

Global Inequity of COVID-19 Vaccines Manufacture and Distribution

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ABSTRACT

This research review is aimed at understanding the reasons for the growing disparity of globally unvaccinated lower-income populations. The mitigative global initiatives whose goal is to increase the equity of COVID-19 vaccination across all populations. Context regarding the fast pace of which coronavirus vaccines were researched and manufactured is discussed from the three varying perspectives: the scientific community, global affairs, and the manufacturers of the vaccine. Finally, the impact on equity is analyzed with the passing or vetoing of the intellectual property waiver for pharmaceutical companies' vaccine patents.

An Overview of the Global Vaccine Inequity

A major dilemma the world faces during the pandemic is the global inequity regarding COVID-19 vaccine distribution. Factors that can limit any country's access to this are as simple as raw material availability and even qualified personnel to work in the manufacturing facilities. However, the inequity in quality vaccine access occurs when a low-income country is unable to afford dosages or support local production. The World Health Organization (WHO) has been working towards the goal of global immunity since the emergency approval of the first mRNA vaccines in late 2020. With vaccine donations from the Organization for Economic Co-operation and Development (OECD) member countries, a path to global immunity is slowly being achieved. However, with the rise of new variants, low-income countries fall even farther behind as vaccine demands exceed donation supply, and large pharmaceutical companies such as Johnson and Johnson, AstraZeneca, and Pfizer enforce the patents on their vaccine technologies.

To aid in minimizing the inequity, the WHO oversees the global vaccine hub that allows low-income countries to research and develop vaccine alternatives for their local communities. Additionally, the World Trade Organization (WTO) is in charge of managing the international discussion for an intellectual property waiver regarding vaccine patents, with the assurance that it will increase global immunity.

Ironically, the rise of the Omicron variant has indefinitely postponed the international conference meant to discuss the waiver (Khodor, 2022). Ultimately, to understand the request for an intellectual property waiver from the WTO, three main spheres need to be analyzed for a holistic comprehension of the effects the waiver may have.

The first sphere to consider is that of the scientific community. All research that has been conducted on vaccines is still relatively new. One of many benefits is that research is self-correcting. Therefore, with more data accrued from multiple sources, the development of vaccines is accelerated and so logically, global immunity would also increase accordingly. However, with the influx of data also comes misinformation as it takes time for errors to be corrected in the process. Overall, this sphere explores whether the patents protecting the pharmaceutical companies' vaccines could stifle or promote an innovative approach toward global immunity.

The next sphere that will be explored is that of government and world affairs. Being that the spread of variants and lack of access to vaccines has prolonged the pandemic, understanding the legal perspective of the US intellectual property laws provides insight as to how the waiver could potentially alter or bypass patent laws. The benefits that low-income countries may gain from this waiver must also be investigated to better understand the legal affairs.

The final sphere required to best analyze the effects of a vaccine patent waiver is the pharmaceutical companies' long-term strategic goals. From a general overlook, these companies are what control the manufacturing as well as distribution of immunity. Referring to the long-term strategic goals of the leading pharmaceutical companies, termination of vaccine production while IP licenses protect their manufacturing process begs to question the implications on low-income countries' vaccinated populations. The driving force behind manufacturing a vaccine is mainly due to funding incentives, so if the incentive is diminished by the passing of a waiver, a low-income country that depends on donated dosages may have to change its path towards immunity to a more self-sufficient path. These populations will encounter financial hardships if they are to pay high sums for vaccine licenses, in the event that they are able to afford the license. In addition to the monetary analysis, another complication resulting from patent protection is the increased cyber-espionage attacks. These cyberattacks aimed to steal private data from the pharmaceutical companies may have caused them to further focus their time on strengthening their defenses rather than perfecting the vaccine production and distribution.

The Scientific Perspective

Ongoing research on the COVID-19 pandemic directly impacts the vaccine manufacturing process, creating a continuously evolving environment.

At the beginning of the pandemic, when research regarding the coronavirus was difficult to find or follow, many vaccine manufacturers researched the mRNA process. Two of the widely used vaccines by Pfizer and Moderna utilize this process where the messenger RNA holds the genetic instructions to replicate the antigen (*mRNA Vaccines*, 2022). This process allows for immunity to be created without the virus itself being introduced to the system as in the case of Johnson and Johnson and AstraZeneca vaccines.

