

HAVE VULNERABLE POPULATIONS BEEN EXCLUDED FROM COVID-19 VACCINATION AS A RESULT OF STATES' FAILURE TO COOPERATE WHEN CONCLUDING INDEMNIFICATION AGREEMENTS?

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I. INTRODUCTION

The process of obtaining global access to COVID-19 vaccines can be conceptualized as a cooperation game over collective goods, which has shades of the prisoner's dilemma. That is, although cooperation would achieve the best results for all players, states consistently betray that cooperation for individual reward. There are multiple ways poorer and less powerful actors have been disregarded and disadvantaged in this process. This article focuses on the role of agreements used to indemnify manufacturers from liability for vaccine injuries in creating unequal global access to vaccines. Wealthier and more powerful states acceded to vaccine manufacturers' demands for indemnities in order to secure immediate access to vaccines. In so doing, they created an indemnity market in which it was not possible for some other states and organizations to participate. This process had a major impact on the COVAX Humanitarian Buffer, which was designed to provide access to COVID-19 vaccines as a measure of last

resort for high-risk and vulnerable populations in humanitarian settings. Non-state actors such as humanitarian agencies, who are instrumental in vaccine delivery in these areas, were asked to indemnify manufacturers in the same way as states. However, of all impacted actors they are the least able to comply with these demands.¹

Section II begins by clarifying various options from which states may choose to address vaccine manufacturers' liability for vaccine injuries, and to provide compensation for injured people. Section III examines the distinct liability problems associated with vaccination to explain why manufacturers have demanded, and states agreed to provide, such far-reaching immunities and indemnities. Section IV explores the particular liability protections demanded by vaccine manufacturers during the COVID-19 pandemic. Section V argues that states' failure to cooperate in relation to the indemnity provisions requested by manufacturers has had severe negative impacts on vaccine equity. Finally, Section VI suggests potential solutions to these cooperation problems and Section VII briefly concludes.

II. APPROACHES TO LIABILITY

It is inevitable that vaccines will give rise to injuries (commonly known as "serious adverse events"), and that those injuries will give rise to claims for compensation. Any medication can induce side effects, allergies, or harmful reactions. In the case of vaccines, such injuries may arise out of the composition of the vaccine product itself, faults related to manufacture or storage, or errors at the point of vaccine delivery.² It is difficult to estimate the global scale of this problem. However, in the United States, for every 1 million doses of vaccine distributed between 2006 and 2021, approximately one individual was compensated for vaccine injury under the federal

1. See Paisley Dodds & Ben Parker, *EXCLUSIVE: Emergency COVID vaccination scheme in legal jeopardy*, THE NEW HUMANITARIAN (June 9, 2021), <https://www.thenewhumanitarian.org/news/2021/6/9/COVAX-covid-vaccine-buffer> (last visited Dec. 31, 2021) (describing the risks of legal liability NGOs face when distributing vaccines); *'Broken' humanitarian COVID-19 vaccine system delays vaccinations*, MEDECINS SANS FRONTIERES (Apr. 27, 2022), <https://www.msf.org/broken-covax-covid-19-vaccination-system-must-be-fixed-allow-people-access> (describing the challenges faced by non-state actors distributing vaccines in northern Syria).

2. See, e.g., *Adverse events following immunisation: what are they, and when are they cause for concern?*, GAVI (Nov. 11, 2020), <https://www.gavi.org/vaccineswork/adverse-events-following-immunisation-what-are-they-and-when-are-they-cause-concern> (detailing five major types of adverse events following immunization).

vaccine compensation program.³ Depending on the legal regime in operation in a given jurisdiction, vaccine recipients may advance civil claims for personal injury arising out of, for example, defects or negligence in the vaccine's design or manufacture, or failure to warn about particular side effects or drug interactions.⁴

There are a variety of ways that states may address manufacturer liability to injured vaccine recipients. States may place no limits on liability and permit civil claims to be filed against manufacturers.⁵ Alternatively, states may grant legal immunities to manufacturers, barring injured people from bringing suit against vaccine manufacturers, save in some very limited circumstances.⁶ Finally, states may agree to indemnify vaccine manufacturers, and compensate companies for any liability or loss associated with vaccines.⁷

Separately, there are also various schemes which offer no-fault compensation to individuals injured by vaccines.⁸ These schemes are

3. NATIONAL VACCINE INJURY COMPENSATION PROGRAM DATA REPORT, HEALTH RESOURCES & SERVICES ADMIN., <https://www.hrsa.gov/vaccine-compensation/data> (last updated May 1, 2023).

4. See, e.g., Derry Ridgway, *No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program*, 24 J. HEALTH POLIT. POL'Y L. 59, 60-61 (1999) (detailing the liability from immunizations in an American context); Mary S. Holland, *Liability for Vaccine Injury: The United States, the European Union, and the Developing World*, 67 EMORY L. J. 415 (2018) (comparing and contrasting the American and European models of liability for vaccine injury).

5. As discussed below, this was generally the situation in the United States prior to the enactment of the 1986 National Childhood Vaccine Injury Act and the 2005 Public Readiness and Emergency Preparedness (PREP) Act. See Mary Holland, *Liability for Vaccine Injury: The United States, the European Union, and the Developing World*, 67 EMORY L. J. 415, 420 (2018).

6. For example, the Public Readiness and Emergency Preparedness (PREP) Act in the United States and the COVID-19 Vaccination Programme Act in the Philippines addressed in greater detail in this article. See Sara M. Tharakan & Nina M. Hart, CONG. RSCH. SERV., IF11905, LIABILITY ISSUES RELATED TO COVID-19 VACCINE MANUFACTURING AND GLOBAL DISTRIBUTION, CONGRESSIONAL RESEARCH SERVICE (2021).

