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ESSAY

Long-Term Immunity: Protecting Drug Developers from Liability for Late–Occurring Serious Reactions to Emergency Vaccines

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Introduction

A woman in the Bahamas perishes after smallpox-laced bioweapons escape from a U.S. laboratory. She and twenty other Bahamians do not die from the scourge but from a serious reaction to an emergency vaccine that occurs years after injection. Consequently, the vaccine developer folds under the weight of crushing liability. Later, when another accident spreads the same strain among Americans, vaccine developers and the public refuse to tolerate a repeat performance: Developers will not distribute new smallpox vaccines, and healthcare workers will not get vaccinated. This hypothetical scenario is not far off from a real smallpox vaccination campaign that failed amid bioterrorism threats in the early 2000s, and nothing is to stop it from happening in the future.[1]

True story: Five years after receiving trial vaccines for a fatal virus as children, adolescents in the Philippines experienced adverse reactions that

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1. *See* Steve Bice & Kevin Yeskey, *Poxvirus Countermeasures During an Emergency in the United States*, 9 DISASTER MED. & PUB. HEALTH PREPAREDNESS 121, 121-22 (2015); Pascale M. Wortley, Benjamin Schwartz, Paul S. Levy, Linda M. Quick, Brian Evans & Brian Burke, *Healthcare Workers Who Elected Not to Receive Smallpox Vaccination*, 30 AM. J. PREVENTIVE MED. 258, 258, 261 (2006).

killed them.[2] The virus itself, dengue, kills about 20,000 people each year, mainly children, typically in low-income, tropical countries.[3] Accordingly, an effective inoculation against the disease can save lives and cut healthcare costs. However, an estimated 10 to 600 deaths[4] were attributed to the dengue vaccine, and Sanofi Pasteur, the vaccine developer, confronted criminal indictments, compensation costs, and other liabilities.[5] As a result, people in the Philippines and other dengue-plagued countries[6] rejected the potentially-lifesaving vaccine and other immunizations.[7]

The injuries following the dengue vaccine campaign and any ones that follow a future, potential smallpox vaccine rollout exemplify "latent" serious adverse reactions,[8] meaning deaths, life-threatening injuries, or hospitalizations that occur years after a medical intervention.[9] The problem—

2. *See* Michaeleen Doucleff, *Rush to Produce, Sell Vaccine Put Kids in Philippines at Risk*, NPR (May 3, 2019, 2:53 PM ET), https://perma.cc/Z8V9-R5H4 (estimating "more than 100,000 Philippine children received a vaccine that health officials say increased their risk of a severe and sometimes deadly condition"); Saranya Sridhar et al., *Effect of Dengue Serostatus on Dengue Vaccine Safety and Efficacy*, 379 NEW ENG. J. MED. 327 (2018). The Sanofi Pasteur Protocol for the dengue vaccine child trial is available at https://perma.cc/7UMD-W2W8 (archived Nov. 18, 2023) ("Planned Trial Period: June 2011 to March 2016… The study duration is 4 years to enable observation of the incidence of dengue for 5 years after the completion of the injection schedule of the first efficacy study of CYD dengue vaccine candidate.").

3. Sam F. Halabi, *Solving the Pandemic Vaccine Product Liability Problem*, 12 U.C. IRVINE L. REV. 111, 129 (2021).

4. *See* Doucleff, *supra* note 2.

5. *See* Halabi, *supra* note 3, at 129-31.

6. *See* Michaeleen Doucleff, *Vaccine Safety Concerns Shut Down Immunization Campaign in Philippines,* NPR, (Dec. 5, 2017, 12:38 PM ET), https://perma.cc/J3XT-7UM6. ("[T]he Philippines suspended a mass immunization campaign, which has already given one dose of the vaccine to more than 700,000 children. And the Brazilian government has tightened restrictions on the shot.").

7. *See* Heidi J. Larson, Kenneth Hartigan-Go & Alexandre de Figueiredo, *Vaccine Confidence Plummets in the Philippines Following Dengue Vaccine Scare: Why It Matters to Pandemic Preparedness*, 15 HUM. VACCINES & IMMUNOTHERAPEUTICS 625, 625-27 (2019); *see also Questions and Answers on the Measles Outbreak in the Philippines*, WORLD HEALTH ORG. (Feb. 26, 2019), https://perma.cc/L5WM-VU2U (noting confidence in the measles vaccine decreased in the Philippines following the dengue vaccine issue).

8. *See* 21 C.F.R. § 312.32 (2021) ("*Serious adverse event* or *serious suspected adverse reaction.* An adverse event or suspected adverse reaction is considered 'serious' if, in the view of either the investigator or sponsor, it results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.").

9. *See* Kirsten S. Vannice et al., *Clinical Development and Regulatory Points for Consideration for Second-Generation Live Attenuated Dengue Vaccines*, 36 VACCINE 3411, 3412-13 (2018) ("[U]nexpected findings . . . raised concerns of late onset vaccine-associated enhanced disease, which were later corroborated by [Sanofi's] new analysis.").

though rare[10] and greatly outweighed by the benefits of most vaccines[11]—is unavoidable and devastating. Exigent circumstances accelerate vaccine development to the point where companies cannot monitor for the kinds of side effects that surface over time.[12] The lack of safety data has a ripple effect: Drug developers often stall distributions of life-saving vaccines for fear of unknowable and potentially bankrupting liabilities, and, in turn, the public has little access to or confidence in the safety of measures that can end an epidemic.[13] The issue is most pronounced in low-income countries that cannot afford to immunize companies against liability for injury compensation claims.[14]

While latent reactions may be unavoidable, the legal issues that delay the development and reach of emergency vaccines are not. To ensure that lives are not lost on the negotiating table in the future, the international community must immediately create a standard, ample window between the date of an emergency vaccination and the onset of symptoms, during which developers receive immunity against injury liability. Granted, countries must install the

10. *Vaccines and Immunization: Vaccine Safety*, WORLD HEALTH ORG. (Mar. 30, 2020), https://perma.cc/3FVF-UXPA ("[Side effects] are usually very minor and of short duration, such as a sore arm or a mild fever. More serious side effects are possible, but extremely rare. A person is far more likely to be seriously harmed by a disease than by a vaccine."); *see* Pam Belluck & Reed Abelson, *Vaccine Injury Claims Are Few and Far Between*, N.Y. TIMES (Jun. 18, 2019), https://perma.cc/X8JB-N35Z.