While the well-known vaccines utilize this mRNA translation process, there are many other options that have proven to be cheaper to produce and distribute around the globe. Overall, the WHO had set a goal in 2021, to “vaccinate 10% of every country's economy and territory by the end of September” however, as the date to discuss the waiver agreement has been indefinitely postponed, this goal falls further and further from being achieved (World Health Organization, 2021). With the three most prominent variants spreading globally, the need for a cheaper vaccine for middle and low-income countries has become increasingly necessary.

Does the waiver stifle scientific innovation?

The scientific community's main argument against waiving vaccine intellectual property rights is the possibility that providing access would stifle innovative strategies to combat the mutating virus. This section of the review will provide recent case studies to introduce various perspectives to this argument.

A South African group of scientists have been able to reverse engineer the Moderna mRNA vaccine without access to vaccine patents. With the help of the WHO, the company, Afrigen Biologics had a major breakthrough when replicating the vaccine. The reason this is possible is due to Moderna waiving its rights to patent protection for the duration of the pandemic (*Moderna*, 2020). This statement has allowed Afrigen Biologics to further its research and recently create the first of its dosages to begin testing on mice (Maxmen, 2022). While there are still many steps left in the production of this vaccine, this is one of many positive examples of how loosening IP restrictions could alleviate the strain of vaccine demand around the world while consequently increasing innovation.

Conversely, the Afrigen Biologic's study does not come without its own downfalls. If each smaller pharmaceutical company had access to Pfizer or Moderna's vaccine patents, the demand for raw materials to mass-produce the vaccines would cause a global shortage. Interestingly enough, even the larger manufacturers have had to re-invent their own manufacturing processes due to material shortages. For example, a Pfizer employee was recognized by the company when she led an effort to produce large quantities of the required lipid membrane for their vaccine in-house

(Silver, 2022). This further pushes the argument that having the large manufacturers' intellectual property freely available would cause even greater demand as smaller companies compete to gain control of required instruments and materials.

To better visualize the disparity between vaccine equity around the world, data sets, provided by Our World in Data, compare a high-income country and a low-income country's vaccinated populations. In Figure 1, the percentage of people in the US and South Africa who have received at least one dose of the COVID-19 vaccine is displayed in a graphical format. Analyzing the graph reveals that there was no data available for South African populations until April 2021. However, the Pfizer vaccine had been approved in early December 2020.