7. For example, during the 2009 swine flu pandemic, governments in the United Kingdom and Republic of Ireland agreed to indemnify GlaxoSmithKline from liability or loss associated with the Pandemrix vaccine. See Jerome Reilly, *State indemnified drug firm behind swine flu vaccine*, IRISH INDEPENDENT (Apr. 24, 2011), <https://www.independent.ie/irish-news/state-indemnified-drug-firm-behind-swine-flu-vaccine-26726426.html> and Tom Porter, *Brain-Damaged UK Victims of Swine Flu Vaccine to Get £60 Million Compensation*, INT'L BUS. TIMES, (Feb. 3, 2014), <https://www.ibtimes.co.uk/brain-damaged-uk-victims-swine-flu-vaccine-get-60-million-compensation-1438572>.

8. For example, the Vaccine Damages Payment Scheme in the United Kingdom and the National Vaccine Injury Compensation Program and the Countermeasures

related to immunities and indemnities, insofar as they provide a mechanism for compensating vaccine injuries without liability (or direct responsibility for damages payments) attaching to manufacturers. The details of no-fault compensation schemes differ between states. However, they generally provide financial compensation for a specific list of injuries associated with identified vaccines on presentation of some proof of causation, with no need for evidence of negligent conduct by manufacturers.⁹ These programs are sometimes used to soften the blow of immunity regimes, so that when injured people are barred from issuing civil claims, they are not left completely without compensation.¹⁰ No-fault compensation schemes may also run alongside litigation in jurisdictions where states have offered vaccine manufacturers indemnities rather than immunities.¹¹ Presumably, the hope is that these schemes will disincentivize civil claims and reduce their overall number, thereby reducing the burden on the government to compensate litigants when standing in the shoes of the vaccine manufacturer.

III. THE PROBLEM OF VACCINE LIABILITY

This section considers what, if anything, is unique about injuries caused by vaccination, and attempts to unravel why governments have been willing to accept that they should offer indemnities or immunities to manufacturers in respect of such harms.

A. *Vaccine Liability in the United States: A Case Study*

In the United States, there is evidence that indemnity regimes evolved, in part, due to the reluctance of pharmaceutical companies to engage in manufacturing vaccines. In 1976, the U.S. government feared

Injury Compensation Program in the United States. For a detailed list of such schemes, see Tommie Crum et al., *Current situation of vaccine injury compensation program and a future perspective in light of COVID-19 and emerging viral disease*, 10 F1000 RSCH. 652 (2021).

9. See Sam Halabi, *Solving the COVID-19 Vaccine Product Liability Problem* 35-38 (Center for the Study of the Administrative State Working Paper 21-11, 2021) (describing various restitution regimes in the United States and globally for vaccine liability).

10. This is the case in the United States, where the National Vaccine Injury Compensation Program and the Countermeasures Injury Compensation Program make provision for vaccine recipients injured by vaccines covered by immunity regimes. See Holland, *supra* note 5, at 442.

11. This is the case in the United Kingdom, where injured people are not barred from pursuing civil actions if they have received a payment pursuant to the Vaccine Damages Payment Act. *Vaccine Damage Payment*, GOV.UK, <https://www.gov.uk/vaccine-damage-payment> (last visited Feb. 25, 2023).

that an outbreak of swine flu would lead to rates of infection on the scale of the 1918–1919 flu pandemic.¹² The government wanted to pursue a mass vaccination program. However, insurance companies informed vaccine manufacturers that they would not provide liability coverage for claims arising out of the proposed immunization program and, as a result, manufacturers ceased production.¹³ To address this impasse, Congress passed the Swine Flu Act.¹⁴ In addition to establishing the National Swine Flu Immunization Program, this law provided for government indemnification of swine flu vaccine manufacturers and prompted vaccine production to restart.¹⁵ Forty million Americans were vaccinated before the program was halted because vaccination increased the risk of Guillain-Barré syndrome.¹⁶ As a result of the federal government's indemnification of manufacturers, it ultimately paid over \$90 million in damages to vaccine recipients who contracted Guillain-Barré.¹⁷

It is evident from this example that the key factor prompting the government's agreement to indemnify was the cessation of vaccine manufacture, which in turn was prompted by the refusal of insurance cover. But why did insurers refuse to cover this risk? Some scholars have laid the blame on the Fifth Circuit's holding in *Reyes v. Wyeth Laboratories* that vaccine manufacturers were liable for failing to issue an adequate warning to the ultimate consumer of a vaccine, which resulted in massively expanded liability for vaccine injury for manufacturers (and their insurers).¹⁸ In the late 1970s, the incoming Secretary of State of the Department of Health, Education, and Welfare asked political scientist and former Presidential Advisor Richard Neustadt and physician Harvey Fineberg to examine the Swine Flu immunization debacle.¹⁹ Their analysis suggests that insurers were most worried not by the risk of liability, but by the fear that an

12. Richard Gaskins, *Equity in Compensation: The Case of Swine Flu*, in 10 THE HASTINGS CNTR. REP., 5, 5 (1980).

13. *Id.*

14. 42 U.S.C. §§ 247b (j) et seq., 90 Stat. 1113, Pub. L. 94-380.

15. Gaskins, *supra* note 12.

16. Joanna Apolinsky, *Rethinking Liability for Vaccine Injury*, 19 CORNELL J. L. & PUB. POL'Y 537, 546–49 (2010).

17. *Id.* at 549.

18. 498 F.2d 1264 (5th Cir. 1974); *see, e.g.*, Angela Marino, The Cost of a Countermeasure: The Expansive Liability Protection of the Public Readiness and Emergency Preparedness Act of 2005, 20 UNIV. OF FLA. J. L. & PUB. POL'Y, 199, 202 (2009) (justifying vaccine manufacturers' cost concerns after the expansion of liability in *Reyes*).

