Intellectual Property Protections and Profits Limit Global Vaccine Access

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Abstract

Since December 2019, more than 580 million cases of COVID-19 have resulted in more than 6.4 million deaths globally. The COVID-19 pandemic has had devastating impacts on human health as well as national and international economies. Beginning in 2020, highly effective medical products were developed to treat and prevent COVID-19. Vaccines such as those developed by Pfizer-BioNTech and Moderna have demonstrated high efficacy in preventing COVID-19 infection in clinical trials and offer flexibility in designing new vaccines to address variants. However, these companies have been unwilling to share patents and technologies with other countries to scale up production worldwide. It is essential that the public health community advocate for global access to life-saving biotechnologies, including the manufacture and distribution of vaccines, therapies, and diagnostics to limit morbidity and mortality from COVID-19, its variants, and newly emerging viruses such as monkeypox. We must strengthen our clinical and public health infrastructure in preparation for future outbreaks and pandemics. APHA calls on the World Trade Organization to reconsider and waive patent enforcement to encourage technology transfer and redistribution of expertise, technical assistance, resources, and finances and, failing that, to allow countries to act independently without penalty; calls on pharmaceutical companies to voluntarily pledge nonenforcement of intellectual property rights and share the technology needed to produce treatments and vaccines; and calls on the broader public health community to support education and outreach efforts intended to address misinformation, reluctance, and other potential barriers to uptake of and access to current and future vaccines.

Relationship to Existing APHA Policy Statements

- APHA Policy Statement 201512: Ensuring That Trade Agreements Promote Public Health
- APHA Policy Statement 20021: Int'l Trade Policy Issues of Improving Access to Drugs for Life-Threatening and Disabling Diseases (archived)
- APHA Policy Statement 200121: Threats to Global Health and Equity: The General Agreement on Trade in Services (GATS), and the Free Trade Area of the Americas (FTAA)
- APHA Policy Statement 20218: Call for Urgent Actions to Address Health Inequities in the U.S. Coronavirus Disease 2019 Pandemic and Response

Problem Statement

Since December 2019, more than 580 million cases of COVID-19 have resulted in more than 6.4 million deaths globally.[1] The COVID-19 pandemic has had devastating impacts on human health as well as national and international economies. It is estimated that there were 18.2 million excess deaths attributable to the COVID-19 pandemic in 2020 and 2021, with potential causes being underreporting, lack of access to testing, and increased mortality from other diseases because of pandemic-related changes in behavior or in access to care.[2]

However, beginning in 2020, highly effective medical products were identified and developed to treat and prevent COVID-19. Vaccines using mRNA technology, such as those developed by Pfizer-BioNTech and Moderna, have been highly efficacious in preventing severe COVID-19 infection in clinical trials.[3] By conservative estimates, COVID-19 vaccines prevented 14.4 million deaths globally in 2021 and could have prevented many more had even modest vaccine distribution goals been met.[4] Unfortunately, global vaccine distribution has been characterized by stark inequities. COVID-19 has exposed issues in the world distribution system and in our ability to respond to global diseases. It is essential that the public health community address inequities in global access to life-saving biotechnologies, including the manufacture and distribution of vaccines, new therapeutics, and tests. The U.S. Food and Drug Administration (FDA) has recommended that, in light of new COVID-19 variants such as BA.4 and BA.5, vaccines should be modified to limit morbidity and mortality and that researchers should continue to seek an overarching vaccine for all COVID types.[5] In addition, some vaccines currently being developed, such as Corbevax, Soberana 02, and Novavax, may have logistical, therapeutic, and financial advantages in the long term.

Therapeutics to limit morbidity and mortality from COVID-19 are also chasing a moving target as mutations in the virus can create resistance to medications such as injectable Veklury (remdesivir) and monoclonal antibodies (bebtelovimab) and oral Paxlovid (nirmatrelvir and ritonavir).[6] Medication to prevent infection includes Evusheld (tixagevimab and cilgavimab). The ability to “test and treat” requires available diagnostics and medications that are not available in most of the world.[7] Increased production of new treatments and diagnostics will be needed to respond in a timely fashion. This need has been recognized in a recent G7 communique that pledges support for the Coalition for Epidemic Preparedness Innovations (CEPI) and the goal of the “100 Days Mission.”[8] This support must become real as emerging diseases will bring new challenges. For example, prior to COVID-19 CEPI’s work focused on developing vaccines for Ebola virus, Lassa virus, Middle East respiratory syndrome coronavirus, Nipah virus, Rift Valley fever virus, and Chikungunya virus; it has more than 20 vaccine candidates against these pathogens in development. The mRNA technology offers a new tool for vaccine development and

may yet show effectiveness in preventing HIV as Moderna contributes to new clinical trials.[9] However, as with the HIV epidemic, the World Trade Organization (WTO) has prioritized intellectual property (IP) rights and profit over widespread access to and production of therapeutics. This has limited the global availability of vaccines as high-income countries (HICs) have kept vaccines for domestic use, provided vaccines near expiration, failed to adequately fund international organizations, and charged low- and middle-income countries (LMICs) more than they can pay.[10,11]

