Vaccine equity: This is what the US is doing to ensure widespread global access to COVID-19 vaccines

The U.S. is expected to soon have enough COVID-19 vaccine doses on hand to fully vaccinate just about everyone in the country once, and, with additional doses already purchased, could likely vaccinate the population twice over. The same cannot be said for the majority of countries around the world, especially low- and middle-income countries (LMICs) where access has been limited and will remain so for some time.

While manufacturers are scaling up vaccine production, total projected production in 2021 of 9.8 billion is still short of estimated need of up to 11.5 billion to vaccinate everyone globally. Recent actions restricting or pausing the use of the AstraZeneca and Johnson & Johnson vaccines in some countries due to extremely rare but serious side effects could reverberate globally, potentially prolonging the vaccine access gap given that these two vaccines have been positioned as key workhorses for ramping up vaccinations in LMICs in particular.

Further, the expected need for booster doses and reformulated vaccines to address waning immunity and variants means global demand is likely to remain extremely high for the foreseeable future. Ultimately, ensuring widespread global access to COVID-19 vaccines, which is key to preventing cases and deaths and contributing to global population immunity, is a significant challenge and one that could threaten the ability to control the pandemic.

Federal officials, from Federal Reserve Chair Jerome Powell to Secretary of State Anthony Blinken, have argued that addressing global vaccine inequity is in the U.S. interest, and the Biden administration has already taken some steps to address the issue. But with global COVID-19 cases reaching their highest levels to date in recent weeks and many countries facing unprecedented waves of cases and deaths, there have been increasing calls for the U.S. to do more. This brief reviews the main policy options that have been proposed, and related questions, and identifies the actions taken by the administration thus far (see Table 1). These policy options fall into four main areas:

- Scaling up in-kind donations of surplus COVID-19 vaccines
- Providing additional funding for global vaccine efforts such as COVAX
- Helping to expand vaccine manufacturing
- Relaxing or waiving intellectual property (patent) restrictions on COVID-19 vaccine technologies

