Vaccine Procurement: The Changes Needed to Close Access Gaps and Achieve Health Equity in Routine and Pandemic Settings

Shawn H.E. Harmon[1], *Ksenia Kholina*[1], *Janice E. Graham*[1]

1. DALHOUSIE UNIVERSITY, HALIFAX, NOVA SCOTIA, CANADA.

Keywords: Pandemics, Vaccination, Vaccine Procurement, Equity, Regulation

Abstract: Vaccines are not the only public health tool, but they are critical in routine and emergency settings. Achieving optimal vaccination rates requires timely access to vaccines. However, we have persistently failed to secure, distribute, and administer vaccines in a timely, effective, and equitable manner despite an enduring rhetoric of global health equity.

Though not all vaccines are maximally effective and not all vaccination programs are effectively designed or delivered, immunization is a critical component of public health programs aimed at combatting infectious diseases and improving population health.[1] Achieving optimal vaccination rates requires *timely access* to vaccines. This is even more critical — and more difficult — during public health emergencies of international concern (PHEICs), such as the recent and ongoing COVID-19 pandemic.[2] Defined in Article 1 of the International Health Regulations (IHR), a PHEIC is an extraordinary event which is determined to constitute a public health risk to multiple states through the international spread of disease that potentially requires a coordinated international response.[3] In PHEICs, rapid immunization of at-risk populations — the demographics of which will depend on the epidemiology of the disease — becomes a priority with profound implications for population health, and for social and economic stability.

While at-risk individuals will often drastically outnumber the doses of vaccine available — and the number of doses that can be manufactured and administered in the short-term — it is not beyond our capabilities to effectively and fairly accommodate surges. And yet, from H1N1, to Ebola, to Zika, and again during COVID-19, we have struggled to secure, distribute, and administer relevant vaccines in a timely, effective, and equitable way, a bewildering failing given that the destructive and disruptive power of infectious diseases has long been understood, and the outbreak and spread of infectious diseases are largely predictable given the development of infectious disease surveillance systems since the 1890s. The continued (mis)handling of PHEICs through systems that remain largely unchanged despite their failings lays the groundwork for competition, opportunism, conflict, shortages, and loss of life during breakouts, all of which is avoidable.

There exists ample international policy and law aimed at alleviating and avoiding inequity, particularly as a chronic condition of life dependent on geography and income. For example, the Universal Declaration of Human Rights (UDHR)[4] states that the inherent dignity and equality of all members of the human fam-

Shawn H.E. Harmon, LL.M., Ph.D., PGCert, FHEA, *is a Partner at C3 Legal Inc, and a Research Associate at Dalhousie University interested in equity and the operationalization of values in law and governance frameworks.* **Ksenia Kholina, M.Sc.,** *is a Dietician and Family Medicine Resident Physician and former Research Associate at Dalhousie University.* **Janice E. Graham, Ph.D., FCAHS, FRSC,** *is a Professor in Pediatrics (Infectious Diseases) and Anthropology at Dalhousie University who studies the regulation of emerging biotherapeutics and vaccines. She is a Fellow of the Royal Society of Canada.*

The Journal of Law, Medicine & Ethics, 52 (2024): 467-479.
DOI: 10.1017/jme.2024.109

ily is the foundation of freedom, justice, and peace,[5] and that all humans are born free and equal in dignity and rights, are endowed with reason and conscience, and should act towards one another in a spirit of solidarity,[6] and that everyone is entitled to rights without discrimination.[7] The International Covenant on Economic, Social and Cultural Rights (ICESCR),[8] which is legally binding on signatories, states that everyone has the right to the enjoyment of the highest attainable standard of physical and mental health, and it imposes on member states the responsibility to take action aimed at, *inter alia*, the prevention, treatment, and control of epidemic, endemic, occupational, and other diseases, and the provision of medical service.[9] It also affirms that everyone has the right to enjoy the benefits of scientific progress and its applications, and that member states must assist with the diffusion of science and culture through multiple means.[10]

Many other international instruments reiterate these rights. For example, see the UN Charter 1945,[11] WHO Constitution,[12] Declaration of Alma-Ata 1978,[13] Ottawa Charter for Health Promotion 1986,[14] Bangkok Charter for Health Promotion in a Globalised World 2005,[15] Final Report of the Commission on Social Determinants of Health 2008,[16] Adelaide Statement on Health in All Policies 2010,[17] Rio Political Declaration on the Social Determinants of Health 2011,[18] Helsinki Statement on Health in All Policies 2013,[19] Shanghai Declaration on Promoting Health in the 2030 Agenda for Sustainable Development 2016,[20] Adelaide Statement II on Health in All Policies 2017,[21] and more. In other words, there has long existed a desire for and rhetoric of global and regional health equity, tools developed to achieve same, and opportunities to apply them. Unfortunately, equitable access to vaccines — a core tool in many of these instruments — is confounded by an international social order characterized by:

- the commercialization of science, assured by instruments like the TRIPS Agreement 1994, and the primary development of science through private actors intent on science-for-profit;
- massive and widening health disparities within and across countries, contributed to by multiple social and infrastructural shortcomings; and
- a general retreat from known needs (i.e., the need for greater attention to the social determinants of health impeded by concentration on spending on technological innovations in acute care; the need for data on health and social conditions across the life-course impeded by hyper-focus on privacy).

In this paper, we outline the operation of the vaccine market from a procurement perspective, noting how existing practices serve to disempower the most vulnerable countries. We then re-conceptualize vaccine technology as a "global public good" rather than a market commodity, a shift that demands a realignment of how vaccines are produced and distributed. Finally, we offer legal and practical solutions for realizing a new access to vaccines environment, one more in keeping with global health justice as envisioned by the above instruments. These solutions rely on existing and new international law, improved domestic programs, and increased cross-border cooperation.

The Market and Marginalization

Absolutely fundamental root causes of inequitable access to vaccines globally are the positioning of vaccines as non-essential commodities, and the reliance on neoliberal capitalist market dynamics and

The Journal of Law, Medicine & Ethics, 52 (2024): 467-479.

self-interested market actors/advocates/beneficiaries (primarily from high income countries (HICs)) for vaccine development and manufacture, *and for gatekeeping access to vaccines*. Within this market, the act of procuring vaccines is usually achieved in one of several ways:

- **Self-Procurement by State:** Vaccines purchased from manufacturers directly by governments who aggregate the needs of their various sub-jurisdictions. The benefits of this approach are independent State-based selection of manufacturer, direct negotiation, responsiveness to domestic health needs, and development of capacity to assess and prequalify or license vaccines, including supplier assessment, preparation of bidding documents, development of financial arrangements, quality monitoring, all of which draws on and builds technical capacity in medicine, law, finance, and licensing/regulation, and encourages the development of infrastructure.[22]
- **Interstate Agreements:** Interstate donations and sales are made directly from one State to another, without using an international organization as an intermediary or procurement agent. These are rare but occurred during the 2009 H1N1 influenza pandemic.
- **Procurement & Donation by International Organizations:** Various non-governmental and intergovernmental organizations — GAVI Alliance, WHO, UNICEF — acquire vaccines through donations from manufacturers and States, or by acting as a procurement agent, purchasing the vaccines directly through a financing program, sometimes featuring technical capacity-building elements. One version of such an approach was the Access to COVID-19 Tools Accelerator (ACT-A), a WHO-led global collaboration to accelerate the development, production, and access to COVID-19 tests, treatments, and vaccines, with its vaccine pillar, COVAX.[23]
- **Procurement & Administration by International Organizations:** International organizations (WHO, UNICEF, the World Bank) sometimes procure vaccines and administer them directly, often on behalf of low-income countries (LICs) which lack sufficient infrastructure to administer vaccines themselves.

