

THE COVID-19 VACCINE RACE:
INTELLECTUAL PROPERTY, COLLABORATION(S),
NATIONALISM AND MISINFORMATION

Ana Santos Rutschman*

ABSTRACT

The COVID-19 pandemic has brought a national and global vaccine race. This Article examines the race with respect to contemporary frameworks for biopharmaceutical research and development. Specifically, this Article focuses on the effect of patents, pre-production agreements, public-private partnerships, and vaccine misinformation. This Article analyzes lessons learned from the COVID-19 pandemic, advocates for promoting vaccine affordability and equity, and suggests modifications to existing preparedness frameworks to prepare for upcoming outbreaks of infectious disease.

* Assistant Professor of Law, Saint Louis University School of Law, Center for Health Law Studies, Center for International and Comparative Law. S.J.D., LL.M., Duke Law School. This essay benefited from early-stage discussions at the following events, held remotely due to the COVID-19 pandemic: the panel on *Innovation During COVID-19: From Vaccines to Open-Source Ventilators to Homemade Masks*, organized by the NYU Law School Engelberg Center on Innovation Law and Policy and the R Street Institute; the panel on *IP Protection and Access to Medical Technology in Health Emergencies*, organized by the World Trade Institute in Berne; and the *First Mini-Conference on Coronavirus and Law*, organized by the University of Oklahoma College of Law. I am also grateful to Nathan Gardner for outstanding research assistance.

INTRODUCTION

Vaccines have long played a crucial role in the prevention, mitigation and eradication of infectious diseases.¹ More than any other recent outbreak, the COVID-19 pandemic has brought the phenomenon of the vaccine race to the forefront of personal, national, and global preoccupations. This symposium contribution examines the early features and takeaways of the COVID-19 vaccine race in four parts. The essay begins by situating the ongoing vaccine race into contemporary frameworks for biopharmaceutical research and development (R&D). Part II examines the role of proprietary and nationalistic modes of vaccine production and distribution, with an emphasis on the effects of patents and pre-production agreements on distributive outcomes of the COVID-19 vaccine race. Part III then turns to emerging efforts to counter overly patent-dependent and nationalistic approaches to vaccine R&D. It describes and assesses the role(s) played by the World Health Organization, as well as public-private partnerships like CEPI (the Coalition for Epidemic Preparedness Innovations) and Gavi, a Geneva-based vaccine procurement organization. Moreover, it offers a case study on COVAX, a quasi-global push and pull mechanism designed during the early stages of the COVID-19 pandemic to promote vaccine affordability and equity. Part IV concludes the essay by looking ahead to the end of the race and pondering the increasingly salient role of vaccine misinformation and disinformation in the uptake of emerging COVID-19 vaccines.

1. See, e.g., Walter A. Orenstein & Rafi Ahmed, *Simply Put: Vaccination Saves Lives*, 114 PROCS. NAT'L ACAD. SCI. 4031 (2017); Robert F. Breiman, *Vaccines as Tools for Advancing More than Public Health: Perspectives of a Former Director of the National Vaccine Program Office*, 32 CLINICAL INFECTIOUS DISEASES 283 (2001).

I. THE BEGINNING OF THE VACCINE RACE: INCENTIVES FRAMEWORKS AND LINKS WITH INTELLECTUAL PROPERTY

The COVID-19 pandemic has illustrated the need for the swift development of new vaccines targeting emerging pathogens causing outbreaks of infectious diseases. Yet, absent a catalyst like a large-scale, transnational public health crisis, vaccine R&D is traditionally neither particularly fast nor especially well-funded, at least in the case of emerging diseases like COVID-19.

Virologist Stephen Morse coined the term “emerging infectious diseases” to designate “infections that have newly appeared in the population or are rapidly increasing their incidence or geographic range.”² This group of diseases includes many of the pathogens that have recently triggered large outbreaks,³ including the 2014–16 Ebola outbreak⁴ and the 2015–16 Zika outbreak.⁵ It also includes viruses in the influenza family,⁶ as well as different types of coronaviruses associated with severe respiratory disease, such as MERS⁷ and SARS⁸—the latter being the family of diseases to which COVID-19 infection belongs, being caused by the SARS-CoV-2 virus.⁹

2. Stephen S. Morse, *The Public Health Threat of Emerging Viral Disease*, 127 J. NUTRITION 951S (1997). See also Stephen S. Morse, *Factors in the Emergence of Infectious Diseases*, 1 EMERGING INFECTIOUS DISEASES 7 (1995).

3. See generally *NIAID Emerging Infectious Diseases/Pathogens*, NAT’L INST. ALLERGY & INFECTIOUS DISEASES (July 26, 2018), <https://www.niaid.nih.gov/research/emerging-infectious-diseases-pathogens> [<https://perma.cc/P79U-ATNX>].

4. See generally *Ebola Virus Disease*, WORLD HEALTH ORG., https://www.who.int/health-topics/ebola/#tab=tab_1 [<https://perma.cc/FWF5-BMPF>].

5. See generally *Zika Virus: Key Facts*, WORLD HEALTH ORG. (July 20, 2018), <https://www.who.int/en/news-room/fact-sheets/detail/zika-virus> [<https://perma.cc/G6VF-8MCA>].

6. See *Understanding Influenza Viruses*, CTRS. FOR DISEASE CONTROL & PREVENTION (July 10, 2019), <https://www.cdc.gov/flu/about/viruses/index.htm> [<https://perma.cc/8QUN-JMXM>].

7. Middle East Respiratory Syndrome Coronavirus. See generally *Middle East Respiratory Syndrome Coronavirus (MERS-CoV): Key Facts*, WORLD HEALTH ORG. (Mar. 11, 2019), [https://www.who.int/en/news-room/fact-sheets/detail/middle-east-respiratory-syndrome-coronavirus-\(mers-cov\)](https://www.who.int/en/news-room/fact-sheets/detail/middle-east-respiratory-syndrome-coronavirus-(mers-cov)) [<https://perma.cc/7MA8-WJ3G>].

8. Severe Acute Respiratory Syndrome. See generally *Severe Acute Respiratory Syndrome (SARS)*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 6, 2017), <https://www.cdc.gov/sars/index.html> [<https://perma.cc/M2R7-65GK>].

9. See Coronaviridae Study Group of the International Committee on Taxonomy of Viruses, *The Species Severe Acute Respiratory Syndrome-Related Coronavirus: Classifying 2019-nCoV and Naming It SARS-CoV-2*, 5 NATURE MICROBIOLOGY 536 (2020), <https://www.nature.com/articles/s41564-020-0695-z> [<https://perma.cc/K2QX-4C6K>].

In the wake of a large 2016 Ebola outbreak, the World Health Organization (WHO) published a plan of action—entitled *R&D Blueprint*—to increase preparedness for future outbreaks of emerging infectious diseases.¹⁰ The *R&D Blueprint* listed coronaviruses as “top emerging pathogens likely to cause severe outbreaks in the near future,” and the plan grouped them with other viruses that needed to be “urgently addressed.”¹¹ Additionally, the WHO diagnosed an ongoing “lack of R&D preparedness” for diseases like Ebola, which tend to be chronically underfunded areas of research.¹² These diseases, often referred to as “neglected diseases,” are estimated to affect over 1 billion people across the globe.¹³ Even though they exert a heavy toll on public health, funding for R&D nevertheless pales in comparison to funding for research on other diseases.¹⁴

10. *An R&D Blueprint for Action to Prevent Epidemics*, WORLD HEALTH ORG. (May 2016), https://www.who.int/blueprint/about/r_d_blueprint_plan_of_action.pdf?ua=1 [https://perma.cc/PFE4-WQPB] [hereinafter *R&D Blueprint*].

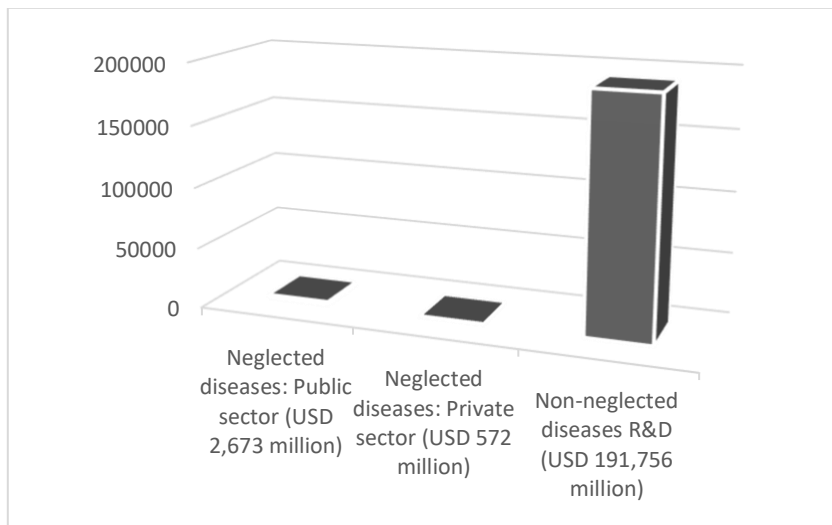
11. *Id.* at 22.

12. *Id.* at 6, 12.

13. *Neglected Diseases*, NAT'L INSTS. HEALTH, https://rarediseases.info.nih.gov/files/neglected_diseases_faqs.pdf [https://perma.cc/U7KH-RWTV].

14. *R&D Blueprint*, *supra* note 10, at 6.

Figure 1: Funding for R&D¹⁵



The lack of a robust R&D support system for these diseases entails significant opportunity costs—of great consequence for public and global health, and especially for populations in economically disadvantaged areas of the globe, where neglected diseases have historically been prevalent.¹⁶ Many of the health technologies that, from a scientific and manufacturing perspective could be developed before an outbreak occurs, will often go undeveloped until a major public health crisis like COVID-19 alters R&D priorities. In assessing preparedness for Ebola outbreaks, the WHO noted that before the 2014–16 outbreak “[t]here were no vaccines, no treatments, few diagnostics, and insufficient medical teams and trained responders.”¹⁷ A similar statement could be made, almost verbatim, in characterizing

15. Adapted from *R&D Blueprint*, *supra* note 10, at 6.

16. See, e.g., Peter von Philipsborn et al., *Poverty-related and Neglected Diseases – An Economic and Epidemiological Analysis of Poverty Relatedness and Neglect in Research and Development*, 8 GLOB. HEALTH ACTION (2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4306754/> [<https://perma.cc/27GB-QB93>]; See also Peter J. Hotez, *One World Health: Neglected Tropical Diseases in a Flat World*, 3 PLOS NEGLECTED TROPICAL DISEASES e405 (2009), <https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0000405> [<https://perma.cc/V4MQ-FQ9H>] (noting the expansion of the geographical burden of emerging infectious diseases).

