The Unintended Consequences of National Pharmacare Programs

The Experiences of Australia, New Zealand, and the UK

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Executive summary

In combined public and private spending on pharmaceuticals, Canada spends more per capita than other OECD countries apart from the United States and Switzerland. Moreover, some analysts have claimed that Canada pays more while providing less access. This has given rise to calls for a Canadian pharmacare program, in the hopes that it would improve access and reduce pharmaceutical expenditures. While claims of inadequate coverage are controversial, they do explain the public perception that a national pharmacare program is needed. Fundamentally, inadequate coverage may result in inadequate access and treatment, and Canadians recognize the need to address this.

Accordingly, the national systems for drug coverage in nations such as New Zealand, Australia, and the United Kingdom have been proposed for implementation in Canada (see e.g. Gagnon and Hebert, 2010). While these programs have reduced both expenditures and the average price paid per drug, they have also had some unintended consequences that may not be so favorable.

This paper seeks to analyze these consequences. Through an examination of the experiences of New Zealand, Australia, and the United Kingdom, this paper brings to light some of the difficult decisions that accompany a national publicly-funded pharmacare scheme, and the consequences of such programs for patients, physicians, innovators, and the industry. Specifically, the potential consequences take the form of more limited access to new drugs, poorer healthcare outcomes, excess burdens of taxation, and reduced pharmaceutical innovation. While these consequences are not necessary, they are typical of such policies. As with many public policy proposals, the devil is in the details and the true consequences for Canadian patients remain to be determined.

First, the paper describes the national plans of Canada, the United Kingdom, New Zealand, and Australia, focusing on key characteristics of the programs. Next, the paper provides an overview of many of the cost containment strategies that are frequently incorporated into a publicly-funded pharmacare program. These are policies that are relied upon to achieve the necessary cost savings required to administer such a program, but they do not come without a price. These policies generally limit patient (and physician)

choice, restrict access, ration drugs and therapies, and reduce treatment effectiveness. The strategies considered in this section include sole tendering, reference-based pricing, restrictive formularies, and cost-effectiveness analysis.

The consequences of these cost containment strategies are then explored. A description is included of the potential for reducing pharmaceutical expenditures, the cost burden shifted to taxpayers, the risks of drug shortages, the implications for international reference pricing, the effect on formulary decisions, the risks of therapeutic substitution, the potential for reduced access and worsening health outcomes, as well as the reduced incentive to innovate.

Arguably, the single most significant benefit of universal pharmacare would be lower pharmaceutical expenditures for insurers and individuals. While the prices of new substances under the programs employed in New Zealand, Australia, and the UK are lower than in the United States and Canada, prices for generics and incremental innovations are higher than in the United States.

Ultimately, these programs may not deliver everything their advocates propose. While the cost savings on pharmaceuticals are frequently touted, it is critical to examine whether those results can be replicated in Canada. Moreover, the additional consequential expenditures in other areas of the healthcare system are a reality that is rarely mentioned.

In sum, the consequences of a publicly-funded pharmacare program must be thoroughly explored and properly costed in order to determine whether this is a policy that would benefit Canada and Canadian patients. There are a number of potentially very detrimental consequences and policymakers should have answers for how they will be addressed and avoided. First, the true tax burden should be calculated and transparently presented. In addition, it must be recognized that drug shortages and reduced access may result from such a policy. There is also substantial evidence indicating that lower revenues and profits will reduce pharmaceutical R&D spending. Finally, it is essential to acknowledge the potential for worsening health outcomes and suboptimal therapeutic substitution. Accordingly, Canada must cautiously approach any policy change that puts patients, innovation, and innovative industries at risk. A national pharmacare program is no exception.

Arguably, a national drug plan would require significant administrative coordination across provinces and add complexity to the existing system, without providing significant benefit. The projections of cost savings to consumers, taxpayers, and the nation are flawed. Moreover, given the tremendous administrative costs of consolidating pharmaceutical benefits into a national pharmacare program, it is unlikely that the estimated cost savings would be realized. Notably, any savings accruing in the short to medium term will be outstripped by the transition costs. All the while, provincial

governments have experience in delivering drug coverage plans tailored to their populations' specific needs, while maintaining the flexibility within the current system that allows for a sustainable combination of public and private payers for medications. In reality, Canadians already benefit from the best aspects of a national drug coverage plan, and evidence suggests that the formal institution of such a plan will only increase bureaucracy and complicate delivery of services, without adding value for patients.

Introduction

In combined public and private spending on pharmaceuticals, Canada spends more per capita than other OECD countries, apart from the United States and Switzerland (OECD, 2017; CIHI, 2017). Moreover, some analysts have claimed that Canada pays more while providing less access (Boothe, 2016). "Canadian coverage for outpatient drugs is a patchwork of public and private drug insurance plans providing coverage that is, unfortunately, neither universal nor comprehensive. … Moreover, the current system lacks equitability. The criteria for drug coverage vary across provinces. For example, drugs are covered on the basis of income in British Columbia, whereas age is the major determinant in Ontario" (Minhas et al., 2016). This has given rise to calls for a Canadian pharmacare program, in the hopes that it would improve access and reduce pharmaceutical expenditures.

Globally, pharmaceutical expenditures are rising at a rate that outpaces the growth of the economy, requiring government providers to balance consumer needs against budgetary realities (Franki, 2018; Maranjian, 2017). The complications of reigning in drug expenditures are exacerbated by the combination of factors that drive escalating drug costs. According to the Canadian Institute for Health Information and others, the drivers of escalating drug costs include:

- increases in the volume of use;
- changes in the mix of treatments being used;
- increased disease prevalence;
- changes in the size and demography of the population, specifically population growth and aging;
- increases in the unit price of drugs;
- changes in the prescribing patterns of physicians;
- increases in the number of drugs dispensed per patient;
- changes in the number of drug options available for specific health conditions;
- increasing utilization of newer, more expensive and/or more effective drugs;
- increasing reliance on drug therapy instead of other medical treatments;
- emerging conditions and diseases requiring drug therapy.
(CIHI, 2012; PMPRB, 2013; Canadian Pharmacists Association, 2005)

Given that spending on drugs averages approximately 15 percent of total healthcare spending for countries in the Organisation for Economic Co-operation and Development (OECD), improved management of pharmaceutical expenditures can make an important contribution to containing health budgets. (Cumming, Mays, and Daube, 2010). In light of such considerations, it is perhaps not surprising that many commentators and pundits have proposed the implementation of a publicly-funded national pharmacare program to reduce expenditures and improve coverage. The need in Canada for improved coverage is apparent in statistics such as the following: "One in every 10 Canadians cannot afford the drugs they are prescribed. They end up ill, go to emergency rooms, and in some cases need surgery. Only a third of Canadians are covered by public drug plans which vary from province to province. Most are covered through their workplace by private insurance plans that are expensive and unreliable. Another 10% of Canadians have no coverage at all" (Canadian Health Coalition, 2017). While such claims are controversial, they do explain the public perception that a national pharmacare program is needed. Fundamentally, inadequate coverage results in inadequate access and treatment, and Canadians recognize the need to address this.

Accordingly, the national systems for drug coverage in nations such as New Zealand, Australia, and the United Kingdom have been proposed for implementation in Canada (see e.g. Gagnon and Hebert, 2010). Under such plans, "prescription medicines are financed predominantly by government, and either government or an arm's-length public body manages the selection and the price-setting of medicines to be covered by the universal system or public financing" (Morgan et al., 2017). While these programs have reduced both expenditures and the average price paid per drug, they have also had some unintended consequences that may not be so favorable.

This paper seeks to analyze these consequences. Through an examination of the experiences of New Zealand, Australia, and the United Kingdom, this paper brings to light some of the difficult decisions that accompany a national publicly-funded pharmacare scheme, and the consequences of such programs for patients, physicians, innovators, and the industry. The potential consequences take the form of more limited access to new drugs, poorer healthcare outcomes, excess burdens of taxation, and reduced pharmaceutical innovation. While these consequences are not necessary, they are typical of such policies. As with many public policy proposals, the devil is in the details and the true consequences for Canadian patients remain to be determined.

First, the paper describes the national plans of Canada, the United Kingdom, New Zealand, and Australia, focusing on key characteristics of the programs. Next, the paper outlines a number of cost containment strategies commonly used to reign in pharmaceutical expenditures. These include sole tendering, reference-based prices, restrictive formularies, and the use of cost-effectiveness analysis. This is followed by an analysis of the consequences of

such strategies and the implications for payers, patients, industry, and innovation. Finally, the paper concludes with a word of caution. While the benefits of a national pharmacare program may seem straightforward, it is critical to examine the subtleties of the costs and requisite tradeoffs before embracing such a drastic change.

Description of national policies

Canada

Canada's publicly funded health care system is an interlocking set of ten provincial and three territorial health systems. "Medicare," as it is known, is the system that provides access to a broad range of health services. Canada's publicly funded health care system provides universal coverage for medically necessary health care services on the basis of need rather than the ability to pay. The Canadian Constitution largely determines the organization of Canada's health care system, specifying roles and responsibilities and their division between the federal, provincial, and territorial governments. The provincial and territorial governments have most of the responsibility for delivering health and other social services. Healthcare is publicly funded with general revenue raised through taxation, including personal and corporate taxes, sales taxes, payroll levies, and other revenue. Health Canada describes the division of services between the federal government and the provinces and territories as follows:

> The federal government's roles in health care include setting and administering national principles for the system under the Canada Health Act; financial support to the provinces and territories; and several other functions, including funding and/or delivery of primary and supplementary services to certain groups of people. These groups include: First Nations people living on reserves; Inuit; serving members of the Canadian Forces; eligible veterans; inmates in federal penitentiaries; and some groups of refugee claimants.
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> The provinces and territories administer and deliver most of Canada's health care services, with all provincial and territorial health insurance plans expected to meet national principles set out under the Canada Health Act. Each provincial and territorial health insurance plan covers medically necessary hospital and doctors' services that are provided on a pre-paid basis, without direct charges at the point of service. The provincial and territorial governments fund these services with assistance from federal cash and tax transfers. (Health Canada, 2018)

A drug benefit plan for eligible groups is offered by each provincial and territorial government. While some are income-based universal programs, the majority provide particular programs for population groups that may require more enhanced coverage for high drug costs. As identified by Health Canada, these groups include seniors, recipients of social assistance, and individuals with specific diseases or conditions that are associated with high drug costs (Canada, 2017). Notably, "lower-income Canadians have access to at least some form of provincial insurance that helps limit out-of-pocket costs for prescription drugs to a small percentage of income, if not more extensive coverage, in every Canadian province. It's worthwhile also noting that recipients of social assistance have coverage at very low or even zero cost in every province" (Barua, Jacques, and Esmail, 2018). The Canada Health Act does not cover prescription drugs, resulting in reliance by most Canadians on private insurance from their employers, or the government, to pay for those costs.

Canadian public spending on pharmaceuticals is significantly lower than the OECD average (**table 1**). Given that the Canada Health Act does not cover prescription drugs, it is not surprising that the public spending in this area is lower in Canada than OECD nations that provide publicly funded coverage for pharmaceuticals.

Table 1: Public spending as a share of total spending, major health spending categories, Canada and 22-OECD-country average, 2012

	Percent public spending			
	Prescription drugs	**Hospitals**	**Doctors' offices**	**Dentists' offices**
Canada	42	91	99	6
OECD average	70	88	72	34

Notes: Doctors' offices figure for Sweden is from 2009.

OECD data on public spending was always problematic for countries with mandatory insurance schemes (which could include private financers), which is why they now often call it government and compulsory schemes. The author is grateful to an anonymous reviewer for this comment.

Source: Adams and Smith, 2017, using OECD Statistics.

Health technology assessment (HTA) in Canada is performed by the panCanadian Oncology Drug Review (pCODR), which assesses cancer products, and the Common Drug Review (CDR), which reviews all other types of medications. Both entities fall within the Canadian Agency for Drugs and Technologies in Health (CADTH) ,which operates on behalf of nine of the 10

provinces. The CDR and pCODR make recommendations about drug reimbursements to the participating provincial governments.[1]

While a description of the details of the Canadian healthcare system is beyond the scope of this paper, the Commonwealth Fund provides a nice overview of the specifics of the Canadian healthcare system (Allin and Rudoler, n.d.).