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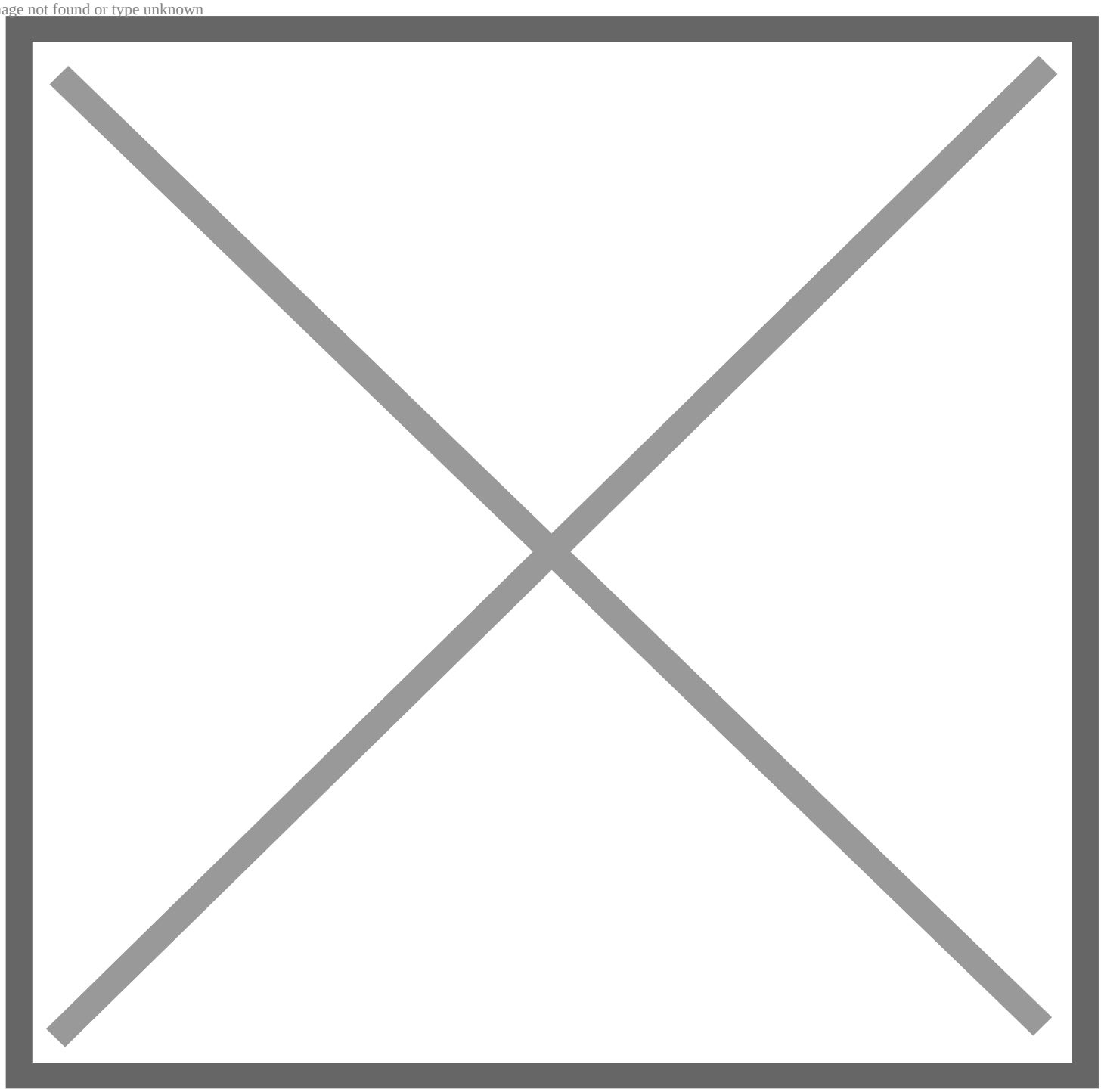

Policy Options

In-Kind Vaccine Donations

The U.S. has already purchased enough of the three authorized vaccines to fully vaccinate its entire population. Counting the purchased doses from two other vaccines that are not yet authorized by the FDA but may be soon, AstraZeneca (already being used in more than 90 countries) and Novavax (yet to be authorized for use), the U.S. will own enough doses soon to vaccinate its population twice over (see Table 2).

