A BETTER PATH
for Canadian Health Care

#1 in the Macdonald-Laurier Institute Series

MLI
True North in Canadian public policy

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The Unkindest Cut

How a new plan for slashing drug prices could harm the prosperity and health of Canadians

Wayne Critchley and Richard C. Owens

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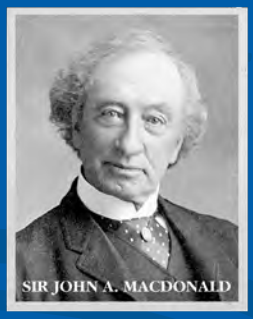
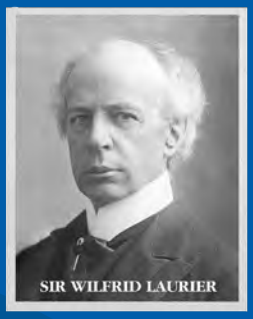
True North in Canadian public policy





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Executive Summary

The federal government is currently consulting on sweeping regulatory changes related to pharmaceutical pricing in Canada. The consultation process will soon come to an end. Then the government will need to determine if or how to proceed.

The purpose of this study is to help inform this process. It examines the proposed regulatory changes and assess, based on a review of a wide body of research, their possible effects on investment, innovation, drug access, and the health and well-being of Canadians. The findings are clear: adopting more stringent price controls will have deleterious economic and health effects. The only real question is about their magnitude. The government would therefore be wise to revisit its regulatory proposal and, in fact, reconsider the ongoing utility of the Patented Medicine Prices Review Board (PMPRB).

The government's proposed changes will almost certainly be more harmful than helpful.

The PMPRB is not well-known among most Canadians. Its origins are rooted in a 30-year-old political compromise. It was established to support consumers by protecting against "excessive" pharmaceutical prices as the Canadian government enacted changes to the *Patent Act*. There has been only minimal analysis of whether its mandate is needed or if it is contributing positively to drug accessibility in Canada. And yet, the government is now proposing to expand the PMPRB's mandate and impose more stringent price caps.

This appears to be a solution in search of a problem, with insufficient consideration of the trade-offs. Just consider the following:

- in 2016, Canadian drug prices were in the mid-range of the seven comparator countries the PMPRB uses to set prices,
- in terms of annual price changes, prices have not increased by more than the rate of inflation and in fact have even declined in some years,
- drug spending as a share of total health expenditures has been stable for the past 15 years, and
- Canada's accessibility to new drugs is presently above the OECD median, below the US, and markedly higher than New Zealand (whose model the federal government has lauded), which ranked last among OECD countries for new drug availability between 2009 and 2014.

As we highlight in the paper, these proposed reforms are not only unjustified based on Canada's current pricing, they will invariably have negative effects on Canada's investment climate and Canadians' access to new drugs. Put differently: the government's proposed changes will almost certainly be more harmful than helpful.

Therefore, the authors recommend the following:

- suspend the regulatory process and properly analyse the "affordability" question and whether there is need for any federal action – with a particular focus on the inherent trade-offs between controlling pricing and supporting a pro-innovation and investment environment,
- consider alternative models to deal with "affordability" if the government is determined to act, and
- conduct a comprehensive review of the PMPRB and what role, if any, it should have in the broader health and innovation policy landscape.

This study is the first in a series of MLI policy papers on the federal Department of Health and its attendant agencies and their role in our health care system and the broader innovation ecosystem. It is important for parliamentarians, media, and Canadians to understand Ottawa's involvement in health care and how it fits with the government's overall agenda.

The key takeaway from this first study is that the government's proposed PMPRB reforms are anti-innovation and will contribute to poorer health outcomes. Therefore they should not proceed.

Sommaire

Le gouvernement fédéral mène actuellement des consultations sur de profondes modifications à la réglementation relative aux prix des produits pharmaceutiques au Canada. Le processus de consultation tire à sa fin, et le gouvernement devra bientôt déterminer s'il doit procéder aux réformes et, dans un tel cas, de quelle manière.

Le but de cette étude est de fournir des informations utiles à ce processus. Nous examinons les propositions réglementaires, puis faisons appel à un abondant corpus de recherches pour évaluer leur impact potentiel sur l'investissement, l'innovation, l'offre de médicaments, la santé des Canadiens ainsi que leur bien-être. Les conclusions de l'étude sont claires : adopter des mesures de contrôle des prix plus strictes influera négativement sur l'économie et la santé. La seule véritable question qui se pose porte sur l'ampleur de cet effet. Il serait donc judicieux pour le gouvernement de revoir sa proposition de réglementation et, en fait, de reconsidérer l'utilité du Conseil d'examen du prix des médicaments brevetés (CEPMB).

Peu de Canadiens connaissent le CEPMB.

Peu de Canadiens connaissent le CEPMB. La création du Conseil a résulté d'un compromis politique négocié il y a 30 ans. Il a été établi en vue de protéger les consommateurs contre une tarification « excessive » des produits pharmaceutiques alors que le gouvernement canadien adoptait des modifications à la *Loi sur les brevets*. L'utilité du mandat et l'influence positive du Conseil relativement à l'offre de médicaments au Canada n'ont fait l'objet que d'une analyse minimale. Et pourtant, le gouvernement propose actuellement d'élargir le mandat du CEPMB et d'imposer des limites de prix plus strictes.

Sans analyse suffisante ni recherche de compromis, cette façon de faire semble en voie d'engendrer des difficultés en guise de solution. Il suffit de considérer ce qui suit pour s'en convaincre :

- En 2016, le Canada figurait au milieu des sept pays de comparaison utilisés par le CEPMB pour fixer les prix.
- En calcul annuel, les prix n'ont pas augmenté plus rapidement que le taux d'inflation, et ont même, en fait, diminué certaines années.
- En pourcentage du total des dépenses de santé, les dépenses en médicaments ont été stables au cours des 15 dernières années.
- L'offre de nouveaux médicaments au Canada est actuellement supérieure à la médiane de l'OCDE, inférieure à celle des États-Unis et nettement plus élevée que celle de la Nouvelle-Zélande (modèle que le gouvernement fédéral louange), pays qui s'est classé dernier parmi les pays de l'OCDE en ce qui a trait à l'offre de nouveaux médicaments entre 2009 et 2014.

Comme nous le soulignons dans la présente étude, non seulement les prix courants au Canada ne permettent pas de justifier les réformes proposées, mais ces dernières ne manqueront pas d'avoir des effets négatifs sur le climat d'investissement au pays et l'offre de nouveaux médicaments aux Canadiens. En d'autres termes, l'adoption des modifications proposées par le gouvernement sera presque certainement nuisible plutôt qu'utile.

Par conséquent, les auteurs recommandent ce qui suit :

- Ajourner le processus réglementaire et analyser de façon appropriée la question de l'« abordabilité » et de l'utilité d'une action fédérale – en s'attachant tout particulièrement au compromis intrinsèque entre le contrôle des prix et l'appui à un environnement favorable à l'innovation et à l'investissement.
- Si le gouvernement est déterminé à agir, envisager d'autres modèles pour composer avec l'« abordabilité ».
- Procéder à une revue exhaustive du CEPMB et du rôle qu'il pourrait être appelé à jouer, le cas échéant, dans le contexte général des politiques en santé et en innovation.

Premier d'une série de documents de politique de l'IML, celui-ci porte sur le ministère fédéral de la Santé, ses organismes auxiliaires et leur rôle dans notre système de soins de santé et l'écosystème plus étendu de l'innovation. Il est important que les parlementaires, les médias et les Canadiens soient bien au fait des interventions du gouvernement fédéral dans le domaine de la santé et de la place de ces interventions au sein de son plan d'action général.

