Volume 12 | Issue 2 Article 6

2022

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Cover Page Footnote

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THE COVID-19 VACCINE: A SPOTLIGHT ON DISTRIBUTION CHALLENGES

ERICA GRAY*

INTRODUCTION

"Vaccine equity is the challenge of our time… And we are failing."
- Tedros Adhanom Ghebreyesus, Director-General of the WHO

The response to the COVID-19 pandemic has produced one of the fastest vaccine developments in history, but it has also been a global wake-up call that vaccine development and distribution processes need improvement. By March 3, 2021, roughly three months after vaccine distribution had begun, only 3.54% of the world's population had received a COVID-19 vaccine.[1] Israel had vaccinated 52% of its population, and many other countries had yet to receive any vaccine doses.[2] The United States had vaccinated only about 18% of its population.[3] Vaccines are a critical factor in achieving global public health.[4] They are extremely economical when considering the reduced cost of healthcare and harm to society.[5] Furthermore, the nature of vaccines requires that a large percentage of the population be inoculated to truly eliminate a disease; as such, vaccines offer an opportunity to reduce a population's inequity that may

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1 Hannah Ritchie et al., *Coronavirus (COVID-19) Vaccinations*, OUR WORLD IN DATA, https://ourworldindata.org/covid-vaccinations (last updated Mar. 4, 2021); *A Timeline of COVID-19 Developments in 2020*, AJMC (Jan. 1, 2020), https://www.ajmc.com/view/a-timeline-of-covid19-developments-in-2020.

2 *Id.*; *see also 'Wildly unfair': UN says 130 countries have not received a single Covid vaccine dose*, THE GUARDIAN (Feb. 17, 2021, 7:55 PM), https://www.theguardian.com/world/2021/feb/18/wildly-unfair-un-says-130-countries-have-not-received-a-single-covid-vaccine-dose.

3 Ritchie et al., *supra* note 1.

4 The World Health Organization has defined "health" as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." *WHO Remains Firmly Committed to the Principles Set Out in the Preamble to the Constitution*, WORLD HEALTH ORG., https://www.who.int/about/governance/constitution (last visited Feb. 14, 2022). However, this definition has not changed since 1948 and there have been calls to redefine health. *See generally* Ido Badash et al., *Redefining Health: The Evolution of Health Ideas from Antiquity to the Era of Value-Based Care*, 9 CUREUS 1, 1 (2017).

5 Ana S. Rutschman, *The Intellectual Property of Vaccines: Takeaways From Recent Infectious Disease Outbreaks*, 118 MICH. L. REV. ONLINE 170, 173 (2020).

otherwise be multiplied by disease.[6] However, the magnitude of the potential impact of vaccines is also detrimental to their success. Vaccines are a form of preventative medicine, which means there is no real sense of demand by the market until it is too late. Vaccines are expensive to research, discover, and produce, which limits companies' desire to develop them. There are many legal questions surrounding the development of vaccines, including intellectual property topics such as patentability and how it affects wide-scale public benefit, as well as questions regarding the process of legal recourse against manufacturers in the event of an adverse reaction. In short, vaccines are both a risky and expensive business that offers a conditional or limited return on investment. As we create a more interdependent and densely populated world, we become more vulnerable to the spread of disease, which puts our global health in jeopardy. But we also have an opportunity to oversee the challenges of global public health by operating above the individual needs of countries. International organizations can create a system of vaccine development, regulation, and production. The next step for global public health may start with an organization dedicated to regulating and distributing vaccinations internationally.

The structure of this Note aims to provide a large-scale picture of the current state of vaccine development and distribution, shed light on major challenges and problems, and propose an overarching solution. In order to understand the present status of vaccine regulation and before discussing the challenge of global distribution, Part I provides an overview of vaccine history and describes the regulatory trends that have taken place within the U.S. over the years. The pharmaceutical industry and U.S. legislation have allowed public health strategies to be placed into the hands of profit-driven companies. Part I also shows the ways that government regulation has incentivized and altered the relationship between the private sector and the public sector in vaccine development. Part II looks at the way that the COVID-19 pandemic has necessitated an increase in direct government funding, and it further explains the importance of government involvement in the development of vaccines on a national level. Part III then turns to the international stage and emphasizes the limitations of domestic government involvement. It considers relevant existing international organizations involved in vaccine production and distribution and points out areas of weakness. Finally, this Note proposes the creation of an authoritative body, likely within an existing organization, that has binding legal power regarding the development and distribution of vaccines.

I. AN OVERVIEW OF VACCINE REGULATION

Vaccines are not a novel discovery, and they have always generated questions about property rights. Evidence shows the first ideas for vaccines surfaced as early as medieval China or 17th century Turkey.[7] In the 18th century, Edward Jenner developed the first successful vaccine against smallpox by introducing a version of the virus found in animals to the system of a healthy 8-

6 *See generally* Ana S. Rutschman, *Article: Vaccine Race in the 21st Century*, 61 ARIZ. L. REV. 729, 731 (2019).

7 Rutschman, *supra* note 6, at 736.

year-old boy.[8] Shortly after, American physician Benjamin Waterhouse attempted to achieve property rights in the vaccine.[9] This attempt at a monopoly was largely through physical control and refusal to sell to other physicians, and his attempts failed after demand became too great and individuals began importing materials from England.[10] Vaccines continued to develop over the next few centuries, and one of the first major vaccines to be created as we know them today was in response to the Polio pandemic in America. At the time, in part because of the novelty of vaccines and the influence of the vaccine's creator, American virologist Jonas Salk, there was a noble intention that the vaccine would operate as a gift to the world.[11] Salk recognized that the vaccine was only possible due to private donations and wanted the benefits of vaccines to be accessible by all. When asked who owned the patents he famously answered, "There is no patent. Could you patent the sun?"[12] But twenty-five years later, in 1980, the Supreme Court held that one essentially *could* patent the sun in *Diamond v. Chakrabarty*.[13] It held that vaccines, which often require living organisms to be created or processed, are patentable.[14] Regulation has impacted the way that vaccine development is incentivized and caused noble intentions like that of Jonas Salk to become all but extinct in vaccine development.[15]

To understand the development of vaccine law, it is important to understand the current process of vaccine development. The process of developing a vaccine today is a long and difficult road, with many potential barriers to success. The process is complex, often lasting ten to fifteen years and requiring private and public sector participation.[16] For about a century now, the federal government

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8 *Id.* at 735.

9 *Id.* at 736.

10 *Benjamin Waterhouse*, ONVIEW: DIGITAL COLLECTIONS & EXHIBITS, http://collections.countway.harvard.edu/onview/exhibits/show/to-slay-the-devouring-monster/benjamin-waterhouse. The smallpox vaccine would not become the vaccine as we know it today until 1980.; Rutschman, *supra* note 6, at 735.

11 Ruby Mellen, *Vaccines have never been distributed equally. A coronavirus vaccine would be no different, history suggests*, WASH. POST (Nov. 12, 2020), https://www.washingtonpost.com/world/2020/11/12/vaccine-distribution-history-coronavirus-h1n1-h5n1/.

12 Sophie Ochmann & Max Roser, *Polio*, OUR WORLD IN DATA (Nov. 9, 2017), https://ourworldindata.org/polio.

13 Rutschman, *supra* note 6, at 744. *See generally* Diamond v. Chakrabarty, 447 U.S. 303 (1980).

14 NATIONAL RESEARCH COUNCIL (US) DIVISION OF HEALTH PROMOTION AND DISEASE PREVENTION, ECONOMIC ASPECTS OF VACCINE INNOVATION AND MANUFACTURING 51 (1985). This has been recognized as essentially the start of the biotech industry, promising biotech companies and investors that the value of their technology would be recognized. Gene Quinn, *June 16, 2010: 30th Anniversary of Diamond v. Chakrabarty*, IP WATCH DOG (June 16, 2010), https://www.ipwatchdog.com/2010/06/16/june-16-2010-30th-anniversary-of-diamond-v-chakrabarty/id=11268/.

