

Policy Analyses

Canada and the pharmaceutical industry in the time of COVID-19

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Abstract

The COVID-19 pandemic showed the close relationship between the Canadian government and the pharmaceutical industry when it came to both domestic and international issues. Domestically, the government chose to prioritize advice about vaccine acquisition from a panel of heavily conflicted people; it signed contracts worth billions of dollars with companies for vaccines but the contents of contracts were largely kept secret. The government also committed over CAD\$1 billion in funding for research on COVID-19 but without any requirement that any forthcoming intellectual property or diagnostic and therapeutic products had to be accessible and affordable in low- and middle-income countries (LMICs). On the international stage, Canada did not support the COVID-19 Technology Access Pool that aimed to provide a one-stop shop for scientific knowledge, data, and intellectual property to be shared equitably by the global community. It delayed donating vaccines to LMICs and bought vaccines from a facility designed mainly to provide vaccines to that group of countries. The government did not dismantle roadblocks that prevented a Canadian company from sending vaccines to Bolivia. Finally, it was ambiguous about whether it supported a patent waiver for COVID-19 technologies at the World Trade Organization.

Keywords

Canada, pharmaceutical industry, COVID-19, vaccines, World Trade Organization, Bolivia, Biolyse, COVAX

Near the start of the pandemic, two events occurred that would define Canada's approach to the pandemic both domestically and internationally. First, the federal government created the COVID-19 Vaccine Task Force with a one-year mandate (subsequently extended) to provide it with advice around a range of vaccine-related issues. These included prioritizing vaccine projects seeking support for activities in Canada, attracting to Canada promising non-Canadian vaccine candidates, or partnering with developers of non-Canadian vaccine candidates and facilitating solutions to manufacture the most promising COVID-19 vaccines in Canada (1). In setting up the Task Force, the government made a conscious decision to include people who might have current or past ties with companies engaged in vaccine research and/or manufacturing (1). Second, Justin Trudeau, the Canadian prime minister, along with other world leaders, authored an opinion piece in The Washington Post that proclaimed "...we must urgently ensure that vaccines will be distributed according to a set of transparent, equitable and scientifically sound principles. Where you live should not determine whether you live, and global solidarity is central to saving lives and protecting the economy" (2).

This article draws on a 40-year history of analyzing the relationship between the pharmaceutical industry and the

Canadian federal government, as well as a close reading of the academic and mass media literature and reports from government and civil society organizations about how Canada dealt with the pandemic at the domestic and international levels. It will examine how the ideology that produced these two early events unfolded, intertwined, and ultimately revealed the relationship between the Canadian government and the multinational pharmaceutical industry.

COVID-19 AT HOME

COVID-19 Vaccine Task Force, and Conflict of Interest

When the pandemic started, there was no capacity for domestic production of a COVID-19 vaccine in Canada (3). A Sanofi plant in suburban Toronto was producing a wide variety of vaccines for the domestic and international markets, including those for meningococcal disease, polio, tetanus, pertussis,

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and diphtheria, while the GlaxoSmithKline (GSK) operation in St. Foy, Quebec, focused on the influenza vaccine. However, as subsidiaries of multinational companies, the decisions about which vaccines to develop and manufacture were made outside of Canada. The government-owned Connaught Labs was privatized in the 1980s (4) and Quebec-based IAF BioChem went through a couple of sales in the 2000s and ended up being owned by GSK (5).

The most prominent review of the 2003 SARS epidemic in Toronto recommended that Canada develop a "national vaccine strategy" and prioritize the security of vaccine supply (6). A second warning about the need for a secure and steady supply of vaccines happened with the H1N1 pandemic of 2009, when there were production delays at the GSK plant in St. Foy (3). But both of these cautionary tales were largely ignored, such that at the start of the COVID-19 pandemic, the government had no domestic options and as such, it appointed the COVID-19 Vaccine Task Force to provide it with advice. The following description of the activities of and controversies surrounding the Task Force is an updated version of a previous analysis (7).

The government seemed comfortable with its decision to include people with conflicts of interest (COIs) on the Task Force because, according to its webpage, it had "a robust process in place to manage potential COIs. The process related to this advice is in line with similar task forces around the world" (1). As part of that process, members of the Task Force were "required to sign a Conflict of Interest and Confidentiality Agreement and to disclose activities and interests that could place them in a COI situation with respect to the work of the Task Force" (8). From the government website, it was not clear who was responsible for deciding whether the COI should preclude someone from taking part in the discussions and voting. More importantly, the criteria used to determine what was a relevant COI were not disclosed.