17. *R&D Blueprint*, *supra* note 10, at 6.

preparedness for outbreaks caused by coronaviruses.¹⁸ This preparedness deficit ultimately hampered part of the response to COVID-19.¹⁹

The development of vaccines targeting emerging infectious diseases should be understood against this larger R&D backdrop. While shortcomings in preparedness frameworks relate to numerous areas—from a multiplicity of governmental actions²⁰ once an outbreak occurs to pre-outbreak interventions by international organizations²¹—the development of health technologies constitutes an integral part of pandemic preparedness frameworks and sound public health policies. These technologies are heterogenous, ranging from vaccines,²² to diagnostics, personal protective drugs, ventilators and other life-support equipment. While this essay focuses on vaccines, many of the features of the contemporary pandemic vaccine ecosystem replicate themselves elsewhere across the spectrum of health-related technologies. Similarly, some of the more hopeful takeaways

18. See, e.g., Jamison Pike et al., *Catastrophic Risk: Waking Up to the Reality of a Pandemic?*, ECOHEALTH 1 (2020), <https://pubmed.ncbi.nlm.nih.gov/32350634/> [<https://perma.cc/CE7K-HBA3>]. See also Stephanie Oum et al., *The U.S. Response to Coronavirus: Summary of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020*, KFF (Mar. 11, 2020), <https://www.kff.org/coronavirus-covid-19/issue-brief/the-u-s-response-to-coronavirus-summary-of-the-coronavirus-preparedness-and-response-supplemental-appropriations-act-2020/> [<https://perma.cc/NTV2-H7P7>] (describing early preparedness efforts in the COVID-19 pandemic).

19. See, e.g., David P. Fidler, *Coronavirus: A Twenty-Year Failure*, THINK GLOB. HEALTH (Mar. 23, 2020), <https://www.thinkglobalhealth.org/article/coronavirus-twenty-year-failure> [<https://perma.cc/B2JR-TDWM>]; Elizabeth Rosenthal, *We Knew the Coronavirus Was Coming, Yet We Failed*, N.Y. TIMES (May 6, 2020), <https://www.nytimes.com/2020/05/06/opinion/coronavirus-health-care-market.html> [<https://perma.cc/U7C2-76JD>] (analyzing preparedness failures in the United States); Alicia Ault, *COVID-19 Exposes Potential Gaps in PPE Training, Effectiveness*, MEDSCAPE (Apr. 6, 2020), <https://www.medscape.com/viewarticle/928163> [<https://perma.cc/7SEM-4MNX>] (focusing on failures related to the use of personal protective equipment).

20. Such as the development of public health guidelines or decisions regarding border closures. See, e.g., *Comparing Nations' Responses to COVID-19*, REG. REV. (Apr. 20, 2020), <https://www.theregreview.org/2020/04/20/comparing-nations-responses-covid-19/> [<https://perma.cc/A9UH-KQCV>].

21. Such as procurement and/or stockpiling of drugs and vaccines. See, e.g., *Procurement Mechanisms and Systems*, WORLD HEALTH ORG. (2018), https://www.who.int/immunization/programmes_systems/procurement/mechanisms_systems/en/ [<https://perma.cc/6STL-SSXR>].

22. Vaccines can be used to prevent outbreaks, mitigate their impact and help build herd immunity to a specific disease. See Gypsyamber D'Souza & David Dowdy, *What is Herd Immunity and How Can We Achieve It With COVID-19?*, JOHNS HOPKINS SCH. PUB. HEALTH EXPERT INSIGHTS (Apr. 10, 2020), <https://www.jhsph.edu/covid-19/articles/achieving-herd-immunity-with-covid19.html> [<https://perma.cc/468T-SQ45>] (defining herd immunity as large-scale immunity to a pathogen resulting in indirect protection to non-immune individuals). But see William Haseltine, *We're Wasting Time Talking About Herd Immunity*, CNN (July 13, 2020), <https://www.cnn.com/2020/07/13/opinions/herd-immunity-covid-19-uncomfortable-reality-haseltine/index.html> [<https://perma.cc/2D8Z-ERE9>].

from the response to COVID-19—described in Part III under the umbrella of collaborative approaches to vaccine development and distribution—can and possibly should be extended to cover other forms of health technology.

Questions surrounding levels of investment in biopharmaceutical R&D bear a partial yet significant and direct relationship to intellectual property. From the twentieth century onwards, pharmaceutical companies—and, from its inception in the 1970s, the biotech industry as well—have largely operated in a race-to-patent R&D format.²³ Under this model, the possibility of obtaining a patent serves as an incentive to investment in R&D projects deemed especially risky, costly, and time-consuming. According to this often-cited strand of intellectual property discourse, one of the primary roles of the patent system is thus to provide incentives to overall risky R&D, of which pharmaceutical and biopharmaceutical are often listed as classical examples.²⁴

In theory, goods with projected limited markets, either numerically or temporally, would benefit the most from this catalyzing function of intellectual property. Catalyzing effects can be especially valuable for public health if the goods in question may lead to an increase in social welfare, as is the case with vaccines and other types of health technologies needed to prepare for, and respond to, the spread of emerging infectious diseases. In practice, nonetheless, a corollary of predominantly patent-driven R&D models has been the inability of patents to provide meaningful incentives to R&D on welfare-enhancing goods like vaccines.²⁵ In previous work, I have discussed the main characteristics of vaccines targeting emerging infectious diseases that lead to the underfunding of R&D in this field²⁶ and noted how the catalyzing moment for vaccine R&D tends to

23. For an overview of the emergence of the biotech industry, see Ronald Evans & Kenneth Kaitin, *The Evolution of Biotechnology and Its Impact on Health Care*, 34 HEALTH AFF. 210 (2015), <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.1023> [<https://perma.cc/US9Q-JX6Z>].

24. See, e.g., WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* (2003). For a criticism of narratives that over-emphasize IP incentives frameworks, see, e.g., Amy Kapczynski, *Order Without Intellectual Property Law: Open Science in Influenza*, 102 CORNELL L. REV. 1539 (2017); Rochelle Cooper Dreyfuss, *Does IP Need IP? Accommodating Intellectual Production Outside the Intellectual Property Paradigm*, 31 CARDOZO L. REV. 1437 (2010).

25. This problem is not exclusive to vaccines. See, e.g., Aaron S. Kesselheim & Kevin Outterson, *Fighting Antibiotic Resistance: Marrying New Financial Incentives to Meeting Public Health Goals*, 29 HEALTH AFFS. 1689 (2010).

26. See Ana Santos Rutschman, *The Intellectual Property of Vaccines: Takeaways from Recent Infectious Disease Outbreaks*, 118 MICH. L. REV. ONLINE 170 (2020) (noting that vaccines targeting

come from outbreaks rather than intellectual property channels.²⁷

In the case of coronaviruses in the SARS family, which were first identified in the early 2000s,²⁸ the first vaccine race was brought about by the 2002–04 outbreak, which was caused by the SARS-CoV-1 virus and affected over 8,000 people in more than 30 countries, resulting in over 700 deaths.²⁹ Development of different types of SARS vaccine candidates commenced during the outbreak and progressed in the years that followed it,³⁰ but quickly thinned out as the virus somewhat uncharacteristically disappeared.³¹ To date, there is no fully developed, tested and approved SARS vaccine.³²

However, a closely related virus, SARS-CoV-2, emerged in late 2019, originating the ongoing COVID-19 pandemic and ensuing vaccine race. The

emerging infectious diseases have tendentially smaller average patient populations and repeat consumers than drugs targeting more mainstream conditions; further noting that savings to health systems attributable to vaccination are notoriously hard to calculate, as they relate to a negative event); *See also* Yaniv Heled et al., *The Problem with Relying on Profit-Driven Models to Produce Pandemic Drugs*, 7 J. L. & BIOSCIS. 1 (2020) (arguing that profit-driven R&D models are largely at odds with the development of drugs needed during a pandemic).

27. Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases*, 65 UCLA L. REV. 1200, 1203 (2018).

28. *Severe Acute Respiratory Syndrome (SARS)*, WORLD HEALTH ORG., <https://www.who.int/csr/sars/en/> [<https://perma.cc/6YJN-J7N9>].

29. *See, e.g.*, Shibo Jiang et al., *SARS Vaccine Development*, 11 EMERGING INFECTIOUS DISEASES 1016 (2005), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3371787/> [<https://perma.cc/3ZYL-UDQE>] (summarizing the SARS vaccine race); *SARS (Severe Acute Respiratory Syndrome)*, WORLD HEALTH ORG., <https://www.who.int/ith/diseases/sars/en/> [<https://perma.cc/YZA6-EB37>] (describing the 2002–04 SARS outbreak); *Cumulative Number of Reported Probable Cases of SARS*, WORLD HEALTH ORG., https://www.who.int/csr/sars/country/2003_07_11/en/ [<https://perma.cc/2L9X-QXEG>]; *SARS 10 Years Later*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 14, 2013), <https://wwwnc.cdc.gov/eid/page/sars-10th-anniversary> [<https://perma.cc/4G9N-BAY4>] (collectively reporting probable SARS-related deaths).

30. *See generally* Deborah R. Taylor, *Obstacles and Advances in SARS Vaccine Development*, 24 VACCINE 863 (2006), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7115537/> [<https://perma.cc/NYV4-FZUS>]; Rachel L. Roper & Kristina E. Rehm, *SARS Vaccines: Where Are We?*, 8 EXPERT REV. VACCINES 887 (2009), https://www.medscape.com/viewarticle/706717_1 [<https://perma.cc/K7EH-DM3U>]; Jiang et al., *supra* note 29.

31. *See, e.g.*, Wei-Jie Guan et al., *Severe Acute Respiratory Syndrome: A Vanished Evil?*, 5 J. THORACIC DISEASE S87 (2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3747533/> [<https://perma.cc/7K96-9UFB>].

32. *SARS (Severe Acute Respiratory Syndrome)*, NAT'L HEALTH SYS. (U.K.) (Oct. 24, 2019), <https://www.nhs.uk/conditions/sars/>. During the early stages of COVID-19 vaccine development, there was renewed interest in SARS vaccine candidates. *See, e.g.*, *Could a Vaccine Candidate for SARS Also Prevent COVID-19?*, PATH (May 7, 2020), <https://www.path.org/articles/could-vaccine-candidate-sars-also-prevent-covid-19/> [<https://perma.cc/7UQC-JKZ5>].

magnitude of this vaccine race is unprecedented.³³ A few months after the World Health Organization declared COVID-19 a pandemic,³⁴ there were well over 100 different vaccine development projects across the world.³⁵ By July 2020, the number had risen to 150, of which 23 had moved on to clinical trials.³⁶ As one commentator put it:

The speed with which this vaccine has been developed is remarkable—from publication of the first SARS-CoV-2 sequences through phase 1 [clinical trials] in 6 months, as compared with a typical timeline of 3 to 9 years. . . . The world has now witnessed the compression of 6 years of work into 6 months.³⁷

To further put these numbers in perspective, consider the fact that players involved in COVID-19 vaccine R&D know that many vaccine candidates will never reach phase III clinical trials, and that among those which do, many fail.³⁸ The head of the leading vaccine procurement international partnership, Gavi,³⁹ recently estimated that only 7% of vaccine candidates successfully complete preclinical development, with only around 15% to 20% of candidates going through clinical trials receiving market approval.⁴⁰ “Contestants” in the vaccine race thus know that the

33. See generally Ewen Callaway, *The Race for Coronavirus Vaccines: A Graphical Guide*, NATURE (Apr. 28, 2020), <https://www.nature.com/articles/d41586-020-01221-y> [<https://perma.cc/M8HC-GBY7>]; Caroline Y. Johnson, *Inside the Extraordinary Race to Invent a Coronavirus Vaccine*, WASH. POST (May 3, 2020, 2:57 PM), <https://www.washingtonpost.com/science/2020/05/02/coronavirus-vaccine/> [<https://perma.cc/7B55-9J3W>].