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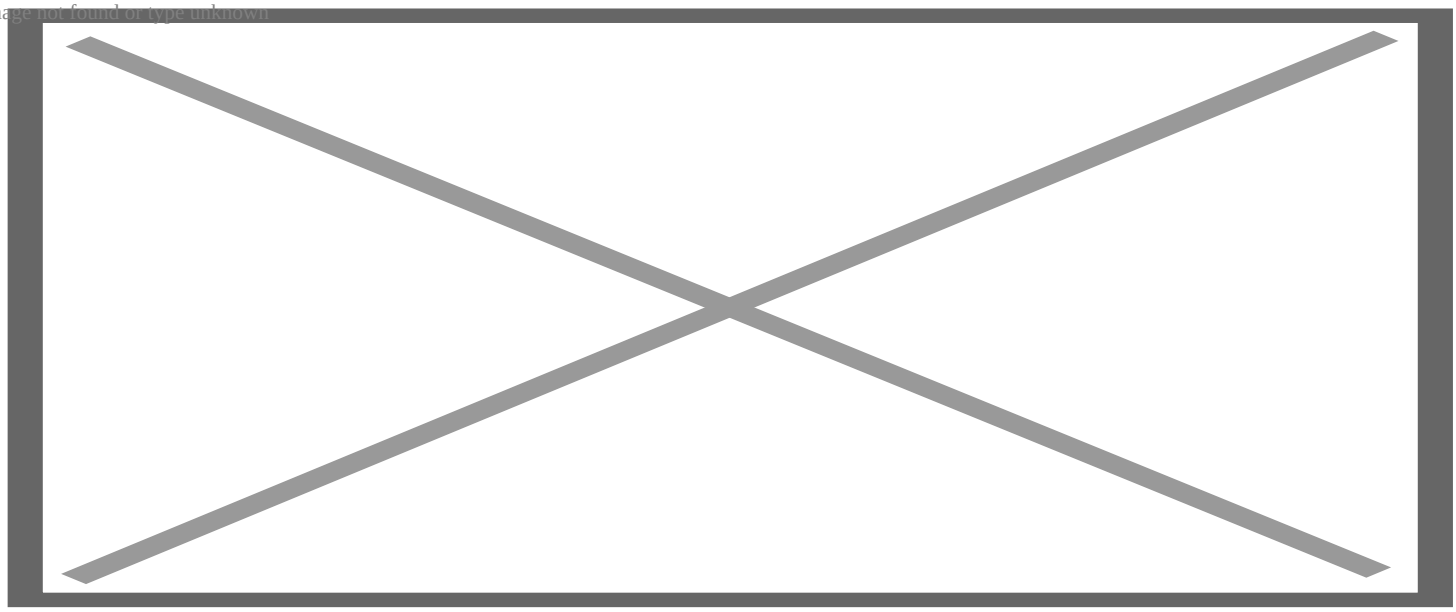

If current production and delivery goals are met, the number of U.S. doses in hand would be more than enough to vaccinate every U.S. adult by June this year, with additional projected deliveries beyond that enough to vaccine all children as well. This means the U.S. will soon have a significant number of "surplus" doses, at least enough to vaccinate an additional 150 million people and perhaps as many as 300 million beyond its own population. Even considering some doses may be held in reserve to address the problem of variants, it is clear many U.S.-owned doses are likely to go unused here.

In a National Security Memorandum released in the early days of the Biden administration, the President directed the Secretaries of State and Health and Human Services to develop a framework for donating surplus vaccines, once there is sufficient supply. While plans for such donations have not been finalized, the U.S. recently announced that it would "loan" 4 million U.S.-owned doses of the AstraZeneca vaccine to Canada and Mexico, with some expectation the doses will be paid back by these countries in the future. And, with the COVID-19 crisis in India escalating quickly, the administration announced it would donate 60 million AstraZeneca doses to India, pending an FDA safety review.

Going forward, there are several outstanding issues to be considered, including the timing, volume, and specific mix of vaccines that could be donated, as well as legal issues around the act of international donation. On timing, it could still be several months until the U.S. reaches the point when policymakers

feel all who want a vaccine have received one, opening up the possibility for more donations.

It is also possible the U.S. may seek to hold a portion of its surplus doses in reserve in anticipation of the need for booster shots. It is not yet clear if existing vaccine formulations and purchased vaccine doses would be sufficient to serve as booster shots, or if purchase of additional, modified vaccine formulations will be needed to vaccinate against variants. How our understanding of this scientific question evolves in the coming months and the timing will likely have implications for the availability of U.S. doses for donation. Regarding the mix of vaccines for donation, AstraZeneca is the first candidate of choice for in-kind donations, given that there is a 20 million dose (and growing) stockpile of this vaccine that sits unused in the U.S., the "loans" to Mexico and Canada and the donation to India have involved this vaccine, has not yet been authorized for use in the U.S., and Administration officials have said the U.S. may not need that vaccine for domestic purposes.

However, any of the other U.S. owned vaccines, including the Novavax vaccine which has yet to be authorized by the FDA, could be candidates for donations as well. Still, which vaccines are eligible to be donated may hinge on legal issues that arise around the contracts signed between the U.S. government and pharmaceutical companies supplying the vaccines. Concerns have been raised about the legality of donating U.S. purchased vaccines due to potential indemnification and liability issues for vaccine manufacturers.