Global vaccine disparities between high-income and low- and middle-income countries: Since the start of the pandemic, disparate international responses have affected LMICs disproportionately. The World Health Organization (WHO) reports that, globally, 164 vaccine doses have been administered per 100 people and that 63.46 per 100 people are fully vaccinated with the last dose of the primary series.[1] In addition, 28.96 per 100 people have received a vaccine booster globally. But there is wide geographic variation. The number of total vaccines administered per 100 people in the Western Pacific, Europe, the Americas, and Southeast Asia is more than 1.4 times that of the Eastern Mediterranean and 4 times that of Africa.[1] Also, the number of individuals fully vaccinated with the last doses of the primary series per 100 population in the Western Pacific, Europe, the Americas, and Southeast Asia is more than 1.3 times that of the Eastern Mediterranean and more than 2.8 times that of Africa.[1] Finally, the number of people boosted per 100 population in Europe, the Americas, and the Western Pacific is more than 1.5 times that of Southeast Asia, more than 1.9 times that of the Eastern Mediterranean, and more than 11 times that of Africa.[1] Solidarity among HICs has made possible the development of valuable technologies yielding more COVID-19 vaccines than they can feasibly distribute. Meanwhile, LMICs are desperate for the vaccines and technology needed to prevent infections and death.[11] Health is recognized as a human right in the United Nations Universal Declaration of Human Rights, but under our current profit- and competition-based global health care system IP is afforded more rights than human lives. This hoarding by HICs has been characterized as “vaccine apartheid” by Fatima Hass, director of the Health Justice Initiative in South Africa.[12,13]

Harms of vaccine apartheid—From variants to racist immigration policy: Failure to provide vaccines, IP, and the technology to manufacture them worldwide will mean ongoing public health crises in both the short and the long term. In the short term, ongoing spread of COVID-19 in countries with low vaccination rates may lead to the development of additional variants. Existing vaccines prevent infection and transmission of the alpha and delta variants.[14] Booster shots provide protection against infection from the original Omicron COVID-19 variants.[2] Existing vaccines are less effective at preventing infection for variants BA.4 and BA.5 but are effective in preventing severe illness and death. Infections provide an

opportunity for the virus to replicate, with more severe infections and sicker hosts (such as those who are immunocompromised), leading to longer periods of active infection.[15] This increases the likelihood of multiple mutations arising that could be more virulent, pathogenic, or capable of immune escape.[16] Preventing infections with vaccinations and other public health measures is crucial to preventing the evolution of new coronavirus variants.

New variants have been used to justify racist immigration and travel policies. For example, the Title 42 policy was invoked in March 2020 to expel and return to danger individuals seeking asylum under the guise of protecting the public health of U.S. citizens from COVID-19. This racist and inhumane policy was maintained even under a new administration and continues to be supported by Congress. The ongoing spread of variants exposes the uselessness of this order.[17] Travel bans were instituted against South Africa and other African countries in December 2021 in response to the Omicron variant, even though the variant had already been found in the United States and in other countries that were not placed under a travel ban. Prominent public health experts denounced this unscientific act.[18] Ongoing variants and low vaccination rates provide cover for these racist policies, which discourage global cooperation and sharing of information about new variants; they also affect the ability of LMICs to acquire supplies and medical expertise.[18]

In the long term, we are certain to face future pandemics as deforestation and factory farming lead to spillover of viruses from animals to people.[19] If we fail now to implement technological advances, manufacturing capabilities, and distribution systems at the global level, we will compromise our ability to recognize and respond in the future.[20] We will continue to experience events such as the cholera outbreaks in Haiti and Yemen and the negative impact of the COVID-19 pandemic on measles vaccinations in 37 low-income countries.[21] The initial and ongoing interruptions in childhood vaccination for measles (and other diseases) due to the COVID-19 pandemic have led to spikes in global measles cases.[22,23] The lack of public health infrastructure will also worsen outcomes of disasters caused by climate change and wars. Showing global solidarity by building resilient and capable health systems is a crucial part of long-term health and safety. When, and if, a universal coronavirus vaccine is developed, the ability to make it available globally will also depend on current decisions to share information and technology and build infrastructure. We must learn from this pandemic that “COVID-19 anywhere is COVID-19 everywhere”; when it comes to infectious diseases, national and global interests are truly the same.[20]

The current vaccine apartheid is part of a larger global social, economic, and political system that maximizes the rate of profit of large corporations, including pharmaceutical companies, and ignores long-term harms. Seventeen large corporations, such as Pfizer, Johnson & Johnson, Amazon, Visa, Microsoft, and Google, made $85 billion in extra profits during 2020. Oxfam estimates that a pandemic profit tax (similar to the profit tax used during World War II) would cover the cost of universal vaccination research, manufacturing, and delivery as well as fund sick leave, food, and other support.[24] The current global social, economic, and political system also allows damaging environmental conditions to promote diseases. There are many options for primary prevention of COVID-19 and similar zoonotic infections.[25,26] Bernstein et al. estimate that the world could save $106 billion in global gross national income if the number of outbreaks decreased by 50%.[27] To achieve this outcome, surveillance of zoonotic diseases would create a “pathogen catalog” to identify what vaccines need to be developed. Practices that reduce deforestation and wild animal farming and trade, increase veterinary care, and implement more sustainable food production can reduce spillover.[27]