In total, the Task Force held 15 meetings with 20 different companies between June 26, 2020, and June 22–23, 2022 (9). Of the 13 Task Force members, only one did not declare a COI at any of the meetings. For the remaining 12 members, the number of COI declarations ranged from one to 13 per person. Neither of the two co-chairs were conflict-free. Conflicts held by chairs and co-chairs are generally thought to be the most relevant because these are typically the people with the most power on a committee or task force. One co-chair of the Task Force, Dr. Joanne Langley, was the person with 13 COI declarations. The other co-chair, Marc Lievonen, was the president of the Canadian branch of Sanofi-Pasteur, a vaccine manufacturer, for 17 years until 2016. When the Task Force discussed the vaccine that was under development by Sanofi/GSK, Mr. Lievonen's COI was not deemed relevant and recusal was not considered necessary, although he recused himself "in an abundance of caution" (10).

Equally as important as the actual COI of the various Task Force members was the process for managing COIs. First, the information in the Conflict of Interest and Confidentiality Agreements was not made public; the only information disclosed was what was declared at the individual meetings. Second, treating each COI as a discrete event failed to recognize that COI is not based on isolated relationships with a single company but rather an understanding of the nature of interactions between individuals and industry and how those interactions can affect decision-making in general. Third, the process for deciding what was and was not a relevant COI was not articulated; as such, decisions could be seen as arbitrary and possibly biased. Finally, when it came to dealing with COI, the government did not go beyond the concept that declaring a COI was all that was necessary to ensure that the Task Force recommendations were free from bias. The cumulative effect of these gaps meant that it was not possible to see what influence, if any, the COIs may have had on the final decisions made by the Task Force.

COVID-19 Vaccine Contracts

According to a March 2021 news release, the federal government, through the Public Health Agency of Canada, expected to spend \$5 billion (all monetary amounts are in Canadian dollars) on COVID vaccines and other treatments (11). Those purchases entailed signing contracts with the manufacturers, but while there were eventually contracts with seven vaccine manufacturers—Moderna, Pfizer, Johnson & Johnson (J & J), Novavax, Sanofi and GSK, AstraZeneca, and Medicago—by mid-fall 2020, their contents were kept secret until June 2021 and then, when released, some sections were heavily redacted (12). According to Matthew Herder, who is the director of the Health Law Institute at Dalhousie University, the redactions made it "impossible to know whether Canada negotiated competitive prices and what assurances it negotiated for the delivery schedules...The government fully or partly redacted more than 20 pages of the Moderna contract, and in several cases also withheld the terms listed in the definitions section" (12). It was not clear who was responsible for the redacted material: the government, Moderna, or both.

The contract between the federal government and Novavax, obtained through the U.S. Securities and Exchange Commission, stipulated that there were no financial penalties imposed on Novavax for failure to submit the vaccine for regulatory approval or for not supplying the product. In those situations, the only recourse Canada had was to recoup its money. Other provisions in the contract meant that any intellectual property (IP) the government generated belonged to Novavax and the Canadian government was required to indemnify Novavax for any claims even if the fault rested with the company (13).

The language in the contract between Novavax and the European Union said that the company would make "best reasonable efforts" to meet delivery timelines, meaning, in simplistic terms, that Novavax would do anything in its power to accomplish the goal, up to declaring bankruptcy.

In contrast, the Canadian contract only said that the company would use "commercially reasonable efforts" to deliver its vaccine on time. "Commercially reasonable" translates into some conscious effort, but Novavax was not obligated to take steps that did not make economic sense for the company (14).

Contributions to Vaccine Research and Development

Early in the pandemic, the federal government committed \$1.1 billion in funding for research on COVID-19, including "close to \$115 million for research into vaccines and treatments...and more than \$662 million for clinical trials led by Canadian researchers" (15). Doctors Without Borders/Médecins Sans Frontières delivered a petition with more than 91,000 signatures to the Canadian Minister of Health, "calling on the Canadian government to take immediate steps to ensure fair, affordable and equitable access to any medicines, vaccines or other health technologies developed with Canadian public funds, including for any innovations developed in response to the COVID-19 pandemic" (16).

