

11-2021

Solving the Pandemic Vaccine Product Liability Problem

Sam F. Halabi

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Sam F. Halabi, *Solving the Pandemic Vaccine Product Liability Problem*, 12 U.C. IRVINE L. REV. 111 (2021).
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Solving the Pandemic Vaccine Product Liability Problem

Sam F. Halabi*

The global rollout of COVID-19 vaccines is underway, and with it the inevitable occurrence of severe side effects that accompany, rarely, even the safest and most effective vaccines. Governments have invested billions of dollars in supporting research, development, logistics, and supply chains, as well as supporting the creation of networks of healthcare providers to deliver vaccines to recipients all over the world. The European Commission and several international organizations have established the COVAX Facility to pool resources in promising vaccine candidates and to subsidize their procurement by low- and middle-income countries. Yet up-front investment in vaccine development and delivery solves only half the problem with respect to vaccine access. Risks of legal liabilities, particularly product liability for severe side effects, will serve as an important, if not decisive, factor in how vaccine manufacturers participate in the response with Emergency Use Authorized and recently-licensed COVID-19 vaccines. If manufacturers do not receive sufficient assurance against legal liability, especially product liability, they will not ship vaccines. There is limited experience with developing coronavirus vaccines, and severe side effects following immunization are inevitable, as evidenced from Phase III trials and strongly suggested by early administration of Emergency Use Authorized vaccines. Therefore, there is a critical need to balance the risk calculations of manufacturers with justice for immunization recipients who become seriously ill or die in order to contribute to herd immunity in the community. This Article outlines the components of a global no-fault liability, indemnification, and compensation system that includes leveraging current no-fault systems in thirty-nine countries, a World Health Organization insurance mechanism, and a combination of insurance and compensation fund construction based on claims-processing precedents from the Deepwater

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Horizon Oil Spill and Boeing 737 Max crashes—both of which had tens of thousands of claims originating from dozens of countries and processed in at least six languages. The proposed system will be essential for vaccine manufacturer response and to address vaccine hesitancy and injury in populations across the globe.

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INTRODUCTION

The world's greatest mass vaccination campaign is underway.¹ Since the first COVID-19 vaccines were authorized in the United Kingdom, approximately hundreds of millions of doses have been administered, with billions more planned.² Vaccines are the most important public health intervention to prevent the spread of infectious disease, and, as a result, the whole world is racing to deploy a safe and effective vaccine against COVID-19.³ As of August 15, 2021, there are 179 vaccine candidates in pre-clinical and clinical development, thirty-three of which are in Phase III trials.⁴ As of February 27, 2021, the U.S. Food and Drug Administration (FDA) had granted Emergency Use Authorization (EUA) for Moderna/NIH's, Pfizer/BioNTech's, and Johnson & Johnson's vaccines.⁵ Pfizer/BioNTech's was given full licensure on August 23, 2021. The United Kingdom's Medicines and Healthcare products Regulatory Agency has approved those vaccines plus AstraZeneca's candidate for full licensure.⁶ Additional vaccine candidates from

1. German Lopez, *The Covid-19 Vaccine's 2 Big Challenges*, VOX (Dec. 14, 2020, 8:00 AM), <https://www.vox.com/future-perfect/22161047/covid-19-coronavirus-vaccine-manufacturing-distribution-persuasion> [<https://perma.cc/Q2XJ-XYSY>] (“This is going to be the largest mass vaccination campaign that the US has ever attempted.”).

2. Tom Randall, Cedric Sam, Andre Tartar, Paul Murray & Christopher Cannon, *More than 4.13 Billion Shots Given: Covid-19 Tracker*, BLOOMBERG, <https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/> [<http://web.archive.org/web/20210802000047/https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/>] (Aug 1, 2021, 2:53 PM).

3. Press Release, World Health Org., *More than 150 Countries Engaged in COVID-19 Vaccine Global Access Facility* (July 15, 2020), <https://www.who.int/news-room/detail/15-07-2020-more-than-150-countries-engaged-in-covid-19-vaccine-global-access-facility> [<https://perma.cc/F6FM-8TDK>]. See generally Sam F. Halabi & Saad B. Omer, *Evidence, Strategies, and Challenges for Assuring Vaccine Availability, Efficacy, and Safety*, in GLOBAL MANAGEMENT OF INFECTIOUS DISEASE AFTER EBOLA 223 (Sam F. Halabi, Lawrence O. Gostin & Jeffrey S. Crowley eds., 2016).

4. Trefis Team, *What to Expect as Moderna's COVID-19 Vaccine Moves to Phase 3 Trials*, FORBES (July 29, 2020, 9:30 AM), <https://www.forbes.com/sites/greatspeculations/2020/07/29/what-to-expect-as-modernas-covid-19-vaccine-moves-to-phase-3-trials/?sh=7c049f761e96> [<https://perma.cc/CT5M-GZ9F>] (“These trials will determine if the vaccine protects against Covid-19 and whether it will be cleared for use in the general public. Patients who recover from Covid-19 generate antibodies that help to prevent re-infection and per interim data from its phase 1 trials that involved 45 people, Moderna said that the people inoculated with the vaccine generated antibodies that were 4x compared to people who'd recovered from Covid. The phase 3 trial will help to validate this at a larger scale and is expected to enroll 30,000 participants in the U.S.”); Carl Zimmer, Jonathan Corum & Sui-Lee Wee, *Coronavirus Vaccine Tracker*, N.Y. TIMES, <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html> [<https://perma.cc/PNS7-AXUK>] (Aug. 2, 2021).

5. Press Release, Pfizer, *Pfizer and BioNTech to Submit Emergency Use Authorization Request Today to the U.S. FDA for Covid-19 Vaccine*, (Nov. 20, 2020, 6:45AM), <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-submit-emergency-use-authorization> [<https://perma.cc/XLT4-F87R>]; Press Release, Moderna, *Moderna Announces Primary Efficacy Analysis in Phase 3 COVE Study for Its COVID-19 Vaccine Candidate and Filing Today with U.S. FDA for Emergency Use Authorization* (Nov. 30, 2020), <https://investors.modernatx.com/node/10421/pdf> [<https://perma.cc/65AC-RCPY>].

6. Michael Mezher, *MHRA Authorizes Pfizer-BioNTech COVID Vaccines as FDA, EMA Set more Conservative Timeline*, REGUL. AFFS. PROS. SOC'Y (Dec. 2, 2020), <https://www.raps.org/news-and-articles/news-articles/2020/12/mhra-authorizes-pfizer-biontech-covid-vaccine-as-f> [<http://web.archive.org/web/20201212100540/https://www.raps.org/news-and-articles/news-articles/2020/12/>]

Novavax and others are entering regulatory review for EUA. The World Health Organization has granted emergency use listing to those vaccines in addition to Sinopharm and Sinovac vaccines.⁷

Wealthy governments have already invested billions of dollars in the effort to bring more vaccine candidates to licensure, or at least EUA.⁸ Many countries are attempting to secure access to vaccines by offering funding to scale-up manufacturing and assisting with clinical trials.⁹ The Global Alliance for Vaccines and Immunizations (GAVI), an international vaccine procurement consortium aiding low-income countries, is pursuing a similar strategy for securing equitable access to COVID-19 vaccines.¹⁰ The Coalition for Epidemic Preparedness Innovations (CEPI), an international financing partnership, has supported at least ten candidates, including Moderna's.¹¹ Instead of waiting until after vaccines are approved and then bidding for them, GAVI, CEPI, the World Health Organization (WHO), and the European Commission, as well as a number of global health charities, have developed the "COVAX Facility," an international organization aimed at procuring vaccine doses for all its participating governments, including subsidies for the purchase of vaccines by low- and middle-income countries.¹²

Governments have entered into bilateral arrangements to lay claim to early production. For example, AstraZeneca has received payments from the United Kingdom (U.K.), the United States, and the Serum Institute of India, and in return has promised delivery of 100 million doses, delivery of 300 million doses, and

mhra-authorizes-pfizer-biontech-covid-vaccine-as-f]; *Pfizer-BioNTech COVID-19 Vaccine*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine> [http://web.archive.org/web/20210723073821/https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine] (last visited July 23, 2021).

7. *Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process*, World Health Org. (Sept. 29, 2021), https://extranet.who.int/pqwweb/sites/default/files/documents/Status_COVID_VAX_29Sept2021_0.pdf [https://perma.cc/73YJ-2VDW].

8. See generally Matthew Herper, *AstraZeneca Lays Out Plan for Producing 2 Billion Doses of Covid-19 Vaccine, if It Works*, STAT (June 4, 2020), <https://www.statnews.com/2020/06/04/astrazeneca-lays-out-plan-for-producing-2-billion-doses-of-covid-19-vaccine-if-it-works/> [https://perma.cc/98K4-X8JL].

9. *Id.*

10. Press Release, Gavi, the Vaccine Alliance, *Gavi Launches Innovative Financing Mechanism for Access to COVID-19 Vaccines* (June 4, 2020), <https://www.gavi.org/news/media-room/gavi-launches-innovative-financing-mechanism-access-covid-19-vaccines> [https://perma.cc/ZY9T-9FNB].

11. Press Release, World Health Org., *COVAX Announces Additional Deals to Access Promising COVID-19 Vaccine Candidates; Plans Global Rollout Starting Q1 2021* (Dec. 18, 2020) [hereinafter WHO, *COVAX Announces Additional Deals*], <https://www.who.int/news/item/18-12-2020-covax-announces-additional-deals-to-access-promising-covid-19-vaccine-candidates-plans-global-rollout-starting-q1-2021> [https://perma.cc/M6FM-KPXX].

12. *Id.*; Press Release, Gavi, the Vaccine Alliance, *Up to 100 Million COVID-19 Vaccine Doses to Be Made Available for Low- and Middle-Income Countries as Early as 2021* (Aug. 7, 2020), <https://www.gavi.org/news/media-room/100-million-covid-19-vaccine-doses-available-low-and-middle-income-countries-2021> [https://perma.cc/Q4CH-RFMA].

assistance in producing 1 billion doses, respectively.¹³ However, there are far fewer details on what happens after the doses arrive.¹⁴

While *ex ante* investment in the development of vaccines, manufacturing capacity, and related material like vials and syringes is critical, so too is the *ex post* consideration of what happens should emergency-authorized or fully licensed vaccines cause significant side effects. Most of the leading COVID-19 vaccine candidates are based on technologies unlicensed anywhere in the world, and the potential for sizable product liability claims is significant.¹⁵ On December 8, 2020, the first day of the U.K. vaccination campaign, two severe allergic reactions caused the U.K. government to require monitoring patients for fifteen minutes after each injection.¹⁶ In the United States, the Centers for Disease Control and Prevention (CDC) has detected twenty-one anaphylactic reactions to COVID-19 vaccines out of nearly 1.9 million doses administered, a rate of approximately 11.1 severe reaction

13. Herper, *supra* note 8.

14. Eileen Drage O'Reilly, *The Coming Clash Over the First Coronavirus Vaccines*, AXIOS (Apr. 30, 2020), <https://www.axios.com/coronavirus-vaccine-supplies-availability-16264fa9-ccd5-4705-abd5-6d208e864ba9.html> [<https://perma.cc/V7ZD-2Q6H>] (“There will not be enough vaccines to meet initial demand, experts say. That’s left nations racing to secure future supplies and international organizations scrambling to make sure there is equitable access to any vaccines for the novel coronavirus. . . . The COVID-19 vaccine race is underway, with at least 92 in development and more expected. They’re based on different approaches that have different manufacturing processes. There are a limited number of facilities that are large enough for massive scale-ups and/or are flexible enough to switch to a different type of vaccine than they were originally intended to produce. Over the next several months, there’s expected to be a ‘winnowing’ of these potential vaccines as data from initial trials are collected, but it will take time before it’s known which vaccine(s) are best, according to a group of experts at a press briefing hosted by the nonprofit ONE on Thursday. Having a global dialogue now on how vaccines should be scaled up and distributed is key, experts say.”); Costas Paris & Jared S. Hopkins, *Pfizer Sets Up Its ‘Biggest Ever’ Vaccination Distribution Campaign*, WALL ST. J. (Oct. 21, 2020, 6:13 AM), <https://www.wsj.com/articles/pfizer-sets-up-its-biggest-ever-vaccination-distribution-campaign-11603272614> [<https://perma.cc/DJF5-TC5Q>] (“[T]he biggest complications in distribution likely would come closer to the final point of delivery rather than the first stages of shipping.”); Jared S. Hopkins, *Covid-19 Vaccines to Be Stored Secretly Under Tight Security*, WALL ST. J. (Oct. 21, 2020, 3:48 PM), https://www.wsj.com/articles/covid-19-vaccines-to-be-stored-secretly-under-tight-security-11603278002?mod=hp_lead_pos4 [<https://perma.cc/6ULY-S4BC>] (detailing the complications of vaccine theft and possible precautions that will be taken to hopefully protect the COVID-19 vaccine from theft).

15. John Parkinson, *FDA Fast Tracks 2 COVID-19 Vaccines*, CONTAGIONLIVE (July 13, 2020), <https://www.contagionlive.com/view/fda-fast-tracks-2-covid19-vaccines> [<https://perma.cc/A4KW-NXM8>].

16. Joanna Sugden, *Rollout of Pfizer-BioNTech Covid-19 Vaccine Slows in U.K. Due to Allergic-Reaction Monitoring*, WALL ST. J. (Dec. 14, 2020, 12:46 PM), <https://www.wsj.com/articles/rollout-of-pfizer-biontech-covid-19-vaccine-slows-in-u-k-due-to-allergic-reaction-monitoring-11607967990> [<https://perma.cc/VHU5-VMPK>].

cases per million.¹⁷ AstraZeneca and Johnson & Johnson vaccines have been associated with rare blood-clotting disorders.¹⁸

Although the United States has granted immunity to COVID-19 vaccine manufacturers pursuant to its Public Readiness and Emergency Preparedness Act (PREP Act),¹⁹ and manufacturers are securing “protection from future product liability claims” where possible on a bilateral basis, there remains no comprehensive plan for the potentially massive claims related to product liability.²⁰

For one or more vaccines likely to be distributed worldwide, there is inevitable risk of serious adverse events. For the H1N1 pandemic vaccine, the only vaccine distributed pursuant to a declared pandemic, serious adverse events following immunization varied widely. Among those reported in the United States through its Vaccine Adverse Event Reporting System, the H1N1 pandemic vaccine produced a serious adverse event rate of 2.45 per 100,000.²¹ In the People’s Republic of China, the National Adverse Events Following Immunization (AEFI) Surveillance System reported that a

total of 6552 of the 8067 adverse events there (81.2%; rate, 73.1 per 1 million doses) were verified as vaccine reactions; 1083 of the 8067 (13.4%; rate, 12.1 per 1 million doses) were rare and more serious (vs. common, minor events), most of which (1050) were allergic reactions. Eleven cases of the Guillain–Barré syndrome were reported, for a rate of 0.1 per 1 million doses.²²

17. Tom Shimabukuro, *Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14–23, 2020*, 70 MORBIDITY & MORTALITY WKLY. REP. 46, 46–51 (2021), <https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7002e1-H.pdf> [<https://perma.cc/W6GN-GWYM>].

18. EUR. CTR. FOR DISEASE PREVENTION & CONTROL, TECHNICAL REPORT, OVERVIEW OF EU/EEA COUNTRY RECOMMENDATIONS ON COVID-19 VACCINATION WITH VAXZEVRIA, AND A SCOPING REVIEW OF EVIDENCE TO GUIDE DECISION-MAKING 1 (2021), <https://www.ecdc.europa.eu/sites/default/files/documents/Overview%20EU%20EEA%20country%20recommendations%20on%20COVID-19%20vaccination%20Vaxzevria%20and%20scoping%20review%20of%20evidence.pdf> [<https://perma.cc/X3AC-3KBE>]; Press Release, U.S. FDA, FDA and CDC Lift Recommended Pause on Johnson & Johnson (Janssen) COVID-19 Vaccine Use Following Thorough Safety Review (Apr. 23, 2021), <https://www.fda.gov/news-events/press-announcements/fda-and-cdc-lift-recommended-pause-johnson-johnson-janssen-covid-19-vaccine-use-following-thorough> [<https://perma.cc/F892-N537>].

19. 42 U.S.C. § 247d-6d.

20. Ludwig Burger & Pushkala Aripaka, *AstraZeneca to be Exempt from Coronavirus Vaccine Liability Claims in Most Countries*, REUTERS (July 30, 2020, 6:19 AM), <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/5L9F-QP3F>].

21. Barbara H. Bardenheier, Susan K. Duderstadt, Renata J.M. Engler & Michael M. McNeil, *Adverse Events Following Pandemic Influenza A (H1N1) 2009 Monovalent and Seasonal Influenza Vaccinations During the 2009-2010 Season in the Active Component U.S. Military and Civilians Aged 17-44 Years Reported to the Vaccine Adverse Event Reporting System*, 34 VACCINE 4406, 4408 (2016).

22. Xiao-Feng Liang, Da-Wei Liu, Wen-Di Wu, Bao-Ping Zhu, Hua-Qing Wang, Hui-Ming Luo, Ling-Sheng Cao, Jing-Shan Zheng, Da-Peng Yin, Lei Cao, Bing-Bing Wu, Hong-Hong Bao, Di-Sha Xu, Wei-Zhong Yang & Yu Wang, *Safety of Influenza A (H1N1) Vaccine in Postmarketing Surveillance in China*, 364 N. ENG. J. MED. 638, 638 (2011).

Compensation costs similarly varied.²³ One specific H1N1 pandemic vaccine that contained an adjuvant was associated with an increased risk of narcolepsy, resulting in significant compensation claims in Northern European countries.²⁴

Solving the vaccine injury problem is crucial not only for populations injured by serious adverse events following immunization but also for the companies that may not participate in the response at all if not given sufficient assurances of immunity or indemnity and for governments with populations that may be disadvantaged because their internal legal systems do not allow the immunities or indemnities to be arranged through bilateral contracts (i.e., there must be a legislative measure undertaken). This Article outlines the components of a global system, leveraging currently existing no-fault vaccine injury compensation systems in thirty-nine countries, private-sector insurance alternatives based on a proposed program at the WHO, and a centralized mass claims system based on models for compensation from the Deepwater Horizon oil spill and the Boeing 737 Max airplane crashes, both of which involved hundreds or thousands of claimants from dozens of countries.

Part I of this Article analyzes the legal landscape for vaccine regulation including premarketing review by regulatory agencies and postmarketing regulation through product liability claims. Part I also uses specific aspects of COVID-19 vaccine technology and recent mass vaccination episodes to contextualize the scale of potential liability as well as the potentially significant lifelong costs imposed on those suffering rare but serious side effects after immunization. Part II introduces and details the COVAX Facility, an international partnership that aims to procure vaccine doses for low- and lower-middle-income countries unable to afford them. However, the COVAX Facility has not addressed the COVID-19 vaccine product liability problem, which is likely to thwart the vaccine's effectiveness. Part III provides a three-part plan for no-fault vaccine injury compensation based on leveraging existing, national no-fault systems; small-scale insurance regimes; and mass claims models based on human-caused disasters.

23. *Id.*

24. Ian Sample, *Ministers Lose Fight to Stop Payouts Over Swine Flu Jab Narcolepsy Cases*, GUARDIAN (Feb. 9, 2017, 5:56 AM), <https://www.theguardian.com/science/2017/feb/09/ministers-lose-fight-to-stop-payouts-in-swine-flu-jab-narcolepsy-cases> [https://perma.cc/D3MP-5PGF]; Rory Carroll, *Swine Flu Vaccine Case Settled but Hopes for Legal Precedent Dashed*, GUARDIAN (Nov. 19, 2020, 08:35 AM), <https://www.theguardian.com/world/2019/nov/20/swine-flu-vaccine-case-settled-but-hopes-for-legal-precedent-dashed> [https://perma.cc/4Z9Y-FQA3].