11. *See, e.g.*, Rontgene Solante et al., *Expert Review of Global Real-World Data on COVID-19 Vaccine Booster Effectiveness and Safety During the Omicron-Dominant Phase of the Pandemic*, 22 EXPERT REV. VACCINES 1, 1 (2023) (finding that the benefits of the COVID-19 vaccine vastly outweighed any harms); Peter J. Hotez et al., *COVID-19 Vaccines and the Pandemic: Lessons Learnt for Other Neglected Diseases and Future Threats*, BMJ GLOB. HEALTH, June 2023, at 1, 2 ("[M]ultiple COVID-19 vaccines were developed, tested, manufactured 'at risk' (meaning their production started before completing the clinical trials) and approved. Over 11 billion doses have been delivered globally, with estimates that such vaccines may have saved millions of lives.").

12. *See* John D. Winter, Camille L. Fletcher & Greg Margolis, *Vaccine-Related Liability: Past Approaches, Current Challenges, and Proposals for Encouraging Future Innovation and More Widespread Vaccine Use*, 76 FOOD & DRUG L.J. 270, 315 (2021) ("The safety profile of COVID-19 vaccines necessarily should and will evolve over time.").

13. *See id.* at 276 (noting that vaccine development "create[s] disincentives for manufacturers" because "vaccines are notoriously difficult to develop, vaccines can have deadly consequences, even an effective vaccine may not be adopted because of fears about side effects that create expensive litigation, and vaccines are not nearly as profitable as treatments for chronic illnesses"); Adam Cancryn, Sarah Owermohle & Erin Banco, *Moderna Nears Deal to Pledge More Vaccines to Lower-Income Countries*, POLITICO (Nov. 15, 2021, 9:01 PM EST), https://perma.cc/N24K-Q9SY (noting the "delays and difficulties" in delivering COVID vaccine doses to low-income countries).

14. *See* Josh Michaud & Jennifer Kates, *The COVAX Humanitarian Buffer for COVID-19 Vaccines: Review and Assessment of Policy Implications*, KFF (Nov. 30, 2022), https://perma.cc/5AMS-W52C ("Lower-income countr[ies] . . . faced the same liability issues, but many were not in a position to address them fully or in a timely fashion.").

window in a way that deters developers from short-shifting safety.[15] For this reason, the window must waive corporate immunity for negligence[16] and stretch no farther than the average timespan required to discover latent reactions.[17]

Stalled rollouts of COVID-19 vaccines jumpstarted experimentation with liability immunity windows. Most safe harbors were part of no-fault compensation programs, initiatives where a claimant does not need to prove a vaccine caused an injury so long as it occurred within a specified time limit for the onset of symptoms.[18] In particular, a World Health Organization (WHO)-sanctioned program, COVAX—conscious of the five-year timespan between dengue vaccinations and discoveries of fatalities—provided no-fault compensation for COVID-19 vaccine injuries that occurred up to five years after the date of vaccination, depending on how early in the distribution cycle the claimant was vaccinated.[19]

Legal scholarship has since begun to evaluate programs adopted pursuant to the COVID-19 pandemic that immunize developers against liability for injuries during emergencies in low-income countries.[20] But little scholarship has assessed the problem of liability for injuries that emerge years after the dispensation of emergency countermeasures.

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15. *See* Duncan Fairgrieve et al., *Comparing No-Fault Compensation Systems for Vaccine Injury*, 31 TUL. J. INT'L & COMPAR. L. 75, 117 (2023) ("[I]t is equally important to ensure that a deterrence function of liability is maintained, and that states avoid a systematic and unjustifiable socialization of risk and privatization of profits.").

16. *See* Ezekiel J. Emanuel et al., *What Are the Obligations of Pharmaceutical Companies in a Global Health Emergency?*, 398 LANCET 1015, 1018-19 (2021), ("Pharmaceutical companies should not bear strict liability: that is, liability for harms that occur despite reasonable precautions" because "[c]ompanies are accelerating vaccine availability at society's behest" and "strict liability would incentivise companies to sell the vaccine primarily to countries that can provide greater insulation from liability . . . . By contrast, companies should be liable for harms due to negligence in manufacturing or postmarketing surveillance or due to data concealment.").

17. *See infra* Part III.

18. *See generally* Sam Halabi, Katherine Ginsbach, Katie Gottschalk, John Monahan & Judith Murungi, *No-Fault Vaccine Injury Compensation Systems Adopted Pursuant to the COVID-19 Public Health Emergency Response*, 37 EMORY INT'L L. REV. 55 (2022).

19. *See Program Protocol*, COVAX AMC, https://perma.cc/SL3U-6B3A (archived Nov. 18, 2023) ("[I]f the Vaccine was administered to the Patient before 30 June 2024, add another 36 months to establish the Reporting Period that applies to the Patient; or if the Vaccine was administered to the Patient between 30 June 2024 and 30 June 2025, the Reporting Period that applies to the Patient ends on 30 June 2027."); Webinar on Promoting Legal Preparedness & Equity Through Liability Risk Management, held by the Global Health Security Agenda (Oct. 12, 2022).

20. *See, e.g.*, Fairgrieve et al., *supra* note 15; Halabi, Ginsbach, Gottschalk, Monahan & Murungi, *supra* note 18; Halabi, *supra* note 3.

Immunity windows covering side effects of vaccines along with other emergency interventions (such as reactions to Cold War nuclear testing material and debris at September 11th attack sites) vary from country to country.[21] Some policies indemnify developers and governments for injuries that occur mere hours[22] after the intervention while others provide coverage for symptoms that manifest years after the trigger event.[23] In addition, some programs extend the window to cover new injuries and injured populations.[24]

By contrast, systems that hold companies or low-income countries liable for vaccine injuries in perpetuity may do more harm than good. For instance, India instituted a program holding developers responsible for clinical trial injuries that critics argued will discourage companies from investing in Indian