This market approach for procuring vaccines has multiple negative consequences. First, it advances and fortifies an innovation/distribution structure driven by commodification and commercialization, supply and demand sensibilities, and enclosure of scientific and commercial knowledge.[24] Second, it has contributed to a market occupied by a relatively small field of manufacturers capable of meeting the technical demands of vaccines set by evolving certification systems,[25] producing to the large-scale and relatively stable demand generated by national and international vaccine programs,[26] and distributing via agreements with governmental purchasers who may or may not be capable of handling the biological demands of the products. In short, it has created a cartel of vaccine producers powerful enough to set prices that many countries — even if they have the infrastructure to operate an immunization program — cannot easily afford.[27] This creates an environment where manufacturers can ignore the needs of jurisdictions with low capacities. Third, it accepts (and promotes) as benign discretely negotiated procurement arrangements which are veiled by the operation of business practices that favor privacy and confidentiality. Fourth, it ensures that access to essential medicines is wealth-dependent, and such surge capacity as exists is monopolized by HICs, particularly those capable of affording and equipped to negotiate Advance Procurement Agreements or Advance Purchase Agreements (APAs).

APAs are contracts between the manufacturer and a government for an agreed number of vaccine doses for specified diseases under specified conditions and at a specified price which lays dormant until triggered by a pre-determined event, at which stage it becomes legally binding.[28] While the commercial benefits of patent rights have often been advanced as the prime motivator for health innovation, it has been observed that these contracts are in fact a key motivator for the novel technologies of current generation vaccines in the effort against COVID-19.[29] APAs can address vaccine doses for existing strains of diseases, or for emerging or as yet unknown sub-types. For states that can afford these agreements, there is undeniably some value to having in place an agreement to secure rapid access to vaccines that become necessary due to evolving epidemiological conditions. However, instead of solving healthcare disparities, APAs compound them, in at least three ways.

First, while APA-reserved vaccines are paid for at the time of purchase during the pandemic, the APAs are maintained during their "dormant phase" by states paying annual pandemic preparedness fees to the manufacturer. These fees essentially cover access to vaccines that may never be needed during the life of the contract and are prohibitive for LICs and least

The Journal of Law, Medicine & Ethics, 52 (2024): 467-479.

developed countries (LDCs). While some manufacturers (e.g., GlaxoSmithKline) have made commitments to supply vaccines via an APA at tiered prices based on GDP, it is unrealistic to expect states with very limited healthcare budgets to spend a sizeable portion of that budget on maintaining a contract that guarantees vaccines for a pandemic which may not occur. In short, LICs and LDCs have little to no opportunity to benefit from the "safety net" represented by APAs, and the intervention of organizations like the UN or the GAVI Alliance has not measurably disrupted the access shortfalls generated by this financial deficit.

Second, there is little or no correlation between the maintenance of an APA and the actual initial disease burden within a country, or — perhaps more importantly — to its comparative need. In 2009, for example, 20 countries classified by the WTO as "developed states" had APAs in place, including Canada, New Zealand, Switzerland, the USA, and 16 countries from the EU. Many of those APAs were triggered by the 2009 H1N1 outbreak, guaranteeing these contracting countries priority access to vaccines though their need may not have been as great as other countries, and in fact was not.[30] Nonetheless, many of them further supplemented their APA allocation with additional purchases to cover a large proportion of their population, with the result that manufacturers were unable to take or fulfill orders from other countries or international organizations in the early stages of the outbreak.[31] In the event that a state's needs in a pandemic are less than the minimum number of vaccines available through its APA, the state *may* be able to reduce their purchase (as was attempted by some states during the H1N1 pandemic), giving them some scope to control their expenditure. But this flexibility is not guaranteed and will depend on the negotiating power of the state, which means that those most in need of such flexibility will often be least likely to secure it as a contract provision.

Third, neither the content nor annual fees associated with APAs are regularly publicized; indeed, secrecy is the hallmark of their negotiation and operation. This is in keeping with many international (and domestic) commercial agreements, which are premised on the myth of equality of power and the legal fiction of fair bargaining. Worryingly, the UK Minister claimed that it was "rather difficult to give exact figures" as to the cost of the pandemic preparedness fee associated with the UK's H1N1 APA, and freedom of information requests by academics have been refused on the basis that making such information available could limit the contractors' negotiating position with other customers.[32] In short, public scrutiny was barred to protect the commercial interests of the producer, an approach reproduced in relation to government negotiations with manufacturers in the COVID-19 pandemic.[33]

The absence of transparency profoundly undermines the ability of states to make informed decisions about APAs, to ensure fair treatment by manufacturers, or to develop capacity that might enhance their negotiating power. Setting aside the special handling procedures and technologies that a vaccine may impose, states seeking to negotiate effectively for APAs need a high degree of "procurement capacity," including specialized integrated commercial and technical knowledge, special vaccine management knowledge, and a competent regulatory environment which enables transmission of accumulated experience and expertise within and across government institutions.[34] However, despite long-standing efforts to enhance national capacity around the globe, many states have not developed these skills; they have limited or no expertise around best suppliers, comparative product profiles, market dynamics, or contract negotiation, and limited evidence for comparative pricing and contract value assessments, or means of imposing delivery and quality expectations. The result is that their negotiation position vis-à-vis manufacturers is weak, which undermines transparency, candidness, and fair dealing.[35]

Ultimately, different countries end up paying very different amounts for the same product, with price bearing no relation to ability to pay or burden of disease. And LICs and LDCs often end up paying too much for vaccines. While the factors contributing to price variation are not easy to determine or isolate,[36] pricing factors can include: income level, volume purchased, length and type of contract and payment modality, product maturity, and vaccine industry strategies, including competition and partnering in the cause of market shaping.[37] On the number of market actors and volume of product sought, it has been observed that:

> … countries do not necessarily have wide variety of choices or benefit from a competitive market particularly if they are self-procuring. Vaccine supply is constrained. For example, in 2016, for 58% of the procured vaccines, there were only two suppliers per vaccine available to the countries. Due to limited availability for some vaccines, manufacturers are not always interested in supplying vaccines to small markets at competitive prices.[38]

The Journal of Law, Medicine & Ethics, 52 (2024): 467-479.