I. COVID-19 VACCINES AND PRODUCT LIABILITY

A. *The Uniqueness of Vaccines as Regulated Medical Products*1. *Premarket Review*

Legally and medically, vaccines are sui generis. Despite their immense value in terms of lives saved and resources preserved—between 1980 and 2018, the WHO estimates vaccines have saved 150 to 200 million lives and avoided \$586 billion in costs of illness—they are medicines given to otherwise healthy people to prevent disease.²⁵ Like all medicines, vaccines carry risks of side effects, from the minor and common (like soreness at the injection site) to the severe and rare, such as allergic reactions and Guillain-Barré syndrome (a condition in which the body's immune system attacks peripheral nerves), that may result in disability or death.²⁶

The potential for vaccines to cause harm in otherwise healthy people is the reason that most countries and international organizations look to scientific review agencies to verify the soundness of animal and human testing data, quality control of manufacturing facilities, and clarity of product information provided with the immunization. The U.S. FDA and the European Medicines Agency are two of the most important of these review agencies, and they provide services not only for the populations under their territorial authority but also for international organizations that procure vaccines for countries without the ability to undertake their own regulatory review.²⁷

The FDA's Center for Biologics Evaluation and Research is responsible for regulating vaccines in the United States, and its approval facilitates the use of

25. Samantha Vanderslott, Bernadeta Dadonaite & Max Roser, *Vaccination*, OUR WORLD IN DATA n.3 (2015) (“UNICEF (1996) and Hinman, A. R. (1998) estimate that in the absence of a vaccine the world would have seen 5 million deaths due to smallpox every year in the mid-1990s. Assuming that the estimate for the mid-1990s provides a midpoint estimate for the period since 1980 and therefore multiplying the 5 million per year estimate by the number of years between 1980 and 2016 means that since the eradication of the disease 190 million people's lives were saved. UNICEF (1996) – Vaccines bring 7 diseases under control.”). See generally Sachiko Ozawa, Samantha Clark, Allison Portnoy, Simrun Grewal, Logan Brenzel & Damian G. Walker, *Return on Investment From Childhood Immunization in Low- and Middle-Income Countries, 2011-20*, 35 HEALTH AFFS. 199 (2016); Anya E.R. Prince, *Prevention for Those Who Can Pay: Insurance Reimbursement of Genetic-Based Preventative Interventions in the Liminal State Between Health and Disease*, 2 J.L. & BIOSCIENCES 365, 369 (2015) (“Public health literature references prevention by type—primary, secondary, and tertiary. Primary prevention occurs before a disease manifests through symptoms or biological changes. A common example is vaccination to protect against certain infectious childhood diseases. Whereas primary prevention reduces both incidence and prevalence of a condition because it blocks an individual from getting a disease, secondary prevention occurs after biological changes have arisen in an individual but reduces disease severity by preventing progression or mortality.”).

26. Sam F. Halabi & Saad B. Omer, *A Global Vaccine Injury Compensation System*, 317 JAMA 471, 471 (2017); Richard A.C. Hughes & David R. Cornblath, *Guillain-Barré Syndrome*, 366 LANCET 1653, 1653 (2005).

27. See generally Sam Halabi & John Monahan, *Regulatory Capacity in Low- and Middle-Income Countries: Lessons from the H1N1 Influenza Pandemic*, in FOOD AND DRUG REGULATION IN AN ERA OF GLOBALIZED MARKETS 63 (Sam Halabi ed., 2015).

vaccines in countries that lack regulatory capacity.²⁸ The vaccine clinical development process—including that of COVID-19 vaccines—follows the same general pathway as for drugs and other biologics.²⁹

As researchers identify and isolate the relevant pathogen, they seek to understand, to the greatest extent possible, the biological mechanism or mechanisms that lead to disease.³⁰ While some candidate vaccines occur naturally (like that for smallpox), most candidates are developed using empirical approaches: historically, serial propagation of a pathogen through media that diminishes pathogenicity, or that is killed or dissected after cultivation and used in relatively large doses, with adjuvants or in multiple doses to prompt an immune response.³¹ More recent techniques like “reverse vaccinology” start from genomic sequences and, by computer simulation, predict those antigens that are most likely to be vaccine candidates.³² Vaccine candidates are then tested in animals after developing models for immunogenicity and safety.³³

After animal testing, the vaccine sponsor applies for Investigational New Drug (IND) status from the U.S. FDA, which authorizes the sponsor to undertake clinical trials on humans for safety and efficacy and, ultimately, to build the evidentiary case for licensure.³⁴ The first of these trials (Phase I) is designed to assess the safety, immunogenicity, and dose-response of the vaccine in, typically, 20–100 healthy volunteers.³⁵ The IND describes the vaccine, its method of manufacture and quality control tests for release, information about the vaccine’s safety and ability to prompt a protective immune response in animal testing, and the proposed clinical studies protocol.³⁶

In Phase II, the sample size is increased to several hundred healthy volunteers, and investigators focus on safety as well as immunogenicity. In Phase II(b) “proof-of-concept” studies, dose-ranges and vaccine components are confirmed

28. *Vaccine Development – 101*, U.S. FDA, <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101> [<https://perma.cc/HUD8-DBS9>] (Dec. 14, 2020).

29. See 42 U.S.C. § 262 (outlining the regulation of biological products).

30. See generally PRINCIPLES OF BACTERIAL PATHOGENESIS (Eduardo A. Groisman ed., 2001).

31. Nicola P. Klein, Joan Bartlett, Ali Rowhani-Rahbar, Bruce Fireman & Roger Baxter, *Waning Protection After Fifth Dose of Acellular Pertussis Vaccine in Children*, 367 N. ENG. J. MED. 1012, 1013 (2012); Bo Ma, Li-Fang He, Yi-Li Zhang, Min Chen, Li-Li Wang, Hong-Wei Yang, Ting Yan, Meng-Xiang Sun & Cong-Yi Zheng, *Characteristics and Viral Propagation Properties of a New Human Diploid Cell Line, Walvax-2, and Its Suitability as a Candidate Cell Substrate for Vaccine Production*, 11 HUM. VACCINES & IMMUNOTHERAPEUTICS 998, 1004–05 (2015).

32. Rino Rappuoli, *Reverse Vaccinology, a Genome-Based Approach to Vaccine Development*, 19 VACCINE 2688, 2689 (2001).

33. *Vaccine Development – 101*, *supra* note 28.

34. 21 C.F.R. § 312.23 (2020).

35. *Vaccine Development – 101*, *supra* note 28.

36. U.S. FDA, INVESTIGATIONAL NEW DRUG (IND) APPLICATION, <https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application> [<https://perma.cc/L9TJ-RQ6Y>] (Feb. 24, 2021).

before moving to much larger Phase III studies.³⁷ Phase III vaccine trials enroll up to thousands or tens of thousands of human subjects in order to detect rare adverse events.³⁸ In 1998, for example, a rotavirus vaccine was licensed for use in the United States after Phase III trials on approximately 10,000 infants showed safety and efficacy. However, when administered to a larger population, physicians and researchers observed an association between the vaccine and bowel obstruction, resulting in the withdrawal of the vaccine.³⁹ If larger Phase III studies confirm safety and efficacy, the vaccine is approved for marketing after the FDA's review of study data.⁴⁰

Safety evaluations are essential during each phase of the clinic trials and continue after the approval of the vaccine. It is especially important to develop a systematic approach to classifying side effects to be able to assess causality when a side effect is observed in the clinical trial.⁴¹ Until a vaccine is given to the general population, not all potential adverse reactions can be anticipated.⁴² Thus, many vaccines undergo Phase IV: postmarketing surveillance and strict safety reporting standards during and after clinical trials.⁴³ A key criterion during Phase IV studies is to determine if there was a “reasonable possibility that the drug (or biologic) caused [an adverse] event and whether the event (or pattern of events) [was] unexpected.”⁴⁴

Vaccine approval also requires adequate product labeling to allow health-care providers to understand the vaccine's proper use (including its potential benefits and risks), to communicate with patients and parents, and to safely deliver the vaccine to the public.⁴⁵ A product's package insert, also known as the “label,” is a critical element of the evaluation of a vaccination.⁴⁶

2. Tort Liability as a Regulatory Mechanism

Under the laws of most countries, regulatory review of medical products does not generally preclude the liability for manufacturers of those products for injuries

37. See Bernd Schmidt, *Proof of Principle Studies*, 68 EPILEPSY RES. 49, 49 (2006).

38. *Vaccine Development – 101*, *supra* note 28.

39. Brian R. Murphy, David M. Morens, Lone Simonsen, Robert M. Chanock, John R. La Montagne & Albert Z. Kapikian, *Reappraisal of the Association of Intussusception with the Licensed Live Rotavirus Vaccine Challenges Initial Conclusions*, 187 J. INFECTIOUS DISEASES 1301, 1301 (2003).

40. *Vaccine Development – 101*, *supra* note 28.

41. Jeffrey N. Roberts & Marion F. Gruber, *Regulatory Considerations in the Clinical Development of Vaccines Indicated for Use During Pregnancy*, 33 VACCINE 966, 969 (2015); see Alberto E. Tozzi, Edwin J. Asturias, Madhava Ram Balakrishnan, Neal A. Halsey, Barbara Law & Patrick L.F. Zuber, *Assessment of Causality of Individual Adverse Events Following Immunization (AEFI): A WHO Tool for Global Use*, 31 VACCINE 5041, 5041 (2013) (detailing a study commissioned to review the WHO's “Adverse Event Following Immunization (AEFI) causality assessment methodology and aid-memoire, and to develop a standardized and user friendly tool to assist health care personnel in the process and interpretation of data on individual, and to assess the causality after AEFIs”).

42. See generally Tozzi et al., *supra* note 41; *Vaccine Development – 101*, *supra* note 28.

43. *Vaccine Development – 101*, *supra* note 28.

44. Roberts & Gruber, *supra* note 41, at 969.

45. *Vaccine Development – 101*, *supra* note 28.

46. 21 C.F.R. § 201.56–.57 (2020).

attributable to them. In EU member states, laws generally place liability for vaccine side effects on pharmaceutical companies.⁴⁷ Over the course of the H1N1 pandemic, it was discovered that legal liabilities across the world, by default, remained with manufacturers for the pandemic vaccine's side effects, a matter that resulted in significant delays as countries, the WHO, and manufacturers negotiated over indemnity provisions.⁴⁸

Within the United States, vaccine side effects were (before 1986) generally susceptible to state law claims made under principles of strict liability as well as tort regimes specific to “unavoidably unsafe” products, which require only that producers of medicines and vaccines properly prepare and market them and supply sufficient warnings about their use.⁴⁹ The general idea for maintaining the possibility of liability for side effects is that it supplies an incentive for manufacturers to continually invest in the safety of their products and that, between an uninjured (and presumptively compensated) manufacturer and an injured vaccine recipient, the law should favor making the injured person whole.⁵⁰ After the adoption of the National Childhood Vaccine Injury Act of 1986, vaccine side effects are now almost entirely routed to a no-fault compensation system administered through the U.S. Court of Federal Claims.⁵¹

Worldwide, the law of product liability generally imposes three kinds of obligations on vaccine manufacturers: to ensure that they manufacture vaccines consistently with current good manufacturing practices (cGMPs); that they design their vaccines so severe side effects are minimized to the greatest extent possible without compromising their cost and utility; and that they properly label vaccines, including the risks and benefits of administration.⁵² In U.S. legal nomenclature, these obligations are generally understood to give vaccine recipients the right to receive vaccines free from manufacturing defects, design defects, and labeling

47. Francesco Guarascio, *Limited Legal Protection for COVID Vaccine Makers Hampers EU Deals*, REUTERS (Aug. 26, 2020, 1:01 AM), <https://www.reuters.com/article/us-health-coronavirus-eu-vaccines/limited-legal-protection-for-covid-vaccine-makers-hampers-eu-deals-idUSKBN25M0RQ> [<https://perma.cc/AE4Y-TDC3>].

48. Sam F. Halabi, *Obstacles to pH1N1 Vaccine Availability: The Complex Contracting Relationship Between Vaccine Manufacturers, the World Health Organization, Donor and Beneficiary Governments*, in *THE PUBLIC HEALTH RESPONSE TO 2009 H1N1: A SYSTEMS PERSPECTIVE* 203, 207 (Michael A. Stoto & Melissa A. Higdon eds., 2015).

49. RESTATEMENT (SECOND) OF TORTS §§ 402, 402A cmt. k (AM. L. INST. 1965).

50. *Bruesewitz v. Wyeth*, 562 U.S. 223, 250 (2011) (Sotomayor, J. dissenting).

51. *Vaccine Claims/Office of Special Masters*, U.S. CT. FED. CLAIMS, <https://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters> [<https://perma.cc/KCN7-SA43>] (last visited Aug. 3, 2021).

52. Sam Halabi & John Monahan, *Sharing the Burden of Ebola Vaccine-Related Adverse Events*, 24 TUL. J. INT'L & COMP. L. 131, 136 (2015); see also John C. Reitz, *Doubts About Convergence: Political Economy as an Impediment to Globalization*, 12 TRANSNAT'L L. & CONTEMP. PROBS. 139, 140 (“Since virtually all modern legal systems in the world are modeled to a substantial degree on aspects of either the common or the civil law or both, especially with regard to their commercial law and some of their public law, the convergence thesis seems relevant to all countries in the world.”); *Bruesewitz*, 562 U.S. at 250 (Sotomayor, J. dissenting).

defects (labeling defects include “failures to warn” of relevant risks, benefits, and other relevant information).⁵³ This latter right enjoyed by vaccine recipients overlaps to some degree, although not completely, with principles of informed consent.⁵⁴

This Article focuses specifically on the possibility that legal action will be taken because of a manufacturer’s actions, inactions, products, services, or other activities, leading to claims based on: (1) product liability (including perception and attribution of injury) and (2) informed consent/product labeling.

B. Product Liability and COVID-19 Vaccines

1. Real and Unknown Risks

Even safe and effective vaccines generate adverse events among those inoculated, ranging from (common) soreness at the injection site, fever, discomfort, and muscle pain to (rare) anaphylaxis and other severe reactions.⁵⁵ For vaccines incorporating traditional platforms—like an inactivated virus (i.e., a killed virus, commonly used for flu shots) or live-attenuated virus (i.e., a virus that has been weakened under laboratory conditions, used for measles, mumps, and rubella (MMR))—there are decades of evidence and well-controlled postimmunization surveillance to confirm both safety and efficacy.⁵⁶ The occurrence of serious side effects, such as those that result in death, threaten life, require inpatient hospitalization, or result in significant disability, are rare (e.g., less than one adverse event occurs per ten million doses for tetanus toxoid vaccines, one to two adverse events per one million doses for inactivated influenza vaccine, and none for hepatitis A).⁵⁷

a. New Vaccine Technologies

Robust data sets are essential to better define risk to specific subgroups, clearly demonstrate clinical benefit, better define and continue to evaluate as part of an ongoing process the safety profile of the vaccine, and facilitate

53. W. PAGE KEETON, DAN B. DOBBS, ROBERT E. KEETON & DAVID G. OWEN, PROSSER AND KEETON ON THE LAW OF TORTS § 99, at 695 (5th ed. 1984) (student ed.).

54. Sheldon F. Kurtz, *The Law of Informed Consent: From “Doctor is Right” to “Patient Has Rights”*, 50 SYRACUSE L. REV. 1243, 1245 (2001) (“Today, the right of a patient to participate to some extent in medical decision making affecting the patient is universally dictated by the ‘informed consent’ laws of all states.”).

55. Luana Raposo de Melo Moraes Aps, Marco Aurélio Floriano Piantola, Sara Araujo Pereira, Julia Tavares de Castro, Fernanda Ayane de Oliveira Santos & Luís Carlos de Souza Ferreira, *Adverse Events of Vaccines and the Consequences of Non-Vaccination: A Critical Review*, 52 REVISTA DE SAÚDE PÚBLICA 1, 3 (2018) (“The administration of these compounds may lead to adverse reactions, such as local inflammatory reactions and, much less frequently, systemic effects, such as the exacerbation of autoimmune diseases and allergies.”).

56. See generally Stanley Plotkin, *History of Vaccination*, 111 PNAS 12283 (2014).

57. Halabi & Omer, *supra* note 26, at 471.

communication of benefit/risk data and information that will mitigate litigation risk.⁵⁸ The safety profile of vaccination with newer platforms like DNA, non-replicating viral vector, protein subunit, and RNA vaccines, including adjuvants,⁵⁹ is less extensive than with platforms with long safety profiles like inactivated or live-attenuated vaccines.⁶⁰ The use of DNA vaccines, for example, has raised safety concerns mainly regarding the probability of stable integration of transfected DNA into the genome of somatic or even germ cells, causing dysregulated gene expression and mutations.⁶¹

Most COVID-19 vaccine candidates, and certainly the leading ones, are generally based on these new kinds of technologies, which are not licensed for use in humans anywhere in the world.⁶² AstraZeneca's candidate, ChAdOx1 nCoV-19, for example, uses a chimpanzee adenovirus (the same that causes the common cold) to deliver a SARS-CoV-2 spike protein, which then prompts an immune response to that protein when exposure to the actual SARS-CoV-2 pathogen occurs.⁶³ Moderna's and Pfizer's vaccine candidates are based on messengerRNA (generally

58. Michael M. McNeil, Julianne Gee, Eric S. Weintraub, Edward A. Belongia, Grace M. Lee, Jason M. Glanz, James D. Nordin, Nicola P. Klein, Roger Baxter, Allison L. Naleway, Lisa A. Jackson, Saad B. Omer, Steven J. Jacobsen & Frank DeStefano, *The Vaccine Safety Datalink: Successes and Challenges Monitoring Vaccine Safety*, 32 VACCINE 5390, 5393 (2014) ("Recognizing the need for a flexible, timely and robust system to evaluate vaccine safety and supplement information provided by VAERS, CDC established the Vaccine Safety Datalink (VSD) in 1990 to conduct post-marketing vaccine safety evaluations in defined populations.").

59. Takehiro Ura, Kenji Okuda & Masaru Shimada, *Developments in Viral Vector-Based Vaccines*, 2 VACCINES 624, 632 (2014) ("Viral vector-based vaccines can be easily manufactured alongside traditional vaccines in large manufacturing units, and their safety profiles can be tested easily.").

60. Claudia Maria Trombetta, Elena Giancchetti & Emanuele Montomoli, *Influenza Vaccines: Evaluation of the Safety Profile*, 14 HUM. VACCINES & IMMUNOTHERAPEUTICS, 657, 658 (2018) ("Inactivated vaccines have an excellent safety profile.").

61. Jacob Glenting & Stephen Wessels, *Ensuring Safety of DNA Vaccines*, MICROBIAL CELL FACTORIES (Sept. 6, 2005), <https://microbialcellfactories.biomedcentral.com/track/pdf/10.1186/1475-2859-4-26.pdf> [<https://perma.cc/CE26-63GN>] ("[I]nternational regulatory groups have recently questioned the safety of certain existing DNA vaccine constructs.").

62. Asher Mullard, *COVID-19 Vaccine Development Pipeline Gears Up*, 395 LANCET 1751, 1751 (2020).

63. Pedro M. Folegatti, Katie J. Ewer, Parvinder K. Aley, Brian Angus, Stephen Becker, Sandra Belij-Rammerstorfer, Duncan Bellamy, Sagida Bibi, Mustapha Bittaye, Elizabeth A. Clutterbuck, Christina Dold, Saul N. Faust, Adam Finn, Amy L. Flaxman, Bassam Hallis, Paul Heath, Daniel Jenkin, Rajeka Lazarus, Rebecca Makinson, Angela M. Minassian, Katina M. Pollock, Maheshi Ramasamy, Hannah Robinson, Matthew Snape, Richard Tarrant, Merryn Voysey, Catherine Green, Alexander D. Douglas, Adrian V.S. Hill, Teresa Lambe, Sarah C. Gilbert & Andrew J. Pollard, *Safety and Immunogenicity of the ChAdOx1 nCoV-19 Vaccine Against SARS-CoV-2: A Preliminary Report of a Phase 1/2, Single-Blind, Randomised Controlled Trial*, 396 LANCET 467, 468, (2020); Allison Martell & Julie Steenhuisen, *Explainer: How Common Cold Viruses are Being Used in Vaccines from Russia, China*, REUTERS (Aug. 31, 2020, 3:09 AM), <https://www.reuters.com/article/us-health-coronavirus-vaccines-adenoviru/how-common-cold-viruses-are-being-used-in-vaccines-from-russia-china-idUSKBN25R192> [<https://perma.cc/W2QZ-NSJ7>].

known as mRNA) that instruct human cells to produce protein antigens.⁶⁴ The idea is that once a person receives those RNA instructions in an injected vaccine, their cells express proteins. These are then displayed on cell surfaces or released into the circulation, where the body's natural immune system recognizes them.⁶⁵ The regulatory review process generally vets vaccine candidates, not vaccine platforms; thus, there is no additional scrutiny given to new technologies that raise risks of causing dysregulated gene expression and/or mutations.⁶⁶

b. Side Effects Following Phase III and EUA COVID-19 Vaccines

Incidents from Phase III trials have given a reasonable basis to prepare for severe side effects not only because the technologies are new but because the scale of mass vaccination is unprecedented. AstraZeneca's Phase III trial was paused worldwide after two volunteers experienced inflammation of the spinal cord.⁶⁷ Johnson & Johnson's vaccine trial was also paused during Phase III for rare blood-clotting events.⁶⁸ Two people in the U.K. had severe reactions to Pfizer's vaccine within the first week.⁶⁹ In the United States, there have been twenty-one cases of anaphylaxis and at least one suspected case linking vaccine administration to severe bleeding.⁷⁰

After significant doses were administered, safety signals were recorded for all leading vaccines: AstraZeneca's (marketed as Vaxzevria in the EU), Johnson & Johnson's, and Pfizer-BioNTech's. In March 2021, with more than twenty-five million people receiving the Vaxzevria vaccine, more than twenty countries stopped vaccinations after reports of young patients suffering severe clotting disorders and rare types of strokes.⁷¹ The European Medicines Agency (EMA) safety committee

64. Amber Dance, *Coronavirus Vaccines Get a Biotech Boost*, NATURE (July 21, 2020), <https://www.nature.com/articles/d41586-020-02154-2> [<https://perma.cc/W96K-U5B2>].

