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

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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. As vaccines are distributed worldwide throughout 2021, this essay analyzes the problem of vaccine access as a critical question in the literature on sources of international law and the influence of those sources. As with past pandemics, research and development capacity is largely concentrated in the wealthy countries of Europe and North America with growing capabilities in East and South Asia. 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. Other governments balanced the needs of their domestic populations with regional or global diplomatic objectives. 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 coordinated by international organizations. 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.

This essay 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 (APA), to secure vaccines for populations in the world's richest countries, those in poor countries remained at risk. 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 essay 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. A third, more regional epidemic, Ebola, demonstrated similar characteristics. Even more importantly, this regime has been formed and implemented by international organizations, rather than coordinated through individual governments.

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Within the broader context of international law scholarship, the essay contributes a significant case of international organizations as international law-makers.[1] The essay focuses on two international agreements — the 2011 Pandemic Influenza Preparedness Framework (PIP), 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. These organizations include specialized U.N. agencies like the World Health Organization and UNICEF, as well as international organizations technically formed under national law, but which include a broader set of decision-makers, including governments, like CEPI and GAVI.[2] Each agreement represented a legal 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. 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.[3] COVAX has conditioned the diplomatic outcomes China, India, and Russia may realize through vaccine dipomacy.

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.[4] 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 the World Health Organization, that indicate an interest in collaboration, division of gains from trade, and sustained governance structures: the Pandemic Influenza Preparedness Framework and COVAX. The recurrence of these legal arrangements suggests that in order to save the transaction costs generated by repeated development of ad hoc structures that centralize vaccine distribution, that 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 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.

[1] Jose Alvarez, *International Organizations as Lawmakers* (OUP 2006).
[2] Steven R Ratner & Anne-Marie Slaughter, 'Appraising the Methods of International Law: A Prospectus for Readers' [2004] Stud Transnat'l Legal Pol'y 1, 6.
[3] Peter Hotez, *Preventing the Next Pandemic: Vaccine Diplomacy in a Time of Anti-science* (Johns Hopkins 2021).
[4] While China shared the genetic sequence of SARS-CoV-2 in January 2020, sharing of live samples was delayed.

Whatever alternative materializes, this essay 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.

1. 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.[5] 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. 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 Advance Purchase Agreements (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. As regulators greenlight the use of a vaccine, the obligations set forth in an APA mature into the legal framework governing the immediate purchase of vaccine doses.

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. 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."[6] 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."[7]

1.1. Vaccine Nationalism: Polio, Smallpox, and Influenza

[5] Harry Kretchmer, 'Vaccine Nationalism – and How it Could Affect Us All,' (*World Economic Forum*, 6 January 2021) <www.weforum.org/agenda/2021/01/what-is-vaccine-nationalism-coronavirus-its-affects-covid-19-pandemic/> accessed 27 April 2021.

[6] David P Fidler, 'Vaccine Nationalism's Politics' (2020) 369 SCI. MAG. 749, 749.

[7] James Bacchus, 'The Antidote to Vaccine Nationalism'(*Centre for International Governance Innovation*, 21 December 2020) <www.cigionline.org/articles/antidote-vaccine-nationalism> accessed 27 April 2021. Muhammad Zaheer Abbas, 'Practical Implications of "Vaccine Nationalism": A Short-Sighted and Risky Approch in Response to COVID-19' (*South Centre,* 2020) 1, 18 <https://www.southcentre.int/wp-content/uploads/2020/11/RP-124.pdf> accessed 27 April 2021.

Vaccine nationalism is not new. 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.[8] Vaccine nationalism was also illustrated during the pandemic that preceded COVID-19: the 2009 H1N1 influenza pandemic.[9] 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.