Élément clé à retenir ici dans cette première étude : le gouvernement a proposé des réformes relatives au CEPMB qui seront dommageables en matière d'innovation et contribueront négativement aux résultats en santé. Par conséquent, le gouvernement ne devrait pas aller de l'avant.

Introduction

Ottawa has proposed tighter price controls for patented pharmaceuticals. These controls will have significant implications for investment, innovation, drug access, and the health and well-being of Canadians.

Yet the proposed regulatory changes to the Patented Medicine Prices Review Board's (PMPRB)'s mandate and decision-making process have not received much media or political attention. This paucity of scrutiny precludes a substantive debate about which objectives and priorities ought to guide federal drug policy.

The PMPRB is obscure to most Canadians. Its work seems technocratic and detached from our everyday lives. Even keen federal observers can overlook the PMPRB and the broader health portfolio in debates about health and innovation policy.

But it is wrong to assume that the Department of Health (frequently referred to as Health Canada) in general and PMPRB in particular are not worth our attention. PMPRB's draft regulatory changes – which would fundamentally reshape how it evaluates new patented drugs and sets their maximum prices – is good (or bad) evidence of why Ottawa's role in health care policy ought to be the subject of far more analysis and debate.

This study by the Macdonald-Laurier Institute (MLI) will:

- provide a primer on the PMPRB and its historical evolution over the past 30 years,
- assess the problems with the current draft regulations,
- examine the research literature on the relationship between price controls on drugs and economic and health-related outcomes,

- study the experience with price controls in New Zealand, and
- set out recommendations to better support investment, innovation, and drug access for Canadians.

This study is the first in a series of MLI policy papers on the federal Department of Health and its attendant agencies and their role in our health care system and the broader innovation ecosystem. It is important for parliamentarians, media, and Canadians to understand Ottawa's involvement in health care and how it fits with the government's overall agenda.

The government wants the benefits of investment and innovation at prices found in countries that rank lower in economic wealth and health care performance.

The ostensible goal of the PMPRB's proposed regulatory changes is to lower drug prices for provincial and territorial governments and other Canadian drug purchasers. But there appears to have been minimal if any consideration of what these changes may mean for Canada's climate for investment, innovation, and drug access – and even whether there is a problem of affordability to be addressed at all. The government seemingly wants the benefits of the latest developed world investment and innovation but at prices found in countries that rank lower in economic wealth and health care performance.

A body of theoretical and empirical research shows that there are important trade-offs inherent in these policy choices. It is essential that these trade-offs are properly evaluated and judged to be in Canada's best interests. The draft regulations ignore these considerations.

As an alternative, we have set out some key recommendations to ensure that federal policy is rooted in a clear understanding of these trade-offs including:

- suspend the regulatory process and properly analyse the "affordability" question and whether there is need for any federal action – with a particular focus on the inherent trade-offs between enabling a pro-innovation and investment environment and the role of pricing,
- consider alternative models to deal with "affordability" if the government is determined to act, and
- conduct a comprehensive review of the PMPRB and what role, if any, it should have in the broader health and innovation policy landscape.

What is the PMPRB?

The PMPRB is a Canadian government agency that regulates prices of drugs with unexpired patents. It establishes the maximum prices that can be charged in Canada for patented drugs. It thus has an important role to play in our health care system and for creating the conditions for a pharmaceutical ecosystem.

The PMPRB's origins date back to 1987. Its creation was part of a major update to the *Patent Act* that sought to bring our laws and policies into closer alignment with Canada's major trading partners. One of the principal changes at the time was to restrict the availability of compulsory licensing of pharmaceutical patents. Compulsory licensing is an exception to patent law that allows someone to work another person's patent in exchange for a royalty payment. Beginning in 1969, Canada applied this policy to pharmaceuticals to encourage the development of a domestic generic drug industry and improve the availability of lower cost generic drugs. By the 1980s, it had achieved those objectives but had become an irritant with trading partners and the pharmaceutical sector.

The 1987 amendments to the *Patent Act* sought to achieve a delicate government-wide balance among major policy objectives including:

- enhancing intellectual property protection;
- supporting international trade;
- encouraging research and investment;
- improving health care; and
- ensuring consumer protection.

As part of this comprehensive legislative package, the government established the PMPRB. Its practical mandate was to ensure that patentees could not abuse their improved exclusivity periods to increase prices to "excessive" levels. Its political purpose was to assuage concerns that the legislative reforms tipped the scale in favour of the pharmaceutical sector and would ultimately hurt provincial budgets and patients.

The PMPRB was therefore established as a quasi-judicial body with a price regulatory mandate to ensure that patent holders did not charge "excessive" prices during their statutory monopoly period (Government of Canada 2017). Differing interpretations of "excessive" and a narrow focus on its "consumer protection" role are topics that we will address in greater detail later in this study.

But the key point is that the PMPRB is a unique feature of intellectual property policy that was born more than 30 years ago partly to mollify public concerns about the impact on drug prices in light of changes to intellectual property protection for pharmaceuticals. Despite major changes in the biopharmaceutical sector and in government pricing and reimbursement policies at the provincial level, there has been no major review of the PMPRB in the subsequent three decades.

How does the PMPRB carry out its mandate?

Its annual budget is about $10 million per year and it has approximately 75 employees (PMPRB 2017a). It is part of the Heath portfolio.

The *Patent Act* and the *Patented Medicines Regulations* together form the patented medicines price regulatory framework for the PMPRB. Although the *Act* falls under the responsibility of the Minister of Innovation, Science and Economic Development (ISED), the Minister of Health is responsible for the regulations. As an administrative tribunal, the PMPRB carries out its mandate at arm's length from the Minister.

Federal oversight of drug prices is limited to patented drugs. While its own reports have historically suggested that high generic drug prices are an even bigger problem, the PMPRB has no legal authority to control them (PMPRB 2016).[2]

Its principal work is the regulation of what it refers to as the "factory gate" ceiling prices for all patented drug products sold in Canadian markets – that is, the prices at which patent holders sell their products to wholesalers, hospitals, pharmacies, and other large distributors.

Here is where the question of "excessive" comes into play. The legal standard of "excessive" price is novel in systems of government regulation and differs from other models of pricing regulation historically used in other industries such as ones based on rate of return. The *Patent Act* sets out specific factors the PMPRB must consider in determining whether a price is excessive:

- the prices of other medicines that treat the same disease;
- the price of the medicine in other countries; and
- changes in the Consumer Price Index.

Only if the PMPRB cannot make a decision based on these factors may it consider other factors such as the cost of making and marketing the medicine.

Because it is required to follow a quasi-judicial process and can only make binding decisions following a

full public hearing, the PMPRB has opted to rely heavily on voluntary compliance. The goal is to have companies essentially adopt prices that fit within its *Compendium of Policies, Guidelines and Procedures* (PMPRB 2017b).

The PMPRB *Guidelines* are based on the price determination factors in the *Act*. Although the detailed guidelines are complex, their essence is straightforward:

- most new drugs may not be priced higher than drugs in the same therapeutic class. In other words, a new drug to lower blood pressure cannot be priced more than the current most expensive drug to treat blood pressure;
- breakthrough and first-in-class drugs may be priced no higher than the median of the prices in the seven comparator countries;
- over time prices cannot increase by more than changes in the Consumer Price Index; and
- the Canadian price may not exceed the highest price in the comparator countries (this may happen if prices decline elsewhere but not in Canada or even if currency fluctuations cause the Canadian price to rise relative to other countries.)