Further, rather than facilitate LICs and LDCs and cater to their needs — as instructed by the plethora of policy and legal instruments noted above — manufacturers have resisted their attempts to pool procurement, preferring weak-positioned purchasers so as to secure market advantages (contrary to the rights of people to access the benefits of scientific progress, and to access essential medicines). And despite the rhetoric of togetherness that fortified the public health measures in response to COVID-19, the pandemic has not been the platform it should have been for actors to model solidarity, and for the world to unite and close global health disparities.[39]

The Vaccine Market and COVID-19

An early response to the COVID-19 pandemic was the ACT-A, which consisted of 10 UN agencies and global health organisations, including the WHO, UNICEF, GAVI Alliance, the Global Fund, the World Bank, the Wellcome Trust, and the Gates Foundation. Its aim was to accelerate the development of health products to combat COVID-19.[40] The first ACT-A budget was for $33 billion, but donors contributed only about half the agreed-upon amount, leaving huge funding gaps.[41] Of the funds collected, most of the ACT-A's resources were earmarked for COVAX, the vaccine procurement pillar of the ACT-A.[42] COVAX had the laudable aims of accelerating the manufacture and fair access of COVID-19 vaccines and had the target of procuring enough doses to vaccinate at least 20% of people in 92 poorer countries by the end of 2021. These aims were not achieved. This is not surprising given that commercial actors like Pfizer declared early on their intention to profit from their involvement.[43] By early 2022, the following was observed:

> According to its financial filings, Moderna received US$1.7 billion from the US government, while BioNTech received €375 million from the German government, and an additional €100 million from the European Commission to develop their vaccines. The real pull for development came, however, from the mammoth procurement contracts issued by governments, entered well before any patents were issued. While procurement contracts paid out only if the research was successful, the same is true for patents. As a result, Pfizer gained revenues of US$36.7 billion in 2021 from vaccine sales and expects another US$32 billion in 2022 for its vaccine and US$22 billion from Paxlovid; Moderna had revenues of US$17.7 billion in 2021 and is expecting sales of US$19 billion in 2022.[44]

Ultimately, while contributing to incredible wealth-growth of vaccine manufacturers, the ACT-A failed to achieve, or even measurably advance, health equity.[45] By mid-April 2021, 87% of the approved COVID-19 vaccine supply had gone to HICs and upper-middle-income countries (UMICs), while LICs received just 0.2%.[46] As of November 2022, some 12,885,748,541 vaccine doses had been administered worldwide.[47] However, with a combined population of 735,138,181 representing 9.3% of the global population, LICs had only 176,700,582 individuals with at least one dose of vaccine, and they represented only 3.6% of the world's population with 1+ dose. Only 24% of LIC individuals had one dose of COVID-19 vaccine. Only 142,830,806 (19.4% of LIC population) had both primary doses, and only 11,366,726 booster doses were held by LICs.[48] By contrast, with a population of 38,454,327, Canada had 32,512,884 individuals with 1+ dose (84.6% of population), 31,330,332 with both primary doses (81.5% of population), and 18,845,713 booster doses. Neither the 2021 nor the 2022 vaccine targets for LICs had been met,[49] and one of the ACT-A's architects, Olusoji Adeyi, was quoted as saying, "… in the fullness of hindsight, it is now eminently clear that the power structures have favoured the Global North over the Global South. These power structures crippled the functions of [ACT-A], including [COVAX]."[50]

In short, the equity aims of COVAX were pushed well off target in large part by market relations and procurement practices, including the purchase queue created by HICs with APAs that could be legally enforced. An August 2020 government press release from Canada stated:

> The Government of Canada is aggressively pursuing the purchase and development of COVID-19 vaccines, treatments and related supplies to protect Canadians, and is working to strengthen Canada's biomanufacturing sector. This includes engaging with international and domestic scientists and with businesses and manufacturers that are stepping up to fight COVID-19. The Government of Canada is investing in projects that will position Canada at the forefront of the global race to find a treatment and a vaccine for COVID-19, while building domestic capabilities to fight future pandemics.[51]

This proved a massive benefit to pharmaceutical companies and other for-profit enterprises, and for biomedical faculties at research universities who have for two decades been encouraged — and are now expected — to partner with industry and pursue marketable

The Journal of Law, Medicine & Ethics, 52 (2024): 467-479.

innovation. By November 2020, Public Services and Procurement Canada had signed APAs with 7 companies to secure access to the AstraZeneca (20m doses), Sanofi and GlaxoSmithKline (72m doses), Johnson & Johnson (38m doses), Pfizer (76m doses), Moderna (56m doses), Medicago (76m doses), and Novavax (76m doses) vaccine candidates.[52] Canadian APAs secured up to 414 million doses of COVID-19 vaccines for a population of 38 million, some of whom would be unable to receive these vaccines for a variety of reasons.[53]

The Canadian experience can be contrasted with Indonesia, a lower-middle-income country (LMIC), which — with a population of some 270 million — had secured only 18 million doses by November 2020 with the expectation of receiving another 195 million doses from multiple sources in 2021.[54] Despite adopting a multi-pronged approach to managing the pandemic, Indonesia became the epicenter of the pandemic in Asia, with 43,000 deaths in a 1-month period over the summer of 2021. Like many other countries, it was hampered by limitations on access to vaccines driven at least in part by the functioning of the market and the behaviour of more resourced market actors. Like many countries with limited negotiating and purchasing power, Indonesia has been captive to a market which it cannot influence, with the result that public debates in that country became binary: should policies focus on protecting public health through restrictions or should they encourage pursuit of economic activity in the face of risk?[55]

Despite countries with some of the most vulnerable populations having vaccinated less than 20% of their population and facing significant challenges in accessing vaccines, many HICs — having already taken most of the global supply through APAs — have been administering third- and fourth-dose "boosters," while sitting on large vaccine surpluses and discarding past-due stock.[56] In 2021, the WHO called for a moratorium on booster purchase and distribution, but HICs rebuffed the call.[57] Canada entered into further APAs that secured 35 million booster doses for 2022, and 30 million for 2023, including bivalent vaccines, which are only approved as boosters.[58] Further, while India and South Africa, supported by over 100 other countries, sought temporary waivers of intellectual property protection on COVID-19 technologies, HICs and vaccine manufacturers blocked these discussions at the WTO,[59] which itself was reluctant to entertain them,[60] causing actors such as Oxfam to accuse the G20 nations of putting relations with pharmaceutical companies ahead of effective pandemic responses.[61]

Ultimately, the neoliberal marketized approach to vaccines that is strongly favoured by the field's most powerful and wealthy actors has, once again, failed to deliver good outcomes evenly (or even good products). Even with substantial public contributions, the current models of production and distribution have failed to meet the needs of LICs. The result is that COVID-19 has not been a global unifier, or a point of pride in international relations. But it could be — and ought to be — a launchpad for international pandemic vaccine access and procurement reform. The question remains: What solutions exist to relieving this relentless cycle of inequality?

Ultimately, the neoliberal marketized approach to vaccines that is strongly favoured by the field's most powerful and wealthy actors has, once again, failed to deliver good outcomes evenly (or even good products[62]). Even with substantial public contributions, the current models of production and distribution have failed to meet the needs of LICs.[63] The result is that COVID-19 has not been a global unifier, or a point of pride in international relations. But it could be — and ought to be — a launchpad for international pandemic vaccine access and procurement reform. The question remains: What solutions exist to relieving this relentless cycle of inequality?

Solutions

The starting point is to accept that existing international law aimed at social justice compels us to acknowledge that the above approach is entirely wrong. Vaccines — like other essential medicines — are not and must not be viewed as commodities, but

The Journal of Law, Medicine & Ethics, 52 (2024): 467-479.

as global public goods (GPGs). GPGs offer benefits that are not easily confined to a single user (or set of users); once they are provided, they benefit many.[64] A habitable environment, quality education, and effective rights-sensitive national security are all examples of GPGs. Health must be viewed as a GPG. Individual health does not detract from others' health and indeed benefits society beyond the individual, for all human activity and production relies on human health.[65] As such, *components* of healthcare, especially those focused on population health, should be understood as GPGs, particularly in light of global linkages and mobility, social convergence, and pressure on common global resources (e.g., water, air, livable habitat, and healthcare resources).