15 This is not to say that there should not be any patents available for vaccine-related developments. The circumstances around Jonas Salk's polio vaccine were unique in that so many people donated to the organization (the National Foundation for Infantile Paralysis) that "patenting it for profit would have represented double charging." Brian Palmer, *Jonas Salk: Good at Virology, Bad at Economics*, SLATE (Apr. 13, 2014, 9:21 PM), https://slate.com/technology/2014/04/the-real-reasons-jonas-salk-didnt-patent-the-polio-vaccine.html. Secondly, though this did not influence Salk's famous statement, the organization's lawyers found that an application for a patent would have failed and therefore did not ever apply. *Id.*

16 *Vaccine Development, Testing, and Regulation*, HISTORY OF VACCINES, https://www.historyofvaccines.org/content/articles/vaccine-development-testing-and-regulation (last updated Jan. 17, 2018). The quickest development of a vaccine on record, prior to COVID-19, is the mumps vaccine. Merck scientist Maurice Hilleman began working on a vaccine when his daughter was infected with mumps in March of 1963, gaining FDA approval just four years later in 1967.

has played an important role in regulating, licensing, and funding vaccines.[17] In the US, Congress passed its first regulatory legislation regarding the quality of "viruses, serums, toxins, and analogous products," in 1902 with the Biologics Control Act.[18] The act created what would eventually become the National Institutes of Health (NIH), and also gave the government control over the institutions creating vaccines.[19] The regulatory authority of the NIH would be transferred to the US Food and Drug Administration (FDA) upon its creation in 1972. In the European Union, the European Medicines Agency operates as the vaccine regulatory institution.[20] Other similar FDA counterparts include the National Medical Products Administration in China, the Taiwan Food and Drug Agency (TFDA) in Taiwan, the Federal Commission for the Protection Against Sanitary Risks in Mexico, and the Health Products and Food Branch in Canada.[21] The World Health Organization has also published recommendations for the standards of biological products, which most states adopt on national levels.[22] The most important federal organization for health in the United States is the Center for Disease Control and Prevention (CDC). The CDC is unique because it does not have a primary statute that created it since it was a result of executive action as a war-time agency in 1942.[23] There are, however, specific statutes that delegate certain duties to the CDC, such as issuing federal quarantine orders.[24]

The regulatory process for vaccine development is somewhat similar internationally.[25] The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) aims to harmonize and somewhat standardize the regulatory systems between countries.[26] In the U.S., the process begins with research and exploration, which lasts about two to four years.[27] In order to fund the process, private organizations often accept funding from the government or academic institutions.[28] This process is followed by the pre-clinical stage, which often lasts one to two years, and consists of animal testing to determine the most effective dose and safest method of administration.[29] Once a research group believes it has a safe and effective vaccine, regulatory testing begins with an application for an Investigational New

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David E. Sanger et al., *Profits and Pride at Stake, the Race for a Vaccine Intensifies*, N.Y. TIMES, https://www.nytimes.com/2020/05/02/us/politics/vaccines-coronavirus-research.html (last updated May 20, 2020).

17 INSTITUTE OF MEDICINE (US) COMMITTEE ON THE EVALUATION OF VACCINE PURCHASE FINANCING IN THE UNITED STATES, FINANCING VACCINES IN THE 21ST CENTURY: ASSURING ACCESS AND AVAILABILITY (2003).

18 Vaccine Development, Testing, and Regulation, *supra* note 16.

19 *Id.*

20 Id.

21 *Regulatory Resources*, PARENTERAL DRUG ASS'N, https://www.pda.org/scientific-and-regulatory-affairs/regulatory-resources/global-regulatory-authority-websites (last visited Feb. 14, 2022).

22 *Vaccine Development, Testing, and Regulation*, *supra* note 16.

23 Dorit Rubinstein Reiss, *Institutionalizing the Centers for Disease Control and Prevention's Independence*, 12 CONLAWNOW 107, 110 (2020).

24 *Id.* at 111.; *See* 42 C.F.R. §§ 70–71.

25 Part of the reason for these similarities is that the FDA has been able to act as a regulatory model as a result of its earlier establishment, and the FDA has made a significant effort over the last few decades to expand its outreach globally. *FDA Goes Global*, U.S. FOOD AND DRUG ADMIN. (Feb. 2006), https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/fda-goes-global.

26 *See generally* ICH, MISSION, https://www.ich.org/page/mission.

27 *Vaccine Development, Testing, and Regulation*, *supra* note 16, at 3.

28 *Id.*

29 *Id.* However, this is the stage at which many research studies fail. *Id.* It is estimated that only 6% of projects to develop a vaccine ever succeed. Sanger, Kirkpatrick, et al., *supra* note 16, at 3–4.

Drug (IND) through the FDA.[30] Within thirty days, the institution that plans to conduct the clinical trials will review the application. If accepted, the institution will begin three phases of clinical trials, beginning in a small group of adults and progressing to tens of thousands of people.[31] If a vaccine developer successfully passes these trials, a Biologics License Application will then be submitted to the FDA.[32] The FDA will investigate the factory and vaccine labeling before license approval, and continue to monitor the production, quality, and safety of the vaccine.[33] At its discretion, the FDA may decide to conduct its own testing, known as Phase IV Trials.[34] In an attempt to further regulate safety, the CDC and FDA created The Vaccine Adverse Event Reporting System (VAERS) in 1990, which is a voluntary and public reporting system open to anyone that suspects an association between an adverse event and a vaccination.[35]

Once vaccines are ready to go to market in the U.S., they are often purchased in large quantities by the government.[36] In a pandemic situation such as the COVID-19 crisis, this is especially true as a result of the lack of availability to smaller buyers such as insurance companies and hospitals.[37] Vaccines fall into the class of biologics, which usually enjoy a very high value and price.[38] However, government programs buy these vaccines in large quantities and therefore often at a discounted price. The significance of that discount may be due to the contractual promise to manufacturers that the government will continue to purchase the vaccine, eliminating some of the financial risk involved in production.[39] Another major challenge is that few manufacturers dare to produce vaccines due to unprofitability, which means there is little room for error and any setback can result in a vaccine shortage.[40] Therefore, the government is incentivized to buy in bulk, conditional on the realization of supply, from multiple companies in order to ensure there is enough supply for the population. Conversely, many developing countries are both unable to afford a vaccine and unable to safely create their own. As a result, they rely on the World Health Organization to first review and approve a vaccine, then grant prequalification, which allows agencies such as the United Nations International Children's Emergency Fund (UNICEF) to purchase vaccines on behalf of these countries that otherwise cannot afford them.[41]

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30 *Vaccine Development, Testing, and Regulation*, *supra* note 16, at 4.
31 *Id.* at 4–5.
32 *Id.* at 5.
33 Id.
34 Id.
35 *Id.* VAERS receives approximately 30,000 reports every year. *Immunization Policy Issues Overview*, NAT'L CONF. ST. LEGISLATURES (Feb. 26, 2021), https://www.ncsl.org/research/health/immunizations-policy-issues-overview.aspx.
36 Austin Frakt, *Low Prices for Vaccines Can Come at a Great Cost*, N.Y. TIMES (June 27, 2016), https://www.nytimes.com/2016/06/28/upshot/low-prices-for-vaccines-can-come-at-a-great-cost.html.
37 Other hindrances to purchase include the restrictions of the emergency use license granted by the FDA regarding scope of authority, and the high maintenance storage requirements. *See generally* https://www.fda.gov/media/144412/download.
38 Frakt, *supra* note 36, at 2.
39 Id.
40 Some diseases have a vaccine that is only manufactured by one company. *Id.* at 2.
41 Mansour Yaïch, *Investing in vaccines for developing countries: how public–private partnerships can confront neglected diseases*, 5 HUMAN VACCINES 368, 368 (2009), https://doi.org/10.4161/hv.5.6.8172.

A. *THE BEGINNING OF REGULATION*

In 1955, in the wake of the polio epidemic, a failure in manufacturing caused the polio vaccine to infect around 220,000 people with the virus, now known as the Cutter Incident.[42] This provided proof that the government needed to be involved in the vaccine process and prompted a significant increase in regulation. One of the most concerning aspects of this incident is that the government, which was responsible for the licensing and approval of the vaccine, was not aware of the problem until it was too late.[43] In a quick response, increased government regulation resulted in vaccine production becoming the most regulated form of medicine, which remains true to this day.[44] One of the most important takeaways from this incident is that the pharmaceutical company responsible, Cutter, was liable but without fault because it was found not to be negligent.[45] This resulted in *Gottsdanker v. Cutter Laboratories*, a case that created precedent allowing for liability without fault.[46] The aftermath of this case made financial liability a real risk for pharmaceutical companies and restricted willingness to enter the market.[47] It is possible that this created a market that was so unprofitable that it was difficult to enter, contributing to the oligopoly that has often existed in vaccine production.[48] However, government liability did not exist in this case, which indicates that eliciting government funding was a more viable option than private sector investment.

