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The Kindest Cut

Excising the Patented Medicine Prices Review Board from the Canadian Body Politic

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A BETTER PATH on Canadian drug prices
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Contents

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Executive Summary

Canada's drug price controls, implemented through the Patented Medicine Prices Review Board (PMPRB), hurt both innovation in the life sciences sector and Canadians' access to pharmaceuticals. The PMPRB was created in 1987 as an expedient to placate opposition to the passage of much-needed intellectual property (IP) law reforms. Pharmaceutical science has changed dramatically since then; the PMPRB has not.

In 2018 the federal government attempted to modernize the PMPRB through ill-conceived New Regulations. While the government appears to have bowed to constitutional inevitability and withdrawn key portions of the New Regulations, there is no guarantee that similar regulations will not be promulgated in their place. As such, it is important to assess the fundamental problems with them.

Like the bulk of the New Regulations, the PMPRB itself has no constitutional foundation. It exceeds the powers of the federal government, amounting to industrial price controls, which are a provincial, not a federal, power. Moreover, even if the PMPRB edifice continued to stand on its shaky constitutional footings, case law makes clear that the *Patent Act* doesn't authorize price controls as PMPRB applies them.

To the PMPRB and its defenders, drugs are products uniquely inimical to distribution in a free market. But drugs are also goods, subject to market scarcity and value calculations, and their prices are normal prices. PMPRB price controls, like any price control, limit supply and availability and curtail the development of new products. If government and the courts want to encourage Canadians' good health, they should stop supporting price controls.

A 2018 MLI study addressed the question of whether Canada can lower prices and simply rely on the US for its innovation. But that is not a sustainable approach to pharmaceutical innovation in Canada, nor health care. Like the rest of the world, we exploit the US consumer to fund our drug supplies. As a result, the US itself is now considering its own price controls. If implemented, they would effectively slaughter the world's pharmaceutical golden goose.

Leadership is urgently needed to re-balance cost-sharing internationally. Canada can demonstrate that leadership, benefiting its innovation economy and leading the world toward a more equitable allocation of the costs and benefits of pharmaceutical science. A low-price regime will inevitably hurt the life sciences sector and adversely impact industry employment and, ultimately, the Canadian economy. US prices should be reduced as other nations, including Canada, shoulder a more proper share of their economic burden.

Life sciences patent monopolies bring into being the very things to which they apply. Profits are well-earned and a necessary incentive. A patent on a successful drug offers the potential for a financial prize. Only with such a promise can the economy of drug discovery function. Innovation can never be centrally planned or controlled; it arises from sound economic, institutional and legal conditions that we mess with at our peril.

Evidence also strongly suggests that a pharmaceutical market without price controls works well. Competition among therapies, as well as other market constraints on pricing power, are among the factors that limit pricing freedom. Without price controls, Canada would benefit from greatly improved access to new drugs and therapies.

By preserving price controls, we depress our life sciences industry and hurt health care. Worse still, the PMPRB and its adherents have political incentives to demonize and diminish the life sciences sector, since the more it grows and contributes, the harder it would be to justify confiscatory PMPRB price controls. We could hardly have a policy better aimed at undermining Canadian science and industry than institutionalized drug price controls.

The PMPRB alleges that it saves Canadians money. But it is never clear how much. The PMPRB is a clumsy tool that harms drug access rather than promoting it. Price ceilings limit drug revenues, which reduce R&D spending on drug discovery and make Canada an undesirable location for conducting clinical trials and launching new drugs. Importantly, removing price controls will have little impact on most drug purchases in Canada. It is time to scrap the PMPRB altogether.

Sommaire

Le contrôle des prix des médicaments au Canada, mis en œuvre par le Conseil d'examen du prix des médicaments brevetés (CEPMB), nuit à la fois à l'innovation dans le secteur des sciences de la vie et à l'accès des Canadiennes et des Canadiens aux produits pharmaceutiques. Le CEPMB a été mis sur pied en 1987 pour surmonter l'opposition à l'adoption d'indispensables réformes du droit de propriété intellectuelle (PI). La science pharmaceutique a évolué de façon spectaculaire depuis, ce qui n'a pas été le cas du CEPMB.

En 2018, le gouvernement fédéral a tenté de moderniser le CEPMB au moyen d'une nouvelle réglementation peu avisée. Bien qu'il semble avoir dû se rendre à l'évidence constitutionnelle et supprimer certaines parties clés de la nouvelle réglementation, rien ne garantit que des réglementations similaires ne soient pas promulguées à leur place. Il est donc important d'évaluer les problèmes fondamentaux qu'elles posent.

La majeure partie de la nouvelle réglementation n'a, comme le CEPMB lui-même, aucun fondement constitutionnel. Elle va au-delà des pouvoirs du gouvernement fédéral en instituant l'équivalent d'un contrôle des prix industriels, système qui relève d'une compétence provinciale et non pas fédérale. De plus, même si la structure du CEPMB continue de s'appuyer sur des bases contestables sur le plan constitutionnel, il n'empêche que la jurisprudence indique clairement que la Loi sur les brevets n'autorise pas les contrôles de prix tels que les applique le CEPMB.

Pour le CEPMB et ses défenseurs, les médicaments sont des produits qui ne se prêtent pas à une distribution sur un marché libre. Or, les médicaments sont aussi des biens, c'est-à-dire qu'ils sont soumis aux impératifs de rareté et du calcul marchand et qu'ils sont tarifés aux prix habituellement pratiqués. Les contrôles de prix du CEPMB, comme tous les contrôles de prix, limitent l'offre et la disponibilité et freinent la conception de nouveaux produits. Le gouvernement et les tribunaux doivent cesser de les appuyer s'ils souhaitent préserver la santé des Canadiens.

Dans une étude publiée par l'Institut Macdonald-Laurier en 2018, la question est posée de savoir si le Canada peut réduire les prix et simplement compter sur les États-Unis pour progresser dans le domaine de l'innovation. Il s'agit d'une approche qui n'est pas viable pour l'innovation pharmaceutique au Canada et qui ne l'est pas non plus pour les soins de santé. À l'instar du reste du monde, c'est en exploitant le consommateur américain que nous finançons notre approvisionnement en médicaments. Et c'est pourquoi les États-Unis eux-mêmes envisagent maintenant de mettre en place leurs propres contrôles des prix qui, s'ils sont mis en œuvre, tueront la poule aux œufs d'or qu'est l'industrie pharmaceutique mondiale.

Il est urgent de faire preuve d'esprit d'initiative pour rééquilibrer le partage des coûts à l'échelle internationale. Le Canada peut donner l'exemple, ce qui profitera à son économie de l'innovation et pourra guider le monde vers une répartition plus équitable des coûts et des avantages de la science pharmaceutique. Un régime de prix bas nuira inévitablement au secteur des sciences de la vie et aura un impact négatif sur l'emploi dans l'industrie et, en fin de compte, sur l'économie canadienne. Les prix américains devraient être réduits à mesure que d'autres nations, dont le Canada, assumeront une part plus adéquate du fardeau économique.

Les monopoles conférés par les brevets dans le domaine des sciences de la vie donnent naissance aux résultats mêmes qu'ils sont censés atteindre. Les bénéfices sont bien mérités et constituent une incitation nécessaire. Un brevet sur un médicament efficace offre la possibilité d'obtenir une récompense financière, et ce n'est qu'avec une telle promesse que s'exerce la fonction économique de la découverte de médicaments. L'innovation ne peut jamais être planifiée ou contrôlée de manière centralisée; intervenir sur les conditions économiques, institutionnelles et juridiques à son origine se fait à nos risques et périls.

Les faits laissent également fortement supposer que les marchés pharmaceutiques fonctionnent bien sans contrôle des prix. La concurrence entre thérapies ainsi que d'autres contraintes du marché sur le pouvoir de fixation des prix font partie des facteurs ayant un effet de limitation sur la libre fixation des prix. Sans contrôle des prix, le Canada bénéficierait d'un accès grandement amélioré aux nouveaux médicaments et aux nouvelles thérapies.

En conservant les contrôles des prix, nous affaiblissons notre industrie des sciences de la vie et les soins de santé. Ce qui est encore plus préoccupant, c'est que le CEPMB et ses défenseurs sont fortement inclinés, pour des raisons politiques, à diaboliser et à fragiliser le secteur des sciences de la vie, car plus ce secteur devient florissant, plus il devient difficile de justifier les contrôles confiscatoires des prix. On pourrait difficilement trouver une politique plus efficace que le contrôle institutionnalisé des prix des médicaments pour nuire à la science et à l'industrie canadiennes.

Le CEPMB prétend qu'il permet de réaliser des économies. Or, il ne précise jamais dans quelle mesure. Le CEPMB est un outil inefficace qui nuit à l'accès aux médicaments plutôt que de le favoriser. Les plafonds de prix limitent les recettes, ce qui réduit les dépenses de R et D pour les découvertes pharmaceutiques et fait du Canada un endroit indésirable pour la réalisation d'essais cliniques et le lancement de nouveaux médicaments. Fait important, la suppression des contrôles de prix aura peu d'impact sur la plupart des achats de médicaments au Canada. Il est temps d'éliminer complètement le CEPMB.

Introduction

Canada's drug price controls, implemented through the Patented Medicine Prices Review Board (PMPRB), diminish both innovation in the life sciences sector and Canadians' access to pharmaceuticals. The PMPRB is grounded on unsound policy and the illegitimate exercise of federal power, and it is ill-suited to respond to changes in modern pharmaceutical science.

The PMPRB bureaucracy and its defenders seem to think drug pricing to be unique, as if drugs were products uniquely inimical to distribution in a free market. Recently, the Quebec Court of Appeal wrongly sustained federal power to control drug prices, effectively shrugging its collective judicial shoulders, by saying that drug patents are special and that "public interest" justifies extending federal jurisdiction over them. But drug patents are not special. Indeed, for many reasons, they are no less well suited to a free market than any other good. Canadians would benefit greatly from removing government interference in drug pricing and distribution.

The PMPRB was improvised in 1987 to placate opposition to the passage of much-needed intellectual property (IP) law reforms. Pharmaceutical science has changed dramatically since then; the PMPRB has not. In 2018 the federal government attempted to modernize the PMPRB through new regulations (New Regulations). These poorly thought out amendments would have only dragged the PMPRB backward.[1] While the government has quietly shelved portions of the New Regulations, they have yet to announce their replacement at the time of writing – and there is no guarantee that similar regulations will not be promulgated in their place. As such, and because of the importance the PMPRB placed on passing the New Regulations, it remains important to assess the fundamental problems with them.

The destructive impacts of the PMPRB are not confined to Canada; like the rest of the world, we exploit the US consumer to fund our drug supplies. This exploitation has created economic pressures so great that the US itself is now considering price controls. Were price controls to be implemented in the US they would effectively slaughter the world's pharmaceutical golden goose. Leadership is urgently needed to re-balance cost-sharing internationally. Can-

ada can demonstrate that leadership, benefiting its innovation economy and leading the world toward a more equitable allocation of the costs and benefits of pharmaceutical science.

This is the first of two papers in this series. The first paper will examine the peculiarities and weaknesses of PMPRB and the New Regulations and set out comprehensive recommendations for reform. The second paper will critically examine drug price controls and their theoretical and empirical underpinnings in the context of international markets for pharmaceuticals.

A legislative history of the PMPRB

The PMPRB was created by amending the 1920 *Patent Act*. At first, the Act did not specifically refer to drugs (Eastman Commission 1985); medicines were merely patentable like other inventions (Smith 1993). In 1923, the Act was amended to provide for compulsory licensing for manufacturing purposes of food and drugs (Smith 1993), which was meant to encourage multiple companies to manufacture the same product in Canada to increase competition (Lexchin 1993). However, until the compulsory licensing power was extended in 1969, only 22 licences were granted (Eastman Commission 1985), largely because compulsory licences required that manufacturers produce the chemical ingredients for their drugs in Canada (Orlhac 1990). Two issues arose: first, generic producers did not have the capacity to manufacture in Canada and second, those who had the capacity abused their licences by increasing the prices of patented medicines (Morin and Forcier 2011). Not surprisingly, protectionist rules gave rise to abuse, not self-sufficiency.

A royal commission was established, and the report of the Special Committee on Drug Costs and Prices was published (Canada 1966). It found that Canada's drug prices were among the highest in the world.[2] Prime Minister Pierre Trudeau decided to amend the Act in 1968 to extend compulsory licensing, allowing holders to import medicines into Canada rather than manufacture them domestically (Lexchin 1993).[3] The Commissioner was given powers to grant licences to anyone he deemed fit, with the result that most licences were granted to interested parties (Morin and Forcier 2011). In 1983, drug prices in Canada were about $200 million lower than they would otherwise have been, in part, due to the 1969 Act (Morin and Forcier).

Throughout this time, the Pharmaceutical Manufacturers Association of Canada (PMAC) campaigned consistently against compulsory licensing, specifically promising to spend more on research and development (R&D) in Quebec in exchange for an end to compulsory licensing (Lexchin 1993). Yet, the Eastman report found that the generic producers had only taken 3.1 percent more market share than brand-name producers and Canada's drug profit lev-

els were still high compared to other developed countries (Eastman Commission 1985). However, while overall industry profits were arguably maintained, there was a transfer of wealth from innovators to copiers – hardly a sensible allocation of incentives.