Open and effective infectious disease surveillance — one of the objectives of the IHR 2005 — is certainly a GPG,[66] for a global surveillance system with significant buy-in will benefit many more than those who contribute directly, detract nothing from those who do not, and can create many spill-over benefits. At the 73rd World Health Assembly in 2020, immunization was declared to be a GPG.[67] Curiously, the Assembly did not identify vaccines as GPGs, though they are fundamental to health and represent the foundational physical component of immunization. As such, they are surely examples of GPGs. Unlike investments in acute care, vaccines protect both individuals and communities, spreading their protection to those who cannot be vaccinated. Vaccines contribute to reduced health resource expenditure and, importantly, are developed through reliance on significant public investment. For example, public institutions and academic researchers spearheaded research into infectious diseases and the platform technologies on which immunization relies, while industry retreated from the field, reentering only when massive amounts of public funds were committed in response to COVID-19 (Canada: C$1b;[68] USA; US$1b+;[69] EU: €7b[70]).[71] As such, it has been argued that, unlike surveillance and financing, the innovation required to combat pandemic flu most closely reflects a "single best effort" GPG.[72]

While commercial actors who stand to benefit most from the existing commodity approach to vaccine procurement dismiss the idea of GPGs — and of vaccines as being GPGs — and discourage political leaders from appreciating that vaccines are GPGs, an understanding of vaccines as GPGs better acknowledges the public contribution to vaccines and could blunt the more harmful aspects of nationalism and regionalism observed during the COVID-19 pandemic. Approaching vaccine development, manufacturing, and procurement/access as one implicating GPGs should encourage actors to think more critically and more imaginatively about the solutions that might be deployed to close the health gap and ensure more equitable access to vaccines (for COVID-19 and other infectious diseases). Without such mechanisms, GPGs are almost always underproduced because private actors adhering to market and profit imperatives are unlikely to invest in them despite their reliance on them and benefit from them.[73]

Below, we discuss three complimentary solutions for achieving equitable and timely access to vaccines and other essential medicines: (1) existing and new international law; (2) new and blended institutions; and (3) new partnerships and programmatic interventions.

1. Existing and New International Law

If vaccine procurement is to be improved and destratified, two legal reforms are warranted. First, the IHR 2005 should be amended. Second, a Global Framework Convention on Health should be adopted.

With respect to the former, the IHR 2005 is a binding instrument aimed at international public health and global responses to infectious diseases. It focuses primarily on:[74]

- encouraging open communication (i.e., avoiding the secrecy around infectious disease outbreaks that has characterized past pandemics);
- imposing a common mechanism for declaring a PHEIC (i.e., erecting standard considerations, certainty, timeliness); and
- ensuring continued mobility and trade during a PHEIC (i.e., minimizing disruptions to travel and economic activity).

These aims go some way to facilitating global health justice, but they miss some of the most direct influencers, being procurement of and access to vaccines, and they typically lose out to more rigorously pursued and enforced commercial rights such as WTO-monitored intellectual property rights.

If the IHR 2005 is ever to meaningfully advance the values identified in Article 3 — dignity, human rights, and fundamental freedoms of persons, and the principles contained in the UN Charter and the WHO Constitution, both of which recognize science as a "public good," and the benefits of science as the "heritage of humanity" — then the IHR 2005 needs to be amended. Three critical amendments/additions are warranted in the short term. First, and importantly, the IHR 2005 should articulate a principles-based approach to fairly and equitably determining

The Journal of Law, Medicine & Ethics, 52 (2024): 467-479.

priority access to vaccines by countries, and a similarly principles-based model for priority access to vaccines by critical populations within countries impacted by a PHEIC.[75] Second, the IHR 2005 should include a Vaccine Procurement section which identifies structures and practices more in keeping with access to vaccines as a GPG. For example, it could identify common "good practices" around vaccine procurement/contracting, and articulate market-evening standards such as mandatory contract reporting, and market-altering standards such as prohibitions against certain types of provisions, fees, and actions. Third, the IHR 2005 should specifically reference the Doha Declaration on the TRIPS Agreement and Public Health (2001), which affirms the TRIPS Agreement flexibilities around compulsory licensing of patented products and confirms that countries should not be prevented from taking measures to protect public health and promote access to medicines. This same provision should also formally adopt the "Bolar Exception" to patent terms.

First articulated in the US *Drug Price Competition and Patent Term Restoration Act*,[76] the Bolar Exception seeks a compromise between so-called innovators and generics producers, the latter of which were permitted to use a patented product prior to the expiry of the patent for the purpose of complying with regulatory procedures necessary to pursue market authorization for its (related) generic product. If producers of a generic or bio-similar product have to wait until the last day of patent term on the original product (like a vaccine), the owner of the expired patent enjoys an additional period of product monopoly power and pricing, that being the time it takes the generic version to wind its way through the regulatory authorization process. This reduces access. The name of the exception derives from *Roche Products Inc. v Bolar Pharmaceutical Co. Inc.*,[77] wherein the US federal court held that the experimental use exemption in US patent law did not allow for Bolar's testing in support of its generic product market approval requirements.

On the second legal action — a convention — we admit that the WHO has never embraced its convention-making powers, in part due to the realities of its funding, but a Global Framework Convention on Health (GFCH) would be a natural and necessary response to the persistently impoverished position of health and health governance internationally, and to the inability of existing laws and frameworks to overcome obvious and solvable inequalities. Such a GFCH could acknowledge that populations are interdependent and affected by extra-jurisdictional events and actions, that health and immunization are GPGs to which all ought to contribute and benefit (a point emphasized by the cooperation and assistance provisions of the ICESCR), and that local populations can only be protected by strengthening all *health systems*. First proposed in 2008,[78] and encouraged again in the post-Ebola period,[79] a GFCH could:

- set globally applicable norms and priorities for health systems and essential human needs;
- entrench clear and functional flexibilities in relation to commercial constraints on countries seeking to meet domestic needs and take ownership of national policies/programs;
- establish a sustainable funding mechanism scalable to needs;
- govern the proliferating number of actors and activities in a crowded global health landscape dominated by economic/trade organizations;
- create methods for holding state and non-state actors accountable to their obligations under the right to health, including for monitoring progress and achieving compliance; and
- devise a process for the international community to establish further commitments beyond those in the initial GFCH.

This would, of course, require massive political will and work on the part of the WHO, MICs, LICs and LDCs, with their first hurdle being to get developed countries on board and fulfilling their global responsibilities. But it is a worthwhile effort that could have numerous positive consequences.

2. New and Blended Institutions

At the state level, attention needs to be paid to the institutions that are critical to population health and infectious disease infrastructure. Two particular institutions are fundamental to improved vaccine access and health outcomes in times of public health emergencies: national immunization technical advisory groups (NITAGs), and vaccine manufacturers.

It is important for countries — or groups of similarly-situated and geographically close countries — to have an effective NITAG that is expertly staffed, and that meets certain criteria.[80] These NITAGs should be grounded in legal instruments that address specific elements of structure and operation.[81] NITAGs should be staffed and trained to develop (flexible) multi-year visions of the epidemiological and vaccine needs of their host country, but also to simultaneously design clear priority-setting mechanisms. Importantly, procurement needs to be a key action with which the NITAG is involved, a critical function that needs to be

The Journal of Law, Medicine & Ethics, 52 (2024): 467-479.

approached as a strategic action, not an administrative support function. For this, market dynamics need to be understood, meaning that new training programs must be made available to NITAGs. A well-balanced vaccine ecosystem with appropriate budget allocated to vaccination, and procurement methods that maximize public health goals (e.g., contracting with multiple manufacturers, using different vaccines, etc.) is critical, and NITAG deliberations and decisions need to be publicly transparent.