The 2009 flu pandemic started in April in North America and quickly spread across the world, commencing a vaccine race.[10] A month into the outbreak, several higher-income countries negotiated APAs that reserved most of the earliest doses of vaccine.[11] At the time, it was estimated that, in a best-case scenario, global capacity for short-term vaccine manufacturing was around 2 billion doses, while estimated only 1 billion.[12] 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.[13] Other developed or quasi-developed economies negotiated similar pre-production agreements.[14] Outside of APAs, approximately 56% of vaccine manufacturers surveyed could guarantee 10% of real-time vaccine production for purchase by U.N. agencies to support low-income countries.[15] 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.[16]

1.2. 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 U.S. 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

[8] Ana Santos Rutschman, 'The Reemergence of Vaccine Nationalism' [3 July 2020] Georgetown Journal of International Affairs Online <https://gjia.georgetown.edu/2020/07/03/the-reemergence-of-vaccine-nationalism/> accessed 27 April 2021.
[9] Sam Halabi and Rebecca Katz, *Viral Sovereignty and Technology Transfer* (CUP 2020).
[10] Paul C Hébert and Noni MacDonald, 'The H1N1 Vaccine Race: Can We Beat the Pandemic?' (2009) 181 Canadian Med Ass'n J E125 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2761457/> accessed 27 April 2021.
[11] See David Brown, 'Most of Any Vaccine for New Flu Strain Could Be Claimed by Rich Nations' Preexisting Contracts' *The Washington Post* (Washington, DC, 7 May 2009) <www.washingtonpost.com/wp-dyn/content/article/2009/05/06/AR2009050603760.html> accessed 27 April 2021.
[12] Ibid.
[13] Ibid.
[14] Ibid.
[15] Alexandra L Phelan et al., 'Legal Agreements: Barriers and Enablers to Global Equitable COVID-19 Vaccine Access' (2020) 396 *Lancet* 800, 800–801 <https://doi.org/10.1016/S0140-6736(20)31873-0> accessed 27 April 2021.
[16] Margaret Chan, 'Pandemic Vaccine Donations for the Developing World' (*World Health Organization*, 18 September 2009) <www.who.int/mediacentre/news/statements/2009/pandemic_vaccine_donations_20090918/en/> accessed 27 April 2021.

agreements accounted for the purchase of over 1 billion doses by the U.S. government, all of which were dedicated to the U.S. market.[17]

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,[18] noting that "Germany is not for sale" and noting that "if a vaccine is developed in Germany, then it is for Germany and the world."[19] A few months later, the German government invested €300 million (roughly $337 million) to guarantee a 23% stake in CureVac.[20]

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 U.S. had "the right to the largest pre-order."[21] A day after the announcement, on the heels of mounting criticism, both the French government and Sanofi announced that the deal would not move forward.[22] Several other countries acted according to nationalistic paradigms. India's Serum Institute—the world's largest vaccine manufacturer—[23]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 of COVID-19 vaccines for its domestic population.[24]

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 50% of soon-to-be available vaccine doses.[25] While effectively in control of the majority of

[17] Congressional Research Service, 'Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials' (1 March 2021) <https://crsreports.congress.gov/product/pdf/IN/IN11560> accessed 27 April 2021.
[18] Hans Von Der Burchard and Jakob Hanke Vela, 'EU Weighs Into German-American Spat Over Vaccine Company' *Politico* (16 March 2020) <www.politico.eu/article/eu-weighs-into-german-american-spat-over-vaccine-company/> accessed 27 April 2021.
[19] See e.g. Andy Gregory, '"This Should Be Worldwide, Not Regional": German Drug Firm Chief Rebukes Trump "Attempt to Monopolise Vaccine"' *The Independent* (London, 16 March 2020) <www.independent.co.uk/news/world/europe/coronavirus-vaccine-trump-germany-us-dietmar-hopp-carevac-a9404646.html> accessed 27 April 2021.
[20] Barbara Kollmeyer, 'Germany Investing in Coronavirus Vaccine Maker that it Accused the Trump Administration of Trying to Poach' *Marketwatch* (15 June 2020) <www.marketwatch.com/story/germany-investing-in-coronavirus-vaccine-maker-that-it-accused-the-trump-administration-of-trying-to-poach-2020-06-15> accessed 27 April 2021.
[21] France 24, 'Covid-19: Sanofi Backpedals on US Vaccine Priority after French Outrage' (15 May 2020), <www.france24.com/en/20200514-france-says-unacceptable-for-sanofi-to-give-coronavirus-vaccine-to-us-first> accessed 27 April 2021.
[22] Ibid.
[23] Serum Institute, 'About Us' <www.seruminstitute.com/about_us.php> accessed 27 April 2021.
[24] See Zeba Siddiqui, 'India's Serum Institute to Make Millions of Potential Coronavirus Vaccine Doses' *Reuters* (28 April 2020) <www.reuters.com/article/us-health-coronavirus-india-vaccine/indias-serum-institute-to-make-millions-of-potential-coronavirus-vaccine-doses-idUSKCN22A2YY> accessed 27 April 2021.
[25] Asher Mullard, 'How COVID Vaccines are being Divvied Up Around the World' *Nature* (30 November 2020) <www.nature.com/articles/d41586-020-03370-6> accessed 27 April 2021.