21. *See* AXA, TERMS AND CONDITIONS FOR THE INDEMNITY FUND FOR ADVERSE EVENTS FOLLOWING IMMUNIZATION WITH CORONAVIRUS DISEASE-2019 (COVID-19) VACCINES (AEFI FUND) (last updated 2022), https://perma.cc/D6DY-JP52 ("The time limit of which an applicant can apply . . . is within two (2) years after the last dose of the vaccine was received. . . . In the event where the applicant had been confirmed of one or more SAEs, and who subsequently succumbed within two (2) years of vaccination of the last dose of the vaccine, then the applicant would be entitled to the death payout."); PHILHEALTH, IMPLEMENTING GUIDELINES ON THE COVERAGE OF COVID-19 VACCINE INJURY DUE TO SERIOUS ADVERSE EFFECTS (SAES) FOLLOWING IMMUNIZATION RESULTING IN HOSPITALIZATION, PERMANENT DISABILITY, OR DEATH UNDER THE COVID-19 NATIONAL VACCINE INDEMNITY FUND (THE COVID-19 VACCINE INJURY COMPENSATION PACKAGE) (2021), https://perma.cc/4QRR-KFWG; *see also* An Act Establishing the Coronavirus Disease 2019 (COVID-19) Vaccination Program Expediting the Vaccine Procurement and Administration Process, Providing Funds Therefor, and for Other Purposes, Rep. Act No. 11525, (Feb. 26, 2021) (Phil.), https://perma.cc/U2S8-P4DX. *See generally Countermeasures Injury Compensation Program (CICP)*, HEALTH RES. & SERVS. ADMIN., https://perma.cc/6GU6-XBKL (archived Nov. 18, 2023) ("You must file a Request for Benefits Package within one year of receiving or using the countermeasure that you believe caused the injury.").

22. *See* 42 C.F.R. § 110.100 (2021).

23. *E.g.*, SEPTEMBER 11TH VICTIM COMPENSATION FUND, VCF GENERAL INFORMATION (last updated 2023) https://perma.cc/U3SB-G4KA.

24. *Cf.* SCOTT D. SZYMENDERA, CONG. RSCH. SERV., R43956, THE RADIATION EXPOSURE COMPENSATION ACT (RECA): COMPENSATION RELATED TO EXPOSURE TO RADIATION FROM ATOMIC WEAPONS TESTING AND URANIUM MINING 11 (2022) [hereinafter SZYMENDERA, RECA] ("The current downwinder eligibility area was established with the enactment of the 2000 RECA amendments, which added geographical areas in Arizona and Utah"); SCOTT D. SZYMENDERA, CONG. RSCH. SERV., R45969, THE SEPTEMBER 11TH VICTIM COMPENSATION FUND (VCF) 2 (2019) [hereinafter SZYMENDERA, VCF] ("The original VCF closed to new claims in December 2003. However, concerns about injuries and illnesses incurred by persons involved in emergency response, recovery, and debris removal operations at the September 11th aircraft crash sites led Congress to reopen the VCF."); *About the Victim Compensation Fund*, SEPTEMBER 11TH VICTIM COMPENSATION FUND, https://perma.cc/6AB5-DHXU (archived Nov. 18, 2023) (On July 29, 2019, the VCF Permanent Authorization Act extended the claim filing deadline to October 1, 2090.").

laboratories.[25] And a tentative WHO contract for smallpox vaccine distribution that holds recipient governments, even low-income ones, liable for injuries may leave much of the globe unvaccinated.[26]

The reason why immunity windows vary is that they were adopted impromptu in a time of urgency. To this point, each immunity program has addressed one health crisis[27] on a temporary basis,[28] often with little forethought.[29] Now, in advance of the next global health crisis, transnational and civil society organizations,[30] including the WHO, are preparing an emergency vaccine injury compensation regime that will serve low-income countries in any crisis.[31] The duration of liability immunity for vaccine developers is a part of those discussions.[32]

Given such global inconsistency, this Essay argues that, to accelerate emergency vaccine innovation and global access, the WHO must set a standard, five-year no-fault window—spanning from the date of vaccination to the onset of symptoms—that allows extensions to cover new symptoms, and during which developers receive immunity against injury liabilities except for those caused by negligence. Unless otherwise stated, this paper presupposes that a compensation pool is in place, where wealthy nations and the vaccine industry bear the cost of compensation to receive the benefits of herd

25. Mark Barnes, Jamie Flaherty, Minal Caron, Alishan Naqvee & Barbara Bierer, *The Evolving Regulatory Landscape for Clinical Trials in India*, 73 FOOD & DRUG L.J. 601, 609, 616-17 (2018).

26. *See* WORLD HEALTH ORG., OPERATIONAL FRAMEWORK FOR THE DEPLOYMENT OF THE WORLD HEALTH ORGANIZATION SMALLPOX VACCINE EMERGENCY STOCKPILE IN RESPONSE TO A SMALLPOX EVENT 6 (2017).

27. *See, e.g.*, WORLD HEALTH ORG., WORKSHOP ON EXPANDED ACCESS TO EXPERIMENTAL EBOLA VACCINES DURING OUTBREAKS 21 (2017).

28. *See, e.g.*, COVAX AMC, *supra* note 19 ("The Program's application process will come to an end on 30 June 2027.").

29. *See* Ann Silversides, *Fault/No Fault, Part 3: Vested Interests and the Silence of Suffering Patients Cited as Obstacles to System Change*, 179 CMAJ 515, 515 (2008) ("The federal and provincial compensation plans that were introduced in the wake of Canada's tainted blood scandal are one example of the ad hoc no-fault programs that have sprung up, usually in response to a crisis.").

30. *Legal Preparedness Action Package*, GLOB. HEALTH SEC. AGENDA, https://perma.cc/8ND5-KHCJ (archived Nov. 18, 2023).

31. *See* Global Health Security Agenda, *Public Launch of the GHSA Legal Preparedness Action Package*, YOUTUBE (Mar. 31, 2022), https://perma.cc/6HXK-SHGW; Webinar on Promoting Legal Preparedness & Equity Through Liability Risk Management, held by the Global Health Security Agenda (Oct. 12, 2022).

32. Webinar on Promoting Legal Preparedness & Equity Through Liability Risk Management, held by the Global Health Security Agenda (Oct. 12, 2022).

immunity[33] and appropriate risk allocation,[34] and injuries meet all other criteria for any compensation, including causation and severity. Part I describes liability issues surrounding unknown side effects that obstructed widespread use of vaccines during the dengue outbreak in the Philippines, COVID-19 pandemic, and smallpox bioterrorism threats. Part II explores strengths and weaknesses of existing liability regimes in addressing latent reactions to emergency interventions. Part III concludes by constructing a five-year adjustable system that draws on the strengths and weaknesses of liability immunity windows within those existing regimes.