In the aftermath of the Cutter Incident, regulation quickly followed. In 1962, the Vaccination Assistance Act became the first national immunization program in the United States.[49] Intended to allow the CDC to support vaccination campaigns, it has remained one of the most important legislative instruments in allowing federal funds to support vaccination programs.[50] The federal government made its first mass purchase of vaccines in the fiscal year of 1966, obtaining the vaccines at a discounted price and then providing them directly to state and local governments as opposed to grants.[51] Section 317 of the Public Health Service Act was enacted in 1972, which provided further grants to state and local governments.[52] Throughout the 1960s and 70s, the federal government also took advantage of 28 U.S.C. § 1498, originally created in 1948, which effectively allows the federal government to use a patented product as long as

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42 Nathaniel L. Moir, *To Boldly Remember Where We Have Already Been*, 2 J. APPLIED HIST. 17, 27 (2020), https://brill.com/view/journals/joah/2/1-2/article-p17_2.xml.

43 Moir, *supra* note 42, at 26. It should also be noted that while the federal government was not legally responsible for the incident, the director of the National Microbiological Institute was fired, and the United States Secretary of Health, Education and Welfare and the NIH Director both resigned, indicating an understanding of responsibility. *Id.* at 27.

44 PAUL A. OFFIT, M.D., THE CUTTER INCIDENT: HOW AMERICA'S FIRST POLIO VACCINE LED TO THE GROWING VACCINE CRISIS 178-179 (New Haven: Yale University Press, 2005).

45 *See generally* Gottsdanker v. Cutter Laboratories, 182 Cal. App. 2d 602 (1960).

46 OFFIT, *supra* note 44, at 179.

47 Moir, *supra* note 42, at 22.

48 *See generally Immunization, Vaccines and Biologicals*, WORLD HEALTH ORG., https://www.who.int/immunization/programmes_systems/procurement/market/global_supply/en/ (last visited Feb. 27, 2021).

49 Alan R. Hinman, Walter A. Orenstein, et al., *Morbidity and Mortality Weekly Report (*MMWR*)*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Oct. 7, 2011), https://www.cdc.gov/mmwr/preview/mmwrhtml/su6004a9.htm.

50 *Id.*

51 ORIGINS AND RATIONALE OF IMMUNIZATION POLICY, *supra* note 17.

52 Id.

the patent owner is reasonably compensated.[53] This utilization has been entirely forgotten in recent years, with the only notable usage as a threat during the anthrax scare of 2001.[54]

Though not specific to vaccine regulation, patents are one of the main sources that can encourage private investors to fund vaccine research and development. A driving reason to develop a vaccine is the knowledge that no one else will be able to copy the product. Patents are a strong incentive for creating a vaccine, and a lack of patenting rights would undoubtedly deter pharmaceutical companies from developing vaccines; however, patents also create a barrier to entry in vaccine development.[55] The arguments for and against patents have always been that patents create incentives for research and development by granting exclusive access to results, but also may weaken the motivation to enter the field in the first place by keeping competitors in the dark.[56] Part of the reason the COVID-19 vaccine was developed so quickly was because information was shared. In the U.S., patent incentives may have kept this information from being publicly released for much longer than it was. Chinese virologist Zhang Yong-Zhen bravely agreed to release the coronavirus genome, despite an order from China's National Health Commission not to disclose any information regarding the virus to the public.[57] This was a brave act against the Chinese government by Zhang, but would this have been the same if Zhang had any intellectual property rights to the genome or had been part of a private company that did?[58] It may be the case that the virus emerging in a communist country, by eliminating private intellectual property rights, could have been a benefit to global public health.[59] If it were a U.S. company that privately discovered the genome, it is questionable whether the genome would have so quickly entered the public domain.

B. *REAGAN REGULATION*

During and around the Reagan Administration, a large push for regulation in favor of the private sector resulted in the rise of what is known as Big Health or Big Pharma.[60] On the production side, one of the greatest hindrances to vaccine development is that it is an unprofitable business, and this was an

53 Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 280 (2016).

54 Id.

55 Currently, companies are racing against each other to create the first COVID-19 vaccine because it presents a very rare business opportunity for developers, especially if demand makes it a valued part of standard immunizations globally. *See generally* Alan Story, *A patented Covid-19 vaccine could price out millions*, GREEN WORLD (May 7, 2020), https://greenworld.org.uk/article/patented-covid-19-vaccine-could-price-out-millions.

56 *See generally* U.S. CONST. art. I, § 8, cl. 8.

57 Charlie Campbell, *Exclusive: The Chinese Scientist Who Sequenced the First COVID-19 Genome Speaks Out About the Controversies Surrounding His Work*, TIME (Aug. 24, 2020, 10:07 PM), https://time.com/5882918/zhang-yongzhen-interview-china-coronavirus-genome/.

58 *See generally* Misha Angrist & Robert M. Cook-Deegan, *Who Owns the Genome?*, THE NEW ATLANTIS (2006), https://www.thenewatlantis.com/publications/who-owns-the-genome.

59 *See generally* Richard McGregor, *How the state runs business in China*, THE GUARDIAN (JULY 25, 2019), https://www.theguardian.com/world/2019/jul/25/china-business-xi-jinping-communist-party-state-private-enterprise-huawei.

60 Jeffrey D. Sachs, *Ending the Ronald Reagan lie*, BOSTON GLOBE (July 11, 2017, 12:00 AM), https://www.bostonglobe.com/opinion/2017/07/10/ending-ronald-reagan-lie/RF3guIcPrjoZI3WWagT3rM/story.html.

incentive that the federal government began to develop regulation to protect. One of the most obvious reasons for low profitability in vaccine production is the low demand that exists for such a preventative medicine. The only time the demand increases is when a new disease creates a need, creating a panic that results in demand beyond actual need.[61] While this increase in demand may also increase funding, that funding will decline as soon as a pandemic begins to wane.[62] In the past, companies that have invested in developing vaccines in response to a public health crisis have suffered immense sunk costs after an epidemic wanes and the need for a vaccine diminishes.[63] Federal safety regulations, though a benefit to society, also present a barrier to vaccine innovation and increases production costs.[64] Though the potential economic value of vaccines is great, that value does not go into the hands of the developers and manufacturers.[65] Much of that economic value is in its preventative nature. Another disincentive for developers is that the economic value of a vaccine is such that many vaccines are one-time use, with long-lasting immunization.[66] It is not surprising, therefore, that more lucrative pharmaceuticals may be more attractive to investors and developers.

Even when companies can profitably develop new drugs and vaccines, these are often aimed toward treating chronic diseases in the wealthiest, most industrialized countries.[67] The treatment of infectious diseases in developing countries is often the least profitable, for reasons such as low market returns, distribution challenges, or lack of awareness, and is therefore neglected by profit-driven companies.[68] Even if there is a tangible disease with a foreseeable spread in a developing or low-income country, preventative medicine is still not economically valued enough for sponsors to want to invest in a disease that has not yet arrived on domestic soil. One of the most illustrative examples of this is in the Ebola outbreaks prior to 2014.[69] One vaccine had been developed but could not find a private investor to sponsor the clinical trials necessary for regulatory approval. As a result, the vaccine was placed in storage and untouched until the Ebola 2014-2016 outbreak.[70] Reported to be 100% effective, the vaccine likely could have prevented the epidemic if it had been administered before or at the start of the outbreak.[71] On the market side, because vaccine production is largely a private sector endeavor, it is difficult to ensure affordable prices for the public.[72] Concerns about profitability are at odds with the

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61 ECONOMIC ASPECTS OF VACCINE INNOVATION AND MANUFACTURING, *supra* note 14.

62 Id.

63 Nicholas Florko, *Major drug makers haven't stepped up to manufacture NIH coronavirus vaccine, top U.S. health official says*, STAT (Feb. 11, 2020), https://www.statnews.com/2020/02/11/major-drug-makers-havent-stepped-up-to-manufacture-coronavirus-vaccine-top-u-s-health-official-says/. *See infra* note 69–71 and accompanying text.