19. RICHARD E. NEUSTADT & HARVEY V. FINEBERG, THE SWINE FLU AFFAIR: DECISION-MAKING ON A SLIPPERY DISEASE 45 (1978).

indeterminate number of vaccine recipients may decide to file claims, which would be costly to defend in court, whether those claims were ultimately upheld or not.²⁰

Several unique facets of vaccination liability are expressed or implied in this account. First, many vaccines are expected to be distributed to the entire population, or as close to it as possible. Second, the accelerated production of urgent vaccines makes it more difficult to anticipate the potential side effects and scope of any injury. Third, there are costs associated with potential lawsuits, even when unsuccessful, that are difficult to predict accurately. All these factors made insurers reluctant to provide coverage which, in turn, made manufacturers reluctant to continue production at their own risk. The final piece of the puzzle is the nature of the outbreak for which vaccination is sought. It was fears of a destructive pandemic that increased manufacturers' leverage and prompted the government to offer indemnities to ensure a supply of vaccines.

In 2004, the United States' approach to vaccine liability was again transformed in the wake of 9/11. Growing fears around bioterrorism led the federal government to announce an \$887 million contract to develop and manufacture a new anthrax vaccine.²¹ However, it failed to obtain a single bid from large pharmaceutical manufacturers.²² In the absence of the government indemnity offered for swine flu vaccines in 1976 there had been "a mass exodus of manufacturers from the vaccine market in the 1970s and early 1980s."²³ In addition to concerns about liability, vaccines were much less profitable to pharmaceutical companies than other products.²⁴

To incentivize manufacturers to produce vaccines, Congress enacted the Public Readiness and Emergency Preparedness (PREP) Act in 2005.²⁵ During a public health emergency, the Act empowers the Secretary of Health and Human Services to issue a declaration providing immunity for particular countermeasures designed to diagnose, mitigate, prevent, treat, cure, or limit the harm a particular

20. *Id.*

21. Marino, *supra* note 18, at 202.

22. *Id.*

23. *Id.* at 203.

24. *Id.* at 204 n.33 (summarizing studies that reported in 2002 that vaccine development accounted for only 1.5% of the pharmaceutical market and, in 2006, the market for one cholesterol-lowering agent exceeded the global market for the totality of all vaccines).

25. P.L. 109-148, div. C, Dec. 30, 2005, 119 Stat. 2818 (42 U.S.C. § 247d-6d).

emergency may cause.²⁶ In tandem with these immunity provisions, a no-fault compensation scheme was established that provides limited compensation to individuals injured by any countermeasures subject to a declaration.²⁷

The American government's historic response to managing manufacturer liability for vaccine injury is relevant to the global COVID-19 pandemic in several ways. The United States is a lucrative pharmaceutical market.²⁸ Thus, the history of vaccine liability provides a wealth of evidence of the types of problems particular to the manufacture and distribution of vaccination. The United States is also the site of the headquarters of several major pharmaceutical companies and important players in the COVID-19 vaccination effort, including Pfizer, Johnson & Johnson, and Moderna.²⁹ Therefore, American experiences and approaches may exert a powerful influence on the concerns of vaccine manufacturers, and the responses that those manufacturers expect and demand from the global community.

B. *Application of these Principles to the Global COVID-19 Vaccination Effort*

The COVID-19 pandemic necessitated the development of vaccines on an urgent basis. As a result, pharmaceutical companies exerted a significant degree of leverage in their negotiations with governments. The urgent nature of the pandemic response also meant that vaccine delivery was fact-tracked pending full regulatory approval using global mechanisms such as the World Health Organization's (WHO) Emergency Use Listings (EUL).³⁰ Under circumstances such

26. KEVIN HICKEY, CONG. RSCH. SERV., LSB10443, PREP ACT AND COVID-19: LIMITING LIABILITY FOR MEDICAL COUNTERMEASURES 21 (2020).

27. Countermeasures Injury Compensation Program, 42 C.F.R. § 110.1 (2016).

28. Since 2014, the United States pharmaceutical market has consistently accounted for more than 45% of the global market. *See* Distribution of the total global pharmaceutical market sales from 2014 to 2021, by submarket, Statista, <https://www.statista.com/statistics/266547/total-value-of-world-pharmaceutical-market-by-submarket-since-2006/> (last visited Feb. 25, 2023).

29. Pfizer has its headquarters in New York, *see Pfizer Inc.: Locations*, GLOBALDATA, <https://www.globaldata.com/company-profile/pfizer-inc/locations/> (last visited June 19, 2023); Moderna in Massachusetts, *see Moderna Inc.*, BLOOMBERG, <https://www.bloomberg.com/profile/company/MRNA:US> (last visited May 14, 2023); and Johnson & Johnson in New Jersey, *see Locations: Corporate Office*, JOHNSON & JOHNSON, <https://jninnovation.com/locations/johnson-&-johnson-corporate-office> (last visited June 19, 2023).

30. *See Emergency Use Listing*, WORLD HEALTH ORGANIZATION, <https://www.who.int/teams/regulation-prequalification/eul> (last visited Apr. 3, 2023).

as these, where vaccines have not yet undergone complete testing and regulatory approval, it is difficult to fully anticipate the likelihood of specific side effects or the level of litigation risk posed by serious adverse events. Furthermore, the scale of the COVID-19 pandemic and the prospect of vaccinating very large proportions of the global population only served to magnify manufacturer—and insurer—concerns regarding the potential scope of exposure to litigation.

