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Legal and Ethical Implications of U.S. and Canadian Vaccine Contracts: The Impact of Vaccine Nationalism on the Global Pandemic Response

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Legal and Ethical Implications of U.S. and Canadian Vaccine Contracts: The Impact of Vaccine Nationalism on the Global Pandemic Response

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This note explores the COVID-19 vaccine contracts between the U.S. and Canada and the impact of these types of agreements on the global pandemic response. These "pre-purchases," many of which were executed before the development of a vaccine, have afforded a select few nations the opportunity to stockpile vaccines, while other nations with fewer resources are unable to secure any doses. An effective method to counter the effects of the pandemic is the creation of a global vaccine network that provides equitable access to vaccine doses for nations in need. COVAX was launched to ensure that lower and middle-income nations have the opportunity to purchase vaccine doses at reduced costs for their respective populations. This initiative offers a realistic solution to shortening the timeline of the COVID-19 pandemic and bringing the global population closer to herd immunity.

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I. INTRODUCTION

On January 9, 2020, when the World Health Organization (WHO) announced the arrival of the novel coronavirus ("COVID–19") in Wuhan, China, few could have predicted the trajectory of the

pandemic.[1] As COVID–19's case count grew exponentially and the global death toll began to spike, the WHO declared the COVID–19 pandemic a public health emergency.[2] Shortly after, the United States government followed suit and declared the COVID–19 pandemic a public health emergency.[3] In March 2020, President Trump declared the COVID–19 pandemic a national emergency, which triggered the release of billions of dollars to be funneled towards fighting the virus and researching a cure.[4] Countries across the world have struggled to contain and respond to the health and economic effects of the COVID–19 pandemic, as it is the first health crisis of this magnitude in over a century, the last of which dates back to the arrival of the Spanish flu in 1918.[5]

As part of its pandemic response, the U.S. began funding large pharmaceutical companies in an effort to develop a COVID–19 vaccine.[6] These companies, including Pfizer, Moderna, Johnson & Johnson, and Novavax, are all based in the U.S. and have received upwards of $9 billion for research and development.[7] The U.S. government has provided billions of dollars in funding to U.S. pharmaceutical companies as part of "Operation Warp Speed,"[8] an operation dedicated to successfully developing, manufacturing, and distributing 300 million vaccine doses by January 2021.[9] Agreements between the federal government and U.S. pharmaceutical

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[1] *A Timeline of COVID–19 Developments in 2020*, AJMC, https://www.ajmc.com/view/a-timeline-of-covid19-developments-in-2020 (last updated Jan. 1, 2021).
[2] *Id*.
[3] *Id*.
[4] *Id*.
[5] Mark Terry, *Compare:1918 Spanish Influenza Pandemic Versus COVID–19*, BIOSPACE (Apr. 2, 2020), https://www.biospace.com/article/compare-1918-spanish-influenza-pandemic-versus-covid-19/.
[6] Karen Weintraub & Elizabeth Weise, *Federal spending on COVID_19 vaccine candidates tops $9 billion, spread among 7 companies*, USA TODAY, https://www.usatoday.com/story/news/health/2020/08/08/feds-spending-more-than-9-billion-covid-19-vaccine candidates/5575206002/ (last updated Aug. 10, 2020, 9:32 AM).
[7] *Id*.
[8] *Explaining Operation Warp Speed*, U.S. DEP'T HEALTH & HUMAN SERVICES, https://health.mo.gov/living/healthcondiseases/communicable/novel-coronavirus-lpha/pdf/fact-sheet-operation-warp-speed.pdf (last visited Oct. 3, 2021) [hereinafter *U.S. Dep't of Health & Human Servs.*].
[9] *Id*.

companies stipulate that the U.S. would receive the first batch of doses produced.[10] For example, the U.S. and Pfizer agreed that the U.S. would receive the first 100 million doses, with the option to acquire an additional 500 million.[11] The federal government included this provision in every vaccine contract with U.S. manufacturers to ensure the initial batches of vaccine doses were prioritized for U.S. residents.[12] Certainly, this favorable agreement is linked to the U.S.'s predominant role in vaccine funding.[13] Providing $11 billion to pharmaceutical companies in the first months of the pandemic, the U.S.'s financial contributions to the vaccine race are unparalleled.[14] Without this significant level of U.S. funding, manufacturers could have opted to sell the vaccines to nations that offered higher prices.[15]

U.S. pharmaceutical companies have also entered into contracts to supply vaccine doses to Canada, among other countries.[16] The Canadian government committed over $1 billion in future vaccine contracts with several pharmaceutical companies, including Moderna, Pfizer, Johnson & Johnson, and Novavax.[17] These contracts included up–front costs followed by incremental payments throughout the development process, which were contingent upon the successful completion of clinical trials and regulatory approval.[18] By entering into these future agreements with

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[10] Noah Weiland, Denise Grady & David E. Sanger, *Pfizer Gets $1.95 Billion to Produce Coronavirus Vaccine by Year's End*, N.Y. TIMES, https://www.nytimes.com/2020/07/22/us/politics/pfizer-coronavirus-vaccine.html (last updated Nov. 10, 2020).
[11] *Id*.
[12] *Id*.
[13] Richard G. Frank, Leslie Dach, & Nicole Lurie*, It Was The Government That Produced COVID–19 Vaccine Success*, HEALTH AFFAIRS (May 14, 2021), https://www.healthaffairs.org/do/10.1377/hblog20210512.191448/full/.
[14] James C. Robinson, *Funding of Pharmaceutical Innovation During and After the COVID-19 Pandemic*, JAMA (Jan. 14, 2021), https://jamanetwork.com/journals/jama/fullarticle/2775400.
[15] Weiland, *supra* note 10.
[16] *Procuring vaccines for COVID–19*, GOV'T OF CAN., https://www.canada.ca/en/public-services-procurement/services/procuring-vaccines-covid19.html (last updated Oct. 7, 2021).
[17] *Id*.
[18] *Id*.

manufacturers, the Canadian government effectively secured priority access to potential vaccine doses for its residents.[19]

This article will begin by addressing the recently executed COVID–19 vaccine agreements between the Canadian government and U.S. pharmaceutical companies, and comparing these new agreements to previous vaccine agreements between U.S. pharmaceutical companies and foreign states. Part II of this article will lay out the relevant legal frameworks surrounding previous pandemic responses and future vaccine contracts. Part III of this article will then explore the contractual relationships between the U.S. federal government, the Canadian government, and U.S. pharmaceutical companies to dissect potential business and legal implications. Following that, Part IV will focus on the various ethical issues raised by these types of vaccine agreements, such as vaccine nationalism and the limited liability of vaccine manufacturers. Part V of this paper will discuss the effect of these agreements on the global pandemic response and explore alternatives to these types of agreements for future crises. Finally, Part VI will explore the various alternatives to bilateral vaccine contracts—including vaccine alliances, Advanced Market Commitment Models, and multilateral agreements—that provide equitable access to vaccines for lower and middle–income countries, comparing and contrasting the different approaches to the pandemic response, and offering insight on how to respond to future public health crises.

To shorten the timeline of the COVID–19 pandemic, countries should continue implementing a coordinated, global response. The creation of a global vaccine network is an integral component to providing equitable access to COVID–19 vaccines and mitigating the effects of the pandemic.

II. BACKGROUND

In the event of a public health emergency in the U.S., the Public Health Service ("PHS") Act grants the Department of Health and Human Services ("HHS") the power to make critical decisions in an effort to address and mitigate the emergency situation.[20] The PHS

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[19] *Id*.

[20] *Regulations and Laws That May Apply During a Pandemic*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/flu/pandemic-

Act serves as the basis for the HHS' authority by permitting "the HHS Secretary to take key actions, such as lead all federal public health and medical response, declare a public health emergency, assist states in meeting health emergencies, maintain the Strategic National Stockpile, and control communicable diseases."[21]

On February 4, 2020, Alex Azar, the Secretary of the HHS, issued a Declaration pursuant to the PHS Act "to provide liability immunity for activities related to medical countermeasures against COVID–19."[22] The HHS stated that when a Declaration under the PHS Act is in effect, "the [PHS] Act precludes, for example, liability claims alleging negligence by a manufacturer in creating a vaccine, or negligence by a health care provider in prescribing the wrong dose, absent willful misconduct."[23] The threshold to reach "willful misconduct" is high, as it requires that "the covered person act (i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; *and* (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit."[24] As expected, this immunity provision does not cover actions grounded in "willful misconduct," yet it covers actions of negligence, even in vaccine development.[25] The PHS Act likely included this liability shield provision to incentivize manufacturers to develop vaccines in an expeditious and efficient manner.[26] Regardless of the intention, this provision acts as a de facto absolute immunity status for vaccine manufacturers.[27] Given the unlikelihood of a manufacturer engaging in willful misconduct while developing a vaccine, there are few legal recourses for individuals harmed by a newly–developed COVID–19 vaccine.[28]

Manufacturers may point to the assumption of risk doctrine, as the patient waives certain legal remedies as a prerequisite to

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resources/planning-preparedness/regulations-laws-during-pandemic.htm (last updated Nov. 3, 2016).