Beyond these issues, and, given the pressure to vaccinate Americans, the topic of U.S. donations is a politically sensitive one, where the administration will need to balance domestic need for vaccination with the reality that global coverage is critical to controlling the pandemic. This was reflected in President Biden's recent remarks stating that he expects the U.S. to be the "arsenal of vaccination" for other countries, but only after "every American" has access to vaccines.

Funding for global vaccine access

A number of international efforts to expand access to COVID-19 vaccines have already been launched. The most prominent of these is COVAX, an international partnership led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, the Vaccine Alliance, and the World Health Organization (WHO), which supports vaccine development, procurement, and distribution globally. COVAX has an initial goal of procuring and distributing enough doses to be able to vaccinate up to 20% of the populations in 92 low- and middle-income countries, and over 100 countries have already started to receive doses through COVAX with these deliveries set to expand further over the coming months.

Despite the successes so far, COVAX faces a number of challenges to meeting its goal, including a significant funding gap. The initiative has received commitments of approximately $8.5 billion to date, but estimates it needs at least $11.5 billion through 2021 to achieve its goal. One recently published analysis [pre-print, not yet peer reviewed] estimates that $74 billion in funding will be required to support COVAX or other global vaccination efforts in order to reach 70% of the population vaccinated in low- and middle income countries.

The U.S. is already providing significant levels of funding for global vaccine distribution, with Congress appropriating $4 billion

in emergency funding to Gavi in support of COVAX. The White House announced that it would provide an initial $2 billion contribution to Gavi for COVAX, and work to leverage further global contributions by releasing the remaining $2 billion through 2022, of which the first $500 million would be made available when existing donor pledges were fulfilled and initial doses delivered.

To date, the U.S. has provided $2.5 billion, making the U.S. the largest single donor to COVAX. The U.S. also hosted the recent launch of a campaign to stimulate further donor investment in COVAX, with the goal of raising an additional $2 billion for the effort by June of this year. While some have called for the U.S. to provide more funding for COVID-19 vaccines, it is unclear whether there will be further appetite among U.S. policymakers to do more in this regard, though it is likely the administration will continue to play a leadership role in encouraging a more robust response by others.

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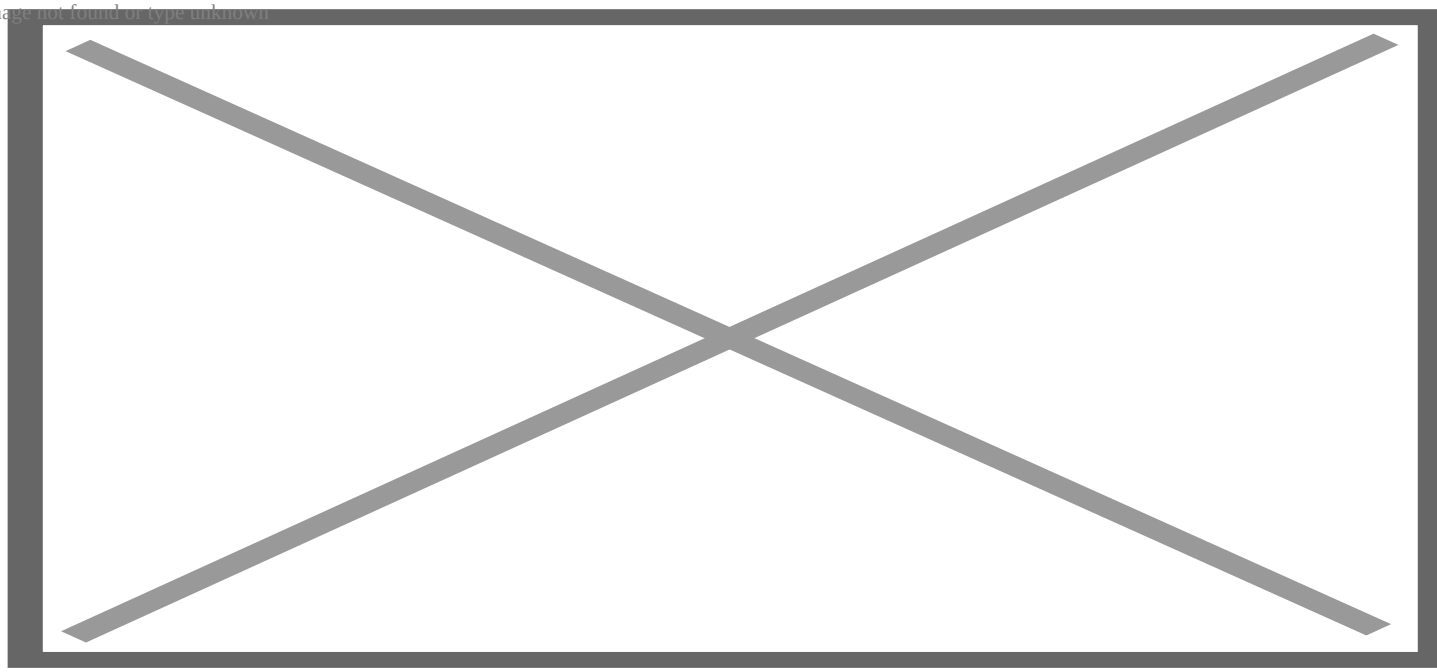