An important question is whether vaccine manufacturers have, in fact, faced difficulty obtaining insurance coverage during the COVID-19 pandemic. There is limited information about the availability of insurance during this period of emergency authorization, due to the fact that the purchase agreements concluded between vaccine manufacturers and states are, for the most part, confidential. However, a number of contracts between Pfizer and national governments have been leaked.³¹ Many of these include a standard term on insurance coverage, which confirms that Pfizer will not obtain insurance to cover third party/patient claims, which would include compensation claims made by individuals who sustain injury as a result of vaccination.³² Still, this language does not clarify whether insurance for compensation claims would have been available to manufacturers, nor the levels of coverage on offer. Further, a COVAX briefing note suggested that normal insurance would not be available for vaccine manufacturers from the outset of vaccine delivery but did not provide any further detail or a timeline when normal coverage could be expected.³³ There is an indication that some limited insurance was available to Indian

(explaining how the WHO Emergency Use Listing procedure works); *COVID-19 Vaccines with WHO Emergency Use Listing*, WORLD HEALTH ORGANIZATION, <https://extranet.who.int/pqweb/vaccines/vaccinescovid-19-vaccine-eul-issued> (last visited May 14, 2023) (providing a list of vaccines with the listing).

31. Zain Rivzi, *Pfizer's Power*, PUBLIC CITIZEN (Oct. 19, 2021), <https://www.citizen.org/article/pfizers-power/> (noting in footnotes 5–7 that contracts entered into by Albania, Brazil, and Colombia with Pfizer were leaked).

32. Brazil-Pfizer Contract, March 15, 2021, at 9.1, <https://aurores.org/wp-content/uploads/2021/08/Brazil-Pfizer.pdf>.

33. COVAX, *Briefing Note: Additional Information on Indemnification for COVAX AMC Participants*, WORLD HEALTH ORGANIZATION (Nov. 29, 2020), <https://www.who.int/docs/default-source/coronaviruse/act-accelerator/briefing-note-indemnification-and-compensation-covax-amc-countries.pdf> [hereinafter November 2020 COVAX Briefing Note]. The statement that standard insurance is unavailable for COVID-19 vaccines is also reflected in *Frequently Asked Questions: The COVAX Humanitarian Buffer*, INTER-AGENCY STANDING COMMITTEE (May 16, 2022), <https://interagencystandingcommittee.org/inter-agency-standing-committee/covax-humanitarian-buffer> [hereinafter *Frequently Asked Questions*].

manufacturers as of January 2021.³⁴ However, the relatively low levels of coverage on offer would be unlikely to satisfy manufacturers that all financial risk would be mitigated.

There are at least two important differences between the history of vaccine liability in the United States and the progress of vaccine manufacture during the COVID-19 pandemic. First, although there were initial uncertainties regarding the side effects and risks of COVID-19 vaccines, those vaccines have now been delivered on a massive scale, far exceeding the scope of any realistic clinical trial.³⁵ It no longer seems accurate to say that the frequency or severity of potential vaccine injury is difficult to predict. Second, unlike in the historic United States examples, it may no longer be correct to say that vaccine manufacture is a relatively unprofitable enterprise. Some companies saw their profits increase significantly during the pandemic as a result of vaccine manufacture.³⁶

Arguably, better knowledge of risks and an increase in profit margins should mean that extraordinary incentives such as indemnities or immunities from liability are no longer required. However, this power shift away from manufacturers has not materialized in practice. This may be because path dependencies have become embedded as a result of decisions taken in previous contexts, or because governments and policymakers remain focused on obtaining vaccines and beating the pandemic at any cost.

IV. MANUFACTURERS' PREFERRED APPROACH TO LIABILITY: INDEMNIFICATION

There is ample evidence that vaccine manufacturers have refused to market COVID-19 vaccines unless buyers—ordinarily governments—agree to provide satisfactory assurance that they will be

34. Stated to be \$5 million. Subrata Panda, *Firms rush for vaccine liability cover as India kicks off vaccination drive*, BUSINESS STANDARD (Jan. 18, 2021), https://www.business-standard.com/article/companies/firms-rush-for-vaccine-liability-cover-as-india-kicks-off-vaccination-drive-121011700872_1.html.

35. As of February 19, 2023, more than 5.54 billion people worldwide have received a dose of a Covid-19 vaccine, equal to about 72.2 percent of the world population. See Josh Holder, *Tracking Coronavirus Vaccinations Around the World*, N.Y. TIMES (Mar. 13, 2023), <https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html>.

36. Mark Wilson, *Vaccine Manufacturers Are Profiteering. History Shows How to Stop Them*, POLITICO (Nov. 4, 2021), <https://www.politico.com/news/magazine/2021/11/04/vaccine-manufacturers-are-profiteering-history-shows-how-to-stop-them-519504>.

protected against losses from compensation claims.³⁷ Where immunities from suit are not provided for in domestic law, as is the case in most jurisdictions, manufacturers prefer to reallocate any potential responsibility for paying future compensation to purchasers by including indemnity clauses in their contracts with states.³⁸

The degree of indemnification demanded by some manufacturers is quite extreme. During negotiations with Pfizer, Brazil and Argentina complained that they were required to offer sovereign assets as collateral and to indemnify the manufacturer even in the case of fraud, malice, or gross negligence.³⁹ The final agreement between Brazil and Pfizer confirms that both parties remain liable for fraud or fraudulent misrepresentation.⁴⁰ However, Brazil did concede to waive its right of sovereign immunity, including immunity over any assets.⁴¹

There are two primary issues that arise out of this factual matrix. The first is whether, on a normative basis, vaccine manufacturers should be able to insist that their liability be reduced to zero, particularly in circumstances where they have already received ample public funding for vaccine development and are selling the resultant vaccines for a profit.⁴² The second is whether agreement by some states to offer indemnities reduces the bargaining power of other actors, such that they must either conclude similar agreements with manufacturers or forego access to certain vaccines. The remainder of this article will focus on the second of these issues.

