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Universal Pharmacare and Federalism: Policy Options for Canada

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SUMMARY

Canada is the only OECD country with universal health insurance that does not include coverage of prescription pharmaceuticals. Some provinces have taken steps to provide drug insurance coverage for the poor, the elderly and people facing catastrophic costs (there are some 70 drug funding programs across the country). However, access to essential medicines depends on factors such as age, medical condition, income and province of residence. It is estimated that approximately 20 percent of Canadians have no drug insurance.

A number of reports have recommended that Canada's public health services be expanded to cover pharmaceuticals. This possibility is now under serious consideration, with the establishment by the federal government of the Advisory Council on the Implementation of National Pharmacare, led by Eric Hoskins (a former Ontario cabinet minister). The council is mandated to report by spring 2019.

This study explores options for universal pharmacare in the context of Canadian federalism. The authors define universal pharmacare as a system of insurance for important medicines that is progressively financed (i.e., contributions reflect users' income) and has no access barriers due to costly copayments. Such a system would ensure access to important medications for millions of Canadians and improve the return on investment for the money spent on pharmaceuticals. However, there is very strong opposition to universal pharmacare from private insurers and pharmaceutical companies, which often argue for "filling the gaps" rather than comprehensive reform.

The authors outline two policy options that, based on their analysis, are feasible given the constitutional division of powers. The first would be for the provinces to delegate the power to administer drug insurance plans to a new arm's-length agency funded by the federal government. An example of such an organization is Canadian Blood Services, which on behalf of the federal, provincial and territorial governments is responsible for the provision and management of a $500-million drug portfolio.

The second option would be for the federal government to adopt legislation similar to the *Canada Health Act* and provide an annual pharmacare transfer to the provinces and territories. This would give them flexibility in the design of their respective insurance systems, with federal contributions contingent on compliance with two critical criteria: (1) universal coverage should be provided for a basket of essential drugs, without copayments or deductibles; and (2) decisions over what to include in the basket should be made by an arm's-length body (or bodies) that would negotiate with drug companies for the best prices.

The authors point out that, under either option, private insurers would not be eliminated. However, their business model would need to change to focus on brands of drugs not included in the universal public plan.

Acknowledging the challenges of reaching the necessary intergovernmental agreement, the authors call on the federal government to make a firm commitment to leading Canada toward universal pharmacare and to begin negotiations with the provinces and territories.

RÉSUMÉ

Le Canada est le seul pays de l'OCDE dont le régime universel d'assurance-maladie ne couvre pas les médicaments d'ordonnance. Certaines provinces ont entrepris de fournir une assurance-médicaments aux aînés, aux citoyens les plus pauvres et à ceux qui ont besoin de médicaments onéreux (on compte environ 70 programmes de financement de médicaments au pays). Mais l'accès à des médicaments essentiels dépend de facteurs comme l'âge, l'état de santé, le revenu et la province de résidence. Quelque 20 p. 100 des Canadiens n'auraient ainsi aucune assurance-médicaments.

Dans plusieurs rapports, on a recommandé d'intégrer la couverture des médicaments aux services de santé publique, ce que le gouvernement fédéral envisage sérieusement aujourd'hui. Il a créé à cet effet le Conseil consultatif sur la mise en œuvre d'un régime national d'assurance-médicaments, dirigé par Eric Hoskins (ancien ministre ontarien) et dont le rapport est attendu au printemps 2019.

Cette étude examine différentes approches pour élaborer une assurance-médicaments universelle dans le cadre du fédéralisme canadien. Selon la définition des auteurs, l'assurance-médicaments universelle consiste en un régime au financement progressif (les cotisations reposant sur le revenu des usagers) qui rembourse d'importants médicaments, sans barrières d'accès causées par de coûteuses quotes-parts. Un tel régime permettrait à des millions de Canadiens d'accéder à des médicaments clés, tout en améliorant le rendement des capitaux investis dans les médicaments. L'assurance-médicaments universelle est toutefois fortement décriée par les assureurs privés et les sociétés pharmaceutiques, qui préconisent souvent de « corriger les lacunes » du système sans le réformer en profondeur.

Les auteurs présentent deux options politiques qui, selon leur analyse, tiennent compte de la répartition constitutionnelle des pouvoirs. Selon la première, les provinces délégueraient à un nouvel organisme indépendant financé par le gouvernement fédéral le pouvoir d'administrer des régimes d'assurance-médicaments. Cet organisme pourrait s'apparenter à la Société canadienne du sang, qui est chargée de l'approvisionnement et de la gestion d'un portefeuille de médicaments de 500 millions de dollars au nom des gouvernements fédéral, provinciaux et territoriaux.

Selon la seconde option, Ottawa ferait voter une loi semblable à la *Loi canadienne sur la santé* et effectuerait des paiements de transfert annuels d'assurance-médicaments aux provinces et territoires. Les provinces et territoires disposeraient ainsi de la souplesse nécessaire pour élaborer leurs propres régimes et recevraient les transferts fédéraux sous réserve de deux conditions clés : 1) la couverture universelle s'appliquerait à un panier de médicaments essentiels, sans quote-part ni franchise ; 2) les décisions sur le contenu de ce panier seraient prises par au moins un organisme indépendant qui négocierait les meilleurs prix avec les sociétés pharmaceutiques.

Les auteurs précisent qu'aucune de ces deux options n'exclurait les assureurs privés. Toutefois, ceux-ci devraient recentrer leur modèle commercial sur les marques de médicaments qui ne figurent pas au régime public universel.

Conscients des défis à relever pour conclure un accord intergouvernemental sur la question, les auteurs exhortent le gouvernement fédéral à prendre le ferme engagement de doter le Canada d'un régime universel d'assurance-médicaments et d'amorcer à cet effet des négociations avec les provinces et territoires.

INTRODUCTION

Canada is the only OECD country with universal health insurance that does not include coverage of prescription pharmaceuticals (Morgan et al. 2015a). Calls to redress this failing have long been made. In 1964, Mr. Justice Emmett Hall – Chair of the Royal Commission on Health Services, which recommended universal insurance for physician services – argued for prescription drug insurance to be the next frontier for Canadian medicare (Canada 1964). Many subsequent advisory bodies and commissions have echoed this call (National Forum on Health 1997; Royal Commission on the Future of Health Care in Canada 2002). The implementation of national pharmacare ranked as the top policy resolution at the Liberal Party's 2018 national convention (Liberal Party of Canada 2018b). In April 2018, the House of Commons Standing Committee on Health released a report recommending expansion of the *Canada Health Act* (*CHA*) to include pharmaceuticals. But despite some provincial initiatives, Canada has been unsuccessful in ensuring nationwide access to even a basic set of prescription drugs. In February 2018, the federal government announced that Ontario's former Minster of Health Eric Hoskins would lead an Advisory Council exploring options for the implementation of a national pharmacare scheme, though scant information has been provided as to the principles that will guide the Council's findings (Canada, 2018a).

One in five Canadians report that they or someone in their household is not taking their medicine as prescribed owing to concerns about costs (Angus Reid Institute 2015). In a 2016 study of 11 comparator countries, only the United States showed a higher percentage of adults not filling prescriptions owing to cost (CIHI 2017a). These gaps in access to essential medicines cannot be rationalized as part an overall strategy to contain costs. For one thing, prescription nonadherence (i.e., patients not taking drugs as prescribed) drives up costs in other parts of the health care system through increased doctor visits, emergency room care and hospital admissions (Law et al. 2018). Even if one looks at drug spending alone, Canada performs badly, with the third-highest per capita drug expenditures in the OECD – exceeded only by Switzerland and the US (CIHI 2017b). What Canada and these other top-spending countries have in common is a fragmented approach to drug coverage, which opens the door to very high drug prices.

Medicare's legislative blueprint, the *CHA*, does not require provinces to provide universal coverage for prescription drugs outside of hospitals.[1] Most provinces have nevertheless chosen to cover the very poor, the elderly and people facing catastrophic costs. The resulting system exhibits many of the same shortcomings as the US's poorly performing health care system: the majority of Canadians (approximately 58 percent) rely on expensive employer-based private insurance (Law et al. 2018); high-risk groups such as the elderly and low-income families rely on the patchwork of public programs; while approximately 20 percent have no drug

[1] Indeed, the *CHA* offers vague guidance and accountability regarding the specific health services that fall in the medicare basket, apart from stating that "medically necessary" hospital services and "medically required" physician services are covered. This has led to opaque and seemingly *ad hoc* decisions over the medicare basket. See Flood (2006).

coverage (Law et al. 2018). As we discuss below, some provinces have taken steps to ensure that all residents do have some drug coverage, but these schemes are expensive and regressively financed, with access problems due to high deductibles and copayments.

We begin by making the case for universal pharmacare for Canada. Next we provide a brief overview of existing provincial drug plans and explain how our present patchwork system emerged – detailing the barriers to universal pharmacare that have steered decision-makers toward piecemeal incrementalism, rather than comprehensive reform. We then survey the relevant constitutional landscape, exploring Canadian federalism and the allocation of constitutional responsibility as they relate to moving forward on universal pharmacare. Finally, we discuss two policy options for federal and provincial governments to implement universal pharmacare, which we argue are both constitutionally compliant and economically feasible.

