

Toward a Global Solution on Vaccine Liability and Compensation

JOHN D. WINTER, CASSYE COLE, AND JONAH WACHOLDER*

ABSTRACT

In the past five years, the global community has had to confront several deadly pandemics. These threats have generated increased attention to the need to promote robust vaccine development, which has the potential to reduce the dangers posed by these pandemics. To ensure robust vaccine development, it is important to address the liability concerns of vaccine manufacturers, which impede efforts to develop and distribute vaccines. Building on existing domestic and international models, we propose several approaches to protecting vaccine manufacturers from liability, while ensuring that those injured by vaccines are compensated.

I. INTRODUCTION

In the past five years, there have been multiple instances when the global community has had to confront deadly pandemics. In each of these public health emergencies, there were gaps in the vaccine development and production process aimed at addressing the infectious agent responsible for the public health emergency. During and after each of these emergencies, recommendations were made to address the liability concerns of vaccine manufacturers and to provide incentives for the creation of more robust vaccine development programs.

This paper sets forth proposals for how vaccine manufacturer liability concerns could be addressed at the global level. Looking to examples of domestic programs in the United States and Europe, this paper proposes limitations on liability for vaccine manufacturers tied to a global compensation fund to support those injured by vaccines. First, it provides an overview of the concerns surrounding manufacturer liability for vaccines and the rationale for seeking better means of ensuring safety and protecting vaccine recipients. Second, it describes existing approaches in the United States and Europe for limiting vaccine manufacturer liability and compensating people injured by vaccines. Third, it discusses potential approaches for limiting manufacturer liability globally, in combination with the creation of a global vaccine compensation fund.

The ultimate proposal is a comprehensive treaty granting manufacturers protection from vaccine injuries, combined with a global compensation fund to cover those injuries. The paper also considers and discusses existing programs and global proposals providing for epidemic-specific immunity or compensation as less ambitious alternatives.

* Mr. Winter is a partner and Ms. Cole and Mr. Wacholder are associates at Patterson Belknap Webb & Tyler LLP

II. GLOBAL CONCERNS ABOUT VACCINE LIABILITY

History has shown that vaccines are an invaluable means of ameliorating diseases or eradicating them entirely. Vaccines were essential to the worldwide eradication of smallpox and to the eradication of polio from large parts of the globe.¹ They remain vital tools for global public health.² The critical importance of vaccines highlights the need to ensure robust vaccine innovation to combat global health threats. Yet existing schemes for vaccine liability and compensation often impair rather than reinforce vaccine innovation in this context.

The 2014 and 2018 Ebola outbreaks and the 2015-2016 Zika outbreak have highlighted the need for additional focus on the development and deployment of vaccines for infections of epidemic potential. The epidemics have demonstrated the shortfall in the world's ability to respond to these types of public health emergencies. The Ebola and Zika epidemics were both longstanding regional public health issues that expanded to create larger threats on a global scale. The expansion of threat illustrates the risks for people, both in developing and developed countries, of permitting infectious diseases to fester without effective preventive mechanisms being developed. In the large-scale Ebola outbreak in 2014, World Health Organization ("WHO") data suggests that 28,646 people were infected, and 11,323 people killed by the disease.³ Although the outbreak was concentrated in Guinea, Liberia, and Sierra Leone, international travel brought cases to seven other countries, including the United States and the United Kingdom.⁴

The Zika epidemic in the Americas in 2015 and 2016 infected hundreds of thousands of people, and was associated with neurological disorders among infants whose mothers were infected while pregnant.⁵ The 2018 Ebola outbreaks in the Democratic Republic of Congo ("DRC") have been more successfully contained than the 2014 outbreaks, in part, because of the vaccines used to prevent infection in people likely to have been exposed to the disease.⁶ Working with Merck and Gavi, a non-governmental vaccine alliance organization, WHO distributed thousands of vaccines in the DRC to front-line health workers and people who had contact with those infected.⁷ The vaccines were distributed pursuant to an Advance Purchase Agreement between Merck and Gavi that limited Merck's financial risk by Gavi pre-committing

¹ See F.E. Andre et al., *Vaccination greatly reduces disease, disability, death and inequity worldwide*, 86 *Bulletin of the World Health Org.* (2008), <http://www.who.int/bulletin/volumes/86/2/07-040089/en> [<https://perma.cc/6BM3-C9CP>].

² *See id.*

³ See WORLD HEALTH ORGANIZATION, *EBOLA SITUATION REPORT* (2016), <http://apps.who.int/ebola/current-situation/ebola-situation-report-30-march-2016> [<https://perma.cc/9Z5N-ZA8G>].

⁴ *Id.*

⁵ Jon Cohen, *Zika has all but disappeared in the Americas. Why?*, *SCIENCE* (Aug. 16, 2017), <http://www.sciencemag.org/news/2017/08/zika-has-all-disappeared-americas-why> [<https://perma.cc/AE44-TQRZ>].

⁶ See Helen Branswell, *A spot of good news in an Ebola crisis: Vaccine supplies are expected to last*, *Stat News*, Jan. 22, 2019, <https://www.statnews.com/2019/01/22/some-needed-good-news-on-ebola-vaccine-supplies-are-expected-to-last/>.

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

to purchasing a large number of vaccines if certain conditions were met, including Merck providing an emergency stockpile.⁸

Despite the importance of vaccines, the development of vaccines for infectious diseases largely affecting developing countries remains slow.⁹ While an Ebola vaccine that may prove effective is now being distributed, there is still no Zika vaccine demonstrated to work in humans.¹⁰ Even when a vaccine has already been developed, its deployment may be unduly delayed by a company's worry about liability risk. International organizations have taken note of these concerns. For example, in 2012, following the H1N1 pandemic and accelerated introduction of H1N1 vaccines that did not undergo full "standard" licensure processes, the World Health Organization ("WHO") recommended that global leaders prepare a framework that would expedite legal agreements during future pandemics or outbreaks so that deployment of vaccines would not be slowed.¹¹ Thereafter, in 2014, UNICEF published a suggested operational framework for continued development and stockpile preparation of a vaccine in the event of a type 2 polio outbreak. The UNICEF draft evaluated legal and regulatory considerations for manufacturers of the vaccine pre- and post-licensure.¹²

At least three aspects of the liability risks facing vaccine manufacturers pose obstacles for vaccine innovation and for their development and deployment. First, as many observers have noted that liability risks are an important aspect of the difficulties faced in vaccine development and deployment.¹³ Such development and deployment in the face of a risk of expansive manufacturer liability puts companies in a difficult situation that poses public health challenges. It is hard for pharmaceutical companies to anticipate the extent of the potential liability they may face for a vaccine, which interferes with their ability to insure or hedge against the risk of the loss. This concern only multiplies in a public health crisis, when there may be a need to get a vaccine distributed before it has gone through a significant period of testing. Because the risk of a vaccine injury often cannot be eliminated, even when there is an opportunity for testing, the potential for liability is difficult to predict. The unpredictability of liability

⁸ See *Ebola vaccine to help tackle DRC outbreak*, GAVI (May 21, 2018), <https://www.gavi.org/library/news/statements/2018/ebola-vaccine-to-help-tackle-drc-outbreak/> [<https://perma.cc/HGX4-8CS6>].

