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## Inequitable by Design: The Patent Culture, Law, and Politics Behind COVID-19 Vaccine Global Access

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**INEQUITABLE BY DESIGN:  
THE PATENT CULTURE, LAW, AND POLITICS BEHIND  
COVID-19 VACCINE GLOBAL ACCESS**

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Ximena Benavides\*

*COVID-19 vaccine access has been highly inequitable worldwide, with coverage depending largely on a country's wealth. By the end of 2021, 64.1% of people living in high-income countries had received at least one dose of the vaccine, compared to only 5.4% of those in low-income countries. Similarly, only high- and upper-middle-income countries had received the most effective vaccines.*

*The uneven distribution of these lifesaving vaccines is made complex due to the convergence of several factors, but it suggests that the extraordinary expanding and ossifying market and political power of a few vaccine manufacturers founded on intellectual property and complementary policies is a decisive factor in shaping our healthcare systems and securing equitable access to vaccines.*

*This Article analyzes the power dynamics of vaccine manufacturing and distribution of U.S. pharmaceutical companies in the context of global COVID-19 vaccination. Drawing on the health-justice and law-and-political-economy scholarship of the last decade, this Article demonstrates how a "patent culture" shaped by intellectual property law fundamentally neglects health-equity principles while politicizing healthcare access. These contemporary frameworks suggest that the global COVID-19 vaccine-access problem is the result of avoidable policy choices made by big manufacturers and affluent governments. Despite a long history of inequities in access to healthcare, policy choices—as predicted by Hart's inverse equity theory—have favored a purposely inequitable-by-design vaccination program driven by the wealth and power of those allowed to control vaccine production and supply globally.*

*Finally, this Article proposes ways to challenge the normalized and institutionalized*

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*patent culture that has commodified access to lifesaving medicines beyond national borders. As it examines national and international legal strategies to address the vaccine-access problem, the Article suggests equity-based principles of public value, transparency, and inclusivity to guide healthcare governance and future reformation of the vaccine-access landscape. An interdisciplinary analysis of the first year of the global vaccine rollout provides an account critical to future policies aiming to address the structural conditions needed to attain equitable health outcomes, even after the pandemic.*

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## I. INTRODUCTION

Healthcare inequity<sup>1</sup> has been a salient feature of the COVID-19 global vaccine rollout despite its large scale, which has been more massive than any other mobilization of people, resources, and planning since the Second World War.<sup>2</sup> Data from the first year of the COVID-19 vaccine deployment after its approval for emergency use in December 2020 shows dramatic gaps in global access to the lifesaving vaccines.

With about 49% of the global population fully vaccinated by the end of 2021, vaccines have been mostly administered in high- and upper-middle-income countries.<sup>3</sup> High-income countries have fully vaccinated nearly 75% of their population, whereas low-income countries have fully vaccinated only about 21%.<sup>4</sup> Distribution of the most effective vaccines against COVID-19 has not been equitable either; they have disproportionately gone to wealthy nations.<sup>5</sup> This is not primarily a problem of shortages but of distribution—vaccine surpluses in the United States were triple the quantity distributed in all eight African countries where the United States imposed a travel ban in response to the surge of the

1. The subject of study of this article is healthcare and equity. In contrast to *health*, which includes a broad group of factors that affect people's health conditions (housing, environment, employment, food system, sanitation, etc.), *healthcare* refers to the complex network of providers, products, and services involved in the delivery of medical care. Vaccines are products used in providing medical care. By *healthcare inequity*, this Article means differences in access to healthcare resources that are systematic, socially produced (thus, fixable and evitable), and unfair and unjust. Section IV develops the idea of inequity in healthcare further. This Article notes, though, that the terms *inequality* and *inequity* in healthcare have been used in equivalent manners, with the same connotations, in the public health community. See MARGARET WHITEHEAD & GÖRAN DAHLGREN, CONCEPTS AND PRINCIPLES FOR TACKLING SOCIAL INEQUITIES IN HEALTH: LEVELLING UP PART I (2006).

2. Peter A. Singer, *Vaccine Equity Will Be the Defining Challenge of 2021*, TORONTO STAR (Dec. 30, 2020), <https://www.thestar.com/opinion/contributors/2020/12/30/vaccine-equity-will-be-the-defining-challenge-of-2021.html> [https://perma.cc/LX5K-986Q].

3. See *Coronavirus (COVID-19) Vaccinations*, OUR WORLD IN DATA, <https://ourworldindata.org/covid-vaccinations> (last visited Dec. 11, 2021) (On top of the graph and to the right of "COVID-19 Data Explorer," select metric "People fully vaccinated," and check "Relative to Population."). On December 31, 2022, 3.89 billion people were fully vaccinated. Compared to the global population of 7.91 billion in 2021, this equates to about 49.17% of people being fully vaccinated. See Max Roser, Hannah Ritchie, Esteban Ortiz-Ospina & Lucas Rodés-Guirao, *World Population Growth*, OUR WORLD IN DATA, <https://ourworldindata.org/world-population-growth> (last visited Mar. 7, 2023) (Below the label "Population & Demography Data Explorer" to the left of the graphic, select country "World.").

4. *Coronavirus (COVID-19) Vaccinations*, OUR WORLD IN DATA, (On top of the graph and to the right of "COVID-19 Data Explorer," select metric "People fully vaccinated," and check "Relative to Population." In the column directly under "COVID-19 Data Explorer" select the boxes for "High income" and "Low income" under "country.").

5. Stephanie Baker & Vernon Silver, *Pfizer Fights to Control Secret of \$36 Billion Covid Vaccine Recipe*, BLOOMBERG (Nov. 14, 2021), <https://www.bloomberg.com/graphics/2021-pfizer-secret-to-whats-in-the-covid-vaccine/?sref=qneqM2kv?srnd=premium-europe> [https://perma.cc/2DQY-3V48].

Omicron variant.<sup>6</sup> These numbers demonstrating a deeply skewed vaccine distribution<sup>7</sup> suggest the vaccine-access problem is not one of low production or scarcity but rather the result of deliberate decisions to inequitably distribute vaccines to the world.

The reason behind the uneven global distribution of COVID-19 vaccines is complex to decipher due to the presence of several converging factors, including vaccine nationalism and artificial vaccine monopolies, among others. These are manifestations of *policy choices* central to the root causes of health disparities. The ability of a few actors to control vaccine production and supply, deciding who gets vaccinated—and who does not—exemplifies why the allocation of power through laws and policies shaping healthcare systems is a decisive factor in securing equitable access to vaccines (and more, broadly, to healthcare). By distributing power unevenly and inequitably, laws and policies result in the provision of healthcare in a way that affects health outcomes, favors the perpetuation and dissemination of stark health inequities, and undermines the structural foundation of healthcare systems' architectures, corrupting their mission by prioritizing economic self-interest over public health concerns.<sup>8</sup>

Using novel law-and-political-economy (LPE) and health-justice theoretical frameworks, this Article analyzes the power dynamics favored by intellectual property (IP) law in the healthcare sector and the context of global access and distribution of COVID-19 vaccines. The LPE project questions the utilitarian-efficiency approach to IP, guided for decades by the law-and-economics theory, and proposes a different institutional approach by urging a political examination of the drug "free market" that goes beyond economic efficiency. In turn, the health-justice movement argues that laws are determinants of health that can compound and perpetuate health disparities. This movement supports a health-equity approach that critiques existing intellectual-property laws and argues for greater pharmaceutical corporate and law and policy-making accountability. Together, these theoretical frameworks claim that the allocation of market and political power in healthcare systems supports inequities. On this view, global vaccine inequities are symptoms of a drug production model that is broken not only because of firms' single-minded pursuit of profits but also because of *poor policy*

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6. *Id.* (reporting the surpluses); Zain Rizvi, *Vaccine Apartheid*, PUB. CITIZEN (Nov. 29, 2021), [https://www.citizen.org/article/vaccine-apartheid/#\\_ftn1](https://www.citizen.org/article/vaccine-apartheid/#_ftn1) [<https://perma.cc/6B6C-FMEH>]. (background on travel ban).

7. See Rizvi, *supra* note 6.

8. See generally VICTOR MONTORI, *WHY WE REVOLT: A PATIENT REVOLUTION FOR CAREFUL AND KIND CARE* (2d ed. 2020) (discussing the corrupted mission of healthcare organizations).

*choices*. While the LPE project maps the fault lines of the vaccine production model and suggests a legal system-design problem, the health-justice movement brings awareness of the tragic consequences of a flawed legal system. Failing to ensure wide and quick access to safe and effective vaccines necessary to end the COVID-19 pandemic is not a bug in an overwhelmed system during exceptional times but rather a feature of coalescing legal policy choices, driven by wealth and power, influencing vaccine production.

This Article is divided into four sections. Section I describes global vaccine inequities during the first year of the COVID-19 vaccine rollout by examining four driving factors: vaccine population (who gets vaccinated and who does not), affordability and procurement (how much do vaccines cost and how vaccines are secured), opportunity (where is one's place in a vaccination queue), and deployment (how vaccines are administered to populations). Section II explains the main theoretical frameworks the Article uses: the LPE framework—and how it contrasts with the dominant law-and-economics theory—and the health-justice framework. Section III identifies the politics of vaccine inequities by analyzing the market and political power of the U.S. vaccine makers leading the development of mRNA COVID-19 vaccines. It concludes that despite a long history of inequities in access to healthcare, policy choices—as predicted by the inverse equity theory—have favored a purposely inequitable-by-design vaccination program driven by the wealth and power of manufacturers and governments who control vaccine production and supply globally. Finally, using the LPE and health-justice theoretical frameworks, Section IV proposes how to challenge the “patent culture,” which the U.S. pharmaceutical industry normalizes and institutionalizes, resulting in commodification of access to life-saving treatments. This Article examines national and international legal strategies to address the vaccine supply problem and suggests equity-based principles of public value, transparency, and inclusivity to guide reformation of the access-to-vaccines landscape.

This Article concludes that this particular global vaccine-access problem exemplifies how highly politicized access to healthcare has become more broadly. Although vaccine-supply strategies and outcomes will change over the pandemic, an interdisciplinary analysis focusing on the first year of the global vaccine rollout provides accounts that are critical if we are to address the root causes of inequity in healthcare and the pharmaceutical sector and develop policies to address the structural conditions necessary to attain equitable health outcomes, even after the pandemic.

## II. VACCINATING THE WORLD AGAINST COVID-19

At the end of 2019, the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)—or COVID-19, as the World Health Organization (WHO) named it<sup>9</sup>—was identified in Wuhan, China, and spread rapidly, resulting in a global pandemic.<sup>10</sup> The disease became one of the leading causes of death in 2020 in affluent and poor nations alike, including the United States.<sup>11</sup> A year after the first reported COVID-19-related death, in 2020 the coronavirus had caused at least 3 million cumulative deaths globally.<sup>12</sup>

Vaccines to prevent the spread of the COVID-19 infection—considered the most promising approach for curbing the global pandemic<sup>13</sup>—were developed and produced with unprecedented speed.<sup>14</sup> By the end of 2020, over 40 candidate vaccines were in human trials and over 150 were in preclinical trials.<sup>15</sup> A diversified COVID-19 vaccine portfolio included several different and new vaccine platforms. These included RNA or mRNA vaccines, which met WHO's requirements for emergency use.<sup>16</sup> The world's first known COVID-19 vaccine<sup>17</sup> dose in-

9. WHO Director-General's remarks at the media briefing on 2019-nCoV on 11 February 2020, WORLD HEALTH ORG. (Feb. 11, 2020), <https://www.who.int/director-general/speeches/detail/who-director-general-s-remarks-at-the-media-briefing-on-2019-ncov-on-11-february-2020> [https://perma.cc/5Z6L-CG4V].

10. WHO Director-General's opening remarks at the media briefing on COVID-19 – 11 March 2020, WORLD HEALTH ORG. (Mar. 11, 2020), <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020> [https://perma.cc/6YUW-JDRB]. The first case of COVID-19 was reported on December 8, 2019 in Wuhan city, in Central China. See Qun Li, Xuhua Guan, et al. *Early transmission dynamics in Wuhan, China, of Novel Coronavirus-Infected Pneumonia*. N, 382 NEW ENGL. J. MED. 1199 (2020), <https://www.nejm.org/doi/10.1056/nejmoa2001316>.

11. Farida B. Ahmad & Robert N. Anderson, *The Leading Cause of Death in the US for 2020*, 325 J. AM. MED. ASS'N. 1829 (2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8145781/> [https://perma.cc/S2XQ-ESEZ].

12. *The True Death Toll of COVID-19: Estimating Global Excess Mortality*, WORLD HEALTH ORG., <https://www.who.int/data/stories/the-true-death-toll-of-covid-19-estimating-global-excess-mortality> [https://perma.cc/ZAT3-F7S8] (last visited Dec. 5 2022).

13. ARTHUR BAKER, ESHA CHAUDHURI & MICHAEL KREMER, *ACCELERATING VACCINATIONS*, (Dec. 2021), <https://www.imf.org/external/pubs/ft/fandd/2021/12/Accelerating-Vaccinations-Baker-Chaudhuri-Kremer.htm> [https://perma.cc/XP7U-9KU4].

14. The mumps vaccine set the previous record for vaccine development and distribution, taking four years. Helen Branswell, *Why Covid-19 Vaccines Are a Freaking Miracle*, STAT (Feb. 14, 2022), <https://www.statnews.com/2022/02/14/why-covid-19-vaccines-are-a-freaking-miracle/> [https://perma.cc/E9AT-M]7G].

15. See *COVID-19 Vaccine Tracker and Landscape*, WORLD HEALTH ORG., <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines> [https://perma.cc/85DM-XWSS] (last visited March 3, 2022).

16. Walter Isaacson, *mRNA Technology Gave Us the First COVID-19 Vaccines. It Could Also Upend the Drug Industry*. TIME (January 11, 2021) <https://time.com/5927342/mrna-covid-vaccine/> [https://perma.cc/U887-CX4Z]; see *Regulation and Prequalification: Emergency Use Listing*, WORLD



oculation happened on December 8, 2020, in the United Kingdom, when a RNA vaccine produced by Pfizer-BioNTech was administered to a 91-year-old grandmother.<sup>18</sup>

By the end of 2021, 8.30 billion vaccine doses had been administered globally:<sup>19</sup> 45% of the global population was fully vaccinated<sup>20</sup> and 54% had received at least one vaccine dose.<sup>21</sup> However, these numbers did not approach WHO's target of 40% of the population of *every country* being fully vaccinated by the end of 2021.<sup>22</sup> Ninety-two countries did not meet WHO's vaccination target, the majority of them in Africa.<sup>23</sup> With the surge of many virus variants during the second half of 2021, scientists estimated that close to three times the number of doses of high-quality vaccines deployed in 2021 would be needed to bring the spread of the disease under control in 2022.<sup>24</sup>

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HEALTH ORG., <https://www.who.int/teams/regulation-prequalification/eul> [<https://perma.cc/Z78K-ZJ5N>] (last visited Mar. 9, 2023).

17. This Article will refer to COVID-19 vaccine candidates that WHO considered safe for emergency, although the COVID-19 vaccine candidates portfolio is larger (hereinafter, the "vaccines" or "COVID-19 vaccines"). See *COVID-19 Vaccine Tracker and Landscape*, WORLD HEALTH ORG., <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines> [<https://perma.cc/85DM-XWSS>] (last visited March 3, 2022).

18. *Covid-19 Vaccine: First Person Receives Pfizer Jab in UK*, BBC NEWS (Dec. 8, 2020), <https://www.bbc.com/news/uk-55227325> [<https://perma.cc/LCL6-RQ68>].

19. *Coronavirus (COVID-19) Vaccinations*, *supra* note 3 (select "vaccine doses" metric, "cumulative" interval, and "world" as country) (doses from Dec. 8, 2020 to Dec. 7, 2021) (Data updated Jan. 1, 2023).

20. According to the CDC, a person is considered fully vaccinated after completion of a two-dose mRNA series or one dose of the Janssen vaccine. See *Reporting COVID-19 Vaccinations in the United States*, CDC, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/reporting-vaccinations.html#:~:text=To%20ensure%20adequate%20time%20for,dose%20of%20Janssen%20vaccine> [<https://perma.cc/ACE5-G7D2>] (updated Mar. 9, 2023). This article notes that this definition may change with vaccine rollout, emerging variants, and booster shots becoming mandatory. See also Victoria Knight, *Is It Time to Change the Definition of "Fully Vaccinated"?*, KHN (Dec. 6, 2021), <https://khn.org/news/article/fully-vaccinated-definition-boosters-ambiguity/> [<https://perma.cc/3SCC-8DQE>].

21. *Coronavirus (COVID-19) Vaccinations*, *supra* note 3 (select "people vaccinated (by dose)" as metric, "cumulative" as interval, "world" as country, and move date marker to Dec. 7) (data updated Dec. 8, 2021).

22. WORLD HEALTH ORG., *STRATEGY TO ACHIEVE A GLOBAL COVID-19 VACCINATION BY MID-2022* (2021), [https://cdn.who.int/media/docs/default-source/immunization/covid-19/strategy-to-achieve-global-covid-19-vaccination-by-mid-2022.pdf?sfvrsn=5a68433c\\_5](https://cdn.who.int/media/docs/default-source/immunization/covid-19/strategy-to-achieve-global-covid-19-vaccination-by-mid-2022.pdf?sfvrsn=5a68433c_5) [<https://perma.cc/S3YN-G7ZP>]; see generally WORLD HEALTH ORG., *GLOBAL COVID-19 VACCINATION—STRATEGIC VISION FOR 2022* (2021), [https://cdn.who.int/media/docs/default-source/immunization/sage/covid/global-covid-19-vaccination-strategic-vision-for-2022\\_sage-yellow-book.pdf?sfvrsn=4827ecod\\_5](https://cdn.who.int/media/docs/default-source/immunization/sage/covid/global-covid-19-vaccination-strategic-vision-for-2022_sage-yellow-book.pdf?sfvrsn=4827ecod_5) [<https://perma.cc/6PT5-VZ9P>].

23. See *Coronavirus (COVID-19) Vaccinations*, *supra* note 3 (select "people vaccinated" for metric, "cumulative" for interval, set date marker to Dec. 8, 2021, and select each country in turn).. The majority of the population in 73 of the 92 countries had not received even a first dose.

24. Dan Diamond, *Advocates Call for 22 Billion More mRNA Vaccine Doses to Ward Off Global Omicron Threat*, WASH. POST (Jan. 5, 2022, 2:50 PM EST), <https://www.washingtonpost.com/world/2022/01/05/covidvaccine-22billion-doses-needed/> [<https://perma.cc/KC3C-786E>].

Vaccinations have lagged behind WHO's vaccination goal due to a *vaccine-access* problem.<sup>25</sup> Vaccine supply worldwide has been delayed due to a convergence of factors including limited supplies and production, delayed regulatory approval, and restricted exports of vaccines.<sup>26</sup> Because these factors and others to be explained in this section have not equally affected the global population, the vaccine-access problem has had a disproportionate impact on certain countries and regions.

To describe the vaccine-access problem, this section explores four drivers of inequitable access to vaccines: population (who gets vaccinated and who does not), affordability and procurement (how much vaccines cost and how vaccines are secured), opportunity (when the world will get vaccinated), and deployment (how vaccines are administered to populations).

#### A. *The COVID-19 Vaccine-Access Problem*

##### 1. Population

Although the development and approval of effective COVID-19 vaccines by the end of 2020 was promising from multiple vantage points, inequity in access to vaccines has been clearly evident from the beginning of the pandemic.

Forty-six percent of the global population was fully vaccinated by the end of 2021, though these vaccines were mostly administered in high- and upper-middle-income countries.<sup>27</sup> Nearly nine of every ten vaccinations in the world have gone to people in high- and upper-middle-income countries; this is sixteen more vaccinations per capita

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25. "Vaccine access" refers to inequities in access to healthcare. On the differences between inequities in healthcare access and health outcomes and the relevance of the United States shifting the conversation from access to outcomes, see generally Clare Bamba, Julia Lynch & Katherine E. Smith et al., *Pandemic Politics: Inequality Through Public Policy*, in *THE UNEQUAL PANDEMIC: COVID-19 AND HEALTH INEQUALITIES* (2021).

26. Baker et al., *supra* note 13. The document covers two factors that especially affect vaccine manufacturing capacity. First, based on historical data, developing vaccines can be risky and time-consuming. But COVID-19 vaccine formulation proceeded much faster than expected due to unusually large R&D investments by countries like the United States and the United Kingdom and the fact that vaccines for COVID-19 were easier to develop than those for diseases such as malaria and AIDS. Second, vaccine-producing facilities require regulatory approval. Because it is difficult to anticipate which vaccine candidates will work, it was hard to install manufacturing capacity in parallel with clinical trials.

27. See *Coronavirus (COVID-19) Vaccinations*, *supra* note 3.

than in poorer nations.<sup>28</sup> High-income countries fully vaccinated nearly seventy percent of their populations; low-income countries, only 3%.<sup>29</sup> 75% of the population in high-income countries was partly vaccinated; in low-income countries, only 7% of the population was.<sup>30</sup> These numbers exclude refugees, migrants, and asylum-seekers, unvaccinated populations who are beyond the reach of governments' vaccination plans.<sup>31</sup>

75% of the 3.8 billion vaccine doses administered globally as of June 26, 2021 have gone to only ten countries.<sup>32</sup> Although high- and upper-middle-income countries such as Canada, Chile, Japan, Portugal, and Spain had each vaccinated between 83 and 90% of their populations, vaccination was less than 2 to 8% in many low-income countries.<sup>33</sup> Africa is the region with the lowest vaccination rates, with only 12% of the continent's population partially vaccinated.<sup>34</sup> Low confirmed and reported deaths for COVID-19 in the populous region even prompted the indication that "Africa might not even need as many vaccines as the West," suggesting that populations with high rates of exposure to malaria were less likely to die from COVID-19.<sup>35</sup> But the data for Africa surely undercounts fatalities given the lack of testing and the limitations of official statistics.<sup>36</sup>

Low vaccination rates in Africa are not attributable to vaccine hesitancy. Vaccine hesitancy—the reluctance or refusal to vaccinate despite the availability of vaccines—has not been a major concern in low-income countries. In fact, data suggest that people in low- and middle-income countries (LMICs) have a considerably higher willingness to receive a COVID-19 vaccine than those in wealthy countries. A 2021 study

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28. See Josh Holder, *Tracking Coronavirus Vaccinations Around the World*, N.Y. TIMES (Oct. 30, 2022), <https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html> [https://perma.cc/6HKV-TANN].

29. See *Coronavirus (COVID-19) Vaccinations*, *supra* note 3.

30. See *id.* "Partly vaccinated" means vaccinated with one dose if one is administered a two-dose vaccine.

31. Francisco Guarascio & Panu Wongcha-um, *Refugees Lack COVID Shots Because Drugmakers Fear Lawsuits, Documents Show*, REUTERS (Dec. 16, 2021), <https://www.reuters.com/world/refugees-lack-covid-shots-because-drugmakers-fear-lawsuits-documents-2021-12-16/> [https://perma.cc/PY6L-RPVB].

32. GLOBAL COVID-19 VACCINATION—STRATEGIC VISION FOR 2022, *supra* note 22, at 12 (2021).

33. *Coronavirus (COVID-19) Vaccinations*, *supra* note 3.

34. Holder, *supra* note 28.

35. Maria Cheng & Farai Mutsaka, *Scientists Mystified, Wary, as Africa Avoids COVID Disaster*, AP NEWS (Nov. 19, 2021), <https://apnews.com/article/coronavirus-pandemic-science-health-pandemics-united-nations-fcf28a83c9352a67e50aa2172e01a2f> [https://perma.cc/9433-7W5S].

36. See *Tracking Covid-19 Excess Deaths Across Countries*, ECONOMIST (Oct. 20, 2021), <https://www.economist.com/graphic-detail/coronavirus-excess-deaths-tracker> [https://perma.cc/VR2X-VU4C].

found that LMICs showed a mean vaccine acceptance of close to 80%; in the United States the vaccine acceptance rate is only 64%.<sup>37</sup> A national survey carried out in August 2021 showed that Botswana had a 76% vaccine acceptance rate,<sup>38</sup> yet only 13.58% of its population was able to get fully vaccinated against COVID-19 by November 10, 2021.<sup>39</sup>

## 2. Affordability and Procurement

One of the biggest challenges low-income countries face is the availability of funds to vaccinate at scale.<sup>40</sup> The average cost to fully vaccinate a person is \$35, including the vaccine per-dose cost (which ranges between \$2 and \$40) and the distribution cost (\$3.70).<sup>41</sup> Considering that many low-income countries have an annual healthcare per-person budget of \$41, vaccine prices are a significant financial barrier for vaccination programs in poor nations.<sup>42</sup>

Vaccine affordability has had a direct impact on countries' vaccine procurement mechanisms. Poorer countries need to rely on vaccine donations or international health initiatives to provide funding for vaccine access. As part of the WHO's Access to COVID-19 Tools (ACT) Accelerator global initiative, the international vaccine distribution initiative COVID-19 Vaccine Global Access (COVAX)—administered by GAVI, the Vaccine Alliance—was formed to work, together with the Coalition for Epidemic Preparedness Innovations (CEPI), the United Nations Children's Fund (UNICEF), and WHO toward equitable vaccine funding and supply.<sup>43</sup> COVAX began distributing COVID-19 vaccines in 2021 with

37. Julio S. Solis Arce et al., *COVID-19 Vaccine Acceptance and Hesitancy in Low- and Middle-Income Countries*, 27 *NAT. MED.* 1385, 1386 (2021), <https://www.nature.com/articles/s41591-021-01454-y> [<https://perma.cc/NC9M-G9MH>]. The study compared COVID-19 vaccine acceptance rates of seven low-income countries (Burkina Faso, Mozambique, Rwanda, Sierra Leone, and Uganda), five in lower-middle-income countries (India, Nepal, Nigeria, and Pakistan), and one in an upper-middle-income country (Colombia) and compared findings to vaccine acceptance rates in the United States. *Id.*

38. *Learning From Botswana's COVID-19 Vaccine Rollout*, WORLD HEALTH ORG. (Aug. 19, 2021), <https://www.afro.who.int/news/learning-botswanas-covid-19-vaccine-rollout> [<https://perma.cc/29PW-RKZW>].

39. *Coronavirus (COVID-19) Vaccinations*, *supra* note 3.

40. Edward M. Choi, *COVID-19 Vaccines for Low- and Middle-Income Countries*, 115 *TRANSACTIONS ROYAL SOC'Y TROPICAL MED. & HYGIENE* 447, 449 (2021).

41. Philippa Nicole Barr, *Whipping the COVID-19 Vaccine Market into Shape*, GAVI (Sept. 27, 2021), <https://www.gavi.org/vaccineswork/whipping-covid-19-vaccine-market-shape> [<https://perma.cc/PM3J-5H3W>]; see also *Vaccine Affordability*, DATA FUTURES (last visited Dec 8, 2021), <https://data.undp.org/vaccine-equity/affordability/> [<https://perma.cc/BVG5-ECY4>].

42. *Vaccine Affordability*, *supra* note 40.

43. The Access to COVID-19 Tools (ACT) Accelerator is a global initiative to accelerate the development and production of and equitable access to COVID-19 tests, treatments, and vaccines.

the goal to deliver two billion doses to low-income countries in 2021, expected to be enough to protect at least 30% of their tions.<sup>44</sup> After a year of vaccine rollout, COVAX had shipped 934 million doses—less than half of its vaccine distribution goal.<sup>45</sup>

According to UNICEF, 76% of vaccines delivered to low-income countries have been sourced through COVAX, whereas 74% of vaccines deployed to high-income countries were self-procured through known bilateral and multilateral agreements.<sup>46</sup>

As has happened with vaccine races in the past,<sup>47</sup> rich countries—individually or through alliances<sup>48</sup>—secured a substantial number of COVID-19 vaccine doses for their own populations through pre-production agreements even before vaccines were fully developed, tested, and approved by the relevant regulatory authority.<sup>49</sup> Thus, a few countries with substantial economic power were able to reserve most of the early supply of vaccines for their populations.<sup>50</sup> Failing to vaccinate the world exposes even wealthy nations to the risks of variants and a never-ending pandemic.<sup>51</sup> Nonetheless, this vaccine nationalism has undermined global solidarity and the equitable and inclusive distribution of COVID-19 vaccines to LMICs through COVAX.<sup>52</sup> By early 2021,

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See *The Access to COVID-19 Tools (ACT) Accelerator*, WORLD HEALTH ORG., <https://www.who.int/initiatives/act-accelerator> [https://perma.cc/WA89-JB9X] (last visited Oct. 12, 2022).

44. Seth Berkley, *If We're Not Careful, Booster Vaccines Could End Up Giving the Coronavirus a Boost*, GAVI (Aug. 9, 2021), <https://www.gavi.org/vaccineswork/if-were-not-careful-booster-vaccines-could-end-up-giving-the-coronavirus-a-boost>, [https://perma.cc/SKA4-SDZV].

45. COVAX, by March 2023, has since shipped over 1 billion COVID-19 vaccines to 144 participants (including some high- and upper-middle-income countries). See *COVAX Vaccine Roll-out: Country Updates*, GAVI, THE VACCINE ALLIANCE, <https://www.gavi.org/covax-vaccine-roll-out> [https://perma.cc/3FLP-SDS5] (last updated Jan. 17, 2022).

46. Donato Paolo Mancini, Chelsea Bruce-Lockhart & Andres Schipani, *Covax Falts as Rich Countries Buy up Covid Vaccines*, FIN. TIMES (Oct. 24, 2021), <https://www.ft.com/content/0e240929-033a-457f-a735-ec7cf93b2f3c> [https://perma.cc/ZE79-QTDQ]; see also Jean Shaoul, *Global Vaccine Inequality: "A Policy Decision by the Rich Countries"*, WORLD SOCIALIST WEB SITE (Dec. 3, 2021), <https://www.wsws.org/en/articles/2021/12/04/vacc-d04.html> [https://perma.cc/28SJ-VEP3].

47. Ana Santos Rutschman, *The Reemergence of Vaccine Nationalism*, GEO. J. INT'L AFF.'S (2020); forthcoming, Saint Louis U. Legal Studies Research Paper No. 2020-16), <http://dx.doi.org/10.2139/ssrn.3642858> [https://perma.cc/R87X-XEJL] (referring to the use of advance commitment agreements in the 2009 H1N1 vaccine race).

48. A. Kayum Ahmed, *Decolonizing the Vaccine*, AFRICA IS A COUNTRY (June 24, 2020), <https://africasacountry.com/2020/06/decolonizing-the-vaccine> [https://perma.cc/6GD2-YGJ4] (discussing the alliance of France, The Netherlands, Germany, and Italy).

49. Ana Santos Rutschman, *The COVID-19 Vaccine Race: Intellectual Property, Collaboration(s), Nationalism and Misinformation*, 64 WASH. UNIV. J. L. POL'Y 167, 183 (2021).

