Blake Lee-Whiting – 999631082
PPG1000 Governance and Institutions
Professor Ian Clark
December 19th, 2016

A Pragmatic Canadian Pharmacare Program

Despite enacting universal healthcare coverage in 1984, gridlock between provincial and federal decision-makers has prevented meaningful pharmacare dialogue from occurring: Canada has "the dubious distinction of being the only country with universal healthcare coverage, but not universal pharmacare" (Stanbrook 1). The Patented Medicine Prices Review Board (PMPRB) ensures that patented drugs are regulated in Canada, however it does not take on the same overarching drug regulation roles as the United Kingdom's National Institute for Health and Clinical Excellence (NICE), which helps decide which "drugs are provided to all British citizens through the National Health Service (NHS)" (Clement et al. 1438). The United Kingdom's national pharmacare program demonstrates an alternative to the current Canadian provincial drug coverage system. This paper argues that Canadian policymakers can overcome multi-jurisdictional gridlock by reforming the PMPRB to more closely resemble NICE and by aligning its new objectives with those of provincial and federal policymakers.

This paper is divided into five sections; the first of which explains how the central gridlock governance challenge affects provincial and federal policymakers. The paper's second section analyzes the history of gridlocked discussion, highlighting the role of institutions. The third section utilizes a cross-jurisdictional scan approach to discuss the United Kingdom's pharmacare program. The fourth section briefly analyzes the feasibility of reforming the PMPRB, drawing on the constraints discussed in the second section. The final section briefly consolidates the paper's arguments.

Central Gridlock Governance Challenge

While Canada does have universal healthcare, it does not have a "single system of public insurance coverage for prescription drugs" (Phillips 1), which means that while "all drugs needed for treatment in hospitals are provided free of charge, outpatient prescriptions, or prescriptions written in physicians' offices for the non-institutionalized are not universally covered" (Anis et al. 316). Instead, a patchwork of provincial, territorial, and private drug insurance programs provide varying levels of drug coverage, eligibility and benefit payments. This patchwork system of plans means that "drug coverage outside the hospital setting remains the sole responsibility of the provinces and territories" (Philips 2) for those who are not covered by private drug insurance programs, resulting in "3.2 million seniors, 3.2 million people with low incomes, and 1.5 million others depending on provincial drug benefit programs for drug coverage" (Grégoire 307) out of a population of roughly 30 million in 2001. This patchwork system is the result of "Canada's unique form of decentralized power-separating federalism which presents challenges for any healthcare reform: enacting national standards for pharmacare requires consensus among all ten provinces and the federal government" (Morgan 5). Despite remarks by former health minister Allan Rock that "in an ideal world… few would doubt that a publicly-funded, single payer universal system would be the best outcome" (Morgan 5), general distrust on behalf of provincial governments and cost-saving measures at the federal level have created gridlock, stalling pharmacare negotiations and preventing the consensus required between the provinces and the federal government to enact national standards.

Provincial governments have been unwilling to work with the federal government to create a national pharmacare program out of fear that a national pharmacare program might be "somewhat of a Trojan horse, a gift from the federal government whose proper implementation

would put the provinces in the poorhouse" (Anis 565) as funding for the program would partially come from provincial governments, barring a constitutional change that would give the federal government total responsibility; such a constitutional change has not been suggested thus far by any federal government, indicating that a national pharmacare program would require some funding from the provinces. The idea that the provinces would be at least partially responsible for funding a national pharmacare program is reinforced by Minister Philpott's position that a federally-funded program "might be expensive and that's one of the reasons we're not in the position where we're about to implement pharmacare" (Butler 1). Unless "federal and provincial policy-makers act cooperatively" (Coombs 19) by agreeing to share costs, a national pharmacare program is impossible; a brief analysis of the history of pharmacare gridlock, and the roles played by federal and provincial institutions, is necessary to understand how policymakers could be convinced to act cooperatively.

Responses to Gridlock by Canadian Institutions

Federal and provincial institutions have responded to gridlock by pursuing pharmacare solutions independent of one another. The federal government, during Prime Minister Mulroney's 33rd parliament, responded to the pharmacare gridlock governance challenge by passing bill C-22 in 1987 which "extended the period of patent protection before compulsory licensing could be possible and created the federal Patented Medicine Prices Review Board" (Menon 93). Provincial institutions have responded to pharmacare gridlock by creating drug coverage programs which can be categorized into three groups: catastrophic drug coverage plans, universal public drug coverage plans, and targeted drug coverage plans (Philips 8). This section briefly details the history of these responses by federal and provincial institutions to the pharmacare governance challenge.