United Kingdom

Healthcare services in the United Kingdom are primarily provided by the UK's National Health Service (NHS), although a robust private parallel system also exists. Despite recent criticism, the NHS is beloved and according to Frayer (2018) it "polls better than the queen. U.K. politician Nigel Lawson once said 'the NHS is the closest thing the English people have to a religion.' It featured prominently in the opening ceremony of the 2012 London Olympics, with doctors dancing to swing music and hospital beds arranged to spell out the letters N-H-S in aerial views from above." All citizens in the UK have the costs of their prescription drugs mostly covered, as part of their health care. The cost sharing is among the lowest in the industrialized world and the vast majority of prescriptions do not involve personal out-of-pocket expenses. The National Institute for Health and Care Excellence (NICE) provides recommendations on whether new branded drugs should be covered by the publicly funded NHS. The agency considers clinical effectiveness as well as cost effectiveness simultaneously.[2] "Since pharmaceuticals come out of the overall healthcare budget, however, paying for drugs can have unexpected results. 'When NICE makes a recommendation for a new drug, which costs the NHS more money, the NHS has to find the money. ... So, it has to do less of other things—what economists call opportunity costs. And NICE has not

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1. "A medication does not have to be reviewed by CADTH and an HTA recommendation from the CDR or pCODR does not have to be accepted by the provinces. In Quebec, which does not participate in CADTH, HTA is performed by the Institut national d'excellence en santé et en services sociaux (INESSS). The INESSS makes recommendations to the Quebec government, which usually accepts the agency's advice but is not required to do so. Following an HTA recommendation from the CDR or pCODR, provincial governments may decide to negotiate pricing collectively through the pan-Canadian Pharmaceutical Alliance (pCPA). Quebec has recently agreed to participate in the pCPA but has yet to be part of a negotiation. The provinces may alternatively decide that each province will conduct negotiations individually or that there will be no negotiations. Whether or not collective pCPA negotiations are pursued, each provincial government is the ultimate decision maker in assessing whether the need, benefit and price are appropriate for its residents and its budget before adding a drug to its formulary" (Rawson 2016).

2. Cost effectiveness is effectively a measure of cost per unit of benefit measured in quality-adjusted life years.

formally considered those opportunity costs very carefully." A new drug being funded, for example, might increase wait lists for surgery" (Milne, Laupacis, and Tierney, 2015).

While a description of the details of the English healthcare system is beyond the scope of this paper, the Commonwealth Fund provides a nice overview of the specifics of the English healthcare system (Thorlby and Arora, n.d.).

New Zealand

New Zealand provides universal public health insurance coverage through the geographically based District Health Boards.[3] These Boards also pay for medicines and are required to provide the drug subsidies published in the national Pharmaceutical Schedule. This is how approximately 80 percent of all of New Zealand's drug expenditures are funded, while the remainder are covered by patient co-pays and charges for drugs outside the Pharmaceutical Schedule (Morgan et al., 2007). The Pharmaceutical Management Agency of New Zealand (PHARMAC) was established as a non-profit government agency in 1993 to improve the management of the Pharmaceutical Schedule, to address unsustainable budgetary increases, and to stem the growth of pharmaceutical expenditures. PHARMAC's original mandate was to obtain "the best possible health outcomes from money the government spends" on drugs, vaccines, and other treatments. PHARMAC's role has expanded, and the agency manages the community drug budget in addition to working to ensure the optimal use of medicines, negotiating pricing and supply terms for some hospital medicines, managing the basket of essential cancer drugs that must be made available to New Zealanders, and managing exceptional circumstances schemes that supply drug funding for people with rare conditions (Cummings et al., 2010). PHARMAC decides which medicines to fund publicly and is governed by the District Health Boards. New Zealand has had great success in managing pharmaceutical expenditures while maintaining universal access.[4] The New Zealand experience demonstrates that strong negotiations, under particular circumstances, can reduce pharmaceutical expenditures—by up to 90 percent on some drugs (Fayerman, 2007). PHARMAC has successfully controlled pharmaceutical expenditures, "saving the equivalent of its originally allocated budget [i.e., [amount budgeted in the first year of the program] every year, despite a 50% increase in volumes" (Davis, 2004: 171).

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3. These Boards are funded by the New Zealand Ministry of Health.

4. In New Zealand, healthcare access aims to be universal and free from financial and other barriers, such that all New Zealanders should have equal access to the same standard of treatment, and that the health system should be integrated and preventive rather than curative in focus (Gauld, 2014).

PHARMAC's decisions apply nationally and the funding decisions are based on clinical and economic assessments that examine the need and health benefit of a new medicine and its costs and potential savings relative to other drugs and alternative, more expensive treatment options. The agency has a fixed budget for expenditures on pharmaceuticals such that when assessing a new medicine for inclusion in the Pharmaceutical Schedule, the agency considers other drugs that must be forgone and price concessions that must be obtained to fund the new product. As a result, PHARMAC considers the recommendations from its expert committees and negotiates with manufacturers to reach a provisional listing agreement. It is only when an acceptable proposal is reached that a product is added to the national Pharmaceutical Schedule (Rawson 2016).

While a description of the details of the New Zealand healthcare system is beyond the scope of this paper, the Commonwealth Fund provides a nice overview of the specifics of the New Zealand healthcare system (Gauld, n.d.).

Australia

The Pharmaceutical Benefits Scheme (PBS) was instituted in Australia in 1948. The PBS is a national program to subsidize medications for Australians and for the individual. The price at the pharmacy is proportional to one's income, and once an annual threshold payment is reached many prescriptions are free of charge to the patient. It is the role of the government to negotiate the price of medicines with manufacturers, in order to keep prices low for consumers. An advisory committee evaluates new medicines to decide which should be subsidized. The pharmaceutical formulary has no budgetary cap, so as demand and medication availability grow, so do allocated funds (Dhara, 2017).

The Pharmaceutical Benefits Scheme now covers approximately 600 drugs in more than 1,500 formulations. This equates to more than 90%percent of all prescriptions written in Australia (Commonwealth Fund, 2018). As of June 2017, the number of brands listed on the PBS is 5,271 (PBS, 2017). Patients pay a set co-payment (proportional to income) regardless of the drug they are prescribed, though there are safety net provisions to limit total expenditure. All prices are directly negotiated between the Government and the pharmaceutical company, and new prescriptions that are added must be recommended for listing by an independent committee based on an assessment of safety, clinical-effectiveness and cost-effectiveness. Notably, Australia was the first country to introduce a mandatory requirement for comparative

clinical-effectiveness and economic evaluation (Commonwealth Fund, 2018; Lopert and Elshaug, 2013; Yoongthong et al., 2012).[5]

For the year 2018, the maximum amount payable is AU$39.50 per prescription, or AU$6.40 for a low-income patient, a retiree, a disabled person, or a veteran with a valid "concession" card. Any amount exceeding these thresholds is covered by the government program (PBS, 2018). Also, it is worth emphasizing that 50 percent of total drug expenditure is directly borne by patients, one of the highest cost-sharing rates in OECD countries after Iceland (58 percent) and Denmark (51 percent), and just ahead of Sweden (48 percent) and Finland (47 percent) (OECD, 2015).

While a description of the details of the Australian healthcare system is beyond the scope of this paper, the Commonwealth Fund provides a nice overview of the specifics of the Australian healthcare system (Glover, n.d.).

[5.] "Comparative Effectiveness Research (CER) is research that identifies what clinical and public health interventions work best for improving health. Interventions include not only the elements of direct clinical care such as diagnosis and treatment protocols, but also innovations in health care delivery, organization and financing, as well as public health interventions in the community, including those intended to modify health awareness, lifestyle, diet, or environmental exposures. In a CER study, interventions should, at a minimum, be compared on the basis of some health-related outcome measure. Study methods may include randomized trials with at least two active (non-placebo) intervention arms, database studies, observational studies, model-based studies, and decision analysis. Research projects that develop methods or infrastructure for CER would also be classifiable as CER" (Harvard, 2018).

Cost containment strategies

This section provides an overview of many of the cost containment strategies that are frequently incorporated into a publicly-funded pharmacare program. These are policies that are relied upon to achieve the necessary cost savings required to administer such a program, but they do not come without a price. These policies generally limit patient (and physician) choice, restrict access, ration drugs and therapies, and reduce treatment effectiveness. The strategies considered in this section include sole tendering, reference-based pricing, restrictive formularies, and cost-effectiveness analysis.

Sole tendering

Tendering is a process through which a purchasing agent—insurer, government, or firm—negotiates the lowest price for a pharmaceutical product. The lowest bidder frequently becomes the only supplier, the sole tender, and its drug is the only one available within a specific therapeutic class of drugs to patients in the participating drug plan (BPC, 2010).

Sole tendering is one of the aspects that distinguishes the New Zealand market. Whenever possible, New Zealand utilizes sole tenders to bid down the price of pharmaceutical medications. Utilizing sole tendering, one product or a limited number of products are procured for each indication. Ultimately, the winning bidder provides a lower price in exchange for the opportunity to supply the entire market. As described by Morgan et al. (2007), this sole-supply auction-type mechanism can drive costs down to "commodity pricing" levels that characterize perfectly competitive markets and serve as the benchmark of economic efficiency. In the experience of New Zealand, the first drug put up for tender was paracetamol in 1997. "A price reduction of 44% was achieved . . . (and) at a later date for a period of three years, a further price fall of 34% was secured" (Davis, 2004: 176-77).

The financial savings that accrue to the plan sponsor are the most obvious benefit of sole tendering. According to Lewis (2001), direct savings result from more competitive discounts, lower dispensing fees from pharmacies, and more competitive administrative fees, while indirect savings stem

from the ability to apply consistent and focused pharmacy management strategies across a larger number of participants. Administrative costs are lowered by dealing with a single provider. These benefits are elaborated on by Krause (2004) who describes the benefits realized from bulk purchasing in three categories: market power, efficiency, and benefits and care management.[6] The market clout of purchasing agencies increases with bulk purchasing and may result in more generous rebates. Further, by streamlining the size and number of purchases, administrative costs and fees per patient decrease as the number of covered beneficiaries increases, enhancing the efficiency of the program. While some proportion of these savings would accrue to a private insurer, the scale of operation and bargaining power available at the national level is able to lower costs more dramatically.

While the benefits to sole tendering can be significant, notably cost savings and increased organizational and administrative efficiencies, it is essential to recognize the risks that may also accompany these benefits. Sole tendering policies may result in limited access to medications, reduced medication supplies, worsening health outcomes, restricted choices, and a stifling of innovation. This is explored in greater detail below. Given this, it is essential that governments balance the need to contain costs while remaining mindful of the potential risks for specific patient population. In addition, the policy may lead to the elimination of competition, forcing patients to switch to other therapeutic options, and higher prices for consumers who wish to utilize their preferred brand, paying the full, unsubsidized price.

Consider the dilemma described by Nelson (2017): hospital chains that grant drug contracts to a single vendor may find that only one drug supplier is able to make a profit and remain viable, leading competitors to drop out of the market. Given that this has occurred in Australia at the hospital level, one must question how much more serious the problem will be at the national level. Nelson (2017) describes how pricing pressure has forced generic drug companies out of the market or into mergers. A Fall 2017 study in *Globalization and Health* found that "generics companies were folding into each other at a greater rate than ever before. In 1995 there were no completed merger and acquisition deals that had a generic drug company being taken over. In 2014, there were 22 of these deals. This jumped to 34 deals in 2015, and 42 deals in 2016" (Nelson, 2017). As a result, in Australia, generic prices dropped so far that the government stepped in to increase the prices of close to 60 medicines where continued supply was identified as being at risk (Nelson, 2017).

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6. Bulk purchasing, the purchase of a large quantity of a particular medicine, may result in the ability to purchase the treatment at a lower cost due to economies of scale and the negotiating power of the purchaser.