However, despite the petition, and like other governments that provided much larger amounts for research and development, there is no evidence that any of the Canadian funding was accompanied by a requirement that any forthcoming IP or diagnostic and therapeutic products had to be accessible and affordable in low- and middle-income countries (LMICs). The House of Commons Standing Committee on Foreign Affairs and International Development recommended "the Government of Canada ensures that its agreements to provide research and development funding include clauses that allow intellectual property resulting from that funding—including vaccines, therapeutics, and diagnostics—to be easily licensed to manufacturers serving low- and middle-income countries" (17). The response from the government was that "public benefit is maximized when IP terms and conditions are tailored to address the specific context and objective of each funding opportunity on voluntary, mutually agreed terms" (18).

This apparent disregard for the public health uses of products that result from publicly funded research mirrors what happened in the development of the Ebola vaccine that the Canadian government initially financed and then largely abandoned to the private sector, where it sat mostly untouched for five years (19).

COVID-19 Internationally

COVID-19 Technology Access Pool

On May 29, 2020, the World Health Organization (WHO) launched the COVID-19 Technology Access Pool (C-TAP), an initiative to accelerate and broaden global access to any forthcoming COVID-19 vaccines, treatments, and diagnostics (20). WHO outlined five priorities for

C-TAP as "a one-stop shop for scientific knowledge, data and intellectual property to be shared equitably by the global community." These included transparency around the publication of clinical trial results, that public research funds should come with strings attached for affordable and equitable distribution, and that any potential discoveries should be licensed to the established and United Nations-backed Medicines Patent Pool.

An article by Jarvis and Lexchin outlined the position that Canada took on C-TAP (21). Initially, C-TAP had the endorsement of 37 countries, including developed ones such as Belgium, the Netherlands, and Norway. The opinion piece in *The Washington Post* with Justin Trudeau as the lead author that appeared a few months later opened with the statement, "None of us is safe until all of us are safe" (2). But Canada was nowhere to be found in the list of C-TAP endorsers. Ms. Jarvis and I noted that "Based on Canada's absence during the launch it appears that ensuring future COVID-19 drugs, vaccines and technologies are shared equitably, particularly with countries with less economic might and global power, is not a priority for the government" (21). Canada's position seemed to be more aligned with that of Albert Bourla, CEO of Pfizer, who said, "I think it [C-TAP] is nonsense and at this point of time it's also dangerous" (22).

COVAX and Equitable Distribution of Vaccines

When the H1N1 worldwide influenza outbreak occurred in 2009, high-income countries placed large advance orders for the vaccine and bought virtually all the vaccines that manufacturers could make. WHO and the United Nations attempted to secure monetary donations to purchase vaccines for LMICs, but donations fell far short of what was needed (23). (Eventually, Canada donated 5 million doses of excess vaccine to the WHO [22], but early in the pandemic, it did not join other developed countries in pledging to donate vaccine because of shortages within the country [21].)

Faced with the knowledge of what had happened in 2009 and concerned that LMICs were going to have difficulty procuring COVID-19 vaccines once they were developed, COVAX was set up in 2020 "to purchase vaccines on behalf of 177 participating countries through Advanced Purchase Agreements (APA) made with manufacturers while vaccines were still being developed" (25). The objective was to procure enough vaccine doses through a combination of donations of vaccine and money from wealthy countries to vaccinate at least 20 percent of the population in participating countries. "Self-financing countries" such as Canada would pay for their own vaccines while 92 LMIC members would receive donor-funded vaccines (25).

An article in *Globalization and Health* pointed out the difference between donating doses versus donating money to buy doses: "Donated doses were an important source of COVAX's vaccine supply in 2021, accounting for 60

percent of the doses the initiative delivered (543 million out of 910 million). However, donations could not compensate fully for COVAX's persistent procurement struggles: it delivered less than half of the two billion doses it originally projected for 2021, a fraction of the 9.25 billion doses that were administered globally in 2021. Donor countries and vaccine manufacturers systematically broke COVAX's principles for maximizing the impact of dose-sharing, delivering doses late, in smaller quantities than promised, and in ad hoc ways that made roll-out in recipient countries difficult" (25). In addition, by the time that COVAX had the capital to begin purchasing vaccines, the wealthy countries had already bought the majority of the supply.