THE CASE FOR UNIVERSAL PUBLIC PHARMACARE

By "universal pharmacare," we mean a system of insurance for important medicines that is progressively financed (i.e., contributions are income-based, either through taxes or income-adjusted premiums), with no access barriers in the form of costly copayments. The principles and evidence in support of universal pharmacare fall into six streams.

A more competitive Canadian economy: Employee benefits now account for 10 percent of gross payroll in Canada, with drugs representing the biggest line item. Under a system of universal tax-financed coverage, the price of pharmaceuticals would no longer be a major consideration in labour negotiations or affect Canadian labour market competitiveness. Substantial benefits to employers could be expected, and it is postulated that unemployment rates could decline as an important cost of labour supply is reduced (Morgan et al. 2015b). Employers, who struggle with the high and growing costs of sponsored benefit plans, would like to see Canada seize the economic advantages of government-provided insurance (Aon Hewitt 2016; BC Chamber of Commerce 2016).

Reduced health care costs: High out-of-pocket expenditures on drugs result in prescription nonadherence. As the Canadian population ages and chronic disease rates increase, prescription nonadherence may lead to increased visits to hospitals and doctors' offices (Law et al. 2018; Adams, Soumeria and Ross-Degnan 2001).

Safer, more appropriate prescribing: Canadians are often prescribed drugs that show little promise of therapeutic benefit, which can have very serious health consequences. It is estimated that one in six hospitalizations could be prevented if prescription drugs were used more appropriately (Samo et al. 2006). In 2013, six provincial drug plans for seniors spent $419 million on inappropriate drugs taken outside of hospital (Morgan et al. 2016). A universal pharmacare program could help reduce inappropriate prescribing through the use of a consistent core formulary based on the best possible evidence. In addition, pharmacare could be designed to ensure that prescribing and

health outcome data are routinely collected and fed back to prescribers, reducing the fragmented system of information currently available to clinicians.

Equitable financing: Out-of-pocket expenses for pharmaceuticals are starkly regressive under the status quo, with households in the lowest quintile spending four times as much, as a percentage of pretax income, as the top quintile (PBO 2017, 23). When it comes to physician and hospital services, Canada has long recognized that it is unfair to saddle patients with costly medical bills.

More affordable medicines: International evidence suggests that universal plans are less expensive to administer than multipayer systems, and can use their consolidated purchasing power to negotiate lower prices from drug manufacturers (Morgan, Daw and Thomson 2013). Lower prices mean that governments can afford to insure more people for the same cost. Under its current fragmented approach, Canada's per capita spending on pharmaceuticals is 35 percent higher than the OECD average, while millions of people are left uninsured or underinsured (CIHI 2017b).

Equitable access: The health impact of current access barriers is indisputable: current estimates are that, every year, failure to take medications results in up to 640 deaths among Canadians with ischemic heart disease; up to 420 deaths among working-age Canadians with diabetes; up to 70,000 Canadians (age 55+) suffering health status deterioration; and up to 12,000 Canadians (age 40+) with cardiovascular disease requiring overnight hospitalization (Lopert, Docteur and Morgan 2018; Booth et al. 2012). Universal access to medically necessary prescription drugs would allow two million Canadians to adhere to prescriptions they could otherwise not afford. This includes over 500,000 older Canadians, who face higher prescription costs than older people in comparable countries, notwithstanding provincial programs targeting this demographic (Morgan et al. 2015b).

Having identified six core arguments in favour of universal pharmacare, we now present background on *current* programs in order to illustrate the gaps and inefficiencies in Canada's public drug plans.

OVERVIEW OF EXISTING PROVINCIAL DRUG PROGRAMS

As the *CHA* does not establish any requirements for public funding of out-of-hospital pharmaceuticals, each province has forged its own approach. What has emerged is a bewildering assortment of some 70 drug funding programs across the provinces (Canada 2018b), making Canadians' access to public funding for essential medicines a lottery based on their age, income, medical condition and province of residence (see table 1).

As indicated in table 1, many provinces have achieved *some* level of coverage for their entire population. However, these plans are often meant to protect only against catastrophic costs and are triggered when a household's pharmaceutical spending rises to a significant portion of its annual income. For example, under PEI's plan, a household with an income greater than $25,000 will qualify for catastrophic coverage only after

Table 1. Publicly funded drug coverage, Canada, by province

	Seniors	Social assistance/ low income	Disease-/ condition-specific funding	Youth (not low income)	General population under 65 (comprehensive or only patients with high drug costs)
British Columbia	Same coverage as <65, albeit with slightly lower deductibles and coinsurance.	No copays or deductibles	Copay coverage for cystic fibrosis; disabled children who would otherwise require institutional care; psychiatric medications where there is clinical and financial need; nicotine replacement therapies; antiretrovirals; palliative care	Part of general population	Deductibles (0% to 3% of net family income); 30% coinsurance after deductible to an income-based maximum (2% to 4% of net family income)
Alberta	30% coinsurance cost to a maximum of $25 per prescription	No copays or deductibles	Diabetes; cancer; tuberculosis and STDs; vision loss; palliative care; specialized high-cost drugs	Part of general population	Public option with premiums with 30% coinsurance to maximum of $25 per prescription
Saskatchewan	Copayment to a maximum of $25 per prescription	Maximum copay of $2 per prescription	Insulin pump (under 25); palliative care; disabled	14 and under	Deductibles (3.4% of net family income); coinsurance (35% of prescription cost after deductible)
Manitoba	No age-based plan; part of general population	No copays or deductibles	Home care and nursing home users; palliative care; cancer drugs; pediatric insulin pump	Part of general population	Deductibles (varies by income, from 2.97% to 6.73% of net income)
Ontario	Income-based copayment (maximum $6.11 per prescription); income-based annual deductible (maximum $100 annually)	$2 copay per prescription	Home care and nursing home; Special Drugs Plan covers full cost of a range of outpatient drugs	24 and under (incoming Ford administration in 2018 will restrict this to those without private insurance coverage but specific details are not yet available)	Deductible (4% of annual net income); $2 copay after deductible
Quebec	For those not eligible for private insurance: income-based premiums (maximum $638); dispensing fees (maximum $6 per prescription)	No copays or deductibles	Part of general population	Part of general population	Public option with premiums (maximum $660 annually) plus coinsurance and deductibles to a maximum of $1,029 annually

Table 1. Publicly funded drug coverage, Canada, by province (cont.)

	Seniors	Social assistance/ low income	Disease-/ condition-specific funding	Youth (not low income)	General population under 65 (comprehensive or only patients with high drug costs)
Newfoundland and Labrador	For residents receiving OAS and GIS: dispensing fees (maximum $6 per prescription)	No copays or deductibles for families receiving income support; coinsurance (20% to 70%) for low-income families	Cystic fibrosis and growth hormone deficiency	Part of general population	Income-based coinsurance ranging from 5% to 10% of annual income
Nova Scotia	Income-based premiums (maximum $424 annually)	$5 copay	Cancer drugs for low income; disabled; palliative care	Part of general population	Deductibles (1% to 20% of net family income); coinsurance (20% of prescription costs); to an income-based maximum (0% to 35% of net income)
New Brunswick	For residents receiving GIS (income-based copayment maximum $9 per prescription).	$4 copay for >18 years; $2 copay for >18 years	Cystic fibrosis; residents of nursing homes and adult residential facilities; special needs children; multiple sclerosis; organ transplant drugs; growth hormone deficiency; antiretrovirals	Part of general population	Public option for those without private coverage; income-based premiums apply
Prince Edward Island	Maximum $8.25 copay per prescription	No copays or deductibles	HIV/AIDs antiretrovirals; children in care of Child Protection; Cystic Fibrosis; Diabetes; anemia; growth hormone deficiency; hepatitis; insulin pump; meningitis; nursing homes; smoking cessation; STDs; organ transplant antirejection; tuberculosis	Part of general population	For residents without private insurance: catastrophic drug coverage with income-based deductible (3% to 12% of net income); public coverage of generics above $19.95

Sources: F.M. Clement, L. Soril, H. Emery, D. Campbell and B. Manns, *Canadian Publicly Funded Prescription Drug Plans, Expenditures, and an Overview of Patient Impacts* (Calgary, AB: O'Brien Institute for Public Health, 2016); Canada, 2018.

[1] Territorial drug plans have been excluded owing to a lack of information.

STDs = sexually transmitted diseases; OAS = Old Age Security; GIS = Guaranteed Income Supplement; HIV/AIDS = human immunodeficiency virus/acquired immunodeficiency syndrome.

spending 5 percent (or $1,250) out of pocket on eligible prescription drugs (Health PEI 2015).[2] Studies from other provinces have linked high-deductible plans with problems of cost-related nonadherence to prescriptions (Law et al. 2012).

Beyond the access barriers, a heavily fragmented approach also means that provinces are ill equipped to negotiate competitive drug prices. Consider, for example, Ontario's purchasing of generic drugs (which are not innovative advances but replicas of already discovered chemical compounds): a 2017 report by Ontario's Auditor General study found that, in 2015-16, Ontario's public drug programs paid about $100 million (or 70 percent) more than New Zealand for 20 common generics (Office of the Auditor General of Ontario 2017).

