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Viral Sovereignty, Vaccine Diplomacy, and Vaccine Nationalism: The Institutions of Global Vaccine Access

Sam F. Halabi

Ana Santos Rutschman

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VIRAL SOVEREIGNTY, VACCINE DIPLOMACY, AND VACCINE NATIONALISM: THE INSTITUTIONS OF GLOBAL VACCINE ACCESS

Sam F. Halabi*
Ana Santos Rutschman**

ABSTRACT

The COVID-19 pandemic has triggered a global vaccine race. Distributive questions about which countries will receive scarce doses and under which conditions pervade international law and diplomacy. This Article is the first to describe the phenomena that have driven the development of international vaccine-sharing mechanisms, identify the international organizational forces that explain the phenomena, and explain how international organizations may facilitate international cooperation before, during, and after global crises.

This Article explores the longstanding dissociation between global public health imperatives and nationalist responses to pandemics within the frameworks of “vaccine nationalism,” “viral sovereignty,” and “vaccine diplomacy.” The Article then considers two international agreements indicative of an interest in international collaborations, division of gains from trade, and sustained governance structures—the 2011 Pandemic Influenza Preparedness Framework, and the 2020 COVAX Vaccines Pillar of the ACT Accelerator. The

* Senior Scholar and Visiting Professor, O’Neill Institute for National and Global Health Law, Georgetown University Law Center. Senior Associate Vice-President for Health Policy and Ethics, Colorado State University. Professor, Colorado School of Public Health. JD, Harvard; MPhil, Oxford (St. Antony’s College); B.A., B.S., Kansas State University. Professor Halabi’s research career has focused on the ethical, legal, and regulatory dimensions of biomedical innovation and collaboration, especially in the context of epidemic and pandemic preparedness and response. He has published four books and more than seventy manuscripts in areas including data sharing during infectious disease emergencies, the development and deployment of vaccines in routine and emergency circumstances, the philosophy of medicine, international technology transfer, public health ethics, and vector-borne disease surveillance. He is the 2018 Fulbright Canada Research Chair in Health Law, Policy, and Ethics and the 2020 Husch Blackwell Outstanding Teacher.

** Outgoing Assistant Professor of Law, Saint Louis University School of Law, Center for Health Law Studies, Center for International and Comparative Law. Incoming Professor of Law, Villanova University. S.J.D., Duke Law School. Professor Rutschman teaches and researches in the areas of health law, intellectual property, innovation policy in the life sciences, and law and technology. She has been named a Health Law Scholar (2018) and a Bio Intellectual Property Scholar (2017) by the American Society of Law, Medicine & Ethics for her scholarly work on the intellectual property of vaccines. Her ongoing book, *Vaccines as Technology: Innovation, Barriers and the Public Health*, will be published by Cambridge University Press in 2022.

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recurrence of these legal arrangements suggests that, to save the transaction costs generated by repeated development of ad hoc structures that centralize vaccine distribution, a permanent facility may be developed. One possibility for such a facility is the Pandemic Influenza Preparedness Framework, adapted to become an all- or most-pathogen-sharing international organization. A second possibility, which gained some momentum during the COVID-19 pandemic, is a Pandemic Treaty establishing the terms under which pandemic vaccines will be developed and shared in the future.

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INTRODUCTION

The COVID-19 pandemic has triggered a global vaccine race, and distributive questions about which countries will receive scarce doses, and under which conditions, pervade international law and diplomacy.¹ As vaccines are

¹ See Eileen O'Reilly, *The Coming Clash Over the First Coronavirus Vaccines*, AXIOS (Apr. 30, 2020), <https://www.axios.com/coronavirus-vaccine-distribution-america-a12c4e95-df80-47f0-beec-d17d7e7657db.html> (“There will not be enough vaccines to meet initial demand, experts say. That’s left nations racing to secure future supplies and international organizations scrambling to make sure there is equitable access to any vaccines for the novel coronavirus. . . . The COVID-19 vaccine race is underway, with at least 92 in development and more expected. They’re based on different approaches that have different manufacturing processes: There are a limited number of facilities that are large enough for massive scale-ups and/or are flexible enough to switch to a different type of vaccine than they were originally intended to produce. Over the next several months, there’s expected to be a ‘winnowing’ of these potential vaccines as data from initial trials are collected, but it will take time before it’s known which vaccine(s) are best. . . . Having a global dialogue now on how vaccines should be scaled up and distributed is key, experts say.”); Costas Paris & Jared S. Hopkins, *Pfizer Sets Up Its ‘Biggest Ever’ Vaccination Distribution Campaign*, WALL ST. J. (Oct. 21, 2020, 6:13 AM), <https://www.wsj.com/articles/pfizer-sets-up-its-biggest-ever-vaccination-distribution-campaign-11603272614> (“[T]he biggest complications in distribution likely would come closer to the final point of delivery rather than the first stages of shipping.”); Jared S. Hopkins, *Covid-19 Vaccines to Be Stored Secretly Under Tight Security*, WALL ST. J. (Oct. 21, 2020,

distributed worldwide over the first few months of 2021, this Article analyzes the problem of vaccine access as a critical question in the literature on sources of international law and the influence of those sources.² As with past pandemics, research and development (R&D) capacity is largely concentrated in the wealthy countries of Europe and North America with growing capabilities in East and South Asia.³ Over the course of 2020, some governments exercised extreme forms of “vaccine nationalism,” refusing to share, or contemplate sharing, COVID-19 vaccines or related knowledge with any populations but their own.⁴ According to Rutschman:

As some governments began narrowing down the roster of projects receiving priority status in late spring, the first hints of “vaccine nationalism” appeared. The expression is linked to agreements that reserve the bulk of emerging vaccines for a limited number of countries, traditionally in the developed world. While these strategies are not new, they have become a recent hallmark of negotiations during large-scale outbreaks of vaccine-preventable diseases. If left unaddressed, vaccine nationalism can have serious consequences for equitable access to the first COVID-19 vaccines to come to market.⁵

Other governments balanced the needs of their domestic populations with regional or global diplomatic objectives.⁶ Within this latter category, some governments shared bilaterally as a means of furthering local or international influence, while others participated in a multilateral sharing mechanism

3:48 PM), https://www.wsj.com/articles/covid-19-vaccines-to-be-stored-secretly-under-tight-security-11603278002?mod=hp_lead_pos4 (detailing the complications of vaccine theft and possible precautions that will be taken to hopefully protect the COVID-19 vaccine from theft).

² Gavin Yamey, *A Coronavirus Vaccine Should Be for Everyone, Not Just Those Who Can Afford It*, STATNEWS (Mar. 5, 2020), <https://www.statnews.com/2020/03/05/coronavirus-vaccine-affordable-for-everyone> (“Without price controls, poor countries are unlikely to be able to afford or access enough vaccines to protect their populations.”).

³ J. Smith, M. Lipsitch & J.W. Almond, *Vaccine Production, Distribution, Access, and Uptake*, 378 LANCET 428, 428–38 (2011) (“In contrast to the [Expanded Programme of Immunization] vaccines, it is a reality that for the new and more complex vaccines, availability in developing countries lags substantially behind that in wealthier countries. At present, the reasons are partly due to manufacturing capacities which, due to investment cost, are seldom sufficient to satisfy global demand in the early years of licensure, and partly due to the economic realities of companies needing to recoup R&D investment [which may be in the region of 1B \$US for a new vaccine] by prioritizing supply to markets that can sustain a high price. In the absence of specific purchasing and supply agreements, newer vaccines are thus often unavailable or unaffordable for many countries for extended periods.”).

⁴ Ana Santos Rutschman, *The Reemergence of Vaccine Nationalism*, GEO. J. INT’L AFFS. ONLINE (July 3, 2020), <https://gija.georgetown.edu/2020/07/03/the-reemergence-of-vaccine-nationalism>.

⁵ *Id.* (citation omitted).

⁶ Aurélia Nguyen, *COVAX Governance Explained*, GAVI (Nov. 13, 2020), <https://www.gavi.org/vaccineswork/covax-facility-governance-explained>.

coordinated by international organizations.⁷ Of course, as with past pandemics, the great majority of governments were left without vaccine development and manufacturing capacity, possessed few resources with which to procure vaccines under prevailing commercial circumstances, and were therefore vulnerable and open to overtures from both bilateral and multilateral acquisition sources.⁸

As Adam Hancock noted in the EU Observer:

Inequality in vaccine coverage between rich and poor countries is stark. More than 1.5 million people die from vaccine-preventable diseases every year around the world, with the vast majority of these deaths in low-income countries.

Coronavirus is only making things worse.

The Global Alliance for Vaccines and Immunisation (Gavi) recently announced that 80 million children in at least 68 countries may now be at risk of contracting a range of regular diseases after the pandemic heavily disrupted routine immunisation programmes.

Systems to deliver and administer vaccines have been hit by a mixture of travel restrictions, delivery delays and people choosing not to leave their homes to be vaccinated due to the ever present threat of infection.

If this continues, health experts fear that low income countries won't be able to effectively administer a new coronavirus vaccine.

“If we neglect the supply chains and immunisation infrastructure that keep these programmes running, we also risk harming our ability to roll out the Covid-19 vaccine that represents our best chance of defeating this pandemic,” said Gavi chief executive Seth Berkley.

⁷ Oliver Stuenkel, *Vaccine Diplomacy Boosts China's Standing in Latin America*, FOREIGN POL'Y (June 11, 2021), <https://foreignpolicy.com/2021/06/11/vaccine-diplomacy-boosts-china-in-latin-america> (“Yet none of this has dampened China’s strategic advantage for a simple reason: It has been running largely unopposed. This has allowed Beijing to project itself as Latin America’s most trusted ally in times of hardship, when other powers failed to respond. So far, the numbers are indeed on Beijing’s side. By mid-May, China had exported more than 250 million doses overall, or 42 percent of its total production, while the United States had only exported 3 million doses, about 1 percent of its production. It has not been lost on observers in the region that more than half of China’s total exports—roughly 165 million doses—have been administered in Latin America. In Brazil, for example, the majority of all shots given by late May were made with Chinese raw materials.”); see also Alexander Smith, *Russia and China Are Beating the U.S. at Vaccine Diplomacy, Experts Say*, NBC NEWS (Apr. 2, 2021), <https://www.nbcnews.com/news/world/russia-china-are-beating-u-s-vaccine-diplomacy-experts-say-n1262742> (further describing vaccine diplomacy strategies adopted by some national governments); Nguyen, *supra* note 6 (detailing the structure and dynamics of international vaccine procurement coordinated by international organizations).

⁸ Adam Hancock, *Why Developing Countries May Be the Last to Get the Vaccine*, EU OBSERVER (May 28, 2020), <https://euobserver.com/coronavirus/148470>.

Traditionally, the cost of securing vaccines has always hindered developing countries. To put it bluntly, they simply can't afford most of the new vaccines being produced.⁹

This Article aims to explain this unique constellation of vaccine development and access from the lens of international law, focusing on the nascent global governance regime for vaccine research, development, and distribution. As wealthy governments used bilateral contracts—Advanced Purchase Agreements (APAs)—to secure vaccines for populations in the world's richest countries, those in poor countries remained at risk.¹⁰ Yet both multilateral and bilateral mechanisms emerged that prioritized vaccine access to those populations, an occurrence arguably at odds with realpolitik conceptions of how and why governments assess their legal options during international emergencies. We explore this dissociation between global public health imperatives and nationalist responses to the pandemic within the frameworks of “vaccine diplomacy,” “vaccine nationalism,” and “viral sovereignty.” The Article ultimately argues that, over the course of the last thirty years, a global regime of vaccine access has emerged and, while not yet cohesive or uniform, it has manifested common characteristics through two vaccine-preventable global public health emergencies: H1N1 pandemic influenza and COVID-19.¹¹ A third, more regional epidemic, Ebola, demonstrated similar characteristics.¹² Even

⁹ *Id.*

¹⁰ Ewen Callaway, *The Unequal Scramble for Coronavirus Vaccines—By the Numbers*, NATURE (Aug. 24, 2020), <https://www.nature.com/articles/d41586-020-02450-x> (“Wealthy countries have struck deals to buy more than two billion doses of coronavirus vaccine in a scramble that could leave limited supplies in the coming year. Meanwhile, an international effort to acquire vaccines for low- and middle-income countries is struggling to gain traction. . . . By mid-August, the United States had secured 800 million doses of at least 6 vaccines in development, with an option to purchase around one billion more. The United Kingdom was the world's highest per-capita buyer, with 340 million purchased: around 5 doses for each citizen. The European Union nations—which are buying vaccines as a group—and Japan have locked down hundreds of millions of doses of vaccines for themselves”); see also Ernst R. Berndt & John A. Hurvitz, *Vaccine Advance-Purchase Agreements for Low-Income Countries: Practical Issues*, 24 HEALTH AFFS. 653 (2005) (describing the general design of vaccine APAs).