[21] *Id*.

[22] *Id*.

[23] *Id*.

[24] *Id*.

[25] *Id*.

[26] CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 20.

[27] *Id*.

[28] *Id*.

obtaining the vaccine.[29] Given the novelty and unprecedented timeline of vaccine development, there is no guarantee as to the effects of the vaccine.[30] Without inserting a waiver and assumption of risk provision in the vaccine contracts, manufacturers would find themselves in a vulnerable position that would likely open the floodgates of litigation.[31]

In Canada, the federal government's public health power comes from several sources.[32] The first source is the power to quarantine pursuant to Canada's Constitution Act.[33] Under Section 91 of the Constitution Act, "the federal government derives its jurisdiction to directly or indirectly regulate on public health–related issues principally from its powers to legislate on quarantine."[34] Further, the Constitution Act provides the federal government with the power to make laws "for the peace, order and good government of Canada."[35] Two laws have been passed that specifically address the federal government's emergency powers.[36] The first, the 2007 Emergency Management Act, provides a framework to assist provinces in the event of an emergency and to coordinate responsive actions between the federal government and provinces.[37]

The second piece of legislation, The Emergencies Act of 1985, provides the federal government authority to declare a national emergency and act unilaterally.[38] This Act grants the federal government more power than the 2007 Emergency Management Act in that the government is not required to collaborate with the provinces in crafting an emergency response.[39] However, questions arise

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[29] *Id*.
[30] *Id*.
[31] *Id*.
[32] Amy Swiffen, *The limits of Canada's federal emergency law during the coronavirus pandemic*, THE CONVERSATION (Apr. 1, 2020, 10:27 AM), https://theconversation.com/the-limits-of-canadas-federal-emergency-law-during-the-coronavirus-pandemic-134309.
[33] *Id*.
[34] *Legal Responses to Health Emergencies*, LIBRARY OF CONG. 39 (Feb. 2015), https://tile.loc.gov/storage-services/service/ll/llglrd/2014504236/2014504236.pdf.
[35] Swiffen, *supra* note 32.
[36] *Id*.
[37] *Id*.
[38] *Id*.
[39] *Id*.

surrounding the effectiveness of these laws given that the federal government may take action only after the effects of the pandemic have surpassed the provincial response capacities.[40]

A. Pandemic Influenza Preparedness (PIP)

1. History

The Pandemic Influenza Preparedness ("PIP") Framework is the sole international legal tool regarding equitable vaccine distribution.[41] The PIP Framework was adopted in 2011 to apply a global approach to influenza pandemics, and governs all 194 member states of the WHO.[42]

2. Objectives

The objectives of the PIP Framework are to "improve and strengthen the sharing of influenza viruses with human pandemic potential; and to increase the access of developing countries to vaccines and other pandemic related supplies."[43] Pursuant to this framework, the WHO seeks to organize influenza vaccine distribution to countries that have obtained vaccine contracts with manufacturers.[44] The vaccine rollout under PIP is typically affected by countries' respective health needs.[45] However, given the global impact of the COVID–19 pandemic, vaccine doses are in high demand in virtually every country worldwide.[46] Vaccines, as a result, have been distributed based on priority access rather than on a need basis.[47]

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[40] *Id*.
[41] Alexandra L. Phelan, Mark Eccleston–Turner, Michelle Rourke, Allan Maleche & Chenguang Wang, *Legal agreements: barriers and enablers to global equitable COVID–19 vaccine access*, THE LANCET (Sept. 7, 2020), https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31873-0/fulltext.
[42] *Pandemic Influenza Preparedness (PIP) Framework*, WHO, https://www.who.int/initiatives/pandemic-influenza-preparedness-framework (last visited Oct. 3, 2021) [hereinafter *PIP Framework*].
[43] *Id*.
[44] Phelan et al., *supra* note 41.
[45] *Id*.
[46] *Id*.
[47] Jennifer Tolbert, Jennifer Kates, & Josh Michaud, *The COVID–19 Vaccine Priority Line Continues to Change as States Make Further Updates*, KFF (Jan.

B. COVID–19 Law Lab

1. History

Due to the novel nature of the global COVID–19 pandemic, a perfect international legal framework has not yet been put in place.[48] But despite the fact that there is no universal legal instrument specific to COVID–19, the majority of countries worldwide are bound under the International Covenant on Economic, Social and Cultural Rights ("ICESCR").[49] Pursuant to this agreement, member nations must "take steps, individually and through international assistance, to realise the right to health and the right to enjoy the benefits of scientific research and its applications, without discrimination."[50] Taking steps to realize these rights would likely translate to ensuring equitable availability and access for member countries.[51] Although the PIP Framework is the sole legal precedent for international vaccine distribution, it has yet to apply to a pandemic of this magnitude.[52] To counter the effects of the COVID–19 pandemic, the United Nations Development Programme ("UNDP"), WHO, the Joint United Nations Programme on HIV/AIDS (UNAIDS), and the O'Neill Institute for National and Global Health at Georgetown University collaborated in July 2020 to develop the COVID–19 Law Lab.[53]

2. Objectives

The COVID–19 Law Lab is a collection of legal documents and resources from more than 190 countries worldwide compiled to aid countries in implementing legal frameworks to control the pandemic.[54] The COVID–19 Law Lab is based off of the work of the UHC Legal Solutions Network, an entity that was created to assist

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21, 2021), https://www.kff.org/policy-watch/the-covid-19-vaccine-priority-line-continues-to-change-as-states-make-further-updates/.

[48] Phelan et al., *supra* note 41.

[49] *Id*.

[50] *Id*.

[51] *Id*.

[52] *Id*.

[53] *About the Collaboration*, COVID–19 L. LAB, https://covidlawlab.org/about-the-collaboration/ (last visited Oct. 3, 2021).

[54] *Id*.

countries in "achiev[ing] universal health coverage through the implementation of rights–based legal frameworks."[55] The principal objective of this initiative is to provide a framework for countries to safeguard the health of residents, while adhering to international human rights standards.[56] The project also aims to help countries evaluate and improve upon their current legal and public health systems.[57] Following the launch of this initiative, countries now have access to an expansive database of legal frameworks and are in a position to reform legislation, particularly on the subject of vaccine development and approval.[58]

C. Advance Purchase Agreements (APAs)

1. History

Advance Purchase Agreements ("APAs") are "pre–purchases" of vaccines that have not yet been developed or approved for the general public.[59] Through this legal instrument, a country pledges to purchase a fixed amount or a percentage of future vaccine doses from a vaccine manufacturer, pending research and development, public health approval, licensing, manufacturing, and distribution.[60] The U.S. government entered into APAs with multiple pharmaceutical companies, including Pfizer and Novavax, among others.[61] The federal government typically does not execute APAs with pharmaceutical companies, as public insurers and the private sector typically purchase vaccine doses.[62] However, given the urgent need for

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[55] *New COVID–19 Law Lab to provide legal information and support for COVID-19 response*, SECURITY (July 28, 2020), https://www.securitymagazine.com/articles/92934-new-covid-19-law-lab-to-provide-legal-information-and support-for-covid-19-response.
[56] *Id*.
[57] *Id*.
[58] *Id*.
[59] Nicholson Price, Rachel Sachs, Jacob S. Sherkow & Lisa Larrimore Ouellette, *Covid–19 Vaccine Advance Purchases Explained*, HARVARD L. SCHOOL BILL OF HEALTH (Aug. 11, 2020), https://blog.petrieflom.law.harvard.edu/2020/08/11/covid19-vaccine-advance-purchases-explained/.
[60] Phelan et al., *supra* note 41.
[61] Price et al., *supra* note 59.
[62] *Id*.