Canada gave approximately \$840 million to COVAX (26) and donated 51 million vaccine doses, ranking it tenth among donors (27), but it was not as generous as the data may make it seem. COVAX was designed primarily to try and ensure that LMICs received vaccine doses, but there was no prohibition against wealthy countries also buying from COVAX. So, despite Canada having advanced purchase agreements with seven companies for up to 379 million doses (28), it also took advantage of the opportunity to purchase vaccine through COVAX and bought 1.9 million doses of the Astra-Zeneca vaccine at a time when virtually no African country and many Asian countries had not received any vaccine doses. No other G7 country purchased vaccine through COVAX, although New Zealand and Singapore did so (29). International Development Minister Karina Gould defended the purchase, saying, "Our top priority is to ensure Canadians have access to vaccines.... COVAX's objective is to provide vaccines for 20 percent of the populations of all member states, both self-financing and those who will receive donations....Canada made the decision, as other countries have, to take on this first allocation, because we recognise how important it is that all Canadians have access to vaccines" (29). Vaccine nationalism was rearing its head in Canada.

Although Minister Gould maintained, in September 2020, that Canada was working behind the scenes to ensure that the new global health architecture taking shape during the pandemic would lead to "a fair, equitable, accessible and affordable vaccine" for Canada and the world (30), in January 2021 Canada rejected a WHO request for an immediate donation of surplus vaccine. A spokesperson for Minister Gould said questions about Canada's surplus doses were hypothetical: "We will be making these decisions once we have a better sense of which vaccines are approved and of what stage our vaccination efforts are at" (31). As of June 2021, Canada was the only G7 nation that still had not committed to donating excess vaccine supply after the United States and the United Kingdom had announced donations of a combined total of 600 million doses over the next year. The Canadian government's response about when donations would be delivered remained vague. They said that they were "waiting to confirm the size of its surplus before making a pledge" (32). In September 2021, Canada finally donated 800,000 doses to Nigeria through COVAX (33), but those doses were set to expire within a few weeks of reaching Nigeria, raising questions about whether Nigeria would be able to distribute them in time.

A year later, according to a report in the *Toronto Star*, Canada had donated the equivalent of 137 million doses, including "50 million surplus doses from Canada's own supply—of which less than half, or 20.8 million, have been delivered—plus the money to buy an additional 87 million more.... Canada has also donated about 3.76 million of its own shots directly to countries in need" (34). Canada had pledged to donate 200 million doses by the end of 2022, but the government always maintained that the pledge consisted of both actual vaccine doses and the money to buy vaccine doses. However, in the absence of any available vaccine to purchase, money was far less valuable than actual physical doses (34). Canada failed to meet its stated goal of the equivalent of 200 million doses by the end of 2022 and, as of April 2023, had donated 197 million (35).

The failure of Canada to donate vaccine doses earlier in the pandemic dosen't entirely rest with the federal government but was also the product of the contracts that the government signed with Pfizer and Moderna in early August 2020 (9). Provisions in the contracts banned Canada from donating surplus doses to LMICs. Those contracts were only renegotiated in late October 2021 to permit donations (36).

Bolivia and Biolyse

Bolivia is a lower-middle-income country with a gross domestic product of just over US\$3,600 per person (37). According to a report for the South Centre, in September 2021 it was experiencing over 300 new cases of COVID-19 per day and had more than 18,600 deaths due to COVID-19 since the start of the pandemic (38). Without any domestic capacity to make a vaccine, Bolivia made the decision to try and avail itself of the provisions of Canada's Access to Medicines Regime (CAMR). CAMR was set up in the mid-2000s in order to take advantage of the World Trade Organization (WTO) provision allowing generic companies based in a country with domestic production capacity to apply for a voluntary or compulsory license to manufacture and export generic drugs to countries unable to produce them on their own (39). The organization representing the major multinational pharmaceutical companies operating in Canada, while giving lip service to the principle behind CAMR, proposed amendments when it was being studied by a House of Commons committee that would have significantly weakened its usefulness (40).

