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Solving the COVID-19 Vaccine Product Liability Problem

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LAW SCHOOL

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SAM F. HALABI*

ABSTRACT

The global roll-out of COVID-19 vaccines is under way. Governments have invested billions of dollars in supporting research, development, logistics and supply chains, as well as 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 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 they 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 evidence from Phase III trials and early administration of EUA vaccines strongly suggests. Therefore, there is a critical need to balance the risk calculations of manufacturers with the 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 which includes leveraging current no-fault systems in 25 countries; a World Health Organization insurance mechanism, and a combination of insurance and compensation fund construction based on claims processing precedents from the Deep Horizon Oil Spill and Boeing 737 Max crashes, both of which had claims originating from dozens of countries, tens of thousands of claims, processed in at least 6 languages. This 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

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 find a safe and effective vaccine against COVID-19.¹ As of September 27, 2020, there are over 200 vaccine candidates in pre-clinical and clinical development, eleven of which are in Phase III trials.² As of December 4, 2020, Moderna/NIH and Pfizer/BioNTech have submitted dossiers to the US Food and Drug Administration data to support emergency use authorizations for their vaccine candidates.³ The United Kingdom's Medicines and Healthcare products Regulatory Agency approved Pfizer's candidate for full licensure on December 3, 2020 and the FDA granted Emergency Use Authorization (EUA) one week later. Several vaccine candidates from firms based in China are already being administered to its military and healthcare worker populations in addition to priority groups in Bahrain, Indonesia, and the United Arab Emirates.⁴

Wealthy governments are investing billions in the effort to bring more vaccine candidates to licensure, or at least emergency use authorization.⁵ Many countries are attempting to secure access to vaccines by offering

¹ World Health Organization, More than 150 Countries Engaged in COVID -19 Vaccine Global Access Facility, (July 15, 2020) available at <https://www.who.int/news-room/detail/15-07-2020-more-than-150-countries-engaged-in-covid-19-vaccine-global-access-facility>; Sam Halabi and Saad Omer, *Evidence, Strategies, and Challenges for Assuring Vaccine Availability, Efficacy, and Safety* in Halabi, Gostin, and Crowley (eds) GLOBAL MANAGEMENT OF INFECTIOUS DISEASE AFTER EBOLA (2016).

² Trefis Team, *What to Expect as Moderna's COVID-19 Vaccine Moves to Phase 3 Trials*, FORBES (July 29, 2020) ("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.").

³ Bojan Pancevski and Jared Hopkins, *Pfizer Could Apply for Emergency Use of COVID-19 Vaccine by Late November*, WALL. ST. JOURNAL, Oct. 16, 2020 available at <https://www.wsj.com/articles/pfizer-could-apply-for-emergency-use-of-covid-19-vaccine-by-late-november-11602842906>

⁴ David Cyranoski, What China's speedy COVID vaccine deployment means for the pandemic, Nature, Oct. 8, 2020 available at <https://www.nature.com/articles/d41586-020-02807-2>; *China's Sinopharm launches Phase III trial of Covid-19 vaccine in UAE*, CLINICAL TRIALS ARENA, (July 17, 2020), available at <https://www.clinicaltrialsarena.com/news/sinopharm-covid-vaccine-uae-trial>.

⁵ Matthew Herper, *AstraZeneca lays out plan for producing 2 billion doses of Covid-19 vaccine, if it works*, STAT (Jun. 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/>.

funding to scale-up manufacturing and assist with clinical trials.⁶ GAVI, an international vaccine procurement consortium aiding low-income countries, is pursuing a similar strategy for securing equitable access to COVID-19 vaccines.⁷ The Coalition for Epidemic Preparedness Innovations (CEPI), an international financing partnership, has supported at least 10 candidates, including Moderna's. Instead of waiting until after vaccines are approved and then bidding for them, GAVI, CEPI, the World Health Organization, 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.⁸

Governments are also entering into bilateral arrangements to lay claim to early production. For example, AstraZeneca has received payments from the U.K., the U.S., and the Serum Institute of India, and in return, has promised delivery of 100 million doses, 300 million doses, and to assist in producing 1 billion doses, respectively.⁹ However, there are far fewer details on what happens after the doses arrive.¹⁰

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

⁶ *Id.*

⁷ *Gavi launches innovative financing mechanism for access to COVID-19 vaccines*, GLOBAL ALLIANCE FOR VACCINES AND IMMUNIZATIONS (Jun. 4, 2020), <https://www.gavi.org/news/media-room/gavi-launches-innovative-financing-mechanism-access-covid-19-vaccines>.

⁸ *Id.*; *Up to 100 million COVID-19 vaccine doses to be made available for low- and middle-income countries as early as 2021*, GLOBAL ALLIANCE FOR VACCINES AND IMMUNIZATIONS (AUGUST 7, 2020), <https://www.gavi.org/news/media-room/100-million-covid-19-vaccine-doses-available-low-and-middle-income-countries-2021>

⁹ Herper, *supra* note 5.

¹⁰ Eileen O'Reilly, *The coming clash over the first coronavirus vaccines*, AXIOS (Apr. 30, 2020), <https://www.axios.com/coronavirus-vaccine-distribution-america-a12c4e95-df80-47f0-beec-d17d7e7657db.html> ("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."); <https://www.wsj.com/articles/pfizer-sets-up-its-biggest-ever-vaccination-distribution-campaign-11603272614>; https://www.wsj.com/articles/covid-19-vaccines-to-be-stored-secretly-under-tight-security-11603278002?mod=hp_lead_pos4

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.¹¹ On December 8, 2020, the first day of the U.K. vaccination campaign, two severe allergic reactions caused the UK government to require monitoring patients for 15 minutes after each injection.¹²

Although the United States has granted immunity to COVID-19 vaccine manufacturers pursuant to its Public Readiness and Emergency Preparedness Act (PREP Act), 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.¹³

For one or more vaccines likely to be distributed worldwide, there is inevitable risk of serious adverse events. For pandemic H1N1 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, H1N1 pandemic vaccine produced a serious adverse event rate of 2.45 per 100,000. 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.¹⁴ Eleven cases of the Guillain–Barré syndrome were reported, for a rate of 0.1 per 1 million doses. Compensation costs similarly varied. 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.¹⁵

¹¹ <https://www.contagionlive.com/view/fda-fast-tracks-2-covid19-vaccines>

¹² <https://www.wsj.com/articles/rollout-of-pfizer-biontech-covid-19-vaccine-slows-in-uk-due-to-allergic-reaction-monitoring-11607967990>

¹³ 42 USC 247d-6d, <https://www.reuters.com/article/us-astrazeneca-results-vaccine-liability/astrazeneca-to-be-exempt-from-coronavirus-vaccine-liability-claims-in-most-countries-idUSKCN24V2EN>; Couronne, Ivan, “Virus Vaccine Will Be ‘Global Public Good’: Top US Official,” *Barron’s*, May 20, 2020. As of August 17, 2020: <https://www.barrons.com/news/virus-vaccine-will-be-global-public-good-top-us-official-01589972705>.

¹⁴ <https://www.medpagetoday.com/upload/2011/2/3/NEJMoa1008553.pdf>

¹⁵ <https://www.theguardian.com/science/2017/feb/09/ministers-lose-fight-to-stop-payouts-in-swine-flu-jab-narcolepsy-cases#:~:text=The%20Pandemrix%20compensation%20case%20was,when%20vaccines%20cause%20severe%20damage,;https://www.theguardian.com/world/2019/nov/20/swine-flu-vaccine-case-settled-but-hopes-for-legal-precedent-dashed>

Solving the vaccine injury problem is crucial not only for populations injured by serious adverse events following immunization, but for the companies that may not participate in the response at all if not given sufficient assurances of immunity or indemnity, and 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 25 countries, private-sector insurance alternatives based on a proposed program at the World Health Organization, and a centralized mass claims system based on models for compensation from the Deep 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 pre-marketing review by regulatory agencies and post-marketing 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 life-long 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 middle-income countries unable to afford them, but which has not addressed the COVID-19 vaccine product liability problem, which is likely to thwart its 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. Part IV provides a brief conclusion.

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 2016 around 150 to 200 million lives and \$536 billion in costs of illness avoided – they are medicines given to otherwise healthy people to prevent disease.¹⁶ Like all medicines, vaccines carry risks of side effects, from the

¹⁶ 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

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.¹⁷

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 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.¹⁸

The Food and Drug Administration’s Center for Biologics Evaluation and Research (“CBER”) is responsible for regulating vaccines in the United States and its approval facilitates the use of vaccines in countries that lack regulatory capacity.¹⁹ The vaccine clinical development process – including COVID-19 vaccines – follows the same general pathway as for drugs and other biologics.²⁰

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.²¹ While some candidate vaccines occur naturally (like that for smallpox), most candidates are developed using empirical approaches, historically serial propagation of a pathogen

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; Ozawa S, et al. Return on investment from childhood immunization in low- and middle-income countries, 2011-20. *Health Aff (Millwood)* 2016;35:199–207; Anya 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.”).

¹⁷ Halabi SF, Omer SB. A Global Vaccine Injury Compensation System. *JAMA*. 2017;317(5):471–472. doi:10.1001/jama.2016.19492.

¹⁸ Sam Halabi, FOOD AND DRUG REGULATION IN AN ERA OF GLOBALIZATION (2015).

¹⁹ *Vaccine Product Approval Process*, U.S. FOOD AND DRUG ADMIN. (July 13, 2015 (9:30 PM)), <http://www.fda.gov/biologicsbloodvaccines/developmentapprovalprocess/biologicslicenseapplicationsblaprocess/ucml33096.htm>

²⁰ See 42 U.S.C.A. § 262

²¹ Groisman, Eduardo, A., (ed.) *Principles of Bacterial Pathogenesis*, (2001).

through media that diminishes pathogenicity, or which is killed or dissected after cultivation and used in relatively large doses, with adjuvants or in multiple doses to prompt immune response.²² 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.²³ Vaccine candidates are then tested in animals after developing models for immunogenicity and safety.

After animal testing, the vaccine sponsor applies for Investigational New Drug (IND) status from the U.S. Food and Drug Administration which authorizes the sponsor to undertake clinical trials on humans for safety, efficacy, and, ultimately, to build the evidentiary case for licensure. 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.²⁴ 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.²⁵

In phase II, the sample size is increased to several hundred healthy volunteers and investigators focus on safety as well as immunogenicity. In phase IIb “proof of concept” studies, dose-ranges and vaccine components are confirmed before moving to much larger phase III studies. Phase III vaccine trials enroll up to thousands or tens of thousands of human subjects in order to detect sometimes rare adverse events. In 1998, for example, a rotavirus vaccine was licensed for use in the U.S. 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.²⁶ If larger phase III studies confirm safety and efficacy, the vaccine is approved for marketing after FDA review of study data.

Safety evaluations are essential during each phase of the clinic trials, but continue after the approval of the vaccine. It is especially

²² Nicola P. Klein et al., Waning Protection After Fifth Dose of Acellular Pertussis Vaccine in Children, 367 *NEW ENG. J. MED.* 1012, 1013 (2012), <http://www.nejm.org/doi/pdf/10.1056/NEJMoa1200850> [<https://perma.cc/FA8C-W3B7>]; Bo Ma et al., 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).

²³ Rappuoli, R. Reverse Vaccinology, a genome based approach to vaccine development, *Vaccine*. 2001 Mar 21;19(17-19):2688-91.