50. *Id.* at 184.

51. See *infra* section II-B.

52. The COVAX vaccine supply was severely affected by India's vaccine nationalism—an internal crisis forced it to ban vaccine exports and focus on domestic rollout. See Sarah Newey, *Another Blow for Global Vaccine Rollout as India Looks Set to Extend Export Ban Until October*, TELEGRAPH

when models predicted there would not be enough vaccines to cover the world's population until 2023,<sup>53</sup> affluent countries representing 18% of the world's population had already amassed the majority of vaccine orders worldwide.<sup>54</sup> As most affluent countries purchased enough vaccines to vaccinate their populations—several times over in some cases<sup>55</sup>—poor countries could only access vaccine leftovers, if any were available. Rich nations which financially contributed to the development of vaccines exercised their political and economic power to hoard vaccine doses.<sup>56</sup> Manufacturers have argued they had no choice but to give most of their production to the richest governments.<sup>57</sup> Additionally, “vaccine diplomacy” contributed to “biased donations,” as countries decided on vaccine donations that had more to do with geopolitical relationships than public health concerns.<sup>58</sup>

Manufacturers were well aware of their control over vaccine supply and knew that the primary supply mechanism for poor countries was donations.<sup>59</sup> Nonetheless, controlling vaccine supply disrupted donations rather than favor or increase them. For instance, by the second half of 2021, vaccine manufacturers pushed hard for rich countries to administer booster doses, which contributed to those countries dishonoring their vaccine donation commitments.<sup>60</sup> In the end, the control over vaccine supply had a discriminatory effect over some populations with respect to vaccine access. Affluent countries have not done enough to prevent this from happening.

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(May 18, 2021), <https://www.telegraph.co.uk/global-health/science-and-disease/another-blow-global-vaccine-rollout-india-looks-set-extend-export/> [https://perma.cc/H3M3-CB3U].

53. *More Than 85 Poor Countries Will Not Have Widespread Access to Coronavirus Vaccines Before 2023*, ECONOMIST INTEL. (Jan. 27, 2021), <https://www.eiu.com/n/85-poor-countries-will-not-have-access-to-coronavirus-vaccines/> [https://perma.cc/SZ5C-DRXJ].

54. Aisling Irwin, *What It Will Take to Vaccinate the World Against COVID-19*, NATURE (Mar. 25, 2021), <https://www.nature.com/articles/d41586-021-00727-3> [https://perma.cc/DG8Z-YJYT].

55. Gordon Brown et al., *The G7 Must Act to Vaccinate the World*, PROJECT SYNDICATE (Apr. 15, 2021), <https://www.project-syndicate.org/commentary/g7-must-finance-equitable-global-covid19-vaccine-access-by-gordon-brown-et-al-2021-04> [https://perma.cc/4KR4-YFSK].

56. *See infra* section II-A.

57. Shaoul, *supra* note 46 (“In the U.S., we were told we had no choice but to give 60 percent of our output to the US government.”); *see also* Stephanie Baker, Cynthia Koons & Vernon Silver, *Inside Pfizer's Fast, Fraught, and Lucrative Vaccine Distribution* (Mar. 4, 2021, 5:00 AM EST), <https://www.bloomberg.com/news/features/2021-03-04/pfizer-pfe-has-a-moral-dilemma-deciding-where-the-vaccines-will-go?sref=raq2brko> [https://perma.cc/QKT3-237Y].

58. *See* Thomas J. Bollyky, Christopher J L Murray & Robert C Reiner, Jr., *Epidemiology, Not Geopolitics, Should Guide COVID-19 Vaccine Donations*, 398 LANCET 97 (2021).

59. Pfizer's approach has been “let us control supplies and we'll work with countries to increase donations.” *See* Baker & Silver, *supra* note 5.

60. *See* discussion *infra* Section II.A.4.

### 3. Vaccine Deployment

By the end of 2021, ten distinct COVID-19 vaccines were approved by WHO.<sup>61</sup> Although all offered strong protection against severe disease, clinical reports have shown that some vaccines offer higher effectiveness than others.<sup>62</sup> The U.S. Centers for Disease Control & Prevention (CDC) endorsed a clinical preference for Pfizer-BioNTech and Moderna, the only mRNA vaccines approved by WHO.<sup>63</sup> Oxford-AstraZeneca and Novavax vaccines also had high degrees of effectiveness.<sup>64</sup> Oxford-AstraZeneca was distinguished for its lower production cost and easier storage, but its distribution in the United States was cancelled because of quality problems.<sup>65</sup> Novavax has been shown to be simpler to manufacture, but its emergency use was not approved by WHO until late December 2021.<sup>66</sup>

The most effective vaccines were distributed to wealthy nations.<sup>67</sup> At the beginning of the vaccine rollout, Oxford-AstraZeneca, Moderna, and Pfizer-BioNTech vaccines were sent overwhelmingly to wealthy countries.<sup>68</sup> Throughout the year, Oxford-AstraZeneca took a different path; it licensed its formula to an Indian producer and led the way in supplying Western vaccines to poorer nations.<sup>69</sup> In contrast, through the second quarter of 2021, Moderna expanded from not supplying to

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61. COVID-19 Vaccine Tracker, WORLD HEALTH ORG., <https://covid19.trackvaccines.org/agency/who/> [<https://perma.cc/Q2TG-NH6U>] (last visited Dec. 27, 2021). The ten vaccines approved for use by WHO are Moderna (mRNA-1273), Pfizer/BioNTech (BNT162b2), Janssen-Johnson & Johnson (Ad26.COV2.S), Oxford/AstraZeneca (AZD1222), Serum Institute of India-Covishield (Oxford/AstraZeneca formulation), Bharat Biotech (Covaxin), Sinopharm-Beijing (BBIBP-CorV (Vero Cells), Sinovac (CoronaVac), Novavax (NVX-CoV2372), and Serum Institute of India-COVAVAX (Novavax formulation).

62. See Kathy Katella, *Comparing the COVID-19 Vaccines: How Are They Different?*, YALE MED. (Feb. 24, 2021), <https://www.yalemedicine.org/news/covid-19-vaccine-comparison> [<https://perma.cc/Z9GV-CBJH>].

63. *Id.* Note that three COVID-19 vaccines are administered in the United States, including Johnson & Johnson's. The Pfizer-BioNTech vaccine was approved by the FDA in August 2021, and Moderna's was approved in January 2022. The U.S. indicated its vaccine preference through travel bans prohibiting entrance into the country to non-citizen visitors vaccinated with, for example, Sputnik V. See Adam Taylor, *New U.S. Travel Rules Close Door on Those Fully Vaccinated with Russia's Sputnik V*, WASH. POST (Sept. 27, 2021), <https://www.washingtonpost.com/world/2021/09/27/us-travellers-sputnik-russia/> [<https://perma.cc/EA3L-KSPB>].

64. See *id.*

65. Chris Hamby & Sheryl Gay Stolberg, *Beneath a Covid Vaccine Debacle, 30 Years of Government Culpability*, N.Y. TIMES (Dec. 23, 2021), <https://www.nytimes.com/2021/12/23/us/covid-vaccine-biden-trump.html> [<https://perma.cc/9T6A-D248>].

66. Katella, *supra* note 62. The WHO approved Novavax for emergency use in December 2021, so data on its usage is not included in this Article.

67. Baker & Silver, *supra* note 5.

68. *Id.*

69. *Id.*

barely supplying upper-middle- and lower-middle-income countries. According to Moderna, export restrictions and early supply commitments to the United States and Europe prevented it from supplying any place other than the wealthy countries.<sup>70</sup> Still, Moderna has largely only supplied the United States, not other high-income countries.<sup>71</sup> Pfizer-BioNTech had initially been the largest COVID-19 vaccine supply source for the richest countries. But during the second half of 2021, Pfizer-BioNTech sped up vaccine deliveries outside the wealthiest countries, and by November 7, 2021, out of the two billion vaccine doses delivered by Pfizer, more than 658 million doses went to LMICs.<sup>72</sup>

In summary, people in LMICs have not been able to access enough vaccines and those they have been able to access are of lower-efficacy. From the pool of most effective COVID-19 vaccines approved by WHO, supply to LMICs has been dominated by Oxford-AstraZeneca vaccine, whereas supply to high-income countries has been dominated by Pfizer-BioNTech and Moderna. By the end of 2021 it was widely recognized that the mRNA vaccines—Pfizer-BioNTech and Moderna—were the most effective vaccines against the coronavirus.<sup>73</sup>

The inequitable supply of the most effective vaccines raises not only moral questions of health justice<sup>74</sup> but also public health issues, including problems of herd immunity, the necessity of vaccine boosters in shorter periods of time, and vaccination distrust and hesitancy based on low efficacy among other concerns.

#### 4. Vaccine Opportunity

With the vaccine supply model in place, LMICs were left with no other option but to get vaccinated late in the queue. Pfizer has publicly claimed that it will be able to vaccinate the entire world by the middle of 2022.<sup>75</sup> However, at the 2021 vaccination pace, studies have shown that

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70. *Id.*

71. *See id.*

72. *Id.* *See also* Press Release, Pfizer, Pfizer and BioNTech to Provide 500 Million Doses of COVID-19 Vaccine to U.S. Government for Donation to Poorest Nations (June 10, 2021), <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-500-million-doses-covid-19>, [<https://perma.cc/58LZ-7928>]

73. Diamond, *supra* note 24.

74. *See infra* section IV.

75. Baker & Silver, *supra* note 5.



many LMICs will not achieve widespread vaccination coverage before the first four years of the pandemic.<sup>76</sup>

In late July 2021, when only 5% of the population of LMICs were fully vaccinated,<sup>77</sup> affluent nations moved toward a vaccine booster policy. The same wealthy countries that overwhelmingly procured vaccines for their populations began to administer booster shots, initially for immunocompromised and elder populations and later for anyone age twelve and older.<sup>78</sup> WHO, seconded by many other global health organizations and initiatives, called on countries to put the booster policy on hold so poorer countries could access more vaccines.<sup>79</sup> The number of booster shots administered daily and globally until November 1, 2021, was three times the number of vaccines administered daily in low-income countries.<sup>80</sup> While governments in wealthy countries—like the United States and the United Kingdom—had prioritized booster vaccines, the majority of the population in LMICs—especially in Africa and the Indian subcontinent—had not received a first dose. According to the CDC, 37.5 million people had received a COVID-19 vaccine booster dose in the U.S.—a number higher than the number of people (30.25 million) who had received a single dose in the eight African countries that were the subject of the United States’ travel ban imposed in response to the surge of the Omicron variant.<sup>81</sup>

Critically, wealthy economies’ prioritization of booster shots over global vaccination compromised vaccine global supply as vaccine hoarding by a few increased and forced COVAX to rely heavily on

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76. Ingrid T. Katz, Rebecca Weintraub, Linda-Gail Bekker, & Allan M. Brandt, *From Vaccine Nationalism to Vaccine Equity—Finding a Path Forward*, 384 *NEW ENGL. J. MED.* 1281 (2021) (“our current global vaccination rates of roughly 6.7 million doses per day translate to achieving herd immunity (70 to 85% of the population having received a two-dose vaccine) in approximately 4.6 years”), <https://www.nejm.org/doi/full/10.1056/NEJMp2103614> [<https://perma.cc/S9NZ-QL32>].

77. See *Coronavirus (COVID-19) Vaccinations*, *supra* note 3 (data as of Aug. 1, 2021) (select “people fully vaccinated” for metric, “lower-middle income” for country, “cumulative” for interval, and check the “relative to population” box).

78. See Berkley, *supra* note 44 (referring to booster policies in wealthy countries).

79. *Id.*

80. See Donato Paolo Mancini & John Burn-Murdoch, *Global COVID-19 Death Toll Tops 5m but Underestimates True Figure, Say Experts*, *FIN. TIMES* (Nov. 1, 2021), <https://www.ft.com/content/35a3d40a-f71f-4fca-893d-884fec5633d8> (providing information of boosters available and administered since August 2021, according to WHO’s chief scientist, Soumya Swaminathan).

81. Rizvi, *supra* note 6; see also, Nandita Bose & Davod Shepardson, *U.S. Imposes Travel Ban From Eight African Countries Over Omicron Variant*, *REUTERS* (Nov. 27, 2021, 2:32 AM EST), <https://www.reuters.com/world/us/us-impose-travel-curbs-eight-southern-african-countries-over-new-covid-19-2021-11-26/> [<https://perma.cc/5P2Z-TNKS>]; *COVID Data Tracker*, CDC, [https://covid.cdc.gov/covid-data-tracker/#vaccinations\\_vacc-people-booster-percent-total](https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-booster-percent-total) (view Historic Vaccination Data) (last visited Feb. 6, 2023).

pledged donations, even as many pledges were not fully delivered.<sup>82</sup> GAVI's chief executive officer signaled to public health problems and the inefficiency that a vaccination policy that distributes "a third [booster] before it is absolutely necessary" would represent to the global vaccine supply.<sup>83</sup> Wealthy countries did not deliver the donations they committed to, and long before the end of 2021 COVAX recognized it would miss its 2021 vaccination target by more than 25%.<sup>84</sup>

Vaccination statistics demonstrate that the vaccine-access problem is not one of low vaccine production, but rather one of a deliberately inequitable distribution and an unwillingness to vaccinate *all* of the world. By the end of 2021, wealthy countries were expected to have a cumulative surplus of between 1.06 to 1.2 billion vaccine doses, out of the 12 billion vaccine doses produced.<sup>85</sup> As a result of rich countries ordering more doses than needed for their populations, such a vaccine surplus was unsurprising. By March 2021, there was already speculation that rich countries would have vaccine surpluses to donate.<sup>86</sup> The uncomfortable truth is that despite a surplus of vaccines in the rich world, LMICs received far fewer doses of vaccines than the volume they were led to expect. Inequities in access to vaccines have worsened, while supply has increased.

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82. The United States called a decision in favor of boosters over donations a "false choice," meaning that its administration was capable of doing both and calling on the global community—particularly, the G7—to do more. See *Covid-19 Vaccine Market Dashboard*, UNICEF, <https://www.unicef.org/supply/covid-19-vaccine-market-dashboard> [https://perma.cc/DKA7-F7E9] (last visited Dec. 3, 2021); see also Press Briefing by Press Secretary Jen Psaki, WHITE HOUSE (Aug. 4, 2021, 12:52 PM EDT), <https://www.whitehouse.gov/briefing-room/press-briefings/2021/08/04/press-briefing-by-press-secretary-jen-psaki-august-4-2021/> [https://perma.cc/9E8F-L6XL]; Antoine de Bengy Puyvallée & Katerini Tagmatarchi Storeng, *COVAX, vaccine donations and the politics of global vaccine inequity*, GLOBALIZATION AND HEALTH, Mar. 2022, at 6, <https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-022-00801-z> [https://perma.cc/3VM2-5GU9].

83. See Berkley, *supra* note 44.

84. Nick Dearden, *Vaccine Apartheid: The Global South Fights Back*, ALJAZEERA (Sept. 30, 2021), <https://www.aljazeera.com/opinions/2021/9/30/vaccine-apartheid-the-global-south-fights-back> [https://perma.cc/Y23B-WRSY]. COVAX 2021 vaccination target was 2 billion COVID-19 vaccines. See Press Release, UNICEF, COVAX Joint Statement: Call to Action to Equip COVAX to Deliver 2 Billion Doses in 2021 (May 27, 2021), <https://www.unicef.org/press-releases/covax-joint-statement-call-action-equip-covax-deliver-2-billion-doses-2021-0> [https://perma.cc/DTW6-JMHA].

85. *G20 Should Redistribute Surplus COVID-19 Vaccines, Ex-Leaders Say*, REUTERS (Oct. 28, 2021, 7:11 PM), <https://www.reuters.com/business/healthcare-pharmaceuticals/g20-should-redistribute-surplus-covid-19-vaccines-ex-leaders-say-2021-10-28/> [https://perma.cc/R8G5-BA9N]; see also Dearden, *supra* note 84; Barr, *supra* note 41.

86. Jon Cohen & Kai Kupferschmidt, *Countries Now Scrambling for COVID-19 Vaccines May Soon Have Surpluses to Donate*, SCIENCE (Mar. 9, 2021), <https://www.science.org/content/article/countries-now-scrambling-covid-19-vaccines-may-soon-have-surpluses-to-donate>, [https://perma.cc/GB6M-22EH].

A comprehensive and faster global vaccine rollout also was frustrated by vaccine manufacturers who did not permit other countries to scale up vaccine production.<sup>87</sup> At the beginning of COVID-19 vaccine production, manufacturers claimed that scaling production to satisfy the global demand would be very difficult, especially for novel mRNA vaccines.<sup>88</sup> Manufacturers blamed low production on a short supply of the raw materials used to produce the vaccines. Scholars have counter-argued that mRNA manufacturing “is even easier to scale” because mRNA vaccines require chemical, rather than biological, processes.<sup>89</sup> Vaccine makers also argued that vaccines were too complex to make in less-wealthy countries to justify their reluctance to expand production facilities abroad.<sup>90</sup> However, developing countries such as Bangladesh, India, Indonesia, and South Africa,<sup>91</sup> and even other countries such as Canada,<sup>92</sup> contend that they are capable enough and ready to mass-produce vaccines.<sup>93</sup> In fact, 80 to 90% of the world’s medicines are already produced in these countries.<sup>94</sup>

### B. Immediate Consequences of the Vaccine-Access Problem

Prolonging the pandemic is a concern not only for LMICs, but for the broader international community. Vaccine nationalism, vaccine di-

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87. Big pharmaceutical companies are not concerned with lowering production costs by producing in other countries. *See infra* section IV.

88. Irwin, *supra* note 54.

89. Amy Kapczynski, *How to Vaccinate the World, Part 1*, LPE BLOG (Apr. 30, 2021), <https://lpeproject.org/blog/how-to-vaccinate-the-world-part-1/> [perma.cc/DV68-4AQ6].

90. *Id.*

91. Regarding the factories with new equipment to produce COVID-19 vaccines, see Maria Cheng & Lori Hinnant, *Countries Urge Drug Companies to Share Vaccine Know-How*, AP NEWS (Mar. 1, 2021), <https://apnews.com/article/drug-companies-called-share-vaccine-info-22d92afbc3ea9ed519be007f8887bcf6> [perma.cc/XW9B-DJSU].

92. Regarding Ontario’s Biolyse Pharma Corp.’s capacity to produce up to twenty million doses per year, see Mari Serebrov, *Canadian Company to J&J License, or Else . . .*, BIOWORLD (Mar. 15, 2021), <https://www.bioworld.com/articles/504737-canadian-company-to-jj-license-or-else> [perma.cc/2UW6-D89C].

93. The Editorial Board, *A Global Covid Vaccine Heist: India and South Africa Want the WTO to Vitiolate Private U.S. Patents*, WALL ST. J., (Nov. 19, 2020), <https://www.wsj.com/articles/a-global-covid-vaccine-heist-11605829343> [perma.cc/BEQ3-49SD]; *see also* Stephanie Nolen, *Here’s Why Developing Countries Can Make mRNA Covid Vaccines*, N.Y. TIMES (Oct. 22, 2021), <https://www.nytimes.com/interactive/2021/10/22/science/developing-country-covid-vaccines.html> [perma.cc/2ZF9-K2TS].

94. Sarah Newey, Jennifer Rigby & Anne Gulland, *Vaccinating the World: the Obstacles Hindering Global Rollout—and How to Overcome Them*, TELEGRAPH (June 1, 2021, 4:54 PM), <https://www.telegraph.co.uk/global-health/science-and-disease/vaccinating-the-world/> [perma.cc/7ZVC-QEFA] (referring to declarations of Abdul Muktair, Chairman and Managing Director of Incepta Pharmaceuticals in Bangladesh).

plomacy, and manufacturers' control of vaccine supply risk prolonging the pandemic.<sup>95</sup> The risk of infection by new variants is high without global vaccination. On average, a major new COVID-19 variant has been detected every four months during the pandemic.<sup>96</sup> "Variants of concern" with high transmissibility, such as Delta and Omicron, emerged in areas with lower vaccination rates. Variants may cause more severe disease and may result in first-generation vaccines becoming outdated and obsolete as billions remain unvaccinated due to lack of access.<sup>97</sup> History reminds us how variants cause peak mortality in past pandemics, such as influenza.<sup>98</sup> As a result of uncontrolled outbreaks and higher risks of spread of virus variants in a globalized world, global health security weakens, and the world remains exposed to an increased risk of a never-ending pandemic.

As the pandemic continues in LMICs, the number of cases and deaths continues to rise and healthcare systems become overwhelmed, facing collapse. Controlling the virus' spread through extended lockdowns (despite material impossibility) leads to school closures or transitions to remote learning (when available); workplaces with reduced personnel, interrupted operations, or permanent closure; increased gender disparities; collapsed healthcare systems and exhausted health workers; and a myriad of others negative consequences that undermine populations' fundamental rights and delay economic recovery.<sup>99</sup>

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95. Gregg S. Gonsalves & Fatima Hassan, *Vaccine Nationalism Is Killing Us: How Inequities in Research and Access to SARS-CoV-2 Vaccines Will Perpetuate the Pandemic* (Martin Delaney Presentation), YOUTUBE, (2021), [https://www.youtube.com/watch?v=2ZYxBQHq8&feature=emb\\_title](https://www.youtube.com/watch?v=2ZYxBQHq8&feature=emb_title) [perma.cc/LQH9-UBMJ].

96. Rehan M. El-Shabasy, et al., Three waves changes, new variants strains, and vaccination effect against COVID-1 pandemic. 204 *Int. J Biol Macromol*, 161-168. April 15, 2022 (referring to different variants identified in three waves over the first year of the corona virus).

97. U.N. DEVELOPMENT. PROGRAMME, BEYOND RECOVERY: TOWARDS 2030 (2021), <https://www.undp.org/publications/support-vaccine-equity-beyond-recovery-towards-2030> [perma.cc/GG5C-NDWZ] (stating that first-generation vaccines may become ineffective in less than a year as a result of a convergence of variants); see *Scientists Warn New COVID Mutations in a Year as Vaccines Stall*, ALJAZEERA (Mar. 30, 2021), <https://www.aljazeera.com/news/2021/3/30/scientists-warn-new-covid-mutations-in-a-year-as-vaccines-stall> [perma.cc/RB7W-TUVG].

98. John M. Barry, *What We Can Learn from How the 1918 Pandemic Ended*, N.Y. TIMES, (Jan. 31, 2022) <https://www.nytimes.com/2022/01/31/opinion/covid-pandemic-end.html> [https://perma.cc/6NP9-L72X] (referring to the 1918, 1957, 1968, and 2009 influenza pandemics, and how such variant precedents should make us wary).

99. See Julie Turkewitz & Mitra Taj, *After a Year of Loss, South America Suffers Worst Death Tolls Yet*, N.Y. TIMES (Apr. 29, 2021), <https://www.nytimes.com/2021/04/29/world/americas/covid-latin-america.html>; see also Gregg Gonsalves, Opinion, *The Moral Danger of Declaring the Pandemic Over Too Soon*, N.Y. TIMES (Feb. 17, 2022), <https://www.nytimes.com/2022/02/17/opinion/aids-pandemic-covid.html>.

In economic terms, prolonging the pandemic by failing to vaccinate the world could cost the world economy an estimated \$22 trillion.<sup>100</sup> WHO estimates that a more equitable vaccination plan would enable the United States and nine other industrialized nations to accrue between \$153 billion (in 2020–2021) and \$466 billion (by 2025) in economic benefits.<sup>101</sup> With longer projections and greater reach, the UNDP has reported that for the first time in thirty years, global human development is on course to decline<sup>102</sup> and one-eighth of the global population could be living in extreme poverty by 2030 as a result of the COVID-19 pandemic.<sup>103</sup> In other words, equitable vaccine allocation can dictate the pace and extent of economic recovery.<sup>104</sup>

Vaccine inequities undermine trust in public health agencies and organizations. As vaccines become instruments of power wielded by those few groups who decide what to produce and to whom to distribute, global society becomes suspicious that manufacturers' true motives are prioritizing profits over health. Some of the mistrust also stems from a long history of medical disenfranchisement and infamous experiments conducted by the wealthy on certain populations without disclosure and consent. This history has raised suspicions about the healthcare system at large and led to vaccine skepticism based on racial discrimination claims,<sup>105</sup> especially in the United States, given the exploitation of Black people by the medical system since the days of slavery.<sup>106</sup>

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100. See Gita Gopinath, Petya Koeva Brooks, Malhar Nabar & Raphael Anspach, *Transcript of the World Economic Outlook Update Press Briefing*, INT'L MONETARY FUND (Jan. 28, 2021), <https://www.imf.org/en/News/Articles/2021/01/28/tr012621-transcript-of-the-world-economic-outlook-update-press-briefing>. Vaccine nationalism alone could cost rich countries \$4.5 trillion. See *Study Shows Vaccine Nationalism Could Cost Rich Countries US\$4.5 trillion*, INT'L CHAMBER COM. (Jan. 25, 2021), <https://iccwbo.org/media-wall/news-speeches/study-shows-vaccine-nationalism-could-cost-rich-countries-us4-5-trillion/> [<https://perma.cc/C7SS-BRL7>].

101. *Global Equitable Access to COVID-19 Vaccines Is Estimated to Generate Economic Benefits of at Least US\$ 153 Billion in 2020–21, and US\$ 466 Billion by 2025, in 10 Major Economies, According to New Report by the Eurasia Group*, WORLD HEALTH ORG. (Dec. 3, 2020), <https://www.who.int/news/item/03-12-2020-global-access-to-covid-19-vaccines-estimated-to-generate-economic-benefits-of-at-least-153-billion-in-2020-21> [<https://perma.cc/9TUK-K6EE>].

102. UNDP, COVID-19 AND HUMAN DEVELOPMENT: ASSESSING THE CRISIS, ENVISIONING THE RECOVERY 6, <http://hdr.undp.org/en/hdp-covid> [<https://perma.cc/A6VZ-JUBU>].

103. *Impact of COVID-19 on the Sustainable Development Goals*, SDG INTEGRATION (Dec. 2020), <https://sdgintegration.undp.org/accelerating-development-progressduring-covid-19> [<https://perma.cc/KST5-ZAL3>].

104. Singer, *supra* note 2.

105. See generally A. Kayum Ahmed, *Can Vaccines be Allocated on Antiracist Terms?*, PROJECT SYNDICATE (Aug. 10, 2020), <https://www.project-syndicate.org/commentary/antiracist-approach-allocating-covid-19-vaccine-by-a-kayum-ahmed-2020-08> [<https://perma.cc/6W46-LQPD>].

106. For historians writing on colonialism, slavery, and infectious diseases in the United States, see generally HARRIET A. WASHINGTON, *MEDICAL APARTHEID: THE DARK HISTORY OF MEDICAL*

Similarly, vaccine inequity undermines science. While the progress of science and the innovative products it yields are noble, science that prioritizes high profits over people's lives is not. Health authorities endorsed by their constituents have supported scientists and drug manufacturers to act in record time to develop and deliver lifesaving vaccines during the COVID-19 pandemic.<sup>107</sup> However, once vaccines were ready to distribute, the firms did not follow through on promises to scale production faster.<sup>108</sup>

### III. THEORETICAL APPROACHES

The global vaccine-access problem has been shaped by national and international IP laws and policies. In the United States, the dominant theoretical justification for IP is the law-and-economics theory.<sup>109</sup> According to this theory, two distinctive sets of economic incentives—promotion of worthwhile investments in research and widespread diffusion of the benefits of innovation—reach equilibrium with a temporary monopoly over an invention and its later diffusion on competitive terms.<sup>110</sup> While some scholars have noted that the economics of IP do not always work as law-and-economics theory predicts,<sup>111</sup> others have questioned IP rights, particularly patents, being granted at the expense of social costs—and the efficiency test that law-and-economics preaches.<sup>112</sup>

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EXPERIMENTATION ON BLACK AMERICANS FROM COLONIAL TIMES TO THE PRESENT (2008); JIM DOWNS, *MALADIES OF EMPIRE: HOW COLONIALISM, SLAVERY, AND WAR TRANSFORMED MEDICINE* (2021); KATHRYN OLIVARIUS, *NECROPOLIS: DISEASE, POWER, AND CAPITALISM IN THE COTTON KINGDOM* (2022).

107. See generally Branswell, *supra* note 14.

108. Regarding the failure to keep these promises, see discussion *infra* section V (regarding CEPI and U.S. government funding for R&D of vaccines).

109. Richard A. Posner, *The Law & Economics of Intellectual Property*, 131 *DAEDALUS* 5 (2002). Prominent representatives of law and economics especially regard intellectual property as a “natural field for economic analysis of law.” See William M. Landes & Richard A. Posner, *An Economic Analysis of Copyright Law*, 18 *J. LEGAL STUD.* 325, 325 (1989). Other substantive theories that support intellectual property include the personality theory, which focuses on the personality of creators, and the Lockean labor theory, which focuses on the fruits of the creator.

110. Richard C. Levin, Alvin K. Klevorick, Richard R. Nelson & Sidney G. Winter, *Appropriating the Returns from Industrial Research and Development*, 3 *BROOKINGS PAPERS ON ECON. ACTIVITY* 783 (1987), [https://www.brookings.edu/wp-content/uploads/1987/12/1987c\\_bpea\\_levin\\_klevorick\\_nelson\\_winter\\_gilbert\\_griliches.pdf](https://www.brookings.edu/wp-content/uploads/1987/12/1987c_bpea_levin_klevorick_nelson_winter_gilbert_griliches.pdf) [<https://perma.cc/RME8-QPQR>].

111. *Id.* at 784 (suggesting that imperfect appropriability may lead to underinvestment in new technology and less economic growth).

112. See Andreas Rahmatian, *International Intellectual Property Scholars Series: A Fundamental Critique of the Law-and-Economics Analysis of Intellectual Property Rights*, 17 *MARQ. INTELL. PROP. L. REV.* 190 (2013), <https://scholarship.law.marquette.edu/iplr/vol17/iss2/2/> [<https://perma.cc/L6UV-VPUJ>].

In the last decade, the market utilitarian-efficiency model of law-and-economics has faced examination by new *law-and-political-economy scholarship*. This scholarship challenges the idea that the field of IP is only about the efficiency of the market.<sup>113</sup> Claiming that markets embody the exercise of political power by the few, this movement asserts that a political economy approach to institutions shows stark market-mediated inequities in sectors, such as healthcare. In parallel, *health-justice scholarship* arose and challenged the role of law as furthering an equitable determinant of health.<sup>114</sup> This scholarship posts that law- and policy- making, informed by health equity principles, can prevent poor health outcomes and greater barriers to healthcare access. Together, these frameworks signal a grounding political inequity present in IP settings that has favored a group to become the rule makers and referees of access to health care.

This section examines these two contemporary theoretical frameworks.