Federal Institutional Response

The PMPRB is a federal institution with the dual mandate of ensuring "that prices charged by patentees for patented medicines sold in Canada are not excessive… [and reporting] on pharmaceutical trends of all medicines and on R&D spending by pharmaceutical patentees" (PMPRB). This mandate is a reaction to previous regulations in the Canadian pharmaceutical industry which did not protect pharmaceutical patents, such as a ruling by the Commissioner of Patents in 1922 that allowed Canadian pharmaceutical manufacturers "to imitate and produce a drug of another manufacturer, even if there was an existing patent" (Anis 2000, 524); in exchange for ensuring that pharmaceutical patents would be protected, patented drugs are subject to PMPRB price control. There is an unintended side-effect however for drugs which do not require patent protection: the "prices of non-patented drugs are under less control… [and are] on average, 30 percent higher than the median international price" (Menon 99).

The PMPRB has the ability to enforce the first part of its mandate by imposing "fines equal to or double the amount of the excessive increase in price" (Anis 2000, 524) to manufacturers found to be in violation of the pricing guidelines outlined by the PMPRB. The PMPRB utilizes the "Patented Medicine Price Index (PMPI) as a measure of manufacturers' reported prices for patented products" (Menon 95) which ranks the price of a drug against others in its drug class. While the PMPRB ensures that provincial drug coverage programs are not overcharged for medications, the PMPRB does not negotiate prices beyond ensuring that drug prices are within the industry pricing standards set by the PMPI.

Provincial Institutional Response

When the Harper government invested $16 billion into the Health Reform Fund, aimed partially at improving drug coverage, the British Columbia, Ontario, Manitoba, and

Saskatchewan governments expanded upon their existing catastrophic drug coverage programs, while "Newfoundland and Labrador, Nova Scotia and Prince Edward Island introduced catastrophic drug coverage programs" (Philips 4) with the federal funding. As a result of the National Reform Fund, about 25% of Canadians are solely covered by catastrophic drug coverage plans (Kapur and Basu 192). Catastrophic drug coverage plans provide coverage in case of extraordinary circumstance for "individuals with high drug expenses, usually measured in relation to their income" (Kapur and Basu 184), who take medications which have been pre-approved by the drug coverage plan.

Universal public drug coverage plans decrease the cost of all non-hospital medications for Canadians who would not otherwise have drug coverage. Three provinces offer universal or semi-universal drug coverage plans: "Quebec, through its Public Prescription Drug Insurance Plan; Alberta, through its Non-Group Coverage Benefit; and New Brunswick, through its New Brunswick Drug Plan" (Philips 9). These plans range in coverage but "all provinces establish a list of drugs that are eligible for cost reimbursement under the provincial drug plan" (Anis et al. 316) after a drug review evaluation process that evaluates safety, efficacy, and cost-effectiveness.

All ten provinces offer targeted drug coverage plans which decrease the costs of medications for "people with specific illnesses that require high-cost prescription drugs… people on social assistance, and seniors with low incomes" (Phillips 10). These types of drug coverage plans have specific eligibility requirements; the British Columbia Ministry of Health's Pharmacare program, a targeted drug coverage plan, requires that the individual reside full-time in British Columbia, be 65 years of age or older, and live in the community, instead of long-term care institutions, which have their own targeted drug coverage plans (Anderson 200).

Federal and Provincial Institutional Responses

The federal response to the pharmacare governance challenge, as evident by the PMPRB's dual mandate, demonstrates that the federal government is interested in minimizing costs while ensuring that quality patented drugs are available to Canadians. The three provincial responses to the pharmacare governance challenge demonstrate three distinct objectives: catastrophic drugs plans demonstrate that some provincial jurisdictions want to ensure a base level of coverage for citizens in extraordinary circumstances, universal public drug coverage plans demonstrate that some provincial jurisdictions want a high-level of drug coverage, while targeted drug coverage plans demonstrate the base level of coverage that provinces require to address inequalities. An alternative to the current patchwork of provincial plans must incorporate, at least to some degree, responses by provincial and federal institutions to the pharmacare governance challenge.