²⁴ 21 C.F.R. § 312.23

²⁵ *Vaccine Product Approval Process*, U.S. FOOD AND DRUG ADMIN. (July 13, 2015 (9:30 PM)), <http://www.fda.gov/biologicsbloodvaccines/developmentapprovalprocess/biologicslicenseapplicationsblaprocess/ucm133096.htm>

²⁶ http://jid.oxfordjournals.org/content/192/Supplement_1/S36.full

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.²⁷ Until a vaccine is given to the general population, all potential adverse reactions cannot be anticipated.²⁸ Thus, many vaccines undergo Phase 4, or post-marketing surveillance, studies once released, and strict safety reporting standards during clinical trials and afterward.²⁹ A key criterion during Phase 4 studies is to determine if there is a “reasonable possibility that the drug (or biologic) caused an adverse event and whether the event (or pattern of events) was unexpected.”³⁰

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.³¹ A product’s package insert, also known as the “label” is a critical element of the evaluation of a vaccination.³²

2. Tort Liability as 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 attributable to them. In EU Member States, laws generally place liability for vaccine side effects on pharmaceutical companies.³³ 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 World Health Organization, and manufacturers negotiated over indemnity provisions.³⁴

²⁷ Roberts & Gruber, *supra*. Alberto E. Tozzi et al., *Assessment of Causality of Individual Adverse Events Following Immunization (AEFI): A WHO Tool For Global Use*, 31 VACCINE 5041-5046 (2013), available at <http://www.sciencedirect.com/science/article/pii/S0264410X13011997>

²⁸ *Vaccine Product Approval Process*, <http://www.fda.gov/biologicsbloodvaccines/developmentapprovalprocess/biologicslicensapplicationsblaprocess/ucm133096.htm>

²⁹ *Id.*

³⁰ Roberts & Gruber, *supra*.

³¹ *Vaccine Product Approval Process*, <http://www.fda.gov/biologicsbloodvaccines/developmentapprovalprocess/biologicslicensapplicationsblaprocess/ucm133096.htm>

³² 21 C.F.R. 201.56 and 201.57

³³ <https://www.fiercepharma.com/vaccines/side-effect-liability-a-potential-hurdle-for-eu-covid-19-vaccine-negotiations-reuters>

³⁴ Sam 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). <https://www.japantimes.co.jp/news/2020/10/17/world/science-health-world/who-coronavirus-vaccine-payment/>

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.³⁵ 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, as between an uninjured (and presumptively compensated) manufacturer and an injured vaccine recipient, the law should favor making the injured person whole.³⁶ After the adoption of the National Vaccine Injury Act of 1986, vaccine side effects are almost entirely routed to a no-fault compensation system administered through the U.S. Court of Federal Claims.

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 that 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.³⁷ 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 defects, or “failures to warn” of relevant risks, benefits, and other relevant information.³⁸ This latter right enjoyed by vaccine recipients overlaps to some extent, although not coextensively, with principles of informed consent.³⁹

This article focuses specifically on the possibility that legal action will be taken because of a manufacturer’s actions, inactions, products, services

³⁵ Restatement (Second) of Torts §402A (1965), Restatement (Second) of Torts § 402 cmt. k (Am. Law Inst. 1975)

³⁶ *Bruesewitz v. Wyeth*, 562 U.S. 223 (2011) (Sotomayor, J. dissenting).

³⁷ Sam Halabi & John Monahan, *Sharing the Burden of Ebola Vaccine Related Adverse Events*, 24 TUL. J. INT’L & COMP. L. 131 (2015); see also John Reitz, *Doubts About Convergence: Political Economy as an Impediment to Globalization*, 12 Transnat’l. L. & COntemp. P. 139 (“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.”)

³⁸ W. Keeton, D. Dobbs, R. Keeton, & D. Owen, *PROSSER AND KEETON ON LAW OF TORTS* 695 (5th ed. 1984).

³⁹ Sheldon Kurtz, *The Law of Informed Consent: From “Doctor is Right” to “Patients’ 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.”).

or other activities: (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 to fever, discomfort and muscle pain to (rare) anaphylaxis and other severe reactions.⁴⁰ For vaccines incorporating traditional platforms, like an inactivated (i.e. killed) virus (common for flu shots) or live-attenuated virus (i.e. a virus that has been weakened under laboratory conditions) like that for measles, mumps, and rubella (MMR), there are decades of evidence and well-controlled post-immunization surveillance to confirm both safety and efficacy. 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 (eg, <1 adverse event occurs per 10 million doses for tetanus toxoid vaccines, 1-2 adverse events per 1 million doses for inactivated influenza vaccine, and none for hepatitis A).⁴¹

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 to facilitate communication of benefit/risk data and information which will mitigate litigation risk.⁴² The safety of vaccination with newer platforms like DNA, non-replicating viral vector, protein subunit, and RNA vaccines, including adjuvants,⁴³ is less extensive than with platforms with long safety profiles like inactivated or live attenuated vaccines.⁴⁴ The use of

⁴⁰ Luana Raposo de Melo Moraes Aps, et al. *Adverse events of vaccines and the consequences of non-vaccination: a critical review*, REVISTA DE SAUDE PUBLICA 52(40) (2018), doi:10.11606/s1518-8787.2018052000384 (“The administration of these compounds may lead to adverse reactions 8 , such as local inflammatory reactions and, much less frequently, systemic effects, such as the exacerbation of autoimmune diseases and allergies.”).

⁴¹ Halabi SF, Omer SB. A Global Vaccine Injury Compensation System. *JAMA*. 2017;317(5):471–472. doi:10.1001/jama.2016.19492.

⁴² (“Recognizing the need for a flexible, timely and robust system to evaluate vaccine safety and supplement information provided by VAERS”)

⁴³ Takehiro Ura et al., *Developments in Viral Vector-Based Vaccines*. 2(3) VACCINES 624. (2014), doi:10.3390/vaccines2030624 (“Viral vector-based vaccines can be easily manufactured alongside traditional vaccines in large manufacturing units, and their safety profiles can be tested easily”).

⁴⁴ Claudia Maria Trombetta et al., *Influenza vaccines: Evaluation of the safety profile*, 14(3) HUM VACCIN & IMMUNOTHER, 647 (2018), doi:10.1080/21645515.2017.1423153 (“Inactivated vaccines have an excellent safety profile”).

DNA vaccines, for example, has raised safety concerns mainly concerning the probability of stable integration of transfected DNA into the genome of somatic or even germ cells, causing dysregulated gene expression and mutations.⁴⁵

Most COVID-19 vaccine candidates, and certainly the leading ones, are generally based on these kinds of technologies, which are not licensed for use in humans anywhere in the world.⁴⁶ 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.⁴⁷ Moderna's and Pfizer's vaccine candidates are based on messenger RNAs that instruct human cells to produce protein antigens. 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.⁴⁸ 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.

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 a volunteer experienced an inflammation of the spinal cord and, as of writing, that trial remains paused in the U.S. although it has resumed in the United Kingdom, Brazil, and South Africa.⁴⁹ Johnson & Johnson's vaccine candidate was also paused during Phase III for an illness that, as of writing, remained

⁴⁵ Jacob Glenting, and Stephen Wessels, *Ensuring safety of DNA vaccines*, 4(26) MICROBIAL CELL FACTORIES (2005), doi:10.1186/1475-2859-4-26 (“[I]nternational regulatory groups have recently questioned the safety of certain existing DNA vaccine constructs”).

⁴⁶ Mullard A. COVID-19 vaccine development pipeline gears up. *Lancet*. 2020;395(10239):1751-1752. doi:10.1016/S0140-6736(20)31252-6. Adenovirus vaccines, which deliver through have been licensed only for a single commercially available vaccine to immunize wild animals against rabies.

⁴⁷ [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31604-4/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31604-4/fulltext)

⁴⁸ <https://www.nature.com/articles/d41586-020-02154-2>

⁴⁹ <https://www.scientificamerican.com/article/scientists-react-to-halt-of-leading-coronavirus-vaccine-trial/>

undisclosed. Two people in the UK had severe reactions to Pfizer’s vaccine within the first week.⁵⁰

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 – the scale of adverse events would be significant. The World Health Organization estimates the delivery of 2 billion vaccine doses that will necessarily involve deployment of adenovirus (AstraZeneca and J&J) and mRNA (Moderna and Pfizer) vaccines as well as some based on conventional technologies.⁵¹ The same rate of severe side effects – those suffering disability or death or with illnesses requiring hospitalization – would reach nearly 50,000 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 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 U.S.⁵²

In the 2009 H1N1 pandemic, the negotiations over indemnification and immunity for manufacturers caused significant delays.⁵³ 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 (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

⁵⁰ <https://www.wsj.com/articles/rollout-of-pfizer-biontech-covid-19-vaccine-slows-in-u-k-due-to-allergic-reaction-monitoring-11607967990>

⁵¹ <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/>

⁵² *Liability for the Production and Sale of Vaccines*, from VACCINE SUPPLY AND INNOVATION, National Research Council (US) Division of Health Promotion and Disease Prevention (Washington DC: National Academies Press 1985), Available from <https://www.ncbi.nlm.nih.gov/books/NBK216813/> (“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”).

⁵³ Halabi, *supra* note 1, at 136; Institute of Med., *The Domestic and International Impacts of the 2009-H1N1 Influenza A Pandemic: Global Challenges, Global Solutions: Workshop Summary*, NAT’L ACAD. PRESS (2010) (“Progress toward mass immunization was temporarily stalled when the vaccine manufacturers demanded indemnification against claims of any adverse reactions associated with the vaccines.”).

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 vaccines.⁵⁴

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 which had paid for them; second, the vaccine manufacturers insisted on legal protections in countries where they are not licensed to produce or distribute a vaccine.⁵⁵

The U.S. experience with the 1976 H1N1 outbreak demonstrates some of these risks.⁵⁶ The influenza pandemic of 1918 killed an estimated 50 million people, so governments around the world and the World Health Organization have invested steeply in preparation for influenza.⁵⁷ In 1976, a handful of soldiers in Ft. Dix, New Jersey were diagnosed with the virus. The CDC hosted a press conference and although the virus never spread out of the base, the outbreak garnered significant media attention.⁵⁸ President Ford initiated a program to vaccinate “every man, woman, and child in the United States.”⁵⁹ Vaccine manufacturers began developing a vaccine, but during clinical testing, two subjects died of complications (unrelated to the vaccine). This generated negative sentiment toward the vaccine. Then, over 400 people developed a rare neurological condition

⁵⁴ Sam F. Halabi, *The Uncertain Future of Vaccine Development and Deployment for Influenza Pandemics*, O’NEILL INSTITUTE, briefing paper 8 (Apr. 16, 2014).

⁵⁵ *Id.*; W.H.O., *Report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009*, A64/10 64th WORLD HEALTH ASSEMBLY (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.”).

⁵⁶ Halabi, *supra* note 5.