COVID–19 vaccinations across the U.S., the federal government has assumed control of the allocation and distribution process.[63]

2. Objectives

APAs offer numerous benefits to both the participating country and the vaccine manufacturer.[64] By securing COVID–19 vaccine doses ahead of time, countries have helped mitigate the significant health and economic costs posed by the pandemic.[65] And although purchasing a vaccine that has not yet been developed was inherently risky, this practice accelerated each stage of the typical vaccine timeline, from production to distribution.[66] Some studies have shown that, even under a conservative analysis, the net benefit of investments in potential COVID–19 vaccines is substantial.[67] One study estimates that investing in one vaccine manufacturer to vaccinate 20% of a country's population would cost the investing country $2.6 billion, yet provide $8.7 billion in benefits.[68] The net gain of $6.1 billion is realized through avoiding significant health costs, such as medical care related to COVID–19 and economic costs—the investment has allowed countries to reopen the economy and allow industries to recover from the pandemic.[69] Applying the previous example on a larger scale, investing in three candidates to vaccinate 60% of the population would cost $19 billion, yet provide $35 billion in benefits, rendering a net gain of $16 billion.[70] Another

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[63] *Id*.
[64] Arthur Baker, Juan Camilo Castillo, Greg Larson, Alex Tabarrok & Brandon Tan, *3 reasons why countries should purchase COVID–19 vaccines at risk*, INTER–AM. DEV. BANK (Nov. 9, 2020), https://blogs.iadb.org/salud/en/countries-covid-19-vaccines/.
[65] Richard G. Frank, Leslie Dach, & Nicole Lurie*, It Was The Government That Produced COVID–19 Vaccine Success*, HEALTH AFFAIRS (May 14, 2021), https://www.healthaffairs.org/do/10.1377/hblog20210512.191448/full/.
[66] Baker et al., *supra* note 64.
[67] *Id*.
[68] *Id*.
[69] Joseph E. Gagnon, Steven Kamin, & John Kearns, *Economic costs and benefits of accelerated COVID–19 vaccinations*, PETERSON INST. FOR INT'L ECON. (May 2021), https://www.piie.com/publications/policy-briefs/economic-costs-and-benefits-accelerated-covid-19-vaccinations ("[A] faster pace of vaccination that hastens the end of the pandemic by 10 months would lead to an additional $970 billion in world GDP.").
[70] Baker et al., *supra* note 64.

benefit of APAs is that the urgency and competition inherent in the race to develop a novel COVID–19 vaccine oftentimes drives innovation and leads to a more efficient method of vaccine development for future crises.[71]

However, critics of APAs have argued that these legal tools only benefit developed countries with sufficient financial resources to secure COVID–19 vaccine doses, and only serve to act as a barrier for developing countries to obtain vaccines.[72] It is argued that the execution of APAs between developed countries and vaccine manufacturers may serve as an obstacle to global equitable access to vaccines.[73] Moreover, bilateral APAs, while beneficial for the countries involved, arguably widen existing inequities between developed and developing countries and continue to extend the timeline of the pandemic.[74]

III. LEGAL IMPLICATIONS OF VACCINE AGREEMENTS

A. Contracts Between the U.S. and U.S. Pharmaceutical Companies

To expedite the development and distribution of a COVID–19 vaccine, the U.S. government initiated Operation Warp Speed in May 2020.[75] The objective of this operation was to produce and distribute 300 million vaccine doses by January 2021.[76] The standard timeline for vaccine development, from research and development to distribution, is roughly six years.[77] However, by accelerating each component of the process, Operation Warp Speed aims to develop a vaccine in an unprecedented timeline of 14 months.[78] This accelerated approach involves the collaboration of multiple government agencies, including the HHS, the Centers for Disease Control and Prevention ("CDC"), the Food and Drug Administration ("FDA"), the National Institutes of Health ("NIH"), and the Department of

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[71] Price et al., *supra* note 59.
[72] Phelan et al., *supra* note 41.
[73] *Id*.
[74] *Id*.
[75] U.S. DEP'T OF HEALTH AND HUMAN SERVS, *supra* note 8.
[76] *Id*.
[77] *Id*.
[78] *Id*.

Defense ("DOD"), among others.[79] The federal government has thus far executed vaccine agreements with the following companies: Novavax, Johnson & Johnson, Moderna, and Pfizer.[80]

Under its agreement with the U.S., Novavax would secure roughly $1.7 billion in U.S. funding to develop a COVID–19 vaccine.[81] In return, the government, specifically the HHS and DOD, would receive the first 100 million doses produced by Novavax,[82] and U.S. residents would receive the vaccine at no cost.[83] One potential area of concern with this agreement was the fact that the agreement between the federal government and Novavax was brokered by a third party, Advanced Technology International.[84] Typically, these types of agreements are negotiated directly between the manufacturer and the federal government without an external party.[85] The government has expressed concerns surrounding the involvement of a third party in the agreement, particularly toward the potential exclusion of safeguards, including those that counter price–gouging.[86] However, to circumvent this provision, the government may technically opt to "march–in" and exercise its powers of eminent domain.[87] The Johnson & Johnson agreement is similar to Novavax's. The Johnson & Johnson contract with the U.S. was valued at just over $1 billion and provided that the U.S. would receive the first 100 million doses of its vaccine.[88] Like the Novavax

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[79] *See id.*
[80] *Id*.
[81] *Novavax COVID–19 Vaccine Granted Fast Track Designation by U.S. FDA*, NOVAVAX (Nov. 9, 2020), https://ir.novavax.com/2020-11-09-Novavax-COVID-19-Vaccine-Granted-Fast-Track-Designation-by-U-S-FDA.
[82] *HHS, DOD Collaborate with Novavax to Produce Millions of COVID-19 Investigational Vaccine Doses in Commercial–Scale Manufacturing Demonstration Projects*, U.S. DEP'T. DEF. (Jul. 7, 2020), https://www.defense.gov/Newsroom/Releases/Release/Article/2310955/hhs-dod-collaborate-with-novavax-to-produce-millions-of-covid-19-investigationa/.
[83] *Id*.
[84] Sydney Lupkin, Novavax Posts Coronavirus Vaccine Contract That Government Didn't Disclose, NPR (Nov. 11, 2020, 1:10 PM), https://www.npr.org/sections/health-shots/2020/11/11/933864908/novavax posts-coronavirus-vaccine-contract-that-government-didnt-disclose.
[85] *Id*.
[86] *Id*.
[87] *Id*.
[88] *Id*.

agreement, the Johnson & Johnson contract was brokered by a third party and omitted typical protections such as those safeguarding against price–gouging.[89]

The U.S.'s agreements with the remaining vaccine companies are also worth examining. U.S. government and Moderna reached an agreement where the U.S. would provide $1.5 billion to develop a vaccine.[90] In exchange, the government received the first 100 million vaccine doses, with an option to purchase an additional 400 million.[91] Unlike the government's previous agreements, the agreement with Moderna remains largely undisclosed to the public.[92] However, it does include a similar "march–in" clause for the government to assume control of the vaccine if Moderna does not make it "reasonably" available.[93] Moderna's agreement can be compared with Pfizer's—pursuant to its agreement with the U.S., Pfizer would receive $1.95 billion in funding to distribute a COVID–19 vaccine.[94] However, Pfizer is the sole company that refused to accept federal funding in the research and development stage, opting instead to receive funding for distribution purposes.[95] Pfizer reasoned that federal funding would have delayed the vaccine's path to clinical trials.[96] Unlike the other agreements, the agreement with Pfizer provided that the first 100 million doses would be produced before the end of 2020.[97] Once this occurred, the federal government was able to exercise the option to secure up to 500 million more doses.[98]

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[89] *Id*.
[90] *Id*.
[91] *Id*.
[92] *Id*.
[93] *Id*.
[94] Weiland et al., *supra* note 10.
[95] *Id*.
[96] *Id*.
[97] Ankur Banerjee & Vishwadha Chander, *Pfizer, U.S. strike 100 million COVID–19 vaccine deal with 70 million due by June*, REUTERS (Dec. 23, 2020, 7:10 AM), https://www.reuters.com/article/us-health-coronavirus-usa-pfizer-idUSKBN28X1GC ("[T]he company halved its 2020 production target due to manufacturing issues…").
[98] *Pfizer And BioNTech To Provide 500 Million Doses of COVID–19 Vaccine To U.S. Government For Donation To Poorest Nations*, PFIZER (June 10, 2021, 2:00 AM), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-500-million-doses-covid-19 ("Pfizer . . . and BioNTech . .

1. Accelerated Vaccine Development Timeline

Given the inherent urgency to create a vaccine at the height of a global pandemic, biotech companies fast–tracked and continue to fast–track the development timeline.[99] Typically, clinical development of vaccines occurs in three phases.[100] This process is sequential and contingent upon the results of the previous phases.[101] However, companies have consolidated significant steps in the vaccine development process by simultaneously performing different phases of clinical trials.[102] Since the development of the COVID–19 vaccine was grounded in novel technology that had not formed the basis for previous vaccines,[103] its accelerated timeline raised concerns over the effectiveness and safety of COVID–19 vaccines.[104]

2. Bayh–Dole Act of 1980

Moreover, the accelerated development of a COVID–19 vaccine continues to raise multiple legal concerns.[105] One such issue may arise if a company were to secure a patent so that it is the exclusive producer of the COVID–19 vaccine.[106] In this situation, the federal government could theoretically invoke the power of eminent domain to grant other manufacturers the right to produce the vaccine.[107] Pursuant to 28 U.S.C. § 1498, in cases where the federal government

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. announced plans to provide the U.S. government . . . 500 million doses of the companies' COVID–19 vaccine . . . .").