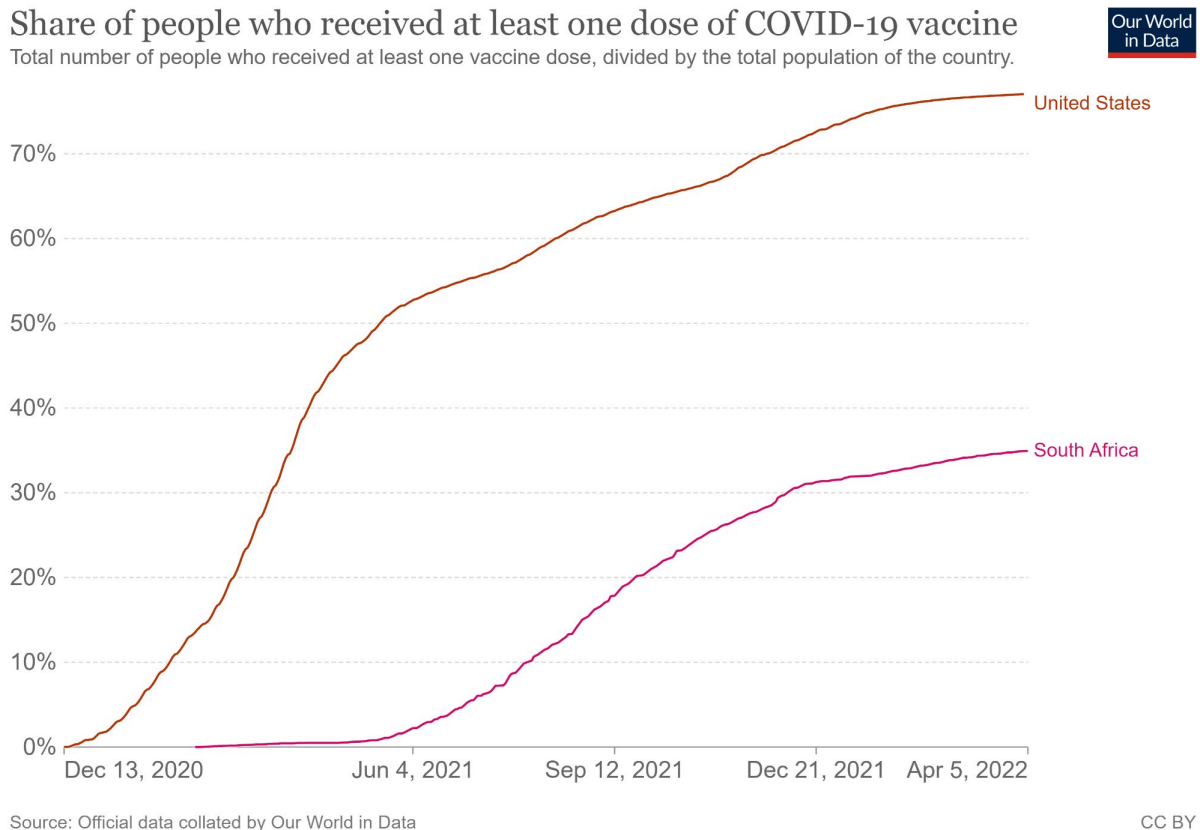


Figure 1. Percentages of US and South African Populations with at Least a Single Vaccine

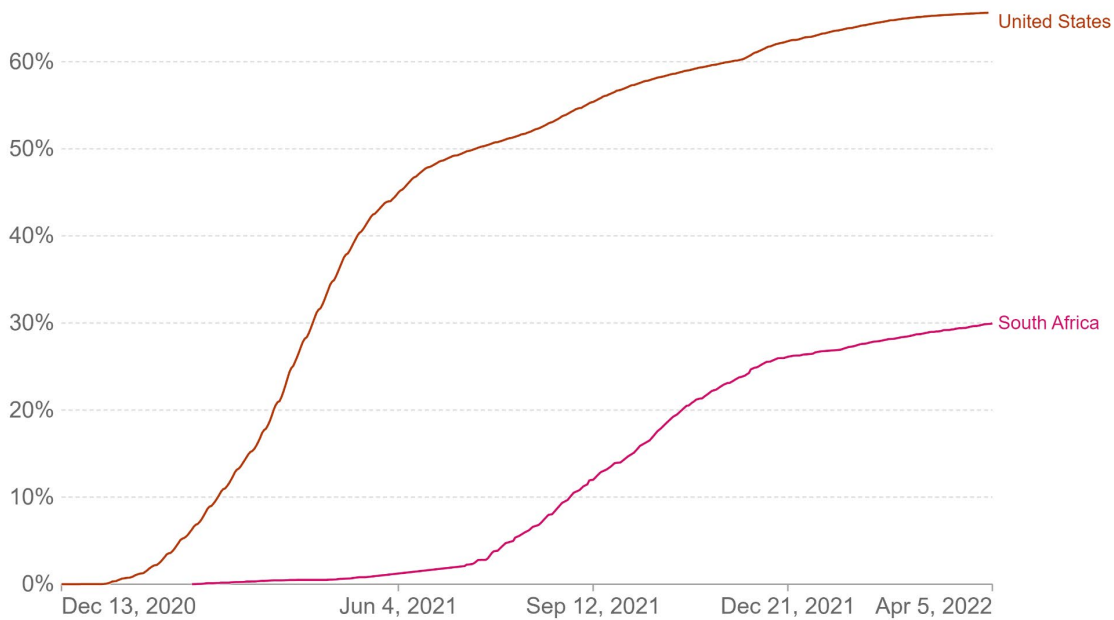
Note. Data provided by Our World in Data. Copyright 2019 by the Our World in Data CC BY license.

An important discussion to be made is that the lack of data was not due to a lack of reporting, but due to the lack of available vaccines to distribute to the population. Additionally, Figure 1 is only demonstrating the population of people who received the first dose and not the boosters which are useful for defending against variants of the virus.