65. *Id.*

66. JOHNS HOPKINS, VACCINE PLATFORMS: STATE OF THE FIELD AND LOOMING CHALLENGES 5 (2019) (noting that "regulatory agencies approve products, not platforms").

67. Rachel Arthur, *AstraZeneca Resumes US COVID-19 Vaccine Trial; Expects Results Later this Year*, BIOPHARMA-REP. (Nov. 5, 2020, 10:00 AM), <https://www.biopharma-reporter.com/Article/2020/10/26/AstraZeneca-resumes-US-COVID-19-vaccine-trial> [<https://perma.cc/JX53-9LMK>].

68. Rachel Arthur, *Johnson & Johnson Pauses COVID-19 Vaccine Trial Due to an Unexplained Illness*, BIOPHARMA-REP. (Oct. 13, 2020, 10:58 AM), <https://www.biopharma-reporter.com/Article/2020/10/13/Johnson-Johnson-pauses-COVID-19-vaccine-trial-due-to-an-unexplained-illness> [<https://perma.cc/VH5X-BJJN>]; <https://www.fda.gov/news-events/press-announcements/fda-and-cdc-lift-recommended-pause-johnson-johnson-janssen-covid-19-vaccine-use-following-through>

69. Sugden, *supra* note 16.

70. Amy Goldstein, Laurie McGinley, Isaac Stanley-Becker & Fenit Nirappil, *Biden Plans to Release Nearly All Available Vaccine Doses to Speed Inoculations*, WASH. POST (Jan 8, 2021, 8:40 PM) https://www.washingtonpost.com/health/biden-plans-to-release-of-nearly-all-available-vaccine-doses-to-speed-inoculations/2021/01/08/93d58c72-51db-11eb-83e3-322644d82356_story.html [<https://perma.cc/FYZ2-Q55X>].

71. Kai Kupferschmidt & Gretchen Vogel, *European Countries Resume Use of AstraZeneca's COVID-19 Vaccine, Hoping Pause has Not Dented Confidence*, SCIENCE (Mar. 18, 2021), <https://www.sciencemag.org/news/2021/03/european-countries-resume-use-astrazenecas-covid-19-vaccine-hoping-pause-has-not-dented> [<https://perma.cc/B4YN-X8RW>].

did an in-depth review of sixty-two cases of cerebral venous sinus thrombosis and twenty-four cases of splanchnic vein thrombosis, eighteen of which were fatal, that had been reported in the EU drug safety database as of March 18, 2021.⁷² On April 7, 2021, the EMA concluded that unusual blood clots with low blood platelets should be listed as a very rare side effect of Vaxzevria.⁷³ Several countries updated their recommendation on the use of Vaxzevria, with fifteen countries adopting specific recommendations to administer Vaxzevria only to certain age groups and twelve countries recommending use of Vaxzevria based on EMA guidelines with exceptions for those with a history or risk of thromboembolism and pregnant women.⁷⁴ Two countries discontinued the use of Vaxzevria.⁷⁵

In the United States, the Johnson & Johnson vaccine was paused after reports of six cases of a rare and severe type of blood clot in individuals following administration of the vaccine.⁷⁶ The FDA and CDC scientific teams examined available data of the 6.8 million doses that had been administered to assess the risk of thrombosis.⁷⁷

The EMA agency has concluded a review of the Pfizer-BioNTech vaccine that has reports of facial swelling for people who have received dermal fillers and is continuing to follow reports of heart muscle inflammation after receipt of the Pfizer-BioNtech vaccine.⁷⁸

c. H1N1

Assuming a severe side effect rate of 2.45 per 100,000—a measure based on the U.S. experience with pandemic H1N1 vaccine—and certainly at 11.1 cases per million, the scale of adverse events would be significant.⁷⁹ The WHO estimates the delivery of two billion vaccine doses that will necessarily involve deployment of adenovirus (AstraZeneca and Johnson & Johnson) and messenger RNA (Moderna

72. Press Release, Eur. Meds. Agency, AstraZeneca's COVID-19 Vaccine: EMA Finds Possible Link to Very Rare Cases of Unusual Blood Clots with Low Platelets (July 4, 2021), <https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood> [https://perma.cc/Z75E-VJQM].

73. *Id.*

74. EUR. CTR. FOR DISEASE PREVENTION & CONTROL, *supra* note 18, at 1.

75. *Id.*

76. Press Release, U.S. FDA, FDA and CDC Lift Recommended Pause on Johnson & Johnson (Janssen) COVID-19 Vaccine Use Following Thorough Safety Review (Apr. 23, 2021), <https://www.fda.gov/news-events/press-announcements/fda-and-cdc-lift-recommended-pause-johnson-johnson-janssen-covid-19-vaccine-use-following-thorough> [https://perma.cc/ZUK3-DY3C].

77. *Id.*

78. Kari Oakes, *PRAC Investigates Heart Inflammation Reports with Pfizer Vaccine*, REGUL. AFFS. PROS. SOC'Y (May 7, 2021), <https://www.raps.org/news-and-articles/news-articles/2021/5/prac-investigates-heart-inflammation-reports-with> [http://web.archive.org/web/20210507215317/https://www.raps.org/news-and-articles/news-articles/2021/5/prac-investigates-heart-inflammation-reports-with].

79. Bardenheier et al., *supra* note 21, at 4408.

and Pfizer) vaccines as well as some based on conventional technologies.⁸⁰ The same rate of severe side effects—those suffering disability or death or with illnesses requiring hospitalization—would reach 50,000 to 200,000 worldwide. That number may underestimate the prevalence and severity of side effects following COVID-19 immunizations. Over the course of the H1N1 pandemic, an adjuvanted vaccine distributed by GlaxoSmithKline (GSK) was associated with a heightened risk of narcolepsy, a condition associated with people of Northern European descent. Adjuvanted H1N1 vaccines were not licensed in the United States.⁸¹

In the 2009 H1N1 pandemic, the negotiations over indemnification and immunity for manufacturers caused significant delays.⁸² When the 2009 H1N1 virus began emerging as a potential pandemic, pharmaceutical firms began negotiating with the WHO over conditions for the global distribution of a vaccine, which is the most important defense against a pandemic.

From the manufacturers' perspective, these negotiations occurred in the shadow of potentially large liabilities related to their existing contractual arrangements with governments, detailed processes for vaccine approval, distribution and marketing, as well as more general exposure should quickly-developed vaccines generate unexpected adverse reactions or safety problems. . . . In many jurisdictions, manufacturers bear legal responsibility for these adverse events, although many states change these liabilities in cases of public health emergencies. Nevertheless, manufacturers faced a range of legal barriers to production, donation and discounted sale of pandemic vaccines⁸³

The negotiations had two sources of delay: first, both manufacturers and countries had entered into agreements regarding purchasing vaccines, which severely curtailed manufacturers' ability to donate vaccines as large numbers of their production were promised to wealthy states that had paid for them; second, the

80. Helen Branswell, *WHO, Partners Unveil Ambitious Plan to Deliver 2 Billion Doses of Covid-19 Vaccine to High-risk Populations*, STAT (June 26, 2020), <https://www.statnews.com/2020/06/26/who-partners-unveil-ambitious-plan-to-deliver-2-billion-doses-of-covid-19-vaccine-to-high-risk-populations/> [<https://perma.cc/7EZJ-PA5A>].

81. DIV. OF HEALTH PROMOTION & DISEASE PREVENTION, INST. OF MED., VACCINE SUPPLY AND INNOVATION 85 (1985) (“A manufacturer who produces and sells a defective vaccine that creates a risk of significant injury to the recipient is liable to any person injured by that defect.”); *Narcolepsy Following 2009 Pandemrix Influenza Vaccination in Europe*, CTNS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vaccinesafety/concerns/history/narcolepsy-flu.html> [<https://perma.cc/HG6C-2SQC>] (last visited Aug. 20, 2020).

82. INST. OF MED., *THE DOMESTIC AND INTERNATIONAL IMPACTS OF THE 2009-H1N1 INFLUENZA A PANDEMIC: GLOBAL CHALLENGES, GLOBAL SOLUTIONS: WORKSHOP SUMMARY 12* (2010) (“Progress toward mass immunization was temporarily stalled when the vaccine manufacturers demanded indemnification against claims of any adverse reactions associated with the vaccines.”).

83. Sam F. Halabi, *Obstacles to pH1N1 Vaccine Availability: the Complex Contracting Relationship between Vaccine Manufacturers, WHO, Donor and Beneficiary Governments* in MA Stoto and M Higdon (eds.), *THE PUBLIC HEALTH RESPONSE TO H1N1: A SYSTEMS PERSPECTIVE* 203-16 (Oxford University Press, 2015).

vaccine manufacturers insisted on legal protections in countries where they were not licensed to produce or distribute a vaccine.⁸⁴

The U.S. experience with the 1976 H1N1 outbreak demonstrates some of these risks.⁸⁵ The influenza pandemic of 1918 killed an estimated fifty million people, so governments around the world and the WHO have invested steeply in preparation for influenza.⁸⁶ In 1976, a handful of soldiers in Fort Dix, New Jersey, were diagnosed with the virus.⁸⁷ The CDC hosted a press conference and, although the virus never spread out of the base, the outbreak garnered significant media attention.⁸⁸ President Ford initiated a program to vaccinate “every man, woman, and child in the United States.”⁸⁹ Vaccine manufacturers began developing a vaccine, but during clinical testing, three subjects died of complications for reasons unrelated to the vaccine.⁹⁰ This generated negative sentiment toward the vaccine. Then, over 400 people developed a rare neurological condition after receiving the vaccine, which resulted in the termination of the vaccine program.⁹¹

The U.S. government and pharmaceutical manufacturers agreed in advance to an indemnification of risk for the manufacturer, which resulted in the U.S. government being the defendant in the suits arising from the vaccine complications. Ultimately, the United States was named as defendant in over 1,000 lawsuits and paid approximately \$83 million in claims.⁹² For comparison, the vaccination program as a whole was estimated to cost \$134 million, with \$100 million for the development of the vaccine.⁹³

84. *Id.*; WHO Director-General, *Report of the Review Committee on the Functioning of the International Health Regulations (2005) in Relation to Pandemic (H1N1) 2009*, WHO Doc. A64/10 (May 5, 2011) (“Among the key difficulties was a variation in willingness to donate, concerns about liability, complex negotiations over legal agreements, lack of procedures to bypass national regulatory requirements and limited national and local capacities to transport, store and administer vaccines.”).

85. Rebecca Kreston, *The Public Health Legacy of the 1976 Swine Flu Outbreak*, DISCOVER MAG. (Sept. 30, 2013, 1:30 PM), <https://www.discovermagazine.com/health/the-public-health-legacy-of-the-1976-swine-flu-outbreak> [<https://perma.cc/85W6-YZPR>].

86. Brooke Killian Kim & Jessica C. Wilson, *COVID-19: Tort Immunity for Vaccines and Antivirals — Lessons from the Swine Flu of 1976*, DLA PIPER (April 8, 2020), <https://www.dlapiper.com/en/us/insights/publications/2020/04/covid-19--tort-immunity-for-vaccines-and-antivirals/> [<https://perma.cc/M4S5-GLWV>]; *see generally* H.R. DOC. NO 77-115 (1977).

87. Kim et al., *supra* note 86.

88. President Gerald R. Ford, Remarks Announcing the National Swine Flu Immunization Program in the White House Briefing Room (March 24, 1976) (transcript available in the Gerald R. Ford Presidential Library & Museum); H.R. DOC. NO 77-115 (1977); RICHARD E. NEUSTADT & HARVEY V. FINEBERG, *THE SWINE FLU AFFAIR: DECISION-MAKING ON A SLIPPERY DISEASE* 4, 6–7 (1978).

89. President Gerald R. Ford, *supra* note 88.

90. Kim et al., *supra* note 86.

91. *Id.*

92. *Id.*

93. *Id.*

d. Dengue

The dengue virus, transmitted by the *aedes aegypti* mosquito in tropical regions of the world, causes a range of symptoms, from subclinical, when people might not know they are infected, to symptoms similar to that of a severe influenza disease, which causes “bleeding, organ impairment, and/or plasma leakage.”⁹⁴ The WHO estimates that there are 390 million dengue infections per year; of those, 96 million present with some severity of the virus and around 20,000 cases result in death—usually among children.⁹⁵ Dengue is present in 129 countries, and over the last fifty years, it is believed that dengue has increased at least thirtyfold with a sharp increase after 2000.⁹⁶ Since that point, it has been labeled a priority pathogen for the development of a licensed vaccine, but as with many diseases affecting poorer countries (seventy percent of cases occur in low-income countries in Asia), the actual market incentive for doing so is limited.⁹⁷

After nearly twenty years of research and development, Sanofi Pasteur finally produced the CYD-TDV vaccine, licensed under the name Dengvaxia, the first and only approved vaccine to inoculate against dengue infection.⁹⁸ To date, Dengvaxia has been registered in twenty⁹⁹ countries including the EU member states and the United States.¹⁰⁰ There have been two subnational¹⁰¹ immunization implementation

94. *Dengue and Severe Dengue*, WORLD HEALTH ORG. (June 23, 2020), <https://www.who.int/news-room/fact-sheets/detail/dengue-and-severe-dengue> [<https://perma.cc/X4J6-T6U2>].

95. *Dengue Vaccine: WHO Position Paper –September 2018*, 36 WKLY. EPIDEMIOLOGICAL REC. OF THE WORLD HEALTH ORG. [WHO] 457, 458 (2018) [hereinafter *Dengue Vaccine: WHO Paper*], <https://apps.who.int/iris/bitstream/handle/10665/274315/WER9336.pdf?ua=1> [<https://perma.cc/Q4WF-NV42>]; Sarah Murrell, Suh-Chin Wu & Michael Butler, *Review of Dengue Virus and the Development of a Vaccine*, 29 BIOTECHNOLOGY ADVANCES 239, 240 (2011).

96. See Murrell et al., *supra* note 95, at 240 (noting the belief that Dengue “DENV” is under reported because it can present asymptomatic or misreported because symptoms are similar to other viruses, additionally, the uptake after 2000 is believed to be sparked by “geographic expansion of the vector”); *Dengue and Severe Dengue*, *supra* note 94.

97. See CTR. FOR GLOB. DEV. & GLOB. HEALTH POL’Y RSCH. NETWORK, MAKING MARKETS FOR VACCINES: A PRACTICAL PLAN, 1, 24 <https://www.who.int/intellectualproperty/news/en/SubmissionBarde1.pdf> [<https://perma.cc/VV9G-THE5>] (last visited Jan. 14, 2021) (Consultation Draft); *Dengue Vaccine: WHO Paper*, *supra* note 95, at 476.

98. However, there are two vaccine candidates in Phase III trials at this time. *Dengue Vaccine: WHO Paper*, *supra* note 95, at 463.

99. Some of the countries include: Mexico, the Philippines, Brazil, El Salvador, Costa Rica, Paraguay, Guatemala, Peru, Indonesia, Thailand, and Singapore. *Sanofi’s Dengue Vaccine Approved in 11 Countries*, REUTERS (Oct. 3, 2016, 10:55 PM), <https://www.reuters.com/article/us-sanofi-vaccine-idUSKCN1240C5> [<https://perma.cc/3TN5-V9T7>].

100. Dengvaxia has been approved by the FDA in the U.S. only for nine-to-sixteen-year-old children in Puerto Rico, the U.S. Virgin Islands, American Samoa, and Guam. Angus Liu, *After Safety Mess, Sanofi’s Dengue Shot Nabs a Sharply Limited FDA Nod*, FIERCE PHARMA (May 2, 2019, 10:55 AM), <https://www.fiercepharma.com/vaccines/sanofi-nabs-fda-nod-for-dengvaxia-despite-philippines-mess-but-a-much-smaller-population> [<https://perma.cc/U5CZ-FB4U>]; Stephen J. Thomas & In-Kyu Yoon, *A Review of Dengvaxia®: Development to Deployment*, 15 HUM. VACCINES & IMMUNOTHERAPEUTICS 2295, 2295 (2019).

101. In a three-tiered governmental system—national, regional, and local government—subnational refers to regional and local government. Katja Rohrer, *Chapter*

public health programs in Brazil and the Philippines.¹⁰² The vaccine was studied over twenty-six clinical trials that included more than 41,000 volunteers.¹⁰³ The clinical trial participants were monitored for up to five years after the trial.¹⁰⁴

Despite the large trial enrollment and postimmunization monitoring, it happens that for children under nine and for a subset of children who had never before been exposed to the virus, the vaccine increases the chance of severe disease, an occurrence that resulted in significant liabilities in the Philippines.¹⁰⁵ On average, 200,000 cases of dengue infection are reported every year in the Philippines.¹⁰⁶ The aggregate direct medical cost for these infections in the country is estimated to be over \$345 million per year and causes children to lose on average 5.6 days of school and adults to lose 9.9 days of work per episode.¹⁰⁷ Dengvaxia was licensed in the Philippines in 2016.¹⁰⁸ After licensure, a subnational Dengvaxia immunization program costing \$67.7 million¹⁰⁹ was developed with the goal of vaccinating one million Filipino children.¹¹⁰ The Philippines vaccinated 830,000 children ages nine to ten living in highly endemic regions¹¹¹ before it was realized or acknowledged that there was an enhanced risk for severe illness for children who were seronegative—without antibodies to the virus.¹¹² Sanofi Pasteur reported the safety issues in 2017, and the program was promptly ended.¹¹³ In 2019, the Philippines

11: *Strategizing for Health at Sub-national Level*, in STRATEGIZING NATIONAL HEALTH IN THE 21ST CENTURY: A HANDBOOK 1, 1 (Gerard Schmets, Dheepa Rajan & Sowmya Kadandale eds., 2016), <https://apps.who.int/iris/bitstream/handle/10665/250221/9789241549745-chapter11-eng.pdf?sequence=35&isAllowed=y> [<https://perma.cc/B29Z-2U3K>].

102. Thomas & Yoon, *supra* note 100, at 2303, 2308.

103. *Id.* at 2297.

104. Stefan Flasche, Annelies Wilder-Smith, Joachim Hombach & Peter G. Smith, *Estimating the Proportion of Vaccine-Induced Hospitalized Dengue Cases Among Dengvaxia Vaccines in the Philippines*, WELLCOME OPEN RSCH. (Oct. 31, 2019), <https://wellcomeopenresearch.org/articles/4-165/v1> [<https://perma.cc/5CA2-MHZJ>] (version 1; peer review: 2 approved).