Bill C-22

In 1968, Prime Minister Pierre Trudeau took a further step and abolished patents for pharmaceuticals; according to Paul Lucas, retired president and CEO of GlaxoSmithKline Canada, this caused the decline of the innovative pharmaceutical industry in Canada (Corbella 2021). Trudeau's objective was to encourage domestic drug manufacturing and lower drug prices, but his actions instead resulted in research centres shutting down operations in Canada (Lucas 2020).

In the background, PMAC continued to lobby against compulsory licensing into the 1980s, eventually gaining support from Quebec where much of the pharmaceutical industry was located (Lexchin 1993). In the 1980s, the Mulroney government was encouraged to act in favour of the innovator companies (Lexchin 1993). On top of that, the government was in free trade negotiations with the United States, which was pressuring Canada to change its compulsory licensing legislation (Lexchin 1993). The lower prices created by Trudeau's removal of patent protection had hit American drug companies the hardest (Burns 1987). America claimed that Canadian policy was undercutting efforts to gain patent protection in developing countries (Burns 1987). By late 1987, the Conservative government passed Bill C-22 as a means to get drug companies to invest in Canada's drug market by extending patent protection to pharmaceutical products and stopping generic producers from circumventing patent protection (Morin and Forcier 2011). C-22, in turn, provided for the creation of the PMPRB (PMPRB 2004).

Bill C-22 guaranteed patent holders protection against compulsory licences to import for 10 years, and protection of seven years against compulsory licences to manufacture (Smith 1993; Harrison 2001). It also included an exception to the 10-year limit for those who chose to produce within Canada, contrary to the US government's wishes (Morin and Forcier 2011). Further, it granted protection to the product itself, rather than protecting only the process by which the product was made (Smith 1993). This made it harder for generic drug companies to manufacture similar drugs by using slightly different processes with the same compounds as the brand-name products.

C-22 was delayed for several months by the Senate and was criticized for its potential impact on the introduction of generic drugs into the Canadian market (Smith 1993). However, the most controversial aspect of the bill was the creation of the PMPRB, which the Senate vehemently opposed (Chromecek 1987). The Senate feared that the proposed reforms were conditions of the

Canada-US Free Trade Agreement, which the federal Liberal and NDP parties opposed at the time (Blake 2007, 22). Opposition parties were also worried that PMPRB would not be able to keep drug prices consistent with the rate of change in the Consumer Price Index (CPI) while ensuring new drugs were priced at a reasonable level (Smith 1993). These reforms barely made it past the Senate (Trew 2013). Far too much opposition to free trade and property rights persists in Canada.

The association of Canada's research-based pharmaceutical companies, Rx&D (now Innovative Medicines Canada (IMC)), had expressed its intention to invest 10 percent of its annual sales in Canadian R&D to support C-22 (Williams 2012). This Faustian agreement was heavily targeted by opposition Liberals skeptical of C-22 and the PMPRB's impact on Canada's pharmaceutical and research market. For the most part, Parliamentary debates in 1986 and 1987 focused on two main criticisms of the PMPRB: that it would increase drug costs by extending patent holders' rights, and that the promise of investment in R&D was an empty one.

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Indeed, according to PMPRB statistics, research levels have fallen short of the promise. This may be for several reasons. First, the structure of industry R&D has changed and the PMPRB statistics gathering methodology has failed to account for this. Also, a representation from an industry association is one thing, but to actually coordinate member investments is something else. Continuing poor government policy on pharmaceuticals, including common-law developments, created powerful disincentives to invest in Canada. There never was a legal mechanism to enforce the promised investment. And anyway, such bargains for investment are not productive. They are based on horse-trading political favours for static market share, rather than on nurturing open-ended growth in a well-structured innovation ecosystem.

While the pharmaceutical industry was initially on the path towards reaching IMC's 10 percent investment goal, R&D investment since 2001 has been consistently below 10 percent (Lexchin 1993; Blackwell 2014). In its 2019 Annual Report, Innovative Medicines Canada claimed to have invested "more than $1-billion" on R&D every year, supposedly 10 percent of its yearly revenues (Innovative Medicines Canada 2019). However, according to the PMPRB's 2019 annual report, R&D investment by Canadian pharmaceutical companies has fallen below $1 billion since 2011 (PMPRB 2019). Further, industry R&D

spending by fell 9.9 percent between 2011 and 2019 (PMPRB 2019). Canada is on the lower end of R&D investment globally, especially when compared to the US$83 billion spent in the United States in 2019. This represents a marked increase of almost 10 times what the US was investing in the pharmaceutical industry in the 1980s (Congressional Budget Office 2021).

In its 2019 report, the PMPRB added a disclaimer – that a multitude of factors drive pharmaceutical R&D, including where companies find reasonably priced bases for operations and clinical trial infrastructure. It should also be noted that PMPRB's statistics only account for companies that sell patented medicines; those manufacturing non-patented medication do not need to report their R&D expenditures (Annual Report 2019). The PMPRB's R&D statistics do not properly account for all pharmaceutical research in Canada; a large percentage of research investment is missed.

A main challenge is placing the costs of R&D within the context of the new molecular entities (NMEs) that companies can launch each year (Schuhmacher et al. 2016). Thus, more companies have realized their in-house R&D is inefficient, leading them to reduce R&D costs by outsourcing (Schuhmacher et al. 2016). In a study published in the *Journal of Commercial Biotechnology*, Sarah Kruse and colleagues found 73 percent of companies had re-evaluated their R&D departments. The same study also found the preferred cost-saving method was "strategic partnerships" that allowed them to externalize expenses while growing innovation (Kruse et al. 2014). Indeed, most research-based pharmaceutical companies are accessing research and drug candidates from external sources to "supplement their in-house pipeline and meet … their growth objectives by product innovation" (Schuhmacher et al. 2016).

Schuhmacher and colleagues also found that the industry standard for multinational pharmaceutical companies was 50 percent of R&D being externally generated (Schuhmacher et al. 2013). As such, because they don't account for external factors, PMPRB statistics on R&D annual investments might not be accurate. An Ernst & Young report noted that the PMPRB's assessment of R&D investments has not kept up with the evolving infrastructure of the industry (Ernst & Young 2017). Their data showed that R&D investments totalled 9.97 percent of gross patented produce revenues in 2016. But this misses the point – economic growth is not a product of politics, but of creating a healthy innovation ecosystem.

Misleading commentary on drug patents and pricing has remained a constant, with some professors claiming the research deal was a "cash grab" or that patent protection in a country that only holds just over 2 percent of the world market will not influence how much companies spend on research in Canada (Blackwell 2014). Carleton professor Marc-André Gagnon described the current state of Canada's R&D and the promises to fund it "as empty as west Montreal's abandoned research centres." Gagnon argues there is no reason

to invest if the government keeps extending patent protections, alleging that global pharmaceutical companies can now choose from an array of jurisdictions "much more freely than a consumer can shop for drugs" (Webster 2015).

Such comments seem fixated on outdated notions of coercion and industrial policy instead of sound structures to encourage growth through new investment. Moreover, in the 21st century, their arguments are moot. As a member of the World Trade Organization and signatory to treaty pledges of IP protection, Canada no longer has significant room to degrade its IP protection for the life sciences sector in ineffectual attempts to bully investment from that sector. It is time instead to adopt policies that will be socially and economically constructive.

Bill C-91

The five-year review of Bill C-22 resulted in Bill C-91, introduced in 1992 in the House of Commons (Smith 2001). Bill C-91 eliminated compulsory licences for pharmaceutical products and allowed two exceptions to patent infringement. The "early working" exception allowed someone to use a patented invention while an existing patent was in force only for obtaining regulatory approval for a similar product after that patent has expired. The "stockpiling" exception allowed for someone to manufacture and store a product they intended to sell after the patent expired (Smith 2001). In effect, Bill C-91 "eliminated all routes to generic competition through compulsory licences and left several options whereby patentees could gain even longer periods of market exclusivity" (Morgan and Barer 1997).

Like its predecessor, Bill C-91 aroused controversy and a "great debate on all sides" about the impact of the bill on both industry and consumers in the health care sector (MacDonald 1994). NDP members like Ron Fisher, James Capsey Karpoff, and John Solomon presented petitions that argued Bill C-91 would make drugs more costly to the public and add a financial burden on provincial and private drug plans. The early working and stockpiling exemptions also had to be rescinded as offensive to Canada's treaty obligations. Parliament's populist focus on drug costs alone instead of life sciences sector investment underscores the short-sightedness of our political approach, and why Canada remains so unproductive and pessimistic. As is often the case, limitations imposed by treaties on government policies prove beneficial.

In short, the PMPRB was never a principled policy initiative targeted to address any actual harm. It was, and remains, a red herring, a sop to political opposition to patent law amendments. This ad hoc distraction never served a *bona fide* purpose and still does not. It was a bad, but expedient, bargain. Canada has suffered its consequences for far too long.

Constitutionality of the PMPRB

While judicial decisions are mixed on the subject, close examination of the constitutionality of the PMPRB argues that it remains an unconstitutional exercise of federal power. However, this view has yet to be fully upheld by the courts, so it will be up to the Supreme Court of Canada (SCC) to finally resolve the question. Of course, its recent record in upholding the powers of the provinces in the face of federal government incursions has been less than stellar. But even if the PMPRB is not taken out of the picture for constitutional reasons, it should be abolished simply for being a weak, outdated, and destructive policy instrument.

The *Constitution Act* 1982 (CA) divides legislative powers between the federal and provincial governments. Canada benefits from this division of powers, which is not meant to be sacrificed to the overreaching ambitions of the central government. Patents belong to the federal government but property rights and health care belong to the provinces, with varying degrees of legal clarity. Courts match legislation to permitted powers by determining its "pith and substance": first, the court must define the dominant characteristic, then it must classify to which jurisdiction this characteristic belongs (Factum of the Attorney General of Quebec).

To regulate drug prices, the federal government relies on its patent power but actually legislates on something else – provincial matters of property and civil rights, and health care. Few cases have examined the scope of the federal IP power. The argument has always been that to prevent "excessive" prices of patented drugs we need to prevent the "abuse" of the patents granted for them. Of course, the idea of "abuse" has always been a pretext; there is nothing abusive per se about setting a price for a patented good in an open market. Courts have accorded insufficient respect to the meaning of "patent abuse" in dealing with it as a basis for federal jurisdiction.

Kirkbi AG v Ritvik Holdings Inc, an IP-related case, sets out the "ancillary powers" doctrine. This doctrine states that so long as a provision that impinges on provincial jurisdiction is sufficiently integrated within a valid federal act, it will be deemed constitutional. Thus, the codification of a civil remedy within the *Trademarks Act* was upheld despite encroaching on provincial jurisdiction. This makes sense; trademarks are important intellectual property and civil defence of them is inherently necessary. Yet this is not remotely the same as creating a federal price control body. Oddly enough, in the recent Quebec cases litigating PMPRB, the federal government didn't even plead the ancillary powers doctrine – so for now, it is not much in the picture.

The *Reference re Assisted Human Reproduction Act* dealt with the federal government using criminal law to encroach on the provincial power over health care. In addition to creating many new criminal provisions, the *Assist-*

ed Human Reproduction Act also prohibited "controlled" human reproductive activities that were not performed in accordance with the regulations set out in the Act. Quebec's attorney general (AG) launched a successful constitutional challenge against these latter provisions. Quebec's system to regulate assisted human reproduction has provisions that conflicted with the federal regulations. The SCC declared these provisions unconstitutional and inoperative. Similar logic could easily defeat the federal intrusion into provincial power to regulate drug prices.

Coupled with the provincial power over hospitals, sections 92(13) and 92(16) of the *Constitution Act* have been interpreted as assigning primary constitutional authority over public health to the provinces (Jackman 2000). This includes the power to regulate health professions, the education of physicians, and the definition of medical practices. Furthermore, the provinces also have authority over health insurance, with the ability to set up regimes to administer insurance to the population. This is well settled and makes a head-scratcher of the recent Quebec Court of Appeal case, *Merck et al. v. Attorney General of Canada*, in which the court upheld federal power to regulate patented drug prices because the underlying patents related to health care.

The federal government has no constitutional authority to regulate commerce, nor industries other than federal undertakings like railroads, banks, and telecommunications networks (*General Motors*). It may have the power to correct or penalize patent abuse. Yet the PMPRB does not address patent abuse; that is a flimsy constitutionality cover story. The compliance rate with PMPRB pricing regulations has fluctuated between 90 and 95 percent over the last 15 years; in 2019, the compliance rate was 99.9 percent (Annual Report 2019) Those companies that are deemed to be pricing their drugs excessively usually undertake voluntary compliance (PMPRB 2019). In any event, changing the PMPRB's price review mechanism in a way that mandates price cuts of up to 83 percent in an economy that has low and stable drug prices is wholly unrelated to preventing patent abuse.

Ongoing constitutional challenges

Ontario

In the 2020 case *Innovative Medicines Canada v. Canada (Attorney General)*, the Federal Court ruled that the New Regulations' use of pharmacoeconomic factors in price assessments and the reconstitution of the PMPRB11 (the basket of 11 countries for international comparison) was within the Governor-in-Council's broad regulation-making authority, as set out in the *Patent Act*. However, the provision related to the reporting of rebates was struck out as being beyond the scope of federal authority. An appeal has been filed and heard but no judgment issued at the date of writing.

Quebec

In a Quebec Superior Court case, several pharmaceutical companies – Merck Canada, Janssen Canada, Servier Canada, Bayer, and others – challenged the constitutionality of the *Patent Act* provisions governing the PMPRB and the New Regulations. The AG of Quebec did not intervene at trial, as is its practice, but has intervened in the appeal.