the worldwide vaccine supply, these thirty-two countries represented only around 13% of the global population.[26] 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.[27] 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.[28]

At a broader level, vaccine nationalism showcases a fracture between theoretical approaches to the production and management of health goods and transactional practices determining actual allocation of these goods. The former emphasize principles of global solidarity and equity,[29] while the latter result 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."[30] 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. The essay now explores this connection by surveying the closely related phenomenon of viral sovereignty.[31]

2. 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. "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.[32] Viral sovereignty slowly emerged over the course of vaccine nationalist episodes covering polio, smallpox, and influenza. 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

[26] Ibid.
[27] See Arthur Allen, 'The Case for Donating US Covid Vaccines Overseas' *Kaiser Health News* (19 March 2021) <https://khn.org/news/article/the-case-for-donating-us-covid-vaccines-overseas/> accessed 27 April 2021.
[28] Duke Global Health Institute, 'Will Low-Income Countries Be Left Behind When COVID-19 Vaccines Arrive?' (9 November 2020) <https://globalhealth.duke.edu/news/will-low-income-countries-be-left-behind-when-covid-19-vaccines-arrive> accessed 27 April 2021.
[29] See e.g. Suerie Moon et al., 'Global Public Goods for Health: Weaknesses and Opportunities in the Global Health System', Health Economics, Policy and Law (2017) 12(2: Towards a Coherent Global Framework for Health Financing) 195; Max H Bazerman et al, 'How Should We Allocate Scarce Medical Resources?' (29 April 2020) Harv Bus Rev < https://hbr.org/2020/04/how-should-we-allocate-scarce-medical-resources> accessed 27 April 2021.
[30] Keith E Maskus and Jerome H Reichman, 'The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods' (2004) 7 J Int'l Econ L 279. See also Gregory Shaffer, 'International Law and Global Public Goods in a Legal Pluralist World' (2012) 23 Eur J Int'l L 669.
[31] Sam Halabi, Michelle Rourke and Rebecca Katz, 'The Effect of Proprietary and Attribution Claims on Data Sharing During Infectious Disease Emergencies' (2021) 23(2) J Healthcare L & Pol'y 203.
[32] Fidler, 'Vaccine Nationalism's Politics' (n 6), 749.

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.[33]

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 primarily commodities like petroleum, rubber, and agricultural goods. [34] But the general call for control over natural resources expanded in the early 1990s to include biological and genetic resources, including pathogens. [35]

In 1972, the U.N. held the first of many global conferences, on the Human Environment at Stockholm, Sweden.[36] In the decade after the 1972 conference, scientists and non-governmental organizations had elevated the issue of biodiversity as a global policy priority.[37] In 1987, the first steps were taken toward a Convention on Biological Diversity.[38]

Eventually these movements led to the 1992 UN Conference on Environmental 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 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 investors and the recipient state".[39]

Article 2 of the CBD defines "genetic resources" as "genetic materials of actual or potential value", 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.[40]