64 ECONOMIC ASPECTS OF VACCINE INNOVATION AND MANUFACTURING , *supra* note 14.

65 Rutschman, *supra* note 5, at 173.

66 *See also id.* at 173, 175 (comparing the income of the measles vaccine after an outbreak, at $675 million, with the typical yearly income of diabetes treatment, at $6 billion per year, and the income of cancer biologic Keytruda, which is expected to surpass $20 billion in income).

67 Craig Wheeler & Seth Berkley, *Initial Lessons from Public-Private Partnerships in Drug and Vaccine Development*, 79 BULLETIN OF THE WORLD HEALTH ORG. 728 (2001).

68 Id.

69 Rutschman, *supra* note 5, at 176.

70 Id.

71 COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS, WHY WE EXIST, https://cepi.net/about/whyweexist/ (last visited May 4, 2022)

72 ECONOMIC ASPECTS OF VACCINE INNOVATION AND MANUFACTURING, *supra* note 14.

accessibility of what many believe should be free vaccinations. This was seen in the HIV-AIDS crisis in 1996 when an antiretroviral treatment became available, but only for thousands of dollars per person.[73] As a result, millions of people in low-income countries like India and South Africa died before the treatment became affordable.[74]

Another major problem for profitability has been the liability and risk that is involved in the occurrence of adverse vaccine reactions. This presents legal trouble for manufacturers. While legally considered "unavoidably unsafe," there is a question as to who should be responsible for such liabilities.[75] Of course, this is an issue that all pharmaceutical companies and companies in the business of manufacturing medicine must face. However, this is possibly a reason for the steep decline in vaccine suppliers over the years, going from over fifty licensed American vaccine manufacturers in the 1940s, to less than ten by the late 1990s.[76]

One major contributor to the growth of Big Pharma was the return of the Institutional Patent Agreement program in 1968, which allowed for monopolies on licenses developed through funding by the NIH, as opposed to returning these rights to the federal government.[77] In 1980, the Bayh-Dole Act further allowed private pharmaceutical companies to profit by broadening intellectual property rights.[78] Shortly after, the *Diamond v. Chakrabarty* decision would instill newfound confidence in investors that the pharmaceutical industry could be a lucrative venture. Other legislation that boosted the profitability of Big Pharma include the 1983 Orphan Drug Act and the FDA Act of 1997.[79] Now, if an adverse reaction results in permanent damage, a claim can be filed with the

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73 Story, *supra* note 55.

74 Id.

75 Restatement (Second) of Torts § 402A, comment k (Am. L. Inst. 1965).

76 Rutschman, *supra* note 5, at 174–75. In the 1970s, a number of lawsuits were filed against vaccine manufacturers for adverse reactions to vaccines. This caused the prices of vaccines to increase, and several manufactures stopped producing all together. In an effort to address this situation, Congress passed the National Childhood Vaccine Injury Act in 1986, which offered compensation to consumers on a "no fault" basis. CENTERS FOR DISEASE CONTROL & PREVENTION, *Overview, History, and How the Safety Process Works*, https://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html (Sept. 9, 2020). *See generally*, 42 U.S.C. §§ 300aa-21 to -23 (1988). The National Vaccine Injury Compensation Program (NCVIP) was established by the U.S. Department of Health and Human Services (HHS) in 1988, which taxes vaccine manufacturers $0.75 per vaccine dose for vaccines that are routinely given to children, as well as some adult vaccines. This program allows an individual to claim an injury from a covered vaccine, and presumes that events at issue are side effects of the vaccine as long as there is no other cause to be found. *Vaccine Injury Compensation Programs*, THE HISTORY OF VACCINES, https://www.historyofvaccines.org/content/articles/vaccine-injury-compensation-programs (Jan. 17, 2018).

77 Alexander Zaitchik, *How Big Pharma Was Captured by the One Percent*, THE NEW REPUBLIC (June 28, 2018), https://newrepublic.com/article/149438/big-pharma-captured-one-percent.

78 The Act "promotes the use of federally funded inventions by small businesses and nonprofit organizations . . . by allowing (1) nonprofit organizations such as universities to retain title to and market the inventions they created using federal research funds and (2) federal agencies to grant exclusive licenses for federally owned inventions to provide more incentive to businesses." U.S. GEN. ACCOUNTING OFFICE, GAO/RCED-98-126, *Administration of the Bayh-Dole Act by Research Universities* (1998), https://www.gao.gov/archive/1998/rc98126.pdf. It also authorizes the government to exercise what are known as "march-in rights" by licensing a generic competitor if a company funded by taxpayers is determined to be pricing unreasonably. However, this authority has never been exercised. Christopher Rowland, *Trump administration makes it easier for drugmakers to profit from publicly funded coronavirus drugs, advocates say*, WASH. POST (July 1, 2020, 4:43 PM), https://www.washingtonpost.com/business/2020/07/01/vaccine-coronavirus-barda-trump/.

79 Zaitchik, *supra* note 77.

National Vaccine Injury Compensation Program (VICP), a federal program designed to take financial responsibility for reactions that are possibly caused by a vaccination.[80]

Encouraging the private sector to enter the pharmaceutical industry is not inherently bad; However, regarding an issue as broad and unique as public health, it is wrong to assume that the private sector will not take advantage of profit opportunities at the expense of public health. Despite the pro-pharma regulation, the federal government has always played an important role in the pharmaceutical industry. Between 2010 and 2016, every single medicine approved by the FDA involved government or university laboratories.[81] But the amount of government funding for vaccines in the United States has decreased and flattened consistently since the 1960s. The National Science Foundation has found that, for the first time since World War II, federal funding makes up less than 50% of basic research.[82]

II. COVID-19 AND THE IMPORTANCE OF GOVERNMENT INVOLVEMENT

The increase in private investment in the pharmaceutical industry has been a result of increased opportunity for profit, but this has resulted in taking on much more risk that ultimately is taken on by customers through higher pricing. To prioritize public health, there needs to be an increase in government funding as well as more structured regulation to create limitations or caps on certain methods of profit. One of the solutions for this in recent years for this has been the creation of public-private partnerships (PPPs) in the pharmaceutical industry. Put simply, PPPs offer an opportunity to pool resources and add caveats to intellectual property protections through agreements with the government.

PPPs have long been present in other industries such as construction, but only recently have they begun to be recognized for their potential in the pharmaceutical business. The pharmaceutical industry has always suffered from a disconnect between the public and private sectors. Few private companies are willing to engage in vaccine research and development as a result of costly investment and high risk for return, and public organizations lack the capacity to complete the process of either developing or manufacturing without the help of the private sector.[83] The economic reluctance of the private sector is not surprising. As explained by the National Institute of Allergy and Infectious Diseases (NIAID) Director Dr. Anthony Fauci, "[c]ompanies that have the skill to be able to [produce and manufacture vaccines] are not going to just sit around and have a warm facility, ready to go for when [the government] need[s] it."[84]

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80 This likelihood is determined by a table of known adverse reactions. NAT'L CONFERENCE OF STATE LEGISLATURES, *Immunization Policy Issues Overview* (Feb. 26, 2021), https://www.ncsl.org/research/health/immunizations-policy-issues-overview.aspx.

81 Zaitchik, *supra* note 77.

82 Jeffrey Mervis, *Data check: U.S. government share of basic research funding falls below 50%*, AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE (Mar. 9, 2017, 1:15 PM), https://www.sciencemag.org/news/2017/03/data-check-us-government-share-basic-research-funding-falls-below-50.