⁵⁷ Brooke Killian Kim, Jessica C. Wilson, Marcus Sandifer, *COVID-19: Tort Immunity for Vaccines and Antivirals—lessons from the Swine Flu of 1976*, DLA PIPER (2020), <https://www.dlapiper.com/en/us/insights/publications/2020/04/covid-19--tort-immunity-for-vaccines-and-antivirals/>; Comptroller General of the United States, *The Swine Flu Program: An Unprecedented Venture in Preventative Medicine*, Washington, D.C.: U.S. General Accounting Office, HRD-77-115, June 27, 1977. As of August 20, 2020: <https://www.gao.gov/assets/120/119314.pdf>

⁵⁸ Gerald R. Ford, “President Gerald R. Ford’s Remarks Announcing the National Swine Flu Immunization Program,” White House Briefing Room, Washington, D.C., March 24, 1976; Comptroller General of the United States, *The Swine Flu Program: An Unprecedented Venture in Preventative Medicine*, Washington, D.C.: U.S. General Accounting Office, HRD-77-115, June 27, 1977; Richard E. Neustadt and Harvey V. Fineberg,

⁵⁹ Kim et. al., *supra* note 55.

after receiving the vaccine which resulted in the termination of the vaccine program.⁶⁰

The US government and pharmaceutical manufacturers agreed in advance to an indemnification of risk for the manufacturer, which resulted in the US 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.⁶¹ For a comparison, the vaccination program as a whole was estimated to cost \$134 million, with \$100 million for the development of the vaccine.⁶²

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.”⁶³ The World Health Organization 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.⁶⁴ Dengue is present in 129 countries and over the last 50 years, it is believed that dengue has increased at least 30-fold with a sharp increase after 2000.⁶⁵ Since that point, it has been a priority pathogen for development of a licensed vaccine, but, as with many diseases affecting poorer countries (70% of cases occur in low-income countries in Asia), the actual market incentive for doing so is limited.

After nearly 20 years of research and development, Sanofi Pasteur finally produced the CYD-TDV vaccine, licensed under the name Dengvaxia, the first and, as of this writing, only approved vaccine to inoculate against dengue infection.⁶⁶ To date, Dengvaxia has been

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Dengue and severe dengue: Key Facts*, WHO (June 23 2020), <https://www.who.int/news-room/fact-sheets/detail/dengue-and-severe-dengue>.

⁶⁴ WHO, *Dengue vaccine: WHO position paper – September 2018*, 36 WEEKLY EPIDEMIOLOGICAL RECORD 457, 458 (September 7, 2018), <https://apps.who.int/iris/bitstream/handle/10665/274315/WER9336.pdf?ua=1>; Sarah Murrell et al., *Review of dengue virus and the development of a vaccine*, 29 BIOTECHNOLOGY ADVANCES 239, 240 (2011).

⁶⁵ See Murrell, *supra* note 5 (noting that it is believed that 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”).

There are two other vaccine candidates in phase 3 trials at this time. Stephanie Soucheray, *Sanofi restricts dengue vaccine but downplays antibody enhancement* CENTER FOR

registered in 20⁶⁷ countries including the EU and the US.⁶⁸ There have been two subnational⁶⁹ immunization implementation public health programs in Brazil and the Philippines.⁷⁰ The vaccine was studied over 26 clinical trials which included more than 41,000 volunteers.⁷¹ The clinical trial participants were monitored for up to 5 years after the trial.⁷²

Despite the large trial enrollment and post-immunization monitoring, it happens that for children under 9 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. On average, 200,000 cases of dengue infection are reported every year in the Philippines.⁷³ The aggregate direct medical cost for these infections in the country is 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.⁷⁴ Dengvaxia was licensed in the Philippines in 2016.⁷⁵ After licensure, a subnational Dengvaxia immunization program costing \$67.7 million⁷⁶ was developed with the goal of vaccinating 1 million Filipino

INFECTIOUS DISEASE RESEARCH AND POLICY: U. MN. (Dec. 1, 2017)

<file:///C:/Users/alhon/Downloads/cidrap.umn.edu-Sanofi%20restricts%20dengue%20vaccine%20but%20downplays%20antibody%20enhancement.pdf>.

⁶⁷ Some of the counties include: Mexico, the Philippines, Brazil, El Salvador, Costa Rica, Paraguay, Guatemala, Peru, Indonesia, Thailand and Singapore. Reuters Staff, *Sanofi's dengue vaccine approved in 11 countries*, REUTERS (Oct. 4, 2016) <https://www.reuters.com/article/us-sanofi-vaccine-idUSKCN1240C5>.

⁶⁸ WHO, *supra* note 42. Dengvaxia has been approved by the FDA in the US for only for 9-16 year old children in Puerto Rico, the US 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>.

⁶⁹ Subnational: In a three-teared governmental system – national, regional, and local government – subnational refers to regional and local government. Katja Rohrer, *Chapter 11: Strategizing for health at sub-national level*, in STRATEGIZING NATIONAL HEALTH IN THE 21ST CENTURY: A HANDBOOK 1, 1 (Schmets, Rajan & Kadandale eds., 2016) <https://apps.who.int/iris/bitstream/handle/10665/250221/9789241549745-chapter11-eng.pdf?sequence=35&isAllowed=y>.

⁷⁰ Stephen J. Thomas & In-Kyu Yoon, *A review of Dengvaxia®: development to deployment*, 15 HUMAN VACCINES & IMMUNOTHERAPEUTICS 2295, 2295-296 (2019).

⁷¹ Id.

⁷² Stefan Flasche et al., *Estimating the proportion of vaccine-induced hospitalized dengue cases among Dengvaxia vaccines in the Philippines*, WELLCOME OPEN RESEARCH 1,5 (2019).

⁷³ REP. OF THE PHIL. DEP. OF HEALTH, DOH puts dengue immunization on hold after new findings from Sanofi-Pasteur (December 1, 2017) <https://www.doh.gov.ph/node/11831>.

⁷⁴ Measured in 2012 USD. Ronald U. Mendoza et al., *A Crisis of Confidence: The Case of Dengvaxia in the Philippines*, 1, 5 (Ateneo School of Gov., Working Paper, 2020) <file:///C:/Users/alhon/Downloads/ASOGWP20-002DENGVAxia.pdf>.

⁷⁵ Flasche, *supra* note 66 at 3.

⁷⁶ Karen Lema & Matthias Balmont, *Philippines to charge officials of Sanofia, government over dengue vaccine*, REUTERS (March 1, 2019 2:51 AM)

children.⁷⁷ The Philippines vaccinated 830,000 children ages 9-10 living in highly endemic regions⁷⁸ before it was realized or acknowledged that there was an enhanced risk for severe illness for children that were seronegative, or without antibodies to the virus.⁷⁹ Sanofi Pasteur reported the safety issues in 2017 and the program was promptly ended.⁸⁰ In 2019, the Philippines permanently banned Dengvaxia.⁸¹ Alleged delays by Sanofi in disclosing safety signals following Dengvaxia campaigns have resulted in criminal indictments against Sanofi executives, demand for repayment of the price of the Dengvaxia doses, and additional liabilities related to 10 deaths attributed to Dengvaxia administration.⁸²

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-19.⁸³ 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.⁸⁴ Even if a

<https://www.reuters.com/article/us-sanofi-fr-philippines/philippines-to-charge-officials-of-sanofi-government-over-dengue-vaccine-idUSKCN1Q141L>.

⁷⁷ Flasche, *supra* note 69.

⁷⁸ “The dengue seroprevalence 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 trials.” Flasche, *supra* note 71 at 3.

⁷⁹ Flasche, *supra* note 72 at 1.

⁸⁰ *Id.* at 3.

⁸¹ Carol Isoux, *Are Philippine Children’s deaths linked to dengue vaccine?* POST MAGAZINE (April 21, 2019 at 9:30 AM) <https://www.scmp.com/magazines/post-magazine/long-reads/article/3006712/philippines-suspicion-dengue-vaccine-linked>.

⁸² Vince Nonato, *Solon: Sanofi Will Be Held Liable for “Misrepresenting” Dengvaxia Safety*, Philippines Daily Inquirer (Dec. 10, 2017) available at <http://newsinfo.inquirer.net/951181/solon-sanofi-will-be-held-liable-for-misrepresenting-dengvaxia-safety> (“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 in fact pursuing criminal allegations against Sanofi for omissions that are in fact attributable to the corporations, not its president or other indicted officers. See. Mihailis E. Diamantis, *Corporate Criminal Minds*, 91 NOTRE DAME L. REV. 2049, 2071 (2016).

⁸³ *Vaccine Availability: Concerns, Barriers, and Impediments*, In VACCINE SUPPLY AND INNOVATION, National Research Council (US) Division of Health Promotion and Disease Prevention (Washington DC: National Academies Press, 1985) Available from <https://www.ncbi.nlm.nih.gov/books/NBK216807/> (“Testimony . . . from Squibb-Connaught indicated that they had continued manufacturing vaccine and would be willing to distribute it if some federal protection were provided from liability risks”).

⁸⁴ Clare Looker and Heath Kelly. *No-fault compensation following adverse events attributed to vaccination: a review of international programmes*, 89(5) BULLETIN OF THE WORLD HEALTH ORGANIZATION 371 (2011), doi:10.2471/BLT.10.081901 (“This process presumes causation if any injury listed in the table occurs within a specified time frame after vaccination . . . programmes are based on the premise that the

manufacturer took due care, that is, manufactured the vaccine non-negligently, vaccines will cause these rare severe injuries.⁸⁵

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.⁸⁶ 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.⁸⁷

2. Perceived and Falsely Attributed Risks

Not only real and unknown risks, but perceived associations will shape legal liabilities as well.⁸⁸ In many countries, propaganda campaigns inducing fears of sterility or of contracting HIV from vaccination inhibit use as well as fuel suspicions that firms from wealthy countries use people in developing countries as human “guinea pigs.”⁸⁹ For example, in 2013, a subset of religious leaders in Kenya initiated an antivaccine campaign based in part on these kinds of accusations.⁹⁰ Demonstration projects with 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

adverse outcome is not attributable to a specific individual or industry but due to an unavoidable risk associated with vaccines”).

⁸⁵ *Id.*

⁸⁶ Institute of Medicine (US) Committee on the Children's Vaccine Initiative: Planning Alternative Strategies *National Vaccine Injury Compensation Program In THE CHILDREN'S VACCINE INITIATIVE: ACHIEVING THE VISION* (VS Mitchell, NM Philipose, JP Sanford eds. Washington DC: National Academies Press 1993) Available from <https://www.ncbi.nlm.nih.gov/books/NBK236419/> (“If the conditions of the petitioner are not included in the table, they must then prove causation by a covered vaccine”).

⁸⁷ National Research Council (US) Division of Health Promotion and Disease Prevention, *Vaccine Injury Compensation and Liability Remedies*, in *VACCINE SUPPLY AND INNOVATION* (Washington DC, National Academies Press US, 1985) Available from <https://www.ncbi.nlm.nih.gov/books/NBK216805/> (“These efforts to prove causation will be time-consuming, expensive, and probably inconclusive.”).

⁸⁸ Eve Dubé, Caroline Laberge, Maryse Guay, Paul Bramadat, Real Roy, & Julie Bettinger, *Vaccine hesitancy: an overview*, *HUM VACCIN IMMUNOTHER* 9(8), 1763–1773. <https://doi.org/10.4161/hv.24657> (“risk perceptions are predictors of adult vaccination behavior”).

⁸⁹ Tara C Smith, *Vaccine Rejection and Hesitancy: A Review and Call to Action*, 4(3) *OPEN FORUM INFECTIOUS DISEASES* (2018), doi:10.1093/ofid/ofx146 (“multiple studies have demonstrated concerning patterns of decline of confidence in vaccines”).