Finally, as the need to vaccinate the world is critical to the long-term healthy survival of humanity, education campaigns to combat vaccine reluctance and misinformation should be developed alongside testing and treatment initiatives. It is crucial that trusted public health institutions and practitioners in each country engage in proactive, antiracist, evidence-based campaigns to educate the public and encourage vaccine acceptance.[28]

Effects of supply chain issues on vaccinations: Highly effective vaccines cannot provide protection if they are not administered to individuals, and doing so requires an adequate supply chain. In our global health architecture, supply chain management dictates who does and does not get vaccinated based on where they are born and live. Supply chain issues include limited vaccine manufacturing, supply-side bottlenecks (raw materials and consumables), cold-chain storage infrastructure, training, and support.[21] Establishing local manufacturing hubs will not only curb the cost of delivering vaccines to people in LMICs but also help combat challenges associated with export bans, vaccine hoarding by HICs, and delivery of vaccines before they expire; all of this will contribute to achieving global herd immunity more quickly.[29]

Economic impact on low-wage and informal workers: Vaccine access and uptake have economic effects on the global economy, particularly harming LMICs. Although advanced economies suffer from both trade and economic costs of the pandemic, most of these costs stem from their trade linkages with unvaccinated countries that limit exports and imports.[30] These declines are amplified through both

domestic and global input-output linkages. Because in the near term global supply chains are fixed under price stickiness, there is no reallocation of labor across sectors or substitution between intermediate inputs.[30] Even in HICs, establishments paying the lowest average wages and the lowest-wage workers experienced the steepest decline in employment and are still the furthest from recovery.[31] Moreover, because of the race and class divisions in the United States and other HICs, the burden of disease and economic downturn in those countries falls disproportionately on poor, Black, and Latinx workers.

Loss of life among health workers was a serious blow to the global workforce. For example, more than 100 Ugandan health workers died between March 2020 and July 2021.[32] U.S. public health workers also suffered high rates of depression and other mental health disorders exacerbated by long working hours without adequate breaks.[33] Beyond health workers, the pandemic has had serious consequences for workers in terms of morbidity and mortality. In the United States, data on long COVID are sobering, as Brookings reported in January 2022 that it is the cause of as many as 4 million people being out of work, costing at least $170 billion a year.[34] A study of California transportation workers revealed higher rates of COVID-19 than in other industries, ranging from more than three to five times the rate among other groups from January to May 2022, requiring more targeted vaccination efforts in this group of workers.[35]

The COVID-19 pandemic has had a particularly harsh impact on workers in the informal economy owing to a lack of labor protections, social safety nets, and access to government relief. The International Labour Organization (ILO) estimates that informal workers represent around 60% of the world's employed population, equal to 2 billion workers.[36] At the beginning of the pandemic, the ILO projected that 1.6 billion workers could lose up to 60% of their earnings because of lockdown restrictions and reduced demand for their labor.[37] A 12-city longitudinal study conducted among informal workers in summer 2020 confirmed the magnitude of earning losses, particularly among domestic workers and street vendors as well as women, who have been affected disproportionately.[38] The extent to which affected workers were able to access government relief varied widely depending on the existing social protection infrastructure, the presence of grassroots organizations, and eligibility requirements and application procedures; almost 60% of surveyed workers did not receive government-provided cash or food relief.[38]

Corporate greed as a driver of vaccine inequity: Pharmaceutical companies base the price of medical products on what the market will bear to maximize their profits rather than on the cost of research and development (R&D) or manufacturing.[39] Under the current paradigm for vaccine manufacturing and

delivery, private companies have created artificial scarcity by concealing IP rights in the name of protecting innovation.[40] In the first year of availability of their vaccines, Pfizer and Moderna earned approximately $54 billion from sales of their mRNA vaccines; Pfizer's projected profits for November 2021 were $36 billion, and Moderna's were $18 billion.[41]

Currently, the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires signatory countries to allow pharmaceutical companies to have monopoly patent protections for their medical products.[42] The TRIPS Agreement is a barrier to equitable and timely access to novel medical products, including COVID-19 vaccines. LMICs such as India and Brazil are among of the largest vaccine manufacturers in the world and thus have existing infrastructure to produce enough vaccines to dramatically increase COVID-19 vaccination rates among their populations.[43] Yet, these countries are unable to autonomously produce mRNA COVID-19 vaccines because of IP restrictions put in place through the TRIPS Agreement. In a global public health crisis such as the COVID-19 pandemic, private companies should not hold this type of power over supply, price, and distribution of vaccines.

Evidence-Based Strategies to Address the Problem

Waive the TRIPS Agreement and share access to technology for vaccine development: The WTO can temporarily waive patent protections under the TRIPS Agreement. The production processes for COVID-19 vaccines are protected by patent thickets, and it is important to waive enforcement of all patents surrounding the production and use of the vaccines.[44] A coalition of public health and international justice organizations has called on the WTO to waive patent protections under the TRIPS Agreement as a necessary first step to ensuring greater global vaccine access.[45] India and South Africa formally requested a waiver of the TRIPS Agreement for the prevention, containment, and treatment of COVID-19 in October 2020, and now more than 100 countries support it.[46] Nevertheless, the WTO refused to support it again in June 2022.