This reality is echoed in a 2012 study by Hollis and Grootendorst, who find that tendering reduces pharmaceutical margins and therefore the advantages to early market entry by generics. Accordingly, it exposes potential early generic entrants to additional damages in the event of successful patent infringement litigation. Hollis and Grootendorst therefore predict delayed arrival of low-cost generics to markets employing tendering systems. They find support for their hypotheses in evidence from New Zealand, where many important drugs are genericized much later than other markets, including Canada, resulting in a delay in price competition. A notable example is that of Atorvastatin which became generically available in New Zealand almost two years later than in Canada. In addition, Olanzapine and Venlafaxine were genericized in New Zealand almost four years later than in Canada (Hollis and Grootendorst, 2012).

Further, sole-supply contracts may also be applied to therapeutic subgroups in order to generate further savings. Consequently, it may be the case that "patients have no option to pay a premium for their preferred brand; their only choice is to pay full, unsubsidized price for their preferred brand" (Sundakov and Sundakov, 2005: 9). The result is that patients are forced to switch not just from a branded product to a generic version, but frequently to a completely different compound. In the context of New Zealand, Maling (2002) reports on the ACE inhibitor reference pricing initiative, noting widespread concern for significant health loss. In an evaluation of the brand switch, a "disturbing finding was that 30% of the patients did not sustain the initial switch and 11% of those patients with previously controlled blood pressure remained uncontrolled six months after the switch" (Maling, 2002: 12). That is, close to half of all patients either could not tolerate the new medicine or found that it did not control their blood pressure while the previous medication had controlled it.

The link between sole tendering and shortages of medicines is becoming increasingly clear. According to senior British health service figure, Maggie Dolan, 2017 was one of the worst years for medicine shortages for NHS patients, and the situation is unlikely to improve.[7] "Procurement had previously been based around ensuring that at least three companies were included on tenders for drugs, a system that ensured that there are at least two other suppliers who could step in should shortages occur" (Staines, 2018). Following a legal challenge to the procurement policy, Dolan described NHS legal experts determining that the arrangements were not legal, which gave rise to an increasing number of tenders with a single supplier. She noted, "What we have seen in 2017 and 2018 is we have more and more single responses to tenders for molecules in the generic space. That is proving very

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[7.] In some cases, the NHS utilizes sole tenders to procure treatments. See Pauwels et.al., 2013.

challenging" (Staines, 2018). At an extreme, some drugs are no longer supplied. "The PHARMAC tendering process had 'screwed down' drug companies' profits, causing some to pull out of New Zealand, others to downsize, and some to reduce the amount of drug stock on hand" (NZPA, 2003). "'It is very dangerous in some circumstances. … In other cases it's inconvenient. But if it carries on and the type of product that it's happening to, it's potentially fatal'" (NZPA, 2003).

While the most significant consequences are medical and financial, sole tendering agreements have the potential to also generate political consequences. The threat of lower revenues and lost profit for firms and shareholders may result in increased lobbying efforts. "Firms will thus lobby government, health professionals, patient groups and the general public to try to muster opposition to any formulary-based policy that requires competitive pricing" (Morgan et al., 2007). Not surprisingly, the potential for and magnitude of an industry response is directly correlated with the size and importance of the market. The case of New Zealand is illustrative. Due to the small size of the market and the absence of brand name drug manufacturers, one would expect modest industry efforts. Nevertheless, in the early years PHARMAC was almost constantly plagued by litigation from pharmaceutical companies challenging the competitive pricing; defending these efforts accounted for 18 percent of operating costs for PHARMAC (Morgan et al., 2006).

Reference-based pricing

One of the prominent features of pharmacare programs is their use of reference-based pricing.[8] Reference-based pricing amounts to clustering drugs according to some equivalence criteria and establishing a reference price for each cluster.[9] As described by Galizzi, Ghislandi, and Miraldo (2011), drugs may be clustered according to several characteristics: chemical (identical products with same active principal), pharmacological (chemically different but pharmacologically related drugs), or therapeutic equivalence (all drugs used to treat a particular condition). In the context of reference pricing, the third-party payer will reimburse no more than the reference price for any drug in that cluster. The policy is problematic for several reasons, notably the adverse reactions resulting from imperfect interchangeability and the consequences for drug pricing.

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8. This discussion refers explicitly to reference based pricing that is internal within a group, as opposed to the discussion of international reference pricing which is discussed below in the section on consequences.

9. One of the consequences of reference-based pricing is therapeutic substitution in which a patient is switched from one drug to another because the former is not provided at the reference-based price. Due to imperfect interchangeability, patients may suffer from adverse reactions or receive less therapeutic benefit from the replacement drug.

As compared to other pharmaceutical cost control measures such as best available price or least cost alternative, reference-based pricing differs in that drugs within a class are not required to have the same active ingredients and need not be bioequivalent. Critics of reference-based pricing "claim that lack of perfect interchangeability can induce adverse reactions in patients, as well as increases in non-drug health care costs" (Lindsey and West, 1999). It is well established that drug substitution can induce adverse reactions, in addition to patient non-compliance and patient destabilization. A study by Abraham and Taylor (1998) concludes that deadly drug reactions are more common than is generally perceived. Strikingly, evidence on reference-based pricing's contribution to this problem is lacking (Lindsey and West, 1999).

Several Canadian studies provide evidence on a variety of therapeutic substitutions and their associated costs.

> In 2003, British Columbia's PharmaCare programme implemented a drug reimbursement policy called Therapeutic Substitution, which required patients with acid-related diseases, primarily gastro-oesoph-ageal reflux disease (GERD), to make a medically unnecessary switch from their prescribed proton pump inhibitor (PPI) to the cheapest available brand name PPI. … After controlling for individual case vari-ation in age, gender and a proxy for pre-existing health status, regres-sion analysis revealed statistically significant greater overall use of PPIs, physician services and hospital services independently associated with patients who complied with Therapeutic Substitution. Over the 3-year period 2003–2005, this represented net healthcare expenditures total-ing approximately C$43.51 million (C$9.11 million in total PPI drug expenditures, C$24.65 million for physician services and C$9.75 mil-lion for hospital services). (Skinner, Grey, and Attara, 2009)

Opponents of reference-based pricing identify problems such as the following, in which a British Columbia program only reimburses for one diltiazem formulation:

> [I]n treating hypertension once-a-day diltiazem is superior to diltia-zem tablets in terms of patient compliance, avoidance of hypoten-sion, and persistence of drug effects. … The cost of drug treatment for hypertension is small compared to the cost of the illnesses that can result, such as stroke and hypertensive and ischemic heart diseases. Only a few additional cases of adverse reaction would offset any bud-getary savings. The additional time and monetary costs incurred by patients and physicians from extra visits should also be considered. (Lindsey and West, 1999)

The detrimental impact of the program in British Columbia is further described in the context of substitution of inputs:

> Ambulatory care, hospital care, and medicines are alternative inputs in providing health services, and substitution between them is possible in response to changes in policy in any one area. Substitutions did occur in some European countries after the adoption of RBP, but it is difficult to disentangle the effects of RBP from the effects of other policy changes that were implemented concurrently or soon after. BC government studies indicate that neither hospitalizations nor physician visits increased in response to the introduction of any of the five RBP classes . … Contradictory claims have been made by the Better Pharmacare Coalition. And a study by the Canadian Association of Retired Persons found that most doctors and pharmacies have had patients who experienced difficulties when their medications were switched. (Lindsey and West, 1999)

Restrictive formularies

Drug formularies have emerged as a principal tool for policymakers seeking to manage pharmaceutical costs and expenditures. A drug formulary is a list of both branded and generic prescription drugs that the plan sponsor prefers. Under some national pharmacare plans, prescription coverage may only extend to medicines that are on this preferred list, effectively steering prescribers and patients to the least costly medications sufficiently effective for treating the particular health condition. Drug formularies are described as either "positive" or "negative." Positive listings indicate which medicines are covered under a given program, including information about the subsidy level and the conditions under which it applies (Morgan et al., 2006). Drugs that are not listed are generally not covered. Alternatively, under a "negative" formulary virtually all drugs are covered unless listed on the negative formulary. Both types of formularies utilize centralized reviews to determine which drugs will be placed on the formulary, to either receive or be excluded from coverage. For negative formularies, drugs need not be formally reviewed to be eligible for coverage, but drugs placed on the negative formulary and omitted from coverage are all reviewed.

Consider the experiences of Australia, the UK and New Zealand. Australia employs a positive formulary while the UK uses a negative formulary. In both cases, the formularies are regulated by cost-effectiveness analysis and considerations such as "the availability of alternative therapies, the severity of the disease or condition the drug is approved to treat, and the impact on drug budgets" (Boothe, 2016). Fundamentally, a national pharmacare system

must be cost effective. In describing the case of the United Kingdom, "sadly this means that many drugs which could extend the life of a patient are not available through the system. This is because the NHS believes that the cost far outweighs the benefit. The only way in which people are able to access these drugs is outside of the universal health care system. … it does happen, and people and families do suffer as a result. It is worth noting that this [the unavailability of drugs through the system] only extends to 'life extending' drugs i.e. if somebody is terminally ill. It does not apply to drugs which could be seen as 'life saving'" (Formosa Post, 2017). The situation in Australia is slightly different:

> Australia has an expert body analogous to the CDR's Canadian Drug Expert Committee, called the Pharmaceutical Benefits Advisory Committee (PBAC). PBAC's official mandate is to recommend new drugs for listing on the national formulary, taking into account clinical effectiveness, safety and cost-effectiveness compared with other treatments. The committee's recommendation may include a requirement that a drug be subsidized only for a restricted population, and it can make recommendations regarding price or cost offsets. If the committee makes a positive recommendation, the drug goes to the Pharmaceutical Benefits Pricing Authority to discuss a final listing price. If the committee's recommendation is negative, the manufacturer may resubmit the drug after gathering new evidence or proposing a more limited patient population or lower price. Australian policy experts often refer to this as a system of "no means no, and yes means maybe": drugs can only be listed on the national formulary with expert approval, but the minister has the final say. (Boothe, 2016)

New Zealand's "positive" formulary documents the entire list of subsidized medicines. PHARMAC first established a public formulary, the Pharmaceutical Schedule listing the drugs subject to either full or partial government subsidy. As documented by Morgan et al. (2006), positive listings indicate which medicines are covered under a given program, providing information about the subsidy level and the conditions under which it applies. Drugs that are not listed are generally not covered. As described above, centralized reviews determine which drugs will be placed on the formulary. Braae, McNee, and Moore (1999: 652–53) note that "drugs are assessed for the health gain they provide to patients as well as whether they provide savings in other parts of the system, such as avoided hospitalizations … the decision criteria exclude the impact on the pharmaceutical industry."

Measuring New Zealand's pharmaceutical expenditure, both as a proportion of total health expenditure and as a proportion of GDP, one finds that it decreased significantly over the years, largely in response to innovative

treatments and increased reliance on pharmaceutical rather than surgical interventions. In contrast, these expenditures have grown in the OECD. While the New Zealand agency keeps drug prices down, it does risk a single negotiated price for an entire class of drugs that may be so broad as to not be clinically substitutable. Consequently, prescribers and patients in New Zealand face a restricted range and quantity of medications. Indeed, the New Zealand population has access to a smaller range of drugs than other developed countries. The list of medications that the government, via PHARMAC, agrees to cover amounts to far fewer than what is funded by most provincial drug plans in Canada.

As described by Sundakov and Sundakov (2005), this generates increased costs elsewhere in the health system. Specifically, this results from lower health outcomes resulting from limited access to pharmaceuticals, the disruption of established clinical routines and limited clinical choice. Such restrictions reduce the opportunities for minimizing side effects. Moreover, in the end, non-pharmaceutical treatments and interventions may cost more than the equivalent medicines-based treatments would have cost. According to a recent PMPRB (2016) report, of all the drugs approved in New Zealand from January 2009 to December 2016, a mere 16 percent were added to the public drug formulary, the worst result of the 31 countries compared. "According to a recent study, 75 percent of New Zealand general practitioners said they had wanted to prescribe an unfunded medicine in the previous six months. Some New Zealand patients have even emigrated to Australia to access required medical treatments for multiple sclerosis and HIV infection" (Labrie, 2015). Moreover, it may take several years before a drug available in other countries obtains coverage in New Zealand. Even when the PHARMAC Advisory Committee has made a positive decision about a drug, it can take more than 10 years before it is funded by the government agency, since the budget ceiling is reached (Della Barca, 2018).

