

Legal Paradigms and the Politics of Global COVID-19 Vaccine Access

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Well before an effective COVID-19 vaccine had been developed, governments and global health institutions were structuring efforts to equitably disseminate them worldwide. Heads of state from many of the world's most powerful governments, United Nations officials, leaders of global health institutions, powerful philanthropists, and CEOs gathered on private zoom calls and then at public events. They pledged global solidarity and designed a complex web of new institutional arrangements intended to ensure distribution of vaccines would happen on a globally fair basis.

The opposite happened. A year after the first vaccines were registered, 9 billion doses had been administered, but just 1 percent of them were delivered in low-income countries;¹ 72 percent of the population in Western Europe had been fully vaccinated, but just 4 percent in Western Africa.² The highest profile global vaccine equity effort, the COVID-19 Vaccine Global Access Facility (COVAX), achieved less than half of its goal of distributing 2 billion doses in 2021.³ While global governance efforts may yet manage wide vaccination coverage, they did not achieve their stated goal of equitable distribution.

The explanation for this failure, despite backing from powerful individuals and institutions, lies at the intersection of law and politics – in the rise of dueling law and policy paradigms for the achievement of vaccine equity, the success of a paradigm based on voluntary action over legal instruments, and the prevailing political context that made the dominant paradigm predictably ineffectual.

One paradigm assumed that governments should leave in place intellectual property (IP) and other market arrangements that create global monopolies over

¹ Our World in Data, *COVID-19 Data Explorer* (2022), <https://ourworldindata.org/explorers/coronavirus-data-explorer> (last visited Feb. 2, 2022).

² Philip Schellekens, *Distribution of Excess Mortality by World Bank Region*, Pandem-IC (2022), <https://pandem-ic.com/share-in-cumulative-excess-deaths-by-world-bank-region/> (last visited Feb. 2, 2022).

³ UNICEF, *COVID-19 Vaccine Market Dashboard* (2022), www.unicef.org/supply/covid-19-vaccine-market-dashboard (last visited Feb. 4, 2022).

production of each vaccine developed – limiting supply. Constructed primarily by high-income country governments, philanthropies, and private sector actors, that paradigm focused on coordinating demand and incentivizing countries to voluntarily pool their purchases so that, as effective vaccines came online, limited supply could be fairly distributed. But these assumptions were not shared by all, or even most, governments of the world. An alternative supply-focused paradigm supported largely by low- and middle-income country (LMIC) governments and civil society organizations, instead concentrated on a principle of openness. It proposed greater use of legal authority and sharing of vaccine knowledge to open production worldwide.

These approaches could have been complementary (for example, pooling procurement while compelling the sharing of technology) but, in a remarkable breakdown of international cooperation, there was never serious arbitration among powers. None of the major international venues for negotiation – the UN General Assembly, World Health Assembly, World Trade Organization (WTO), and so on – took up these questions to reach agreement across different interests. As such, two separate paradigms developed, competing for attention, and the interests of powerful global actors ultimately kept the supply/openness paradigm from gaining political traction on the global health policy agenda.

In theory, either approach could have worked. Indeed, some suggest the model behind the dominant approach of voluntary coordinated action amidst monopolies was sound, undermined primarily by the lack of a permanent, rapid financing mechanism and by “unexpected” behaviors by states and companies.⁴ Next time, it is argued, it could work.

We argue that this rationale lacks a firm understanding of politics. Robert Putnam long ago described the “two-level game” in geopolitically important issues in which engagement between states is shaped by the politics inside countries.⁵ In that context, vaccine nationalism and hoarding by wealthy nations was entirely predictable to observers of the politics of 2020–2021 – characterized by rising populism, growing international rivalries, and a retreat from multilateralism. Yet the paradigm that gained dominance in global health policy required norms of sharing and international cooperation to compel states to limit their own access so other, less-powerful states could get doses, and to ensure pharmaceutical companies filled orders for global health initiatives ahead of those of powerful governments. Missing was a realistic vision of delegated authority as no legal measures bound either states

⁴ Donato Paolo Mancini, *Countries Weigh How to Buy Vaccines for the Next Pandemic*, FINANCIAL TIMES (Feb. 1, 2022), www.ft.com/content/9147b3e4-7426-479d-881d-6b8731f3dbaz (last visited Feb. 4, 2022).

⁵ Robert D. Putnam, *Diplomacy and Domestic Politics: The Logic of Two-Level Games*, 42 INTERNATIONAL ORGANIZATION 427 (1988).

or companies to allocate limited doses ethically.⁶ Failure to achieve vaccine equity, we argue, is explained not by unforeseen technical challenges, but by the fundamental misalignment between the dominant policy paradigm and the international and domestic politics of the moment.

Authors in this volume make a wide range of important proposals on IP, innovation, and access. The question we ask is: which of these might work in an actual pandemic? By tracing the first year of COVID-19 vaccine distribution, we show the critical importance of aligning choice of policy mechanisms with political forces. Indeed, we argue that an openness paradigm may have been more effective not only for reasons of justice, but because it could accommodate populist politics and vaccine nationalism. Important nonstate actors from international organizations and foundations appear to have believed they could work with monopolies and motivate states to prioritize working toward vaccine equity without a robust use of law. They were mistaken. The alternative was a strategy based on legal agreements between states to share knowledge and technology and the use of legal authority by states to compel companies to share so that each country or regional bloc could set up production of effective vaccines for their own population. This strategy did not require countering broad state self-interest and might well have achieved a more equitable outcome.

If global governance mechanisms are to succeed in stopping future pandemics, far greater emphasis will be needed on sharing technology – not just for normative reasons of justice but for the practical crafting of approaches capable of achieving equitable outcomes in the real-world geopolitical context.

1 CREATING VACCINES, CREATING VACCINE INEQUITY

That a safe and effective vaccine against the SARS-CoV-2 virus could be developed within a year was far from guaranteed – the previous record was four years for mumps in the 1960s.⁷ Yet a mix of previous investment, global coordinated effort, and a bit of luck rapidly produced multiple COVID-19 vaccines. In December 2020, the United States, United Kingdom, and European Union all approved key vaccines and they began deploying them in large numbers. China and India also quickly approved domestically developed vaccines, following Russia, which had been the first country to do so.

By the end of June 2021, six months into vaccine roll-out, the United States had enough vaccines to cover all its priority populations of health workers and people

⁶ Curtis Bradley & Judith Kelley, *The Concept of International Delegation*, 71 LAW AND CONTEMPORARY PROBLEMS 1 (2008).

⁷ Philip Ball, *The Lightning-Fast Quest for COVID Vaccines and What It Means for Other Diseases*, NATURE (Dec. 18, 2020), www.nature.com/articles/d41586-020-03626-1 (last visited Jul. 1, 2022).

over sixty-five. High-income countries (HICs) had 90 percent of what they needed.⁸ Low-income countries, on the other hand, had received only enough vaccines to cover 12 percent of their highest priority populations.

While official mortality figures imply that the majority of COVID-19 deaths occurred in HICs – which might make vaccine inequality more justifiable or less harmful – mortality data is highly underreported from LMICs.⁹ Indeed, the majority of cases and deaths in LMICs have likely gone unreported. An analysis of “excess deaths,” accounting for this underreporting, shows that, once vaccines began rolling out, the share of excess deaths in HICs fell and the vast majority of COVID-19 deaths were occurring in LMICs by early 2021.¹⁰ As vaccine coverage rose and cases fell, HICs lifted restrictions and moved to resume normal life. On July 4, 2021, US President Joe Biden declared that “we’re closer than ever to declaring our independence from a deadly virus.”¹¹

As many had predicted, however, leaving large portions of the world unvaccinated led to several new variants as the virus mutated. In mid-March the Delta variant arose in India, which at the time had 2 percent vaccine coverage. Later the Omicron variant arose – likely in Southern Africa, where vaccine coverage rates remained below 25 percent and high levels of immunocompromised individuals are suffering from HIV, cancer, and other diseases.¹² These variants led to a push for boosters throughout HICs – re-exerting pressure on vaccine supply in LMICs.¹³ Throughout this period, HICs focused first and foremost on covering their entire populations.

By the end of the year, vaccine inequity had continued unabated (Figure 4.1) and more booster shots had been administered in HICs than first shots in LMICs. The World Health Organization (WHO) reported that just one in four African health workers received a full course of vaccine.¹⁴

⁸ Philip Schellekens, *Trackers of Vaccination by Income Group*, Pandem-IC (2022), <https://pandem-ic.com/trackers-of-covid-19-vaccination-by-world-bank-income-group/> (last visited Feb. 2, 2022).

⁹ Matthew M. Kavanagh, Ingrid T. Katz & Charles B. Holmes, *Reckoning with Mortality: Global Health, HIV, and the Politics of Data*, 396 THE LANCET 288 (2020).

¹⁰ Philip Schellekens, *Distribution of Daily Excess Mortality by Income Group*, Pandem-IC (2022), <https://pandem-ic.com/share-in-daily-estimated-excess-deaths-by-income/> (last visited Feb. 8, 2022).

¹¹ Remarks by President Biden Celebrating Independence Day and Independence from COVID-19, The White House (2021), www.whitehouse.gov/briefing-room/speeches-remarks/2021/07/05/remarks-by-president-biden-celebrating-independence-day-and-independence-from-covid-19/ (last visited Feb. 4, 2022).

¹² *Omicron: South African Scientists Probe Link between Variants and Untreated HIV*, BBC NEWS (Dec. 21, 2021), www.bbc.com/news/world-africa-59697807 (last visited Feb. 4, 2022).

¹³ Ngozi Erondu & Renu Singh, *New Donation Pledges Won't Fill Global COVID-19 Vaccine Shortfalls. Here's Why*, THE CONVERSATION (2021), <http://theconversation.com/new-donation-pledges-wont-fill-global-covid-19-vaccine-shortfalls-heres-why-168789> (last visited Feb. 4, 2022).

¹⁴ WHO, *Only 1 in 4 African Health Workers Fully Vaccinated against COVID-19* (2021), www.afro.who.int/news/only-1-4-african-health-workers-fully-vaccinated-against-covid-19 (last visited Feb. 2, 2022).