83 Rutschman, *supra* note 6, at 731.

84 Florko, *supra* note 63. This comment is describing in particular the unwillingness of manufacturers to build and prepare the facilities necessary for vaccine production until a vaccine has been approved. *See generally* Seth Berkley, *COVAX explained*, GLOBAL ALLIANCE FOR VACCINES AND

Furthermore, there is often concern that the public sector will not be able to guarantee the confidentiality of important industry information, or that contracting and regulatory procedures will be more complex than their worth.[85] On the public side, especially in the United States, many federal agencies have responsibility for and power to influence vaccine production, but lack a central framework for overarching policy and concrete objectives.[86]

The emergence of PPPs is a somewhat modern solution to the problems surrounding fully private or fully public vaccine development. PPP models began to enter the global health arena in the early 2000s.[87] The two general models that exist are access partnerships and product development partnerships. Access partnerships rely on gathering resources in order to guarantee the purchase and distribution of biopharmaceuticals.[88] These partnerships place an emphasis on the distribution of existing drugs. Product development partnerships, on the other hand, focus more on the research and development of new vaccines and drugs that are underfunded and have insufficient demand.[89] The benefit of these partnerships is the jump-start the public funding can provide to private industry or vice versa, and the balance of sharing information for the good of global public health while retaining a worthwhile return on investment.[90] The expertise required in vaccine development is typically found either in academia or the public sector.[91] The private sector often brings to the table funding and skills applied in developing safe and effective products for the market as well as experience and facilities to enable large-scale production.[92] Distinct from other international or philanthropic organizations, PPPs create an opportunity for high-level funding of certain high-risk and costly initiatives.[93] One of the greatest benefits of these PPPs is their ability to pool together multiple resources with varying strengths and skills toward a common goal: namely, creating a lower cost-benefit ratio for vaccine development and distribution for certain neglected diseases.[94]

IMMUNIZATIONS (Sept. 3, 2020), https://www.gavi.org/vaccineswork/covax-explained ("To avoid this, the Facility is working with manufacturers to provide investments and incentives to ensure that manufacturers are ready to produce the doses we need as soon as a vaccine is approved.").

85 NATIONAL RESEARCH COUNCIL (US) DIVISION OF HEALTH PROMOTION & DISEASE PREVENTION, AN APPROACH TO THE PROBLEMS OF COMMUNICATION, COORDINATION, AND COLLABORATION IN VACCINE POLICY (1985), https://www.ncbi.nlm.nih.gov/books/NBK216816/.

86 *Id.*

87 Rutschman, *supra* note 5, at 179.

88 Id.

89 *Id.* at 180.

90 HANNAH KETTLER & ADRIAN TOWSE, PUBLIC PRIVATE PARTNERSHIPS FOR RESEARCH AND DEVELOPMENT: MEDICINES AND VACCINES FOR DISEASES OF POVERTY 8 (2002).

91 NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, A REVIEW OF PUBLIC–PRIVATE PARTNERSHIP ACTIVITIES IN HEALTH SYSTEM STRENGTHENING (2016).

92 NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, THE ROLE OF PUBLIC-PRIVATE PARTNERSHIPS IN HEALTH SYSTEMS STRENGTHENING: WORKSHOP SUMMARY (Jill Jenson ed., 2015), https://www.ncbi.nlm.nih.gov/books/NBK373286/.

93 Wheeler & Berkley, *supra* note 67, at 729.

94 *Id.* The Medicines for Malaria Venture (MMV) is an example of the way a PPP has allowed for the advancement of knowledge against a neglected disease. Malaria is a disease that predominantly affects the poor, and as such does not offer high profitability. The private sector will not fight Malaria alone because they need to make a profit. Similarly, the public sector cannot take on Malaria alone because it does not have the know-how. A PPP, on the other hand, allows for action on several fronts and with several parties. A PPP can receive knowledge that no one else has because it is concentrated on one specific disease. *What Advantages Do Public-Private Partnerships Such As MMV Bring to the Development of New Antimalarial Drugs?*, MEDICINES FOR MALARIA VENTURE (2010), https://www.mmv.org/newsroom/interviews/what-advantages-do-public-private-partnerships-such-

The value and necessity of the government in these PPPs cannot go unnoticed. As expected, COVID-19 has required the government to invest billions of dollars into the search for a vaccine. As of March 1, 2021, Moderna had received $954 million in federal funding for development alone, and another $4.94 billion for a contract of 300 million doses.[95] The federal government's Health and Human Services (HHS) agency alone had obligated or spent about $13.8 billion in coronavirus vaccine funding.[96] This type of federal funding places a significant portion of the cost on the federal government, allowing investment that the private sector alone would never risk. As a result, the pricing of these vaccines, in theory, could be lower and still turn a profit for these private business investments.[97] Some large companies that have developed a vaccine, such as Johnson & Johnson and GlaxoSmithKline PLC, have announced that they plan to make the vaccine available at cost, temporarily forgoing a profit.[98]

There are other factors that may temporarily be affecting price. Due to the pandemic crisis across the globe, governments have made significant purchases, some far beyond what is necessary, of vaccines that are not yet in existence in an effort to be first in line. The reasoning is that, if a government must over-estimate or under-estimate vaccine purchases, it is certainly better to overshoot. It seems that, by buying in such large quantities, a price ceiling has been created for the time being.[99] But it is likely, if not guaranteed, that in the future these prices will increase as insurance companies and other buyers begin to emerge. Another way this profit will likely be realized is in the event that the vaccine requires annual booster shots, similar to the annual influenza vaccine. As of February 9, 2021, Pfizer had charged $19.50 per coronavirus vaccine dose, while Moderna had charged $15 per dose, a total of $30 due to the two-dose requirement.[100] Moderna is the only company that has relied on almost complete government funding, but it also requires storage temperatures that create a high maintenance cost.

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mmv-bring-development-new.

95 CONG. RESEARCH SERV., IN11560, OPERATION WARP SPEED CONTRACTS FOR COVID-19 VACCINES AND ANCILLARY VACCINATION MATERIALS (Mar. 1, 2021). In describing the speed at which Moderna has developed the vaccine, CEO Stephane Bancel stated that Moderna "couldn't have done this" without such funding. Kevin Stankiewicz, *Moderna Soars After Getting $483 Million in Federal Funding for Coronavirus Vaccine Development* (Apr. 17, 2020, 8:26 PM), https://www.cnbc.com/2020/04/17/moderna-soars-on-483-million-in-funding-for-coronavirus-vaccine.html.

96 CONG. RESEARCH SERV., IN11556, FUNDING FOR COVID-19 VACCINES: AN OVERVIEW (Jan. 11, 2021), https://crsreports.congress.gov/product/pdf/IN/IN11556#:~:text=According%20to%20a%20Government%20Accountability,the%20rest%20in%20BARDA%20allocations.

97 It is necessary to note that the apparent counter argument would be that by increasing government funding and decreasing private investment, this would result in a cumulative price increase for taxpayers. While this is possible, the benefit of having government funding is potential for extra resources as well as contractual price limitations that, when balanced with private investment, would counteract the marked-up prices that are made possible by Big Pharma.

98 Julie Steenhuysen, Peter Eisler, et al., *Special Report: Countries, Companies Risk Billions in Race for Coronavirus Vaccine*, REUTERS (Apr. 25, 2020, 3:38 PM), https://www.reuters.com/article/us-health-coronavirus-vaccine-specialrep-idUSKCN2270U1. However, these companies also stand to see nonfinancial gains, as this may improve reputation and boost shares, which may contribute to a financial gain in the future.

99 It should be noted that there have been other significant philanthropic and private contributions, including the Gates Foundation, Alibaba founder Jack Ma, and country music singer Dolly Parton.

100 Jonathan Gardner, *As COVID-19 Becomes A Business, Vaccine Makers Confront Thorny Pricing Questions*, BIOPHARMA DIVE (Feb. 9, 2021), https://www.biopharmadive.com/news/coronavirus-vaccines-pricing-questions-moderna-pfizer/594762/.

The COVID-19 vaccine could not have been produced as quickly as it has without immense government funding. These funds have allowed manufacturing facilities to build and prepare for the approval of vaccines so that they may be manufactured immediately after approval. Though this involvement has cost billions of taxpayer dollars, it has sped up the process of development, which will save many lives as well as other economic expenses. Furthermore, the government has purchased vaccines in bulk quantities that will be provided to the American public at no cost.[101]

III. DISTRIBUTION AND THE NEED FOR A STRONG INTERNATIONAL PLAYER

Even if government funding creates a more affordable vaccine, distribution remains an issue. On a domestic and practical level, the distribution of vaccines presents costly maintenance concerns. Many vaccines, especially "live virus" vaccines, require specific temperature maintenance.[102] Many countries simply cannot afford this type of vaccine maintenance. However, even many of the countries that have been able to afford such cold chain technology have been unable to care for the equipment properly or lacked the funding necessary for staffing or some other form of cold chain maintenance.[103] Supply and availability of many products are necessary for a smooth distribution process.[104] There are also concerns over improper disposal of biohazard waste, a shortage of trained professionals to inoculate populations, a lack of a tracking system for vaccinations provided (especially if multiple doses are required), and the possibility of misinformation and mistrust in certain political climates.[105]

Furthermore, these domestic differences could have an international impact. There are vast variances between countries in their ability to regulate and distribute. It was not until 1972 that the United States created the Food and Drug Administration (FDA) to regulate vaccine distribution and use, and the FDA equivalents in many other countries took even longer.[106] The way vaccines are supplied has been changing in the globalized market as well. As developing countries become more competent and skilled as vaccine manufacturers, they are replacing the multinational firms that used to manufacture vaccines. For

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101 CONG. RESEARCH SERV., IN11560, *supra* note 95.