34. *Timeline of WHO's Response to COVID-19*, WORLD HEALTH ORG. (Jun. 29, 2020), <https://www.who.int/news-room/detail/29-06-2020-covidtimeline> [<https://perma.cc/B2D8-SL7B>].

35. See, e.g., Jonathan Corum et al., *Coronavirus Vaccine Tracker*, N.Y. TIMES, <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html> [<https://perma.cc/V7RS-2UX8>].

36. *Id.*; see also Jonathan Gardner et al., *The Coronavirus Vaccine Frontrunners Have Emerged. Here's Where They Stand*, BIOPHARMA DRIVE (Jun. 9, 2020), <https://www.biopharmadive.com/news/coronavirus-vaccine-pipeline-types/579122/> [<https://perma.cc/4V3H-QZAP>].

37. Penny M. Heaton, *The Covid-19 Vaccine-Development Multiverse*, N. ENG. J. MED. (July 14, 2020), <https://www.nejm.org/doi/full/10.1056/NEJMe2025111> [<https://perma.cc/UE24-B4CX>].

38. *Id.*

39. See *infra*, Part III.

40. See Helen Branswell, *WHO, Partners Unveil Ambitious Plan to Deliver 2 Billion Doses of Covid-19 Vaccine to High-Risk Populations*, STAT (Jun. 26, 2020), <https://www.statnews.com/2020/06/26/who-partners-unveil-ambitious-plan-to-deliver-2-billion-doses->

likelihood of market entrance is small and that the vast majority of participants will drop out within relatively short timelines.

Attrition in a vaccine race prompted by a large-scale public health crisis is a predictable, and to some extent unavoidable, phenomenon.⁴¹ What separates the COVID-19 vaccine race from previous races is the sheer number of participants, and how quickly discrete multi-party R&D collaborations came together: in a paradoxical way, the outbreak of SARS-CoV-2 eliminated the traditional incentives problem that vaccine R&D frameworks often display. Unlikely diseases that slowly build up momentum and struggle to attract meaningful funding for the development of a new vaccine for years or decades, COVID-19 created a scenario in which intellectual property scarcely played a role at the incentives level.

Yet, intellectual property frameworks—and other tendentially proprietary, or rightsholder-centered approaches—still inform this vaccine race. The following section explores the role of patents in both the development and the distribution of eventually successful COVID-19 vaccines.

of-covid-19-vaccine-to-high-risk-populations/ [https://perma.cc/2KS7-NTD7].

41. See Rutschman, *supra* note 27 (further exploring the attrition phenomenon in vaccine races).

II. PROPRIETARY APPROACHES TO VACCINE DEVELOPMENT AND DISTRIBUTIONS

A. Vaccine Patients and the Covid-19 Race

Some components of vaccine technology elude intellectual property protection. The most salient case is perhaps that of standard formulation for several vaccines which have been in use for decades and whose formulation is no longer covered by patents.⁴² Examples of standard formulations that are no longer subject to proprietary rights include the case of the yellow fever, measles, mumps and rubella vaccines.⁴³

Many of the components of the majority of newly developed vaccines, on the other hand, are protectible—and often protected—by one or more patents.⁴⁴ The days of groundbreaking vaccine R&D unencumbered by intellectual property frameworks, including the decade in which the first polio vaccine was deemed unpatentable by lawyers advising Jonas Salk’s team, have been replaced by a patent-intensive culture.⁴⁵ For instance, recently developed vaccines targeting some cervical cancers (HPV vaccines like Gardasil) are covered by over 80 patents issued in the United States.⁴⁶

Emerging COVID-19 vaccines—or, more precisely, one or more components thereof—are thus likely to be covered by proprietary rights. Patent protection for these vaccines is also likely to have a near global reach, as article 27(1) of the TRIPs Agreement mandates countries to grant patents to inventions that are “new, involve an inventive step and are capable of industrial application” according to the domestic laws of member states.⁴⁷

42. Martin Friede, *Intellectual Property and License Management with Respect to Vaccines*, WORLD HEALTH ORG. (2010), <https://www.who.int/phi/news/Presentation15.pdf> [<https://perma.cc/2PXF-QRRS>], at 4. Improved formulations for these vaccines, on the other hand, may be—and often are—subject to patent protection. *Id.* Exceptions to the diminished relevance of intellectual property rights over what the World Health Organization designates as “basic vaccines” include components used in pertussis and pneumonia vaccines. *Id.* at 5-6.

43. *Id.* at 4.

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

45. *Id.* at 742–43; 745–47; See generally DAVID M. OSHINSKY, *POLIO: AN AMERICAN STORY* (2006).

46. Swathi Padmanabhan et al., *Intellectual property, technology transfer and manufacture of low-cost HPV vaccines in India*, 28 NATURE BIOTECH. 671 (2010).

47. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27(1), Jan. 1, 1995, 1869 U.N.T.S. 299.

The exceptions to patentability contemplated in article 27(3) of the Agreement—namely, “diagnostic, therapeutic and surgical methods for the treatment of humans or animals”⁴⁸—fall largely outside the field of vaccine-related technology.

As the first set of leading COVID-19 vaccine candidates enters clinical trials, the intellectual property landscape associated with these candidates is still evolving. There is a time lag between the filing of a patent application and publication of said application by national patent offices. For example, in the United States, Europe, and Japan, patent applications are published, as a general rule, around eighteen months after the date of filing or the earliest priority date.⁴⁹ As such, most of the COVID-19 vaccine race is taking place in an environment in which there is some degree of opacity regarding the universe of potentially emerging intellectual property rights.⁵⁰ It should be noted, however, that this is not a unique feature of the COVID-19 vaccine race, but rather a feature of patent-driven R&D models and the administrative apparatus that supports them. Moreover, in addition to classic intellectual property rights in the form of patents, some components of vaccine technology and vaccine production—such as manufacturing processes and genomic information—may be protected under trade secrecy frameworks.⁵¹

48. *Id.* at 27(3)(a). The additional exceptions to patentability established in article 27(3) relate to “plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.” *See id.* at 27(3)(b). Article 27(2) further contemplates the possibility of exceptions to patentability rooted in *ordre public* or morality reasons.

49. *See* 35 U.S.C. § 122(b)(1)(a); EUROPEAN PATENT OFFICE, EUROPEAN PATENT GUIDE: HOW TO GET A EUROPEAN PATENT ch. 5.3.001 (2019), https://www.epo.org/applying/european/Guide-for-applicants/html/e/ga_c5_3.html [<https://perma.cc/5VXN-FL8A>]; JAPAN PATENT OFFICE, PROCEDURES FOR OBTAINING A PATENT RIGHT (2019), <https://www.jpo.go.jp/e/system/patent/gaiyo/patent.html> [<https://perma.cc/85AH-H7YG>] (collectively setting publication of patent applications at 18 months after the relevant filing or priority date).

50. Some of this information has nonetheless begun to emerge. In early June 2020, the Chinese National Intellectual Property Administration published the first known patent application directly related to a COVID-19 vaccine. *See* Aaron Winger, *Chinese Patent Application for Coronavirus Vaccine Published*, NAT’L L. REV. (Jun. 3, 2020), <https://www.natlawreview.com/article/chinese-patent-application-coronavirus-vaccine-published> [<https://perma.cc/S5JL-6TQT>].

51. *See generally* UNIF. TRADE SECRETS ACT (UNIF. LAW COMM’N 1985); Michael Ricsh, *Why Do We Have Trade Secrets?*, 11 MARQ. INTELL. PROP. L. REV. 1 (2007); Sharon K. Sandeen, *The Evolution of Trade Secret Law and Why Courts Commit Error When They Do Not Follow the Uniform Trade Secrets Act*, 33 HAMLINE L. REV. 493 (2010); Sharon K. Sandeen & Christopher B. Seaman, *Toward a Federal Jurisprudence of Trade Secret Law*, 32 BERKELEY TECH. L.J. 829 (2017); Mark A. Lemley, *The Surprising Virtues of Treating Trade Secrets as IP Rights*, 61 STAN. L. REV. 311 (2008);

Even though the intellectual property puzzle surrounding COVID-19 vaccines remains at this point incomplete, there are already emerging questions in the United States about known aspects of patented, federally funded vaccine-related research that is relevant to the COVID-19 race. At the time of writing, the leading COVID-19 vaccine candidate is the mRNA-1273 vaccine,⁵² which was developed by Moderna, a newcomer biotech company based in Massachusetts,⁵³ following an early-stage research collaboration with the National Institutes of Health (NIH).⁵⁴ When federal agencies like the NIH enter into scientific collaborations with private-sector companies or other non-federal research players, the public sector may hold certain rights over emerging patentable research.⁵⁵ Recently, there have been indications that the role of the NIH during research on the technology that led to the development of mRNA-1273 may confer the Agency an “intellectual property stake” in the vaccine, which in turn would have an

U.S. PATENT & TRADEMARK OFFICE, TRADE SECRET POLICY, <https://www.uspto.gov/ip-policy/trade-secret-policy> [<https://perma.cc/S43X-AJSG>]; *see also* Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 47, at art. 39. (establishing an enabling framework for domestic protection of trade secrets); 2016 O.J. (L 157) 1 (providing the legal framework for trade secrecy in the European Union).

52. Christopher Rowland & Carolyn Y. Johnson, *A Coronavirus Vaccine Rooted in a Government Partnership is Fueling Financial Rewards for Company Executives*, WASH. POST (July 2, 2020), <https://www.washingtonpost.com/business/2020/07/02/coronavirus-vaccine-moderna-rna/> [<https://perma.cc/NX9Z-SDN8>] (describing Moderna’s vaccine candidate as “leading the race in the United States for a coronavirus vaccine”); 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/QFA7-YAYY>]. (calling mRNA-1273 the “Covid Vaccine Front-Runner”). For an explanation of how mRNA vaccines work, *see* Marcus A. Banks, *What Are mRNA Vaccines, and Could They Work Against COVID-19?*, SMITHSONIAN MAG. (July 16, 2020), <https://www.smithsonianmag.com/science-nature/mrna-vaccines-covid-19-180975330/> [<https://perma.cc/L2SL-UFFB>] (describing mRNA vaccine as “contain[ing] a synthetic version of the RNA that a virus uses to form proteins”). For a more technical overview of the underlying technology, *see* Wolfgang W. Leitner et al., *DNA and RNA-based Vaccines: Principles, Progress and Prospects*, 18 VACCINE 765 (1999).

53. Moderna is a newcomer biotech company based in Massachusetts. MODERNA, <https://www.modernatx.com> [<https://perma.cc/XZ9L-VE3C>]; *see also* Loftus & Zuckerman, *supra* note 52 (explaining that, although Moderna has no approved products, its structure and capabilities differ starkly from those of a start-up newcomer).

54. *See* Ed Silverman, *NIH May Own Patents for the Moderna Covid-19 Vaccine; Icer Boosts Recommended Price for Remdesivir*, STAT (June 25, 2020), <https://www.statnews.com/pharmalot/2020/06/25/nih-covid19-coronavirus-vaccine-gilead-remdesivir/> [<https://perma.cc/8TPH-DK4N>].