Finding an Alternative

Federal policymakers around the world are faced with difficult "choices when making drug coverage decisions… the ever-increasing availability of medicines of varying cost and clinical benefit forces drug benefit providers to set limits on which products to cover and under what circumstances" (Morgan et al. 2006, 337). Decision-makers in the United Kingdom have made those difficult choices and created a universal drug coverage plan. The unique cost-minimization and drug approval techniques that United Kingdom pharmacare program utilizes are detailed below.

Cost Minimization

In terms of cost, "Canada's multi-payer system is among the most expensive systems in the world" (Morgan et al. 2015, 13) because it diminishes purchasing power; as a result, generic

drug prices in Canada are nearly double the median price of other OECD countries and the "prices of brand-name drugs in Canada are 30% higher than in the United Kingdom" (Ibid.). The United Kingdom has been able minimize costs and maximize purchasing power by creating the National Institute for Health and Clinical Excellence (NICE): "NICE was established in 1999 to provide health care professionals in England and Wales with advice on securing the highest attainable standards of care for National Health Service (NHS) patients" (Pearsons and Rawlins 2618). NICE acts as a drug purchasing and regulatory institution which shares a joint mandate with, but operates independently of, the NHS. The operational structure of NICE and the NHS allows the NHS to "ensure equal access to new technologies while saying no when the cost does not represent acceptable value for money" (Pearsons and Rawlins 2620) by separating the healthcare provider, NHS, from the drug coverage entity, NICE. The NICE governance structure gives the United Kingdom "better access to medicines than Canada… and 45% lower total cost of pharmaceuticals" (Morgan et al. 2015, 15). The United Kingdom's program also decreases costs for the consumer, which is most evident by a 2013 Commonwealth Fund General Public Survey which that found "8% of Canadians did not fill a prescription or skipped a dose in the last ten months because of cost… compared to only 2% in the United Kingdom" (Drummond and Calder 7).

Drug Dynamism

The drug approval process for NICE utilizes a dynamic approach to drug subsidization: NICE "does not have a national list of [approved drugs]; rather, it has a negative list of drugs that are excluded from the subsidy" (Morgan et al. 2006, 341). Unlike Canada, wherein studies "show that public access to the same prescription medications differs widely across provinces" (Anis et al. 315) due to different approval criteria for various provincial drug coverage services,

NICE regulates drugs eligible for coverage through a blanket coverage method, ensuring that all British citizens receive access to the same medications. NICE also utilizes a comprehensive national database to help doctors prescribe medications: “fewer than 1 in 3 doctors in Canada use electronic prescribing tools… in contrast, about 9 in 10 doctors use such systems in the United Kingdom” (Morgan et al. 2015, 11).

Discussing the Feasibility of the United Kingdom Approach

The federal response to the pharmacare governance challenge, the creation of the PMPRB, provides a vehicle in which pharmacare reform can be enacted. The provincial responses to the pharmacare governance challenge illustrate that “none of the provincial models that exist today is perfect… but by breaking the political gridlock” (Blomqvist and Busby 12) a national program which highlights the positive aspects of each plan is possible. The feasibility of a plan which would reform the PMPRB to better reflect the interests of the provinces, while replicating the cost minimization and drug dynamism strategies of NICE in the United Kingdom, is discussed below.

Negotiating the Prices of Non-Patented Medications

The PMPRB currently has “no authority to regulate the prices of non-patented drugs, including generic drugs sold under compulsory licenses, and does not have jurisdiction over prices charged by wholesalers or retailers nor over pharmacists' professional fees” (PMPRB), resulting in provincial healthcare institutions independently negotiating the prices of non-patented medications. Reforming the PMPRB to nationally negotiate the prices of non-patented drugs would “lower prices through the benefits of greater bargaining power” (Drummond and Calder 7). The current PMPRB mandate is the reflection of issues surrounding patented medication which are no longer impacting healthcare in Canada, as the PMPRB has been

successful at protecting patents and regulating the price of patented medications. By extending the PMPRB's mandate to include non-patented medications, the federal government would be able to fulfill its objectives of ensuring high-quality medications, while also minimizing costs. This reform reflects cost-minimization strategies implemented by NICE, wherein the price negotiation institution is separate from the health provider; under a new mandate, the PMPRB would be the price negotiator while the provinces would remain health providers. Opponents of a national pharmacare program argue that such a regulatory body "would constrain individuals to consume the same package of health services" (Lindsey 19), however if the PMPRB utilizes the PMIP system to regulate non-patented medications, then provinces would still be able to choose from a wide range of pharmaceutical options. While this reform could be seen as minor to many national pharmacare supporters, it is an extremely feasible first step to creating a national pharmacare program in Canada.