¹¹ See *Pandemic Influenza Preparedness Framework*, WORLD HEALTH ORGANIZATION [WHO] (2011), https://apps.who.int/gb/pip/pdf_files/pandemic-influenza-preparedness-en.pdf (“The objective of the Pandemic Influenza Preparedness Framework is to improve pandemic influenza preparedness and response, and strengthen the protection against the pandemic influenza by improving and strengthening the WHO global influenza surveillance and response system [‘WHO GISRS’], with the objective of a fair, transparent, equitable, efficient, effective system for, on an equal footing: (i) the sharing of H5N1 and other influenza viruses with human pandemic potential; and (ii) access to vaccines and sharing of other benefits.”).

¹² Sam F. Halabi, Michelle Rourke & Rebecca Katz, *The Effect of Proprietary and Attribution Claims on Data Sharing During Infectious Disease Emergencies*, 23 J. HEALTHCARE L. & POL’Y, 203, 205 (2020) (“Biomedical firms, largely working from research funded by Canadian and U.S. militaries, accelerated the development of therapeutics and vaccines. Several firms worked in partnership with the ministries of health of the affected countries, including the WHO, the U.S. National Institute for Allergy and Infectious Diseases (NIAID), and the Norwegian Institute of Public Health.”).

more importantly, this regime has been formed and implemented by international organizations, rather than coordinated through individual governments.¹³

Within the broader context of international law scholarship, this Article contributes a significant case for international organizations as international law-makers.¹⁴ The Article focuses on two international agreements—the 2011 Pandemic Influenza Preparedness (PIP) Framework, and the 2020 COVAX Vaccines Pillar of the ACT Accelerator (COVAX)—neither of which is a treaty, neither of which codifies customary international law as it would be conventionally defined, but both of which have been negotiated and implemented by international organizations.¹⁵ These organizations include specialized U.N. agencies like the World Health Organization (WHO) and United Nations Children’s Fund (UNICEF), as well as international organizations technically formed under national law, but which include a broader set of decision-makers (including governments) like the Coalition for Epidemic Preparedness Innovations (CEPI) and the Global Alliance for Vaccines and Immunizations (GAVI).¹⁶ Each agreement represented a legal

¹³ Cf. Rita Guerreiro Teixeira, *The Role of International Organizations in the Development of International Environmental Law: Adjusting the Lenses of Analysis*, 53 CASE W. RES. J. INT’L L. 237 (2021) (“International organizations have gradually moved beyond constituting mere fora for negotiations between states and have assumed a more active role in law-making. . . . For example, the UN has convened the Global Conferences, leading to the adoption of foundational declarations of principles, and numerous other international organizations have prepared draft texts, promoted the conclusion of environmental agreements, adopted standards, guidelines and recommendations, and prepared influential studies. Additionally, novel institutional arrangements have been established by multilateral environmental agreements, which often include a Conference of the Parties empowered to develop the treaty obligations through innovative legislative processes which do not always require consent by all state parties.”).

¹⁴ See generally JOSÉ E. ALVAREZ, INTERNATIONAL ORGANIZATIONS AS LAWMAKERS (2006) (arguing that states delegate various types of authority to international organizations: lawmaking, providing technical assistance by setting standards and recommended practices, facilitating loans to governments and foreign investments, facilitating dispute settlement between them, and making binding decisions).

¹⁵ Seth Berkley, *COVAX Explained*, GAVI (Sept. 3, 2020), <https://www.gavi.org/vaccineswork/covax-explained>; *The Scramble for Vaccines and the COVAX Facility*, CTR. FOR STRATEGIC & INT’L STUD. 1, 3 (Aug. 19, 2020, 9:00 AM), https://csis-website-prod.s3.amazonaws.com/s3fs-public/publication/200811_Scramble_Vaccines.pdf; *Donor Profiles*, GAVI (Dec. 15, 2020), <https://www.gavi.org/investing-gavi/funding/donor-profiles>; NAT’L ACADS. OF SCI., ENG’G, & MED., *The Development of the PIP Framework: Global Lessons on Equity and Fairness for Pandemic Preparedness*, in EXPLORING LESSONS FROM A CENTURY OF OUTBREAKS: READINESS FOR 2030: PROCEEDINGS OF A WORKSHOP (A. Nicholson et al. eds., 2019), <https://www.ncbi.nlm.nih.gov/books/NBK544063> (describing the PIP Framework as not binding).

¹⁶ Steven R. Ratner & Anne-Marie Slaughter, *Appraising the Methods of International Law: A Prospectus for Readers*, 92 AM. J. INT’L L. 291 (1999) (explaining the proliferation of actors and influences on international law); Sam F. Halabi, *The Origins and Future of Global Health Law: Regulation, Security, and Pluralism*, 108 GEO. L.J. 1607, 1621 (2020) (“Between 1977 and 1979, the regulation of corporations became part of WHO’s broader strategy in ensuring infant and children’s health. Regulating corporations also shifted the global-health-lawmaking approach from making recommendations to states to directly regulating nonstate actors through law.

solution to disputes between high-income countries seeking to hoard medicines for their citizens, and low-income countries seeking greater shares of vaccines manufactured in high-income countries.¹⁷ Yet realizing those agreements depended on the coordinating and facilitating efforts of international organizations, rather than by individual or collective action by governments.

The importance of this development is significant not only in the context of sources of international law, but in the relative influence of those sources. Vaccine diplomacy—the efforts of primarily China, India, and Russia to use access to COVID-19 vaccines for regional or international influence—has been fundamentally shaped by international organizations advocating an international norm of vaccine access codified in multilateral legal instruments.¹⁸ COVAX has conditioned the diplomatic outcomes China, India, and Russia may realize through vaccine diplomacy.

The international norm of vaccine access did not emerge because of altruism or self-interest. Rather, it represents a brokered institutional compromise between vaccine nationalism and viral sovereignty—the proprietary claims over pathogens by mainly biodiverse countries that limit access to the genetic resources necessary for the development of many therapeutics and vaccines.¹⁹

This practice was bidirectional: not only did WHO seek to regulate corporations but also to negotiate the terms of the regulation with the firms themselves.”)

¹⁷ Sam F. Halabi, *Viral Sovereignty, Intellectual Property, and the Changing Global System for Sharing Pathogens for Infectious Disease Research*, 28 ANNALS HEALTH L. 101, 104, 119 (2019) (“While Indonesia’s withholding of H5N1 samples generated greater systems for benefit sharing both in the short-term and through the 2011 WHO’s Pandemic Influenza Preparedness Framework, it presented a major threat to global public health. As David Fidler, a global expert on the law of infectious diseases, noted, ‘[w]ithout access to Indonesia’s influenza strains, global surveillance was jeopardized, as was the refinement of diagnostic reagents and the development of intervention strategies, which depend on the information surveillance provides.’ At that point in time, H5N1 exhibited a sixty percent fatality rate among those infected, and its potential to spread more easily between humans was unknown.”)

¹⁸ Smith, *supra* note 7 (“Soon after Moscow sold 5.2 million doses of its Sputnik V vaccine, President Vladimir Putin was on the phone with his Bolivian counterpart, Luis Arce, in late January, discussing topics as varied as building a nuclear power plant to lithium mining and gas reserves. In North Africa, Algeria didn’t pay a dime for the Chinese vaccines that arrived in March. What it did offer was to support Beijing’s ‘core interests’ and oppose interference in its ‘internal affairs’—language China has used to defend against criticism over Hong Kong’s autonomy and allegations of human rights abuses in Xinjiang, which it denies. Although China and Russia deny it, experts say they are beginning to see how Beijing’s and Moscow’s strategy of selling or donating their vaccines abroad is greasing the wheels of their international relationships and allowing them to expand their influence throughout the world. It’s a development that should cause grave concern for the United States and other democracies, according to former U.S. ambassadors and other ex-diplomats. What rankles these observers is not that China and Russia are winning at vaccine diplomacy, it’s that the U.S. and others aren’t even in the game yet. Washington and its allies have instead chosen to prioritize their domestic populations, keeping most doses at home and causing resentment abroad.”); PETER HOTEZ, PREVENTING THE NEXT PANDEMIC: VACCINE DIPLOMACY IN A TIME OF ANTI-SCIENCE (2021).

¹⁹ Halabi, *supra* note 17, at 119–20 (2019) (“In the context of MERS-CoV, some argue that the dispute

Without that access, there may be no vaccines; and without vaccines, there may be no vaccine nationalism. This balance has resulted in consecutive international legal arrangements, mostly facilitated by WHO, that indicate an interest in collaboration, division of gains from trade, and sustained governance structures: the PIP Framework and COVAX. The recurrence of these legal arrangements suggests that to save the transaction costs generated by repeated development of ad hoc structures that centralize vaccine distribution, a permanent facility may be developed. One possibility for such a facility is the PIP Framework, adapted to become an all- or most-pathogen-sharing international organization.²⁰ A

between the Erasmus Medical Center and the Saudi government caused substantial delays in researchers' access to viral samples. According to the Saudi Ministry of Health, Erasmus had obtained the virus illegally and the conditions it imposed on other researchers delayed development of treatments and vaccines. Negotiations between the U.S. and Saudi governments for virus samples involved elaborate demands for research in Saudi territory, participation by Saudi scientists, and other technological requirements. Similar difficulties emerged after clusters of microcephaly and other neurological disorders in newborns were associated with the Zika virus in Brazil in 2015. Even before cases became known in the United States, Paulo Gadelha, President of Fiocruz, a major Brazilian research institution, said he could not send samples abroad due to a new Brazilian law that protects national genetic resources. Researchers at the CDC relied on Zika viruses taken from earlier outbreaks in French Polynesia to work on Zika diagnostics, and other researchers attempted to sequence Zika's genetic code using virus samples from Puerto Rico. In the U.K., researchers used samples drawn from Micronesia, the site of an outbreak in 2007. The French relied on samples from Polynesia and Martinique. In Spain scientists used a Ugandan strain of Zika supplied by the United States. Even scientists in Portugal, a country that shares extensive cooperative ties to Brazil, had to work with a U.S. sample from the 1980s. The result was, again, delays in the development of diagnostics, therapeutics and vaccine candidates for the vector-borne illness." While China shared the genetic sequence of SARS-CoV-2 in January 2020, sharing of live samples was delayed. *China Delayed Releasing Coronavirus Info, Frustrating WHO*, ASSOCIATED PRESS (June 1, 2020), <https://apnews.com/article/united-nations-health-ap-top-news-virus-outbreak-public-health-3c061794970661042b18d5aeaaed9fae> ("Throughout January, the World Health Organization publicly praised China for what it called a speedy response to the new coronavirus. It repeatedly thanked the Chinese government for sharing the genetic map of the virus 'immediately,' and said its work and commitment to transparency were 'very impressive, and beyond words.' But behind the scenes, it was a much different story, one of significant delays by China and considerable frustration among WHO officials over not getting the information they needed to fight the spread of the deadly virus. The Associated Press has found. Despite the plaudits, China in fact sat on releasing the genetic map, or genome, of the virus for more than a week after three different government labs had fully decoded the information. Tight controls on information and competition within the Chinese public health system were to blame, according to dozens of interviews and internal documents. Chinese government labs only released the genome after another lab published it ahead of authorities on a virologist website on Jan. 11. Even then, China stalled for at least two weeks more on providing WHO with detailed data on patients and cases, according to recordings of internal meetings held by the U.N. health agency through January—all at a time when the outbreak arguably might have been dramatically slowed."); Amy Maxmen, *Divisive Covid Lab Leak Debate Prompts Dire Warning from Researchers*, NATURE (May 27, 2021), <https://www.nature.com/articles/d41586-021-01383-3>.