[99] Jonathan Gardner, Ned Pagliarulo, Shoshana Dubnow & Ben Fidler, *Coronavirus vaccines are rolling out quickly. Here's where the pipeline stands.*, BIOPHARMA DIVE, https://www.biopharmadive.com/news/coronavirus-vaccine-pipeline-types/579122/ (last updated Oct. 1, 2021).

[100] *Vaccine Testing and the Approval Process*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccines/basics/test-approve.html (last updated May 1, 2014).

[101] *See id*.

[102] Weintraub et al., *supra* note 6.

[103] *Id*.

[104] Brit Trogen, David Oshinsky, & Arthur Caplan, *Adverse Consequences of Rushing a SARS–CoV–2 Vaccine*, JAMA NETWORK (May 26, 2020), https://jamanetwork.com/journals/jama/fullarticle/2766651.

[105] Kevin J. Hickey & Erin H. Ward, *Legal Issues in COVID–19 Vaccine Development*, CONG. RSCH. SERV., https://crsreports.congress.gov/product/pdf/R/R46399 (last updated Nov. 25, 2020).

[106] *Id*.

[107] *Id*.

uses or manufactures a patent without the owner's license, "the owner's remedy shall be by action against the U.S. . . . for the recovery of his reasonable and entire compensation for such use and manufacture."[108] Congress passed the Bayh–Dole Act of 1980 for this specific purpose.[109] This act provides for patents on inventions to be exclusively licensed if they were supplemented by federal funding.[110] Because the majority of vaccine manufacturers have accepted federal aid in developing potential vaccines, they are accordingly subject to the federal government's eminent domain powers authorized by the Bayh–Dole Act.[111]

Specifically, the Act allows the government to "march–in" and grant licenses to other actors in particular circumstances.[112] According to 35 U.S.C. § 203, the government may exercise its march–in rights if it determines that "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees."[113] This approach is unlikely given the fact that the federal government has never exercised its march–in rights on a patent in the history of the Bayh–Dole Act.[114] Nevertheless, the emergence of an unprecedented global health crisis may cause the government to consider exercising this power.[115] The U.S. government would likely invoke this power if a pharmaceutical company failed to make the COVID–19 vaccine available "on reasonable terms."[116]

One example of failing to adhere to the clause "on reasonable terms" includes setting prohibitively high prices for products, which is not an atypical practice in the pharmaceutical industry. Normally, pharmaceutical companies offer their products at steep prices to

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[108] 28 U.S.C. § 1498 (2011).
[109] Michael Liu, William B. Feldman, Jerry Avorn & Aaron S. Kesselheim, *March–In Rights And Compulsory Licensing – Safety Nets For Access To A COVID–19 Vaccine*, HEALTH AFFAIRS (May 6, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200501.798711/full/.
[110] *Id*.
[111] *Id*.
[112] *Id*.
[113] 35 U.S.C. § 203(a)(2) (2002).
[114] John R. Thomas, *March–In Rights Under the Bayh–Dole Act*, CONG. RSCH. SERV. (Aug. 22, 2016), https://fas.org/sgp/crs/misc/R44597.pdf.
[115] *Id*.
[116] Liu et al., *supra* note 109.

recoup the significant investment in researching, developing, and manufacturing their product.[117] However, because the government provided billions in federal funding to U.S.–based companies working towards developing vaccine candidates as part of Operation Warp Speed, these companies were able to assume less financial risk throughout the process.[118] As such, concerns over profit margins were mitigated by the government's research grants.[119] From a domestic perspective, U.S. pharmaceutical companies do not offer the vaccinations to the consumer directly, as the government controls allocation.[120] Additionally, because the vaccine doses were funded and purchased by U.S. taxpayer dollars, vaccine providers offer vaccinations to U.S. residents free of charge.[121] The federal government, as a result, is less inclined to exercise its "march in" rights because the government controls the distribution process.[122]

B. Contracts Between Canada and U.S. Pharmaceutical Companies

The U.S. plays a fundamental role in vaccine development, as the U.S. market constitutes 60% of vaccine–related profits worldwide.[123] U.S. companies have previously made agreements with foreign countries to supply vaccine doses.[124] For instance, in 2019, the Canadian government executed an agreement with Seqirus, a U.S. vaccine company, as a secondary influenza vaccine supplier in the

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[117] *Id*.
[118] *Id*.
[119] *Id*.
[120] *COVID–19*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/no-cost.html (last updated May 24, 2021).
[121] *Id*.
[122] *Id*.
[123] Julie B. Milstien, Miloud Kaddar, & Marie P. Kieny, *The Impact of Globalization on Vaccine Development and Availability*, 25 HEALTH AFFAIRS 1061, 1063 (Jul. 2006) https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.25.4.1061.
[124] Charlie Pinkerton, *Contracts prepared feds to distribute H1N1 vaccine; $450 million in similar deals don't apply to COVID–19*, IPOLITICS (Apr. 20, 2020), https://ipolitics.ca/2020/04/20/contracts-prepared-feds-to-distribute-h1n1- vaccine-450-million-in-similar-deals-dont-apply-to-covid-19/.

case of a flu outbreak.[125] In a typical year, the Canadian government would notify one of its routine influenza vaccine suppliers and place an order depending on demand.[126] The primary difference between previous APAs and COVID–19 vaccine APAs is that Canada had contracts in place for previous flu outbreaks, whereas now the country has had to negotiate with multiple nations to secure APAs over the course of the pandemic.[127]

Canada's practice of executing APAs with several vaccine manufacturers in an attempt to secure future vaccine doses, with the total count at roughly five vaccines per Canadian, has raised the issue of "vaccine nationalism."[128] This trend of purchasing large batches of vaccines prior to their development has drawn criticism from lower and middle–income countries as coming into conflict with a more coordinated global strategy.[129] However, the issue of vaccine nationalism raised by APAs for future vaccine doses is not new.[130] Often, vaccines developed by U.S. companies and other companies based in developed nations are too costly for developing countries to afford.[131] This trend is due in part to the expensive and time–consuming process of vaccine development.[132] For example, the research, development, and distribution of a novel vaccine may

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[125] *Id*.
[126] *Id*.
[127] *Id*.
[128] Ana Santos Rutschman, *The Reemergence of Vaccine Nationalism*, GEO. J. OF INT'L AFFS. (Jul. 3, 2020), https://gjia.georgetown.edu/2020/07/03/the-reemergence-of-vaccine-nationalism/.
[129] *Id*.
[130] Rebecca Weintraub, Asaf Bitton, & Mark L. Rosenberg, *The Danger of Vaccine Nationalism*, HARV. BUS. REV. (May 22, 2020), https://hbr.org/2020/05/the-danger-of-vaccine-nationalism; Debbie Andalo, *Cost of vaccines becoming unaffordable in developing countries, charity warns*, THE PHARM. J. (Jan. 21, 2015), https://www.pharmaceutical-journal.com/news-and-analysis/cost-of-vaccines-becoming-unaffordable-in- developing-countries-charity-warns/20067637.article?firstPass=false ("[T]he cost of vaccines recommended by the [WHO] has gone up 68–fold . . . . many [developing countries] are facing tough choices about which deadly diseases they can afford to protect their children against.").
[131] Milstien et al., *supra* note 123.
[132] *Id*.

require over ten years of commitment and hundreds of millions of dollars.[133]

The Canadian government and multiple U.S. pharmaceutical companies executed agreements for future COVID–19 vaccine doses.[134] The Canadian government, advised by the Public Services and Procurement Canada ("PSPC"), the Public Health Agency of Canada ("PHAC"), Health Canada and Innovation, and Science and Economic Development Canada, has since invested more than $9 billion in securing APAs with various vaccine manufacturers.[135]

More specifically, Canada executed contracts with the following companies: Novavax for 76 million doses, Johnson & Johnson for 38 million doses, Moderna for 56 million doses, and Pfizer for a minimum of 20 million doses.[136] These agreements, which were contingent upon successful completion of clinical trials and a license from Health Canada, provided for the delivery of doses in early 2021.[137]

Canada and Novavax reached an agreement whereby Canada would receive 76 million doses of Novavax's potential COVID–19 vaccine pending approval from Health Canada, the agency responsible for federal health policy.[138] Although the financial terms of the agreement have yet to be disclosed, the Canadian government is likely paying a substantial premium relative to that of the U.S. government.[139] Canada will likely have to pay a higher price due to its hands–off approach in the research and development, manufacturing, and distribution phases, relative to that of the U.S.[140] Nonetheless, the Canadian government executed a similar agreement with