#### A. *The-Law-and-Political-Economy Project*

The law-and-political-economy (LPE) project developed out of crises in the political environment in the early twenty-first century, crises that have become increasingly apparent during the COVID-19 pandemic: precarity of work, economic inequality, political polarization, vulnerable democratic institutions, racial disparities, climate change, and gender inequality. In response to these interconnected crises, a group of legal scholars<sup>115</sup> has called for a reorientation of legal thought—and, ultimately, law and policy—through the LPE project.<sup>116</sup> The project

113. See *infra* notes 113–14. See also Amy Kapczynski, *Why “Intellectual Property” Law*, *LAW LPE BLOG* (Nov. 6, 2017), <https://lpeproject.org/blog/why-intellectual-property-law> [<https://perma.cc/EUL2-DM3Z>].

114. Emily A. Benfer, *Health Justice: A Framework (and Call to Action) for the Elimination of Health Inequity and Social Injustice*, 65 *AM. UNIV. L. REV.* 275 (2015).

115. The LPE project is dominated mostly by legal scholars but joined and advanced by a network from different disciplines—economists, sociologists, political scientists, historians, geographers, and ethnic studies scholars.

116. See generally Jedediah Britton-Purdy, David Singh Grewal, Amy Kapczynski & K. Sabeel Rahman, *Building a Law-and-Political-Economy Framework: Beyond the Twentieth-Century Synthesis*, 129 *YALE L.J.* 1784 (2020) [hereinafter Britton-Purdy et al., *Building a Law-and-Political-Economy Framework*]; Jedediah Britton-Purdy, Amy Kapczynski & David Singh Grewal, *Law and Political Economy: Toward a Manifesto*, *LPE PROJECT* (Nov. 6, 2017), <https://lpeproject.org/blog/law-and-political-economy-toward-a-manifesto/> [<https://perma.cc/3D2C-9F2S>]; Martha T. McCluskey, Frank Pasquale & Jennifer Taub, *Law and Economics: Contemporary Approaches*, 35 *YALE L. POL’Y REV.* 297 (2017); Frank Pasquale et al., *Eleven Things They Don’t Tell You About Law and Economics: An Informal Introduction to Law and Political Economy*, 37 *MINN. J.L. INEQ.* 96 (2019); Angela P. Harris & James J.

claims that neoliberal laws have facilitated these crises and urges scholars to unearth their political foundations and implications to address future crises. Fundamentally, the LPE movement argues that our political order and democracy affect the democratization of markets as much as the democratization of politics.

Essentially, this scholarship questions the prominence given to furthering the *efficiency* of markets. Economic efficiency, as taught in law schools in subjects like antitrust, property, and contracts, is not the neutral value that creates markets that work for all.<sup>117</sup> A focus on market efficiency is criticized because it prioritizes the interests of those with more resources,<sup>118</sup> and “offers no framework for thinking systematically about the interrelationships between political and economic power.”<sup>119</sup> In other words, legal thought and its accompanying rules and policies “have shielded economic power from meaningful legal scrutiny and weakened public institutions precisely when they may be needed most.”<sup>120</sup>

To LPE scholarship, the economy is not separate from politics. In fact, markets are creatures of law and policy choices and represent the political order and representative democracy at a moment in history.<sup>121</sup> The study of markets, thus, will be incomplete without paying attention to the political roots of institutions. As such, the LPE project rejects the idea of a “free” market and contests the idea of a spontaneously competitive market order. Neoliberal efficiency offers no means to analyze “contemporary concentrations of wealth and power, except insofar as they interfere with overall efficiency.”<sup>122</sup> In contrast, the LPE project calls on scholars to examine the ways in which power speaks through law—“who should exercise power, of what sort, and over whom?” If healthcare were an iceberg, many legal and policy structures beneath the water’s surface would favor the economic and political control of the sector by a few actors—obviously, many as unintended consequences.

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Varellas, *Introduction: Law and Political Economy in Times of Accelerating Crises*, 1 J.L. POL. ECON. 1 (2020).

117. Britton-Purdy et al., *Building a Law-and-Political-Economy Framework*, *supra* note 116, at 1789–90.

118. *Id.* at 1790; see also Zachary Liscow, *Is Efficiency Biased?*, 85 U. CHI. L. REV. 1649 (2018).

119. Britton-Purdy et al., *Building a Law-and-Political-Economy Framework*, *supra* note 116, at 1790.

120. Jeremy Bearer-Friend, Ari Glogower, Ariel Jurow Kleiman & Clinton G. Wallace, *Taxation and Law and Political Economy*, 83 OHIO ST. L.J. 471, 473 (2022) (referring to Britton-Purdy et al., *Building a Law-and-Political-Economy Framework*, *supra* note 116, at 1807–09); Harris & Varellas, *supra* note 116, at 5.

121. Britton-Purdy et al., *Building a Law-and-Political-Economy Framework*, *supra* note 116, at 1804–06, 1816.

122. Britton-Purdy et al., *Building a Law-and-Political-Economy Framework*, *supra* note 116, at 1790.



What is apparent to the tip of the iceberg is mostly first-level policy choices that formally promote equal access to healthcare, “a vision of constitutional equity and liberty that enshrines structural inequality and economic power.”<sup>123</sup>

The most recent publication to advance the LPE emerging field is a feature article in the *Yale Law Journal* by Jedediah Britton-Purdy, David Singh Grewal, Amy Kapczynski, and K. Sabeel Rahman.<sup>124</sup> The article critiques the dominance of neoclassical economics in contemporary legal thought and proposes to redirect legal scholarship around the themes of power, equality, and democracy.<sup>125</sup> Although the article serves more as a broad legal argument that the authors expect readers to use to identify confirming examples, it gives an LPE account of some specific legal fields, such as IP law.<sup>126</sup>

According to the LPE project, law and economics theory remade the field of IP in a manner that empowered rights holders and rendered the pursuit of efficiency their aim, to the detriment of the notion that information is a public good.<sup>127</sup> That is, it justified “over-propertization” to internalize externalities that affected the efficiency of the market—although sacrificing, in practice, the efficient balance between social benefits and costs.<sup>128</sup> The economic model of property rights recommends that the law should assign property rights so that utility-maximizing rights holders will use their exclusive rights efficiently because they bear the harmful and beneficial effects of alternative uses.<sup>129</sup> As section IV further explains, scholars have claimed that conferring stronger rights on patent holders has not closely followed the theoretical economic conditions of efficiency<sup>130</sup> and the general statement that “the social benefits of property rights must be balanced against the costs.”<sup>131</sup> In particular, IP law in the form of patents neglects the values of equity and justice that should underpin efficient allocation of live-or-die innovation.<sup>132</sup>

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123. *Id.* at 1791.

124. Britton-Purdy et al., *Building a Law-and-Political-Economy Framework*, *supra* note 116.

125. *See id.* at 1835.

126. *Id.* at 1802–04.

127. For an economic account of public goods, see *infra* section V.

128. Posner, *supra* note 109. On Coase’s economic analysis of externalities, see Ronald Coase, *The Problem of Social Cost*, 3 J.L. ECON. 1 (1960).

129. Harold Demsetz, *Toward a Theory of Property Rights*, 57 AM. ECON. REV. 347 (1967).

130. *See* sources cited *supra* note 116 on economic efficiency.

131. Posner, *supra* note 109, at 6–7.

132. Amy Kapczynski, *supra* note 113.

B. *The Health-Justice Movement*

Frequently, health is thought of as the product of people's individual choices.<sup>133</sup> While one's behaviors do play a part in one's health, health is also socially determined by one's background and environmental context.<sup>134</sup> For example, health depends on whether a person is rich or poor, a person of color or white, and living in violent or peaceful conditions. Thinking structurally, individual health is influenced by broader social and economic environments such as living in a more or less equal society or in a developed or less developed country. All these factors combined—what public health advocates call “social determinants of health” (SDoH)—explain why individuals may experience health disparities within the same community, country, or region.<sup>135</sup> Under-theorized and just recently becoming of interest are the commercial determinants of health (CDoH).<sup>136</sup> These are the corporate and commercial conditions of SDoH that affect global health outcomes, such as globalization of trade, regulatory systems, articulation of social and economic power, and neoliberal and capitalist ideologies.<sup>137</sup> Predominantly analyzed in the context of non-communicable diseases such as diet disorders and alcohol and tobacco abuse, CDoH influence health such that diseases are considered ‘profit’ or corporate-driven diseases.<sup>138</sup>

In the pandemic context, SDoH and CDoH are blatant. A person who lives in a LMIC is at greater risk of not having access to effective

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133. “Healthism” emerged in the late 1970s as a public frame defined as “the preoccupation with personal health as a primary—often *the* primary—focus for the definition and achievement of well-being” that blames bad health on bad moral character. For example, obese people are judged as lazy and ignorant. See Robert Crawford, *Healthism and the Medicalization of Everyday Life*, 10 INT’L J. HEALTH SERVS. 365, 365–78 (1980).

134. Angela P. Harris & Aysha Pamukcu, *The Civil Rights of Health: A New Approach to Challenging Structural Inequality*, 67 UCLA L. REV. 758, 766–67 (2020).

135. See WORLD HEALTH ORG., CLOSING THE GAP IN A GENERATION: HEALTH EQUITY THROUGH ACTION ON THE SOCIAL DETERMINANTS OF HEALTH 1 (2008).

136. Cassandra de Lacy-Vawdon, Brian Vandenberg & Charles Henry Livingstone, *Recognising the Elephant in the Room: The Commercial Determinants of Health*, BMJ GLOB. HEALTH, Feb. 2022, <https://gh.bmj.com/content/7/2/e007156> [<https://perma.cc/ND9X-NET4>].

137. Cassandra de Lacy-Vawdon & Charles Livingstone, *Defining the Commercial Determinants of Health: A Systematic Review*, 20 BMC PUB. HEALTH 1022 (2020), <https://bmcpubhealth.biomedcentral.com/articles/10.1186/s12889-020-09126-1> [<https://perma.cc/DGB2-SN8F>].

138. See Kent Buse, Sonja Tanaka & Sarah Hawkes, *Healthy People and Healthy profits? Elaborating a conceptual framework for governing the commercial determinants of non-communicable diseases and identifying options for reducing risk exposure*, GLOBALIZATION & HEALTH, June 2017, at 2, <https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-017-0255-3> [<https://perma.cc/2LYC-YTT4>]; John S. Millar, *The Corporate Determinants of Health: How Big Business Affects Our Health, and the Need for Government Action!*, 104 CAN. J. PUB. HEALTH e327 (2013), <https://link.springer.com/article/10.17269/cjph.104.3849> [<https://perma.cc/GUY7M7MU>].

COVID-19 vaccines or to hospitalization if they contract the disease.<sup>139</sup> That is, poverty and a country's development can be discriminatory factors that subordinate some populations to others in the context of the pandemic.<sup>140</sup> Similarly, the availability of the most effective COVID-19 vaccines is conditioned by the laws and policies regulating pharmaceutical companies, the economic and power dynamics these regulations favor, and the economic and political ideologies supporting these regulations. As section IV further examines, a global IP landscape inspired by neoliberalism translated into which and how many vaccines are available to the world and who is prioritized in their distribution.

By definition, inequitable health and access to healthcare create unjust, unnecessary, and *avoidable* health disparities.<sup>141</sup> Health disparities have withstood public health advocates' work addressing the determinants of health<sup>142</sup> and legal advocates fighting disparities based on moral fairness and fidelity to constitutional principles.<sup>143</sup> To health-justice legal scholars, the persistence of avoidable health disparities indicates that the centrality of *subordination* that lies at the root of health disparities has not been fully confronted.<sup>144</sup> Subordination favored by policies, practices, norms, and culture holds down one social group while benefitting another and transforms disparities into structural inequities.<sup>145</sup> As hierarchies scale up, harmful structural and superstructural discriminatory dynamics are replicated systemically and organically across healthcare systems, and subordination expands within countries and between regions at national and supranational levels, creating enduring power differentials among population groups.<sup>146</sup>

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139. The lower an individual's socioeconomic status that prevents them from isolating, maintaining social distance, accessing housing and water public services, or affording to travel to a territory with access to vaccines, the greater the risk. *See generally* Efrat Shadmi, Yingyao Chen, Inês Dourado, et al., *Health equity and COVID-19: global perspectives*, 19 INT'L. J. EQUITY HEALTH, June 2020, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7316580/> [<https://perma.cc/HQ3R-H7CK>].

140. In this article, "discriminatory" includes actions described as such in the nonlegal literature, even when they may not be deemed legally actionable by domestic courts.

141. Paula Braveman, *What Are Health Disparities and Health Equity? We Need to Be Clear*, 129 PUB. HEALTH REP., SUPP. Jan.-Feb. 2014, at 2, 5, 7, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3863701/> [<https://perma.cc/X4LZ-EUBR>].

142. Emily Benfer et al., *Health Justice Strategies to Combat the Pandemic: Eliminating Discrimination, Poverty, and Health Disparities During and After COVID-19*, 19 YALE J. HEALTH POL'Y L. ETHICS (2020).

143. Harris & Pamukcu, *supra* note 134 at 792–805.

144. *Id.* at 770.

145. Benfer et al., *supra* note 142.

146. *See* Katharina Pistor, *Joe Biden's Pro-Market Agenda*, PROJECT SYNDICATE (July 20, 2021), <https://www.project-syndicate.org/commentary/biden-promoting-competition-in-the-american-economy-by-katharina-pistor-2021-07> [<https://perma.cc/5VNV-PF9N>]. .

Health inequities are categorized as *wicked problems*.<sup>147</sup> In social science literature, wicked problems are hard to fully predict, prevent, and deal with because of their complex nature.<sup>148</sup> They “transcend the borders of traditional policy domains, involve a wide variety of actors across different scale levels and resist our attempts to solve them.”<sup>149</sup> As such, they are “embedded in a complex system with many unclear interdependencies, and possible solutions cannot readily be selected from competing alternatives.”<sup>150</sup> That is, as they overlap with different disciplines, they have multiple root causes and operate at varying levels, “making it difficult to inventory all their implications” and craft true solutions.<sup>151</sup>

According to wicked problems’ theoretical framing, if health inequity is “wicked,” one cannot simply overcome it with superficial solutions. Instead, one must identify and address a variety of concurrent social, economic, and political deficiencies or injustices at the interpersonal, community, national, regional, and global level in which health inequities are rooted. On one hand, legal and policy interventions ought to account for the power dynamics that sustain health inequities. On the other hand, the wicked problems’ framework suggests that solutions to health inequities need interdisciplinary collaborations and creative strategies to target structural health determinants, including the laws and policies that shape our social, political, and economic institutions.<sup>152</sup> Section V suggests and discusses equity-focused, governance-based solutions derived from an interdisciplinary approach to law and public health, which this Article proposes public and private market actors ought to adopt to reduce or eliminate unjust health disparities.

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147. Emily Benfer, James Bhandary-Alexander, Yael Cannon, Medha Makhoulouf & Tomar Pierson-Brown, *Setting the Health Justice Agenda: Addressing Health Inequity & Injustice in the Post-Pandemic Clinic*, 28 CLIN. L. REV. 45, 51–53 (2021).

148. See generally Claes Andersson & Petter Törnberg, *Wickedness and the Anatomy of Complexity*, 95 FUTURES 118 (2018); Catrien J.A.M. Termeer, Art Dewulf & Robbert Biesbroek, *A Critical Assessment of the Wicked Problem Concept: Relevance and Usefulness for Policy Science and Practice*, 38 POLY & SOC’Y 167 (2019); Judith Welch Wegner, *Reframing Legal Education’s Wicked Problems*, 61 RUTGERS L. REV. 867 (2009); Brian W. Head, *Problem Definition and the Policy Process: Wicked Problems*, OXFORD RSCH. ENCYCLOPEDIA OF POLS. (2017).

149. Termeer et al., *supra* note 148, at 167–68.

150. Wegner, *supra* note 148, at 871.

151. Benfer et al., *supra* note 147, at 52.

152. *Id.*

## IV. THE POLITICS OF GLOBAL COVID-19 VACCINE INEQUITIES

Global vaccinations did not come close to meeting WHO's target of fully vaccinating 40% of each country's population.<sup>153</sup> Section II suggested that the vaccine-access problem is caused by drug manufacturers' control over vaccine supply, coupled with rich countries' nationalist behaviors. However, these factors do not fully explain the vaccine-access problem because they are only symptoms of foundational problems.

The LPE and health-justice frameworks, together, suggest that global vaccine inequities are symptoms of a drug-production model shaped by *poor policy choices*. The LPE framework maps the fault lines of the vaccine production and distribution model based on a false understanding of efficiency and suggests a system-design problem. In turn, the health-justice framework underscores the discriminatory consequences of systems that exclude the (involuntarily) "unvaccinated."<sup>154</sup> The market and political power of vaccine manufacturers has created "monopoly control over critical public-health technologies" and prevented the global community from accessing needed vaccines.<sup>155</sup> By supporting the interests of vaccine manufacturers, governmental bodies, lawmakers, and policy makers of affluent nations have played decisive roles in facilitating morally questionable opportunities to consolidate power and exercise it for their own interests.

This Section explores the root causes of the vaccine-access problem—what this Article refers to as the politics of global COVID-19 vaccine inequities—by using the LPE and health-justice frameworks outlined in Section III. This Article argues that failing to ensure equitable and quick access to safe and effective vaccines to end the COVID-19 pandemic is not just another mistake from the past but rather the result of *policy choices* that translate into a vaccine-production legal model driven by wealth and power. Since this Article focuses on COVID-19 vaccines with mRNA technology, this Section zooms into the so-called "iceberg" of the two mRNA vaccine producers—Pfizer and Moderna—and the U.S. pharmaceutical sector's laws and policies. The goal is to recognize

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153. See *supra* notes 22 and 23 and accompanying text.

154. Seth Berkley, *The World Isn't Getting Vaccinated Fast Enough. Here Are 4 Ways to Fix That*, TIME (May 11, 2021), <https://time.com/6047516/covax-covid-19-vaccine-access/> [<https://perma.cc/76LN-F4US>]; see also Gonsalves & Hassan, *supra* note 95 ("disposable people"); UN DEVELOPMENT PROGRAMME SUPPORT TO VACCINE EQUITY—BEYOND RECOVERY: TOWARDS 2030, *supra* note 97 ("people excluded from COVID-19 vaccine").

155. Mariana Mazzucato, Jayati Gosh and Els Torrele on Waiving Covid Patents, THE ECONOMIST: BY INVITATION (Apr. 20, 2021), <https://www.economist.com/by-invitation/2021/04/20/mariana-mazzucato-jayati-ghosh-and-els-torrele-on-waiving-covid-patents> [<https://perma.cc/3X8F-BGMU>].

the role of law and policy in allowing a few companies that dominate global COVID-19 vaccines to supply the market and ultimately control global access to healthcare.

#### A. Structural Power Imbalances in Health Care

The healthcare sector is flooded with difficult-to-overcome, harsh economic dynamics stemming from agency subordination and information asymmetry.<sup>156</sup> The coexistence of multiple actors with different levels of power in a complex network allows those with greater access and control of medical information to dominate the sector.

In economics parlance, healthcare is a *credence good*.<sup>157</sup> As healthcare users heavily rely on the knowledge and experience of medical providers to guide their decisions, providers tend to lead users' healthcare choices.<sup>158</sup> Giving credence to others fuels *agency subordination*. Principals (i.e., physicians and vaccine makers) can exert influence on the decision-making process of agents (i.e., patients and governments) at the risk of choices being shaped by principals' conflicting profit motives. Especially in health care, principals benefit from a tremendous *information asymmetry* that positions them strategically over other healthcare actors, favoring notorious informational power imbalances.

Together, information asymmetry and agency subordination among healthcare actors create considerable uncertainty. These factors are major barriers to separating the theory of a competitive healthcare market from its practice, and the market cannot restore its competitiveness by itself. Uncertainty explains why healthcare users, providers, and suppliers cannot freely and independently make decisions, particularly in market-based healthcare sectors governed by principles of competition and consumerism choice. To the contrary, the uncertainty from a free-market model benefits some stakeholders at the expense of others. In Kenneth Arrow's words, the economic consequence of uncertainty is that "information or knowledge becomes a commodity . . . [that] has a cost of production and a cost of transmission, and so it is naturally not spread out over the entire population but concentrated

156. Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 946–47 (1963).

157. See Esben S. Andersen and Kristian Philipsen, *The Evolution of Credence Goods in Customer Markets: Exchanging 'Pigs in Pokes'* (Paper presented at the DRUID Winter Seminar, Middelfart, Jan. 8–10, 1998); see generally Phillip Nelson, *Information & Consumer Behavior*, 78 J. POLIT. ECON. 311 (1970) (referring to consumer behavior and information asymmetries).

158. See Ximena Benavides, *The Law and Policital Economy of the Right to Health and Health Care in the United States*, in MARKETS, CONSTITUTIONS, AND INEQUALITY 55 (A. Chadwic et al. eds., 2022).

among those who can profit most from it.”<sup>159</sup> Profiting from uncertainty is a moral concern; the Hippocratic oath taken by healthcare providers pledges to take best care of peoples’ lives.

Healthcare actors’ different levels of power exacerbates the problem of uncertainty. Across the sector, even within the same class or group, healthcare stakeholders are empowered differently. For instance, not all hospitals, insurance companies, or drug manufacturers have the same financial position in the market. Furthermore, every stakeholder has a different level of uncertainty and different abilities to adapt.<sup>160</sup> The distinct information asymmetry of the healthcare sector suggests that power imbalances between stakeholders are hard to avoid. Further, the laws and policies that shape healthcare governance’s architecture exacerbate power differentials among healthcare market actors. Instead of restoring some balance in the very asymmetrical power dynamics of the sector, law creators and policy makers “code” certain health stakeholders and their interests over others.<sup>161</sup> Far from being equals under the law, some actors are powerless, invisible, and voiceless, whereas others lead the sector without further accountability. In other words, laws and policies ossify power differentials and create hierarchies among market actors that otherwise would make efforts to act in partnership. The economic credence-goods theory therefore suggests that entrusting the global vaccine rollout to powerful Big Pharma is a mistake, and further empowering it is a *big mistake* if the goal is policies that advance access to healthcare for all.

### B. Market Power

Health care in the United States is not only a large industry but a highly profitable one. The pharmaceutical industry,<sup>162</sup> in particular, is one of the most profitable industries in the country.<sup>163</sup>

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159. Arrow, *supra* note 156, at 946.

160. *Id.*

161. See KATHARINA PISTOR, *THE CODE OF CAPITAL: HOW THE LAW CREATES WEALTH AND INEQUALITY*, 158–61 (2019) (referring how law ‘codes’ certain assets and turner them into capital, where lawyers are the keepers of the code).

162. The pharmaceutical industry includes pharmaceutical companies, pharmacies, wholesalers, academic laboratories, and biotechnology companies, among many other healthcare providers and suppliers.

163. See Fred D. Ledley, Sarah Shonka McCoy, Gregory Vaughan, & Ekaterina Galkina Cleary, *Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies*, 239 J. AM. MED. ASSOC. 1 (2020). A cross-sectional study compared the profits of thirty-five large pharmaceutical companies with 357 large, nonpharmaceutical companies in the S&P 500 Index from 2000 to

Scholars argue that more than in any other social policy sector, profit-seeking is an inherent characteristic of the U.S. healthcare market under both Republican and Democratic administrations.<sup>164</sup> Although governed by principles of consumerism and competition, the U.S. model has fallen short in dispersing market power among all healthcare actors and adequately serving the needs of consumers. For health scholar Allison Hoffman, such principles have produced exactly the opposite result: a myth of choice and a market bureaucracy “captured by powerful, vested interests.”<sup>165</sup>

Production of COVID-19 vaccines by U.S. pharmaceutical companies is a contemporary example of these concerns. This Subsection analyzes the laws and policies that favor concentration of market power by Pfizer and Moderna and allow them to hoard the mRNA technology necessary to massively produce vaccines, set vaccine prices at their discretion, and control supply of vaccines globally.

### 1. Intellectual Property and Patents

Vaccine manufacturers have the power to control vaccine supply through IP law and patents.

As discussed in Section III, law and economics is the prevailing theory that justifies IP in the United States. According to this theory, IP laws grant inventors *monopoly*<sup>166</sup> privileges and exclusive rights to their work during a specific period of time to incentivize investment of time and financial resources in research and development of novel non-obvious products that are useful to society.<sup>167</sup> In law-and-economics terms, IP *rewards* inventors with a guaranteed temporary market exclu-

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2018. It found that large pharmaceutical companies were more profitable than other large companies, with a significantly greater median net income (earnings) expressed as a fraction of revenue.

164. See Frank Pasquale, *The Hidden Costs of Health Care Cost-Cutting: Toward a Post-Neoliberal Health-Reform Agenda*, 77 L. CONTEMP. PROBS. 171, 176 (2014); Deborah Stone, *The False Promise of Consumer Choice*, 51 ST. LOUIS U. L. J. 474 (2007), <https://scholarship.law.slu.edu/lj/vol51/iss2/12> [<https://perma.cc/37ZH-VTB3>]; Allison K. Hoffman, *Health Care's Market Bureaucracy*, 66 UCLA REV. 1926 (2019).

165. Hoffman, *supra* note 164, at 1931–35.

166. To modern economists, the exclusive rights that a patent confers on a patent holder are not equivalent to a monopoly, although they are used for economic monopolies and patent holders can abuse a market exclusivity position. See, e.g., Consolidated Treaty on the Functioning of the European Union arts. 34, 36, 102, Dec. 13, 2007, 2007 O.J. (C., 202); Sherman Antitrust Act, 15 U.S.C. § 2 (2006). The monopolizing effect of patents has been under suspicion by classical liberal thought. See Roger E. Meiners & Robert J. Staaf, *Patents, Copyrights, and Trademarks: Property or Monopoly?*, 13 HARV. J.L. PUB. POL'Y 911 (1990); Edmund W. Kitch, *Property Rights in Inventions, Writings, and Marks*, 13 HARV. J. LAW PUB. POL'Y 119 (1990).

167. 35 U.S.C. §§ 101–103.



sivity.<sup>168</sup> Patents prevent free-rider users or competitors from appropriating, imitating, or enjoying their work without their permission (e.g., licenses) or proper compensation (e.g., royalties).<sup>169</sup>

Under U.S. patent law, exclusive rights to an invention last twenty years.<sup>170</sup> During this time, no one else can manufacture or sell the patented product without the permission of the patent holder, and the patent holder can charge prices above the marginal cost of production with no limitation. Once the exclusivity expires, the rights to the invention are transferred to the public and the invention becomes part of the public domain. Patents slow down the diffusion of useful new inventions in the short term but offer public access to knowledge in the long term. Thus, the question is whether the statutory time limits are well-tailored to conditions in the health sector.

The challenge of patents is reaching an optimal balance of exclusive rights valuable enough to be a spur to invention, but not so extensive in scope or duration as to discourage public access in the future. Unfortunately, the U.S. patent system is off-balance. The number of exclusive monopolies has skyrocketed over the past few decades without a commensurate acceleration of competitive environments that advance innovation or productivity.<sup>171</sup> Concurrently, there have been few advancements in public access. Patenting requirements have been relaxed in favor of patent holders, and drug makers have abused patent law to extend their monopolies beyond the statutory twenty-year term.<sup>172</sup> The fact that patents have become increasingly hard to license and too easy to renew has translated into a system that is prone to gaming by pharmaceutical companies. For instance, drug makers tweak patented drugs with trivial changes to look like new ones to fit the IP rights checklist.<sup>173</sup> Although patents are useful tools, their applicability should be *narrowed*, rather than their current breadth which facilitates the own-

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168. 35 U.S.C. § 154.

169. *Id.* (provisional rights of patents).

170. *Id.* § 154(a)(2).

171. BRINK LINDSEY, *Why Patents and Pandemics Don't—or Shouldn't—Mix*, BROOKINGS (June 3, 2021), <https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/> [<https://perma.cc/MK4W-4SUA>].

172. GRAHAM DUTFIELD, *THAT HIGH DESIGN OF PUREST GOLD: A CRITICAL HISTORY OF THE PHARMACEUTICAL INDUSTRY 1880–2020* 449 (World Sci. ed., 2020) (referring to the creation of 'me-too' drugs and how large pharmaceutical companies obtain new patents for 'trivial and minor' inventions).

173. Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL'Y L. & ETHICS 293, 322 (2015) (referring to the 'evergreening' of patent abuse).

ing of large swathes of human knowledge and the preventing of public access to the promising benefits of inventions.<sup>174</sup>

Evidence shows that IP law and patents have made drugs very expensive in the United States. Drugs are expensive not only because they are costly to produce, but also because the companies that benefit from patents are permitted to set prices. During the term of exclusivity, in the absence of competition, drug makers can essentially charge whatever prices they deem the market can bear<sup>175</sup> and exclude generic manufacturers who promise lower costs.<sup>176</sup> Patents can last decades and become monopolies in practice. During that time, commercial interests and financial returns mostly inform manufacturers' decisions rather than consumer-focused decisions such as the price and number of doses to produce.<sup>177</sup> IP law does not provide a system of price control, and antitrust laws do not police patents.<sup>178</sup> Together with trade secrets, which make it hard to know which COVID-19 vaccines are being manufactured, the patent model facilitates monopolies in the pharmaceutical industry at the risk of social welfare as medicines become unobtainable luxuries, selectively available to those who can afford to pay their high prices.<sup>179</sup>

Because medicines are life-changing and lifesaving, the risk of this protected invention model is that it creates *harmful silos of market power* that stand in the way of widespread, affordable, and timely access to high-quality medicine. "With rare exceptions, the set of entitlements" that patents and other IP laws create "has grown steadily and dramatically since the eighteenth century."<sup>180</sup> By the end of the twentieth century, the patent system expanded with the Trade-Related Intellectual

174. See ELLEN F.M. "T HOEN, THE GLOBAL POLITICS OF PHARMACEUTICAL MONOPOLY POWER (2009). On "narrow patents," see R. Mazzoleni & R.D. Nelson, *Economic Theories About the Costs and Benefits of Patents*, 32 J. ECON. ISSUES 1031 (1998) (stating that to incentivize innovation, patents should protect only the area that is fundamentally new and be focused downstream to prevent excluding access to tools and processes for research while at the same time enabling licensing and diffusion).

175. UCL INST. FOR INNOVATION & PUB. PURPOSE, *THE PEOPLE'S PRESCRIPTION: RE-IMAGINING HEALTH INNOVATION TO DELIVER PUBLIC VALUE* 18 (2018).

176. JOSEPH ADAMCZYK ADRIENNE LEWIS & SHIVANI MORRISON, *1498: A GUIDE TO GOVERNMENT PATENT USE. A PATH TO LICENSING AND DISTRIBUTING GENERIC DRUGS* (2020).

177. Kapczynski, *supra* note 113. To patent scholar Benjamin N. Roin, intellectual property only provides a right to exclude others from the market but not monopoly pricing. See Benjamin N. Roin, *Intellectual Property versus Prizes: Reframing the Debate*, 81 U. CHI L. REV. 999, 1027 (2014).