Second, countries — or partnering groups of countries — should invest in developing vaccine manufacturing capacity so that they are less reliant on disproportionately powered multinational corporations. Canada is an example of the creeping nature of foreign and private sector reliance. In the 1970s-80s, Canada had a robust large-scale vaccine manufacturing industry.[82] Its capacity, however, was gradually eroded, replaced by vaccine research and development that exported knowledge to "offshore" physical/production operations. This led to almost complete reliance on European and US vaccine production, which has had disastrous consequences.[83] To rectify Canada's reliance on foreign-based manufacturing entities throughout the COVID-19 pandemic, the federal government has committed to building new manufacturing facilities in Toronto and Montreal.[84] While these are not purely public facilities — they are being developed in partnership with commercial entities and will surely be a financial boon to those entities — they represent an improvement on the conditions that existed in Canada as it entered the pandemic. The expectation, one assumes, is that they may function in a way reflective of the Oxford-AstraZeneca partnership,[85] though they have not met their target timelines for actually producing any vaccines.[86]

When public institutions do partner with private actors, it is critical that the parties strike the proper balance of authority between the partners and clearly articulate that balance in enforceable governing documents. Moreover, that balance must reflect the public nature of the endeavour, and the profound contribution of public funds to its outputs must be valued. That valuing demands that the eventual products will be subject to fair and equitable distribution in accordance with transparent agreements. Such would be in keeping with vaccines as GPGs, and reflective of the reality that vaccines are grounded on work performed by public institutions. Private actors subsequently draw on that work to develop products by which they profit enormously, including through APAs.[87] With respect to COVID-19, the genome sequencing of the virus and the predictive mapping of its evolution, the development of the lipid-nanoparticles for mRNA delivery, the identification of the effect of specific proteins on viral proliferation and lethality, and the cooling technologies for transport and storage all benefitted from work performed in the public sector.[88] However, the secrecy around tech-sharing and procurement agreements (including APAs) failed to sufficiently reflect this reality, as did the pricing of the products.

Neither intellectual property rights nor commercial agreements should be wielded as weapons of profit in settings of public need, or in respect of products that are properly characterized as GPGs. Production and access agreements should, in recognition of this public contribution, include terms and conditions that not only permit but encourage and enable access to the technologies (and the expertise required to implement them) in a fair and timely manner.[89]

3. New Partnerships and Programmatic Interventions

Finally, states must think much more strategically about their capacity to avert emergencies, to respond to rapidly changing circumstances in an evidence-informed manner, and to move vaccines effectively from conception to distribution. The "just-in-time" approach has been relied on for multiple pandemics now, and to generally poor reviews; dedicated and broader-based infrastructure — *systems* — in support of access to vaccines would make responses more robust and equitable.[90] Two policy movements are recommended.

First, countries within a region, or generally sharing broad epidemiological characteristics, should take steps to collaborate more effectively and strategically. For example, they could collaborate in:[91]

- harmonizing their processes for regular and emergency assessment of vaccine needs;
- formulating their individual and collective vaccine needs in routine and emergency situations;
- generating evidence around supplier performance and developing metrics by which to assess that evidence; and
- developing processes for mutual recognition of product registration, and for sharing information, resources, and lessons learned.

Taking such actions relies on the development of relationships of trust. To facilitate this, responsibilities and actions could initially be set out in Memoranda of Understanding, with measures articulated to ensure cooperation and compliance, particularly in PHEICs.

Second, given the deeply inequitable performance of APAs, common multi-national, regional, or pooled

The Journal of Law, Medicine & Ethics, 52 (2024): 467-479.

legal instruments for vaccine procurement should be executed. Currently, many countries maintain their own procurement rules. This fragments the market and disincentivizes manufacturers, particularly emerging suppliers, from responding to needs in a timely and equitable manner. Instruments that address joint procurement should avoid imposing a need for a product to be used in the routine program of the country of origin of production (a common provision currently), should establish shared or harmonized import and delivery infrastructure, and should agree on a common payment currency and documentation language.

Conclusions

The equity gap made stark by the COVID-19 pandemic is all too familiar and has resulted in an unfair multitier recovery profile that will cost LICs and LDCs more than others, and so they remain the usual losers in international interactions. The concentration of death and disruption in some of those countries is as much a consequence of the market and its actors as it is of the virus. Our again-demonstrated difficulty in dealing with pandemics — which are expected to increase in regularity and severity — should compel decision-makers to re-think preparation and readiness, and to ensure better access to the key technologies for combating pandemics (i.e., vaccines and personal protective equipment).

Bearing in mind that it *is* possible to make enough vaccines for the world,[92] we encourage all concerned to recall the words of that great activist and orator, Martin Luther King Jr., who pled for a revolution of values that would cause us to question the fairness and justice of our policies, and to amend those policies and their machinery in compliance with compassion.[93] A true revolution of values, he contended, would look uneasily on the glaring contrast of poverty and wealth, and would tremble with righteous indignation at the capitalists taking huge profits out of the world with no concern for social betterment. This, he declared, cannot be reconciled with wisdom, justice, and love.

We concur.

The redoubtable Dr. King instructed us to remove, through positive action, the conditions of poverty, insecurity, and injustice, and to help nations secure the very basic medicines they need. Instead, throughout the COVID-19 pandemic, we stood aloof, disposing of vaccines and preparing to vaccinate the already vaccinated while others remained unvaccinated and fell ill or died. Though COVID-19 offered an opportunity for the revolution of values that was called for almost six decades ago, we have not taken up the mantle.

But we still could. And here we have offered some solutions for taking the first steps necessary to emerge from this global calamity in a better state of health.

Note

This paper was written as part of the Public Health Governance project (https://www.dal.ca/diff/trru/research-projects/public-health-governance-project.html) and the authors would like to acknowledge the support of the CIHR. The authors have no other conflicts of interest to disclose.

References

1. WHO, *Vaccination Greatly Reduces Disease, Disability, Death and Inequity Worldwide* (2016), *available at* <http://www.who.int/bulletin/volumes/86/2/07-040089/en/> (last visited June 3, 2024).
2. On 30 January 2020 the WHO Director General declared the COVID-19 pandemic to be a PHEIC: WHO, *Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV)* (January 30 2020), *available at* <https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)> (last visited June 3, 2024).
3. WHO, *International Health Regulations (2005)*, 3rd ed. (WHO: 2016).
4. Universal Declaration of Human Rights, G.A. Res. 217 (III) A, U.N. Doc. A/RES/217(III) (December 10, 1948), *available at* <https://www.un.org/en/universal-declaration-human-rights/> (last visited June 3, 2024).
5. *Id.*, Preamble
6. *Id.*, Article 1.
7. *Id.*, Article 2.
8. G. A. Res. 2200A (XXI), U.N. Doc. A/RES/2200A(XXI) (December 16 1966), in force 3 January 1976, *available at* <https://www.ohchr.org/en/professionalinterest/pages/cescr.aspx> (last visited June 3, 2024).
9. *Id.*, Article 12.
10. *Id.*, Article 15.
11. United Nations, Charter of the United Nations, 1945, 1 UNTS XVI, *available at* <https://www.un.org/en/about-us/un-charter/full-text> (last visited June 3, 2024).
12. See Const. of the WHO, *available at* <https://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf?ua=1> (last visited June 3, 2024).
13. See World Health Organization, Regional Office for Europe, *Declaration of Alma-Ata* (1978), *available at* <https://cdn.who.int/media/docs/default-source/documents/almaata-declaration-en.pdf> (last visited June 3, 2024).
14. See WHO International Conference on Health Promotion, *Ottawa Charter for Health Promotion* (November 21, 1986), *available at* <http://www.who.int/healthpromotion/conferences/previous/ottawa/en/> (last visited June 3, 2024).
15. See WHO, *Bangkok Charter for Health Promotion in a Globalized World* (August 11, 2005), *available at* <http://www.who.int/healthpromotion/conferences/6gchp/hpr_050829_%20BCHP.pdf> (last visited July 3, 2024).
16. *Closing the Gap in a Generation: Health Equity Through Action on the Social Determinants of Health: Final Report of the Commission* (2008), WHO Commission on Social Determinants of Health, *available at* <https://www.who.int/publications/i/item/WHO-IER-CSDH-08.1> (last visited June 3, 2024).
17. See WHO, *Adelaide Statement on Health in All Policies* (2010), *available at* <https://apps.who.int/iris/bitstream/handle/10665/44365/9789241599726_eng.pdf?sequence=1&isAllowed=y> (last visited June 3, 2024).