⁹⁰ Jill Olivier, *Interventions with Local Faith Communities on Immunization in Development contexts*, 14(3) *REVIEW OF FAITH & INTERNATIONAL AFFAIRS* 36 (2016), DOI: 10.1080/15570274.2016.1215843 dr(“Kenyan Catholic Bishops called for a boycott of the ... vaccine, arguing... [it] was dangerous”).

expanded HPV coverage.⁹¹ 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.⁹² 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.⁹³

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.⁹⁴ Many countries suffer from high background levels of morbidity and mortality, and coincidental deaths associated with vaccine administration and attributed to the vaccine may give rise to litigation, even if rigorous analysis of objective data ultimately vindicates the manufacturer and its product.⁹⁵ It is well established that there is widespread misunderstanding in developing countries about what respiratory illnesses are, how they are transmitted, as well as their effects.⁹⁶ Background skepticism of vaccine campaigns may increase the chance that specific events or injuries are attributed to COVID-19 vaccines.⁹⁷ Moreover, COVID-19 vaccines are unlikely to be as efficacious as the most efficacious vaccines, like measles, increasing the chance that someone who received an immunization and becomes ill may conflate the two.⁹⁸

⁹¹ R. Prasad, *A Second Chance for the HPV Vaccine*, (Oct. 8, 2017) available at <http://www.thehindu.com/todays-paper/tp-opinion/a-second-chance-for-the-hpv-vaccine/article19821936.ece>

⁹² *Controversy over HPV vaccines in India accelerates*, THEPHARMALETTER (October 5, 2018), available at <https://www.thepharmaletter.com/article/controversy-over-hpv-vaccines-in-india-accelerates>.

⁹³ Sanjay Kumar and Declan Butler, *Calls in India for legal action against US Charity*, NATURE (September 9, 2013), available at <https://www.nature.com/news/calls-in-india-for-legal-action-against-us-charity-1.13700>.

⁹⁴ RK Zimmerman et al., *Physician concerns about vaccine adverse effects and potential litigation*, 152(1) ARCH PEDIATR ADOLESC MED 12 (1998) (“Physicians’ perceptions about the risk for adverse effects and protection afforded by the Vaccine Injury Compensation Program influence their concern about litigation and, to a lesser extent, their reported likelihood to administer immunizations.”).

⁹⁵ Miller, Elaine R et al. *Deaths following vaccination: What does the evidence show?*, 33(29) VACCINE 3288 (2015), doi:10.1016/j.vaccine.2015.05.023.

⁹⁶ Oria, P.A., et. al., *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*, *BMC Public Health* 2013, 13:391 (“A few also said smoke, contact with influenza-infected persons and allergic reactions could cause influenza.”).

⁹⁷ *Id*; Y. Payaprom, *Understandings of influenza and influenza vaccination among high-risk urban dwelling Thai adults: a qualitative study*, *J. Pub. Health*, 32: 26-31.

⁹⁸ <https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2931976-0>; <https://www.npr.org/sections/health-shots/2020/09/12/911987987/a-covid-19-vaccine-may-be-only-50-effective-is-that-good-enough>

Similarly, vaccine-related injuries may be attributable to contamination or infection from vaccines or syringes used improperly.⁹⁹ The introduction of Johnson & Johnson’s Ebola vaccine candidate into the DRC was complicated precisely because it required the administration of two doses, two months apart.¹⁰⁰ 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.¹⁰¹ 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 both patients and subjects of medical research. Informed consent is a process, based on verbal and written communication between patients and health care workers.¹⁰² 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

⁹⁹ https://www.who.int/vaccine_safety/initiative/tech_support/Vaccine-safety-E-course-manual.pdf (“• Reuse of disposable syringe or needle leading to contamination of the vial, especially in multi-dose vials, • Improperly sterilized syringe or needle, • Contaminated vaccine or diluent.”).

¹⁰⁰ <https://www.statnews.com/2019/07/17/debate-testing-second-ebola-vaccine/>

¹⁰¹ K. Moodley, M. Pather, L Myer, *Informed consent and participant perceptions of influenza vaccine trials in South Africa*, J MED ETHICS 2005;31:727-732 (“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”,³ the principle of informed consent is enshrined in all major guidelines for the ethical conduct of biomedical research.^{4–6} 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.^{4–6} To enhance understanding of informed consent forms and related patient information materials, it is essential that these documents are highly readable.”).

¹⁰² Elizabeth Gross Cohn et al., *Measuring the Process and Quality of Informed Consent for Clinical Research: Development and Testing*, 38(4) ONCOL. NURSE FORUM 417-22 (JULY 2011) (“Results also indicated that a successful consent process must include, at a minimum, the use of various communication modes (e.g., written, verbal, 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.”).

because of linguistic and other barriers.¹⁰³ Informed consent for licensed and emergency use authorized 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.¹⁰⁴

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 public sector or other procuring entity and unaffiliated, front-line health care workers will translate product information to recipients.¹⁰⁵ 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 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.¹⁰⁶

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, violations of the principle of informed consent may be serious and widespread in an accelerated global immunization campaign,

¹⁰³ *Id.*; David J. Diemert et al., *A Comparison of the Quality of Informed Consent for Clinical Trials of an Experimental Hookworm Vaccine Conducted in Developed and Developing Countries*, 11(1) PLOS NEGL. TROP. DIS. (Jan. 23, 2017) (“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”).

¹⁰⁴ Heena Kakar et al., *Informed Consent: Corner Stone in Ethical Medical and Dental Practice*, 3(1) J. Fam. Med. Prim. Care 68-71 (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.’”).

¹⁰⁵ Nat'l Res. Council, *Liability for the Production and Sale of Vaccines*, Nat'l Acad. Press (1985) (“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).”).

¹⁰⁶ *Id.*

and such breaches of informed consent may also be untied from any injury resulting from product use.¹⁰⁷

Second, the law of informed consent in many jurisdictions is ambiguous, and often forged from existing codes of medical ethics and broadly worded constitutional and statutory protections.¹⁰⁸

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 which favor presumption toward the recipient's or the health care worker's testimony.¹⁰⁹ 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 language barriers may not meet standards of sufficient informed consent.¹¹⁰ 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.¹¹¹

¹⁰⁷ Zagaja, A., Patryn, R., Pawlikowski, J., & Sak, J. (2018). Informed Consent in Obligatory Vaccinations?. *Medical science monitor : international medical journal of experimental and clinical research*, 24, 8506–8509.

<https://doi.org/10.12659/MSM.910393> (“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.”).

¹⁰⁸ *Medical and Dental Practitioners Disciplinary Tribunal v. Okonkwo*, A.H.R.L.R. 159 (Ng. S.C. 2001) (“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.”).

¹⁰⁹ A.O. Adejumo, *Sociocultural factors influencing consent for research in Nigeria: Lessons from Pfizer's Trovan clinical trial*, 11 AFR. J. PSYCH. STUDY SOC. ISSUES 228-37, (2008).

¹¹⁰ Stella Burch Elias, *Regional Minorities, Immigrants, and Migrants: the Reframing of Minority Language Rights in Europe*, 28 BERKELEY INT'L L.J. 261 (2010) (emphasizing the role of language recognition in achieving full realization of rights in the EU).

¹¹¹ Oria, *supra* note 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

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 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. Yet negotiations between manufacturers, the World Health Organization, donating and receiving governments over liability and indemnity delayed the distribution of vaccines until late December and early January 2010.¹¹² In October 2014, the World Health Organization, supporting governments and their agencies (especially the U.S., the UK 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 Ebola virus disease. Again, the issue of liability and compensation thwarted such deployment and the experimental vaccine was never administered outside the clinical trial context.¹¹³

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: bilateral contracts with manufacturers that include assurances against product liability claims or 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 emergency use authorization.

come.”); Julie Leask, Annette Braunack-Mayer & Ian Kerridge, *Consent and public engagement in an era of expanded childhood immunization*, 47 J. PAEDIATRICS & CHILD. HEALTH 603-07 (Sept. 27, 2011), <https://onlinelibrary.wiley.com/doi/full/10.1111/j.1440-1754.2011.02160.x> (“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.”).

¹¹² Sam 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).

¹¹³ Sam Halabi, Andrew Heinrich, and Saad Omer, *No-Fault Vaccine Injury Compensation – the Other Side of Equitable Access to COVID-19 Vaccines* [forthcoming]

By mid-August, the United States had secured 800 million doses of at least 6 vaccines in development, with an option to purchase around one billion more. The United Kingdom was the world's highest per-capita buyer, with 340 million purchased: around 5 doses for each citizen. The European Union nations — which are buying vaccines as a group — and Japan have locked down hundreds of millions of doses of vaccines for themselves.¹¹⁴

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.¹¹⁵ Even for wealthier governments, bilateral contracts may not be a panacea. There remains no safe and effective vaccine approved, and pre-human trial vaccines have about a 7% success rate and those entering Phase III only succeed at about 17%.¹¹⁶ The consequence of richer and poorer countries dealing with the 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 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 CCOVID-19 Tools) Accelerator,¹¹⁷ an initiative led by the World Bank, the World Health Organization, G20, European Commission, and a consortium of major global public health non-governmental organizations including the Bill & Melinda Gates Foundation and the Wellcome Trust to advance the goal of fostering the development and production of diagnostics, therapeutics, and vaccines to combat the COVID-19 pandemic.¹¹⁸ 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

¹¹⁴ <https://www.nature.com/articles/d41586-020-02450-x>

¹¹⁵ Gavin Yamey, *A Coronavirus Vaccine Should Be for Everyone, Not Just Those Who Can Afford it*, STATNEWS, Mar. 5, 2020

<https://www.statnews.com/2020/03/05/coronavirus-vaccine-affordable-for-everyone/> (“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*, May 28, 2020, EU OBSERVER (“To put it bluntly, they simply can't afford most of the new vaccines being produced.”).

¹¹⁶ See generally Id.

¹¹⁷ *The COVAX facility, Global procurement for COVID-19 Vaccines* 1,3 (2020), <https://www.gavi.org/sites/default/files/covid/COVAX-Facility-background.pdf>.

¹¹⁸ *The Scramble for Vaccines and the COVAX Facility*, CSIS 1,3 (Aug. 19, 2020, 9:00 AM), https://csis-website-prod.s3.amazonaws.com/s3fs-public/publication/200811_Scramble_Vaccines.pdf.

the Global Fund to Fight Aids, Tuberculosis, and Malaria (Global Fund), the Therapeutics Pillar supported by Unitaid and Wellcome Trust, the Health Systems Pillar supported by the World Bank, Global Fund and WHO, and the Vaccine Pillar supported by Gavi, the Vaccine Alliance (GAVI), the Coalition for Epidemic Preparedness Innovations (CEPI) and the World Health Organization.¹¹⁹

The Vaccine Pillar, “COVAX” or the “COVAX Facility”¹²⁰ was established in June 2020.¹²¹ It was founded to support the quick and safe development, manufacture, and delivery of a COVID-19 vaccine worldwide.¹²² COVAX aims to deliver two billion doses of a safe and effective COVID-19 vaccine by the end of 2021.¹²³ In order to achieve this objective, COVAX invests across a wide portfolio of vaccine candidates using contributions from 79 “self-financing” governments and supporting international organizations and charities and, at the same time, requiring financial commitments from 92 “donor supported” governments that will receive subsidized prices for doses.¹²⁴

Within COVAX, the Coalition for Epidemic Preparedness Innovations (CEPI) leads the development and manufacturing workstream which supports R&D and manufacturing expansion through direct financial investments.¹²⁵ GAVI is lead for the vaccine procurement and delivery at scale workstream as well as the COVAX Advance Market Commitment

¹¹⁹ WHO, *ACT-Accelerator update: Publication of investment cases* (June 26, 2020), <https://www.who.int/news-room/detail/26-06-2020-act-accelerator-update>; Jonathan Carlson, *Strengthening the Property Rights Regime for Plant Genetic Resources: the Role of the World Bank*, 6 *TRANSNAT'L. L. & CONTEMP. P.* 91 (1997) (identifying the evolving role of the World Bank from discrete project funding to broader, structural efforts).