There have been recent efforts to consolidate buying power across these myriad public plans. Established in 2010, the pan-Canadian Pharmaceutical Alliance (pCPA) is tasked with negotiating lower prices for some drugs. The federal government joined the pCPA in 2016, seeking savings for its programs covering First Nations and Inuit, veterans and RCMP, Armed Forces, federal inmates, federal public servants and some categories of refugees. To date, the pCPA has completed negotiations for 207 products. This approach holds significant promise, but the pCPA presently falls well short in serving Canadians as it does not negotiate prices for those who are uninsured (who thus must pay out of pocket some of the highest prices in the world, even for generics); nor does it benefit the 58 percent of the population that is privately insured. Note as well that the pCPA's negotiations are not *binding* on participating public plans, and this inability to commit to purchasing undermines the pCPA's negotiating power (Kaur et al. 2014).

Quebec's scheme has received a great deal of media and scholarly attention, and its approach is worth understanding in contemplating a national scheme. In 1997, the province launched a hybrid public-private scheme requiring that all residents enlist with either their employer-based plan (where available) or a public option. On the private side, Quebec employers that offer health insurance are required to include drug coverage, and workers are required to participate in any plan offered through their employer. Premiums are not income-based, and participation in a private plan can be punishing for the working poor (Gagnon 2015). The remainder of Quebec's population must contribute an income-based premium to a public insurance plan.

Quebec's scheme has been heavily criticized for its high costs and lack of progressivity. Morgan et al. calculate that two-adult households earning $40,000 spend 3 percent of income on premiums and user charges, while those earning $80,000 spend only 1.6 percent (2017a). Copayments under Quebec's public scheme – which can be more than $1,000 a year – have been tied to problems of prescription nonadherence and a heightened risk of adverse events (Quebec 2017; Tamblyn et al. 2001; Tamblyn et al. 2014). Perhaps unsurprisingly, household out-of-pocket expenditures are higher in Quebec than in any other province (PBO 2017, 22). Overall costs are also high, with Quebec spending 35 percent more on drugs per capita than the average

[2] Families with an annual income of $50,000+ are eligible for assistance only after spending 8 percent of their income on prescription drugs; for families earning over $100,000, the threshold is 12 percent.

of all provinces (Smolina and Morgan 2014), an average that itself is among the very highest in the world (CIHI 2017b). This possibly explains why other provinces have not followed its policy lead (Gagnon 2015).

Quebec's approach to date, although it constitutes a "universal" scheme, has not been implemented in such a way as to achieve the access, cost-reduction and efficiency goals we see achieved by other publicly insured health care systems (e.g., in the UK, Sweden and New Zealand). Quebec-style plans can only work with significant regulation to ensure access and to rein in drug prices. Indicative of this need and in response to spiralling costs (notwithstanding high copayment requirements), the Quebec Minister of Health recently took the step of threatening to move to competitive tendering in the spirit of the New Zealand model, which prompted generic companies to agree at the last minute to price concessions totalling $1.5 billion over five years (Rastello 2017). We discuss in more detail below the extent to which any future universal pharmacare plan in Canada should be based on some version of the Quebec model.

OBSTACLES TO PHARMACARE AND CALLS FOR INCREMENTALISM

Canada's fragmented approach to drug financing and purchasing has persisted due to a variety of political and economic factors that stand in the way of comprehensive reform. It is worth understanding these factors, and the enormous force of opposition to meaningful reform, before exploring policy solutions.

1. Opposition from 132 private insurers that risk losing market share (CLHIA 2017).
2. Opposition from pharmaceutical companies that may see reduced profit margins if public plans seek price reductions and otherwise adopt more aggressive bargaining (e.g., requiring repayment if promised therapeutic benefits are not realized).
3. Opposition from pharmacies that receive a portion of their revenue from payments by drug companies to position their brands above others, and that would also see reduced markups on prescriptions under a more competitive pricing scheme. These lost profits would, however, be at least partly offset by increased prescription volume under a universal scheme (PBO 2017).
4. Reluctance among provincial leaders in light of provincial budgets that are already stretched thin, with most provinces devoting close to 40 percent of their total program expenditures to health care.
5. Complacency of the general public, the majority of which hold some form of private insurance through their employers and therefore do not perceive the shortcomings of the status quo. The inefficiencies of the current system are passed along through wage and salary reductions that pay for costly drug benefit plans, and added costs to medicare stemming from prescription nonadherence.
6. Resistance by those who are presently publicly insured (e.g., those over 65), who are persuaded that a move to a universal plan may lead to a clawback of

the range of drugs that are presently insured for them. However, as we discuss below, much of the "choice" presently provided is relatively illusory, being in the nature of "brands" of the exact same chemical compound.

The interests opposed to universal pharmacare are formidable and motivated. They have consistently organized to push Canada in the direction of, at best, incremental reforms. Broadly speaking, in response to concerns about access, Canadian provinces have looked to "plug holes" by providing coverage for people with specific diseases requiring high-cost treatments and to discuss policy options for universality only in terms of covering catastrophic costs (Daw and Morgan 2012). Drug companies and private insurers, which benefit enormously from the present dysfunctional system, will both argue there is no need for reform and/or push strongly for "incremental" reform. For example, private insurers benefit from a public plan that covers catastrophic costs, permitting them to offload high-cost patients to the public system; drug companies are also happy to have public plans cover catastrophic costs as this quells public demand for comprehensive reform that may affect their profit margins (Evans 2009).

By merely attempting to fill gaps in this way, Canadian governments have forgone the vast savings realized in other public health care systems that come from negotiating drug purchases on behalf of the entire population – savings that could be used to fund a broader range of drugs, to reduce wait times, to fund home care and long-term care, etc. As well, under a truly universal scheme with no or minimal copayments, government can take steps to ensure appropriate prescribing – something that is difficult, if not impossible, when merely plugging gaps in the existing fragmented scheme. Lastly, the catastrophic drug coverage plans used to fill gaps very often leave patients with high deductibles, which have been linked to problems of patients not following their prescriptions (Law et al. 2012), potentially resulting in illness and death.

An incremental approach was touted in 2018 by federal Minister of Finance Bill Morneau, who stated that any federal attempt to achieve universal pharmacare "will be 'fiscally responsible' and designed to fill in gaps, not provide prescription drugs for Canadians already covered by existing plans" (*CBC News* 2018).[3] But arguments to integrate the present patchwork of public and private schemes unfortunately often prove to be euphemisms for arrangements where profitable enrollees stream to the private sector, while the needs of high-risk patients are left to public drug programs.[4] A "fill the gaps" or "plug the holes" approach would result in a high-cost, inefficient system. What Canadians need is durable, comprehensive reform.

[3] This perhaps is not so surprising given that the Liberals had signalled their stance on pharmacare in the mandate letter given to (then) Health Minister Jane Philpott, which did not speak to universal pharmacare as a goal but instead directed her to make "prescription drugs more affordable" and improve "access to necessary prescription medications" by buying drugs in bulk, reducing the government purchase price for drugs and exploring the need for a national formulary. See Minister of Health Mandate Letter (October 4, 2017).

[4] In Ontario, privately covered employees facing prohibitive copayments are currently able to apply for financial support from the Trillium plan, but private insurers now want to "integrate" with public plans such that cases are automatically adjudicated, and once costs reach a certain threshold, coverage is *automatically* shifted to the public catastrophic plan. This explains the push from private insurers and drug companies for a national catastrophic drug plan.

In stressing the need for comprehensive reform, we do not in any way mean to downplay the strength of political obstacles. Although every other universal health care system has managed to incorporate drug coverage, this does not mean that Canada is destined to follow suit. The politics of pharmacare reform in Canada bear important similarities to the intractable politics of health care reform in the US: in both cases, a fragmented, dysfunctional system has evolved over decades, creating entrenched interests and expectations that are highly resistant to change (Evans 2009). And, as in the US, reform efforts are handicapped by the need for coordination among federal, provincial and territorial (FPT) governments, which are home to diverse vested interests, political outlooks and health care needs. Although this report does not purport to offer a "magic bullet" political strategy, we outline two reform options that would allow flexibility for diverse provincial approaches, while achieving the core criteria of a universal pharmacare scheme as we defined it earlier.

THE JURISDICTIONAL BOUNDARIES OF HEALTH CARE

The move from concept to substantive reform requires an understanding of the legal and financial mechanisms available to FPT governments and their implications for what is possible in implementing universal pharmacare. Below we lay out a brief primer on how jurisdictional lines in health care have been drawn thus far between FPT governments and legislatures, specifically with respect to prescription drugs. Within those jurisdictional boundaries, we put forward two options for universal pharmacare design.

Constitution Act, 1867: Provincial and federal roles in health care

At Confederation, the *Constitution Act, 1867* (the *1867 Act*) laid out the enumerated powers of newly minted Canada and her provinces, dividing responsibilities in a way that accorded with a nineteenth-century understanding of the principles of federalism. Where provinces were given the power to legislate, the federal government was not to tread, and vice versa. The *1867 Act* has very little to say *directly* with respect to today's health sector – a complex milieu of private and public economy, regulation and cross-jurisdictional funding. Courts have been forced to interpret the *1867 Act*'s implications for health care, particularly its delivery and financing.