²⁰ Bingzhe Li et al., *Expanding the Pandemic Influenza Preparedness Framework to the Epidemic of COVID-19*, 54 ZHONGHUA YU FANG YI XUE ZA ZHI [CHINESE J. PREVENTIVE MED.] 597, 597–601 (2020) ("Since the transmission route and transmission capacity of COVID-19 are similar to that of influenza A [H1N1] in 2009, which conforms to the basic elements of 'human pandemic', and the epidemic scale has exceeded that of influenza A [H1N1], it is probable to incorporate COVID-19 epidemic response into PIPF, and at the same time to verify and improve PIPF in practice. It is recommended that WHO, other international organizations and

second possibility has been introduced in light of the COVID-19 pandemic: a Pandemic Treaty that establishes the terms under which pandemic vaccines will be developed and shared in the future.

Whatever alternative materializes, this Article is the first to describe the phenomena that have driven the development of international vaccine sharing mechanisms, identify the international organizational forces that explain the phenomena, and explain how international organizations may facilitate international cooperation before, during, and after global crises.

I. VACCINE NATIONALISM

Vaccine nationalism describes situations in which “countries prioritize their own vaccine needs,” failing to take into account those of populations located elsewhere in the world.²¹ This prioritization is achieved through bilateral channels, when a country negotiates individually with one or more pharmaceutical companies and reserves a significant amount of initial vaccine doses.²² This particular form of nationalism is typically operationalized through orders placed before a vaccine has been granted market authorization or approval by drug regulators. Through APAs, buyers communicate interest in a vaccine candidate, giving suppliers an economic incentive to bring the candidate through the R&D pipeline and regulatory review as quickly as possible.²³ As regulators greenlight the use of a vaccine, the obligations set forth in an APA

relevant countries make full use of the PIPF system to respond to the epidemic and better coordinate national actions at the global level.”)

²¹ Harry Kretchmer, *Vaccine Nationalism—and How it Could Affect Us All*, WORLD ECON. F. (Jan. 6, 2021), www.weforum.org/agenda/2021/01/what-is-vaccine-nationalism-coronavirus-its-affects-covid-19-pandemic (“As COVID-19 vaccines are developed and approved, national leaders face a dilemma: which to prioritize—country or planet? Both, most people would answer. Nonetheless, ‘vaccine nationalism,’ where countries prioritize their own vaccine needs, is forecast to handicap not just the global health recovery but the economic one, too, with one report estimating its impact at more than \$1 trillion per year. That’s because although progress has been made through initiatives like COVAX [the global effort to ensure access to COVID-19 vaccines for all countries], the majority of the world’s poor are still unlikely to be immunized in 2021—prolonging disruption. The world’s richest nations have pre-ordered billions of doses of vaccines—enough to protect some populations several times over. However, in doing so they have left less for others and may push up treatment prices, too.”).

²² See *id.*

²³ Mark Eccleston-Turner, *Vaccine Procurement During an Influenza Pandemic and the Role of Advance Purchase Agreements: Lessons From 2009-H1N1*, 11 GLOB. PUB. HEALTH 322, 327 (2016) (“A 2009 survey by the WHO of pandemic influenza vaccine manufacturers asked whether they would be willing to reserve 10% of real-time production for acquisition by UN agencies, 14 out of 25 were unable to meet the request to set aside 10% of their production capacity, because they were constrained by meeting the volume of vaccines reserved via APAs . . .”).

mature into the legal framework governing the immediate purchase of vaccine doses.²⁴

Contractual bilateralism might appear efficient, as it incentivizes suppliers to come to market in a timely fashion while diminishing uncertainty and delays at the time the vaccines become commercially available.²⁵ Yet, in situations of product scarcity, vaccine nationalism is bound to benefit those with greater resources, while further disadvantaging those with more limited buying capacity, bargaining power, or both. As illustrated by the COVID-19 pandemic, the global vaccine manufacturing infrastructure is ill-equipped to produce enough doses to meet pandemic—and in some cases even epidemic—demand for vaccines. By capturing a substantial amount of vaccine during a period of heightened vaccine scarcity, countries with the highest bargaining and purchasing power thus have the ability to effectively exclude or drastically limit the ability of other countries to gain timely access to critically-needed vaccines. This outcome should not come as a surprise to so-called “realists” who emphasize the idea that “[g]eopolitical calculations have shaped national responses to COVID-19[.]”²⁶ Vaccine nationalism highlights how “[n]ational policies are rarely based on what is thought to be just. They are almost always based instead on a country’s pragmatic perception of what is in its self-interest.”²⁷

²⁴ Sam F. Halabi, *Obstacles to pH1N1 Vaccine Availability: The Complex Contracting Relationship Between Vaccine Manufacturers, WHO, Donor and Beneficiary Governments*, in PUBLIC HEALTH RESPONSE TO 2009 H1N1: A SYSTEMS PERSPECTIVE 203 (Michael A. Stoto & Melissa A. Higdon eds., 2015).

²⁵ *Questions and Answers on Vaccine Negotiations*, EUR. UNION (Jan. 8, 2021), https://ec.europa.eu/commission/presscorner/detail/en/QANDA_21_48 (“In the negotiation process, Member States tell the Commission how much of a certain vaccine they want to order. But they are then responsible for purchasing the vaccines when they become available, once they prove to be safe and effective. The Commission does not sign contracts for deliveries to individual countries. Advance Purchasing Agreements allow the Commission to secure a certain number of doses. It is then for Member States to purchase these doses, activate potential options included in the APA to order additional doses, and conclude specific contracts with the companies.”).

²⁶ David P. Fidler, *Vaccine Nationalism’s Politics*, 369 SCI. MAG., Aug. 14, 2020, at 749 (“However, the politics of the coronavirus catastrophe do not reflect such national interests or international solidarity. ‘Vaccine nationalism’ is more evidence that efforts to elevate health cooperation—and the sciences that inform it—have produced more rhetoric than political roots within countries and the international community. Concerns about vaccine nationalism were escalating even before the United States announced on 31 July its largest deal to date with pharmaceutical companies to secure COVID-19 vaccines. Other countries—including China, India, the United Kingdom, and members of the European Union—are pursuing similar strategies. To critics, this scramble to secure vaccine supplies is one of many decisions by governments that have failed to control spread of the virus, destroyed economic activity, and damaged international cooperation. Ineffective nationalistic policies appear to create a gap between science and politics that makes the pandemic worse and undermines what science and health diplomacy could achieve. In fact, vaccine nationalism reflects ‘business as usual’ in global health.”).

²⁷ James Bacchus, *The Antidote to Vaccine Nationalism*, CTR. INT’L GOVERNANCE INNOVATION (Dec. 21, 2020), www.cigionline.org/articles/antidote-vaccine-nationalism (“The world is rightly celebrating the unprecedented speed with which vaccines for COVID-19, the novel coronavirus, are approaching manufacture

A. *Vaccine Nationalism: Polio, Smallpox, and Influenza*

Vaccine nationalism is not new.²⁸ Vaccine nationalism patterns occurred during the rollout of the smallpox and polio vaccines, which were only available to developing countries after high-income states secured enough doses to vaccinate their domestic populations.²⁹ The first vaccines against polio were developed collaboratively between the United States and Soviet Union in the 1950s.³⁰ Polio declined rapidly in wealthy countries over the course of the 1950s.³¹ It took many more decades, however, to eradicate the disease in most poorer countries, and there remain pockets of endemic polio in Afghanistan and Pakistan.³²

and distribution stages. When COVID-19 vaccines become widely available, millions of lives can be saved, and the loss of US \$375 billion to the global economy every month can be prevented. Yet, while billions of people worldwide await their doses of the new vaccines, many countries are also courting ‘the tragedy of vaccine nationalism.’ With potentially lethal global consequences, these countries are giving unwise priority to the immediate universal *national* vaccination of their own citizens instead of to a scientifically targeted *national and international* vaccination, which would be the most effective means of saving lives everywhere and should be the global goal during the COVID-19 pandemic. Wherever we may live, giving preference to vaccinating our fellow nationals who are the least at risk of COVID-19 infection over people from other countries who are the most at risk is not only morally wrong, but also contrary to our national self-interest. To provide the most protection to people from anywhere, the COVID-19 vaccines must be distributed in ways that will save the most lives everywhere. They must not be deployed in ways that will hasten the turn away from internationalism and toward an insular nationalism. Vaccine nationalism will save fewer lives, and it will pull the nations of the world farther apart at a time when the world must unite to confront the global emergency of the COVID-19 pandemic.”); Muhammad Zaheer Abbas, *Practical Implications of “Vaccine Nationalism”: A Short-Sighted and Risky Approach in Response to COVID-19* 18 (S. Ctr., Research Paper No. 124, Nov. 2020), <https://www.southcentre.int/wp-content/uploads/2020/11/RP-124.pdf> accessed (“To end the COVID-19 pandemic and ensure a return of normalcy, an effective and safe vaccine is the best hope. The vaccine nationalism approach, adopted by some countries to gain preferential access to emerging COVID-19 vaccines, poses a threat to the fair and equitable distribution of the potential vaccines across the globe [V]accine nationalism [is] self-centred political behaviour of leaving others behind [and] is short-sighted, potentially risky, morally indefensible, and practically inefficient in containing the pandemic [I]t is important for national governments to support the collaborative and coordinated effort of the COVID-19 Vaccines Global Access (COVAX) facility for the timely development and efficient delivery of potential COVID-19 vaccines. It concludes that an effective response to the current health and economic crisis should be guided by values of international solidarity, multilateralism, equality, and global collaboration.”).

²⁸ Kretchmer, *supra* note 21 (“Is vaccine nationalism new? In a word, no. A similar pattern was seen during the 2009 H1N1 influenza pandemic. Before that, vaccines for smallpox and polio were only available in developing nations after developed countries had secured enough stocks for domestic needs. Indeed, historic limitations in international cooperation may have spurred the development of home-grown immunological capabilities among countries such as China and India. But while there may be a certain inevitability to nations’ desires to protect themselves first, such decisions have consequences for all.”).

²⁹ See, e.g., Fidler, *supra* note 26, at 749.

³⁰ Peter J. Hotez & K.M. Venkat Narayan, *Restoring Vaccine Diplomacy*, 325 J. AM. MED. ASSOC. 2337, 2337 (June 15, 2021).

³¹ *History of Polio*, BBC NEWS (Sept. 25, 2015), <https://www.bbc.com/news/health-17045202>.

³² *Id.*

Similarly, smallpox ravaged the global population equally between rich and poor until the twentieth century, killing an estimated 300 to 500 million people in that century alone.³³ In the United States, individual states like Massachusetts required smallpox vaccination, leading to the spread of immunization policies across North America and Europe. Many wealthy countries had eliminated smallpox by 1900, and by 1914, the incidence in most industrialized countries had decreased to comparatively low levels.³⁴ It took a global effort led by WHO to mobilize the resources necessary to eliminate smallpox in poor countries as late as 1980.³⁵

Vaccine nationalism was also illustrated during the pandemic that preceded COVID-19: the 2009 H1N1 influenza pandemic.³⁶ This was the first global influenza pandemic of the twenty-first century and the second pandemic caused by the H1N1 influenza strain, which originally triggered the 1918–1920 Spanish Flu pandemic.³⁷

The 2009 Flu Pandemic started in April in North America and quickly spread across the world, commencing a vaccine race.³⁸ A month into the outbreak, several higher-income countries negotiated APAs that reserved most of the earliest doses of vaccine.³⁹ At the time, it was estimated that, in a best-case scenario, global capacity for short-term vaccine manufacturing was between one and two billion doses.⁴⁰ Against this backdrop, the United States alone entered into agreements that reserved up to 600,000 doses of the first batch of vaccines to be produced targeting the novel strand of H1N1.⁴¹ Other developed or quasi-

³³ Kelsey Piper, *Smallpox Used to Kill Millions of Humans Every Year. Here's How Humans Beat It*, VOX (Feb. 5, 2021, 11:00 AM), <https://www.vox.com/future-perfect/21493812/smallpox-eradication-vaccines-infectious-disease-covid-19>.

³⁴ W.A. ORENSTEIN & S.A. PLOTKIN, *VACCINES* (3d ed. 1999).

³⁵ See also Halabi, *supra* note 16 (analyzing the constitutional authorities WHO may use to effect international law and its general hesitation to do so); *Smallpox*, WHO, https://www.who.int/health-topics/smallpox#tab=tab_1.

³⁶ SAM HALABI & REBECCA KATZ, *VIRAL SOVEREIGNTY AND TECHNOLOGY TRANSFER* (2020).

³⁷ Darisuren Anhlan et al., *Origin of the 1918 Pandemic H1N1 Influenza: A Virus as Studied by Codon Usage Patterns and Phylogenetic Analysis*, 17 *RNA* 64, 64–73 (2011).