105. Thomas & Yoon, *supra* note 100, at 2303, 2308.

106. Mong Palatino, *The Health of Thousands of Filipino Children Could Be at Risk, Thanks to Sanofi's Dengue Vaccine*, GLOB. VOICES (Dec. 7, 2017, 5:35 GMT), <https://globalvoices.org/2017/12/07/the-health-of-thousands-of-filipino-children-could-be-at-risk-thanks-to-sanofis-dengue-vaccine/> [<https://perma.cc/25ZB-GVAG>].

107. \$365 million per year is measured in 2012 USD. Ronald U. Mendoza, Sheena A. Valenzuela & Manuel M. Dayrit, *A Crisis of Confidence: The Case of Dengvaxia in the Philippines* 1, 5 (Ateneo Sch. of Gov't, Working Paper No. 20-002, 2020).

108. Flasche et al., *supra* note 104, at 3.

109. Karen Lema & Matthias Balmont, *Philippines to Charge Officials of Sanofi, Government Over Dengue Vaccine*, REUTERS (Mar. 1, 2019, 12:51 AM), <https://www.reuters.com/article/us-sanofi-fr-philippines/philippines-to-charge-officials-of-sanofi-government-over-dengue-vaccine-idUSKCN1QI41L> [<https://perma.cc/959H-D2VY>].

110. Flasche et al., *supra* note 104, at 3.

111. “The dengue seroprevalance in this population is not known, but has been estimated to be between 80 and 85%, extrapolating from data from the trial sites in the Philippines included in the Phase 3 trial.” *Id.* at 3.

112. *Id.* at 1.

113. *Id.* at 3.

permanently banned Dengvaxia.¹¹⁴ Alleged delays by Sanofi in disclosing safety signals following Dengvaxia campaigns have resulted in criminal indictments against Sanofi executives, demands for repayment of the price of the Dengvaxia doses, and additional liabilities related to ten deaths attributed to Dengvaxia administration.¹¹⁵

For these and other reasons, governments and global leaders must plan for liability and compensation as a component of the broader international response to COVID-19.¹¹⁶ In countries with strict liability regimes for vaccines, there is a limited obligation for a plaintiff to prove causation between the vaccination and the injury, only that the immunization and the injury are related in place and time.¹¹⁷ Even if a manufacturer took due care, that is, manufactured the vaccine non-negligently, vaccines will cause these rare severe injuries.¹¹⁸

In most countries, a plaintiff (whether individual or governmental) is under an obligation to prove causation between an injury and the vaccine that preceded it.¹¹⁹ The method by which causation is established under product liability law differs in key respects from the accepted method of establishing causation in science and epidemiology.¹²⁰

114. Carol Isoux, *Are Philippine Children's Deaths Linked to Dengue Vaccine?*, POST MAG. (April 21, 2019, 2:30 AM), <https://www.scmp.com/magazines/post-magazine/long-reads/article/3006712/philippines-suspicion-dengue-vaccine-linked> [<https://perma.cc/DUY9-X85F>].

115. Vince F. Nonato, *Solon: Sanofi Will Be Held Liable for 'Misrepresenting' Dengvaxia Safety*, PHIL. DAILY INQUIRER (Dec. 10, 2017, 6:30 PM), <http://newsinfo.inquirer.net/951181/solon-sanofi-will-be-held-liable-for-misrepresenting-dengvaxia-safety> [<https://perma.cc/SHC4-B7XD>] (“The House of Representatives Committee on Good Government and Public Accountability will hold Sanofi Pasteur liable for allegedly misrepresenting the side effects of Dengvaxia, as the French pharmaceutical giant only recently disclosed the risks months after the congressional inquiry had ended.”). The indictments are a good example of using respondeat superior theories when the Philippines Department of Justice is pursuing criminal allegations against Sanofi for omissions that are in fact attributable to the corporations, not its president or other indicted officers. *See generally* Mihailis E. Diamantis, *Corporate Criminal Minds*, 91 NOTRE DAME L. Rev. 2049 (2016).

116. DIV. OF HEALTH PROMOTION & DISEASE PREVENTION, INST. OF MED., *supra* note 81, at 28 (“Testimony [in response to the expected DTP vaccine shortage due to unstable supplies] . . . from Squibb-Connaught indicated that [the vaccine distributors of DTP in 1984] had continued manufacturing vaccine and would be willing to distribute it if some federal protection were provided from [the high] liability risks.”).

117. Clare Looker & Heath Kelly, *No-fault Compensation Following Adverse Events Attributed to Vaccination: A Review of International Programmes*, 89 BULLETIN OF THE WORLD HEALTH ORGANIZATION [WHO] 371, 375 (2011), <https://apps.who.int/iris/bitstream/handle/10665/270902/PMC3089384.pdf?sequence=1&isAllowed=y> [<https://perma.cc/B7Z4-6P3V>] (“This process presumes causation if any injury listed in the table occurs within a specified time frame after vaccination. . . . [P]rogrammes are based on the premise that the adverse outcome is not attributable to a specific individual or industry but due to an unavoidable risk associated with vaccines.”).

118. *See id.* at 371.

119. *See, e.g.*, COMM. ON THE CHILD’S VACCINE INITIATIVE, INST. OF MED., THE CHILDREN’S VACCINE INITIATIVE: ACHIEVING THE VISION 163 (Violaine S. Mitchell, Nalini M. Philipose & Jay P. Sanford eds., 1993) (“If the conditions of the petitioner are not included in the table, they must then prove causation by a covered vaccine.”).

120. DIV. OF HEALTH PROMOTION & DISEASE PREVENTION, INST. OF MED., *supra* note 81, at 85–86, 155 (“The difficulty of proving or disproving a causal relationship between a given vaccine and a particular injury suggests that if causation is required, for payment of compensation, outcomes

2. Perceived and Falsely Attributed Risks

Not only will real and unknown risks shape legal liabilities but perceived associations will shape them as well.¹²¹ In many countries, propaganda campaigns inducing fears of sterility or of contracting HIV from vaccination inhibit use as well as fuel suspicions that manufacturers from wealthy countries use people in developing countries as human “guinea pigs.”¹²² For example, in 2013, a subset of religious leaders in Kenya initiated an antivaccine campaign based in part on these kinds of accusations.¹²³ Demonstration projects with the HPV vaccine, aimed at preventing the cause of cervical cancer in virtually all cases, in the Indian states of Andhra Pradesh and Gujarat resulted in the preliminary (and erroneous) association of the vaccine with seven deaths, resulting in the suspension of those vaccination efforts, the discovery of defects in informed consent communications, and a significant delay of expanded HPV coverage.¹²⁴ Reports of adverse events prompted litigation at the Supreme Court of India as well as a ministerial review of the informed consent protocols used by researchers.¹²⁵ While no panel convened by the Supreme Court, the legislature, or the Ministry of Health and Welfare found any evidence that the vaccines caused any injuries, those entities found defects in informed consent procedures, and although not technically parties, GSK and Merck were required to respond to official inquiries.¹²⁶

Because causation will be a key aspect of any action to recover money damages, litigation risk is far more significant for perceived injuries or false attribution of background events to a vaccination.¹²⁷ Many countries suffer from

will depend on who is required to carry the burden of proof. . . . [T]hese efforts to prove causation will be time-consuming, expensive, and probably inconclusive.”)

121. Eve Dubé, Caroline Laberge, Maryse Guay, Paul Bramadat, Réal Roy & Julie Bettinger, *Vaccine Hesitancy: An Overview*, 9 HUMAN VACCINES & IMMUNOTHERAPEUTICS 1763, 1769 (“[R]isk perceptions are predictors of adult vaccination behavior.”).

122. See Tara C. Smith, *Vaccine Rejection and Hesitancy: A Review and Call to Action*, OPEN F. INFECTIOUS DISEASES, Summer 2017, at 1, 1 (“[M]ultiple studies have demonstrated concerning patterns of decline of confidence in vaccines.”).

123. Jill Olivier, *Interventions with Local Faith Communities on Immunization in Development Contexts*, REV. FAITH & INT’L AFFS., Fall 2016, at 36, 36 (“Kenyan Catholic Bishops called for a boycott of the . . . vaccine . . . , arguing that the vaccine was dangerous.”).

124. R. Prasad, Opinion, *A Second Chance for the HPV Vaccine*, HINDU (Oct. 8, 2017, 3:33 PM), <http://www.thehindu.com/todays-paper/tp-opinion/a-second-chance-for-the-hpv-vaccine/article19821936.ece> [https://perma.cc/GR3W-EUAX]; Sanjay Kumar & Declan Butler, *Calls in India for Legal Action Against US Charity*, NATURE (Sept. 9, 2013), <https://www.nature.com/news/calls-in-india-for-legal-action-against-us-charity-1.13700> [https://perma.cc/NJB7-6AT8].

125. Kumar & Butler, *supra* note 124; Carolijn Terwindt, *Health Rights Litigation Pushes for Accountability in Clinical Trials in India*, HEALTH & HUM. RTS. J., Dec. 2014, at 84, 87–88, <https://cdn1.sph.harvard.edu/wp-content/uploads/sites/2469/2014/12/Terwindt-final1.pdf> [https://perma.cc/G5XT-TVXL].

126. Terwindt, *supra* note 125, at 88.

127. See Richard Kent Zimmerman, James J. Schlesselman, Tammy A. Mieczkowski, Anne R. Medsger & Mahlon Raymund, *Physician Concerns About Vaccine Adverse Effects and Potential Litigation*, 152 ARCHIVES PEDIATRICS & ADOLESCENT MED. 12, 12 (1998) (“Physicians’ perceptions about the risk for adverse effects and protection afforded by the Vaccine Injury Compensation Program

high background levels of morbidity and mortality, and coincidental deaths associated with vaccine administration attributed to the vaccine may give rise to litigation, even if rigorous analysis of objective data ultimately vindicates the manufacturer and its product.¹²⁸ It is well established that there is widespread misunderstanding in developing countries about what respiratory illnesses are, how they are transmitted, and what their effects might be.¹²⁹ Background skepticism of vaccine campaigns may increase the chance that specific events or injuries are attributed to COVID-19 vaccines.¹³⁰ Moreover, COVID-19 vaccines are unlikely to be as efficacious as the most efficacious vaccines, like the measles vaccine, increasing the chance that someone who received an immunization and becomes ill may conflate the two.¹³¹

influence their concern about litigation and, to a lesser extent, their reported likelihood to administer immunizations.”).

128. Elaine R. Miller, Pedro L. Moro, Maria Cano & Tom Shimabukuro, *Deaths Following Vaccination: What Does the Evidence Show?*, 33 VACCINE 3288, 3288 (2015).

129. Prisca Adhiambo Oria, Geoffrey Arunga, Emmaculate Lebo, Joshua M. Wong, Gideon Emukule, Philip Muthoka, Nancy Otieno, David Mutonga, Robert F. Breiman & Mark A. Katz, *Assessing Parents’ Knowledge and Attitudes Towards Seasonal Influenza Vaccination of Children Before and After a Seasonal Influenza Vaccination Effectiveness Study in Low-income Urban and Rural Kenya, 2010–2011*, 13 BMC PUB. HEALTH 391, 395 (2013), <https://bmcpubhealth.biomedcentral.com/track/pdf/10.1186/1471-2458-13-391.pdf> [<https://perma.cc/5UTV-7XJW>] (“Of the 36 pre-vaccination focus group discussion participants, a majority said the main causes of influenza were low temperatures and dust. A few also said smoke, contact with influenza-infected persons and allergic reactions could cause influenza.”); Farhanah Abd Wahab, Sarimah Abdullah, Jafri Malin Abdullah, Hasnan Jaafar, Siti Suraiya Md Noor, Wan Mohd Zahiruddin Wan Mohammad, Abdul Aziz Mohamed Yusoff, John Tharakan, Shalini Bhaskar, Muthuraju Sangu, Mohd Shah Mahmood, Fauziah Kassim, Md. Hanip Rafia, Mohammed Safari Mohammed Haspani, Azmi Alias, Rogelio Hernández Pando, *Updates on Knowledge, Attitude and Preventive Practices on Tuberculosis among Healthcare Workers*, 23 Malay. J. Med. Sci. 25, 30 (“A preliminary study of knowledge, attitudes and practices towards TB prevention was done in 2013 from two selected hospitals. Five family members were interviewed based on a questionnaire of knowledge, attitudes and practices (KAP) of TB cases among nurses (30). It was found that only 20% of them had good knowledge. TB infection is commonly associated with lungs was correctly answered by 80% of the family members, while 80% said it is treatable and curable. However, 60% of them were still unaware that TB is caused by a bacterium called Mycobacterium tuberculosis. All of them believed that smoking (100%) is the main risk factor for TB, apart from alcohol and drug use (40%), other chronic diseases (20%), overcrowding and malnutrition (20%) and poverty (20%).”); Adela Ngwewondo, Lucia Nkengazong, Lum Abienwi Ambe, Jean Thierry Ebogo, Fabrice Medou Mba, Hamadama Oumarou Goni, Nyemb Nyunai, Marie Chantal Ngonde, Jean-Louis Essame Oyono, *Knowledge, attitudes, practices of/towards COVID 19 preventive measures and symptoms: A cross-sectional study during the exponential rise of the outbreak in Cameroon*, 14 PLOS Neglected Tropical Diseases 9 (2020).

130. *See id.* at 397 (“While most parents in the fully vaccinated group had no concerns about the vaccine, half the parents in the partially and non-vaccinated groups had concerns about the vaccine; most said they were concerned about side effects because it was a new vaccine. Few parents of partially vaccinated children said they were concerned about side effects because they had heard of a child who had reacted negatively to vaccination. Parents of non-vaccinated children . . . ‘had serious doubts about it.’” (quoting parent on non-vaccinated children in Kibera and Lwak)).

131. Malik Peiris & Gabriel M. Leung, *What Can We Expect from First-generation COVID-19 Vaccines?*, 396 LANCET 1467, 1468 (2020), <https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2931976-0> [<https://perma.cc/RYE2-XRH3>]; Allison Aubrey, *A COVID-19 Vaccine May Be Only 50% Effective. Is That Good Enough?*, NPR (Sept. 12, 2020, 7:00 AM), <https://>

Similarly, vaccine-related injuries may be attributable to contamination or infection from vaccines or syringes used improperly.¹³² The introduction of Johnson & Johnson's Ebola vaccine candidate into the Democratic Republic of the Congo was complicated precisely because it required the administration of two doses two months apart.¹³³ Nearly all current COVID-19 vaccine candidates require two doses administered months apart.

C. Informed Consent and Product Labeling

Informed consent is “an autonomous authorization by individuals of a medical intervention or of involvement in research,” which includes a decision to accept a health-care worker's administration of a vaccine.¹³⁴ Given the substantial interest by both manufacturers and third-party sponsors in obtaining as much information as possible about COVID-19 vaccine planning, implementation, and outcomes, there is likely to be a high correlation between individuals receiving vaccinations as patients and subjects of medical research. Informed consent is a process based on verbal and written communication between patients and health-care workers.¹³⁵

www.npr.org/sections/health-shots/2020/09/12/911987987/a-covid-19-vaccine-may-be-only-50-effective-is-that-good-enough [<https://perma.cc/8DVT-8H3F>]. As of January 13, 2020, AstraZeneca's vaccine is seventy percent effective and requires two doses, and Pfizer's vaccine is ninety-five percent effective and requires two doses. Compare these to the MMR vaccine which is ninety-seven percent effective and requires two doses. Aylin Woodward & Shayanne Gal, 3 *Coronavirus Vaccines So Far Seem to Prevent COVID-19. Here's How Their Efficacy Compares to Vaccines for Flu, Measles, and More.*, BUS. INSIDER (Nov. 30, 2020, 2:01 PM), <https://www.businessinsider.com/how-pfizer-coronavirus-vaccine-compares-other-vaccines-2020-11?international=true&r=US&IR=T> [<https://perma.cc/5H5U-7ZfV>].

132. World Health Org. [WHO], *Vaccine Safety Basics: Learning Manual*, at 75 (2013), https://www.who.int/vaccine_safety/initiative/tech_support/Vaccine-safety-E-course-manual.pdf [<https://perma.cc/AC6U-VMPU>] (outlining common immunization errors: “[r]euse of disposable syringe or needle leading to contamination of the vial, especially in multi-dose vials; [i]mproperly sterilized syringe or needle; [c]ontaminated vaccine or diluent”).

133. Helen Branswell, *Debate over Whether to Test a Second Ebola Vaccine Turns Acrimonious*, STAT (July 17, 2019) <https://www.statnews.com/2019/07/17/debate-testing-second-ebola-vaccine/> [<https://perma.cc/N8LX-KMCJ>].

134. K. Moodley, M. Pather & L. Myer, *Informed Consent and Participant Perceptions of Influenza Vaccine Trials in South Africa*, 31 J. MED. ETHICS 727, 727 (2005) (“Informed consent is fundamental to the ethical conduct of randomised controlled trials and is a critical component of the research process. Defined as ‘an autonomous authorization by individuals of a medical intervention or of involvement in research,’ the principle of informed consent is enshrined in all major guidelines for the ethical conduct of biomedical research. Informed consent is a process, based on verbal and written communication between participants and trial staff (or other individuals recruiting participants). The main pragmatic worry about informed consent is the different ways in which the process can fail—for example, because consent is not sought or because participants may not adequately understand the issues involved. Written trial materials are a central component of the informed consent process that is required by most major ethical guidelines. To enhance understanding of informed consent forms and related patient information materials, it is essential that these documents are highly readable.”).

135. Elizabeth Gross Cohn, Haomiao Jia, Winifred Chapman Smith, Katherine Erwin & Elaine L. Larson., *Measuring the Process and Quality of Informed Consent for Clinical Research: Development and Testing*, 38 ONCOLOGY NURSING F. 417, 418 (2011) (“Results also indicated that a successful consent process must include, at a minimum, the use of various communication modes (e.g., written, verbal,

“The main pragmatic concern about informed consent in the vaccine context is the different ways in which the process can fail—for example, because consent is not sought or because participants may not adequately understand” the factors involved in the decision to vaccinate because of a linguistic or other barrier.¹³⁶ Informed consent for licensed and EUA vaccines must include information about the disease the vaccine is intended to prevent, the risks of contracting that disease without the vaccine, risks and benefits of the vaccine itself, and who should and who should not get the vaccine.¹³⁷

Liabilities arising from breaches of informed consent and product labeling accuracy are related. In many situations and contexts, manufacturer liability and provider liability will be distinct. A manufacturer will provide relevant information about the vaccine to the public sector or other procuring entity, and unaffiliated frontline health-care workers will translate product information to recipients.¹³⁸ However, vaccine manufacturers are often deeply involved in training health-care workers or support health-care worker training in partnership with governments and national and international organizations. Indeed, in many cases, it would be a best practice for a manufacturer to do so, or at least to monitor point-of-contact activity, given its interest in effective quality control. If a manufacturer’s product insert for a COVID-19 vaccine limits its use to specific subgroups, but the manufacturer simultaneously directly encourages health-care workers or supports the training of health-care workers to emphasize the known benefits of the vaccination in a way that deviates from the product labeling or discourages the dissemination of key evidence gaps in the product’s safety profile, the manufacturer is potentially liable for violations of the recipient’s informed consent.¹³⁹

These liability risks are even more relevant in a manufacturer’s assessment of wider participation in COVID-19 programs for at least three reasons. First,

asking the participant to repeat what he or she understands), and is likely to require one-on-one interaction with someone knowledgeable about the study, such as a consent educator.”).

136. Moodley et al., *supra* note 134, at 727; *id.*; David J. Diemert, Lucas Lobato, Ashley Styczynski, Maria Zumer, Amanda Soares & Maria Flavia Gazzinelli, *A Comparison of the Quality of Informed Consent for Clinical Trials of an Experimental Hookworm Vaccine Conducted in Developed and Developing Countries*, PLOS NEGL’D. TROPICAL DISEASES, Jan. 23, 2017, at 1, 2 (“The informed consent process depends upon five criteria: the willingness to participate, the capacity to make a decision, disclosure of information, comprehension, and the decision to participate.”).

137. Heena Kakar, Ramandeep Singh Gambhir, Simarpreet Singh, Amarinder Kaur & Tarun Nanda, *Informed Consent: Corner Stone in Ethical Medical and Dental Practice*, 3 J. FAM. MED. & PRIMARY CARE 68, 68 (2014) (“In medical terms, informed consent implies to ‘providing sufficient information for a patient to make an informed and rational choice, the information includes the inherent risks and alternatives that a reasonable doctor would provide having regard to the particular circumstances of the patient.’”).