There have been exceptions to the enforcement of patent protections under the TRIPS Agreement. Article 31 allows governments to issue licenses to use an existing patent without a patent holder's consent. The exception was used 144 times between 2001 and 2016 to create flexibilities for 89 countries.[47] Two decades ago, when the HIV/AIDS global pandemic threatened the stability and existence of some LMICs, the Doha Declaration of 2001 addressed the barriers that the TRIPS Agreement posed to global public health. It enabled developing countries to provide access for their populations to effective antiretroviral medications without bankrupting their health care budgets and has had a substantial impact on HIV/AIDS morbidity and mortality beginning a generation ago and lasting to the present time.[48] However, this

exception to the TRIPS Agreement is insufficient for addressing current public health needs because "after applying for an exception, exporting countries must prove products go only to destination nations, are readily identifiable based on variations of color or shape, and include only product necessary to meet requirements of an eligible country; importing nations must notify the TRIPS council of receipt."[47] Other efforts to free IP are sought worldwide, showing the importance of bypassing patent protections. The World Intellectual Property Organization has established a COVID-19 search facility within its global database.[49] The tool offers predefined search strings that support the searching of COVID-19-related patent information. Regional patent organizations (such as the European Patent Office) and regional technical cooperation initiatives (such as PRO SUR/PROSUL, bringing together Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, Paraguay, Peru, and Uruguay), as well as national IP authorities, have developed similar tools.[50] Application of regulations in the General Agreement on Trades and Services, including e-commerce, may also be useful. Moderna did indicate that the company will not enforce patents for its vaccine but has not shared the knowledge and technology needed for others to produce the vaccine themselves.[51]

Because LMICs face inadequate vaccine supplies, diagnostic capabilities, health technology, and infrastructure, the TRIPS waiver alone is unlikely to achieve the expected impact without transfer of expertise relating to COVID-19 vaccines.

WTO members are free to regulate their service sectors to pursue their domestic policy objectives. However, Article VI:4 of the General Agreement on Trade in Services (GATS) (Domestic Regulations) calls for the Council for Trade in Services to develop any necessary disciplines to ensure that domestic regulation in services does not create unnecessary trade barriers.[52] GATS requires treatment of services or suppliers of all other members that is "no less favourable than that accorded to like services and services suppliers of any other country as long as GATS applies to services produced, distributed, marketed, sold or delivered electronically, as well as to services involved in the marketing, sale, and delivery of goods through e-commerce such as telehealth."[53] Many regional trade agreements trade in services beyond the GATS service provision and regulate a broader investment framework, including investment in IP.

The provisions under GATS recognize that regulations may affect trade in services adversely, especially health services, and therefore undermine health equity. It is crucial that the authorization process toward supplying a service follows good regulatory practices and, thereby, does not constitute an unnecessary impediment to business activity. The full implementation of GATS will benefit small- and medium-sized

enterprises for which navigating regulatory procedures can be costly and complex. Establishing common approaches and recommendations while providing precise and timely information across developed and developing countries would enhance trade and health system resilience in LMICs.

Develop infrastructure in low- and middle-income countries: Development of vaccine manufacturing in LMICs is essential. Although many LMICs currently face challenges such as limited availability of diagnostic tools, health technology, and infrastructure, they can address these challenges with adequate support. Investment in infrastructure is essential to responding to the COVID-19 pandemic and also strengthens our ability to respond to future emerging public health threats such as monkeypox. Experts concurrently identified the need to expand infrastructure for producing medical products while responding to HIV.[54]

Technology transfer is necessary for the development of manufacturing in LMICs, including a cold chain for newer mRNA vaccines. Through the power of the executive branch, the U.S. government has the authority under the Defense Procurement Act to require Moderna to share vaccine technology with the WHO mRNA hubs.[55] The act has been enforced during this pandemic to increase the production of vaccines to be distributed to people in the United States and to help vaccine manufacturers in the country secure the necessary materials to produce vaccines more quickly.[56]

There are multiple examples of the capacity for such developments in LMICs. In 2017, an optimized immunization supply chain model was implemented in the Democratic Republic of the Congo, resulting in a 34% cost reduction and no recurrences of immunizations being out of stock.[57] The country was then able to address Ebola in 2019 by setting up an ultracold chain using backup power generators.[41,58] Examples of technology transfer from HICs to LMICs include the oral cholera vaccine and typhoid conjugate vaccine technologies, which were shared with vaccine manufacturers in several developing countries.[59] In spite of India’s ban on exporting vaccine technology from the Serum Institute of India, Bangladesh has become self-reliant in its response to the pandemic. Icepta Vaccine Limited, a vaccine manufacturing facility in Bangladesh, will be cooperating with Sinopharm to produce a viable COVID-19 vaccine.[60] As of December 2021, more than 50% of the Bangladeshi population had received one dose of the vaccine.[60] In South Africa, work to reverse engineer mRNA vaccines was nearly complete at the time of this writing. Along with the identification of the Omicron variant, this further demonstrates the scientific expertise available around the world. While significant manufacturing capacity exists in LMICs, international trade agreements hinder their ability to leverage patent-protected technology. Furthermore, trade agreements may serve to discourage a country from investing in pharmaceutical manufacturing if

such technology does not already exist in the country. Given that vaccines currently being developed may have therapeutic, logistical, or financial advantages, it benefits the global population and economies to diversify and increase manufacturing capacity in LMICs as well as HICs.