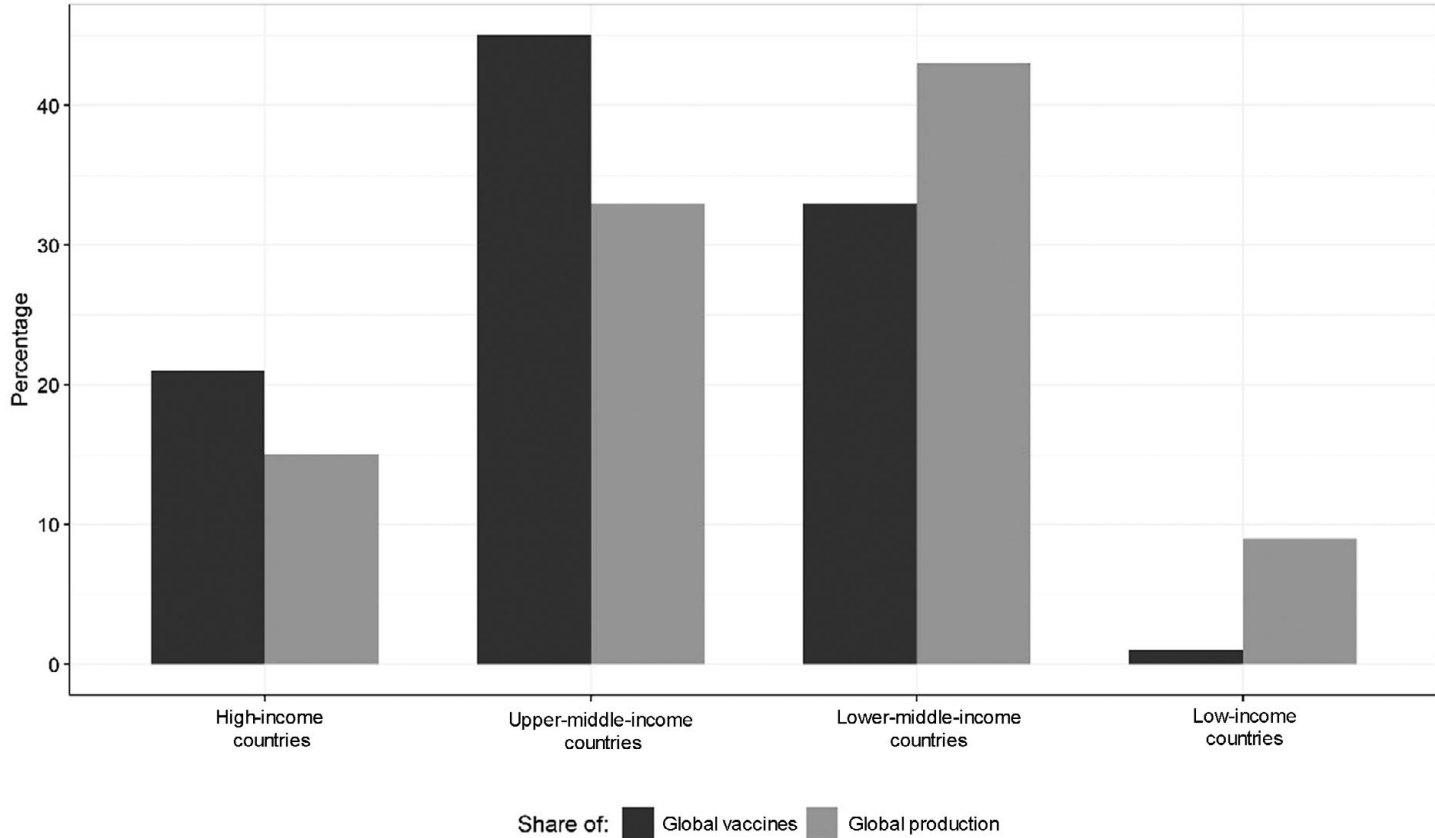


FIGURE 4.1 Global distribution of vaccines v. population, January 2022

Sources: Our World in Data, Schellekens, Pandem-IC, World Health Organization.

2 COMPETING LAW AND POLICY PARADIGMS

Which ideas become policy solutions and which of those make it onto the political agenda of international policymaking has long been studied.¹⁵ In global health, this is particularly complex because of the number of different levels and fora in which international deliberations happen over health – from the World Health Assembly of the WHO to the UN General Assembly to the boards of various health financing agencies.¹⁶ In this case, none of these emerged as a single legitimate space for authoritative policymaking on vaccine access. Instead, groupings of governments and private actors came together in a more ad hoc way. Politically important gaps emerged, like the absence of both the United States and China – the world’s largest economies – which for different domestic, political reasons absented themselves from global coordination efforts.¹⁷ With neither a hegemonic country nor an authoritative international organization forcing all actors into negotiation, policy was made by self-selected groups and little political negotiation occurred directly between higher- and lower-income countries over the equity approach. Vaccine equity efforts emerged into what we characterize as two competing policy paradigms.¹⁸ While there is much that is synergistic about the approaches, the actors, ideas, and context of global public health in 2020 resulted in framing these as different and opposing paradigms. A handful of actors, notably the WHO, unsuccessfully sought to advance both approaches. This division is at the heart of the limited equity achieved to date.

*A Leaving IP and Monopolies in Place: A Voluntary Paradigm
Focused on Demand*

At the March 2020 meeting of the G20, policy leaders from some of the world’s biggest economies began to coalesce around a plan for vaccine access to be built not through global agreement but instead through voluntary action by a group of

¹⁵ Jeremy Shiffman & Stephanie Smith, *Generation of Political Priority for Global Health Initiatives: A Framework and Case Study of Maternal Mortality*, 370 THE LANCET 1370 (2007); Sakiko Fukuda-Parr & David Hulme, *International Norm Dynamics and the “End of Poverty”*: Understanding the Millennium Development Goals, 17 GLOBAL GOVERNANCE 17 (2011).

¹⁶ Stephanie L. Smith et al., *The Rise and Fall of Global Health Issues: An Arenas Model Applied to the COVID-19 Pandemic Shock*, 17 GLOBALIZATION AND HEALTH 33 (2021); Marcos Cueto, *The ORIGINS of Primary Health Care and SELECTIVE Primary Health Care*, 94 AM. J. PUBLIC HEALTH 1864 (2004).

¹⁷ Carla Norrlöf, *Is COVID-19 the End of US Hegemony? Public Bads, Leadership Failures and Monetary Hegemony*, 96 INTERNATIONAL AFFAIRS 1281 (2020); Ş İlgü Özler, *The United Nations at Seventy-Five: Passing the COVID Test?*, 34 ETHICS & INTERNATIONAL AFFAIRS 445 (2020).

¹⁸ Peter A. Hall, *Policy Paradigms, Social Learning, and the State: The Case of Economic Policymaking in Britain*, 25 COMPARATIVE POLITICS 275 (1993).

“countries, international organizations, the private sector, [and] philanthropies.”¹⁹ The Access to COVID-19 Tools Accelerator (ACT-A) was launched at an event a month later, co-hosted by the leaders of France, the European Commission, the WHO, and the Gates Foundation. ACT-A set up a time-limited collaboration focused on cooperation between existing global public health actors – Gavi (formerly the Global Alliance for Vaccines and Immunization), the Coalition for Epidemic Preparedness Innovations (CEPI), the Global Fund, Unitaid, and the WHO.²⁰ Its initial governance centered around ten HIC governments along with key private foundations and the WHO (see Figure 4.2). Representatives of the pharmaceutical industry were key players involved from the start, with LMIC governments appearing in its governance only at a later stage.²¹

COVAX, housed at Gavi, became the vaccine pillar of ACT-A. Its goal was to bring the acute phase of the pandemic to a swift end by guaranteeing “rapid, fair and equitable access” to vaccines – aiming to “ensure that people in all corners of the world will get access to COVID-19 vaccines once they are available, regardless of their wealth.”²²

The law and policy agenda behind COVAX was based on the preferences of its main political sponsors – governments, companies, and foundations located in HICs. It positioned the private sector as the main driver of innovation and had little to say about IP – accepting, without debate, that the same system of global monopolies that governed other pharmaceuticals would be maintained. This predominant agenda grounded its strategy in voluntary interventions by companies and donor governments meant to organize the demand side of vaccine production. It focused on the creation of advanced purchase agreements to incentivize development, pooling demand through centralized procurement to increase purchasing power, negotiations with companies making vaccines, and clear demand-signaling that would act as a market-based incentive for producers to expand their capacity. “Self-financing” upper- and upper-middle-income countries were to pay in advance for the option to buy vaccines for their own populations while also financing the purchase of vaccines for LMICs. The primary incentive for HICs to procure their vaccines through COVAX was that it would serve as a de-risking mechanism and “insurance policy” – limiting the need to invest in multiple vaccine candidates (some of which would fail) and ensuring that they would have access to whichever

¹⁹ G20, Extraordinary G20 Leaders’ Summit: Statement on COVID-19 (2020), www.g20.utoronto.ca/2020/2020-g20-statement-0326.html (last visited Feb. 4, 2022).

²⁰ European Union, *Coronavirus Global Response: United to Make the World a Safer Place*, Coronavirus Global Response (2020), https://global-response.europa.eu/outbreak-coronavirus-president-european-commission-ursula-von-der-leyen-has-rallied-international_en (last visited Jun. 27, 2021).

²¹ Suerie Moon et al., *Governing the Access to COVID-19 Tools Accelerator: Towards Greater Participation, Transparency, and Accountability*, 399 THE LANCET 487 (2021).

²² Gavi, COVAX Explained (2020), www.gavi.org/vaccineswork/covax-explained (last visited Jun. 27, 2021).

