not relevant to liability determinations because evaluation of the adequacy of product labeling should be based on what was known, or reasonably should have been known, at the time the labeling was created.[254] Moreover, looking at events in hindsight, people, and more particularly judges and jurors, are more likely to conclude that: 1) a party (usually the defendant manufacturer) was capable of preventing a bad outcome, 2) a type of conduct or a product was "riskier" due to a bad outcome or serious injury, or 3) the outcome or injury was more foreseeable (usually to the manufacturer defendant).[255] These ways of thinking generally result in bias and, therefore, the use of post-event evidence in a courtroom is normally circumscribed. The exclusion of post-event evidence in a courtroom works to reduce hindsight bias because jurors usually do not have personal knowledge of the timeline of safety information about the product at issue in the case. With COVID-19 vaccines, that will not be the case.

The safety profile of COVID-19 vaccines necessarily should and will evolve over time.[256] However, if sufficient safeguards are not put in place to better minimize vaccine litigation liability risks, hindsight bias will not only tilt the courtroom playing field dramatically against manufacturers, but hindsight bias is going to adversely impact deployment and acceptance of vaccines for current and future pandemics.

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[254] *See, e.g.*, Toole v. McClintock, 999 F.2d 1430, 1434 (11th Cir. 1993) (FDA report issued years after plaintiff's surgery and alleged injury was "irrelevant and inadmissible on what [the manufacturer] knew or should have known about the risks before"); Lindsay v. Ortho Pharm. Corp., 637 F.2d 87, 91 (2d Cir. 1980) (under New York law, manufacturer must warn of particular risks "which it knew, or in the exercise of reasonable care should have known, to exist"); Arnold v. Riddell, Inc., 882 F. Supp. 979, 993 (D. Kan. 1995) (video made six years after plaintiff's injury "was not relevant as evidence of warnings available . . . or community expectations" at the time of plaintiff's injury): *see also* Martin v. Hacker, 83 N.Y.2d 1, 8 (1993) (warnings deemed adequate where drug manufacturer unambiguously warned of potential dangers that it "knew, or in the exercise of reasonable care, should have known to exist" at the time); Krasnapolsky v. Warner-Lambert Co., 799 F. Supp. 1342, 1345 (E.D.N.Y. 1992) (same).

[255] *See, e.g.*, Sutphin v. Ethicon, 2020 WL 5079170, at *6 (S.D.W. Va. Aug. 27, 2020) (excluding evidence of revisions defendant made to its medical device after plaintiff's injury pursuant to Fed. R. Evid. 407).

[256] *E.g.*, despite reports of serious illness, including blood clots and abnormal bleeding, in individuals who had received the AstraZeneca vaccine, health officials remained steadfast in their view that the vaccine was safe and effective. *See* Denise Grady & Rebecca Robbins, *Should You Be Concerned About Blood Clots, Bleeding and the AZ-Vaccine?*, N.Y. TIMES (Mar. 16, 2021), https://www.nytimes.com/2021/03/15/health/astra-zeneca-vaccine-blood-clots-bleeding.html [https://perma.cc/8YMV-EJXD]; Holly Ellyatt, *WHO Recommends AstraZeneca Vaccinations Continue, Says Benefits Still Outweigh Risks*, CNBC (Mar. 17, 2021), https://www.cnbc.com/2021/03/17/who-on-astrazeneca-vaccinations-should-continue.html [https://perma.cc/YBF3-3SH9].

3. The Law of Small Numbers

Research conducted by Amos Tversky and Daniel Kahneman some decades ago identified a bias in the way people think: the law of small numbers.[257] People tend to quickly conclude that what is observed in a small sample is representative of a general population, we tend to come to broad conclusions based on small data sets, and we dislike or discount the applicability of the laws of chance to an event—"my uncle was struck by lightning because he got a COVID vaccine." While this is an extreme example of erroneously linking a random event (getting struck by lightning) with a cause (getting vaccinated), the politicization of discussions about the importance of mandatory vaccinations for COVID-19 may, unfortunately, result in some slightly less extreme examples being publicly cited as reasons why people should not get vaccinated.