Enhancing Catastrophic and Targeted Drug Coverage

Understanding that some provincial healthcare institution are uninterested in creating a national pharmacare program is important for addressing the feasibility of implementing such a program. All provinces currently employ catastrophic drug coverage programs which provide "residents protection against *catastrophic* drug costs" (Morgan et al. 2015, 4); standardizing this minimum level of care, while allowing "the provinces to decide how they would integrate a plan of this type with their existing drug plans" (Blomqvist and Busby 8) would receive minimal opposition, so long as the new minimum degree of coverage does not overtly exceed the standards of coverage currently offered by provincial plans. The PMPRB could mandate that any demonstrated cost-savings as a result of negotiated non-patented drug negotiations be put towards enhancing these mandatory catastrophic drug coverage programs. This reform would

probably not be heralded as a comprehensive pharmacare program, but this reform is extremely feasible and does technically satisfy the requirements, at the minimum level, for a national pharmacare program; as a result of this reform, all Canadians would be covered by a nationally standardized drug coverage program.

Expanding Upon the Second Aspect of PMPRB's Mandate

The final feasible reform which could be made to the PMPRB is an expansion of the second part of its mandate: "report on pharmaceutical trends of all medicines and on R&D spending by pharmaceutical patentees" (PMPRB). Morgan et al. argues that "transparency, rigor, and robustness of centralized review processes are critically important for them to be effective decision-supporting policy tools… if drug review processes are designed with these attributes in mind, they can help policymakers make "tough" but evidence-based choices in this health care sector" (347): by better reporting on pharmaceutical trends, by means of an electronic drug information system modeled after NICE's system, the PMPRB can better inform doctors and patients of which medications have been successfully prescribed across Canada. Better access to information could change the drug demands of Canadians, which in turn could lead to more demand for coverage of medications; patients in Alberta would benefit from being able to easily determine when a patient in Ontario has access to medications that they do not. The federal government could couple this program with an agreement to cost-share the price of medications which have been determined by the PMPRB to be successful, aligning "federal and provincial incentives with respect to policies… in the development of a common evidence-based formulary" (Blomqvist and Busby 9). This reform would be difficult to implement without some cost-sharing between provinces and the federal government, however the outcome of this program is aligned with the objectives of both groups, increasing the probability that cost-sharing

negotiations could be successful; provincial healthcare institutions benefit from having doctors which are better informed, while the federal government fulfills its goal of encouraging evidence based drug standards.

A Pragmatic Plan

Canada's patchwork of provincial drug coverage plans will remain "an accident of history that no sensible planner would design… a policy compromise with shortcomings that have long been identified" (Morgan 16) unless policymakers in provincial and federal institutions are able to compromise and end gridlock. Federal and provincial policymaker are uninterested in pursuing an all-inclusive system which would radically shape pharmacare in Canada, as "such an all inclusive plan will also make it unaffordable and render all gains made toward ensuring cost-effective prescribing to be lost" (Anis et al. 322). The small reforms in this paper are extremely feasible given the current gridlocked political climate, and should therefore be considered instead of a large overarching national system. Allowing provincial institutions to participate as much as possible, such as in "joint price negotiations with pharmaceutical suppliers" (Blomqvist and Busby 9), will better increase the odds of a Canadian national pharmacare program, albeit a more modest and pragmatic program than some healthcare scholars suggest.

3,026 words.

Works Cited

Anderson, Geoffrey M. et al. “Trends and Determinants of Prescription Drug Expenditures in the Elderly: Data from the British Columbia Pharmacare Program.” *Inquiry*, vol. 30, no. 2, (1993): 199–207.