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[133] *Id*.
[134] Wency Leung & Kelly Grant, *Ottawa signs COVID–19 vaccine deals with two U.S. companies*, GLOB. & MAIL (Aug. 31, 2020), https://www.theglobeandmail.com/canada/article-ottawa-signs-covid-19-vaccine-deals- with-two-us-companies/.
[135] *Procuring vaccines for COVID–19*, *supra* note 16.
[136] *Id*.
[137] Will Feuer, *Canada to purchase 76 million doses of Novavax coronavirus vaccine, company says*, CNBC (Aug. 31, 2020, 9:55 AM), https://www.cnbc.com/2020/08/31/canada-to-purchase-76-million-doses-of-novavax-coronavirus-vaccine-company-says.html.
[138] *Id*.
[139] *Id*.
[140] *Id*.

another U.S.–based pharmaceutical company, Johnson & Johnson, for 38 million doses of a future COVID–19 vaccine.[141] Neither party has disclosed the financial terms of the agreement in principle, which was contingent upon the vaccine candidate's safety and efficacy and subject to Health Canada's approval.[142] Nor have the financial terms of Canada's agreement with Moderna for 56 million doses been disclosed.[143]

Lastly, Pfizer and the Canadian government reached an agreement in principle for 20 million doses of Pfizer's vaccine candidate, with the option in January 2021 to purchase 20 million additional doses.[144] The distribution of the vaccine is subject to regulatory approval and was realized in December 2020.[145] Nevertheless, the Canadian government has been outspoken in its criticism towards Pfizer's vaccine distribution process.[146] According to the Ontario Premier Doug Ford, Pfizer has delayed its vaccine deliveries to Canada to increase production in its Belgian plant, which provides vaccine deliveries outside the U.S.[147]

The delay in vaccine distribution not only affects the amount of people who can receive vaccinations, but also the precise period of time in which high–risk candidates are expecting to receive both

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[141] *Johnson & Johnson Announces Agreement in Principle with Government of Canada to Supply its COVID–19 Vaccine Candidate*, JOHNSON & JOHNSON (Aug. 31, 2020), https://www.jnj.com/johnson-johnson-announces-agreement-in-principle-with-government-of-canada-to-supply-its-covid19-vaccine-candidate.

[142] *Id*.

[143] *Canada Exercises Increased Option for 20 Million Doses of mRNA Vaccine Against COVID–19 (mRNA–1273)*, MODERNA (Sept. 22, 2020, 12:22 PM), https://investors.modernatx.com/news-releases/news-release-details/canada-exercises-increased-option-20-million-doses-mrna-vaccine.

[144] *Canada orders 20 million more doses of Pfizer/BioNTech COVID–19 vaccine: PM*, REUTERS (Jan. 12, 2021, 11:31 AM), https://www.reuters.com/article/us-health-coronavirus-canada-pfizer/canada-orders-20-million-more-doses-of-pfizer-biontech-covid-19-vaccine-pm-idUSKBN29H2AT.

[145] Ian Austen, *Canada Approves Vaccine and Could Start Shots Next Week*, N.Y. TIMES, https://www.nytimes.com/2020/12/09/world/americas/canada-vaccine-approve.html (last updated Jan. 7, 2021).

[146] Rob Gillies, *Ontario leader blames Pfizer for COVID–19 vaccine delays*, AP NEWS (Jan. 22, 2021), https://apnews.com/article/toronto-ontario-coronavirus-pandemic-coronavirus-vaccine-canada-9cee79ec89d8981e087f1fb5b2244b13

[147] *Id*.

doses.[148] The U.S. government's agreement with Pfizer stipulates that all vaccines produced in the Michigan facility are to be distributed in the U.S.[149] Pursuant to the Canadian government's contract with Pfizer, Canada's doses are to be delivered from Pfizer's factory in Belgium.[150] Canada has reached out to the U.S. government in an attempt to secure doses from the Pfizer facility in Michigan, although Pfizer is not permitted to provide Canada with vaccines from the U.S. facility.[151] Canada eventually received vaccine doses from Pfizer pursuant to the vaccine contract.[152]

IV. POTENTIAL ETHICAL ISSUES RAISED BY VACCINE AGREEMENTS

A. Vaccine Nationalism

Throughout all global pandemics, wealthier nations have traditionally negotiated contracts with vaccine manufacturers to secure doses for their citizens.[153] In 2009, at the height of the Swine Flu pandemic, wealthy countries entered into APAs with vaccine manufacturers to secure doses of the newly–developed vaccine.[154] As a result, developed countries, including the U.S., were able to reserve bulk orders of vaccine doses through APAs while poorer countries had fewer opportunities to do so.[155] The use of bilateral APAs was so prevalent during the H1N1 pandemic "that more than 56% of pandemic influenza manufacturers surveyed by WHO were unable to commit to guaranteeing 10% of real–time vaccine production for purchase by UN agencies due to pre–existing commitments under APAs with HICs [high–income countries]."[156] This trend led to an

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[148] *Id*.
[149] *Id*.
[150] *Id*.
[151] *Id*.
[152] *Vaccines for COVID–19: Canada's vaccine supply*, GOV'T OF CAN., https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/prevention-risks/covid-19-vaccine-treatment/vaccine-rollout.html (last updated Nov. 4, 2021)[hereinafter Canada's Vaccine Supply].
[153] Rutschman, *supra* note 128.
[154] Weintraub et al., *supra* note 130.
[155] *Id*.
[156] Phelan et al., *supra* note 41.

inequitable distribution of swine flu vaccines among developed and developing countries, rooted primarily in purchasing power as opposed to public health risk and need.[157]

Moreover, Canada has implemented a process of securing contracts with vaccine manufacturers while demand is low in order to ensure that the country has access to vaccines in the event of a public health emergency.[158] During the H1N1 pandemic, Canada's public health response proved to be effective: the PHAC noted that "Canada's preparedness allowed it to have one of the highest H1N1 immunization rates in the world."[159] Following the H1N1 pandemic, the PHAC published a report on which actions helped Canada to counter the health emergency.[160] Of the four key activities listed, two were based on the existence of vaccine contracts: "[m]anaging a contract with a domestic manufacturer to develop a vaccine" and "arranging a contract with Public Works and Government Services Canada (now Public Services and Procurement Canada) for the purchase of sufficient vaccines for Canadians on behalf of the provinces and territories."[161] This strategy, however, is only beneficial during an influenza pandemic, as vaccine manufacturers that have negotiated with Canada are solely required to supply influenza vaccines.[162] Specifically, these agreements are restricted to influenza vaccines, so the Canadian government would have to renegotiate the terms of the agreements to include COVID–19 vaccines.[163] These types of agreements with vaccine manufacturers do not anticipate a non–influenza pandemic, and thus left Canada searching for new vaccine contracts with other manufacturers amidst a public health emergency.[164] Given Canada's lack of production and supply chain capacity, the country was forced to enter into agreements with other nations to ensure its residents receive vaccinations.[165]

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[157] Weintraub et al., *supra* note 130.
[158] Pinkerton, *supra* note 124.
[159] *Id*.
[160] *Id*.
[161] *Id*.
[162] *Id*.
[163] *Id*.
[164] *Id*.
[165] Canada's Vaccine Supply, *supra* note 152.