More than 355,000 doses of COVID-19 vaccines shipped by COVAX arrive in Niamey, the capital of Niger. Credit: UNICEF/Frank Dejongh

Expansion of manufacturing

While recognizing a significant financing gap exists, the most significant short-term constraint to scaling access remains the inadequate supply of vaccines globally. Additional donor financing would make a difference but alone cannot change the gap between supply and demand the world faces over the short term. As the WHO Director-General remarked recently: “more funding is needed, but that’s only part of the solution. Money doesn’t help if there are no vaccines to buy.”

Currently much of the capacity to make COVID-19 vaccines, especially those employing newer technological approaches like mRNA, is concentrated in the hands of a few pharmaceutical companies primarily in high-income countries, and production occurs in only a small number of locations.

Expanding this capacity is constrained by many factors, including: the challenging, complex process to make COVID-19 vaccines; limited quantities of necessary raw materials and supplies; a shortage of adequate manufacturing facilities and know-how; and weak governance and regulatory structures for vaccine production in many places. Key policy options, and actions to date, are as follows:

Bolstering production supply chains

Ensuring adequate raw materials and supplies is essential for scaling up vaccine production, but global COVID-19 vaccine supply chains are complex and fragile and have experienced shortages as production has scaled up. The U.S. has invoked the Defense Production Act over a dozen times in the last year in part to bolster access to raw materials and capacity for domestic manufacturing purposes, actions which helped spur U.S.-based vaccine production.

It is possible that further action prioritizing vaccine manufacturing inputs broadly, where the federal government has jurisdiction to do so, could help address global supply limitations. In one recognition of how U.S. actions can affect the global supply of raw materials, the Biden Administration recently announced it was removing impediments to the export of vaccine raw materials to India as part of a set of actions meant to assist that country.

Still, there is a potential for negative secondary effects when a government directs or exerts influence over supply chains. For example, supply disruption can ensue and some producers could have more difficulty accessing inputs if they are being channeled elsewhere. Exerting influence this way might disrupt or delay manufacturing of other types of products that use some of the same inputs.

Production partnerships, licensing agreements, and technology transfer

As of February 2021, at least 70 private production and licensing agreements have been announced publicly in support of COVID-19 vaccine manufacturing, including Pfizer and Novartis, AstraZeneca and Serum Institute of India, and Novavax and SK Bioscience. Many of these private sector deals have been undertaken by industry actors on an ad-hoc and voluntary basis, though at times governments have played an active role in forging them.