Anis, Aslam H., Daphne Guh, and Xiao-hua Wang. "A Dog’s Breakfast: Prescription Drug Coverage Varies Widely Across Canada." *Medical Care* 39.4 (2001): 315-326.

Anis, Aslam H. "National Pharmacare: A Dog's Tale." *Canadian Medical Association Journal* 171.6 (2004): 565-566.

Anis, Aslam H. "Pharmaceutical policies in Canada: Another Example of Federal-Provincial Discord." *Canadian Medical Association Journal* 162.4 (2000): 523-526.

Blomqvist, Ake, and Colin Busby. "Feasible Pharmacare in the Federation: A Proposal to Break the Gridlock." *CD Howe Institute eBrief* 217 (2015).

Butler, Michael. “Liberals Veto National Pharmacare as more Canadians Can’t Fill their Prescriptions.” *Council of Canadians* (2016). Accessed online October 19, 2016: http://canadians.org/blog/liberals-veto-national-pharmacare-more-canadians-cant-fill-their-prescriptions

Coombes, Megan E., et al. "Who's the fairest of them all? Which provincial pharmacare model would best protect Canadians against catastrophic drug costs?" *Healthcare Quarterly* 7.4 (2004).

Daw, Jamie R., and Steven G. Morgan. "Stitching the gaps in the Canadian public drug coverage patchwork? A review of provincial pharmacare policy changes from 2000 to 2010." *Health Policy* 104.1 (2012): 19-26.

Drummond, Don, and Talitha Calder. "An Action Plan for Reforming Healthcare in Canada." *Managing a Canadian Healthcare Strategy* (2016): 79.

Grégoire, Jean-Pierre, et al. "Inter-provincial variation in government drug formularies." Canadian Journal of Public Health 92.4 (2001): 307.

Kapur, Vishnu, and Kisalaya Basu. "Drug coverage in Canada: Who is at Risk?" *Health Policy* 71.2 (2005): 181-193.

Lindsey, Robin, and Douglas S. West. "National pharmacare, reference-based pricing, and drug R&D: A critique of the National Forum on Health's recommendations for pharmaceutical policy." *Canadian Public Policy/Analyse de Politiques* (1999): 1-27.

Menon, Devidas. "Pharmaceutical cost control in Canada: does it work?" *Health Affairs* 20.3 (2001): 92-103.

Morgan, Steven, and Jamie R. Daw. "Canadian pharmacare: Looking back, looking forward." *Healthcare Policy* 8.1 (2012): 14.

Morgan, Steven, D. Martin, MA Gagnon, B Mintzes, J.R. Daw, and J. Lexchin. *Pharmacare 2020: The future of drug coverage in Canada*. Vancouver, Pharmaceutical Policy Research Collaboration, University of British Columbia. 2015.

Morgan Steven, Meghan McMahon, Craig Mitton, Elizabeth Roughead, Ray Kirk, Panos Kanavos and Devidas Menon. "Centralized Drug Review Processes In Australia, Canada, New Zealand, And The United Kingdom" *Health Affairs* 25.2 (2006): 337-347.

Pearson, Steven, and Michael D. Rawlins. "Quality, innovation, and value for money: NICE and the British National Health Service." *Journal of the Medical Association* 294.20 (2005): 2618-2622.

Phillips, Karin. "Catastrophic drug coverage in Canada." *Parliamentary Information and Research Service*. Library of Parliament, 2016.

PMPRB. *Mandate and Jurisdiction.* Accessed online: http://pmprb-cepmb.gc.ca/about-us/mandate-and-jurisdiction.

Stanbrook, Matthew, et al. "Can Canada get on with national pharmacare already?" *Canadian Medical Association Journal* 183.18 (2011): E1275-E1275.

Works Consulted

Clement, Fiona M., et al. "Using effectiveness and cost-effectiveness to make drug coverage decisions: a comparison of Britain, Australia, and Canada." *Journal of the Medical Association* 302.13 (2009): 1437-1443.

Closson, Tom. "The goldilocks principle and Canadian health care system governance." *Healthy Debate*. (2014) Accessed online October 19, 2016: http://healthydebate.ca/opinions/the-goldilocks-principle-and-canadian-healthcare-system-governance.

Stanbrook, Matthew. "Canada can afford Universal Pharmacare – no more excuses" *Canadian Medical Association Journal* 187.7 (2015): 475.