Address misinformation and potential vaccine reluctance: As the need to vaccinate the world is critical to the long-term healthy survival of humanity, education campaigns to combat vaccine reluctance and misinformation must be developed alongside testing and treatment initiatives. According to a World Bank working paper on sub-Saharan Africa, "Vaccine acceptance ranges from nearly universal in Ethiopia (97.9%) to below what would likely be required for herd immunity in Mali (64.5%)…. Safety concerns about the vaccine in general and its side effects emerge as the primary reservations toward a COVID-19 vaccine across countries."[61] In addition, the failure to distribute vaccines in a timely way and support local production contributes to distrust of the product. As stated in a December 2021 Lancet editorial, "Although the global community recognizes the need for global vaccine coverage to end the COVID-19 pandemic, it exhibits no firm commitment to expedite vaccine deployment to the African continent…which further reinforces and perpetuates vaccine hesitancy."[62] The editorial went on to make several proposals to improve the situation, such as making use of the resources of the African Centres for Disease Control and Prevention and WHO and sharing experiences and lessons from other vaccination efforts such as that involving Ebola.

Implement broad social and economic approaches to prevent future pandemics and mitigate COVID-19: Understanding that the current vaccine apartheid and the conditions that led to this pandemic are directly related to the larger economic and political system—capitalism—is crucial in considering future directions for prevention of pandemics and responses to them. There are many options for primary prevention of COVID-19 and similar zoonotic infections. Reducing malnutrition can strengthen people's immune responses, and living wages, employment, and universal health care can make health services affordable and available. Changing industrial food production methods is a critical element in preventing spillovers and disease.[26,63]

The global response to the COVID-19 pandemic builds on historical experience with prior crises. Collective efforts have led to profound advances. For example, the USSR (Union of Soviet Socialist Republics) Sanitation and Epidemiological Services developed five laboratories and sent health workers throughout the Soviet Union to eradicate diphtheria, smallpox, malaria, and polio.[25] Also, according to one study, "The HIV epidemic showed that biomedical advances alone are insufficient to sustainable control a pandemic. Each country will have its own unique challenges in vaccine distribution."[64] In

fact, LMICs have addressed issues of distribution within their countries in a number of ways. The expansion of infrastructure and reporting under the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) in Africa demonstrated that poor countries can provide health care services to difficult-to-reach populations with the complex treatment of HIV. Daily doses for years and lab monitoring are more difficult than vaccination programs, but great success has occurred with HIV and with COVID vaccinations. The structures have helped these countries pivot to COVID vaccinations, which have been more limited by vaccine availability than internal outreach.[65] When the United Nations brought cholera vaccines to Haiti after the devastation of the 2010 earthquake, the Ministry of Health and Paul Farmer's Partners in Health vaccinated more than 75% of the population in large sections of the country, with 91% returning for the second dose.[66] National Geographic vividly reported on multiple countries' outreach with COVID-19 vaccines even in the face of complex storage issues. Health care workers were shown transporting coolers in Kashmir in mountainous and remote areas, down the rivers of Peru, and in rural Colombia among others. Even the United States had its challenges using dogsleds in Alaska: "This is not the first time health care workers traveled far and wide to deliver vaccines but '[w]e've never had a preventable pandemic before.'"[67]

Opposing Arguments

Multinational efforts exist to distribute vaccine donations equitably: COVAX, a multilateral instrument directed by Gavi (The Vaccine Alliance), WHO, the United Nations Children's Fund (UNICEF), and other global institutions, was proposed to create a mechanism to supply COVID-19 vaccines to all countries equitably. However, the rollout has not met its stated objectives. COVAX has failed to meet expectations, accounting for less than 5% of all vaccines administered globally and not meeting its own goal of vaccinating 40% of Africa in 2021 because of supply chain issues.[68]

One of the main hindrances to the success of COVAX has been HICs entering into bilateral agreements with pharmaceutical companies. The United States has entered into seven deals with six companies for 800 million doses, which are enough to vaccinate 140% of its population.[69] This process has put HICs in front of the queue, leaving COVAX to wait to receive its share. Because of the outmaneuvering by HICs, COVAX has had to make concessions to attract participation in the program. The first concession was made to allow self-financing countries the ability to choose what vaccines they would receive. The second concession allowed self-financing countries to receive enough vaccines for up to 50% of their population, while the original agreement allowed for 20%. These concessions gave HICs privileges that undermined COVAX's goal of equitable distribution. The European Union, United Kingdom, and United

States received more doses of vaccines to prepare for the winter holidays than African countries received in all of 2021.[38]