138. DIV. OF HEALTH PROMOTION & DISEASE PREVENTION, INST. OF MED., *supra* note 81, at 87 (“If a product is not sold directly to the public, but is distributed through intermediaries who can be expected to know about the product and its risks and to be responsible for informing the ultimate consumer on its proper use, then the manufacturer does not have a duty to warn the public (although it does have a duty to warn the intermediaries of risks not known to them).”).

139. *See id.*

violations of the principle of informed consent may be serious and widespread in an accelerated global immunization campaign, and such breaches of informed consent may also be independent from any injury resulting from product use.¹⁴⁰ Second, the law of informed consent in many jurisdictions is ambiguous, often forged from existing codes of medical ethics and broadly worded constitutional and statutory protections.¹⁴¹ Third, informed consent law is context-specific. Legal liabilities may turn on the relative age, education, and sophistication of a recipient; disclosures a health-care worker makes about commercial influences; and rules of evidence that favor presumption toward the recipient's or the health-care worker's testimony.¹⁴² For example, written communication that is not in the recipient's native tongue or is not properly translated may fail to meet the necessary standard of informed consent. Further, written communication that does not account for cultural, sociological, and linguistic barriers may not meet standards of sufficient informed consent.¹⁴³ While evidence is sparse, there has been sufficient fieldwork concluded by public health researchers to establish that the demand for information by potential immunization target populations may be complex and introduce a number of difficulties in respecting informed consent law while furthering the goal of broader immunization efforts.¹⁴⁴

140. Anna Zagaja, Rafal Patryn, Jakub Pawlikowski & Jaroslaw Sak, *Informed Consent in Obligatory Vaccinations?*, 24 MED. SCI. MONITOR 8506, 8507 (2018). (“Currently over 100 million children are vaccinated each year against infectious diseases such as measles, hepatitis B, diphtheria, tuberculosis, or polio. According to the European Commission, vaccinations prevent approximately 2.5 million deaths worldwide annually and reduce disease-specific treatment costs. . . . In the case of a vaccination obligation . . . , individual autonomy is faced off against the state rules and regulations and a clash between individual's rights and public safety becomes apparent. Here we consider 2 mechanisms. The first is protecting individual autonomy (i.e., informed consent); the second is protecting the common good of society (i.e., public health protection through obligatory vaccinations). Currently, a lot of pressure is placed on obtaining informed consent from patients prior to invasive procedures, including vaccinations.”).

141. See, e.g., *Med. & Dental Prac. Disciplinary Tribunal v. Okonkwo* [2001] AHRLR 159, ¶ 72 (Nigeria) (“The scope and limit of the duty of a practitioner [with respect to informed consent] . . . cannot be considered in isolation of the right of the patient. Although, there is a dearth of local authorities in this area of our law, there are ample provisions of our Constitution which show the basis on which the Court should proceed in these matters.”).

142. See A.O. Adejumo, *Sociocultural Factors Influencing Consent for Research in Nigeria: Lessons from Pfizer's Trovan Clinical Trial*, 11 AFR. J. PSYCH. STUD. SOC. ISSUES 229, 229, (2008).

143. See Stella Burch Elias, *Regional Minorities, Immigrants, and Migrants: The Reframing of Minority Language Rights in Europe*, 28 BERKELEY J. INT'L L. 261, 311 (2010) (emphasizing the role of language recognition in achieving full realization of rights in the EU).

144. See Oria et al., *supra* note 129, at 5 (“Whether or not I accept to vaccinate my child will depend on the information I receive from those promoting the vaccine. I must be told how safe the vaccine is, how the vaccine will benefit my child, and from where the vaccine has come.” (quoting a mother in Kibera)); Julie Leask, Annette Braunack-Mayer & Ian Kerridge, *Consent and Public Engagement in an Era of Expanded Childhood Immunization*, 47 J. PAEDIATRICS & CHILD HEALTH 603, 603 (2011) (“For consent to be valid, patients (or their parents) must be competent to make the decision, sufficiently informed, understand the information provided and be able to act freely and voluntarily.”).

II. GLOBAL PANDEMIC RESPONSE DEPENDS ON FAIRNESS TO THOSE
SUFFERING SEVERE SIDE EFFECTS FOLLOWING IMMUNIZATION AND LEGAL
ASSURANCE TO MANUFACTURERS

National and global public health leaders have long known that the response to a global viral pandemic would require a system to develop and distribute vaccines, including a system for liability and compensation, but governments and organizations have done relatively little in light of that knowledge.

The H1N1 pandemic was declared in April 2009, and a vaccine specific to the pathogen was developed by September 2009.¹⁴⁵ Yet negotiations between manufacturers, the WHO, and donating and receiving governments over liability and indemnity delayed the distribution of vaccines until late December 2009/early January 2010.¹⁴⁶ In October 2014, the WHO; supporting governments and their agencies (especially the United States, the U.K., and France); and the governments of Guinea, Liberia, and Sierra Leone convened a meeting to discuss the possibility of deploying, on an emergency use basis, vaccine candidates against the Ebola virus disease.¹⁴⁷ Again, the issue of liability and compensation thwarted such deployment, and the experimental vaccine was never administered outside the clinical trial context.¹⁴⁸

The failure to resolve the vaccine product liability problem stands in the way of access to vaccines for the world's most vulnerable countries. In the wake of COVID-19, there are two general approaches to procuring vaccines: (1) bilateral contracts with manufacturers that include assurances against product liability claims or (2) distribution through the COVAX Facility, an international organization that invests in vaccine candidates, requires financial commitments from procuring governments, and ultimately will match recipient governments with manufacturers when vaccines have been licensed or authorized pursuant to an EUA.¹⁴⁹

By mid-August 2020, the United States had secured 800 million doses of at least six vaccines in development, with an option to purchase around one billion more.¹⁵⁰ The U.K. was the world's highest per-capita buyer, with 340 million doses

145. *The 2009 H1N1 Pandemic: Summary Highlights, April 2009-April 2020*, CTRS. FOR DISEASE CONTROL & PREVENTION (June 16, 2010), <https://www.cdc.gov/h1n1flu/cdcresponse.htm> [<https://perma.cc/7M8Y-UJY7>].

146. Halabi, *supra* note 48, at 207.

147. Ana Maria Henao-Restrepo, Marie-Pierre Preziosi, David Wood, Vasee Moorthy, Marie Paule Kieny & The WHO Ebola Research, Development Team, *On a Path to Accelerate Access to Ebola Vaccines: The WHO's Research and Development Efforts During the 2014–2016 Ebola Epidemic in West Africa*, 17 CURRENT OP. VIROLOGY 138, 139 (2016).

148. Sam Halabi, Andrew Heinrich & Saad B. Omer, *No-Fault Vaccine Injury Compensation – The Other Side of Equitable Access to COVID-19 Vaccines*, 383 NEW ENG. J. MED. e125(1)–(2) (2020), <https://www.nejm.org/doi/pdf/10.1056/NEJMp2030600?articleTools=true> [<https://perma.cc/7C8V-9WJ8>].

149. Ewen Callaway, *The Unequal Scramble for Coronavirus Vaccines*, 584 NATURE 506 (2020), <https://media.nature.com/original/magazine-assets/d41586-020-02450-x/d41586-020-02450-x.pdf> [<https://perma.cc/AYX6-LDMZ>].

150. *Id.*

purchased: around five doses for each citizen. The EU nations—which are buying vaccines as a group—and Japan have locked down hundreds of millions of doses of vaccines for themselves.¹⁵¹

A. The Structure of the COVAX Facility

For the vast majority of the world's governments, bilateral procurement is out of reach for purely financial reasons.¹⁵² Even for wealthier governments, bilateral contracts may not be a panacea. As of early January 2021, there have been a limited number of safe and effective vaccines approved. Vaccines entering Phase III clinical trials only succeed at about sixteen percent.¹⁵³ The solution to the dichotomy between richer and poorer countries dealing with the vaccine access problem is the COVAX Facility, an international partnership that convenes wealthy (“self-financing”) governments interested in diversifying their investments in potentially successful vaccine candidates, manufacturers of those candidates, and low- and lower-middle-income countries (“donor countries”) that may offer a relatively modest up-front commitment but cannot afford bilateral procurement—certainly not for candidates that may fail.

The COVAX Facility originated within a broader international collaboration known as the ACT (Access to COVID-19 Tools) Accelerator,¹⁵⁴ an initiative led by the World Bank, the WHO, G20, European Commission, and a consortium of major global public health non-governmental organizations including the Bill & Melinda Gates Foundation and other private donors to advance the goal of fostering the development and production of diagnostics, therapeutics, and vaccines to combat the COVID-19 pandemic.¹⁵⁵ The ACT Accelerator, launched in April 2020, is comprised of four pillars: the Diagnostic Pillar supported by the Foundation for Innovative New Diagnostics (FIND) and the Global Fund to Fight Aids, Tuberculosis, and Malaria (Global Fund); the Therapeutics Pillar supported by

151. *Id.*

152. Gavin Yamey, Opinion, *A Coronavirus Vaccine Should Be for Everyone, Not Just Those Who Can Afford It*, STAT (Mar. 5, 2020), <https://www.statnews.com/2020/03/05/coronavirus-vaccine-affordable-for-everyone/> [<https://perma.cc/2E2L-H3T4>] (“Without price controls, poor countries are unlikely to be able to afford or access enough vaccines to protect their populations.”); Adam Hancock, *Why Developing Countries May Be the Last to Get the Vaccine*, EU OBSERVER (May 28, 2020, 07:04 AM), <https://euobserver.com/coronavirus/148470> [<https://perma.cc/GC6F-9GYG>] (“To put it bluntly, they simply can’t afford most of the new vaccines being produced.”).

153. Shanay Rab, Afjal, Mohd Javaid, Abid Haleem & Raju Vaishya, *An Update on the Global Vaccine Development for Coronavirus*, 14 DIABETES & METABOLIC SYNDROME: CLINICAL RSCH. & REVS. 2053, 2053 (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7582051/pdf/main.pdf> [<https://perma.cc/WCS9-GA2R>].

154. Seth Berkley, *COVAX Explained*, GAVI, THE VACCINE ALLIANCE (Sept. 3, 2020), <https://www.gavi.org/vaccineswork/covax-explained> [<https://perma.cc/SM29-JVVF>].

155. Margaret “Peggy” Hamburg, Former Comm’r, U.S. FDA, Remarks at The Scramble for Vaccines and the COVAX Facility 3 (Aug. 11, 2020), https://csis-website-prod.s3.amazonaws.com/s3fs-public/publication/200811_Scramble_Vaccines.pdf [<https://perma.cc/E3CK-GRP2>]; *Donor Profiles*, GAVI, THE VACCINE ALLIANCE, <https://www.gavi.org/investing-gavi/funding/donor-profiles> [<https://perma.cc/F9ZN-YTMM>] (May 28, 2021).

Unitaid and Wellcome Trust; the Health Systems Pillar supported by the World Bank, Global Fund, and the WHO; and the Vaccine Pillar supported by Gavi, the Vaccine Alliance (GAVI), the Coalition for Epidemic Preparedness Innovations (CEPI), and the WHO.¹⁵⁶

The Vaccine Pillar, “COVAX” or the “COVAX Facility,”¹⁵⁷ was established in June 2020.¹⁵⁸ It was founded to support the quick and safe development, manufacture, and delivery of a COVID-19 vaccine worldwide.¹⁵⁹ COVAX aims to deliver two billion doses of a safe and effective COVID-19 vaccine by the end of 2021.¹⁶⁰ In order to achieve this objective, COVAX invests across a wide portfolio of vaccine candidates using contributions from eighty-nine self-financing governments and supporting international organizations and charities and, at the same time, requiring financial commitments from ninety-two “donor supported” governments that will receive subsidized prices for doses.¹⁶¹

Within COVAX, CEPI leads the development and manufacturing workstream, which supports research and development and manufacturing expansion through direct financial investments.¹⁶² GAVI is the lead organization for vaccine procurement and as well as the COVAX Advance Market Commitment (AMC), which helps finance low- and lower-middle-income countries’ access to a future COVID-19 vaccine.¹⁶³

156. Press Release, World Health Org., *ACT-Accelerator Update: Publication of Investment Cases*, (June 26, 2020) [hereinafter *ACT-Accelerator Update*], <https://www.who.int/news-room/detail/26-06-2020-act-accelerator-update> [<https://perma.cc/J7YS-CXNJ>]; Jonathan C. Carlson, *Strengthening the Property-Rights Regime for Plant Genetic Resources: The Role of the World Bank*, 6 TRANSNAT’L L. & CONTEMP. PROBS. 91, 112–13 (1996) (identifying the evolving role of the World Bank from discrete project funding to broader, structural efforts).

157. The Vaccine Pillar is also referred to as “COVAX Facility” or “the Facility” in online sources.

158. *ACT-Accelerator Update*, *supra* note 156.

159. *Id.*

160. *More than 150 Countries Engaged in COVID-19 Vaccine Global Access Facility*, *supra* note 3.

161. WHO, COVAX Announces Additional Deals, *supra* note 11. (announcing that CEPI-Support candidate vaccines include: Invivo in United States (Phase II); Moderna in United States (Phase III); CureVac in Germany (Phase IIB/III); Institut Pasteur/Merck/Themis in France, United States, Austria (Phase I); AstraZeneca/University of Oxford in U.K., Northern Ireland (Phase III); University of Hong Kong in China (Preclinical); Novavax in United States (Phase III); Clover Biopharmaceuticals in China (Phase I); University of Queensland/CSL in Australia (Phase I)).

162. Gavi, the Vaccine Alliance, *Report to the Board on COVAX Facility Structure and Governance*, Agenda Item 04b (July 30, 2020) [hereinafter *Gavi Facility Structure and Governance*], https://www.gavi.org/sites/default/files/board/minutes/2020/30-july/04b%20-%20COVAX%20Facility%20Structure%20and%20Governance_1.pdf [<https://perma.cc/SA9M-X6KE>].

163. *Id.* at 2–3; Mark Turner, *Vaccine Procurement During an Influenza Pandemic and the Role of Advance Purchase Agreements: Lessons from 2009-H1N1*, 11 GLOB. PUB. HEALTH 322, 327 (2016) (“A 2009 survey by the WHO of pandemic influenza vaccine manufacturers asked whether they would be willing to reserve 10% of real-time production for acquisition by UN agencies, 14 out of 25 were unable to meet the request to set aside 10% of their production capacity, because they were constrained by meeting the volume of vaccines reserved via APAs.”).

The COVAX Facility itself has no legal personality—it cannot enter into contracts, and it is not susceptible to legal process in any of the jurisdictions where its stakeholder organizations reside. GAVI, an international organization incorporated under the Swiss Host State Act, is the administrator and legal personality of COVAX.¹⁶⁴ The GAVI Board is responsible for overseeing GAVI’s role in COVAX, and its CEO, Seth Berkley, coordinates with the leaders of the other stakeholder organizations in managing GAVI’s role.¹⁶⁵ GAVI’s Market Sensitive Decision Committee is responsible for reviewing proposed agreements, and GAVI’s Audit and Finance Committee is responsible for tracking and reviewing all COVAX funding.¹⁶⁶

GAVI is also responsible for the office of the COVAX Facility. In this role, GAVI is responsible for negotiating agreements with self-financing countries, tripartite agreements with multilateral development banks, and agreements with manufacturers with volume guarantees; managing the vaccine candidate portfolio (along with other advisors); assembling the Shareholders Counsel and Independent Product Group; and overseeing all administrative functions.¹⁶⁷ Prior to becoming the legal personality of COVAX, GAVI spent \$1.4 million on setup activities for COVAX and AMC.¹⁶⁸ As the legal personality, GAVI will seek reimbursement for these fees through money paid into COVAX by the self-financing participants.¹⁶⁹ The self-financing participants’ COVAX payments are expected to cover all operating costs, which are expected to be around seven million dollars for the next year.¹⁷⁰

Additionally, within COVAX, GAVI is responsible for vaccine procurement and scaling-up delivery of a vaccine for low- and lower-middle-income countries

164. Bd. of Dirs., *Review of Decisions of July 30, 2020 Board Meeting*, 7 (July 30, 2020), <https://www.gavi.org/sites/default/files/board/minutes/2020/30-july/Board-2020-Mtg-4-Review%20of%20Decisions.pdf> [https://perma.cc/47GN-G5SG].

165. *Id.* at 11; *Dr Seth Berkley, Gavi CEO*, GAVI, THE VACCINE ALLIANCE, <https://www.gavi.org/operating-model/gavi-secretariat/seth-berkley> [https://perma.cc/2FXB-LU7H] (June 8, 2021).

166. Gavi Facility Structure and Governance, *supra* note 162, at 10–11. (noting that the MSDC is comprised of the “Board Chair . . . the Program and Policy Committee Chair, representatives of multilaterals, a representative of [the Bill and Melinda Gates Foundation], representatives of implementing country governments (2), representatives of donor country governments (3), a representative of the Civil Society Organizations,” and most likely representatives of self-financing countries).

167. *Id.* at 11–12 (noting that the Shareholders Council includes representatives from self-financing countries as well as AMC (financed) countries. The Council provides strategic guidance for vaccine development and vaccine allocation).

168. *Id.* at 14.

169. *Id.*

170. *Id.*

through COVAX AMC.¹⁷¹ All AMC-approved countries¹⁷² are also eligible for cold chain support to effectively and safely deliver the COVID-19 vaccine.¹⁷³ GAVI will be providing support to AMC countries over the next ten years; however, current estimations predict that COVAX will only need to be active for the next three years.¹⁷⁴ Therefore, the AMC program is designed to support lower- and lower-middle-income countries for an extended period of time—long after the shut-down of COVAX.¹⁷⁵

AMC was founded through a Stakeholder Agreement with GAVI.¹⁷⁶ Members of the Stakeholder group include AMC donors such as the United Nations Children’s Fund (UNICEF), Pan American Health Organization, AMC participant country representatives, development and regional banks involved in funding, and private sector and philanthropic donors.¹⁷⁷ The AMC Stakeholder group will be represented on the COVAX Shareholders Council.¹⁷⁸

The candidate vaccine portfolio is currently being run by CEPI and GAVI.¹⁷⁹ All proposed candidate vaccines are vetted by the Independent Product Group.¹⁸⁰ The Independent Product Group is comprised of five to seven experts who continuously review data on candidate vaccines, provide a score based on predetermined criteria in order to make recommendations, and support COVAX’s portfolio management.¹⁸¹

High-income, self-financing governments can invest in the diverse portfolio of candidate vaccines.¹⁸² When self-financing governments join COVAX as “participating countries,” a binding agreement is established to purchase a predefined number of doses, determine an initial investment in the program proportionate to the number of doses requested, and set dose contributions if the country has entered into other bilateral agreements.¹⁸³ Self-financing governments must also commit to numerous nonfinancial obligations such as supporting the

171. More than 150 Countries Engaged in COVID-19 Vaccine Global Access Facility, *supra* note 3.

172. See 172 Countries and Multiple Candidate Vaccines Engaged in COVID-19 Vaccine Global Access Facility, *infra* note 195 (listing all AMC-supported countries).

173. More than 150 Countries Engaged in COVID-19 Vaccine Global Access Facility, *supra* note 3.

174. Gavi Facility Structure and Governance, *supra* note 162, at 15.

175. *Id.*

176. Margaret “Peggy” Hamburg, *supra* note 155, at 3.

177. Aurélia Nguyen, *COVAX Facility Governance Explained*, GAVI, THE VACCINE ALLIANCE (Nov. 13, 2020), <https://www.gavi.org/vaccineswork/covax-facility-governance-explained> [<https://perma.cc/45PL-B6N4>].

178. Gavi Facility Structure and Governance, *supra* note 162, at 11.

179. Margaret “Peggy” Hamburg, *supra* note 155, at 3.

180. ACT ACCELERATOR COVAX PILLAR - INDEPENDENT PRODUCT GROUP, GAVI, THE VACCINE ALLIANCE 1–2 (2020), https://www.gavi.org/sites/default/files/document/2020/IPG_Call-for-nominations-8jul.pdf [<https://perma.cc/54BF-BVUD>].