Canadian provinces are often said to have jurisdiction over the delivery of health care due to three provisions of the *1867 Act*. First, section 92(7) provides for provincial jurisdiction over the "establishment, maintenance, and management of hospitals, asylums, charities, and eleemosynary institutions."[5] Second, the provinces have a general jurisdiction over "property and civil rights" (s. 92 (13)), which has been interpreted to include regulation of professional services such as doctors, nurses and other health professionals as well as over the market conduct of insurance companies.[6] Third, the provinces' section 92(16) power over "matters of a strictly local or private nature" has been interpreted as granting

[5] *Constitution Act, 1867* (UK), 30 & 31 Vict, c 3, s 92(7), reprinted in RSC 1985, Appendix II, No 5 s. 92(7).
[6] *Landers v N.B. Dental Society* (1957), 7 DLR (2d) 583 (NB CA). For a general discussion, see Flood, Thomas and Lahey (2017).

them extensive jurisdiction over the regulation of health care[7] and public health.[8] However, jurisdiction over the *financing* of health care has been more evenly shared between levels of government, which we discuss further below under the federal government's use of the spending power. Furthermore, the federal government has specific powers to regulate health, health care and prescription drugs, particularly through its criminal law powers, its powers over (as s. 91 (24) of the *1867 Act* states) "Indians and land reserved for Indians," its power with respect to patents and, potentially, under its "peace, order and good government" powers, all of which we discuss below.

Thus, while pundits frequently describe provinces as having jurisdiction over health care, the reality is much more complicated, with FPT governments having overlapping, and at times confusing, jurisdiction.[9] This porousness of roles was explained by Justice Estey in *Schneider v R*:

> *In sum "health" is not a matter which is subject to specific constitutional assignment but instead is an amorphous topic which can be addressed by valid federal or provincial legislation, depending in the circumstances of each case on the nature or scope of the health problem in question.*[10]

To illustrate this, we now survey the heads of power within the Constitution that would empower the federal Parliament and government to legislate and enact policies with respect to pharmaceuticals.

THE FEDERAL ROLE VIS-À-VIS PHARMACEUTICALS

Currently, the federal government exercises some of its constitutionally ascribed powers to shape and direct pharmaceutical policy, playing a larger role in this domain than with respect to other parts of health care. Arguably, this provides a foundation for Ottawa to take a far stronger leadership role in the establishment of universal pharmacare than it has to date. In what follows, we review these heads of power and discuss their potential role in implementing universal pharmacare.

Patents

This enumerated power has allowed the federal level of government to develop complex intellectual property regimes specific to drugs, which *ideally* strive to balance the need to incentivize research and development through patent protections against the need to foster price competition by allowing limited market entry to generics. There is good reason to question whether the federal government has properly struck this balance to date.

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[7] *Reference re Assisted Human Reproduction Act*, 2010 SCC 61, [2010] 3 SCR 457
[8] *Schneider v R,* [1982] 2 SCR 112.
[9] For instance, jurisdiction over the health services for Indigenous peoples is especially complex, involving roles for both the federal and provincial governments, grounded in various sources of law (constitutional, statutory and treaty law). See MacIntosh (2017); Lavoie (2018).
[10] *Schneider v R, [1982]* 2 SCR 112 at 142.

Prior to 1987, the federal Commissioner of Patents issued compulsory licences allowing the production of generic versions of patented drugs, and patentees were paid a fixed royalty of 4 percent. This regime opened the door to large-scale entry of generic medicines into Canada. In 1987, Bill C-22 created a 10-year exclusivity period for on-patent medicines before a compulsory licence could be issued. The same legislation also created the Patented Medicine Prices Review Board (PMPRB) to help control the pricing of exclusive medicines, by pegging the Canadian price to the median price recorded in seven developed countries. In 1993, to comply with the North American Free Trade Agreement, compulsory licensing was abolished altogether.[11] The PMPRB has since been much criticized for its failure to control drug prices (Gagnon and Hébert 2010), and Health Canada is now undertaking consultations on amending the relevant regulations (Health Canada 2017).

In its regulation of patents, the federal government's approach has arguably been one of pursuing economic development goals at the expense of the health policy goal of ensuring that pharmaceuticals are accessible at a reasonable cost. The federal government has lengthened patent terms, increased patent protection to accord with international obligations and limited generic competition – all fuelling increased drug prices for patients and provincial drug plans (Anis 2000; Grootendorst, Bouchard and Hollis 2012). According to the PMPRB's own reporting, investment in research and development by pharmaceutical companies, relative to sales, declined significantly in the period from 1988 to 2016 (PMPRB 2016). The federal government is somewhat insulated from the practical effect of decisions to protect and expand patents for drugs due to the fact that, apart from a limited number of populations (Miller-Chenier 2004), it does not purchase the drugs whose patents it protects (Anis 2000). Should the federal government assume responsibility for a larger proportion of total pharmaceutical costs, its policies may better balance the concerns of pharmaceutical manufacturers for higher profits with the importance of accessible medicines.

Criminal law

The federal government, using its criminal law powers, regulates the safety and efficacy of medicines entering the market under the *Food and Drug Act*.[12] Within this framework, the federal government has the power to prosecute violations of the licensing regime with fines and, where appropriate, imprisonment. All drugs sold in Canada must be authorized for sale by Health Canada, through the jurisdiction of the Therapeutic Products Directorate. This body reviews safety and efficacy data for every "New Drug Submission."[13] *The Patented Medicine (Notice of Compliance) Regulations,* enacted under the *Food and Drug Act,* create a link between these drug safety regulations and the patent system, with

[11] The federal government reintroduced compulsory licensing in 2004, but only for the purpose of exporting the licensed medicines outside of Canada.

[12] *Astra Zeneca Canada Inc. v Canada (Minister of Health),* 2006 SCC 49, at para. 12.

[13] Where a New Drug Submission (NDS) is found to be acceptable on the basis of clinical trial efficacy and toxicity data, the Therapeutic Products Directorate issues a Notice of Compliance (NOC) and approves the associated product labelling. Once a drug has received an NOC, it may be prescribed and dispensed. Generic drug manufacturers, unlike holders of an NOC in the first instance, need not establish safety and efficacy, but must prove bioequivalence (bioequivalence means that two substances have similar in vivo mechanisms of action, including similar uptake and degradation times).

the effect of enhancing protection for pharmaceutical patents. These regulations prohibit Health Canada from granting a generic company a Notice of Compliance unless the generic company can "clear" the relevant patents by receiving the consent of the patent holder, demonstrating that there is no infringement, or otherwise proving that the patent is invalid (Grootendorst, Bouchard and Hollis 2012). Again, the unintended consequence of this federal policy is to make it more difficult for provincial payers to control the cost of prescription drugs and to expand coverage to more citizens.

Spending power

The federal spending power is defined as the power to make payments to people or institutions or governments, even in matters falling outside federal jurisdiction, providing this does not constitute a regulatory arrangement falling within provincial jurisdiction (Driedger 1981; Watts 1999). Using this power, the federal government funds prescription drug benefits for specific populations, such as prisoners, members of the Armed Forces, members of the RCMP and veterans. Further, the spending power combined with the power to regulate with respect to Indigenous peoples, the fiduciary duty owed by the federal government to Indigenous peoples and various treaties enables (or, arguably, requires) the federal government to finance medications for all First Nations people registered under the *Indian Act* or Inuit under an Inuit Land Claim.[14]

The provinces' constitutional powers over "property and civil rights" and "matters of a merely local or private nature" have been interpreted as granting them jurisdiction over social insurance and health insurance programs.[15] However, the court rulings in which this jurisdiction was described also recognized the overlapping scope of the federal spending power, permitting the federal government to fund provincial social insurance programs, but more importantly *to attach conditions* to the funding, in an effort to influence the national design of the programs. While some dispute the constitutional basis for this federal spending power (Telford 2003), in our view the court rulings remain "good law." The options presented in this paper are premised on this view.

The history of the federal government's use of its spending power to support hospital and physician services (medicare) has been long and rather contested. At present, funding for the provinces in the form of health care transfer payments is contingent upon the provinces' adherence to the five principles listed in the *CHA*. Whereas these transfers were originally based on a 50/50 cost-sharing formula, they now represent approximately 25 percent of the relevant provincial government costs.[16] This history has

[14] The Non-Insured Health Benefits (NIHB) Program uses a Drug Benefit List to indicate what drugs will be funded. Changes made to the list are based upon what the NIHB Drugs and Therapeutics Advisory Committee recommends should be included, as well as the Common Drug Review process of the Canadian Agency for Assessment of Drugs and Technologies in Health (CADTH). Final decisions are made by the Pharmacy Policy Development Division, on the basis of existing scientific and clinical knowledge of the effectiveness of drugs, utilization by participants, cost-benefit analyses, the specific health care needs of First Nations and Inuit populations, as well as listings in provincial drug formularies.

[15] *Reference re Employment and Social Insurance Act,* [1936] SCR 427 at 451.

[16] Estimates of the federal government's contribution to health spending vary, due to disagreements over how it should be measured. As Deber (2018, 62) explains,

> There is considerable scope for creative accounting, both in terms of what will be included in the numerator and what will be considered in the denominator. Should the numerator include cash transfers

likely diminished the provincial appetite for this kind of approach to implementation of universal pharmacare, absent rock-solid guarantees of federal funding into the future. We elaborate upon this issue in our discussion of policy options.