The Journal of Law, Medicine & Ethics, 52 (2024): 467-479.

18. See WHO World Conference on Social Determinants of Health, *Rio Political Declaration on Social Determinants of Health* (October 21, 2011), *available at* <https://cdn.who.int/media/docs/default-source/documents/social-determinants-of-health/rio_political_declaration.pdf?sfvrsn=6842ca9f_5&download=true> (last visited June 3, 2024).
19. See 8th Global Conference on Health Promotion, *Helsinki Statement on Health in All Policies* (2014), *available at* <https://www.who.int/publications/i/item/9789241506908> (last visited June 3, 2024).
20. See WHO, *Shanghai Declaration on promoting health in the 2030 Agenda for Sustainable Development* (2016), *available at* <https://www.who.int/publications/i/item/WHO-NMH-PND-17.5> (last visited June 2, 2024).
21. See WHO, *Adelaide Statement II on Health in all Policies* (2019), *available at* <https://www.who.int/publications/i/item/adelaide-statement-ii-on-health-in-all-policies> (last visited June 2, 2024).
22. T. Hyde, et al., "The Impact of New Vaccine Introduction on Immunization and Health Systems: A Review of the Published Literature," *Vaccine* 30 (2012) 6347-6358.
23. See WHO, *COVAX*, *available at* <https://www.who.int/initiatives/act-accelerator/covax#:~:text=COVAX%20was%20the%20vaccines%20pillar,tests%2C%20treatments%2C%20and%20vaccines> (last visited June 2, 2024).
24. For more on the right to scientific outcomes, see Harmon, S. "A Tale of Two Legacies: Drawing on Humanist Interpretations to Animate the Right to the Benefits of Science" in E. Dove and N. Nic Shuibhne (eds.), *Law and Legacy in Medical Jurisprudence: Essays in Honour of Graeme Laurie* (Cambridge, Cambridge U Press, 2022).
25. In 2008, 5 suppliers (GSK, Sanofi-Aventis, Merck, Wyeth, Novartis) controlled 85% of the vaccine market by value. In 2018, 4 producers (Sanofi, GSK, Pfizer, Merck) dominated the global market with parallel quasi-monopolies for several newer vaccines (RV, PCV and HPV): M. Kaddar, et al., "Vaccine Procurement in the Middle East and North Africa Region: Challenges and Ways of Improving Program Efficiency and Fiscal Space," *Vaccine* 37 (2019) 3520-3528.
26. S. Srinivas, "Industrial Development and Innovation: Some Lessons from Vaccine Procurement," *World Development* 34 (2006) 1742-1764.
27. T. Wilsdon, et al., "The Impact of Vaccine Procurement Methods on Public Health in Selected European Countries," *Expert Review of Vaccines* 19 (2020) 123-132.
28. A. Phelan, et al., "Legal Agreements: Barriers and Enablers to Global Equitable COVID-19 Vaccine Access," *Lancet* 396 (2020) 800-802.
29. R. Gold, "What the COVID-19 Pandemic Revealed About Intellectual Property," *Nature Biotech* 40 (2022) 1428-1430.
30. The H1N1 influenza pandemic of 2009–2010, the first pandemic for which many States had comprehensive pandemic plans, nonetheless saw between 151,700–575,400 deaths globally in its first year, with children and young adults disproportionately affected (as compared to COVID-19 by which they are some of the least severely affected): WHO Europe, *Past Pandemics* (2010), *available at* <https://www.euro.who.int/en/health-topics/communicable-diseases/influenza/pandemic-influenza/past-pandemics> (last visited June 2, 2024); CDC, *2009 H1N1 Pandemic (H1N1pdm09 virus)* (2010), *available at* <https://www.cdc.gov/flu/pandemic-resources/2009-h1n1-pandemic.html> (last visited July 3, 2024). Although getting accurate data on H1N1 burdens and outcomes is sparse, it was estimated that it resulted in some 284,000 deaths, with Mexico hardest hit: R. Roos, "CDC Estimate of Global H1N1 Pandemic Deaths: 284,000," *CIDRAP*, 27 June 2012, *available at* <https://www.cidrap.umn.edu/news-perspective/2012/06/cdc-estimate-global-h1n1-pandemic-deaths-284000> (last visited July 3, 2024).
31. M. Turner, "Vaccine Procurement During an Influenza Pandemic and the Role of Advance Purchase Agreements: Lessons from 2009-H1N1," *Global Public Health* 11 (2016) 322-335.
32. *Id.* See also, House of Lords Science and Technology Committee, *Pandemic Influenza: Report with Evidence, 4th Report of Session 2005–06*, HL Paper 88, 2005, *available at* <http://www.publications.parliament.uk/pa/ld200506/ldselect/ldsctech/88/8802.htm> (last visited July 3, 2024).
33. With respect to Canada's negotiation with pharma companies, see R. Subramanya, "Canada Must Rethink Its Vaccine Procurement Strategy," *National Post*, 29 June 2022, *available at* <https://nationalpost.com/opinion/rupa-subramanya-canada-must-rethink-its-vaccine-procurement-strategy> (last visited July 4, 2024).
34. D. Woodle, "Vaccine Procurement and Self-Sufficiency in Developing Countries" *Health Policy & Planning* 15 (2000) 121-129.
35. *Id.*
36. WHO Department of Immunization, Vaccines and Biologicals, *WHO-V3P 2014: Factors to Consider when Comparing Vaccine Prices* (Geneva, WHO, 2014).
37. M. Hinsch, et al., "Enhancing Medicine Price Transparency Through Price Information Mechanisms," *Global Health* 10 (2014) 1-11.
38. Kaddar et al., *supra* note 25.
39. C. McGregor, "Coronavirus, Community and Solidarity," *Concept* 11 (2020) 1-5; M. Perzyna, *The Substance of Solidarity: What the Response to the COVID-19 Pandemic Says about the Global Refugee Regime*, Ryerson Centre for Immigration & Settlement Working Paper 2020/15; F. Tomasini, "Solidarity in the Time of COVID-19?" *Cambridge Quarterly of Healthcare Ethics* 30 (2021) 234-247; D. Silva, et al., "Mere Rhetoric? Using Solidarity as a Moral Guide for Deliberations on Border Closures, Border Reopenings and Travel Restrictions in the Age of COVID-19," *BMJ Global Health* 6 (2021) e006701.
40. A persistent emphasis on "products" rather than "systems" benefits the private sector producers of those products at the expense of populations and governments and serves to further concentrate wealth at a time when disparity is greater than it has ever been: G. Zucman, "Global Wealth Inequality" *Annual Review of Economics* 11 (2019) 109-138; L. Chancel, et al. (eds.), *World Inequality Report 2022* (Cambridge, Harvard U Press, 2022).
41. A. Usher, "New Budget and Strategy for ACT-A," Lancet 398 (2021) 1677.
42. None of the ACT-A's initial three pillars were health systems, which are known to be the most important aspect of pandemic preparedness, and most of the US$9 billion subsequently added to the health systems connector pillar is for procurement of personal protective equipment and medical oxygen: A. Usher, "Health Systems Neglected by COVID-19 Donors," *Lancet* 397 (2021) 83.
43. F. Hassan, et al., "Profiteering from Vaccine Inequality: A Crime Against Humanity?" *BMJ* 347, no. 2027 (2021), citing reports in the *New York Times* and *Guardian* newspapers. See also B. Mueller, and R. Robbins, "Where a Vast Global Vaccination Program Went Wrong," *NY Times*, 2 August 2021, *available at* <https://www.nytimes.com/2021/08/02/world/europe/covax-covid-vaccine-problems-africa.html> (last visited July 4, 2024); A. Usher, "Decolonise COVAX: An African Critique," *Development Today*, 13 July 2021, *available at* <https://www.development-today.com/archive/dt-2021/dt-5--2021/decolonising-covax-a-ugandan-epidemiologists-perspective> (last visited July 4, 2024).
44. Gold, *supra* note 29.
45. F. Stein, "Risky Business: COVAX and the Financialization of Global Vaccine Equity," *Globalization & Health* 17 (2021) 1-11; A. Usher, "ACT-A: "The International Architecture Did Not Work for Us"," *Lancet* 400 (2022) 1393-1394.
46. WHO, *COVID-19 Virtual Press Conference*, 9 April 2021, *available at* <https://www.who.int/docs/default-source/coronaviruse/transcripts/covid-19_virtual_press_conference_-_9_april.pdf?sfvrsn=cc0bd5c1_1>.