At trial, Justice Sophie Picard concluded that the Act and Regulations are constitutionally valid under the federal patent power, characterizing the pith and substance of the Act and Regulations as regulating the price of patented medicines to ensure that they are not excessive (Factum of the AG of Quebec). Justice Picard also held that it is constitutional for the federal government to modify the list of comparator countries in the PMPRB's price review scheme, and to use pharmacoeconomic analysis to determine if patented drug prices are excessive.

However, Justice Picard ruled that sections 4(4)(a) and (b) of the New Regulations were a direct incursion into the provincial jurisdictions over property and civil rights, matters of a merely local or private nature, and the establishment of hospitals (Factum of the AG of Quebec). These sections allowed the PMPRB to obtain information on the average selling price of a drug and its net revenue after adjusting for discounts and other rebates. Thus, disclosure is no longer limited to price information, but also to revenues, market size, and confidential rebates given to the provinces.

According to the AG of Quebec, the pith and substance of the New Regulations would have incorporated new criteria into the PMPRB's price review system to control patented drug prices and would have significantly depressed patented drug prices. This oversteps the PMPRB mandate of preventing patent abuse, which it acknowledges to be a valid exercise of federal powers. Moreover, the New Regulations jeopardized the true pith and substance of 91(22), which is to encourage R&D and innovation, with the factum noting that both Quebec and Ontario are worried about the future of innovative drugs in Canada (Factum of the AG of Quebec).

Quebec also argues that the provinces are fully capable of regulating drug prices. With the rise of product listing agreements (PLAs) between drug manufacturers and public health institutions, as well as confidential discounts, the provinces have great power over drug prices. For example, the *Insitut national d'excellence en santé et services sociaux* evaluates the pharmacoeconomic and therapeutic values of a new drug prior to listing it on Quebec's provincial formulary (Factum of the AG of Quebec). Ultimately, Quebec is worried that the federal PMPRB will diminish provincial competencies in health care and health insurance.

Quebec Court of Appeal

On appeal, *Merck et al.* was partially upheld, but the pharmacoeconomic factors in the New Regulations were struck down. The power to change the basket of comparator countries used to assess excessiveness of Canadian prices remained intact. However, the constitutionality of the provisions of the Act creating and governing the PMPRB were upheld – on extremely questionable reasoning.

The court seems to base its reasoning on the principle that the federal government lacks a general power to regulate the prices of patented goods, which is correct. But it departs astonishingly from the constitutionality pretext of patent abuse to state that a "public interest" permits the extension of federal jurisdiction to drug price controls. The court bases this on a simple, one-sided narrative of patent history and economics. It further asserts that drug patents have always been special, even when the clear trend in legislation and treaties has been to extend full patent benefits to drugs as to any other invention. Indeed, the long-term trend for drugs has been to augment patent protection with lengthened maturities, data protection rules, and special incentives for pediatric and orphan illnesses.

Patent history does not justify the PMPRB's confiscatory regime; it undermines it. Indeed, drugs are not even unique in relating to health: many patented inventions do so as well. The court further suggested that patented drugs face no competition, which would be news to participants in the pharmaceuticals market. The court was presented with evidence that price controls reduce the availability of medicines and of new discoveries. If it wanted to encourage Canadians' good health, it would invalidate drug price controls, not uphold them.

Instead, in sustaining the PMPRB sections of the Act, the ruling seems to reflect an institutional or cognitive bias favouring the status quo, one justified by using selective, questionable assertions. Moreover, it does so by saying that drugs are special because they relate to health – which is an entirely a provincial jurisdiction. How can the court go to all this trouble to single drugs out for a unique and unprecedented extension of federal jurisdiction, then do so on the basis that they relate to a concern under provincial jurisdiction? It is hard to imagine the SCC having much time for reasoning like that.

In arriving at its conclusion, the Court chose not to reject earlier cases like *Canada (Attorney General) v Sandoz Canada Inc.* that, on equally weak reasoning, upheld federal jurisdiction to control the exploitation of drug patents. Instead, it made it clear it was not bound by that reasoning; however, it didn't reject it but gave different reasons entirely. Instead of clear reasons, we have a growing cluster of judicial fig leaves over naked federal impotence. One hopes the SCC sees through such obfuscation.

Ontario support for the AG of Quebec in challenging PMPRB constitutionality

Ontario's current government had expressed its concerns over the New Regulations, with a letter sent to the federal government over delayed access to innovative medicines and longer wait times for patients (Martell and Lampert 2019). Ontario Health Minister Christine Elliott also petitioned against the changes when they were first discussed and urged then Health Minister Ginette Petitpas Taylor and Innovation Minister Navdeep Bains to conduct more consultation with industry before progressing with the reforms.

Quebec sent a similar letter, noting its fear that drug makers would be more reluctant to negotiate with provincial and territorial governments if they had to disclose those agreements under the now withdrawn amendment. Both provinces' letters pointed out the potential adverse impacts of the New Regulations on their growing life sciences sectors. Pharmaceuticals and medical devices are a major part of Ontario's key manufacturing industries (Ontario 2019). In fact, there are more pharmaceutical companies located in Ontario than in any other Canadian province.[4]

Alexion Pharmaceuticals v. Canada

One tremendously important recent case for determining PMPRB constitutionality is *Alexion Pharmaceuticals v. Canada (Attorney General)*, based on a dispute over the PMPRB price control methodology used with respect to the Alexion drug Soliris. The PMPRB found that Alexion priced Soliris excessively and ordered Alexion to forfeit its excess revenues from the years 2009 to 2017. The reason: Alexion's price was not lower than it was in all seven comparator countries, which is the first time the PMPRB ever used this criterion. Alexion first appealed to the Federal Court, which dismissed the application. Alexion then appealed to the Federal Court of Appeal and won, decisively, with major implications for the PMPRB's future.

The court determined that the PMPRB misunderstood its mandate and, at a minimum, failed to give a well-reasoned explanation for its decision. The *Patent Act* is meant to balance encouraging R&D and granting manufacturers a monopoly; general price control is not part of this purpose. The PRPRB failed to examine the price within the context of this balance. Further, the court determined there to be a difference between "excessive" pricing and "reasonable" pricing; the PMPRB drew from the standard of the latter, not even trying to explain how the price was excessive. The fact that the medicine is expensive did not in itself mean its price is excessive. The court further determined that the PMPRB departed from its normal procedure by comparing the price of Soliris in Canada to the country where it was priced the lowest of all the comparator countries. Without a detailed explanation about why they would change their standards, the PMPRB decision seemed "arbitrary" and "without regard to principles or laws" (para 60).

The court could hardly have been more caustic in its analysis of PMPRB failings: "It may be that the Board was trying to reach an outcome that on the facts and the law was not reasonably open to it. So at times in this analysis, the failure to discern a reasoned explanation closely relates to the possible unreasonableness of the outcome the Board was trying to reach" (para 32); "By obfuscating, the Board has effectively put itself beyond review on this point, asking the Court to sign a blank cheque in its favour. But this Court does not sign blank cheques" (para 45); and "A more fundamental concern is that the Board has misunderstood the mandate Parliament has given to it under section 85. At a minimum, a reasoned explanation on this is missing" (para 48). In reference to the Board's explanation that Canadians should not pay a higher price for Solaris than the price in the cheapest comparator country, it noted: "Statements like these, unless explained against the statutory standard, smack as price control, not policing for excessiveness" (para 55).

This is an extremely important decision for the future of the PMPRB. It dismisses the PMPRB's Soliris decision as not grounded in the purpose of the Act; it proves that the PMPRB is practising price control, not avoiding patent abuse. Constitutionally, to police patent abuse might be within the federal patent power, with some plausibility; to control the prices of drugs is not within the powers granted by the *Patent Act* or even within the competencies granted to the federal government. It means the PMPRB has two big strikes against it: it has no constitutional basis to exist or act as it does, and no legislative authority to act as it does.

Canadian Charter of Rights and Freedoms

The *Canadian Charter of Rights and Freedoms* would have likely led to a successful challenge of the New Regulations, and indeed to the current ones. As discussed elsewhere in this paper, PMPRB price controls discourage importing drugs into Canada. Many fewer drugs are available in Canada than in the US. This deficit was projected to grow greatly with the New Regulations; indeed, the very threat of the implementation of the New Regulations had that effect. Section 7 of the Charter reads: "Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice."

To implement regulations that deprive Canadians of life-saving cures amounts to deprivation of the section 7 rights in a manner that does not accord with the principles of fundamental justice. A similar argument held in *Carter v Canada (AG) (Carter)*. Kay Carter's suffering from spinal stenosis (and her fellow plaintiff, Gloria Taylor, from ALS) led the SCC to determine that the federal government had to allow her to access the services of a doctor to help her die – a doctor who would in turn be exempt from the *Criminal Code* provisions against murder.

Surely if such suffering entitles a Canadian to the extraordinary legal remedy to accomplish her death, then the sufferings of mortally ill patients demand relief from arbitrary and punitive drug price regulations that prevent them from living. Could a court find the compassion to make death available, but not the opportunity to continue to live or to live without suffering and pain?

Extensive bulk purchasing of pharmaceuticals sidelines PMRPB

The PMPRB intends to regulate the wholesale price of every patented drug. The PMPRB has estimated that that means it has authority over 59.3 percent of total drug sales in Canada ($12.8 billion) (Lexchin 2015). But how much of the theoretical maximum scope is taken up in practice?

Government agencies sideline and avoid the PMPRB by negotiating lower prices on their own (Lexchin 2015). This is done through product listing agreements (PLAs) with manufacturers to receive rebates by volume, resulting in prices lower than those set by the PMPRB. PLAs have become widespread since the establishment of the pan-Canadian Pharmaceutical Alliance (pCPA), a collaboration between the provincial, territorial, and now federal governments to negotiate drug prices uniformly (Canada 2018). PLA terms are confidential. Once an agreement has been made for a price discount, it is up to each jurisdiction to enter into a separate PLA with the manufacturer (Canada 2018).

PLAs make the PMPRB's price review methods less reliable, while substantially reducing its impact on the patented drug market. The PMPRB's executive director has said that its approach to regulating prices is "no longer effective" in the current drug market (PDCI Market Access 2015). This is because the increase of confidential rebates makes certain prices of patented drugs unknown, both in Canada and among its comparator countries. The price review method relies on both previous drug prices in the same therapeutic class and international reference prices; as these become shrouded in confidentiality, the PMPRB is in the dark.

Another limitation of the PMPRB is the rise since 2014 of private payer PLAs. Currently, for certain classes of drugs like biologics, PLAs are frequently a condition of listing (Abunassar et al. 2020). Unfortunately, with no private market equivalent of the pCPA, the number of private PLAs is unknown. One study (Abunassar et al. 2020) illustrates that the PMPRB's scope and impact is much lower than its claim of 100 percent over the patented drug market and 59.3 percent of total drug sales; however, they are difficult to assess exactly (see Appendix 1).

Out of this modified scope, approximately one-third comes from uninsured Canadians who do not benefit from either public PLAs or private PLAs. Theoretically, the PMPRB still has authority over 100 percent of patented drug sales that are sold to uninsured and out-of-pocket consumers. Yet, this scope is diluted by the fact that the PMPRB does not have jurisdiction over retail prices charged by pharmacies (Reguly, McMahon and Singh 2021). Thus, wholesale and retail mark-ups can offset the affordability that the PMPRB strives for.

In any event, PLAs have effectively consumed much of the PMPRB's purpose. The PMPRB is trying to reclaim that lost purpose, but in doing so, it demonstrates that its purpose has always been about price controls.

The PMPRB does not confront or control patent abuse

PMPRB price controls are based on the thin constitutional pretext that they prevent patent abuse; this is premised on the federal government having some authority over patents, but not over prices. Accordingly, the PMPRB operates under the premise that any price it does not like – which is *every* patented drug price – is patent abuse. Some arbitrary measure of "affordability" becomes the criterion for the existence of abuse. But "patent abuse" means something quite narrow. Since a patent is a grant of exclusivity, merely taking advantage of that market exclusivity is not abuse.

Competition law authorities have considered the issue. All of this is confirmed in the detailed analysis of the report by economist Jorge Padilla, submitted as evidence in the Quebec constitutional challenge. Padilla concludes that neither the processes nor the results of the PMPRB process is, or even could plausibly be construed to be, based on patent abuse. On the other hand, its procedures and resultant prices are essentially the same as those demonstrated by price-controlling health agencies around the world (Padilla Report 2021). He's plainly right. There is no rational basis to sustain PMPRB activity as either authorized by statute or as constitutional. Patent abuse has been investigated by Canadian competition law authorities only twice, and the target was Union Carbide – and nothing to do with pharmaceuticals.

Not every price can constitute abuse. That premise makes nonsense of the very idea of "abuse." Drug prices are just normal prices. In fact, actual abuse can never arise since drugs do not get into the Canadian market without PMPRB compliance. Since prices are so regulated, there is no way to detect if any price were abusive, as there is no market anywhere, except in the US, to compare the price to. Indeed, "abuse" is nothing more than a very rude fiction, allowing PMPRB and its adherents to demonize life science industries to justify high-handed powers to confiscate the value of pharmaceutical inventions.