Peace, order and good government

While we have noted that provinces are generally recognized as having jurisdiction over health care, a plain reading of the constitution may suggest that the federal government could unilaterally establish universal pharmacare using its "peace, order and good government" (POGG) head of power. The Supreme Court has recognized three broad areas, or "branches," where POGG power may be used. The rarely used "gap branch" allows the federal government jurisdiction over matters that are overlooked in the Constitution, such as aeronautics.[17] The "emergency branch" allows the federal government to tread on areas of provincial jurisdiction to address temporary crises, such as invasions, major political unrest and out-of-control inflation.[18] Given the cost concerns and access barriers under the current fragmented system for drug financing, some experts have ventured that universal pharmacare qualifies under the third "national concern branch" (Canada 2018b, 14).

However, the Supreme Court has established fairly stringent tests for exerting POGG powers under the national concern branch. The federal government would need to establish that pharmacare has "a *singleness*, *distinctiveness* and *indivisibility* that clearly distinguishes it from matters of provincial concern." [19] While we have emphasized the advantages of a single buyer of drugs, which conceivably could be the federal government, it is nevertheless feasible that individual provinces could negotiate affordable drug prices for their respective populations. After all, New Zealand has succeeded at this with a population comparable to British Columbia's. To put the point another way, it is not clear that one province's inability or failure to address the issue of pharmaceutical accessibility and affordability would have an adverse effect on other provinces.[20]

No doubt, further legal arguments could be made in favour of using of the POGG power to establish a national pharmacare scheme. However, it seems risky to invest the current political momentum behind universal pharmacare reform in an approach that rolls the dice with an adventurous interpretation of the federal government's

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only, or also include the cash value of tax points? Should the denominator include all health care costs or only the doctor and hospital costs included under [the CHA]? Depending on the choices, the federal contributions will look larger or smaller. This dispute was reflected in the 2016 negotiations about the new transfers, where the provinces argued that the offer from Ottawa would have reduced the federal share of health spending from 23% to closer to 20% and argued instead for increasing it to 25%. Others might argue that these numbers have little meaning without clarifying what is being included in the numerator and the denominator.

See also Picard (2017).

[17] *Johannesson v Municipality of West St. Paul,* [1952] 1 SCR 292.

[18] *Reference Re Anti-Inflation Act,* [1976] 2 SCR 373.

[19] *R v Crown Zellerbach,* [1988] 1 SCR 401.

[20] Of course, we acknowledge that interprovincial tensions may present challenges for individual provinces seeking to establish universal drug coverage: drug companies may threaten to relocate to other provinces, patient groups may attack prioritization choices by pointing to neighbouring provinces' formularies, and the prospect of tax increases to fund pharmacare may trigger a "race to the bottom."

powers. The danger here is illustrated in the fate of the *Assisted Human Reproduction Act* — legislation the federal government spent years researching and enacting, only to be significantly undone by the courts on the grounds that it infringed on provincial powers.[21] An expansive reading of the POGG power would also be inconsistent with the very essence of federalism, which is intended to be a combination of shared rule with self-rule by subnational governments (Elazar 1987). Thus, we are of the view that the legal and political risks of any attempt by the federal government to utilize this head of power to unilaterally institute pharmacare are too high.

Delegation/transfer of power

In the past, provinces have considered transferring power to administer pharmaceutical insurance to the federal government. For example, at its July 2004 meeting, the Council of the Federation asked the federal government to take over responsibility for pharmaceuticals, with only Quebec dissenting (Hudon 2018). The Liberal federal government at the time chose not take up this offer.

From a constitutional perspective, it would be difficult[22] for one level of government to formally transfer a constitutional power to another, as the Supreme Court of Canada closed the door on legislative or horizontal interdelegation in 1951.[23] Still, the door remains open for provinces and the federal government to utilize other mechanisms to this same end (Adam 2008). One such method is administrative interdelegation, where a provincial legislature, while formally retaining legal jurisdiction, enacts a statute and entrusts its implementation to an agency or executive branch of another order of government. Thus, for example, one could imagine a provincial government authorizing a federal government agency to administer drug insurance benefits on its behalf pursuant to provincial legislation.

Collaboration through intergovernmental delegation of administrative responsibility is thus a possibility for the achievement of policy objectives that go beyond provincial borders. The Canadian blood system is an example of how such an agreement can be effective. In 1996, FPT governments initiated plans for a new blood system, after tainted blood scandals involving transfusion transmission of HIV and hepatitis C (Krever 1997). Governmental responsibilities were allocated through a memorandum of understanding, which stated that regulatory authority for the safety of blood products was to reside with the federal government under the *Food and Drug Act*, while the delivery of transfusion services, a fundamentally provincial concern, would be carried out by the Canadian Blood Services (CBS). Under the memorandum of understanding, any province or territory can withdraw from the arrangement by giving

[21] *Reference Re Assisted Human Reproduction Act,* 2010 SCC 61.
[22] Arguably section 94 of the *Constitution Act, 1867* permits some limited legislative delegation. The section allows Parliament to legislate in relation to property and civil rights where it does so with the consent of the provincial legislatures. However, the section expressly refers only to Ontario, Nova Scotia and New Brunswick, making it unclear as to whether it applies to other common law jurisdictions and Quebec. As well, it creates the possibility for asymmetrical federalism, where some provinces may opt in to such delegation and other provinces may opt out; the consequences of any financial prejudice that may result are unclear.
[23] *Nova Scotia v Attorney General of Canada,* [1951] SCR 31.

one year's notice, which may arise should a province find the costs imposed upon it unacceptable (Wilson and MacLennan 2005).

The CBS example shows that intergovernmental collaboration to implement universal delivery of health care products can be achieved where sufficient political will exists. There is no constitutional barrier to the creation of an independent national pharmacare authority, funded by the federal government and with administrative powers delegated by the provinces.

TWO POLICY OPTIONS FOR PHARMACARE

Some might have the impression from our discussion so far that calls for a national pharmacare scheme *must* imply a single, centralized payer – presumably the federal government. However, universal pharmacare across Canada could be achieved if *each* province administered its own universal pharmaceutical plan, as is presently the approach for insurance for hospital and physician services, albeit subject to broad criteria laid out in *CHA*-style legislation. What is more, it may prove easier to implement universal public insurance for pharmaceutical drugs on a province-by-province basis, supported by federal funding and common criteria to ensure nationwide standards in access. This is, after all, how Canadian medicare was established.

To be sure, there would be benefits from complete centralization of market power at the federal level in negotiations with pharmaceutical companies. But to achieve this by other means, provinces could agree to collaborate in bargaining with drug companies if they wished (and indeed have started to do so through the pCPA discussed earlier). Even relatively small countries such as New Zealand – with a population of 5 million – have successfully bargained for reduced prices to achieve universal access to pharmaceuticals. In short, achieving the equity and efficiency goals of universal access does not depend so much on the *size* of the population as on the willingness of any level of government to be a *proactive negotiator and purchaser on the part of the whole public it serves*. In what follows, we therefore explore two options: an FPT plan built around a centralized agency funded by the federal government and a decentralized plan modelled on the *CHA*.[24]

Another common assumption that is important to rebut is that, in the Canadian context, universal pharmacare requires the elimination of private insurance. In fact, neither of the two options discussed below requires a prohibition on private pharmaceutical insurance. In the case of medicare, there is a legitimate worry that allowing parallel private insurance will lead to problems such as queue-jumping and the siphoning of human and capital resources to the private system. This has led to legal restrictions

[24] We do not explore a third, recently proposed option for federal government funding of national pharmacare through direct transfers to individual Canadians (Hartman, Davidson and Alwani 2018). Although this approach may be effective in the case of Old Age Security and the Canada Child Benefit, it would not achieve the key policy objective of negotiating lower drug prices through bulk purchasing.

tamping down possibilities for private health insurers. Such concerns about siphoning do not arise with pharmaceuticals – apart from exceptional cases of drug shortages – and so our suggestions for a universal plan do not imply any ban or restrictions on parallel private insurance. Of course, to attract enrollees in the supplemental insurance market, private insurers would need to offer coverage for high-cost, less-efficient drugs that are not covered by the public plan(s).

Option 1: A delegated national agency

A bold vision for universal pharmacare in Canada would see the provinces agree to delegate to a federally funded agency the authority to fund and administer a public pharmacare plan. As mentioned above, the federal government will encounter constitutional roadblocks should it attempt to unilaterally implement a universal drug insurance plan. It could, however, with the agreement of the provinces, either through a memorandum of understanding or other instrument, set up an arm's-length agency (similar to CBS) to which the provinces would delegate authority to administer drug insurance benefits.

There are multiple advantages to this option for the federal government. First, it provides visibility in taking the lead on a matter of national concern. Relatedly, a move to administer and finance a universal pharmacare scheme may provide some relief from provincial and territorial accusations that the federal government is not pulling its weight or will later renege on its commitments in the area of health care financing. Lastly, by taking a leadership role in funding this area, the federal government, having more "skin in the game" in insuring Canadians for drug benefits, may spur better alignment with, for example, trade and innovation policies. A concern with concentrating responsibility at the federal level is that the pharmacare scheme may be less well integrated with the rest of the health care system, which is financed at the provincial level. But of course, as can be seen in table 1, Canada's present system of drug coverage is splintered and fragmented between hundreds of public and private payers. Reasonable people may disagree as to whether a single central funder is the optimal solution, but it would undoubtedly be a major improvement on the status quo.