⁹ See Stanley A. Plotkin, M.D., Adel A.F. Mahmoud, M.D., Ph.D., and Jeremy Farrar, M.D., Ph.D., *Establishing a Global Vaccine-Development Fund*, 373 *NEW ENG. J. MED.* (2015), <http://www.nejm.org/doi/full/10.1056/NEJMp1506820> [<https://perma.cc/P9YP-ZBGG>]; RICHARD HAASS, *A WORLD IN DISARRAY* 144-45 (2017).

¹⁰ Plotkin, *supra* note 9; Julie Steenhuisen, *Zika vaccine shows promise in early human trial*, *REUTERS*, (Oct. 4, 2017), <https://www.reuters.com/article/us-health-zika-vaccine/zika-vaccine-shows-promise-in-early-human-trial-idUSKBN1C92Y0> [<https://perma.cc/KF7N-GGCB>].

¹¹ See *Report of the WHO Pandemic Influenza A (H1N1) Vaccine Deployment Initiative*, *WORLD HEALTH ORG.* (2012), http://www.who.int/influenza_vaccines_plan/resources/h1n1_deployment_report.pdf [<https://perma.cc/5FE6-UYP6>].

¹² See *Operational Framework for Monovalent Oral Poliovirus Type 2 (mOPV2) deployment and replenishment*, *UNICEF* (2014), http://www.who.int/immunization/sage/meetings/2014/october/4_Polio_mOPV2_stockpile_v4_09_10_2014.pdf [<https://perma.cc/4TQG-MH7R>].

¹³ Paul A. Offit, *Why Are Pharmaceutical Companies Gradually Abandoning Vaccines?*, 24 *Health Affairs* 622 (2005), at 626-28; Sam Halabi & John Monahan, *Sharing the Burden of Ebola Vaccine Related Adverse Events*, 24 *TUL. J. INT'L & COMP. L.* 131 (2015); Amir Attaran & Kumanan Wilson, *The Ebola Vaccine, Iatrogenic Injuries, and Legal Liability*, *PLOS Medicine* (December 1, 2015), <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001911> [<https://perma.cc/XP8U-CPRJ>].

is only worsened when operating in countries where court systems may be less developed, or less familiar to American or European pharmaceutical companies.¹⁴

Second, the problems posed by the unpredictability of this risk are compounded by herd immunity. For infectious diseases, a sufficient level of immunity in a population is protective for everyone, even people who are not immune, by making it more difficult for a disease to spread. As a result, it is generally accepted that the social gain of a vaccine dose is greater than the private gain to the recipient, making it difficult for companies to monetize the true value of a vaccine.¹⁵ This problem is exacerbated in low-income countries where the price of vaccines is usually deeply discounted, so the associated revenue from those vaccine sales is a smaller proportion of research and development costs.¹⁶ Thus, a manufacturer exposed to liability bears the cost of vaccine injury without recovering the social benefit of vaccination. This issue only gets compounded as seemingly local infections transform themselves into global problems.¹⁷

Third, the reliance on litigation to compensate victims also poses difficulties for individuals possibly injured by vaccines. Globally, litigation is often a high-cost and unpredictable way to recover damages from an alleged vaccine injury.¹⁸ Further, the costs of litigation and compensation are borne by the plaintiff, the manufacturer, and other purchasers of the vaccine to whom the costs may be passed on, rather than by society as a whole, which obtains the benefit of vaccination through the reduction in infectiousness.¹⁹

Liability limitations by themselves are not enough, however, to ameliorate this problem. Both as a matter of fairness and as a matter of maintaining public support for vaccination programs, people injured by vaccines should not be denied access to compensation. The current controversy over the safety risks of the dengue vaccine recently distributed in the Philippines, where many children may have been harmed by a government vaccination initiative²⁰, highlights both the potential liability facing

¹⁴ See Halabi & Monahan, *supra* note 13.

¹⁵ See *Bruesewitz v. Wyeth*, 562 U.S. 223, 227 (2011) (noting that vaccination rates are a matter of social concern because “vaccines are effective in preventing outbreaks of disease only if a large percentage of the population is vaccinated”); Jennifer Keelan & Kumanan Wilson, *Designing a No-Fault Vaccine-Injury Compensation Program for Canada*, MUNK SCHOOL BRIEFINGS (2011), at 7-8 (discussing herd immunity and its significance for compensation schemes).

¹⁶ Attaran & Wilson, *supra* note 13, <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001911> [<https://perma.cc/L7SH-6PBA>].

¹⁷ See, e.g., David L. Heymann et al., *Global health security: the wider lessons from the west African Ebola virus disease epidemic*, 385 LANCET 1884, 1889-91 (2015).

¹⁸ See Jennifer Keelan & Kumanan Wilson, *Designing a No-Fault Vaccine-Injury Compensation Program for Canada*, MUNK SCHOOL BRIEFINGS (February 2011), at 8-9 (discussing pitfalls of litigation as a means to compensate those suffering from vaccine injury).

¹⁹ Clare Looker & Heath Kelly, *No-fault compensation following adverse events attributed to vaccination: a review of international programmes*, WHO, Mar. 21, 2011, <http://www.who.int/bulletin/10-081901.pdf> [<https://perma.cc/AAW7-Y792>].

²⁰ See, e.g., Adrian Ayalin, *Aquino, Garin face complaints over Dengvaxia mess*, ABS-CBN NEWS (Dec. 15, 2017), <https://news.abs-cbn.com/news/12/15/17/aquino-garin-face-complaints-over-dengvaxia-mess> [<https://perma.cc/K9F5-BSB5>]; Karen Lema, *Philippine lawyers sue Sanofi over dengue vaccine*, REUTERS (Feb. 5, 2018), <https://www.reuters.com/article/us-sanofi-dengue-philippines/philippine-lawyers-sue-sanofi-over-dengue-vaccine-idUSKBN1FP1M5> [<https://perma.cc/E2P9-FJTR>].

manufacturers in developing and deploying new vaccines and the need to encourage public support for vaccination programs.