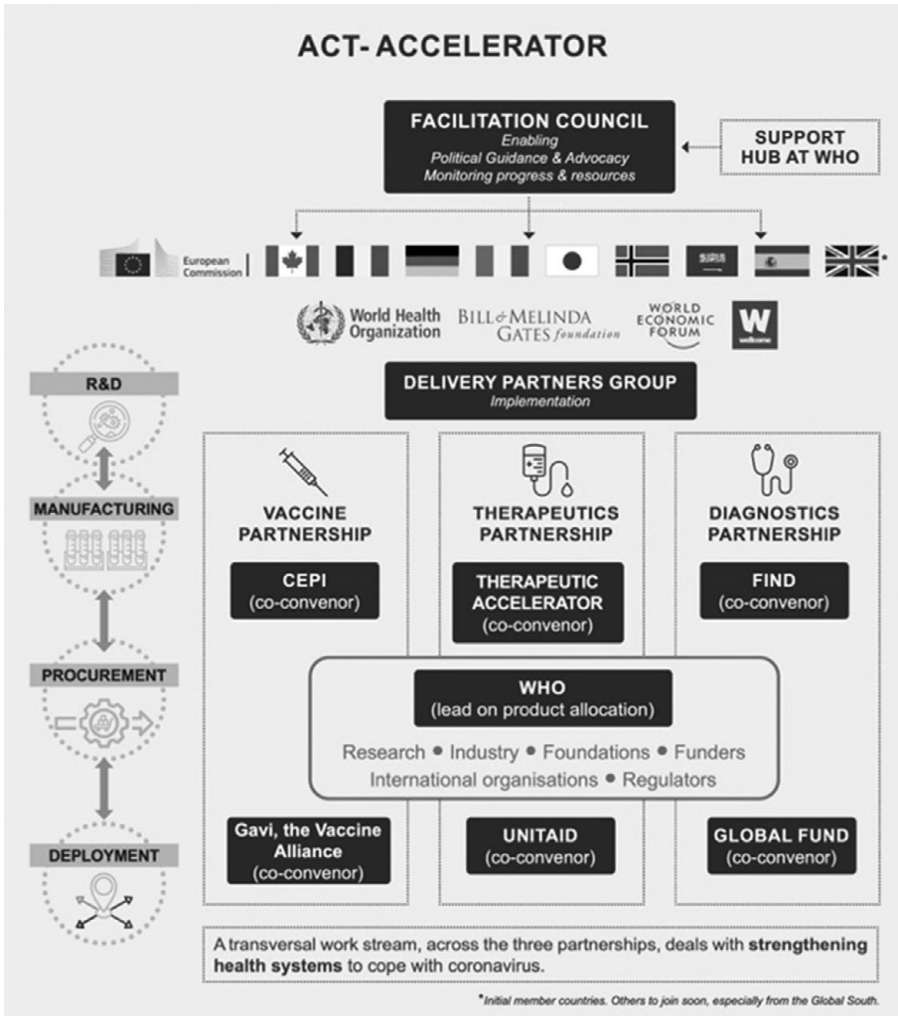


FIGURE 4.2 ACT Accelerator governance structure, June 20, 2020

Source: European Union, Coronavirus Global Response, June 2020, https://global-response.europa.eu/system/files/2020-06/CGRS_United_final.pdf

vaccines proved successful without having to gamble their investments on the right vaccines.²³ However, these countries still had the option to negotiate bilateral deals with vaccine makers. LMICs, meanwhile, would have access to doses through the advanced market commitment, financed by donations from philanthropy and governments, as well as the contributions of self-financing countries. By pooling

²³ David McAdams et al., *Incentivising Wealthy Nations to Participate in the COVID-19 Vaccine Global Access Facility (COVAX): A Game Theory Perspective*, 5 *BMJ GLOBAL HEALTH* e003627 (2020).

procurement, all countries would benefit from economies of scale and improved buying power.

Equity was to be achieved through two phases – first by procuring and allocating at least 2 billion doses by the end of 2021 – enough to equally cover 20 percent of all participating countries’ populations, protecting the individuals at highest risk everywhere.²⁴ Afterwards, additional doses would be allocated in response to epidemiological conditions, according to a threat and vulnerability formula developed by a joint taskforce of the WHO and Gavi.²⁵

COVAX’s focus was on procuring and delivering the vaccine doses, and on assisting LMICs to ensure that they had the logistical frameworks needed to deliver vaccines to their people. By November 2020, COVAX had raised \$2 billion, meeting its 2020 goal.²⁶ That was augmented by a US pledge shortly after President Biden’s inauguration, along with other funders, such that by April 2021 \$6.3 billion had been pledged and by June COVAX exceeded its goal with \$9.6 billion pledged.²⁷ Funding was, however, slow to arrive as HICs focused more on financing their own purchases first.

This approach did not seek to reach enforceable agreements among states or to place legal obligations on either states or vaccine manufacturing companies. States did not require companies that received public research funding to share technology or agree to COVAX allocations in advance. Companies maintained monopoly control over the production of each vaccine, including IP rights, and it was up to each company to decide whether to sell doses to COVAX (or to LMICs directly), in what quantity, and on what timeline. Neither states nor companies were compelled to prioritize COVAX orders, though companies were urged to voluntarily sell to COVAX and countries to share “surplus” doses from their bilateral negotiations.²⁸

From the start, many leaders in the Global South expressed concern about this approach. African leaders, for example, said their goals were to vaccinate far more than 20 percent of their populations and complained they were scarcely consulted in

²⁴ Ann Danaiya Usher, *A Beautiful Idea: How COVAX Has Fallen Short*, 397 THE LANCET 2322 (2021).

²⁵ World Health Organization, *Fair Allocation Mechanism for COVID-19 Vaccines through the COVAX Facility* (2020), www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility (last visited Jun. 27, 2021).

²⁶ Gavi, *Over US\$ 2 Billion Raised to Support Equitable Access to COVID Vaccines with Additional US\$ 5 Billion Needed in 2021* (2020), www.gavi.org/news/media-room/over-us-2-billion-raised-support-equitable-access-covid-vaccines-additional-us-5 (last visited Feb. 20, 2022).

²⁷ Gavi, *One World Protected: The Gavi COVAX AMC Investment Opportunity* (2021), www.gavi.org/gavi-covax-amc-launch-event-april-2021 (last visited Jun. 28, 2021); Gavi, *World Leaders Unite to Commit to Global Equitable Access for COVID-19 Vaccines* (2021), www.gavi.org/news/media-room/world-leaders-unite-commit-global-equitable-access-covid-19-vaccines (last visited Jun. 28, 2021).

²⁸ Wellcome, *Why We Need to Share Vaccine Doses Now and Why COVAX Is the Right Way to Do It* (2021), www.gavi.org/vaccineswork/why-we-need-share-vaccine-doses-now-and-why-covax-right-way-do-it (last visited Feb. 20, 2022).

mid-2020 when the program set that target.²⁹ They questioned why COVAX was based on a model that included no obligations for companies to fulfill African orders or share technology so African companies could make vaccines for their own populations.³⁰

These measures could be complementary. But the agenda of the initiative was narrowed to fit the policy preferences of key members of the coalition backing it, including HIC governments and companies. Pooled demand, for example, could be complementary to an open approach that compelled sharing of knowledge and IP. Ironically, HICs pursued at least limited use of legal mechanisms domestically. US President Joe Biden, for example, used the Defense Production Act to compel companies to collaborate on expanding vaccine production. The WHO and many LMIC leaders also advocated for an integrated strategy.³¹ In addition, there was a global precedent set earlier in the HIV/AIDS pandemic, when the Doha Declaration on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and Public Health clarified the urgency and legality of sharing of information and compulsory licenses so that antiretroviral drugs became more accessible and affordable in LMICs.³² But the ACT-A paradigm explicitly excluded calls for more compulsory legal efforts at a national or international level or for a focus on sharing technology.

While political leaders such as EU President Ursula von der Leyen spoke about the “global public good”³³ – such an approach to shared know-how and public production, aligned with economic understandings of a “public good,”³⁴ was not on the agenda.

B Few Doses, Little Equity: Failure of a Paradigm

Ultimately, during the first year of vaccine delivery, the demand-focused/voluntary mechanisms were unable to secure anywhere near the doses needed to achieve

²⁹ Benjamin Mueller & Rebecca Robbins, *Where a Vast Global Vaccination Program Went Wrong*, N.Y. TIMES (Aug. 2, 2021), www.nytimes.com/2021/08/02/world/europe/covax-covid-vaccine-problems-africa.html (last visited Feb. 2, 2022).

³⁰ Cara Anna, *Africa's COVID-19 Envoy Blasts EU, COVAX over Vaccine Crisis*, AP NEWS (Jul. 1, 2021), <https://apnews.com/article/africa-europe-coronavirus-pandemic-health-business-926c80134a8543efef6e2c7ca4d43c2> (last visited Feb. 2, 2022); John N. Nkengasong et al., *Covid-19 Vaccines: How to Ensure Africa Has Access*, 586 NATURE 197 (2020).

³¹ Tedros Ghebreyesus, *WHO Director-General's Remarks at the 1st International Forum on Vaccine Cooperation – 5 August 2021* (2021), www.who.int/director-general/speeches/detail/who-director-general-s-remarks-at-the-1st-international-forum-on-vaccine-cooperation-5-august-2021 (last visited Feb. 20, 2022).

³² Carlos María Correa & Duncan Matthews, *The Doha Declaration 10 Years on and Its Impact on Access to Medicines and the Right to Health*, UNDP (2011), www.undp.org/content/undp/en/home/librarypage/hiv-aids/doha10yearson/ (last visited Feb. 20, 2022).

³³ European Commission, *Von der Leyen on Coronavirus Global Response* (2020), https://ec.europa.eu/commission/presscorner/detail/en/ac_20_811 (last visited Jun. 27, 2021).

³⁴ INGE KAUL, ISABELLE GRUNBERG & MARC STERN, *GLOBAL PUBLIC GOODS: INTERNATIONAL COOPERATION IN THE 21ST CENTURY* (1999).

equity – even after defining equity and setting goals that some criticized as insufficient. In April, COVAX forecast that it would have 835 million doses to distribute by August, 1.4 billion by October, and 2.2 billion by the end of 2021.³⁵ But major producers refused to commit to selling doses to it. Pfizer, for example, agreed to sell less than 2 percent of its supplies to COVAX; by November, Moderna had promised just 34 million doses and delivered none.³⁶ Instead, these companies prioritized delivery to HICs. Initially, COVAX depended on major deliveries of the vaccine developed by Oxford–AstraZeneca and produced by the Serum Institute of India (SII). However, when there was a major surge of the virus in March, the Indian government put a halt to vaccine exports, much as the EU had done previously.³⁷ COVAX ultimately reached half its 2021 goal of 2 million doses in January 2022.