The Journal of Law, Medicine & Ethics, 52 (2024): 467-479. © The Author(s), 2024. Published by Cambridge University Press on behalf of American Society of Law, Medicine & Ethics.

47. WHO, *WHO Coronavirus (COVID-19) Dashboard*, *available at* <https://covid19.who.int/> (last visited July 4, 2024).
48. WHO, *WHO Coronavirus (COVID-19) Vaccine Dashboard*, *available at* <https://data.who.int/dashboards/covid19/vaccines> (last visited July 4, 2024).
49. Gold, *supra* note 29.
50. Quoted in A. Usher, "Health Leaders Criticize Limited ACT-A Review," *Lancet* 398 (2021) 650-651.
51. Government of Canada, *Government of Canada announces major steps in treating and preventing COVID-19 through vaccines and therapies*, 5 August 2020, *available at* <https://www.canada.ca/en/innovation-science-economic-development/news/2020/08/government-of-canada-announces-major-steps-in-treating-and-preventing-covid-19-through-vaccines-and-therapies.html> (last visited July 4, 2024).
52. Public Services & Procurement Canada, *Public Services and Procurement Canada has signed agreements with seven companies to secure access to seven COVID-19 vaccine candidates*, 19 November 2020, *available at* <https://www.tpsgc-pwgsc.gc.ca/medias-media/2020-11-19-00-eng.html> (last visited July 4, 2024).
53. Public Services & Procurement Canada, *Canada's vaccine agreements: A strategy to cover all bases*, 8 December 2021, *available at* <https://www.tpsgc-pwgsc.gc.ca/comm/aic-scr/ententes-agreements-strat-eng.html> (last visited July 4, 2024).
54. I. Dwipayana, "Efforts in Securing Vaccine for COVID-19 Outbreak in Indonesia," *Health Notions* 4 (2020) 313-317.
55. D. Gandasari and D. Dwidienawat, "Content Analysis of Social and Economic Issues in Indonesia During the COVID-19 Pandemic," *Heliyon* 6 (2020) e05599; S. Susilawati, et al., "Impact of COVID-19's Pandemic on the Economy of Indonesia," *BIRCI-Journal: Humanities and Social Sciences* 3 (2020) 1147-1156.
56. Editorial, "WHO Calls for Moratorium on Third Doses Amid Stark Global Vaccine Inequity," *Democracy Now*, 5 August 2021, *available at* <https://www.democracynow.org/2021/8/5/headlines/who_calls_for_moratorium_on_third_doses_amid_stark_global_vaccine_inequity> (last visited July, 2024); Editorial, "Canada's Top Doctor Says Discussion on COVID-19 Booster Shots Still 'Evolving'," *Global News*, 5 August 2021, *available at* <https://globalnews.ca/video/8089199/canadas-top-doctor-says-discussion-on-covid-19-booster-shots-still-evolving> (last visited July 4, 2024); Editorial, "There Just Isn't Enough Supply": Vaccine Gap Between Rich & Poor Countries Fuels Indonesia's COVID Crisis," *Democracy Now*, 12 August 2021, *available at* <https://www.democracynow.org/2021/8/12/vaccine_gap_indonesia_covid_crisis> (last visited July 4, 2024); W. Leung, "COVID-19 Vaccines Should Be Prioritized for Poorer Countries, Not Booster Shots at Home: Experts," *Globe & Mail*, 10 August 2021, *available at* <https://www.theglobeandmail.com/canada/article-covid-19-vaccines-should-be-prioritized-for-poorer-countries-not/> (last visited July 4, 2024).
57. Z. Chagla and M. Pai "COVID-19 Boosters in Rich Nations Will Delay Vaccines for All," *Nature Medicine* 27 (2021) 1659-1660.
58. Government of Canada, *Vaccines for COVID-19: How to Get Vaccinated*, *available at* <https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19/vaccines/how-vaccinated.html#a9> (last visited July 4, 2024).
59. R. Labonté, et al., "Canada, Global Vaccine Supply, and the TRIPS Waiver," *Canadian Journal of Public Health* 112 (2021) 543-547.
60. J. Zarocostas, "What Next for A COVID-19 Intellectual Property Waiver?" *Lancet* 397 (2021) 1871-1872.
61. Médecins Sans Frontières, *Countries Obstructing COVID-19 Patent Waiver Must Allow Negotiations to Start*, 9 March 2021, *available at* <https://www.msf.org/countries-obstructing-covid-19-patent-waiver-must-allow-negotiations> (last visited July 4, 2024); E. Mahase, "COVID-19: Rich Countries are Putting "Relationships with Big Pharma" Ahead of Ending Pandemic, Says Oxfam," *BMJ* 373, no. 1342 (2021).
62. For a detailed consideration of the scientific evidence and a finding that the COVID-19 vaccines generally had poor effectiveness, see *Teamsters Local Union No. 31 v Purolator Canada Inc.*, 2023 CanLII 120937 (Can Lab Arb), at paras. 155-221 and 257-312.
63. M. Herder, et al., "University Technology Transfer Has Failed to Improve Access to Global Health Products during the COVID-19 Pandemic," *Health Policy* 17 (2022) 15-25.
64. In usual moral discourse, pure public goods are characterized as non-rival (can be consumed/enjoyed with depletion) and non-excludable (cannot be enclosed from enjoyment), but goods can be categorized as public without having these characteristics in their strongest construction. See B. Buchholz and T. Sandler, "Global Public Goods: A Survey," *Journal of Economic Literature* 59 (2021) 488-545.
65. L. Chen, et al., "Health as a Global Public Good," in Kull, I. et al. (eds.), *Global Public Goods* (Oxford: OUP, 1999) 284-304.
66. M. Zacher, "Global Epidemiological Surveillance: International Cooperation to Monitor Infectious Disease," in *Id.*, 284-304.
67. World Health Assembly, *COVID-19 Response*, 19 May 2020, *available at* <chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf> (last visited July 4, 2024), per Clause 6, which states: "The seventy-third World Health Assembly ... RECOGNIZES the role of extensive immunization against COVID-19 as a global public good for health in preventing, containing and stopping transmission in order to bring the pandemic to an end, once safe, quality, efficacious, effective, accessible and affordable vaccines are available."
68. Prime Minister J. Trudeau, "Canada and International Partners Launch the Coronavirus Global Response," News Release, 4 May 2020, *available at* <https://www.pm.gc.ca/en/news/news-releases/2020/05/04/canada-and-international-partners-launch-coronavirus-global-response#:~:text=The%20Government%20of%20Canada%20is,and%20prosperous%20future%20for%20everyone> (last visited July 4, 2024); Canadian Institute of Health Research, *Government of Canada invests $27M in Coronavirus Research — Details of the Funded Projects* (2020), *available at* <https://www.canada.ca/en/institutes-health-research/news/2020/03/government-of-canada-invests-27m-in-coronavirus-research--details-of-the-funded-projects.html> (last visited July 4, 2024).
69. J. Steenhuysen, "J&J, Moderna Sign Deals with U.S. to Produce Huge Quantity of Possible Coronavirus Vaccines," Reuters, 30 March 2020, *available at* <https://www.reuters.com/article/us-health-coronavirus-johnson-johnson-idUSKBN21H1OY> (last visited July 4, 2024).
70. EU, Funds Raised (2020), *available at* <https://ec.europa.eu/commission/presscorner/detail/en/ip_20_710> (last visited July 4, 2024).
71. J. Hughes, and A. Rai "The Public Role in Drug Development: Lessons from Remdesivir," 8 May 2020, *available at* <https://www.statnews.com/2020/05/08/acknowledging-public-role-drug-development-lessons-remdesivir/> (last visited July 4, 2024); N. Vanderklippe, "National Research Council Strikes Deal with China to Develop COVID-19 Vaccine in Canada," *The Globe and Mail*, 12 May 2020, *available at* <https://www.theglobeandmail.com/world/article-national-research-council-strikes-deal-with-china-to-develop-test/> (last visited July 4, 2024); House of Commons, Standing Committee on Health, 43-1, No 16 (30 April 2020), *available at* <https://www.ourcommons.ca/DocumentViewer/en/43-1/HESA/meeting-16/evidence> (last visited July 4, 2024). Disappointingly, the additional funding that has been pumped into the private sector in response to the COVID-19 pandemic has not been conditional on ensuring affordable pricing or equitable access.