All of these considerations support a broad-based global initiative to combine liability protections for manufacturers with a global compensation fund for those subject to vaccine injury. Together, liability protections and a compensation fund provide incentives for vaccine manufacturers to innovate, while also protecting individuals potentially injured by vaccines.

III. APPROACHES TO VACCINE LIABILITY AND COMPENSATION IN THE UNITED STATES AND EUROPE

A. *Broad-based vaccine compensation schemes*

The question of how to provide incentives to develop and manufacture vaccines, while fairly compensating the people who suffer from vaccine injury, is not new. Faced with similar issues on the domestic level in the past, the United States, several European countries, and a few countries in East Asia implemented no-fault vaccine compensation programs to compensate victims and protect manufacturers. Such programs allow a person who was injured as a consequence of vaccination to be compensated financially for those injuries, without having to attribute fault or error to a specific individual or manufacturer.

Multiple policy considerations have led countries to create compensation funds. One reason is to respond to vaccine safety panics. In the face of public worry about adverse effects from vaccines, the guarantee of compensation can partially insure the public against the risk and reduce the likelihood of a large drop off in vaccination rates.²¹ Another reason is fairness. Governments strongly promote and sometimes mandate vaccines, due to the social benefits vaccinations provide, and people injured as a result of a vaccination program can make a strong argument that they are owed compensation by society because their injury stems from a welfare-enhancing social policy.²² A third reason, especially in the United States, has been to protect manufacturers from excessive liability risks interfering with the development and manufacture of vaccines.²³

To date, nineteen countries have adopted some type of no-fault vaccine injury compensation fund. The specifics of processing claims and receiving compensation vary from country-to-country. Some of these programs are outlined below to illustrate how a global compensation fund might work. The contours of the global problem differ somewhat from the domestic situations in the countries in which such programs exist, but the programs still provide helpful precedents for how such a policy might work.

²¹ See Gareth Millward, *A Disability Act? The Vaccine Damage Payments Act 1979 and the British Government's Response to the Pertussis Vaccine Scare*, 30 SOC. HIST. MED. 429, 432, 434-437, 440-442 (2016), <https://academic.oup.com/shm/article/30/2/429/2669669>, [<https://perma.cc/2TZ2-ZWDW>].

²² Millward, *supra* note 21 at 437; Keelan & Wilson, *supra* note 18 at 1.

²³ See *Bruesewitz*, 562 U.S. at 227-28.

United States Vaccine Injury Compensation Program (VICP)

The National Childhood Vaccine Injury Act of 1986 (NCVIA)²⁴ established the Vaccine Injury Compensation Program (VICP), a no-fault alternative to traditional tort remedies for resolving vaccine injury claims for vaccines routinely administered to children and pregnant women. The VICP authorizes compensation to individuals for vaccine-related injuries or death, if causation is proven.

The VICP emerged out of a history of vaccine manufacturer concerns about the risk of tort lawsuits, combined with a sense of obligation to protect people injured by vaccines. Products liability doctrines developed in the 1960s and 1970s expanded manufacturer liability for product harms, and vaccine manufacturers became targets of lawsuits for real and purported safety issues with vaccines.²⁵ Concerns about the impact of liability on vaccine development and manufacture led to proposals on possible approaches for compensating people who may have been injured by vaccines through systems outside of tort law.²⁶

The idea that vaccine manufacturers should have protection is longstanding. The Second Restatement of Torts, whose products liability section was a key part of the development of doctrines relating to biologic and pharmaceutical products, commented that vaccine manufacturers should not be held liable for unavoidable safety risks in vaccines or for safety risks in a vaccine when there was not adequate time to guarantee its safety as long as the vaccine was properly prepared and accompanied by proper warnings.²⁷ The Second Restatement's approach, however, did not protect against warning liability, which reduced its ability to protect manufacturers from liability.²⁸

The Office of Technology Assessment (OTA) produced a report in 1980 for the House Interstate and Foreign Commerce Committee on potential options for a compensation fund, coupled with some level of immunity for vaccine manufacturers. In making the case for vaccine compensation, OTA emphasized that vaccination was a public good, recommended or required by government to achieve social benefits going beyond the individual recipient.²⁹ It additionally noted worries that, in the absence of a compensation program, more people would refuse to be vaccinated, and manufacturers fearful of lawsuits would withdraw from the market.³⁰

Ultimately, the VICP was established in 1986, in response to these concerns and specifically prompted by a crisis that had developed in the manufacture of pertussis vaccines. Pertussis vaccine manufacturers were subjected to a wave of liability lawsuits because of reports that the pertussis vaccine caused encephalopathy. In response to this litigation, the number of vaccine manufacturers in the United States dropped precipitously. Concerned about a loss of access to vaccines, Congress

²⁴ Nat'l Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660 (1986).

²⁵ *A Review of Selected Federal Vaccine and Immunization Policies*, OFFICE OF TECH. ASSESSMENT, 87-92 (1981).

²⁶ *See id.* at 141-42.

²⁷ RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

²⁸ *Id.*

²⁹ OFFICE OF TECHNOLOGY ASSESSMENT, COMPENSATION FOR VACCINE-RELATED INJURIES 19-20 (1980).

³⁰ *Id.* at 21.

established the VICP, protecting manufacturers of childhood vaccines from lawsuits, while providing an alternative path to compensation.