102 *See generally Vaccine Storage and Handling*, CENTERS FOR DISEASE CONTROL AND PREVENTION: THE PINK BOOK, https://www.cdc.gov/vaccines/pubs/pinkbook/vac-storage.html (last updated July 2020).

103 WORLD HEALTH ORG., WHO/IVB/14.05, IMMUNIZATION SUPPLY CHAIN AND LOGISTICS - A NEGLECTED BUT ESSENTIAL SYSTEM FOR NATIONAL IMMUNIZATION PROGRAMMES, 1 (2014) (Table 1 lists some common challenges in vaccine distribution and maintenance). The Pfizer COVID-19 vaccine, for example, requires a constant temperature of negative 70-80 degrees Celsius. Jane Byrne, *COVID-19 Vaccine Distribution: Gaps Remain in Immunization Logistics and Real-Time Tracking of Vaccine Storage and Demand*, BIOPHARMA-REPORTER, https://www.biopharma-reporter.com/Article/2020/11/19/COVID-19-vaccine-distribution-Gaps-remain-in-immunization-logistics-and-real-time-tracking-of-vaccine-storage-and-demand (last updated Nov. 19, 2020, 9:47 AM GMT).

104 Bill Gates has warned of a shortage of medical glass, which may limit the number of vaccine doses distributable. Sanger, Kirkpatrick, et al., *supra* note 16.

105 LAUNCH & SCALE SPEEDOMETER, https://launchandscalefaster.org/COVID-19 (last visited March 5, 2021).

106 Julie B. Milstien, Miloud Kaddar, & Marie Paule Kieny, *The Impact of Globalization On Vaccine Development And Availability*, HEALTH AFFAIRS (July, 2006), https://doi.org/10.1377/hlthaff.25.4.1061.

infectious diseases such as the novel coronavirus and other future diseases, the circumstances of globalization make the safety and health of all countries a priority for each country.[107] The emergence of a disease in one area of the world does not limit treatment to that area. Globalization means that not only are the economic effects of disease felt across the world, but the disease itself has the ability to travel quickly. As the world begins to operate as a more interconnected force in vaccine development and production, having a different regulatory procedure at each step is inefficient and fails to adapt to a changing world.

Looking beyond domestic distribution challenges, one major challenge in global health is the natural inclination toward nationalism over globalism, a tension that has only heightened in recent years. Wealthy countries that have companies with the means to develop a vaccine have indicated that they will reserve a large number of initial doses strictly for national use.[108] This is hardly a blameworthy sentiment as no government would want to send the solution to an existing national problem elsewhere in the world. However, this seems to create a kind of prisoner's dilemma. Each country operating only for itself may take longer to succeed, losing lives domestically in the process, but also losing lives internationally, damaging the global economy and harming political relations. But countries do not want to do this because if they do not have power and control over vaccine development, then they cannot ensure that vaccines go to their people first.[109]

A. *CHOOSE YOUR PLAYER*

In order to improve the distribution efforts for vaccines, there needs to be a central international authoritative power when it comes to distribution. There is no single institution that has primary authority over vaccine development and production on a global scale. One major reason for this is that private institutions have monetary incentives to create these vaccines, and private risk in bearing the costs allows for more research than would be possible in a strictly public sector or government setting. However, because these private institutions are contributing to global public health, there should be an international regulatory system in place that includes and monitors the contributions of private investment while still allowing the private sector to profit. Currently, there are a few key international players involved in global health and vaccines.

On the international level, the most prominent health organization is the World Health Organization (WHO). Founded in 1948, the WHO succeeded and replaced the League of Nations' Health Organization.[110] The WHO has three types of legislative instruments: conventions, regulations, and

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107 Mellen, *supra* note 11.

108 Michaeleen Doucleff, *How Rich Countries Are 'Hoarding' The World's Vaccines, In Charts,* NAT'L PUB. RADIO (Dec. 3, 2020), https://www.npr.org/sections/goatsandsoda/2020/12/03/942303736/how-rich-countries-are-hoarding- the-worlds-vaccines-in-charts, (Canada, the U.S., the U.K., and Australia have all purchased vaccinesdoses in numbers beyond 200% of their population).

109 Many countries have resorted to a zero-sum mentality, banning exports of many healthcare related products such as masks and anti-viral drugs. Peter S. Goodman, Katie Thomas, et al., *A New Front for Nationalism: The Global Battle Against a Virus*, N.Y. TIMES (Apr. 10, 2020), https://www.nytimes.com/2020/04/10/business/coronavirus-vaccine-nationalism.html.

110 WORLD HEALTH ORG., WHO WE ARE, https://www.who.int/about/who-we-are/history.

recommendations.[111] However, the WHO has only ever created three binding pieces of legislation. Two of these legally binding documents, the Nomenclature Regulations, and the International Health Regulations, already had predecessors before the WHO was originated.[112] The only original and binding legislation the WHO has ever enacted is the Framework Convention on Tobacco Control (FCTC), which was adopted by the World Health Assembly (WHA) via a requisite two-thirds vote in 2003.[113] The FCTC is binding upon all member states of the WHO (as long as they have not expressly opted out) and has been applied in several domestic tobacco-related cases.[114] The WHO has other non- binding, but authoritative recommendations, the most notable of which is the International Code of Marketing of Breast-Milk Substitutes (1981).[115] When the coronavirus had infected over 9,800 people, killed over 200, and Wuhan had gone into quarantine, the WHO declared COVID-19 a Public Health Emergency of International Concern (PHEIC) on January 31, 2020.[116] This kind of declaration can motivate state-level reactions on both a public and political level, but it gives no additional power or resources to the WHO or any other organization.[117] In fact, the WHO had published an "R&D Blueprint" in which it addressed the need for increased research and development, and specifically acknowledged an "urgent need" for countermeasures against coronaviruses such as MERS-CoV.[118] Of course, that need was not sufficiently addressed until a global pandemic was well underway.

Another key player is the Global Alliance for Vaccines and Immunizations (Gavi) was founded in 2000 to specifically allow for public-private partnerships to focus on international vaccines and immunizations. Gavi was founded with the help of a $750 million investment and a 5-year pledge from the Bill & Melinda Gates Foundation, and it has created partnerships with the WHO, the World Bank, UNICEF, individual state governments, as well as private sector partners.[119] As a public-private partnership itself, Gavi is an example of an access partnership, as much of its efforts go to improving vaccine access for both

111 Brigit Toebes, *International health law: an emerging field of public international law*, 55 INDIAN J. OF INT'L L. 299, 305 (2015).

112 IWAO M. MORIYAMA, RUTH M. LOY, & ALASTAIR H.T. ROBB-SMITH, *History of the Statistical Classification of Diseases and Causes of Death* 1–2 (Harry M. Rosenberg & Donna L. Hoyert eds.) (2011), https://www.cdc.gov/nchs/data/misc/classification_diseases2011.pdf; WORLD HEALTH ORG., *Frequently Asked Questions About the International Health Regulations (2005)*, https://www.who.int/ihr/about/FAQ2009.pdf.

113 MORIYAMA, *supra* note 112, at 306.

114 *Id*. *See also* WORLD HEALTH ORG. CONSTITUTION, Art. 22. It should also be noted that though the FCTC has 181 parties that are bound to its rules, it is often considered a *sui generis* treaty because the tobacco industry is widely accepted to be purely harmful to health. Lawrence O. Gostin, Devi Sridhar, & Daniel Hougendobler, *The Normative Authority of the World Health Organization*, 129 PUB. HEALTH J. 854, 856 (2015).