Finally, Sundakov and Sundakov (2005) describe concerns about the transparency of the New Zealand process for listing new medicines. Specifically, they note growing concern that evaluations of the effectiveness of new medicines is being compromised by judgments about their costs rather than by the relevant clinical considerations. Without absolute clarity in the process, such evaluations risk being tainted by nonclinical factors, and willfully underestimating or ignoring clinical benefits because of the expense of the drugs.

The approach taken by New Zealand is likely too extreme to be replicated in Canada. According to Marc-Andre Gagnon of Carleton University, "'I don't think it could work here. It's based on the idea that you have one reference drug per category,' he says, referring to the fact that the system only reimburses the lowest-priced drug in each therapeutic category. 'For Canadian doctors, I think they would think this is absolutely unacceptable'" (Milne, Laupacis, and Tierney, 2015). Durhane Wong-Rieger, president of

the Canadian Organization for Rare Disorders, echoes this sentiment: "New Zealand has taken a very draconian view towards this. Unfortunately, it means that most of the patients don't get any access to even what we would consider standard medicines, and they are blocked out of any of the innovative medicines" (Milne, Laupacis, and Tierney, 2015).

While progress has been made to standardize drug prices and coverage on a national scale through the Pan-Canadian Pricing Alliance (pCPA) and the Common Drug Review, unless "Canada can achieve improved participation on such initiatives it is unlikely that a federal government could successfully negotiate a national system with the provincial governments that hold the health care bargaining power" (Crosby, Lefebvre, and Kovacs-Litman, 2016).

Cost-effectiveness analysis

Health Technology Assessment (HTA) is the policy analysis that studies the medical, social, ethical, and economic implications of the development, diffusion, and the use of health technology. The objective is to offer guidance to policymakers in balancing expanding expenditures for health care, the availability of remarkable new innovations in healthcare technology, and constrained budgets. Health technology assessment examines short-term and long-term consequences of the application of a healthcare technology. Properties assessed include evidence of safety, efficacy, patient-reported outcomes, real-world effectiveness, cost, and cost-effectiveness in the context of social, legal, ethical, and political impacts. O'Donnell et al. (2009) provide an excellent concise history of HTA. Critics of Health Technology Assessment argue it is used simply to restrict access to new healthcare technology, while HTA advocates underscore its use to promote efficient resource allocation and to advance population-based health.

To make comparisons across treatments, the British National Institute for Health and Care Excellence (NICE) analyzes each for its cost-effectiveness, using a scale known as quality-adjusted life-years (QALYs). As described by Gillett (2014), "[t]he idea is to estimate the additional life expectancy gained by the patient while also accounting for their quality of life during that time. For instance, a drug which gave you five years of life at perfect health would equate to five QALYs, as would a drug which extended your life by ten years at half that quality of life. … The 'cost-per-QALY' is then calculated and compared to a threshold value before deciding whether the drug provides enough value to be commissioned."[10]

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10. The threshold value is established nationally and will differ across countries. For example, "NICE's 'threshold,' over which treatments are less likely to be recommended for use in the NHS, is typically between £20,000 and £30,000 per QALY" (Dillon, 2015).

Clearly there is an ethical dilemma in the process of placing a monetary value on the quality of human life. However, there are also practical challenges in the QALY-based system. While a thorough analysis of those challenges is beyond the scope of this piece, it is worth noting that such decision-making has been described as "mathematically flawed" due to the fact that a patient's attitudes toward their quality of life vary dramatically with age, complicating the accurate calculation of long-term QALY benefits. In a 2013 study, the European Consortium in Healthcare Outcomes determined that NICE was not using "a scientific way to classify and prioritise drugs" (Dreaper, 2013).

Additional challenges emerge in an examination of the way in which QALYs are measured, and in answering the question of whether it is possible to quantify something as abstract as quality of life (Gillett, 2014). Consider, for example, the fact that patients with disabilities record a lower quality of life with regard to mobility, therefore leading to a likely lower QALY benefit calculation for any potential treatments. Thus, QALY benefit calculations for treatments for patients with disabilities are more likely to fail to meet the established threshold for coverage. A very accessible discussion of the limitations of QALY calculations may be found in Gillett (2014).

The choice of comparators is of critical importance. The preference is to use the most prescribed pharmacological analogue used for the same indication. In Australia, if the drug is in a new pharmacological class, then the drug most prescribed for the same indication is used, and if no currently listed drug is available then standard medical nondrug management is the comparator. Critics argue these criteria disadvantage new drugs since they are compared to older, cheaper, off-patent drugs. "The industry has argued for using the drug with the best 'head-to-head' trial evidence available, rather than the most appropriate pharmacological comparator. This nearly always results in the choice of the most expensive existing drug, as companies generally do not do trials against older cheaper drugs" (Birkett, Mitchell, and McManus, 2001).

Cost-effectiveness analysis may successfully be used to extend the understanding of efficacy data, which often come from clinical trials, allowing for more than the comparisons of cost alone. "The optimal [cost-effectiveness] ratio … is quite sensitive to income and attitudes toward risk. If a single … ratio is applied to all interventions and to all individuals in a group, for some of them the marginal benefit will fall much lower than the marginal cost, and for others, just the opposite. … [Cost-effectiveness] analysis applied at the population level may give the most efficient egalitarian distribution of heath resources, but it is not likely to be Pareto optimal" (Garber and Phelps, 1997). While QALYs will not vary across patients, their valuations of the treatment will, creating an inherent conflict. However, as described by Weintraub and Cohen (2009), there are also significant problems with cost-effectiveness analysis.

There are real problems with cost-effectiveness analysis, which deserve mention. The first is with the quality of data. If a cost-effectiveness analysis is based on 1 or more randomized clinical results, it will only be as good as the data in the trial. If the trial is biased in some way or not adequately generalizable, the cost-effectiveness analysis will suffer from these same limitations. If a cost-effectiveness analysis is based on a disease simulation model rather than a clinical trial, it will only be as meaningful as the input values. It is also necessary to have an appropriate control group for comparison. Ideally, the control group should represent the current standard of care, assuming that this standard is, itself, reasonably cost-effective. If an inappropriate control group is chosen, the resulting comparison will not lead to efficient resource utilization. Unfortunately, clinical trials of new therapies are often driven by regulatory concerns rather than by addressing important issues of healthcare policy or medical decision making. Finally, the time horizon of a cost-effectiveness analysis may extend beyond the data that are available, requiring modeling of outcome as opposed to direct measurement. (Weintraub and Cohen, 2009)

However, that which may be good for the group is not necessarily good for individual members of the group. Accordingly, "a proper accounting of marginal costs and benefits—not their ratio—is the more sensible starting point for strategic decisions from a societal perspective. Only patient-specific costs and patient-specific benefits will have relevance to clinical decisions regarding individual patients" (Diamond & Kaul, 2009). While the use of cost-effectiveness analysis does provide policymakers with guidance on how to spend scarce health resources, it is an imperfect mechanism and one with vocal critics.

Consequences

This section reviews the consequences of the cost containment strategies described above. A description is included of the potential for reducing pharmaceutical expenditures, the cost burden shifted to taxpayers, the risks of drug shortages, the implications for international reference pricing, the effect on formulary decisions, the risks of therapeutic substitution, the potential for reduced access and worsening health outcomes, as well as the reduced incentive to innovate. While these results are not necessarily going to come to pass, they are typical of what can be expected. As with many complicated policy changes, the devil is in the details and the actual consequences for Canadians remain to be determined in the future.

Reduced pharmaceutical expenditures

The most significant benefit of universal pharmacare would be lower pharmaceutical expenditures for insurers and individuals. "Decreased redundancy lowers administrative expenses, reduces dispensing fees on large volume orders accepted by provider pharmacies and secures more favourable deals through bulk purchasing agreements" (Crosby, Lefebvre, and Kovacs-Litman, 2016). Consider the case of Australia, where the use of evidence-based medicine has lowered costs for new substances relative to other countries. The prices of new substances in Australia are approximately 50 percent lower than in the United States (Yoongthong et al., 2012). The prices for generics and incremental innovations, however, are relatively higher than in the United States, partly due to the use of value-based pricing.[11] "For example, a 40-mg tablet

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11. "Value-based pricing is an umbrella term, encompassing a number of different possible payment arrangements. At its administratively simplest, a company could link the single price it charges for a given drug to an assessment of how well it works. More sophisticated versions of value-based pricing in the marketplace would allow insurers and patients to receive rebates from drug manufacturers if a drug failed to work, an arrangement known as "outcome-based pricing." Another variant would involve "indication-based pricing," in

of simvastatin is AUS$1.00 compared with an equivalent cost of AUS$0.11 in the United Kingdom and AUS$0.05 in New Zealand" (Yoongthong et al., 2012). In the case of Canada, several provinces currently consistently engage in bulk purchasing agreements, though they are separate and less efficient, undermining their purchasing power and contributing to higher administration costs. It is argued that a single, unified federal agreement would increase purchasing power and deliver additional economic surplus.

While a publicly-funded pharmacare program may lower pharmaceutical expenditures, the subtleties must be carefully considered. Arguably, one advantage would likely be the reduction in the incidence of cost-related non-adherence (CRNA). **Table 2** utilizes 2007 data to examine the percent of the population in various countries reporting not filling a prescription or skipping a dose because of drug cost during the previous 12 months. In Canada, this was eight percent of the population. In a more recent study, Morgan and Lee (2017) find some improvements, noting that observed differences in national prevalence of CRNA correspond with prescription drug coverage and direct patient charges for prescription drugs under the plans employed. Across all income levels, the average in Canada is 8.3 percent. These results are exacerbated by lower incomes (**table 3**). Access to medicines is a function of both availability and affordability. In the context of access due to affordability, the United States, Canada, and Australia fall below international comparators. The 2017 study notes that access in the US and Canada may improve with the adoption of universal coverage of medication costs, while a reduction of the standard copayment in Australia may improve access to Australian patients. The results indicate that the subtleties of universal pharmacare, as well as the copayment structure, are critical to reducing CRNA and improving access.

Table 2: Percent of population reporting not filling a prescription or skipping a dose because of cost during the previous 12 months (2007 data)

Country	Rate
United States	23.1%
Australia	13.4%
Germany	11.5%
New Zealand	10.0%
Canada	8.0%
United Kingdom	5.4%
Netherlands	2.0%

Source: Morgan and Kennedy, 2010.

which drug companies charge different prices for the same drug when it is used to treat different conditions." (Sachs, Bagley, and Lakdawalla, 2017)

Table 3: 2014 national prevalence and adjusted odds of cost-related non-adherence (CRNA) among respondents, stratified by income

All incomes

Country	CRNA%	Adjusted OR (95% CI)
Australia	6.8	**2.17 (1.28 to 3.67)**
Canada	8.3	**2.76 (1.66 to 4.59)**
France	1.6	**0.47 (0.23 to 0.94)**
Germany	3.7	0.99 (0.52 to 1.91)
Netherlands	4	1.18 (0.63 to 2.23)
New Zealand	4.8	1.68 (0.87 to 3.23)
Norway	2.4	0.66 (0.33 to 1.31)
Sweden	2.4	0.80 (0.47 to 1.37)
Switzerland	2.9	0.86 (0.48 to 1.56)
UK	3.1	Reference
USA	16.8	**6.09 (3.60 to 10.20)**
Pseudo R²		*0.148*

Below-average income

Country	CRNA%	Adjusted OR (95% CI)
Australia	6.8	**2.17 (1.28 to 3.67)**
Canada	8.3	**2.76 (1.66 to 4.59)**
France	1.6	**0.47 (0.23 to 0.94)**
Germany	3.7	0.99 (0.52 to 1.91)
Netherlands	4	1.18 (0.63 to 2.23)
New Zealand	4.8	1.68 (0.87 to 3.23)
Norway	2.4	0.66 (0.33 to 1.31)
Sweden	2.4	0.80 (0.47 to 1.37)
Switzerland	2.9	0.86 (0.48 to 1.56)
UK	3.1	Reference
USA	16.8	**6.09 (3.60 to 10.20)**
Pseudo R²		*0.165*

Average income or above

Country	CRNA%	Adjusted OR (95% CI)
Australia	5.5	1.48 (0.74 to 2.98)
Canada	4.5	1.23 (0.64 to 2.40)
France	2.5	0.57 (0.25 to 1.30)
Germany	2	0.52 (0.19 to 1.44)
Netherlands	2.9	0.73 (0.31 to 1.75)
New Zealand	4.3	1.32 (0.54 to 3.23)
Norway	2.2	0.52 (0.19 to 1.39)
Sweden	1.5	**0.41 (0.20 to 0.81)**
Switzerland	2.2	0.59 (0.24 to 1.44)
UK	3.4	Reference
USA	9.7	**3.30 (1.68 to 6.49)**
Pseudo R²		*0.086*

Notes: Results reported in bold are significant at p=0.05. Adjusted Ors are from sample-weighted logistic regression models. Pooled income model controls for age group, sex, health status and household income (not shown). Income stratified models control for age, sex and health status.