181. *Id.*

182. Berkley, *supra* note 154.

183. *Id.*

movement of a vaccine, fast-tracking licensure of a vaccine, reporting all epidemiological and virological data, and maintaining transparency about all bilateral vaccine agreements.¹⁸⁴ The benefit of becoming a participating country includes access to the diverse candidate vaccine portfolio, which translates to a higher probability of accessing a COVID-19 vaccine.¹⁸⁵

The WHO is leading the policy and allocation workstream to develop global policy recommendations and an allocation framework including the Strategic Advisory Group of Experts (SAGE) on Immunization.¹⁸⁶ The WHO SAGE will make recommendations and advise on how a vaccine will be distributed within a country.¹⁸⁷

“COVAX is the only truly global solution to the COVID-19 pandemic.”¹⁸⁸ The COVAX model for vaccine procurement with its portfolio-based investment advertises a higher probability of a successful vaccine for self-financing countries. For self-financing countries, COVAX is an insurance policy to enhance a country’s probability of securing a vaccine beyond the current bilateral agreements.¹⁸⁹

Originally, the COVAX Facility had arrangements for first-wave access for around two billion doses of COVID-19 vaccine candidates,¹⁹⁰ making COVAX one of the largest and most diverse vaccine portfolios in the world (export controls imposed by India during its delta variant wave and problems with J&J procurement have reduced this initial ambitious goal).¹⁹¹ AstraZeneca-Oxford University and Novavax, both vaccine developers, have entered into contracts with COVAX.¹⁹² Serum Institute of India, a manufacturer, has agreed to limit the price of a vaccine produced by AstraZeneca or Novavax to three dollars per dose for low- and lower-middle-income countries also through a COVAX agreement.¹⁹³ Seven of the

184. Gavi Facility Structure and Governance, *supra* note 162, at 4.

185. Berkley, *supra* note 154.

186. Gavi Facility Structure and Governance, *supra* note 162, at 3.

187. World Health Org. [WHO], *Allocation Mechanism for COVAX Facility Vaccines*, at 1, 3 (Nov. 12, 2020) [hereinafter WHO, *Allocation Mechanism*].

188. More than 150 Countries Engaged in COVID-19 Vaccine Global Access Facility, *supra* note 3.

189. *Id.*

190. WHO, COVAX Announces Additional Deals, *supra* note 11.

191. Divya Rajagopal, *WHO Reviews Nine Vaccine Candidates for COVAX Alliance*, ECON. TIMES (Aug. 25, 2020, 6:40 PM), <https://economictimes.indiatimes.com/industry/healthcare/biotech/who-reviews-nine-vaccine-candidates-for-covax-alliance/articleshow/77733032.cms> [https://perma.cc/2WSM-79XA]. Neha Arora and Krishna N. Das, Rupam Jain, EXCLUSIVE: India unlikely to resume sizable COVID-19 vaccine exports until October, Reuters, <https://www.reuters.com/world/india/exclusive-india-unlikely-resume-sizable-covid-19-vaccine-exports-until-october-2021-05-18/> [https://perma.cc/QR2N-RF4Q].

192. *Id.*

193. Divya Rajagopal, *Serum Institute to Price Covid-19 Vaccine at \$3 per Dose for India and Lower Middle Income Nations*, ECON. TIMES (Aug. 7, 2020, 2:41 PM), <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/serum-institute-to-price-covid-19-vaccine-at-3-per-dose-for-india-and-lower-middle-income-nations/articleshow/77410667.cms?from=mdr> [https://perma.cc/5YCP-Q4RH].

nine current partnership candidate vaccines are in clinical trials.¹⁹⁴ Eighty-nine higher-income countries have joined COVAX.¹⁹⁵ These self-financing governments will help support the ninety-two COVAX AMC member countries, which are considered “funded” or “donor supported” participants.¹⁹⁶ Some governments, like France and Germany, have agreed to financially support COVAX although they will not buy candidate vaccines through the COVAX program, rather, opting to procure through a EU scheme.¹⁹⁷ Before 2021, the United States rejected COVAX, declaring, “we will not be constrained by multilateral organizations influenced by the corrupt World Health Organization and China” but has since decided to contribute financially to the organization.¹⁹⁸

194. WHO, COVAX Announces Additional Deals, *supra* note 11.

195. *Id.*; GAVI, THE VACCINE ALLIANCE, COVAX: COMMITMENT AGREEMENTS 2–3 (2020), https://www.gavi.org/sites/default/files/covid/pr/COVAX_CA_COIP_List_COVAX_PR_15-12.pdf [<https://perma.cc/VLK4-LXZX>] (listing the countries that have entered into commitment agreements with COVAX and agreed to be publicly named: Albania, Andorra, Antigua and Barbuda, Argentina, Armenia, Australia, Austria, Azerbaijan, Bahamas, Bahrain, Barbados, Belgium, Belize, Bosnia and Herzegovina, Botswana, Brazil, Brunei Darussalam, Bulgaria, Canada, Chile, Colombia, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Dominican Republic, Ecuador, Estonia, Finland, France, Georgia, Germany, Greece, Guatemala, Hungary, Iceland, Iran, Iraq, Ireland, Israel, Italy, Jamaica, Japan, Jordan, Kuwait, Latvia, Lebanon, Lithuania, Libya, Luxembourg, Malaysia, Malta, Mauritius, Mexico, Monaco, Montenegro, Namibia, Netherlands, New Zealand, North Macedonia, Norway, Oman, Palau, Panama, Paraguay, Peru, Poland, Portugal, Qatar, Romania, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, St. Kitts and Nevis, Suriname, Sweden, Switzerland, Trinidad & Tobago, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland, Uruguay, and Venezuela).

196. Press Release, World Health Org., 172 Countries and Multiple Candidate Vaccines Engaged in COVID-19 Vaccine Global Access Facility (Aug. 24, 2020), <https://www.who.int/news/item/24-08-2020-172-countries-and-multiple-candidate-vaccines-engaged-in-covid-19-vaccine-global-access-facility> [<https://perma.cc/Q4MZ-XKGG>] (noting that the GAVI board agreed in July 2020 that the following countries will be supported by the COVAX AMC: Low income countries include Afghanistan, Benin, Burkina Faso, Burundi, Central African Republic, Chad, Democratic Republic of the Congo, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Haiti, Democratic People’s Republic of Korea, Liberia, Madagascar, Malawi, Mali, Mozambique, Nepal, Niger, Rwanda, Sierra Leone, Somalia, South Sudan, Syrian Arab Republic, Tajikistan, Togo, Uganda, United Republic of Tanzania and Yemen. Lower-middle income countries include Angola, Algeria, Bangladesh, Bhutan, Bolivia, Cabo Verde, Cambodia, Cameroon, Comoros, Congo, Côte d’Ivoire, Djibouti, Egypt, El Salvador, Eswatini, Ghana, Honduras, India, Indonesia, Kenya, Kiribati, Kyrgyzstan, Lao People’s Democratic Republic, Lesotho, Mauritania, Micronesia, Moldova, Mongolia, Morocco, Myanmar, Nicaragua, Nigeria, Pakistan, Papua New Guinea, Philippines, São Tomé and Príncipe, Senegal, Solomon Islands, Sri Lanka, Sudan, Timor-Leste, Tunisia, Ukraine, Uzbekistan, Vanuatu, Vietnam, West Bank and Gaza, Zambia and Zimbabwe. Additional IDA-eligible countries include Dominica, Fiji, Grenada, Guyana, Kosovo, Maldives, Marshall Islands, Samoa, St. Lucia, St. Vincent and the Grenadines, Tonga and Tuvalu).

197. Andreas Rinke, *EXCLUSIVE-Germany Won’t Buy Vaccines Through WHO’s COVAX Scheme - Sources*, REUTERS (Sept. 18, 2020), <https://www.reuters.com/article/health-coronavirus-who-germany/exclusive-germany-wont-buy-vaccines-through-whos-covax-scheme-sources-idUSL8N2GF3JM> [<https://perma.cc/4JUM-42UT>].

198. Stephanie Nebehay, U.S., *Staying in WHO, to Join COVID Vaccine Push for Poor Nations - Fauci*, REUTERS (Jan. 21, 2021, 1:32 AM), <https://www.reuters.com/world/china/us-staying-who-join-covid-vaccine-push-poor-nations-fauci-2021-01-21/> [<https://perma.cc/N6SZ-7Z79>]; Emily Rauhala & Yasmeen Abutaleb, U.S. *Says It Won’t Join WHO-linked Effort to Develop, Distribute Coronavirus Vaccine*, WASH. POST (Sept. 1, 2020, 2:42 PM) <https://www.washingtonpost.com/>

After the creation of a safe and effective vaccine, the next hurdle COVAX will face is prioritizing to whom the vaccine will be available in the initial low-production period.¹⁹⁹ The WHO Allocation Mechanism is responsible for making dose allocation assessment in line with three goals: to “set . . . overarching principles for access to and allocation of health products for COVID-19,” to set a “global framework to ensure equitable and fair access and allocation of COVID-19 health products,” and to establish “fair and equitable allocation mechanisms for each product stream.”²⁰⁰ Currently, the WHO is recommending that priority populations such as health-care workers, adults over sixty-five, and high-risk adults with underlying conditions receive one of the first doses of the vaccine.²⁰¹ All COVAX participants (self-financing and funded) will initially receive doses to cover up to twenty percent of their population through a proportional allocation scheme.²⁰² Next, all participants will receive weighted allocation beyond twenty percent of their population.²⁰³ Weighted allocation is invoked if there is a severe supply constraint. If such a case were to occur, a country’s requested vaccine supply would be dispersed in accordance with a risk assessment score that evaluates the country’s “threat and vulnerability,” resulting in a risk rating. A higher risk rating means vaccine doses will be provided more quickly.²⁰⁴

As of October 19, 2021, COVAX-facilitated vaccines had shipped 371 million doses to 144 participants (almost all of which are recognized countries).²⁰⁵ It is known that those countries have agreed to indemnify AstraZeneca and Serum Institute of India, the manufacturers, against liability for adverse events. It is not known, however, which, if any, steps they have taken to compensate those who may suffer adverse events among their own populations.²⁰⁶

world/coronavirus-vaccine-trump/2020/09/01/b44b42be-e965-11ea-bf44-0d31c85838a5_story.html [https://perma.cc/3Q6X-PGAD].

199. COVAX, COVAX, THE ACT-ACCELERATOR VACCINES PILLAR: INSURING ACCELERATED VACCINE DEVELOPMENT AND MANUFACTURE 1, 3 (2020) [hereinafter COVAX, THE ACT-ACCELERATOR VACCINES PILLAR], <https://www.gavi.org/sites/default/files/covid/COVAX-Pillar-background.pdf> [https://perma.cc/H4BS-XRDF].

200. World Health Org. [WHO], *WHO Concept for Fair Access and Equitable Allocation of COVID-19 Health Products*, at 1, 6 (2020), <https://www.who.int/docs/default-source/coronaviruse/who-covid19-vaccine-allocation-final-working-version-9sept.pdf> [https://perma.cc/ZMZ4-M7AV].

201. *Id.* at 24; *See* COVAX, the Act-Accelerator Vaccines Pillar, *supra* note 199 at 3 (noting that “[p]olicy recommendations will lay out the priority populations” listed to be considered for the first round of vaccinations).

202. WHO, *Allocation Mechanism*, *supra* note 187.

203. *Id.*

204. *Id.* at 5.

205. COVAX Vaccine Roll-Out, GAVI, THE VACCINE ALLIANCE, <https://www.gavi.org/covax-vaccine-roll-out> [https://perma.cc/C3RY-AMHQ] (last visited Oct. 7, 2021).

206. Press Release, World Health Org., First COVID-19 COVAX Vaccine Doses Administered in Africa (March 1, 2021) <https://www.who.int/news/item/01-03-2021-first-covid-19-covax-vaccine-doses-administered-in-africa> [https://perma.cc/T33D-JWW5].

B. Liability and Compensation for Vaccine Injury Pose Barriers to both Manufacturer and Government Participation in COVAX

Despite the tremendous amount of ex ante planning for equitable vaccine access, there is no resolution at the COVAX Facility about what to do about ex post liability for vaccine injury.²⁰⁷ According to internal documents, GAVI has communicated to donor supported governments that manufacturers will require “assurances that they won’t face product liability claims over deaths or side effects from their vaccines.”²⁰⁸ Thailand, for example, has entered into only a nonbinding commitment with COVAX and has identified the liability and compensation matter as material to its decision to participate.²⁰⁹ Kenya, which is eligible for COVAX AMC membership,²¹⁰

said it was premature to say who should carry the liability for potential adverse effects but expected the vaccine makers to bear some of the responsibility, according to Rashid Aman, chief administrative secretary at the [M]inistry of [H]ealth. . . .

. . . .

This is one of the reasons why the EU has decided not to take delivery of vaccines through COVAX even though the 27-nation bloc has pledged money to the facility, [an EU] official said, noting that deals the EU is separately negotiating with vaccine companies involve clauses that make firms liable for potential compensation.²¹¹

Manufacturers, for their part, have made it clear that without legal assurances, they will not ship vaccines to any country, whether or not it participates in

207. GAVI, THE VACCINE ALLIANCE, COVID-19 VACCINE GLOBAL ACCESS (COVAX) FACILITY, PRELIMINARY TECHNICAL DESIGN: DISCUSSION DOCUMENT 17 (2020), <https://www.keionline.org/wp-content/uploads/COVAX-Facility-Preliminary-technical-design-061120-vF.pdf> [<https://perma.cc/WM7V-MZL6>] (“In addition to the pull funding design elements described above, there are other critical design elements of manufacturer-specific volume guarantees, in the form of contractual conditions, to be considered, which may include: Meeting minimal and/or preferred characteristics of normative WHO standards for COVID-19 pandemic response vaccines; Regulatory approval by a maturity level (ML)3/ML4 regulatory authority and WHO prequalification; Desirability of vaccine profile potentially influencing size of volume guarantee (e.g. if some product presentations are unsuitable for LICs / LMICs e.g. intravenous administration or large below-freezing cold chain requirements); Confirmed ability to export from supplier and host government; If the supplier also produces routine life-saving antigens, agreement that disruption of supply of other vaccines to Gavi / LICs / LMICs will be minimized; *Agreement with conditions of liability / indemnity mechanisms being created.*” (emphasis added)).

208. Maria Cheng & Lori Hinnant, *Push to Bring Coronavirus Vaccines to the Poor Faces Trouble*, AP NEWS (Sept. 30, 2020), <https://apnews.com/article/international-news-lifestyle-business-science-virus-outbreak-6656cba6143eb097da3dc7c8b360bfa4> [<https://perma.cc/M4KP-J4D5>].

209. *Id.*

210. *See supra* note 196 and accompanying text.

211. Francesco Guarascio, *Lack of Clarity on Liability Could Cause Delay with WHO Coronavirus Vaccine Drive*, INS. J. (Oct. 16, 2020), <https://www.insurancejournal.com/news/international/2020/10/16/586726.htm> [<https://perma.cc/SV3E-ALFB>].

COVAX.²¹² AstraZeneca, for example, has stated that in its bilateral contracts, it has been granted protection from legal claims arising from the use of its products, as it “cannot take the risk” of liability for side effects.²¹³ As early as 2006, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the global industry lobbying group, stated publicly that it demanded legal immunity for vaccine adverse events in order to participate in pandemic response.²¹⁴ In 2006, the IFPMA, in the wake of a potential H5N1 pandemic, stated

[I]n some countries, existing pharmacovigilance systems may fail to detect key signals until after the vaccines have already been administered to hundreds or thousands or millions of people. Many of the individuals vaccinated could develop medical conditions, by chance alone and unrelated to the vaccine, at some point following vaccination. It is inevitable that many will expect to be compensated. This is why [IFPMA] call(s) for a waiver of liability for the manufacturing and use of pandemic vaccines.²¹⁵

During the 2009–2010 H1N1 pandemic, manufacturers reiterated their concerns with potential product liability lawsuits, and negotiations regarding manufacturer indemnification caused substantial delays.²¹⁶ In one instance, GSK required indemnity from the Japanese government, which the government, in turn, replied it could not provide without a change in its law.²¹⁷ Manufacturers expressed similar concerns with respect to Ebola vaccines in 2014.²¹⁸

C. Principles of Fairness and Justice Require Compensation for Those Suffering from Severe Adverse Events Following Immunization with COVID-19 Vaccines

Globally, “there are three approaches to addressing vaccine injury: patients with adverse events may bear the costs associated with their injuries; they may seek compensation through litigation against private-sector actors (principally manufacturers); or they may seek compensation from publicly supported systems that draw from public-sector and private-sector contributions.”²¹⁹ Each type of approach is supported by an ethical rationale. The first approach is an “extreme utilitarian version of the fundamental social contract supporting immunization.”²²⁰

212. See Halabi et al., *supra* note 148, at e125(2).

213. Burger & Aripaka, *supra* note 20.

214. Halabi & Monahan, *supra* note 52, at 136.

215. *Id.*

216. *Id.*

217. See Yoko Nishikawa, *Japan to Buy H1N1 Flu Vaccine from Glaxo, Novartis*, REUTERS (Oct. 6, 2009, 5:28 AM), <https://www.reuters.com/article/us-flu-japan/japan-to-buy-h1n1-flu-vaccine-from-glaxo-novartis-idUSTRE5953AJ20091006> [<https://perma.cc/3VYS-T78M>] (noting that the Japanese government submitted a bill to parliament to compensate patients who suffer side effects).

218. Ben Hirschler & Stephanie Nebehay, *Drugmakers May Need Indemnity for Fast-Tracked Ebola Vaccines*, REUTERS (Oct. 23, 2014, 1:51 AM), <https://www.reuters.com/article/us-health-ebola-vaccine-idUSKCN0IC0TZ20141023> [<https://perma.cc/NA2T-3YZY>].

219. Halabi & Omer, *supra* note 26.

220. *Id.*

“From the claimant’s perspective, litigation is adversarial, protracted, uncertain, and requires that an attorney agree to take the case, which may pose a considerable obstacle for claimants with low earnings or fairly minor injuries.”²²¹ It effectively pushes the costs of herd immunity onto innocent parties.²²² In this utilitarian view, the benefits of vaccination so outweigh the risks that communities accept that some individuals will experience adverse events in return for herd immunity.²²³

“The second approach, requiring manufacturers to pay, is based on the integrity and dignity of the individual person—those whose products cause injury should make whole those individuals who experienced an adverse event.”²²⁴ “Vaccine manufacturers dislike tort because of the uncertainty involved in allowing juries to determine injury causation and damages awards. Even if catastrophically large awards rarely occur, the threat of them weighs heavily on manufacturers and their insurers.”²²⁵ These two approaches are commonly applied worldwide, yet they “destabilize the effort to promote immunization by failing fundamental tests for fairness” by (1) requiring people with few resources to pay for serious (if rare) injuries and (2) introducing economic uncertainty.²²⁶

The third approach, a no-fault compensation system for adverse events attributed to vaccination, balances these competing principles. Under a no-fault vaccine injury compensation system, governments compensate individuals who are harmed by properly manufactured vaccines instead of requiring them to use legal or other processes against manufacturers. A no-fault system acknowledges that a community that promotes immunization, knowing individuals will be injured, must share the burden of the cost of injuries. This approach also acknowledges that manufacturers are a critical part of vaccine access and that they must have a basic level of economic certainty. It fulfills the utilitarian and communitarian expectations of a democratic society.²²⁷

Over time, no-fault vaccine injury compensation systems have become a cornerstone of advanced public health systems, first in wealthier countries, but

221. Michelle M. Mello, *Rationalizing Vaccine Injury Compensation*, 22 *BIOETHICS* 32, 33 (2008).

222. Cristina Carmody Tilley, *Tort Law Inside Out*, 126 *YALE L.J.* 1320, 1392–93 (2017) (analyzing community perceptions of mandated vaccines).

223. *Id.*

224. Halabi & Omer, *supra* note 26; RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 1 (AM. L. INST. 1998) (“One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect.”); GUIDO CALABRESI, *THE COSTS OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS* (1970).

225. Mello, *supra* note 221.

226. Halabi & Omer, *supra* note 26; Adrien Katherine Wing, *Conceptualizing Global Substantive Justice in the Age of Obama*, 13 *J. GENDER RACE & JUST.* 705, 712 (2010) (“Justice issues transcend borders. We are beyond the time when we can segregate national and international issues.”).