Nations need to prioritize vaccination for their own population: COVID-19 is not the first situation in which countries have practiced "vaccine nationalism" and hoarded vaccines to guarantee that they will have more than enough to vaccinate their own population. By paying in advance and putting in orders early, HICs hinder manufacturers' ability to supply globally. As prices increase and supply decreases, economic pressures increase alongside death rates in LMICs.[70] Vaccine nationalism was in play for the United States and India, among others. Covishield exports from the Serum Institute of India were stopped in mid-April 2022 under pressure from the Indian government to use the vaccine at home; prior to that, many doses had already been sold to HICs. The United States held up exports of raw materials, such as liners for bioreactors and filters, because of its concern for its own vaccine supplies, which contributed to Serum's shortfall of vaccine.[71] Vaccine nationalism also increases risks in HICs as it allows the virus to spread in other countries, providing an opportunity for the virus to mutate and for new variants to emerge. At that point, new variants may already be circulating that are not well controlled, as was seen with Novavax in South Africa.[72] Furthermore, vaccine hoarding in HICs has led to vaccine waste. More than 82 million doses have been wasted in the United States (more than 10% of all doses distributed in the country).[73] Globally, in December 2021, more than 100 million doses intended for donation through COVAX were wasted because they were donated too close to the expiration date.[74]

Low- and middle-income countries do not have the capacity to produce vaccines themselves: Opponents of waiving IP rights to COVID-19 vaccines argue that infrastructure and technology capabilities in LMICs are insufficient, which could result in compromised quality and safety of vaccine manufacturing and distribution. However, high gross domestic product is not an accurate predictor of whether countries are prepared for large-scale vaccine manufacturing.[75] Currently, there are 19 LMICs that have the infrastructure and capability to produce mRNA COVID-19 vaccines on a significant scale. Furthermore, even LMICs that do not yet have the infrastructure and technology capabilities to produce vaccines autonomously will benefit from expanding vaccine technology access to LMICs that do already have the means to produce vaccines on a large scale. If the number of LMICs that have access to vaccine technology and infrastructure is increased, other LMICs would have the opportunity to learn from successful LMIC models to inform their vaccine manufacturing and infrastructure moving forward.

In addition, it is likely that LMICs with manufacturing capacity will effectively export vaccines to other LMICs that are not yet equipped with the necessary technology and production infrastructure. During the

COVI-19 pandemic, South Africa has pledged 2 million doses of the Johnson & Johnson vaccine to other African countries, and India has exported COVID-19 vaccines to neighboring LMICs such as Nepal, Bangladesh, and Myanmar.[76,77] There is further precedent for LMICs with medical production capability sharing life-saving technology and medication with other LMICs: during the AIDS crisis, the Thai government collaborated with Indian vaccine manufacturers and African governments to produce and distribute antiretroviral drugs.[78] India is the world's largest vaccine manufacturer, producing 60% of vaccines globally, enabling one of the fastest COVID-19 vaccine rollouts of any nation.[43] Also, the dose production of mRNA vaccines is faster than that of cell-based vaccines, and the vaccines can be produced in existing facilities more easily in some cases.[79] Continued support from WHO would ensure consistency in vaccine quality and safety across all vaccine-producing countries.

For 19 LMICs, the barrier to producing and distributing vaccines is not a lack of capacity and infrastructure to manufacture vaccines but rather the result of pharmaceutical companies preventing access to vaccine technology in order to protect profit margins. Pharmaceutical companies seek to profit from the work of LMICs with capacity for large-scale vaccine production, demonstrating that the decision to prevent LMICs from producing vaccines is not based on material capacity. Pfizer has announced a business deal with Eurofarma Laboratórios SA, a Brazilian biopharmaceutical company, to manufacture COVID-19 vaccines for distribution within Latin America. Moderna plans to build its own mRNA vaccine production site in South Africa while still denying the South Africa WHO mRNA hub access to vaccine technology, preventing South Africa from producing vaccines autonomously and ultimately ensuring large profits for Moderna.[80] LMICs that currently do not have the capacity for vaccine production are still affected by these profit-driven decisions on the part of pharmaceutical companies. As demonstrated by Moderna and Pfizer in South Africa and Latin America, leading pharmaceutical companies have the means to both promote autonomous infrastructure for vaccine production and share vaccine technology with LMICs that currently do not have capacity, but they have chosen not to do so in the interest of protecting profits. Furthermore, historic technology hoarding on the part of pharmaceutical companies and HICs may be a disincentive for LMICs to prioritize developing large-scale vaccine production infrastructure.