³⁸ Ignacio Mena et al., *Origins of the 2009 H1N1 Influenza Pandemic in Swine in Mexico*, *ELIFE* (Jan. 28, 2016); Paul C. Hébert & Noni MacDonald, *The H1N1 Vaccine Race: Can We Beat the Pandemic?*, 181 *CAN. MED. ASS'N J.* E125 (2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2761457>.

³⁹ See David Brown, *Most of Any Vaccine for New Flu Strain Could Be Claimed by Rich Nations' Preexisting Contracts*, *WASH. POST* (May 7, 2009), www.washingtonpost.com/wp-dyn/content/article/2009/05/06/AR2009050603760.html.

⁴⁰ *Id.*

⁴¹ Ana Santos Rutschman, *How Academics Can Address Rise in Vaccine Nationalism*, *UNIV. WORLD NEWS* (Apr. 13, 2021), <https://www.universityworldnews.com/post.php?story=20210413081054270> (“The United States alone, for example, pre-ordered 600,000 doses of H1N1 vaccines. This left lower-income countries facing a very long waiting period for additional doses of vaccine to be made available to them. Vaccine

developed economies negotiated similar pre-production agreements.⁴² Outside of APAs, approximately fifty-six percent of vaccine manufacturers surveyed could guarantee ten percent of real-time vaccine production for purchase by U.N. agencies to support low-income countries.⁴³ As the pandemic unfolded, however, several high-income countries pledged to donate H1N1 vaccines to lower-income countries, a pattern of conduct that ran in parallel with the development of a multilateral pandemic-influenza vaccine-sharing mechanism.⁴⁴

B. Vaccine Nationalism: SARS-CoV-2/COVID-19

Vaccine nationalism reemerged again during the COVID-19 pandemic. The policy followed by the United States is instructive. The United States relied on a public-private partnership known as Operation Warp Speed (OWS) as the primary mode to procure COVID-19 vaccines. The partnership supported work on six vaccine candidates through the provision of direct funding, as well as the use of APAs to secure millions of doses of vaccine: by March 2021, these contractual agreements accounted for the purchase of over one billion doses by the U.S. government, all of which were dedicated to the U.S. market.⁴⁵

nationalism is a repeat-player game. In 2020, as demand for COVID-19 vaccines spiked, higher-income countries were again at the front of the pre-order line: even before the first COVID-19 vaccines came to market, 32 countries had reserved more than 50% of the global supply of vaccines. This group of countries included the states that form the European Union, the United Kingdom, the United States, Canada, Australia and Japan. Collectively, they account for 13% of the world's population.”)

⁴² See Brown, *supra* note 39.

⁴³ Alexandra L. Phelan et al., *Legal Agreements: Barriers and Enablers to Global Equitable COVID-19 Vaccine Access*, 396 LANCET 800, 800–801 (2020), [https://doi.org/10.1016/S0140-6736\(20\)31873-0](https://doi.org/10.1016/S0140-6736(20)31873-0) (“APAs are legally binding contracts whereby one party, such as a government, commits to purchasing from a vaccine manufacturer a specific number or percentage of doses of a potential vaccine at a negotiated price if it is developed, licensed, and proceeds to manufacture. These bilateral agreements often secure priority access to vaccine and manufacturing capacity. Governments of countries that disagree with the ethics and effectiveness of APAs or that do not have the financial resources to purchase vaccines at comparable prices or engage in commercial negotiations are at risk of not having access to vaccines when they first become available and of having access delays while manufacturing capacity is fulfilled first by wealthy countries’ orders. This was the case during the 2009 influenza A H1N1 pandemic when many APAs held by high-income countries (HICs) were used to secure their priority access to vaccine, making procurement in other countries more difficult. APAs were used so extensively in 2009 that more than 56% of pandemic influenza vaccine manufacturers surveyed by WHO were unable to commit to guaranteeing 10% of real-time vaccine production for purchase by UN agencies due to pre-existing commitments under APAs with HICs. Governments that enter into APAs for candidate vaccines that do not demonstrate evidence of safety and efficacy also risk not getting immediate or sufficient access to successful vaccine candidates.”)

⁴⁴ Margaret Chan, *Pandemic Vaccine Donations for the Developing World*, WHO (Sept. 18, 2009), www.who.int/mediacentre/news/statements/2009/pandemic_vaccine_donations_20090918/en.

⁴⁵ SIMI SIDDALINGAIH, CONG. RSCH. SERV., IN11560, OPERATION WARP SPEED CONTRACTS FOR COVID-19 VACCINES AND ANCILLARY VACCINATION MATERIALS (2021), <https://crsreports.congress.gov/product/pdf/IN/IN11560> (“Operation Warp Speed [OWS] is an interagency partnership between the Department

While making OWS its primary vaccine procurement tool, the U.S. government sought to further diversify its vaccine candidate portfolio during the earlier stages of the pandemic. In March 2020, the German press reported that the White House approached German biotech company CureVac in an attempt to guarantee exclusive access to its vaccine. The German government warded off this effort by a foreign government to lay claims to CureVac's vaccine candidate, noting that "Germany is not for sale" and that "if a vaccine is developed in Germany, then it is for Germany and the world."⁴⁶ A few months later, the German government invested €300 million (roughly \$337 million USD) to guarantee a twenty-three percent stake in CureVac.⁴⁷

of Health and Human Services [HHS] and the Department of Defense [DOD] that coordinates federal efforts to accelerate the development, acquisition, and distribution of COVID-19 medical countermeasures. Collaborating HHS components include the Centers for Disease Control and Prevention [CDC], the National Institutes of Health [NIH], and the Biomedical Advanced Research and Development Authority [BARDA]. OWS is a Trump Administration initiative, and while the Biden Administration has indicated that the interagency response to COVID-19 will continue, it plans to restructure and rename the effort. Although the stated goals of OWS include therapeutics and diagnostics, most of the money awarded to date has focused on vaccines. This Insight summarizes OWS's vaccine-related contracts, including those for ancillary vaccination materials [e.g., needles and vials]. BARDA is currently supporting six vaccine candidates through funding research and development, funding increases in manufacturing capacity, and/or advance purchase contracts. A vaccine candidate from Merck/IAVI also received funding support from BARDA, but was discontinued in January 2021 because it failed to demonstrate sufficient efficacy against COVID-19.").

⁴⁶ Hans Von Der Burchard & Jakob Hanke Vela, *EU Weighs into German-American Spat Over Vaccine Company*, POLITICO (Mar. 16, 2020), www.politico.eu/article/eu-weighs-into-german-american-spat-over-vaccine-company ("After days of being identified as the bad guys in the EU coronavirus saga—for banning the export of medical equipment within Europe—German politicians are now queuing up for an opportunity to portray themselves as defenders of the public in Europe and beyond. Economy Minister Peter Altmaier said 'Germany is not for sale,' while Health Minister Jens Spahn on Sunday insisted to public broadcaster ZDF that CureVac would develop any potential coronavirus vaccine 'for the whole world' and 'not for individual countries.' Foreign Minister Heiko Maas told the Funke media group on Monday that 'we cannot allow others to seek exclusive results.'"); see, e.g., Andy Gregory, "This Should Be Worldwide, Not Regional": German Drug Firm Chief Rebukes Trump "Attempt to Monopolise Vaccine", INDEPENDENT (Mar. 16, 2020) (quoting Helge Braun), www.independent.co.uk/news/world/europe/coronavirus-vaccine-trump-germany-us-dietmar-hopp-carevac-a9404646.html ("The owner of a German drug manufacturer has delivered an apparent rebuke to Donald Trump after the White House was accused of trying to procure a coronavirus vaccine it is developing—but 'only for the United States'. Mr. Trump offered 'large sums of money' to German biopharmaceutical firm CureVac to move its vaccine research to the US, with a view to securing exclusive rights to the resulting drug, *Die Welt* reported. The German government then scrambled to financially incentivise the drug firm to remain in the country, according to the report—published on the front page of the paper's Sunday edition under the headline: 'Trump versus Berlin.'").

⁴⁷ Barbara Kollmeyer, *Germany Investing in Coronavirus Vaccine Maker that It Accused the Trump Administration of Trying to Poach*, MARKETWATCH (June 15, 2020), www.marketwatch.com/story/germany-investing-in-coronavirus-vaccine-maker-that-it-accused-the-trump-administration-of-trying-to-poach-2020-06-15 ("The German government has taken a stake in privately held biotech group CureVac—the company it accused the U.S. of trying to lure away as the coronavirus pandemic was starting to spread in Europe and the U.S. earlier this year. Germany's federal minister for economic affairs and energy, Peter Altmaier, and Dietmar Hopp, co-founder of software group SAP SE and of the investment company dievini Hopp BioTech holding GmbH & Co. KG, jointly announced the government would invest €300 million [\$337 million] in CureVac,

The French government also intervened to stymie APA negotiations between the French pharmaceutical company Sanofi and foreign governments, after the CEO of Sanofi publicly announced that the United States had “the right to the largest pre-order.”⁴⁸ One day after the announcement, on the heels of mounting criticism, both the French government and Sanofi announced that the deal would not move forward.⁴⁹ Several other countries acted according to nationalistic paradigms. India’s Serum Institute—the world’s largest vaccine manufacturer⁵⁰—initially announced that it was committed to “equitable” distribution of COVID-19 vaccines globally but soon thereafter narrowed that commitment by reserving the majority of initial doses for its domestic population.⁵¹

Widespread use of APAs by a reduced number of countries during the COVID-19 pandemic illustrated the profound allocative disparities resulting from vaccine nationalism. Within a few months from the beginning of the pandemic, thirty-two countries had placed APAs for more than fifty percent of

according to the company website. The investment will be made by the state-owned development bank Kreditanstalt für Wiederaufbau [KfW]. Funds will partly be used to further develop the company’s drug pipeline, including its COVID-vaccine. Under the agreement, KfW will end up with a 23% stake in CureVac.”)

⁴⁸ *French Pharma Giant Sanofi to Give United States Preference on Future COVID-19 Vaccine*, FRANCE 24 (May 13, 2020), <https://www.france24.com/en/20200513-french-pharma-giant-sanofi-to-give-us-preference-on-future-covid-19-vaccine>; *Covid-19: Sanofi Backpedals on US Vaccine Priority after French Outrage*, FRANCE 24 (May 15, 2020) [hereinafter *Sanofi Backpedals*], www.france24.com/en/20200514-france-says-unacceptable-for-sanofi-to-give-coronavirus-vaccine-to-us-first (“French drugmaker Sanofi said on Thursday it would ensure a future vaccine against Covid-19 reaches all regions of the world at the same time, a day after its CEO angered the French government by saying the US would enjoy priority access. ‘There will be no particular advance given to any country,’ Serge Weinberg, chairman of the French pharmaceutical giant, told France 2 television. ‘We are organised with several manufacturing units. Some of them are in the United States but even more of them are in Europe and France,’ Weinberg said, adding that earlier comments by the company’s chief executive had been ‘altered’. Paul Hudson, Sanofi’s CEO, told Bloomberg on Wednesday that vaccine doses produced in the United States could go to US patients first, given the country had supported the research financially. His comments prompted outrage in France, with French Prime Minister Édouard Philippe stressing that Sanofi was ‘profoundly French’ and warning that equal access to a vaccine was ‘non-negotiable.’”).

⁴⁹ *See Sanofi Backpedals*, *supra* note 48.

⁵⁰ *About Us*, SERUM INST. INDIA PVT. LTD., www.seruminstitute.com/about_us.php.

⁵¹ *See Zeba Siddiqui, India’s Serum Institute to Make Millions of Potential Coronavirus Vaccine Doses*, REUTERS (Apr. 28, 2020) www.reuters.com/article/us-health-coronavirus-india-vaccine/indias-serum-institute-to-make-millions-of-potential-coronavirus-vaccine-doses-idUSKCN22A2YY (“‘A majority of the vaccine, at least initially, would have to go to our countrymen before it goes abroad,’ Poonawalla said, adding that Serum would leave it to the Indian government to decide which countries would get how much of the vaccine and when. Serum envisages a price of 1,000 rupees per vaccine but governments would give it to people without charge, he said. Responding in a statement on Wednesday, Wellcome’s Weller said: ‘We need a vaccine that will work for the world, and any advances must be available to all countries equally, without exception.’ Poonawalla said that Indian Prime Minister Narendra Modi’s office was ‘very closely’ involved and that the company hopes the government will help cover the cost of making the experimental vaccine.”).

soon-to-be-available vaccine doses.⁵² While effectively in control of the majority of the worldwide vaccine supply, these thirty-two countries represented only around thirteen percent of the global population.⁵³ They were also countries belonging to the higher-income economies of the “Global North”: the group included Canada, the United States, the United Kingdom, the member-states of the European Union, Japan, and Australia.⁵⁴ In late 2020, the Duke Global Health Institute published a study calculating that, given the persisting imbalances in the global distribution of the first batches of COVID-19 vaccines, the majority of low-income countries would only be able to fully vaccinate their populations in 2024.⁵⁵

At a broader level, vaccine nationalism showcases a fracture between theoretical approaches to the production and management of health goods and transactional practices determining the actual allocation of these goods. The former emphasizes principles of global solidarity and equity,⁵⁶ while the latter

⁵² Asher Mullard, *How COVID Vaccines Are Being Divvied Up Around the World*, NATURE (Nov. 30, 2020), www.nature.com/articles/d41586-020-03370-6.