CRNA, cost-related non-adherence, sample-weighted prevalence.

Source: Morgan and Lee, 2017, drawing on 2014 Commonwealth Fund International Health Policy Survey of Older Adults.

Table 3 considers the national prevalence and adjusted odds of CRNA by income level. "Lower incomes were associated with higher levels of CRNA in most countries, particularly in the USA and Canada, where the prevalence of CRNA among older adults with below-average incomes were 24.9% and 11.7%, respectively. … After adjusting for age, sex and health status, low-income residents of the USA, Canada and Australia were significantly more likely to experience CRNA than low-income residents of the UK" (Morgan and Lee, 2017).

Proponents of a national pharmacare program suggest that immediate cost barriers, such as copayments and deductibles, would decrease. Notably though, countries with national drug coverage plans do not fully cover out-of-pocket expenses. Accordingly, Canadians should expect to continue to pay these costs, as they exist under current provincially delivered plans. "For example, out-of-pocket expenses represent more than 30% of total spending in Australia, Norway, and New Zealand—all countries with national pharmacare plans. This proportion is comparable to that in Canada, where out-of-pocket expenses are 25%, less than the aforementioned countries" (Beach et al., 2016; also see Labrie, 2015). Before being able to obtain a prescription, New Zealand patients must pay a fee of up to $50 for the medical consultation, which prevents many of them from obtaining required medication.[12] The most recent survey data from the New Zealand Department of Health indicates that 14.3 percent of adults admitted to being unable to afford their consultation with family doctor in 2017 (New Zealand Ministry of Health, 2017). Not surprisingly, patients from disadvantaged backgrounds are even more likely to avoid filling their prescription due to these financial barriers (Norris et al., 2016).

While New Zealand is cited as an example of the type of program that should be adopted, in reality such a program may not deliver everything its advocates propose. Adoption of a New Zealand-style program in Canada "would likely fail to satisfy patients and physicians and could result in higher costs in other healthcare sectors. For example, denying patients the benefits of newer, more effective drugs for cardiovascular diseases, diabetes and cancer could lead to an increased risk of hospitalization. In which case, the cost to the healthcare system would be much greater than the drug savings and the patient's quality of life, and perhaps its extent, would be negatively impacted" (Rawson, 2016). While the cost savings on pharmaceuticals are frequently touted, it is critical to examine whether those results can be replicated in Canada. Moreover, the additional consequential expenditures in other areas of the healthcare system are rarely mentioned. The full extent of the tradeoff must be examined before the cost calculation—savings or loss—may be estimated.

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12. For example, see the fee structure applied by the general practices in South Canterbury: <https://www.scdhb.health.nz/info-for-you/gps/fees>. The author is grateful to an anonymous reviewer for this reference.

Cost burden to taxpayers

According to an opinion poll conduct by the Angus Reid Institute in 2015, while 91 per cent of Canadians support the concept of 'pharmacare,' "70 per cent are against increasing the GST to six per cent—from the current five per cent—to pay for the program. If you're not willing to pay for something you want, that may be a sign you don't really want it that badly" (Labrie, 2015). While Canadians embrace the benefits that they envision emerging from a pharmacare program, these benefits do not come without a cost, a cost that Canadians are clearly reticent to accept.

Advocates argue that a national pharmacare program would generate cost savings through bulk purchasing and generic prescribing. Whatever the ultimate savings in the short to medium term, it is estimated that the transition costs of establishing the administrative infrastructure will greatly exceed the CA$11.5 billion in savings that the federal government put forward for the next ten years (in addition to the three percent increase in the Canadian Health Transfer (CHT)). Notably, "even the incremental proposals most recently costed by the Conference Board (2015) and Morgan et al. (2017(a)) exceed this amount (assuming an annual average [cost] of C$1.15 billion)" (Adams and Smith, 2017).

Given that the funds needed to provide a publicly-funded pharmacare program would be raised through taxation, it is essential to fully account for these funds as well as the excess burden of taxation, that is, the marginal costs of raising tax revenues. Dahlby and Ferede (2011) estimate the marginal cost of public funds for the federal government. They find that "at the existing tax rate, raising an additional dollar of tax revenue costs society $1.25" (Dahlby and Ferede, 2011). In any case, the implication is that, all things considered, there wouldn't be any savings to expect from a single-payer pharmacare program, quite the opposite.

It is critical to account for this deadweight loss of taxation, and to recognize the important ways in which this contrasts with insurance premiums. Insurance premiums are sometime mischaracterized as "hidden taxes." The fact is, these premiums do not impose the deadweight loss on society that income taxes do. The efficiency gains and cost savings generated by insurance premiums, relative to tax revenues raised through income taxes, must be recognized and appreciated.[13]

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13. There is a huge body of empirical literature that addresses this issue. Interested readers should see the works of Martin Feldstein, Don Fullerton, and Lawrence Summers, among others. In the context of healthcare spending, please see Baicker and Skinner (2011). The author is grateful to an anonymous reviewer for suggestions that led to this discussion and significantly improved the paper.

The Parliamentary Budget Office claims that a pharmacare plan would lead to CA$4 billion in savings, all things considered. However, the major flaw of the analysis done by the PBO is that it excluded the "marginal cost of public funds" as described above. According to Brett Skinner, CEO of the Canadian Health Policy Institute (CHPI), "[t]he idea that a government-run insurance monopoly will cost less and deliver the same benefits as the current system is laughable. The Parliamentary Budget Office estimated that even a bare-bones pharmacare plan would impose a net additional tax burden of at least $7.3 billion. CHPI estimated that pharmacare will shift over C$25 billion off the provinces and the private sector onto the federal budget, including more than $13 billion in new costs for taxpayers, assuming no changes to prices and drug plan benefits" (Skinner, 2018). While the ultimate costs of a government-run pharmacare program are unknown, it is important to recognize that some experts estimate that the program will be less efficient and transfer expenditures from the private sector onto the federal budget.

Monopsony (a single buyer) power can only work, and thus prices can only decline, if access to new drugs is restricted on the public drug formulary (Ellison and Snyder, 2010). Publicly-funded pharmacare programs, such as New Zealand's, decrease drug expenditure by negotiating lower drug pricing from manufacturers and rationing access, leading proponents to suggest that unified national negotiating power will reduce costs in Canada. However, Canada already has an avenue for achieving this: the pan-Canadian Pharmaceutical Alliance. Through this Alliance, provinces and territories negotiate savings on both brand and generic drug costs. "As of March 31, 2017, the pCPA's efforts have led to a $1.28 billion a year in estimated combined jurisdictional savings" (Canada's Premiers 2018).[14] This establishes that a single-payer pharmacare plan is not a necessary condition for achieving this goal.

Drug shortages

Drug shortages are an increasingly prevalent problem in Canada, one that is likely to worsen with the adoption of a national pharmacare program if a sole tendering process is put into place.

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14. Following a review by Health Canada, "the alliance decides whether to negotiate jointly for the drug. If it decides to do so, one jurisdiction assumes the lead on the negotiations with the manufacturer. If they reach an agreement, the manufacturer and lead jurisdiction will sign a letter of intent. It's then up to each participating jurisdiction to decide whether to fund the drug through its public drug plan and enter into a product-listing agreement with the manufacturer" (Benefits Canada, 2016).

In Canada, some critics blame shortages on the hospitals' procurement methods, a tendering process in which the cheapest supplier wins the whole market. This system favours sole suppliers and makes finding an alternative supplier difficult in cases when production is halted. One solution could be to "favour competition" by purchasing drugs from multiple suppliers, but this path wouldn't be cheap. New Zealand went this route, and in 2009 the PHARMAC annual review reported that dividing the tendering process in two increased prices on average by 17%. This is a significant price to pay for an "insurance premium." Generic manufacturers are certainly in favour of increasing prices, but this would be difficult to justify at a time when cost containment in healthcare services has become a priority. Furthermore, trying to create more competition in this sector in the context of global industrial mergers might prove futile, while impeding savings for Canadians. (Gagnon, 2012)

Fundamentally, there is a critical tradeoff between procurement and expenditures. Sole tendering may reduce pharmaceutical expenditures, but it also increases the risk of a drug shortage. Alternatively, expenditures may be higher when drugs are purchased from several suppliers, but the risk of a shortage is diminished.

Shortages harm consumers when they cannot obtain their medicines, but the damage extends beyond that. Ongoing shortages increase the risk of a delay in beginning the optimal treatment, and the necessity of selecting a substitute may create of product mix-up due to unfamiliar packaging (Nelson, 2017). For some patients, the shortages are inconvenient, but for others they are potentially fatal. Specifically, while some products can be substituted, those to treat epilepsy, for example, cannot. (ThePharmaLetter, 2003) These risks are compounded by the dangers of switching therapies, the difficulties in mitigating side effects, and price changes.

Evidence suggests that bulk purchasing and sole tendering contracts, common in national pharmacare programs, may result in monopolies or limited numbers of drug suppliers. When the government awards a contract to a single manufacturer, that firm becomes an effective monopoly. This reduction in competition can result in the exit of some manufacturers from the market, further restricting opportunities for substitution. Such concentrated market power increases the risk of a limited supply of a particular drug when the market is dominated by a single (or few) manufacturers. "Experience demonstrates that bulk purchasing contracts often lead to a centralization in manufacturing and distribution, with a market dominated by a very limited number of suppliers of any one drug" (Poston, 2010: 2). Moreover, Hollis and Grootendorst (2012) note that sole tendering may result in the concentration of the domestic generic industry and describe the case of New Zealand in

which almost all tenders are sourced by foreign manufactures and only one domestic generic manufacturer remains in operation.

Ultimately, such concentration may result in drug shortages when manufacturing problems arise. Notably, drug shortages occur and most commonly result from reliance on a single provider, since it is difficult to arrange supply with a previously unused manufacturer and such manufacturers may not have the capacity to supply a new market. The experience of New Zealand is illustrative: the nation has experienced a number of drug shortages in cases in which the medicine was provided by a sole supplier. In 2005, New Zealand's PHARMAC awarded the sole tender of the nation's flu vaccines to Sanofi-Pasteur of France. When all of the vaccines were declared unsuitable, New Zealand scrambled to locate an alternative supply. McKay (2005) estimates that close to one-third of the 2600 chemicals on PHARMAC's Pharmaceutical Schedule were sourced through sole-supply tenders, resulting in numerous stories of drug shortages and unavailable pharmaceuticals: "iron tablets, allopurinol for gout prevention, the only stat treatment for chlamydia, certain doses of progesterone, diltiazem" (McKay, 2005: 3). "The numbers of frequently used pharmaceuticals that are unavailable has skyrocketed as sole supply has become more common" (McKay, 2005: 2).