The countries used for international comparisons are set out by regulation. The initial list included France, Germany, Italy, Sweden, Switzerland, the UK, and the US. These countries were ostensibly chosen because of their similarities to Canada – namely, they are highly developed countries and have a significant pharmaceutical industry presence. The list of comparator countries has not been subsequently changed – though it is revisited in the government's current proposed regulations as we discuss later in the paper.

One can argue that the PMPRB has delivered on its consumer-oriented mandate.

The PMPRB follows this process to oversee a large number of new patented drug products each year. There were 128 in 2016, which was the highest in a single year since its inception (PMPRB 2017a). Of these 128 new patented drug products, the prices of 70 were reviewed as of the end of the 2016/17 fiscal year. The outcomes were as follows:

- 45 were found to be within the price boundary set out in the *Guidelines*;
- 13 appeared to exceed the price boundary set out in the *Guidelines* by a small amount that did not trigger the investigation criteria; and
- 12 were at levels that appeared to exceed the price boundary set out in the *Guidelines* and resulted in investigations (PMPRB 2017a).

How has the system worked over the past 30 years? If the measure is primarily about controlling prices, then one can argue that the PMPRB has delivered on its consumer-oriented mandate. Consider:

- in 1987, when the PMPRB was established, Canadian prices were 23 percent higher than the median of foreign prices (compared to 2016, which were 25 percent lower);
- in 2016, Canadian prices were in the mid-range of the seven comparator countries;
- in terms of annual price changes, prices have not increased by more than the rate of inflation and in fact have even declined in some years (PMPRB 2017a).

In addition, Canadian governments (including federal, provincial, and territorial) have become effective in using their collective buying power to negotiate drug prices. According to the Council of the Federation, governments negotiated additional confidential rebates from drug manufacturers of about $1.28 billion in 2016/17. In Ontario, the savings that year represented one-quarter of the total drug plan expenditures on drugs.[3]

Note that the provinces are accorded purchase rebates rather than price concessions, so that the prices are generally maintained at the permitted level set by the manufacturer and the PMPRB. The existence of substantial provincial bulk purchasing power results in negotiated savings irrespective of any PMPRB action.

A review of the PMPRB's activities and the general direction of drug pricing in Canada suggests little need for alarm. The evidence simply does not support any claim that drug prices are unacceptably high.

PMPRB's Regulatory Proposals

Yet, last May, then-federal Health Minister Jane Philpott claimed that she was pre-positioning sweeping new changes to the PMPRB's mandate and activities (Kirkup 2017). Subsequently, draft regulations giving new powers to the PMPRB were published in the *Canada Gazette* (Government of Canada 2017). Health Canada is moving quickly to meet a target date for implementation of January 1, 2019.

The proposed reform "will result in the biggest shake-up in prescription drug pricing in 30 years" (Picard 2017). Not only are the changes intended to immediately reduce prices for new patented drugs in the range of 20 to 25 percent, or more, they would also have the federal government undertake, and duplicate, work now done by provincial governments. The government estimates that the proposals will result in reduced industry revenues of $8.6 billion "net present value" (meaning the cost will be much higher when inflationary factors are considered) over 10 years.[4] But a recent study (PDCI 2018) finds that Health Canada has significantly underestimated the negative impact of the proposed changes and overestimated the positive impact. It concludes that industry revenues will be reduced by more than three times the government's estimate with predictable negative impacts on investment, employment, and the availability of new drug therapies.

The changes intended to immediately reduce prices for new patented drugs would also have the federal government duplicate work now done by provincial governments.

Incredibly, there is no evidence the government even attempted to make a meaningful assessment of the impact on access to innovative therapies and the health care system. To the extent that there has been any analysis, it has tended to downplay any costs or other negative effects. The proposals and analysis appear to have been rushed with no broad consultation. Physicians and patients should be very concerned.

Even though drug spending as a share of total health expenditures has been stable for the past 15 years,[5] public and private payers are flagging questions about the potential impact of new treatments. Significant breakthroughs such as CAR-T therapy (engineering immune cells to treat cancer) illustrate the changing nature of pharmaceutical research and innovation and the huge potential to save lives and improve health care. This innovation is expensive and the well-publicized price tags of individual treatments have made payers anxious about the capacity of existing systems to manage demand. But the PMPRB program and proposed federal reform are ill-suited to this emerging world of biologic therapies. Government is patching up 20th century policy for a 21st century world where it will have no useful application and may cause harm.

To support its claim that Canadian prices are too high, Health Canada wants to change the reference countries. What does this mean? Remember part of the PMPRB's assessment of whether a patented drug

price is "excessive" is to compare domestic pricing with that found in other countries. The current "basket" of seven countries used by the PMPRB was selected in 1987 as part of the balance in patent law reform; they are highly developed countries with good health care systems and a robust pharmaceutical sector.[6] It makes sense. We ought to be comparing our circumstances with countries that have similar economic structures and innovation ecosystems.

The proposed regulations will amend the "basket" of comparator countries to remove countries with higher drug prices such as the US and Switzerland and add lower-priced ones, such as Spain and South Korea. The new target is the median of prices in the Organisation for Economic Cooperation and Development (OECD) countries, which is 20 to 25 percent below Canada.[7] This is a curious target. It is difficult to think of other areas where Canada aims to be in the middle of the OECD.

Pharmacoeconomics

The proposed regulations would introduce a number of new economic price determination factors to require the PMPRB to assess the value and affordability of a new drug. These changes appear aimed at changing the statutory standard of "excessive" price; it is arguable that this is an improper use of the government's regulation-making power. To change "excessive" to "affordable" or some other standard requires an amendment of the *Act* by Parliament. Proposals to amend the *Patent Act* would require the agreement of the Minister of ISED and a broader consideration of the impacts on innovation and industrial policies.

The most controversial proposal is to add pharmacoeconomics to the equation. Pharmacoeconomics is widely used by drug funders in the developed world to assess new drug therapies on the basis of cost-effectiveness and Canada is recognized as a leader in the field. The Canadian Agency for Drugs and Technologies in Health (CADTH 2018) conducts assessments for federal and provincial public drug programs outside Quebec through distinct processes for oncology and non-oncology drugs; in Quebec, the *Institut national d'excellence en santé et en services sociaux* (INESSS 2018) performs pharmacoeconomic evaluations for the province of Quebec.

We ought to be comparing our circumstances with countries that have similar economic structures and innovation ecosystems.

Pharmacoeconomics attempts to assess the relative "value" of a new treatment compared to existing therapies and therefore it may appear logical to ask the PMPRB to take it into account. Currently, the PMPRB only assesses "value" in a crude way by differentiating drugs based on the degree of therapeutic improvement they offer relative to other drug products sold in Canada. But in practice pharmacoeconomics is too imprecise and based on a wide range of assumptions to be compatible with the PMPRB's quasi-judicial mandate under the *Patent Act* to calculate an "excessive" price.

If implemented, Canada would be the first and only jurisdiction to attempt to fix a precise price for a drug in this way. In Canada and elsewhere, pharmacoeconomic analysis is used to support and inform coverage decisions and price negotiations by indicating ranges and conditions under which a drug may be cost-effective. This is an appropriate tool for drug plan managers, who are tasked with making funding decisions. A cost-effectiveness evaluation may not be easily transferable from one circumstance to another because of variations due to the population to be covered, conditions that may apply, and the perspective of the plan.[8]

A review of recommendations from CADTH illustrates the point: In most cases, CADTH recommends listing for only a subset of patients or under more narrow conditions than approved by Health Canada; it also identifies a range of cost-effectiveness analysis based on that limited coverage and makes a general recommendation that the reimbursement price and conditions should reflect it. It makes no effort, and

arguably would be unable, to propose a specific price for the full Canadian population as the PMPRB is required to do.