⁵³ *Id.*

⁵⁴ See Arthur Allen, *The Case for Donating US Covid Vaccines Overseas*, KAISER HEALTH NEWS (Mar. 19, 2021), <https://khn.org/news/article/the-case-for-donating-us-covid-vaccines-overseas> (“In particular, Lurie and others are urging the Biden administration to make plans for getting surplus U.S. covid vaccine supplies overseas once Americans are vaccinated. They note that the administration has secured at least 700 million doses of vaccines—more than enough to fully vaccinate every adult and child in the U.S.—by the end of July. The current focus must be the United States, which has had more covid cases and deaths than any other country. But in the longer term, global immunization will be crucial. ‘We need to take care of the problem everywhere to be able to take care of it anywhere,’ said Dr. Mark Feinberg, president and CEO of the International AIDS Vaccine Initiative, a remark echoed in a petition circulated by leading U.S. scholars. ‘Even if we get high-level vaccine coverage here, we’ll still be vulnerable to imported variants that are less responsive to the first-generation vaccines. It’s going to be an ongoing problem.’”).

⁵⁵ *Will Low-Income Countries Be Left Behind When COVID-19 Vaccines Arrive?*, DUKE GLOB. HEALTH INST. (Nov. 9, 2020), <https://globalhealth.duke.edu/news/will-low-income-countries-be-left-behind-when-covid-19-vaccines-arrive> (“A new global assessment of purchasing agreements for COVID-19 vaccines reveals that high-income countries, as well as a few middle-income countries flush with manufacturing capacity, have already purchased nearly 3.8 billion doses, with options for another five billion. The analysis, released by the Duke Global Health Innovation Center, shows that many of these countries will be able to vaccinate their entire populations—and some will be able to do so many times over—before billions of people are vaccinated in low-income countries. ‘An ambitious effort to create a global system of vaccine equity is being undermined as a handful of countries—including those who made a commitment to equality—secure as many doses as they possibly can,’ said Elna Urli Hodges, MSPH, who leads the Center’s Launch and Scale Speedometer, an initiative that identifies impediments to delivering health innovations to low-income countries. Urli Hodges added, ‘Countries are hedging bets by making direct deals while also participating in multilateral platforms, which drives inequality and threatens to prolong a global pandemic.’ While other assessments have warned of potential inequalities in vaccine access, this new analysis is the first to carefully quantify the amount of vaccine doses that are being claimed by country-level agreements and how this could delay access to COVID-19 protection across large regions—including sub-Saharan Africa—until almost the middle of the decade.”).

⁵⁶ Max H. Bazerman et al., *How Should We Allocate Scarce Medical Resources?*, HARV. BUS. REV. (Apr. 29, 2020), <https://hbr.org/2020/04/how-should-we-allocate-scarce-medical-resources> (“Their preferences

results in a country-based encirclement of transnationally-needed resources. Keith Maskus and Jerome Reichman have aptly characterized this progressive erosion of cooperative international frameworks as “the globalization of private knowledge goods and the privatization of global public goods.”⁵⁷ In this sense, vaccine nationalism must be understood in connection with other contemporary sovereignty-asserting behaviors that further contribute to the enclosure—even if temporary—of health goods and, more broadly, biological resources. This Article now explores this connection by surveying the closely related phenomenon of viral sovereignty.⁵⁸

II. VIRAL SOVEREIGNTY

Just as wealthy countries used capital, research, and manufacturing capacity to encircle vaccines and their contributory processes, biodiverse but capital-poor states have increasingly leveraged their genetic resources for individual and collective gain.⁵⁹ “Viral sovereignty” is the term applied when a country provides access to pathogenic samples as a research input in exchange for benefits arising from the utilization of those samples to develop drugs and vaccines.⁶⁰

Viral sovereignty slowly emerged over the course of vaccine nationalist episodes covering polio, smallpox, and influenza.

tell us something about fairness principles. ‘First come, first served’ is a morally plausible principle. So is ‘Save the most years of life.’ Which rule is fairer in the current moment? When participants put themselves in the shoes of both patients, the majority indicated that saving more life-years is fairer: It’s what they would want for themselves if they did not know whom they were going to be. Our most important conclusion is not that the young should be favored over the old, or that any group should be favored over any other, but rather that decisions should be made through an impartial process.”); see, e.g., Suerie Moon et al., *Global Public Goods for Health: Weaknesses and Opportunities in the Global Health System*, 12 HEALTH ECON., POL’Y & L. 195 (2017).

⁵⁷ Keith E. Maskus & Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods*, 7 J. INT’L ECON. L. 279 (2004); see also Gregory Shaffer, *International Law and Global Public Goods in a Legal Pluralist World*, 23 EUR. J. INT’L L. 669 (2012).

⁵⁸ Halabi, *supra* note 17, at 101 (“Instead of the open system of sharing bacterial and viral human pathogens that characterized the research system for much of the 20th Century, notions of ‘viral sovereignty,’ access contingent upon provisions like sharing research benefits, and acrimonious negotiations, are far more common. The increasing barriers to the flow of research material and related data like genetic sequencing information are posing threats to public health responses and the potential use of such resources in diagnostic, therapeutic, and vaccine innovation.”).

⁵⁹ See generally Ciara Staunton & Keymanthj Moodley, *Data Mining and Biological Sample Exportation from South Africa: A New Wave of Bioexploitation Under the Guise of Clinical Care?*, 106 S. AFR. MED. J. 136, 138 (2016) (“For decades there has been a unidirectional flow of samples out of Africa to various destinations in developed countries, with no benefit to local populations or local researchers.”).

⁶⁰ Halabi, *supra* note 17, at 101 (“Indonesia’s actions introduced the previously unknown concept of ‘viral sovereignty’ to the scientific sharing process. ‘Viral sovereignty’ refers to situations in which countries assert that viruses located and isolated from within their territories are their sovereign property.”).

Over the course of the 1960s and 1970s, many low- and middle-income countries questioned the structure of global biological research as part of a broader evaluation of the distribution of technological capacity worldwide. Building technological capacity, in this view, was a crucial part of leveling the playing field between the poorer states of Africa, Asia, and Latin America and the wealthier states of North America and Europe.⁶¹

Because the development of a technological base was perceived as intricately tied to control over industrial processes applied to raw materials, it was sovereignty over natural resources that informed much of the technology distribution debate. In their earliest forms, calls for control over natural resources covered commodities like petroleum, rubber, and agricultural goods primarily.⁶² But the general call for control over natural resources expanded in the early 1990s to include biological and genetic resources, including pathogens.⁶³

In 1972, the United Nations held the first of many global conferences on the Human Environment in Stockholm, Sweden.⁶⁴ In the decade after the 1972 conference, scientists and non-governmental organizations elevated the issue of biodiversity to a global policy priority.⁶⁵ In 1987, the first steps were taken toward the Convention on Biological Diversity.⁶⁶

Eventually, these movements led to the 1992 U.N. Conference on Environment and Development held in Rio De Janeiro, the result of which included the Rio Declaration, the Convention on Biological Diversity (CBD), the U.N. Framework Convention on Climate Change, and the U.N. Convention to Combat Desertification. The CBD traced a direct line to the earliest debates on sovereign control over natural resources, which claimed that it was the

⁶¹ U.N. Conference on Trade and Development, *Proceedings of the United Nations Conference on Trade and Development on its Second Session*, 272 (UNCTAD II) (Feb.–Mar. 1968), http://unctad.org/en/Docs/td97vol1_en.pdf; PETER DRAHOS, *THE GLOBAL GOVERNANCE OF KNOWLEDGE: PATENT OFFICES AND THEIR CLIENTS* xiv (2010).

⁶² Charles N. Brower & John B. Tepe, Jr., *The Charter of Economic Rights and Duties of States: A Reflection or Rejection of International Law?*, 9 INT'L LAW. 295 (1975).

⁶³ Halabi, *supra* note 17, at 101.

⁶⁴ See generally U.N. Conference on the Human Environment, *Stockholm Declaration*, U.N. Doc. A/CONF.48/14 (1972).

⁶⁵ *History of the Convention*, CONVENTION ON BIOLOGICAL DIVERSITY, www.cbd.int/history.

⁶⁶ See generally UNEP Res. 14/26 (1987) (summarizing the findings of fourteenth session of the Governing Council of the U.N. Environment Programme [UNEP]). UNEP took place over the course of twelve meetings in Nairobi in 1987. *Id.* The following year, UNEP convened the Ad Hoc Working Group of Experts on Biological Diversity, which began work on a legal framework to protect biological diversity. *Id.*; see also Convention on Biodiversity, *History of the Convention*, <https://www.cbd.int/history>.

inalienable right of each state to handle natural resources as they saw fit and that exploitation of these resources—commercially, technologically, etc.—should be shared “between the investors and the recipient State.”⁶⁷

Article 2 of the CBD defines “genetic resources” as “genetic material of actual or potential value.”⁶⁸ Article 15 incorporates prior informed consent and mutually agreed terms as conditions for both access and use of resources, while Article 16 incorporates the demand for technology transfer as a form of benefit that could be available to provider countries.⁶⁹

The Convention on Biological Diversity (and the negotiations leading to it) thus paved the way for the transfer of biological resources to take place through mediums of proprietary claims—especially government permits and material transfer agreements—often regulated by governments, rather than through informal sharing through scientific networks.⁷⁰ After the CBD, some

⁶⁷ See G.A. Res. 1803 (XVII), ¶ 3, Permanent Sovereignty over Natural Resources (Dec. 8, 1962).

⁶⁸ Convention on Biological Diversity art. 2, June 5, 1992, 1760 U.N.T.S. 79.

⁶⁹ See *id.* arts. 15, 16(1). See generally GÜNTHER HANDL, DECLARATION OF THE UNITED NATIONS CONFERENCE ON THE HUMAN ENVIRONMENT (STOCKHOLM DECLARATION), 1972 AND THE RIO DECLARATION ON ENVIRONMENT AND DEVELOPMENT, 1992, at 1 (2012), https://legal.un.org/avl/pdf/ha/dunche/dunche_e.pdf (“The Stockholm and Rio Declarations are outputs of the first and second global environmental conferences, respectively, namely the United Nations Conference on the Human Environment in Stockholm, June 5-16, 1972, and the United Nations Conference on Environment and Development [UNCED] in Rio de Janeiro, June 3-14, 1992. Other policy or legal instruments that emerged from these conferences, such as the Action Plan for the Human Environment at Stockholm and Agenda 21 at Rio, are intimately linked to the two declarations, conceptually as well as politically. However, the declarations, in their own right, represent signal achievements. Adopted twenty years apart, they undeniably represent major milestones in the evolution of international environmental law, bracketing what has been called the ‘modern era’ of international environmental law [Sand, pp. 33-35]. Stockholm represented a first taking stock of the global human impact on the environment, an attempt at forging a basic common outlook on how to address the challenge of preserving and enhancing the human environment. As a result, the Stockholm Declaration espouses mostly broad environmental policy goals and objectives rather than detailed normative positions. However, following Stockholm, global awareness of environmental issues increased dramatically, as did international environmental law-making proper. At the same time, the focus of international environmental activism progressively expanded beyond transboundary and global commons issues to media-specific and cross-sectoral regulation and the synthesizing of economic and development considerations in environmental decision-making. By the time of the Rio Conference, therefore, the task for the international community became one of systematizing and restating existing normative expectations regarding the environment, as well as of boldly positing the legal and political underpinnings of sustainable development.”).