As a first step in the process of availing itself of the provisions of CAMR, Bolivia self-identified as a country wishing to purchase COVID-19 vaccines from Biolyse Pharma, a Canadian pharmaceutical company, and made a general notification of its intent to the WTO in February 2021 (38). Less

than a month later, Biolyse asked J & J for a voluntary license to Canadian and U.S. patents covering the vaccine and its manufacture. Biolyse suggested a 5 percent royalty, but its request was rejected and J & J refused to negotiate (41). The next step was to seek a compulsory license, but before that could happen, the J & J vaccine had to be added to Schedule 1, the list of products eligible for export under CAMR. However, the process to set in motion an order to amend Schedule 1 was not transparent. The CAMR website said that "[a]s of April 2006, an advisory committee was being established and a website will be created" to advise the Ministry of Health and Ministry of Industry about amending Schedule 1. The 2007 Report on the Statutory Review of CAMR repeated the request for an expert committee to be established by May 2008 to advise the two ministries on what drugs should be eligible for export under the regime. As of early 2021, there was still no website and the advisory committee had never been constituted (42). Representatives for Biolyse had close to 30 meetings with high-level officials of the Canadian government's Innovation, Science and Economic Development program; Health Canada; and the Canadian Intellectual Property Office to discuss the process of adding the COVID-19 vaccine to Schedule 1, but after nearly six months of effort, Biolyse was not able to even get the CAMR process started.

In addition to adding the J & J vaccine to Schedule 1, companies seeking a compulsory license needed to fill in a number of prescribed forms. To help advise companies on this process, the CAMR contact website listed two phone numbers: "The first number provided is invalid and out of service and when calling and leaving a message for the second number, there was no response. Additionally, the compulsory license application forms are not readily available. Applicants are directed to call the Canadian Intellectual Property Office (CIPO) to gain access to the forms. Yet the only contact numbers provided are general CIPO phone numbers, there is no specific compulsory license contact number, enquiry form, or CIPO webpage" (42). Biolyse was never successful in being able to export a COVID-19 vaccine to Bolivia.

When asked about the Biolyse-Bolivia case, the Acting Senior Assistant Deputy Minister, Strategic and Innovation Policy, Department of Industry, took the position that "Canada has not received a formal proposal through the CAMR process." Mr. Benjamin Blanco Ferri, the Plurinational State of Bolivia's Vice Minister, Foreign Trade and Integration, countered by saying, "Bolivia's request was clear and direct with Canada" and that it only required "political will", referring to political will on the part of the Canadian government (17).

Due to what happened with Biolyse and Bolivia, the House of Commons Standing Committee on Foreign Affairs and International Development recommended that the government immediately launch a public consultation on CAMR (17). The government responded that it "takes note of the recommendation" but dismissed it on the

grounds that "the complex legal and technical considerations that must inform any potential reforms to Canada's Access to Medicines Regime" broad public consultation would not be the most effective platform to gather insight on the mechanism (18).

World Trade Organization and the Waiver of Intellectual Property Rights

In anticipation of the difficulty of LMICs gaining early access to any COVID-19 vaccine if a business-as-usual approach was applied, in October 2020 India and South Africa, eventually supported by more than 100 other developing countries, proposed to the WTO that intellectual property rights (IPR) provisions in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement should be waived on a limited-time basis. The waiver would free up scientific knowledge, technology, and other IP to allow for scaling up the manufacturing of vaccines, diagnostics, treatments, and other products necessary to deal with the pandemic (38). The waiver was meant to not only increase the independent supply of the various COVID-19 vaccines that were currently available, but also to ensure a supply of vaccines for booster shots, ensure vaccines would continue to be affordably priced once companies such as Pfizer (43) and Moderna (44) increased their prices, and allow for much wider manufacturing of other medications and products necessary for the pandemic.

Countries opposed to the waiver raised a number of objections that were summarized in a report from the Third World Network: (a) TRIPS flexibilities already provided various options for members, including through Article 31 and Article 31bis; (b) global voluntary mechanisms would ensure that members had access to vaccines, therapeutics, and diagnostics; (c) pharmaceutical companies were already entering into licensing agreements to produce vaccines; (d) companies had pledged not to enforce their IPR or they undertook not to profit until COVID-19 came to an end; (e) the waiver proposal would destroy innovation, research, and investment in the pharmaceutical sector and would act as a disincentive for pharmaceutical companies; (f) the mechanism for the waiver to be implemented was not clear; (g) there was no evidence that IPR was a barrier to accessing vaccines, treatments, or technologies in the global response to COVID-19; and (h) the waiver would facilitate trade in counterfeit medicines (45). These objections were addressed by various proponents of the waiver, including South Africa, India, Pakistan, Egypt, Zimbabwe, Indonesia, and China (45).