1. Disparity Between Wealthy and Non–Wealthy Nations

The People's Vaccine Alliance released a report in December of 2020 which pointed to the fact that wealthy nations making up 14% of the world's population had already pre–purchased over 50% of potential COVID–19 vaccines worldwide.[166] Similar reports have estimated that Canada has been pre–purchasing vaccines in excess, with as many as five vaccines per person.[167] On the other hand, in low and middle–income countries, including Brazil and Indonesia, the ratio of pre–purchased vaccines to people is roughly one vaccine to every fourth person.[168] The U.S., for example, has set aside 800 million doses despite only having a population of roughly 330 million people.[169] Similarly, Japan, Australia, and Canada pre–purchased a combined one billion vaccine doses even though these three nations make up less than 1% of current COVID–19 cases globally.[170] These trends demonstrate that vaccines are being over–purchased with respect to total population and COVID–19 case count.[171] To illustrate the disparity between developing and developed nations, high and middle–income countries have received more than 80% of doses worldwide, while only 1% of people in low–income countries have received at least on dose.[172] The practice of bidding for bilateral agreements artificially has raised the purchase price for vaccine doses, which in turn has negatively impacted non–wealthy countries that do not have comparable financial resources.[173]

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[166] William A. Haseltine, *Billions in Low–Income Nations Will Not Receive Their Covid–19 Vaccine Anytime Soon*, FORBES (Jan. 21, 2021), https://www.forbes.com/sites/williamhaseltine/2021/01/21/billions-in-low-income-nations-will-not-receive-their-vaccine-anytime-soon/?sh=49a89f706208.
[167] *Id*.
[168] Ed Silverman, *One–quarter of the world may not get a Covid–19 vaccine until 2022, experts warn*, STAT (Dec. 15, 2020), https://www.statnews.com/pharmalot/2020/12/15/covid19-coronavirus-vaccine-covaxi-who/.
[169] *Id*.
[170] *Id*.
[171] *Id*.
[172] T.V. Padma, *COVID vaccines to reach poorest countries in 2023–despite recent pledges*, Nature, https://www.nature.com/articles/d41586-021-01762-w (last updated Jul. 9, 2021).
[173]Marco Hafner, Erez Yerushalmi, Clement Fays, Eliane Dufresne & Christian van Stolk, *COVID–19 and the cost of vaccine nationalism*, RAND EUROPE 1, 22

2. Inequitable Distribution and Opportunity

The vaccine nationalism approach of U.S. manufacturers entering into APAs with wealthy countries has, and will likely continue to, lead to an inefficient distribution of vaccine doses, providing more opportunity for lower–risk individuals in wealthier countries as opposed to higher–risk individuals in developing countries.[174] Developing nations have not possessed the requisite infrastructure and technology found in more developed nations to carry out the entire vaccine cycle, from manufacturing to distribution.[175] In contrast to developing nations, high–income countries have increased access to vaccine doses because of the sophisticated infrastructure needed to distribute and preserve them.[176] For example, many vaccines must be shipped in climate–controlled containers and stored in cold temperatures.[177] But low and middle–income countries, even those that are able to secure vaccine doses independently or with assistance, do not have the infrastructure to meet these requirements to ensure the vaccine doses remain effective.[178] Without a concerted approach among countries, there is a higher likelihood that vaccine supply chains will stall and not reach their maximum potential.[179] To date, vaccine manufacturing capacities remain below the level needed to meet demand, with only several nations being able to produce vaccines.[180]

(2020), https://www.rand.org/content/dam/rand/pubs/research_reports/RRA700/RRA769-1/RAND_RRA769-1.pdf.

[174] Padma, *supra* note 172.

[175] Abu Baker Sheikh, Suman Pal, Nismat Javed, & Rahul Shekhar, *COVID–19 Vaccination in Developing Nations: Challenges and Opportunities for Innovation*, MDPI, https://www.mdpi.com/2036-7449/13/2/41/pdf (published May 14, 2021).

[176] Silverman, *supra* note 168.

[177] *Id*.

[178] *Coronavirus (COVID–19) vaccines for developing countries: An equal shot at recovery*, OECD, https://www.oecd.org/coronavirus/policy-responses/coronavirus-covid-19-vaccines-for-developing-countries-an-equal-shot-at-recovery-6b0771e6/ (Feb. 4, 2021).

[179] Hafner, *supra* note 173, at 6.

[180] Claire Felter, *A Guide to Global COVID–19 Vaccine Efforts*, COUNCIL ON FOREIGN RELATIONS, https://www.cfr.org/backgrounder/guide-global-covid-19-vaccine-efforts (updated Oct. 11, 2021, 1:45 PM).

B. Manufacturers' Limited Liability Under the Public Readiness and Emergency Preparedness (PREP) Act

1. Background

Other ethical concerns arise throughout the process of vaccine development.[181] In an effort to expedite the development of a vaccine, the HHS will likely limit liability for manufacturers under the PREP Act.[182] The PREP Act was passed in 2005, as Public Law 109–148, Division C, Section 2, under the Bush administration to manage public health emergencies by safeguarding vaccine manufacturers from incurring most forms of liability, thereby incentivizing manufacturers to produce a vaccine as quickly as possible.[183] In order to invoke the PREP Act, the Secretary of HHS "must determine that a disease or other threat to health constitutes a public health emergency, or that there is a credible risk of such an emergency."[184] The Secretary is required to publish the PREP Act declaration in the Federal Register and "identify, for each countermeasure, the particular disease, time period, population, and geographical area that the declaration covers." As long as the COVID–19 PREP Act Declaration is in effect, vaccine manufacturers, distributors, and health care providers are mostly immune from legal liability for losses stemming from the vaccine.[185]

2. Purpose

The PREP Act was passed to widen the scope of immunity from liability for covered persons.[186] Pursuant to this Act, "covered persons—including COVID–19 vaccine developers, manufacturers, [and] distributors . . . are generally immune from legal liability for losses relating to administration or use of an FDA–approved COVID–19 vaccine."[187] If a covered person falls within the scope of immunity, the PREP Act immunizes a covered person from legal

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[181] Hickey & Ward, *supra* note 105, at 7.
[182] *Id* at 35.
[183] *Id* at 2.
[184] *Id* at 36.
[185] *Id*.
[186] *Id* at 35.
[187] Hickey & Ward, *supra* note 105, at 7.

liability for all claims for loss relating to the administration.[188] The requirements for PREP act immunity are as follows: "(1) the individual or entity must be a 'covered person,' (2) the legal claim must be for a 'loss,' (3) the loss must have a 'causal relationship' to the administration or use of a covered countermeasure, and (4) the medical product that caused the loss must be a 'covered countermeasure.'"[189]

However, individuals may seek recourse for damages sustained as a result of willful misconduct leading to death or serious injury.[190] Under these circumstances, an individual may pursue damages through the Countermeasures Injury Compensation Program ("CICP"), a mechanism overseen by the HHS.[191] The CICP provides an exception to the liability immunity for covered persons: "[a]n individual seriously injured or killed by the administration of a covered countermeasure, whether or not as a result of willful misconduct, may seek compensation through CICP."[192] This program is funded by Congress via emergency appropriations to the Covered Countermeasure Process Fund.[193] Although the CICP offers remedies for individuals who suffer damages as a result of a COVID–19 vaccine, the program is independent of the National Vaccine Injury Compensation Program ("VICP").[194] The VICP provides remedies for injuries caused by routine vaccines in the U.S., while the CICP exclusively applies to vaccines covered by a PREP Act declaration of a public health emergency, such as the COVID–19 pandemic, influenza pandemic, and the Ebola virus.[195]

Canada, on the other hand, has yet to declare a federal act related to the COVID–19 pandemic.[196] Similar to the federalism framework in the U.S., each province in Canada retains power independent

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[188] *Id* at 36.
[189] *Id*.
[190] *Id* at 38.
[191] *Id* at 39.
[192] *Id* at 40.
[193] Hickey & Ward, *supra* note 105, at 7.
[194] *Id*.
[195] *Id*.
[196] Swiffen, *supra* note 32.

from that of the federal government.[197] As such, the federal government of Canada would be required to collaborate with the individual provinces in crafting an emergency response to the effects of the pandemic, pursuant to the 2007 Emergency Management Act.[198] However, if the federal government declared a national emergency, it could theoretically implement an emergency response for the entire nation without having to coordinate with the provinces.[199] This piece of legislation, The Emergencies Act of 1985, grants the federal government unilateral power to implement a public health strategy, acting as a last resort in a public health crisis.[200] However, Canada has never declared a national public health emergency in its history.[201] As a result, the federal emergency declarations have never been tested and the efficacy of both acts remains unknown.[202]

Moreover, the Canadian government does not have an urgent need to implement emergency acts limiting legal liability for vaccine manufacturers, vaccine developers, and others involved in the administration of a potential vaccine due to the lack of domestic vaccine development, production, and distribution.[203] The Canadian government has primarily been entering into APAs with foreign vaccine manufacturers as opposed to funding the vaccine development process domestically.[204] While numerous countries around the world raced to develop the first successful COVID–19 vaccine, Canada was unable to compete in vaccine production—an issue dating

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[197] *Federalism in Canada*, GOV'T OF CAN., https://www.canada.ca/en/intergovernmental-affairs/services/federation/federalism-canada.html (last updated Oct. 5, 2021).
[198] Swiffen, *supra* note 32.
[199] *Id*.
[200] *Id*.
[201] *Id*.
[202] Swiffen, *supra* note 32; Trevor Lawson, Lara Nathans, Adam Goldenberg, Marco Fimiani, & David Boire–Schwab, *COVID–19: Emergency Measures Tracker*, McCarthy Tetrault, https://www.mccarthy.ca/en/insights/articles/covid-19-emergency-measures-tracker (Nov. 10, 2021) (Although the Canadian government has yet to declare a national emergency, each Canadian jurisdiction has implemented emergency measures in response to COVID–19).
[203] Jonathan Forani, *'We took our eye off the ball': How Canada lost its vaccine production capacity*, CTV NEWS (Nov. 25, 2020, 12:30 PM), https://www.ctvnews.ca/health/coronavirus/we-took-our-eye-off-the-ball-how-canada-lost-its-vaccine-production-capacity-1.5204040.
[204] *Id*.