⁷⁰ See Halabi, *supra* note 17, at 116–117 (“The effect of these movements in international law - toward greater assertion of sovereign proprietary rights over biological resources - and the practicalities of transferring biological samples across borders has been profound. The Nagoya Protocol established a complex framework for regulating scientists’ [including botanical gardens, universities, libraries, and certainly for-profit firms] ability to conduct research in low- and middle-income countries. Under the Nagoya Protocol, a researcher would ideally contact the country’s national focal point [NFP], an administrative body suggested by the treaty, to commence access-and-benefit sharing negotiations. The NFP, in turn, would identify the correct ‘competent national authority’ to discuss prior informed consent and mutually agreed terms for benefit sharing. While this

governments made it more difficult to obtain resources from their territories.⁷¹ The CBD adopted as one of its objectives the promotion of conservation, and sustainable use, of biological diversity while seeking “fair and equitable” sharing of benefits derived from their genetic resources.⁷² The CBD created a legal zone in which biodiversity-rich countries could set terms for exploitation and the protection of their citizens to share in the benefits of any commercialization of their resources.⁷³ More than sixty nations have created Access and Benefit Sharing regimes via their domestic laws, with particular activity from biodiversity-rich states like Brazil, China, Costa Rica, Kenya, the Philippines, and South Africa.⁷⁴

In late 2006, Indonesia withheld H5N1 avian flu samples from the WHO’s Global Influenza Surveillance Network system.⁷⁵ This constituted a significant measure since the H5N1 avian flu outbreak that had spiked beginning in early 2005 was not only spreading along avian flyways, but threatened to become transmissible between humans; those infected experienced a terrifying fifty percent fatality rate.⁷⁶ Indonesia asserted its decision was a response to an Australian company’s patent on a vaccine derived from a virus sample Indonesia provided to the WHO’s pathogen-sharing network.⁷⁷ More importantly, for purposes of human pathogen sharing, Indonesia argued that the H5N1 virus samples that came from its territory constituted the same kinds of natural resources as petroleum or rubber, as well as forms of biodiversity protected under Articles 15 and 16 of the Convention on Biological Diversity.⁷⁸ Indonesia

seems straightforward, the competent national authority may be a ministry of health, ministry of environment, ministry of indigenous issues, ministry of interior, or some other department. In Brazil, for example up to nine ministries may have jurisdiction over the pathogen at issue.”).

⁷¹ Jerome H. Reichman, Paul Uhlir & Tom Dedeurwaerdere, *Tightening the Regulatory Grip: From the Convention on Biological Diversity in 1992 to the Nagoya Protocol in 2010*, in GOVERNING DIGITALLY INTEGRATED GENETIC RESOURCES, DATA, AND LITERATURE: GLOBAL INTELLECTUAL PROPERTY STRATEGIES FOR A REDESIGNED MICROBIAL RESEARCH COMMONS 89–90 (2016).

⁷² See Convention on Biological Diversity, June 5, 1992, 1760 U.N.T.S. 79. There are 198 states party to the CBD. *Id.* The United States is not a party. *See id.*

⁷³ Michiel Korthals & Bram De Jonge, *Two Different Ethical Notions of Benefit Sharing of Genetic Resources and Their Implications for Global Development*, 28 NEW GENETICS & SOC’Y 87, 89 (Mar. 2009).

⁷⁴ Nicolas Pauchard, *Access and Benefit Sharing Under the Convention on Biological Diversity and Its Protocol: What Can Some Numbers Tell Us About the Effectiveness of the Regulatory Regime?*, 6 RESOURCES 1 (Feb. 19, 2017).

⁷⁵ J.S. Malik Peiris, Menno D. de Jong & Yi Guan, *Avian Influenza Virus (H5N1): A Threat to Human Health*, 20(2) CLINICAL MICROBIO. REV. 243 (Apr. 2007).

⁷⁶ *Id.*

⁷⁷ David P. Fidler, *Influenza Virus Samples, International Law, and Global Health Diplomacy*, 14 EMERGING INFECTIOUS DISEASES 88 (Jan. 1, 2008).

⁷⁸ Sam Halabi, *supra* note 17, at 114 (“In 2006, Indonesia withheld H5N1 avian flu samples from WHO GISRS, compromising efforts to monitor and produce vaccines in response to the avian flu outbreak that

agreed to resume sharing under an interim agreement that granted it access to antivirals and vaccines, and the promise to develop a broader international agreement on influenza pathogen access and benefit sharing. Indonesia's actions introduced to the scientific sharing process the theretofore unknown concept of "viral sovereignty."⁷⁹

Soon after, CBD countries negotiated the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol).⁸⁰ The Nagoya Protocol regulates commercial, non-profit, university-driven, and all other forms of microbiological research that leads to drugs, medical therapies, vaccines, and other products derived from genetic resources in member states.⁸¹ Additionally, given the limited reach of current international instruments, it fundamentally changes the nature and process of international scientific research.⁸²

The purpose of the Nagoya Protocol was explicit.⁸³ The CBD, as it was originally formed, lacked an agreed-upon legal framework for cross-border

threatened to become easily transmissible from birds to humans and then between humans. Indonesia asserted that its decision was a response to an Australian company's patent on a vaccine derived from a virus sample that Indonesia provided to WHO. More importantly for purposes of human pathogen sharing, Indonesia argued that the H5N1 virus samples it had collected in its territory constituted the same kinds of natural resources as petroleum or rubber would previously have been considered, as well as a form of biodiversity protected under Articles 15 and 16 of the CBD. Indonesia agreed to resume sharing under an interim agreement that granted it access to antivirals and vaccines, and promised to develop a broader international agreement on influenza pathogen access and benefit sharing. Indonesia's actions introduced the previously unknown concept of 'viral sovereignty' to the scientific sharing process.").

⁷⁹ Dennis Normile, *Indonesia to Resume Sharing Under New Terms*, 316 SCIENCE 37 (Apr. 6, 2007).

⁸⁰ Wan Izatul Asma Wan Talaat, *Protection of the Associated Traditional Knowledge on Genetic Resources: Beyond the Nagoya Protocol*, 91 PROCEEDIA—SOCIAL AND BEHAVIORAL SCIENCES 673 (2013).

⁸¹ See Halabi, *supra* note 17.

⁸² See *id.* at 117 ("In some countries, the competent national authority [designated pursuant to the Nagoya Protocol] will issue permits generally known as 'internationally recognized certificates of compliance,' which 'serve as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and mutually agreed terms as required by the domestic legislation or regulatory requirements of the Party providing prior informed consent'. The terms of the agreement outline how the samples are to be used and stored, whether the samples may be kept after the term of the initial permission, whether they should be returned to the provider or destroyed, and whether the samples or any part thereof may be transferred to third parties and under which conditions. Benefit-sharing terms cover topics such as how the research results will be disseminated, how related data will be managed, how intellectual property rights [including monetary terms for royalties and licenses] will be developed, and how the provider country ought to be acknowledged in research publication.").

⁸³ See Halabi et al., *The Nagoya Protocol and the Legal Structure of Global Biogenomic Research*, 45 YALE J. INT'L L. 133, 154 (2020) ("The 2010 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization [Nagoya Protocol] aimed to encompass the broader universe of drugs, medical therapies, agrochemical products, vaccines and other products derived from genetic resources not clearly governed by the CBD. The Nagoya Protocol, formed to give specific content to Article 15 of the CBD, regulates access to genetic resources in party states and establishes mechanisms for fair and equitable sharing of benefits arising out of the utilization of genetic resources. It is committed to the equitable

enforcement of its international regime, diminishing the ability for providers subjected to misappropriation of their resources to seek adequate redress. Additionally, user-country governments were in no way obligated to address complaints or assist with providing redress.⁸⁴ After six years of negotiations, the Nagoya Protocol brought “greater legal certainty and transparency” regarding the exchange of genetic resources while “reaffirm[ing] and clarif[y]ing the [CBD’s] broad economic scope.”⁸⁵ It further addressed issues concerning scientific research, also neglected by the CBD and created new enforcement provisions for user and provider nations to implement within their respective national legal systems.⁸⁶

III. INTERNATIONAL INSTITUTIONS AND THE EMERGENCE OF THE LEGAL NORM OF VACCINE ACCESS

A. *The Pandemic Influenza Preparedness Framework*

Thus described, the world between 1993, when the CBD entered into force, and 2020, when WHO declared COVID-19 a pandemic, appeared headed for a classic prisoner’s dilemma. Biodiverse but capital-poor countries possessed the biological inputs necessary to create vaccines, but lacked the capacity to develop and manufacture them.⁸⁷ Wealthy countries possessed vast capacity to research, develop, and produce vaccines, but were potentially at risk of lacking the basic biological information they needed to do so. Indeed, politicized pathogen-sharing confrontations over MERS-CoV in 2012 and Zika in 2015 suggested that this was precisely the likely outcome.⁸⁸ What happened instead was the

sharing of research collaborations and ensuing benefits.”).

⁸⁴ Evanson Chege Kamau et al., *The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What Is New and What Are the Implications for Provider and User Countries and the Scientific Community?*, 6 L., ENV’T & DEV. J. 246, 249 (2010).

⁸⁵ *Id.* at 156 (“The effect of the CBD and the Nagoya Protocol is that there are a variety of domestic rules and regulations for accessing genetic resources all around the world. Some countries are operating under the ABS [Access and Benefit Sharing] regime outlined in the CBD, others have agreed to comply with both the CBD and the Nagoya Protocol, and others still are yet to implement domestic ABS laws despite being Party to one or both of these instruments.”).

⁸⁶ *Id.* (“The Nagoya Protocol requires its Parties to put in place measures ensuring that users within their jurisdiction have accessed genetic resources [and any traditional knowledge of Indigenous Peoples and local communities that is associated with genetic resources] in compliance with the provider nation’s ABS rules. Non-compliance can result in more than just reputational damage to the researchers involved. In some jurisdictions, non-compliance will attract penalties under civil law [e.g., fines] and even prosecution under criminal law.”).

⁸⁷ Fidler, *supra* note 77 (“Without access to Indonesia’s influenza strains, global surveillance was jeopardized, as was the refinement of diagnostic reagents and the development of intervention strategies, which depend on the information surveillance provides.”).

⁸⁸ Halabi, Rourke & Katz, *supra* note 12 (detailing the politicization of these outbreaks).

emergence of legal regimes committed to vaccine access for the global population, even if disparities lingered: the PIP Framework in 2011 and the COVAX Facility in 2020.

The process that eventually led to the PIP Framework began with the WHO developing solutions to the problem Indonesia raised in 2006, followed by Resolution WHA 60.28 by the World Health Assembly in 2007.⁸⁹ The resolution required that the Director-General of the WHO “formulate mechanisms and guidelines, in close consultation with Member States, aimed at ensuring fair and equitable distribution of pandemic-influenza vaccines at affordable prices in the event of a pandemic, in order to ensure timely availability of such vaccines to [low-income] Member States in need.”⁹⁰ The resolution was an agreed-to text that conveyed national level decision-making based on the juxtaposition of the Convention on Biological Diversity and the International Health Regulations (2005).

There are two components to the PIP framework: (1) the sharing of influenza viral samples to members of the WHO Global Influenza Surveillance and Response System, and (2) the sharing of viral samples with vaccine manufacturers in return for benefits shared with the WHO and its members.⁹¹ The vaccine manufacturers and some other related industrial players pay to support the system. This model ended the previous ad hoc influenza vaccine donations by vaccine manufacturers, and created a system in which influenza vaccines would be contractually guaranteed to low-income countries in exchange for biological material through a Standard Material Transfer Agreement.⁹² The PIP framework stipulates that, in exchange for biological material, vaccine manufacturers virtually guarantee a percent of their real-time vaccine production to the WHO. The WHO, in the event of an influenza outbreak, then transfers the vaccine to the country in need.⁹³ As of 2021, seventy-one Standard Material Transfer Agreements had been entered into by

⁸⁹ WHO, World Health Assembly Res. 60.28, Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits.

⁹⁰ Mark Eccleston-Turner, *The Pandemic Influenza Preparedness Framework: A Viable Procurement Option for Developing States?*, 17 MED. L. INT’L 227, 228 (2017) (“Prior to the Pandemic Influenza Preparedness [PIP] Framework being enacted by the World Health Organization [WHO] in 2011, much discussion on access to pandemic influenza vaccines [PIVs] had centred on the fact that samples of the virus used to produce a PIV were likely to have been supplied by developing states, which then struggled to purchase the resulting vaccine.”).

⁹¹ Halabi, *supra* note 17.