Furthermore, as Labonté and Johri noted in their commentary in *The Globe and Mail*, support for the TRIPS waiver did "not mean that patent-holding companies will go unrewarded, though controls will need to be developed to determine the extent of that reward and limit the knowledge monopoly at least until the pandemic is over. The waiver

would treat such health products and knowledge as 'global public goods,' which is quite reasonable, given the billions in public monies that supported the private sector research that led to their discoveries" (46).

It might have naively been assumed that Canada would support the waiver since at the beginning of the pandemic, Parliament passed Bill C-13, which, among other things, contained a clause allowing for compulsory licensing for drugs if the supply was interrupted because of the effects of COVID-19. Under the bill, the government could issue the license almost immediately without having to first enter into negotiations with drug companies (47). Some of Canada's closest allies, such as the United States (48) and Australia (49), also supported the patent waiver, although in the case of the United States, it was only for vaccines. When asked about the TRIPS waiver in a press conference shortly after the U.S. announcement of support, Justin Trudeau refused to say whether his government supported or opposed the call for a temporary suspension of vaccine patents. He assured reporters that "Canada is not interfering or blocking, Canada is very much working to find a solution that works for everyone" (36).

However, the Canadian government sent out decidedly mixed messages depending on the audience. On the one hand, through the Ottawa Group for WTO reform that it established in 2018 with likeminded WTO members, Canada "championed a Trade and Health Initiative that called for implementation of trade-facilitating measures in the areas of customs, services and technical regulations; the temporary removal of tariffs on essential medical goods; and improved transparency" (17). On the other hand, according to a South Centre report, Canada was reinforcing its position on neither supporting nor opposing the waiver. "On May 7, Mary Ng, Canada's Minister of Small Business, Export Promotion and International Trade, stated that '[t]he Government of Canada remains committed to working with all international partners to reach a rapid and just end to the COVID-19 pandemic.... We remain committed to finding solutions and reaching an agreement that accelerates global vaccine production and does not negatively impact public health.... Canada has always been, and remains, a strong advocate for equitable access to vaccines and medical supplies around the world" (38). At the same time, Minister Ng was also saying that Canada "firmly believes in the importance of protecting IP, and recognizes the integral role that industry has played in innovating to develop and deliver life-saving COVID-19 vaccines" (38). (Minister Ng did not explain why, if the government was supportive of IP, it had passed a bill that temporarily allowed for compulsory licensing.) Canada's ambassador to the United States, Kirsten Hillman, stressed that "[o]ur position [on the TRIPS Waiver] is to discuss this with our allies, to discuss this with our WTO partners, and to make sure that we proceed in a way that is going to achieve the goals of ensuring the continued development of these vaccines" (38). Finally, just to add to the ambiguity, the Canadian

ambassador to the WTO maintained that Canada's position had always been that it was "ready to join a consensus on the waiver issue" and would "actively engage in discussions should a text come forward" (17).

In May 2021, the federal government said it would take part in international talks at the WTO about the waiver, but it did not say which side of the debate it would be arguing on, despite 30 Liberal members of Parliament signing a multi-party letter urging it to support the waiver (50). At the WTO meeting, Canada and six other countries called on the WTO to convene discussions with vaccine manufacturers to encourage licensing agreements and technology transfers. Canada argued this proposal would provide a broader range of solutions than the patent waiver (51), ignoring the failure of any pharmaceutical company to participate in C-TAP. Canada also continued to ask for convincing evidence information that IPR posed a genuine barrier to accessing COVID-19 vaccines. Despite all these contradictory statements, the press secretary for Minister Ng denied that Canada was rejecting the waiver proposal: "We are committed to finding consensus-based solutions.... Canada welcomes any further information on these questions, and continues to engage WTO members...in order to identify specific IP-related barriers" (51).