115 Toebes, *supra* note 111, at 307. Though the WHO has very little binding legal documents, there is an argument that these non-binding recommendations can be more effective than mandatory law. This is because states may be more inclined to accept such non-binding documents and, despite a non-binding nature, may have more irrevocable effects in practice. *See generally* Oscar Schachter, *The Twilight Existence of Nonbinding International Agreements*, 71 AM. J. INT'L L. 296–304 (1977).

116 *A Timeline of COVID-19 Developments in 2020*, AMERICAN J. MANAGED CARE (Jan. 1, 2021), https://www.ajmc.com/view/a-timeline-of-covid19-developments-in-2020.

117 Lawrence O. Gostin, *What Questions Should Global Health Policy Makers Be Asking About The Novel Coronavirus?*, HEALTH AFFAIRS (Feb. 3, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200203.393483/full/.

118 WORLD HEALTH ORG., AN R&D BLUEPRINT FOR ACTION TO PREVENT EPIDEMICS (2016), https://www.who.int/blueprint/about/r_d_blueprint_plan_of_action.pdf?ua=1.

119 GAVI, ABOUT OUR ALLIANCE, https://www.gavi.org/our-alliance/about.

new and underused vaccines.[120] One of the most recent public-private partnerships and international organizations that aims specifically to improve the vaccine development arena is the Coalition for Epidemic Preparedness Innovations (CEPI), a Norwegian association founded in 2017 that focuses on public-private partnerships with the goal of putting a stop to future epidemics.[121] Like Gavi, CEPI is a PPP, but CEPI also allocates significant efforts toward product development. CEPI's two main foci are accelerating the development process of vaccines and facilitating equitable access of vaccines for all.[122] Notably, CEPI agreed to provide financial support for the research and development of three different types of COVID-19 vaccines in January of 2020, just two weeks after scientists in China made a genome sequence of COVID-19 publicly available.[123]

One noteworthy aspect of CEPI is all contributing investors in CEPI are invited to join CEPI's Investors Council, which is responsible for nominations of investor representatives to the Board.[124] This includes private investors.[125] Four of the Board's twelve seats are selected by and reserved for members of the Investors Council.[126] This is in stark contrast to the World Health Organization's system of governance, which only allows states to become members and the scope of influence for nonstate actors that invest in the WHO is limited to earmarking their donation amounts for specific purposes.[127] Another unique aspect of CEPI is its approach to intellectual property and licensing. CEPI's general rule is it prefers for intellectual property to belong to the awardee of a grant.[128]

One attempt to resolve the distribution problem has been through COVAX.[129] Founded in early 2020 by Gavi, CEPI, and the WHO in response to the COVID-19 pandemic, COVAX is a project that aims to provide COVID-19 vaccine access to developing countries and high-risk populations around the world.[130] COVAX acts as a platform for a multitude of vaccine candidates,

120 Rutschman, *supra* note 5, at 179.

121 COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS, WHY WE EXIST, *supra* note 71. *See generally* COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS, WHO WE ARE, https://cepi.net/about/whoweare/ ("CEPI was founded in Davos by the governments of Norway and India, the Bill & Melinda Gates Foundation, Welcome, and the World Economic Forum." It has received funding from a number of countries, though the United States is not one, and a number of private sector entities).

122 COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS, WHY WE EXIST, *supra* note 71.

123 Rutschman, *supra* note 5, at 178.

124 COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS, INVESTORS COUNCIL TERMS OF REFERENCE, 1 (2019), https://cepi.net/wp-content/uploads/2019/01/IC_Terms-of-reference-Feb2019_final-valid.pdf.

125 COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS, POLICY ON GOVERNING CONTRIBUTIONS FROM THE PRIVATE SECTOR AND FROM INDIVIDUALS, 1, 2 (2020), https://cepi.net/wp-content/uploads/2020/02/Policy-on-contributions-from-the-private-sector-and-individuals_website.pdf ("The CEPI Board can, with the consent of the CEPI Investors Council, accept financial contributions that will result in the funder being invited to join the CEPI Investors Council").

126 COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS, *supra* note 125.

127 Lawrence O. Gostin & Allyn L. Taylor, *Global Health Law: A Definition and Grand Challenges*, 1 PUB. HEALTH ETHICS 53–63 (2008).

128 CEPI, CEPI POLICY DOCUMENTATION, 1, 3 (2017), https://msfaccess.org/sites/default/files/2018-09/CEPIoriginalPolicy_2017.pdf (However, the caveat is awardees may be required to allow information to be accessible to third parties "through a non-exclusive, royalty-free, sub-licensable, worldwide license."); *Id.* at 9.

129 Mellen, *supra* note 11.

130 Sam Meredith, '*Rule of the Jungle': Health Expert Sounds the Alarm on Fair Access to Covid*

providing funding for the development of vaccines and guaranteeing access to countries. For wealthier countries that are self-financing, assurance of access to vaccines depends on donation levels. Their goal is to distribute two billion doses of coronavirus vaccines before the end of 2021.[131] Furthermore, COVAX is attempting to accelerate the production process by incentivizing and investing in manufacturers to be prepared before a vaccine is approved.[132]

As of October 19, 2020, 184 countries had joined the initiative, but the U.S. was not one of them.[133] As of October 11, 2021, that number increased to 190 with the inclusion of the U.S.[134] Though many wealthy countries have promised to support COVAX, they are also making deals with vaccine distributors to receive a high quantity of doses for their own use.[135] These deals limit the number of doses available to COVAX to the point that only 10% to 15% of the populations of countries in need are likely to receive a vaccine, though COVAX's goal has been to provide vaccines to a minimum of 20% of the populations of countries in need.[136] As of December 4, 2020, researchers at Duke University's Global Health Innovation Centre found that 9.85 billion doses of COVID-19 vaccines had been purchased or reserved before any vaccine had even been approved for market.[137] Unfortunately, these countries have also purchased vaccines in quantities well over the size of their population.[138] The reason they do this is that it is likely some of these vaccines will not receive approval to go to market, but this overshooting usually leads to an oversupply of doses. But wealthy countries that buy excess quantities of vaccines for their population, often leaving vaccines to spare, is a recurring global trend.[139] This was the case during the H1N1 and H5N1 outbreaks, where the outbreaks subsided before the vaccine became necessary and therefore eliminated a need for any distributive sharing system.[140] For the coronavirus vaccine, Canada has already purchased a quantity over five times that of its population.[141] One of the most promising qualities of COVAX is it operates as a single source to which countries can donate excess vaccines. However, this frustrates the purpose of

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Vaccines, CNBC (Nov. 16, 2020, 9:01 AM EST), https://www.cnbc.com/2020/11/16/coronavirus-health-expert-says-vaccine-race-akin-to-law-of-the-jungle.html.

131 Julia Belluz, *171 Countries Are Teaming Up for a Covid-19 Vaccine. But Not the US*, VOX (Oct. 9, 2020, 8:10 AM), https://www.vox.com/21448719/covid-19-vaccine-covax-who-gavi-cepi.

132 Seth Berkley, *COVAX Explained*, COVAX (Sep. 3, 2020), https://www.gavi.org/vaccineswork/covax-explained.

133 *WHO Says 184 Countries Have Now Joined COVAX Vaccine Program*, VOA NEWS (Oct. 19, 2020, 4:39 PM), https://www.voanews.com/covid-19-pandemic/who-says-184-countries-have-now-joined-covax-vaccine-program#:~:text=The%20United%20States%20is%20not,program%2C%20calling%20it%20too%20constraining. (This was a notable exception and a risky gamble, as the U.S. was essentially eliminating any chance of receiving doses from promising candidates associated with COVAX. According to Kendal Hoyt, an assistant professor at Dartmouth's Geisel School of Medicine, this was a "short sighted" decision similar to opting out of an insurance policy); Emily Rauhala & Yasmeen Abutaleb, *U.S. Says It Won't Join WHO-Linked Effort to Develop, Distribute Coronavirus Vaccine*, WASH. POST (Sept. 1, 2020, 2:42 PM), https://www.washingtonpost.com/world/coronavirus-vaccine-trump/2020/09/01/b44b42be-e965-11ea-bf44-0d31c85838a5_story.html.