55. *See infra* notes 57, 64, 69 and 71 and accompanying text.

impact on its ultimate commercialization.⁵⁶

Federal agencies routinely enter into R&D collaborations with the private sector.⁵⁷ In recent years, NIH and Moderna have worked together on a number of both vaccines and coronavirus-related technologies.⁵⁸ Documents released in June 2020 by digital news company Axios include an agreement regulating the transfer of material related to “mRNA coronavirus vaccine candidates developed and jointly owned by NIAID [an institute within the NIH structure] and Moderna” to the University of North Carolina.⁵⁹ The agreement is dated December 2019, just before the first cases of COVID-19 were reported.⁶⁰

Upon reviewing these documents, some commentators and activists have posited that the “agreements suggest that NIH has not transferred its rights, but instead maintains a joint stake” in the mRNA-1273 vaccine.⁶¹ These commentators further identify two patent applications listing “federal scientists as co-inventors” of the vaccine.⁶² Having reviewed the same documents, I merely note that current evidence suggests that the federal government *might* have retained some rights over the vaccine,¹ or some components thereof. Additionally, as discussed below, a clarification of the intellectual property status of mRNA-1273 is necessary, as the possibility

56. *Virtual Signature Event with Dr. Francis Collins, Chris Nassetta, and Mary Brady*, ECON. CLUB at 3 (May 29, 2020), <https://www.economicclub.org/sites/default/files/transcripts/Interview%20with%20Collins%20Nassetta%20Brady%20Edited%20Transcript.pdf> [https://perma.cc/NU5P-4XVV] [hereinafter *Virtual Signature Event*]; see generally Bob Herman, *The NIH Claims Joint Ownership of Moderna's Coronavirus Vaccine*, AXIOS (Jun. 25, 2020), <https://www.axios.com/moderna-nih-coronavirus-vaccine-ownership-agreements-22051c42-2dee-4b19-938d-099afd71f6a0.html> [https://perma.cc/R4YL-HN6Z].

57. See 15 U.S.C. § 3710a (allowing federal agencies to enter into “cooperative research and development agreements”). See also *id.* § 3710a(d)(1) (defining these agreements as “between one or more Federal laboratories and one or more non-Federal parties”).

58. See Herman, *supra* note 56; see also *Virtual Signature Event*, *supra* note 56.

59. *Material Transfer Agreement*, NIH at 105, <https://assets.documentcloud.org/documents/6935295/NIH-Moderna-Confidential-Agreements.pdf> [https://perma.cc/NBE4-U9U9 at 105].

60. *Id.* at 107.

61. Zin Rizvi, *The NIH Vaccine*, PUBLIC CITIZEN (June 25, 2020), <https://www.citizen.org/article/the-nih-vaccine/> [https://perma.cc/JPS2-UWHK].

62. *Id.*; see also Kizzmekia S. Corbett et al., *SARS-CoV-2 mRNA Vaccine Development Enabled by Prototype Pathogen Preparedness*, BIORXIV (2020), <https://www.biorxiv.org/content/10.1101/2020.06.11.145920v1.full> [https://perma.cc/D4E3-4MNH] (reporting pending patent applications on “prefusion coronavirus spike proteins and their use” and “2019-nCoV Vaccine”).

of joint ownership triggers licensure and affordability considerations. Moreover, the joint ownership possibility appears to be corroborated by a quote from NIH Director Francis Collins, who has stated that “we [NIH] do have some particular stake in the intellectual property” of Moderna’s vaccine candidate.⁶³

If joint ownership is confirmed, and in the absence of an agreement to the contrary, federal patent law enables each joint owner to perform several actions—including manufacturing, using or selling the vaccine—without the consent of the other.⁶⁴ If mRNA-1273 maintains its status as the vaccine frontrunner,⁶⁵ the NIH would therefore have ample latitude under this provision to take the necessary steps to produce and distribute vaccine doses in furtherance of public health principles and goals—namely, first to those in greater need and then to indicated populations, and in both cases at affordable prices, irrespective of economic ability. Some commentators have suggested that the NIH should share mRNA-1273 “intellectual property and know-how with the World Health Organization,”⁶⁶ which is currently co-coordinating the development of a risk-sharing and procurement mechanism for emerging COVID-19 vaccines, more fully described in Part III.A. This possibility, however, seems at odds with the isolationist policies of the current administration, which set in motion the withdrawal of the United States from the World Health Organization in July 2020.⁶⁷

Independently from the joint ownership possibility, if NIH has provided funding for the development of mRNA-1273,⁶⁸ federal patent law gives the

63. See *Virtual Signature Event*, *supra* note 56, at 3.

64. See 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.”).

65. Early clinical test results have been encouraging. See Lisa A. Jackson et al., *An mRNA Vaccine Against SARS-CoV-2 — Preliminary Report*, N. ENGL. J. MED. (July 14, 2020), <https://www.nejm.org/doi/full/10.1056/nejmoa2022483> [<https://perma.cc/23WB-KHH9>].

66. See Rizvi, *supra* note 61.

67. See, e.g., Emily Rauhala et al., *Trump Administration Sends Letter Withdrawing U.S. from World Health Organization Over Coronavirus Response*, WASH. POST (July 7, 2020), https://www.washingtonpost.com/world/trump-united-states-withdrawal-world-health-organization-coronavirus/2020/07/07/ae0a25e4-b550-11ea-9a1d-d3db1cbe07ce_story.html [<https://perma.cc/62GB-WEY7>].

68. Based on publicly available information at the time of writing, it is impossible to ascertain the funding situation.

government the ability to take several steps to ensure that the vaccine is widely made available and that it is priced affordably.⁶⁹ For example, if Moderna were unable to produce sufficient vaccine doses or if the vaccine was priced unaffordably,⁷⁰ the Patent Code gives funding agencies march-in rights, which NIH could potentially exercise to issue non-exclusive licenses to other manufacturers.⁷¹

Nevertheless, the options outlined in the preceding paragraphs would require government interventions that face significant political economy challenges extending well beyond the idiosyncrasies of the current administration. For example, march-in rights have not been used in the forty years that have passed since the Bayh-Dole Act introduced them.⁷² This historical reluctance in terms of governmental interventions aimed at ultimately guaranteeing the availability and/or affordability of drugs has in recent years crept into the field of emerging vaccines.⁷³ Most recently, when asked during a congressional hearing whether coronavirus vaccines would be priced affordably in the United States, Secretary of Health and Human Services Alex Azar stated: “[W]e [the government] can’t control that price, because we need the private sector to invest. Price controls won’t get us there.”⁷⁴

This statement—which disregards the legal tools available to the

69. Over the past few years, the growing scholarly attention has also focused on 28 U.S.C. § 1498, which allows the government to buy generic medicines in exchange for the payment of a reasonable royalty. Recent work by scholar Amy Kapczynski and colleagues has illustrated how this provision can be applied to expand access to, and guarantee affordability of, hepatitis C drugs, laying out a pathway that could be potentially applicable to emerging vaccines. *See* 28 U.S.C. § 1498; Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J. L. & TECH (2017).

70. Moderna has stated that it is on track to produce between 500 million and 1 billion doses annually. *See, e.g.*, Eric Sagonowsky, *Moderna Has Started Turning Out Covid-19 Vaccine Doses for Quick Shipment if Approved*, FIERCE PHARMA (July 15, 2020), <https://www.fiercepharma.com/pharma/moderna-has-started-producing-commercial-covid-19-vaccines-at-risk-ceo> [<https://perma.cc/G7EG-4GPS>].

71. 35 U.S.C. § 203.

72. *See generally* Ryan Whalen, *The Bayh–Dole Act & Public Rights in Federally Funded Inventions: Will the Agencies Ever Go Marching In?*, 109 NW. U. L. REV. 1083 (2015).

73. *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. F. 651 (2018) (providing an overview of the relationship between intellectual property and vaccine affordability issues during the 2015–16 Zika outbreak).

74. Nicole Wetsman, *Health Secretary Alex Azar Won’t Promise that a Coronavirus Vaccine Would be Affordable*, VERGE (Feb. 27, 2020), <https://www.theverge.com/2020/2/27/21155879/alex-azar-coronavirus-vaccine-affordable-insurance> [<https://perma.cc/KUY4-WNP9>].

government to ensure drug and vaccine affordability—harks back to notions of intellectual property as incentives to R&D.⁷⁵ It illustrates how reliance on patents and other proprietary frameworks has come to dominate the innovation processes that lead to the production and distribution of public health goods. Elsewhere, I have made the argument that vaccines targeting emerging infectious diseases, in particular, are best understood as global public goods.⁷⁶ Yet, the current proprietary ethos undergirding the development and distribution of vaccines is scarcely compatible with global needs and transnational public health. While so far, the essay has focused primarily on the case of the United States and its patent law framework, the problems posed by siloed approaches to vaccine development and distribution are global and increasingly stretching into intellectual property-adjacent fields. In the following section, the essay transitions to a less United States-centric view of these problems by briefly describing the problem of vaccine nationalism as a global phenomenon. Part III will then provide an overview of emerging solutions designed to counter the combination of both intellectual property and nationalistic frameworks.

B. Vaccine Nationalism

The expression “vaccine nationalism” made it into popular press headlines during the COVID-19 pandemic.⁷⁷ It refers to attempts by some countries to secure doses of emerging COVID-19 vaccines for their own populations—generally to the detriment of indicated populations elsewhere in the world.⁷⁸

While vaccine nationalism affects distributive outcomes after R&D is complete, it is enabled by behaviors that take place during the vaccine R&D stages: countries use advance commitment agreements, also known as pre-production agreements, to reserve a substantial amount of vaccine early on during a vaccine race.⁷⁹ They place these orders before vaccines are fully

75. *Supra*, Part I.

76. Ana Santos Rutschman, *The Reemergence of Vaccine Nationalism*, GEO. J. INT'L AFFS. (July 3, 2020), <https://gjia.georgetown.edu/2020/07/03/the-reemergence-of-vaccine-nationalism/> [https://perma.cc/NK73-3J4K].

77. *See, e.g.*, Greg Myre, *In the Battle Against COVID-19, a Risk of 'Vaccine Nationalism*, NPR (May 27, 2020), <https://www.npr.org/2020/05/27/861886520/in-the-battle-against-covid-19-a-risk-of-vaccine-nationalism> [https://perma.cc/MTQ9-UAZV]; Loftus & Zuckerman, *supra* note 52.

78. Rutschman, *supra* note 76.

79. It should be noted that vaccine nationalism is not a new phenomenon. *See* Rutschman, *supra*

developed, tested and approved by the relevant regulatory authorities, such as the Food and Drug Administration in the United States or the European Medicines Agency, with the goal of guaranteeing access to successful vaccines as soon as possible.⁸⁰

The manufacturer(s) of the first COVID-19 vaccine(s) that eventually come to market will have the ability to produce large quantities of vaccine, but not nearly as much as is needed by all the indicated populations across the globe.⁸¹ The growing use of advance commitment agreements means that in practice, a reduced number of countries—those with greater economic power⁸²—are able to reserve most of the early supply of vaccines for themselves.