As described by the New Zealand Press Association, PHARMAC's tendering process has cut so far into profits that some drug companies have left the country, while some have downsized and still others have cut back the levels of medicines kept in stock (NZPA, 2003). "PHARMAC's policy of selecting only one company to supply a medication was hurting the pharmaceutical industry, leading manufacturers to reduce stocks in case the government agency switched to a cheaper supplier... Other local reports quote NZ pharmacists, concerned at the implications of the drug shortages for their customers, as considering the possibility of importing the missing products from Australia, although this would be illegal" (ThePharmaLetter, 2003).

Examples of shortages are plentiful. "A shortage of Metoprolol, a blood pressure and angina drug that is among the most prescribed medicines in the country, is forcing tens of thousands of patients to cut their three months' supply to a monthly prescription. In January, the nation completely ran out of the BCG vaccination, which is used to immunize newborns at risk of tuberculosis. … Some blame shortages on the PHARMAC model that often relies on just the one supplier" (Heather, 2016). PHARMAC is unable to determine the number of shortages faced in New Zealand, but Operations Director Sarah Fitt agrees that there was "nearly always a shortage in something. It is pretty ongoing, really" (Heather, 2016).

> PHARMAC will often enter into contracts with manufacturers, in which PHARMAC agrees to subsidize the medicine—and often provide a New Zealand monopoly—in return for continuity of supply and

cheap prices. These medicines, there are roughly 3500 of them, are then available for pharmacists and hospitals at the subsidized rate. When a particular medicine runs low, PHARMAC can require a manufacturer to find an alternative source. If they can't, PHARMAC will look [for] another manufacturer and, in urgent cases, even import a substitute medicine that is unregistered in New Zealand. Often PHARMAC asks pharmacies to ration medicine in short supply to prevent panic buying. Many PHARMAC contracts require the manufacturer to meet any cost of sourcing alternatives. (Heather, 2016)

PHARMA offers drug manufacturers a virtual monopoly in New Zealand, providing medicines to patients and hospitals at a subsidized price that eliminates competitors from the market. The result can be shortages. As reported by Heather (2016), "[s]everal suggested that it is precisely the cheapness of the drugs that is responsible for the shortages." While lower prices benefit consumers and taxpayers, shortages mean that patients may pay the ultimate price.

The experiences of other nations are also illustrative. As reported in the UK's *Telegraph* in 2015, "last year nine out of ten GP's said they had been forced to write prescriptions for 'second choice' medicines because their preferred drug was out of stock" (Jamieson, 2015). Writing in the *British Medical Journal*, Dr. Margaret McCartney, a GP in Glasgow, said, "A combined total of 5% of my latest day on call was spent trying to fix prescription supply problems, one by tedious one" (Jamieson, 2015). In the case of England, "[t]he reasons [for the shortages] are complex, but many stem from consolidation within the production process reducing the resilience in the supply chain, combined with the low cost of many generics, which reduces incentives to invest" (Iacobucci, 2018).

Globalization has created global competition between buyers, and priority is given to markets with the highest return on investment. As described by Nelson (2017), "Australia represents only 2% of the global pharmaceutical market, we do not have the purchasing power to secure supply in times of global shortage." This concern is worsened by the reduced competition that results from sole sourcing. Given that Canada represents 1.9% of the global pharmaceutical market, these sentiments are particularly relevant (Canada, 2018).

Finally, drug shortages may result in additional costs for the healthcare system. Despite the claims of some pundits, single-payer systems are not a panacea that prevent drug supply disruptions from happening. In the UK in 2017, at least 100 drugs were affected by supply problems, "forcing health officials to approve temporary price rises of up to 4,000 percent to boost stocks. The NHS is spending more than £50 million a month overpaying for the medicines, but pharmacies are still running out for days at a time" (Kenber,

2017). As "more emergency price increases were agreed to boost stocks. … A record 91 emergency price rises were agreed in November, as the NHS continued to experience supply problems that are estimated to have cost the service more than £200m since April 2017" (Iacobucci, 2017). Shortages are exacerbated by the reduced competition in production resulting from sole sourcing, resulting in higher drug costs. Shortages forced the health officials to seek out alternative sources of medicines, at significantly higher prices. The overpayments raised costs for taxpayers, while failing to ensure a reliable supply of medicines.

International reference pricing and the reference basket

An additional consequence is the impact this program may have on international drug prices. International reference pricing has the potential to significantly impact the prices and availability of drugs in Canada. This policy creates an interdependence of prices across countries, giving innovative firms an incentive to launch new drugs in high-price countries first and to delay launch or even not to launch new drugs in low-price countries (Houy and Jelovac, 2015). Given that Canada is a reference nation for many other countries, the pricing of drugs in Canada has global consequences and impacts the prices of drug in many other jurisdictions. "Brand-name drugs are produced by multinational companies with sales in many countries. Canada is a small player on the world market, accounting for less than 2 percent of total sales. Pricing of drugs in Canada may therefore be dominated by considerations external to the Canadian market" (Lindsey and West, 1999). While the Canadian market, in isolation, is relatively inconsequential in the global arena, reference pricing magnifies the impact of Canadian pricing decisions and amplifies them across multiple countries. Consequently, multinational companies must consider not only the implications of price reductions in Canada, but the global implications of such changes. Ultimately, the international consequences may determine the pricing of medicines in Canada.

Formulary decisions

As a practical matter, the administrative considerations surrounding the national formulary have not been addressed. Important questions remain unanswered and the success of the program will hinge on their answers. As enumerated in a recent report commissioned by the Canadian Pharmacists Association, it is essential to identify:

◆ Who prepares and maintains the national formulary?
◆ How are tiered co-payments established for less cost-effective drugs?
◆ How will claims be adjudicated?
◆ How are "medically necessary" prescription drugs defined?
◆ What values or definitions are considered to determine the relative cost-effectiveness of drugs for the purposes of establishing appropriate co-payments?
◆ How will a national HTA body ensure timely access to new drugs? (PDCI Market Access Inc., 2016)

Without additional information about these issues, it is impossible to know how the formulary will be established and which drugs will be covered, and a thorough review of the proposed program is impossible.

Therapeutic substitution

One implication of a national pharmacare program and the resulting drug clusters and consequential drug shortages may be the necessity to find therapeutic substitutions. Substitutions may be necessitated when particular drug clusters are reimbursed at a rate that is lower than the price of the chosen therapy, or when shortages make a particular therapy unavailable. According to a 2013 survey conducted by the Canadian Pharmacists Association and the Canadian Medical Association, "[h]ospital pharmacist respondents reported spending considerable time dealing with shortages, including communicating with stakeholders, rationing medications, compounding from alternative concentrations or formulations of the same medication, changing the route of administration, or altering therapy to a medication not currently in shortage. Additional patient safety concerns are arising, such as drug substitutions that require changes to the drug libraries used in 'downstream' technologies like smart IV infusion pumps" (Mann, 2013).

Ultimately, national pharmacare programs may discourage pharmaceutical innovation and thus the development of alternative (and better) drug therapies for patients. All too often, the policies forcing therapeutic substitutions lead to unintended consequences, consequences that may harm patients.

For a good discussion of this issue, please see Nguyen et al. (2016). Notably, the British strategy for controlling prescription drug prices rewards breakthrough research while discouraging "me too" research or patent manipulation (Light, 2003). Although cost-savings accrue to the healthcare system, this approach risks denying patients access to important incremental advances in medical therapies. The value of incremental innovation, for a diverse patient population, is well established:

> [I]ncremental innovation provides physicians with the flexibility to treat the individual needs of diverse patients with precision. Therapeutic alternatives within the same drug class may differ in their metabolism, molecule, regimen, dosing schedules, speed of action, delivery system, adverse effects, therapeutic profile and/or interactions. In addition, incremental innovation increases the number of available dosing options, uncovers new physiological interactions of known medicines, encourages children's compliance through reformulations, increases the shelf-life or heat-stability of a given medicine to ensure effectiveness in diverse environments, expands the number of treatment options available, improves patient administration, allows for the elimination or treatment-limiting drug reactions or side effects, and offers significant options to patients with different physiologic and pathophysiologic status. … In addition to the health benefits described above, incremental innovation in the pharmaceutical industry delivers cost savings. One of the principal advantages of the development of follow-on drugs is the price competition that results from the availability of multiple drugs in a single therapeutic class. (Lybecker, 2014)

By restricting access to particular classes of drugs, or specific drugs within a therapeutic class, or by failing to fully reimburse the cost of a particular medicine, national pharmacare programs are able to realize cost savings.[15] These savings, however, come at a cost to patients and to their health. Not all therapies—even within a single class—work in the same way for all patients or result in the same level of therapeutic success. Patients benefit when physicians have the ability to treat the individual needs of diverse patients with precision.

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15. For evidence of this and further discussion, please see Rawson (2016), Krebs et al. (2016), Labrie (2015), Alla and Mason (2014), and Lybecker and Esmail (2013).

Lack of access

The implementation of a publicly-funded national pharmacare program combined with other cost containment initiatives (such as reference pricing, therapeutic substitution, preferred drug lists, etc.) may limit the choice of medicines for physicians and patients if their preferred therapy (or the most effective therapy) is not covered. This may negatively impact patients, and ultimately prevent the initiative from reducing overall expenditures. Given that patients react differently to different medicines in terms of both benefits and side effects, changes in therapies may have negative health impacts for patients or increase the disability burden of disease.[16] Private costs might also increase if patients choose to remain on their preferred medicine and are forced to fully cover the cost or pay the price differential between their preferred medicine and the one covered by the national program. Furthermore, the lack of access may play out in other ways too: through the delayed introduction of new innovative medicines and delayed introduction of low-cost generics. Each of these can lead to poorer health outcomes, additional expenditures on non-pharmaceutical forms of care, and avoidable prescription costs.

Overall, Canadian physicians have more expansive prescribing choices than their counterparts in New Zealand, which ensures that the most effective and best tolerated product is available for each patient. Notably, a recent study revealed that the marketing approval rate in New Zealand was 70 percent or less in half of the drug classes considered, while the rate in Canada was 90 percent or more in all classes. In addition, several of the drugs lacking marketing approval in New Zealand once had approval which had since elapsed. This indicates that pharmaceutical companies decided not to renew approval, perhaps because of poor sales. Accordingly, fewer products were approved and covered in most drug classes in New Zealand than in many Canadian provinces (Rawson, 2016). This availability, or lack of availability, has direct health consequences for patients.

> Of 248 drugs in the analysis, 90% were approved for marketing in Canada compared with only 74% in New Zealand. The discrepancy in marketing approval between the two countries resulted in the benefit listing rates[17] for anti-retrovirals, angiotensin receptor blockers, statins, proton pump inhibitors, non-steroidal anti-inflammatory drugs and oral hypoglycemic drugs in New Zealand being reasonably high (≥67%), but the number of drugs with benefit listing as a percentage of the total number of drugs in the class being less than 60%. Benefit listing

16. For an excellent discussion of this issue, please see Evans and McLeod (2003).
17. The benefit listing rate is the percentage of drugs approved for marketing in a specific market relative to the total number of drugs available.

and overall rates for histamine-2 receptor antagonists and recently approved oncology and rare disease drugs were much lower in New Zealand than in Canada. Mortality rates for acute myocardial infarction, cerebrovascular disease, chronic obstructive pulmonary disease, musculoskeletal conditions and peptic ulcer in 2011 were more than 30% higher in New Zealand than in Canada. (Rawson, 2016)[18]

According to a review of the New Zealand experience by Lybecker and Esmail (2013), bulk purchasing in combination with approaches such as therapeutic substitution and preferred drug lists resulted in poorer care for some patients including increased prevalence of uncontrolled blood pressure, deteriorated lipid control, and worsened cardiovascular health. Ultimately, New Zealand's approach resulted in negatively impacting both the disability burden and health outcomes, generating higher patient costs, and shifting utilization to other more invasive, costlier treatments.