The PMPRB's price analyses are rife with technical complexities. Yet they are largely a façade. Even a brief overview of this process reveals a highly artificial

system of price controls unmoored from control of patent abuse. Its price review process establishes either a Maximum Average Potential Price (MAPP) for a new patented drug or assesses whether the price of an existing patented drug product is excessive (PMPRB 2021). There are different presumptions for each type of new drug. For instance, the introductory price of a breakthrough new drug will be presumed to be excessive if the National Average Transaction Price (NATP) or any Market-Specific Average Transaction Price (MSATP) exceeds the MAPP at introduction (PMPRB 2021). This is determined by the Median International Price Comparison test, which compares the price of the same patented drug product against the prices listed by the basket of comparator countries.

> *The PMPRB's price analyses are rife with technical complexities. Yet they are largely a façade.*

On the other hand, a new drug introduced that provides slight or no improvement will be presumed to be excessive if the NATP or the MSATP exceeds the MAPP, as determined by the highest non-excessive price of the comparable drugs in the same class (PMPRB 2021). No new drugs can exceed the Highest International Price Comparison (HIPC) test (PMPRB 2021). Of course, the very idea that a price higher than the HIPC is necessarily "excessive" is absurd. When the US – the only market price jurisdiction – is removed from the basket of comparator countries, as is still intended under the remaining provisions of the New Regulations, absurdity becomes abusive farce.

For existing patented drug products, the price is presumed to be excessive if the NATP exceeds the National Non-Excessive Average Price (NNEAP), as determined by the lower of the change in the CPI or the result of the HIPC test (PMPRB 2021). The former criterion is measured by the CPI-Adjustment Methodology that involves two calculations: first, adjusting the benchmark prices of the drug product for the cumulative change in the CPI *from the benchmark year to the year under review*; and second, applying a cap on the maximum price increase in any one year equal to two-and-a-half times the change in the latest CPI. In times of high inflation, which is described as over 10 percent by the Board, the limit on a price increase will be five percentage points more than the latest actual lagged change in the CPI (PMPRB 2021). The lower number from either calculation will set the Non-Excessive Average Price for that particular year the drug is in review. It is perhaps worth noting that PMPRB's further confiscation of value by limiting even responsiveness to CPI changes is another example of the unconstitutionality of its processes.

The PMPRB was created in a time of high inflation and in response to the appearance of inflationary pressure on drug prices. This explains in part the continued focus on inflation in what has been a prolongedly low inflation environment (although it is not a factor the PMPRB should lose track of). A discussion of the recent history of inflationary impacts on drug prices is set out in Appendix 2. One must recall, of course, that drug companies, like other businesses and citizens generally, are the victims, not the perpetrators, of inflation.

Ironically, while there is no evidence that the PMPRB actually forestalls patent abuse, but clear evidence of practice that amounts to price controls, the actions of the PMRPB are *themselves* profoundly abusive of patents. Without constitutional validity and without the justification of patent abuse by patent holders, the PMPRB confiscates the pricing power of patents. That systemic confiscation is no less unconscionable and is more damaging to the economy and the health of Canadians than either the normal course of drug pricing or even the occasional instance of actual patent abuse. The alleged cure is far worse than any notional harm avoided by it.

The New Regulations

In 2017, then federal Health Minister Jane Philpott released a policy document titled *Protecting Canadians from Excessive Drug Prices*. It claimed that Canadians pay higher prices for prescription medication than do people in other developed countries, resulting in less access to innovative medicines and a heavy burden on the country's health care system (Canada 2017). Its conclusion was to give the PMPRB more sweeping powers over pricing rules of patented medicines.

The proposed changes, the New Regulations, would have been the biggest change to Canada's drug price regime since PMPRB's creation in 1987 (Martell 2019). However, the government appears to have bowed to constitutional inevitability and withdrawn portions of the New Regulations specifically found to be unconstitutional. Yet the government has not yet made their replacement available. Furthermore, the PMPRB has made much of the New Regulations being essential to its continued viability. These amendments still, therefore, merit our attention.

The New Regulations included changing comparator countries by removing the US and Switzerland; adding new economic price determination factors for the PMPRB to assess new drugs, including the controversial pharmacoeconomics that purports to assess, among other things, the value of new medicines relative to existing treatments; and, creating a framework for manufacturers to report discounts and rebates for third-party payers (Critchley

and Owens 2018). Another change included the introduction of the Maximum Rebated Price (MRP), which would have regulated negating price ceilings. The changes were originally scheduled for January of 2019 but were stalled multiple times before being quietly shelved by the government in its 2022 budget.

The COVID-19 pandemic has further exposed the flaws in Canada's drug control pricing mechanisms. While the United States, France, and the United Kingdom were able to partner early with vaccine developers, Canada initially struggled to access vaccines before eventually securing its supplies. Industry associations such as Life Sciences Ontario and IMC had warned that PMPRB restrictions could be a key determinator of Canada's vaccine shortages but they were criticized for exaggerating PMPRB's role in the matter (Raza 2021). The Vaccine Industry Committee of BIOTECanada stated that issues of access and supply would likely arise due to Canada's unique price regulations and that COVID-19 treatments could be adversely affected (Rawson and Koester 2020). Despite assertions that the PMPRB had no impact on vaccine availability, the federal government quickly lifted PMPRB oversight over COVID vaccines and other COVID therapies.

"The COVID-19 pandemic has further exposed the flaws in Canada's drug control pricing mechanisms.

Because of the poor reception of the PMPRB reforms among health experts, policy analysts, and patient advocacy groups, the Canadian government delayed their implementation time and again before apparently shelving them. When announcing the amendments, the PMPRB asserted that the reforms would not generate adverse impacts on the pharmaceutical industry, job numbers, or investment in the Canadian economy (Canada 2017). The PMPRB further stated that one qualitative impact of the reform is to improve access to drugs and allocate resources to important areas of Canada's health care system (Canada 2017).

PMPRB Executive Director Doug Clark defended the changes, falsely claiming that "there is no evidence that lower prices reduce access to new drugs" (Martell 2020). Then Health Minister Patty Hajdu further defended them, claiming they would save Canadian consumers billions of dollars and lead to a more unified, sustainable health care system. These mendacious claims came after 68 briefs were submitted from a variety of organizations, including unions, health workers, patients, and manufacturers documenting evidence to the contrary (Rawson and Adams 2021). Given this past support, we need to remain vigilant to determine whether the government has truly backtracked by

shelving the most troubling aspects of the New Regulations or if it will introduce similar amendments in another manner in the future.

At the same time, in the PMPRB's 2020-2021 Departmental Plan, Minister Hajdu warned about "the potential for unintended consequences" following the implementation of the New Regulations (Eversana 2020). She did not specify what these unintended consequences might be, or why one might not try to avoid them. She later signed the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19* (Canada 2020), which would take down barriers to authorizing and overseeing COVID-19 drugs and expedite the review process (Canada 2020). A day later, on September 17, 2020, the government announced an exception to certain drugs from the PMPRB's pricing rules (Canada 2020). As a result, any patented medicines on that list were not subject to a price review unless a complaint was submitted to the federal minister of health or any provincial or territorial health ministers.

The government stated that the policy was put into place to "ease the regulatory pathway for drugs and medical devices… needed for COVID-19 diagnosis, treatment, mitigation or prevention" (Canada 2020). This move contradicts the policy behind the PMPRB's new pricing rules (Skinner 2021). While the PMPRB justifies the changes on the basis that excessive prices are creating a health care crisis, COVID-19 has shown the opposite; price controls hinder access to new, life-saving treatments. Skinner has argued that the PMPRB has pushed a "misleading narrative" about the impact of drug prices on national health expenditures and falsely assumes that innovative drug companies will continue to supply the Canadian market with new drugs at steeply discounted prices (2020).

The PMPRB uses a reference-based pricing scheme to evaluate whether patented drug prices are excessive, which aims to price drugs at the median international price of the PMPRB-7 (PMPRB 2017). The New Regulations would have added a value-based approach. Instead of ensuring that patented drug list prices are not excessive, the New Regulations had proposed allowing the PMPRB to effectively fix drug prices to new, pharmacoeconomics-based levels, and to regulate maximum rebated prices from confidential PLAs. When reviewing new drugs, the PMPRB would look at the pharmacoeconomic value of the drug using a complicated price review method. This was simply another example of overreach.

The maximum list price (MLP) would be set at the lower of the median international price and the domestic therapeutic class comparison (Rawson and Lawrence 2020). Category 1 drugs (those that cost over $30,000 annually) would be subject to a maximum rebated price, using a cost-effectiveness ratio (Rawson and Lawrence 2020). These drugs would be measured against a pharmacoeconomic value threshold of $60,000 per quality-adjusted life-year

(QALY), meaning that the PMPRB sets $60,000 as the maximum price to be paid for a drug that gains one extra life year for a Canadian patient (Rawson and Lawrence 2020). This quite literally puts a price on life. Additionally, if these drugs sell over $25 million in revenues, they would be subject to further price reductions (regardless of whether there are profits) (Rawson and Lawrence 2020). Such a simplistic equation based on cost-effectiveness and QALY was insufficient to account for the many complexities and variables in pharmaceutical drug development and production.

Pharmacoeconomic models are plagued by uncertainties. They do not account for drug benefits that accrue outside the health care system, such as the benefit of certain drugs on caregivers, workplace productivity, absenteeism, or other societal benefits. The arbitrary figure of $60,000 per QALY was one for which there was no real consensus from economists or health care experts (Amgen Canada 2018). The market size threshold of $25 million in revenues was also arbitrary, because it penalized high-costing drugs regardless of their profitability measures or therapeutic benefits and cost savings. A pill that costs $100,000 to make and is priced at $105,000 (assuming this is 5 percent profit), would be much more likely to exceed the $25 million in revenues and face additional price reductions than a pill that costs $1 and is sold at $10 (assuming a 900 percent profit). It would have created a regime in which no "price" – no expression of how much buyer or seller value the product – exists; instead, it would merely regulate market access.

In general, pharmacoeconomic analysis is limited globally to reimbursement strategies (Pfizer Canada 2017). It is not used to determine non-excessive prices. This is because a single cost per QALY threshold cannot account for the levels of willingness of different Canadians to pay for a drug. Alternatives to the New Regulations existed for the PMPRB. The safest and most obvious would have been to lie low and do nothing. The existing system has problems but was not facing anything like the fierce resistance the New Regulations had provoked. Bold new change proved to be a very bad tactic.

Criticisms of the New Regulations

In 2018, when the New Regulations were introduced, the Macdonald-Laurier Institute (MLI) published a detailed critique on their anticipated impacts (Critchley and Owens). We refer the reader to that study. The main findings were:

1. The proposed reforms would likely reduce industry revenues by "more than three times the government's estimate," thereby discouraging investment, employment, and access to new drugs.

2. The proposed reform was maladapted to the continuing evolution of biologic therapies which have great potential to save lives and improve patient care.

3. Using pharmacoeconomics as a health technology assessment tool to assess what an "excessive" price is came with a host of risks and was incompatible with IP law and the PMPRB mandate.

4. The proposed reform threatened the practice of negotiated purchase rebates, which have been a useful practice in helping payers and manufacturers cover new therapies.

5. Stricter price controls would mean less profitability, leading to an environment that does not encourage investment or innovation.

Pharmacoeconomics creates great arbitrariness in the judgment of "excessive" price. It is a branch of health economics that analyses the costs and consequences of pharmaceutical products by combining drug research, production and distribution, pricing, and use (Rai and Goyal 2018). It is usually used to inform coverage decisions and price negotiations, helping with insights about how a drug may be cost-effective "to the right medication to the right patient at the right time" (Rai and Goyal 2018). This mode of evaluation does not fit with a framework that attempts to propose a specific price for a class of drugs available to the entire Canadian population, as the PMPRB is required to do.

Moreover, price control is incompatible with IP law. When negotiating with a legal monopoly, how can an agreed-upon price be considered "excessive"? If two free and knowledgeable parties negotiate and arrive at a price, or the price is willingly paid, what better measure of fairness or value is there? It is also inconsistent with the statutory standard of "excessive" price because pharmacoeconomics is meant to assess the value of a drug subjectively in light of individual needs and coverage. Thus, a drug price might be excessive to one consumer at a specific time, but not to another. Finally, this approach would duplicate what is already being done by existing federal, provincial, and territorial tax credit programs (BIOTECanada 2018).

The New Regulations also required that manufacturers report all confidential rebates and discounts provided under their listing agreements (PMPRB 2021). This would essentially put an end to negotiations of purchases using rebates that have in the past given an incentive to manufacturers to provide discounts on their products. Introducing such a requirement would also make it impossible to truly compare the price of drugs to the median Organisation for Economic Co-operation and Development (OECD) level since all other developed countries use purchase rebates and keep them confidential.

Some claim the New Regulations would have reduced prices for new patented drugs by a further 20 to 25 percent: the reality may be as high as 82.9 percent (Rawson and Lawrence 2020). This could have had disastrous impacts on health care and the pharmaceutical industry. Such punitive price controls would very likely lead to reduced drug quality, increased black market activity, additional resource waste, and lower investment in R&D. While price and the loss of R&D investment is not a "one-for-one relationship," empirical studies have concluded that there is a strong correlation between lower drug prices and a drop in investment and innovation in the pharmaceutical market (Kessler n.d). The logic is obvious: less revenue means less economic incentives with a resulting smaller market for new, innovative treatments.