V. COOPERATION AND COVID-19

Thus far, this article has focused on the concerns of vaccine manufacturers and governments. However, there is at least one other way to conceptualize negotiations over the terms of vaccine delivery, which is to focus on the interests of the recipients of vaccination. In

37. Madlen Davies et al., *'Held to ransom': Pfizer demands governments gamble with state assets to secure vaccine deal*, BUREAU OF INVESTIGATIVE JOURNALISM (Feb. 23, 2021), <https://www.thebureauinvestigates.com/stories/2021-02-23/held-to-ransom-pfizer-demands-governments-gamble-with-state-assets-to-secure-vaccine-deal>.

38. See Ludwig Burger & Pushkala Aripaka, *AstraZeneca to be exempt from coronavirus vaccine liability claims in most countries*, REUTERS (July 30, 2020), <https://www.reuters.com/article/us-astrazeneca-results-vaccine-liability/astrazeneca-to-be-exempt-from-coronavirus-vaccine-liability-claims-in-most-countries-idUSKC N24V2EN> (quoting a member of AstraZeneca's senior executive team saying "In the contracts we have in place, we are asking for indemnification.").

39. Davies et al., *supra* note 37.

40. Brazil-Pfizer Contract, *supra* note 32, at 9.3.

41. *Id.* at 9.4.

42. Matiangai Sirleaf, *Disposable Lives: COVID-19, Vaccines, and the Uprising*, 121 COLUM. L. REV. F., 71 (2021).

this heuristic, vaccines are framed as a collective good which is both rivalrous and excludable, meaning that actors have an interest in attempting to capture or appropriate vaccine supply, leaving less for others. Still, attempting to capture vaccines in this way will not necessarily further the interests of vaccine recipients. In a globalized world, states and their citizens have a shared interest in ensuring a reduction in transmission of COVID-19. If some states are left behind and COVID-19 remains uncontrolled, there is a risk that negative externalities—such as viral mutations or disruption in productive supply chains—will spill over into the broader global community. Furthermore, given the differential impacts of COVID-19 within populations, with higher mortality rates in sick and elderly individuals, there is a rational argument for ensuring that these groups are prioritized in worldwide vaccine delivery. To accomplish these collective goals, states must act in concert and not simply pursue their own immediate self-interest.

In this way, the global vaccination effort is a cooperation game in which players—states and their citizens—will be better off if they reach agreement on how to act and comply with that agreement. However, states are also engaged in a kind of prisoner’s dilemma.⁴³ Any agreeable mutual solution among states regarding vaccine distribution would be unstable since all states would be tempted to cheat by negotiating directly with manufacturers to obtain a preferential vaccine supply. In so doing, they would lose the benefits of cooperation outlined above. Furthermore, states arguably reduce their bargaining strength relative to vaccine manufacturers by failing to act in concert, leading to a “race to the bottom” in the contract terms that vaccine manufacturers are able to insist upon. In particular, the failure of inter-state cooperation makes it easier for vaccine manufacturers to insist on indemnity clauses that are ultimately damaging to the global vaccination effort.

This model of a failed cooperation game is evident at multiple levels of the COVID-19 vaccination effort. However, the negative impacts are most starkly felt by the most vulnerable and disregarded populations. The following sections consider the impact of failed cooperation between states on the COVAX Facility, on vaccine donations between States, and on the COVAX Humanitarian Buffer.

43. The thrust of the prisoner’s dilemma being (in summary) that, in certain circumstances, multiple parties will achieve the optimal results if they cooperate, yet each will be tempted to betray that cooperation for perceived individual reward.

A. *Cooperation and COVAX*

The COVAX Facility, directed by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI), and the World Health Organization (WHO), is “a platform [to] support the research, development and manufacturing of a wide range of COVID-19 vaccine candidates, and negotiate their pricing.”⁴⁴ States could buy into the Facility to secure access to a portfolio of vaccines in development. It was designed to operate as follows:

The Facility continually monitors the COVID-19 vaccine landscape to identify the most suitable vaccine candidates, based on scientific merit and scalability, and works with manufacturers to incentivize them to expand their production capacity in advance of vaccines receiving regulatory approval The Facility will also use the collective purchasing power that comes from having so many countries participate in order to negotiate highly competitive prices from manufacturers that are then passed on to participants.⁴⁵

The COVAX Advance Market Commitment (AMC) was meant to provide low- and middle-income countries the same access to vaccines as wealthier states, to ensure global vaccine coverage.⁴⁶ COVAX would invest in a wide portfolio of vaccine candidates,⁴⁷ as described above, using contributions from 79 wealthy self-financing governments.⁴⁸ Ninety-two lower-income donor supported governments would provide reduced financial commitments and obtain subsidized prices for doses, which they would receive at the same time as wealthier partner states.⁴⁹

If all participating states utilized COVAX to procure their vaccine doses, the Facility would, in theory, have been able to coordinate the equitable distribution of vaccines. Instead, self-financing states “cheated” by entering into bilateral agreements with vaccine

44. *COVAX Explained*, GAVI (Sept. 3, 2020), <https://www.gavi.org/vaccineswork/covax-explained>.

45. *Id.*

46. *Id.*

47. At this time, it was not yet known which vaccines would be effective, so investing in a wider portfolio of vaccines increased the probability that wealthy states would have access to effective vaccines in future.

48. *The Gavi COVAX AMC Explained*, GAVI (Feb. 15, 2021), <https://www.gavi.org/vaccineswork/gavi-covax-amc-explained>.