The VICP's coverage is limited; it extends only to vaccines listed on a Vaccine Injury Table required by the statute.³¹ The table consists of a list of covered vaccines, of injuries and conditions presumed to be caused by those vaccines, and of the time periods in which the first symptom of these injuries must occur after receiving the vaccine. For a vaccine to be added to the list of covered vaccines, the Centers for Disease Control and Prevention (CDC) and the Secretary of Health and Human Services ("HHS") must recommend a vaccine for the "routine administration to children" or "routine administration in pregnant women," or the HHS Secretary must go through an administrative process. The VICP also does not generally have extraterritorial application. It can have extraterritorial application only in limited circumstances, defined by the statute, when there is a clear nexus to the United States.³²

To be entitled to compensation under the VICP, a claimant must establish causation. Causation may be established in two ways. First, causation is presumed when an individual's injury is included among the injuries listed in the Vaccine Injury Table and falls within a prescribed time-frame set forth in that table. Second, if an injury falls outside the table, the individual can still recover by presenting evidence establishing that the vaccination was in fact the cause of his or her injury. The VICP covers medical expenses, lost income, and pain and suffering damages up to a maximum of \$250,000.³³

The VICP provides substantial, but not absolute, protection to vaccine manufacturers. If a vaccine is included in the VICP, manufacturer *immunity is likely, but not guaranteed*. The VICP provides that any person with an injury resulting from the use of any vaccines listed on the Vaccine Injury Table must seek compensation through the VICP, which provides for an administrative proceeding before special masters appointed by the United States Court of Federal Claims.³⁴ The persons covered include vaccine recipients and health care workers, irrespective of how the vaccine is administered. However, a petitioner may ultimately file a claim in civil court against the vaccine company and/or the vaccine administrator, but only after first filing a claim under the VICP, and then rejecting the outcome of the proceeding. Further, the scope of manufacturer liability is narrowed for such claims: under the NCVIA's preemption clause, design defect claims are barred.³⁵ Thus, for example, while a plaintiff could bring a claim in a court outside the VICP process alleging that a vaccine was improperly manufactured or did not contain adequate warnings, a plaintiff could not bring a claim alleging that the vaccine's design was excessively dangerous.³⁶

³¹ Vaccine Injury Table, 42 U.S.C. § 300aa-14 (2018).

³² 42 U.S.C. § 300aa-11(c)(1)(B) (2018).

³³ 42 U.S.C. § 300aa-15 (2018).

³⁴ See 42 U.S.C. § 300aa-12 (2018).

³⁵ *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011) (holding that the preemption clause, 42 U.S.C. § 300aa-22, bars design defect claims); Aaron Kesselheim, *Safety, Supply, and Suits – Litigation and the Vaccine Industry*, 364 THE NEW ENG. J. MED. 1485, 1485 (Apr. 21, 2011), <http://www.nejm.org/doi/pdf/10.1056/NEJMp1102182> [<https://perma.cc/8GQH-P7FV>] (discussing *Bruesewitz* and its implications).

³⁶ See *Bruesewitz*, 562 U.S. at 231-33. Failure to warn claims also are limited to cases when the plaintiff shows that the manufacturer failed to comply with regulatory requirements or shows by clear and convincing evidence that the manufacturer failed to exercise due care. 42 U.S.C. § 300aa-22(b)(2).

Because of the limitation on the VICP's extraterritorial scope, the Act does not protect against manufacturer liability for vaccines administered abroad to non-US persons.³⁷

The VICP is funded by an excise tax of \$0.75 imposed on each dose of an administered vaccine recommended by the CDC. This tax is put into the Vaccine Injury Compensation Trust Fund to compensate individuals for vaccine-related injuries or deaths. The excise taxes are collected by the United States Department of the Treasury, which also manages the Fund.³⁸ Once a new vaccine has been recommended to be added to the Vaccine Injury Table, Congress must update the excise tax to include the newly added vaccine.

The VICP has been used by a substantial number of claimants since its creation. As of March 2017, 17,935 petitions had been filed with the VICP, with 5,269 petitions determined to be compensable, and 10,918 dismissed. Of the dismissals, about half involve petitions based upon vaccines not covered or petitions that do not provide sufficient information to determine which vaccine is at issue. \$2.8 billion in compensation has been paid out since the program's onset.³⁹

UK Vaccine Damage Payments Act 1979

The Vaccine Damage Payments Act 1979 (the "VDP Act") in the United Kingdom established a national fund administered through the Department for Works and Pensions to compensate people injured by vaccines. Like the VICP in the United States, the VDP Act was enacted in response to health scares concerning the pertussis vaccine. In the United Kingdom, however, the main supporters of the legislation were advocates for people injured by vaccines. Their principal argument was that people harmed by vaccination should be compensated by society, since vaccine injury was caused by a public program seeking an overall public benefit. They also invoked the language of social security and disability rights, then prevalent in politics, and were helped by the British government's fears at the time that high-profile public scandals around vaccine safety would lead to lower vaccination rates.⁴⁰

To qualify for a vaccine damages payment, a person must have been injured by a vaccine for a disease on the statutory list; the vaccination must have been received in the United Kingdom before the age of eighteen; and the injury must have resulted in that person becoming 60% disabled. For instances when injuries are sustained due to vaccines administered in the United Kingdom during an "outbreak of a disease," there is an exception to the age requirement. The circumstances of eligibility can be expanded by statutory instrument.⁴¹ The payment is a flat £120,000 and is not adjusted

³⁷ 42 U.S.C. § 300aa-11(a)(9) (2018) (restricting the bar on civil suits to those eligible to apply for compensation under the program).

³⁸ *About the National Vaccine Injury Compensation Program*, HEALTH RESOURCES AND SERVICES ADMINISTRATION (September, 2018), <https://www.hrsa.gov/vaccine-compensation/about/index.html> [<https://perma.cc/2H3X-ZYZG>].

³⁹ *Data and Statistics*, HEALTH RESOURCES AND SERVICES ADMINISTRATION (March 1, 2017), https://www.hrsa.gov/sites/default/files/vaccinecompensation/data/vicpmonthlyreporttemplate3_1_17.pdf [<https://perma.cc/45GK-977G>].

⁴⁰ Gareth Millward, *A Disability Act? The Vaccine Damage Payments Act 1979 and the British Government's Response to the Pertussis Vaccine Scare*, 30 SOC. HIST. MED. 429, 439, 445 (2016), available at academic.oup.com/shm/article/30/2/429/2669669/ [<https://perma.cc/V7LF-BJLK>].