The 2018 MLI study addressed the question of whether Canada can lower prices and simply rely on the US for its innovation. This is not a sustainable approach to pharmaceuticals and innovation for Canada. A low-price regime will inevitably hurt the life sciences sector and adversely impact industry employment and, ultimately, the Canadian economy.

> *"There is a strong correlation between lower drug prices and a drop in investment and innovation in the pharmaceutical market.*

The New Regulations had also been heavily criticized by economists and scientists who argued that the new methods were "at best subjective, assumption-dependent estimates" (Skinner and Rawson 2020). A study by Nigel Rawson and Donna Lawrence for Canadian Health Policy found that the New Regulations could have hypothetically cut the price ceiling for drugs targeting a rare disorder to between 45 and 84 percent below existing levels, detrimentally affecting the desire of manufacturers to send new drugs to Canada's market (2020). Chair of the Canadian Forum for Rare Disease Innovators Bob McLay reiterated this worry, stating that the changes "run directly counter to the federal government throne speech commitment to pursue a national rare disease strategy" (RAREi 2020).

Health experts fear that the changes might impact access to new and existing life-saving and life-altering drugs (Gastrointestinal Society 2020), by decreasing the attractiveness of Canada as a priority jurisdiction for new drugs. A study published by Life Sciences Ontario showed that 100 percent of pharmaceutical executives said the new PMPRB changes would have negatively impacted their business plans in Canada. Multiple executives were quoted

as saying they no longer trust Canada's governments and that further price restrictions would put the country at the lower end of international pricing (Life Sciences Ontario 2020a; 2020b). This would, in turn, result in long delays in patient access to new therapies or completely cut off access to some treatments by Canadian patients (Skinner 2018).

Policy researchers worry these changes showed a trend towards a universal formulary of inexpensive genericized drugs, whereby specialty medications would be limited to only those manufacturers who were willing to take a severe price cut to their products (Skinner 2018). It is concerning that PMPRB, already accused of being cut off from other institutions in Canada, has become increasingly alienated from the reality of the market and modern health care.

In fact, manufacturing companies have already started pulling away from the Canadian market. Swiss drugmaker Roche withdrew its new immunotherapy Tecentriq from evaluation in Canada citing concerns of uncertainty due to PMPRB changes (Martell 2020). Earlier, Merck & Co warned that 145 jobs might be cut from its Canadian staff due to the new policy (Martell 2020). President and CEO of BioAlberta Mel Wong warned that the federal government's mission to lower drug prices will ultimately damage the 16,000 people who rely on the life sciences sector for their livelihood (Wong 2019).

Aside from its impact on employment, patient advocacy groups were worried that the PMPRB's amended pricing policies would push them further down the wait list for life-saving drugs. Despite claims of a willingness to meet with patient groups to talk about their concerns and a rare disease strategy in development, the government had excluded patients from their consultation process for the PMPRB changes (CORD 2020). President and CEO of the Canadian Organization for Rare Disorders said that "rare disease drugs have been in the bulls-eye of these pricing policies" and the federal government had shown "wanton disregard for the impact on the lives of Canadians with rare diseases" (CORD 2020). John Adams, representing a coalition of 30 patient organizations, expressed his concern over the New Regulations despite its uncertain impact on patient care in Canada and recommended a thorough study on the assumptions underlying them (Rawson and Adams 2020).

Innovative Medicines Canada further stated that there is no doubt the New Regulations would have delayed vaccine distribution and forced companies to re-evaluate their launch in Canada (Kirkup and Hannay 2021). It released a statement on the PMPRB changes as well, stating that such regulatory changes would have a direct and negative impact on Canadian patients that would be made worse due to the current inadequacy of PMPRB's consultation processes (IMC 2020). Christina Antoniou, director of Pfizer Canada, one of the vaccine developers, admitted that the pricing guidelines in Canada restricted the speed at which vaccine research could be developed (Kirkup and Hannay 2021).

Critics ranging from patient advocacy groups to health experts to policy researchers had largely agreed that the New Regulations were irresponsible. Data support their claims that narrowing the PMPRB agenda while widening its scope would have detrimentally lowered drug prices in Canada while adversely affecting the country's health and pharmaceutical sectors (Gastrointestinal Society 2020).

PMPRB's impact on innovation and life sciences

The impact of the PMPRB on innovation in Canada has been clear. While Canadians boast of drug innovations like insulin and stem cells, insulin was discovered 100 years ago and transplantable stem cells 50 years ago. Well, what have we done lately? Is Canada still a contributor to global innovation?

R&D expenditure has waned in Canada. As of 2010, gross domestic expenditure of R&D as a percentage of GDP was below 2 percent in Canada. Canada imports 70 percent of its drugs – more, if only patented drugs are included – and 90 percent of the components used in drug production (Powell 2020). It also ranks as a low-priority country for R&D investment, as most multinational pharmaceutical companies spend less than 1 percent of their R&D investment in Canada (Industry Canada 2013). Canada also lacks R&D capacity, with numerous research facilities closing in Canada (Industry Canada 2013). Between 2007 and 2015, pharmaceutical R&D fell by 55 percent even as it increased by 63 percent in aerospace and 41 percent in the science sector.

The biologics sector has suffered too. Despite having 800 products under development, Canadian biopharmaceutical companies do not possess the capital to finance them so they can become commercial products. Biologic investment moves to other jurisdictions, where IP protection and innovation policy are stronger. Canada ranks 15th out of 38 global economies in IP protection, lagging particularly in the biologics sector (Dawson 2016). Where the United States allows for 12 years of data protection for biologics, Canada allows for only eight. The Pugatch Consilium, which runs the global Biopharmaceutical Competitiveness and Investment Survey, has gone so far as to call Canada an "outlier" among developed countries (Dawson 2016).

Canada's poor life-sciences performance is particularly tragic given Canadian talent and research. Canada produces a large volume of life-science papers through its universities. Indeed, the Nature Index ranks Canada as 7th in the top 10 countries in the life-sciences sector based on research output (Conroy 2020). The SJR International Science Ranking also ranks Canada as 7th in producing life-science citations over the period 1996 to 2020 (Scimago 2021).

In addition, Canada's IP protection lags behind other developed nations (Terry and Lesser 2019). Drug development is an inherently risky process, costing billions and taking an average of 10 to 15 years with no guarantee of com-

mercial success (Crowley and Lybecker 2012). IP protection promotes drug innovation and allows for pharmaceutical companies to recover their R&D costs through the development process. Stronger IP protection for pharmaceuticals and biologics stimulates R&D investment and drug innovation. And this is why Canada's weak IP protection threatens its ability to innovate.[5]

Canada's weak R&D, manufacturing performance, and IP protection, as well as its confiscatory price controls played out as one would expect during the COVID-19 pandemic. We were unprepared, lacking in both facilities to produce vaccines and therapies and good relations with those who had them. For those reasons and others, it's a perverse system. By preserving price controls, we depress our life sciences industry and hurt health care. Worse still, the PMPRB and its adherents have political incentives to demonize and diminish the life sciences sector, since the more it grows, the harder it would be to justify the PMPRB. We could hardly have a policy better aimed at undermining Canada than institutionalized drug price controls.

Orphan, personalized, and biologic drugs exceed PMPRB methods and capabilities

Orphan, personalized, and biologic drugs are the future of pharmaceutical science, and of health care – and yet, these are most at risk from the PMPRB. However, not only do political and economic change conspire to consign the PMPRB to the dustbin of bureaucracy; pharmaceutical science may be its *coup de grâce*.

So-called "orphan drugs" treat rare diseases. Rare diseases entail small patient populations and, hence, uneconomic markets (Orphanet 2021). In the US, the Office of Orphan Products Development was created under the Food and Drug Administration to promote the production of orphan drugs via tax credits on clinical research, a simplified administrative process for approvals, and exclusive marketing for seven years after approval (Orphanet 2021). Canada is one of the few developed countries that does not have a regulatory framework for orphan drugs (McMillan and Campbell 2017), leaving Canadians with rare diseases out in the cold.

Biologic drugs are those that are produced from "living organisms or contain components of living organisms," and include vaccines, allergens, and tissues (Ogbru and Davis 2019). Biologic drugs can be used for a variety of diseases and conditions and are the most advanced therapies available (Ogbru and Davis 2019). Unlike "small-molecule" drugs, biologics are not chemically synthesized and have complex mixtures that are not easily defined (US FDA 2018). Biologic drugs are complex, difficult to manufacture, and extremely sensitive, being affected by slight amounts of impurity, oxygen, or heat. Biologic medicines, many of which are high-cost, have captured an increasing share of the

Canadian market, from 16 percent of patented medicine sales in 2008 to 41 percent in 2019 (PMPRB 2019). In 2019, Humira, Eylea, and Stelara were the top-selling biologics, collectively accounting for 10 percent of all patented medicine sales (PMPRB 2019).

Personalized medicine entails drugs and treatments tailored to the unique molecular and genetic profiles of individuals. While they tend to be more expensive than other drugs, they help contain health care costs by targeting illness or disease in specific patients rather than having those patients undergo a trial-and-error process in their disease treatment (Personalized Medicine Coalition n.d). Personalized medicine will improve health care by lowering costs, allowing early diagnoses, and providing the best treatments (Vogenberg, Barash, and Pursel 2010).

Biologic, personal, and orphan drug pricing misconceptions

In testimony to the House of Commons, Professor Larry Lynd stated, "I think we need to control the prices. I think if we look at where the prices are going with pharmaceuticals, particularly given the paradigm shift in drug development, we're looking at more development of personalized and precision medicines with drugs that are going to be orphan priced. That's just going to increase the need for price control with prices continuing to be pushed to the limit, as I foresee it" (Lynd 2016).

Views like Professor Lynd's are backward. Indeed, orphan drugs, biologics, and personalized drugs are generally high-priced. Take Zolgensma, a US$2.1 million orphan drug used to treat spinal muscular atrophy, a disease that affects one in 10,000 newborns (Stein 2019). While perhaps the world's most expensive medicine, a single dose provides immediate, long-lasting benefits. According to Nicolas Chrestian, Zolgensma could possibly halt "the progression of this degenerative condition that can rob children of regular developmental milestones" (Novartis Pharmaceuticals Canada 2020).

Zolgensma was developed and approved through the US's orphan drug regime (Jandl, Tus, and Koridc 2020). Some common biologic drugs used for arthritis, such as Enbrel, Humira, and Remicade, have complex manufacturing processes and expensive materials, causing them to cost around US$20,000 to US$50,000 per person, per year (Franchi 2014).

Favouring price controls for these and other drugs would only inhibit the development and distribution of orphan, personalized, and biologic drugs. Special incentives exist for companies to produce orphan drugs. To argue that orphan drug prices are too high and need to be capped ignores the need for manufacturers to be able to recoup their costs and make returns from an

otherwise small consumer base (Jandl, Tus, and Kordic 2020). These drugs also commonly have complex manufacturing processes and thus a higher cost base than other types of drugs (Moors and Faber 2007).

This illustrates the chaotic and perverse policy thinking around pharmaceutical development and pricing. We do not have and cannot get orphan drugs, so we – at least, the rest of the developed world except Canada – develop specific incentives to enhance cost recovery and profitability so that these drugs come to market. We do that because, presumably, we acknowledge and regret the human suffering and lost opportunity caused by these conditions. Yet Canada creates a pricing regime that takes away these incentives and ensures patients will not benefit from the drugs.

> *The higher price of personalized medicines can reduce the costs of future therapy.*

The answer to these expensive treatments does not lie in price controls (see Appendix 3 for a review of the criticism and theory of price controls generally). The higher price of personalized medicines can reduce the costs of future therapy – by "spending more money to buy more health" (Mangan 2015). Capping prices will only drive these types of treatments out of the market, cutting off access to drugs that have proven to have measurably more efficient outcomes than older or alternative therapies. Thus, when weighed against alternative therapies and the costs of suffering and lost life, expensive biologic and other drugs may prove cost-effective despite a high price.

These biologic therapies are often the only ones available to treat a particular condition. By restricting access to these high-cost drugs, we are effectively saying we would prefer that those afflicted have no treatment at all. Biologic drugs in 2013 cost Canada's public health plans around half a billion dollars for about 30,000 beneficiaries (Sachgau 2015). We cannot wish such therapies away. It must be our objective to maximize the quality of care available to our citizens while acknowledging that some of that care may not be reasonably funded from the public purse. But it must not be unavailable for that reason alone. It may or may not be reasonable for a wealthy 80-year-old to use $1 million of her retirement savings to buy six months of quality life from a biological treatment. It may be more clearly unreasonable, however, to tax average Canadians to buy that treatment. It is absolutely wrong to give her, and other Canadians, no choice in the matter, and it may as well breach her s.7 right to life under the Charter.

The figure in Appendix 4 lists the patented drug price ratios between Canada and other OECD countries. The ratio examines the average price of patented drugs in foreign countries as compared with Canada. For instance, the US has a patented drug price ratio of 3.49, which indicates the patented drugs are 3.49 times more expensive in the US than they are in Canada. Canada's price ratio is 1, because it is the comparator country. While much has been made of Canada's prices being higher than that of other countries, it is evident they are not so by any material difference – especially compared to the US.

The virtues of patents: Why the PMPRB should stop attacking them

Perceptions

Canada's control of drug prices springs out of naive fear of the pricing power afforded by those drugs' patents. This unreasoned fear is not supported by experience. Patents are not market monopolies. Patents are brief slivers of autonomy, recognition for creative effort and investment, carefully defined through an exacting and grueling process of challenge and examination with patent offices worldwide (Klein 2019). Pharmacological inventions are those for which the patent system is most finely tuned to maintain incentives without being excessive. For other technologies, the extent of the 20-year monopoly is more arbitrary, relative to the fine-tuning from which the pharmaceutical industry has benefited (Rothenberg 2004).