178. To be sure, this Article does not encourage price control mechanisms but conditions to real competition with public value. See *infra* Section V.

179. Kapczynski, *supra* note 113.

180. William W. Fisher III, *The Growth of Intellectual Property: A History of the Ownership of Ideas in the United States*, in *EIGENTUM IM INTERNATIONALEN VERGLEICH* 265 (1999), <https://cyber.harvard.edu/people/ffisher/iphistory.pdf> [<https://perma.cc/G8XN-8MB7>].

Property Rights (TRIPS) Agreement, the main legal international IP framework implemented by essentially all countries.<sup>181</sup> The TRIPS Agreement of 1994 mandated global minimum standards for the protection of IP, a harmonized twenty-year patent term, and mandated patents in all fields of technology—including medicine.<sup>182</sup>

The TRIPS Agreement's implications for health care were first visible during the HIV/AIDS crisis. The high cost of medicine drew "attention [to] the relationship between patent[s] . . . and high drug prices."<sup>183</sup> The 2001 Declaration on TRIPS and Public Health in Doha, Qatar (the Doha Declaration) responded to these concerns by introducing "TRIPS flexibilities."<sup>184</sup> Among them were allowing governments to use compulsory licensing to protect public health and to not grant or enforce pharmaceutical product patents.<sup>185</sup> Introduction of TRIPS flexibilities is considered one of the most significant developments of the early twenty-first century in trade and health. It marked a change in thinking about patents and medicine by suggesting the reformulation of IP protection as a "social policy tool . . . rather than a mechanism to protect . . . [makers'] commercial interests" in the name of innovation.<sup>186</sup>

Following the Doha Declaration, some initiatives emerged to counterbalance the expansion of these monopolies and improve access to patented medicine, though most of them are voluntary and rely on political and corporate willingness.<sup>187</sup> Even though the Doha Declaration can offer relief in dealing with medicine-access problems and high drug

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181. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197.

182. *Id.* art. 27.1 (requiring patents "for any inventions, whether products or processes, in all fields of technology").

183. T HOEN, *supra* note 174.

184. World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/MIN(01)/DEC/2, 45 I.L.M. ILM 755 (2002) [hereinafter "TRIPS and Public Health"].

185. *Id.* To ensure attainment of paragraph 7 of the Doha Declaration, the least-developed countries will not have to protect pharmaceutical patents and test data or give exclusive marketing rights to pharmaceuticals that are the subject of a patent application. The 2015 TRIPS General Council extended this provision until January 1, 2033. See *TRIPS and Public Health*, WORLD TRADE ORG., [https://www.wto.org/english/tratop\\_e/trips\\_e/pharmpatent\\_e.htm#:~:text=This%20Decision%20extends%20the%20earlier,data%20until%201%20January%202033](https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm#:~:text=This%20Decision%20extends%20the%20earlier,data%20until%201%20January%202033) [https://perma.cc/BZ9V-2PRF]; see World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations With Respect to Pharmaceutical Products, WT/IP/C/73, (2015).

186. TRIPS and Public Health, *supra* note 184; see also ELLEN F.M. T HOEN, PRIVATE PATENTS AND PUBLIC HEALTH: CHANGING INTELLECTUAL PROPERTY RULES FOR PUBLIC HEALTH (2016).

187. See *infra* section V (referring to a "Medicines Patent Pool" and a "COVID-19 Technology Access Pool").

prices, it does not eliminate the TRIPS Agreement's detrimental effect on access to medicine nor the heavy dependence of the pharmaceutical system on patents as the main mechanism for financing innovation.<sup>188</sup>

The IP and patent model that incentivizes innovation in general may not be ideal to encourage invention during a pandemic. Patents are offered for whatever new products the pharmaceutical companies can come up with, even without commercial guarantees ensuring sufficient demand for the new product. But a pandemic is a different scenario. Governments know they need a drug or vaccine to fight a specific virus; in relation to COVID-19 it was particularly clear which vaccine was most effective after the initial rollouts in 2021. A pandemic's time constraints ought to urge private research to align with governments' needs and the general public's interest in the development of new drugs, which is difficult to successfully accomplish with a model that incentivizes invention and production in a decentralized way.

There is an obvious mismatch between the policy of vaccines as IP and policy for an effective pandemic response.<sup>189</sup> While patents encourage needed invention and innovation during public health and life-threatening circumstances, they do not necessarily encourage technological expansion. Instead, patents—and, more specifically, the power which exclusivity rights confer to the patent holder—give big pharmaceutical companies incentives to stand in the way of quick and wide global vaccination. Instead of accelerating vaccine diffusion, patent tools favor global vaccination slowdown. These tools allow vaccine makers to block competitors and control how fast global vaccination occurs, while prioritizing fast returns—getting the vaccines to (some) markets faster.

## 2. Vaccine Prices

Historically vaccines cost pennies to purchase, but regulatory reforms in response to the HIV/AIDS crisis changed the drug value and pricing model.<sup>190</sup> As explained above, IP law grants pharmaceutical companies the market and political power to set drug prices, at least in the U.S. market. Unfortunately, their unrestricted ability to determine prices may incentivize manufacturers to produce and sell drugs that will be demanded by wealthy households and give them continuous, higher returns. Physician and author Elisabeth Rosenthal has written

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188. T HOEN, *supra* note 174.

189. LINDSEY, *supra* note 171.

190. ELISABETH ROSENTHAL, AN AMERICAN SICKNESS: HOW HEALTHCARE BECAME BIG BUSINESS AND HOW YOU CAN TAKE IT BACK 97–101 (2017).

that pharmaceutical companies have progressively tested—and manipulated—every frontier of price and propriety of the IP and patent legal model.<sup>191</sup> Similarly, some legal scholars’ perception of the patent system is that, at its core, “[it] represents a quid pro quo between inventors and the U.S. government.”<sup>192</sup> Although the patent system plays an important role in the development of groundbreaking medical treatments, the exchange balance may be too far in favor of drug companies. Patents permit them to keep drug prices “astronomically high,” much higher than needed to fund future R&D and very much higher than drug manufacturing costs.<sup>193</sup>

At least in theory, if manufacturers focused on maximizing revenue, a marketing strategy based on high volume and low prices would incentivize them to keep drug prices low so the largest possible number of patients could afford them.<sup>194</sup> But the ability to discretionarily set drug prices has favored price strategies focused on high volume *and* high prices. With R&D concentrated on drugs to treat diseases of the wealthy countries, drug makers are incentivized to produce drugs that represent better prospects for sales and high returns.<sup>195</sup> Health economists claim this marketing strategy delivers short-term returns to manufacturers’ shareholders.<sup>196</sup> Of course, keeping drug prices high is not the only practice manufacturers use to generate high profits.<sup>197</sup>

Following law-and-economics principles, drug manufacturers generally justify high prices based on “value-based pricing,”<sup>198</sup> under which prices reflect the product’s social value: what health systems are willing to pay now for better future health outcomes because of the deployment

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191. *Id.* at 105 (referring to the IP federal rules established during the 1980s and 1990s). Rosenthal considers “manipulated” practices litigating patents, playing to FDA’s blind spots, and creating patented products by combining general drugs, among others. *See id.* at 105–14.

192. ADAMCZYK ET AL., *supra* note 176, at 9.

193. *Id.*

194. In fact, this possible pricing strategy was noted in a bipartisan Senate investigation concerning production of a hepatitis C cure by the multinational drug maker Gilead in the context of a slower-moving epidemic. *See* Christopher Morten & Matthew Herder, *We Can’t Trust Big Pharma to Make Enough Vaccines*, NATION (May 31, 2021), <https://www.thenation.com/article/world/covid-vaccines-pharma/> [<https://perma.cc/Z4AD-7WAT>].

195. *See* text accompanying *infra* notes 213–14 and 376–77.

196. UCL INST. FOR INNOVATION & PUB. PURPOSE, *supra* note 175.

197. Other examples of (generally) legal yet morally questionable marketing strategies include buying back their own shares to boost value of remaining shares and stock options, *see id.* at 7, and mining prescriber-identifiable data for data-driven marketing strategies targeting physicians for drug sales. *See* Sorrell v. IMS Health Inc., 564 U.S. 552 (2011) (holding that a Vermont statute that restricted the sale, disclosure, and use of data that revealed physicians’ prescribing practices violated the First Amendment).

198. UCL INST. FOR INNOVATION & PUB. PURPOSE, *supra* note 175.

of a therapeutic advance.<sup>199</sup> Drugs' intrinsic value is the cost to society if a disease is not treated or treated with the second-best therapy available.<sup>200</sup> However, lack of transparency about drug costs hampers how manufacturers estimate the social value of medicine.<sup>201</sup> Health economists counterargue, in line with LPE scholarship, that the value-based pricing argument hinders the political-economic drivers of higher prices. High prices represent the maximization of financial returns and the monopolistic ability to determine drugs prices.<sup>202</sup>

When it comes to vaccines and medical treatments for the coronavirus, the patent model prevents full access to healthcare through high prices. For example, South Africa's patent model for lifesaving COVID-19 treatments, such as baricitinib, impedes production of and access to affordable generic versions,<sup>203</sup> although their use has been encouraged by WHO.<sup>204</sup> While a fourteen-day treatment with baricitinib costs \$270 per person in South Africa (and \$1,109 in the United States), generic versions in India and Bangladesh cost \$7.

COVID-19 vaccines were sold to countries from different regions at differentiated prices. For example, bilateral deals between governments

199. See RICHARD A. POSNER & WILLIAM M. LANDES, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* (2003).

200. UCL INST. FOR INNOVATION & PUB. PURPOSE, *supra* note 175.

201. Pharmaceutical companies estimate that it takes over \$1 billion to bring a new drug to market. They include in the estimate the costs of basic science, developing a new compound, figuring out the right dose, the FDA process of human testing for safety and efficacy, and even opportunity costs—the profits that could have been made by investing the money elsewhere. “It is unclear how much [of the \$1 billion] is for testing markets, advertising, and promotion.” ROSENTHAL, *supra* note 190; see also Richard T. De George, *Intellectual Property and Pharmaceutical Drugs: An Ethical Analysis*, 15 *BUS. ETHICS Q.* 549, 549 (2005) (arguing the industry spends its substantial profit margins more on advertising and marketing than R&D).

202. UCL INST. FOR INNOVATION & PUB. PURPOSE, *supra* note 175. There are examples of drug prices outrageously increasing over time (i.e., medicines to treat Alzheimer's disease and diabetes) despite not offering innovation or advancement yet affecting a significant U.S. population support this claim. See Josh Katz, Sarah Kliff & Margot Sanger-Katz, *New Drug Could Cost the Government as Much as It Spends on NASA*, *N.Y. TIMES*, (June 23, 2021), <https://www.nytimes.com/2021/06/22/upshot/alzheimers-aduhelm-medicare-cost.html>; ROSENTHAL, *supra* note 190, at 7.

203. *South Africa Must Urgently Revoke Patents on Key COVID-19 Treatments and Vaccines*, MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN (Feb. 9, 2022), <https://msfaccess.org/south-africa-must-urgently-revoke-patents-key-covid-19-treatments-and-vaccines> [<https://perma.cc/5B5L-JB92>]. On the patent model in South Africa, see FIX THE PATENT LAWS, *PATENT BARRIERS TO MEDICINE ACCESS IN SOUTH AFRICA: A CASE FOR PATENT LAW REFORM* (Sept. 2016). On the patent model that applies to medicines in the African Region following the adoption of the TRIPS, see Marion Motari et al., *The Role of Intellectual Property Rights on Access to Medicines in the WHO African Region: 25 Years After the TRIPS Agreement*, *BMC PUB. HEALTH*, Mar. 2021, <https://bmcpubhealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y> [<https://perma.cc/Z9V7-Z4T5>].

204. *WHO Recommends Two New Drugs to treat COVID-19*, *WORLD HEALTH ORG.* (Jan. 14, 2022), <https://www.who.int/news/item/14-01-2022-who-recommends-two-new-drugs-to-treat-covid-19#:~:text=The%20two%20newly%20recommended%20drugs,access%20in%20lower%20income%20countries> [<https://perma.cc/C2AB-WHZG>].

and Moderna resulted in differentiated vaccine prices for European Union countries.<sup>205</sup> Similarly happened with Pfizer; the European Union and the United States paid \$19 for the Pfizer two-dose vaccine, while Israel paid \$30.<sup>206</sup> As Pfizer pitched for higher prices per dose, a former U.S. government officer accused Pfizer of ‘war profiteering’.<sup>207</sup> In early 2021, Pfizer pledged to provide 50 million doses at \$6.75 a dose to the African Union vaccine plan.<sup>208</sup> In addition to these price differentials, there was a vaccine price markup of at least four times the per-dose production cost.<sup>209</sup> Furthermore, vaccine prices are expected to be different during and after the pandemic. Pfizer has suggested a vaccine price increase over time, distinguishing “pandemic” vaccine prices (“low-cost” \$20 a dose) and “normal” future prices (an estimated \$175 a dose).<sup>210</sup> It is uncertain how these increases would work with the differential prices that already exist. The threat of differential pricing incites discriminatory sales practices that prevent access to healthcare. Indeed, high vaccine prices compelled LMICs to rely heavily on initiatives like COVAX, not only because of financial hardship but to secure supply and equitable access—although distribution results were poor.<sup>211</sup>

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205. The European Union bought Moderna vaccines at a price of \$22.50 per dose, with a \$4.50 discount for EU countries that pay for vaccines out of their own budgets. See Jillian Deutsch, *Moderna Accused of Parking Vaccine Profits in Tax Havens: Report*, POLITICO (July 13, 2021), <https://www.politico.eu/article/moderna-vaccine-profits-tax-havens/> [https://perma.cc/9LEJ-T8WQ].

206. David Lewis & Alexander Winning, *Exclusive: COVID-19 Shots to cost \$3 to \$10 Under African Union Vaccine Plan*, REUTERS (Jan. 20, 2021), <https://www.reuters.com/article/uk-health-corona-virus-africa-vaccine-exc-idUKKBN29POLN> [https://perma.cc/64WU-3XV6].

207. The former director of the U.S. Centers for Disease Control and Prevention accused Pfizer of “war profiteering” once Pfizer pitched for \$100 a single dose. See Jon Ungeod-Thomas, “Wall of Secrecy” in Pfizer Contracts as Company Accused of Profiteering, THE GUARDIAN (Dec. 5, 2021), <https://www.theguardian.com/uk-news/2021/dec/05/wall-of-secrecy-in-pfizer-contracts-as-company-accused-of-profiteering> [https://perma.cc/823U-86B4].

208. *Id.*

209. For instance, Pfizer has reportedly charged the United Kingdom £18 a dose for the first 100 million doses purchased and £22 a dose for the next 89 million doses, with a £4.98 per dose cost of production. See Samuel Lovett, *Pfizer Set for Record Vaccine Revenue as World’s Dose-Sharing Initiative Runs Out of Cash*, INDEPENDENT (Feb. 8, 2022), <https://www.independent.co.uk/news/health/pfizer-vaccine-sales-cost-covax-doses-b2009234.html> [https://perma.cc/3TUN-HB4L].

210. Eric Sagonowsky, *Pfizer Eyes Higher Prices for COVID-19 Vaccine After the Pandemic Wanes: Exec. Analyst*, FIERCE PHARMA (Feb. 23, 2021), <https://www.fiercepharma.com/pharma/pfizer-eyes-higher-covid-19-vaccine-prices-after-pandemic-exec-analyst> [http://perma.cc/A6KR-D4EQ].

211. See generally *infra* Section II.

### 3. Profit-Driven Industry

In 2021, Moderna and Pfizer COVID-19 vaccine sales alone were worth tens of billions of dollars in the global market.<sup>212</sup> Some estimate that vaccine manufacturers' revenues are \$65,000 every minute alone during the pandemic.<sup>213</sup>

COVID-19 mRNA vaccines are among the most lucrative drugs in history, with exceptionally high profit margins for vaccine makers. Established in 1849, Pfizer had a net profit of \$9.6 billion in 2020<sup>214</sup> and reported a record annual net income of \$21.97 billion in 2021<sup>215</sup> considering COVID-19 vaccine sales.<sup>216</sup> Moderna is a newcomer biotech company<sup>217</sup> founded in 2010 that had never made a profit or produced a commercial drug before the pandemic.<sup>218</sup> Moderna's own projections indicated it would make between \$15 and \$18 billion in sales in the United States and European Union in 2021, with less than 20% representing cost of sales.<sup>219</sup> Pfizer's and Moderna's profits are several times higher than the U.S. pharmaceutical industry's profit margin average of 13.8% during the last two dec-

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212. For a financial examination by pharmaceutical company and beneficial shareholders, see Julia Kollwe, *From Pfizer to Moderna: Who's Making Billions from COVID-19 Vaccines?*, GUARDIAN (Mar. 6, 2021), <https://www.theguardian.com/business/2021/mar/06/from-pfizer-to-moderna-whos-making-billions-from-covid-vaccines> [https://perma.cc/Z7SA-578G].

213. Pfizer, *BioNTech and Moderna making \$1,000 Profit Every Second While World's Poorest Countries Remain Largely Unvaccinated*, OXFAM INT'L (2021), <https://www.oxfam.org/en/press-releases/pfizer-biotech-and-moderna-making-1000-profit-every-second-while-worlds-poorest> [https://perma.cc/2TJ7-2M7T].

214. Kollwe, *supra* note 212.

215. PFIZER, PFIZER 2021 ANNUAL REPORT - FINANCIAL PERFORMANCE, [https://www.pfizer.com/sites/default/files/investors/financial\\_reports/annual\\_reports/2021/performance/](https://www.pfizer.com/sites/default/files/investors/financial_reports/annual_reports/2021/performance/) [https://perma.cc/YKU2-PTKC] (last visited Dec. 6, 2022).

216. Pfizer estimated \$15 billion in annual COVID-19 vaccines sales in 2021. See Michael Erman & Manas Mishra, *Pfizer Sees Robust COVID-19 Vaccine Demand for Years, \$26 Bln in 2021 Sales*, REUTERS (May 4, 2021, 6:55 AM EDT), <https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-lifts-annual-sales-forecast-covid-19-vaccine-2021-05-04/> [https://perma.cc/2WN9-G9AZ]. Pfizer revenues were underestimated. Out of \$81.3 billion annual total revenues, COVID-19 vaccine sales in 2021 represented \$36.8 billion, equivalent to forty-five percent of 2021 total revenues. See *id.*

217. See Peter Loftus & Gregory Zuckerman, *Inside Moderna: The Covid Vaccine Front-Runner with No Track Record and an Unsparing CEO*, WALL ST. J. (July 1, 2020), <https://www.wsj.com/articles/inside-moderna-the-covid-vaccine-front-runner-with-no-track-record-and-an-unsparing-ceo-11593615205> [https://perma.cc/3NR9-FCEH] (explaining Moderna's unique structure and history compared to any start-up newcomer).

218. Moderna's facility in Massachusetts was a former Polaroid facility. See Peter Loftus, *Drugmaker Moderna Delivers First Experimental Coronavirus Vaccine for Human Testing*, WALL ST. J. (Feb. 24, 2020), <https://www.wsj.com/articles/drugmaker-moderna-delivers-first-coronavirus-vaccine-for-human-testing-11582579099> [https://perma.cc/GS69-JD8B].

219. *Moderna Reports Third Quarter Fiscal Year 2021 Financial Results and Provides Business Updates*, MODERNA (Nov. 4, 2021), <https://investors.modernatx.com/news/news-details/2021/Moderna-Reports-Third-Quarter-Fiscal-Year-2021-Financial-Results-and-Provides-Business-Updates-11-04-2021/default.aspx> [https://perma.cc/5JZ9-4D7Q].



ades.<sup>220</sup> Vaccine makers' pricing freedom largely explains these outrageous profits, the legitimacy of which is questionable especially because government funding subsidized COVID-19 vaccine development upfront in the form of R&D grants.<sup>221</sup>

Pharmaceutical companies have not denied that profits govern their vaccine allocation plans. For example, in November 2021, Pfizer's chief executive officer said the company decides "vaccine allocation 'in relation with how many doses [Pfizer] had and who wants to get them . . . [m]ainly with high income.'"<sup>222</sup> Vaccine allocations were based on volume and buyers' capacity to pay high prices instead of, for example, a country's incidence of COVID-19 (e.g., prioritizing vaccination in countries with the highest death tolls or where deadly variants originated). Marketing decisions seem to be aligned with manufacturers' shareholders' interests. In the case of Pfizer, the company's shares are widely disseminated, with more than half the company's stock held by institutional investors.<sup>223</sup> Its largest shareholder, Vanguard Group, Inc., is an investment management firm.<sup>224</sup> This structure pushes the board to pay attention to atomized shareholders' investment profiles and preferences and align company decisions with interests of large shareholders. The general public investing in Pfizer represents considerable aggregated ownership, yet it is not strong enough to change company policies. As a result, society is left with a vaccine manufacturer that behaves more like a hedge fund than a medical research company. This business-only-for-profit mindset is consistent with the broader pharmaceutical industry's practices. A U.S. Government Accountability Office report revealed that the pharmaceutical industry is increasingly inclined to buy smaller firms to acquire knowledge about drugs *already invented* (and patented) and maximize returns by increasing medicine prices over a patent's lifetime while reducing research and trials investment risks.<sup>225</sup>

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220. Vincent Kiezebrink, *Moderna's Free Ride*, CTR. FOR RSCH. ON MULTINATIONAL CORPS. (SOMO) (July 13, 2021), <https://www.somo.nl/modernas-free-ride/> [<https://perma.cc/C6PB-MHK3>].

221. See Amy Kapczynski, *Realizing Public Rights Through Government Patent Use*, 49 J.L. MED. & ETHICS 34, 35 (2021).

222. Baker & Silver, *supra* note 5.

223. With no dominant shareholder, the top twenty-five shareholders collectively control less than half the shares. See *How Many Pfizer Inc. Shares Do Institutions Own?* NASDAQ (Sept. 3, 2021) <https://www.nasdaq.com/articles/how-many-pfizer-inc.-nyse:pfe-shares-do-institutions-own-2021-09-03>.

224. *Id.*

225. See U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-40, DRUG INDUSTRY: PROFITS, RESEARCH AND DEVELOPMENT SPENDING, AND MERGER AND ACQUISITION DEALS, (2017), <https://www.gao.gov/assets/gao-18-40.pdf> [<https://perma.cc/L2Y6-HRMF>]. The world's most lucrative drug before the COVID-19 vaccine is Humira, a treatment for autoimmune diseases owned by AbbVie. See U.S.

As noted in the preceding subsection, vaccine makers' profit strategies extend beyond the pandemic. Emerging variants offer manufacturers the potential for vaccine price hikes.<sup>226</sup> If the coronavirus stays in society and vaccinations become recurrent (as with influenza, for which vaccinations of varying compositions are routinely offered annually), drug companies can expect large financial returns for years to come.<sup>227</sup> Furthermore, companies estimate boundless profits from the potential use of mRNA technology for other diseases beyond the coronavirus.<sup>228</sup>

Manufacturers (and the patent model) usually justify their large profits by pointing to the considerable investments they must make for research and development (R&D) of drugs.<sup>229</sup> The irony is that governments give manufacturers billions of dollars to fund R&D, and makers retain exclusive rights over their production and sale to scale up revenues.<sup>230</sup> In other words, taxpayers' contributions are used by governments to enrich vaccine makers while they hold vaccines hostage from the general population.

The U.S. government is the largest public investor in medical R&D worldwide.<sup>231</sup> Federal agencies routinely enter into early-stage research

HOUSE OF REPRESENTATIVES, COMM. ON OVERSIGHT & REFORM, DRUG PRICING INVESTIGATION: INDUSTRY SPENDING ON BUYBACKS, DIVIDENDS, AND EXECUTIVE COMPENSATION (2021). On Humira 'patent thickets,' biosimilars, and buyouts plans, see Jonathan Gardner, *Two Decades and \$200 Billion: AbbVie's Humira Monopoly Nears Its End*, BIOPHARMA DIVE (Mar. 17, 2022), <https://www.biopharmadive.com/news/humira-abbvie-biosimilar-competition-monopoly/620516/> [<https://perma.cc/9EQF-7RN2>].

226. REFINITIV STREETEVENTS, EDITED TRANSCRIPT: PFE.N – PFIZER INC AT BARCLAYS GLOBAL HEALTHCARE CONFERENCE (VIRTUAL) (2021), [https://www.documentcloud.org/documents/20514141-pfe-usq\\_transcript\\_2021-03-11](https://www.documentcloud.org/documents/20514141-pfe-usq_transcript_2021-03-11) [<https://perma.cc/PYJ5-PNSZ?type=image>].

227. Eric Sagonowsky, *Pfizer Expects Higher COVID-19 Vaccine Prices and Yearly Boosters, CFO Says. And That Means Big Sales Long-Term*, FIERCE PHARMA (Mar. 17, 2021, 10:25 AM), <https://www.fiercepharma.com/pharma/pfizer-sees-need-for-annual-revaccinations-and-rationale-for-higher-prices-after-pandemic> [[perma.cc/6AAE-X4ZE](https://perma.cc/6AAE-X4ZE)].

228. See *infra* text accompanying notes 300–03.

229. Fred D. Ledley et al., *Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies*, 323 J. AM. MED. ASSOC. 834843 (2020) (comparing research and development expenses of pharmaceutical companies and S&P 500 companies; the difference in median profits was close to four percent, where pharmaceutical companies were not more profitable).

230. According to the U.S. Center for Medicare & Medicaid Services, close to 20% of the national health expenditure, which represents almost a fourth of government spending, goes to pharmaceuticals. See TABLE 45. NATIONAL HEALTH EXPENDITURES, AVERAGE ANNUAL PERCENT CHANGE, AND PERCENT DISTRIBUTION, BY TYPE OF EXPENDITURE: UNITED STATES, SELECTED YEARS 1960–2018, U.S. CTRS. FOR DISEASE CONTROL (2019), <https://www.cdc.gov/nchs/data/hsr/2019/045-508.pdf> [<https://perma.cc/AC9G-8QN9>].

231. Hamilton Moses et al., *The Anatomy of Medical Research: U.S. and International Comparisons*, 313 JAMA 174 (2015). According to independent research by doctor groups, the National Institute of Health spends on average \$40 billion annually on biomedical R&D. See Kyle LaHucik, *Doctor Groups Urge Biden Administration to Disclose Costs of Federally Funded Clinical Trials*, FIERCEBIOTECH (Feb. 1, 2022), <https://www.fiercebiotech.com/cro/doctor-groups-urge-hhs-biden-admin-to-disclose-costs-federally-funded-clinical-trials> [<https://perma.cc/U6BD-RS6B>]. Between 2010 and 2016, the United

collaborations with the private sector,<sup>232</sup> yet their funding is below pharmaceutical firms' spending on R&D.<sup>233</sup> Public funding of R&D for COVID-19 vaccines and treatments has not been the exception.<sup>234</sup> In fact, COVID-19 vaccine public R&D investments have been extraordinary compared to other diseases.<sup>235</sup> The U.S. government provided roughly \$4.1 billion to Moderna for development of mRNA COVID-19 vaccines.<sup>236</sup> Although Moderna has not publicly disclosed how much it spent on developing the vaccine, health advocates have suggested that mRNA vaccine development was entirely taxpayer-funded.<sup>237</sup> Documents indicate that back in 2015, the U.S. National Institutes of Health (NIH) collaborated with Moderna in scientific research to develop vaccines for a number of viruses.<sup>238</sup> In 2019, before the identification and spread of COVID-19, the NIH and Moderna signed an agreement to co-develop coronavirus vaccines.<sup>239</sup> Because mRNA vaccine research was funded by and jointly developed with a federal agency, the public sector

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States funded research on all 210 new drugs approved by the Federal Drug Administration. See Ekaterina Galkina Cleary, Jennifer M. Beierlein, Navleen Surjit Khanuja & Fred D. Ledley, *Contribution of NIH Funding to New Drug Approvals 2010–2016*, 115 PNAS 2329 (2018).

232. See generally Rutschman, *supra* note 49.

233. The U.S. private biopharmaceutical industry spent \$83 billion on R&D in 2019. See Lukas Dascoli, *Fact of the Week: The Pharmaceutical Industry Invested \$83 Billion on R&D in 2019, a Tenfold Increase Since the 1980s*, INFO. TECH. & INNOVATION FOUND. (Aug. 16, 2021), <https://itif.org/publications/2021/08/16/fact-week-pharmaceutical-industry-invested-83-billion-rd-2019-tenfold> [<https://perma.cc/U2BZ-NVY5>]. In contrast, the National Institutes of Health's budget for outside R&D in 2019 was \$31.7 billion. See *NIH Extramural and Intramural Funding: FY 2019 Operating Plan*, NIH, <https://report.nih.gov/nihdatabook/report/283> [<https://perma.cc/MQ2C-G2KQ>].

234. The development of COVID-19 vaccines received the direct support of public funds via Operation Warp Speed. Remdesivir, a drug that treats COVID-19, was partly developed with funding by the public sector. See Yaniv Heled, Ana Santos Rutschman & Liza Vertinsky, *The Problem with Relying on Profit-Driven Models to Produce Pandemic Drugs*, 7 J.L. & BIOSCI. 1 (2020).

235. Ruchil Agarwal & Patrick Gaule, *What Drives Innovation? Lessons from COVID-19 R&D* (IMF Working Paper No. 2021/048, Feb. 1, 2021).

236. Deutsch, *supra* note 205; see also Stephanie Nolen & Sheryl Gay Stolberg, *Pressure Grows on U.S. Companies to Share Covid Vaccine Technology*, N.Y. TIMES (Sept. 22, 2021, updated Nov. 9, 2021), <https://www.nytimes.com/2021/09/22/us/politics/covid-vaccine-moderna-global.html> [<https://perma.cc/Q84E-X3XT>].

237. Zain Rizvi, *The NIH Vaccine*, PUB. CITIZEN (June 25, 2020), <https://www.citizen.org/article/the-nih-vaccine/> [<https://perma.cc/R4XR-KXN9>].

238. See *NIH Vaccine Research Center Leads the Way to Safe, Effective COVID-19 Vaccines*, NAT'L INST. OF HEALTH <https://covid19.nih.gov/news-and-stories/nih-vaccine-research-center> [<https://perma.cc/66GR-RZAD>]; Press Release, NIH Clinical Trial of Investigational Vaccine for COVID-19 Begins, Nat'l Insts. of Health (Mar. 16, 2020), <https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins> [<https://perma.cc/R2XK-7TU7>] ("Scientists at [NIH] and Moderna were able to quickly develop mRNA-1273 because of prior studies of related coronaviruses that cause severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS).").