¹²⁰ The Vaccine Pillar is also referred to as “COVAX Facility” or “the Facility” in online sources.

¹²¹ WHO, *supra* note 3.

¹²² *Id.*

¹²³ WHO, *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>.

¹²⁴ WHO, *172 countries and multiple candidate vaccines engaged in COVID-19 vaccine Global Access Facility* (Aug. 24, 2020), <https://www.who.int/news-room/detail/24-08-2020-172-countries-and-multiple-candidate-vaccines-engaged-in-covid-19-vaccine-global-access-facility> (CEPI-Support candidate vaccines include: Invio – United States (Phase I/II), Moderna, United States (Phase III), CureVac - Germany (Phase I), Institute Pasteur..Merck/Themis - France, United States, Austria (Preclinical), AstraZeneca/University of Oxford – UK and Northern Ireland (Phase III), University of Hong Kong – China (Preclinical), Novavax – United States (Phase I/II), Clover Biopharmaceuticals - China (Phase I), University of Queensland/CSL – Australia (Phase I)).

¹²⁵ GAVI, *Report to the Board: GAVI COVAX AMC 1,2* (July 30, 2020) <https://www.gavi.org/sites/default/files/board/minutes/2020/30-july/04a%20-%20Gavi%20COVAX%20AMC.pdf>.

“AMC” which helps to finance lower and lower-middle-income countries’ access to a future COVID-19 vaccine.¹²⁶

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.¹²⁷ 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.¹²⁸ Gavi’s Market Sensitive Decision Committee “MSDC” is responsible for reviewing proposed agreements and Gavi’s Audit and Finance Committee “AFC” is responsible for tracking and reviewing all COVAX funding.¹²⁹ Gavi is also responsible for the “Office of the COVAX Facility”. In this role, Gavi is responsible for negotiating agreements with self-financing countries, tri-partite agreements with multilateral development banks, agreements with manufacturers with volume guarantees, managing the vaccine candidate portfolio (along with other advisors), assembling the Shareholders Counsel and Independent Product Group, and all administrative functions.¹³⁰ Prior to becoming the legal personality of COVAX, GAVI spent \$1.4 million on set-up activities for COVAX and AMC. As legal personality, Gavi will seek reimbursement for these fees through money paid into COVAX by the self-financing participants.¹³¹ The Self-financing participants’ COVAX payments are expected to cover all operating costs which are expected to be around \$7 million for the next year.¹³²

¹²⁶ Id. at 2-3. Mark Turner, *Vaccine Procurement During an Influenza Pandemic and the Role of Advance Purchase Agreements: Lessons From 2009-H1N1*, GLOBAL PUB. HEALTH 6 (July 24, 2015) (“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.”).

¹²⁷ GAVI, *Review of Decisions* 1,7 (July 30, 2020) <https://www.gavi.org/sites/default/files/board/minutes/2020/30-july/Board-2020-Mtg-4-Review%20of%20Decisions.pdf>.

¹²⁸ Id. at 11.

¹²⁹ Id. (The MSDC is comprise 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 a representatives of self-financing countries).

¹³⁰ Id. at 11-12 (The Shareholders Counsel includes representatives from self-financing countries as well as AMC (financed) countries. The Counsel will provide strategic guidance for vaccine development and vaccine allocation.).

¹³¹ Id. at 14.

¹³² Id.

Additionally, within COVAX, Gavi is responsible for vaccine procurement and scaling-up delivery of a vaccine for lower and lower-middle-income countries through COVAX AMC.¹³³ All AMC approved countries¹³⁴ are also eligible for cold chain support to effectively and safely deliver the COVID-19 vaccine.¹³⁵ 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.¹³⁶ 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.¹³⁷

AMC was founded through a Stakeholder Agreement with Gavi.¹³⁸ Members of the Stakeholder group include AMC donors such as the United Nations Children’s Fund “UNICEF”, Pan American Health Organization “PAHO”, AMC participant country representatives, development and regional banks involved in funding, and private sector and philanthropic donors.¹³⁹ The AMC Stakeholder group will be represented on the COVAX Shareholders Council.¹⁴⁰

The candidate vaccine portfolio is currently being run by CEPI and GAVI.¹⁴¹ CEPI’s current agreements with vaccine developers and manufacturers have been transferred to COVAX, and COVAX is actively seeking new agreements.¹⁴² All proposed candidate vaccines are vetted by The Independent Research Group.¹⁴³ The Independent Research Group is comprised of 5-7 experts who review data on candidate vaccines, provide a score based on predetermined criteria in order to make recommendations, continuously review candidate vaccines, and support COVAX’s portfolio management.¹⁴⁴

¹³³ WHO, *supra* note 117.

¹³⁴ *Id.*

¹³⁵ GAVI, *Report to the Board: GAVI COVAX AMC*, *supra* note 12 at 7.

¹³⁶ *Id.*

¹³⁷ GAVI, *COVAX Facility Structure and Governance*, *supra* note 48 at 15.

¹³⁸ *The Scramble for Vaccines and the COVAX Facility*, *supra* note 2 at 3.

¹³⁹ GAVI, *Report to the Board: GAVI COVAX AMC*, *supra* note 52 at 2.

¹⁴⁰ *Id.*

¹⁴¹ WHO Member States Briefing, *Briefing on the COVAX Facility* (June 11, 2020), https://apps.who.int/gb/COVID-19/pdf_files/11_06/GAVI.pdf.

¹⁴² *The COVAX facility, Global procurement for COVID-19 Vaccines*, *supra* note 1 at 4 (Gavi as legal personality will be negotiating all legally binding agreements with self-financing countries).

¹⁴³ *ACT Accelerator COVAX Pillar – Independent Product Group 1, 1-2* (2020) https://www.gavi.org/sites/default/files/document/2020/IPG_Call-for-nominations-8jul.pdf.

¹⁴⁴ *Id.*

High-income, “self-financing” governments can invest in the diverse portfolio of candidate vaccines.¹⁴⁵ When self-financing governments join COVAX as ‘participating countries,’ a binding agreement is established to purchase a pre-defined number of doses, an initial investment in the program proportionate to the number of doses requested, and dose contributions if the country has entered into other bilateral agreements.¹⁴⁶ Self-financing governments must also commit to numerous non-financial obligations such as supporting the movement of a vaccine, fast-track licensure of a vaccine, report all epidemiological and virological data, and maintain transparent about all bilateral vaccine agreements.¹⁴⁷ 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.¹⁴⁸

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.¹⁴⁹

“COVAX is the only truly global solution to the COVID-19 pandemic.”¹⁵⁰ 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 countries’ probability of securing a vaccine beyond the current bilateral agreements.¹⁵¹

To date, COVAX has established nine partnerships with COVID-19 candidate vaccines¹⁵² and negotiations are underway with an additional nine, making COVAX the largest and most diverse vaccine portfolio in the

¹⁴⁵ *The COVAX facility, Global procurement for COVID-19 Vaccines, supra* note 14 at 5.

¹⁴⁶ WHO Member States Briefing, *supra* note 13.

¹⁴⁷ GAVI, *COVAX Facility Structure and Governance* 1,4 (July 30, 2020) https://www.gavi.org/sites/default/files/board/minutes/2020/30-july/04b%20-%20COVAX%20Facility%20Structure%20and%20Governance_1.pdf.

¹⁴⁸ *The COVAX facility, Global procurement for COVID-19 Vaccines, supra* note 17 at 4.

¹⁴⁹ GAVI, *Report to the Board: GAVI COVAX AMC, supra* note 10 at 2.

¹⁵⁰ WHO, *supra* note 8.

¹⁵¹ *Id.* at 3.

¹⁵² WHO, *172 countries and multiple candidate vaccines engaged in COVID-19 vaccine Global Access Facility* (Aug. 24, 2020), <https://www.who.int/news-room/detail/24-08-2020-172-countries-and-multiple-candidate-vaccines-engaged-in-covid-19-vaccine-global-access-facility> (CEPI-Support candidate vaccines include: Invio – United States (Phase I/II), Moderna, United States (Phase III), CureVac - Germany (Phase I), Institute Pasteur..Merck/Themis - France, United States, Austria (Preclinical), AstraZeneca/University of Oxford – UK and Northern Ireland (Phase III), University of Hong Kong – China (Preclinical), Noavax – United States (Phase I/II), Clover Biopharmaceuticals - China (Phase I), University of Queensland/CSL – Australia (Phase I)).

world.¹⁵³ AstraZeneca-Oxford University¹⁵⁴ and Novavax, both vaccine developers, have entered into contracts with COVAX.¹⁵⁵ Serum Institute of India, a manufacturer, has agreed to limit the price of a vaccine produced by AstraZeneca or Novavax to \$3 per dose for lower and lower-middle-income countries also through a COVAX agreement.¹⁵⁶ Seven of the nine current partnership candidate vaccines are in clinical trials.¹⁵⁷ To date, 79 high-income countries, most recently the People’s Republic of China, have joined COVAX.¹⁵⁸ These self-financing governments will help support the 92 countries that are members of the COVAX AMC, “funded” or “donor supported” participants.¹⁵⁹ Some governments, like France and Germany, have agreed to support COVAX, although they do not intend to commit to the standard agreement, and will procure

¹⁵³ Divya Rajagopal, *WHO reviews nine vaccine candidates for COVAX alliance*, THE ECONOMIC 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>.

¹⁵⁴ *The COVAX facility, Global procurement for COVID-19 Vaccines*, supra note 26 at 4 (An MOU has been signed with AstraZeneca-Oxford University for 300 million doses).

¹⁵⁵ Rajagopal, supra note 152.

¹⁵⁶ Divya Rajagopal, *Serum Institute to price Covid-19 vaccine at \$3 per dose for India and lower middle income nations*, THE ECONOMIC 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>.

¹⁵⁷ WHO, *172 countries and multiple candidate vaccines engaged in COVID-19 vaccine Global Access Facility*, supra note 27.

¹⁵⁸ Id. (Countries that have expressed an interest in participate in COVAX and agreed to be publically named: Andorra, Argentina, Armenia, Botswana, Brazil, Canada, Chile, Colombia, Croatia, Czech Republic, Dominican Republic, Estonia, Finland, Greece, Iceland, Iraq, Ireland, Israel, Japan, Jordan, Kuwait, Lebanon, Luxembourg, Mauritius, Mexico, Monaco, Montenegro, New Zealand, North Macedonia, Norway, Palau, Portugal, Qatar, Republic of Korea, San Marino, Saudi Arabia, Seychelles, Singapore, South Africa, Switzerland, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland and Venezuela. 37 other countries have submitted expressions of interest).