If there is a disagreement in assessment between CADTH, INESSS, and PMPRB, which one will prevail? If provincial governments want to cover a new treatment, will they be able to do so if the PMPRB price review remains unsettled? Will they be expected to fund all drugs if the PMPRB finds the price non-excessive? Nothing in the federal proposals suggests there has been any consideration of how this new system will be integrated into the existing complex processes.

There are other problems with adding pharmacoeconomics including:

- It is inconsistent with established standards under intellectual property law. An "excessive" price suggests abuse of a patent monopoly. The *Patent Act* creates a legal monopoly; in an environment where sophisticated funders currently rely on robust analysis to assess and negotiate prices and conditions of coverage, how could that agreed-upon price be considered "excessive" or an abuse of a patent?
- It is inconsistent with the statutory standard of "excessive" price. "Value" reflects a subjective assessment; it reflects individual needs and priorities and varies from one person to another. A price may not provide sufficient value to one drug plan to offer coverage, but still not be excessive for others who consider it does offer value to them.[9]
- Assessments by most agencies, such as CADTH, use the narrow perspective of a public drug program; they do not take into account the broader health system or societal impacts.
- Finally, it represents a duplication of work done by existing agencies. Not only does the federal proposal duplicate existing FPT programs, it runs a great risk of creating conflicts among them as they apply different perspectives.

A report by the Institute of Health Economics, which was commissioned by Health Canada in 2013, essentially comes to the same conclusions. After studying the use of pharmacoeconomics and value-based pricing in Canada and other countries, the authors concluded such an approach would not be consistent with the PMPRB's mandate, would duplicate existing programs, and would require a totally new approach working with payers and all stakeholders:

> The paper finds that value-based pricing would require a departure from the current approach to excessive price determination within the PMPRB. Notably, value-based pricing would require a much closer relationship with public and private payers, and the institutions that support them, as prices can be further regulated in the marketplace. Any attempt to introduce value-based pricing for ex-factory prices would likely duplicate existing systems that attempt to affect purchase prices based on cost-effectiveness, as seen across individual provinces and in the newly-formed pan-Canadian purchasing alliance. Finally, value-based pricing cannot be simply reduced to a mathematical algorithm. Rather, it would require the full participation and consent of representative societal actors who can deliberate and negotiate with information regarding how prices will affect the health and welfare of consumers, both now and in the future. (Husereau 2013, iii)

Health Canada appears to have ignored this study in developing its current proposals. The risk is that the PMPRB's determination of "excessive" will become more arbitrary – particularly as it pursues its new low-cost target. The consequences could be significant.

Confidentiality and rebates

Another proposed change threatens to actually increase costs to public drug plans rather than lower them. This proposal would require manufacturers to report information on the confidential rebates paid to governments under their listing agreements. As noted above, these purchase rebates are not included in the price reimbursed by drug plans but rather are collected by governments after the fact based on re-

cords of volumes of drug reimbursed. In most cases, such as the Province of Ontario, they are not treated as a price reduction and in fact the rebates are not credited to the drug plan budget; they are credited to the provincial treasury.

Why are these rebates at risk if reported to the PMPRB? The PMPRB proposes to use this information to discount the prices of existing medicines in order to set a lower maximum price for a new drug in the market. And that new lower price will apply not only to those markets that have been able to negotiate rebates, but to all markets. The incentives for a manufacturer to offer a purchase rebate as part of a listing agreement will all but disappear.

Moreover, their ability to do so may also disappear. The PMPRB has outlined its plan to cap the entry price of all new patented medicines at the new median international price, or about 20 to 25 percent lower than prevailing today. It would then apply the new economic factors to potentially lower the price even further. The plan seems intended to end the practice of negotiated purchase rebates, which have proved to be a valuable tool in allowing payers and manufacturers to accommodate coverage of new therapies.

Ironically, in light of the objective to lower prices to the median OECD level, including purchase rebates in calculating the Canadian price will make apples-to-apples comparison with other countries impossible. Purchase rebates are used in all developed countries and they are always confidential. It will be impossible to compare the price net of rebates in Canada with the comparable net price in other countries.

The purpose of the proposed regulatory changes is clear: To dramatically lower the prices of patented medicines across the board by at least 20 to 25 percent. It should be obvious to policy-makers that such a dramatic change will not be achieved without consequences.

Possible Economic and Health-Related Effects of Tighter Price Controls

There is a considerable body of theoretical and empirical research on the importance of the pricing system in a market economy. Prices play a powerful role in signaling market demand, informing market supply, and ultimately bringing the two into equilibrium without a centralized authority.

In the long run, government attempts to substitute bureaucratic decision-making for the decentralized pricing mechanism have consistently failed, sometimes spectacularly so. Price controls have been enacted with different motives. Sometimes they are driven by concerns about scarcity (such as wartime production). Other times they are driven by concerns about potential inflation (such as the PMPRB). Often times they are motivated principally by political economy considerations (such as protection for politically-relevant constituencies).

In some cases, entire economies were touched by government control of the pricing mechanism, while in other cases otherwise market-based economies have had episodic periods of price controls, or pricing controls in key sectors. The general outcome is the same: government interference in pricing mechanisms produces suboptimal results. As a Yale University professor concludes having examined the failed historical experiences with price controls in different sectors:

> The imposition of price controls on a well-functioning, competitive market harms society by reducing the amount of trade in the economy and creating incentives to waste resources. Many researchers have found that price controls reduce entry and investment in the long run. The controls can also reduce quality, create black markets, and stimulate costly rationing. In

the case of pharmaceuticals, the most damaging area is likely to be the reduction in innovation, which will harm all future generations of patients (Morton 2001).

That is certainly what a wide body of empirical literature finds. It is well-established that there is a negative relationship between price controls and various economic indicia, including investment, innovation, employment, and ultimately patient well-being (Kessler; Cressanthis 2016; Vernon 2005; Vernon 2004; Kutyavina 2010). Some proponents of price controls recognize these trade-offs – even if they disagree on the magnitude or ultimately believe they are worth it (Kliff 2016).

It is worth unpacking these points so as to avoid any confusion. We are not claiming that there is a one-for-one relationship between price and local R&D investment and innovation. Business decisions about where, when, and how to invest involve various factors and considerations. MLI has previously shown for instance that Canada's IP regime (which has weaker patent restoration) contributes to a poorer climate for investment and innovation. Other factors such as our proximity to the US market, high levels of human capital, and reasonably competitive corporate income tax rates probably are in favour. The point is it's complicated. We recognize that.

Some proponents of price controls recognize these trade-offs.

But evidence-based policy-making is about making judgements based on the best available evidence and the preponderance of analysis and facts. The evidence suggests rather strongly that lower drug prices in the form of more stringent government-imposed price caps will undermine conditions for investment and innovation. Will it lead to less local R&D investment and by how much? Of course we cannot say for sure. But surely the onus is not on us but rather the government who is proposing the policy change to justify its rationale and adequately assess it trade-offs. The evidence below suggests that Ottawa has failed to do so.

The US remains one of the only jurisdictions without national pharmaceutical pricing restrictions.[10] It has no national body responsible for overseeing or mandating drug prices although segments of the market may restrict and control pricing (for example, the Department of Veterans Affairs's drug plan). Drug companies are able to essentially set their own prices based on market conditions. It is notable that the United States maintains a leading role in innovation and drug development – responsible for nearly half of the world's R&D in the life sciences (UNESCO 2017). A coincidence? No. These are some of the real trade-offs that policy-makers must grapple with.