⁴¹ Vaccine Damage Payments Act 1979, c.17, §§ 1-2 (UK).

for medical expenses or lost income.⁴² The program does not immunize manufacturers from liability. However, damages available from a lawsuit are reduced by the amount of the vaccine damages payment.⁴³ The vaccine damages payment program is funded out of general revenue raised by Parliament.⁴⁴

Other Programs

Some other European countries, Taiwan, and Japan also have compensation programs. As in the United States and the United Kingdom, these schemes emerged both as a way to reduce litigation pressure on vaccine manufacturers, and from a desire to protect the well-being of those injured by vaccines. Again, as in both the U.S. and U.K., the concerns about adverse effects of the pertussis vaccine, especially as administered together as the diphtheria-tetanus-pertussis (“DTP”) vaccine, were an important basis for the creation of vaccine compensation programs in many countries.⁴⁵

Policies differ on the extent and nature of coverage. Some schemes limit coverage to a specified list of vaccines, while others broadly cover licensed vaccines. Certain schemes make special provision for vaccines necessary for travel or occupation. Similar to the United Kingdom’s 60% disability requirement, several schemes require a certain level of severity before offering compensation. Similarly, the extent of compensation differs across countries; the United Kingdom is the only country that has a flat payment, and some countries cover noneconomic losses like pain and suffering, while others do not.⁴⁶

For the most part, European countries legislate that claimants can seek either damages through the courts or a compensation fund payout but not both. For example, in France, victims of injuries resulting from state-mandated vaccinations may receive compensation for disabilities and lost income through a state administered fund.⁴⁷ Other countries, such as Denmark and the United Kingdom, adjust compensation payments if damages have already been paid through the courts.⁴⁸ Several countries also grant subrogation rights to the state to recover moneys paid from a compensation program.⁴⁹

While many countries have successfully created and maintained their own compensation funds through taxes and private donations, shifting to a global focus will make funding a compensation program more difficult. Nevertheless, the existence of a meaningful global compensation fund is a critical element of reducing liability risk

⁴² See *Vaccine Damage Payments*, GOV.UK, <https://www.gov.uk/vaccine-damage-payment/what-youll-get> [<https://perma.cc/RNM8-PM82>] (last visited Dec. 7, 2018). The UK requests that claimants provide permission to access the claimant’s medical records. It appears that, as in Quebec, these are used as evidence of the vaccine’s relation to the injury by the evaluating committee.

⁴³ Vaccine Damage Payments Act 1979, c.17, § 6(4) (UK).

⁴⁴ *Id.* § 12(4).

⁴⁵ Clare Looker & Heath Kelly, *No-Fault Compensation Following Adverse Events Attributed to Vaccination: A Review of International Programmes*, WHO, 3 (Mar. 21, 2011), <http://www.who.int/bulletin/10-081901.pdf> [<https://perma.cc/CW9B-XB85>].

⁴⁶ See *id.* at 9.

⁴⁷ See *id.* at 6-7.

⁴⁸ See *id.* at 3.

⁴⁹ See NATIONAL RESEARCH COUNCIL, VACCINE SUPPLY AND INNOVATION app. E (1985), available at <https://www.ncbi.nlm.nih.gov/books/NBK216811/> [<https://perma.cc/D2U8-9ZH7>].

for vaccine manufacturers, as well as individual use and broader societal acceptance of vaccinations.

B. Epidemic-specific compensation schemes

General vaccine compensation programs apply to routinely administered vaccines that have gone through some type of regulatory licensing review. When a new public health threat emerges, vaccinations not covered by general programs are sometimes needed. Vaccines to address infections associated with epidemics and pandemics pose similar liability and compensation concerns as general vaccine compensation programs, but epidemics and pandemics create more uncertainty for vaccine manufacturers because vaccines that have not been exhaustively tested may need to be distributed to address a serious public health emergency. To address epidemic situations, other programs have been developed at national and international levels. Two examples of policies providing for epidemic-specific immunity and compensation are the United States PREP Act, and the H1N1 Letters of Agreement, provided by the WHO during the H1N1 epidemic.

United States PREP Act Declaration

The U.S. Public Readiness and Emergency Preparedness Act (“PREP Act”)⁵⁰ was enacted in December 2005, and authorizes the Secretary of Health and Human Services to issue a declaration in the *Federal Register* providing **absolute immunity** from tort liability for claims of loss or injury caused by countermeasures against diseases or other threats of public health emergencies.⁵¹ The Act emerged amidst worries about the vulnerability of Americans to flu pandemics, and sought to ensure that vaccine manufacturers would be willing to cooperate with public health efforts in a health emergency, without fear of liability.⁵²

The Act provides immunity and compensation for covered countermeasures, such as vaccinations, specified in the Secretary’s declaration. The Secretary has wide discretion when deciding what qualifies as a covered countermeasure.⁵³ If she determines that a disease, health condition, or other threat to health constitutes—**or may in the future constitute**—a public health emergency, the Secretary may make a declaration recommending the administration or use of a covered countermeasure.⁵⁴ Notably, a PREP Act Declaration may be made in advance of a public health emergency, and may provide liability **immunity for activities, both before and after** a declared public health emergency. For example, in response to the Ebola outbreak, the Secretary issued a PREP Act Declaration in December 2014, covering Ebola vaccinations for 24 months from the date the Declaration was entered.⁵⁵ In the past it

⁵⁰ PREP Act, Pub. L. No. 109-148.

⁵¹ See 42 U.S.C. § 247d-6d, 6e.

⁵² *Pandemic Funding, Liability Shield Clear Congress*, CENTER FOR INFECTIOUS DISEASE RESEARCH AND POLICY (Dec. 28, 2005), <http://www.cidrap.umn.edu/news-perspective/2005/12/pandemic-funding-liability-shield-clear-congress> [<https://perma.cc/K848-W85P>].

⁵³ 42 U.S.C. § 247d-6d(b)(6).

⁵⁴ 42 U.S.C. § 247d-6d(b)(1).

⁵⁵ Ebola Virus Disease Vaccines-Amendment, 80 Fed. Reg. 76541 (Dec. 9, 2015), <https://www.federalregister.gov/articles/2015/12/09/2015-31088/ebola-virus-disease-vaccines-amendment#h-3> [<https://perma.cc/S27W-G2JG>].

has not been difficult to extend the duration of coverage for a vaccine that is protected by a PREP Act Declaration.⁵⁶

The PREP Act provides compensation to residents and health care workers for injuries directly caused by the administration or use of a countermeasure covered by the Secretary's declaration. Protection is granted, irrespective of the method by which the vaccine is sold and distributed (*i.e.*, government contracts, hospitals, etc.). Compensation is provided only for "serious injury," generally meaning injuries that warranted hospitalization or injuries that "led to a significant loss of function or disability," or for death.⁵⁷ Compensation extends to medical expenses, lost income, and death benefits.⁵⁸

The PREP Act's liability protection covers persons and entities involved in the manufacture, testing, distribution, administration, and use of covered countermeasures. The Act specifies that manufacturers are protected from liability, irrespective of how and under what conditions the vaccine is administered.⁵⁹ Once a PREP Act Declaration is published, immunity from tort lawsuits is absolute for the prescribed time period and within the designated area. The only statutory exception to this immunity is for actions or failures to act that constitute willful misconduct. Further, the statute defines "willful misconduct" narrowly, "establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness" and requiring wrongful intent.⁶⁰ A PREP Act Declaration does not create immunity for suits brought in jurisdictions outside the United States. The funding mechanism for PREP is an emergency fund administered by the Health Resources and Services Administration (HRSA), via the Countermeasures Injury Compensation Program (CICP). Although the CICP must be funded by congressional appropriation, Congress does not have to make the appropriation for the Secretary to issue a declaration.