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. After the CBD, some

[33] UNCTAD, 'Proceedings of the United Nations Conference on Trade and Development, Second Session (UNCTAD II). 1 February – 29 March 1968. New Delhi (India)' 272 <http://unctad.org/en/Docs/td97vol1_en.pdf> accessed 27 April 2021; Peter Drahos, *The Global Governance of Knowledge: Patent Offices and Their Clients* (CUP 2010) xiv.
[34] Charles N Brower and John B Tepe Jr, 'The Charter of Economic Rights and Duties of States: A Reflection or Rejection of International Law?' (1975) 9 Int'l Lawyer 295.
[35] Daniel Yergin and Joseph Stanislaw, *The Commanding Heights: The Battle Between Government and the Marketplace That Is Remaking the Modern World* (Free Press, 1998) 88–90.
[36] Declaration of the United Nations Conference on the Human Environment (Stockholm Declaration, 1972).
[37] 'History of the Convention' (2021) *Convention on Biological Diversity* <www.cbd.int/history/> accessed 27 April 2021.
[38] UNEP Resolution 14/26, adopted in 1987.
[39] Permanent Sovereignty over Natural Resources, GA Res 1803, UN GAOR, 17th Sess Supp No 17 UN Soc A/5127, 15 (1962); Stockholm Declaration, GA Res 2998, UN Doc A/CONF/48/14 (15 December 1972).
[40] CBD art 16(1).

governments made it more difficult to obtain resources from their territories.[41] 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.[42] The CBD created a legal zone in which biodiverse rich countries could set terms for exploitation and the protection of their citizens to share in the benefits of any commercialization of their resources.[43] More than 60 nations have created Access and Benefit Sharing (ABS) regimes via their domestic laws, with particular activity from biodiverse rich states like Brazil, China, Costa Rica, Kenya, the Philippines, and South Africa.[44]

In late 2006, Indonesia withheld H5N1 avian flu samples from the World Health Organization's Global Influenza Surveillance Network system, a significant measure since the H5N1 avian flu outbreak that had spiked from early 2005 was not only spreading along avian flyways but threatened to become transmissible between humans; those infected experienced a terrifying 50% fatality rate.[45] Indonesia asserted that its decision was a response to an Australian company's patent on a vaccine derived from a virus sample Indonesia provided to the World Health Organization's pathogen sharing network.[46] 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 theretofore petroleum or rubber would have been considered as well as a form of biodiversity protected under Articles 15 and 16 of the Convention on Biological Diversity. Indonesia 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."[47]

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).[48] The Nagoya Protocol regulates commercial, non-profit, university-driven, and all other forms of microbiological research that lead to drugs, medical therapies, vaccines and other products derived from genetic resources in member states and, given the limited reach of current international instruments, fundamentally changes the nature and process of international scientific research.

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[41] Jerome H Reichman, Paul Uhlir and Tom Dedeurwaerdere, *Governing Digitally Integrated Genetic Resources, Data, and Literature: Global Intellectual Property Strategies for a Redesigned Microbial Research Commons* (CUP 2016) 89–90.

[42] Convention on Biological Diversity, *open for signature* 5 June 1992, 1760 UNTS 79. There are 198 states party to the CBD. The United States is not a party.

[43] Michiel Korthals and Bram De Jonge, 'Two Different Ethical Notions of Benefit Sharing of Genetic Resources and Their Implications for Global Development' (March 2009) 28 New Genetics and Society 87, 89.

[44] 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?' (2017) 6 Resources 1.

[45] JS Peiris, MD de Jong and Y Guan. 'Avian Influenza Virus (H5N1): A Threat to Human Health' (2007) 20(2) Clinical Micro Rev 243 <doi:10.1128/CMR.00037-06>.

[46] David Fidler, 'Influenza Virus Samples, International Law, and Global Health Diplomacy' (2008) 14(1) Emerg Infect Dis 88.

[47] Dennis Normile, 'Indonesia to Resume Sharing under New Terms' (6 April 2007) 316(5821) *Science* 37.

[48] Wan Izatul Asma Wan Talaat, 'Protection of the Associated Traditional Knowledge on Genetic Resources: Beyond the Nagoya Protocol' (2013) 91 Procedia – Social and Behavioral Sciences 673.

