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Is There a Cure for Vaccine Nationalism?

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The expression "vaccine nationalism" made headlines throughout 2020, from the *Wall Street Journal* to National Public Radio. It became a regular feature of public and scholarly debates during the COVID-19 pandemic, coloring discussions about the broader topics of public–private scientific collaboration and the role of international organizations in public health.

In the context of a vaccine race, nationalism appears in the act of reserving millions of doses of new vaccines for domestic use during a transnational public health crisis. For over a decade, vaccine nationalism has been associated with the use of contractual agreements, usually between a national government and one or more pharmaceutical companies engaged in late-stage development and production of leading vaccine candidates. Because these agreements are typically struck well before vaccines are fully licensed, they are known as advance market commitments or preproduction agreements.

An important feature of advance commitments is that they can be deployed as incentives to encourage investments in traditionally underfunded areas in global public health. By signaling relatively robust levels of demand for a drug or vaccine, albeit conditioned on regulatory authorization or approval, these agreements help attract private-sector manufacturers that might otherwise choose to invest their time and resources in more profitable areas of scientific research and development (R&D).

Since most emerging infectious diseases historically have circulated in the global South, most vaccines and drugs to counter them have long been associated with underfunded or neglected disease-control efforts, which the World Health Organization (WHO) has characterized as lacking in "R&D preparedness." Despite these market-driven dynamics, organizations like GAVI, a Geneva-based vaccine procurement alliance, have successfully resorted to advance commitments in the past to drum up private- and public-sector interest in the development of vaccines for low-income populations.

In 2009, for instance, GAVI's advance commitment to buy pneumococcal vaccines was instrumental in bringing them to children in 60 countries across the global South. Without such a commitment, it is estimated that these vaccines would not have been made available in low-income countries until 10 to 15 years after being introduced in high-income countries.

Although advance commitments may be desirable as a financing and risk-management mechanism, heavy reliance on them can become problematic during large-scale public health crises—all the more so if powerful players exert a disproportionate influence on the transnational allocation of health goods, especially those that have to be developed from scratch, as is the case with vaccines targeting a new pathogen. COVID-19 was officially declared a pandemic in March 2020. By midsummer, high-income countries accounting for just 13 percent of the global population had placed orders for more than half of the projected available doses in the first batches of COVID-19 vaccines.

Aside from the lopsided demographic and geographic distribution of emerging vaccines, this prioritized channeling of vaccine doses to the global North is hard to square with public health frameworks and epidemiological data that show COVID-19 spreading widely across the global South, imposing associated burdens on individuals, communities, and health systems.

By late August 2020, high-income countries had placed orders for over 2 billion vaccine doses,

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a number that almost certainly exceeds the initial manufacturing capacity at the global level for the first batches of a fully licensed COVID-19 vaccine or vaccines. The United Kingdom was the largest per capita buyer of COVID-19 vaccines in the world, pre-ordering 340 million doses, or five doses per citizen. The United States had pre-ordered 800 million doses, with an option to purchase an additional 1 billion.

Most low-income countries had not entered into direct agreements with pharmaceutical companies, with the exception of some of the largest economies in the global South, such as Brazil. This divergence is why vaccine nationalism has been criticized by public health–oriented institutions like the WHO as well as commentators concerned about equitable distribution of vaccines and other emerging health goods needed in the response to the pandemic.

THE SWINE FLU RACE

Contractual mechanisms that skew the allocation of emerging vaccines are not a new phenomenon. COVID-19 merely amplified geoeconomic strategies that were already at play during a previous global pandemic triggered by an outbreak of a novel H1N1 influenza virus in 2009—often referred to as the swine flu pandemic.

There is no binding mechanism that would shift the dominant negotiating paradigm.

The virus was first detected in April 2009 in the United States, though later studies suggested it might have originated in Mexico. By June it had spread across the United States, reaching all 50 states, the District of Columbia, Puerto Rico, and the US Virgin Islands, as well as over other 60 countries. This was the first global flu pandemic since 1968 (the H3N2 pandemic), and the second since the 1918 Spanish flu pandemic, which remains the deadliest on record.

Given the quick spread of the disease and the toll it took on populations under the age of 65, scientists and public health authorities initially feared that the H1N1 pandemic would place an enormous burden on public health systems. Early in the outbreak, it was recognized that existing seasonal flu vaccines did not offer protection against the novel pathogen. Developing new vaccines was widely perceived as a critical response. R&D proceeded in a compressed schedule amid uncertainty about the length and likely effects of the outbreak—circumstances similar to those in the early stages of the COVID-19 vaccine race.