I. Injury Liabilities Obstruct the Fight Against Pandemics

The vaccine development process typically lasts a decade, which allows developers to fully understand and find ways of alleviating latent side effects.[35] When a public health emergency turns deadly, governments understandably feel that the benefit of mass distribution of a life-saving vaccine outweighs the risk involved in fast-tracking approval of a drug with a limited safety profile.

The distribution of Sanofi's dengue vaccine to Filipinos is one such case. While not an emergency-use drug, the vaccine never underwent a reliable regulatory review[36] before mass distribution to 830,000 children in the Philippines region where dengue is endemic.[37]

After a five-year trial period between June 2011 and March 2016,[38] Sanofi discovered that vaccinated children who had never been infected with dengue were at high risk of deadly side effects.[39] Sanofi then struggled with profit

33. *See* Halabi, Ginsbach, Gottschalk, Monahan & Murungi, *supra* note 18, at 61-62 ("Leaving those individuals and their families to bear the costs of their injuries would mean that the community would benefit from these individuals' contributions to herd immunity, leaving the uninjured to receive a health benefit at the cost of the injured.").

34. *See* Fairgrieve et al., *supra* note 15, at 117 ("[A]ccountability and deterrence-based arguments might suggest that there should also be a participation from industry, which is responsible for developing, producing, and ultimately selling vaccines. Otherwise, there may be an unjustifiable transfer of risk to the public sector.").

35. *See COVID-19: Federal Efforts Accelerate Vaccine and Therapeutic Development, but More Transparency Needed on Emergency Use Authorizations*, U.S. GOV'T ACCOUNTABILITY OFF. (Nov. 17, 2020), https://perma.cc/AM5S-T4ZD.

36. *See* Eric Sagonowsky, *Years Into Troubled Launch, Vaccine Head Says Sanofi's Learned Some Dengvaxia Lessons*, FIERCE PHARMA (Jan 8, 2019, 8:36 AM), https://perma.cc/X54E-X83X ("[L]aunching a new shot without FDA or EMA approvals is 'really hard,' because other regulatory authorities often look to those agencies for their own guidelines.").

37. Halabi, *supra* note 3, at 130.

38. Saranya Sridhar et al., supra note 2.

39. *See* Vannice et al., *supra* note 9, at 3413 (2018) ("There were several unexpected findings in the trials that challenged previously held ideas about how this vaccine protects and

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losses[40] and liabilities[41] for vaccine injuries in the low-middle-income country. Relatedly, people in the Philippines and other dengue-plagued countries who were not at risk of adverse reactions rejected the otherwise effective dengue vaccine and vaccines for a measles epidemic.[42] These consequences that Sanofi and Filipinos suffered underscore the need for an immunity window that spans at least five years.

At the peak of the COVID-19 pandemic, mindful of Sanofi's losses, vaccine-makers refused to contract with low- and middle-income countries that were unable to afford to indemnify them against liabilities. Consequently, economically unstable countries, including Afghanistan, Burundi, the Philippines, and Nigeria, were among the least vaccinated populations.[43] And most of the top 50 unvaccinated countries were low- and middle-income countries.[44]

At present, the latency of COVID-19 vaccine injuries is unknown. New reactions to the 2020-2023 vaccine cycle are still emerging, other ones may erupt in the future,[45] and data collection on known reactions, including blood

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the groups in whom protection might be greatest, and raised concerns of late onset vaccine-associated enhanced disease, which were later corroborated by the company's new analysis.").

40. Matthias Blamont, *Sanofi's Return to Profit Growth this Year Slower than Hoped*, REUTERS (Feb. 6, 2018, 10:46 PM), https://perma.cc/865H-85UC ("[N]et profit in the fourth quarter of 2017 was hit by an impairment of 87 million euros ($107 million) related to Dengvaxia, its dengue vaccine at the center of a health scare in the Philippines.").

41. Halabi, *supra* note 3, at 131 ("Alleged delays by Sanofi in disclosing safety signals following Dengvaxia campaigns have resulted in criminal indictments against Sanofi executives, demands for repayment of the price of the Dengvaxia doses, and additional liabilities related to ten deaths attributed to Dengvaxia administration.").

42. Doucleff, *supra* note 6 ("[T]he Philippines suspended a mass immunization campaign, which has already given one dose of the vaccine to more than 700,000 children. And the Brazilian government has tightened restrictions on the shot."); *see* Larson et al., *supra* note 7, at 625 (2019) ("The result was broken public trust around the dengue vaccine as well [as] heightened anxiety around vaccines in general . . . . The findings reflect a dramatic drop in vaccine confidence from 93% 'strongly agreeing' that vaccines are important in 2015 to 32% in 2018 . . . similarly confidence in the effectiveness of vaccines dropped from 82% in 2015 to only 22%."); *see also Questions and Answers on the Measles Outbreak in the Philippines*, WORLD HEALTH ORG. (Feb. 26, 2019), https://perma.cc/N7KS-LK6H ("Vaccine confidence has also decreased in the Philippines following the dengue vaccine (Dengvaxia) issue."); Doucleff, *supra* note 2 ("As result, vaccine coverage for childhood diseases in the Philippines, such as the measles, has dropped . . . . And the Philippines is now facing a large measles outbreak, with more than 26,000 cases and more than 355 deaths during 2019.").

43. *See* Philip Schellekens, *The 50 Least Vaccinated Countries of the World*, PANDEMIC (2022), https://perma.cc/BB5U-CKL4 (last updated Sept. 13, 2023).

44. *Id.*

45. *See* Kawthar Mohamed et al., *COVID-19 Vaccinations: The Unknowns, Challenges, and Hopes*, 94 J. MED. VIROLOGY 1336, 1340 (2022).

clots, heart conditions, and potential risk of autoimmune diseases, is limited. For instance, adolescent and young adult men appear at risk of developing myocarditis, an inflammation of the heart muscle,[46] and long-term follow-up data is meager.[47] Meanwhile, young women and people with a genetic background of autoimmunity may be more vulnerable to developing autoimmune diseases after vaccination.[48] And the WHO reports that some cases of thrombosis with thrombocytopenia syndrome (TTS), which causes blood clots in large blood vessels and low platelets (blood cells that help form clots),[49] are presenting beyond 30 days of vaccination.[50] Also, doctors are calling for further research into risk factors that predispose certain populations to TTS.[51] COVID-19 has shown that the immunity window for future emergency vaccines must be longer than three years to ensure that companies invest in drug development and avoid disparities in vaccination rates.