The purpose of the Nagoya Protocol was explicit.[49] The CBD, as it was originally formed, lacked an agreed upon legal framework for cross-border 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. 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[ying] the [CBD] broad economic scope."[50] 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.[51]

3. International Institutions and the Emergence of the Legal Norm of Vaccine Access

3.1. 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 the capacity to develop and manufacture them. 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. What happened instead was the emergence of legal regimes committed to vaccine access for the global population, even if disparities lingered: the Pandemic Influenza Preparedness Framework (PIP Framework) in 2011 and the COVAX Facility in 2020.

The process that eventually led to the PIP Framework began with the World Health Organization developing solutions to the problem Indonesia raised in 2006, followed by Resolution WHA 60.28 by the World Health Assembly in 2007. 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."[52] The resolution was an agreed 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; the sharing of influenza viral samples to members of the WHO Global Influenza Surveillance and Response System (GISRS), the successor to GISN, and the sharing of viral samples with vaccine manufacturers in return for benefits shared

[49] Sam Halabi, Michelle Rourke, Rebecca Katz and Gian Luca Burci, 'The Nagoya Protocol and the Legal Structure of Global Biogenomic Research' (2020) 45 Yale J Int'l L 133.
[50] Ibid.
[51] Ibid.
[52] Mark Eccleston-Turner, 'The Pandemic Influenza Preparedness Framework: A Viable Procurement Option for Developing States?' (2017) 17 Med Law Int'l 227, 228.

with the WHO and its members.[53] 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.[54] 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.[55] As of 2021, 71 Standard material Transfer Agreements had been entered into by the WHO, 29 of which promised benefits (academic research centers, who also enter the agreements, rarely offer benefits).[56] 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."[57]

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 was a meaningful global objective without binding their interests (or of their pharmaceutical companies) too stringently. As of 2021, 71 Standard material Transfer Agreements had been entered into by the WHO, 29 of which promised benefits (academic research centers, who also enter the agreements, rarely offer benefits).[58] 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."[59]

3.2. The COVAX Facility

When atypical pneumonia cases arose in China in late 2019, a new chapter in viral sovereignty emerged.[60] While the genetic sequence of SARS-CoV-2 was shared in early January 2020, the actual biological sample sharing was delayed and, but for the rapid spread of the pathogen worldwide (rendering sharing less relevant), it is not clear the same claims may not have emerged. But as recounted in Part 1.2, the spread of vaccine nationalism was met with a countervailing effort to ensure access to vaccines for the world's most vulnerable populations: the COVAX Facility.[61]

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[53] Sam Halabi, 'Viral Sovereignty, Intellectual Property, and the Changing Global System for Sharing Human Pathogens for Infectious Disease Research' (2019) 28(1) Annals of Health L 101.
[54] Michelle Rourke et al., 'Access and Benefit-Sharing: Implications for Accessing Biological Samples for United Nations Secretary-General Mechanism Investigations' [2019] Geo Univ Med Ctr, Ctr Glob Health & Sec 1, 2.
[55] Sam Halabi, *International Intellectual Property Shelters*, (2016) 90 Tulane L Rev 903.
[56] WHO, 'Influenza: Standard Material Transfer Agreements 2' (SMTA2) <www.who.int/influenza/pip/smta2/en/> accessed 27 April 2021.
[57] Eccleston-Turner, 'The Pandemic Influenza Preparedness Framework' (n 51) 227.
[58] SMTA2 (n 56).
[59] Eccleston-Turner, 'The Pandemic Influenza Preparedness Framework' (n 51) 227, 132.
[60] Fidler, 'Vaccine Nationalism's Politics' (n 6), 749.
[61] WHO, 'Coronavirus Global Response: Access to COVID-19 Tools-Accelerator Facilitation Council holds inaugural meeting' (2020) <www.who.int/news-room/detail/10-09-2020-coronavirus-global-response-access-to-covid-19-tools-accelerator-facilitation-council-holds-inaugural-meeting> accessed 27 April 2021.