Importantly, patents do not grant an exclusive right to serve or supply a market demand (e.g., treatment for a particular disease), but merely temporarily prohibit the unfair competitive use of a specific novel means – usually among many – of serving that market. Pharmaceutical patentees are subject to competition within and across drug classes, between patented products, and between patented and non-patented (patent-expired or generic) products, as well as from non-pharmaceutical forms of treatment.

Instead of monopolies, patents are property (Skinner 2004). While this is elementary, the PMPRB mandate seems, on its own admission, to be based on a misconception of patents as monopolies. This misconception amplifies the perceived risk of patent abuse out of any realistic proportion. According to the PMPRB, "In a monopoly situation, a seller with market power can set a higher price than would exist if the product were subject to competition" and "the PMPRB's regulatory mandate is to ensure that patentees do not abuse their patent rights by charging consumers excessive prices during this statutory monopoly period" (Canada 2017). This is profoundly misleading. It

implies that the drug is some public good over which an unentitled actor has acquired a market monopoly – rather than being an entitlement to market a widely beneficial new invention.

Life sciences patent monopolies are well-earned by bringing into being the very things to which they apply. No one loses anything since nothing pre-exists the act of invention. Many gain, however. Profits can be large, but they are earned, and they are a necessary incentive. Perhaps a dedicated life scientist will spend her spare time hunting for cures, but the money and legal apparatus and everything else required for safe approval and commercialization will not cost nothing. A patent on a successful drug offers the potential for a financial prize. Only with such a promise can the economy of drug discovery function. It is highly efficient, if complex and dynamic. Innovation is never centrally planned or controlled.

“Life sciences patent monopolies are well-earned by bringing into being the very things to which they apply.

Some allege we could make drug discovery a regulated utility, a bureaucracy, with perhaps government awards for success, or subject to regulated rates of return. That could, in theory, be done – but not in reality. Price controls, after all, are a bad idea, albeit a fact. Such a regulated system would generate vastly fewer life-saving and life-enhancing successes, and would be far less efficient and cost a great deal more. If you pay people and entities to generate research, you will have it in great volume, all assiduously invoiced. But success will be much rarer, the incentives for it being greatly attenuated and diffused (Wagner 2005).

A similar analysis applies to those who argue for de-linking – the idea that, *inter alia*, a new drug should only be priced to recover the costs of research dedicated to that drug alone, and not the costs of less-directly successful research, corporate overheads, and other costs. What kind of economic bargain would that be? Facing such absurdity, capital would simply flee.

Research has estimated that “between-patent competition, most of which occurs while a drug is under patent, costs the innovator at least as much as within-patent competition, which cannot occur until a drug is off-patent. The reduction in the present discounted value of the innovator’s return from between-patent competition appears to be at least as large as the reduction from competition within-patents and may be much larger” (Philipson and Dai,

2003). Research further determines that the utility of virtually all inventions accrues to the consumer – which is hardly consistent with the idea of a patent's conferral of excessive pricing power (Ezell 2021).

A property rights-driven, private-sector drug discovery and distribution enterprise serves us most efficiently and best. We cannot wish its advantages away in favour of a collectivist system that would inevitably fail and lead to more death and sickness. Fears about the excesses of private enterprise and its need for profit are grossly uninformed. Private enterprise is more humane, honourable, and beneficial than any collectivist, controlled system. And as a last resort, patent abuse law exists to address any colourable excesses in the exploitation of private rights.

Patent abuse

Patent abuse law is based on the notion that some exercises of the rights granted by a patent abuse the privilege of the patent. In certain aspects of patent law, the conscience of the Crown remains implicated, as will be explained in more detail below; perhaps this is one. In the US, patent abuse is a common law concept developed by the courts and rarely applied; it is meant to curb unconscionable excesses. But in Canada, patent abuse has instead been codified in the *Patent Act*, and is defined in s.65(1). In other words, patent abuse powers are already available to curb limitations in Canada on availability or excessive pricing.

Historically, patents in the British Commonwealth were seen as *privileges*, granted by the Queen to advance her economic and industrial policies until views about patents shifted to it being a legal right (Mossoff 2001). The question is whether this shift from privilege to legal right severed the idea that a patent is an extension of her Majesty's powers. The language describing patents, as powers or licences, points to vestiges of the idea that patent holders are limited-time carriers of a state-granted privilege.

To contrast Canada's patent abuse law with US law highlights how Canada's relations with the Crown might have led to a stricter patent misconduct jurisdiction. In the US, the doctrine of patent misuse rules over whether a patent can be rendered unenforceable (Too, Lu, and Norman 2012). The doctrine is narrowly applied, with misuse pertaining only to the use of the patent and not to things such as wrongful commercial conduct (Too, Lu, and Norman 2012). In contrast, Canada's description of what amounts to patent abuse is far broader. It includes language such as "in the public interest" or that trade is "unfairly prejudiced." These terms possibly capture improper licensing practices even if they do not lead to anti-competitive effects. As described by Too, Lu, and Norman, Canada's abuse of patents can "be raised as a sword, not just as a shield" (2012).

If patent abuse is defined in the Act, and actionable under the Act, where does PMPRB get its legitimacy? Lawsuits or actions by the Commissioner of Patents would suffice. Pricing regulations are plainly not in keeping with the patent abuse mission. Instead, the PMPRB is pushing price controls; it merely exists to control costs and apply an unnecessary political salve to an issue of some political sensitivity. The very existence of s.65 of the *Patent Act* argues the unconstitutionality of the PMPRB.

It might also be, of course, that the patent abuse sections of the Act are excessively broad so as to be themselves *ultra vires* the federal government. They are also clearly nationalistic in intent and therefore likely in conflict with Canada's obligations under patent treaties not to play favourites based on nationality.

A counterargument might say that patent abuse is incompletely defined in the Act and that the PMPRB addresses it more, and better. But how can that be? And if so, why only for the pharmaceutical industry when surely the exclusivity of any patented article may be abused? Moreover, variability of prices from place to place can be far more readily explained by factors other than patent abuse. Price discrimination is an important aspect of the pricing power granted by patents and one that serves less-wealthy jurisdictions by enhancing access. Prices for patented articles can vary internationally for that reason alone, as well as due to variations in market size, regulation, local inflationary effects, demand, and innumerable other factors that bear on pricing.

Finally, setting a market price is not patent abuse, plain and simple. However, confiscating that market pricing power is abusive. It is, ironically, governments who abuse patents, far more than patent holders do just as, by the deleterious effects of price controls, approval delays, and obscure bulk purchase arrangements, it is government that denies us access to drugs far more than willing sellers do by charging for them.

Phasing out the PMPRB

It is time to scrap the PMPRB altogether. The PMPRB is a clumsy tool and it harms drug access rather than promoting it. Price ceilings limit drug revenues which reduce R&D spending on drug discovery and make Canada an undesirable location for conducting clinical trials and launching new drugs. Removing price controls will have little impact on most drug purchases in Canada. The creation of the pCPA has enabled centralized negotiation and substantial discounts for public drug plans. In 2017, Ontario received an average rebate of 36 percent off the regulated list price for patented drugs on its formulary (Skinner 2021).

Proponents of the PMPRB may look to the high drug prices in the US as cautionary for Canada, fearing that abolishing price controls may cause drug prices to rise exorbitantly. But the US has higher drug prices because of price controls in other countries. To recover the staggering costs of developing new drugs, firms keep prices high in the US, while Canada, Europe, and the rest of the world free ride on the American consumer (Pitts 2017). According to Health Affairs, introducing drug price controls to the US would, ironically, impose $8 trillion in costs on consumers around the world over the next 50 years (Lakdawalla et al. 2008).

Cost savings from reduced prices simply do not begin to equal lost value from greater health, better lives, and reduced health care costs. Using similar logic, if the EU repealed its price controls, Europeans would be $10 trillion wealthier (Lakdawalla et al. 2008). All these benefits – and losses – are shared internationally. The PMPRB is based on a nationally parochial calculation, and a very flawed one. Drug development is for all mankind. Price controls in Canada deprive not only Canadians of cures, but our fellow men and women around the world, too.

> *The PMPRB is based on a nationally parochial calculation, and a very flawed one.*

Without price controls, Canada would benefit from improved access to new drugs. Innovative drugs allow patients to avoid expensive hospital visits, surgery, and other medical procedures, and any increase in drug expenditure will be offset by welfare gains. Each dollar spent on drug discovery has a net welfare gain of $7 (Hasset 2004).

There is a caveat on timing, however. The US has drug price levels over three times those in Canada (Mikulic 2021). The rate and extent to which abolishing the PMPRB would increase prices in Canada, especially while other countries have price controls in place, are uncertain. This is because absent price controls, Canadians could become another potential source of subsidy to foreign consumers, like the US is now. Abolishing price controls ought to become a global endeavour. While the pharmaceutical drug industry may not be a zero-sum game, there may still be a coordination problem where there is too much of an incentive to defect back to price controls. But the prize of removing them is not only freedom – it is economic and health gains far in excess of increased expenditures.

While PMPRB reports that it saves Canadians money, it is nowhere clear how much; what a market price for any drug would be in Canada is pure speculation. Such uncertainty can make losing price controls seem risky. If price controls were suddenly lifted, would prices rise a little, perhaps by the percentage differential between Canada's GDP and that of the US? Or would they triple to US levels? Here, and indeed worldwide, price signals are so massively distorted by government interventions that they are essentially mute. Because such a vastly disproportionate share of the burden of R&D has been shirked by everyone and borne by the US consumer, prices in the US are heavily, and unduly, inflated. If Canada joined the US in accepting market prices, it too might shoulder a disproportionate, economically inevitable burden.

There are several ways to address this problem. The first would be only to move in step with other nations in relaxing price limitations. Another would be to further investigate, by more detailed microeconomic analyses, what market pricing would be in the absence of controls. Another would be to negotiate limits on price increases with industry – who, after all, should be motivated to help prove that lifting price controls works. We could, for instance, offer capped annual increases in exchange for good faith negotiations to wean other jurisdictions off of drug value confiscation. Another option would be to manage a transition to market pricing by imposing caps that are lifted over time, while pushing for better R&D burden-sharing globally.

This calculation must stress the wealth gains that will accrue from innovation and investment. Offsetting costs to drug consumers would be wealth gains through a more innovative economy and growth in life sciences industries and improvements in health through the availability of better cures. Absent such constructive approaches from Canada and other countries, the US should take unilateral measures to recoup its subsidies to the world. Trade measures such as export levies and duties could be used, as will be described in the second paper in this series.

PMPRB bias and mission drift

The PMPRB is drifting, and its efforts to find relevancy are beginning to smack of some desperation. Nowhere is this more in evidence than in its Communications Plan, of February 9, 2021, obtained in response to an Access to Information request from Conservative MP Tom Kmiec, and in a February 2021 letter by Mitchell Levine, Chair and Deputy Head of the PMPRB.

Even a perfunctory textual critique of the Communications Plan (PMPRB 2021) reveals hubris and dishonesty. The plan aims to spread disinformation to the effect that price controls have no impact on innovation or drug availability when the PMPRB's own information gathering demonstrates the opposite. It misconstrues the operation of health insurance by suggesting it will be more effective if price controls are made more severe. It slanders

industry and patient groups for spreading disinformation. It repeats the lie that Canadian drug prices are high. It characterizes producers as spreading mendacious threats. It states that the PMPRB extensively consulted on the New Regulations when patient representatives have accused it of ignoring and maligning them (Macleod 2021). It characterizes criticisms of the New Regulations as without evidence, illogical, and counterfactual, and as disinformation designed to provoke fear. It refers to documented claims included, *inter alia*, in these critiques as "knowingly disseminating false information," which is particularly ironic given that the Communications Plan itself consists of a plethora of false information. Patients' pleas for adequate health care are labelled "aggressive public relation strategies" (p. 2).

After the PMPRB Communications Plan became public, Levine stepped forward with a letter to accept responsibility. He admitted commissioning and approving the plan, but also doubles down on its errors. Levine pleads the old canard – the good intentions of his staff – as though it were the real issue:

> What I find extremely disappointing is the level of vitriol and invective increasingly directed at the PMPRB and its public servant staff in social media and elsewhere by members of the patient advocacy community… As proud as I am of our work, I am prouder still to work alongside the conscientious staff at the PMPRB. These women and men embody the very highest ideals of public service and ask only for an opportunity to make their country a better place for their fellow Canadians. (Levine 2021)

The letter is a response to one from John Adams, head of the Best Medicines Coalition, complaining about the Communications Plan. Levine ignores the substance of Adams's letter in order to try to deflect the well-deserved – and constructive – criticism. There is no "vitriol and invective" in Adams's letter; its tone is wounded, not aggressive. Levine is trying to re-write the record and mislead his audience.

These documents demonstrate an unaccountable PMPRB, beset by narrow groupthink, sterile and isolated intellectually, that has become rigid and unresponsive to the needs of both industry and patients. Most importantly, the PMPRB oversees pharmaceutical companies as a quasi-judicial regulatory body. Unbiased fairness is a critical attribute of such a body. The Communications Plan demonstrates such deeply ingrained hostility and bias, and such misguided zeal for an improper purpose (price controls) that trust or confidence in the PMPRB – by suppliers or patients – would be misplaced.