During the COVID-19 pandemic, several developed countries placed pre-production orders directly with different pharmaceutical companies working on leading vaccine candidates.⁸³ At the same time, as further detailed in Part III.A, international actors like the World Health Organization, as well as vaccine development and procurement organizations, have been working to build an inclusive global network for the distribution of COVID-19 vaccines.⁸⁴ Widespread use of bilateral contractual mechanisms largely undermines attempts to treat vaccines as global public goods, as well as the development of equitable distribution frameworks for newly developed vaccines outside nationalistic frameworks. In the ongoing pandemic, this risk is exacerbated by flaws in

note 76 (describing the use of advance commitment agreements in the 2009 H1N1 vaccine race). *See also* Sam F. Halabi & Ana Santos Rutschman, *From Viral Sovereignty to Vaccine Nationalism: Lessons for the Post-COVID-19 World* (forthcoming, 2021); Sam F. Halabi, *Viral Sovereignty, Intellectual Property, and the Changing Global System for Sharing Pathogens for Infectious Disease Research*, 28 ANNALS HEALTH L. 101 (2019); Peter K. Yu, *Virotech Patents, Viropiracy, and Viral Sovereignty*, 45 ARIZ. ST. L.J. 1563 (2013). A related strand of scholarship has framed these issues of the securitization of infectious diseases; *see* Stefan Elbe & Nadine Voelkner, *Viral Sovereignty: The Downside Risks of Securitizing Infectious Disease*, THE HANDBOOK OF GLOBAL HEALTH POLICY 305 (Garrett W. Brown et al. eds., 2014). Moreover, vaccine nationalism can be inscribed into larger R&D frameworks, which one legal scholar has aptly described as “innovation nationalism.” *See* Sapna Kumar, *Innovation Nationalism*, 51 CONN. L. REV. 205, 208–09 (2019) (observing that “[t]he U.S. patent system is intertwined with economic nationalism, beyond simple protectionism” and further noting that “[b]ecause patent law is not subject to the high degree of harmonization that exists for copyrights and trademarks, the U.S. government can formulate domestic patent law to protect its strongest industries, such as pharmaceutical drug manufacturing”).

80. *See* Rutschman, *supra* note 76.

81. *See infra*, Part III.A.

82. Rutschman, *supra* note 76.

83. *Id.*

84. *See infra*, Part III.A.

the design of the global network which, as explained in Part III.B, offers a two-tiered vaccine distribution scheme based on financial metrics rather than public health needs.⁸⁵ In so doing, it further accentuates the economic and social divide between higher and lower-income countries.

In the case of some countries, nationalistic strategies exceed the contractual domain and translate into other forms of non-cooperative behavior at the transnational level. During the early stages of the COVID-19 vaccine race, several countries elected not to be part of international vaccine-related discussions and negotiations. For example, in May 2020, the European Union hosted a meeting to discuss equitable development and distribution of COVID-19 vaccines; the United States, Russia, India, Brazil and Argentina decided not to participate.⁸⁶

Nationalism thus adds yet another layer of commodification and privatization to the production and distribution of new vaccines—beyond those already inculcated into vaccine R&D through adherence to a patent-based format for the development of new vaccines or components thereof. In so doing, and without an actionable misuse of any international or domestic laws or legal instruments, it prolongs and enhances longstanding inequalities separating the Global South from the Global North.

Finally, vaccine nationalism is not merely detrimental to populations in the Global South. It may prove short-sighted within the countries that opt for siloed approaches to vaccine distribution. Keeping in mind the possibility that governments like that of the United States might not intervene if a new vaccine is priced too high, economically disadvantaged populations at the domestic level also stand to lose from contractual bilateralism.⁸⁷ Already in the ongoing pandemic, data shows that the most vulnerable populations in the United States are the ones facing the greatest burden from COVID-19.⁸⁸ So far, there is only one drug treating COVID-

85. See Rutschman, *supra* note 76 (further explaining how, during the 2009 H1N1 pandemic, developed countries reserved the entirety of vaccine doses that was logistically possible to produce and only moved to donate vaccines to developing countries once it became clear that the magnitude of the pandemic was considerably less severe than originally anticipated—at which point, demand for vaccines, even in the developing world, had already declined).

86. Richard Milne & David Crow, *Why Vaccine 'Nationalism' Could Slow Coronavirus Fight*, FIN. TIMES (May 13, 2020), <https://www.ft.com/content/6d542894-6483-446c-87b0-96c65e89bb2c> [https://perma.cc/B3DU-7WGB] (further noting that China sent its EU ambassador, instead of “a head of state or government like other countries).

87. See Rutschman, *supra* note 76.

88. See, e.g., Maria Godoy, *What Do Coronavirus Racial Disparities Look Like State by State?*,

19—remdesivir, as yet unapproved—for which pricing details have been made available: in June 2020, California-based pharmaceutical company Gilead announced that a full course of treatment would cost Medicaid, Medicare and privately insured patients in the United States \$3,120.⁸⁹ In other developed countries, remdesivir will be sold at a 25%-discounted price.⁹⁰ The company also announced that the price in developing countries would be “substantially lower,” without offering further information.⁹¹

The pricing of remdesivir—a potentially life-saving drug which was partly developed through funding and involvement of the public sector⁹²—has received substantial criticism.⁹³ Yet, no changes to the prices announced in June are expected to occur. Access to this drug will therefore be more challenging—and in some cases outright impossible—for underinsured and non-insured populations, which include a disproportionate number of Black and Latino communities.⁹⁴

If a problem of excessive pricing arises in a country with a predominantly nationalistic approach to vaccine distribution, there is a risk that vulnerable populations will face increased economic challenges in obtaining access to a vaccine. It is also possible that many indicated individuals will be unable to afford it.

Given the extraordinarily high degree of attention that vaccine-related issues have attracted during the COVID-19 pandemic, it is likely that overpricing may become less of a problem for vaccines than for pharmaceutical products, such as remdesivir. However, as policy makers

NPR (May 30, 2020), <https://www.npr.org/sections/health-shots/2020/05/30/865413079/what-do-coronavirus-racial-disparities-look-like-state-by-state> [<https://perma.cc/D2RH-FJA7>] (reporting that Black and Latino populations “bear the brunt” of COVID-19 in the United States).

89. See Matthew Herper, *Gilead Announces Long-Awaited Price for Covid-19 Drug Remdesivir*, STAT (June 29, 2020), <https://www.statnews.com/2020/06/29/gilead-announces-remdesivir-price-covid-19/> [<https://perma.cc/8FJS-8MEB>]. If the drug is obtained through the Department of Veterans Affairs and the Indian Health Service, a division of the Department of Health and Human Services, the price tag will be \$2,340. *Id.*; see also Hannah Denham et al., *Gilead Sets Price of Coronavirus Drug Remdesivir at \$3,120 as Trump Administration Secures Supply for 500,000 Patients*, WASH. POST (June 29, 2020), <https://www.washingtonpost.com/business/2020/06/29/gilead-sciences-remdesivir-cost-coronavirus/> [<https://perma.cc/R2GS-RAYB>].

90. Hannah Denham, *supra* note 89.

91. *Id.*

92. For a case study on the development of remdesivir, see Heled et al., *supra*, note 26.

93. See, e.g., Rohan Chalasani & Wallid Gellad, *The US Is Paying Way Too Much for Remdesivir*, WIRED (July 17, 2020 7:00 AM), <https://www.wired.com/story/the-us-is-paying-way-too-much-for-remdesivir/> [<https://perma.cc/TW38-4KNJ>].

94. Heled et al., *supra* note 26.

begin to consider ways in which to improve both domestic and international vaccine policies, current nationalistic frameworks—and the inequitable behaviors they potentially enable—should be closely examined. More broadly, the current blend of intellectual property and vaccine nationalism raises recurring affordability and equity concerns that, if left unaddressed, will likely reemerge in future public health crises.⁹⁵

The essay now turns to emerging efforts to address the current shortcomings in the vaccine development and distribution ecosystem. These efforts aim to address both insufficiencies at the funding and R&D levels, as well as ongoing problems with equitable distribution of vaccines outside nationalistic frameworks.

III. COLLABORATIVE VACCINE R&D: EMERGING SOLUTIONS

A. Public-Private Partnerships: CEPI, GAVI and COVAX

One of the emerging responses to the limitations of the current R&D incentives landscape for vaccines targeting emerging infectious diseases—or otherwise underfunded areas in vaccinology—has been the formation of public-private partnerships.⁹⁶ These partnerships alter the incentives landscape by functioning either as push mechanisms (product development partnerships) or pull mechanisms (procurement or access partnerships). Product development partnerships are typically non-profit organizations designed to fund and coordinate R&D, or a segment thereof, from basic research to clinical testing, extending possibly into licensure or manufacturing of a product.⁹⁷ Access partnerships are non-profit organizations that focus on the purchase (often pre-purchase) of developed products, operating as coordinators and possibly negotiators between funders, country-level purchasers and manufacturers.⁹⁸ In the health and pharmaceutical space—and especially in the field of vaccines—many of

95. In the same way that vaccine nationalism in 2020 is a replica of vaccine nationalism during the 2009 H1N1 pandemic. *See supra* note 79 and accompanying text.

96. *See generally* CAMBRIDGE HANDBOOK ON PUBLIC-PRIVATE PARTNERSHIPS, INTELLECTUAL PROPERTY GOVERNANCE, AND SUSTAINABLE DEVELOPMENT (Margaret Chon et al., eds. 2018) [hereinafter CAMBRIDGE HANDBOOK]; JON F. MERZ, WORLD HEALTH ORG., INTELLECTUAL PROPERTY AND PRODUCT DEVELOPMENT PUBLIC/PRIVATE PARTNERSHIPS (2005) (focusing on product development partnerships).

97. MERZ, *supra* note 96, at 2.

98. *Id.*

these partnerships have traditionally targeted economically disadvantaged markets and populations, particularly in the Global South.⁹⁹

While public-private partnerships operating in the health space have proliferated throughout the first two decades of the twenty-first century,¹⁰⁰ very few have worked primarily in vaccine development or distribution. The most notable exception is Gavi, a Switzerland-based public-private partnership created in 2000 and entirely focused on vaccine supply and procurement.¹⁰¹ In contrast, the first large-scale product development partnership focused solely on vaccines did not emerge until 2017: the Coalition for Epidemic Preparedness Innovations (CEPI) came together as a direct response to many of the vaccine R&D gaps evidenced by the 2014–16 Ebola outbreak, and focuses specifically on vaccines targeting emerging infectious diseases.¹⁰² CEPI is currently funded by ten countries, the Bill and Melinda Gates Foundation, the Wellcome Trust in the United Kingdom, and the European Commission.¹⁰³

Both Gavi and CEPI became key players early on in the COVID-19 vaccine race. As early as January 2020—two weeks after essential genomic information about the novel coronavirus was first made available to the scientific community¹⁰⁴—CEPI started three funding programs to speed the development of vaccine candidates.¹⁰⁵ At this point, CEPI relied significantly on pre-existing relationships with several players in vaccine R&D,¹⁰⁶ including Inovio, which had been funded by CEPI since April 2018

99. *Id.*

100. See generally Roy Widdus, *Public-private Partnerships for Health: Their Main Targets, Their Diversity, and Their Future Directions*, 79 BULL. WORLD HEALTH ORG. 713 (2001). See also Rutschman, *The Intellectual Property of Vaccines: Takeaways From Recent Infectious Disease Outbreaks*, 118 MICH. L. REV. ONLINE 170 (2020).

101. . . *About Our Alliance*, GAVI, <https://www.gavi.org/our-alliance/about> [<https://perma.cc/855Y-F4MB>]; *Market Shaping*, GAVI, <https://www.gavi.org/our-alliance/market-shaping> [<https://perma.cc/4GZD-86P9>].