The COVAX Facility originated within a broader international collaboration known as the ACT (Access to COVID-19 Tools) Accelerator,[62] an initiative led by the World Bank, the World Health Organization, G20, European Commission, and a consortium of major global public health non-governmental organizations including the Bill & Melinda Gates Foundation, and other private donors to advance the goal of fostering the development and production of diagnostics, therapeutics, and vaccines to combat the COVID-19 pandemic.[63] The ACT Accelerator, launched in April 2020, is broader than COVAX and includes four "pillars": the Diagnostic Pillar supported by the Foundation for Innovative New Diagnostics (FIND) and the Global Fund to Fight Aids, Tuberculous, and Malaria (Global Fund), the Therapeutics Pillar supported by Unitaid and Wellcome Trust, the Health Systems Pillar supported by the World Bank, Global Fund, and WHO, and the Vaccine Pillar supported by Gavi, the Vaccine Alliance (GAVI), the Coalition for Epidemic Preparedness Innovations (CEPI), and the World Health Organization.[64]

After being hosted by UNICEF for almost a decade, GAVI became, in 2009, an independent international institution under Swiss law.[65] Now identified as its own international organization, GAVI was the first organization to receive such recognition under the Swiss Host State Act. GAVI is now a foundation under Swiss law and an independent international institution with privileges and immunities similar to those of U.N. agencies.[66] CEPI is even newer, having been formed under Norwegian law and maintaining a governance structure that incorporates formal international organizations, non-goernmental organizations, and governments, including their medicines regulators.

The Vaccine Pillar, now known simply as "COVAX" or the "COVAX Facility"[67] was established in June 2020.[68] It was founded to support the quick and safe development, manufacture, and delivery of COVID-19 vaccines worldwide.[69] COVAX aims to deliver two billion doses of a safe and effective COVID-19 vaccine by the end of 2021.[70] In order to achieve this objective, COVAX invests across a wide portfolio of vaccine candidates using contributions from 89 "self-financing" governments and supporting international organizations and charities

[62] Seth Berkley, 'COVAX Explained' (GAVI, 3 September 2020), <www.gavi.org/vaccineswork/covax-explained> accessed 27 April 2021.
[63] 'The Scramble for Vaccines and the COVAX Facility,' Center for Strategic and International Studies 1, 3 (19 August 2020) <https://csis-website-prod.s3.amazonaws.com/s3fs-public/publication/200811_Scramble_Vaccines.pdf> accessed 27 April 2021.; *Donor profiles,* GAVI (Dec. 15, 2020), <www.gavi.org/investing-gavi/funding/donor-profiles> accessed 27 April 2021.
[64] 'ACT-Accelerator Update: Publication of Investment Cases,' WHO (26 June 2020) <www.who.int/news-room/detail/26-06-2020-act-accelerator-update> accessed 27 April 2021; Jonathan C Carlson, 'Strengthening the Property Rights Regime for Plant Genetic Resources: The Role of the World Bank' (1996) 6 Transnat'l L & Contemp Probs 91, 112–113 (identifying the evolving role of the World Bank from discrete project funding to broader, structural efforts).
[65] GAVI, *Alliance Progress Report 2012*, 44, 46, <www.gavialliance.org/resources/2012_GAVI_Alliance_Progress_Report_2.pdf> accessed 8 May 2021.
[66] Ibid 47.
[67] The Vaccine Pillar is also referred to as "COVAX Facility" or "the Facility" in online sources.
[68] ACT-Accelerator Update (n 64).
[69] Ibid.
[70] WHO, 'More than 150 Countries Engaged in COVID-19 Vaccine Global Access Facility' (15 July 2020) <www.who.int/news-room/detail/15-07-2020-more-than-150-countries-engaged-in-covid-19-vaccine-global-access-facility> accessed 27 April 2021.

and, at the same time, requiring financial commitments from 92 "donor supported" governments that will receive subsidized prices for doses.[71]

Within COVAX, CEPI leads the development and manufacturing workstream which supports R&D and manufacturing expansion through direct financial investments.[72] GAVI is the lead for the vaccine procurement and delivery at scale workstream as well as the COVAX Advance Market Commitment "AMC" which helps to finance low- and lower-middle-income countries' access to a future COVID-19 vaccine.[73] As of May 4, 2021, COVAX had shipped over 53 million vaccines to over 100 economies (COVAX provides vaccines to "economies", a broader set of international actors than recognized governments).[74]