A major reason for the government's failure to decisively support the waiver was its relationship with the pharmaceutical industry regarding domestic policy. At the time of the May 2021 WTO meeting, Canada was still negotiating vaccine deliveries and facing off with drug companies about controversial changes to the Patented Medicine Prices Review Board guidelines that would significantly lower drug prices (52). Innovative Medicines Canada (IMC), the group representing the major multinational pharmaceutical companies, firmly rejected the idea of a waiver (50), a position it repeated six months later in a press release: "Waiving TRIPS Intellectual Property (IP) protections will not address the real issues of trade barriers, global supply chain bottlenecks, and scarcity of raw materials that are impacting the supply of COVID-19 vaccines. IP protection is a crucial element for a thriving life sciences sector and therefore we urge Canada and other nations to ensure that any negotiated agreement effectively addresses the problem of global vaccine access and does not undermine vaccine production or negatively impact public health.... Since it will not address the real issues afflicting vaccine supply and distribution, Innovative Medicines Canada does not support the proposed TRIPS IP waiver for COVID-19 vaccines at the WTO" (53). IMC made it clear to the government that "temporarily suspending patents at the WTO would be 'a disappointing step that will create greater uncertainty and unpredictability' for the future supply of vaccines" (36).

The Canadian government was also being heavily lobbied over the waiver by the industry and there were frequent meetings between the two parties, according to reports in *Politico* (54) and *The Breach* (36). Government officials provided

detailed updates to the industry about how discussions of the waiver among WTO members were proceeding. A summary of one government-industry meeting says the participants appreciated the "delicate political situation" Canada was facing and underscored "the importance of further collaboration with industry" (54). In a September 2021 meeting, government officials provided industry with another update on negotiations at the WTO, and all parties agreed to "remain in contact and to share information and developments on the waiver" (54).

The Breach's extensive documentation of the lobbying (36) found that there were at least 28 lobbying contacts by the industry with ministers and high-level bureaucrats responsible for international trade policy at the WTO. On April 29, 2021, lobbyists from Pfizer, J & J, and IMC lobbied Innovation Minister François-Philippe Champagne and his policy advisor about international trade and IPRright before an April 30 meeting of the WTO's TRIPS Council where negotiations over the waiver were on the agenda. Pfizer and IMC each lobbied Minister Ng and her chief of staff shortly after the U.S. announcement of its support of the patent waiver. IMC contacted Steve Verheul, the deputy minister responsible for Canada's trade policy at the WTO and other forums. Pfizer lobbyists followed up with Verheul shortly after. All these communications had to do with international trade and IPR, according to the lobby registry. According to the report in The Breach, Big Pharma was clearly satisfied with the work done on its behalf and IMC offered fulsome praise for the Trudeau government's "ongoing collaboration" with the industry, declaring that Canadian trade officials "should be commended for their work" at the WTO (36).

Ultimately, on June 17, 2022, during the twelfth WTO Ministerial Conference, a decision was reached on the TRIPS waiver. However, it was an extremely watered-down version of the original proposal. It only covered exporting vaccines under a compulsory license and expired after five years. It did not include any other COVID-19-related medical products, including treatments and diagnostics or transfer of know-how and technology needed to safely and effectively scale up production in the fastest way possible. Furthermore, according to WEMOS, a Dutch development organization, the "WTO decision is not a proper recognition of intellectual property rights as a barrier for increased production capacity of key medical products" and amounts to a "prioritization of the economic interests of high-income countries over global health equity" (55). Finally, according to WEMOS, "there is a risk that the decision will function as blueprint for pandemic accord negotiations, compromising meaningful provisions to achieve equitable access to medical products in future frameworks" (55).

While discussions on expanding what was covered by the decision were supposed to take place within six months, that debate has been postponed indefinitely. The House of Commons Standing Committee on Foreign Affairs and International Development recommended that the Government of Canada advocate for an extension to cover the production and supply of COVID-19 diagnostics and therapeutics (17). The government responded with an anodyne statement that it "continues to engage with WTO Members on this matter, and to encourage an evidence-based exchange among WTO Members, with a view to identifying whether Members have experienced challenges related to the production and supply of COVID-19 diagnostics and therapeutics, related to or arising from the TRIPS Agreement" (18).

While strong and ongoing opposition to the original proposal from the European Union, United Kingdom, Norway, Switzerland, Singapore, and Japan—and only limited support from the United States—played the dominant role in the final decision about the waiver, there is no doubt that the lack of leadership from Canada was also significant.