239. Mario Gaviria & Burcu Kilic, *A Network Analysis of COVID-19 mRNA Vaccine Patents*, 39 NATURE BIOTECHNOLOGY 546 (2021).

may hold certain rights over patented research—but this is still being litigated.<sup>240</sup> In other words, a patent for the mRNA COVID-19 vaccine could, in theory, be co-owned by Moderna and the U.S. government. After analyzing the NIH-Moderna collaboration agreements, some scholars have suggested “NIH has not transferred its rights, but instead maintains a joint stake” in the mRNA-1273 vaccine.<sup>241</sup> Others maintain that the federal government *might* have retained some rights over the vaccine or its components.<sup>242</sup>

Although Moderna initially pledged not to assert its mRNA patents against other COVID-19 vaccine makers,<sup>243</sup> in a July 2021 filing with the U.S. Patent Office, Moderna said that the NIH’s scientists did not co-invent the mRNA vaccine or its composition.<sup>244</sup> In response, the NIH challenged Moderna’s ownership of the rights to mRNA.<sup>245</sup> After Moderna’s stock price dropped by over 50% by mid-November 2021, Moderna decided to delay the issuance of an mRNA patent until the dispute with the NIH is resolved.<sup>246</sup> The NIH-Moderna dispute could determine joint ownership over the most effective vaccine technology to

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240. See 15 U.S.C. § 3710a (allowing federal agencies to enter cooperative research and development agreements); 35 U.S.C. § 262 (“In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners.”).

241. Rizvi, *supra* note 237.

242. Rutschman, *supra* note 49.

243. *Statement by Moderna on Intellectual Property Matters During the COVID-19 Pandemic*, MODERNA (Oct. 8, 2020), <https://investors.modernatx.com/Statements—Perspectives/Statements—Perspectives-Details/2020/Statement-by-Moderna-on-Intellectual-Property-Matters-during-the-COVID-19-Pandemic/default.aspx> [<https://perma.cc/H372-P253>]. (“[W]hile the pandemic continues, Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic.”)

244. See *Read Moderna’s Filing With the United States Patent and Trademark Office*, N.Y. TIMES (Nov. 9, 2021), <https://www.nytimes.com/interactive/2021/11/09/us/moderna-patent-filing.html> [<https://perma.cc/T8HR-DRE6>].

245. See Jorge Contreras, *Will NIH Learn from Myriad when Settling Its mRNA Inventorship Dispute with Moderna?*, BILL OF HEALTH (Jan. 6, 2022), <https://blog.petrieflom.law.harvard.edu/2022/01/06/nih-moderna-mrna-covid-vaccine-patent/> [<https://perma.cc/SY45-JTAU>] (explaining that the main issue at stake was whether three researchers at the NIH’s Vaccine Research Center contributed enough to vaccine technology during the years they collaborated with Moderna to qualify as “inventors” on Moderna’s vaccine patents).

246. See *id.* Several equivalent patents pursued by Moderna in other countries, such as Australia, Canada, China, India, Israel, Japan, Mexico, Singapore, and South Korea, have been rejected by national patent offices or withdrawn or abandoned by Moderna. See *Removing Intellectual-Property Barriers from COVID-19 Vaccines and Treatments for People in South Africa*, MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN (Mar. 8, 2022), <https://msfaccess.org/removing-intellectual-property-barriers-covid-19-vaccines-and-treatments-people-south-africa> [<https://perma.cc/A3U7-3RVS>].

date.<sup>247</sup> If confirmed, each joint owner will be able to manufacture, sell, or use the vaccine without the consent of the other under federal patent law.<sup>248</sup> The outcome of this dispute could affect global vaccine supply because of the expectation that the NIH shares the mRNA-1273 patent. And beyond the pandemic, it could affect access to medicine with the potential to treat many other diseases using mRNA technology.<sup>249</sup>

Aside from the NIH's potential success in the dispute with Moderna, the fact that a federal agency provided R&D funding to a private vaccine developer should give the government the ability to make vaccines widely available and priced affordably, at least in theory.<sup>250</sup> This Article will further examine this point in Section V.

Overall, the incentives of a highly profit-driven industry explain why the R&D agendas for drugs are not always set up according to public health needs.<sup>251</sup> Evidence published over the last two decades shows that drug makers' *commercial bias* is manifested every time drugs are designed and clinically tested.<sup>252</sup> The profit incentive for COVID-19 vaccines exhibits why vaccine manufacturers have "perfectly rational reasons to restrict supply" by focusing on producing doses for richer countries and "keep[ing] the know-how secret to control the market for vaccines in the long run."<sup>253</sup>

#### 4. Corporate and Fiscal Privileges

Tax haven laws provide pharmaceutical companies with an additional layer of economic power. Besides benefiting from the flexible corporate tax laws of Delaware, Moderna's parent company benefits

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247. Sheryl Gay Stolberg & Rebecca Robbins, *Moderna and U.S. at Odds Over Vaccine Patent Rights*, N.Y. TIMES (Nov. 9, 2021), [https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html?\\_sm\\_au=iHV8nvZffSvHttQQvMFckKo232CoF](https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html?_sm_au=iHV8nvZffSvHttQQvMFckKo232CoF) [https://perma.cc/WWN2-DP98].

248. 35 U.S.C. § 262.

249. See *infra* text accompanying notes 282–285.

250. Rutschman, *supra* note 49, at 182 (“[T]he Patent Code gives funding agencies march-in rights, which NIH could potentially exercise to issue non-exclusive licenses to other manufacturers.”); see 35 U.S.C. § 203 (referring to the federal agency's right to grant a nonexclusive or exclusive license to applicants). Rutschman noted that march-in rights have not been used in the forty years since the Bayh-Dole Act introduced them. This government reluctance has crept into the field of emerging vaccines. See Ana Santos Rutschman, *Vaccine Licensure in the Public Interest: Lessons from the Development of the U.S. Army Zika Vaccine*, 127 YALE L.J. 651 (2018). Alternatively, section 1498 may be used to expand vaccine production at affordable prices. See *infra* Section V.

251. See V. J. Wirtz et al., *Essential Medicines for Universal Health Coverage*, 389 LANCET 403 (2017) (discussing, for instance, why diseases prevalent mostly in the Global South, such as tuberculosis, remain greatly ignored in the twenty-first century).

252. See UCL INST. FOR INNOVATION & PUB. PURPOSE, *supra* note 175, at 16.

253. Kapczynski, *supra* note 89.

from a tax-exempt state income status and, beneficially for any drug manufacturer, state policies that do not tax income generated through intangible assets such as patents.<sup>254</sup> Delaware is a secrecy jurisdiction, so annual accounts for Moderna are not publicly available.<sup>255</sup> While Moderna was in the midst of vaccine clinical trials, the company incorporated in Basel, Switzerland and now enjoys low taxation there, with rates as low as 7.83% of income.<sup>256</sup> Additionally, Swiss laws demand very little financial transparency from companies.<sup>257</sup> Moderna makes vaccine components in Switzerland, but the vaccine is produced by a subsidiary in Switzerland and the Netherlands<sup>258</sup>—facts that could be used to claim that Moderna’s income should be taxed according to the laws “where its real economic activity” to develop, produce, and market vaccines takes place.<sup>259</sup> Transnational fiscal and corporate benefits also favor the exercise of market power across country borders and regions.<sup>260</sup>

Benevolent and permissive corporate and tax laws are not new. Nevertheless, they are troubling when applied to an industry’s business model that already favors manufacturers’ excessive profits through patents and supply control and an unlimited creation of wealth. This set of corporate and tax rules undermines drug manufacturers’ mission: developing *public* goods.<sup>261</sup> With increasingly exponential returns, manufacturers can easily abandon their mission in favor of higher revenue. High profits have encouraged practices intended to build corporate influence and increase vaccine sales through unethically funding charities and patient-advocacy groups.<sup>262</sup> The goal of maximum profit has also

254. See DEL. CODE ANN. tit. 30, §1902. On a historical-legal account on how Delaware legislation attracts intellectual property (IP) holding companies and enables companies to avoid paying taxes on the income generated from the use of IP assets, see Xuan-Thao Nguyen, Promoting Corporate Irresponsibility? Delaware as the Intellectual Property Holding State. 46 (3) *The Journal of Corporation Law*, 717 (2021).

255. Kiezebrink, *supra* note 220.

256. Beat Meyer, *Corporate Tax in Switzerland*, EXPATICA (Jan. 8, 2022), <https://www.expatica.com/ch/finance/taxes/corporate-tax-in-switzerland-452226/> [https://perma.cc/M]73-VF84].

257. *Id.*

258. Deutsch, *supra* note 205.

259. Kiezebrink, *supra* note 220.

260. Everaldo Lamprea claims that transnational pharmaceutical companies influence litigation of the right to health in Global South countries. This is what he calls a “pharmaceuticalization of health care,” which molds medical prescribers’ preferences for branded drugs and controls the availability of cheaper generics and biosimilars. See EVERALDO LAMPREA-MONTEALEGRE, LOCAL MALADIES, GLOBAL REMEDIES: RECLAIMING THE RIGHT TO HEALTH IN LATIN AMERICA (2022). On the “pharmaceuticalization of health care,” see also Everaldo Lamprea-Montealegre & Tatiana S. Andia, *Is the Judicialization of Health Care Bad for Equity? A Scoping Review*, 18 INT’L J. EQUITY HEALTH 61 (2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6545687/> [https://perma.cc/7283-ZFV3].

261. For this Article’s account of public goods, see *infra* Section V.

262. Pfizer was among the largest funders of patient-advocacy groups during the opioid crisis as a way to secure high drug sales. See Memorandum from Sens. Chuck Grassley & Ron Wyden on

prompted manufacturers to incorporate sanctions for misbehavior and breaches of law and regulations into their budgets.<sup>263</sup> U.S. Department of Justice and Securities and Exchange Commission filings show that some of the major pharmaceutical companies behind COVID-19 global vaccination have been previously charged with representative fines in connection with bribes offered by their management teams.<sup>264</sup>

### C. Political Power

As explained above, IP protections and patents are primary factors in vaccine production. These proprietary rights grant producers not only market power in the form of “temporary” market exclusivity but also political power. Patent holders control the production and price of patented products and the power to control—and maintain—the status quo and their elite position.<sup>265</sup>

The U.S. pharmaceutical industry is by far the largest lobby in the country.<sup>266</sup> Studies show that between 1999 and 2018, the drug industry spent an average of \$233 million per year on lobbying the U.S. federal government, \$414 million on campaign contributions to presidential

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Findings from the Investigation of Opioid Manufacturers’ Financial Relationships with Patient Advocacy Groups and Other Tax-Exempt Entities to Members of the Sen. Fin. Comm. 9–12 (Dec. 16, 2020), <https://www.finance.senate.gov/imo/media/doc/2020-12-16%20Finance%20Committee%20Bipartisan%20Opioids%20Report.pdf> [https://perma.cc/JKP7-HTQV].

263. Matt Smith, *The Global Vaccine Rollout Means Heightened Corruption Risk. Here’s What to Know*, BARRON’S (Mar. 27, 2021), <https://www.barrons.com/articles/the-global-vaccine-rollout-means-heightened-corruption-risk-heres-what-to-know-51616796521> [https://perma.cc/WUN5-VMWZ].

264. *Id.*

265. On an economic approach to political capitalism and lobbying, see generally J.M. BUCHANAN & G. TULLOCK, *THE CALCULUS OF CONSENT: LOGICAL FOUNDATIONS OF CONSTITUTIONAL DEMOCRACY* (1962); G. KOLKO, *THE TRIUMPH OF CONSERVATISM: A REINTERPRETATION OF AMERICAN HISTORY, 1900–1916* (1963). Lobbyists are powerful elites whose low transactional costs allow them to bargain with legislators and offer campaign contributions and other forms of political support. For U.S. modern economist Randall G. Holcombe, when the same people hold both economic and political power the result is stagnation, in contrast to progress through cooperation when economic power and political power are separate. Yet Holcombe contrasts economic with market power. See RANDALL G. HOLCOMBE, *COORDINATION, COOPERATION, AND CONTROL: THE EVOLUTION OF ECONOMIC AND POLITICAL POWER* (2020); see also RANDALL G. HOLCOMBE, *POLITICAL CAPITALISM: HOW ECONOMIC AND POLITICAL POWER IS MADE AND MAINTAINED* (2018).

266. In 2021, the pharmaceutical industry spent an average of \$353 billion on federal lobbying, followed by the electronics industry with \$185 billion. Between 1998 and 2021, on average, the pharmaceutical industry spent the most on federal lobbying, showing an increase of 500%. See *Lobbying*, OPENSECRETS, <https://www.opensecrets.org/federal-lobbying/industries?cycle=a> [https://perma.cc/H5J8-72L6] (including the most recent data from the Senate Office of Public Records downloaded on January 24, 2022).

and congressional electoral candidates,<sup>267</sup> and \$877 millions on contributions to state candidates. Contributions targeted those involved in drafting healthcare laws, which suggests that the pharmaceutical industry influences U.S. health policy.<sup>268</sup> The largest campaign contributions during the 1999–2018 time frame occurred near in time to political and legislative events critical to the industry, such as the enactments of Medicare Part D in 2003, the Patient Protection and Affordable Care Act in 2010, and the 2016 presidential election in which drug pricing was a key concern.<sup>269</sup> The pharmaceutical industry supplements its lobbying activity by launching campaigns to change public perception of drug costs,<sup>270</sup> funding patient advocate groups to increase support for drug prescriptions,<sup>271</sup> and economically supporting pharma financial assistance programs that cover access to their drugs.<sup>272</sup> The pharmaceutical industry also makes voluntary economic contributions to global health organizations.<sup>273</sup>

Drug pricing (including vaccine pricing) is a policy issue on which spending on and the number of companies lobbying has significantly increased in the last decade.<sup>274</sup> With the pandemic, lobbying spending

267. During the 2016 election campaign, the industry gave an average of more than \$40,000 to 399 members of the House of Representatives and \$75,000 to ninety-seven members of the Senate. The industry gave \$2.3 million to Hillary Clinton's campaign and \$343,000 to Trump's. See *Money to Congress*, OPENSECRETS, <https://www.opensecrets.org/industries/summary.php?cycle=2016&ind=HO4> [<https://perma.cc/4ES9-NNKH>] (last visited Feb. 2, 2022).

268. See Olivier J. Wouters, *Lobbying Expenditures and Campaign Contributions by the Pharmaceutical and Health Product Industry in the United States 1999–2018*, 180 JAMA INTERNAL MED. 1 (2020).

269. *Id.*

270. For example, the “Innovation Saves” or “Understanding Your Drug Costs: Follow the Pill” campaigns launched by BIO in 2016. See *A Bitter Pill: How Big Pharma Lobbies to Keep Prescription Drug Prices High*, CITIZENS FOR RESP. & ETHICS IN WASH. (June 18, 2018), <https://www.citizensforethics.org/reports-investigations/crew-reports/a-bitter-pill-how-big-pharma-lobbies-to-keep-prescription-drug-prices-high/> [<https://perma.cc/8H37-NL8Y>].

271. Jim Rendon, *How Nonprofits Helped Fuel the Opioid Crisis*, CHRON. PHILANTHROPY (Jan. 13, 2022), [https://www.philanthropy.com/article/how-nonprofits-helped-fuel-the-opioid-crisis?cid=gen\\_sign\\_in](https://www.philanthropy.com/article/how-nonprofits-helped-fuel-the-opioid-crisis?cid=gen_sign_in) [<https://perma.cc/Z5MX-T7XG>].

272. ROSENTHAL, *supra* note 190, at 117 (“PAN [Patient Access Network] does not disclose its donors, but says they include “pharmaceutical companies, medically related organizations, individuals and foundations.” . . . According to a report by the [Office of the Inspector General of the] U.S. Department of Health and Human Services (HHS), most of PAN’s funding is provided by manufacturer of the drugs covered by the program.”).

273. WHO reports several pharmaceutical companies as donors. Neither Pfizer nor Moderna is included as a contributor. Instead, the Bill & Gates Foundation is, who is a contributor to Pfizer. In 2020–21, the Gates Foundation contributed \$592 million to WHO. See *Contributors*, WORLD HEALTH ORG., <https://open.who.int/2020-21/contributors/contributor?name=Bill%20%26%20Melinda%20Gates%20Foundation> [<https://perma.cc/F6BF-WLY7>] (last visited Feb. 3, 2022); *Committed Grants*, BILL & MELINDA GATES FOUND., <https://www.gatesfoundation.org/about/committed-grants> [<https://perma.cc/6KP8-7R6Q>] (last visited Feb. 3, 2022).

274. Between 2013 and 2017, the number of companies and organizations that lobbied on some variation of the term “drug pricing” has more than quadrupled. See *A Bitter Pill*, *supra* note 270.



reached a record-breaking \$92 million during the first three months of 2021.<sup>275</sup> But as mRNA vaccine makers gained control over vaccine supply during 2021 and the patent waiver proposal lost momentum,<sup>276</sup> federal lobbying spending decreased each quarter (and was lower than the total contributions of Pfizer in 2020).<sup>277</sup>

Lobbying has become a practice of pharmaceutical companies acting both individually and collectively. For instance, Pharmaceutical Research and Manufacturers of America (PhRMA), which represents the country's largest drug makers and is considered the industry's largest lobbying spender, raised \$100 million specifically to lobby for drug pricing during the 2016 presidential campaign.<sup>278</sup> By examining recent attempts at legislation aimed at controlling drug prices, Citizens for Responsibility and Ethics in Washington found that the pharmaceutical lobby operates by "opposing new legislation, protecting and expanding existing loopholes, and delaying the implementation of new regulations."<sup>279</sup> Lobbying by the pharmaceutical industry has become normalized as the best practice for fighting regulation to the point that people in the pharmaceutical business consider it a "meaningful mistake" to not spend significant money on lobbying.<sup>280</sup> Pfizer has been one of the top lobbying spenders and campaign contributors in the United States over the last two decades.<sup>281</sup> A recent RepTrak's reputational rank of pharmaceutical companies in the United States shows that Pfizer has the lowest reputational score.<sup>282</sup> The general public believes that Pfizer plays a role in drug shortages and uses charity to mask drug price hikes, and condemns it for not committing to limit drug price increases and disclose overall drug costs.

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275. Alyce McFadden, *Pharma Loses Vaccine IP Battle Despite Record Q1 Lobbying*, OPENSECRETS (May 5, 2021), <https://www.opensecrets.org/news/2021/05/big-pharma-shatters-q1-lobby/> [<https://perma.cc/D35Q-L9GF>].

276. See *infra* Section IV.B.

277. Tara Suter, *Lobbying Efforts by Companies Making COVID-19 Rapid Tests and Vaccine Fluctuate*, OPEN SECRETS (Nov. 8, 2021), <https://www.opensecrets.org/news/2021/11/lobbying-efforts-by-companies-making-covid-19-rapid-tests-and-vaccines/> [<https://perma.cc/R96F-E9N5>] (stating that while Pfizer spent on average over \$7 million on lobbying in 2021, Moderna spent \$280,000).

278. In 2016, PhRMA increased its membership fees by fifty percent to raise an additional \$100 million that could be used "in a drug pricing battle." See *A Bitter Pill*, *supra* note 270, at 2.

279. *Id.* at 6.

280. *Id.* (regarding Turing Pharmaceuticals and the increase in the price of Daraprim, a drug to treat rare infection, by more than five thousand percent in 2015).

281. Wouters, *supra* note 268.

282. Charlotte Hu, *These Are the Most—and Least—Reputable Drug Companies in the U.S.*, INSIDER (June 19, 2018), <https://www.businessinsider.com/pharmaceutical-company-reputation-rankings-2018-6?r=US&IR=T#22-pfizer-reptrak-points-545-1> [<https://perma.cc/P6HZ-ZE2K>] (using RepTrak 2018 scores and comparing with previous years' scores).

*D. Inequitable-by-Design Global COVID-19 Vaccine Rollout*

The global inequitable access to COVID-19 vaccines is consistent with the “inverse equity hypothesis” observed by Julian Tudor Hart fifty years ago.<sup>283</sup> According to this hypothesis, new healthcare innovations, such as the mRNA vaccine technology used to produce the most effective COVID-19 vaccines to date, exacerbate health disparities in predictable patterns. Because equity is centered around allocating *existing* resources evenly, common wisdom would assume that *new* available resources would fulfill unattended needs and favor disparities less.<sup>284</sup> But the inverse equity hypothesis proves common wisdom wrong.

At an early stage of allocation of new technologies, the inverse equity hypothesis explains, the wealthiest groups gain access to advances more rapidly than other groups. In other words, there is a tendency for initial vaccine distribution to be inequity forcing rather than equity building.<sup>285</sup> Once demand is saturated among high and middle affluent groups, the poorest populations slowly begin to obtain access to new technologies. The inverse equity hypothesis also predicts that when vaccine supply expands, disparities begin to narrow. Studies of innovations, including immunizations, have confirmed the inverse equity hypothesis by demonstrating that advances in healthcare are transferred first to wealthy populations.<sup>286</sup> But other studies have shown that not all dissemination of healthcare innovations follow the inverse equity path. Innovations can be *purposefully* delivered in a successful, equitable manner.<sup>287</sup> Therefore, even though the inverse equity hypothesis is discouraging, its value to healthcare policy is in informing us that inequities in healthcare innovation are *predictable* and *avoidable*. Thus, not ac-

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283. The inverse equity hypothesis derives from the “inverse care law” introduced by British physician Julian T. Hart, according to which, in market-based healthcare systems, “the availability of good medical care tends to vary inversely with the need for it in the population served.” See Julian Tudor Hart, *The Inverse Care Law*, 297 LANCET 405, 405 (1971). Hart’s hypothesis has been extensively used across countries. See Michael Marmot, *An Inverse Care Law for Our Time*, 362 BRIT. MED. J. k3216 (2018); Richard Cookson et al., *The Inverse Care Law Re-Examined: A Global Perspective*, 397 LANCET 828, 828 (2021).

284. Kristen Underhill & Olatunde C. A. Johnson, *Vaccination Equity by Design*, 131 YALE L. J. F. 53, 58 (2021).

285. *Id.* at 58, 59.

286. See Cesar Gomes Victoria et al., *The Inverse Equity Hypothesis: Analyses of Institutional Deliveries in 286 National Surveys*, 108 AM. J. PUB. HEALTH 464 (2018). For early application of the inverse equity hypothesis on COVID-19 immunizations, see Adam Todd & Clare Bamba, *Learning from Past Mistakes? The COVID-19 Vaccine and the Inverse Equity Hypothesis*, 31 EUR. J. PUB. HEALTH 2 (2021).

287. See Victoria et al., *supra* note 286. Examples of successful equitable distributions include HIV treatment and flu vaccination for high-risk populations.

complishing equitable healthcare outcomes ultimately is a result of *policy choices*.

The inverse equity hypothesis makes *two relevant policy choices* explicit. Despite the exceptional circumstances of a pandemic, affluent nations and powerful drug makers opted for the profit incentive strategy over public health to lead drug manufacturing and distribution and, thus, decided not to vaccinate the world and end the pandemic. The basic inequities of these decisions are highlighted by COVID-19's fast and wide global reach. Indeed, the global COVID-19 vaccination fell into the inverse equity pattern: early access for the wealthy followed by lagging access for the poorest countries. Moreover, inequities worsened while vaccine supply increased.<sup>288</sup> This *first policy choice* is evidenced by drug manufacturers' reluctance to scale vaccine production or change their vaccine supply strategy and rich countries' nationalist behaviors: procuring the most effective vaccines for their citizens in volumes beyond their populations' needs (while failing to honor donation pledges through COVAX). It is also evidenced by the U.S. government opting to not exercise its express legal authority (and even entitlements with respect to vaccine technology)<sup>289</sup> to increase vaccine production, denying opportunities for broad, global access to vaccines.

The mere fact that affluent nations and drug makers are in a position to opt to not vaccinate the world is evidence of the extraordinary power that a few drug makers hold under the current drug legal model, and of the strong incentives that the system offers them to preserve their power and advance commercial interests over public health. Such a model is the result of a *second policy choice* and, for us, the most critical one. Access to healthcare is highly politicized, to the point where health and lives are commodified. Law and policy makers' policy choices have a direct effect on the design and governance of vaccine production and the vaccination model at large. As demonstrated by the ongoing pandemic, their policy decisions support inequality.

While the first policy choice calls into question the morality of drug manufacturers and rich nations under the extraordinary circumstances of a pandemic, the second challenges the global health principle of attaining equitable health outcomes even during normal times. Inequity-forcing policies affecting immunization and preventive care are particularly disturbing obstacles to achieving the sustainable development

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288. See *supra* section II (referring to the vaccine booster policy).

289. Zain Rizvi, Jishian Ravinthiran & Amy Kapczynski, *Sharing the Knowledge: How President Joe Biden Can Use the Defense Production Act to End the Pandemic Worldwide*, HEALTH AFFS. BLOG (2021), <https://www.healthaffairs.org/doi/10.1377/hblog20210804.101816/full/> [https://perma.cc/287U-YBRK]. For further discussion of U.S. legal authorities, see *infra* Section V.

goal of universal health coverage.<sup>290</sup> A model that heavily relies on vaccine manufacturers' will, vaccine buyers' wealth, and the exercise of political power suggests a critical point of deflection where the legal system is complicit in the production of vaccines overtly for profits rather than for public health and science.<sup>291</sup> The COVID-19 inequitable global access problem is bringing the inequity-by-design problem into focus again, fifty years after Hart's inverse care law was first suggested.

Vaccine nationalism and drug makers' control over vaccine production suggests that wealth and power drive the global vaccine production and distribution model. Health advocates and the media have highlighted the discriminatory consequences of this reality for populations in the African continent and for people of color,<sup>292</sup> calling the global COVID-19 vaccine rollout a "vaccine apartheid"<sup>293</sup> and "vaccine terrorism," respectively.<sup>294</sup> By contrast, manufacturers recognize being "slow in getting vaccines to Africa."<sup>295</sup> This claim is supported by a history of vaccine programs disproportionately affecting certain populations and regions. The COVID-19 vaccine-access problem is re-creating a situa-

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290. David N. Durrheim, *Thwarting the Inverse Care Law Through Immunisation*, 397 LANCET 1708 (2021).

291. Big pharmaceutical companies' executives have unremorsefully confirmed to the general public that the global COVID-19 vaccine deployment was planned based on "who wants to get [the vaccine]," mainly high-income countries, suggesting a normalized for-profit-over-public-health-value primary mission of the drug industry over. See text accompanying note 222.

292. Fatima Hassan, Leslie London & Gregg Gonsalves, *Unequal Global Vaccine Coverage Is at the Heart of the Current Covid-19 Crisis*, 375 BMJ n3074, n3074 (2021), <https://www.bmj.com/content/375/bmj.n3074.long> [<https://perma.cc/VJ2U-L5SQ>] ("[t]he response of the global North has been to further discriminate against and isolate the global South.").

293. Mariana Mazzucato, Jayati Ghosh & Els Torrelee, *Mariana Mazzucato, Jayati Ghosh and Els Torrelee on Waiving Covid Patents*, THE ECONOMIST (Apr. 20, 2021), <https://www.economist.com/by-invitation/2021/04/20/mariana-mazzucato-jayati-ghosh-and-els-torrelee-on-waiving-covid-patents> [<https://perma.cc/VKH2-VNBN>]; see also Aruna Kashyap & Margaret Wurth, *Rights Key to Tackle Corruption, Inequity in Vaccine Access*, HUM. RTS. WATCH (Mar. 11, 2021), <https://www.hrw.org/news/2021/03/11/rights-key-tackle-corruption-inequity-vaccine-access#> [<https://perma.cc/D43Z-PBS5>]; Winnie Byanyima, *A Global Vaccine Apartheid Is Unfolding. People's Lives Must Come Before Profit*, THE GUARDIAN (Jan. 29, 2021, 2:45 PM), <https://www.theguardian.com/global-development/2021/jan/29/a-global-vaccine-apartheid-is-unfolding-peoples-lives-must-come-before-profit>; [<https://perma.cc/6NUW-QMND>]; @akapczynski, TWITTER (Apr. 30, 2021, 9:36 AM), <https://twitter.com/akapczynski/status/1388125147392000006> [<https://perma.cc/3MNG-CCGK>] (regarding her contribution on NPR's marketplace.org); Jessica Glenza, *Coronavirus: How Wealthy Nations Are Creating a "Vaccine Apartheid,"* GUARDIAN (Mar. 31, 2021), <https://www.theguardian.com/world/2021/mar/30/coronavirus-vaccine-distribution-global-disparity> [<https://perma.cc/5RBS-PWTY>].

294. WION, *Gravitas: Revealed: How Pfizer Blackmails Countries for Shots*, YOUTUBE (Oct. 20, 2021), <https://www.youtube.com/watch?v=nYIJxoh7gqw> [<https://perma.cc/YW4Z-9ESE>].

295. Andrea Shalal, *Moderna Says Aim to Name 'Country of Choice' for COVID vaccine Production in Africa Soon*, FIN. POST (Jan. 20, 2022), <https://financialpost.com/pmn/business-pmn/moderna-says-aims-to-name-country-of-choice-for-covid-vaccine-production-in-africa-soon> [<https://perma.cc/FGA7-8RUS>].

tion where “the ‘disease is in the Global South and the vaccines are in the Global North.’”<sup>296</sup>

Between 1997 and 2007, Africa suffered twelve million deaths from HIV/AIDS.<sup>297</sup> Drug makers based in the United States and Europe made drugs for the disease abundantly available elsewhere but Africa, a region brutally exposed to the virus. Although manufacturers in India and other countries of the Global South were initially accused of lacking the technical sophistication to produce drugs reliably, they produced HIV drugs in high quality and at a massive scale and “did so more efficiently than the original makers.”<sup>298</sup> Similarly, during the 2009 influenza A H1N1 epidemic, high-income countries procured the vaccine for the illness at surplus rates while low-income countries were left behind.<sup>299</sup> In other words, inequitable access to vaccines has deliberately occurred over time as a result of decisions made by a few—those who set the laws and policies of the drug industry and the drug makers who benefit from the system and perpetuate it. A reasonable fear is that the vaccine apartheid might be just the beginning of a global drug apartheid for many critical diseases, including cancer, since scientists have suggested—and Moderna<sup>300</sup> and Pfizer<sup>301</sup> have confirmed—that the application of the mRNA technology could expand in the short term to terminal or common diseases.<sup>302</sup> In fact, Moderna has started human trials of mRNA vaccine for multiple sclerosis.<sup>303</sup>

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296. ELLEN T HOEN, *The Medicines Patent Pool at 10: From Crazy Concept to Real Results*, MEDS. PATENT POOL (Dec. 10, 2020), <https://medicinespatentpool.org/story-post/mpp-10-years-ellen-t-hoen-story> [<https://perma.cc/M7GV-L3DW>].

297. John N. Nkengasong, Nicaise Ndembi, Akhona Tshangela & Tajudeen Raji, *COVID-19 Vaccines: How to Ensure Africa Has Access*, 586 NATURE 197, 198 (2020).