4. The Future of Pandemic Vaccine Access after COVID-19

After the world's experience with Ebola Virus Diseaes in West Africa 2014–16, the World Health Organization's IHR Review Committee called for the use of the Pandemic Influenza Preparedness Framework's principles to be applied to a broader set of pathogens including Ebola and Zika.[75] Indeed, that remains a possibility after the significant efforts required to spontaneously form and adapt COVAX to the COVID-19 threat. Indeed, 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.[76] But the establishment of COVAX and the formation of the other ACT Accelerator Pillars has 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.[77] In December 2020, Michel met with Tedros Adhanom Ghebreyesus, the Director

[71] WHO, '172 Countries and Multiple Candidate Vaccines Engaged in COVID-19 Vaccine Global Access Facility' (24 August 2020) <www.who.int/news-room/detail/24-08-2020-172-countries-and-multiple-candidate-vaccines-engaged-in-covid-19-vaccine-global-access-facility> accessed 27 April 2021.

[72] 'Facility Structure and Governance: Report to the Board', COVAX 1, 2 (30 July 2020) <www.gavi.org/sites/default/files/board/minutes/2020/30-july/04b%20-%20COVAX%20Facility%20Structure%20and%20Governance_1.pdf> accessed 27 April 2021.

[73] Ibid 2–3; Mark Turner, 'Vaccine Procurement During an Influenza Pandemic and the Role of Advance Purchase Agreements: Lessons From 2009-H1N1' (2016) 11 Global Pub Health 322, 327.

[74] WHO, 'COVAX Reaches over 100 Economies, 42 Days After First International Delivery' (8 April 2021) <www.who.int/news/item/08-04-2021-covax-reaches-over-100-economies-42-days-after-first-international-delivery> accessed 27 April 2021.

[75] '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, Report by the Director-General' (13 May 2016, A69/21) World Health Organization <http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_21-en.pdf> accessed 20 September 2016.

[76] BZ Li, MS Li, JY Huang, YY Chen and YH Lu. 'Expanding the Pandemic Influenza Preparedness Framework to the Epidemic of COVID-19' (6 June 2020) 54(6) Zhonghua Yu Fang Yi Xue Za Zhi 597. Chinese. <doi: 10.3760/cma.j.cn112150-20200316-00357. PMID: 32842276>.

[77] David M Herszenhorn, 'Charles Michel Proposes "International Pandemic Treaty"' *Politico* (12 November 2020) <www.politico.eu/article/charles-michel-proposes-international-pandemic-treaty/> accessed 27 April 2021.

General of the World Health Organization (WHO), to discuss the treaty.[78] In January 2021, Tedros endorsed the pandemic treaty proposal "as a way to guarantee countries' political commitment to fighting future disease outbreaks."[79] He expressed WHO's support of such a treaty, saying "[i]t will give the IHR [International Health Regulations] the political dimension" it needs.[80]

In theory, an international pandemic treaty could deal with a variety of issues, including a fair and equitable distribution structure for vaccines.[81] 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."[82]

5. 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 the World Health Organization as the global public health coordinating mechanism. While the 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 the WHO remains critical to the development of new international legal regimes that can assist in navigating global crises.[83]

This essay 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 response system for health threats and the World Health Organization's in particular. Governments and companies look to it when infectious disease threats emerge and, so far, it 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.

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[78] Svět Lustig Vijay, 'WHO Proposes New "Pandemic Treaty" To Tighten Global Monitoring and Enforcement of Disease Outbreak Response] (20 January 2021) Health Policy Watch <https://healthpolicy-watch.news/who-proposes-new-pandemic-treaty-to-tighten-global-monitoring-and-enforcement-of-disease-outbreak-response/> accessed 27 April 2021.
[79] Ibid.
[80] Ibid.
[81] Herszenhorn (n 77).
[82] Haik Nikogosian and Ilona Kickbusch, 'The Case for an International Pandemic Treaty' [25 February 2021] BMJ 1.
[83] Fidler, 'Vaccine Nationalism's Politics' (n 6), 749.