227. Halabi & Omer, *supra* note 3. *Cf.* Gregory H. Shill, *Should Law Subsidize Driving?*, 95 *N.Y.U. L. REV.* 498, 574 (2020) (“No-fault insurance, which works a partial preemption of tort suits, adds an additional layer of subsidy for driving via torts.”).

increasingly in low- and lower-middle-income countries such as Nepal and Vietnam.²²⁸ The first such system was adopted in Germany in 1961 and has expanded to thirty-nine countries as well as the Canadian province of Quebec.²²⁹

III. SOLVING THE COVID-19 VACCINE PRODUCT LIABILITY PROBLEM

So far, solutions to the vaccine product liability problem have been achieved only by a small number of wealthy countries and a handful of middle-income countries. Those solutions follow one of two approaches. First, the domestic law of the procuring government provides separately for legal immunity to manufacturers and a compensation system for those suffering side effects. Second, governments and manufacturers agree through contract on the division of liabilities between them, with presumptive recourse to litigation for those suffering severe vaccine side effects. The first approach is adopted by the United States under its PREP Act, detailed below. The second approach has been adopted by the EU, which has offered varying levels of liability protection to AstraZeneca and Sanofi based on price per dose of vaccine.²³⁰

But the need to compensate those suffering severe side effects following immunization is worldwide, especially through COVAX, as is the need to provide manufacturers legal certainty regarding their participation. This Part provides solutions for the rest of the world by combining together three approaches: requiring existing national no-fault systems to incorporate injuries attributable to COVID-19 vaccines distributed through COVAX, leveraging an existing small-scale insurance regime administered by the WHO, and constructing a system for no-fault vaccine injury compensation using mass claims models deployed after the Deepwater Horizon oil spill in the Gulf of Mexico and the compensation systems used after the Boeing 737 mass casualty airplane crash events.

A. No-Fault Compensation for Vaccine Injury

1. No-Fault Compensation Systems for Public Health Emergencies

Some jurisdictions, like the United States, have extended immunity against legal claims related to the manufacturing, testing, development, distribution, and

228. Randy G. Mungwira, Christine Guillard, Adiel 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 21, 2020, at 5; see Josephine Gittler, *Controlling Resurgent Tuberculosis: Public Health Agencies, Public Policy, and Law*, 19 J. HEALTH POLS., POL'Y & L. 107, 139–40 (1994) (analyzing public health measures as part of broader social safety planning).

229. Looker & Kelly, *supra* note 117, at 371–72.

230. Francesco Guarascio, *Exclusive: AstraZeneca Gets Partial Immunity in Low-cost EU Vaccine Deal*, REUTERS (Sept. 24, 2020, 11:14 PM), <https://www.reuters.com/article/health-coronavirus-eu-astrazeneca/exclusive-astrazeneca-gets-partial-immunity-in-low-cost-eu-vaccine-deal-idUSL5N2GK3NE> [<https://perma.cc/3BSW-2AMP>].

administration of COVID-19 vaccines.²³¹ The law provides for a publicly funded and administered program of compensation for those suffering severe side effects. The Public Readiness and Emergency Preparedness (PREP) Act was enacted on December 30, 2005.²³² The purpose of the Act is to encourage companies to promptly release medical countermeasures during public health emergencies.²³³ The PREP Act precludes liability for defects in diagnostics, therapeutics, and vaccines under both federal and state law for any loss “caused by, arising out of, or resulting from” the application of a “covered countermeasure.”²³⁴ PREP Act declarations have been made for H1N1, Ebola, botulism toxin, anthrax, smallpox, and acute radiation syndrome.²³⁵

For COVID-19, a “covered countermeasure” is any antiviral, any other drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine, used (a) to treat, diagnose, cure, prevent, mitigate or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or (b) to limit the harm that COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, might otherwise cause. A “covered countermeasure” is also any device used in the administration of any such product and all components and constituent materials of any such product that has been authorized pursuant to a declaration by the Secretary of U.S. Health and Human

231. See generally Looker & Kelly, *supra* note 117.

232. Notice of Amendment and Republished Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, 85 Fed. Reg. 79190, 79191 (Dec. 9, 2020).

233. KEVIN, J. HICKEY, CONG. RSCH. SERV., LSB10443, THE PREP ACT AND COVID-19: LIMITING LIABILITY FOR MEDICAL COUNTERMEASURES 1 (2021), <https://crsreports.congress.gov/product/pdf/LSB/LSB10443> [<http://web.archive.org/web/20210928005052/https://crsreports.congress.gov/product/pdf/LSB/LSB10443>].

234. Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198, 15200 (Mar. 17, 2020).

235. Ebola Virus Disease Vaccines, 79 Fed. Reg. 73314 (Dec. 10, 2014); HHS Secretary’s Declaration for Utilization of Public Readiness and Emergency Preparedness Act for Botulism Countermeasures, 73 Fed. Reg. 61864 (Oct. 17, 2008); HHS Secretary’s Declaration for Utilization of Public Readiness and Emergency Preparedness Act for Anthrax Countermeasures, 73 Fed. Reg. 58239 (Oct. 6, 2008); HHS Secretary’s Declaration for Utilization of Public Readiness and Emergency Preparedness Act for Smallpox Countermeasures, 73 Fed. Reg. 61869 (Oct. 17, 2008); Letter from Brian L. Strom, Kristine M. Gebbie, Robert B. Wallace & Committee on Smallpox Vaccination Program Implementation to Dr. Julie Gerberding (Jan. 16, 2003), in THE SMALLPOX VACCINATION PROGRAM: PUBLIC HEALTH IN AN AGE OF TERRORISM 123, 123–159 (Alina Baciu, Andrea Pernack Anason, Kathleen Stratton & Brian Strom eds., 2005); HHS Secretary’s Declaration for Utilization of Public Readiness and Emergency Preparedness Act for Acute Radiation Syndrome, 73 Fed. Reg. 61866 (Oct. 17, 2008); David W. Ogden, Bruce S. Manheim Jr., Sean Hayes & Ariel Dobkin, *COVID-19: Immunity Under the PREP Act: When Does It Apply to Private Sector Efforts to Help Combat COVID-19?*, WILMERHALE (Mar. 30, 2020), <https://www.wilmerhale.com/en/insights/client-alerts/20200330-immunity-under-the-prep-act-when-does-it-apply-to-private-sector-efforts-to-help-combat-covid19> [<https://perma.cc/C3SL-ZGJ8>].

Services (HHS).²³⁶ The HHS Secretary, Alex Azar, issued the initial PREP Act declaration covering COVID-19 vaccines on March 10, 2020.²³⁷ In order to qualify for PREP Act immunity, a covered countermeasure, including a COVID-19 vaccine, must be approved by the U.S. FDA, either pursuant to conventional licensure or under an EUA.²³⁸ Manufacturers and distributors are immune from liability regardless of the geographical area where the countermeasure was administered or used.²³⁹

As part of the same law limiting manufacturer liabilities for covered countermeasures, the United States provides for a system of compensation for those suffering severe side effects. The Countermeasures Injury Compensation Program (CICP) was created by the PREP Act.²⁴⁰ Should an individual experience an injury as a result of the use of a covered countermeasure, he or she is allowed to submit a claim to the Health Resource and Services Administration (an agency within the HSS). A claimant must complete a Request for Benefits form and submit medical evidence within a year of being administered or using the countermeasure.²⁴¹ Once a claim has been submitted, it is reviewed by medical staff within the program to determine a causal link.

If HHS has published an injury table for the covered countermeasure, the claimant is entitled to a presumption of causation. If not, the claimant must prove causation through “compelling” evidence.²⁴² Once causation is established, claimants are compensated.²⁴³ There is no adversarial process or presentation of further evidence to a court or special tribunal.²⁴⁴ The CICP has received 485 claims since it began accepting claims related to H1N1 vaccines in 2010.²⁴⁵ Of those claims,

236. 42 U.S.C. § 247d-6d(i)(1) (2020); ROBERT P. CHARROW, U.S. DEP’T OF HEALTH & HUM. SERVS., ADVISORY OPINION ON THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT AND THE MARCH 10, 2020 DECLARATION UNDER THE ACT (May 19, 2020).

237. HICKEY, *supra* note 233, at 2.

238. Ogden et al., *supra* note 235.

239. Notice of Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198, 15201 (Mar. 17, 2020).

240. 42 U.S.C. § 247d-6d (2020).

241. *Filing for Benefits*, HRSA, <https://www.hrsa.gov/cicp/filing-benefits> [https://perma.cc/4FCK-2ZFQ] (last visited Apr. 2020).

242. Peter H. Meyers, *Fixing the Flaws in the Federal Vaccine Injury Compensation Program*, 63 ADMIN. L. REV. 785, 835 (2011) (citing 42 U.S.C. §§ 239a(c)(2), 247d-6e(b)(4)) (“[C]ompelling, reliable, valid, medical and scientific evidence.”).

243. See Robert Roos, *HHS: 386 Injury Claims Filed Over H1N1 Countermeasures*, CIDRAP (Mar. 16, 2011), <https://www.cidrap.umn.edu/news-perspective/2011/03/hhs-386-injury-claims-filed-over-h1n1-countermeasures> [https://perma.cc/29LU-HWCN]; Mungwira et al., *supra* note 228, at 9.

244. See HRSA, *supra* note 241.

245. Tom Hals, *COVID-19 Era Highlights U.S. ‘Black Hole’ Compensation Fund for Pandemic Vaccine Injuries*, REUTERS (Aug. 21, 2020, 4:08 AM), <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/HFC6-Z8QE].

thirty-nine individuals have received compensation with a total \$5.7 million paid.²⁴⁶ Of the 485 claims filed with the CICP, 386 were related to the H1N1 vaccine.²⁴⁷

The United States is the only country in the world with such an extensive system for covering manufacturers of emergency deployed vaccines and providing for ex post compensation.²⁴⁸

2. *Adapting No-Fault Compensation Systems for Routine Immunizations*

Similar no-fault systems for routine immunization existed before COVID-19 for twenty-five countries (including the United States) and the province of Quebec in Canada.²⁴⁹ Fourteen additional countries have adopted such systems pursuant to the COVID-19 pandemic. The first prong of solving the COVID-19 vaccine product liability problem requires that countries with established no-fault systems agree to incorporate COVID-19 vaccines into their no-fault systems if they receive vaccines through the COVAX Facility.²⁵⁰ All of these systems provide a schedule of automatic compensation based on the injury without establishing fault. None of these systems require the vaccine recipient to prove the maker of the vaccine was negligent.²⁵¹

There are variations in how the programs are funded, who is eligible, who administers the program, and what limits exist on collection for the claimant should they be successful. Any one of the given models may be incorporated into a global system run by the COVAX Facility, but for those countries with pre-existing systems, the most straightforward approach is to require those countries to affirm that COVID-19 vaccines with a table of compensable injuries generated from Phase III trials and ongoing monitoring and experience will be incorporated into their systems.

a. *Funding*

In most countries with no-fault systems, the government stands in as the defendant, and as a result, most programs are government-funded.²⁵² Fifteen

246. *Id.*

247. *See* Roos, *supra* note 243.

248. NICHOLAS M. PACE & LLOYD DIXON, RAND CORP., COVID-19 VACCINATIONS: LIABILITY AND COMPENSATION CONSIDERATIONS CRITICAL FOR A SUCCESSFUL CAMPAIGN 6 (2020), https://www.rand.org/content/dam/rand/pubs/perspectives/PEA700/PEA761-1/RAND_PEA761-1.pdf [<https://perma.cc/9FJ2-JZ4F>] (“Although some countries have legal processes through which vaccine-injury claims can be addressed outside traditional litigation, few countries provide any level of immunity to entities and individuals within the supply chain that compares with the sweeping protections available under PREP.”).

249. Mungwira et al., *supra* note 228, at 1, 4–5.

250. *See id.* at 9; INST. OF MED., *Liability for the Production and Sale of Vaccines*, in VACCINE SUPPLY AND INNOVATION 85, 85 (1985) (“Manufacturers have complained about the costs, the unpredictability of the law, and the unavailability and cost of insurance.”).

251. Mungwira et al., *supra* note 228, at 8.

252. JENNIFER KEELAN & KUMANAN WILSON, DESIGNING A NO-FAULT VACCINE-INJURY COMPENSATION PROGRAMME FOR CANADA: LESSONS LEARNED FROM AN INTERNATIONAL

current systems are funded by their governments, while eight fund themselves from other sources, including levies on manufacturers.²⁵³

For example, France, Denmark, Quebec, and Italy all use general tax revenues to pay damage awards to injured parties.²⁵⁴ In Sweden, Taiwan, and Norway, manufacturers pay a premium to fund the no-fault program.²⁵⁵ While administered at the government level, Norway's program is actually funded by a special insurance organization called the Drug Liability Association.²⁵⁶ Membership in this association is mandatory for any drug producer in Norway.²⁵⁷ Members pay for an insurance regime that is used to fund the no-fault program.²⁵⁸

The United States collects a \$0.75 levy on each dose (so MMR, for example, would be \$2.25) of the vaccine sold, then funds the no-fault program with the levy.²⁵⁹ The Vaccine Injury Compensation Program trust holds approximately three billion dollars from this levy with about \$150 million being deposited every year.²⁶⁰

b. Eligibility

With respect to eligibility, fifty-seven percent of no-fault systems compensate injuries for those vaccines which are registered and recommended by their respective governments.²⁶¹ This is the broadest category of vaccines, encompassing any vaccine the government (through public health agencies) may recommend. However, a minority of programs (twenty-two percent) only cover those vaccines that are mandated or recommended through law.²⁶² The U.K. and Quebec both only cover vaccines which are specifically listed in the legislation establishing the no-fault program.²⁶³ Eligibility provisions of national regimes would require amendment for COVID-19 vaccines in some cases.²⁶⁴

All no-fault programs maintain at least some threshold of injury for compensation.²⁶⁵ Quebec allows for any serious injury, for example, while the

ANALYSIS OF PROGRAMMES 2, 10 (2011), https://munkschool.utoronto.ca/wp-content/uploads/2012/07/Keelan-Wilson_NoFaultVaccine_CPHS_2011.pdf [<https://perma.cc/CJ4H-2MHV>].

253. Mungwira et al., *supra* note 228, at 6, 10.

254. *Id.* at 5–6.

255. KEELAN & WILSON, *supra* note 252, at 3.

256. Mungwira et al., *supra* note 228, at 6.

257. LEGEMIDDELANSVARSFORENINGEN, LIABILITY INSURANCE IN CONNECTION WITH CLINICAL TRIALS OF DRUGS 1 (2019), http://www.laf.no/dm_documents/8366497_1_Liability_insurance_in_connection_with_clinical_trials_of_drugs_QPvgv.PDF [<https://perma.cc/8ALU-KUYV>].

258. *Id.* at 1–2.

259. Mungwira et al., *supra* note 228, at 6.

260. Nora Freeman Engstrom, *A Dose of Reality for Specialized Courts: Lessons from the VICP*, 163 U. PA. L. REV. 1631, 1660, 1713 (2015).

261. Mungwira et al., *supra* note 228, at 6.

262. *Id.*

263. *Id.*

264. *See id.*

265. *Id.* at 7.

U.K. offers compensation if the vaccine is solely responsible for causing sixty percent or more disability in an individual.²⁶⁶

All current programs also require some sort of causal link to be established between the injury and the vaccine.²⁶⁷ Generally, no-fault systems require a balance-of-probabilities test that, in the United States, is understood as “more likely than not” or through a “preponderance of the evidence” analysis.²⁶⁸

c. Administration

Most (sixty-five percent) of current no-fault programs are administered at the national government level through public bureaucracies.²⁶⁹ Few programs, such as China and Switzerland, administer their programs at the provincial level.²⁷⁰

Finland and Sweden both administer their no-fault programs through a private drug insurance scheme. Sweden’s drug companies have private insurance to which they pay premiums. Those premiums are then used to fund a program, with injured parties filing claims with insurers.²⁷¹

d. Limits on Compensation

Systems vary with respect to those damages qualifying for compensation. Some programs include medical costs, lost earnings, pain and suffering compensation, emotional distress, and even loss of earning capacity.²⁷² Quebec, for example, refers to an automobile insurance act in setting claimant compensation and pays claimants the same as automobile accident victims.²⁷³

In the U.K., compensation is set at £120,000.²⁷⁴ This amount reflects the lifelong support those on disability already receive from the British government, while also attempting to “ease the burden of affected families.”²⁷⁵

266. KEELAN & WILSON, *supra* note 252, at 10.

267. Mungwira et al., *supra* note 228, at 8.

268. *Id.*

269. Mungwira et al., *supra* note 228, at 5.

270. *Id.* at 6. In 2014, China required all thirty-one provinces to implement the compensation programme for vaccine injuries. Administration of the programme involves all levels of government: “filing of claims and causality assessment of events is done at district or county level; operational procedures for compensation are set at province level and general vaccine injury compensation policies including definitions of what constitutes a vaccine injury are determined at the central government level.” *Id.* The programme was enacted by the central government but is actually run by local governments. Each province, autonomous region, or municipality directly under the central Chinese government needs to formulate its specific local regulations for compensation for AEFI. Lanfang Fei & Zhou Peng, *No-Fault Compensation for Adverse Events Following Immunization: A Review of Chinese Law and Practice*, 25 MED. L. REV. 99, 103–04 (2017).

271. KEELAN & WILSON, *supra* note 252, at 2, 10.

272. Mungwira et al., *supra* note 228, at 8.

273. *Id.*

274. KEELAN & WILSON, *supra* note 252, at 18.

275. *Id.*

B. Expanding Small-Scale Insurance Plans

While thirty-nine countries, including Nepal, the Philippines, and Vietnam, maintain no-fault vaccine injury compensation systems that could be used for COVID-19 vaccines, the vast majority of countries do not. The second prong of a comprehensive solution to the vaccine injury product liability problem is the use of small-scale insurance regimes that exist under the auspices of the WHO that may be expanded in response to the COVID-19 pandemic.

The WHO maintains a small-scale insurance regime for EUA vaccines that it procures and distributes. The plan for a no-fault insurance regime followed the 2014–2016 West Africa Ebola public health emergency. While there was a leading vaccine candidate—rVSV-ZEBOV, now marketed as Ervebo—that had been developed over a fifteen-year period before the outbreak, there was no system for addressing liability and compensation if it were to be deployed on an emergency use basis.²⁷⁶ One of the most afflicted countries refused to accept responsibility for product liability claims, and the manufacturer limited its participation to the sponsorship of clinical trials organized after the peak of the epidemic had passed.²⁷⁷

Given the uncertainty about permanent licensure, the WHO sought an insurance product that would apply after the clinical trial stage—where insurance is relatively easy to obtain and inexpensive—and full licensure—when manufacturers are expected to assume liability for their products.²⁷⁸

276. Ann Maria Henao-Restrepo, Marie-Pierre Preziosi, David Wood, Vasee Moorthy Marie Paule Kieny & the WHO Ebola Research, Development Team, *On a Path to Accelerate Access to Ebola Vaccines: The WHO's Research and Development Efforts During the 2014–2016 Ebola Epidemic in West Africa*, CURRENT OP. VIROLOGY, Apr. 2016, at 138, 140–41, <https://www.sciencedirect.com/science/article/pii/S1879625716300384> (click “View PDF”) [<https://perma.cc/22BT-TT9X>].

277. See Sam Halabi, Andrew Heinrich & Saad B. Omer, *No-Fault Compensation for Vaccine Injury—The Other Side of Equitable Access to Covid-19 Vaccines*, 383 New England Journal of Medicine 23 (2020).