49. *Id.*

manufacturers.⁵⁰ The primary impact of these agreements was a reduction in doses of effective vaccines immediately available to the COVAX Facility.⁵¹ In February 2021, WHO Director-General Tedros Adhanom Ghebreyesus noted in an opinion piece on vaccine nationalism that rich countries with just sixteen percent of the world's population had purchased sixty percent of the world's vaccine supply, leaving COVAX struggling to procure sufficient doses to cover twenty percent of the population of lower-income countries.⁵²

Furthermore, it is arguable that, if all states had utilized the COVAX Facility, they could have presented a united front to manufacturers on specific contractual terms like indemnity clauses and could perhaps have enjoyed greater leverage as a result. Instead, bilateral negotiations set the tone in relation to indemnities, both by leading manufacturers to believe that demands for indemnities would be satisfied, and by setting a precedent that such indemnities would be concluded on a state-by-state basis between individual governments and manufacturers, rather than on a global basis through the COVAX Facility. Indeed, donor-supported governments receiving vaccines through COVAX have since been informed that they must provide direct assurances to manufacturers that they won't face product liability claims before they can take delivery of any doses.⁵³ Therefore, the failure by states to cooperate in relation to agreements with vaccine manufacturers has created an environment in which low-income states are bound to offer the same indemnity commitments as more powerful states to receive access to vaccines.

B. *Additional Negative Externalities of Indemnity Regimes*

The failure to mount an effective resistance to vaccine manufacturers' demands that their liability be reduced to zero has also resulted in the restriction of donations or other transfers of vaccine

50. See Carmen Paun, *Gavi on the defensive over vaccine-equity effort*, POLITICO, (May 8, 2021), <https://www.politico.com/newsletters/global-pulse/2021/08/05/gavi-on-the-defensive-over-vaccine-equity-effort-493855> (describing how rich states "ultimately did not surrender their negotiating power to international organizations," and "bought as many doses as they could for themselves," before then donating money to COVAX).

51. Tedros A. Ghebreyesus, *Vaccine Nationalism Harms Everyone and Protects No One*, FOREIGN POLICY (Feb. 2, 2021), <https://foreignpolicy.com/2021/02/02/vaccine-nationalism-harms-everyone-and-protects-no-one/>.

52. *Id.*

53. Halabi, *supra* note 9, at 29; November 2020 COVAX Briefing Note, *supra* note 33.

doses between states.⁵⁴ In April 2021, Vanity Fair reported that agreements between the U.S. government and Pfizer, Moderna, AstraZeneca, and Janssen provide that any vaccine materials purchased under those agreements may only be used in the United States.⁵⁵ The article stated that inclusion of these provisions was motivated by manufacturer concerns regarding liability protection.⁵⁶ While the aforementioned PREP Act provides immunity to vaccine manufacturers in the United States, this immunity would be lost if vaccines were donated and used in third-party countries.⁵⁷ Indeed, when the U.S. government shared 1.5 million doses of AstraZeneca vaccine with Mexico, both countries had to negotiate separate indemnification agreements with the manufacturer.⁵⁸ This is a further indication that states' bilateral agreements with manufacturers have occupied the field, restricting weaker actors from accessing vaccines, apart from on the same terms accepted by the powerful. These terms may not be feasible for poorer states and actors, who lack the resources to indemnify vaccine manufacturers.

C. *The Humanitarian Buffer*

The cooperation issues discussed above have had a particularly profound impact on the operation of the COVAX Humanitarian Buffer. This scheme was designed to provide access to COVID-19 vaccines as a measure of last resort for high-risk and vulnerable populations in humanitarian settings.⁵⁹ Up to five percent of COVAX's doses are available through this "Buffer" arrangement.⁶⁰ Applications can be made by governments that are COVAX participants and by humanitarian agencies.⁶¹ Buffer doses are intended for use in scenarios where governments are unwilling or unable to include particular populations in their national vaccination plans, including where a national authority does not have control over or access to certain parts

54. Katherine Eban, *We Are Hoarding: Why the U.S. Still Can't Donate COVID-19 Vaccines to Countries in Need*, VANITY FAIR (Apr. 6, 2021), <https://www.vanityfair.com/news/2021/04/why-the-us-still-cant-donate-covid-19-vaccines-to-countries-in-need>.

55. *Id.*

56. *Id.*

57. *Id.*

58. *Id.*

59. *The COVAX Humanitarian Buffer Explained*, GAVI (Mar. 30, 2021), <https://www.gavi.org/vaccineswork/covax-humanitarian-buffer-explained>.

60. *Id.*

61. *Id.*

of its population and where humanitarian crises have occurred.⁶² Consequently, humanitarian agencies are key participants in Buffer arrangements.

Initially, the Buffer scheme treated humanitarian agencies like state actors. These agencies were required to conclude direct agreements with manufacturers, who demanded that any potential liability be eliminated before they would ship vaccine doses. After opening applications for Buffer doses in May 2021,⁶³ the Gavi COVAX website confirmed that “shipments to humanitarian agencies . . . are subject to successful conclusion of contracts with manufacturers, including on indemnity and liability-related arrangements.”⁶⁴

This approach thwarted the Humanitarian Buffer’s mandate. In June 2021, the WHO, UNICEF, the Red Cross, and Médecins Sans Frontières (MSF) stated they would not be able to apply for or administer vaccines under the Humanitarian Buffer if they were required to assume liability.⁶⁵ As of May 2022, Humanitarian Buffer doses had been delivered to the Ministries of Health in Iran and Uganda alone.⁶⁶ Doses had not been delivered to any humanitarian agencies.

Since instituting the Humanitarian Buffer scheme, key COVAX actors have recognized the impossibility of requiring humanitarian agencies to indemnify manufacturers. In a June 2022 Discussion Paper, Gavi observed:

In 2020, precedents were set by sovereign states and manufacturers on the overall approach to manufacturer indemnification . . . during the course of the Humanitarian

62. Frequently Asked Questions, *supra*, note 33, at 1-2.

63. For a detailed timeline of the COVAX Humanitarian Buffer, see Josh Michaud and Jennifer Kates, *The COVAX Humanitarian Buffer for COVID-19 Vaccines: Review and Assessment of Policy Implications*, KAISER FAMILY FOUNDATION (Nov. 30, 2022), <https://www.kff.org/global-health-policy/issue-brief/the-covax-humanitarian-buffer-for-covid-19-vaccines-review-and-assessment-of-policy-implications/>.