Even before the WHO declared H1N1 a pandemic on June 11, 2009—and before the decision to initiate large-scale production of vaccines targeting the novel pathogen—several high-income countries pre-ordered doses from pharmaceutical companies known for producing flu vaccines, including Sanofi Pasteur, GlaxoSmithKline, and Novartis. By early May 2009, it was reported that the United States had already placed advance orders that would enable it to buy over 600 million doses of vaccine, based on calculations that it would be necessary to administer two doses per person. Several European countries had also entered into contractual agreements to reserve vaccine doses, though order volumes were not disclosed.

At the time, the projected global capacity to manufacture a vaccine during a pandemic was around two billion doses at best; some commentators suggested that a more realistic projection would be closer to one billion doses. Within this range, advance commitments involving the United States alone would have exhausted 30 to 60 percent of the worldwide vaccine supply, depending on actual manufacturing capacity.

A small number of countries, mostly in the global North, had availed themselves of a commonly used legal instrument, a bilateral contract, to secure the earliest possible access to emerging vaccines, leaving low-income countries in the likely position of having very limited, if any, access to the first batches. However, manufacturing capacity and global South–North distribution dynamics were never really put to the test. The H1N1 pandemic began to wane sooner than originally expected, and the most extreme, catastrophic scenarios never came to pass. And clinical trials showed that a single dose of vaccine was likely protective, reducing the demand from each country.

By the time the US Food and Drug Administration approved four vaccines on September 15, 2009, vaccination strategies were much less urgent in high-income countries than they had been just a few months earlier. The European Medicines Agency issued a recommendation favoring approval a few weeks later. On September 18, several countries that had pre-ordered vaccines—

mostly high-income ones—pledged to donate doses to low-income countries.

These donations were portrayed as a much-needed goodwill gesture in a context of relative vaccine scarcity. The WHO issued a written statement "applauding" the pledge as a "commitment to fairness" on the part of participating countries—the United States, the United Kingdom, Italy, France, Norway, Switzerland, Australia, New Zealand, and Brazil. Yet the arc of the 2009 flu pandemic left unanswered the most fundamental questions about North–South relationships in situations in which there is sustained global demand for scarce health goods.

These questions have resurfaced during the coronavirus pandemic. Unlike the 2009 H1N1 vaccine pursuit, COVID-19 has set off a crowded race. Over 200 vaccine R&D projects were still formally ongoing at the time of this writing, though the number of frontrunners is currently in the single digits and the market is unlikely to accommodate many more manufacturers.

The impact of COVID-19 has also been far more extensive than that of the 2009 pandemic. The Centers for Disease Control and Prevention have calculated that there were 60.8 million cases of H1N1 in the United States between April 2009 and April 2010, resulting in an estimated 274,304 hospitalizations and 12,469 deaths. In contrast, with the COVID-19 pandemic still unfolding, by late September 2020 the United States had already recorded over 200,000 deaths among some 7 million cases.

Despite these and other material differences between the two pandemics, the COVID-19 vaccine race has been partly shaped by forces that replicate and magnify the transnational dynamics that were already seen in 2009. A group of wealthier players is able to guarantee de facto priority access to an emerging health good through the use of a lawful and commonly used contractual mechanism. By skewing the global distribution of vaccines, these players contribute to widening the divide between high-income and low-income countries, further complicating transnational responses to a globalized public health crisis.

THE COVAX CHALLENGE

While the COVID-19 pandemic has accentuated these long-standing inequities in global public health, it has also shed some light on potential short- and long-term fixes for imbalances in vaccine distribution. In an attempt to bridge the existing gulf between populations in high- and low-income countries, multi-institutional responses to the COVID-19 pandemic have adopted the advance commitment model as a way to temporarily coordinate the global allocation of emerging vaccines. This effort has been carried out by means of a newly created mechanism, the COVID-19 Vaccine Global Access Facility (COVAX).

COVAX is part of a set of initiatives undertaken by several international public health organizations with the goal of speeding up both the development and the equitable distribution of health goods necessary to hasten the end of the pandemic. These initiatives came together under the umbrella of the Access to COVID-19 Tools (ACT) Accelerator, a collaborative platform sponsored by the WHO, the World Bank, the Global Fund to Fight AIDS, Tuberculosis, and Malaria, the Gates Foundation, the Wellcome Trust, GAVI, the Coalition for Epidemic Preparedness Innovation (CEPI), the Foundation for Innovative New Diagnostics, and Unitaid.