There is meaningful precedent for medical expertise being adapted efficiently and effectively in LMICs. The Medical Education Partnership Initiative (MEPI) is another example of how rapidly expertise can be learned and adapted. MEPI was established to support medical education, enhance research capabilities, and ensure sustainability in sub-Saharan Africa from 2010 to 2015. More than $130 million went to medical schools in 12 different countries. MEPI monitoring and evaluation was dynamic and allowed to

change according to need. Because there was local control, the pool of potential partners was larger than when outside funders were the only ones involved. More than 1,000 manuscripts were submitted, along with 552 applications for grants and fellowships. Of these applications, 34% (187) were successful. MEPI fellows have mentored 866 students and postgraduates.[81]

People in low- and middle-income countries will not take available vaccines: Opponents of equitable global distribution of COVID-19 vaccines argue that if provided the chance to become vaccinated, populations from LMICs would simply refuse the vaccine. This is not supported by evidence: COVID-19 vaccine acceptance rates are generally higher in LMICs than in HICs. Studies conducted in 2020 revealed that average acceptance rates across 24 LMICs in Asia, Africa, and South America were significantly higher (80%) than in the United States (65%) and across seven HICs in Europe (74%).[82]

Studies assessing the data more closely have shown that some countries in sub-Saharan Africa such as Ethiopia, Nigeria, Uganda, and Malawi have universal acceptance rates of up to 98%, 86%, 85%, and 82%, respectively.[53] Data from Latin America and the Caribbean show a vaccine intention rate of 78%, and a study focusing on Southeast Asia revealed that 77% to 80% of respondents would take the vaccine.[83,84] In another study in South Asia, the percentages of respondents willing to be vaccinated against COVID-19 were 65%, 66%, 72%, and 74% in Bangladesh, India, Pakistan, and Nepal, respectively.[85] Rather than asking whether people from LMICs would get vaccinated, the question is whether they will receive the opportunity. Racism, colonialism, and oppression are the driving forces behind today's vaccine inequities.[86]

As of fall 2021, only 2% of low-income countries (LICs) had received one dose of the COVID-19 vaccine, in comparison with 30% of low- to middle-income countries, 54% of upper-middle-income countries, and 65% of high-income countries; in order to achieve a global vaccination rate of 70% by 2022 as set by WHO, LICs would have had to significantly increase their daily COVID-19 vaccination rates by as much as 24-fold.[87,88] Despite these goals and the increased need to prioritize vaccinations for high-risk groups, as of June 2022 LICs were able to provide primary series vaccinations for only 28% and 37% of their older adult and health care worker populations, respectively.[88,89] While shocking, this is not the first time in history when low-resource areas such as Africa were deprived of life-saving resources; during the HIV epidemic, some countries were unable to access antiretroviral therapy.[90]

Countries receiving PEPFAR funding are meaningful examples of how LMICs have leveraged existing public health infrastructure to increase access to COVID-19 vaccines and prevention resources. As a

result of expanded PEPFAR funding, Zambia was able to administer nearly 2 million COVID-19 vaccines as of January 2022 and engage 500 health facilities across the country in supporting COVID-19 vaccination efforts. Similarly, Eswatini has been able to expand vaccination efforts, leverage existing HIV treatment infrastructure, and collaborate with community organizations to increase COVID-19 vaccinations across the country, and South Africa has used the funds to support existing efforts of community health workers and increase resources for health staff (e.g., personal protective equipment, medical equipment, and transportation for medical staff).[91] In addition, COVID-19-responsive adaptations to HIV treatment resources in countries with PEPFAR funding created more opportunities to expand public health messaging about COVID-19, contact tracing, and COVID-19 screenings that are uniquely effective given the preexisting relationships between community members and local community health organizations that often work in collaboration.[92] Health care workers in LMICs also adapted existing infrastructure of PEPFAR-funded public health services to mitigate interruptions in maternal health care and continue offering tuberculosis screening services, both of which were negatively affected by the spread of COVID-19.[93] The effectiveness of expanded support in countries currently receiving PEPFAR funding shows that there are numerous examples of LMICs with existing public health infrastructure that, when supported through multinational economic cooperation, is successful in mitigating the effects of pandemics. Furthermore, as noted above, global public health crises are not new phenomena, and as such there are existing infrastructures in place that, with continued economic investment and solidarity from HICs, have the capacity to increase access to health care services and vaccines and have already been strategically adapted by LMICs to meet national health care needs.

In a world where many countries are excluded from the vaccine marketplace and there are enough vaccines available to vaccinate countries up to eight times over, there is no denying that vaccine apartheid, racism, colonialism, and oppression are the driving forces behind the vaccine inequities that exist today.[90,94] As the pandemic progresses, new strains of the virus driven by viral evolution will continue to manifest and worsen, with a high likelihood of increased transmissibility and immune escape and a risk of increased virulence. Without equitable vaccine distribution, we will continue to experience significant COVID-19 transmission, hospitalizations, and deaths.[89]

Patents are a necessary reward to encourage pharmaceutical innovation: A purported benefit of strong patent protections is a greater incentive for innovation resulting in more novel medications. However, stronger IP protection has been associated with higher drug costs, less access to medications, and a proliferation of slightly modified products of little or no additional therapeutic value created entirely to extend monopoly prices protected by patents.[38] Assessments of the actual investment by

pharmaceutical companies in pioneering R&D to develop truly innovative drugs estimate that up to 80% of the industry's R&D spending goes toward me-too drugs, which are replicas of previously created drugs and do not add any clinical value to medical treatment. Furthermore, it is estimated that in the United States about two thirds of funding for R&D of pharmaceutical products comes from public sources, and all of the 210 new drugs approved by the FDA between 2006 and 2016 received funding from the National Institutes of Health.[54] COVID-19 vaccines are no exception: the U.S. government is estimated to have spent between $18 billion and $23 billion on the development of COVID-19 vaccines, including hundreds of millions of dollars of investments in the mRNA platform, more than $900 million in support of nonclinical studies and research to accelerate movement of candidate vaccines into clinical trials, $2.7 billion in funding to pharmaceutical companies to cover expenses related to human trials, about $3 billion in manufacturing investments, and decreases of market risk through advance purchase contracts for a value of at least $12 billion.[95]