Governments in Africa, Asia, and Latin America that tried to obtain access to vaccines directly had the same problem. South Africa bilaterally and the African Union as a bloc both deployed emissaries to try to secure supplies from major producers, and only after many months did they finally begin receiving supplies toward the end of 2021.³⁸ Drug companies dragged out negotiations, and they demanded that governments absolve them of all liability and promise sovereign assets as collateral.³⁹ It was even revealed that millions of COVID-19 vaccines being produced at a Johnson & Johnson-contracted factory in South Africa were being shipped to Europe and North America instead of filling African orders.⁴⁰

Meanwhile, HICs used their economic and political power to secure first access to doses in excess of what was needed for their priority populations – in many cases enough to vaccinate their entire populations many times over. The EU, for example, ordered 1.75 billion doses from Pfizer/BioNTech, 300 million from AstraZeneca, 310 million from Moderna, and 240 million from Johnson & Johnson to cover a population of 447 million people.⁴¹ The United Kingdom, United States, Canada, and Israel ordered enough doses to cover their entire populations between 2.5 and 5

³⁵ Gavi, *COVAX Global Supply Forecast* (2021), www.who.int/publications/m/item/covax-global-supply-forecast (last visited Jun. 27, 2021).

³⁶ Rebecca Ribbons & Peter Goodman, *Pfizer Reaps Hundreds of Millions in Profits from COVID Vaccine*, N.Y. TIMES (May 4, 2021), www.nytimes.com/2021/05/04/business/pfizer-covid-vaccine-profits.html (last visited Feb. 4, 2022).

³⁷ Aniruddha Ghosal, *India Bars Virus Vaccine Maker from Exporting*, AP NEWS (Jan. 3, 2021), <https://apnews.com/article/ap-top-news-global-trade-immunizations-india-coronavirus-pan-demic-c0c881c0f07166e8fd494e078171a7cc> (last visited Feb. 6, 2021).

³⁸ Anna, *supra* note 30.

³⁹ Kyle Cowan, *A Cancelled Meeting, Delays and Secrecy: Inside Sa's Efforts to Procure COVID-19 Vaccine Doses*, NEWS24 (Jan. 6, 2021), www.news24.com/news24/southafrica/investigations/a-cancelled-meeting-delays-and-secrecy-inside-sas-efforts-to-procure-covid-19-vaccine-doses-20210106 (last visited Feb. 8, 2021).

⁴⁰ Rebecca Robbins & Benjamin Mueller, *COVID Vaccines Produced in Africa Are Being Exported to Europe*, N.Y. TIMES (Aug. 16, 2021), www.nytimes.com/2021/08/16/business/johnson-johnson-vaccine-africa-exported-europe.html (last visited Feb. 3, 2022).

⁴¹ Duke GHIC, *Vaccine Purchases | Launch and Scale Speedometer* (2022), <https://launchandscalefaster.org/covid-19/vaccinepurchases> (last visited Feb. 5, 2022).

times. In total, HICs, home to 1.2 billion people, placed orders for over 7 billion vaccine doses. Leaders applied a range of tactics to ensure they were at the front of the line – from export controls to personal contact from presidents asking CEOs to put their orders at the top of the list.⁴² While wealthy governments ordered based on uncertainty of which vaccines would prove effective early on, laying bets on all products to cover their risk, by mid-2021 multiple effective vaccines were approved in Europe and North America. Yet there were few moves to release ordered doses so that high-risk populations in LMICs could get access before young, healthy populations in the Global North.

Amidst scarce vaccine supply, doses became a diplomatic tool. The United States and “Team Europe” distributed hundreds of millions of vaccines bilaterally and through COVAX. China and Russia moved even earlier to promise their vaccines to dozens of Latin American, Asian, and African countries.⁴³ Many of these promises came with subtle or not-so-subtle strings attached. Danish journalists, for example, reported that Rwanda rejected 250,000 doses when it became clear they were meant to help persuade Rwanda to host asylum seekers deported from Denmark.⁴⁴

C *Avoiding Monopolies and Waiving IP: An Alternative Paradigm*

While it did not win the day, an alternative paradigm did emerge at almost the same time as the dominant paradigm. It took aim directly at the assumption that monopoly production could deliver during a pandemic and proposed instead a new set of agreements to share technology, waive WTO rules on patents and IP, and focus on maximizing global production. The key idea of this paradigm was to focus more on supply than on demand – achieving equity not by sharing of doses or by signaling demand to originator companies, but by removing monopolies over knowledge and using state power to spur production of effective vaccines by multiple manufacturers throughout the world. In this way, the subject of the policy paradigm was not limited doses but knowledge. The transfer of technology from a handful of originator

⁴² Martina Stevis-Gridneff, *How Europe Sealed a Pfizer Vaccine Deal with Texts and Calls*, N.Y. TIMES (Apr. 28, 2021), www.nytimes.com/2021/04/28/world/europe/european-union-pfizer-vonder-leyen-coronavirus-vaccine.html (last visited Feb. 5, 2022); TOI Staff, *Netanyahu Bullish on Deal for Pfizer Vaccine after Talks with CEO*, TIMES OF ISRAEL (Nov. 11, 2020), www.timesofisrael.com/netanyahu-bullish-on-deal-with-pfizer-for-vaccines-after-talks-with-ceo/ (last visited Feb. 5, 2022).

⁴³ Bethany Allen-Ebrahimian, *China and Russia Vaccinate the World – for Now*, AXIOS (Mar. 2, 2021), www.axios.com/2021/03/02/china-and-russia-vaccinate-the-world-for-now (last visited Jun. 2, 2022).

⁴⁴ Mads Bonde Broberg & Anders Redder, *Danmarks Gode Ven I Afrika: Danmark Gav 250.000 Gratis Vacciner – Men Nu Vil Landet Ikke Have Dem*, JYLLANDS-POSTEN (Jan. 14, 2022), <https://jyllands-posten.dk/indland/ECE13627586/topembedsmaend-rejste-til-rwanda-og-kort-efter-donerede-danmark-250000-vacciner-til-landet-men-nu-vil-de-ikke-have-dem/> (last visited Feb. 5, 2022).

companies to public and private sector producers, particularly in the Global South, was the goal to maximize supply.

These ideas draw in part from experience with the global AIDS response.⁴⁵ The international community had been incredibly slow to build mechanisms to get HIV drugs to LMICs. Even after action began, success was found only after a shift from distributing a limited supply of high-priced, brand-name medicines to licensing of technologies, production in LMICs, and a supply focus that reduced the price of AIDS drugs by 99 percent.⁴⁶ Coming after millions had died and via pressure from global social movements, the focus on open, affordable supply was key alongside increased aid and pooled procurement.⁴⁷ Many of the same transnational HIV advocacy networks of physicians, lawyers, activists, and Global South governments proposed this alternative paradigm during COVID-19.

Political leaders from the Global South advanced this alternative paradigm at the same time the voluntary/demand paradigm was being put forward by leaders based largely in the Global North. On March 23, 2020 the President of Costa Rica, Carlos Alvarado Quesada, proposed a memorandum of understanding among states to share rights to technologies funded by the public sector among all member countries of the WHO. This included pooling patent rights and designs as well as “regulatory test data, know-how, cell lines, copyrights and blueprints for manufacturing diagnostic tests, devices, drugs, or vaccines.”⁴⁸ The Presidents of South Africa and Senegal and the Prime Minister of Pakistan expanded on this idea in May 2020 in an open letter, joined by dozens of former heads of state and international leaders.⁴⁹ They called for a global agreement implemented under the authority of the WHO that ensured mandatory sharing of COVID-19-related knowledge, data, and technologies; the pooling of intellectual property; coordinated expansion of manufacturing capacity; and a commitment to make COVID-19 vaccines free at the point of service.

In many ways, the vaccines developed by US, EU, and UK sources are good candidates for a public goods approach that focuses on the sharing of technologies. The Moderna vaccine was developed by the US National Institutes of Health (NIH) and supported by \$2.5 billion in public funding from the United States for

⁴⁵ Winnie Byanyima, *HIV or COVID-19, Inequity Is Deadly*, 6 NATURE HUMAN BEHAVIOUR 176 (2022), <https://doi.org/10.1038/s41562-022-01307-9> (last visited Feb. 5, 2022).

⁴⁶ MSF Access Campaign, *Untangling the Web of Antiretroviral Price Reductions (15th Edition)* (Jul. 25, 2012), www.msfacecess.org/content/untangling-web-antiretroviral-price-reductions-15th-edition (last visited Feb. 5, 2022).

⁴⁷ ETHAN KAPSTEIN & JOSHUA BUSBY, *AIDS DRUGS FOR ALL: SOCIAL MOVEMENTS AND MARKET TRANSFORMATIONS* (2013).

⁴⁸ Carlos Alvarado Quesada, *Letter to Dr. Tedros Adhanom Ghebreyesus* (Mar. 23, 2020), www.keionline.org/wp-content/uploads/President-MoH-Costa-Rica-Dr-Tedros-WHO24March2020.pdf (last visited Jun. 28, 2021).

⁴⁹ David Pilling & Andrew Jack, “*People’s Vaccine*” for Coronavirus Must Be Free, *Leaders Urge*, FINANCIAL TIMES (May 13, 2020), www.ft.com/content/af929941-7c02-415a-a692-bf8443ede58a (last visited Jun. 28, 2021).

development, clinical trials, and production.⁵⁰ The European Union was a major contributor to BioNTech's work developing its vaccine through the European Investment Bank and multiple EU research and development (R&D) programs.⁵¹ And the Oxford vaccine was made possible by major public support from both EU and UK governments.