The Journal of Law, Medicine & Ethics, 52 (2024): 467-479.

72. D. Gartner, "Global Public Goods and Global Health," *Duke Journal of Comparative & International Law* 22 (2011) 303-318.
73. I. Kaul, "Enhancing the Provision of Global Public Goods: Ready for More Realism?" in S. Waglé and K. Wignaraja (eds.), *The Great Upheaval* (Cambridge: CUP, 2022) 271-298.
74. IHR 2005, Articles 1 and 2.
75. On this, guidance has already been offered: SAGE, *Values Framework for the Allocation and Prioritization of COVID-19 Vaccination*, 14 September 2020, *available at* <https://apps.who.int/iris/bitstream/handle/10665/334299/WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng.pdf> (last visited July 4, 2024).
76. 1984, 35 USC § 271(e)(1).
77. 733 F.2d 858, 1984.
78. L. Gostin, and E. Friedman, "Towards a Framework Convention on Global Health: A Transformative Agenda for Global Health Justice," *Yale Journal of Health Policy Law & Ethics* 13 (2013) 1.
79. S. Harmon, "In Search of Global Health Justice: A Need to Reinvigorate Institutions and Make International Law," *Health Care Analysis* 23 (2015) 352-375.
80. P. Duclos, "National Immunization Technical Advisory Groups (NITAGs): Guidance for their Establishment and Strengthening," *Vaccine* 28 (2010) A18-A25.
81. S. Harmon, et al., "National Immunization Technical Advisory Groups (NITAGs): A Schema for Evaluating and Comparing Foundation Instruments and NITAG Operations," *Medical Law International* 21 (2021) 69-98.
82. A. Beaulnes, "Vaccine Development and Production in Canada: A Challenge in Search of a Policy," *Canadian Medical Association Journal* 124 (1981) 118.
83. A. Gilmore, "Ottawa's 'Operation Meningo': When the Data are Insufficient, You Go with Judgement," *Canadian Medical Association Journal* 147 (1992) 925.
84. City of Toronto, "New Vaccine Manufacturing Facility Announced in Toronto," 31 March 2021, *available at* <https://www.toronto.ca/news/new-vaccine-manufacturing-facility-announced-in-toronto/> (last visited July 4, 2024); CBC News, "Government, Sanofi officials unveil $925M in vaccine funding in Toronto," 31 March 2021, *available at* <https://www.cbc.ca/news/canada/toronto/flu-vaccine-production-north-york-toronto-sanofi-1.5970870> (last visited July 4, 2024); M Lowrie, "Feds Hold Ground-Breaking Ceremony for Moderna's MRNA Vaccine Factory in Montreal Area," *Global News* 7 November 2022, *available at* <https://globalnews.ca/news/9258211/groundbreaking-moderna-mrna-vaccine-factory-montreal/> (last visited July 4, 2024).
85. Oxford University, "Oxford University Announces Landmark Partnership with Astrazeneca for The Development and Potential Large-Scale Distribution Of COVID-19 Vaccine Candidate," 30 April 2020, *available at* <https://www.ox.ac.uk/news/2020-04-30-oxford-university-announces-landmark-partnership-astrazeneca-development-and> (last visited July 4, 2024).
86. J. Tasker, "Two years after Trudeau Promised A Made-In-Canada COVID Vaccine, the Country is Still Waiting: The National Research Council Site Hasn't Produced A Single Vial of A COVID-19 Vaccine," CBC News, 20 Aug 2022, *available at* <https://www.cbc.ca/news/politics/canada-waiting-for-made-in-canada-shot-1.6556411> (last visited July 4, 2024).
87. Gold, *supra* note 29.
88. *Ib.* See also A. Edwards, et al., "Stopping Pandemics Before They Start: Lessons Learned from SARS-CoV-2," *Science* 375 (2022) 1133-1139.
89. Herder et al., *supra* note 63.
90. Edwards et al., *supra* note 88.
91. Kaddar et al., *supra* note 25.
92. Z. Kis and Z. Rizvi, "How to Make Enough Vaccine for the World in One Year," *Public Citizen*, 26 May 2021, *available at* <https://www.citizen.org/article/how-to-make-enough-vaccine-for-the-world-in-one-year/> (last visited July 4, 2024).
93. M Luther King Jr., "A Time to Break Silence," Riverside Church, NY, USA, 4 April 1964, *available at* <https://www.americanrhetoric.com/speeches/mlkatimetobreaksilence.htm> (last visited July 4, 2024).

The Journal of Law, Medicine & Ethics, 52 (2024): 467-479.