Moreover, absent such protection, the public and vaccine distributors will confront a danger that eclipses those of the dengue and COVID-19 situations if smallpox breaks out. There are three reasons for concern.

First, no one has tested the only U.S.-licensed smallpox vaccine, ACAM2000, on a large civilian population.[52] Wetvax and IMVAMUNE, backup vaccines, are unapproved emergency-use drugs.[53] Second, the severity

46. *Selected Adverse Events Reported After COVID-19 Vaccination*, CDC (last updated Sept. 12, 2023), https://perma.cc/SAG8-JND7.

47. Jennifer Pillay, Lindsay Gaudet, Aireen Wingert, Liza Bialy, Andrew S Mackie, D. Ian Paterson & Lisa Hartling, *Incidence, Risk Factors, Natural History, and Hypothesised Mechanisms of Myocarditis and Pericarditis Following Covid-19 Vaccination: Living Evidence Syntheses and Review*, 378 BMJ, e096445, at 10 (2022).

48. Rossella Talotta, *Do COVID-19 RNA-Based Vaccines Put at Risk of Immune-Mediated Diseases? In Reply to "Potential Antigenic Cross-Reactivity Between SARS-CoV-2 and Human Tissue with a Possible Link to an Increase in Autoimmune Diseases"*, 224 CLINICAL IMMUNOLOGY 108665, 108665 (2021); *see also* Mohamed et al., *supra* note 45, at 1340.

49. *Selected Adverse Events Reported After COVID-19 Vaccination*, *supra* note 49.

50. WORLD HEALTH ORG., GUIDANCE FOR CLINICAL CASE MANAGEMENT OF THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME (TTS) FOLLOWING VACCINATION TO PREVENT CORONAVIRUS DISEASE (COVID-19) 6 (2021), https://perma.cc/RR5T-5JGF.

51. *See, e.g.*, Michel Goldman & Cédric Hermans, *Thrombotic Thrombocytopenia Associated with COVID-19 Infection or Vaccination: Possible Paths to Platelet Factor 4 Autoimmunity*, 18 PLOS MED. e1003648, at 5 (2021), https://perma.cc/D3Y7-VJEF.

52. *See* Dirk Haselow, *Vaccination-Related Side Effects, Humoral Immunity, and Adverse Events During the Civilian Smallpox Vaccination Campaign, Arkansas, 2003*, 33 PUB. HEALTH NURSING 129, 129-30 (2016), https://perma.cc/V9CT-B3PV.

53. Bice & Yeskey, *supra* note 1, at 123; *see* Catherine Yen et al *The Development of Global Vaccine Stockpiles*, 15 LANCET INFECTIOUS DISEASES 340, 345 (2015) ("[M]ost available smallpox vaccines are either no longer licensed (first generation vaccines) or not widely licensed (second and third generation vaccines) and this might be a barrier to vaccine acceptance in the event of an epidemic.").

of adverse reactions to smallpox vaccines, in general, surpasses the gravity of those associated with any other vaccine.[54] ACAM2000 can lead to cardiac disease and other fatal conditions, such as encephalopathies, progressive vaccinia, generalized vaccinia, erythema multiforme major, eczema vaccinatum, and fetal death.[55] Third, when bioterrorism spiked in the wake of the September 11, 2001 attacks, a U.S. program aimed at vaccinating 500,000 civilian public health workers with Dryvax[56] (a no longer available smallpox vaccine) to protect the workforce in the event of a smallpox attack vaccinated only 39,213 (10%) of them.[57] Acceptance faltered because, among other things, most civilians, including healthcare workers, did not expect to receive compensation for serious side effects.[58] Today, studies still have not pinpointed any early symptoms that may predict the onset of serious reactions.[59] For these reasons, a moderate-length window for corporate immunity and no-fault compensation must be in place and communicated before the start of biowarfare or any other public health crisis.

II. Strengths and Weaknesses of Existing Immunity Windows for Late-Occurring Vaccine Injuries

Global experiments with liability immunity windows for reactions to COVID-19 vaccines, routine inoculations, and toxic exposures suggest that a baseline of at least five years will suit the bulk of reactions to emergency interventions.

Most notably, during the COVID-19 pandemic, the WHO's COVAX launched a no-fault compensation program in low-and-middle-income

54. Bice & Yeskey, *supra* note 1, at 122 ("Severe adverse events associated with traditional replicating smallpox vaccine are generally considered more dangerous than adverse events associated with other vaccines.").

55. *Id.* at 123.

56. Haselow, *supra* note 52, at 129-30.

57. Bice & Yeskey, *supra* note 1, at 121-22 ("[T]he National Smallpox Vaccination Program, a campaign aimed at voluntarily vaccinating 500,000 health care workers and first responders against smallpox aimed to ensure a protected workforce in case of an intentional release of the virus . . . . [and] used Dryvax, a previously manufactured [vaccine]."); Edward P. Richards, Katharine C. Rathbun & Jay Gold, *The Smallpox Vaccination Campaign of 2003: Why Did It Fail and What Are the Lessons for Bioterrorism Preparedness?*, 64 LA. L. REV. 851, 851-52 (2004) (noting that "[t]here were no specific plans to vaccinate the general population," and, after nearly a year, "only 39,213 civilian health-care and public health workers were vaccinated, less than ten percent of the original goal.").

58. *See* Pascale M. Wortley, Benjamin Schwartz, Paul S. Levy, Linda M. Quick, Brian Evans & Brian Burke, *Healthcare Workers Who Elected Not to Receive Smallpox Vaccination*, 30 AM. J. PREVENTIVE MED. 258, 260-62 (2006).

59. *See, e.g.*, Haselow, *supra* note 52, at 136.

countries[60] for injuries that occur up to five years after vaccination, depending on the date of vaccination.[61] In "recognition of the fact that certain serious adverse events may take a long time to manifest, think about, for example, the dengue vaccine," a vaccinated individual has "a long reporting period" after an injury to apply for compensation, Anne Mazur, the WHO principal legal officer, said in October 2022.[62] COVAX pooled funds from advanced economies, donors, and the vaccine industry to subsidize injury claims. By having drug developers partially underwrite claims, the program may have had the added benefit of discouraging risk-taking.[63]

Unlike the COVAX window, a U.S. government-funded safe harbor for emergency countermeasures caps immunity at one year after a COVID-19 vaccination[64] and at only 0 to 28 days after a smallpox vaccination.[65] The system, called the Public Readiness and Emergency Preparedness (PREP) Countermeasure Injury Compensation Program (CICP),[66] immunizes companies against liability for reactions to U.S. health emergency treatments and health threats.[67] The U.S. activated the program during the COVID-19 and Ebola crises, among other emergencies.[68] In early 2020, the window protected Moderna, then a small, financially unstable company, to the extent that it felt comfortable initiating vaccine rollout in the U.S.[69] However, despite 8,000 injury claims, the short window and few resulting payouts forced many

60. Fairgrieve, *supra* note 15, at 86-87; Sara M. Tharakan & Nina M. Hart, *Liability Issues Related to COVID-19 Vaccine Manufacturing and Global Distribution*, CONG. RSCH. SERV., IF11905 (Aug. 19, 2021), https://perma.cc/9QTW-MBPU.