64. *COVAX Facility*, GAVI, <https://web.archive.org/web/20230514024606/https://www.gavi.org/covax-facility> (last visited July 4, 2021).

65. Paisley Dodds & Ben Parker, *EXCLUSIVE: Emergency COVID vaccination scheme in legal jeopardy*, THE NEW HUMANITARIAN (June 9, 2021), <https://www.thenewhumanitarian.org/news/2021/6/9/COVAX-covid-vaccine-buffer>.

66. Jenny Lei Ravelo, *COVID-19 vaccine delivery and demand ‘slowing down’*, DEVEX (May 6, 2022), <https://www.devex.com/news/covid-19-vaccine-delivery-and-demand-slowing-down-103187>; Ted Chaiban, *We must take the rapid action needed to accelerate vaccination*, UNICEF REMARKS (Apr. 12, 2022), <https://www.unicef.org/press-releases/we-must-take-rapid-action-needed-accelerate-vaccination>.

Buffer's design and operationalization, these factors generated product liability and other residual risks and created a range of roadblocks for humanitarian access.

First, with the general precedent set being that indemnity and liability (I&L) obligations would fall on those receiving vaccines, it was critical to secure I&L waivers for doses delivered via the buffer. This was essential because humanitarian agencies – particularly those operating in specific national contexts – in no way have the ability to take on this risk as sovereign states can.⁶⁷

Gavi and the Inter-Agency Standing Committee (IASC), the UN's humanitarian coordination platform, have called on manufacturers to waive the requirement for indemnification, particularly where the most vulnerable populations of concern can only be reached by humanitarian agencies utilizing the Buffer.⁶⁸ Gavi reports that it has secured such waivers for a total of seven vaccines within the COVAX portfolio for deployment by humanitarian agencies.⁶⁹ However, Gavi previously stated that more than two-thirds of COVAX doses had come from Pfizer, AstraZeneca, and Moderna,⁷⁰ which have not provided indemnity waivers.⁷¹ Furthermore, the waivers that manufacturers have provided are not exhaustive, requiring additional risk-sharing negotiations before vaccines can be delivered to agencies.⁷² If more manufacturers do not agree to comprehensive waivers of their indemnity requirements, the Buffer may face difficulties and delays in coordinating sufficient vaccine doses to send to vulnerable populations. If states had cooperated effectively, demands for indemnification might have been rejected at an earlier stage, or at least tempered, such that manufacturers may not have attempted to impose them on these actors.

67. TAKING STOCK OF HUMANITARIAN ACCESS TO PANDEMIC VACCINES, GAVI 3–4 (2022), <https://www.gavi.org/sites/default/files/covid/covax/taking-stock-of-humanitarian-access-to-pandemic-vaccines-dp.pdf>.

68. Frequently Asked Questions, *supra* note 33.

69. Those vaccines being SII AZ Covishield, SII AZ Covovax, Janssen J&J, Clover, Sinopharm, Sinovac, and Novavax. See *Covax in Humanitarian Settings*, GAVI, <https://www.gavi.org/covax/humanitarian-settings> (last visited Feb. 25, 2023).

70. Francesco Guarascio & Panu Wongcha-um, *Refugees lack COVID shots because drugmakers fear lawsuits, documents show*, REUTERS (Dec. 16, 2021), <https://www.reuters.com/world/refugees-lack-covid-shots-because-drugmakers-fear-lawsuits-documents-2021-12-16/>.

71. TAKING STOCK OF HUMANITARIAN ACCESS, *supra* note 67.

72. *The COVAX Humanitarian Buffer Explained*, *supra* note 59, at 4.

D. *Impact of the Slow Rollout of Humanitarian Buffer Doses*

As of March 2022, an estimated 155 million people did not have access to COVID-19 vaccines in humanitarian settings.⁷³ This represents a small percentage of the global population but leaves a huge number of individuals overlooked by the vaccination effort.

In complex humanitarian settings where disease and malnutrition are endemic, COVID-19 may not be the most pressing risk to life. Furthermore, access to COVID-19 testing is often limited or nonexistent in these areas, so it is difficult to measure the excess mortality attributable to COVID-19.⁷⁴ However, high levels of pre-existing disease, poor sanitation and nutrition, overcrowding, and limited access to healthcare may increase vulnerability to COVID-19.⁷⁵ Additionally, there is a risk that vaccine exclusion will exacerbate other forms of exclusion. In particular, as proof of vaccination increasingly becomes a prerequisite for accessing a range of public goods, including employment,⁷⁶ exclusion from vaccination may doubly disadvantage these populations.

VI. SOLUTIONS

It is unlikely that the power and influence currently wielded by the pharmaceutical industry will easily or rapidly be vanquished. It is perhaps most realistic to focus initially on an approach that addresses vaccine manufacturers' liability concerns, whilst also ensuring less powerful states and vulnerable populations are not left behind. One option is a global solution that mirrors the PREP Act.⁷⁷ States could agree to limitations on liability for vaccine manufacturers combined

73. *Q&A: COVAX and the Humanitarian Buffer*, GAVI (Mar. 10, 2022), <https://www.gavi.org/vaccineswork/qa-covax-and-humanitarian-buffer>.

74. See, e.g., Oliver J. Watson et al., Leveraging community mortality indicators to infer COVID-19 mortality and transmission dynamics in Damascus, Syria, 12 *NATURE COMM'NS.* 1, 2 (2021) (studying excess mortality due to COVID in Damascus); E.S. Koum Besson et al., *Excess mortality during the COVID-19 pandemic: a geospatial and statistical analysis in Aden governorate, Yemen*, 6 *BMJ GLOB. HEALTH* 1, 1 (2021) (detailing excess deaths from COVID in Yemen and the difficulties with trusting official COVID-19 mortality figures).