In operationalizing a universal plan, FPT governments could empower an organization akin to CBS. CBS is presently responsible for the provision and management of a $500-million drug portfolio, including the tendering and procuring of 35 biological drugs on behalf of provinces and territories (Sher 2015); in Quebec, that function is carried out by a parallel organization, Héma-Québec. Through the use of public tendering and bulk-purchasing, CBS has been able to achieve dramatic cost savings for blood products and certain pharmaceuticals. For instance, through a round of tendering for five key blood plasma protein products, CBS was able, over five years, to negotiate a cumulative $600-million cost reduction (Sher 2016).

As mentioned, past experience suggests that many provinces may be supportive of the federal government's assuming such a role: when the idea of a federally financed and administered pharmacare plan was proposed in 2004, Quebec Premier Jean Cha-

rest was the only premier to dissent – insisting that Quebec maintain its existing program, with federal funding.[25] While little explanation was offered, commentators have speculated that Charest was partly maintaining Quebec's long-standing opposition to federal involvement in social policy and partly protecting the pharmaceutical industry, which is heavily concentrated in that province (Marchildon 2007). Moreover, the Quebec government is also under pressure to protect the interests of large private insurance companies based in Quebec that currently administer drug benefit plans (Ontario faces similar pressure).

At the 2018 meeting of the Council of the Federation, the premiers discussed national pharmacare and released a communiqué setting out principles to govern discussions with the federal government:

- the focus should be on removing cost barriers for patients;
- development should be based on the best available evidence about potential benefits, risks, costs and reliability of supply;
- provinces and territories must retain responsibility for the design and delivery of public drug coverage;
- federal pharmacare funding must be long-term, adequate, secure and flexible and take into consideration present and future cost pressures (Council of the Federation 2018).

The communiqué reiterates premiers' support for "the principle of asymmetrical federalism" and states that "any jurisdiction that wishes to maintain full control over drug insurance should have the right to opt out unconditionally, with full financial compensation, should the federal government participate financially in the establishment of a pharmacare plan." The federal government will need to stake out its preconditions for negotiating universal pharmacare, and clearly it would be self-defeating to agree to provide all the equivalent funding to a given province ("full compensation") with no strings attached. Moreover, a failure to insist on national standards as a quid pro quo for federal contributions may result in interprovincial inequities (Hartmann, Davidson, Alwani 2018).

Admittedly, a refusal to participate on the part of Quebec (and, indeed, any other province) would leave a major "policy doughnut" in a future universal pharmacare program (Hartman, Davidson, Alwani 2018, 43). It is nevertheless possible that a province might be coaxed into establishing a provincial plan mirroring the essential features of the federal model (e.g., covering a formulary of important medications free of charge to all residents of the province even if, in the Quebec case, this is achieved through regulation of private insurance plans). Precedents for such a workaround can be found in the Canada Pension Plan/Quebec Pension Plan and Canadian Blood Services/Héma-Québec. Alternatively, if one or more provinces opted out completely, they might over time see the relative benefits achieved for other Canadian provinces and agree to join the national plan.

[25] See *CBC News* (2004).

A major hurdle is the question of which level of government would pay the cost of a universal plan – a universal plan as we propose will save money overall but at least initially will call for more public expenditures. A recent report by the Parliamentary Budget Officer (PBO) found that the federal government could establish a universal pharmacare scheme, covering all drugs listed on Quebec's formulary, for a *total* cost of $19.3 billion (PBO 2017). This estimate is likely an overestimate of what it should cost, because of the PBO's reliance upon Quebec's extremely high-cost scheme as a model for its estimates. The report notes as well that governments *currently* spend $11.9 billion on existing public plans – meaning that the *incremental* public cost of shifting to a universal plan would be around $7.3 billion. This incremental amount could be further offset by the elimination of current tax deductions that in effect subsidize private plans, at a cost of $1.6 billion annually. Others estimate (using other price scenarios, not those in the Quebec formulary) that only $1.2 billion would be required in *new* public investment for universal coverage for the basket of drugs that Canadians currently use (Morgan et al. 2017b).[26] And savings for the private sector are predicted with both of these scenarios, owing to reduced out-of-pocket spending on drugs and reduced costs for employer drug plans.

However, neither of the calculations above takes account of the fiscal and political challenges for the federal government in inducing the provinces to participate in a central plan. In our view, to induce participation by the provinces, the federal government would need to not only pay the costs of insuring those presently uninsured or underinsured *but also assume some of the costs presently incurred by provincial plans and private insurers*. Evidence-based arguments in favour of universal pharmacare have not been sufficient to galvanize reform on the part of the provinces, and it seems likely that provinces would need to see some financial relief in exchange for participation in a national plan.

Presently public and private expenditures on pharmaceuticals together total approximately $26 billion (Morgan et al. 2017b, table 5). If the federal government took over payment for this entire sum (as well as the additional resources required to fund the uninsured or underinsured), it would likely result in too big a price tag to swallow, even though savings would quickly accrue if the central funder was galvanized to negotiate lower prices in exchange for whole-of-country access for drug companies. One possibility would be to start with a base investment by the federal government to ensure that the most important medicines are covered for all Canadians. For example, the federal government could commit $6.5 billion to a centrally run plan – an estimate that aligns with recent estimates of the total cost of universal coverage for 117 essential medicines commonly used by Canadians (Morgan et al. 2017b). With the $6.5 billion, the agency would be charged with buying at least these 117 essential medications and as many additional medicines as possible, employing an evidence-based process for priority setting. Setting this fixed budget for the central buying agency would also increase its ability to bargain for prices nationwide on behalf of Canadians (i.e., in negotiations with drug manufacturers, the central agency can credibly claim that it cannot offer more). As we discuss below, the list of drugs on the central

[26] Morgan et al.'s $1.2-billion estimate reflects the average of best- and worst-case cost scenarios, ranging from $373 million to $1.98 billion in added costs to government.

formulary should then, if prescribed, be available at no cost to the patient at the point of service: prescriptions for these medicines would be billed by the pharmacy directly to the central agency funded by the federal government.

A national agency allocated $6.5 billion a year could not cover all brands of drugs currently included in provincial plans. But most of the essential chemical compounds would be covered (Morgan et al. 2017b). Provinces could opt to transfer additional funding to the central agency to expand the central formulary for their respective populations – and both save on administrative costs and increase their own prospects for getting lower prices for drugs. We realize this would not be a "perfect" plan in terms of centrally covering all brands of drugs for all people, but the combination of a national plan with a resource constraint working to cover as many key drugs as possible, coupled with a desire by the provinces for the national plan to pick up a greater number of drugs to reduce provincial costs would, we think, be a healthy dynamic. As mentioned earlier, there would still be a supplemental role for private insurance plans, which could choose to insure medications beyond the drugs funded by the central agency (e.g., medications with insufficient cost-effectiveness and brand coverage and so on).

Option 2: Legislation similar to the *Canada Health Act*

An alternative path forward for universal pharmacare would be one similar to that found within the *CHA*. Using its spending power, the federal government could commit to providing a base transfer of $6.5 billion, increased each year according to a formula reflecting inflation, population growth, age and advances in drug technologies (e.g., the advent of new oncology drugs or personalized medicines). Using *CHA*-style legislation, the federal government could then require, as a condition of this transfer, that the provinces offer their residents drug coverage under some of the same terms that now govern hospital and physicians' services, including universality, accessibility and portability. Such a decentralized approach may align better with the premiers' demands at the 2018 Council of the Federation meeting and is consistent with recommendations of various high-level commissions (National Forum on Health 1997; Royal Commission on the Future of Health Care in Canada 2002; HESA 2018; Liberal Party of Canada 2018b). A recent report has called for a similar approach – provincially delivered pharmacare, supported with federal transfers – albeit *outside* the *CHA* framework (IFSD 2018).

The advantage of approaching universal pharmacare through legislation similar to the *CHA* is that the provinces would have fairly broad parameters to craft their own approaches to the design and implementation, of universal pharmacare for their residents. The disadvantage of this approach is that, in turn, the provinces may wish to take different approaches to implementation, which could see the persistence of effective public subsidies of both pharmaceutical companies and private insurers. Further, the provinces' experience with the *CHA* may not dispose them to adopt such an approach: specifically, they may be concerned that the federal government's financial commitments may decline over time or as the result of a change of government. This concern was highlighted in the 2018 Council of the Federation communiqué, which listed adequate, long-term

and secure federal funding as one of the principles to govern negotiations with the federal government. To quell this concern, it would be essential for the federal government to make a long-term commitment to year-over-year funding and a fair method for increases to the original base, and to enshrine such a commitment in legislation, making it more difficult for subsequent governments to renege.

Any new *CHA*-type legislation for pharmacare should make new federal transfers contingent on provincial compliance with two critical criteria: (1) universal coverage should be provided for a basket of essential drugs, without copayments or deductibles; and (2) decisions over what to include in the basket should be made by an arm's-length body (or bodies) that would negotiate with drug companies for the best prices.