back decades.[205] The Prime Minister of Canada, Justin Trudeau, explained that the nation does not possess sufficient supply chain capability to mass produce a COVID–19 vaccine, even if one could have been produced domestically.[206] According to Earl Brown, an infectious disease expert and former member of the swine flu vaccine task group in Canada, "[w]e had great vaccine producers in Canada– world leaders essentially– 50 years ago."[207] Canadian manufacturers, including Connaught Laboratories in Toronto and Institut Armand Frappier in Montreal, were known producers of insulin, inoculants, and vaccines.[208] However, these companies were unable to generate enough profit to remain competitive and were eventually absorbed by or sold to foreign companies.[209]

Although some Canadian companies, such as Medicago in Quebec and VIDO–InterVac in Saskatchewan, have been progressing towards developing a successful vaccine candidate, these companies would be unable to mass produce vaccines at a level to supply all Canadians.[210] Looking to the future, Canadian pharmaceutical companies intend to develop supply chains that would produce vaccines regularly to anticipate future public health emergencies.[211] One company, VIDO–InterVac, plans to construct a facility to manufacture vaccines, but the process will take time.[212] For the foreseeable future, Canada will be forced to rely on foreign vaccine manufacturers to obtain vaccine doses.[213] Canada has received vaccines from U.S. manufacturers, specifically Johnson & Johnson, Moderna, and Pfizer, over the course of 2021.[214] As of October 2021, nearly 75% of the population is fully vaccinated.[215]

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[205] *Id*.
[206] *Id*.
[207] *Id*.
[208] *Id*.
[209] Forani, *supra* note 203.
[210] *Id*.
[211] *Id*.
[212] *Id*.
[213] *Id*.
[214] *Vaccines for COVID–19,* GOV'T OF CAN., https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19/vaccines.html (last updated Oct. 30, 2021).
[215] *Id*.

V. GLOBAL PANDEMIC RESPONSE

A. Effect of Bilateral APAs

Many wealthy nations began entering into bilateral APAs with manufacturers as the pandemic grew worse.[216] Countries with significant financial resources had the opportunity to secure vaccine doses before the vaccines were even developed.[217] While bilateral agreements may be beneficial in the short term, they fail to address the larger issue of global herd immunity.[218] Even if the nation that executed the bilateral APA were to achieve herd immunity domestically, the rest of the world would lag behind, potentially posing lasting public health problems.[219] This process may have a significant negative impact on affected countries' relations moving forward.[220]

However, bilateral APAs yield significant advantages.[221] The inherent competition among vaccine manufacturers to produce the first successful COVID–19 vaccine has driven innovation and has likely altered the vaccine development process for the better moving forward.[222] Typically, the timeline for vaccine development, ranging from research through distribution, is nearly six years.[223] Given the urgency and increased demand for a vaccine, pharmaceutical companies have sought to complete development within a fraction of that time.[224] This unprecedented and accelerated method may provide the blueprint to produce a safe and effective vaccine in future public health emergencies.[225] Proponents of APAs argue that the far–reaching benefits of producing a successful

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[216] Price et al., *supra* note 59.
[217] Phelan et al., *supra* note 41.
[218] *Id*.
[219] *Id*.
[220] *Id*.
[221] Price et al., *supra* note 59.
[222] *Id*.
[223] *Vaccine Research & Development: How Can Covid–19 Vaccine Development Be Done Quickly And Safely?*, JOHNS HOPKINS UNIV. & MED., https://coronavirus.jhu.edu/vaccines/timeline (last visited Sept. 16, 2020).
[224] *Emergency Use Authorization for Vaccines Explained,* U.S. FOOD & DRUG ADMIN. (Nov. 20, 2020), https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained.
[225] *Id*.

vaccine outweigh the costs of funding multiple pharmaceutical companies and the risk of several vaccine candidates failing.[226]

1. Impact on Global Pandemic

Without a continued collaborative approach, the timeframe of the COVID–19 pandemic will continue to extend, leading to higher economic costs and public health concerns.[227] We now know that the lack of access to a COVID–19 vaccine worldwide hindered the global economy, particularly high–contact industries including tourism, health care, and retail.[228] One study shows the effect on global GDP in the absence of worldwide access to effective vaccines that would permit high–contact sectors to return to normal levels of activity.[229] This report indicated that roughly $3.4 trillion in global GDP may be lost per year, even when operating under the assumption that countries will not revert back to home confinement and lockdown measures.[230] Although bilateral agreements may improve a nation's public health and economic outlook, they have minimal impact on the duration of a global pandemic.[231] In order to return to a sense of normalcy, 'herd immunity' will need to be realized.[232] This phenomenon refers to "the indirect protection from an infectious disease that happens when a population is immune either through vaccination or immunity developed through previous infection." However, according to the WHO, herd immunity should only be achieved through vaccination due to the potential negative health

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[226] *Id*.
[227] *Id*.
[228] *Vaccine inequity undermining global economic recovery*, WHO, https://www.who.int/news/item/22-07-2021-vaccine-inequity-undermining-global-economic-recovery (Jul. 22, 2021).
[229] JOHNS HOPKINS UNIV. & MED., *supra* note 223.
[230] JOHNS HOPKINS UNIV. & MED., *supra* note 223; M. Szmigiera, *Impact of the coronavirus pandemic on the global economy – Statistics & Facts*, Statista, https://www.statista.com/topics/6139/covid-19-impact-on-the-global-economy/#topicHeader__wrapper (Sept. 15, 2021) ("While there is no way to tell exactly what the economic damage from the global COVID–19 coronavirus pandemic will be . . . . most major economies will lose at least 2.9 percent of their [GDP].").
[231] *Coronavirus disease (COVID–19): Herd immunity, lockdowns and COVID–19*, WHO (Dec. 31, 2020), https://www.who.int/news-room/q-a-detail/herd-immunity-lockdowns-and-covid-19.
[232] *Id*.

effects of infection.[233] The most effective way to vaccinate a significant proportion of the world's population, as we have seen, is through a concerted, global effort to provide equitable vaccine access.[234]

B. Potential Alternatives

Global health entities can nonetheless continue to execute APAs to obtain vaccine doses for developing countries and other countries that do not have equitable access to newly–developed vaccines.[235] This process can occur through an Advanced Market Commitment ("AMC") model, where donors pledge to fund the purchase of a potential vaccine intended for developing countries that are unable to front the cost.[236] For example, in 2007, five countries along with the Bill and Melinda Gates Foundation pledged $1.5 billion to create the first AMC.[237] Through this initiative, the AMC was able to secure pneumococcal vaccines for low and middle–income nations in need.[238] In June 2021, multiple countries pledged roughly $2.4 billion in vaccine doses at an AMC.[239]

1. Advanced Market Commitment Models (AMCs)

i. Gavi: The Vaccine Alliance

Other models have proven to be effective in committing funds to obtain vaccine doses for developing countries, including the International Finance Facility for Immunisation ("IFFlm").[240] This

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[233] *Id*.
[234] *Global leaders commit further support for global equitable access to COVID–19 vaccines and COVAX*, WHO, https://www.who.int/news/item/23-09-2021-global-leaders-commit-further-support-for-global-equitable-access-to-covid-19-vaccines-and-covax (Sept. 23, 2021) ("Global leaders . . . have again underlined their commitment to ensuring equitable access to COVID–19 vaccines for all countries through COVAX – noting that equitable access is essential to end the acute stage of the pandemic.").
[235] Phelan et al., *supra* note 41.
[236] *Id*.
[237] Weintraub et al., *supra* note 130.
[238] *Id*.
[239] Jenny Lei Ravelo, *Gavi COVAX AMC Summit raises $2.4B, sees new vaccine dose pledges*, DEVEX (Jun. 2, 2021)., https://www.devex.com/news/gavi-covax-amc-summit-raises-2-4b-sees-new-vaccine-dose-pledges-100057.
[240] Weintraub et al., *supra* note 130.