If a significant number of Americans do not believe that any approved COVID-19 vaccine is safe and effective, then they are unlikely to take it, thereby decreasing the ability to reach herd immunity and contain the pandemic. Increasing the public's confidence in the safety and efficacy of any COVID-19 vaccine is an important step in the fight against the pandemic. Thus, to offset the law of small numbers problem, public health officials should undertake robust educational campaigns that carefully explain that the vaccines were thoroughly vetted and proven safe and effective by experts. They should also describe and disclose any risks reasonably associated with the vaccine, while being mindful to contextualize those risks, by explaining that risks are associated with any medical intervention. The point that no medical intervention is 100% safe, but the individual and societal benefits vastly outweigh the risks, should be a central tenet of the messaging around any COVID-19 vaccine. To increase the odds of public acceptance, the messaging should come from many avenues, including the highest levels of federal, state, and local governments, as well as from public health experts, employers, community organizers, educators, religious leaders, and frontline healthcare professionals.

VI. CONCLUSION

Hopefully our country and the rest of the world will be able to finally put an end to the COVID-19 pandemic. But we must avoid "global amnesia" in the future. Successful vaccines are among the most cost-effective medical interventions, with their clear public health benefits far outweighing their occasional harm. While deaths associated with COVID-19 are staggering, more than 4.5 million deaths from other diseases have been prevented through the use of vaccine programs around the globe. A key to increasing the use of vaccines is increasing the public's trust in and understanding of vaccines.

While the utility of vaccines to the global community seems clear, the public's fears and reservations concerning the deployment of COVID-19 vaccines need to be addressed. And, vaccine manufacturers alone cannot address this risk management issue. Multiple voices—government, scientific, industry, and community groups—are needed to improve the communication with, and education of, the public about the benefits of vaccines. The success of any COVID-19 vaccine will depend on

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[257] *See* Amos Tversky & Daniel Kahneman, *Belief in the Law of Small Numbers*, 76 PSYCH. BULLETIN 105 (1971).

transparent and robust public communications about the vigorous review and thorough vetting of every vaccine candidate and its possible side effects.

Some may say the "system" worked with vaccines for COVID-19: within a year, several vaccines were developed after billions of dollars for research were made available, so there is no need to improve liability protections for manufacturers, or to improve compensation for vaccine-related injuries, or to better coordinate vaccine administration and education programs globally, or to create better funding mechanisms for future vaccine research and development. This logic ignores, however, that more than two million people have already died due to COVID-19, and if a better system had been put in place after the RSV or SARS outbreaks as vaccine experts had suggested, the morbidity and mortality associated with COVID-19 could have been greatly reduced. If the efforts to contain COVID-19 are successful, this success will be precarious—and will be no guarantee of success in future pandemics. The pharmaceutical industry responded to this pandemic with several successful vaccines, but our ability to navigate the next global pandemic depends on the collective willingness of global stakeholders to address the ongoing challenges related to vaccine development and use. To the extent efforts to criminally investigate vaccine manufacturers continue or increase, as has occurred in the Philippines and Italy, or if there is a boom in litigation related to the COVID-19 vaccines the United States, the disincentives associated with investing in new vaccines could be significant.

The United States was far less litigious at the time of the 1918 Spanish flu epidemic than it is today. The number of lawsuits that will be filed based on some type of COVID-19-related injury is difficult to predict, but it has been reported that thousands of COVID-related lawsuits already have been filed in state and federal courts in the United States.[258] Litigation related to DTP vaccines forty years ago caused manufacturers to exit the vaccine business and led to the creation of the VICP.[259] But the VICP needs to be modified and needs more resources to properly address COVID-related lawsuits and other future vaccine-injury lawsuits. Without better, more comprehensive liability protections for vaccine manufacturers and healthcare professionals, as well as better and more comprehensive compensation for individuals, courts may become overwhelmed with COVID-19 vaccine-injury litigation. The public will become disenchanted with the vaccine system in this country, and vaccine manufacturers again will be disincentivized from investing in vaccine research to mitigate future pandemics. The possible solutions identified in this Article seek to help us minimize the risk of this outcome.

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[258] *See* AMERICAN TORT REFORM FOUNDATION, JUDICIAL HELLHOLES 2020/2021 67 (2020); *COVID-19 Employment Litigation Tracker and Alerts*, FISHER PHILLIPS, https://www.fisherphillips.com/covid-19-litigation (last visited Dec. 31, 2020) [https://perma.cc/EL5Q-3VYB].

[259] Bruesewitz v. Wyeth, 562 U.S. 223, 227–28 (2011); Gregory A. Poland & Robert M. Jackson, *The Age-Old Struggle against the Antivaccinationists*, 364 NEW ENG. J. MED. 97, 98 (2011).