If the constitutionality of the PMPRB is upheld by the SCC, then it is bound to face further consequences from the evidentiary record created to challenge its constitutionality. This includes internal documents that plainly state the bias of the PMPRB and its purpose to impose price controls. These will

ground continued challenges against the PMPRB for reviewable bias in its decision-making and for exceeding its statutorily authorized purpose. Given the ongoing damage the PMPRB is causing, such challenges are unavoidable and necessary, but they amount to a wasteful war of attrition. This is especially true given the obvious alternative of doing away with the PMPRB altogether.

Conclusions and recommendations

Canada needs a radical reform of its drug pricing. While the Canadian government has quietly shelved elements of the PMPRB's New Regulations, it remains silent on its future plans for reforming the organization. The government should take a different tack and openly admit that the New Regulations had gone much too far and were a mistake. To rescind them completely will send an important signal to Canadians and internationally, and, hopefully, reverse the trend of declining registrations of new medicines, departing companies, and lack of research investment in Canada.

Canada should phase out the PMPRB as soon as possible before its unconstitutionality is formally confirmed by the courts and any phased transition becomes more difficult or even impossible. The legislation governing it should be rescinded. The *Patent Act* contains patent abuse provisions that are adequate to deal with excessive drug pricing and may be within federal government powers, unlike the PMPRB. Most of the market the PMPRB was made to regulate has been taken over by negotiated bulk purchase agreements that are outside the scope of the PMPRB, which makes this body less relevant and less able to reliably discharge its duties. Moreover, the patented pharmaceutical market will increasingly be dominated by biologics and personalized and orphan medications for which PMPRB will not work as a regulatory tool.

To facilitate the phase-out of the PMPRB, we should analyse how markets would level without price controls. It is difficult to anticipate the consequences of abolishing price controls on the price of drugs overall, and on patented drugs specifically. Given the wide difference between Canadian and US prices, hikes could be steep. Detailed economic analyses of the effects of removing price controls should be undertaken, but they should be objective studies, not ones conducted by the PMPRB or its supporters. If undue hardship were to result in a disadvantaged population, then procedures to mitigate or delay that hardship, including subsidies or a graduated relaxation of price controls, should be designed and applied. Canada is among the wealthiest countries and a very large proportion of its citizens have insurance plans to absorb the costs of prescription drugs. We must pay our fair share and stop free-riding on US consumers.

Interestingly, since Canada is among the higher price jurisdictions globally (although not by much), it could see its drug prices fall if price controls dropped worldwide. As it is, one country alone, the United States, absorbs a wildly disproportionate share of the cost of new pharmaceuticals. If its share were widely divided amongst other nations, it may not lift prices in relatively more expensive countries by much even if, as we would hope, the industry would become more profitable overall.

On an international level, Canada should begin projects within the OECD and the World Trade Organization to abolish drug price controls and develop guidelines for bulk pricing negotiations. Price controls place the world at risk of gravely depleting drug development funding, especially if the US joins the drug price control club, as it threatens now to do. Price controls cause massive distortions in international trade in goods based on life sciences IP and these distortions are not otherwise addressed by treaty. For Canada to take the lead on projects so important to world health would be to make Canada more relevant on the world stage.

Canada should improve access to new drugs by adopting foreign drug registration reviews. Availability and quick approvals of pharmaceuticals must be key objectives of Canadian policy. To that end, Canada should rely on (and not repeat) foreign reviews of pharmaceuticals submitted for registration here. Delays in access and non-access occasioned by price controls and price negotiations should be avoided. Government pharmaceutical negotiations must also be transparent, particularly concerning delays in access and unavailability. All Canadians have an interest in a fast and comprehensive supply of pharmaceuticals.

Finally, the US should stand up for itself and take on the world's piratical price controls that exploit loopholes in international trade law. It could use techniques such as tariffs, taxes, and penalties to level the playing field and deprive countries like Canada from relying on the American consumer and on confiscating value from innovative drugs.

It is time for Canada to unequivocally commit to building an innovation ecosystem. Coercion and horse-trading under industrial policy are wasteful, ineffective measures for economic growth and innovation. We must create favourable conditions for R&D investment in Canada – principally better IP protection, no price controls, lower taxes (especially on capital gains), and quicker market uptake of products – if we are to have economic growth and innovation in life sciences in the 21st century.

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Endnotes

1 On April 14, 2022, the government announced its intention to abandon some, but not all, of the New Regulations, specifically those found unconstitutional in court challenges (although that was not the reason given). At the time of writing, amended regulations have not been published or Gazetted.

2 This is not to say they were much higher. The PMPRB makes much of our prices being higher than those in many countries, but the difference is trivial. Moreover, as a wealthy nation, our prices should be higher than those in less advantaged nations.

3 The underlying rationale for the compulsory licensing system was stated in the amendments under s.41(1): "the Commissioner shall have regard to the desirability of making the food or medicine available to the public at the lowest possible price consistent with giving the inventor due reward for the research leading to the invention."

4 The insurance industry, incongruously, supported the New Regulations. It is difficult to see why, since their revenues would have likely decreased with drug pricing and availability since premiums for health insurance grow with insured costs. Moreover, the deleterious impacts of price controls would hurt policy-holders.

5 Canada also reduces the already shortened exclusivity period for patented drugs by undertaking drug approvals that duplicate those already conducted by the manufacturing country and with longer approval processes (90 days longer, on average, than in the US or Europe) (Shajarizadeh and Hollis 2015). Canada also lags behind other countries in protecting proprietary information filings. Canada must respond to the growing need for IP protection both in the form of longer effective-patent terms and longer exclusivity periods in order to spur its lackluster drug innovation sector.

Appendix I:
The PMPRB's economic impact

PMPRB reporting does address savings in comparing Canadian prices to foreign prices by asking two questions: (1) how much more/less would Canadians have paid for the patented medicines they purchased in X year had they paid Country Y prices rather than Canadian prices; and (2) how much more/less consumption of other goods and services would Canadians have sacrificed for the patented drug products they purchased in X year had they lived in Country Y (PMPRB 2015a).

The first question is answered by looking at the average price ratios provided by the PMPRB, which are "sales-weighted arithmetic means of price ratios obtained for individual drug products" (PMPRB 2015b). For instance, in 2012, the average France-to-Canada price ratio was 0.76, meaning Canadians would have paid 24 percent less for patented drug products had they purchased a particular drug in 2012 at French prices (PMPRB 2015b). In 2017, the same price ratio was 0.75 (PMPRB 2017). Also in 2017, US prices were much higher than in Canada (and the other comparator countries) with a price ratio of 3.36 while Sweden, the UK, and Italy had lower prices than Canada.

It should be noted that the PMPRB cannot always find a matching foreign price for a patented drug sold in Canada and so will not have a figure for the amount Canadians have saved on those drugs.

The PMPRB calculates the relevant statistics for the second question by reporting foreign-to-Canadian price ratios with currency conversion at purchasing power parity (PPP). PPP measures the relative costs of living measured between two different countries by pricing out a standard basket of goods and services at the prices in the comparator country. In the 2017 report, data showed that Canadians "incurred a larger consumption cost for the patented medicines they purchased in [that year] than residents of France, Sweden, Switzerland and the UK" (PMPRB 2017).

In the same report, the PMPRB revealed that average generic medicine prices in Canada have been reduced to 50 percent of what they were 1- years ago. Nonetheless, it did not provide a figure for the amount that Canadian consumers saved (2017). Neither did it specify who was benefiting from the cut in generic prices and only discussed it in the context of how Canadian prices live up to foreign standards.

It is obvious from these data that the actual price differences of any drug attributable to PMPRB intervention are all but impossible to discern. Part of the problem is that we have effectively no way to know what market prices of drugs would be in a Canada without price controls. What we can tell is that

Canada's drug prices are low and consistent with those of its OECD peers, all of whom have controlled, low prices that reflect regulatory interference far more than market value. Astonishingly, one of the most beneficial goods in the world is the one almost universally selected to be discouraged by price controls.

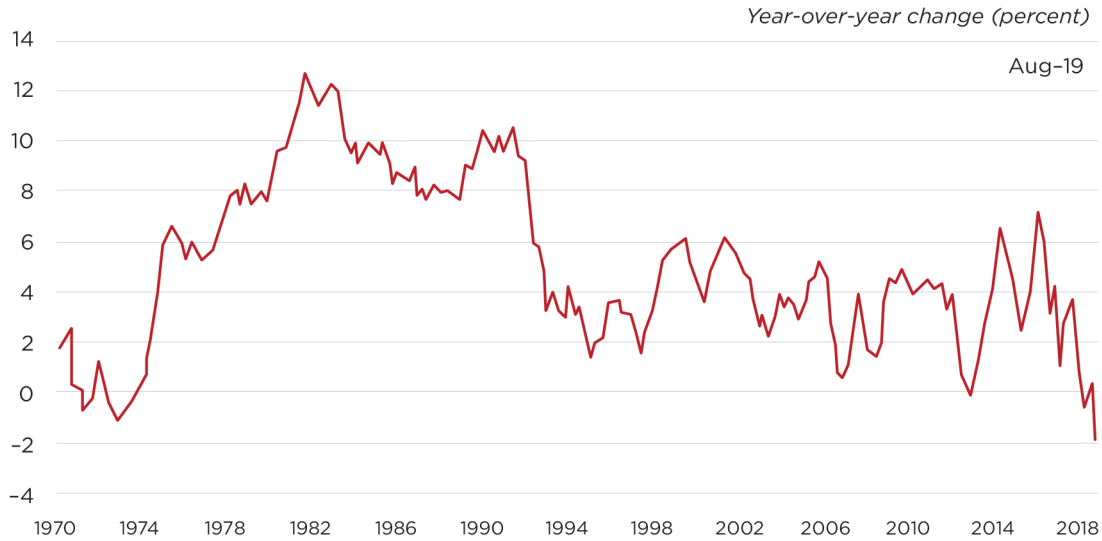
Appendix II:
Comparative price changes: The United States and the role of Inflation

The United States is rare, in that it is a developed country that does not have a national pharmaceutical price regulator (Danzon 2018).

Patented drug price trends in the US are measured and calculated using a different methodology than the Patented Medicines Price Index (PMPI). The US uses a CPI Prescription Drug Index (called CPI-Rx), which examines price changes within a basket of prescription drugs over time (Council of Economic Advisers 2019). The CPI-Rx is used to calculate the inflation of prescription drug prices. One important difference between the CPI-Rx and the PMPI is that the CPI-Rx includes both patented and generic drugs within its basket of drugs. It also does not include any rebates or discounts offered on the list price.

Figure 1 depicts the urban CPI-Rx from 1970-2019. Unlike PMPRB figures it includes generic drugs, but there are similarities in drug price trends between the US and Canada.

FIGURE 1: CPI-U FOR PRESCRIPTION DRUGS, 1970 – 2019



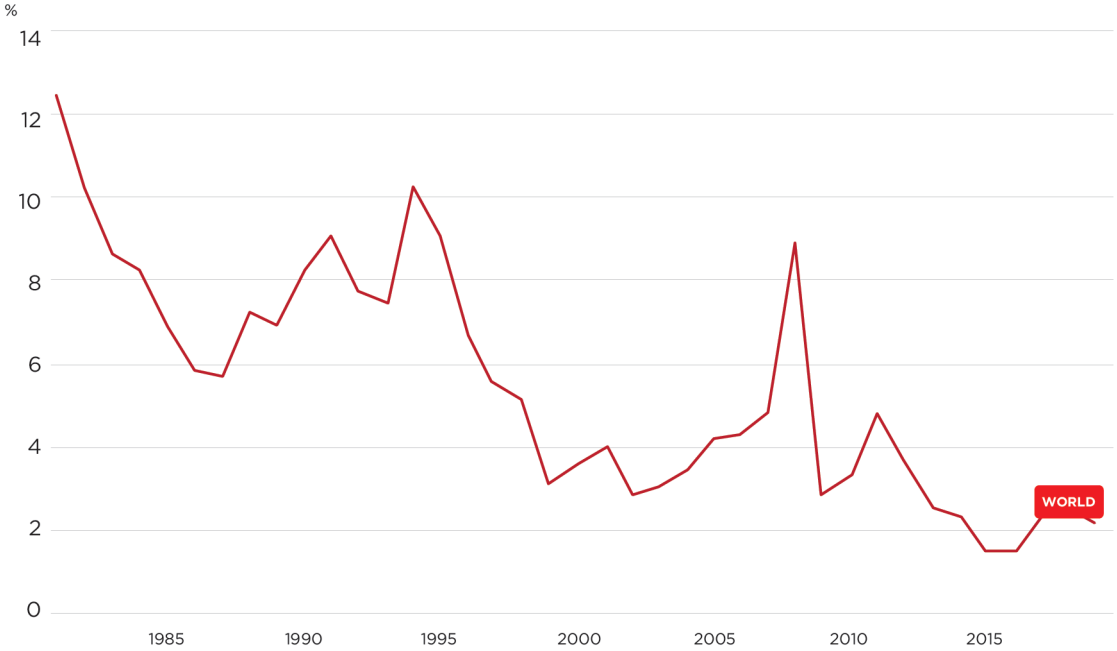
Source: Council of Economic Advisers 2019.