In Figure 2, the data retrieved from people who were fully vaccinated in the US and South Africa is presented. Using the goal set out by the WHO as a benchmark, this data set demonstrated that over 10% of South Africa's population had been vaccinated. This primary goal was achieved prior to September as set out by the WHO. However, the secondary goal to have more than 30% by the end of 2021 has yet to be reached.

Share of people who completed the initial COVID-19 vaccination protocol

Total number of people who received all doses prescribed by the initial vaccination protocol, divided by the total population of the country.



Source: Official data collated by Our World in Data

Note: Alternative definitions of a full vaccination, e.g. having been infected with SARS-CoV-2 and having 1 dose of a 2-dose protocol, are ignored to maximize comparability between countries.

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Figure 2. Percentages of US and South African Populations with Full Vaccination Status

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While this is only a single case study regarding South African populations, the gap between vaccinated populations in high-income countries in comparison to low-income countries continues to grow with the increase in variants of the virus. As the high-income countries create new boosters, the low-income countries are still in need of the initial vaccine doses for their populations.

In a study presented by the U.S. Government Accountability Office (GAO), the large pharmaceutical companies were investigated to determine if the timeline with which the vaccines were needed would be met by 2021. The investigation titled, *Operation Warp Speed*, found that “five of the six OWS vaccine companies had started commercial sale manufacturing” (*Operation Warp Speed*, 2021). The pressured timeline was necessary because of the lack of medical interventions on the market during the height of the pandemic, however, the same manufacturing limitations still apply a year after this investigation was conducted. The limitations for manufacturing that the large companies faced included a lack of space for facilities, supply chain shortages, and an overall lack of a skilled workforce.

To combat the need for the same raw materials, one obvious solution would be to utilize other methods of creating immunity. For instance, a Texas research team is using more traditional methods of vaccine production to create the CORBEVAX vaccine. In 2003, the SARS outbreak initially caused the need for researching its own vaccine. However, the outbreak did not last long and the promising research at the time was stored away. Being that the coronavirus is a later derivative of the SARS virus, the research on the protein subunit vaccine could be quickly altered to work for the coronavirus. In manufacturing this vaccine, the team reduced the overall cost per dose to approximately \$1.50 (Palca, 2022). The Texas Children’s Center of Vaccine Development created its vaccine using a protein subunit rather than using a lipid or mRNA foundation. This process is useful for low-income countries as it is cheap to manufacture and obtain the required materials. In addition, to assist with the goal of global immunity, CORBEVAX will not have any patent restrictions. Their company motto is that some protection against the virus is better than none

(Palca, 2022). The CORBEVAX vaccine has proven to be effective against both the Alpha and Delta variants, however, the results against the Omicron variant are less promising. The clinical tests have almost entirely taken place in India, where the majority of the population has yet to receive even its first dose of vaccines from large manufacturers.

The Global Affairs Perspective

As the pandemic and the variants continue to spread globally, the inequity in vaccines is a pressing issue low-income countries and isolated communities face. In terms of how intellectual property law is applied to vaccines, the WHO claims that for a majority of “existing vaccines, patents are not a barrier to production” (World Health Organization, 2010). This same issue is applicable to the various COVID-19 vaccines being mass-produced. Some of the major issues cited by the WHO were focused on how IP is managed, especially how many low-income countries lack skills in negotiating licenses.

There are many organizations that have pledged their support toward creating strategies to mitigate the lack of funding for low-income countries. Among the various world organizations, the WHO, the Gavi the Vaccine Alliance (GAVI), and the Coalition for Epidemic Preparedness Innovations (CEPI), are the three main leaders of the COVAX program. The COVAX program is an initiative that optimizes the development and production of COVID-19 vaccines and guarantees vaccine equity for all countries affected by the pandemic (Gavi, 2022). This program acts as an insurance policy for the high-income countries, while simultaneously allowing lower-middle-income countries a guaranteed set of pre-funded vaccines. This guarantee is held accountable by the Advanced Market Commitment (AMC), which ensures a safeguard for all the parties involved in the COVAX program. Overall, the high-income countries are funding the up-front costs of a set amount of doses, while vaccine approval is discussed. The excess funding then is considered to be a donor contribution for the lower-income countries that cannot afford to buy the quality vaccine sets in bulk up-front.