61. *Program Protocol*, *supra* note 19.

62. Webinar on Promoting Legal Preparedness & Equity Through Liability Risk Management, held by the Global Health Security Agenda (Oct. 12, 2022).

63. *See* Fairgrieve et al., *supra* note 15, at 117 ("Funding from public sources is particularly apposite in respect of schemes established concerning emergency vaccines. Set against this, accountability and deterrence-based arguments might suggest that there should also be a participation from industry, which is responsible for developing, producing, and ultimately selling vaccines. Otherwise, there may be an unjustifiable transfer of risk to the public sector. In such a case, the operation of schemes must evidently remain free from undue influence by industry.").

64. KEVIN J. HICKEY, HANNAH-ALISE ROGERS & ERIN H. WARD, CONG. RSCH. SERV., R46982, COMPENSATION FOR COVID-19 VACCINE INJURIES 4 (2023).

65. 42 C.F.R. § 110.100(c) (2021).

66. 42 U.S.C. § 247d-6d; Public Readiness and Emergency Preparedness Act, Pub. L. No. 109-148, 119 Stat. 2818 (2005) (codified as amended at 42 U.S.C. § 247d-6d).

67. *See Countermeasures Injury Compensation Program*, *supra* note 21.

68. *Covered Countermeasures*, HEALTH RES. & SERVS. ADMIN., https://perma.cc/9PJG-K5LK (archived Nov. 18, 2023).

69. Cancryn et. al, *supra* note 13 (noting the "delays and difficulties" in delivering COVID vaccine doses to low-income countries).

claimants to break the window and head to a lawyer instead.[70] To ensure that the injured are properly compensated during all U.S. emergencies, many reformers propose that U.S. legislators extend the one-year window.[71] Other countries established longer immunity windows for COVID-19 vaccine developers. For example, in Hong Kong, symptoms must present within two years of vaccination.[72] In the Philippines, a no-fault program covers claims for vaccinations that occur between March 2021 and March 2026, or the end of the vaccination cycle, whichever comes first—ostensibly this includes reactions that appear five years after vaccinations began.[73]

Similar to PREP, the U.S. National Vaccine Injury Compensation Program (NVICP) narrowly restricts immunity windows for symptom manifestation.[74] When the U.S. government enacted the initiative, which covers routine vaccinations including seasonal flu shots, clinicians believed that almost all vaccine injuries occurred within hours or days of vaccination.[75] But, today, scientists understand that some adverse reactions occur years after injection.[76] The program sometimes acknowledges this—but only when claimants denied compensation resort to the legal system. For instance, after lengthy litigation, plaintiffs won NVICP compensation for a complex partial seizure disorder that

70. Jenna Greene, *COVID-19 Vaccine Claims Yield Small Payouts from U.S. Government*, REUTERS (Apr. 19, 2023), https://perma.cc/HLG3-YKC9 (One attorney said his 25-lawyer firm "has been contacted by thousands of people who believe they've suffered serious injuries from COVID-19 vaccines . . . . By and large, lawyers who specialize in vaccine injury cases are not representing clients [in the government program]. The prospects of recovery are too slim to justify the expense. It's not just that the awards tend to be small. It's that winning at all is a long-shot.").

71. *See* Jason Onyediri, Note, *Social Insurance for the Socially Distant: Reforming the Countermeasures Injury Compensation Program*, 101 TEX. L. REV. 237, 264 (2022); Mary S. Holland, *Liability for Vaccine Injury: The United States, the European Union, and the Developing World*, 67 EMORY L. J. 415, 450 (2018) ("With effective access only to an administrative tribunal, with a one-year statute of limitations, and with no opportunity for appeal or review in any court, consumers have exceptionally limited recourse under the PREP Act.").

72. AXA, *supra* note 21. ("The time limit of which an applicant can apply… is within two (2) years after the last dose of the vaccine was received.…In the event where the applicant had been confirmed of one or more SAEs, and who subsequently succumbed within two (2) years of vaccination of the last dose of the vaccine, then the applicant would be entitled to the death payout…").

73. *See* PHILHEALTH, *supra* note 21; *see also* COVID-19 Vaccination Program Act of 2021, Rep. Act No. 115251, (Jul. 27, 2020) (Phil.), https://perma.cc/3AAS-C87M.

74. HEALTH RESOURCES AND SERVS. ADMIN., VACCINE INJURY TABLE (2022), https://perma.cc/E6S4-CZX9.

75. Holland, *supra* note 71, at 435.

76. *Id.* ("That injury occurs so quickly is no longer the view of many physicians and scientists. Some disabilities that may be related to vaccination occur years after the event.").

manifested nearly six years after a measles, mumps, and rubella vaccination.[77] And, often, the legal system denies such claims.[78]

While U.S. no-fault vaccine injury compensation programs do not cover latent injuries, the country's 9/11 victim compensation fund[79] and radiation exposure compensation program[80] do just that. They reassess and expand indemnification periods if safety data uncovers new complications. Initially, the 9/11 program opened in 2001 to compensate relatives of victims who died in the attacks and shut down in 2003.[81] When dust diseases and cancers began appearing in survivors and first responders who were at attack sites, the fund, in 2011, reopened for five years[82] and, in 2015, was reauthorized for another five years.[83] Most recently, in 2019, the government expanded the window to 90 years from the date of the attacks[84] to cover discoveries of new reactions to

77. *See* Poling v. Sec'y of HHS, No. 02-1466V, 2011 WL 678559, at *1-3 (Fed. Cl. Jan. 28, 2011) ("Hannah's encephalopathy eventually manifested as a chronic encephalopathy with features of autism spectrum disorder and a complex partial seizure disorder as a sequela . . . [P]etitioner is entitled to compensation under the Vaccine Program."); Poling v. Sec'y of HHS, No. 02-1466 V, 2008 WL 1883059, at *1 (Fed. Cl. Apr. 10, 2008) (observing "the onset of Hannah's complex partial seizure disorder, nearly six years after her July 19, 2000 vaccinations.").