A considerable body of research suggests that the US's leadership might not be as dynamic in a price-regulated environment. Consider the following:

- A 2005 study by John Vernon on the potential effects of implementing price regulations on the US drug sector estimates that doing so could reduce R&D investment in the sector by approximately 23 to 33 percent.
- A Giaccotto, Santerre, and Vernon 2005 study published by the University of Chicago predicts similar results. It estimates that had price regulations been implemented in the US between 1980 and 2001, approximately $265 billion to $293 billion in R&D investments would not have occurred – amounting to approximately 30 percent less R&D spending in the pharmaceutical sector over the period (211). The study predicts this investment reduction would have translated to between 330 and 365 fewer drugs being brought to market (approximately 38 percent of the new drugs brought to market during the period) (211–212).
- The same study holds that a 10 percent increase in real drug prices resulted in an approximate 6 percent increase in R&D expenditures (212). The mechanism, of course, by which R&D falters in a regulated environment is simple. The marginal efficiency of investment will be determined by the cost of capital, which, in a risky business, is high, demanding a high return from investment

> to justify. Where return is capped, investment simply becomes unrewarding sooner. The impact of price regulation in the US, were it to be applied, has clearly been shown to diminish R&D (Vernon 2002). An excellent paper from the Montreal Enterprise Institute draws the same conclusions (Petkantchin 2004).[11]

This point is intuitive: greater profitability enables more investment, R&D, and ultimately drug development. As a recent report by the Brookings Institution explains:

> There has been a variety of evidence assembled regarding the relationship between profitability and innovation in the pharmaceutical industry. One major strand of evidence involves natural experiments regarding industry responses to growth in the size of markets. The logic behind this quasi-experimental approach is simple: Larger markets generate greater revenues that in turn create expectations of more profits to manufacturers, which expand investment in new drugs to pursue those profits. (Frank and Ginsburg 2017)

Put differently: profitability and the economic incentives inherent in the pricing and profit system are key to the innovation ecosystem – including the pipeline of new drugs.

In a case such as pharmaceuticals, where R&D investments tend to be made globally, some might suggest that Canada exerts little influence. Canada's share of total worldwide drug sales has been steadily declining according to the PMPRB (2017a, figure 19) from 2.7 percent in 2010 to 1.9 percent in 2016. In our case, why not follow the lead of some poorer countries and insist on lower prices – will we not still be able to rely on the US for the bulk of innovation? There are many reasons why a freeloading policy is not in Canadians' interest.

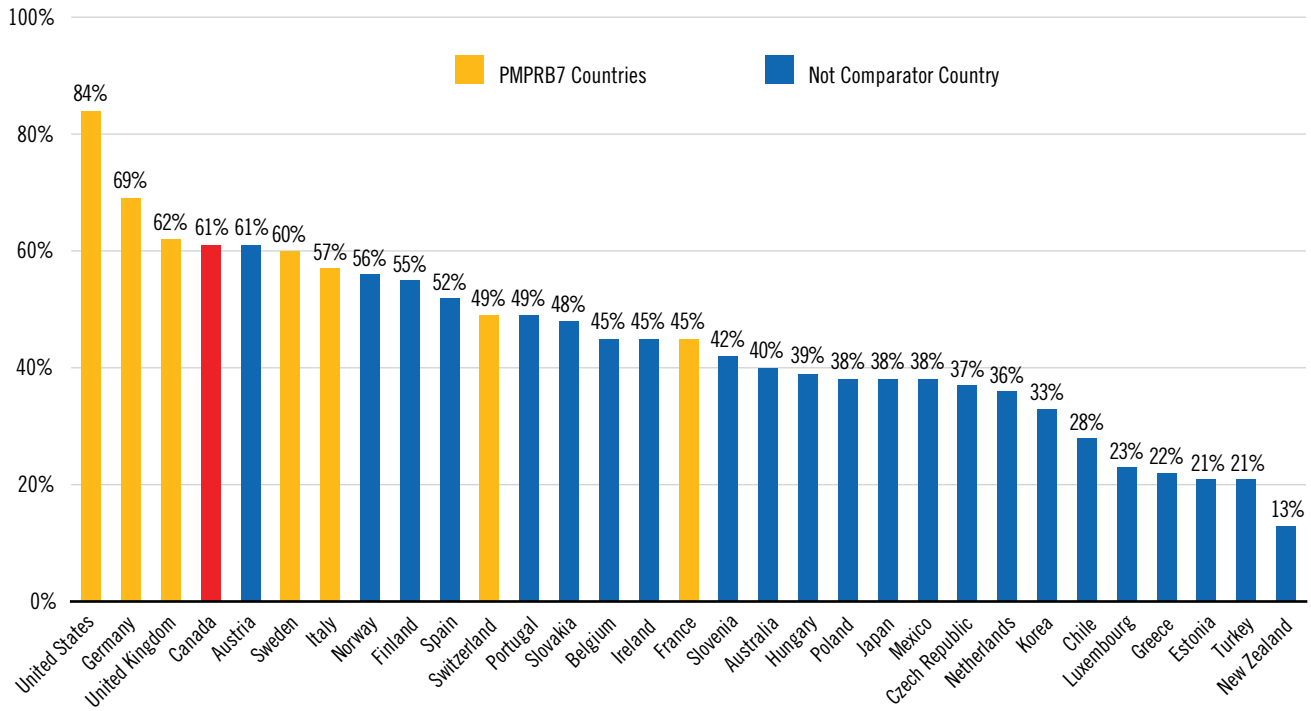
Greater profitability enables more investment, R&D, and ultimately drug development.

First, a low-price regime sends the wrong signals to researchers and new biopharmaceutical developers in Canada. Such a strategy runs counter to the objectives of the federal "Innovation Agenda" and provincial policies to spur innovation and high-technology sectors. A low-price strategy in the life sciences sector could undo all the incentives and policy initiatives of government to promote that sector for the future. In effect, it could amount to a troubling case of the left hand and the right hand failing to work together in the name of innovation. The regulatory analysis supporting the current PMPRB reform fails to take into account the impact of the policy change on investments in the sector, including high quality research and employment.

Second, a low-price policy assumes that manufacturers will continue to bring the same new drugs to Canada at the same time as they would have. In fact, the government's regulatory statement states: "It is not anticipated that these amendments would generate adverse impacts on industry employment or investment in the Canadian economy" (Government of Canada 2017). The government does not provide any empirical evidence to support this statement nor that the amendments might impact the availability of new medicines in the Canadian health care system. In fact, the PMPRB itself has produced evidence that suggests the opposite.

Analysis published last year by the PMPRB shows that in OECD counties with lower drug prices than Canada, the number of new drugs launched is also lower. Of the new drugs introduced in current PMPRB comparator countries, the "PMPRB7," in 2009–2014, 61 percent were available in Canada by the end of 2015, slightly lower than Germany and the UK, and well below 84 percent in the US. By comparison, the median for the OECD was 45 percent, well below Canada. New Zealand ranked last, at 13 percent (see chart 1).

CHART 1: New drugs launched in the PMPRB7 in 2009–2014, status at Q4 2015 in OECD countries



Source: NPDUIS 2017, appendix 1, figure 1.1.

The data suggest that countries with aggressive low-price policies received delayed access, if at all, to important new drugs. Look no further than Europe.

The European experience with price controls is telling. A 2009 study by the American Enterprise Institute (AEI) found that price regulation reduced R&D investment in the EU. AEI found that in the mid 1980s, R&D drug investment in the EU exceeded US investment by 24 percent (Vernon and Golec 2008, 4). However, between 1985 and 2004, the EU imposed strict regulation in pharmaceutical prices, resulting in almost 0 percent drug inflation over the period (4). These price controls had a corresponding impact on R&D investment – with EU R&D in pharmaceuticals growing at only half the rate of US R&D from 1985 to 2004. By 2004, EU R&D investment lagged US investment by 15 percent (4). The decline in EU R&D investment was estimated to translate to $5 billion in foregone R&D spending, 1680 fewer research jobs, and 46 fewer new drugs (Golec and Vernon 2006, 6).