An example of this multilateral approach would be how in August of 2021, the US government provided over 100 million vaccine donations, however simultaneously, the government privately funded the research and development of the Moderna vaccine (White House Briefing Room, 2021). The funding allows low-income and middle-income countries that have limited or no access to vaccines to have access to a percentage of donated vaccine doses (Gavi, 2022). Ultimately, the WHO wants to ensure that at least some protection against the virus is made for even the most remote communities.

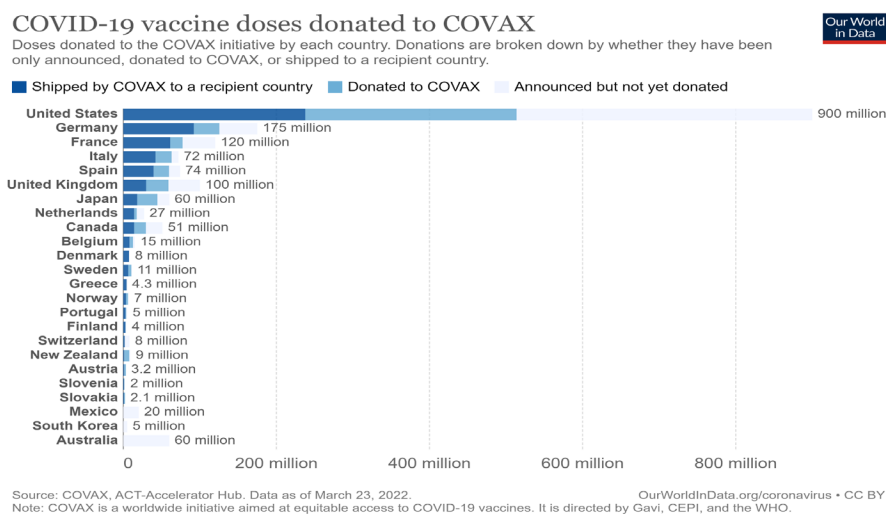


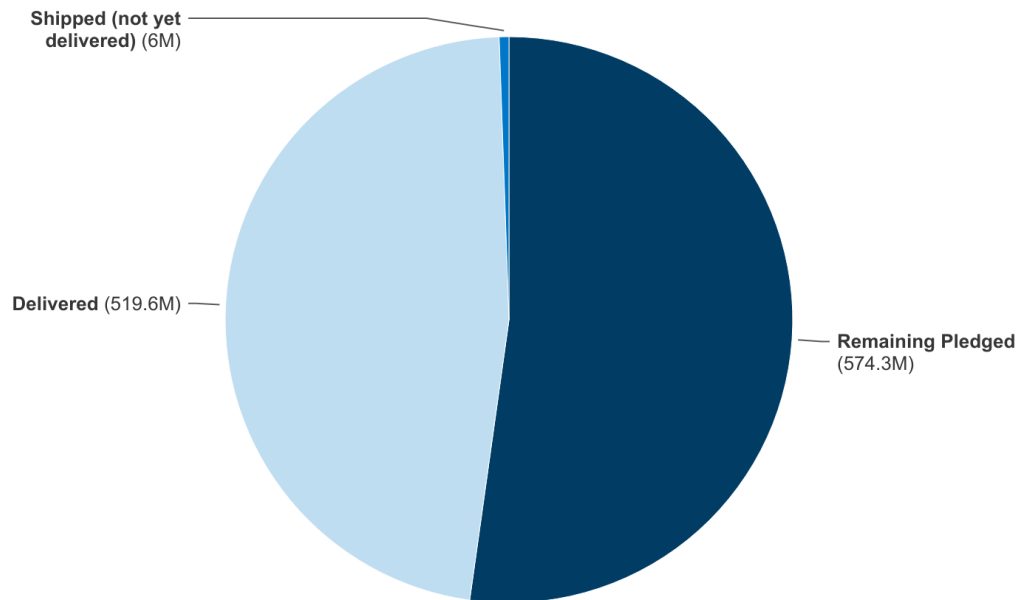
Figure 3. COVID-19 vaccine doses donated to the COVAX Program

Note. Data provided by Our World in Data. Copyright 2019 by the Our World in Data CC BY license.