298. Morten & Herder, *supra* note 194 (referring to Andrew Jack, *The Man Who Battled Big Pharma*, FIN. TIMES (Mar. 28, 2008), <https://www.ft.com/content/bd8dccee-f976-11dc-9b7c-000077b07658> [<https://perma.cc/QC6P-KW7D>]); see also Fatima Hassan, *Don't Let Drug Companies Create a System of Vaccine Apartheid*, FOREIGN POL'Y (Feb. 23, 2021, 7:20 AM), <https://foreignpolicy.com/2021/02/23/dont-let-drug-companies-create-a-system-of-vaccine-apartheid/> [[perma.cc/FA5J-49XT](https://perma.cc/FA5J-49XT)].

299. Aishat Jumoke Alaran et al., *Uneven Power Dynamics Must Be Levelled in COVID-19 Vaccines Access and Distribution*, PUB. HEALTH IN PRAC.. Nov. 2021, at 2, <https://pubmed.ncbi.nlm.nih.gov/33615282/> [[perma.cc/MRT2-GM2J](https://perma.cc/MRT2-GM2J)].

300. *Moderna's Pipeline*, MODERNA, <https://www.modernatx.com/pipeline> [[perma.cc/242T-TFMR](https://perma.cc/242T-TFMR)] (last visited Jan. 13, 2022).

301. *Pipeline*, BIONTECH PIPELINE, <https://biontech.de/science/pipeline> [[perma.cc/SC42-W2MD](https://perma.cc/SC42-W2MD)] (last visited Jan. 13, 2022).

302. See Robert Langreth, *Moderna's Next Act is Using mRNA vs. Flu, Zika, HIV, and Cancer*, BLOOMBERG BUSINESSWEEK (July 14, 2021, 10:15 AM), <https://www.bloomberg.com/news/features/2021-07-14/moderna-mrna-targets-hiv-cancer-flu-zika-after-covid-vaccine> [[perma.cc/E2RC-3NLZ](https://perma.cc/E2RC-3NLZ)].

303. Robert Hart, *Moderna Starts Human Trials of mRNA Vaccine for Virus That Likely Causes Multiple Sclerosis*, FORBES (Jan. 14, 2022), <https://www.forbes.com/sites/roberthart/2022/01/14/moderna-starts-human-trials-of-mrna-vaccine-for-virus-that-likely-causes-multiple-sclerosis/?sh=6a87f5d51a04> [<https://perma.cc/3Y8P-P7Y9>].

The inverse equity theory shows that through history, the healthcare sector economy has not been separate from politics and legal contexts that favored its existence. The healthcare system cannot preach health equity with market fanaticism while politicizing access to healthcare by concentrating market and political power in a few private actors. The greatest risk of doing so is commodifying health and disregarding people's lives. Unless we map and attend with political judgment access-to-healthcare inequities, inequities will persist, expand, and continue in cycles, with this and other pandemics, diseases, and medical treatments, and we will not be able to interrupt the continuous corruption<sup>304</sup> of healthcare systems' mission and global health governance.

#### V. ADDRESSING THE POLITICS OF GLOBAL COVID-19 VACCINE INEQUITIES

The global deployment of the COVID-19 vaccine has shown the limits of the IP and patent model especially during life-threatening, extraordinary circumstances. Section IV outlined the structural problems around production and delivery of vaccines that have led to global vaccine inequity and how these problems are avoidable through public choices. This Section examines legal mechanisms and suggests policy strategies to address the legal and moral barriers drawn by the model, whether exercising existing legal rights or implementing principles for a transformative global vaccine governance. This Section suggests concrete policy actions, both quick fixes and long-term strategies, to effectively reduce the inverse equity effects of the IP landscape.

##### *A. Regulatory Options for Sharing Patent-Protected Vaccines*

Considering the status quo of the IP and patents legal model in the context of the COVID-19 pandemic, this Subsection examines existing legal tools and proposals for scaling up vaccine production and distribution through sharing technology and knowledge of mRNA COVID-19 vaccines.

Scientists estimate that twenty-two billion doses of mRNA vaccines will be needed in 2022 to universally vaccinate the global population, blunt evolution of the virus, and bring the pandemic under control.<sup>305</sup> A

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304. Here, corruption has a social, rather than legal, connotation.

305. This target is, however, more aggressive than the goal of fully vaccinating seventy percent of the global population, set by the World Health Organization. See WORLD HEALTH ORG., STRATEGY TO ACHIEVE GLOBAL COVID-19 VACCINATION BY MID-2022, *supra* note 22.

2022 modeling study on global vaccination suggests that 1.3 million lives could be saved with scaled-up production and delivery of mRNA vaccines.<sup>306</sup> mRNA vaccine makers provide for production of seven billion doses in 2022, a volume that could decrease depending on the need for variant-updated vaccines.<sup>307</sup> If scientists' and drug makers' projections are accurate, there will be a vaccine shortfall of fifteen billion doses of mRNA vaccines in 2022.

Independent reports surveying global manufacturing capacity and vaccine supply and distribution chains conclude that vaccine production can be ramped up if makers shared resources and knowledge.<sup>308</sup> There are voluntarily and compulsory mechanisms for sharing technology and improving access to patented vaccines. One of the most successful voluntary mechanisms is the Medicines Patent Pool (MPP), a United Nations-backed public health organization conceived of in the context of the HIV/AIDS public health crisis to improve access to medicines in LMICs.<sup>309</sup> The MPP works by identifying medicines that are greatly needed by LMICs but remain inaccessible due to their patents, then requesting requests the drug maker who holds the patent to grant generic pharmaceutical companies a license to manufacture generic versions of the medicine before the patent expires. Generic pharmaceutical companies are chosen based on their manufacturing track record, capacity, and country/market presence. The rationale behind this initiative is that it will expand generic drug production promote competition and decrease drug prices. For example, during the HIV/AIDS crisis, the majority of patented HIV medicine used in LMICs was through MPP (although other voluntary sharing approaches were available, such as tiered pricing and bilateral licensing).<sup>310</sup>

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306. See Alexandra Savinkina et al., *Model-Based Estimates of Deaths Averted and Cost per Life Saved by Scaling-up mRNA COVID-19 Vaccination in Low and Lower-Middle Income Countries in the COVID-19 Omicron Variant Era*, MEDRXIV (Feb. 9, 2022), <https://www.medrxiv.org/content/10.1101/2022.02.08.22270465v1> [<https://perma.cc/3XEY-N337>].

307. Diamond, *supra* note 24 (citing a report of health data research firm Airfinity published on Dec. 16, 2021).

308. See JAMES KRELLENSTEIN & CHRISTIAN URRUTIA, HIT HARD, HIT FAST, HIT GLOBALLY: A MODEL FOR GLOBAL VACCINES ACCESS (2021), <https://static1.squarespace.com/static/5e937afb7a75746167b39c/t/6054fdd855fb270753f4b0c9/1616182745295/P4A++Hit+Hard+Hit+Fast+Hit+Globally+Report.pdf> [<https://perma.cc/3TPH-JUHV>]; \$25 Billion to Vaccinate the World: The U.S. Government Must Ramp up Vaccine Production and End the Global Pandemic, PUB. CITIZEN (May 24, 2021), <https://www.citizen.org/article/25-billion-to-vaccinate-the-world/> [<https://perma.cc/3FJJ-DQHG>].

309. T HOEN, *supra* note 296 (referring to antiretroviral medicine to treat over 30 million patients in LMICs). The idea of an MPP was first discussed at the International AIDS Conference in 2002, but it was founded by Unitaid in 2010.

310. Tiered pricing is where the patent holder reduces its patented medicines' prices for lower-income countries. Bilateral licensing is where the patent holder directly issues a license to a generic pharmaceutical company of its choice. See Rosalie Hayes, *Voluntary Licensing via the Medicines Patent*

Following the MPP's successful experience with HIV/AIDS, WHO created the COVID-19 Technology Access Pool (C-TAP) to provide a voluntary technology, IP, and know-how sharing mechanism in the context of the pandemic. The diagnostic technology to detect SARS-CoV-2 antibodies and immunity was the first to be available through the C-TAP.<sup>311</sup> The Biden administration announced in early March 2022 its intention to share U.S. government–devised coronavirus technologies developed by the NIH with WHO through C-TAP; they can also be sublicensed to the United Nations–backed MPP. This policy is not intended to apply to mRNA vaccines, however.<sup>312</sup> Moderna and Pfizer, the only pharmaceutical companies that produce mRNA vaccines at the time of this writing, have emphasized they would produce more doses “if only they could.”<sup>313</sup> Both *could* voluntarily share their vaccine formulas through C-TAP or partner with other manufacturers (for example, through outsourcing part of their manufacturing processes) and sell more. Even though this could be a way to reach a greater population and increase sales, manufacturers have claimed that when drug manufacturers share trade secrets (precise lists of ingredients, detailed instructions for production, etc.), they are exposed to a high risk of information leaks.<sup>314</sup> Despite nondisclosure agreements and similar legal tools, some knowledge inevitably leaks to competitors. That is, vaccine manufacturers may end up preferring avoiding the—eventual and unpredictable—harm caused by information exchanges rather than the harm of—quantifiable and avoidable—vaccine scarcity.<sup>315</sup>

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*Pool Is Saving Hundreds of Thousands of Lives*, AIDS MAP (Feb. 9, 2022), <https://www.aidsmap.com/news/feb-2022/voluntary-licensing-medicines-patent-pool-saving-hundreds-thousands-lives> [<https://perma.cc/VZ9X-UKAV>].

311. By the end of November 2021, the MPP license for a diagnostic technology that detects SARS-CoV-2 antibodies and immunity. The technology license grants all necessary know-how and material transfer, royalty-free for all LMICs (with a 15% royalty applied only in high-income countries where a patent is in force or where a licensee has used material transfer). See Kaitlin Mara, *The WHO Covid-19 Technology Access Pool Signs First License Agreement; Will Hopefully Be a Turning Point*, MED. L. POL'Y (Nov. 23, 2021), <https://medicineslawandpolicy.org/2021/11/the-who-covid-19-technology-access-pool-signs-first-license-agreement-will-hopefully-be-a-turning-point/> [<https://perma.cc/X39V-AEVJ>].

312. See Dan Diamond, *U.S. to Share Some Coronavirus Technologies with World Health Organization*, WASH. POST (Mar. 3, 2022), <https://www.washingtonpost.com/health/2022/03/03/us-coronavirus-technologies-world-health-organization/> [<https://perma.cc/D2AK-KJH6>].

313. Morten & Herder, *supra* note 194 (stating that Moderna and Pfizer-BioNTech had argued that there is no mRNA manufacturing capacity in the world thus justifying scarcity of vaccines based on production and distribution challenges).

314. Morten & Herder, *supra* note 194.

315. Morten & Herder, *supra* note 194 (noting that the Financial Times has reported that manufacturers have warned U.S. government officials that “giving up intellectual property rights [to COVID-19 vaccines] could allow China and Russia to exploit platforms such as mRNA.”); see Hannah Kuchler & Aime Williams, *Vaccine Makers Say IP Waiver Could Hand Technology to China and Rus-*



The big challenge of the C-TAP initiative is overcoming the seductiveness of accumulating unlimited profits to manufacturers without rigorous regulatory oversight. Attempts to limit patent monopolies could constitute, to policy makers, “attacks on private property,” as they deem patents to be *the* way to ensure innovation.<sup>316</sup>

Based on vaccine makers’ profits during 2021, it seems likely that manufacturers will not make doses available to the global population through voluntary mechanisms. Pfizer expects slightly lower 2022 revenues from vaccine sales compared to 2021—although analysts suggest revenues will be higher. Furthermore, Pfizer’s profit incentives to produce other COVID-19 related treatments might divert its attention away from COVID-19 vaccines in 2022.<sup>317</sup> Because incentivizing vaccine manufacturers is favored by the IP and pharmaceutical industry’s complementary rules, the vaccine-for-public-health ideal will remain unrealized. Under these circumstances, can the world reach the number of doses needed before the end of 2022?

Health law scholars claim that the current IP model provides legal tools in the form of compulsory licenses<sup>318</sup> to share mRNA patented vaccines at both the national and international levels. Despite patent holders’ negative reaction to the TRIPS flexibilities incorporated by the Doha Declaration, developing and least-developed countries have issued compulsory licenses on certain patented products. Pharmaceutical groups like PhRMA have expressed their discontent with health organizations like WHO that provide technical support to countries engaging in compulsory licensing.<sup>319</sup> Of course, ideally, a more satisfactory solution to compulsory licensing is to encourage competition for a particular drug rather than extend monopolistic patents.

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sia., FIN. TIMES (Apr. 25, 2021), <https://www.ft.com/content/fa1e0d22-71f2-401f-9971-fa27313570ab> [<https://perma.cc/G56U-7KT4>].

316. LINDSEY, *supra* note 171. For a critical perspective to a property-based regime of IP, see Ana Santos Rutschman, *Property and Intellectual Property in Vaccine Markets*, 7 TEX. AM. J. PROP. L. 110 (2021).

317. In 2022, Pfizer expects \$32 billion in revenue from BioNTech-partnered vaccine Comirnaty and \$22 billion in revenues from oral antiviral Paxlovid. See Fraiser Kansteiner, *Pfizer Sticks to Guns on \$22B Paxlovid Sales Despite Reports of Lagging Demand*, FIERCE PHARMA (May 3, 2022), <https://www.fiercepharma.com/pharma/pfizer-echoes-hopes-22b-paxlovid-sales-despite-reports-lagging-demand> [<https://perma.cc/R7YT-TCJV>].

318. See *infra* note 342 (compulsory licensing enables a competent government authority to license the use of a patented product or process to a third-party entity or government agency, without the consent of the patent holder, for compensation).

319. Zachary Brennan, *PhRMA Goes on the Offensive Attacking the WHO and Putting the EU, UK, Australia and Others on Notice*, ENDPOINTS (Feb. 2, 2022) <https://endpts.com/phrma-goes-on-the-offensive-attacking-the-who-and-putting-the-eu-uk-australia-and-others-on-notice/> [<https://perma.cc/3LF2-T999>] (referring to the 2022 White House report on the global state of IP).

This subsection examines two compulsory tools: the use of a U.S. federal statute, 28 U.S.C. § 1498, for government patent use and the TRIPS waiver proposal. However, as is discussed below, neither offers a simple, straightforward solution to the vaccine-access problem.

### 1. Patent Use Under § 1498

Under 28 U.S.C. § 1498 (section 1498), the U.S. government can use any technology covered by a U.S. patent that was developed with either public or private funding. The aim of the provision is to facilitate the U.S. government's use or manufacture of any patented invention anytime a U.S. patent stands in the way of government procurement, without the consent of the patent holder, in return for "reasonable and entire compensation."<sup>320</sup> Thus, the statute allows the U.S. government to procure the patented product from competitors or to manufacture the product itself.

There are no limitations regarding which or how many patents the U.S. government can use or when it can use them. If a product is covered by several patents, such as the mRNA COVID-19 vaccine, the government can use all available patents at the same time. Likewise, there are no circumstantial preconditions other than that the patent use be "by or for the United States."<sup>321</sup> That is, no patent use justification is required by the statute. Moreover, the statute affirms the government's power to use any patent without permission of the patent holder. The U.S. government may use the patent for any reasons, such as to address a supply shortage, support military strategy, or respond to an emergency situation such as insufficient access to lifesaving vaccines during a pandemic.<sup>322</sup> Government patent use under section 1498 can also be used to accelerate competition and expand access to any critical product in short supply that would be otherwise constrained by the existence of a patent. The U.S. government (or third-party entities it authorizes) can immediately use or manufacture the patented product however it deems convenient, without advance notice to the patent holder or any-

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320. 28 U.S.C. § 1498 (a). A "reasonable and entire" compensation is determined by a federal court. Historically, federal courts have taken a conservative approach and awarded a royalty based on the market value of the patented invention. See ADAMCZYK ET AL., *supra* note 176.

321. Amy Kapczynski & Aaron S. Kesselheim, "Government Patent Use": A Legal Approach to Reducing Drug Spending, 35 HEALTH AFFS. (MILLWOOD) 791 (2016). Courts have interpreted "for the United States" as meaning that the patent use is covered by the statute only when it is both "authorized" by and undertaken "for" the government. See Hannah Brennan & Amy Kapczynski, A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health, 18 YALE J.L. TECH. 275, 330 (2016).

322. ADAMCZYK ET AL., *supra* note 176, at 12.

one else.<sup>323</sup> The patent holder can later seek compensation under the statute by filing a lawsuit against the United States in a specialized federal court of claims for patent infringement.<sup>324</sup> Compensation determined in such a proceeding could be significantly lower for royalties paid to patent holders against sales of the patented invention.<sup>325</sup> By using this statute, governments could lower patent prices and increase public access to patented products that are in short supply if they are able to expand the manufacturing capacity beyond what could be achieved by the patent holder.<sup>326</sup> Eventually, this practice could have an impact on drug market prices as generic manufacturers step in to produce the patented product.<sup>327</sup>

There is a long history of government patent use and patent holders' compensation under section 1498. The government has previously used the statute to obtain lower patent prices or a greater supply of goods to satisfy the government's procurement needs for pharmaceuticals, software, and military supplies.<sup>328</sup> One example in the pharmaceutical industry is Cipro. Cipro is an instance of the U.S. government bargaining in the shadow of section 1498 instead of going to the court for "reasonable and entire" compensation, considering patent holders' incentives to accept a deal that represents a discount from the "normal," "open market" price of the patented product under such statute.<sup>329</sup> The U.S. government sought to use the drug which treats anthrax, patented by Bayer, after concerns about anthrax attacks were heightened following September 11.<sup>330</sup> After initially informing the government it was unable to meet the government's demands for quantities of Cipro or sell it at a price rea-

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323. Christopher J. Morten & Charles Duan, *Who's Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises*, 23 YALE J.L. TECH. 1 (2020), <https://yjolt.org/whos-afraid-section-1498-case-government-patent-use-pandemics-and-other-national-crises> [<https://perma.cc/K9KM-6B77>].

324. ADAMCZYK ET AL., *supra* note 176 (stating that "[i]n the narrowest, technical sense, it is patent holders, not the U.S. government, that 'use' §1498, by filing lawsuits that reference that statute[.] . . . the government implicitly 'uses' §1498 any time it uses a patent."). The previous version of the statute did not provide a remedy to the patent holder. *See also* Morten & Duan, *supra* note 323.

325. *See* Kapczynski & Kesselheim, *supra* note 321, at 793–94. Kapczynski and Kesselheim present an argument that governments could make to limit the compensation received by the patent holder to "reasonable or average profits" for the invention with regards to the amount invested in researching and developing the subject invention, plus an adjustment for risk of the invention's failure. *See id.* at 793.

326. *See* Kapczynski and Kesselheim, *supra* note 321, at 793.

327. *See id.* at 796. However, as Elisabeth Rosenthal explained, referring to the economics of the dysfunctional medical market, the presence of more competitors in the drug market does not necessarily mean better prices; it can drive prices up, not down. *See* ROSENTHAL, *supra* note 190, at 114.

328. ADAMCZYK ET AL., *supra* note 176, at 14–15.

329. *See id.* at 30.

330. *Id.* at 31.

sonable to the government, Bayer agreed to ramp up production and lower prices by half once the government announced its intention to use section 1498 and purchase the antibiotic from generic manufacturers.<sup>331</sup> Bayer was still able to profit off its patent—it met the government’s demand for the drug itself instead of allowing generic manufacturers to do so. The government obtained a benefit for the public’s health and taxpayers “while fully respecting patent law.”<sup>332</sup>

A “threatening use of [section] 1498” brought Bayer to the negotiating table with the government despite Bayer’s initial unwillingness to license generic competitors to sell the drug in the United States.<sup>333</sup> Comparing the Cipro case to mRNA vaccines, the amounts pharmaceutical companies spent on lobbying was much lower in 2001 than current levels.<sup>334</sup> The Cipro case shows how section 1498 can provide the U.S. government with the necessary leverage to obtain concessions from patent holders.<sup>335</sup> Negotiations like those between Bayer and the U.S. government can—and ought to—take place whenever there is a risk associated with a low supply or high prices of drugs. Government patent use under section 1498 could solve the proprietary/exclusivity rights of mRNA vaccine patents that undermine the global COVID-19 vaccine supply. But this tool requires government intervention, which is highly dependent on the aims of any given presidential administration. For instance, at the beginning of the COVID-19 pandemic, Alex Azar, the Secretary of Health and Human Services (HHS)—who also participated in the Cipro negotiations on behalf of the U.S. government as General Counsel of HHS—said that “[the government] can’t control [the vaccine] price, because we need the private sector to invest. . . . Price control won’t get us there.”<sup>336</sup>

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331. *Id.* at 30–31.

332. *Id.* at 30.

333. Keith Bradsher, *Bayer Agrees to Charge Government a Lower Price for Anthrax Medicine*, N.Y. TIMES, Oct. 25, 2001, at B8; see also Dan Ackman, *A New Deal on Cipro*, FORBES, Oct. 24, 2001 (“[Bayer] is going to meet our price, which is less than \$1, or else we’re going to go to Congress and ask for some support to go in and do some other business.” (quoting then Health and Human Services Secretary Tommy Thompson)).

334. Annual lobbying by pharmaceutical manufacturers totaled close to \$358 million in 2021, compared to \$100 million in 2001. Likewise, in 2001, Bayer AG’s lobbying spending was close to \$1.5 million, compared to Pfizer’s \$10 million in 2021 (Pfizer is the largest manufacturer of COVID-19 mRNA vaccines). See *Industry Profile: Pharmaceuticals/Health Products*, OPENSECRETS, <https://www.opensecrets.org/federal-lobbying/industries/summary?cycle=2021&id=H04> [<https://perma.cc/UK4T-92TB>] (last visited Feb. 11, 2022).

335. Brennan & Kapczynski, *supra* note 321.

336. Nicole Wetsman, *Health secretary Alex Azar won’t promise that a coronavirus vaccine would be affordable*, VERGE (Feb. 27, 2020, 11:53 AM EST), <https://www.theverge.com/2020/2/27/21155879/alex-azar-coronavirus-vaccine-affordable-insurance> [<https://perma.cc/Q9W8-39SN>].

In contrast to the COVID-19 pandemic, the Cipro case incited the U.S. government to exercise its sovereign power. Nonetheless, the Cipro example also shows how the U.S. ability to use tools like section 1498 can be at odds with efforts to expand patent access and vaccine production to countries in the Global South. Instead, U.S. political power exercised in the form of vaccine nationalism can deflate the government's interest in patent use and undermine the public call to expand vaccine production to nations in the Global South. After successfully obtaining authorization to use Cipro from Bayer, "the Bush administration was then embroiled in an effort to prevent countries in the Global South from using their own government-patent-use-like powers on patents owned by U.S. drug companies."<sup>337</sup> In other words, nationalism took primacy over global vaccine access. Additionally, a web of multiple patents and trade secrets surrounding vaccines can limit the use or production of vaccines like the mRNA COVID-19 vaccine.

## 2. Patent Licensing Proposal Under the TRIPS Agreement

Another immediate policy action that could expand vaccine supply is waiving mRNA vaccine technology patents under the TRIPS Agreement. This could enlarge production capacity by temporarily compelling manufacturers to transfer vaccine know-how and technology while simultaneously expanding production in LMICs.

There are two primary arguments for sharing patent-protected vaccine technology under the TRIPS Agreement. Some health law scholars argue that the TRIPS Agreement already offers compulsory licensing of patented products during public health crises, an option used during the first decade of the twenty-first century for drugs for the treatment of HIV/AIDS.<sup>338</sup> That is, the option of a compulsory licensing would reach in practice the ultimate access goals of a TRIPS waiver proposal. The strongest justification of their position, however, circles the idea of an *infrastructural problem* rather than an IP problem to overcome the global vaccine-access issue.<sup>339</sup> Other scholars, representing a majority position, propose a TRIPS waiver suspending various provisions of the

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337. ADAMCZYK ET AL., *supra* note 176, at 31.

338. Ana Santos Rutschman & Julia Barnes-Weise, *The COVID-19 Patent Waiver: The Wrong Tool for the Right Goal*, BILL OF HEALTH (2021), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3840486](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3840486) [<https://perma.cc/B82E-YM3D>] (referring to the examples of compulsory licenses by Malaysia in 2004 and Thailand in 2007). Rutschman and Barnes-Weise argued that a TRIPS waiver is the wrong tool.

339. See *infra* notes 365-366 and accompanying texts.

TRIPS Agreement. This position is based on the idea that it is a complex intellectual property problem which jeopardizes global vaccine supply.

Before unpacking the arguments for and against the TRIPS waiver proposal, understanding the challenges of the TRIPS Agreement is fundamental. The twentieth century's most comprehensive multilateral agreement on IP surged when national regulatory authority—the central goal of the agreement—was highly regarded. Each member state was to adapt its patent law in alignment with an international IP law framework. Nonetheless, the TRIPS Agreement became a “supranational code” that precludes national law and dictates how WTO members must protect innovative goods.<sup>340</sup> Because different economic and cultural conditions prompt countries to adopt specific country-based approaches to IP, the shortcoming of the TRIPS Agreement was creating a one-size-fits-all code. Such a code is not only undesirable but also detrimental to the goal of balancing the interests of exclusive proprietors (inventors) in securing a return on their investments and the interests of the public in having access to a robust domain of knowledge.<sup>341</sup>

Although the universality of a pandemic equalizes need across nations (i.e., all countries need to end the pandemic with the most effective treatment), the TRIPS Agreement was largely designed with a proprietary focus rather than a human rights approach. This is the hardest challenge to overcome. In the twenty-first century, understandings of pharmaceutical international IP law have shifted from an economic, property-centric understanding of IP to a human rights view, largely due to the social criticism that the property-based model hinders access to essential medicines.<sup>342</sup> The Doha Declaration signaled a change in thinking about patents and their role in access to medicines.<sup>343</sup>

India and South Africa introduced a formal proposal for a temporary waiver of patents under the TRIPS Agreement early in the pandemic.<sup>344</sup> This call, initially joined by 60 of 164 WTO members and supported

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340. See Jane C. Ginsburg, *International Copyright: From a “Bundle” of National Copyright Laws to a Supranational Code?*, J. COPYRIGHT SOC'Y USA, Vol. 47, 8 (Columbia L. Sch. Pub. L. Rsch. Paper No. 10, 2000).

341. See GRAEME B. DINWOODIE & ROCHELLE C. DREYFUSS, *A NEOFEDERALIST VISION OF TRIPS: THE RESILIENCE OF THE INTERNATIONAL INTELLECTUAL PROPERTY REGIME* (2012).

342. See Laura G. Pedraza-Fariña, *The Intellectual Property Turn in Global Health: From a Property to a Human Rights View of Health*, 36 OSIRIS 241 (2021), <https://www.journals.uchicago.edu/doi/10.1086/713703> [<https://perma.cc/65RK-WLRB>] (tracing how a human rights perspective on IP also emerged as a strategy to reconcile WHO's and the WTO's sociomedical views of health with the economic approach of the supranational IP code).

343. See discussion *supra*, Section IV.A.1.

344. Gabriel Scally, *The World Needs a Patent Waiver on Covid Vaccines. Why Is the UK Blocking It?*, GUARDIAN (Apr. 18, 2021), <https://www.theguardian.com/commentisfree/2021/apr/18/patent-waiver-covid-vaccines-uk-variants>.

by prominent health advocates, gained momentum by mid 2021 before the WTO's General Council meeting.<sup>345</sup> The WHO Director-General<sup>346</sup> and the President of the U.S.<sup>347</sup> supported the waiver proposal against criticism from pharmaceutical groups.<sup>348</sup> PhRMA claimed that a raw materials shortage and limited vaccine distribution capacity were the true challenges that needed to be addressed to increase global access to vaccines.<sup>349</sup> WTO's Director-General also raised this manufacturing capacity issue.<sup>350</sup> Pharmaceutical companies alleged that a waiver would further weaken already strained supply chains, proliferate counterfeit vaccines, "undermine public confidence in vaccine safety," and undermine U.S. leadership in biomedical discovery.<sup>351</sup> The European Union, Canada, Japan, Norway, Switzerland and the United Kingdom also opposed the waiver proposal.<sup>352</sup>

Patent waivers can be particularly challenging to obtain when manufacturers are too comfortable with a system heavily based on profits, which strengthens their political power and economic ties to legal and

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345. Robert Hart, *Fauci Warns Covid Patent Waivers May Not Be Best Way to Help Boost Vaccine Access*, FORBES (May 4, 2021), <https://www.forbes.com/sites/roberthart/2021/05/04/fauci-warns-covid-patent-waivers-may-not-be-best-way-to-help-boost-vaccine-access/?sh=730568a32388>.

346. Tedros Adhanom Ghebreyesus, *Waive Covid Vaccine Patents to Put World on War Footing*, WORLD HEALTH ORG. (Mar. 7, 2021), <https://www.who.int/news-room/commentaries/detail/waive-covid-vaccine-patents-to-put-world-on-war-footing> [https://perma.cc/T49E-WSVL].

347. See Statement from Ambassador Katherine Tai on the COVID-19 TRIPS Waiver (May 5, 2021) <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver> [https://perma.cc/3DQY-6U5E]; see also U.S. President Biden Calls for Intellectual Property Protection Waivers After Omicron Discovery, REUTERS (Nov. 26, 2021, 7:29 PM EST), <https://www.reuters.com/business/healthcare-pharmaceuticals/us-president-biden-calls-intellectual-property-protection-waivers-covid-19-2021-11-26/> [https://perma.cc/29BE-RWA9] (evidencing support to the TRIPS waiver as COVID-19 variants emerged).

348. Hart, *supra* note 345. Despite the Administration's support, the Chief Medical Advisor to the President of the U.S., Dr. Anthony Fauci, has been critical of the waiver proposal. See *id.* (summarizing Fauci's comments about how a TRIPS waiver could bring legal challenges regarding IP rights and compensation possibly leading to delays in global vaccination efforts).

349. Press Release, PhRMA, PhRMA Statement on WTO TRIPS Intellectual Property Waiver (May 5, 2021), <https://www.phrma.org/coronavirus/phrma-statement-on-wto-trips-intellectual-property-waiver> [https://perma.cc/UC8R-8PP8].

350. Shaoul, *supra* note 46 (referring to Ngozi Okonjo-Iweala's statement, "The WTO's work is not just defined by the IP waiver. If you get the waiver but you don't have manufacturing capacity, you can't use it. If you have manufacturing capacity but no technology transfer, you can't use it.").