¹⁵⁹ WHO, *172 countries and multiple candidate vaccines engaged in COVID-19 vaccine Global Access Facility*, supra note 33 (The Gavi board agreed in July 2020 that the following countries will be supported the COVAX AMC. Low income: 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: 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: Dominica, Fiji, Grenada, Guyana, Kosovo, Maldives, Marshall Islands, Samoa, St. Lucia, St. Vincent and the Grenadines, Tonga and Tuvalu).

bilaterally. The U.S. has rejected COVAX declaring, “we [U.S.] will not be constrained by multilateral organizations influenced by the corrupt World Health Organization and China.”¹⁶⁰

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.¹⁶¹ The WHO Allocation Mechanism is responsible for making dose allocation assessment; governance for this branch is under development.¹⁶² Currently, the COVAX facility is recommending that priority populations such as healthcare workers, adults over 65, and high-risk adults with underlying conditions receive one of the first doses of the vaccine.¹⁶³ All COVAX participants (self-financing and funded) will initially receive doses to cover 3% of their population intended to cover health and social care workers.¹⁶⁴ Next, all participants will receive a vaccine to cover up to 20% of their population to cover the adults over 65 and high-risk adults. After the two dispersals within this phase one period, participants could receive doses to cover more than 20% of their citizens.¹⁶⁵ COVAX has published information stating that the distribution of the vaccine intra-country will be left to the discretion of each individual country.¹⁶⁶

B. Liability and Compensation for Vaccine Injury Poses Barriers to Both Manufacturer and Government Participation in COVAX

Despite the tremendous amount of planning, ex ante, for equitable vaccine access, there is no resolution at the COVAX Facility about what to do about ex post liability for vaccine injury.¹⁶⁷ According to internal

¹⁶⁰ Emily Rauhala & Uasmeen Abutaleb, *U.S. says it won't join WHO-linked effort to develop, distribute coronavirus vaccine* WASH. POST (Sept. 1, 2020) https://www.washingtonpost.com/world/coronavirus-vaccine-trump/2020/09/01/b44b42be-e965-11ea-bf44-0d31c85838a5_story.html.

¹⁶¹ *COVAX, the act-accelerator vaccines pillar: Insuring accelerated vaccine development and manufacture* 1, 3 (2020) <https://www.gavi.org/sites/default/files/covid/COVAX-Pillar-background.pdf>.

¹⁶² GAVI, *COVAX Facility Structure and Governance*, supra note 20 at 12; see also generally WHO, *A Global Framework to Ensure Equitable and Fair Allocation of COVID-19 Products* (July 23, 2020), https://apps.who.int/gb/COVID-19/pdf_files/23_07/MS-Briefing.pdf (explains that at the end of August 2020 there will be a Member State briefing with a working version of the Allocation Mechanism for Vaccines – as of September 1, 2020 this brief cannot be located.).

¹⁶³ *COVAX*, supra note 35 at 3.

¹⁶⁴ GAVI, *COVAX Facility Structure and Governance*, supra note 160, at 5.

¹⁶⁵ *Id.*

¹⁶⁶ *The COVAX facility, Global procurement for COVID-19 Vaccines*, supra note 29 at 5 (While not explicitly stated, this marketing material's target audience is self-financing countries; therefore, the dispersal of the vaccine being left to the individual country might only extend to self-financing countries.).

¹⁶⁷ <https://www.keionline.org/wp-content/uploads/COVAX-Facility-Preliminary-technical-design-061120-vF.pdf> (“In addition to the pull funding design elements

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.”¹⁶⁸ Thailand, for example, has entered into only a non-binding commitment to COVAX, and has identified the liability and compensation matter as material to its decision to participate.¹⁶⁹ Kenya, which is also eligible, 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 ministry of health.¹⁷⁰ “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, the official said, noting that deals the EU is separately negotiating with vaccine companies involve clauses that make firms liable for potential compensation.”¹⁷¹

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 COVAX. 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.¹⁷² As early as 2006, IFPMA, the global industry lobbying group, stated publicly that it demanded legal immunity for vaccine adverse events in order to participate in pandemic response.¹⁷³ In 2006, the IFPMA issued a statement in the wake of a potential H5N1 pandemic:

[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

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 minimised • Agreement with conditions of liability / indemnity mechanisms being created.”)

¹⁶⁸ <https://www.modernhealthcare.com/safety-quality/push-bring-coronavirus-vaccines-poor-faces-trouble>

¹⁶⁹ Id.

¹⁷⁰ <https://www.insurancejournal.com/news/international/2020/10/16/586726.htm>

¹⁷¹ Id.

¹⁷² <https://www.reuters.com/article/us-astrazeneca-results-vaccine-liability/astrazeneca-to-be-exempt-from-coronavirus-vaccine-liability-claims-in-most-countries-idUSKCN24V2EN>

¹⁷³ GAO, *Influenza Pandemic: Efforts Under Way to Address Constraints on Using Antivirals and Vaccines to Forestall a Pandemic*, GAO-08-92 (Dec. 21, 2007).

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.¹⁷⁴

During the 2009-10 H1N1 pandemic, manufacturers restated their concerns with potential product liability lawsuits. In fact, negotiations regarding indemnification for manufacturers caused substantial delays.¹⁷⁵ In one instance, GSK required indemnity from the Japanese government, which the government in turn replied that it could not do so without a change in its law.¹⁷⁶ Manufacturers expressed similar concerns with respect to Ebola vaccines under development.¹⁷⁷

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 to be made whole through litigation against private-sector actors (principally manufacturers); or they may be compensated through publicly supported systems that draw from public-sector and private-sector contributions.¹⁷⁸ Each type of approach is supported by an ethical rationale. The first approach, requiring individuals with vaccine injury to bear their own costs, is an extreme utilitarian version of the fundamental social contract supporting immunization.¹⁷⁹ “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.”¹⁸⁰ It effectively pushes the costs of herd immunity to

¹⁷⁴ Int'l Fed'n of Pharmaceutical Manufacturers & Ass'ns [IFPMA], *Pandemic Influenza Vaccines and Liability Protection for Manufacturers* (May 19, 2006), http://www.ifpma.org/fileadmin/content/Global%20Health/Influenza/Ref_56_IFPMA_IVS_Request_on_Liability_May_19_2006.pdf

¹⁷⁵ Sam Halabi & John Monahan, *Sharing the Burden of Ebola Vaccine Related Adverse Events*, 24 TUL. J. INT'L & COMP. L. 131 (2015).

¹⁷⁶ <https://www.reuters.com/article/us-flu-japan/japan-to-buy-h1n1-flu-vaccine-from-glaxo-novartis-idUSTRE5953AJ20091006>

¹⁷⁷ *Id.*

¹⁷⁸ Halabi SF, Omer SB. A Global Vaccine Injury Compensation System. *JAMA*. 2017;317(5):471–472. doi:10.1001/jama.2016.19492.

¹⁷⁹ *Id.*

¹⁸⁰ Michelle Mello, *Rationalizing Vaccine Injury Compensation*, *BIOETHICS*, Vol. 22, Issue 1, pp. 32-42, January 2008

innocent parties.¹⁸¹ 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.¹⁸²

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.¹⁸³ “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.”¹⁸⁴ These types of approaches are representative of the common approach worldwide, yet they destabilize the effort to promote immunization by failing fundamental tests for fairness by asking people with few resources to pay for serious (if rare) injuries with the first approach versus introducing economic uncertainty with the second.¹⁸⁵

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.¹⁸⁶

Over time, no-fault vaccine injury compensation systems have become a cornerstone of advanced public health systems, first in wealthier countries, but increasingly in low- and middle-income countries such as Nepal and

¹⁸¹ Christina Tilley, *Tort Law Inside Out*, 126 *YALE L.J.* 1320, 1345 (2017) (analyzing community perceptions of mandated vaccines).

¹⁸² *Id.*

¹⁸³ RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 1 (1998) [hereinafter RESTATEMENT (THIRD)] (“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* (1970).

¹⁸⁴ Mello, *supra* note 100.

¹⁸⁵ Adrienne Katherine Wing, *Conceptualizing Global Substantive Justice in the Age of Obama*, 13 *J. GENDER, RACE, AND JUSTICE*, 705, 712 (2010) (“Justice issues transcend borders. We are beyond the time when we can segregate national and international issues.”).

¹⁸⁶ Halabi and Omer, *supra* note 98. See also Gregory Shill, *Should the Law Subsidize Driving?*, 95 *N.Y.U. L. REV.* 498, 572 (2020) (“No-fault insurance, which works a partial preemption of tort suits, adds an additional layer of subsidy for driving via torts”).

Vietnam.¹⁸⁷ The first such system was adopted in Germany in 1961, and has expanded to 24 countries as well as the Canadian province of Quebec.¹⁸⁸

III. SOLVING THE COVID-19 VACCINE PRODUCT LIABILITY PROBLEM

So far, solutions to the vaccine product liability product problem have been achieved only by a small number of wealthy 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 European Union, which has offered varying levels of liability protection to AstraZeneca and Sanofi based on price per dose of vaccine.¹⁸⁹

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 World Health Organization; and, finally, constructing a system for no-fault vaccine injury compensation using mass claims models deployed after the Deep Horizon oil spill in the Gulf of Mexico, and the compensation systems used after the Boeing 737 mass casualty airplane crash events.

¹⁸⁷ Mungwira RG, Guillard C, Saldaña A, et al. Global landscape analysis of no-fault compensation programmes for vaccine injuries: A review and survey of implementing countries. *PLoS One*. 2020;15(5):e0233334. Published 2020 May 21. doi:10.1371/journal.pone.0233334; see also Josephine Gittler, *Controlling Resurgent Tuberculosis: Public Health Agencies, Public Policy, and Law*, 19 J HEALTH POL POLICY & L 107 (1994) (analyzing public health measures as part of broader social safety planning).

¹⁸⁸ Looker C, Kelly H. No-fault compensation following adverse events attributed to vaccination: a review of international programmes. *Bull World Health Organ*. 2011;89(5):371-378. doi:10.2471/BLT.10.081901

¹⁸⁹ <https://www.reuters.com/article/health-coronavirus-eu-astrazeneca/exclusive-astrazeneca-gets-partial-immunity-in-low-cost-eu-vaccine-deal-idUSL5N2GK3NE>

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 administration of COVID-19 vaccines. Separately, 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, 2005.¹⁹⁰ The purpose of the act is to encourage companies to promptly release medical countermeasures during public health emergencies.¹⁹¹ 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.”¹⁹² PREP Act declarations have been made for H1N1, Ebola, botulism toxin, anthrax, smallpox, and acute radiation syndrome.¹⁹³

For COVID-19, a “covered countermeasure,” is:

¹⁹⁰ *Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, Pub. L. No. 2020-05484, 85 FR 15198 (2020).

¹⁹¹ *The PREP Act and COVID-19*, Cong. Res. Serv., <https://crsreports.congress.gov/product/pdf/LSB/LSB10443>, at *1 (last visited Sep. 22, 2020).

¹⁹² *Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, Pub. L. No. 2020-05484, 85 FR 15198, 15200 (2020).