H1N1 Letters of Agreement

In response to the swine flu epidemic in 2009, WHO sought to ensure that H1N1 vaccines would be available to the world's most vulnerable populations.⁶¹ The H1N1 Letters of Agreement were part of WHO's Vaccine Deployment Initiative, which coordinated the support of governments, foundations, and manufacturers facilitating access to H1N1 vaccines, and provided immunity to manufacturers and vaccine distributors.⁶² One of the primary functions of the Vaccine Deployment Initiative was organizing vaccine donations, working to craft legal agreements to protect donors (both manufacturers and distributors), and providing compensation for victims of

⁵⁶ See Pandemic Influenza Medical Countermeasures-Amendment, 80 Fed. Reg. 76506 (Dec. 9, 2015), <https://www.federalregister.gov/articles/2015/12/09/2015-31087/pandemic-influenza-medical-countermeasures-amendment> [<https://perma.cc/2HAD-F5RE>] (PREP Act Declaration for Pandemic Influenza amended several times since Oct. 2008 to provide additional time for coverage).

⁵⁷ 42 C.F.R. §§ 110.20, 110.3(z) (2018).

⁵⁸ 42 C.F.R. § 110.3 (2018).

⁵⁹ 42 U.S.C. § 247d-6d(a)(1) (2018).

⁶⁰ 42 U.S.C. § 247d-6d(c)(1) (2018).

⁶¹ See Report of the WHO Pandemic Influenza A (H1N1) Vaccine Deployment Initiative, World Health Organization (2012), available at http://www.who.int/influenza_vaccines_plan/resources/h1n1_deployment_report.pdf [<https://perma.cc/W49W-SALR>].

⁶² *Id.* At 9.

vaccine-related injuries. In coordination with key stakeholders, WHO adopted a global framework to provide comprehensive liability protections.⁶³

Provisions limiting liability were included in the Letters of Agreement between WHO and manufacturers.⁶⁴ For example, the Letters of Agreement provided that, in the event of any injuries as a result of the vaccine's use, manufacturers were discharged from liability, unless the injury was caused by a failure of the company to comply with current cGMP standards. These Letters of Agreement were signed by each recipient-country's government as a condition of receiving vaccines.⁶⁵

IV. PREFERRED APPROACH FOR MINIMIZING VACCINE MANUFACTURER LIABILITY

As previously discussed, the liability risks facing vaccine manufacturers are substantial and hard to predict. The risks are an important factor often cited as to why there is insufficient research and production of vaccines.⁶⁶ This insufficiency in research and production impairs global public health by leaving the world vulnerable to outbreaks of diseases like Ebola and Zika.⁶⁷

Domestic-level immunity and compensation programs provide precedents and potential models for a global solution to the problems of manufacturer liability and vaccine injury compensation. However, developing countries in Africa, most of Asia,⁶⁸ Central and South America, and the Middle East do not have compensation fund programs. Moreover, in the West African countries most seriously afflicted by epidemic outbreaks, the local legal systems present challenges to creating no fault compensation funds.⁶⁹ Future epidemics are likely to occur in parts of the world where such schemes do not exist, but the exact location of future epidemics is difficult to predict. Manufacturers developing vaccines for diseases in those regions or deploying vaccines there thus continue to face substantial liability risks. To incentivize manufacturers to support the development of vaccines against future epidemics and

⁶³ *Id.* at 8 (describing the dual donation system for manufacturers).

⁶⁴ *Id.* at 8-9.

⁶⁵ *Id.* at 9.

⁶⁶ See Paul A. Offit, *Why Are Pharmaceutical Companies Gradually Abandoning Vaccines?*, 24(3) HEALTH AFF. 622, 626-28 (2005); Sam Halabi & John Monahan, *Sharing the Burden of Ebola Vaccine Related Adverse Events*, 24 TUL. J. INT'L & COMP. L. 131 (2015); Amir Attaran & Kumanan Wilson, *The Ebola Vaccine, Iatrogenic Injuries, and Legal Liability*, 12(12) PLOS MED. Dec. 1, 2015, at 1, 2-4, <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001911> [<https://perma.cc/CU8D-M9RB>].

⁶⁷ See Stanley A. Plotkin, MD, Adel A.F. Mahmoud, MD, PhD, & Jeremy Farrar, MD, PhD, *Establishing a Global Vaccine-Development Fund*, 373 N. ENG. J. MED. 297-300 (2015), <http://www.nejm.org/doi/full/10.1056/NEJMp1506820> [<https://perma.cc/Q5VX-ZDDE>].

⁶⁸ South Korea, Taiwan, and Japan also have vaccine compensation funds that are government administered programs funded through vaccine taxes and donations. See Clare Looker & Heath Kelly, *No-Fault Compensation Following Adverse Events Attributed to Vaccination: A Review of International Programmes*, World Health Organization (Mar. 21, 2011), <http://www.who.int/bulletin/10-081901.pdf> [<https://perma.cc/ALG9-U8TT>].

⁶⁹ See Halabi, *supra* note 63, at 1 (noting the weakness of judicial systems in the countries most affected by Ebola).

pandemics, global mechanisms to address and restrict liability risks for manufacturers that develop or disseminate vaccines should be created.⁷⁰

A. *Global Treaty / Legislated Immunity*

For manufacturers, the solution that best minimizes liability risk is a globally-coordinated ***treaty-based immunity*** for injuries sustained as the result of the use of a vaccine for an infection of epidemic or pandemic potential. Immunity would not be available, however, if the injury was caused by a company's failure to comply with current Good Manufacturing

Practice (cGMP) standards. CGMP standards are safety standards set by the WHO to ensure that the production and control of medicinal products adheres to appropriate standards of quality. By tying immunity to adherence to these pre-set safety standards, vaccine manufacturers can be incentivized to maintain safe practices, while limiting their exposure to unpredictable liability. Such a treaty would establish a scheme somewhat like the VICP, with protections from liability to protect vaccine innovation and development, coupled with a no-fault compensation program to support people injured by vaccines.