78. *See, e.g.*, Hughes v. Sec'y of HHS, No. 16-930V, 2021 WL 839092, at *16, 33 (Fed. Cl. Jan. 4, 2021) ("Dr. Miller did not also explain how a diagnosis obtained almost three years after vaccination could be credibly linked to that event."); Chinea v. Sec'y of HHS, 144 Fed. Cl. 378, 384 (Fed. Cl. 2019) ; Holt v. Sec'y of the HHS, No. 05-0136V, 2015 WL 4381588, at *78-80 (Fed. Cl. June 24, 2015) ("She did not persuasively connect the laboratory evidence of mitochondrial dysfunction discovered years after the vaccinations were administered to the symptoms . . . displayed post-vaccination or the behavioral symptoms that manifested with speech delay many months later.").

79. *See generally* SYZMENDERA, VCF, *supra* note 24.

80. *See* U. S. GOV'T ACCOUNTABILITY OFF., GAO-07-1037r, RADIATION EXPOSURE COMPENSATION ACT: PROGRAM STATUS 2 (2007), https://perma.cc/F2E9-LGE5 (The RECA Amendments of 2000 expanded "both the time periods and geographic areas covered, and add[ed] compensable diseases, thus allowing more individuals to be eligible to qualify.").

81. *See* SYZMENDERA, VCF, *supra* note 24, at 1-2 (The original victim compensation fund provided cash benefits to "persons who were present at the World Trade Center, Pentagon, or aircraft crash site in Shanksville, PA, at the time of or in the immediate aftermath of the aircraft crashes at those sites on September 11, 2001; and passengers and crew of any aircraft that crashed on September 11, 2001 . . . The original VCF closed to new claims in December 2003.").

82. *Id.* at 2 (In 2011, the "reopened VCF extended eligibility for cash benefits to persons who suffered physical injuries or illnesses as a result of rescue, recovery, or debris removal work . . . as well as for certain persons who lived, worked, or were near the World Trade Center on September 11, 2001.").

83. *Id.* at 1-2 ("The reopened [fund] was authorized through October 3, 2016. However, the [fund] was reauthorized in December 2015 (P.L. 114-113).").

84. SEPTEMBER 11TH VICTIM COMPENSATION FUND, VCF GENERAL INFORMATION (last updated 2023), https://perma.cc/BNW5-RK7V.

toxins.[85] Similarly, the U.S. extended the filing window to 2022 (and then, for other reasons, to 2024) for a no-fault compensation program initiated in 1990 for members of the public, uranium miners, and government workers who were accidentally exposed to Cold War nuclear testing material.[86] The identification of latent diseases and other impacted populations required expansions long beyond five years.[87] These adjustments to no-fault public health compensation programs balanced unavoidable latent injuries and avoidable unaccountability.

III. Now Is the Time to Set a Five-Year Clock for the Future

A comparison of the above liability regimes reveals that the interventions that accelerated innovation and global access contained an immunity window spanning at least five years and left open the possibility of adjustments for injuries that manifest more than five years later. As explained, shorter windows discount discoveries of late-onset reactions, while longer ones may generate distrust in vaccine safety. Consequently, programs with baseline windows of under five years either floundered or produced few measurable results. And, conversely, infinite immunity is infeasible.

As an illustration, the complete absence of an immunity window failed dengue vaccine distributor Sanofi and children in the low-middle-income Philippines. Both Filipino families and Sanofi suffered costly[88] and deadly repercussions[89] when latent reactions emerged five years after the children were vaccinated. In addition, confidence in all vaccines in the Philippines dropped as the dengue outbreak continued and measles erupted.[90] Perhaps

85. *See* SEPTEMBER 11TH VICTIM COMPENSATION FUND, 2022 ANNUAL REPORT (2023), https://perma.cc/Y3G9-SWWR ("On January 18, 2023, [the government issued] a final rule to add all types of uterine cancer, including endometrial cancer" to various survivor healthcare programs. "Individuals who are certified for one of these cancers may also receive compensation from the [fund] if all other eligibility requirements are met.").

86. Radiation Exposure Compensation Act Amendments of 2000, Pub. L. No. 106-245, 114 Stat. 501; *see also* U. S. GOV'T ACCOUNTABILITY OFF., *supra* note 80 (Since its inception in 1990, benefits have been available to onsite participants, downwinders, and uranium miners, millers, and ore transporters.); SZYMENDERA, RECA, *supra* note 24, at 2 ("Pursuant to the RECA Extension Act of 2022 . . . the RECA program is scheduled to sunset on June 7, 2024.").

87. SZYMENDERA, RECA, *supra* note 24, at 6; U. S. GOV'T ACCOUNTABILITY OFF., *supra* note 80, at 2.

88. Blamont, *supra* note 40.

89. Halabi, *supra* note 3, at 131.

90. *See* Doucleff, *supra* note 2; *see also* Larson et al., *supra* note 7, at 626-627; WORLD HEALTH ORG., *supra* note 10.

worse, a tentative WHO contract for smallpox vaccine distribution that holds recipient governments, even low-income ones, liable for adverse reactions may prolong a pandemic if the COVID-19 vaccine shortages are any indication.[91] Similarly, India recently instituted a program offering no immunity to companies for clinical trial injuries, which critics imagine will dissuade companies from locating laboratories in India.[92]

Companies aiming to pioneer COVID-19 vaccines in advanced economies succeeded with a one[93] - to two[94] -year safe harbor. But this arrangement discounted the developing world. Moderna delayed vaccine distributions to low-income countries for more than a year, at which time the United States escalated pressure on the company.[95] Further, even in the United States, a one-year window and small payouts forced the injured to plead with the traditional legal system,[96] with little prospect for relief.[97]

When Moderna and other developers belatedly agreed to distribute in low- and middle-income countries through COVAX, the serious injuries that appeared five years after dengue vaccinations influenced negotiations. Resultantly, COVAX immunized COVID-19 vaccine developers for five years.[98] And so did the Philippines.[99] The WHO, a United Nations agency, drew authority under the agency's "directing and co-ordinating" constitutional mandate to establish five years of immunity for COVAX vaccine-makers and is negotiating an international instrument to strengthen pandemic prevention under its constitutional regulatory authority.[100] Thus, precedent exists for the

91. WORLD HEALTH ORG., *supra* note 27, at 6.

92. Mark Barnes, Jamie Flaherty, Minal Caron, Alishan Naqvee, and Barbara Bierer, *Post-Submission Update: The Evolving Regulatory Landscape for Clinical Trials in India*, FOOD & DRUG L.J., July 2019, at 1, 2, https://perma.cc/8D56-AHM8 ("The 2019 Rules . . . preserve the broad list of circumstances described in the article that are deemed 'related to' a clinical trial, which could continue to deter the siting of clinical trials in India given their greater reach as compared to conventional standards of causality.").