A 2010 study exploring the effect of more stringent price regulations in the EU relative to the US confirms that US firms spend more on R&D than European firms (Golec and Vernon 2010, 615). The researchers estimate that had the US imposed European-style price controls between 1986 and 2004, it would have resulted in $12.7 billion less in R&D investments – resulting in 117 fewer new drugs and 4368 fewer research jobs (616).

As one patient advocate writes: "Dictating drug prices is a sure-fire way to stop pharmaceutical firms from creating new medicines" (Ladd 2015).

Drug development is a stunningly expensive process. The average FDA-approved medicine requires an investment of $2.6 billion and over a decade of research, according to a 2016 study from Tufts University (Center for the Study of Drug Development 2016), although estimates vary.

A 2015 study in the *American Journal of Medical Research* estimates that a patented pharmaceutical's annual cost of capital is approximately $1.5 billion per year – and thus a successful drug must earn

$1.5 billion in revenues each and every year just to cover the capital costs for the R&D expenditures (Winegarden 2015, 59).

Price is the means by which companies can recoup the costs associated with development and cross-subsidize the next discovery and product development. Capping a company's ability to earn a reasonable return can thus undermine the innovation ecosystem. A National Bureau of Economic Research study estimates that cutting prices by 40 to 50 percent in the United States will lead to between 30 and 60 percent fewer R&D projects being undertaken in the early stage of developing a new drug (Francis 2018).

A 2009 academic study found a slightly less significant yet still positive relation between the number of new drugs in development to treat a disease and the average price for on-patent drugs currently used to treat that disease. The authors' estimates imply that a 50 percent decrease in drug prices, holding disease incidence and severity constant, decreases drug development by as much as 25 percent. This result implies that government policies that would significantly reduce the price of drugs could substantially reduce drug development (Civan and Maloney 2009).

The story in each of these cases is the same: Government-imposed pricing that was too disconnected from market forces and too punitive had negative effects on investment, innovation, and access to new medicines.

The average FDA-approved medicine requires an investment of $2.6 billion and over a decade of research.

Moreover, to reduce price and thereby delay access to new medicines is no simple tradeoff of lower price for more sickness and death during the delay in new drug introduction in Canada. Innovative medicines greatly improve patient outcomes, and improve patient well-being. In the long- and even the short-run, they often have the potential to shorten hospitalization and other forms of treatment and reduce costs of care. In other words, extensive overall cost savings from access to new drugs, are jettisoned in favour of the simple and non-inclusive indicator of price. In this light, there is some theoretical consistency, at least, in using pharmacoeconomic factors to increase price – but one is suspicious of this being the government's intention. Studies indicate that the size of drug expenditure correlates positively with longevity as well as with shorter hospital stays and better health outcomes. It even correlates with lower overall health care costs (Kessler). Moreover, competition from new drugs will reduce prices of earlier treatments, making them more available to poorer sick people.

Delay in introducing new drug therapies has been shown to increase costs of already-established therapies (PMPRB 2018). Price regulation of innovative therapies increases costs of generic medicines (Danzon and Chao 2000a; Danzon and Chao 2000b), a major problem for Canada (Anis and Wen 1998). Generic price competition is far higher in the US, for example.

And it must be asked, where is Canada's affordability crisis? What on earth would justify the government incurring all these costs and disadvantages to change PMPRB regulation? Remember, as discussed, drug prices have held steady in this country and they are not high by international standards. Even if there were an affordability problem in this country, for the many reasons cited herein it should be clear that the way to address it is not to reduce price for all, but rather to directly subsidize the few needy.

How much truer will all this be with drugs priced high for small genetic populations where scarcity will always be a factor? We should be eager to get our hands on such drugs, not putting up ill-considered barriers.

Moreover, even assuming lower drug prices to be a good thing, which it appears they are not, certainly not unalloyedly, there is a moral question: is it appropriate to free ride on the US consumer to fund the costs of our drug development?

It also needs to be remembered that Canada is not alone in this game. Reluctance to enter a low-price

market like Canada will be compounded by "spillover" of Canada's regulated price into other jurisdictions through their indexation process; that is, not only is price in Canada low, disincentivizing sales, but starting to sell in Canada could reduce price in still more jurisdictions. Take for granted that companies will find opportunities to game the international pricing system. They would have to.

New Zealand's Experience

The Canadian government has cited New Zealand as a model to be emulated by Canada (Sawa and Ellenwood 2017). But the truth is New Zealand presents a stern warning on the risks of price regulation.

New Zealand provides 100 percent coverage for pharmaceuticals in hospital and generous subsidies for drugs purchased outside hospitals (Cumming, Mays, and Daubé 2010). In 1993, the country established the Pharmaceutical Management Agency (PHARMAC), with a mandate to manage the government's spending on pharmaceuticals. PHARMAC determines which drugs will be subsidized by the government (Cumming, Mays, and Daubé 2010). It has a fixed annual budget and engages in various practices to manage prices, such as sole supply contracts and promoting generics (Babar 2015). This type of government control enables it to essentially set prices in the New Zealand marketplace. It may sound good, but the outcomes are quite the opposite.

New Zealand's price controls have been blamed for lackluster R&D spending in the pharmaceutical sector (Katt 2011). A 2006 report (Watson) shows a series of instances where innovative firms withdrew from the market or reduced their presence. It is perhaps no surprise therefore that between 1993 and 1999, New Zealand saw almost zero growth in pharmaceutical R&D (Watson 2006).

New Zealand's approach to price controls has had negative implications on drug availability. A 2011 study published in the *New Zealand Medical Journal* found that the country has slower drug approvals and access to fewer medicines than its Australian neighbour. Specifically, the study found that between 2000 and 2009, New Zealand had government-subsidized access to less than half of the drugs subsidized in Australia (Wonder and Milne 2011, 22). It also found that where medicines were subsidized in both countries, it took, on average, approximately *9 months longer* for drugs to be registered in New Zealand (Wonder and Milne 2011, 22). The system of government pay and government approval provides profound incentives for delay, unlike an unregulated, or even somewhat regulated, market. Nine months, to a sick or dying person, is a very, very long time.

Is 'equality' of suffering really a governing principle?

A more recent study by Medicines Australia found that New Zealand lags several OECD countries on access to new medicines (Hamilton News 2015). The CEO of PHARMAC has acknowledged this delay, arguing that the purpose of the PHARMAC model is not to ensure access to all new medicines as soon as they are available – but rather to ensure equal access across the country (Sawa and Ellenwood 2017). This seems to be a breathtaking admission. How many needy patients are knowingly sacrificed to "equality"? Is "equality" of suffering really a governing principle?

Think about it this way. Of all new medicines registered between 2009 and 2014, only 13 percent were added to the list of products that are funded by PHARMAC. According to a recent study, three-quarters of New Zealand doctors report that they had wanted to prescribe an unfunded medicine in the previous six

months. New Zealand patients – including those with multiple sclerosis and HIV infection – are increasingly going to Australia for treatment (Labrie 2015).

The PHARMAC model has thus rightly faced criticism that financial objectives are prioritized over proper patient care, given the restrictions on access to pharmaceuticals (Cumming, Mays, and Daubé 2010, 1225). Concerns have also been raised that the model risks patient health by requiring more frequent switches between medicines as a result of drugs moving on and off the list of medicines subsidized by the government, based on financial considerations (Cumming, Mays, and Daubé 2010, 1225–1226).