The COVAX program has had much success in acquiring donations from various countries that are members of the OECD. Figure 3 displays the reported vaccine doses that have been pledged and donated to the COVAX program. Additionally, as observed by the large margin of vaccines in Figure 3, the United States has been leading the effort to donate vaccines abroad. According to the Kaiser Family Foundation (KFF) vaccine tracker, the United States has pledged to donate at least 1.1 billion doses abroad (KFF, 2022). In Figure 4, the ratio of vaccines that have been delivered to those that are remaining from the large pledge is almost reaching the midway point.

U.S. COVID-19 Vaccine Dose Donations Pledged that Have Been Shipped and Delivered

To date, the U.S. has pledged to donate at least 1.1 billion doses.



NOTE: Data as of April 21, 2022.
SOURCE: U.S. State Department



Figure 4. United States’ vaccine dose donation pledge and current statistics

Note. Data provided by KFF. Copyright 2022 by the KFF CC BY-NC-ND 4.0 license.

In the grander scope, the vaccine donations have allowed many low-income countries to have access to a set of vaccines for their most at-risk populations. However, the overall issue of global vaccine inequity still stands. As more donations for vaccine funding or doses are pledged and shipped abroad, it is important to ask whether the gap between the inequity has been lessened or if these combined donation efforts are not enough.

Supporting an Intellectual Property Waiver for Vaccines

While the mitigation strategies the WHO has assisted in have been somewhat successful, the WTO has been advocating for an intellectual property waiver for COVID-19 vaccines in order to have an even greater impact with respect to global distribution. The discussion for this waiver allows for analysis regarding the benefits and issues that arise when global affairs are interwoven with the current status of the US patent system.

In order to best understand how the waiver will hypothetically affect various vaccine manufacturing and distribution processes, an analysis from the pharmaceutical perspective as well as the global perspective is necessary.

In an article published by Brookings, the author argues for the restructuring of the current US Intellectual Property and Patent laws (Lindsey, 2021). As previously mentioned by the WHO, the main conflict is the lack of negotiation skills when it comes to buying vaccine licenses for low-income countries (World Health Organization, 2010). If the means to produce vaccines can be negotiated well, both the country in need and the pharmaceutical company is favored. In the article, Lindsey argues that the current patent law protects the big pharmaceutical companies from having virtually any competition in the global market.

As the patent system currently operates, it protects the entire process of manufacturing the vaccines from the beginning of research to the final product. On a global scale, this causes issues for other competitor companies from the US or abroad as they are blocked from access to the market to further innovate vaccines. In addition to the overarching argument, Lindsey argues that the US government should use varying tactics to promote an equal playing field for the vaccine manufacturers. An idea that was discussed by experts in the field, is the public funding of a vaccine, to provide a direct incentive from the government to the pharmaceutical company. The US government did utilize this reactive strategy with Moderna to provide upfront funding for vaccine development, however, it was not as effective as projected. While many billion-dollar research donations were contributed, the government still had virtually no control over the patented process of the company (Sagonowsky, 2020). Overall, unless the low-income country receives training for license negotiations, the issues have been left unmitigated.

Another option discussed by author Omar Khodor (2022), in the University of Pennsylvania's publication, *The Regulatory Review*, required international pressure from other OECD countries to push the US to enforce provisions on vaccine patents. The approach would be for a government provision on the Moderna and Pfizer vaccine patents to ultimately increase vaccination rates in low-income countries. While in theory, this idea solves the main issue of vaccine inequity, Khodor explains how it simultaneously creates an imbalance between government and private company innovation. This provision would allow the US government to hypothetically release the intellectual property of these companies with no repercussions. This would directly increase the vaccination rates, as low-income countries would have access to the process to create them locally. However, in regard to global supply, a bottleneck may ensue if each smaller pharmaceutical company attempts to make a cash grab for a highly sought product. Additionally, for the Pfizer and Moderna companies, their privately funded research would be accessible by all countries globally. This concept raises more ethical questions on how to protect the manufacturer's intellectual property rights while also providing equal access to quality vaccines. From a more general perspective, these issues may lead many to question whether the US patent system needs restructuring to be more applicable to modern-day world affairs.