102. *Why We Exist*, CEPI, <https://cepi.net/about/whyweexist/> [<https://perma.cc/V72N-KY9D>].

103. *Who We Are*, CEPI, <https://cepi.net/about/whoare/> [<https://perma.cc/F4KN-EANN>].

104. Jon Cohen, *Chinese Researchers Reveal Draft Genome of Virus Implicated in Wuhan Pneumonia Outbreak*, SCI. (Jan. 11, 2020, 3:00 PM), <https://www.sciencemag.org/news/2020/01/chinese-researchers-reveal-draft-genome-virus-implicated-wuhan-pneumonia-outbreak> [<https://perma.cc/6KRS-MSU5>].

105. *CEPI to Fund Three Programmes to Develop Vaccines Against the Novel Coronavirus, nCoV-2019*, CEPI (Jan. 23, 2020), https://cepi.net/news_cepi/cepi-to-fund-three-programmes-to-develop-vaccines-against-the-novel-coronavirus-ncov-2019/ [<https://perma.cc/38FF-BP6M>].

106. *Id.*

for work on vaccines targeting MERS and Lassa fever.¹⁰⁷ But it also entered into an agreement with a new partner, Moderna, funding development of a vaccine that Moderna had previously designed in collaboration with the Vaccine Research Center (VRC) at the National Institute of Allergy and Infectious Diseases (NIAID).¹⁰⁸ By July 2020, CEPI had become one of the major funders of the COVID-19 vaccine R&D, having raised \$1.4 billion.¹⁰⁹ At the time of writing, if a CEPI-sponsored vaccine receives market approval, CEPI and its partners project having two to three manufacturing vaccine plants per vaccine, and eight to ten regional distribution sites, for an estimated production capacity of at least two billion doses of vaccine by late 2021.¹¹⁰

CEPI is by no means the sole product development public-private partnership involved in this vaccine race—although it is the only one entirely focused on vaccine R&D—nor the largest COVID-19 vaccine R&D funder. The United States government, for instance, awarded pharmaceutical company AstraZeneca \$1.2 billion to develop an adenovirus vaccine,¹¹¹ and a partnership between AstraZeneca and the University of Oxford moved this vaccine candidate into phase II clinical trials in late May.¹¹² The United States has also funded several other vaccine candidates in smaller amounts, bringing its total estimated investment to over \$3 billion.¹¹³ However, when considered alongside longstanding funders of

107. Rachel Grant, *Inovio Awarded up to \$56 Million from CEPI to Advance DNA Vaccines Against Lassa Fever and MERS*, CEPI (Apr. 11, 2018), https://cepi.net/news_cepi/inovio-awarded-up-to-56-million-from-cepi-to-advance-dna-vaccines-against-lassa-fever-and-mers/ [https://perma.cc/QD8B-ZDZ3].

108. *CEPI to Fund Three Programmes to Develop Vaccines Against the Novel Coronavirus, nCoV-2019*, *supra* note 105.

109. *COVAX: CEPI's Response to COVID-19*, CEPI, <https://cepi.net/covid-19/> [https://perma.cc/ME9V-C82D].

110. Julie Steenhuisen, *Vaccine Alliance Finds Manufacturing Capacity for 4 Billion Doses of Coronavirus Vaccines* REUTERS (June 24, 2020, 6:10 PM), <https://www.reuters.com/article/us-health-coronavirus-cepi-vaccines-excl/exclusive-vaccine-alliance-finds-manufacturing-capacity-for-4-billion-doses-of-coronavirus-vaccines-idUSKBN23V3D0> [https://perma.cc/QN5T-2JMD].

111. Elizabeth Cohen, *US Taxpayers Are Funding Six Covid Vaccines. Here's How They Work*, CNN (Jun. 23, 2020), <https://www.cnn.com/2020/06/22/health/us-coronavirus-vaccine-funding/index.html> [https://perma.cc/QVG9-P87V].

112. Nick Paul Taylor, *AstraZeneca's COVID-19 vaccine enters phase 2/3 clinical trial*, FIERCEBIOTECH (May 22, 2020, 8:25 AM), <https://www.fiercebiotech.com/biotech/astrazeneca-s-covid-19-vaccine-enters-phase-2-3-clinical-trial> [https://perma.cc/6GUJ-4KBY].

113. Cohen, *supra* note 111; *see also* Zain Rizvi, *BARDA Funding Tracker*, PUB. CITIZEN (July 5, 2020), <https://www.citizen.org/article/barda-funding-tracker/?eType=EmailBlastContent&eId=714a5728-7a38-40ab-bb93-bae5b639ca0f>

R&D on emerging or neglected diseases, such as national governments or the philanthropic sector, CEPI does illustrate the growing capacity of newer models of promoting and expediting R&D on traditionally underfunded diseases. Moreover, the role played by CEPI emphasizes the importance of international collaborations—and the need for expanded modes of international governance—in the development and production of new vaccines. And while vaccines are an exemplary case in point when discussing the health, techno-scientific and economic challenges posed by emerging infectious diseases, they are not the only area in which existing R&D incentives models have recently been complemented through the creation of large-scale product development public-private partnerships. In the related area of antibacterial drug resistance,¹¹⁴ a large-scale public-private partnership, Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), was founded in 2016 in Boston and raised \$500 million for the 2016–2021 period.¹¹⁵

In addition to drawing increased attention to vaccine development issues, COVID-19 has shed light on the importance of addressing distributive problems at the end of the R&D pipeline early on during an outbreak.¹¹⁶ Vaccine manufacturing, distribution, pricing, and equitable access frameworks are intertwined both contractually and from a policy perspective.¹¹⁷ For the past two decades, much of the vaccine procurement for childhood vaccines needed in developing countries has been performed by access public-private partnership Gavi, which has introduced 496

[<https://perma.cc/8X29-QBQQ>] (calculating public-sector funding for COVID-19 vaccines in the United States at \$3.8 billion as of July 5, 2020).

114. This area includes antibiotic resistance, now deemed one of the “biggest threats to global health” by the World Health Organization. See *Antibiotic Resistance*, WORLD HEALTH ORG. (July 31, 2018), <https://www.who.int/news-room/fact-sheets/detail/antibiotic-resistance> [<https://perma.cc/Z84G-HW46>].

115. *About CARB-X, COMBATING ANTIBIOTIC-RESISTANT BACTERIA* <https://carb-x.org/about/overview/> [<https://perma.cc/FU7M-D78Y>]. CARB-X funds a variety of products, from diagnostics to antibiotics, including vaccines. *Id.*; see also *Vaxxilon Awarded CARB-X Grant to Advance Novel Prophylactic Vaccine to Prevent Klebsiella pneumoniae Infections*, BUSINESS WIRE (Aug. 20, 2019, 1:00 AM), <https://www.businesswire.com/news/home/20190819005417/en/Vaxxilon-Awarded-CARB-X-Grant-Advance-Prophylactic-Vaccine> [<https://perma.cc/2Z4K-5XJZ>] (describing a CARB-X grant for vaccine development).

116. See *supra*, Part II.B. I have argued elsewhere that several components of these negotiations should preferably be discussed before an outbreak occurs, rather than during the compressed and constrained timelines inherent to public health crises. See Rutschman, *supra* note 76.

117. See Rutschman, *supra* note 76.

vaccines and contributed to the vaccination of 760 million children.¹¹⁸ During the COVID-19 pandemic, Gavi entered into procurement agreements reserving vaccine doses to populations in both developing and developed countries, setting up the process of what might become the largest vaccine procurement scheme in history.¹¹⁹ It did so through the formation of the COVID-19 Vaccine Global Access Facility (COVAX), which, in addition to a procurement mechanism, functions as a resource-pooling, risk-sharing and push financing mechanism on a nearly global level.¹²⁰

COVAX offers participants the possibility to place advance commitment orders for pre-established doses of COVID-19 vaccine in exchange for a financial contribution.¹²¹ COVAX procures pre-defined quantities of vaccine doses from pharmaceutical companies, which in turn have an incentive to engage in at-risk manufacturing of vaccines, reserving sufficient doses to meet COVAX commitments.¹²² If a given vaccine is successfully approved by regulatory authorities and becomes commercially available, countries that have joined COVAX will receive a share of available doses.¹²³

Because COVAX negotiates high-volume orders, the price paid by participating countries will in all likelihood be lower than the price paid by countries that elect to negotiate directly with individual vaccine manufacturers.¹²⁴ As such, COVAX is designed to promote vaccine affordability.¹²⁵

COVAX is also designed to reduce the risk associated with predicting

118. GAVI, FACTS AND FIGURES (June 2020), <https://www.gavi.org/sites/default/files/document/2020/Gavi-Facts-and-figures-June.pdf> [https://perma.cc/6F9B-DET6].

119. *Id.*

120. See Helen Branswell, *WHO, Partners Unveil Ambitious Plan to Deliver 2 Billion Doses of Covid-19 Vaccine to High-Risk Populations*, STAT (June 26, 2020), <https://www.statnews.com/2020/06/26/who-partners-unveil-ambitious-plan-to-deliver-2-billion-doses-of-covid-19-vaccine-to-high-risk-populations/> [https://perma.cc/2KS7-NTD7]; see also GAVI, COVAX, THE ACT-ACCELERATOR VACCINES PILLAR (Aug. 6, 2020), https://www.gavi.org/sites/default/files/document/2020/COVAX-Pillar-backgrounder_3.pdf [perma.cc/2RLE-G48F].

121. GAVI, WHO MEMBER STATES BRIEFING ON THE COVAX FACILITY at 5 (June 11, 2020), https://apps.who.int/gb/COVID-19/pdf_files/11_06/GAVI.pdf [https://perma.cc/XW8P-G3NV].

122. *Id.* at 4.

123. *Id.* at 3.

124. *Id.*

125. *But see infra* Part III.B (noting current limitations of the COVAX model).

which vaccine candidates will eventually come to market and avoid “all eggs in one basket” problems. At the time COVAX was announced, there were 16 vaccine candidates in clinical trials and at least 125 in pre-clinical stages.¹²⁶ COVAX works with multiple vaccine manufacturers.¹²⁷ From a probabilistic perspective, a country that decides to negotiate individually with one or two manufacturers instead of joining COVAX has an overall lower chance of picking the right vaccine(s). This problem is more acute in the case of countries with limited financial capacity, as further discussed in the following section. As Gavi has put it,

through portfolio diversification, pooling of financial and scientific resources, and economies of scale, participating governments and blocs can hedge the risk of backing unsuccessful candidates just as governments with limited or no ability to finance their own bilateral procurement can be assured access to life-saving vaccines that would otherwise have been beyond their reach.¹²⁸

COVAX was designed in May 2020.¹²⁹ Gavi announced the advance market commitment option in June.¹³⁰ By mid-July, 75 countries had submitted expressions of interest and indicated that they would self-fund their participation.¹³¹ Additionally, 90 lower-income countries are eligible for financial assistance in joining COVAX, bringing the expected number of participants to over 150.¹³² Since the advance market commitment mechanism is open to any and all countries wishing to participate—and given the significant number of countries signaling they will make use of it—COVAX has emerged as the main international forum for, among other things, the coordination of vaccine distribution and the setting of quasi-

126. Branswell, *supra* note 120.

127. GAVI, *supra* note 121, at 5.

128. GAVI, *supra* note 120, at 1.

129. GAVI, *supra* note 121, at 5.

130. *Gavi Launches Innovative Financing Mechanism for Access to COVID-19 Vaccines*, GAVI, <https://www.gavi.org/news/media-room/gavi-launches-innovative-financing-mechanism-access-covid-19-vaccines> [<https://perma.cc/EQN6-9RQB>].