Under the open paradigm, it was proposed that the know-how behind the vaccines resulting from these public investments would be shared widely. Several models were proposed, including licensing by originator companies to multiple other manufacturers, pooling of knowledge and IP, open-source sharing of vaccine know-how, creation of technology transfer hubs.⁵² In addition, a major focus was to be placed on expanding manufacturing capacity, particularly in LMICs, to make the vaccines.⁵³

Key to this would be the effective use of legal and policy tools and of state power to incentivize action by companies, create structures for cross-national sharing, overcome IP barriers, and, where necessary, compel sharing.⁵⁴ Various enforceable global legal frameworks have been proposed to ensure these rights and tackle vaccine nationalism.⁵⁵

In May 2020, a month after the launch of ACT-A, the WHO and several national leaders launched the COVID-19 Technology Access Pool (C-TAP). This followed a resolution by states at the World Health Assembly calling for the pooling of technology and the recognition of COVID-19 vaccinations as a global public good.⁵⁶

⁵⁰ Denise Grady, *Early Data Show Moderna's Coronavirus Vaccine Is 94.5% Effective*, N.Y. TIMES (Nov. 16, 2020), www.nytimes.com/2020/11/16/health/Covid-moderna-vaccine.html (last visited Jun. 28, 2021).

⁵¹ European Commission, *€50 Million to BioNTech* (2019), https://ec.europa.eu/commission/presscorner/detail/hr/IP_19_6796 (last visited Feb. 5, 2022).

⁵² Quesada, *supra* note 48; WHO, *Operationalising the COVID-19 Technology Access Pool (C-TAP)* (2020), https://cdn.who.int/media/docs/default-source/essential-medicines/intellectual-property/who-covid-19-tech-access-tool-c-tap.pdf?sfvrsn=1695cf9_36&download=true (last visited May 18, 2021); Joseph E. Stiglitz, Arjun Jayadev & Achal Prabhala, *Patents vs. the Pandemic*, PROJECT SYNDICATE (Apr. 23, 2020), www.project-syndicate.org/commentary/covid19-drugs-and-vaccine-demand-patent-reform-by-joseph-e-stiglitz-et-al-2020-04 (last visited Jul. 6, 2021); Tahir Amin, *The Folly of Hoarding Knowledge in the COVID-19 Age*, FOREIGN AFFAIRS (Jan. 29, 2021), www.foreignaffairs.com/articles/world/2021-01-29/folly-hoarding-knowledge-covid-19-age (last visited Feb. 7, 2021).

⁵³ Africa CDC, *Framework for Fair, Equitable and Timely Allocation of COVID-19 Vaccines in Africa* (2020), <https://africacdc.org/download/framework-for-fair-equitable-and-timely-allocation-of-covid-19-vaccines-in-africa-highlights-of-day-1/> (last visited Jul. 6, 2021); Nkengasong et al., *supra* note 30.

⁵⁴ Matthew M. Kavanagh, Lawrence O. Gostin & Madhavi Sunder, *Sharing Technology and Vaccine Doses to Address Global Vaccine Inequity and End the COVID-19 Pandemic*, JAMA (2021), <https://doi.org/10.1001/jama.2021.10823> (last visited Jul. 8, 2021).

⁵⁵ Frederick M. Abbott & Jerome H. Reichman, *Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic*, 23 J. OF INTERNATIONAL ECONOMIC LAW 535 (2020).

⁵⁶ WHO, *COVID-19 Response. WHA73.1* (May 19, 2020), https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf (last visited Feb 20, 2022).

Thirty countries and several international organizations supported the launch of the pool, but there was very little overlap between the coalition of HICs, foundations, and industry groups backing ACT-A and the primarily Global South countries backing C-TAP.⁵⁷ Under C-TAP, partners including Unitaid, the UN Technology Bank, Medicines Patent Pool, United Nations Development Programme (UNDP), and Joint United Nations Programme on HIV/AIDS (UNAIDS) would support technology transfer and voluntary licensing of COVID-19 vaccines, along with capacity-building efforts, so that companies primarily in Africa, Asia, and Latin America could make the vaccines.

Apart from the WHO, few of the ACT-A political backers and no G7 countries joined the C-TAP effort. By the end of 2021, no major company had agreed to license its technology through the voluntary C-TAP mechanism, and no country had tied its R&D funding to the sharing of technologies globally. There was also no move toward a global agreement on the sharing of COVID-19 vaccine doses or technologies between HICs and LMICs.

In October 2020, South Africa and India proposed a third element to the openness paradigm – waiving states' obligations under the WTO to recognize IP protections on COVID-19-related technologies.⁵⁸ This proposal would return national legal prerogative to governments to decide the level of IP protection for COVID-19 vaccines and technologies without facing sanction under WTO TRIPS rules.⁵⁹ This would allow governments to provide legal certainty to those considering investment in new and retrofitted factories to produce vaccines in LMICs, similar or identical to those approved globally, even without the full permission of originator companies.⁶⁰ It would also remove legal barriers to coordinated multi-country production and approaches, since TRIPS provisions for countries without manufacturing capacity are cumbersome and have only been used once – by Rwanda and Canada in a complex process that took years.⁶¹ Producers would still have to secure

⁵⁷ WHO, *International Community Rallies to Support Open Research and Science to Fight COVID-19* (May 29, 2020), www.who.int/news/item/29-05-2020-international-community-rallies-to-support-open-research-and-science-to-fight-covid-19 (last visited Feb. 20, 2022).

⁵⁸ India & South Africa, *Waiver from Certain Provisions of the Trips Agreement for the Prevention, Containment and Treatment of COVID-19* (Oct. 2, 2020), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True> (last visited Jul. 7, 2020).

⁵⁹ Mark Eccleston-Turner & Harry Upton, *International Collaboration to Ensure Equitable Access to Vaccines for COVID-19: The ACT-Accelerator and the COVAX Facility*, 99 *MILBANK QUARTERLY* 426 (2021).

⁶⁰ Biswajit Dhar & K. M. Gopakumar, *Towards More Affordable Medicine: A Proposal to Waive Certain Obligations from the Agreement on TRIPS*, ARTNeT Working Paper Series, No. 200, Asia-Pacific Research and Training Network on Trade (ARTNeT), Bangkok (2020); Siva Thambisetty et al., *The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to End the COVID-19 Pandemic*, No. 06/2021 LSE LEGAL STUDIES WORKING PAPER (2021).

⁶¹ Carlos M. Correa, *Expanding the Production of COVID-19 Vaccines to Reach Developing Countries. Lift the Barriers to Fight the Pandemic in the Global South* (Apr. 2021), www.southcentre.int/wp-content/uploads/2021/04/PB-92.pdf (last visited Feb 20, 2022).

the know-how – from existing producers, from others who know how these vaccines are produced, or from their own research – but they would not face IP lawsuits or prosecution, which would be important for spurring global production.

The proposal was, in many ways, a very limited one – it did nothing to change patent status in any country that did not wish to act, and it was only temporary. Nonetheless it came up against fierce opposition from industry, governments with significant originator pharmaceutical industries, and IP maximalists who said it would undermine innovation, among other claims.⁶² The proposal ultimately gained the support of over 100 countries, but the WTO's norm of operating by consensus allowed a handful of countries including the United States, several in Europe, and Japan to block full negotiations on the text of any waiver.

The Biden Administration reversed the US position shortly after taking office – announcing on May 5 that it would back a waiver and support moving to text-based negotiation.⁶³ This shifted the international politics of the question significantly, pushing other holdouts to agree to serious negotiations. However, this shift had little immediate effect, as the focus of opposition simply changed to within-negotiation stalling. The EU, for example, put out its own alternative proposal which many saw as a tactic to distract.⁶⁴ By the end of 2021 – a year after vaccine approvals – a waiver had still not been authorized by the TRIPS council.

Industry and some HIC governments claimed that manufacturing in LMICs, particularly for the most effective mRNA vaccines, was not feasible and could not be started soon enough to matter.⁶⁵ They claimed LMIC producers lacked capacity, financing, and technical acumen, and that originator producers like Pfizer, Moderna, and Johnson & Johnson were the only feasible solution to expand production.

Supply-focused proponents showed that each of these barriers could be overcome. Funding to expand manufacturing became available even before vaccines were approved – with \$4 billion announced by the World Bank in October 2020.⁶⁶ The

⁶² Thiru Balasubramaniam, *WTO TRIPS Council (October 2020): European Union Dismisses Concerns That IPRs Are a Barrier to Covid-19 Medicines and Technologies*, Knowledge Ecology International (2020), www.keionline.org/34275 (last visited Jul. 6, 2021).

⁶³ Katherine Tai, *Statement from Ambassador Katherine Tai on the COVID-19 Trips Waiver*, United States Trade Representative (May 5, 2021), <http://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver> (last visited Feb. 5, 2022).

⁶⁴ Health Action International, *European Commission is Offering No Meaningful Solutions for Equitable Access* (Jun. 29, 2021), <https://haiweb.org/european-commission-is-offering-no-meaningful-solutions-for-equitable-access/> (last visited Feb. 6, 2022).

⁶⁵ Sam Cedric, Stephanie Baker & Vernon Silver, *Pfizer Fights to Control Secret of \$56 Billion Covid Vaccine Recipe*, BLOOMBERG (Nov. 15, 2021), www.bloomberg.com/graphics/2021-pfizer-secret-to-whats-in-the-covid-vaccine/ (last visited Jul. 1, 2022).

⁶⁶ World Bank, *How the World Bank Group Is Helping Countries Address COVID-19 (Coronavirus)* (2020), www.worldbank.org/en/news/factsheet/2020/02/11/how-the-world-bank-group-is-helping-countries-with-covid-19-coronavirus (last visited Jun. 2, 2022).

African Union launched the Partnership for African Vaccine Manufacturing in April and secured a major commitment from the Africa Export–Import Bank and African Finance Corporation to fund expansion in multiple countries. Technical know-how was also procured. Thailand, for example, built a partnership between University of Pennsylvania researchers – who had done much of the original research behind the mRNA vaccines – and the Ministry of Health’s pharmaceutical production company to set up mRNA production, even designing their own.⁶⁷ Untapped production capacity was identified in a wide range of countries, including Bangladesh, South Africa, Senegal, Egypt, India, Brazil, and Thailand.⁶⁸

Perhaps the clearest example came when the South African government and the WHO announced an mRNA vaccine production hub that put all the pieces together – the South African company Biovac would act as manufacturer, Afrigen Biologics and Vaccines as developer, a consortium of universities would provide the mRNA know-how, and the Africa Centres for Disease Control and Prevention (Africa CDC) would provide technical support.⁶⁹ What was missing, however, was the “recipe” for an approved vaccine – which neither Moderna nor BioNTech/Pfizer was willing to share.