¹⁹³ Notice of Declaration under the Public Readiness and Emergency Preparedness Act, 79 Fed. Reg. 73,314 (December 10, 2014); HHS Secretary's Declaration for Utilization of Public Readiness and Emergency Preparedness Act for Botulism Countermeasures, 73 Fed. Reg. 61,864 (October 17, 2008); HHS Secretary's Declaration for Utilization of Public Readiness and Emergency Preparedness Act for Anthrax Countermeasures, 73 Fed. Reg. 58,239 (October 6, 2008); HHS Secretary's Declaration for Utilization of Public Readiness and Emergency Preparedness Act for Smallpox Countermeasures, 73 Fed. Reg. 61,869 (October 17, 2008); Committee on Smallpox Vaccination Program Implementation, Board on Health Promotion and Disease Prevention, Institute of Medicine of the National Academies, “Review of the Centers for Disease Control and Prevention’s Smallpox Vaccination Program Implementation, Letter Report 1,” letter to Julie Gerberding, director, Centers for Disease Control and Prevention, January 16, 2003, reprinted in Alina Baciú, Andrea Pernack Anason, Kathleen Stratton, and Brian Strom, eds., *The Smallpox Vaccination Program: Public Health in an Age of Terrorism*, Washington, D.C.: The National Academies Press, 2005, pp. 123–159; HHS Secretary's Declaration for Utilization of Public Readiness and Emergency Preparedness Act for Acute Radiation Syndrome, 73 Fed. Reg. 61,866 (October 17, 2008); David W. Ogden et al., *COVID-19: Immunity Under the PREP Act: When Does It Apply to Private Sector Efforts to Help Combat COVID-19?*, (March 30th, 2020), available at <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>.

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; or

(2) any device used in the administration of any such product, and all components and constituent materials of any such product

and has been authorized pursuant to a declaration by the Secretary of Health and Human Services.¹⁹⁴ US Secretary of Health and Human Services Alex Azar issued the initial PREP Act declaration covering COVID-19 vaccines on March 10, 2020.¹⁹⁵ In order to qualify for PREP Act immunity, a covered countermeasure, including a COVID-19 vaccine, must be approved by the US Food & Drug Administration, either pursuant to conventional licensure or under an emergency use authorization.¹⁹⁶ Manufacturers and distributors are immune from liability regardless of the geographical area where the countermeasure was administered or used.¹⁹⁷

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.¹⁹⁸ 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 & Services Administration (an agency within the Department of Health and Human Services). A claimant must complete a Request for Benefits form and submit medical evidence within a year of being administered or using the countermeasure.¹⁹⁹ Once a claim has been submitted, it is reviewed by medical staff within the program to determine a causal link.

¹⁹⁴ 42 U.S.C. § 247d-6d(i)(2,7) (2020).

¹⁹⁵ *The PREP Act and COVID-19*, Cong. Res. Serv., <https://crsreports.congress.gov/product/pdf/LSB/LSB10443>, at *2 (last visited Sep. 22, 2020).

¹⁹⁶ David W. Ogden et al., *COVID-19: Immunity Under the PREP Act: When Does It Apply to Private Sector Efforts to Help Combat COVID-19?*, WILMERHALE (March 30th, 2020), available at <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>.

¹⁹⁷ *Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, Pub. L. No. 2020-05484, 85 FR 15198, 15201 (2020).

¹⁹⁸ 42 U.S.C. § 247d-6d (2020).

¹⁹⁹ HRSA, *Filing for Benefits* (April 2020), available at <https://www.hrsa.gov/cicp/filing-benefits>.

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.²⁰⁰ Once causation is established, claimants are compensated.²⁰¹ There is no adversarial process or presentation of further evidence to a court or special tribunal.²⁰² The CICP has received 485 claims since it began accepting claims related to H1N1 vaccines in 2010. Of those claims, 39 individuals have received compensation, with a total \$5.7 million paid.²⁰³ Of the 485 claims filed with the CICP, 386 were related to the H1N1 vaccine.²⁰⁴

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.²⁰⁵

2. Adapting No-Fault Compensation Systems for Routine Immunizations

But similar “no-fault” systems for routine immunization *do* exist for 24 countries (including the U.S.) and the province of Quebec in Canada.²⁰⁶ 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.²⁰⁷ All of these systems provide a schedule of automatic compensation based on the injury without

²⁰⁰ Peter H Meyers, *Fixing the Flaws in the Federal Vaccine Injury Compensation Program*, 63 ADMLR 785, 835 (2011) (citing 42 U.S.C. §§239a(c)(2), 247d-6e(b)(4) (“compelling, reliable, valid, medical and scientific evidence”).

²⁰¹ Robert Roos, *HHS: 386 injury claims filed over H1N1 countermeasures*, CIDRAP (March 16, 2011), available at <https://www.cidrap.umn.edu/news-perspective/2011/03/hhs-386-injury-claims-filed-over-h1n1-countermeasures>.

²⁰² HRSA, *Filing for Benefits* (April 2020), available at <https://www.hrsa.gov/cicp/filing-benefits>.

²⁰³ Tom Hals, *COVID-19 era highlights U.S. 'black hole' compensation fund for pandemic vaccine injuries*, REUTERS (August 21, 2020).

²⁰⁴ Peter H Meyers, *Fixing the Flaws in the Federal Vaccine Injury Compensation Program*, 63 ADMLR 785, 842 (2011).

²⁰⁵ <https://www.rand.org/pubs/perspectives/PEA761-1.html> (“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.”).

²⁰⁶ Randy G. Mungwira et. al., *Global Landscape Analysis of No-Fault Compensation Programmes for Vaccine Injuries: A Review and Survey of Implementing Countries*, 15(5) PLOS ONE (May 21, 2020).

²⁰⁷ *Id.*; Nat’l Res. Council, *Liability for the Production and Sale of Vaccines*, NAT’L ACAD. PRESS (1985) (“Manufacturers have complained about the costs, the unpredictability of the law, and the unavailability and cost of insurance.”).

establishing fault. None of these systems require the vaccine recipient to prove the maker of the vaccine was negligent.²⁰⁸

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 on-going monitoring and experience will be incorporated into their systems.

a. Funding

In most countries with no-fault systems, the government stands in as defendant, and as a result most programs are government-funded.²⁰⁹ Fifteen current systems are funded by their governments, while 8 fund themselves from other sources including levies on manufacturers.²¹⁰

For example, France, Denmark, Quebec, and Italy all use general tax revenues to pay damage awards to injured parties.²¹¹ In Sweden, Taiwan, and Norway, manufacturers pay a premium to fund the no-fault program.²¹² While administered at the government level, Norway's program is actually funded by a special insurance organization called the Drug Liability Association.²¹³ Membership in this association is mandatory for any drug producer in Norway.²¹⁴ Members pay for an insurance regime which is used to fund the no-fault program.²¹⁵

The United States collects a \$.75 levy on each dose (so MMR, for example, would be \$2.25) of the vaccine sold, then funds the no-fault

²⁰⁸ *Id.* at 8.

²⁰⁹ Jennifer Keelan & Kumanan Wilson, *Designing a No-Fault Vaccine-Injury Compensation Programme for Canada: Lessons Learned from an International Analysis of Programmes*, MUNK SCH. OF GLOBAL AFFAIRS 10 (Feb. 1, 2011), <https://munkschool.utoronto.ca/research-articles/designing-a-no-fault-vaccine-injury-compensation-programme-for-canada-lessons-learned-from-an-international-analysis-of-programmes/>.

²¹⁰ Mungwira, *supra* note 17, at 10.

²¹¹ *Id.*

²¹² Keelan, *supra* note 20, 3.

²¹³ Mungwira, *supra* note 21, at 6.

²¹⁴ Legemiddelansvarsforeningen, *Liability Insurance in Connection with Clinical Trials of Drugs*, DRUG LIAB. ASS'N (Jan. 2, 2019), accessed at http://www.laf.no/dm_documents/8366497_1_Liability_insurance_in_connection_with_clinical_trials_of_drugs_QPgvg.PDF.

²¹⁵ *Id.*

program with the levy.²¹⁶ The VICP trust holds approximately \$3 billion from this levy with about 150 million being deposited every year.²¹⁷

b. Eligibility

With respect to eligibility, 57% of no-fault systems compensate injuries for those vaccines which are registered and recommended by their respective governments.²¹⁸ This is the broadest category of vaccines, encompassing any vaccine the government (through public health agencies) may recommend. However, a minority of programs (22%) only cover those vaccines which are mandated or recommended through law. The United Kingdom and Quebec both only cover vaccines which are specifically listed in the legislation establishing the no-fault program.²¹⁹ Eligibility provisions of national regimes would require amendment for COVID-19 vaccines in some cases.²²⁰

All no-fault programs maintain at least some threshold of injury for compensation.²²¹ Quebec allows for any serious injury, for example, while the United Kingdom offers compensation if the vaccine is solely responsible for causing 60% or more disability in an individual.²²²

All current programs also require some sort of causal link to be established between the injury and the vaccine.²²³ Generally, no-fault systems require a balance of probabilities test, in the U.S. generally understood as “more likely than not” or the “preponderance of the evidence.”²²⁴

c. Administration

Most (65%) of current no-fault programs are administered at the national government level through public bureaucracies.²²⁵ Few programs, such as China and Switzerland, administer their programs at the provincial level.²²⁶

216 Nora Freeman Engstrom, A Dose of Reality for Specialized Courts: Lessons from the VICP, *University of Pennsylvania Law Review*, Vol. 163, p. 1631, 2015
Stanford Public Law Working Paper No. 2623756

87 Pages Posted: 28 Jun 2015

²¹⁷ Mungwira, *supra* note 26 at 6.

²¹⁸ *Id.* at 6

²¹⁹ *Id.*

²²⁰ *Id.*

²²¹ *Id.* at 7

²²² *Id.* at 18.

²²³ *Id.* at 8.

²²⁴ *Id.*

²²⁵ Mungwira, *supra* note 39 at 5.

²²⁶ *Id.* at 6. In 2014, China required all 31 provinces to implement 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

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.²²⁷

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.²²⁸ Quebec, for example, refers claimant compensation to an automobile insurance act and pays claimants the same as automobile accident victims.²²⁹

In the United Kingdom, compensation is set at £120,000.²³⁰ 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.”²³¹

B. Expanding Small-Scale Insurance Plans

While 24 countries (and Quebec), including Nepal and Vietnam, maintain no-fault vaccine injury compensation systems that could be used for COVID-19 vaccines, the vast majority of countries do not. Indeed, there is no nationally organized no-fault vaccine injury compensation system on the entire African continent. 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 World Health Organization, and may be expanded in response to the COVID-19 pandemic.

The World Health Organization maintains a small-scale insurance regime for emergency use authorized vaccines that it procures and distributes. The plan for a no-fault insurance regime followed the 2014-

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.” 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. Fei L, Peng Z. No-Fault Compensation for Adverse Events Following Immunization: A Review of Chinese Law And Practice. *Med Law Rev.* 2017;25(1):99-114. doi:10.1093/medlaw/fwx001.

²²⁷ Keelan at 2.

²²⁸ Mungwira at 8.

²²⁹ *Id*

²³⁰ Keelan at 18.

²³¹ *Id*.