While New Zealand maintains tighter controls on drug prices, purchasing, prescribing, and access than Canada, these controls reduce pharmaceutical costs in New Zealand, but simultaneously restrict or deny access to important medicines, transferring costs from the state to patients. Consider the following two studies, among many, that describe this occurrence in New Zealand:

> [Regarding diabetes-related drugs] … not a single example of any of these three classes has yet been funded in New Zealand, even where conventional treatment is contraindicated, as in chronic kidney disease, or where funded drugs are not tolerated or not effective. Even the inexpensive extended-release metformin, which is better tolerated than its simple counterpart and widely used internationally, remains unfunded. (Krebs et al., 2016)

> [Regarding multiple sclerosis-related drugs] … NZ has three funded first line disease-modifying drugs: inter- feron beta 1-a, interferon beta 1-b and glatiramer acetate. However, the strict funding criteria for these medications means that less than 20% of patients are eligible for funded treatment, in stark contrast to Australia where between 42% and 55% (data from Australian state MS societies) of patients receive treatment. In addition, the requirement for established disability (EDSS 2.0–5.5) prior to the initiation of treatment in NZ raises the possibility that treatments are initiated too late to impart significant

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18. "A particular strength of this analysis is that it examines a wide range of drugs for a diverse group of disorders. Unlike other studies that have focused on access to new drugs, this analysis includes both recently introduced and older products" (Rawson, 2016).

benefit. In most other Western countries those with severe disease and those who "fail" first line treatments are switched to newer and more potent therapies. The availability of newer treatments in NZ is restricted to a single agent, natalizumab, which receives limited funding in some but not all district health boards. Similarly effective oral treatments that are funded in Australia are not available in NZ. (Alla and Mason, 2014)

Not surprisingly, when costs are transferred to patients, some patients will elect not to fill their prescriptions. "According to a study by the Commonwealth Fund, in 2013, 8 percent of Canadians with below-average incomes said that they had not filled a prescription or had skipped doses in the previous year because of cost. Although there is room for improvement, this is on par with Germany (8 percent) and is notably better than France (11 percent), Australia (14 percent) and New Zealand (18 percent)—all countries with national pharmacare programs" (Labrie, 2015).

Relative to 20 comparable OECD countries, New Zealand ranks last for access to innovative medicines. Moreover, in the case of cancer medicines specifically, New Zealand has the lowest ranking for access relative to 13 other countries (Cheema et al., 2012). While New Zealand has a universal drug plan which has helped to contain pharmaceutical costs, this was accomplished in the face of serious challenges surrounding access to new treatments. "Selective benchmarking certain measures, such as New Zealand's per capita drug spending, provides a cautionary note on the need to consider the broader healthcare context" (PDCI Market Access Inc., 2016).

Consider **table 4**. A low mean ranking score indicates that the country's use of medicines is higher for the total sample of medicines, compared to the other countries in the comparison. Overall, the relative positions of the nations have not significantly changed, but the ranking scores have converged. It is worth noting that the three nations discussed in this study, the United Kingdom, Australia, and New Zealand, were ranked 8th, 9th, and 13th (last), all well below the mean of the 13 nations.

The challenges of the New Zealand scheme are familiar in nations that maintain a national pharmacare program. In the case of Australia, there is evidence that a number of new drugs are not listed for subsidy coverage. For example, drugs that have entered the public domain, in use in countries other than Australia, include "naltrexone for opioid dependence, sildenafil for impotence, finasteride for benign prostatic hypertrophy, and alglucerase for Gaucher's disease. In two of these examples, marginal effectiveness has been the main issue, while in the other two, economic issues have been dominant" (Birkett, Mitchell, and McManus, 2001). Other cases cited by critics have generally been drugs that were determined to provide little or no incremental benefit over currently listed drugs.

Table 4: Summary table of international rankings by therapy area, 2008/09 and 2012/13, top 13 ranked countries

	France		Spain		USA		Austria		Italy		Canada	
	2009	2013	2009	2013	2009	2013	2009	2013	2009	2013	2009	2013
Acute MI	6	9	4	1	12	12	10	6	11	7	9	2
Antipsychotics	9	13	2	7	1	8	5	1	13	11	3	2
Dementia	2	5	3	1	1	2	5	3	12	10	4	4
Hepatitis C	3	2	2	5	6	3	4	4	1	1	11	13
Multiple sclerosis	10	7	7	10	3	5	11	11	2	3	4	9
Osteoporosis	2	7	1	2	3	10	11	5	5	4	9	1
RDS	6	6	7	9	1	1	3	4	2	5	12	13
Rheumatoid arthritis	8	6	6	7	1	4	7	12	11	11	4	1
Statins	7	3	9	8	3	1	12	11	13	10	4	6
Wet AMD	3	3	9	10	7	8	11	12	12	11	5	4
Cancer < 5 years	1	5	5	10	3	8	2	1	8	11	12	9
Cancer 6-10 years	1	1	4	4	7	6	3	2	5	3	11	10
Cancer > 10 years	1	3	3	1	7	12	6	7	2	2	10	10
Cancer hormones	4	7	2	2	12	1	6	10	1	5	10	12
Total ranking points	*63*	*77*	*64*	*77*	*67*	*81*	*96*	*89*	*98*	*94*	*108*	*96*
Mean ranking	*4.5*	*5.5*	*4.6*	*5.5*	*4.8*	*5.8*	*6.9*	*6.4*	*7*	*6.7*	*7.7*	*6.9*
Overall rank	**1**	**1**	**2**	**2**	**3**	**3**	**5**	**4**	**6**	**5**	**10**	**6**

	Switzerland		Australia		UK		Germany		Norway		Sweden		New Zealand	
	2009	2013	2009	2013	2009	2013	2009	2013	2009	2013	2009	2013	2009	2013
Acute MI	n/a	13	3	5	1	8	8	10	7	4	5	11	2	3
Antipsychotics	7	4	4	3	10	9	11	5	8	10	12	12	6	6
Dementia	9	11	11	12	10	8	8	9	6	7	7	6	13	13
Hepatitis C	9	6	5	10	13	11	8	8	10	9	7	7	12	12
Multiple sclerosis	8	2	9	8	12	12	1	1	5	6	6	4	13	13
Osteoporosis	4	9	8	6	6	3	7	11	10	8	12	12	13	13
RDS	13	12	5	3	4	2	8	8	11	11	10	10	9	7
Rheumatoid arthritis	5	3	10	9	9	8	12	10	2	2	3	5	13	13
Statins	8	2	1	5	2	4	11	12	5	7	10	13	6	9
Wet AMD	2	1	1	2	4	5	8	6	10	9	6	7	13	13
Cancer < 5 years	6	2	10	12	11	7	4	3	9	4	7	6	13	13
Cancer 6-10 years	2	7	9	9	8	12	6	5	12	11	10	8	13	13
Cancer > 10 years	5	11	12	6	9	4	4	9	11	13	8	5	13	8
Cancer hormones	9	13	11	11	5	9	3	8	8	4	7	3	13	6
Total ranking points	*87*	*96*	*99*	*101*	*104*	*102*	*99*	*105*	*114*	*105*	*110*	*109*	*152*	*142*
Mean ranking	*6.7*	*6.9*	*7.1*	*7.2*	*7.4*	*7.3*	*7.1*	*7.5*	*8.1*	*7.5*	*7.9*	*7.8*	*10.9*	*10.1*
Overall rank	**4**	**7**	**8**	**8**	**9**	**9**	**7**	**10**	**12**	**11**	**11**	**12**	**13**	**13**

Source: Association of the British Pharmaceutical Industry, 2014.

In 2014, the British NHS announced that abiraterone, a new prostate cancer drug, would not routinely be covered for patients before receiving chemotherapy. The decision was criticized by both patient groups and scientists since the drug was proven to increase the health and life expectancy of patients. The rejection came after a failure to meet the cost-effective threshold required. In fact, between 2012 and 2014, 22 new cancer drugs were rejected for use by the NHS, comprising 61 percent of the cancer treatments analyzed over that period (Gillett, 2014). This example is illustrative of a larger phenomenon of reduced access in the UK. Numerous studies have shown that access to new and innovative medicines is delayed relative to other industrialized countries (Owens, Evangelou, and Whynes 2013).

In response to ongoing criticism, the UK government was urged in 2010 to create a special fund to make new cancer drugs more accessible, although results have so far been mixed. More recently, the government has established an Independent Review Board—Accelerated Access Review—to examine ways to improve the uptake of new medical technologies, including drugs. For products whose prospect of efficacy remains promising but uncertain, NICE will still be able to provide conditional approval, for the time needed to gather evidence that these products do indeed improve the health of patients (see Naci and Mossialos, 2017).

As described above, in the context of the cost burden to taxpayers, Canada already has a system in place to negotiate the cost of prescription drugs. Accordingly, the main alternative to reduce spending is to institute a more restrictive formulary. Such a change would undoubtedly generate backlash from patients, prescribers, and advocacy groups that would no longer receive drug funding for treatments that were previously covered under provincial plans. The Ontario Health Insurance Plan (OHIP+) provides a cautionary tale.[19] While enthusiastically embraced early, in the months since implementation, the program has faced criticism from physicians and patients. The bureaucratic forms and time required, especially to care for many of the sickest children, are burdensome, and the process is far from easy. Moreover, the program is not up-to-date with prescribing guidelines (Alam, 2018). In the larger Canadian context, for universal drug coverage to achieve meaningful cost savings, a unified, more restrictive national formulary would need to be instituted, which would decrease accessibility to medications for Canadians (Beach et al., 2016).

Finally, access to medicines is directly impacted by the adoption of sole tendering agreements which may result in monopolies or a limited numbers of drug suppliers. The effect on the market is twofold: the departure of smaller manufacturers, which may lead to the concentration of the domestic industry,

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19. OHIP+ makes more than 4,400 drug products free for anyone age 24 years or younger. All babies, children and youth age 24 years and under who have OHIP coverage are automatically covered by OHIP+.

and restrictions on opportunities for therapeutic substitutions, which may lead to drug shortages and harm to patients.

Health outcomes

The analysis of a national pharmacare program must also consider the impact on health outcomes for the nation's patient population. The restricted access to some drugs may have significant implications for the treatment options for some patients and conditions. In the case of New Zealand, PHARMAC's decisions not to fund particular drugs have raised concerns about access to clinically effective medicines. Critics focus on the medical concerns over switching patients not only to different brands, but to different chemicals within the same sub-groups. "Concern was also expressed about repeated changes in the reference priced statin, resulting in patients having to switch medicines, some several times. … [this] shows that PHARMAC has focused more on financial imperatives than evidence-based medicine and good patient care, and that such switching between drugs is not good for patients" (Cummings, Mays, and Daube, 2010).

New Zealand has experienced both restricted access to medicines due to the preferred drug list, as well as delayed introduction of new innovative medicines. The result has likely been poorer health outcomes and additional expenditures on non-pharmaceutical forms of care. In a 2007 study of mortality rates from acute myocardial infarction in Canada, Australia, and New Zealand, the analysis suggests "an association between decreasing cardiovascular drug sales and markers of declining cardiovascular health in New Zealand" (LeLorier and Rawson, 2007). The study also cautions that reduced access to drugs could result in more hospitalizations, increasing the burden on the healthcare system.

> As a result of the cost containment system for prescription drugs, fewer new products are available in New Zealand than in Australia and Canada. Eighty-five new drugs were released into the world market between 1994 and 1998, 56 of which were made available for sale in Canada, 43 in Australia and only 28 in New Zealand. … patients in New Zealand are disadvantaged when it comes to access to the newest therapies. In contrast to the evidence that cardiovascular health improved significantly in New Zealand until the early 1990s, our analysis of the OECD health data points to declining cardiovascular health in New Zealand which is supported by other findings.
> (LeLorier and Rawson, 2007: 717)

In December 1996, fluvastatin became the reference-priced statin and New Zealand physicians were immediately forced to shift their patients from the drug on which they were stabilized to fluvastatin.