⁹² Michelle Rourke et al., *Access and Benefit-Sharing: Implications for Accessing Biological Samples for United Nations Secretary-General Mechanism Investigations*, GEO. UNIV. MED. CTR., CTR. GLOB. HEALTH SCI. & SEC. 1, 2 (2019).

⁹³ Sam F. Halabi, *International Intellectual Property Shelters*, 90 TUL. L. REV. 903 (2016).

the WHO, twenty-nine of which promised benefits (academic research centers, who also enter the agreements, rarely offer benefits).⁹⁴ The PIP framework was the first international agreement to address the inequalities of vaccine access and has been described as a “milestone for global health”.⁹⁵

The Indonesian (and supporting) government(s) saw the negotiations themselves as a key victory in the legal reach of the CBD while high-income governments saw the relatively limited language of the resolution as acknowledging the reality that vaccine access is a meaningful global objective without binding their interests (or of their pharmaceutical companies) too stringently.⁹⁶

B. *The COVAX Facility*

When atypical pneumonia cases arose in China in late 2019, a new chapter in viral sovereignty emerged.⁹⁷ While the genetic sequence of SARS-CoV-2 was shared in early January 2020, the actual biological sample sharing was delayed. But for the rapid spread of the pathogen worldwide (rendering sharing less relevant), it is not clear the same claims may not have emerged. However, as recounted in Section I.B., the spread of vaccine nationalism was met with the

⁹⁴ WHO, *Influenza: Standard Material Transfer Agreements (SMTA2)*, [https://www.who.int/initiatives/pandemic-influenza-preparedness-framework/standard-material-transfer-agreement-2-\(smta2\)](https://www.who.int/initiatives/pandemic-influenza-preparedness-framework/standard-material-transfer-agreement-2-(smta2)) (last visited Feb. 22, 2022).

⁹⁵ Eccleston-Turner, *supra* note 90.

⁹⁶ *Id.* (“The Framework has been hailed as an innovative mechanism for guaranteeing access to vaccines and affordable life-saving drugs during an influenza pandemic. A number of papers have considered the PIP Framework and attempted to determine the impact the vaccine stockpile it creates will have on procurement of PIV in developing states. However, some of the literature expresses concern that the Framework is unable to make any real changes to vaccine allocation due to its inability to close the gap between developed and developing states where procurement of PIV is concerned. This literature has only considered the benefit sharing provisions of the SMTAs as they were presented in the appendix of the PIP Framework, as at the time, no SMTAs had been concluded with PIV manufacturers. The major development since this literature was generated is the fact that nine SMTAs have now been concluded between the WHO and pandemic influenza vaccine manufacturers. Each of these agreements outlines the ‘Obligations of the Company’ agreed between the WHO and pandemic influenza vaccine manufacturers, and it is the content of these obligations which is the focus of this Article. Through examining the content of the Obligations of the Company which have been secured by the WHO, I argue this Article gives a clearer indication of the true practical impact the PIP stockpile will have on procurement of PIV during the next pandemic.”).

⁹⁷ Fidler, *supra* note 26, at 749 (“With COVID-19, history is repeating itself. Countries with the resources to obtain vaccines have not subordinated their needs and capacities to the objective of global, equitable access. And the worldwide spread of the coronavirus eliminates leverage that viral sovereignty might have provided countries without such means. International and nongovernmental organizations launched an ad hoc effort—the COVID-19 Vaccines Global Access (COVAX) Facility—to achieve equitable access . . . In keeping with the longstanding pattern of political behavior during pandemics, vaccines will eventually reach most populations, but only after powerful countries have protected themselves.”).

COVAX Facility—a countervailing effort to ensure access to vaccines for the world’s most vulnerable populations.⁹⁸

The COVAX Facility originated within a broader international collaboration known as the Access to COVID-19 Tools (ACT) Accelerator.⁹⁹ The ACT Accelerator began as an initiative led by the World Bank Group (WBG), WHO, G20, European Commission, and a consortium of major global public health non-governmental organizations (including the Bill & Melinda Gates Foundation and other private donors), to advance the goal of fostering the development and production of diagnostics, therapeutics, and vaccines to combat the COVID-19 pandemic.¹⁰⁰ The ACT Accelerator, launched in April 2020, is broader than COVAX and includes four “pillars”: (1) the Diagnostic Pillar supported by the Foundation for Innovative New Diagnostics and the Global Fund to Fight Aids, Tuberculosis, and Malaria (Global Fund), (2) the Therapeutics Pillar supported by Unitaid and Wellcome Trust, (3) the Health Systems Pillar supported by the Global Fund, WBG, and WHO, and (4) the Vaccine Pillar supported by GAVI, CEPI, and WHO.¹⁰¹

After being hosted by UNICEF for almost a decade, GAVI became, in 2009, an independent international institution under Swiss law.¹⁰² Now identified as its own international organization, GAVI was the first organization to receive such recognition under the Swiss Host State Act.¹⁰³ GAVI is now a foundation under Swiss law and an independent international institution with privileges and immunities similar to those of U.N. agencies.¹⁰⁴ CEPI is even newer, having been formed under Norwegian law and maintaining a governance structure that incorporates formal international organizations; non-governmental organizations; and governments, including their medicines regulators.

⁹⁸ *Coronavirus Global Response: Access to COVID-19 Tools-Accelerator Facilitation Council Holds Inaugural Meeting*, WHO (Sept. 10, 2020), www.who.int/news-room/detail/10-09-2020-coronavirus-global-response-access-to-covid-19-tools-accelerator-facilitation-council-holds-inaugural-meeting.

⁹⁹ Berkley, *supra* note 15.

¹⁰⁰ *The Scramble for Vaccines and the COVAX Facility*, CTR. STRATEGIC & INT’L STUD. 1, 3 (Aug. 19, 2020), https://csis-website-prod.s3.amazonaws.com/s3fs-public/publication/200811_Scramble_Vaccines.pdf; *Donor Profiles*, GAVI (Dec. 15, 2020), www.gavi.org/investing-gavi/funding/donor-profiles.

¹⁰¹ *ACT-Accelerator Update: Publication of Investment Cases*, WHO (June 26, 2020) [hereinafter *ACT-Accelerator Update*], www.who.int/news-room/detail/26-06-2020-act-accelerator-update; Jonathan C. Carlson, *Strengthening the Property Rights Regime for Plant Genetic Resources: The Role of the World Bank*, 6 TRANSNAT’L L. & CONTEMP. PROBS. 91, 112–13 (1996) (identifying the evolving role of WBG from discrete project funding to broader, structural efforts).

¹⁰² *GAVI Recognised as International Institution*, GAVI (June 23, 2009), <https://www.gavi.org/news/media-room/gavi-recognised-international-institution>.

¹⁰³ *Id.*

¹⁰⁴ *Id.* at 47.

The Vaccine Pillar, now known simply as COVAX,¹⁰⁵ was established in June 2020.¹⁰⁶ It was founded to support the quick and safe development, manufacture, and delivery of COVID-19 vaccines worldwide.¹⁰⁷ COVAX aimed to deliver two billion doses of a safe and effective COVID-19 vaccine by the end of 2021.¹⁰⁸ In order to achieve this objective, COVAX invested across a wide portfolio of vaccine candidates using contributions from eighty-nine “self-financing” governments and supporting international organizations and charities and, at the same time, required financial commitments from ninety-two “donor supported” governments that will receive subsidized prices for doses.¹⁰⁹

CEPI is an international public–private partnership committed to developing vaccines for otherwise neglected diseases.¹¹⁰ Within COVAX, CEPI leads the development and manufacturing workstream, which supports R&D and manufacturing expansion through direct financial investments.¹¹¹ GAVI is the

¹⁰⁵ The Vaccine Pillar is also referred to as “COVAX Facility” or “the Facility” in online sources.

¹⁰⁶ *ACT-Accelerator Update*, *supra* note 101, at 3.

¹⁰⁷ *Id.*

¹⁰⁸ *More than 150 Countries Engaged in COVID-19 Vaccine Global Access Facility*, WHO (July 15, 2020), www.who.int/news-room/detail/15-07-2020-more-than-150-countries-engaged-in-covid-19-vaccine-global-access-facility.

¹⁰⁹ *172 Countries and Multiple Candidate Vaccines Engaged in COVID-19 Vaccine Global Access Facility*, WHO (Aug. 24, 2020) [hereinafter *172 Countries*], www.who.int/news-room/detail/24-08-2020-172-countries-and-multiple-candidate-vaccines-engaged-in-covid-19-vaccine-global-access-facility; *COVAX Announces Additional Deals to Access Promising COVID-19 Vaccine Candidates; Plans Global Rollout Starting Q1 2021*, WHO (Dec. 18, 2020), <https://www.who.int/news/item/18-12-2020-covax-announces-additional-deals-to-access-promising-covid-19-vaccine-candidates-plans-global-rollout-starting-q1-2021> (describing CEPI-Support candidate vaccines, including: InVivo—United States [Phase II]; Moderna—United States [Phase III]; CureVac—Germany [Phase IIB/III]; Institute Pasteur/Merck/Themis—France, United States, and Austria [Phase I]; AstraZeneca/University of Oxford—United Kingdom and Northern Ireland [Phase III]; University of Hong Kong—China [Preclinical]; Novavax—United States [Phase III]; Clover Biopharmaceuticals—China [Phase I]; and University of Queensland/CSL—Australia [Phase I]).

¹¹⁰ Dave Kovaleski, *CEPI Invests \$4.9M in Consortium to Develop COVID-19 Vaccine*, HOMELAND PREPAREDNESS NEWS (Mar. 23, 2020), <https://homelandprepnews.com/stories/46200-cepiinvests-4-9m-in-consortium-to-develop-covid-19-vaccine>.

¹¹¹ *172 Countries*, *supra* note 109. The Gavi board agreed in July 2020 that the following countries will be supported the COVAX Advance Market Commitment: Low income: Afghanistan, Benin, Burkina Faso, Burundi, Central African Republic, Chad, Democratic Republic of the Congo, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Haiti, Democratic People’s Republic of Korea, Liberia, Madagascar, Malawi, Mali, Mozambique, Nepal, Niger, Rwanda, Sierra Leone, Somalia, South Sudan, Syrian Arab Republic, Tajikistan, Togo, Uganda, United Republic of Tanzania, and Yemen. *Id.* Lower-middle income: Angola, Algeria, Bangladesh, Bhutan, Bolivia, Cabo Verde, Cambodia, Cameroon, Comoros, Congo, Côte d’Ivoire, Djibouti, Egypt, El Salvador, Eswatini, Ghana, Honduras, India, Indonesia, Kenya, Kiribati, Kyrgyzstan, Lao People’s Democratic Republic, Lesotho, Mauritania, Micronesia, Moldova, Mongolia, Morocco, Myanmar, Nicaragua, Nigeria, Pakistan, Papua New Guinea, Philippines, São Tomé and Príncipe, Senegal, Solomon Islands, Sri Lanka, Sudan, Timor-Leste, Tunisia, Ukraine, Uzbekistan, Vanuatu, Vietnam, West Bank and Gaza, Zambia, and Zimbabwe. *Id.* Additional IDA eligible: Dominica, Fiji, Grenada, Guyana, Kosovo, Maldives, Marshall Islands, Samoa, St. Lucia, St. Vincent and the Grenadines, Tonga, and Tuvalu. *Id.*

lead for the vaccine procurement and delivery, as well as the COVAX Advance Market Commitment, which helps to finance low- and lower-middle-income countries' access to a future COVID-19 vaccine.¹¹² GAVI was originally established to continue long-standing global immunization for childhood diseases that had stalled around the end of the 1980s. In a renewed effort to complete the work that began with the WHO's Expanded Programme on Immunization, the Bill and Melinda Gates Foundation, together with WHO, UNICEF, WBG, and several large pharmaceutical firms, established GAVI.¹¹³ GAVI is funded through the International Finance Facility for Immunisation (IFFIm), which is itself funded by the governments of Australia, Brazil, France, Italy, the Netherlands, Norway, South Africa, Spain, Sweden, and the United Kingdom.¹¹⁴ Under the GAVI model, low-income and middle-income states identify immunization needs, apply for funding, and implement approved vaccination programs.¹¹⁵ As of April 8, 2021, COVAX had shipped over 38 million vaccines to over 100 economies, a broader set of international actors than recognized governments.¹¹⁶

IV. THE FUTURE OF PANDEMIC VACCINE ACCESS AFTER COVID-19

After the world's experience with Ebola Virus Disease in West Africa in 2014 to 2016, the WHO's International Health Regulations Review Committee was called for the use of the PIP Framework's principles to be applied to a broader set of pathogens including Ebola and Zika.¹¹⁷ Indeed, that remains a possibility after the significant efforts required to spontaneously form and adapt

¹¹² Kovaleski, *supra* note 110, at 2–3; Eccleston-Turner, *supra* note 23, at 327.