organization raises funds for vaccines through the use of bonds and is part of The Vaccine Alliance ("Gavi"),[241] Gavi has partnered with other organizations including the WHO, UNICEF, the World Bank, and the Bill and Melinda Gates Foundation, with the goal of increasing equitable access to vaccines worldwide.[242] Gavi was founded in 2000 and serves as a conduit between vaccine manufacturers and developing countries that otherwise would not be able to afford high–priced vaccines.[243] Through this model, Gavi has been able to vaccinate nearly half of the children worldwide.[244] Gavi's proven track record in obtaining vaccines for low and middle–income countries has provided the alliance significant bargaining power when dealing with vaccine manufacturers.[245] For example, in the U.S., the estimated overall cost to vaccinate a child with the eleven WHO–recommended vaccines is $1,100 per child.[246] However, in countries supported by Gavi, the total cost of providing the same vaccines is $28.[247]

ii. COVAX

COVAX is one of the three components of the Access to COVID–19 Tools (ACT) Accelerator, which was launched in April of 2020 by the WHO, the European Commission, and France to counter the COVID–19 pandemic.[248] COVAX links governments, global health organizations, vaccine manufacturers, scientists, the private sector, civil society, and philanthropists with the ultimate goal of ensuring equitable access to COVID–19 vaccines, diagnostics, and treatments.[249] Additionally, COVAX is coordinated by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations ("CEPI"), and the WHO, and intends to reach its objectives by backing the research, development, and

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[241] *Id*.
[242] *About our Alliance*, GAVI, https://www.gavi.org/our-alliance/about (last updated Oct. 13, 2021) [hereinafter *About our Alliance*].
[243] *Id*.
[244] *Id*.
[245] *Id*.
[246] *Id*.
[247] *Id*.
[248] Seth Berkley, *COVAX explained*, GAVI (Sept. 3, 2020), https://www.gavi.org/vaccineswork/covax-explained.
[249] *Id*.

manufacturing of vaccine candidates and negotiating purchase prices.[250] Without this "lifeline," many lower and middle–income countries that are unable to execute APAs and independently purchase vaccine doses would be plagued by this virus indefinitely.[251] This solution offers all participating nations—regardless of wealth––a unique symbiotic relationship: "it . . . provide[s] direct protection by increasing their chances of securing vaccine doses . . . . [y]et, at the same time by procuring COVID–19 vaccines through COVAX, these nations will also indirectly protect their citizens by reducing the chances of resurgence by ensuring that the rest of the world gets access to doses too."[252]

The objective of this initiative is to have two billion vaccine doses accessible by the end of 2021, primarily for frontline healthcare workers and high–risk populations.[253] By creating a global, collaborative vaccine network, low and middle–income countries, who would not have been able to front the cost for APAs, can now obtain vaccine doses for their residents.[254] As part of the initiative, the first deliveries of vaccine doses are expected to go to lower–income nations who are unable to execute APAs with vaccine manufacturers.[255] Moreover, even countries that have APAs in place would still benefit from COVAX in the event that they are unable to secure enough doses from the manufacturers.[256] As such, both developed and developing countries have an incentive to join the collaboration and help coordinate a global pandemic response.[257]

Another aspect of COVAX is the Gavi COVAX AMC, which was launched to ensure that the ninety two lower and middle–income countries lacking the financial resources to independently

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[250] *Id*.
[251] Berkley, *supra* note 248; *Lower–income countries and indigenous populations receive WHO assistance amid the ongoing threat of COVID–19*, WHO, https://www.who.int/news-room/feature-stories/detail/lower-income-countries-and-indigenous-populations-receive-who-assistance-amid-the-ongoing-threat-of-covid-19 (Aug. 20, 2021) (The United States recently donated three million doses to the Philippines as it prepares for another lockdown.).
[252] Berkley, *supra* note 248.
[253] *Id*.
[254] *About our Alliance*, *supra* note 242.
[255] *Id*.
[256] *Id.*
[257] *Id*.

afford COVID–19 vaccines would be able to gain the same access to vaccines as higher–income countries.[258] Although lower and middle–income countries can participate in the general COVAX program, COVAX AMC is an independent branch which keeps the funds raised by self–financing participants separate from funds raised through Official Development Assistance ("ODA"), philanthropy, and the private sector.[259]

However, numerous criticisms have been raised about COVAX and its methods.[260] Critics point to COVAX's practice of negotiating prices for lower and middle–income countries that bake–in profits as opposed to providing the vaccines at cost.[261] Further, COVAX has been criticized for not divulging the specific terms of agreements executed with vaccine manufacturers, along with not reconciling intellectual property issues related to the newly–developed vaccines.[262] Certain nations in the European Union claimed that APAs are more efficient and cost–effective than the COVAX method, and opted out of utilizing the COVAX facility to purchase vaccine doses.[263] Nevertheless, in the summer of 2020, the European Union pledged 400 million dollars to COVAX to collaborate in the future and secure vaccines for lower and middle–income countries.[264]

Despite attempts to withdraw from the WHO in July 2020, the U.S. recently reaffirmed its commitment to remaining in the organization.[265] As part of the announcement to continue as a member of the WHO, President Biden's chief medical adviser, Anthony Fauci, also confirmed that the U.S. will join the COVAX initiative to

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[258] *Id*.
[259] *Id*.
[260] Phelan et al., *supra* note 41.
[261] *Id*.
[262] *Id*.
[263] *Id*.
[264] *Id*.
[265] Stephanie Nebehay, *U.S., staying in WHO, to join COVID vaccine push for poor nations: Fauci*, REUTERS (Jan. 21, 2021), https://www.reuters.com/article/us-health-coronavirus-who-usa-idUSKBN29Q12B; *Covax: How many Covid vaccines have the US and other G7 countries pledged?*, BBC, https://www.bbc.com/news/world-55795297 (Sep. 23, 2021) ("The US joined Covax . . . in January 2021.").

facilitate the delivery of vaccine doses to lower–income countries.[266] In echoing the support of a coordinated, global response to the pandemic, Britain's ambassador to the UN, Julian Braithwaite, "welcome[d] the decision by the U.S. to join the COVAX facility, because vaccinating our own populations is not enough scientifically or morally."[267]

Canada, which has secured a stockpile of potential vaccine doses through its multiple APAs, recently committed 75 million Canadian dollars in funding for the delivery of COVID–19 vaccines to lower–income nations.[268] Moreover, Canada announced an additional investment of five million Canadian dollars towards the equitable reallocation of COVID–19 vaccines that are processed through the COVAX facility.[269]

VI. CONCLUSION

In order to effectively counter the impact of a worldwide pandemic, countries should continue their global response.[270] The COVID–19 Law Lab, which collects and makes available legal documents and frameworks from over 190 countries worldwide, is a promising start.[271] The objective of this initiative is to provide access to any country seeking to improve its existing legal framework in order to keep the pandemic under control.[272] As part of this collaboration, countries can mimic aspects from other countries' public health strategies and implement effective laws to "help build strong health systems; evaluate and approve safe and effective drugs and

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[266] Nebehay, *supra* note 265.
[267] *Id*.
[268] *COVAX Announces additional deals to access promising COVID–19 vaccine candidates; plans global rollout starting Q1 2021*, WHO (Dec. 18, 2020), https://www.who.int/news/item/18-12-2020-covax-announces-additional-deals-to-access-promising-covid-19-vaccine-candidates-plans-global-rollout-starting-q1-2021.
[269] *Id*.
[270] Phelan et al., *supra* note 41.
[271] *About the Collaboration,* COVID–19 LAW LAB, https://covidlaw-lab.org/about-the-collaboration/.
[272] *Id*.

vaccines; advance human rights; and enforce actions to create healthier and safer public spaces and workplaces."[273]

Another component to a coordinated pandemic response is providing equitable vaccine access to participating nations through a global vaccine network.[274] Although bilateral agreements are beneficial for the participating nations, they do not properly address the overarching goal of achieving herd immunity.[275] But regardless of whether the nation realizes herd immunity on a domestic level, it may still be vulnerable to negative health impacts caused by other countries' lack of equitable vaccine access.[276] So if countries commit to participating in a concerted effort to obtain vaccines for as many countries as possible, it will likely shorten the time frame of the pandemic, and reduce economic and health costs.[277]

COVAX, launched by Gavi, helps create equitable access to COVID–19 vaccines.[278] This initiative provides a "lifeline" to lower and middle–income countries that lack the financial resources to enter into APAs with manufacturers[279] by affording all participating countries the opportunity to obtain effective vaccine doses at reduced costs.[280] Thus, we can see that the benefits of the global vaccine network that has been created over the past two years are twofold: nations may directly protect their citizens through an increased likelihood of securing vaccine doses while indirectly countering the effects of the pandemic on a global level, as increased vaccine access will gradually lead to herd immunity.[281]

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[273] *Id*.
[274] *About our Alliance*, *supra* note 242.
[275] Phelan et al., *supra* note 41.
[276] *Id*.
[277] *Id*.
[278] *About our Alliance*, *supra* note 242.
[279] *Id*.
[280] *Id*.
[281] *Id*.