131. *More Than 150 Countries Engaged in COVID-19 Vaccine Global Access Facility*, WORLD HEALTH ORG. (July 15, 2020), <https://www.who.int/news-room/detail/15-07-2020-more-than-150-countries-engaged-in-covid-19-vaccine-global-access-facility> [<https://perma.cc/SK6V-BH3Y>].

132. *Id.*; see also *infra* Part III.B.

global access frameworks to emerging vaccines.¹³³ In this sense, COVID-19 helps make the case that non-nationalistic approaches to vaccine distribution are not only preferable, but possible. While the following section delves into the shortcomings of current distributive solutions, including several ongoing (and likely structural) limitations of COVAX, the pandemic has shown that the advance commitment model is scalable, at least to some extent. The model relies squarely on the same type of legal instruments that are used to pursue nationalistic approaches—advance commitment agreements between governments and vaccine manufacturers, mediated in the case of COVAX by a third set of players situated internationally.

Questions of scalability and geopolitical preference for predominantly nationalistic or non-nationalistic models will continue to play out after the end of the current pandemic. But it is worth noting that these discussions should not be pared down to a focus on domestic frameworks versus COVAX-like collaborations: the COVAX model already coexists with additional efforts from national governments to secure vaccine doses from leading manufacturers in the race.¹³⁴ Rather, the expedited creation of COVAX underscores the longstanding need to broaden procurement models beyond the remedial circumstances of outbreak response and management.

Moreover, the specific institutional placement of COVAX provides relevant design clues for more permanent solutions to problems surrounding vaccine development and distribution. COVAX does not operate as a stand-alone program. It is integrated into a broader structure in which CEPI and the World Health Organization play separate but complementary roles. This structure is known as the “vaccines pillar” of the Access to Covid-19 Tools (ACT) Accelerator, a network of international heterogeneous actors in the

133. For further discussion of these access frameworks, *see infra* Part III.B.

134. *See, e.g.*, Maria Cheng, *Global Vaccine Plan May Allow Rich Countries to Buy More*, AP NEWS (July 13, 2020), <https://apnews.com/8903d5988545383d7c0b3796a9bc1a14> [<https://perma.cc/TW5F-5QBX>] (“[S]ome countries — including Britain, France, Germany and the U.S.—already have ordered hundreds of millions of doses before the vaccines are even proven to work[.]”); Divya Rajagopal, *Activists Urge India to Push for Fair Allocation of Covid-19 Vaccine Under COVAX*, ECON. TIMES (July 17, 2020, 4:16 PM), <https://economictimes.indiatimes.com/news/politics-and-nation/activists-urge-india-to-push-for-fair-allocation-of-covid-vaccine-under-covax/articleshow/76987509.cms> [<https://perma.cc/8JNX-GVCS>] (“Several high-income countries such as the US are simultaneously striking their own deals with pharmaceutical companies to secure their vaccine supply.”).

global health space, from international organizations to private-sector companies.¹³⁵ This network defines itself as “time-limited” and as having “the shared aim of equitable global access to innovative tools for COVID-19 for all.”¹³⁶ In addition to its work on vaccines, the two other pillars of the Accelerator are diagnostics and therapeutics.¹³⁷ The vaccines pillar is divided into three workstreams: CEPI coordinates vaccine “development and manufacturing,” the World Health Organization oversees “policy and allocation” issues, and Gavi is responsible for “procurement and delivery at-scale.”¹³⁸ COVAX is housed under Gavi’s workstream. As far as it is possible to extract any lessons at this stage of the pandemic, the quick mobilization of players and resources to form COVAX, as well as its ability to tap into pre-existing commercial and funding channels, seems to indicate that there are advantages to further embedding vaccine procurement into end-to-end vaccine development and distribution approaches.

At an even broader level, the case for the globalization of vaccine distribution and access will be made stronger if the COVAX procurement pathway proves to be successful. I argue that, at a minimum, the recent emergence of CEPI and COVAX suggests that the possibility of greater centralization and internationalization of vaccine development and procurement warrants deeper exploration beyond the temporally limited initiatives that have arisen in connection with the COVID-19 pandemic. Reliance on gargantuan international organizations like the World Health Organization, or smaller transnational structures like public-private partnerships, is not exempt from faults, as discussed in the following section. However, in the fragmented universe of vaccine innovation, such reliance is likely preferable to the disjointed and increasingly siloed modes of vaccine development and distribution in the field of emerging infectious diseases.

135. *COVAX: Working for Global Equitable Access to COVID-19 Vaccines*, WORLD HEALTH ORG. <https://www.who.int/initiatives/act-accelerator/covax>; *Access to COVID-19 Tools (Act) Accelerator*, WORLD HEALTH ORG. (Apr. 24, 2020), [https://www.who.int/publications/m/item/access-to-covid-19-tools-\(act\)-accelerator](https://www.who.int/publications/m/item/access-to-covid-19-tools-(act)-accelerator) [<https://perma.cc/YJC4-JDFT>] (noting that the collaboration is comprised of “[a]n initial group of global health actors (BMGF, CEPI, Gavi, Global Fund, UNITAID, Wellcome Trust, WHO) and private sector partners and other stakeholders[.]”); Gavi, *What is the COVAX pillar, why do we need it and how will it work?* (Jun. 26, 2020), <https://www.gavi.org/vaccineswork/gavi-ceo-dr-seth-berkeley-explains-covax-pillar>.

136. *Id.*

137. GAVI, *supra* note 121, at 2.

138. *Id.*

B. Lingering Problems with Emerging Solutions

While the developments identified in the previous section can be considered as generally positive steps towards addressing some of the recurring problems in vaccine innovation, the essay here introduces a brief note on the limitations of these solutions—and in particular of those that were induced by the pandemic.

A first line of limitations is of temporal nature. As noted above, the COVID-19 Accelerator was conceived as a time-limited endeavor. Many of its components, including COVAX, were not designed as permanent structures. It is too soon to assess whether they might outlast the current pandemic—and if they do, under what terms.

Temporal limitations are not negligible. They are partly a symptom of structural shortcomings in global vaccine governance. COVAX, for instance, constitutes a short-term solution to a recurring problem. From a policy perspective, the response to future outbreaks should rely predominantly on permanent mechanisms that adjust to specific crises rather than hastily crafted remedies to problems that abruptly erupt as a public health crisis unfolds.

Many public-private partnerships face different problems linked to permanency issues, which are intertwined with funding considerations. CEPI appears poised to become not only a permanent fixture in the vaccine R&D ecosystem, but also one with a growing footprint. In the world of health-oriented public-private partnerships, this is not necessarily always the case.¹³⁹ Smaller partnerships, especially those relying heavily on philanthropic funding, regularly experience problems related to donor fatigue.¹⁴⁰ Their strategic planning and budgeting does not often extend beyond short- or mid-term frameworks. Consider the case of the Innovative Medicines Initiative (IMI), a large partnership between the European Union and the pharmaceutical industry:¹⁴¹ IMI1 lasted from 2008 to 2013, and IMI2 from 2014 to 2020.¹⁴²

139. See MERZ, *supra* note 96, at 14.

140. *Id.*

141. INNOVATIVE MEDICINES INITIATIVE, <https://www.imi.europa.eu> [<https://perma.cc/NJF6-EUZN>].

142. *History*, INNOVATIVE MEDICINES INITIATIVE, <https://www.imi.europa.eu/about-imi/history-imi-story-so-far> [<https://perma.cc/7Q9S-Z2S7>].

In addition to permanency and funding constraints, a second line of limitations of emerging solutions in the vaccine space relates to structural concerns increasingly associated with the proliferation of public-private partnerships.¹⁴³ While in this essay I do not have the opportunity to delve into the respective literature, it would be remiss not to highlight the main recurring concerns.

A growing strand of commentators have diagnosed bargaining asymmetries within different players in a given partnership—and especially between players on opposite sides of the public-private divide.¹⁴⁴ Commentators have further noted that a large breadth of players may lead to coordination inefficiencies;¹⁴⁵ that new collaborative relationships may lead some of the participants to underestimate or miscalculate transaction costs;¹⁴⁶ that information related to intellectual property and knowledge-sharing obligations attaching to products developed by these partnerships is often “vague;”¹⁴⁷ and that there might be potentially uncharted effects as these partnerships take on actual and symbolic tasks that have in recent history fallen to international organizations and national governments.¹⁴⁸

Finally, it is worth noting that while the solutions described in the essay constitute direct responses to significant problems in vaccine R&D, manufacturing and distributions, they will not necessarily translate into equitable access to emerging COVID-19 vaccines. The example of COVAX is, once again, illustrative. Even though COVAX was expressly created with the purpose of promoting “equal access” to vaccines for populations in both developing and developed countries,¹⁴⁹ documentation released in June

143. See generally CAMBRIDGE HANDBOOK, *supra* note 96; Jens K. Roehrich et al., *Are Public-Private Partnerships a Healthy Option? A Systematic Literature Review*, 113 SOC. SCI. & MED. 110 (2014); RACHEL M. TAYLOR & JENNIFER CHRISTIAN, THE ROLE OF PUBLIC-PRIVATE PARTNERSHIPS IN HEALTH SYSTEMS STRENGTHENING: WORKSHOP SUMMARY (2016); Hilde Stevens et al., *Intellectual Property Policies in Early-Phase Research in Public-Private Partnerships*, 34 NATURE BIOTECH. 504 (2016), <https://www.nature.com/articles/nbt.3562?proof=true> [<https://perma.cc/8HJH-SR7R>].

144. See generally TAYLOR & CHRISTIAN, *supra* note 143; see also Liza Vertinsky, *Boundary-Spanning Collaboration and the Limits of Joint Inventorship Doctrine*, 55 HOUS. L. REV. 401, 426-27 (2017) (describing over-rewarding of private-sector players).

145. TAYLOR & CHRISTIAN, *supra* note 143, at 42.

146. Roehrich et al., *supra* note 143, at 113.

147. Stevens et al., *supra* note 143, at 504.

148. See, e.g., Kenny Bruno & Joshua Karliner, *Tangled Up in Blue: Corporate Partnerships at the United Nations*, CORPWATCH (Sept. 1, 2000), <https://corpwatch.org/article/tangled-blue> [<https://perma.cc/Y5YL-49UM>].