134 Hannah Kettler, *What is COVAX?*, PATH (Feb. 5, 2021), https://www.path.org/articles/what-covax/.

135 Meredith, *supra* note 130.

136 Id.

137 LAUNCH & SCALE SPEEDOMETER, *supra* note 105.

138 Id.

139 Mellen, *supra* note 11.

140 Id.

141 LAUNCH & SCALE SPEEDOMETER, *supra* note 105.

COVAX in its efforts to distribute vaccines globally and opens up a new list of possible pitfalls in the accumulation and maintenance of vaccines. As University of Oxford researcher Sandy Douglas has put it, "The only solution is to make a hell of a lot of vaccine[s] in a lot of different places."[142]

B. *ADDING EGGS TO THE COVAX BASKET*

COVAX has been an important development in global public health, but because it was established quickly and in response to the COVID-19 pandemic, there is much room for improvement. One of the most obvious areas of potential is that COVAX should not only be responsible for the distribution of vaccines, but also the development of them. COVAX has impressively orchestrated the participation of the majority of the world's sovereign states in a matter of months, with the alluring promise of providing vaccines based on ability to pay. In the coming years, rather than using funds to purchase vaccines from other companies and organizations, COVAX should establish its own development process. Furthermore, perhaps with the help of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), which is focused on harmonizing and standardizing the domestic regulatory systems of sovereign states, COVAX can ultimately develop an international regulatory system for vaccine development and licensing. Moreover, there should be payment requirements in order to proactively fund vaccine development. This could be through membership dues, whether to COVAX itself or as an extension of WHO membership dues. Because the nature of vaccine market demand is such that there is often little incentive to invest in vaccine production, especially for lesser-known diseases and those diseases that affect lower-income countries, the concept of COVAX has an opportunity to provide preemptive and practical investment that benefits each paying member.

Additionally, the development of Gavi and CEPI has been beneficial to public health but act as a second and third voice competing with the WHO. Though they largely work together, these three organizations require a more central, guiding force. The United Nations (UN) Security Council is an example of a powerful, legally binding force that exists within the United Nations.[143] The UN General Assembly offers what is more similar to the WHO's Assembly; that is, influential but nonbinding recommendations. The UN Security Council is made up of five permanent members: France, Russia, China, the United Kingdom, and the United States. Pursuant to Article 23 of the UN Charter, there are an additional six nonpermanent members at any given time that are elected for two-year terms.[144] The WHO currently lacks such an authoritative division, but the nature of global vaccine distribution requires a commanding force that supersedes the demands of individual countries. Paired with an authoritative group such as the UN Security Council model, COVAX may be able to combine both carrot and stick incentives.

CONCLUSION

142 Sanger, Kirkpatrick, et al., *supra* note 16.
143 U.N. CHARTER art. 25.
144 U.N. CHARTER art. 23.

The importance of a strong international organization that is ultimately responsible for international vaccine development, regulation, and distribution has become evident. Despite having two years to restructure incentives and take advantage of the global spotlight on the vaccination system, the world has largely failed to create effective change. As the virus continues to infect, it is presented with more opportunities to mutate into versions of itself that are less responsive to existing vaccines, known as variants. The last couple of years have seen the emergence of many variants, some of which have been labeled variants of concern, which are more likely to cause breakthrough infections or reinfections of COVID-19.[145] As of January 4, 2022, the U.S. has experienced over one million new cases per day, likely a result of the more resistant and transmissible omicron variant.[146] As of January 15, 2022, the total COVID-19 death toll is estimated at over 5.5 million worldwide, and this is not considering the likely massive under-reporting happening for various reasons relating to political incentives and reporting methods.[147] This high death toll is certainly related to the inequality in vaccine accessibility.[148] Not only does this mean many of these deaths were preventable, but in a globalized world unprevented deaths are detrimental to all on both a public health and economic front.

The unfolding of the COVID-19 pandemic has made it clear that the unique nature of vaccines is such that the private sector cannot be left to its own devices. It is rational that the private sector is interested only in turning a profit, just as it is rational that the U.S. and other domestic governments will scramble to ensure the safety of their own citizens even if at the detriment of others. This has been seen recently with the EU's (as well as other countries') opposition to the TRIPS waiver, which would waive certain intellectual property rights related to the development of COVID-19 vaccines.[149] It is because of this global attitude that WHO Director-General Tedros Adhanom Ghebreyesus has called the global situation a "vaccine apartheid."[150]

To maximize vaccine production and distribution efforts, there needs to be an international and overarching source of power. COVAX offers significant potential in ensuring under-developed countries have access to vaccines, but it is limited in that it currently focuses only on distribution efforts, and domestic governments will continue to make deals outside of COVAX until their

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145 Robert Bollinger & Stuart Ray, *COVID Variants: What You Should Know*, JOHNS HOPKINS MEDICINE, https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/a-new-strain-of-coronavirus-what-you-should-know (last updated Jan. 14, 2022).

146 Sam Meredith, *'Rule of the Jungle': Health Expert Sounds the Alarm on Fair Access to Covid Vaccines*, CNBC (Nov 16, 2020, 9:01AM), https://www.cnbc.com/2022/01/04/us-counts-over-1-million-new-daily-covid-cases-in-global-record-.html.

147 *Coronavirus Death Toll*, WORLDOMETER https://www.worldometers.info/coronavirus/coronavirus-death-toll/; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8219996/ (last updated Jan. 16, 2022).

148 *See generally* Pablo Gutiérrez & Ashley Kirk, *Vaccine Inequality: How Rich Countries Cut Covid Deaths as Poorer Fall Behind*, THE GUARDIAN (June 28, 2021, 10:08 BST), https://www.theguardian.com/world/ng-interactive/2021/jun/28/vaccine-inequality-how-rich-countries-cut-covid-deaths-as-poorer-fall-behind (As of January 14, 2022, only 15% of Africa has received at least one dose of a vaccine while every other continent has reached over 65%). Ritchie & Ortiz-Ospina et al., *supra* note 1.

149 *See generally WTO TRIPS Waiver for COVID-19 Vaccines*, JOHNS HOPKINS (May 10, 2021), https://publichealth.jhu.edu/2021/wto-trips-waiver-for-covid-19-vaccines.

150 Emma Frage & Michael Shields, *World Has Entered Stage of "Vaccine Apartheid" – WHO Head*, REUTERS (May 17, 2021 11:44 AM), https://www.reuters.com/business/healthcare-pharmaceuticals/world-has-entered-stage-vaccine-apartheid-who-head-2021-05-17/.

population is fully vaccinated. Of course, COVAX is also currently a stand-alone program that can be opted into or left alone. While beneficial to join in its current form, it has significant potential to develop a more comprehensive international vaccine development and distribution program.

With a central force, there are ways global public health can be encouragedand ensured. A single source can support initiatives in wealthy countries and should encourage its member states by supporting their individual, and nationalendeavors to improve the health of their citizens. Mutually, member states should be encouraged and incentivized to implement policies that go beyond domestic issues. Countries cannot be required to join an international organization. But in the same way that it would be politically detrimental for a country to leave the United Nations, there should be incentives for member states to want to be a part of an international vaccination system.

Global public health is recognized by individual states as an important development to advance, but rather than having direct monetary incentives likethe work of the World Trade Organization (WTO), the pursuit of global public health is more similar to environmental law in that the return on investment is not always clear. However, the state of the globalized world is such that the status of vaccinations in one country creates an impact in every other country. Unlike more altruistic aims such as ending starvation and treating chronic disease, the futures of all nations are mutually linked by infectious diseases. Allcountries have self-serving reasons to ensure global vaccinations and prevent viral mutations. Therefore, there should be a vaccine-specific source of power responsible for ensuring vaccines are distributed globally and equitably. Countries could be incentivized by grants, tax cuts, or alternative reimbursementplans, organized and provided by an international organization and managed onindividual state levels. Though the specific answers about how to achieve this are unclear, and there will undoubtedly be many more questions about ensuring vaccine distribution on the state and individual level, the most important takeaway is the unique condition of the vaccine development industry, and the importance of an international authority responsible for ensuring global vaccinations. Government is a necessity in vaccine production, but only by allowing for international control beyond domestic governments can the needs of global vaccine production and distribution be met.