Precedents for a comprehensive international vaccine development treaty exist. For example, a treaty established the International Vaccine Institute in 1996. This Institute was the result of an agreement by the Children's Vaccine Initiative (CVI), which is a coalition of governments, multilateral and bilateral agencies, NGOs, and industry that is dedicated to ensuring the availability of safe, effective and affordable vaccines; the development and introduction of improved and new vaccines; and strengthening the capacity of developing countries in vaccine development, production and use in immunization programs. While the Institute's core funding sources are from Korea and Sweden, the Institute also is funded by other Member States, international organizations, and also public and private agencies and institutions.⁷¹ In addition, the treaty provides for privileges and immunities for members of the Institute when exercising official duties.⁷²

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

⁷⁰ See Offit, *supra* note 63, at 628-29; Halabi, *supra* note 63; Attaran, *supra* note 63.

⁷¹ Accelerating Vaccines Critical to Global Health: 2017 Annual Report, International Vaccine Institute, 24-25, https://www.ivi.int/wp-content/uploads/2018/08/IVIAnnualReport2017_ENG.pdf.

⁷² Article XVII Privileges and Immunities, 1979 U.N.T.S. 214 (1997), <https://treaties.un.org/doc/Publication/UNTS/Volume%201979/v1979.pdf> [<https://perma.cc/L3MP-YRAQ>]; see also Agreement on the Establishment of the International Vaccine Institute, Amendments To The Constitution Of The International Vaccine Institute, Dec. 27, 2011, C.N.810.2011, U.N., <https://treaties.un.org/doc/Publication/CN/2011/CN.810.2011-Eng.pdf> [<https://perma.cc/8ZXL-QSFW>].

B. Alternative Frameworks for Protection: Epidemic Specific Immunity

An alternative and less ambitious approach to a comprehensive global treaty covering vaccines in general is to focus specifically on vaccines needed for particular epidemics. Such an approach could build on the approach of the United States Prep Act and the H1N1 Letters of Agreement discussed above.

1. CEPI Declaration Modeled After PREP Act Declaration

The Coalition for Epidemic Preparedness Innovations (“CEPI”) works to expand development of future vaccines. CEPI could work with the United Nations or other supranational bodies to create a framework that activates immunity protection, as well as compensation funding for vaccine-related injuries at the time of a future outbreak. Such a mechanism would provide immunity from suit in all Member States. Funding for a compensation fund enacted in conjunction with the triggering of an epidemic-specific declaration of immunity could be obtained by shifting monies from disease-specific funds (e.g., Ebola Recovery Fund) into a global disease fund.

A CEPI Declaration structure could be based on the blueprint of the PREP Act. As with the PREP Act, an official could declare an epidemic, and alongside the declaration specify certain covered medical treatments. Those treatments would fall within a liability shield protecting manufacturers, and be subject to a compensation program, perhaps one along the lines outlined below.

A global declaration of immunity of this magnitude should encourage manufacturers to cooperate readily with global health organizations and countries in responding to epidemics. There would not be the same certainty of immunity with a CEPI global declaration approach as will exist with treaty-based guaranteed immunity, however, because it will not always be clear beforehand whether a declaration will be issued for a particular vaccine. Ironically, with a global declaration approach, use of a vaccine to successfully prevent an epidemic before a declaration is issued could deny the manufacturer immunity protections because a vaccine prevented an epidemic and, therefore, did away with the basis for an emergency declaration. These drawbacks do not make an emergency declaration scheme a bad idea, but they illustrate why it remains inferior to a comprehensive global treaty.

2. Letters of Agreement Modeled After H1N1 Letters

Until a comprehensive global legislative solution is achieved, another option is to use the framework of the H1N1 Letters of Agreement discussed above. The Letters of Agreement would require the country receiving the vaccines or vaccine regimens to accept liability on behalf of its citizens before any vaccines could be deployed.

For vaccines deployed in times of emergency that are not licensed in the country of distribution, UNICEF similarly has recommended that the country or government receiving a vaccine during an outbreak be required to accept complete liability for any injuries its citizens sustained as a result of the use of that vaccine. UNICEF also has explained that the *waiver of liability* in favor of the manufacturer would be included

as a part of the terms and conditions on the vaccine request form, before the vaccine was shipped.⁷³

While Letters of Agreement need to be entered on a case-by-case basis, it is an alternative that has proven useful in the past and could be utilized until a comprehensive global legislative solution is achieved. A drawback to this mechanism, however, is that, without the existence of a global compensation fund, there will be countries that are unable to compensate their citizens for vaccine-related injuries. This is why immunity legislation and the creation of a global fund should be addressed together.

C. Global Compensation Fund

Whether the mechanism of immunity is a global treaty, a country-specific declaration, or an epidemic-specific declaration, the necessary complement to manufacturer immunity is a compensation scheme. An immunity regime without compensation may potentially leave people injured by vaccines in some parts of the world without a remedy. Combining an immunity scheme with a compensation program will protect individuals by giving them a prospect of compensation, while at the same time helping to insulate manufacturers from expensive and unpredictable litigation costs and liability determinations. Indeed, at the height of a West Africa Ebola outbreak in 2014 and 2015, non-governmental organizations advocated for the creation of a global no-fault compensation fund and an International Vaccine Court, but little progress appears to have been made on these initiatives.⁷⁴

Given these considerations, the global community needs to develop no-fault compensation systems that provide appropriate compensation to residents in low-income countries for vaccine-related injuries, as well as provide liability protection for manufacturers.⁷⁵

In this regard, CEPI could evaluate current compensation programs or funds that exist, and consider combining frameworks from the VICP⁷⁶ and the VDP Act,⁷⁷ as models for broader vaccine compensation coverage programs or funds for developing countries. Importantly, most existing compensation schemes are not the exclusive remedy for vaccine injury, while a global compensation fund would need to be the exclusive remedy for the cases it covers to provide the desired protection for vaccine manufacturers. Such a fund thus might need to be more robust than the compensation funds that currently exist. For example, once created, a global fund might cover noneconomic losses or have a relatively lower eligibility threshold. Similarly, in most countries, compensation schemes are secondary sources of funding for medical and

⁷³ See *Operational Framework for Monovalent Oral Poliovirus Type 2 (mOPV2) Deployment and Replenishment*, UNICEF (Oct. 9, 2014), http://www.who.int/immunization/sage/meetings/2014/october/4_Polio_mOPV2_stockpile_v4_09_10_2014.pdf [<https://perma.cc/9GZB-DWQR>].