As in Canada, there is a period of increasing average drug price levels in the 1980s, then a downward trend in the late 1990s followed by greater stability in the 21st century. There are also some notable differences. For instance,

there is more variability in the CPI-Rx than in the PMPI, as the range in the rate of change is -2 to 13 percent. The PMPI instead ranges between -2 to 6 percent. Additionally, the absolute values of the rate of change tend to be larger in the US than in Canada, suggesting higher drug price levels in the US. Where the CPI-Rx increased by up to around 10 percent annually in the 1980s, the PMPI increased up to 6 percent annually. In the 21st century, the CPI-Rx stabilized between 0 and 6 percent annually, while the PMPI stabilized around 0 percent for average list price levels.

Since the rate of change of drug price levels in the US has been largely positive and of a higher magnitude than in Canada, average drug price levels have been increasing at a faster rate since 1987. Surprisingly, the data also raise doubt about the myth that drug price levels have skyrocketed in recent years (Hopkins 2019). In both Canada and the US, drug price levels saw their largest rate of increase in the 1980s. What explains this spike – a spike simultaneous with the creation of the PMRPB? The answer is inflation. Figure 2 depicts the world inflation rate from 1981 to 2019. Figures 3 and 4 show the inflation rate in Canada and in the US.

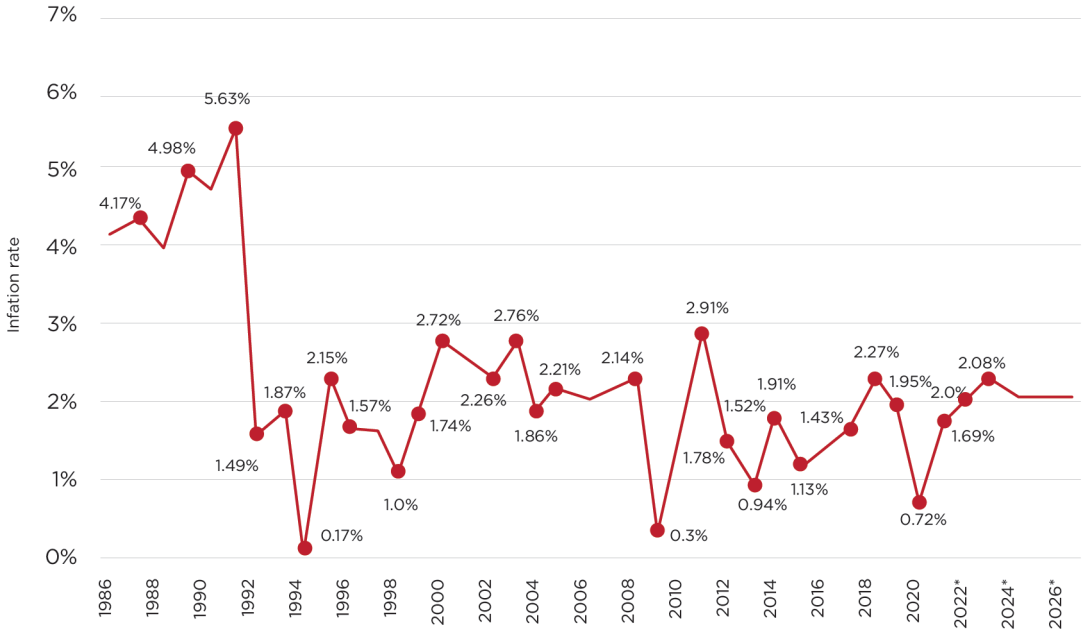
FIGURE 2: WORLD INFLATION RATE, 1981 – 2019



Source: World Bank Undated.

The role of inflation demonstrates that drug price levels have not arbitrarily increased at the whim of manufacturers to increase profit margins. Instead, drug price levels generally increase with the rate of inflation.

FIGURE 3: INFLATION RATE IN CANADA, 1986 – 2026



Source: O'Neill, 2022

FIGURE 4: INFLATION RATE IN THE US, 1980 – 2020

Source: Trading Economics Undated.

High inflation in the 1980s also partially explains the origins of the PMPRB, which was founded in that environment. The increasing costs for drugs was reinforced by the trend in R&D in the 1980s. With the rise of computers, the pharmaceutical industry underwent a period of rapid change. Computation, imaging, X-ray crystallography, scanning electron microscopy, and other techniques replaced the trial-and-error method to an R&D-centred approach to

develop drugs (American Chemical Society 2000). One study called this a "paradigm change in pharmaceutical research" (Pazderka 1999). This caused R&D investment to soar, and with global inflation pushing drug prices upward, short-sighted and fiscally irresponsible governments turned to price controls.

Appendix III:
Price Controls Generally

Governments have long implemented price control mechanisms, pretending that they protect the lower classes and bring uncontrolled markets into equilibrium (Bourne 1919). Experience with price control has now been so extensive, and their impacts so uniformly negative, that any claim of good intentions is disingenuous.

Price controls are a governmental policy implemented to avoid the market price of a good. They can be a price ceiling (a maximum price the product can be sold at) or a price floor (a minimum price it can be sold at), depending on whether a price is deemed "too high" or "too low" by policy-makers. However, economists are uniformly critical of price controls because of their unintended deleterious effects. A price ceiling below the equilibrium price leads to excess demand and shortages. Price floors can lead to a surplus of supply, at least for a period of time. A fluctuation in supply stifles competition and is a disincentive to producers in the market.

It is wishful to believe that drug price controls behave differently than any other price control.

Economist David Schmidtz proposes that price controls are problematic because price signals inform companies about the desirability of their goods. Price controls distort this process by creating artificially high or low prices. When governments interfere with the natural workings of the pricing system, they disrupt the free flow of goods and autonomy of market participants (Schmidtz 2016).

Price controls also deter quality products and retailers from entering the market. In 1997, the Quebec government established price floor regulation in its retail gasoline market (Carranza et al. 2010). A study published from the *Centre sur la productivité et la prospérité* found that this price control method was a major contributor to a more homogenous gas market in Quebec as compared to full service, multi-purpose stations in other Canadian provinces (Carranza et al. 2010). It also prevented the entry of high-quality stations into Quebec's gas market, hampering consumers' access to better quality gasoline (Carranza et al. 2011).

Aside from quality deterioration and market suppression, price controls leave sectors open to political corruption. In the realm of price controls, individuals or companies are motivated to bribe officials to maintain a flow of their goods or to convince legislators to restrict competition to benefit the more powerful monopolies (Mauro 1997). On the consumer side, shortages can lead buyers to bribe or offer favours to gain access to a good. Ironically,

because of governments' attempts to maintain fair prices, many people are forced to buy regulated goods at a higher markup through illicit means (Gupta 2015). Long wait lines for state-regulated products may further encourage participation in black markets and other illegal avenues (Murphy, Pierru, and Smeers 2019). This can be particularly fatal with respect to unregulated pharmaceutical distribution.

The PMPRB imposes maximum allowable prices. At such capped prices, manufacturers are less willing to supply their product, and demand exceeds supply, leading potentially to shortages. Investment is under-rewarded and thus will not be made. Available supplies are more likely to be misallocated. At the same time, there will be excessive demand.

Another consequence of price controls is the deterioration in quality of the product being sold. This could be the substitution of low-quality ingredients or poor-quality conditions. In the pharmaceutical industry, this substitution is not possible because of the strict conditions and specialized equipment necessary to produce a drug that will be approved for human use. Instead, costs must be limited through other means, and this is usually done by cutting R&D expenses or not supplying the pharmaceutical in unprofitable conditions.

During the COVID-19 pandemic, jurisdictions enacted regulations to stop companies from unreasonably increasing the price of products that were deemed necessities, like hand sanitizer and toilet paper (Nicholson 2021). Canadian federal law does not include price-gouging within its competition laws and so regulations on price-gouging fall under provincial consumer protection. In exceptional circumstances, like COVID-19, price-gouging can fall under an emergency order (Bhattacharjee, Rothschild, and Persaud 2020). In March 2020, Doug Ford called price gouging "UN-CANADIAN" and used the *Emergency Management and Civil Protection Act* to prohibit selling essential items at unreasonable prices (Office of the Premier 2020). Alberta Premier Jason Kenney and BC Premier John Horgan followed suit (Cowley, Tomlinson, and Matteis 2020). Yet, a poll conducted by the IGM Forum in 2012 on whether Connecticut should pass a bill that would prevent distributors from raising prices in an emergency showed that only 8 percent agreed or strongly agreed that it should (Henderson 2017). Richard Thaler of the University of Chicago notes that price gouging can be beneficial by giving incentives for one-off suppliers to bring in more supplies for a higher price (Henderson 2017).

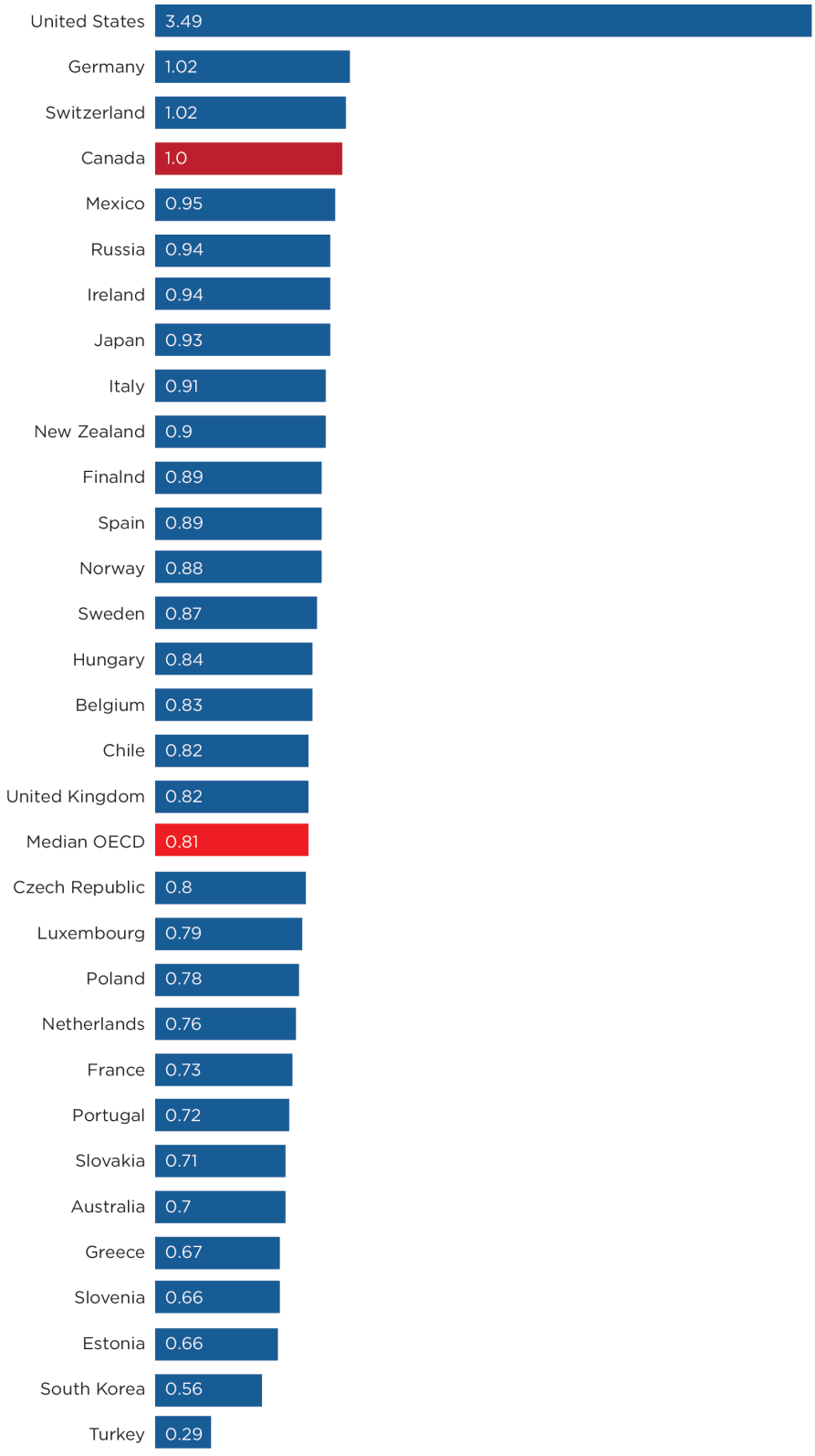
High prices during a time of need signal to consumers that resources of a certain nature are scarce while deterring hoarders from overbuying and taking from others who need it (Lau 2020). One might understand why many oppose anti-price gouging laws that interfere with the constantly changing supply and demand flow that comes during a time of uncertainty. This kind of intuitive approach to economics was coined "do-it-yourself economics" by OECD Chief Economist David Henderson and sees the government expand-

ing control over things they should not be controlling (Lau 2020). Sticking with the theme of this study, government interference with little thought toward possible ramifications is a recipe for poor policy.

Laws against so-called "price-gouging" are another species of price control and cause similar harms. They are a government expedient to smother the signalling effects of price to the market, which may sometimes require political sophistication to weather, but free markets are always salutary.

Source: Mikulic 2021.

Appendix IV:
Relative drug prices internationally



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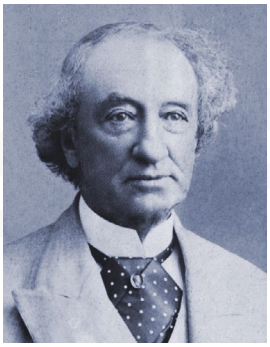

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