The Manufacturer's Perspective

To best discuss this next perspective, it is important to remark that the pharmaceutical industry is a business industry like any other profit-based company. With this contextual lens, monetary incentives are one of the major driving factors for the companies. Most often with the production of other vaccines, like the HIV vaccine, financial gain takes precedence over saving lives (Marriott & Maitland, 2021). The pharmaceutical market is like any other market where monopolies are in charge of levying the price of vaccines and competition is scarce. The respective government then has little-to-no leverage to dispute the production and selling margins. An ethical question to be aware of then is: what factors are preventing the large pharmaceutical companies from halting the production of the vaccines in the late-pandemic timeline?

In an analysis of the cost of production for the vaccines, the Pfizer vaccine licenses have been well-over paid for by the high-income countries. However, even in low-income countries like Uganda, history is seen to repeat itself as health workers in the past had died of HIV “because the medicines that could save them were priced too high” (Marriott & Maitland, 2021). The analysis continues to explain how the market has overpriced the production of the vaccines and made it virtually impossible for lower-income countries to purchase licenses or doses for their populations. The controversial prices from large pharmaceutical companies are being scrutinized under the lens of the global pandemic when large organizations like the WHO and WTO are advocating for global vaccine equity. The vaccine

manufacturers must now support their prices with reasons as to why their product is more expensive than another lesser-known competitor's product.

Ethical Hacking

When addressing vaccine inequity, the perspective of the large pharmaceutical company cannot be overlooked. In addition to the supply chain challenges during mass-production of the vaccine, pharmaceutical companies had to defend against cyberattacks aimed at their IP. When each superpower and manufacturer was racing to create viable vaccines for their populations and the world, Moderna faced a cyberattack from Chinese nationalists who attempted to steal clinical data. It caused Moderna to “shut down its plants and isolate its data centres across the world” in order to minimize the effects of the attack (Bhattacharya, 2021). This cyberattack begs the question of if it is ethical to steal data if it is to be utilized for the greater good and innovation of vaccines? The motive behind the attack was to improve vaccine quality as it was reported that the Chinese vaccines were not as effective during their initial clinical stages. Moderna is also not the first nor the last of the large companies that have faced a cyberattack regarding vaccine data. In a review written for *Reuters* by Jack Stubbs (2020), the cyberattacks for information have only increased during the pandemic as “attackers ranging from state-backed spies to cybercriminals hunt” for any valuable data. The main reasoning behind these attacks may not be to further innovation, however, for low-income countries' facilities, any leaked information is still vital as they are only just beginning the process of production. In the context of global health, our world has to determine when the goal for global immunity surpasses economic superiority.

Conclusion

The inequity the world currently faces is in part due to the profiteering of pharmaceutical companies. However, as previously discussed in earlier sections, the solution to inequity is not a linear path. Simply providing the processes for vaccine manufacturing alone is not beneficial for the pharmaceutical industry as a whole, as while there would be more competition from lower-middle-income producers, the monopolies previously established will still take precedence in the market. Additionally, the strain on the supply chain for materials needed to produce the vaccines, as well as the innovative staff needed to more effectively produce quality vaccines is another cause for concern. The discussions of the WTO regarding the waiver will have many conflicting arguments between the three spheres discussed, inclusive of the scientific community, world affairs/governments, and private pharmaceutical companies. The overarching goal to vaccinate 10% of every country's population and the global ethics regarding the state of the pandemic will ultimately be the decisive factors when the intellectual property waiver for vaccine patents is debated.

In the event that the waiver is accepted, the local production of vaccines is still an unknown risk factor, as many lower-income and lower-middle-income countries will not have the financial means to create facilities to produce the vaccines. The converse to this argument is the WHO's ability to introduce an increased number of COVAX manufacturing facilities to best mass-produce high-quality vaccine doses. While these mitigated strategies may be sufficient, the raw materials are ideally abundant in these situations.

In the event that the waiver is denied, the inequity would still be a leading concern for the WHO and the low-income countries aiming to be vaccinated. The government would have no legal authority to force the manufacturers to provide their intellectual property. Consequently, the mitigative approach of providing training to the lower-income countries to better negotiate vaccine licenses from the major companies becomes the greatest obstacle. This obstacle paired with the competitive over-priced production costs by the vaccine monopolies once again reinforces the inequity of global vaccine access.

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