351. PhRMA Statement on WTO TRIPS Intellectual Property Waiver, *supra* note 349; McFadden, *supra* note 275.

352. By the end of 2021, the U.S. was stonewalling to block progress toward a waiver. See D. Ravi Kanth, *Developed Countries Continue to Block TRIPS Waiver Proposal*, THIRD WORLD NETWORK BERHAD (Nov. 23, 2021), [https://www.twn.my/title2/intellectual\\_property/info.service/2020/ip201108.htm](https://www.twn.my/title2/intellectual_property/info.service/2020/ip201108.htm) [https://perma.cc/BZ4H-N4NP]. On countries blocking the waiver, see generally *Opposing Countries Must Stop Filibustering Negotiations on "TRIPS Waiver" at WTO*, MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN, (July 26, 2021), <https://msfaccess.org/opposing-countries-must-stop-filibustering-negotiations-trips-waiver-wto> [https://perma.cc/7FCQ-ECRU].

political agents. The waiver scenario is even more unrealistic when governments do not have the political will to intervene and exercise their legal authority to deploy control over the vaccine supply.<sup>353</sup> Still, not pursuing a patent waiver under the extraordinary, life-threatening circumstances of the pandemic could be seen as a signal of immoral complicity.

A patent waiver is based on the idea that a patent model should not apply by default, especially when vaccine makers benefit from direct government support to cover the upfront costs of drug development and advance purchase commitments that guarantee good returns on their investments. It is precisely these benefits which provide manufacturers and countries with no legitimate moral basis for objecting to a TRIPS waiver.

Legal scholars claim two key practical problems that a TRIPS waiver cannot address: (i) an infrastructural gap (low manufacturing capacity and a shortage of raw materials to produce vaccines), and (ii) a knowledge-sharing gap.<sup>354</sup> These two problems signal, as waiver critics claim, “short-term needs” and challenges that are “too intense” and “too complex” for waivers to fully address.<sup>355</sup> According to this argument, in the context of the COVID-19 pandemic the real problem to overcome with regard to vaccine scarcity is infrastructural, not IP-related. Thus, critics contend that a patent waiver alone is the wrong policy to address the global vaccine-access problem.<sup>356</sup>

Independent research and examples of manufacturing capacity in LMICs in the Global South discredit the infrastructural gap argument.<sup>357</sup> Vaccine experts have identified over a hundred companies located in developing countries with the potential to make mRNA COVID-19 vaccines.<sup>358</sup> Furthermore, in February 2022, scientists from South Africa’s Afrigen Biologics challenged the argument that mRNA vaccines could not be produced in poorer countries. Using publicly available data regarding mRNA COVID-19 vaccines, scientists came to-

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353. Rizvi et al., *supra* note 289; *see also* Morten & Duan, *supra* note 323 (discussing the ability of the U.S. government to obtain the rights to use patented technologies via 28 U.S.C. § 1498).

354. *See* Santos Rutschman & Barnes-Weise, *supra* note 338.

355. *Id.*

356. Santos Rutschman & Barnes-Weise also pointed out a contractual problem in connection with vaccine allocation and the bargaining dynamics between higher-income countries and a vaccine manufacturer. *See id.*

357. *See* KRELLENSTEIN & URRUTIA, *supra* note 308; *Experts Identify 100 Plus Firms to Make Covid-19 mRNA Vaccines*, HUM. RTS. WATCH (Dec. 15, 2021, 12:01 AM EST), <https://www.hrw.org/news/2021/12/15/experts-identify-100-plus-firms-make-covid-19-mrna-vaccines#> [<https://pera.cc/C7XY-5XYB>].

358. These include countries in Africa, Latin America, and South East Asia. *See Experts Identify 100 Plus Firms to Make Covid-19 mRNA Vaccines*, *supra* note 357.



gether from around the world—including the NIH—and announced that their own mRNA vaccine version could be tested in humans before the end of 2022. This would be the first mRNA vaccine designed, developed, and produced in Africa.<sup>359</sup>

The existence of other forms on intellectual property rights in addition to patents justifies this knowledge-sharing-gap argument. Webs of IP rights underpin the production, distribution, and marketing of mRNA vaccines protected by patents and trade secrets.<sup>360</sup> Additionally, there is a degree of opacity regarding the universe of IP rights as a result of the time-intensive nature of patent processing.<sup>361</sup> The foundational technology to develop the mRNA vaccine was invented in academic laboratories and small biotech research companies and then further licensed to larger companies for product development.<sup>362</sup> While the technology can be protected by patents, some components of vaccine technology and production (e.g., manufacturing processes and genomic information) may be protected by trade secrets.<sup>363</sup> Different components of a vaccine and their combinations can be subject to one or multiple patent protections.<sup>364</sup> In other words, COVID-19 vaccine technology is surrounded by a complex patent landscape that involves many patents (creating overlapping protections) and licenses between mRNA inventors and innovators (many of which go back to the early 1990s when mRNA was studied as a novel therapeutic).<sup>365</sup> Even if countries opted for compulsory licensing, it might not cover all forms of IP protections affecting all aspects of vaccine technology and production of mRNA vaccines.<sup>366</sup>

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359. Wendell Roelf, *In World First, South Africa's Afrigen Makes mRNA COVID Vaccine Using Moderna Data*, REUTERS (Feb. 4, 2022, 12:58 AM EST), <https://www.reuters.com/world/africa/world-first-safricas-afrigen-makes-mrna-covid-vaccine-using-moderna-data-2022-02-03/> [<https://perma.cc/P29Y-9RK8>].

360. See Gaviria & Kilic, *supra* note 239, at 546.

361. There is a time lag between the filing of a patent application and publication of that application by national patent offices. In the U.S., patent applications are published, as a general rule, approximately eighteen months after the filing date. See 35 U.S.C. § 122(b)(1)(a); Rutschman, *supra* note 49.

362. See Gaviria & Kilic, *supra* note 239, at 548. Because larger companies transform the foundational technology into the final market product, larger entities are designated as innovators while academic labs or research firms are inventors. *Id.* at 546.

363. *Id.* at 546.

364. Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZ. L. REV. 729, 745 (2019).

365. See, e.g., Jon A. Wolff, Robert W. Malone, Phillip Williams, Wang Chong, Gyula Acsadi, Agnes Jani & Philip L. Felgner, *Direct Gene Transfer into Mouse Muscle in Vivo*, 247 SCIENCE 1465–68 (1990) (discussing studies of RNA and DNA vectors).

366. Nick Dearden, *Putting Big Pharma in Charge of Global Vaccine Rollout Was a Big Mistake*, GUARDIAN (Feb. 8, 2022), <https://www.theguardian.com/commentisfree/2022/feb/08/big-pharma-global-vaccine-rollout-covid-pfizer> [<https://perma.cc/569A-7BNL>] (discussing the patent problem that compulsory licensing cannot resolve in the African Union).

*B. Equity-Enabling Strategies in the Patent Culture*

As argued in Section IV, the worldwide vaccine-access problem has made evident a mismatch between the policy design of IP protection of drugs, including vaccines, and the policy of an effective pandemic response. Patents have not encouraged innovation expansion when fast and widespread vaccination with the most effective vaccines is imperative to end the pandemic. Ideally, a better IP and patent legal model would be flexible enough to move away from profit maximization being the sole incentive to include *public value* maximization.

As discussed above, there are some legal mechanisms that would provide this flexibility, which could overcome the barriers that the current model raises to quickly and widely vaccinating the global population.<sup>367</sup> The complexity of the vaccine-access problem demands a more comprehensive legal and policy approach. Among many challenges, lack of corporate and political determination is one of the greatest barriers to the full exercise of voluntary legal tools and the enforcement of compulsory mechanisms for sharing patent-protected vaccine technology, respectively.

This Article argues that the greatest obstacle to vaccine supply is not the patent legal model itself but rather the *patent culture* institutionalized by IP laws, together with coexisting regulations shaping the vaccine industry. This set of laws and policies nourishes a landscape of absolute, proprietary-exclusive rights, and singularly exacerbates profit-driven interests. To use the term introduced by Joseph Fishkin in the context of equality of opportunity, these interests create a “bottleneck” in equitable access to vaccines by limiting the range of opportunities open to individuals and communities to access fast and universal global vaccination.<sup>368</sup> Unlimited lobbying, tax benefits and exemptions, friendly corporate jurisdictions and regulations, unconditional funding from public coffers, and unrestricted control over vaccine supply and prices have established a relationship between governments and drug manufacturers that prioritizes profits over caring for people’s lives. This patent culture provides governments with incentives to prioritize manufacturer interests over universal vaccination. Unlimited lobbying and nationalism have led wealthy nations to preserve manufacturers’ vaccine supply-controlling power at the cost of structurally undermining the de-

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367. For a discussion of the universal consensus to vaccinate the global population, see Sarah Newey, *Pharmaceutical Leaders Admit “We Dismally Failed” at Global Covid Vaccine Rollout*, TELEGRAPH (Dec. 16, 2021), <https://www.telegraph.co.uk/global-health/science-and-disease/pharmaceutical-leaders-admit-dismally-failed-global-covid-vaccine/> [https://perma.cc/REM9-RZ3E].

368. JOSEPH FISHKIN, BOTTLENECKS: A NEW THEORY OF EQUAL OPPORTUNITY (2014).

velopment of equitable vaccine distribution frameworks. For example, a “patent-intensive culture”<sup>369</sup> enabled vaccine nationalism in the form of preproduction commitments during the vaccine R&D stage.<sup>370</sup> In turn, the Cipro case demonstrates how the government can directly intervene to control vaccine supply justified on innovation nationalism, in disharmony with medical innovation equitable principles.<sup>371</sup> Nationalistic frameworks can represent a threat of the commodification and privatization of new vaccine production and distribution and the risk of not treating vaccines as global public goods.<sup>372</sup>

As the patent culture expands and ossifies in health care and health-related institutions, it will be extremely hard to change. While the LPE framework suggests how overly political vaccine invention, production, and distribution can be, the health-justice framework offers guidance on the importance of designing vaccination with social commitment at the forefront. In their own ways, both frameworks suggest that the democratization of healthcare through universal access to affordable and effective vaccines requires changing how access to health care is framed in legal and public policy settings. A new and better way to research, develop, produce, and distribute medicines is mandatory.

This Subsection moves away from the pattern of critique and reform in the study of law. Instead of suggesting legal reforms in IP law, it aims to explore the fundamental pillars that ought to govern the production and distribution of vaccines.<sup>373</sup> By recognizing the reasons internal to the patent culture explained throughout this Article, this Subsection proposes public value, transparency, and inclusivity as principles of vaccine governance committed to health equity. Mechanisms inspired by these principles would be most effective at reducing the preventable inverse equity effects of vaccination *and* advancing the human rights approach the TRIPS Agreement needs to incorporate. Furthermore, governance under those pillars seeks to hold private and public actors accountable to those who are ultimately affected by their decisions: citizens. These principles are particularly relevant during a global public health emergency, but they also transcend the current pandemic by contributing to

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369. Santos Rutschman, *supra* note 49, at 177.

370. *Id.* at 183–84.

371. See, e.g., discussion *supra* note 338. On innovation nationalism, see Sapna Kumar, *Innovation Nationalism*, 51 CONN. L. REV. 205, 208–09 (2019).

372. Santos Rutschman, *supra* note 49 (emphasizing the “public good” character of vaccines that target emerging infectious diseases).

373. These are principles that are different from those, endorsed by 175 U.N. member states in G.A. Res. 342/21, Political Declaration on Equitable Global Access to COVID-19 Vaccines (Mar. 11, 2021), <https://www.un.org/pga/75/wp-content/uploads/sites/100/2021/03/PGA-letter-The-Political-Declaration-on-Equitable-Global-Access-to-COVID-19-Vaccines.pdf> [<https://perma.cc/AXT4-3WXR>].

the (re)design of *social* institutions for the *collective* interest and value. Adopting a more equitable approach to vaccine access is, in fact, the goal that health scholars both for and against a TRIPS waiver proposal have endorsed.

### 1. Public Value

Vaccine production and distribution—and research that leads to both—ought to be governed by the purpose of creating public value above all. This entails designing a landscape that rewards public health priorities over market demands. The idea of public value relates to the broader concept of a mission-oriented healthcare model that values vaccines as *public goods*. In this Article, the idea of public goods is not based on the economics of the consumption of goods<sup>374</sup> but rather the indispensable benefits that consumption of certain goods provide to a community. Medicine is *essential* for health and well-being and, therefore, is not like other consumer goods. An optimal level of vaccine supply provides communities with positive and scaled externalities. Widespread and timely access to effective vaccines contributes to controlling a global public health crisis and eventually reaching its end, lowering hospitalizations and the risk of emergent variants, and increasing positive public health outcomes. All these ends are difficult to achieve if we engage in an approach to vaccines based on rivalries and exclusion.<sup>375</sup>

Although a patent culture heavily based on profit motives may be hard to overturn overnight, the current IP model offers opportunities for incremental changes toward a public value-based system. The

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374. The instinctive reaction to the use of the terms “private” and “public” is conceiving of them as opposites or substitutes. Economists define public goods as things whose benefits are inherently open to all (nonexclusive) and that do not reduce benefits to others (non-rival). See Paul Samuelson, *The Pure Theory of Public Expenditures*, 36 REV. ECON. STAT. 387, 387 (1954). However, that goods or services *can* be provided in a nonexclusive way or that their consumption is non-rivalrous does not mean they have to be provided in that way. Exclusivity and rivalrousness are characteristics that do not inherently identify to ways of consumption but rather describe ideals for the public provision of goods. See generally RICHARD MUSGRAVE & PEGGY MUSGRAVE, *PUBLIC FINANCE IN THEORY AND PRACTICE* (5th ed. 1989) (examining the appropriateness of exclusion or limited access to certain goods and services, remarking that inherently nonexclusive goods are rare; for non-rivalrous goods, they argue for their, and arguing the collective provision (non-exclusion) of non-rivalrous goods to keep barriers to their use low).

375. For an argument that vaccines are not public goods but rather humanitarian entitlements, see Ezekiel J. Emanuel & Govind Persad, Opinion, *Can Covid-19 Vaccines Be Global Public Goods?*, BMJ OPIN. (2021), <https://blogs.bmj.com/bmj/2021/07/22/can-covid-19-vaccines-be-global-public-goods/> [perma.cc/4GKC-64JN]. According to Emanuel and Persad, information to produce a vaccine should be considered a public good necessary to promote the humanitarian entitlement they consider vaccines to be. *Id.*

question this subsection aims to answer is which policy decisions from governments, health authorities, and private market actors related to production and distribution of vaccines can move the needle closer to public value and equity by addressing public health concerns and further from the exclusive profit motives of a few. Public value is not a departure from profits per se; profit incentives should be aligned with health care's mission.

*a. R&D Government Funding*

Some experts argue that direct government support is an effective approach during a health crisis to guide invention and innovation toward public health needs.<sup>376</sup> The principal advantage of governments funding R&D to develop vaccines should not be to give governments preemptive rights to be first in line for vaccine supply or leverage to bargain for low vaccine prices. Instead, governments should exercise their political power to push vaccine makers to vaccinate the global population, thus accelerating the resolutions of public health emergencies. Nevertheless, it is not obvious that publicly-funded clinical trials alone will make access to vaccines more equitable globally. If R&D funding comes from governments, it is going to be very difficult for them to not make their own citizens and residents their top priority. In this regard, governments' investment in mRNA COVID-19 vaccine R&D is instructive.

R&D public funding conferred on the wealthiest nations a sort of preemptive right over vaccine production, and they wrongly assumed they could over-satisfy national demand. Governments' extraordinary investment in COVID-19 vaccine R&D has favored differentiated vaccine prices, vaccine nationalism, vaccine hoarding, and secret bilateral vaccine procurement agreements. These manifestations of rich countries' self-prioritization concurred with low efforts to secure vaccination elsewhere. For example, as explained earlier in this section, countries like Canada, Japan, and the United Kingdom refused to support compulsory vaccine licensing that otherwise would have helped to scale up vaccine production and satisfy global production demand.<sup>377</sup> Although public R&D gives manufacturers no moral basis for objecting to a TRIPS waiver, manufacturers have been firmly opposed to it. In turn, the U.S. government lost opportunities to exercise its sovereign power

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376. See UCL INST. FOR INNOVATION & PUB. PURPOSE, *supra* note 175.

377. See *supra* note 357 and accompanying text.

and manufacturers proved their market and political power to be greater.<sup>378</sup>

Alternatively, governments could have conditioned committed R&D funding to equity-enhancing strategies and equity-based distribution goals.<sup>379</sup> Under the Spending Clause, Congress has the authority to attach conditions to financial assistance, such as federal aid to vaccination programs, and enforce an equity-enhancing strategy requirement.<sup>380</sup> Examples of equity-principled goals could be fully vaccinating part of the population or scaling up vaccine production successfully in a period of time, and filing a vaccine-equity plan that public health experts can evaluate. Moderna, for instance, received a grant from COVAX partner, CEPI, to develop its mRNA vaccine on the condition that vaccines were to be distributed according to public health needs and at affordable price for at-risk populations, especially in LMICs.<sup>381</sup> However, Moderna failed to deliver any of its early production to CEPI and instead served the highest bidders.<sup>382</sup>

#### *b. Prizes Over Patents*

Performance-based prizes have been proposed for health technologies. For example, the proposed Health Impact Fund of the non-profit organization Incentives for Global Health would provide pharmaceutical companies payments based on the assessed global health impact of their technologies.<sup>383</sup> For vaccines specifically, suppliers of pneumococcal vaccine received performance-based prizes as advance market commitments, in the form of a subsidy per vaccine dose sold.<sup>384</sup>

Yet the question around prize schemes is whether they can be used as tools to spur innovation in lieu of patents.<sup>385</sup> Compared to patents,

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378. See discussion *supra* part V.A.1–2; see also Zain Rizvi, *Pfizer's Power*, PUB. CITIZEN (Oct. 19, 2021), <https://www.citizen.org/article/pfizers-power/> [perma.cc/XUS7-Y22N] (highlighting manufacturers' influence over governments by describing Pfizer's practices).

379. Penalties for failure to innovate on the basis of equity could be regarded as innovation sticks and play a role in innovation policy. On innovation sticks, see Ian Ayres & Amy Kapczynski, *Innovation Sticks: The Limited Case for Penalizing Failures to Innovate*, 82 U. CHIC. L. REV. 1781 (2015).

380. See U.S. CONST. art. I, § 8, cl. 1.

381. See, e.g., Deutsch, *supra* note 205.

382. *Id.*

383. AIDAN HOLLIS & THOMAS POGGE, INCENTIVES FOR GLOBAL HEALTH, THE HEALTH IMPACT FUND: MAKING NEW MEDICINES ACCESSIBLE FOR ALL 1, 13–26 (2008).

384. See Tania Cernuschi, Eliane Furrer, Nina Schwalbe, Andrew Jones, Ernst Berndt & Susan McAdams, *Advance Market Commitment for Pneumococcal Vaccines: Putting Theory into Practice*, 89 BULL. WORLD HEALTH ORG. 913, 913–14 (2011).

385. See Benjamin N. Roin, *Intellectual Property versus Prizes: Reframing the Debate*, 81 U. CHI. L. REV. 999 (2011). For examples of prize schemes see, e.g., Prize Fund for HIV/AIDS Act, S. 1138, 112th

prizes yield “limited profits in the marketplace but significant benefits for society.”<sup>386</sup> Prizes can be particularly beneficial in contexts of medical innovation affecting large populations with heterogenous economic capacities. As Hemel and Ouellette explained more recently,

“[p]atents are preferable to prizes when market signals provide superior information about social benefits than the government can easily acquire (such as for pharmaceuticals affecting wealthy populations), and prizes are preferable to patents when willingness to pay is a poor proxy for social value (such as for vaccines aimed at contagious diseases primarily afflicting the very poor).”<sup>387</sup>

The highlight of prizes as policy tools, in contrast to patents and R&D grants for innovation, is that they are awarded to *successful* innovators ex post, which may favor vaccine production in a more socially optimal way.

### *c. Equity-Based Governance*

The development of new pharmaceutical products such as the mRNA vaccine is subject to several constraints that can undermine its social benefits.<sup>388</sup> Although the U.S. government in a way already addresses the underproduction risk through a combination of tools (prizes, patents, and R&D grants, as discussed above), William Fisher is concerned that, still, “too few resources are devoted to . . . vaccines or therapies aimed at infectious diseases” and the concurrent risk of global health disparities that such underproduction brings about.<sup>389</sup> Disease prevention innova-

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Cong. § 5 (2011) (proposing to eliminate exclusive rights to HIV/AIDS treatments); Medical Innovation Prize Fund Act, S. 1137, 112th Cong. § 5 (2011) (proposing to eliminate exclusive rights to market drugs and biological products).

386. Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 303, 381 (2013).

387. Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 YALE L. J. 544, 557 (2019).

388. William W. Fisher III, *Regulating Innovation: A Response to Ian Ayres and Amy Kapczynski*, *Innovation Sticks: The Limited Case for Penalizing Failures to Innovate*, 82 U. CHI. L. REV. ONLINE 251, 253, 256–60 (2015). According to Fisher, whether the risk of underproducing innovation is exacerbated or mitigated is highly dependent on the field the innovation belongs to. Fisher lists as exacerbating factors costly innovation, high likelihood of failure, low costs of copying or imitating innovation, easily to discern through reverse engineering, and strong positive externalities making it hard for the innovation market price to reflect its true value. *Id.* at 253.

389. *Id.* at 257 (pointing out that infectious diseases are less common in developed countries than in developing ones).

tions and vaccines are often sidelined in favor of treatments for high-incidence, chronic, or lifelong medical ailments.<sup>390</sup> Some scholars and health advocates suggest addressing underproduction with *more* prizes to successful innovators.<sup>391</sup> Others propose a nonmonetary incentive: requiring pharmaceutical companies to reach a minimum social-responsibility index.<sup>392</sup> Compliance with the index might be encouraged with either compulsory licensing of some of the firm's patents or *penalties*—in line with the “innovation sticks” that Ian Ayres and Amy Kapczynski suggested for penalizing private actors who fail to innovate in socially beneficial directions.<sup>393</sup>

The idea of a social-responsibility index should prompt discussion about equity-based corporate governance practices. Such an index counters the assumption that corporations must maximize shareholder value at the expense of social value.<sup>394</sup> In health care, this means challenging the assumption that companies must maximize shareholders' value rather than infuse a public value orientation into the healthcare sector. For example, in the case of pharmaceutical companies, commercial plans for vaccines that address equity concerns give manufacturers ex ante incentives to produce and distribute vaccines with the ultimate mission of serving the populations that need them the most. Fisher points out other ways for manufacturers to achieve equity goals, such as supplementing R&D project portfolios with projects focused on products capable of generating large health benefits (e.g., vaccines for neglected diseases). Manufacturers can acquire companies that have developed such products as

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390. Elvira Thissen, *Focus on Pharma: Creating a Market for Disease Prevention*, GREENBIZ (Dec. 5, 2014), <https://www.greenbiz.com/article/focus-pharma-creating-market-disease-prevention> [<https://perma.cc/VQ84-XBUX>].

391. See James Love & Tim Hubbard, *Prizes for Innovation of New Medicines and Vaccines*, 18 ANN. HEALTH L. 155, 162 (2009).

392. The proposed index is a ratio, where the numerator is the aggregate health benefits during a year from the distribution and consumption of the firm's products and the denominator is the firm's income. WILLIAM W. FISHER III & TALHA SYED, *INFECTION: THE HEALTH CRISIS IN THE DEVELOPING WORLD AND WHAT WE SHOULD DO ABOUT IT* 14, 18–19 (forthcoming) <https://cyber.harvard.edu/people/tfisher/Infection.htm> [<https://perma.cc/J4LA-LGL9>]; See also William W. Fisher III & Talha Syed, *A Prize System as a Partial Solution to the Health Crisis in the Developing World*, in *INCENTIVES FOR GLOBAL PUBLIC HEALTH: PATENT LAW AND ACCESS TO ESSENTIAL MEDICINES* 181, 184–86 (2010).

393. Ayres & Kapczynski, *supra* note 379; see also Fisher, *supra* note 388, at 258, 260. Fisher argues that Ayres and Kapczynski's approach underestimates the complexity of the underproduction problem and can be applied only to particular industries. *Id.* at 260–62.

394. See generally WILLIAM LAZONICK, MATT HOPKINS, KEN JACOBSON, MUSTAFA ERDEM SAKING, ÖNER TULUM, *U.S. PHARMA'S BUSINESS MODEL: WHY IT IS BROKEN, AND HOW IT CAN BE FIXED* 2, 7 (2017)

(referring particularly to the shareholders' maximization value strategy in the Gilead Sciences buyout of Pharmasset, in 2011) [http://www.isigrowth.eu/wp-content/uploads/2017/06/working\\_paper\\_2017\\_13.pdf](http://www.isigrowth.eu/wp-content/uploads/2017/06/working_paper_2017_13.pdf) [<https://perma.cc/6ADP-E8FA>].



part of their business expansion plans and increase the affordability of such products, or they can collaborate with public health agencies to ensure that products reach the populations that need them most.<sup>395</sup>

Governments (e.g., health agencies) can also propose a default equity plan to manufacturers producing and distributing vaccines and hold them accountable for departures from the equity plan. Openly disclosing equity-enhancing plans could incentivize other manufacturers to consider equity issues in future drug production cycles. Collecting data on equity outcomes at the end of drug production cycles could help build equity-based metrics that encourage comparisons and foster reputational motivations among vaccine manufacturers.<sup>396</sup> Additionally, promoting equity outcomes could incentivize other vaccine makers to improve equity outcomes as part of their vaccine production and distribution plans, and at the same time provide information to community-based advocates that would be helpful in encouraging equity-based improvements across the industry.

Arguing in favor of equity-based governance strategies, Peter Singer suggested these strategies be extended to shareholders of and investors in pharmaceutical companies because they play essential roles in exercising corporate equity goals.<sup>397</sup> For example, the board of directors of a leading vaccine manufacturing company is responsible for the actions of the corporation and ought to be held accountable for failing to meet the spirit of international corporate governance principles, such as the U.N. Guiding Principles on Business and Human Rights,<sup>398</sup> the OECD Guidelines for Multinational Enterprises,<sup>399</sup> and the voluntary

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395. See Fisher, *supra* note 388, at 19 (discussing efficiency considerations of Ayres and Kapczynski's proposal). With vaccine distribution, ideally, plans should follow the WHO Equitable Allocation Framework with priority given to frontline workers, people at risk, and resource-poor countries with the least capacity to save lives. This framework is a compilation of recommendations to implement equitable allocation of COVID-19 vaccines. See NAT'L ACAD. OF MED., FRAMEWORK FOR EQUITABLE ALLOCATION OF COVID-19 VACCINE 78 (Helene Gayle et al. eds., 2020).

396. Underhill & Johnson, *supra* note 284, at 82, 84–85.

397. See Peter A. Singer, *Investors Must Tackle Vaccine Inequity*, JACKSON HOLE ECON., <https://jheconomics-com.cdn.ampproject.org/c/s/jheconomics.com/investors-must-tackle-vaccine-inequity/amp/> [https://perma.cc/6UEE-9JSB].

398. See Off. of the High Comm'r, U.N. Hum. Rts., *Guiding Principles on Business and Human Rights*, ¶ 13-26, U.N. Doc. HR/PUB/11/04 (2011), [https://www.ohchr.org/sites/default/files/documents/publications/guidingprinciplesbusinesshr\\_en.pdf](https://www.ohchr.org/sites/default/files/documents/publications/guidingprinciplesbusinesshr_en.pdf) [https://perma.cc/EQM2-SLK5] (referring to the corporate responsibility to respect human rights).

399. See ORG. FOR ECON. COOP. AND DEV., OECD GUIDELINES FOR MULTINATIONAL ENTERPRISES, 51–59 (2011), <https://www.oecd.org/daf/inv/mne/48004323.pdf> [https://perma.cc/UHA9-RSEP] (referring to chapters entitled “Consumer Interests,” “Science and Technology,” and “Competition” because they apply to the pharmaceutical industry).

Ten Principles of the United Nations Global Compact.<sup>400</sup> Furthermore, shareholders could change the approach of biopharmaceutical companies by advocating for equity-based corporate governance practices, which should be in their economic self-interest. Otherwise, segmenting access to vaccines puts economies globally, manufacturers' reputations, social licenses to operate, and ethical corporate values at risk.<sup>401</sup>

Singer proposed a few alternatives for adopting equity-based governance practices. One way is by integrating WHO's vaccine equity goals into companies' executive remuneration strategies in a "meaningful, material, measurable, and transparent way."<sup>402</sup> For example, pharmaceutical CEO compensation could be tied to goals of global vaccine equity, such as WHO's goal to vaccinate seventy percent of each country's population by July 2022.<sup>403</sup> Early in January 2022, a group of sixty-five institutional investors representing \$3.5 trillion in assets including vaccine manufacturers such as Moderna and Pfizer, signed a letter urging pharmaceutical companies to link their executives' payments to prioritizing and achieving global equitable access to COVID-19 vaccines.<sup>404</sup> Investors stressed concrete actions that would make "business sense" in vaccinating the world, such as better participation in international vaccine programs and licensing and sharing technology so countries can produce vaccines locally.<sup>405</sup> Another way to embrace pro-equity practices is setting penalties for failing to meet equity goals. Singer suggested that investors "could vote against the reappointment of directors, the chair of the compensation committee, or the chair of the board."<sup>406</sup>

Alternatively, a non-penalty option Singer suggests is appointing principled civil society leaders to corporate boards who are "clearly focused on vaccine equity," like individual health advocates and leaders of health grassroots.<sup>407</sup> This proposal can certainly be extended to everyone from top to bottom in an organization, beyond directors or executive staff and could be reframed to personnel who resonate with public health interests. According to a recent report by an investigative jour-

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400. See U.N. Global Compact, Ten Principles of the United Nations Global Compact, <https://www.unglobalcompact.org/what-is-gc/mission/principles> [https://perma.cc/4LJX-QJH5].

401. Singer, *supra* note 397.

402. *Id.*

403. WORLD HEALTH ORG., STRATEGY TO ACHIEVE GLOBAL COVID-19 VACCINATION BY MID-2022, *supra* note 22, at 4.

404. Toby Sterling, *Tie Pharma CEO Pay to Fair Global COVID-19 Vaccine Access, Investors Say*, REUTERS (Jan. 6, 2022), <https://www.reuters.com/business/healthcare-pharmaceuticals/investors-tie-pharma-ceo-pay-fair-global-covid-19-vaccine-access-2022-01-06/> [https://perma.cc/LNH5-FZDS].