¹¹³ *History of GAVI*, GAVI, <https://perma.cc/2ZTP-YFK4>.

¹¹⁴ *Overview*, INT'L FIN. FACILITY OF IMMUNISATION, <https://perma.cc/4GJM-C4GL> (last visited Dec. 23, 2019).

¹¹⁵ See GAVI, *HOW WE WORK TOGETHER* 14 (May 2019).

¹¹⁶ *COVAX Reaches over 100 Economies, 42 Days After First International Delivery*, WHO (Apr. 8, 2021), www.who.int/news/item/08-04-2021-covax-reaches-over-100-economies-42-days-after-first-international-delivery.

¹¹⁷ Rep. of Dir. Gen., *Implementation of the International Health Regulations (2005): Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response*, WHO A69/21, at 35 (May 13, 2016), http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_21-en.pdf (“One incentive-based approach is for WHO to provide or facilitate technical and financial support. Incentivizing compliance of countries through collaboration and support is a feature that the IHR share with a large number of other instruments and multilateral treaties. Innovative funding sources within the WHO context could improve implementation of the IHR. For example, a number of States Parties and the International Federation of Pharmaceutical Manufacturers pointed favourably to the PIP Framework. Under the PIP Framework, influenza vaccine, diagnostic and pharmaceutical manufacturers who use the WHO Global Influenza surveillance and Response System [GISRS]—a WHO-coordinated network of public health laboratories—pay an annual cash contribution to WHO. WHO uses the funds to strengthen influenza preparedness and response capacities in countries that require such support. Manufacturers also agree to provide benefits such as pandemic influenza vaccines, antiviral medicines and other pandemic related products or technologies at the time of a pandemic.”).

COVAX to the COVID-19 threat. Early in the pandemic, a team of researchers at Fudan University called for precisely that mechanism as the most efficient means to allocate COVID-19 vaccines.¹¹⁸ But the establishment of COVAX and the formation of the other ACT Accelerator Pillars have also spurred calls for more permanent legal solutions to the challenge COVID-19 has posed to the world.

A novel proposal that emerged alongside the COVID-19 pandemic is a pandemic-specific treaty, which might impose additional, specific obligations on countries during the next international infectious disease emergency. In November 2020, Charles Michel, President of the European Council, began circulating the idea of an “international pandemic treaty” at the Paris Peace Forum.¹¹⁹ In December 2020, Michel met with Tedros Adhanom Ghebreyesus, the Director General of the WHO, to discuss the treaty.¹²⁰ In January 2021, Tedros endorsed the pandemic treaty proposal “as a way to guarantee countries’ political commitment to fighting future disease outbreaks.”¹²¹ He expressed WHO’s support of such a treaty, saying “[i]t will give the [International Health Regulations] the political dimension” they need.¹²²

The international treaty proposal is modelled after the Framework Convention on Tobacco Control (FCTC), which went into force in 2005.¹²³ The FCTC was implemented to curb tobacco consumption and marks the only time WHO used its treaty-making authority under Article 19 of its constitution.¹²⁴ It transformed public health functions into legally binding obligations and “showed the feasibility of working with non-health sectors within an international legal system, the feasibility of negotiating further protocols and

¹¹⁸ Bingzhe Li et al., *supra* note 20.

¹¹⁹ David M. Herszenhorn, *Charles Michel Proposes ‘International Pandemic Treaty’*, POLITICO (Nov. 12, 2020), www.politico.eu/article/charles-michel-proposes-international-pandemic-treaty.

¹²⁰ Svět Lustig Vijay, *WHO Proposes New “Pandemic Treaty” to Tighten Global Monitoring and Enforcement of Disease Outbreak Response*, HEALTH POL’Y WATCH (Jan. 20, 2021), <https://healthpolicy-watch.news/who-proposes-new-pandemic-treaty-to-tighten-global-monitoring-and-enforcement-of-disease-outbreak-response>.

¹²¹ Stephanie Nebehay, Catherine Evans & Peter Graff, *WHO Chief Welcomes EU Proposal for Pandemic Preparedness Treaty*, REUTERS (Jan. 20, 2021), <https://www.reuters.com/article/us-health-coronavirus-who-treaty/who-chief-welcomes-eu-proposal-for-pandemic-preparedness-treaty-idUSKBN29P1CI>.

¹²² Vijay, *supra* note 120.

¹²³ Herszenhorn, *supra* note 119; see Sam F. Halabi, *The World Health Organization’s Framework Convention on Tobacco Control: An Analysis of Guidelines Adopted by the Conference of the Parties*, 144 GA. J. INT’L L. 138 (2010) (analyzing the history and provisions of the FCTC).

¹²⁴ Haik Nikogosian & Ilona Kickbusch, *The Case for an International Pandemic Treaty*, 372 BMJ n.527 (Feb. 25, 2021), <https://www.bmj.com/content/372/bmj.n527>; VIJAY, *supra* note 120; see also Halabi, *supra* note 16 (analyzing the constitutional authorities WHO may use to affect international law and its general hesitation to do so).

guidelines promptly, and the power to safeguard the interests of health in the face of conflicting agendas and legal disputes.”¹²⁵ A pandemic treaty would be the first global public health accord since the FCTC.¹²⁶

Conceivably, an international pandemic treaty could be negotiated under WHO, the United Nations, or both.¹²⁷ While proceeding under WHO is the most likely possibility, there are concerns about “WHO’s ability to cover important areas such as finance, trade, supplies, law enforcement, and the broader economic and social disruptions caused by a pandemic.”¹²⁸ Although proceeding under the United Nations may be more effective on these issues, the “highly political UN environment in New York” could make it more challenging to hammer out the details.¹²⁹ The U.N. system’s valuable features in this regard include: cross-sectoral working on very large scale challenges (e.g., the U.N. Framework Convention on Climate Change); legal provisions that are highly relevant to pandemics (e.g., the Nagoya Protocol on use of genetic resources); joint treaty administration by existing U.N.-system bodies (e.g., the Protocol on Water and Health); a human-rights-based approach (e.g., U.N. human rights treaties); and other important treaty practices such as finance mechanisms (e.g., the Global Environment Facility for environmental conventions) and monitoring compliance (e.g., the International Narcotics Control Board for drug control conventions).¹³⁰

Perhaps the easiest path would be “[a] framework convention approach, which leaves some of the detail to later protocols and guidelines[.]”¹³¹ This path, however, would require countries to “agree on short definite timelines for negotiating such instruments.”¹³² A final consideration would “be to draft and provisionally negotiate articles requiring specialized expertise in Geneva before final negotiations in New York[.]”¹³³ A treaty under both WHO and the United Nations could prove “the most viable way forward given the urgency and the implications of the current pandemic beyond health to livelihoods, economics, security, solidarity, and human rights.”¹³⁴

¹²⁵ Nikogosian & Kickbusch, *supra* note 124, at 1.

¹²⁶ Nebehay, Evans & Graff, *supra* note 121.

¹²⁷ Nikogosian & Kickbusch, *supra* note 124.

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² *Id.*

¹³³ *Id.*

¹³⁴ *Id.* at 2.

Alternatively, a broad UN framework on pandemics “with built-in power and mandate to negotiate a treaty could be” considered.¹³⁵ Features that could be useful for an international pandemic treaty include “a focus on risk management, responsibilities across sectors and stakeholders, protection of livelihoods along with protection of lives and health, use of UN interagency mechanisms, and global targets to measure progress.”¹³⁶ A framework such as this, however, is not a legally binding instrument, even though it could lead to one in the future.¹³⁷

With respect to vaccine development, Tedros called on all member states to join a voluntary initiative to share samples of infectious pathogens through the new Swiss-based “biohub.”¹³⁸ So far, Italy, South Africa, and Thailand have signed on to share SARS-CoV-2 samples through the biohub initiative.¹³⁹ Tedros advocated that the initiative might help combat the difficulties in sharing genetic material in order to “help us in the emergency preparedness and response.”¹⁴⁰ The uncertainties of the initiative that still need to be defined include benefits that member states will gain through the biohub and the extent to which member states will have access to available data.¹⁴¹

Various member states also called for additional measures to aid in pandemic responses. Norway’s delegate suggested a WHO-mandated program “for generating knowledge on non pharmaceutical interventions,” such as wearing masks, physical distancing, or lockdowns.¹⁴² In response, Mike Ryan, WHO’s head of emergencies, concurred that “[w]e do need to work to understand how to implement, how to measure them, and how to monitor them” as tools for the community.¹⁴³

According to Charles Michel, an international pandemic treaty would better protect citizens by allowing for a “stronger international commitment to prevent [pandemics]” through quicker and more coordinated response times that would ensure proper supply of medical equipment and improved information exchange.¹⁴⁴ Exchangeable information would include data regarding virus and

¹³⁵ *Id.*

¹³⁶ *Id.* at 1.

¹³⁷ *Id.*

¹³⁸ Vijay, *supra* note 120.

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ Herszenhorn, *supra* note 119.

infectious disease outbreaks.¹⁴⁵ Sharing this information, however, may require signatory countries to contribute all the data they have on an outbreak.¹⁴⁶

In theory, an international pandemic treaty could deal with a variety of issues, including a fair and equitable distribution structure for vaccines.¹⁴⁷ In order to be successful, a treaty “must cover disruptions both in and beyond health, bind all relevant sectors, engage international actors, activate financial mechanisms, define signatories’ obligations (and breaches), and agree mechanisms to evaluate compliance.”¹⁴⁸

CONCLUSION

From an institutional governance perspective, the emerging lessons on nationalism and sovereignty-asserting behaviors in the context of pandemic responses also reinforce the centrality of the role of WHO as the global public health coordinating mechanism. While WHO has been often criticized for both its bureaucracy and some aspects of pandemic and epidemic response, the COVID-19 pandemic once again showed that WHO remains critical to the development of new international legal regimes that can assist in navigating global crises.¹⁴⁹

This Article has underscored how nationalistic or otherwise sovereignty-asserting behaviors fare poorly in the face of transnational health crises, challenging global governance at its core; taken to their extremes, the realpolitik result of these trends could be stymied by vaccine research, vaccine hoarding, and a slowing economy. A multilateral approach, however, obtains cooperation and promised equitable distribution. This cooperation is impossible without international organizations’ contributions to the global preparedness and

¹⁴⁵ Holly Ellyatt, *Calls for Global ‘Pandemic Treaty’ Grow as Anxiety Swells over Covid Origins*, CNBC (Feb. 17, 2021), <https://www.cnbc.com/2021/02/17/covid-origin-global-pandemic-treaty-proposed-amid-china-mistrust.html> (“The U.K. currently holds the presidency of the Group of Seven, an intergovernmental organization that includes Canada, France, Germany, Italy, Japan and the U.S., and looks set to use a meeting on Friday to push for a treaty. The U.K. government said in a statement Saturday that Johnson ‘will call for a new, global approach to pandemics that learns lessons from the division that characterised the initial international response to the coronavirus pandemic.’ ‘International pandemic preparedness will be a major priority for the UK’s G7 Presidency’ it said, and Johnson would look to work with fellow G-7 leaders to implement a five-point plan that was announced at the U.N. General Assembly last year. ‘The five point plan includes a worldwide network of zoonotic research hubs, developing global manufacturing capacity for treatments and vaccines, the design of a global pandemic early warning system, the agreement of global protocols for a future health emergency and the reduction of trade barriers.’”).

¹⁴⁶ *Id.*

¹⁴⁷ Herszenhorn, *supra* note 119.

¹⁴⁸ Nikogosian & Kickbusch, *supra* note 124.

¹⁴⁹ Fidler, *supra* note 26.

response system for health threats, and WHO's contributions in particular. Governments and companies look to WHO's contributions when infectious disease threats emerge and, so far, WHO has met each challenge with sustained solutions. In the context of COVID-19, it did so in close coordination with CEPI and GAVI. Each of these solutions, in turn, has required the expansion of governance to private actors—the global pharmaceutical industry—in both the PIP Framework and COVAX. Together, these trends portend greater influence for norms of global redistribution of wealth, collective response to global health security threats, and mutually agreed governance solutions housed at international institutions with strong reputations for technical competence.