16 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 15-year period leading to the outbreak, there was no system for addressing liability and compensation if it were to be deployed on an emergency use basis.²³² One of the most afflicted countries refused to accept responsibility for product liability claims, and the manufacturer limited its participation to sponsorship of clinical trials organized after the peak of the epidemic had passed.²³³

Given the uncertainty about permanent licensure, the World Health Organization 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.²³⁴

The WHO scheme insures against serious injuries resulting from experimental vaccines which the WHO administers on an emergency use basis.²³⁵ The World Health Organization must declare an Emergency Use Assessment Listing for vaccines which are still experimental or have not been completely clinically verified in emergency situations. 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.²³⁶ So, the

²³² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5524177/>

²³³ *Id.*

²³⁴ World Health Organization, “Workshop on Expanded Access to Experimental Ebola Vaccines During Outbreaks,” *available at* <http://origin.who.int/blueprint/expanded-access-ebola-vaccines.pdf>. (“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). 22 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).”).

²³⁵ *Id.*

²³⁶ *Id.*

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.²³⁷

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 injuries within that country which occur as a result of immunization.²³⁸ 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 experimental vaccine, must assume liability and indemnify 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. 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).

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. Yet there are large insurers who may be able to scale up the WHO system for COVID-19 vaccines including Allianz Multinational, Chubb, Swiss Re and Zurich Multinational.²³⁹ In 2011, Swiss Re opened its subsidiary, Corporate Solutions, whose focus is on underwriting risk for medium and large corporations.²⁴⁰ The Corporate Solutions arm of the company offers coverage in about 150 countries.²⁴¹

C. *Centralized Mass Claims Administration*

There are currently no-fault vaccine injury compensation programs across 25 countries.²⁴² The World Bank lists 217 separate countries, and

²³⁷ *Id.*

²³⁸ *Id.*

²³⁹ Swiss Re Corporate Solutions “About Us,” available at <<https://corporatesolutions.swissre.com/about-us.html>>. ; Brian Till, *How Drug Companies Keep Medicine Out of Reach*, THE ATLANTIC, May 15, 2013 available at <http://www.theatlantic.com/health/archive/2013/05/how-drug-companies-keep-medicine-out-of-reach/275853/>

²⁴⁰ *Id.*

²⁴¹ *Id.*

²⁴² Mungwira et Al., “Global Landscape Analysis of No-Fault Compensation Programs for Vaccine Injuries,” PLoS ONE 15(5): e0233334. <https://doi.org/10.1371/journal.pone.0233334> (2020).

with a current global population at 7.67 billion people.²⁴³ The 25 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 66% of the human population.²⁴⁴ There are currently 5.03 billion people living without a no-fault compensation program for their vaccine injuries.²⁴⁵ As noted above, the WHO insurance regime is small in scale, perhaps at this point only able to cover 1 to 5 million individuals.

There is therefore a need to provide a mechanism through the COVAX Facility or a system of country opt-outs that satisfy 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 \$.05 or \$.10 per levy dose. Given the billions of doses to be administered, even a small levy would quickly generate a pool of resources for compensation.

1. Deep 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 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. The resulting legal claims were massive in number and scope, but were effectively limited by claims processes required under US 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.²⁴⁶ 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 \$20 billion trust to finance the claims resulting from the spill.²⁴⁷ As a part of these negotiations, the Gulf Coast Claims Facility was established.²⁴⁸

²⁴³ The World Bank, "Population Total," *available at* <<https://data.worldbank.org/indicator/SP.POP.TOTL>>.

²⁴⁴ *Id.*

²⁴⁵ *Id.*

²⁴⁶ Gulf Coast Claims Facility Protocol for Interim and Final Claims, February 8, 2011.

²⁴⁷ BDO Consulting "Independent Evaluation of the Gulf Coast Claims Facility Report," 5 June 2011, *available at*

<<https://www.justice.gov/sites/default/files/opa/legacy/2012/06/06/gccf-rpt-find-obs.pdf>>.

²⁴⁸ *Id.* at 12.

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.²⁴⁹ The GCCF only paid out compensation to those injuries proximately caused by the oil spill.²⁵⁰ 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).²⁵¹ During Phase 1 of the GCCF's operations, it paid a minimum of \$1,000, even to claimants whose damages totaled less.²⁵²

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.²⁵³

The GCCF received claims from claimants from all 50 states in the United States and from 40 countries. 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. During its 18-month existence, the GCCF paid over six billion dollars to more than 200 thousand individual claimants.²⁵⁴

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

²⁴⁹ Gulf Coast Claims Facility Protocol for Interim and Final Claims, February 8, 2011 at 2-4.

²⁵⁰ *Id.* at 4.

²⁵¹ BDO *supra* note 16 at 31.

²⁵² *Id.* at 32.

²⁵³ *Id.* at 34.

²⁵⁴ *Id.* at 58.

concern regarding the GCCF was error. Upon an independent investigation of the program by an outside party at request of the Department of Justice, it was determined about 10,000 claimants were either negatively affected by error or erroneously denied compensation due to an error.²⁵⁵ In a broader context, this represented about a 5% 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 judgements 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 relatively modest, \$.05 or \$.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.²⁵⁶ Globalizing the system, instead of programs in a select few countries, would also 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, resulting in 189 deaths.²⁵⁷ Five months later, on March 10, 2019, Ethiopian Airlines flight 302 crashed, killing all 157 people on board.²⁵⁸ In both catastrophes, the plane that crashed was a Boeing 737 Max, a new and popular model.²⁵⁹ Investigations into both crashes, which followed

²⁵⁵ *Id.* at 67, 70.

²⁵⁶ Anya Prince adds that this per dose charge could vary based on EUA or full licensure status, with EUA-administered doses incurring a larger levy to reflect greater risk.

²⁵⁷ Scott Neuman, *Indonesia Report: Pilots, Ground Crew Share Blame With Boeing For Lion Air Crash*, NPR (October 25 2019), available at <https://www.npr.org/2019/10/25/773291951/pilots-ground-crew-share-blame-for-lion-air-737-max-crash-indonesian-report-says>.

²⁵⁸ Hadra Ahmed, Norimitsu Onishi, Dionne Searcey and Hannah Beech, *Aftermath of Deadly Ethiopian Airlines Plane Crash*, NY TIMES (MARCH 10, 2019), available at <https://www.nytimes.com/2019/03/10/world/africa/ethiopian-airlines-plane-crash.html>

²⁵⁹ Avie Schneider, *Boeing 737 Max, Involved In 2 Crashes, Is Fastest-Selling Plane In Company's History*, NPR (March 11, 2019) available at <https://www.npr.org/2019/03/11/702211493/boeing-737-max-involved-in-two-crashes-is-fastest-selling-plane-in-companys-hist#:~:text=flight%20on%20Jan.-,29%2C%202016%2C%20in%20Seattle.,plane%20in%20the%20company's%20history.&text=17%20p.m.%20ET->

similar stories of crashing after failing to gain altitude after takeoff, indicated a defect in the plane which caused the accidents.²⁶⁰ 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 American FAA.²⁶¹ The nationalities of the victims from the two crashes spanned 35 different countries, from the United States to Kenya to China.²⁶²

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.²⁶³ 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 live on board are lost, there is a presumption of a causal relationship.

Under the Montreal Convention, a carrier is liable for up to 100,000 Special Drawing Rights (a weighted basket of currencies generated by the IMF with implications for a broad range of international organizations and private parties), or about USD\$140,000. The convention applies to carriers, not manufacturers.²⁶⁴ However, if compensation exceeds this amount, a claimant may recover if he, she, or it is able to prove another party is at fault: the carrier is not held 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 the 737 Max had a design flaw in its sensors.²⁶⁵

,The%20Boeing%20737%20Max%20is%20the%20fastest%2Dselling%20plane%20in,in
%20less%20than%20five%20months.

²⁶⁰ *Lion Air JT610 crash: What the preliminary report tells us*, BBC (November 28, 2018), available at <https://www.bbc.com/news/world-asia-46373125>.

²⁶¹ David Slotnick, *The Boeing 737 Max just made a huge step towards getting back in the skies. Here's the complete history of the plane that's been grounded since 2 crashes killed 346 people 5 months apart*, BUSINESS INSIDER (June 29, 2020), available at <https://www.businessinsider.com/boeing-737-max-timeline-history-full-details-2019-9>.

²⁶² Ethiopian Airlines, *Accident Bulletin Number 3* (March 10, 2019) available at <https://web.archive.org/web/20190310180520/https://www.ethiopianairlines.com/corporate/media/media-relations/press-release/detail/1080>; Sinéad Baker, *What we know about the victims of the Lion Air plane crash off Indonesia, where there were 'likely no survivors'*, BUSINESS INSIDER (October 31, 2018), available at <https://www.businessinsider.com/lion-air-plane-crash-victims-indonesia-2018-10?r=UK>.

²⁶³ Montreal Convention (1999), Article 3, Chapter 21.

²⁶⁴ *How the Montreal Convention Works in Air Crashes*, Baum Hedlund Aristei and Goldman, available at <https://www.baumhedlundlaw.com/aviation-accident/montreal-convention-air-crashes/>.

²⁶⁵ Ainur Rohmah, Ian Duncan, Michael Laris and Shibani Mahtani, *Lion Air crash investigators fault Boeing 737 Max's flight-control system, regulatory lapses and pilot*

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.²⁶⁶ Boeing is insured in multiple layers, with both self-insurance then a stop-loss policy with the British insurer Global Aerospace.²⁶⁷ Claimants then came to Boeing to recover the rest needed to adequately compensate them for the loss of their family members.

In September, Boeing announced the creation of a fund designed to compensate families. The fund was capitalized to around USD\$ 50 million, and each passenger's family was paid \$144,500.²⁶⁸ Accepting payment did not foreclose any litigation rights for the victims.²⁶⁹ 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.²⁷⁰ Boeing did not publicize payment amounts, but report suggest approximately \$1.2 million per claim.²⁷¹

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

training, WASHINGTON POST (October 25, 2019), *available at* 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.

²⁶⁶ Noor Zainab Hussain, Carolyn Cohn, Suzanne Barlyn, *Insurers face large claims after second Boeing 737 MAX crash*, REUTERS (March 11, 2019) *available at* <https://www.reuters.com/article/us-ethiopia-airplane-insurance/insurers-face-large-claims-after-second-boeing-737-max-crash-idUSKBN1QS1D8>.

²⁶⁷ *Id.*

²⁶⁸ Reuters, *Boeing to pay 737 Max victim's families \$144,500 each*, BUSINESS INSURANCE (September 23, 2019), *available at* [https://www.businessinsurance.com/article/20190923/NEWS06/912330798/Boeing-to-pay-737-MAX-crash-victims-families-\\$144,500-each](https://www.businessinsurance.com/article/20190923/NEWS06/912330798/Boeing-to-pay-737-MAX-crash-victims-families-$144,500-each).

²⁶⁹ *Id.*

²⁷⁰ Eric M. Johnson, *Boeing Settle Nearly All Lion Air 737 MAX Crash Claims; Filing*, REUTERS (July 7, 2020), *available at* <https://www.reuters.com/article/us-boeing-737max-settlement/boeing-settles-nearly-all-lion-air-737-max-crash-claims-filing-idUSKBN24838P#:~:text=In%20a%20filing%20in%20federal,been%20fully%20or%20partially%20settled.&text=In%202019%2C%20Reuters%20reported%20that,least%20%241.2%20million%20per%20claim>.

²⁷¹ *Id.*

IV. CONCLUSION

Tremendous strides have been made toward assuring equitable access to COVID-19 vaccines for low- and 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 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.²⁷²

²⁷² Rahim Moloo and Alex Khachaturian, *The Compliance with the Law Requirement in International Investment Law*, 34 FORDHAM INT'L. L.J. 1473 (2011).