278. World Health Org. [WHO], *Workshop on Expanded Access to Experimental Ebola Vaccines During Outbreaks*, at 21–22 (2017) [hereinafter WHO, *Experimental Ebola Vaccines*] <https://www.who.int/blueprint/expanded-access-ebola-vaccines.pdf> [<https://perma.cc/3X8W-4MBR>] (“The ultimate objective of this special insurance product is to facilitate emergency response action and timely deployment of experimental vaccines in the event of infectious disease outbreaks for which no licensed vaccine exists. While manufacturers of experimental vaccines will be required to assume liability arising from failure to manufacture their product in accordance with current Good Manufacturing Practices and agreed specifications, recipient countries will (as was the case during the 2014–2016 Ebola outbreak) as a condition for receiving experimental vaccine be required to assume liability and indemnify WHO, donors and manufacturers for other risks arising out of the use of the product. At the same time, WHO would obtain insurance coverage for the benefit of recipient countries, to provide compensation to individuals who suffer from serious AEFI. The insurance would have two levels: (i) a first level based on an annual premium, to keep the insurance open over time; and (ii) a second level of insurance to be obtained when an outbreak occurs, with a premium based on agreed criteria (vaccine safety profile, Gross Domestic Product of the country where the experimental product would be used and the number of people that would receive the product). The insurance could also include a certain coverage for manufacturers, i.e. in case an individual refuses to accept the compensation offered under the insurance and wishes to pursue a liability claim against the manufacturer in a court of law (or any similar forum).”).

The WHO scheme insures against serious injuries resulting from experimental vaccines that the WHO administers on an emergency use basis.²⁷⁹ The WHO must declare an Emergency Use Assessment Listing for vaccines that are still experimental or have not been completely clinically verified in emergency situations.²⁸⁰ Granting such an assessment listing expedites immunization response during disease outbreaks for which no licensed vaccine currently exists. However, risks naturally occur alongside such an assessment listing, as the vaccine is still relatively untested and can present unknown dangers when deployed widely to all types of people with varying health conditions.²⁸¹ So, the WHO provides, through a private insurer, compensation and protection for those countries receiving and using an experimental vaccine, as well as legal protection as an incentive to manufacturers to donate needed immunizations.²⁸²

This insurance is procured through both an annual premium and a heightened cost in the event of an outbreak. The premium during an outbreak is based on criteria such as the GDP of the country where the vaccine is being deployed. This insurance compensates for immunization-caused injuries within the country in which they occur.²⁸³ While manufacturers of experimental vaccines are required to assume liability arising from failure to manufacture their product in accordance with current good manufacturing practices and agreed specifications, recipient countries, as a condition for receiving the experimental vaccine, must assume liability and indemnify the WHO, donors, and manufacturers for other risks arising out of the use of the product in order to receive the benefits of the insurance policy.²⁸⁴ The insurance also includes contingent coverage for manufacturers, “i.e. in case an individual refuses to accept the compensation offered under the insurance and wishes to pursue a liability claim against the manufacturer in a court of law (or any similar forum).”²⁸⁵

The biggest limitation in this plan is its scope. The current plan only grants coverage to countries for a specific vaccine when the WHO specifically brands the vaccine as emergency use and then distributes it. Although the WHO has expanded its current mechanism for COVID-19 in partnership with ESIS, Inc., a unit of Chubb Insurance, it has also made clear that “dozens of middle-income countries, such as South Africa, Lebanon, Gabon, Iran and most Latin American states, [will] not be offered this protection.”²⁸⁶ Yet there are large insurers who may be able to

279. *Id.*

280. *Regulation and Prequalification: Emergency Use Listing*, WORLD HEALTH ORG., <https://www.who.int/teams/regulation-prequalification/eul> [<https://perma.cc/CD3W-DHT6>] (last visited July 13, 2021).

281. WHO, *Experimental Ebola Vaccines*, *supra* note 278.

282. *Id.*

283. *Id.*

284. *Id.* at 21.

285. *Id.* at 22.

286. Francesco Guarascio, *WHO to Form COVID Insurance Scheme for Vaccine Side-Effects in Poor Nations*, INS. J. (Oct. 29, 2020), <https://www.insurancejournal.com/news/international/2020/>

scale up the WHO system for COVID-19 vaccines including Allianz Multinational, Chubb, Swiss Re, and Zurich Multinational.²⁸⁷ In 2011, Swiss Re opened its subsidiary, Corporate Solutions, whose focus is on underwriting risk for medium and large corporations.²⁸⁸ The Corporate Solutions arm of the company offers coverage in about 150 countries.²⁸⁹

C. Centralized Mass Claims Administration

There are currently no-fault vaccine injury compensation programs across twenty-five of the 217 countries currently listed by the World Bank.²⁹⁰ The twenty-five countries with compensation programs include a handful of large countries (including the United States and China), but the 192 countries without any form of compensation programs encompass about sixty-six percent of the human population.²⁹¹ There are currently 5.03 billion people living without a no-fault compensation program for their vaccine injuries.²⁹² As noted above, the WHO insurance regime is small in scale, perhaps at this point only able to cover one-to-five million individuals.

There is, therefore, a need to provide a mechanism through the COVAX Facility or a system of country opt-outs that satisfies manufacturer demands for indemnity or immunity from legal claims. The models below may serve as effective options for running a no-fault compensation system out of the COVAX Facility. As with the no-fault systems described above, funding for a centrally administered system could be from funds already earmarked for COVAX purposes or a \$0.05 or \$0.10 levy per dose. Given the billions of doses to be administered, even a small levy would quickly generate a pool of resources for compensation.

1. Deepwater Horizon Oil Spill

On April 20, 2010, an explosion occurred on the *Deepwater Horizon*, an offshore oil drilling rig owned by Transocean Ltd. [BP's offshore drilling

10/29/588706.htm [https://perma.cc/SSB7-EQUR]. See also covaxclaims.com [https://perma.cc/G8AK-8XBY] for the specifics of the expanded WHO system.

287. See, e.g., *About Us*, SWISS RE CORP. SOLS., <https://corporatesolutions.swissre.com/about-us.html> [https://perma.cc/5CM6-K23M] (last visited July 13, 2021); Brian Till, *How Drug Companies Keep Medicine Out of Reach*, ATLANTIC (May 15, 2013), <http://www.theatlantic.com/health/archive/2013/05/how-drug-companies-keep-medicine-out-of-reach/275853/> [https://perma.cc/CV8F-9K6S].

288. SWISS RE, 2011 BUSINESS REPORT 13 (2011), https://www.swissre.com/dam/jcr:1651ad7b-3bff-457b-a59a-b1756611c7f9/2011_AR_business_report_en.pdf [https://perma.cc/BCA9-YF8Q].

289. *International Programs*, SWISS RE CORP. SOLS., <https://corporatesolutions.swissre.com/insurance-solutions/international-programs.html> [https://perma.cc/9W54-YGKP] (last visited July 13, 2021).

290. See Mungwira et al., *supra* note 228; *Population, Total*, WORLD BANK, <https://data.worldbank.org/indicator/SP.POP.TOTL> [https://perma.cc/6VXG-KEE2] (last visited July 13, 2021).

291. *Id.*

292. *See id.*

contractor], which resulted in, among other things, the deaths of eleven crewmen and the discharge of oil into the Gulf of Mexico for several months. The Spill dwarfed the 1989 *Exxon Valdez* oil spill (which gave rise to the Oil Pollution Act of 1990) both in terms of the amount of oil discharged and the extent of the impact.²⁹³

The resulting legal claims were massive in number and scope but were effectively limited by claims processes required under U.S. law. Under the Oil Pollution Act of 1990 (OPA), BP (lessor of the Deepwater Horizon drilling platform) was designated the responsible party for the spill by the United States Coast Guard.²⁹⁴ Under the OPA, responsible parties must construct a claims process against themselves for all affected by the spill. The United States negotiated with BP to create a twenty-billion-dollar trust to finance the claims resulting from the spill.²⁹⁵ As a part of these negotiations, the Gulf Coast Claims Facility (GCCF) was established.²⁹⁶

The GCCF was created to process claims in a neutral and efficient manner. First, a claimant's eligibility was determined through a classification analysis. Claimants would bring their claims under five categories: removal and cleanup costs, real or personal property damage, lost profits or earning capacity, subsistence use of natural resources, or physical injury or death.²⁹⁷ The GCCF only paid out compensation to those injuries proximately caused by the oil spill.²⁹⁸ Once a claimant was determined eligible, a GCCF claims reviewer used a standardized calculator to determine the claimant's losses (claimants would submit documentation wherever possible to substantiate their claims).²⁹⁹ During Phase I of the GCCF's operations, it paid a minimum of \$1,000, even to claimants whose damages totaled less.³⁰⁰

The methods by which the GCCF offered compensation evolved as claimants continued filing. One option included a one-time payment of \$5,000 alongside an agreement to release claims. This "Final Payment" option was rapid, as no damages were calculated, and little paperwork or evidence was required to be submitted.³⁰¹

The GCCF received claims from claimants from all fifty states in the United States and from forty countries.

293. BDO CONSULTING, INDEPENDENT EVALUATION OF THE GULF COAST CLAIMS FACILITY: REPORT OF FINDINGS & OBSERVATIONS TO THE U.S. DEPARTMENT OF JUSTICE 11 (2012), <https://www.justice.gov/sites/default/files/opa/legacy/2012/06/06/gccf-rpt-find-obs.pdf> [<https://perma.cc/UWC3-F6MX>].

294. GULF COAST CLAIMS FACILITY, PROTOCOL FOR INTERIM AND FINAL CLAIMS (2011).

295. BDO CONSULTING, *supra* note 293, at 12.

296. *Id.* at 12.

297. GULF COAST CLAIMS FACILITY, *supra* note 294, at 2–4.

298. *Id.* at 4.

299. BDO CONSULTING, *supra* note 293, at 31.

300. *Id.* at 32.

301. *Id.* at 34.

The GCCF undertook several steps . . . to meet the language needs of claimants. These included, but were not limited to, staffing of the GCG-operated call center with persons fluent in Spanish, Vietnamese and French and creation of a process by which a telephone translation service would be used for callers who spoke other languages; staffing of certain site offices with people who were fluent in Spanish, Vietnamese, Laotian, Khmer, French and Croatian; making all claim forms available in hardcopy in Spanish, Vietnamese and Khmer; posting all website content in Spanish, Vietnamese and Khmer; sending all correspondence that did not require the inclusion of claimant specific claims information in Spanish, Vietnamese or Khmer for all claimants who had notified the GCCF of a preference for one of these languages; providing claimants with an opportunity for a special appointment with a translator present; and creating an online claims filing process, accessible through the GCCF website, through which claimants could file claims in Spanish and Vietnamese.³⁰²

During its eighteen-month existence, the GCCF paid over six billion dollars to more than 200 thousand individual and business claimants.³⁰³

It is important to acknowledge that what was true of the GCCF will be true of any system established through the COVAX Facility. The primary concern regarding the GCCF was error. Upon an independent investigation of the program by an outside party at the request of the Department of Justice, it was determined about 10,000 claimants were either negatively affected by error or erroneously denied compensation.³⁰⁴ In a broader context, this represented about a five percent error rate.

The program implemented by the GCCF was designed by policy and activated upon a disaster. But there are themes and design elements that are applicable to a global immunization context. The idea of a centralized claims facility for every person injured by one vaccine would be much simpler than the current system of relying on governments to establish their own systems and potentially resulting in inconsistent judgments against the manufacturer or similar claimants. A centralized system is also efficient. Instead of 192 separate systems, each independently staffed, one program for the globe would require fewer resources.

A centralized compensation program, financed through international donations and a relatively modest \$0.05 or \$0.10 per dose levy, administered by a third party, and adjudicating claims in a standardized manner would offer rapid compensation to those harmed as well as confidence for manufacturers.³⁰⁵ Globalizing the system, instead of programs in a select few countries, would also

302. *Id.* at 33.

303. *Id.* at 59.

304. *Id.* at 67, 70.

305. *Vaccine Injury Financial Assistance Programme for COVID-19 Vaccination*, SING. MINISTRY OF HEALTH, (Sept. 16, 2021), <https://www.moh.gov.sg/covid-19/vaccination/vifap> [<https://perma.cc/Z27K-CQWD>].

enable manufacturers to distribute vaccines to countries where litigation risk is not effectively calculable.

2. Boeing 737 Max Crash Compensation System

On October 29, 2018, Lion Air flight 610 crashed, killing every person on board and resulting in 189 deaths.³⁰⁶ Five months later, on March 10, 2019, Ethiopian Airlines flight 302 crashed, killing all 157 people on board.³⁰⁷ In both catastrophes, the plane that crashed was a Boeing 737 Max, a new and popular model.³⁰⁸ Investigations into both crashes, which followed similar stories of crashing after failing to gain altitude after takeoff, indicated a defect in the plane which caused the accidents.³⁰⁹ Boeing was held liable for the deaths of 346 people, and the Boeing Max was grounded until the defect was cured and a fix was approved by the U.S. Federal Aviation Administration.³¹⁰ The nationalities of the victims from the two crashes spanned thirty-five different countries, from the United States to Kenya to China.³¹¹

International aviation accidents are governed by the Montreal Convention. This international treaty determines which country's courts may hear lawsuits regarding the accident and how much the families of victims may be compensated.³¹² Airline accidents such as the 737 Max crashes are relevant to the construction of a compensation system for vaccine injuries in that what *caused* the harm is not relevant. When a plane crashes and all lives on board are lost, there is a presumption of a causal relationship.

306. Scott Neuman, *Indonesia Report: Pilots, Ground Crew Share Blame with Boeing for Lion Air Crash*, NPR (Oct. 25, 2019, 4:41 AM), <https://www.npr.org/2019/10/25/773291951/pilots-ground-crew-share-blame-for-lion-air-737-max-crash-indonesian-report-says> [https://perma.cc/DM89-JSMX].

307. Hadra Ahmed, Norimitsu Onishi, Dionne Searcey & Hannah Beech, *Ethiopian Airlines Plane Is the 2nd Boeing Max 8 to Crash in Months*, N.Y. TIMES (Mar. 10, 2019), <https://www.nytimes.com/2019/03/10/world/africa/ethiopian-airlines-plane-crash.html> [https://perma.cc/S9V2-T3PS].

308. Avie Schneider, *Boeing 737 Max, Involved in 2 Crashes, Is Fastest-Selling Plane in Company's History*, NPR (Mar. 11, 2019, 1:55 PM), <https://www.npr.org/2019/03/11/702211493/boeing-737-max-involved-in-two-crashes-is-fastest-selling-plane-in-companys-hist> [https://perma.cc/VM6Q-GJWS].

309. *Lion Air JT610 Crash: What the Preliminary Report Tells Us*, BBC (Nov. 28, 2018), <https://www.bbc.com/news/world-asia-46373125> [https://perma.cc/YD4L-MP2R].

310. David Slotnick, *The First Boeing 737 Max Crash Was 2 Years Ago Today. Here's the Complete History of the Plane That's Been Grounded Since 2 Crashes Killed 346 People 5 Months Apart*, BUS. INSIDER (Oct. 29, 2020, 10:55 AM), <https://www.businessinsider.com/boeing-737-max-timeline-history-full-details-2019-9> [https://perma.cc/V25M-5JKD].

311. Press Release, Ethiopian Airlines, Accident Bulletin Number 3 (Mar. 10, 2019), <https://corporate.ethiopianairlines.com/Press-release-open-page/accident-bulletin-no.-3-issued-on-march-10-2019-at-4-59-pm> [https://perma.cc/Y3HK-37P5]; see also Sinéad Baker, *What We Know About the Victims of the Lion Air Plane Crash Off Indonesia, Where There Were 'likely no survivors'*, BUS. INSIDER (Oct. 31, 2018, 7:24 AM), <https://www.businessinsider.com/lion-air-plane-crash-victims-indonesia-2018-10?r=UK> [https://perma.cc/F3XJ-D3UY].

312. Convention for the Unification of Certain Rules for International Carriage by Air, ch. 3, May 28, 1999, T.I.A.S. No. 13,038 [hereinafter Montreal Convention].

Under the Montreal Convention, a carrier is liable for up to 100,000 Special Drawing Rights (a weighted basket of currencies generated by the International Monetary Fund with implications for a broad range of international organizations and private parties) or about \$140,000. The convention applies to carriers, not manufacturers.³¹³ However, if compensation exceeds this amount, a claimant may recover if they are able to prove another party is at fault and the carrier is not responsible. This is the only element of causation open to dispute—compensation above the limit. Even this element is relatively straightforward. In the 737 Max context, several aviation authorities investigated the crashes to determine fault and decided definitively that the 737 Max had a design flaw in its sensors.³¹⁴

Both Ethiopian Airlines and Lion Airlines paid out their initial compensations pursuant to the Montreal Convention. The airlines compensated the victims through their insurance carriers. Their insurers then recovered from Boeing after the evidence clearly indicated the fault was with the design of the plane.³¹⁵ Boeing is insured in multiple layers, with both self-insurance then a stop-loss policy with the British insurer Global Aerospace.³¹⁶ Claimants then came to Boeing to recover the rest needed to adequately compensate them for the loss of their family members.

In September 2019, Boeing announced the creation of a fund designed to compensate families. The fund was capitalized to around fifty million dollars, and each passenger's family was paid \$144,500.³¹⁷ Accepting payment did not foreclose any litigation rights for the victims.³¹⁸ In the Lion Air Crash (189 fatalities), 150 claims were filed in the U.S. District Court for the Northern District of Illinois in Chicago. Boeing recently announced they settled 171 claims out of the 189 people on board, including 140 of those claims filed in the Northern District of Illinois.³¹⁹

313. *How the Montreal Convention Works in Air Crashes*, BAUM HEADLUND ARISTEI & GOLDMAN, <https://www.baumhedlundlaw.com/aviation-accident/montreal-convention-air-crashes/> [<https://perma.cc/QR55-JDQL>] (last visited July 19, 2021).

314. Ainur Rohmah, Ian Duncan, Michael Laris & Shibani Mahtani, *Lion Air Crash Investigators Fault Boeing 737 Max's Flight-Control System, Regulatory Lapses and Pilot Training*, WASH. POST (Oct. 25, 2019, 10:31 AM), https://www.washingtonpost.com/world/asia_pacific/investigators-fault-boeing-737-maxs-flight-control-system-regulatory-lapses-and-pilot-training-in-lion-air-crash/2019/10/25/e8143d06-f69c-11e9-b2d2-1f37c9d82dbb_story.html [<https://perma.cc/VZD3-GHWX>].

315. Noor Zainab Hussain, Carolyn Cohn & Suzanne Barlyn, *Insurers Face Large Claims After Second Boeing 737 MAX Crash*, REUTERS (Mar. 11, 2019, 4:51 AM), <https://www.reuters.com/article/us-ethiopia-airplane-insurance/insurers-face-large-claims-after-second-boeing-737-max-crash-idUSKBN1QS1D8> [<https://perma.cc/6N7V-UX2G>].

316. *Id.*

317. David Shepardson, *Boeing to Pay 737 Max Victim's Families \$144,500 Each*, REUTERS (Sept. 23, 2019, 11:50 AM), <https://www.reuters.com/article/us-ethiopia-airplane-victims/boeing-to-pay-737-max-crash-victims-families-144500-each-idUSKBN1W8288> [<https://perma.cc/RE8G-T6BU>].

318. *Id.*

319. Eric M. Johnson, *Boeing Settles Nearly All Lion Air 737 MAX Crash Claims; Filing*, REUTERS (July 7, 2020, 4:29 PM), <https://www.reuters.com/article/us-boeing-737max-settlement/boeing-settles-nearly-all-lion-air-737-max-crash-claims-filing-idUSKBN24838P> [<https://perma.cc/NB2A-M3T9>].

Boeing did not publicize payment amounts, but reports suggest approximately \$1.2 million per claim.³²⁰

Under the system organized by Boeing, claimants who were unable to afford litigation either in the United States or in their home countries were able to receive compensation. The system also managed Boeing's liability and expected losses.

CONCLUSION

Tremendous strides have been made toward assuring equitable access to COVID-19 vaccines for low- and lower-middle-income countries. But affordability *ex ante* is not enough. Manufacturers will not ship vaccines to countries where liability looms, and the populations in those countries that are unable or unwilling to promise indemnity should not go without vaccines and, if they receive them, should not be left to subsidize herd immunity enjoyed by the world's uninjured. This Article has endeavored to address the liability barrier through analysis of existing and proposed mechanisms including current no-fault systems, the expansion of current insurance regimes, and the establishment of a centralized no-fault system centered at the COVAX Facility.³²¹ Doing so would address the pandemic threat, ensure that those suffering rare adverse events are not left to shoulder the costs associated with the massive benefits accrued by everyone else, and set an important precedent for future global pandemic planning.

320. *Id.*

321. See Rahim Moloo & Alex Khachaturian, *The Compliance with the Law Requirement in International Investment Law*, 34 FORDHAM INT'L L.J. 1473 (2011).