AstraZeneca made some partial moves, striking a deal with the Global South’s biggest producer of vaccines, the SII, to make hundreds of millions of doses on its behalf for sale to COVAX and directly to countries in the Global South. This deal, however, did not approach the kind of open sharing advocated by the supply/open paradigm’s proponents – using an exclusive licensing agreement for certain territories to simply expand the SII’s monopoly over production. As a result, in March 2021, when India was hit by a second wave, the government’s ban on exports shut down supplies for much of the world. COVAX at this point was largely dependent on SII – which was to produce a majority of its planned supplies for the first half of 2021 – and had no alternative in a context of constrained supplies and monopoly production.

A set of vaccines from China, Russia, and Cuba were shared with greater openness. The Russian Sputnik V vaccine, for example, was offered on an open license basis to manufacturers in many LMICs.⁷⁰ However, in the context of vaccine diplomacy, supplies were negotiated country by country and their quality and

⁶⁷ Josh Sullivan, *Homegrown mRNA Thai Vaccine for Covid-19 Could Be Ready by Year End – Report*, ENDPOINT NEWS (May 9, 2022), <https://endpts.com/homegrown-mrna-thai-vaccine-for-covid-19-could-be-ready-by-year-end-report/> (last visited Jun. 2, 2022).

⁶⁸ Matthew Kavanagh et al., *To Democratize Vaccine Access, Democratize Production*, FOREIGN POLICY (Mar. 1, 2021), <https://foreignpolicy.com/2021/03/01/to-democratize-vaccine-access-democratize-production/> (last visited Feb. 5, 2022).

⁶⁹ Madlen Davies, *COVID-19: WHO Efforts to Bring Vaccine Manufacturing to Africa Are Undermined by the Drug Industry, Documents Show*, 376 BMJ 0304 (2022).

⁷⁰ Svět Lustig Vijay, *Russia Pushes Ahead with Open License Approach to Sputnik V – Despite WHO Concerns over Manufacturing Practices*, Health Policy Watch (Feb. 7, 2021), <https://healthpolicy-watch.news/russia-pushes-ahead-with-open-license-approach-to-sputnik-v-despite-who-concerns-over-manufacturing-practices/> (last visited Feb. 28, 2023).

efficacy was questioned compared to the more sought-after mRNA vaccines.⁷¹ Technology transfers and vaccine sharing of Russia's Sputnik V and its further iterations were already taking place before it had undergone all clinical trials, and by the end of 2021 there was still skepticism among international scholars about the validity of the results provided.⁷² Nevertheless, producers in India, Serbia, Argentina, and Iran set up production lines.⁷³ And yet a continuing lack of data, broken promises, corruption, and the start of the Ukraine conflict complicated Russia's efforts.⁷⁴ Meanwhile, China became one of the major COVID-19 vaccine providers to LMICs in 2021 through donations and mostly bilateral commercial mechanisms, initially focusing on its neighboring countries and those in Africa. Even amidst concerns about how China would vaccinate its own large population and still be able to provide doses abroad, by August 2022 it had delivered at least 140 million doses as donations to 100 countries.⁷⁵

HIC governments have the legal authority to compel sharing of vaccine know-how.⁷⁶ In the United States, for example, the Defense Production Act gives the government wide authority to compel actions from companies during crises. Title 1 gives the government explicit power to allocate "technical information" needed to secure "national public health" – which clearly covers know-how to produce vaccines.⁷⁷ The government could, for example, compel sharing of vaccine-production know-how through the Biomedical Advanced Research and Development Authority (BARDA), which could then train producers around the world to make vaccines. BARDA, established in 2006, is part of the US Department of Health and Human Services and provides a system to address public health emergencies with medical countermeasures including the development of necessary

⁷¹ Samantha Kiernan et al., *Vaccine Spheres of Influence Tracker*, Think Global Health (2020), www.thinkglobalhealth.org/article/vaccine-spheres-influence-tracker (last visited May 16, 2021).

⁷² Enrico Bucci et al, *Safety and Efficacy of the Russian COVID-19 Vaccine: More Information Needed*, 396(10256) THE LANCET E53 (2020)

⁷³ Vijay, *supra* note 70.

⁷⁴ Serena Tinari, *COVID-19: Ukraine Conflict Calls Russia's Vaccine Diplomacy into Question*, 376 BMJ 0626 (2022); Grace Kier & Paul Stronski, *Russia's Vaccine Diplomacy Is Mostly Smoke and Mirrors*, Carnegie Endowment for International Peace (Aug. 3, 2021), <https://carnegieendowment.org/2021/08/03/russia-s-vaccine-diplomacy-is-mostly-smoke-and-mirrors-pub-85074> (last visited Feb. 24, 2023).

⁷⁵ Veronika Blablová, *Assessing China's Vaccine Diplomacy*, China Observers in Central and Eastern Europe (CHOICE) (Sep. 29, 2022), <https://chinaobservers.eu/assessing-chinas-vaccine-diplomacy/> (last visited Feb. 27, 2023); Wang Xiaoyi, *China, not COVAX, Led Vaccine Exports to the World's Middle Income Countries in 2021*, Health Policy Watch (Oct. 2, 2022), <https://healthpolicy-watch.news/china-covax-led-vaccine-exports-lmic-2021/> (last visited Feb. 27, 2023).

⁷⁶ Kavanagh, Gostin & Sunder, *supra* note 54.

⁷⁷ Zain Rizvi, Jishian Ravinthiran & Amy Kapczynski, *Sharing the Knowledge: How President Joe Biden Can Use the Defense Production Act to End the Pandemic Worldwide*, Health Affairs Forefront (2021), www.healthaffairs.org/doi/10.1377/forefront.20210804.101816/ (last visited Feb. 28, 2023); Amy Kapczynski, *The Political Economy of Market Power in Pharmaceuticals*, 48(2) J. OF HEALTH POLITICS, POLICY AND LAW 215 (2022).

vaccines. With governments having invested heavily in the development of these vaccines, statutes such as the US Bayh–Dole Act also provide authority to compel sharing of government-funded know-how for the public good. The NIH even holds a patent on key mRNA technologies and could demand broader access in exchange for licensing the patented technology.⁷⁸

While HICs had the legal authority to act, they chose not to – likely because of the power of the pharmaceutical industry and the high political level at which a decision to use a mechanism such as the Defense Production Act would have to be taken.⁷⁹ This suggests that further reforms, clarifications, and legal avenues for compelling the sharing of government funding during a crisis would be helpful. For example, proposals to embed clear clauses in government funding contracts for research on pandemic-related technologies like vaccines that explicitly authorize government use or compel the sharing of intellectual property and technology transfer with lower-income countries would make this legal authority clear and perhaps more easily used.⁸⁰

By the end of 2021, however, despite multiple opportunities and backing from NGOs, LMIC governments, and international public health authorities, the supply-focused/openness paradigm had failed to garner sufficient political support to advance significantly. No agreement was ever struck at the WHO on sharing technologies, and while a significantly altered version of the WTO proposal was eventually passed in June 2022, its late timing and provisions significantly narrowed which member states could use it and called into question whether it could still have an impact.⁸¹ Ultimately, a strong norm of maintaining IP rights and monopoly power and the prioritization of domestic concerns won out over a worldwide public health emergency.

3 POLITICS AND POWER: EXPLAINING THE FAILURE OF THE DOMINANT PARADIGM

Both policy approaches could theoretically deliver vaccine equity. Real-world success, however, depended on the global and domestic political contexts in 2020 and 2021. In international politics, states make a wide variety of international commitments – whether, and under what conditions, they are likely to keep them has been

⁷⁸ Donato Paolo Mancini & Kiran Stacey, *Vaccine Patent Gives Us “Leverage” over Manufacturers*, FINANCIAL TIMES (Apr. 21, 2021), www.ft.com/content/doc70cc2-offa-42dd-bodo-of76eeb273fo (last visited Feb. 20, 2022).

⁷⁹ Kapczynski, *supra* note 77.

⁸⁰ Peter Lee, *Patents and the Pandemic: Intellectual Property, Social Contracts, and Access to Vaccines: 2021 Shidler Lecture*, 17 WASH. J.L. TECH. & ARTS 193 (2022); Suerie Moon et al., *Embedding Global Access in Development of Future Pandemic Vaccines*, 374 BMJ n2256 (2021).

⁸¹ WTO, *Ministerial Decision on the Agreement on Trade-Related Aspects of Intellectual Property Rights*, 30 WT/L/1141 WT/MIN(22) (2022).

widely studied.⁸² Even in the absence of formal treaties, international norms play a key role in motivating state behavior, including the area of health, but compliance is based in part on the strength and socialization of a given international norm.⁸³ Compliance with international commitments also depends greatly on domestic politics and the political attributes of “competing interests.”⁸⁴

In this case, failure of the demand-focused/voluntary paradigm to secure equity was foreseeable and foreseen. Achieving equity under this paradigm, which preserved production monopolies and placed allocation in the hands of vaccine manufacturers, required that pooled procurement mechanisms such as COVAX would be able to get equal access to vaccine doses, that companies would fill orders based on a framework of equity, and that powerful states would refrain from monopolizing doses so that vulnerable groups in all countries could be vaccinated before turning to young, healthy people.

Yet the norms supporting equitable shared access between countries to a limited pool of vaccine doses were remarkably weak. Meanwhile, dominant political forces were lined up in the most powerful states to drive vaccine nationalism. Indeed, leaders’ own statements and actions revealed, early on, that their “two level game”⁸⁵ involved ambiguous commitments to equity alongside simultaneous actions to secure enough doses to cover their entire populations as quickly as possible (often several times over). It also comes as no surprise that countries will look inward and focus on their own security when faced with an external threat, regardless of whether it is a public health emergency. Thus, a global health approach dependent on avoiding vaccine nationalism was, from the start, set against political forces it was unlikely to overcome.