Development of a global strategy for patent relations is blocked by complex, obstructive patent policies across countries that cannot be untangled: The current asymmetry of power between HICs and LMICs is the most important consideration and barrier to progress. A TRIPS waiver would have opened the door for much wider vaccine production and access, and such a waiver was requested by many LMICs but blocked by Germany and Switzerland and not demanded by other HICs.[96]

However, there have been efforts at global solutions to patent protections. In response to the HIV/AIDS epidemic, the Medicines Patent Pool (MPP) was founded in 2010, and private pharmaceutical companies voluntarily agreed that LMICs could access licensed essential medicines.[97] LMICs thus can identify existing patents on needed medications and advocate for lower rates or generic production. This library of information includes medications for HIV, hepatitis C, and tuberculosis and newly added COVID-19 data. It forms a basis for an expanded data set of patents in a centralized location. Also, when patents have been included in the MPP, there has been a large increase in licensing of life-saving medications and an increase in generic drug supplies.[98,99] In 2021, Merck and Pfizer allowed the manufacture of molnupiravir and Paxlovid for treatment of COVID-19.[100] The agreement with Merck involved 27 generic companies spanning 11 countries (Bangladesh, China, Egypt, India, Indonesia, Jordan, Kenya, Pakistan, South Africa, South Korea, and Vietnam). The more recently created WHO COVID-19 Technology Access Pool offers additional paths to development. These examples illustrate the potential for voluntary collaboration and decreases in the current power asymmetry.

As the ability to expand pharmaceutical production evolves in LMICs and regional cooperatives, TRIPS waivers will offer even more opportunities. Even without waivers, however, the improved capacity to develop vaccines and therapeutics locally will have benefits in responding to global pandemics and more local epidemics. Populations may be even more receptive to locally developed vaccines than imports (often delayed and near expiration). Continued investments in LMICs' infrastructure and research by HICs can advance global health.[96]

U.S. government officials are doing everything they can to help vaccinate the world: In 2021, the U.S. government stated its commitment to bolstering vaccine production and contributing to global vaccine efforts through initiatives such as COVAX.[101] The U.S. executive branch verbally supported waiving patents for COVID-19 vaccines (TRIPS) but has yet to follow through. Vaccine apartheid exists, in large part, because of American pharmaceutical companies' corporate greed and the lack of accountability for the U.S. government and its role in the unequal distribution and manufacturing of COVID-19 vaccines. The Defense Procurement Act can still be used to push Moderna mRNA vaccine production worldwide because it was developed with U.S. taxpayer dollars.[55]

Action Steps

The COVID-19 pandemic continues to devastate communities at local, national, and global levels, both in terms of morbidity and mortality from the disease and negative economic effects. Ensuring timely and equitable access to medical products for the prevention and treatment of COVID-19 is vital to limiting further impact of the pandemic. COVID-19 is not a problem that individual countries can solve alone; rather, it is the responsibility of countries with access to vaccines to show global solidarity and share life-saving information and technology. This policy statement demonstrates APHA's strong support for global vaccine development efforts and rapid dissemination of the tools needed for countries to develop, manufacture, and deliver effective vaccines. Therefore, APHA:

- Calls on the U.S. president and the U.S. trade representative to actively work with international leaders to negotiate a waiver for patent enforcement under the TRIPS Agreement.
- Calls on WHO and HIC governments to commit additional financial and other resources to support broader vaccine production.
- Calls on pharmaceutical companies to voluntarily pledge nonenforcement of IP rights and to share the IP and technology needed to produce treatments and vaccines.
- Calls on WHO, HIC governments, and LMIC governments to ensure that, once vaccines are available in LMICs, they are administered for free and that other barriers to individuals receiving vaccines are reduced to the extent possible.

- Calls on the U.S. president, the director of the Centers for Disease Control and Prevention, and Congress to repeal non-evidence-based immigration and asylum policies implemented under the auspices of COVID-19 precautions.
- Calls on international government leaders to commit financial and other resources to build public health and clinical infrastructure to shore up near- and long-term preparedness.
- Calls on U.S. government leaders and international government leaders to provide financial assistance, food and water assistance, and plentiful home testing kits to low-income workers and those who work in the informal economy in order to ameliorate the effects of the pandemic.
- Calls on the broader public health community, including but not limited to local health departments, academic centers, nongovernmental organizations, nonprofit organizations, and local grassroots community groups, to support education efforts intended to address misinformation and potential vaccine reluctance.
- Calls on public health experts to educate the public and Congress about the ecological and food production causes of COVID-19 and to oppose factory farming and deforestation.

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