The upshot is that the minister is not wrong to focus on New Zealand's experience. The only problem is that the government has come to see New Zealand as a model to emulate rather than one to avoid.

What Does it all Mean for Policy-Makers?

Canada's pharmaceutical industry is a key contributor to the Canadian economy. The industry has an economic footprint of approximately $19.2 billion and supports over 300,000 jobs (12,836 direct, 10,287 indirect, and 7416 induced) (Innovative Medicines Canada 2017, 6). After aerospace and software/computing services, the pharmaceutical sector is the third largest source of R&D funding in Canada (6). Policies penalizing the sector could therefore have a meaningful effect on the economy and Canada's R&D spending.

Yet, apart from a handful of bureaucrats in Ottawa and pricing managers for pharmaceutical companies, few people know and understand what the PMPRB program is and how the proposed reforms may affect Canada's pharmaceutical ecosystem and health care system. As a result, the short time frame for the federal proposals creates a real barrier to meaningful consultation by key stakeholders, including patient organizations.

If the 1987 amendments that created the PMPRB reflected a careful balance among many policy objectives, the 2018 proposed changes represent a laser focus on only one – to lower patented drug prices. And they will dramatically disrupt the long-standing policy balance.

Canada is currently one of the first countries in which new drugs are launched.

An immediate question is how the pricing environment will affect global decisions on when and whether to launch a new therapy in Canada. Canada is currently one of the first countries in which new drugs are launched, due to the quality of our health care system and relative accessibility through the public and private insurance systems. Will Canada continue to be as attractive if launch prices are reduced by 20 percent or more and subject to lengthy and disputed legal review following launch? As the previous discussion plainly demonstrates, the answer is a sure no. Do we really want to follow New Zealand?

A recent anecdote is telling: an author of this paper spoke to an executive of a European pharmaceutical company, newly established in Canada, who felt betrayed by the announcement of the new regulations. Known in advance, there would have been no investment here. The assumption that pharmaceutical companies are rich enough to be beyond the dictates of market economics is an empty prejudice.

If prices are reduced to the OECD median, Canadian patients will see a comparable decline in the availability of new breakthroughs. Delays to resolve cost-effectiveness reviews among multiple agencies will

add to the launch delays. Will governments in Canada be prepared to tell patients requiring a new treatment "Go to the US", and then debate who will pay for it?

The proposed new pricing rules are also anti-innovation. Current PMPRB rules limit prices for new drugs to the maximum of existing drugs but breakthrough drugs can be priced higher, up to the median of international prices. By comparison, the new regulations are designed to impose lower thresholds on truly innovative drugs relative to others.[12] This is also the group of drugs that is likely to be caught up in lengthy review and price uncertainty as the manufacturers and various regulatory agencies attempt to complete their pharmacoeconomic reviews and sort out their varying conclusions. A supplier of a breakthrough drug may spend a long time attempting to obtain certainty on the price it will be able to charge in Canada.

If the "drug problem" our health care system faces is how best to allocate resources in light of life-changing technological breakthroughs, the proposed PMPRB reforms are the wrong answer. They will impede access to new innovations in Canada and lower the quality of health care. The solutions to the "drug problem" are not easy but can best be achieved by an open dialogue with all stakeholders. The federal government has an opportunity to show leadership and start that dialogue.

Before going further, the government, including the Department of Health and ISED, should work with the biopharmaceutical industry and other stakeholders to assess the issue through a much broader lens including improved health care and patient access to new therapies, the integrity of Canada's intellectual property regime, and the role of life sciences in our high technology future.

Recommendations

The purpose of this paper has been to educate federal policy-makers, the media, and the general public on the PMPRB's role in health and innovation policy, and how they ought to think about its current alignment or divergence from these broader policy objectives. It is the contestation of our analysis that the current regulatory reforms would cause the PMPRB to diverge further from the government's stated health and innovation objectives. In light of this finding, we propose three specific recommendations.

1. **Suspend the regulatory process to determine whether any new federal action is needed**

   The government and minister have regularly spoken about Canada's "affordability" challenges but have provided little evidence accordingly. This is particularly notable in light of evidence that (i) Canada's drug prices are internationally comparable and (ii) lowering them further via government fiat would invariably involve trade-offs.

   The onus is on the government therefore to make the case that further intervention is required. Ottawa has not done that – certainly not relative to the compelling evidence set out above that its decision will likely lead to less investment, innovation, employment, and ultimately health care.

   The government should suspend its regulatory process and undertake a comprehensive analysis that places its "affordability" agenda in a broader context involving clear trade-offs. Only then can Canadians be confident that this process was rooted in evidence rather than ideology.

2. **Consider alternative models to deal with "affordability" if the government is determined to act**

   To the extent that Ottawa remains convinced that the system is mired by "affordability" challenges, it still has a responsibility to consider alternative options with less detrimental trade-offs. Put differently: just because it has concerns about drug affordability does not mean that the top-down PMPRB regulations are the right solution.

Quite the contrary. There is compelling evidence that this approach may only worsen the circumstances. Instead the government should look to alternative solutions to bolster investment, innovation, employment, and drug access. Previous MLI analysis has pointed to the role of the IP regime in this regard (Owens 2017). There are various steps that the government can consider including addressing gaps in insurance coverage for low-income Canadians and supporting public and private insurers, manufacturers, and patients in developing risk-sharing schemes. To explore each of these possibilities is beyond the scope of this paper but it should certainly not be beyond the scope of government policy analysis.

3. **Conduct a comprehensive review of the PMPRB and its role in the broader health and innovation policy landscape**

   As discussed above, the PMPRB was established more than 30 years ago as part of a political compromise. Yet its mandate, operations, and record have since received only minimal scrutiny. Past governmental review efforts such as the mid 1990s Program Review and the 2012 Deficit Reduction Action Plan were principally focused on cutting spending. There is scope for a much broader review of the PMPRB and its role in the health and innovation policy landscape. It is far from clear that the PMPRB is still necessary.

   We should not let a 30-year policy compromise remain frozen in time and in so doing preclude a broader debate about how to fit drug pricing in a much broader context. But that is what has happened. We need a fresh perspective rooted in evidence rather than political horse-trading to judge whether the PMPRB is still useful and what, if any, reforms to its mandate and operations ought to be considered.

Conclusion

We approached this review with minds open to the potential for renewed PMPRB activity. What we saw, however, has left us with no doubt about how harmful the PMPRB would be with its revised mandate. We are most gravely concerned with the potential for revised PMPRB regulation to further diminish Canadians' access to new pharmaceuticals. Price controls correlate positively with morbidity and ill-health. It is far from clear that price reductions result in net cost savings by health care systems and patients.

The PMPRB reform proposals are anti-innovation.

We are also concerned that a major regulatory initiative, with major impacts on the health and well-being of Canadians, appears to have been conceived on a whim and without proper cost-benefit analysis. The addition of pharmacoeconomics to the evaluative criteria of the PMPRB will greatly slow the adjudication process and result in much more confusing and subjective proceedings, with no added value since it will duplicate work currently being done by other agencies. Moreover, one would expect PMPRB proceedings to be far more contentious as pharmacoeconomic evidence is adduced for increased, not only decreased, price.

Clearly, the PMPRB reform proposals are anti-innovation. They risk reducing investments in Canada in the high technology life sciences sector, in pursuing science and research and developing innovation clusters. They will result in delays in the availability in Canada of ground-breaking new drugs and therapies to the detriment of Canadian patients and our health care sector.

New Zealand is an example of a country that has chosen low prices over access – and over patients' needs. We should do well to heed its example, and not to follow it.