Copayments and deductibles

For medicare more broadly, the *CHA* bans user charges for "medically necessary" hospital and "medically required" physician services. We argue that universal pharmacare legislation should similarly ban required payments from patients (which can take the form of deductibles, user charges or copayments). There are strong arguments for a ban on such charges for important medications, given the extensive evidence that payment at the point of service may impede access to needed medications and create problems of prescription adherence (Sinnott et al. 2013; Gagnon 2017). For example, a 2001 study found that Quebec's experimentation with cost-sharing for pharmaceuticals resulted in reduced use of essential drugs and a higher rate of serious adverse events among the province's elderly persons and welfare recipients (Tamblyn et al. 2001). User charges/copayments not only risk the health of an individual patient but also result in further costs to the health care system (Drummond and Towse 2012).

Some claim that the system will be unaffordable without copayments, as the incremental cost of additional drug usage will not be borne by patients (the economic problem of "moral hazard"). There is, however, evidence from European health systems' experience with copayments that rebuts the argument that patient cost-sharing will in fact deliver the imagined cost savings (Tambor et al. 2015). The decision to issue a prescription primarily lies with the physician, after all, who does not feel the pinch of patient copayments. If drugs are being prescribed unnecessarily, the appropriate response is to implement better clinical governance to monitor and regulate prescribing behaviour, not to apply financial pressure on patients – who usually lack the training and knowledge necessary to second-guess their physician's prescribing. While comparisons with other countries are not ideal in all circumstances, with respect to drug coverage, countries such as the UK and New Zealand manage to cover everyone for a broad range of prescription drugs, with minimal copayments, from which poor and high-needs users are exempted. They also spend much less than Canada or the US (CIHI 2017a).

A key policy choice, related to copayment centred on a ban on payments by patients, is whether to adopt "reference-based reimbursement," as is used in British Columbia, Australia and the Netherlands. In this model, public funding would fully subsidize the most cost-effective brand; patients can use the public subsidy and pay extra out of pocket or through private health insurance to access other brands.

A potential downside of a system geared toward reference-based pricing is that it will undermine a public plan's purchasing power. This is because, in setting the reference price, the public plan cannot guarantee the drug manufacturer the entire market – the size of the market will depend on the brand preferences of prescribers and patients. In a reference-based pricing scheme, patients may choose to use a public subsidy to help them buy more expensive brands (which are not any more effective). The propensity to do this will be exacerbated by the extent to which private insurance coverage defrays the price differential (in Australia, to reduce incentives in this regard, private insurers are banned from covering the cost of the additional amount payable above the reference price; Colombo and Tapay 2003, 19). There are advantages and disadvantages with reference-based reimbursement, and any restrictions on copayments built into legislation should likely permit provinces, if they wish, to utilize this policy tool. In such a system, the "medically necessary" drug would be free of user charges even though other more expensive brands might attract a copayment for any added costs above the reference price.

Arm's-length decision-making

Having said that free access to essential medicines must be a core feature of universal pharmacare, the critical questions are which drugs are "essential" and who is charged with making this determination. For medicare more broadly, the *CHA* protects "medically necessary" and "medically required" hospital and physician services. However, it has long been criticized for not defining those key terms or imposing any requirements of independence or accountability on the decision-making process (Flood 2006).

As part of pharmacare reform, it is important to signal to all Canadians that not any and all brands will be funded and, possibly, that not *all* potentially beneficial drugs will receive public funding. The goal of the public plan, on behalf of all Canadians, will be to set priorities, make the best use of available resources, and be guided by available evidence of clinical effectiveness. It is thus important to ensure that both the purchasing of drugs and decision-making about what drugs to fund are based as much as possible on objective evidence of clinical and economic value and are, to the greatest extent possible, divorced from short-term political considerations and pressures.

In our view, an essential element of any reform is that Canada must follow the path of other high-performing countries and delegate decision-making and negotiation to an arm's-length agency that is removed from day-to-day politics and shielded, for example, from lobbying by drug companies or patient groups. This feature is so important to the ongoing legitimacy and durability of high-performing public plans in other countries that we recommend a requirement for arm's-length administration in any *CHA*-type legislation used to create public pharmacare. Each participating province could establish *its own* arm's-length body to purchase prescription drugs for its population. Alternatively, to save administrative costs and pursue greater purchasing power, the provinces could agree to transfer that responsibility to a national agency similar to the CBS, as discussed earlier.[27] Here we see that our two policy options may converge.

[27] Canada has an internationally acclaimed agency for drug and technology assessment, the CADTH, which advises provinces on the effectiveness of drugs (for more information, visit *www.cadth.ca*). The CADTH is not, however, a buying agency in the same way that the CBS is.

The governance of these arm's-length institutions should be informed by the philosophical literature on "accountability for reasonableness" (Daniels and Sabin 2002). Briefly stated, accountability for reasonableness sets four criteria for legitimacy and fairness in priority-setting decisions:

1. The rationales for priority setting must be explained to the general public (*publicity* condition).
2. Only relevant considerations, such as clinical and cost-effectiveness, should be given weight in priority setting, to the exclusion of irrelevant considerations, such as the short-term political consequences of funding a drug (*relevance* condition).
3. Patients must have a formal channel for challenging priority-setting decisions (*appeal* condition).
4. Some oversight mechanism must be in place to ensure that the arm's-length body complies with the three previous conditions (*enforcement* condition). For example, the arm's-length body could be required to report to the legislature and might, in limited circumstances, be subject to judicial review.

Provincial variation and the Quebec model

As mentioned earlier, Quebec's model of providing universal insurance has attracted substantial criticism but, to its credit, it is the only province offering a coherent universal plan. Should such a model be permitted under any *CHA*-like model for universal pharmacare? Given the strong opposition of large private insurers to universal pharmacare, the federal government (not to mention Quebec and other provincial governments) may be drawn to this model as it permits a continued role for private insurers without too much change to their business models.

Although there have been significant concerns about the efficiency and equity of the Quebec model as we discussed earlier, in theory it would be possible for governments to regulate private health insurers to better achieve equity goals; internationally, such a model is known as "managed competition."[28] However, this presupposes that governments will aggressively regulate the private sector, mandating that all essential care be covered and that all enrollees be accepted on equal terms, irrespective of age or pre-existing conditions; to date in Canada there has been little attention to the need for regulating private markets in health care (Flood, Thomas and Harrison-Wilson 2010). Furthermore, unlike the Quebec system, the gold-standard managed competition model, although not tax-funded, is nonetheless progressively funded: people or their employers contribute a percentage of their annual income as a premium; this amount is pooled centrally; and insurers receive a risk-adjusted premium for their particular subscribers. Consequently, if the Quebec-style model is permitted under a new *CHA* for pharmacare, there should be a requirement that it be progressively funded in order to attract federal contributions.

[28] Under a managed competition scheme, universality could be achieved by mandating that all individuals purchase private drug coverage, with the government facilitating by regulating insurers (e.g., prohibiting denial of coverage for pre-existing conditions) and subsidizing the premiums of lower-income people. See Flood, Thomas and Tanner (2015).

Apart from a managed competition model, the federal government could allow flexibility for provinces to achieve universality without completely disrupting existing private insurance coverage. Aidan Hollis has proposed one such model as a way of moving forward with universal pharmacare (Hollis 2015). Under his model, the patchwork of provincial plans would be expanded to cover all residents, financing this expansion of coverage through income-contingent mandatory premiums. For employees with health coverage, the premium would be paid by their private insurer, meaning, in effect, that the government would reinsure all of the private insurers' enrollees under the public formulary. This proposal has the benefit of not requiring a conspicuous increase in income tax; rather, premiums currently paid to private insurers would be diverted, in part, to a centrally administered plan. The downside to Hollis's plan is that it is difficult to know to what extent the resulting cost savings would be transmitted back to employers and employees (as opposed to increased profit margins for insurers).

CONCLUSION

The case for universal pharmacare is manifold and clear-cut. Gaps in access under the current patchwork system seriously threaten the health, and the very lives, of thousands of Canadians annually – a fact that, in 2018, is simply unconscionable. And our stinginess in access does not save us money. As Canadians well understand from their vantage point on the US's dysfunctional health care system, a mix of public and private programs inevitably leads to gaps in access and results in high prices and high costs. To put it bluntly, we do not get anywhere near the return on investment we need and deserve for the money we spend on pharmaceuticals in Canada. Moreover, as the economy sees more workers in precarious employment and employers try to cut costs by limiting insurance to certain classes of employees, the number of Canadians who have to pay outright for medication will continue to increase.

Many Canadians still do not directly feel the insecurity of access barriers because they have private insurance. But this is a false sense of security. For example, one of the authors of this study has a regular prescription for the seasonal allergy medication, cetirizine, a generic medicine. Upon recently filling the prescription, she was asked for a $22 copayment, with private insurance covering the balance. Altogether, the prescription would cost $88.00. The New Zealand government, with its steelier approach to price negotiations, pays $2.02 for this same generic – which, combined with a $1.53 dispensing fee, means that a patient in New Zealand pays approximately $4.00 for the same (generic) drug.[29] Although it is not transparent, ordinary Canadians who have private health insurance shoulder the cost of these inefficiencies, whether through reduced salary and other benefits or rising copayments, deductibles and annual limits on private insurance (LePage 2015; Law, Kratzer and Dhalla 2014).