Indeed, HIC governments responded by putting coverage of their entire adult populations as their top priority, and they secured preferential access to the vast majority of supplies available through HIC-based producers, leaving little supply for the rest of the world. Even as inequity prolonged the pandemic and gave rise to variants that disrupted life worldwide, throughout the first year of the global distribution of COVID-19 vaccines, access for LMICs was primarily dictated not by globally coordinated efforts but by the relative scarcity of doses and the location of the manufacturers.

In prioritizing sharing of vaccine know-how so that production could take place in Africa, Asia, and Latin America, the supply/openness paradigm explicitly recognized

⁸² Beth A. Simmons, *Compliance with International Agreements*, 1 ANNUAL REVIEW OF POLITICAL SCIENCE 75 (1998).

⁸³ Martha Finnemore & Kathryn Sikkink, *International Norm Dynamics and Political Change*, 52 INTERNATIONAL ORGANIZATION 887 (1998); SARA E. DAVIES, ADAM KAMRADT-SCOTT & SIMON RUSHTON, *DISEASE DIPLOMACY: INTERNATIONAL NORMS AND GLOBAL HEALTH SECURITY* (2015).

⁸⁴ XINYUAN DAI, *INTERNATIONAL INSTITUTIONS AND NATIONAL POLICIES* 40 (2007).

⁸⁵ Putnam, *supra* note 5.

and sought to accommodate the effects of vaccine nationalism and weak international norms by shifting the actors involved.⁸⁶ Even if this was theoretically not the fastest route to deliver doses, expanding the number and geographic location of producers would have shifted the incentives – allowing HIC-based companies to serve “their” markets first while Asian, Latin American, and African producers served theirs. This aligned with political forces of the time, but remained low on the global health agenda, allowing inequity to thrive.

A Weak Norm Building and Soft International Commitment

The primary mechanism to secure state compliance under the demand-focused/voluntary paradigm was the building of international norms of shared allocation by HICs, appeals to enlightened self-interest, and a project designed to “de-risk” investment. In this sense, global health actors worked as norm entrepreneurs – a familiar role for global health institutions⁸⁷ – trying to disseminate and encourage internalization of the idea that equitable sharing of limited supplies was in the enlightened self-interest of all countries.

A series of global public events, largely virtual due to the pandemic, were created to give governments and global health leaders a platform for norm-building. The launch of ACT-A and COVAX in April 2020 was co-hosted by the French and EU Presidents, Bill Gates, and WHO Director-General Tedros Adhanom Ghebreyesus. President von der Leyen promised the EU’s commitment to develop a vaccine, “produce it and to deploy it to every single corner of the world.”⁸⁸ This was followed in September 2020 by a high-level event that featured heads of state claiming “to build stronger political consensus for a coordinated global response to COVID-19, and champion the importance and urgency of equitable access to new tools, especially effective vaccines.”⁸⁹ Speakers included heads of state from Germany, the United Kingdom, Canada, Norway, South Africa, and Sweden as well as executives from Johnson & Johnson, AstraZeneca, and various UN agencies and nongovernmental organizations (NGOs).

Pledging sessions and political events aimed to raise funding for COVAX, secure donated doses from HICs, and build norms that appealed to the enlightened self-interest of HICs. In one official’s words, “no nation can act alone in a global pandemic. Vaccinating as many people as possible, as quickly as possible, is the

⁸⁶ Kavanagh et al., *supra* note 68.

⁸⁷ Obijiofor Aginam, *Mission (Im)Possible? WHO as a “Norm Entrepreneur” in Global Governance*, in *LAW AND GLOBAL HEALTH: CURRENT LEGAL ISSUES*, OXFORD ACADEMIC (Michael Freeman, Sarah Hawkes & Belinda Bennett eds, 2014).

⁸⁸ Ursula Von der Leyen, *President Von der Leyen at the WHO Press Conference*, European Commission (Apr. 24, 2020), https://ec.europa.eu/commission/presscorner/detail/en/statement_20_741 (last visited Jul. 1, 2022).

⁸⁹ United Nations, *ACT Together to End COVID-19* (2020), www.un.org/en/coronavirus/act-accelerator (last visited Feb. 8, 2021).

only way to reduce the tragic loss of life, end the pandemic, and move us toward economic and social recovery.”⁹⁰ Special envoys were appointed to lead this norm-building work – Ngozi Okonjo-Iweala, former Nigerian Finance Minister (before her election to lead the WTO); Andrew Witty, former CEO of GlaxoSmithKline; and later Carl Bildt, former Prime Minister of Sweden. These efforts, however, built only very weak normative infrastructure, with commitments to funding but little that would constrain powerful states from acting in their own self-interest.

Meanwhile, the international context of rising populism and nationalism was hardly conducive to norm-building. Governments from the world’s two largest economies, the United States and China, did not meaningfully participate in ACT-A. The Trump Administration’s “America First” foreign policy was driving withdrawal from the WHO and disengagement from international efforts, while the United States’ and Europe’s increasingly aggressive stance toward China on COVID-19 undermined trust. Even in Europe, much of the political energy was taken up negotiating Brexit, pushing vaccine equity low on the agenda.

There was no use of formal mechanisms, legal or political, to achieve compliance with actions to promote equity. International instruments for ensuring state compliance range from “hard” binding international law with precise commitments, obligations to act, sanctions for noncompliance, and a third party delegated to implement (for example, WTO rules), to “soft” commitments between states that lack these characteristics.⁹¹ In this case, commitments were even softer than past political declarations on global health from the UN General Assembly. The United Kingdom, for example, promoted an “unprecedented global agreement” called the COV-Access Agreement “to give everyone equal access to new coronavirus vaccines and treatments around the world.”⁹² However, the document bore none of the hallmarks of a significant international agreement. It was signed by twenty countries, almost all HICs, and included only vague promises, such as “commit to the shared aim of equitable global access to innovative tools for COVID-19 for all.” It did not give any international institution (such as the WHO) power to control global allocation, and it established no firm commitments or definition of equity. For example, it did not commit HICs to prioritize the vaccination of vulnerable people in LMICs before young, healthy people in their own countries or even to share excess vaccine doses.

⁹⁰ Gavi, *Global Leaders Rally to Accelerate Access to COVID-19 Vaccines for Lower-Income Countries* (2021), www.gavi.org/news/media-room/global-leaders-rally-accelerate-access-covid-19-vaccines-lower-income-countries (last visited Feb. 5, 2022).

⁹¹ SHARIFAH SEKALALA, *SOFT LAW AND GLOBAL HEALTH PROBLEMS: LESSONS FROM RESPONSES TO HIV/AIDS, MALARIA AND TUBERCULOSIS* (2017); Kenneth W. Abbott & Duncan Snidal, *Hard and Soft Law in International Governance*, 54 *INTERNATIONAL ORGANIZATION* 421 (2000).

⁹² UK Government, *UK Leads Way as Nations Endorse Landmark Pledge to Make Coronavirus Vaccines and Treatments Available to All* (2020), www.gov.uk/government/news/uk-leads-way-as-nations-endorse-landmark-pledge-to-make-coronavirus-vaccines-and-treatments-available-to-all (last visited Feb. 5, 2022).

With little firm commitment and no significant stick to ensure compliance, the carrot offered under this paradigm to induce participation also proved quite weak. COVAX sought to incentivize HICs to participate in the pool, which would enable it to allocate ethically among all countries. COVAX was framed as “a critical insurance policy that will significantly increase their chances of securing vaccines, even if their own bilateral deals fail.”⁹³ The risk of making advanced financial commitments to vaccines with unknown efficacy would be spread across countries. COVAX would guarantee the ability to cover up to 50 percent of the population, though without a specific timeline.⁹⁴ But most powerful countries did not actually see these issues as a major risk or excessive investment. They made deals for all or most viable candidates and, with a desire to cover 100 percent of their populations, had every incentive to defect even if they participated in COVAX.

B Domestic Political Incentives Make Demand-Side Paradigm Untenable

Political leaders in most countries have relatively short time horizons, particularly those facing an election in the near term.⁹⁵ In a context of weak international norms and political agendas dominated by COVID-19, leaders prioritized the threat of their own citizens having to wait for their vaccines over the injustice of highly unequal vaccine distribution or even over the threat of a long-lasting pandemic continuing to cause disruption. Even as global health plans focused on vaccinating vulnerable people and health workers worldwide first and HIC leaders were promising to share, they were signaling a very different intention domestically.⁹⁶ None made real plans to slow vaccine access for their populations in order to make supplies accessible to those most in need in LMICs. Efforts were on full display to use political, economic, and strategic power to secure doses for their entire populations as rapidly as possible to the exclusion of others. This was clear long before the first vaccines were available.⁹⁷ Key leaders in LICs voiced their concern that this meant voluntary mechanisms would not work, yet gained little traction.

In the United Kingdom, for example, Prime Minister Boris Johnson came under significant pressure domestically to address the failed British response and remove unpopular lockdown orders such as the much-criticized 10pm pub curfew. Promising everyone in the United Kingdom would get rapid COVID-19 vaccine

⁹³ Gavi, *supra* note 22.

⁹⁴ COVAX, *COVAX Facility Explainer: Participation Arrangements for Self-Financing Economies* (2020), www.gavi.org/sites/default/files/covid/covax/COVAX_Facility_Explainer.pdf (last visited Aug. 21, 2021).

⁹⁵ Kim Yi Dionne, *The Role of Executive Time Horizons in State Response to AIDS in Africa*, 44(1) *COMPARATIVE POLITICAL STUDIES* 55 (2010).

⁹⁶ Eccleston-Turner & Upton, *supra* note 59.