For example, in March the Biden Administration announced it had helped broker a partnership between Johnson & Johnson and Merck, in which Merck agreed to convert some of its manufacturing capacity to producing the Johnson & Johnson COVID-19 vaccine. The deal was aided by the U.S. invoking the Defense Production Act and providing over $200 million in government financing to help Merck pay for upgrades to their manufacturing facilities.

Therefore, a potential avenue to expand manufacturing further is for the U.S. and others to intervene more

directly and more aggressively in support of additional partnerships, which could include identifying and bringing together potential partners, actively brokering deals, and/or providing incentives such as financing and/or advance purchase guarantees, or even a "technology buyout" where the government pays a company a lump sum to make their specialized vaccine production knowledge and processes public.

This set of approaches includes supporting "technology transfer" – sharing COVID-19 vaccine manufacturing know-how from companies already making the vaccine mostly in higher income countries to other companies primarily in lower-income countries. Additional potential manufacturing capacity does exist beyond the relatively small number of higher income countries currently producing vaccines but tapping into that capacity requires companies to share and instruct others on (often) proprietary techniques, components, and processes.

WHO has recently launched a global mRNA vaccine technology transfer hub to assist in the transfer of vaccine know-how. Given the complexity of production chain for these vaccines and the multiple suppliers and steps involved, technology transfer agreements can cover manufacturing from any point from generating individual components of the vaccines, to producing the vaccines themselves, to the final "fill-finish" step of placing the product in vials.

For the most part, pharmaceutical companies have resisted most government intervention to accelerate technology transfer beyond industry-led voluntary licensing. A common argument against more forceful action on this front is that tapping into new and unproven manufacturing partners could jeopardize the quality and safety of COVID-19 vaccines, especially where there is inadequate regulatory systems and poor oversight to ensure quality of the product.

In addition, there is a question about how much money and time it takes to successfully transfer technology for COVID-19 vaccine production; some have estimated it can take up to a year and cost up to $1 billion to see the process through and obtain regulatory approval for new facilities. However, one analysis of COVID-19 vaccine technology transfer and licensing deals to date estimates companies that had pre-existing drug/vaccine manufacturing capabilities started producing doses about 6 months on average after a deal was made.

Whether or not the U.S. will seek to further enhance manufacturing capacity, including technology transfer more broadly, is unknown. Key questions include whether the government will push for greater action in light of industry resistance, what kind of incentives and how much additional monetary support the U.S. might provide to help advance these kinds of deals, and whether the U.S. can and would engage to help overcome barriers around regulation, oversight and quality of production elsewhere.

Relaxing/Waiving Intellectual Property Protections

Companies with authorized COVID-19 vaccines often have intellectual property protection (i.e., patents) on key technologies or innovations related to their vaccines and/or manufacturing processes, most of which predated the pandemic. Such protections are designed to protect the patent holder from unfair competition and unlicensed copying of these innovations, and are often defended as being necessary to provide companies with the incentive to invest in research, development and innovation.

Many advocates, governments, world leaders, and others have called for relaxing or waiving patent protections, either temporarily or permanently, for COVID-19 vaccines to allow other manufacturers access to these technologies without being concerned about violating intellectual property protections, which may incentivize increased global production.