405. *Id.*

406. Singer, *supra* note 397.

407. *Id.*

nalist, a negative organizational staffing practice has also been recurrent of key financial contributors in global health, like the Bill and Melinda Gates Foundation.<sup>408</sup> Staffing organizations with outsourced management consultants who could exploit the too-business-friendly ethos of health care is inapposite to the appointment of equity-oriented personnel. In contrast, initiatives such as the Patvocates Network in Europe, a patient-driven think tank run by pan-European patient advocates, support healthcare institutions and the private sector in equity-based organizational strategy development, project planning, and implementation.<sup>409</sup>

Strategies to encourage civil society's participation in pharmaceutical corporate governance can be distorted. For example, a recent BioPharma Dive report revealed that twelve of the largest biotech companies in the world had at least one director or top officer serving in a leadership position of a healthcare and life sciences nonprofit institution, including top U.S. medical schools.<sup>410</sup> In the case of Pfizer specifically, the report showed that its director, Dennis Ausiello, MD,<sup>411</sup> also directs the Center for Assessment Technology and Continuous Health (CATCH),<sup>412</sup> part of the Massachusetts General Hospital Department of Medicine which promises a cultural change in medical research by using technology with a preventive monitoring approach. The report noted that directors owned shares in the drug companies they served.<sup>413</sup> Singer is critical to the conflicts of interest this practice represents and advocates instead for giving taxpayers, healthcare end-users, and members of civil society a voice on corporate boards at pharmaceutical companies in order to minimize conflicting interests.<sup>414</sup>

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408. Julia Belluz & Marine Buissonniere, *How McKinsey Infiltrated the World of Global Public Health*, VOX (Dec. 13, 2019, 9:10 AM), <https://www.vox.com/science-and-health/2019/12/13/21004456/bill-gates-mckinsey-global-public-health-bcg> [<https://perma.cc/RUV4-PVF9>] (examining how management consultants, such as BCG, Deloitte, and McKinsey, exercise some practices that shape global health organizations such as WHO, GAVI, the Global Fund, and UNITAID).

409. See *Who We Are*, PATVOCATES (last visited Feb. 22, 2022), <https://www.patvocates.net/about-patvocates/> [<https://perma.cc/V4UQ-DX9U>].

410. Andrew Dunn, *Who Are the 22 Pharma Board Members Who Also Lead Healthcare Nonprofits?*, BIOPHARMA DIVE, <https://www.biopharmadive.com/news/who-are-the-22-pharma-board-members-who-also-lead-healthcare-nonprofits/543144/> [<https://perma.cc/7NBP-QLCS>].

411. *Id.* Dennis Ausiello has served on the Board of Directors of Pfizer since 2006. *About – Dr. Dennis A. Ausiello*, EMPIRIKO <https://www.empiriko.com/about-dennis-ausiello> [<https://perma.cc/YE7J-GTM8>].

412. *About CATCH*, MASS. GEN. HOSP. <https://www.massgeneral.org/medicine/catch/about/> [<https://perma.cc/XX59-X77M>].

413. Dunn, *supra* note 410. For example, the value of Dennis Ausiello's shares of Pfizer in 2017 was \$1.8 million. *Id.*

414. Singer, *supra* note 397.

*d. Patent Taxes*

As discussed above, scholars (with a utilitarian economic approach to IP) are mostly in favor of pluralism of innovation policies, whether in the way of government grants, prizes, patents, “innovation sticks,” or tax incentives. All of these programs have the potential to limit or expand production and distribution of vaccines (although not necessarily under equitable conditions). Within the universe of tax incentives, some tax income benefits can replicate many of the advantages of government prizes and grants. Therefore, discussing whether these incentives should be pursued to supplement (or in lieu of) grants and prizes is relevant.

It is a reality that the research and development of vaccines have been funded by taxpayers while manufacturers simultaneously enjoyed tax privileges in tax havens. There is “tangible economic injustice” in publicly funding a product that is sold back at a high, untaxable, margin.<sup>415</sup> A well-designed patent system can provide tax credits for R&D investments to stimulate technological advances instead of nontaxable patents for the duration of the exclusivity monopoly. This would stimulate gaming the system to expand patents and benefit from large profits—a part of which are used for lobbying to preserve the system.

*e. Public Vaccine Hubs*

Citing pressure to address the COVID-19 global vaccine-access problem<sup>416</sup> and as part of a broader pandemic preparedness plan,<sup>417</sup> the Biden Administration has been working on a plan to create a taxpayer-funded “vaccine hub” to produce doses in partnership with experienced drug makers,<sup>418</sup> promising federal oversight. The idea of a vaccine hub has been explored by presidential administrations three times over the past three decades, but major pharmaceutical companies have been reluctant to enroll in a so-called “federal factory” and divert commercial returns.<sup>419</sup> The feasibility of a vaccine hub has been hindered by pharmaceutical lobbying, political contention, and cost concerns. For example, the U.S.

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415. Deutsch, *supra* note 205.

416. See Hamby & Stolberg, *supra* note 65.

417. *Id.*

418. *Id.* Assessments commissioned by the U.S. government in connection with the U.S. bio-defense policy have concluded that “[e]nsuring access to specialized vaccines is a public good that cannot be left entirely to the market; yet it [was] unrealistic for the government to take on the task alone.” *Id.*

419. *Id.*

government partnered with biotech firm Emergent BioSolutions to produce COVID-19 vaccines and secure manufacturing capacity, but the partnership failed.<sup>420</sup>

To be sure, several Army research centers are active in medical centers in the U.S. Near the end of 2021, the Walter Reed Army Institute of Research in Maryland, announced it had developed a vaccine effective against COVID-19 and all its variants.<sup>421</sup> The U.S. military lab worked on the SpFN vaccine for almost two years and human clinical trials were ongoing in 2022.<sup>422</sup>

The vaccine hub and Army research centers' vaccine production are examples of state-directed, purpose-led initiatives to deliver public value. As missions with a centralized interest, purpose-led initiatives require identifying unmet health needs and deciding what disease areas to make priorities. In making these kinds of global access-to-health policy choices, the government and a wide array of stakeholders consider the nationalist risk that citizens and residents can be (over) prioritized at the expense of citizens of other countries.<sup>423</sup>

## 2. Transparency

During the pandemic, the lack of transparency with respect to vaccine data gathering and reporting has been noticeable.<sup>424</sup> Our World in Data, a data publisher of the Global Change Data Lab in Oxford, U.K.,

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420. See *id.* The U.S. government entrusted Emergent to produce Johnson & Johnson and Oxford AstraZeneca's COVID-19 vaccines, but contracts with Oxford AstraZeneca were canceled and a volume of Johnson & Johnson vaccines were discarded. *Id.*

421. Tara Copp, *US Army Creates Single Vaccine Against All COVID & SARS Variants, Researchers Say*, DEFENSE ONE (Dec. 21, 2021), <https://www.defenseone.com/technology/2021/12/us-army-creates-single-vaccine-effective-against-all-covid-sars-variants/360089/> [<https://perma.cc/QE76-AWD4>].

422. *Id.*

423. MARIANA MAZZUCATO, MISSION-ORIENTED RESEARCH & INNOVATION IN THE EUROPEAN UNION: A PROBLEM-SOLVING APPROACH TO FUEL INNOVATION-LED GROWTH 4 (2018), [https://ec.europa.eu/info/sites/default/files/mazzucato\\_report\\_2018.pdf](https://ec.europa.eu/info/sites/default/files/mazzucato_report_2018.pdf) [<https://perma.cc/AJ3S-U247>] (noting, for example, that this mission approach is guiding innovation processes in the European Commission to address social challenges).

424. See, e.g., Edouard Mathieu, *Commit to Transparent COVID Data Until the WHO Declares the Pandemic Is Over*, 602 NATURE 549, 549 (2022), <https://www.nature.com/articles/d41586-022-00424-9> [<https://perma.cc/7VH3-BPFP>].

("There are huge inequalities in data reporting around the world. . . . Some countries, including China and Iran, have provided no files at all. Sometimes, it's a lack of awareness: government officials might think that a topline figure somewhere in a press release is sufficient. Sometimes, the problem is reluctance: publishing the first file would mean a flood of requests for more data that authorities can't or won't publish.")

assembled country-by-country data during the pandemic. In 2021, it built a global data set on COVID-19 vaccination metrics and included data on vaccine boosters in August 2021 as they were rolled out.<sup>425</sup> When governments did not make available data for others to download to produce their own analyses, “volunteer groups []stepped in.”<sup>426</sup> Although these private efforts are laudable, it is problematic that global populations had to rely on private initiatives to announce—for example, to announce when 60% of the global population was vaccinated—and otherwise fly blind during the pandemic.<sup>427</sup>

Lack of transparency signals a failure of several parties, including national and international authorities and vaccine manufacturers.<sup>428</sup> Data-disclosing tools and good data management practices in health promote and advance transparency, which leads to equitable allocations of medical resources. Furthermore, a lack of transparency negatively impacts public and private accountability. Practices promoting transparency have the potential to urge institutions and health partners to disclose information to *citizens* and *consumers* about how and why policy decisions are made.<sup>429</sup> Transparency allows citizens and consumers to know what public and private institutions are doing and how they justify their actions. Accountability makes those behind policy choices responsive to the demands of those affected by their decisions. Transparency enables holding rich nations, health authorities, law- and policy-makers, and vaccine makers accountable for inequitable strategies for research, production, and distribution of vaccines.<sup>430</sup>

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425. Edouard Mathieu, Hannah Ritchie & Max Roser, *Our World In Data Is Now Tracking Coronavirus (COVID-19) Vaccinations Across the World*, OUR WORLD IN DATA (Jan. 8, 2021), <https://ourworldindata.org/covid-vaccination-dataset> [<https://perma.cc/P3BH-MFE9>].

426. See Mathieu et al., *supra* note 425 (“Where governments haven’t done it, volunteer groups have stepped in: the Sledilnik project in Slovenia, the COVID LIVE and CovidBase websites in Australia, and the COVID Tracking Project in 2020 in the United States are heroic efforts.”).

427. See *id.* at 433 (“[T]he world should not rely on a private university to tally the pandemic’s death toll or announce when 60% of the global population is vaccinated.”).

428. Mathieu asserts that, compared to data sets on global development, WHO has not played a similar role with respect to the world’s public-health data. Mathieu specifically refers to the management of long-term pandemic data, which would allow national authorities to become better producers and managers of health data. See Mathieu, *supra* note 425.

429. See Jillian Clare Kohler, Tim Ken Mackey & Natalia Ovtcharenko, *Why the MDGs Need Good Governance in Pharmaceutical Systems to Promote Global Health*, 14 BMC PUB. HEALTH 63 (2014), <https://bmcpubhealth.biomedcentral.com/articles/10.1186/1471-2458-14-63> [<https://perma.cc/ZD5N-LT7C>].

430. Cf. Jillian Clare Kohler & Andrea Bowra, *Exploring Anti-corruption, Transparency, and Accountability in the World Health Organization, the United Nations Development Programme, the World Bank Group, and the Global Fund to Fight AIDS, Tuberculosis and Malaria*, 16 GLOBALIZATION & HEALTH, Oct. 2020, at 2 (noting that absent or insufficient transparency may contribute to poor governance of the sector and favor acts of corruption).

This Subsection analyzes different ways a lack of transparency during the global vaccine rollout disfavored equitable vaccination.

*a. Vaccine Supply Demands and Prices*

Vaccine makers' opaque agreements undermined countries' bargaining power to secure vaccines for themselves.<sup>431</sup> This is especially troubling with regards to supply contracts of affluent countries, whose vaccine supply demands accounted for a significant portion of vaccines available. Similarly, lack of transparency hindered COVAX from anticipating manufacturers' supply priorities and determining where COVAX (and the LMICs it primarily advocated for) was in the vaccine supply queue.<sup>432</sup> COVAX and participant countries abided by producers' non-disclosure vaccine distribution agreement provisions, which have been deemed indicators of makers abusing market power and benefiting from an emergency.<sup>433</sup>

Transparency of vaccine purchase agreements would have favored disclosure of information about vaccine prices and prevented differentiated vaccine prices.<sup>434</sup> One of the forceful battles against patent culture has been how it undermines access to vaccines (and tests and treatments) by increasing prices. Following the principle that vaccines are public goods that must reach all populations, health advocates' and scholars' central claim has been that vaccines ought to be sold "at a price as close to the 'true cost' as possible."<sup>435</sup> Lack of transparency of drug costs hampers manufacturers from estimating the cost of medicine.<sup>436</sup> Nevertheless, the opportunity to use transparency as a tool to bring vaccine prices closer to true costs has been once again lost. Vaccine makers do not openly disclose the cost of vaccine production—nor are they required to do so by governments—not even to countries that provided generous vaccine R&D funding for the vaccines' development. To those who critically examine the profitability of pharmaceutical companies,

431. Mazzucato et al., *supra* note 293.

432. Olivia Goldhill, Rosa Furneaux & Madlen Davies, 'Naively ambitious': How COVAX Failed on its Promise to Vaccinate the World, *STAT* (Oct. 8, 2021), <https://www.statnews.com/2021/10/08/how-covax-failed-on-its-promise-to-vaccinate-the-world/> [<https://perma.cc/7DAT-3NKX>].

433. Rizvi, *supra* note 378.

434. *See supra* Section IV.

435. PEOPLE'S VACCINE ALL., A FIVE STEP PLAN FOR A PEOPLE'S VACCINE 3 (2022), <https://peoplesvaccine.org/wp-content/uploads/2022/01/A-Five-Step-Plan-for-a-People-Updated-Jan-2022.pdf> [<https://perma.cc/S2W2-A9M6>]. The People's Vaccine Alliance is a global movement of organizations, world leaders, and activists who campaign for a COVID-19 "people's vaccine"—one based on shared knowledge and freely available to everyone everywhere. *Id.*

436. *See supra* text accompanying note 201.

addressing the true costs of drugs is as important as understanding to what extent reducing drug prices may affect the pharmaceutical industry that makes drugs available.<sup>437</sup> The recurrent problem is that neither—true costs or profitability—have been meaningfully confronted.

Research shows that lack of transparency affects the public perception that pharmaceutical companies' profit strategy contributes to the high price of prescribed drugs.<sup>438</sup> Likewise, a high degree of uncertainty about drug makers' profits projections has been linked to the lack of transparency over vaccine prices.<sup>439</sup>

#### *b. Clinical Trials Funding*

The total costs of clinical trials are not openly disclosed to the public, including trials funded both by the U.S. government and by private drug developers. This lack of transparency adds another layer of concern to the health-justice implications for public funding of vaccine R&D pointed out earlier in this subsection.

Transparency of the full and disaggregated costs of clinical drug trials would contribute to a more effective and equitable approach to biomedical R&D. For example, in the case of tax-funded R&D, information about financial contributors signals whose interests vaccine production considers and whose interests are not honored. Lack of transparency makes it difficult for the public to hold manufacturers and government accountable for fair prices of vaccines, treatments, and tests.

Early in 2022, stakeholders including international nonprofits and physicians' groups as well as the U.S. Congressional Oversight and Reform Committee in its 2021 report on the pharmaceutical industry, specifically requested transparency of clinical trials funding from the Biden administration.<sup>440</sup>

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437. Ledley et al., *supra* note 163 (claiming that, despite the relevance and urgency of drug costs transparency, there has been little research on the profitability of pharmaceutical companies).

438. See Ashley Kirzinger, Lunna Lopez, Bryan Wu & Mollyann Brodie, *KFF Health Tracking Poll – February 2019: Prescription Drugs*, KFF, (Mar. 1, 2019), <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/> [https://perma.cc/Q5P8-MY2J] (research findings assert eighty percent of respondents believe that prescription drug prices are high because of companies' profit strategies).

439. See Kiezebrink, *supra* note 220 (stating that uncertainty about drug makers' profits projections is also linked to lack of transparency about companies' assets).

440. See LaHucik, *supra* note 231 (referring to the letter on January 31, 2022, by Doctors Without Borders, Doctors for America, Drugs for Neglected Diseases, and other groups to President Biden's administration science advisor, the HHS Secretary, and leaders at the NIH, Biomedical Advanced Research, and Development Authority-BARDA).



*c. Use of Pharma's Profits*

Section IV described how vaccine manufacturers use part of their profits to fund law and policy makers, politicians, international health organizations, and patient advocacy groups. Pharma companies fund these individuals and organizations to maintain the patent culture status quo that benefits them. Despite social moral condemnation, these practices continue and proliferate.

In varying degrees, funding by vaccine makers is publicly disclosed, either directly or through the funding recipients. As information about these activities becomes publicly available, there is a risk of normalizing—and institutionalizing—them. For example, with the enactment of the Sunshine Act,<sup>441</sup> which requires drug makers to disclose payments or other transfers of value to prescribers, financial conflicts that skew drug consumption have become more apparent in the last decade. During the same period, lobbying expenditures by pharmaceutical companies have grown exponentially.<sup>442</sup> Making lobbying and unethical payments difficult to hide has neither brought down levels of lobbying or activities embedding financial conflicts nor deterred the consumption of drugs.<sup>443</sup>

Transparency in reporting is necessary but not sufficient. Making information available does not prevent lobbying or conflicts of interest if the conditions for accountability are weak. Here, one must distinguish transparency initiatives established by regulators that ignore users' motivations in seeking reporting (non-agent-controlled transparency) from initiatives led by those who aim to benefit from reporting (agent-controlled transparency). Agent-controlled information laws and transparency requirements are more effective initiatives (e.g., free press or watchdog activities). However, improvements in transparency must be accompanied by tools to strengthen people's capacity to access and process information as well as impose sanctions.<sup>444</sup>

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441. The Physician Payment Sunshine Act of 2013 requires manufacturers of drugs, medical devices, and other medical products covered by public health insurance programs to report ownership or investment interests and transfers of value made to medical providers. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6002, 124 Stat. 119 (2010).

442. See *supra* Section IV.

443. See Ximena Benavides, *The Shadows of Sunshine Laws* (unpublished essay, on file with the author).

444. See generally Catharina Lindstedt & Daniel Naurin, *Transparency is Not Enough: Making Transparency Effective in Reducing Corruption*, 31 INT'L POL. SCI. REV. 301 (2010).

Transparency rules must also be supported by good governance practices,<sup>445</sup> a system of incentives aimed at reducing drug manufacturers' potential discretionary benefits. Examples are increasing the competitiveness of the sector by disfavoring monopolies in specific cases, limiting the scope and size of pharmaceutical companies' gifts to funds, or avoiding tax exemptions that encourage overaccumulation of profits for morally questionable uses. Incentives for lobbying and unethical payments exist whenever drug makers have market and political power allowing them to control the drug market. Whether power is justified or unjustified, once a successful pattern is institutionalized, powerful actors—here, drug makers—are incentivized to seek new ways to increase their profits aside from the social purpose of the activity that permits the accumulation of profits.<sup>446</sup>

### 3. Inclusivity

Transparency efforts also require strategies to enhance community participation in health governance through health literacy and empowerment (i.e., democratization of health) and hold accountable drug manufacturers as well as law and policy makers (i.e., accountability).

#### *a. Democratization*

Public participation in executive policy-making is an imperative of modern democratic government.<sup>447</sup> A regulatory system encapsulates democracy in action as long as it invites and empowers members of society to work with a responsive administrative state to design and implement policies.<sup>448</sup> Despite the U.S. healthcare sector being highly regulated and socially transcendent, it has rarely been subject to demo-

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445. See SUSAN ROSE-ACKERMAN, *CORRUPTION AND GOVERNMENT: CAUSES, CONSEQUENCES, AND REFORM* 255–57 (1999).

446. See generally Susan Rose-Ackerman, *Redesigning the State to Fight Corruption: Transparency, Competition, and Privatization*, VIEWPOINT (Apr. 1996), <https://openknowledge.worldbank.org/bitstream/handle/10986/11627/multiopage.pdf?sequence=1&isAllowed=y> [<https://perma.cc/SK8Z-EBY7>] (discussing incentives for bribery to members of governments).

447. See SUSAN ROSE-ACKERMAN, *DEMOCRACY AND EXECUTIVE POWER: POLICYMAKING ACCOUNTABILITY IN THE US, THE UK, GERMANY, AND FRANCE* 147–48 (2021).

448. See, e.g., Alejandro Camacho et al., *Memo to the Next President*, CTR. FOR PROGRESSIVE REFORM, (2016), [https://cpr-assets.s3.amazonaws.com/documents/CPR\\_Memo\\_to\\_Next\\_Pres\\_Prog\\_Vision\\_1606.pdf](https://cpr-assets.s3.amazonaws.com/documents/CPR_Memo_to_Next_Pres_Prog_Vision_1606.pdf) [[perma.cc/KY74-K86Y](https://perma.cc/KY74-K86Y)] (challenging the idea that governments restrict people's liberty and suggesting how governments can become agents of liberty by promoting opportunity for all).

cratic or administrative scrutiny.<sup>449</sup> The work of public health advocates over decades has acknowledged the relevance of SDoH to individuals' health choices yet health and access to health care are still not deemed entitlements integral to democracy or assets of social citizenship.<sup>450</sup>

Community empowerment and public participation promise to democratize health decision-making processes and systems. The challenge of public participation is opening up the rulemaking process to ordinary citizens without sacrificing expertise in life sciences.<sup>451</sup> For Susan Rose-Ackerman, who analyzes public participation in the context of executive policy making in the United States and other leading Western democracies, public participation is not an easy task and is complicated by two factors.<sup>452</sup> The first factor is that ordinary citizens often do not have the technical knowledge necessary for constructive participation. This is particularly true and troubling within healthcare, which is considered a credence good with high agency subordination risks and information asymmetry costs.<sup>453</sup> This factor can overly narrow the range of deliberation by informed citizens. Initiatives like Global Health Advocates in Europe strengthen civil society in countries with high health inequities. By identifying neglected global health issues with the least financing and political attention, the French NGO aims to fill the gap through advocacy and building the capacity of members of civil society so they are better equipped to participate in health policy making.<sup>454</sup> In contrast, for some global health advocates, the lack-of-technical-knowledge argument is an assumption resulting from the legacy of colonialism. These advocates urge a less paternalistic approach and strategies for de-colonializing health.<sup>455</sup>

The second factor that challenges public participation is that members of the executive often override agency expertise and regulate crucial areas to maximize partisan political objectives. As examined in Section IV above, pharmaceutical companies' lobbying of members of the executive and legislative branches is very strong and has been especially so

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449. See generally Alicia Ely Yamin & Tara Boghosian, *Democracy and Health: Situating Health Rights Within a Republic of Reasons*, 19 YALE J. HEALTH POL'Y L. ETHICS 96 (2020).

450. *Id.*

451. ROSE-ACKERMAN, *supra* note 447, at 146–57 (offering an analogy with the tension between public participation and bureaucratic expertise).

452. *Id.* at 147–50.

453. See *supra* Section IV.

454. *Identity*, GLOB. HEALTH ADVOCES., <https://www.ghadvocates.eu/> [<https://perma.cc/VXE6-8J9U>] (last visited Feb. 22, 2022).

455. See, e.g., Tammam Aloudat, *Covid-19 and Reframing the Discourse on Global Health Equity: Challenges, Trade-offs and Opportunities*, YOUTUBE (Mar. 1, 2022), <https://youtu.be/SoVLnodDz1Q>. [<https://perma.cc/2TE8-4XGX>].

during the last decade. Policy choices ought not to be purely technical exercises, either. This is not about displacing technical expertise by turning policy decisions over to citizens. Rather, governments need technical experts' input, but they should not "leave final policy choices to technocrats with no special claims either to make value choices or represent the voting public."<sup>456</sup> The government's process of measuring and weighing costs and benefits to the population when making policy is as important as the substance of the policy choice itself. The point is that in the policy-making process, the government needs "to be sure that the citizenry has bought into policy conclusions built on expert analysis."<sup>457</sup>

This approach to public decision-making is replicable in the private sphere. Private institutional arrangements should not fall short of democratic values. Democratization of health processes, from drug research and development to sale and distribution, aims to avoid financial returns being the exclusive driver of populations' critical health decisions, such as access to medicine. For example, the IP model can benefit from a participatory system through which research priorities, the scope of public funding, and equity plans during drug development processes are channeled through an interdisciplinary and diverse cohort (including affected communities, scientists, drug investors, lawyers, movement leaders, journalists, and patients). Representation of more community voices is well aligned with the goal of creating a mission-driven reform "blueprint" with the affected communities (healthcare users) at the center. However, the patron-client relationship between politicians and private actors as a result of epidemic, grotesque lobbying makes citizen participation difficult to institutionalize.

Double agents can greatly contribute to sustainable and impactful community governance, particularly when access to health policies have global implications. "Double agents," or "bridge builders," are individuals with deep, foundational understanding of health needs from ground level and in a very relatable way (e.g., as a result of growing up and being trained in a LMIC) and of the benefits that accessing more equitable ecosystems represent (e.g., living and working in a high-income country). To the Director of the Health, Nutrition and Population Global Practice at the World Bank Group, Olusoji Adeyi, the "double privilege" of double agents is understanding polarized perspectives of the global south and north, which gives double agents the opportunity to work "to change a system from within," according to Boghuma Titanji, a

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456. ROSE-ACKERMAN, *supra* note 445, at 255.

457. *Id.*

Cameroonian-born physician-scientist at Emory University.<sup>458</sup> Thus, double agents become effective allies, responsive to equity concerns and naturally inclined to advocate for them and critical of the historical, social, and economic underpinnings of global health inequities. Double agents are compelled to address power differentials with an equity approach, avoiding complicity with power asymmetries and bring those traditionally not included to the table. Calling on double agents at the national and global levels is aligned with the community governance goal described above: getting government, manufacturers, and law and policy makers surrounded by the people who will demand that they be accountable. A double agent policy is also aligned with Singer's proposal to include civil society in drug makers' corporate governance practices.<sup>459</sup>

Shifting from nationalistic to regional and global health governance is another way of achieving community empowerment. The nationalistic and individualistic approach of healthcare management has historically driven vaccine deployment efforts. Moving from country-by-country to regional and global health strategies creates opportunities for decision-making that addresses governance weakness and impacts on broader equity goals, which is particularly relevant with global public goods such as medicine. For example, Everaldo Lamprea called for a major shift of decision-making responsibilities from a local to a global level.<sup>460</sup> He drew this conclusion after observing how transnational pharmaceutical companies influence litigation of populations' rights to health in Global South countries, from molding medical prescribers' preferences for branded drugs to controlling the availability of cheaper generics and bio-similars—what Lamprea has called the “pharmaceuticalization of health care.”<sup>461</sup>

### *b. Accountability*

Public discourse tends to focus more on strategies to dismantle the power of big pharmaceutical companies and less on initiatives to empower users. To address public health needs through collaborative environments where an informed civil society can be active in health

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458. Madhukar Pai, *Double Agents in Global Health*, FORBES (Feb. 6, 2022), <https://www.forbes.com/sites/madhukarpai/2022/02/06/double-agents-in-global-health/?sh=73e32e021a2e> [<https://perma.cc/H5L7-RSVX>].

459. See discussion *supra* notes 410–17.

460. LAMPREA-MONTEALEGRE, *supra* note 260, at 15.

461. *Id.* at 13. On the “pharmaceuticalization of health care,” see also Lamprea-Montelagre & Andia, *supra* note 260.

decision-making, strategies that promote community empowerment and public participation are necessary.

Community empowerment is about promoting political equity. Philanthropic practices, such as vaccine donations, cannot rectify the political power imbalances that prevent some populations from taking action to overcome the barriers to accessing health care.<sup>462</sup> The health-justice framework explains well the subordination that SDoH and CoH barriers create for certain populations.<sup>463</sup> The agency of informed citizens allows people to demand *accountability* from public and private actors in the healthcare market that favor conditions that create, expand, and ossify such barriers. As questioned earlier, if health care is a credence good with massive agency subordination and information asymmetry problems, how is it possible to be sure that citizens are well informed and to balance market power dynamics with accountability to citizens?

As outlined before in this section, transparent procedures with public purposes are a starting point. Individuals, watchdogs, and the media can critique government action. Criticism could be detrimental to the social acceptance of reform, and may have an impact at election time. However, the ballot box is an imperfect instrument for connecting citizens to policy outcomes since it often comes into play too late, when policy choices have already been made.<sup>464</sup> Transparency efforts which follow policy-making are not coherent with intentional public-value policies.

With respect to private market actors, it is less evident how citizens can effectively channel their criticism, particularly in a sector with life-or-death consequences. Reducing or avoiding consumption of drugs when no alternative, effective, and affordable medical treatments are available is an imperfect response. For example, declining the mRNA vaccine produced by drug makers while they are under scrutiny may not be a realistic option during a pandemic. Furthermore, corporate accountability is particularly weak when the regulated industry is politically powerful and able to cultivate political allies through lobbying. Therefore, as suggested earlier, additional equity-based government interventions in the form of prizes, conditioned grants, or “innovation

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462. On monopolistic R&D systems, see Priti Krishtel, *An Entrepreneur's Quest to Fix Drug Patents and Save Lives*, FORBES (May 26, 2020), <https://www.forbes.com/sites/ashoka/2020/05/26/an-entrepreneurs-quest-to-fix-drug-patents-and-save-lives/?sh=afi35c67308b> [<https://perma.cc/9XMQ-D3E3>].

463. See discussion *supra* Section III.A.

464. ROSE-ACKERMAN, *supra* note 445, at 374–412.

sticks” can be helpful to infuse and gradually cement equity values in private health care governance.

## VI. CONCLUSION

The inequitable global access to COVID-19 vaccines illustrates how politicized access to health care has become in recent decades. An evaluation of the conditions and factors that led us to this health crisis would therefore be incomplete without examining the healthcare market economy and the pharmaceutical industry model that produces and distributes vaccines globally. The inordinate discretionary market power of pharmaceutical companies allowing them to selectively determine vaccine production and prices based mostly on their commercial interests and financial returns, despite their receiving substantial public R&D subsidies and tax exemptions, has resulted in a vaccine supply problem and misdirected innovation. Coupled with the political power to preserve the status quo in the form of lobbying, the vaccine-making model dangerously blurs the line between a profitable industry and an outrageously profitable industry in spite of the public-interest-driven mission of healthcare systems.

The COVID-19 vaccine-access problem brings the inequitable-by-design problem into sharp relief. The IP framework and patent conflicts have stirred the attention of the general public as contemporary forms of monopolies that are offensive under most economic ideologies. They are the consequence of healthcare systems predominantly designed based on wealth and power rather than public health and health outcomes. Global vaccine inequity did not transpire accidentally—to the contrary, it is the result of policy choices that build a patent culture that neglects TRIPS with its human-rights focus and ignores strategies to avoid the inverse equity theory. The tragic life-or-death consequences of the global vaccine-access problem are particularly blatant in the extraordinary circumstances of a pandemic but raise structural equity-based concerns beyond the pandemic. The design and governance of the healthcare system itself are at fault and urgently requires of the attention of both private and public actors.

We need to depoliticize access to healthcare. If a global pandemic with the largest vaccination rollout in history is not enough to make us rethink how political pursuing and attaining health care access has become, we can only conclude with disappointment that the patent culture in place has largely contributed to commodifying health and lives. Nor is a fanatical focus on market-based models for providing health

care helpful. A transformative regulatory process needs cross-sectorial and interdisciplinary policies, with public participation in health policy making, that promote transparency and accountability in public and private health care governance principled in equity. Our priority should be ensuring that vaccine users survive, not that vaccine inventors and manufacturers thrive—and we can *all thrive* from that.