75. See, e.g., Nneoma E. Okonkwo et al., *COVID-19 and the US response: accelerating health inequities*, 26 *BMJ EVIDENCE-BASED MEDICINE* 176, 176-79 (2021) (concluding that COVID-19 "has the greatest implications for the most vulnerable people," including those in prison, immigrants, those with disabilities, and the unhoused).

76. *Factbox: Countries making COVID-19 vaccines mandatory*, REUTERS (Dec. 31, 2021), <https://www.reuters.com/business/healthcare-pharmaceuticals/countries-making-covid-19-vaccines-mandatory-2021-08-16/>.

77. John Winter et al., *Toward a Global Solution on Vaccine Liability and Compensation*, 74 *FOOD & DRUG L.J.* 1, 1 (2019).

with a global no-fault scheme to compensate vaccine recipients for injuries.⁷⁸ Once agreed upon, this model could be activated for specific pandemics or vaccines through a declaration by an appropriate international body, such as the Coalition for Epidemic Preparedness Innovations (CEPI).⁷⁹

Identifying a viable approach is perhaps the easiest piece of the puzzle. The more difficult task is for all states to agree to such an approach, and to ensure that any resulting agreement is not immediately undermined by the temptation to cheat. A Framework Convention on Global Health could provide an answer.⁸⁰ Such a Framework could be used to require States to participate in equitable distribution mechanisms.⁸¹ It could also enshrine an agreed approach to vaccine manufacturer liability that would apply in future pandemics.

This still leaves open the question of how to address cheating by self-interested states. Eyal Benvenisti, Director of the Lauterpacht Centre for International Law at the University of Cambridge, has recently argued in relation to the WHO that, to be effective in future global pandemics, international organizations “charged with managing global health must have the tools to overcome the most complex cooperation problems among mutually distrustful sovereigns.”⁸² It is questionable whether the WHO would be the appropriate body to undertake this task, as its mandate is broader than vaccination, and states have already imposed restrictions on the WHO’s autonomy and powers.⁸³ Another agency that might be able to assume this task is the Access to Covid-19 Tools Accelerator (ACT-A), which is a framework for collaboration that already includes the most powerful global actors.⁸⁴ This platform could be repurposed to operate beyond the

78. *Cf. id.* (explaining that the PREP Act provides liability protection for certain persons or entities, including vaccine manufacturers, and provides compensation to certain injured persons within the United States).

79. *Id.* at 14.

80. Lawrence Gostin et al., How the Biden Administration Can Reinvigorate Global Health Security, Institutions and Governance, 115 *AJIL UNBOUND*, 74, 74–79 (2021).

81. *Id.* at 78.

82. Eyal Benvenisti, The WHO – Destined to Fail?: Political Cooperation and the COVID-19 Pandemic, 114 *AM. J. INT’L L.* 588, 592 (2020).

83. *See id.* at 595–96 (describing states utilizing the International Health Regulations to reduce the autonomy of the WHO and to “reify member states’ sovereignty”).

84. Including, among others, states, Gavi, CEPI, the WHO, the World Bank, and philanthropic organizations like the Bill and Melinda Gates Foundation. *See generally*, Suerie Moon et al., *Governing the Access to COVID-19 Tools Accelerator: towards greater participation, transparency, and accountability*, 399 *LANCET* 487 (2022).

current pandemic. However, there are concerns about inadequate transparency, accountability, and legitimacy in ACT-A's governance, particularly as states have increasingly taken a backseat to organizations governed by a mix of public and private interests.⁸⁵ Furthermore, ACT-A would require strengthened monitoring and enforcement powers in view of the difficulties that its vaccine pillar, COVAX, has already faced in relation to cooperation issues. The crucial question is whether states would recognize the long-term benefits of a cooperative venture with more 'teeth' and be willing to cede some of their sovereignty to such an organization to bind themselves from cheating in the future.

VII. CONCLUSION

It is well-recognized that the failure to cooperate during the COVID-19 pandemic, and the resulting 'vaccine nationalism' pursued by self-interested states, has undermined efforts by COVAX to distribute vaccines equitably among the global community.⁸⁶ As a result, wealthier and more powerful states quickly vaccinated their populations, leaving behind states in the Global South.⁸⁷

This article illuminates a less-frequently studied aspect of this cooperation failure; the impact that bilateral indemnity agreements concluded between powerful states and vaccine manufacturers have had on the capacity of vulnerable populations to obtain vaccine doses. Global cooperation around indemnities for vaccine manufacturers was already identified as an issue impeding efficient vaccine rollout prior to the COVID-19 pandemic. During the 2009 H1N1 pandemic, the immunization process stalled for more than 3 months due to negotiations over liability and indemnity.⁸⁸ Following the H1N1 pandemic, the WHO advised that world leaders should agree a framework to "expedite legal agreements during future pandemics or outbreaks."⁸⁹ The aim was to avoid delay in rolling out vaccines, however, such a framework may also have been of assistance in encouraging cooperation on contract terms, thereby mitigating the problem of exclusion from vaccine access for actors who cannot afford indemnities.

85. *Id.*

86. See Paun, *supra* note 50 (describing how rich states' efforts to acquire vaccines for themselves undercut vaccine distribution to vulnerable areas).

87. See, e.g., Victoria Pilkington et al., *Global COVID-19 Vaccine Inequity: Failures in the First Year of Distribution and Potential Solutions for the Future*, 10 FRONTIERS IN PUB. HEALTH 1, 1–2 (2022) (describing the disparities in vaccine access between high-income countries and low-income countries).

88. Halabi, *supra* note 9, at 21.

89. Winter et al., *supra* note 77, at 3.

This will not be the last pandemic. The opportunity to regulate relationships between manufacturers and recipients of vaccines that was squandered following the H1N1 pandemic should be taken up now; states should endeavor to prevent a recurrence of harmful cooperation problems when the world next faces a global health emergency.