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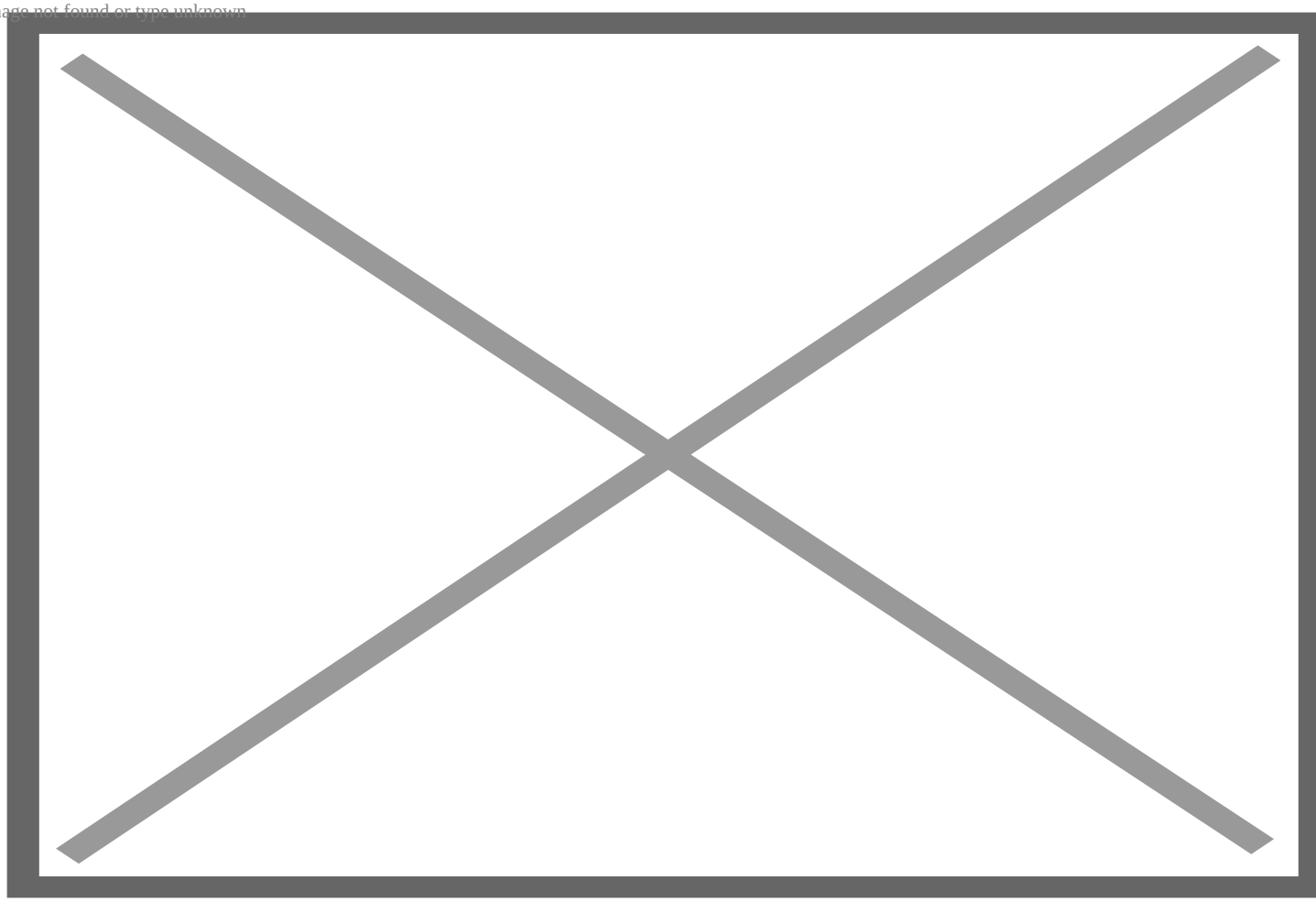

Credit: Mike Hutchings/Reuters

Several proposals along these lines have been made. One calls for manufacturers to voluntary share intellectual property via a multilateral technology patent pool, such as the World Health Organization's COVID-19 Technology Access Pool (C-TAP). This mechanism, endorsed by over 40 countries, could allow generic or other manufacturers around the world to access the protected technologies and use them

to start producing vaccines.