⁹⁷ Kai Kupferschmidt, “Vaccine Nationalism” Threatens Global Plan to Distribute COVID-19 Shots Fairly, *SCIENCE* (Jul. 28, 2020), www.science.org/content/article/vaccine-nationalism-threatens-global-plan-distribute-covid-19-shots-fairly (last visited Feb. 5, 2022).

access became a clear political priority for a threatened government. Trying to stave off a revolt within the Tory party, a government source was quoted promising: “There is a possibility that one day soon we will wake up and Brexit will be done and we’ll have the Oxford vaccine.”⁹⁸ In May 2020, the United Kingdom signed an £84 million deal with AstraZeneca, giving it priority access to 100 million doses. Business Secretary Alok Sharma said, “[t]his deal with AstraZeneca means that if the Oxford University vaccine works, people in the UK will get the first access to it.”⁹⁹ By August, the government has secured preferential access to 340 million doses from Pfizer, Johnson & Johnson, and Novavax – enough for five doses per person in the United Kingdom.¹⁰⁰

In the United States, the Trump Administration failed to respond effectively to the start of the pandemic and was already facing a political crisis in a presidential election year. This dramatically increased the stakes for providing a safe and effective vaccine as soon as possible – and ideally before the November election, as Trump himself said. Indeed, a major point of contention in the campaign became whether Trump was putting undue pressure on regulators to approve a vaccine in time to help him politically.¹⁰¹ Operation Warp Speed (OWS), a public–private partnership initiated in May 2020, aimed to have “substantial quantities of a safe and effective vaccine available for all Americans by January 2021.”¹⁰² By October 2020, OWS had spent at least \$12 billion on COVID-19 vaccine contracts to ensure priority access for the United States.¹⁰³ Facing pressure from Congress at the time, Dr. Anthony Fauci predicted that enough doses could be secured for all Americans by April 2021.¹⁰⁴

⁹⁸ David Wilcock & Anna Mikhailova, “Show Us It’s Worth It”: Boris Johnson Faces New Coronavirus Rebellion from 70 Anti-tier Tory MPs, DAILY MAIL ONLINE (Nov. 22, 2020), www.dailymail.co.uk/news/article-8974691/Show-worth-Boris-Johnson-faces-new-coronavirus-rebellion-70-anti-tier-Tory-MPs.html (last visited Feb. 5, 2022).

⁹⁹ UK Government, *Funding and Manufacturing Boost for UK Vaccine Programme* (May 17, 2020), www.gov.uk/government/news/funding-and-manufacturing-boost-for-uk-vaccine-programme (last visited Feb. 5, 2022).

¹⁰⁰ Lina Saigol, *U.K. Strikes Two COVID-19 Vaccine Deals for 90 Million Doses*, MarketWatch (Aug. 14, 2020), www.marketwatch.com/story/uk-strikes-two-new-deals-for-90-million-covid-19-vaccine-doses-2020-08-14 (last visited Feb. 5, 2022).

¹⁰¹ Philip Rucker, Josh Dawsey & Yasmeen Abutaleb, *Trump Fixates on the Promise of a Vaccine – Real or Not – as Key to Reelection Bid*, WASHINGTON POST (Sep. 5, 2020), www.washingtonpost.com/politics/trump-vaccine-election/2020/09/05/coda86d6-edf5-11ea-99a1-7134d03bc29_story.html (last visited Feb. 5, 2022).

¹⁰² U.S. Department of Defense Press Office, *Trump Administration Announces Framework and Leadership for “Operation Warp Speed”* (2020), www.defense.gov/News/Releases/Release/Article/2310750/trump-administration-announces-framework-and-leadership-for-operation-warp-speed/ (last visited Feb. 5, 2022).

¹⁰³ Stephanie Baker & Cynthia Koons, *Inside Operation Warp Speed’s \$18 Billion Sprint for a Vaccine*, BLOOMBERG (Oct. 29, 2020), www.bloomberg.com/news/features/2020-10-29/inside-operation-warp-speed-s-18-billion-sprint-for-a-vaccine (last visited Feb. 5, 2022).

¹⁰⁴ *Most Americans to Be Vaccinated for COVID-19 by July, CDC Chief Expects*, REUTERS (Sep. 23, 2020), www.reuters.com/article/us-health-coronavirus-usa-hearing-idINKCN26E2NJ (last visited Feb. 5, 2022).

Senator Tom Tillis also introduced the America First Vaccine Act, which would have required that any vaccine developed with US funding go first to Americans “before it goes to other countries.”¹⁰⁵ Trump agreed, saying, “Day 1 that it’s approved, it’ll be available to the American people immediately,”¹⁰⁶ and issuing an executive order stating that sharing could only happen after all Americans had access. Even after the Biden Administration took charge, powerful domestic political actors pushed for a faster roll-out to all Americans. Congressional committees investigated what more companies and the government could do to procure more supplies “as quickly as possible so we can get them into the arms of more Americans.”¹⁰⁷

In the European Union, President von der Leyen faced pressure from member states frustrated that there was no unified plan to purchase enough COVID-19 vaccines to rapidly vaccinate all of Europe. A letter from six member states warned, “[t]he present situation has raised questions about Europe’s preparedness for pandemics.”¹⁰⁸ This came after a “traumatic event” in which the Trump Administration was rumored to have tried to buy up preferential access to the German company CureVac’s vaccine – resulting in an emergency meeting and announcement of an €80 million plan to help CureVac test and manufacture its vaccine in the EU.¹⁰⁹ France, Germany, Italy, and the Netherlands joined together to create the “Inclusive Vaccine Alliance,” which aimed to ensure vaccines would be produced “on European soil” to secure preferential access for European populations – threatening EU cohesion. Von der Leyen, a leading voice for COVAX, responded to this pressure by working to secure any available vaccines, not for COVAX, but for the EU – texting and calling company CEOs herself to secure doses.¹¹⁰ The eventual European plan that emerged focused on getting 70 percent of Europeans vaccinated as rapidly as possible, with no provision to delay roll-out to young, healthy people in favor of the most vulnerable in LMICs.¹¹¹

¹⁰⁵ Office of Thom Tillis, *Tillis Introduces the America First Vaccine Act* (Sep. 2020), www.tillis.senate.gov/2020/9/tillis-introduces-the-america-first-vaccine-act (last visited Feb. 5, 2022).

¹⁰⁶ Vernon Silver, *COVID Vaccine: Nationalism Will Only Make the Coronavirus Pandemic Much Worse*, BLOOMBERG (2020), www.bloomberg.com/features/2020-covid-vaccine-nationalism/ (last visited Feb. 5, 2022).

¹⁰⁷ Office of Diana DeGette, *All Five COVID-19 Vaccine Manufacturers to Testify before Key Congressional Panel*, Congresswoman Diana DeGette (2021), <https://degette.house.gov/media-center/press-releases/all-five-covid-19-vaccine-manufacturers-to-testify-before-key> (last visited Feb. 5, 2022).

¹⁰⁸ Rym Momtaz, *National Capitals Question EU’s Pandemic Preparedness*, POLITICO (Jun. 10, 2020), www.politico.eu/article/eu-national-capitals-question-coronavirus-pandemic-preparedness/ (last visited Feb. 7, 2022).

¹⁰⁹ Jillian Deutsch & Sarah Wheaton, *How Europe Fell Behind on Vaccines*, POLITICO (Jan. 27, 2021), www.politico.eu/article/europe-coronavirus-vaccine-struggle-pfizer-biotech-astrazeneca/ (last visited Feb. 5, 2022).

¹¹⁰ Stevis-Gridneff, *supra* note 42.

¹¹¹ European Commission, *EU Vaccines Strategy* (2022), https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en (last visited Feb. 5, 2022).

In addition, facing an upcoming election, Israel's then-Prime Minister Netanyahu also made securing COVID-19 vaccines for the entire population a center of his campaign – even negotiating directly with Pfizer's CEO and paying top dollar to receive enough mRNA vaccines to vaccinate the entire population in a matter of months.¹¹² Further, Canada's Minister of Public Services and Procurement, announcing a major vaccine deal in August 2020, said, “[g]iven intense global competition, we are taking an aggressive approach to secure access to the most promising candidates so that we will be ready to vaccinate all Canadians as quickly as possible.”¹¹³

In this context, political analysis shows that an approach based on pooled procurement and voluntary action by HIC governments and pharmaceutical companies was always unlikely to secure vaccine equity.

4 CONCLUSION

The global law and policy approach to securing shared, equitable access to COVID-19 vaccines failed. It did so despite remarkable science and despite commitments that came from powerful states well before a vaccine was even available. And it failed despite a great deal of work by impressive institutions to develop an innovative and complex approach to coordinated demand.

Fundamentally, the law and policy paradigm that came to dominate the response – based on a consensus of mostly HIC actors – was misaligned with the political realities of 2020–2021. Vaccine nationalism was predictable in a global context of rising populism and a serious public health emergency. The world's biggest economies were led by the Trump and Xi administrations, and even those states promising cooperation and shared access signaled their intention to prioritize vaccines for their own populations. Further, key actors decided not to pursue significant legal agreement among states to bind governments or companies to provide vaccines for priority populations in LMICs before shipping enough to HICs to vaccinate, and even boost, their entire populations. Domestic political pressures trumped weak international norms in ways predicted by international relations literature.¹¹⁴ Alternative proposals might have made a difference – providing an option that did not require countries to abandon their immediate self-interest in securing doses for their whole populations. Focusing on sharing vaccine

¹¹² TOI Staff, *supra* note 42.

¹¹³ Government of Canada, *Government of Canada Announces Major Steps in Treating and Preventing COVID-19 through Vaccines and Therapies* (Aug. 5, 2020), www.canada.ca/en/innovation-science-economic-development/news/2020/08/government-of-canada-announces-major-steps-in-treating-and-preventing-covid-19-through-vaccines-and-therapies.html (last visited Feb. 5, 2022).

¹¹⁴ Sara E. Davies & Clare Wenham, *Why the COVID-19 Response Needs International Relations*, 96 INTERNATIONAL AFFAIRS 1227 (2020).

knowledge and technology through waiving intellectual property and compelling technology transfer might have allowed rapid expansion of production to Africa, Asia, and Latin America to expand supply. It would have required overcoming opposition from the pharmaceutical industry, but that at least represents a far narrower interest to counter than nationalism and populism, and one with some precedent. The structure of global health policymaking, however, kept this off the table.

COVID-19 will not be the last pandemic. Looking ahead, far more attention is needed to deploying law in ways designed to succeed in the real-world political context. Commitments to share knowledge and technologies are not easy to secure – but they are far more likely to succeed in moments of crisis than the sharing of limited supplies. Rethinking the policy paradigm for access to medical technologies in a pandemic as well as reorganizing power in global health will both be needed to prevent pandemic inequalities of the future.