The ACT Accelerator is based on four pillars: diagnostics, therapeutics, vaccines, and health systems. COVAX, part of the vaccines pillar, is coordinated by the WHO, GAVI, and CEPI, a public–private partnership for product development that was established in 2017 to promote investment in vaccines targeting emerging infectious diseases. The initial goal of COVAX is to ensure the equitable distribution of 2 billion doses of COVID-19 vaccines by the end of 2021, an amount deemed sufficient to protect the populations at highest risk within all the countries that have opted into the facility.

The facility is designed to procure vaccines before they receive regulatory approval on behalf of countries that elect to join COVAX. Within weeks of the announcement of the facility's establishment, over 150 countries had expressed interest in joining. Participation is conditioned on a payment in exchange for a predetermined number of doses as vaccines become available, proportional to each country's population.

COVAX has committed to procuring enough vaccine doses to cover at least 20 percent of the population of participating countries. The process will start with an initial tranche of doses sufficient to cover 3 percent of the population in each country. That should enable countries to vaccinate most of their highest-risk groups, such as frontline health care workers. After the 20 percent threshold is reached, follow-up distribution of vaccines may

be subject to weighted allocation based on each country's public health vulnerabilities if demand outstrips the vaccine supply.

COVAX mimics GAVI's strategy for obtaining vaccine doses for distribution in low-income countries, even though it is open to both lower- and higher-income countries. COVAX relies on high-volume purchasing to lower the price of vaccines—by placing larger orders than most individual countries, especially lower-income ones, would ordinarily be able to. It also functions as a risk-sharing mechanism by negotiating advance commitments with multiple pharmaceutical companies, thus guaranteeing vaccine portfolio diversification. Only the wealthiest countries in the global North have traditionally been in a position to accomplish that, through individual negotiations with multiple drugmakers. COVAX provides an incentive for these companies to engage in large-scale manufacturing of doses, without any assurance that they will receive regulatory approval, by creating a contract-based market for emerging vaccines.

The ongoing COVAX experiment directly counters the exclusionary ethos of bilateralism, which allows only countries with certain levels of economic and negotiating capacity to take part in the earliest rounds of allocation of a globally needed health good. COVAX also offers an encouraging example of swift design and implementation of transnational solutions to some of the problems posed by major public health crises.

After COVAX was launched in May 2020, it rolled out a financing instrument, the Advance Market Commitment (AMC), in June to enable the participation of lower- and middle-income countries. The AMC, modeled after GAVI's own procurement mechanisms, is used to fund vaccine pre-orders from different manufacturers. When a vaccine is licensed and approved by the WHO, those funds are used to pay for doses to be distributed among participating countries.

By late September, 92 lower-income countries and 54 higher-income countries had officially joined COVAX, with 38 more expected to follow suit. Collectively, the countries that decided to participate within this compressed time frame represent nearly two-thirds of the global population.

From a distributive justice perspective, these efforts to pool resources and coordinate the distribution of emerging vaccines in a global framework are an improvement over siloed, nationalistic approaches. Nevertheless, they are necessarily limited in scope and corrective force. COVAX describes its overall mission as promoting the distribution of vaccines in ways that are "fair." But can a remedial intervention halfway through a pandemic truly infuse fairness into a process that has deep roots in systemic inequality and in modes of biomedical innovation heavily dependent on noncollaborative approaches?

FLAWED BLUEPRINT?

Although initiatives like COVAX hint at the possibility of at least some centralization and coordination of vaccine acquisition and distribution, they must operate in the long shadow of contractual bilateralism. A closer look at the structure of COVAX illustrates the immediate shortcomings of corrective interventions taking place amidst a pandemic or similarly disruptive international crises.

Countries brought together under the aegis of equitable access to vaccines are yet again treated differently according to their economic status. Higher-income countries are able to finance their share of advance market commitments, whereas many lower-income countries cannot afford to do so. The AMC financing mechanism was created to enable the latter to buy their way into COVAX. Countries with a gross national income per capita under $4,000 (currently there are 92), as well as countries eligible through the World Bank's International Development Association, may take advantage of the AMC and receive funding to meet their financial obligations under COVAX.

Skewing the global distribution of vaccines widens the divide between high-income and low-income countries.

Whether a country joins COVAX through the self-funded or the assisted funding pathway has important ramifications. COVAX's vaccine allocation policy, released in June 2020, puts no restrictions on the ability of self-funded countries to enter into parallel bilateral vaccine purchase agreements. By contrast, if a country receiving financial assistance enters into bilateral agreements for doses covering 20 percent of its population, it will not receive access to its COVAX share until all other participating countries have taken their 20 percent shares.

An economically defined distinction that further curtails the ability of less affluent countries

to negotiate access to more vaccine doses makes little sense. It was justified by the COVAX leadership as necessary in light of geopolitical and time constraints. Yet it is hard to reconcile with the principles of proportionality and fairness by which the facility is supposed to be guided.