> Professor Jim Mann from Dunedin published observational data suggesting that the switch to fluvastatin resulted not only in deterioration in control of lipid concentrations in most patients, but also a significant increase in the frequency of thrombotic vascular events compared to the previous six months of simvastatin therapy. … This was not surprising, because fluvastatin, in its suggested dosage range, operates at a lower part of the dose-response curve than the other statins, and the same lowering of lipids in the same number of people could not be expected. … The deficiencies of fluvastatin were so marked that they were quickly perceived, not only by practitioners, but presumably also by PHARMAC, who raced to reference price another, more powerful, statin. The statin chosen was atorvastatin—the most potent, and in the doses selected, the most powerful lipid-lowering agent available at the time. The problem with atorvastatin was that, like fluvastatin, its evidence basis was lacking compared with simvastatin and pravastatin. (Begg et al., 2003: 1)

These findings are echoed in a 2005 study by Sundakov and Sundakov which suggests that restrictions on pharmaceutical availability have had a negative impact on New Zealand's disability burden and health outcomes. The study cites evidence that these restrictions are shifting costs to other, more invasive, costlier treatments. "Non-pharmaceutical treatments and interventions are likely to be costing New Zealand more than the equivalent medicines-based treatments would have cost. For example, reductions in end-stage renal dialysis which could be achieved with more emphasis on earlier pharmaceutical interventions may alone generate tens of millions of dollars of net savings" (Sundakov and Sundakov, 2005: 31).

Drawing on more recent OECD data, Rawson (2016) compares current health outcomes in Canada and New Zealand. "The mortality rates for acute myocardial infarction, cerebrovascular disease, chronic obstructive pulmonary disease, musculoskeletal conditions and peptic ulcer in 2011 were more than 30% higher in New Zealand than in Canada. … In addition, the hospital discharge rate in New Zealand in 2013 was more than 30% higher than in Canada for cerebrovascular disease, malignant neoplasms, musculoskeletal conditions and diabetes" (Rawson, 2016).

The OECD statistics point to some interesting distinctions between Canada and New Zealand. Specifically, in the disease categories in which New Zealand approves and lists fewer drugs, the mortality and hospital discharge rates are higher than in Canada. "Although it is not possible to prove that lack

Table 5: Selected health outcome measures in Canada and New Zealand

Measure	Disease/condition	Canada	New Zealand	Percentage difference
Deaths per 100,000 in 2011	Acute myocardial infarction	39.6	64.5	62.9
	Cerebrovascular disease	37.8	66.7	76.5
	Malignant neoplasms	207.5	215.7	4
	Chronic obstructive pulmonary disease	31.1	40.5	30.2
	Musculoskeletal conditions	4.7	6.3	34
	Peptic ulcer	1.1	2.1	90.9
Hospital discharges per 100,000 in 2013	Acute myocardial infarction	200.1	238.8	19.3
	Cerebrovascular disease	135.4	201.7	49
	Malignant neoplasms	581.2	787.8	35.5
	Chronic obstructive pulmonary disease	229.3	259.2	13
	Musculoskeletal conditions	494.4	800.7	62
	Diabetes	100.5	173.2	35.5

Source: Rawson, 2016, drawing on OECD statistics.

of drug access has a negative impact on patient health, patients and physicians should be concerned about an inverse association between the rate of drugs listed and mortality and discharge rates" (Rawson, 2016).

Similar results have been found in the United Kingdom. As described by Labrie (2015), "[t]he United Kingdom is among the countries that have pushed this line of reasoning [limiting spending by rationing access to new drugs rather than by increasing efficiencies] the furthest. As a result, U.K. patients for many years had to do without drugs that were approved and recognized as effective and available all across Europe. These restrictions have in all likelihood played a role in the U.K.'s lower cancer-survival rates compared with most other industrialized countries." Again, while it is impossible to prove direct causality, the UK experience seems to provide additional evidence of the association between the availability of drugs and health outcomes.

Although a causal effect cannot be established, it is suspected that more difficult access to certain drugs has a role to play in the lower survival rates for various cancers in the UK compared to other developed countries. According to a 2015 report in the medical journal *The Lancet*, the United Kingdom scores among the worst of all developed countries in terms of survival rates for the ten types of cancers listed. In the case of liver and lung cancer, the five-year survival rate is half that observed in Canada (Allemani et al., 2015), Strikingly, these poor results are achieved in a health system that is characterized by good access to primary care. Indeed, the data show that British patients have easier access to different screening tests and receive results in shorter timeframes than Canadian patients. For many types of cancer, such as breast and cervical cancer, UK screening rates are among the highest in the world (Rose et al., 2015).

Reduced incentives to innovate

Finally, it is essential to address the question of innovation. Opponents argue that price pressure from a national pharmacare program will reduce the incentives for pharmaceutical research and development, stifling innovation and reducing the number of breakthrough therapies in the pipeline (Acri, 2018; Frank and Ginsberg, 2017; Innovative Medicines Canada, 2018). Alternatively, as described by the Office of Fair Trade in the United Kingdom, "such value-based pricing and reimbursement policies would improve innovation by diverting resources from imitative research efforts and related me-too advertising towards the science and product development required to bring break-through drugs for otherwise unmet health needs to market" (Morgan et al., 2007: 14).

However, it is critical to recognize that these duplicative research efforts are not without benefit, to the extent that they change adverse reaction profiles in different population groups. Pharmaceutical innovation is an inherently dynamic process, such that one innovation builds on another and improvements draw from a history of previous technological advances. In her classic paper on innovation, Scotchmer (1991) emphasizes that virtually all technical progress builds on a foundation provided by earlier innovators. Given that innovation is an cumulative event, progress happens both in leaps and bounds (radical innovation) and in small modest steps (incremental innovation). In the context of the pharmaceutical industry, radical innovations encompass breakthrough discoveries of first-in-class medicines with new mechanisms of action. In contrast, incremental innovations may enhance an existing therapeutic class through the development of a new therapy based on differences in adverse effects, delivery systems, dosing schedules, or heat stability (Lybecker, 2014).

Incremental innovation provides both follow-on medicines as well as new uses for existing therapies, and supplemental indications. Since first-in-class drugs are rarely optimal, improvement innovations may become best-in-class and first line therapies. A recent study by Cohen and Kaitin (2008) finds that 63 percent of the drugs on the World Health Organization's Essential Drug Lists are follow-on drugs (Lybecker, 2013). In addition to the therapeutic value provided by these drugs, they offer physicians and their patients additional choices, which is also of great value. Incremental innovation offers physicians the flexibility to treat the individual needs of diverse patients with precision. Within the same drug class, therapeutic alternatives will vary in their metabolism, molecule, regimen, dosing schedules, speed of action, delivery system, adverse effects, therapeutic profile, and/or interactions. Moreover, incremental innovation amplifies the number of available dosing options, uncovers new physiological interactions of known medicines, encourages children's compliance through reformulations, increases the shelf-life or

heat-stability of a given medicine to ensure effectiveness in diverse environments, expands the number of treatment options available, improves patient administration, provides for the elimination or treatment-limiting drug reactions or side effects, and presents significant options to patients with different physiologic and pathophysiologic status. These differences increase a patient's probability of finding a treatment that is both effective and tolerated. Moreover, multiple therapies ensure an uninterrupted supply and availability of vital medications if the initial drug fails in the development stage or in the market, or suffers from manufacturing interruptions (Lybecker, 2014; Lybecker, 2013; Labrie, 2013; Wertheimer, Levy, and O'Connor, 2001).

In sum, the consequences of a publicly-funded pharmacare program must be thoroughly explored and properly costed in order to determine whether this is a policy that would benefit Canada and Canadian patients. There are a number of potentially very detrimental consequences, and policymakers should have answers for how they will be addressed and avoided. First, the true tax burden should be calculated and transparently presented. In addition, it must be recognized that drug shortages and reduced access may result from such a policy. There is also substantial evidence indicating that lower revenues and profits will reduce pharmaceutical R&D spending. Finally, it is essential to acknowledge the potential for worsening health outcomes and suboptimal therapeutic substitution. Accordingly, Canada must cautiously approach any policy change that puts patients, innovation, and innovative industries at risk. A national pharmacare program is no exception.

Conclusions

This essay examined the potential unseen and unintended consequences of a publicly-funded national pharmacare program. Reflecting on the experience with such programs in New Zealand, Australia, and the United Kingdom, the analysis documents numerous ways in which the programs fail to live up to the promise of their mandates. Specifically, the risks of sole tendering, reference-based pricing, and cost-effectiveness analysis put therapies and reliable supply in jeopardy. In addition, additional information is required to truly understand how medications will be selected and what the costs will be, to patients and to taxpayers. Moreover, it is essential to examine the likely impact of drug shortages, lack of access, worsening health outcomes, increased costs, and diminished innovation for patients, physicians, the market and the economy.

Confronting the possibility of a national pharmacare program, Canadians must be mindful of the potential consequences of such a program, including a number that are unanticipated. Many of the studies considered here establish that drugs recently approved in Canada are not approved in New Zealand, Australia, or the UK. Moreover, many drugs approved in these countries in the past are no longer available (Rawson, 2016). Accordingly, fewer products were insured in most drug classes in these countries than in many Canadian provinces. The adoption of a national pharmacare system in Canada, one modeled after the systems of New Zealand, Australia, or the UK, would result in less choice for Canadian patients and the potential for poorer health outcomes.

> The principles of universality, fairness of access, safe and appropriate prescribing, and value for money proposed by Canadian health policy analysts are likely to resonate with most Canadians. However, when polls report that 'an overwhelming majority of Canadians (91%) express support for the concept of a national pharmacare program that would provide universal access to prescription drugs,' Canadians are likely envisaging access to more products for more patients, not universal coverage of a limited range of mainly low-cost medicines. Canadians should be careful about what they wish for. (Rawson, 2016)

Finally, the government faces a lack of constituent support for the potential increases in public spending and the reduced patient choice that would be associated with switching from a predominantly private system to a predominantly public system. The majority of Canadians would oppose increasing the goods and services tax (GST) or income tax by 1% for incomes over CA$40,000 to achieve the additional $1 billion in public funds needed for pharmacare. Public support may fall even further considering that a universal system would likely mean reduced patient choice and delayed access to new drugs. Depending on the extent to which choice and access are limited, universal pharmacare may not be sufficient to improve inequities in coverage. (Crosby, Lefebvre, and Kovacs-Litman, 2016)

Proponents of a national pharmacare program argue that savings will be generated by reducing generic and brand name prices and increasing cost-effective product selection. However, a universal pharmacare system is not required to improve performance on these indicators (Crosby, Lefebvre, and Kovacs-Litman, 2016). It is essential to recognize that such programs keep spending in check by rationing access to new drugs, rather than by being more efficient (Labrie 2015).

Arguably, a national drug plan would require significant administrative coordination across provinces and add complexity to the existing system, without providing significant benefit. The projections of cost savings to consumers and taxpayers are flawed and are unlikely to be realized in the confines of the enormous consolidation of pharmaceutical benefits. Notably, any savings accruing in the short to medium term will be outstripped by the transition costs. It is estimated that the transition costs of establishing the administrative infrastructure will greatly exceed the $11.5 billion in savings that the federal government put forward for the next ten years; "even the incremental proposals most recently costed by the Conference Board (2015) and Morgan et al. (2017(a)) exceed this amount" (Adams and Smith, 2017). All the while, provincial governments have experience in delivering drug coverage plans tailored to their populations' specific needs, while maintaining the flexibility within the current system that allows for a sustainable combination of public and private payers for medications. "In practice, Canadians already experience the best aspects of a national drug coverage plan; the formal institution of such a plan will only increase bureaucracy and complicate delivery of services, without adding value for patients" (Beach et al., 2016).

Admittedly, not all these outcomes are inevitable, though some are, and experience suggests others are highly likely. Again, this is a case in which the devil is in the details. While it makes some sense for provinces to join forces and negotiate better pricing for new drugs in return for greater market access, a national pharmacare program may not be needed. Moreover, to the extent

that such a national program reduces patient choice, it may lead to worse health care experiences and worse outcomes, without reducing expenditures by the government insurer.

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