⁷⁴ See generally *WHO High-level Meeting on Ebola Vaccines Access and Financing*, World Health Organization (Oct. 23, 2014), <http://www.who.int/mediacentre/news/ebola/23-october-2014/en/> [<https://perma.cc/F7RJ-EACU>]; Haass, at 247–48, 255.

⁷⁵ See Halabi, *supra* note 63; see also Attaran *supra* note 63. Both articles provide high level analysis of strategies for creating a no-fault compensation system for vaccine injuries.

⁷⁶ See Vaccine Injury Compensation Fund, 42 U.S.C. § 300aa-10 (1994).

⁷⁷ See Vaccine Damage Payments Act 1979, c.17 § 1 (1979), <http://www.legislation.gov.uk/ukpga/1979/17/section/1> [<https://perma.cc/8888-GNPW>]; see also *Vaccine Damage Payment*, GOV.UK, <https://www.gov.uk/vaccine-damage-payment/overview> [<https://perma.cc/8BC4-2KB4>]. In the UK victims may also go through the court system to receive compensation.

disability expenses, while government-sponsored healthcare program or insurance companies provide the primary form of relief.⁷⁸ The funding for a global compensation scheme, operating in countries where government-sponsored healthcare or insurance is not readily available, will need to be sufficiently robust to account for this difference.

A global compensation fund, modeled on the VICP and/or the VDP Act, needs to be part of a new international approach that combines limitations on manufacturer liability with reasonable sources of compensation for injured vaccine recipients. The overarching issue with the creation and maintenance of a global compensation program is funding. Citizens in developing countries should not be expected to pay anything for access to vaccinations during an epidemic. Further, implementing an excise tax in developed countries for vaccinations that are meant for people in undeveloped countries is a regressive way to capitalize a compensation fund. Researchers have suggested it will be more equitable for donors to capitalize the fund directly.⁷⁹ According to vaccine experts, this approach should hasten the deployment of vaccines in developing countries, without delays associated with worries about liability risks.⁸⁰ Researchers also have suggested that donor funding is consistent with a global collective interest of security from future epidemic outbreaks.⁸¹

In the context of a new epidemic, an additional advantage of liability protections coupled with a global compensation fund is that it may serve as an incentive for vaccine manufacturers to share information amongst themselves about research and safety testing data. Such information is generally considered proprietary, and not usually disclosed to protect a manufacturer's investment in research and testing, which can lead to slowdowns in vaccine development at a time when speed is of the essence. Participation in an immunity and compensation program, a protection of substantial value to manufacturers, could perhaps be conditioned on manufacturers agreeing to share information with public health authorities and other manufacturers.⁸²

V. IMPROVING AWARENESS

In conjunction with developing risk-reduction strategies, supranational bodies should enter into dialogues with governments and stakeholders around the world, to develop a better mutual understanding of the risks and benefits associated with immunization, vaccine development and vaccine liability.⁸³ Because vaccines may be associated with serious adverse events,⁸⁴ a necessary component of this dialogue should address both community and cultural views on the importance of mass immunization generally, as well as the importance of having manufacturers work expeditiously on the development of vaccines that are needed in case of outbreaks in

⁷⁸ Looker, *supra* note 65.

⁷⁹ Attaran, *supra* note 63, at 4.

⁸⁰ *Id.* at 4–5.

⁸¹ *Id.* at 4.

⁸² See generally Suerie Moon et al., *Will Ebola Change the Game? Ten Essential Reforms Before the Next Pandemic*, 386 *Lancet* 2204, 2213–14 (2015) (on the significance of information-sharing).

⁸³ See, e.g., Innovative Medicines Initiative, *Project Factsheets*, <http://www.imi.europa.eu/content/ongoing-projects?training=118> [<https://perma.cc/S276-SJFJ>] for a list of Europe's Partnership Projects.

⁸⁴ Aaron Kesselheim, *Safety, Supply, and Suits – Litigation and the Vaccine Industry*, 364 *N. ENG. J. MED.* 1485, 1485 (2011), <http://www.nejm.org/doi/pdf/10.1056/NEJMp1102182> [<https://perma.cc/872Z-G3GD>].

developing countries. A better understanding of the benefits and risks of vaccination could improve awareness as to why removing or reducing liability considerations makes sense.

VI. CONCLUSION

Vaccines are among the most cost-effective interventions in health care, and the public health benefits of vaccination are clear. Some years ago, WHO estimated that more than 2.5 million deaths have been prevented through the use of vaccine immunization programs.⁸⁵ And a key to increased use of preventative care and early vaccination is increased trust in and understanding of vaccinations.⁸⁶

While the utility of vaccines to the global community seems clear, the fact that the risks concerning the deployment of vaccines during an outbreak currently fall largely on the vaccine manufacturers needs to be addressed. There is little incentive for vaccine manufacturers to invest in developing and deploying vaccines during outbreaks, when the risk of civil liability is great. Until this issue is solved by way of treaty-based immunity, linked with some type of global compensation fund, there will continue to be gaps in immunization programs in many parts of the world because effective vaccinations will not be readily available for future pandemics and epidemics.

In addition to addressing this risk management issue, better dialogue on the benefits of vaccination programs, and transparent information on the expenses and time necessary for completing clinical trials and licensing vaccines,⁸⁷ should lead to better understanding and acceptance that manufacturers cannot, and should not, solely bear the burden of liability for vaccines that are deployed to combat epidemics or neglected diseases.

⁸⁵ Aaron Kesselheim, *Safety, Supply, and Suits – Litigation and the Vaccine Industry*, 364 N. ENG. J. MED. 1485, 1485 (2011), <http://www.nejm.org/doi/pdf/10.1056/NEJMp1102182> [<https://perma.cc/872Z-G3GD>].

⁸⁵ Looker, *supra* note 65.

⁸⁶ Sandra Crouse Quinn et al., *Exploring Communication, Trust in Government, and Vaccination Intention Later in the 2009 H1N1 Pandemic: Results of a National Survey*, 11(2) BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC., & SCI. 96, 96 (2013).

⁸⁷ Thomas J. Hwang & Aaron S. Kesselheim, *Vaccine Pipeline Has Grown During the Past Two Decades with More Early-Stage Trials from Small and Medium-Size Companies*, 35(2) HEALTH AFF., 219, 220-221 (2016), <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2015.1073> [<https://perma.cc/JEN5-HZWF>].