Though this mechanism was formally proposed almost a year ago, no pharmaceutical company has voluntary shared its patents for COVID-19 vaccines through this mechanism, and in fact some have come out strongly against it, instead expressing preference for voluntary licensing deals (as discussed above). Another proposal, initiated in October 2020 by India and South Africa at the World Trade Organization (WTO), calls for patent protections on COVID-19 vaccines to be waived altogether for the duration of the pandemic.

While a majority of WTO member states have supported this idea, it has been met with opposition from Western countries with large pharmaceutical industries including the United Kingdom, Switzerland, members of the European Union and the United States.

Advocates for waiving intellectual property rights in this case point out that much of the innovation costs related to COVID -19 vaccines have been borne by governments and non-profit/philanthropic organizations, not the companies that now hold the patents. According to one recent estimate, public and non-profit funders have provided over $10 billion in funding to support vaccine research, development, and manufacturing globally.

The U.S. government in particular has significant leverage over some COVID-19 vaccine intellectual property because of long-standing government investments in advancing this technology. In fact, as of March 30 of this year the government holds a patent to one of the key technologies used in vaccines from Moderna, Johnson & Johnson, Novavax, CureVac and Pfizer-BioNTech, and could potentially use this as leverage to sway these companies to share technology.

For these reasons some have argued the government could relax or waive patents via legal provisions such as “march-in” rights, potentially opening up production to generic competition. Many advocates, and over 30 members of Congress, have already called on the Biden administration to support an intellectual property waiver for COVID-19 vaccines along these lines. While the Biden administration is reported to be considering it and officials have met with pharmaceutical companies to discuss the issue, few details are available as to if and to what extent the government will move in this direction, and pharmaceutical companies so far have been publicly resistant to the idea of intellectual property waivers.

There are several arguments commonly raised against waiving intellectual property rights for global production of COVID -19 vaccines. For one, many pharmaceutical companies say it would undermine incentives for investment in research and development if patent protections are not provided for their innovations; a coalition of these companies recently re-stated this principle, saying that intellectual property protections are the “cornerstone” of a “dynamic and thriving” research ecosystem.

In addition, some have argued that intellectual property rights are not even an important barrier to expanding access, and actions to relax or waive patents – on their own – would do little to incentivize greater investment and production in needed vaccines. For example, it has been Moderna’s policy since at least October 2020 that the company “will not enforce” its COVID-19 related patents for the duration of the pandemic, and the company is willing to “license its intellectual property for COVID-19 vaccines to

others", but so far no companies other than the ones Moderna itself has reached licensing deals with have pursued this. Finally, it has been argued that undermining patent rights might not even be legal under U.S. law.

Conclusion

As the U.S. and several other high-income countries continue to accelerate their own vaccine efforts, and have secured enough supply for their own populations at least once over, attention to global disparities in vaccine access is rising. The issue is all the more urgent as daily cases globally reach the highest reported numbers since the start of the pandemic, and deaths in many countries are at record highs with many countries lacking access to vaccines.

Beyond the inequities across countries, the lack of global access directly impact U.S. national interests and the U.S. economy, because limited vaccinations worldwide has the effect of extending the pandemic, raising risks for all countries, and causing social and economic disruptions. While there is a cost associated with increasing vaccine production and distribution, it is likely to be dwarfed by the cost of a longer, deadlier pandemic.

For this reason many policy leaders and economists have argued that the U.S. economic recovery from the pandemic rests on the success of the global vaccination campaign. While recognizing the U.S. has already taken a number of steps to address the vaccine inequity crisis, we can expect that the pressure to do more will only increase over time.

Dr. Jen Kates is Senior Vice President and Director of Global Health & HIV Policy at KFF, where she oversees policy analysis and research focused on the U.S. government's role in global health and on the global and domestic HIV epidemics. Find Jen on Twitter @jenkatesdc

Josh Michaud is an Associate Director for Global Health Policy at the Henry J. Kaiser Family Foundation, where he helps guide and oversee KFF's research and analysis in the area of global health. Find Josh on Twitter @joshmich

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