Current COVAX policies recommend but do not require that self-funded countries—the ones making ample use of parallel bilateral negotiations—donate excess doses of COVID-19 vaccines. Technically, if a higher-income country were to achieve herd immunity or vaccinate all the people who need protection, it could sit on its stockpiles indefinitely. It might elect to donate doses anyway, motivated by altruism or public relations, but this loophole nonetheless is at odds with COVAX's goals of distributive justice and fairness.

These shortcomings do not detract from the achievement of such a large multilateral network of heterogeneous players, including international organizations, private-sector firms, and governments, in coming together so quickly to mitigate the hoarding effects of vaccine nationalism. But they do undermine the guiding principles that brought these players together.

COVAX coexists with bilateral approaches to vaccine acquisition, which high-income countries still pursue as their primary mode of procurement in response to pandemics. That pathway is limited or unavailable for most lower-income countries. Even if COVAX were to evolve into a permanent fixture in the international public health apparatus, there is no legal or otherwise binding mechanism that would shift the dominant negotiating paradigm from contractual bilateralism to a largely centralized vaccine procurement system to prevent or respond to epidemics and pandemics. That would require nothing short of a fundamental change in the rapport between the global North and South.

Signs that these imbalances are likely to persist in the post–COVID-19 world were observable during the embryonic stages of COVAX, when some of the largest powers—the United States, China, and Russia—declined to join the facility. China eventually joined in October 2020. At the time of this writing, India, which is home to the largest vaccine manufacturer in the world by volume, the Serum Institute, was still pondering whether to join COVAX.

By late September 2020, COVAX had raised $700 million in funding, well short of its initial goal of $2 billion by the end of the year. The gap led some commentators to question the long-term financial stability of any such organization that pools resources to procure vaccines.

COVAX could be improved in the short term through relatively minor corrections to the allocative framework currently in use. But these problems raise concerns about the COVAX model as a blueprint for future, possibly permanent structures designed to counter nationalistic tendencies in vaccine acquisition and distribution.

Reality Check

Contractual bilateralism and global efforts to procure health goods will likely coexist in future epidemics and pandemics. These overlapping but also potentially exclusionary dynamics turn the problem of allocating emerging vaccines into a deadly serious game that must be played across different chessboards.

This divided approach meshes poorly with the borderless ways in which pathogens propagate in an increasingly globalized world. It also contradicts public health precepts for effective pandemic preparedness and response. As legal scholar Lawrence Gostin points out in his 2014 book *Global Health Law*, "globalized health hazards" underscore the "need for collective global action."

Perhaps the main problem with ad hoc solutions to dilemmas of allocating public health goods is that these plans tend to emerge late, as an emergency unfolds. It will be difficult to achieve equitable allocation across the global South–North divide if policymakers do not address the larger framework that determines how pandemic and epidemic health goods are produced in the first place.

Vaccine nationalism and the contractual bilateralism that fuels it are twin embodiments of a systemically siloed approach to the production of health goods. While scientific endeavors remain intrinsically collaborative and borderless, R&D processes for vaccine development have become antithetical to the scientific ideals of communality and disinterestedness. As with virtually every other type of emerging health technology, new vaccines produced from the mid-twentieth century onward are protected by patents and often regarded more as commodities than as goods that should be made universally available to promote public health.

Funding decisions in pre-pandemic periods tend to fail to account for prospective public health value, focusing more often on market-based considerations. Financing and coordination of R&D geared toward the prevention and

management of future public health crises are peripheral in the agendas of commercial and institutional players indispensable to the development and production of these goods. By the time a need materializes for a specific vaccine or other pandemic health needs, such as therapeutics or ventilator parts, the ensuing race usually follows the proprietary modes of innovation that have come to dominate mainstream drug and vaccine development.

Vaccine nationalism—or any other nationalistic approach to the allocation of health goods needed transnationally—is an extension of siloed and competition-driven frameworks in the pharmaceutical industry. The manifestations of vaccine nationalism in recent pandemics should serve as a reality check for the status of global health cooperation in the twenty-first century, as well as the wobbly post–World War II institutional architecture of global health.

During the early stages of the COVID-19 pandemic, the Trump administration chose to pursue isolationism as its default, multipurpose policy, complemented by bilateralism. The incoming Biden administration seems poised to reverse some of the recent forms of isolationism adopted by the United States, including its withdrawal from the WHO. It also may be more inclined to participate in more collaborative approaches, such as those adopted by other countries, international organizations, and various private, public, and public–private actors during the COVID-19 pandemic. These efforts are far from perfect. But they mark the first step toward incrementally better collaborations. ■