Canadians deserve better.

About the Authors

Wayne Critchley has a long track record of success as a senior executive with over 20 years of experience in government departments, boards and agencies dealing primarily with issues that impact the pharmaceutical sector. He served as Executive Director of the Patented Medicine Prices Review Board from 1990 to 2005 and as a Vice President of the Canadian Agency for Drugs and Technologies in Health in 2009. Prior to 1990, Wayne occupied several senior positions in the Competition Bureau.

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He conducted his practice with three of Canada's leading law firms. Richard is past chair of the board of directors of the University of Toronto Innovations Foundation, and member of the advisory committee to the Office of the Privacy Commissioner of Canada. He is a member of the board of the Center for Innovation Law and Policy at the University of Toronto Faculty of Law, and served as a director of the International Technology Law Association.

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Endnotes

1 The 1987 amendments to the *Patent Act* resulted from years of public debate and study including a Royal Commission of Inquiry into the Pharmaceutical Industry and contentious debate in Parliament. Within a short period of time, the key intellectual property provisions were embedded in international trade agreements (GATT-WTO, the Canada-US Free Trade Agreement, and NAFTA).

2 Despite this fact, the government has proposed to exempt the small number of patented generic drugs from PMPRB jurisdiction. In 2014, median generic drug prices in Canada were over 30 percent higher than the median prices in the PMPRB comparator countries; in contrast, patented drug prices were 13 percent below the median of international prices in that year and 25 percent below in 2016. The FPT pan-Canadian Pharmaceutical Alliance has taken several actions to lower generic drug prices in recent years, including an agreement announced January 29, 2018 to lower the prices of 70 of the most commonly prescribed generic drugs (Hoskins 2018).

3 In fact, the total savings are likely much larger due to separate agreements individual jurisdictions have with manufacturers that are not counted in the pan-Canadian Pharmaceutical Alliance total. Total rebates in Ontario alone were $1.1 billion in 2016/17 (Ministry of Health and Long Term Care, 477). Total "drug costs" were $4.5 billion in 2016/17; the province received confidential rebates of $1.1 billion, or over 24 percent. These rebates are credited to general revenues, not the drug plan. These rebates are not reflected in PMPRB data on patented drug sales in Canada.

4 The government's cost-benefit analysis calculates a wide range in potential benefits, illustrating how speculative the estimates are. The $21.4 billion "benefit" assumes a loss in manufacturer revenues of $8.6 billion and a gain of $12.7 billion "in the public health care system from removing the opportunity cost of paying for excessively priced medicines" (Government of Canada 2017).

5 According to the Canadian Institute for Health Information (2018), spending on drugs has consistently represented between 16.0 percent and 16.8 percent of total health expenditures between 2002 and 2017, forecast 16.4 percent in 2017.

6 France, Germany, Italy, Sweden, Switzerland, the UK, and the US.

7 There are currently 35 countries in the OECD including many G7 countries and other highly developed countries along with others such as Turkey, Estonia, and Chile. Health Canada's *Regulatory Impact Analysis Statement* claims that median OECD prices were 22 percent below those in Canada in 2015; the median of the proposed new basket is the equivalent to the OECD median (Government of Canada 2017).

8 CADTH is required to do its analysis based on a public drug plan perspective; INESSS and private insurers use a broader societal perspective including factors such as impact on labour productivity.

9 In 2015, the PMPRB adopted a new vision statement describing a system where "Canadians have access to patented drugs at **affordable prices**" (emphasis added). References to the objective of "affordable" rather than "non-excessive" prices also appear in the Scoping Paper.

10 Although there are some state-level pricing controls in place. See Eric Sagonowsky, 21 December 2017, "Pharma's State-Level Pricing Headache Isn't Going Anywhere in 2018," *fiercepharma.com*.

11 See also Daniel Kessler, "The Effects of Pharmaceutical Price Controls on the Cost and Quality of Medical Care: A Review of the Empirical Literature."

12 "The new factors are intended to impact **most heavily** on high-priority medicines, which are subset of medicines with higher potential to exert market power due to greater demand, fewer (if any) substitutes, or very small patient population" (emphasis added) (Government of Canada 2017, 18). Ironically, the pharmaceutical industry has been much criticized for the introduction of "me-too" drugs, or subsequent entries into an existing therapeutic class. The new PMPRB pricing rules may actually encourage such drugs as they will have be given a "lighter" touch in the price review process.

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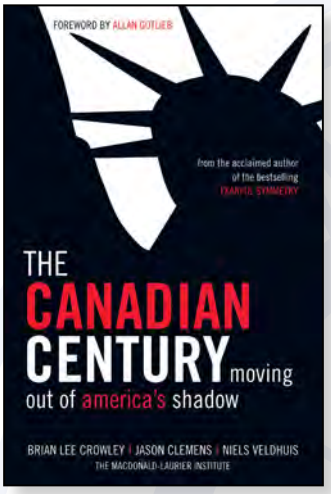

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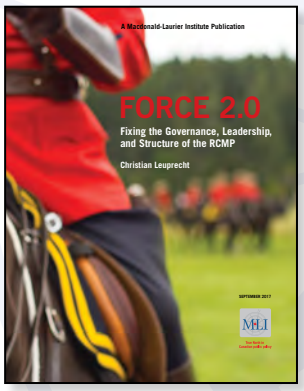

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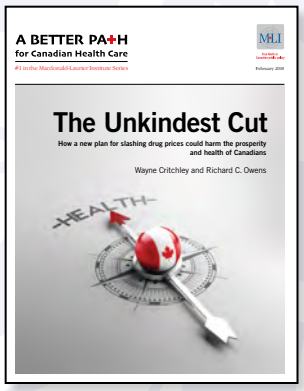

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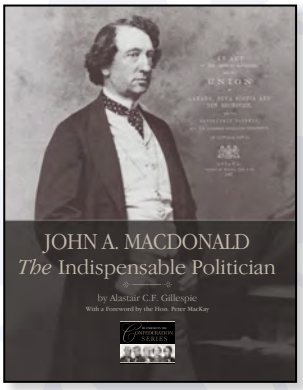

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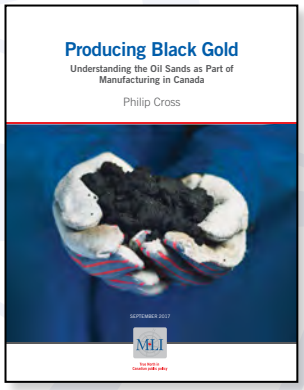

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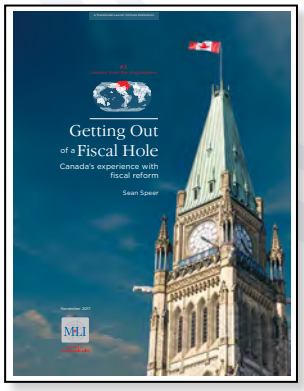

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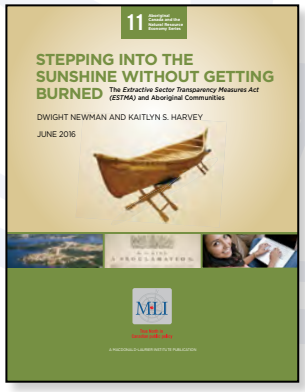

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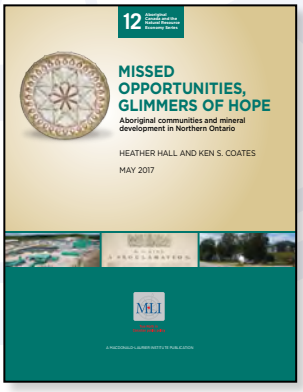

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