93. HICKEY ET AL., *supra* note 64, at 4.

94. AXA, *supra* note 21, at 5 (stating that an affected individual must apply "within two (2) years after the last dose of the vaccine was received").

95. Cancryn et al., *supra* note 13.

96. Greene, *supra* note 70 ("One attorney said his 25-person-lawyer firm "has been contacted by thousands of people who believe they've suffered serious injuries from COVID-19 vaccines . . . . By and large, lawyers who specialize in vaccine injury cases are not representing clients [in the government program]. The prospects of recovery are too slim to justify the expense. It's not just that the awards tend to be small. It's that winning at all is a long-shot.").

97. *See supra* note 78.

98. *Program Protocol*, *supra* note 19.

99. PHILHEALTH, *supra* note 21, at 2.

100. Constitution of the World Health Organization art. 2, July 22, 1946, 14 U.N.T.S. 185; *see also Procurement at WHO,* WORLD HEALTH ORG., https://perma.cc/B942-4ZZA

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WHO to set a five-year baseline of immunity for emergency vaccine campaigns in low-income countries.

Still, even five years is not enough time for safety data to uncover all possible reactions to emergency interventions or identify all injured populations. U.S. no-fault toxic exposure compensation programs are instructive on this point. Their strategy of adjusting the immunity period when new symptoms and sufferers surfaced maximized equity. The 9/11 victim compensation program, as of 2022, had awarded more than $10 billion to almost 49,000 claimants,[101] after, in 2011, re-establishing[102] and then extending the window[103] to cover new injuries[104] and new victims.[105] Most claimants—80 percent as of 2022—received compensation, and the majority of those who did not for any given year ran afoul of procedures.[106] The U.S. radiation exposure compensation program has met similar success. The program had approved more than 39,000 of 53,000 claims as of May 2022,[107] after starting in 1990 and expanding, in 2000, to recognize newly identified impacted populations and diseases.[108] These adjustments to no-fault windows erred on the side of caution, a standard that the international community might do well to follow.

Ideally, the WHO will set a five-year window, between the date of an emergency vaccination and the onset of symptoms, that allows extensions to cover new symptoms and during which developers receive immunity against

("Procurement is a critical function in support of the effective discharge of the WHO mandate" as the "Directing and Coordinating authority on international health work"); *No-fault Compensation Programme for COVID-19 Vaccines is a World First*, WORLD HEALTH ORG. (Feb. 22, 2021), https://perma.cc/YS94-SYLD (The WHO and Chubb Limited "signed an agreement on behalf of the COVAX Facility . . .for the administration of a no-fault compensation programme"); *see Program Protocol*, *supra* note 19; *Pandemic Prevention, Preparedness and Response Accord*, WORLD HEALTH ORG. (June 28, 2023), https://perma.cc/232J-YMA3 (The WHO member states agreed to draft and negotiate an international instrument under the WHO Constitution to strengthen pandemic prevention, preparedness and response, in line with the International Health Regulations, which grants authority to "to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.").

101. SEPTEMBER 11TH VICTIM COMPENSATION FUND, *supra* note 85, at 3.

102. SZYMENDERA, VCF, *supra* note 24. at 1.

103. SEPTEMBER 11TH VICTIM COMPENSATION FUND, *supra* note 85.

104. SEPTEMBER 11TH VICTIM COMPENSATION FUND, *supra* note 85, at 15.

105. SZYMENDERA, VCF, *supra* note 24, at 2.

106. SEPTEMBER 11TH VICTIM COMPENSATION FUND, *supra* note 85, at 23.

107. SZYMENDERA, RECA, *supra* note 24, at 14.

108. U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 80, at 2; *see also* SZYMENDERA, RECA, *supra* note 24, at 11.

injury liabilities except for those caused by negligence. This approach will address unknown reactions, similar to the toxic exposure programs, and accelerate vaccine innovation and access, similar to the COVAX program. To illustrate, the WHO can employ this standard to immunize vaccine-makers against claims for injuries that onset five years after a smallpox vaccination and, perhaps 15 years later, reopen or extend the window if safety data shows an increased risk of cancer among the vaccinated or congenital problems[109] in their children.

Unless the WHO creates and communicates a standard ahead of the next emergency, contracts will not be ready to facilitate vaccine development the moment smallpox or another outbreak strikes. For, as scholars correctly predicted before and during the COVID-19 crisis, when "sufficient safeguards are not put in place" to minimize liability litigation risks, "hindsight bias will not only tilt the courtroom playing field dramatically against manufacturers," but also "adversely impact deployment and acceptance of vaccines for current and future pandemics."[110]

109. *Cf.* Pedro L. Moro, Janet Cragan, Paige Lewis & Lakshmi Sukumaran, *Major Birth Defects after Vaccination Reported to the Vaccine Adverse Event Reporting System (VAERS), 1990 to 2014*, 109 BIRTH DEFECTS RSCH. 1057, 1058-59 (2017), https://perma.cc/F5ZW-RNWH (During the period January 1, 1990 through December 31, 2014, VAERS received 440,529 reports, 158 (0.03%) of which were reports of major birth defects).

110. Winter et al., *supra* note 12, at 315; *see also* Maria Julia Marinissen, Lauren Barna, Margaret Meyers & Susan E. Sherman, *Strengthening Global Health Security by Developing Capacities to Deploy Medical Countermeasures Internationally*, 12 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC., & SCI. 284, 287 (2014), https://perma.cc/D38M-JZM8 ("Negotiating complex legal terms and conditions, including liability protections in the midst of a public health event that requires immediate action (eg, containing a disease outbreak or avoiding the spread of a threat agent), can delay or jeopardize an international response, resulting in a significant impact on global health security.").