[29] New Zealand pharmaceutical schedule information: http://www.pharmac.govt.nz/Schedule?osq=cetirizine. Information on the dispensing fees can be found here, p. 161 (accessed April 6, 2018). https://tas.health.nz/assets/Publications/Pharmacy-Documents/The-Agreement/CPSA-12-contracts/Consolidated-version-2017/21081836-CPS022CPSAExtensionConsolidated-20170706.pdf

People with either private or public health insurance may be persuaded that it is not in their interest to support universal pharmacare because, it is argued, the trade-off for expanded access and cost control is a reduction in the number of drugs that would be covered. However, there is nothing inherent in any future pharmacare plan that would prevent private insurers from covering prescription drugs not covered by a universal public plan. The supply of pharmaceuticals is more elastic than the supply of physician and hospital services. Therefore, there is no concern in pharmacare that a two-tier scheme would emerge, where the private tier would siphon scarce pharmaceuticals from the public system, as exists in physician services (Flood and Thomas 2018). Thus, choice for people with private health insurance should not be limited in any way: indeed, with a core public plan in place for medications, private insurers should be able to expand their coverage in other domains (e.g., home care and medical devices).

For those who are presently publicly insured (e.g., the poor, seniors and patients with chronic conditions) the claim is made that they should fear a universal plan because it will limit their choices. Reports by industry-funded research groups have suggested that a move to a New Zealand-style system may involve a sharp reduction in the number of drugs that are funded (PDCI Market Access Inc. 2016; Innovative Medicines Canada 2016). But when we look more closely at, for example, the 4,400 pharmaceutical products listed on the Ontario Drug Benefit Program (ODBP), we see that many of them are *brands* – that is, they are the *same chemical compound* but with a different brand name. Referring to our earlier example of seasonal allergies, if we compare the therapeutic class of antihistamines offered by Ontario and New Zealand, a search of the ODBP lists 14 "products," but most of these are different brands or dosage sizes; there are only, in fact three *different* chemical products.[30] The New Zealand formulary lists multiple presentations (strengths and forms) of seven *different* chemicals (including the three listed on the ODBP).[31] It may well be that there are cases where different chemical compounds are excluded from the New Zealand plan and presently included in Canadian public plans, but a superficial look at the number of products insured does not tell one much about the extent to which choice is actually constrained. Furthermore, we do not think that the choice of a long list of brands of the *same chemical product* should be prioritized over, for example, access to essential medicines such as insulin for all Canadians.[32]

A few general points are worth reiterating to highlight the reform paths open to Canada. First, a universal pharmacare plan does not necessarily have to be centrally administered by the federal government. After all, Canadian medicare achieves universal coverage for hospital and physician services, even though the provinces have diverse public insurance plans. To be sure, economies of scale would be achieved by having one national plan. But the size of the plan is secondary in importance relative to the plan's ability to negotiate reasonable drug prices. Recall that presently

[30] Ten of these are for different strengths of five brands and strengths of cetirizine hydrochloride, two for different strengths of one brand of loratadine and two for different strengths of one brand of promethazine: https://www.formulary.health.gov.on.ca/formulary/results.xhtml?class=040000000.

[31] http://www.pharmac.govt.nz/Schedule?code=A280401.

[32] In some circumstances, there may be a reason why a patient needs a different brand (e.g., they are allergic to a particular binding agent in one brand and not in another), but that can be dealt with on a case-by-case basis and is part of the New Zealand universal plan.

Canada pays very high prices from a global perspective – not just for drugs on patent but also for generics. Rather than subsidize pharmaceutical companies through high prices across the board – including generics and "me too" drugs that merely tinker with existing compounds – public funding should be targeted to reward truly significant innovations.

Commentators often bluntly assert that provinces have exclusive jurisdiction in health care. That is incorrect in law. There is shared responsibility for health care, as the Supreme Court has clearly and repeatedly indicated; which level of government has primary jurisdiction depends on the particular issue at hand. It is noteworthy that the federal government has carved out a very significant role in drug policy.

To be sure, there are challenges in securing intergovernmental agreement. Canada's intergovernmental institutions are relatively weak (Schertzer, McDougall and Skogstad 2018; Adam, Bergeron and Bonnard 2015). Although intergovernmental processes have delivered multi-year funding agreements in the health field, real reform has proven more elusive (Fafard 2013). Agreement for a reform as significant as pharmacare will be difficult to achieve. Moreover, because a pharmacare scheme would create winners and losers among large insurance and pharmaceutical companies, they can be expected to lobby hard and try to turn a dysfunctional intergovernmental system to their advantage. One could imagine, for example, one or more pharmaceutical companies pushing Ontario or Quebec to block a national pharmacare scheme in exchange for new investments in pharmaceutical research and development. We can expect multiple efforts to sabotage a national pharmacare scheme, which might come in the form of proposals for a more narrowly defined federal role, focusing on areas that are of specific concern to the provinces, such as expensive drugs for rare diseases.

Despite the formidable political foes lined up against pharmacare, we urge the federal government not to fall for the refrain of "fill the gaps" and, instead, to seize the opportunity for durable, comprehensive reform. Although this study has not offered detailed guidance on navigating Canada's complex intergovernmental machinery, we have outlined two broad pathways by which the federal government could spearhead a universal pharmacare scheme and ensure affordable access for all Canadians.

The first, and bolder, model involves a new national agency, funded primarily by the federal government and with the provincial and territorial governments adding more funding on a voluntary basis. Although health insurance has been interpreted as falling primarily under provincial jurisdiction, there is nothing preventing FPT governments from delegating the administration of a drug insurance plan to an arm's-length agency. Indeed, this is how Canadian Blood Services is organized: it is a high-performing organization that buys a range of drugs on behalf of FPT governments. There is a risk that Quebec and some other provinces may decline to participate in a national agency and demand matching federal funding for their own programs. The federal government could respond with counterdemands – such as stipulating that provinces that opt out cannot charge user fees and must entrust decision-making to an arm's-length body.

The second option is modelled on the *CHA*. The federal government could offer additional funding to persuade the provinces to comply with national criteria for public drug insurance. These criteria should include, in our view, a restriction on copayments for a core list of "medically necessary" medicines (leaving open the possibility of additional payments for more expensive brands for a particular condition) and the establishment of an arm's-length body to bargain with drug companies and determine the core formulary. The federal government's spending power has been found to be constitutional, meaning it could use increased transfer payments to elicit provincial compliance, while leaving reasonable leeway for the provinces to develop their own pharmacare plans. For example, if Quebec wanted to receive federal funding but still keep a version of its present plan, we suggest it should be able to do so, provided it ensured that its plan was progressively financed (income-related premiums) and that a core list of essential drugs was available to all with no copayments attached.

In either scenario, the federal government would need to make a credible investment to advance the reform process. We have suggested $6.5 billion as an initial investment, which aligns with past estimates of the cost of establishing universal coverage for a basic formulary of 117 essential medicines (Morgan et al. 2017b). To put that number in perspective, it amounts to approximately 2 percent of the federal government's 2017-18 budget of $330 billion (Ministry of Finance 2017). It would, of course, be offset by savings for provincial governments, employers and taxpayers themselves (avoiding out-of-pocket costs for prescriptions and reducing the need for private health insurance). As well, the federal government would recover a portion of the taxable deductions currently offered for employer-based plans, estimated at $2.61 billion for 2016 (PBO 2017, 17).

A large part of our focus has been on identifying constitutionally viable pathways to universal pharmacare. This perspective does not provide any strong motivation for preferring one option over the other. Provided adequate funding commitments are forthcoming from the federal government, either option can be achieved. We see advantages and disadvantages for each approach. The relative simplicity of a single, national agency modelled on CBS may offer greater administrative efficiency and afford a stronger federal role in health care, breaking away from dysfunctional federal-provincial relations of the past. Having said that, a decentralized approach modelled on the *CHA* could allow more room for policy experimentation across the provinces and better immediate fusion with existing provincial insurance efforts for prescription drugs.

Likewise, the national agency model might achieve greater interprovincial equity by ensuring that all Canadians have access to the same pharmacare basket. Indeed, the concerns addressed by the *CHA*'s criterion of "portability" would be a non-issue. Having said that, there may be some value in allowing provinces to calibrate pharmacare coverage to local needs (e.g., to prioritize drugs that better serve an aging population in provinces with an older age structure). This points to another important consideration: in high-performing health care systems, such as the UK's National Health Service, pharmaceuticals are financially integrated with the rest of the system

(Morgan et al. 2015b). Although it may appear that the *CHA* model is the winner from this perspective, again much depends on the details of implementation. As the experience of Canadian medicare amply attests, the mere fact that hospital and physician services both fall under provincial budgets is no guarantee of seamless coordination.

What matters most is that the federal government lead the country toward universal pharmacare by making a firm commitment and beginning negotiations with the provinces and territories. As it works to reach an intergovernmental agreement, the federal government should be guided by the overarching principles outlined above: universality, income-based financing, no copayments and accountable decision-making by an arm's-length agency (or agencies). These are the truly imperative commitments we must keep in view while exploring constitutionally viable options such as the two examined in this study.

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