149. GAVI, COVID-19 VACCINE GLOBAL ACCESS (COVAX) FACILITY, PRELIMINARY TECHNICAL DESIGN: DISCUSSION DOCUMENT 2 (June 11, 2020), <https://www.keionline.org/wp->

2020 showed that the current COVAX allocation policy distinguishes between two categories of countries:¹⁵⁰ countries that are able to meet the financial requirement by self-funding their participation in COVAX, a group that consists of high-income and upper middle-income countries;¹⁵¹ and countries that will be funded to participate in COVAX, a group that consists of lower middle-income and low-income countries.¹⁵² Once COVID-19 vaccines become available, fully self-funded countries will receive doses of vaccine to cover twenty percent of their population, which they are free to distribute domestically according to their own sets of priorities.¹⁵³ Funded countries, on the other hand, will receive vaccine doses which must be “allocated across them using [forthcoming] guidance from the global allocation frame work under development by WHO.”¹⁵⁴ Moreover, the policy shrinks the ability of countries with lesser developed economies to pursue multiple vaccine purchase or pre-purchase pathways, a requirement that is not imposed on self-funded countries:

if a country in this group [funded countries] successfully concludes a bilateral deal and receives enough doses to cover e.g. 20% of their population, the Facility [COVAX] requests that these countries delay receipt of any additional doses from the Facility until all other Facility country participants have received enough supply to also cover their highest priority populations.¹⁵⁵

This differentiation between countries based on economic purchasing power is far from conducive to a global equitable distribution framework. In fact, it drives a wedge into economic fissures separating countries in the Global North from the ones in the Global South. Adding to this skewed

content/uploads/COVAX-Facility-Preliminary-technical-design-061120-vF.pdf
[<https://perma.cc/HD4D-V2WK>].

150. *World Leaders Make Historic Commitments to Provide Equal Access to Vaccines for All*, GAVI (June 15, 2020), <https://www.gavi.org/news/media-room/world-leaders-make-historic-commitments-provide-equal-access-vaccines-all> [<https://perma.cc/4FA9-MADE>].

151. *Id.*

152. These countries will be funded through “official development assistance.” GAVI, *supra* note 149, at 4.

153. *Id.* at 11.

154. *Id.*

155. *Id.* (further establishing that “[o]nce all countries in this group have received sufficient supply from the Facility to cover e.g. 20% of their population, any additional supply of vaccines would be offered to countries in line with a needs-based allocation framework”).

prioritization of financial metrics over global public health, the current embodiment of COVAX’s policy establishes that self-funded countries are “encouraged (but not required) to donate vaccines if they have more than they need,”¹⁵⁶ a provision which once again runs counter to the goals of equity and ample access to emerging vaccines across the world. Unlike some of the structural issues described earlier in this section, at least some of the inequality-perpetuating features of COVAX’s policy could, and should, be corrected during the COVID-19 pandemic.

IV. AT THE END OF THE VACCINE RACE: NASCENT PROBLEMS POSED BY VACCINE MISINFORMATION AND DISINFORMATION

The COVID-19 vaccine race will be won by innovators who successfully bring novel vaccines to market, as well as the institutions and people who support them in multiple ways. Yet, from a public health perspective, the vaccine race will come meaningfully to an end when resulting vaccines are administered to those who need them—much like what happened with the polio vaccine race in the mid-twentieth century, leading to a 99% reduction in the incidence of the disease.¹⁵⁷ Unlike the years preceding the near-eradication of polio, during which there was a strong vaccine uptake, it is far from clear that COVID-19 vaccines will be as widely accepted by indicated populations as necessary to achieve herd immunity.¹⁵⁸

A recent survey reported that only half of Americans responded that they planned to receive the vaccine, if one were developed.¹⁵⁹ The rejection of a recommended vaccine by an individual is one of the facets of vaccine

156. *Id.* at 4 (referring to vaccine doses obtained through bilateral agreements outside the COVAX procurement system).

157. *10 Facts on Polio Eradication*, WORLD HEALTH ORG. (2017), <https://www.who.int/features/factfiles/polio/en/> [<https://perma.cc/NA9W-RGSA>]. See also DAVID OSHINSKY, *POLIO: AN AMERICAN STORY* (2006); Rutschman, *supra* note 44.

158. See, e.g., Emily A. Harrison & Julia W. Wu, *Vaccine Confidence in the Time of COVID-19*, 35 EUR. J. EPIDEMIOLOGY 325, 328 (2020). See also OSHINSKY, *supra* note 157.

159. Warren Cornwall, *Just 50% of Americans Plan to Get a COVID-19 Vaccine. Here’s How to Win Over the Rest*, SCIENCE (June 30, 2020), <https://www.sciencemag.org/news/2020/06/just-50-americans-plan-get-covid-19-vaccine-here-s-how-win-over-rest> [<https://perma.cc/UH72-2GVH>]; see also Alex Hartlage, *Vaccine Hesitancy Post-Covid-19: Will Our Memory Fade or Last?*, VACCINES TODAY (July 1, 2020), <https://www.vaccinestoday.eu/stories/vaccine-hesitancy-post-covid-19-will-our-memory-fade-or-last/> [<https://perma.cc/XMV9-5RWG>].

hesitancy, a concept defined as the “reluctance or refusal to vaccinate despite the availability of vaccines.”¹⁶⁰ In 2019, the World Health Organization named vaccine hesitancy as one of the top ten threats to global health.¹⁶¹ While addressing topics related to vaccine hesitancy far exceeds the purpose of this work, I conclude by noting that the ultimate outcome of the COVID-19 vaccine race might depend almost as much on vaccine acceptance as it does on the articulation of complex scientific, legal, and institutional interactions.

Over the last few years, vaccine hesitancy has been on the rise across the world, including developed countries in the West.¹⁶² While this rise is attributable to several factors,¹⁶³ a recent development that has reshaped and increased hesitancy boundaries has been the propagation of misinformation and disinformation in the online environment.¹⁶⁴

Misinformation and disinformation both relate to the propagation of “false or misleading content.”¹⁶⁵ Misinformation is an umbrella expression for “incorrect information,” irrespective of the intention of the propagator.¹⁶⁶ The concept of disinformation is increasingly treated separately by commentators and policymakers to refer to instances in which inaccurate information is circulated with the specific aim of sowing doubt or increasing disagreements between people or institutions with different viewpoints.¹⁶⁷ In the case of vaccines, the circulation of misinformation and disinformation has increased exponentially as social media usage has

160. *Ten Threats to Global Health in 2019*, WORLD HEALTH ORG. (2019), <https://www.who.int/news-room/feature-stories/ten-threats-to-global-health-in-2019> [https://perma.cc/EKX4-DH2Y].

161. *Id.*

162. See Peter Hotez, *America and Europe’s New Normal: The Return of Vaccine-Preventable Diseases*, 85 PEDIATRIC RESEARCH 912 (2019).

163. See generally Daniel A. Salmon et al., *Vaccine Hesitancy: Causes, Consequences, and a Call to Action*, 49 AM. J. PREVENTIVE MED. S391 (2015).

164. See generally Andis Robeznieks, *Stopping the Scourge of Social Media Misinformation on Vaccines*, AM. MED. ASS’N (Mar. 15, 2019), <https://www.ama-assn.org/delivering-care/public-health/stopping-scurge-social-media-misinformation-vaccines> [https://perma.cc/8VCU-6MA5].

165. Gordon Pennycook et al., *Understanding and Reducing the Spread of Misinformation Online*, PSYARXIV (2019), <https://psyarxiv.com/3n9u8/> [https://perma.cc/4NB5-DHBL].

166. Dietram A. Scheufele & Nicole M. Krause, *Science Audiences, Misinformation, and Fake News*, PROCEEDINGS NAT’L ACAD. SCI. USA (2019), <https://www.pnas.org/content/116/16/7662> [https://www.pnas.org/content/116/16/7662].

167. See, e.g., CLAIRE WARDLE & HOSSEIN DERAKHSHAN, INFORMATION DISORDER: TOWARD AN INTERDISCIPLINARY FRAMEWORK FOR RESEARCH AND POLICY MAKING 20 (Sept. 27, 2017); David A. Broniatowski et al., *Weaponized Health Communication: Twitter Bots and Russian Trolls Amplify the Vaccine Debate*, 108 AM. J. PUB. HEALTH 1378 (2018).

become more common.¹⁶⁸

An even more recent twist in the field of vaccine-specific online disinformation has been the use of malicious software to automatize anti-vaccine or vaccine-questioning discourses, especially among users of social media in the United States.¹⁶⁹ In one case, online bots that were traced back to Russia were spreading both pro- and anti-vaccine content on Twitter as a way to bolster discord among Americans.¹⁷⁰

While problems related to the propagation of inaccurate information have long plagued the twin fields of vaccines and vaccination—more so than most other fields of medical or health technologies¹⁷¹—I would submit that COVID-19 triggered the first vaccine race fully immersed in far-reaching, globalized misinformation and disinformation, particularly in the online environment.¹⁷² Researchers in the relatively new fields of online vaccine misinformation and disinformation have asked for “more research . . . to determine how best to combat bot-driven content.”¹⁷³ While scholars and policymakers explore possible solutions to these emerging problems, it is perhaps useful to keep in mind that vaccine races have become increasingly intertwined with extra-scientific, extra-legal and extra-economic considerations. The recent growth of vaccine hesitancy and the emergence of online vaccine misinformation and disinformation illustrate

168. See, e.g., Neil F. Johnson et al., *The Online Competition Between Pro- and Anti-Vaccination Views*, 582 NATURE 230 (2020); Ana Santos Rutschman, *Mapping Misinformation in the Coronavirus Outbreak*, HEALTH AFF. BLOG (Mar. 10, 2020), <https://www.healthaffairs.org/doi/10.1377/hblog20200309.826956/full/> [perma.cc/XF24-XTGQ] (describing the larger context of coronavirus-related misinformation).

169. See Broniatowski et. al, *supra* note 167; see also *As if Bots Weren't Bad Enough Already, Now They're Anti-Vaccine*, WASH. POST (Aug. 28, 2018), https://www.washingtonpost.com/opinions/as-if-bots-werent-bad-enough-already-now-theyre-anti-vaccine/2018/08/28/a945efa0-aa2d-11e8-b1da-ff7faa680710_story.html?noredirect=on [perma.cc/3U9C-6WMW]; Rene F. Najera, *The Anti-Vaccine Misinformation You Read on Twitter Probably Came from Russia*, HISTORY OF VACCINES (June 1, 2019), <https://www.historyofvaccines.org/content/blog/anti-vaccine-russian-trolls> [https://perma.cc/3LTK-PW38].

170. Broniatowski et. al, *supra* note 167, at 1381.

171. See, e.g., Jan Hoffman, *How Anti-Vaccine Sentiment Took Hold in the United States*, N.Y. TIMES (Sept. 13, 2019), <https://www.nytimes.com/2019/09/23/health/anti-vaccination-movement-us.html> [https://perma.cc/Q4DR-XMEH]; David A. Broniatowski et al., *Weaponized Health Communication: Twitter Bots and Russian Trolls Amplify the Vaccine Debate*, 108 AM. J. PUB. HEALTH 1378 (2018); Walter A. Orenstein et al., *Assessing the State of Vaccine Confidence in the United States: Recommendations from the National Vaccine Advisory Committee*, 130 PUB. HEALTH REP. 573 (2015).

172. See Rutschman, *supra* note 168.

173. Broniatowski et. al, *supra* note 167, at 1378.

how internet policy, or the regulation of social media, may bear indirect fruit on the successful deployment of vaccines as tools for the promotion of public health.

CONCLUSION

This essay began by noting that (over)reliance on intellectual property incentives can often lead to underinvestment in vaccine R&D because of limited prospects of return-on-investment. It ends by pointing out that, if adoption of COVID-19 vaccines is low, this might have a detrimental effect on incentives to R&D on other pathogens causing emerging infectious diseases—at least in a world in which patent-driven frameworks remain dominant. Hopefully some of the solutions surveyed in Part III can be further developed and improved upon as we learn from the COVID-19 pandemic and tweak existing preparedness frameworks for upcoming outbreaks of infectious diseases.