Ongoing Domestic and International Issues

As vaccination rates in Canada were rising in 2021, the federal government announced a biomanufacturing and life sciences strategy with the aim of building resilience in this critical sector. The strategy was built on the foundation that "the ability [of Canada] to ensure priority access to a domestically produced, filled and finished pandemic vaccine is critical to mitigating the risks of a global health emergency" (56). As part of the strategy, the government so far has invested more than \$2.1 billion in 36 COVID-19 domestic biomanufacturing, vaccines, and therapeutics projects across the country (57). Separately, the government announced a partnership with Sanofi to invest \$925 million in a flu vaccine facility, with the federal and provincial public sectors contributing \$470 million of the total. Negotiations with Sanofi were underway over a contract to supply the federal government with vaccines during a future flu pandemic, but no details about the contract are available (58).

The only part of the strategy that even approaches the notion of public ownership is the public-private partnership that runs the Biologics Manufacturing Centre that opened in Montreal in 2022. The Centre is a contract production facility that "participates in the production of vaccines and other biologics according to the specifications and quality characteristics specified by each client" (59). As a contract production facility, the Centre will not be the organization making the initial decision about what kind of vaccines to produce. The viability of public ownership of an agency that could develop and manufacture vaccines has been contested by a report from a free-market think tank (60), but the Canadian government has not even committed to fully exploring the issue.

Internationally, the most important initiative in dealing with future pandemics is the ongoing negotiation on a pandemic treaty under the sponsorship of the WHO (61). The Canadian government has taken the lead in one aspect of

treaty negotiations by convening a two-day meeting of approximately 100 representatives of Canadian provinces and territories, Indigenous peoples, youth, civil society, the private sector, and academia (and another 100 participants virtually) to "help inform the development of Canada's priorities and objectives in the creation of a pandemic instrument" (62). But while the meeting was a good first step, it was also flawed. There is no evidence that Health Canada's Office of International Affairs consulted with any of the stakeholders it invited to discuss issues on which the stakeholders wanted to provide feedback. The questions posed to the attendees, while interesting, seemed to reflect issues that the Office wanted feedback on, rather than issues that the attendees wanted to discuss. The background document only mentioned positive actions that the Canadian government undertook during the pandemic and did not deal with any of the criticisms about the government's actions and inactions. The document also cited a statement made by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) without acknowledging the COI that the IFPMA has in discussing the volume of vaccine production.

One of the core principles that should underlay any final treaty is an acceptance of "common but differentiated responsibilities" (CBDR). The principle holds that those with greater culpability and capability and less vulnerability must step up and take the responsibility of addressing any future pandemic. Habibi and Wenham note that "while some entities see CBDR as the key to achieving health equity among the world's nations, others, including Canada, view it as a divisive and unworkable concept in global health law" (63).

Médecins Sans Frontières has analyzed Canadian amendments to the current version of the draft pandemic treaty. According to the organization, "Canada seems more insistent than any other country—except possibly the U.S.—that any tech transfer under the pandemic treaty take place on voluntary and/or mutually agreed terms. In other words, even in a pandemic, the maker of a life-saving vaccine or drug would have no obligation to help" other countries access its vaccine. The Canadian amendments would insert language about voluntary and mutually agreed-upon terms directly into a treaty article "which sets out equity as a guiding principle of the treaty" (64).

Conclusion

The actions of the government described here should not be seen as isolated events but rather as a continuation of the relationship between the Canadian state and the pharmaceutical industry. When there are choices to be made, they reflect a set of underlying values, values that can be analyzed. Private values are antithetical to democracy; they speak to the need to earn a profit, not to protect public health. When government adopts the values of private industry, it is in essence telling its people that the needs and values of the private sector take precedence over their health. When the

former came into conflict with the latter during the pandemic, the Canadian government took the side of the industry. On the domestic front, Canada prioritized secrecy, an acceptance of COI, and a free-market system when it came to vaccines. Internationally, Canada continued a two-decade tradition of favoring IPRs when they came into conflict with promoting access to vaccines in LMICs (65).

When the Liberals were elected in 2015, Justin Trudeau proclaimed that "Canada is back" (66). The pandemic showed that the government never left the side of the pharmaceutical industry.

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